Biomedical Engineering in Gastrointestinal Surgery

Armin Schneider and Hubertus Feussner

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FOREWORD

"Biomedical Engineering" (BME) is a rather young entity in the history of interventional medicine, natural science, and engineering. It is an impressive subject, which is considered by the public either with unlimited admiration since it promotes significant progress in health care or with a deep concern since it favors inhuman "apparatus-based medicine."

The discussion of the ethical aspects of BME will not be the subject of this book, since the debate upon the ethical frame is more or less a luxury problem. A discussion about active life support by means of artificial ventilation, dialysis, or mechanical circulation support, etc. may be well justified or even necessary in individual cases but it became only possible as soon as the engineers were able to provide suitable devices and as soon as physicians were ready to use them. Hundred years ago, philosophers, theologists, and the interested public were not troubled by this dimension of medical care, simply because the problem did not exist at all. The technical means were not given.

In fact, nobody would be inclined to avoid (ostensibly) difficult ethical questions by terminating the development of even more effective support systems. On the contrary, we need more innovative devices, procedures, and systems to intensify the fight against diseases, injuries, and other threats of health and well-being. Insofar, any research and development activities in BME are, beyond a doubt, morally correct and of merit as compared to other branches of technical R&D, just to mention in particular, military technology as an example.

If it is even a moral obligation to contribute to further progress in BME, the question of how to do it has to be answered. All those who are involved should possess a sound and comprehensive knowledge of the relevant medical problems and, simultaneously, of the available scientific and technical potential to solve them.

However, no individual is able any longer to maintain more than a superficial overview of all aspects of the numerous knowledge domains. Surgeons, for example, are considered as a rather homogenous group of professionals, but in reality, they are highly specialized and even subspecialized. An abdominal surgeon is today no longer an adequate counterpart for an engineer who considers to design a new operating table for spine surgery. Likewise, a cardiac surgeon would never be able to give an expert insight into the special requirements of visceral surgery, etc.

The same holds true for the large community of engineers or computer scientists. One engineer might be an expert in mechanical engineering, but he/she has only a marginal knowledge of electrical engineering. The computer scientist is, perhaps, highly reputated in modern imaging procedures, but is by far less familiar with the special problems of state-of-the-art speech recognition.

Accordingly, it becomes more and more difficult to shape purpose-tailored teams of all the scientific and technical experts who are required to solve a specific medical problem successfully. The authors of this book aim at creating a comprehensive knowledge platform to bridge the different worlds of all partners involved, including the decision makers in the BME industry. Necessarily, many compromises have, therefore, to be made concerning the range of medical aspects and the informational depth of the technical chapters. The result can only be an overview.

In this book, medicine is confined to surgery—and even more exclusively focused upon visceral surgery. We deliberately renounced to cover all aspects of surgery, since the available frame and space of this book is limited; the book is dedicated to visceral surgery, which still is neglected as compared to the rather copious literature upon BME in bone-, neuro-, and ENT surgery (due to the fact that BME, in general, can be more easily applied in rigid environments). Likewise, the readers should not expect textbook-like chapters upon the basics of mechanical or electrical engineering or of computer science. We are unable to give more than an orientation about these knowledge domains. Insofar, the visceral surgeon who expects some information upon new sophisticated details of visceral surgery will certainly be disappointed when reading the medical aspects of this book. On the other hand, he could be fascinated by the promising and realistic options of intraoperative tissue differentiation. The specialist in navigation technology will be bored by the description of various navigation technologies, but could be very much interested in the range of potential clinical applications.

Last but not least, we strive to point out severe deficits and clinical challenges which still exist in our currently available therapeutic armamentarium with the hope to stimulate the readers to take active part in a continuous improvement of surgical care.

Textbooks of this kind are mostly compiled of specialized chapters written by various experts in their field and put together by one or two editors.

We preferred to present the content comprehensively by only two authors: A practicing surgeon and a biomedical engineer who are looking back on more than 15 years on close, daily-based cooperation. Regarding the wealth of existing knowledge in a broad range of medical, scientific, and engineering specialties, this concept is not without risk, but we expect it makes the book more easy to read.

We look forward to a positive echo of the readership. Hopefully, this helps to promote the support of visceral surgery by biomedical engineering.

Armin Schneider and Hubertus Feussner

ACKNOWLEDGMENTS

When we decided to mold our experiences and knowledge into a textbook as the publishing house asked us to do, it was quite obvious for us that this ambitious undertaking was only conceivable at all with the help of many coworkers, colleagues, and other experts in their fields and a highly motivated team. Their essential contributions are acknowledged with gratitude. Ms. Sabrina Stoeppke is the first one who has to be mentioned here. To call her the midwife of the book would be wrong. The midwife is mainly responsible for the delivery, but Sabrina Stoeppke catalyzed every single step of the way—so to say from the state of blastulation until the day of delivery. The main support came from our Institute for Minimally Invasive Interdisciplinary Therapeutic Intervention (MITI) with the scientific head Sebastian Koller and the surgical head Dr. Dirk Wilhelm. Daniel Ostler has to be mentioned in particular, as he never failed to overcome so many difficulties which presented during the making of this manuscript. His outstanding expertise contributed much to the scientific substance. Dr. Silvano Reiser provided lots of the historical background in the development of modern medicine. We are grateful for the support of Nils Kohn and the graduate and undergraduate students. The assistance of Tereza Baude is highly appreciated. Martina Scholle provided impressive illustrations. Precious feedback came from Prof. Nassir Navab, Chair of Computer Aided Medical Procedures and Augmented Reality, and Prof. Tim Lüth, Chair of the Institute of Micro Technology and Medical Device Technology, Technische Universität München. We are much obliged to Dr. Alexander Fingerle, Dr. Daniela Muenzel, and Dr. Konstantin Holzapfel from the Department of Radiology and Profs. Stefan von Delius and Monther Bajbouj as well as Dr. Jeannine Bachmann from the Department of Gastroenterology of Klinikum rechts der Isar, Technische Universität München for their substantial contributions.

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CHAPTER 1

Surgery and Biomedical Engineering

It goes without saying that surgery cannot be performed with bare hands. Accordingly, surgeons were always compelled to use more or less dedicated instruments. Descriptions of specialized tools of the surgeons are found early in the history of mankind. The papyri of ancient Egypt deal in detail with surgical instruments, as do many manuscripts of Greek and Roman antiquity. Often ignored, ancient India had also a profound surgical legacy. In a classical Sanskrit text of Sushruta written in the 6th century BC, more than 100 instruments are described, including saws, needles, scalpels, etc. They certainly reflected the spearhead of contemporary technological innovation.

The obviously high level of surgical care as related to general development was not maintained in the following centuries.

Conservative medicine always remained the reserve of academics. However, this only meant drug oriented noninvasive medicine. Diagnosis and therapy were based upon the humoral pathology of Galenos. Accordingly, the only "invasive" procedure was phlebotomy (bloodletting). Human diseases were treated with drugs, ointments, diets, or similar conservative measures. Surgical tasks, such as the treatment of fractures, open wounds, and hernia, were completely left over to the surgeons. Surgeons at that time were looked down upon and avoided by physicians since they were considered unlettered, lower class men, who learned their graft by apprenticeship (Fig. 1.1). In addition to surgery they often practiced as barbers as well. The situation improved only gradually. In England and in France surgical guilds were created. A main impact came again from the military since it was evident that contemporary warfare needed qualified surgeons. In 1724 a collegium medico chirurgicum was founded in Berlin (Charité) to provide sufficiently educated surgeons for the army. However, it took another century until it developed to academic surgery with full integration into the medical studies at the university. Famous names like Joseph Lister (1827−1912), Bernhard von

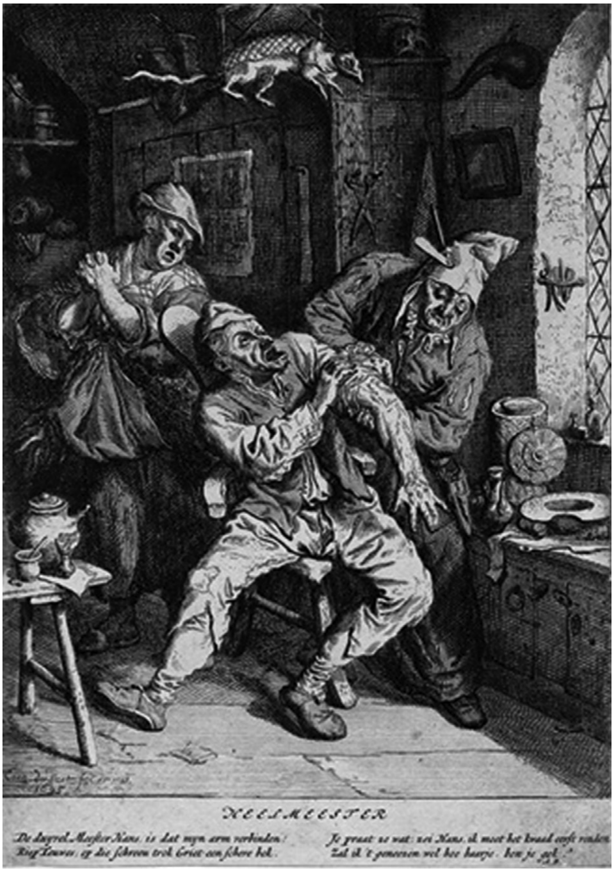

Figure 1.1 Rural surgeon treating a lesion of the left arm. A variety of medical equipment is visible but the rough scenario shows clearly the big differences between academic medicine and the world of the "barber surgeon." Etching by Cornelis Dusart (1660–1704).

Langenbeck (1810–87), and Theodor Billroth (1829–94) are representatives of this historical progress. From then on surgery achieved one triumph after another and is still considered today as the spearhead of medicine. However, this formally unchanged position is currently heavily in danger: Interventional medicine of today is characterized by the idea of further trauma reduction. Increasingly, open surgical procedures are replaced by minimally invasive interventions or even by interventional gastroenterology and radiology. In this very competitive environment surgery is forced to improve continuously its own therapeutic armamentarium. Otherwise, surgery may not survive as a discipline of its own right.

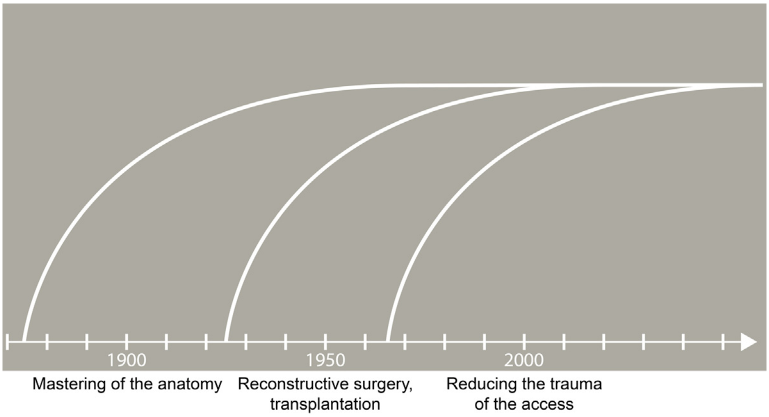

Figure 1.2 Three eras of interventional medicine: In the beginning, surgeons had to conquer the various anatomical regions of the body: Abdomen, thorax, etc., and finally the brain. As soon as this was achieved, the focus was laid upon reconstruction/substitutes. About 20 years ago, surgery entered the era of trauma reduction. *From MITI.*

As shown in Fig. 1.1, scientific surgery has existed as an academic discipline for only 150 years. Retrospectively, this comparatively short period of time can be subdivided into three different eras (Fig. 1.2).

In the beginning, surgeons learned to master the specific challenges of the different anatomical regions—beginning with the abdomen and ending with the brain. In the next phase, surgery was not any longer confined to resection/amputation, etc. but the focus was now laid on substituting deficits: Destroyed joints were replaced by artificial implants, so-called pouches were developed to take over the role of the stomach, the rectum after resection, etc. The final highlight of the era was the transplantation of whole organs (heart, liver, kidney).

The trend of today is to further minimize the surgical trauma—collateral damage to other organs, functional impairment, and pain. This third era of surgery started with the introduction of laparoscopic surgery. Laparoscopy was, however, only the beginning of a broad development in many medical disciplines toward less trauma and lower invasiveness. Many surgical operations are now substituted by new interventions that do not need skin incisions, general anesthesia, etc. One of the classical surgical emergency cases in former days was, e.g., gastroduodenal bleeding from peptic ulcers, forcing the surgeons frequently to spend another few hours in the operating room (OR) during nighttime. This type of surgery has almost vanished from the surgical departments, since upper gastrointestinal bleedings are now treated successfully by interventional gastroenterologists who have learned to stop the bleeding from inside. Another impressive example of how surgery became superseded by non-surgical interventions is portal hypertension. Blood perfusion of the liver is impaired in the case of liver cirrhosis. Prehepatic blood is deviated and induces life-threatening bleeding into the esophagus. The surgical answer was to create artificial shunts (portocaval shunts). Admittedly, shunt surgery was highly demanding and complicated. If the patient survived, the functional results usually were not particularly satisfying. Today, shunt surgery is obsolete. It has been successfully replaced by a radiological intervention called transjugular intraparenchymatous shunt. Surgery of portal hypertension is no longer an issue in surgery. Many similar examples exist.

This development will certainly continue and it is doubtful what will be left for traditional surgery (Fig. 1.3). One thing, however, is clear: In order to achieve further progress in medicine, the surgeons and physicians need more than ever the active support of basic sciences, engineers, and computer scientists. Without innovative tools and methods—delivered by biomedical engineering (BME)—the medical doctors will be unable to further improve their armamentarium of interventional therapeutic approaches. This is why an intensive continuous dialogue between

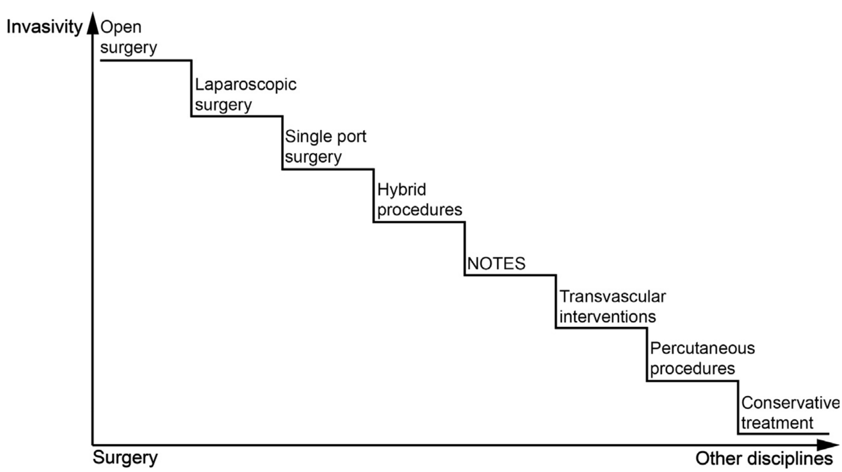

Figure 1.3 Developments in invasive medicine: Classical "open" surgery is rather invasive, but remains to be the gold standard of all competitive less-invasive procedures. Step by step, alternative interventional options were developed. The latest ones lost their connexion to conventional surgery. *From MITI.*

science, development, and medicine is today mandatory. It has been shown that the translation of innovative surgical devices into the OR is markedly improved by this interdisciplinary interaction [1].

Fortunately, a corresponding response can be observed on the technical/scientific side: The community of natural sciences developed the concept of BME.

The definition of BME in brief:

> *"Application of engineering principles and design concepts to medicine for diagnostic or therapeutic purposes."*
>
> ***Wikipedia***

Admittedly, this definition is not very sharp and could include almost everything. As a matter of fact, BME is the intersection of at least three mighty disciplines: medicine, engineering, and basic science. Like surgery or perhaps it would be better to say interventional medicine, many of the natural sciences like chemistry, biology, and the engineering had a long way to go in academic history to achieve the status of becoming their own academic disciplines. Therefore, it is little wonder, that the overlap of these three disciplines appears to be academically doubtful since it resembles too much pure application rather than science for its own right.

It is the question now of whether BME has got the chance at all to achieve in the long run an equal academic status to the other now well-acknowledged disciplines. In other words, whether BME can be released of its ostensibly scientific interiority and gain a well-respected place in the academic community ("academic emancipation").

Disregard of natural science or even more of engineering is based upon very old traditions. Greece was the cradle of the classical academy. It is well known that only theoretical work like philosophy was considered as science. The reputation of productive physical work like producing food or building houses or ships was considered low. This point of view dominated academic reality in European universities for many centuries. They mainly comprehended only four faculties: Theology, law, medicine, and fine arts. Of course, the societies acquired in parallel considerable technical knowledge in all fields—in particular in mining, ship building, navigation, etc.—but the academic value of these impressive intellectual efforts was not recognized.

It took until the French revolution to come to the first educational institution for practical/technical knowledge. The highly reputative École Polytechnique in Paris was originally founded in 1794 to provide the

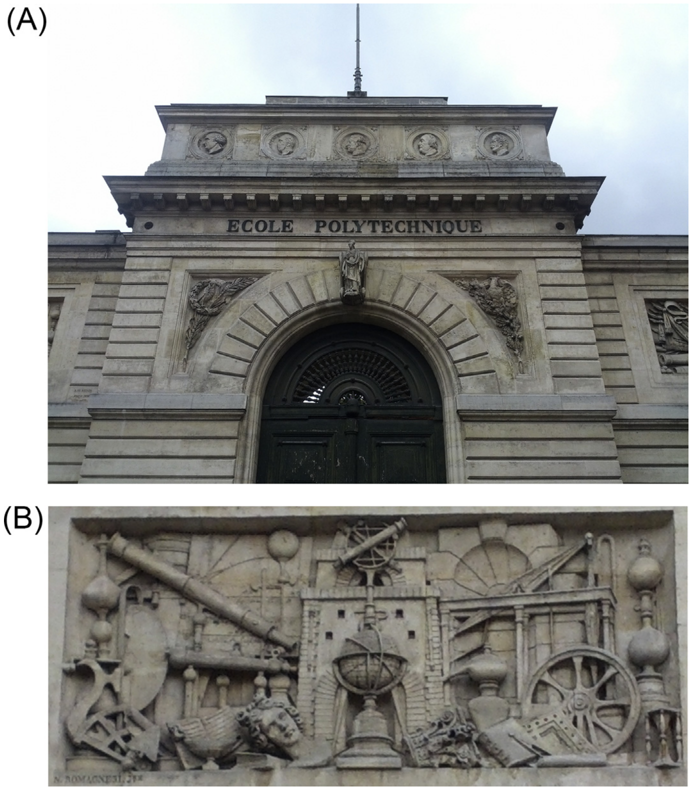

Figure 1.4 (A) The beginnings of systematical higher technical education: École Polytechnique in Paris, founded in 1794. (B) Coat of arms of the École Polytechnique: Besides of the military aspect, it also refers to civilian engineering. *From MITI.*

army with well-trained pioneers for the engineer units, but later on, civilian professions were trained as well (Fig. 1.4).

The idea found an overwhelming interest in other states and similar "schools" for trade and industry were soon created in various European countries (Fig. 1.5).

Many of the famous pioneers of the industrial revolution started their career at these places. The rapidly growing industry required more and more competent young engineers. Accordingly, the number of institutions increased significantly in the following decades and they were upgraded to "Technical high schools" beginning from 1879. This development was observed all over Europe, notwithstanding some differences in different areas.

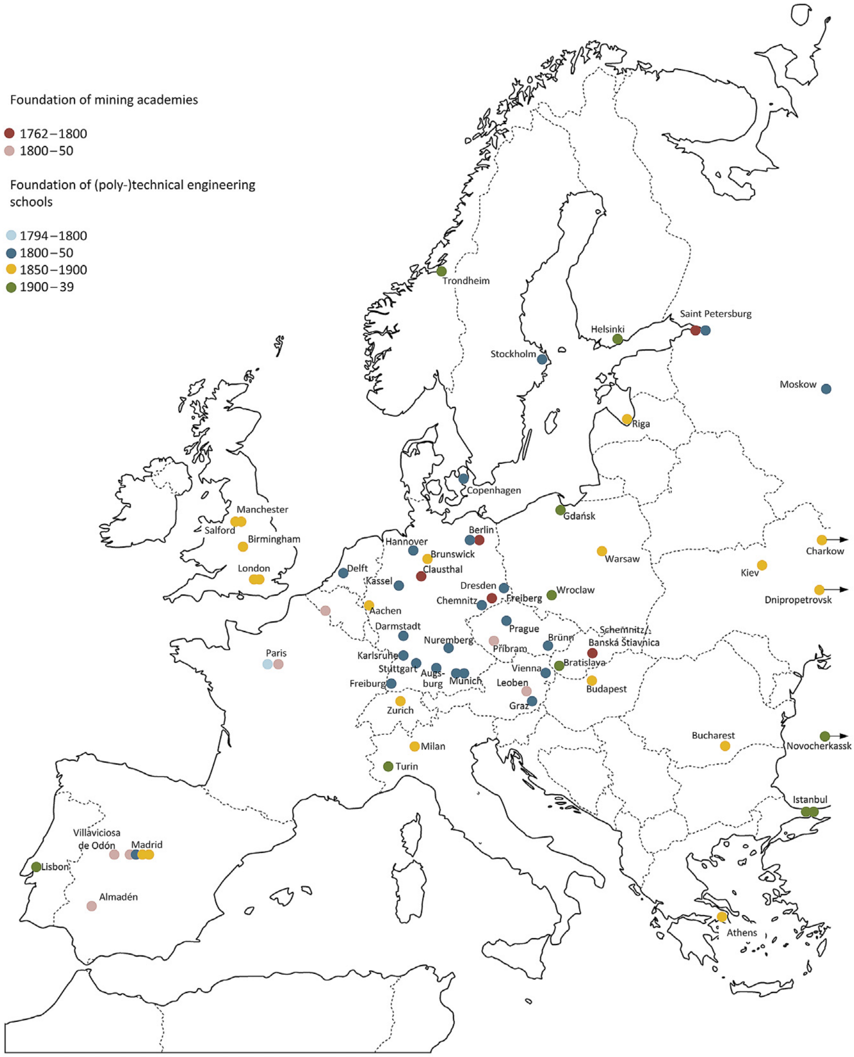

Figure 1.5 Foundation of advanced technical education institutes. *Modified by Dr. A. Schneider.*

The amazing flood of new scientific insights and the outbreak of technical innovations augmented significantly the acceptance and prestige of the technical and engineering disciplines in the society. The German government under emperor Wilhelm II was the first one which, accordingly, entitled Technical High Schools to offer diplomas and even a doctor's degree to their students (1899). In real life, these academic qualifications soon got broad acceptance and acknowledgment, but in the "classical" academic world, esteem was low. Despite the impressive number of Nobel Prize winners, the new faculties were still scorned as "grease oil faculties."

Over the coming years, the impact of natural science, engineering, and computer science was increasing so much that the differentiation between technical high schools and real universities could no longer be maintained. All over Europe, they were now—in between 1970 and 1980—denounced as Technical Universities. Two exceptions, however, still exist in Europe. The "Eidgenössische Technische Hochschule (ETH)" in Zurich and the "Rheinisch-Westfälische Technische Hochschule (RWTH)" decided to keep their original name, though it is beyond doubt that they are full universities of outstanding position.

Self-evidently, the special problems in medical engineering had always been a part of disciplines like physics, electrical or mechanical engineering, or computer science, but the idea to define its own scientific entity arose no earlier than 1990. Most probably, this was induced by the end of the cold war, since research and development for military purposes sharply declined, and new fields of activities had to be found and these were found in medicine.

It is an optimistic statement that BME has emerged in the meantime as a discipline of its own right rather than being a cross-disciplinary hybrid specialization of other disciplines. In reality, many consider BME still as a nonfertile hybrid, just like a mule. A mule is stronger, more resilient and more apt to achieve tasks than its father (donkey) and its mother (horse), but it is unable to reproduce its own kind. This comparison is impressive and plausible at first glance, but we are convinced that it is not adequate to describe the situation of BME.

There is a real chance for BME to flourish as its own discipline: Natural science/engineering and medicine have to cooperate as intensively as possible. This is not as easy as it seems to be: Actually, surgeons and engineers are still living in different worlds, considering each other from a different point of view (Tables 1.1 and 1.2).

Engineers complain that physicians use a highly specific terminology which is difficult to understand. Cooperation is often difficult since surgeons are considered to have only a limited awareness of the significance of technical innovations, they are impatient and time management is often chaotic. On the other hand, many surgeons are not really motivated to

Table 1.1 Why is cooperation difficult? The engineer's view

Difficult medical terminology
Low precision in defining the requirements
Impatience
Little understanding of systematic work
Chaotic time management
Limited awareness of the significance of technical innovations

focus on BME problems since the majority expect to be provided with innovative devices or methods by the industry and are not inclined to take part in the development for themselves. Above all, the academic output of BME for surgeons is up to now low. Other fields of scientific activities are far more interesting in regards to academic qualification, such as oncology, transplantation, and so on. Fund raising is also far more difficult than in other fields and a high number of impact factors can be collected faster.

What can/should be done?

On the medical side, BME topics have to be integrated into the study of medicine. The medical curriculum is continuously modified and new topics such as gender are integrated. Accordingly, BME should become also an obligatory part of the catalogue of learning objectives. Secondly, attractive career prospects for BME qualified physicians have to be created at the hospitals. The importance of BME has to be dissipated by the professional medical associations. Better means of academic credits have to be introduced. It is not the primary task of a surgeon but he/she is able to offer substantial contributions to BME:

- Identify and define the clinical need
- Critical support of the various stages of development
- Preclinical evaluation
- Clinical evaluation (proof of concept, application studies, randomized controlled trials)

Table 1.2 Why is cooperation difficult? The surgeon's view

The industry should provide us with effective, innovative devices.
The engineers don't need us. They prefer to do it alone.
Cooperation with engineers is tedious and takes a lot of time.
The academic output is low.

The technical community has to become more active as well. It is urgently needed that the profile of BME science should be defined more clearly worldwide. Dedicated literature with high ranking journals and well-accepted textbooks have to be created. Education and training has to be standardized and has to be made transparent. BME lighthouses should give an increased momentum to BME worldwide. Beyond that, much is left for both sides to be done together. Interdisciplinary national and international interest and lobby groups have to be established. Society and politics have to be informed by regular public statements, most desirably in an international frame. Much has already been done but the activities have still to be intensified.

Conclusively, BME is still on the threshold of being perceived by the academic community as an academic discipline of its own right. Due to the rapid development of typical BME tasks and the distinct dependence of interventional medicine—which is far more today than just conventional surgery—of technical innovations, medical doctors should have a particular interest to contribute to make BME thrive.

BME as a new academic discipline should not attempt to monopolize all types of BME. On the contrary, other disciplines like electrical or mechanical engineering and many others should continue or even intensify their work on specific one-to-one issues with medical partners. As soon as more systemic solutions are required, however, the expert in BME should be involved. BME has to manage successfully the balancing act of being brought to life as an offspring of various disciplines but being nevertheless able to found its own entity. This is certainly difficult, but the emerging of computer science which was originally coming both from mathematics and electrical engineering is an example showing that the goal can be reached.

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CHAPTER 2

Anatomy, Physiology, and Selected Pathologies of the Gastrointestinal Tract

As seen from the biomedical engineering point of view, the anatomy and even the physiology of the gastrointestinal tract are not too difficult to understand. The task of this part of the body is the intake of food, transportation, resorption, and digestion, and finally defecation. It consists of the esophagus, stomach, duodenum, small and large bowel. In addition, the two important glands (liver and pancreas) have to be considered (Fig. 2.1).

The liver and pancreas can be understood as auxiliary but nevertheless essential laboratories to process the substances which are taken up by the GI tract and finally eliminated. Food is processed mechanically and chemically. Biomedical engineering (BME) concerns mainly the mechanical aspects, although gray zones exist. Transportation is a major issue. In the alimentary tract, straightforward transportation is as important as controlled regurgitation (retrograde movement). Sphincters serve as valves to prevent retrograde flow. Some parts like the stomach or the rectosigmoid serve for temporary storage.

Beyond the description of the necessary basic insights into human anatomy and physiology, we make the attempt to delineate in this chapter some urgent and up to now unsolved therapeutic problems which could become an attractive field of BME activities.

Though medical treatment has contributed a lot to overcome gastrointestinal diseases without surgery (just to think of the introduction of proton pump inhibitors) and will still contribute much more in the future, there is still a lot to be expected from advances in operative medicine based upon further impulses of BME. This ranges from a further minimalization of the surgical access and the avoidance of collateral damage to the replacement of whole organs by artificial organs or the implantation of pacemakers to modulate intestinal motility, etc.

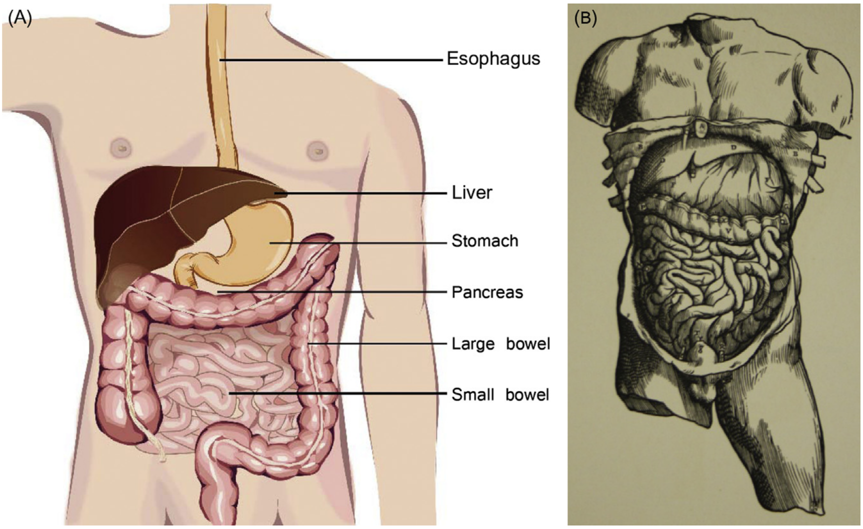

Figure 2.1 An overview of the viscerum: (A) Note: the pancreas is subtotally covered by the stomach and the transverse part of the colon; (B) Illustration of the abdominal viscera by Vesalius: *De humani corporis fabrica libri septem* 1543. *From (A) M. Scholle, (B) Courtesy: PD Dr. S. B. Reiser, Klinikum rechts der Isar.*

2.1 THE GASTROINTESTINAL TRACT: AN OVERVIEW

The gastrointestinal tract can be compared with a coal *power* plant in its organization. The "coal" (food) is delivered preprocessed, stored in an intermediate place, finally transported to the furnace, then burnt and the remnants are finally discarded.

The mouth, the teeth, and the esophagus are comparable to the primary mill and to the transportation belt which deliver the substrate to the intermediate store—the stomach. Here, food is stored in the upper two thirds (receptive part). The distal third is characterized by intensive motility activities ("antral mill") which delivers the food in distinct portions into the small bowel. Digestion occurs in the small intestine. In the final part of the GI tract the feces are dehydrated and transported to the rectosigmoid, where they are temporarily stored before it is decided to empty it. All in all, food intake and digestion is a highly complex process which, accordingly, is prone to a wide range of potential malfunctions or damages.

In addition, various types of maldigestion or metabolic diseases occur, but these are usually not the focus of BME. In the following, a brief overview of the GI tract is given, together with some aspects of physiology and pathophysiology (the mechanism of diseases).

It is quite natural that a complicated mechanism like our coal power plant and even more the human organism is prone to malfunctions. Taking again this example, the problems can be classified as follows:

2.1.1 Structural Defects

Either parts of the construction are wrongly designed or the original structure is altered during use.

In the GI tract, structural or anatomical defects occur as hernia (bulging of the wall), diverticula (outpouching of the wall of the GI tract, in particular in the esophagus or colon), obstruction (e.g., by adhesions), or malpositions. Not all of them must be treated. If so, a surgical repair is mostly required.

2.1.2 Functional Defects

If a transportation belt stands still, or if a valve does not open or close, the workflow is severely impaired. In the human body, functional deficits may also occur.

Transportation problems are known in the esophagus (achalasia), the stomach, and the large bowel (constipation, diarrhea). Seldom, the small intestine is involved as well. Most often, they are caused by innovation failures.

At least three valves play a major role: The so-called upper esophageal sphincter (usually opening problems leading to clinically significant swallowing problems—dysphagia), the lower esophageal sphincter between esophagus and stomach (if it does not close properly, gastric acid flows back into the esophagus and causes pain and erosions), and the anal sphincter (causing constipation if it does not open properly or fecal incontinency if it does not close).

2.1.3 Attrition and Erosion

Continuous use of a technical construction inevitably results in attrition and aging which deteriorates the function and finally leads to a breakdown. This can be delayed by careful mending and immediate repair when required, but no technical system can be designed for eternity. Attrition and erosion (rust) contribute to this natural process.

In the human body, attrition or aging affects the GI tract far less intensively than the brain, or the bones and joints (osteoporosis, arthrosis), or, just to name it, sexual function. With growing age, the colorectum may slow down its function, leading to constipation, but in general, the GI tract is rather resistant to aging.

The system is by far more endangered by two different hostile factors:

Bacterial or nonbacterial inflammation and cancer.

It may be surprising that bacterial inflammation is still a problem today, so many decades after the detection of effective antibiotics. Nonetheless, bacterial inflammation requires surgical intervention still today, such as the inflammation of the gallbladder (cholecystitis) or the sigmoid colon (diverticulitis).

Chronic noninfectious inflammation like Crohn's disease may appear within the whole GI tract, whereas ulcerative colitis is strictly confined to the colon. In case of severe complications, they often require surgical intervention.

The most clinically relevant disorder is cancer. In some regards, it can be compared with rust in a steel construction. The best way to handle the problem is prevention.

If rusting begins, it is extremely difficult to stop this destructive process. The construction loses functionality and finally it will break down completely.

This is similar to cancer. It grows and infiltrates neighboring organs, impairs them to deliver their natural functionality, and finally leads to the complete breakdown of the system—death.

In opposition to the technical model of rust formation, cancer formation is accompanied by an additional feature: Cancer is able to create distant manifestations of the disease—so-called "metastases." Cancer cells migrate via blood circulation or lymphatic vessels to distant locations and induce new tumor growth in distant regions.

Usually, they prefer the liver, the lungs, and the bones. Up to today, it is poorly understood why these organs are primary targets. Abundant blood perfusion cannot be the explanation, since some extremely well perfused organs (heart, spleen) practically never develop manifest metastases.

If cancer is detected at an early stage, it can be healed by surgical resection. The more advanced it is, the more difficult it becomes to achieve a cure. In order to describe malignant lesions more precisely, the so-called TNM classification was developed.

T (tumor) describes the depth of invasion of the primary tumor. T_1 is a very superficial type, whereas T_4 means that the tumor has already invaded neighboring organs. The range is from T_1 to T_4.

N (node for lymph node) describes whether lymph nodes are inflicted or not. N_0 means no lymph node infliction, N_1 is the infliction of nearby nodes, and N_2 of distant ones.

M (metastases) describes whether distant spread of cancer (metastases) is present or not. M_0 means no presence of metastases. T_X (or N_X or M_X) means no statement can be made.

Often, additional letters such as a "G" for "grading" are used.

G defines the rate of growth of a malignant tumor. It ranges from G_1 (well differentiated, low grade) to G_4 (undifferentiated, high grade).

The individual constellations of the TNM classes are integrated into a "stage." Usually, four tumor stages are used, beginning with stage 0 (cancer cells present, but not yet infiltrating), stage I and II (tumor stages which usually can be surgically removed), and the advanced stages III and IV. Since a reliable and precise staging of malignant tumor is of outstanding importance for further improvement of therapy, the Union for International Cancer Control implemented a process for continuous improvement of the TNM classification systems. The modifications are regularly published in new editions [1].

Modern imaging provides a very precise insight into normal and pathological anatomy (Fig. 2.2). CT or MRI scans create a 3D volume data set which enables to visualize the topography of all sections of the GI tract.

As compared to former times, modern imaging procedures do show not only static anatomical situations but also functional processes. Insofar, they are superior not only to anatomical textbooks to get an insight into normal anatomy but also to learn more about physiological activities.

2.2 ESOPHAGUS

2.2.1 Anatomical Description

The esophagus is the first part of the gastrointestinal tract as far as it concerns gastrointestinal medicine. It begins at the end of the hypopharynx, at the level of the sixth cervical vertebra (C6) at the height of the cricoid cartilage (Fig. 2.3), passes the chest behind the trachea and its bifurcation. Remaining positioned above the spine, it enters the abdominal cavity through the diaphragm at about the level of the tenth thoracic vertebra (T10) and ends in the cardia—the transit zone between esophagus and stomach.

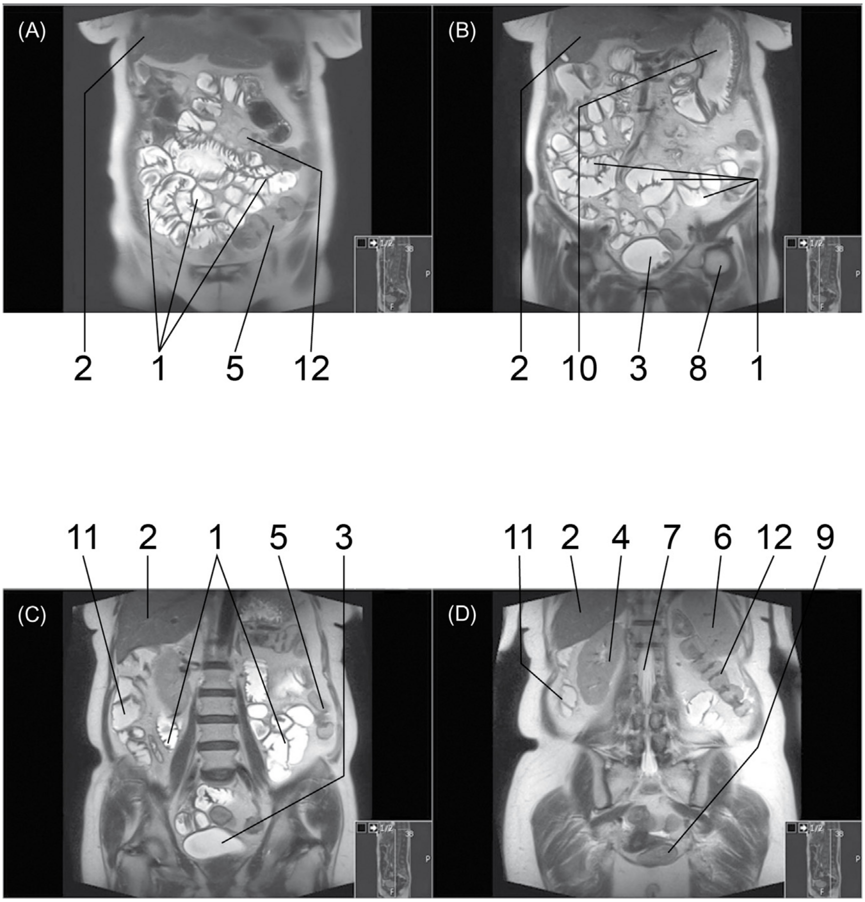

Figure 2.2 MR Sellink of the abdomen: The abdomen in four coronary slices. The small inserts (right side; bottom) indicate the height. (A) Coronary plane, a few cm below the abdominal wall; (B) upper middle; (C) lower middle; (D) deep. (1) small bowel; (2) liver; (3) urinary bladder; (4) right kidney; (5) descending colon; (6) spleen; (7) spine column; (8) left femoral head; (9) rectum; (10) stomach; (11) ascending colon; (12) transverse colon. *Courtesy: Dr. K. Holzapfel, Klinikum rechts der Isar.*

2.2.2 Functional Task

The primary function is the transportation of ingested food into the stomach and the prevention of reflux. Two high pressure zones occlude the esophagus which open only during swallowing: The upper (UES) and the lower esophageal sphincter (LES). The function of the upper high pressure zone is still poorly understood. It is assumed to create a "second barrier" against reflux coming from the stomach.

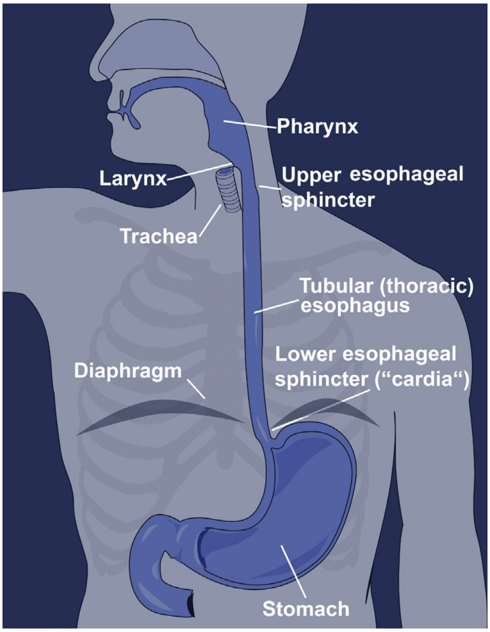

Figure 2.3 The esophagus: The esophagus is a muscular hose which begins at the so-called upper esophageal sphincter ("esophageal mouth") and guarantees the intestinal passage from the hypopharynx to the stomach. *From M. Scholle.*

The lower esophageal sphincter prevents gastric contents, in particular acid, being regurgitated into the esophagus.

Since the esophageal mucosa (so-called squamous cell epithelium) would be severely damaged by acid or other components of the gastric content, the protective function of the LES is crucial.

Under resting conditions, both the UES and the LES are closed. If the patient swallows, the ingested food ("bolus") enters the esophagus through the upper esophageal sphincter UES. The UES is actively opened by relaxation and contraction of the respective muscles. As soon as the bolus has passed, the sphincter is closed again and remains occluded until the next act of swallowing is initiated.

The bolus is now advanced through the tubular esophagus to the region of the esophagogastric junction. It is achieved by the strong muscle wall of the esophagus with its circular and longitudinal layers. The contracted circular muscle segment is pulled down by the longitudinal muscle layer in a strict sequence from oralad to caudad, resulting in a "peristaltic wave." As soon as the bolus comes close to the lower esophageal sphincter

(LES), the LES relaxes enabling the transit into the stomach. After the bolus passage, it closes again to prevent acid gastric reflux from the stomach which may severely damage the esophageal mucosa.

2.2.3 Disorders and Diseases

The most frequent disorder is a decrease of resting pressure in the lower esophageal sphincter resulting in pathological reflux. The regurgitation of gastric content into the esophagus makes pain ("heartburn") and causes inflammation ("esophagitis"). In severe cases, bleeding, ulcers, or even stenosis (narrowing of the esophageal lumen) may occur. Severe chronic reflux favors the development of (Adeno-) carcinoma of the esophagus (see Section 2.2.4 Cancer). In most cases, medical treatment is sufficient. In about 10% of cases, an interventional treatment is required.

The contrary is a missing opening reflex of the sphincter during swallowing, leading to severe dysphagia ("achalasia"). The injection of Botox is only temporarily helpful. The classical approach is either dilatation or surgery (cardiomyotomy).

2.2.4 Cancer

Two types of cancer may occur: Squamous cell carcinoma arises on each height of the esophagus. It is most often caused by heavy drinking and concomitant smoking. Adenocarcinoma is induced by severe, chronic reflux disease and obesity. Although squamous cell carcinoma predominates worldwide, Western nations have seen a marked rise in the incidence of adenocarcinoma. Radical resection is the first therapeutic choice, frequently accompanied by radio/chemotherapy. Esophageal cancer surgery is highly demanding. Any further technical support would be highly appreciated to make the intervention safer and simpler. Maybe robotic surgery will become an option [2].

2.2.5 Biomedical Engineering Aspects

Since *gastroesophageal reflux* is a very frequent disease and a very promising market, artificial reinforcement of the lower esophageal sphincter is the focus of many biomedical approaches. Several approaches are currently being evaluated:

2.2.5.1 Internal (Endoscopic) Reinforcement

The history of endoscopic approaches to augment the sphincter is long. During the past 15 years, a multitude of endoscopic therapies have emerged as potential alternatives to conventional surgical treatment. These options can be categorized into three groups:

1. Radiofrequency energy delivery to the esophagocardiac junction
2. Injection of nonabsorbable inert material into the wall of the cardia
3. Endoluminal suturing.

Despite very promising concepts, it is still a matter of debate as to whether these techniques may really gain a role in gastroesophageal reflux disease management [3,4].

2.2.5.2 Implants

The first implant was clinically evaluated about 30 years ago. The so-called Angelchik prosthesis had a sausage-like form filled with silicone. Though effective in preventing reflux, it frequently had foreign body-related side effects like perforation and migration. Soon it became obsolete. A new implant is a ring with magnetic beads (LINX). Although the first reports are promising, some concerns exist in regard to the typical problem of the perforation of foreign bodies [5].

2.2.5.3 Electrical Stimulation

Though electrical stimulation of the lower esophageal sphincter is quite an old idea, only now are the first devices commercially available.

Two electrodes attached to the sphincter deliver electrical impulses produced by a subcutaneously implanted pacemaker. This principle appears to be effective, although little is known about the mode of action [6].

Achalasia can be relieved either by endoluminal dilatation of the LES or by dissecting the sphincter muscle. The design of dilatation devices still needs improvement (e.g., pressure control to avoid the risk of perforation). Electrical stimulation could be at least conceivable.

In case of cancer, radical surgical resection is the treatment of choice. Different techniques are available. Most commonly, the right thorax has to be opened to get access to the esophagus. When it is cut out, its former function is restored either by a gastric pull-through or by a colonic segment. Esophagectomy is major surgery and should be only performed in particularly experienced and well-equipped centers. In early cases, innovative technologies are now available to avoid classical resection. Early cancer can be locally excised. In rare cases, local destruction by thermo-ablation may be justified.

For advanced, otherwise inoperable stages, various types of stents are provided to overcome the obstruction. If food intake is completely impossible, enteral nutrition can be maintained by a "percutaneous endoscopic gastrostomy" (PEG) (see Chapter 8.4.2: Percutaneous Endoscopic Gastrostomy).

Table 2.1 Esophagus: selected diseases/disorders and BME aspects

Disease/disorder	Therapy	BME aspects
Gastroesophageal reflux disease	Medical treatment or surgery (fundoplication)	Antireflux implants Sphincter stimulation Endoluminal augmentation
Achalasia	Balloon dilatation, surgery (cardiomyotomy)	Balloon dilatation stimulation?
Cancer	Surgical resection Chemotherapy Radiotherapy	Stents, robotic surgery Endoluminal resection Ablation

Over many decades it was attempted to create artificial substitutes of the esophagus. Up to now, none of these experimental designs has been successful and the clinical need is comparatively low (Table 2.1).

Self-evidently, this list of esophageal disorders is not complete. Esophageal function is also impaired by diverticles (outpouching of the wall), motility disorders, etc., but these diseases are of low BME relevance.

2.3 STOMACH

2.3.1 Anatomical Description

The stomach is the section of the GI tract between the esophagus and the duodenum, located beneath the diaphragm, in the center and to the left of the abdomen (Fig. 2.4A). It is a hollow, curved organ. The right edge is denominated "lesser curvature" and the left one as "greater curvature." The stomach is usually closed to the esophagus by the lower esophageal sphincter, which opens during swallowing, belching, or vomiting. Furthermore, temporary "transient" relaxations occur.

The region between the stomach and the esophagus is called the esophagogastric junction or "cardia." The stomach is divided into three parts: the proximal (fundus), the middle (corpus), and the distal third (antrum) (Fig. 2.4B). The frontier between the stomach and the adjacent duodenum is marked by the so-called "Pylorus." This is another functional sphincter region which regulates the transit of ingested food into the small bowel.

The gastric wall consists of a strong muscular layer and a relatively thick mucosa. The latter is able to produce both highly concentrated hypochloric acid as well as mucus which protects the gastric wall from self-digestion.

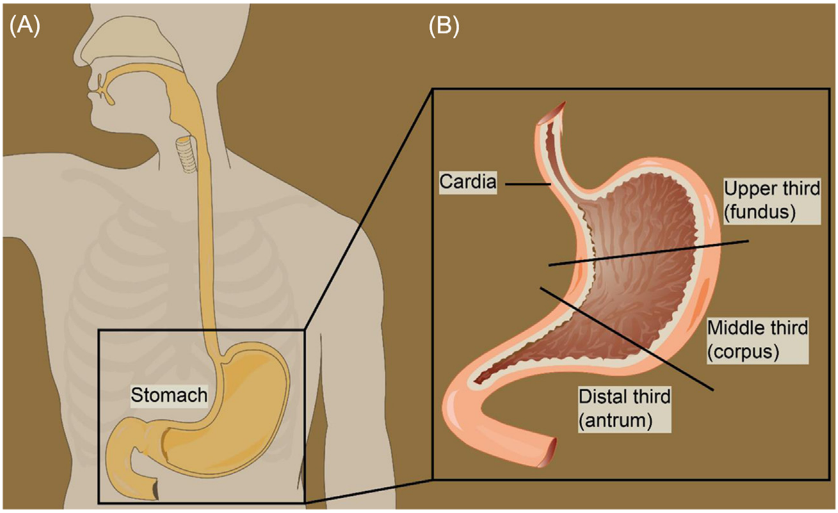

Figure 2.4 (A) The stomach is localized in the epigastrium—beneath the rib arches and the space between the sternum and the navel. (B) For practical reasons, it is divided into three sections. The upper (oral) part relaxes during food intake to augment the volume. The distal part produces strong, rhythmic contraction and transports the food via the pylorus into the duodenum. *From M. Scholle.*

2.3.2 Functional Task

The main task of the stomach is to take up the ingested food and to deliver it in adequate quantities into the small bowel. However, preprocessing is included as well. Gastric acid production reduces bacterial contamination and prepares digestion. Furthermore, mechanical alteration takes place, induced by continuous rotation in the distal part of the stomach ("antral mill"). Whereas the proximal two-thirds part has mainly a receptive function, the distal part is mechanically active.

However, the stomach is more than just a "food bag" with some motor activity. It is proven that the distension of the proximal stomach influences via hormonal control the degree of satiety—or hunger. In addition, an electrical pacemaker is assumed to exist in the fundus/fornix region which stimulates the electromechanical phenomena like the antral motility and the digestive waves of the distal stomach, the duodenum, small and large bowel. Many of these aspects are still poorly understood. A better understanding of physiological and pathological processes would be fundamental to design better therapeutic tools.

2.3.3 Disorders and Diseases

Historically, acid-related disorders were of outstanding importance. Peptic gastric ulcers led to perforation and bleeding. Due to the detection of *Helicobacter pylori* and the availability of cheap proton pump inhibitors, the significance of peptic ulcer disease decreased. Nevertheless, ulcer bleeding or perforation are still severe problems worldwide. They frequently require emergency surgery. Endoscopic treatment has become an option as well [7].

The number one problem today is gastric cancer, although its incidence has declined as well. Major parts or even the whole stomach have to be removed, resulting in a more or less significant reduction of quality of life afterward. A better understanding of tumor biology could help in the future. In many instances a too radical resection could be avoided if it were possible pre- or intraoperatively to assess whether lymph nodes are inflicted or not (precise "staging"). If the tumor is still localized, i.e., not inflicting adjacent structures like lymph nodes, local excision is sufficient and radical resection is not required. If intraoperative tissue differentiation were possible a big step toward individualized surgery would be achieved.

Less frequently gastric motility disorders occur, such as gastroparesis. Gastric motility disappears which leads to emptying disturbances. Electrical stimulation can be helpful (see Chapter 14: Visceral Surgery of the Future: Prospects and Needs).

Due to its essential role in food intake, the stomach is also a particular target of bariatric surgery.

The main aim is to reduce the reservoir capacity.

2.3.4 Biomedical Engineering Aspects

Gastric bleeding was formerly a clear indication for emergency surgery. Due to the rapid development of endoscopic techniques and technology, they can now be stopped in the majority of cases by injecting techniques, the application of clips, or by banding. Further refinement of the technology could make surgery completely avoidable.

Perforation is still today a case for the surgeon. However, the first promising approaches are underway to occlude the hole by means of specially designed endoluminal clips or sutures (see Chapter 8.4.1: Gastrointestinal Bleeding).

The standard answer to *gastric cancer* is radical surgical resection. However, this is changing gradually today. Early cancer can be excised endoscopically using sophisticated new dissection techniques. Even full wall resection could become mature for routine clinical use if reliable occlusion techniques are provided.

In advanced cases, palliation can be improved by stenting techniques or PEG.

Gastroparesis is an emptying disorder of the stomach due to motility impairment. Bizarre dilatation of the stomach is the consequence. In advanced cases, partial resection is recommended, but the results are poor. Gastric electrostimulation could become helpful [8].

Morbid obesity: The stomach is a key target of biomedical engineering approaches to cure morbid obesity. Currently, there are a large variety of surgical procedures to reduce food intake which can be subdivided into restrictive (limitating the quantity of food during a meal), malabsorptive, or combined. One example of a restrictive approach is the so-called "gastric band." It is positioned like a belt around the upper part of the stomach. A similar restrictive effect is achieved by a so-called "gastric sleeve" operation. Large parts of the stomach are removed and only a narrow tube is left. In malabsorptive surgery, a bypass is created between the stomach and the distal ileum. Thus, a considerable length of the small bowel is excluded from digestion. Usually, they are significant surgical interventions, and the results are not completely satisfying.

Many efforts are focused upon internal (endoscopic) solutions [9]. One popular approach is to position an inflatable balloon into the gastric lumen. The large volume of the balloon reduces the internal gastric volume for further food intake.

Another approach is gastric stimulation [10]. The idea is to modify the gastric motility by electrical impulses delivered by a dedicated pacemaker. Many questions are still to be answered.

BME will play a major role in the treatment of these very frequent diseases. A closer cooperation between researchers, clinicians, and engineers would certainly help to identify innovative, less invasive treatment options (Table 2.2).

Table 2.2 Stomach: selected diseases/disorders and BME aspects

Disease/disorder	Therapy	BME aspects
Bleeding	Surgical hemostasis	Clipping Injection technique Banding
Perforation	Surgical excision and closure	Endoscopic closure using specially designed clips
Cancer	Radical surgical resection Chemotherapy (Radiotherapy)	Local excision with specially designed clips Endoscopic submucosal dissection (ESD) Stenting PEG
Gastroparesis	Medical treatment Partial gastric resection	Gastric pacemaker
Morbid obesity	Sleeve resection	Gastric band
	Gastric bypass	Endoluminal restriction techniques Gastric balloon Implantable deviation devices Gastric electrostimulation

2.4 DUODENUM AND SMALL INTESTINE

2.4.1 Anatomical Description

The next part of the alimentary tract is the small bowel, which is subdivided into the duodenum, the jejunum, and the ileum (Fig. 2.5).

The duodenum—directly adjacent to the stomach—has a smaller diameter than the stomach (1–3 cm under normal conditions) and is roughly C-shaped.

It is fixed to the retroperitoneum. Only after the duodenojejunal flexure does the small intestine become mobile. The duodenum is localized in close vicinity to the pancreas, the caval vein, and the liver. The distinct S-shaped transit into the jejunum is denominated the duodenojejunal flexure.

Whereas the border between the duodenum and the jejunum is anatomically rather clearly defined, it is not easy to define where the jejunum ends and where the ileum begins. The length of these sections of the alimentary tract varies considerably, depending upon the physiological state. Usually, a length of about 2–3 meters is quoted in the literature.

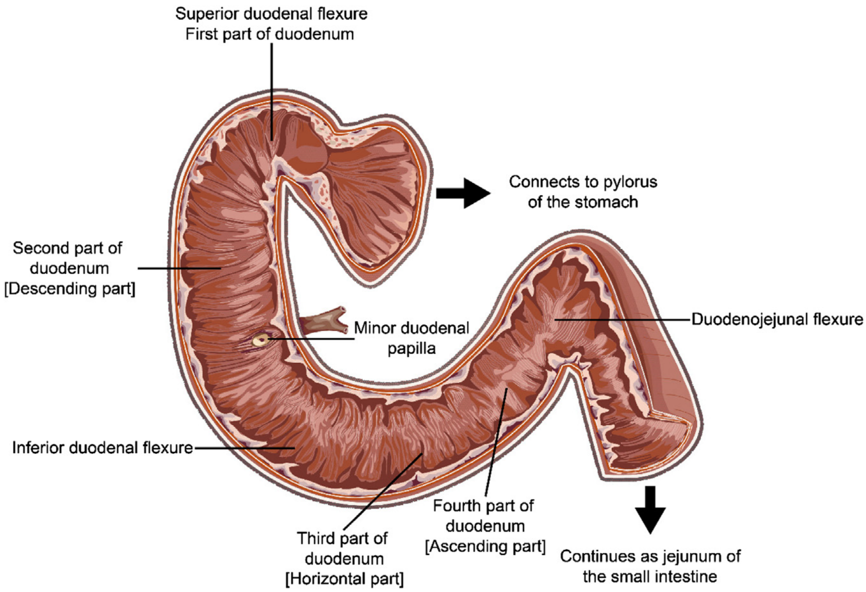

Figure 2.5 The duodenum: This part of the small intestine deserves special mention because of its specific anatomical and physiological features. *From M. Scholle.*

This is significantly more than is needed, since it is known from surgical experience that as little as 120 cm is sufficient to guarantee normal digestion (Fig. 2.6).

The end of the small intestine is clearly defined. It is the orifice into the large bowel. It is called the ileocecal (or Bauhin's) valve.

The microscopical aspects of the jejunum and the ileum are rather homogenous: The inner mucosal layer, the muscular layer (longitudinal and circular), and the peritoneum.

2.4.2 Functional Task

As soon as the acidic gastric content leaves the stomach, it is immediately neutralized by the alkalic bile/pancreatic juice mixture injected into the intestinal lumen via the Vater papilla.

The preprocessed intestinal content is now digested in the jejunum and ileum. All valuable components like fats, sugars, and proteins are extracted and delivered via the portal vein system to the liver. A complicated motility pattern with forward and backward transportation leads to a prolonged contact time with the intestinal mucosa to increase the effectiveness of absorption. The uptake of lipids, including fat soluble

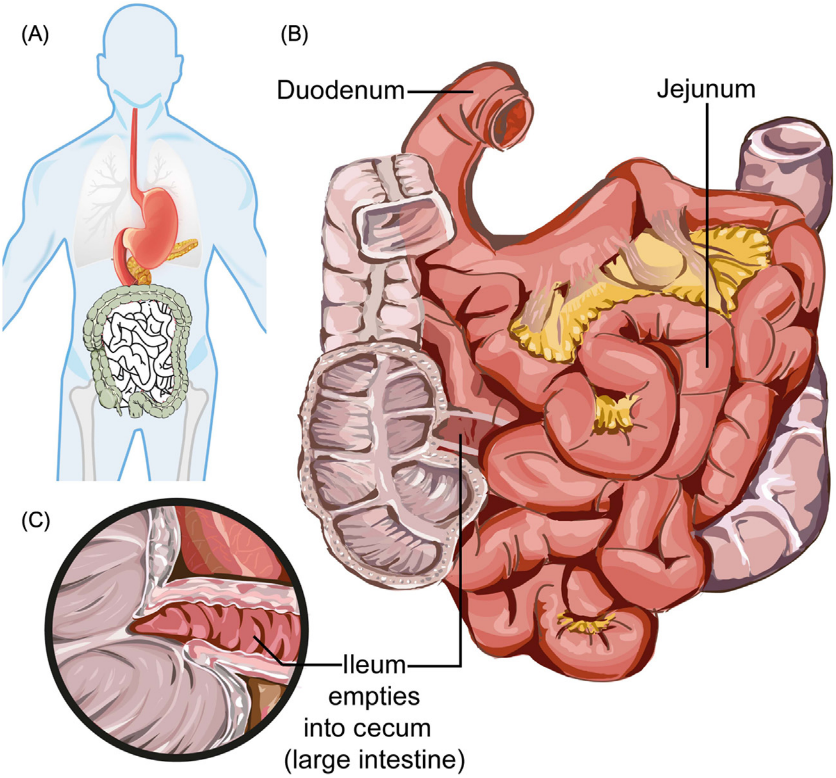

Figure 2.6 The small intestine: (A) The colon is the frame of the convolute of small bowel loops; (B) The stomach and parts of the colon removed: Beginning with the duodenum, the small intestine is now visible in its whole length; (C) The distal ileum joins with the colon: Bauhin's valve. *From M. Scholle.*

vitamins, is enhanced by bile acids, whereas pancreatic enzymes are responsible for the digestion of proteins, etc.

2.4.3 Disorders and Diseases

As compared to the other sections of the GI tract, the duodenum and the small bowel are relatively "peaceful" areas. Cancer is rare. In the duodenum, peptic ulcers may cause bleeding or perforation. Basically, they are treated in a similar way as described for gastric ulcers.

A major problem is duodenal obstruction due to pancreatic cancer or distal cancer of the stomach. Gastric outlet obstruction would lead to starvation, often accompanied by bile duct obstruction with jaundice. The classical approach is to create a deviation from the stomach into the small intestine (gastroenteric anastomosis) and a so-called hepaticojejunostomy, i.e., an anastomosis between the bile duct system and the small bowel.

Bleeding can occur in the small bowel and this is often difficult to localize.

The Meckel's diverticulum is a structural (anatomical) disorder.

It is more or less a large bulge of the distal ileum as a remnant of the yolk stalk. It often mimics appendicitis.

Last but not least obstructions of the jejunum are frequent in the case of gastroenteritis regionalis (Crohn's disease), a nonbacterial inflammation process. This disease is still not yet completely understood. Medical treatment is always the first option. However, surgery may become necessary in case of fistula or stenosis.

It is postulated that disorders of the small intestine may be the cause of a broad range of dysfunctional syndromes of the alimentary tract. Up until now, our knowledge of normal intestinal motility has been very limited; the real significance is still unknown.

2.4.4 Biomedical Engineering Aspects

Duodenal obstruction is currently increasingly often treated by stenting of the bile duct and the duodenum. Much has still to be improved, but there is no doubt that so-called palliation in the case of noncurable pancreatic or bile duct cancer will become a domain of nonsurgical interventions [11].

Advanced BME enabled the surgeons/gastroenterologists to explore the last white spot on the gastrointestinal map—the small bowel.

Around the year 2000, the first capsule was provided by the industry for visual exploration of the whole gastrointestinal tract (see Chapter 5.7.8: Wireless Capsule Endoscopy). Soon, specially designed endoscopes became available which allowed to promote the tip of the endoscope actively by sophisticated balloon techniques (see Chapter 5.7.2.6.2: Enteroscopy, "Deep Endoscopy"). Thus, endoluminal therapeutic procedures became possible which had been unthinkable before. Argon beaming of bleeding angiodysplasia as well as balloon dilatation of stenosis are now on the threshold of clinical maturity (Table 2.3).

Maybe, BME aspects can also contribute the "crux medicorum" of so-called dysfunctional abdominal syndromes. If motility disturbances are really the cause, electrical stimulation could, theoretically, become a promising approach.

Table 2.3 Duodenum and small intestine: selected diseases/disorders and BME aspects

Disease/disorder	Treatment	BME aspects
Bleeding (duodenum)		See Table 2.2
Perforation (duodenum)		See Table 2.2
Obstruction (duodenum)	Bilioenteric and gastroenteric anastomosis	Stenting PEJ
Obstruction (small intestine)	Segmental resection	Double balloon dilatation
Bleeding (small intestine)	Surgical hemostasis	Capsule endoscopy for localization Enteroscopy for hemostasis
Intestinal dysfunction	Medical treatment	Electrostimulation

2.5 COLON AND RECTUM

2.5.1 Anatomical Description

The colorectum is the last part of the alimentary tract. It begins with the ileocolic valve ("valvula Bauhini") and terminates with the anal sphincter. Its general outline resembles an M or inverted U (with the exception of the rectosigmoid) (Fig. 2.7).

The length of the colon is not more than about one fourth of the length of the small intestine. As compared to the small bowel it is less mobile and its position is much more constant. Two subdivisions, however, may vary considerably in shape and length and localization: the transverse and the sigmoid colon (Fig. 2.8).

The external appearance of the large bowel is quite characteristic: three longitudinal muscle bands ("taenia") shorten the bowel thus producing the typical pouches ("haustra") separated by transverse furrows. The inner diameter of the colon decreases gradually from about 5 cm at its beginning in the cecum to about 2.5 cm in the sigmoid. If the colon is empty and in a contracted state, the lumen is very small, but it is capable of great increase.

The last part of the GI tract—the rectum—deserves special notice. The length is defined as 15 cm and divided into the upper, middle, and lower third, which encompasses the anus.

The anorectum (Fig. 2.9) is part of the complex anatomical region of the pelvic floor [13].

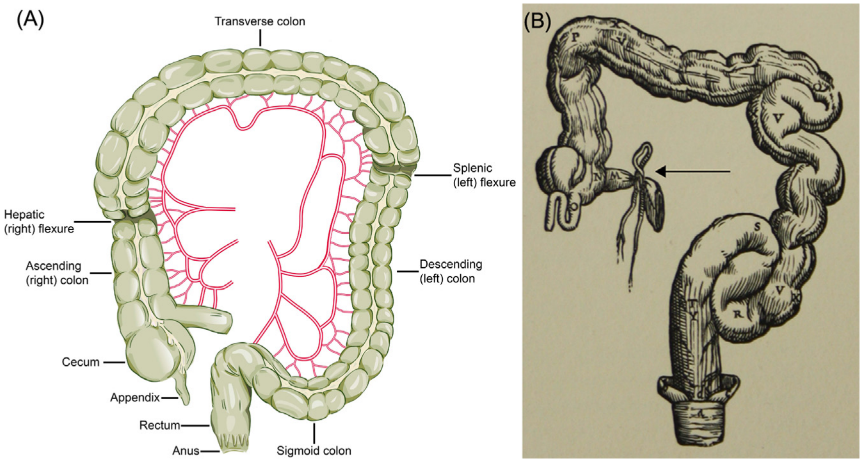

Figure 2.7 (A) The colorectum: Beginning with the cecum, the next part is the ascending colon on the right side of the body. After a sharp-angled bend ("right flexure") the transverse colon follows. The left (splenic) flexure is formed by the junction of the transverse colon and the descending colon. The length of the colon varies considerably. Of particular notion is the "appendix vermiformis." (B) Historical illustration by Vesalius (1543): Note the detailed and realistic representation of the appendix, etc. including the anal sphincter. The last part of the ileum is ligated (arrow). *From (A) M. Scholle, (B) Courtesy: PD Dr. S. B. Reiser, Klinikum rechts der Isar.*

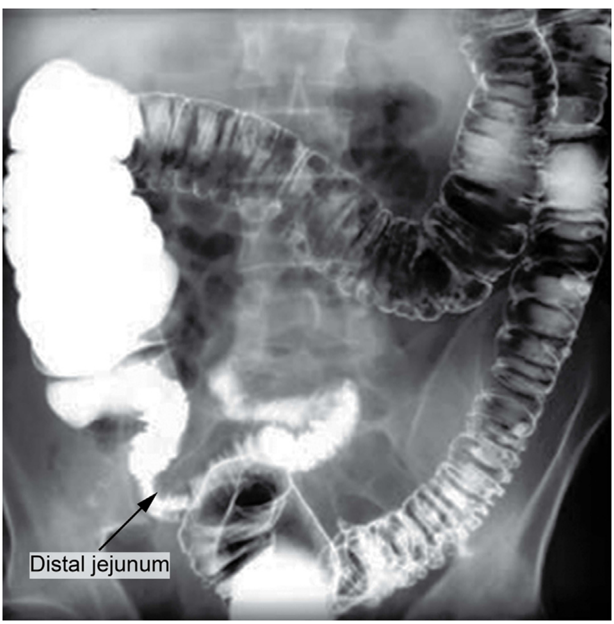

Figure 2.8 The Barium enema of the colorectum gives a good impression of the anatomy. A contrast medium (Barium) is instillated into the colon via the anus. The retrograde filling depicts the configuration of the colorectum. The last loop of the small bowel is also visible (arrow). *Courtesy: Dr. A. Fingerle, Klinikum rechts der Isar.*

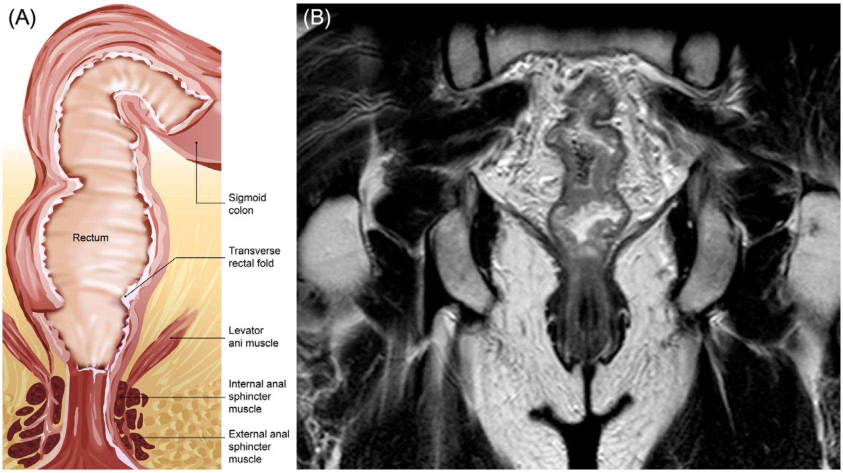

Figure 2.9 Anatomy of the anorectum: (A) The upper and middle third mainly function as storage space, whereas the lower third consists of the anal sphincter complex. The anal sphincter is a multilayered cylindrical structure, consisting of the smooth muscle internal sphincter and the external striated muscle layer. The sphincter is elevated by the funnel-shaped levator ani muscle [12]. (B) MR image of the anorectum. *From (A) M. Scholle, (B) Courtesy: Dr. A. Fingerle, Klinikum rechts der Isar.*

2.5.2 Functional Task

The main task of the colorectum is to reduce the mass of the feces and to enable a controlled defecation. Any remaining absorbable nutrients including water are removed, as well as vitamins produced by colonic bacteria. At the end, the feces are compacted and stored in the rectum until they can be discharged via the rectum. The anorectum and the pelvic floor provide continence and enable controlled evacuation of the indigestible mass.

2.5.3 Disorders and Diseases

Epidemiologically, the appendix most frequently needs surgical intervention. Appendectomy is not a great deal in surgical terms, but it has to be performed very often and is, thus, of distinct economical importance.

Diverticulitis is an inflammation of small colonic pouches ("diverticles") which mainly occur in the sigmoid region. The primary treatment is conservative (antibiotics). Recurrent diverticulitis needs surgical resection.

Inflammatory bowel disease such as Crohn's disease or ulcerative colitis are also the domain of medical treatment but often need surgery as well.

A problem of increasing importance is cancer of the colorectum. Large parts of the colon can be removed without any significant influence upon the quality of life of the patient. The closer the lesion comes to the anorectum, the more critical becomes resection since bladder function, sexual activity, and fecal continence may be concerned.

Last but not least, fecal incontinence is a major issue either after surgical procedure or noniatrogenic causes.

2.5.4 Biomedical Engineering Aspects

Though significant progress could be achieved in the treatment of colorectal diseases, much has still been left to BME-based improvements.

For many reasons, it would be very attractive to develop alternative options for the surgical treatment of appendicitis. First attempts were made to implant stents into the appendix to relieve inflammation. Another approach is so-called "scarless surgery" via natural orifices. Table 2.4 enumerates some innovative BME applications.

2.6 LIVER/GALLBLADDER

2.6.1 Anatomical Description

The liver is the largest glandular organ of the body. It is situated in the right upper abdomen and extends to the left hypochondrium.

The convex upper surface is molded to both halves of the diaphragm (Fig. 2.10).

Accordingly, it rises and falls during respiration. The internal anatomy differs from that of other organs, since the blood supply comes from two vessels: the hepatic artery provides arterial blood, and the portal vein carries blood to the liver which has passed before through the alimentary tract (including pancreas, spleen, and gallbladder). After circulating through the liver the blood is returned to the inferior caval vein via the hepatic veins.

The liver produces bile which is collected by the intrahepatic bile ducts. The main bile duct is formed by the union of these smaller

Table 2.4 Colorectum: selected diseases/disorders and BME aspects

Disease/disorder	Treatment	BME aspects
Appendicitis	Appendectomy	Endoscopic stenting Scarless appendectomy
Cancer	Surgical resection	Endoscopic resection Tailored surgery Improved anastomotic techniques Notes
Fecal incontinency	Surgical sphincter augmentation	Electrostimulation

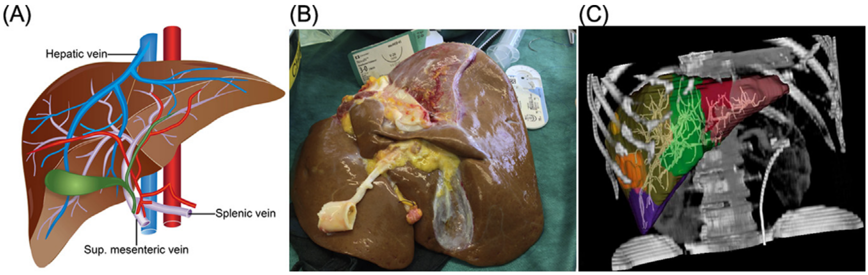

Figure 2.10 Schematic drawing of the liver. (A) Blood inflow to the liver comes from the hepatic artery and the portal vein; (B) Explanted liver before transplantation; (C) 3D data reconstruction of the liver with color-coded segments. *From (A) M. Scholle, (B, C) MITI.*

ducts. The bile flows via the common bile duct into the duodenum. Immediately prior, the bile duct joins with the pancreatic duct. Bile and pancreatic juice are mixed and injected into the duodenum.

Based upon the intrahepatic architecture of bile ducts, branches of the portal vein, and the hepatic artery, the liver can be subdivided according to the Couinaud classification. It divides the liver into eight independent segments (I–VIII), which is important for surgery and other interventions.

The gallbladder is a pear-shaped pouch attached to the inferior surface of the right liver lobe. Via the cystic duct it is connected to the main bile duct.

2.6.2 Functional Task

The liver is called the "central laboratory" of the body. The liver synthesizes and stores glycogen via glycogenesis and is responsible for gluconeogenesis to provide glucose. In addition, protein metabolism with degradation and neosynthesis are located here. Coagulation factors are produced as well as bile, a yellowish-green liquid which is necessary to emulsify fat in the GI tract. The bile juice is either transported directly into the duodenum or intermediately stored in the gallbladder where it is considerably concentrated.

2.6.3 Disorders and Diseases

Global destruction of the liver is caused by a variety of diseases such as inflammation ("hepatitis"), alcohol, or metabolic diseases. In the case of acute or chronic liver failure, the only option is liver transplantation. Countless attempts have been made to create systems capable of taking over the functional role of the liver—comparable to dialysis machines in the case of kidney failure—but none of the designs is ready for clinical use yet.

Severe damage to the liver leads to cirrhosis. The normal internal architecture of the parenchyma is destroyed and replaced by connective tissue and scars. Blood perfusion is impaired and the pressure in the portal vein increases (portal hypertension). Due to the higher resistance in the liver, the blood flow seeks for deviations/shunts to reach its final goal—the right heart. Portovenous shunts are opened (e.g., via the esophageal veins ≙ esophageal varices). However, these may cause life-threatening bleedings. The surgical answer is to create dedicated portocaval shunts, but this type of surgery is highly complicated with very high morbidity and mortality. Today, transjugular intraparenchymatous shunts (TIPS) are the superior option.

Another severe complication of liver cirrhosis is the collection of fluid in the abdomen (ascites). If medical treatment fails, dedicated shunt systems may be required to provide the drainage of ascites back into the venous vascular system ("peritoneovenous shunts"). Today, they can be placed percutaneously [14]. The shunts consist of the hose-system and a valve. To prevent occlusion, the patient has to trigger an integrated pump regularly. Recently, the first battery driven shunting pump was published [15].

Primary (hepatocellular or cholangiocarcinoma) or secondary malignant lesions (metastases) of the liver are the domain of hepatic surgical resection whenever possible. Hepatic surgery is demanding and a less traumatic alternative would be desirable. In the last few years, less invasive interventions were developed pertaining to local tumor obstruction either by freezing (cryotherapy), electrical energy (radio ablation), or by focused ultrasound.

In addition, transvascular tumor treatment by occluding hepatic blood flow or the treatment with radioactive particles could become attractive options.

In epidemiological regards, however, diseases of the biliary system are dominating. Surgical removal of the gallbladder (cholecystectomy) because of symptomatic gallstones is one of the most often performed surgeries all over the world (USA: approx. 500,000 cases/year). If stones are present in the gallbladder only (cholecystolithiasis), a removal of the gallbladder is the adequate treatment. If stones are also present in the bile ducts they must be removed by additional interventions. In most instances, interventional endoscopy is adequate today (see Chapter 8.4.4: Endoscopic Interventions on the Bile Duct (ERCP)).

2.6.4 Biomedical Engineering Aspects

Healthy liver tissue (parenchyma) is very soft and difficult to handle. It is covered by a thin capsule. The structure is mainly maintained by the

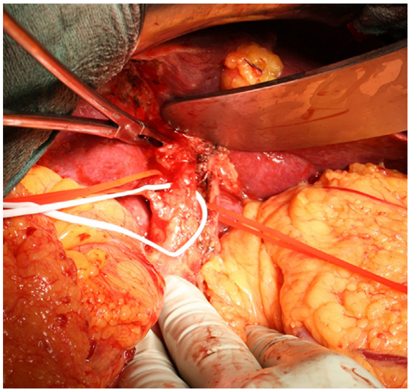

Figure 2.11 The so-called hilus of the liver. Prior to resection, the left and right liver artery and the hepatic duct have to be isolated. *From MITI.*

architecture of the internal canicular formations such as the arteries, the portal veins, the hepatic veins, and the biliary tree (Fig. 2.11). This explains why dissection of the parenchyma is feasible with, e.g., the water jet or ultrasound.

Producing an artificial implantable liver is still the "Holy Grail" of biomedical engineering. Though many approaches are promising, they are still far away from clinical maturity [16]. Artificial livers would certainly revolutionize medicine. Beyond the treatment of liver failure, new treatment options would become available for oncological diseases (primary or secondary liver lesions).

Today, still too many patients are lost since hepatic tumor manifestations are irresectable since the tumor mass is too extended or if too many small tumors are diffusely infiltrating the whole organ. Transplantation would be the only choice, but donors are by far too scarce, and liver transplants are usually reserved for the treatment of nonmalignant disease.

If artificial organs were available "from the shelve," a real breakthrough in oncological surgery could be expected. Hopefully, this ambitious goal can be reached as soon as possible.

In the meantime, BME could help to solve mid-term problems.

Table 2.5 numerates some important aspects, but the contribution of BME must be even more comprehensive.

Improvement in local ablation techniques can only be fully utilized if the destructive power is localized as precisely as possible to the target area. This is why we need even better intraoperative intervention systems.

Table 2.5 Liver: selected diseases/disorders and BME aspects

Disease/disorder	Treatment	BME aspects
Focal lesions	Surgical resection	Local ablation • Radiofrequency ablation • Cryotherapy • Highly focused ultrasound • Electroporisation
Portal hypertension (bleeding, ascites)	Portocaval shunts	TIPS, mechanical shunts, Alfa pump
Liver failure	Transplantation	"Artificial liver"

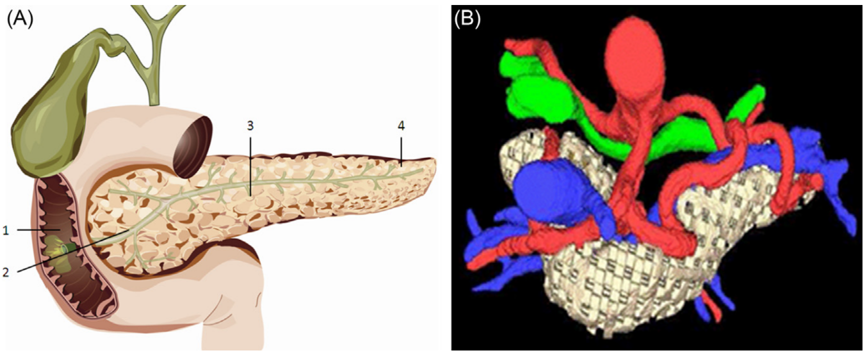

Figure 2.12 Pancreas: (A) Schematic drawing of the pancreas: (1) duodenum; (2) head of the pancreas; (3) body; (4) tail; (B) 3D model of the pancreas. *From (A) M. Scholle, (B) MITI.*

2.7 PANCREAS

2.7.1 Anatomical Description

The pancreas is an elongate, hand axe-shaped gland which is hidden deep in the human body in a retroperitoneal position behind the stomach and the transverse colon. It is divided into a head, body, and tail (Fig. 2.12).

The head of the pancreas is embraced by the duodenum. In the contact area between the head of the pancreas and the descending part of the duodenum, the joint orifice of the bile duct and the pancreatic duct, the so-called papilla, is located. The main pancreatic duct (Wirsung's duct) begins in the tail (which is very close to the spleen) and transverses the whole gland.

Via branches from all sides, the pancreatic juice is collected into the pancreatic duct. Gaining gradually in diameter the pancreatic duct opens together with the bile duct into the ampulla of Vater or papilla. The parenchyma has a very delicate soft consistency which makes it difficult to perform surgical manipulations.

2.7.2 Functional Task

The function of the pancreas is to produce both internal and external secretion. The external secretion—pancreatic juice—contains various enzymes like trypsin, amylase, and maltase. which are required for the digestion of proteins, carbohydrates, and fat. The internal secretion—insulin—is the product of the islands of Langerhans—a special subgroup of cells in the pancreatic parenchyma. Insulin plays a key role in glucose metabolism. Its production is part of a sophisticated regulatory circuit.

2.7.3 Disorders and Diseases

Diabetes mellitus is a very common metabolic disorder with increasing incidence. It results from a relative or absolute deficit in insulin production. It has to be treated with regular insulin injections, since insulin would be destroyed and inefficient if taken by mouth. Insulin-dependent diabetes has still today a severe impact on the duration and quality of life.

Inflammation of the pancreas ("pancreatitis") is an often life-threatening event caused by bile or pancreatic obstruction, alcohol, or of unknown reasons. Abscess formation and pseudocysts may arise.

Pancreatic cancer is often detected late because of the hidden position of the gland and surgical resection is frequently impossible. In these cases, chemotherapy and radiotherapy is used but the long-term success is poor.

2.7.4 Biomedical Engineering Aspects

It is little wonder, if the health care and economic impact of diabetes is considered, that numerous attempts have been made already to develop implantable insulin-regulating systems. Yet, not one single device is actually mature for a broader clinical use. The "insulin pump" is still a challenge for BME [17].

The loss of the exocrine function of the pancreas is less severe, since enzymes for digestion can easily be substituted by oral intake.

The reduced acid buffering capacity is compensated by proton pump inhibitors.

Insofar, the practical interest in developing an artificial implantable pancreas is rather low. The regulation of insulin secretion remains the dominant problem.

Innovative endoscopic instruments and procedures continuously improve the treatment options in acute and chronic pancreatitis (e.g., stents and abscess drainage), but more has to be done to reduce morbidity and mortality.

The most important problems, however, are malignancies of the pancreas.

Both the diagnosis and the treatment of pancreatic cancer are still far from being satisfying. Even the most sophisticated diagnostic modalities are not sufficiently sensitive and specific to discriminate between inflammation and cancer. Radical surgical resection is most often impossible in advanced cases and the 5-year survival rates after chemotherapy and radiation are disappointingly low.

Thermal ablation is not very suitable in pancreatic cancer due to difficult navigation, the proximity to many large vessels, and the risk of collateral damage [18]. Innovative approaches for local tumor destruction with high selectivity would be required. Maybe, electroporation could be helpful. Endoluminal photodynamic therapy could be helpful as well (Table 2.6). Most probably, the long-expected breakthrough in the treatment can only be achieved by an alliance of improved diagnostic methods, a more specific and effective chemotherapy, and advanced BME tools [19,20].

Table 2.6 Pancreas: selected diseases/disorders and BME aspects

Disease/disorder	Treatment	BME aspects
Internal pancreatic insufficiency	Insulin injection Pancreatic transplantation	Insulin-regulating systems ("insulin pump")
Necrotizing pancreatitis	Surgical drainage	Percutaneous drainage Endoscopic debridement
Cancer	Surgical resection Chemo/radiotherapy	Improved diagnostic tools Local ablation

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CHAPTER 3

Principles of Gastrointestinal Surgery

3.1 DEFINITION

Surgery is the medical specialty which uses interventional techniques to treat pathological conditions, such as disease or injury, in order to maintain or improve bodily function and quality of life.

The act of performing surgery is called a surgical procedure or surgical operation.

At the beginning of modern surgery, the individual surgeon was well capable of covering the whole range of surgical interventions—from the trepanation of a hematoma within the skull to the removal of the gallbladder or the treatment of a bone fracture. Even anesthesia was performed by a member of the surgical team.

Since the specific knowledge grew continuously, it became increasingly difficult to master all the requirements of modern surgical therapy in all fields of surgery. Soon, some surgeons focused exclusively on the treatment of diseases of the eye. Ophthalmologic surgery became one of the first surgical specialties. Gynecology and obstetrics as well as ear-nose-throat-surgery followed soon after. Later on, urologists specialized in the surgical treatment of the kidneys, the ureters, the bladder, and the urethra. Anesthesia did not remain the additional task of a surgeon but was taken over by professional anesthetists.

The next wave of specialization brought up vascular, cardiac, thoracic, pediatric, and orthopedic/trauma surgery, as well as neurosurgery.

What was left was now denominated gastrointestinal (GI) surgery.

GI surgery is the subspecialty which is focused upon the anatomical parts of the body belonging to the GI tract from the gullet to the rectum including the liver and the pancreas (see Chapter 2: Anatomy, Physiology, and Selected Pathologies of the Gastrointestinal Tract).

The term "GI surgery" is increasingly substituted by the denomination "visceral surgery." Visceral surgery comprises not only the surgery of the alimentary tract but also the surgery of the endocrine organs (thyroid, parathyroid, and suprarenal gland) but also, which do not belong to the GI tract. The same holds true for the spleen, inguinal, or incisional hernia or tumors of inflammatory processes of the body surface or soft parts inside the body.

"GI surgery" in the strict sense does not include endoluminal endoscopic interventions which are the domain of the interventional gastroenterologist. Gastroenterologists are often inclined to denominate major interventions, such as full thickness resection and endoscopic submucosal dissection as endoscopic surgery, but, basically the term is not adequate and confusing. However, there is no doubt that visceral surgery and interventional gastroenterology are growing together. Natural orifice transluminal endoscopic surgery (NOTES, see Chapter 9: Combined Laparoscopic-Endoscopic Procedures and Natural Orifice Transluminal Endoscopic Surgery (NOTES)) is a new field of interventional visceral medicine where the frontier between both disciplines has completely disappeared. Nonetheless, today a clear discrimination between "visceral/GI surgery" and "interventional GI endoscopy" is still valid.

3.2 BASIC SURGICAL PRINCIPLES

Some basic principles of surgery have to be known prior to a more detailed description of medical instrumentation: the principle of wound healing and wound treatment, the indications for surgery, and the structure and organization of surgical care.

3.2.1 Wound Healing, Wound Treatment

It is quite natural that the human body is potentially exposed to numerous damage to its structure during a lifetime, ranging from simple lesions of the skin to severe damage of the bones/muscles or internal organs. They may be caused by accident, by self-infliction, or surgery.

Fortunately, the overwhelming majority of lesions/wounds do not lead to death—due to the healing potential of the living organism. The ability of the human body to mobilize effective repair mechanisms in the case of structural damage is a key precondition of surgery—otherwise, any surgical intervention would inevitably lead to a final outcome.

The mission of surgery is, accordingly, to promote the self-healing capability as effectively as possible. Lesions to the body due to accidents, etc. have to be treated adequately, which is the core competence of trauma surgeons.

In visceral surgery, which usually deals with nontraumatic indications for surgery, the main challenge is to minimize the surgical trauma which is inevitably induced by a surgical intervention and to optimize the chances of fast, safe, and reliable wound healing.

For this end, a thorough knowledge of the mechanisms of wound healing is necessary.

The process of wound healing can be divided into three phases:

- inflammatory,
- proliferative,
- remodeling.

The first phase lasts for about 10 days. After the first 2—10 days, it overlaps with the beginning of the second phase, which is followed by the third phase after about 3 weeks. The last phase ends after about 12 months.

A regular wound healing can be expected, if both edges of the wound are

- clean, i.e., not contaminated,
- well perfused by oxygen-rich blood,
- in close contact to each other without any tension.

Contrary to external injuries, much can be done in visceral surgery to create "ideal" healing conditions before, during, and after the surgery and biomedical engineering (BME) plays an essential role in this context.

Whenever tissue is dissected, the cut has to be sharp-edged with minimal collateral damage. The instruments (knife, scissors, etc.) have to be as sharp as possible. Bleeding has to be stopped to avoid wound hematoma.

Self-evidently, the greatest care has to be taken to avoid any contamination, since bacterial inflammation severely impairs normal wound healing.

After the surgery, the incision has to be closed in an adequate way with the aim of healing the primary intention.

Suturing is the classical means in surgery to approximate the tissue. In the last decades, stapling (see Chapter 6.5: Stapling Devices) and gluing were added to the surgical armamentarium.

If the edges of a wound cannot be brought together or if a bacterial inflammation is present, secondary closure has to be awaited for.

The gap in the tissue (wound defect) is slowly filled by a granulation tissue matrix. In addition, the size of the lesion will be gradually reduced by spontaneous tissue retraction. This process can be fastened by surgical wound treatment, e.g., by vacuum-assisted closure: in this case, a piece of foam is inserted into the wound and covered with an adhesive. Now, negative pressure is created in this artificial chamber. Thus, fluid germ and necrotic tissue is drawn into the sponge which has to be exchanged regularly.

3.2.2 Indications for Surgery

The medical decision to perform a surgical operation is called "indication." Whether an operation is indicated or not can only be decided by a physician/surgeon. The opposite of it is a "contraindication." If an operation is contraindicated, it must not be performed.

Different types of indications exist that are discussed below.

3.2.2.1 Emergency Surgery

Surgery has to be performed promptly and immediately in order to prevent irreversible damage or death. A ruptured aortic aneurysm or mesenteric ischemia have to be operated upon at any instance and at the spot. If necessary, other operations have to be interrupted to get space in the OR.

3.2.2.2 Urgent Surgery

This type of surgery has generally to be done on the same day and as soon as possible, but it may wait until the next OR is available. A perforated gastric ulcer or colonic obstruction belong into this category.

3.2.2.3 Semielective Surgery

The operation has to be done soon to prevent irreversible damage, but it is not a matter of the next few hours or the same night. Some delay does not deteriorate the outcome. Many cases of appendicitis or cholecystitis are semielective.

3.2.2.4 Elective Surgery

The surgical procedure is necessary but can be prescheduled at a time that is convenient for the patient and the surgeon/hospital. Most instances of tumor diseases can be operated upon electively. Symptomatic gallstones, groin hernia, or recurrent diverticulitis are further examples.

3.2.3 Steps of the Operation

Each single operation consists of at least the following steps:

- positioning of the patient,
- incision,
- exposure of the surgical site,
- dissection,

- resection,
- specimen retrieval,
- viscerosynthesis,
- wound closure.

3.2.3.1 Positioning on the OR Table

Depending upon the type of surgery, the positioning of the patient may vary to provide an optimal access to the respective anatomical region. Many abdominal surgeries can be done with the patient in a flat, prone position. If the anorectum is the target, the so-called lithotomy position is required. The patient is laid on their back with knees bent, positioned above their hips and spread apart through the use of stirrups. If laterally positioned regions have to be operated upon, the patient must be positioned tiltedly. Modern OR tables enable all conceivable positions (see Chapter 4.3: Dedicated Workplace: The Operating Room).

3.2.3.2 Incision

If a surgery has to be done within the abdominal cavity, access to the surgical site has to be created first. An opening has to be cut into the abdominal wall. This step of severing the different layers of the abdominal wall is called incision. The position, direction, and length of the incision depends upon the target region (Fig. 3.1A). The skin is usually opened with a surgical knife/scalpel, whereas the deeper layers like fat, fascia, and muscle are cut through with scissors or the electrical knife (Fig. 3.1B).

3.2.3.3 Exposure

Most anatomical sites which have to be operated on are hidden among neighboring structures and covered by adjacent organs. The aim of exposure is to create the necessary space for surgery by moving adjacent and covering tissue aside. For this purpose, specially designed instruments called retractors are available (see Chapters 6.1.5: Retractors and 6.1.6: Self-Retaining Retractors).

Exposure starts in open surgery with keeping the abdominal wall open by retracting the edges of the abdominal wall. This is usually done by self-retaining devices. Keeping the internal organs aside is not as easy, since they are mobile, slippery, and do not tolerate too much force. Abdominal retractors are positioned by the surgeon and held by an assistant. To improve friction and to avoid lacerations of the structure which is kept aside, a sponge is often laid under the retractor.

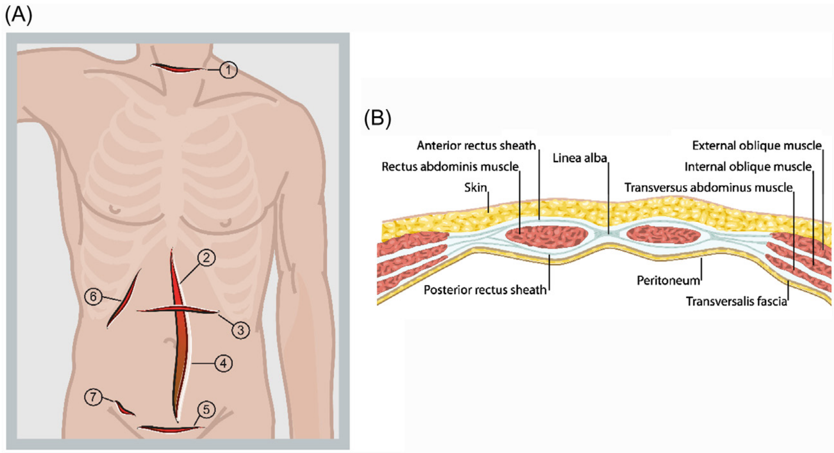


Figure 3.1 (A) Common incisions in visceral surgery: (1) Kocher's incision: Transverse, slightly curved incision of the neck for thyroid surgery; (2) upper midline incision for surgeries of the hiatus, stomach, spleen; (3) transverse incision for all major operations in the upper abdomen; (4) lower midline incision for the small and large bowel (also typical incision for urology); (5) Pfannenstiel incision offers a good access to the pelvis (most often used in gynecology), (6) left subcostal incision for cholecystectomy; (7) Davis incision: "muscle splitting" incision in the right lower quadrant for appendectomy. (B) Transverse section of the abdominal wall. *All from M. Scholle.*

3.2.3.4 Dissection

In the next step, the surgical focus/the lesion has to be liberated and mobilized. In contrast to most anatomical illustrations, the different segments and organs of the abdominal cavity do not float freely in the intraabdominal space (with the exception of the small bowel), but are mostly adherent to their vicinity (abdominal wall or neighboring organs). These connections have to be interrupted using adequate dissection instruments (scissors, electrical knife, etc.) (see Chapter 6.1: "Classical" Surgical Instruments for Conventional Surgery). Prior to cutting through vessels, bleeding has to be prevented by coagulation and ligatures. Modern dissecting instruments allow coagulation and cutting in one step (see Chapter 6.3: Ultrasound Dissection).

3.2.3.5 Resection

If the specimen is adequately mobilized, it can now be cut out in order to be removed. Resection encompasses the interruption of the blood supply (one or more arteries and veins) and the excision out of the GI continuity. The extent of the resection depends upon the underlying disease and the localization. In benign diseases, the surgeon will always attempt to resect as scarcely as possible to save as much healthy tissue as possible.

This is different in cancer surgery.

In oncological resection, it is always striven for removing the tumor and its surroundings as radically as possible. The aim is to achieve a so-called "R_0 resection."

Today, the resectional success is classified according to the "R" determination. "R_0" means that the tumor is removed completely. All margins of the specimen are free of tumor. In case of an R_1 resection, the tumor appears to be completely removed, but under the microscope it becomes manifest that the margins are infiltrated. Accordingly, only the pathologist can define whether it is R_0 or R_1.

If it is already clear at the OR table that tumor has been left in situ, it is called an R_2 resection. It is important to note that only the R_0 resection is beneficial for the patient. An oncological intervention resulting in an R_1 or R_2 resection is in vain. The patient had to tolerate major surgery without any improvement of prognosis/survival. Therefore, it is of outstanding importance to finish the operation with an R_0 situation achieved.

If it is not completely clear during the operation whether the margins are free, a so-called "frozen section" is performed. The surgeon sends a specimen of the area which is suspected to be still infiltrated by the tumor to pathology. In an accelerated preliminary examination, it can be found out after about 15–30 min whether the margin is free or not. In the latter case, the resection has to be extended.

3.2.3.6 Specimen Retrieval

The excised tissue (specimen) has now to be taken out of the body and is delivered for pathohistological examination.

In conventional open surgery, this is not a major issue since the incision is usually large enough to get the specimen out of the body.

In minimally invasive surgery, this might be a real problem. More often than not the diameter of the resected tumor is by far wider than the 10–12 mm of the trocars. In these cases, an additional incision has to be made (which initially should be avoided). In benign disease, morcellation of the tumor (cutting it into small pieces) is feasible, e.g., for the removal of the spleen. In cancer—or even if cancer is only suspected—morcellation is strictly forbidden for at least two reasons: Intraabdominal morcellation—even if performed in a retrieval bag—could lead to tumor cell dissemination which is almost a catastrophe. Secondly, the pathologist needs the specimen intact to provide a reliable staging of the disease.

It has to be stated that the problem of specimen retrieval in laparoscopy, minilaparoscopy, and NOTES is still waiting for better solution than those available today.

3.2.3.7 Viscerosynthesis/Reconstruction

The tissue defect caused by resection has to be compensated. Anatomical structures have to be reconstructed. This may be one of the most demanding steps of the procedure.

If a segment of the GI tract had to be removed, the continuity of the GI tract has to be restored to maintain the transit. The unification of two tubular structures in surgery is called an "anastomosis." Three different types are in use (Fig. 3.2).

The challenge is to make them gas- and water-tight, but to avoid too much compression, which deteriorates the blood perfusion and favors delayed leakages.

If the anastomosis is primarily not created properly, GI content spills over into the abdominal cavity and causes peritonitis with a very high mortality. This type of "primary leakage" is infrequent, since it can be avoided by a careful surgical technique. In case of doubt, instillation of dye into the GI lumen indicates a primary leakage clearly.

So-called "secondary leakages" are far more worrying. After an apparently normal postoperative course of 3–6 days, the clinical state of the patient deteriorates all of a sudden with concomitant fever and pain. As each experienced visceral surgeon knows, a secondary leakage has happened, which is also called the "crux chirurgicorum." Up to now, secondary perforation has to be accepted as an immanent risk of GI anastomoses.

Various techniques have been developed to provide an optimal reunification of GI stumps. For many decades, they had to be hand-sewn (Fig. 3.3).

Figure 3.2 The most commonly used versions of GI anastomoses: (A) end-to-end; (B) end-to-side; (C) side-to-side. *All from M. Scholle.*

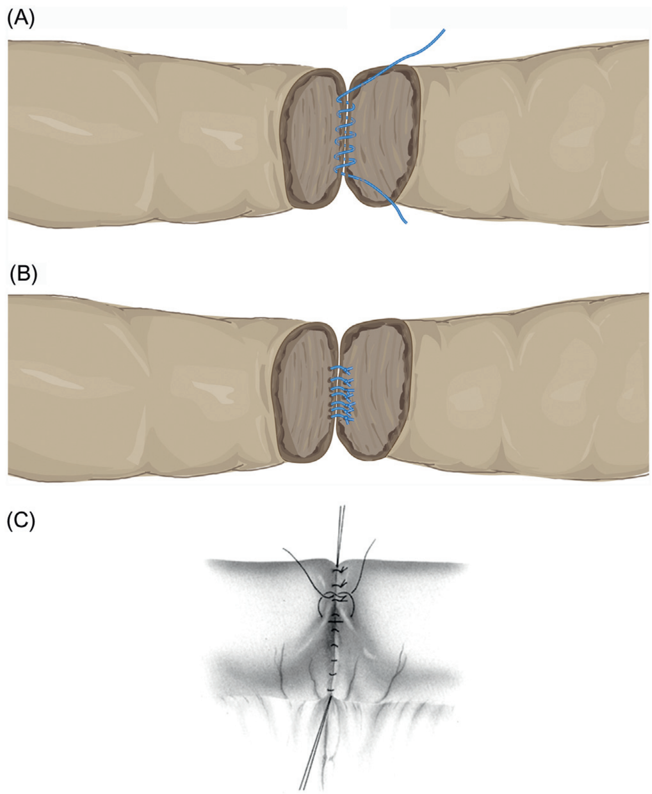


Figure 3.3 Hand-sewn anastomoses: (A) running suture; (B) one layer, interrupted stitches; (C) hand-sewn, double layer suture: the first suture line is covered by a second one. *From (A, B) M. Scholle, (C) M. Scholle, PD Dr. D. Wilhelm, Klinikum rechts der Isar*.

Fig. 3.3 just gives an impression of the different variations which were propagated up to now to make anastomoses more reliable.

Though thousands of papers have been published up to now on this topic, the problem of secondary anastomotic leakage is still a cause of concern.

Stapling devices (see Chapter 6.5: Stapling Devices) were expected to be better. Unfortunately, they certainly made the procedure easier to perform, but not significantly safer.

Anastomotic complications remain to be the Achilles heel of visceral surgery.

3.2.3.8 Wound Closure

Finally, the hole in the abdominal wall has to be closed again in an adequate manner.

The most important aspect is the reliable closure of the fascia. Strong sutures are required. Today, reabsorbable sutures are applied, either as single stitch or as running sutures.

Two complications may occur: "burst" of the suture a few days after the operation or incisional hernia later on.

In difficult cases or in the closure of incisional hernia, synthetic meshes are often used to reinforce the abdominal wall.

3.3 STRUCTURE AND ORGANIZATION OF SURGICAL CARE

In former times, medical care was usually provided at the patient's home if he/she was unable to see the physician in his medical practice. A few centuries ago, it became increasingly popular to establish specialized institutions to care for the sick, aged, or disabled. Later on, this type of institution specialized in delivering medical care. After treatment, the patients were discharged and new patients were referred.

Gradually, the separation of ambulant (outpatient) and in-hospital medical care took place.

3.3.1 Outpatient Surgical Care

Minor surgical diseases or lesions can be treated on an outpatient basis. Outpatient treatment is advantageous both for the patient and the social systems. The patient is not forced to stay in the foreign environment of the hospital and this type of surgery is significantly less expensive. Outpatient surgical care is continuously extended. Many surgical interventions which formerly required in-hospital treatment are now performed without a hospital bed. Typical examples are herniotomies, appendectomies, or even cholecystectomies. Considerable differences exist all over the world, depending upon the medical care structure, the gross national product, and surgical traditions.

3.3.2 In-Hospital Surgical Care

More complex surgical procedures can only be performed within the comprehensive care environment of the hospital.

Stationary care in a hospital is, of course, more expensive which is why in many countries of the world the governments are striving for a further reduction of hospital beds.

Initially, there was no separation between conservative and medical treatment. With the growing significance of interventional therapy, the division between internal medicine and operative surgery was gradually established.

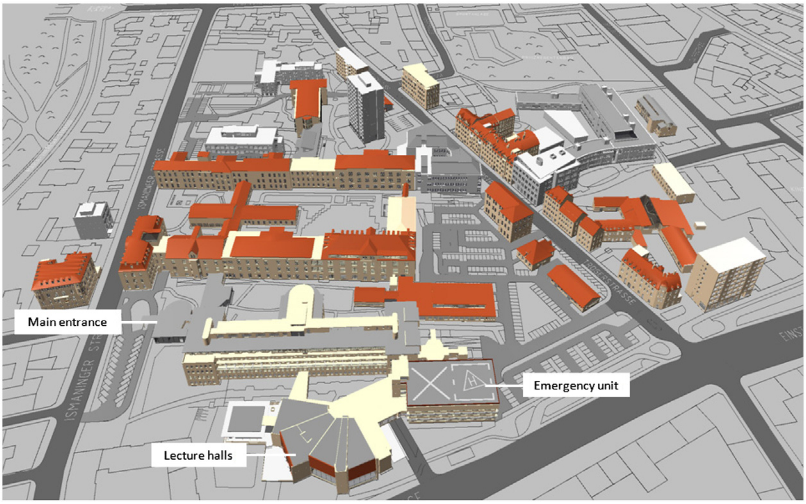


Figure 3.4 The Klinikum rechts der Isar, Technische Universität München, Germany, as an example of a modern university medical center.

Table 3.1 Departments, institutes, and additional facilities of a modern tertiary care hospital

Anesthesiology	Cardiology	Dermatology
Ear-nose-throat medicine	Gynecology	Hemato-oncology
Human genetics	Internal medicine	Interventional radiology
Nephrology	Neuroradiology	Neurosurgery
Nuclear medicine	Nutritional medicine	Obstetrics
Ophthalmology	Oral and maxillofacial surgery	Orthopedics
Physiotherapy	Plastic and cosmetic surgery	Psychiatry
Psychosomatic	Radiation therapy	Radiology
Surgery	Toxicology	Urology
Vascular surgery		

In the past, a hospital consisted of two departments only: internal medicine and surgery. Today, these are still the core structures, but a medical center of today encompasses many more diagnostic (X-ray department, nuclear medicine, numerous clinical laboratories) and therapeutic units (Fig. 3.4). The traditional disciplines are subdivided into many fields of specialization as shown in Table 3.1.

The comprehensive spectrum is offered in university hospitals or tertiary level units. Smaller or particularly specialized institutions mostly offer a selection.

Patients are referred to the hospital either electively by their family doctor or come as cases of emergency.

3.3.2.1 Emergencies in Visceral Surgery

Emergencies in visceral surgery are mostly less spectacular than in trauma surgery. Typical examples are GI perforation or bleeding (stomach, duodenum, colon), acute inflammation (appendicitis, cholecystitis, pancreas, etc.), ischemia, or GI obstruction (ileus).

Emergency patients are physically examined by the surgeon on-call in the emergency department (Fig. 3.5). A complete history is taken and laboratory examinations are performed. In addition, sonography is carried out by the surgeon for screening. In cases of doubt, this examination is followed by a CT-scan (Fig. 3.6). In mild cases, the patient is referred to the clinical unit for further surveillance and/or conservative treatment. In a few cases, an immediate referral to the surgical OR is indicated.

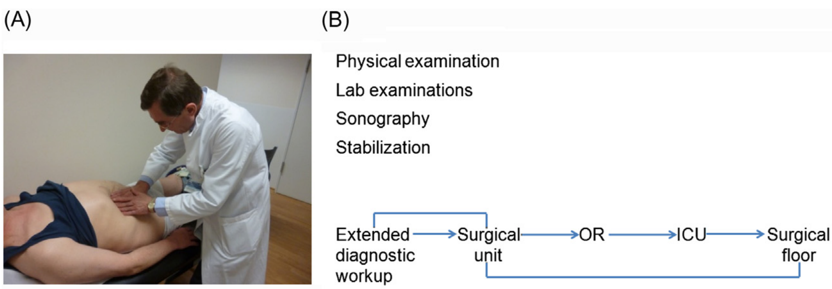


Figure 3.5 (A) First physical examination, history; (B) flow sheet of emergency surgical care. *All from MITI.*

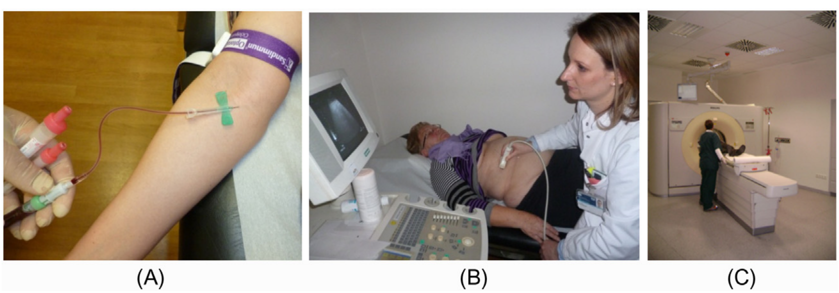


Figure 3.6 Preoperative diagnostic workup: (A) peripheral or central venous line to take blood samples and for intravenous infusion of fluids and drugs; (B) ultrasonography; (C) emergency CT-scan. *All from MITI.*

In the next step, the patient enters the surgical floor if conservative treatment is considered or to wait for the surgery.

In a few cases, the patient has to be brought immediately to the OR, but the majority of patients go to the surgical floor first.

On the surgical floor, nurses and the doctoral team take over further care (Fig. 3.7). The patients are registered and a treatment plan is established. As soon as it is adequate and required, the patient is transported into the OR (Fig. 3.8).

Depending upon the severity of the procedure, the intraoperative course, and the general state of the patient, a postoperative stay in the intensive care unit (ICU) may be required. In this department, intensive care medicine is delivered to critically ill patients by specially trained physicians and nurses with a significantly higher staff-to-patient ratio than in normal wards (Fig. 3.9).

(A) (B) (C)

Figure 3.7 Impressions of a surgical floor: (A) the corridor which gives access to the patients rooms; (B) nurses point; (C) the doctor's room. *All from MITI.*

(A) (B)

Figure 3.8 Surgical OR: (A) contemporary surgical OR for abdominal/visceral surgery; (B) typical scenario of a laparoscopic operation. Each surgical hospital should provide at least one OR around the clock (including the surgical and anesthesiological team and the logistic staff) for emergency and urgent cases. *From (A) Courtesy TRUMPF Medical, Puchheim, Germany, (B) MITI.*

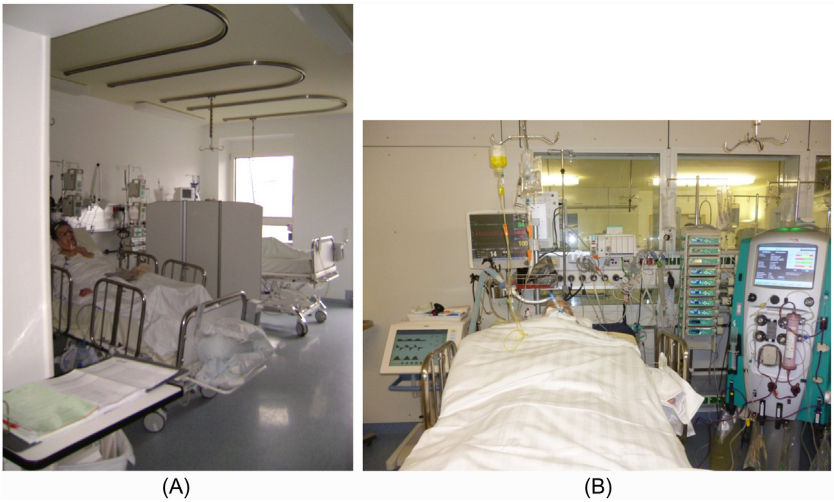


Figure 3.9 (A) ICU; (B) fully equipped ICU bed for monitoring and continuous treatment. Artificial ventilation, extracorporal membrane oxygenization, and extracorporal circulation support are provided, as well as renal dialysis, etc. *All from MITI.*

In many countries, hospitals have, in addition, so-called intermediate care units or high dependency units for patients who require special observation and intensive nursing not available on a normal floor but whose state is not so critical as to justify a treatment on an ICU.

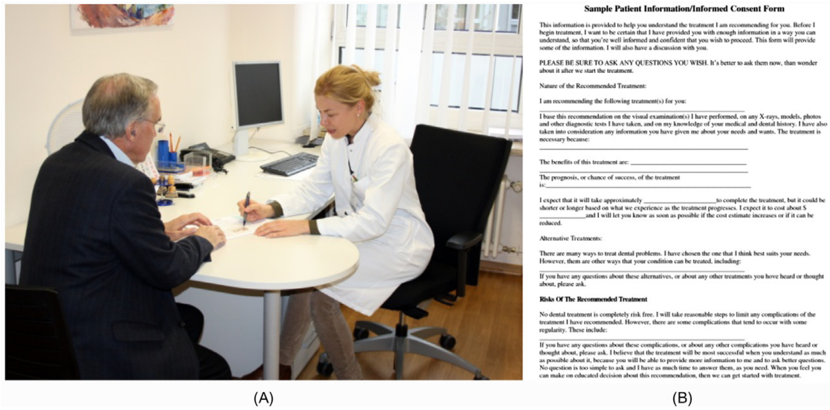
As soon as the patient's state is stable again, he/she can be brought back to the regular surgical unit. Oral feeding is started again. The patients are mobilized. Wound dressings are renewed and drainages are removed. Nutritional recommendations are given. If necessary, patients also learn to handle artificial body openings ("stoma") or to cope with other changes to the previous normal conditions.

After recovery, he/she is dismissed into ambulatory care or specialized facilities for after-treatment.

3.3.2.2 Elective Surgery

This is a surgical intervention which should be performed/is necessary but not urgent. The patient and the caregiver can decide when the operation should be done. To some extent, the interval between decision making and the surgery also depends on the type of the disease. In the case of a malignancy, the surgical treatment should be performed earlier than, e.g., in the case of gastroesophageal reflux disease.

Nowadays, all over the world it is striven for doing the necessary examinations, etc. on an outpatient base to reduce costs. On his/her first



Sample Patient Information/Informed Consent Form

This information is provided to help you understand the treatment I am recommending for you. Before I begin treatment, I want to be certain that I have provided you with enough information in a way you can understand, so that you're well informed and confident that you wish to proceed. This form will provide some of the information. I will also have a discussion with you.

PLEASE BE SURE TO ASK ANY QUESTIONS YOU WISH. It's better to ask them now, than wonder about it after we start the treatment.

Nature of the Recommended Treatment:

I am recommending the following treatment(s) for you:

I base this recommendation on the visual examination(s) I have performed, on any X-rays, models, photos and other diagnostic tests I have taken, and on my knowledge of your medical and dental history. I have also taken into consideration any information you have given me about your needs and wants. The treatment is necessary because:

The benefits of this treatment are: ____

The prognosis, or chance of success, of the treatment is:____

I expect that it will take approximately ____to complete the treatment, but it could be shorter or longer based on what we experience as the treatment progresses. I expect it to cost about $ ____and I will let you know as soon as possible if the cost estimate increases or if it can be reduced.

Alternative Treatments:

There are many ways to treat dental problems. I have chosen the one that I think best suits your needs. However, them are other ways that your condition can be treated, including:

If you have any questions about these alternatives, or about any other treatments you hove heard or thought about, please ask.

Risks Of The Recommended Treatment

No dental treatment is completely risk free. I will take reasonable steps to limit any complications of the treatment I have recommended. However, there are some complications that tend to occur with some regularity. These include:

If you have any questions about these complications, or about any other complications you have heard or thought about, please ask. I believe that the treatment will be most successful when you understand as much as possible about it, because you will be able to provide more information to me and to ask better questions. No question is too simple to ask and I have as much time to answer them, as you need. When you feel you can make on educated decision about this recommendation, then we can get started with treatment.

Figure 3.10 (A) The first contact between the patient and his/her surgeon. Taking the history, a comprehensive physical examination and a thorough analysis of preoperative findings are essential. The next step is to get informed consent after detailed information of the patient. (B) Sample Patient Information/Informed Consent Form. *All from MITI.*

appointment with the surgeon, the patient should be able to deliver the comprehensive information (Fig. 3.10).

As soon as the relevant problem of the patient is identified, a careful medical history of the patient and in particular his/her specific complaints are taken. In the next step, all relevant documentation of medical findings which already have been elaborated previously are checked.

Additional tests and examinations—if required—are performed. Finally, it is decided whether a surgical intervention is indicated (should be done) or not. If a surgery is considered, the patient has to be informed in detail about what has to be done to get his/her informed consent. It is of utmost importance to document precisely and reliably the content and extent of this oral communication, since it may, later on, play a decisive role in medicolegal issues.

Finally, the date of the surgery is scheduled. The patient is instructed where to go on the morning of the respective day (building, floor, ward).

On the scheduled day, the patient is received at his surgical floor (Fig. 3.11). It is checked again whether all documents are at hand, and a room and a bed-place are allocated using the hospital information system (HIS; see Chapter 12: Health Informatics/Health Information Technology).

The surgical unit is—from now on—the temporary and provisional home of the patient. From here, he/she will be brought to the OR, and he/she will return here afterward, potentially after a shorter or longer

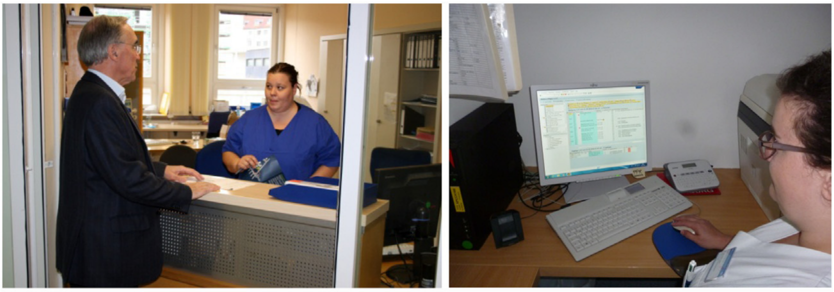

(A) (B)

Figure 3.11 (A) Reception on the ward; (B) after a personal introduction, the responsible nurse checks the documents and provides a bed-place using the HIS (see Chapter 12: Health Informatics/Health Information Technology). *All from MITI.*

stopover at the ICU. At the end of the procedure, he/she is dismissed into outpatient care.

A surgical floor is more than a specialized hotel (Fig. 3.12). BME plays an essential role to provide the specific requirements of modern health care delivery. Highly sophisticated surveillance and alert systems, multifunctional beds and devices, as well as a highly efficient administration are hidden behind a warm, convenient hotel-like environment which should offer an atmosphere of well-being.

Patient care on the floor needs special surveillance. Each patient should be able to alarm the staff in case he/she requires help (Fig. 3.13). Accordingly, each hospital bed is equipped with a so-called "nurse call button" which often offers additional functionalities.

Fig. 3.14 shows a typical scenario in a patient's room in a surgical floor.

3.3.2.3 Hospital Beds

In former times, hospital beds were more or less identical to those used in daily life at home.

Today, modern hospital beds are complex multifunctional systems to provide as much comfort as possible to the patient and to warrant safe, effective health care delivery. Much has also been done to improve the convenience to the medical staff (Fig. 3.15).

A modern hospital bed has to be mobile. The wheels must be firmly locked as long as the bed is placed in its designated position. For

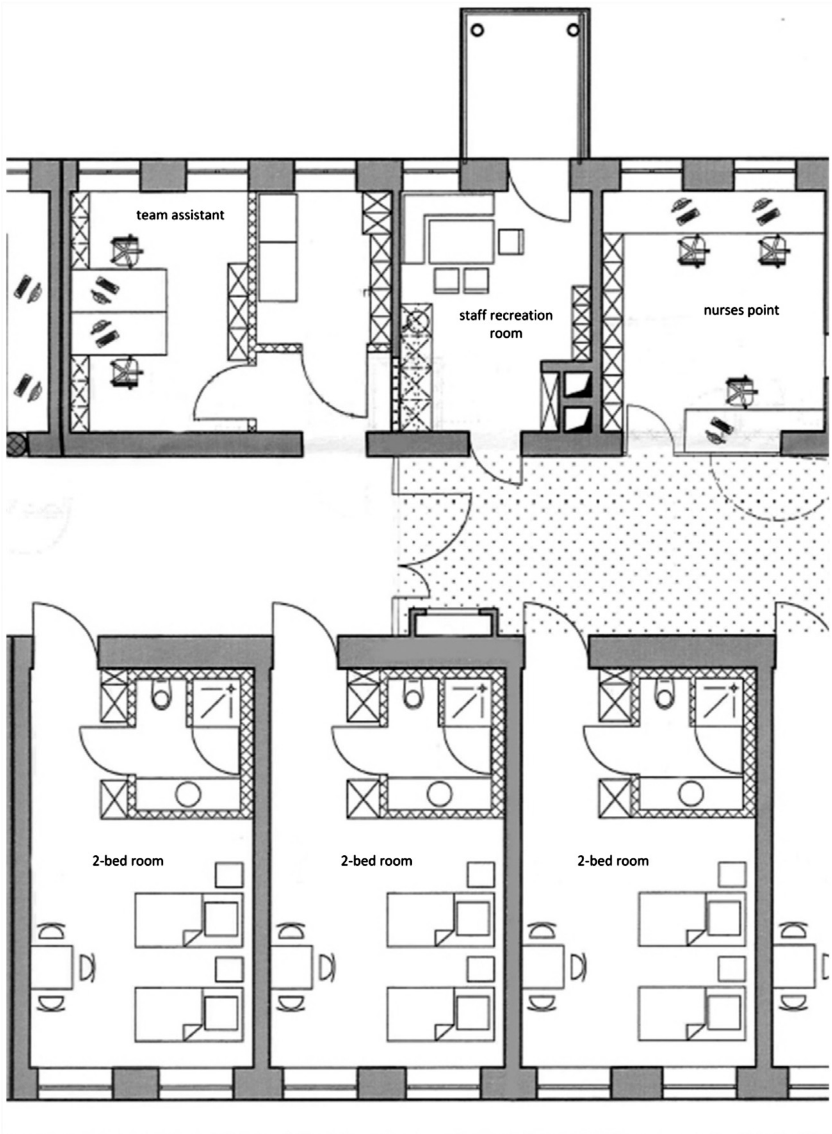


Figure 3.12 Floor plan of a modern surgical unit. The two-bed patient rooms are opposite to the functional area including the nurses point and the floor office.

transportation of the patient (e.g., into the OR), the bed should be easily movable. To enable single persons to move the bed, the pair of wheels of one axis can be locked making it better steerable.

(A) (B)

Figure 3.13 (A) Typical "nurse call button"; (B) additional functionalities like TV control and intercom function. *All from MITI.*

Figure 3.14 Patient room with three beds in a typical surgical unit: patients in various states of convalescence or a few hours before surgery. *From MITI.*

(A) (B) (C)

Figure 3.15 Hospital bed: (A) fully equipped with bed gallow; (B, C) different positions of the surface. *All from MITI.*

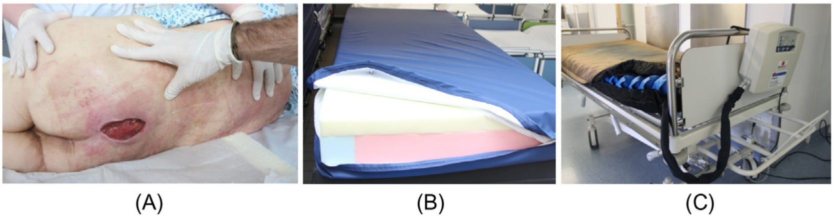


Figure 3.16 (A) Typical decubital ulcer; (B) antidecubitus mattress; (C) pneumohydraulic antidecubitus system. *All from MITI.*

The bed is commonly divided into three differently adjustable segments to provide optimal conditions according to the different needs. These functions, including the raising and lowering of the entire bed, are carried out electronically, initiated by the patient or the staff.

For the patient's safety, most beds have side rails which can be activated by raising them, which can be done manually or electronically as well. For facilitating the patient's mobility, bed gallows can be helpful.

Critically ill patients are particularly prone to develop a decubitus. This is a more or less deep ulceration of the parts of the body which are in direct contact with the surface due to pressure and reduced blood perfusion (Fig. 3.16A). Antidecubitus mattresses (Fig. 3.16B) and technical systems (Fig. 3.16C) are available.

Although modern hospital beds are highly effective, a lot of room is left for further improvement. The bed could contribute to a better surveillance of the patients. Bed exit alarms are already available on the market. Other parameters such as humidity or body weight control would be helpful as well. Physical activity, vital signs, and mental state could be valuable too, just to name a few.

CHAPTER 4

Preconditions of Successful (Gastrointestinal) Surgery

The development of modern academic surgery was almost breath-taking and highly appreciated by the public. Quite a number of books of popular literature glorified the advances in surgery, e.g., "The century of the surgeon" by J. Thorwald (London 1957). However, it would not have been conceivable without some significant achievements which modified the frame conditions. At least three of them have to be addressed in detail:
- antisepsis,
- anesthesia,
- specialized surgical environment.

Each of these issues deserves special mention.

4.1 ASEPSIS

4.1.1 The Detection of Antisepsis

It is elementary school knowledge today that bacteria cause inflammation and infectious diseases. Each of us knows that disinfectants have to be applied in case of a skin lesion to prevent infection and impaired wound healing.

In the past, surgeons were well aware of the fact that some wounds healed on the spot without any tissue irritation ("primary healing") (Fig. 4.1A), but the majority healed—if at all—after a long tedious process of inflammation, pus formation, and granulation formation ("secondary healing") (Fig. 4.1B). However, it was completely unclear why a happy few were saved from secondary wound healing. Because of the high risk of (frequently lethal) inflammation, surgery was avoided whenever possible.

A first breakthrough in a better understanding of primary and secondary wound healing was achieved in the second third of the 19th century. Independently of each other, Ignaz Semmelweis in Vienna (Fig. 4.2A) and Oliver Wendell Holmes in the United States were concerned about

(A) (B)

Figure 4.1 (A) Primary wound healing: normal aspect of the sutured incision; (B) secondary wound healing: swelling, reddish color, elevated temperature, and pain. The edges of the wound did not unite. When the stitches were removed, a large amount of pus emptied (arrow). *All from MITI.*

(A) (B)

Figure 4.2 (A) Ignaz Semmelweis (1818–65) copperplate engraving by Jeno Doby *(© Deutsches Medizinhistorisches Museum Ingolstadt, Stephanie Papelitzky)*; (B) Semmelweis in Vienna: The detection of contamination. In the famous painting of Robert Thom, the key message is made clear: hands have to be cleaned and disinfected before the next patient is examined. (B) From the collection of Michigan Medicine, University of Michigam Gift of Pfizer, UMHS.

the high mortality rate of puerperal fever of women hospitalized for childbirth.

Close clinical observation made it clear that direct contamination with the hands transmitted the infection and not—as hypothesized—spread by air, food, or other transmitters. Regular washing of hands, changing of clothing, and, in particular, remaining away from other patients after attending one with clinically manifest infection drastically reduced morbidity and mortality (Fig. 4.2B). However, the true nature of the vehicle

(A) (B)

Figure 4.3 (A) Lister's carbolic acid sprayer *(© Deutsches Medizinhistorisches Museum Ingolstadt, Michael Kowalski)*; (B) carbolic acid (phenol) is a poisonous substance. Highly diluted it was used as a powerful antimicrobial agent. *From MITI.*

remained unknown until two additional advances could be achieved: Pasteur detected a special type of microorganism—bacteria—and Lister recognized their implications in secondary wound healing. The challenge now was to find suitable ways to eliminate or destroy these agents.

Lister propagated carbolic acid sprays and soaking of suture material, including the consequent washing of hands (Fig. 4.3).

Lister's ideas were most effectively promoted in Germany due to the pioneer activities of Ernst von Bergmann. The success was striking, but the distribution of carbolic acid sprays was not very practical and harmful for the OR team. The better idea was to deliver all items after primary sterilization to the OR table. A few years later, a reliable and nondestructive method was identified. The technique of steam sterilization was developed in 1886 and strict aseptic rituals were established (Fig. 4.4).

In the following decades, antisepsis was continuously refined. The patients were covered with sterile sheets which left open only the surgical site.

Next, surgeons learned to protect the patient from contamination by the OR team. Face masks and OR caps were introduced. The body was covered by sterile coats. The famous American surgeon Dr. William Halsted stimulated Goodyear Rubber company in 1889 to produce thin rubber gloves [1]. Though originally intended to protect the hands against toxic disinfective agents, the importance of gloves to prevent infections of the surgical incision was soon realized.

In the beginning, almost everything had to be reusable, since reprocessing (washing, sterilization) was by far cheaper than the procurement

Figure 4.4 (A) Historical instrument container for sterilization *(© Deutsches Medizinhistorisches Museum Ingolstadt, Michael Kowalski)*; (B) a sterile container with surgical pliers to handle the instruments. *From MITI.*

Figure 4.5 (A) Patient completely covered by surgical drapes; (B) surgeon with clothes, OR cap, surgical mask, and gloves. *All from MITI.*

of sterile disposables. Today, the overwhelming majority of clothes, drape, masks, gloves, sponges, etc. are provided as sterile disposable items, being a huge market of its own right in the health care business (Fig. 4.5).

Another important aspect of surgical asepsis is to reduce the germ load of the patient's skin (and of the surgeon's hands, since gloves alone are not 100% safe to avoid contamination).

A large variety of highly effective and skin-friendly antiseptics was developed and these are now commonly available (Table. 4.1).

Table 4.1 Commonly used surgical skin disinfectants

Group	Agent	Additional use
Alcohols	Ethyl alcohol 70%; isopropyl alcohol 70%	Preservative
Quaternary ammonium compounds	Benzalkonium chloride; cetrimide; methylbenzethonium chloride; benzethonium chloride; cetalkonium chloride; cetylpyridinium chloride; dofanium chloride; domiphen bromide	Irrigations; eye drops; preservative; soaps
Chlorhexidine and other diguanides	Chlorhexidine gluconate; chlorhexidine acetate	Suitable for mucosa
Quinolone derivatives	Hydroxyquinoline sulfate; potassium hydroxyquinoline sulfate; chlorquinaldol; dequalinium chloride; diiodohydroxyquinoline	Treat wounds; throat lozenges
Antibacterial dyes	Proflavine hemisulfate; triphenylmethane; brilliant green; crystal violet; gentian violet	Treatment of skin lesions
Peroxides and permanganates	Hydrogen peroxide solution; potassium permanganate solution; benzoyl peroxide	Wound cleanser; irrigations
Halogenated phenol derivatives	Chlorocresol; chloroxylenol; chlorophene; hexachlorophane/ hexachlorophene; triclosan	Medicated soaps and solutions

Application has to be performed according to the recommendations of the provider. At any rate, the skin has to be cleansed before disinfection. Very hairy regions of the body are mostly shaved immediately prior to disinfection.

Additional measures are established to prevent contamination of the patient. After each individual surgery, the OR has to be cleansed thoroughly according to well defined standards. All surfaces have to be easy-to-clean. Any devices or equipment not in use have to be removed.

In the past, even so-called laminar air flow systems were established. Specially treated air (filtering, temperature control, etc.) enters the surgical site unilaterally (mostly from the air distributor mounted to the ceiling) in a laminar flow with minimal turbulence to minimize the risk of infection. However, its effectiveness is still unclear [2] (see Section 4.3: Dedicated Workplace: The Operating Room).

At any rate, antisepsis remains a key pillar of modern surgery [3], even more so with the rising importance of hospital-acquired infections and multidrug resistance in bacteria (e.g., methicillin-resistant *Staphylococcus aureus* which is not only resistant to methicillin but also resistant to most other types of antibiotics).

4.1.2 Reprocessing of Surgical Instruments

Surgical instruments are high quality products with a more or less complex function which cannot be thrown away after a single use. Reprocessing is required after their use in a surgery, which includes thorough cleaning, check of function, and sterilization.

Immediately after use, the instruments should be rinsed under warm water to remove all blood, body fluids, and tissue. The next step is cleaning, either manually or by an automatic washer or ultrasonic device. The aim is to remove completely all organic deposits since even minimal staining makes sterilization ineffective.

