Improving patient safety in image-based procedures

bridging the gap between preferred and actual proficiency

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Proefschrift

ter verkrijging van de graad van doctor
aan de Technische Universiteit Delft,
op gezag van de Rector Magnificus prof. ir. K.C.A.M. Luyben,
voorzitter van het College ÖÏÏ0 Promoties,
in het openbaar te verdedigen op dinsdag 7 september 2010 om 12:30

door
Sonja Nandine BUZINK

Ingenieur Industrieel Ontwerpen
geboren te Haarlem

Dit proefschrift is goedgekeurd door de promotoren:

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Samenstelling promotiecommissie:

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The research that forms the basis of this thesis was supported by a grant from the Scientific Fund of the Catharina Hospital Eindhoven.

Cover design by S.N. Buzink
Printed by Ipskamp Drukkers B.V., Enschede

ISBN/EAN: 978-94-6113-021-1

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Chapter 1.

General introduction

Undergoing surgery is a necessary evil that often evokes traumatising experiences. For the patient, the aftermath of traditional open surgery typically involves excessive pain, extended stay in the hospital, slow recovery, and last but not least some clearly visible scars to remember the whole event by. Luckily for many patients, less invasive approaches of treatment have been developed in recent years for a broad range of surgical procedures. Luckily, because technical innovations allow physicians to perform surgery through small incisions or natural body orifices, by making use of imaging equipment to visualise the operating field. These so-called image-based procedures (IBP) involve all types of medical procedures that enable therapeutic intervention by minimal access while the physician intra-operatively perceives the operating area in real-time, though indirectly, through the use of imaging equipment. Some examples of image-based procedures are laparoscopy, flexible gastrointestinal endoscopy, and endovascular surgery (Figure 1.1).

For patients these less invasive minimal access procedures have many benefits in comparison to traditional open surgery, such as shorter hospital stay, less trauma, faster

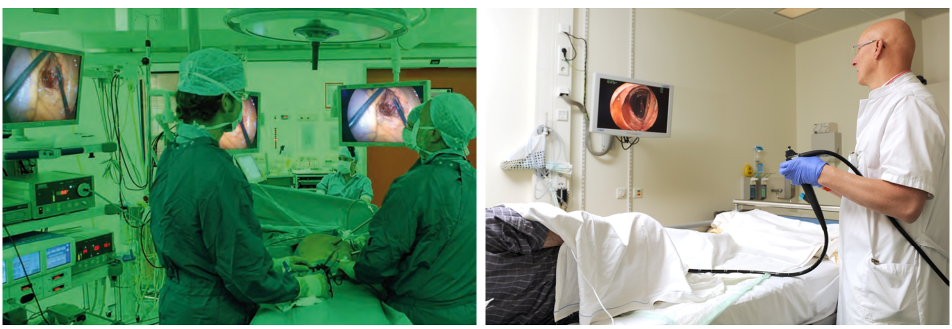

Figure 1.1 Examples of image-based medical procedures: laparoscopy (left) and flexible lower gastrointestinal endoscopy (colonoscopy) (right).

reconvalescence, and fewer scars as shown, for example, for laparoscopic surgery[42-44]. But this comes with a price: for the surgical team the advent of IBP has brought about many changes and challenges in the performance of surgery. To perform IBP effectively and safely the surgical team is more dependent on technology, the manipulation of the instruments is often counterintuitive and the three-dimensional operating field is perceived two-dimensionally on a monitor, all of which requires extensive additional training[14-16, 43, 58]. And while patients already benefit from well established image-based minimal access procedures, such as laparoscopy and flexible gastrointestinal endoscopy, surgical techniques and technology keep advancing further. Currently, innovations such as Natural Orifice Transluminal Endoscopic Surgery (NOTES) and Single Port/Incision Laparoscopic Surgery are emerging[29, 56]. And for the near future, even more advanced types of surgery involving intraoperative multimodal imaging and image-based interventions on cell level are foreseen[142, 159].

1.1 The need to better safeguard patient safety in surgery

Patient safety means staying free from accidental injury[93]. The report of the United States Institute of Medicine called attention to the incidence of medical error and adverse events (see Table 1.1 for explanation of terminology). Following two studies by the American Hospital Association it was estimated that annually at least 1.3 million people are harmed and 44 000 people die in the United States as a result of medical error[93]. In The Netherlands it was estimated that in 2004 about 76 000 patients suffered from adverse events while admitted to a Dutch hospital, of which an estimated 30 000 could probably have been prevented[20]. Worldwide, it is estimated that about 10% of patients admitted to the hospital suffer from adverse events. Within the hospital, the operating room (OR) has been identified as the most common site for adverse events, of which many were regarded as preventable[20, 100, 181]. In the Dutch adverse events study about two-third of the surgical adverse events were related to human errors of the surgical team. And, almost all of the adverse events (90%) in this study that were related to organisational errors were judged as preventable[20, 182] (Table 1.2). Most adverse events involve a combination of an active error and a latent error component (Table 1.1). Especially latent errors can escape notice for a long time until one combines with an active error or triggers to produce a noticeable error opportunity[93, 100, 135]. Thus to avoid adverse events healthcare professionals need to be always vigilant to identify errors and compensate for the influence of those errors on patient safety.

Table 1.1 Terminology as used in this thesis related to medical error as used in this thesis.

Medical error: the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim[93]
Adverse event: an error that causes harm to the patient, which is not related to the underlying condition of the patient[93]
Near miss: an error which does not cause harm to the patient[93]
Active error: errors committed by people who are in direct contact with the patient, caused by a slip, lapse, mistake, and/or procedural violation[93, 135]
Latent error: errors caused by components of the system, which are removed from the immediate control of the people who are in direct contact with the patient, such as poor equipment design, incorrect installation, and faulty maintenance[93, 135]

Table 1.2 Some examples of different origins of medical error.

Human: errors originating in behaviour of individual members of the surgical team, lack of knowledge or skills, inattention, misbehaviour
Organisational: lack of (adequately trained) staff, ineffective teamwork, miscommunication, hierarchical/cultural issues, time pressure, overwork
Technological: malfunctioning, availability or improper design of equipment, instruments, or additional materials, inadequate training of staff to use technology
Legal/regulatory: poor leadership, unclear protocols, negligence, lack of evidence-based practise
Procedural: errors caused by the nature of the surgical procedure, for example the complexity of the surgery, situational awareness skills, decision making skills
Ambient: distractions, unsuitable ergonomics, information overload

Quality of surgical performance

Many factors have an influence on patient safety and the outcome of surgery. Besides risk factors related to the pathophysiology of the patient and the quality of performance of the surgeon, the outcome of surgery is also dependent on the skills of the other healthcare professionals involved in the care process as well as the environment they all work in. This multidisciplinary team, in which each member has his/her own role and goals and varying training knowledge and background, has to work closely together within the complex environment of the OR under highly demanding conditions[14]. Besides the obvious influence of the medico-technical skills of the surgeon (e.g. understanding the application of instruments and the interaction with different types of tissue), factors such as teamwork skills, equipment problems, ergonomic shortcomings of the instruments, distractions, and fatigue can have a considerable impact on the quality of the surgical performance of IBP[33, 58, 101, 181]. Each encounter of a professional with the patient, and each treatment within the overall care process, presents a chance for error[100, 181, 182]. Vincent et al. (2004) claimed that, amongst others, attention to ergonomics, equipment design, and team performance may have a stronger influence on the quality of performance than surgical skill as such[181]. Experienced teams have shown to have lower rates of errors and recover from minor errors better than less experienced surgical team[166].

The image-based performance of surgical procedures brought along a lot of additional and new technology in the OR. As a consequence, it considerably changed the interaction of the surgeon with the operating field and the interaction within the surgical team. In IBP, the equipment and instruments forms the interface between the surgical team and the operating field (Figure 1.2 and Figure 1.3). In comparison to traditional open surgery, the dependence on the equipment to effectively perform an image-based procedure is much higher[33, 43, 181]. Obviously, the operating field has to be visualised for which different types of imaging technology can be applied, depending on the type of procedure to be performed. Furthermore, the instruments used to perform the surgical intervention image-based differ considerably from that used in traditional open surgery. The enforced dependability on and interaction with IBP equipment and instruments has resulted in increased mental and physical workload for the surgical team which may affect patient safety directly because of fatigue and reduced focus on the execution of the procedure[14-16, 43, 58].

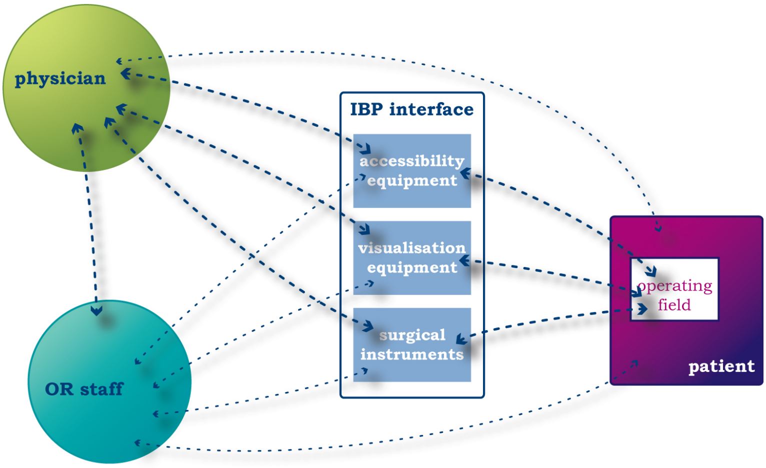

Figure 1.2 In image-based procedures the physician and assisting operating room staff interacts with the operating field indirectly, through the components of the IBP interface.

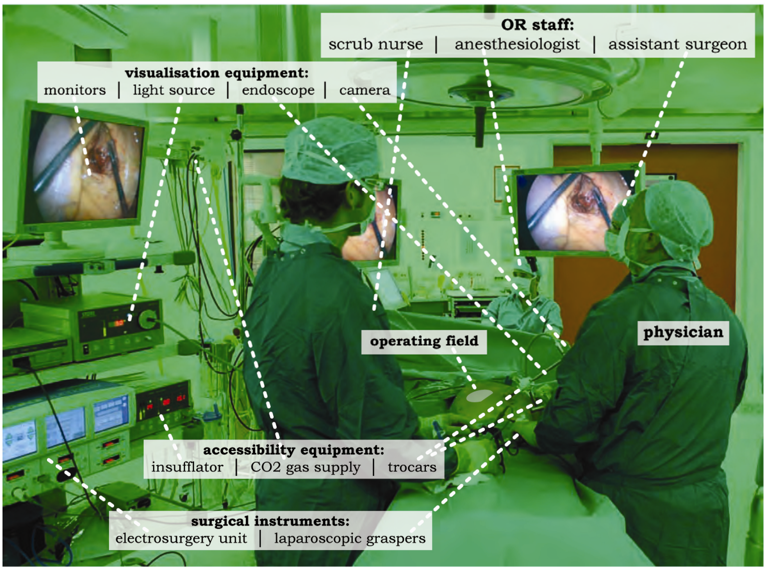

Figure 1.3 The situation in an operating room during laparoscopic surgery.

The need for preclinical training and objective proficiency assessment

By tradition, surgical training is based on the Halstedian model (a residency-based master-apprenticeship system) and accreditation is based on the number of performed procedures and the semi-subjective evaluation of a preceptor (expert physician)[137, 140]. Physicians, and thus also surgeons, are considered competent when they are sufficiently proficient in all six core competency components that have been identified by the Accreditation Council of Graduate Medical Education (ACGME) and the American Board of Medical Specialties (ABMS). Each of the competency components comprises a combination of technical, cognitive, and judgment/clinical skills (Figure 1.4 & Table 1.3). After graduating from medical school, which already comprises vast amounts of practical training in the clinic, physicians have to continuously keep working on expanding their skills, proficiency, and competence to keep up-to-date. Besides purposeful training, clinical experience and exposure to vast amount of cases is imperative, as these all add to the overall competence of the physician[68, 140].

In addition to general medico-legal and ethical concerns for patient safety, new work time restrictions, such as the European Working Time Directives (EWTD), have considerably reduced the amount of time available to train and supervise trainees[62, 86, 137]. Hospitals are also more and more run as businesses, with an emphasis on increasing quality and efficiency while reducing costs. The increased costs due to extended operating room time and higher rate of surgical complications plus adverse events for procedures performed by physicians in training are also forcing hospitals to look for training possibilities outside the operating room[137, 141]. All of this has put the traditional system for surgical training under increasingly more stress and has raised the need for preclinical training and objective assessment of proficiency[77, 86, 137, 140, 141]. For this purpose, surgical skills laboratories (skills labs) have been established that offer courses to train and assess the broad range of surgical skills outside the clinical setting. These courses generally consist of a mixture of lectures, surgical videos, and a vast amount of hands-on psychomotor training, ranging from basic surgical skills to (parts of) advanced procedures. For the hands-on psychomotor training a variety of simulation tools have been developed. In this thesis, a simulation tool is defined as a device (tangible or digital) that imitates or

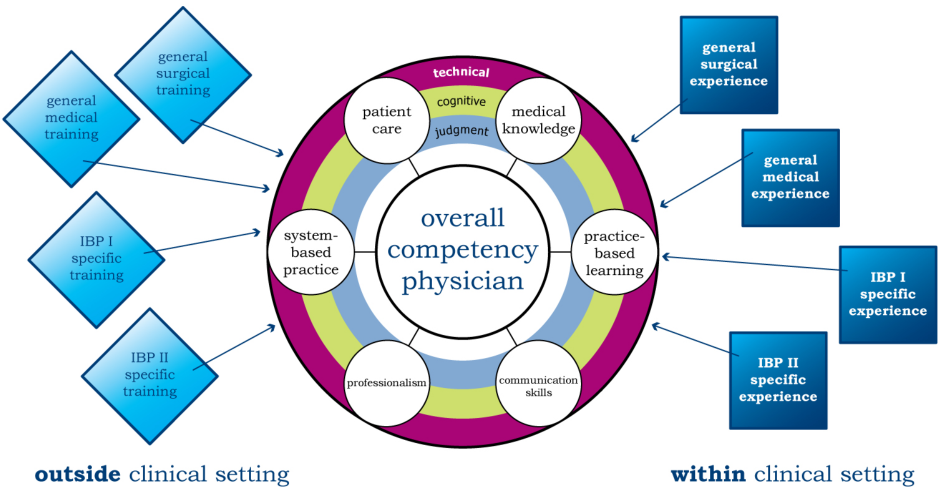

Figure 1.4 Different types of training and experience add to the skills and the six core competency components that have been identified by the Accreditation Council of Graduate Medical Education (ACGME) and the American Board of Medical Specialties (ABMS) [77, 146]

Table 1.3 Terminology as used in this thesis related to surgical performance.

Ability: the natural state or condition of being capable, aptitude[146]
Skill: a developed proficiency or dexterity in some art, craft, or the like[146]
Knowledge: understanding of a subject which has been obtained by experience or study[28]
Task: a piece of work to be done[146]
Competent: fulfilling all requirements[146]
Proficient: well advanced in any branch of knowledge or skill[146]

reproduces the appearance, character, and/or conditions of a specific surgical task. For training of psychomotor skills for laparoscopic surgery for example, these tools range from simple pick and place exercises in an abstract box trainer to component task training on virtual reality simulators and training of full procedures on human cadavers or live animals.

As the field of IBP is a relatively new one, the research and development of simulation tools to train and/or assess IBP skills is still ongoing. Currently all available simulation tools to train dedicated IBP skills or assess IBP performance have considerable shortcomings (e.g. being very expensive, no built-in objective assessment, not allowing repetitive usage, lacking realistic haptic feedback)[143]. More research is needed to gain insight in the added value of the most promising simulation modalities to train certain basic IBP skills and/or assess performance of specific IBP tasks. The procedure commonly followed to make sure that a surgical simulation tool is actually teaching or evaluating what it is intended to teach or measure involves a combination of subjective and objective investigations[10, 32, 120] (this is usually described as establishing the validity of surgical simulations; see Table 1.4 for an overview of the different types of validity).

Table 1.4 The different types of studies to establish the validity of surgical simulators [10, 32, 120].

Face validity: the realism of the simulator and appropriateness of the simulator as a teaching modality judged by experts in the field and proposed trainees
Construct validity (assessment of experience): the degree to which the simulator can discriminate between subjects from different experience levels (following established experience assessment methods)
Construct validity (skills improvement): the degree to which the performance of the trainees improves by repetitive training on the simulator
Criterion validity (concurrent): the degree to which the simulator measures up to outcomes from already established tools to train/assess the same skills or attributes
Criterion validity (predictive): the degree to which the simulator can predict future performance on the specified tasks

The gap between preferred and actual level of surgical performance

Physicians in training actively work in the clinic throughout their training whereby their individual skills and overall competence increase by deliberate practise, observing experts, and clinical experience. In time, they are allowed to perform tasks with gradually greater complexity. In comparison to traditional open procedures, physicians go through an extended learning curve to become proficient in a specific IBP type[58]. While passing through this extended learning curve and often even well after reaching the required threshold number of performances for accreditation, the elevated level of mental and physical workload leaves less room to simultaneously cope with all of the factors that affect the quality of performance. Especially for the physician less experienced in IBP, this could cause a decrease in the physician's concentration on the execution of the procedure[14, 15, 42, 176]. This loss of focus in turn increases the chance that errors and adverse events occur.

Following theories of psychomotor skill acquisition[55, 134, 137], a physician needs to pass through three stages of learning: the early or cognitive phase, the intermediate or associative phase, and the final or autonomous phase. This means that over time and with increasing experience IBP skills proceduralise until the required actions are performed increasingly more intuitive and the image-based performance of the procedure requires gradually less conscious attention[88, 134, 137]. When the physician reaches this skill-based level of performance, the extent in which factors such as distraction and fatigue influence the quality of performance is reduced[88, 138]. This implies that, until the physician reaches this skill-based level of performance, his/her level of proficiency can be adequate, but not optimal. Thus, a discrepancy is often present between the preferred and the actual level of proficiency of a physician performing IBP in the OR (Figure 1.5). It is clear that this discrepancy jeopardises patient safety and, as the performance of procedures by less experienced physicians often takes longer, increases the occupation of costly OR's.

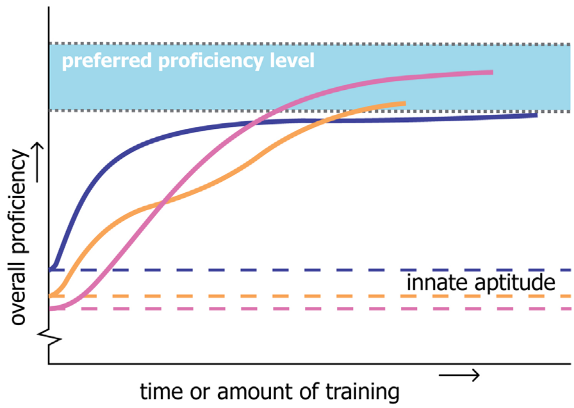

Figure 1.5 Visualisation of the discrepancy between actual and preferred proficiency-level. The curves represent hypothetical overall proficiency curves of three different trainees at various stages of their training for a specific (undefined) IBP type.

1.2 How to safeguard patient safety in image-based procedures?

The performance of IBP comprises several factors that endanger the quality of performance and patient safety more than the performance of traditional open procedures does. Key elements in ensuring quality of performance during IBP are the level of proficiency of the physician performing the procedure and the influence of his proficiency on the interaction with the operating field via the IBP interface. The discrepancy or gap between preferred and actual level of proficiency affects the quality of performance of the physician and consequently patient safety. To allow physicians to perform image-based procedures in the operating room such that they can focus on the therapeutic tasks rather than on the interaction with the IBP interface, the gap between the preferred and actual level of proficiency should first of all be diminished, by preclinical enhancement of the level of proficiency of the physician in IBP. Second, the influence of the remaining gap on the physician's quality of performance should be bridged by improving the IBP workflow and interaction with IBP interfaces in the clinical environment.

In this thesis the overall aim is to improve patient safety in image-based procedures by better safeguarding the quality of performance of physicians performing these procedures. Within this scope, the focus is on the interaction of the physician with the IBP interface. The main objective is to investigate how simulation tools can be used for preclinical enhancement of the proficiency of physicians in the specific psychomotor skills needed to perform IBP. Second, the influence of tools to improve the workflow and interaction with IBP interfaces in the clinical environment is evaluated.

The multifaceted and interdisciplinary approach from a user-interface interaction perspective followed in this thesis sets this work apart from others. It aims to stay close to practice and provide pragmatic solutions. This work not only contributes to the knowledge on training of IBP skills and assessment of IBP proficiency to better match the physician with the technology, but also investigates the role of technology to take the needs of the physician better into account.

Reducing the gap preclinical

To improve the quality of performance of IBP and reduce the gap between preferred and actual proficiency level, it is not enough to gain more knowledge about how to better train and objectively assess the proficiency of physicians in IBP using simulation tools. More insight is also required about the extent in which different basic skills for IBP relate with each other. In addition, a better understanding is needed on how to extend the efficacy (effectiveness and added value) of preclinical training on simulators, as various aspects of the interaction with the simulator interface can affect (positively or negatively) the learning experience. With these insights, design engineers and educationalists will subsequently be able to develop IBP training tools that suit the needs of the individual trainee best and objectively assess IBP performance comprehensively.

Bridging the gap in the clinic setting

For the development of tools that can help to improve the quality of performance and bridge the remaining gap between preferred and actual proficiency level in the clinical setting, first we require an understanding of human factors issues closely related to the performance of the physician and his/her interaction with the IBP interface. Second, we need to gain insight on the impact on the performance of previous technological innovations for improving the working environment. The added value and usability of newly developed tools to improve the quality of performance have to be evaluated. In the future, the knowledge gathered may be used to develop proficiency-adaptable interfaces for equipment facilitating image-based medical procedures.

Focus on laparoscopy and flexible gastrointestinal endoscopy

Because the overall field of IBP is too extensive to cover completely within this project, we chose to select two types of IBP as representatives: laparoscopy and flexible gastrointestinal endoscopy. This selection was based on the representative positions of these IBP types within the medical field (see Chapter 2). By including more than one type of IBP, we aim to collect data applicable to a broader range of IBP.

1.3 Thesis outline

This thesis begins with a brief description of the human factors issues affecting IBP performance (Chapter 2) (Figure 1.6). Next, the value of virtual reality simulators for assessment and training of basic psychomotor skills for laparoscopy and colonoscopy is investigated (Chapter 3 & Chapter 4). In addition, the relation between IBP skills is explored; the relation between performances on two laparoscopy tasks which differ considerably in eye-hand coordination is studied (Chapter 3.1), as well as the transfer of basic skills between laparoscopy and colonoscopy (Chapter 5). Next, the influence of characteristics of the simulator interface on the effectiveness of preclinical simulator training is evaluated (Chapter 6). And the influence of two tools for the clinical environment (integrated OR system and Pro/cheQ, a procedural checklist) that aim to improve the performance of the surgical team performing laparoscopic surgery is examined (Chapter 7). The general discussion summarises and discusses the results and conclusions of this thesis, and provides recommendations for future research and design projects (Chapter 8).

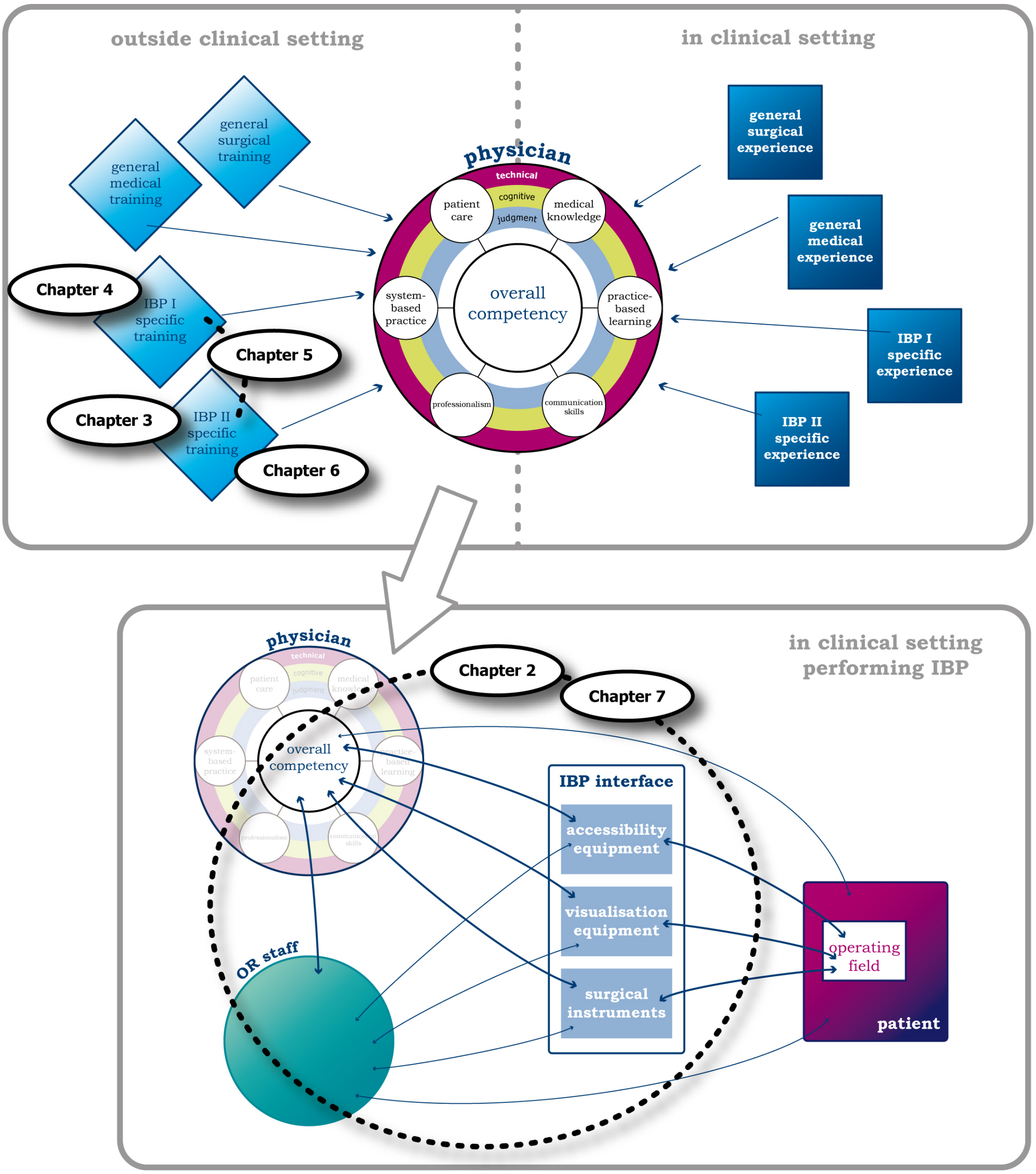

Figure 1.6 Schematic outline of the thesis.

Chapter 2.

Performance of image-based procedures - an overview

In this chapter the human factor issues of image-based medical procedures (IBP) are discussed. It presents a brief historic overview of the developments in the field of IBP. A categorisation of the overall field of IBP is provided, based on the role of the interface and the interaction characteristics of the various procedures. Next, insight is given in the human factors issues affecting the performance of IBP and the training and assessment of IBP-related skills.

2.1 Brief history of image-based procedures

Even though performance of surgical procedures on the basis of an intra-operatively obtained image on a monitor is sometimes treated as a novelty, the use of tools for intra-operative visualisation of the operating field by physicians is not. Magnification tools developed from lenses in ancient times to the microscope in the late 16th century. By the early 20th century, surgeons started to use the microscope in clinical surgery[98]. Since the discovery of X-rays at the end of the 19th century, and later Computed Tomography (CT) and Magnetic Resonance Imaging (MRI), imaging techniques have played an important role in operation planning[132]. Records state that since the beginning of the 19th century, physicians attempted to construct and use endoscope-like instruments that allowed inspection of areas using not just ambient light, but also candle light[87, 157, 160]. This made it possible to inspect the inside of the bladder, rectum, vagina, and upper throat. It took many decades until the problems of using candlelight to illuminate the operating field like directing the light and the risk of burns (for both physician and patient) were solved by applying lenses, mirrors and sometimes also small lamps, which could be placed inside orifices such as the bladder[157, 160]. Around the turn of the 20th century it was attempted for the first time to examine the peritoneal cavity; by making use of a trocar the abdominal cavity could be inflated which simplified inspection[75, 160]. In the early 1930s, the first reports of laparoscopic interventions for therapeutic purposes were published[75, 87, 160]. Optical and lens innovations in the early 1950s introduced intense illumination of the operating field and transport of a more clear image of it, using cold light fibreglass bundles[75, 160]. However, the surgeon still had to peer through the endoscope-end, while aiming it at the operating field with one hand; leaving only one hand free to perform the therapeutic actions. The introduction of computer-chip video (CCD) cameras in the 1980s made it possible to project the image from the scope onto a monitor, allowing surgeons to work two-handed again and benefit from proper surgical assistance[75, 87].

Parallel to the technical innovations facilitating laparoscopic surgery, more flexible endoscopic instruments were developed to allow investigation and later also treatment of areas further along the gastrointestinal and urinary tracts or in the bronchial tubes[157, 158]. And where first only visible light was used to examine the area of interest and follow the course of treatment, in the 1980s flexible endoscopes were developed using ultrasonography as imaging technique instead[158]. Advanced computer-aided intra-operative real-time imaging, like interventional MRI or Ultrasound techniques (US), can nowadays provide the surgeon with high quality three-dimensional images that not only present the anatomy, but also track instruments in real time during the procedure, and register them in relation to the patient in three-dimensional space[132]. The number of medical procedures in which intra-operative imaging plays an important role is vast, still increasing, and diversifying; from micro-surgery to flexible gastrointestinal endoscopy and from laparoscopy to image-guided brain surgery. Amongst others, promising developments currently lay in the intraoperative application of narrow band imaging, intraoperative multimodal imaging, robotic surgery, and real-time overlay of images (augmented reality)[75, 142, 158]. The latest, yet still controversial, additions to the endoscopic spectrum of image-based procedures are Natural Orifice Transluminal Endoscopic Surgery (NOTES) and Single Port/Incision Laparoscopic Surgery (SILS)[17, 22, 35]. The expectation is that the demand for minimally invasive performance of medical procedures will continue to grow in the future, and with this also the application of imaging techniques and related technology and their role within the operating room.

2.2 Classifying image-based procedures

While the various types of image-based procedures show many similarities, the interface and principal interaction characteristics often differ considerably. In flexible gastrointestinal endoscopy procedures, for example, an endoscope is inserted trough a natural body orifice to explore the operating area using video images. Interventions are performed by inserting additional instruments through the endoscope shaft and manipulation of the camera directly affects the application of the instrument. For minimally invasive cardio-vascular stent grafting, the operating field is observed by means of X-ray images, while interventions are performed using independently manipulated instruments inserted through a small opening in the vascular system. The medical specialist does not have direct visual contact with the operation area in image-based procedures and often also lacks direct tactile feedback; this is in strong contrast with open procedures. The interface stands between the specialist and the operating area, which implies a modified style of interaction with the operating area. The role of the image and type and degree of image-guidance can differ considerably in the various types of image-based procedures. Three main categories can be identified with increasing image-dependency of the performance of the procedure (see Figure 2.1). First, the role of image within the overall procedure can either be directive or revealing. The 'directive' category entails types of image-based procedures in which the image plays a directing role. The imaging is, more or less, part of the instruments; it fulfils the guiding role by displaying instrument positions compared to the ideal position for example. In 'revealing image-based procedures' imaging is used to reveal the otherwise for the human eye

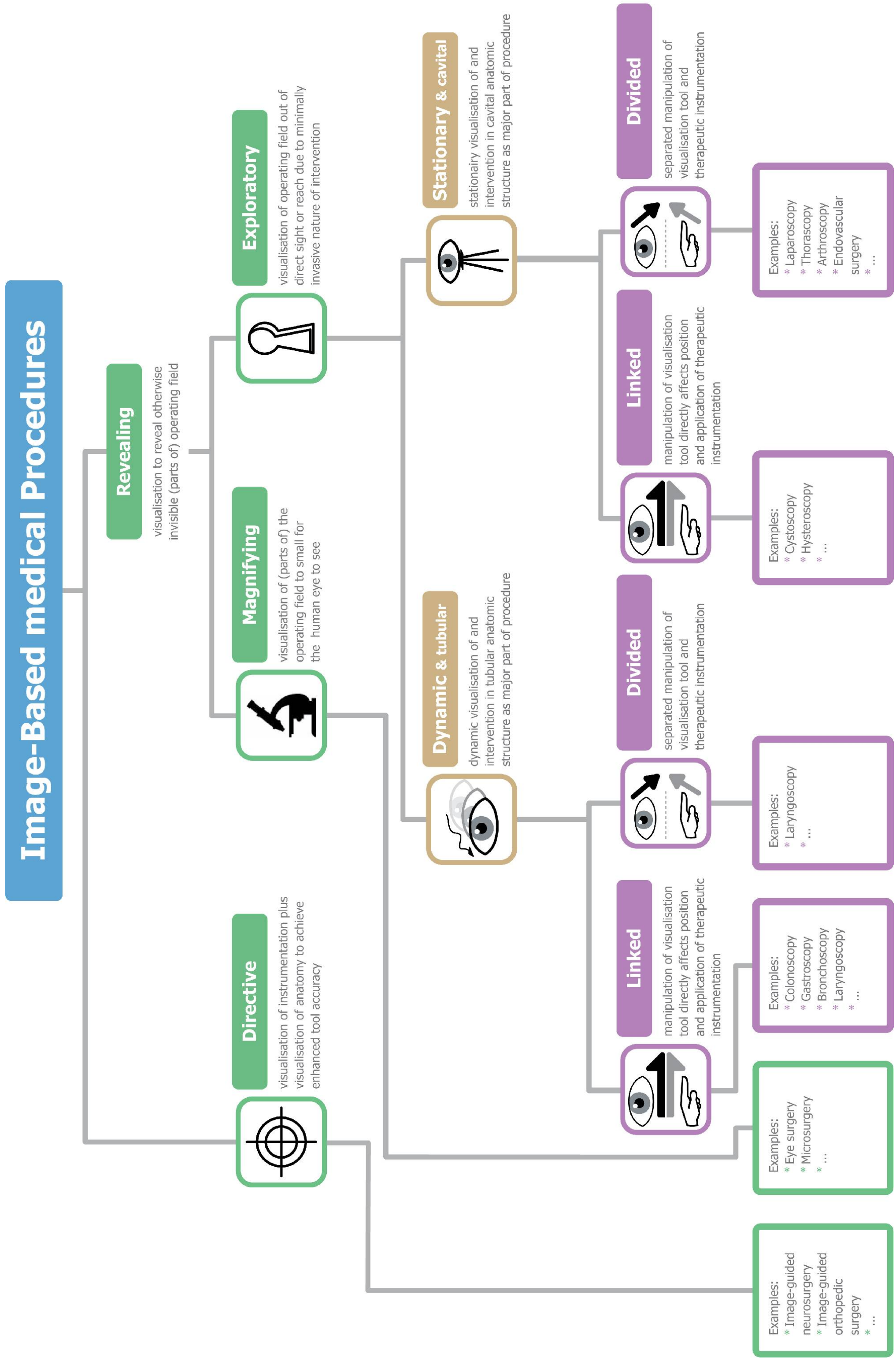

Figure 2.1. The classification presented in a tree diagram.

invisible operating area, by either magnification or (minimally invasive) exploration; the imaging facilitates the minimally invasive nature of the procedure by visualising the operating field.

