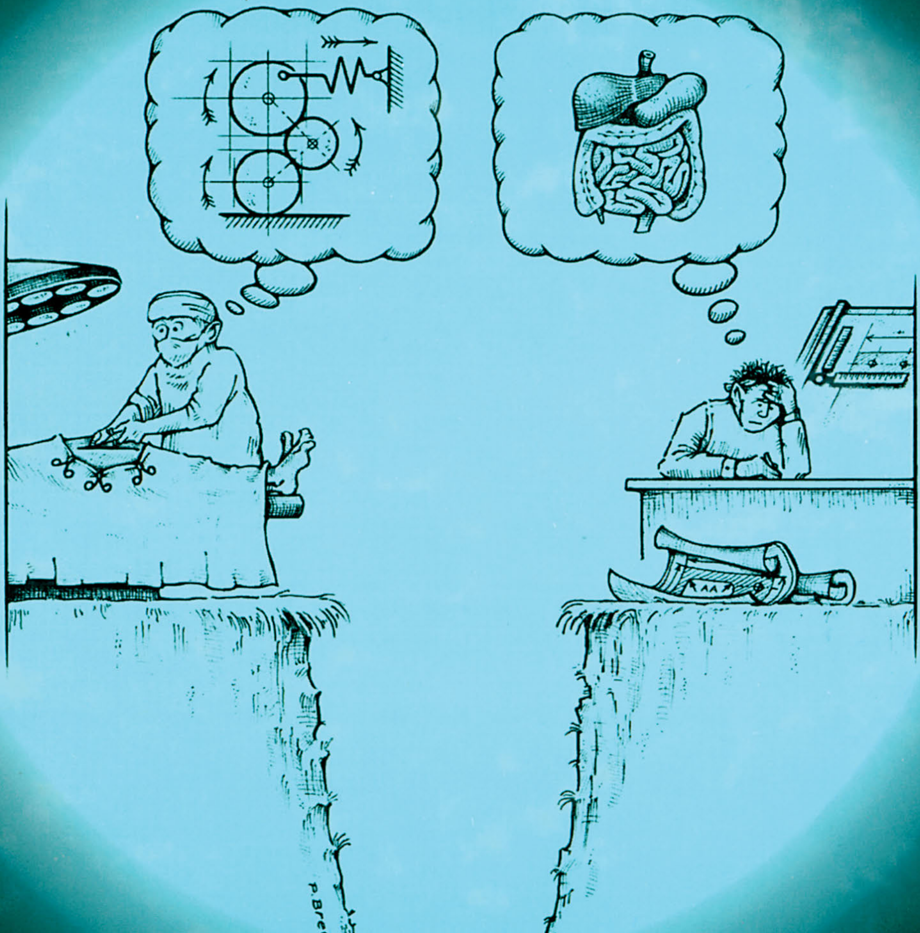
ENGINEERING FOR PATIENT SAFETY

Issues in Minimally Invasive Procedures



Edited by

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Engineering for Patient Safety

Issues in Minimally Invasive Procedures

Human Error and Safety
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Bogner • Misadventures in Health Care: Inside Stories

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Contents

Series Foreword

This book, the first in the Patient Safety series, describes a novel if not revolutionary approach to designing medical equipment—that of design professionals observing the actual use of equipment *in situ*—as it is used in performing medical procedures with the goal of identifying issues that might compromise the safety of the patient. The approach of observing the phenomenon being studied as it occurs naturally is not novel—the approach is integral to the study of cultural anthropology and ecological psychology as well as the realm of consumer products; it is the approach of classic human factors. Indeed, observation is the traditional means of learning medical procedures—observe, then emulate. The uniqueness of the approach discussed in this book is that the observation conducted in cooperation with the care providers is directed not only to understanding what is transpiring, but also to discern how the equipment being used affects the care provider's performance *so its design might be modified to enhance patient safety.* This topic—addressing the role of equipment in patient safety—is an issue of emerging importance.