Manual cleaning is time-consuming and tedious, but often inevitable in case of micro- and delicate instruments (Fig. 4.6A). However, the majority of instruments can be treated in an ultrasonic cleaner (Fig. 4.6B).

The ultrasonic cleaner removes debris by cavitation. The effect is enhanced by a special cleaning solution with detergents and enzymes. It is a comparatively fast (10−15 minutes) process and the instruments are treated rather gently. However, they should not touch each other and a mixture of instruments of different metallic material should be avoided.

(A) (B)

Figure 4.6 (A) Manual instrument cleaning; (B) ultrasound cleaning. *All from MITI.*

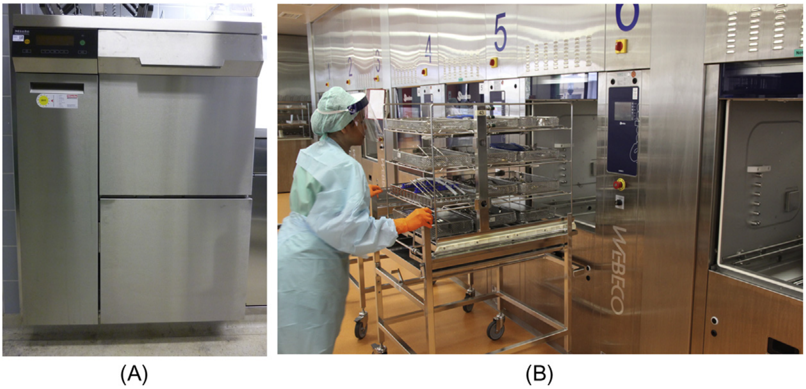


Figure 4.7 Modern instrument processing unit: (A) instrument washing machine in the OR; (B) washing machines in a central reprocessing and sterilization unit. *All from MITI.*

After washing, the instruments have to be rinsed again with deionized or distilled water and dried, which is done fully automatically by modern washing machines (Fig. 4.7).

The first step of reprocessing is finished by inspecting each instrument for proper function and condition. It has to be made sure that all of them are visibly clean and free from stains and tissue.

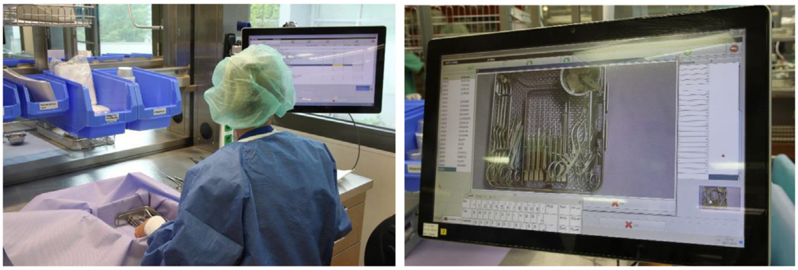
Scissor blades must glide smoothly all the way (they must not be loose when in the open position). Forceps should have properly aligned tips. Hemostats and needle holders should not show light between the jaws and should lock and unlock easily. The jaw faces of needle holders have to be checked for wear. Cutting instruments and knives should have sharp, undamaged blades.

4.1.3 Sterilization

After the sterilization procedure, no living organism should have survived on the instrument. All instruments which have a "metal-to-metal" action such as scissors, hemostats, and needle holders have to be lubricated with dedicated surgical lubricants before they are put into the sterilization container.

Before the sterilization begins, instrument sets have to be stored in containers which are locked and not opened again until they finally come into use at the OR table (Fig. 4.8).

The most important method is steam sterilization: autoclaving. Sterilization is achieved by the high temperature that steam under pressure can reach (134°C). Other possibilities are Ethylene oxide sterilization



(A) (B)

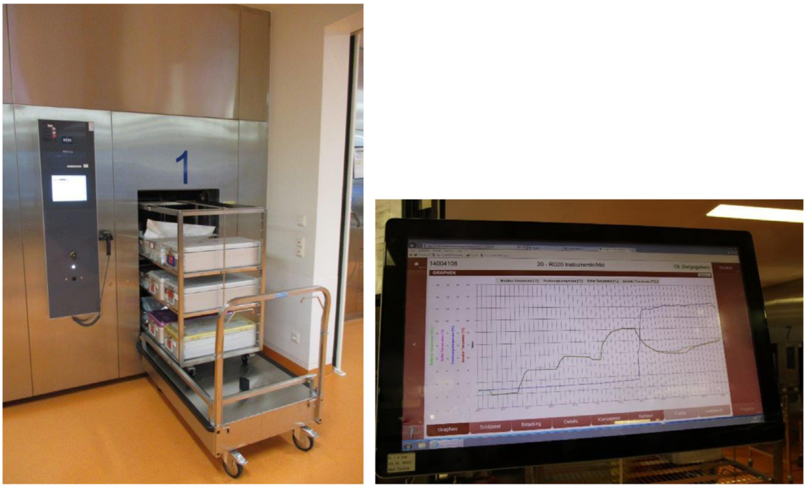
Figure 4.8 (A) Repacking of the instrument containers according to pack lists; (B) to avoid any mistakes during this procedure, images of the standard instrument content are provided. *All from MITI.*

Table 4.2 Sterilization methods

Method	**Duration**	**Comment**
Steam: (autoclaving) 134°C 30 PSI	 60 min	Including prions
Gas/plasma: ETO; Formaldehyde; Hydrogen peroxide plasma; Ozone	 16–18 h 16–18 h 1 h 4.5 h	Materials which are moisture- and heat-sensitive
Chemical: Peracetic acid; Glutaraldehyde; Formaldehyde	50 min	Endoscopes
Ionizing radiation: Beta particles; Gamma rays	Variable	Only for industrial use
Microwave	30 s	Surfaces only
Dry heat	170°C/30 min 160°C/60 min 150°C/150 min	Anhydrous oils; Petroleum, bulk Powders

(ETO gas), chemical sterilization, and radiation sterilization. Gas plasma is especially appropriate for very delicate instruments and materials (Table 4.2).

Modern reprocessing and sterilization units in hospitals provide most of the methods as mentioned above with the exception of radiation which is almost exclusively used for industrial purposes.



(A) (B)

Figure 4.9 (A) Delivering the containers into the sterilization machine; (B) surveillance of the sterilization procedure by computerized control. *All from MITI.*

Figure 4.10 Central store of sterilized items ready for delivery to the OR units. *From MITI.*

The reprocessing and sterilization process today is a highly industrialized segment within the overall activities of a surgical hospital (Fig. 4.9). It goes without saying that it is prone to strict quality control. For example, regular biological tests are mandatory, such as spore testing. Spores belong to the most resistant biological systems. It has to be proven that they are completely destroyed during the sterilization process.

An adequate amount of sterilized instrument sets has always to be available at the central store (Fig. 4.10).

The aspect of further resterilization has always to be considered if a new instrument or device is created. Effective processing of used instruments always requires the complete removal of any organic material, which becomes increasingly difficult the more complex the mechanical construction is. Despite modern sophisticated cleansing methods (e.g., ultrasound), it soon becomes impossible to clean reliably tiny gears, working channels, and Bowden wires.

An instructive example is the instruments of modern master-slave systems. These very complex devices are too expensive to be thrown away. They have to be resterilizable. However, reprocessing is not reliable enough to guarantee 100% effectiveness. As a compromise, their use is stopped automatically after the ninth or tenth case of application by an in-built deactivation mechanism.

The alternative is to use disposable instruments which are becoming increasingly more popular.

4.2 ANESTHESIA

Pain is an uncomfortable sense but of high biological importance since it indicates any damage in the body. It activates mechanisms of avoidance and protection and insofar it also promoted the development of medicine since one of the most important aspects of medical care is to eliminate pain.

For many thousands of years, only a few and low-effective agents were available to fight pain: morphine derivates, alcohol, nicotine enemas, etc. did not help much but were accompanied by severe side effects and were very difficult to control.

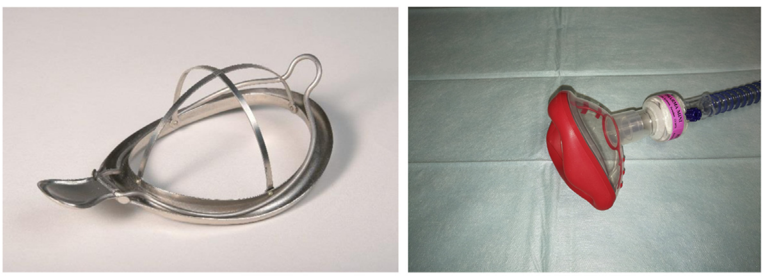
Evidently major, long-lasting surgical operations were inconceivable, since human beings were simply unable to tolerate the stress and pain induced by, e.g., an abdominal operation.

Amputation of the extremities was the utmost limit.

It can only be acknowledged retrospectively, how revolutionary an event it was that took place in Boston in 1846 (Fig. 4.11).

On October 16, 1846, a Boston dentist by the name of William T.G. Morton demonstrated the use of ether during surgery. Using an ether-soaked sponge, Morton anesthetized a Boston printer named Gilbert Abbott. Once Mr. Abbott was unconscious, surgeon John Collins Warren removed a tumor from under his jaw. When the patient came to and reported he had felt no pain, Dr. Warren turned to the audience in

Figure 4.11 The world's first operation in general anesthesia in 1846: "Gentlemen, this is no humbug." Painting by Warren and Lucia Prosperi and displayed in "The Ether Dome" of Massachusetts General Hospital, Boston, MA, United States.



(A) (B)

Figure 4.12 (A) Schimmelbusch mask for ether anesthesia: sponges were compressed between the two grids which were sprinkled with ether. When it was positioned over nose and mouth, the patient was forced to inhale the agent *(© Deutsches Medizinhistorisches Museum Ingolstadt, Michael Kowalski)*; (B) a more advanced face-modeled mask for inhalative anesthetics. *From MITI.*

attendance and said the famous words "Gentlemen, this is no humbug." Very soon, alternative anesthetic agents came into use: chloroform, N_2O, and others, which had to be inhaled, i.e., applied via the upper airways during respiration.

Dedicated devices were developed and produced for the delivery of "inhalative" anesthetics (Fig. 4.12).

The apparatuses were continuously refined, but anesthesia remained a side-aspect of surgery. Nonetheless, remarkable innovative approaches were elaborated. Local anesthesia was the next step ahead.

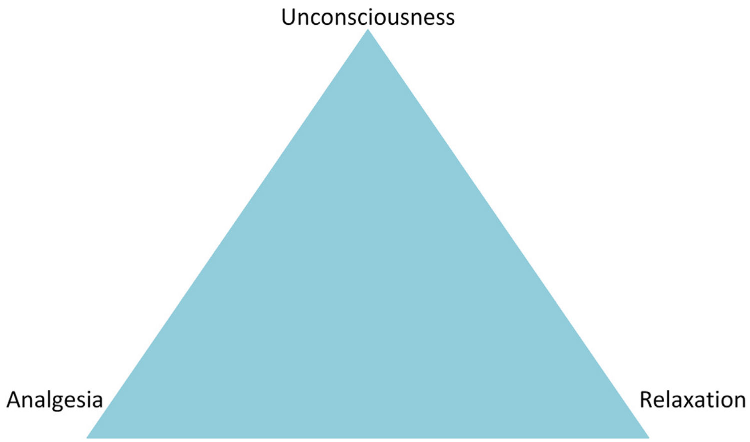


Figure 4.13 The three anchor points of modern anesthesia. *From MITI.*

By injecting and infiltrating drugs that produce a neural blockade by interrupting impulse transmission in peripheral nerves, spinal roots, or nerve endings, sensation is eliminated distal to the site of application. Local anesthesia was a big step forward to make surgery safer, faster, and less expensive. Today, local anesthesia is often combined with parenteral drugs for sedation and analgesia [4].

With the advent of World War II, the task of providing anesthesia was taken over by a new medical subspecialty: anesthesia. Anesthetists became the experts to deliver optimal conditions for the surgeons to carry through the intervention.

In addition to inhalational anesthesia, intravenous anesthetics completed the options to guarantee the three main goals. Relief of pain or prevention of pain, muscle relaxation, and unconsciousness were no longer effected by one single agent but divided (Fig. 4.13). Relaxation, however, required active ventilation support.

Relaxation is the complete paralysis of all skeletal muscles of the body. Normal tonic contraction is completely eliminated in order to prevent movements of the patient during the operation and to facilitate surgery (e.g., by a better exposure or additional space during laparoscopy). However, this also means that the patient is completely unable to breath. Controlled artificial ventilation is mandatory. For this purpose, an endotracheal tube has to be passed through the mouth or the nose and the vocal apparatus into the upper airways (trachea) (Fig. 4.14). As soon as the tip of the tube is in its correct position, a balloon cuff is inflated to

(A) (B)

Figure 4.14 (A) Endotracheal tube; (B) intubation: the endotracheal tube is inserted into the trachea using a laryngoscope. *All from MITI.*

secure it in place and to seal the trachea to prevent gas leakage. In addition, aspiration of saliva or gastric juice is prevented.

Once it is correctly positioned and secured, it is connected to the mechanical ventilator. The mechanical ventilator is a part of the anesthetic machine.

These are highly sophisticated technical systems including numerous specialized components. In addition to the ventilator, the vaporizer is integrated for volatile anesthetics enabling exact dosage control. The machine is connected to piped hospital gases like oxygen, nitrous oxide, and CO_2, but reserve gas cylinders are additionally provided. The third element is a comprehensive monitoring system both for the ventilation procedure as well as vital parameters.

Waste gas is not blown into the atmosphere but eliminated by a waste gas scavenging system.

The most commonly used intraoperative ventilation modes are volume-controlled, pressure-controlled, dual-controlled, and assisted ventilation [5].

Modern anesthesia carts allow anesthetists easy access to all anesthesia tools in one movable location (Fig. 4.15). Today, comprehensive monitoring is also provided. They integrate many functions that were once exclusive to intensive care units (Fig. 4.16).

Today, the tasks of anesthetists are not confined to the OR any longer. They have to monitor the patient as well in the postoperative course until the patient is sufficiently recovered to be brought back to the ward. Intensive care units are mostly led by anesthetists. In conclusion, the range of highly specialized anesthesia biomedical technology is too broad to be described within the frame of this overview.

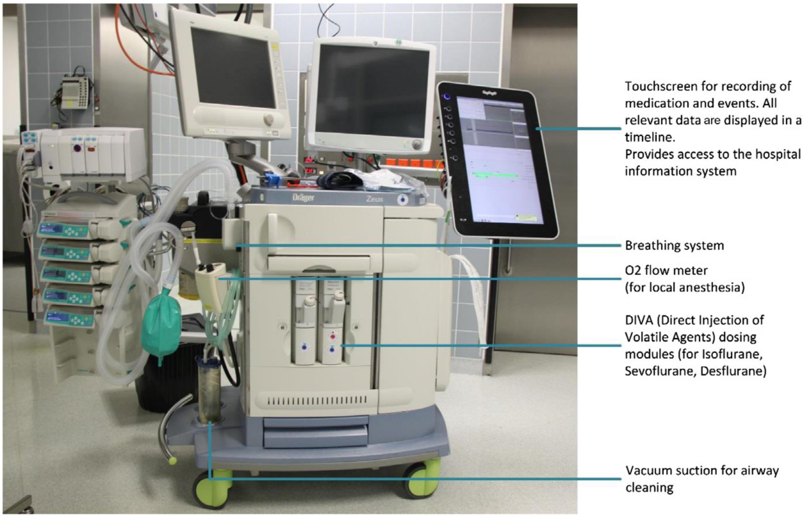


Figure 4.15 Current state-of-the-art anesthesia unit: an anesthetic machine delivering artificial ventilation and integrated monitoring of a broad range of vital parameters. *From MITI.*

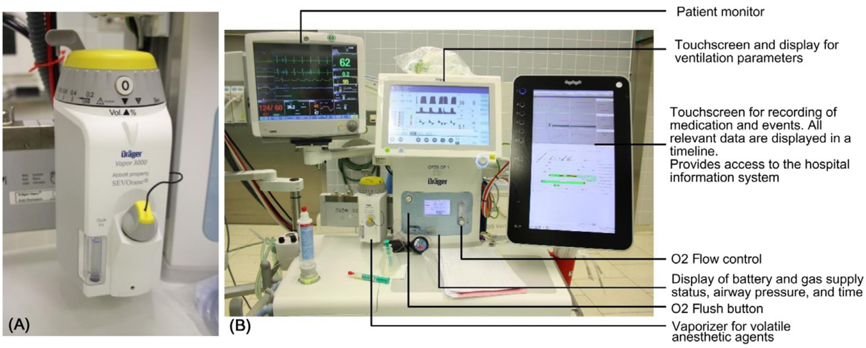


Figure 4.16 (A, B) Anesthesia workplace with vaporizer (A), vital signs monitoring, ventilation control, and touchscreen for medication and event reporting (B). *All from MITI.*

4.2.1 Sedation

Sedation is a method different from general or local anesthesia which is aimed at calming the patient temporarily by means of a sedative i.v. drug. Thus, he/she tolerates unpleasant diagnostic or therapeutic interventions more easily. Conscious sedation is commonly used in diagnostic and therapeutic flexible endoscopy. The most popular agent today is Propofol.

Sedation is ideally suited for outpatients, but aftercare in a recovery room is mandatory. The patient can be discharged with stable cardiorespiratory parameters and as soon as previous brain function has returned.

In most countries, administration of a sedative drug (≙ sedation) is not the exclusive domain of the anesthetist but can also be done by, e.g., a gastroenterologist or a surgeon [6].

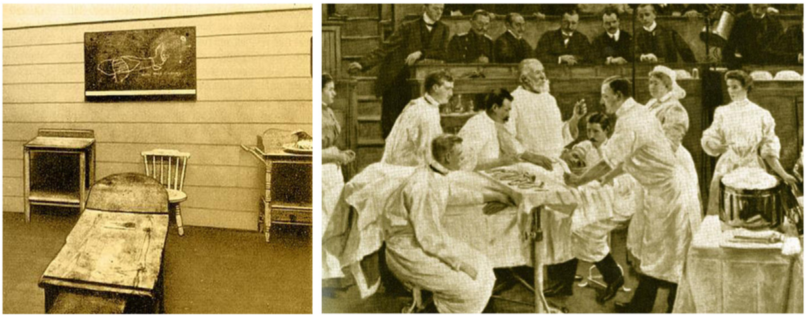
4.3 DEDICATED WORKPLACE: THE OPERATING ROOM

4.3.1 The Surgical Workplace

Originally, the places in a hospital where operations were performed were common rooms without special features. The patient laid on a simple table without any additional functionality (Fig. 4.17A). Later on, so-called operating theaters came into use. They resembled lecture halls with the operating table in the center. Students and visitors could attend the interventions celebrated by the surgeon in chief (Fig. 4.17B).

At the end of the 19th century, the first modern designs of operating rooms were implemented, which regarded the aspects of antisepsis, ergonomy, and the growing requirements of technical support. A trend toward specialized workplaces could be recognized. Supply of water and electrical current became mandatory (Fig. 4.18).

Easy-to-clean surfaces (tiles, glass, etc.), metal chairs and tables were preferred. As soon as electrical power became available, the illumination of the surgical site could be significantly improved. Gradually, the



(A) (B)

Figure 4.17 (A) Typical chamber of a hospital where surgeries could be performed. (B) Advanced scenario of an "operating theater" at the beginning of scientific surgery. *From reprints from our library.*

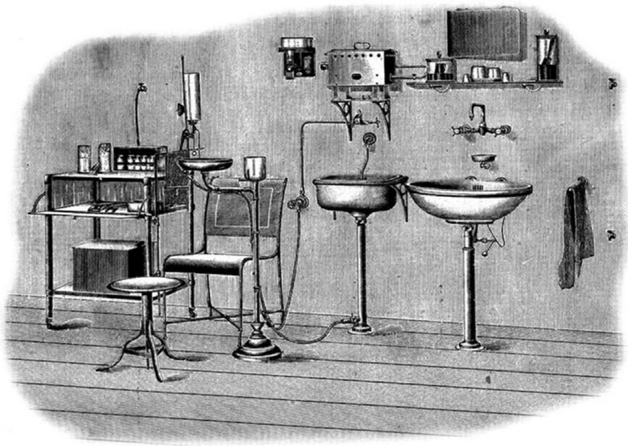


Figure 4.18 A dedicated workplace for ear, nose, and throat surgery around 1900. *From a contemporary catalog.*

operating room attained its position of being the most expensive, most dangerous, and most productive segment of the hospital.

The OR of today is a complex technical environment designed to offer any support to the surgeon to fulfill his task.

It should be designed to be as effective as possible to achieve a high throughput of cases in regular business hours, since maximal capacity utilization is essential in this most expensive facility of the hospital. Besides an optimized process organization, the architecture and the design of the surgical suite has a strong influence upon workflow efficiency. Formerly, all pre- and postoperative activities took place in the operating theater. Today, it is clear that a special distribution helps to optimize efficiency since the functions of key personnel from the nursing, anesthesia, and OR teams can be better synchronized.

The patient makes his/her way from the entrance, where he/she switches from the bed/stretcher onto the OR table, to the induction room. This is the realm of the anesthetists. The patient is prepared for the surgery, including i.v. lines, intubation, etc. Then, he/she is brought into the OR, where surgery is performed. After the operation, the patient is brought to the recovery room until he/she is fit enough to go back to the surgical floor. The workflow is smoothened if all units are located closely together (Fig. 4.19).

A similar workflow is described in an instructive paper of the "OR of the Future" of Massachusetts General Hospital, Boston, MA, United States [7] (Fig. 4.20).

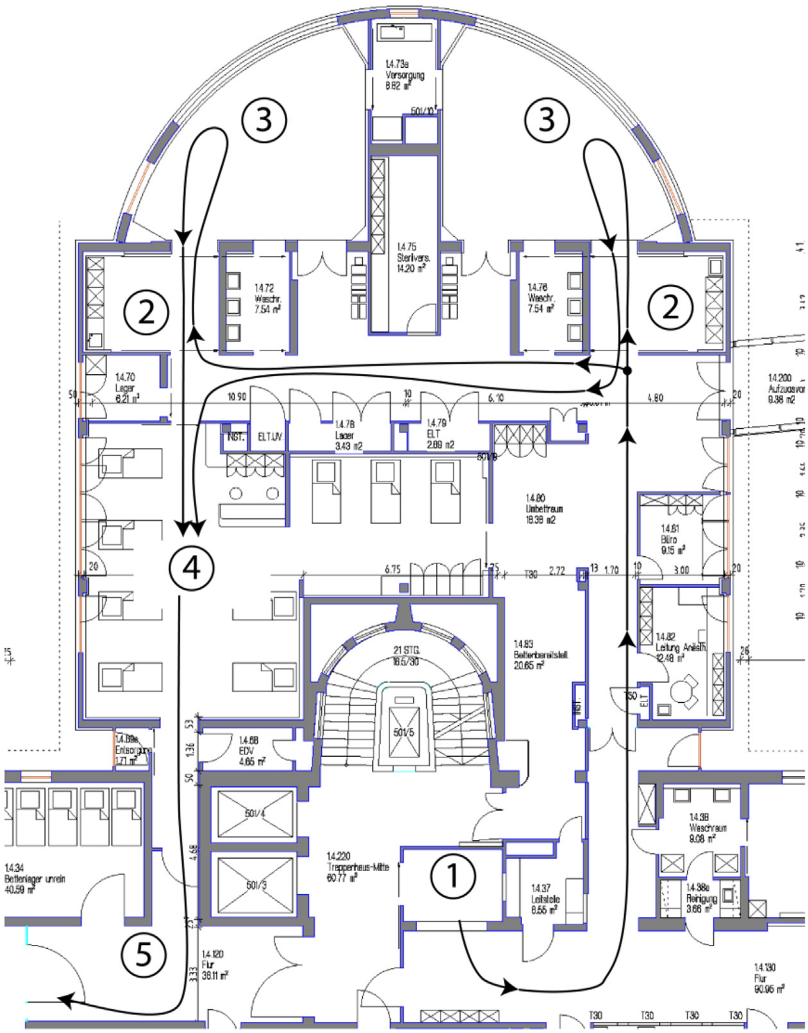


Figure 4.19 OR architecture: ground plan and patient flow: (1) OR entrance; (2) induction room; (3) operating room; (4) early recovery room; (5) exit. *From MITI.*

4.3.2 Core Elements of the Surgical Site

Even the most different, highly specialized OR rooms have at least three core elements in common:

- OR table,
- surgical lights,
- anesthesia equipment.

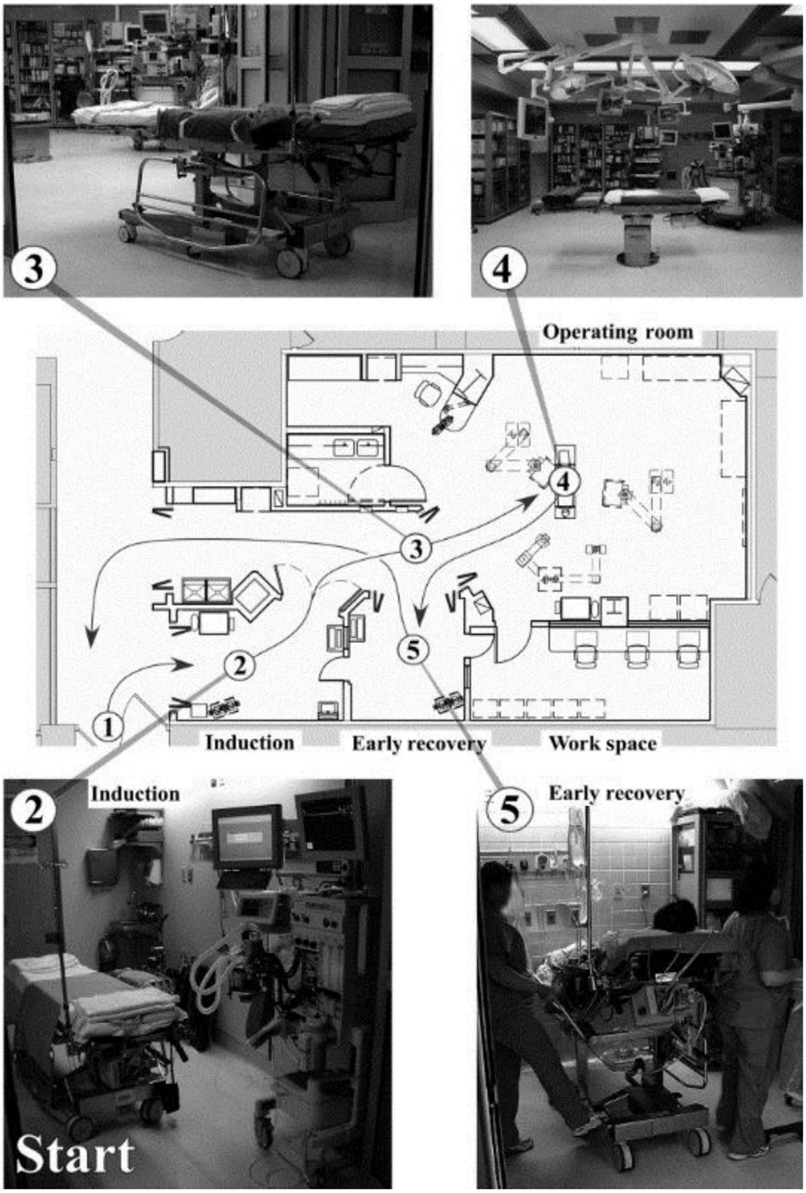


Figure 4.20 Ground plan and patient and equipment flow of the "OR of the Future" of Massachusetts General Hospital. The numbers in the central schematic drawing are illustrated by the surrounding images: (1) Entrance. *From Stahl JE, Sandberg WS, Daily B, Wiklund R, Egan MT, Goldman JM, et al. Reorganizing patient care and workflow in the operating room: a cost-effectiveness study. Surgery 2006;139:717–28.*

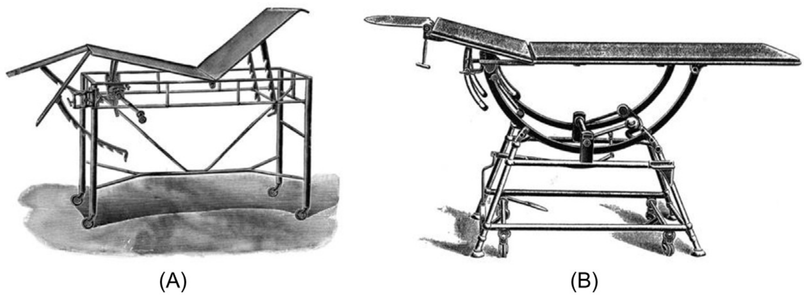


Figure 4.21 (A, B) Specially designed OR tables of the beginning of the 20th century. *From a contemporary catalog.*

Anesthesia equipment was already described in Section 4.2: Anesthesia.

OR tables are the tables on which the patient is positioned during the surgery. They have a central role, since they must guarantee an optimal approach to the individual anatomical site, prevent positioning-induced complications, and offer as much ergonomy to the surgical team as possible. More than 120 years ago, increasingly multifunctional, purpose-built tables were produced (Fig. 4.21).

Modern operating tables have to meet numerous requirements.

The height has to be adjustable, even during the interventional procedure. Furthermore, the table top must offer the possibility of tilting to provide optimal access to more lateral anatomical sites. Trendelenburg and Antitrendelenburg positioning has to be possible as well as special positioning of the extremities (arms, legs). In most cases, the table top consists of several segments which are adjustable according to the patient's anatomy and the type of operation. A further property of modern table systems is that the table top can be shifted on the column (Fig. 4.22).

To enable intraoperative X-ray examination, it has to be made of radiolucent materials. Last but not least, an adequate padding by special mattresses of the table top is mandatory to avoid pressure lesions (decubital ulcers) (see Chapter 3: Principles of Gastrointestinal Surgery).

Nowadays, two types of operating tables exist: stationary systems and mobile units. Both of these consist of three modules: the table top, the column, and the transporter. The way they are combined, however, varies.

4.3.3 Stationary Systems

They are more commonly used in Europe, and, in particular Germany (Fig. 4.23A). The table column is firmly anchored to the floor, and the

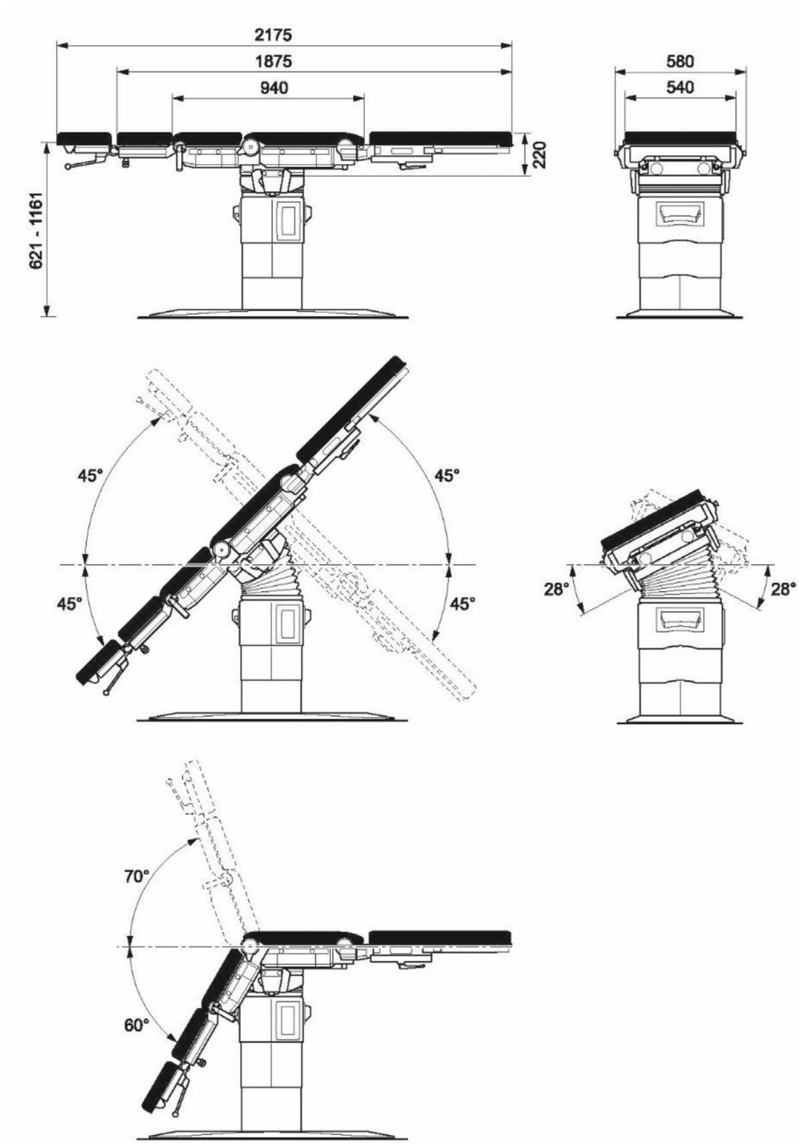


Figure 4.22 Measures and functionality of a modern OR table system. Adjustments in height, tilting in both directions and of the individual segments. *Courtesy: B. Kulik, Maquet, Rastatt, Germany.*

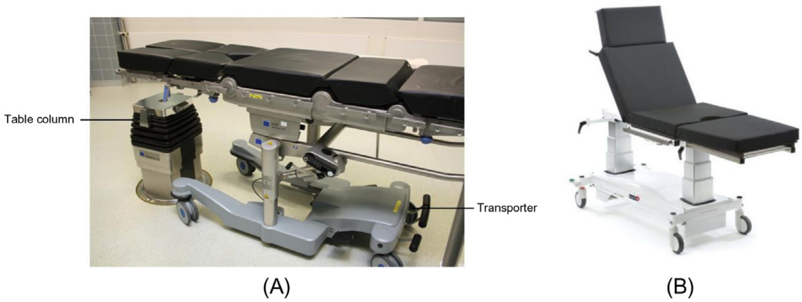


Figure 4.23 (A) Stationary system; (B) mobile operating table. *All from MITI.*

table top is brought to it using the transporter. Mobile systems are compact units integrating each of the three modules (Fig. 4.23B).

Each has their own particular advantages and disadvantages. Stationary systems provide larger leg space to the OR team, are favorable in regards to hygiene, and are better suitable for intraoperative diagnostic procedures.

4.3.4 Typical Surgical Positions in Visceral Surgery

In visceral surgery, the standard position is prone (on the back) (Fig. 4.24A). If access to the anorectum is necessary, the so-called lithotomy position is required (Fig 4.24B). Surgical operations on the spleen, the pararenal glands, etc. need a side position. In (laparoscopic) surgery, the Antitrendelenburg position is preferable.

In special cases, a stomach position is preferable (Fig. 4.24C). Tilting of the OR table is required as well, in particular horizontally (Fig. 4.24D,E).

A few surgeries even need a left- or right-lateral position (e.g., thorax, retroperitoneum) (Fig. 4.24F).

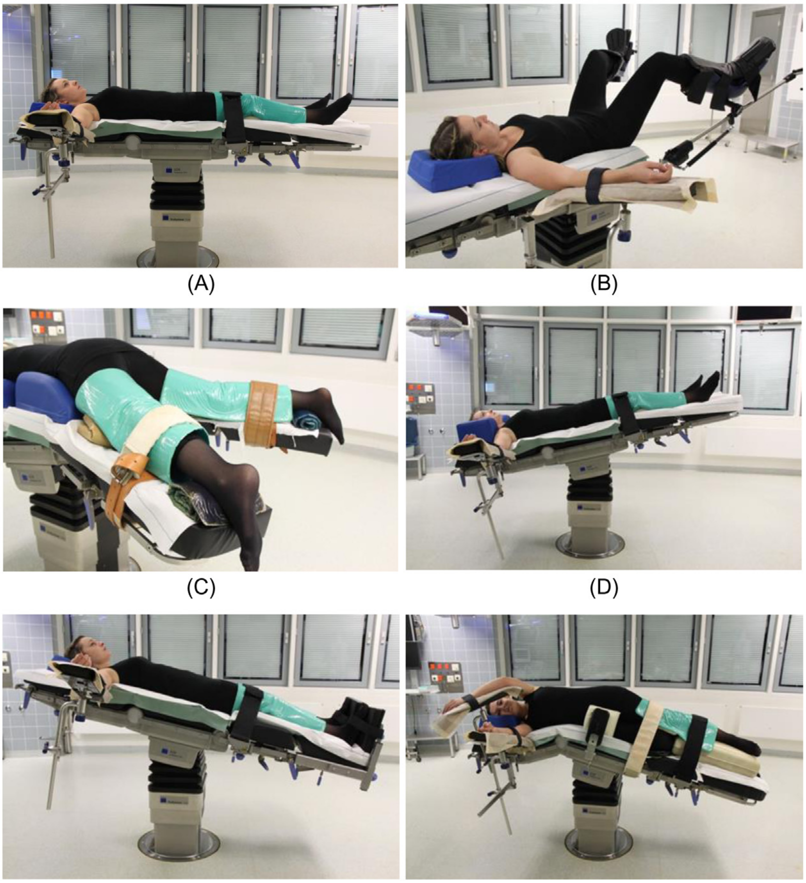
Most of the older OR tables were manually controlled by mechanical or hydraulic operations. Today, remote control is the standard. Advanced control handsets even give the operator information regarding the condition of the table and the position of the respective segments (Fig. 4.25).

The table function is an important module of the future integrated OR environment (see Chapter 14: Visceral Surgery of the Future: Prospects and Needs).

4.3.5 Maximum Load

The average patient is becoming increasingly obese.

Surgical tables are rated to support patients up to 150, 230, or 450 kg in the "normal" patient orientation. These values are considerably lower with side tilt or in a Trendelenburg/Antitrendelenburg position [8].



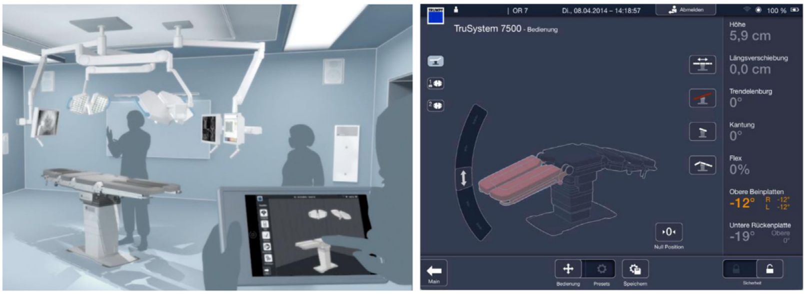
(A) (B) (C) (D) (E) (F)

Figure 4.24 (A) Surgical positions: standard prone position. The majority of all abdominal surgeries can thus be performed. (B) Lithotomy position; (C) stomach position; (D) Trendelenburg position; (E) Antitrendelenburg (often used in laparoscopic operations); (F) lateral position: To give good access to the thorax and retroperitoneum, the table has to be bent. *All from MITI.*

The problem is even more relevant in hybrid ORs when the table has to be shifted horizontally.

4.3.6 Cleaning and Disinfection

Though antisepsis is not required, OR tables have to be cleaned and disinfected after each single surgery. This is mostly done by hand, but at least in larger surgical units dedicated washing machines are preferable.



(A) (B)

Figure 4.25 (A) Remotely controlled OR table: graphical display of selection of function; (B) the modification is indicated. *Courtesy: TRUMPF Medical, Puchheim, Germany.*

(A) (B) (C)

Figure 4.26 Currently available lamp systems: (A) TRUMPF: multiple LED in a two-halved body; (B) multiple lamp bodies; (C) central light source with cone-shaped reflector. *All from MITI.*

4.3.7 Operating Lights

In the preelectrical era, adequate illumination during surgery was always critical. The entrance of electric lights into the OR improved this significantly. Today, the surgeon expects a brilliant illumination even in deep cavities without shadowing effects. As soon as it is switched on, the illumination should promptly reach its full intensity (e.g., in case of an emergency conversion in laparoscopic surgery).

The standard requirements for surgical lightheads are defined by the document IEC60601−2−41 of the International Electrotechnical Commission (IEC): the amount of visible light (lux) should be between 40,000 and 160,000 lux in the center of the beam (central illuminance). To meet the requirements a multitude of different designs have been developed (Fig. 4.26).

Most lamps can be moved by sterilized handles on the body of the light ensemble.

(A) (B)

Figure 4.27 In modern integrated operation rooms, (A) remote lamp control is provided; (B) the parameters illustrated by icon are shown on the right. *Courtesy: TRUMPF Medical, Puchheim, Germany.*

In R&D, a recognizable trend seems to be to replace conventional lamp systems attached to a boom by static ceiling light systems. The direction and intensity of the light beam is electronically modified instead of a mechanical change of the position of the light source (Fig. 4.27).

4.3.8 Peripheral Devices

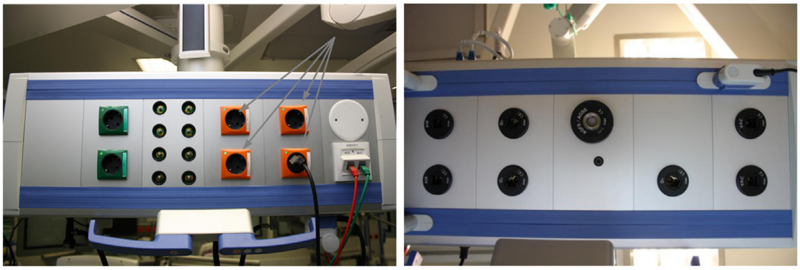
Though the OR table, the surgical lamp, and the anesthesia equipment play a central role, many more items are required to perform the operation, such as the electrocautery machine (see Section 6.2: Electrosurgery), laparoscopy cart, the C-arm for intraoperative imaging, and instrument tables.

4.3.9 Structural Preconditions

The highly specialized workplace "surgical OR" requires the consideration of hygienic, climatic, energy-providing, etc. aspects [9].

Electrical power supply plays a central role in modern hospitals, since most devices are electrically powered and must be ready for operation with highest availability. Therefore, already hospitals of average size are supplied with high-voltage current directly from the electricity supplier.

To guarantee the safety of the patients and for retention of the functional capability of the hospital, technical arrangements are required by law to ensure that essential devices can still operate for at least 24 hours with loss of the central electric power [10]. The most reliable electrical power supply is necessary for OR lamps and all medical-technical devices which are necessary for maintaining vital functions [11]. Therefore, typically two different emergency power systems are installed in hospitals:



(A) (B)

Figure 4.28 (A) Battery- or generator-based current can be identified by the red signal color (arrows); (B) terminal wall outlets (gases). *All from MITI.*

Figure 4.29 Central gas supply of a modern hospital with an easy to reach channel of supply for big trucks. *From MITI.*

uninterruptible power supply (UPS, battery-based) and generators, usually diesel engine driven.

The battery backup provides uninterrupted power to critical lifesaving devices while the generator needs about 15 seconds to start up. To reduce load on the UPS, in hospitals red colored outlets indicate that they are on the battery backup current supply (Fig. 4.28A).

Contemporary ORs are equipped with piped medical gas and vacuum systems. The supply of oxygen, nitrous oxide, and carbon dioxide comes from cylinder batteries whose size is based on the individual requirements. The central gas supply is typically located in an area where fresh supply from the provider can be carried out easily (Fig. 4.29) [12].

Compressed air is generated with compressors, driven by electric motors, additional dryers then withdraw the humidity. Filters and catalytic converters ensure an oil-free, medically pure compressed air. Finally, a pressure-relief valve reduces the air pressure to the required operating pressure.

The gases are passed through a branched pipe network. Gas outlets are either fitted flush on walls or as overhead booms (Fig. 4.28B). The terminal gas outlets are labeled and the connection probe assembly differs to avoid false connections. For the continuity of patient care with medical gases, pressure monitoring with optical and acoustical alarms is provided in all rooms connected to the central gas supply.

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CHAPTER 5

Diagnostic Procedures

Surgery is a therapeutic discipline. Nevertheless, the diagnostic workup of a surgical patient prior to the operation is an essential part of the surgeon's obligations. For centuries, surgical examination was confined to so-called "physical examination." Physical examination, which is still today mandatory, encompasses:

a. Visual inspection

Optical impressions provide valuable information about the general state of the patient, including the nutritional state, etc.

b. Auscultation (Fig. 5.1A)

Listening to the internal sounds of the body gives valuable information about its function. The physiological movement of the bowel (peristalsis) produces typical sounds which may be altered by inflammation (subtotal), obstruction, or other pathological conditions. If the bowel is paralyzed, nothing is heard any longer ("deathly silence"). Though auscultation of the abdomen is generally not as sophisticated as cardiac auscultation, it requires sufficient experience.

The characteristic tool for auscultation is the stethoscope. Today, electronic stethoscopes are available with signal enhancement and noise reduction.

c. Percussion (Fig. 5.1B)

Striking the body with sharp blows of the fingers produces a sound more or less specific to the density of the underlying anatomy. In the abdomen, percussion is helpful to determine the size of the liver or to estimate the air content of the bowel.

d. Palpation (Fig. 5.1C)

For palpation, the hands are used to feel the position, size, and consistency of internal organs. In the abdomen, liver and spleen are palpable as well as tumors. Palpation may be difficult in obese patients. Nonetheless, it is a basic component of the surgical exploration since the patient's complaints (pain) give valuable information upon the underlying disease (e.g., lower right quadrant: appendicitis; upper right quadrant: cholecystitis; epigastrium: ulcer disease; and lower left quadrant: sigmoiditis).

(A) (B) (C)

Figure 5.1 (A) Auscultation: Bowel motility (peristalsis) produces a typical noise which may be irregular or completely absent in the case of impaired transit; (B) percussion: characteristic sound is produced by percussion which helps to determine the underlying tissue; (C) palpation: organs and their borders or atypical masses can be felt with experienced fingers. *All from MITI.*

If performed by experienced clinicians, the sensitivity and specificity of these tests together with clinical observation is rather high [1]. Nonetheless, they do not reach the precision of modern technical diagnostic procedures. The detection of X-rays was a first breakthrough. Roentgenographic tools were continuously improved (dynamic fluoroscopy computed tomography, etc.) and complimentary approaches were invented [e.g., ultrasonography, magnetic resonance imaging (MRI)]. Further developments are in the pipeline. This chapter gives an overview.

5.1 CONVENTIONAL RADIOLOGY

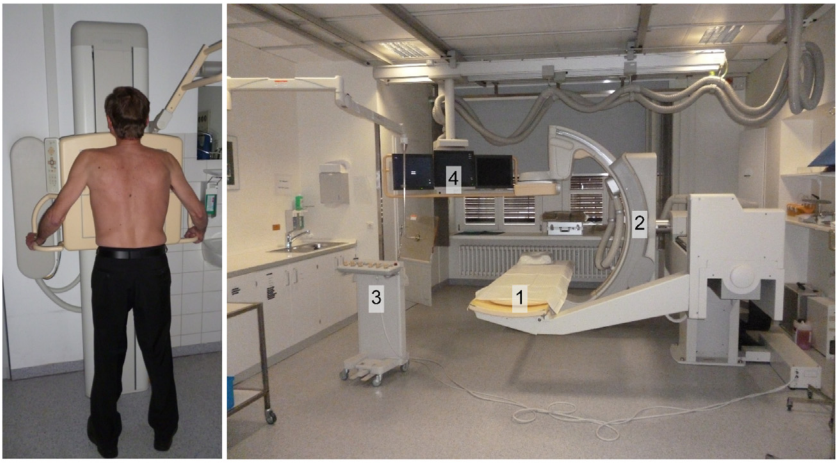
X-rays are electromagnetic, indirectly ionizing radiation. They are situated between ultraviolet and gamma rays with wavelengths between 10^{-6} and 10^{-10} cm and frequencies in the range of 10^{10} and 10^{14} MHz.

Medical X-ray imaging is a noninvasive and painless method to diagnose diseases and monitor therapies. It further helps to support the planning of medical and surgical treatment. Unfortunately, due to the high energy of the ionizing radiation, X-rays can potentially cause damage to DNA, which can lead to the development of cancer. Accordingly, the use must be strictly limited.

The objective of medical X-ray imaging is to provide information about pathologies of the body structure or function. The image quality is influenced by the properties of the object examined, hardware components of the imaging system, and the imaging technique used. The image quality is affected by contrast, spatial resolution, and noise. Contrast means the amount of the measured signal differences between the point of interest and the surrounding area. The ability of an X-ray detector to display different anatomical features within the imaged object is described by the spatial resolution. The noise represents defective variances of the true measured signal in the image. For the quantification of contrast, spatial resolution, and noise, and their relationships to each other, the parameters contrast-to-noise ratio (CNR), signal-to-noise ratio (SNR), modulation transfer function, noise power spectrum, and the detective quantum efficiency are used [2].

5.1.1 Technical Aspects

A radiographic system or an X-ray unit consists of an X-ray tube with a generator, a collimator, an X-ray detector, and a device to ensure the geometrical arrangement of patient, tube, and detector [3]. The X-ray tube generates the X-radiation, which is shaped by the collimator and passes through the human body thus creating a latent image in the image plane. This image was formerly detected by X-ray film, an image intensifier, or today by a set of X-ray detectors (digital radiography) (Fig. 5.2).



(A) (B)

Figure 5.2 (A) Plain X-ray of the thorax. The X-ray source on the right side (not visible). The patient is positioned against the flat detector (posterior—anterior X-ray); (B) conventional dynamic fluoroscopy suite: 1, stretcher; 2, C-arm; 3, steering unit; 4, video screens. The patient's bed and the C-arm can be moved in all required degrees of freedom independently of each other. *All from MITI.*

5.1.2 Generation and Detection of X-Rays

The generation of X-rays occurs inside an X-ray tube where fast moving electrons emitted by a heated cathode are suddenly decelerated by impinging on an anode material. The electron beam is concentrated to form a small spot on the anode. The X-rays emerge in all directions from this spot, which can be considered as a point source for the radiation. When the electrons strike the target, only a small part of their energy is converted into X-rays and the rest is dissipated in the form of heat. This condition makes materials with a high melting point and a cooling system for the X-ray tube necessary. The influencing factors for the wavelength of X-rays are the anode material and the velocity of the electrons hitting the anode. The intensity of X-rays depends on the current inside the tube. Typical for diagnostic purposes are target voltages in the range of 30–150 kV, while the current is in the range of several hundred milliampere.

A detector registers the radiation behind the human body. In the past, X-ray film delivered the typical shadowgraph. Today, detection of X-rays is achieved either by a directly converting semiconductor or by a scintillation material followed by a light sensor such as a photodiode. In both methods, radiation is ultimately converted into an electrical signal. The sensitive area of a detector is divided into an array of detector elements. Each delivers a signal representing the amount of absorption. There are two different options to use the signal. It is called integrating detection if the signal is integrated over a certain time. When every single event is analyzed individually, it is called counting detection [4]. The quantification of the performance of X-ray detectors is usually made by the modulation transfer function and the detective quantum efficiency [5].

X-ray detectors can be subdivided into gas ionization, scintillation, semiconductor, direct conversion or flat panel, charge-coupled device (CCD), and photon-counting detectors.

A gas ionization detector measures the beam flux instead of individual photons. It is normally used as an integrating detector, and consists of a gas cell with a small entrance and exit windows. Several X-rays in the beam interact with the chamber gas to produce photoelectrons and photons. These electrons generate additional electron–ion pairs by inelastic collisions, and the photons either escape or are absorbed in a photoelectrical way. Electrons and ions are then collected at the plates. The efficiency of this detector depends on the X-ray absorption cross-section, the active length of the chamber, and the properties of the chamber gas.

Scintillation detectors (Fig. 5.3) consist of a scintillation material that converts X-rays into optical photons, an optical relay element to focus or amplify them, and a photomultiplier or a photodiode to detect these particles and transfer them into electrical signals for further processing [6,7]. Scintillation materials can be divided into organic scintillations or single crystals of different chemical elements. The energy resolution of single crystals is higher than the energy resolution of organic scintillations. Moreover, a time resolution better than 1 ns and a count rate capability up to 2×10^6 photons per second are achievable with semiconductor materials. Scintillation detectors in conjunction with gas ionization detectors are called gas scintillation detectors. By combining the operation of gas ionization chambers and photon detectors, overall performance can be improved [8].

Semiconductor detectors are solid-state devices that operate essentially like ionization chambers, but offer higher detection efficiency and better spectrometric resolution [9]. In contrast to gas ionization detectors, the charge carriers are not electron–ion pairs, but rather pairs of electrons and holes. An electron–hole pair is generated due to an electron that moves from the valence band to the conduction band. In this process, a free hole is created in the valence band. Under the influence of the electric field, the electrons and holes are swept away, and the proper electronics can collect the charge in a pulse [10].

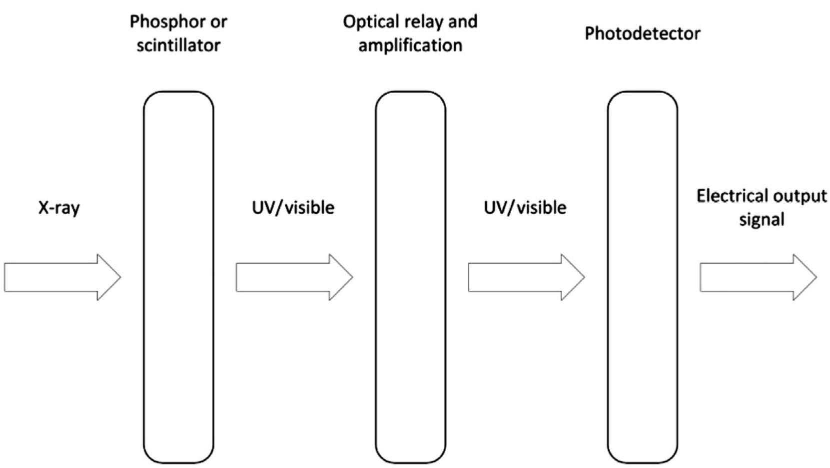


Figure 5.3 A sketch of a scintillation detector with the main constituent parts. *From MITI.*

In direct conversion flat panel detectors, X-rays are directly converted to electron-hole pairs and the resulting charge is collected from individual pixel electrodes. These detectors usually possess photoconductors made of amorphous selenium and thin film transistors to read the charge signal. The detectors enable a high spatial resolution and high X-ray absorption efficiency at low energies [2].

A conventional differential detector is a light-sensitive sensor for recording images, and consists of an integrated circuit containing an array of linked or coupled capacitors. The X-ray energy is converted into light by a scintillation material. The CCD then records the quantity of light emitted. The light is converted into electrical charges [11]. The available amount of pixels goes up to 4096 × 4096 pixels, with pixel sizes of 12 × 12 μm and readout times of less than 1 second. For high spatial resolution, a 5−20 μm thick sapphire scintillation screen is optically coupled with a high-quality microscope lens to give a spatial resolution of around 1 μm [8].

Photon-counting detectors generate additional information by counting individual photons and measuring their energy. For computed tomography (CT), this facilitates the reconstruction of images free of spectral artifacts and with identical quantum efficiency; it also reduces the image noise in comparison with images obtained by energy integration [12].

5.1.3 Projection Radiography

The possibility to use X-rays for diagnostic purposes hinges on the fact that various body tissues have differences in their density. According to which kind of tissue is examined, X-rays are absorbed at different intensities. The result of projection radiography is a so-called shadow image of the internal structure that displays the variation of spatial intensity of the radiation transmitted. Bones and foreign matter such as metallic devices appear in white colors, and air-filled cavities are shown up in black. These structures are well displayed in the image obtained because they have either a higher or a lower density in contrast to the surrounding softer tissue. Body organs are shown in shades of gray because of their lower density and lower attenuation.

Projection radiography can be subcategorized into digital projection radiography (DPR) and real-time imaging or fluoroscopy.

DPR uses digital detectors to generate a digital image, which is then stored on a digital medium. This double-stage approach differs from analog or screen-film radiography, in which the film combines detection

(A) (B)

Figure 5.4 (A) Historical and (B) current state-of-the-art viewing station: digital radiography. *All from MITI.*

and storage functions. DPR can be divided according to its readout process into computed radiography and direct radiography. The application of DPR covers most body areas [11].

In the past, each single image had to be handled physically. The archiving required much space and a strict order to find them again in case they were needed later on. X-ray archives were nicknamed "silver mines" since they housed thousands of photographic images. Digital radiography significantly improves the handling, archiving, and reidentification of radiologic information.

Digital imaging consists of four separate steps: generation, processing, archiving, and presentation of the image. After detecting the absorbed energy and transforming it into electrical charges, they are recorded, digitized, and quantified. Postprocessing software is needed then to arrange the raw data into a final and medically useful image, which is subsequently sent to a digitized storage system. The image can be either presented as a hard copy film or viewed on a computer workstation [11] (Fig. 5.4).

Compared to screen-film radiography, DPR is advantageous because images can be stored digitally into a digital picture archiving and communication system (PACS). This offers a space-saving storage method and allows the information to be accessed anytime.

Recent Developments and Current Research

Research on DPR involves the investigation of new storage phosphors and scanning systems for computed radiography and improvements of the detective quantum efficiency and SNR of the detectors, which results in further exposure reduction or higher image quality. An optimized architecture of the readout array could be achieved by reducing the size of circuits and pixels [11].

5.1.4 Real-Time Radiography

Real-time radiography or fluoroscopy gives a detailed view of the movement of a body part, of a medical instrument, or of a contrast agent moving through the body by displaying continuous X-ray images on a screen. Real-time radiography is versatile for diagnostic and interventional purposes such as angiographic examinations, catheter insertions, or the manipulation and the placement of devices within the body.

The arrangement of tube, detector, and patient does not differ from projection radiographic systems. The substantial element behind real-time radiography is a fluoroscopic screen, which converts radiation to light. The light signals can be observed directly, intensified, and/or converted to a video signal which is presented on a screen.

In visceral surgery, fluoroscopy still has an important role. Preoperatively, the highly dynamic motor responses of the upper GI tract—in particular fast movements in the hypopharyngeal region—can still be assessed best by high-speed fluoroscopy. Likewise, the dynamic behavior of the small intestine can be examined reliably by means of a Sellink's procedure. The same holds true for the barium enema of the colon (Fig. 5.5).

For contrast enhancement, iodine-based or barium-sulfate compounds are used. Barium is cheaper but should be avoided if a perforation/leakage of the GI tract is suspected. In these cases, water soluble iodine-based contrast media should be preferred.

Another important application is angiography. The arterial vascular system is visualized by direct injection of the contrast medium into an artery. Visualization can even be combined with therapeutic approaches (Fig. 5.6).

The wide field of application of real-time radiology is beneficial. However, radiation exposure, especially during longer examinations, is higher compared to DPR.

DPR is currently one of the most common diagnostic procedures in medical imaging. Its simplicity and versatility, in addition to its low costs compared to other imaging techniques, such as CT or MRI, mean that DPR is expected to remain as relevant as it is today for the foreseeable future.

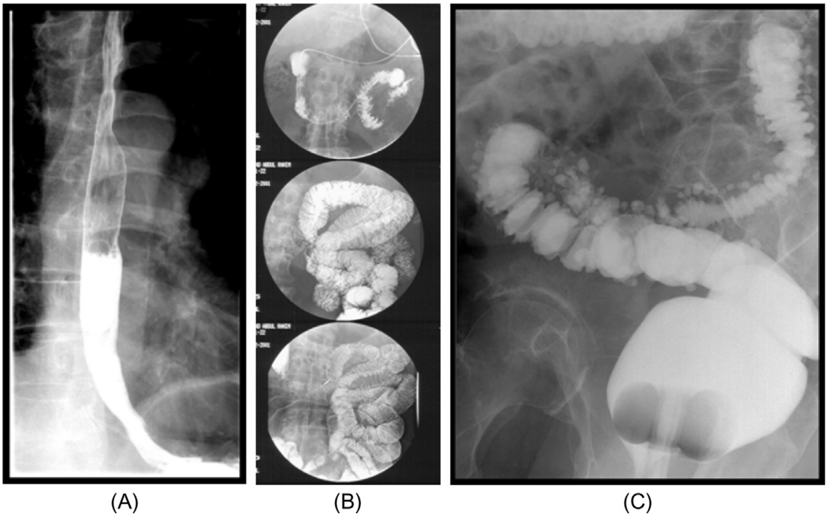


Figure 5.5 (A) High-speed fluoroscopy of the esophagus; (B) dynamic radiographic examination (fluoroscopy) of the small intestine (so-called Sellink examination): Initially, the duodenum and the first jejunal loops become visible (middle up); middle center: after a few minutes, the loops of the jejunum are visible; middle bottom: the last loops of the ileum appear. (C) Exploration of the rectum/descending colon using a barium enema. *All: Courtesy: Dr. K. Holzapfel, Klinikum rechts der Isar.*

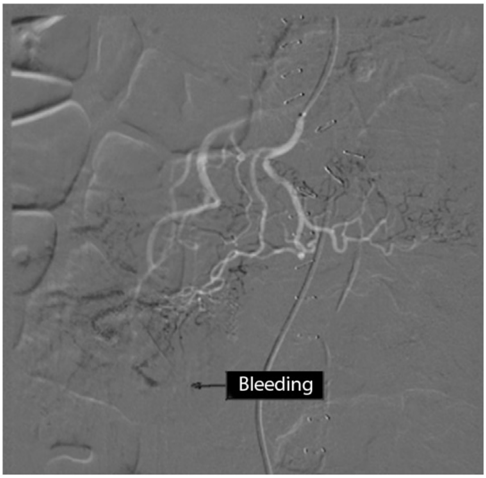


Figure 5.6 Direct angiography of intestinal vessels. The leakage of contrast medium is clearly visible. A coil was positioned at the same session which stopped the bleeding immediately. *Courtesy: Dr. A. Fingerle, Klinikum rechts der Isar.*

5.2 COMPUTED TOMOGRAPHY

CT (synonyms: X-ray CT or computerized axial tomography scan) is an innovative tool to gain 3D data sets instead of 2D information as provided by conventional radiology.

5.2.1 Principle of Computed Tomography

CT is an advancement of conventional projection radiography and overcomes one of its key problems: that certain features cannot be precisely located because of overlapping parts or because features of interest are out of the range of the plane. The solution offered by CT is to combine information from a series of 2D X-ray absorption images, as the X-ray source and the corresponding detector are rotated about a single axis. Afterward, tomographic algorithms are used for reconstructing this series of images to produce a 3D digital image. In this image, each voxel (volume element or 3D pixel) represents the X-ray absorption at a specific point. The 3D internal structure and the unique position of internal features can be inferred from the images due to the known relationship between X-ray absorption and material density. De facto, 3D images are represented as a series of 2D slices [13] (Fig. 5.7).

In general, there are seven main topics of CT imaging modifications. All CT applications are based on at least one acquisition system, which

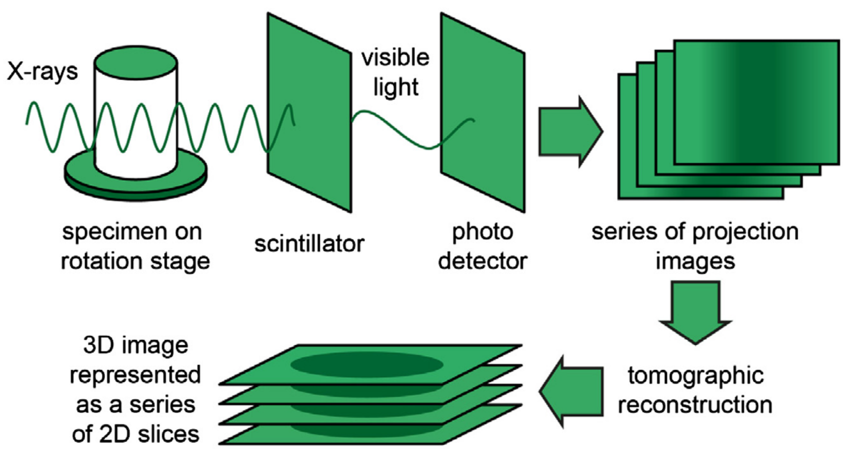


Figure 5.7 Schematic illustration of X-ray CT acquisition and reconstruction processes. A volume data set is created by adding numerous levels of 2D data. *From Landis EN, Keane DT. X-ray microtomography. Materials Character 2010;61 (12):1305–16. Modified by D. Ostler.*

means one tube-detector pair. *Multislice CT* uses multiple rows of detectors and a widened X-ray beam to use the X-ray beam more effectively. *Cone beam CT* allows a different image acquisition process due to the use of a conical X-ray beam. *Dual-energy and dual-source CT* have two acquisition systems and can operate in different voltage settings. *Phase-contrast CT* is a medical imaging technique that makes use of the phase shift, which emerges when X-rays pass through different tissue. *X-ray microtomography* is used to characterize tissue in its microstructure. *Electron beam CT* detects calcium build-up in coronary arteries by using an electron emitter to generate X-rays.

5.2.2 Multislice Computed Tomography

Multislice CT (MSCT) is an advancement of single-slice CT (SSCT). The basic idea of MSCT is the use of multiple rows of detectors in conjunction with widening the X-ray beam in the *z*-direction (slice thickness) to use the X-ray beam more effectively. This indicates that the data can be collected for more than one slice at a time [14].

Real volumetric images are obtained in a shorter period of time. However, radiation dose is higher. Even dynamic processes can be evaluated (Fig. 5.8).

The major difference between SSCT and MSCT is in the design of the detector arrays (Fig. 5.9). The SSCT uses detector arrays that form a 1D array. In MSCT, each detector element is divided into several smaller detector elements in the *z*-direction. These detector elements form a 2D array. There are various types of rows of detector elements. Current hospital systems have 64 rows or more of detector elements in order to reach a very high resolution [15].

Figure 5.8 Contemporary MSCT workplace. *From MITI.*

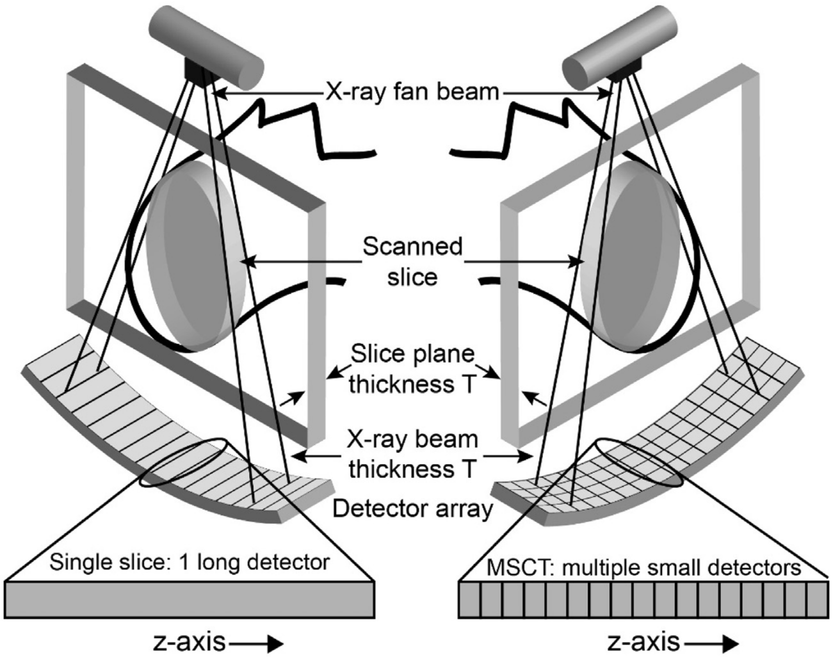


Figure 5.9 Single-slice computed tomography (left) versus multislice computed tomography (right). *From Goldman LW. Principles of CT: multislice CT. J Nucl Med Technol 2008;36(2):57–68. Modified by D. Ostler.*

In MSCT, the slice thickness is not determined by the X-ray beam collimation. Instead, it is determined by the detector configuration. This length is often referred to as detector collimation due to the length each individual detector has. There are several ways to combine detector elements, as shown in Fig. 5.10 [14].

The major advantages of MSCT are the shorter acquisition times, the retrospective creation of thinner or thicker sections from the same raw data set, and the improved 3D rendering. The possibilities of MSCT acquisition are widespread: the scan of anatomical volumes with standard techniques at significantly reduced scan times, scanning larger volumes previously not accessible in practical scan times, or the scan of anatomical volumes with high axial resolution [16]. The disadvantages of MSCT are the high radiation doses for the patients being subjected to an examination, and the high costs of purchase and maintenance for such systems [17].

Current developments and trends show systems with a larger number of slices driven by clinical applications, which become possible through the use of such detectors. Recent systems by Toshiba (Shimoishigami, Japan) and Siemens (Erlangen, Germany) target these applications by introducing

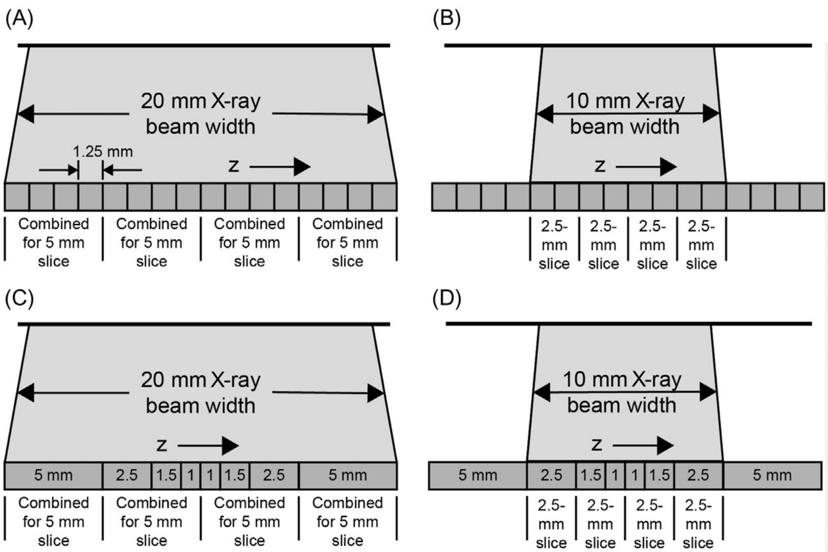


Figure 5.10 Examples of fixed array detectors (A, B) and adaptive array detectors (C, D) for four-slice MSCT scanners. (A) Four 5-mm detectors built out of four linked 1.25-mm elements. (B) Paired linking of the inner eight elements to act as four 2.5-mm detectors. (C) Four 5-mm slices built with adaptive-array elements. (D) Four innermost elements are paired to form 2.5-mm detectors which, along with the two 2.5-mm detectors, collect data for four 2.5-mm slices. *From Goldman LW. Principles of CT: multislice CT. J Nucl Med Technol 2008;36(2):57–68. Modified by D. Ostler.*

systems with 128 slices (Siemens) and 320 slices (Toshiba) using different technological paths. These technological improvements offer the possibility to acquire 4D images (3D plus time). There are prototype systems that use a special flat-panel detector technology that was originally used for conventional catheter angiography. As the high radiation dose patients are subjected to is the key problem, the introduction of dynamic collimators will eliminate the increasing problem of overradiation in spiral scans, which has increased as a result of increasing detector width [18].

5.2.3 Cone Beam Computed Tomography

Cone beam CT (CBCT) or digital volume CT is an advancement of conventional CT that uses a divergent pyramidal or conical X-ray beam instead of a fan-shaped beam [19].

The geometrically different beam configuration of CBCT enables the acquisition of sequential planar projection images of the field of view (FOV) in a complete or sometimes partial arc. The resolution of CBCT images is defined by the individual volume elements or voxels, which are produced from the volumetric data set. The voxel dimensions are primarily influenced by the pixel size on the area detector, whereas in conventional CT, the voxel dimensions depend on slice thickness [19].

A CBCT system impresses with its simple operability and integration into routine practices, shorter examination times—including higher image sharpness and lower radiation dose—increased X-ray tube efficiency and lower image distortion because of movements of the patient. The disadvantages of CBCT systems are based on the detection of large amounts of scattered radiation during the acquisition, especially of larger FOVs. This results in limitations in image quality related to noise and contrast resolution [19,20].

Recent Developments and Current Research

Future trends in CBCT imaging will probably lead to further reduction of scan time, improvements in image quality and accuracy—including soft-tissue contrast—and a further reduction of radiation dose [19].

5.2.4 Dual-Energy Computed Tomography

Dual-energy CT (DECT) acquires two image data sets of the same anatomic body area with the help of a low-energy and a high-energy X-ray spectrum. As a result, an analysis of energy-dependent changes in the attenuation of different materials becomes possible. For the acquisition of these different energy data sets, three DECT scanners are available: a single-source dual-energy scanner with fast kilovoltage switching (SSDESKS), a single-source dual-energy scanner with dual detector layers (SSDESDDL) and a dual-source scanner with dual detector arrays. The latter scanner type will be covered as a separate modification called dual-source CT (DSCT) further on.

A SSDESKS has a single radiation source and uses its ability to alternate rapidly between two kilovoltage settings (80 and 140 kVp) to generate the different spectra while the CT gantry makes a single rotation [21]. To sustain the higher tube output at 140 kVp, the exposure time ratio is varied between 80 and 140 kVp acquisitions to maximize the CNR. The alternating high- and low-energy data are captured by a detector with a fast response and a data system with a fast sampling ability [22].

A SSDESDDL is based on a modified detector array with two-scintillation layers positioned one above the other to receive the separate energy image data streams from a single X-ray source. The overlying layer captures low-energy data, whereas the underlying detector captures high-energy data. Two different image series are then reconstructed from the two data sets [21].

In general, DECT is beneficial because it provides significant morphologic detail and supplies material-specific and quantitative information. The usage of a SSDESKS offers good spatial and temporal registration, greater flexibility due to projection-space dual-energy decomposition, and a simple quantification of iodine density. The weaknesses are a restricted spectral separation between high- and low-energy scans, the incapability to measure attenuation on virtual unenhanced images, and higher noise on images received with lower peak voltage. A SSDESDDL possesses a good temporal and spatial registration, but the spectral energy separation is limited [22].

Recent Developments and Current Research

Other recent approaches for DECT acquisition are rotate-rotate software and photon-counting detectors combined with special k-edge filters, both of which are not yet commercially available. Rotate-rotate software is used when the scanner does not have built-in hardware to allow simultaneous dual-energy acquisition. A photon-counting detector combined with special k-edge filters generates monochromatic radiation and prohibits the overlap of the low-energy spectra with the high-energy spectra [23].

5.2.5 Dual-Source Computed Tomography

DSCT is an imaging technique that simultaneously acquires two partial segments shifted by 90 degrees rotation angle at the same anatomic level. As a result, the two sets of projection data are combined to form a complete sonogram (180 degrees) [24,25]. This technique is mainly used in cardiology and emergency care.

This process is carried out by two tube-detector (acquisition system) pairs, which are mounted at an angular offset of 90 degrees on the rotating gantry [25]. While one detector covers the entire scan FOV, the other detector is limited to a more central and smaller FOV because of the space limitations on the gantry. DSCT can operate in a single- or dual-energy mode [26]. Assuming that only one acquisition system is used, DSCT is a multislice single-source CT and therefore applicable for general radiologic issues. In the case of two acquisition systems, both tubes can be operated simultaneously in a standard spiral or sequential acquisition mode to provide higher X-ray peak power for longer scan sessions, among other things. Moreover, both X-ray tubes can be conducted independently with regards to their voltage and current settings. This allows the acquisition of dual-energy data [24].

Strengths and Weaknesses

Compared to a single-source CT, DSCT has a higher temporal resolution—especially for cardiac CT examinations—an increased speed of acquisition, and therefore a lower radiation dose [27]. Further benefits are the possibility of combining the resulting acquisition data, the flexibility of different modes to operate with, and therefore the acquisition of dual-energy data. These data can principally add functional information to the morphological information. The separation of bones and iodine-filled vessels in CT angiographic examinations can be a further application [25].

Recent Developments and Current Research

To achieve a better evaluation of cardiac functions, improvements that increase the z-coverage of the detectors are necessary.

5.2.6 Phase-Contrast Computed Tomography

X-ray CT phase imaging methods can be classified into three different techniques: the interferometric methods, techniques using an analyzer (or diffraction enhanced imaging), and propagation-based phased contrast [28].

When X-rays pass through different tissue, a phase shift is caused, and this phase information is used to generate a higher contrast image of soft tissue. This technique is called phase-contrast CT and represents a suitable alternative to conventional CT [29].

The utilization of phase-contrast has several attractive sides. The major advantage is the possibility to study the refractive properties of the medium, rather than the absorption properties as in conventional CT. Furthermore, the total spent dose may be diminished, whereas the resolution is increased [30].

The main disadvantage is the limitation of the phase-contrast effect due to a limited coherence. Highly developed equipment is required, such as a synchrotron source, which is very expensive [28].

Currently under research and discussion is the translation of this method into a clinical scenario. This is achieved by increasing compatibility with conventional X-ray tube sources instead of synchrotron radiation. However, there are several challenges, mostly of a technological nature, which have to be addressed. They relate in particular to the production of sufficiently large and efficient gratings for typical acceleration voltages of about 120 kVp in human CT scanners with typical FOVs of about 70 cm [29].

5.2.7 X-Ray Microtomography

X-ray microtomography is a technique to noninvasively characterize material microstructures in 3D at a micron level spatial resolution [13]. X-ray microtomography is mainly used to detect lung tumors.

X-ray microtomography systems need a synchrotron X-ray source, high-speed algorithms for tomographic image reconstruction, and a high-resolution imaging X-ray detector [31].

The advantages of X-ray microtomography are multifaceted. Internal structures of soft tissue are depictured in 3D at a very high spatial resolution, up to 0.7 μm pixel size. However, the actual resolution depends on the examined structures and the exposure time. For X-ray microtomography, a limitation includes the penetrating ability of the X-rays relative to the density of the tissue sample. Because of its limited availability, the use of synchrotron X-ray sources is not very prevalent [13].

Due to artifacts caused by breathing or other movements, an accurate estimate of the resolution of X-ray microtomography is only possible for motionless objects.

Despite the fact that current studies indicate that this technique has potential for other types of applications, there are physical limitations of what is possible with X-rays. Nevertheless, the amount of information extracted from CT scans continues to grow, accompanied by still growing increases in computing power. Improvements in conventional X-ray sources lead to a spatial resolution into the submicrometer range for some systems, by either using more sensitive detectors or by increasing the energy [13]. Another promising future development is the implementation of synchronization between image acquisition and respiratory and cardiac frequencies in order to increase the resolution of in vivo scanning of the lung.

5.2.8 Electron-Beam Computed Tomography

Electron-beam CT (EBCT) is a fast, highly sensitive, and noninvasive technique to assess dynamic processes. EBCT is also called ultrafast CT [32].

EBCT makes use of a stationary electron emitter which does not circle around the patient. This electron emitter is large and partially surrounds the imaging circle. An electron beam focus is swept electronically, not mechanically, as in conventional CT, along a tungsten target to emit X-rays from different angles. This technique permits very rapid scanning times of almost 0.03 seconds and consequently eliminates motion artifacts related to cardiac contraction [33].

There are several advantages over conventional CT. The major advantage is the fast acquisition time, which results in less need for sedation of the central nervous system. The imaging of moving structures is less blurry. As EBCT generates X-rays with an electron beam, the radiation exposure is decreased.

However, this technique is not likely to be used as a standard screening tool yet, as the scan is very expensive and it is necessary to inject the patient with a contrast agent.

Clinical Application

Computed tomography angiography (CTA or CT angiography) is a special technique to visualize arterial and venous vessels in the whole body.

To achieve a contrast of the vascular system, X-ray contrast agent is applied, but in contrast to classical angiography, it must not be applied directly in the vessel system to be visualized, it can be administered in an arm vein. The acquisition sequence is then started manually or automatically after a delay needed for the contrast agent to pass the region of interest (ROI) and usually lasts only a few seconds.

Strengths and Weaknesses

CTA is technically easier and less risky than X-ray angiography and an option for diagnosis of aneurisms or stenosis of vessels. However, the detail resolution even in modern CT scanner is lower (typical voxel size: 0.5–1 mm). The radiation exposure of CTA is relatively high (up to 13 mSv).

Competing alternatives to CTA are duplex ultrasound (US) and magnetic resonance imaging MRI angiography.

5.3 MAGNETIC RESONANCE IMAGING

A variety of magnetic field systems is provided by the medical industry to visualize diseases in the human body. These systems share several similar hardware components. The main components of each system are the coils, which create different magnetic fields or receive signals from magnetic fields. These signals are then reconstructed by a computer system using advanced and specialized algorithms.

Magnetic field systems do not use ionizing radiation, which makes them significantly less harmful for the patient. Therefore, magnetic field systems are generally preferred over radiographic systems whenever possible.

The most significant technological applications of magnetic field systems are MRI and its modifications, and magnetic particle imaging (MPI), a new and upcoming technology. Electromagnetic navigation is described in Chapter 11.2: Electromagnetic Tracking Systems.

5.3.1 General Considerations

MRI is a medical imaging technique used to visualize detailed structures in any part of the human body by using the body's natural magnetic properties. Imaging is mainly performed using hydrogen nuclei (single protons), since these are mostly located in water and fat. Under ordinary circumstances, these hydrogen protons spin in the body with their axes oriented at random. However, when the body is placed in a powerful magnetic field, such as that generated by an MRI scanner, the protons' axes all line up. This uniform alignment creates a magnetic vector oriented along the axis of the MRI scanner. The magnetic vector is deflected when additional energy, in the form of radio waves, is added to the magnetic field. The radio wave frequency (RF), which varies on the element being sought and the magnetic field itself, causes the hydrogen nuclei to resonate. The strength of the magnetic field can be modified electronically using gradient electric coils. When the local magnetic field is modified in small increments, the resonance of different slices of the body can be measured by applying different radio wave frequencies. By switching off the RF source, the magnetic vector returns to its resting state, causing a signal to be emitted. This signal is also a radio wave, and is used to acquire the MR images. The receiver coils are placed at the ROI, and act as aerials to improve the detection of emitted signals. The received signals have varying intensities, which are plotted by a computer and subsequently turned into cross-sectional images. In order to emphasize particular tissues or identify abnormalities, multiple radiofrequency (RF) pulses are transmitted in sequence. This creates differences in

Figure 5.11 Medical MRI scanner: The patient is positioned on the couch (foreground) which will be advanced into the coil. *From MITI.*

emphasis, which occur because different tissues relax at different rates once the transmitted RF is switched off. There are two measurements of the time needed for the protons to fully relax. The first is the time needed for the magnetic vector to return to its resting state, called the T_1 relaxation. The second one is the time needed for the axial spin to return to its resting state, called the T_2 relaxation. For this reason, an MRI examination is composed of a series of pulse sequences. Different tissues in the body, such as fat and water, have different relaxation times and can thus be identified separately. Most diseases can be identified by an increase in water content, making MRI a sensitive test for the detection of diseases [34] (Fig. 5.11).

5.3.2 Technical Insights

An MRI system is composed of several different hardware components. These are the magnet, which creates the homogenous magnetic field, also called B_0 field, for the imaging procedure; the gradient coils that produce the gradients for the B_0 field; the RF coils, which create the B_1 field, and a processing computer system. The B_0 field is generated to align the axes of the proton spins, whereas the B_1 field is generated in order to deflect these spins. The different magnets are able to generate fields of varying strengths; in medical applications, field strengths from 0.5 to 3 T are used. The RF coils can be divided into three parts: transmit and receive coils, transmit only coils, and receive only coils. Though not part of the hardware, contrast agents, which are used to create higher-quality images, are an essential part of the overall system; these are explained in more detail below [35].

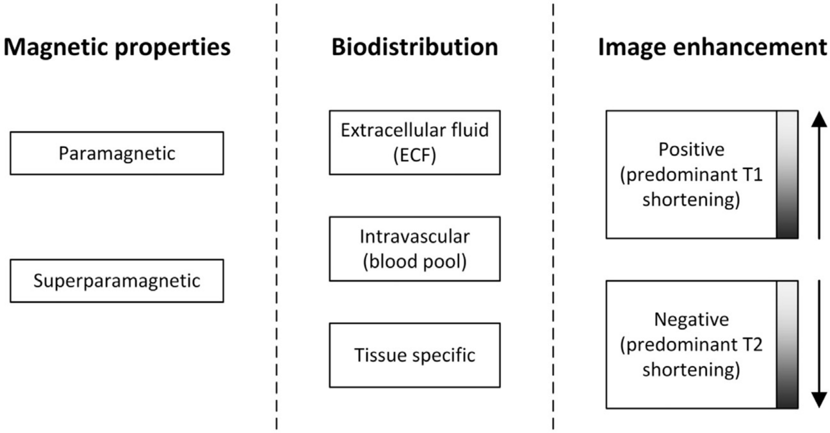


Figure 5.12 Classification of MRI contrast agents based on magnetic properties, biodistribution, and dominant image enhancement. *From Bjørnerud A. The physics of magnetic resonance imaging. <http://www.uio.no/studier/emner/matnat/fys/FYS-KJM4740/v14/kompendium/compendium-mri-feb-2009.pdf>; 2008 [accessed 22.09.16]. Modified by D. Ostler.*

5.3.3 Contrast Agents for Magnetic Resonance Imaging

Contrast agents are chemical substances that are used to improve the visibility of internal body structures by altering the relaxation times of different tissues. Despite this, the agents themselves are not directly visible. Contrast agents are injected into the patient's bloodstream.

Contrast agents can be classified in many ways. Generally, however, they are categorized by their effect on the relaxation times of different tissues (Fig. 5.12).

Paramagnetic contrast agents, also called positive contrast agents, cause a reduction in the T_1 relaxation time. These paramagnetic contrast agents are metals that have unpaired electrons in their outer orbital shells, giving rise to magnetic dipoles when exposed to a magnetic field.

Superparamagnetic contrast agents, also called negative contrast agents, cause a reduction of the T_1 and T_2 relaxation times. They are based on nanoparticles. Superparamagnetic contrast agents can significantly enhance the T_1 relaxation time of water particles, but predominantly affect T_2 relaxation times [36].

5.3.4 Magnets

In order to generate a uniform magnetic field, a strong magnet is used. This magnet is the most important and also the most expensive component of the MRI system. Currently, two major types of magnets are employed: permanent magnets, with a magnetic field strength ranging from 0.01 to approximately 0.35 T, and superconducting magnets, with magnetic field strengths of 0.5–3.0 T or higher (in research systems, for instance, superconducting magnets can generate field strengths of up to 10 T). The advantages of higher magnetic field strength include higher contrast for soft tissue, as well as a more detailed overall resolution. Currently, there are no commercial systems capable of generating field strengths of 7 T or higher, but these are currently under research by several health care developers. Some promising advances have already been made toward commercializing such systems. Normal conducting electromagnets are rarely used today.

Permanent magnets consist of large blocks of a ferromagnetic alloy in shapes like a horseshoe magnet (C-shape). The poles are located above and below the patient. The main field is therefore vertical in relation to the long axis of the body. This minimizes the pole shoe gap and allows a high field homogeneity to be achieved. This form allows them to be used in open systems. Permanent magnets need a stable operating temperature in order to guarantee that a sufficiently large homogenous field can be generated. The operating costs of such magnets are very low. However, their field strength is limited to less than 0.5 T.

The strong magnetic field of superconducting magnets is generated by large current-carrying coils. The conductor wire of the coil is not made out of copper, but from a frozen niobium–titanium alloy embedded in copper. To keep the coils at their optimal operating temperature, a liquid helium coolant is used; under some circumstances, this coolant will be precooled with liquid nitrogen. Superconducting magnets are primarily used for tubular systems. The magnetic field lies in a coil at the center of the tube, parallel to the long axis of the body.

MRI offers additional information upon soft tissue (e.g., liver, pancreas) as compared to CT (Fig. 5.13).

Furthermore, MRI makes the general diagnostic workup less invasive. This is not confined to the reduced use of radiation, but includes other even more invasive examinations as well. A good example is MRCP, an abbreviation for MRI-retrograde cholangio-pancreaticography. The denomination sounds strange, but it is a result of historical reasons.

The first method to visualize the biliary tree and the pancreatic duct was endoscopic retrograde cholangio-pancreaticography (ERCP) (see Chapter 8.4.4: Endoscopic Interventions on the Bile Duct (ERCP)).

ERCP provided excellent images of the biliary and pancreatic duct system, but the complication rate was too high for diagnostic purposes.

(A) (B)

Figure 5.13 Patient suffering from pancreatic cancer: (A) CT scan: The liver seems to be free of metastases; (B) MRI scan: multiple small lesions are detected (arrows). *All: Courtesy: Dr. A. Fingerle, Klinikum rechts der Isar.*

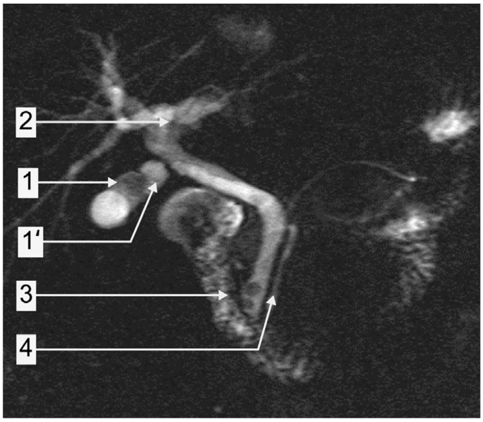


Figure 5.14 MRCP: MRI visualization of the hepatobiliary-pancreatic duct system: liquid-filled spaces appear as light structures: 1, gallbladder with gallstone (1′); 2, intrahepatic bile duct; 3, duodenum; 4, Pancreatic duct. *Courtesy: Dr. A. Fingerle, Klinikum rechts der Isar.*

Today, almost the same information can be gained without any risk by MRI (Fig. 5.14) and ERCP lost its value in diagnostic (but not therapeutic!) regards. However, since the term ERCP had been coined for the visualization of the hepatobiliary-pancreatic system, the MRI examination was called MRCP, although "retrograde" is not justified.

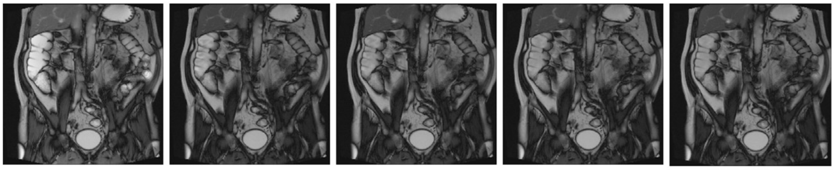


Figure 5.15 (A–E) A rapid sequence of images of the GI tract: by projecting them in a rapid sequence, peristalsis is visible as in a video. *Courtesy: Prof. R. Braren, Klinikum rechts der Isar.*

5.3.5 Real-Time Magnetic Resonance Imaging

Using fast MRI scanners, dynamic procedures can be visualized almost in real time ("filming"). Based on radial flash and iterative reconstruction, a very high temporal resolution can be achieved. In visceral medicine, real-time MRI is becoming a valuable tool to visualize dynamic processes such as swallowing or gastrointestinal peristalsis (Fig. 5.15).

They are displayed in a video, allowing a good evaluation of dynamic peristalsis like in a conventional Sellink examination (see Section 5.1.4: Real-Time Radiography) but without any radiation.

5.3.6 Magnetic Particle Imaging

MPI is a new tomographic imaging technique that evaluates the spatial distribution of ferromagnetic nanoparticles, in particular superparamagnetic iron oxide (SPIO), in the human body. Currently, MPI is still in development and cannot safely be used in a medical environment [37] but the first clinical applications are already visible, e.g., the treatment of stenosis [38].

The MPI technique exploits the nonlinear magnetization properties of SPIO nanoparticles in order to localize their spatial positions. MPI systems require ferromagnetic nanoparticles; a static magnetic field, also called a selection field; an oscillating field, also the called drive field; and a signal receiver coil. The selection field is a strong magnetic field in whose origin a free field point (FFP) exists; at all other spatial positions, it is nonzero. These field characteristics are achieved by using a Helmholtz coil setup with opposing currents (Fig. 5.16).

Close to the FFP, the magnetic orientation of the ferromagnetic nanoparticles is aligned by the oscillating drive field. At all other positions, the nanoparticles are forced to align with the direction of the local selection field. Ferromagnetic nanoparticles in the FFP are not magnetically saturated, whereas the particles outside the FFP are magnetically saturated.

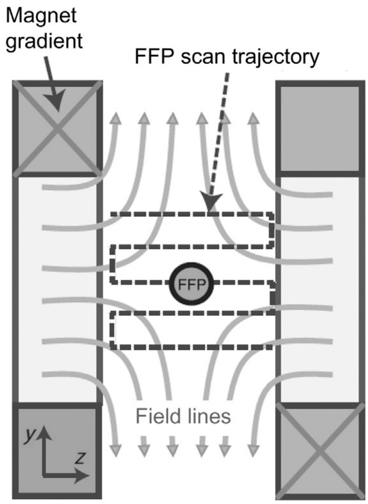


Figure 5.16 The opposite magnetic fields and the FFP at the origin. *From Goodwill PW, Saritas EU, Croft LR, Kim TN, Krishnan KM, Schaffer DV, et al. X-space MPI: magnetic nanoparticles for safe medical imaging. Adv Mater 2012;24(28):3870–7. Modified by D. Ostler.*

Table 5.1 Key facts on MPI

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Intracanalicular	No line-of-sight restrictions Integrable into every tool Less accuracy Field distortion by electromagnetic objects	Superior spatial resolution High contrast No attenuation	Real-time MPI and projection MPI

The unsaturated ferromagnetic particles produce an MPI signal in the receiver coil, while those that are not saturated do not. This is further affected by the fact that the receiver coil can only detect time-varying magnetization. By rapidly shifting the FFP across the field-of-view, an image is acquired and a voltage is induced in the receiver coil. The raw MPI signal from the ferromagnetic nanoparticles is then reconstructed. Currently, there are two principal methods for reconstructing an MPI image: harmonic-space MPI and x-space MPI (Table 5.1).

Human tissue does not generate an MPI signal. This means MPI images have near-perfect contrast, with no obscuring background tissue. In addition, there is a zero depth attenuation even with low-frequency magnetic fields, which means that the MPI scan is quantitative at any depth. The outstanding contrast in MPI images offers a clear advantage over today's standard angiography techniques, such as X-ray, CT, and MRI angiography. In addition, MPI does not require the use of toxic CA.

Current research efforts in MPI focus on real-time MPI and projection MPI.

Future directions for MPI are uncertain, but the number of procedures that could be carried out using this technique is significant. Next steps will involve developing this technique into a medical imaging modality, and ultimately, introducing new imaging technologies and new hardware components. MPI can also be a useful method for cancer detection and angiography in further clinical applications.

5.4 DIAGNOSTIC ULTRASOUND

According to the World Health Organization, ultrasound (US) is defined as "sound of frequencies above 20,000 hertz (Hz), beyond the range of human hearing." Frequencies of 1—30 megahertz (MHz) are typical for diagnostic purposes.

Ultrasonic waves are produced by devices containing transducer elements that convert electrical energy into ultrasonic energy and vice versa. An US probe (also referred to as a transducer) emits ultrasonic pulses, which propagate through tissues in the body and return an ultrasonic echo at each tissue interface that is encountered.

5.4.1 History

The piezoelectric effect, which is the base of US generation and reception, was detected in 1880 by the brothers Jacques and Pierre Curie. It was technically applied first by Paul Langevin in 1916 as a depth finder (sonar) for the French naval forces. The first medical application came from Karl Dussik who used US to examine the cerebral ventricles in 1942 ("Hyperphonographic"). W. D. Keidel introduced A-mode examinations into cardiology in 1950. In 1952, the first B-mode-like images of the abdomen were produced by J. J. Wild and J. H. Holmes.

Diagnostic US imaging depends on the computerized analysis of reflected US waves, which noninvasively build up (highly detailed) images of internal body structures. The resolution is higher with shorter wavelengths, with the wavelength being inversely proportional to the frequency. However, the use of high frequencies is limited by their greater attenuation (loss of signal strength) in tissue and thus shorter depth of penetration. For this reason, different ranges of frequency are used for the examination of different parts of the body: 3–5 MHz for abdominal areas, 5–10 MHz for small and superficial parts, and 10–30 MHz for the skin or the eyes.

There are different basic imaging modes involved in the visualization of US image data (Fig. 5.17).

A-mode (amplitude mode) is the original type of US as it was used for depth measurement. The transducer sends a beam through the anatomy with the echoes plotted on screen as a function of depth.

The B-mode (brightness modulation) uses a linear array (LA) of transducers to obtain a planar (2D) set of echo data, oriented parallel to the longitudinal axis. The B-mode denotes the acquisition of 2D echo data at a fixed depth while the transducer is moved in the 2D plane to sample

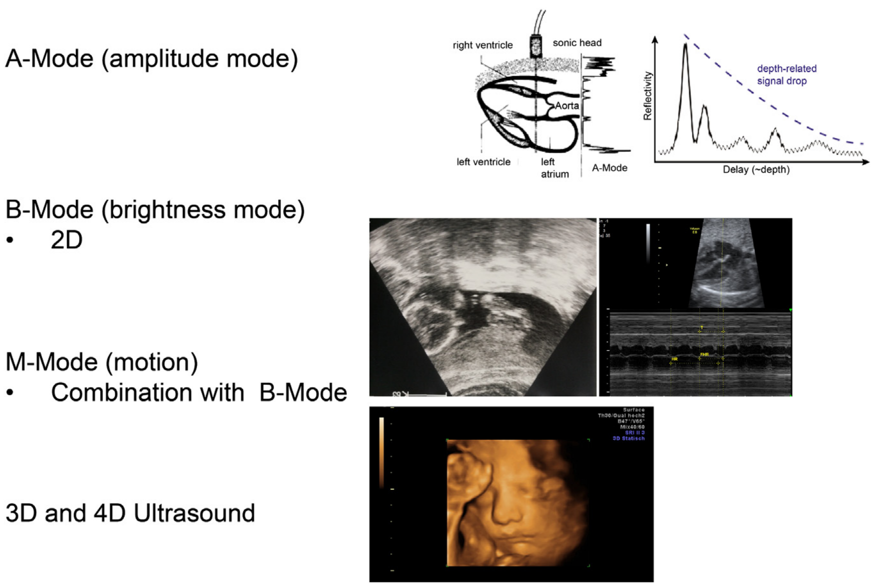


Figure 5.17 Current imaging modes in medical US application: A-mode: Mere depth measurement (original image W. D. Keidel); B-mode: Using a LA of multiple transducers, a planar set of echo data generates a 2D image. 3D images are achieved by filtering together 2D images of different direction to get a volume data set. The fourth dimension is time. *Courtesy: PD Dr. B. Kuschel, Klinikum rechts der Isar.*

the entire region at this fixed depth. The M-mode provides real-time visualization of organ motion.

Volumetric imaging refers to the rendering of 3D image data by acquisition of multiple adjacent cross-sectional images. Dynamic volumetric imaging provides the ability to display motion. The modification of US imaging to acquire volumetric data is based to a great extent on positioning technologies and computerized image processing.

An additional mode is the Doppler principle, which measures the shift in the frequency of the returning signals, providing information about the velocity motion, e.g., of blood flow or muscle (see Section 5.4.2: Transducer Arrays).

In general, there are four main topics in US imaging modifications. All US applications are based on transducer array technology. Doppler US and volumetric imaging are modifications involving visualization. Elastography, especially acoustic radiation force impulse (ARFI) imaging and shear wave elastography (SWE), which uses US for the displacement of tissue, is a different application principle for US. Hybrid US systems are of increasing relevance, combining different imaging technologies with US imaging.

Recent Developments and Current Research

There is continuous technical advancement in US. Developments include portable scanners, miniature pocket-size scanners, and high-frequency scanners. A reduction in physical size has been made possible by incorporating application-specific integrated circuits into the imaging system. A couple of pocket-sized scanners have been introduced onto the market recently [40]. High-frequency (above 20 MHz) scanners have been developed for eye, skin, small animal, and intravascular imaging. They have improved spatial resolution at the expense of penetration depth.

5.4.2 Transducer Arrays

A transducer is a component in US devices that translates electrical impulses into sound waves and sound waves into electrical impulses detected by using the pulse-echo method. A transducer usually applies elements of silicon or piezoelectric crystals to code sound waves into electric signals. They are also named transceivers because they both transmit and receive US waves. There are multiple different transducers, ranging from a single element to broadband transducer arrays of hundreds of different elements. Different probes applied in different medical imaging procedures generally have to satisfy varying criteria in terms of shape, depth of penetration, resolution, and other application-driven requirements (Fig. 5.18) [41]. Therefore, different transducers are installed in order to achieve the performances necessary in each particular procedure. The main parameters for the performance of transducers are element pitches, numbers, apertures, gaps, and width. The arrays employed can be classified by the pattern in which the elements are embedded on the array, as either 1D or 2D arrays. Another way to distinguish transducers is by the underlying procedure of image acquisition, separated into mechanical sector (MS) transducers and phased array (PA) transducers [42].

MS probes use a single or a group of single crystal transducers. The probes employing MS transducers have to be moved physically for the beam to scan a field, usually via an electric motor that rotates the crystals.

Figure 5.18 A selection of typical transducers. Left: Sector scanner, most often used in cardiology; middle: convex scanner, standard in abdominal US; right: linear scanner. In addition, a large number of purpose-designed probes (transanal, transvaginal, transesophageal, etc.) are available. *Courtesy: PD Dr. M. Kranzfelder, Klinikum rechts der Isar.*

Mechanical transducers have two advantages over electrically driven modifications. First, the single element design requires less sophisticated electronics; secondly, visual aspects unique to electrical steering and artifacts caused by improper reflections are decreased. The main disadvantages of MS probes include a fixed-beam focus that requires the whole probe to be replaced in order to change the focus. Furthermore, the frame rate depends on the speed of the transducer rotation which may lead to the problem of frame rates occasionally dropping too low when a wider FOV is necessary.

PA modifications are a more sophisticated form of transducer technology compared to MS transducers. They provide electrical steering through sequenced pulses of aggregated beams, causing backscatter that makes different interferences detectable on a time scheme. The detected interferences give information that make it possible to determine the angle at which the beam should be aimed. Consequently, electrical steering makes a physical movement of the probe unnecessary and provides better resolutions. As the maximum angle is decreased the FOV decreases in turn, resulting in higher frame rates. With a PA, the probe can be small and facilitate imaging of otherwise inaccessible body areas. For example, in cardiology PAs are favored because they easily fit between the ribs and allow simultaneous Doppler- and M-mode imaging [5].

As already mentioned, the term "1D-transducers" refers to the 1D arrangement of the elements, and includes linear array (LA), annular array (AA), and curved array (CA) transducers.

A LA consists of a line of transducer elements that emit an array of parallel beams, resulting in a rectangular image. The beams can be aimed sequentially and steered electronically so that no movement of the probe is required. A probe using an LA is capable of producing good near-field images, which makes it favored for imaging fetuses and the lower abdomen. On the other hand, it comes with the disadvantage of creating blurred images as a result of insufficient flush contact. Due to that, the body surface often has to be compressed to meet the transducer's footprint. LA transducers are generally inexpensive, but their imaging quality is inferior to other systems.

In AA transducer configurations, the transducer elements are arranged in concentric circles to create a cylindrical or conical wave front.

CA transducers only differ from other 1D configurations of elements in being arranged in a curved- or fan-pattern. The convex form helps produce a sector-shaped image with a larger FOV compared to flat LAs. Both AA and

CA transducers can employ PA technology to provide electrical beam-steering.

The 2D transducers basically consist of elements formed in a pattern along two axes. The field of 2D arrays is subdivided into two different types: Matrix arrays (MAs) and segmented AA.

In a MA, the transducers are arranged in a matrix pattern. Probes with MA transducers are capable of simultaneously acquiring two orthogonal spatial planes [43].

In a segmented AA, the transducer elements are arranged in nested concentric rings. One important advantage of this design is that focusing can be achieved in two dimensions and that the focal zone can be altered without changing the probe. When PA technology is employed, beam-steering in 3D space becomes feasible. The use of 2D transducers maximizes the advantages of PA technology [42].

Application-fitted transducers include endocavity transducers, intraoperative transducers, and transesophageal transducers. There are technical difficulties in fitting a high number of elements and cables on the surface of a transducer. It is, therefore, the aim to reduce the number of elements without a loss of imaging quality [44].

Recent developments and current research

Evolution in microelectromechanical systems (MEMS), especially in complementary metal oxide semiconductors (CMOS), has vastly contributed to recent growth in all performance parameters, allowing frequencies of more than 50 MHz [45]. Those developments will continue making medical applications more portable due to weight reductions, as well as improving live volumetric imaging catheters [46] through further decreases in size. A change from piezoelectric to silicone-based modalities has led to more sensitivity in detection and is currently helping to minimize transducer elements, facilitating larger transducer arrays with better imaging qualities. Moreover, optical sensors have matured over the past decades and found their way to clinical applicability [47]. In medical US, they have a promising potential, especially in the field of high-frequency applications, as they allow higher sensitivity at increased frequencies compared to piezoelectric modalities [48].

5.4.3 US Application in Visceral Medicine

US offers a long row of advantages: The examination is noninvasive, quick and cheap, easily repeatable, and extremely informative. As the US units are portable, the examination can be performed bedside. US is not confined to one medical specialty (e.g., as X-ray is confined to the radiologist) but is utilized by practically all clinical disciplines. However, it is examiner dependent and objective documentation is difficult. For visceral medicine, another drawback is more decisive: the limitations of the method because of air and bone. The examination of the abdomen is disturbed by both of them (Fig. 5.19).

The stomach and, in particular, the colon usually contains gas which makes an examination of deeper laying structures impossible. Whenever feasible, the examination should accordingly be done after a longer fasting period (8 hours) of the patient. The liver, usually not covered by other organs, is not camouflaged by air, but the ribs impede visibility. Nonetheless, an experienced examiner is able to achieve a high diagnostic yield. US is, e.g., the standard diagnostic procedure for diseases of the gallbladder (Fig. 5.20).

Medium	Velocity (m/s)
Air	330
Blood	1570
Fat	1460
Muscle	1580
Bone	3500

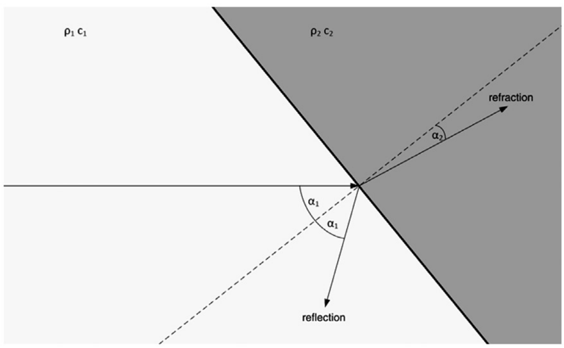


Figure 5.19 US speed in various tissues and media: the significant difference in impedance of air and bone makes them to the classical foes of the US examiner. *From MITI.*

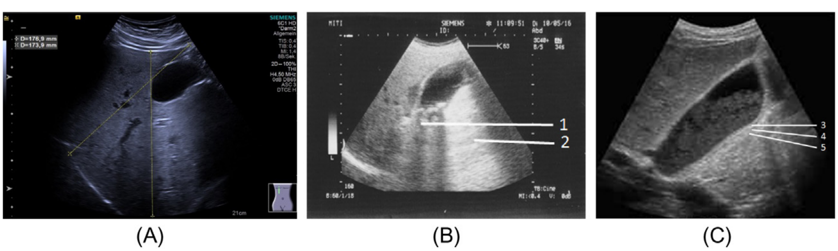


Figure 5.20 US check of the gallbladder. (A) Normal gallbladder; (B) multiple gallstones in an otherwise normal gallbladder. The quality of the image is low due to suboptimal selection of US parameters. Nonetheless, at least two stones with their typical shadow are visible (1). Note the total reflection by air in the adjacent colon (2); (C) severely inflammated gallbladder: "3 layer wall" (3, light, 4, dark, 5, light). *All from MITI.*

Another classical indication for US is the checkup of the liver (Fig. 5.21).

Moreover, other organs or organ systems can be assessed, although the diagnostic impact may vary (Table 5.2).

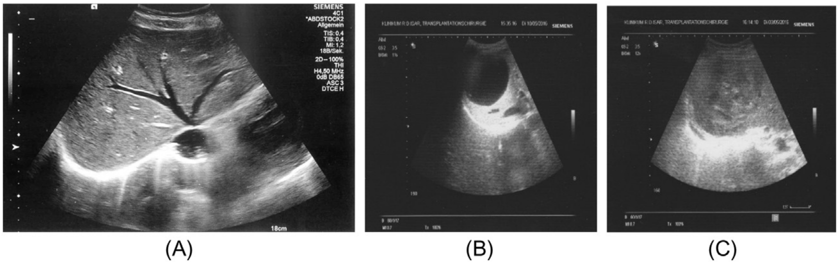


Figure 5.21 US of the liver. (A) Normal aspect of the liver; (B) typical image of an asymptomatic liver cyst; (C) liver metastases. *All from MITI.*

Table 5.2 The role of US in visceral medicine

Indications and organs	Potential diagnostic yield	Practicability/ importance
Free intraabdominal fluid	Ascites, blood	+++
Gallbladder	Inflammation, stones	+++
Liver	Size, consistency, bile duct obstruction, primary and secondary tumors	+++
Spleen	Size, traumatic or atraumatic lesions	+++
Kidney	Tumors, cysts, stones, dilatation of the pelvis	+++
Thyroid gland		+++
Aorta/caval vein	Aneurysms	+++
Pancreas	Cysts, tumors, dilatation of the duct	++ often hidden behind stomach/ colon
Appendix	Enlargement, inflammation	++
Ureter	Stones, dilatation	++
Stomach	Major tumors	+
Colon		(+)

5.4.4 Doppler Imaging

The Doppler-effect enables US to be used to detect motion. US Doppler systems display the Doppler frequency shift produced by moving objects in an US beam (Fig. 5.22). Commonly, it is used to measure the velocity of the blood flow but also in detecting the velocity of structure movements, such as the heartbeat.

There are three main types of Doppler systems: continuous wave, pulsed wave, and power Doppler. They differ in transducer design and operating features, signal processing procedures, and in the types of information provided. Additionally, there are two main display modes used in Doppler systems: Spectral Doppler measurements display the spectrum of flow velocities graphically on the y-axis and time on the x-axis. In color Doppler mode, velocities are measured in points within a B-mode plane and represented by a color-coded image that is coregistered with a B-mode scan. Power Doppler imaging (PDI) is a technique for evaluating the vascular system. It uses special processing to display the amplitude or strength of the Doppler signal, rather than velocity and directional information as in conventional color Doppler. This allows a much greater sensitivity in detecting small vessels and slow-moving blood. Currently, PDI is being used in conjunction with color Doppler, but it has proven valuable in many applications. This approach makes an image very similar to an X-ray angiogram, which is easy to interpret. In addition, it avoids the aliasing problem of conventional color Doppler [40].

In general, Doppler US is used in any application that may need to evaluate the blood flow. In this manner, it is possible to find blood clots and blocked or narrowed blood vessels in almost any part of the body (Fig. 5.23).

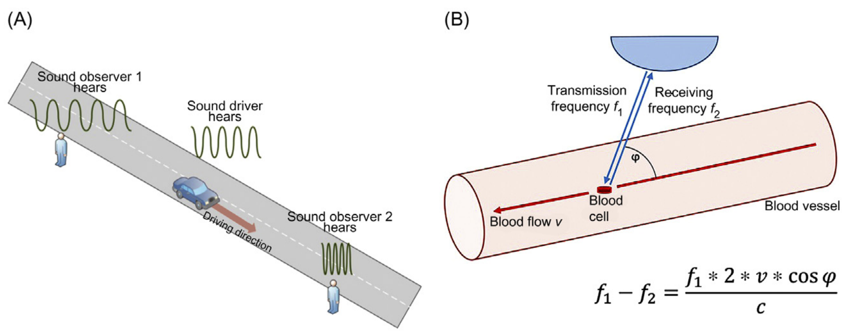
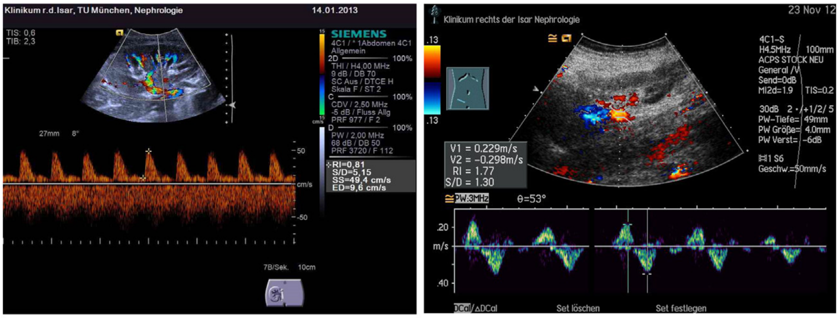


Figure 5.22 (A, B) Principle of Doppler sonography. *Modified by Dr. A. Schneider.*



(A) (B)

Figure 5.23 (A) Normal blood flow of the kidney; (B) complete interruption of blood inflow into the kidney due to thrombosis. *All: Courtesy: Dr. E. Matevossian, Klinikum rechts der Isar.*

In visceral medicine, it is of outstanding importance to assess the blood flow in the hepatic artery and portal vein (e.g., in case of portal hypertension or after kidney transplantation).

A continuous wave Doppler (CW Doppler) continuously generates and receives US waves. A CW Doppler uses two transducers. One transducer continuously transmits and one transducer continuously receives signals.

In contrast to CW Doppler systems, PW Doppler Systems use a single transducer for transmission and reception. Pulsed wave (PW) Doppler systems transmit short pulses of US into the tissue. The pulse travels for a given time until it is reflected back. It then returns to the transducer over the same time interval, but at a shifted frequency. A timing mechanism controls the range gating that samples the returning Doppler shift data from a given region. Only Doppler shift data from inside that area is displayed. The transducer alternates transmission and reception of US. Doppler signals can be acquired from a known depth. Today, pulsed Doppler systems for spectral Doppler measurements are typically used in combination with US B-mode imaging, which is known as duplex US. Duplex scanners use arrays of elements to produce both the B-mode image and the Doppler spectrum. This facilitates accurate anatomical location of the blood flow under investigation.

An advantage of CW Doppler systems is their capability for measuring movements with high velocity, which is needed in applications like cardiography, where high blood flow rates occur. A CW Doppler cannot provide range resolution because it is unable to separate Doppler signals that arise from different points along the transmitted US beam. If two blood vessels intersect the US beam, it will not be possible to separate velocities at the different points along the beam, so it cannot be used to produce color flow images.

One main advantage of pulsed Doppler is its ability to provide Doppler shift data selected from a small segment along the US beam, referred to as the "sample volume." The location of the sample volume can be controlled by the operator.

Recent Developments and Current Research

There are recent developments in measuring blood flow via low-peak frequency-modulated continuous wave (FMCW) and stepped frequency-modulated continuous waves (step-FMCW) US Doppler systems. Low-peak FMCW uses a new demodulation technique: the Doppler signals are demodulated with a reference FMCW signal to adjust delay times so that they are equal to propagation times between the transmitter and the receiver. Doppler signals can be obtained from a selected position, as with a sample volume in PW Doppler systems [49].

Step-FMCW leads to a high SNR and a high range resolution compared to traditional pulse-echo signals. In step-FMCW ultrasonic ranging, the phase and magnitude differences at stepped frequencies are used to sample the frequency domain. Step-FMCW features lower peak power, wider dynamic range, lower noise figure, and simpler electronics in comparison to pulse-echo systems [50].

Technologies using the Doppler-effect with pulsed US waves are widely matured. Recent developments are not based on developments of the CW Doppler technology but mostly on combinations of Doppler visualizations with other modifications of US, like elastography.

5.4.5 US Elastography

US elastography is an imaging technique to evaluate the mechanical properties of soft tissue by applying strain on the organ examined and detecting differences in its tissue density and stiffness [51,52]. It has been found useful in showing abnormalities of muscle and breast tissue, and in the detection of tumors [53].

The stiffness of the liver correlates, e.g., with its content of fibrous tissue. A fibrotic liver is harder in the case of fibrosis, and even harder in cirrhosis than a healthy liver. Most malignant tumors are, likewise, harder than the surrounding tissue, a feature which was always used in medicine to detect pathological findings (manual palpation).

The following techniques of US elastography will be considered in detail below: acoustic radiation force impulse imaging (ARFI), shear wave elastography (SWE), and shear wave dispersion US vibrometry (SDUV).

5.4.5.1 Acoustic Radiation Force Impulse Imaging

ARFI imaging is a form of strain elastography which is mainly used for liver, thyroid, and breast imaging. In this technique, the tissue is excited internally by a focused US pulse. ARFI is based on the principle that as the US pulse passes a tissue, the displacement of soft tissues is larger than the displacement of hard tissues. As a result, this technique offers a qualitative color-coded or grayscale elastogram representing relative tissue stiffness [51].

Characteristics of the Modification

ARFI transmits a brief acoustic radiation force (0.003−1 ms) to generate a localized displacement in tissue. This technique utilizes a single transducer for both transmitting the radiation force and tracking the resulting displacement of tissue.

To obtain displacement information for a spatial location through ARFI imaging, a reference line is first acquired by a conventional US pulse. Afterward, a radiation force impulse is induced in the same location to create a slight displacement. Thereafter, with the help of conventional US, a series of tracking lines are acquired for monitoring displacement and recovery of the tissue. To observe the recovery of tissue as it returns to its original configuration, approximately 4−6 ms of tracking are required. The repetition of this reference push-track procedure over other spatial locations allows the creation of a 2D image by aligning the displacements of each location in time relative to its pushing pulse [54].

Strengths and Weaknesses

A general strength of ARFI is its ability to image deeper tissue, which is not reachable by external compression [51]. Moreover, ARFI requires merely slight hardware modifications to add an alternative imaging mode similar to Doppler or M-mode [54] (Table 5.3).

Table 5.3 Key facts on ARFI

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Oncology Endocrinology	High depth penetration No spatial resolution	n/a	Real-time scanning Heat management

A weakness of ARFI imaging is its inability to identify the tissue's composition. Nowadays, it is only possible to detect differences in the tissue's softness or stiffness in comparison with adjacent tissue. A further limitation is often encountered as a result of the obscurity of the acoustic force, as its influencing factors—the acoustic intensity and the degree of attenuation to the acoustic pulse—are normally unknown.

Recent Developments and Current Research

Technical challenges for this imaging technique involve the implementation of real-time scanning into a clinical US unit and its heat management. The former may easily be achieved because the imaging sequence of ARFI fits with the software and hardware performances of clinical scanners. The latter, which is mainly influenced by ARFI pushes, may be addressed by using parallel beamforming.

5.4.5.2 Shear Wave Elastography

SWE is a type of US elastography that uses shear waves to assess tissue elasticity and display it in a quantitative manner. Unlike acoustic compressive waves, which spread in the same direction as the particle compression, the propagation of shear waves proceeds orthogonal to the stimulated displacement. Shear waves can result from an acoustic radiation force, mechanical punch, or external sources [55]. SWE is used for breast imaging [56].

Characteristics of the Modification

The attenuation of shear waves is approximately 10,000 times more rapid than conventional US [51]. SWE provides a quantitative real-time elastogram, whereby elasticity can be depicted as a superimposition of a color-coded image measured in kPa over a B-mode image. In the images, stiffer tissues appear in red while softer tissues are coded in blue. The image resolution remains around 1 mm [56].

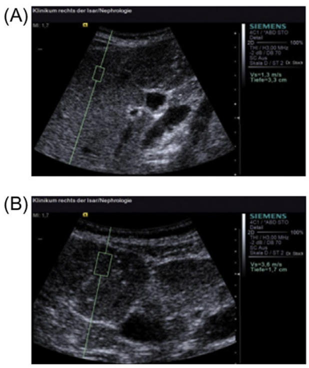
Strengths and Weaknesses

SWE is currently the only approach with the ability to provide quantitative and local elastic information in real time.

A limitation of this technique is the weakness of the generated shear waves due to dissipation, which occurs after spreading a few millimeters. Stronger shear waves need increased US power, which causes overheating in the hardware and concerns over acoustic power [56] (Table 5.4).

Table 5.4 Key facts on SWE

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Oncology, e.g., liver tumors Detection of liver cirrhosis	Quantitative and local elasticity information Low power of shear waves	n/a	Increasing acoustic power



Shear wave velocity Tumor	Shear wave velocity Adjacent tissue
Average	Average
4.0 m/s	1.3 m/s

Figure 5.24 SWE: Focal nodular hyperplasia of the liver (A) as compared to normal tissue (B). *Courtesy: Prof. K. Stock, Klinikum rechts der Isar.*

Currently, the detection of liver diseases is the main clinical application (Fig. 5.24).

Recent Developments and Current Research

Future challenges must deal with creating an upswing in the shear waves' amplitude in order to increase their ability to travel through tissue while still limiting the acoustic power to safe levels.

5.4.5.3 Shear Wave Dispersion Ultrasound Vibrometry

In contrast to other imaging techniques mentioned earlier, shear wave dispersion ultrasound vibrometry (SDUV) quantifies not only the elasticity of tissue, but also its viscosity. This technique utilizes shear wave propagation speed, which is measured in tissue at multiple frequencies within the range of hundreds of Hertz. One sample application of this technique is liver fibrosis staging.

In general, SDUV is a fast imaging technique, especially when repeated pulses are used. Accordingly, only 50–200 ms are needed to achieve measurements [57].

Unlike ARFI, which is based on transient shear waves, SDUV uses periodic shear waves and the dispersion of their velocity to qualify viscosity. The estimation of shear wave speed is based on the phase differences and multiple cycles of shear wave vibration.

Strengths and Weaknesses

The main benefit of SDUV is the quantification of elasticity with simultaneous consideration of viscosity. SDUV seems to be more beneficial than ARFI when tissue displacement or SNR is low. The shear wave propagation depends only on the material properties and not on US intensity and beam shape. Therefore, measurements are device-independent. In addition, the risk of interference due to shear wave echo is reduced. Finally, short acquisition times of SDUV (about 0.1 s per acquisition) "also allows fast acquisition of multiple measurements at different locations within the organ of interest to get a comprehensive assessment of tissue state" [57].

The limitation of SDUV rests in its ability to provide a single-point measurement. 2D imaging may be theoretically possible, but is time-consuming under the current SDUV technique (Table 5.5).

Recent Developments and Current Research

One notable future development for SDUV is an extension in the field of applications. Another trend is an optimization in radiation force delivery to create shear waves that produce better information. Beyond this, there is a need to develop better methods for detection of shear waves and solving for the viscoelastic material properties of the tissue will further enhance the performance of SDUV.

Table 5.5 Key facts on SDUV

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Examination of liver fibrosis	Quantification of elasticity and viscosity of tissue Long examination of 2D imaging	n/a	Optimizing radiation force delivery Extending field of applications

Elastography in general is expected to remain in broad use in medical diagnostics. It is even predicted to gain further relevance in the future. It combines techniques which have high potential to detect cancerous diseases. Therefore, it is necessary to improve modifications like SWE, which is currently limited in its performance.

5.4.6 3D/4D Ultrasound

3D US is a volumetric imaging technology that provides a 3D view of internal structures. Dynamic volumetric imaging, also known as "4D US" or "real-time 3D US," extends the visualization with a time frame so that it is able to display motion instead of a static 3D data set.

3D data are usually acquired as a large number of consecutive tomographic images through movement of an US transducer array. Each tomographic image has to be gathered along with its positional information to construct a 3D data set. Accurate positional information is obtained through an electromagnetic position sensor, an electric gyro attached to the probe, or by defining previous movement (Table 5.6).

Static 3D images can be acquired manually by moving a 2D transducer across a ROI, or automatically through the use of a 3D transducer that sweeps a 2D array of beams across the ROI. 3D/4D US requires rapid automatic sweeps of multiple adjacent 2D cross-sections.

Software

The software is the core of volumetric imaging technologies, especially 4D visualizations, which need highly optimized algorithms. For applications like scanning a heart, a gated technique is applied to avoid distortion of a 3D data set due to movement. Tomographic images are rearranged according to the phase of the cardiac cycle and a 3D data set is constructed with only tomographic images at the same phase of the

Table 5.6 Key facts on 3D/4D US

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Obstetrics, cardiovascular medicine Visceral medicine	Vague depiction of internal structures	USCT/Warm bath US	Optimizing 3D US, Increasing image quality

cardiac cycle. The heart can be seen beating three-dimensionally by reconstructing many 3D data sets into a single cardiac cycle.

Strengths and Weaknesses

3D images provide examiners with an abundance of information, reducing the amount of interpretation needed and limiting the probability of misdiagnoses.

Compared to common US modifications, the amount of data involved is much higher. The depiction of one ROI demands up to 20 GB of data storage. Despite the increasing capability of computers, the processing time of data sets is still a limiting factor.

Recent Developments and Current Research

US travels through soft tissue at an average speed of 1540 m/s, which limits 3D scanning speed. The parallel receiving technique uses one broad US beam that is transmitted; its echoes are received as plural ultrasonic beams. In a 2D array probe, a high degree of parallel receiving is used and high-speed 3D scanning is possible. As a result, the profound advancements in 3D/4D imaging are mainly due to a general evolution of electronics and transducer arrays from linear systems to 1.25D, 1.5D, 1.75D, and 2D arrays and the latest matrix phase transducers, which are a current field of research [58].

Currently, there are plans to make 4D US available through handheld devices, which has already been achieved in high-end devices [59].

Today, the relevance of 3D/4D US systems is still low due to high purchasing costs and technological performance issues. In the future, the relevance of these systems is expected to rise as a result of technical improvements and mass-market adoption.

5.4.7 Ultrasound Computed Tomography

Ultrasound CT (USCT) is a new digital imaging technique that creates reconstructed 3D images of inhomogeneous media, such as soft tissue. It attempts to solve the problem of the inverse-scattering field. A few research groups have developed such systems to test its usability. One of them built a USCT that consists of a water-filled cylinder and contains 1920 transducers—384 sending and 1536 receiving transducers—which are grouped in three rings on the cylinder surface. The water-filled cylinder can be moved in six different positions via an electric motor. The advantage of this method is the high spatial resolution and the high tissue contrast. There are different algorithms currently under research for evaluating the emerged data sets, such as the synthetic aperture focusing technique (SAFT) algorithm developed and optimized by the Forschungszentrum Karlsruhe/Germany, the multifrequency nonlinear 3D inverse-scattering algorithm, or new concepts like the 3D refraction corrected 360 degrees compounded reflection algorithm [60,61]. The early diagnosis of breast cancer is still a major challenge in spite of recent developments in research [62]. The current diagnostic procedure only detects cancer that is already in a developed state. In order to diagnose early-stage cancer within the breast, an application using USCT is currently under development.

Future developments will focus on introducing this technique to clinical use and to reduce the time needed to evaluate the examined data sets [63].

5.5 NUCLEAR IMAGING SYSTEMS

Nuclear imaging systems use gamma rays, which, like X-rays, are a form of electromagnetic, indirectly ionizing radiation, but possess more energy due to higher frequencies [64].

Images generated in nuclear medicine are a result of the selection and injection of a suitable radioactive tracer, the detection of the radiation, the use of tomographic reconstruction algorithms, and finally the conduction of a series of corrections [65]. The tracer principle works as a basis for the image acquisition. A radioactive biologically active substance is chosen in such a way that its spatial and temporal distribution in the body reflects a particular body function or metabolism. To avoid disturbances of vital functions while studying the distributed radiation, only small amounts of the tracers are administered to the patient. The gamma rays of positrons are emitted as the tracer decays. The distribution of the radioactive tracer is inferred from the detected radiation and mapped as a function of time and/or space [65,66].

Medical nuclear imaging assesses the functional aspects of organs, whereas other techniques describe their anatomical structure. With its current techniques, medical nuclear imaging offers high-resolution multidimensional images of organs in order to analyze complex structures and physiologic functions for—among other things—computer-assisted diagnosis, evaluation of treatments, and interventions [65].

Nuclear imaging systems can be divided into three main categories: positron emission tomography (PET), single-photon emission tomography, and the hybrid systems (see Section 5.8: Hybrid Systems).

5.5.1 Gamma Camera

The gamma camera, also called scintillation camera, is the most commonly used imaging device in nuclear medicine. It simultaneously detects radiation from the entire FOV and enables the acquisition of dynamic as well as static images of the area of interest in the human body [67]. In general, the gamma camera consists of a collimator, a scintillation crystal, and photomultiplier tubes (PMTs).

Recent Developments and Current Research

Recent developments in gamma ray detection have addressed its implementation within multimodal or hybrid systems. The fusion of PET and single-photon emission computed tomography (SPECT) with MRI systems (see Section 5.8: Hybrid Systems) has been a particular challenge because PMTs and nuclear imaging electronic hardware are sensitive about magnetic fields. To overcome the problem of incompatibility, two approaches have been developed.

The first approach uses optical fibers to couple the scintillation crystals inside the magnet to either PMTs and electronics outside the fringe of the magnetic field, or to solid-state photosensors situated at the end of the magnet bore. However, such a connection tends to lose light signals and limits the axial extent of the PET detector array due to difficulties in connecting the fiber bundles to the scintillation crystals and then to routing them out of the magnet [65,68].

The other approach substitutes the PMT with avalanche photodiodes, which are magnetic field-insensitive, solid-state photon detectors. These photodiodes are directly coupled to the scintillation element [69].

5.5.2 Positron Emission Tomography

PET is a noninvasive nuclear imaging technique that can help detect anatomic, functional, and biochemical abnormalities in organs. Furthermore, measurements of body functions such as blood flow, oxygen usage, glucose metabolism, and tissue perfusion are possible. This wide range of applications makes PET highly attractive for diagnostic and interventional purposes in cardiology, neurology, and oncology [70].

A PET scanner consists of a dedicated camera system, including multiple rings of detectors. Similar to gamma cameras, the PET detectors comprise of scintillation crystals with coupled PMTs. The ring design utilizes the concept that two photons detected in close temporal proximity by two opposed detectors in the ring are likely to have originated from a single annihilation event in the body. This simultaneous detection is called coincidence. All of these coincidence events detected during an imaging period are recorded by the PET computer system as a raw data set. This data set is then reconstructed to produce cross-sectional images. Unlike conventional gamma cameras, the positron decay can be detected and therefore localized without the need for a collimation [71]. This results in more sensitivity and better spatial resolution compared to conventional gamma cameras [66,70].

Time-of-Flight Positron Emission Tomography

In a PET scan using time-of-flight (ToF) technology, the location of an annihilation event can be detected in a more precise way. ToF PET can be applied for the same fields of application as a conventional PET examination.

Unlike normal PET examinations, which offer line pair data at many angles to create a tomographic image, a ToF PET notes the precise time of the detection of both coincident photons and calculates the difference. As the closer photon is detected first, differences in the arrival times help to precisely localize the annihilation events along the line between the two detectors [72].

Strengths and Weaknesses

ToF PET offers an increase in effective sensitivity compared to conventional PET scans. Its reconstructions lead to a higher contrast recovery at matched noise with faster and more uniform convergence, and the benefit is even greater for larger patients [73] (Table 5.7). Image quality

Table 5.7 Key facts on ToF PET

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Oncology Cardiology Neurology	Increase in sensitivity High contrast Beneficial for obese patients	Progress of ToF increases image quality Experimental result translated to clinical practice	Faster scintillators for better timely resolution

scales down for larger patients using conventional PET scans because of higher attenuation. The attenuation results in the loss of image quality and in an increase of scattering [72].

Recent Developments and Current Research

Current research is dealing with the influence of ToF estimations on image quality, the adoption of experimental results into clinical practice, more efficient reconstruction, and improvements in scintillators and photosensors. The creation of new and faster scintillators will be helpful in increasing the timely resolution through a higher light output [68,73].

PET is expected to gain more relevance in the following years due to the increasing prevalence of hybrid imaging and the diseases requiring PET diagnostics. It is estimated that the hybrid systems PET/CT and PET/MRI are going to play a significant role in the growing relevance of this technology.