These three major categories split up in multiple sub-categories, based on characteristics of the interaction with the image, the imaging tools, and the interventional instruments. The dynamics of the image has a big influence on the interaction with the image, especially when taking the spatial interaction with the interventional instruments into account as well. The interaction can take place using a dynamic type of imaging in tubular anatomic structures, for example the intestines, or by means of a nearly stationary perspective in more cavital anatomic structures, like the inflated abdomen during laparoscopy. In procedures involving a dynamic type, like in almost all procedures performed using a flexible endoscope, the image keeps moving alongside the instrumentation while being manipulated collectively. The imaging device and therapeutic instruments are in these cases often joined, due to which the interaction and manipulation also merges. In procedures that are dependent on a stationary imaging technique within a more cavity-shaped anatomic structure, the medical specialist perceives the operating area mainly from one single perspective, while he is independently manipulating the therapeutic instruments within this space.

This classification does not take all characteristics of the broad range of IBPs into account. The imaging technique used to acquire the image is purposely not included for example, as the innovations in this area quickly follow after each other. In addition, there are also procedures in which different imaging techniques are being combined, but where there is no difference in the positioning of the imaging equipment or manipulation of the imaging therapeutic instruments (e.g. flexible gastrointestinal Endoscopic Ultrasonography (EUS) versus video-based flexible gastrointestinal endoscopy). This classification is applicable for most common procedures. Some procedures entail a combination of different categories though. The different types of interaction during these procedures almost always takes place consecutively. This can be the case in endourological procedures for example, where first the bladder (a cavital shaped anatomical structure), is inspected, and maybe treated, while using video images. Subsequently, the urinary tract (which of course is tubular in shape) can be examined by ureteroscopy, using video and additional x-ray imaging. When looking at the current state of the newest endoscopic arrivals, NOTES and SILS, in the classification, one can conclude that these procedures do not differ that much from the IBP types from which they are derived, except that the manipulation of the therapeutic instruments became considerably more complicated and less ergonomic, being linked instead of divided.

In this thesis laparoscopic surgery and lower gastrointestinal flexible endoscopy have been selected as subjects for future studies. Both IBP types are part of a large group of IBP with similar styles of interaction, involve procedures of various degrees of complexity, exceed medical specialties, and have been studied relatively thoroughly before from different perspectives and in different frameworks. This provides a knowledge base to build on in our studies that will facilitate and ease this project’s focus on studying the aspects of IBP proficiency and its influence the interaction with IBP interfaces.

2.3 The increased technology dependency of image-based procedures

The IBP operating room is a high-risk environment where high-tech equipment is used to offer patients the most advanced level of surgical care and where everything is focussed on serving the patient’s well-being and quick recovery best. To perform IBP effectively, efficiently, and most of all safely, the surgical team is highly dependent on the technology facilitating the procedure[33, 43, 58, 181]. The surgical team working in the image-based OR have become used to adapt to the increasingly physically and mentally demanding environment they work in and to use the high-tech equipment in highly demanding conditions[14, 58]. Complaining about physical discomfort, stress or fatigue is traditionally discouraged within the surgical environment[14]. This exposes several factors that could affect patient safety negatively. To ensure patient safety it is therefore important that the surgical team has the appropriate skills and experience to perform the surgery image-based and does not think lightly about the impact that image-based performance of the procedure can have on patient safety.

In comparison to traditional open procedures, the performance of IBP involves more equipment and different instruments. The additional technology changed the interaction of the surgeon with the operating field and also the interaction within the surgical team. The minimal access approach often requires additional equipment to make the operating field accessible and tangible for the physician. In laparoscopic surgery for example the abdomen needs to be inflated with carbon dioxide gas and kept at a stable pressure throughout the procedure to create space to manoeuvre the instruments[43]. In laparoscopic surgery video technology is used, the image of the operating field is displayed on a monitor. The instruments used to perform the surgical intervention image-based also differ considerably from those used in traditional open surgery. The instruments need to be inserted through small openings and sometimes have to traverse a relatively long distance to the operating field, not always following a straight or direct path. Handling the instruments to approach tissue becomes extra challenging. Laparoscopic instruments for example are commonly about 300 mm long and have to fit through ports with a diameter of 4 to 15 mm. In intraluminal gastrointestinal endoscopy a flexible endoscope of about 1200 mm long, 15 mm in diameter, and with instrument shafts of about 3 mm wide is used is used to access and visualise an operating field and perform interventions somewhere inside the twisting large intestines. The additional equipment and increase of technology that IBP brought along also had consequences for the overall lay-out of the operating room and the support needed to perform interventions. Not only does the additional equipment congest the space within the operating room, the required placement of the equipment sometimes also limits the workspace which has considerable consequences for the ergonomics of the activities performed by the physician or other members of the surgical team[13, 14]. The many additional cables and tubing leading from and to the IBP equipment also pose potential hazards[14, 90].

2.4 Human factors and ergonomic issues of image-based procedures

Besides the medico-technical skills of the surgeon (understanding and application of instruments and interaction with different types of tissue), various other factors (Figure 2.2), such as ergonomic shortcomings of the equipment, teamwork skills, distractions, and fatigue, are of influence on the surgical performance and patient safety of IBP[33, 58, 101, 181]. During IBP, the surgical team often has to stand in awkward positions for extended periods of time and their postures are more static, leading to postural fatigue and physical complaints[14, 42, 103, 118, 176]. Altogether, the physical and cognitive workload is considerably increased in IBP in comparison to open procedures[15, 16, 42, 103]. Human factors and ergonomics is a discipline that concerns the interaction between products and the human body and its capacities. Three ergonomic sub-domains are identified: physical, sensorial, and cognitive. When performing image-based procedures the surgical team has to deal with various ergonomic challenges. Some of these issues and potential hazards could be solved by creating larger and IBP dedicated integrated operating rooms and redesigning the equipment to fit the needs of the user better under the extreme circumstances of IBP[13, 14, 84, 90, 116, 169]. To illustrate which types of ergonomic issues have to be dealt with, a description is given for the laparoscopic setting in the following paragraphs.

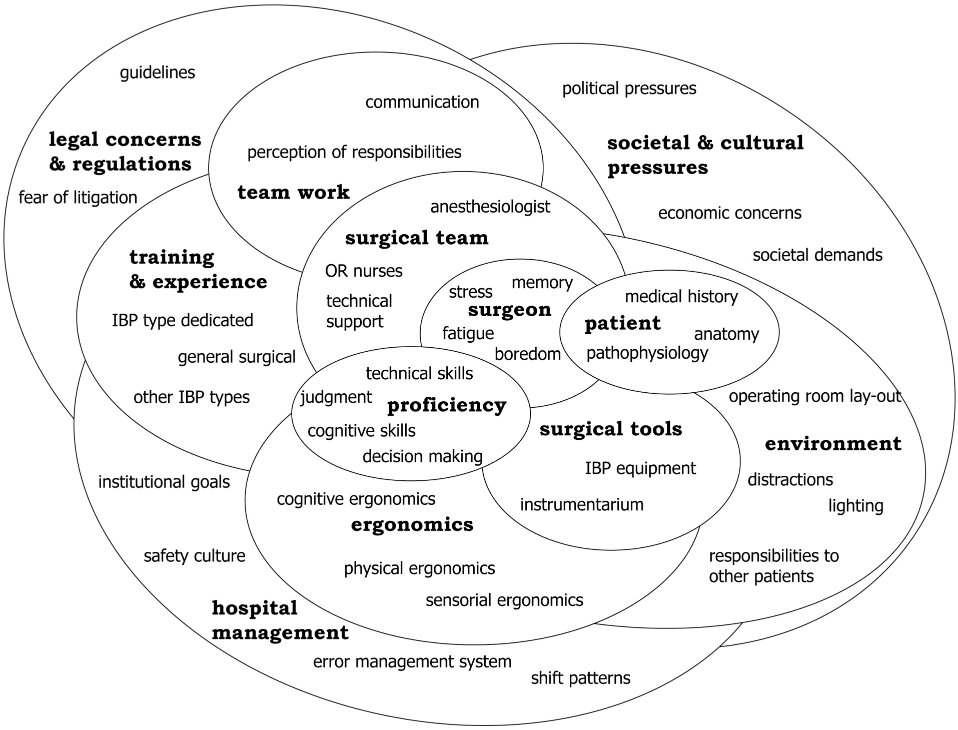

Figure 2.2 Factors of influence on patient safety. (adapted from: Calland et.al 2002 [27])

Physical ergonomic issues of laparoscopy

In laparoscopy the fixed minimal access of the instruments, positioning of the dedicated equipment around the operating table, and limitations to instrument design are the main causes leading to physical inconvenience and physical complaints for the members of the surgical team[176, 183]. First of all, laparoscopic surgery requires more equipment than open surgery, crowding the already limited space around the operating table[90]. Placement of the laparoscopy equipment (too) closely around the operating table also makes the patient less accessible in case of emergency and can pose a hazard to damage the sterile field[90]. The relatively fixed access points of the laparoscopic instruments leads to a more static posture for the surgeon, which allows fewer back movements and less weight shifting than during open surgery[14]. The many cables connecting the equipment can easily cause trip and fall accidents, especially in the cart-based setting where all equipment is placed on individual carts positioned around the operating table[90]. The placement of the monitor displaying the endoscopic view has been shown to directly influence the quality of performance[72, 117, 172]. It is important that the surgeon’s gaze, direction of the endoscope and the monitor are properly aligned, as this will improve task performance and reduces strain in the neck[72, 117]. The operating table needs to be lower than for open surgery, because of the elongated instruments used to reach the operating field within the inflated abdomen. Improper operating table height can lead to physical stress in the upper extremities[14, 125, 176]. In addition, in many designs of operating tables the lifting mechanism restricts the surgical team in respect to where they can place their feet and the possible location to position the foot pedals to control diathermia equipment[184]. The use of these foot pedals themselves are also a physical ergonomic issue[177]. To use these, the surgeon has to keep his balance while keeping one foot flexed above the pedal for a prolonged time.

Most laparoscopic instruments have been designed with a one-size handle that should accommodate use by all surgeons for various tissue manipulation tasks. Due to inefficient transmission of forces between the instrument handle and tip, some instruments require the exertion of relatively large forces using small contact areas on the fingers or palm of the hand. Manipulating tissue over a longer time using laparoscopic instruments can lead to muscle fatigue, discomfort, and numbness of the fingers[14, 176]. Technological innovations such as the integration of the dedicated equipment in the operating room, the integrated OR system, could reduce OR clutter, increase safety, prevent technical problems, improve the comfort of the OR staff, and enhance the efficiency of the preparation and dismantling of equipment between cases[81, 90].

Cognitive and sensorial ergonomic challenges of laparoscopy

In IBP, the physician perceives the operating field indirectly on a monitor instead of looking directly into an open wound. The information the physician perceives about the operating field and the manipulations of the tissue within it is almost completely visual and created by imaging equipment. In the image on the monitor depth perception is commonly lost, as it presents a two dimensional visual representation from a single point, shadowless perspective of the three dimensional operating field[14, 58]. Altogether, the IBP interface through which the physician perceives the operating field diminishes the perception of tactile information and interferes with kinaesthetic information from the tissue and the surgical instruments used to manipulate the tissue[14, 185]. The visual and the motor axis of the physician are no longer aligned as in open surgery; instead of looking downward on his hands, he looks up to a monitor and does not see his hands while manipulating the surgical instruments. To manipulate the instruments, the physician therefore requires additional spatial perception skills. He has to mentally translate the required movement of the instrument into the appropriate, frequently counterintuitive manual input. The forces applied to the instruments and tissue have to be take into consideration by the physician as well, the transmission of forces through the instruments is often limited, non-linear, and considerably disturbed[14, 97, 185].

The handling of the laparoscopic instruments involves a different, more complex type of hand-eye coordination than the application of standard surgical instruments used in open procedures. The fixed minimal access to the operating field limits the movements and degrees of freedom of the instruments and the area that can be reached by the instruments[6, 14]. In laparoscopic surgery the long instruments are inserted trough a trocar in the abdominal wall, which acts as a fulcrum point. To move the instrument tip to the right over a certain distance, the physician should move the instrument handle to the left, while taking the influence of the instrument insertion depth on the deflection into account. In comparison to IBP that make use of flexible elongated instruments, such as in flexible intraluminal endoscopy, the physician also has to consider the torque along the lengthy instrument shaft and the interaction between forces exerted on the shaft and deformation of the intestine.

The role of team work, distraction, and fatigue

In addition to the ergonomics issues discussed in the previous two sections, there are also several factors related to working in complex environments like the operating room, which can have an impact of the quality of performance and patient safety during image-based surgery. First of all, the performance of image-based procedures involves healthcare professionals from different disciplines who together form the surgical team for the particular patient on the operating table. To achieve their common goal, making the patient better, they have to combine their professional knowledge, skills, and experience. In the prevention of adverse events, teamwork skills are therefore also considered as important[33]. This involves skills like situation awareness (SA), conflict resolution, task management, interpersonal communication, leadership, and vigilance[33, 190]. Some even state that to achieve and maintain a high level of surgical performance over time these non-technical skills are more important than the technical skills of the surgical team[190]. To ensure patient safety during surgery, the healthcare professionals should work as a cohesive team and have similar perceptions of communication and teamwork[184]. To this end, the traditional surgical culture has to change and become less authority-centred. A safety culture should be created in which all members of the surgical team should feel equally free to speak up when they notice something that could jeopardise patient safety[27, 33, 184]. Standardisation of the basic ‘rules of engagement’ could provide a solution to ensure the members of the surgical team share one mental model of the procedure and minimise discrepancies in their perception of communication, team work, and situational awareness[33, 184]. The current persistent fear of litigation following an error report should be eradicated and openness should be encouraged. In this, the use of a so-called ‘black-box’ to record the performance of the team in the OR could be helpful to improve the quality of currently common written operating report describing the course of the procedure[181, 184].

Two other factors that pose a risk to the quality of performance are fatigue and distractions, such as noise, music, phone calls, and case-irrelevant communication. By themselves they might not have a direct effect on the performance, but they do reduce the concentration of the operating team and their capacity to recognise other issues that could lead to error and compensate for these events[34, 79, 166]. Fatigue is a factor that can jeopardise safety and the quality of performance in a similar way. Even though the European Working Time Directive (EWTD) has limited the work week considerably, especially for residents, their workload and pressure is still considerable. In addition, fatigue caused by disruptions in the circadian rhythms of the surgical team members, caused by their night shifts for example, remains a factor that deteriorates performance[101, 166].

2.5 The challenge of learning IBP skills

Performing surgery is a complex activity during which constant interactions take place between the surgeon’s technical, cognitive, and judgment skills within the six core competency components identified by the Accreditation Council of Graduate Medical Education (ACGME) and the American Board of Medical Specialties (ABMS) (Figure 1.4 and Table 2.1)[77, 146]. Physicians are considered competent when they are sufficiently proficient in all six core competences. Physicians in training actively work in the clinic throughout their training, beginning at medical school. They are allowed to perform tasks with gradually greater complexity, as their individual skills and overall competence increase by deliberate practise, observing experts, and clinical experience. Besides purposeful training, clinical experience and exposure to vast amount of clinical cases is imperative, as these all add to the overall competence of the physician[68, 140]. However, objective assessment of overall surgical competence and performance in the operating room is very difficult. Instead, the number of procedures performed is commonly used to estimate and certify physicians in combination with expert observations and sometimes very crude measures, such as the time needed to accomplish the procedure or the complication rate[45, 77, 86, 137]. In addition, simulation tools are available to assess proficiency in some of the specific component competencies or essential technical, cognitive, or judgment skills[77, 146]. To estimate proficiency of experienced surgeons, volume of work and case mix are also sometimes added to the equation[31, 74]. All these separate determinants to estimate competence do not take the actual quality of the performance of the physician into account.

Table 2.1 Definitions of the six general core competencies defining competence of physicians[77].

Patient care: compassionate, appropriate, effective
Medical knowledge: knowledge about established and evolving sciences and its application to patient care
Professionalism: commitment to professional responsibilities, adherence to ethical principles, and sensitivity to a diverse patient population
System-based practice: ability to interact with and call upon resources of a health-care system to provide optimal care
Practice-based learning: evaluation of one's own practice, appraisal, and assimilation of scientific evidence for improvement of patient care
Communication skills: interpersonal skills to exchange information with patients, families, and other health professionals

Competence in IBP partly overlaps with the knowledge and skills required for physicians and surgeons in general. And although for some procedures the image-based approach has become the golden standard, such as for cholecystectomy (removal of the gallbladder), surgeons are still expected to be able to perform the same procedure following an open surgical approach. For example in cases where the pathophysiology of the patient does not allow IBP or when due to complications during the procedure a conversion is necessary. IBP require additional IBP type-specific skills and knowledge, for example in relation to spatial perception, eye-hand coordination, and the control of the equipment[6, 14, 77, 140]. In particular the challenges brought about by the counterintuitive interaction with the operating field through the IBP interface and handling the dedicated equipment and instruments requires extensive training. This means that for many specialties (e.g. general surgery, gynaecology, vascular surgery), the introduction of IBP has led to a considerable transformation and sometimes also expansion of the required set of skills that a physician has to learn to become competent in those specialties [3, 6]. And in some cases it has led to sub-specialties, such as in gastrointestinal endoscopy and interventional radiology.

Just like for any other complex psychomotor task, physicians need to pass through the three phases of learning described by the theory of Fitts and Posner to become an expert in a specific IBP task[55, 137]. These three phases can be linked to the three levels of human behaviour described by Rasmussen[134]. While going through these phases, the type of behaviour and the perception of the information alters from the high conceptual knowledge-based level of behaviour to the skill-based level of task performance where the performance of the task requires almost no conscious attention (Table 2.2). As the context of task performance and the type of abilities that is required to perform the task shifts to mainly be dependent of psychomotor abilities, the quality of performance of the physician will become less susceptible to factors like stress or distractions in the environment[1, 137]. In the early/cognitive phase the IBP trainee is focused on understanding the task and formulating task strategies, while in the intermediate/associative phase the gained knowledge is integrated into the proper motor action using deliberate practise, in the final/autonomous phase the focus is on perfecting the speed, efficiency, and precision of the task performance[1, 137].

Table 2.2 The phases of skill acquisition and the different characteristics of task performance.

Phase of skill acquisition[47]	*Type of behaviour*[134]	*Information perception mode*[134]	*Context of task performance* [1]	*Type of abilities demanded* [1]
early / cognitive	knowledge-based	symbolically conditioned action	familiarisation with task goals and formulation of task strategies	general and broad-contents (figural, numerical, verbal and general)
intermediate / associative	rule-based	reflex action	proceduralised task strategies	perceptual speed
final / autonomous	skill-based	intuitive action	automatised task skills	psychomotor

For open surgery, technical and judgment skills are traditionally transferred primarily in the operating room by a master-apprenticeship model. For IBP though, this model is not adequate, amongst others due to the indirect interaction with the operating field and the fact that senior physicians are not necessarily as experienced in IBP as they are in open procedures[3, 6, 140]. The IBP interface disconnects the perception and action for the assisting trainee, thus a trainee can not adequately learn about the nuances and consequences of actions mainly by observation of an expert[6, 77, 86].

To train and assess the skills needed to perform the different types of IBP outside the clinical setting, in a so-called skills laboratory environment (skillslab), different types of simulations are used depending on the task or skill to be trained. Within this environment the trainee can focus completely on the performance of the task, without having to take care of other patient related issues. It creates a setting in which the trainee can learn a task by deliberate practise and is allowed to make mistakes and learn from them, without the risk of harming the well being of patients[19, 137, 143, 147]. The simulation models used to train IBP skills can involve human cadavers, living animals, organic or synthetic material, computer generated virtual reality, or a combination of those, such as in augmented reality[3, 6, 19, 85, 86, 137, 140, 143]. The training possibilities and level of fidelity that these simulations offer can differ considerably[137]. Currently, simulation is predominantly used to train technical skills and component tasks, but they are gradually more employed in procedural training, training of cognitive skills, and team training as well. Assessment of performance and meaningful feedback are crucial for the process of learning[45, 137, 143]. For many types of simulation however, an expert preceptor is still required to provide the trainee with feedback on his performance and on how to improve it. This feedback is mainly observation-based, and hence at least partly subjective. Computer based simulators, such as virtual reality (VR) simulators, can fulfil the growing need for objective performance assessment and detailed feedback on performance. Accordingly, VR simulators are obtaining an increasingly prominent position in medical education, and they have enhanced training programmes for IBP[66, 137, 143, 147]. Even though the overall potential, general value, and construct of VR simulators for surgical training has been proven in various studies[32, 66, 156, 165]; the application and role of the various available tools and simulators within the curriculum are still thoroughly being investigated[3, 147, 163]. The field of IBP is still young and the knowledge about the skills required for IBP and the development of these skills is limited. Research is needed to raise the understanding and increase the insight of the set of skills needed to perform medical procedures image-based.

Chapter 3.

Training and assessment of basic laparoscopy skills using simulation

Simulators could provide an effective alternative for clinical training of laparoscopy skills and can additionally fulfil the growing need for objective proficiency assessment. In this chapter the use of a virtual reality (VR) simulator for training and performance assessment of basic laparoscopic tasks, such as angled laparoscope navigation and tissue manipulation is investigated. Several experiments are discussed in which the validity and the didactic value of VR simulation for basic laparoscopic tasks are studied. In addition, the relation between performances on angled laparoscope navigation and tissue manipulation is explored. Together with the results presented in chapter 4, the outcomes of these experiments form the basis for an exploration of transfer between basic laparoscopy and colonoscopy skills in chapter 5. These studies also provided input for the investigations presented in chapter 6 into aspects of the simulator interface that affect the efficacy of training laparoscopic skills using simulation.

3.1 Laparoscope navigation and tissue manipulation; are these laparoscopic skills related? [*]

Laparoscopic surgery is not as straightforward as open surgery and requires a range of additional psychomotor and visual-spatial skills. The surgeon has to become proficient in dealing with the counter-intuitive manipulation of the instruments, the 2D representation of the 3D operating field, and a considerable loss of haptic feedback[23, 51]. Currently, expertise in laparoscopy is still mainly assessed on the basis of the number and type of clinical laparoscopic procedures performed (clinically-based expertise)[86, 147]. It is tacitly assumed that a surgeon who is proficient in laparoscopic tissue manipulation and can perform complex tasks like laparoscopic suturing well, will also be proficient in tasks

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[*] Published as: Buzink SN, Botden SMBI, Heemskerk J, Goossens RHM, de Ridder H, Jakimowicz JJ (2009) *Camera navigation and tissue manipulation; are these laparoscopic skills related?* Surgical Endoscopy 23: 750-757.

commonly rated lower in complexity, like translocation and tissue manipulation. Navigation with a 30 degree angled laparoscope is considered to be an even easier task. Therefore, the least experienced person of the surgical team often has the assignment to control the laparoscope during a procedure. However, it is important to realise that the nature of laparoscopic tasks like tissue manipulation and navigation with an angled laparoscope differ considerably and that the required eye-hand coordination partly relies on different visual-spatial and psychomotor abilities. Hence, the interaction with the various features of laparoscopy interfaces (handling of instruments and information) may be difficult to compare and rank in terms of complexity.

Virtual reality (VR) simulators are becoming a popular tool for training basic laparoscopy skills. In addition, they can fulfil the growing need for objective proficiency assessment and provide an effective alternative for clinical training[86, 131, 147]. The overall potential, general value, and construct of VR simulators have been proven in multiple studies[12, 32, 48]. Most studies involved either tasks related to tissue manipulation or tasks related to navigation with an angled laparoscope[51, 59, 69, 95, 162]. Only a limited number of studies incorporated both laparoscopic tissue manipulation and navigation with an angled laparoscope[9, 49, 173]. The majority of the studies investigated the realism or value of a VR trainer, focusing predominantly on the performances of novices. Little is known about the relation between the performances on fundamentally different laparoscopic tasks, like bimanual tissue manipulation and angled laparoscope navigation, and the influence of experience. The main objective of this study is to fill this gap by investigating the relation between the performances in these tasks by novice and experienced laparoscopists. The Camera Navigation task (CN) with a 30° angled laparoscope and the Place Arrow task (PA) of the SEP VR simulator (SimSurgery AS, Oslo, Norway) were used as representative tasks. Prior to investigating this relation however, we established the face and construct validity of these two tasks on the SimSurgery SEP.

Materials and methods

Sixty-six participants took part in this study either at the Annual Congress of the Dutch Surgical Society 2007 or at the Catharina Hospital Eindhoven, The Netherlands. The test environments were equivalent: a separate room in which the participants could perform the tasks on the simulator. The participants were allotted to one of two groups based on their indicated clinical laparoscopic experience (Figure 3.1). The 'Novices' have not performed any clinical laparoscopic procedures, and their medical knowledge and experience were at least at the level of a Dutch medical intern. The 'Experienced' have performed more than 50 clinical laparoscopic procedures, and are familiar with using a 30° angled laparoscope.

Simulator

This study focused on the SEP simulation software (SimSurgery AS, Oslo, Norway), which includes a range of tasks in a VR environment to train different laparoscopy skills. The software provides learning objectives, instructions, and a demo video before each task. The tasks included in this study were the Camera Navigation (CN) task with a 30° angled laparoscope and the Place Arrow (PA) task, which represents a bimanual tissue manipulation task (Figure 3.2). The software was used on two different hardware platforms (Figure 3.3): the SimPack surgical interface (SimSurgery AS, Oslo, Norway), and a Xitact/Mentice platform consisting of two IHP manipulators (Mentice AB/Xitact SA, Morges, Switzerland). The software produced the same data in both hardware-software combinations and provided numerical data and graphical presentation of the scores after the performance of each task (Table 3.1).

A preliminary analysis revealed several extraordinary results for the ‘dropped arrow’ and the ‘closed entry’ scores for the PA task on the Xitact/Mentice platform, in comparison to the scores on the SimPack platform. Further investigation revealed that these extreme scores could only be explained by differences in the technical characteristics of the hardware and the hardware-software interaction between the SEP simulation software and the Xitact/Mentice platform. Therefore, the scores for ‘dropped arrows’ and ‘closed entries’ were excluded from further data analysis for the simulator system with the Xitact/Mentice hardware platform.

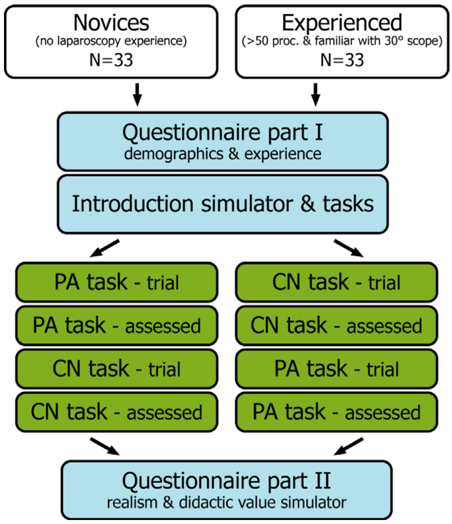

Figure 3.1 Overview of the study protocol

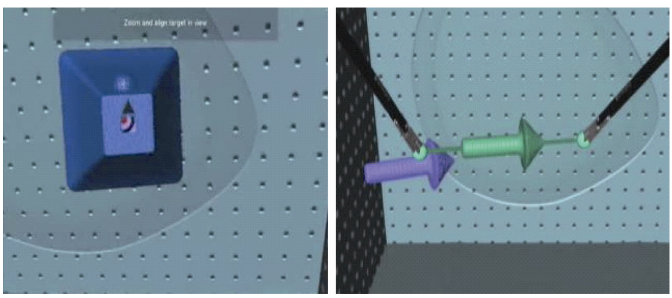

Figure 3.2 Screenshots of the CN task (left) and the PA task (right).
In the CN-task, the pyramid shaped target placed somewhere in the virtual box environment needs to be properly visualised by manipulation of the angled laparoscope and camera. The target is visualised properly when it is displayed and presented steady on screen for five seconds from a proper distance, centred on the screen, horizontally oriented, and the bull’s-eye inside the pyramid visible. In the PA-task, the arrow-shaped object needs to be grasped at both ends, placed over another arrow-shaped target elsewhere in the virtual box environment and held steady for five seconds by manipulation of the two graspers.

Figure 3.3 The SimSurgery SimPack surgical interface (left) and the Xitact/Mentice IHP simulator platform. Both systems used the SimSurgery SEP simulation software.

Protocol

First, the participants filled out the first part of the questionnaire on demographics and laparoscopy experience (Figure 3.1). Next, they received an introduction to the simulator and explanation of the tasks following a standardised procedure. During the introduction it was clearly stated that the researchers were not affiliated with the manufacturer of the simulator and that all data would be analysed anonymously. All participants performed each task twice on one of the hardware platforms. The tasks and type of hardware platform were presented to the participants in random order. Only the scores of the second runs were used to assess the performances. Finally, the participants filled out the remaining part of the questionnaire, in which they were asked to rate the realism, didactic value of the simulator on 5-point scales, plus the difference between the perceived and anticipated level of difficulty of the tasks.

Data analysis and statistics

SPSS 13.0 software (SPSS Inc., Chicago, USA) was used for statistical analysis of the simulator performance data and questionnaire data. A $p \leq .05$ was considered statistically significant.

Results

Twenty-nine participants performed the tasks on the SimPack (11 Novices, 18 Experienced) and 37 participants performed the tasks on the Xitact/Mentice platform (22 Novices, 15 Experienced) (Table 3.1).

Validity of simulator tasks

The opinion of the participants was not affected by the hardware platform that the participants used (Mann-Whitney U test, two-tailed). Both the Novices (Referent group, N=33) and the Experienced (Expert group, N=33) rated the tasks and representation of the behaviour of the laparoscope and graspers as realistic (Table 3.2). SimSurgery SEP was rated as a realistic and valuable didactic tool by both groups. However, there are some differences in the ratings between the groups, and the level of agreement within the groups. In both groups the participants stated that the CN task was more difficult than expected, while the PA task was not rated as being more difficult than expected. These ratings correlated with some of the performance scores for these tasks (Spearman's correlation, two-tailed). Such as in the CN task with the total tip trajectory in both groups (Novices: r_s=.435; Experienced: r_s=.447) and the number of targets lost out of view in the Novices group (r_s=.464). The ratings for the difference between anticipated and perceived level of difficulty for the PA task correlated in both groups with the time to accomplish this task (Novices: r_s=.404; Experienced: r_s=.428) and the number of lost arrows (Novices: r_s=.535; Experienced: r_s=.362).

Table 3.1 Performance data and comparison of performances between Novice and Experienced participants (Mann-Whitney U test, two-tailed). (IQR = Interquartile Range; ns = not significant).

			SimPack platform			*Xitact/Mentice platform*		
			Novices (N=11)	*Experienced (N=18)*	*sign.*	*Novices (N=22)*	*Experienced (N=15)*	*sign.*
CN task	Time to accomplish (s)	median	259.0	109.5	.002	241.5	118.0	.000
		IQR	144.0-381.0	92.8-191.8		186.8-331.8	82.0-137.0	
	Total tip trajectory (cm)	median	514.9	298.7	.007	395.9	241.5	.000
		IQR	389.3-640.3	222.8-381.2		334.0-606.4	172.9-306.2	
	Lost targets out of view	median	15.0	7.5	ns	12.0	5.0	.039
		IQR	5.0-26.0	4.8-7.5		2.8-17.3	3.0-10.0	
	Camera target collision	median	0.0	0.0	ns	0.0	0.0	ns
		IQR	0.0-0.0	-		0.0-0.0	-	
PA task	Time to accomplish (s)	median	143.0	65.0	.000	109.0	56.0	.000
		IQR	115.0-173.0	61.3-82.8		82.0-167.0	51.0-62.0	
	Total tip trajectory (cm)	median	279.7	180.7	.001	293.2	182.5	.000
		IQR	246.8-358.9	147.6-248.2		230.3-464.1	172.4-228.9	
	Dropped arrows	median	1.0	1.0	ns	-	-	-
		IQR	0.0-2.0	0.0-1.3				
	Lost arrows	median	0.0	0.0	ns	0.0	0.0	.005
		IQR	0.0-1.0	0.0-0.0		0.0-2.3	0.0-0.0	
	Closed entries left tool	median	1.0	0.0	ns	-	-	-
		IQR	0.0-2.0	0.0-2.3				
	Closed entries right tool	median	0.0	.5	ns	-	-	-
		IQR	0.0-1.0	0.0-2.0				

Dropped arrows = excessive opening grasper while holding the arrow. Lost arrows = excessive stretching arrow. Closed entries = attempts to grasp end of arrow with semi-closed grasper.