In considering patient safety, typically the focus is on the care provider associated with an injury, an adverse outcome; however, there is growing evidence that such a focus is too narrow. An article in the *Journal of the American Medical Association* (January 21, 2004) reported that medical devices—a term used to refer to all medical equipment—can and do negatively affect patient safety. Various surveillance methods in a 520-bed teaching hospital identified medical devices as hazards (accidents waiting to happen) that have the potential to harm a patient as well as being involved in adverse events in which patient harm occurred. Combining the findings from all surveillance methods resulted in a rate of 83.7 problems per 1000 patients. Even if there were overlap among the various surveillance methods—the article states there wasn't—the rate would be formidable. Given the emphasis on product safety in other industries, one may query why medical devices are implicated in so many potential and actual patient safety problems.

The problems with medical devices reflect in some part the typical device designer's lack of experience using such devices to actually provide care. With experience comes sensitivity to and knowledge of what is involved in performing the task; however, there is little opportunity to extrapolate such experience because medical devices are so unlike other products. Experience with equipment in other industries such as aviation and space is provided by simulation—simulations can be changed to assess the impact of product or context change. Although there are simulators in health care, they are used almost exclusively for training. The simulators are mannequins or parts of mannequins on which specific procedures are practiced as well as full-blown operating rooms or emergency rooms complete with personnel that typically are used to assess and train reactions to unusual circumstances. It would be a rare occurrence if the effect of the design of a medical device on performance were explored in either type of simulator. Admittedly, medical devices are studied in usability laboratories; however, they are laboratories and as such are insulated from the rigors and competing demands of the actual context of care. Thus, the response to the question of how could medical devices be implicated in so many potential and actual patient safety problems is that their use is not studied in the context of care.

The usual response to questioning why medical devices aren't tested in a real or simulated context of care is that actual patients might be harmed. Medical device testing in a simulated context of care would identify use issues; however, there is no concerted effort to do so in the remotely foreseeable future. The documented problems with medical devices and the need to address them attest to the importance of the engineering for patient safety approach described in this book. Although that approach is applicable to any medical device, the discussion of its application to issues in minimally invasive procedures is particularly insightful and appropriate.

As is pointed out in the book, minimally invasive otherwise known as keyhole surgery is very popular and becoming more so. Because of the popularity of this type of surgery, the technological sophistication of the devices used to perform the procedures and the un-natural postures the devices require of the surgeon as well as the constraints and demands of the context of care, it is particularly important that the devices are designed to optimize patient safety. This book describes an approach to meet that challenge. It is a fitting inauguration of the LEA Patient Safety book series.

—*Marilyn Sue Bogner*
Series Editor

Preface

In 1996, the Board of the Delft University of Technology decided to focus the research activities of the university on a limited number of themes that are scientifically challenging, socially important and needed, and multidisciplinary, to stimulate the cooperation of the more or less isolated research groups of 13 faculties. A total of 10 Delft Interfaculty Research Centers (DIRCs) was formed. One of them, the DIRC on Biomedical Engineering, was initiated by the Man–Machine Systems section of the Faculty of Mechanical Engineering and Marine Technology and contained two research programs, the program on Minimally Invasive Surgery and Interventional Techniques (MISIT) and the program on the Development of an Improved endoProsthesis for the upper EXtremities (DIPEX). This book is devoted to the MISIT program that started in mid-1997.

The program has mainly been executed in six laboratories of the Faculties of Mechanical Engineering and Marine Technology, Applied Physics, Informatics, and Electrical Engineering, in close cooperation with the academic hospitals of the universities of Amsterdam and Rotterdam, as well as some peripheral hospitals, such as the Reinier de Graaf Hospital in Delft. A total of 4 postdoctoral and 10 PhD students have been involved; they are supervised by the permanent staff of Delft University of Technology and staff of the hospitals.

To meet the goals of the DIRC, scientific relevance, social need, and multidisciplinarity, all projects follow the ensuing procedure. The first year of research is focused on problem definition, research methodology, the milestones to be expected, and the cooperation with a medical doctor, for the full period of 4 years. Therefore, all researchers have to spend quite some time in one of the operation theaters to define a realistic clinical problem that is significant in minimally invasive surgery. In this way, the integration of technology and medicine is guaranteed; it also yields that all publications and PhD theses are monitored both by biomedical engineers and medical professionals. The total length of each research project typically is 4 years.