5.5.3 Single-Photon Emission Computed Tomography

SPECT is a technology in nuclear medicine used for molecular imaging. It produces cross-sectional images and belongs to the field of photon emission CT. SPECT images display radiation distributed by a radiopharmaceutical in the body. It can be used to assess the function of various organs [74].

SPECT is based on the principle of scintigraphy. At the beginning of each examination, a radionuclide or a radionuclide-labeled substance is administered, usually by injection into a vein in the arm. These radionuclides are precisely targeted to different chemical compositions of tissues and organs. If a radionuclide reaches the targeted structure, it emits gamma radiation, marking the ROI. The emitted radiation is then detected by a gamma camera [75]. One or more of such cameras rotate 180 or 360 degrees around the body and detect the emitted radiation from different directions in space. A collimator narrows the beam, and ensures that only the rectangular impinging photons are detected. The images are then reconstructed from the three-dimensionally distributed radiation from the radionuclides [76].

In contrast to static SPECT studies, where the ray distribution from the radiopharmaceutical is determined at a fixed time, these are dynamic tests wherein assessments of temporal changes in radioactivity distribution are repeated at intervals of minutes, hours, or days [75].

The major advantage of SPECT is that it can be used to observe biochemical and physiological processes, as well as the size and volume of the organ. The disadvantage is that unlike PET, where the positron–electron annihilation results in the emission of two photons detected at 180 degrees from each other, SPECT requires physical collimation to line up the photons, resulting in the loss of many available photons and subsequent image degradation. Attenuation correction is not implemented accurately in SPECT [76].

In future, the relevance for SPECT is expected to remain low. Most SPECT systems have already been replaced with PET systems, among others. As a result, the option to connect SPECT with other imaging modalities would have a positive impact.

5.5.4 Conclusion

Recent developments in medical nuclear imaging have mainly focused on the fusion of nuclear imaging methods with other imaging techniques to enhance image quality and to generate additional information during a single examination. In the future, it will probably be dealt with through improvements for detectors, which help to diversify applications of the ToF technology. The precise localization of abnormalities will lead to optimized medical interventions. A general trend in nuclear medicine is the research into new radiotracers to extend application areas.

5.6 ADVANCED OPTICAL SYSTEMS

Photonics is a field of science and engineering that deals with technologies and scientific phenomena related to the generation, transmission, manipulation, detection, and further usage of light.

Photonics is one of the key technologies in the 21st century and is comparable to the importance of electronics in the 20th century [77]. Optical systems involved in medical imaging include any form of imaging system based on optical technology that is designed for the purpose of image acquisition in a medical application.

Over the last 20 years, optical technologies have become increasingly important all over the world, mainly due to the relatively new ability to control the coherence characteristics of light. Depending on the area of application, this allows the greatest level of stability, or continuous output with the shortest pulse durations. Optical systems also have further potential advantages over common imaging modalities, like their use of

Table 5.8 Overview of modern optical systems

Time-domain optical coherence tomography Fourier-domain optical coherence tomography Fourier-domain Doppler optical coherence tomography	OCT
Hyperspectral imaging	HIS
Optical fluorescence imaging	OFI
Diffuse optical imaging	DOI
Photoacoustic imaging	PAI
Light field systems	Light field

nonionizing radiation. Therefore, reasonable doses can be employed without any risk of harm to a patient. It is also possible to distinguish precisely between different types of soft tissues, due to the significant differences in the way they absorb and scatter light [78].

Optical imaging is considered to have great research potential, both in the field of diagnostics and therapy. Optical imaging modalities, in combination with minimally invasive procedures, are also anticipated to be an ongoing contributor to decreasing costs in health care systems (Table 5.8) [77].

5.6.1 Photodetectors

Photodetectors are microelectronic devices that can detect light in order to record image information. Over the last few decades, numerous innovations in optical systems have been introduced, driven by advances in optical detection. Many photonic applications require the use of optical radiation detectors. In most medical imaging applications using light, optical detectors are employed to measure the output of a laser or another light source. Different types of optical detectors are available for ultraviolet, visible, and infrared light. In general, the incoming optical energy is converted into electrical signals during the detection process. Optical detectors can be subdivided into two main types: thermal detectors and photon detectors [79]. There is a large number of different photodetectors. In each field in which they are employed, photodetectors are set up according to the performance parameters required for that particular application. Among other things, these parameters include the SNR, response time, detectivity, and spectral response.

Thermal detectors convert photon energy into heat. They are rather inefficient and slow due to the time required for a temperature change to take place. Therefore, thermal detectors are not suitable for most photonic imaging applications.

Photon detectors detect incoming photon energy. Photons reach the detector, resulting in a current or voltage representing information about the incoming light as a function of its intensity. Based on the materials employed, photon detectors can be classified as photoconductive or photovoltaic detectors. Both require a bias voltage and are semiconductor-based. On the other hand, photoemissive detectors are photoelectric-based and work without a bias voltage [80].

In photovoltaic detectors, a phenomenon called the photovoltaic effect is used in order to acquire image information. The phenomenon takes place at a junction in the semiconductor [81]. This junction is usually a pn-junction, referring to a positive and a negative part in the semiconductor. The photovoltaic effect takes place when enough light strikes this junction, resulting in a voltage that encodes the image information.

Photoemissive detectors represent another important class of detectors. They use the photoelectric effect by which free electrons are emitted from a surface through impinging photons. A main disadvantage of photoemissive detectors is that at wavelengths over 1000 nm, no photoemissive response is available, making the detector unsuitable for applications requiring detections at such wavelengths. One important variation of the photoemissive detector is the photomultiplier.

A photomultiplier is useful for light detection of very weak signals. It can provide a combination of extremely high sensitivity, even for photon counting, and high detection speed, but it is expensive and needs a high operating voltage [80]. It acquires light through a little window, under which a photocathode is situated. This photocathode releases electrons if it is struck by light. These electrons pass through the case of the photomultiplier, where they are repeatedly reflected between dynodes that amplify the electric signal. Inside the case is a vacuum, allowing electrons to move freely.

Photoconductive detectors are produced from semiconductor materials such as silicone. They are most widely used in the infrared region, at wavelengths where photoemissive detectors are not available. The incoming light produces free electrons that can carry a current. Due to this process, the electrical conductivity of the detector material changes as a function of the intensity of the incident light. The most frequently used form of photoconductive detector is the photodiode [81].

Photodiodes are semiconductor devices that also employ pn-junctions, or pin-junctions, where the "i" refers to an intrinsic material such as silicon [82]. At this junction, incident light again is transformed to an electric signal. There are a number of different photodiode structures and material combinations. They include silicon photodiodes—mainly used for detecting visible, near ultraviolet, and NIR light—but also germanium, indium, and gallium in the near-infrared (NIR) wavelengths. Another example are germanium diodes doped with elements like copper and gold, used to detect longer-wavelength infrared. This underlines the fact that there is not a single diode or any other detector suitable for all applications, but that different types are employed according to need and medical specialization [81].

Current developments are continuing to improve detection speed, contrast, and sensitivity, as well as the detectable wavelength ranges and other performance parameters. Promising research is also being pursued on the semiconducting materials employed, which may revolutionize photodetection through the usage of molybdenum disulfide in conjunction with silicon. Furthermore, new parallel detection systems that allow the simultaneous detection of hybrid frequencies and continuous wave domains are currently in testing for clinical applications [83]. All in all, photodetectors and their enhancements are a particular asset in developing more effective tools in diagnostic workup and therapy [84].

5.6.2 Optical Coherence Tomography

Optical coherence tomography (OCT) is a relatively new and rapidly emerging medical imaging technology that was first described in 1991 [85] and originally used for imaging the retina. Comparable to US, OCT scanners generate a sequence of A-scans that use light from a broadband superluminescent diode or lasers to sweep a semitransparent surface. The acquired A-scans create cross-sections (B-scans) when put together. Later, these cross-sections can be synthesized to create 3D volume stacks (C-scans) [86] (Fig. 5.25). The technology is mainly used in ophthalmology, but also gastroenterology (see Section 5.7.6: Endoscopic Optical Coherence Tomography) and dermatology as well as in dentistry. OCT is usually noncontacting and noninvasive. Due to OCT being fiber optics-based, various applications in minimally invasive surgery (MIS) in combination with endoscopy (EOCT) and intravascular imaging and other examples of optical biopsy are feasible [87]. The images acquired are depth resolved with resolutions that reach down to the micron scale [88] and offer video exposure in real-time. OCT makes it possible to gather various pieces of information about different aspects of biological tissue,

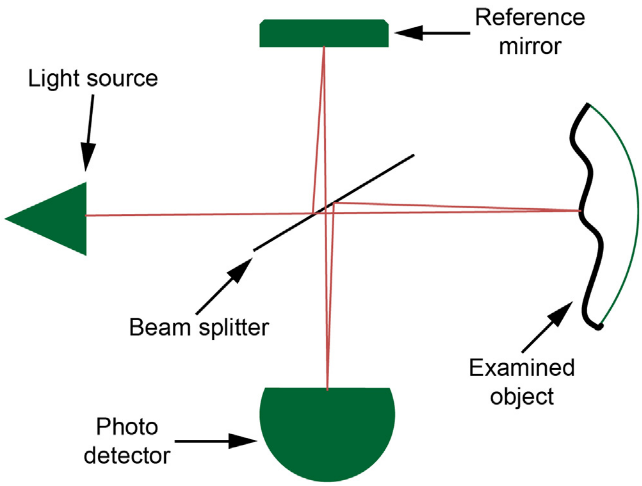


Figure 5.25 Interferometer. *Modified by D. Ostler.*

like molecular content and other structural information, in order to detect pathologies at an early state. OCT applies at wavelengths between 700 and 1400 nm, and uses the principle of interferometry [89].

In order to detect pathologies at an early stage, the scanner looks for interferences that result from a superposition in wavelength and create a time delay in photodetector acquisition. The superposition originates from light scattering back from the examined object and a reference light from a reference arm. Turning the acquired data and signals into false-color images is a processing-intensive process. Clinical applications usually have freely movable scanner heads, which acquire images that are then assembled inside a main unit. Those probes are often removable in order to make it easier to prepare for the next procedure. The technology can be separated into three different modifications based on the underlying principle used for image acquisition. The oldest is the time-domain OCT (T-D OCT), which was followed by the later Fourier-domain OCT (F-D OCT). Another modification is Fourier-domain Doppler OCT (F-D D. OCT), which generates information about liquid flow by making use of the Doppler effect [86].

5.6.2.1 Time-Domain Optical Coherence Tomography

T-D OCT is the oldest form of OCT, and only allows measurements within the coherence length.

Table 5.9 Key facts of T-D OCT

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Arthroscopy Ophthalmology	Fine resolution Slow repetition rates only 400 axial scans/s Only imaging within the coherence length	Widely substituted by F-D OCT	n/a

T-D OCT applies broadband light with a short coherence. Interference can only be detected if the reference arm and the object examined are located at the same distance. Furthermore, two scans have to be performed to obtain 3D information.

Strengths and Weaknesses

T-D OCT is only capable of detecting interference if the difference in travel distance between reference and scanning light is within the coherence length. Therefore, the reference arm in the interferometer has to be moved mechanically. These slow mechanical movements only support repetition rates of a few rounds per second due to T-D OCT not being capable of producing high frame rates, and is therefore inconvenient for 3D imaging (Table 5.9).

Recent Developments and Current Research

T-D OCT was the underlying technological principle behind older generations of OCT scanners. The limitation in speed that results from having to mechanically adjust the mirrors results in low scanning rates. Further weaknesses relating to the amount of information extracted from the backscattered light in T-D OCT have led to a widescale substitution with F-D OCT.

5.6.2.2 Fourier-Domain Optical Coherence Tomography

F-D OCT is the name of a cluster of OCTs that are based on mathematical processing using Fourier transformation [90]. This helps to overcome problems of T-D OCT, like low frame rates and acquisition speed, and makes it possible to image large areas of an object in real-time. F-D OCT can be separated into four characterization types: frequency domain F-D,

Table 5.10 Key facts of Fourier-domain OCT

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Arthroscopy Ophthalmology Flexible and rigid endoscopy	Resolution of 1−15 μm Rapid acquisition rates up to 40,000 axial scans/s Low penetration depth	Intravascular catheter Imaging on a cellular level	Real-time airway imaging and other applications Enhancements on microelectronic components

spectral domain F-D and swept source F-D, and another type using full-field technique (Table 5.10).

Frequency domain F-D takes advantage of the fact that a signal is defined not only by how its value changes over a certain period of time, but also by its spectral information. The superposition of the different spectral lengths that results from differing penetration depths in the tissue can be detected. Thus, the reflectivity of the object can be measured for all depths at once by measuring the interferences on a spectral domain. This allows real-time imaging with scanning rates upward of 20,000 axial scans per second [91].

Spectral domain F-D does not operate with a single photodetector, but with a linear array (LA) of detectors. The interfering light is split into several different beams, separated according to their wavelength by a dispersive element such as a prism. This makes it possible to measure multiple wavelengths at the same time, which makes the system 100 times faster than T-D OCT with scanning rates of 40,000 axial scans per second. It gives the technology the additional advantage of an increased SNR because less noninterfering light reaches the detector.

Swept source F-D uses a narrow band light source that can rapidly emit different light frequencies over a broad bandwidth. The interference is detected with a single photodetector over the span of one sweep. One advantage of swept source F-D is having the speed of bandwidth change determine scanning rates, rather than a linear detector array, which is typically composed of silicone-based detectors. These detectors usually lack sensitivity in higher wavelengths, around 1000−1300 nm.

Full-field OCT (F-F OCT) differs from T-D OCT and F-D OCT in producing cross-sections that are synthesized not in the line of vision, but orthogonally or in the *en-face* orientation. Unlike other forms of OCT where the area of interest is scanned point by point, in F-F OCT the entire FOV is illuminated with low spatial coherence light. F-F OCT is often referred to as a coherence microscope because the transversal resolution reaches down to ~1 μm. The tomographic images are generated by using simultaneously acquired interferometric images [92].

The first use of high-speed, high-resolution F-D OCT in gastroenterology was published in 2008 [93]. A large area 3D image of the esophagus was achieved by using an endoscopic balloon probe. Penetration was deep enough to visualize the esophageal mucosa in full thickness (see Section 5.7.6: Endoscopic Optical Coherence Tomography).

Strengths and Weaknesses

F-D OCT, and OCT in general, is a promising new technology. Currently, resolutions from 1 to 15 μm and penetration depths of 1–3 mm are being achieved. This makes it possible to perform optical biopsies in places where tissue excision could potentially be hazardous or even impossible. OCT can provide high-resolution images of pathologies in situ that cannot be obtained with any other imaging technology [94]. Another advantage is the potential for miniaturizing the scanners; currently a catheter for intravascular imaging has a diameter of 1.1 mm [95]. The technique is cheap compared to common imaging techniques like MRI [88] and offers the ability to image structures too small to be captured with conventional methods of medical imaging. In addition, it is free of harmful radiation.

Recent Developments and Current Research

OCT has the potential to increase imaging sensitivity and to carry out highly specific types of optical biopsies. The field of OCT technology is currently being advanced with investigations into potentially imaging airway wall structures in real-time, and may have a future role in areas as diverse as the evaluation and treatment of patients with obstructive sleep apnea, tracheal stenosis, airway remodeling, and inhalation injury [96]. An application of this technique that detects intravascular plaque via intravascular imaging has recently found its way into clinical use. One of the weaknesses of OCT is the low penetration depth compared to US technologies—only a few millimeters—due to the fact that light is applied in order to acquire an image [97]. In general, microelectronic advances such as high-speed CMOS or adaptive optics, more sophisticated reconstructional algorithms, and improved real-time tracking algorithms that allow the OCT scanner to target a continuously moving area will help to overcome current limitations [98]. Furthermore, longer-wavelength OCT may help to improve the detection of microstructural changes [99]. Further developments into the additional detection of polarization properties [100] and its accompanying contrast enhancements will be of particular interest in dentistry [101]. OCT has also shown the potential to match the imaging sensitivity of histology when carrying out neurosurgical imaging of brain tissue for tumor examinations. F-F OCT has captured slices of tissue samples en-face and in 3D at a resolution of 1 μm, with a penetration depth of around 200 μm [102].

5.6.2.3 Fourier-Domain Doppler Optical Coherence Tomography

An extension to the conventional F-D OCT, F-D D. OCT is an OCT modification used to determine objects' velocities, especially in blood flow measurements. It can also be applied to estimating elasticity by detecting relevant phase information in the interference signal.

Characteristics of the Modification

F-D D. OCT can be applied in T-D OCT and F-D OCT. In T-D OCT, the Doppler-frequency-shift of the interference modulation is directly measured in order to determine the axial velocity component. However, the simplest and most common methods use the principle of F-D OCT, and are referred to as phase-resolved Doppler OCT. This procedure is based on the linear relation between the phase shift of sequentially detected interference signals and the axial velocity of the examined sample. Due to high phase-stability of spectral domain F-D OCT, it is usually the modification of choice for Doppler flow measurements [103].

Strengths and Weaknesses

The F-D D. OCT allows in vivo real-time 3D flow imaging at a micron scale and provides finely resolved 4D imaging [104] that can be displayed bidirectionally in false colors [105]. Doppler information can be combined with regular OCT imaging. Current devices deliver performances of $<$50 μm spatial resolution and $<$0.6 mm/s velocity precision [106] (Table 5.11).

Table 5.11 Key facts for F-D D. OCT

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Ophthalmology Dermatology Cardiovascular medicine	Real-time flow measurements <50 μm spatial resolution <6 mm/s velocity precision	In vivo real-time imaging Combination of Doppler and regular OCT	Further clinical applications Finer resolution More advanced computations

Recent Developments and Current Research

Several useful strategies, such as dual beam F-D D. OCT and narrow bandwidth phase reference OCT, have been recently reported to increase F-D D. OCT's sensitivity. Among other things, it is currently being investigated whether F-D D. OCT can create angiographic images that are capable of substituting for regular fluorescein angiography [107]. Future improvements are mainly expected to arise from solving problems with the computational complexity of image processing, but also from the development of new high-speed swept source lasers [108]. Additionally, the developments of new sterile probes and ongoing miniaturization efforts may allow OCT to offer further applications in intraoperative use [109].

As a whole, the new technology of OCT has quickly risen to prominence, and can be expected to gain further relevance in the future. The full potential of the technology has not yet been exploited. As OCT matures, new applications will arise and support further growth in the field.

5.6.3 Optical Fluorescence Imaging

Fluorescence imaging or fluorescence microscopy is a valuable technique for histology and the imaging of living specimens [110]. It is used in a broad variety of preclinical investigations, and there is great interest in finding further ways to translate the principle into clinical applications [111]. Optical fluorescence imaging provides cellular and subcellular resolutions and image enhancement in 3D and real-time [112]. Fluorescence imaging is one of the key technologies capable of advancing molecular imaging. It has also been found to have great use in preclinical research, and has aided recent advances in proteomics, genomics, and oncology [111,113].

In fluorescence imaging, fluorescent markers are employed to enhance regular images. The markers reflect the light at a specific wavelength and color. An external light source of a well-defined wavelength, supplies photon energy which is absorbed by the specimen and molecules. The absorbed light is reradiated almost immediately at characteristic wavelengths. This characteristic amount of energy makes it possible to identify the substance imaged [114]. The readout in optical fluorescence imaging is usually realized via a spectral sensitive wide-field CCD or a PMT used for raster-scans [112].

Targets in fluorescence imaging may be endogenous molecules and proteins, such as collagen nicotinamide, adenine dinucleotide, flavin, and porphyrins (autofluorescence) [115]—so-called endogenous fluorophores. However, the range of natural fluorophores is small. Artificial markers were developed to enable excitation of the relevant tissue [116]. Different markers are employed according to the nature of the investigation. Examples include fluorescent dyes that are directly taken up by the targeted cells. Another commonly used option is to employ specially raised antibodies that target and label the molecules of interest when induced [114].

Optical fluorescence imaging can be applied in a trans-illuminating and an epi-illuminating fashion. In trans-illuminating fluorescence imaging, the examined object is placed between a broad-beam source and the detector. The light beam induces fluorescence inside the object that is measured by the detector on the opposite site. In epi-illuminating fluorescence imaging, the object is placed on a base plate. Again, a light source induces the energy to cause an excited state in the molecules. Unlike trans-illuminating fluorescence imaging, the readout module that detects the fluorescence is situated on the same side of the object as the light source [112].

Strengths and Weaknesses

Fluorescence is free of radiation and mainly harmless, except for possible toxicity of the markers [111]. It enables the imaging of cellular and molecular processes ex vivo and in vivo [111]. It is cost- and time-effective and relatively easy to use, as many investigators will already be familiar with this technique [117]. In clinical applications, the detection of fluorescence properties adds increased contrast to white light reflectance imaging. This provides the surgeon with a better foundation to distinguish between different types of tissues [118]. Typical applications extend from dermatology over oncology to gastroenterology (Fig. 5.26).

Perhaps the largest limitation of conducting optical imaging via fluorescence is the low penetration depth. Micro- and macroscopic components

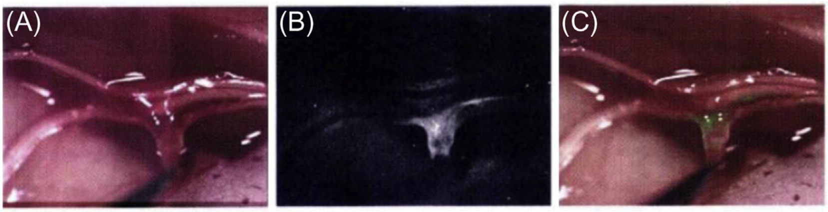


Figure 5.26 Imaging of fluorescence labeling aids tumor excision. (A) Normal white light: the malignant lesion is invisible; (B) using fluorescence, the lesion can now be seen; (C) mapping A + B enables precise excision. *From Orosco RK, Tsien RY, Nguyen QT. Fluorescence imaging in surgery. IEEE Rev Biomed Eng 2013;6:178–87.*

in the tissue collectively absorb the light at the visible and ultraviolet wavelengths, limiting the effective penetration depth to a few hundred microns. Higher penetration depths can be achieved through the use of NIR and far-red spectra. In this case, detectable signals can be measured after traveling the tissue over the span of several centimeters [112].

Recent Developments and Current Research

The imaging of fluorescence properties has already gained great importance in the medical imaging field. So-called "smart probes" are already able to detect fluorescence and provide the surgeon with intraoperative real-time and high-contrast delineation of healthy and pathologic tissue. This augmentation enhances the ability to protect structures like fine nerves and can improve the surgical outcome.

Furthermore, the development and commercialization of small-animal fluorescence imaging systems has progressed rapidly over the past decade. Their vast variety of components and approaches has been used for preclinical assessments of therapeutic methods and medication, as well as for development in the pharmaceutical sector [112].

There is a substantial interest of implementing novel optic fluorescence imaging modalities for clinical use. There, they could efficiently aid in quantitative screening, disease diagnostics, and posttreatment monitoring. For surgical applications, the development of optimal and tissue-specific contrast agents will help to extend the exploitation of optical fluorescence imaging [117].

5.6.4 Hyperspectral Imaging

Hyperspectral imaging (HSI) is a technique that analyzes a wide spectrum of light instead of just assigning primary colors (red, green, blue) to each pixel. The light striking each pixel is broken down into many different spectral bands in order to provide more information on what is imaged. The algorithms and the image processing methodologies associated with

HSI are a product of military research, and were primarily used to identify targets and other objects against background clutter. In the past, HSI has seen civil applications, and has particularly been useful in satellite technology. It might become an inexpensive, promising, and quick tool for the assessment of tissue conditions at diagnosis and during surgery. The medical applications include forensics, detection of colorectal and gastric cancer [119,120] or ulcers [121].

In HSI, the unique color signature of an individual object can be detected. Unlike other optical technologies that can only scan for a single color, HSI is able to distinguish the full color spectrum in each pixel. Therefore, it provides spectral information in addition to 2D spatial images (Table 5.12).

Many spectrally sensitive sensors collect hundreds of different narrow, adjacent spectral bands. In medical applications, HSI is often referred to as medical HSI or MHSI. MHSI provides near-real-time images of biomarkers in tissue. The key benefit is the potential to better distinguish between different tissues based on their spectral characteristics and colors [122], as seen in Fig. 5.27. Doctors do not have to make an educated guess; instead, specific wavelengths can be interpreted by the system automatically. Even the smallest areas of malignant tissue could be distinguished. Furthermore, the assessment of functional properties can be aided. The color-enhanced images make it possible to clearly discriminate between different elements in Fig. 5.28.

With a hyperspectral camera, the light is captured through a lens and split into different spectral lengths by a dispersive element such as a prism or a diffraction grating [123]. Also possible is a recording of different wavelengths at different positions in the FOV. The heart of the MHSI camera is a CCD or CMOS detector array that reads out the information inherent to the captured light (Fig. 5.29).

Table 5.12 Key facts of HSI

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Dermatology Gastrointestinal diseases Ear, nose and throat diseases	Additional imaging information Slow acquisition rates Very expensive	First translations to medical application Introduction of first miniaturized prototypes	Further miniaturization Introduction to mass production Enhanced image processing

Figure 5.27 Tumor region. Expert labeling (left) and classifier prediction of tumor regions (right). *From MITI.*

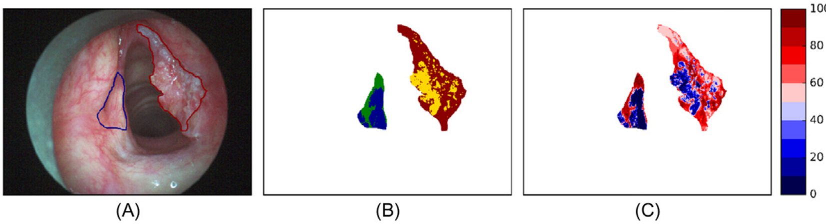


Figure 5.28 Hyperspectral imaging of a carcinoma of the larynx: (A) Intraoperative image: clinical assessment normal => blue (black in print), pathologic => red (gray in print); (B) yellow (white in print): falsely negative, blue (black in print): correctly negative, red (dark gray in print): correctly positive, green (light gray in print): falsely negative; (C) probability of pathologic lesion: depending upon color intensity, the likelihood is higher or lower that this pixel is malignant (red, gray in print), or normal (blue, black in print). *Courtesy: Dr. Wiebke Laffers, ENT, University of Bonn.*

The cameras can be customized to meet the wavelength or the application-specific performance needed. Furthermore, the right calibration is crucial. The tissue imaged provides a complex multicolor data set. In order for the analyzing algorithms to extract the color information needed, the distinct reference spectra have to be implemented precisely.

Strengths and Weaknesses

HSI provides additional diagnostic information that can be exploited in various different ways. It can aid in the discrimination between healthy and malignant tissue [125]. Furthermore, automated detection of pathologies is possible. A vast number of potential applications have been shown for this novel imaging technology—for instance, the accuracy rate of tongue tumor detection with computer-aided HSI is 96.5%.

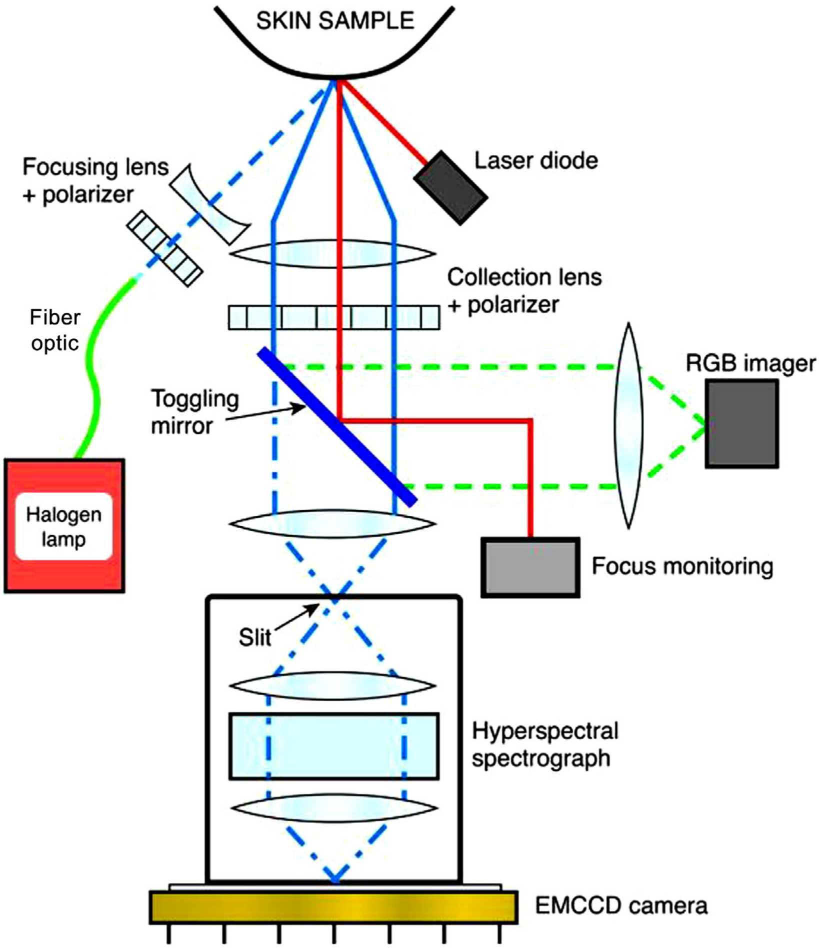


Figure 5.29 Schematic setup of a hyperspectral camera. *From Andor Technology. Schematic Setup of hyperspectral imaging camera, <http://www.truepr.co.uk/news/at/PR14/011.asp?>; [accessed 22.09.16].*

Probably the greatest weakness of HSI is the technologies' immaturity. Current devices are highly expensive, large, and difficult to use [123]. Their low frame rates are another disadvantage negatively affecting the possibility of further medical application.

Recent Developments and Current Research

Today, most HSI use is confined to laboratories. The devices currently available are large, expensive, and difficult to handle. Making HSI cheaper, user friendly, and more compact is the major goal in HSI research.

Furthermore, existing HSI cameras are only able to scan one line at the time, mainly due to their design and mechanically moving components, limiting frame rates. This restraint makes the technology unsuitable for time-critical applications and requires further research.

On the other hand, extended research is currently being conducted on microelectronic parts. Innovative designs for CMOS arrays using elements such as Fabry-Pérot staircase concepts have helped create the first miniaturized prototype, sized at a little over 1 cm^3. This prototype was first presented at the SPIE Photonics West conference in 2012. Further miniaturization down to the millimeter scale is needed if the highly interesting opportunity of integrating with endoscopes and other miniature devices is to be pursued. HSI for medical purposes has not yet reached mass production and a broad market. If mechanical components are replaced by etched silicon, production could integrate well with existing process flow used for chip manufacturing.

Another field of research is the development of algorithms for the automated detection of malignant tissue [124].

The technology has great potential for implementation and further translation into medical applications due to its ability to provide additional diagnostic information in examined objects [125]. As a result, HSI will be increasingly meaningful in the future.

5.6.5 Diffuse Optical Imaging (Near-Infrared Optical Tomography)

Diffuse optical imaging (DOI) is a technique that is also referred to as *diffuse optical tomography*, *near-infrared optical tomography*, or *fluorescence diffuse optical tomography*. It is used for examination of biological tissues at a macroscopic scale [126] (Table 5.13).

Table 5.13 Key facts on DOI

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Preclinical research Neurology Oncology Surgery	High depth penetration Portability Very low resolution High frame rates	Combination with new biomarkers	Image reconstruction Introduction to clinical practice Overcoming the problems of low resolution

In general, tissue is illuminated with visible or NIR light. The scattered light is received by photodetectors to acquire image information. It allows tomographic (3D), noninvasive reconstructions of optical tissue properties for biomedical applications. Besides information about the tissue, the concentration of oxygenated and deoxygenated hemoglobin can also be measured to get information about spatial variations in oxygenation and blood volume within the tissue. There are continuous wave systems, time-domain systems, and frequency-domain systems.

DOI has various clinical applications: functional brain imaging, imaging for breast cancer [127], or wound imaging [128]. The examination of vessels and joints is also possible [129]. DOI is beginning to be accepted as a method of choice for studying brain development in infants.

DOI uses visible light or NIR light at a wavelength of 650–1000 nm. It is projected across an object in parallel beams to an array of sensitive photodetectors. If this is repeated at various angles, a 3D image of the tissue can be acquired.

In contrast to other tomographic imaging modalities, DOI does not use cross-sectional images. The reconstruction of 3D images is achieved by mathematical algorithms, which refer to the so-called forward and inverse problem. One way to improve the quality of the image reconstruction is to use a priori structural information provided by an alternative imaging modality, such as MRI. This is used to construct a 3D tissue model which is then used to solve the forward problem—in other words, to predict the distribution of light at the detector locations.

In general, light interacts with biological tissue predominantly by absorption and scattering. Biological tissue is a highly scattering medium, causing the photons to take very irregular paths. There are several molecules that have characteristic absorption spectra. In particular, the spectra of oxyhemoglobin, deoxyhemoglobin, and cytochrome oxidase differ considerably. Hemoglobin provides an indicator of blood volume and its oxygenation, whereas the cytochrome enzymes indicate tissue oxygenation. Like these natural chromophores, there are optical contrast agents such as Indocyanine Green that are used for fluorescence imaging, which provide high sensitivity and specificity for biomedical diagnosis [130].

Strengths and Weaknesses

Red and infrared light passes relatively easily through structures as the skull, brain, and breast, and is well tolerated in large doses. Unfortunately, the high scattering results in a very low resolution in the acquired images.

Current devices provide a spatial resolution of approximately 1 cm^3. Image artifacts are a common problem of DOI. An increase in resolution is possible, but DOI will never compete with other imaging techniques like radiography, US, or MRI in terms of spatial resolution. A large number of measurements are needed in order to minimize these artifacts [131]. In general, the more accurate the mathematical model, the more computationally demanding the reconstruction algorithm is. Consequently, real-time imaging is only possible at the expense of image quality.

Nevertheless, DOI offers several distinct advantages in terms of sensitivity to functional changes, safety, and costs [132]. Advantages are the large optical penetration depth of several centimeters, the high temporal resolution, the high intrinsic contrast associated with hemoglobin, and the capability of spectral discrimination of multiple contrast agents [133]. DOI provides access to a variety of physiological parameters that otherwise are not accessible, including subsecond imaging of hemodynamics and other fast-changing processes. Furthermore, DOI can be incorporated into compact, portable instrumentation that allows for bedside monitoring at relatively low costs.

Recent Developments and Current Research

Though DOI has been under research for many years, it is still primarily a laboratory-based technique that has still not reached its full potential in routine clinical use due to technological limitations.

The most recent development is the usage of DOI in conjunction with upconverting nanoparticles (UCNPs), a recently developed class of luminescent biomarkers. They are in several aspects superior to organic dyes and quantum dots. For DOI, the multiphoton process involved in the upconversion process can be used to obtain images with unprecedented resolution. The unique properties of UCNPs make them extremely attractive in the field of biophotonics. UCNPs have already been applied in microscopy, small-animal imaging, multimodal imaging, and highly sensitive bioassays [134].

The further capabilities of DOI in optical breast imaging are still under research. Here, the technique can reveal changes in blood volume and oxygen saturation that are specific for early stages of cancer. DOI may identify cancers before they are structurally evident (i.e., visible on X-ray) because it focuses on these functional changes [132]. Other medical studies address the prevention and treatment of Alzheimer's disease or stroke rehabilitation.

As mentioned above, the low spatial resolution is the main disadvantage of DOI. That is why it is a constant field of interest in research. A high connector density is one approach to counter this problem. Currently, systems with 24 sources and 28 detectors embedded in a small (13×6 cm) probe array are the state-of-the-art [129]. However, one of the most significant improvements in image quality is achieved by optimization of image reconstruction techniques. Image reconstruction allows multiple measurements to contribute to each pixel, leading to improvements in spatial resolution, spatial and quantitative accuracy.

The spatial resolution can be enhanced by combining DOI with other imaging methods. Combination with MRI seems to be particular promising. Optical probes can easily be made to be MRI-compatible, and optical imaging provides complementary information to MRI.

5.6.6 Confocal Laser Scanning

Confocal laser scanning (CLS) or confocal scanning laser is a special kind of microscopy that uses laser light instead of a bright flash of white light. The reflected light is captured through a small aperture that allows the acquisition of high-resolution, high-contrast images at various depths of an object. The images are reconstructed with a computer and can also be obtained in a 3D image.

The most common medical application for confocal scanning laser is the examination of the retina or cornea of the eye, called confocal scanning laser ophthalmoscopy (cSLO) but it is also used in examinations of the human skin. CLS can also be integrated into endoscopes for applications in gastroenterology (see Section 5.7.5: Confocal Endomicroscopy).

The images are obtained by scanning an object point by point with a focused laser beam. The reflected light has to pass through a small aperture, so only the in-focus area is captured by the detector. The light from out-of-focus planes is suppressed by the confocal pinhole.

To illuminate a point of the specimen, a beam splitter or dichroic mirror is used. Emitted or refracted light from the illuminated point that retraces the incident light path (the solid line in Fig. 5.30) is captured through the confocal pinhole. This confocal effect depends both on the focused illumination of a single point in the specimen, so that the illuminating intensity falls off, and on the use of a pinhole in the image plane to exclude the majority of residual out-of-plane emissions (the dotted lines in Fig. 5.30).

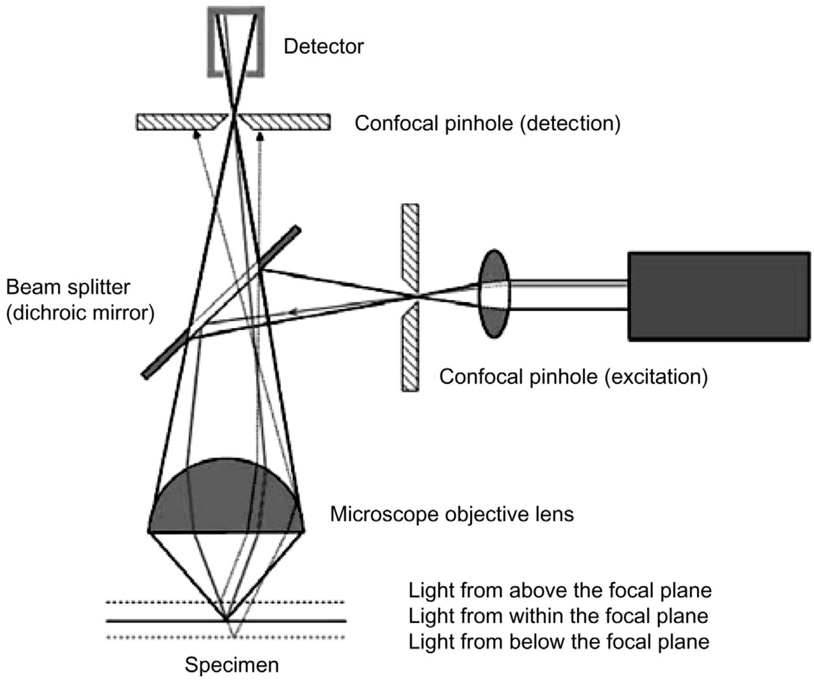


Figure 5.30 Principle of confocal microscopy. *From Lee YJ, Wang D, Jow GM. Confocal microscopy in biomedical and clinical applications. Fu-Jen J Med 2004;2:263–71.*

A 3D image of the sample is created by successively scanning planes of different depths and stacking them together. In the examination of cells, the usage of fluorescent substances are very common.

Modern instruments are equipped with three to five laser systems controlled by high-speed acousto-optic tunable filters, which allow very precise regulation of wavelength and excitation intensity. Coupled with photomultipliers that feature high quantum efficiency in the near-ultraviolet, visible, and NIR spectral regions, these microscopes are capable of examining fluorescence emissions ranging from 400 to 750 nm [136].

Strengths and Weaknesses

Images obtained by CLS are characterized by their high contrast and resolution. However, the point-to-point acquisition leads to a comparatively slow acquisition speed, which is problematic in medical imaging due to movements of the considered object (Table 5.14). There are different methods to overcome this disadvantage, such as using adaptive optics or resonant scanning mirrors [137].

Table 5.14 Key facts of CLS

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Ophthalmology Dermatology Gastroenterology	Microscopy with very high contrast and resolution 3D-images reconstructable	Adaptive optics scanning laser Endoscopic confocal microscopy Dual-axis confocal scanning laser	Combination of CSL with other modalities MEMS-technology Handheld devices

Recent Developments and Current Research

In the last few years, confocal microscopy has been adapted to flexible fiber probes that can be used with endoscopic methods to obtain images of sites that were previously inaccessible. With endoscopic systems such as those manufactured by Mauna Kea Technologies (Paris, France), it is possible to obtain images of $\sim$2.5 μm lateral resolution and 15–20 μm axial resolution at depths up to 80 μm. This progress has been accelerated by the availability, variety, and low cost of optical fibers, scanners, and light sources, in particular for semiconductor lasers. The addition of a real-time, high-resolution imaging instrument can help guide tissue biopsy and reduce pathology costs.

Conventional single-axis confocal microscopes have a trade-off between resolution, size, and working distance. The need for high resolution requires a larger high-numerical aperture objective, resulting in a shorter working distance. To overcome the limitations in miniaturizing CLS optics in particular, a dual-axis confocal architecture has been developed that uses separate illumination and collection objectives. Two low-numerical aperture objectives are oriented with the illumination and collection beams crossed at an angle, which results in a significant reduction of the axial resolution (black oval in Fig. 5.31), an increase in long working distance, and a decrease in light scattering [138,139].

Technological developments allow new designs and improved imaging capacity. The application of MEMS-technology is, like in many optical systems, a driving factor of development. The integration of a 2D MEMS scanner with dual-axis confocal architecture enables the microscope system to be contained in a miniature package while enhancing imaging performance, so even the development of handheld devices is possible. In

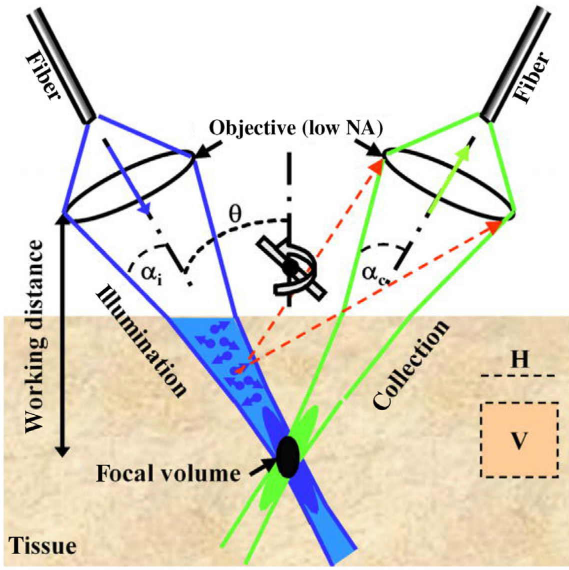


Figure 5.31 Dual-axis confocal endomicroscopy. *From Piyawattanametha W, Wang TD. MEMS-based dual axes confocal microendoscopy. IEEE J Sel Top Quantum Electron 2010;16(4):804–14.*

2008, the first fully packaged handheld dual-axis confocal microscope, capable of 3D reflectance and fluorescence imaging, was presented [140].

CLS is increasingly used in routine clinical settings for diagnostic purposes and assessment of treatment effects. It has become a valuable research tool due to its ability to examine mucosal morphology in vivo. Technological development has matured in the past 10 years significantly [141], but minimizing the effects of ocular aberrations and imaging artifacts are still a matter for further research [142].

Combining CLS with other technologies is of growing interest for clinical settings. Simultaneous cSLO/OCT imaging combines two different imaging technologies in one device with various subsequent advantages, including the exact correlation of tomographic and topographic findings [141].

5.6.7 Photoacoustic Imaging

Photoacoustic imaging (PAI), also called photoacoustic spectroscopy, is based on the principle of thermal expansion of an object caused by the absorption of light. When the emitted light is pulsed, it induces an oscillating movement in the tissue, resulting in pressure waves that can be interpreted as a sound signal. This principle is called the photothermal or photoacoustic effect. PAI is a promising structural, functional, and molecular imaging modality for a wide range of biomedical applications. Most of them are still under research, often only applied in preclinical studies. However, the technology is starting to see use in clinical settings [143]. In medical diagnostics, photoacoustic tomography (PAT), also called optoacoustic tomography, is the main means of generating 3D images. It has been recognized as a technology with very high potential for early-stage cancer detection.

Traditional optical imaging methods suffer from scattering in biological tissues (Fig. 5.32). In contrast to conventional transmission spectroscopy, neither scattered nor reflected light contributes to the signal [144]. Using laser pulses to generate elastic pressure waves (US) allows high-resolution optical information to be obtained. Ultrasonic scattering is two to three orders of magnitude weaker than optical scattering [145,146].

It is necessary to use very short pulses—only if the laser pulse is short enough will the thermal expansion cause a pressure wave proportional to the locally absorbed energy density, which is generated by the photoacoustic effect [147].

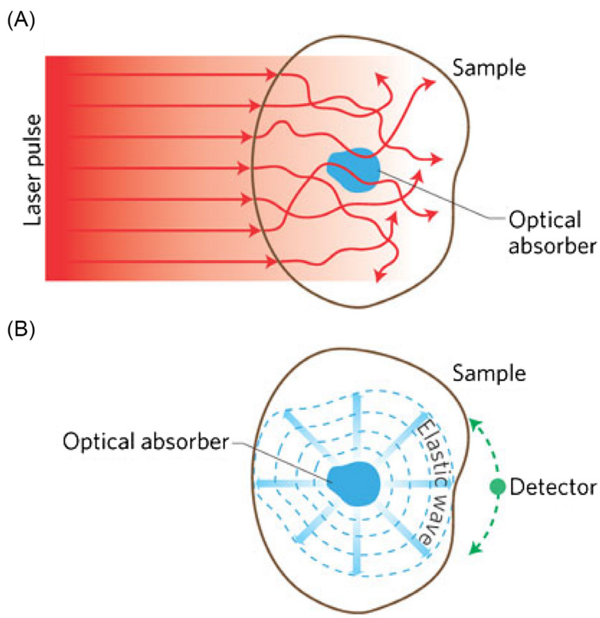


Figure 5.32 Laser-induced photoacoustic effect. (A) A laser pulse irradiates tissue, the absorbed energy causes local heating. (B) Thermoelastic expansion and generation of pressure waves (ultrasound) which can be detected outside the sample. *From Burgholzer P, Grün H, Sonnleitner A. Photoacoustic tomography: sounding out fluorescent proteins. Nat Photon 2009;3(7):378–9.*

The application of a Nd:YAG laser and an optical parametric oscillator allows light pulses of different spectra and a repetition rate from 10 Hz up to 100 Hz to be used. Some high-speed PAT systems can even go up to 1000 Hz. Pulse duration in the nanosecond range allows a theoretical resolution of several micrometers in tissue [145].

Like in US techniques, pressure-sensitive elements such as piezoelectric transducers are used. An image of the photo-generated pressure distribution in the sample is acquired by collecting the US at many different locations with transducers. The electric signals produced by the transducer are amplified, digitized, transferred to a computer, and processed using a suitable algorithm. Though the algorithms have already found application in other imaging modalities such as CT, MRI, and US, reconstruction is still a major challenge in PAT systems. It arises from the fact that the location of the acoustic waves' source is unknown [147]

Different molecules in the tissue have different absorption spectra, which are the basis of DOI. PAT is also able to benefit from this effect. There are developments in multispectral imaging methods for acquiring images excited with different wavelengths.

Generally, blood is the major absorbent of light in biological tissue, meaning the signal comes mainly from regions with a high concentration of blood. By using multiwavelength measurements, one can simultaneously quantify concentrations of multiple chromophores of different colors, such as oxygenated and deoxygenated hemoglobin molecules in red blood cells. Such quantification of hemoglobin can provide functional imaging of the concentration and oxygen saturation of hemoglobin. Both parameters are related to hallmarks of cancer, and can also be used to image brain activity. In addition, extrinsic optical absorption contrast agents can be used to provide molecular imaging of biomarkers [148].

Strengths and Weaknesses

PAT benefits from the same advantages of optical imaging and US imaging, without the major disadvantages of each technique [149] (Table 5.15). It combines the high contrast from light absorption with the high resolution of the US imaging response signal [147]. It has a high SNR, due to the fact that nonlight-absorbing molecules do not produce a signal, effectively making the images free of background noise. In contrast to CT or MRI, PAT is nonionizing, does not necessarily require contrast agents, and could potentially deliver real-time scans with extremely high resolution [143].

Table 5.15 Key facts of PAI

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Oncology	Nonionizing High contrast and resolution Limited imaging penetration depth Long data collection times	First introduction to clinical use	Reduction of acquisition times 4D PAT Intravascular PAT Image-guided therapy

Disadvantages are the long data collection times, from 24 seconds up to 8 minutes in existing 3D PAT systems [150]. In general, many optical techniques suffer from a limited imaging depth compared to MRI or CT. Until now a maximum imaging depth of 7 cm is possible [143], which is still extraordinary for optical imaging systems [148].

Recent Developments and Current Research

PAT is a very promising technology, with high capabilities and still extensive research potential [151].

Long acquisition times are the main challenge in the development of PAT. Recently, array-based PAT systems have been developed to reduce the imaging time. In addition, high frame rate PAI has been performed in 2D using LAs [150].

4D PAT in particular would benefit from shorter acquisition times. 4D PAT techniques generate motion pictures of imaged tissue. There are already devices integrating time resolution with 3D spatial resolution, but further research is still needed. Enabling real-time tracking of dynamic physiological and pathological processes at hundred micrometer- and millisecond resolutions is already technically possible. It can also be used to image drug delivery and pharmacokinetics, among other things [152].

Intravascular photoacoustic applications are another area currently under research. They have been only performed in ex vivo studies based on intravascular US catheters, and may be used to detect atherosclerotic plaque [153].

The ability to support thermal therapies through image guidance—during cancer treatment, for instance—has already been demonstrated, although the thermal maps used have primarily been 2D. Unfortunately, 2D visualizations of heating patterns do not provide sufficient accuracy, so it was not possible to use PAI to effectively steer the heating focus into the tumor. This often left parts of the tumor unheated while generating too much heat in the surrounding healthy tissues. 3D PAT systems for the purpose of image-guided therapy are currently under development. The visualization of 3D temperature distributions is desirable in order to provide comprehensive temperature monitoring during clinical applications. Currently, they only have been tested with excised tissue or animal specimens [150].

There are many promising possible applications for PAT. These extend to various pathologies such as traumatic brain injury, cancer, and intestinal fibrosis [154]. Photoacoustic endoscopy, simultaneous functional and molecular PAT, PAT of gene expression, Doppler PAT for flow measurement, photoacoustic mapping of sentinel lymph nodes, and multiscale PAI are conceivable and in development [148]. Advanced studies have identified promising potential in breast cancer diagnostics [147]. Another application of photoacoustic technology is to link spectroscopic PAI to conventional transrectal US for prostate cancer detection and evaluation. PAT may also be used for therapeutic monitoring in the future [155].

5.6.8 Conclusion

Optical imaging technologies are a rapidly emerging field in medical diagnostics. Different technologies have been introduced for a broad range of new applications during the past decade. A general trend in medicine is a rising pressure on health care due to an aging population, especially in developed countries. Changing demographics are resulting in a higher prevalence of major diseases, as well as an increased pressure on the health care systems to maintain medical supplies. Therefore, early-stage diagnostics can be crucial. Optical technologies offer great potential not just due to their—in many cases superior—resolution, but also due to their inherent ability to save costs compared to conventional methods. In the short-term, new applications will be introduced as optical imaging technologies mature. In the long-term, completely new modifications will be introduced. They are expected to be of even greater value in the future, especially in some of the most meaningful and fastest-emerging medical fields like cardiovascular imaging and gastrointestinal oncology. In fundamental medical research and approaches toward personalized medicine, optical technologies are considered fundamental for driving innovations and developments. The full potential of optical imaging in medicine has not yet been exploited. These technologies hold the chance to revolutionize diagnostics and health care in gastrointestinal medicine.

5.7 ENDOSCOPY

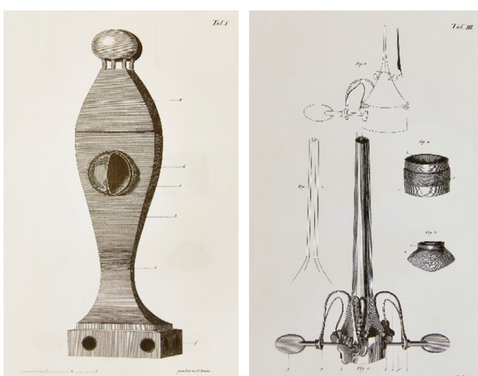
Endoscopy is the art to look into the interior of an object. In medicine, the term is broadly used to describe any examination of the inside of the body.

In former times, many attempts had been made to look into the interior of the human body, but due to technical limitations, this was mainly confined to the oral cavity, the rectum, the vagina, ear, and nose.

Among the numerous constraints, one major problem was illumination. A big step forward was the development of a light source by Bozzini about 200 years ago, but even after Bozzini's invention of an illumination system, quite a number of further hurdles had to be overcome (Fig. 5.33).

Further necessities for the exploration of anatomical lumina and cavities are adequate optical systems and auxiliary features like insufflation and working channels. Nowadays, after a long history of technological innovations (Table 5.16), dedicated endoscopes are available for literally all use cases.

Today, two different concepts prevail: the flexible or rigid design. Beyond, there are two types of image acquisition and transmission. Normally, the tip of the endoscope is fitted with an objective lens and the image is transmitted with optical components such as prisms and lenses or



(A) (B)

Figure 5.33 (A) Bozzini's "Lichtleiter"; (B) exploration tube. *From a reprint of Bozzini 1807.*

Table 5.16 Short history of endoscopy

1807	Bozzini	Instruments for examinating the oral cavity, the rectum, and the vagina (light conductor)
1822	Beaumont	First human endoluminal endoscopic examination
~1908	David	Integration of a bulb into existing endoscopes
1901	von Kelling	Endoscopic examination of the peritoneal cavity
1950		Fiber optics—Hopkins Fibroscope
1952		First gastroscope (Olympus, Suguira+Uji)
~1980		Chip-on-the-tip endoscopes
2005		Multichannel endoscopes
2007		Multiarm endoscopic intervention devices

glass fibers to the eyepiece. More frequently, the tip of an endoscope may be fitted with a camera, which is generally a CCD camera ("chip-on-the-tip" design). It converts the optical signals into electrical signals, and transmits them to the camera controller.

The field of application of endoscopy is multifaceted, as is the design of endoscopes. The names of these endoscopes indicate the area of use. There are arthroscopes to look into joints like the knee, ENT endoscopes for the exploration of ear and nose, gastrointestinal endoscopes for the stomach and the large bowel, gynecology endoscopes to examine the vagina, laparoscopes to look into the abdominal cavity, neurology endoscopes, pulmonary endoscopes (so-called bronchoscopes), urology endoscopes (urethroscopes), and others. Each field additionally has application-specific designs. Both flexible as well as rigid endoscopes are used.

Minimally invasive surgery (MIS) is one of the best-known therapeutic applications of endoscopy. This comparatively small but increasing field of application mainly belongs to laparoscopy.

5.7.1 Rigid Endoscopes

Rigid endoscopes are the oldest type on the market. They are used in the majority of surgical endoscopic applications and enable endoscopists to visualize the surface of organs, their vessels, or pathological changes without large incisions of the body and delivering a view even more clear than with the naked eye. The main design criteria are the viewing angle, depth-of-field, magnification, image brightness, image quality, distortion, and image size, which have to be appropriately balanced.

Rigid endoscopes are commonly used in minimally invasive surgical procedures like rhinoscopy (nose), cystoscopy (urinary bladder), and laparoscopy (abdomen).

Rigid endoscopes are made of metal tubes which contain the lenses, and the light channel(s) and are available in a large range of external diameters, from 1 to 12 mm.

Commonly, rigid endoscopes have a series of high-resolution optical glass rod lenses. The endoscopes can be forward viewing (0 degrees) or angled (10–120 degrees) to allow visualization out of the axis of the telescope and increase the FOV by rotating the instrument. The optical quality of lens-generated images of rigid endoscopes still surpasses that of the fiber-optic or digital images produced by flexible scopes.

In gastrointestinal surgery, however, rigid endoscopy for diagnostic purposes (diagnostic laparoscopy) completely lost its former role. Nowadays, laparoscopy is performed almost exclusively as a therapeutic procedure (see Chapter 7: Operative (Surgical) Laparoscopy).

In visceral medicine flexible endoscopy dominates now for the exploration of the whole GI tract from the interior (endoluminally).

5.7.2 Flexible Diagnostic Endoscopy

With flexible endoscopes, it is possible to advance through twisted paths of the body. They consist of an elongated plastic-coated endoscope sheath containing optical components such as the objective lens and the image guide as well as the light-transmitting glass fibers. There are two types of flexible endoscopes: fiber-optic and video endoscopes. Video endoscopes use digital image transmission, whereas fiber-optic endoscopes, also called fiberscopes or fiber endoscopes, use glass fiber bundles to transmit images. These individual fibers have a diameter between 4 and 14 μm. Between 3000 and 50,000 fibers are used, depending on the diameter and field of use.

Flexible endoscopes are most commonly used in areas of the body cavity that are difficult to access, like the gastrointestinal, respiratory, and male urinary tracts. A special design of flexible endoscopes is the catheter endoscope, which enables intravascular image acquisition. They are mostly used during intravascular US and have a great potential in intravascular OCT image acquisition.

Flexible endoscopes are considerably more expensive and require more maintenance than rigid endoscopes. One improvement in flexible endoscopy is the creation of portable or handheld units. This has been possible due to

Figure 5.34 Portable unit for flexible endoscopy (Storz Gastropack) (TFT flat screen folded down). It offers all basic functionalities, making it suitable for many applications outside the endoscopy unit (intensive care unit, outpatient department, etc.). *From MITI.*

technical advancements in miniaturization. Due to its higher flexible usability, it is beneficial, e.g., in emergencies and for intensive care units (Fig. 5.34).

In principle, an endoscope is a hollow hose that is inserted into the human body.

Most endoscopic procedures involve more than a simple visual examination. Diagnostic and therapeutic procedures demand a wide range of specialized accessories. Besides the imaging equipment, numerous peripheral devices and instruments such as lights, insufflators, suction and irrigation equipment, forceps, snares, loops, drains, stents, balloons, dilators, needles, blades, and many other tools are required.

Combination with other imaging modalities, like US or optical imaging systems, is generally possible. This requires a miniaturization of the respective technology. In the following section, important and novel visualization technologies for endoscopes are presented. Promising new imaging techniques, including fluorescence endoscopy, OCT, confocal microendoscopy, and molecular imaging, are briefly depicted.

5.7.2.1 Flexible Scopes

Standard video gastroscopes (for the examination of the esophagus, the stomach, and the duodenum) or colonoscopes (for the examination of the large bowel) have a direct forward view. The flexible shaft is not

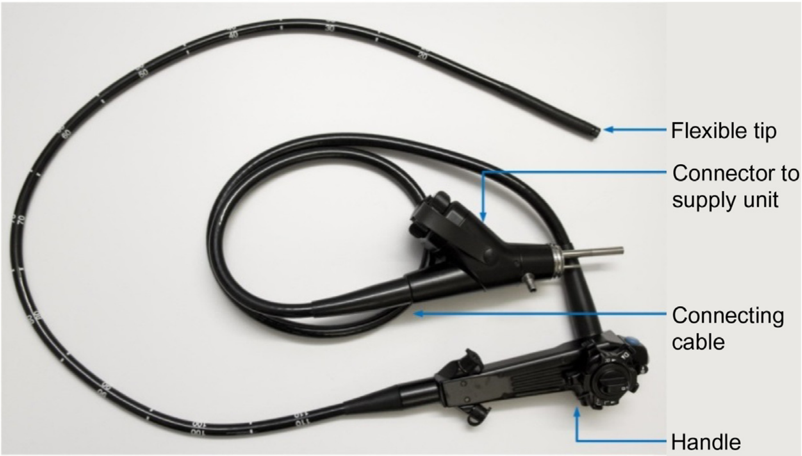


Figure 5.35 "Classical" flexible gastroenterological endoscope with the main components shaft, handle, and connecting cable. *From MITI.*

actively controlled, but the flexible tip can be bent in two axes by two wheels at the handle (Fig. 5.35).

5.7.2.1.1 The Handle

The handle is held by the endoscopist's left hand at the grip. The fingers of his left hand additionally activate the suction and instillation pins (Fig. 5.36).

The fingers of his right hand usually move the smaller steering wheel (for the *x*-axis) whereas the larger, inner steering wheel is turned by the thumb of the left hand. This sounds more complicated as it is. Experienced endoscopists are able to perform most sophisticated manipulations with ease.

If the suction pin is pressed, aspiration into the working channel is initiated. If the hole in the air/water pin is gently occluded by a fingertip, gas/air will be insufflated. If it is pressed down, water will be flushed to clear the view or to clean the working site.

The challenge is to integrate the maximum of functionality into a minimal diameter of the tip/shaft and to facilitate the navigation (Fig. 5.37A, B).

5.7.2.1.2 Connection to the Control/Supply Unit

A key issue of flexible endoscopy is a fast and safe connection of the flexible endoscope to the control/supply unit.

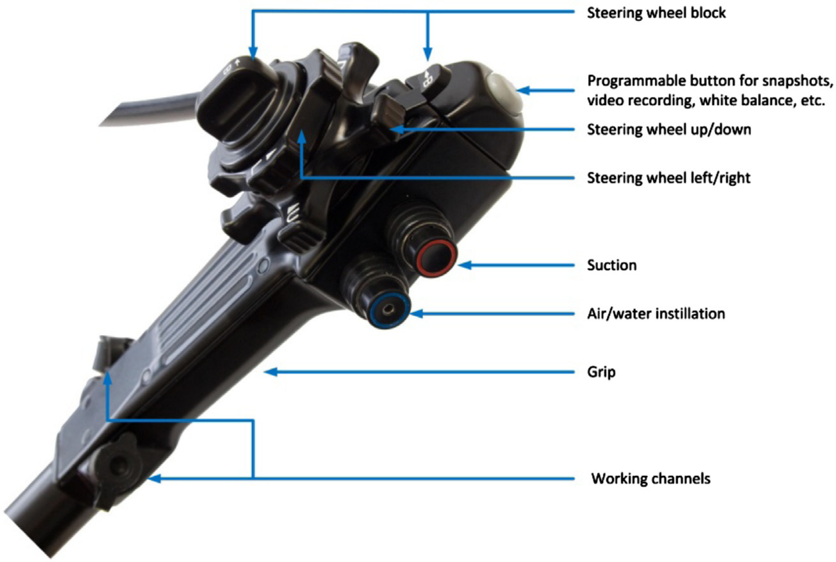


Figure 5.36 Close-up view of the handle of a standard video endoscope. *From MITI.*

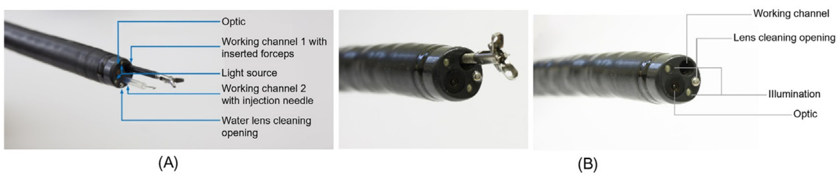


Figure 5.37 Tip of the flexible endoscope: (A) Standard diagnostic endoscope. A biopsy forceps is inserted through the working channel. (B) Two-channel endoscope. *All from MITI.*

Multiple functionalities have to be transferred though this needle hole (Fig. 5.38).

5.7.2.2 Control/Support Unit

In opposition to the architecture of laparoscopy units, the necessary peripheral functionality of the control/support units are integrated into one entity.

These compact units of only two or three elements provide the decisive functions of a state-of-the-art flexible endoscope (Fig. 5.39).

5.7.2.2.1 Imaging/Illumination

The main components of the control/support unit are the image processor and the light source (Fig. 5.40).

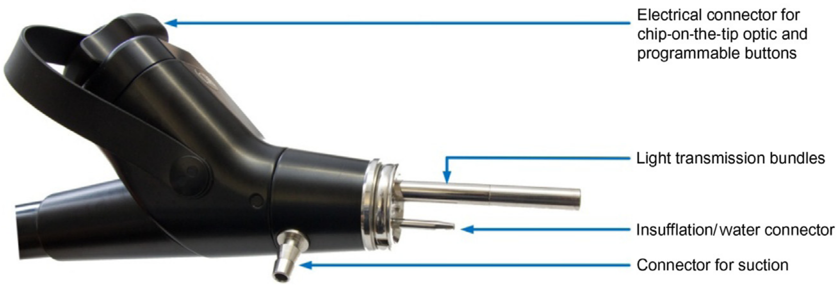


Figure 5.38 Connector: Light, vacuum, optical transmission, irrigation have to be provided to the tip of the endoscope. *From MITI.*

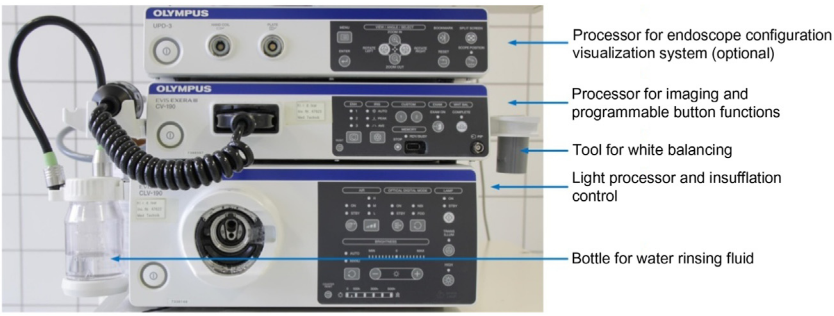


Figure 5.39 Control/support peripheral unit for flexible gastroenterological endoscopy. *From MITI.*

5.7.2.2.2 Suction/Irrigation/Insufflation

In flexible endoscopy, the necessary conditions have to be created by insufflating gas into the respective part of the gastrointestinal tract to get the overview. Usually, normal air is suitable, since the danger of air embolism (as in laparoscopy) is practically nonexistent in flexible diagnostic endoscopy. However, the use of CO_2 is becoming increasingly popular since it is assumed to be more patient-friendly (in particular during colonoscopy), since it is reabsorpted faster. The pump is integrated with the processor into one common housing.

Water is required to wash the mucosa of the gastrointestinal tract and/or the lens of the endoscope to get a better visualization ("flushing"). Flushing pumps are mostly provided as roller pumps. Technically more simple are pressurized bottles (Fig. 5.41A). Aspiration can be achieved by using the vacuum line of the OR. The aspirated fluid is stored in bottles or disposable bags (Fig. 5.41B).

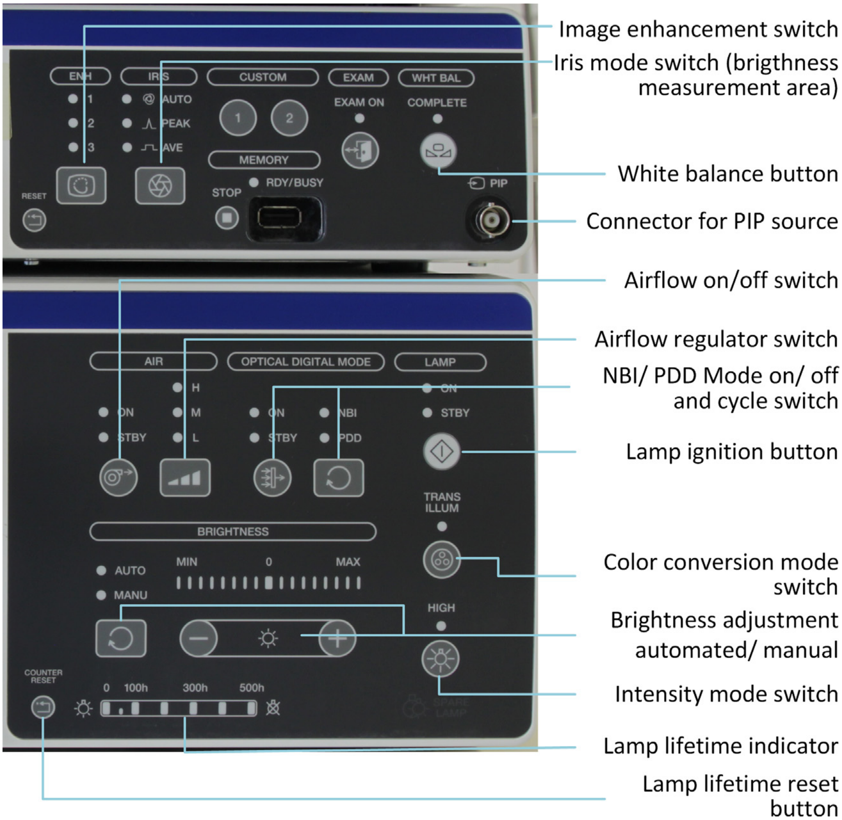


Figure 5.40 Various functions are available: White balancing adapts the image sensor to the color temperature of the light at the pickup location and ensures a correct representation of the colors. Since light emission differs between the various endoscopes, and is also caused by different numbers of fibers for light transmission, white balancing has to be performed before every examination and after a change of the endoscope. Image enhancement: Fine patterns or edges in the image can be enhanced electronically. Modern processors even provide a fog-free function. *From MITI.*

5.7.2.3 Instruments

The most important instrument in flexible diagnostic endoscopy is the biopsy forceps for tissue sampling (Fig. 5.42). Biopsy forceps are available with various jaws and in all diameters.

Because of their simple functioning (Fig. 5.43), production costs are low and they are offered as disposables. The required force at the jaws is comparatively low.

(A) (B)

Figure 5.41 (A) Irrigation water bottle with connecting hose; (B) suction: disposable bag for the aspirated fluid. *All from MITI.*

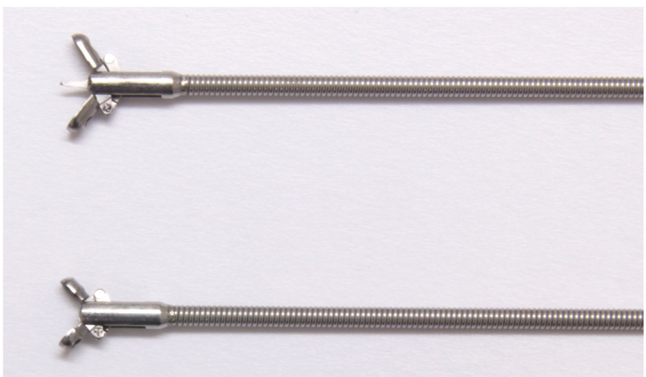


Figure 5.42 Typical biopsy forceps for flexible endoscopy. The sharp tip of the upper one facilitates the stable positioning of the jaws. *From MITI.*

Figure 5.43 Handle of a biopsy forceps: the open/close function is activated by moving the cylindrical structure forward and backward with two fingers. The thumb is positioned within the ring. *From MITI.*

5.7.2.4 The Endoscopic Trolley

The whole range of electromechanical devices is mostly stored in mobile workstations (Fig. 5.44). They also incorporate the monitor. By moving the trolley, the video screen can be positioned for convenience. The devices are controlled by the central switch, allowing all equipment to be powered up simultaneously for time-saving.

5.7.2.5 Instrument Reprocessing

Flexible endoscopes are complex devices which require careful reprocessing before being used in subsequent patients. The normal reprocessing procedures used for surgical instruments would inevitably lead to complete destruction.

Accordingly, adequate reprocessing procedures had to be developed with the aim to obtain decontamination and high-level disinfection. Flexible endoscopes should first be completely cleaned to remove any bioburden, in particular proteins.

Subsequently, high-level disinfection is achieved by exposure to 2% glutaraldehyde solution at ~25°C. Glutaraldehyde has an excellent biocidal activity and is relatively inexpensive. It does not degrade endoscopes, since it is noncorrosive to metal, rubbers, and plastics. However, the endoscopes

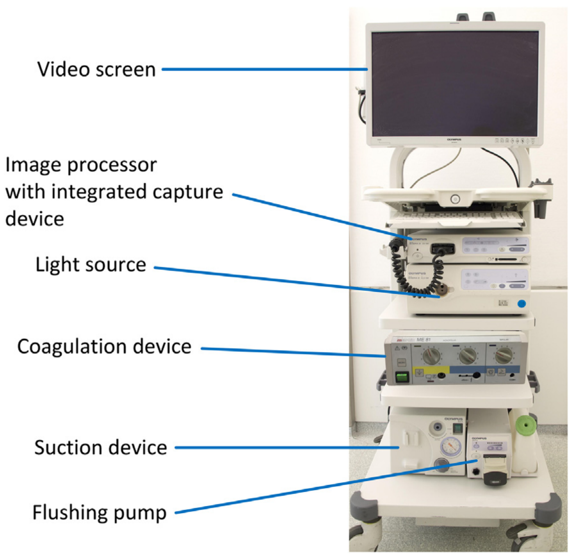


Figure 5.44 Mobile endoscopy unit. *From MITI.*

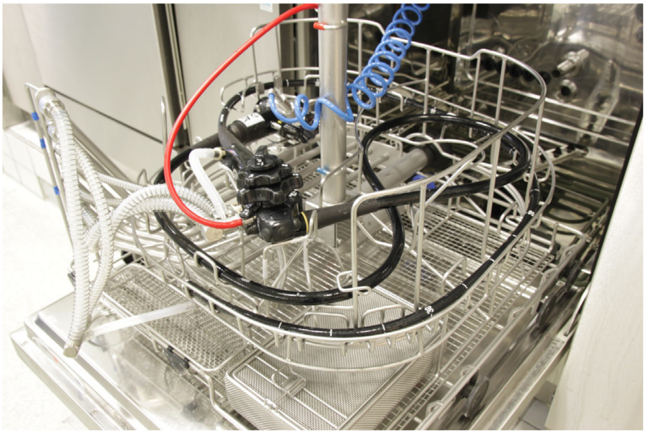


Figure 5.45 Automated endoscope reprocessor. *From MITI.*

have to be thoroughly rinsed after treatment with glutaraldehyde since it is highly irritating on human mucosa and eyes. It fixes proteins which allows for biofilm formation if the endoscope had not been meticulously cleaned before disinfection. Alternatives to glutaraldehyde are ortho-phthalaldehyde (does not coagulate blood or fix tissue to the surface), peracetic acid, and hydrogen peroxide.

Manual high-level disinfection is possible, but usually specially designed machines are used today. Automated endoscope reprocessors provide the whole disinfection cycle which saves time and limits the exposure of personnel to the chemical disinfectants (Fig. 5.45).

After high-level disinfection, each internal channel must be flushed with 70% alcohol and dried with forced air before it can be used on another patient or stored. The alcohol flush enhances the drying process and, thus, protects from recontamination.

Reprocessing of flexible endoscopes is challenging. The presence of crevices, hinges, channels, valves, etc. makes it extremely difficult to remove all bioburden without endangering the normal life cycle of the endoscope. A (partly) disposable endoscope could overcome the problems of reprocessing, but up to date, reusable designs still prevail.

5.7.2.6 Clinical Applications

Flexible gastroenterological endoscopy is used to examine the interior of the gastrointestinal tract to detect (or to exclude) diseases and to classify them. Upper GI endoscopy encompasses the exploration of the esophagus, the stomach, and parts of the duodenum (descending duodenum) (Fig. 5.46). Typical indications are cancer screening or cancer staging (classification of the severity), the detection of inflammation (e.g., reflux esophagitis, gastritis), or the identification of sources of gastrointestinal bleedings.

Gastroscopies are performed in high numbers all over the world. In the United States, about 600,000 procedures are performed per year.

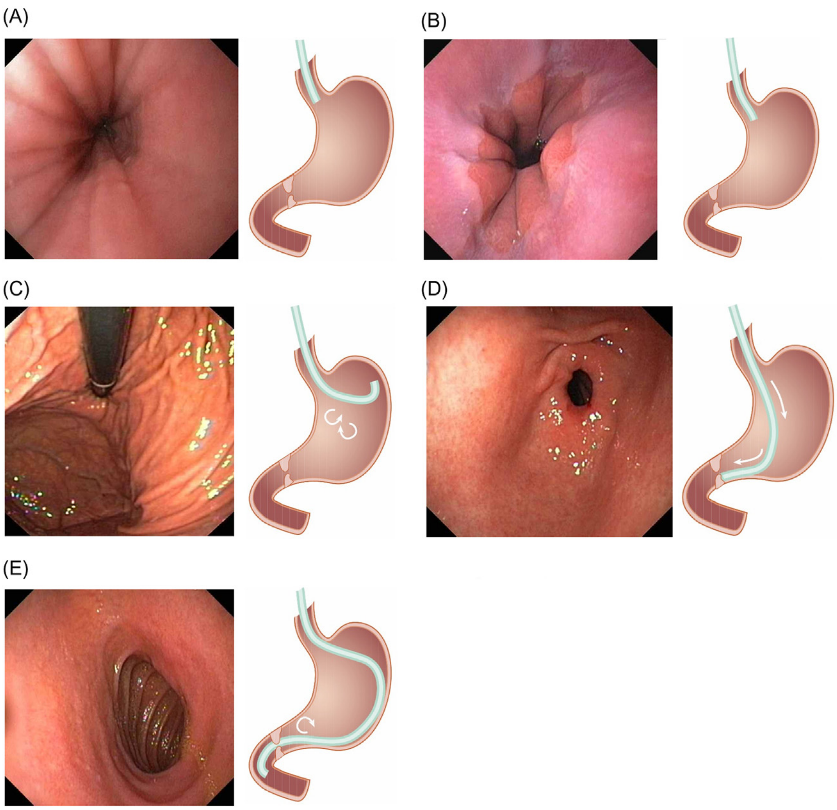


Figure 5.46 (A) Esophagus: A look into the middle part of the esophagus. Anterograde view into the muscular hose. The wall is covered by squamous cell epithelium (schematic drawing of the position of the endoscope on the right). (B) Cardia/Z-Line: The entrance into the stomach. Note: The squamous cell epithelium ends and the typical mucosa of the stomach begins (Z-line). (C) Cardia/Fundus/Corpus: The endoscope is in retroflexion. A look from beneath onto the gastric cardia. (D) Antrum with pylorus: Anterograde view of the pylorus—a valve-like structure between stomach and duodenum. (E) Bulbus duodeni: A look into the first part of the duodenum (bulbus). *All from MITI, M. Scholle.*

5.7.2.6.1 Colonoscopy

Lower GI endoscopy is mainly confined to the large bowel. However, experienced endoscopists are able to intubate the last loops of the ileum. Screening of cancer or preforms (polyps) is the most common cause. Inflammatory bowel disease and bleeding are additional indications.

Colonoscopy is technically considerably more demanding than upper GI endoscopy (Fig. 5.47).

Prior to colonoscopy, the patient has to undergo full bowel preparation, which means that stool has to be removed completely. The list of bowel preparation regimens is long, encompassing strong laxatives, polyethylene-glycol balanced electrolyte solutions and others. A complete washout of the colon has to be achieved to facilitate a comprehensive exploration. For the patient, this is the most unpleasant part of the procedure, but still unavoidable [156].

5.7.2.6.2 Enteroscopy, "Deep Endoscopy"

The small intestine was, for many decades, something like a "white spot" on the map of flexible endoscopy, since it could be reached through neither the mouth nor the anus.

The length and the mobility of the jejunum and the ileum did not allow to introduce the endoscope by "push and retract" methods like in gastroscopy and colonoscopy. The mobile segments are just stretched if the endoscopist tries to push the endoscope forward. Hence, an active forward moving element is required. Since it did not exist for a long time, the assessment of small intestine disorders remained the domain of the radiologists (see Section 5.1.4: Real-Time Radiography).

With the advent of capsule endoscopy in the beginning of the new millennium, the diagnostic gap concerning the small intestine could be closed, at least to a limited degree.

However, locomotion of the capsule is passive only. The localization of a lesion is less than precise and it does not offer any therapeutic option (see Section 5.7.8: Wireless Capsule Endoscopy).

Since a couple of years, even the small intestine is now endoscopically accessible via the mouth using the so-called "balloon" technique (so-called "device-assisted enteroscopes") [157].

The tip of the specially designed, long endoscope is advanced by pulling it stepwise forward according to the inchworm principle (see Chapter 10.1.3.2: Systems With Elements of Autonomous Locomotion).

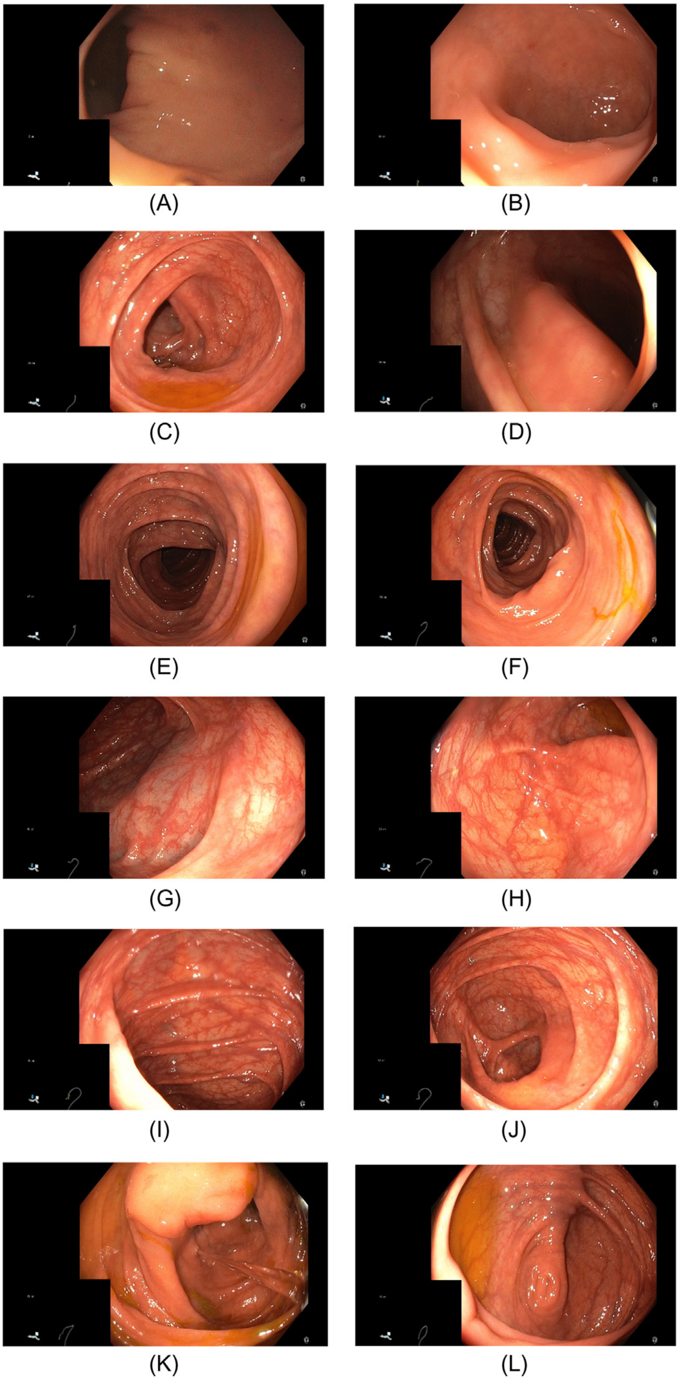


Figure 5.47 A voyage through the colon. The insert in the left lower corner represents the actual configuration of the colonoscope: (A) The entrance of the colorectum: the rectal ampulla. (B) The curved sigma between rectum and descending

(*Continued*)

Either one or two balloons are used. Fig. 5.48 illustrates the use of a single-balloon system.

The most common indication for enteroscopy of the small bowel is obscure gastrointestinal bleeding with a high rate of identification and treatment of bleeding spots. Other indications are the staging of Crohn's disease, evaluation of findings on capsule endoscopy, and investigation of small bowel tumors [158,159].

Enteroscopy, with its rather short history, has still a slightly higher complication rate than the upper GI endoscopy or colonoscopy. Hopefully, further technical improvements will make it even safer and easier to perform.

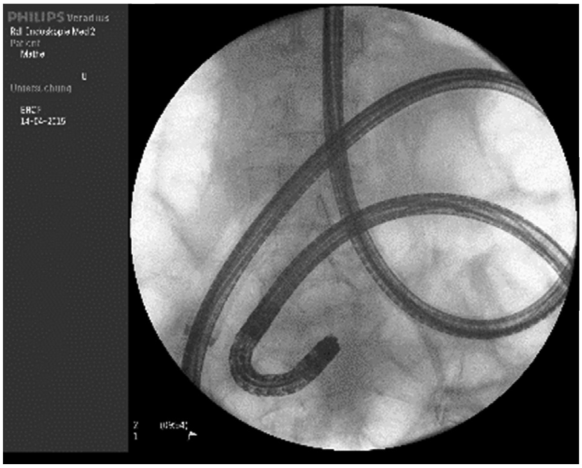


Figure 5.48 Balloon enteroscopy: Plain abdominal X-ray. The endoscope can be easily recognized. *Courtesy: Prof. S. v. Delius, Klinikum rechts der Isar.*

◀ colon. (C) The ascending colon. (D) Left (splenic) flexure which is often difficult to pass. (E) As soon as the left flexure is overcome, the transverse colon with the characteristic triangular diameter of the transverse colon becomes visible. (F) In the middle of the transverse colon. (G) The tip of the colonoscope close to the right (hepatic) flexure. (H) A few centimeters further on, a glimpse into the ascending colon is offered (right upper corner). (I) After passing the right flexure, a full view of the ascending colon. (J) In the middle of the ascending colon. Deep down, the end of the colon (cecum) can already be recognized. (K) Bauhin's valve: The entrance into the terminal ileum can be observed at the upper left corner. (L) A closer look on the end of the colon (cecum). Note the entrance of the appendix (center). *All from MITI.*

5.7.3 Autofluorescence Imaging Endoscopy

Fluorescence imaging is mainly used in microscopy. With endogenously or exogenously induced fluorescence, it is possible to visualize and quantify fluorescent markers distributed in tissue and to identify pathological lesions. Autofluorescence imaging (AFI) is based on the detection of natural tissue fluorescence emitted by fluorescent molecules (see Section 5.6.3: Optical Fluorescence Imaging). The overall fluorescence emission differs among various tissue types due to corresponding differences in fluorophore concentration, metabolic state, and/or spatial distribution [160].

In endoscopy, the principle of autofluorescence is mainly used in gastrointestinal diagnostic workup to detect diseases such as Barrett's esophagus, gastric cancer, and polyps. It also finds application during bronchoscopy.

In autofluorescence endoscopy, the tissue is excited by a short-wavelength light source that emits ultraviolet, blue, or green light. After the excitation, the fluorophores emit light of longer wavelengths. Autofluorescence endoscopy is based on the acquisition exclusively of this light, which is emitted by fluorescing molecules. Therefore, a CCD with a barrier filter is incorporated to exclude the excitation light and capture only the weak reflected autofluorescence.

There are autofluorescence imaging systems that postprocess the images and enhance them in real-time with pseudocolors. In this case, the image is composed of three parts: the total autofluorescence, exclusively the green reflectance, and exclusively the red reflectance light.

With AFI, it is possible to visualize and quantify fluorescent molecules distributed in tissue and to identify malignant tissue more easily because early cancer sites are better visualized (Fig. 5.49). Tissues may contain several fluorophores such as NADH, elastin, collagen, and flavin.

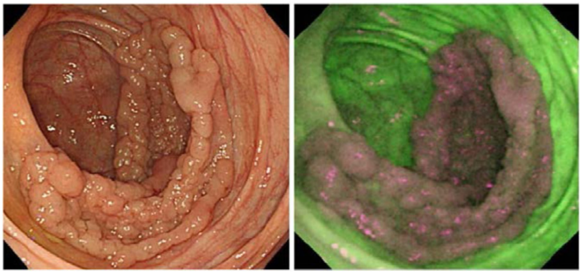


Figure 5.49 Comparison of white-light (left) and autofluorescence endoscopy (right) in depiction of cancerous tissue. *From Aihara H, Tajiri H, Suzuki T. Application of autofluorescence endoscopy for colorectal cancer screening: rationale and an update. Gastroenterol Res Pract 2012;2012:971383.*

Table 5.17 Key facts on AFI endoscopy

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Pulmonology Gastroenterology	High contrast without color markers High false positive detection rate	Improvement of image quality Trimodal imaging Smaller devices	FLIM Identification of distinct molecules and their concentration

Autofluorescence emission has been reported mainly with respect to collagen, which is distributed in the submucosal layer. By spectrally measuring the fluorescence of tissue, it is possible to learn about the relative concentrations and redox states of many molecules and the biochemical state of the tissue, which is not yet fully applied in medicine [162].

Strengths and Weaknesses

AFI provides a very high sensitivity in early-stage cancer detection. It allows the identification of areas of abnormality in the GI tract that may not be visible under white-light examination. Unfortunately, it has a high false positive rate, which makes follow-up testing necessary (Table 5.17).

Recent Developments and Current Research

The image quality of AFI still needs to be improved and the false positive rate needs to be decreased further. Additional enhancements are clearly desired in clinical applications, and may be achieved with computerized visualization [163]. The measurement of distinct fluorescence spectra and a resulting specialized analysis of the tissue and its diseases is a field of current research. Currently, autofluorescence endoscopes have a relatively thick outside diameter (up to 14.8 mm), which might limit maneuverability [161].

Recent developments cope with the introduction of fluorescence lifetime imaging (FLIM) in endoscopes. In 2013, a compact wide-field time-gated FLIM flexible endoscope was presented. It is capable of continuous lifetime imaging of up to three fluorescence emission bands simultaneously, but has not proven its clinical applicability until now [164]. In 2011, the first confocal FLIM endomicroscope for subcellular confocal imaging was demonstrated [165]. FLIM allows the characterization of the biochemical composition of tissue. Fluorescence of organic molecules is

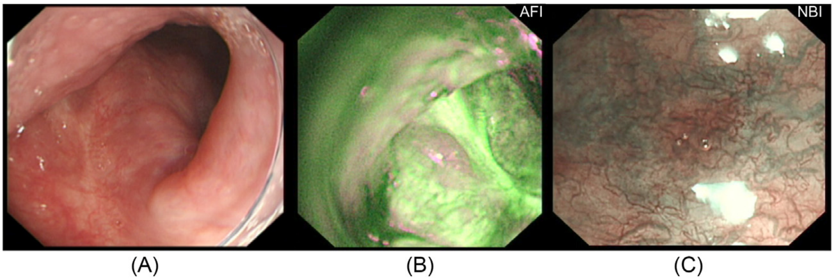


Figure 5.50 Olympus "trimodal imaging" (autofluorescence): (A) overview; (B) detection; (C) differentiation. *Courtesy: Prof. S. v. Delius, Klinikum rechts der Isar.*

not only characterized by the emission spectrum, it has also a characteristic lifetime. The lifetime does not depend on the concentration of the chromophore, and allows direct approach to all effects that involve energy transfer.

Combining AFI with other imaging modalities in one device overcomes the problem of the high false positive rates of AFI and necessary follow-up testing. Endoscopic trimodal imaging (ETMI) is a novel endoscopic technique that combines white-light endoscopy (WLE), magnification endoscopy, or high-resolution endoscopy (HRE) with AFI and narrow band imaging (NBI) [166]. Trimodal imaging endoscopes have the ability to switch between these three modalities (Fig. 5.50). Currently, ETMI is mostly applied in academic settings, but is expected to see use in the near future as a standard endoscopy technique in gastrointestinal pathology, with an emphasis on the diagnosis of early-stage gastrointestinal tract cancers [115].

5.7.4 Computed Virtual Chromoendoscopy/Narrow Band Imaging (NBI)

Computed virtual chromoendoscopy (CVC) is a technique that digitally enhances the contrast of images of the mucosal surface and highlights the vascular pattern without the need for dye spraying as in conventional chromoendoscopy.

CVC systems make use of the principle that different light spectra have different tissue penetration depths [167]. Thus, the analysis of images acquired by different light spectra allows early detection of small superficial mucosal lesions that are undetectable using conventional WLE.

It is mainly used in gastrointestinal endoscopy, bronchoscopy, for diagnosing bladder cancer during cystoscopy, and ENT medicine.

There are two approaches to CVC image acquisition. In NBI, light of varying spectra is sequentially emitted. However, there are also CVC systems that use normal WLE and reconstruct the images with enhanced contrast by estimating the different light spectra.

NBI endoscopes provide white-light examination and an NBI mode. In NBI endoscopy, the emitted light is directed through bandpass filters, which split the light into excitation wavelengths of blue light (390–445 nm) and green light (530–550 nm) (Fig. 5.51). The penetration depth before being scattered depends on the wavelength of the light. The shorter the wavelength (e.g., blue), the earlier it is reflected. Longer wavelengths (e.g., green) penetrate deeper [168].

The low brightness of the reflected light requires special high-sensitive dual-mode CCD chips. A video processor decomposes the light by its wavelengths and creates a composite pseudocolor image that is displayed directly on a monitor. In the resulting image, the superficial mucous layers are displayed in blue, the capillary network of the deeper submucosal layer in green.

This blue light is particularly useful for detecting tumors, which are often highly vascularized. The green light penetrates deeper than blue light. It is absorbed by blood vessels located deeper within the mucosal layer, and appears cyan on the NBI image. This wavelength allows a better understanding of the vasculature of suspect lesions (Fig. 5.52).

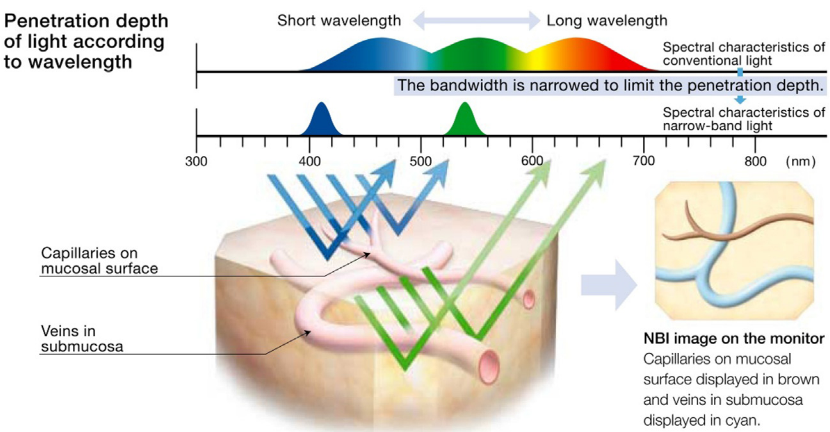


Figure 5.51 Narrow band imaging. *From Lukes P, Zabrodsky M, Plzak J, Chovanec M, Betka J, Foltynova E, et al. Narrow band imaging (NBI)-endoscopic method for detection of head and neck cancer. In: Amornyotin S, editor. Endoscopy. Rijeka: InTech; 2013.*

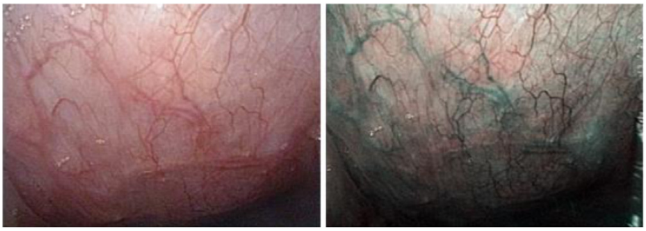


Figure 5.52 Mucosal blood vessels displayed in brown and submucosal vessels in cyan. The different colors indicate the different height. *Courtesy: Prof. S. v. Delius, Klinikum rechts der Isar.*

Table 5.18 Key facts on narrow band endoscopy

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Pulmonology Gastroenterology Otolaryngology	High contrast images of mucosal tissue and lesions Frequently false positive findings	Trimodal imaging Virtual image enhancement HD-CCD chips	Combination with other modalities and virtual image fusion

Narrow band imaging is applied in Olympus Narrow Band Imaging Systems. There are two further CVC systems available: the Fujinon Intelligent Color Enhancement (FICE) and the Pentax iScan. They reconstruct the video images virtually with special algorithms to improve the contrast.

Strengths and Weaknesses

NBI offers a significantly increased diagnostic accuracy compared to WLE and autofluorescence endoscopy. Blue light has less penetration and less scattering, thus enhancing image resolution. Image processing allows high contrast images without the usage of dyes, as would be the case in chromoendoscopy. Dye-sprays like methylene blue, used for polyp characterization, have the risk of possible DNA damage, which is avoided using NBI. Nevertheless, NBI can lead to false positive findings in some cases (Table 5.18).

Recent Developments and Current Research

Advances in CCD technology have resulted in smaller CCDs with an increased number of pixels and increased resolution.

As explained in the discussion of AFI endoscopy, NBI has high potential in combination with other imaging modalities. ETMI is a novel endoscopic technique that combines WLE, magnification endoscopy, or HRE with AFI and NBI [166]. Trimodal imaging endoscopes have the ability to switch between these three modalities. The combination of NBI with autofluorescence endoscopy overcomes the main disadvantages of each technique [115]. Using magnifying HDTV endoscopy in combination with NBI dramatically improves the sensitivity and specificity of endoscopic examination [167].

5.7.5 Confocal Endomicroscopy

Confocal endomicroscopy is a novel technology that enables real-time imaging at the cellular level by using miniature optical systems integrated into the tip of a small imaging probe or endoscope [169]. The term "optical biopsy" is sometimes used to underline that the resulting images previously could have only been acquirable using histological or cytological analysis; in contrast, no tissue is removed in confocal endomicroscopy. The most common endomicroscopy application is confocal laser imaging, which is described in more detail in Section 5.6.6: Confocal Laser Scanning.

Confocal endomicroscopy provides instantaneous histopathology during upper and lower endoscopy. The main applications currently lie in imaging of the gastrointestinal tract, particularly for the diagnosis and characterization of Barrett's esophagus, pancreatic cysts, and colorectal lesions. It also has high potential in the screening and surveillance of ulcerative colitis and gastric cancer [170].

In confocal endomicroscopy, a special confocal optical unit detects backscattered light alone at a precisely defined horizontal level (see Section 5.6.6: Confocal Laser Scanning). This produces high-resolution microscopic images, making it possible to assess structures up to the size of a cell nucleus. A resolution of 0.5–3.0 μm, an axial resolution of 3–10 μm, and a subsurface depth of 250–500 μm are possible in this manner [171]. In most cases, the fluorescein sodium is intravenously administered as fluorophore for subsequent excitation by a laser light, allowing cell structures to be easily identified. Either scan can be performed at the proximal end of a fiber bundle or the distal tip using a piezoelectric fiber scanner, a MEMS scanning device, or a technique called spectral encoding [172] (Table 5.19).

Table 5.19 Key facts on confocal endomicroscopy

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Gastroenterology Oncology	High resolution High contrast at certain depths Low penetration	Dual-axis confocal endomicroscopy New specialized molecular markers	Telepathology Introduction to new applications

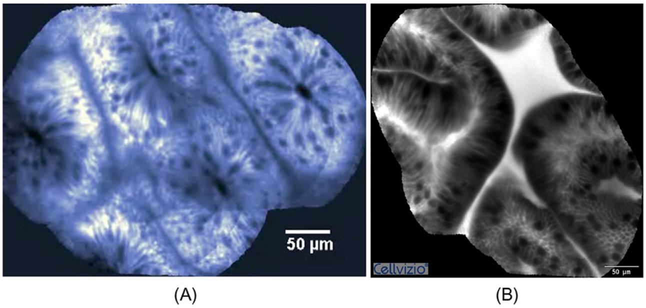


Figure 5.53 (A) Nonneoplastic Barrett mucosa of the esophagus; (B) normal, healthy mucosa of the colon. *Courtesy: Prof. A. Meining, University of Ulm.*

Strengths and Weaknesses

The confocal images have a very high resolution on the order of histology and can be acquired in vivo (Fig. 5.53). Therefore, it can guide excisional biopsies for a better diagnostic yield.

Although the depth resolution is very high, confocal endomicroscopy has, like most optical technologies, a very limited penetration depth [173]. Confocal endomicroscopy does not provide information about biological behavior either above or below the achieved depth, but cancer may nonetheless occur in deeper tissues. Moreover, horizontal cross-sections are an atypical view of the tissue when compared to traditional biopsy specimens that pathologists are accustomed to view. Hence, a specialist must be trained to interpret confocal endomicroscopy images [171].

Recent Developments and Current Research

There are various applications of confocal endomicroscopy that are still not used in the field of human medicine. In animal models of human diseases, confocal endoscopy has provided molecular imaging of cancer, functional imaging of altered perfusion in malignant and inflammatory disease by coupling fluorophobes to specific antibodies, and high-resolution in vivo morphological diagnosis [169]. Fields of ongoing research are the development of molecular markers for in vivo immunohistochemistry and the application of confocal microscopy to intraabdominal organs in humans. Confocal endomicroscopy is evolving as a novel technique for rapid intravital diagnosis of gastrointestinal neoplastic diseases at the microscopic level, and has the potential to allow molecular imaging in humans in the future [169].

Dual-axis confocal microscopy is seen as the major technological improvement of CLS, and is applicable in endoscopy. Dual-axis confocal endomicroscopy has the ability to perform deep 3D optical sectioning using simple and inexpensive optical components and light sources [173].

As a completely new application, confocal endomicroscopy could play a central role in the emerging area of telepathology.

5.7.6 Endoscopic Optical Coherence Tomography

The technical details of OCT are described in Section 5.6.2: Optical Coherence Tomography.

Endoscopic imaging probes are key devices for internal high-resolution OCT scanning of luminal structures and hollow organs. The modalities usually find application in early-state or precancer detection in the urinary and gastrointestinal tract, cardiology, and in examining other microstructural anatomy and features in places like the ears [174]. Other parts of the head and neck are also in the range of application—for instance, when patients are undergoing surgeries in the upper respiratory organs [174–176]. OCT is a powerful imaging technology because it provides real-time imaging in situ without the need for tissue excision like in conventional biopsy. OCT can be employed in capsule endoscopy, and a number of different devices have been introduced that can be distinguished by the case that encloses the technical components: rigid endoscopes such as biopsy needles, flexible endoscopic devices for uses like gastrointestinal imaging, and catheters for intravascular examinations [86,177]. The integration of OCT in clinical procedures benefits significantly from OCT being fiber-based. In situations where OCT finds application in a clinical environment, it is of high importance that the technical setup remains operational or that applicability can be restored within minutes after use or after it has been moved inside the hospital environment.

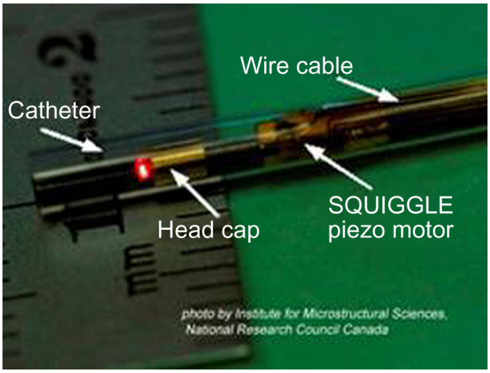


Figure 5.54 Stationary-fiber rotary probe with unobstructed 360 degrees view for OCT. *From Chang S, Murdock E, Mao Y, Flueraru C, Disano J. Stationary-fiber rotary probe with unobstructed 360° view for optical coherence tomography. Opt Lett 2011;36 (22):4392–4.*

As mentioned, OCT can be applied in rigid/flexible endoscopes to bring the high-resolution properties of OCT to internal imaging (Fig. 5.54).

Flexible endoscopic OCT has great potential, and is still finding application in many different fields of internal imaging. These fields extend from cancer diagnosis in the gastrointestinal and urinary tract and examinations of the respiratory organs to identify issues like reductions in gas exchange efficiency to intravascular imaging [86,179]. Rotary probes with a diameter of approximately 1 mm and a transparent housing are inserted into the ROI either noninvasively or invasively. In intravascular OCT, a thin flexible tube or catheter is pushed in and pulled back inside the artery [97]. As with the other devices, the catheter also has a small rotating tip from which the light is emitted in order to generate circumferential OCT images of the insides of blood vessels [178].

Biopsy needles are another way to enable transcutaneous micron scale OCT. They can be inserted into solid tissue and organs to allow imaging of their internal microstructures with minimal trauma [180]. They suit a variety of different applications in which transdermal OCT imaging is required, such as in mammographic cancer detection [86]. Biopsy needles for OCT usually consist of a needle-shaped housing defining a bore, in which an optical fiber is positioned. Parts of the needle housing are transparent to allow a beam director to emit light outward and receive the backscattered light. A motor or other actuating device again causes motion to move or rotate parts of or the entire optical fiber and beam director in order to allow a scanning of the specimen [181].

Strengths and Weaknesses

This technology is of special interest because of the high image and depth resolution provided by OCT imaging. This gives it advantages over standard endoscopy that can only visualize surface features, making it a valuable tool for detecting conditions like prevalent esophageal, stomach, and colon cancer [175].

Conventional procedures like MRI or US do not have a sufficient resolution to identify atherosclerotic plaque at an early stage [94]. OCT provides a resolution of approximately 10 μm [33], which is much higher compared to intravascular US [86], enabling it to provide additional structural information as seen in the images below [182,183] (Fig. 5.55).

Endoscopic OCT (EOCT) has also become a very valuable tool in gastrointestinal imaging, with a wide range of applications. One of the main advantages in most of its applications remains the fact that it can be used where excisional biopsy would be hazardous or impossible, providing information similar to that gained from histology [94] (Table 5.20).

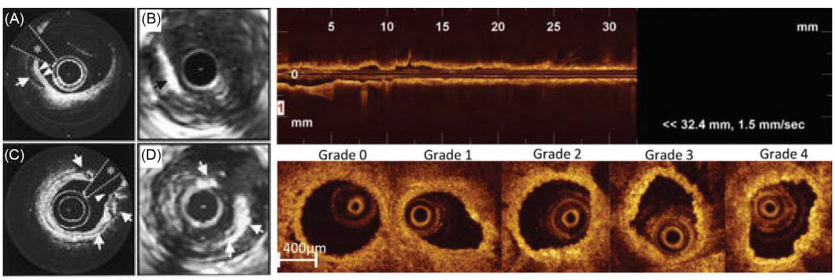


Figure 5.55 Comparison of intravascular US (left) and intraaorticoptical coherence tomography (right). *From Tahara S, Morooka T, Wang Z, Bezerra HG, Rollins AM, Simon DI, et al. Intravascular optical coherence tomography detection of atherosclerosis and inflammation in murine aorta. Arterioscler Thromb Vasc Biol 2012;32(5):1150–7.*

Table 5.20 Key facts on EOCT

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Cardiovascular medicine Gastroenterology Oncology	High resolution, wide range of applications Low depth penetration	High frame rates Better reconstruction	Integration of F-F OCT setup Miniaturization Avoidance of direct contact to the tissue

Recent Developments and Current Research

Catheter-based OCT has been made commercially available worldwide, and has found an active user base that is continuously increasing [33]. The latest devices that have been introduced allow imaging with frame rates up to 400 fps with a diameter at the tip of 1.1 mm. During ex vivo testing, complete 3D volumetric images of an entire coronary artery were achieved at a pull-back speed of 100 mm/s [95]. Furthermore, recent advances have been made in reconstructional algorithms, providing enhanced imaging of stent struts among other things [184]. Sophisticated data fusion methodologies with other imaging modalities to help further understanding of plaque characteristics and vessel pathophysiology are also of great potential [185].

The standard F-F OCT setup did not match miniaturization requirements for in situ needle imaging. Therefore, a new development has been introduced where an external interferometer processing the in-depth scan information is coupled with an internal common-path interferometer at the tip that collects the backscattering light from the tissue. This makes it possible to bring full-field technology into optical needle-biopsy, providing resolutions of almost 1 μm and revealing information about malignant tissue en-face and on a cellular level [186]. Other superminiaturized optical biopsy needles capable of acquiring 3D OCT images have also been demonstrated, and achieve an outer diameter of 0.31 mm by using an all-fiber probe. The astigmatism ratio was brought down to 1.8, resulting in a working distance of 300 μm and a depth-of-field of 550 μm [187].

Another current challenge in EOCT is the implementation of optics that avoid direct contact with inflamed tissue in imaging areas like the tympanic membrane. A possible approach to this problem could be an extended working distance by allowing manual adjustments in focus [174].

The high sensitivity and depth resolution might allow EOCT to substitute for several biopsy applications on a broad basis, and reduce the role of conventional endoscopy in general [188].

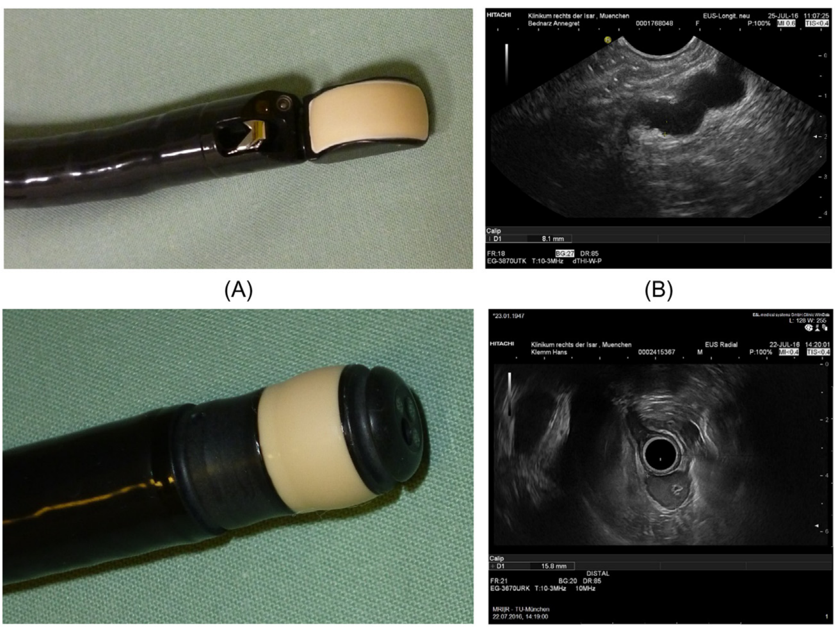
5.7.7 Endoscopic Ultrasound

Endoscopic ultrasound (EUS) is a technique combining endoscopy and US in order to obtain images and information from the digestive tract and the respiratory system and their surrounding tissue and organs [189]. EUS has the ability to identify the component layers of the bowel wall, which can be used for the staging of gastrointestinal cancer [190].

In addition to the evaluation of esophageal, gastric, and rectal cancer, EUS is mainly used for the assessment of pancreatic diseases, but other fields of application are under investigation [191]. Other uses of EUS include studying blood flow and guiding biopsies such as fine needle aspiration, in which tissue samples can be obtained by passing a special needle into tissue, lymph nodes, or suspicious tumors [192].

The technical principles of diagnostic US are described in Section 5.4: Diagnostic Ultrasound.

In EUS, the endoscope is inserted into the respiratory system or into the upper or lower digestive tract and the US transducer generates high-quality images of the organs inside the body [189]. EUS probes consist of a small US transducer, which is installed on the tip of an endoscope (Fig. 5.56). Two different designs are available. Linear probes consist of a number of transducers in multiple rows, providing a segmental image of the anatomy. Radical probes deliver a 360 degrees panorama of the anatomical environment. The endoscope has a flexible shaft with a central wire, which is responsible for rotating the mechanical transducer. It is surrounded by oil, which serves as an acoustic interface with tissue,



(A) (B) (C) (D)

Figure 5.56 (A) Tip of a linear EUS probe; (B) linear EUS image; (C) tip of a rotating scanner; (D) radial EUS image. *All from MITI.*

providing 360 degrees imaging perpendicular to the axis of the probe. Depending on the purpose, EUS probes range from 2 to 2.9 mm in diameter for miniature probes applicable through the endoscope working channel to 12 mm for echoendoscopes, 12 to 30 MHz in frequency, and 170 to 220 cm in length [193].

Strengths and Weaknesses

Images obtained by EUS are more accurate and more detailed than those obtained by conventional US due to the proximity of the EUS transducer to the tissue of interest. EUS offers further a high accuracy in detecting small lesions and assessing the size of tumors, and helps the surgeons to determine the extent of spread of certain cancers [189].

Recent Developments and Current Research

EUS is a relatively new diagnostic tool and is still in its development stage (Table 5.21). Research concerning EUS involves increasing US image quality and finding more sophisticated interventional endoscopic devices [194]. A recent development is the combination of real-time elastography with EUS. This relatively new technique allows the evaluation of tissue stiffness with the intent of better characterizing lesions during EUS examinations [195].

In the future, endoscopy is expected to become even more relevant. Numerous technological enhancements and a general trend in medicine toward minimally invasive diagnostics and surgery support the growing relevance of endoscopy and EUS.

5.7.8 Wireless Capsule Endoscopy

Capsule endoscopy is a technology that uses a swallowed video capsule to take photographs of the inside of the gastrointestinal tract: examinations of the esophagus, stomach, colon, and the small and large intestines are the main applications. Conventional endoscopes are inserted transorally or

Table 5.21 Key facts of EUS

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Gastroenterologic and pulmonary oncology	Accurate and detailed images High penetration depth	Combination of real-time EUS and elastography	Increasing image quality More interventional devices

transanally, which can be undesirable for the patient, especially as the small intestine can be very difficult to reach during a classic endoscopic examination. Wireless capsule endoscopes (WCE) are rapidly emerging devices that help to overcome the possible discomfort of oral or anal insertion from a classic endoscope and allow easier access to narrow parts in the gastrointestinal tract. The first capsule endoscopes were developed in the middle of the 1990s and were approved for clinical use at the beginning of the 21st century [196]. Since then, they have emerged to be the gold standard in evaluating diseases in the small intestine [197], but WCEs are also suited for investigating other parts of the gastrointestinal tract. In terms of application, the most common indications include bleedings in the gastrointestinal tract and Crohn's diseases, but cancer detection, especially in the small intestine, is also possible.

The capsule has a size of around 26 mm × 11 mm [196]. The essential components are inside an ingestible coating with an optical dome, behind which LEDs are situated to provide the necessary lighting. An image sensor translates the signals acquired through a short-focus lens, which are later processed by a microcontrol unit (Fig. 5.57).

The information is then transmitted via a radiofrequency transmitter to electrodes placed on the abdomen of the patient. Finally, the images are stored in a receiving box as seen in Fig. 5.58. The necessary energy comes from a cell battery inside the capsule [199].

At the beginning of the procedure, the capsule is swallowed by the patient after the receiving sensors are placed on their abdomen and

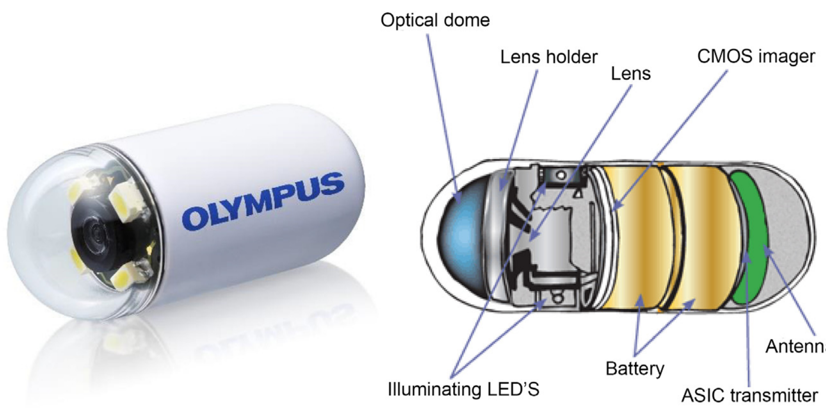


Figure 5.57 Small intestine capsule endoscope. *From Olympus Press Center. Small intestinal capsule endoscope. Available from <https://www.olympus.de/corporate/de/press_centre/press_releases/medical/small_intestinal_capsule_endoscope_.jsp?view = img>; 2013 [accessed 23.09.16].*

Figure 5.58 Capsule endoscope image receiving box. *From MITI.*

connected to the data recorder. The capsule travels through the whole gastrointestinal tract, driven by peristalsis. During that time the patient can move freely and continue with his/her daily routines. Of note, 50,000–60,000 digital images are acquired and sent to the data recorder worn around the chest. The images are then analyzed in a workstation after the patient returns to the clinic. The capsule is disposable and usually passes out of the patient's gastrointestinal tract unnoticed. It is possible to apply the procedure in children as young as 2 years old [196].

Real-time imaging is also feasible [200], but in WCE only 2D images are acquired. Therefore, 3D reconstruction algorithms are employed in order to gain 3D information and display of the wall of the gastrointestinal tract. One possible approach is reconstruction using the so-called shape from shading technique [201], where surface and depth information are extracted from differences in gray shades [202]. It can be applied even if as little information as only one picture is available [203].

Strengths and Weaknesses

WCE overcomes the problem of conventional tools not being able to conveniently explore the complete gastrointestinal tract [201], especially

Table 5.22 Key facts on WCE

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Gastroenterology (especially the small intestine)	Increased patient comfort Accesses difficult Low energy supply Low frame rates	Introduction of first locomotion	Wireless power supply Energy saving components Better locomotion

the small intestine, where conventional endoscopy carries the risk of intestinal perforation and cross-contamination. The procedure is completely pain-free for the patient and is considered rather safe with a complication rate of 1–3%. The most feared complication is capsule retention [204], which can theoretically lead to the need for surgical removal [197] (Table 5.22).

The disposability of the capsule has the advantage of improving hygiene. In conventional gastrointestinal screening, sterilization can be a major concern if the same endoscope is used in multiple persons.

Compared to conventional endoscopes, the low frame rate of 2–18 fps, low image resolution, and limited working time due to the constraints in energy supply are limiting factors [199]. The battery cells shorten the working time to approximately 9 hours [205] and influences the choice of inherent components such as the image sensor. CMOS is often the sensor of choice over the more light-sensitive CCD sensors due to its lower power consumption [206]. Probably the biggest limitation is that WCE is a purely diagnostic tool, and cannot be used to perform procedures like biopsies [196]. Some similar technologies in the form of ingested capsules have begun to make approaches toward biomonitoring and smart drug delivery [58].

Recent Developments and Current Research

The limited power supply is still a bottleneck for capsule endoscopes and their performance [199]. Wireless power supply could offer a promising solution and might help to increase performance by allowing for the integration of high power components which would increase resolution [207]. There have been several approaches to energy savings in WCE, like processor steered shut-down times that would allow image acquisition to be paused while the capsule passes an area of lower interest for the procedure in question. Different inventions have been introduced in recent years that could potentially help to overcome problems with necessary power transfer in capsule endoscopy. These approaches show an efficiency in voltage and power transmitted of 82.14% and 83.50%, respectively [208]. Improving the quality factor of the coils employed might effectively increase the system's efficiency.

On the other hand, a tethered capsule endoscope employing OCT has recently been introduced. The capsule is mainly suited for imaging the esophagus, after which the capsule reaches the stomach driven by nothing but peristalsis and can be pulled out using the elastic tether. The images are superior to other high-resolution devices and tethered capsules could provide a possible cheap alternative for dischargeable capsules with enhanced image quality [209].

These developments go hand in hand with the necessity of finding approaches for capsule locomotion [199]. The capsule previously traveled passively using natural peristalsis. Therefore, the position of the device and the imaging of the area of interest could not be controlled. Active locomotion inside the gastrointestinal tract is very difficult to achieve because the tissue is soft and viscoelastic.

However, a number of innovations have been introduced that enable capsule steering and navigation. For instance, the Fraunhofer Institute for Biomedical Engineering in Sulzbach/Germany has introduced a magnetic steerable capsule in cooperation with their industrial partner, Given Imaging Ltd., from Yokneam/Israel. The imaging capsule was partly filled with a magnetic material and can be remotely controlled from the outside with a complementary magnetic paddle. In initial tests, it was possible to control the imaging time inside the esophagus from only a few seconds up to 10 minutes. Further, almost 80% of the stomach walls were imaged, which has never been possible using conventional capsules. Steering brings the additional advantage of imaging at multiple angles and obtaining close-ups of the areas of interest.

Engineers are working continuously to overcome a number of challenges associated with these devices [189]. With further approaches in active locomotion, the development of a microrobotic capsule capable of conducting microsurgeries and biopsies could be possible, ultimately replacing conventional capsule and tube endoscopes [199].

The 50,000 images acquired during one examination create another problem, making the analysis of the results a very time-consuming task [201]

Figure 5.59 Very high volume of high-quality visual information. The evaluation is time-consuming and tedious for the physician. Decreasing attentiveness makes it mistake-prone. *From MITI.*

(Fig. 5.59). Therefore, algorithms are being introduced to detect automatically anomalies, such as bleeding, during WCE examinations [210] (Fig. 5.60).

Research for improving pixel resolution, frame rate, and video capture facility is also on the rise, and developments will significantly benefit from further emerging microelectronics [189]. Ongoing research is also being carried out to improve application in colon cancer detection [205].

Furthermore, it has been shown to be possible to apply chromoendoscopic imaging to magnetically steered capsule endoscopy, which could have great impact on enhancing the visibility of mucosa irregularities [211].

Capsule endoscopy has great potential for the future. Patients' preference for this procedure over conventional endoscopy and technological opportunities support the rising relevance of capsule endoscopy in the future [212].

Last but not least, one additional weak point of the capsule has to be eliminated. They still lack the ability to provide insufflation. The colon, in particular, is very difficult to explore if the lumen is not distended for a

Figure 5.60 Future colon cancer screening? A scenario like this one is very improbable. It is assumed that the diagnostic workup will soon be carried out by advanced image processing and interpretation. *Courtesy: PD Dr. M. Kranzfelder, Klinikum rechts der Isar.*

clear view of the internal wall. First approaches were published to use biocompatible effervescent chemical reactions to convert liquids and powders carried on board a capsule to gas [213].

5.7.9 Conclusion

Endoscopy is a field that has undergone a high level of technological development in recent years, and innovations promise to even improve the capabilities of endoscopy significantly in the near future. These technological improvements are very multifaceted. Advances in semiconductor technology have allowed detectors to become miniaturized, and have led to the development of video endoscopes and wireless capsules. The addition of US technology to endoscopy has allowed structural information to be collected beyond the tissue surface to depths of several millimeters and even into adjacent tissue structures. New methods are being developed to elicit even more diagnostic information from tissue. OCT and confocal endomicroscopy provide morphologic information with subcellular resolution for real-time histopathology. Autofluorescence endoscopy reveals biochemical and molecular information below the tissue surface. WCE provides images from previously unattainable regions such as the small bowel. Finally, virtual chomoendoscopy enhances the images of videoendoscopy and brings the visualization to a higher level.

5.8 HYBRID SYSTEMS

Various medical imaging technologies can be integrated with other units and principles. In medical visualization, a hybrid system combines two or more technological principles to operate jointly [214] in order to overcome problems and limitations from individual systems [215]. One example has already been presented in form of EUS (see Section 5.7.7: Endoscopic Ultrasound). For instance, US has been proven highly effective in medical applications. The information detected by the acoustic sensor is transmitted by optical fiber, which makes US flexible and easily combinable with several endoscopic instruments. It has a high penetration depth and already provides high resolutions for internal examinations, but its resolution is inferior to other fiber optic-based imaging systems [216]. SPECT/MRI and PET/MRI scanners are similar examples. In the following section, hybrid systems of interest, their characteristics, and performance data will be presented. The systems mainly offer a high application potential and research opportunities, and are being examined for this reason (Table 5.23).

5.8.1 Real-Time Virtual Sonography

Real-time virtual sonography (RVS) is a new fusion technique that combines the use of an US B-mode image with MRI or CT images in real-time by using a magnetic positioning system in order to achieve identical cross-sectional images [217] (Fig. 5.61).

The RVS system includes a magnetic positioning sensor that is fixed on the probe of the US scanner in order to create images with identical cross-sections in real-time. The achieved images are compared to the previously acquired CT or MRI volume data with due regard to the position and the angle of the probe. It is necessary to transfer the CT or MRI

Table 5.23 Overview of hybrid diagnostic systems

Hybrid OCT-US	Assessed
RVS	Not assessed
SPECT/MRI	Assessed
PET/MRI	Assessed
SPECT/CT	Assessed
X-ray/MRI	Assessed
Microscope Integrated OCT and OCM	Not assessed
Integrated OCT and Positron Detection	Not assessed

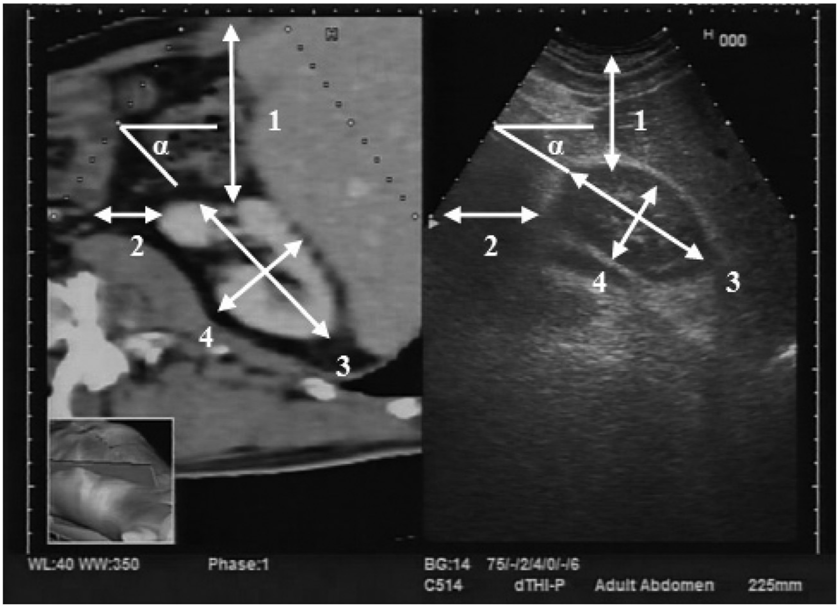


Figure 5.61 CT-navigated US: The actual US slice (right) is correlated with the respective CT image by electromagnetic tracking (see Section 5.4: Diagnostic Ultrasound). *Courtesy: PD Dr. M. Kranzfelder, Klinikum rechts der Isar.*

volume data to the US system to display virtual images, either wirelessly or with a cable connected to the computer system. The magnetic sensor detects the changes in location, direction, and rotation of the probe during normal US scanning of the patient. The workstation monitor displays two images: the US real-time image and the virtually reconstructed CT/MR image. Currently, there are only a few systems available on the market, such as Hitachi's RVS.

Strengths and Weaknesses

RVS combines the advantages of US imaging and CT/MR imaging. In consequence, RVS has an increased diagnostic confidence and offers a direct comparison of lesions using different imaging modalities, a more precise monitoring of interventional procedures, and reduced radiation exposure (Table 5.24).

One disadvantage of RVS is the magnetic positioning sensor unit itself. It provides steady state interruptions, a low scan efficiency and signal saturation. Another limitation shows up because the software and hardware integrations of these two modalities are not yet fully exploited.

Table 5.24 Key facts on RVS

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Gastroenterology Cardiovascular medicine	Increased diagnostic precision Low scanning efficiency	Clinical application Training and education	Motion correction Guided biopsies

Recent Developments and Current Research

Currently, RVS is not yet common in medical use, but this technique could potentially become relevant for examinations of the GI tract and to provide more reliable abdominal sonographic images. Another possible function for future development is using this hybrid system for motion correction in different organs, fusing anatomic hemodynamic and perfusion images, and for image-guided biopsies.

5.8.2 Positron Emission Tomography/Computed Tomography

PET/CT offers additional information to correct attenuation, to precisely localize lesions, and therefore to optimize medical procedures. PET/CT is mainly applied for cardiologic and oncologic issues [65] (Fig. 5.62).

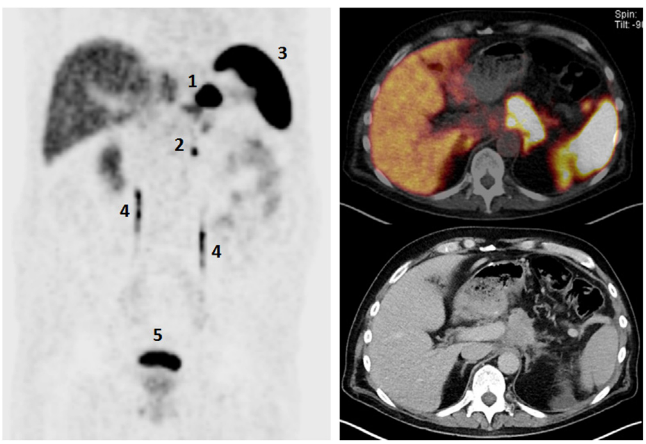


Figure 5.62 Neuroendocrine tumor of the stomach (Ga-68)-DOTANOC PET-CT, pT4a, pN0 (0/14), pL1, pV1, G2 (Ki67: 12%): 1, primary tumor, 2, lymph node metastases; 3, spleen, 4, ureters, 5, urinary bladder. *Courtesy: Prof. R. Braren, Klinikum rechts der Isar.*

Table 5.25 Key facts on PET/CT

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Oncology	Attenuation correction of PET images Short examination times Better localization of lesions	n/a	Improved components New radiotracers

PET/CT combines anatomic CT data with functional or metabolic information given by the PET. In this case, CT images are helpful for correcting the attenuation of the PET data. In conventional PET scanners, the attenuation is corrected by using data from a radioactive transmission source similar to CT tubes. However, the photon flux is lower than in CT tubes. If the CT scan is only used as a support of the PET findings, it is performed as a "low dose" CT. Self-evidently, diagnostic PET/CT combinations are also available.

Strengths and Weaknesses

Using a combination PET/CT instead of performing both examinations separately not only offers anatomic and functional or metabolic information at the same time, but also results in shorter examination time and provides additional information on the location of abnormalities, which creates diagnoses that are more accurate. Shorter examination times also help to use the fast-decaying PET radiotracer more efficiently (Table 5.25).

Recent Developments and Current Research

Recent as well as future developments deal with improvements in radiotracers and system components, such as different detector materials and newer electronic designs. All this can improve the speed of image acquisition and the spatial resolution. The discovery of new radiopharmaceuticals can help to expand the field of application for PET/CT into areas like the diagnosis of infections.

5.8.3 Single-Photon Emission Computed Tomography/Computed Tomography

SPECT/CT offers synergies of functional and anatomic information (Fig. 5.63). In addition, it allows precise anatomic localization of radioactivity foci. SPECT/CT is mainly applied in oncology, cardiology, and for the diagnosis of bone lesions and infections.