Preliminary analysis of the performance data of both set-ups showed that the type of hardware platform did affect some performance scores significantly (Mann-Whitney U test, two-tailed). Therefore, the performance data was assessed for both hardware platforms separately (Table 3.1). For the SimPack platform, the Mann-Whitney U test (one-tailed) showed a significant, difference between the scores of the Novices and the Experienced on the total time to accomplish both tasks and the total tip trajectories. On the Xitact/Mentice platform, the Experienced performed both tasks in significantly less time than the Novices, with significantly shorter tip trajectories. Additionally, the Experienced also lost significantly less targets out of view during the CN task and lost fewer arrows during the PA task.

Correlations within and between tasks

On the SimPack platform, for both groups jointly, the total time to accomplish the tasks correlated with the total tip trajectory of the same task (Figure 3.4 and Figure 3.5). The time to accomplish the CN task correlated with the time to accomplish the PA task (Figure 3.6). The tip trajectories of the CN and the PA task also correlated (Figure 3.7). The error scores on lost targets out of view and lost arrows correlated with the total tip trajectory of the according tasks (CN: r_s=.722; PA: r_s=.375). Within the Novices groups, the time to accomplish the tasks and the total tip trajectories correlated. In the Experienced group they only correlated for the CN task. The tip trajectory of the CN task correlated with the tip trajectory of the PA task within both groups. The error scores on lost targets out of view correlated with the total tip trajectory of the CN task (Novices: r_s=.788; Experienced: r_s=.639). However, the scores on number of lost arrows correlated with the total tip trajectory of the PA task only in the Experienced (r_s=.573). On the Xitact/Mentice platform, for both groups jointly, the time to accomplish the tasks correlated with the total tip trajectory of the same task (Figure 3.4 and Figure 3.5). The time to accomplish the CN task correlated with the time to accomplish the PA task (Figure 3.6), and so did the tip trajectories of the CN and PA tasks (Figure 3.7). The error scores on lost targets out of view and lost arrows correlated with the total tip trajectory of the according tasks (CN: r_s=.757; PA: r_s=.671). Within the Novices group, the time to accomplish the task and the total tip trajectory correlated within the CN task and within the PA task. The time to accomplish the tasks and the total tip trajectory of the same task were also correlated in the Experienced group. However, only the tip trajectories scores of the Experienced group for the CN and PA tasks correlated significantly with each other. Within both groups, the error scores on lost targets out of view correlated with the total tip trajectory of the CN task (Novices: r_s=.905; Experienced: r_s=.624). And for the Novices, the scores on number of lost arrows correlated with the total tip trajectory of the PA task (r_s=.554).

Table 3.2 The rated realism and value of SimSurgery SEP (5-point scale) and comparison of ratings between Novice and Experienced participants (Mann-Whitney U test, two-tailed). (ns = not significant)

	Novices mean (sd)	*Experienced mean (sd)*	*sign.*
Global impression	3.58 (.79)	3.87 (.63)	ns
Realism CN task	3.58 (1.06)	3.67 (.88)	ns
Realism PA task	3.42 (.90)	4.07 (.83)	.003
Virtual representation movements laparoscope	3.88 (1.11)	3.83 (.71)	ns
Virtual representation movements other instruments	3.97 (.73)	4.14 (.69)	ns
SEP measures the proper values to estimate expertise	3.71 (.69)	3.25 (.72)	.017
Experience on SEP is directly clinical applicable	3.90 (.65)	3.36 (.99)	.023
Implementation of SEP in training programmes for novices is useful	4.45 (.62)	3.88 (.89)	.006
SEP offers a user-friendly environment to train laparoscopy skills	4.48 (.62)	4.12 (.89)	ns
The Camera Navigation task was more difficult than expected	4.45 (.56)	3.76 (1.00)	.002
The Place Arrow task was more difficult than expected	2.30 (.98)	2.21 (.89)	ns

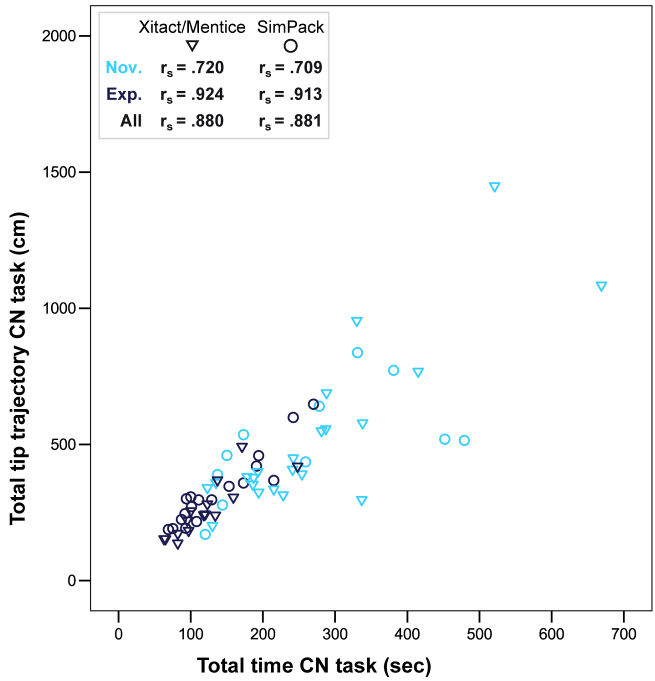

Figure 3.4 Scatter plots of the tip trajectory as a function of the time for the CN task.

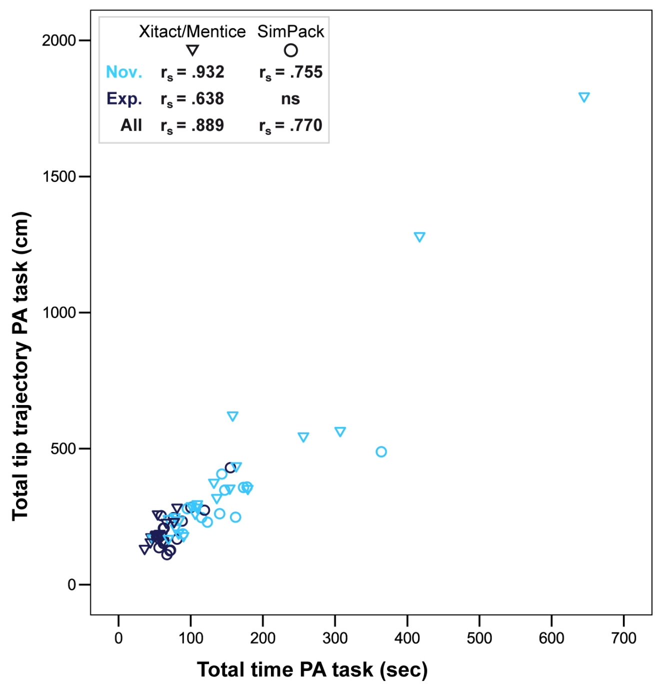

Figure 3.5 Scatter plots of the tip trajectory as a function of the time for the PA task.

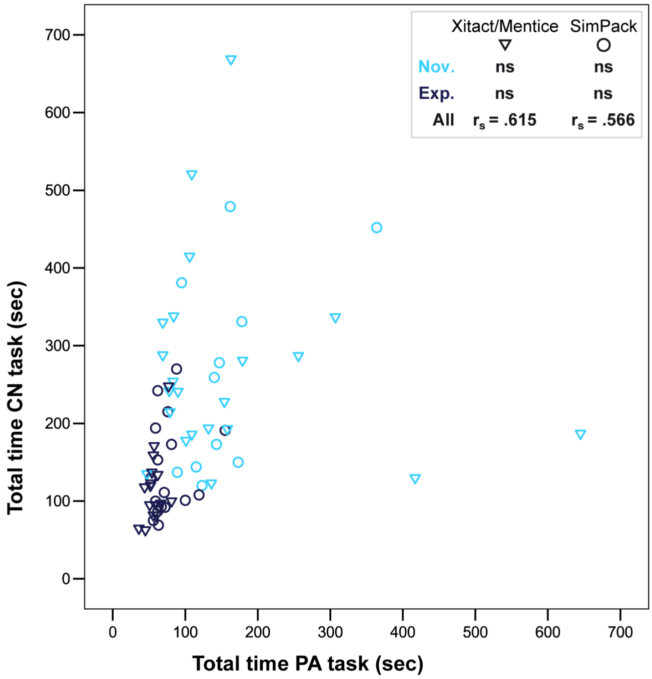

Figure 3.6. Scatter plots of the time to accomplish the two tasks

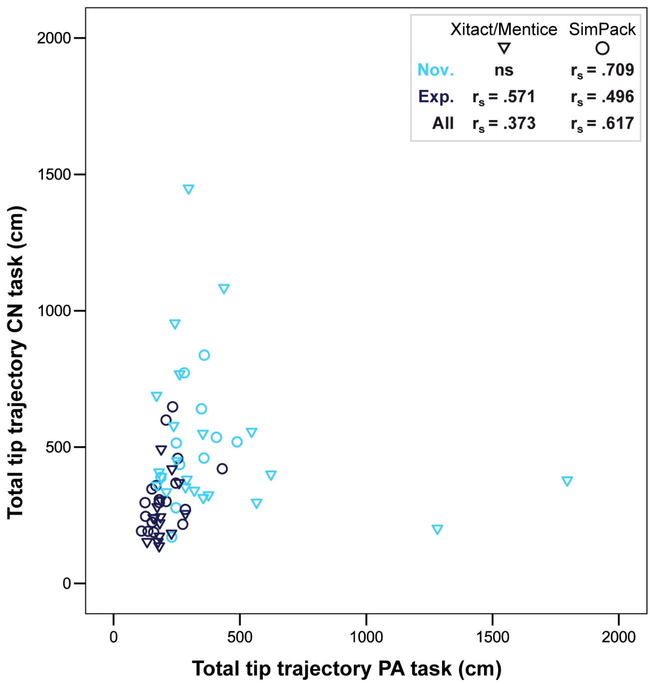

Figure 3.7 Scatter plots of the tip trajectory in the two tasks

Discussion

This study shows that the SimSurgery SEP is a valid and valuable tool to assess skills in bimanual tissue manipulation and navigation with a 30 degree angled laparoscope, enabling a differentiation between novice and experienced laparoscopists on both the SimPack platform and the IHP manipulators of Xitact/Mentice. Face validity was established for the Camera Navigation and Place Arrow tasks. However, it is important to realise that the ratings given by the participants could be affected by social-psychological effects. Although VR simulation of laparoscopic tasks is no longer a novelty in the field, the opinion of especially the novices could still be influenced by the novelty of this particular system (Table 3.2). The combination of the subject-expectancy effect and attribution theory most likely influenced the ratings on the realism and didactic value as well. These effects are well-known within the field of product usability assessment[126]. The subject-expectancy effect is a cognitive bias that occurs when a participant expects a given result, which could unconsciously influence the outcome of the experiment. The attribution theory relates to the reasoning people use to explain their behaviour with something else; how they attribute causes to events and how their cognitive perception affects their reasoning[126]. Most Novices were probably not expecting to get excellent scores yet or did not have any idea what scores to expect. Therefore, they most likely attributed any experience of difficulties with performing the task well to themselves. The experienced participants could have been expecting an excellent score for both tasks. Therefore, they might have attributed any disappointing performance scores predominantly to the simulator, and rated the properties of the simulator accordingly. The correlation of ratings with some of the performance scores for the tasks could partly be explained by the presence of these effects. Several Experienced participants made an additional remark, stating that the abstract visual environment could have affected their performance negatively, as they are used to have anatomical landmarks as reference points when manipulating the laparoscope. Stefanidis et al. also discussed this aspect in relation to participant’s frustration, but concluded that the difference in their study was too small to be of practical significance[162].

Comparison of the performance scores within and between the two tasks revealed that there is an obvious trend between the scores on time to accomplish the PA or CN task and the total tip trajectory for the same task, in general and within the Novices and Experienced groups (Figure 3.4 and Figure 3.5). When comparing the performances of both tasks it is more difficult to discover such a trend within the groups, as the scores are more scattered (Figure 3.6 and Figure 3.7). The scores for the total tip trajectory in both tasks correlated in the Experienced group for both platforms, while the scores on the time to accomplish both tasks did not correlate. This could imply that overall experience in handling laparoscopic instruments, like dealing with the fulcrum effect, does result in better general coordinated aiming or a smoother motion with laparoscopic instruments, and thus a shorter total tip trajectory.

The differences between the performances by the Novices and the Experienced are more distinctive for the PA task than for the CN task. Together with the overall complexity and inconsistency of the relation between the performance scores on both tasks, this supports our assumption that the eye-hand coordination and interaction with laparoscopy interfaces during different tasks deviate considerably, and involve different psycho-motor abilities. None of the previously published studies on the performance of angled laparoscope navigation and bimanual tissue manipulation on VR simulators investigated the relation between performances of these tasks. It appears that the general assumption that clinically-based expertise in laparoscopic tissue manipulation entails skilfulness in angled laparoscope navigation persisted in all these studies, including those focusing only on camera navigation[59, 69, 95].

VR simulators could play an important role in fulfilling the desire for objective proficiency assessment and in accomplishing a shift towards criterion-based training[86, 131, 147]. Imperative prior to such a shift however, is a better understanding of how to define proficiency for laparoscopy in general, and for the broad range of activities that laparoscopy includes in particular. The proficiency thresholds for different tasks could also be dissimilar. Proficiency assessment and training should match the characteristics of each specific type of activity or task, in particular when the eye-hand coordination and interaction with the interface in these tasks is fundamentally different.

Limitations

There are some technical limitations to this study, as mentioned before in 'Materials and Methods'. Due to a communication issue between the SEP software and the Xitact/Mentice hardware, the scores for the number of dropped arrows and closed entries were unreliable and had to be excluded. This situation was previously unidentified by the manufacturers. Following our findings, SimSurgery has adjusted the software to interpret the hardware output better. Overall, the tasks were performed in slightly less time and with a shorter tip trajectory on the Xitact/Mentice platform. This could originate from the fact that the Xitact/Mentice IHP manipulators leave the instruments less freedom of movement than the canulas in the operating surface of the SimPack.

Conclusions

Within the Camera Navigation task and the Place Arrow task, the performance scores on time to accomplish the task and the total tip trajectory generally correlated significantly. Between these tasks however, a correlation was not always found. This suggests that the general assumption that clinically-based expertise in tissue manipulations entails skilfulness in navigation with an angled laparoscope is not completely true. Training and assessment of basic laparoscopic skills should focus on both these tasks independently. More research is needed to better identify which skills are minimally required for fundamentally different laparoscopic tasks, and at what proficiency level. The physical and cognitive aspects of the interaction with the interface by different proficiency levels also need to be studied further, to ensure a good match between proficiency assessment and training in the virtual setting and performance in the clinical setting.

Acknowledgments

The authors would like to thank all participants for their engagement in this study and Cees Schot and Guy van Dael of the Catharina Hospital Eindhoven for their technical and audiovisual support. The authors also thank SimSurgery and Xitact/Mentice for unconditionally providing equipment support. This study was partly funded by a grant of Tyco Healthcare (now Covidien).

3.2 Training of basic laparoscopy skills on SimSurgery SEP *

Surgical training has rapidly changed over the past decades. The introduction of new techniques, such as laparoscopy, expanded the set of skills that surgical trainees need to acquire. Simultaneously, the amount of time available for training is becoming limited by the new European working time directives and due to economical and ethical considerations clinical training is loosing acceptance[48, 86, 148]. Virtual reality (VR) simulators are becoming a popular tool to train and assess surgical skills preclinically, in particular for image-based procedures such as laparoscopy[48, 148]. The overall potential, general value, and construct validity of VR simulators for basic laparoscopic skills have been proven in multiple studies[12, 48, 156]. The SimSurgery Surgical Education Platform (SEP) (SimSurgery AS, Oslo, Norway) is a relatively new VR simulator for laparoscopy, which has not been completely validated yet. A small number of studies have been published that investigated face validity, construct validity, or concurrent validity of several of the SEP training tasks[18, 25, 80, 105, 119]. However, none of these studies included angled laparoscope navigation. So far, only one study investigated the repetitive performance SEP training tasks; however, it only involved four small groups of novices (N=5) for four of the basic tissue manipulation tasks[119]. To implement SEP training tasks in an existing teaching programme or develop a curriculum around SimSurgery SEP, its construct and didactic value need to be validated further.

The aim of the study presented here was to assess the performances of novices on SEP over the course of a basic laparoscopic skills training programme focussing on bimanual tissue manipulation and angled laparoscope navigation. In addition, we compared the performances of novices on these tasks with those of experienced laparoscopic surgeons. This study was purposely focussed on bimanual tissue manipulation and angled laparoscope navigation. Both these tasks are considered to be fundamental laparoscopic skills, but at the same time these tasks are still rather challenging; requiring bimanual tool manipulation, higher level visual spatial perception and visuo motor translation.

Materials and methods

The performances of 14 medical trainees (Novices) over the course of four VR simulator training sessions on bimanual tissue manipulation and angled laparoscope navigation were analysed. In addition, we compared these performances with the performances of the 15 experienced laparoscopic surgeons that took part in our previous validation study[25]. The participants in the Novices group had no experience with performing laparoscopy or other types of endoscopy. Their medical expertise was at least at the level of a Dutch medical intern. The participants in the Experienced group had previously performed more than 50 clinical laparoscopic procedures, and stated to be familiar with using a 30° angled laparoscope.

Protocol and simulator tasks

Prior to the simulator training all participants were informed about the study protocol after which they filled out an informed consent form and a questionnaire about demographics and their general medical and laparoscopic experience. Next, they received an introduction to laparoscopy in general, the SimSurgery SEP VR simulator, and the SEP

* Published as: Buzink SN, Goossens RHM, de Ridder H, Jakimowicz JJ (2010) *Training of basic laparoscopy skills on SimSurgery SEP.* Minimally Invasive Therapy and Allied Technologies 19: 35-41.

training tasks included in this study. Within one week, the participants performed four simulator training sessions on the SimSurgery SEP VR simulator, with a maximum of one training session per day. The SEP simulation software (SimSurgery AS, Norway) was used in combination with a Xitact/Mentice IHP hardware platform (Mentice AB/Xitact SA, Morges, Switzerland) (Figure 3.3), thus creating a look and feel of the camera tool that may be considered to closely resemble the handling of a laparoscope. The Xitact/Mentice IHP hardware platform can also provide force feedback; but the tasks used in this study do not require such feedback. The settings of the instrument trocars were therefore set to compensate for the additional required effort for inserting the instruments in the trocars.

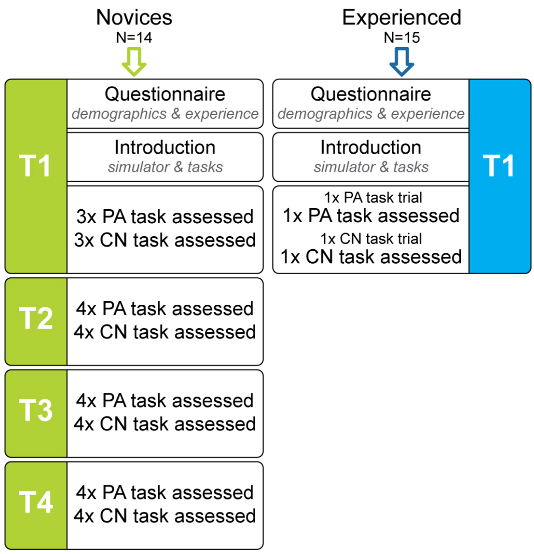

Figure 3.8 The study protocol (T1-T4: training session 1-4; PA task: Place Arrow task; CN task: Camera Navigation task)

Each training session contained a fixed number of repetitions of the Camera Navigation (CN) task with a 30° angled laparoscope and the Place Arrow (PA) task, representing bimanual tissue manipulation (Figure 3.8 and Figure 3.2). Over the course of the training programme, each novice participant performed 15 repetitions of each task (three in first session, four in consecutive sessions) (Figure 3.8). The sessions were designed such that each of them never took more than one hour in total, including filling out the questionnaire and introducing the simulator and tasks in the first session. After each task repetition, the simulator presents several performance scores and a graph that visualises the overall progress in task performance. The scores include time to accomplish the task, total instrument tip trajectory, and numbers of different types of task errors. The participants were given the assignment to perform each task as good and quick as possible. They only received feedback on performance generated by the simulator during and after each task. Questions asked by trainees related to the use of the instruments were answered, but no advice was given on how to improve performance.

Data analysis

SPSS 16.0 software (SPSS Inc., Chicago, USA) was used for statistical analysis of the data. To assess progression in performance within the Novices group, we used the performances in the last repetition of each task in the sessions (repetition 3, 7, 11, and 15).

Friedman's ANOVA (*p*<.05) and the Wilcoxon Signed Ranks test with a Bonferroni correction (one-tailed, *p*<.0125) were used to compare the performances within the Novices group between these training sessions. The Experienced participants performed each task twice; only the performances in the second repetition were used for comparison. To compare the performances of the Experienced with those of the Novices, the Mann-Whitney U test was used (two-tailed, *p*<.05).

A preliminary analysis of the data showed several remarkable excessive 'dropped arrow' and 'closed entry' scores, especially in comparison to scores of these same tasks performed on the SimPack hardware platform[25]. Further investigation and communication with the manufacturers indicated that these scores could only be explained by, up to that time unidentified, differences in the technical characteristics of the hardware and the hardware-software interaction between the SEP simulation software and the Xitact/Mentice platform. These differences only affected the scores related to the exact moment of opening/closing of the graspers: the 'dropped arrow' and the 'closed entry' scores. Therefore, these scores were regarded as unreliable and thus excluded from further analysis in this study. Following our findings, SimSurgery has adjusted the software to interpret the hardware output by the Xitact/Mentice platform better. In the CN tasks participants only rarely recorded a collision between the camera and the target; the collision score was therefore also excluded from the analysis.

Results

For the novices, the overall performance on both tasks improved significantly over the course of the training sessions (time to accomplish CN task: *p*<.001; total tip trajectory CN task: *p*=.002; number of targets lost out of view: *p*=.037; time to accomplish PA task: *p*<.001; total tip trajectory PA task: *p*<.001; Number of lost arrows: *p*=.029) (Friedman's ANOVA). The Wilcoxon Signed Ranks test showed that the performances of both tasks differed significantly (*p*<.0125) for all performance scores between repetition 3 and 15 (Figure 3.9, Figure 3.10, and Figure 3.11). For the CN task, the performances differed also significantly between repetition 11 and 15 for the time to accomplish the task and the total tip trajectory. Additional significant differences were found between repetition 3 and 7 for all performance scores of the Place Arrow task.

The Experienced performed both the PA task and the CN task significantly better than the Novices did in repetition 3 on almost all performance scores, except for the number of targets lost out of view (Mann-Whitney U test) (Figure 3.9, Figure 3.10, and Figure 3.11). Overall, the Experienced performed both tasks better than the Novices in repetitions 7 and 11, but not significantly. At the end of the training programme (by repetition 15), the Novices on the whole outperformed the Experienced participants on both tasks, although only significantly for the number of targets lost out of view (*p*=.015).

Discussion

This study shows that medical trainees can extensively improve their skills in navigation with 30 degree angled laparoscope and bimanual tissue manipulation by training on SimSurgery SEP following a relative short training programme of only 15 task repetitions. Besides the overall progression in task performance, the dispersion in performances within the group reduced considerably as well. During 15 repetitions the Novices learned how to cope with the counterintuitive manipulation of the laparoscopic tools and perform both tasks in less time, with higher efficiency of movements, and with fewer errors. After only a couple of repetitions in the introductory session, the performances by the Novices

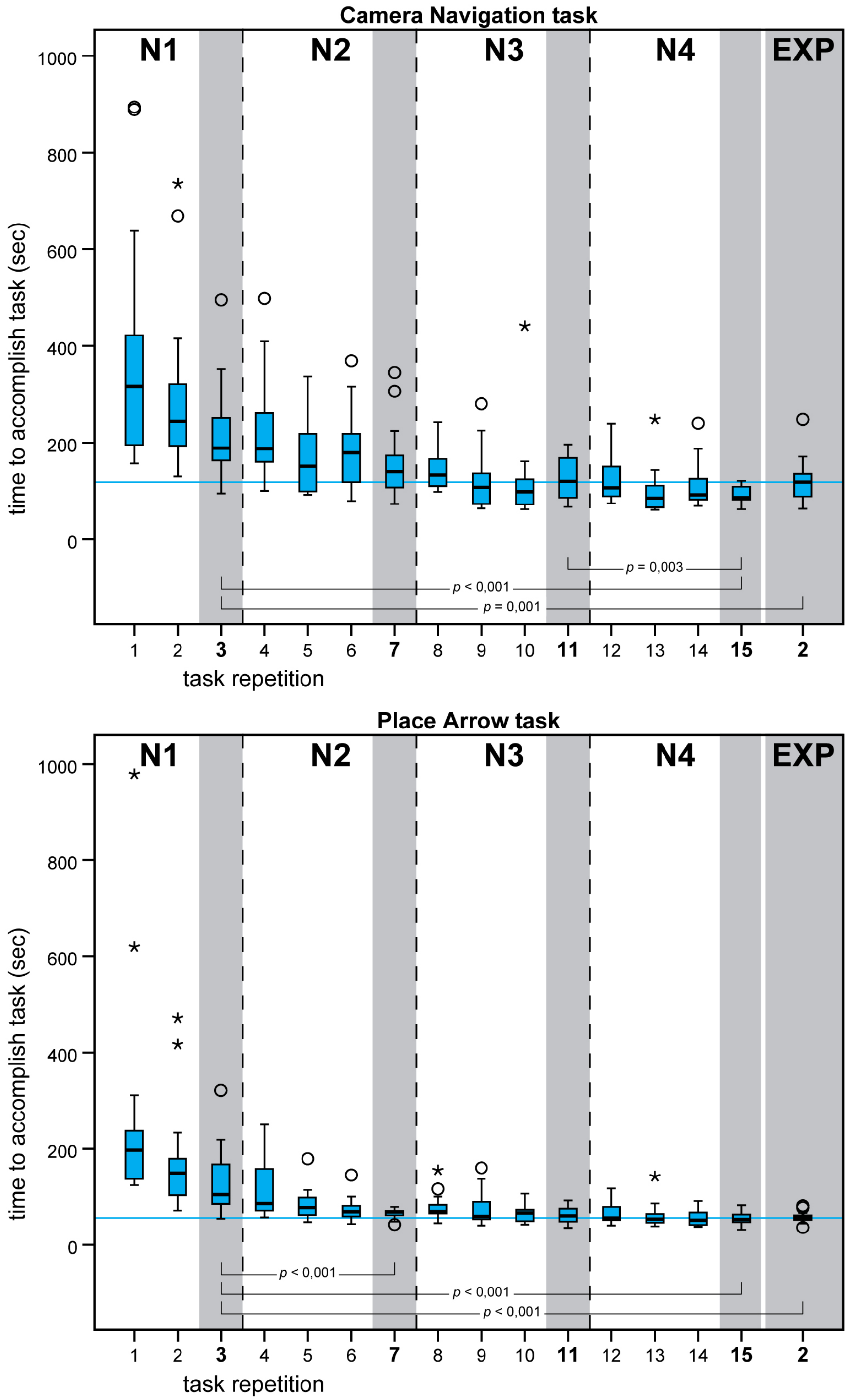

Figure 3.9 Box plots for the time to accomplish each task. In these and the following figures, the horizontal line represents the median score of the Experienced. The same holds for the comparisons within the Novices group being performed with the Wilcoxon Signed Ranks test and those between the Novices and the Experienced groups with the Mann-Whitney U test (only the significant differences are presented).

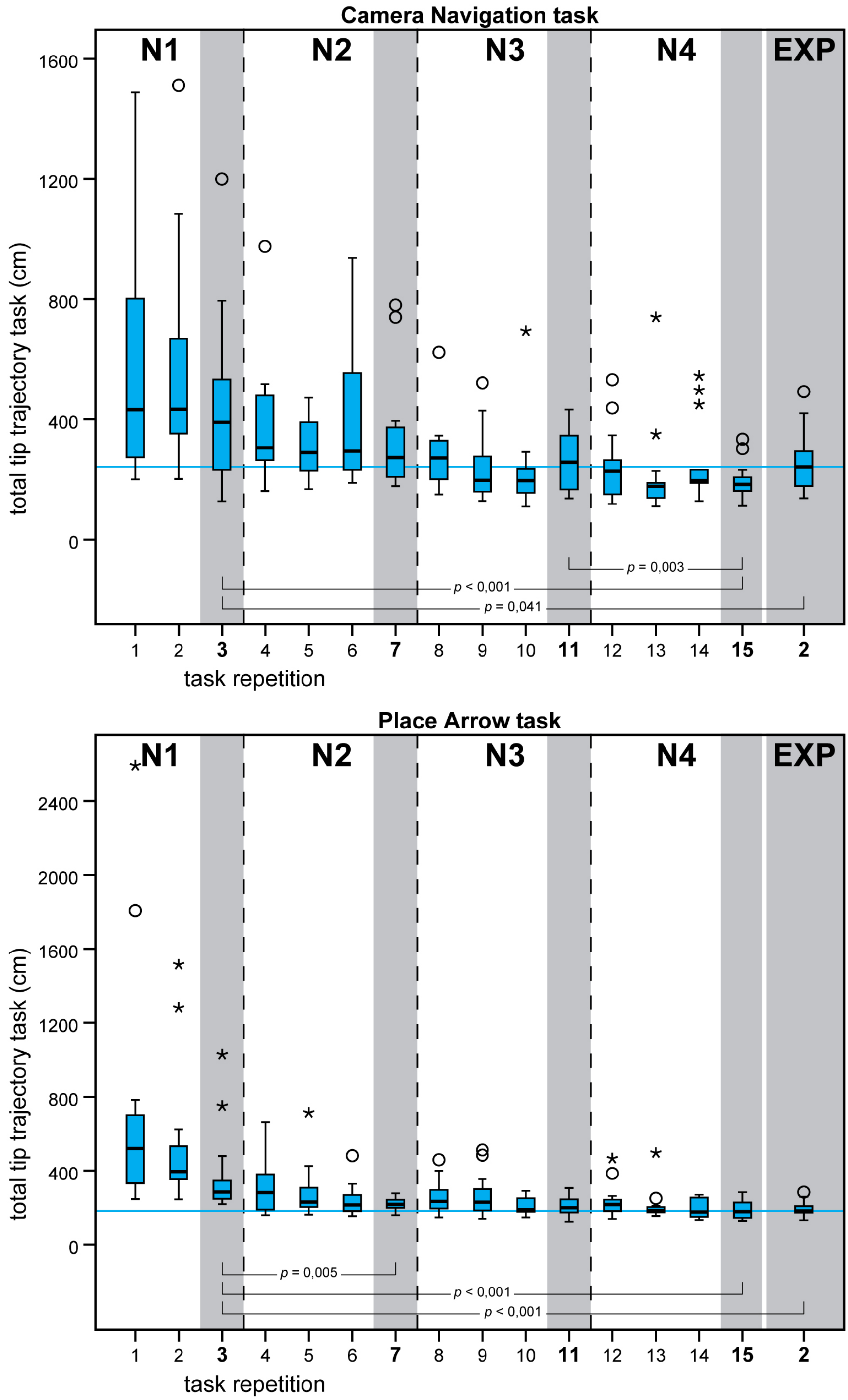

Figure 3.10 Box plots for the total tip trajectories. (See Figure 3.9 for further details)

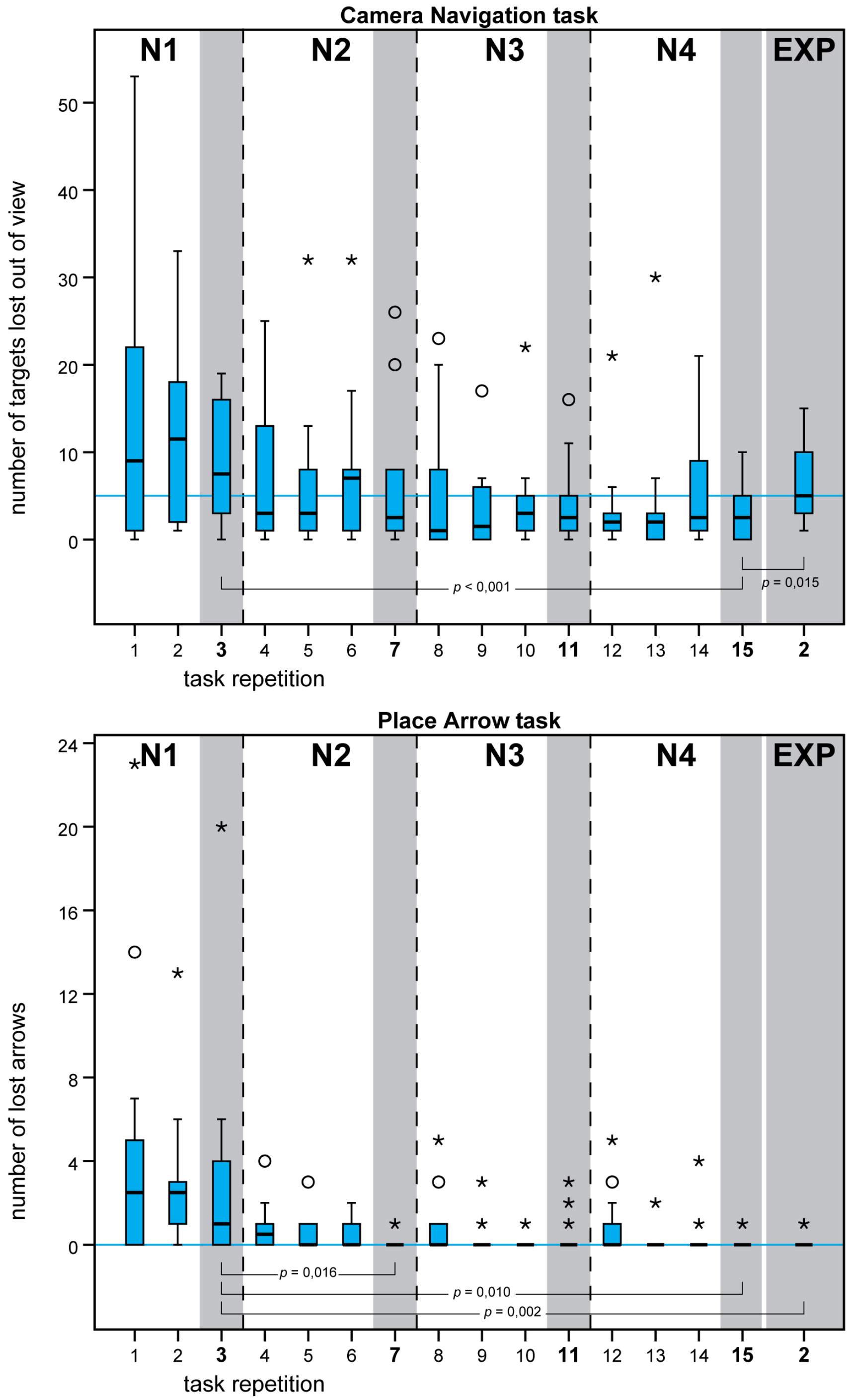

Figure 3.11 Box plots for the number of task errors. (See Figure 3.9 for further details)

still differed significantly from the performances of the Experienced on almost all performance scores. After a few more repetitions, the performances of the Novices improved greatly. By repetition 15, the performances of the Novices overall exceeded the performances of the Experienced on both task; however, these differences were only significant for the error score in the CN task. Brunner et al. showed that the learning curve for various laparoscopic skills is lengthy, possibly beyond 30 repetitions for some tasks, and that some skills are developed step wise, following a curve with several plateaus[21]. Our study included just 15 repetitions of the two tasks. At first glance the overall performance curve appears to flatten for both tasks around the level of the Experienced. However, this does not necessarily mean that all the individual participants reached their plateau within these 15 repetitions or even their training end-point for this task on SimSurgery SEP. Possibly, they could have improved their performance even further by extended training.