Engineers should study problems in the real world. They should analyze medical tasks, their difficulties, and define in close cooperation with the medical professionals real field problems. The engineer is not able to understand the medical needs and problems if he or she has not actually observed the medical process. Furthermore, just making a device or system on request of a medical doctor may not result in a suitable solution or device because the medical doctor does not have the knowledge about the technological possibilities and limitations. Our clinically-driven approach is a method to solve real problems in close cooperation with clinicians. On the basis of the resulting problem definitions, new technology is introduced.

This volume describes the history, the current state, and problems related to the minimally invasive approach. The development of new technologies to improve minimally invasive procedures, starting with task analysis, problem assessment, instrument design, and evaluation of the new technologies, are elucidated. Examples from laparoscopy, arthroscopy, virtual colonoscopy, and cardiovascular catheter interventions are given. Finally, some future projects and research fields are indicated.

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Chapter 1

1

Introduction to Minimally Invasive Surgery

Henk G. Stassen, Cornelis A. Grimbergen, and Jenny Dankelman

1.1 MINIMALLY INVASIVE SURGERY

Minimally invasive surgery or keyhole surgery is an important recent development in surgery. This operation technique is based on the access to the body of a patient via a limited number of round cannulas (trocars), inserted via small incisions in the skin. The method of access allows the introduction of thin rigid instruments to treat the internal tissue of a patient. To be able to observe the actions, a small camera is introduced through one of the trocars. Minimally invasive surgery can be applied to the abdomen (laparoscopy), chest (thorascopy), joints (artheroscopy), gastrointestinal tract (coloscopy of the colon), uterus (hysteroscopy), and blood vessels (angioscopy).

As we are mainly concerned with the abdominal applications of the technique, most of the material presented herein pertains to laparoscopy (Fig. 1.1). The laparoscope equipped with a video camera system is used to observe the interior of the abdomen. It consists of a rigid tube, containing a lens system and a fiber optical channel. This channel is connected to a xenon light source that illuminates the operation scene. The lens is connected to the video camera and a monitor. In this way, a 2D image is presented to

FIG. 1.1. Minimally invasive gallbladder removal (cholecystectomy). The surgeon (center) is manipulating the scissors and grasping forceps, while the assistant surgeon (right) is manipulating the laparoscope and the bowel clamp (from Sjoerdsma,1998).

the surgeon, enabling him or her to observe the internal anatomy of the patient and to control the instrument handling.

The laparoscope is operated by a camera assistant, usually an assistant surgeon. For the manipulation and the treatment of tissue, long rigid instruments like scissors and forceps are used to move, to retract, and to cut (Jansen & Cuesta, 1993; Melzer, 1992). Exposure of the working space inside the abdominal cavity is created by insufflation with carbon dioxide gas. This technique is called a pneumoperitoneum.

Laparoscopic surgery has been the most significant progress in general surgery over the last 10 years. Laparoscopic cholecystectomy has become the standard method of the treatment of gallstone disease. With the improvement of instruments and methods of training, laparoscopic surgery is being applied increasingly as an alternative to conventional surgery (Cuschieri, 1991; Cuschieri et al., 1997; Satava, 1993; Satava & Ellis, 1994).

1.2 HISTORY OF MINIMALLY INVASIVE SURGERY

The technique of laparoscopy was first reported by Kelling (1902) and by Jakobeus (1910). Kelling used a pneumoperitoneum with filtered air and a scope, whereas Jakobeus inserted the scope directly into the peritoneal cavity without prior induction of a pneumoperitoneum. Fervers recommended in 1933 the change from room air to O_2 or CO_2 as the insufflation gas for the creation of the pneumoperitoneum. In 1938, Verres introduced a spring-loaded needle with an inner stylet which automatically converted the sharp cutting edge to a rounded end incorporating a side hole. The design of the Veress needle allowed the safe creation of a pneumoperitoneum (Veress, 1938).

For a long time, laparoscopy was widely practiced by gynecologists and rarely by surgeons. The first laparoscopic surgeons used an eyepiece attached to the laparoscope, which was held in the surgeon's hand. The operation conditions were tremendously improved by the development of the CCD (charged coupled device) camera and the video endoscopy, enabling more people to see the laparoscopic image and making more complex operations possible. The first laparoscopic gallbladder removal was performed by Mouret in France in 1987 (Mouret, 1990). After that, other open procedures were carried out laparoscopically, such as the appendix resection, the hernia repair, and the colon (bowel) resection (Jakimowicz, 1993; Johnson, 1997).