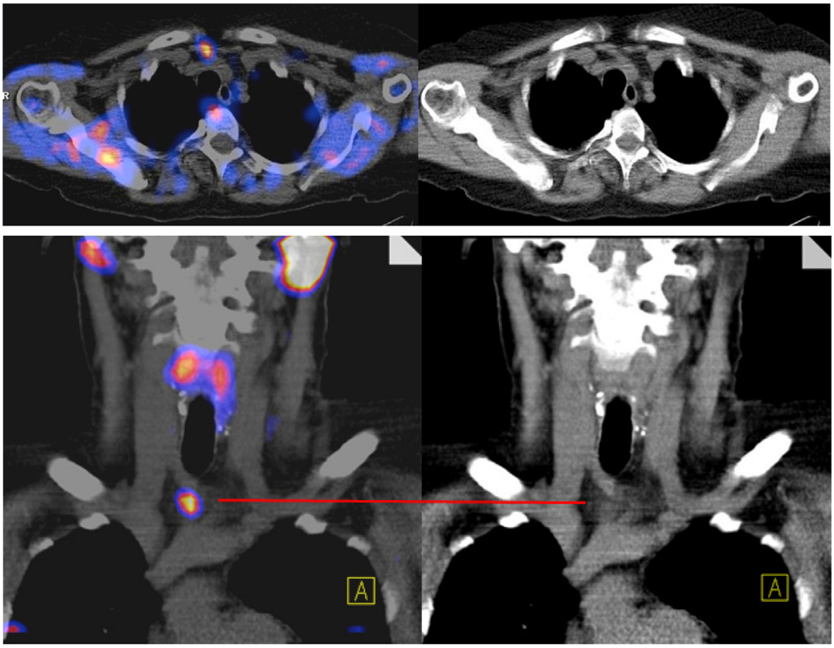


Figure 5.63 Neuroendocrine tumor of the neck in the transverse (above) and coronary plane. Normal CT on the right, SPECT on the left. The active lump is clearly visible on SPECT (red bar, gray bar in print, marks the corresponding site). *All: Courtesy: Prof. K. Scheidhauer, Klinikum rechts der Isar.*

Characteristics of the Modification

An integrated SPECT/CT system allows the sequential acquisition of SPECT and CT data in a single examination. As in PET/CT, the CT data are used for attenuation correction of the SPECT data.

Strengths and Weaknesses

The major advantage of SPECT/CT is the improved localization and diagnostic certainty for a wide spectrum of applications. Further advantages for patients and physicians arise from the seamless acquisition of anatomical and functional image data. As a result, SPECT/CT minimizes the logistical delays and consequently improves the image attenuation correction. A benefit is the immediate availability of complementary image information.

Limitations include the sequential acquisition of CT data and then SPECT data. Because of the patient's movements, misregistrations can occur, which leads to artifacts in the corrected images. There is

Table 5.26 Key facts on SPECT/CT

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Oncology Cardiovascular medicine Orthopedics	Combination of CT and SPECT information Minimized logistical delay Movement-sensitive	n/a	Dose reduction Increased resolution Introduction to further applications

also the fact that additional radiation exposure is caused by the CT component.

Recent Developments and Current Research

Future developments for SPECT/CT include the possibility for patients to undergo a full diagnostic procedure at a single location, as well as continuously reduced radiation exposure. It is expected that the use of SPECT/CT in clinical practice will continue to gain importance as areas of clinical application increase in the future (Table 5.26).

Recent developments in detector technology offer the potential for a better spatial resolution and energy resolution, while the stability is greater and devices are more compact. But these new detectors have to be implemented into newly designed systems.

5.8.4 Positron Emission Tomography/Magnetic Resonance Imaging

PET/MRI combines metabolic and molecular information of PET with excellent anatomic details of MRI systems to enhance the image quality. PET/MRI is applied for cancer in areas of the brain, neck, and pelvis, which require a good distinction between diseased and healthy tissue due to their complex anatomic structure [65].

The usage of PET/MRI, especially in an integrated system, depends on the development of components that avoid deleterious interactions caused by high magnetic fields of the MRI scanner and RF interference between the MRI and PET systems [69] (Table 5.27).

Table 5.27 Key facts of PET/MRI

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Oncology	Enhanced image quality Revealing further structural information Shorter examination time	Introduction to clinical practice	Improved components New radiotracers

Strengths and Weaknesses

A PET/MRI system can help to improve diagnoses and to monitor treatments due to the combination of information and the resulting image enhancement of both systems. It provides intricate structural details compared to CT scans, especially in imaging soft tissues. If the PET system is fully integrated in an MRI system, examination times can be shorter because there is no need to move patients from one system to the other. Compared to PET/CT, the radiation dose is lower in PET/MRI [65].

Disadvantages from the view of the operators are the relatively high costs of PET/MRI systems [69].

Recent Developments and Current Research

Recent developments have integrated PET/MRI into clinical settings. In 2010, Philips introduced a system of a 3 T MRI system and a high-resolution PET scanner with an integrated rotating table, which allows sequential image acquisition by moving the patient from one machine to the other. The first integrated PET/MRI scanner was introduced by Siemens in 2011, which is able to do simultaneous whole-body MRI and PET scans. This system combines a 3 T MRI system with a PET scanner [65].

5.8.5 Single-Photon Emission Computed Tomography/Magnetic Resonance Imaging

SPECT/MRI offers images that combine the high spatial resolution given by MRI and the high sensitivity of SPECT. However, the implementation of an integrated SPECT/MRI scanner has not yet happened in clinical practice due to the incompatibility of SPECT components with magnetic fields.

Due to the incompatibility of SPECT components like PMTs and electronics with magnetic fields, SPECT/MRI is still under development. However, semiconductor detectors have been used in preclinical settings that show insensitivity to magnetic fields of up to 7 T, and could have high application potential.

Strengths and Weaknesses

The main advantage lies in combining the strengths of both imaging techniques. SPECT offers a high sensitivity and the ability to display multiple biological processes through energy discrimination, while MRI involves high contrast of soft tissue and sensitivity to tissue alterations. Unlike the hybrid method of SPECT/CT, SPECT/MRI uses only the ionizing radiation that appears in view of SPECT (Table 5.28).

Limitations of SPECT/MRI are similar to those of PET/MRI, and affect the compatibility of SPECT components inside higher magnetic fields.

Recent Developments and Current Research

Recent developments include new findings in detector technologies like semiconductor detectors to overcome the problem of incompatibility. To make SPECT/MRI possible for clinical settings, further research into magnetic field-insensitive SPECT devices has to be done. However, researchers recently developed a stationary ring-type SPECT prototype in a preclinical setting that is compatible with MRI. All the components used in this prototype are made of nonferrous materials. The detector of this system is a solid-state detector. However, todays developments are still far away from the range of clinically usable SPECT/MRI systems, although work is in progress to produce the first prototype [218].

Table 5.28 Key facts on SPECT/MRI

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
n/a	Enhanced image quality Reveals structural information Technology not yet mature	MRI-compatible Introduction of prototypes to preclinical setting	Development of improved devices Introduction to clinical practice

5.8.6 X-Ray/MRI

The X-ray/MRI system (XMR) is a fusion of X-ray fluoroscopy and MRI. It enables the simultaneous acquisition of information on anatomic structures and functional processes within the body. XMR is still under research and not commercially available. However, it will have a medium-high impact on preclinical settings in the next 4 years [219]. In the future, it could be helpful for navigated medical interventions like catheter-based procedures in cardiology or brain biopsy in neurology.

The system basically consists of the same components as the individual technologies. An X-ray tube and detector, which are compatible with MRI systems, are arranged in a bore of a magnet. The detector used in XMR is a digital flat panel detector (Table 5.29).

Strengths and Weaknesses

The main advantage of this hybrid system is the combination of the strengths of MRI, such as the flexible selection of planes, the excellent soft-tissue contrast and functional information, with those of X-ray fluoroscopy, such as the excellent display of anatomic structures, and the creation of high-resolution projection images. The integration of both systems into one enables a rapid switch between imaging modalities without moving the patient. This reduces examination times.

The weaknesses of XMR arise from its novelty. Current X-ray components like image intensifiers or rotating anode X-ray tubes are not yet compatible with magnetic fields.

Table 5.29 Key facts of XMR

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Potential applications are catheter-based procedures in cardiology and GI surgery	Combination of strengths of both technologies Shorter examination time	n/a	High research potential in the development of more devices, which are compatible with magnetic fields

Recent Developments and Current Research

Because of the novelty of XMR, any potential impact on diagnostic and interventional procedures requires further research. To adopt XMR into routine care, it is necessary to develop a wider range of devices and monitoring equipment that is compatible with magnetic fields. This is the fundamental requirement for accessing the true impact of XMR systems.

XMR is currently under research and only applied in preclinical settings. It is expected to be of greater relevance in the future, especially in neurology and oncology.

5.8.7 Integrated Optical Coherence Tomography Ultrasound Imaging System

OCT-US is an integrated dual modality that combines optical components with an US transducer, enabling OCT and US imaging at the same time. This hybrid modification has recently successfully been tested under experimental conditions (animals).

Characteristics of the Modification

The consequences of atherosclerosis are one of the major causes for morbidity in developed countries. In contrast to common imaging methods for diagnostic purposes like MRI and CT, OCT-US not only reveals the shape of arterial lumen—which can remain unaffected until the final stages of the disease—but provides direct tomographic cross-sectional images of the vessel wall [220].

Strengths and Weaknesses

The two imaging modalities, US and OCT, provide complementary information. OCT adds highly detailed resolution to the high penetration depth of US, allowing real-time 3D imaging (Table 5.30).

Table 5.30 Key facts of OCT-US

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Cardiovascular medicine	Fine resolution High penetration rate Cross-sectional images of vessel walls	USCT/warm bath US	Optimization of 3D reconstruction algorithms Increase of image quality

Recent Developments and Current Research

Research on clinical applicability is currently being carried out. Current devices achieve axial and lateral resolutions of 10–20 μm with OCT and 38–400 μm with OCT-US [221] with a maximum outer diameter of 1.18 mm. OCT-US improves diagnostics for intravascular diseases and has the potential to replace common technologies like MRI and CT in this particular field [220]. In vitro 3D imaging of human arteries and in vivo imaging of atherosclerotic microstructure in a rabbit abdominal aorta has been achieved using this technology.

OCT-US is expected to gain further relevance as a superior and highly specific imaging modality. As it matures and is adapted, its relevance can be expected to rise.

5.8.8 Integrated Optical Coherence Tomography and Positron Detection

Integrated OCT and positron detection is a means of combining OCT with a common imaging modality. These probes allow simultaneous OCT and scintillator proton detection.

Regular PET, such as for the purposes of ovarian cancer diagnosis or detection of intravascular plaque or cancer, usually provides low resolution and often does not offer detailed information about malignant tissue. This novel hybrid imaging modality consists of multiple scintillating fibers and an OCT probe, allowing simultaneous OCT scanning and positron detection [222]. It can be designed in the form of a catheter and can be used in intravascular as well as during interventional procedures.

Strengths and Weaknesses

This hybrid imaging modality provides a combination of 3D volumetric OCT imaging and information gathered from positron detection, which helps to overcome problems in distinguishing between signals from early-stage cancer and healthy tissue as well as in localizing lesions. Prototypes offer both structural and functional information in surroundings with high radiotracer uptake [223].

Recent Developments and Current Research

Recently, initial ex vivo studies have been obtained after a variety of animal testing. The feasibility of detecting ovarian cancer at an early state using this technique has been proven [222]. Positron detectors with optical coupling between optical and scintillating fiber have been developed in order to reduce the SNR. There is a potential role for this hybrid imaging modality in intraoperative application, as well as in early-stage cancer detection. Current research is also focusing on designs for application fields other than detection of ovarian cancer, such as endoscopic diagnosis in laparoscopy [224].

5.8.9 Microscope Integrated Optical Coherence Tomography and Optical Coherence Microscope

Integrated OCT and microscopy (MIOCT) combines different microscopes with interferometry-based coherence tomography, providing microscopic resolutions with OCT depth scan information. There is also the possible integration of interferometry directly into microscopic devices, creating a so-called optical coherence microscope, or OCM [225].

Characteristics of the Modification

This hybrid modification finds use in both intraoperative and general pathologic applications, such as tumor excision and ophthalmologic operations, as well as in other tissue imaging, such as endoscopy for gastrointestinal investigations [226]. As mentioned earlier, the fiber optic-based OCT can be placed in the optical path of a microscope, a technique referred to as OCT mounted microscopy that allows simultaneous image acquisition [227]. The principle of interferometry, employed in OCT, is also brought directly into microscopic imaging [226].

Strengths and Weaknesses

MIOCT and OCM can provide complementary information. It combines cellular sensitive imaging with depth resolution to generate real-time 3D information. The images obtained can have resolutions greater than 1 μm axially and 0.5 μm transversally [92], yet current devices reach acquisition rates of 210,000 A-scans per second with an axial resolution of 4.2 μm and a transversal sensitivity of 2.9 μm [225].

Recent Developments and Current Research

MIOCT has passed testing on clinical applicability and has found its way to a wide range of applications such as intrasurgical use, which expands as this quickly developing technology is being improved [228–230]. Current devices have not been able to leverage advances in molecular-targeted contrast agents. MIOCT is undergoing research and might reach molecular sensitivity, providing structural information about the tissues examined as well as their pathological state [231].

Two sample market and technology assessments are being conducted. It is intended to underline the differences and similarities between the original modification and the hybrid systems, as well as drawing the attention to their potential and possible specificity.

5.9 INTRAOPERATIVE DIAGNOSTIC PROCEDURES

Intraoperative decision making is based upon the knowledge of preoperative findings (e.g., CT, US, MRI) and the actual findings and conditions while doing the surgery.

In some cases, however, it would be helpful to perform diagnostic imaging in the acute surgical situation either to "refresh" the preoperative findings or to get new information upon the actual conditions [232].

Intraoperative US is the most popular intraoperative diagnostic tool for the surgeon at the time being.

Intraoperative radiography is older than US, but it certainly lost importance over the past decades. Modern variants of X-ray application, however, seem to have gained a new role in intraoperative imaging in vascular surgery.

5.9.1 Ultrasound

Intraoperative ultrasonography (IOUS) has been established for almost 30 years. Primarily, it was introduced to detect pathological findings which had not been revealed during preoperative imaging (metastases, lymph nodes, general tumor staging). IOUS had a significant impact upon intraoperative changes in surgical strategy [233]. Even today, after considerable advances in preoperative diagnostic imaging, IOUS still plays a major role [234,235].

A large variety of specially designed intraoperative US probes is available both for open and laparoscopic surgery (Fig. 5.64).

5.9.2 Conventional Radiography (C-Arm)

Intraoperative radiography is the oldest imaging modality in surgery. In the beginning, radiographic cassettes were placed beneath the patient to produce an image. Later on, dynamic fluoroscopy using a C-arm was

Figure 5.64 (A) IOUS probes in laparoscopic use; (B) IOUS in open liver surgery; (C) laparoscopic IOUS. *All from MITI.*

Figure 5.65 C-arm positioned for intraoperative cholangiography. *From MITI.*

introduced. The key domain of intraoperative radiography is orthopedic surgery. However, it is also still in use in visceral surgery. The most common application is intraoperative cholangiography, i.e., the examination of the bile duct (Fig. 5.65).

Highly informative images are provided in real time (Fig. 5.66).

If intraoperative fluoroscopy has to be considered, special care should be taken to select the right OR table. It has to be translucent at the area where the X-rays have to be taken.

This spot should be accessible for the C-arm.

5.9.3 Isocentric Radiography

A normal C-arm can be rotated manually to provide X-ray images of the object in two planes. Due to the construction, the arm does not move in a perfect semicircle but the orbit resembles an egg shape.

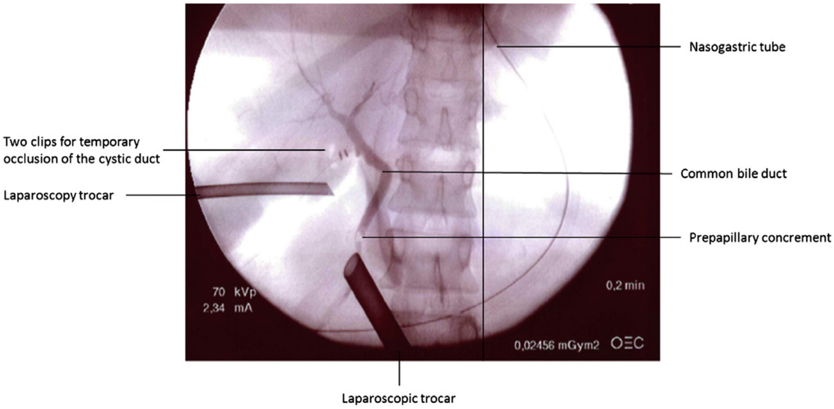


Figure 5.66 Intraoperative cholangiography during laparoscopic cholecystectomy: a catheter is inserted via the cystic duct stump into the common bile duct. Though the common bile duct is not dilated, a small biliary stone can be seen in the distal duct. *From MITI.*

If the device is designed as an "isocentric" C-arm, the central X-ray remains in the isocenter of the object independent of the actual position of the arm. The distance of the X-ray tube and the image intensifier is always constant. Thus, by continuous (automatic) rotation around the object a series of images can be produced which serve as a basis to create a real 3D data set, similar to CT.

5.9.4 Intraoperative Volume Data Acquisition

The SIEMENS ARTIS pheno is an isocentric C-arm which is moved by a KUKA robot into the appropriate position. The multiaxis robotic arm is floor mounted. The Syngo DynaCT is a special imaging procedure which creates a 3D data set from a series of images and projections acquired as the X-ray tube and the detector rotate around the patient (Fig. 5.67).

Currently, the system is mainly used in vascular surgery (hybrid ORs) and spinal surgery [236]. However, its usability has already been proven in visceral surgery [237–239].

5.9.5 Intraoperative Computed Tomography/Magnetic Resonance Imaging

Prior to the era of 3D arms, CT machines or MRI were established in the OR to gain intraoperative information. Despite some technical improvements (e.g., open MRI), intraoperative examinations remained

Figure 5.67 Robotically positioned isocentric C-arm. *From © Siemens Healthcare GmbH.*

difficult, interrupting the normal workflow significantly. Nonetheless, some groups found it valuable enough to do intraoperative CTs or MRI regularly, mainly in neurosurgery [240]. In visceral surgery, intraoperative CT/MRI did never play a role.

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CHAPTER 6

Classical (Open) Surgery

6.1 "CLASSICAL" SURGICAL INSTRUMENTS FOR CONVENTIONAL SURGERY

Surgical instruments have a very long history but those currently in use were mostly developed in the relatively short era of scientific surgery. They often bear the name of the respective surgeon who introduced them into clinical practice. A systematic overview including names and images is given in [1].

Although many of them do not represent "modern" biomedical engineering, a sound knowledge is necessary, since the understanding of the mode of action is fundamental to the design of innovative tools.

6.1.1 Surgical Knives/Scalpels

A scalpel is a bladed surgical instrument used to make cuts into the body. This is a very sharp instrument and comes in various sizes for different types of cuts and surgeries. Most blades are made of either carbon or stainless (medical grade) steel (Fig. 6.1).

The shape of the blade is designed according to the intended use. Scalpels are often used as a symbol of surgery, but actually they do not play a major role any longer in surgery. It is more or less confined to skin incision (Fig. 6.2).

Today, scalpels are most commonly disposable since they are more cost effective and safer. Reusable scalpels have to be sharpened regularly. Reprocessing often leads to injuries due to careless handling. All these problems including resterilization can be avoided by the use of rather cheap disposable knives.

6.1.2 Forceps/Tweezers

Forceps are hinged surgical instruments used to grasp, hold, and to move tissue or other objects during an operation. The instrument comes in a variety of types and sizes, and is one of the most important elements of the surgical armamentarium. Forceps are also used to grasp blood vessels, tissues, and other objects (Fig. 6.3).

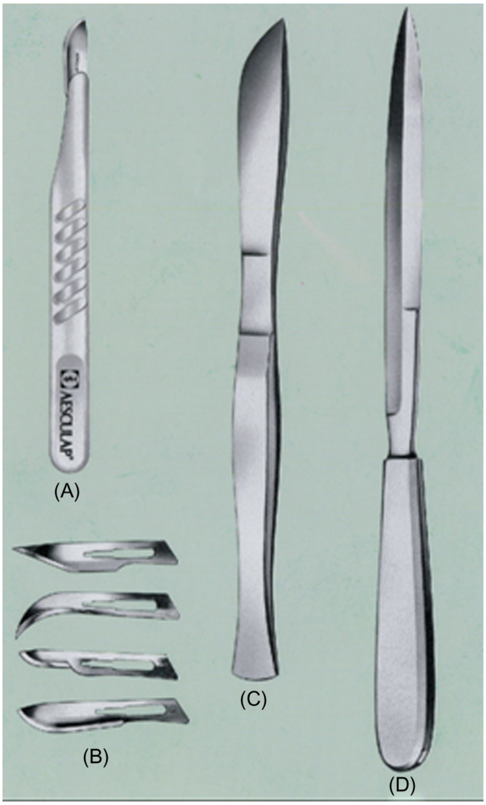
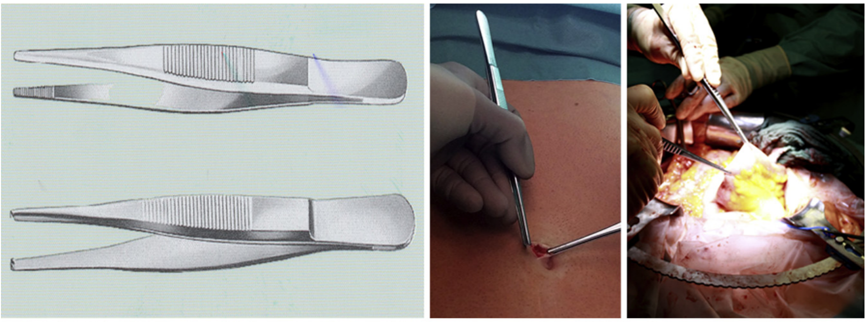


Figure 6.1 (A) Standard disposable surgical scalpel; (B) four different blades (top down): incision scalpel, scalpel to remove skin sutures, small scalpel for small, delicate incision, standard blade for incision of the abdominal wall; (C) historical reusable scalpel; (D) amputation knife. *From MITI.*

Figure 6.2 Inguinal skin incision. Note the characteristic grip with three fingers. *From MITI.*



(A) (B) (C)

Figure 6.3 (A) Anatomical forceps have a blunt tip with groove for gently grasping the tissue like small bowel (top left). Surgical forceps have three or more teeth to fixate firmly a more robust anatomical structure, e.g., the skin (bottom left). (B) The two edges of a skin incision are gripped firmly by two "surgical" forceps. (C) An intestinal loop is grasped with two anatomical forceps. *All from MITI.*

Forceps are not only necessary to grasp structures when fingers are too large to grasp them, but also necessary to avoid direct contact between the surgeon and the anatomical site. This "mediating" tool can easily be sterilized, whereas the hand of a surgeon—even though being washed and wearing gloves—may lead to contamination.

6.1.2.1 Basic Forceps Designs

There is a large range of forceps available today. Those in use in general surgery differ from those used in neuro- or vascular surgery. The challenge is always to find a good compromise between secure fixation and minimal trauma.

In abdominal surgery, blunt-nosed (anatomical) forceps of different lengths are most commonly used. Since forceps are often used to coagulate small vessels, it is helpful if part of the shaft is insulated (Fig. 6.4).

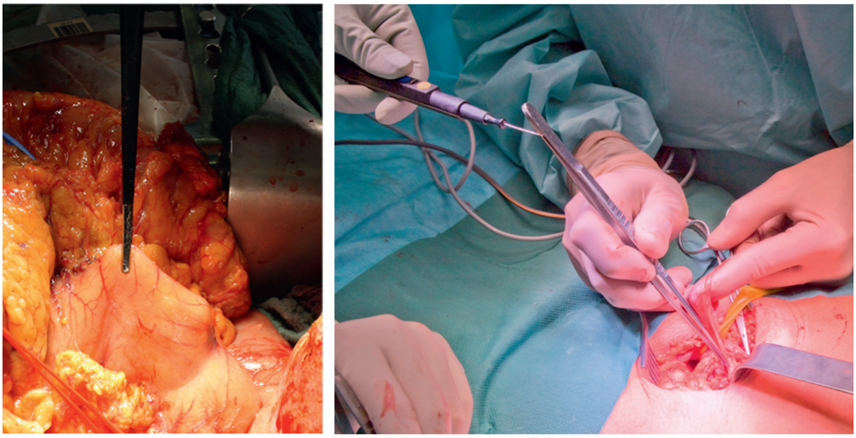
A high quality of the forceps is required to hold tissue in place when a suture has to be applied, even within a deep cavity (Fig. 6.5).

6.1.3 Scissors

Surgeons use surgical scissors during an operation in order to cut tissues at the surface or inside the human body. The blades can be either curved or straight.

The effect of tissue dissection is achieved when the sharpened edges slide against each other when the bows opposite to the joint are closed.

Figure 6.4 Standard forceps for visceral open surgery. They are provided in different lengths with broad or slim tips according to the purpose. They are almost completely covered by an insulating plastic cover. *From MITI.*



(A) (B)

Figure 6.5 (A) Long forceps used to fixate the tissue (stomach); (B) coagulation of a small vessel by means of the forceps. The instrument closes the circuit between the thermocauter and the patient. *All from MITI.*

For a better wound healing, scissors should cut exactly at the point where the blades meet. Shearing effects due to bluntness or floppy joints have to be avoided. Scissors are usually designed for right-handed persons. High-quality surgical scissors with good tension can also be used by left-handed individuals.

Scissors are the most important and valuable items of the surgical instrument set [2]. They are produced of high grade medical stainless steel, frequently hardened (tungsten carbide). Some approaches have already been made to offer disposable scissors to the market. Up to now, the success is limited [3]. Still today high-quality surgical scissors are reusable. About 2000 different types of surgical scissors are in use (Fig. 6.6).

In visceral surgery, however, the need for highly specialized scissors is low. The most frequently used one is the Metzenbaum type (Fig. 6.7).

For the handling of abdominal tissue and organs which are mostly delicate and fragile, the Metzenbaum scissors are ideally suited. The blades are usually blunt and curved. Since the shanks are comparatively long as compared to the blade, the haptic feedback is excellent. The surgeon

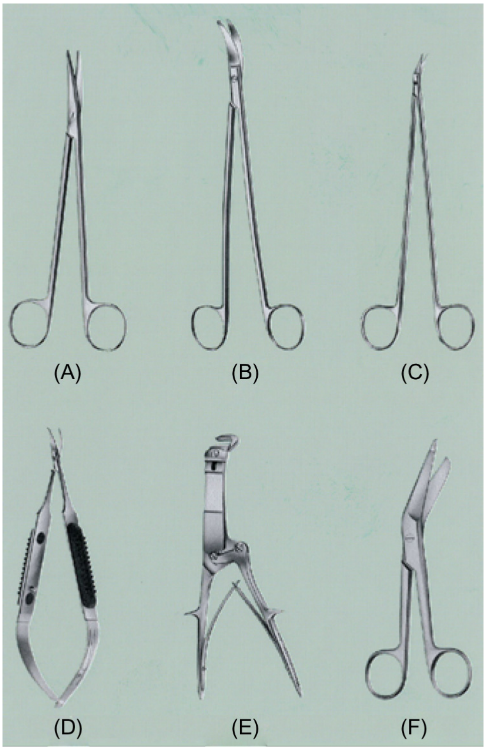
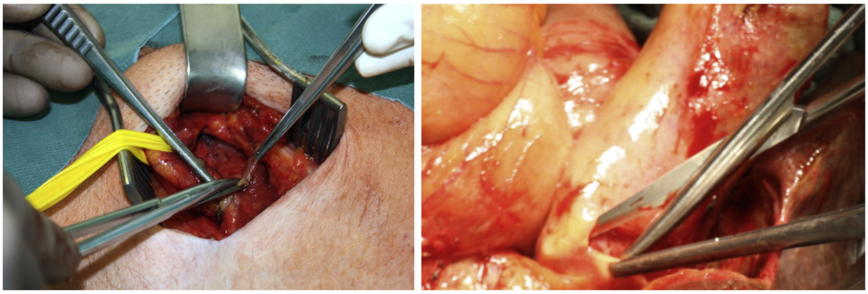


Figure 6.6 (A) Standard Metzenbaum scissors as largely used in visceral surgery. Note the relatively long shank-to-blade ratio. The blades are curved. (B) Robust variant of the Metzenbaum scissors as used in gynecology and orthopedics. (C) Typical issue of a vascular scissors. (D) Microscissors for neurosurgery. (E) Rib scissors. (F) Bandage scissors. *From MITI.*

Figure 6.7 Medium size Metzenbaum scissors. *From MITI.*



(A) (B)

Figure 6.8 In addition to severing tissue (A), Metzenbaum scissors are also used for blunt dissection (B). *All from MITI.*

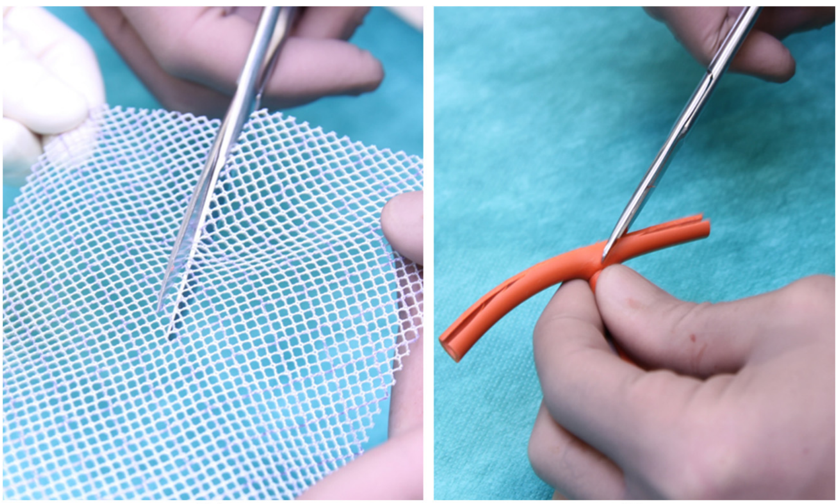
feels well whether the structure dissected is soft or hard which helps him to discriminate the border between critical areas (Fig. 6.8A). Even more important is this "sensitivity" of the scissors in case of blunt dissection, since the scissors can also be used to spread the tissue (Fig. 6.8B).

High-quality Metzenbaum shears are expensive and should not be used for too rough tasks, e.g., cutting of material like sutures, meshes, or sponges. For these purposes Mayo scissors are very adequate (Fig. 6.9).

Mayo scissors have semiblunt tips. The blades and handlings are stronger than in Metzenbaum scissors. Often they are called suture scissors or material scissors. Meshes (Fig. 6.10A), plastics, and rubber (Fig. 6.10B) require higher cutting forces than most tissues. The sharp branch of the Mayo scissors facilitates a precise elaboration of the object.

An interesting, relatively new development is so-called "electrical" shears: to prevent smaller bleeding out of capillaries and tiny arteries,

Figure 6.9 Mayo scissors. The joint is positioned to the middle of the instrument. One branch of it is sharp, one is blunt. *From MITI.*



(A) (B)

Figure 6.10 (A) Mayo scissors used to shape a mesh for inguinal hernia repair; (B) cutting out a segment of the circumference of a T-tube. *All from MITI.*

specially insulated scissors are available (Fig. 6.11A). Prior to the definitive cut, coagulation of the tissue between the blades is induced by an electrical impulse.

This is usually initiated by the surgeon via a foot pedal. Necessarily, this type of scissors needs two cables which is found irritating by many surgeons (Fig. 6.11B).

Electrical scissors avoid bleeding and speed up the surgical manipulation. However, lateral heat spread has to be considered, which may lead to injuries

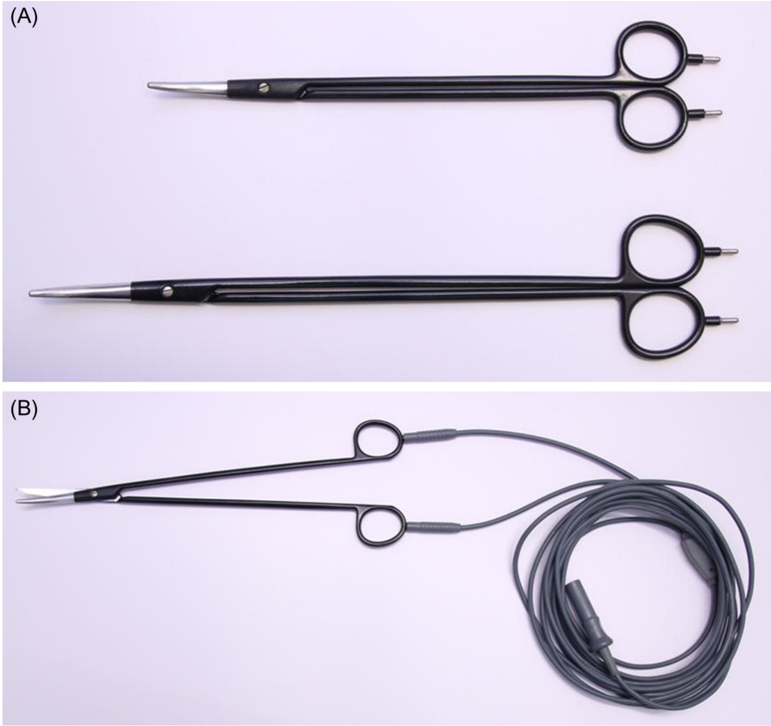


Figure 6.11 (A) Electrical scissors are available in various lengths. They resemble Metzenbaum scissors in shape. The body is insulated with exception of the tips. (B) Half-opened scissors with cables. *All from MITI.*

of adjacent tissue (e.g., nerves). The risk may even be higher than with ultrasound activated dissectors (see Section 6.3: Ultrasound Dissection) [4].

6.1.4 Fixation Instruments/Locking Forceps

Surgical clamps (Fig. 6.12) are locked forceps designed to grasp, hold, or occlude anatomical structures and objects. The tips are shaped according to the purpose. The forces exerted vary considerably. A strong Mikulicz clamp is suitable to grip the fascia but far too strong to hold vessels.

6.1.4.1 Hemostats

Surgical clamps that are used to avoid bleeding by temporarily occluding the vessel either completely or partially are called hemostats. If a vessel has to be severed, it is firstly mobilized. Then a pair of (usually curved) hemostats is positioned. The vein/artery is cut and the stumps finally

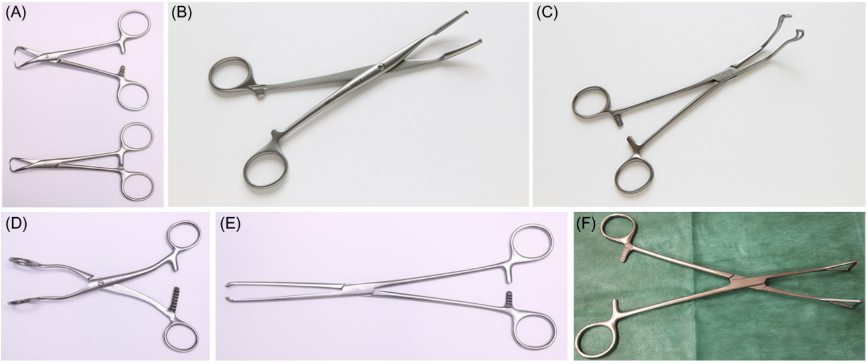


Figure 6.12 A selection of typical surgical clamps: (A) Backhaus: Very sharp tips to fixate robust objects firmly; (B) Mikulicz: Enable the surgeon to hold tough tissue reliably, e.g., the fascia of the abdominal wall; (C) Babcock: Smooth grip, e.g., for ligaments or tubular shaped objects; (D) Collin or Foerster: Characteristic circular eyelet. Used to hold the gallbladder or the stomach; (E) Allis: Popular instrument with distinct coarsely ribbed grip panel to hold and manipulate intestinal organs; (F) Duval or Pennington clamp with characteristic triangular eyelet, e.g., for colorectal surgery. *All from MITI.*

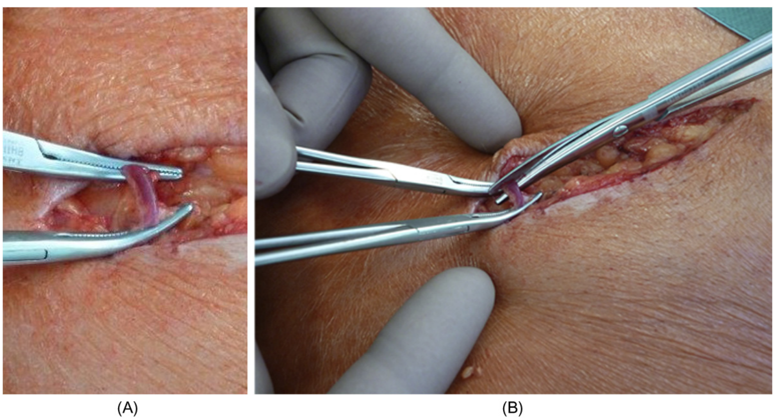


Figure 6.13 (A) Severing a small blood vessel using Kelly clamps. The tip may be either straight or curved. (B) If both sides are secured with the clamps, the vessel can be cut through in-between. *All from MITI.*

occluded by means of a ligature. As soon as the stump is secured, the hemostat can be taken off (Fig. 6.13).

As compared to the relatively small Kelly clamps, Overholt forceps are longer and stronger (Fig. 6.14).

Overholt clamps are widely used in visceral surgery since they do not only serve as hemostats but are, in addition, ideally suited for blunt

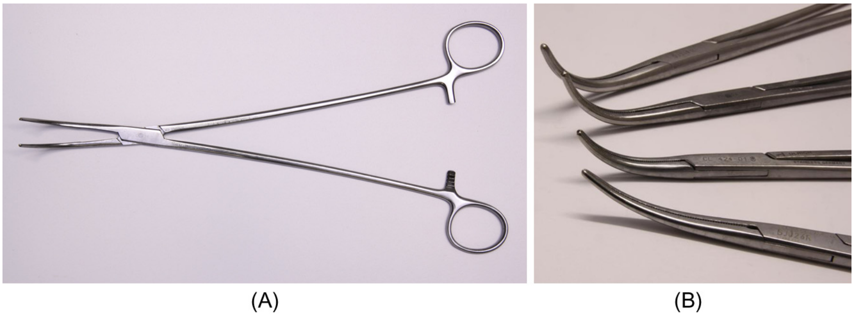


Figure 6.14 Overholt clamp. This type of forceps is available in various lengths with different angles of bending. If the ends are positioned in a 90 degrees angle to the main axis, it is also denominated "rectangle." (A) Typical Overholt clamp. Note the clamp mechanism. (B) Different angles of the tips. *All from MITI.*

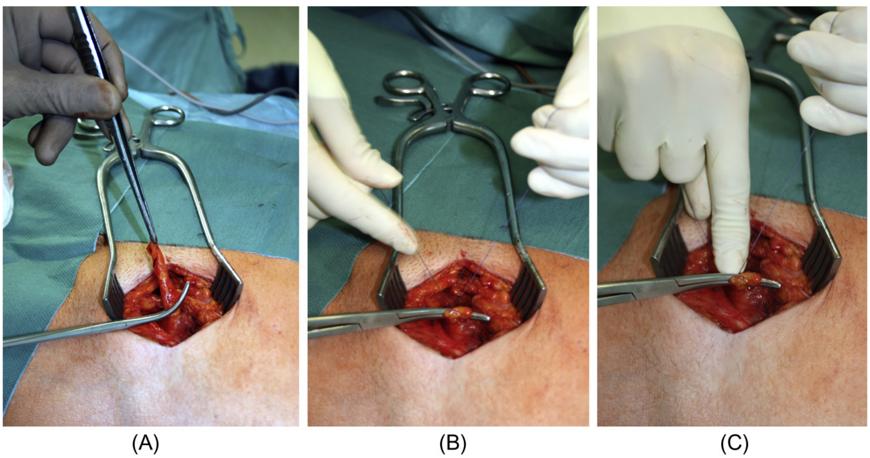


Figure 6.15 (A) A finger-shaped tissue specimen has to be resected. To avoid bleeding out of the remnant, a clamp is positioned. (B) After resection a thread is slung around it. (C) After 3–4 knots, the clamp can be released. The wound is held open by a self-retaining retractor. *All from MITI.*

dissection. A typical application of the Overholt clamp is demonstrated in Fig. 6.15.

6.1.4.2 Vascular Clamps

Successful vascular surgery is only possible if the surgical site is dry, i.e., the bleeding has to be stopped first before the lesion can be repaired or a bypass be sutured. Accordingly, a special type of clamp is required which compresses the arterial wall as firmly and reliably as an ordinary hemostat but

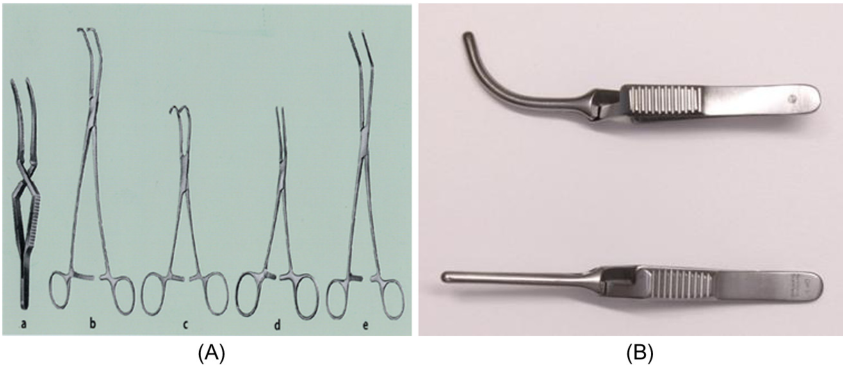


Figure 6.16 (A) A selection of dedicated vascular clamps: (a) Bulldogs forceps: This is a class of forceps differing considerably from normally hinged forceps. It is spring loaded. By squeezing the proximal shanks, the tip opens and the forceps is positioned on the artery. By releasing the pressure, the vessel is occluded. (b) Satinsky clamp; (c) Cooley clamp. Particularly suitable for tangential temporary exclusion of larger vessels; (d) Dardik; (e) De Bakey: The long tips enable to modify the pressure exerted to the tissue: The closer to the articulation the tissue is positioned, the stronger is the force. (B) Straight and curved Bulldog clamps (magnified). *All from MITI.*

exerts significantly less trauma. After successful surgical repair, blood flow is reestablished by releasing the clamps. Any pressure damage to the vascular wall—in particular of the intima (innermost layer)—favors the formation of thrombosis and endangers the success of the surgery.

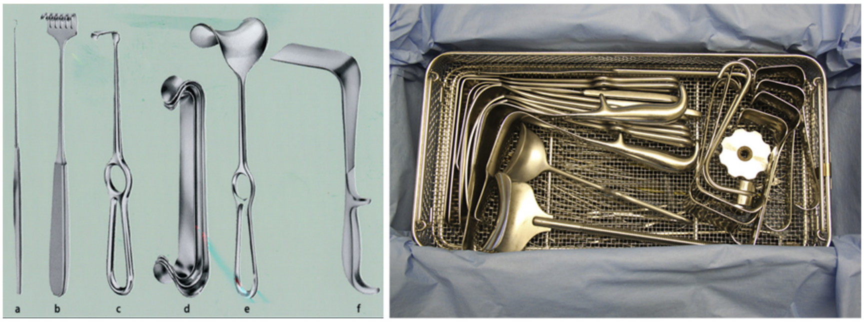
The difficult combination of (elastic) strength and gentle manipulation of the tissue stimulated the design of very sophisticated vascular clamps (Fig. 6.16).

Bulldog clamps are a particular subtype of hemostats with a very short handle. They can be positioned in the surgical site when it is very crowded. The jaws are opened by squeezing the handle. When the pressure is released from the handles, the clamp closes and stops blood flow until it is removed again.

Vascular clamps are not exclusively used by vascular or cardiac surgeons but by visceral surgeons as well.

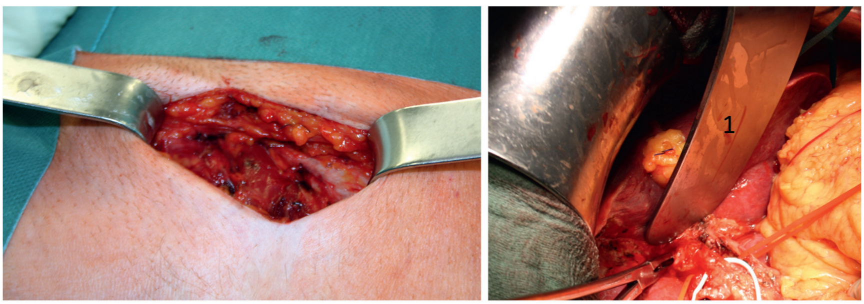
6.1.5 Retractors

Surgical retractors are medical instruments used to separate the edges of a wound or incision. This instrument offers surgeons access to an area, while inflicting a minimal amount of damage to the wound. Surgical technologists or assistants may be responsible for holding these



(A) (B)

Figure 6.17 (A) Handheld retractors: (a) Gillies hook with sharp, thorn-shaped tips for skin retraction; (b) Volkmann hook: Sharp teeth to retract skin/subcutaneous tissue; (c) Langenbeck hook: Smooth blades; (d) Roux hooks; (e) Abdominal wall retractor (Fritsche); (f) Retractor for internal organs (Doyen), such as liver and small bowel. (B) Instrument tray with a variety of retractors. *All from MITI.*



(A) (B)

Figure 6.18 (A) A pair of Roux hooks to separate the edges of an inguinal incision; (B) Liver hook (1) maintains the adequate position of the liver to give access to the hepatoduodenal ligament. *All from MITI.*

instruments in place during an operation. In addition to handheld retractors (Fig. 6.17A), so-called self-retaining retractors are available. They are usually provided together in the so-called retractor tray (Fig. 6.17B).

For an optimal exposure of the surgical site, it is of utmost importance to hold back the adjacent tissues and organs, which is often a tedious and boring task for the assistant whose task it is (Fig. 6.18).

6.1.6 Self-Retaining Retractors

Retractors have to distract incisions and accesses by exerting traction forces on both sides of the access. Accordingly, two hooks are required.

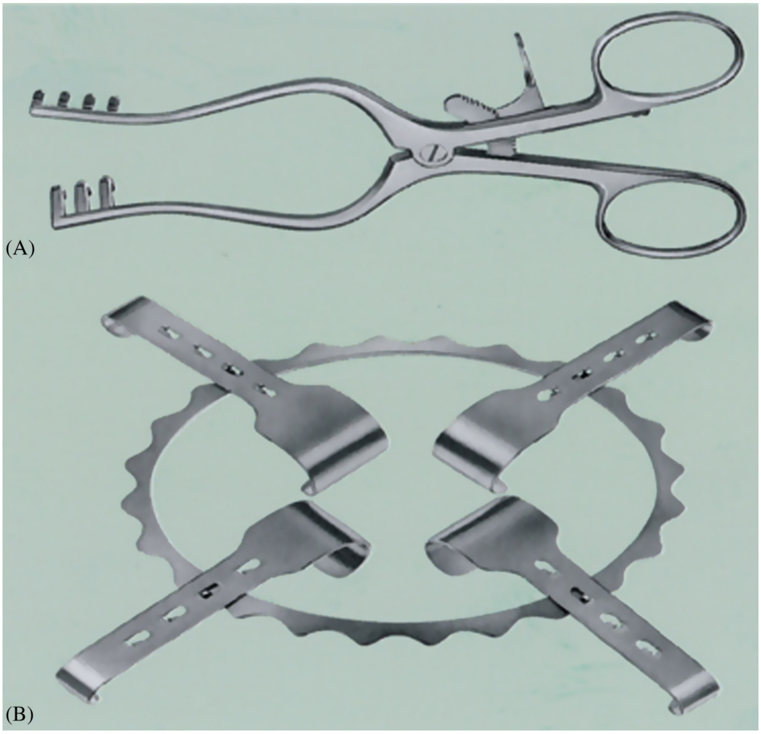


Figure 6.19 Two types of self-retaining retractors: (A) Self-retaining retractor for skin incision (Weilander). The jaws are kept within their selected position by the arresting mechanism with the liver. (B) Four (or more) hooks are mounted on a ring to keep an abdominal incision open (Zenker). *From MITI.*

If these are connected by a hinge, the distension force can be maintained mechanically (Fig. 6.19).

Self-retaining retractors often enable the surgeon to do the operation (usually smaller ones) without the help of an assistant ("solo surgery") (Fig. 6.20).

For larger incisions, in particular of the abdominal wall, more complex devices are in use. In Fig. 6.21 a ring-shaped retractor (Zenker) and an additional pulled hook are shown. The pulled hook is connected to an anchor. The traction can be varied to permit a wide access to the abdominal cavity.

6.1.7 Needle Holders

The purpose of this hemostat-like instrument is to hold the surgical needle firmly during surgery. Whereas a tailor is able to manipulate the

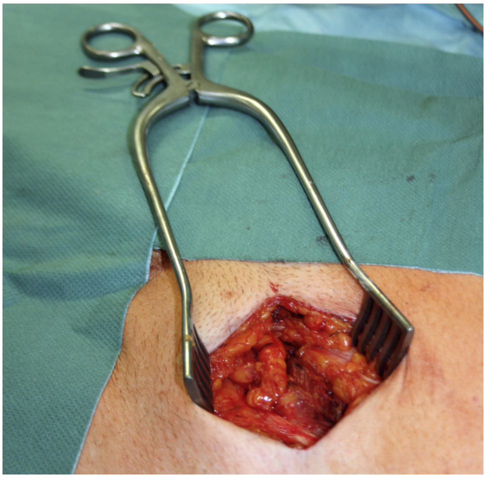


Figure 6.20 Self-retaining retractor in situ. The two edges of skin/subcutaneous tissues are kept apart, facilitating further tissue dissection in deeper layers. *From MITI.*

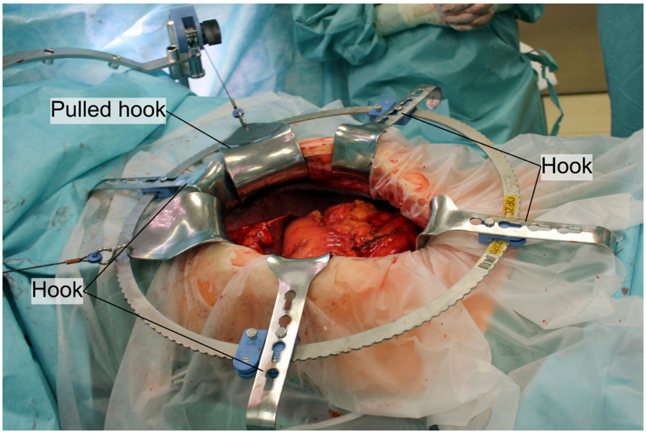


Figure 6.21 Abdominal incision. Hooks mounted to the metal ring permit a good access to the abdominal organs. Note the additional pulled hook. *From MITI.*

needle with bare fingers, suturing in surgery is only feasible by the use of needle holders. Usually, needle holders have an integrated clamp mechanism which locks the needle in place as long as it is required. Two main types exist: The Mayo-Hegar (Fig. 6.22A) and the Mathieu variant (Fig. 6.22B). In a Mayo-Hegar needle driver the clamp mechanism is released by lateral pressure to the bows. The Mathieu-type needle holder is opened by squeezing the handles beyond the point of arrestment.

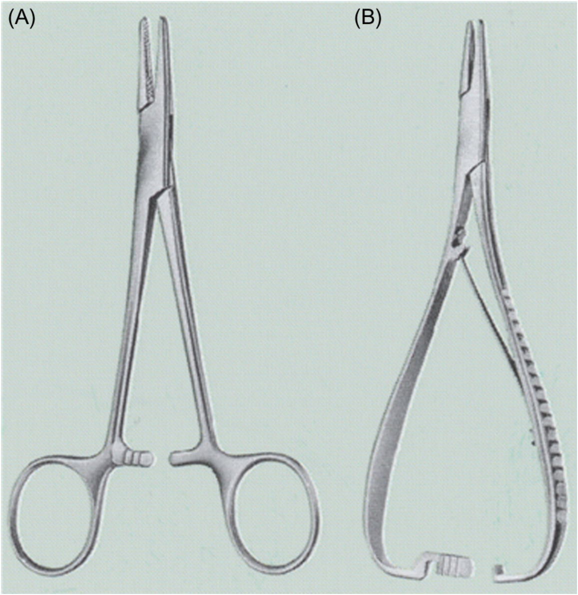


Figure 6.22 The most often used needle drivers in abdominal surgery: (A) Mayo-Hegar; (B) Mathieu. *From MITI.*

The design of the tip is a particular challenge. On the one hand, a firm grip on the needle has to be maintained. On the other hand, any mechanical deformation of the needle has to be avoided strictly. The texture or structure of the jaws must offer the best trade-off. As soon as they are becoming blunt, they have to be exchanged (Fig. 6.23).

In surgical ORs all over the world, it is striven to provide the instruments in a very standardized manner and adapted to the particular application. Standardized containers for basic surgical operations (Fig. 6.24) are complemented by additional specialized containers.

6.1.8 Others

In addition to the "general purpose" instruments as mentioned above, a wide range of highly specialized instruments is additionally provided. They are designed to enable the surgeon to perform only one or just a few well defined—but crucial—steps of the operation.

Stone forceps are a typical example. These funny shaped instruments are required to remove stones out of the common bile duct or the pelvis of the kidney/ureter (Fig. 6.25).

Figure 6.23 Needle driver in action. It is locked, keeping the needle in a stable position which overcomes tissue resistance. The needle is fixed in a rectangular position. *From MITI.*

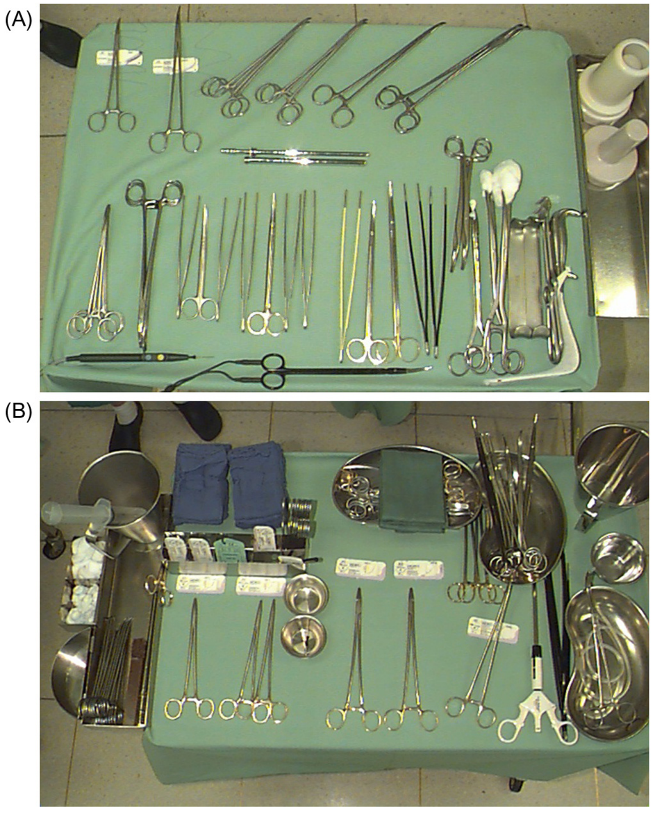


Figure 6.24 Two instrument trays for basic surgical interventions. (A) Clockwise: Hemostats, retractors, scissors, forceps. (B) Clockwise: Pads, kidney dishes, clip applier. *All from MITI.*

Figure 6.25 Stone forceps. The different angles allow for a good anterograde and retrograde positioning of the forceps within the duct system. *From MITI.*

Another instructive example of a highly specialized instrument is the so-called purse string clamp. If it is considered necessary to perform a so-called "staple anastomosis" using a circular stapler, the stump of the GI tract which will later on bear the anvil of the stapler (usually distal esophagus or proximal colonic stump) has to be prepared by means of a purse string (see Section 6.5: Stapling Devices). A purse string is a continuous suture which is stitched around the circular edge of the stump.

When it is closed by knotting, the shaft of the anvil will fit snugly into the stump. This time-consuming process of stitching the suture around the edge can be considerably simplified by applying the suture clamp (Fig. 6.26).

For the nonsurgical reader, the detailed mode of action is perhaps difficult to understand, but the message should be clear: Even in conventional surgery, particular problems which were valid in surgery for many decades can be overcome by the invention of an apparently simple and logical new approach ("the egg of Columbus"). The authors are convinced that there is—still after about 150 years of conventional surgery—a high potential for improvements, like the one shown above.

6.2 ELECTROSURGERY

When using the principles of electrosurgery to cut tissue, heat is applied only to small locally distinct tissue areas. Electrosurgery does not have an impact on the systemic temperature of the patient, but it does have

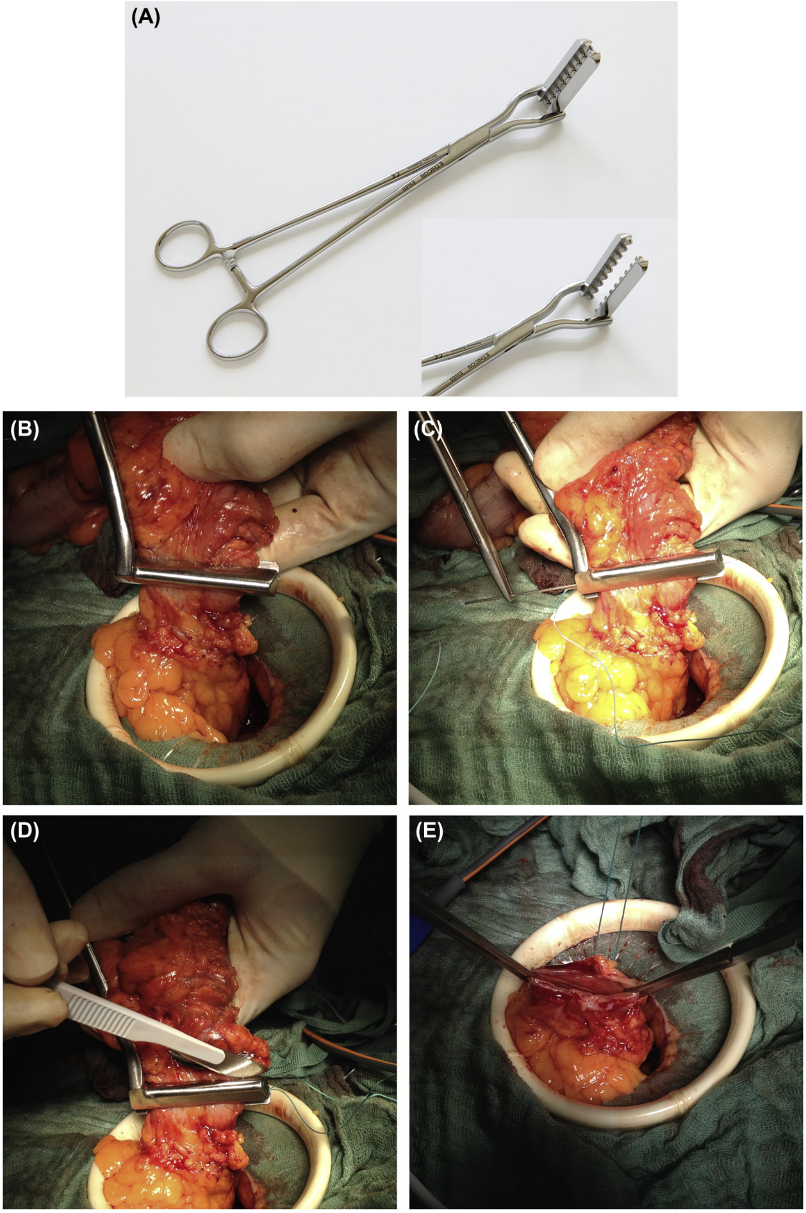


Figure 6.26 The purse string clamp: (A) The highly sophisticated jaws have specially designed teeth with needle canals. After correct positioning of the clamp, the surgeon just has to place the two needles of a double armed suture through the two needle channels and to remove the clamp. (B) Sigmoid resection: The upper part has to be removed. The lower part remains in the body. Later, it has to receive the anvil of the circular stapler (see Section 6.5: Stapling Devices). The clamp is positioned on the border. (C) The two needles of a thread are inserted into the needle channels. (D) The upper part of the sigmoid is cut off with a scalpel. (E) The clamp is removed. Note the two ends of the purse string suture (above). The anvil can now be introduced. *All from MITI.*

a severe impact on local tissue and therefore cells adjacent to the heat input. Thermal effects occur if cells are exposed to temperatures out of the thermo-neutral zone between 35°C and 41.5°C. All thermal effects are dependent on the intensity and duration of the thermal input. It is, therefore, not important how the specific temperature is reached and how it is induced. This chapter will further breakdown low- and high-temperature effects into five groups of thermal effects that biological tissue can pass through when it is heated above 37°C.

6.2.1 Thermal Low-Temperature Effects

Human beings are homeothermic. That means that the core temperature is regulated by internal metabolic processes within a narrow bandwidth of 0.5 K. The human body core temperature is 37°C independently of the ambient conditions. This core temperature is needed to maintain all physiological processes running and is regulated by the hypothalamus by dilation and contraction of blood vessels. Human cells are very sensitive to temperature changes. The first effects occur at around 35°C if the temperature is lowered and 41.5°C if the temperature is increased. Both effects are used for medical purposes.

Targeted lowering of local temperature is used, e.g., for cryotherapy to destroy lesions. Heating of tissue has an influence which is used for different purposes. Since electrosurgery is mainly based on heat, only tissue effects due to increasing temperature are described in detail. Fig. 6.27A gives an overview of the low-temperature effects of hyperthermia, devitalization, coagulation, and desiccation, furthermore showing the different thermal effect zones exemplified for a monopolar active electrode [5]. The thermal effect which is induced by the highest thermal input always lies in the closest proximity to the active electrode.

6.2.2 Hyperthermia and Devitalization

When normal body temperature is raised no irreversible effects will occur until the tissue temperature reaches 41.5°C. This temperature zone is called "hyperthermia." If the temperature of human tissue is raised above 41.5°C an irreversible "devitalization" effect will occur. At this temperature level time is of great importance. With increasing temperature the devitalization will stride forward and will irreversibly damage the tissue. The devitalization effect is time-dependent up to a temperature of 49°C. If temperatures of more than 49°C are reached the devitalization of the

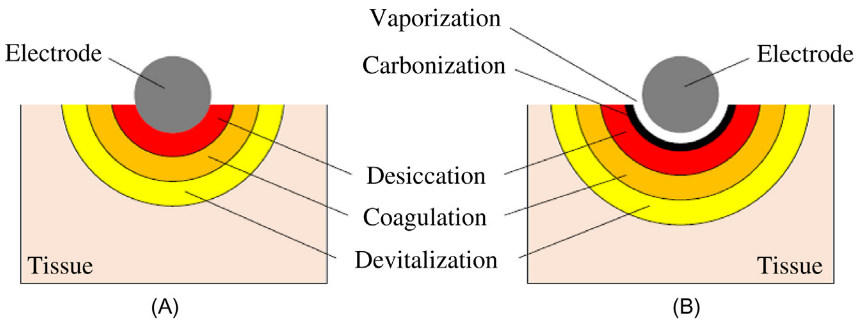


Figure 6.27 Thermal low- and high-temperature effects—high-frequency current application to tissue through a monopolar electrode causes diverse thermal defects. (A) Low-temperature effects are caused through ohmic current flow from the electrode to the tissue and can be divided into three zones: temperatures above 41.5°C lead to devitalization; temperatures above 60°C lead to coagulation; and temperatures up to 100°C lead to desiccation. (B) High-temperature effects are caused by electrical arcs sparking from the electrode to the tissue and can be divided into two zones: temperatures above 200°C leading to carbonization and temperatures above 500°C leading to vaporization of tissue. To achieve high-temperature effects temperature ranges that cause low-temperature effects have to be passed through. Thermal effects occurring at the highest temperatures are always in closest proximity of the electrode. *From MITI.*

target tissue will occur almost instantaneously. One of the two treacherous characteristics of devitalization is the low-temperature difference to the standard tissue temperature by only 4.5°C. Furthermore, the fact that devitalized tissue does not change in tissue color or structure and therefore cannot be seen with reasonable effort is crucial. If heat input has raised the tissue temperatures above 41.5°C and below 60°C, the tissue will be damaged irreversible, nevertheless not noticeable for the human eye [6]. Surgeons and endoscopists do not have the ability to make the devitalization zone visible. If the devitalization reaches into the muscularis propria and the damaged muscle tissue disintegrates several hours after the intervention, delayed perforations and bleedings may occur. These are dangerous to life and must be surgically treated instantly. During cutting and coagulation processes, the devitalization is an unintended side effect, but it can also be used meaningful, e.g., for tumor destruction.

6.2.3 Thermal Coagulation

The second low-temperature effect is called "thermal coagulation" and sets in at a temperature level above 60°C. Coagulation is defined as the conversion of colloidal systems from sol to gel state (see Section 6.3: Ultrasound Dissection). This effect can be seen while boiling an egg. In medical common speech the term coagulation is often used as a synonym for hemostasis by high-frequency current applications incorporating a series of thermal effects like devitalization, coagulation, and desiccation. The thermal coagulation effect must not be mixed up with the synonym for hemostasis. If the tissue temperature is raised to above 60°C a transition in the cell structure takes place. This effect can be characterized by a change in tissue color, by the formation of derivatives of collagen, and by tissue contraction. Tissue contraction can be used to seal bleedings from minor blood vessels [7].

6.2.4 Thermal Desiccation

Thermal desiccation refers to the event of the drying out of a cell, also known as dehydration. At temperatures of up to 100°C intra- and extracellular water dehydrates causing cells to dry out and shrink. The contraction of the tissue in addition to the glue effect, caused by the dehydration in conjunction with the derivatives of collagen formed during tissue coagulation, leads to effective sealing of blood vessels to a diameter of 0.5 mm. For the hemostasis of larger sized vessels, additional mechanical compression, e.g., by high-frequency forceps, is necessary. Two issues during high-frequency application can be associated with thermal desiccation. The glue effect not only is useful to seal vessels, but can also cause tissue to adhere to the active electrode. Tearing away of the adhering electrode might do further damage to the target tissue. Furthermore, the high electrical resistance of dehydrated tissue acts as an isolator between the active electrode and the target tissue and can hinder further thermal effects, such as the ignition of an electric arc necessary to cut tissue. Both mentioned cases can lead to severe problems during high-frequency applications.

6.2.5 Thermal High-Temperature Effects

Thermal effects that are present at temperatures above 100°C are classified in the group of thermal high-temperature effects (Fig. 6.27). High-temperature effects are essential for cutting tissue as tissue can only be separated when tissue temperature is raised above 100°C. To heat tissue above the boiling point of water, the tissue has to be dry and high power density is required. This can be achieved either with high-frequency current with a peak voltage of above 200 V generating electric arcs between the active electrode and the target tissue or by the use of laser sources. Fig. 6.27B gives an overview of the high-temperature effects carbonization and vaporization, showing the different thermal effect zones for a monopolar active electrode. The localization of the thermal effect zones start at the active electrode: vaporization zone, carbonization zone; followed by the low-temperature effects starting from the highest to lowest temperature effect as described above (Fig. 6.27).

6.2.6 Carbonization

Carbonization is the first of two high-temperature effects and is defined as partial oxidation of tissue hydrocarbon compounds if the temperature exceeds 200°C and the tissue is within an oxygen-containing atmosphere. As temperatures above 100°C cannot be achieved by endogenous heat, exogenous heat in the form of electric arcs or laser has to be inducted into the desiccated tissue. Tissue carbonization produces smoke that limits the visual sight to the target area. Furthermore, inflammable gases can be present in the smoke, which mixed with oxygen can lead to fires or explosions if electric arcs or lasers are ignited. The effect of carbonization is undesired but has to be passed to achieve the cutting effect during tissue vaporization when temperatures of above 500°C are reached [7].

6.2.7 Vaporization

The desired tissue effect for cutting tissue by high-frequency current or laser is achieved when temperatures of above 500°C are reached within an atmosphere containing oxygen. These temperatures are sufficient to evaporate the tissue structures. The downside of the vaporization of tissue is the smoke created with the risk of explosion or fire breakout when sparks are present.

6.2.8 Principles of Electrosurgery

Electrosurgery uses radio-frequency, respectively, high-frequency alternating current, to achieve thermal effects within biological tissue as described in the previous section. The alternating current within the active electrode is used to activate oscillating movements of ions within cells and therefore raises the intracellular temperature due to intracellular frictional forces. The heat input is used for the modification or destruction of tissue, leading to ablation, hemostasis, and cutting effects.

6.2.9 Physical Theories of Electrosurgery

Biological tissue acts in several different ways if an electrical current is introduced within. Some of the effects can be used for medical diagnosis or therapy. This chapter explains the physical principles of the effects involved in electrosurgical applications. The main physical effects occurring when an electrical current is introduced into living tissue are the *galvanic*, *faradic*, and *thermal effects*. Depending on the polarity of the current and on the frequency for alternating currents, different physical effects take place. As for electrosurgery, the thermal effect is most relevant. Other effects, such as the galvanic and faradic effects, are mentioned to give the reader the understanding about the advantages of high-frequency current over other electrical current forms.

Direct current or low-frequency current that is introduced into tissue leads to an ionic displacement, which is called *galvanic effect*. This effect has no relevance for high-frequency applications. Nevertheless, this effect can be used to introduce medication into specific areas of the human body; this therapy is known as iontophoresis [8].

The *faradic effect* takes place when low-frequency alternating current with frequencies from 1 to 20,000 Hz is applied to biological tissue. This type of current brings anions and cations to oscillate in synchrony to the applied current leading to action potentials within the cells. These action potentials are responsible for a depolarization of muscles and nerves, resulting in muscle fasciculation that is unpleasant and dangerous for the patient. The maximum muscle stimulation level lies between 10 and 100 Hz, which makes an electric shock from a standard electric outlet voltage of 230 V at 50 Hz dangerous. The faradic effect is used for electric stimulation therapy in patients with muscular paralysis. For high-frequency application these frequency bands must be avoided at all times.

The *thermal effect* makes use of alternating currents of more than 300 kHz. Frequencies of 300 kHz or more are considered as high-frequency, given the name high- or radio-frequency application. The pulses of currents with such a high-frequency are able to evade the galvanic and the faradic effect. The applied current stimulates the ions within the cells to oscillate. Electric energy is converted into oscillation movement of the cell particles which is mechanical energy. The frictional forces between the oscillating particles, especially large proteins, convert the mechanical energy into thermal energy which leads to an increase in intracellular temperature. The conversion of electrical energy to thermal energy via mechanical energy takes place extremely quickly and without losses.

According to the Joules Law the heat Q produced due to the current flow within an electrical resistor is proportional to the converted energy P in a certain time period Δt and represents the fundamental principle of electrosurgical procedures (Formula 6.1).

$$Q = P \times \Delta t = I^2 \times R \times \Delta t = \frac{U^2 \times \Delta t}{R}, \tag{6.1}$$

Q: heat,
P: converted energy,
Δt: activation time,
I: current,
R: resistance,
U: voltage.

The Joules Law can be converted to a formula that incorporates all important electrosurgical parameters—current density j, specific tissue resistance ρ, tissue volume V, and activation duration Δt.

$$Q = j^2 \times \rho \times V \times \Delta t, \tag{6.2}$$

Q: heat,
j: current density,
ρ: specific tissue resistance,
V: tissue volume,
Δt: activation duration.

The current density is an essential electrical variable in regards to cutting tissue with a high-frequency current. The current density j is defined as the current I flowing through a defined area A at a certain point in time t. The current density and therefore the cutting behavior can be affected by changing either the affected area or the current flow through this area. Only when a current density of 1–6 A/cm^2 is present, can electrosurgery be conducted efficiently. As formula (6.2) shows the heat input into the tissue is proportional to the square of the current density. Fig. 6.28 depicts the effect of the current density to the temperature rise when the same current flow is applied through different tissue areas. The temperature rise in Fig. 6.28 ranges from 0.004°C to 40°C, due to current densities ranging from 0.01 to 1 A/cm^2.

Furthermore, two important variables for electrosurgery are the specific electrical resistance ρ of the tissue and the volume V involved. Biological tissue can be treated as an ohmic resistor. Values of specific resistance vary strongly. Muscle tissue and tissue well supplied by blood

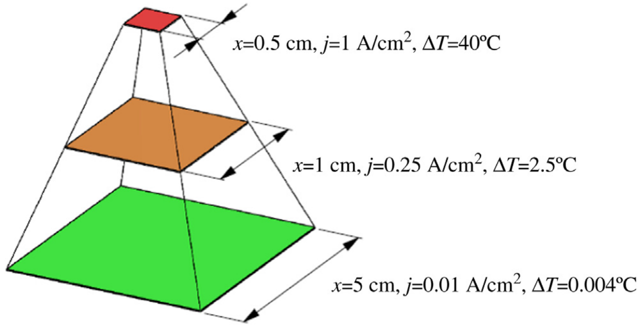


Figure 6.28 Effect of current density on rise in tissue temperature—the temperature rise is proportional to the square of the current density. In the pictured diagram a constant current is applied to three differently sized areas. The areas are variable in size with a factor of 100 ranging from 25 cm^2 in the lowermost area to 1 cm^2 in the middle area and 0.25 cm^2 in the uppermost area. The reduction in area leads to a temperature rise from 0.004°C to 40°C, which is a factor of 100^2. *From MITI.*

have low resistance values in the range of 160−300 Ω. Tissue with low fluid content as bone, cartilage, and fat have high specific resistance values ranging from 500 to 1000 Ω.

The thermal distribution within the tissue in a given time is complex as a series of combinations of thermal conductivity, convection, perfusion of blood, and metabolic heat production have to be included in the consideration. Pennes introduced a simplified bioheat model in 1948 which describes the heat transfer within living tissue including the blood transfusion and metabolic heat production for a small defined control volume (Formula 6.3). His consideration was initially developed for a heat transfer observation of a human forearm. The bioheat equation formulated in 1948 is considered the standard and most current literature is derived from it due to its simplifying assumptions [9].

$$\rho m_f \Delta h + \rho c \frac{\partial T}{\partial t} = P + Q_m + \lambda \frac{1}{r}\frac{\partial}{\partial r}\left(r \frac{\partial T}{\partial r}\right) + w_b c_b \rho_b (T - T_b), \qquad (6.3)$$

ρ: density of medium,
m_f: mass which changes phase,
Δh: phase change enthalpy,
c: specific heat capacity,
T: tissue temperature,
t: activation time,
P: externally applied power density,

Q_m: basal metabolism,
λ: thermal conductivity,
r: distance from active electrode,
w: blood perfusion,
b: values of blood.

The Pennes bioheat equation includes heat gain mechanisms in the form of metabolic heat and externally induced power and heat loss mechanisms in the form of blood perfusion and heat transfer. The first term of the equation on the left side depicts the amount of water or tissue that runs through a phase change from liquid to gaseous. The second term on the left is the rate of temperature increase in the control volume. The first term on the right side represents the externally induced power density, the second term is the heat produced by metabolism, the third term characterizes the heat transfer from and to the control volume, and the last term represents the thermal effect of the blood perfusion.

The equation is valid for application duration shorter than approximately 30 s. For electrosurgical applications the metabolic heat, heat transfer, and perfusion can be neglected. According to the bioheat equation the surgeon has three means of controlling the effect of the electrosurgical application which are the contact surface between the active electrode and the tissue, the induced current density which is dependent on the contact surface and the introduced current flow, and the activation time. Still today, the equation is the base for more sophisticated applications [10].

6.2.10 Electrosurgical Techniques

Electrosurgical applications make use of the physical theory explained in the previous chapter to achieve the desired thermal effects. To avoid the faradic effect and the related adverse effects, frequencies higher than 300 kHz are used. Temperature of up to 100°C can be reached with the implementation of endogenous energy. For tissue cutting purposes higher temperatures have to be achieved. This is only possible if exogenous energy is applied to the tissue by electric arcs. Electric arcs can be generated with a minimum peak voltage of 200 V independent from the flowing current. The major advantage of electrosurgical cutting over mechanically cutting tissue with a scalpel is the hemostasis effect at the edge of the incision which minimizes bleeding.

Electrosurgical applications can be conducted in two different forms—monopolar and bipolar techniques are state-of-the-art. The setup for both procedures is the same—an active electrode and a neutral electrode have to be conductively interconnected with the human body, closing the electric circuit to the high-frequency voltage source, the electrosurgical unit (ESU). The current flow always follows the same route from the generator to the active electrode into the target tissue and back to the generator through adjacent tissue, departing the human body through the neutral electrode. The difference between the two application forms lies within the size and arrangement of the two electrodes. Tissue cutting is only possible by means of the monopolar technique.

6.2.11 Monopolar Technique

Monopolar application is by far the most commonly used form, incorporating an active electrode with an extremely small surface area compared to the neutral electrode which has a huge surface area. The small surface area of the active electrode in conjunction with high current generates very high current densities at the target tissue (Fig. 6.29A). The high current density is important for adequate thermal input to achieve the desired coagulation or cutting effects. The current flows through the body to the large surface return electrode which is placed on the skin of the patient. Due to the large surface area the current density is considerably smaller and the thermal effect is negligible.

Nonetheless, severe burns at the contact site of the neutral electrode may occur due to current leakage [11]. Modern electrode designs (Fig. 6.29B) with divided electrodes and active electrode monitoring lower the risk of electrical damages but do not completely eliminate them [12].

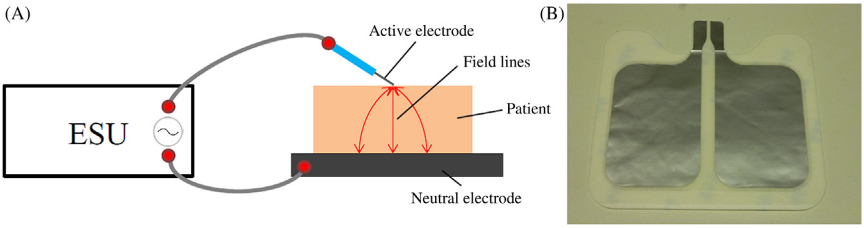


Figure 6.29 Monopolar high-frequency technique for therapeutic heat introduction into the target tissue. (A) The technique incorporates an extremely small surface area active electrode compared to the neutral electrode which has a huge surface area. The current flows through the body to the large surface neutral electrode, which is placed on the skin of the patient. The desired coagulation or cutting effects are realized at the active electrode due to the present high current density leading to the necessary high temperatures; (B) state-of-the-art design of a return electrode. *All from MITI.*

6.2.12 Electrosurgical Coagulation and Desiccation (Hemostasis)

Electrosurgical hemostasis is achieved by the means of applying a high-frequency current into the target tissue. The current is dispersed divergently within the tissue and the current density decreases with the distance to the contact surface. As the tissue heating is proportional to the square of the current density, higher temperatures are reached in proximity to the contact surface. In close proximity to the contact surface temperatures of up to 100°C are reached, vaporizing intra- and extracellular water. The hemostatic effect strives forward until the tissue loses its electrical conductivity due to dehydration and the formation of vapor covering the tissue. As long as a peak voltage of 200 V is not reached, and the tissue is strongly dehydrated, no further coagulation and desiccation is possible.

6.2.12.1 Impedance-Controlled Electrocoagulation

The effect of "self-insulation" during electrocoagulation can be significantly reduced by a computer-controlled output of the electrical energy. By measuring continuously the tissue impedance/resistance at the tip of the instrument (bipolar electrodes), the pulsed energy output can be adapted in a way to avoid early carbonization [13]. Today, a wide range of specifically designed instruments is available (Fig. 6.30).

The combination of pressure and pulsed energy enables a far higher sealing effect than conventional electrocoagulation. Arterial vessels can be

Figure 6.30 An impedance-controlled sealing dissection device. Note the gray lever in the middle. If it is turned counter clockwise, a knife in the tip is pushed forward dissecting the tissue after sealing. *From MITI.*

reliably occluded up to a diameter of 5−7 mm. In most devices, a knife is integrated. It can be activated after the sealing procedure to sever the tissue.

6.2.12.2 Argon Plasma Coagulation

A new contactless technology for (superficial) hemostasis was introduced into surgery in the 1990s: argon plasma coagulation (APC) [14]. The device is a monopolar coagulator which conducts radio-frequency current to the tissue in a jet of argon gas [15]. The ionized gas (plasma) gains a characteristic blue color (gray in print versions) (Fig. 6.31). However,

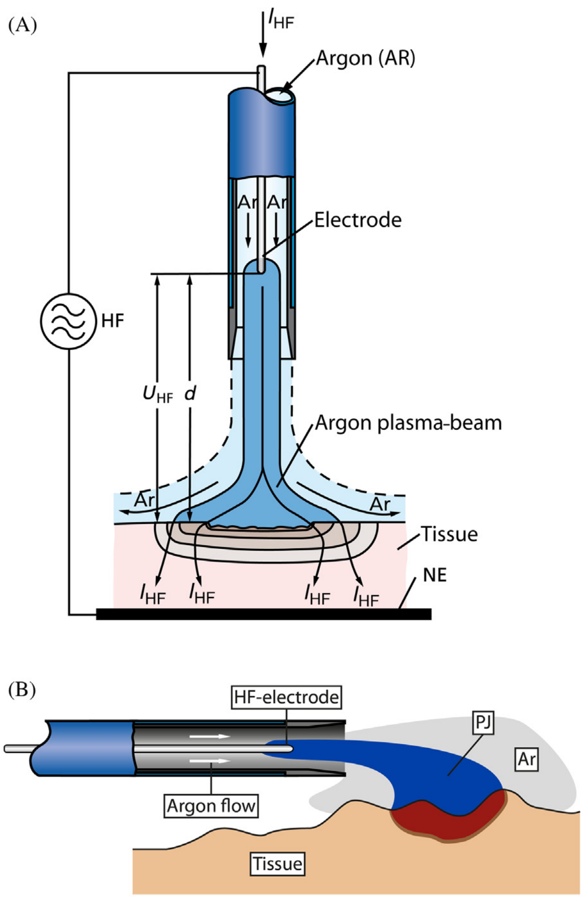


Figure 6.31 (A) The principle of APC. A jet stream of argon is blown against the tissue surface providing an electrical bridge. (B) Even though the application angle is well below 90 degrees, the plasma hits the tissue precisely (*PJ*, plasma jet; *Ar*, argon; *HF*, high frequency; *NE*, neutral electrode; *d*, distance between tip of the electrode and tissue surface; *U*, voltage). *All from Erbe Elektromedizin GmbH.*

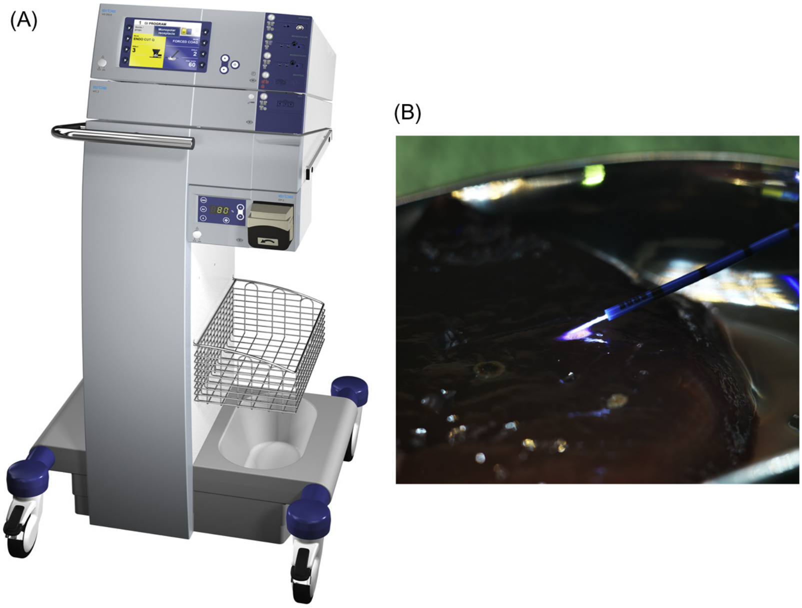


Figure 6.32 (A) The APC generator and gas supply unit; (B) the plasma hits the liver surface. The sharp gas blow displaces blood and improves the coagulation effect. *All from Erbe Elektromedizin GmbH.*

argon is more than just a vehicle for the current, since it also blows away the blood covering the tissue, which improves the efficacy (Fig. 6.32) [15].

Currently, APC becomes increasingly popular in interventional endoscopy, since it is ideally suited to stop diffuse bleeding of surfaces, such as telangiectasias [16].

6.2.13 Electrosurgical Cutting

To overcome the nonconductive dehydrated tissue and the thin vapor layer an electrical arc has to be ignited to cut tissue. An ohmic current flow is avoided due to the nonconductive vapor layer. Only when peak voltages above 200 V are present is a dielectric breakdown between the biological tissue and the electrode reached and an electric arc is ignited. Electric arcs are necessary to cut tissue, as the temperature within cells has to be raised above 100°C which is not possible through endogenous heating. The temperature of electrical arcs is assumed to reach about 1300°C. The arcs are striking the tissue in small spots with only 10−20 μm in diameter leading to a very high current density (Fig. 6.28).

The consequence is a fast temperature rise within the cells above 100°C as well as a volume increase of the intracellular water leading to the bursting of the cells and tissue severance. The thermal expansion within the tissue is directly correlating to the course of current density within the tissue. It is assumed that while cutting tissue, the current density field distribution of every electrical arc impact is spherical. This assumption is made as several electrical arcs are sparking along the cutting electrode at the same time and the average distance between the electrical arcs are so far apart, that the thermal impact of these events can be regarded as independent events. The current density and thermal effect decrease with the fourth power of the distance from the active electrode. The current density at the electrical arc striking point is very high and decreases strongly with increasing distance into the tissue. Electrical arcs are only ignited when the complete electrode is insulated from the tissue by a vapor film. The arcs strike at the point where the vapor film is thinnest. Once the discharge has taken place, the thickness of the vapor film at this spot increases and the next electrical strike is at another position of the active electrode. The electrical arcs spread out over the total length of the active electrode [7].

The ignition of electrical arcs is polarity dependent. During the sinusoidal voltage course only electrical arcs originating from the metal electrode are ignited as it is easier to withdraw electrons from metal than from the tissue. The intensity of the electrical arc is directly correlating with the peak voltage and with increasing electrical arc intensity the depth of the thermal defect increases.

The cutting and coagulation properties are furthermore affected by the modulation of the voltage applied to the tissue. A sinusoidal unmodulated voltage results in a smooth cut with a minor hemostasis effect in the cut edges. The application of strongly modulated voltage with duty cycles of less than 10% of the same voltage amplitude is preferably used for hemostasis purposes, due to the higher thermal impact.

A fast ignition of electrical arcs is of great importance for a safe cutting process. For every cut there is a prevalence of a cut delay. Only when the voltage of more than 200 V and an insulating layer between the electrode and the tissue is present can electrical arcs be ignited. As long as ohmic current flow is present, the ignition of arcs and therefore the start of the cut is not possible. During this period an extensive thermal damage is introduced to the surrounding tissue. The higher the initial power introduction chosen, the faster the intracellular water is evaporated to form an insulating vapor layer around the electrode. The cut delay duration is therefore dependent on the initial introduced power level. Once the vapor cushion is present and the cut is running, less than 10% of the initial current density is required to maintain the cut. In a worst case consideration, e.g., if the initial peak voltage is just below 200 V, a high power density is introduced into the tissue—too high for coagulation purposes but too low to initiate a cut. The tissue quickly dehydrates, coagulants are formed, and a large extent of thermal damage is induced, causing perforations on the one hand and on the other hand the electrode can get stuck within the tissue to be dissected. No further cut can be initiated.

6.2.14 Electrosurgical Unit

Modern ESUs convert the low-frequency alternating current from the wall outlet to high-frequency alternating currents from 300 kHz to a maximum 5 MHz according to the International Electrotechnical Commission standard 60601-2-2. Today's ESUs are controlled by microprocessors and are capable of producing a series of different current waveforms that are necessary for electrosurgery. Diverse current waveforms, current blends, and predefined cutting and coagulation modes can be selected by the means of monitor-based user interfaces. Furthermore, manifold safety monitoring features, such as neutral electrode monitoring and control algorithms in the form of impedance-controlled voltage management, are implemented in state-of-the-art ESUs.

6.2.15 Clinical Aspects of Electrosurgery

Modern surgery would be inconceivable without electrosurgery. However, it is also potentially dangerous, mainly through causing thermal injuries, frequently leading to significant morbidity and mortality and medicolegal actions.

According to surveys, 18% of general surgeons and gynecologists have seen at least once visceral burns, and many of them admitted one or more ongoing causes of litigations due to these burns [17]. Insulation failure [18] plays a major role as well as burns due to the neutral electrode.

Great care has to be taken to avoid these specific risks of electrosurgery, e.g., through continuous training and education. In order to improve the surgeons knowledge [19], some specific programs like the "Fundamental use of surgical energy (FUSE) certification" were developed [20].

6.3 ULTRASOUND DISSECTION

Dissection of living tissue is inevitably accompanied by bleeding and surgeons dreamed of "dry" cutting. Electrocautery was the first step forward, but the effect of vessel occlusion (hemostasis) was very limited. More effective tools were required. It was about 40 years ago that a new principle was introduced into clinical practice to dissect living tissue: cavitation. The phenomenon of cavitation and its effects was originally detected in early tests of naval propellers: high-frequency vibrations cause the creation, expansion, and implosion of cavities in liquids. The gases inside these cavities are compressed and the local temperature is significantly elevated leading to fast corrosion of the propellers. In living tissue, cavitation leads to the well-known effects of overheating. Fat is melted away and proteins are transduced from the gel to the sol state (Fig. 6.33).

Under practical conditions, the cavitation effect during surgery is generated by ultrasound dissection devices.

In medicine, ultrasound is also the denomination of an imaging technique using sound waves. Ultrasonic dissection (and coagulation), however, has nothing to do with imaging but is derived from the vibration frequency.

The principle of ultrasonic tissue manipulation is to exert relatively high amplitude vibrations (80–360 μm) to the tissue in a frequency range between 23.5 and 60 kHz. The vibrations are produced by electrical energy, predominantly by piezoelectric crystals. In an electric field, piezos deform in a linear and reversible manner. The generator induces a potential difference

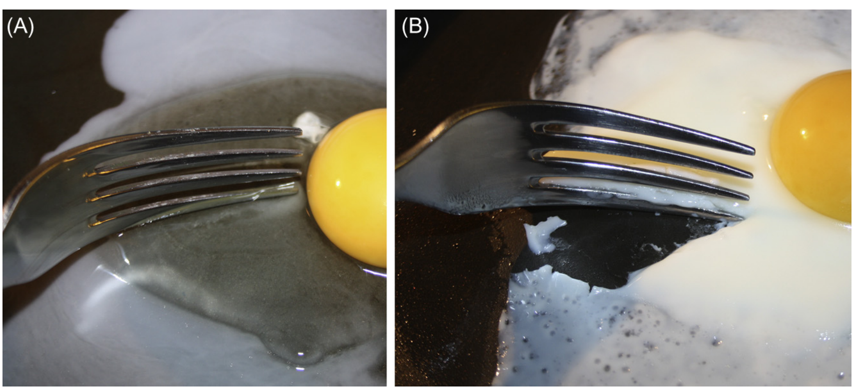


Figure 6.33 (A) The protein of a raw egg is resilient and cannot easily be divided by force. (B) As soon as it is heated it becomes friable and can be cut easily. *All from MITI.*

across the crystal, and polarity changes lead to vibrations. The vibrational energy is, then, transmitted via the steel rod to the tip of the instrument.

The system consists of the power supply and control unit which is connected with a cable to the hand piece. The latter consists of the piezoelectric vibration generator and the (exchangeable) instrument tip (Fig. 6.34). The instrument tip is most commonly designed as a scissors (either curved or straight bladed). One blade is shaped by the vibration steel rod. The correspondent jaw is deflectable with a silicone cushion.

By means of the deflectable arm, tissue can be squeezed against the vibrating steel rod. Vibration energy initiates collagen denaturation and breaks tertiary hydrogen bonds between collagen and other extracellular matrix proteins [21]. This produces a viscous coagulum which leads to the sealing effect. Tissues and vessels become an amorphous, condensed necrotic structure which prevents bleeding out of the cutting edge. Mechanical pressure and cavitation finally lead to complete dissection. The process is very similar to baking an egg. By heating the egg protein, the state is changed from gel to sol. Under surgical conditions this leads to a reliable occlusion of vessels up to a diameter of 5–7 mm. Surgical dissection is facilitated, but a significant reduction of OR time cannot (yet) be observed [22].

Ultrasonic dissection devices are provided by several companies, either as reusable or as partly disposable systems. Most frequently, the scissors are for single use, whereas the part of the piezoelectric elements can be

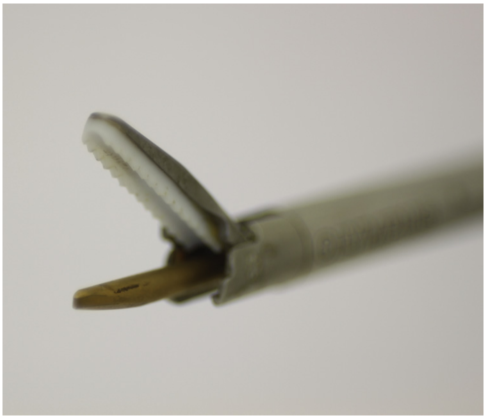


Figure 6.34 Tip of reusable laparoscopic ultrasound scissors. The tissue is pressed against the vibrating steel rod. After mechanical coagulation, it will fall into its two parts. *From MITI.*

sterilized (Fig. 6.35). The control units are available as stand-alone systems or embedded into a multifunctional power station (Fig. 6.36).

As in other energetic soft-tissue treatment modalities, collateral thermal damage is an issue in ultrasonic dissection as well. Though data from the literature vary, clinically relevant injury may only be expected in the immediate vicinity of the rod.

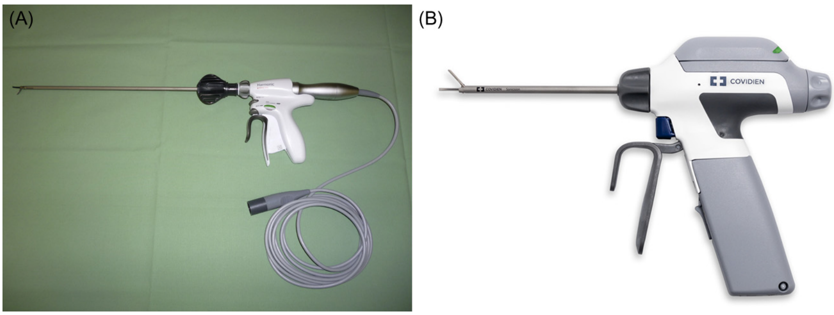


Figure 6.35 (A) Hand piece with cable bound power supply. (B) Battery driven ultrasonic dissection device. *From (A) MITI and (B) Medtronic GmbH.*

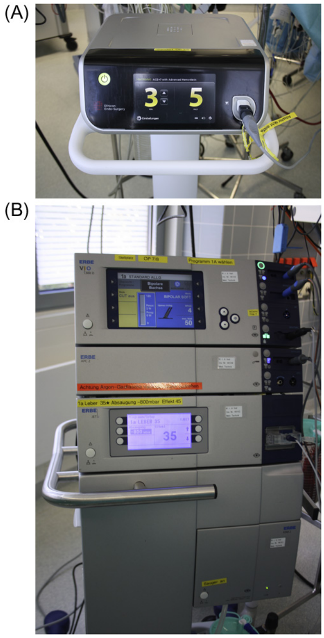


Figure 6.36 Power supply and control unit. (A) Stand-alone device; (B) integrated into a multifunctional unit. *All from MITI.*

Plume—or mist—production during ultrasonic dissection is nasty but immanent to the procedure. In laparoscopic surgery, visualization is deteriorated (see Chapter 7.2.9: Laparoscopic Ultrasound Dissection). The particles produced are larger than electrosurgery smoke. They consist of fat or, in rare cases, even of vivid material [23]. However, up to now, no relevant side effects have been reported upon.

Conclusively, ultrasonic dissection is an essential pillar of modern open and minimally invasive surgery.

6.4 WATER JET

Cutting with a high pressure water jet was initially used in industrial applications. At pressure levels about 20,000 bar the water beam reaches supersonic speed enabling it to cut wood without the development of heat or to remove rubber from airplane landing strips. The first applications in surgery were attempted in the 1980s. It soon became clear that parenchymal organs, in particular the liver, were best suited to this technique (Fig. 6.37A).

Using the thin laminar liquid-jet effect (Fig. 6.37B), liver cells can be removed without destroying cord-like fibrous structures such as the bile ducts or blood vessels. These decisive structures can be excellently visualized and severed after occlusion (Fig. 6.38).

Water jet dissection has also been successfully employed in procedures concerning the prostate, kidney, and parotid gland.

Despite the clear advantages of hydro jet dissection, the initial euphoria was lost in the last couple of years. The large amount of water combined with cell spillage is not without problems, in particular in the case of malignant disease.

Pulsed water jet is today gaining interest in endoluminal endoscopic interventions such as endoscopic submucosal dissection.

6.5 STAPLING DEVICES

Reliable closure of anatomical structures or joining visceral organs is crucial in surgery. Over the long history of surgery, hand stitched sutures were the single option. Surgical sutures need special skills and are time-consuming, in particular when bowel anastomoses have to be created. Not surprisingly, numerous approaches were attempted in the history of modern surgery to develop mechanical assistance in the forming and closing procedures. First, the concept of mating cylinders in various design variants was developed. H. Hültl is considered as the father of the stapling

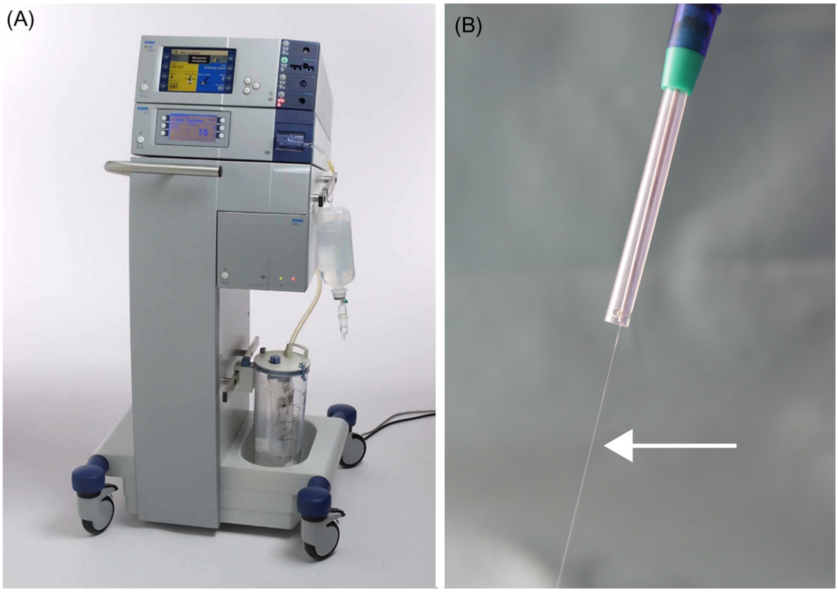


Figure 6.37 Water jet dissection: (A) Helix Hydro-Jet pressure generator [24]; (B) nozzle tip of the instrument with the thin, sharp water jet (arrow). *From (A) Rau HG, Duessel AP, Wurzbacher S. The use of water-jet dissection in open and laparoscopic liver resection. HPB (Oxford) 2008;10(4):275-80 and (B) MITI.*

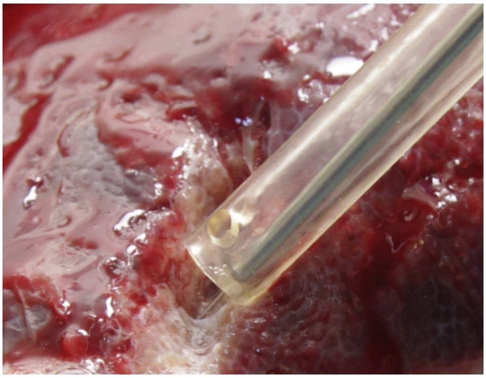


Figure 6.38 Water jet dissection of liver parenchyma: Removal of the parenchymal cells. Small bile ducts and blood vessels are left over. Occlusion and cutting of the remaining canalicular structures can then be performed. *From MITI.*

principle. He disclosed in 1908 the idea of approximating the two wound edges by means of an U-shaped metallic clip: By pressing it against a staple forming bucket, the typical B-shape is created and adequate compression is exerted on the tissue to provide healing. By combining several lines of multiple clips, effective tissue sealing could be achieved. A. von Petz introduced an improved version in 1921 and the "Petz clamp" found moderate success in clinical surgery over the next decades. The real breakthrough of the stapling devices, however, began in 1967, when the United States Surgical Corporation introduced the first reliable circular stapler. It was a significantly improved version of former Russian developments [25]. Today, various companies provide a wide range of different stapling devices [26]. They are slightly different in design, but all of them mature and reliable [27].

There are three main modern stapler types:

Linear staplers,

Linear cutting staplers,

Circular staplers.

6.5.1 Linear staplers

This type of a stapler, in its numerous variants, joins the tissue by inserting a linear, staggered double or triple row of staples into it. After closure, the tissue protruding between cartridge and anvil is cut off with a scalpel (Fig. 6.39).

The exchangeable cartridge containing the clips is mounted in the stapler exactly opposite to the anvil. The tissue to be dissected is positioned in-between. With the first squeeze of the firming handle (or trigger) the tissue is approximated. A pen is pushed forward to prevent any escape of the tissue. At this point, the process is still reversible. Using the release button, the stapler can be opened again and readjusted. If the trigger is squeezed for the second time, the staples perforate the tissue layer and are shaped into the "B" form thus inducing a water- and \airtight closure. A scalpel is used to divide the tissue from the side of the specimen. Now, the trigger is released and the device can be removed.

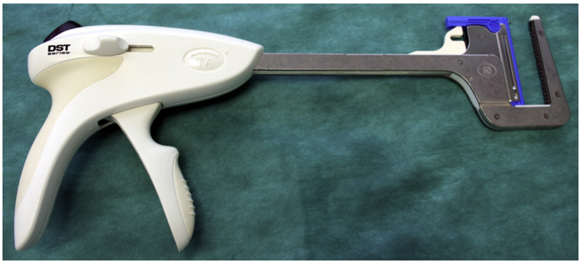


Figure 6.39 Linear stapler. *From MITI.*

Originally, staplers were provided as reusable instruments with reloadable cartridges. They were high precision tools made of steel.

Today, staplers are disposable instruments primarily made of plastics. The cartridges can still be reloaded for multiple use on the same patient.

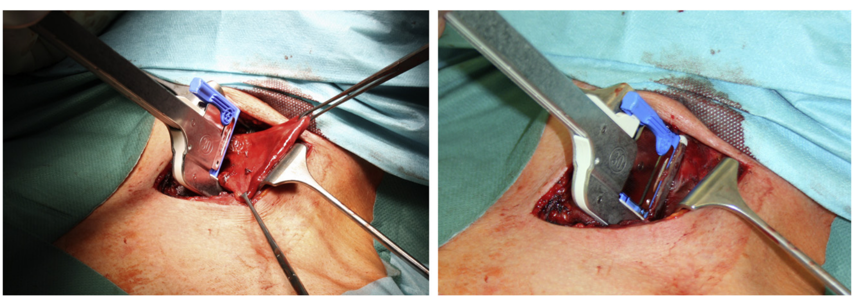
Initially, the clips were made of silver. Later on, surgical steel was used. Today, titanium is preferred.

"Simple" linear staplers are used if a certain part of the GI tract has to be resected, i.e., to be removed completely. The removal of a Zenker's diverticulum is one typical example (Fig. 6.40).

6.5.2 Linear Cutting Devices

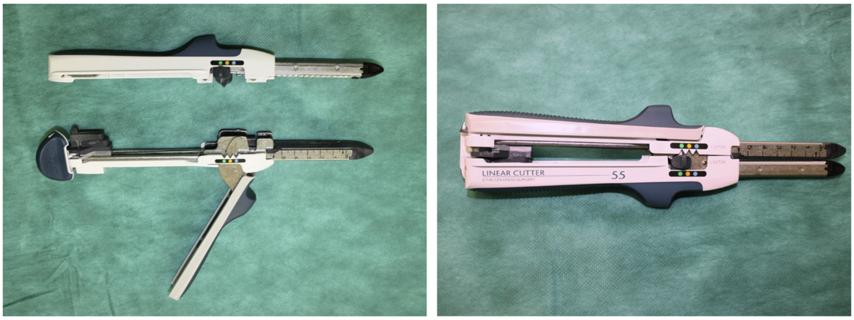
As opposed to simple "linear" staplers, linear cutting devices are designed to seal both edges of the anatomical structure to which it is applied. Accordingly, two parallel, linear, staggered double or triple rows of clips are inserted and dissection is performed in-between. Formerly, tissue separation was achieved by a scalpel inserted into the slit between the middle of the rows of staples. Today, a knife is simultaneously driven between the staple rows, dividing them up to one and one half staple lengths from the distal end (Fig. 6.41).

Linear cutters consist of two separate assemblies which are inserted independently into the respective segment of the GI tract. Then, they are mated together and locked during tissue approximation. The stapler is fired by pushing the firing knob forward toward the distal end of the instrument.



(A) (B)

Figure 6.40 (A) The linear stapler is used to occlude just one edge of the tissue. Here: Removal of a so-called Zenker's diverticulum (small bag of the esophagus). The communication with the esophagus has to be occluded with three stapler lines, whereas the specimen is removed. (B) After excision of the diverticulum, the stapler is released and removed. *All from MITI.*



(A) (B)

Figure 6.41 Linear cutting device: (A) It consists of two branches which can be inserted independently of each other into the respective tubular structure. (B) In the next step, they are mated together and locked. If the firing knob is moved forward to the distal end, the staple lines are closed and, simultaneously, divided. *All from MITI.*

This knob drives the knife and, simultaneously, the staple pusher along the cartridge, thus inserting the staple lines and dividing them.

The devices are disposable and provided in various lengths (3–15 cm). Should more than one firing be required, the device can be reloaded by a new cartridge.

Linear cutting devices were intelligently adapted to various applications.

Linear cutters do not only facilitate (Fig. 6.42) resection but also facilitate the creation of side-to-side anastomoses (see Chapter 3.2.3: Steps of the Operation).

Special designs of cutting staplers are available for laparoscopic surgery (see Chapter 7: Operative (Surgical) Laparoscopy).

6.5.3 Circular Staplers

Circular staplers are designed to perform anastomoses between the two ends of a hollow organ (see Chapter 3.2.3: Steps of the Operation).

Circular staplers consist of the head, a slightly bent tubular body, and the handle (Fig. 6.43). The head encompasses the staple cartridge and a detachable anvil unit. The cartridge contains two or three staggered concentric arrays of numerous staples and a circular knife, which is positioned radially inward from the staples. The bucket of the anvil, which forms the staples, forms an annular array so that each staple in the cartridge has a corresponding bucket in the anvil. A plastic ring is located inside the array of buckets in alignment with the knife in the cartridge. Turning the wing nut approximates or separates the head and the anvil (Fig. 6.44).

(A) (B)

Figure 6.42 The use of a linear cutting device for open abdominal surgery. Resection of an intestinal segment: (A) The device is closed at the resection line and fired; (B) the bowel is severed. Both edges are closed with stapler lines. *Courtesy: PD Dr. D. Wilhelm, Klinikum rechts der Isar.*

Figure 6.43 Circular stapler: Note the slightly curved shape which facilitates the insertion into the rectum. *From MITI.*

Figure 6.44 The head of the circular stapler in the "open" state. The anvil is at a distance to the shaft but still connected to it. *From MITI.*

By squeezing the handle, the staples are pressed out of the cartridge and formed against the anvil. In the same moment, the circular knife is moved forward as well and pushed against the plastic ring of the anvil, thus cutting the tissue which protrudes into the lumen (Fig. 6.45).

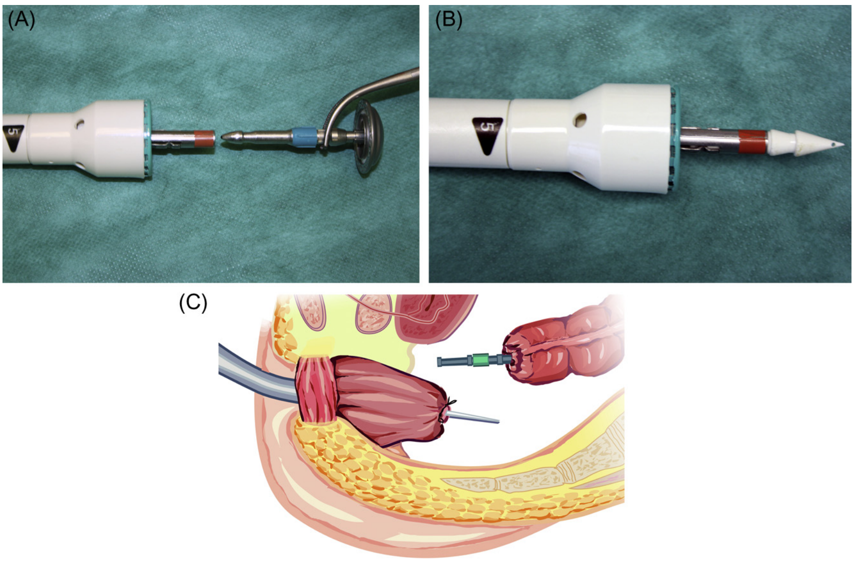


Figure 6.45 (A) The anvil is removed and will now be positioned into the contralateral stump of the colon using a purse string suture. (B) A spearhead-like plastic tip is attached to the central rod of the stapler. It helps to perforate the blindly occluded distal stump. (C) Immediately before the stapler can be fired: The central rod of the stapler is visible. The sharp plastic tip is already removed. The shaft of the anvil will now be reunited. *From (A,B) MITI and (B) M. Scholle.*

The rigid design of today's staplers limits their application to the rectosigmoid area. Attempts have been made to create flexible circular staplers to reach higher segments of the colon or—inserted through the mouth—for esophageal or gastric anastomoses. Despite considerable R&D efforts, flexible staplers are still lacking on the market. The gap is still waiting to be closed.

6.6 BIOMATERIALS

Visceral surgery requires not only instruments and devices but, additionally, biomaterials as well. A well-known example is surgical sutures. Less known is the widespread use of surgical meshes.

6.6.1 Surgical Suture Materials

Ancient surgery was performed with natural organic materials, such as cotton, flax, hairs, silk, or catgut, the latter being collagen from sheep or goat intestines. Today, synthetic threads have almost completely replaced the suture material of former times.

In order to classify the very broad range of suture materials on the market, two different categories should be used: absorbability and internal structure.

6.6.1.1 Absorbability

Absorbable sutures keep their tensile strength as long as it is required over the healing process. Parallel to the increasing strength of the tissue, they are degraded by the tissue metabolism (proteolytic enzymatic degradation) until they are completely dissolved. Table 6.1 gives an overview of the most commonly used suture materials.

Nonabsorbable sutures remain in place forever, as long as they are not removed. In general and visceral surgery they are still used for skin closure. It is assumed that the cosmetic result is superior since immune response is lower. At any rate, they are cheaper and easier to remove.

More evidence-based is the use of nonabsorbable sutures in highly dynamic anatomical regions. Hernia repair (groin, scar, hiatal hernia) is a classic example.

6.6.1.2 Internal Structure

The threads either may be produced as one homogenous fiber (monofilament) or consist of multiple cords, which are often braided (Fig. 6.46).

Monofilament threads pass smoothly through the tissue, but are less easy to knot than braided ones.

The strength of the thread has to be adapted to the anatomical structure and the local force. Most remarkably, the diameter of surgical threads is not defined metrically (mm) but according to the Unites States Pharmocopeia (USP) standard. Table 6.2 gives an overview about diameters which are commonly in use in visceral surgery.

Table 6.1 Suture materials

Absorbable	**Nonabsorbable**
Polyglycolic acid	Polypropylene
Polylactic acid	Polyester
Polydioxanon	Nylon
Caprolactone	

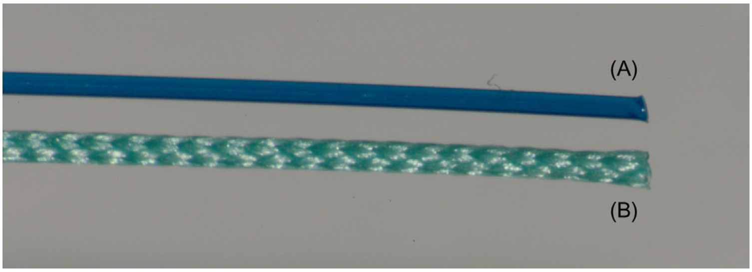


Figure 6.46 (A) Monofilament thread (nylon); (B) multifilament thread, braided (polyglycolic acid). *From MITI.*

Table 6.2 USP codes and diameter

USP designation	Diameter (mm)
5-0	0.1
4-0	0.15
3-01	0.2
2-0	0.3
0	0.35
1	0.4
2	0.5

In other surgical subdisciplines, thinner (ophthalmology) or thicker threads are used, ranging from 0.01 mm (USP 11-0) to 0.7 mm (USP 5).

In the past, suture materials were delivered on coils. The suture was threaded at the OR table with reusable, eyed needles. Today, practically all suture materials are delivered as a fixed combination of threads and needles (swaged needle or atraumatic suture) (Fig. 6.47).

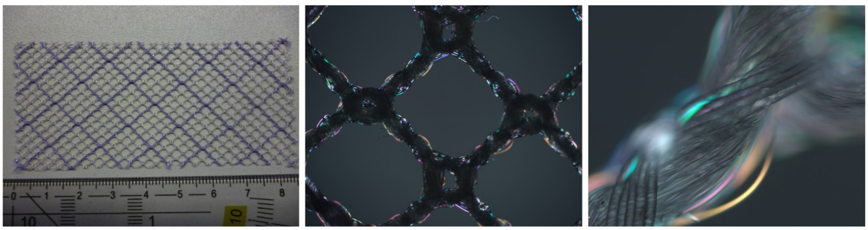
Reusable needles are becoming less popular, since the eye of the needle dilates the suture channel inadequately and the handling of the sutures is more time-consuming.

6.6.2 Surgical Mesh

Certain pathologies, such as hernia, require a reinforcement of the anatomical structures. For this purpose, surgical meshes were developed about 60 years ago. The first meshes (Marlex) were heavyweight, rather rigid sheets made of polypropylene. They induced significant scar formation which was mechanically stable but often irritating.

(A) (B) (C)

Figure 6.47 (A) Prepacked swaged sutures: The prepacked needle–suture combination is delivered in a transparent cover. (B) The running nurse peels it open and throws the sterile content onto the Mayo stand. (C) The needle can now be fixed with the needle holder. *All from MITI.*



(A) (B) (C)

Figure 6.48 (A) Strip of a VYPRO II mesh (Ethicon). The meshes are available in different sizes, the smallest being 10 × 15 cm; (B) microstructure of the mesh; (C) magnified (100×) view of a strand: Note the multifilament structure. *All: Courtesy: G. Babaryka, Klinikum rechts der Isar.*

Beyond excessive scar formation, erosion of surrounding tissue, migration of the implant due to inadequate elasticity, or perforations into bowels or bladder were observed. Surgical site infection with a mesh in situ is a catastrophe since biofilm forming bacteria cannot be eliminated as long as the implant is still in place. Nonetheless, textile prosthetic devices became a promising market. According to Sanders, about 20 millions of them are used worldwide per year [28]. A vast amount of R&D efforts was invested by the manufacturers to develop the "ideal mesh." Currently, more than 200 different designs are on the market.

Contemporary meshes are lightweight and loosely woven, being either absorbable, nonabsorbable, or partly absorbable (Fig. 6.48).

A more sophisticated classification was developed by Klinge et al. [29] (Table 6.3).

Table 6.3 Classification of mesh materials based on porosity

Class I: Large-pore meshes with a low risk for bridging, defined by textile porosity >50% and effective porosity >0% (1a) monofilament (1b) multifilament (1c) mixed structure or polymer
Class II: Small-pore meshes with a high risk for bridging, defined by textile porosity <50% and effective porosity of 0% (2a) monofilament (2b) multifilament (2c) mixed structure or polymer
Class III: Porous mesh with special features in addition to the pure textile construction, e.g., to prevent adhesions
Class IV: Film-like mesh without porosity, submicron pore size or secondarily excised pores
Class V: Complex textiles difficult to uniformly characterize, either preshaped, preformed, or three-dimensional
Class VI: Tissue-derived biologicals (6a) noncross-linked (6b) cross-linked (6c) special features

Up to now, meshes are still a matter of debate in surgery, since the continuous development of new types has impaired a systematic evaluation of those in use (Fig. 6.48).

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CHAPTER 7

Operative (Surgical) Laparoscopy

Laparoscopy is a technique to look into the abdominal cavity via a tiny incision using a (rigid) telescope, allowing a visual exploration of the internal organs. The history of diagnostic laparoscopy is comparatively long, since it was performed first in 1901. Georg Kelling in Germany examined the peritoneal space in dogs using a cystoscope, but did not dare yet to use this new approach in humans. This was done in Sweden some 10 years later by Hans Christian Jacobaeus, who published the first series of clinical cases. To reduce the risk of injury to intestinal organs when inserting "blindly" the trocar, he selected patients only with ascites (fluid collection in the abdomen). At any rate, he could prove that laparoscopy permitted an excellent diagnostic approach to the liver, the peritoneum, and partly of the intestine. Up to that time, any other imaging procedures of the viscerum were not yet available which explains why diagnostic laparoscopy soon became extremely popular, in particular for the diagnostic workup of liver diseases.

In 1927, the first monography upon laparoscopy was published by Robert Kortsch. The technical equipment was continuously improved and the range of indications was widened. Laparoscopy did not only become a valuable diagnostic tool but also become a means of therapeutic intervention. Conrad Fervers first dissected adhesions in 1930 and four years later, Theodor Stolze even argued that laparoscopy could potentially replace laparotomy in the future. Despite these visionary concepts, laparoscopy remained at that time merely a diagnostic procedure. However, the technique was continuously refined. Being rather primitive in the beginning (Fig. 7.1), more advanced modifications followed soon, driven by pioneers like Heinz Kalk and others. Simultaneously, the safety of this rather invasive procedure could be proven by systematic studies.

The diagnostic impact could even be multiplied as soon as Kalk demonstrated the feasibility of taking biopsies (1942).

The early development of (diagnostic) laparoscopy is briefly reported in Table 7.1. For about 40 years laparoscopy was an important element of diagnostic workup in gastroenterology.

(A) (B) (C)

Figure 7.1 The beginnings of diagnostic laparoscopy (ca. 1930): (A) Via a large bore puncture needle, air is pumped into the peritoneal cavity using a bladder syringe. The patient is awake. (B) While the patient is summoned up to press the abdominal musculature as firmly as possible, the trocar is inserted into the abdominal cavity through the abdominal wall. (C) Direct visual exploration of the internal organs. Note the low standard of asepsis. *Courtesy: Dr. Hanfried Kalk, Bad Kissingen.*

Table 7.1 The history of laparoscopic surgery

1901	Kelling	Celioscopy (animal studies)
1910	Jacobaeus	Laparoscopy
1913	Renon	Laparoscopy
1924	Steiner	Abdominoscopy
1927	Kortsch	Textbook of laparoscopy
1929	Kalk	Technical improvements, standardization
1930	Fervers	Adhesiolysis
1934	Stolze	Laparoscopy instead of laparotomy
1942	Kalk	Laparoscopic liver biopsy

Later on, the clinical importance of diagnostic laparoscopy declined. Gastrointestinal physicians could increasingly use more sophisticated laboratory tests and new imaging procedures such as ultrasonography and computed tomography to establish an accurate diagnosis of abdominal diseases. Laparoscopy appeared to be too invasive and too limited in its diagnostic value as compared to more recent imaging modalities.

Maybe, laparoscopy would have become completely obsolete at that time, if some surgeons had not detected the huge therapeutic potential of laparoscopy. Kurt Semm, a gynecologist, demonstrated that even "real" surgical operations were feasible through small trocar openings, like the removal of an appendix in case of appendicitis.

The pioneers of laparoscopic surgery recognized some technical innovations which have brought laparoscopy almost to perfection. Three milestones deserve special mention:

The Hopkins optic. In the beginnings of the 1960s, Karl Storz, one of the technical pioneers of modern instrument design and production, became interested in the scientific activities of a young British physicist, John Hopkins. Hopkins strongly recommended a new principle of image transmission through the telescope (see below). Storz soon detected the dramatic improvement of image quality and made it commercially available. The benefit was enormous.

Flexible fiber bundles for light transmission. Before a camera can take images out of a large cavity, the latter has to be illuminated. Due to the lack of flexible light transmission devices, laparoscopic telescopes usually had a small light bulb at the tip. This solution was not only impractical but even dangerous, since severe burning of the tissue occurred if it was touched by the bulbs, and in some cases, the bulbs even exploded. As soon as glass fiber cables became available, the light source could be situated apart and illumination could be provided as so-called "cold light" from a distance.

Real-time image transmission. An objective documentation of the actual state of diseases is always crucial, in particular in chronic morbidity. In the early 1940s, photographic documentation was introduced into laparoscopy. Thirty years later, small and comparatively cheap video cameras appeared on the market. Video camera mounted on a laparoscopic telescope now enabled not only the surgeons but also the whole team to observe the interior making active assistance possible if required.

The sum of these innovations made surgical laparoscopy feasible and opened the door for "minimally invasive surgery."

The theoretical (and practical, as we know today) advantages were significant: Whenever an incision is used to penetrate the abdomen, it is unavoidable to cut anatomical structures like nerves, muscles, and fascia. Even after subtle suturing at the end of the surgery, the original integrity cannot be restored. Dissection of sensitive nerves and muscles leads to severe postoperative pain and temporary physical impairment. Scars of the fascia are less force resistant which raises the incidence of scar hernias. This does not happen if the abdominal wall is only perforated by a trocar (Fig. 7.2).

Nonetheless, laparoscopic approaches were considered extremely skeptically by the majority of surgeons at the beginning. Despite massive resistance, laparoscopic surgery soon became the gold standard for numerous operations and is today an integral part of surgery (Table 7.2).

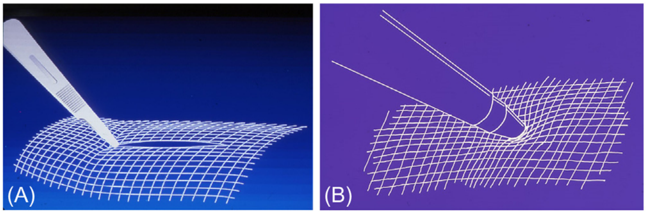


Figure 7.2 The difference of tissue trauma induced by an incision (A) or trocar insertion (B). Once the fibers of the fascia are cut, its original stability can never be regained again. In opposition, the microscopic structure is practically not altered by the trocar: As soon as it is withdrawn, the original configuration of the fiber net is restored. *All from MITI.*

Table 7.2 The introduction of laparoscopic surgical procedures

1981	Semm	Appendectomy
1985	Mühe	Cholecystectomy
1987	Mouret	Cholecystectomy
1990	Pinotti, Shimi	Cardiomyotomy
1990	Dallemagne	Fundoplication
1991	Wexner	Colonic resection
1992	Ablaßmaier	Gastric resection
1993	Grundman	Whipple's procedure

Appendectomy: removal of the appendix; cholecystectomy: removal of the gallbladder; cardiomyotomy: dissection of the muscles of the esophagogastric junction; fundoplication: reinforcement of the lower esophageal sphincter to prevent reflux; colonic resection: removal of a part of the large bowel; gastric resection: subtotal/partial or complete removal of the stomach.

7.1 BASICS

Regardless of the procedure, certain basic instruments are always required in laparoscopic surgery. These include the Veress needle, trocars, telescope, various hand instruments, graspers, and cautery electrodes that can also irrigate and aspirate and an electronic insufflator as well as the visualization chain.

7.1.1 Pneumoperitoneum

7.1.1.1 Creation of the Necessary Space

Under physiological conditions, there is no space left between the abdominal wall and the viscerum. Accordingly, sufficient space has to be created first before a visual exploration and the use of instruments is considered. To this end, gas is pumped (insufflated) into the abdomen to establish a so-called pneumoperitoneum. In principle, three different options are available:

Historically, normal air was used. Air is available everywhere and is free. One particular drawback, however, is that it causes air embolism (blockade of the pulmonary arteries) if it accidently enters the veno-vascular system. Carbon dioxide (CO_2) is a better option, since the risk of air embolism is significantly lower and it is chemically inert. Inert gases like helium or argon would be suitable as well, but they are far too expensive for routine use. In the past, N_2O was used in some centers but is now obsolete because of severe accidents (intraabdominal explosions after contamination with colonic gas). Currently, CO_2 insufflation is the most popular technique worldwide.

Since more than 15 years, alternatives to the pneumoperitoneum have been also on the market. "Gasless laparoscopy" is carried out by elevating the abdominal wall by means of specially designed hook systems. Thus, a tent-like space can be created. Due to many specific drawbacks, this method did not become really popular. Nonetheless, lifting hooks are still commercially available (Table 7.3).

In some instances (e.g., preperitoneal hernia repair, retroperitoneal tumors), artificial space has to be created which is usually accomplished by balloon dilatators. A large variety of dedicated balloon systems is available on the market.

Since creation (and maintenance) of an adequate pneumoperitoneum is decisive for successful and safe laparoscopy, the first challenge now is how to bring the gas safely into the peritoneal cavity. One option is to make a tiny surgical incision into the abdominal wall and to introduce the first trocar under visual control to avoid lesions to the internal organs (semiopen approach, often also denominated as the "Hasson" approach). Many surgeons like it since they feel safer, but an incision, of course, offends against the philosophy of the laparoscopic technique.

Table 7.3 Providing intraabdominal space

Pneumoperitoneum
– CO_2
– Air
– N_2O
– Helium
Gasless laparoscopy

A more elegant method is the use of the Veress needle which has been the common technique in laparoscopy since 70 years ago.

7.1.2 The Veress Needle

The needle consists of a sharp outer sheath and a blunt spring-loaded obturator designed to guard against organ injury upon penetration.

As long as the needle passes through the tissue of the abdominal wall, the blunt tip of the inner mandrin is pressed into the lumen of the sharp outer cannula. As soon as the peritoneal cavity is reached, the blunt tip can move forward and gas is able to flow into the abdomen via the lateral window. Disposable needles are based on the same design, their advantage being a sharper tip and visible introduction mechanisms (Fig. 7.3).

The "Veress" principle is imitated still today in many similar applications.

The sophisticated construction of reusable Veress needles gives way to several causes of malfunction. If the lumen is obstructed by blood or tissue due to inadequate instrument reprocessing, gas flow will be impaired or completely blocked. The surgeon could assume, during insertion, that the peritoneal space has not yet been reached and proceed the needle mistakenly too deep into the bowel.

The same will occur if a free motion of the internal mandrin is restrained. This is caused by kinking of the needle or if the space between mandrin and trocar is soiled.

The potential sources of risk are avoided if disposable Veress needles are applied. However, the cost factor has to be considered (Fig. 7.4).

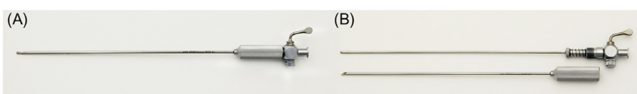


Figure 7.3 (A) Classical Veress needle. (B) Veress needle disassembled for cleaning with spring for closing the sharp tip after entering the abdominal cavity visible. *All from MITI.*

Figure 7.4 A selection of commercially available disposable Veress needles. *From MITI.*

7.1.2.1 Insertion of the Veress Needle

After a small incision of the skin the abdominal wall is elevated to induce an intraabdominal vacuum. The Veress needle is now cautiously inserted. As soon as the sharp tip of the needle perforates the parietal peritoneum and enters the separation line between parietal and visceral peritoneum, the inner spring-loaded stylet moves forward. Now the lateral hole is given free which enables CO_2 gas to be delivered intraabdominally (Fig. 7.5).

7.1.3 Gas Insufflators

7.1.3.1 Insufflation Device

The insufflator is a pump to deliver the CO_2 into the abdomen which is required to create the artificial space to perform surgery. It is designed to produce adequate pressure (ca. 15 mmHg) and to maintain it during the

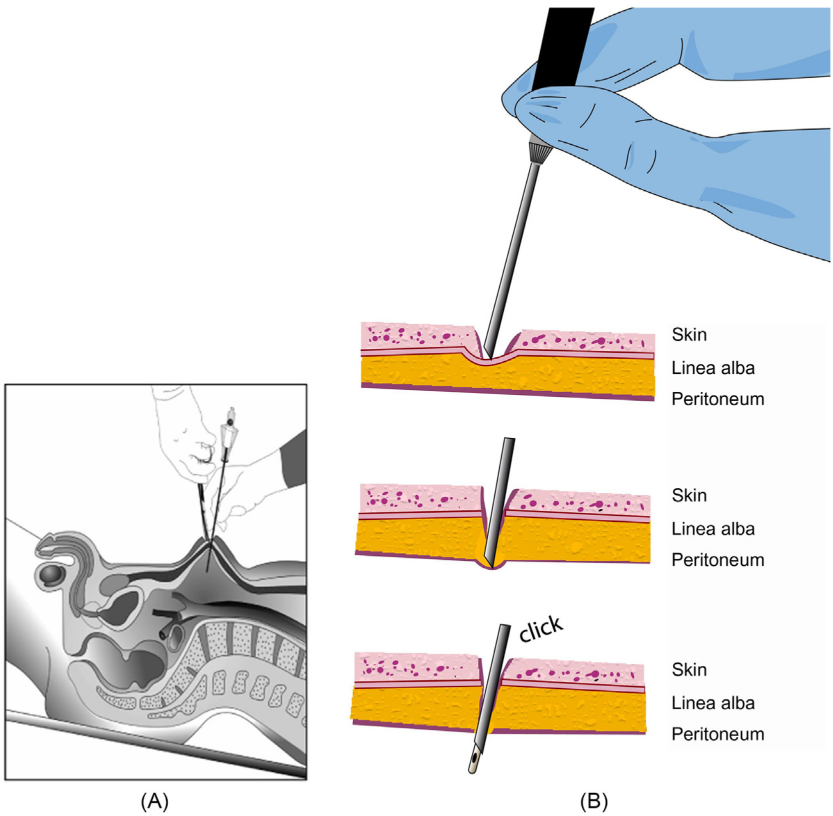


Figure 7.5 Pneumoperitoneum: (A) Elevation of the abdominal wall; (B) after the incision of the skin, the abdominal wall is punctured with the needle. The resistance of the tissue pushes the mandrin back. As soon as the peritoneal space is reached the blunt tip moves forward. *From M. Scholle.*

procedure even in case of gas leaks, but, simultaneously, pressure peaks which would be harmful for the patients have to be avoided. Accordingly, pressure and flow sensors are essential components of an insufflator (Fig. 7.6).

Insufflators are equipped with displays indicating the preselected and the effective intraabdominal pressure as well as gas flow and the total amount of insufflated gas (Figs. 7.7 and 7.8).

If there is no central gas supply provided in the OR, gas cylinders have to be used. In this case, it is important to know when a change of the bottle is imminent. A gas supply display is therefore an integral part of the device.