In general, transfer of laparoscopy skills trained on a VR simulator to the clinical setting has been proven[156]. Still, the transfer of skills learned by training on the SimSurgery SEP simulator to the clinical setting also needs to be studied. Preferably, such an investigation includes training following a criterion-based approach. VR simulators could play an important role in fulfilling the desire for objective proficiency assessment and in accomplishing a shift towards criterion-based training which also focuses better on the needs of the individual trainee[86]. Such a criterion-based approach will most likely improve the efficiency and efficacy of laparoscopy curricula and skills assessment, as the incidence of under-training or overtraining will decrease. To achieve this goal, we need to obtain a better understanding of the different skills that define laparoscopic proficiency and how to achieve proficiency in these separate skills and laparoscopy overall. Training and assessment of laparoscopic skills should focus on fundamentally different tasks independently. It should take the distinctive characteristics of each type of tasks properly into account, in particular when the physical and cognitive aspects of the interaction with the operating field through the interface is fundamentally different, such as for tissue manipulation and laparoscope navigation[25]. The proficiency thresholds for different types of tasks could also be more divergent than assumed up to now. For the development of effective criterion-based training curricula more knowledge is needed about the proficiency thresholds for each individual task and the corresponding extended performance curve and training end-points for training of these tasks on simulators.

Experienced laparoscopic surgeons are used to perceive some, though limited, haptic cues besides visual cues, when performing tasks that involve stretching or pushing of tissue. The absence of haptic feedback can influence the performance of tasks in which application of forces on tissue play an important role[18, 37, 105]. The SimSurgery SEP simulator does not provide haptic feedback. The PA task on SimSurgery SEP does involve stretching. Thus, the performance of the experienced participants could have been affected to some extend by the lack of haptic cues. The study by Chmarra et al. also showed that the lack of haptic cues can influence the learning effect for this type of tasks[37]. This suggests that, if the PA task had included realistic haptic feedback, the performance of the Novices maybe would have improved even further. In our previous validation study, several of the experienced laparoscopic surgeons expressed the feeling that the abstract visual environment in the laparoscope navigation task could have affected their performance negatively, in particular the unfamiliarity with the landscape[25]. They stated to be so used to have anatomical landmarks as reference points when manipulating the laparoscope, that they found it very difficult to navigate with the laparoscope though an environment without these distinct landmarks. When performing a task on the skill-based level (without needing conscious attention to perform the task), one is not always aware or able to describe what information is used during the performance of the task[134]. This could have implications for the design of simulators for training and assessment of skills, especially if the simulation involves a certain level of abstraction of the true environment. If the abstract environments lacks the cues that are consciously and/or unconsciously used by the experts to perform the task, their performances could be affected and subsequently their proficiency level would wrongfully be rated by the simulator as being lower.

In this study we used the SimSurgery SEP software in combination with a Xitact/Mentice hardware platform, previous findings have shown that this does affect the performances slightly[25]. This should be taken into account when comparing results of different studies on the performance of SEP training tasks. So far, no studies have been published on the repetitive performance of the CN task on SimSurgery SEP. Two research groups have published data on the performance of the PA task[80, 119]. Mathis et al. found a similar difference between the performances of the Novices and the Experts for the PA task[119]. The performances of the Experts in the studies by Mathis et al. and Heinrichs et al. clearly surpass the performances by the Experienced participants of this study, most likely due to the much higher expertise thresholds that they used[80, 119]. This study focuses on fundamental laparoscopic tasks, we therefore chose deliberately to compare the performances of the medical trainees with the performances of laparoscopic surgeons that were more moderately experienced, having performed more than 50 clinical laparoscopic procedures. When comparing the repetitive performances of the Novices with those in the study by Mathis et al., they appear roughly similar for the first few task repetitions; however, after the approximately four repetitions, the performances of the Novices in our study continue to improve further, following a steeper curve. This could be related to the difference in the training distribution; our trainees performed the repetitions following a spaced-training protocol, while the Novices of Mathis et al. performed all repetitions in a single massed session[109, 119, 178].

Conclusions

By following a relatively short training programme on the SimSurgery SEP VR simulator, medical trainees can significantly improve their skills in navigation with 30 degree angled laparoscope and bimanual tissue manipulation. After 15 repetitions of these two SEP training tasks, the performances of the Novices on the simulator were of the same level as the performances of experienced laparoscopic surgeons. Further research should focus on the transfer of skills trained on SimSurgery SEP to the clinical setting and the extension of knowledge on proficiency thresholds and training end-points for pre-clinical criterion-based training of different laparoscopic tasks.

Acknowledgments

The authors would like to thank all participants for their engagement in this study. They also would like to thank Sanne Botden and Jeroen Heemskerk for assisting during the training sessions and Cees Schot and Guy van Dael for providing technical and audiovisual support. We thank SimSurgery and Xitact/Mentice for unconditionally providing equipment support.

Chapter 4.

Training and assessment of basic colonoscopy skills using simulation

This chapter focuses on the realism and value of virtual reality (VR) simulation for training and assessment of flexible lower gastrointestinal endoscopic skills, in particular for colonoscopy. Several experiments are discussed in which the construct validity and the didactic value are investigated. The outcome of these studies, together with the results presented in chapter 3, form the basis for the exploration of transfer between basic laparoscopy and colonoscopy skills in chapter 5.

4.1 Expert and construct validity of the Simbionix GI Mentor II for colonoscopy*

Training skills in endoscopy for diagnostic and therapeutic procedures is essential and requires a great deal of hands-on training[170]. Virtual reality (VR) simulators offer a promising option to train these skills extensively prior to training in real-life colonoscopy, without jeopardizing patients or causing them unnecessary discomfort[152]. The use of VR training prior to performing real flexible endoscopy on patients enables novice endoscopists to go through part of their proficiency curve before submitting patients to their relatively insufficient endoscopy skills. This might not only be advantageous for the patients undergoing endoscopy, but might also prevent complications and potential consequences resulting in medico legal litigation. One of the simulators in the field of flexible endoscopy is the GI Mentor II (see Figure 4.1). VR simulators have been used extensively in different fields of expertise before applying these procedures to patients. In the United States of America simulator training is mandated by the Accreditation Council for Graduate Medical Education (ACGME) in laparoscopic procedures for surgical residents[140]. The first step is to validate the simulator construct properly and verify its

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* Published as: Koch AD, Buzink SN, Heemskerk J, Botden SMBI, Veenendaal R, Jakimowicz JJ, Schoon EJ (2008) *Expert and construct validity of the Simbionix GI Mentor II endoscopy simulator for colonoscopy.* Surgical Endoscopy 22: 158-162.

didactic value, before implementing simulators in teaching programmes or developing a new curriculum for flexible endoscopy around them.

Some studies have already been published on this subject[112, 139, 153], but the presented outcomes lacked power due to their relatively small sample sizes. In addition, some cases did not study the validity of endoscopy, but for example only the EndoBubble module, a computer simulation skills test measuring how long it takes a person to pop 20 balloons in a virtual tunnel. The main objectives of this study were: (1) to establish the degree of representation of real-life colonoscopy on the Simbionix GI Mentor II VR colonoscopy simulation, as judged by experts (expert validity), (2) to determine whether the GI Mentor II simulator can distinguish between various degrees of expertise in endoscopy, judged by novice, intermediate experienced, experienced and expert endoscopists performing VR colonoscopy (construct validity), and (3) to assess the didactic value of the simulator, as judged by experts.

Material and methods

Simulator

The simulator used in this study was the Simbionix GI Mentor II (Simbionix Ltd. Israel, software version 2.7.3.0) (Figure 4.1). The GI Mentor II can simulate upper GI tract endoscopies such as esophagogastroduodenoscopy, endoscopic retrograde cholangiopancreatographies, and endoscopic ultrasound. The lower GI tract endoscopies it simulates are sigmoidoscopy and colonoscopy. The simulator records a range of parameters upon each exercise, which can be used to assess performance objectively. The endoscope used is a customized Pentax ECS-3840F endoscope.

Participants

Participants were allocated to four groups to assess the validity and didactic value of the GI Mentor II simulator. The first group, the novices, was defined as participants without any flexible endoscopy experience; they were all medical interns or residents. The second group was intermediate experienced, with fewer than 200 colonoscopies performed before. In the third group experienced participants all performed more than 200 colonoscopies but fewer than 1000. The fourth group consisted of experts, all of whom had performed more than 1000 colonoscopies. These categories were chosen based upon several other studies, the demands for Dutch accreditation for colonoscopy, and the accreditation demands of the British Society of Gastroenterology, which advocates 200 colonoscopies under supervision during training[46, 112, 139, 167]. All persons were either invited to participate within our hospital, or participated during a national congress of the Dutch Society of Gastroenterology in spring 2006.

The groups consisted of at least 28 persons to ensure sufficient statistical power[54]. A post hoc sample size calculation based on the results for time to finish the EndoBubble task showed a minimal sample of 26 participants in the novices group to achieve a power of 0.95. Originally, the intermediate experienced and experienced participants formed one group, but as the expertise level and performance within this group varied considerably, this groups was split. A schematic setup of the study design is presented in Figure 4.2.

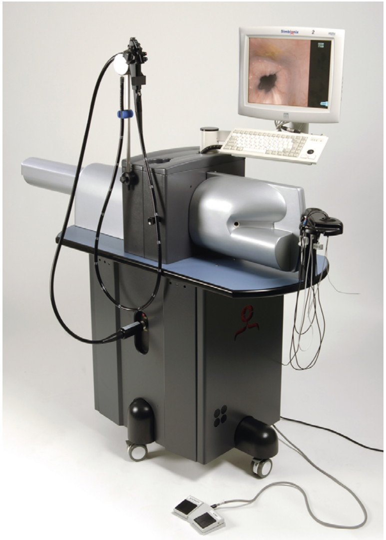

Figure 4.1. The Simbionix GI Mentor II VR simulator for flexible gastrointestinal endoscopy.

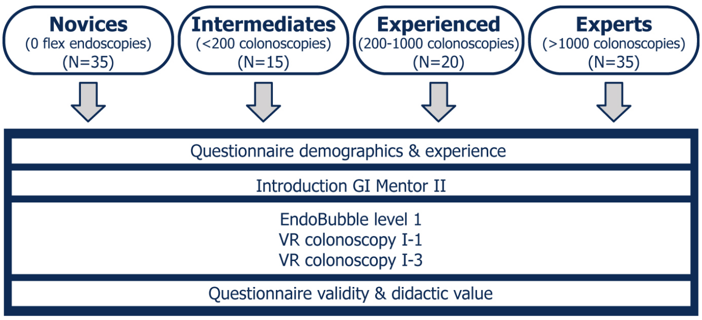

Figure 4.2. The study design for the assessment of expert and construct validity.

Questionnaire

All participants were asked to fill out a questionnaire on demographics and their general medical and endoscopy experience. It also included the number of endoscopies performed annually and number of years registered as a skilled professional endoscopist.

After the simulator run the participants were asked to answer questions about their appreciation of the realism of the colonoscopy exercises performed. Appreciation was expressed on a four-point Likert scale[104] varying from very unrealistic (1) to very realistic (4). Questions were asked about the realism of imaging, simulator setup, endoscope control and both haptic and visual feedback. Experts were asked whether the GI Mentor II could be used as a teaching device for novice endoscopists and whether experience on the simulator could be useful in practice.

Simulation modules

All participants first performed the hand–eye coordination task (EndoBubble level 1) of popping all 20 balloons in the test as quickly as possible, without touching the walls. Next, the participants performed VR case numbers 1 and 3, both from colonoscopy module 1. These cases were carefully selected for their discriminative value; both cases are straightforward colonoscopies, without any abnormalities such as polyps, tumours, or inflammation. Case number 1 is a relatively easy colonoscopy to perform, whereas case number 3 is more difficult, requiring the endoscopist to apply techniques such as straightening the endoscope during loop formation and applying torque to the endoscope shaft. The assignment given for the VR colonoscopies was to reach the cecum as quickly as possible with as little patient discomfort as possible. Patient discomfort was defined as the estimated percentage of time the virtual patient was in excessive pain and the number of times excessive local pressure was caused. Other relevant test parameters were the percentage of time spent with clear view and the number of times view of the lumen was lost. The task was considered accomplished when the cecum was reached.

Data analysis

SPSS 13.0 software was used to perform descriptive statistics and Kruskal–Wallis tests for statistic analysis of the data. A separate analysis between groups was performed using a two-tailed Mann–Whitney exact U test. A p-value of less than 0.05 was considered significant. The data showed a nonparametric distribution, therefore the median and range of performance parameters are presented as primary values.

Results

Thirty-five novices, 15 intermediates, 20 experienced, and 35 expert endoscopists participated in the study. The average number of colonoscopies performed annually by experts was 445, and their mean number of years registered as a gastroenterologist was 7.7 (range 0–35 years).

Data output by the simulator are presented in Table 4.1 and Table 4.2. The EndoBubble task was completed faster by the experts and experienced endoscopists than by novices, with fewer wall collisions. These differences were statistically significant (Kruskal–Wallis test) (Table 4.1). Also the colonoscopy tasks were completed faster ($p<.001$, Kruskal–Wallis test), with less patient comfort and better visibility by experts and experienced endoscopists (Table 4.2). Novice endoscopists (N=35) reached the cecum in a mean time of 30.0 minutes in colonoscopy case 3, intermediate experienced (N=15) in 5.8 minutes, experienced (N=20) in 4.3 minutes, and experts (N=35) in 4.9 minutes. Novices lost view of the lumen significantly more often than the other groups. A separate analysis between groups using a Mann– Whitney exact U test demonstrated no significant difference between the intermediate, experienced and expert groups on all parameters. They all completed the task faster than the novices (see Table 4.3).

The group of expert endoscopists rated the colonoscopy simulation 2.95 on a four-point Likert scale for overall realism. Anatomical representation was rated 2.58, and the simulator setup 3.14. Endoscope control scored 3.21. Haptic feedback was rated 2.57.

Expert opinion was that the GI Mentor II simulator should be included in the training of novice endoscopists (3.51 on a four-point Likert scale) and that expertise gained on the simulator was considered applicable in a clinical curriculum (rated 3.29 out of 4). The simulator was not considered suitable for certification of trained endoscopists (rated 2.29 out of 4).

Discussion

This study represents the largest and most detailed study on the validity of this type of colonoscopy simulator so far. The data show that the simulator can discriminate clearly

Table 4.1 Performances on EB L1 hand-eye coordination task and comparison of performances. (Kruskal Wallis test)

		Time to accomplish (min)	*Number of times wall touched*
Novice N=35	mean	6.9	1.9
	median	6.0	1.0
	min - max	1.4 - 20.4	0 - 20
Intermediate N=15	mean	1.9	1.1
	median	1.7	.0
	min - max	0.9 - 4.0	0 - 5
Experienced N=20	mean	1.6	.9
	median	1.4	.0
	min - max	0.7 - 5.6	0 - 9
Expert N=35	mean	1.4	.3
	median	1.2	.0
	min - max	0.8 - 3.4	0 - 2
Kruskal Wallis	Chi-Square	63.151	9.374
	Sign.	.000	.025

Table 4.2 Performances on VR colonoscopy Module 1, Cases 1 and 3 and comparison of performances (Kruskal Wallis test).

			Time to reach cecum (min)	*% of time spent with clear view*	*Lost view of lumen*	*Excessive local pressure*	*% time patient in pain*	*Excessive loop formed*
VR colonoscopy case I-1	Novice N=35	mean	6.8	96	0.4	0.5	13.3	0.83
		median	6.3	97	0	0	11	0
		min - max	1.9 - 15.1	82 - 99	0 - 3	0 - 3	0 - 44	0 - 6
	Intermediate N=15	mean	1.6	97	0	0	8	0.6
		median	1.7	98	0	0	5	0
		min - max	0.9 - 2.97	91 - 100	0	0	0 - 30	0 - 3
	Experienced N=20	mean	1.4	98	0	0.2	9.2	0.7
		median	1.4	98	0	0	8	1
		min - max	0.8 - 2.7	89 - 100	0	0 - 1	0 - 27	0 - 3
	Expert N=35	mean	1.4	98	0	0	14.5	1.49
		median	1.3	98	0	0	12	1
		min - max	0.7 - 3.3	94 - 100	0 - 1	0	0 - 57	0 - 10
	Kruskal Wallis	Chi-Square	69.043	13.889	18.415	19.783	7.101	10.691
		Sign.	.000	.003	.000	.000	.069	.014
VR colonoscopy case I-3	Novice N=35	mean	30.0	86	3.2	3.89	2.2	4.77
		median	23.7	85	3	3	0	1
		min - max	4.8 - 88.3	72 - 96	0 - 12	1 - 14	0 - 24	0 - 34
	Intermediate N=15	mean	5.8	89	1.1	2.1	0.9	1.13
		median	4.4	92	1	2	0	0
		min - max	2.5 - 13.7	78 - 97	0 - 4	0 - 6	0 - 4	0 - 8
	Experienced N=20	mean	4.3	91	0.6	1.9	1.0	1.6
		median	3.8	91	0	1	0	1
		min - max	2.5 - 7.0	73 - 99	0 - 3	0 - 8	0 - 4	0 - 9
	Expert N=35	mean	4.9	89	0.9	1.6	2	2.51
		median	4.1	90	1	1	1	1
		min - max	1.6 - 15.7	68 - 99	0 - 4	0 - 6	0 - 10	0 - 12
	Kruskal Wallis	Chi-Square	65.559	6.978	41.936	28.794	4.284	4.856
		Sign.	.000	.073	.000	.000	.232	.183

Table 4.3 Differences between groups for VR colonoscopy Module 1, Case 1 (VRC I-1) and Case 3 (VRC I-3) (Mann Whitney Test, Exact Significance, two-tailed).

		Time to reach cecum	% of time spent with clear view	Lost view of lumen	Excessive local pressure	% of time patient in pain	Excessive loop formed
VRC I-1	Novice vs Intermediate	.000	.177	.039	.013	.070	.743
	Intermediate vs Experienced	.166	.617	1.000	.244	.385	.547
	Experienced vs Expert	.962	.621	1.000	.043	.077	.020
	Intermediate vs Expert	.141	.259	1.000	1.000	.018	.009
VRC I-3	Novice vs Intermediate	.000	.104	.000	.004	.584	.040
	Intermediate vs Experienced	.257	.394	.285	.503	.771	.184
	Experienced vs Expert	.969	.297	.153	.942	.154	.726
	Intermediate vs Expert	.326	.757	.870	.416	.111	.090

between endoscopists of different expertise levels performing different colonoscopy tasks. Differences were statistically significant using relatively large sample sizes in all three exercises, the EndoBubble task as well as cases number 1 and 3. The difference between our study and previous studies by others is that we focused on the basic aspects of navigation for colonoscopy itself, rather than on the hand–eye coordination task alone, used for example in the study by Ritter et al. (2003), and that we included more participants in four separate groups with different levels of expertise[52, 64, 112, 139, 153]. in this way we were able to demonstrate that the GI Mentor II can distinguish between expertise levels up to the level of an intermediate experienced endoscopist, who has performed around 200 colonoscopies. In similar study Sedlack et al. (2003) describe a limited construct for a different simulator (AccuTouch, Immersion Medical). Felsher et al. (2005) demonstrated differences between novices and experts in large sample sizes but did not compare novices to intermediate levels of expertise. In this study we have demonstrated convincing expert validity for colonoscopy on the GI Mentor II virtual simulator[52]. This in contrast to other studies focusing on the EndoBubble task as a validation study[139] and not dealing with the subject of expert validity[46, 52, 64, 112, 139].

The colonoscopy tasks were considered as accomplished once the participants reached the cecum. Asking the participants to inspect the mucosa on the way back through the colon does not, in our opinion, provide a proper representation of the endoscopist's skills in manoeuvring through the colon, as other aspects besides the basic navigation skills of the endoscopist could influence the performance parameters provided by the simulator considerably in this case. This might lead to very different end times depending, for example, on the carefulness of the endoscopist.

This study demonstrates that the GI Mentor II simulator offers a convincing, realistic representation of colonoscopy according to experts. The overall assessment was good. Expert opinion was that the simulator can be used as a teaching tool for novice endoscopists. The simulator's haptic feedback is doubtful. Inexperienced residents can be trained in the skills necessary in flexible endoscopy such as steering control, straightening the endoscope during loop formation and applying torque up to a certain level.

Conclusions

The current study demonstrates that the GI Mentor II simulator does offer a convincing realistic representation of colonoscopy according to experts (expert validity) and that the simulator can discriminate up to the level of intermediate experienced endoscopists (construct validity) in colonoscopy. In the cases used the simulator can not discriminate between intermediate, experienced and expert endoscopists. The next step will be a study to determine whether novice endoscopists can develop a learning curve that will actually improve their endoscopic skills applied to real patients.

Acknowledgments

The authors thank all the participants for their engagement in this study. They also would like to thank Cees Schot for his technical support.

4.2 Acquiring basic colonoscopy skills by training on GI Mentor II*

Navigation through the colon with a flexible endoscope is technically demanding, like many other image-based procedures[23]. It requires a high level of both psychomotor and visual-spatial skills. Consequently, trainees need a great deal of hands-on experience to master colonoscopy skills. Traditional assessment and accreditation methods are mainly based on a minimal number of supervised procedures, after which average trainees are expected to have achieved a sufficient level of proficiency. Though there are recommendations regarding these minima[39, 115, 168, 187, 188], the minima suggested differ considerably[50, 139]. There is a growing need for more objective methods for proficiency assessment, and a desire to training until a predetermined level of actual proficiency instead[86, 140, 147]. In addition, training in basic endoscopy skills within a clinical setting is losing acceptance due to ethical and economic considerations[61, 140, 147, 152]. This necessitates novice endoscopists to train in the fundamentals of colonoscopy in a skills-lab setting.

Virtual reality (VR) simulators could provide an effective alternative for clinical training and supply educators objective data about the proficiency of their trainees. Currently, VR simulators are obtaining an increasingly prominent position within medical education, and they have enhanced training programmes for endoscopic skills[23, 154]. VR simulators are currently still being thoroughly evaluated, as their application must be proven valid before widespread integration in education and training programmes[32, 61, 83]. Most VR simulators record multiple performance parameters, which are assumed to provide objective insight into the proficiency level of the trainee. Some of the parameters provided by the simulators are calculated using multiple variables recorded by the simulator. Currently, one of the major issues for the application of VR simulators in training programmes is to determine which types of exercises are most appropriate, and which (combination of) performance parameters represents performance best[86, 147].

Several VR simulator systems are currently available for lower gastrointestinal flexible endoscopy[32, 61, 83]. The validity of the different systems for lower gastrointestinal endoscopy skills has been studied before[46, 50, 52, 53, 61, 64, 83, 108, 112, 113, 139, 153]. However, most of these studies did not focus on the basic tasks first, but included multiple (complex) tasks, or used relatively small numbers of participants. Based on our experience with validation of simulators for assessment and training in laparoscopic skills[32, 150], we evaluated the GI Mentor II for basic navigation skills for colonoscopy, and proved its construct validity and didactic value[92]. However, little is known about the improvement of colonoscopy skills by

* Published as: Buzink SN, Koch AD, Heemskerk J, Botden SMBI, Goossens RHM, De Ridder H, Schoon EJ, Jakimowicz JJ (2007) *Acquiring basic skills by training on the GI Mentor II.* Surgical Endoscopy 21: 1996-2003.

repetitive training on the GI Mentor II. The objective of this study is to gain insight into the first part of the proficiency curve for basic endoscope navigation skills when training on the GI Mentor II.

Materials and methods

This study investigates several aspects of the learning trajectory on the GI Mentor II simulator. First, the performance of 30 novice endoscopists (with no prior flexible endoscopy experience) on the simulator was assessed over a series of training sessions. Second, the performance of five expert endoscopists was investigated for the same series of training sessions. Third, the scores of novice participants were compared with those of 20 experienced (200-1000 colonoscopy procedures performed) and 40 expert (>1000 colonoscopy procedures performed) endoscopists, to assess their performance within a wider context.

Participants

Thirty novices in flexible endoscopy participated in the study (10 males, 20 females, mean age 25.5 years), all of them medical interns (N=23) or residents in training (N=7). Five expert endoscopists (all male, mean age 46.2 years) also performed the four training sessions. In addition, the performance data of 20 experienced and 35 expert endoscopists, who participated in our validation study, was used[92]. The tasks performed on the simulator in the validation study were exactly the same as in the first training session of the study presented here[92].

Simulator

The GI Mentor II VR simulator for flexible endoscopy (Simbionix, Ltd., Israel, software version 2.7.3.0) (Figure 4.1) was used in this study. The GI Mentor II provides hands-on training by various modules for training in basic psychomotor endoscopy skills, lower, and upper flexible endoscopy procedures on a mannequin with a mouth and a rectal end. The endoscope used is a customised Pentax ECS-3840F endoscope. Steering and torque of the endoscope are controlled as in real endoscopy; insufflation and suction are also available. The computer simulation programme supplies visual and audio feedback, while dynamic force feedback devices inside the mannequin provide force feedback sensations, all corresponding to the selected training module and patient scenario. The patient scenarios for VR endoscopy vary in anatomy and pathology. The simulator provides objective measurements and statistics about each performance.

Protocol training sessions

The proficiency of the participants in basic endoscope navigation was assessed during four preset training sessions (one per day) within five consecutive days (see Figure 4.3). Each participant performed one hand-eye coordination task (EndoBubble level 1) per session. Each of the training sessions also involved multiple different VR colonoscopy cases, with varying levels of difficulty, to avoid bias by training on only one patient scenario. The participants were not notified about the repetitive nature of the last VR colonoscopy in each session. VR colonoscopy I-3 was selected as repetitive exercise because of its discriminatory value; it is a fairly complicated case, with a relatively winding sigmoid and a built in loop in the ascending colon and hepatic flexure[92]. The performance of the repetitive exercises within each session is defined as a run.

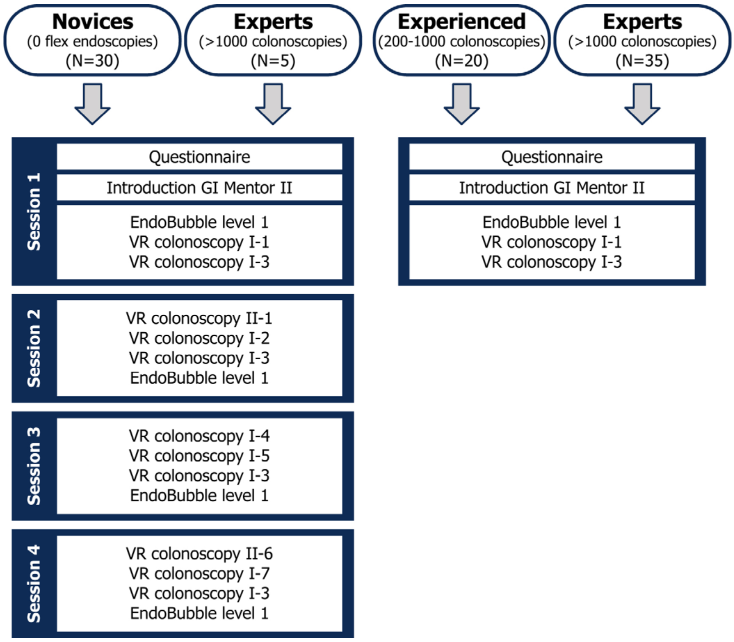

Figure 4.3 The study design for the assessment of the performance curve.

As the study focuses on the manipulation and navigation skills of the participants, the assignment for the VR colonoscopy exercises was to visualise the cecum as quickly as possible, with as little patient discomfort as possible. When the participant reached the cecum, the exercise was considered accomplished. Participants were instructed not to identify or treat the pathologies presented in the cases. No feedback on performance was given, other than produced by the simulator in full screen mode. Prior to the first session, the participants filled out a questionnaire on demographics, and their general medical and endoscopy experience. Next, they received an introduction about the simulator and an explanation on how to operate the controls and steer the endoscope tip. The tour and explanation were given by the researcher, following a preset objective procedure. Questions concerning the functioning of controls were answered, whenever asked during the training sessions, but no instructions were given on how to optimise performance. The participants were informed about the parameters recorded by the simulator and their scores were shown to them after each exercise. All participants performed the tasks on the simulator single-handed, without nurse-assistance for scope insertion.

Performance parameters

A broad range of variables is recorded by simulator; however, time to accomplish the assignment (*time to reach the cecum* in VR colonoscopies or *time to finish the EndoBubble task*) and the *(estimated) percentage of time the patient was in excessive pain* were considered key parameters for this study (see Table 4.4). The *(estimated) percentage of time the patient was in excessive pain* is a composite parameter calculated by the simulator using several pain related variables. When the pain level is above the value 0.6, excessive pain is counted. If the level remains for 15 seconds, excessive pain is recorded again[#].

Statistical analysis

SPSS 11.0.1 software was used for statistical analysis of the data. As the samples are non-parametric, the median and range of performance parameters are presented. Means are also presented in some cases to provide a complete depiction of the data. Friedman's ANOVA test and Wilcoxon Signed Ranks tests (2-tailed significance) were used to assess potential learning effects and differences in performance within groups, while differences between groups were evaluated using the Mann-Whitney U test (one-tailed significance). All differences were considered statistically significant at $p \leq .05$.

Results

Performance of the novices

The novices improved their performance on both VR colonoscopy I-3 and the EndoBubble task considerably (see Table 4.4 and Figure 4.5). In the fourth run, the median *time to finish the EndoBubble task* shortened by 58.5%, while the range decreased with 77%, and the median *time to reach the cecum* for VR colonoscopy I-3 shortened by 72.3%, while the range decreased with 85%. The median *percentage of time the patient was in excessive pain* reached 0% in the fourth run for all participants. Friedman's ANOVA test shows that the performance of the novice participants differed significantly between the four runs ($p<.05$ for *number of wall collisions* in the EndoBubble task, $p<.01$ for all other performance parameters). The Wilcoxon Signed Ranks test shows that the *time to reach the cecum* for VR colonoscopy I-3 differed significantly ($p \leq .001$) for all four consecutive runs (run 1 with run 2, run 2 with run 3, run 3 with run 4) ($Z=-4.08$, $Z=-3.31$, and $Z=-3.60$ respectively, based on positive ranks). The required *time to finish the EndoBubble task* differed significantly ($p \leq .001$) between run 1 and run 2, and between run 2 and run 3 ($Z=-4.64$, and $Z=-3.63$ respectively, based on positive ranks). The performance of the novices in the first and fourth run of the VR colonoscopy I-3 differed significantly for all simulator parameters.

Performance of the experts

At first sight, the performance of the experts appear to differ over the four runs (see Figure 4.4). However, Friedman's ANOVA test shows that they did not differ significantly over the four runs, except for the *percentage of time the patient was in excessive pain*. The Wilcoxon Signed Ranks test did not reveal a significant difference between their

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[#] The (estimated) percentage of time the patient was in excessive pain is calculated by the simulator using several pain related parameters:

$$PL = 0.1*ELP + .04*AC + 0.7*LR^2 \quad \text{(equation 1)}$$

$PL < 0.6 : EP = EP$,

$PL \geq 0.6 : EP = EP + 1$,

after each $t=15$ sec $PL \geq 0.6 : EP = EP + 1$

When the pain level (PL) is above the value 0.6, excessive pain (EP) is recorded. If the excessive pain remains for another 15 seconds excessive pain is recorded again. Excessive local pressure (ELP) is calculated when the tip of the endoscope is pushed into the colon's wall to a depth of 1.5-2cm for more than 2 seconds. The amount of air in the colon (AC) is a value from 0 to 1 (0 meaning no air and 1 meaning the colon is full of air). The loop rate (LR) is a value between 0 and 1 (0 when the colon is totally relaxed, and 1 when the colon is extremely tensed). Percentage of time patient was in pain (P_tEP) is calculated by the time the patient was in excessive pain (EP_t) divided by the total procedural time (TP_t), see equation 2.

$$P_tEP = EP_t / TP_t \quad \text{(equation 2)}$$

Table 4.4. Performance novice participants for EB L1 task and VRC I-3 per session.