1.3 OPEN SURGERY VERSUS MINIMALLY INVASIVE SURGERY

In conventional, open abdominal surgery, access to the internal body is provided via a large incision. This incision allows the surgeon and assistant surgeon to have their hands in direct contact with the tissue; the surgeon is able to use the hands to palpate and to manipulate the tissue. Solely simple hand instruments are used. The operators have a direct view of the anatomy of the patient as well as of their hands and instruments (Fig. 1.2). Exposure of the operation domain is created with mechanical wound spreaders (retractors).

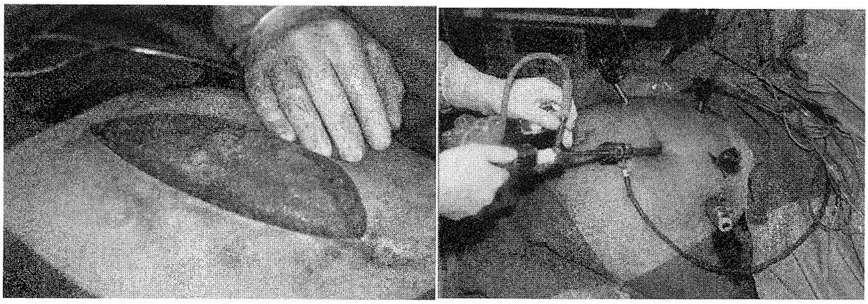

FIG. 1.2. On the left is the conventional open surgical process. On the right is the minimally invasive surgical process (from Stassen, Dankelman, & Grimbergen, 1999, reprinted by permission of Arnold Publishers, and Stassen, Dankelman, Grimbergen, & Meijer, 2001, reprinted by permission of Elsevier).

The difference between open and laparoscopic surgery is in principle only a change in access and not a different treatment of the pathology. Although the laparoscopic approach has great benefits for the patients, the laparoscopic technique brings about several changes in the way the surgeon observes and manipulates the tissue resulting in some disadvantages of the minimally invasive approach.

1.3.1 Description of the Surgical Process; A Man–Machine System Approach

In order to understand the different operation techniques, the operation procedures are presented in the form of block diagrams, elucidating the interactions between patient and surgeon. The first step in surgical process analysis is to distinguish the different subsystems, the actions to be executed (type of procedure, tasks, and basic actions), their mutual interactions, and the disturbances acting on the subsystems. The second step is to analyze the subsystems by evaluating the process parameters. The following four subsystems can be distinguished:

- The persons performing the tasks of the protocol (surgeon or resident)
- The persons assisting the surgeon (e.g., resident, scrub, or running nurse).
- The interface (operation instruments and instrumentation).
- The person undergoing the actions (patient).

Surgeon Patient Interaction. The open surgical process is represented by the block diagram given in Fig. 1.3. In open surgery, the surgeon has two possibilities to manipulate the tissue in the operating area, that is, by the hands and by the surgical instruments; both the activities provide the surgeon with direct feedback. In addition, the surgeon has to integrate information collected prior to the operation (preoperative diagnostic work of the patient, prescribed tasks of the operation protocols) with the information collected during the operation (perceptive and visual information; Stassen et al., 1999). 3D visual cues inform the surgeon about the actual state of the surgical process. The actions are initiated and based on the 3D task to be executed, the preoperative information, such as CT scans, MRIs, and Röntgen images, and the online information that is fed back. In this case, the eye–hand coordination is normal; disturbances or large variations in the patient's anatomy and pathology are accurately detectable by direct vision and direct palpation (Fig. 1.2, left). Finally, the environment (e.g., operating room) and factors that influence the performance of the surgeon (e.g. fatigue) can influence and may possibly disturb the surgical process (Performance Shaping Factors).