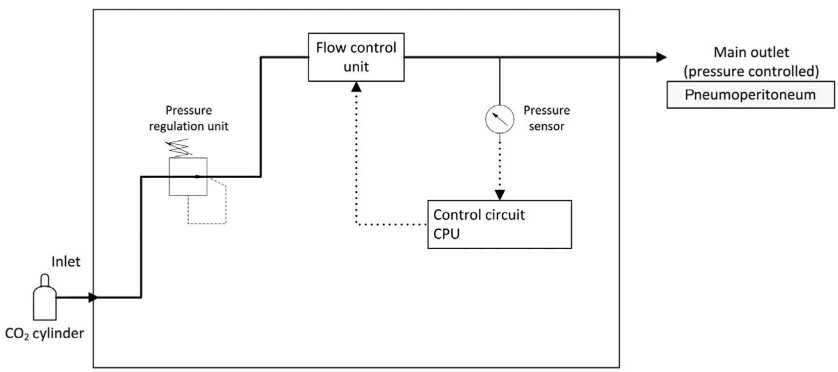


Figure 7.6 Block diagram of an insufflator. The pressure regulation unit reduces the pressure from the source to a certain limit, the flow control unit regulates the flow depending on user preferences and measured intraabdominal pressure. *From MITI.*

Figure 7.7 Gas insufflator, front panel: a, power switch; b, gas supply; c, intraabdominal pressure; d, insufflation flow; e, insufflated volume; f, tube to patient connector. *From MITI.*

Figure 7.8 Gas insufflator, rear panel: a, gas inlet; b, ground connector; c, mains plug; d, SCB (STORZ Communication Bus) connector, bus system to transfer data to other peripheral devices; e, holder for small gas bottle if the insufflator is mounted on a trolley. *From MITI.*

To avoid critical pressure peaks an acoustic/visual alarm is activated as soon as the intraabdominal pressure exceeds the preselected setting, e.g., due to contraction of the abdominal muscles if relaxation decreases.

Medical grade CO_2 is insufflated passing through a filter, commonly at room temperature, with a relative humidity approaching 0%. Currently, there is a trend to integrate additional devices to warm and to humidify the insufflated gas to avoid the potential detrimental effects of desiccation and the loss of temperature. The real clinical significance is still a matter of debate.

7.1.3.2 Creation of the Pneumoperitoneum

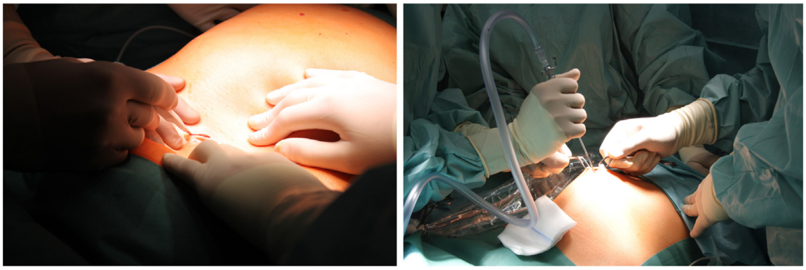
Prior to the insertion of the Veress needle a small incision of the skin has to be made to reduce resistance of the skin (Fig. 7.9).

The next step is to lift up the abdominal wall, e.g., by using Backhaus clamps as seen in Fig. 7.9B to create an intraperitoneal negative pressure. The Veress needle is, then, inserted. It is important to keep the needle firmly at the outer trocar (Fig. 7.10).

In the beginning, a low flow (1 L/min) has to be selected to reduce the risk if the Veress needle is in a wrong position. If it is correctly placed within the peritoneal space, the intraabdominal pressure will be zero or even negative in the beginning.

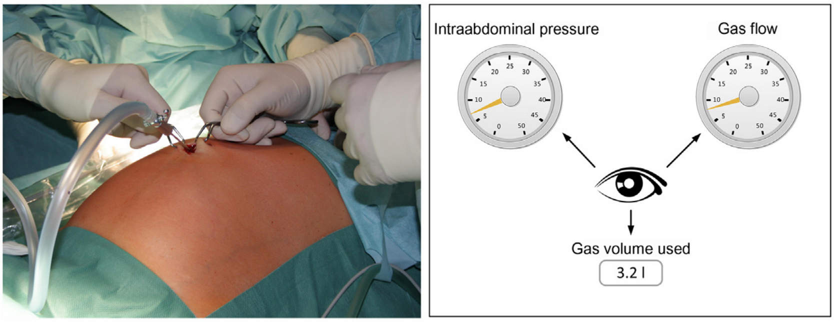
If the gas can flow in freely, the actual flow should be as high as the preselected flow.

With a continuing insufflation, the intraabdominal pressure will gradually increase until the preselected intraabdominal pressure (usually 15 mmHg) is



(A) (B)

Figure 7.9 (A) A scalpel is used to cut through the skin, to facilitate the insertion of the Veress needle; (B) the abdominal wall is lifted up and the Veress needle is advanced. *All from MITI.*



(A) (B)

Figure 7.10 (A) Insufflated abdomen before removing the Veress needle; (B) measuring the key parameters during initial insufflation to make sure that the Veress needle is positioned correctly. *All from MITI.*

reached. Higher intraabdominal pressure causes postoperative pain. Lower pressure is potentially more comfortable for the patient in the postoperative phase, but reduces the available space intraoperatively [1].

As soon as the first trocar has been inserted safely into the abdomen, gas flow is switched to the maximum (30 L/min in most devices).

Recently, a revolutionary new approach was presented on the market. The so-called Air Seal system (SurgiQuest, Milford, CT, the United States) does not require tight fittings of the instrument but allows free use of instruments of large and small diameter. This valve- and membrane-free system is based on a high duty gas pump which provides a gas stream which creates a sealant layer of gas serving as a fitting. Responding immediately to the slightest changes of intraabdominal pressure, a stable pneumoperitoneum is continuously maintained, even under suction. Continuous smoke evacuation always provides good visuability [2]. The system, however, is significantly more expensive than standard insufflation technology. The noise produced may be irritating. Clinical evaluation is currently being performed [3].

7.1.4 Trocars

Trocars are devices made up of an obturator, the cannula (a hollow tube), and a seal. Frequently, an insufflation tap is also integrated.

With trocars, pathways into the abdominal cavity are created to insert the camera and the instruments into the abdomen. Cannula sleeve diameters are usually 1 mm larger than the instruments to be introduced through them. Of note, 10−12-, 10-, and 5-mm trocars with pyramidal or conical obturators are usually employed for laparoscopic surgery. The stylets on reusable trocars should be sharpened regularly. Disposable trocars offer sharp stylets and tip shields that may help avoid organ injury. These, however, are not foolproof and do not supplant proper insertion techniques. The newest single-use trocars incorporate antisplashback features and universal valves that allow instruments ranging from 5 to 11 mm to be introduced without attaching converters. If the patient has had previous surgery, and difficulties are encountered in achieving the pneumoperitoneum, an open laparoscopy may be attempted, using a Hasson cannula. A direct cutdown is made into the abdominal cavity, followed by stay sutures placed in the fascia. The cannula is placed in the abdomen and secured in place with the stay sutures. CO_2 tubing is then attached, and insufflation commences through the Hasson cannula.

Both reusable and disposable trocars have in common the following items (Fig. 7.11).

Trocars are a very lucrative market. Accordingly, the spectrum of commercially available products is very broad.

7.1.4.1 Reusable Trocars

This market is dominated by STORZ, WOLF, AESCULAP, and others, mostly German companies. This type of trocars is usually made of metal (Fig. 7.12). For cleaning, reusable trocars can be disassembled. A major problem of this type of trocars is to provide adequate caliber reduction if instruments are used which have a smaller diameter than the maximum diameter of the trocar. Specially designed converters and reduction tubes are provided.

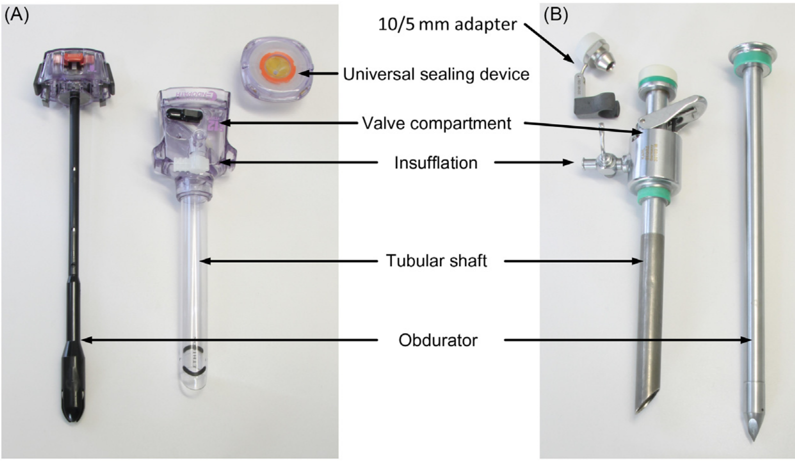


Figure 7.11 (A) Disposable trocar; (B) reusable trocar. *All from MITI.*

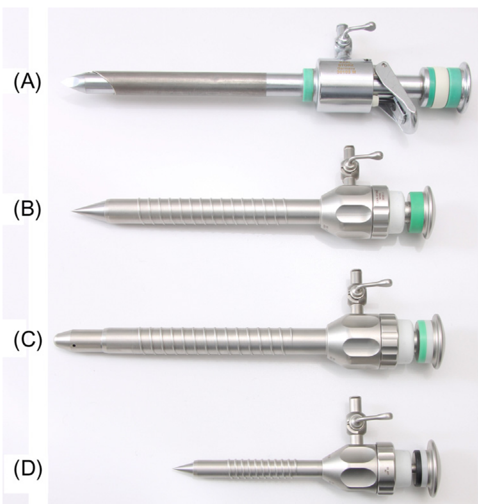


Figure 7.12 (A) Pyramidal, sharp tip. The valve can be opened actively using the lever. Standard length and diameter (10 mm); (B) like in (C) and (D), the shaft bears a helical structure to prevent slipping of the trocar within the port site; (C) Like B with prolonged blunt obturator; (D) trocar for pediatric surgery: it is shorter with a smaller diameter. *From MITI.*

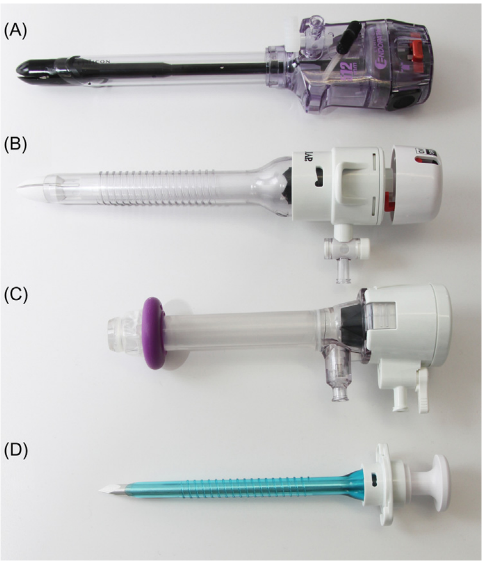


Figure 7.13 Disposable access systems. These instruments are designed for single use. A 12-mm internal diameter with a deployable blade access system is shown in (A). The next device (B) also has a 12-mm internal diameter, but has a blunt tip that is used to pass through the abdominal wall. (C) is a trocar for the semiopen access (Hasson technique). On the left, the inflatable balloon is seen to seal the abdomen. On the right, an additional nozzle is visible below the insufflation cock to inflate/deflate the distal balloon. (D) is a simple trocar for 5-mm instruments. No connection to the insufflation system is provided. (B) and (D) bear a helical structure on the shaft to prevent slipping. *From MITI.*

7.1.4.2 Disposable Trocars

This type of trocars is usually produced as a plastic device. After a single use, they are discarded (Fig. 7.13).

7.1.4.3 Hybrid Systems

Some companies try to combine the advantages of reusable trocars with the advantageous features of disposable trocars by offering partly reusable and disposable systems.

7.1.5 Visualization

7.1.5.1 Laparoscopes (Laparoscopic Telescopes)

The quality of the video image is the key to a safe and fast surgical intervention. Up to now, Hopkins rod lens systems are the gold standard. Rod lens systems were developed by the physicist Harold Hopkins in the 1960s.

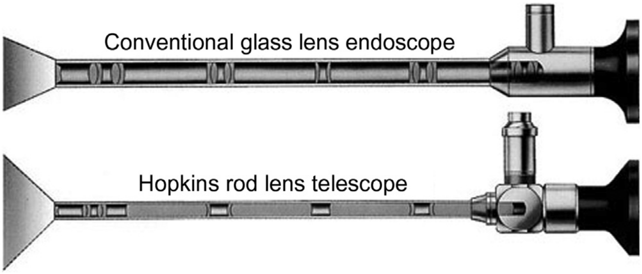


Figure 7.14 The standard endoscope (above) and Hopkins telescope design (below). The glass rods in the Hopkins telescope provides a larger image, better light transmission, and improved clarity of vision. *From Karl Storz GmbH.*

Figure 7.15 Standard laparoscopes with various angles of view. *From MITI.*

His idea to fill the air space between the lenses with glass rod significantly improved light transmittance and image quality (Fig. 7.14).

Laparoscopes are currently available with diameters of 2, 3, 5, 7, 10, and 12 mm. The angle of view is 0, 12, 30, 45, 70, 90, or 120 degrees. Modern laparoscopes can be steam sterilized at 134°C (Figs. 7.15 and 7.16).

7.1.5.1.1 Advanced Laparoscopes

Most innovative designs enable the surgeon to change the angle of view of the laparoscope, e.g., the EndoCAMeleon, by STORZ. The viewing angle can be adjusted continuously between 0 and 110 degrees (Fig. 7.17).

Endoeye Flex is a comparable system provided by Olympus (Tokyo, Japan) which is even capable of 3D visualization (Fig. 7.18).

For different applications, special telescopes are available. Today, fluorescence imaging (see Chapter 5.6: Advanced Optical Systems) is being used increasingly to visualize changes in the abdominal cavity or to visualize the sentinel lymph nodes, for example, which are not visible with conventional light. Therefore, special colorings like Fluorescein or Indocyanine green are

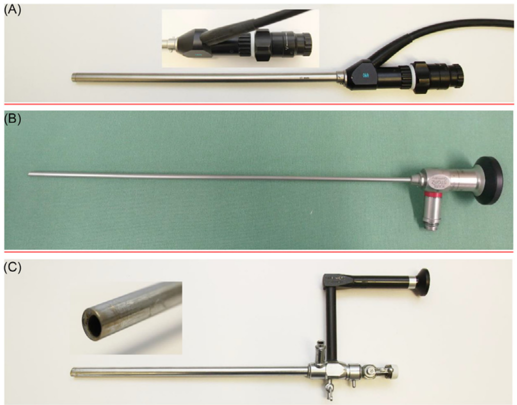


Figure 7.16 Specially designed laparoscopes. (A) Laparoscope with zoom function. (B) Needlescope with a diameter of 2 mm. (C) Working channel laparoscope. *All from MITI.*

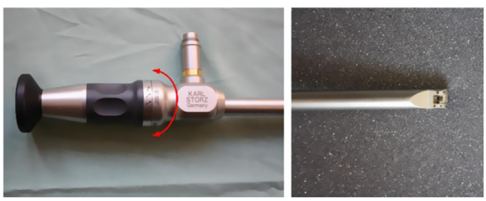


Figure 7.17 Karl Storz EndoCAMeleon with on-the-rod adjustable viewing angle. *From MITI.*

Figure 7.18 Olympus Endoeye. Angulation is achieved by mechanical bending on the tip. *From Olympus Deutschland GmbH.*

applied over the vessel system. To make these colored fluids visible, special light sources with adapted wavelengths are necessary and additional laparoscopes with filters to let only pass parts of the light spectrum to the video chip (Fig. 7.19).

7.1.5.1.2 Future Developments

In flexible endoscopy, glass fiber endoscopes with mounted cameras have long been replaced by chip-on-the-tip endoscopes.

Similarly, it is expected that rod lens scopes will be substituted by photochips which would be certainly advantageous in many regards (less space, less weight, etc.). Up to now, however, the image quality of the Hopkins optic is still unmet.

7.1.5.2 Laparoscopic Cameras

The camera system has two components: The head of the camera (Fig. 7.20) and the processor unit which is positioned apart on the trolley (see Section 7.1.5.3: Laparoscopic Image Processors (Camera Control Unit)).

Figure 7.19 Laparoscope with filter for visualization of different fluorescence agents (see Chapter 5.6: Advanced Optical Systems). *From MITI.*

Figure 7.20 Head of the camera. *From MITI.*

The key elements of the head of the camera which is attached to the ocular of the telescope are the objective lens and the charge coupled device (CCD). The lens focuses the image of the object of the CCD chip. The chips (usually three of them for red, green, and blue) convert the optical image into electrical signals which are conducted to the controller.

The camera has to be focused as soon as it is mounted to the telescope. This is achieved by rotating the ring switch at the front end. An object should be selected with sufficient cues like a suture pack or a surgical instrument at an adequate distance (e.g., 10 cm for a 10-mm telescope).

Modern cameras have, in addition, a second rotating ring to modify the zoom.

White balancing is required prior to any use of the telescope–camera combination to adjust the primary colors (red, green, blue) to make a pure natural white color.

A white object (e.g., a white towel or a sterile sheet of paper) is kept in front of the telescope and the respective button of the head of the camera is pushed. A signal indicates that white balancing is successfully achieved.

The head of the camera is not suitable for sterilization. Prior to use it has to be covered by a sterile plastic hose including the camera cable (Fig. 7.21).

7.1.5.3 Laparoscopic Image Processors (Camera Control Unit)

The image processor is the link between the telescope and the monitor (Fig. 7.22).

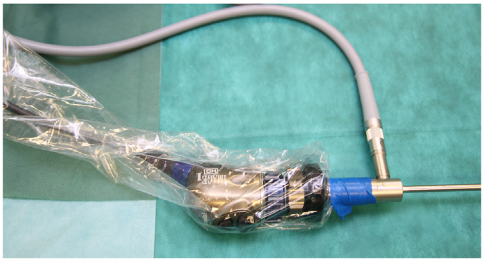


Figure 7.21 Telescope–camera combination. Camera and cable covered by a sterile plastic hose. *From MITI.*

Figure 7.22 Front panel of an image processor (CCU): a, power switch; b, white balancing button; c, USB connectors for mobile storage devices; d, connector for the camera head. *From MITI.*

Figure 7.23 Rear panel of the CCU: a, link connectors to other CCUs for image switching; b, SCB (STORZ Communication Bus) connector, bus system to transfer data between other peripheral devices; c, network connector for storage; d, USB connector for portable storage media; e, DVI and composite video outputs; f, link out for video connection to other CCUs; g, electrical ground connector; h, mains plug. *From MITI.*

Most camera control units (CCUs) are equipped with an automatic gain with a link to the light source control to compensate inadequate illumination (too weak or too high) in a certain range (Fig. 7.23).

7.1.5.4 Monitors

Surgical monitors should offer a higher quality level than standard consumer products.

Especially the color reproduction must be as natural as possible, since diagnostic decisions are made based upon the color tone of tissues. The image has to be completely flicker-free to ensure a nontiring work, as well as distortion-free and with high contrast to maintain a sufficient image representation even in not well dimmed rooms, higher dynamic ranges (minimum to maximum contrast) offer improved visualization of details.

Surgical Monitors are available in sizes from 15 to 46 inches. Large monitors are impressive but they have to be watched from a certain distance. The closer the screen is located to the surgeon the smaller it has to be to obtain a good image (Fig. 7.24). Today, typically 24-inch liquid crystal display (LCD) or thin film transistor (TFT) displays with Full-HD resolution with 1920 × 1080 pixels are widespread in operating rooms. Technically it is the same technique, LCD stands for the use of liquid crystals in the individual pixels of the screen and TFT for smallest transistor elements which control the orientation of the liquid crystals and thus their light transmittance.

These displays use the optical characteristics of small crystals to deflect light at a certain angle. An LCD cell consists of two 90 degrees rotated polarizing films which are per se opaque. However, there is a layer of liquid crystals between these two polarizing films, which is dimensioned such that it rotates the light waves exactly 90 degrees back to the original position. The viewer sees the backlight of the display as "full lighting." By applying a voltage to the liquid crystals, the angle of radiation can be changed, which results in a reduced light transmission, up to completely opaque. This voltage is controlled by the TFT element, a film with thousands of small transistors.

In the TFT element not only the overall brightness, but also the color rendition of the image is controlled. The light for each pixel passes

Figure 7.24 Monitors for laparoscopic surgery. Boom-mounted video screens can easily be positioned to provide "optical correctness." The position of the surgeon, the working field, and the monitor have to be arranged in one line. *From MITI.*

through a color cell that consists of three adjacent RGB (red, green, blue) color filters. Each filter is equipped with a separately controllable transistor—a TFT with 1920 × 1080 pixels consists therefore exactly 3 × 1920 × 1080 transistors, controlling the light transmission for each color cell. By additive mixing, one of the necessary color pixels is then produced.

The most important quality factors which affect the represented image on the monitor are:

- luminance,
- contrast ratio,
- viewing angle,
- color representation,
- constancy of color and luminance.

The screen luminance describes the emitted brightness of the screen in candela/square meter (cd/m^2) and must be higher in brighter rooms. A surgical screen should have a luminance of at least 300 cd/m^2.

The contrast ratio describes the relative brightness difference between black and white on the screen and is a measure of the screen's capability for generation of a well contrasted image. Current surgical displays offer a contrast ratio of 1:1000, wherever possible more is preferable.

Since in a common OR setting typically more persons are looking at the same screen, which results in not all being able to view at a right angle. Depending on the surgical scenario quite large viewing angles are necessary, therefore a display should have a large viewing angle. The viewing angle is defined as the maximum angle where the contrast ratio is reduced to 1/10.

It is self-evident that the surgical display must be able to represent the complete color spectrum. Current CCUs deliver an 8 bit signal per pixel and color channel, which means $2^8 = 256$ different shades per color resulting in $(2^8)^3 = 16.7$ Mio different colors for a typical color model [i.e. RGB (red-green-blue)]. The same must be possible for the monitor to visualize the video signal with true color.

An important quality criterion of medical monitors is the constancy of color and luminance which should not differ over the size of the display.

Picture-in-Picture modes are available on most displays and offer the possibility to display more than one video signal simultaneously. This could be very helpful for combined procedures to visualize the intraluminal and the extraluminal view or for the parallel display of preoperative imaging on the same screen.

Optimal positioning of the screen during the operation is crucial: The rules of "optical correctness" have to be observed. The manual activities of the surgeon have always to be in line with the view. Eyes, hands, and the screen have always to be on one axis. Otherwise, the manual skills of the surgeon will be drastically diminished. Accordingly, the positioning of the monitor must be flexible enough to enable a proper placement anytime.

7.1.5.5 3D Endoscopy

As endoscopy attracts increasing attention in fields like minimally invasive, computer-assisted, and telesurgery, 3D enhanced imaging and better image analysis can be advantageous and improve endoscopic technology. 3D endoscopy can help to reveal meaningful information about anatomical structures, shapes, and conditions. Further, spatial imaging allows improved distinguishing of deformations appearances and general tissue conditions, with great impact on especially surgical applications (Fig. 7.25).

There are different ways to obtain 3D information from endoscopic images. On the one hand, the use of principles like optical coherence tomography can add a third dimension to acquired images (see Chapter 5.6.2: Optical Coherence Tomography). On the other hand, in what is also referred to as a 3D endoscope a pair of two optical channels is used to generate two images of the same site, but from a slightly different angle. This is similar to physiologic conditions, since human beings

Figure 7.25 Full-HD stereo telescope with fixed camera head and four light emersion points with the possibility to switch to 2D by using only one imaging channel. *From MITI.*

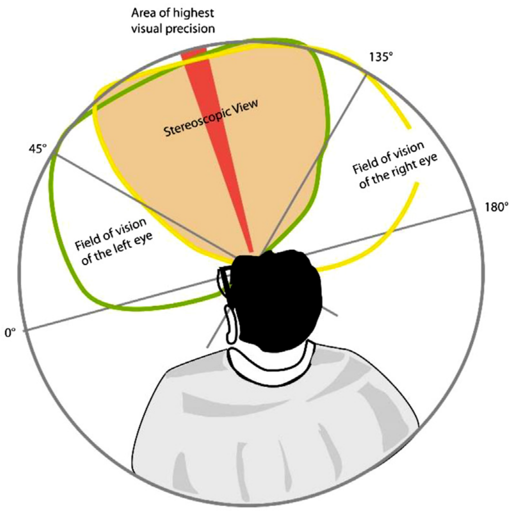


Figure 7.26 Stereopsis: The human FOV is confined to a forward angle of about 140 degrees which is achieved by the two eyes. Stereopsis is possible in the overlapping area of both eyes. *From MITI.*

are able to perceive spatial depth since both eyes produce images at a slightly different angle (Figs. 7.26 and 7.27).

This can be initiated by presenting to the human brain alternately images from the right (right eye) and the left side (left eye) in a rapid sequence. As long as the right image is presented to the right eye, no visual information is given to the left one (and vice versa) (see below).

The images obtained in stereoscopic imaging can be displayed using either two different 2D displays, viewed separately by each of the surgeon's eyes (e.g., in head-mounted displays) or a 3D display (Table 7.4). A 3D monitor presents, in a frequency of at least 25 Hz, the left–right images in a sequence. If the right image is shown, the left eye has to be shuttered and vice versa. Thus, the 3D display requires the use of special 3D glasses, much like in a 3D film screening. Another, even more widespread method to present 3D images is the use of polarization glasses: two images are projected onto the same display through different polarization filters. The glasses with corresponding polarization filters let only pass the light in the same polarization mode, resulting in a separation of the image for the left and the right eye (Fig. 7.28).

In the past, one of the most limiting factors to stereoscopic technology in surgical application was the surgeon‘s reluctance to employ the necessary 3D glasses. The use of such glasses can be experienced to come with

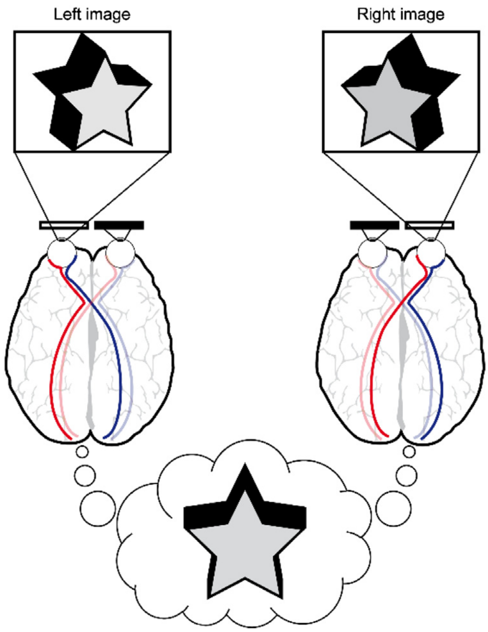


Figure 7.27 3D visualization: The brain is able to synthesize 3D information out of two images of the same objects from different angles. *From MITI.*

Table 7.4 3D viewers

Head-mounted displays	One display for each eye
Shutter systems	The image of one eye is blocked while it is presented to the other one
Passive systems	(a) Polarization systems (b) Interference systems (c) Color anaglyph systems (d) Chromadepth systems

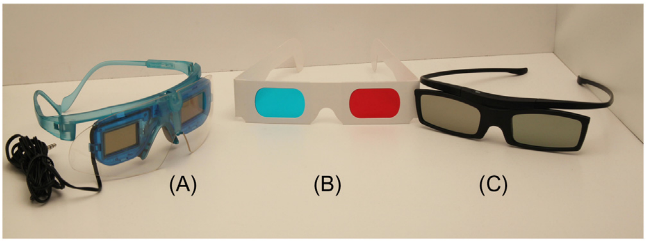


Figure 7.28 Selective left/right visibility is achieved either by shuttering (A), red/cyan splitting (B), or by polarization (C). Shuttering needs to be synchronized with the screen, which is achieved by wireless or wired connections, and must be powered electrically. *From MITI.*

a sensation of dizziness, nausea, and convulsions (visually induced motion sickness). Even heart attacks have been described after 3D visualization [4]. This is due to the fact that the human brain is very sensitive to irregularities in mistakes of the level of coherence and in differences of the stereo images in contrast, color, and brightness. Unstable positioning of the camera as well as the so-called "cross-talk" are additional factors. In the beginning of stereoscopy, these failures were poorly understood. Only step by step, were these problems overcome.

Further, the wide range of high imaging modalities offering HD or even superior optics at a comparably low price, compared to 3D technology, has negatively influenced adoption [5]. Another factor limiting endostereoscopic imaging is the limitation in field of view (FOV) relative to the FOV of 2D HD endoscopy [6].

An approach toward a more application-friendly technology are autostereoscopic displays. Autostereoscopic 3D displays would offer severe improvements. They allow to output 3D data without the use of special 3D glasses, creating additional benefits like speedier diagnosis, reductions of human errors and improved training and education [7]. Autostereoscopic displays were limited by a small viewing angle and low resolution, due to spatial multiplex technology being employed. Nowadays, 3D displays with a resolution of up to 4K are available. The next step will be 8K, realizing a huge improvement of the currently available full-HD images.

In a study recently published it was shown that the use of state-of-the-art 3D technology in endoscopes is actually found beneficial by surgeons. Even with the most experienced physicians, who were very skeptical toward 3D technology in the past, performance gains were observed [8].

Currently, research is being conducted on increasing the viewing angle, while maintaining or even improving the resolution. The potential is great and the field offers many chances for technological improvements and innovations to be introduced. However, the promotion of such solutions has been complicated, due to the prevailing uncertainty in industries according to the current state-of-the-art and future development of 3D display technology. Competitors in the market include Richard Wolf GmbH (Knittlingen, Germany), Olympus, and Visionsense Ltd (Philadelphia, PA, the United States) and many others.

In the future, further "fine-tuning" on stereoscopic technology in general will help to underline the benefits of 3D endoscopy. In particular, research on autostereoscopic displays is required. The displays offer the possibility to boost the popularity of 3D systems in surgical application as they overcome the current necessity to use glasses.

7.1.6 Light Source and Transmission

An adequate illumination of the surgical site is always a crucial element in surgery. Due to the specific conditions, illumination is a condition sine qua non in operative laparoscopy. Looking into the closed abdominal cavity without a light source is impossible. Accordingly, numerous attempts were made to provide adequate illumination, beginning with bulbs at the tip of the laparoscope as mentioned above. Because of the limited efficiency of light sources which result in heat production, "cold light sources" have been used since about 1960 to minimize the heat generated at the tip. This means that the light source is outside the endoscope, with filters for the infrared wavelengths to reduce heat transmission. The light then travels through fiber bundles into the laparoscope and exits at the tip.

Currently, powerful light sources are available using either xenon, halogen, or metal halide (Fig. 7.29). However due to the developments in light-emitting diodes (LED), this technology will soon replace the current light sources because of the improved energy-efficiency, and therewith less waste heat, and the increased lifetime for LED of about 30,000 hours, compared to recommended lamp exchanges after 500 hours for the current light sources.

Figure 7.29 Light source: a, main switch; b, standby button; c, light intensity adjustment buttons; d, controls for main/spare light bulb; e, intensity of light; f, manual/automatic light intensity adjustment; g, light cable connector; h, optional air pump switch and connector to reduce fog on telescope lens. *From MITI.*

7.1.6.1 Halogen Lamps

Halogen lamps consist of a transparent quartz bulb filled with gas including a halogen. Halogen bulbs produce crisp white light with excellent color rendering. They need comparatively low voltage. A color temperature of about 5000 K is achieved. The life span is ca. 2000 hours. Halogen lamps are comparatively cheap.

7.1.6.2 Xenon

Xenon is a highly unreactive gas which is used to fill the bulb which contains a cathode and an anode (arc lamp). The color temperature is about 6000 K. Lifetime is approximately 1500 hours.

As compared to the halogen lamp; the xenon light has a slightly bluish tint, but it is more natural. Most modern cameras, however, are able to analyze and eliminate these variations by an automatic equalization of white. Luminance is excellent [9].

7.1.6.3 Halide Lamps

Metal halide vapor lamps are high intensity discharge lamps which are frequently used for commercial and residential purposes. They deliver a light which is perceived as a "natural white" by the human eye. Halide lamps need a warming up time. Life span is about 6000–15,000 hours. Up to 6000 K may be achieved.

7.1.6.4 Condensing Lens

The light produced by the lamp is collected by mirrors and converged to the area of light cable input by means of the condensing lens.

7.1.6.5 Illumination Control

The intensity of light (luminosity) needed varies depending upon several conditions: Distance to the object, dimension of the area, absorption by tissue, etc. Close-up view produces reflections, whereas a more distant view is too dark. Manual adjustment is helpful to adapt luminosity to the respective conditions.

Modern light sources, however, are equipped with an automatic intensity adjustment function. This is enabled by analyzing the luminance signal of the camera which is sent to the CCU. If the signal is too high (if the image is overexposed), power of the light source is reduced and vice versa.

7.1.6.6 Light Cables

Light transmission is provided by liquid crystal gel cables or fiber bundles. Fluid light cables permit a more even transmission of light across the spectrum, but the loss of brightness is higher as compared to fiber transmission. Glass fiber cables are currently predominating.

In both instances, light is transmitted over the distance due to total internal reflection (Figs. 7.30 and 7.31).

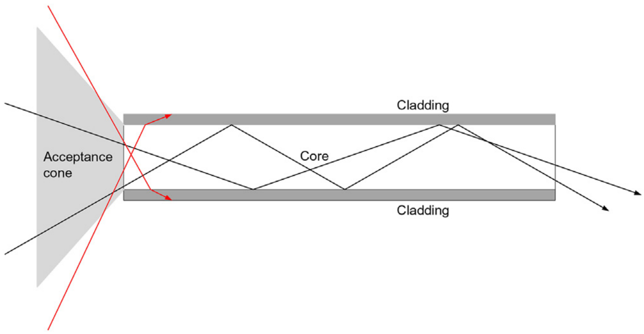


Figure 7.30 Total internal reflection in a fiberoptic cable: Due to the great angle of incidence, the refracted light cannot leave the fiber, as long as the bending of the cable is not too sudden. *From MITI.*

Figure 7.31 Fiberoptic light cable. Black spots indicate that some optical fibers are broken (inset). *From MITI.*

Light transmission cables are very sensitive to mechanical damage. Accordingly they have to be handled with special care. Steam sterilization, however, is possible.

7.1.7 Suction/Irrigation Device

In almost all surgical interventions, minor or major bleedings occur. Major blood collections in the surgical site obscure the view and should be avoided or removed (Fig. 7.32).

The suction/irrigation device provides the vacuum to aspirate fluid and enables to flush the abdomen with cleansing fluid (saline or Ringer's solution). Most frequently, roller pumps are used. Disposable hose/bag systems are used to avoid direct contact with the rinsing/aspiration fluid (Fig. 7.33).

Figure 7.32 Suction/irrigation device: a, main switch; b, maximum flow adjustment and display; c, maximum pressure adjustment; d, minimum aspiration vacuum adjustment and display; e, standby button; f, instillation tube notch; g, aspiration tube connection. *From MITI.*

Figure 7.33 Suction/irrigation unit during surgery. *From MITI.*

7.1.8 Documentation

At the beginnings of laparoscopic surgery, video documentation was quite common, resulting in millions of videotapes which never have been watched again and were thrown away. Proper administration and storage has always been a problem, which only could be lessened with the advent of more recent technologies. Originally, standard video formats were in use, such as S-VHS, Betacam, and U-matic. Nowadays, digital data make storage and handling significantly easier. With the introduction of digital storage, digital storage devices replaced tapes. Today, typically surgeries are recorded on hard disks and then exported to CD, DVD, or USB and other portable media.

The quality of the recorded video is dependent on two main conditions: The quality of the video source and the compression.

The video source is dependent on the laparoscopic camera and its processor; this video signal is transferred for digital storage to a frame-grabbing device and then compressed (Fig. 7.34), since uncompressed (raw) video would produce big file sizes and would need extremely fast or special hard disks. The uncompressed size for an image or a video can be calculated with Eq. (7.1). After compression the video file is stored (temporarily) on a device connected directly to the CCU, where archiving and copying can be made by CD, DVD, or other portable devices. Newer systems allow also a direct connection to the hospital information system for archiving over network connections.

$$\begin{aligned}&\text{Image file size} = \text{number of pixels} \times \text{color depth} \times \text{image channels}\\&\text{Video file size} = \text{image file size} \times \text{framerate} \times \text{time}\end{aligned}$$

Equation (7.1): Calculation of image and video file sizes.

Ten minutes of a surgical HD 1080p50 video would then produce a video file with a size of approximately 1.49 TB (Eq. (7.2)).

$$\text{Video file size}_{1080\text{p},600\text{s}} = 1920 \times 1080 \times 8 \times 3 \times 50\ \text{s}^{-1} \times 600\ \text{s} = 1.49\ \text{TB}$$

Equation (7.2): Example calculation for a 10 minutes 1080p50 video of a HD camera with three color channels and color depths of 8 bit, respectively, 256 shades for each color channel.

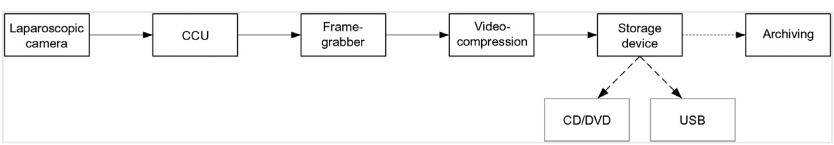


Figure 7.34 Processing of the video stream for documentation. *From MITI.*

To overcome the necessity of the special video hard disks and the large storage, compression is applied to the videos. The aim of video compression is to represent a sequence of images using as few bits as possible while maintaining its visual appearance. This is possible because most frames contain highly redundant data, i.e., adjacent pixels are highly correlated. Therefore, today several video codec (compression/decompression) standards and algorithms are available to not store all complete frames, instead only changes of the pixels between the frames. Currently, MPEG-4 and related codecs as standardized by the International Organization for Standardization (ISO) are mainly used, which provide a sufficient compression with acceptable quality loss. The decompressors for these compressed videos are also available as standard on most operating systems, which is why these are preferable. Nevertheless, there are more effective video compression techniques available; however, these can only be used on dedicated systems or require further processing.

Common video recording systems allow to change different parameters to adjust the recorded videos to the specific needs. Reducing the resolution is the most effective way to reduce file size by maintaining the content of the video, while with higher compression rates the video loses details due to missing/imprecise data of pixel information which result in blurry images (Fig. 7.35).

The increasing use of 3D camera systems demands different recording strategies. For documentation of the surgery, the use of only one channel of the camera is sufficient, if, however, the 3D information is to be maintained, both channels are necessary. The best quality could then be achieved by parallel recording of both video streams for the left and right eye with same parameters; however, synchronicity is the precondition for further use and postprocessing of the video. In common, only one mixed video stream of the left and right video channel (side-by-side) is recorded, which can be decompressed by several present video players.

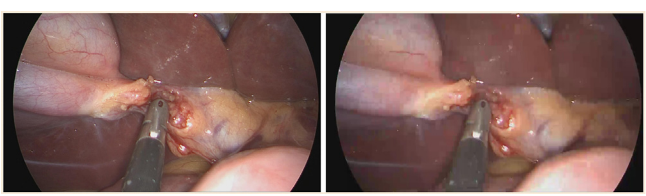


Figure 7.35 Uncompressed versus strong compression with blurring and loss of details. *All from MITI.*

7.1.9 Equipment Cart

The various devices as mentioned above are usually positioned on a trolley to permit flexible use in different OR theaters (Fig. 7.36).

For practical reasons, a central power supply (terminal strip) is provided by most carts. By pushing the main switch, all devices can be activated simultaneously which saves time.

Laparoscopic trolleys are equipped with antistatic rollers and locking brakes. Laparoscopy-specific devices are located on several shelves. In addition, one or more drawers are integrated to store the accessories.

To increase flexibility of monitor positioning an additional screen is fixed to a side arm.

In dedicated laparoscopic OR suites, the equipment is positioned on a rack mounted to a boom. Ceiling-mounted racks are ergonomically better and need less space (Fig. 7.37).

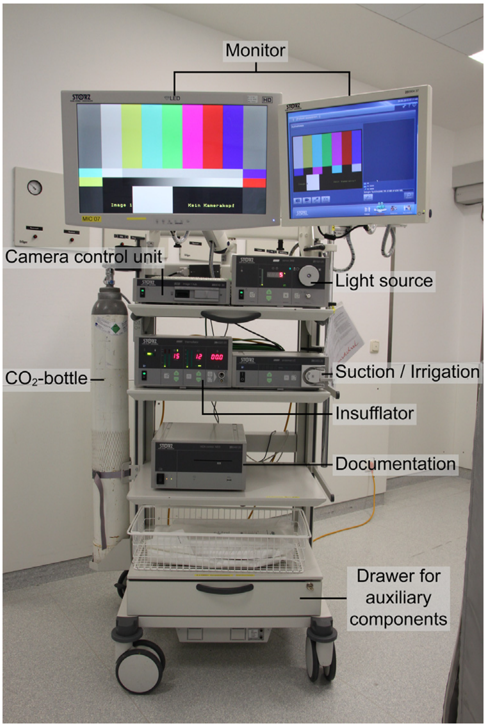


Figure 7.36 Mobile laparoscopy cart: Containing the whole range of laparoscopic devices, it enables to perform laparoscopic surgery at any surgical OR available. *From MITI.*

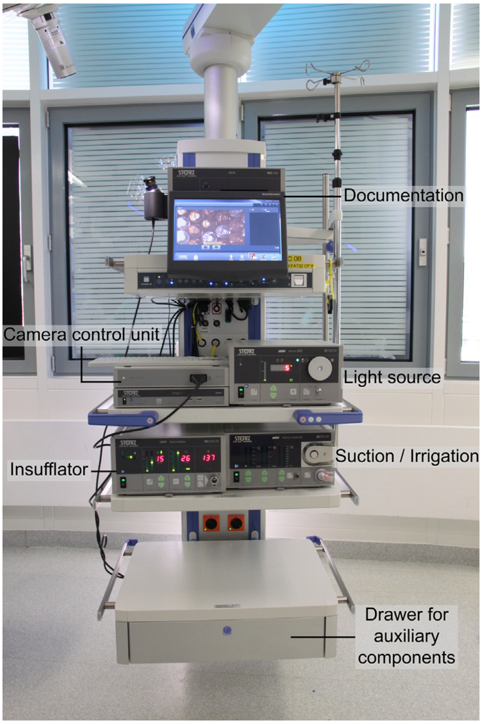


Figure 7.37 "Integrated operating room." Specially designed for minimally invasive surgery, the suite has ceiling-mounted towers. A central provision of CO_2 makes the gas tank superfluous. The laparoscopy unit can be moved freely into the optimal position. *From MITI.*

7.2 HAND INSTRUMENTS

Laparoscopic hand instruments are conventional hand instruments modified according to the specific conditions in laparoscopic surgery. They have to have a long shaft for being suitable for introduction through the port. The diameter is limited by the inner diameter of the trocar (usually 5 and 10 mm).

Some types of hand instruments must have a holding position during use, such as needle holders or graspers. Various arresting mechanisms are available, all of them based, in principle, upon the saw-tooth design.

Similar to trocars, almost every type of hand instrument is available as reusable or disposable issues.

Disposable instruments are expensive and produce garbage. Reusable instruments require much effort due to the need for resterilization. To facilitate the recycling, they should have a minimum of hinges and bolts and must be easily dismountable for cleaning (Fig. 7.38).

On the other hand, high quality reusable hand instruments can be produced in fine craftsmanship, whereas disposable instruments are machined mass products.

7.2.1 Forceps/Graspers

The central push rod can be moved forward and backward by opening or closing the handle. By the appropriate joint at the tip of the instrument, the axial force can be translated into the specific function required. Either one or both branches of the tip are activated. The tip is designed for the particular functionality (Fig. 7.39).

Figure 7.38 Typical hand instrument for laparoscopic surgery: a, tip; b, insulated outer tube; c, insufflation channel; d, rotator; e, dismantling knob; f, attachment for electrosurgical cable (monopolar). *From MITI.*

Figure 7.39 Different graspers/forceps: (A) Unilateral, powerful grasper for secure fixation; (B) bilateral forceps with straight branches; (C) grasper with bent branches. The function is similar to the Overholt clamp in open surgery (also suitable for tissue dissection). *From MITI.*

Graspers enable the surgeon to hold and manipulate organs and tissue, comparable to forceps in open surgery. The design of the tip is always a compromise between a firm fixation and the avoidance of tissue lesions due to excessive compression.

To get a firm grip graspers with teeth are used, especially for robust anatomical structures (Fig. 7.40). For more delicate tissues, so-called atraumatic forceps are available (Fig. 7.41).

Atraumatic forceps allow for a more gentle fixation of soft tissue, in particular the small and large bowel.

7.2.2 Dissectors

The dissector is used to "split" tissue bluntly—comparable to an Overholt in open surgery (Fig. 7.42). So-called "blunt dissection" is frequently used

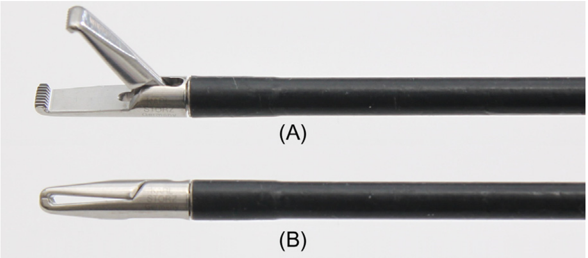


Figure 7.40 Unilateral grasping forceps with a robust stable articulation of one movable branch (e.g., for the stomach or a thickened gallbladder wall): (A) opened; (B) closed. Note the space between the branches. *From MITI.*

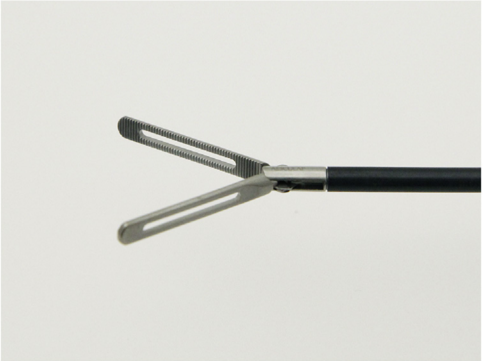


Figure 7.41 Atraumatic forceps: The long, slim, and blunt branches enable to fix soft tissue securely without the danger of laceration. *From MITI.*

Figure 7.42 Dissector: The tip has a bent shape to enable very delicate dissection. The angle of the tip varies, but is limited by the inner lumen of the trocar. Dissectors are usually connected with the electrosurgical generator to apply electrocoagulation if required. *From MITI.*

to divide different tissue layers without bleeding. Vessels are isolated and selectively coagulated.

The majority of laparoscopic procedures require a mixture of sharp and blunt dissection techniques. Blunt dissection avoids bleeding reliably, if the proper layers are respected.

7.2.3 Scissors

As compared to open surgery, the use of scissors in minor access surgery is more limited. They require greater skill since they are potentially harmful.

Scissors are offered with straight, curved, or hook blades. The edges can be serrated to prevent tissue slipping out of the blades (Fig. 7.43).

Curved scissors allow a better visual control during cutting and are generally preferred in laparoscopic surgery. To some degree they are similar to the Metzenbaum scissors of open surgery.

A type of scissors almost exclusively used in laparoscopic surgery are hook scissors. The blades encircle the object to be cut before it is dissected (Fig. 7.44).

The hook scissor is the only scissors that severs the tissue from distal to proximal. Thus, tissue slipping out of the branches is impaired.

Scissors may also be used to apply (monopolar) electrocoagulation to (small) vessels. However, the blades soon loose sharpness. If electrocautery has to be used often during one procedure, the use of

Figure 7.43 Curved scissors with serrated blades. The fine teeth prevent tissue slipping out of the scissors when the blades are closed. *From MITI.*

Figure 7.44 Hook scissors: Both blades are excavated. Robust anatomical structures can be cut easily, but they are less suitable for delicate tissue preparation. *From MITI.*

disposable scissors is preferable (Fig. 7.45). The selection of blades is limited with disposable scissors.

As compared to high quality reusable scissors, disposable ones do not offer the very smooth and sensitive function as one is accustomed to in the other case. Nevertheless they are well suited for clinical use.

7.2.4 Needle Drivers

Needle drivers are tools to enable to sew and tie sutures in laparoscopic surgery. They have to transport the suture—needle combination into the abdominal cavity and must fix the needle in a stable position when the needle is pierced through the tissue (Fig. 7.46).

The gilding indicates that the jaws of the tip are of supreme quality. They can be exchanged when worn out.

As in all needle holders, an easy and reliable locking mechanism is decisive. In contrast to open surgery, laparoscopic needle holder handlings/locking mechanisms of various different types are available (Fig. 7.47).

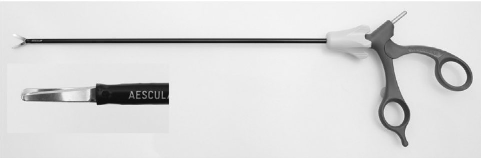


Figure 7.45 Disposable curved scissor. Inset: Clearly recognizable: The blades are simple stamped parts. *From MITI.*

Figure 7.46 Curved needle in the jaws of the needle holder. Tilting of the needle must be reliably prevented as well as mechanical damage to the needle. *From MITI.*

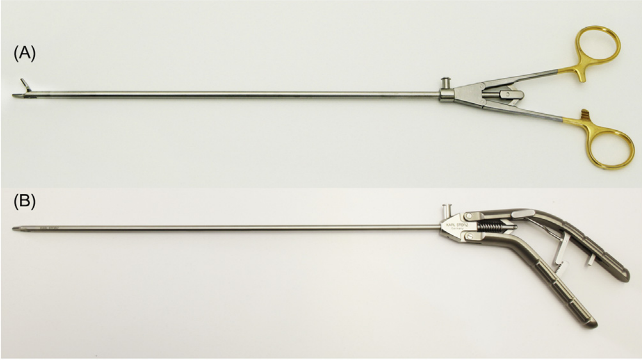


Figure 7.47 Needle holders: (A) With "inline" handling; (B) with typical laparoscopic angulated handling. *From MITI.*

To ensure a firm grip of the needle without causing damage, the surface of the jaws requires particular craftsmanship. Accordingly, they are expensive.

7.2.5 Retractors

In laparoscopic surgery, the task of creating enough space for the surgical manipulation is certainly even more difficult than in open surgery. Retractors are designed to keep aside the adjacent anatomical structures.

Figure 7.48 Various types of laparoscopic retractors: (A) Disposable 10-mm retractor, opened by turning the knob; (B) reusable retractor, opened by shifting the sleeve. *From MITI.*

Due to the peculiarities of laparoscopic surgery, they differ in shape significantly from those used in open surgery (see Chapter 6.1.5: Retractors) (Fig. 7.48).

The challenge is to insert the retractor through a trocar of limited diameter and to unfold afterward a retracting surface as large as possible. Up to now, much potential is existing for the development of better designs.

7.2.6 Laparoscopic Electrosurgery

As in open surgery, electrosurgery is a valuable tool to make surgery safer and faster.

Of course, the disruptive processes that result from electric current running through tissue are identical in both cases, but laparoscopic application requires specially designed application tools. Again, monopolar and bipolar modes are in use. Monopolar instruments may be applied in the cut or the coagulation mode. In addition to specially designed unipolar electrodes like hooks or spatula (Fig. 7.49), single usable instruments like graspers or bilaterally movable instruments as scissors (see Section 7.2.3: Scissors) can also be used for electrocautery (Fig. 7.50).

In laparoscopic surgery, bipolar instruments are even more popular than in conventional surgery. Bipolar coagulation devices are typically designed as forceps with isolated electrodes in the beak (Fig. 7.51).

However, the power which can be applied is comparatively lower. Smaller blood vessels can be successfully sealed.

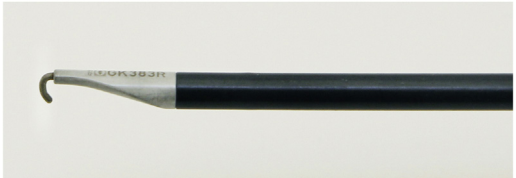


Figure 7.49 Unipolar curved hook: Many different designs are available for the same purpose: To elevate or to pull an anatomical structure selectively in order to cut/coagulate it. *From MITI.*

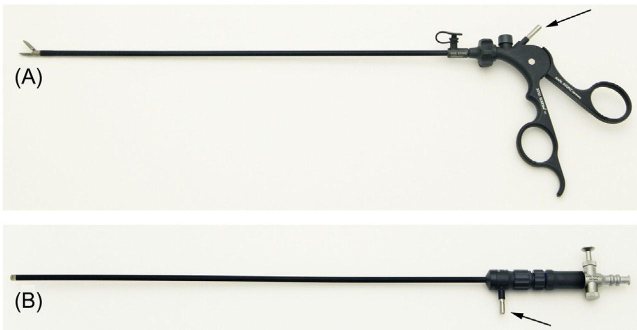


Figure 7.50 Additional unipolar electrosurgery tools: (A) Grasping forceps; (B) suction/irrigation probes. *From MITI.*

The generator/control unit is identical to those used in open surgery (see Chapter 6.2: Electrosurgery).

7.2.7 Clips and Clip Appliers

Tubular structures like blood vessels or the cystic duct are commonly occluded by ligatures in open surgery. Principally this could be done in laparoscopic surgery as well, but since it is easier and faster, the vast majority of closures are performed with clip appliers. Reusable clip appliers deliver one clip at a time (size varies approximately from 7 to 9 mm) and must then be taken out and reloaded. When clip appliers are used in pairs, the scrub nurse always has one loaded, ready to exchange for the empty one which the surgeon withdraws. It is cost-effective and causes minimal delay. Most disposable clip appliers come loaded with 20 clips per unit, which can be applied in rapid succession without removing the instrument from the abdominal cavity (Fig. 7.52).

Absorbable clips are typically made of polydioxanon. Metal clips are produced of titanium. It does not react with the human body and can be left without problems at its site (Fig. 7.53).

Figure 7.51 Bipolar laparoscopic coagulation forceps. The "active" electrode and the "return" electrode are more or less symmetrical and close together. At the tip the blue isolators between the blades are clearly visible (Inset: arrow). *From MITI.*

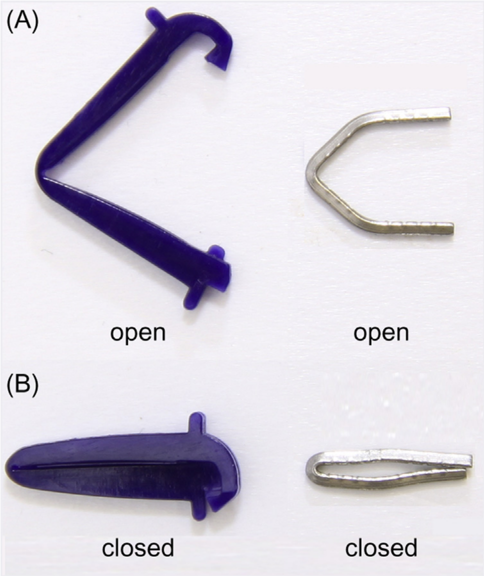


Figure 7.52 Laparoscopic clips: (A) The absorbable clips have an integrated locking mechanism, while (B) titanium clips are simply closed by deformation. *From MITI.*

However, metal clips may migrate in the postoperative course. Perforation into the bile duct or the bladder have been published [10].

In more complex surgeries with multiple vessel dissections, multifire clip appliers are more economical. Repetitive clip application is by far more rapid than reloading each single clip (Fig. 7.54).

7.2.8 Laparoscopic Stapling Devices

Basically, laparoscopic stapling devices are more or less technically similar to those as used in open surgery (see Chapter 6.5: Stapling Devices). Modifications in design, however, were inevitable to insert them through trocars.

Figure 7.53 Clip applier for absorbable clips. Inset: The jaws are designed to make the clips to start occlusion at its tips. Thus, tissue is prevented from slipping out. *From MITI.*

Figure 7.54 Disposable clip applier with consecutively applicable clips. *From MITI.*

Currently available linear staplers are highly sophisticated devices which enable the surgeon even to rotate and to bend the shaft (Fig. 7.55).

As soon as the first linear staplers became available, the range of laparoscopic surgery was significantly widened. Even the creation of circular (triangulated) anastomoses was attempted.

Circular staplers, however, are identical to those of open surgery (Fig. 7.56).

Accordingly, their use is confined to the distal end of the colorectum.

For more than a decade laparoscopists have been waiting for a flexible anastomotic device which could be applied in all sections of the gastrointestinal tract. Former approaches did not function reliably and had to be taken away from the market.

7.2.9 Laparoscopic Ultrasound Dissection

Even more than in open surgery, bleeding has to be avoided in minimally invasive surgery since the removal of blood out of the surgical field is considerably more cumbersome. Accordingly, the introduction of ultrasonic dissection devices was a significant leap forward, extending once more the range of laparoscopic procedures.

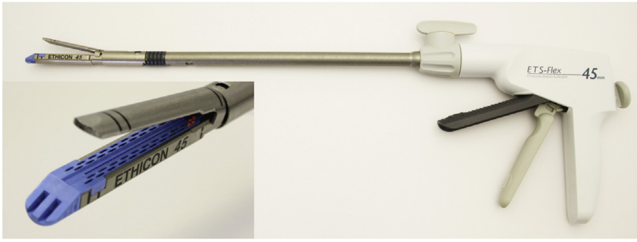


Figure 7.55 Linear stapling device: The length of the stapling line may vary from 30 to 50 mm (in this case: 45 mm). If the white lever is activated, the instrument is closed: the flat, mobile anvil is pressed against the magazine part. The tissue in between is compressed but still left intact. If necessary, the device can be opened again and brought into a better position. If the dark lever is pushed, the clamps (clips) are compressed and the tissue is severed. *From MITI.*

Figure 7.56 Circular stapling device (see Chapter 6.5: Stapling Devices). The clamps are located in the main device, after firing these are bent in the removable anvil, at the same time a circular knife (not visible) opens the lumen inside the stapled colon. *From MITI.*

Ultrasonic cutting is based upon a mechanical impact on the tissue (see Chapter 6.3: Ultrasound Dissection). Accordingly, it can be used even in patients with cardiac pacemakers in whom electrosurgery has to be avoided.

Since laparoscopic ultrasound devices have to be inserted into the abdomen via a trocar, their design has to be accordingly adopted. The instrument has to be longer and has to have a smaller diameter (5 mm) than in open surgery (Fig. 7.57).

Ultrasonic scissors are suitable not only for cutting (Fig. 7.58A) but also for blunt dissection (Fig. 7.58B).

As already mentioned in Chapter 6.3: Ultrasound Dissection, ultrasound dissection inevitably produces surgical plume [11]. The confined abdominal space is soon full of plume deteriorating significantly visibility [12].

Figure 7.57 Disposable ultrasonic shears. The blade is vibrating against the mobile branch which is covered by synthetics or ceramics (on reusable shears). (A) Completely assembled instrument; (B) Tip: The mobile arm is in an oblique (open) position. *From MITI.*

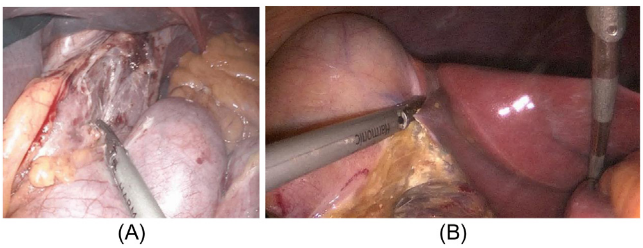


Figure 7.58 Laparoscopic ultrasound dissection: (A) Dissection of the short gastric vessels; (B) excision of the gallbladder. *All from MITI.*

Both the amount and the movement of plume are pivotal [13]. Currently available remedies are less than satisfactory.

The change of the intraabdominal gas is time-consuming and tedious. The options of modifying the blade design are limited [14]. Image processing may be helpful (Fig. 7.59).

7.2.10 Impedance-Guided Dissection

Conventional electrosurgery has the main drawback that it is self-limiting. Desiccated and charred tissue gains increasingly resistance and stops the influx of power.

As described in detail in Chapter 6.2: Electrosurgery, the problem of self-insulation is overcome by impedance-controlled electrocoagulation.

The first designs of impedance-controlled vessel sealing systems were produced for laparoscopic surgery (Fig. 7.60).

Impedance-controlled vessel sealing systems act in the bipolar mode. Per se, they are unable to achieve more than—though very effective—welding of the tissue and vessels. Dissection has to be done by a blade integrated into the device. As soon as the coagulation process is finished

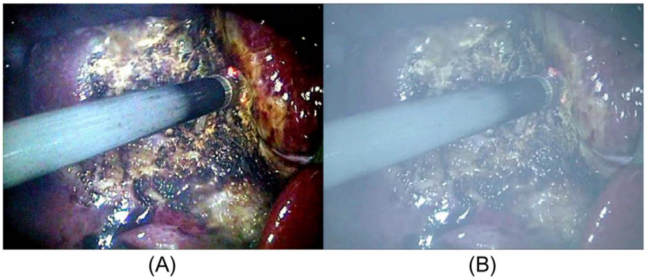


Figure 7.59 Image procession to eliminate surgical plume: (A) Filtering out pixels which are shadowed by floating plume leads to an impressive improvement of visibility; (B) original image. *From MITI.*

Figure 7.60 Vessel sealing generator. *From MITI.*

successfully, an acoustic signal indicates that the blade can be pushed forward by activation of a mechanical handle (Fig. 7.61).

The first devices were only available with a diameter of 10 mm. Currently, 5-mm systems are the standard.

7.2.11 Comparison between ultrasound and impedance-guided dissection

There is plenty of literature comparing the two different dissecting principles with each other in laparoscopic surgery or conventional dissection or clipping under various conditions [15–20].

Many parameters were evaluated like time of performance, collateral damage (thermal spread), burst pressure, and ergonomy.

In most of these studies, there are no significant differences in complication rates, operative time, pain medication, and cost.

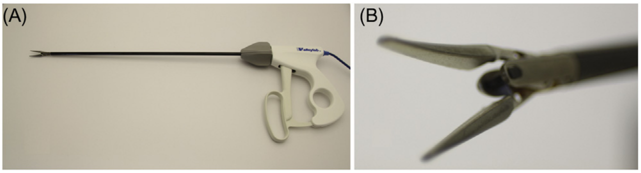


Figure 7.61 (A) Handpiece of impedance-controlled vessel sealing system; (B) tips of the hand instrument. *All from MITI.*

Both types of devices are valuable tools which contributed a lot to the development of minimally invasive surgery.

7.3 MINILAPAROSCOPIC PROCEDURES

With the onset of laparoscopic surgery, surgeons soon thought about ways to make minimally invasive surgery even less traumatic. One approach was to further reduce the diameter of the trocars (instruments) in use. Instead of 10- or 5-mm instruments, it was attempted early in the history of laparoscopic surgery to replace them by instruments of a diameter of 2 or 3 mm. Soon, instruments became available but it became clear that they suffered from distinct mechanical limitations. The small effector tips were suboptimal. Electrosurgical functionality was poor and the instruments' durability low. Most irritating, however, was excessive instrument shaft flexibility. The required force could not be exerted to the tissue. The so-called whiplash effect occurred. Accordingly, minilaparoscopic procedures did not gain widespread acceptance at the beginnings of laparoscopic surgery [21].

Minilaparoscopy was further stigmatized as a complicated approach that only could be applied in low BMI patients without major advantages over conventional laparoscopy with the exception of esthetics.

The situation changed considerably over time. The manufacturers now provide instruments with better designs, using more resilient materials with better durability, and telescopes with a significantly better visualization [22,23] (Fig. 7.62).

Last but not least, the "Achilles heel" of minilaparoscopy, i.e., the occlusion of cannalicular structures such as blood vessels or the cystic duct, could be solved. To apply adequate clips using a 3-mm clip applier is problematic. Instead, new suturing techniques are now available to overcome this typical disadvantage of former minilaparoscopy.

A wide range of suitable instruments is now on the market (Table 7.5).

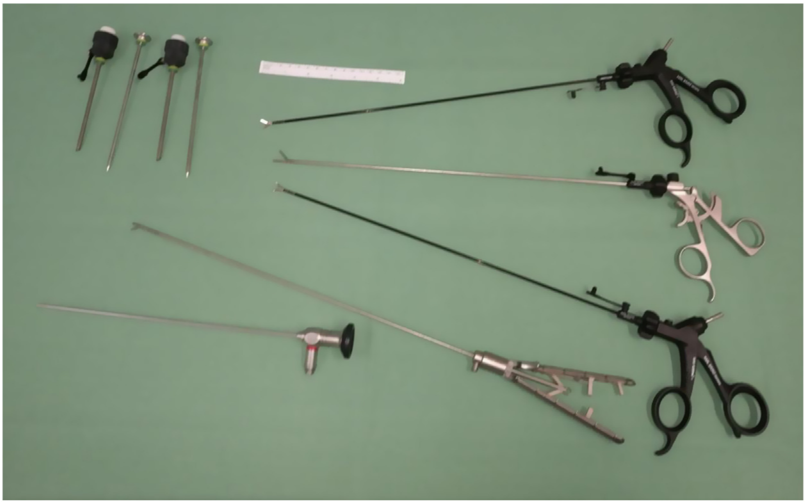


Figure 7.62 The spectrum of commercially available miniinstruments. *From MITI.*

The aim of minilaparoscopic procedures is to do the surgery with only one conventional trocar site (currently 10 mm, but hopefully in future times with 5 mm) which is placed within the umbilicus, but with the additional help of two or three additional tiny incisions (2–3 mm), leaving almost invisible scars. In contrast to mono-port surgery (see Section 7.4: Mono-Port (Single Port) Surgery), there is no need to insert all instruments through one single port. This avoids the enlargement of the single-site incision and allows for the normal kinematics of instrument use.

The search for better technical solutions has already led to fascinating new developments. Visualization is always a crucial aspect of laparoscopy. Small bore telescopes are becoming increasingly more powerful. An interesting alternative is the use of so-called satellite cameras (Fig. 7.63). The idea is to position an independent, remotely guided camera within the abdominal cavity (attached to the abdominal wall) which saves the trocar usually required for the laparoscope.

The small effector tips could cause trouble, since the grip is too weak but, nevertheless, rather traumatic. The artificial enlargement by mounting separate larger tips was already evaluated.

Last but not least, the passive retractor function of some instruments could be taken over by internal or external stay sutures or anchors (Fig. 7.64).

Beyond doubt, technical advancements are still conceivable which certainly will make minilaparoscopic surgery to a most valuable tool in the armamentarium of surgery.

Table 7.5 Current generation of minilaparoscopy hand instruments

	Braun	Gimmi (CareFusion)	Storz	Storz	Stryker	SurgiQuest (ABMedica)	Teleflex	Teleflex	Wolf	Covidien
Product name	Aesculap AdTech Mini	AlphaDur MicroLap	Clickline	Koh	3 mm	Low impact	Percuvance	MiniLap	Eragon Mini	MiniSite MiniShears
Reusability	Reusable	Reusable	Reusable	Reusable	Reusable	Reusable	Reusable handle	Disposable	Reusable	Disposable
Shaft diameter (mm)	3.5	2.8, 3.4	2, 3, 3.5	3	3	3.1	2.9	2.3–2.4	3.5	2
Shaft length (cm)	20, 29	16, 30	20, 30	30	20, 29	31, 35	29, 36	25	24, 33	19, 31, 45
Handle designs	Pistol grip	Castro Viejo	Pistol grip; Straight	Pistol grip; Straight	Pistol grip	Pistol grip	Pistol grip	Thumb handle; Pistol grip	7 designs	Pistol grip
Effectors/tips	11	11	11	6	18	13	7	8	18–21	1
Insulation	Yes	Yes	Variable	No	Yes	Yes	Yes	Yes	Yes	Yes
Rotation	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Trocars	Yes	Yes	Yes, including low friction	Yes		Yes	No	No	Yes	Yes

Figure 7.63 Satellite camera: The "internal" camera is able to replace the classical telescope which requires an own trocar. Experimental design with an outer diameter of 10 mm. *All from MITI.*

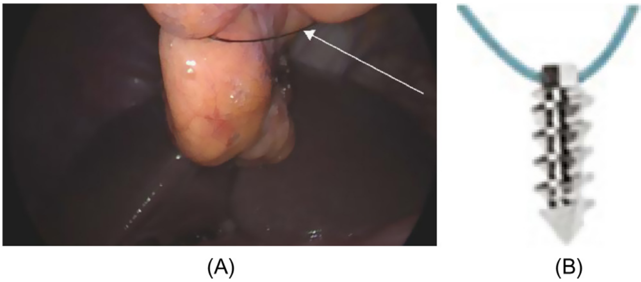


Figure 7.64 (A) External stay sutures: A sling created by a transdermal thread elevates the falciform ligament (arrow); (B) intraabdominal anchor. *All from MITI.*

7.4 MONO-PORT (SINGLE PORT) SURGERY

Even more visionary appears the idea to perform surgery using just one single port instead of additional 3–5 trocars. Nevertheless, it is feasible, as many working groups all over the world have been able to show. Up to now, no clear terminology has been found. Table 7.6 gives an overview upon the different denominations.

In order to avoid a too close proximity to specific manufacturers, we recommend the neutral term of "mono-port surgery" as neutral denomination for this new surgical approach.

Mono-port surgery is technically considerably more challenging than conventional laparoscopic surgery. All instruments have to be inserted through one single port site which makes triangulation and the movement of instruments difficult. The instruments have to be handled against normal intuition (see below). The trocar is the needle hole through

Table 7.6 Company specific denominations of mono-port surgery

OPUS	One-port umbilical surgery
TUES	Transumbilical endoscopic surgery
e-NOTES	Embryonic NOTES
SLAPP	Single laparoscopic port procedure
SPL	Single port laparoscopy
SLIT	Single laparoscopic incision transabdominal surgery
LESS	Laparoendoscopic single site surgery
SILS	Single incision laparoscopic surgery

Figure 7.65 Disposable single port trocars: Deformable soft plastic main bodies bear a number of flexible ports with valves. *From MITI.*

which instruments and the telescope have to be inserted. The team usually consists just of two surgeons. It has been pointed out that mono-port surgery is also particularly apt for solo surgery [24].

7.4.1 Trocars

The incision has to be kept as small as possible, but the trocar must, nonetheless, provide flexible introduction channels for at least two instruments and, separately, the telescope. The industrial companies were very creative in designing both disposable (Fig. 7.65) and reusable mono-port trocars.

Disposable Mono-Port Trocars

Single use mono-port trocars are mostly made of soft material for easy insertion through the 12–25-mm incision in the abdominal wall and to provide sufficient flexibility for the inserted instruments. Some designs are made out of two flexible rings with a transparent plastic film between, making it possible to inspect the wound margins of the abdominal incision. Mostly all disposable trocars are having several ports with a diameter of 5 mm and an additional 10-mm instrument port for stapling devices or other lager instruments. All of the ports are gas-tight closed with a valve.

Reusable Mono-Port Trocars

The design of a reusable trocar is, perhaps, even more of a challenge, since the needs of reprocessing have to be considered. The use of plastics, e.g., is therefore limited. However, some successful solutions could already be found and are commercially available (Fig. 7.66).

Trocars for mono-port surgery must allow an adequate angulation of each single instrument. Each of it has to be sealed gas-tight.

7.4.2 Hand Instruments

If the instruments are inserted through one common hole, collisions are inevitable. A conflict between instruments and the scope is frequent. If normal straight laparoscopic instruments are used, the surgeon is forced to manipulate crosswise which is extremely difficult (Fig. 7.67A). The surgical technique becomes insecure and extremely time-consuming. Surgeons and engineers, looking for better solutions, soon found some improvement. Curved instruments (Fig. 7.67B) allow for a better triangulation, but the problem is still valid that the tips of the instruments are "on the wrong side."

Double-curved instruments (Fig. 7.67C) make life easier, but, nonetheless, considerable training is required.

Currently, all of the most renowned manufacturers provide instrument sets dedicated to mono-port surgery. Producers of reusable instruments offered quite a bunch of funny shaped instruments which never became really popular (Fig. 7.68).

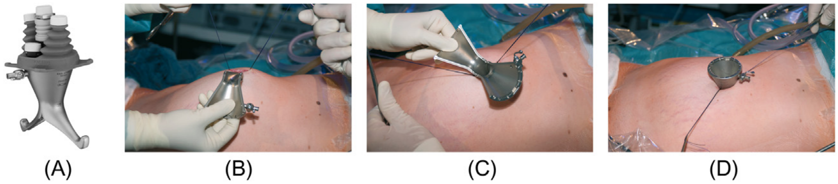


Figure 7.66 X-cone (STORZ): (A) Functional state; (B) the first half of the device is inserted through the miniincision; (C) the second cone half is introduced; (D) by approximation of the two cones a funnel is shaped. The top with the sleeves can now be mounted. *All from KARL STORZ GmbH & Co. KG.*

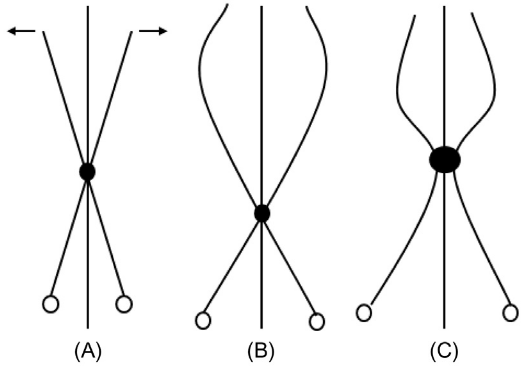


Figure 7.67 Problems of single incision laparoscopy: (A) Standard laparoscopic instruments: triangulation is difficult. Due to the joint point of invariancy (fulcrum), an inverse movement of the tip results. (B) Curved instruments: triangulation is better, but the problem of "crosswise" manipulation remains. (C) Double-bent instruments: the tip follows the movements of the surgeon's hand as he is accustomed to. *From MITI.*

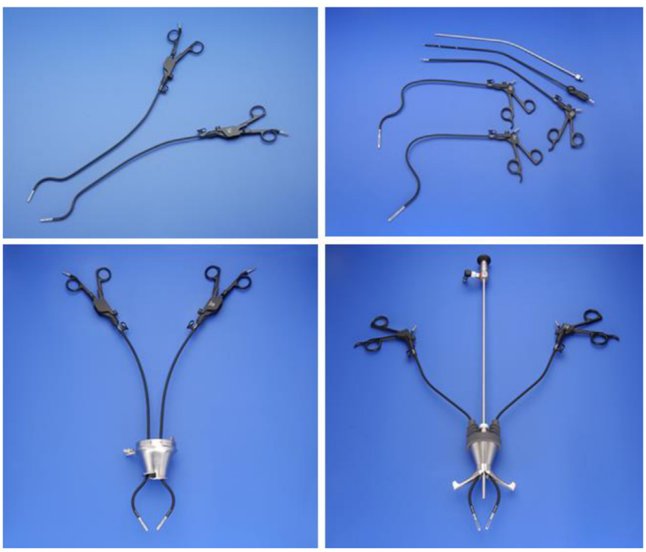


Figure 7.68 A set of double-bent instruments. Reusable tools. *All from KARL STORZ GmbH & Co. KG.*

Companies dedicated to the production of disposable instruments offered even more sophisticated designs (Fig. 7.69).

The search for even more functional hand instruments initiated the design of some very tricky devices with multiple degrees of freedom (Fig. 7.70).

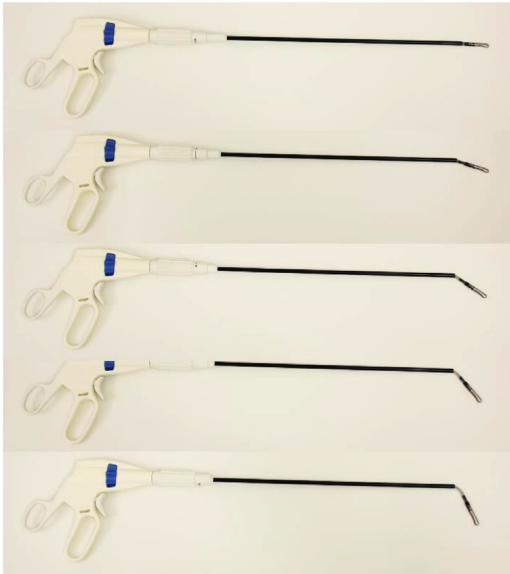


Figure 7.69 Disposable instruments with variable bending. The bending can be scaled. *From MITI.*

Figure 7.70 The SILS hand instrument family. Bending of the tip, rotation of the shaft, and a variable position of the handle provide high flexibility. *From Medtronic GmbH.*

Some surgeons may feel irritated by the additional degrees of freedom. Accordingly, the various functionalities can be neutralized.

A radically new design of hand instruments is the Radius device (Tübingen Scientific Medical, Tübingen, Germany). The aim is to create a natural extension of the human hand. The handle is positioned in a rectangle. The tip is rotatable and deflectable. In addition, the shaft is rotatable as well. Depending upon the actual task, the effector tips can easily and rapidly be changed during the operation (Fig. 7.71).

Last but not least, the Single-Site Instrumentation for the DaVinci surgical system (Intuitive Surgical, Sunnyvale, CA, the United States) has to be mentioned (see Chapter 10.1.2: Master-Slave Systems). It is not surprising that the manufacturers took the advantage of a remotely controlled slave system to perform mono-port surgery (Fig. 7.72).

Though the instruments are crossed, the surgeon is able to use his interfaces at the console as he is accustomed to. The system "translates" the movement of his hands into the appropriate steering commandos.

7.4.2.1 The SPIDER Surgical System

The SPIDER surgical system (TransEnterix, Morrisville, NC, the United States) was the first device specifically designed for mono-port surgery

Figure 7.71 The Radius T surgical system: The specially designed handles enable the use of the multiple degrees of freedom. *From Tuebingen Scientific Medical GmbH.*

Figure 7.72 DaVinci EndoWrist single-site instrumentation. *From Intuitive Surgical.*

and launched to revolutionize the new surgical approach. First clinical experiences were favorable [25].

This well designed device was inserted into the abdomen via a slightly larger than standard trocar. Triangulation could be achieved with true left and true right instrumentation. It is a purely mechanic single operator platform with additional working channels for auxiliary instruments (Fig. 7.73).

The SPIDER could be activated in a very intuitive manner since the effectors worked like standard rigid instruments (Fig. 7.74). One of the only drawbacks was that it was available just in one size. In very small patients, the arms were too long if the device was inserted through the navel (Fig. 7.75).

Figure 7.73 The SPIDER surgical system: (A) When the system is passed through the trocar, the arms are folded together; (B) within the abdomen, the manipulators are spread to allow cooperative manipulations. *All from MITI.*

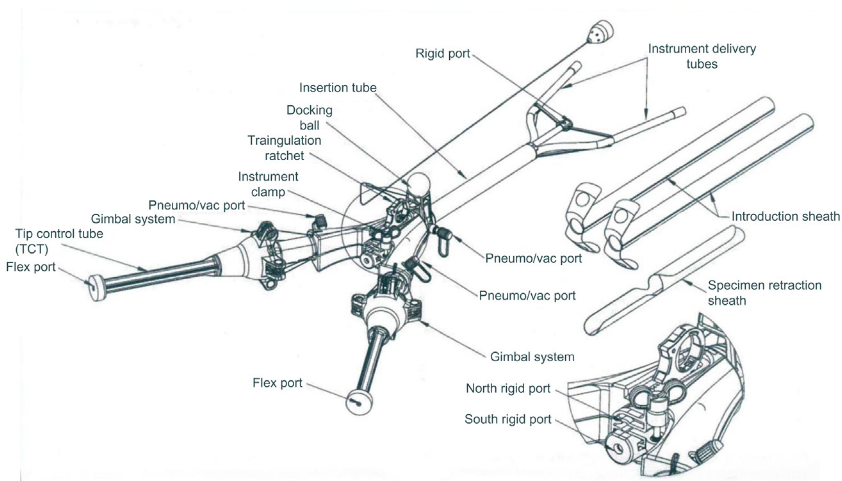
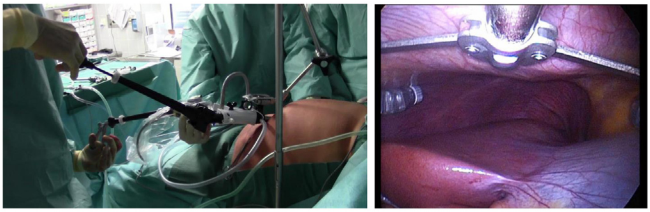


Figure 7.74 Explosive drawing of the SPIDER. The system is mounted to the OR table using a rigid arm. *From the SPIDER user manual.*



(A) (B)

Figure 7.75 (A) External view of the SPIDER in use; (B) the strictly coaxial view reduces to some extent versatility. *All from MITI.*

The SPIDER system was certainly the first step ahead toward clinically mature mono-port surgery.

Unfortunately, the system is no longer available on the market since the company focuses on the development of a roboterized version of the SPIDER called SurgiBot, which is now available as Senhance Surgical Robot System.

7.4.2.2 Critical Comments and Outlook

Even though much progress has already been achieved in instrumentation, mono-port surgery has still many specific drawbacks. Continuous R&D efforts are required to overcome the still existing problems.

Even if double-curved instruments are used, the kinematics of the surgical manipulations are complex and difficult to learn. The operative field exposure is reduced, since the scope is in a coaxial position to the instruments. Since mono-port trocars have to have a larger diameter than standard 10-mm laparoscopic trocars, a real incision of the abdominal wall is necessary. Even if the incision is carefully occluded after the operation, the risk of a cicatricial hernia is considerably higher than after the use of a standard trocar, in particular in the navel. The practical feasibility of mono-port surgery depends strongly upon the individual anatomical situation. In large, very obese patients it may even be impossible. Even in experienced hands, mono-port surgery has a prolonged OR time as compared to conventional laparoscopic procedures, and is more expensive. The only clear advantage seems to be a better cosmesis although even this is argued in a meta-analysis [26]. Careful studies failed to demonstrate pain reduction after mono-port surgery [27] (Fig. 7.76).

Whether mono-port is as safe or even safer is still unclear, but even if only the incidence of incisional hernia would grow, the use of mono-port would become difficult to justify [28] (Table 7.7).

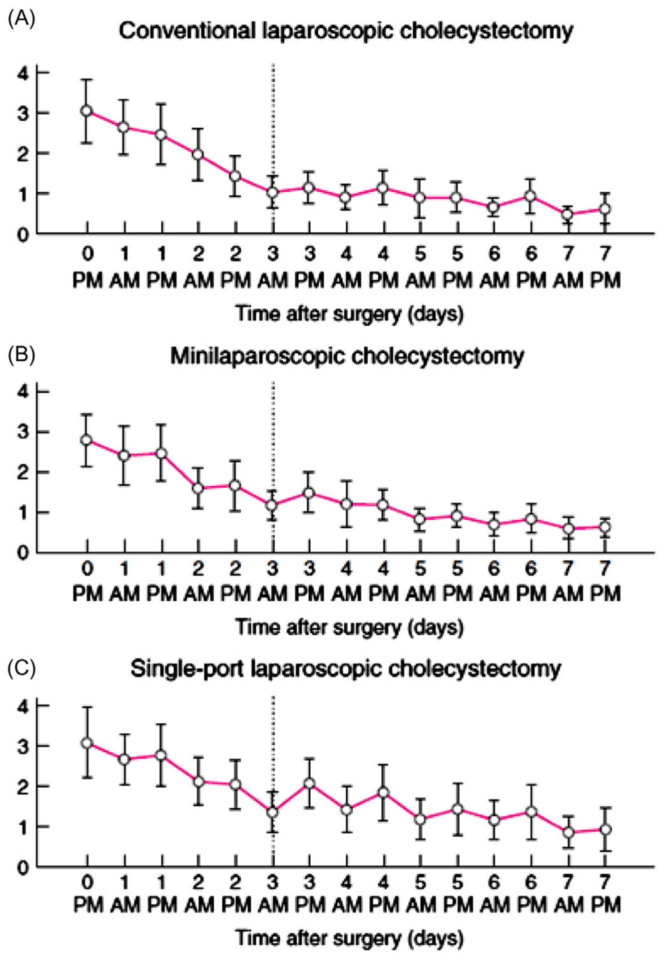


Figure 7.76 Comparison of postoperative pain scores after (A) normal laparoscopic cholecystectomy, (B) minilaparoscopic, and (C) mono-port surgery. No statistical difference is obtained among the techniques [27].

Conclusively, the impact of mono-port is significantly lower on the quality of delivering surgical care as compared with the introduction of multitrocar laparoscopic surgery (Fig. 7.77).

Nonetheless, it should be considered that mono-port surgery is still in its infancy. It is warranted to assume that it will gain more popularity as soon as more advanced instruments are available. They should meet at least the following criteria:

- insertion via a standard trocar,
- free selection of the FOV,
- intuitive command of the instruments,
- availability in more than one size.

Table 7.7 Mono-port surgery as compared to standard laparoscopic procedures

	Superior	Equal	Inferior
Cosmesis	×		
Pain		×	
OR time			×
Blood loss		×	
Complications		?	
Applicability			×
Costs			×

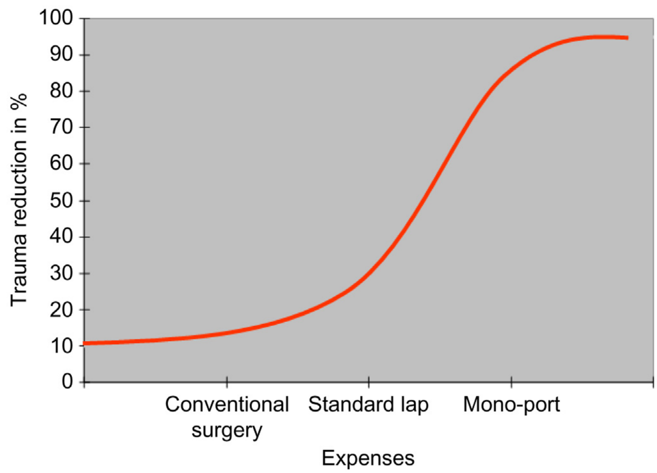


Figure 7.77 Relationship between trauma reduction and costs: a nonlinear function. *From MITI.*

It is certainly not very easy to develop a system as described above and to make it mature for clinical use at a reasonable prize, but the example of the SPIDER system makes one optimistic that it is not impossible.

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CHAPTER 8

Interventional Flexible Endoscopy

Until the early 1970s, flexible gastroenterologic endoscopy was confined to diagnostic purposes. The examination was well accepted by the patients. The esophagus, stomach, and duodenum could be thoroughly investigated, as well as the colon, in an outpatient procedure. At that time, it led to a worldwide explosion in the use of diagnostic endoscopy.

The window to therapeutic endoscopy was opened—independently of each other—by Classen in Germany and Kawai in Japan in the year 1973. Using a papillotome, Classen in Erlangen split the papilla of Vateri and removed a bile duct stone on June 6, 1973 (Fig. 8.1).

Papillotomy was the ignition spark of therapeutic endoscopy. Endoscopic hemostasis with sclerosant agents in case of variceal bleeding was the next step, followed by tissue removal, stenting, and increasingly more advanced therapeutic procedures [1].

8.1 "OPERATIVE" ENDOSCOPES

8.1.1 Upper Gastrointestinal Scopes, Colonoscopes

"Normal" flexible endoscopes, which were originally designed for diagnostic purposes, were the standard equipment in the early days of therapeutic endoscopy. Today, more dedicated endoscopes are available (Fig. 8.2). The working channel is larger (3.8−4.2 mm) which facilitates washing and suction, in particular in the case of bleeding. Interventional endoscopes may even have a second working channel.

Necessarily, they usually have a larger caliber and a higher stiffness than pure diagnostic endoscopes. All of them are forward looking.

8.1.2 Side-Viewing Duodenoscopes

The so-called "endoscopic retrograde cholangiopancreatography" (ERCP) is an endoscopic technique which allows the visualization of the bile duct and pancreatic duct system by direct cannulation under

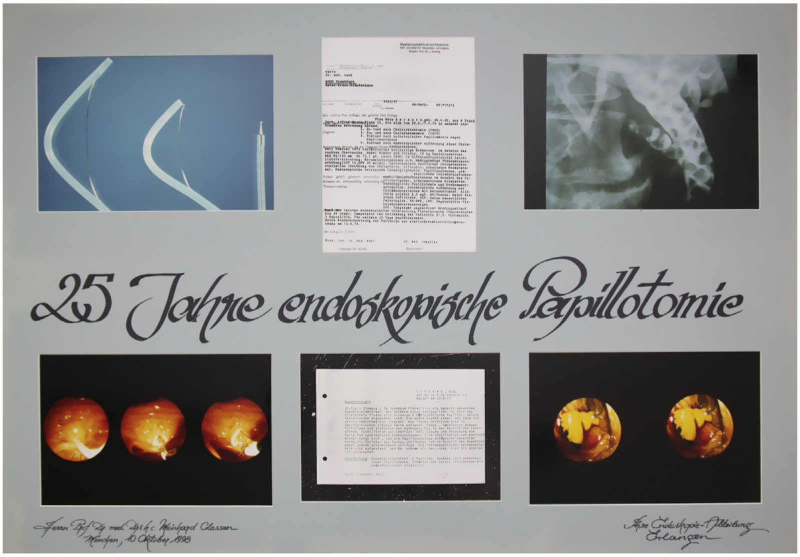


Figure 8.1 Poster commemorating the first endoscopic papillotomy with the original images and documents of 1973. *Courtesy: Prof. M. Classen.*

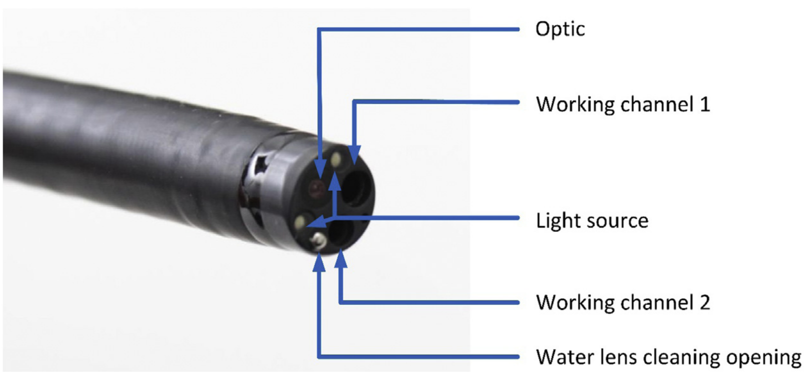
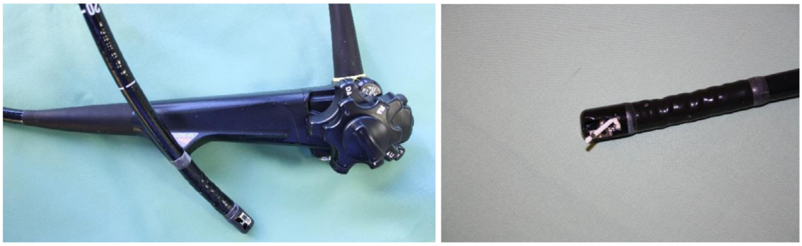


Figure 8.2 Interventional flexible endoscope. *From MITI.*

radiographic control. Primarily, it has been a diagnostic tool, but today it is almost exclusively used for therapy (this is why it is mentioned here and not in Chapter 5.7: Endoscopy). The procedure is described in detail below (see Section 8.4.4: Endoscopic Interventions on the Bile Duct (ERCP)).

Since the papilla is located at the left-lateral circumference of the duodenum, it is easily overlooked with a standard forward looking endoscope.



(A) (B)

Figure 8.3 (A) The handling of a duodenoscope with the Albarran lever; (B) tip of the instrument with the lever for angulation. *All from MITI.*

The scopes for ERCP are, therefore, side-viewing ones. In addition, they also provide a mechanism to deflect the cannula when it leaves the working channel to intubate the papilla (Fig. 8.3).

The principle was originally developed for urology by J. M. Albarran and adopted to flexible endoscopy.

8.2 INSTRUMENTS

In addition to the biopsy forceps which were originally designed for diagnostic endoscopy, an increasing variety of flexible instruments and devices was developed later, which greatly stimulated the introduction of new endoscopic procedures into clinical care. Many new designs were actively created by the endoscopists and found their way into industrial production.

8.2.1 Knives

A knife is required if an incision into the tissue has to be made or if a lesion has to be cut out. Most commonly, the so-called "needle knife" is used. In its basic design, a cutting wire is advanced out of the tip of the instrument. Meanwhile, even more advanced designs are available (Fig. 8.4).

The insulated tip knife carries an insulating bead at the front end. This enables the endoscopist to perform lateral cutting. The triangle knife allows for cutting and targeted coagulation. Which instrument is selected depends upon the specific application and the preference of the endoscopist [2].

The papillotome is a special type of laterally acting knife. A stainless steel wire loop is sheathed on one side by an insulating plastic hose. The contralateral side of the loop lies open (Fig. 8.5A). If traction is exerted

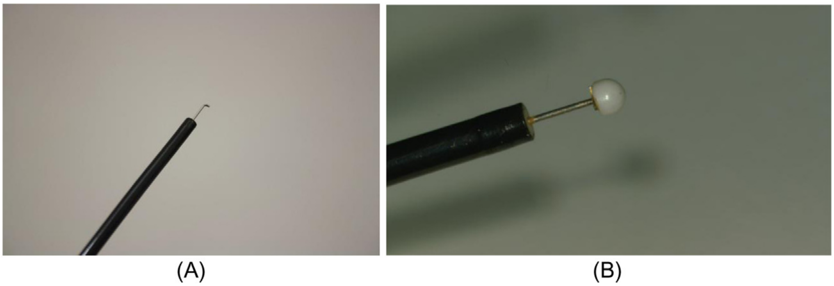


Figure 8.4 (A) Plain needle knife; (B) insulated tip knife. *All from MITI.*

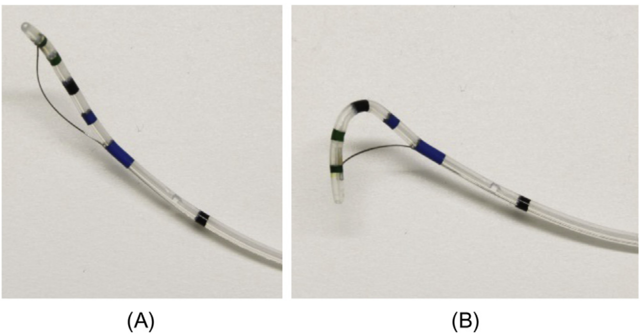


Figure 8.5 (A, B) The principle of a papillotome: If traction is exerted on the bare steel wire, it shapes a tendon which can be used to cut if electrical current is sent through the tendon. *All from MITI.*

to the outer part of the wire, a bow is shaped (Fig. 8.5B). If diathermy is applied, adjacent tissue will be cut.

8.2.2 Hooks

The hook knife has an L-shaped tip. Using the hook, the tissue to be dissected can be brought under tension. Thus, a very precise cut is achieved (Fig. 8.6).

8.2.3 Snares

Snares are lasso-like wires which are positioned around the tissue which has to be removed. Subsequently, the loop is closed while electrocautery is applied, thus cutting the tissue out and sealing bleeding. They are available in a wide variety of shapes and sizes (Fig. 8.7).

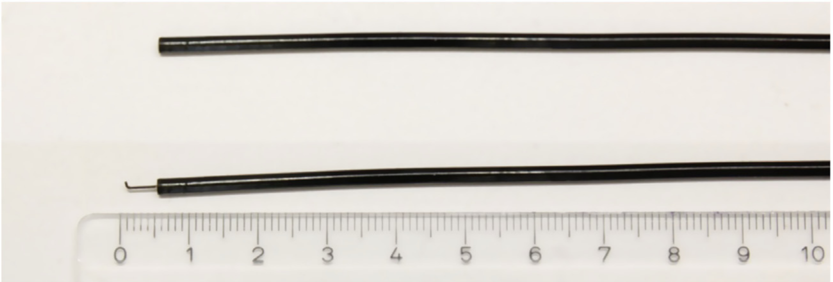


Figure 8.6 Hook knife: Top: Retracted; below: working position of the tip. Monopolar diathermy provides cutting and/or coagulation. *From MITI.*

Figure 8.7 (A) Oval snare; (B) crescent-shaped snare; (C) hexagonal snare. *All from MITI.*

Detachable snares or loops which can be left in place are useful because of the tourniquet effect: They can be, e.g., placed at the base of a pedunculated polyp to occlude blood supply. The polyp can, then, be safely transected by means of another (electrocautery) snare.

Recently, an interesting new application of the detachable snare was published for mucosal closure. The detachable clip is deployed around the mucosal defect and fixated by means of clips to the edges. Closure of the snare occludes the defect (Fig. 8.8).

8.2.4 Injection Needles

Injection needle instruments are inserted into the working channel with the tip of the needle retracted into the internal lumen. Prior to injection, the sharp tip is moved forward to pierce the tissue. Hemostatic agents are injected to stop bleedings (Fig. 8.9).

Fluid is delivered into the submucosal layer of the gastrointestinal (GI) wall to produce a cushion beneath the mucosa which facilitates excision.

8.2.5 Forceps/Graspers

Endoscopic forceps are predominantly used to take biopsies, i.e., for tissue sampling. They usually consist of a pair of sharpened cups, the flexible

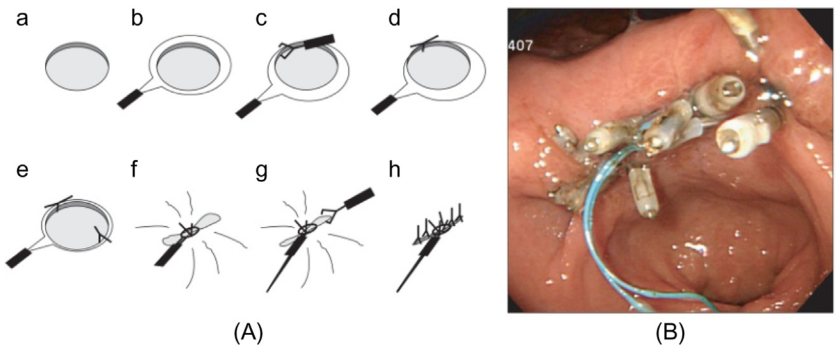


Figure 8.8 (A) Mucosal closure with a detachable snare and clips after endoscopic submucosal dissection. (a) A mucosal defect remains after ESD. (b) A detachable snare is deployed on the mucosal defect through a working channel, and a rotating clip-fixing device with a long clip is inserted through the other working channel. (c) The wire of the detachable snare is placed between both legs of the clip. (d) The clip is applied to the edge of the mucosal defect. (e) Another clip is applied to the opposite side of the mucosal defect in the same manner. (f) The snare is squeezed gently, and the mucosal defect is approximated. (g) Additional clips are applied to close the defect. (h) The defect is closed completely. (B) The mucosal defect at the gastric angle is closed completely with a detachable snare and clips. *From Lee BI, Kim BW, Kim HK, Choi H, Ji JS, Hwang SM, et al. Routine mucosal closure with a detachable snare and clips after endoscopic submucosal dissection for gastric epithelial neoplasms: a randomized controlled trial. Gut Liver 2011;5(4):454–9 [3].*

Figure 8.9 Injector needle: (A) Retracted (up) and locked in working position (below); (B) syringe connected to the external end of the probe. *All from MITI.*

shaft with the Bowden wire and the handling. The jaws are available in a very wide range of designs (Fig. 8.10).

Biopsy forceps are also available for so-called "hot biopsies" (tissue retrieval with concomitant electrocautery). They are insulated.

Graspers are needed to grip tissue or foreign bodies. The function of the jaws is always a trade-off between a firm grip and a gentle treatment of the object.

Today, the industry provides numerous designs which are optimized to the particular purpose (Fig. 8.11).

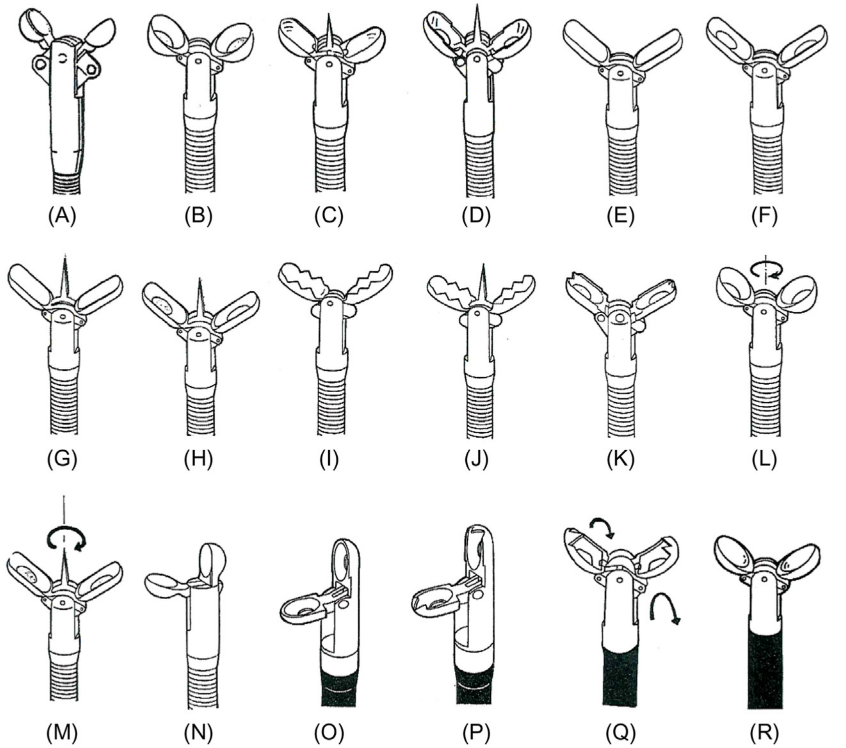


Figure 8.10 Various models of commercially available forceps with a central spike, various types of leg, and optional "hot biopsy." (A) Round; (B) round with windows; (C) round with spike; (D) round with windows and spike; (E) oval; (F) oval with windows; (G) oval with spike; (H) oval with windows and spike; (I) oval, toothed; (J) oval with spike, toothed; (K) oval with windows, rat-toothed; (L) round with windows, rotatable; (M) oval with windows and spike, rotatable; (N) round, alligator; (O) round with windows, alligator; (P) round with windows, rat-toothed; (Q) round with windows, swiveling, rat-toothed; (R) round, hot biopsy. *From Matsuda K, Tajiri H. Tissue and fluid sampling. In: Classen M, Tytgat GNJ, Lightdale CJ, editors. Gastroenterological endoscopy, 2nd ed Stuttgart: Georg Thieme Verlag; 2010. p. 203–9 [4].*

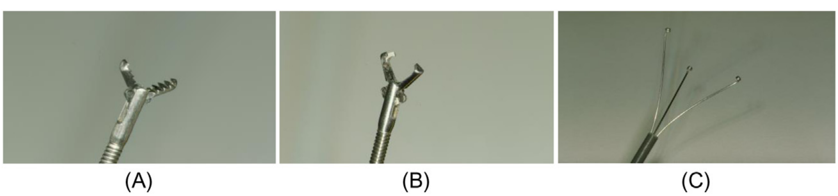


Figure 8.11 Graspers: (A) Alligator jaw: ideal for small, solid objects such as clips; (B) shark tooth: accurate and safe grip; (C) tripod: removal of polyps. *All from MITI.*

8.3 CLIPS

Clips are small, tweezer-like devices for tissue (mucosa) approximation. They work by forcibly approximating the clip arms thus including a volume of tissue to achieve either vascular occlusion or closure of a defect.

8.3.1 Standard endoscopic clips

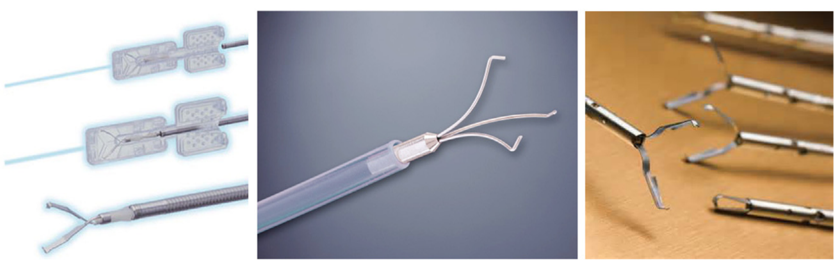
The first description of a clip used in GI endoscopy came from Japan in 1975 [5]. It was another 15 years until they really became popular when the design of the delivery system was improved. The first significant step forward came in the mid-1990s from Olympus (Tokyo, Japan) with the introduction of the reloadable clip, followed by the preloaded QuickClip in 2002 and rotatable QuickClip2 in 2005. Cook's TriClip and Boston Scientific's Resolution clip both were launched in 2003 (Fig. 8.12). In two comparative studies, investigators found that these clips had application times and failure rates that were very similar and all achieved 100% hemostasis.

The design of clips is challenging, since the clinical requirements are high. The users need preloaded clips with reliable deployment, good mucosal adherence, adequate apposition and strength of the arms, rotatability, and a wide opening distance of the arms.

Clips are used as tissue markers or to stop bleeding by occluding vessel stumps. They are even applied to occlude smaller perforations, but this type of closure is insecure since the mucosa only is approximated.

8.3.2 Over-the-Scope-Clip

The so-called "over-the-scope-clip" (OTSC) is an entirely new approach to approximate tissue in full thickness. The system consists of an applicator cap with a mounted OTSC clip and the release accessories. The clip



(A) (B) (C)

Figure 8.12 (A–C) Currently available hemoclips: From left to right: EZ clip (Olympus, Tokyo, Japan), TriClip (Cook Medical, Bloomington, IN, United States), Resolution Clip (Boston Scientific, Marlborough, MA, United States).

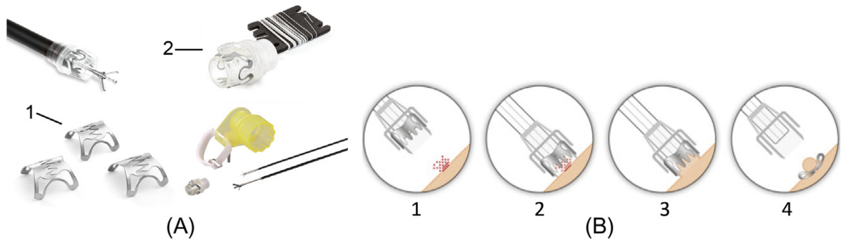


Figure 8.13 (A) Open (1) and closed (2) OTSC clips. (B) The application procedure: (1) targeting the lesion; (2) approximation of the application cap and the target tissue; (3) firing the clip; (4) procedure completed. *All from Ovesco Endoscopy AG.*

is a Nitinol ring with circular teeth. If it is released, two half-rings are shaped which firmly compress the tissue which is placed in-between them (Fig. 8.13).

Using a specially designed bilateral grasper, the two edges of a full-thickness lesion of the wall can be positioned precisely to achieve reliable compression.

The clip is licensed as a long-term implant, but most frequently it leaves the human body within several months. Three different sizes of caps are available, suitable for the majority of endoscopes. The main indication for OTSC clips are hemostasis and full wall occlusions, e.g., after perforation [6]. For the latter, several clips can even be placed in a row.

The introduction of this type of a clip certainly boosted once again the clinical role of therapeutic endoscopy [7].

The refinement of clip technology extended the range of clinical applications considerably. They are no longer limited to stopping bleeding or to occluding small perforations, but they can also be used to close full-thickness resection defects, fistulae, or to anchor stents [8].

8.4 CLINICAL APPLICATIONS

8.4.1 Gastrointestinal Bleeding

Bleeding from the upper or lower GI tract is still today a significant cause of mortality. Only a few decades ago, the treatment was a surgical domain. Today, endoscopic therapy is the treatment of choice. Endoscopic treatment can be broadly categorized into injection, thermal, and mechanical methods.

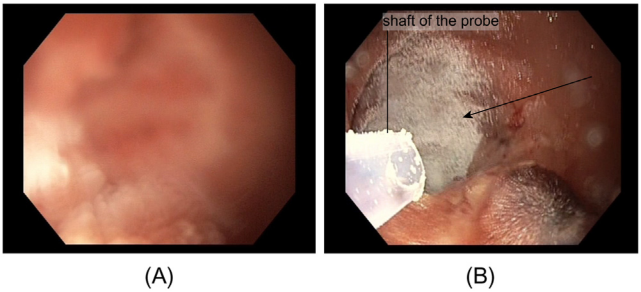


Figure 8.14 GI bleeding: Injection therapy: (A) in an acute bleeding, the image is often difficult to interpret since visualization is poor. The bleeding site is assumed to be in the center of the image. (B) The injection cannula is introduced (left lower corner) and the needle is inserted into the tissue (needle not visible). By injecting epinephrine the bleeding is stopped (whitish area, arrow). *Courtesy: Prof. Dr. S. v. Delius, Klinikum rechts der Isar.*

8.4.1.1 Injection Therapy

If epinephrine (Suprarenin) is injected into a bleeding artery or into the vicinity of it, immediate vasoconstriction is initiated. In addition, the mechanical effect of compression exerted by the injected fluid volume contributes to hemostasis (Fig. 8.14). Fibrin glue is another powerful agent with a higher long-term effect.

Injection hemostatic therapy is mostly less focused than, e.g., clip application and less long-standing. However, it is mostly a helpful option in difficult emergency situations.

8.4.1.2 Thermal Hemostasis

Thermal approaches for hemostasis can be divided into contact methods and noncontact methods.

8.4.1.2.1 Contact Methods

If bleeding tissue is compressed, the local effect of thermal energy is reinforced (reduction of the "heat-sink" effect). The tissues, including the vessels, are sealed by the sol/gel effect.

Direct contact probes exert direct, unilateral pressure onto the bleeding site (Fig. 8.15). Even more effective are specially designed forceps/graspers. If the bleeding structure is hit accurately, it both provides mechanical tamponade and a targeted electrical current flow to provide direct coagulation.

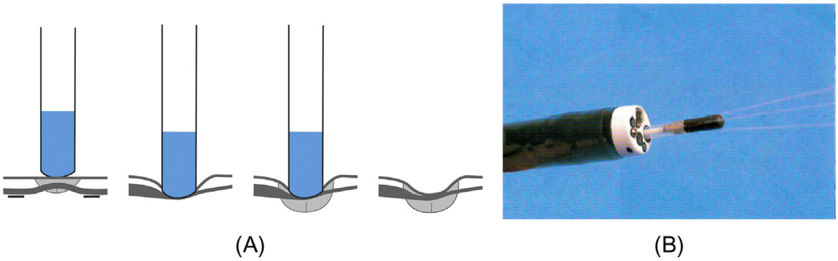


Figure 8.15 Coaptive coagulation. (A) Firm compression by a contact thermal probe stops the blood flow and reduces the heat-sink effect. Thermal energy is then applied to seal the artery. (B) A 3.2-mm Heatprobe (Olympus CD-10Z) in a dual-channel therapeutic endoscope (Olympus GIF-2T240) with 3.7- and 2.8-mm channels). Three irrigation ports are located 1 cm proximal to the Teflon-coated tip. Forceful targeted irrigation of an ulcer bed can be applied through these ports. *From M. Scholle.*

8.4.1.2.2 Noncontact Methods

Laser and argon plasma coagulation (APC) exert thermal energy to opposed objects without contacting them. Theoretically, they should be ideally suited to stop localized or diffuse bleedings. However, the initially high expectations are not (yet) met in clinical reality.

Laser Coagulation

The term "laser" is the abbreviation of "light amplification by the stimulated emission of radiation." If living tissue is hit by a laser beam, hyperthermic destruction with thermal contraction and coagulation occurs.

However, the laser approach was soon overtaken by the widespread use of lower cost and less cumbersome thermal devices. Today, the laser is still used for lithotripsy of gallstones (Holmium laser) [9].

Argon Beaming

Argon plasma coagulation (APC) is a noncontact monopolar electrosurgical technology. Electrical energy is transmitted via an ionized argon gas ("plasma") beam.

The probe is a flexible argon tube containing an electrode in the distal tip which ignites the plasma as soon as argon flows (see Chapter 6.2.12.2: Argon Plasma Coagulation).

APC is effective against superficial bleeding of parenchymatous organs, but less reliable in strong arterial bleedings. However, there is no evidence to suggest that APC is superior to other endoscopic therapies [10].

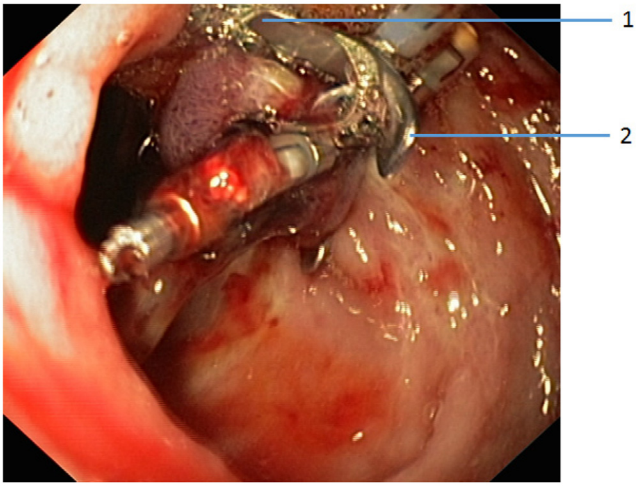


Figure 8.16 Mechanical occlusion using the OVESCO clip: The clip is already closed. Note the two halves (1, 2) of the clip. *Courtesy: Prof. Dr. S. v. Delius, Klinikum rechts der Isar.*

8.4.1.3 Mechanical Methods

If technically feasible, a well-placed hemoclip is still the most effective means to occlude reliably arterial vessels. In clinical practice, repetitive clip applications are often required to achieve the desired hit. The amount of tissue which is effectively compressed is rather small.

Even more effective than standard clip occlusion is the newly developed OTSC clipping method (Ovesco Endoscopy AG, Tuebingen, Germany) (Fig. 8.16).

Theoretically, suturing techniques would also be attractive, but the first sufficiently fast and simple systems are just on the threshold to the market (see Chapter 9.2.2.2: Suturing Devices).

8.4.2 Percutaneous Endoscopic Gastrostomy

Frequently it occurs that patients become unable to eat and drink, e.g., caused by hypopharyngeal or esophageal tumors. In these cases, endoscopy is able to provide an external access to the stomach to enable enteral nutrition. The technique of percutaneous endoscopic gastrostomy (PEG) was developed about 20 years ago.

The idea of the PEG is to insert a feeding tube through the abdominal wall into the stomach. Several steps are necessary. A gastroscope is positioned into the stomach and the anterior wall of the stomach is illuminated. In most cases, the light of the gastroscope can be seen through the abdominal wall.

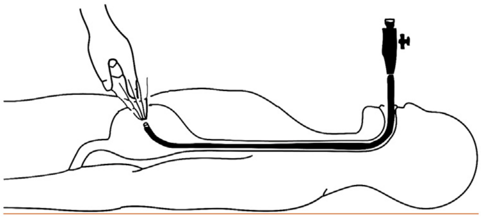
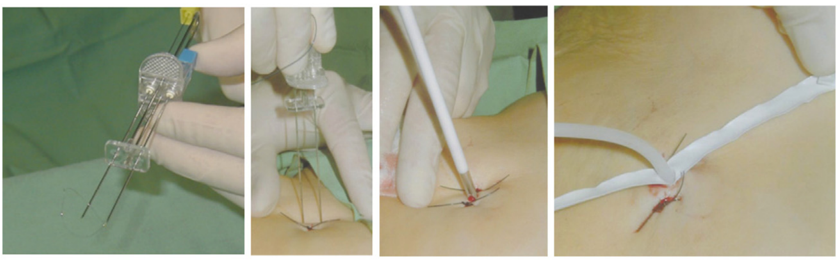


Figure 8.17 The tip of the endoscope is identified by external compression of the abdominal wall. *From MITI.*



(A) (B) (C) (D)

Figure 8.18 (A) Direct puncture of the stomach under endoscopic control; (B) the guide is introduced; (C) the channel is appropriately dilated; (D) the catheter is introduced through a split cannula. *Courtesy: Prof. Dr. S. v. Delius, Klinikum rechts der Isar.*

At this very spot the observer compresses the abdominal wall which can be clearly seen from within. It can be assumed now that the anterior gastric wall is immediately adjacent to the abdominal wall (Fig. 8.17).

A hollow needle is inserted through the abdominal wall into the gastric lumen and a thread is inserted. This thread is caught with biopsy forceps of the endoscope and pulled out through the mouth (Fig. 8.18).

Using the thread as a guide, the puncture site is dilated after skin incision by inserting bougies into the stomach. Thus, the channel is gradually widened until it allows to insert the PEG catheter.

Alternatively, the feeding tube is attached to the oralad end of the guide thread and drawn back until it appears on the outer abdominal wall. The position of the feeding tube is secured by a balloon which is inflated within the gastric lumen.

By pulling the balloon gently against the abdominal wall, the puncture site is sufficiently sealed to prevent leakage. After 7–10 days, a stable channel is established which permits to exchange the catheter in case of need (Fig. 8.19).

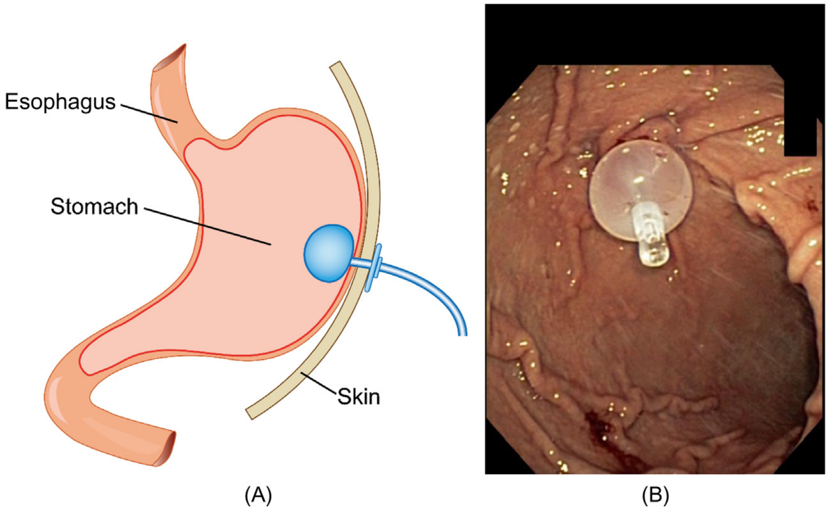


Figure 8.19 (A) Schematic drawing of a PEG in situ. (B) Within the stomach: Inflated balloon at the anterior gastric wall. *Courtesy: (A) M. Scholle, (B) Prof. Dr. S. v. Delius, Klinikum rechts der Isar.*

8.4.3 Endoscopic Resection of Neoplastic Tissue

In premalignant lesions (e.g., polyps) or very early malignancy with no risk of lymph node dissemination, a local excision is sufficient.

8.4.3.1 Snare Polypectomy

Pedunculated polyps are comparably easy to remove (Fig. 8.20). An open snare is placed over the polyp and closed. The wire loop closes concentrically toward the tip of the snare sheet and, thus, transects the base of the tumor.

In case of doubt (if strong vessels are suspected in the pedicle), a detachable loop can be placed underneath beforehand.

8.4.3.2 Endoscopic Mucosal Resection

If the endoluminal lesion is flat, the tangential endoscopic approach is significantly more difficult. The management of these findings is facilitated by making them prominent by injecting fluid into the submucosal layer. The fluid cushion makes the pathological area protrude into the lumen. It now can be removed by a snare (Fig. 8.21) or excised with a needle knife.

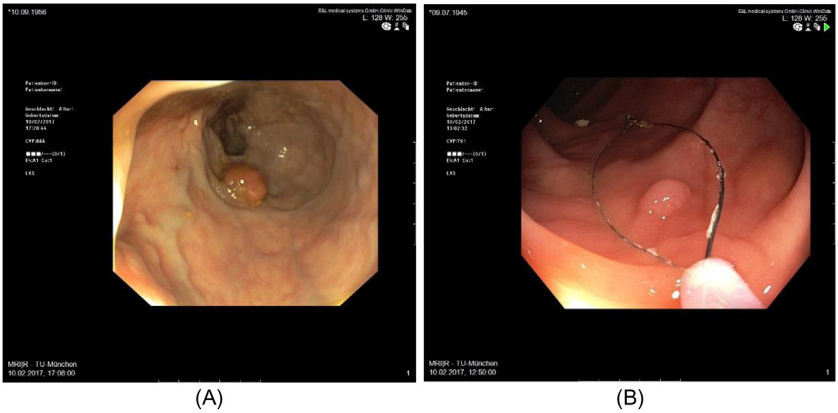


Figure 8.20 Snare polypectomy: (A) Polyp of the transverse colon; (B) the open snare is placed over the lesion. When the loop is closed, electrical current causes transection and, simultaneously, coagulation of the base. *Courtesy: Dr. J. Bachmann, Klinikum rechts der Isar.*

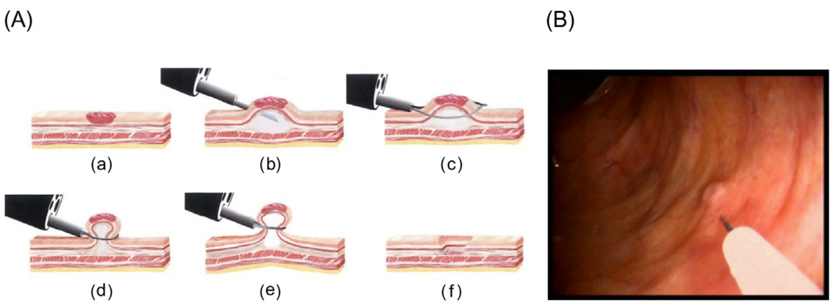


Figure 8.21 The principle of EMR. (A) Schematic description of the workflow. (a) Flat intramucosal lesion; (b) injection of fluid into the submucosa; (c–e) placement of the snare, closure, and transection; (f) the resulting disk of removed mucosa will safely heal in a few days. (B) The first step: Piercing the submucosa to create the fluid cushion. *Courtesy: Prof. Dr. S. v. Delius, Klinikum rechts der Isar.*

Endoscopic mucosal resection (EMR) is a safe technique, but it is limited to mucosal lesions only. Frequently, it is not possible to retrieve the specimen in one piece but in two or more fragments (piecemeal resection) which is not desirable from the oncological point of view.

8.4.3.3 Endoscopic Submucosal Dissection

Some years ago, endoscopists developed a technique to perform even deeper excisions: endoscopic submucosal dissection (Fig. 8.22) [11].

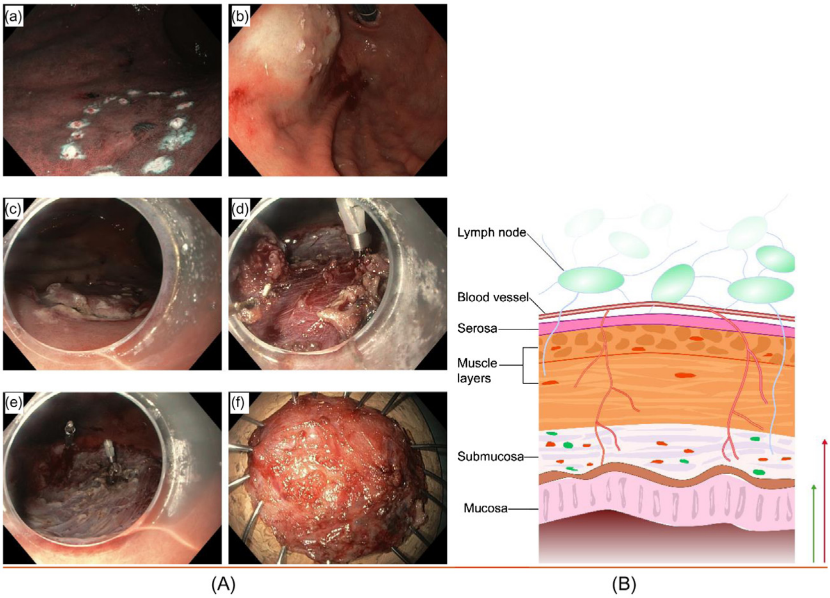


Figure 8.22 (A) Endoscopic submucosal dissection. (a) Markers are coagulated into the mucosa to define the area which has to be resected; (b) the area protrudes into the lumen after submucosal injection is finished; (c) after the first incision with the needle knife; (d) ESD in an advanced stage; (e) view on the muscle layer. Some vessels had to be clipped. (f) En bloc specimen with macroscopically free margins. (B) The histological architecture of the intestinal wall. Right arrow: ESD; left arrow: EMR. *Courtesy: (A) Prof. Dr. S. v. Delius, Klinikum rechts der Isar, (B) M. Scholle.*

Endoscopic submucosa dissection (ESD) is a step forward to better oncological results, but it is more complication-prone than EMR. It is becoming increasingly more popular since with specially designed instruments the management of complications (bleeding, perforation) could be significantly improved [12,13].

8.4.4 Endoscopic Interventions on the Bile Duct (ERCP)

Since 1973, ERCP completely lost the role of a diagnostic tool, since magnetic resonance cholangiopancreatography (MRCP) and endoscopic ultrasound examination (EUS) render comparable information and are less risky.

However, ERCP became indispensable for the treatment of pancreatobiliary disease (Fig. 8.23). The range of ERCP-based

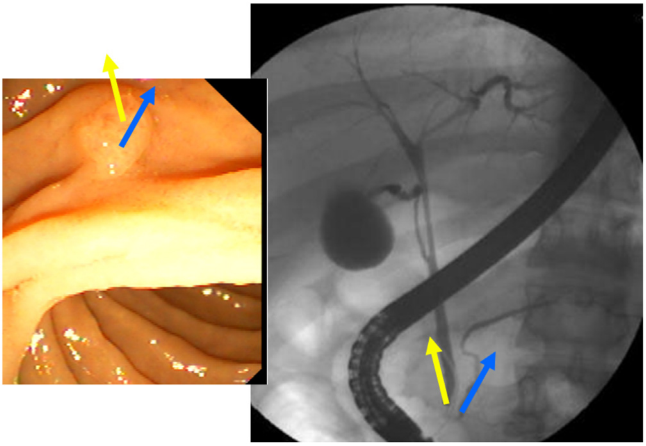


Figure 8.23 A look onto the papilla with the duodenoscope (left side). Contrast medium injected into the bile and pancreatic duct system (right side). The position of the bile duct is indicated with the yellow arrow (white arrow in print). The blue arrow (gray arrow in print) shows the pancreatic duct. *Courtesy: Prof. Dr. C. Prinz, HELIOS Universitätsklinikum Wuppertal.*

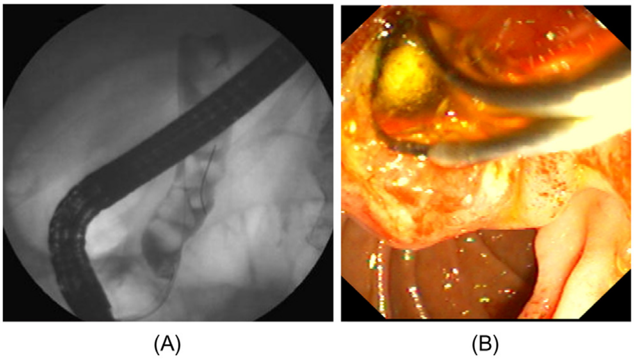
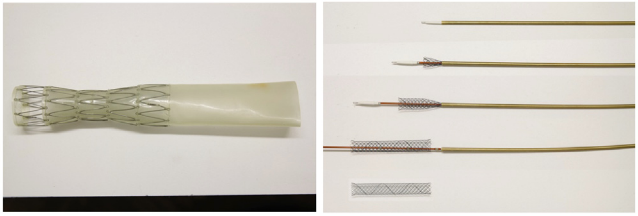


Figure 8.24 (A) Multiple prepapillary bile duct stones; (B) the first cut with the papillotome is accomplished. Note the first stone coming out. *Courtesy: Prof. Dr. C. Prinz, HELIOS Universitätsklinikum Wuppertal.*

therapeutic approaches is wide: beginning with the removal of bile duct stones (Fig. 8.24), it includes stenting of benign and malignant narrowings (stenosis) of the duct, photodynamic therapy, and the treatment of iatrogenic bile duct injuries.



(A) (B)

Figure 8.25 A selection of commercially available stents: (A) The unfolded stent: shape after activation; (B) the process of stent positioning: on the delivery system, the stent is drawn into length to reduce the outer diameter to a minimum. As soon as it is positioned precisely in its future place, it is expanded to its maximum diameter (thus, losing length). Finally, the delivery system is removed and the GI transit restored. *All from MITI.*

ERCP is performed with dedicated, side-viewing endoscopes with a special lever to navigate the bile duct probes (see Section 8.1.2: Side-Viewing Duodenoscopes).

The full therapeutic potential of ERCP has certainly not yet been fully exploited. BME is invited to provide even more advanced tools to promote further this extremely elegant approach.

8.4.5 Gastrointestinal Stenting

Luminal obstruction in the GI tract always leads to dramatic consequences for the patient. If untreated, it results in starvation if the obstruction is located in the upper GI tract, and in sudden death following the ileus in the lower GI tract. As an alternative to (palliative) surgery, interventional endoscopy can now offer dilatation and stenting. Esophageal, duodenal, bile duct, and colonic obstructions can be handled today with dedicated stents [14] (Fig. 8.25).

Stenting often provides immediate help (Fig. 8.26). In many oncological situations, it is a valuable tool for palliation.

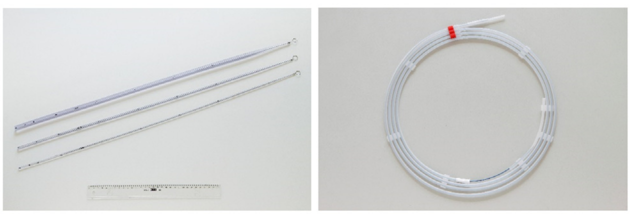
The use of stents is not only confined to the esophagus. Stents are helpful as well in duodenal or colonic obstruction.

8.4.5.1 Bougienage and Balloon Dilatation

Narrowings of the GI lumen (stenoses) due to scar formation or tumorous lesions can be reopened and widened by the so-called "bougienage" maneuver.

(A) (B)

Figure 8.26 Stenting of an esophageal carcinoma: (A) A barium swallow of a subtotally occluding esophageal cancer. A thread-shaped channel of transit is left. The patient is scarcely able to swallow small amounts of fluid. (B) After stent positioning, the patient is immediately capable of normal food intake. *Courtesy: Dr. A. Fingerle, Klinikum rechts der Isar.*



(A) (B)

Figure 8.27 A bougie set (A) with guidewire (B). *All from MITI.*

Under radiographic control, a guidewire is positioned over the stenosis. Bougies of increasing diameter are then passed over the guidewire to expand the internal diameter (Fig. 8.27).

Frequently, a stent is finally positioned to secure the recanalization (see Section 8.4.5: Gastrointestinal Stenting). In case of muscular obstruction, bougienage is not helpful to eliminate the barrier. In these cases, pneumatic dilatation may be helpful.

8.4.6 Outlook

The breathtaking evolvement of interventional endoscopy will continue, supported by technological developments, which are, among others, also stimulated by NOTES (Fig. 8.28).

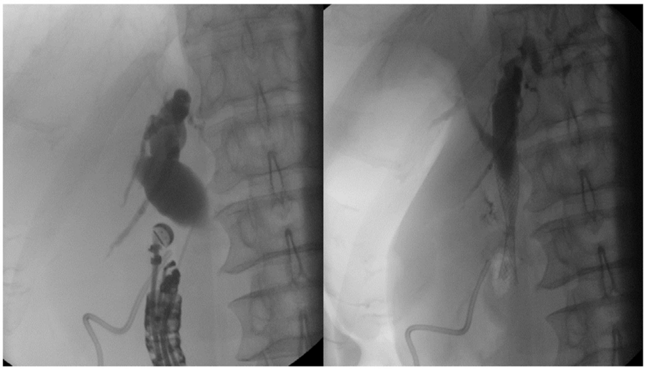


Figure 8.28 Advanced interventional endoscopy: (A) The main bile duct is occluded by a pancreatic tumor. The stricture cannot be overcome through the papilla of Vater. To solve the problem, the dilated bile duct above the stricture is punctured under EUS control from the duodenum. (B) A stent is positioned over a guidewire. The obstruction is now deviated. *Courtesy: Prof. Dr. A. Meining, University of Ulm.*

It may be even assumed that the winning run of therapeutic flexible endoscopy is just beginning—presuming innovative new tools [15].