		EB L1		VRC I-3					
session		*time to finish task (min)*	*number of wall collisions*	*time to reach cecum (min)*	*% of time patient in pain*	*% of time clear view*	*lost view of lumen*	*excessive local pressure*	*total time colon looped (min)*
1	mean	6.9	1.3	30.6	2.5	87.0	3.1	3.9	1.1
	median	5.6	.5	23.2	0	88.0	2.5	3.5	.1
	min-max	2.9-20.4	0-7	8.1-88.3	0-24	72-96	1-12	1-14	0-7.4
2	mean	3.7	.6	16.0	.3	87.2	2.8	3.3	.1
	median	3.5	0	12.5	0	88.0	2.0	3.0	0
	min-max	2.1-7.5	0-7	5.8-50.3	0-4	74-96	0-13	1-13	0-1.0
3	mean	3.0	.5	9.9	.1	89.9	1.3	3.6	0
	median	2.7	0	7.5	0	90.5	1.0	2.0	0
	min-max	1.3-6.1	0-7	3.4-30.2	0-3	77-99	0-5	0-41	0-.8
4	mean	2.7	.5	7.1	0	91.3	1.0	2.0	0
	median	2.3	0	6.4	0	91.0	1.0	2.0	0
	min-max	1.3-5.3	0-3	3.5-15.8	0	83-98	0-4	0-6	0-0

Table 4.5. Performances of experienced and expert endoscopists and comparison with performance of novice participants (Mann-Whitney U test, one-tailed, Exact significance) (ns = not significant).

			EB L1		VRC I-3					
			time to finish task (min)	*number of wall collisions*	*time to reach cecum (min)*	*% of time patient in pain*	*% of time spent with clear view*	*lost view of lumen*	*excessive local pressure*	*total time colon looped (min)*
Experienced endoscopists		mean	1.6	0.9	4.3	1.0	90.5	0.6	1.9	0.1
		median	1.4	0.0	3.8	0.0	91.0	0.0	1.0	0.0
		min-max	0.7-5.6	0-9	2.5-7.0	0-4	73-99	0-3	0-8	0.0-0.5
Expert endoscopists		mean	1.4	0.3	4.9	2.0	88.5	1.0	1.8	0.2
		median	1.2	0.0	4.0	1.0	89.5	1.0	2.0	0.1
		min-max	.8-3.4	0-2	1.6-17.8	0-10	68-99	0-4	0-8	0.0-1.4
novices – experienced	session 1	Z	-5.7	ns	-5.9	ns	-2.0	-5.2	-3.8	ns
		sign.	.000		.000		.022	.000	.000	
	session 2	Z	-5.3	ns	-5.8	-1.9	-1.7	-4.4	-3.0	ns
		sign.	.000		.000	.031	.044	.000	.001	
	session 3	Z	-4.5	ns	-4.7	-2.9	ns	-2.0	ns	-2.6
		sign.	.000		.000	.003		.024		.005
	session 4	Z	-4.2	ns	-4.0	-3.4	ns	-1.8	ns	-4.5
		sign.	.000		.000	.001		.036		.000
novices – experts	session 1	Z	-7.1	-2.9	-7.0	ns	ns	-5.3	-4.6	ns
		sign.	.000	.002	.000			.000	.000	
	session 2	Z	-6.9	ns	-6.3	-3.4	ns	-4.4	-3.5	-3.2
		sign.	.000		.000	.000		.000	.000	.001
	session 3	Z	-6.2	ns	-5.2	-4.3	ns	ns	ns	-4.0
		sign.	.000		.000	.000				.000
	session 4	Z	-5.8	ns	-3.6	-4.8	ns	ns	ns	-5.5
		sign.	.000		.000	.000				.000

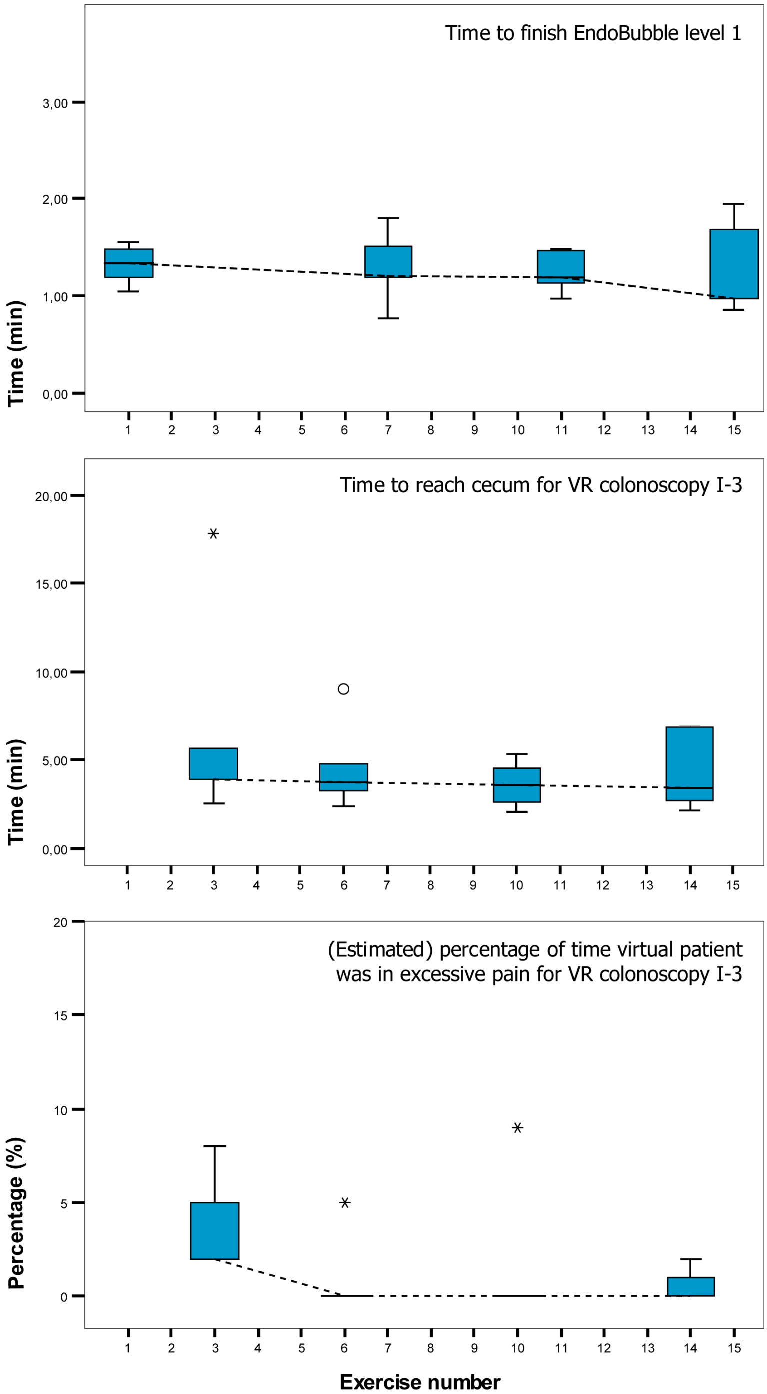

Figure 4.4. Boxplots of performance parameters for repetitive exercises EB L1 task and VRC I-3 for expert (N=5) participants. The line depicts the median performance curve of the group.

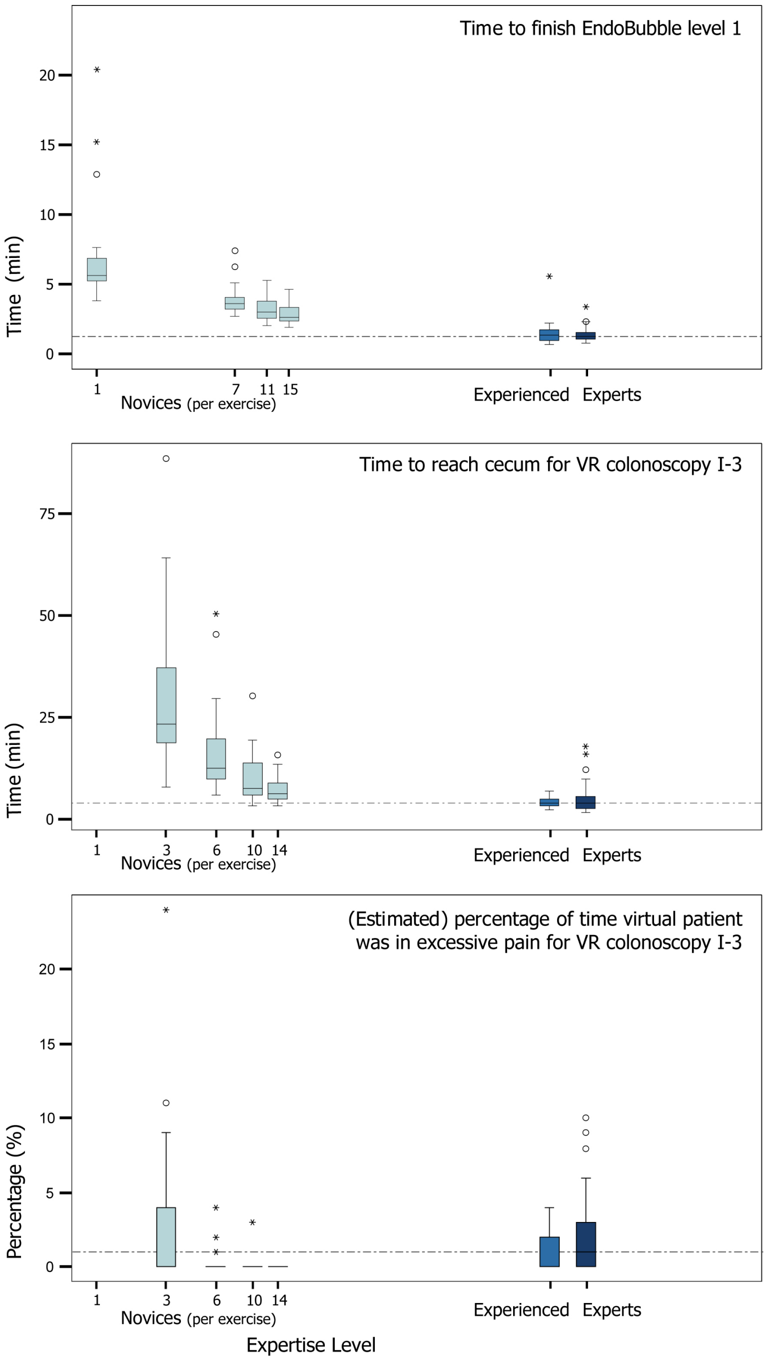

Figure 4.5. Boxplots of performance novice participants (N=30) in comparison to performance of experienced (N=20) and expert endoscopists (N=40) for time to accomplish EB L1 task and VRC I-3 and the percentage of time the virtual patient was in excessive pain. Expertise level is represented by performed exercises or colonoscopy procedures along a logarithmic scale. The reference line represents the median for experienced and expert performances.

performances over the four consecutive runs either, except for the *percentage of time the patient was in excessive pain* in VR colonoscopy I-3 between the first and the fourth run.

Performance of the novices compared with that of the experienced and expert endoscopists

The performance of novice participants in the first run and both experienced and expert endoscopists differed significantly on several parameters (see Table 4.5 and Figure 4.5). For VR colonoscopy I-3, the performance of the novices in the first run differed significantly from those of experienced and expert endoscopists for the *time to reach the cecum*, *occurrence of loss of view of lumen*, and *occurrence of excessive local pressure*. Additionally, the novices' performance in the first run differed from those of experienced endoscopists for *time spent with clear view*. For the EndoBubble level 1 task, the novices required a significantly longer *time to finish the task* than both experienced and expert endoscopists, and caused a higher *number of wall collisions* than expert endoscopists.

Discussion

VR simulators are becoming a popular tool for training in endoscopy skills and could provide medical educators with a tool for objective proficiency assessment and an effective alternative for clinical training[86, 140, 147]. First, the use of simulators in skills-lab oriented training programmes could reduce patient discomfort and increase patient safety[86, 140, 147, 152]. Second, it could reduce workload and costs involved in experts supervising endoscopy trainees[61, 86, 140], thus improving the efficacy of the learning process. However, the construct of VR simulators and their role within training programmes are still being studied.

Our previous validation study showed that, for basic endoscope navigation, the GI Mentor II can differentiate between several levels of expertise. The GI Mentor II was also considered a valuable addition to the training programme of novice endoscopists[92]. Other studies have also established face validity and construct validity of the GI Mentor[52, 53, 64, 139]. So far, few studies have investigated learning of lower GI endoscopy skills when using the GI Mentor[50, 53, 139]. The designs of these earlier studies varied considerably in regard to the focus, tasks included, and sample size. The studies also varied considerably in training time span, type of training, and amount of training. Even though it is difficult to compare, the results encountered in our study appear to be consistent with those studies[50, 53, 139].

It is important to establish validity for all aspects of the simulator and to assess the training potential of simulators for all available training modules. It is imperative, however, to start by assessing the simulator for basic skills, in this case being the ability to navigate through the colon to the cecum. The first attribute a trainee in flexible endoscopy has to adapt to is the counter-intuitive navigation. In our study, the participants were given the assignment to reach the cecum as quickly as possible with minimal patient discomfort for the VR colonoscopies. For the EndoBubble tasks, the assignment was to pop twenty balloons as quickly as possible, while avoiding wall collisions. Assessing procedure related skills and abilities, like identification of pathologies, were intentionally not included. As the focus was on endoscope navigation, the endpoint for the VR colonoscopy exercises was reaching the cecum. For this reason, the parameters on *percentage of inspected mucosa* and *accuracy* and *efficiency of screening* were excluded.

The consistent and organised nature of the training sessions and exercises within a set time-span created a constructive environment to assess proficiency improvement: per subject, within expertise groups, and between them. It is important to minimise the influence of unfamiliarity with the simulator, or familiarity with specific cases, by using a variety of cases in each training session. After the final training session, when some of the novice participants were informed about the repetitive nature of VR colonoscopy I-3, they stated to have been unaware of this.

Performance of the novices

All participants improved their performance significantly over the course of four training sessions, in particular for the key parameters assessed in this study: *time to accomplish* the exercises, and *percentage of time the patient was in excessive pain.* Novices also improved their performance considerably in relation to other parameters associated with ease of navigation through the colon (like *percentage of time with clear view* and *loss of view of lumen*) and the pain level during the procedure (like *excessive local pressure* and *total loop time*) (see Table 4.4). This agrees with earlier studies on learning of tasks related to lower endoscopy on the GI Mentor[50, 53, 139].

The performance improvement of the trainees indicates that the difficulties often experienced by novice endoscopists when navigating through the colon with a flexible endoscope can be considerably reduced by training on the GI Mentor II. The novices appeared to be able to learn how to cope with these difficulties. As in occasions when progression of the endoscope image halted due to loop formation for example, they learned the counter-intuitive response of pulling back the endoscope shaft to progress further into the colon, most likely by trial-and-error. The considerable decrease of the pain-related parameters could entail that they also gained understanding of the factors and actions that cause pain or discomfort for the patient during flexible endoscopy. This disagrees with results of studies by Mahmood and Darzi[113], and Datta et al.[46]. The larger number of exercises, combination of different types of exercises, or influence of knowledge of results could contribute to this difference.

Performance of the experts

The possibility that performance improves by learning tricks that work well on the simulator, but do not necessarily improve real-life colonoscopy performance, should be taken into account when studying learning of tasks on VR systems. To verify that the GI Mentor II is not just an expensive computer game, five expert endoscopists performed the same training sessions as well. The performance of expert endoscopists show a relatively flat profile, which demonstrates that they are on the plateau of the proficiency curve according to the GI Mentor II performance parameters (see Figure 4.4). In addition, the performance of the experts over the four runs is not significantly different, except for the parameter on excessive pain. This indicates that the construct of the simulator provides a valid training tool for basic endoscope navigation for colonoscopy and supports validation studies based on the GI Mentor's capability to distinguish expertise levels[50, 52, 53, 64, 92, 139].

Performance of the novices compared with that of the experienced and expert endoscopists

The simulator is able to distinguish between performance of novices and both experienced and expert endoscopists. However, our validation study showed that the differences between the performance of experienced and expert endoscopists on the GI Mentor II simulator are not significant[92]. In the current study, the difference between the performance of novices and experienced and expert endoscopists reduced considerably after training on the GI Mentor II, as the performance of the novices improved over the four runs. The values in Table 4.5 show a reduction of the difference with most of the performance parameters for both experienced and expert endoscopists, except for the *percentage of time the patient was in excessive pain,* and *total time colon was looped*. For most parameters, and in particular for the *time to accomplish* the repetitive exercises, the difference remains significant over all four runs. The *percentage of time the patient was in excessive pain* and *total time colon was looped* in Table 4.5 show an increase of the difference instead. The novices appear to perform increasingly better on these aspects over the four runs in comparison to the experienced and expert endoscopists (see Table 4.4 and Table 4.5). The mean ranks of the Mann-Whitney U test are lower for the novices than for the experts and experienced endoscopists, except between the novices in the first run and the experienced endoscopists. The sum of ranks was lower for novices as well, compared with the experts. Hesitancy in progression of the endoscope in combination with vigilance to cause excessive pain could play a role in the relatively low *(estimated) percentage of time the patient was in excessive pain* during the performance of VR colonoscopies I-3 by the novice participants. The *total time colon was looped* is a strong factor in the equation used to calculate the composite parameter *(estimated) percentage of time the patient was in excessive pain*, and even though the procedure time shortens significantly by run four, the absolute amount of time the patient experienced excessive pain could still be increased in comparison to the pain levels in the performance of experienced and expert endoscopists.

The performance curves of the novices appeared not to have reached a plateau within four sessions, or fifteen exercises. Even though this study does provide insight into the first part of the proficiency curve for endoscope navigation by training on the GI Mentor II, it does not provide insight into the value of the GI Mentor II for training in complete colonoscopies, which also includes inspection of mucosa or performance of therapeutic interventions. This justifies the need for further studies on the potential of the GI Mentor II for assessment of and training in flexible endoscopy, studies more longitudinal by nature, and involving more complex tasks. Transfer of skills acquired on the simulator to the performance of real-life clinical colonoscopy should be studied as well.

Conclusions

This study confirms the GI Mentor II is a valid tool for training of basic flexible endoscopy navigation skills for colonoscopy. The large sample and the strong focus on basic skills sets this study apart from earlier studies. The data provided is consistent with earlier studies on this topic, even though one-to-one comparison is difficult due to differences in study designs.

In addition, this study proves that combined training in both VR colonoscopies and the EndoBubble task on the simulator has a significant effect on the performance of novice endoscopists. The results provide additional insight into and increase the knowledge about the proficiency curve for flexible endoscope navigation when training on the GI Mentor II.

Acknowledgments

The authors thank all the participants for their engagement in this study. They also thank Cees Schot for his technical support and Sören Johnson for his linguistic advice.

Chapter 5.

Do basic psychomotor skills transfer between different image-based procedures?

Achieving proficiency in image-based procedures (IBP) requires a great deal of training. Part of this training can be performed using simulation systems, as is discussed in chapters 3 and 4. This chapter explores the cross-over of skills for novice endoscopists training on virtual reality simulators in two different types of IBP; laparoscopy and colonoscopy. Does experience in laparoscopy influence the performance of basic colonoscopic tasks (and vice versa)?

Introduction[*]

In recent years, the performance of medical procedures has become increasingly more technology driven and technology dependent and a substantial amount of procedures is now performed image-based[73, 145]. Image-based procedures (IBP) involve all types of medical procedures that enable therapeutic intervention by minimal access while the physician intra-operatively perceives the operating area in real-time, though indirectly, through the use of imaging equipment, such as in laparoscopy. In comparison to traditional open procedures, IBP necessitate additional skills. Extensive training is needed to achieve the required proficiency level, of which a great deal focuses on the interaction with the IBP interface[14, 136, 144, 168]. Besides the visual information presented on the display and additional IBP-dedicated equipment, the interface also includes the control of the tools to perform the procedure. In most IBP, the hand-eye coordination of the instruments is counterintuitive and involves considerable visuomotor translations; in addition, the physician often has to deal with a two-dimensional representation on the display of the three-dimensional operating field[14, 73, 136]. IBP are relatively novel procedures and much still needs to be learned about the human factors of the interaction,

[*] Published as: Buzink SN; Goossens RHM; Schoon EJ; de Ridder H; Jakimowicz JJ (2010) *Do basic psychomotor skills transfer between different image-based procedures?* World Journal of Surgery 34: 933-940.

additionally required skills, training, and proficiency assessment for the already well-established IBP types, such as laparoscopy and flexible endoscopic intraluminal interventions[48, 58, 156, 168]. Simultaneously, due to technological innovations the field of IBP also develops further making it possible to perform increasingly complex procedures image-based. So far, most studies focused on the performance of a particular technique or task for the well-established IBP types. On a higher level of skills acquisition, little is known about IBP skills in general and the relation between type-specific skills for different IBP.

Proper insight in the fundamental aspects of performing IBP is indispensable to develop training programmes, proficiency assessment tools, and trainee selection criteria. Nowadays, flexible endoscopic intraluminal interventions, such as colonoscopy, as well as laparoscopic operations are widespread procedures. Training of basic skills for both types of procedures can well be done preclinical on virtual reality (VR) simulators[24-26, 48, 156]. Colonoscopy and laparoscopy are two IBP that have elements in common, such as the use of video as imaging technique. On other elements however, they differ considerably such as the hand-eye coordination and visuomotor translation to manipulate the camera and surgical instruments. Gastrointestinal surgeons are often accustomed to perform both laparoscopy and colonoscopy and the existing assumption is that experience in one of those techniques is of considerable benefit when learning the other[121, 123, 186]. However, the relation between laparoscopy and flexible intraluminal endoscopy skills has hardly been studied. So far, Adamsen et al. published the only comparative study on these skills [2]. They found a positive correlation between basic skills observed in simulated laparoscopy and basic skills observed in simulated flexible gastrointestinal endoscopy. With the advent of operation techniques that draw from both laparoscopy and flexible intraluminal endoscopy, such as Natural Orifice Transluminal Endoscopic Surgery (NOTES), the lack of knowledge on the relation between skills on these techniques becomes even more apparent[6, 123, 129].

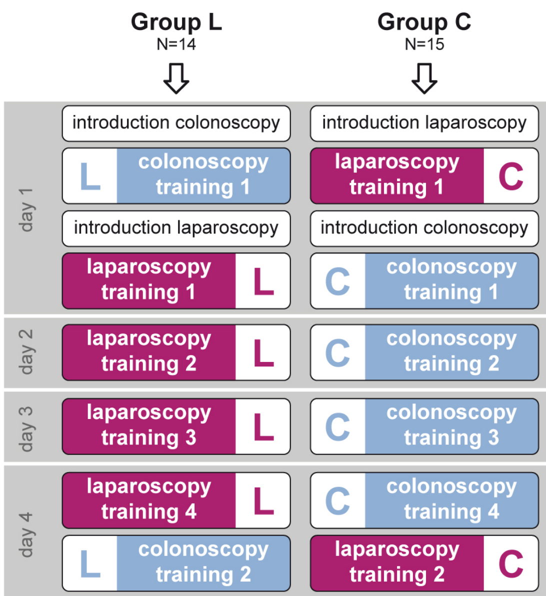

Figure 5.1 The study protocol.

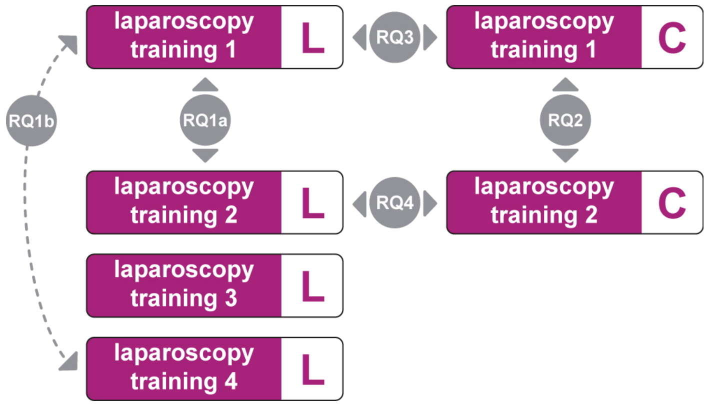

Figure 5.2 Overview of the research questions (RQ) comparing the performances on the laparoscopy tasks. (for the RQ comparing the performances on the colonoscopy tasks, replace laparoscopy by colonoscopy)

Table 5.1 Overview of the research questions and performance comparisons from the perspective of the laparoscopy tasks (for the colonoscopy tasks replace laparoscopy by colonoscopy and colonoscopy by laparoscopy).

Research Question		*compared performance scores*
RQ 1a.	Does the performance of basic laparoscopy tasks improve over the course of two laparoscopy training sessions?	Within group L: Laparoscopy training sessions 1 - 2
RQ 1b.	Does the performance of basic laparoscopy tasks improve over the course of four laparoscopy training sessions?	Within group L: Laparoscopy training sessions 1 - 2 - 3 - 4
RQ 2.	Does the performance of basic laparoscopy tasks improve over the course of two laparoscopy training sessions?	Within group C: Laparoscopy training sessions 1 - 2
RQ 3.	Does one colonoscopy training session influence the performance on basic laparoscopy tasks?	Laparoscopy training session 1 group C versus Laparoscopy training session 1 group L
RQ 4.	Do three additional colonoscopy training sessions influence the performance in a second laparoscopy training session?	Laparoscopy training session 2 group C versus Laparoscopy training session 2 group L

The aim of this study was to explore the influence of training in basic psychomotor skills for colonoscopy on the performance of basic laparoscopy tasks, and the influence of training in basic psychomotor skills for laparoscopy on the performance of basic colonoscopy tasks. For this purpose two groups of medical trainees were trained in either basic colonoscopy or basic laparoscopy tasks following a cross-over study design. After the first and fourth training sessions for each technique the influence of the colonoscopy training on their laparoscopy performance and the influence of the laparoscopy training on their colonoscopy performance were assessed (Figure 5.1). In addition, the progression in performance within each group over the course of the training programme on both image-based techniques was analysed. Thus, the first research question was: does the performance of basic IBP tasks improve within two (RQ1a) and four (RQ1b) training sessions by training on a dedicated simulator for that image-based technique (Figure 5.2 and Table 1)? And, does the performance of basic IBP tasks improve within two training sessions (RQ2) by training on a dedicated simulator for that image-based technique, while in-between performing four training session in another IBP technique? Next, by comparing the performances of the two groups with a different training history (one group with and the other group without additional training in the other image-based technique), the transfer of skills between these two image-based techniques was investigated. Does training in basic laparoscopy skills affect the performance on basic colonoscopy tasks? And, vice versa, does training in basic colonoscopy tasks affect the performance on basic laparoscopy tasks? For example, does the interaction between these skills result in a significant difference in laparoscopy performance after one colonoscopy training session (RQ3)? And what is the difference in colonoscopy performance after three additional laparoscopy training sessions (RQ4)?

Materials and methods

To enhance the clarity of the article we present the methods from the perspective of the influence of colonoscopy training on the performance of basic laparoscopy task. However, as described above, we also investigated the transfer of skills in the opposite direction. By adding the phrase ‘and vice versa’ we refer to the transfer of skills from laparoscopy training to colonoscopy performance.

In this study, twenty-nine medical trainees with no clinical experience in colonoscopy and laparoscopy took part (Figure 5.1). The participants received information about the nature of the study and the activities involved and they filled out an informed consent form. The participants were stratified by their overall performance on psychometric ability tests and then randomly allotted to one of two groups for the simulator training: group L (N=14) or group C (N=15). During the simulator training sessions the participants trained in manipulation of the flexible endoscope and navigation to the cecum on the Simbionix GI Mentor II VR simulator (software version 2.7.4.0, Simbionix Corporation, Cleveland, USA) (colonoscopy training) and in bimanual tissue manipulation and 30 degree angled laparoscope navigation on the SimSurgery SEP VR simulator (SimSurgery AS, Norway) (laparoscopy training).

Colonoscopy Training

The GI Mentor II VR simulator provides different modules for training in basic flexible endoscopy skills, and lower and upper endoscopy procedures. In this study, the EndoBubble Level 1 (EB L1) task and case 3 of VR Colonoscopy Module I (VRC I-3) were performed in each session. To avoid bias, each of the training sessions also involved performance on multiple different VR Colonoscopy cases and the participants were not notified about the repetitive nature of VRC I-3. The number and order of the colonoscopy training tasks were adopted from the training programme used in the study by Buzink et al. [24]. The assignment given to the participants was to perform the EB L1 task as accurate and quick as possible. The assignment for the VRC cases was to visualise the cecum as quick as possible, with as little patient discomfort as possible. When the participant reached the cecum, the VRC task was considered accomplished. Participants were instructed not to identify or treat the pathologies presented in the cases. All participants performed the colonoscopy tasks single-handed, without nurse-assistance for scope insertion. After each task, the simulator presents the scores and statistics on the performance. In this study the scores that were used to analyse performance on the VRC I-3 tasks were: *time to accomplish the task*, the *percentage of time the virtual patient was in* *excessive pain,* and the *percentage of time spent with clear view*. For the EB L1 task the *time to accomplish the task, number of balloon popped,* and the *number of wall collisions* were used.

Laparoscopy Training

For the laparoscopy tasks, the SEP simulation software (SimSurgery AS, Norway) was used, which includes a range of tasks in a VR environment to train different laparoscopy skills. The tasks used in this study were the Camera Navigation (CN) task with a 30 degree angled laparoscope and the Place Arrow (PA) task, which represents a bimanual tissue manipulation task. The structure of the laparoscopy training was based on the training programme used in the study by Buzink et al.[26]. The assignment given to the participants was to perform each task as accurate and quick as possible. The software provides the scores and a graphical representation of the performance after each task. To analyse the performance of the trainees, their scores on *time to accomplish task* and the *total tip trajectory* of the instruments were used together with the number of *lost (over stretched) arrows* (PA task) and the number of times the *target was lost out of view* (CN task). To analyse and compare the performances during the laparoscopy training, the last repetition in every session of the CN task and PA task were used as representative. The SEP software was used in combination with a Xitact/Mentice IHP hardware platform (Mentice AB/Xitact SA, Morges, Switzerland), because the look and feel of the camera tool was considered to resemble the handling of a laparoscope more closely. Although the Xitact/Mentice IHP hardware platform can provide force feedback, the tasks used in this study do not require such feedback. The settings of the instrument trocars were therefore set to compensate for the additional required effort for inserting the instruments in the trocars.

Protocol

The training consisted of six simulator training sessions within one week (Figure 5.1). Prior to the first training session, the participants filled out a questionnaire about demographics and their general medical and endoscopy experience. The participants received a standardised introduction to familiarise them with the techniques, simulators, and tasks in preparation of the training sessions. During the introduction it was clearly stated that the researchers were not affiliated with the manufacturers of the simulators and that all data would be analysed anonymously. On the first test day group C started with one laparoscopy training session to assess baseline laparoscopy performance, followed by one colonoscopy training session. Within the following six days, they performed three more colonoscopy training sessions and afterwards a second laparoscopy training session. On the first day, group L started with a colonoscopy training session and subsequently one laparoscopy training session. Within the subsequent six days this was followed by three more laparoscopy training sessions and finally a second colonoscopy training session. No feedback on performance was given other than produced by the simulators during or after the tasks. Questions related to the use of the tools were answered, whenever asked during the training programme, but no instructions were given on how to optimise performance.

Data Analysis

We compared the performances in the training sessions within and between the groups using SPSS 16.0 software (SPSS Inc., Chicago, USA) (Figure 5.2, Table 1). Using one-way repeated measures MANOVA and ANOVA tests we assessed the performance improvement on each task within group L and within group C between session 1 and session 2 (RQ1a and RQ2) and over the course of 4 training sessions (RQ1b). Separate one-way MANOVA and ANOVA tests were done to analyse the differences in performance between group L and group C in their first training sessions (RQ3) and their second training sessions (RQ4) on each task. To minimize the bias of extreme outliers on the comparison of means, we excluded the performances with a z-score larger than 3,29. To reduce the probability of failing to identify a genuine effect (a type II error) a *p*-value ≤ .05 was considered statistically significant, while a *p*-value between .05 and .07 indicates a considerable tendency of the results.

Results

Performance Improvement within Each Group

Overall, the performances within both groups on the simulator tasks improved considerably after two and four training sessions compared to the baseline performance in the first training session (Figure 5.3 and Figure 5.4). Between the first and second training session in each IBP techniques, the MANOVA tests for group C showed a significant improvement in performance on the PA task and the EB L1 task. For group L the MANOVA tests showed a significant improvement in performance on the PA task, VRC task, and the EB L1 task between the first and second training session in both IBP techniques. Over four simulator training sessions the performance of group C on the EB L1 task improved significantly, while a considerable tendency was found for group L on their performance of the CN task over four sessions.

The ANOVA tests showed that group C performed the CN task and the PA task in laparoscopy session 2 in significantly less *time* than in laparoscopy session 1 and a considerable tendency was found for the *total tip trajectory* (*p*=.061) for the CN task. They performed the EB L1 task in both colonoscopy session 2 and over the course of four colonoscopy sessions in significantly less *time* and with fewer *wall collisions* than in colonoscopy session 1. In colonoscopy session 2 group C performed the VRC I-3 task with a lower *percentage of time the virtual patient was in excessive pain* than in session 1. Over four colonoscopy sessions, they required less *time* to perform the VRC I-3 task and did so also with a lower *percentage of time the virtual patient was in excessive pain* compared to colonoscopy session 1. Group L performed the PA task in both laparoscopy session 2 and over four laparoscopy sessions in significant less *time*, with a shorter *total tip trajectory* than in laparoscopy session 1. In addition, a considerable tendency was found for the number of *lost arrows* (*p*=.064) in laparoscopy session 2 compared to session 1. On the CN task group L did not improve their performance between session 1 and session 2, but over the four laparoscopy sessions they did perform the CN task in significantly less *time*, with a shorter *total tip trajectory* and with fewer *targets lost out of view*. In colonoscopy session 2, group L performed the EB L1 task and VRC I-3 task in significantly less *time* than in colonoscopy session 1.