For laparoscopic surgery, the surgical process is different because the surgeon manipulates the tissue via laparoscopic instruments, inserted through

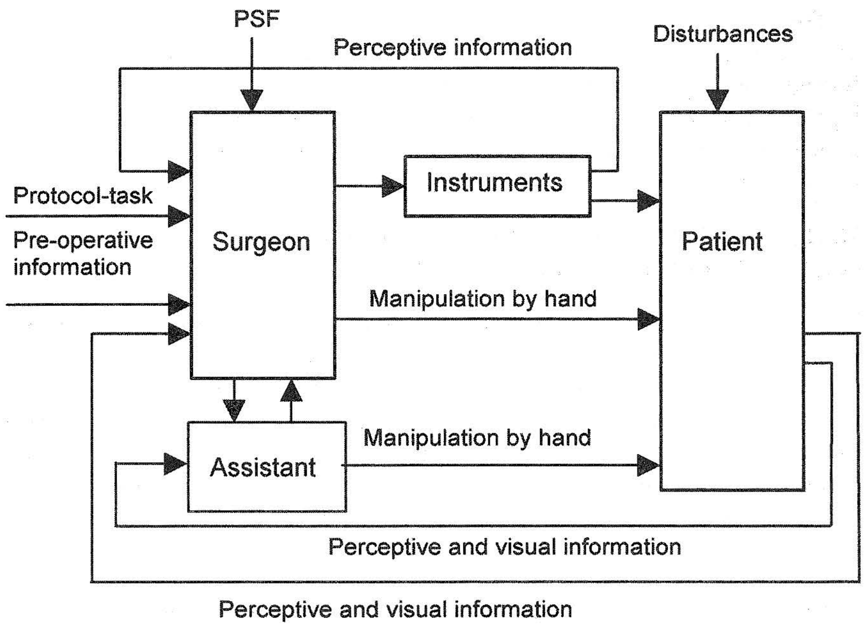

FIG. 1.3. Shown is a block diagram of the open surgical process. The surgeon can manipulate the tissue with the hands and with the surgical instruments, both providing the surgeon with direct feedback. In addition, the surgeon has direct 3D visual feedback (PSF: Performance Shaping Factors; adapted from Stassen et al., 1999, reprinted by permission of Arnold Publishers; and Boer den, Dankelman, Gouma, & Stassen, 2002, reprinted by permission of Springer-Verlag).

small incisions, with limited freedom of movement (Fig. 1.4). The surgeon has no direct contact with the tissue (no direct "manipulation by hand"). Due to friction and, in general, the poor ergonomic design of the instruments, the feedback of perceptive information is disturbed, so only reduced perceptive information will reach the surgeon (Sjoerdsma et al., 1997). In addition, no 3D visual information is available; instead, only 2D visual information originating from the laparoscope controlled by the assistant is fed back. Consequently, the perceptive and visual feedback information is only received indirectly by the surgeon, which makes the laparoscopic procedure different from open surgery (Fig. 1.5). Consequently, the laparoscopic surgical process may have other difficulties than open surgery, hence it may need different solutions.

1.3.2 Advantages and Disadvantages of Laparoscopic Surgery for the Patient and the Surgeon

The trade-off between trauma of access and operation difficulty has led, until now, to several techniques for the treatment of abdominal patholo-

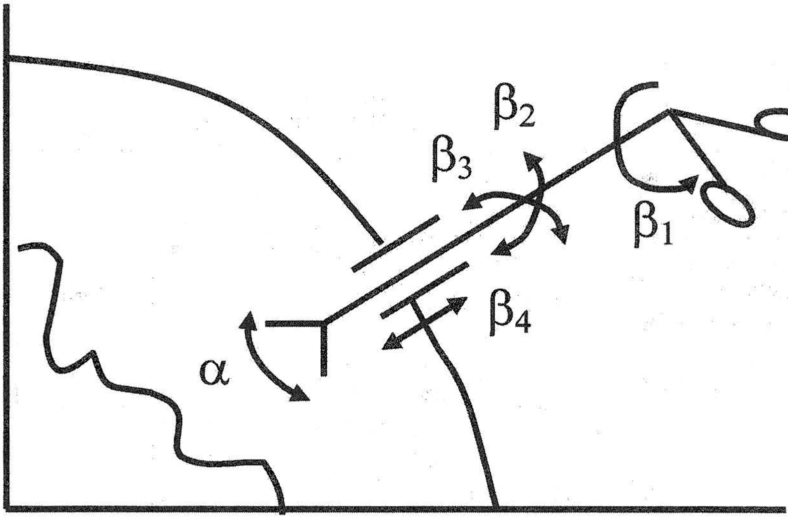

FIG. 1.4. Shown is the five degrees of freedom for the manipulation of the grasping device via the trocar. a: opening and closing; β_1–β_4: positioning; adapted from Stassen et al., 1999, reprinted by permission of Arnold Publishers, and Stassen et al., 2001, reprinted by permission of Elsevier).

gies. The way of access primarily determines the difficulty by restricting the direct-hand contact, the eye-sight, or both. Sjoerdsma gives a taxonomy of the four different techniques which can be distinguished according to tissue contact and visualization, in Table 1.1 (Sjoerdsma, Meijer, Jansen, Boer den, & Grimbergen, 2000).