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CHAPTER 9

Combined Laparoscopic-Endoscopic Procedures and Natural Orifice Transluminal Endoscopic Surgery (NOTES)

In the previous chapters it has been shown how successfully visceral diseases can be treated either by conventional/laparoscopic surgery or interventional endoscopy.

In the following chapter it is demonstrated how the strict borders between both disciplines are gradually vanishing. A closer cooperation opens up new dimensions of trauma reduction in the interventional treatment of gastrointestinal diseases (Fig. 9.1).

Simultaneously to the development in laparoscopy, endoluminal flexible endoscopy changed from a diagnostic tool to an interventional therapeutic approach. Initially, this was regarded critically by surgeons, since new competitors were suspected. The first major endoscopic therapeutic intervention—endoscopic retrograde cholangiopancreatoscopy (ERCP)—had been introduced into clinical care in 1973, which was well before the era of minor access surgery. ERCP rapidly made the corresponding surgical technique—open bile duct exploration—obsolete. Benign and early colonic tumors—formerly a domain of surgical resection—could now be removed safely and fast by colonoscopic polypectomy in outpatients. The clear distance between endoscopists and surgeons was gradually overcome with the introduction of laparoscopy, in particular laparoscopic cholecystectomy. The option to remove bile duct stones by ERCP and papillotomy beforehand and to confine surgery to the resection of the gallbladder was a precondition of the success of laparoscopic cholecystectomy, since laparoscopic treatment of bile duct stones was still technically impossible at that time. In addition, interventional gastroenterologists could help in case of surgically induced bile duct lesions, which were not infrequent in the beginning of laparoscopic surgery. Bile leakage could be sealed by stents or strictures could be dilated which helped to avoid revisional

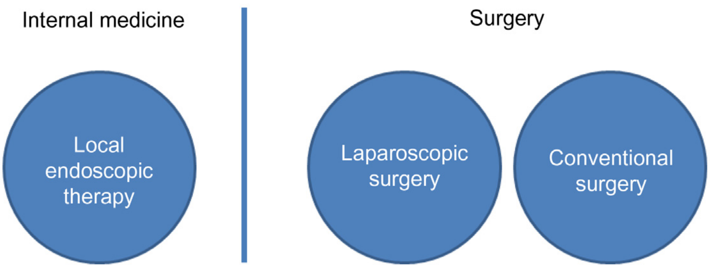


Figure 9.1 In the era of trauma reduction, the development of minimally invasive surgery was accompanied by a rapid advance in interventional endoscopy. Independently of each other, significant improvements could be achieved on both sides. *From MITI.*

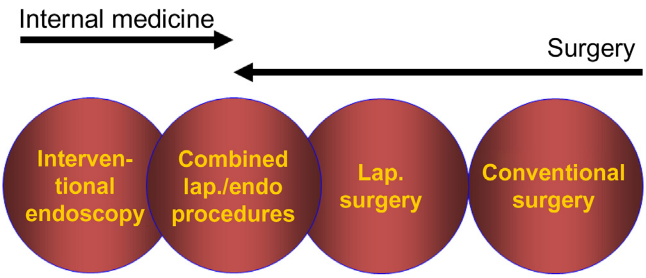


Figure 9.2 The bridge between internal medicine and surgery: Combined laparoscopic/endoscopic procedures. Surgeons and gastroenterologists cooperate at the same workplace. *From MITI.*

surgery. The difficult relations between gastroenterologist and surgeon were increasingly replaced with a cooperative attitude (Fig. 9.2).

Beyond that, it has become clear during the last few years that both laparoscopy as well as flexible interventional endoscopy suffer from immanent limitations. One important shortcoming of laparoscopic surgery is that no information is available about the conditions beyond the surface. Precise localization of endoparenchymatous or endoluminal lesions is impossible.

Interventional endoscopy is primarily confined to endoluminal activities. Additional shortcomings are the difficult hemostases in the case of major bleeding or the management of wall perforation.

Soon, the idea came up to combine laparoscopy and endoscopy to compensate for the shortcomings of either method.

By approaching the respective lesion from both sides, the potential of both methods can be used synergetically. The first clinical reports appeared in the early 1990s [1,2].

The concept became rapidly popular all over the world and soon became known as combined laparoscopic-endoscopic procedures (CLEP) with the synonyms "hybrid visceral surgery" or "rendezvous surgery" [3,4].

The next step is an even more intensive melange of surgical and flexible endoluminal endoscopy: natural orifice transluminal endoscopic surgery (NOTES). To enter the abdominal cavity, an opening through the wall of the gastrointestinal tract is created and a flexible endoscope is used to perform the surgical manipulation from within in order to avoid visible scars. These two innovative approaches are the subjects of the next sections.

9.1 COMBINED LAPAROSCOPIC-ENDOSCOPIC PROCEDURES (CLEP)

The idea is to perform both laparoscopic surgery and endoluminal endoscopy simultaneously during the respective intervention. This sounds easy, but a number of technical preconditions have to be fulfilled before.

(Laparoscopic) surgery is performed in the surgical operating room, whereas flexible gastrointestinal endoscopy is usually done in the endoscopy floor.

This type of surgery has to be located in the surgical OR, since the endoscopy suite does not offer suitable conditions to carry out laparoscopic intervention. Accordingly, the surgical OR has to be equipped with an endoluminal (flexible) endoscopy unit. Adequate education of the surgical OR staff in the use of flexible endoscopy is indispensable.

The position of the laparoscopic team and of the endoscopist depends upon the site of the lesion which has to be treated.

In case of upper GI tract surgery, esophagogastroduodenoscopy is required. Colonoscopy is suitable to assist colonic surgery. Depending upon the intervention, the endoscopist is located either at the head of the patient or between the patient's legs. Care has to be taken that both the surgical team as well as the endoscopist have a good insight into not only their own anatomical site but also into that of their respective partner (Fig. 9.3).

9.1.1 Indications

CLEP can be applied with lesions for which local excision is adequate, but in which it cannot be achieved using peroral or transanal flexible endoscopy due to the size and location of the lesion. Another indication

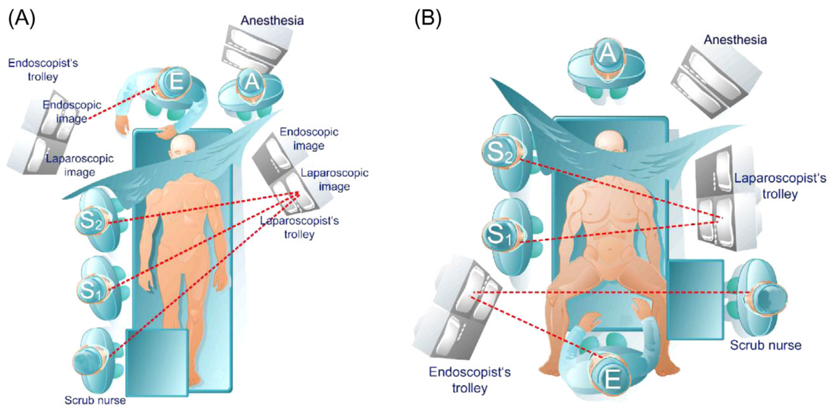


Figure 9.3 Positioning of the endoscopist at the OR table during hybrid procedures (A: anesthetist; S_1: surgeon; S_2: surgical assistant; E: endoscopist). (A) Upper abdominal surgery: The endoscopist enters the abdomen via the mouth. Accordingly, he stands at the head of the patient and has to share this position with the anesthetist. (B) Surgery of the large bowel. Lithotomy position. The endoscopist works from the opposite side. The adequate placement of the screens is more difficult. *Modified by Dr. A. Schneider.*

for CLEP is lesions requiring local full-thickness resection of the gastrointestinal wall.

9.1.2 Esophagus

CLEP is mainly focused upon intramural lesions, such as benign leiomyoma, lipoma, and neurinoma. Unlike for other parts of the GI tract, CLEP is less frequently needed for endoluminal lesions.

9.1.3 Stomach

In the stomach, lesions that are suitable for CLEP are gastric wall tumors, such as benign gastric stromal tumors (leiomyomas and carcinoids), epithelial growths, such as adenomas, and early gastric cancer [5]. Bleeding gastric lesions such as ulcers, Mallory-Weiss tears, and Dieulafoy's lesions can be treated by intragastric laparoscopy if peroral endoscopy does not achieve control of bleeding [5].

9.1.4 Duodenum

Symptomatic diverticula of the duodenum, duodenal carcinoid tumors, and adenomas may be indications for CLEP.

9.1.5 Colon

Indications for CLEP in the colon are similar to those in the stomach—in particular, adenomas, early cancers with invasion no deeper than the mucosa and superficial layer of the submucosa (sm1), and benign submucosal lesions [6].

9.1.6 Contraindications

Lesions of malignant appearance with a high probability of advanced disease should not be considered for local excision by CLEP. Conventional or laparoscopic surgical resection should be performed in these cases.

CLEP is contraindicated in patients who are unfit to undergo anesthesia and in those with clotting disorders.

Endoluminal endoscopy is helpful in multiple regards:

- Exact localization of the lesion.
- Defining the line of resection.
- Selecting the appropriate technique of resection.
- Specimen retrieval.
- Leak tests.

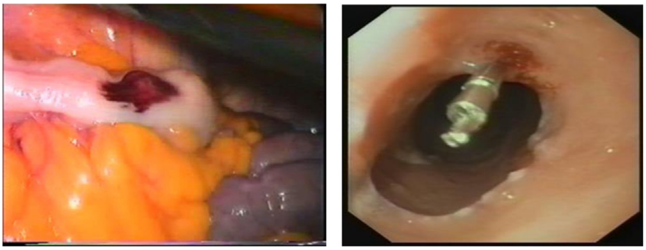
9.1.7 Tumor Localization

Intraoperative flexible endoscopy is the most reliable tool to localize precisely the site of a lesion.

It would be, of course, more convenient for the surgeon if the tumor area could be marked prior to the surgery instead of being dependent upon a demanding intraoperative identification. If the lesion, or better to say the area which has to be excised, could be clearly marked during preoperative colonoscopy, surgery could be performed without intraoperative endoscopy. Many attempts were made to indicate the precise location of the tumor by injecting dye into the gastrointestinal wall. The dye would be visible at the exterior layer of the wall, enabling the surgeon to confine his local resection to the pathological finding plus a security margin. Unfortunately, most dyes, like methylene blue, diffuse in an uncontrolled way and make it difficult to decide what has to be cut out (Fig. 9.4A).

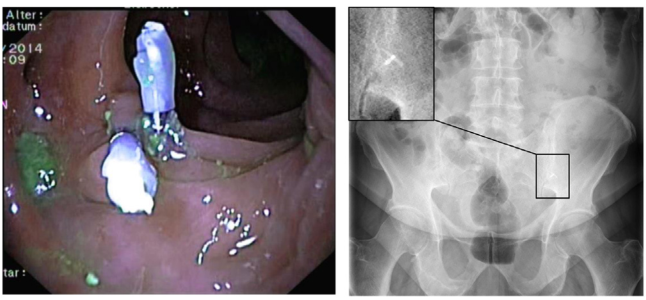
Others tried out marking the lesions with endoscopic (metallic) clips (Fig. 9.4B).

Since intraoperative fluoroscopy with the C-arm is well established in visceral surgery (see Chapter 5.9.2: Conventional Radiography (C-Arm)), it is accordingly easily feasible to perform an intraoperative X-ray to localize the



(A) (B)

Figure 9.4 Preoperative mapping of the lesion: (A) Instillation of dyes. The spot of dye which has been injected priorly into the colonic wall during colonoscopy is clearly visible from outside. However, it does not represent reliably the internal lesion since the color diffuses into the tissue and does not mark clear limits. (B) By placing three or more clips around the lesion, the relevant area can be demarcated. *All from MITI.*



(A) (B)

Figure 9.5 (A) Intracolonic clips marking the lesion which has to be resected. (B) Plain abdominal X-ray: The tiny clips are barely visible. Inset: Even under magnification the accurate site of the lesion is difficult to define. *All: Courtesy: PD Dr. D. Wilhelm, Klinikum rechts der Isar.*

clip-marked region which has to be resected. In clinical practice, however, this is more difficult than it appears to be. The small clips can be identified, but it is very hard to perceive the real configuration and the spatial position of the lesion reliably based on a 2D radiographic image (Fig. 9.5).

Therefore, preoperative marking is not an option in clinical routine. Direct visceral exploration and the dialog between surgeons and endoscopists in a combined approach is superior, using diaphanoscopy and mechanical demonstration.

9.1.8 Defining the Line of Section (Margin)

As soon as it is known where the lesion is located, the extent and the shape has to be demonstrated to enable the surgeon to excise it precisely.

The aim is to cut it out completely. Even if only a few tumor cells are left the surgery is in vain. On the other hand, as much healthy tissue should be left as possible. The extent of the area is marked on the exterior gastrointestinal wall either with coagulation spots or by stitches.

9.1.9 Selection of the Appropriate Technique for Tumor Resection

Four different approaches are available. Some lesions which previously could not be removed during normal endoscopy become suitable for endoscopic resection in a combined procedure. The laparoscopist helps to expose the lesion that enables the endoscopist now to place a snare around or to cut it out with a needle knife. The endoscopist may even risk a full wall excision, since the hole can be easily closed by a laparoscopic suture. This type of hybrid surgery is called "laparoscopically assisted endoscopic resection" (LAER) (Fig. 9.6A).

Other lesions are situated in an area of the GI tract which makes them suitable for a tangential ("wedge") resection using a laparoscopic stapling device (endoscopically assisted wedge resection: EAWR) (Fig. 9.6B). A third group of lesions is only accessible via the transmural route (Fig. 9.6C). In these cases, the laparoscopist has to open the intestinal lumen, supported by the endoscopist who identifies the appropriate place to enter the lumen. As soon as the lesion is removed, the entry site has to

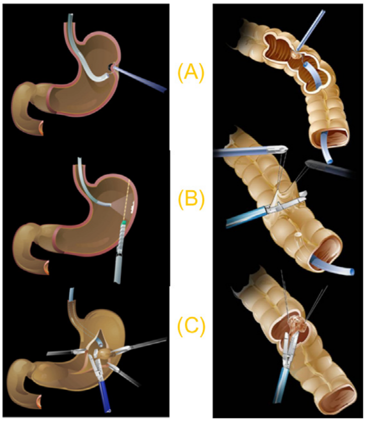


Figure 9.6 Combined endocavitary-endoluminal procedures in the GI tract; left: gastric procedures; right: colonic procedures. (A) LAER, (B) EAWR, (C) EATR. *From MITI.*

be closed again, usually by applying a stapler (endoscopically assisted transluminal resection: EATR). Whenever possible, LAER or EAWR is preferred since they are technically less demanding than EATR.

The fourth version of CLEP (not shown in Fig. 9.6) is combined laparoscopic-endoscopic segment resection. In this case, the whole tubular segment bearing the lesion is cut out and the two stumps are reconnected with a normal anastomosis. This type of a CLEP is infrequently used, since the precision required is less high.

9.1.10 Specimen Retrieval

Large tumors (more than 15–20 mm in diameter) are difficult to retrieve through a 10-mm trocar. Enlarging the incision for specimen retrieval can be avoided if the tumor is pulled out by the endoscopist via the natural path (either esophagus/mouth or the rectum).

9.1.11 Leak Test

Before the intervention is terminated, it has to be proven that the suture/stapling line is absolutely tight. This can be easily done by the endoscopist by instilling diluted methylene blue into the lumen.

Under surgical conditions, flexible endoscopy is technically more challenging than in an endoscopy suite, since the proper positioning of the patient is difficult and gas insufflation should be reduced to a minimum to avoid distension of the GI tract. Maneuvers such as external fixation of the colon are not feasible. Nevertheless, flexible endoscopy is becoming increasingly popular in visceral surgery. In most ORs of today, an endoscopy unit including the scopes is part of the regular equipment.

9.1.12 Technical Considerations

Although combined procedures do not require special devices or instrumentation and can be carried out by using the standard laparoscopic and flexible endoscopic equipment, they are more complex than laparoscopic or endoscopic stand-alone operations. The crowded situation at the OR table is additionally deteriorated by the second trolley and the additional monitors for the complementary view. Dedicated "hybrid ORs" are helpful with boom-mounted video screens and peripheral devices (Fig. 9.7). For endoluminal endoscopy, CO_2 should be regularly used since it is faster reabsorbed.

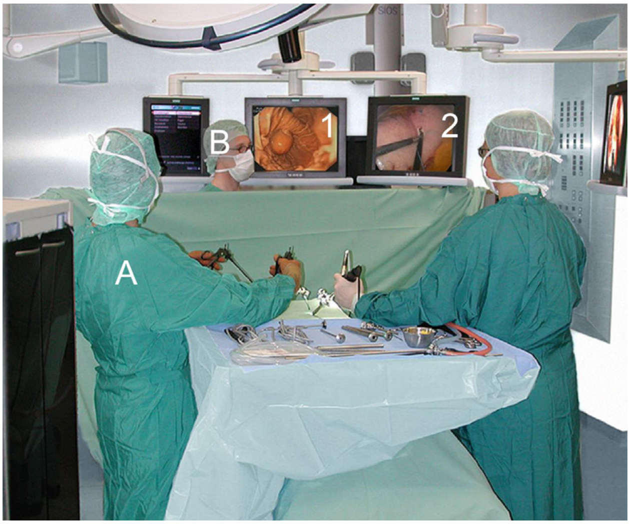


Figure 9.7 Combined laparoscopic-endoscopic intervention: Resection of a spherical gastric tumor of the gastric fundus visible in the endoscopic image (1). The surgeon (A) touches the area from outside with his laparoscopic instruments. The endoscopist (B) observes this manipulation and helps to find the appropriate approach. Both A and B must have an insight into the corresponding site. A minimum of four screens is required. The picture-in-picture mode is a way to save the additional two monitors but is significantly less comfortable [4]. *From MITI.*

CLEP is gaining importance in the clinical treatment of early oncological lesions, but some methodological deficits still have to be eliminated [7].

A special variant of combined laparoscopic-endoscopic surgeries is the so-called "safety laparoscopy" during NOTES operation. The NOTES intervention is monitored by a small (5 mm) laparoscope via the navel (see Section 9.2: Natural Orifice Transluminal Endoscopic Surgery - Surgery without Visible Scars).

9.2 NATURAL ORIFICE TRANSLUMINAL ENDOSCOPIC SURGERY—SURGERY WITHOUT VISIBLE SCARS

It is the vision of all physicians to heal without blood and scars. The use of natural orifices into the human anatomy is one approach to come closer to this goal. If the abdominal cavity is entered via an incision through an internal lumen, the resulting scar is invisible.

The true history of NOTES began in 1901, when Dimitri Oskarovich Ott of Petrograd, Russia, performed the first endoscopic examination of the abdominal cavity through a posterior vaginal incision using a head mirror and a speculum. He examined the pelvic and abdominal viscera and termed the procedure "ventroscopy." This approach remained an exception over decades in visceral surgery, whereas gynecologists started to perform, e.g., hysterectomies through the vagina. In 1998, Hans Seifert in Frankfurt, Germany, introduced the technique of transgastric drainage of pancreatic necrosis. He was, thus, the first physician in the history of visceral medicine to perform surgical interventions without laparotomy.

Abdelghani and Mesallum had a paper in Benha Medical Journal describing "the microaccess approach"—a novel method to access internal organs via natural body tracts. It was a pilot feasibility study of the transesophageal access into the thorax [8] but did not gain much attention at that time.

In 2004, the first published report of peroral endoscopic access to the peritoneal cavity with liver biopsy in an animal model was described by Kalloo. NOTES in humans was first carried out by Rao and Reddy in India in 2005. Using a transoral, transgastric approach, these surgeons successfully carried out an appendectomy. In 2006 in the United States, the American Society for Gastrointestinal Endoscopy and the Society of Gastrointestinal Surgeons (SAGES) established a Working Group on Natural Orifice Translumenal Endoscopic Surgery (NOSCAR). In an attempt to advance NOTES through cooperation and complementary approaches, the members of this group published a so-called "White Paper" to identify goals and tasks in order to make NOTES mature for clinical purposes [9]. Since then gastroenterologists and surgeons around the world have participated in the development of NOTES surgery. In Germany, the first NOTES surgery was performed in June 2007 by the team of Zornig in Hamburg. However, up to now (2016) a real breakthrough has not yet been achieved due to the abundant number of technological problems which were first documented in a SAGES white paper (Table 9.1). All of them will be described in this chapter. The position of NOTES in between internal medicine and surgery is illustrated in Fig. 9.8.

A general definition of NOTES was coined by T. H. Baron [10] in 2007:

NOTES implies surgery endoscopically by initially passing the endoscope transorally or transanally, then transluminally into areas that would not otherwise be accessible endoscopically, such as the abdomen and pelvis.

Table 9.1 Potential barriers to clinical practice (according to [9])

Access to peritoneal cavity
Gastric (intestinal) closure
Prevention of infection
Development of suturing device
Development of anastomotic (nonsuturing) device
Spatial orientation
Development of a multitasking platform to accomplish procedures
Control of intraperitoneal hemorrhage
Management of iatrogenic intraperitoneal complications
Compression syndromes
Training other providers

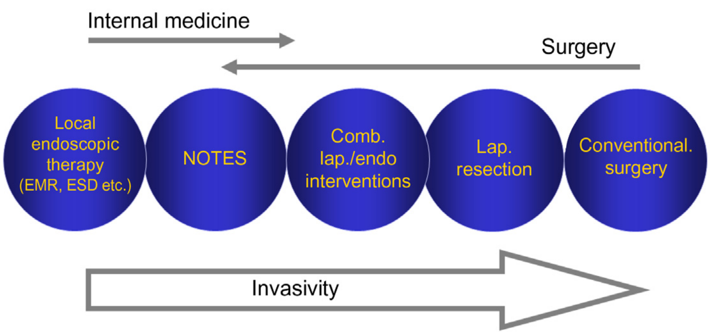


Figure 9.8 A comprehensive therapeutic armamentarium for the interventional treatment of visceral diseases: NOTES requires both perfect endoscopical skills as well as sound surgical experience. *From MITI.*

This definition was reasonably extended by the German NOTES association in 2009 [11]:

NOTES may be performed through other natural orifices as well (e.g., vagina, urethra). Both flexible and rigid instruments may be used.

This addendum was necessary, since it explicitly included the vaginal approach, which is today the most relevant one.

Prior to the detailed discussion of biomedical engineering (BME) aspects of NOTES, it has to be pointed out that the term "NOTES" does not describe one global entity. For example, a NOTES appendectomy via a transgastric access is not the same as a transvaginal NOTES appendectomy. NOTES solely performed through one GI approach differs from laparoscopically assisted NOTES procedures. Basically, NOTES procedures can be subdivided according to numerous criteria. The most relevant ones are [12]:

Flexible versus rigid NOTES: NOTES can be performed by means of rigid (laparoscopic) instruments or by flexible endoscopes. Rigid NOTES (e.g., transvaginal cholecystectomy) is—when possible—easier to perform than flexible endoscopy with flexible endoscopes (e.g., appendectomy).

Hybrid versus "pure" NOTES: The original vision was to perform the surgery just by one natural opening of the body, but it became soon clear that transluminal interventions become easier to perform and safer if concomitant laparoscopic surveillance is provided ("safety laparoscopy; see Section 9.1: Combined Laparoscopic-Endoscopic Procedures (CLEP)).

NOTES determined by the orifice: The type of the orifice selected has a major influence upon the instrumentation and the surgical technique (see Section 9.2.1: Access into the Abdominal Cavity). Theoretically, the mouth, the anus, the vagina, and the urinary tube can be taken into consideration.

Direct-target versus distant-target organ NOTES: In direct-target NOTES, the abdomen is entered more or less directly (e.g., via the rectum or the vagina). If the incision is made into the stomach, a far longer distance (with increasing navigation problems) has to be overcome.

Independent upon the respective subdivision, there are ongoing challenges for NOTES. To deal with them in detail, it is helpful to consider the barriers to the clinical introduction of NOTES as defined by the NOSCAR group [9].

Most of the 11 "barriers" relate to biomedical engineering, in particular intestinal closure, the development of suturing devices, multitasking platforms, and anastomotic instruments.

At any rate, to make NOTES mature for clinical purposes is one of the biggest challenges for BME in clinical medicine.

9.2.1 Access into the Abdominal Cavity

The idea of NOTES is to perform abdominal surgery without any visible scars. Accordingly, natural orifices shall be used to enter the abdominal cavity. Four accesses are conceivable (Fig. 9.9).

Unfortunately, an "ideal" access does not exist. Each of them has its strengths and weaknesses (Table 9.2).

It is amazing how doctors modified well-established endoscopic techniques to create new, safe NOTES access techniques. The so-called

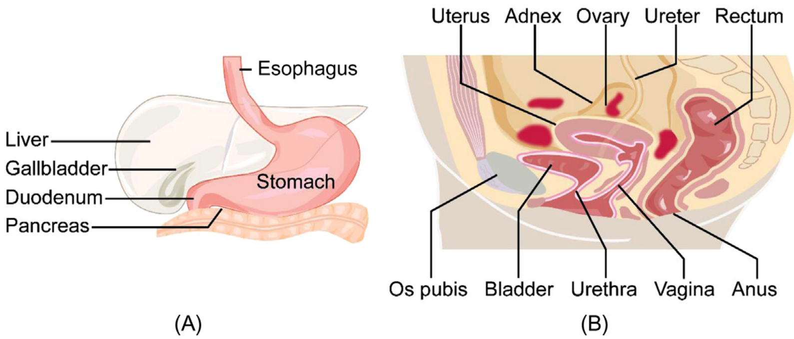


Figure 9.9 Four accesses into the abdominal cavity: (A) Transesophageal/transgastrical: Through the gullet/stomach. (B) Transection through a female pelvis. The accesses from the left to the right: Transvesical: Through the urinary bladder; Transvaginal: Through the female genitalia (vagina); Transrectal/transsigmoidal: Through the rectum/sigmoid colon. *All from M. Scholle.*

Table 9.2 The main advantages and disadvantages of access

	Stomach	**Colorectum**	**Vagina**	**Urinary bladder**
Advantages	Low germ load	Short distance to the entry point, even large bore instruments	Simple, safe access with a low rate of complication	Easy, safe, very low risk of contamination
Disadvantages/ shortcomings	Long distance between mouth and stomach; Difficult closure of the entry site	Risk of infection	In female patients only	Only for small bore flexible instruments

"Achilles heel of NOTES" is to create an entrance into the peritoneal cavity without any harm to the adjacent organs and which can be reliably occluded afterwards.

9.2.1.1 Transgastric Approach

The stomach is easily accessible with the flexible endoscope, and endoscopists are familiar with the management of wall lesions, bleeds, and even perforations. Accordingly, the gastric access was selected first in the beginnings of NOTES. If no acid suppressive medication has been administered before, the low pH value in the stomach prevents germ load.

On the other hand, the comparatively long distance between the mouth and the stomach enables indirect manipulations only. Even if the endoscope is more or less sterile, it has to pass the mouth and the hypopharynx and may be contaminated with these highly contaminated areas.

One major issue is to find an appropriate entrance point which is both suitable for the surgery considered and safe. The stomach is covered by the left liver lobes, flanked by the spleen, liver, and colon, and is positioned above the pancreas.

Kantsevoy modified the percutaneous endoscopic gastrostomy (PEG) technique to gain safe access to the abdominal cavity (Fig. 9.10) for NOTES. The puncture site is enlarged using a

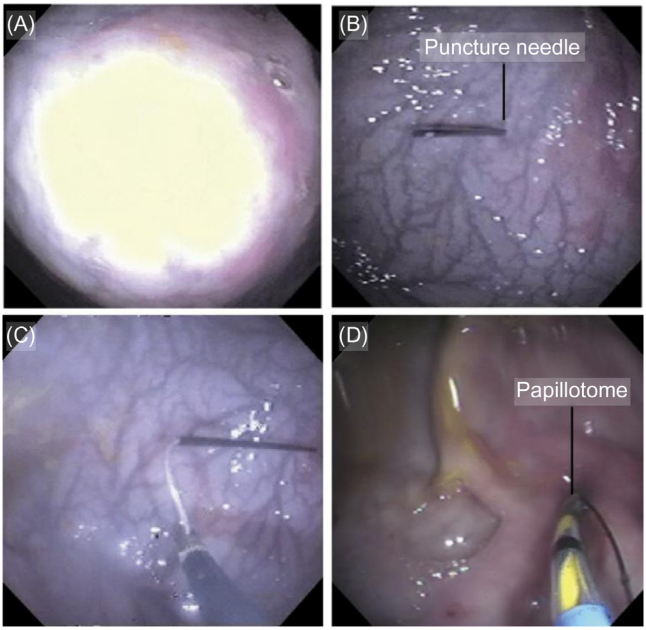


Figure 9.10 Technique of percutaneous endoscopic gastrostomy (PEG)-based creation of a transgastric approach into the abdomen. (A) Endoscopic view of the stomach: The anterior wall is illuminated. The light can be seen from the outside (diaphanoscopy). (B) External puncture on the stomach. A needle is inserted through the skin, the abdominal and anterior gastric wall into the lumen of the stomach. (C) Guidewire insertion through the puncture site. (D) The guidewire is used to deploy a traction papillotome to enlarge the puncture site. *Courtesy: Prof. Dr. S. v. Delius, Klinikum rechts der Isar.*

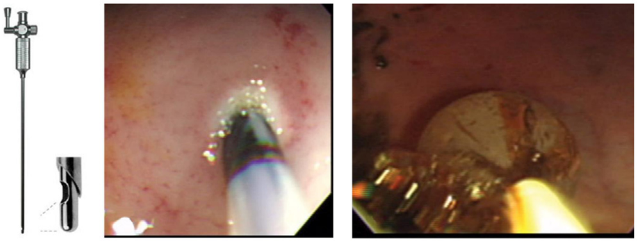


Figure 9.11 (A) Veress needle to create a pneumoperitoneum. (B) As soon as the pneumoperitoneum is created, an incision can be made into the anterior gastric wall using the needle knife without too much risk. (C) The incision is enlarged by balloon dilatation.

papillotome (see Chapter 8: Interventional Flexible Endoscopy). Alternatively, the puncture site can be enlarged by dilatation using a balloon catheter.

This enlarged incision of the PEG technique serves as the access point of the endoscope into the abdominal cavity [13].

The Pneumoperitoneum Technique

An alternative technique is to establish a pneumoperitoneum first to create a certain anterior gastric wall (Fig. 9.11). Under normal circumstances, the middle part of the anterior gastric wall is not covered by adjacent tissue.

The pneumoperitoneum technique can be helpful if the instillation of disinfectant fluids is additionally considered.

The Tunneling Technique

One major concern when using an interior entry point for NOTES is a safe closure of the incision once the intervention has been finished. The submucosal tunneling technique was developed to provide a valve-like mechanism to close the stomach (Fig. 9.12).

Various different techniques including endosonography have been tried out experimentally but up to now, no standard procedure exists.

9.2.1.2 Transurethral Approach

Among the various natural openings of the human anatomy, the urethra/ urinary bladder is the only one which is (under regular circumstances) free of bacterial contamination. Insofar, the transurethral would be the

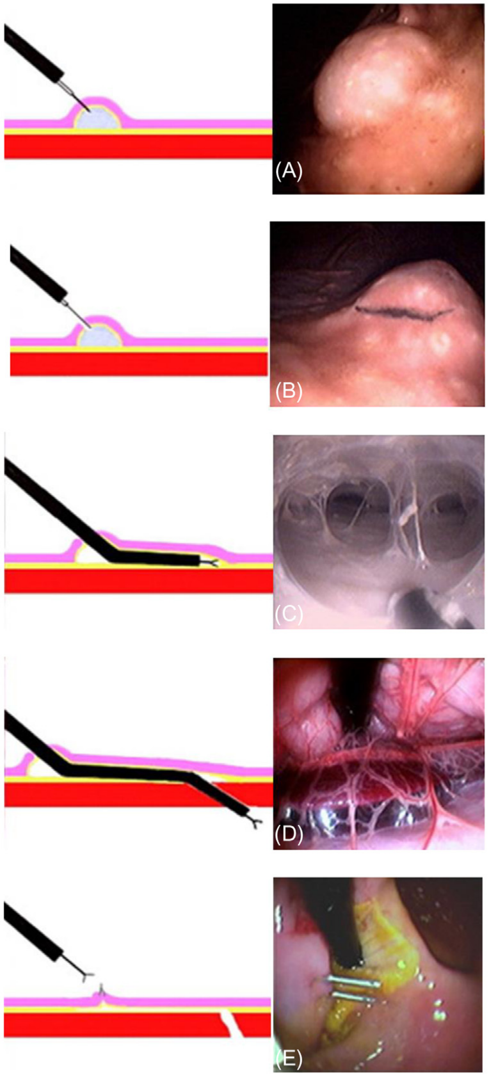


Figure 9.12 Submucosal tunneling method: After withdrawal of the instrument, the submucosal tunnel collapses and seals the transmuscular hole. (A) Saline injected into the submucosa. (B) Needle knife mucosal/submucosal puncture. (C) Creation of submucosal space by blunt dissection and/or balloon dilation. (D) Off-site needle knife penetration of the muscularis propria with subsequent entry into the peritoneum. (E) Offset closure of muscular defect with overlying mucosal flap. *From Moyer MT, Haluck RS, Gopal J, Pauli EM, Mathew A. Transgastric organ resection solely with the prototype R-scope and the self-approximating transluminal access technique. Gastrointest Endosc 2010;72(1):170–6 [14].*

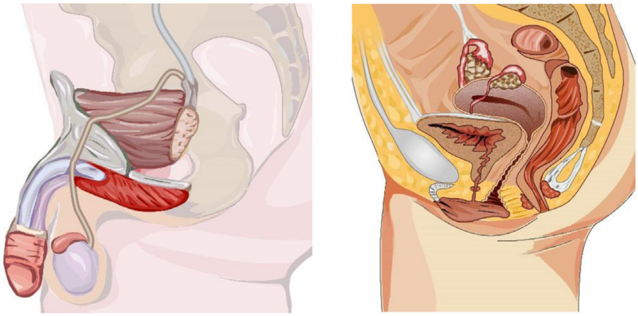


Figure 9.13 Male (left) and female (right) genitourinary anatomy: The long, S-shaped male urethra permits the introduction of rigid instruments, but it is very difficult to position it adequately to get a suitable puncture site. Flexible endoscopes are preferable. The female urethra is shorter, but the sphincter even more sensitive to overdistension. *All from M. Scholle.*

ideal approach (Fig. 9.13). Moreover, the incision of the bladder wall can be easily and safely closed [15].

The main drawback is that only small bore instruments (≤5 mm in diameter) can be used. If large bore instruments are applied, the risk is high to overstretch the internal vesical sphincter resulting in urinary incontinence.

Schneider et al. developed a specially coated set of bougies which allows for a successful bougienage of the urethra up to 36 French (12 mm) without any harm to the sphincter (Fig. 9.14A,B).

In male patients, flexible endoscopes are mandatory since it is impossible to leave the urinary bladder in an adequate angle for NOTES interventions with a rigid telescope. Though currently of minor importance the transurethral approach could potentially gain importance as an auxiliary access [16].

9.2.1.3 Transvaginal Approach

Transvaginal surgery is well-established in gynecology since many decades. The vagina can easily be decontaminated. Even large bore instruments can be inserted without any problems and wound closure is easy and safe (Fig. 9.15).

Most NOTES cholecystectomies are performed via this route. Either rigid or flexible scopes are in use. Though the complication rate is very low [17], many—in particular young—patients are not inclined to accept this special type of approach. Vice versa, surgeons are often concerned about long-term—real or pretended—side effects like dyspareunia due to scar formation, etc.

However, this access is only available in 50% of the patients.

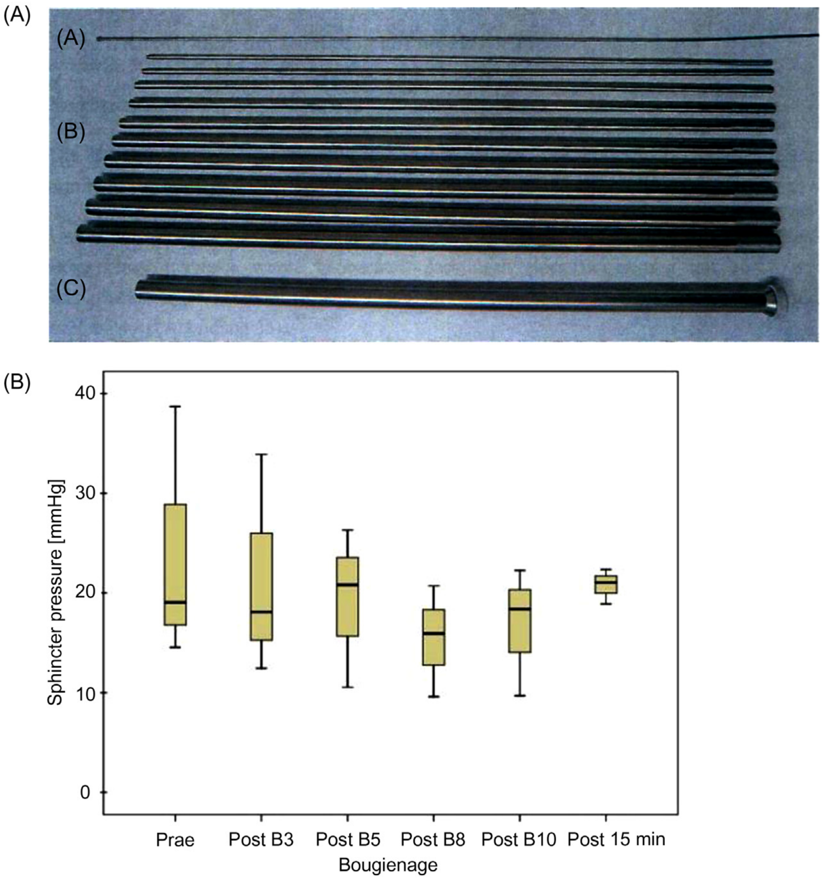


Figure 9.14 (A) A set of specially designed bougies for the sphincter of the urinary bladder: A guide wire is inserted into the abdominal cavity through the urinary bladder wall (A). The rigid (or even flexible) bougies are applied in an ascending line (B) until finally the trocar (C) can be introduced over the bougies. (B) Sphincter manometry before, during, and 15 minutes after bougienage. Note the rapid recovery of the resting pressure after the interval of 15 minutes. *From Schneider A. Application technique for an innovative antireflux device using Natural Orifice Translulminal Endoscopic Surgery (NOTES). Doctoral Thesis, Technical University of Munich; 2010.*

9.2.1.4 Transcolonic Approach

In the early days of NOTES, the idea to use the rectosigmoid as an entry point was not very popular. The rectum is densely contaminated with (dangerous) bacteria and very difficult to clean. Any leakage of wound closure leads inevitably to life-threatening peritonitis. On the other hand, some particular advantages have to be kept in mind. If the anal sphincter is cautiously dilated, instruments with a diameter of 3.5–4 cm can be inserted safely without the risk of fecal incontinence (Fig. 9.16).

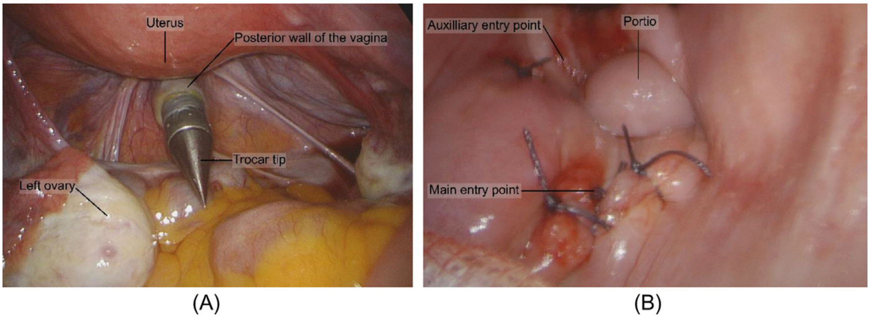


Figure 9.15 (A) Insertion of a trocar through the vagina (a view into the pelvis through a laparoscope). (B) A view into the vagina after the procedure: The main trocar insertion site is closed with two stitches. An additional insertion site for a 5-mm trocar is closed by another suture. *All: Courtesy: Prof. C. Zornig, Israelitisches Krankenhaus Hamburg.*

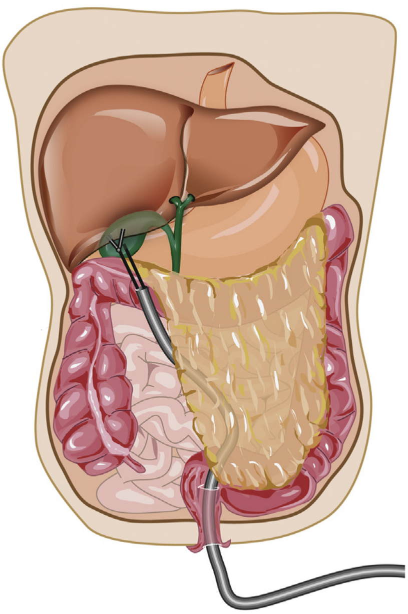


Figure 9.16 Flexible endoscope introduced through the rectum for the removal of the gallbladder: Most target regions can be reached straight forward. Retroflexion is not required. *From M. Scholle.*

After intensive scientific studies, several dedicated overtube systems have been developed [18,19], resulting in a rising interest in transrectal NOTES. Often also denounced as transanal minimally invasive surgery (TaMIS), transrectal scarless colorectal surgeries are increasingly performed under clinical conditions.

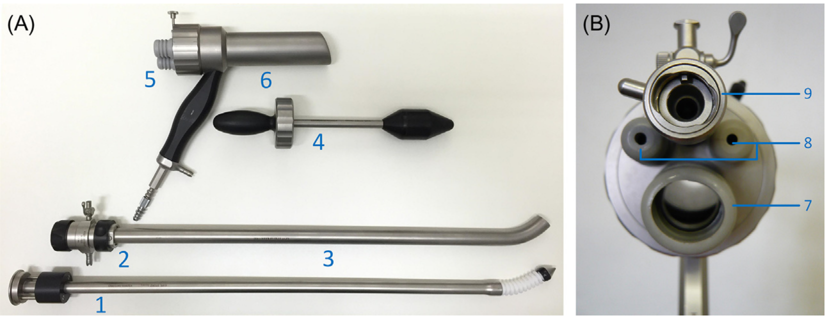


Figure 9.17 A new set of instruments (ISSA) designed to permit sterile sigmoid access for transcolonic surgery: (1) part flexible obturator; (2) trocar head; (3) trocar tube; (4) TEM obturator; (5) modified TEM cap; (6) modified rectoscope; (7) trocar port; (8) instrument ports; and (9) optical port. *From Fiolka A, Can S, Schneider A, Wilhelm D, Feussner H. Instrumentation and surgical technique for an innovative safe sigmoid approach for NOTES. Minim Invasive Ther Allied Technol 2008;17(6):336–40.*

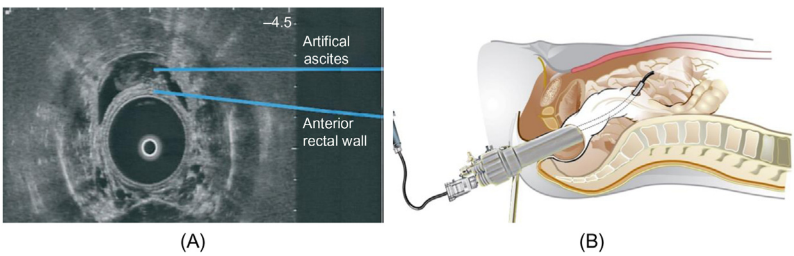


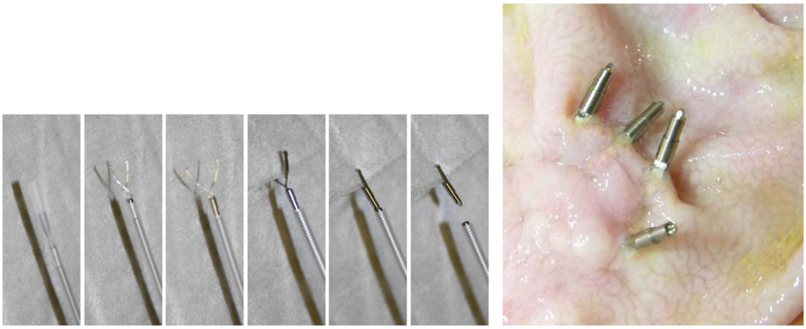
Figure 9.18 (A) The intraabdominal fluid facilitates to identify the optimal entry site without endangering adjacent anatomical structures. (B) The flexible endoscope is advanced into the abdomen via the trocar. *All from MITI.*

Fiolka et al. developed an overtube for the transanal access with an outer diameter of 18 mm (Fig. 9.17). The front access is curved to avoid collision with the promontory. To provide gas-tightness, a valve chamber is integrated. The specially designed trocar is inserted using a modified TEM system.

By instilling a decontaminating fluid into the abdominal cavity via a Veress needle, an artificial ascites is created. Thus, an appropriate entry site within the rectum can be selected using endorectal ultrasound (Fig. 9.18).

At the end of the procedure, the entry site can be reliably occluded using a linear stapler under direct vision.

A similar system was recently reported [19] which additionally includes a balloon system to occlude the colon oralad the entry point.



(A) (B)

Figure 9.19 (A) Conventional endoscopic clips: Commonly, the mucosa is occluded only. (B) Result after 7 days post application. *All from MITI.*

9.2.2 Intestinal Closure

Initially, endoscopic clips (see Chapter 8: Interventional Flexible Endoscopy) were the only tools available. However, efficacy was not very high. Both industrial companies and academic working groups strove for better solutions. Though some progress could be achieved, the problem of intestinal closure is not yet completely solved.

9.2.2.1 Clips

Endoscopists are familiar with the use of conventional endoscopic clips. Application is comparatively easy (Fig. 9.19).

However, closure of full wall defects is unreliable since only the mucosal defect can be closed. Before the application, the edges of the defect have to be approximated which is often impossible in the case of larger lesions.

A big step forward is the development of the over-the-scope-clip as described in detail in Chapter 8, Interventional Flexible Endoscopy. The bilaterally acting forceps significantly facilitates tissue approximation. Since NOTES incisions are comparatively short, they are well covered by one single clip (Fig. 9.20).

The clip will leave the gastrointestinal tract via naturales. If required, it can easily be removed by means of a sort of endoscopic blowpipe. Currently, the OTSC products are cleared for clinical use in the European Union, the United States, Canada, Japan, Korea, China, and selected other markets. Various alternative clips were designed, but none of them have gained clinical acceptance up to now.

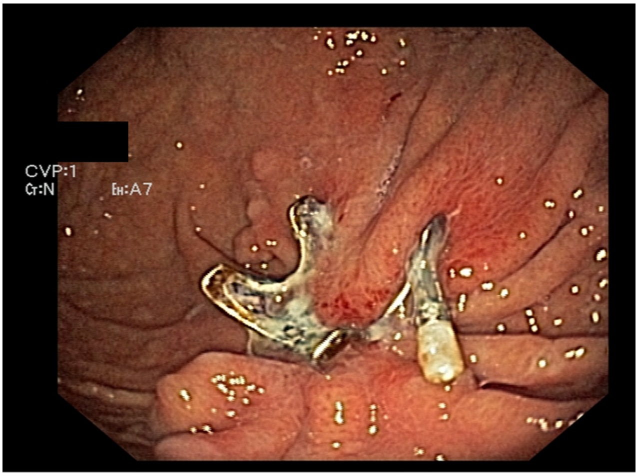


Figure 9.20 The Ovesco clip occluding a NOTES entry site. *Courtesy: PD Dr. D. Wilhelm, Klinikum rechts der Isar.*

9.2.2.2 Suturing Devices

Since robust and secure enterostomy closure is the "Achilles heel" of NOTES, industry sensed that suturing might represent "a disruptive paradigm shift" in endoscopy. An explosion of innovative suturing devices could be observed, whereas others tried to develop bimanual operating platforms that could suture with standard surgical sutures (see Section 9.9: Multifunctional Endoscopes and Mechanical Platforms).

Unfortunately, none of the latter reached commercialization, but today, at least two suturing systems are available. They are based upon two different principles. The first design is based upon the double-anchor principle: If the two edges of a defect can be safely gripped by an anchor connected to a suture on each single side, they will inevitably be approximated as soon as both sutures are knotted. The principle is shown in Fig. 9.21.

The second concept is more or less based upon the design of sewing machines. A mechanically sophisticated device was presented in the short history of NOTES (Fig. 9.22).

The principle has been refined over the last couple of years and is now available as the OverStitch endoscopic surgical system by Apollo Endosurgery (Fig. 9.23).

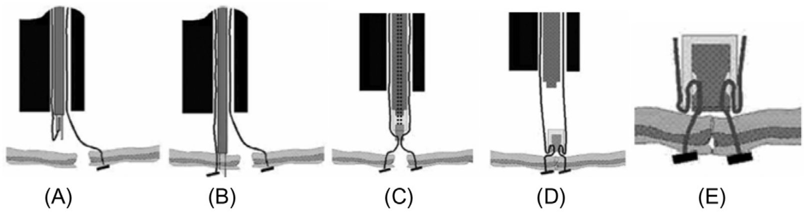


Figure 9.21 (A) The first anchor is already positioned through the full-thickness of the gastrointestinal wall (right side). The needle—already loaded with the second threaded tag—targets the contralateral edge. (B) The second anchor is placed through the whole wall. (C) The so-called thread locking device is pushed forward to tie the threads together. (D) The two threads are firmly approximated and locked by the stopper. (E) Both ends of the threads are cut by a cutter device integrated into the system. Thus a safe interrupted suture line can be created.

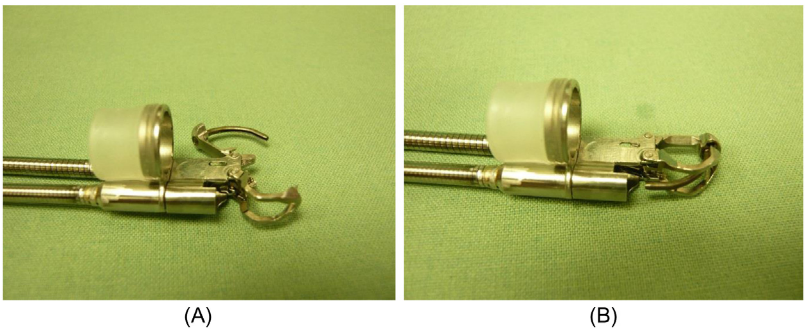


Figure 9.22 First prototype of the endoscopic sewing machine: (A) Starting position; (B) closed. *All from MITI.*

9.2.3 Flexible Staplers

Temporarily flexible linear staplers were available. They were used to perform experimentally to accomplish Roux-en-Y bypasses, sleeve resection of the stomach, and colonic resection (Fig. 9.24). For reasons unknown, this type of stapler is no longer available. They certainly had the potential to stimulate the development of NOTES. Hopefully, improved flexible staplers will become available again.

9.2.4 Plicator-Like Devices

As already pointed out in Chapter 2.2: Esophagus, several innovative endoscopic approaches were started for the endoluminal treatment of gastroesophageal reflux disease about 15 years ago. Not many of the devices

Figure 9.23 The commercially available OverStitch suturing system. Head of the instrument. Inset: Handling system mounted to the endoscope. *From Apollo Endosurgery.*

Figure 9.24 Flexible endoscopic stapler device. *From Sodergren M, Clark J, Beardsley J, Bryant T, Horton K, Darzi A, et al. A novel flexible endoluminale stapling device for use in NOTES colotomy closure: a feasibility study using an ex vivo porcine model. Surg Endosc 2011;25:3266–72* [20].

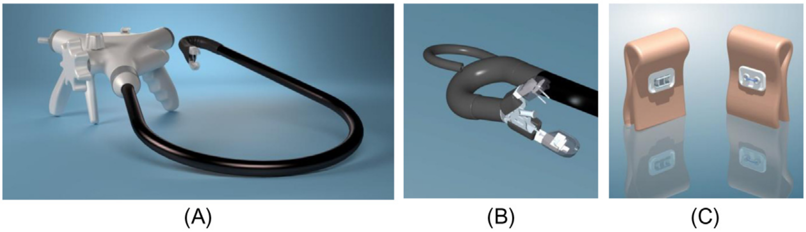


Figure 9.25 The GERDX system: (A) The handling of the device which is guided by means of a small bore gastroscope introduced via the camera channel. (B) The arms at the distal end are opened and closed manually using a microhydraulic system. (C) The pledgeted pretied sutures applied to a model. *All from G-SURG GmbH.*

developed at that time actually survived. One of them is the so-called plicator principle: by means of specially designed fixation elements (clips, sutures, rivets), the fornix wall of the stomach is approximated to the lower esophageal sphincter. This principle was also used to occlude gastric perforation as well as for the closure of the NOTES entry site.

One or two applications are usually sufficient to occlude the NOTES entry site in the stomach. Currently, two systems are commercially available. The GERDX system (Fig. 9.25) from G-SURG, Germany, and the MUSE from Medigus, Israel.

9.2.5 Rivets

The riveting principle was applied in an experimental design.

The endorivet was primarily designed for gastric lesions. Since the sharp tip of the needle is produced from magnesium, it will be soon destroyed by gastric acid, thus becoming unable to hurt the mucosa (Fig. 9.26).

Much has already been attained in the closure of enterotomies after NOTES, but there is still a need for further advances. In particular, low diameter, fully flexible stapling devices could become extremely helpful.

9.3 SPATIAL ORIENTATION

Commercially available flexible endoscopes were developed for use in cavities of relatively small diameter like the stomach or the colon. As compared to these lumina, the abdominal cavity is a huge space, bringing the effectiveness of normal endoscopes to their limit (Fig. 9.27).

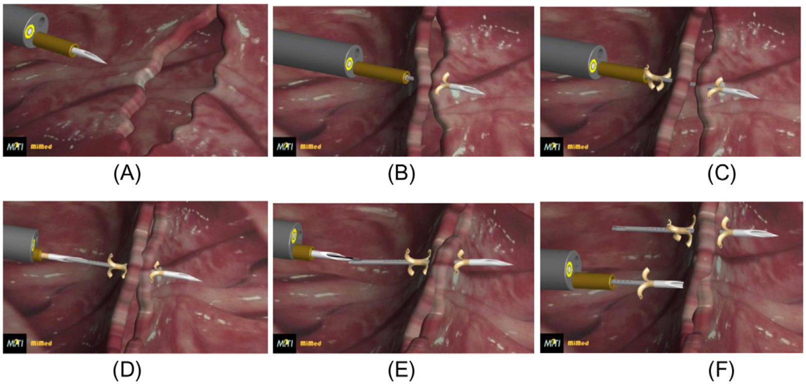


Figure 9.26 The endorivet: (A) The sharp tip of the rivet is inserted into the proximal edge of the lesion. (B) As soon as it has perforated the distal edge, the distal stopper is unfolded. (C) The proximal stopper is unfolded. (D) By approximation of the stopper, the distance between the two edges is gradually reduced until the lesion is occluded. (E) The rivet is set free. (F) Application of the next rivet. *All from MITI & Institute of Micro Technology and Medical Device Technology (MiMed), Technische Universität München.*

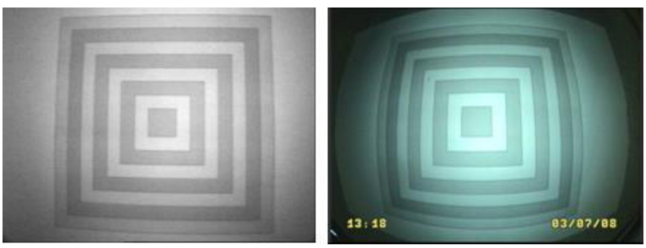


Figure 9.27 Limits of normal endoscopes: Image distortion. At larger distances, the shape of anatomical structures is falsified. *All from MITI.*

The illumination of flexible endoscopes is not optimized for these large spaces in combination with the wide-angle lenses. Therefore, only organs comparatively close to the endoscope are clearly visible which makes orientation and surgical manipulation even more difficult.

Spatial orientation depends on visualization. Visualization is the sum of sufficient insufflation to create the necessary space, a powerful illumination, and a high-quality camera system. In addition, endoscopes have to be steerable under strictly controlled and reliable conditions.

The most relevant needs should be briefly addressed.

9.4 ILLUMINATION

Flexible glass fibers are limited in delivering the amount of light which is required in the peritoneal cavity. An alternative could be the use of

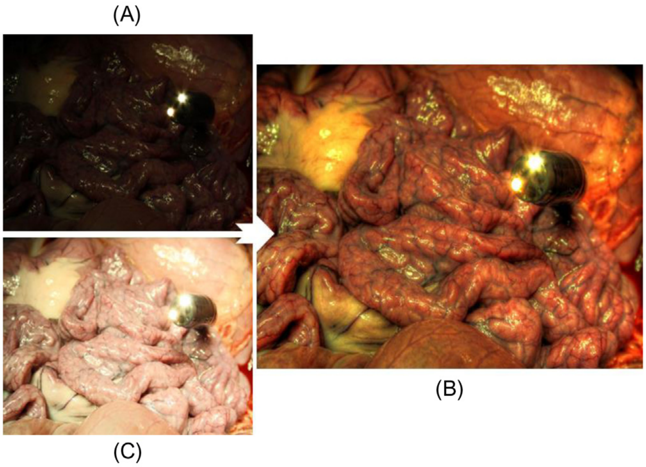


Figure 9.28 The problem of homogenous brightness: The image might be either too dark (A) or overexposed (B). Most often it is a combination of both with a too bright center and darkness in the periphery. (C) High dynamic range sensors lead to a better visibility. *From MITI.*

light-emitting diodes since they are comparatively small. Since only thin cables are required for power supply, the diameter of the instrument can be kept small. However, some drawbacks like heat production still have to be solved. Theoretically, the use of satellite cameras (see Chapter 7.3: Minilaparoscopic Procedures) could be an additional option. Last but not least, it can be expected that the progress in photonics will lead to more efficient optical sensors. High dynamic range sensors would be able to provide better visibility of both objects in the center as well as in the periphery (Fig. 9.28).

9.5 FOG/MIST ELIMINATION

The negative effect of fog and mist on visualization has already been mentioned before (see Chapter 7.2.9: Laparoscopic Ultrasound Dissection). In NOTES this problem is even more relevant. Gas exchange is less rapidly feasible than during laparoscopy [21]. Accordingly, new technologies to eliminate the mist problem would be of particular value for NOTES.

9.6 STABILIZATION OF THE HORIZON

In flexible endoscopy it is impossible to maintain a strictly horizontal view which is of minor importance in endoluminal endoscopy. In NOTES, however, this becomes a serious problem since the perception of the surgical site is massively impaired.

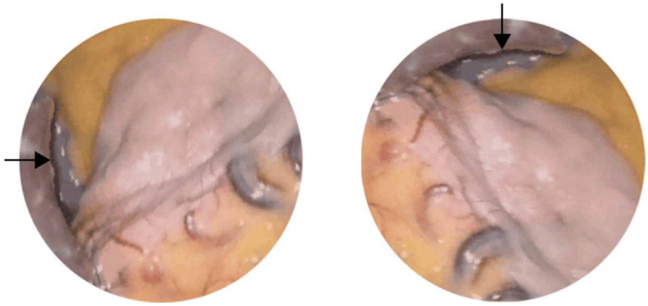


Figure 9.29 Rectification of the horizon. Left: Native image showing the esophagogastric junction. Usually, one expects the junction (arrow) at the top. The oblique view deteriorates intuitive perception of the anatomical plane. Right: After rectification. *From MITI.*

The automatic rectification is technically already feasible today as shown in Chapter 11.6: Inertial Tracking Systems (Fig. 9.29).

9.7 VIEW EXTENSION

The problem of a limited field of view could be overcome by mosaicing or image stitching procedures. Since the field of view is particularly small in NOTES, view extension would be extremely helpful.

9.8 THREE-DIMENSIONAL STEREOSCOPY

Up to today, no stereoscopic flexible endoscopes are commercially available. It is conceivable that 3D vision could additionally ease NOTES performance.

9.9 MULTIFUNCTIONAL ENDOSCOPES AND MECHANICAL PLATFORMS

Beyond of the problems described above, a wide range of additional technical challenges has still to be mastered. All of them relate to the surgical platform. Initially it was thought that just something as a new "superendoscope" would be required. Today it has become clear that more than an upgraded endoscope is necessary. Soon, quite a number of dedicated designs appeared.

Before they are discussed in detail, a brief overview upon currently existing systems is given. The considerable number of different platforms is classified according to the EURO-NOTES classification (Table 9.3) [22].

Table 9.3 Classification of NOTES platforms [22]

Mechanical platforms, e.g.	Computer-assisted platforms	Nontethered systems ("capsules")
R-scope	MASTER	Mechanical capsules
NeoGuide	mod. DaVinci	Magnetic capsules
Transport	HVSPS	Oleynikov device
Cobra	IREP	
Direct drive endoscopic system	Viacath	
EndoSamurai		
Anubis		

The EURO-NOTES did not leave doubts that mechanical platforms most probably will not be suitable to respond to the specific technical challenges of advanced NOTES. The group strongly recommended computer-assisted platforms.

Notwithstanding, several mechanical platforms had already been created by industry.

Bardaro and Swanström did define some specific requirements for this type of mechanical platform (Table 9.4).

Supposedly the first was the "R-scope" of Olympus.

The R-scope was the first response of Olympus to meet the requirements of stability and triangulation for NOTES interventions (Fig. 9.30).

The endoscope has a diameter of 13.5 mm with two articulated 2.8-mm working channels with vertical and horizontal lifting gates. The channels are arranged at right-angles to each other enabling simultaneous separate movements of the instruments in perpendicular planes. This allows off-axis movements, thereby improving tissue handling and raising the potential for its use in transluminal settings [23].

9.9.1 Endosamurai

The next coup of Olympus was the Endosamurai design.

The system consists of an endoscopic unit, an overtube, and two flexible arms. The overtube stabilizes the device once locked into place (Fig. 9.31).

The two arms are in parallel during insertion of the endoscope and can be opened out and controlled with laparoscopic-like handles. The manipulator arms have working channels through which flexible instruments can be deployed and an additional channel through the working shaft.

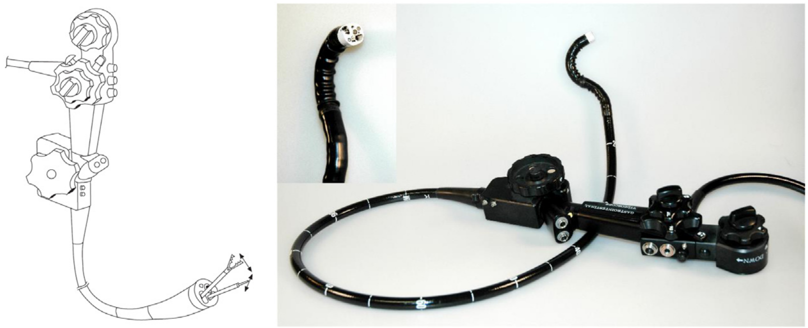
Table 9.4 Requirements for endoscopes to be used for NOTES

Size	The shaft should be between 18 and 22 mm in diameter and should contain at least three channels ranging in size from 3 to 6 mm. One channel for imaging and at least two other channels to maneuver instruments.
Image	The image should have sufficient resolution and adequate illumination to distinguish different anatomical structures. These requirements can be met with the current state of digital imaging used in present day endoscopes and laparoscopes.
Insufflation	The device should have high flow CO_2 insufflation to create sufficient pneumoperitoneum so that there is adequate space to maneuver the instruments safely. Because intraperitoneal pressures in excess of 15 mmHg are injurious, systems that control intraperitoneal pressure are needed.
Suction/irrigation	The device should be able to efficiently remove blood, blood clots, and fluids from the surgical field. Managing potential complications require their prompt recognition and proper instrumentation for timely intervention.
Maneuverability	The tip of the device should have the ability to maneuver in all planes: vertical, horizontal, and lateral and the shaft should have the ability for 180° retroflexion.
Stability	The device should allow complete flexibility for insertion and positioning with subsequent rigidity of the shaft and continued flexibility of the tip. ShapeLock technology currently available could solve this requirement.
Triangulation	It should give the surgeon the ability to manipulate tissue with traction and countertraction in all planes. In order to accomplish this task, efficient grasping technology and a wide multitasking platform need to be developed.

9.9.2 Anubis

Anubis was the answer of STORZ to the NOTES challenge.

It consists of a four-way articulating endoscopic shaft 16 mm in diameter and 110 cm long with a 16-mm vertebrae flexible section. The 18-mm distal tip of the device is tulip-shaped and acts as a blunt trocar tip during insertion, preventing injury to surrounding structures. When at the site of interest, the wings comprising the tulip-shaped distal tip



(A) (B)

Figure 9.30 R-scope: The first "super-scope" (Olympus, Tokyo, Japan): (A) Schematic drawing. (B) View of the R-scope. *From MITI.*

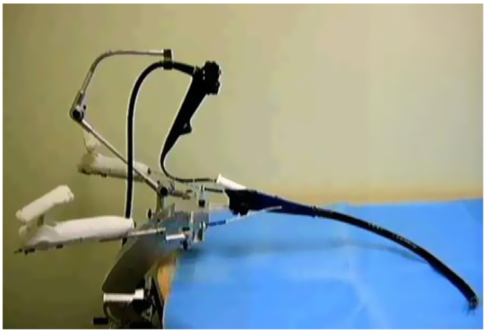


Figure 9.31 The Olympus "Endosamurai": Handling system.

open out, allowing two opposing flexible arms to emerge from working channels located within the wings.

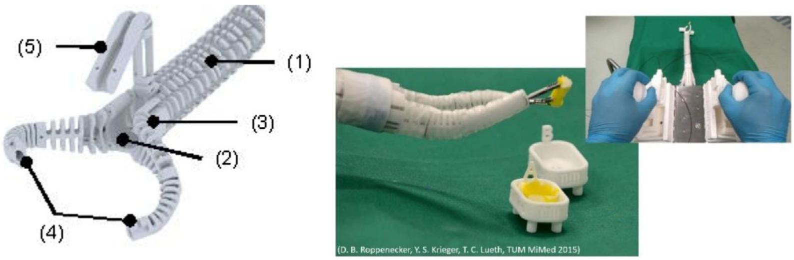
Interchangeable tools can be deployed down the working channels of the arm and a central working channel in the shaft device enables triangulation of up to three instruments. The wings limit the use of the device in confined workspaces (Fig. 9.32).

9.9.3 SPOT (Single Port Overtube System), Technische Universität München

This is a new development for endoluminal endoscopy and NOTES which was developed at the Technische Universität München, Germany (Fig. 9.33). This overtube with two manipulating arms and a camera arm is produced by 3D printing. The fully flexible structure envelopes the commercially available dual-channel endoscope.

(A) (B)

Figure 9.32 The STORZ Anubis system: (A) Handling system; (B) Tip of the instrument. *Courtesy: KARL STORZ GmbH & Co. KG.*



(A) (B)

Figure 9.33 Design of the Single Port Overtube System: (A) (1) Entire overtube consisting of the central channel for the endoscope (2) and the surgical tip (3) with two flexible manipulation arms (4) with working channels for exchangeable instruments and an additional arm for the camera (5). (B) Transfer of a lightweight object from A to B (Inset: Mechanical handlings). *From (A) MITI and (B) © D. B. Roppenecker, Y. S. Krieger, S. V. Brecht, T. C. Lueth, Institute of Micro Technology and Medical Device Technology (MiMed), Technische Universität München.*

Mechanical control is provided by a harness-like unit worn by the endoscopist.

All commercially available flexible instruments can be used to perform the required steps of the surgical manipulation (Fig. 9.34).

3D plotting enables low cost production. The SPOT is for single use, thus avoiding the problems of postprocessing. Custom-made issues (e.g., diameter of the "mother" endoscope) can easily be provided.

The enumeration of mechanical systems is not at all complete. Numerous similar prototypes are under research in laboratories all over the world. Nonetheless, none of the devices have become part of routine patient care up to now.

Computerized platforms ("robots") and nontethered systems are described in Chapter 10, Mechatronic Support Systems and Robots.

(A) (B)

Figure 9.34 (A) Specially designed mechanical interfaces for SPOT: The working conditions are similar to (conventional) endoscopy. (B) Experimental endoscopic submucosal resection (ESD). *All: Courtesy: Prof. Dr. A. Meining, University of Ulm.*

9.10 OUTLOOK

Though the advances in R&D were impressive up to now, the instruments and devices which are currently available for NOTES are still far away from being perfect. Retrospectively, the technological challenges and pitfalls were certainly underestimated in the beginning [24,25]. As compared to the introduction of laparoscopy, the introduction of NOTES is proceeding far more slowly (Fig. 9.35).

In addition, patient request for the new procedure is not as strong as seen with laparoscopic cholecystectomy 25 years ago and is lacking as a major driving force for development. There is no doubt that the initial euphoria of the years 2007–9 has vanished [26] but more recent figures indicate again a growing interest.

The best overview on the development of NOTES is probably provided in Germany due to a very systematic registration of almost all cases in the German NOTES registry. At the beginning of 2016, more than 4000 cases were included, in the majority cholecystectomies and appendectomies via the transvaginal route (Fig. 9.36).

The development in NOTES resembles the well-known hype cycle of innovation: after phase 1 (until 2007) the second phase of inflated expectations began in 2008 and lasted until 2011–13 ending in the trough of disillusionment. There are some hints that we are now entering the slope of enlightenment. Most remarkably, this is not due to advances in the initial fields like appendectomy or cholecystectomy, but due to surprising new applications such as the treatment of achalasia (peroral endoscopic myotomy) or transanal surgeries [27]. The last phase—the plateau of productivity—can only be reached by further support of BME.

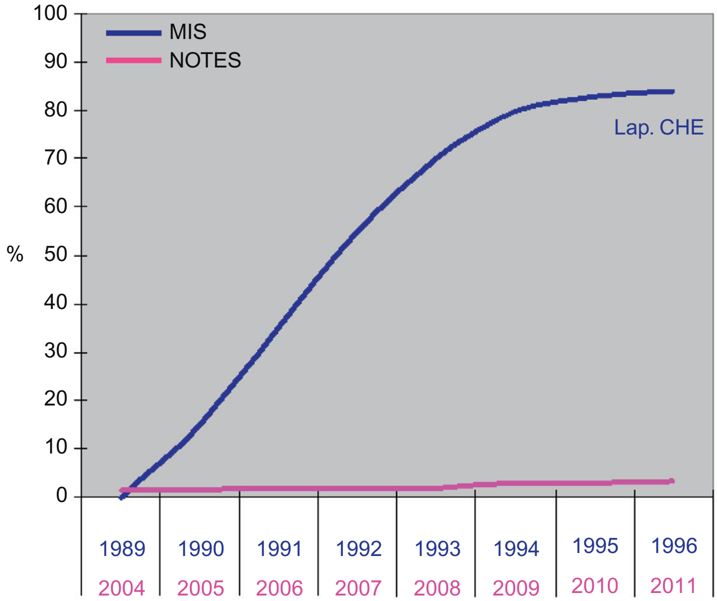


Figure 9.35 Laparoscopic cholecystectomy (Lap. CHE) was successfully introduced into clinical practice in less than 5 years. After the same period time, NOTES is still in its beginning (MIS: minimally invasive surgery). *From MITI.*

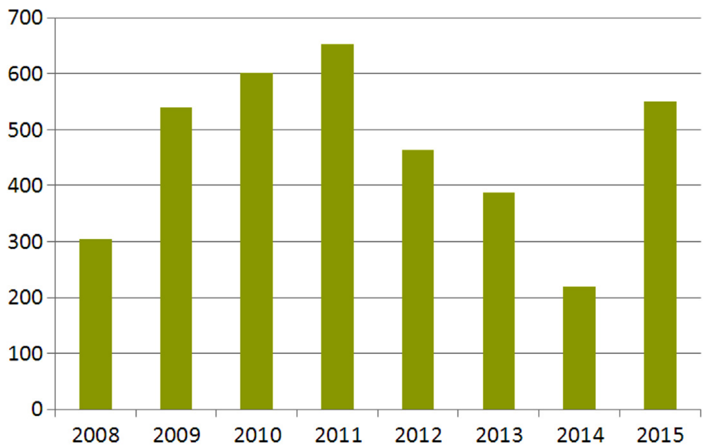


Figure 9.36 NOTES cases of the German NOTES registry: After a peak in 2009, the number of cases continuously declined until 2014. In 2015, an increase was documented again. *From MITI.*

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CHAPTER 10

Mechatronic Support Systems and Robots

A surgical intervention needs manual skills (dexterity), but also cognitive capabilities and precise procedural knowledge. The surgeon has to be able to manage the task in a flexible way, and each procedure is more or less unique. Insofar, the use of robots in surgery appeared to most surgeons, up to now, like a vision of Jules Vernes (Fig. 10.1). The term "robot" was coined in 1921 by the Czech writer Karel Capek. In one of his books he described human-like machines able to work twice as fast as humans. These machines were called robots from the word robota (hard work). After many experiments in the 1940s the breakthrough of modern industrial robots came with the patent of the US American George Devol concerning a manipulator with repeat memory.

However, at least some interventional procedures could benefit from the major advantages of robotic support with its high precision, easy repeatability, and speed. Compared to humans, it will never become tired, inattentive, or nervous.

In bone surgery, drilling or milling could be taken over by a robot. The bone offers a rigid environment, and the material is similar in its quality to wood or metal. Accordingly, the first "robots" were actually developed for knee and hip surgery. Soon, the next "robots" followed for camera guidance in laparoscopy or as master–slave robots for cardiovascular surgery.

> *A 'robot' is defined as a mechanical or virtual artificial agent, usually an electromechanical machine that is guided by a computer program or electronic circuitry.*
>
> ***Wikipedia***

This definition is extremely broad and not very helpful. If we consider medical applications of robots, we prefer the term "mechatronic support system" in order to emphasize the difference to industrial applications.

In the meantime, quite a wealth of machines and devices has been developed which could be denominated as "robots" or mechatronic support systems for medical purposes. Table 10.1 gives a chronological overview.

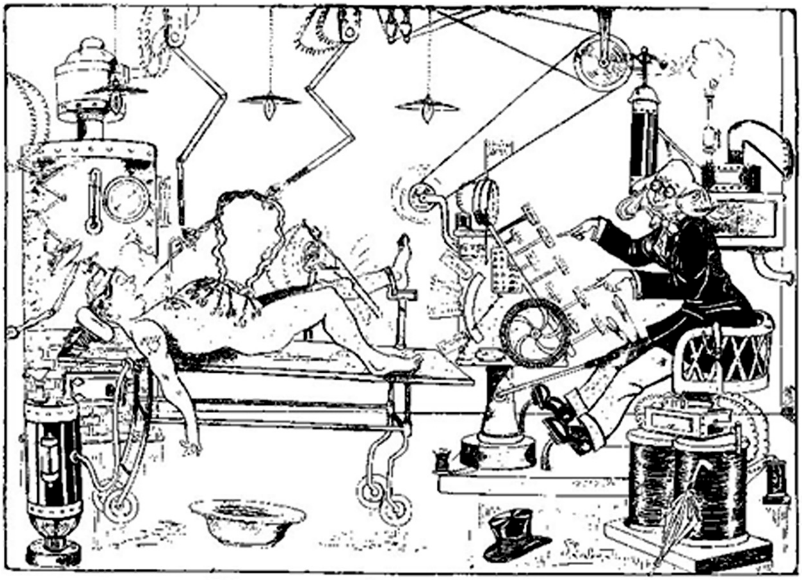


Figure 10.1 The first vision of a master–slave system in the operating room. This depiction was published in *Le Rictus, Journal Humoristique* 1914.

Table 10.1 Early mechatronic support systems and robots in interventional medicine

Year	System	Designer, manufacturer	Application	Country
1992	ROBODOC	ISS	Hip and knee replacement	United States
1994	AESOP	Computer Motion	Camera guidance in laparoscopy	United States
1998	CASPAR	ortoMAQUET	Hip and knee replacement	Germany
1999	NeuroMate	IMMI, ISS	Instrument guidance in neurosurgery	United States
1999	ZEUS	Computer Motion	Master–slave system for cardiovascular surgery	United States
1999	DaVinci	Intuitive Surgical	Master–slave system for cardiovascular surgery	United States
2000	OTTO	SurgiScope, joyumarie	Brachytherapy	Germany
2002	EndoAssist	Armstrong Healthcare	Camera guidance in laparoscopy	United Kingdom

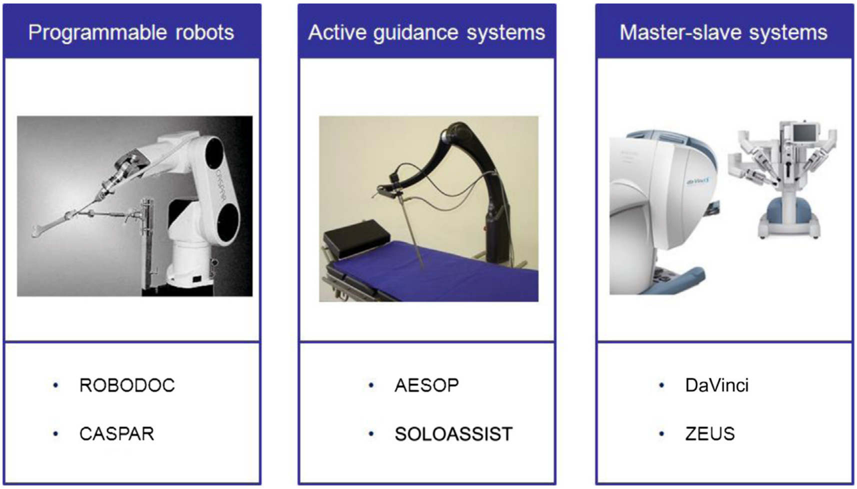


Figure 10.2 We suggest three different classes of mechatronic support systems: Programmable robots, mainly for orthopedic surgery; active guidance systems for camera control or biopsy; master–slave systems, e.g., for laparoscopy and NOTES.

Today, the number of experimental or commercial robots is immense. In order to facilitate an overview, we suggest the classification shown in Fig. 10.2.

Devices such as the ROBODOC were used for cementless hip replacement. If the hole for the endoprosthesis was drilled by the machine, the contact area between the implant and bone was more than doubled. More than 15,000 surgeries were performed with the ROBODOC or the similar system CASPAR, until they vanished out of the ORs practically overnight in 2003. In a massive press campaign starting in Germany, these systems were reproached to cause significantly more "collateral" tissue damage than manual hip and knee surgery. For several years, machines of this type were more or less a taboo in ORs all over the world. However, a revival can be observed. In 2014 FDA approval was achieved for the so-called "TSolution One Surgical System" which combines the presurgical planning workstation TPLAN with a computer-assisted tool like the former ROBODOC, now called TCAT. In 2015, the CE mark was obtained. The system is provided by THINK Surgical, Fremont, CA, United States. Some clinical reports are already available.

In visceral surgery, there has never been an application of programmable robots.

It is very unlikely that there will ever be any, since programmable robots need rigid anatomical structures like the bone. Bone is very stable and keeps the position if properly fixed. Position and dimension can be measured very precisely by X-ray examination, which provides reliable data for programming the machine.

In the abdominal anatomy, the conditions are by far less favorable. The contrast difference between the tissues is very low. Plain X-ray is practically useless. Cross-section imaging like CT or MRI is better (with addition of contrast media) but the precision we are accustomed to in bone surgery is not at all reached (see Chapter 5: Diagnostic Procedures). Even more important is the fact that the configuration of the internal organs permanently changes due to pulse, respiration, gravity, and peristalsis. Accordingly, the development of support systems in visceral surgery has differed completely.

10.1 COMPUTERIZED SYSTEMS

Applications of mechatronic support systems in visceral surgery encompass camera guidance or surgical manipulations with so-called "master−slave systems".

10.1.1 Active Camera Holders

Minimally invasive surgery—videosurgery—needs a laparoscopic camera to get an insight into the surgical site. Since the surgeon has to manipulate his instruments, an assistant has to take over camera guidance (see Chapter 7: Operative (Surgical) Laparoscopy).

In open surgery, the surgeon is the master of his view, i.e., he is able to look at what he wants to see. In laparoscopic surgery, the view has to be presented by the camera assistant, which self-evidently leads to some disadvantages. High-quality laparoscopic surgery needs a perfect functional interaction between both members of the surgical team which is not always guaranteed. Difficulties arise if the camera assistant is not adequately experienced to understand what has to be shown in a particular situation, or even worse if his opinion differs from the surgeon's. With growing fatigue, camera guidance becomes increasingly inattentive and unstable. This is why soon after the introduction of laparoscopic surgery many attempts were made to transfer the task of camera guidance to a machine. As shown below, one of the most crucial challenges is to create a suitable interface between the surgeon and the device.

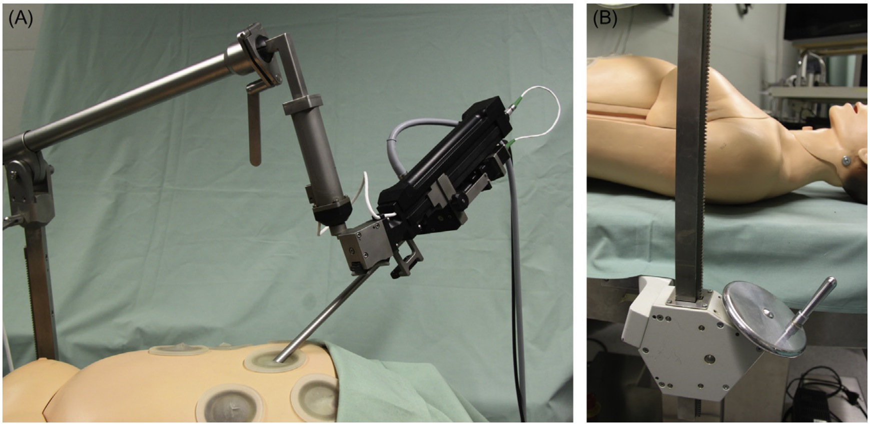


Figure 10.3 The "FIPS" endoarm: (A) The system mounted to the OR table; (B) the height adjustment of the endoarm is achieved by a simple crank which moves the gear rod. *From MITI.*

Soon, attempts were made to transfer this task to a machine.

One of the first devices specially designed to move a rigid endoscope with four degrees of freedom was the so-called FIPS endoarm (KARL STORZ GmbH, Tuttlingen, Germany) (Fig. 10.3). The invariant point of constrained motion coincides with the trocar puncture site through the abdominal wall.

The FIPS camera guiding system consisted of a power supply unit, the operating table attachment, and the guiding device which was clipped onto the handle of the surgical instrument (Fig. 10.4).

Though the FIPS never became more than a prototype and the design was comparatively simple as regarded from today, it was an easy-to-use assisting system which was, at that time, a real competitor to similar systems.

The EndoAssist of Armstrong Healthcare, High Wycombe, United Kingdom and the AESOP (Automated Endoscope System for Optimal Positioning) of Computer Motion, Goleta, CA, United States, were temporarily successful on the market.

The EndoAssist (Armstrong Healthcare) was a free-standing unit (not attached to the OR table) with a curved camera driver (Fig. 10.5A).

Unique in its kind was the steering approach: Movement was executed by a head-mounted infrared emitter. The sensor which receives the signals is placed above the surgical monitor and translates the head

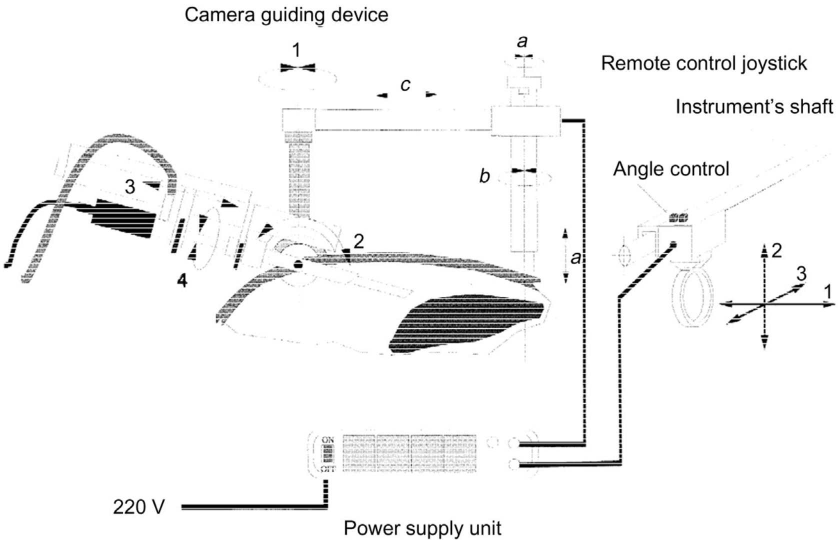


Figure 10.4 Basic design of the FIPS endoarm. *From Buess GF, Arezzo A, Schurr MO, Ulmer F, Fisher H, Gumb L, et al. A new remote-controlled endoscope positioning system for endoscopic solo surgery. Surg Endosc 2000;14:395–9 [1].*

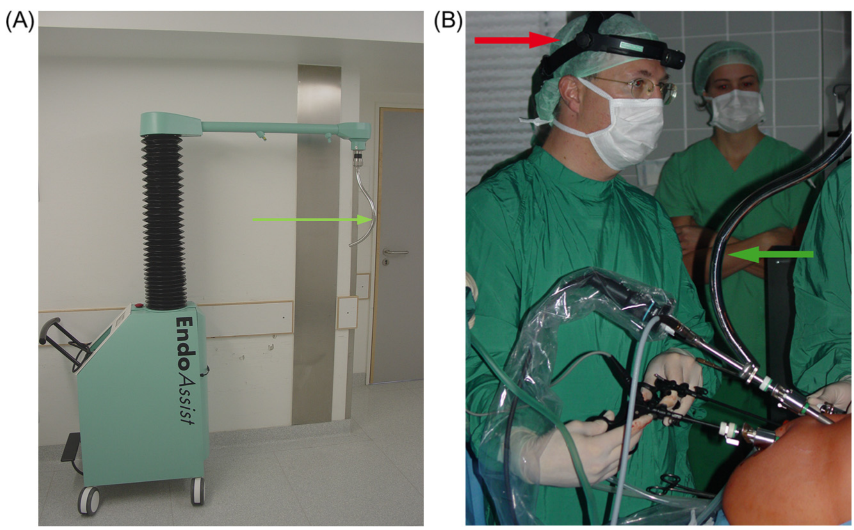


Figure 10.5 The EndoAssist: (A) The unit: the arrow shows the camera driver of the EndoAssist; (B) head-mounted infrared emitter (left arrow) and the camera driver being positioned (right arrow). *All from MITI.*

movements into adequate movements of the camera (Fig. 10.5B). A foot clutch ensured that there was no unintended change of position if they were not conceived by the surgeon.

Whenever the operating table was moved, the device had to be aligned which was a major drawback of the design.

The device had an arc of pan of 350°. Tilt was from 45° below the horizon to 90° vertically and allowed a zoom of 300 mm [2].

Though some clinical experience is available [3] it did not become really popular, supposedly because of the difficult handling.

The EndoAssist has now been replaced by the second generation camera holder FreeHand (Prosurgics, Cambridge, United Kingdom).

It is more compact, easier to set up and use, and substantially more affordable than its predecessor (Fig. 10.6).

The camera holder is now attached to the rail of the OR bed. It consists of the electronic control box, a lockable articulating arm, and the motor unit mounted to the fixating arm.

The system provides hands-free control of pan, tilt, and zoom. Movement of the camera is controlled by head-movements similar to that of the former EndoAssist. The surgeon carries a small, lightweight headset. An infrared transmitter in the headset sends a signal to an indicator unit mounted in a line-of-sight position on the monitor. When the desired direction of movement is selected, an array of light-emitting diodes in the indicator unit confirms the selected direction in the shape of an arrow.

Figure 10.6 FreeHand: The design resembles in some regards the FIPS. *From Prosurgics.*

Movement is activated by pressing a foot switch. Releasing the foot switch stops the motion. There are two modes of operation, standard mode is left/right and up/down (pan and tilt). By simply clicking once on the foot switch, the surgeon can select the zoom/unzoom mode. Clicking the foot switch again, the system is returned to the pan/tilt mode [4].

10.1.1.1 Automated Endoscope System for Optimal Positioning

The most successful system at that time was the AESOP (Computer Motion, Goleta, CA, United States). The company was initially funded by a research grant from NASA in the framework of the US space program. FDA approval was granted in 1994 (Fig. 10.7).

The system promised to give back to the surgeon the control upon the view and to enable him to perform "solo-surgery" or "one man surgery." He/she was no longer dependent upon often inattentive or tired assistants who perform camera control in laparoscopic surgery. The vision was exciting. The commercial administrators of the hospitals expected a significant decrease in staff costs and willingly provided the financial means to procure the new "robots."

It was a horizontally acting arm with three active and two passive joints. Usually, it was mounted to a rail of the OR table, but it could also be operated from the transport trolley. When it was first introduced, the robotic arm was either controlled manually or remotely with a foot switch or hand control. More recent generations of AESOP

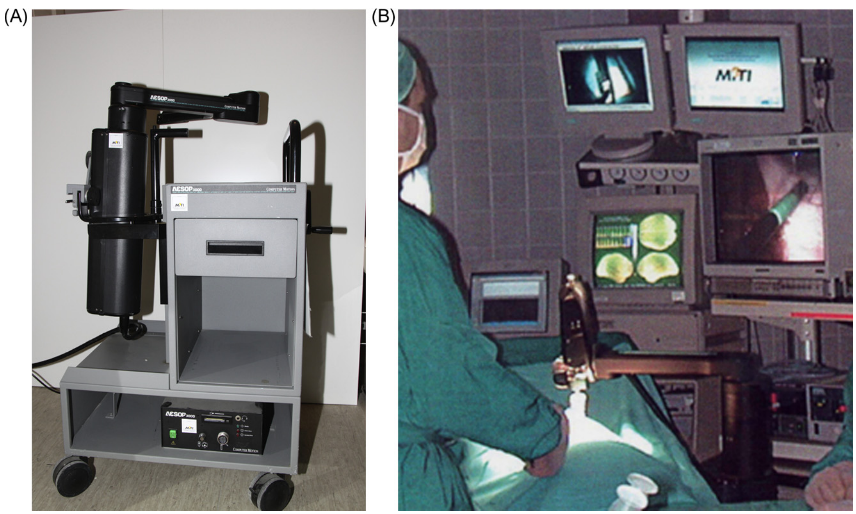


Figure 10.7 The Automated Endoscopic System for Optimal Positioning (AESOP): (A) The AESOP on the transport trolley; (B) mounted to the OR table. *All from MITI.*

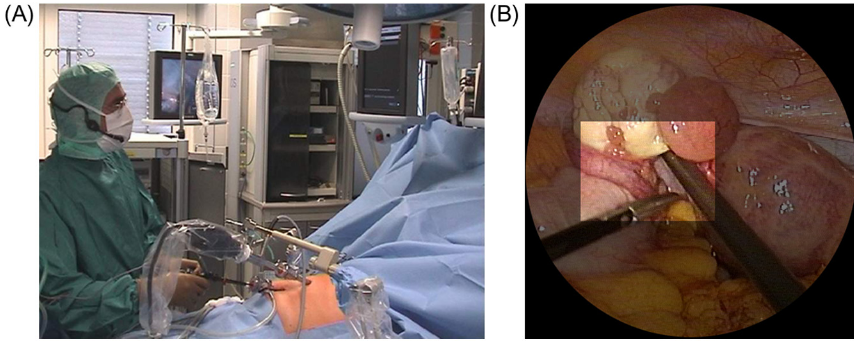


Figure 10.8 (A) ImagTrac; (B) field of view: the content of the square, light box is seen on the monitor. The rest of the circular field of view is invisible for the surgeon. *All from MITI.*

(AESOP 3000) were voice controlled. Voice control required constant chattering by the surgeon, which other members of the team often found distracting. Voice control was rather slow, which encouraged the surgeon to act in a single visual field rather than jumping back and forth among several fields [5]. Nonetheless, quite a number of AESOPs were in clinical use all over the world until the initial hype disappeared. In one of the last papers on its use, both a prolongation of the OR time as well as a relatively low acceptance by the surgeons were described [6]. In addition, the takeover of Computer Motion by Intuitive Surgical (Sunnyvale, CA, United States) has certainly contributed to the fact that the AESOP vanished from the market.

The ImagTrac of Olympus, Tokyo, Japan, offered an interesting technical alternative to any other camera guidance system: The camera was firmly attached to a mechanical holder. Instead of a mechanical movement of the camera, the center of the visual field was changed electronically (Fig. 10.8).

A voice-activated zoom function allows change between overview and detailed view. In the zoom-in position it is possible to select four different fields of view without moving the camera. However, the device did not achieve a clinical breakthrough.

10.1.1.2 Currently Available Active Camera Holders

The ViKY system (Endocontrol Medical, La Tronche, France) is based upon a steel ring which is held in place above the abdominal wall by a mechanical retractor attached to the OR table (Fig. 10.9).

It is steered by a very efficient, rather intuitive voice control system.

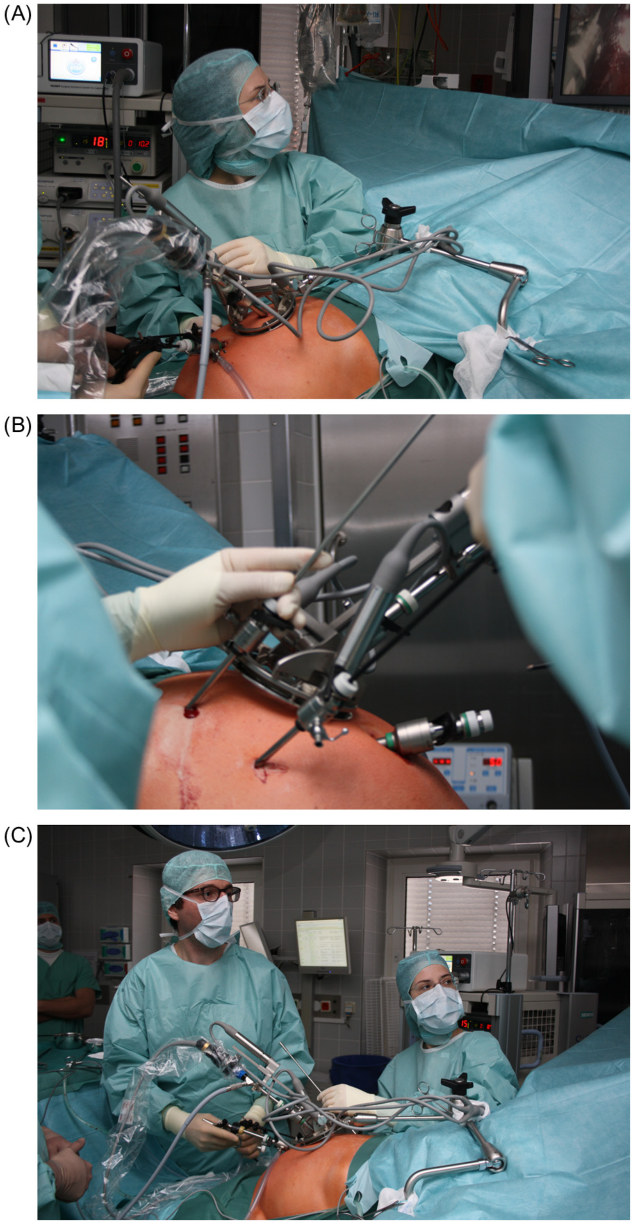


Figure 10.9 (A) The robot unit is directly secured to the positioning arm system which is attached to the surgical table via an OR rail clamp. (B) The robot unit is centered around the trocar for the camera lens and then locked into place. (C) The endoscope is attached with the appropriate adapter. *All from MITI.*

In some regards, the ViKY is technically similar to the FIPS endoarm.

Various reports on clinical applications are available, e.g., upon transrectal ultrasound during radical prostatectomy [7,8], gynecology [9], and abdominal surgery [10].

A newcomer is the AutoLap image-guided robotic laparoscope positioning system produced by MST Medical Surgery Technologies, Yokneam, Israel. Its positioning unit is attached to the OR bed (Fig. 10.10).

A motor unit connects to a horizontal arm holding the laparoscope, enabling motorized movement of the laparoscope.

The position and movement of the laparoscope can either be modified by moving the system directly or by a wireless button-based interface which is provided either as a wearable ring (attached to the surgeon's finger) or as a button clipped to the surgical instrument.

A new interface is the "Follow-me" mode. Using image-analysis software and algorithms, the positioner virtually tags surgical tools within the surgical cavity and centers the view automatically to the area of interest. In addition, it provides automatic zoom adaption, camera horizon correction, and tissue collision warning.

The AutoLap system is cleared by FDA and CE, and is in commercial use with a wide range of general, gynecology, and urology procedures.

The SOLOASSIST of Aktormed GmbH, Barbing, Germany, is supposedly the most popular system worldwide at this time. The arm is mounted to the OR table rail. Initially, it was actuated by hydraulic force, but the current generation (SOLOASSIST II) is driven by electrical motors.

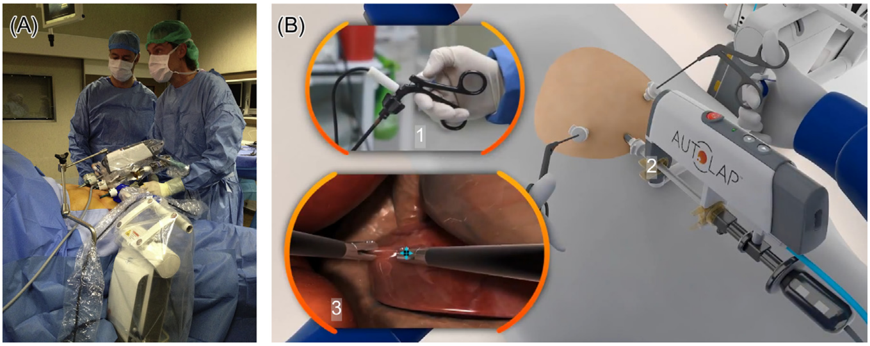


Figure 10.10 (A) The AutoLap in laparoscopic surgery; (B) *1*, wireless button interface; *2*, the motor unit bearing the telescope; *3*, automatic camera control by pattern recognition. *All courtesy of MST Medical Surgery Technologies.*

The SOLOASSIST emulates an arm working within several degrees of movement (Fig. 10.11). The endoscopic camera is registered in the trocar point which is used as a center of rotation. Starting from this point of origin, the device calculates automatically the required individual movements of the axes in order to obtain the entire movement required.

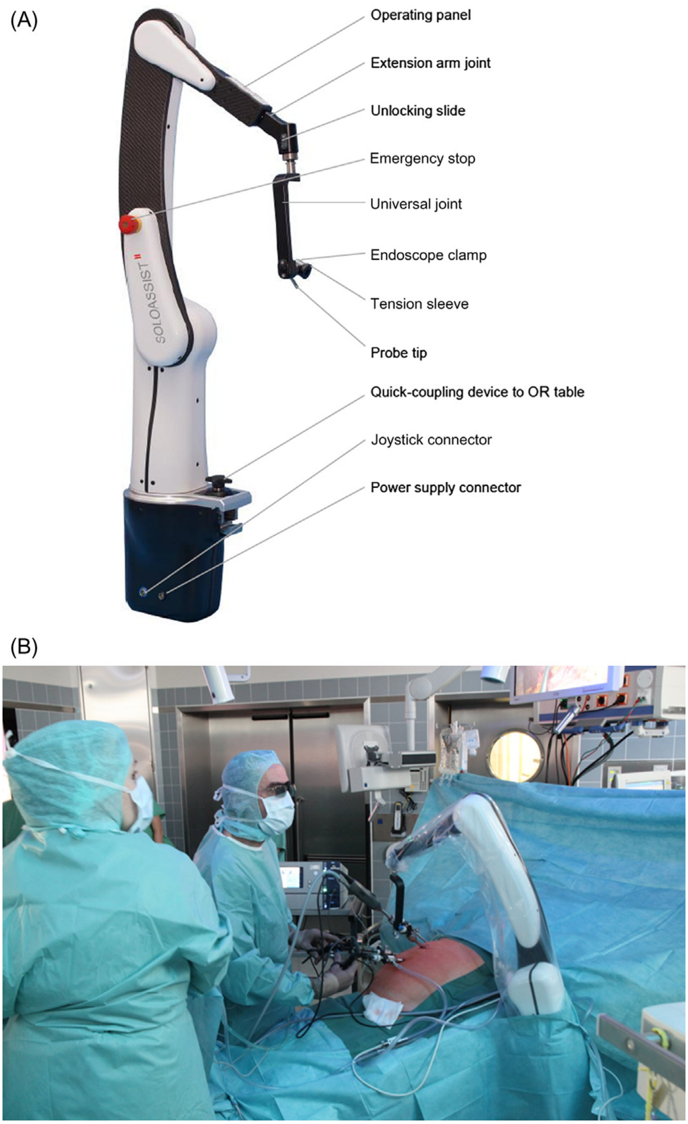


Figure 10.11 (A) The lightweight camera holder SOLOASSIST; (B) the SOLOASSIST in surgery. The universal joint is sterilized. The arm is covered by sterile drapes. *All from Aktormed GmbH.*

An integrated release function permits manual movement of the SOLOASSIST at the push of a button. The control panel is integrated into the extension arm (Fig. 10.12).

The system provides a large range of movement with a 360° panoramic view at an inclination of the endoscope between ~10° and 90° to the perpendicular (Fig. 10.13).

The range of movement compares very favorably with that of similar designs. In case of need, the position of the arm can easily be modified to an optimal position. After a brief recalibration, the surgery can be continued.

An ergonomic joystick for the surgeon's nondominant hand is used as an input device. It can be mounted to all common MIC tools.

The sterile joystick at the instrument can be operated easily with the index finger of the surgeon's nondominant hand during normal movements of the instrument's handle.

The joystick of the SOLOASSIST moves the camera intuitively 360° by tipping (up-and-down and oblique movements). Furthermore, two small buttons offer the opportunity to move the camera diagonally forward and backward (in and out) (Fig. 10.14).

Despite its large scope of movement, the SOLOASSIST is lightweight and compact and is fastened directly to the OR table by means of a quick-acting clamp. Thus, repositioning and registering with reference to

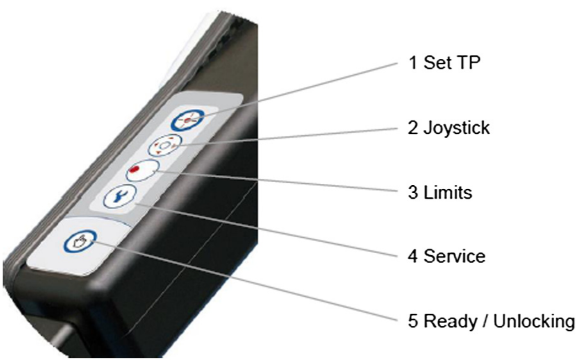


Figure 10.12 The control panel is integrated into the extension arm. The first button helps to define the entry point (TP, trocar point). Button 2 indicates whether the joystick is in use or not. Button 3: If the limits of the workspace are reached (i.e., if one or more axes are close to the maximum angle), this is indicated by a yellow light. Button 4 indicates if an internal malfunction has occurred. Button 5: On/off switch. If it is pushed during operation, the arm is unlocked and can be moved freely by the surgeon to the position selected. If the button is released, the arm is immediately blocked in the new position. *From Aktormed GmbH.*

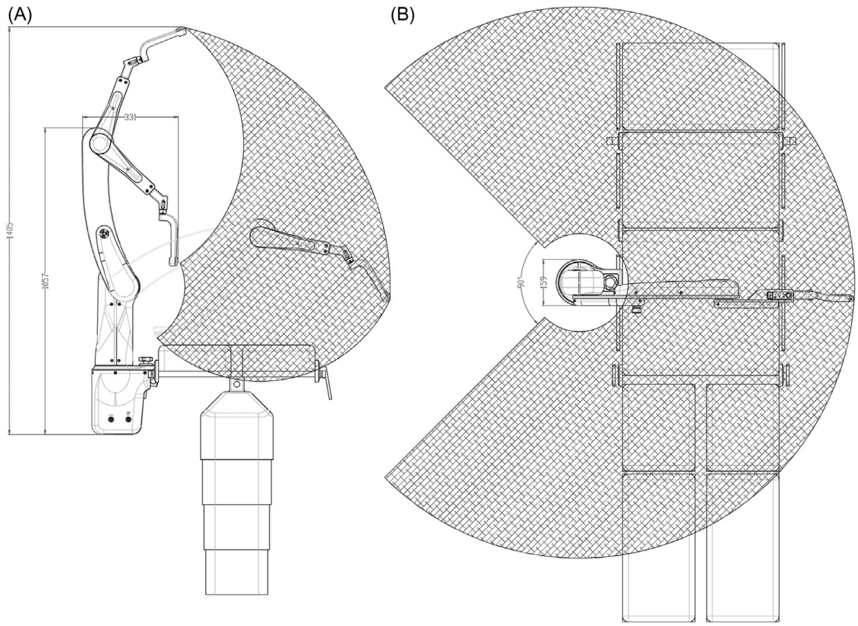


Figure 10.13 Range of movement: (A) Lateral view; (B) top view. The highlighted areas can be reached by the tip of the arm which carries the telescope. *From Aktormed GmbH.*

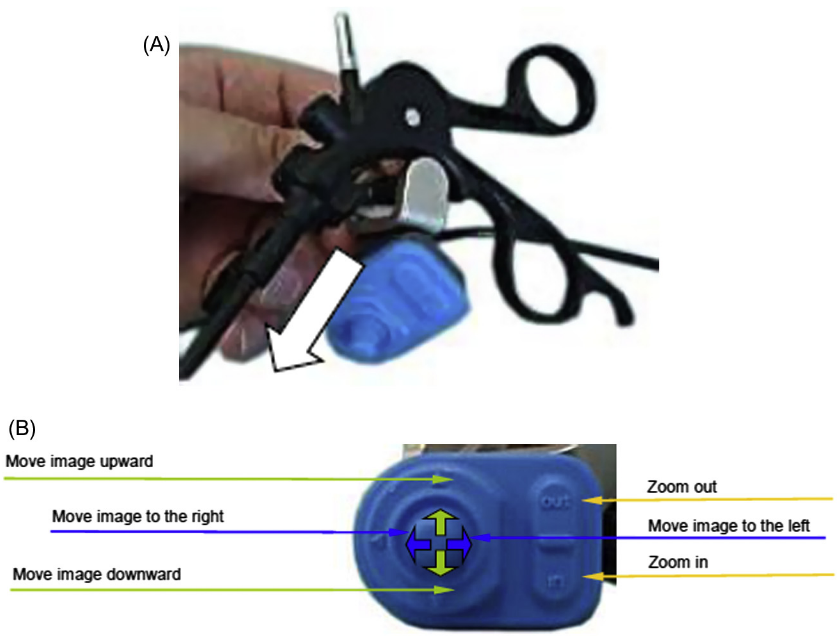


Figure 10.14 (A) The joystick attached to the surgical instrument. Since it is clamped by a small screw, it fits to all commercially available tools. (B) Control of the degrees of freedom. Conventional reprocessing (sterilization) is possible. *All from Aktormed GmbH.*

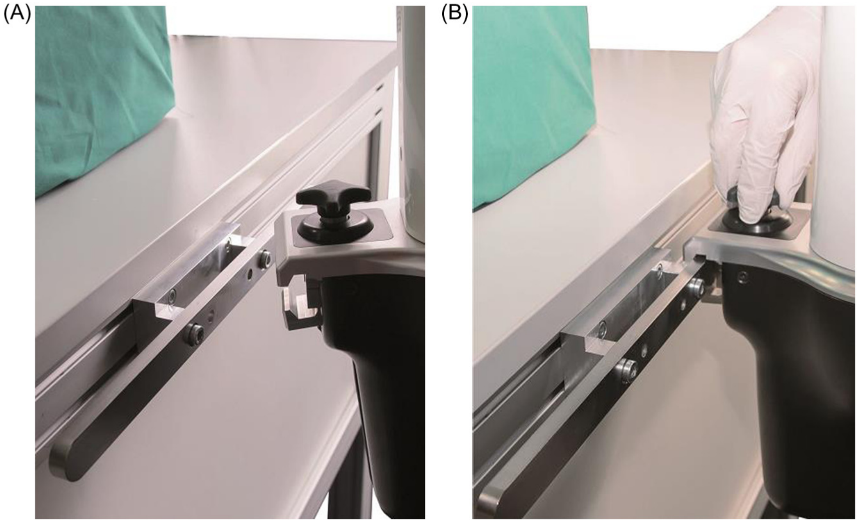


Figure 10.15 Fastening the SOLOASSIST to the OR bed: (A) The device is raised to the standard rail and is hooked up; (B) after the device has been placed on the standard rail of the OR table, it is aligned centrally to the OR table and the clamp screw is tightened safely by hand. *All from Aktormed GmbH.*

the patient is not necessary even if the OR table is moved in the meantime (Fig. 10.15).

To enable the surgeon to convert to major surgery in case of emergency, the SOLOASSIST can be rapidly mounted or removed.

Start-Up of the System

The directions of the camera arm have to be configured after the setup. After insertion of the first trocar, the tip of the camera holder is moved to the trocar point and configured by pressing a button on the console unit (Fig. 10.16). The entrance point, movements, and directions are saved and defined in a system of coordinates for the complete procedure. For safety reasons, the system stops the movements when movements in the coordinate system are recognized as out of range. These measures minimize misguidance and unintended tipping of the joystick [11].

The procedure of positioning and calibration takes a few seconds only. The ease of how it can be performed contributes significantly to user acceptance.

Operating costs are low, since the only disposable item is the plastic bag to cover the arm. The universal joint, the joystick, the endoscope clamp, and the tension sleeve are sterilizable (Fig. 10.17).

(A) (B)

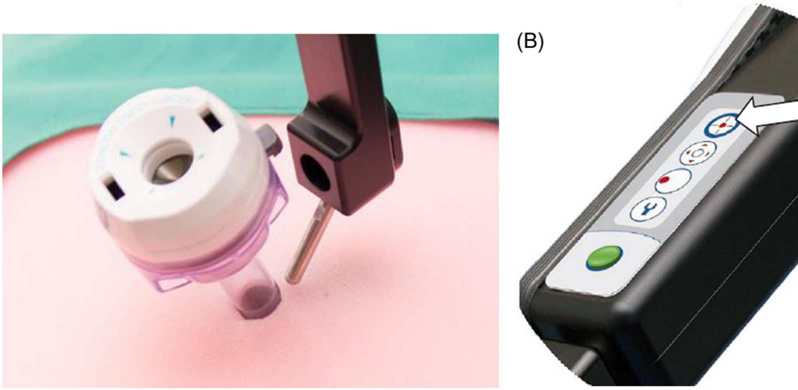


Figure 10.16 Calibration: (A) The arm is manually moved to bring the probe tip of the universal joint into contact with the entry site; (B) the TP button (*arrow*) on the operating panel is pressed. The "ready" button flashes green as soon as the calibration is successfully finished. *All from Aktormed GmbH.*

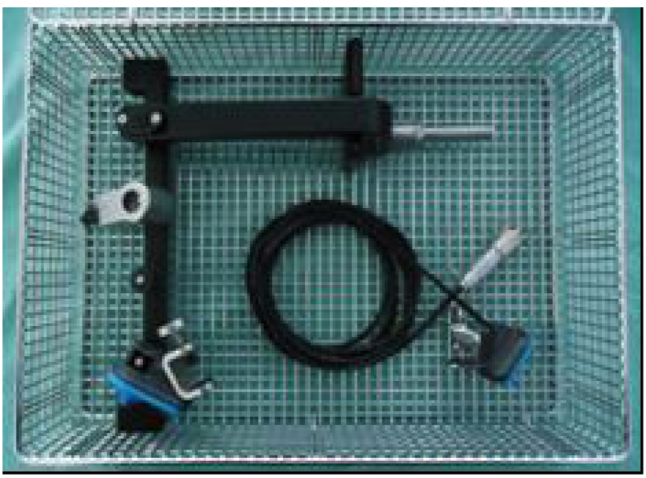


Figure 10.17 Sterilizable components of the SOLOASSIST. *From Aktormed GmbH.*

Clinical Experience

The first report was published in 2011 in an ENT journal [12]. Soon, papers from gynecology [13] and laparoscopic surgery [11] followed.

Studies upon more than 1000 cases are already available [14]. There is one very interesting paper which demonstrates that the use of a camera holder (SOLOASSIST) reduces postoperative pain as compared to manual camera control [15]. The use of camera guidance is as safe as

Figure 10.18 EMARO (exterior view).

human control. It prolongs the operative time slightly, but overall staff time is reduced.

Most probably, the newest active telescope manipulator is the EMARO of Riverfield, Inc., Tokyo, Japan (Fig. 10.18). In some regards it is remarkable to the FreeHand system also based on a mobile unit which is positioned close to the OR bed (it is not attached directly to the table). The four degrees of freedom (vertical, lateral, longitudinal, and rotational) are controlled by sensing vertical and horizontal movements of the surgeon's head through a gyroscope that is worn on the forehead. The additional two degrees of freedom (longitudinal, rotational) are controlled by a foot pedal. In addition, all four degrees of freedom can be used by means of a manual switch or the console panel. Each axis of motion can be moved in five speeds.

The most remarkable feature of the EMARO is that it is driven pneumatically. Up to now, pneumatic manipulation technologies were mostly avoided since they were not able to provide a smooth and continuous movement which is required for the precise manipulation of surgical devices. The sophisticated activation system with continuous air pressure control is claimed to be able to manipulate the telescope as well as conventional driving systems.

Up to now, no clinical reports are available.

10.1.1.3 Conclusion and Further Development

Soon after the advent of laparoscopic surgery the idea was born to replace human camera guidance by dedicated machines. Since then, a broad range of various solutions has been offered (Table 10.2).

Despite considerable initial interest of the surgical community, the first generation of camera guidance systems failed. They were too heavy, too bulky, and augmented the surgical workload rather than reducing it.

The new generation appears to be more successful since the devices are more ergonomic and more flexible. A real breakthrough, however, is only probable if the essential problem of autonomous camera control is solved. The first approaches of the AutoLap and the SOLOASSIST are promising.

10.1.2 Master–Slave Systems

The use of so-called "master–slave systems" was the next step in the evolution of "robotic" surgery. These mechatronic support systems should not be limited to visualization only but really help to do the surgery. The idea is to perform the necessary surgical manipulations (including camera steering) by means of teleactors which are positioned close to the patient. These teleactors translate the movement of the surgeon's hand into

Table 10.2 Camera guidance systems

System	Provider	(Still) commercially available
AESOP	Computer Motion, Inc., Goleta, CA, United States	–
LapMan	Medsys, Gembloux, Belgium	–
EndoAssist/ FreeHand	Prosurgics, High Wycombe, United Kingdom	+
FIPS	Karl Storz GmbH, Tuttlingen, Germany	–
EVOLAP	Universite Catholique de Louvain, Belgium	–
ImagTrac	Olympus Optical Co., Tokyo, Japan	?
ViKY	Endocontrol Medical, Grenoble, France	+
AutoLap	MST Medical Surgery Technologies, Yokneam, Israel	+
SOLOASSIST	Aktormed GmbH, Barbing, Germany	+
EMARO	Riverfield, Inc., Tokyo, Japan	?

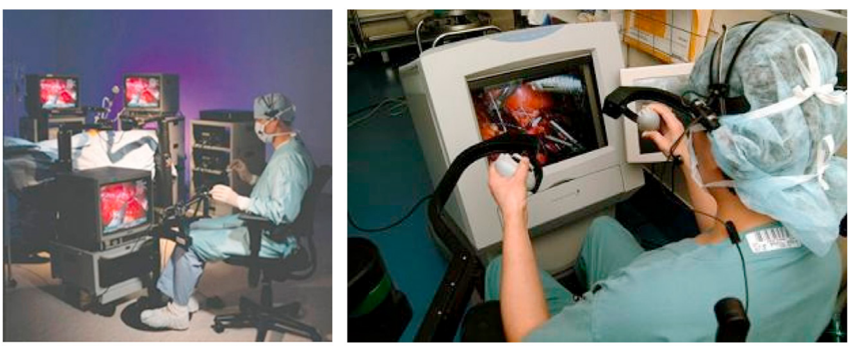
appropriate motions of the surgical tools of the "slave." The surgeon sits at a computer console apart from the patient at a remote site, being the "master" of the scenario. One of the first examples was the "Advanced Robotic Telemanipulator for Minimally Invasive Surgery" (ARTEMIS) [16]. Clinical application was achieved by the ZEUS and the DaVinci design.

10.1.2.1 ZEUS

The manufacturers of the AESOP arm (see above), Computer Motion (Goleta, CA, United States), combined three AESOP arms (see Section 10.1.1: Active Camera Holders) to create a new telerobotic "master—slave" unit. The voice-controlled robot AESOP continues to hold the camera. Two additional AESOP-like arms, also mounted to the OR table, were modified to control surgical instruments. The surgeon controlled the instruments by specially designed interfaces (Fig. 10.19).

The 3D imaging system was provided by Computer Motion (Goleta, CA, United States). The system eliminated the surgeon's resting tremor and was able to scale down the movements of the surgeon's hand over a range of 2:1—10:1 [5]. The 10-mm three-dimensional (3D) telescope was controlled by voice activation like the AESOP, the surgeon wearing a 3D goggle.

The ZEUS was, without any doubt, a remarkable concept and was appreciated by the users who performed cardiothoracic, visceral, and vascular surgery. The ZEUS system was also used for the first transatlantic



(A) (B)

Figure 10.19 The ZEUS system: (A) The console in the foreground with the remote slave in the background; (B) the handpieces of the system resembled joysticks rather than surgical instruments.

surgical procedure, when a laparoscopic cholecystectomy was performed in Strasbourg/France by Jacques Marescaux seated at a console 3800 miles away in New York/United States ("Operation Lindbergh") [17]. Some direct comparisons of the ZEUS and the DaVinci system were published [18−20], demonstrating an almost equal performance of both systems.

However, it vanished from the market when Computer Motion became part of the Intuitive Surgical conglomerate in 2003.

10.1.2.2 DaVinci

In opposition to the ZEUS design, the three arms of this system (Intuitive Surgical) are integrated into a separate robotic arms unit (Fig. 10.20). The slave unit (patient side cart) is a compact device with four arms.

The surgeon is located in an ergonomically comfortable surgeon console distant from the patient (Figs. 10.21 and 10.22).

Comparable to a microscope, the DaVinci system offers a very stable 3D visualization system since the head (and the eyes) of the surgeon are in a steady position to the binoculars. The camera is held by one of the arms and is controlled by the surgeon providing a stable image of the surgical site.

Another remarkable feature is the design of the surgical instruments.

It is an essential limitation of laparoscopic surgery that rigid instruments—inserted through the invariant point of the trocar—have to be used. DaVinci enlarges the number of degrees of freedom at the tip of the instrument by additional articulations (the so-called endowrist) (Fig. 10.23).

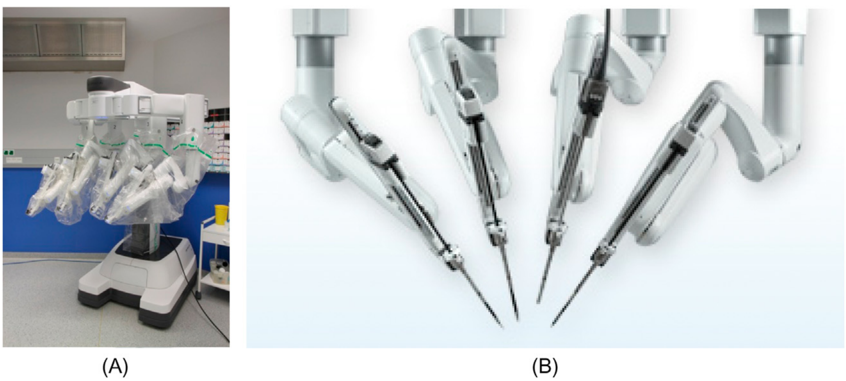


Figure 10.20 The "slave" part of the DaVinci: (A) Patient side cart. Four arms are provided. During use, they are covered by sterile drapes. (B) Detailed view of the arms. *From Intuitive Surgical.*

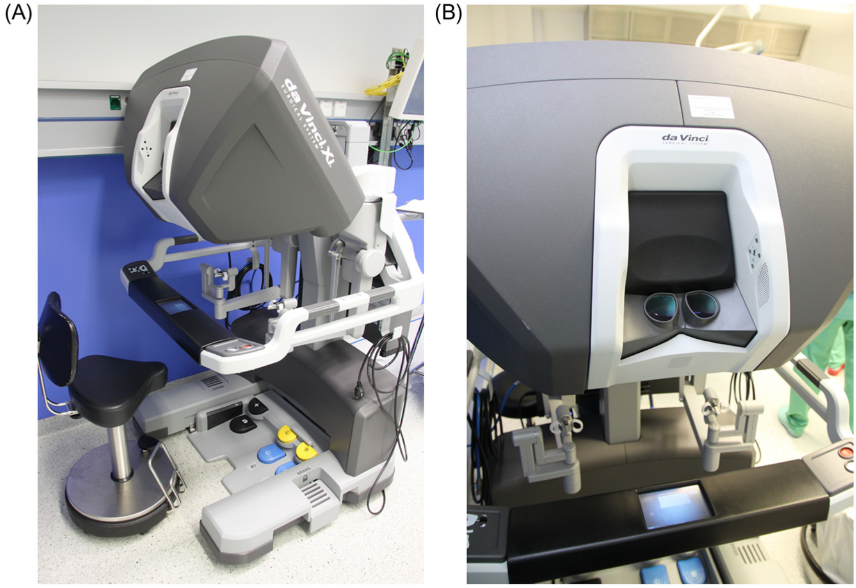


Figure 10.21 (A) The "master" control component of the system; (B) highly magnified 3D HD vision ensures that surgeons can see the surgical site with true depth perception and crystal-clear vision while the surgeon's head is positioned in the console on a cushion. *From Intuitive Surgical.*

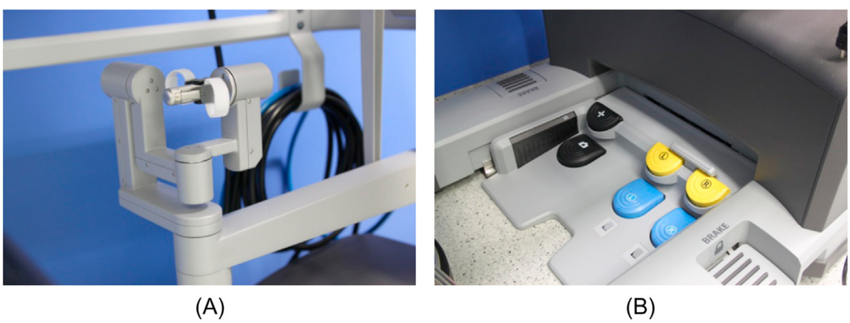


Figure 10.22 Control of the "slave": (A) For manipulation of the instruments, the surgeon's hand is positioned at the master controllers for intuitive control over the instruments; (B) foot pedals for electrosurgery, the "clutch," and camera and instrument control. *From Intuitive Surgical.*

Thus, they offer seven degrees of freedom and 90° of articulation which improves versatility enormously as compared to standard laparoscopic instruments. The range of instruments available is impressive: more than 40 different instruments including graspers, forceps, scissors, clip appliers, and needle drivers in various sizes and shapes.

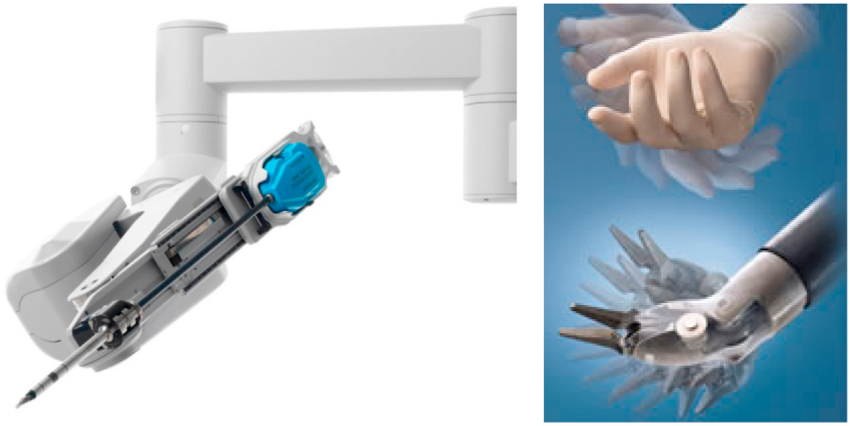


Figure 10.23 (A) Surgical manipulator; (B) the endowrist functionality: the design was clearly inspired by the function of the human hand. *From Intuitive Surgical.*

Even more impressive is the successful adaptation of advanced energy instruments.

Advanced technology with vessel sealing capabilities and cutting function in combination with fully wristed instrument tips (endowrist) are available as well as stapling devices.

The principle of ultrasound dissection (see Section 6.3: Ultrasound Dissection) is available as the DaVinci Harmonic ACE, and impedance-controlled electrocoagulation (see Section 6.2.12.1: Impedance-Controlled Electrocoagulation) as the DaVinci PK dissecting forceps.

It is a common problem of all mechatronic support systems to find the optimal position relative to the target area. The DaVinci Xi System considerably facilitates this process by a laser navigation which is integrated into the boom (Fig. 10.24).

In Chapter 14, Visceral Surgery of the Future: Prospects and Needs, the visions of a so-called "cognitive surgical environment" are developed. Aspects like this one—optimized positioning of "intelligent" mechatronic support systems—are an important piece of the mosaic.

Whenever nontable-mounted systems are used in a surgery, the position of the OR table cannot be modified any longer after initial calibration of the table and the device.

This was initially true for older versions of the DaVinci system. The latest technology, the DaVinci Xi System, can be equipped with an integrated table motion allowing an intelligent communication between the support system and the OR table (Fig. 10.25).

Figure 10.24 A laser targeting system facilitates the optimal positioning of the cart. Once the scope is attached, it has simply to be pointed at the target anatomy and the system will position the boom in an optimized configuration for the procedure. *From Intuitive Surgical.*

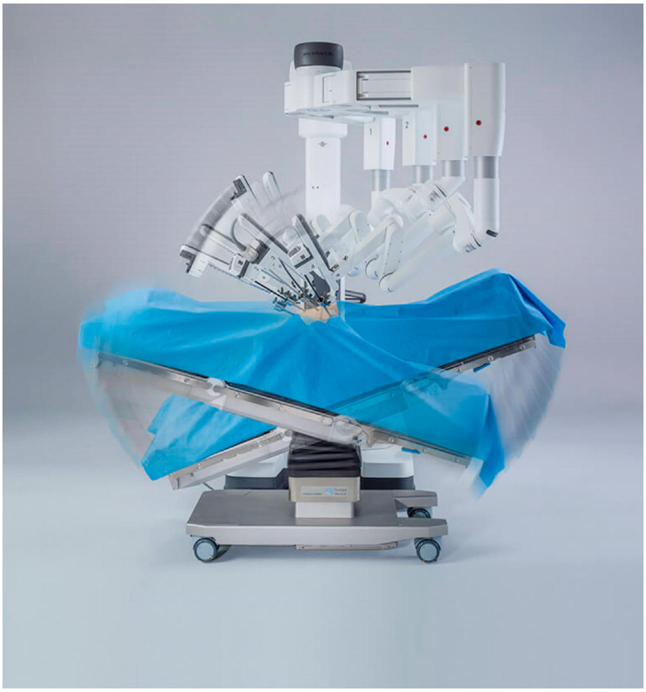


Figure 10.25 The concept of “integrated table motion.” The idea is to connect the DaVinci Xi Surgical system to TRUMPF Medical’s TruSystem 7000dV Operating Table. The patient can be dynamically positioned while the surgeon operates. *From Intuitive Surgical.*

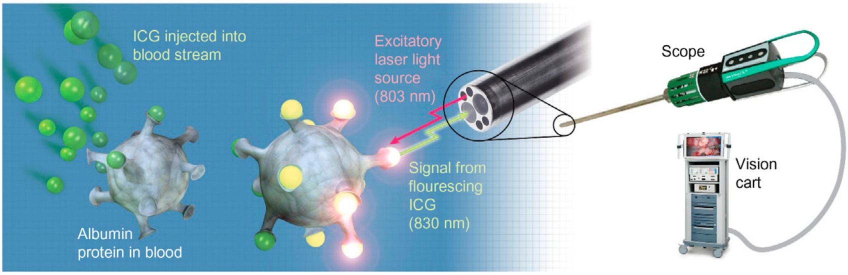


Figure 10.26 Indocyanine green fluorescence: If injected into the bloodstream, the dye is conjugated to albumin and secreted via the bile duct system. After excitation with a wave length of 803 mm, the bile duct system becomes visible. *From Intuitive Surgical.*

Changing the position of the patient is extremely helpful in many surgical procedures (e.g., colorectal surgery). If the position is fixed, the procedure becomes time-consuming and difficult. Integrated table motion enables the surgeon to switch to the optimal positioning anytime during the intervention, which makes surgery faster and safer.

One of the latest innovations concerns the improvement of visualization and anatomical orientation, the DaVinci Xi system now has integrated fluorescence imaging capabilities which facilitate the intraoperative identification of some characteristic landmarks, like the bile duct (Fig. 10.26).

Since indocyanine green is excreted in the bile, it will soon appear in the common bile duct and illuminate it with the specific wave length used. Similarly, the dye appears in urine making the renal hilum visible (Fig. 10.27).

As already briefly mentioned in Section 7.4: Mono-Port (Single Port) Surgery, a mono-port model of the DaVinci is also already available. NOTES protagonists are even waiting for an adaptation for scarless surgery.

Continuous extensions of the DaVinci system can certainly be expected. Most probably, it will even become a good fundament for a cognitive and cooperative support platform (see Chapter 14: Visceral Surgery of the Future: Prospects and Needs).

Critical Aspects

Today, the DaVinci has become more or less a synonym of "surgical robot." It is little wonder that it is also prototypically used for discussing critical aspects of "robotic surgery."

A permanent matter of debate are the surgical manipulations, just to take one example.