Influence Colonoscopy Training on Performance of Laparoscopy Tasks

To assess whether colonoscopy training has an influence on the performance of basic laparoscopy tasks, the performances of group L were compared with the performances of group C for laparoscopy session 1 and laparoscopy session 2 (Figure 5.3). The MANOVA tests showed a significant difference in performance in the second laparoscopy training session on the CN task between group L and group C. This holds for the *total tip trajectory*

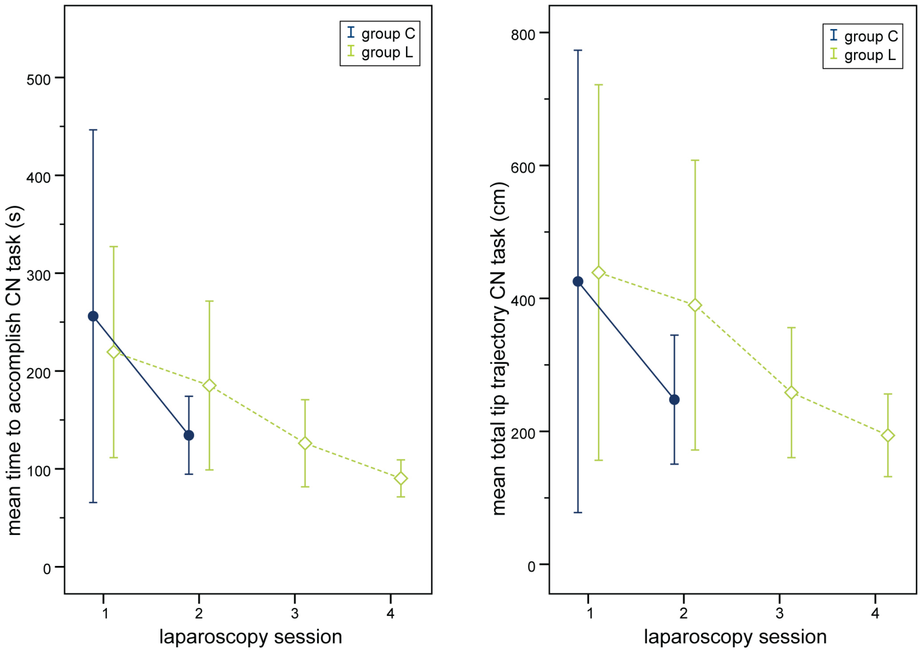

Figure 5.3 Means and standard deviations for the CN task.

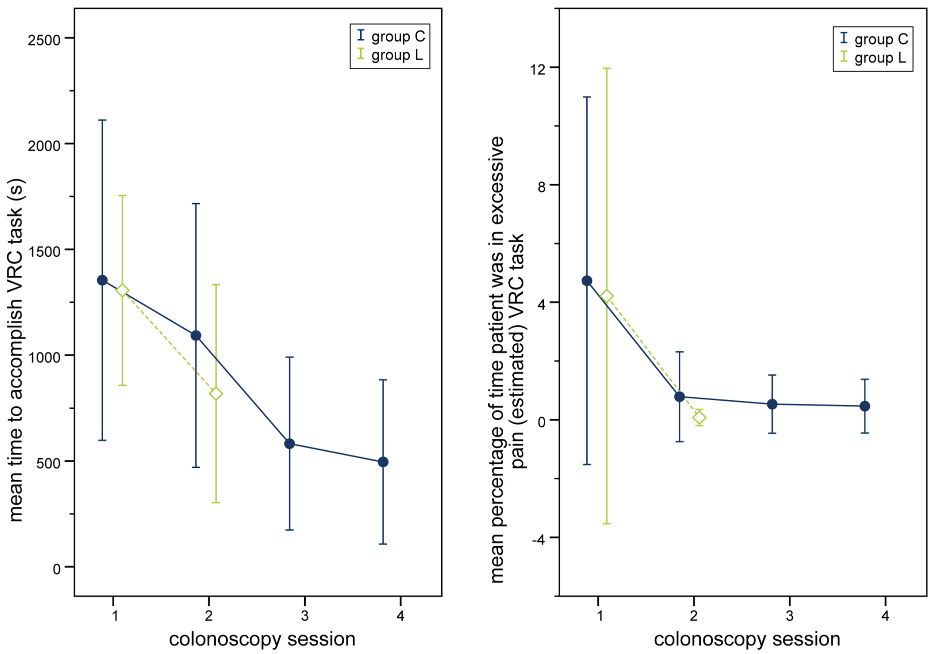

Figure 5.4 Means and standard deviations for the VRC task.

of the CN task whereas a considerable tendency was found for the *time to accomplish* the CN task (*p*=.051); group C performed the CN task better than group L. No significant differences or considerable tendencies were found between the performances of the two groups for the PA task in laparoscopy session 2.

Influence Laparoscopy Training on Performance of Colonoscopy Tasks

To assess whether laparoscopy training has an influence on the performance of basic colonoscopy tasks, the performances of group L were compared with the performances of group C for colonoscopy session 1 and colonoscopy session 2. No significant differences were found in the first and second colonoscopy sessions between the performances of group L and group C over all performance scores (MANOVA) or the separate scores (ANOVA) (Figure 5.4). Similarly, no significant differences or considerable tendencies were found between the performances on the EB L1 task or the VRC I-3 task by group C and group L in their first colonoscopy session. The same holds for the comparison between the performances of the two groups on the EB L1 task and the VRC I-3 task in colonoscopy session 2.

Discussion

Laparoscopy and colonoscopy are two commonly practised image-based procedures, of which the basic skills can be well trained preclinical on VR simulators[24, 26, 48, 156]. Current trends and novelties in technology and surgical techniques, such as NOTES, increase the need for transfer of knowledge and skills amongst specialists in both techniques[6, 123, 129]. However, knowledge on the interaction between the dedicated skills for these two image-based surgical techniques is limited. We therefore explored the influence of colonoscopy training on the performance of basic laparoscopy tasks (and vice versa) by comparing the laparoscopy performances of a group of inexperienced endoscopists who had prior training in colonoscopy with the performances of a group of inexperienced endoscopists without this experience (and vice versa).

First of all, we needed to verify whether the two groups improved over the course of the simulator training for both techniques (RQ1 and RQ2). By practise on the GI Mentor and SimSurgery SEP simulators, task specific skills improved considerably within four training sessions. The range also decreased over the course of the training sessions. These findings match with previously published similar studies: medical trainees with no laparoscopy or flexible endoscopy experience improved their task performance considerably over the course of a VR simulator-based training programme[24-26, 50, 53]. In addition, this study shows that four in-between training sessions in another image-based technique do not impinge on this effect.

The third research question relates to the influence of one colonoscopy training session on the performance on basic laparoscopy tasks (and vice versa) (RQ3 in Table 1). To this end, the performances of group L in their first laparoscopy training session (after performing one colonoscopy training session) were compared with the performances of group C in their first laparoscopy training session (without any colonoscopy experience)(and vice versa) (Figure 5.2). The results showed similar scores for group C and group L on both the laparoscopy tasks and the colonoscopy tasks, no notable differences in performance were found. By comparing the performances of the group C and group L in their second training session, the influence of colonoscopy training on the performances of basic laparoscopy tasks (and vice versa) was assessed (RQ4 in Table 1). In the applied cross-over study design the only difference between group L and group C in their second laparoscopy training session is the amount of additional training on basic colonoscopy tasks (and vice versa) they have had prior to their second laparoscopy training session (Figure 5.2). The ANOVA test showed that in the second laparoscopy training session, the performances of group C on the CN task just surpassed the performances of group L (Figure 5.3). No notable differences were found between the groups for the PA task in their second laparoscopy training session or for the EB L1 task and VRC I-3 task in their second colonoscopy training session (Figure 5.4). These results imply that training in basic laparoscopy skills does not affect the performance of basic colonoscopy tasks. And training in basic colonoscopy skills appears to have, to a limited extent, a positive influence on the performance of a basic angled laparoscope navigation task. Skills are certainly not directly interchangeable between these two IBP types. Experience in basic colonoscopy tasks does not imply better performance of basic laparoscopy tasks, and experience in basic laparoscopy tasks does not mean superior performance of basic colonoscopy tasks.

This study was set up to explore the existing assumption that when learning a new IBP technique, it is advantageous to have experience in another IBP technique. Our findings do not corroborate this assumption, it is important to note that the results also show that training in colonoscopy do not negatively affect performance of basic laparoscopy tasks (and vice versa) either. Several studies previously investigated the clinical performance of general surgeons and colorectal surgeons on flexible endoscopic intraluminal interventions, and colonoscopy in particular, in comparison to gastroenterologists[121, 186]. Most studies were retrospective and focused on clinical outcomes, such as intubation rate and complications. These studies confirmed that it is the amount of training and experience of the individual physician that predicts the safety, efficacy, and outcome of colonoscopy, and not the specialism of the physician or surgeon[121, 186]. To the best of our knowledge there are no studies that likewise compared the clinical performance of gastroenterologists in laparoscopy in comparison to surgeons. Nevertheless, in some countries gastroenterologists perform diagnostic laparoscopic procedures [2]. The study by Adamsen et al. (2005) presented a positive correlation between performances on a VR colonoscopy simulator and a VR laparoscopy simulator. Unfortunately, due to several major differences in the set-up of this study with the study presented here, a comparison of results is not possible. Adamsen et al. included 24 participants in total with different levels of expertise in either colonoscopy, laparoscopy, or in both, but did not distinguish between the background and expertise of the participants.

To fulfil the generally shared desire for objective proficiency assessment and to accomplish a shift towards more criterion-based training, a better understanding of IBP related skills and the interrelation of these skills is indispensable[86, 140]. The growing number of procedures that is prevalently performed image-based and the rise of IBP with increasing technical complexity, such as in NOTES, emphasize the need for knowledge on IBP skills and proficiency assessment even further[6, 86, 123]. Better understanding and more objective assessment of IBP skills is essential for the development of more effective training programmes, which can take the overall IBP proficiency level and individual training needs of the trainee into account.

The set-up of this study also had some limitations. Several participants remarked on their own accord that they experienced the VRC I-3 task and the CN task as being harder work than the EB L1 task and the PA task. The increased challenge on the VRC task and the CN task might have contributed to a stronger learning effect for these particular tasks[8], in comparison to the EB L1 task and the PA task. The study was rather complex and timeconsuming for the participating medical trainees; this impeded the inclusion of large numbers of participants within the available time-frame. With a total sample size of 29 participants the post-hoc power for the between group comparisons was 0,66, which is close to the aimed power of 0,7. In the analysis we applied a correction with the aim to minimize the probability of falsely not identifying a genuine effect (Type II error). Such a correction brings about an increase of the probability of a Type I error (falsely identifying an effect); however, in view of the exploratory aim of this study this is acceptable. The size of the effect could also be smaller than assumed for the analysis based on previous studies, requiring inclusion of a substantially larger group of participants to be detected. However, if the effect of the interaction of skills between different types of IBP would indeed be small to medium for inexperienced endoscopists, this would not affect our conclusions.

Conclusions

This study shows that training in basic colonoscopy tasks does not affect performance of basic laparoscopy tasks (and vice versa). A minor transfer of basic psychomotor skills was found from training of basic colonoscopy skills to the performance of basic laparoscopy tasks, but only for angled laparoscope navigation. Thus, skills required to perform basic laparoscopy and colonoscopy tasks are not directly interchangeable. Training and assessment of IBP-type-specific skills should therefore focus on each type of tasks independently. The minor difference in performance was found for the CN task, which involves complex spatial navigation. The influence of separate psychometric abilities on the performance of image-based procedures and the transferability of skills between different types of IBP therefore needs to be studied further. Future research should also increase the knowledge on the transfer of skills for physicians that are experienced in one IBP type and would like to become proficient in another type of IBP.

Acknowledgments

The authors are grateful to all participants for their engagement in this study, as well as to SimSurgery, Xitact/Mentice, and Simbionix for providing equipment support, and Cees Schot and Guy van Dael (Catharina Hospital Eindhoven) for technical and audiovisual support. In addition, they thank Sanne Botden and Jeroen Heemskerk (Catharina Hospital Eindhoven) for support in carrying out the simulator training, and Ruth Mugge (Delft University of Technology) for providing statistical advice. Finally, the authors thank the anonymous reviewers of the journal for their extensive and very valuable comments on the manuscript.

Chapter 6.

Enhancing the efficacy of training and assessment using simulation

The field of image-based procedures (IBP) is still a relatively new field of research and a lot is still to be learned about training of IBP related skills. The application of simulators to train and assess these skills is still evolving, and so are the simulator tools. In this chapter several aspects of the simulator interface are explored that could influence the efficacy of training and assessment of laparoscopic skills. The investigations presented in chapter 3 provided some input for this chapter. This chapter will provide valuable insights for designers and educationalists for the development of simulators and curricula for training and assessment of IBP skills.

6.1 The influence of visual virtual environment on simulated laparoscope navigation [*]

Extensive training is needed to acquire proficiency in image-based surgery, such as for laparoscopic surgery. Trainees can pass through a major part of the first steep segment of the learning curve for basic laparoscopic skills preclinically by training on simulators[48, 86, 147]. Virtual reality (VR) simulators have the additional advantage that they can be utilised as a tool for objective proficiency assessment. Various VR simulators are available that provide validated tasks to train in laparoscopic tissue manipulation, laparoscope navigation, or both[12, 48]. The character of the skills required to perform laparoscopic tissue manipulation or laparoscope navigation tasks differs, while the most important difference between the tasks is the on-screen visual feedback[25]. In laparoscopic tissue manipulation the visual feedback consists of an instrument tip depicted on-screen as a moving object within a static environment, while a navigational manipulation of the laparoscope changes the on-screen representation of the observed environment as a whole. This

[*] Published as: Buzink SN, Christie LS, Goossens RHM, de Ridder H, Jakimowicz JJ (2010) *Influence of anatomic landmarks in the virtual environment on simulated angled laparoscope navigation.* Surgical Endoscopy, available online ahead of printing.

difference and its influence on the hand-eye coordination are not always taken into account when laparoscopic skills are considered. Yet, fundamental differences in user-interface interaction for different basic laparoscopy skills are important enough to consider before actual implementation of simulators for training or proficiency assessment purposes.

In one of our previous studies, experienced laparoscopic surgeons expressed the feeling that the virtual environment surrounding the laparoscope navigation task affected their performance negatively, in particular due to the high level of abstraction and their unfamiliarity with the landscape[25]. They said to be so used to have anatomical landmarks as reference points when manipulating the laparoscope that they found it very difficult to orientate themselves without these landmarks. Likewise, Stefanidis et al. (2006) and Maithel et al. (2006) pointed out that the performance of expert participants in their studies appeared to be subject to a simulator-associated learning curve when performing a laparoscope navigation task in an abstract environment; needing several repetitions to become acquainted with the task on the simulator[114, 161].

The aim of our study was to investigate the influence of anatomical landmarks in the visual environment on the performance of angled laparoscope navigation on a VR simulator. Is the presence of familiar anatomic landmarks beneficial for the performance of experienced laparoscopic surgeons? To answer this question, a group of experienced laparoscopic surgeons performed the Camera Navigation (CN) task on the SimSurgery SEP simulator (SimSurgery AS, Oslo, Norway) in two different virtual environments: the standard SEP abstract environment (CN-box) and a VR representation of the lower abdomen (CN-abdomen). A group of medical trainees with no laparoscopy experience also performed these tasks to assess whether the results could be related to the level of experience.

Materials and methods

Fifty-four participants took part in this study. During three advanced laparoscopic skills courses and five basic surgical skills courses, trainees, faculty, and staff of the institutes where the courses took place were invited to participate. In the information they received it was clearly stated that the researchers were not affiliated with the manufacturer of the simulator and that all data would be analysed anonymously. The participants filled out an informed consent form and a questionnaire about their demographics, general medical and laparoscopy experience.

The participants were allotted to one of two groups based on their experience with laparoscopic surgery indicated in the questionnaire. Participants in the experienced group (Table 6.1) indicated to have performed more than 100 basic laparoscopic procedures clinically (such as cholecystectomies or appendectomies) and at least 5 advanced laparoscopic procedures (such as Nissen fundoplication or bariatric surgery), plus to be experienced with using a 30 degree angled laparoscope. In addition, the performance on the PA task was used to verify the expertise level of the experienced participants. The performances on the PA task of three participants allotted to the Experienced group were labelled as extreme outlier (z-score>3,29), these participants were therefore excluded from this group. A Novice group was formed by medical trainees with the minimum knowledge level of a general surgical intern, but with no clinical experience in performing laparoscopic procedures (Table 6.1).

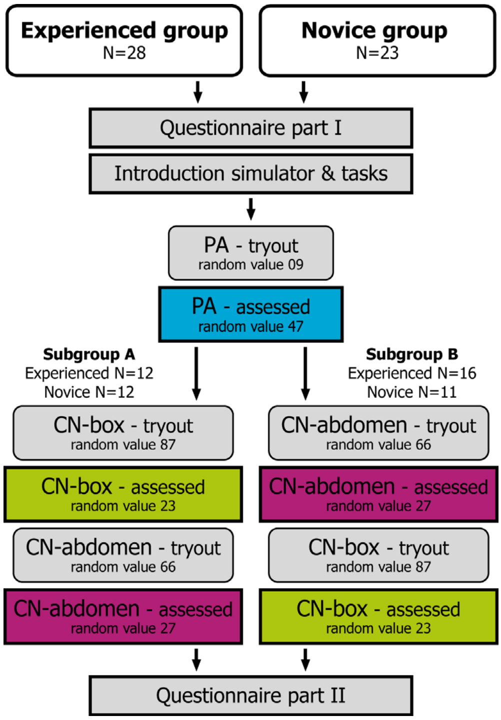

Figure 6.1 The study protocol. (PA: Place Arrow task; CN-box: Camera Navigation task with a 30° angled laparoscope in an abstract virtual environment; CN-abdomen: Camera Navigation task with a 30° angled laparoscope in a virtual representation of the lower abdomen)

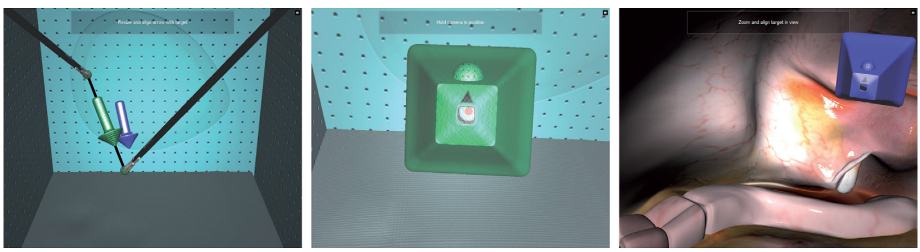

Figure 6.2 Screenshots of the PA task (left), CN-box task (middle), and CN-abdomen task (right). The screenshot of the CN-box task shows a target correctly visualised (zoomed-in sufficiently, centred on screen, with horizon level, and the bull's-eye visible); it turns green and should be held steady for five consecutive seconds.

Protocol

After filling out the questionnaire, the participants received an introduction to the simulator and explanation of the tasks following a standardised procedure. Next, they performed three tasks twice on the SimSurgery SEP VR simulator (SimSurgery AS, Oslo, Norway) (Figure 6.1 and Figure 6.2): the Place Arrow task (PA), the Camera Navigation task with a 30° angled laparoscope in an abstract virtual environment (CN-box), and the Camera Navigation task with a 30° angled laparoscope in a virtual representation of the lower abdomen (CN-abdomen). The order of the CN tasks was randomised. All participants started with performing the PA task twice to become acquainted with the simulator. The PA task performance also functioned as an indicator to verify the expertise level of the experienced participants. The participants were encouraged to use the first repetition of each task as a tryout run to become acquainted with the exercise. Only the second repetition of each task was used to analyse performances. The assignment given to the participants was to perform the second repetition of each task as best they could, but also as quickly as possible. After performing all tasks on the simulator, the participants filled out the remaining part of the questionnaire, in which they were asked to rate the tasks on 7-point Likert-scales.

The SEP software was used in combination with the SimPack surgical interface (SimSurgery AS, Oslo, Norway). The SEP software includes a variety of tasks in a VR environment to train different laparoscopy skills and provides learning objectives, instructions, and a demo video before each task. After each task, the software provides numerical scores and a graph of the performances. In addition to the scores provided by the simulator (including time to accomplish the task, total tip trajectory, and various error scores), the overall average speed per instrument tip was calculated (by dividing the total tip trajectory per tip by the time to accomplish the task).

The PA task represents a basic bimanual tissue manipulation task in which an arrow-shaped object needs to be grasped at both ends and placed over another arrow-shaped target elsewhere in the abstract box-like environment. The simulator calculates the quality of the manipulations by assessing the position, spatial orientation, and size of the grabbed object with respect to the position, spatial orientation, and size of the target object. When the object remains still in the approved position for five seconds, the target is regarded as successfully placed, after which a new target appears elsewhere in the environment. In total, five targets are presented one after the other. During the exercise, the viewpoint is fixed. The on-screen visual feedback consists of the graspers moving while being manipulated within the static abstract surroundings. In the CN task the participant has to locate a pyramid shaped target placed somewhere in the virtual three-dimensional environment and accurately visualise the target and the bull's-eye inside the target, which can only be seen through an opening in the pyramids top (Figure 6.2). Again the task involves meeting several quality parameters; the target is visualised correctly when it is displayed and held steady on screen for five seconds from a proper distance, centred on the screen, horizontally oriented, and with its bull's-eye visible. The CN task requires extensive manipulation of the angled laparoscope controls to visualise the targets properly. The position of the target and the surroundings are tightly fixed to each other and static. Each manipulation of the laparoscope controls alters the on-screen representation of the target within its surrounding, resulting in a very dynamic on-screen image. The CN-tasks included five targets, presented one after the other. For each of the mentioned quality parameters the acceptable range can be set to alter the level of difficulty of the exercise. In this study we used the standard settings of the simulator, which represent a medium level of difficulty according to the manufacturer. To ensure that all participants experienced a similar test situation, the exercise sets were carefully selected on the location of the targets within each task repetition (specified as the 'random value' setting) (Figure 6.1).

Data analysis

SPSS 16.0 software (SPSS Inc., Chicago, USA) was used for statistical analysis of the data. The Wilcoxon Signed Ranks test (two-tailed) was used to compare the performances on the tasks within each group. To compare the performances between the Experienced and Novices groups, the Mann-Whitney U test was used (two-tailed). In addition, we investigated whether the simulator performances within the Experienced group were affected by the age or the years of laparoscopic experience of the surgeons. Using the

Whitney U test (two-tailed), the performances in the Experienced group of the youngest five surgeons (≤ 35 years) were compared with the performances of the five oldest surgeons (≥ 48 years). Also, the performances of five senior residents with six years or less laparoscopy experience were compared with the performances of the six senior surgeons who stated to have at least 15 years of experience in laparoscopic surgery. A $p<.05$ was considered statistically significant.

Results

Within both the Experienced (N=28) and Novices (N=23) groups, no significant differences were found between the performances of subgroups A (CN-box followed by CN-abdomen) and B (CN-abdomen followed by CN-box) on the angled laparoscope navigation task in the abstract environment (CN-box task) or in the virtual representation of the lower abdomen (CN-abdomen task). This implies that the influence of the order in which the CN tasks were performed is negligible. The performances of the subgroups were therefore combined for further analysis. None of the participants encountered a tool-tool collision in the PA task, while in the CN tasks only two participants (one Novice and one Experienced participant) recorded one collision each with the camera to the target. Therefore, the scores on tool-tool collision, tool-tool collision time, and camera target collision were excluded from the analysis.

Table 6.1 Demographics of the participants.

		Experienced	*Novices*
Age	mean	42.07	28.09
	sd	7.91	2.73
	min-max	31 - 68	23 - 33
Who usually handles the laparoscope?	operating surgeon	2	1
	assisting surgeon	19	15
	intern or scrub nurse	5	1
	varying	2	6
Experience with simulators for basic laparoscopic tissue manipulation or translocation	none	8	12
	yes, but only briefly	14	4
	yes, <5 hours training	2	5
	yes, ≥5 hours training	4	2
Experience with simulators for angled laparoscope navigation	none	23	22
	yes, but only briefly	4	0
	yes, ≥5 hours training	1	1

In the Experienced group, the CN-box task was accomplished in significantly less time (Figure 6.3) and with a shorter total tip trajectory (Figure 6.4) than the CN-abdomen task. The same holds for the Novices group. No significant differences were found between the CN task in the two different surroundings for the number of targets lost out of view or the average speed per instrument tip (Figure 6.5 and Figure 6.6). The scores of the Experienced group did not differ significantly from the scores of the Novices group on both the CN-box task and the CN-abdomen task. However, on the PA task the Experienced group significantly outperformed the Novice group. The Experienced group accomplished the PA task in significantly less time ($p<.001$) and with a shorter total tip trajectory ($p<.001$). In the Experienced group the speed per instrument tip was also significantly faster ($p=.032$).

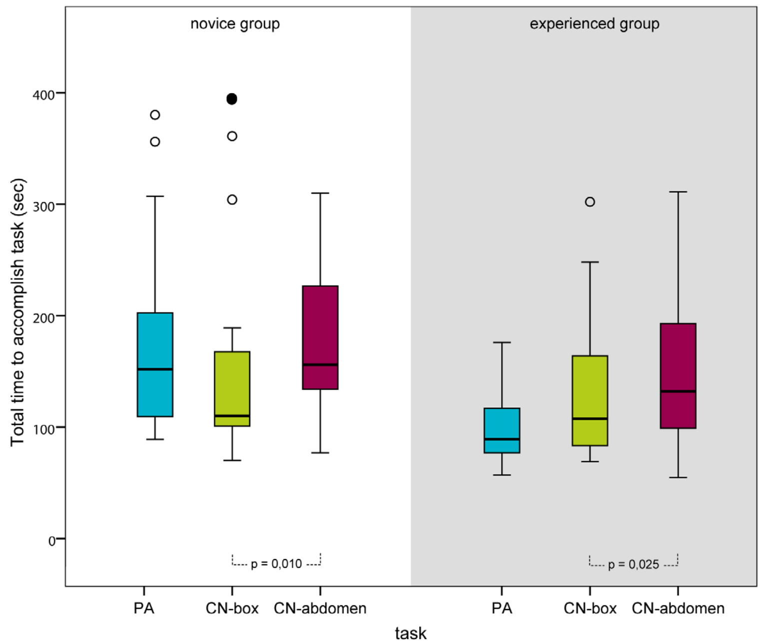

Figure 6.3 Time to accomplish the tasks. Presented p-values represent a significant difference within the groups between tasks (Wilcoxon Signed Ranks test, only the significant differences are presented).

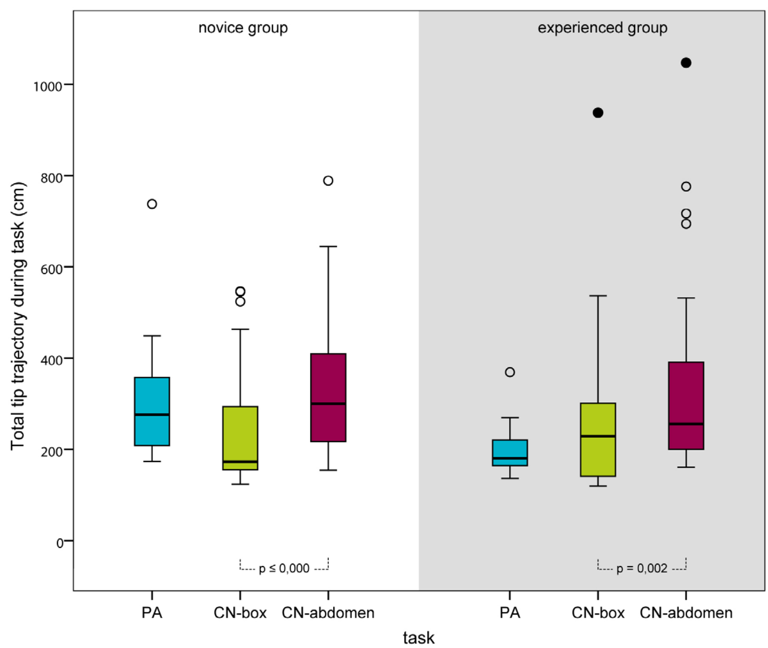

Figure 6.4 Total tip trajectory during the tasks. Presented p-values represent a significant difference within the groups between tasks (Wilcoxon Signed Ranks test, only the significant differences are presented).

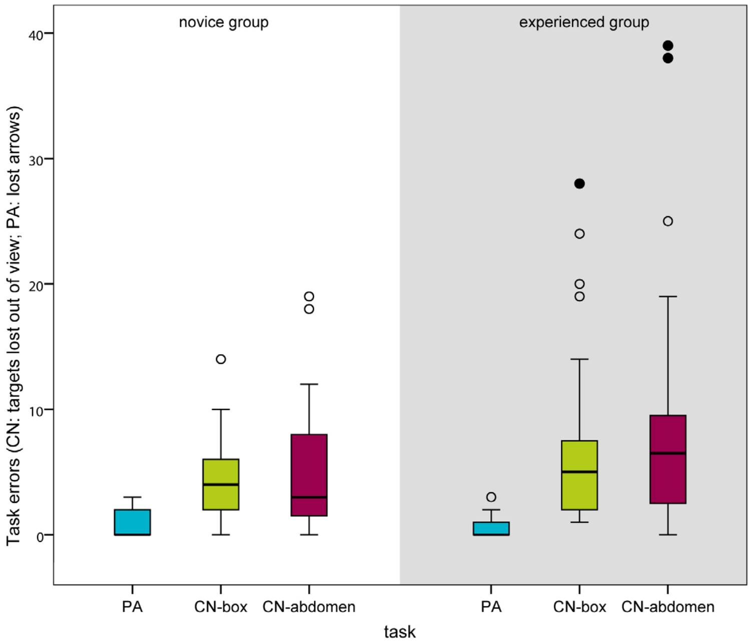

Figure 6.5 Number of main task errors made during the tasks.

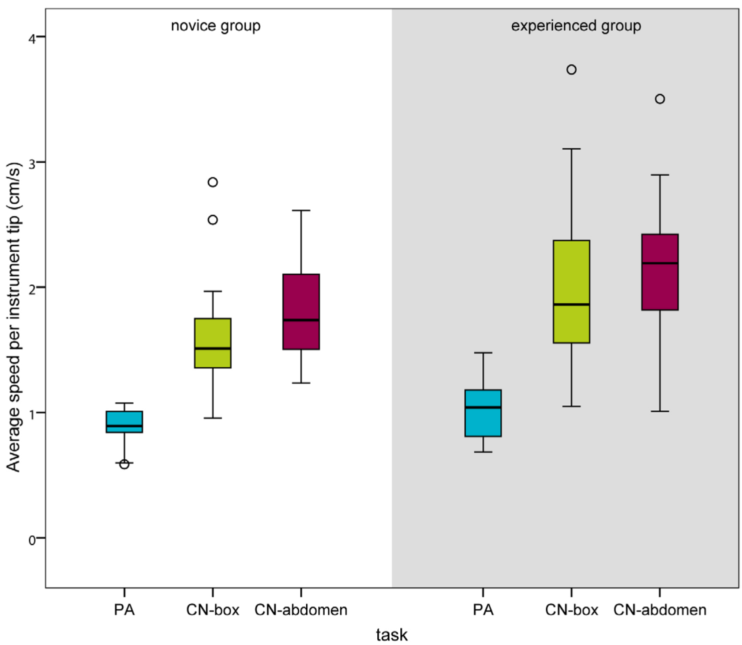

Figure 6.6 Average speed per instrument tip during the tasks.

Table 6.2 Opinion of the participants about the SEP tasks, rated on a 7–point Likert-scale. (1=strongly disagree, 4=neutral, 7=strongly agree)

	Experienced mean (sd)	*Novices mean (sd)*
Manipulating the graspers in the PA task was realistic	4.64 (1.25)	-
I understood the assignment for PA task well	5.93 (1.76)	6.74 (0.45)
It was hard work to complete the PA task well	3.46 (1.77)	4.22 (1.31)
The PA task was more challenging than I expected	3.50 (1.75)	4.74 (1.71)
Manipulating the laparoscope was realistic in both CN tasks	5.07 (1.30)	-
I understood the assignment for the first CN task well	6.21 (1.29)	6.13 (1.25)
It was hard work to complete the CN tasks well	4.46 (1.75)	4.87 (1.60)
The CN tasks were more challenging than I expected	4.86 (1.80)	4.87 (1.79)
The CN-abdomen task was easier to perform than the CN-box task	3.81 (1.94)	3.45 (1.99)
The PA task is an effective tool to train novice laparoscopists in bimanual tissue manipulation	4.75 (1.56)	-
The CN-abdomen task is a more effective tool to train novice laparoscopists in angled laparoscope navigation, than the CN-box task	4.78 (1.67)	-
The PA task is an effective tool to assess the proficiency level of experienced laparoscopists in bimanual tissue manipulation	3.64 (1.37)	-
The CN-abdomen task is a more effective tool to assess the proficiency level of experienced laparoscopists in angled laparoscope navigation, than the CN-box task	4.36 (1.73)	-

The Mann-Whitney U tests did not present any significant differences in performances in the Experienced group between the performances of youngest five surgeons (≤ 35 years) and the five oldest surgeons (≥ 48 years) and neither between the performances of five senior residents and the six senior surgeons with 15 or more years of experience in laparoscopic surgery. After performing all tasks on the simulator, the participants were asked to rate the educational value of the tasks and whether they experienced a difference between the perceived and anticipated level of difficulty of the tasks (Table 6.2). The opinion of the Experienced and Novices groups only differed significantly for the difference between the perceived and anticipated level of difficulty of the PA task (p=.011).

Discussion

Due to the new European working time directives (EWTD) and economical and ethical considerations clinical training of surgical skills is losing acceptance and pre-clinical training and proficiency assessment on VR simulators are becoming increasingly more common[48, 86, 147]. Handling an angled laparoscope and navigating with it within the abdominal cavity are basic laparoscopy skills for which the general value of simulator training and transfer of skills to the clinical setting has been proven[9, 59, 95]. However, more in-depth knowledge is still needed on the physical and cognitive aspects of the interaction with the instruments and interpretation of visual information during image-based procedures such as laparoscopic surgery. The visual environment in which simulator tasks are to be performed could be of influence, as was confirmed in our study.