The open surgery (1) and the laparoscopic surgery (4) have just been introduced. The two newly mentioned techniques (2 and 3) are introduced to partly overcome the disadvantages of the minimally invasive procedure. The small-incision surgery (3), a technique to minimize the incision of open surgery, leads to a technique where the surgeon still has a direct view of the tissue, but where he or she is not able to manipulate the internal tissue by the hands or finger tips (Majeed et al., 1996). The instruments used are the same as with the open surgery. The small-incision access or minilaparotomy is mainly applied for operations where one small incision is sufficient to reach the entire operation field, such as a gallbladder removal or a hernia repair. The hand-assisted laparoscopic procedure (4) is a mixture of the laparoscopic and the open operation techniques (Bemelman, Ringers, Meijer, Wit, & Bannenberg, 1996; O'Reilly, Sage, Mullins, Pinto, & Falkner, 1996). The essential feature is that the surgeon introduces one hand in the abdominal cavity in the standard laparoscopic setup; a plastic sleeve fitted to the abdominal wall and tightened around the arm of the surgeon prevents the leakage of gas. In this way, the sur-

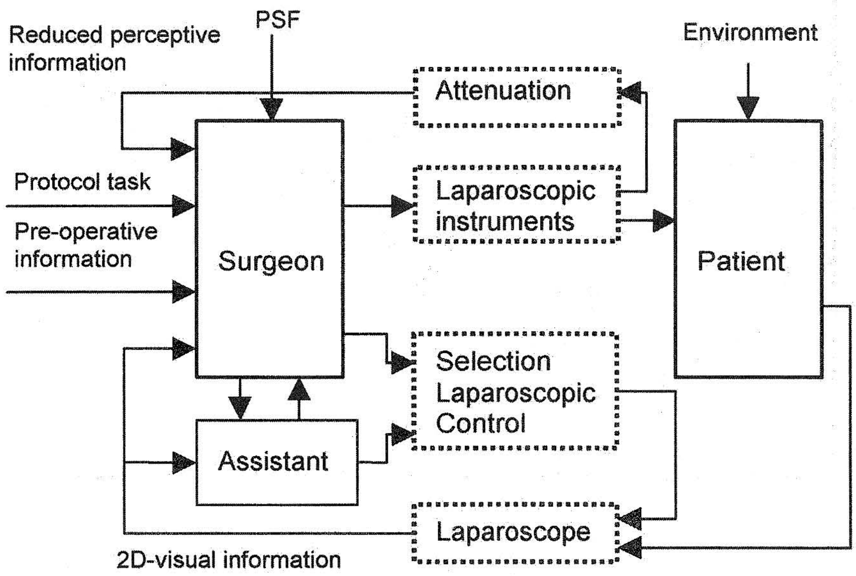

FIG. 1.5. Shown is a block diagram of the laparoscopic surgical process. The surgeon manipulates the tissue via laparoscopic instruments. Due to friction and poor ergonomic design of the instruments, the perceptive information is reduced. The laparoscope is controlled by an assistant, providing the surgeon with a 2D image (PSF: Performance Shaping Factors; the dotted boxes indicate the differences with open surgery; adapted from Stassen et al., 1999. Reprinted by permission of Arnold Publishers, and Stassen et al., 2001, reprinted by permission of Elsevier).

TABLE 1.1
Taxonomy of Abdominal Surgical Techniques

	Visual Observation	
Manipulation	*Direct*	*Indirect Via the Laparoscope*
Direct	Open surgery (1)	Hand-assisted laparoscopic surgery (2)
Indirect via instruments	Small-incision surgery (3)	Laparoscopic surgery (4)

Note. Information from Sjoerdsma, Meijer, Jansen, Boer den, and Grimbergen, 2000. Reprinted with permission of Mary Ann Liebert, Inc.

geon has direct contact with the tissue to be treated with one hand. The method is used in particular for those cases where a larger incision is needed to remove a resected bowel or spleen.