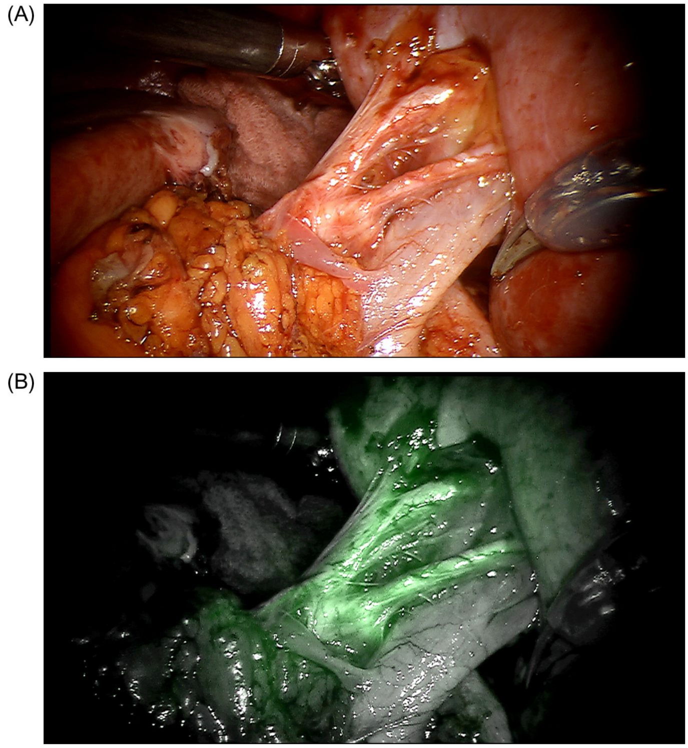


Figure 10.27 (A) Normal laparoscopic view of the renal hilum; (B) activation of fluorescence: parenchymal perfusion and the pelvis can be assessed. *From Intuitive Surgical.*

This complicated mechanical design could cause, however, problems in hygienic regards. The tip is activated by traction wire and the mechanical design is complex. Accordingly, cleansing and reliable resterilizing offer many problems. A disposable design could avoid these problems, but so far, the instruments are far too expensive for single use. Intuitive Surgical chose a compromise: after ten activation cycles, the instruments are deactivated, which appears to be the best trade-off between the strict rules of reprocessing on the one hand and economy on the other one. Beyond that, any complex mechatronic system in surgery is, at least theoretically, prone to immanent safety risks. Only recently, a first systematic retrospective analysis of adverse events in robotic surgery (almost exclusively focused on the DaVinci) was published. This study was based upon the publicly available MAUDE database of the FDA. During the study period (2000–13), 144 deaths (1.4% of the 10,624 reports), 1391 patient injuries (13.1%), and 8061 device malfunctions (75.9%) were reported. The authors found out that the numbers of injury and death events per procedure have stayed relatively constant [mean = 83.4, 95% confidence interval (CI): 74.2–92.7 per 100,000 procedures] over the years. Surgical specialties for which robots are extensively used, such as gynecology and urology, had lower numbers of injuries, deaths, and conversions per procedure than more complex surgeries, such as cardiothoracic and head and neck (106.3 versus 232.9 per 100,000 procedures, Risk Ratio = 2.2, 95% CI: 1.9–2.6). Device and instrument malfunctions, such as falling of burnt/broken pieces of instruments into the patient (14.7%), electrical arcing of instruments (10.5%), unintended operation of instruments (8.6%), system errors (5%), and video/imaging problems (2.6%), constituted a major part of the reports. Device malfunctions impacted patients in terms of injuries or procedure interruptions. In 1104 (10.4%) of all the events, the procedure was interrupted to restart the system (3.1%), to convert the procedure to nonrobotic techniques (7.3%), or to reschedule it (2.5%) [21].

All of us are aware of the fact that nothing in life is obtained for free. Almost any innovation in surgery does not only lead to improvements but is also always accompanied by specifically new, immanent risk. The risk–benefit ratio is essential. Unfortunately, in visceral surgery it is still not yet clear—even after about 15 years—whether currently available master–slave system operations are really superior to laparoscopic or open surgeries. Meanwhile, a wealth of scientific papers and meta-analyses has been published upon this topic. For low or medium routine level surgeries, the master–slave systems do not offer advantages and are, by far, too expensive. The question is whether they might be helpful in more advanced procedures such as esophageal, hepatobiliary, pancreatic, or colorectal interventions. After many meta-analyses, the picture is not yet clear [22–29]. A recent safety and effectiveness analysis concluded: "Gastrointestinal surgery with the da Vinci Surgical System is safe and comparable, but not superior to standard laparoscopic approaches. Although clinically acceptable, its use may be costly for select gastrointestinal procedure. Current data are limited to the da Vinci Surgical System; further analyses are needed" [30].

10.1.2.3 New Developments

The current monopoly of the DaVinci system does not only preserve a relatively high cost level, but it also impairs further progress of development. Fortunately, some independent international competitors have arisen to make the market broader.

10.1.2.3.1 Titan SPORT

Titan Medical, Inc., Ontario, Canada, announced the AMADEUS surgical robot almost six years ago, but up to now, nothing has been heard about clinical evaluation.

Instead, Titan now propagates the SPORT (single port orifice robotic technology) surgical system for laparoscopic single- and multiquadrant surgeries. A preview model was unveiled at the beginning of 2016. Little is known about the system up to now, but it is said that it resembles the next generation DaVinci SP system that Intuitive Surgical is developing now. SPORT consists of two components: the surgical workstation (Fig. 10.28) and the Patient Cart and Camera Insertion Tube (CIT) (Fig. 10.29) [31].

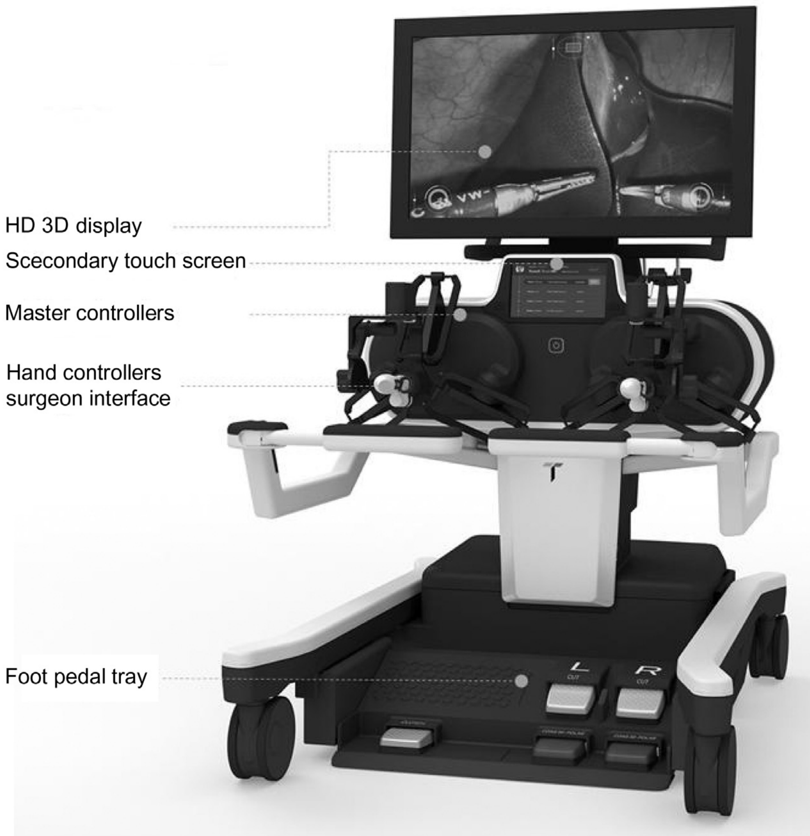


Figure 10.28 Surgical workstation of the SPORT: Ergonomic open workstation with HD flat-screen 3D monitor. Innovative hand controllers and state-of-the-art adjustable elbow controls contribute to optimal ergonomy. *From Titan Medical, Inc.*

Figure 10.29 Patient Cart and CIT in the working configuration for transportation, the boom can be lowered and folded into a very compact configuration. *From Titan Medical, Inc.*

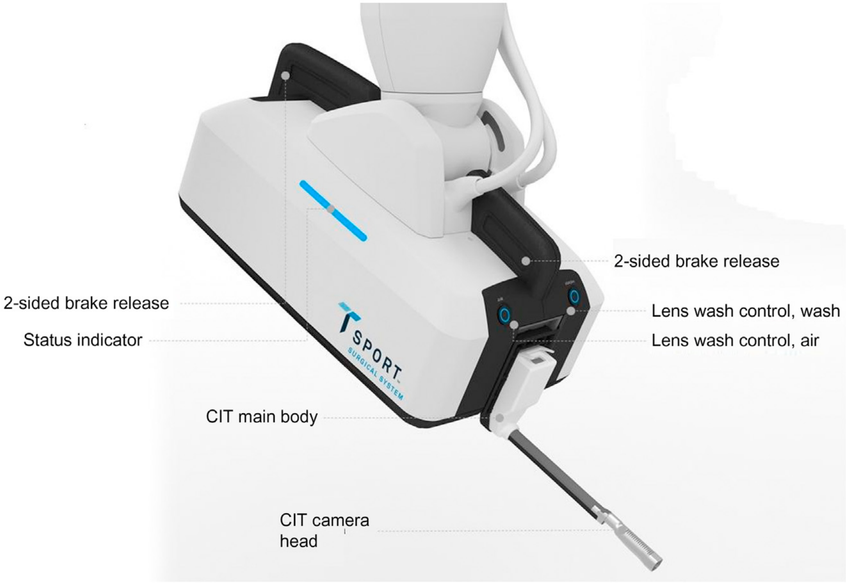


Figure 10.30 The "core" of the SPORT is the central unit. *From Titan Medical, Inc.*

The so-called "Patient Cart and CIT" is the "slave" part of the system. Since the mono-port approach is focused upon, only one arm or "boom" is conceived (Titan Medical). It carries the so-called central unit. The shaft with an outer diameter of 22 mm encompasses two instruments and the camera (Fig. 10.30).

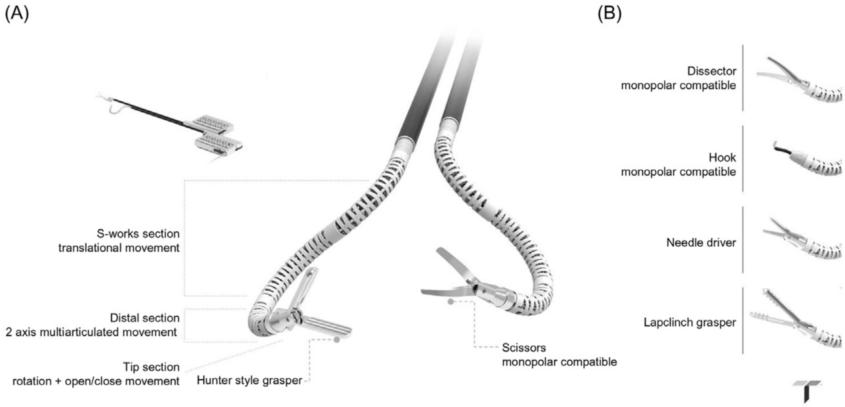


Figure 10.31 The flexible effectors: (A) They can easily be exchanged during surgery; (B) a selection of available instruments (disposable). *From Titan Medical, Inc.*

The mode of action is comparable to other single port and NOTES mechatronic platforms (see Section 9.9: Multifunctional Endoscopes and Mechanical Platforms).

Two flexible actor arms and the camera unit are inserted together in the straight shape into the abdomen. Then, they are unfolded and triangulation is achieved (Fig. 10.31). The augmented degrees of freedom of the flexible actors require more driving elements. These are provided in the chassis of the instrument which is connected to the central unit (Fig. 10.32).

The stereoscopic camera is also mounted to a flexible arm (Fig. 10.33) to always provide a good view on the tips of the instrument in their variable position.

Though nothing is known up to now about practical applicability, the SPORT is elegantly designed and meets many requirements of the user which had not yet been addressed. The system will be significantly less expensive than the main competitor.

10.1.2.3.2 Senhance Surgical Robot System

TransEnterix, Inc, Morrisville, NC, United States, formerly known by the SPIDER device (see Section 7.4.2.1: The SPIDER Surgical System), attempted to produce a robotized version of the mechanical design SPIDER, at that time known as “SurgiBot.” In 2015, the company acquired the surgical robotics division of the Italian health care company SOFAR S.p.A., Trezzano Rosa, Italy The idea was to combine the SurgiBot and Senhance to augment the market opportunity and to accelerate the commercialization timeline of the new system to initiate a new wave of robotic surgery.

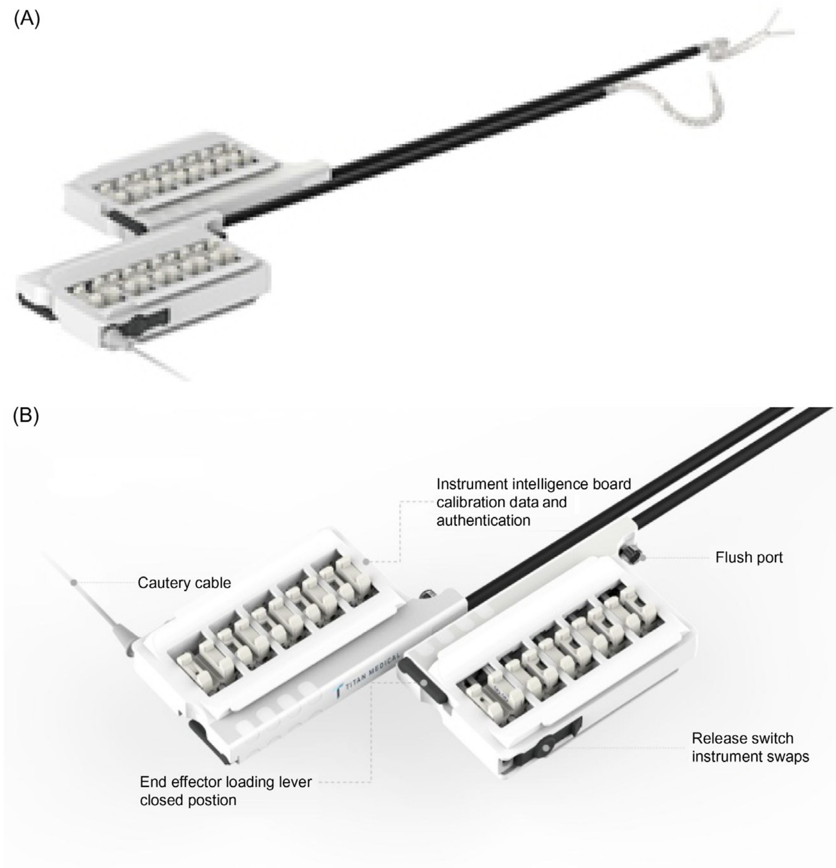


Figure 10.32 (A) A pair of endeffectors; (B) details of the instruments chassis. Note the line of five driving elements. *All from Titan Medical, Inc.*

Figure 10.33 The operating unit consisting of a steerable camera and two flexible endeffectors. *From Titan Medical, Inc.*

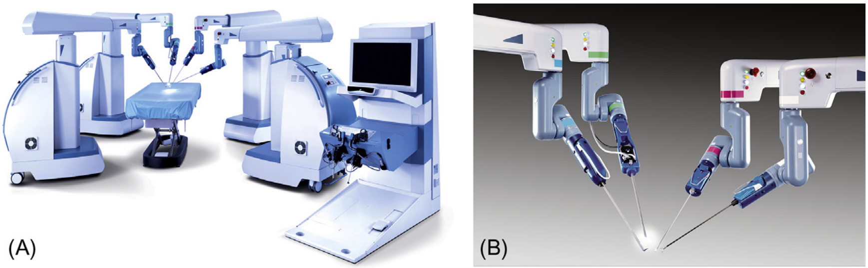


Figure 10.34 The Senhance Surgical Robot System: (A) Surgical console with slave unit in the background; (B) The four arms of the system in detail. *All from TransEnterix, Inc.*

The Senhance system consists of a remote-control unit called the "cockpit," with haptic handles, a 3D high-definition (HD) monitor, an infrared eye-tracking system (ETS), a keyboard and touchpad, one foot pedal, up to four detached and independent robotic arms, a connection node, and reusable endoscopic instruments (Fig. 10.34A).

The detached independent robotic arms (Fig. 10.34B) can be positioned as needed by the surgeon, who can choose access points based on real laparoscopic indications without restrictions imposed by technology. In this way, the surgeon may access different surgical fields just by swapping the positions of the camera and the instruments and choosing the arms with which to work. The cockpit is open and offers a broad view of the whole surgical area as well as easy access to the patient for positive interaction between surgeon and assistant. The haptic feedback allows the surgeon to feel the force used through the instruments and the natural resistance of the tissues. This force feedback is particularly useful for suturing to guarantee the feeling of the needle passing through the tissue and the pull of the stitch. The ETS allows accurate movement of the 3D endoscopic view. The surgeon can move the camera directly by gaze, without leaving the handles holding the instruments, and the picture can be zoomed in and out by the surgeon's head moving forward and backward. The port dimension is the same as that for standard laparoscopy (5 mm) and smaller than that of the DaVinci system (8 mm).

Senhance has different safety tools: a go/no-go foot pedal to control movements, control of the highest usable force during surgery, a sensitive grip for precise manipulation, restricted movement speed, and an emergency stop with warning lights and sounds. Senhance includes a large set of fully reusable instruments, which could offer specific advantages in terms of cost with respect to the DaVinci system, for which each instrument is designed for a limited number of procedures. In addition, different laparoscopic instruments can be adapted for Senhance robotic arms. A possible limitation of Senhance is the lack of wristed instrumentation (except for the RADIA needle driver), which represents the main strength of the DaVinci robot [32].

The main features of the Senhance are:

- preoperative simulation,
- force-controlled tools,
- automated fulcrum point identification,
- real-time patient monitoring to enable VR overlay,
- laser scanners for safe robot positioning.

A CE mark has already been achieved. The first clinical results have been already published, mainly from gynecology, with favorable results [33–35].

It may be assumed that papers from laparoscopic surgery and urology will follow soon.

The denomination "Senhance Surgical Robot System" is rather new. The former name was ALF-X. "Senhance" was selected to symbolize the combination of both senses and enhancement (alluding to eyetracking and haptics).

10.1.2.3.3 MiroSurge

The MiroSurge was developed by the German Aerospace Center (DLR), Oberpfaffenhofen, Germany. This versatile and lightweight design is based on three robotic arms (MIRO) and the respective instruments (MICA).

The robotic arm has a kinematically redundant and fully torque-controlled structure. Due to the compact shape of each MIRO, the setup may easily contain three or even more MIROs working together in close proximity at one operating table (Fig. 10.35).

Due to sophisticated control modes, the arms can even be directly moved at will by the medical staff. Since the mass is comparatively low (~10 kg), the arm can easily be mounted to the table or removed. The specialized instrument (MICA) offers full G-DOF action within the abdomen, offering haptic feedback. The instrument may be separated into the distal end (interchangeable instrument) and the propulsion unit [36].

Though technically mature, the MiroSurge is not yet commercially available.

10.1.3 Computerized Platforms for NOTES

The NOTES community is convinced that computerized platforms are essential to achieve a clinical breakthrough of scarless surgery [37] (see

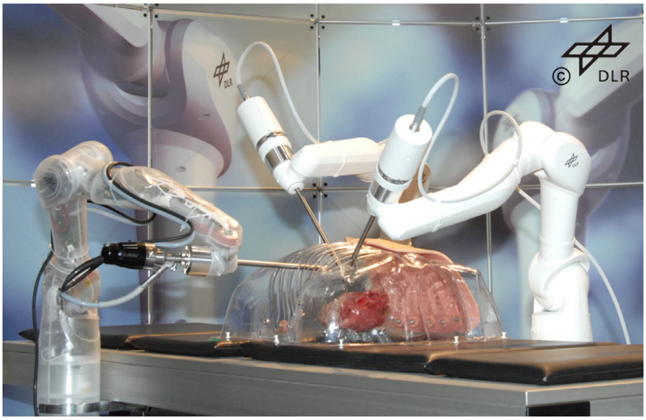


Figure 10.35 MiroSurge telemanipulator: Three MIRO robots mounted on an operating table. White MIROs carrying MICA instruments with force/torque sensing, transparent MIRI carrying a stereo endoscope. *From Tobergte A, Passig G, Kuebler B, Seibold U, Hagn UA, Fröhlich FA, et al. MiroSurge—advanced user interaction modalities in minimally invasive robotic surgery. Presence 2010;19(5):400–14 [36].*

Section 9.9: Multifunctional Endoscopes and Mechanical Platforms). According to Yeung [38], this type of platform can be categorized into three different groups: electromechanically controlled conventional endoscopes, systems with elements of autonomous location, and real robotically driven instrumentation devices. Some examples are given in Table 10.3.

10.1.3.1 Electromechanically Controlled Conventional Endoscopes

It is a logical idea to motorize the control of flexible endoscopes to offer the chance to gain electronic control of the instrument. Some examples are the RS-ALC (robotic steering and automated lumen centralization) design [39], the EOR (endoscopic operation robot) [40], or the invendoscope of the second generation (Invendo Medical GmbH, Kissing, Germany).

In these systems, electromechanical control is limited to the steering of the endoscope. The instrument(s) have to be manually activated.

10.1.3.2 Systems With Elements of Autonomous Locomotion

Early in the history of flexible endoscopy the users dreamt of a suitable solution to move the scope forward automatically, in particular in colonoscopy. Numerous experimental designs were developed, but only a few passed the test of time.

The well-known NeoGuide Endoscopy System (Intuitive Surgical, formerly NeoGuide, San Jose, CA, United States) has to be mentioned

Table 10.3 Computerized platforms for advanced flexible endoscopy and NOTES [38]

	Development status		
	FDA	**CE**	**Sale**
Electromechanical control of conventional endoscopes			
Robotic steering and automated lumen centralization (RS-ALC) (Enschede, The Netherlands)	–	–	–
Endoscopic operating robot (EOR) (Kyushu Institute of Technology, Fukuoka, Japan)	–	–	–
Invendoscope (Invendo Medical GmbH, Kissing, Germany)	Y	Y	Y
Systems with elements of autonomous locomotion			
Neoguide (Intuitive Surgical, Sunnyvale, CA, United States)	Y	N	N
Aer-O-scope (GI View Ltd, Ramat Gan, Israel)	Y	Y	Y
Endotics (Era Endoscopy s.r.l., Peccioli, Italy)	N	Y	Y
CUHK double-balloon endoscope (Chinese University of Hong Kong, China)	–	–	–
Robotic driven instrumentation			
ISIS-Scope/STRAS system (KARL STORZ, Tuttlingen, Germany/IRCAD, Strasbourg, France)	–	–	–
C-SPOT (TUM, Munich, Germany)	–	–	–
MASTER (EndoMASTER Pte Ltd, Singapore, Singapore)	–	–	–
Endomina (Endo Tools Therapeutics, Gosselies, Belgium)	Y	–	Y
Scorpion-shaped endoscopic robot (Kyushu University Japan, Fukuoka, Japan)	–	–	–
Viacath (Hansen Medical, Mountain View, CA, United States)	Y	Y	Y
CUHK robotic gripper (Chinese University of Hong Kong, China)	–	–	–
Imperial College robotic flexible endoscope (Imperial College, London, United Kingdom)	–	–	–

here, although it does not actively move the endoscope forward (Fig. 10.36). However, it improves the insertion of the endoscope considerably by use of computer assistance.

The system detects the insertion depth of the endoscope and the position of the tip of the colonoscope and based on that it creates a real-time 3D map of the patient's colon [41]. The system's sensor attaches to the

(A) (B)

Figure 10.36 (A) The NeoGuide system; (B) the shaft of the flexible endoscope with a shape memory function. *From Eickhoff A, Jakobs R, Kamal A, Mermash S, Riemann JF, van Dam J. In vitro evaluation of forces exerted by a new computer-assisted colonoscope (the NeoGuide Endoscopy System). Endoscopy 2006;38(12):1224–9 [41].*

patient and that sensor indicates the depth of the insertion of the endoscope. The NeoGuide system also has the ability to measure the angle of articulation at the tip. By linking these two data inputs, they are able to track the tip of the scope at any given depth. As the colonoscope is advanced, the computer directs each following segment to take the same shape that the tip had at a given insertion depth. The insertion tube consequently changes its shape at different insertion depths in a "follow-the-leader" manner. The NeoGuide system has a steering mechanism with a simple joystick thumb control. In addition to maneuverability, the NeoGuide system has the ability to become rigid, providing a "bird's eye" view, which is similar to laparoscopy that allows having a wide field of view. The stability is also an advantage. According to the developers, the NeoGuide scope would be able to raise and support tissues, which is very important for NOTES procedures [42].

An early attempt of a "self-propelled" forward movement of the colonoscope was the first version of the Invendo system. It was based on a sleeve technology (desinvagination of a hose). However, the procedure was significantly prolonged as compared to conventional colonoscopy [43] and the idea was left.

10.1.3.2.1 Endotic

A real self-driven colonoscope is the Endotic system of Era Endoscopy s.r.l. (Peccioli, Italy) (Fig. 10.37).

Propagation is achieved by the inchworm principle: it requires two actuators, a clamper, and an extensor. The clamper binds to the colon while the extensor uses positive displacement to push the scope along the colon (Fig. 10.38). The system facilitates a safer and almost pain-free examination, but is less fast than conventional colonoscopy [44].

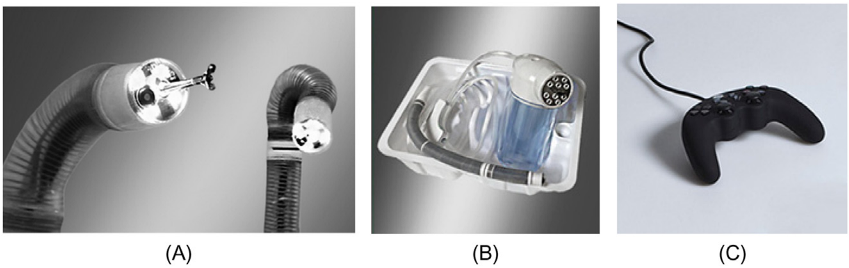


Figure 10.37 The Endotic colonoscope: (A) Steerable tip: integrated LED camera, suction, and insufflation, as well as a working channel; (B) the scope is provided as a sterile disposable; (C) control console.

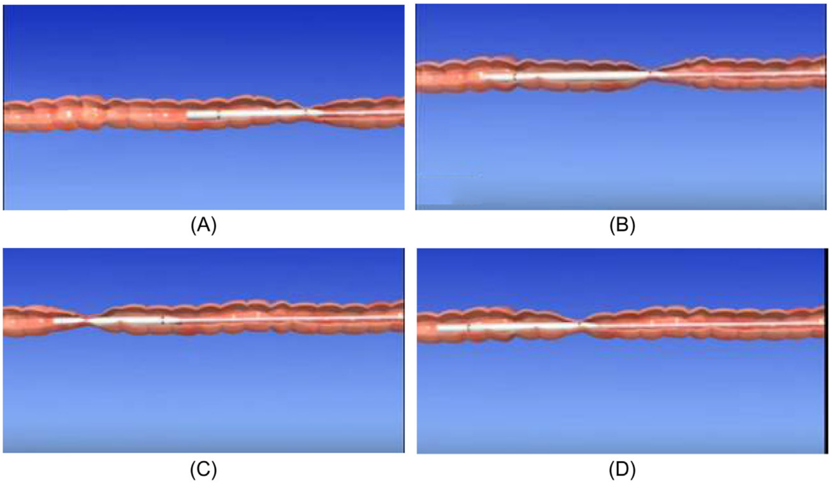


Figure 10.38 (A) The inchworm-like locomotion: The outer shaft of the scope is arrested at the spot by a vacuum. (B) The extensor pushes the tip forward. (C) The tip of the scope aspirates the wall and is now fixated to the new segment of the colon. The vacuum at the outer shaft is released and the outer shaft is pulled forward. (D) The cyclic process is started again with the fixation of the outer shaft within the new segment. *All from MITI.*

The same principle is used in double-balloon enteroscopy (see Section 5.7: Endoscopy). In this case, balloons are used as stoppers.

10.1.3.2.2 Aer-O-Scope

The Aer-O-scope (GI View Ltd, Ramat Gan, Israel) consists of a workstation and a disposable scope unit (Fig. 10.39).

The main elements of the scope are the rectal introducer, the supply cable with the balloons on it and the optical head with camera and LEDs [45].

The disposable scanner is connected to the workstation and via the ultraflexible multiluminal cable supplies gas, water, suction, and low-voltage current. Using a joystick the physician has complete control over the disposable scanner orientation for navigation and visualization. The Aer-O-scope disposable scanner is equipped with two working channels for the provision of therapeutic access. The rectal introducer is inserted through the rectum. The rectal balloon is inflated to seal the anus and the physician gently maneuvers the tube into the colon. The Aer-O-scope has a unique omniview panoramic camera that helps the physician see and navigate around the turns (Fig. 10.40). The scanner balloons are inflated and CO_2 fills the space between the rectal balloon and the

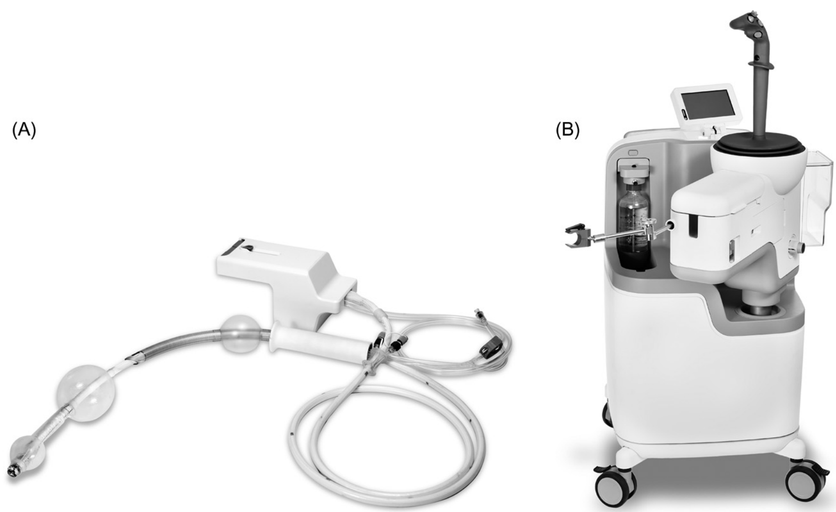


Figure 10.39 Aer-O-scope: (A) Disposable probe; (B) workstation with joystick. *All from © GI View Ltd. All rights reserved.*

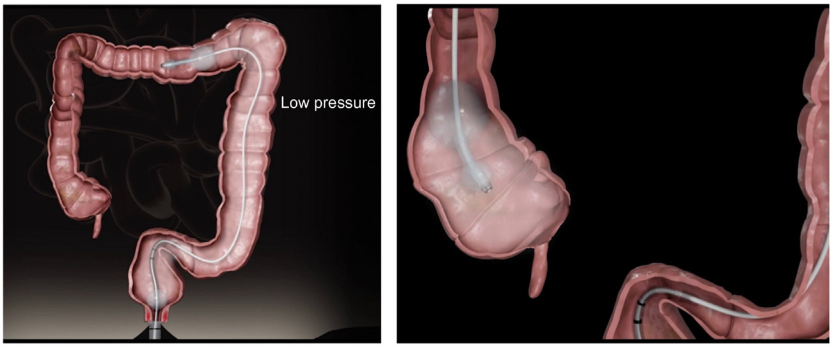


Figure 10.40 Mode of action of the Aer-O-scope: (A) The tip is pushed forward by CO_2 pressure which is insufflated into the space between the migrating balloon and the scaling balloon. (B) Reverse motion: CO_2 behind the migrating balloon is evacuated, whereas CO_2 is now insufflated into the space between cecum and the balloon. *All from © GI View Ltd. All rights reserved.*

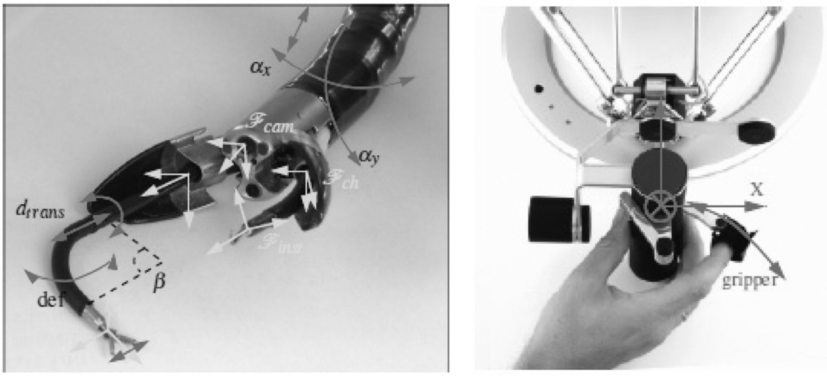
scanner balloons. As the balloons are gently pushed through the colon by the operator and with aid of the CO_2 pressure, their diameter and shape are constantly adjusted to suit colonic anatomy.

When the Aer-O-scope disposable scanner reaches the cecum, CO_2 between the rectal balloon and scanner balloons is vented through the rectum. The space between the cecum and scanner balloons is than inflated with CO_2. The pressure levels gently push the scanner balloons backward. Reverse motion is facilitated by the operator retracting the supply cable.

The wormlike automated robotic endoscope of the Chinese University of Hong Kong (China) [46] was originally developed to propel a camera capsule. Locomotion is achieved again based upon the inchworm principle. The extensor is actuated hydraulically.

10.1.3.3 Robotically Driven Instrumentation

At least two prototypes of computer-based platforms are currently known which are based upon a logical and plausible idea: To create a robotized version of the mechanical platforms as described in Section 9.9: Multifunctional Endoscopes and Mechanical Platforms. Since mechanical platforms utilize traction cable actuation (Bowden wires), electromechanical control should allow partial compensation of hysteresis.



(A) (B)

Figure 10.41 (A) In red (gray in print) DoFs of the slave system: deflection, translation, and rotation of the arm, closing of the grasper, deflections and translation of the endoscope. In yellow (white in print) frames associated with the endoscopic camera, the channels, and the instrument. (B) DoFs of one of two master interfaces: translations along *x*, *y*, *z*, rotations around *x*, *y*, *z* and "gripper". *From De Donno A., Zorn L., Zanne P., Nageotte F., de Mathelin M. Introducing STRAS: a new flexible robotic system for minimally invasive surgery. In: Conference: robotics and automation (ICRA), 2013 IEEE international conference on; 2013. p. 1213–20 [47].*

10.1.3.3.1 Single Access and Transluminal Robotic Assistant for Surgeons (ISIS-STRAS)

The design is a motorized version of the ANUBIS platform (see Section 9.9: Multifunctional Endoscopes and Mechanical Platforms).

All Bowden wire-based functionalities are carried out by motorization [47] (Fig. 10.41).

The internal structure is shown in Fig. 10.42.

The STRAS can be teleoperated by a single person and should be suitable for NOTES. However, in the first paper [47] some weaknesses were pointed out (e.g., man–machine interface) which still have to be eliminated prior to clinical use.

The well-designed ANUBIS platform is certainly a good starting point to realize the badly needed computerized platform for NOTES.

10.1.3.3.2 C-SPOT

The SPOT design of the Technische Universität München (TUM) (see Section 9.9: Multifunctional Endoscopes and Mechanical Platforms) was upgraded in a similar way (Fig. 10.43). All functionalities including forward/backward movement of the "mother-endoscope" and of the overtube are motorized.

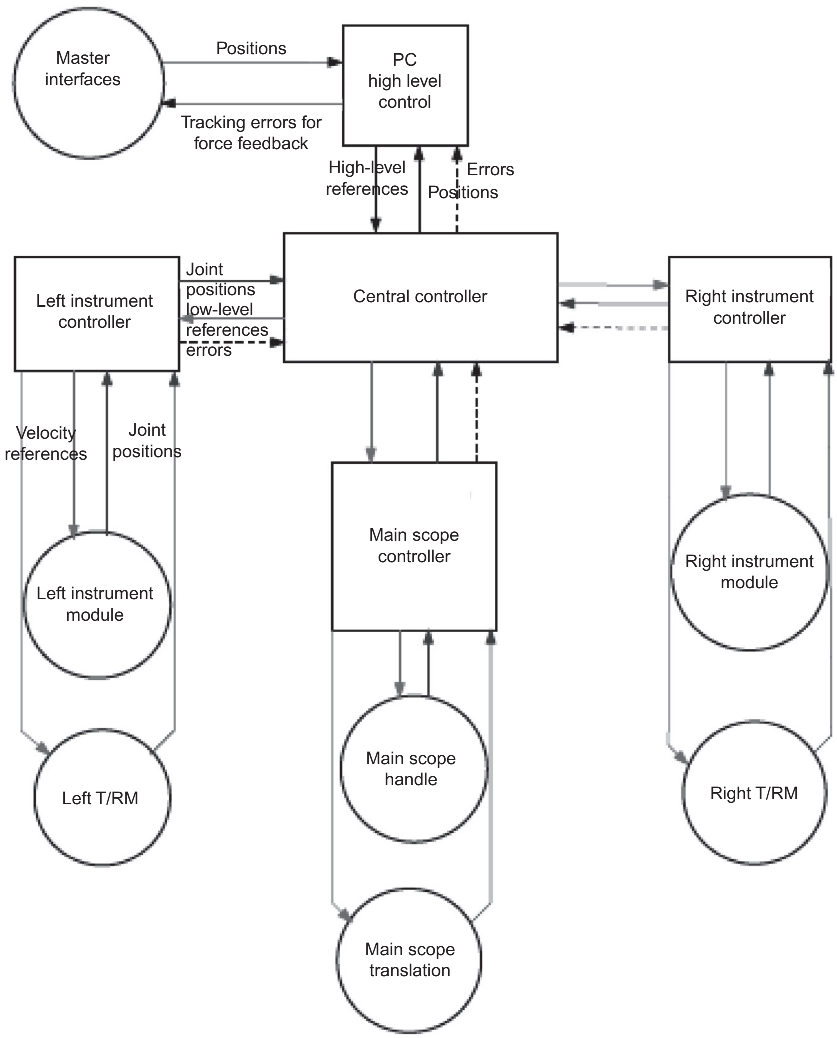


Figure 10.42 Electrical architecture of the STRAS: *Squares* represent control parts. *Circles* represent mechanical elements (T/RM: translation/rotation module). *From De Donno A., Zorn L., Zanne P., Nageotte F., de Mathelin M. Introducing STRAS: a new flexible robotic system for minimally invasive surgery. In: Conference: robotics and automation (ICRA), 2013 IEEE international conference on; 2013. p. 1213–20 [47].*

The system is controlled by a novel interface which was originally developed for the "HVSPS" (Highly Versatile Single Port System) mechatronic support system of the MITI institute of the TUM [48] (Fig. 10.44).

The basic idea was to use control interfaces which are more or less similar to conventional endoscopic and surgical instruments. The users are perfectly familiar with these types of handling. A specific training is not required.

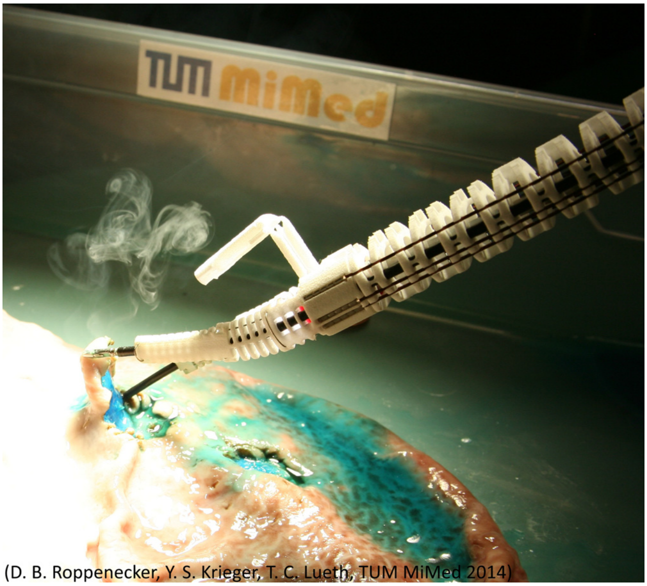


Figure 10.43 The C-SPOT: All functionalities are motorized and controlled by a novel surgical interface. *From © D. B. Roppenecker, Y. S. Krieger, S. V. Brecht, T. C. Lueth, Institute of Micro Technology and Medical Device Technology (MiMed), Technische Universität München.*

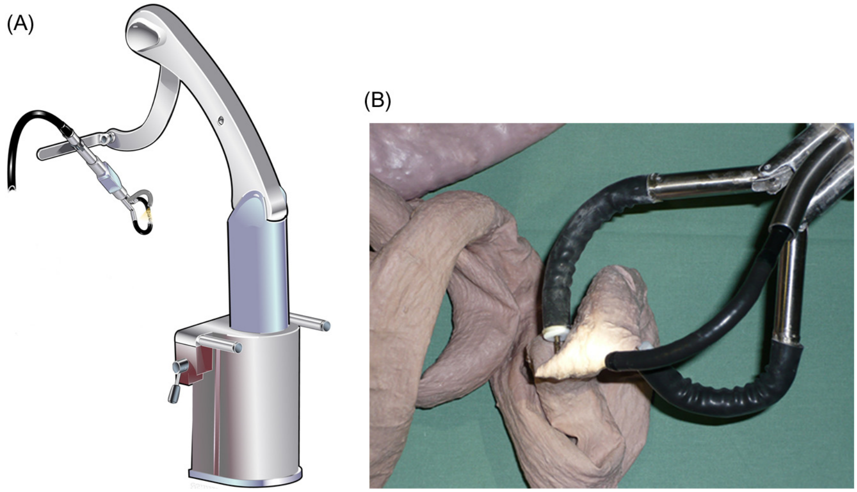


Figure 10.44 (A) The HVSPS attached to the guidance device SOLOASSIST; (B) the actuators and the camera arm. *All from MITI.*

The design of the interface was derived from a thorough analysis of the needs of the users (surgeons and gastroenterologists) who would use NOTES platforms [49].

The control module for the mother-endoscope (backward/forward, rotation, steering of the flexible tip) is shaped like the handpiece of a flexible endoscope.

The entire interface consists of three modules: two modules for the actuators and one module for the camera (Fig. 10.45).

The core of the position measurement is a 3D controller (Novint Falcon, Albuquerque, NM, United States) which delivers the *x*-, *y*-, *z*-coordinates in an area of a cube with 101.6-mm edge length. To record instrument rotation and bending, a laparoscopic instrument with a flexible tip (SILS Dissector XL, Covidien Surgical, Mansfield, MA, United States) was connected with a cardan joint to the 3D controller. The user interface offers the following nine DOFs: The *x*-, *y*-, *z*-coordinates measured by the 3D controller, two angles α and β, describing the bending of the instrument and measured by slide potentiometers, the rotation angle of the flexible tip γ, and the rotation angle δ of the whole instrument measured by precision rotary potentiometers, as well as the opening and closing angle σ of the instrument by a slide potentiometer and two additional buttons *i* and *o*. The voltage signals of the potentiometers were captured by a

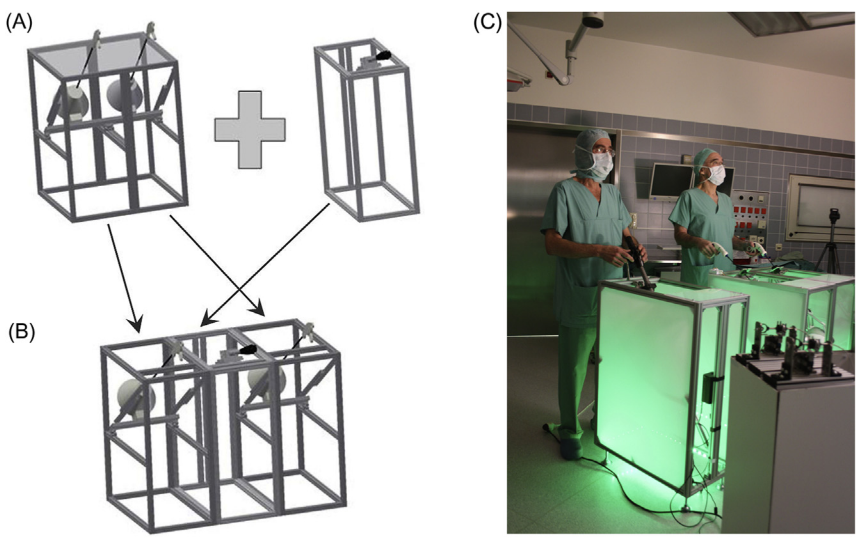


Figure 10.45 Control unit of the C-SPOT: (A) Single use design; (B) dual use design; (C) dual use of the C-SPOT interface: to the left: endoscopist; to the right: surgeon. *All from MITI.*

microcontroller board (Arduino Mega 2560, Smart Projects, Scarmagno, Italy). A program which in parallel records all signals was developed with LabView. Thus, the voltage signals are translated into movement signals.

As shown in Fig. 10.46, a quick and reliable precise response to the steering signals is obtained.

10.1.3.3.3 MASTER (Master and Slave Transluminal Endoscopic Robot)

The MASTER (EndoMaster Pte Ltd, Singapore) is another type of an overtube-like endoscopic master–slave system [50].

The MASTER device is attached to an ordinary dual channel endoscope. The robotic module has two arms, one with a forceps and the other one with a dissection hook [51] (Fig. 10.47A).

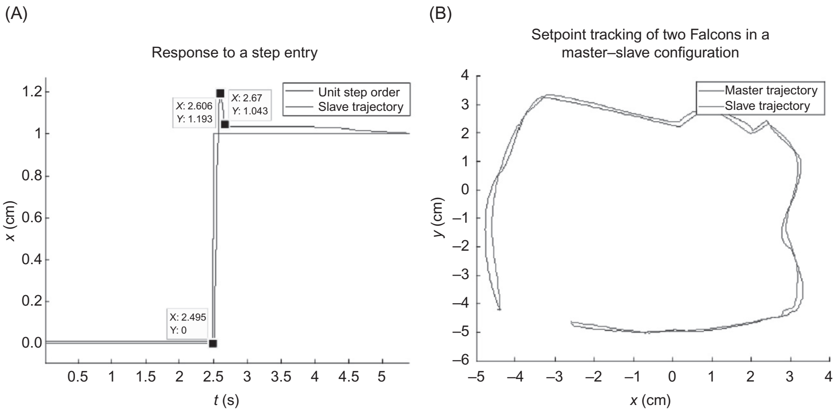
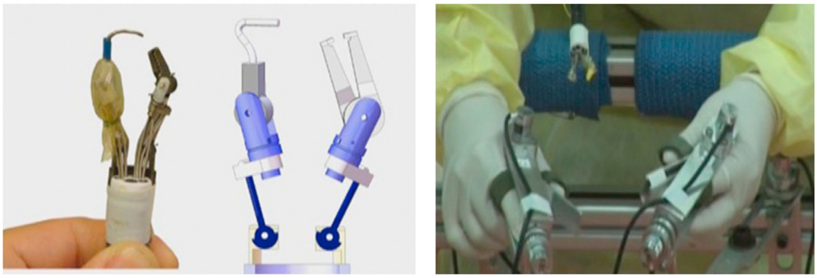


Figure 10.46 (A) Step response of the system; (B) master–slave trajectory. *All from MITI.*



(A) (B)

Figure 10.47 The MASTER system is an overtube system mounted onto a conventional endoscope: (A) Tip: one actuator is shaped as a dissection hook, one as a grasper; (B) interface. *From Sun Z, Ang RY, Lim EW, Wang Z, Ho KY, Phee SJ. Enhancement of a master-slave robotic system for natural orifice transluminal endoscopic surgery. Ann Acad Med Singapore 2011;40(5):223–30 [50].*

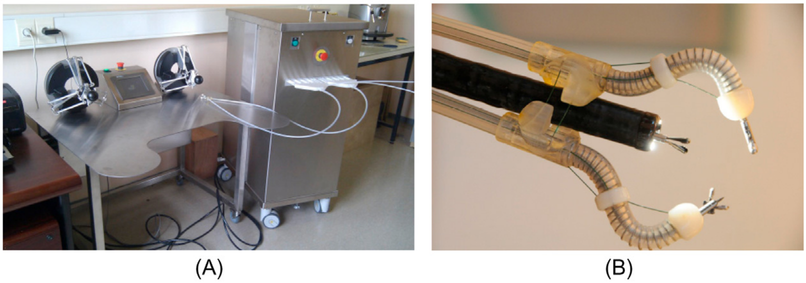


Figure 10.48 The Endomina system: (A) Control platform; (B) the two actuators mounted onto a conventional endoscope. *From Cauche N, Hiernaux M, Chau A, Huberty V, Ibrahim M, Delchambre A, et al. Endomina: the endoluminal universal robotized triangulation system: description and preliminary results in isolated pig stomach. Gastrointest Endosc 2013;77(58):AB204–5 [53].*

The two arms are operated via a rather large man–machine interface (Fig. 10.47B).

The MASTER is definitively a big step ahead toward advanced interventional endoscopy and NOTES. However, the available tools (instruments) are limited to a grasper and a dissection hook.

Originally designed for NOTES, the focus has now shift to interventional endoluminal endoscopy [52]. The first human trials have been performed.

10.1.3.3.4 Endomina

The Endomina (Endo Tools Therapeutics, Gosselies, Belgium) is a similar design. However, the two actuators are not integrated into an overtube but mounted apart from each other onto the endoscope [53] (Fig. 10.48).

Currently, the system is mainly designed for the endoluminal treatment of morbid obesity, gastroesophageal reflux disease, and ESD. It got a CE mark in 2011 and the first 50 clinic cases were done in May 2016.

In principle, it is also suitable for NOTES, since all standard endoscopic instruments can be used, but sealing the entry site airtight might be difficult.

Other experimental prototypes, such as the Scorpion-shaped endoscopic robot (Kyushu University, Japan) [54] or the new flexible snake robot for endoluminal surgery [55], deserve to be mentioned as well, but none of these is already mature for clinical use.

10.2 NONTETHERED (CABLE-LESS) SYSTEMS/MODULAR ASSEMBLING RECONFIGURABLE MINIATURE ROBOTS

To overcome the limitations of single robotic units, a revolutionary idea was the development of modular assembling reconfigurable mini robots.

Modular miniature robots consist of diverse miniature subunits, which could be assembled together to construct a fully functional miniature robot. Reconfigurable modular robots proved to be robust and adaptive in different working environments [56]. These features may also be applied in surgical applications considering the intracorporal workspace. Such a robotic device can be controlled via wireless bidirectional communication by the surgeon.

10.2.1 ARES

An assembling reconfigurable endoluminal surgical (ARES) system was proposed by the working groups of Harada et al. [57] and Nagy et al. [58] and tested in vitro with satisfactory results. In the above systems, millimeter-sized robotic modules may be ingested and then assembled into an articulated robot in the gastric cavity. During the assembly procedure, the stomach may be filled with a liquid to achieve distension and to aid the self-assembly of the minirobotic modules. The modules are assembled according to the target location in order to perform a precise surgical procedure (Fig. 10.49). Two robotic schemes were proposed: the homogeneous and the heterogeneous scheme. The homogeneous scheme is composed of identical modules except for one or two surgical or diagnostic modules. The heterogeneous scheme consists of one or more central branching modules, structural modules, and functional modules. With this scheme, the mini robot has a variety of topologies realized through reconfiguration, by repeated docking and undocking of the modules. The prototypes reported above are of dimension 13 mm in diameter and 23 mm in length for the homogeneous scheme and 15.4 mm in diameter and 36.5 mm in length for the heterogeneous scheme. In theory, the size of the modules should be at least as small as the commercial capsule endoscopes (27 mm × 11 mm), that is small enough to be ingestible. A variety

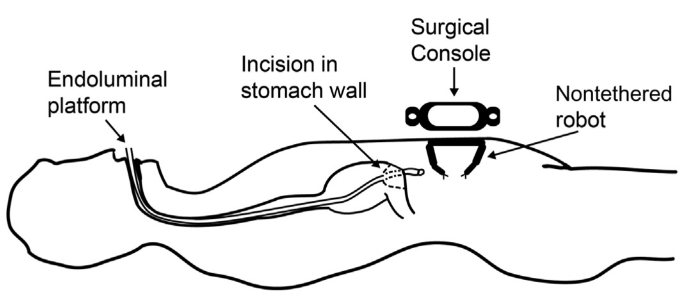


Figure 10.49 Natural orifice surgery using a miniature in vivo robot platform: The modules have already been delivered into the abdominal cavity via the stomach. *From MITI.*

of different surgical tools can be added and used cooperatively during complicated surgical procedures with high accuracy. Furthermore, additional modules can be added later to the miniature robotic structure.

The functionality of the modular reconfigurable mini robots is based on the assembly of the modules. The subunits must be assembled into a precise array in order to achieve a particular functionality for the mini robot. The mechanism of self-assembly is based on magnets. The magnets are placed on the mating faces and the force attracts the different modules toward each other and the magnetic torque orients them. Moreover, the use of electromagnets provides a reversible connection allowing for disconnection or reconfiguration. Each mini module is able to connect to any other module with the aim of increasing the number of possible configurations of the miniature robot. However, during the assembling procedure, a large number of forces like gravity, magnetic force, fluid drag, and friction are involved. As a result, further to the desired end-state of the modular mini robot, other states are possible ranging from misaligned assembly to no interaction at all. Depending on the desired operation that the robot must carry out, some of the misaligned states can be considered as successful. However, for a successful and safe surgical operation, the kinematic configuration of the modular mini robot has to be accurate with 100% success rate for the self-assembly.

The most important characteristic of the modular micro robots is their ability for active locomotion and intervention. Although the actuation of the ARES micro robot has been well described and tested, to our knowledge there is no analysis on the exact method of locomotion of the entire system once inside the stomach or the abdominal cavity. A wormlike or spiderlike motion may be desirable. Furthermore, the use of external magnets is a favorable option.

The long-term functionality of the wireless modular mini robots is constrained by the limits of their power supply. The use of on-board batteries similar to capsule endoscopes is usually employed. In this way, each module carries its own battery with consequently significant reduction of the available volume for payload and tools. Another option is that of using "power modules"; therefore, only one or a few modules need to be powered.

Beyond the power supply, external control and positioning of the intraabdominal device is required. Usually external magnets are used (Fig. 10.50).

10.2.2 ARAKNES

A few years ago, the so-called "Array of Robots Augmenting the KiNematics of Endoluminal Surgery" project (ARAKNES) supported by the European community was started to overcome these problems (Fig. 10.51). The ambitious approach to promote scarless surgery by

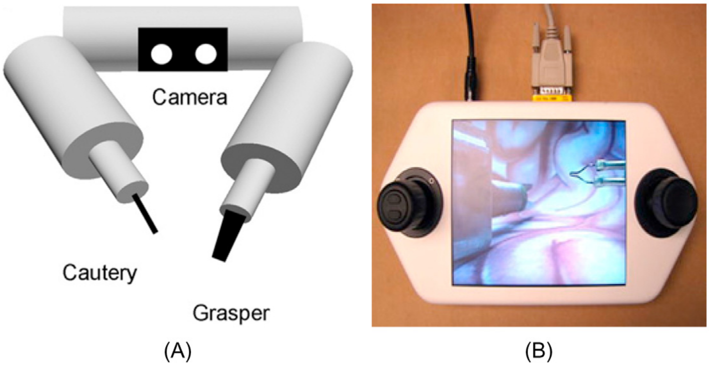


Figure 10.50 (A) The assembled modules ready to act; (B) surgeon console used for control of the NOTES robot. *From Lehman AC, Dumpert J, Wood NA, Redden L, Visty AQ, Farritor S, et al. Natural orifice cholecystectomy using a miniature robot. Surg Endosc 2009;23(2):260–6 [59].*

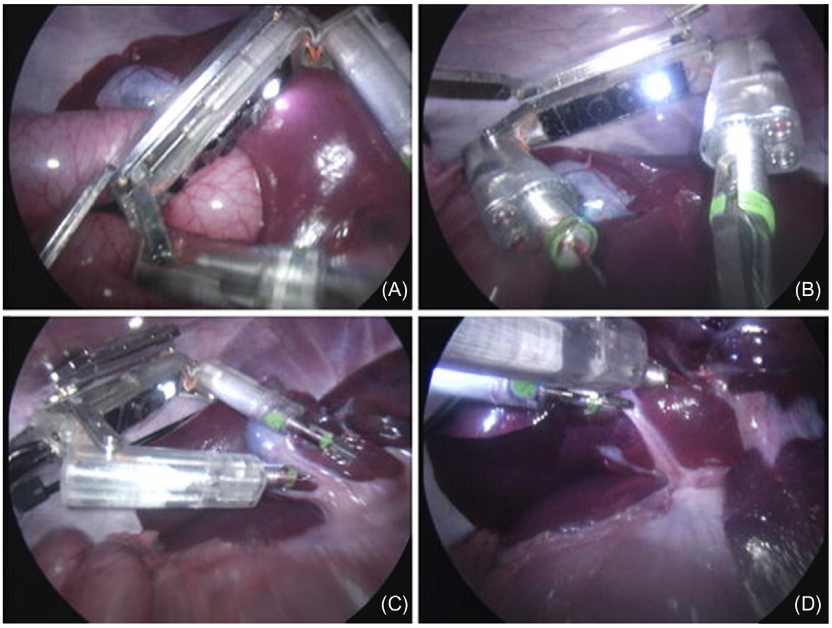


Figure 10.51 Endoscopy view of the robot attachment (A and B) and positioning (C and D) using magnetic coupling with the external magnetic handle. *From ARAKNES project.*

means of a remotely controlled "surgical submarine" had to be given up because of unsurmountable technical platforms.

In the mid-term, it seems probable that untethered systems could play a role in diagnostics, but it is not very likely that they will become helpful therapeutic tools.

10.3 SPECIAL ASPECTS OF ROBOTERIZED SURGERY

10.3.1 Haptic Feedback

Tactile perception is a part of a complex human sensory system consisting of

1. proprioception (body awareness),
2. mechanoreception (touch),
3. thermoreception (temperature),
4. nociception (pain).

In surgery it is of utmost importance to feel a quality of the tissue and the anatomy:

- to identify the surgical planes,
- to locate a tumor,
- to grip tissue firmly but atraumatically,
- to cut and to spread with adequate force,
- to apply the adequate tension when a knot is tied.

In open (conventional/classical) surgery, palpation is an essential part of surgical exploration. It is crucial for palpation of the tissue to discriminate the different layers and anatomical structures. It is the precondition to cut and to spread tissue with adequate force, to find the best trade-off when grasping between a secure grip and trauma or to apply optimal tension when a knot is tied.

In laparoscopic surgery tactile feedback is hampered but not at all completely eliminated. However, in robotic master—slave systems a direct (mechanical) control of the tip of the instrument via the respective handling device is no longer possible. Accordingly, the creation of artificial haptic feedback would be utmost desirable.

At first glance, however, to create robotic haptic feedback seems to be nearly unsurmountable.

Touch or tactile perception is one of the five somatosensory senses encompassing our capability to perceive pressure, stretch, and vibration (Fig. 10.52).

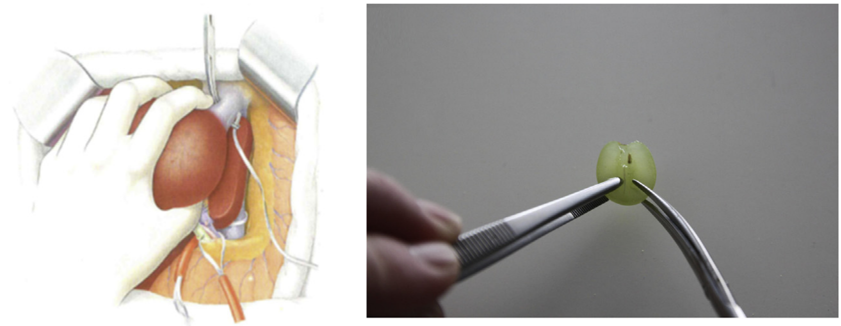


Figure 10.52 With the exception of (bimanual) palpation, tactile feedback is mediated by the respective instrument. *All from MITI.*

The loss of tactile perception is mostly compensated by visual control (otherwise, a DaVinci system would be of no use in clinical care), but, nevertheless, the use of the full range of surgical skills is limited. Accordingly, it would be most desirable to find technical solutions to provide the user with tactile information via the interface. The task is challenging.

The problem may become a bit less complicated if it is considered that haptic feedback in surgery is mainly mediated by the hand instruments in use. Direct manual palpation is of minor importance. Since a tool—a technical system—is per se better suitable to measure forces, the task should become easier to solve.

The main resistive forces which have to be transmitted to the interface are

- orthogonal force to the yaws,
- axial resistive force,
- lateral forces.

Orthogonal force is exerted to the yaws of the instrument when the tip is opened or closed, e.g., to grasp the tissue, or to secure a needle in a stable position, or to cut (Fig. 10.53A).

The opening force plays a role if different plans have to be spread apart (Fig. 10.53B).

If the instrument is moved forward or backward, the amount of resistive force when pushing or pulling is also decisive (Fig. 10.54).

Last but not least, lateral force has to be transmitted as well (Fig. 10.55A).

The next level is to reflect the forces if the two actors are working together (Fig. 10.55B).

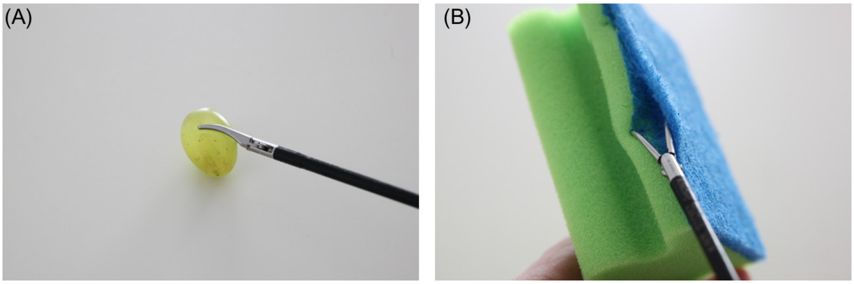
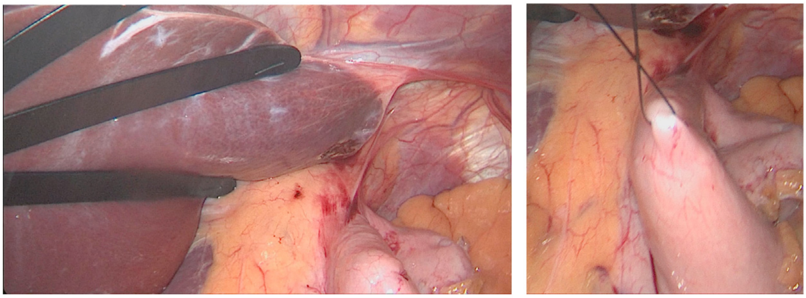


Figure 10.53 (A) Optimal fixation without harm to the object; (B) particular fine touch is required to spread apart different planes. *All from MITI.*



(A) (B)

Figure 10.54 (A) Elevation of the liver; (B) pulling adhesions from the gallbladder: the adequate amount of traction is decisive. *All from MITI.*

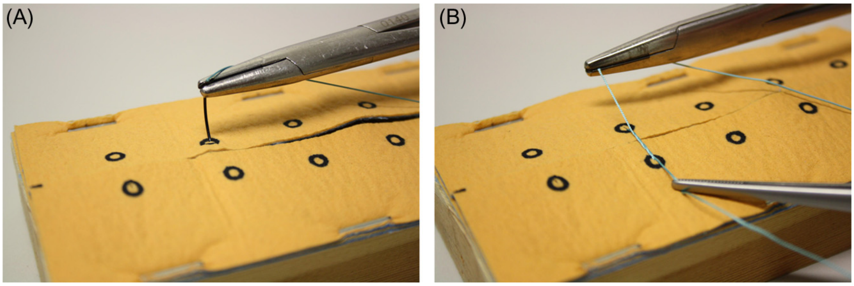


Figure 10.55 Haptic feedback is more than the perception of orthogonal forces! (A) Orthogonal force when piercing the tissue with the needle; (B) traction–countertraction if a knot is tied. *All from MITI.*

In at least two systems, haptic feedback was already successfully implemented: the Senhance Surgical Robot System and the MiroSurge device reflect forces. The clinical effectiveness has still to be evaluated.

10.3.2 Man–Machine Interaction

The way that the surgeon can interact in an intuitive way with the machine is the "Achilles heel" of robotic surgery. As shown above, a variety of technical solutions have been offered up to now.

"Joystick"-like solutions require significant accommodation of the surgeon which seems to be easier for younger surgeons than for those who did not grow up with modern consumer IT devices. The handling of the DaVinci with its two rings is a compromise, whereas the Senhance system uses two laparoscopy-shaped handling devices.

Since we do not even yet know how handheld laparoscopic instruments with wrist-like tip articulation should ideally be designed [60,61], it is difficult to decide upon surgeon preference in "robotic" surgery.

It seems probable that hand controllers with a linkage structure similar to the human upper extremity are most favorable [62].

However, direct manipulation of the surgical instrument is just one aspect of the interaction between the surgeon and the system. Camera control, activation of electrical force for dissection and coagulation, the adjustment of the field of view, etc. are mediated by buttons and pedals. A more intuitive or even adaptive cooperative assistance could significantly decrease surgical workload [63]. A first step into this direction is the eye-tracking-based automatic camera guidance which is implemented in the Senhance system.

A next step could be a purpose designed natural language user interface and knowledge navigator like SIRI (speech interpretation and recognition interface) of Apple, Inc. (Cupertino, CA, United States): verbal orders could replace mechanical signals. The long-term aim is to make the system as cooperative as a human assistant (see Chapter 14: Visceral Surgery of the Future: Prospects and Needs).

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CHAPTER 11

Tracking and Navigation Systems

Tracking and navigation systems are gaining increasing importance in surgery. Initially, they were predominantly used in more or less rigid surgical environments such as orthopedics, ENT, and neurosurgery, but today they are also used in visceral surgery.

While "tracking" refers to the acquisition of position information, the whole process of positioning, precisely displaying information in correlation with specific reference objects, is referred to as "navigation."

The field of application in visceral surgery reaches from tracking objects (beds, devices, etc.) and staff within the whole surgical unit to the positioning of patients, staff, and instruments in the OR suite. The most sophisticated use-case is surgical navigation during the surgical intervention. In this specific case, tracking and navigation systems can provide surgeons with exact information about the location of objects within the body without actually viewing them. Moreover, these systems can provide three-dimensional views of surgical instruments, in relation to the anatomy of a patient's body and visualize the insertion path. Commonly, preoperative images, such as the volume images of MRI or CT devices, are used as a data basis. Additionally, intraoperative imaging procedures, such as computed tomography, MRI, X-ray, or ultrasound, can be used to provide an actual (real-time) 3D dataset.

The surgical navigation system matches the position of the surgical equipment, such as the endoscope, with corresponding points in the tracking field. It computes the relationship between a patient's coordinate system and the image dataset. After registration-the alignment of the coordinate system of the patient ("real" coordinate system) and the corresponding volume dataset ("virtual" coordinate system) in at least three corresponding points-the position of the probe or the surgical instrument equipped with the tracking sensor can be virtually displayed in the image dataset. Alternatively to this paired point-based registration, surface matching routines can be used. If required, additional images during surgery can be acquired, registered, and included in the running navigation (intraoperative image acquisition) [1].

The wide range of applications with very different requirements cannot be covered by one universal technology. Fortunately, a wide variety of real-time locating systems (RTLS) is already available, meeting more or less the needs of the user. Depending upon the specific application, factors such as accuracy, range, update-rate, durability, scalability, and price have to be considered. The "global positioning system" (GPS), which is one of the most known and common technologies, should be, in theory, ideally suitable. However, indoor use for medical purposes is more or less impossible [2].

Early tracking systems were mostly mechanical digitizers, but because of the high accuracy and the large workspace, today optical tracking systems (OTS) are mostly used for navigation systems. On the other hand, they depend on the "line-of-sight," which prevents use for some applications. It is one of the main challenges of BME to identify in detail the strengths and weaknesses of each single technology to define optimal solutions for specific problems.

The basic principle is simple: An RTLS consists of three components as shown in Fig. 11.1, but the specific designs vary considerably.

The most important technologies will be described in the following, including optical and electromagnetic tracking, fiber bragg grating (FBG) localization, and a wide range of radio-based systems. In addition, other solutions including combined methods and distance measurement methods are briefly explained.

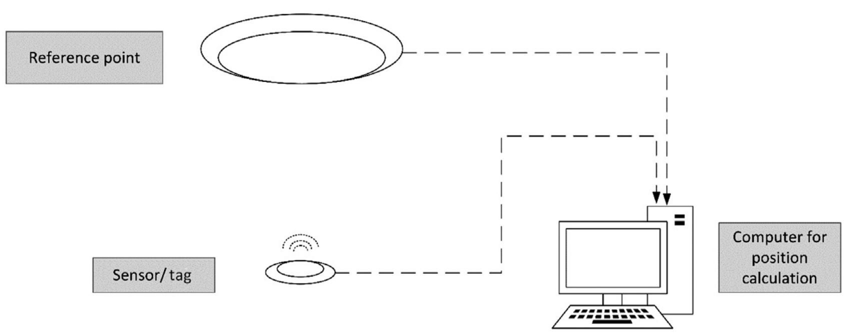


Figure 11.1 The components of an RTLS. The reference point ("anchor") is stationary. The tag (marker) is attached onto a device or a person. The resulting position to the reference is calculated in the computer. *From MITI.*

11.1 OPTICAL TRACKING SYSTEMS

OTS are currently standard in clinical applications (Table 11.1).

The 3D position of an object is triangulated between two or more cameras with overlapping projections. The object whose position shall be tracked has to be equipped with markers. Markers can be passive (light reflectors) or active (light emitters, commonly by LEDs). If not only position but also orientation is required, several ($\geq$3) markers have to be arranged at a known geometry. The 2D information of each single camera are combined to calculate the spatial position and orientation of the body carrying the markers.

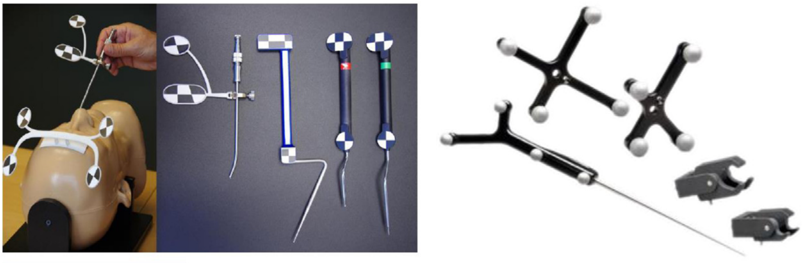
Infrared (IR) tracking systems are the most common optical systems, but videometric tracking systems are also available. Laser tracking systems do not play an important role in clinical settings.

There are a variety of OTS image-guided applications, including surgical procedures in ear, nose, and throat (ENT) medicine, neurosurgery, motion correction during imaging acquisition, or image-guided therapy procedures, performed manually or using robotics.

Instead of infrared cameras, videometric tracking systems use one or more calibrated cameras to detect and track specially marked objects with a known pattern of features. These markers are identified by patterns on video image sequences (Fig. 11.2A). The different 2D projections of the pattern with known features are then used to define a vector going from the sensor to the pattern. If more than at least three vectors are

Table 11.1 Key facts of optical tracking systems

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Tracking of rigid endoscopes (e.g., for liver surgery), Tracking of ultrasound probes	High accuracy, No interference, Line-of-sight restrictions, Bulky design	Application-specific technologic solutions	Miniaturization, Combination with other tracking systems



(A) (B)

Figure 11.2 (A) Probes with markers of a videometric tracking system; (B) Passive IR tracking markers. *(B) Courtesy: NDI.*

available, the position and orientation of the target is computed. One common videometric system is the MicronTracker of ClaroNav, Inc, Toronto, Canada.

Infrared tracking systems use only light of approximately 900 nm in wavelength, so that IR systems are independent of ambient light. Both active as well as passive IR tracking systems are used in practice. Active systems track IR rays emitted by a series of light-emitting diodes (LEDs) located on the surgical instruments. The LEDs are tracked by either two planar or three linear CCD units forming the camera module. Furthermore, LEDs are fired sequentially and are detected by each CCD unit. The central unit uses a process of triangulation based on the known geometric configuration and firing sequence of each LED and the known, fixed distance between the CCD elements. A minimum of three noncollinear LEDs are necessary for determining six degrees-of-freedom position information [3]. Since the LEDs must be powered, active systems are traditionally wired systems.

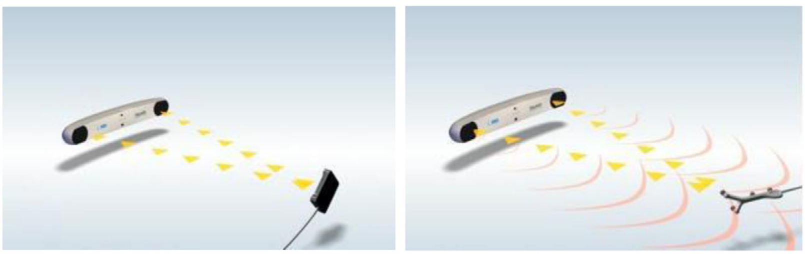
Passive IR tracking systems apply retro-reflective markers, also called reflecting spheres, that are attached to instruments and reflect IR light. In contrast to active tracking systems, passive systems provide wireless tracking (Fig. 11.2B). The pattern of the reflective markers, which has to be unique for each tracking probe, is identified on a 2D image. For this reason, these systems are always equipped with 2D CCD cameras [4].

With optical systems, submillimeter accuracy is possible, but a steady line-of-sight between the markers and the stationary system is needed (Fig. 11.3).

The mode of function is depicted in Fig. 11.4.

(A) (B)

Figure 11.3 (A) Tracking system for active and passive tools; (B) reflecting spheres for passive tracking. *Courtesy: NDI.*



(A) (B)

Figure 11.4 Comparison of active and passive IR tracking systems. *From NDI Optical Measurement Technology, <http://www.ndigital.com/medical/technology-optical.php>; 2013 [accessed 01.09.16] [3].*

Strengths and Weaknesses

Optical systems, especially LED-based systems, benefit from their very high accuracy [5–7]. The technical accuracy of OTS is in the range of 0.1 to 1.4 mm. NDI, Waterloo, Canada, a manufacturer of optical and electromagnetic tracking systems (EMTS), reports a theoretical accuracy of 0.25 mm [8]. In contrast to EMTS, OTS avoid the field distortion problems associated with EM trackers, have nearly no interference with other IR devices in the operating room, and do not necessarily require wired sensors. With optical systems, the field of view is large, but the line-of-sight restrictions are a significant disadvantage, often making them impractical for laparoscopic procedures. Markers can certainly be placed at the end of instruments outside the body, but this will degrade the tracking accuracy for long tools inserted into the body [9]. Additionally, the registration procedure of the markers is time-consuming, and can lead to target registration errors of up to 3 mm positional differences.

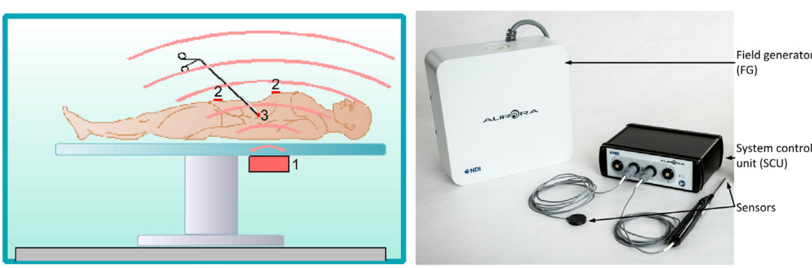
Recent Developments and Current Research

The main disadvantage of OTS, the line-of-sight restrictions, cannot be overcome. Further developments are more application-oriented than oriented toward general improvements of the technology. In 2011, a guidance system that simplifies lung interventional procedures with needles was developed. It uses cheap single-use materials and integrates CT images into both the preplanning of the surgery and the verification of the needle target access.

11.2 ELECTROMAGNETIC TRACKING SYSTEMS

EMTS are tracking technologies in which magnetic fields of known geometry are used to determine the position and orientation of sensors by measuring magnetic flux. The magnetic reference field is either produced by permanent magnets or electromagnetics. Permanent magnets are not relevant for biomedical purposes; artificially induced magnetic fields prevail. The geometry of the emitting coil assembly and the type of current determine the shape and geometry properties of the field. For the measurement inside the field, specific magnetic sensors are required.

Therefore, typically an EM tracking system consists of three components: the sensor(s), a field generator (FG), and a central control unit (Fig. 11.5). The FG has to create the position varying magnetic field, or, more precisely, three different magnetic fields of a well-defined geometry, which is used to establish the coordinate space. The most important feature of the FG is the tracking volume, i.e., the area around the generator where sensors can be tracked reliably. The sensors attached to the tracked



(A) (B)

Figure 11.5 (A) Schematic illustration of electromagnetic tracking: 1. Field generator; 2. Sensors fixed to landmarks of the body; 3. Sensor integrated into the surgical instrument; (B) EM tracking system with field generator, system control unit, and sensors. *Courtesy: (A) MITI, (B) NDI.*

object induce current in the small containing coils. The system control unit controls the FG and interprets the current induced by the sensors to determine the position and the orientation. Today, a broad range of EM sensors adapted to various applications and requirements are on the market (Fig. 11.6).

EM tracking systems can be divided in three categories:

- AC tracking systems
- DC tracking systems
- Passive systems.

In AC tracking systems, driven by alternating current (AC), search coils use inductors to determine the magnetic flux as a function of the time. Thus, an alternating magnetic field is needed for these sensors to measure a voltage.

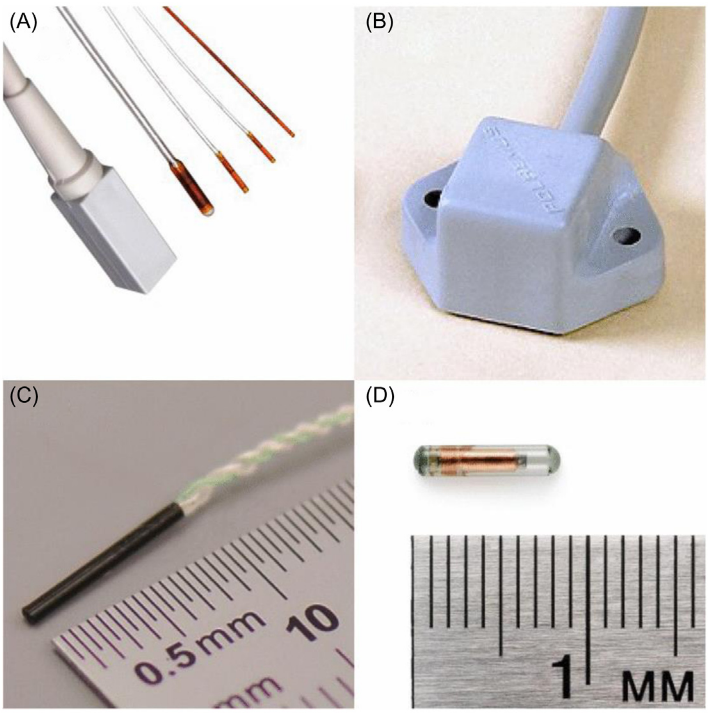


Figure 11.6 (A) Different DC trackers with sizes from 5 to 1.3 mm; (B) Polhemus AC tracking sensor; (C) miniaturized 6 DoF AC tracking sensor; (D) wireless EM tracking sensor for target position monitoring during radiation therapy. *From Franz AM, Haidegger T, Birkfellner W, Cleary K, Peter TM, Maier-Hein L. Electromagnetic tracking in medicine—a review of technology, validation, and applications. IEEE Trans Med Imaging 2014;33(8):1702–25 [10].*

DC tracking systems use quasistatic direct current (DC) and use fluxgate sensors to determine the position and orientation. Fluxgate sensors consist of two inversely arranged inductors to measure the second harmonic Fourier component of the magnetic field. A fluxgate can vectorially measure magnetic fields which are static or alternating with a low frequency.

AC tracking systems can determine distances by use of Hall Effect sensors, operating as an analog transducer, directly returning a voltage, but are of less relevance for exact positioning.

Today, very reliable and very small sensors are available. Even if first wireless devices were introduced in radiation therapy, still in most applications the sensors have to be connected to the control unit with cables. However, a cable is always required to connect them with the control unit.

EM-based surgical navigation and tracking systems are the most common choice for laparoscopic surgery, flexible endoscopy, and other minimally invasive procedures because a clear line-of-sight is not required between the base station and the attached sensors. Fig. 11.7 gives an overview of the specially designed antennas (field generator) for clinical use.

The tracked coils are placed near the end of the tip of the instrument. It is possible to track miniaturized sensors designed for integration into surgical tools and instruments, such as needles, catheters, probes, and scopes (Fig. 11.8).

EMTS reach a technical accuracy in the range of 0.17 to 1.4 mm [11] under laboratory conditions, but it is significantly lower in clinical use.

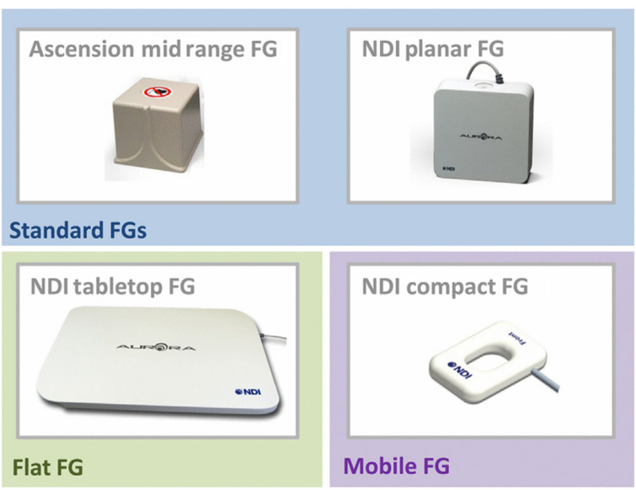
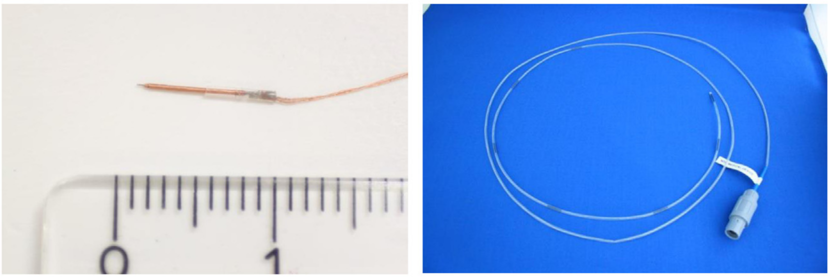


Figure 11.7 A selection of FGs currently in use. *From Franz AM, Haidegger T, Birkfellner W, Cleary K, Peter TM, Maier-Hein L. Electromagnetic tracking in medicine—a review of technology, validation, and applications. IEEE Trans Med Imaging 2014;33 (8):1702-25* [10].



(A) (B)

Figure 11.8 (A) An extremely miniaturized EM sensor. (B) Shape sensor, a series of seven EM tracking sensors integrated into a catheter. *All from MITI.*

Table 11.2 Key facts of electromagnetic tracking systems

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Laparoscopic surgeries	No line-of-sight restrictions	Miniaturization	Improved accuracy
Flexible endoscopy	Integrable into every tool	Integration	Extension of the tracking volume
Catheters	Less accuracy		Electromagnetic immunity
	Field distortion electromagnetic objects		

Strengths and Weaknesses

A major advantage of EMTS is the fact that they do not have line-of-sight constraints; hence, there is no danger of interrupting navigation. The sensors can be very small and integrated into nearly every tool or device so that the tracking point of the surgical instrument can be closer to the anatomical structures than with OTS. That leads to the ability to track flexible endoscopes and catheters, which is the main advantage of EMTS. Since EMTS navigation is based on tracking the coils of the instrument, the relationship between the coils must not be changed during the procedure [11] (Table 11.2). The most serious drawback is field distorsion due to external EM sources.

Recent Developments and Current Research

The use of EM tracking is already clinically established in colonoscopy. The ScopeGuide (Olympus, Tokyo, Japan) shows an accurate 3D reconstruction of the endoscope position and configuration within the colon. The 3D inforamtion generated by the electromagnetic tracking is then displayed in split-screen mode of both the anterior–posterior and lateral view.

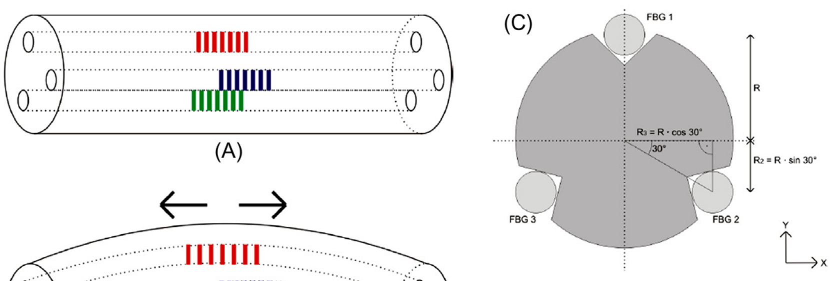
The focus of current developments in EMTS technology is the improvement of EMTS accuracy. Currently, they cannot compete with OTS in terms of tracking accuracy. Additionally, the range of the magnetic field needs to be extended to minimize the spatial limitations of surgeries with EMTS.

One new promising technique for biomedical tracking are superconducting quantum interference devices; however, further research is still necessary [11].

11.3 FIBER BRAGG GRATING SENSORS

Fiber sensing is a new technology based on the principle that the wavelengths of reflected light differ under distinct circumstances, such as a change of temperature or strain, that are achieved by an interference pattern in the optical fiber [12].

FBG is using the effect that a temperature difference, a strain, an acceleration or a tilt has an impact on a change of the index of diffraction, which is caused by concave gratings inside the optical fiber. In diffraction grating, the emitted light is refracted and reflected. The recording of these diffractions by a special camera (interrogator) allows the measurement of differing environmental influences, such as strain [13] (Fig. 11.9).



$$\varepsilon_y = \frac{2}{3}\left(\varepsilon_1 - \frac{1}{2}(\varepsilon_2 + \varepsilon_3)\right)$$

$$\varepsilon_x = \frac{\varepsilon_2 - \varepsilon_3}{\sqrt{3}}$$

Figure 11.9 Basics of fiber-optic 3D tracking: (A) Normal grating pattern in the straight position; (B) depending on the direction, the bars are either dilated or compressed; (C) positioning of three FBGs into one catheter in 120° and respective calculations to compute bending in x- and y-direction. *Courtesy: T. Schossig, MIOPAS GmbH, Goslar, Germany.*

Table 11.3 Key facts of fiber bragg grating

Typical applications	Strengths and weaknesses	Recent developments	Research potential and future trends
Pressure, temperature, and configuration measurement	Lightweight and small size Multiplexing capability Simultaneously sensitive to temperature, strain, and pressure	Cost reduction Optical fibers with FBG to become standard	Specially tailored optical fibers for medical applications

If the fiber cladding and core are applied at different points with different influences, such as a temperature difference, a strain, an acceleration, or a tilt, the refractive index is changed and another wavelength change is seen in the interference reflection. The measurement is thus based on a change in wavelength. The absolute wavelength of the individual measuring points is used for a defined state to be calibrated. A cascading set of different sensors is not a problem [14] (Table 11.3).

One end of the optical fiber is provided with an optical connector, such as those used in the telecommunication and information technology industry. With this connector, the fiber is connected to the polychromator, which contains an LED with a special spectrum that is emitted into the fiber.

The optical fiber includes a light-conducting core, which is set with impurity atoms (doping).

The core is enveloped by the cladding. It reflects stray light back into the core minimizing the loss of light even over long distances.

Multiple measurement points, precise and different interface patterns, may be introduced at any position in the fiber during manufacture. This is done by different high-energy UV exposures of the doped fiber to an interference pattern, depending on the UV light exposure. Due to this exposure, there is a periodic arrangement of refractive index differences in the fiber core. It creates about 10,000 semipermeable mirror surfaces with uniform distances at a measurement point. In every periodic refraction change a narrow wavelength is reflected. These reflected light signals superimpose to one large reflection at a particular wavelength when the grating period is approximately half the input light's wavelength. This is referred to as the Bragg condition (Equation 11.1), and the wavelength at which this reflection occurs is called the Bragg wavelength. Different wavelengths will pass the FBGs without attenuation [15]. As a protection against external influences and for mechanical reinforcement, the so-called buffer coating covers the core and the cladding [12].

$$\lambda_B = 2 \cdot n_{\text{eff}} \cdot \Lambda$$

Equation 11.1 Bragg condition, where λ_B is the center wavelength, n_{eff} the effective index, and Λ the period of the index modulation [15]. Because of the temperature and strain dependence of the parameters n and Λ, the wavelength of the reflected component will also change as a function of temperature and strain.

Strengths and Weaknesses

The main advantages of FBG are the lightweight and small size of the optical fiber, as well as the excellent performance in hazardous environments and its immunity to electromagnetic and radio frequency interferences. In addition, the optical fibers can be very long without losing information quality. It is possible to use single and multipoint sensors, since optical fibers have a high multiplexing capability.

However, there are also some limitations that come along with grating. The most fundamental disadvantage is the fact that they are simultaneously sensitive to strain, temperature, and pressure. Hence, adequate temperature compensation is always essential in the design and commercialization of reliable and repeatable physical sensors [16].

For technical applications, FBGs are already available as:

- Temperature sensors
- Strain sensors
- Displacement sensors
- Tiltmeters
- Pressure sensors.

Medical Applications, Navigation

Future fields of application for FBG sensors depend greatly on a cost reduction and the development of specific application fields with purpose built fibers.

One of the first commercially available applications is the pressure sensor in the TactiCath Quartz ablation catheter (St Jude Medical, St. Paul, Minnesota, United States).

Navigation could become a key application since multiple FBGs integrated into catheters, endoscopes, or introduced into anatomical structures (bile duct, blood vessels) could help to define precisely the shape and position of the respective item. The tiny diameter is particularly favorable. As an example, the intraoperative matching of the actual anatomy with the preoperatively gained 3D dataset could be significantly enhanced by intracanalicular FBGs. Likewise, the configuration of an endoscope could easily be described in real-time (which is currently done by EM tracking) (see Section 11.2: Electromagnetic Tracking Systems).

11.4 RADIO-BASED TRACKING SYSTEMS

Wireless indoor positioning systems have also become very popular in recent years in medicine, partly even in the surgical OR.

As compared to optical, EM, and fiber bragg tracking, the spatial resolution is lower which makes them suitable for the tracking of persons or larger devices, but not for, e.g., surgical instruments or smaller items. Fig. 11.10 gives an overview.

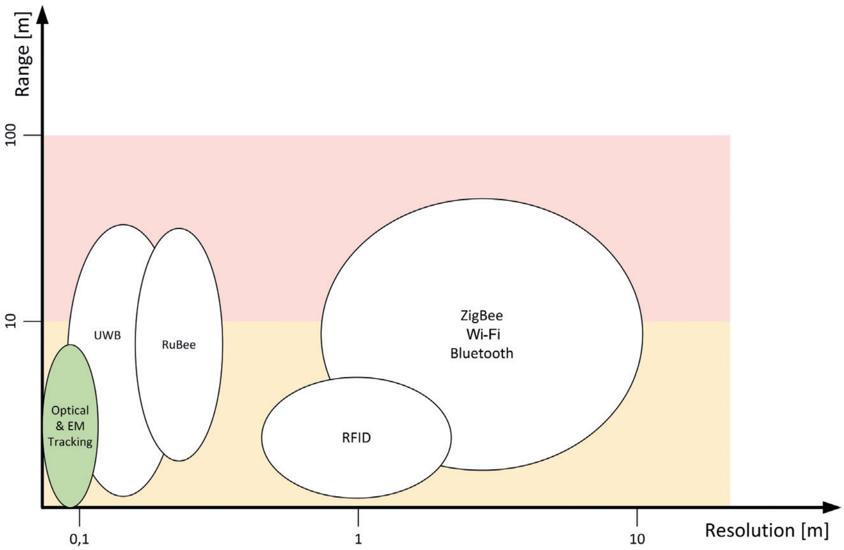


Figure 11.10 The most common radio-based positioning technologies suitable for biomedical use classified by resolution and scale in comparison to optical and electromagnetical tracking technologies. UWB: Ultrawide band, transmitting in microwave wavelength from 3.1 to 10.6 GHz; RuBee: transmitting in long wave at about 131 kHz; RF systems: working in four frequency bands: LF (125 kHz), HF (13.56 MHz), UHF (433, 868-915 MHz) and Microwave (2.45, 5.8 GHz); Wi-Fi, Bluetooth and ZigBee are already implemented techniques in many devices working in frequencies of 868 and 915 MHz, 2.4 and 5 GHz. *Modified according to Liu H, Darabi H, Banerjee P, Liu J. Survey of wireless indoor positioning techniques and systems. IEEE Trans SystMan Cybern Appl Rev 2007;37(6):1067–80* [17].

Radio-based real-time location systems (Radio RTLS) application can be categorized into asset tracking, workflow improvement, and patient/staff location [18].

A major issue in surgery are Radio Identification Devices (RFID).

11.4.1 Radio-Frequency Identification Devices

RFID use electromagnetic fields to localize specific markers (tags) attached to an object.

Currently, four different types of RFID exist.

- Low-Frequency RFID (LF RFID) with frequencies from 30 to 500 kHz (typically 125 kHz)
- High-Frequency RFID (HF RFID) with frequencies from 3 to 30 MHz (typically 13.56 MHz)
- Ultrahigh Frequency RFID (UHF RFID) with frequencies from 433/850 to 950 MHz
- Microwave/Super Ultrahigh Frequency (S-UHF) with frequencies from 2.4 to 2.5 and 5.8 GHz.

The higher the frequency, the better the range and data transfer rate. On the downside, the modules become more prone to interference caused by metallic objects or liquid in the area [19]. There are two main ways to operate RFID tags: active or passive (Fig. 11.11). Active tags are powered by batteries and send out information to the anchors whereas in passive systems, the antenna coil of the RFID reader generates a high frequent electromagnetic field. This induces a voltage in the antenna coil of the transponder tag. Additionally, there are semiactive tags available, which operate similarly to the passive tag. Semiactive tags can power

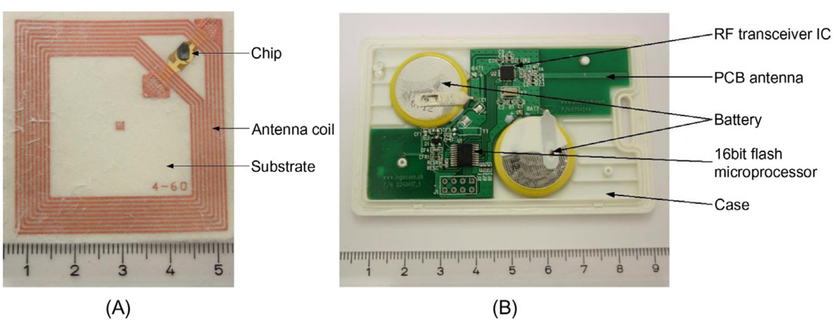


Figure 11.11 Structure of a passive (A) and an active (B) RFID tag. It becomes clearly visible that the design of the active tag is much more complex compared to the passive one. Miniaturization is challenging since a battery is necessary. *All from MITI.*

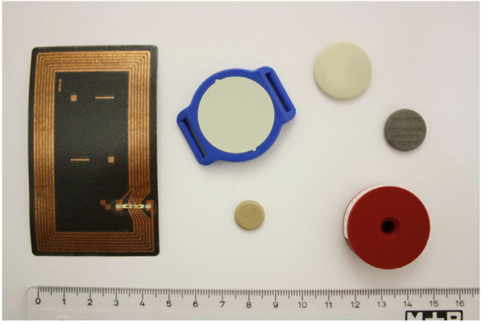


Figure 11.12 Different types of passive RFID tags which can only hold a limited amout of data. Reading range is mainly dependent on antenna size and design. *From MITI.*

electronics used in conjunction with off-board sensors like thermal sensors or accelerometers and can store information in a volatile memory. The range in active systems is specified as around 100 m with an achievable maximum of 500 m and in passive systems as under 10 m.

Simple transponders consist only of the antenna and the chip and can hold a 96-bit long Electronic Product Code, while more sophisticated tags are equipped with a EEPROM which can also be filled with data by special RFID readers (Fig. 11.12).

RFID readers

The RFID reader is a crucial hardware device which is establishing the connection over one or more antennas to the transponder. The RFID reader initiates and controls the communication with one or more transponders.

A microcontroller or an ASIC (Application Specific Integrated Circuit) communicates with the application software on one side with an integrated interface (LAN, Wi-Fi, USB, RS232/485, etc.) and controls the execution of software commands. In addition, the integrated controller is responsible for modulation of the signal for transmission and demodulation of received signals, while the high-frequency module generates, after receiving the corresponding command, the electromagnetic field (Fig. 11.13).

There are a variety of different RFID readers available. Main differences are the working frequencies and transmission protocols which must fit to the used tags, transmitting power, and communication interfaces. Furthermore, more sophisticated readers can prevent interferences by

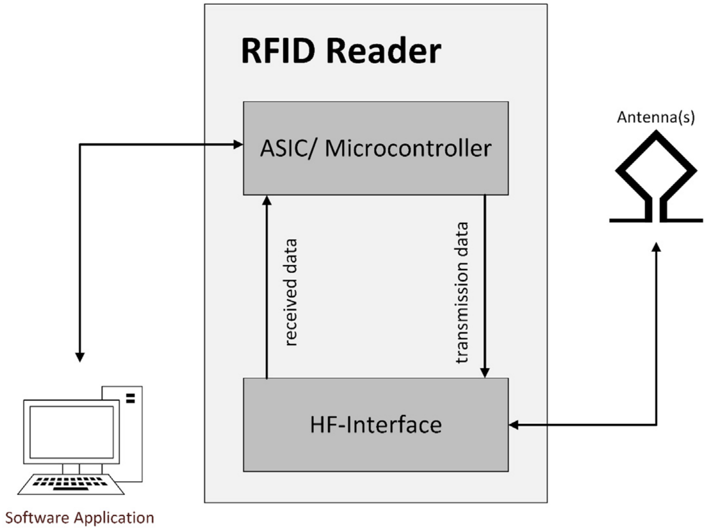


Figure 11.13 Principle of an RFID reader: The ASIC communicates with the host computer and controls the data stream in both directions with the HF-Interface connected to the internal or external antenna(s). *From MITI.*

different anticollision mechanisms. Depending on the application, three major interferences can occur:

1. Tag-to-tag interferences (collision), when multiple tags are simultaneously energized by the reader and reflect the respective signals back. Because of the scattered waves, then the reader cannot differentiate the individual IDs of the tags. This can be overcome by integrated anticollision algorithms [20].
2. Reader-to-tag interferences, where a tag is located at the intersection of two or more reader interrogation ranges and the readers attempt to communicate with the tag simultaneously. This interference can be eliminated by separating the interrogation range of the readers [21].
3. Reader-to-reader interference is induced when a signal from one reader reaches other readers which can be overcome by integrated RFID dense reader modes [22].

In addition to powerful readers with connectors for one or more antennas, RFID readers with already integrated antennas as mobile devices or for less demanding applications are available.

RFID Antennas

There are several different designs of antennas available, which strongly influence reading distance by the specific gain and beamwidth (Fig. 11.14). Higher beamwidth creates a broader area of coverage, but the beam will travel

(A) (B)

Figure 11.14 Comparison of RFID antennas for passive HF (13.56 MHz) RFID tags (A) and for active (2.5 GHz) RFID tags (B). Because of the required energy transmission and technology, antennas for passive RFID tags are much larger than for active technology. *All from MITI.*

a shorter distance. In addition, the maximal allowed energy for generating the electromagnetic field depends on the antenna design. Also installation of several antennas with an overlapping field influences the data transmission—null zones may occur where waves with the same circular motion overlap.

11.4.2 RFID Applications in Health Care

In recent years RFID technology has found its way into health care. Applications to reduce the potential occurrence of adverse events in the process of administration of drugs [23], tracking systems to measure patient flow [24], or even systems to count and track consumables and instruments were developed [25] (Fig. 11.15).

11.4.3 Bluetooth

Bluetooth is part of the 802.15.1 standard and its recent iteration consists of two types of operation modes:

- Classic

  Bluetooth works in the 2.4 GHz frequency band just as ZigBee or Wi-Fi but uses channels which do not overlap with the existing ones from the two other technologies. An integrated frequency-hopping tries to send messages automatically on free Bluetooth channels.

Figure 11.15 (A) Prototype of a surgical RFID application: Counting and localizing of abdominal sponges. In total nine towels are prepared, five are on the Mayo stand, two in the patient, one is used in the bin and one is missing. (B) Surgical sponge with integrated passive RFID tag [25]. *All from MITI.*

- Low Energy

In recent years, the 4.0 standard for Bluetooth was introduced. The new specification included "Low Energy" which, compared to the classic version, offered a compelling price-performance ratio for modules with predefined services, excellent battery performance but a slow update-rate.

According to [26], Bluetooth modules consume 80% less power and are, in general, less expensive compared to similar modules using Wi-Fi, but the data throughput as well as the possible range with these modules is less than that of other comparable technologies [27]. Bluetooth Classic uses 79 channels with a bandwidth of 1 MHz for communication while Bluetooth Low Energy uses just 37 with a bandwidth of 2 MHz and three additional channels for advertising. Both operation modes come with "Adaptive Frequency-Hopping" which allows the modules to jump on frequencies with less interference. In general, Bluetooth Classic requires more channels for inquiry or connection purposes which is why coexisting radio-based technologies in the same 2.4 GHz frequency band (such as Wi-Fi) can interfere. Bluetooth Low Energy, on the other hand, uses frequencies to avoid any interference problems (particularly with Wi-Fi).

Bluetooth trackers are relatively new and became fashionable with the introduction of Bluetooth Low Eenergy. Bluetooth tracking systems estimate the proximity to an anchor (beacon), but cannot calculate the exact location. Use of more than one beacon, however, generates overlapping areas resulting in sectors where something or someone is located.

11.4.4 Wi-Fi

- Advantages: based on standards; networks can be used for other things beside location tracking; high range; already deployed infrastructure can be used.
- Disadvantage: problems with influences/interferences coming from other networks or technologies in the same frequency band.

Access points of routers are used as anchors and small battery-powered Wi-Fi modules are used as tags. These can either work in the 2.4 or 5 GHz frequency band. Information is sent between the anchors and tags to calculate/estimate a position for the user, based on measuring the intensity of the received signal (received signal strength). A big disadvantage is the possibility of interference problems when using Wi-Fi on the same channels/frequencies as other devices that create huge amounts of data traffic. Also, metallic objects or liquid can cause signal fluctuations and subsequently result in inaccurately calculated positions. But on the other hand, existing Wi-Fi infrastructure can be used for location tracking purposes and the possible detection range as well as data throughput rates are high [28].

11.4.5 ZigBee

- Advantages: based on standards; good performance even in difficult environments; long battery life; cheap; tags communicating with each other which can lead to building a bigger network consisting of tags.
- Disadvantage: problems with interference still exist.

ZigBee is based on the IEEE 802.15.4 standard and extends it with a specification regarding radio-based networks with a maximum range of 100 m. One of the features of ZigBee is the ability to link modules to a network of tags (also called "Wireless Sensor Networks") where each device can communicate directly or through neighboring devices with other devices in the network. The connections between the nodes are dynamically updated and optimized in difficult conditions which leads to accuracies of 1 m and a good battery life. ZigBee works in the 2.4 GHz frequency band and is often used in the home automation as well as in the location tracking sector. Problems with ZigBee arise through interference when it is used in coexistence with other technologies in the same frequency band [29].

11.4.6 Ultra-Wide Band

- Advantages: high accuracy; no problems with interferences or difficult environments; high range.
- Disadvantage: high costs.

Ultra-wide band (UWB) uses the frequency spectrum of 3.1 to 10.6 GHz and features a high-frequency bandwidth of more than 500 MHz and very short pulse signals (<1 ns) which lead to very high data rates [17]. These help to reduce reflections, multipath fading, and overlapping signals [30]. UWB is being used more frequently in the last years for accurate location tracking in research but has the big disadvantage of being too expensive. Due to its limited signal power, the maximum range of UWB is usually specified as 50 m [31].

11.4.7 RuBee

RuBee is a radio-based technology designed for military and medical asset tracking. It was developed by the company Visible Assets (Stratham, NH, United States) and is represented by the IEEE standard 1902.1. The technology serves as an alternative to RFID and tries to overcome the problems of this technology.

According to [32], the detection range can be up to 100 feet and the batteries of RuBee tags can last between 5 and 15 years. Low frequencies (131 kHz) lead to less power consumption and with a long wavelength of 2289 m, it is less prone to interferences than other comparable technologies, such as RFID, even penetrating steel and water [33].

Another advantage of RuBee is the high scalability with an anchor being capable of managing up to 1000 tags. The tags come in a really slim form factor (usually credit card size). On the downside, the data throughput is worse than with Wi-Fi or ZigBee.

Although the technology comes with many advantages, such as being classified as a "Non-Significant Risk" class 1 device in medical visibility applications by the FDA or having no electromagnetical interference (EMI) or electromagnetical compatibility (EMC) issues in the operating room, we omitted it from the comparison in Table 11.4. The reason is that there was hardly any literature or empirical data available on RuBee. In addition, we could not get any development kits from providers in order to test and analyze the technology for ourselves.

Table 11.4 Comparison between radio-based technologies

Technology	Scalability	Price	Accuracy	Update-rate	Range	Durability
RFID	/	o	+	o	o	+
Wi-Fi	+	o	o	+	+	o
Bluetooth	o	+	o	o	o	++
ZigBee	++	o	+	o	++	+
UWB	+	−	++	++	+	+

11.5 ACOUSTIC TRACKING SYSTEMS

The efficiency and effectiveness of acoustic tracking and navigation is impressively demonstrated by nature: Bats rely entirely—and very successfully—on this sense. It is amazing how modifications of frequency, loudness, etc., are harnessed to gain maximal information. In medicine, the first applications were in ambient assisted living.

Acoustic sensors receive signals which are emitted by ultrasonic emitters with frequencies above the audible range of the human ear, at approximately 20 kHz, and determine their location via time-of-flight. A simple emitter–receiver pair delivers the distance obtained from the simple beat timing. For estimation of a position in a three-dimensional space at least one emitter and three receivers are required. An increase in resolution can be achieved by three emitters and three receivers tuned at different frequencies. Similar to infrared, the signals are distributed and mostly stay in a room, which is why the technology is commonly used to achieve room level or subroom level accuracy. Its low propagation speed of about 340 m/s returns results with a low time resolution. In addition, precision is affected by environmental variables like media density, reflections of the signal wave, temperature, and humidity. The limited accuracy and working volume limits the use of an acoustic tracking system to applications where low resolution is required. However, with improvements of the tracking algorithm and within a short tracking range, acoustic trackers are used to realize nonelectromagnetic tracking, achieving submillimeter accuracy, and have been found useful in cardiology studies where minimum electrical signal is expected [34].

11.6 INERTIAL TRACKING SYSTEMS

In general, an inertial navigation system (INS) is used with the method "Dead Reckoning" and requires two components: inertial sensors and a starting position. Inertial sensors can include accelerometers, gyroscopes, or magnetometers. They measure the (non)gravitational acceleration, the orientation, or the strength/direction of a magnetic field. With measurements like these, distances, angles, or the cardinal position can be calculated and used for further computation. Since the sensors can only detect changes from one state to another (the difference between state s_1 and s_2), a starting position has to be set and known to the INS. From the state s_0 at the starting position, all changes/measurements are added up to determine the current state. Extremely precise laser-based inertial tracking systems are large, expensive, and mainly developed for military use. However, in recent years small and cheap microelectromechanical systems (MEMS), with sufficient precision for most applications have become available. In contrast to laser-based systems, these have a sensor drift during long-term use. Typically, MEMS-based inertial tracking systems are used for control of robots, axes, acceleration measurements, body tracking, and stabilizations. On the basis of an inertial measurement unit, recently a system to determine the center

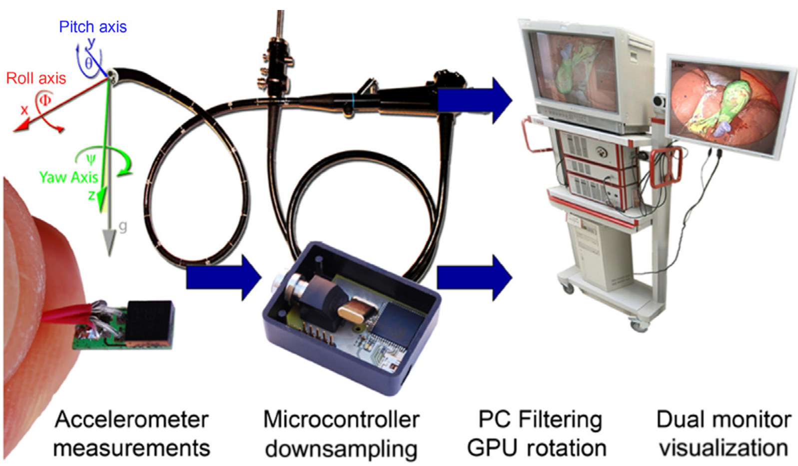


Figure 11.16 A tiny triaxial MEMS is placed on the tip of an endoscope. The impact of gravity on each of the three axes is determined. If the measuring frequency of the sensor is sufficiently higher than the usual endoscopic video frame rate of about 25 Hz, angle rectification of each single image is feasible [36]. *Courtesy: Dr. K. Höller, EIT Health e.V., Erlangen, Germany.*

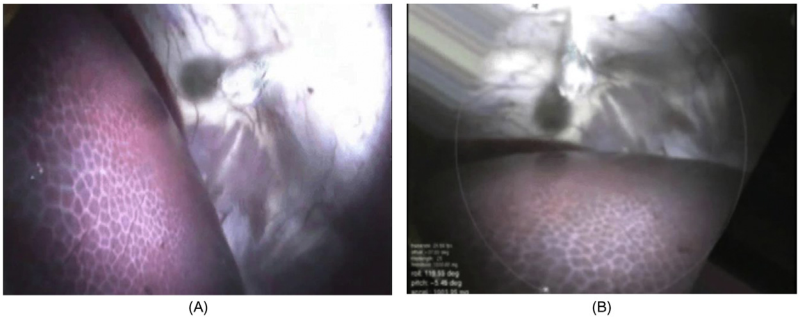


Figure 11.17 (A) A drop of water flying horizontally through the screen contradicts human experience. (B) If the normal horizon is reestablished, a faster and safer "understanding" of the site is facilitated. *All from MITI.*

of rotation of a patient's femur and to calculate the precise angles to cut the bone during knee replacement surgery was developed [35].

Inertial navigation is e.g., helpful to stabilize the image ("horizon") in endoscopic (videoscopic) surgery. If the shaft of the telescope or the videocamera is rotated, the surgical site is presented obliquely. Using an inertial sensor attached to the tip of the endoscope, the horizon of the image can easily be reestablished (Fig. 11.16).

As shown in Fig. 11.17, the intuitive understanding of the anatomy is significantly deteriorated if the angle of the image is altered. Automatic rectification facilitates the perception of the surgical situation [37].

Horizon stabilization was also used for dynamic view extension during laparoscopy by combining it with simultaneous localization and mapping (SLAM) [38].

11.7 OTHERS

11.7.1 Depth Maps, 3D Surface Reconstruction

In advanced surgery, in particular in laparoscopic and robotic surgery and future NOTES, a continuous real-time distance determination would be a key enabling technology for numerous reasons [39]. In a more simple application, three, four, or more simultaneous measurements from different systems at a time could help to avoid collisions between a robotic arm and the anatomy or would be able to change the camera position dynamically to compensate the respiration shift to achieve a "stable" image. If a depth information is gained to each pixel of the image, a real 3D reconstruction of the observed surface is feasible. This would open the door for a broad range of new applications such as detection of the grade of relaxation, image rectification (see Section 11.6: Inertial Tracking Systems), improved intraoperative referencing of preoperative imaging, a more precise image stitching (see Chapter 14: Visceral Surgery of the Future: Prospects and Needs), and augmented reality. Within the few last years, some interesting new techniques have been developed to establish depth maps and to allow for 3D surface reconstruction. They may be categorized into two approaches [39]: passive methods which are based on images only, and active methods which need controlled photonic impulses to be projected onto the respective surface. It is amazing that most of these technologies have already found widespread use in production lines, the games industry, and the film business, but surgical applications are almost nonexistent. This is extremely regrettable, since they would have the potential to truly revolutionize surgical interventions.

11.7.2 Passive Methods

11.7.2.1 Stereoscopy

Stereo reconstruction is the most mature technique to measure the distance and to recover the shape of an object. Based upon the principle of triangulation, a pair of cameras acquires, after calibration, two images of the respective object. The stereo correspondence of each single point in the image is established. Now, structure triangulation based upon the well-defined geometric properties of the cameras can be performed. Stereoscopic reconstruction can easily be implemented in off-the-shelf stereo endoscopes [40]. However, it relies on distinct features for triangulation. 3D accuracy of depth computation for a given scene point can be enhanced by increasing the baseline distance so that the corresponding disparity is large. However such wide angle stereopsis methods introduce other problems. For instance, when the baseline distance is increased, the fraction of all scene points that can be seen by both cameras decreases [41].

11.7.3 Monocular Shape-From-x

Many cues can be used for inferring object shapes from images. Some methods are passive and need just one image-like shape from

- Contours
- Texture

- Shading
- Focus
- Motion

Theoretically, they should be highly interesting for surgical applications, in particular laparoscopy, since one camera only is needed [42].

However, they need considerable computer power and accuracy/velocity are not yet sufficient.

11.7.4 Simultaneous Localization and Mapping

Likewise, SLAM could be suitable for surface reconstruction, in particular visual SLAM, but this technique is still too complex to be used for surgical purposes.

11.7.5 Active Methods

Active methods use controlled light which is projected onto the anatomy. Currently, mainly two methods are evaluated for (laparoscopic) surgery.

11.7.5.1 Time-of-Flight (ToF)

Time-of-Flight (ToF) cameras produce a depth image by measuring the distance for each corresponding pixel in the scene. These cameras can be used to estimate topological information without the help of computer-vision algorithms.

Since the velocity of a light beam is far too fast for any direct measurement at a short distance, e.g., 10 cm, the run time of light emitted from the light source of the camera and the object observed can be determined by measuring the phase difference between emitted and reflected light. Thus, 3D structure information can be acquired noninvasively and without markers.

If a beam splitter is used (Fig. 11.18), depth information can be simultaneously gained with the normal RGB laparoscopic image.

As compared to stereoscopic approaches, the main advantage of ToF is that it is independent of texture information, since it does not need optical correspondences and it is independent from the scene illumination, but the resolution is lower. Another specific problem are specular reflections which have to be eliminated. Considerable pre- and postprocessing is required to gain robust information.

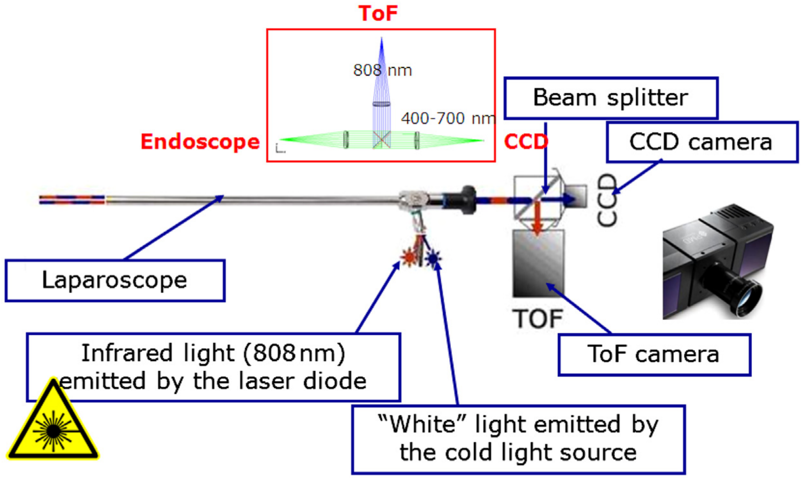


Figure 11.18 ToF/RGB endoscope system using a beam splitter to acquire the laparoscopic view and depth information through one telescope. *Courtesy: Dr. K. Höller, EIT Health e.V., Erlangen, Germany.*

11.7.5.2 Structured Light (Color-Coded Triangulation)

Structured light for measurement of the depths became widely known with the introduction of Microsoft Kinect. A known pattern of light (e.g., grids, horizontal bars, or dot patterns) is projected onto the surgical site. The way they are deformed when striking the different organs allows vision systems to calculate the depth and surface information of the different objects (Fig. 11.19).

To achieve a depth map, an artificial pattern is projected onto the tissue, and imaged with a camera system. By analyzing the distortion of the reflected pattern the surface of the scene can be reconstructed using computational techniques (Fig. 11.20).

11.8 STRENGTHS AND WEAKNESSES OF REAL-TIME 3D SURFACE RECONSTRUCTION METHODS

The main advantage of stereoscopy is that it can be performed with commercially available 3D laparoscopic equipment. Accuracy and point density are high. Unfortunately, textural information is essential which is frequently not present under laparoscopic conditions. Other passive 3D reconstruction methods are not yet mature for clinical purposes.

Active techniques require additional light to be introduced at the surgical site and as a result can reliably deliver dense depth maps at high

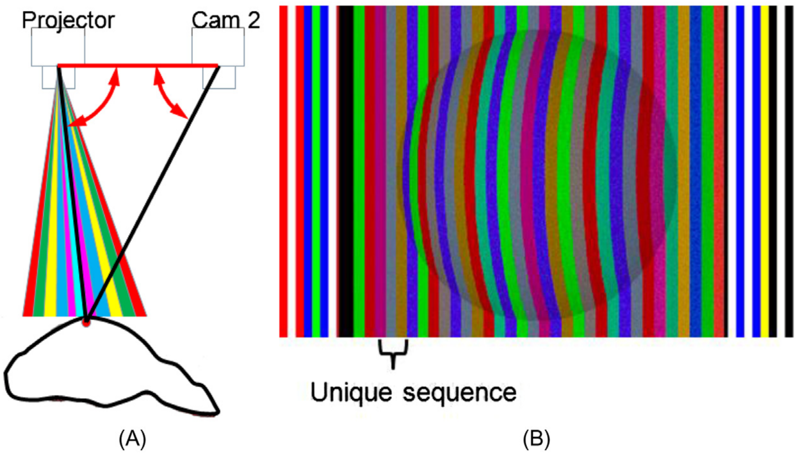


Figure 11.19 (A) and (B) The "structured light" approach requires one (calibrated) light projector and a camera to obtain 3D data. *Courtesy: Dr. P. Rentschler, SIEMENS CT, Munich, Germany.*

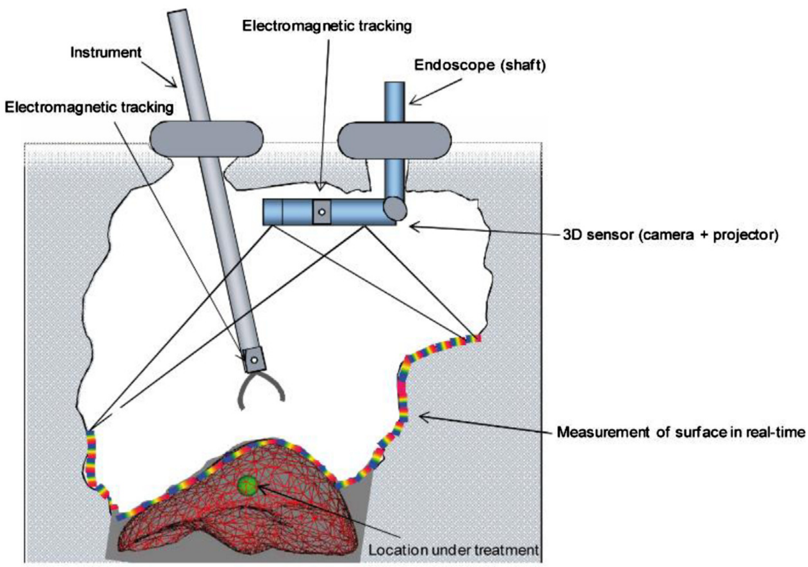


Figure 11.20 Depth map creation for referencing the surgical instrument with the anatomy. The position of the instrument and of the endoscope are electromagnetically tracked. Attached to the endoscope, the color-coded triangulation system provides real-time distance data. *Modified by D. Ostler.*

update rates because they do not rely on natural features. A common limitation is the required hardware equipment adaptation, which becomes important in the context of workflow integration and costs.

Structured light may achieve a reconstruction accuracy close to that of stereo, but density will remain much lower. Further improvements of the device and the projected features will allow for further increases in accuracy and reconstruction density. ToF, as the youngest technique, is still subject to severe systematic errors and noise. Although it is not yet ready for clinical application, it has potential as the only method that can generate dense depth maps in real-time without requiring a baseline.

Common to all techniques is that robustness (with respect to smoke and bleeding, for example) must be improved [43]. Also, online calibration to cope with changes in focus, for example, remains a technical challenge to be addressed, although newly emerging scopes with chip-on-tip designs can solve this by having infinite focus [39].

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CHAPTER 12

Health Informatics/Health Information Technology

Surgery is primarily based on manual activities. At first glance, doing surgery should have little to do with information technology or "digitalization." The contrary is true. The management of the huge amounts of data produced by health care delivery and in particular surgery is only conceivable by smart software support.

In the last decades, a new knowledge domain has evolved: "Health informatics." It is focused upon the communication and use of information in the health care sector with the help of computer science.

Not all aspects of this exponentially growing field are relevant within the range of biomedical engineering in visceral surgery, but many of them play a key role for delivering surgical care and enabling further progress in visceral surgery. The so-called "hospital information system" (HIS) is a key component of any surgical unit.

12.1 HOSPITAL INFORMATION SYSTEMS

A HIS is the comprehensive computer network established in a hospital as the backbone of all medical, organizational, and administrative activities. It is the precondition that each type of information is stored and easily accessible wherever it is needed. It comprehends verbal descriptions (e.g., history, type of complaint, etc.) as well as figures (e.g., laboratory findings) and static or dynamic images (X-ray, endoscopy, sonography, etc.). Beyond simple, easily accessible data storage, the HIS should also facilitate:

- Data processing
- Documentation
- Organization
- Communication
- Decision making

Still today, the terms "HIS" or "electronic health record" (EHR) do not yet allow a precise definition since the concept comprises a wide range of different information systems [1]. Nevertheless, some characteristics of surgical information systems will be pointed out.

12.1.1 Specialty-Specific Extensions

HIS is often composed of additional specialty-specific extensions, such as the picture archiving and communication system (PACS), a pathology, laboratory, or pharmacy system.

12.1.1.1 Picture Archiving and Communication System

Until 1970/1980, radiological information/findings were communicated using X-ray films.

Analog X-ray images had many drawbacks. Under practical conditions, they often vanished or were misplaced. Surgeons spent a lot of time finding the relevant images among the collection of images belonging to the individual patient. Large archives were necessary ("silver mines") with a strict administration. The development of modern imaging modalities like multislice CTs or MRI increased the information load exponentially. Without an effective digital management of visual information, the full potential of modern imaging technologies could never be exploited. Accordingly, both the industry and the users developed radiology information systems (RIS), which were later integrated into the HIS as a PACS.

The most important precondition for developing the PACS solution was a standardization of the content. After many initial problems, the so-called DICOM (Digital Imaging and Communications in Medicine) standard has become sufficiently reliable to allow for a communication between the devices of various manufacturers (handling, storing, printing, transmitting).

DICOM allows for the integration of digital data of scanners, video cameras, servers, workstations, printers, and network hardware provided by different companies into one PACS.

12.1.1.2 Others

Similar modules are available now (though the degree of maturity is lower) for the management of laboratory findings, pathology, and many other medical specialties including nursing. For visceral surgery, endoscopy management systems, and tools for ambulatory surgery and preadmission tasks, as well as operating rooms' scheduling have to be mentioned. The overall construction of an HIS is always a trade-off between monolithic solutions usually designed by one single (universal) provider and a combination of highly specialized "insula-solutions" which often have been developed locally or by special providers (not infrequently companies providing the discipline-specific hardware) (Fig. 12.1).

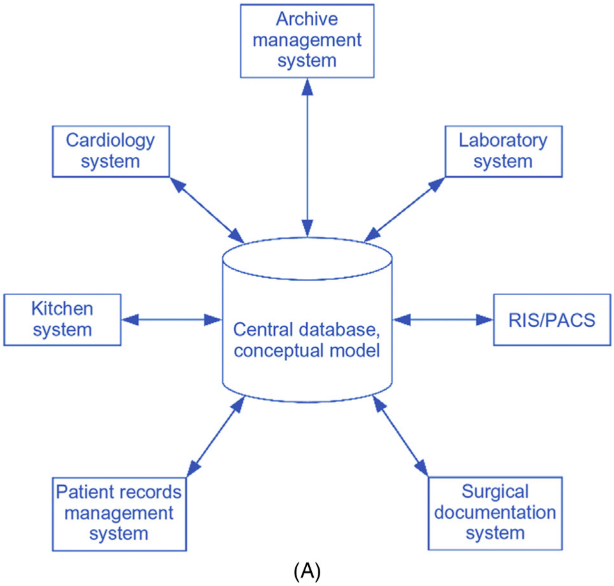
Beyond supporting the clinical and medical care activities, the HIS should also enhance administration (material services, financial tasks including budgeting, payroll, etc.).

Thus, costs and performance can be continuously evaluated. This is of outstanding importance, since the traditional practice for reimbursement on a fee-for-service basis is internationally shifting to capitation or fixed rates for the respective disease. Therefore, health care providers are forced to provide high quality care at the lowest possible price. This can only be achieved if information about the performance is valid, timely, and comprehensive. Accordingly, financial pressure is another driver for high quality HIS. Worldwide, a huge market came into existence with several hundreds of local and international providers. This makes standardization and communication difficult. Surgeons have to take particular care that the pre-, intra-, and postoperative workflow is completely integrated into the HIS [2].

However, the more the function of a surgical unit depends on an HIS, the more it is endangered if something happens to disrupt the HIS operations. White et al. [3] suggest a contingency plan in case an HIS should stop functioning which encompasses the following elements:

- A data backup plan for creating and storing copies of electronic health information
- A recovery plan to restore lost data
- An emergency mode operations plan so facilities can continue performing required operations
- An assessment of all applications that would be affected (including the impact of a widespread outage), and
- Protocol for testing and revising the contingency plan.

The most important aspect in a surgical unit, besides data backup and a disaster recovery plan, is an emergency mode operations plan. Each single surgical unit must have, as a matter of course, a backup of its HIS functions just as it is equipped with an emergency power generator in case of electrical power failure.



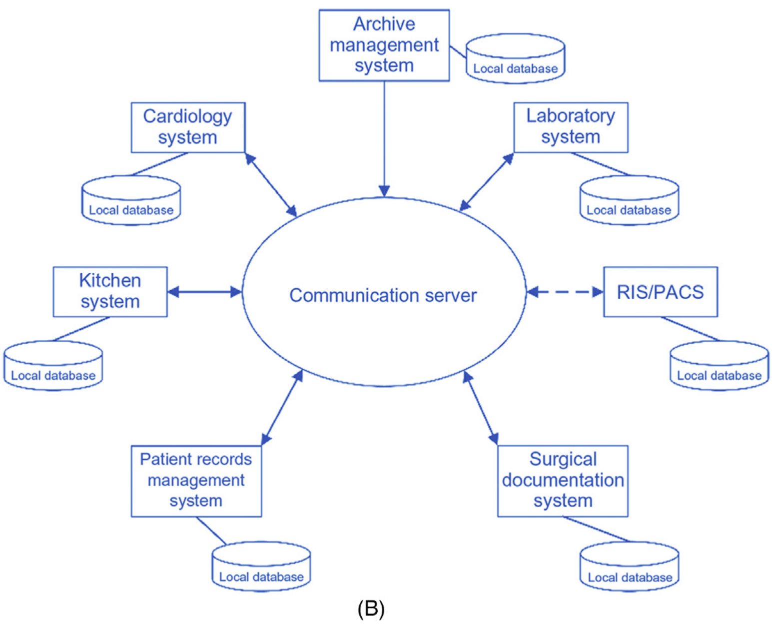


Figure 12.1 Centralized ("holistic") (A) versus distributed ("heterogeneous") (B) HIS solutions. The holistic architecture is easier to mend, but the specifically designed modules of the heterogeneous approach are more user-friendly, since they are better focused on the clinical needs. *All from MITI.*

The first HIS were introduced into surgery more than 20 years ago. Some scientific analyses are available now concerning the real impact upon quality of care which will be presented later.

First, some examples of typical surgical applications will be given.

12.1.2 Health Informatics On-Site

The practical importance of the HIS for surgery will be demonstrated in four typical scenarios: Outpatient department, surgical floor, multidisciplinary conference, and the OR.

12.1.2.1 *HIS in the Outpatients (Preadmission) Department*

Prior to his/her surgery, the patient has to see the surgeon who checks that the indication is given, and, if so, accomplishes the necessary procedures to prepare everything for the operation considered (see Section 3.3: Structure and Organization of Surgical Care).

A new file has to be created for each individual case.

Information gained by previous (external) diagnostic procedures has to be integrated.

Currently, this is still a major problem. Direct digital transfer (e.g., from the referring family physician) is still uncommon. In most cases, the surgeon has to take over the relevant external information manually which costs avoidable time and efforts (Fig. 12.2).

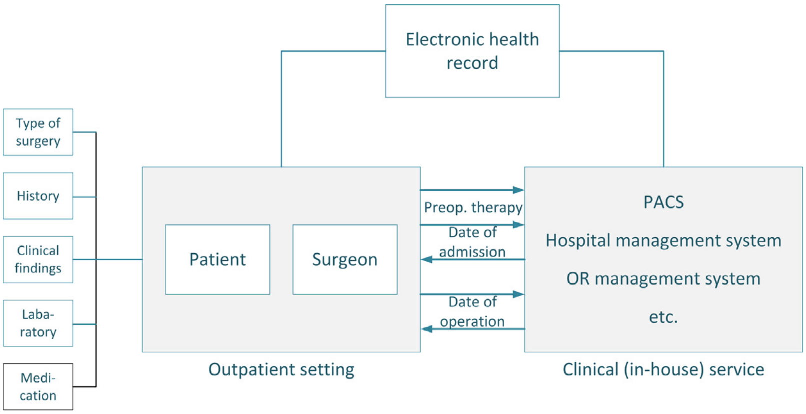


Figure 12.2 Preadmission visit for elective surgery. *From MITI.*

Modern imaging (CT, MR, etc.) are increasingly often presented by the patient on a data storage device.

12.1.2.2 HIS in the Surgical Floor

The HIS is the key tool for the surgeon and the nursing team to organize and to manage the specific tasks to be done on a typical surgical unit.

Admissions, discharges, but also scheduling of additional tests are based on a digital basis.

Documentation of observations, prescription of drugs, etc. during the doctor's visit is increasingly often performed digitally by means of mobile handheld devices, replacing gradually the handwritten notices on the patient charts (Fig. 12.3).

Laboratory findings and imaging results are directly accessible at the point of care—the patient's bed.

The extent of information directly available at the point of care could be theoretically unlimited if the HIS could be used by means of a suitable handheld device. Currently, suitable technical solutions are being evaluated all over the world (Fig. 12.4).