The results of our study indicate that performances on the angled laparoscope navigation task on SimSurgery SEP differed significantly between the abstract environment and the virtual abdomen environment. The performances in the abstract virtual environment surpassed the performances in the virtual environment with anatomic landmarks in both the Experienced group and the Novices group. These results could (partly) be clarified by the fact that the abdominal environment used in this study was still a virtual reality representation of the abdominal cavity. The anatomy of the abdominal cavity is a very familiar environment to laparoscopic surgeons. Hence, minor deviations in the representation of the anatomy or flawed computer graphical representation could have drawn their attention immediately and distracted them from the performance of the CN task. And even though the Novices group was inexperienced in laparoscopic surgery, with the minimum knowledge level of a surgical intern they were all supposed to be familiar with the anatomy of the abdomen. Consequently, just like the experts they may also have been distracted from their task. It could also be that, due to the limitations of computer graphics, the level of detail of the anatomy was not sufficient enough to create a realistic experience of perceiving the abdominal cavity as in the operating room setting to allow skill-based behaviour by the experienced surgeons. Some surgeons commented that the CN task required too precise and sometimes too close visualisation of the targets in this way not representing the flexibility of visualisation of anatomic structures as in the operating room. This relates to personal preferences of some surgeons on visualisation of the operating field or variations that are dependent on the therapeutic task to be visualised. Finally, the performance assessment on the basis of the scores provided by the simulator could have had an influence. Each task on SimSurgery SEP incorporates several quality parameters which play a key role to accomplish the tasks successfully. Still, the output generated by the simulator at the end of each task only presents time needed to accomplish the task, the total tip trajectory, and specific error scores. It could be that a potential difference in navigation with an angled laparoscope is not reflected by these individual rudimentary scores, but should be identified by other, more sophisticated performance parameters (e.g. parameters related to specific aberrations from the optimal tip-trajectory or parameters that take multiple factors into account).

VR simulators could play an important role in fulfilling the desire for objective proficiency assessment and in accomplishing a shift towards criterion-based training. The development of criterion-based training programmes with also a stronger focus on the needs of the individual trainee will most likely improve the efficiency and efficacy of laparoscopy curricula and decrease the incidence of under-training or overtraining[86]. However, this approach necessitates a better understanding of the influence and function of different types of intrinsic and extrinsic feedback when performing different types of tasks on a simulator. The focus of future research should therefore be more on the quality of the performance and the development of more sophisticated and comprehensive performance metrics.

While the CN-box task was accomplished in significantly less time and with a shorter total tip trajectory, the average speed of the instrument tips did not significantly differ. It appears that the participants followed a longer route to find and properly visualise the targets in the CN-abdomen task. The simulator data does not provide details on the actual path followed with the instrument, only on the total length. Chmarra et al. (2008) analysed the shape of the path of instrument tips for a simple eye-hand coordination task with a laparoscopic grasper and identified a retracting phase and a seeking phase. Instead of following the actual shortest route between two points, being a straight line, a pull-back movement is performed first before the target is approached[38]. This pull-back movement is essential to minimize the chance of touching tissue unnecessarily and ensure patient safety. Possibly, the presence of anatomic landmarks instigated a more cautious behaviour. But this could also be related to the irregular shape of the environment and the presence of obstacles in the CN-abdomen task versus the open and clear space in the CN-abstract task. Then again, similar results were found in both the Novices and the Experienced groups, which suggests that the latter is less likely to be the case.

The questionnaire data (Table 6.1) shows that the assisting surgeon usually handles the laparoscope. In the early days of laparoscopic surgery, many surgeons started immediately with performing the therapeutic actions with an assistant or resident holding the laparoscope. While in many teaching hospitals the senior surgeon would fulfil the role of assisting surgeon in less complicated laparoscopic procedures performed by surgical residents. This implies that senior surgeons would handle the laparoscope on a regular basis, but only during procedures involving uncomplicated utilisation of the angled laparoscope. In contrast, the younger generation laparoscopic surgeons generally started their laparoscopic career by handling the laparoscope assisting the primary operating surgeon, during both straightforward procedures and procedures requiring more sophisticated manipulation of the laparoscope. Consequently, one might expect that the younger generation has more experience with manoeuvring laparoscopes. This could be a plausible explanation for the lack of difference in performance of the CN tasks between novices and experienced laparoscopic surgeons. Therefore, we also investigated whether the simulator performances within the Experienced group were affected by the age or the years of laparoscopic experience of the participants in the Experienced group. The results though did not reveal any significant differences.

In the questionnaire, the experienced participants were asked to rate whether the CN-abdomen task was a more effective tool than the CN-box task to train novices or assess experienced laparoscopists in angled laparoscope navigation (Table 6.2). Although the opinions upon these questions were divided, the CN-abdomen task was rated to be more effective to train novices than the CN-box task. This suggests that the requirements for a simulator for training are perceived to be different from the requirements for a simulator for assessment of laparoscopic proficiency. Just as in one of our previous studies, the CN task was rated as being more challenging than anticipated beforehand, and also more so than the PA task [25]. The study was performed during laparoscopic courses that made extensive use of box trainers or living animals, often using 30° angled laparoscopes, and sometimes also VR simulators. Frequently, the participants worked in pairs, with one person handling the laparoscope while the other performed the training task. Yet somehow, the participants did not recognise this as simulation training, because many of the experienced surgeons stated to have none or only brief experience with simulations for either laparoscopic tissue manipulation or laparoscope navigation (Table 6.1).

Conclusions

The performances of experienced laparoscopic surgeons on an angled laparoscope navigation task on the SimSurgery SEP VR simulator differed significantly between the abstract environment and the virtual environment of the abdomen with anatomic landmarks. The task was performed with better simulator scores in the abstract environment, opposite to the propositions of several experienced laparoscopic surgeons in a previous study. In the group with inexperienced medical trainees a similar difference in performances was found. This means that the influence of the virtual environment on the task performance was not related to the level of experience. Further research should focus on extending the knowledge on the influence and function of different types of intrinsic and extrinsic feedback provided by the simulator on the effectiveness of pre-clinical training (e.g. the realism of the task and its surroundings and the added value of haptic feedback). The criteria and parameters used to assess task performance for different types of laparoscopy skills need to be further investigated as well.

Acknowledgments

The authors would like to thank all participants for taking part in this study and the course directors and staff of the Cuschieri Skills Centre in Dundee, UK, the Covidien Training and Education Center in Elancourt, France, and the Skillslab of the Catharina Hospital Eindhoven, The Netherlands, for making it possible to invite participants and faculty of several of their courses to participate in this study. We thank SimSurgery for unconditionally providing the equipment and software used in this study.

6.2 The importance of haptic feedback in laparoscopic suturing training [*]

Extensive practice is of major importance to becoming a skilled laparoscopic surgeon. Traditionally, surgeons have gained their skills hands-on in the operating room under the supervision of expert surgeons. The skills needed for laparoscopic surgery are unique and differ from those used during open surgery and therefore necessitate a different training approach. Preclinical practice using inanimate models such as box trainers or virtual reality (VR) simulators increases psychomotor skills and translates into improved performance in the operating room[70]. For this reason, the use of simulation in surgical training curricula is becoming more widely accepted. Objective assessment of performance is fundamental to provide formative feedback during training, allowing for continuous skill refinement. Traditional box trainers have been criticized for being unrealistic in presented exercises and for the lack of any form of objective assessment[3]. However, during the exercises they provide realistic haptic feedback because the operator practices on real objects or tissue using realistic surgical laparoscopic instruments. Most VR simulators do provide objective assessment and feedback, but lack realistic haptic feedback. A third type of simulator system makes use of augmented reality (AR), merging computer graphics and real imagery into a single, coherent perception of an enhanced world around the user. AR laparoscopic simulators retain the benefits of a box trainer, such as the realistic haptic feedback, but additionally generate objective measures of performance, similar to VR simulators[71]. The image one sees on the AR

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[*] Based on two published journal articles:
Botden SMBI, Buzink SN, Schijven MP, Jakimowicz JJ (2007) *Augmented versus laparoscopic simulation: what is the difference? A comparison of the ProMIS Augmented Reality laparoscopic simulator versus LapSim VR laparoscopic simulator*. World Journal of Surgery 31: 764-772.
Botden SMBI, Torab F, Buzink SN, Jakimowicz JJ (2008) *The importance of haptic feedback in laparoscopic suturing training and the additive value of Virtual Reality simulation.* Surgical Endoscopy 22: 1214-1222.

simulator screen is comprised of a real video image overlaid with a graphics image. This can, for example, be used for directional explanation.

A number of studies[65, 155, 175] have shown that haptic feedback is of importance for adequate laparoscopic training, in particular for laparoscopic suturing. The term 'haptic feedback' refers to the combination of tactile feedback through sensory skin receptors, and kinaesthetic feedback through muscle, tendons, and joint sensory receptors. Especially for laparoscopic suturing skills it is important that the trainees experience haptic feedback when performing the task. Several key aspects of learning these skills involve refined interaction with tissue and suturing materials, which most likely demands a more sophisticated level of feedback than can be obtained by visual feedback alone. Haptic feedback results in significantly improved skills transfer to the trainee, compared with training without haptic feedback[3]. In general, it is assumed that high-fidelity simulations with haptic feedback imply better training effects and a better transfer of skills to the clinical setting[164]. However, realistic haptic feedback during laparoscopic training is currently lacking in VR simulators.

The degree of realism of a simulation varies depending on the hardware and software capabilities of the simulator[102]. Because of limited computing power, most VR simulator systems generally only represent a part of the physical environment. This means that certain limitations have to be accepted for any simulation (e.g., suturing and knot tying). If accepted, this results in simplified representations of organs, which do not behave like they do in the clinical setting (e.g., inadequate haptic feedback, limited visual details, etc.)[102]. Various studies[11, 70, 102, 124, 161, 189] have been performed comparing traditional box trainers with VR simulators for laparoscopic training, most of which focused on basic laparoscopic skills. Only the study by Avgerinos et al. concluded that for the intracorporeal knot-tying task there was no statistically significant difference in the score measures between the two simulator systems[11]. They all additionally conclude that further studies are needed to establish which simulation technique is more effective for training[70, 102, 124, 161, 189].

Therefore we investigated the importance of haptic feedback and the added value of objective performance assessment for laparoscopic suturing training. To this end, two experiments were performed. In study I the aim was to evaluate the suturing training provided by a VR simulator and an AR simulator by having both systems simultaneously tested and their didactic value judged by laparoscopists of different expertise levels. In study II the value of suturing training on a VR simulator in addition to suturing training on a box trainer was investigated.

Materials and methods study I

In total, 90 participants took part in this study. Forty-four participants took part during the 2006 congress of the Dutch Surgical Society in, 34 participants were recruited amongst staff of the Catharina Hospital Eindhoven; and 12 participants took part at the International Student Congress of Medical Sciences (ISCOMS) 2006. Participants were allotted to 3 groups based on their clinical laparoscopic experience: experts, who performed more than 100 clinical laparoscopic procedures; intermediates, with less than 100 clinical procedures; and novices, who had no laparoscopic experience.

In this study a ProMIS AR simulator (Haptica, Dublin, Ireland) and a LapSim VR simulator (Surgical Sciences, Göteborg, Sweden) were used. The ProMIS AR simulator (Figure 6.7) consists of a torso-shaped mannequin with a camera-based instrument tracking system attached to a laptop. To allow tracking by the camera system, the laparoscopic instruments of choice are marked at a fixed distance with yellow-black striped tape at the distal end of the instrument (Figure 6.8). For each task the appropriate exercise tray needs to be placed inside the mannequin, such as the suturing pads for the suture and knot-tying tasks. In this study we used a 1-cm-thick suturing pad, which is used in traditional box trainers. The simulator records time, instrument path length, and smoothness of movement (through changes in instrument velocity and changes in direction) per instrument (right and left hand) for each sub-task. After completion of the task, the system provides measurements and statistics on each performed task and module. The LapSim VR simulator (Basic skills v3.0, Surgical Sciences, Göteborg, Sweden) used in this study was a PC-based trainer for laparoscopic surgery (Figure 6.7) combined with an Immersion VR laparoscopic instrument set (Immersion Medical, San Jose, USA). The image on the monitor is a computer-generated virtual reality representation of laparoscopic tasks. Parameters recorded by the simulator are time, instrument-path length, tissue damage, overall score, and a pass/fail score.

Figure 6.7 The ProMIS AR simulator (left) and the LapSim VR simulator (right).

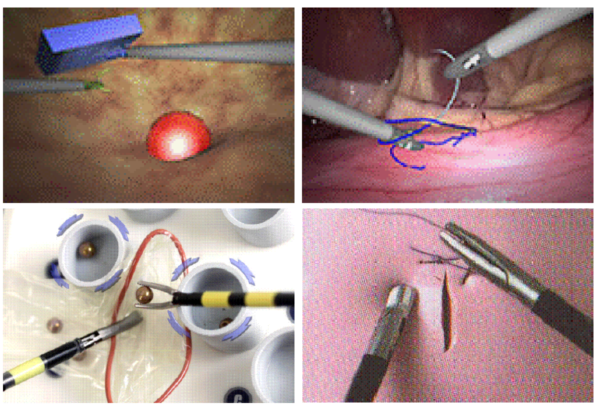

Figure 6.8 Screenshots of the translocation (left) and suturing tasks (right) on the LapSim VR simulator (top) and ProMIS AR simulator(bottom).

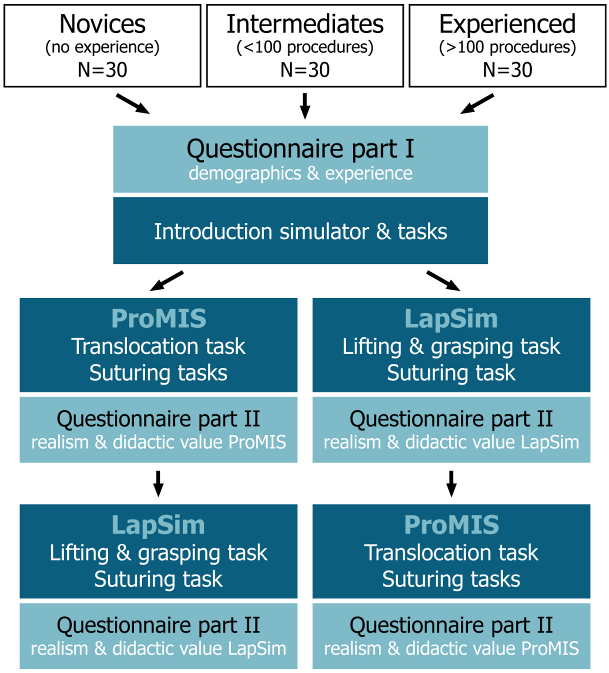

Figure 6.9 Protocol design study I.

Participants were asked to fill out a questionnaire that consisted of 3 parts: the 1st part referred to demographics and laparoscopic and/or simulator experience. The second part referred to realism, didactic value, haptic feedback, and usefulness of the ProMIS AR simulator. The third part referred to realism, didactic value, haptic feedback, and usefulness of the LapSim VR simulator. The latter two parts had to be answered on a 5-point Likert scale. The questionnaire ended with an open-ended question for general remarks on both simulators.

The participants commenced by filling out the first part of the questionnaire (Figure 6.9). Subsequently, all participants received an introduction about both simulators and the simulator tasks by means of posters with a short verbal explanation. Before each task, a demonstration video was additionally shown on the ProMIS AR simulator and an instruction text on the LapSim VR simulator. The order in which the participants encountered the simulators was systemically altered (at random) to avoid possible carryover effects. On each simulator the participants first performed a translocation task to familiarise them with the system (the 'instrument handling task' on the ProMIS and the 'lifting and grasping task' on the LapSim VR simulator), followed by the suturing task(s) (Figure 6.8 and Figure 6.9). After completing the tasks on the first of the simulators, the participants filled out the corresponding questionnaire. They then performed the equivalent tasks on the other simulator, followed by the last part of the questionnaire. A time limit of 3 minutes for the translocation task on the LapSim and 5 minutes for the remaining tasks was used, as trained surgeons are expected to be able to perform such a task easily within this time.

All data was processed and analysed using SPSS 13.0. Difference in opinion about the two simulators was analysed with the paired t-test. The difference in the level of skills extracted from the simulators between the three groups was analysed using the Kruskal-Wallis test. A $p<.05$ was considered statistically significant

Results Study I

A significant difference was found in the participant opinions with regard to features of the 2 simulator systems (Table 6.3). Overall, the ProMIS AR scored higher on all aspects than the LapSim VR simulator. The expert group rated 'resistance of needle and thread' on the LapSim VR as not good, with a mean of 1.57 (Table 6.3). On the 'suturing' features, the ProMIS AR simulator was rated 2.0 points higher on average than the LapSim VR simulator. The didactic value of the ProMIS AR was rated to be higher than the LapSim VR (Table 6.4). The statement 'the ProMIS AR simulator is an appropriate training tool for surgical residents' scored 4.67 in the expert group and 4.30 in the novice group. The LapSim VR simulator was scored 2.67 and 3.03, respectively, by the same groups for this feature. On the learning properties of the simulators, 83.3% of the experts indicated that 'the ProMIS AR can teach trainees the proper skills,' whereas 13.3% stated that the LapSim VR can serve this purpose. The opinions on the LapSim VR were divided amongst all participants, this is demonstrated by the wide standard deviations in Table 6.4. In general, the rating of LapSim VR by the novice group was higher compared with ratings by the intermediate and expert groups. This can be explained because the novice group consists mainly of interns who do not have much reference to which to compare the laparoscopic simulators nor to judge on realism. Especially in this group, one may observe a difference between the part of the group that started the study on the LapSim VR first and the other part that started first on the ProMIS AR. Yet on the final open-ended question in the questionnaire, an often made general remark was that the ProMIS AR simulator was much more realistic and a better training system than the LapSim VR simulator.

The simulator output for the performances of all participants were analysed to establish whether these can be used to distinguish between skill levels (Table 6.5 and Table 6.6). For the ProMIS AR simulator, the performance of the participants significantly differed on all measured parameters, except for the 'path length of the left instrument'. The parameters measured by the LapSim VR simulator did not differ significantly between the expertise groups, except for the 'time' to complete the translocation task and 'tissue damage' on the suturing task.

Table 6.3 Participants' opinions about realism ProMIS AR simulator and LapSim VR simulator

		ProMIS mean (sd)	*LapSim mean (sd)*	*sign.*
Translocation task	Haptic feedback	4.10 (0.937)	2.26 (1.066)	.000
	Instrument movement	4.22 (0.700)	2.18 (1.023)	.000
Suturing task	Realism	4.43 (0.657)	2.49 (1.072)	.000
	Haptic feedback tissue	3.92 (0.800)	1.92 (0.923)	.000
	Resistance needle & thread	4.15 (0.708)	1.84 (0.926)	.000

Table 6.4 Participants' opinions about didactic value ProMIS AR simulator and LapSim VR simulator

	ProMIS mean (sd)	*LapSim mean (sd)*	*sign.*
Training surgical residents	4.51 (0.707)	2.94 (1.105)	.000
Training surgeons	4.38 (0.696)	2.52 (1.094)	.000
Learning proper skills	4.08 (0.651)	2.86 (1.014)	.000
Simulator appeals to me	4.17 (0.706)	2.59 (1.182)	.000

Table 6.5 Mean scores for tasks performed on the ProMIS AR simulator. A time limit was used of 180s on the translocation task and 300s on the suturing task. (differences between groups analysed with Kruskal Wallis test)

		Expert (N=30)	*Intermediate (N=30)*	*Novice (N=30)*	*sign.*
Translocation	Time (s)	122.13	132.93	195.98	.000
	Path length (mm)				
	Left tool	248.57	233.12	309.62	.009
	Right tool	243.28	252.85	373.99	.000
	Smoothness (mm)				
	Left tool	411.50	467.93	717.73	.000
	Right tool	409.63	470.90	695.40	.000
Suturing	Time (s)	357.30	439.42	562.17	.000
	Path length (mm)				
	Left tool	1112.72	1147.19	1220.98	.247
	Right tool	1068.44	1322.71	1624.92	.001
	Smoothness (mm)				
	Left tool	1135.13	1432.40	1911.70	.000
	Right tool	1247.07	1572.67	1998.47	.000

Table 6.6 Mean scores for tasks performed on the LapSim VR simulator. A time limit was used of 180s on the translocation task and 300s on the suturing task. (differences between groups analysed with Kruskal Wallis test)

		Expert (N=30)	*Intermediate (N=30)*	*Novice (N=30)*	*sign.*
Translocation	Time (s)	119.03	111.62	128.31	.021
	Score (%)	60.13	61.43	52.97	.209
	Path length (mm)				
	Left tool	225.21	215.40	220.27	.504
	Right tool	193.57	197.29	200.17	.698
	Tissue damage (mm)	3717.25	3952.37	4501.65	.240
Suturing	Time (s)	281.15	271.40	300.04	.312
	Score (%)	90.17	90.23	89.50	.604
	Path length (mm)				
	Left tool	319.46	3.2027	283.98	.363
	Right tool	509.22	445.60	470.51	.574
	Tissue damage (mm)	5707.62	6013.45	10178.00	.016

Materials and methods study II

Study II took place during several laparoscopic skills courses in the Catharina Hospital Eindhoven, the Netherlands, and the Academic Hospital of Al Ain, United Arab Emirates, from November 2006 till January 2007. The study has two arms: one assessing the influence of additional suturing training on a VR simulator on the performances of 20 trainees taking part in suturing training on a box trainer and the other investigating the opinion of 45 trainees on laparoscopic suturing on traditional box trainers and VR simulators. To participate in the study, the trainees were required to have some laparoscopic experience to ensure a reference point to the clinical setting. Laparoscopic suturing experience was an exclusion criterion for the participation in the arm involving the assessment of the suturing and knot tying skills.

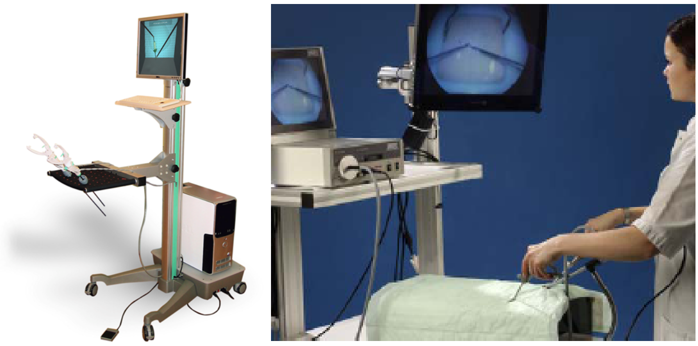

Figure 6.10 The SimSurgery VR simulator(left) and the box trainer (right), composing a foam suturing pad, a Karl Storz Telepac system with, video monitor, and needle holders

Traditional box trainers and SimSurgery VR simulation systems were used in this study. The traditional box trainers were composed of a box inside which the laparoscopic suturing task are performed on a foam suturing pad (Limbs & Things Ltd., Bristol, UK), a Telepac system (Karl Storz Endoscope, Tuttlingen, Germany), and an additional video monitor (Neovo X17a) (Figure 6.10). The endoscope, camera, and laparoscopic needle holders used were from Karl Storz. The SimSurgery combination with one of two hardware platforms; one VR simulator system incorporated the SimPack platform (SimSurgery, Oslo, Norway) (Figure 6.10), while the other system made use of two Xitact IHP manipulators (Mentice AB/Xitact SA, Morges, Switzerland). The SimSurgery VR simulator contains various training modules, including exercises related to basic laparoscopic skills, suturing, and procedural tasks. For this study we only used a selection of tasks from the suturing module: ‘Two-handed stitch with traction’, ‘Realistic surgeon’s knot’, ‘Realistic interrupted suture’, and ‘Realistic free knot’. After completion of each task, the simulator provides numerical data and graphical presentation of the performance scores. Even though the Xitact IHP instrument ports in one of the simulator systems is capable of providing haptic feedback, the SimSurgery software does not support these haptic features.

All participants (N=45) were asked to fill out a questionnaire that consisted of 3 parts: the first part contained questions on demographics and laparoscopic and/or simulator experience. The second part referred to the perceived realism, didactic value, and haptic feedback of the simulators. These questions were answered on a five-point Likert scale. The last part consisted of questions concerning the preferences of the trainees regarding laparoscopic suturing training. Before starting the training sessions on either of the simulators, the participants filled out the first part of the questionnaire (Figure 6.11). A general introduction of the simulators was given, followed by a demonstration and explanation of the laparoscopic ‘surgeon’s knot’ by an expert laparoscopic surgeon. Next, all participants were randomly and blinded divided into two equally sized groups: group A started with a 30 minutes training session on the traditional box trainer followed by a 30 minutes session on the SimSurgery VR simulator; group B started 30 minutes of training on the SimSurgery VR simulator, followed by 30 minutes of training on the traditional box trainer. After finishing all training sessions, the participants were asked to fill out the remaining parts of the questionnaire.

The assessment of the performance was only tested for a subgroup, represented in the Figure 6.11 as group Anl (N=10) and group Bnl (N=10). After following the full training course, the performances of the participants in this subgroup was additionally assessed on the traditional box trainer by an expert laparoscopic surgeon. The assessment of the skills was done using a standard evaluation form, which consisted of eight items scored on a five-point-Likert scale. Table 6.7 presents a summary of the scoring of the assessment criteria examined by the expert observer. The criteria 'Quality (strength) of knot' was tested by the objective observer by taking out the suturing pad with the tied knot and pulling the thread, to observe if the knot was tight and secured. Each of the expert laparoscopic surgeon had done more than 100 clinical laparoscopic procedures and extensive laparoscopic suturing experience. The participants of both subgroups were equally divided between two objective expert observers, to avoid inter-examiner differences. The performance assessment of group Anl after the initial 30 minutes training session on the box trainer was used as a control group (Figure 6.11).

All data was processed and analysed using SPSS 13.0. Differences in opinion regarding the two simulators were analysed using the paired t-test. The differences between the examined final knots were assessed with the independent-sample t-test. A $p<.05$ was considered statistically significant, while a p-value between .05 and .07 indicates a considerable tendency of the results.

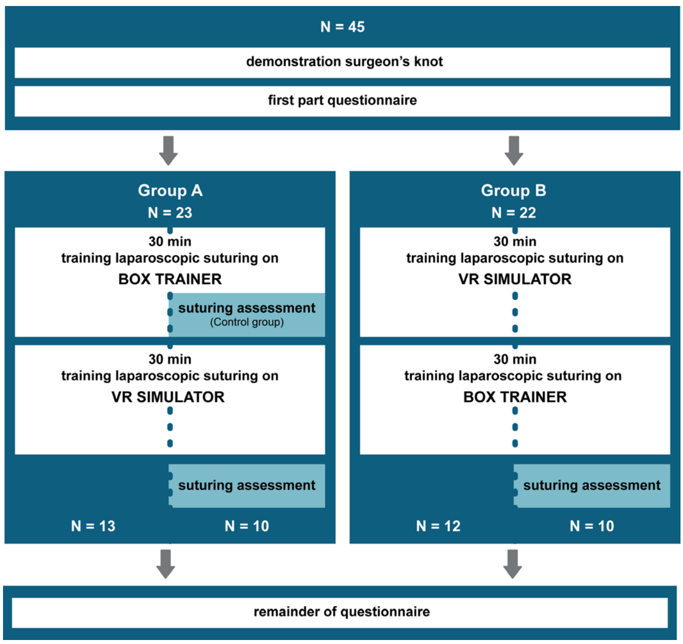

Figure 6.11 Overview of the protocol of the study of all participants (N=45)

Results Study II

The expert observers scored the 'quality of knot' of the suturing task performance of both group Anl and group Bnl slightly better than the 'quality of knot' for the control group (Table 6.7), but these differences were not significant. Overall, group Anl scored higher on the summed value and on most other criteria, but these differences were not significant. Only the scores on 'taking proper bites of the suturing pad, during suturing' showed a considerable tendency towards a difference between groups Anl and Bnl.

No significant differences were found between the opinions of the trainees participating in either the Netherlands or the United Arab Emirates or the order in which the participants performed the tasks on the two simulators (group A versus group B). Thus, the data on the opinions of the participants regarding the realism and haptic feedback of the SimSurgery VR simulator and the box tariner was analysed together. The opinion of the participants on the realism and haptic feedback of the two simulator systems differed significantly (Table 6.8). Overall, the traditional box trainer scored higher on all aspects than the SimSurgery VR laparoscopic simulator. For the VR simulator all standard deviations range between 0.894 and 1.107, which implies that the opinion on the features of this simulator is divided amongst the participants. The standard deviation of the opinion of the box trainer is lower, except for 'haptic sensation of the tissue', for which the opinion is also more diverse. On the question of whether it is necessary to use both simulator systems for laparoscopic suturing training, 53.3% of the participants believed that they were both useful for proper training whereas 46.7% believed that the traditional box trainer alone would suffice for the training. Of all the participants, 53.3% would prefer to practice on the VR simulator first followed by the traditional box trainer, while 37.8% would prefer to start the training on the box trainer instead.

Table 6.7 Performance scores of the suturing task as assessed by expert observers. (Rating of performance on a five-point Likert scale: 1=poor performance, 2=needs more training, 3=acceptable performance, 4=good performance, and 5=excellent performance).

	Group Anl (N=10) mean (sd)	*Group Bnl (N=10) mean (sd)*	*Control (N=10) mean (sd)*
Positioning of needle in needle holder	3.80 (0.632)	3.30 (0.675)	3.30 (0.823)
Running needle through suturing pad	3.90 (0.568)	3.60 (0.516)	3.60 (0.516)
Taking proper bites of the suturing pad, during suturing	4.10 (0.568)	3.60 (0.516)	3.90 (0.568)
Throwing thread around needle holder	3.50 (1.080)	3.10 (0.994)	3.20 (1.135)
Pulling tight of the thread	3.70 (0.949)	3.20 (0.789)	3.70 (0.949)
Tying a correct 'surgical knot'	3.50 (1.080)	3.50 (0.850)	3.20 (0.919)
Quality (strength) of knot (test by pulling on knot)	3.90 (0.994)	3.80 (0.442)	3.60 (1.265)
Global evaluation of performance	3.90 (0.876)	3.50 (0.707)	3.70 (0.675)
Summation of scores	30.80 (5.692)	27.60 (3.893)	28.20 (5.138)

Table 6.8 Opinion of the participants on didactic value of the simulators for laparoscopic suturing. (Rating on a five-point Likert scale, 1=absolutely unrealistic, 3=neutral, 5=very realistic) (paired t-test)

	VR simulator mean (sd)	*Box trainer mean (sd)*	*sign.*
Global impression	3.00 (0.894)	3.95 (0.893)	.000
Movement of the instruments	2.83 (1.093)	4.37 (0.662)	.000
Realism of needle and thread	2.75 (1.056)	4.53 (0.751)	.000
Tying of the knots	2.75 (1.032)	4.53 (0.640)	.000
Pulling tight of the suturing thread	2.68 (1.083)	4.34 (0.794)	.000
Movement of the suturing thread	2.71 (0.929)	4.34 (0.911)	.000
Haptic sensations of the tissue	1.98 (1.107)	3.83 (1.160)	.000
Resistance of needle and thread	1.93 (1.081)	4.17 (0.803)	.000

Discussion

Simulator implementation into surgeon training curricula is of paramount importance, and it progressively gains acceptance[86, 140]. Various simulation tools can be used to aid training in laparoscopic skills. These tools range from simple box trainers to sophisticated VR trainers.

To be an effective educational tool, the metrics provided by a simulator must provide meaningful information to the trainee[57]. Time, tip trajectory, and smoothness are often used in VR simulation and can provide a much more precise and comprehensive evaluation of basic laparoscopic skills than can be measured by timing drills in box trainers. The benefits include an objective analysis of errors and economy of motion; two parameters that cannot be assessed accurately by an observer[130]. However these metrics are not necessarily the most valuable proxies to assess the performance of the trainee. The SimSurgery VR simulator uses various measurements to assess each performance, such as time and tip trajectory (motion analysis); it additionally records various types of errors made during the performance. When the same task is performed more than once, a performance curve will be visualized for each task repetition. This can be used by the trainees and faculty to monitor their performance and progression and aim remedial training to correct specific deficiencies[130]. An essential tenet of educational theory is that learning should be accompanied by evaluation for both formative (feedback) and summative (final assessment) purposes. This feedback can be used to create dedicated learning programs to enhance skills specifically in the areas that are deficient, and to verify that a required skill level has been attained[57]. The feedback after each performance provided by most VR simulators could motivate trainees to practise their skills more extensively, until they have reached their goal. Providing feedback and setting goals tends to motivate trainees more, compared with a self-directed group[63]. With a traditional box trainer, feedback is subjective and an expert needs to be on hand to assess performance, making it more difficult to set specific goals[110]. One downfall of the assessment method used by VR simulators is that they often oversimplify and only provide feedback on the performance of the whole task. To be an effective training tool, the simulator must provide metrics that are meaningful and informative to the trainee. Time as a sole parameter might not be the best criterion on which to grade the trainee. The primary issue is that the correct technique is used and a tight knot is made, in this the time needed to complete this task is a secondary issue. Therefore, it is important to evaluate other metrics recorded by the simulator. In the ProMIS AR simulator, other parameters such as 'path length' and 'smoothness', provide a more comprehensive impression of the performance. However, the quality of the knot is still not included as parameter.

A surgeon must be able to identify tissue properties and handle tissue in a safe manner[164]. Challenges facing the laparoscopic surgeon include the loss of haptic (tactile) feedback due to the interposition of long instruments between the surgeon's hand and the tissue. To compensate for the compromised haptics, the surgeon has to rely on visual input from the operating field[161]. However, with laparoscopic surgery, there is a loss of important depth cues due to the use of a two-dimensional display monitor. Another disadvantage of laparoscopic surgery is the fulcrum effect created by the insertion of the instruments through the abdominal wall, which causes the instrument tips to move in the opposite direction to the surgeon's hand[130]. Because of these additional mental translations and counterintuitive interactions, it is important that laparoscopic skills are practised extensively before application in the clinical setting. During laparoscopic procedures, the major part of the haptic feedback is lost. However the little haptic feedback that remains is valuable and it is therefore important that the simulator system provides haptic feedback, preferably as optimal as possible. A disadvantage of the majority of VR simulators is the absence of haptic feedback to the surgeon[130].