To elucidate the man–machine system challenges, it is fruitful to summarize the advantages and disadvantages for patient and surgeon. Table 1.2 indicates the consequences and the effects of the different operation procedures for patient and surgeon. Here it should be mentioned that some aspects are of vital importance to the patient, whereas others are vital for the surgeon.

TABLE 1.2
Consequences of the Operation Procedures

	Operation Technique							
	Open (1)		*Hand-Assist (2)*		*Small-Inc (3)*		*Laparosc (4)*	
Aspects	*pat*	*surg*	*pat*	*surg*	*pat*	*surg*	*pat*	*surg*
Operation wound	–		O		O		+	
Hospital stay	–		+		+		+	
Recovery time, before going to work–	–		+		+		+	
Operation complexity		+		O		O		–
Observation		+		O		–		–
Handling		+		O		O		–
Operation time	+	+	O	O	O	O	–	–
Disturbances		+		–		+		–
Wound infection	–		O		O		+	
Number of persons in operation room		+		–		+		–
Training surgeons		+		+		–		–
Online teleconsulting		O		+		O		+
Medical cost of surgery	+		–		+		–	–
Overall cost of treatment	–	–	O	O	O	O	+	+

Note. Open = open surgery; Hand-Assist = hand-assisted laparoscopic surgery; Small-Inc = small-incision surgery; Laparosc = laparoscopic surgery; pat = patient; surg = surgeon; – = negative; + = positive; O = no negative or no positive consequence. Information from Stassen, Dankelman, and Grimbergen, 1999, reprinted by permission of Arnold Publishing, and Meijer, 2001, reprinted by permission of Elsevier.

Laparoscopic surgery has the advantage of reduced trauma for the patient, smaller risk of wound infections, reduced postoperative pain and a shorter postoperative hospital stay, and an earlier return to normal activities. Without the large incision, there is less cooling, less loss of water, and less chance on wound infection. In open procedures, metal retractors are used for adequate exposure held by an assistant. These retractors may cause injuries, especially to solid organs such as the spleen and the liver.

Some disadvantages of minimally invasive surgery (MIS) for the patients are the need for mechanical ventilation and general anesthesia, because the carbon dioxide insufflation exerts pressure on the lungs of the patient. Furthermore, the longer operation time results in a longer duration of the anesthesia. Many discussions deal with the advantages of laparoscopic surgery for patients in comparison to open surgery, especially for hernia repairs, appendix resections, and colon resections. The application of the technique for the treatment of cancer is still controversial. The clearance of the tumor and the avoidance of the spread of tumor cells is a great concern (Johnson, 1997).

The minimally invasive technique yields a more complicated technique for the surgeon (Table 1.2; Cuschieri, 1995; Herfath, Schumpelick, & Siewert, 1994; Tendick, Jennings, Tharp, & Stark, 1993). Direct contact with the tissue is lost due to the interposition of instruments (Boer den, Herder, et al., 1999; Sjoerdsma et al., 1997; Tendick et al., 1993). The laparoscopic instruments do not have the same functionality as the human hand. For example, due to the fixed entry points of the instruments in the abdominal wall, the freedom of movement is reduced from six degrees of freedom to four and the movements are mirrored and scaled. Because there is no contact between hands and tissue, tactile information about tissue properties is, to a large extent, lost. The hands are outside the abdominal cavity, therefore information about the position of hand and fingers, called propriocepsis, does not directly support the manipulation of tissue (Simpson, 1974).

The coupling between observation and manipulation, the hand–eye coordination is disturbed. There are several causes. The images on the monitor are not the same as observed with the naked eye. The surgeon has no direct 3D view on the operation field, an unnatural line of sight, and his or her movements are displayed mirrored, scaled, and amplified on the monitor. The surgeon has to perform a 3D task viewed on a 2D screen. The presentation of the images is performed by the camera assistant and is not coupled anymore to the head and eye movements of the surgeon. Furthermore, the images of the laparoscope do not match the proprioceptive information, because the direction of sight differs from that of the surgeon. This results in disturbed hand–eye coordination (Breedveld, 1997).