(A) (B)

Figure 12.3 (A) The doctor's daily visit at the patient's bed together with the nurse. A manual card-filing system is used. (B) The documentation system (here: Kardex) allows quick reference to the condition and needs of the patient. It contains the documentation of physical findings (blood pressure, pulse, body temperature, etc.), the schedule of medications, level of activity allowed, diet, the care plan, and the treatment procedures. *All from MITI.*

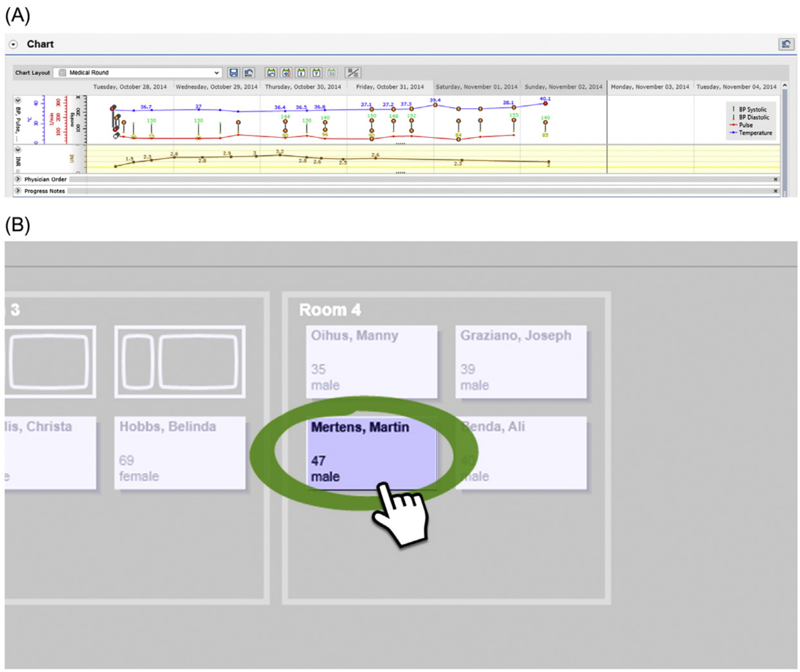


Figure 12.4 (A) The digital chart resembles the physical one, but is far more easily to handle and is more neatly arranged; (B) Instead of turning over the different folders, a simple finger touch leads to the selected patient. *All: Courtesy: Dr. M. Härdtner, Klinikum rechts der Isar.*

12.1.2.3 HIS for Multidisciplinary Conferences

Historically, surgery was the exclusive answer to many, in particular, oncological diseases. If surgery was impossible (or no longer feasible), the disease took its natural course. Nothing was left for the physician to do for his/her patient than provide the best supportive care.

Stepwise, alternative therapeutic options were invented. Radiation therapy was developed, as soon as physicians became aware of the fact that high-energetical X-rays were capable of reducing tumor growth. Later on, chemical agents were identified to reach this aim (chemotherapy). The next step in this line was the detection of immunotherapeutic approaches.

The availability of auxiliary therapeutic principles fostered combined approaches (multimodal treatment strategies). Even if a tumor was not resectable when it was diagnosed, a so-called "pretreatment" with

Figure 12.5 A look into a typical "therapy board." The individual case is presented by the responsible physician. This is followed by the demonstration of the respective findings by the experts (e.g., gastroenterologist: endoscopies; radiologist: X-ray, CT, MRI; pathologist: histopathology). All aspects are discussed among the experts. Finally, a consensus should be found of how to proceed. The recommendation on the details of further treatment is documented. *From MITI.*

radiation and/or chemotherapy could bring it into tumor mass reduction which, finally, made it possible to strive for a surgical resection.

The promising auspices of multimodal therapeutic options require the elaboration of well-differentiated, individualized therapeutic strategies. It is an interdisciplinary task requiring a good coordination and cooperation of gastroenterologists, radiologists, oncologists, representatives of nuclear medicine, pathologists, and some other experts. Well scheduled and structured conferences are required to discuss each individual case and to define the adequate "multimodal" treatment (Fig. 12.5). All necessary information must be available immediately during the "therapy board," since each minute of this meeting of outstanding specialists is valuable [4] (Fig. 12.6).

Waiting breaks are intolerable. In addition, the decisions of the therapy board have to be accessible to all who are involved in the further treatment at anytime and the decision has to be achieved according to the legal requirements.

The use of the HIS, however, is not only a matter of organization (improving velocity and comprehensive access to previous and elaborated information). It is also a great opportunity to explore the data for scientific purposes ("data mining").

12.1.2.4 HIS in the OR

The OR is the central point of care in surgical health care delivery.

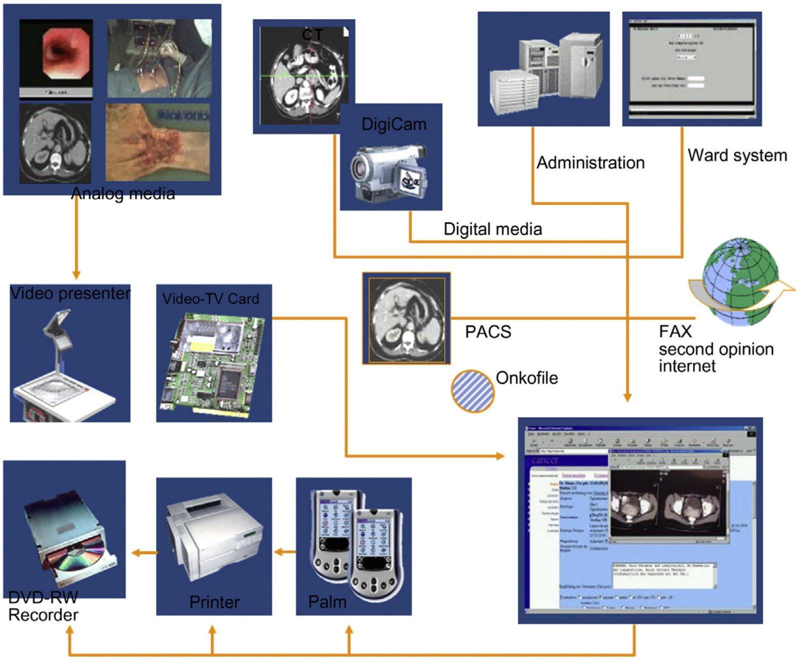


Figure 12.6 Overview of the most common data sources required in a therapy board. The HIS must enable them to be accessed quickly and on the spot. Finally the decision of the board has to be documented in a way that all medical shareholders are able to recall it in the later course of the treatment. *From MITI.*

On the one hand, the surgical team needs access to all the information on the patient which has been collected before. Relevant visual information (e.g., X-ray images, CT scans, endoscopic videos) should be displayed on a dedicated screen if needed (Fig. 12.7).

Likewise, any other information should be available online (laboratory findings, information about allergies, etc.).

No less important is the HIS for organizational purposes, since the efficiency depends upon the OR scheduling. It should facilitate a frictionless patient flow to, through, and from the OR to maximize the number of cases per day and to reduce as much as possible the required resources and related costs.

The decision of how to use the ORs to care for a given number of patients per day—and in which order—depends upon numerous parameters:

Availability (and qualification) of surgeons and anesthetists, availability of qualified nursing staff, but also the capacity of the recovery room, just to name a few. In addition, patient-related aspects strongly influence the

Figure 12.7 During a laparoscopic surgery, a slice of the preoperative CT scan is displayed on the additional monitor (arrow). *From MITI.*

scheduling, like the estimated operating time, the germ load (e.g. MRSA), etc. This makes the organizational part in the OR extremely difficult. The use of an HIS with its specific extension for operating room scheduling management, interlinked with an anesthesia management system, is indispensable.

Again, a wealth of dedicated information systems are on the market which are certainly helpful but still lack the capability of active help. This means they provide comprehensive and reliable data almost in real time and help to prepare decisions, but they do not offer automatic support by performing necessary actions on their own. Only in areas where potential failures are less risky or dangerous, such as material flow, or some autonomous procedures, such as reordering of consumables, are the actions already partially automated.

12.1.2.5 HIS and Quality of Care

Notwithstanding the importance of HIS concerning administrative and financial aspects, the surgeon/clinician is primarily interested in the impact on improving the quality of care. Most of us are convinced that health information technology will improve quality and efficiency of health care institutions, from small practices to large centers [5]. However, as shown clearly by Yanamadala et al. [6], the evidence up to now is comparatively low. Most studies on the topic concentrated on the process quality matrix, analyzing physician level variability and guideline compliance rather than overall quality improvement of patient outcomes [7]. One study suggested that electronic health care records have the potential to decrease medical errors by providing improved access to necessary information, better communication, and integration of care between different providers and visits, and more efficient documentation and monitoring [8]. However, overall improvements in patient outcome associated with health care informatics are still not yet well documented. In particular, the effect of the implementation of HIS on inpatient adverse events, inpatient mortality, and the readmission rate for specific surgical conditions has yet to be explored. Accordingly, Yanamadala et al. [6] tried to find out whether hospitals with fully implemented electronic health care recording (EHR) systems had better patient outcomes compared to hospitals with partial or no implemented EHR system. Insofar, the study provided new information about the relationship between the implementation of HIS and a quality of health care delivery in inpatient setting.

The results were striking. In the cross-sectional analysis surgical patients treated at hospitals with full EHR had higher mortality rates than patients treated in hospitals with partial EHR or at hospitals with no EHR. Patients treated at hospitals with full EHR had higher readmission rates than patients treated at hospitals with partial EHR but lower readmission rates than patients treated at hospitals with no EHR. Surgical patients treated at hospitals with full EHR had higher rates of complications than patients treated at hospitals with partial EHR. Surgical patients treated at hospitals with full EHR had a shorter length of stay measured in days than patients treated at hospitals with partial or no EHR.

Obviously, the effect of EHR introduction was not associated with improved patient outcomes (specifically inpatient mortality, readmissions, and complications). Although EHR systems are thought to improve quality of care, this study suggests that in their current form EHRs have not yet begun to reach meaningful use targets and may have a smaller impact than expected on patient outcomes.

Another study reviewing evidence regarding the impact of health information technologies on surgical practice came to rather disillusioning results as well [9].

In a careful meta-analysis, 32 observational studies and 2 randomized controlled trials were evaluated. EHR improved appropriate antibiotic administration for surgical procedures in 13 comparative observational studies. Another five studies indicated that electronically generated reports had increased accuracy, completeness, and availability in the medical record. Otherwise, no further advantages could be demonstrated. They concluded that the quality of evidence about the effects of health information technologies in surgical practice is still low and further research is needed to optimize the efficacy. The methodology is already well established [10].

12.1.2.6 Data Mining

Each single case produces a vast amount of data: individual state of the patient and medical history, preoperative imaging, intraoperative findings, surgical care including the specific type of intervention and the final outcome. These data will be easily accessible in the future since all of them are stored in a digitalized manner. Self-evidently, these comprehensive databases are too large-sized and complex for manual knowledge extraction, but computer science offers now sophisticated methods of automatic analysis of large quantities of data that will also allow to extract previously unknown information. The hidden treasure of information from a vast number of cases is now accessible to identify the most adequate therapy for each individual patient and to bring surgery to a new level of quality (Fig. 12.8).

Self-evidently, surgeons always tried to evaluate the mass of clinical experience for predicting the prognosis and to individualize/optimize the therapeutic strategy. Prof. K. Maruyama, a highly renowned specialist in

Figure 12.8 The nightmare of scientific surgery: The huge wealth of information collected over decades from tens of thousands of patients/treatments are buried in the archives and destroyed after a certain period of time (mostly 30 years).

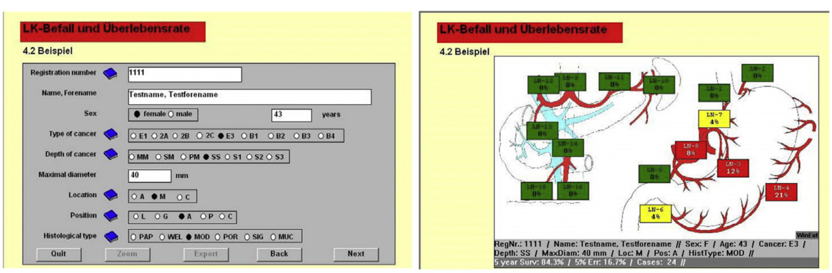
gastric cancer surgery, developed a new classification program for knowledge extraction already decades ago.

In each of his patients with gastric cancer, he documented prospectively any relevant detail (epidemiology, type, localization, grading, etc. of the tumor), then performed surgery (with the opportunity to confirm or modify the preoperative findings) and observed the further course [11]. After about 8000–10,000 individual patients, he was not only able to predict rather reliably the 5-year survival rate of an individual patient but also to give reliable information upon the required extent of the surgical resection. This offered surgery the chance to become individualized (Fig. 12.9).

Based upon the preoperative information of which lymph nodes were inflicted and which ones were negative, lymph node resection could be limited to the minimum. A considerable number of gastric cancer resections could be performed in a less invasive manner.

The value of the Maruyama classification was underestimated. Not too many surgeons recognized it as a basis for "tailored surgery," although the validity, even in Europe, was confirmed [12]. However, the basic idea was excellent. About 30 years later, electronic health records would not offer the chance to exploit the knowledge which is uselessly hidden in the archives.

The rapidly expanding field of big data analysis provides now the tools to accumulate, manage, analyze, and assimilate large volumes of disparate, structured, and unstructured data produced by health information technology [13].



(A) (B)

Figure 12.9 (A) The prospective evaluation of any kind of gastric tumor stage is the basis for the prediction of true tumor extension and lymph node infliction. (B) Close and distant lymph node groups in gastric cancer. Inflicted lymph nodes are marked in red (dark gray box with white labeling). Lymph node groups in green (dark gray box with black labeling) should be free of tumor cells [11].

It can certainly support in decision making, replacing perhaps, in the future, costly and long-lasting clinical trials.

12.2 SURGICAL TELEMATICS/"TELESURGERY"

Surgery of the future will become increasingly more transparent and open-label. Laparoscopic surgery is video based by nature, and in many ORs lights for open surgery video cameras are integrated. Accordingly, the surgical procedure becomes visible not only to the OR team but also to—at least in theory—an unlimited number of spectators. This offers new opportunities for quality control, education, training, etc., if the view into the surgical OR can be shared with others even over great distances.

12.2.1 Teleconsultation

In case of difficult intraoperative decision making, external consultants are sometimes required—e.g., a senior expert or a specialist from other disciplines.

This is time-consuming and tedious both for the OR team (waiting) and the consultant who is forced to walk to the OR, change clothes, etc. To avoid the physical presence of the consultant, teleconsultation could be an answer. The first attempts to use teleconsultation in surgery were made more than 20 years ago [14]. However, consultants needed appropriate equipment in their office or had to go to a room equipped with telemedicine facilities. In daily routine, this was too impractical to make teleconsultation popular [15].

To overcome these limitations, and to allow spontaneous video communication during routine clinical activities, mobile video consultation systems could be better. The first attempts were made about 10 years ago [16] (Fig. 12.10).

It took another 10 years until it is now mature for routine clinical use. Experts are now able to attend virtually any operation. They are able to communicate with the surgeon at the point of care, give advice, etc.

12.2.2 Telepresence

Telepresence is a more sophisticated version of teleconsultation. Whereas the latter is merely based upon visual and oral information, in

Figure 12.10 Mobile device with video at original size (left) and zoomed to full screen (right): laparoscopic view of the liver [16]. *All from MITI.*

telepresence the consultant is able to take an active part in the process at the point of care.

If an active camera holder is used during a laparoscopic surgery, he/she is able to control the camera. In case of open surgery, he/she can remotely move the OR camera mounted in the OR lamp to get optimal insight into the surgical field. In addition, he/she can clearly indicate at the surgical site what he/she is speaking about, e.g., by using a cursor on the monitor in video-based surgery or a "telestrator" in open surgery [17].

The next step would be telesurgery, i.e., the surgery being performed by the remote expert.

12.2.3 Telesurgery

The idea of teleoperation came up about 20 years ago, when the first two master–slave units (DaVinci, ZEUS) appeared on the market (see Section 10.1.2: Master-Slave Systems). In this type of surgical robot, the surgeon in his/her "cockpit" is separated from the OR table and the patient. Thus, the surgeon may be located in the United States, and the operation could be going on in Europe—this has already been demonstrated in a pioneer application in 2001 [18].

However, telesurgery still is too expensive up to now to gain a role in practical care. What weighs even more are the technical shortcomings like the high end-to-end latency and the limited availability. However, this pioneer phase will certainly be left soon [19].

It is expected from the oncoming 5G program that the specific requirements of telesurgery will be met: guaranteed and reliable

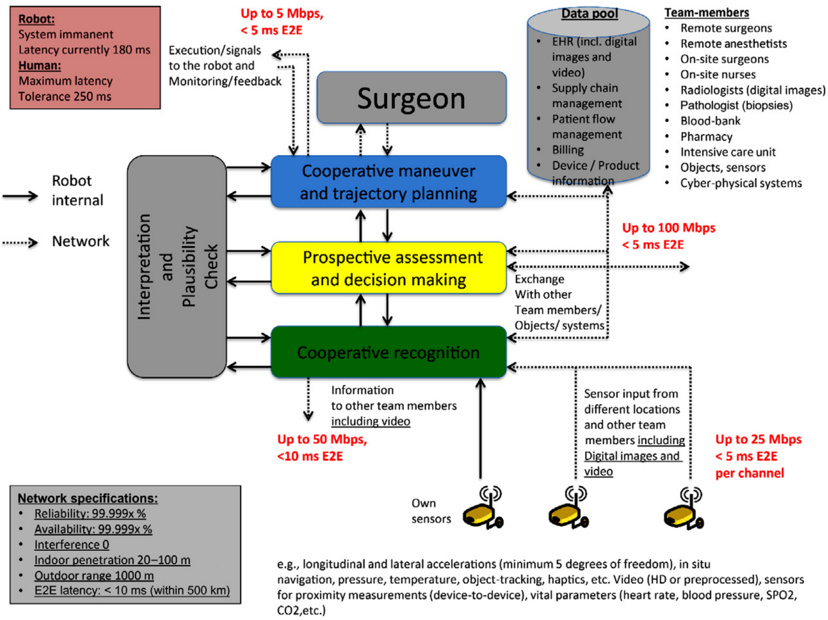


Figure 12.11 Telesurgery is a complex process: Players, functionality, and technical requirement of data streaming. *From MITI.*

availability of information from back and data bases and real-time data streams from a large variety of sources (Fig. 12.11).

However, telesurgery is not only meant to be performed over large distances but even within an OR theater. Even today, the surgeon is already separated from the patient by meters while the operation is mechanically performed by a machine. In the future, the application of uncoupled robots and microsystems will require the further development of telesurgical systems that have to provide a comprehensive sensorial input.

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CHAPTER 13

Training and Simulation

Simulation and training (S&T) in medicine is most often understood as a synonym of surgical education. This is certainly the major field of application, but beyond it, additional fields have to be considered, such as individualized therapy planning for the experienced surgeon or the evaluation of new instruments.

S&T becomes increasingly important in modern visceral surgery because of multiple reasons:

- The rapid development of new surgical techniques requires that surgeons continuously learn to master these new techniques.
- Patients become increasingly demanding in regards to safety. Surgical failures are less accepted than ever.
- OR time becomes increasingly costly. Training at the OR table is time-consuming [1].
- Suitable cases for surgical training are rare. Accordingly, surgical education at the OR table is the "needle hole" of the surgical curriculum (Fig. 13.1).

13.1 TRAINING AND SIMULATION FOR SURGICAL EDUCATION

Surgery needs talent and experience. The natural gift of being particularly dexterous is attributed to outstanding surgeons ("golden hands") to explain their success, but manual skills are mostly overestimated. Beyond personal features like stress resilience, surgical professionalism is coined by additional factors (Fig. 13.2). Before doing the surgery, the surgeon has to have a clear concept of what has to be done and in which sequence the actions have to be executed ("procedural knowledge").

In other words, he should know the precise and detailed "model" of the operation (see Chapter 14: Visceral Surgery of the Future: Prospects and Needs).

The second factor or element of surgical education is the acquisition of cognitive knowledge. The surgeon has to be able to recognize

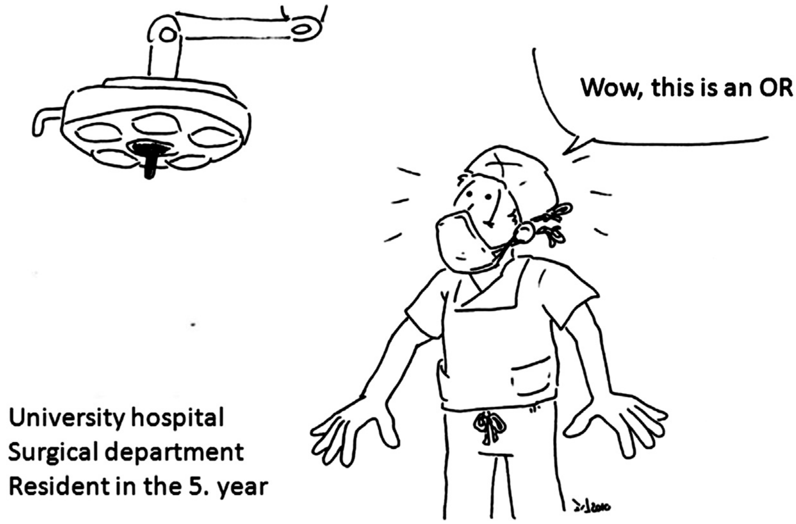


Figure 13.1 Real surgical education in the OR comes often late in the educational curriculum. *Courtesy: Dr. M. Maak, Universitätsklinikum Erlangen.*

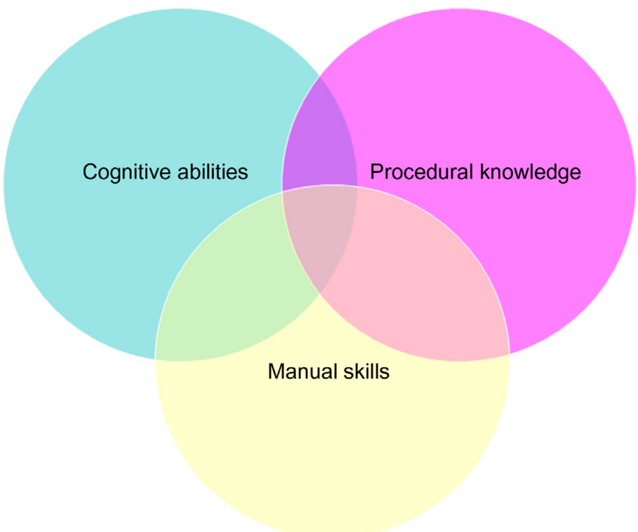


Figure 13.2 Three pillars of surgical success: Every surgeon has, self-evidently, to acquire the necessary manual skills. In addition, he/she must possess the right cognitive abilities, understand the respective situation (knowledge of the visible and invisible anatomy, critical sites, etc.). Last but not least, he/she must be able to execute the task by an adapted surgical strategy. *From MITI.*

Table 13.1 Currently available options for surgical education and training

Cadaver studies	Fresh/preserved corpses
Animal studies	Pigs; Sheep
Analog models	Knot benches; Box trainers; Manikins
Hybrid models	External artificial environment/organ packages
VR models	Basics; Advanced procedures

the anatomy and to identify pathological conditions. The different tissue layers have to be detected. Similarly, dangerous areas have to be respected, etc. Each individual situation has to be interpreted correctly.

Last but not least, he/she should of course be able to carry out what has to be done. Knowing about what has to be done still does not yet mean that the individual is actually able to do it. Intensive manual exercise is required (manual training).

In the past, learning by doing under the surveillance of senior representatives of the art of medical care was the main process to achieve a professional level. This was complemented by theoretical lectures and studies of the literature, but training in surgery remained a matter of apprenticeship.

With the rise of modern academic surgery, additional options were looked for to improve the effectiveness of surgical training/education (Table 13.1).

13.2 CADAVER STUDIES

They offer the opportunity to work under "normal" anatomical conditions.

The surgeon can interact with the very structures he/she also has to manipulate during the surgical operation.

However, getting access to human cadavers for undertaking therapeutic studies is becoming increasingly difficult. Ideally, fresh corpses should be used but they are seldom available in time. Accordingly, preservation is required, which presents quite a number of practical problems. Various methods of preservation are available (Table 13.2):

- Quick-freezing
- Formalin preservation

Table 13.2 Comparison of different preservation methods for cadavers [3]

Method	Formaldehyde concentration	Costs	Advantages	Disadvantages
Fresh-frozen cadaver	0%	Very high initial cost and running cost (cost per cadaver inestimable)	Flexible joints and tissues, realistic color, minimal tissue change, well studied	Infection risk, deterioration throughout usage period (on an hourly basis), mounting of body parts when not using full cadaver
Formalin	About 4–8%	Initially low (about US$15 per cadaver)	Longevity, minimal infection risk, good histological quality, very well studied	Stiff joints and tissues, discolored, unnatural texture, poor imaging quality, not suitable for insufflation or ventilation, health hazards including carcinogenic property
Thiel's method	0.6%	High (about US$300 per cadaver)	Flexible joints and tissues, almost realistic color, good imaging quality, ability to ventilate, well studied	Deterioration throughout usage period (on a daily basis), poor histological quality, technically difficult and need time for embalming process
Saturated salt solution method	0.75%	Low (about US$30 per cadaver)	Natural color, comparatively low deterioration throughout usage period (on a monthly basis), good imaging and histological quality, ability to ventilate (not well validated)	Somewhat rigid joints and tissues, edematous (particularly subcutaneous tissue), change in state during storage period, not well studied

- Thiel's preservation
- Saturated salt preservation

Freshly frozen cadavers, as soon as they are thawed, come very close to real conditions, but they are very costly and endangered by rapid putrefaction.

Since many pathogens are not significantly harmed by deep freezing, the risk of infection is significant.

Formalin preservation has been the most popular technique since it was introduced in 1893. Formalin is cheap and effective, but it hardens tissue leading to extreme rigidity even of soft tissue. The haptic properties are no longer comparable to reality.

A superior technique (Thiel's preservation) uses a composition of ammonium nitrate, potassium nitrate, sodium sulfite with small amounts of formaldehyde, ethylenglycol, boric acid, and p-chlorocresol [2].

It leads to a significant improvement of the biomechanical properties. The tissue remains soft and flexible, and the color comes closer to reality than after formalin treatment. The corpses are suitable for open surgical interventions, laparoscopic surgery, and flexible endoluminal endoscopy. Nonetheless, the difference to living tissue is still striking.

A promising alternative to the latter approach is the saturated salt method.

The latest innovation in cadaver training is the pulsated, revascularized, and reventilated corpse [4].

In general, training in human cadavers is expensive, difficult to organize, and even experienced surgeons often have to overcome some internal resistance to perform human cadaver experiments.

13.3 LIVE ANIMAL TRAINING

Animal studies are the only option if surgery has to be performed in living tissue. They offer important challenges, such as bleeding, perforation, and ischemia, which every surgeon should be able to manage or, even better, to avoid.

Various animal species are in use. Decades ago, monkeys were available which offered excellent working conditions, but today this is inconceivable for ethical reasons. In many parts of the world, pigs are the current standard in visceral surgery, whereas sheep are more popular in bone surgery. In addition, rabbits, dogs, and even chicken may be suitable for training purposes. However, animal studies are hampered by numerous problems.

The cultural or religious background is as important as the increasing bureaucratic workload due to animal protecting activities. Moreover, animal experiments require a dedicated infrastructure and professional (veterinary) care of the animal during the intervention (anesthesia, artificial ventilation, continuous surveillance). Constant supervision of the trainee by an experienced teacher is also mandatory, and the restricted amount of teaching time often makes live animal training difficult. Beyond that, animal anatomy often differs from human anatomy. Even in the pig—the intraabdominal anatomy otherwise being very close to human model—the configuration of the colon is completely different from human anatomy.

The question was raised of whether cadaver or pig training is superior for procedural training of residents outside the OR [5]. Apparently, both of them are necessary and helpful. In one trial, the porcine models were rated lower for anatomic relevance but higher for tissue handling and ability to dissect/identify planes.

At any rate, animal studies are very expensive and they will progressively lose social acceptance.

13.4 INANIMATE MODELS AND BOX TRAINERS

In order to acquire basic surgical skills like the adequate handling of the instruments, hand–eye coordination, simple—often homemade—models are used all over the world. They enable the surgeon to dissect tissue and to learn suturing and knotting ("knot bench") (Fig. 13.3). Many institutions

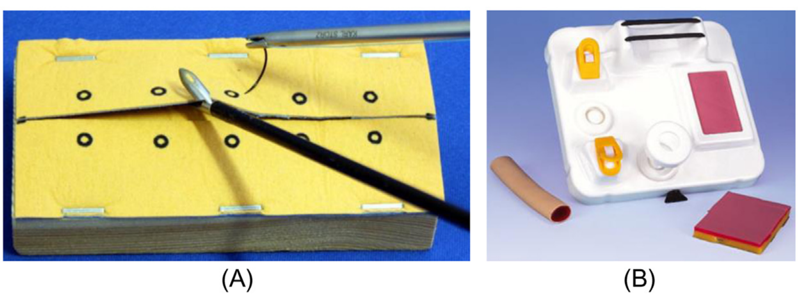


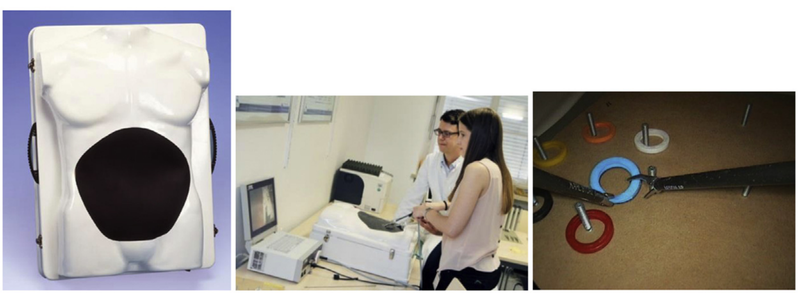
Figure 13.3 (A) Simple, homemade knot bench. Nevertheless, it is very suitable to learn some basic surgical abilities. The trainee has to grasp the edge of the incision with the forceps and to insert the needle into the marked area. This action is executed with laparoscopic instruments under direct vision. (B) Commercial training device for tasks in open surgery. *All from MITI.*

all over the world have developed standardized programs. As an example, the so-called "Training and Assessment of Basic Laparoscopic Techniques" (TABLT) test consists of five different exercises including object transfer, cutting, sharp dissection, blunt dissection, and cyst removal [6].

More advanced are "box trainers," which are mainly used for the training of laparosurgical skills, where the task has to be fulfilled within a closed box (Fig. 13.4). Here, the objects are not visible from the exterior. Accordingly, a videocamera has to be inserted to visualize the scenario, while the surgeon is using conventional laparoscopic instruments. The challenge for the trainee is higher than in open surgery, since he/she has to cope with the particular problems of laparoscopy: visualization is done with a telescope, which results in a limited overview. In addition, most skills labs are equipped with low-cost imaging systems, which means that he/she has only a two-dimensional view, the perception of depth is reduced. By training, this can be compensated by indirect depth clues like motion, shadow, or size.

In addition, the trainees become aware of the importance of a straight eye—hand—target axis ("optical correctness"). Otherwise, dexterity is massively impeded. Beside this, the long, rigid instruments magnify the natural tremor of the hand, which can be suppressed by intensive exercise.

In box trainers the degrees of freedom are reduced due to the fixed entry points both of the instruments as well as the camera. In addition, the "fulcrum effect" is disturbing: If the grip of the instrument is moved to the right, the tip of the instrument will move left and vice versa.



(A) (B) (C)

Figure 13.4 (A) Commercially available box trainer for laparoscopic tasks. (B) The first trainee executes the task, the second trainee controls the videocamera. (C) Inside of the box: A typical task of transporting rings from one pin to another. *All from MITI.*

Although training in box trainers typically focuses on the skills of the surgeon, training in a team of two trainees is even more effective if one of them takes over camera guidance. Both of them will soon recognize how decisive an attentive, stable camera guidance is for success.

Though the impact of box training upon the later clinical performance is not yet completely proven, trainees with no previous laparoscopic experience may have a benefit [7].

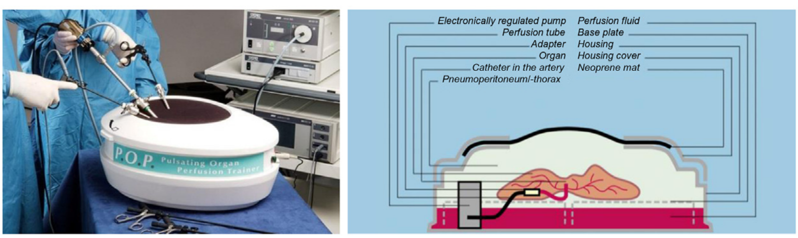
13.5 HYBRID TRAINERS

In this type of a trainer, animal organs are embedded into a specially designed device which looks like a normal box trainer. Advanced devices such as the P.O.P (Pulsating Organ Perfusion) (Optimist, Innsbruck, Austria) provide organ perfusion with a colored blood-like fluid by means of an electronically regulated and pressure-controlled pump (Fig. 13.5). Thus hemorrhagic complications and their management can be simulated [8].

Several organ packages are available:

- Liver, gallbladder, small intestine, colon, spleen, etc. for visceral surgery
- Heart, lungs, aorta for thoracic surgery
- Kidneys with ureters for urology
- Aorta, arteries, and veins for vascular surgery
- Adnexes, uterus, etc. for gynecology

The central artery of the respective organ package is catheterized and connected to the pump system.



(A) (B)

Figure 13.5 (A) Hybrid training system P.O.P for laparoscopy training. (B) The specific elements of the system. *Courtesy: S. Szinicz, Optimist, Innsbruck, Austria.*

The blood-like perfusion medium is conveyed into the organ package in a pulse-like mode. The pulse frequency is pressure-controlled (maximum pressure approximately 140 mmHg) and has a frequency of about 65/min. The perfusion fluid is recovered and sent back into the circuit.

Blood perfusion is an additional challenge for the trainee, since he/she may be forced to handle a bleeding in the case where a vascular structure has been lacerated. This is why the P.O.P training system is also attractive for experts. Face validity has been confirmed by the group of Nickel et al. [9].

13.6 MANIKINS

For the training of more complex tasks and even complete surgical procedures, imitations of the human trunk are available with a more or less detailed copy of the intraabdominal organs which permit both open and laparoscopic surgeries. Some of them even allow for endoluminal endoscopic interventions (upper GI endoscopy, colonoscopy).

13.6.1 EASIE (Endosim LLC, Hudson, MA, United States)

One of the oldest training models in interventional visceral medicine, introduced in 1997, is the "Erlangen Active Simulator for Interventional Endoscopy" (EASIE) [10]. The EASIE is a rotatable plastic torso containing specifically prepared organ packages from the pig connected to adapters and suspension-shells. An artificial blood circulation driven by a roller pump analogous to a heart—lung-machine achieves simulation of arterial pulsatile bleedings [11]. The first EASIE offers a wide range of active training opportunities (including bleeding) but it is limited to endoluminal endoscopy only.

The optimized EASIE-R makes also simulation of natural orifice transluminal endoscopic surgery (NOTES) or single incision laparoscopic surgery (SILS) procedures feasible and provides an observation of the procedure with an acrylic cover. The simulator consists of intact explanted pig organs arranged in a manner to resemble a human's internal anatomy and has ports that mimic the natural orifices such as esophageal and anal access, in order to allow for access into the peritoneal cavity [12]. In addition, a cover with integrated laparoscopic ports permits the use of laparoscopic instruments for simulation of laparoscopy or hybrid NOTES procedures.

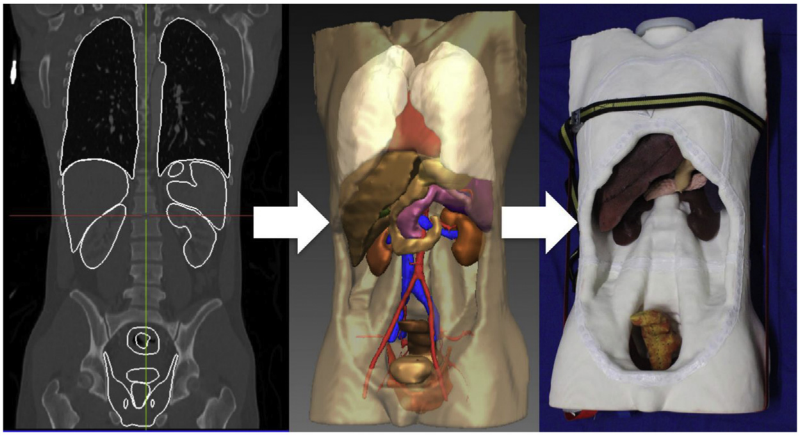


Figure 13.6 OpenHELP with visceral organs. Left: Segmented organs on the computed tomography; Middle: Computer visualization of segmented organs; Right: Materialized model with organs. The open source project is accessible at www.open.cas.org. *Courtesy: Dr. H. Kenngott, University Hospital Heidelberg.*

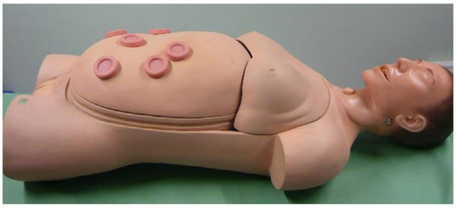
13.6.2 OpenHELP

An interesting new approach is the so-called open-source Heidelberg laparoscopic phantom. The manikin is based on an anonymized CT scan of a male patient. The anatomical organs are segmented to obtain digital three-dimensional models of the torso and the organs. The segmented models, printed in gypsum, were the base for a silicone mold to produce reproducible silicon organs (Fig. 13.6). Costs for a complete organ set are, because of the easy and cheap reproduction in silicone molds, only about 200€. The reusable torso is the most expensive part, amounting to about 5800€ but is subject to be reduced by further development [13]. The phantom is a reusable model combining realistic anatomy and realistic tissue properties which is available free of charge for the use of the scientific community.

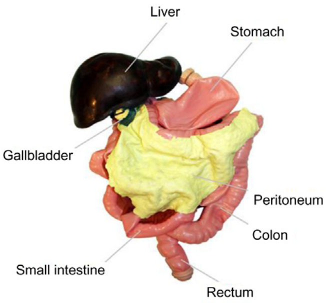
13.6.3 ELITE

A well established, commercially available training phantom is the "endoscopic-laparoscopic interdisciplinary training entity" ELITE (Coburger Lehrmittelanstalt, Coburg, Germany) (Fig. 13.7).

It consists of the reusable human torso with integrated retroperitoneal structures. The torso contains the disposable GI tract package (stomach, small and large bowel, liver, and omentum) made of flexible soft plastics, with realistic optical and haptic features. Since not only the



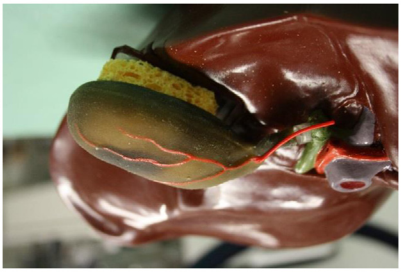
(A)



(B)

Figure 13.7 The "endoscopic-laparoscopic interdisciplinary training entity" (ELITE) is the copy of a human corpse (A) with an exchangeable organ package. (B) The abdominal wall is either rigid with predefined trocar valves (as shown in (A)) or a flexible design of soft material to place the incisions or ports at will or to make a surgical incision. *All from MITI.*

(A)



(B)

Figure 13.8 (A) Open abdominal surgery: After the incision, a self-retaining retractor holds the abdomen open. (B) Surgical site for removal of the gallbladder. *All from MITI.*

exterior has been designed realistically, but also the internal lumina, all types of surgery and flexible endoscopy can be accomplished (Fig. 13.8A). Both the gastric and bowel wall as well as the (soft) abdominal wall can be sutured like in real surgery (Fig. 13.8B). Even staplers can be applied at the GI tract.

For open surgical procedures, a soft abdominal wall is provided which makes it possible to use conventional instruments for open surgery.

For laparoscopic surgery, the soft abdominal wall makes simulation of the pneumoperitoneum feasible and provides the possibility for use of all available types of trocars (Fig. 13.9).

Flexible gastroscopy and colonoscopy, even combined with laparoscopic interventions (so-called "rendezvous surgery" (see Chapter 9: Combined

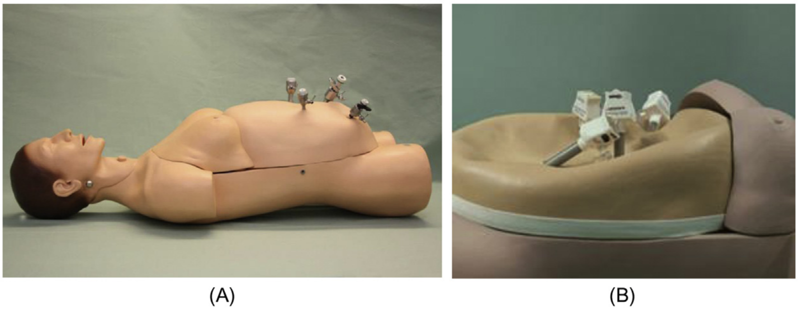


Figure 13.9 The ELITE for laparoscopic surgery. (A) Fully insufflated abdomen with trocars in situ. (B) Significant gas loss, since a gas valves was mistakenly not occluded. *All from MITI.*

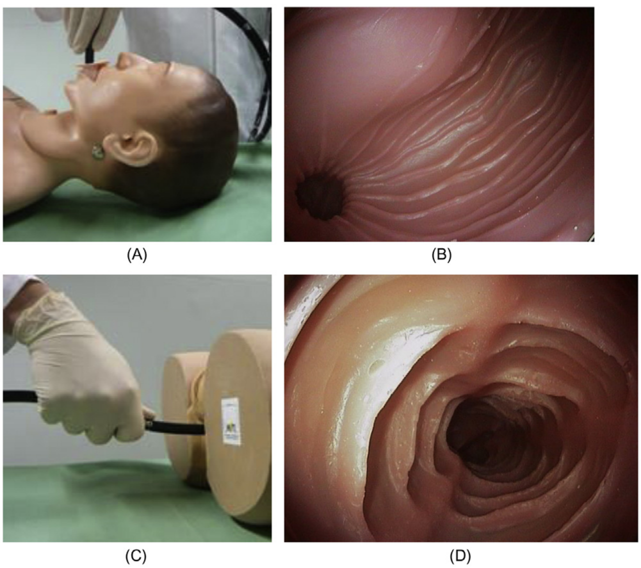


Figure 13.10 Flexible endoscopy training using the ELITE. (A) The gastroscope is inserted via the mouth. (B) Endoscopic image of the stomach. (C) The colonoscope in situ through the rectum. (D) Endoscopic view of the sigmoid colon. *All from MITI.*

Laparoscopic-Endoscopic Procedures and Natural Orifice Transluminal Endoscopic Surgery (NOTES))) is feasible as well (Fig. 13.10).

The ELITE was extensively evaluated [14], in particular in its ability to provide NOTES skills (see below) (Fig. 13.11).

It is also increasingly used in biomedical engineering and in the industry for prototype testing of new instruments.

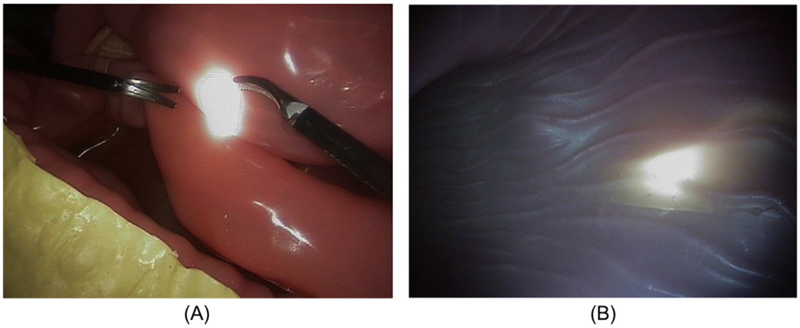


Figure 13.11 (A) Laparoscopic-endoscopic intervention using the ELITE. The endoscope is inserted into the stomach. Laparoscopic view: the light spot marks the position of the tip of the endoscope. (B) Endoscopic image of the stomach. *All from MITI.*

13.7 VIRTUAL REALITY TRAINING SYSTEMS

Early in the era of laparoscopic surgery, many surgeons adopted laparoscopic techniques with little training or experience and negative consequences for some patients. In the current era, the acquisition of basic laparoscopic surgical skills has been moved out of the operating room and into the skills lab. Extensive research has been conducted on simulation-based training as a mechanism for the acquisition of laparoscopic surgical skills. The Fundamentals of Laparoscopic Surgery [FLS, American College of Surgeons (ACS) and the Society of Gastrointestinal Endoscopic Surgeons (SAGES)] curriculum has been validated as a high-stakes simulation-based curriculum in laparoscopic surgery that can be used to develop and assess laparoscopic surgical skills [15]. In 2009, the American Board of Surgery began to require that surgeons seeking board certification successfully complete the FLS program.

Virtual reality trainers have been available for more than a decade. The basic structure is shown in Fig. 13.12.

13.7.1 Basic Trainers

Low fidelity trainers such as the MIST VR (Mentice, Gothenburg, Sweden) (Fig. 13.13) only offer the training of basic skills. Insofar, they are only little superior to basic analog models, since they enable the acquisition of psychomotor skills (hand–eye coordination, surgery by screen) only and do not promote cognitive knowledge. The big advantage, however, is that they deliver metrics. The individual performance

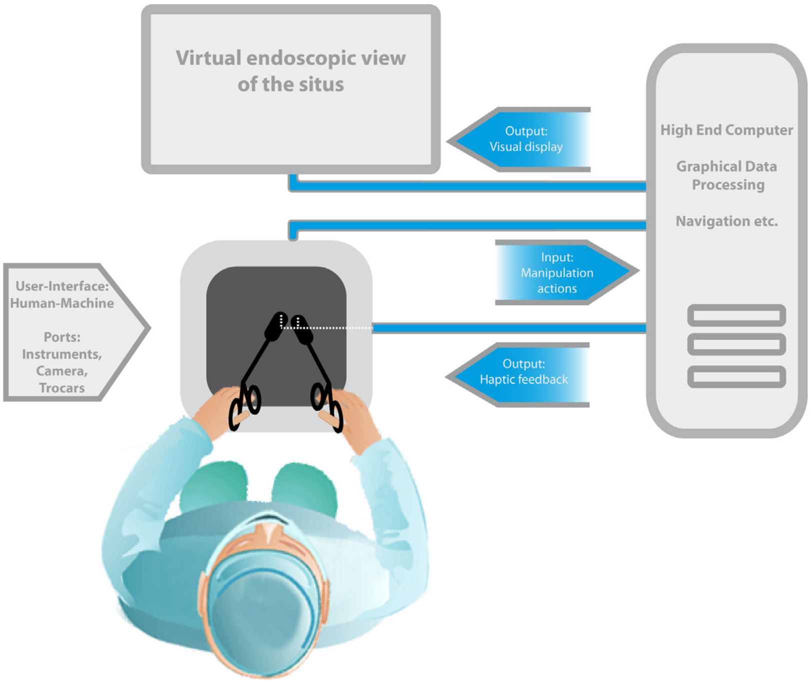
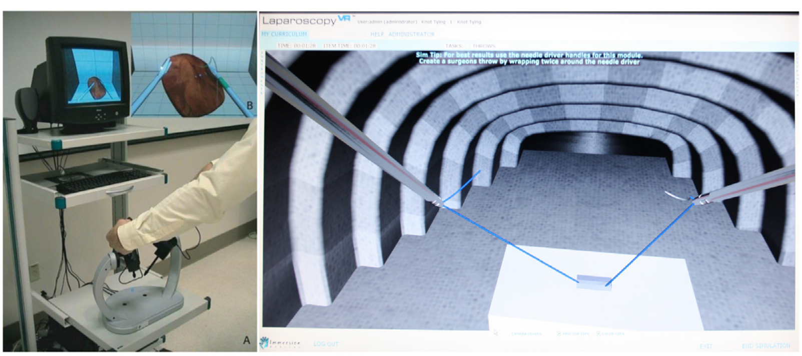


Figure 13.12 The components of a VR training unit. All of them offer not only the acquirement of basic skills, but also the learning of procedural knowledge. *Modified by D. Ostler.*



(A) (B)

Figure 13.13 (A) Basic skills trainer. (B) Basic laparoscopic task on the MIST VR: Knot production. *All from MITI.*

can be evaluated easily, as well as the effect of consequent training. Trainees can repeat the exercises at will without the need for human supervision. The success of their efforts is automatically documented.

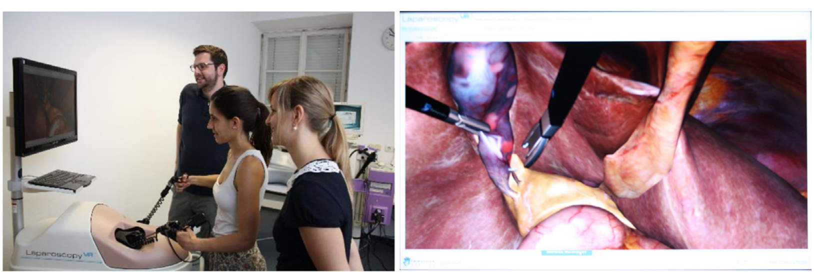
Initial costs are, evidently, higher as with analog models, but running costs are very low, since expensive upgrades are seldom required. There is plenty of literature demonstrating the use of VR basic skill trainers. It is remarkable, however, that the enhancement of novices' performance and normal video box trainers is not completely identical [16,17]. In at least two studies [16,18], the test subjects preferred the box.

13.7.2 High Immersive Trainers

This type of simulator offers more realistic, surgery-like tasks and enables to learn cognitive abilities as well as manual skills and to some extent even procedural knowledge. The anatomical structures are deformable and may bleed or perforate (Fig. 13.14).

In these trainers, mostly different levels of difficulty can be selected.

In general, the degree of immersion (approximately to the real conditions of today's VR training systems) is continuously growing. Advanced devices such as the Lap Mentor III (3D Systems Healthcare, Littleton, CO, United States) offer haptic feedback and rather complex scenarios with real-time complications and injuries. Anatomical details are refined and tissue response to manipulation is becoming better and better. Likewise, the range of surgical procedures that can be trained is growing. Beyond of urological and gynecological interventions, gastric bypass, cholecystectomy with cholangiography, sigmoidectomy, appendectomy, and incisional hernia repair are available for visceral surgery.



(A) (B)

Figure 13.14 (A) Typical training scenario: Cholecystectomy in VR. (B) The "laparoscopic" image: Clip application. *All from MITI.*

After practical performance, proficiency level setting tools and objective, comprehensive reports facilitate the tracking of the training process.

In the past, it was frequently discussed whether the skills acquired on a training system can really be transferred into the OR [19]. It was argued that performing perfectly with the VR machine would not necessarily lead to a better quality of the surgical skills under clinical conditions. Meanwhile, several studies have shown that the quality of at least certain surgical steps can be improved [20–22].

13.7.3 VR Trainers for Flexible Endoscopy

Since patients are often only sedated during endoscopic procedures and the procedure may be associated with discomfort and adverse events, particularly during the learning curve, training with simulators can be an effective way to reduce medical errors and increase procedural efficiency.

For education in a reproductible curricula in a nonstressful environment, VR simulators for flexible endoscopy are available, which measure the performance using objective metrics [23]. Most flexible endoscopy trainers are based on manikins with oral and anal access and mounted on a rotatable platform. Position of the endoscope's tip or looping of the scope is estimated by electromagnetic tracking sensors, haptic feedback simulated by air-filled tube rings. Insufflation and aspiration of air is monitored as well and extensive use is reported to the trainee.

Endoscopic VR simulators offer basic training to practice basic skills and instrument usage, as well as more realistic simulations with clinical tasks like complete inspection of the bowel or the stomach up to therapeutic tasks like stopping of bleedings with electrical current.

A well-evaluated flexible endoscopy simulator with proven construct validity is the Simbionix GI Mentor II (3D Systems Healthcare, Littleton, CO, United States) (Fig. 13.15).

13.8 NOTES TRAINING

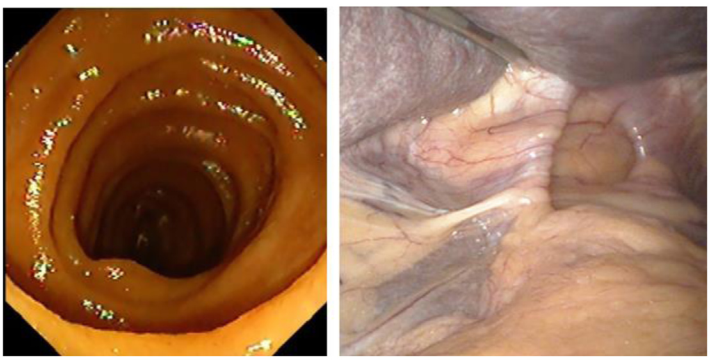
Training and education for NOTES is a particular issue. It must overcome the traditional border between laparoscopic surgery and interventional (flexible) endoscopy.

Primarily, endoscopists and laparoscopists are accustomed to two "different worlds" (Fig. 13.16).

Training for NOTES means, therefore, the education of a new specialist in between laparoscopy and flexible endoscopy. Accordingly, the

(A) (B)

Figure 13.15 (A) Basic training for practicing the use of flexible endoscopy tools. (B) Simulation of pathologies. *All from MITI.*



(A) (B)

Figure 13.16 Training for NOTES: Gastroenterologists and surgeons are entering new worlds: (A) The endoscopist is very familiar with the interior of the GI tract (luminal view), but he/she is less aware of the adjacent anatomy. Leaving the lumen makes him/her entering a vast, dark cavity with difficult spatial orientation. (B) The surgeon is able to navigate precisely within the abdominal cavity and is able to perform the required surgical manipulations easily. Trying to do the same by means of a flexible endoscope is completely different. Control of the flexible endoscope needs special skills as well as the coaxial manipulation of instruments, which is frequently underestimated by surgeons. *All from MITI.*

requirements concerning training models are particularly high. Up to now, most often animal models are used, but increasing activities are focused on artificial models [24–27]. The majority of these research groups utilize the ELITE phantom, which also allows to perform dual approaches (combined transvesical/transanal or transanal/transgastric accesses) (Fig. 13.17).

Theoretically, training and education in NOTES is also conceivable in VR.

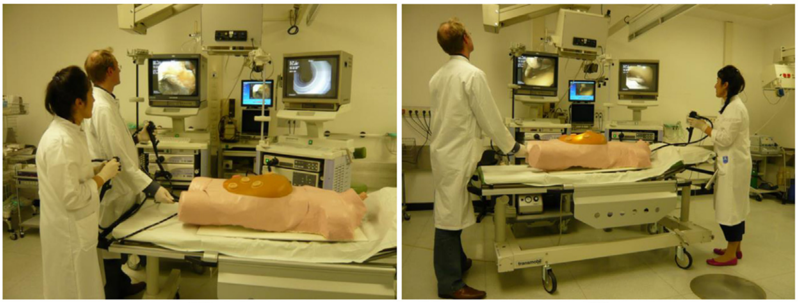


Figure 13.17 Training of dual access NOTES procedures: (A) Transanal/transvesical; (B) transanal/transgastric. *All from MITI.*

VR trainers are available both for laparoscopic and endoscopic interventions. A combination of both should be technically feasible, but up to now, none of the relevant companies did focus on this topic.

13.9 E-LEARNING FOR SURGICAL TRAINING

Analog training and training in VR usually gain considerable attention in surgery, whereas other innovative learning tools, such as Internet and software-based platforms conquered an important place in surgical training far less spectacularly [28].

The widespread use of smartphones and tablets and other multimedia platforms offers new chances to provide evidence-based educational material efficiently and cost-effectively [29].

The range of e-learning tools is very wide: Beginning with online textbooks, instruction videos, and ending with highly interactive cognitive simulators (Table 13.3).

Maertens et al. performed a comprehensive meta-analysis of the literature to evaluate and critically appraise the evidence supporting the use of e-learning as a tool for surgical education compared with either no intervention or other methods of training amongst health care professionals. They concluded:

At their core, e-learning tools are limited to teaching cognitive processes, be it the knowledge base necessary to develop mental models, or the cognitive elements necessary to perform psychomotor tasks. It would therefore seem intuitive that, although e-learning may never completely replace all other methods of education, it could serve as an adjunct to improve the effectiveness of a curriculum, especially when the curriculum has a dominant cognitive component that can feasibly be packaged into web-accessible modules [30].

Table 13.3 Characteristics of e-learning tools

Methodology	Explanation
Multimedia component	Videos, images, animations
Interactive component	Learner interaction with platform requiring decision-making and judgment
Feedback	Learner obtains feedback on surgical skills on previous performance while using platform
Assessment component	Learner is assessed through the platform with formative or summative evaluation
Virtual patients	Case-based scenarios
Spaced education	Interval reinforcement of content
Community-based learning	Learning through web-based discussion groups with colleagues (e.g., blogs)
Gaming	Learning through structured and organized play

Source: Modified from Maertens H, Madani A, Landry T, Vermassen F, Van Herzeele I, Aggarwal R. Systematic review of e-learning for surgical training. Br J Surg 2016;103(11):1428–37 [30].

13.10 INDIVIDUALIZED THERAPY PLANNING FOR CLINICAL SURGICAL CARE

Independent of the education and training of younger surgeons and novices it is a very attractive vision to enable experienced surgeons to simulate the surgical tactics and strategies in the individual case before they have to do it practically. Today, preoperative imaging is very precise and reveals even tiny anatomical details. Based upon this reliable information it should, theoretically, be possible to produce a model of the individual surgical site to decide beforehand upon the surgical strategy and tactics before the real incision has to be made. The actual situation could either be reproduced physically by printing a real reproduction of the anatomy (Fig. 13.18) or by a representation in virtual reality. Currently, VR reconstruction means an incredible expense in programming. However, 3D information gained from preoperative CT or MRI can nowadays be reproduced rather easily by means of 3D printing. Using a realistic model of the individual case the surgeon and his team could be enabled to execute the most important steps of the operation beforehand (Fig. 13.19).

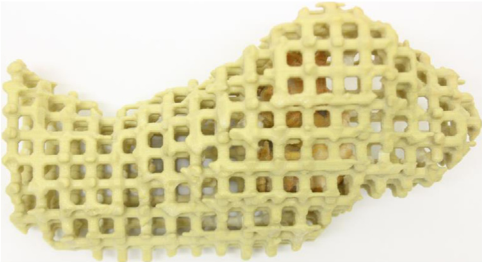


Figure 13.18 3D printed model with integrated finding for surgical planning. *From MITI.*

(A) (B)

Figure 13.19 (A) Cross-section of hepatic cyst (1) in computed tomography. (B) 3D reconstruction of the cyst, which gives a much more detailed overview of the vessel structure and provides the possibility of exact volume calculations and remaining functional rest liver volume. *All from MITI.*

It is a very attractive vision to enable experienced surgeons to simulate the surgical tactics and strategies before they do it on the real case.

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CHAPTER 14

Visceral Surgery of the Future: Prospects and Needs

14.1 INTRODUCTION

The exponential improvement of medical care over the last two centuries was considerably fostered by the fundamental contributions of surgery. Over some decades, surgery was certainly the spearhead of medical progress. This role is perhaps becoming lost—or at least endangered—by new interventional disciplines developed over the last few decades.

As already shown in Chapter 1: Surgery and Biomedical Engineering, health care was, and still is, based on two different fundamentals: conservative (noninvasive) and interventional (more or less invasive) treatment.

The impressive progress in conservative therapy was caused and/or stimulated by a wide range of supporting scientific disciplines, such as chemistry, pharmacy, microbiology, oncology, molecular biology, genetics. These combined efforts led to striking advances in noninvasive treatment of a broad range of diseases which made surgery avoidable—for the sake of the patient.

The classical surgical domains are further reduced by interventional approaches provided by other interventional disciplines like gastroenterology and radiology. With the impressive progress of interventional flexible endoscopy and angiographic treatment, an inevitable decline of classical surgery was predicted.

Up to now, this expectation does not match with reality, since the developments in modern surgery opened up new types and stages of diseases which were formerly either not at all or only insufficiently treatable. Surgery expanded rather than shrunk. Although leaving parts of its former fields of competence to others, it augmented the therapeutic armamentarium by new, most valuable, exclusive therapeutic approaches which still make surgery indispensable.

However, this could soon change in this highly competitive environment if the development in surgery slows down and if it is unable to further present even better therapeutic solutions. A loss in innovative

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power, however, would not only be regrettable from a surgeon's view, but also for the entire medical community.

The active competition among various therapeutic disciplines will always have at least one winner: the patient. Though an oncologist will primarily strive for a promotion of medical cancer treatment, as does the gastroenterologist with interventional endoscopy, or the surgeon with surgical operations, they have a common goal as physicians: to improve the effectivity and quality of care for their patients.

In the last chapter, we attempt to delineate some promising new tendencies in surgical research with the potential to overcome some of the still existing barriers to reach the next level of surgery.

14.2 THE IMPACT OF CONSERVATIVE (MEDICAL) TREATMENT UPON FUTURE VISCERAL SURGERY

A classical example of how surgery could be made superfluous is peptic ulcer disease.

In the past, acid-related gastroduodenal ulcers were very frequent all over the world, leading to chronic pain and often to serious complications such as bleeding or perforation. Medical treatment options were modest: antacids to buffer gastric juice and dietetic recommendations. Surgery was the only effective means; at the beginning of scientific surgery, about two-thirds of the distal stomach were resected to eliminate the acid producing sections (antrum). Later on, surgery was refined. Based upon a better insight into the pathophysiological condition it was found out that in most cases, it was sufficient to sever the fine gastric branches of the vagus nerve which stimulates gastric acid production. In the Western world, these "vagotomies" were some of the most often performed surgeries until the end of the 1980s. Practically overnight this type of surgery disappeared out of the ORs, due to two factors. Firstly, effective acid suppression became pharmacologically feasible with the introduction of so-called proton pump inhibitors. Secondly, and even with a higher clinical impact, the causes and not only the symptoms of the disease could be treated now. Marshall and Warren detected in 1983 the so-called *Helicobacter pylori* germ in the gastroduodenal region and soon it was recognized as the cause of peptic ulcer disease. Accordingly, causative treatment (eradication) became possible by peroral administration of antibiotics for a few days.

This impressive example of how the scalpel can be substituted by pills encourages one to speculate about other "surgical" diseases which could potentially be treated only by drugs in the future.

If we classify "surgical" diseases according to their origin, one might differentiate between "anatomical/structural," "functional," "bacterial or nonbacterial inflammation," and "oncological" diseases.

So-called *anatomical or structural lesions* are, e.g., hernia, diverticula, strictures. It is highly unlikely that they will ever be curable by medical treatment only.

Functional diseases are, e.g., gastroesophageal reflux disease, achalasia, gastric emptying disorders, nonulcer dyspepsia, or anal incontinency, just to name a few.

Despite enormous scientific efforts over many decades, medicine is still unable to stimulate the function of sphincters (such as the lower esophageal or the anal sphincter) effectively by pharmacological agents or to normalize gastrointestinal motility. Knowledge and basic insight into normal and pathological gastrointestinal function is still today too scarce to develop effective drugs, but this will supposedly change. Maybe, surgical implantation of electrical stimulation devices will become a suitable alternative option (see Section 2.3: Stomach).

Bacterial inflammatory diseases like appendicitis or cholecystitis are still a domain of surgery. However, there is now a clear tendency to treat acute appendicitis with antibiotics, though it is still unclear whether this is really a viable alternative to surgical appendectomy. Potentially, improved antibiotics or even vaccination could endanger the up to now well established surgical therapy (appendectomy). Diverticulitis of the sigmoid colon is often an indication for surgery. Over the years, however, repeated antibiotic treatment has been more generously selected. In former times, surgeons (and even the majority of gastroenterologists) firmly recommended sigmoid resection after the second episode of acute inflammation, but this rule is increasingly softened up.

Surgery of symptomatic gallstones/cholecystitis is a major part of routine surgical activities. Cholecystectomy is still the treatment of choice, since despite vast scientific activities to prevent, dissolve, or extract stones, surgery is still the most efficient and effective treatment.

However, bile stone disease is primarily a metabolic disorder. With growing knowledge about its causes, the probability is high that someday effective medical treatment will be available and would make surgical therapy avoidable.

This is even more probable in the case of *nonbacterial inflammatory bowel diseases*, such as Crohn's disease or ulcerative colitis. New insights into the pathomechanism will further improve medical therapy and reduce surgery to marginal importance. The only question refers to the time frame.

Medical treatment of *oncological diseases* has consumed enormous industrial and public resources over the last decades, with comparatively modest results. Still today, not one single type of gastrointestinal cancer can be adequately treated and cured by chemotherapy alone. Surgery will remain to be the essential pillar of cancer treatment for the upcoming years and decades.

Some progress has been achieved in the field of so-called "neoadjuvant" chemotherapy. Neoadjuvant treatment is the administration of chemotherapeutic agents before surgical resection with the aim to reduce the tumor mass for facilitating radical removal. This type of multimodal treatment—sometimes even reinforced with radiotherapy—has already proven successful in case of esophageal, gastric, and rectal cancer and significantly improved the applicability of surgical resection. Though many practical problems still have to be solved (i.e., the problem of response), it is assumed that medical oncological treatment will promote oncological surgery rather than endanger its current role. The vision of defeating GI cancer by pills or injection only will remain a dream within the foreseeable future.

14.3 THE IMPACT OF OTHER INTERVENTIONAL DISCIPLINES

It has been pointed out in Chapter 1: Surgery and Biomedical Engineering, that interventional endoscopy and interventional radiology made many surgical procedures obsolete. The treatment of gastrointestinal bleeding by interventional endoscopy and the therapy of portal hypertension were quoted as examples. However, it would be completely wrong to consider the actual situation as a predatory competition.

The contrary is true. There is no doubt that both disciplines contributed a lot to the development of modern visceral surgery, e.g., by a better management of intra- and postoperative complications or simply by increasing the pressure to improve quality.

Early gastrointestinal cancer will increasingly be treated by the interventional gastroenterologist. The limit is currently the question of lymph node infliction. If the cancer is still confined to its site in the gastrointestinal wall, there is no need to do radical surgery: endoscopic local resection is adequate. Likewise, interventional endoscopy will take over more and more palliative treatment of advanced, nonresectable tumors.

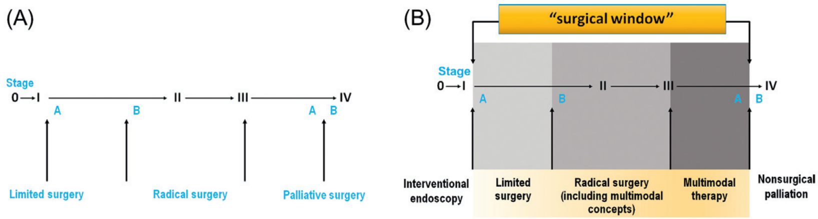


Figure 14.1 The change of therapeutic approaches over the last 50 years illustrated by the treatment of gastric cancer. (A) Initially, surgery was the exclusive answer in all stages of the disease. What is left for surgery today is called the "surgical window," which is embedded in-between interventional endoscopy and innovative palliative approaches. (B) Today, the treatment of early cancer stages and many palliative interventions are in the hands of interventional endoscopists or other disciplines, leaving a relatively narrow "surgical window." However, this did not result in a loss of volume or importance of surgery: the contrary occurred. Formerly inoperable, very advanced cases can now be treated surgically with good success and a reasonable mortality and morbidity. *All from MITI.*

Palliative treatment aims at relieving the symptoms and complications of an underlying disease (usually cancer) which cannot be cured any longer. This may be mostly bleeding, obstruction, or pain. Roughly 50 years ago, the oncological treatment was dominated by surgery (Fig. 14.1). In the past, surgery was required in order to stop a bleeding or to restore gastrointestinal obstruction by local resection or a bypass. Today, bleedings can be stopped endoscopically or by interventional radiology. Obstructions can increasingly often be overcome by endoluminal stents and pain is eliminated by drugs, local drug instillation, or transcutaneous radiation.

We hypothesize, therefore, that further development of successful tumor treatment in visceral medicine will be achieved by a comprehensive interdisciplinary approach. It will definitively come to a win–win situation of all who are involved. The patient will benefit from the advantages of an individual therapy: the lowest invasiveness wherever possible and most effective radicality when needed.

This process is just beginning. In Chapter 9: Combined Laparoscopic-Endoscopic Procedures and Natural Orifice Transluminal Endoscopic Surgery (NOTES), a new invasive approach was described combining both laparoscopy and endoluminal endoscopy. The next step could be to combine laparoscopic surgery with intraoperative interventional radiology, e.g., for tumor localization (navigation) or temporary ischemia. It is even conceivable that laparoscopy and endovascular interventions could be supported by intraoperative radiation and/or highly selective local drug application.

14.4 HOW TO OVERCOME THE CURRENT LIMITATIONS OF VISCERAL SURGERY? NEW THERAPEUTIC APPROACHES

Striving for getting better is a self-evident aspect of each motivated professional, but in medicine it is even a moral obligation. In interventional medicine, health care givers should continuously become more efficient and more effective. The border between both aspects is sometimes difficult to define. Reducing the expenses for a well-defined procedure and maintaining the same successful result is certainly an improvement of efficiency. However, how should one classify a reduction of invasiveness (trauma) of a new surgical procedure which achieves the same therapeutic effects as the traditional approach but is more costly?

Today, the greatest challenge to oncological visceral surgery is to extend the range of reasonable indications in advanced cases.

Only a few years ago, any metastatic disease was considered as inoperable. This has gradually changed. It was learnt that it is worthwhile to resect singular liver and lung metastases of colorectal tumors, since the survival rate can be improved. Even peritoneal spread is not automatically a sign of irresectability. One of the most innovative developments of recent years in visceral surgery is hyperthermic intraperitoneal chemotherapy (HIPEC). As already pointed out in Section 3.2.3: Steps of the Operation, partial removal of a gastrointestinal tumor (R_1 or R_2 resection) usually does not result in a better prognosis or prolonged survival.

Meanwhile, it became evident that in the early stages of peritoneal spread of gastric or colorectal cancer, debulking of the tumor is beneficial, if it is combined with warmed chemotherapeutic agents which are infused and circulated in the abdominal cavity during the operation. It may be expected that the current limits of surgery will be extended with a better understanding of tumor biology and new effective cytotoxic substances.

The main impact upon the further development of surgery, however, has clearly to be expected from BME. Without any doubt, BME will increasingly take over the role of the strongest motor of surgical innovation. A few, sometimes still rather visionary instances are delineated in the following.

14.4.1 Local Tissue Ablation

Many primary tumors are irresectable because of their anatomical localization, the involvement of vascular structures or because of their high number (e.g., liver metastases). Local destruction (ablation) could be an option if the tumor cannot be resected.

Local ablation has been already tried out in surgery over more than two decades. Basically, they consisted either of freezing or overheating the tissue. Cryotherapy was very effective in tissue destruction. It did not have a self-limiting effect like high-frequency ablation, but the "iceball" could be enlarged at will by prolonging the freezing time.

The real disadvantage was the risk of postprocedural bleeding. Freezing does not lead to coagulation. Vessels ruptured as soon as they gained physiological temperature again.

Today, destruction by heat (radiofrequency ablation, high-frequency thermotherapy) is preferred. It usually works well if the probe is precisely positioned (usually using intraoperative ultrasound), but it still has its specific limitations. The lesion has to be comparatively small. In case of a larger size than 2–3 cm, multiple needles can be applied, but this makes navigation difficult. If the tumor is located close to or even infiltrates larger vessels, the cooling effect of circulation impairs effective tumor cell destruction. Last but not least, thermotherapy must not be applied to lesions which are situated in close neighborhood to other structures of the GI tract (stomach, duodenum, colon), since heat conduction may lead to perforation.

Irreversible electroporation could become an option to augment the use of local tissue ablation considerably. By small, repetitive bursts of electricity applied by small electrodes malignant cells are destroyed whereas normal cells are unaffected. It does not create thermal damage to the tissue around, since cancer cells die by apoptosis, not thermal necrosis. Though it is still too early to predict a breakthrough in visceral surgery, the approach is very promising, both for open as well as minimally invasive surgery and NOTES.

14.4.2 Intraoperative Tissue Differentiation

In endoscopic or surgical tumor resection, it is frequently difficult to decide whether the margins are really free of tumor cells or whether they are still (microscopically) infiltrated by cancer. Frozen section examination could be helpful, but in clinical practice it is rather time-consuming and tedious to be used repeatedly. In order to evaluate reliably the three-dimensional extension of a malignant lesion, faster and less expensive tests are required. Some promising candidates are in the pipeline, most likely optical systems as described in Section 5.6: Advanced Optical Systems.

14.4.3 Endoluminal Viscerosynthesis

Coming from another end, the quality of visceral surgery could additionally be augmented. As already pointed out in Section 3.2.3.7: Viscerosynthesis/

Reconstruction, viscerosynthesis or the problem of gastrointestinal anastomosis is still the "Achilles heel" of surgery. The vision is to have available an endoluminal connecting system which can be advanced to any height of the gastrointestinal tract (esophagus, stomach, duodenum, small and large bowel). It should be able to approximate the two stumps without external help and "fire" the anastomosis as easily as we are accustomed to when using rigid stapling devices (see Section 6.5: Stapling Devices) in colorectal surgery. Hopefully, this new type of steerable, flexible stapler can even improve the complication rate due to secondary leakages. Selective compression could offer new chances or even the using of locally effective growth agents integrated into the borderline between the two ends.

14.4.4 Specimen Retrieval

As already pointed out in Section 3.2.3.6: Specimen Retrieval, specimen retrieval is not an issue in open surgery since the incision is usually large enough to get the specimen out of the body. However, visceral surgery must more and more shift to less invasive approaches like laparoscopy or NOTES. In these cases specimen retrieval becomes a real problem since the opening is far smaller than the tumor mass which has to be removed. Theoretically, at least two new concepts can be considered.

14.4.4.1 Controlled Morcellation

Though morcellation of a malignant tumor is unthinkable today, some visions could make it possible to bring the tumor through the needle hole. Controlled morcellation means to divide the tumor within the body in a way that it can be reintegrated after removal outside of the body so that an intact specimen can be delivered to the pathologist.

Of course, this controlled morcellation has to happen in a retrieval bag to avoid tumor dissemination. It has to be taken care that each single part of the tumor can be relocated after removal at its original place in the intact specimen. Premorcellation images could help to reconstruct the tumor afterward. Spatial orientation must be maintained.

14.4.4.2 Mass Reduction of the Tumor

If a tumor is examined by the pathologist the interior of the tumor mass is more or less uninteresting. What is of more interest is what is happening at the borders and the margins. Here it has to be decided whether the margins are free or not. Other parameters to characterize the tumor precisely, like grading, etc., are also usually performed in the margins of the tumor not in the center, which is most often necrotic. If it would be possible to excavate a tumor prior to removal and to preserve only the outer layers the volume could be reduced drastically and easily be pulled out over a trocar. Today, this may sound like an excerpt of a book written by Jules Verne but modern technology certainly will offer solutions which could be used to overcome one of the major barriers of minimally invasive oncological surgery.

14.5 SMART IMPLANTS

Implants in visceral surgery are mainly passive ones. Meshes for hernia repair are popular instances (see Section 6.6: Biomaterials), and similarly, gastrointestinal stents. Though further refinement of passive implants can be awaited for, really disruptive developments can primarily be expected from innovative active and adaptive systems. Certainly the most well-known issue is the insulin pump for the treatment of type I diabetes. The vision of creating a closed loop system measuring the blood glucose level and delivering adapted doses of insulin has a long history: The first pumps were introduced approximately 40 years ago. Today, they are smaller, more precise, and more reliable but still some way from being perfect. They are still associated with severe technological challenges and even potential risks to the patients [1]. Insulin pumps are mainly focused on only one parameter: insulin. The challenges become multifold if more parameters have to be considered (e.g., in case of the artificial kidney) or even complex metabolic processes like those provided by the liver.

The number of experimental approaches to develop an implantable artificial liver is countless, but it is scarcely probable that surgeons will get an implantable, autonomous biochemical device as a substitute for a failing liver. The reason is that metabolic (chemical, biochemical) conditions have to be met which are far more difficult to manage than mechanical, electrical, or computer science challenges.

However, many bodily functions are based upon electrical signals which are more easily understood and which offer both chances for the diagnostic workup and treatment. The best example for illustrating this aspect is cardiology. Contraction of the heart is initiated by electrical signals. These can be easily recorded by electrocardiography and were soon used for diagnostic purposes, which has been well established for nearly a century in internal medicine. The next logical consequence was to provide electrical signals to optimize cardiac function using implantable generators. For many decades, cardiac pacemakers have been available which help to save lives and which are becoming increasingly sophisticated.

In visceral medicine, gastrointestinal motility and in particular the function of the sphincters are modulated by electrical impulses. Despite many decades of scientific efforts, however, the very complex mode of action of gastrointestinal electrical stimulation is still poorly understood. It is known that a "gastric pacemaker" is located somewhere in the upper third of the stomach which dominates all motility phenomena of the GI tract distally to it. It overrides numerous lower level pacemakers.

If the gastric pacemaker is eliminated, lower level pacemakers will take over this triggering function of GI motility.

In our limited knowledge of electromotoric patterns of the GI tract, fastening periods are understood best. Motility events ("slow waves") occur in more or less defined frequencies which may also have an influence on sphincteric function, but principally it is not really clear how and why specific segments of the GI tract contract or relax or maintain a resting tone.

Nonetheless, some spectacular breakthroughs could already be achieved by the pragmatic pilot applications of pacemakers in visceral medicine.

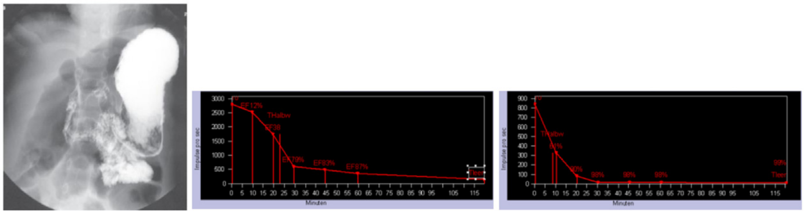
Fecal incontinence—i.e., the inability to control bowel emptying—deteriorates dramatically the quality of life. Patients suffering from incontinence do not dare to leave their homes and take part in social life; in addition, massive dermatologic problems arise. Surgical sphincteroplasty—often encompassing sophisticated techniques—was never really satisfying. Today, the technique of sacral nerve stimulation is available to restore sphincteric function. Though successfully introduced already in 1995 [2], the precise mechanism of action of sacral nerve stimulation is still unknown. At least three different explanations seem to be plausible:

1. Activation of a somatovisceral reflex with inhibition of colonic motoric activity and an improvement of the internal sphincter tone.
2. Influence on the defecatory reflux.
3. Direct reinforcement of the external sphincter tone [3].

It is still unknown which of these hypotheses is valid. Maybe, even another cause could be responsible.

Nonetheless, sacral nerve stimulation is already an extremely valuable tool in clinical care today which is far superior to former surgical techniques [4].

A better understanding of the pathophysiological aspects of fecal incontinence and of potential therapeutic approaches would not only contribute to an optimization of current sacral nerve stimulation but also enable further applications of electrical stimulation.



(A) (B) (C)

Figure 14.2 Gastroparesis: (A) Significantly enlarged stomach filled with contrast agent in the scintigraphic gastric emptying study; emptying is massively prolongated; (B) gastric emptying study before and (C) 6 months after implantation of the pacemaker. *Courtesy: (A) Dr. K. Holzapfel, Klinikum rechts der Isar; (B, C) Dr. I. Yakushev, Klinikum rechts der Isar.*

Gastric stimulation has a shorter history as compared to sacral nerve stimulation. The target is to improve gastric emptying in case of gastroparesis. As described in Section 2.3: Stomach, the lower third of the stomach is characterized by distinctive motility ("antral mill") which leads to controlled emptying of the gastric content into the duodenum.

Gastric motility may be impaired for several reasons (e.g., due to diabetes) which leads to more or less severe gastroparesis (Fig. 14.2). If medical treatment fails (there are only a few prokinetic agents available), partial or even total gastrectomy can be discussed. However, even after these highly invasive interventions success is not at all guaranteed.

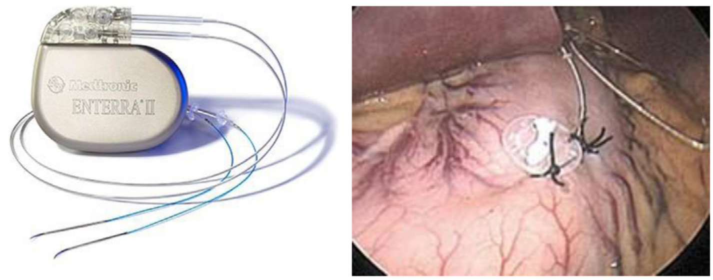
Today, at least one commercially available CE (Europe) and FDA-approved system is available.

Principally, three different methods are available today for gastric electrical stimulation (GES): Low frequency/high energy, high frequency/low energy, and neural sequential GES. High frequency/low energy systems such as the Enterra (Medtronic, Dublin, Ireland) are already in clinical use (Fig. 14.3).

However, the evidence in support of GES in the treatment of gastroparesis is still limited. Large clinical trials are still needed to confirm real efficacy [5].

Almost no approach has been left out in the treatment of morbid obesity. Thus, it is little wonder that GES was attempted as well. Evidence of long-term efficacy in weight reduction, however, is still weak and more controlled clinical trials are required to determine the real value [6].

Last but not least, GES has also been used to treat gastroesophageal reflux disease by stimulation of the lower esophageal sphincter. In a subgroup of patients, it appears to be helpful [7], but again, controlled clinical trials are needed [8].



(A) (B)

Figure 14.3 The Entrerra system: (A) Generator and electrodes; (B) view of the two electrodes implanted into the gastric wall. *All from Medtronic GmbH.*

The common denominator of all fields of application of electrical intestinal tract stimulation is the empirical selection of signal patterns, duration, and power. Comprehensive basic research on physiology and pathophysiology is still required. About 30–40 years ago, research of gastrointestinal electrical activity boomed [9], but the enthusiasm on this topic vanished when it turned out that mathematical methods and computer capacity were not yet adequate at that time. Today, recording tools, computational hardware, and computer science offer far better opportunities to understand the rather complex patterns of the electromechanical mechanisms of the GI tract. The vision is not only to improve the efficacy of GI stimulation as mentioned above, but also to understand better so-called functional diseases of the gastrointestinal tract, such as irritable bowel syndrome, and, hopefully, to improve therapy. We do not know for sure whether impaired motility plays a role in this very frequent disease, but the probability is high [10]. If the relevance of motility disorders could be established, GI electrical stimulation would offer a new treatment option.

14.6 COGNITIVE SURGERY

The most promising and fascinating development in surgery is going on now—although almost hidden—as a clandestine "digitalization" of the surgical area. Digitalization or computerization of surgery has so many different facets which make it difficult to find a characteristic term to define this new phenomenon. The surgical research group in Heidelberg/Germany coined the expression "cognitive surgery" [11–13], which comes closest to the meaning.

Cognitive surgery encompasses all processes to integrate information and communication into surgery. A lot of synonyms are used all over the world to describe the same thing, such as "computer-assisted surgery," "model-based surgery," or "digital surgery." All of them aim at using the tools provided by computer science and intelligent engineering to make surgical care even safer and more effective than today with affordable costs.

The various elements and key processes of this very broad and complex development are described in the following chapters.

14.6.1 Cooperative, Context Aware Support Systems

Computer-based assistance systems for surgery are developed to optimize surgical processes and improve patient safety and outcome. In surgery, research on assistance systems has already achieved remarkable results in supporting the surgeon within the operating room. Beyond the immediate surgical intervention, the perioperative field of surgical treatment has to be addressed as well.

Surgical treatment has become increasingly complex with the continuously growing amount of diagnostic and therapeutic information leading to information overload.

Furthermore, the growing number and functionality of innovative devices makes surgery continuously more demanding and it is conceivable that surgeons will soon become incapable of handling the technical environment adequately. There is clearly a need to make the use of advanced technology in the OR easier and to design the interaction with modern devices more intuitively to facilitate the surgical task.

In addition, future surgical—or interventional—treatment has to become increasingly more patient-friendly, safer, and more cost-efficient.

To reach this goal, new approaches have to be found in surgery, interventional gastroenterology, and interventional radiology. Beyond the development of new therapeutic strategies, new structures and innovative workflows have to be established and optimized in the OR. The aim is to use the ORs, the devices and systems, and so on more efficiently and to optimize the potential of human resources. This could be achieved by the development of a highly integrated cooperative and (partially) autonomous interventional environment.

14.6.2 Integrated ORs

The idea of creating a dedicated, highly specialized OR environment is not entirely new. The first integrated surgical workplace system was introduced by Dornier MedTech GmbH, Weßling, Germany (OREST) in 1994 [14].

The idea was developed by the working group of Gerhard Buess in Tübingen/Germany. The basic idea was to make the laparoscopic operation room easier to handle by three basic measures:

- Reduction of the number of cables and hoses.
- Defined supply of cables and hoses to the sterile field.
- Central operation of all functionalities.

All the devices required were integrated into one single mobile rack. All cables and hoses were guided into the sterile field through an articulated arm. Up to four multiplugs were used to connect all lines at a central terminal within the sterile area. The individual devices were connected to a central computer and could be controlled remotely by the surgeon, via a multifunctional monitor and input panel. This panel also carried information about all function parameters on a graphical computer display (Fig. 14.4).

At that time, the concept was revolutionary. In particular, it was planned as an open system and should allow the integration of new components. Whereas the concept of "monolithic" OR systems has become standard up to now, the problem of an "open platform" is still unsolved.

Soon, several other solutions became available, such as the SIOS by SIEMENS [15] and a system provided by STORZ.

Not all of these pioneers passed the test of time and some have disappeared from the market. Others were more successful after continuous improvements and still belong to the range of commercial systems available today.

Today, encapsulated systems are available from various companies (Table 14.1).

Other prominent providers are:

- Becton Dickinson, Heidelberg, Germany,
- Brainlab, Munich, Germany,
- Doricon, Marco Island, FL, United States,
- EIZO, Plauen, Germany,
- Getinge Group, Gothenburg, Sweden,
- IntegriTech, Reynoldsburg, OH, United States,
- Merivaara, Lahti, Finland,
- Optimus, Nottinghamshire, United Kingdom,
- Philips Healthcare, Hamburg, Germany,
- Skytron, Grand Rapids, MI, United States,
- Synergy Medical, Conshohocken, PA, United States,
- Trumpf Medical, Saalfeld, Germany.

Figure 14.4 OREST system (Dornier). *Courtesy: Prof. M. O. Schurr, Berlin, Germany.*

Table 14.1 Overview of encapsulated OR systems

Manufacturer	Denomination
Karl Storz, Tuttlingen, Germany	OR1
Olympus, Hamburg, Germany	Endo Alpha
Richard Wolf, Knittlingen, Germany	Core
Berchtold, Tuttlingen, Germany	Super Suite
Smith & Nephew, London, United Kingdom	Condor
Stryker, Duisburg, Germany	i.suite

All these integrated systems are proprietary solutions strictly confined to devices of their own brand.

The functionality is still comparatively low. It is mainly confined to control devices like the insufflator, illumination, etc., from the sterile area around the OR table (using touch screen, voice control, etc.). Self-evidently, other foreign components, like the electrocoagulation generator, the room lights, etc., are not part of the integrated world. Accordingly, a more sophisticated use and—later on—a coordination or even cooperation of the numerous elements of a surgical OR environment is impossible. This is extremely regrettable, since surgeons increasingly need help to handle the growing extent of complex technology which is the precondition of further progress of the interventional clinical care.

14.6.3 The Vision of a Cognitive OR Environment

The idea of some working groups worldwide is to upgrade conventional surgical operation rooms into multidisciplinary interventional suites which are even capable of active support of the surgeons.

It goes without saying that it is not intended to make a machine do an operation automatically or autonomously, but to improve safety by controlling and warning functions and to improve workflow by assisting routines (Fig. 14.5).

The new, really integrated and "cooperative" system should be able to provide the appropriate instrument at the right time, to adapt the functional state of auxiliary systems, and should warn in case of imminent danger (e.g., if an instrument is too close to a hazardous anatomical system). In addition, it should filter out unnecessary workflow disruptions, such as telephone calls, to relieve the workload of the surgical team, and facilitate organizational tasks like ordering the next patient just in time, to name just a few examples.

Automotive engineering provides many instances of semiautonomous functions that prove that these visions are more than just utopian.

One main precondition to develop "cooperative" systems is the capability to analyze and to interpret the actual situation in a way that makes the system "context sensitive" or "aware" of the specific situation.

14.6.3.1 Context-Awareness

The idea of context-awareness was originally derived from the concept of pervasive computing. Special investigative research on the term began in 1994.

Whereas pervasive computing strives to provide transparent use of computing facilities to users anytime and anywhere, independently of the environment, context-aware systems focus on providing the right service to the right user at the right time. Context-aware systems acquire context, analyze and interpret the context, and modify the system behavior

Figure 14.5 In some regards, a comparison of the cognitive OR with an autopilot in avionics is helpful. All relevant data are available to analyze and to understand the current state and to decide upon what has to be done next. If there are obvious discrepancies between human behavior (actual workflow) and the optimized procedure model, warnings have to be issued. *From MITI.*

for the user's changing situation. In other words, context-aware systems adapt their services to the user's need without explicit intervention from the user, thus working at least partially autonomously.

Making the context information available to the computer system is the first essential key issue of context-aware systems. Data retrieval by sensors play a central role.

Sensing technology is already well-developed today and allows for the application of context-aware systems [16], context-aware file systems [17], context-aware security [18], context-aware activity recognition, context-based searching [19], and even intelligent health care systems [20,21]. To the best of our knowledge, however, surgical activities in the OR were not yet considered. Data retrieval and capturing is certainly not as easy in the surgical environment as compared to a technical system, e.g., of an airplane. Some special aspects are presented below.

The next challenge is to interpret the data in a senseful manner and finally to derive reasonable suggestions of further activities, as roughly delineated in Fig. 14.6 [22]. Self-evidently, a comprehensive knowledge base for decision making must exist to make the system capable to

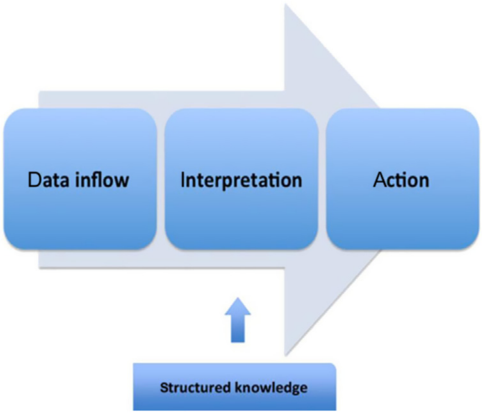


Figure 14.6 The so-called "cognitive operating room" is based upon three pillars: Data capturing, interpretation of comprehensive real-time information ("reasoning"), and the prediction of further activities. *From MITI.*

"understand" what is going on in the moment and what has to be done next ("structured knowledge") (see Section 14.6.6: Data Analysis and Interpretation).

Apparently plausible and easily implementable, this concept is still far away from being mature for clinical practice, since many elementary preconditions are not yet realized. One basic precondition is systems integration in the OR.

14.6.4 Systems Integration

An essential precondition of any approach to make the OR "intelligent" is the integration of all systems and devices used during surgery into a comprehensive surveillance and control system. The need for systems integration in the OR is well appreciated all over the world, but despite many national and international efforts, it is still only a vision today that all machines, devices, and instruments are incorporated and interconnected (Fig. 14.7).

The process of systems integration is far more difficult than initially expected. By nature, the problems are less technical rather than legal. The main question is to find a solution for liability. Few manufacturers are particularly interested in taking over the overall responsibility for a conglomerate of foreign devices. Accordingly, several commissions have been created internationally to promote interoperability. One example is the so-called OR.NET group which was significantly sponsored by the

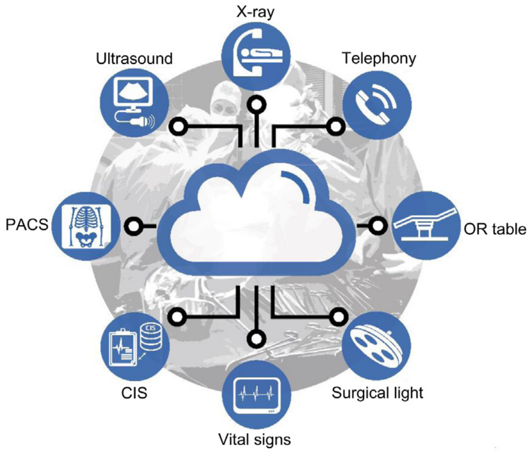


Figure 14.7 In the surgical OR, a heterogeneous equipment is used coming from various manufacturers. The first step to establish a context-aware system is to develop a central, comprehensive control system capable of information capturing from all devices and control steering. *From MITI.*

German government over a period of three years. The project is based on previous work for modular and dynamic networking of medical devices in the OR making use of the paradigm of service-oriented architecture. The goal is the development of certifiable, dynamic, multivendor networking options for existing and future devices and software solutions in the medical environment. The existing approaches will be further developed and improved, especially to support plug-and-play networking, capabilities for approval and risk management. At the same time the developed solutions will be implemented as showcases in the commercial medical products of the SMEs (small and middle enterprises) project partners. By having a wide variety of consortium members—companies, clinics, and R&D facilities—the project covers all significant areas, such as surgical planning, operation monitoring, diagnosis/treatment, and documentation. Besides designing and defining new, transsectoral standards, the project also considers risk analysis, security, interoperability of exchanged data, and developing IT infrastructure, while working on a standardization process with all partners (VDE, DIN, DKE, IHE, and other associations) from the very beginning. Together with the involved companies, responsible users and operators operating models are being developed that allow a transfer of the overall functionality. In the development of operating models, the interests and perspectives of the involved groups must be balanced carefully. Moreover, there is a strong dependency between the technical concepts, the conformity assessment procedures to be defined, as well as the processes of the operators. This means that the operating models must not only consider technical development and operational processes but also conformity assessment procedures. The participation of leading experts brings up new legal aspects, as well as new validation and testing procedures related to the capability for approval of the subcomponents and the entire system. A major goal of the project is to establish a portfolio of methods and tools as well as prototype testing labs and environments that support the certification of new equipment, in particular for SMEs.

A similar project is currently under way in Japan: The "Smart Cyber Operating Theater" (SCOT) was started for networking the operation room. It is based upon ORiN (Open Robot/Resource interface for the Network), a standard network interface for factory automation systems proposed by the Japan Robot Association in 2002.

In the United States, the Medical Device "Plug-and-Play" Interoperability Programme (MDPnP) was established to accelerate the adoption of medical device interoperability to facilitate the development of electronic health records and the cost-effective creation of innovative third-party medical "apps" for diagnosis, treatment, research, safety and quality improvements, equipment management, and adverse event detection and reporting when using networked medical devices for clinical care. MDPnP is one aspect of the Open ICE initiative—a community aiming at creating an Integrated Clinical Environment (ICE). Insofar, the MDPnP concept is broader as compared to OR.NET or SCOT which are mainly focused on the surgical OR. Despite of these intensive international activities, rapid advancements of achieving a comprehensive OR integration can reasonably not be expected in the short term.

14.6.5 Raw Data Capturing

Context-aware systems rely on the acquisition of data/context about the actual situation in which the system is operating and about the activities of the user who is interacting with the system.

Due to major advancements in sensor technology, a wide range of different sensors is available today to capture all information required to understand the context (Table 14.2).

Table 14.2 A list of sensor technologies used for context acquisition [20]

Sensors

Accelerometer	Temperature sensor	Position sensor	Level sensor
Gyroscope	Humidity sensor	Wi-Fi source	
Video sensor	Air pressure sensor	Light sensor	
Audio sensor	Bio sensor	Binary sensor	Soft sensor
Location sensor	Weight sensor	Vibration sensor	Heartbeat sensor
Touch sensor	Current sensor	Free fall sensor	Colorimeter
Motion sensor	Magnetic field sensor	Digital sensor	GSM source
3D images and video	GPS	Depth sensor	Speed sensor
Body sensor	Temporal sensor	Water sensor	Chemical sensor
Smartphone	Smoke sensor	Gas detector	Image sensor

Table 14.3 Main pillars of data acquisition

Information upon objects:	Instrument in use Working state of devices Consumption of disposables
Information upon persons:	Presence of surgical team Position of the team members

Gyroscopes are useful to assess the tilt/inclination of the OR table. Weight sensors enable quantification of the irrigation and suction volume, light sensors detect whether illumination is switched on/off. The presence/absence of team members may be documented by position sensors, e.g., radiofrequency identification devices [23,24]. The same is applicable for instrument detection.

Another option is to identify instruments opto-electronically when they are inserted into the trocar [25].

Information can also be extracted from the video image, e.g., by pattern recognition [26,27] or contextual cues [28] or motif discovery [29].

As compared to systems integration in the surgical OR with its difficult legal aspects, data acquisition is primarily a technical issue. Accordingly, it may be expected that information retrieval can soon be managed successfully (Table 14.3).

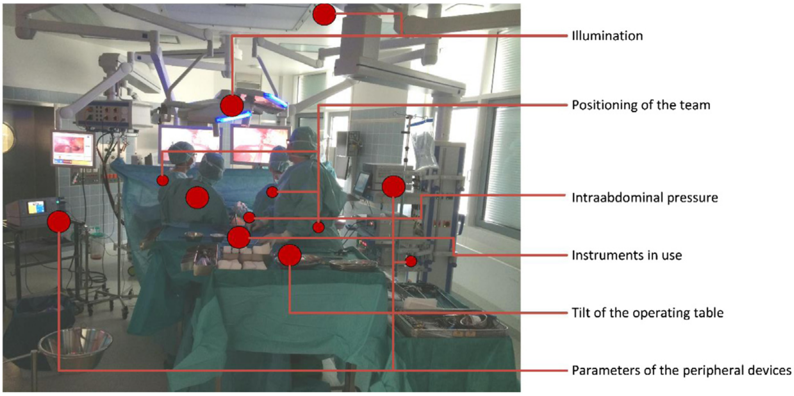


Figure 14.8 Sensor information retrieval in an integrated laparoscopic OR suite. *From MITI.*

Table 14.4 Some examples of sensor information already implemented in the OR

Device	Signal
Room lights	Binary
Surgical lights	Binary
Tilt of operation table	Numerical
Intraabdominal pressure	Numerical
Use of rinsing	Numerical
Use of aspiration	Numerical
Use of coagulation current	Binary
Use of cutting current	Binary
Instrument in use	Eight instruments, each binary

14.6.5.1 Information Upon Objects

Peripheral and installed devices may provide valuable information about the context.

An example is given in Fig. 14.8.

The actual functional state of the various systems gives a hint upon which steps of the operation are currently performed. This is possible if certain rules and interdependencies are known and well defined (Table 14.4). As an example, it is known that laparoscopic surgery or endoscopy is always performed with the room lights off.

Therefore, it is highly probable that the surgery has not begun as long as the OR is still illuminated.

Vice versa, switching the illumination off, is a strong indicator that laparoscopy starts.

On the other hand, the meaning of switching the lights on again is less unequivocal. Under normal conditions, the room lights are only turned on again at the end of the operation (as opposed to the OR lamps which are already switched on in the phase of "gallbladder removal"). The room light, however, may become necessary during the surgery. It may be temporarily required (e.g., for some necessarily alignments) or permanently (in case of conversion).

The timeline is also helpful to interpret this action. No surgical intervention can be carried through below a certain temporal minimum. If the lights are switched on in case of a laparoscopic cholecystectomy five minutes after start, this must not be interpreted as the end of the operation. Other clues will be helpful to explain the meaning.

It is assumed that about two-thirds of all so-called "high-level tasks" during a laparoscopic cholecystectomy can be identified with the information inflow as shown in Fig. 14.8 [30]. This is certainly not sufficient, but is a strong base for improving the situation analysis by complementary data such as staff tracking as mentioned below.

The data acquisition framework has to be integrated as perfectly as possible into the OR setup. It must, under no circumstances, disturb the regular surgical workflow. The sensors should be as invisible as possible—additional wires or cables have to be avoided.

Deduced from the conformance to medical technical regulation, the entire framework needs to behave in a strict read-only manner.

Up to now, only a few devices provide functional data and information via an open interface despite of the above-mentioned approaches, such as OR.NET, SCOT, and MDPnP.

As has been demonstrated by several papers [31], information can also be gained by external sensors attached to "foreign" devices to analyze the display image or acoustical signals. Direct delivery would of course always be preferable, but it is not an absolute precondition.

14.6.5.2 Information About the Staff

The presence and the activities of the individual members of the surgical team are invaluable clues to interpret the actual situation in the OR correctly and reliably.

The scrub nurse and the circulating nurse are the first and the last in the surgical theater.

Accordingly, their presence does not provide specific information about the stage of the surgical procedure.

Table 14.5 Selection of RTLS applicable in the OR

RTLS technologies
Bluetooth low energy (BLE)
Active or passive RFID
Ultra-wide band (UWB)
ZigBee

This is different from the observation of the surgeon. He/she is the last one entering the OR—if everything is prepared and the rest of the team is already present. On the other hand, he is the first one who leaves the scene.

As long as the surgeon is not present in the OR, the operation cannot be started. If he/she appears in the OR and positions himself/herself at the OR table, this is a very significant sign that the procedure will start right now. On the other hand it is most probable that the procedure has come to an end if she is leaving the OR bed.

Once the team is positioned at the OR table (according to strict rules), the individuals remain at their place until the procedure is finished. If they change their respective places, it is a sign that something particular is going on. The meaning depends on the context. If the surgeon is still in training/education, he/she is usually assisted by an experienced surgeon (first assistant). If the experienced assisting surgeon is forced to take over the operation, he/she has to change his place with the surgeon who now takes over the role of the assistant. This is a clear sign that the procedure is significantly more difficult than initially expected.

In another context, however, this change of the roles could mean just the contrary: if the operation was originally begun by an experienced surgeon assisted by a less experienced surgical assistant, it may turn out intraoperatively that it is easier to perform than originally assumed. The surgeon decides now to leave it over to the assistant.

All persons involved have to be equipped with a suitable identification tool as soon as they are entering the OR tract. Hence, they can be identified (and their respective role: anesthetist, scrub nurse, circulating nurse, first assistant, second assistant, surgeon, etc.) as soon as they arrive in the OR.

A suitable real-time locating system (RTLS) is required to locate the players reliably (Table 14.5).

As shown in Table 14.5, there is a variety of technologies applicable for real-time location tracking, differing in metrics such as position

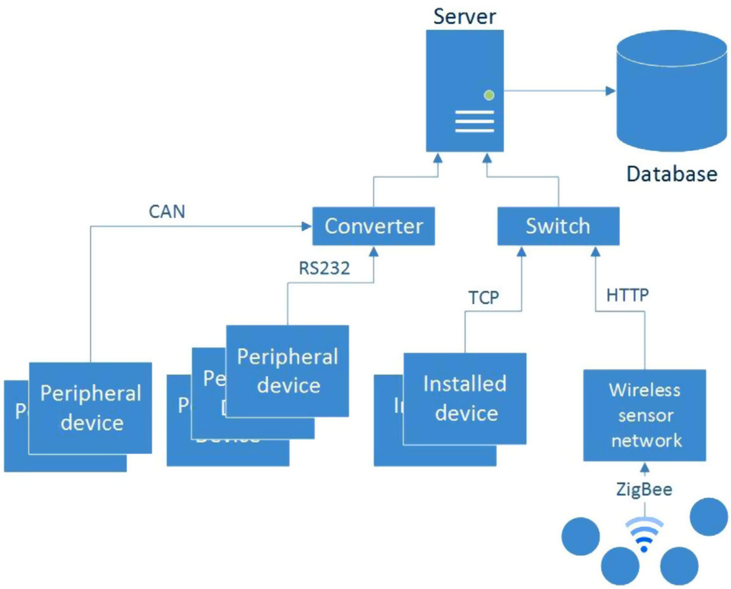


Figure 14.9 Network scheme of the data acquisition framework. The different peripherals are connected via dedicated interfaces to the server with an attached storage database. In this particular case, ZigBee is used as one example for the RTLS implementation for localization of the staff members. *From MITI.*

accuracy, energy consumption, and costs. Those systems usually comprise two functionalities: on the one hand a unique identifiable tag can be located in a certain range (depending on the amount of antennas and the signal strength) via triangulation. On the other hand, those systems usually allow the wireless transmission of sensor data connected to the tags. Modern tags often include sensors for temperature, humidity, acceleration, brightness, and many more. Hence, it is possible to transmit wirelessly sensor data and simultaneously the tracking of the location where the corresponding data were assessed. Such systems open a broad field of applications not only in the OR but the whole hospital, including patient safety, logistics, and asset tracking.

An example of how a centralized data acquisition framework for operating theaters could be implemented is given in Fig. 14.9 [32].

Since sensor data are known to be noisy, a cleaning process is required in many instances. A hidden process is required to determine the true value of the sensors, such as the presence of a tag in the case of RFID, from a noisy and uncompleted set of features.

To cope with the incomplete set of sensor signals, Bouarfa et al. propose to use Bayesian networks to define the structure of the sensor signals

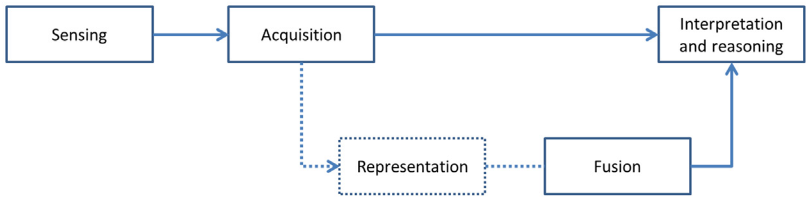


Figure 14.10 Some data may be used directly for the analysis of the actual situation. In the majority of cases, a "fine-tuning" is required beforehand (context representation and context fusion (*dotted line*). *From MITI.*

that occur in a certain action [30]. In the case of RFID, features usually describe one or more characteristics of the tag detected: the unique serial number of the tag, the location where the reading took place, or the device number of the reader of the tag.

However, in most cases additional steps have to be considered as shown in Fig. 14.10.

Context representation means the formal representation of the acquired contextual information, whereas context fusion focuses on the integration of information from different sources in order to merge overlapping data.

Context representation and fusion facilitate detecting and recognizing the dependency or relationship of one data source on another to infer user context. This problem becomes even more critical when context information is emerging from very heterogeneous sources like sensors, patient data, and user profiles.

14.6.6 Data Analysis and Interpretation

Sensing and data capturing is the first step prior to data analysis and interpretation.

If this is provided, the "intelligence" behind the system must "interpret" these data and derive what is actually going on and foresee, in the third and last step, what should come next.

Like in human decision making, this is only feasible if he/she knows what he/she is dealing with and what has to be done.

He/she must understand the situation and must have a clear plan what has to be done why and how.

An experienced surgeon and a well-trained nurse will immediately, when entering an OR with a surgery going on, understand the actual state of this particular operation and will be able to predict the next steps with a very high precision due to their sound empirical knowledge. If a machine is supposed to do the same, this copious wealth of professional

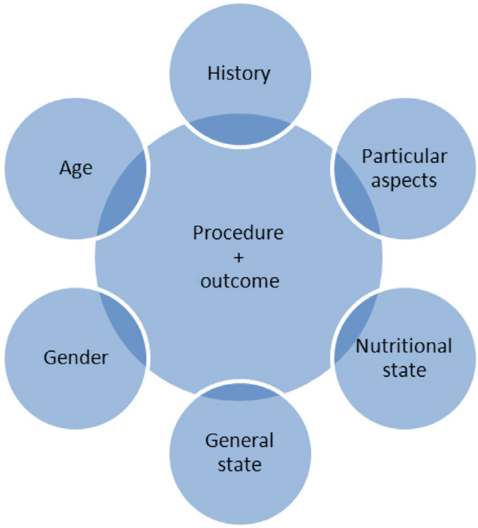


Figure 14.11 Multiple factors contribute to the health care providing process and the surgical workflow. Many aspects, such as age and history, are generic. Particular aspects are relative to the individual surgical procedure. *From MITI.*

knowledge (about the procedure, the stage of the disease, the training level of the OR team, etc.) has to be formalized in a way that it may be understood by the computer. Hundreds and thousands of rules and interdependencies have to be defined beyond providing simple fact. So-called "models" are required [33–36].

In our context, at least two models are a precondition of data analysis and interpretation: the patient model and the surgical model.

14.6.6.1 Patient Model

Each single patient is unique and the actual course of surgery may vary—and this matters even if a standardized surgical procedure is considered. A normal cholecystectomy may be extremely simple and fast in the case of a young lady with a reasonable Body Mass Index (BMI) but extraordinarily time-consuming and challenging in a male patient of 75 years of age with a long history of chronic cholecystitis. In other words, individual features have a considerable influence upon the course of an operation and the outcome. Self-evidently, this has to be regarded if a context-aware system is to be developed (Fig. 14.11).

A patient model is required. This could be defined as a comprehensive robust view of the patient making all relevant data available for surgical intervention. To create a patient model, all achievable information have to be collected (personal data, laboratory findings, results of imaging procedures, etc.), which is the first step. In the second step, the impact of each single information onto the expected course of the procedure has to be quantified.

Above, the impact of BMI on the workflow has already been mentioned. Another example is the number, size, and quality of gallstones if cholecystectomy is considered. In a patient-specific model, it must be documented how many stones are present, and how large they are. In addition, the consistency of the concrements should be known.

The experienced surgeons know that it is comparatively easy to retrieve a gallbladder if only a few small and soft stones are present. Conversely, large hard stones need more effort and time than the average.

Surgeons possess the domain knowledge to help to create a patient-specific model. This could already be shown in case of laparoscopic cholecystectomy, but much has still to be done to provide appropriate patient models for a broader range of surgical interventions.

14.6.6.2 Surgical Model

To understand what is currently going on is necessarily based upon a comprehensive understanding of the entire process. If a particular scenario of a surgical operation is evaluated, one needs to know what has happened before. In order to predict the next steps, it has to be known how the procedure is normally continued. A model of the procedure is required. In our case, a surgical model has to be created. Modeling a simple procedure is relatively easy: "Go from A to B; if B is reached, go to C." It soon becomes less trivial, if more than one option may exist, if some steps have to be repetitive.

The idea to break down a surgical operation into clearly defined segments is still today seen as an academic exercise, but is a prerequisite to enable the machine to understand what is happening.

The surgeons have to define clearly step by step the normal course of the operation, and, concomitantly, potentially deviating actions.

Using an appropriate modeling language, a workflow description can now be designed. Today, numerous languages are in use with specific advantages and drawbacks (Table 14.6). Mainly three of them are considered for surgical workflow modeling:

1. *E*vent-driven *P*rocess *C*hains (EPC),
2. *B*usiness *P*rocess *M*odel and *N*otation (BPMN 2.0),
3. *Y*et *A*nother *W*orkflow *L*anguage (YAWL).

If a workflow description is available (including all conceivable modifications) [37], a fundament is laid to predict the next steps.

Table 14.6 Overview upon currently available workflow languages

Modeling language	Advantages	Drawbacks
EPC	• Multiple process layers • Good depiction of resources organization (IT landscape, devices, assets, etc.)	• Not directly executable • Few possibilities to model surgical process operations
BPMN 2.0	• Defined standard • Easy to understand process models • Executable models • Commonly used	• Few possibilities to depict (shared) resources and responsibilities → can lead to confusing models
YAWL	• Formal language • Good representation of surgical workflow • Executable models • Underlying Petri nets prevent deadlocks	• Much parameterization needed • High programming effort • Few graphical symbols

It is often argued that precisely fitting surgical models cannot be defined for common use since despite any efforts to standardize surgical techniques, most surgeons all over the world prefer their own—even only slight—variations in how they perform a cholecystectomy, appendectomy, or herniotomy, not to mention more complex operations such as gastrectomy or pancreatectomy. This might be true if workflow models had to be written manually. With the advance of modern computer science (e.g., machine learning), most models will be created and refined automatically, with a higher degree of precision and even better reflecting the specific local and personal conditions than a human developer could do it.

14.6.7 Workflow Prediction by Combining Data and Model and Autonomous Support

Fig. 14.12 depicts an exemplary workflow with discrete states and their transitions in a pseudo modeling language (no particular modeling language). Detecting the current state let alone predicting the next state of a surgery within an existing model cannot rely solely on said model. In a model, transitions are based on probabilities or abstract triggers. Hence it is not possible to predict the duration spent in a particular state. In the case of multiple subsequent parallel transitions, external signals are required to define the actual path. Specific transition

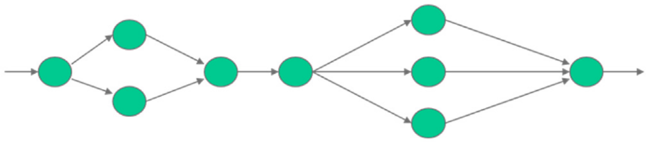


Figure 14.12 Exemplary workflow model. *From MITI.*

triggers usually consist of nonobvious combinations of multiple external signals and events. In order to identify such combinations, it is common to utilize machine learning algorithms. In this case, the set of current measurements is classified as one of the possible model states.

So far mainly methods like Hidden Markov Models (HMM) [22,38–40], Random Forests (RF), and Support Vector Machines (SVM) have been investigated for their applicability for this task.

HMMs build an internal sequence model during the training process based on the provided data. This internal model has no direct connection to any manually created workflow model; however, ideally both models show the same or a very similar structure.

RFs are a collection of multiple generated decision trees, influenced by randomness during the training process. This introduced randomness provides increased robustness for uncommon input data, although it requires slightly larger datasets for training than other classification methods.

SVM try to form an optimal separation between representatives of different classes. Those representatives are called support vectors and define the borders of their respective classes within a multidimensional hyperspace.

A method currently under active research is the so-called deep-learning method, in which huge amounts of unlabeled data are analyzed without manual supervision. Currently this method is not applicable to surgical workflow analysis, since no sufficiently large datasets exist yet.

For all presented methods, an exhaustive collection of relevant surgical data is of utmost importance.

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EPILOG: THE NEW ERA: "DIGITALIZED SURGERY"?

Information is today the real common dominator in social, political, and economical areas. Even in industrial production which aims at the physical creation of real "hardware," the complicated process of precise milling, drilling, welding, and assembling which formerly required hundreds and thousands of experienced skillful craftsmen, is a minor issue today as compared to the processes required before, during, and after "real" production. As soon as a new product is conceived, a complex process of planning has to be initiated. The first design of the product has to be evaluated under financial, production-related, marketing, and recycling aspects, just to name a few.

Procurement of raw materials has to be considered. Everything has to be available in time—not too early to keep storage costs as low as possible and not too late to avoid a stop of production.

Finally, the production workflow has to be organized in a way that each single step fits seamlessly into the whole process. Production itself is then performed by automates or robots. The stand-alone feature of this new type of industrial production is the autonomous interaction of devices and machines via the internet of things (IoT). Many steps of the workflow are coordinated by the productive system via direct communication. A multitude of sensors keeps the machines informed about the actual state of the process. By communication with other systems, they are able to make decentralized decisions. Only in the case of unclear situations, interferences, or conflicting goals, is the decision delegated to a higher level—usually to humans.

Accordingly, the main features of "digitalized production" are self-optimization, self-configuration, and self-diagnosis of the elements of the production line which enables "intelligent support" of the human masters.

This evident development is often denominated as the fourth industrial revolution (Fig. 15.1).

Both the quality and the quantity of the transformation process are amazing. At the end, a high customization of products is striven for which is cost-effective, because of fast and highly flexible (mass-) production. The task of the engineer and worker is to create the ideas and to control the whole process.

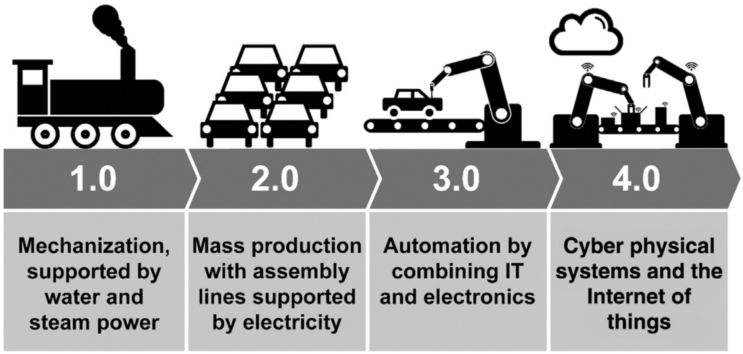

Figure 15.1 Industry 4.0 attempts to describe the transformation process of industrial production from passive automated production to an active, cognitive-supported process of production. *From MITI.*

15.1 HOWEVER, WHAT HAS “DIGITALIZED PRODUCTION” OR “INDUSTRY 4.0” TO DO WITH SURGERY?

Many—if not even the majority of—surgeons are reluctant to compare their professional activities with an industrial or service-oriented business. First of all, a patient is not just a workpiece. He/she is an autonomous personality and individual human being with his/her own mentality, cultural background, expectations, etc. What is even more important for surgery, humans differ considerably in height, shape, body mass, and even internal anatomy. In addition, diseases vary considerably in stages, biological behavior, and individual response of the organism. Most surgeons see their work rather as an art than a science, describing it as “judgement-based work,” “craft work,” or “professional work” [1], which is characterized by the variability in the process, its inputs, and its outputs.

The highly variable environment of a surgical operation seems at first glance to impair any attempt to organize the process in a similar way to industry 4.0.

However, as already pointed out in Chapter 14, Visceral Surgery of the Future: Prospects and Needs, a surgical operation is just a sequence of manual actions that have to be carried out step by step by the surgeon who has to perform each single manipulation as fast and precisely as possible. In the majority of cases (maybe with the exception of emergency surgeries), the single steps of the intervention can be standardized, in particular in high volume but surgically less challenging surgeries, such as herniotomy, cholecystectomy, appendectomy or thyroid resection, which make up at least two-thirds of surgical activity. They are the typical relatively low-risk but also low-reward activities in which it pays to use highly standardized processes. As shown in Section 14.6.6: Data Analysis and Interpretation, it seems to be possible to work out adequate patient models and surgical models which allow to "tame the environment by imposing complex rules that spell out what to do in every possible circumstance" [1].

Two particular aspects have also to be taken into account which favor the "digitalization" of surgery: all surgeries mentioned above can be taught in a strictly standardized and evidence-based way. Secondly, surgical models will gain dynamic flexibility since the ability of modern computational systems to adapt themselves to varying conditions of the environment ("machine learning") is steadily growing.

If it will become possible that machines and systems do "understand" the ongoing processes and are even capable of foreseeing what comes next and what is required to be done, some of the characteristic elements of what has been described before as "industry 4.0" could be adapted to surgery as well.

One of the key ideas is that machines and systems directly communicate with each other (IoT) and decide autonomously upon the next actions. If all devices are connected (see Section 14.6.4: Systems Integration), it is conceivable that a disposable clip applier reports its use to the logistics system which automatically orders a new one from the provider. Many similar examples could be pointed out to demonstrate the application of corresponding systems and devices and autonomous decision making on a machine level. The laparoscopic telescope could switch off the room lights as soon as it is inserted into the abdomen—and could switch it on again automatically as soon as it is removed. The laparoscope could always focus on the tip of the dominant instrument to provide the optimal field of view for the surgeon, and the two graspers could tie a knot automatically and far faster than a human as soon as they have recognized that a knot has to be made in the respective moment. As compared to processes in industrial production, these examples and first steps to "surgery 4.0" might appear very modest and almost trivial. To make "digitalized surgery" a reality does not appear to be too visionary as seen by an industrial expert. The surgical community, however, is currently still skeptical and reserved, since the potential risks and dangers of an autonomous environment seem to outweigh by far the potential benefits.

Let us first consider the potential risks of a (partially) autonomous surgical support environment. The consequences of false decisions always depend upon the decision level. Simple decisions—such as the reordering of consumables—are far less fatal than making a knot at the wrong moment. A rivet in car production fixed at the wrong angle is less dramatic than an unintended incision of the aorta. At any rate, in surgery wrong support is worse than no support which is a specific modification of the more general sentence "no information is better than wrong information."

If the potential risk of digitalized systems in surgery has to approximate almost zero, is any approach to bring "surgery 4.0" into practical surgical care conceivable at all? At a closer look it becomes evident that there cannot be a clear "yes" or a clear "no." We hypothesize that many aspects of daily surgery could draw a considerable benefit from digitalized routines and that there are others which are less suitable for the use of cognitive systems. The processes to prepare the patient for surgery should be clearly structured and highly standardized. The patient should reach the operation room always in a known stable state. Careful therapy planning in advance must ensure the optimal surgical approach. If, as in this case, best clinical practice can be defined and documented in advance and the quality of performance clearly assessed, the optimal conditions for the digitalization of this part of surgical care are given. A set of international guidelines is available and makes decision making rather easy, cutting medical errors nearly in half [2]. Since almost all conceivable situations are covered by evidence-based rules, it is not too big a challenge to enable machines to make low level decisions such as to call the team members just in time they are needed, or to activate and to check the devices required in a particular operation, or to summon up the team members for having the team time-out before surgery is started. It is even probable that this type of intelligent support by machines will become indispensable in the future, since the growing number of devices and subsystems with increasingly sophisticated functionalities in the operation room will soon surmount the acceptable amount of workload of the individual team members. Partial autonomy of the subsystems could offer the opportunity to reduce complexity and to limit the tasks of the team members to the essentials.

Even during the operation, many aspects of the general workflow are suitable to be taken over by an intelligent support system: presentation of the appropriate imaging at the OR table, adjusting the OR table into its required position, automatic documentation of the course of the operation, preparing the next instrument for the scrub nurse, etc. are just a few examples from many.

However, the closer it comes to the real surgical manipulation, the more critical is it to admit autonomous decisions/actions of machines. With only a few exceptions, the role of the "intelligent support system" should be strictly confined to make proposals, which can be accepted by the surgeon or refused. Even if automatic support could theoretically make surgery faster and easier for the surgeon to perform, the consequences of only one wrong decision could be disastrous. Beyond a high degree of standardization in most surgical procedures, surgeons still need creativity, flexibility, and should be able to react dynamically and at instance to unexpected situations. Despite careful standardized education of the surgeons involved, and despite careful preparation of the patient and meticulous therapy planning, critical events or even emergency situations can never be completely ruled out. Currently, it is more than unlikely that these specific human abilities can be replicated even on a mid-term or long-term horizon in a way that machines are able to react as situation-adapted as the experienced surgeon is capable of doing. Accordingly, the vision of an autonomous surgical robot is not only rather naive but also counterproductive. It is counterproductive since the main chances of computerization or digitalization of surgery should not be looked for in the creation of "surgical robots." The real impact of biomedical engineering including computer science onto surgery will certainly come in other areas. Precious resources should be better concentrated on these far more promising aims. In our opinion, the most elegant way to describe the further direction can be found in a paper of Maier-Hein et al.[3]:

"While the current evolution of surgery has been enabled by new devices such as robots and intra-operative imaging modalities, the next wave of evolution will be heavily data driven. Interventional care will shift from an art based on the physician's individual experiences, preferences and traditions towards a discipline that enables objective decision-making based upon holistic processing of data from various sources."

Here again, we can find a striking parallel to the development in industry: what really counts is information. Even in surgery, a paradigm shift from implicit to explicit, from subjective to objective, and from qualitative to quantitative processes can be expected.

In order to systematize and to foster the application of modern biomedical approaches onto surgery, an initiative called "Surgical Data Science" (SDS) was launched in 2016. This new initiative is aimed at dealing with "the manipulation of the patient and dedicated anatomical structures serving as targets." In contrast to general biomedical data science, it should also include procedural data, involving four main major components:

1. Patient: The subject getting a diagnosis or treatment
2. Effectors: Humans and/or devices involved in the manipulation of the patient including surgeons, anesthetists, nurses, and even artificial/mechanical support such as computers and robots
3. Sensors: Devices for perceiving patient- and procedure-related data, such as images, vital signs, and motion data from effectors
4. Domain knowledge: Factual knowledge, such as previous findings from studies, clinical guidelines, or evidence-based standards related to the clinical workflow, as well as practical knowledge from previous procedures.

In an international interactive brainstorming meeting in Heidelberg 2016, a consensus definition of SDS was elaborated [3]:

Surgical data science is an emerging scientific discipline with the objective of improving the safety, quality, effectiveness, and efficiency of interventional diagnosis and therapy by means of data acquisition, analysis and modelling. It encompasses all clinical disciplines in which patient care involves intervention to manipulate anatomical structures with a diagnostic, prognostic or therapeutic goal, such as surgery, interventional radiology, radiotherapy and interventional gastroenterology. Data may pertain to any part of the patient care process (from initial presentations to outcome of care), may be about the patient, caregivers, as well as technology used to deliver care, and analysed in the context of generic domain-specific knowledge from existing evidence, clinical guidelines, current practice patterns, caregiver experience, and patient preferences. Data may be obtained through medical records, imaging, medical devices or sensors that may be either positioned on patients or caregivers or integrated into instruments and technology used to deliver care. Improvement may come from understanding of processes and strategies, predicting events and clinical outcome, assisting physicians in decision making and plan execution, optimizing ergonomics of systems, controlling devices before, during and after treatments well as from advances in prevention, training, simulation and assessment. Surgical data science builds on principles and methods from other data-intensive disciplines such as computer science, engineering, information theory, statistics, mathematics, and epidemiology, and complements other information-enabled technologies such as surgical robotics, smart operating rooms and electronic patient records

According to this definition, SDS is the universal tool to bring all the fields of biomedical engineering together to mobilize the highest degree of synergism in close cooperation with the clinicians. Insofar, SDS could ignite the fourth era of scientific surgery (Fig. 15.2).

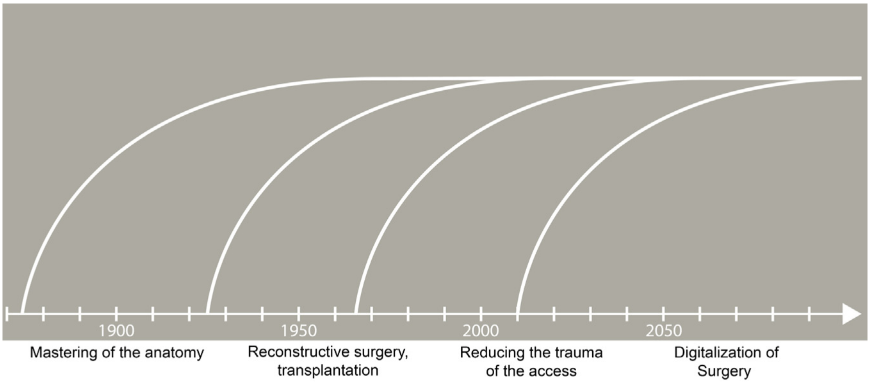

Figure 15.2 Maybe, the fourth era of scientific surgery is the era of digitalization—"cognitive surgery" or "surgery 4.0". *From MITI.*

Since we are at the very beginning of SDS, strong efforts have to be made to promote the dissemination of this new scientific approach to surgery. The consensus conference identified five key points up to now to advance the field of SDS:

- Data access: Overcoming regulatory, technical, and sociological barriers for creating large common annotated data sets
- Standardization: Development of standards for facilitating interoperability and data sharing for both stronger statistical power and validation of methods and models
- Data analysis: Development of new methods for prediction, knowledge extraction, etc.
- Clinical impact: Demonstration of added value with selected clinical applications
- Training: Establishment of SDS as a new career path in academic hospitals.

Most probably, some more key points will have to be added in the future, but already these five will require the concentrated energy and efforts of engineers, computer scientists, basic researchers, and clinicians to advance SDS. However, we are firmly convinced that it is worthwhile to invest the necessary input, since SDS is the most promising way to:

- improve patient safety and quality of care
- improve patient's and caregiver's satisfaction
- reduce cost.

Beyond, SDS could help to solve two problems which were already addressed in Chapter 1, Surgery and Biomedical Engineering. In the first

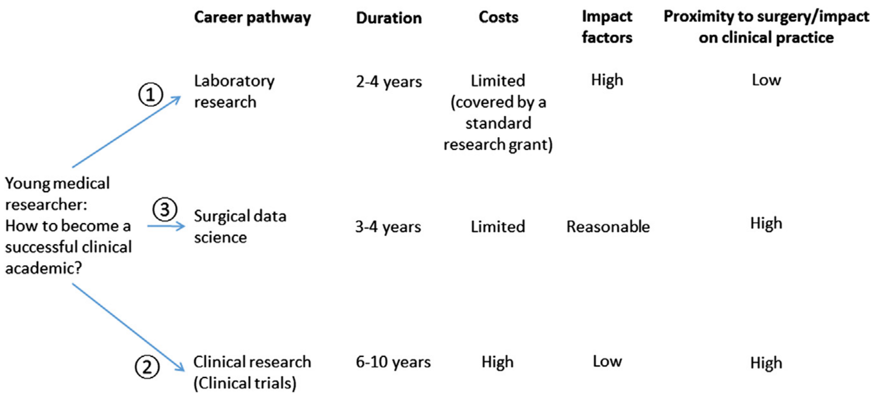

Figure 15.3 Currently, laboratory research (1) is more attractive than clinical research (2) for young surgical academics, since it results in higher impact factors and is more plannable. Surgical data science (3) could become a good trade-off. It is both promising in regards to a fast academic career and has a high input on clinical practice. *Modified from Diener MK, Simon T, Büchler MW, Seiler CM. Surgical evaluation and knowledge transfer—methods of clinical research in surgery. Langenbecks Arch Surg 2012;397(8):1193–1199 [4].*

chapter it was pointed out that BME is still in a stage of development where it is not yet quite clear that it might be able to establish itself as a scientific entity in its own right, which was illustrated by the example of the mule. Now, SDS offers the great chance to give BME its own distinctive identity.

We also raised the question of how to win surgeons with academic ambitions to get involved into BME-related surgical research. As equally shown in the first chapter, young surgeons rather prefer laboratory studies which can be finished in a reasonable amount of time instead of costly and time-consuming clinical studies which often result in a significant delay to an academic career [4].

SDS offers now a realistic new option (Fig. 15.3): it does not only provide a faster chance to earn scientific merits for the young clinician but it also yields surgically relevant new knowledge which improves the surgical therapeutic potential.

Today, prospective clinical trials are still the gold standard of gaining evidence in surgery, but they are very costly, difficult to organize, and often need many years to perform them. Accordingly, they give answers to questions which had been put five, seven, or ten years previously. In the future scientific evidence can be found far more easily and more elegantly by systematic knowledge extraction out of the huge treasure troves of data which are collected worldwide.

Surgery could now really move from being mainly an empirical discipline to an evidence-based science—a vision all of us should strive for. However, it will only be achieved by a new dimension of a close cooperation between surgeons, engineers, computer scientists, and many other researchers.

The authors hope that this book may give a bit of momentum to this development.

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Biomedical Engineering in Gastrointestinal Surgery

Armin Schneider and Hubertus Feussner

A multi-disciplinary view of the role of biomedical engineering in gastrointestinal surgery for engineers and clinicians

- Written by the head of the Institute of Minimally Invasive Interdisciplinary Therapeutic Intervention (TUM MITI) which focusses on interdisciplinary cooperation in visceral medicine
- Provides medical and anatomical knowledge for engineers and puts technology in the context of surgical disease and anatomy
- Helps clinicians understand the technology, and use it safely and efficiently

Biomedical Engineering in Gastrointestinal Surgery is a combination of engineering and surgical experience on the role of engineering in gastrointestinal surgery. There is currently no other book that combines engineering and clinical issues in this field, while engineering is becoming more and more important in surgery. This book is written to a high technical level, but also contains clear explanations of clinical conditions and clinical needs for engineers and students. Chapters covering anatomy and physiology are comprehensive and easy to understand for nonsurgeons, while technologies are put into the context of surgical disease and anatomy for engineers.

The authors are the two most senior members of the *Institute for Minimally Invasive Interdisciplinary Therapeutic Interventions* (MITI) which is pioneering this kind of collaboration between engineers and clinicians in minimally invasive surgery. MITI is an interdisciplinary platform for collaborative work of surgeons, gastroenterologists, biomedical engineers, and industrial companies with mechanical and electronic workshops, dry laboratories, and comprehensive facilities for animal studies as well as a fully integrated clinical "OR of the future."

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