Other important issues are the number of persons in the operation theater, and the training of the surgeons. An additional feature of MIS is the easy access to online teleconsulting. Finally, it is interesting to see that although the actual minimally invasive operation process is more expensive, the total cost of the overall medical treatment can be substantially lower due to the shorter stay in the hospital. For the man–machine disciplines, the consequences of operation complexity, handling of disturbances, number of persons in the operation theater (including the logistics and work organization), the training of the surgeons, and the possibility of teleconsulting, are of direct concern.

1.4 VASCULAR INTERVENTIONAL TECHNIQUES: CATHETERS

Minimally invasive treatment of vascular diseases, for instance stenoses (narrowing) or aneurisms (sac formed by dilation of the vessel wall), is performed with the aid of catheters and guidewires. A catheter is a long flexible device that can be percutaneously introduced in the vascular system. When a catheter is used for diagnostic purposes, it may contain one or more sensors at the tip to measure, for example, pressure, flow velocity, or temperature or O_2 saturation. Injection of a contrast agent via a lumen in the catheter can be used to make an angiogram, to visualize the vascular geometry. A balloon catheter can subsequently be used to reopen a stenotic artery. This is an example of an intervention using a catheter.

A guidewire is a long, thin, solid thread. Its function is primarily to aid navigation of the catheter, but a wire may also contain sensors. Furthermore, a guidewire serves to retain a position during exchanges of catheters, thereby saving the repeated effort of steering or positioning to reach a target site.

Three main functions of a catheter can be distinguished:

- Actuation (e.g., ablation of material, balloon angioplasty, deployment of a stent).
- Sensing (e.g., pressure).
- Transportation of material or energy (e.g., contrast fluid, embolization material, or signals from sensors).

To perform these functions, it is necessary that the catheter can be brought to a desired location via navigation, propulsion, and steering, and that it can be retrieved again from the body.

1.4.1 History

The first reports of catheterization date back to 1711 when Stephan Hales performed the first cardiac catheterization on a horse (Meuller & Sanborn, 1995, for a history overview). It was 1929 before the first documented human cardiac catheterization was performed, by Werner Forssmann. In 1964, the concept of reshaping the artery was introduced by Charles Dotter, who used catheters with increasing diameters to dilate a stenosis in a blood vessel. In 1967, Melvin Judkins improved the technique to gain access to the blood vessels by a puncture in the groin, which remained the main technique for the introduction of vascular catheters. In 1975, Andreas Gruentzig developed the first balloon catheter that lead to massive turnover from open surgery to catheterization treatment. By 1980, the first 1,000 angioplasties had been performed worldwide. In 1986, the first atherectomy devices that remove material from the vessel wall were introduced, followed by the introduction of the first use of a coronary stent, in 1987. By 1997, over one million angioplasties had been performed worldwide.

1.4.2 Steering the Catheter

To navigate the catheter tip, an interventionist must be able to determine a desired movement of the tip and he or she must be able to execute this movement. To determine the desired movement of the tip, the interventionist must know the tip location, the vessel anatomy, and the target site. The information about the tip location and the vessel anatomy may be obtained visually from the X-ray images but also haptically, for instance, when an interventionist feels when a catheter shoots into a side branch. To execute the desired movement, the interventionist must be able to control the tip position and orientation. This is done by pushing and turning the catheter and guidewire at the proximal end outside the patient.

The observations of the interventionist and the interaction with the patient's tissue are indirect. The physical contact of the interventionist with the patient's tissue is mediated by the catheter, and his or her visual observation of the tissue is mediated by the X-ray imaging (Fig. 1.6). Because of the flexible characteristics of the catheter, the interventionist does not precisely feel how the tip of the catheter moves in response to his or her control actions (Ogata, Goto, & Uda, 1997). Furthermore, it may be hard or even impossible to maneuver the catheter into the desired direction.

To observe the catheter or guidewire position during navigation, fluoroscopy (X-ray) is used, which is displayed on a monitor. Furthermore, Digital Subtraction Angiography (DSA) images can be made to visualize the vessels, which cannot be seen during normal fluoroscopy. With DSA, a series of X-ray images is taken during contrast agent injection. An image taken prior to injection is subtracted from these contrast images to obtain the DSA image that contains only the contrasted vessels and no other anatomical structures. The patient needs to be completely stationary during