Shortly after its introduction, laparoscopic surgery was associated with a high complication rate. The term 'performance curve' was introduced to refer to the number of operations a surgeon has to perform to reach an expertise level with an acceptable complication rate[102]. Further studies showed that even experienced laparoscopic surgeons had to go through a performance curve again when they had to learn a new laparoscopic procedure or technique[102], such as laparoscopic suturing. Data from previous studies suggests that training up to a predetermined level on a box trainer suture model provides trainees with skills that translate into improved clinical performance[96, 130]. It has been reported that haptic feedback is very important in laparoscopic simulation and can shorten the first part of the performance curve[164], increasing the effectiveness of laparoscopic training[91, 99, 107]. Currently though, this is also one of the most controversial issues in VR laparoscopic simulator design, as it is very complicated to incorporate realistic haptic feedback into VR systems[99]. In particular for laparoscopic suturing training, because of the interactions between the instruments, needle, thread, and tissue, it is important that haptic sensations during the simulation are optimal, but this has not yet been achieved in VR simulation. For AR simulation tools, this is not an issue because of the nature of the system. The outcome of the studies presented here allows the conclusion that ProMIS AR offers a good alternative to VR laparoscopic simulation, as it retains the benefits of VR and additionally offers more realistic haptic feedback. One advantage of the traditional box trainer and AR simulators over most VR simulators is that they provide realistic haptic feedback, which is absent in most VR systems. Additionally, it allows the trainee to use whatever instruments he or she prefers to use in the operating room[57]. While VR simulators may have some advantages, participants in previous studies comparing simulation modalities feel that traditional box trainers help them more, are more interesting, and are preferred over a VR simulator if only one trainer is allowed[111, 161]. In the studies presented here, the participants again favoured the non-VR simulators. The feedback provided by the VR simulators was not always perceived as representative for their actual skills level and the participants felt that they were better evaluated by an expert observer.

It is important to note that our results do not imply that VR simulator systems are not suitable for training in laparoscopy in general, or for basic skills or component tasks of procedural training in laparoscopic training. Previous studies have proven the value of VR simulation without haptics for several types of laparoscopy training[3, 32, 65, 150]. These studies do show however that, for laparoscopic suturing, haptic feedback is considered a necessity. Training of suturing skills on VR simulator should be avoided until these systems are also capable to provide realistic haptic feedback. There were no significant differences between the scores of the expert observers after laparoscopic suturing training on only a traditional box trainer (control group) or the combination with a VR simulator (groups Anl and Bnl); neither could we find an optimal order in which the training should be followed to master the laparoscopic suturing skills. Group Anl, whom started on the box trainer followed by the VR simulator, had the highest summed score, but it was still not significantly higher than either group Bnl or the control group. From these results we can state that VR simulation in the current form does not have an additional value to traditional box trainers in laparoscopic suturing training.

In these studies, we encountered a combination of the subject-expectancy effect and the attribution theory[126], which most likely influenced the experienced participants' opinion about the simulators following a disappointing individual performance on the tasks. For example, on the LapSim VR simulator, when participants had to perform the 'suturing and knot-tying' task, the majority of the participants (in all groups) were not able to pass the needle through the tissue and therefore could not tie knots. This annoyed most of them and was noticeable when they had to fill out the questionnaire. On the ProMIS AR, these suturing skills were tested separately, which caused less frustration.

Conclusions

These studies show that to acquire laparoscopic suturing skills realistic haptic feedback is essential. Training of laparoscopic suturing skills should therefore best be performed on a simulation system that provides proper haptic feedback, such as traditional box trainers or augmented reality simulators, such as the ProMIS AR simulator. We did not find an additional value of virtual reality simulation over traditional box trainers or augmented reality simulation in laparoscopic suturing training. One should consider that future development of non-haptic VR simulation tools should focus on basic skills and component tasks of procedural training in laparoscopic surgery, rather than on laparoscopic suturing.

Acknowledgments

The authors are grateful to all participants for their engagement in these studies. The authors thank Cees Schot and Guy van Dael for their technical and audiovisual support. We thank SimSurgery for unconditionally providing the equipment and software used in study II.

Chapter 7.

Influence of the integrated operating room and Pro/cheQ on patient safety

In the previous chapters the application of virtual reality simulation tools is explored and some aspects of the simulator interface that affect the efficacy of training on these tools are discussed. However, preclinical training alone is not sufficient to improve the quality of performance of and patient safety in image-based procedures (IBP). In the operating room (OR), the quality of performance and outcome of surgery is depending not only on the skills of the physician but also on other factors, such as on the interaction between the different members of the surgical team and their interaction with the dedicated IBP equipment. In this chapter, two promising design solutions that aim to improve patient safety in laparoscopic surgery are evaluated: the integrated operating room and Pro/cheQ, a procedural checklist and time-out tool. Both these products are developed to support the surgical team in their interactions with the laparoscopic interface and with each other, allowing the surgeon to better concentrate on the therapeutic actions of the procedure.

Risk sensitive events during laparoscopic cholecystectomy [*]

In the early days laparoscopic surgery came with a relatively large number of complications and adverse events[58, 122]. Compared to traditional open surgery, laparoscopic surgery requires a different set of skills and the surgical team is more dependent on technology to perform the procedure effectively and efficiently[33, 47, 181]. The operating room (OR) is considered to be the most common site for adverse events in hospitals, of which many may be prevented[33, 100, 181]. In the OR adverse events can have various origins. They can be related to surgical competence, but also to teamwork skills, equipment problems, ergonomic shortcomings of the instruments, or fatigue[33, 58, 181]. The

[*] Published as: Buzink SN, Van Lier L, de Hingh IHJT, Jakimowicz JJ (2010) *Risk sensitive events during laparoscopic cholecystectomy; the influence of the integrated operating room and a preoperative checklist tool.* Surgical Endoscopy 24: 1990-1995.

Dutch Healthcare Inspectorate established that almost 20 years after the introduction of the technique, there are still no standards to ensure the quality and safety of performing laparoscopic surgery[171]. Patient safety for laparoscopic surgery needs to be better safeguarded by creating barriers to prevent risk sensitive events (RSE). RSE are events that as such appear seemingly unimportant and easy to solve without consequences for the patient; however, under certain circumstances could contribute to and result in an adverse event[135].

Technological innovations such as the integrated OR system can help to prevent technical problems, improve ergonomics, reduce OR clutter, and enhance efficiency by decreasing turn-over time and improving the flow of information[7, 81, 90]. The use of preoperative checklists and time-out briefings to prevent surgery on the wrong patient, site, or side have also shown to improve patient safety, OR efficiency, and surgical outcomes[78, 106, 128, 149, 180]. The aim of this study was to investigate the influence of the integrated OR system and the combined effect of the integrated OR system with Pro/cheQ, a digital procedure-specific checklist tool, on the number and type of instruments and equipment related RSE during laparoscopic cholecystectomies. The cholecystectomy procedure was chosen because it is a very common procedure performed by operating teams of which the composition frequently alters and often includes surgeons and nurses in training.

Materials and methods

In a large non-university teaching hospital 45 random laparoscopic cholecystectomies were recorded and analysed in three different OR settings. Fifteen laparoscopic cholecystectomies were registered in the cart-based laparoscopic OR setting in July and August 2005. The OR staff was given the chance to become acquainted with the Karl Storz OR1™ integrated OR system which was introduced in January 2006, after which 15 laparoscopic cholecystectomies were registered in the integrated setting (April to June 2008). Finally, from July to September 2008, another 15 laparoscopic cholecystectomies were registered in the integrated setting while using the Pro/cheQ tool. During all registered procedures the operating team consisted of a surgeon and surgical trainee performing the surgery, assisted by a scrub nurse, circulating nurse, and often also a surgical intern to handle the laparoscope.

The cart-based OR and integrated OR equipment

In the cart-based OR setting, the standard laparoscopic equipment (insufflator, xenon light source, and camera control unit, all by Karl Storz) was placed on a cart with a CRT monitor on top and a flat-screen monitor on a swivel-arm attached to side of the cart. The diathermy equipment and the suction/irrigation system were each placed on a separate cart. All observed procedures in the integrated OR setting, with and without using Pro/cheQ, took place in the same OR equipped with the Karl Storz OR1™ system, comprising all SCB®, Telemedicine, and AIDA® modules available at the time. The stack comprising the standard laparoscopic equipment, electro surgical equipment, the suction/irrigation system, and a flat screen monitor was suspended on a ceiling-mounted boom-arm. Three flat screen monitors and the OR1 touch screen were each attached to separate ceiling-mounted boom-arms.

Pro/cheQ

Pro/cheQ is a digital checklist tool designed to prevent RSE and enhance the quality control during laparoscopic surgery by structuring and standardising the preparation of equipment and instruments, time-out moments, recording of intra-operative images,

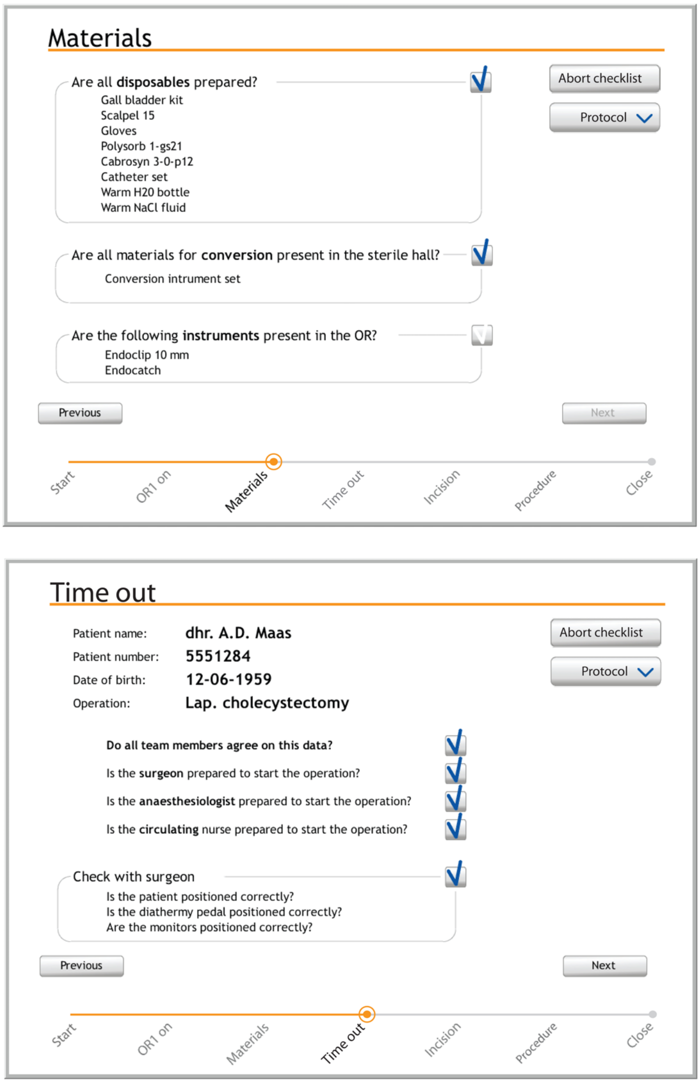

Figure 7.1. Screenshost of the 'prepare materials' and 'time-out' pages of Pro/cheQ.

debriefing, and filling out the operation report (Figure 7.1). Pro/cheQ was developed following an iterative design process with a user-centred and user-participatory approach; combining knowledge from literature review with observations in the OR and multiple experts sessions with surgeons, OR nurses, and anaesthesiologists[174]. The circulating nurse fills out most check items; however, completing Pro/cheQ requires active involvement of the whole surgical team. Therefore, all members of the surgical team of the observed procedures received instructions prior to the start of the preparations on how to use the checklist tool. A stand-alone procedure-specific laptop-based prototype of Pro/cheQ was used in this study, which did not incorporate the functions requiring a link with the digital hospital information system[174]. These functions were therefore simulated by the observing researcher, for example by entering the patient data in Pro/cheQ and the AIDA system before the preparations of the procedure commenced.

Registration of the procedures

All procedures were recorded using a quad-audiovisual recording system that synchronously recorded the input from four cameras and one microphone. The recordings were started just before first incision and stopped when all the trocars were removed. Prior to each procedure, all members of the operating team were informed about the study and recordings and asked for consent. During all procedures, one of the researchers was present in the OR to observe the procedure and assist in the use of the checklist when requested. Procedures that were converted from laparoscopic to open procedures or where technical problems related to the recording equipment occurred were excluded.

In the cart-based OR setting, the quad-audiovisual stream comprised the laparoscope image, a room overview, and close-ups of the surgical team filmed by cameras mounted on top of the CRT monitor and the flat screen monitor, and a microphone. The video and audio streams were combined into one quad-audiovisual stream and recorded on a laptop. In the integrated OR setting, the AIDA and telemedicine facilities of the OR1 system were used to capture the images and combine them into one quad-audiovisual stream. The quad-audiovisual stream comprised the laparoscope image, a room overview, the touch screen interface, a close-up of the surgical team filmed by the OR1 surgical camera on a ceiling-mounted boom-arm, and the OR1 microphone. The quad-audiovisual stream was recorded by a separate DV recorder in the OR1 technical room to maintain availability of all OR1 functionalities for the surgical team.

Data analysis

The recordings were analysed by scoring the number and type of RSE related to the equipment or instruments used to perform the procedure. A RSE was defined as a situation when instruments or equipment were not available when needed by the surgeon. Next, the results for the three different OR settings were compared to each other qualitatively. A randomly selected sample of five procedures for each OR setting was additionally analysed by a second observer. The findings of the two observers for these fifteen procedures were compared and the inter-observer agreement was calculated. The Kappa statistic is often used for measuring inter-observer agreement. However, Kappa presupposes that the total number of events is known or can be estimated. This is not the case in this study, therefore the 'any-two agreement' measure was used[82]. In total, the two observers identified 29 different equipment or instrument related RSE in the sample of fifteen procedures, with a substantial 'any-two agreement' of 0.66.

Results

In 33 of the 45 analysed procedures, one or more risk sensitive events were observed (Table 7.1). Both in the cart-based OR setting and the integrated OR setting at least one event occurred in 87% of the procedures. In the integrated OR setting when using Pro/cheQ this was reduced to 47%. In total, 57 individual RSE were observed related to equipment or instruments (Table 7.1 and Figure 7.2). In the integrated OR with Pro/cheQ considerably less events occurred, compared to the cart-based OR the total number was reduced by 59% and compared to the integrated OR setting alone by 65%. In all three environments most events were related to the equipment. Most of the equipment and instrument related RSE that did occur in the integrated OR while Pro/cheQ was used were related to defects that could not have been identified during the preparation phase beforehand.

Table 7.1. The number of risk sensitive events during the observed laparoscopic cholecystectomies.

	Cart-based OR	*Integrated OR*	*Integrated OR with Pro/cheQ*
Procedures ≥ 1 RSE	13 (87%)	13 (87%)	7 (47%)
Procedures with: 0 RSE	2	2	8
1 RSE	6	5	6
2 RSE	5	6	1
3 RSE	2	1	0
6 RSE	0	1	0
Total number of RSE	22	26	9
Equipment related	15	19	6
Instrument related	7	7	3

Discussion

General awareness has risen that patient safety needs to be improved, especially during procedures that are more dependent on technology and demand extra skills from the surgical team, such as laparoscopic surgery. Besides the skills of the surgeon, various non-technical elements are of influence on the surgical performance and patient safety[33, 58, 181]. Vincent et al. (2004) claimed that, amongst others, attention to ergonomics and equipment design and enhancing communication and team performance could even have a stronger influence on performance than surgical skills[181]. The use of an integrated OR system has the potential to improve the ergonomics, safety, and efficiency of laparoscopic surgery[7, 81, 90]. The application of preoperative checklists has also shown to improve patient safety considerably[78, 106, 128, 180]. We aimed to investigate the combined effect of using an integrated OR system, the Karl Storz OR1, together with a procedure specific digital checklist, the Pro/cheQ tool, on the number and type of equipment and instrument related risk sensitive events (RSE).

This study showed that, in comparison to the cart-based OR, the combined usage of the integrated OR and the Pro/cheQ tool had a stronger reducing effect on the number of RSE than the usage of the integrated OR alone (Table 7.1). The type of events that occurred also differed (Figure 7.2). Most RSE during the 45 observed procedures were restored by adjustment of the equipment settings or position. However, each event did disrupt and prolonged the surgical process. In many cases the origin of the event could be traced back to the circulating nurse, who had forgotten or knowingly omitted to prepare something timely without informing the other members of the surgical team. Routine usage of Pro/cheQ proved to be feasible, it supported the optimal workflow in a natural way and was considered to be constructive by surgeons, anaesthesiologists, and both inexperienced and experienced OR nurses[174]. The findings of this study are in concordance with previous investigations into the occurrence and type of equipment related RSE during laparoscopic surgery, where equipment related RSE were observed in 87% and 42% of the laparoscopic procedures[41, 179]. And a study by Verdaasdonk et al. (2008) showed a similar effect on the reduction of RSE by the use of a reusable preoperative paper checklist for laparoscopic cholecystectomies; the number of procedures with one or more RSE was likewise reduced from 87% to 47% [180].

The impact of using Pro/cheQ extended beyond a reduction of RSE. It raised the general safety awareness amongst the OR staff and improved the understanding of the importance of using all available means to work accordingly. To streamline the understanding of responsibilities and synchronise expectations amongst the members of the surgical team, Pro/cheQ structured several key elements of the communication within

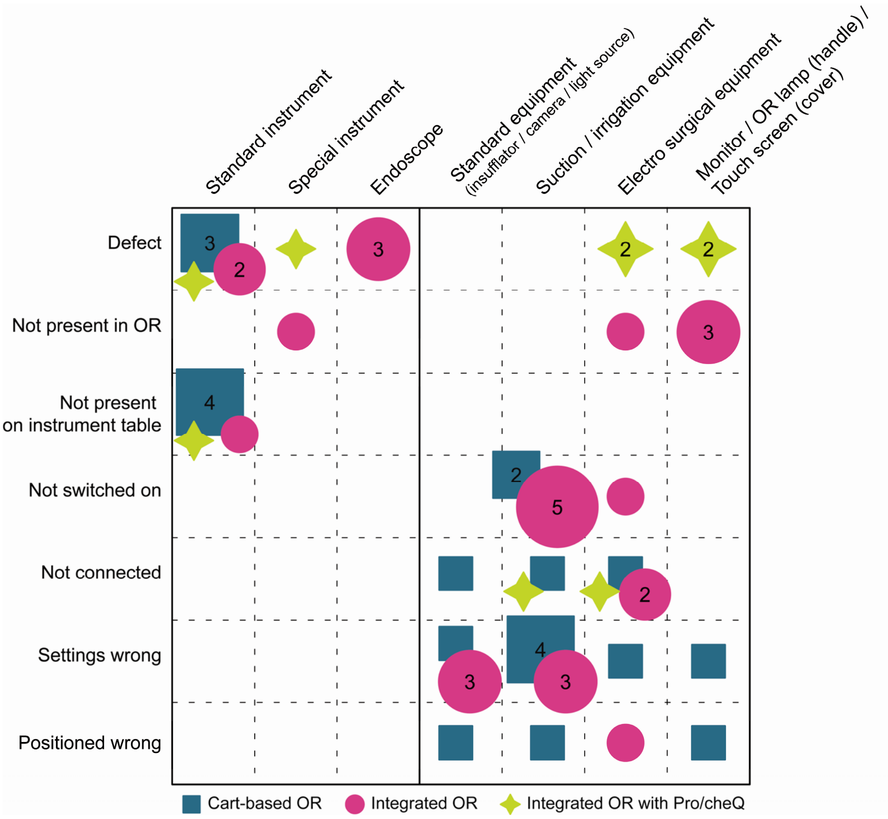

Figure 7.2. Type of equipment and instrument related risk sensitive events in the three different OR settings.

the team and required several issues to be uttered out loud in the presence of the whole team. The circulating nurse had the responsibility to secure the quality and course of the preparation process and filled out most of the checkmarks, but the whole team was responsible to execute Pro/cheQ properly. Catchpole et al. (2008) highlighted that improved team skills are associated with speedier completion of operations[33].

Unfortunately, adverse events can never be completely prevented. The engagement of the OR staff to look after quality and safety and the actual usage of supporting tools and set-ups such as the integrated OR and checklist is very important. In our hospital the technical department routinely checks all equipment following strict protocols and the scrub nurse checks the standard instruments prior to the start of each procedure, still several defects occurred during the observed procedures. Besides opportunities, new technology also brings along new risks and challenges[60]. The introduction and instructions for the use of new instruments and equipment often focuses mainly on functionality, while new tools are not always intuitive or straightforward in use. When using new technology to perform a procedure being already standard, a surgeon might encounter problems that expose previously unidentified gaps in his knowledge (related to the surgical technique or utilisation of the technology, for example), in such a case he can not rely on existing heuristics or experience, but has to find new ways to bridge these gaps on a ad hoc basis. Improper usage of a product can sometimes affect a product's functionality and create unsafe situations. To keep a checklist workable and efficient, it can not comprise all potential issues to ensure detection of equipment defects before surgery. The OR staff should have sufficient knowledge about the working of the equipment and instruments, how to use them aptly, and how to act and troubleshoot if something unexpected occurs.

It can be pivotal for the success of an innovation not to underestimate the value of the implementation process when introducing new products or tools[106, 127]. The implementation process should be broadly based within the hospital; all staff should be familiar and aware of the added value and importance of the innovation. Training should focus on the application of the innovation as a whole, and create awareness and understanding about its added value for the total care chain. Preferably, the future users should also have a sense of ownership of the solution[106, 127]. Pro/cheQ was developed following a user-centred and user-participatory design approach, which diminished the habitual reluctance to changes in the existing workflow. This effect was also recognised in a similar project by Lingard et al. (2008)[106].

The set-up of this study had some limitations. Fifteen months after introduction of the integrated OR system, which did include a brief training of the OR staff, many of its functionalities were not actively used. The use of functionalities such as importing patient data from the digital hospital information system into the AIDA system was highly depended on the circulating nurse’s personal preferences. Using Pro/cheQ in the integrated OR setting enforced the use of the key functionalities of the integrated OR. Possibly, this has influenced the results. The found decrease in RSE in the integrated OR setting where Pro/cheQ was used is probably not only the achieved due to the use of Pro/cheQ, but also by the better use of the OR1 system. Second, Pro/cheQ was designed to run of the touch screen of the OR1 system. For this study though, a laptop-based prototype of Pro/cheQ was used and some Pro/cheQ functionalities were simulated. This made the presence of the checklist tool less prominent and less enforcing. Using an integrated OR system or Pro/cheQ properly does require a change of mindset and routine. And while the teams did receive training, only 15 procedures were analysed per OR setting. Even though a considerable reduction of RSE was found, we expect that when used over a longer period of time, fully embedded and no longer perceived as ‘the new routine’, the benefits for patient safety of these tools can be even larger.

This study focused on equipment and instrument related RSE only. However, Pro/cheQ is more than a preoperative checklist. It was developed not only to prevent equipment and instrument related RSE, but also to improve the quality control throughout laparoscopic surgical procedures. Additional research is needed to further investigate the contribution of the integrated OR and Pro/cheQ on overall surgical performance and safeguarding of quality control. To further improve the safety and quality of surgery, a multifaceted approach should be followed. In this the improvement of the usability of the instruments and equipment is important as well as crew resource management and implementation of protocols and checklist to standardised work routines[41, 179]. The focus should shift from the technical skills of the surgeon to the competence and performance of the whole surgical team.

Conclusions

During laparoscopic surgery patient safety needs to be safeguarded better. Using both an integrated OR system and the Pro/cheQ tool reduces the occurrence of equipment and instrument related risk sensitive events further than using an integrated OR only. The type of events observed in the cart-based OR, the integrated OR and the integrated OR while using the Pro/cheQ tool differed as well. Routine usage of the Pro/cheQ tool proved to support the optimal workflow in a natural way. The impact of using Pro/cheQ extended beyond the reduction of RSE, it raised the general safety awareness and synchronised the mutual understanding of responsibilities and expectations amongst the members of the surgical team. The engagement of the OR staff to value having a safety culture and actively use tools such as the integrated OR and checklist is very important. The implementation process of such tools should be broadly based within the hospital. To further improve the safety and quality of surgery, a multifaceted approach should be followed, which should focus on the performance and competence of the surgical team as a whole.

Acknowledgments

The authors are grateful to the OR staff of the Catharina Hospital Eindhoven for their engagement in this study. The authors also thank the staff of the audiovisual department of the Catharina Hospital Eindhoven for their audiovisual support.

Chapter 8.

General conclusions and discussion

In this thesis the overall aim is to improve patient safety in image-based procedures (IBP) by better safeguarding the quality of performance of physicians performing these procedures. Within this scope, the focus is on the interaction of the physician with the IBP interface.

8.1 Conclusions

When performing image-based procedures physicians should be allowed to concentrate on the therapeutic tasks rather than on the interaction with the IBP interface. To achieve this, the gap between the preferred and actual level of proficiency of the physician should first of all be diminished. Preferably this is done preclinical, by using simulation tools. Therefore, we studied the realism and didactic value of currently available virtual reality (VR) simulators for training and assessment of basic skills for laparoscopic surgery and flexible lower gastrointestinal endoscopy (colonoscopy) (Chapter 3 and Chapter 4). In addition, we investigated the relation between different IBP skills (Chapter 3.1 and Chapter 5) and the influence of specific characteristics of the interaction with the simulator interface on the efficacy of preclinical training on simulators (Chapter 6). Furthermore, the quality of performance should be better safeguarded by improving the interaction with IBP interfaces in the clinical practice. We therefore looked at the impact of a currently available technological innovation (the integrated operating room system) and a promising new tool (Pro/cheQ, a procedural checklist tool) on safeguarding patient safety (Chapter 7).

Training and assessment of basic IBP skills using simulation

The SimSurgery SEP VR simulator (Figure 8.1) for laparoscopy proves to be a valid (face and construct) and valuable tool to train and assess skills in bimanual tissue manipulation (Place Arrow task) and navigation with a 30 degree angled laparoscope (Chapter 3.1). After following a relative short training programme of only 15 task repetitions, the performances of the Novices on the simulator can reach the level of performances of experienced laparoscopic surgeons (Chapter 3.2). When comparing performances on bimanual tissue manipulation and angled laparoscope navigation, performance parameters generally correlate significantly within each task for both the novices and experienced laparoscopists. Between the performances of both these tasks (bimanual tissue manipulation and angled laparoscope navigation) however, a correlation is not always present (Chapter 3.1). Overall, the differences in performance by the novices and the experienced laparoscopists are more distinctive for the bimanual tissue manipulation task than for angled laparoscope navigation. The Simbionix GI Mentor II VR simulator (Figure 8.1) is a valid (face and construct) and valuable tool to train and assess basic colonoscopy skills (Chapter 4.1). When novices take part in a relatively brief training programme of 15 exercises on the GI Mentor II, the difference in performance compared to more experienced endoscopists decreases considerably, but do not reach the performance level of the experienced endoscopists (Chapter 4.2). Comparison of the laparoscopy performances of a group of novices with prior training in colonoscopy with the performances of a group of novices without this experience (and vice versa) shows that training in basic colonoscopy tasks does not affect performance of basic laparoscopy tasks (and vice versa) (Chapter 5). Thus, it can be concluded that training in basic skills for different IBP does not have to be done consecutively and can be mixed. Also this work shows that, when learning a new IBP technique, it is not necessarily advantageous to have experience in another IBP technique. Psychomotor skills required to perform basic laparoscopy and colonoscopy tasks are not directly interchangeable.

Figure 8.1 The SimSurgery SEP VR laparoscopy simulator (left) and the Simbionix GI Mentor II VR colonoscopy simulator (right).

Efficacy of training and assessment of laparoscopy skills using simulation

Differences in user-interface interaction for different basic IBP tasks (e.g. manipulation of an angled laparoscope versus manipulation of a laparoscopic grasper) are important to consider before actual implementation of simulators for training or assessment purposes. Yet, these differences and their influences on the hand-eye coordination are not always taken into account when tools for training of laparoscopic skills are considered. More in-depth knowledge is needed on the physical and cognitive aspects of the interaction with the instruments and interpretation of visual information during laparoscopic surgery, in both the clinic and skillslab setting. In this thesis we found that angled laparoscope navigation task on the SimSurgery SEP VR simulator (Figure 8.1) is performed better in the abstract virtual environment than in the specific virtual environment representing the abdomen with anatomic landmarks (Chapter 6.1). This influence of the virtual environment on the task performance is not related to the level of experience.

The ProMIS augmented reality (AR) simulator is regarded as a better tool to train surgical residents in laparoscopic suturing than the LapSim VR laparoscopic simulator (Figure 8.2) (Chapter 6.2). This is most likely because the tasks offered by the ProMIS simulator provide more realistic haptic feedback than those on the LapSim simulator. In addition, no added value was found for training in laparoscopic suturing on the SimSurgery SEP VR simulator, without haptic feedback, (Figure 8.1) over training in laparoscopic suturing on a traditional box trainer (Figure 8.2) (Chapter 6.2). Even though objective assessment of the performance is an obvious benefit of the VR simulator, for laparoscopic suturing training surgical residents prefer the traditional box trainer. The value of VR simulation without haptic feedback has been proven for training in a broad range of laparoscopy tasks. For training of laparoscopic suturing tasks however, haptic feedback is considered a necessity.

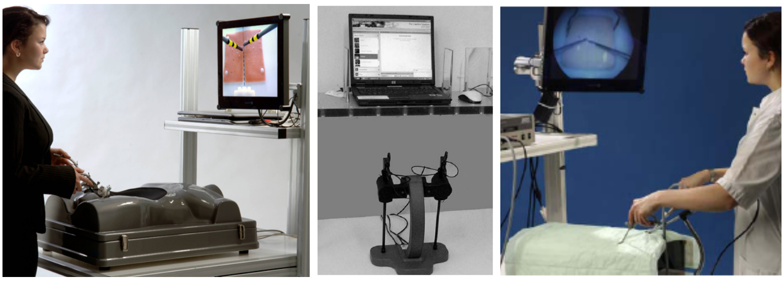

Figure 8.2 The Haptica ProMIS AR laparoscopy simulator (left), the Surgical Sciences LapSim simulator (middle), and the traditional box trainer (right).

The influence of the integrated OR and Pro/cheQ tool on risk sensitive events

To improve patient safety and quality control in the laparoscopic operating room (OR) a substantial change in working routines is required. Technological innovations such as the integrated OR system has the potential to improve the ergonomics, safety, and efficiency of laparoscopic surgery. Pro/cheQ is a digital procedural checklist tool designed to safeguard patient safety and enhance the quality control during laparoscopic surgery by structuring and standardising the preparation of equipment and instruments, time-out moments, recording of intra-operative images, debriefing, and filling out the operating report. Using an integrated OR system together with the prototype of Pro/cheQ reduces the number of equipment and instrument related risk sensitive events further than using only an integrated OR (Chapter 7). The type of equipment and instrument related risk sensitive events that occur in cart-based OR, integrated OR and the integrated OR while using the Pro/cheQ tool change as well. The Pro/cheQ tool proves to support the workflow in a natural way. The impact of using a procedural checklist tool such as Pro/cheQ raises the general safety awareness and synchronises the mutual understanding of responsibilities and expectations amongst the members of the surgical team.

8.2 General discussion

There is general consensus that patient safety during surgery needs to be improved[27, 93, 181]. This applies in particular to image-based procedures, as effective and safe performance of this type of procedures is more technology dependent and brings about an elevated physical and cognitive workload for the team[15, 58]. The outcome of image-based procedures and the level of patient safety during the procedure are influenced, amongst others, by the quality of performance of the surgical team[181]. The quality of performance is dependent on a wide range of human factor elements. Besides the skills of the physician it also depends on aspects related to the interaction within the surgical team, the interaction with the technology and operating room environment, and the safety culture within the hospital in general and in the OR specifically. This intricate combination of factors means that there is no easy solution to ensure the quality of performance and safeguard patient safety[181]. To improve patient safety it is therefore necessary to take measures and create several safety barriers at different levels within the healthcare chain[135]. These system barriers are often relative and reliant on human factors, in contrast to the barriers in other high-risk industries, such as aviation, nuclear and petro-chemical industry, where built-in technology can be applied to create absolute barriers. The overall system of care for each individual patient involves many interactions between different healthcare professionals. Due to the complexity and dynamics of this system, it is unrealistic to believe that, by taking the proper measures and creating enough barriers, all errors can be prevented. Instead, the aim should be to ensure that the overall risk of errors is as low as reasonably possible[44, 135]. And if errors do occur, their consequences should be minimal and not lead to an adverse event. Thus, a broad basis of support is needed from all involved hospital staff. To allow the healthcare professionals who are in direct contact with patients to commit to a safety focused care process, their supervisors and the hospital management should actively support the necessary alterations in mindset and working routines. The socio-economic situation in the western world is changing, making healthcare more expensive. Subsequently, hospitals are more and more run like businesses. Therefore, the necessity to improve patient safety should also be founded on incentives by the healthcare authorities and backed by decisive measures from the appropriate governmental bodies. Improving the quality of care and patient safety is thus a responsibility of all those within the healthcare system; from the OR nurse to the healthcare state officials, the physician to the maintenance engineer, and from the medical educator to the logistic manager of the OR. The implementation of safety measures should be properly overseen and managed to avoid a proliferation of potentially conflicting strategies and keep all staff motivated to jointly strive for a higher level of safety.

It is surprising that in healthcare, being one of the largest industries worldwide, the importance of having a safety focused work environment has been neglected for so long. In other high risk industries, the role of human factors in causing errors has been acknowledged earlier and in those fields various measures have proven to increase the level of safety considerably[27, 135]. The work presented in this thesis specifically focuses on the application of VR simulation tools to train and assess some of the required psychomotor skills that physicians need to perform image-based procedures (Chapter 3-6); something already common practise for pilots in aviation. Studies by others have shown that basic IBP skills acquired on simulators do transfer to the clinic and improve the quality of clinical performance[40, 156, 165]. In other high risk industries, the integration and central control of equipment (like in the integrated OR setting) and the use of checklists and time-outs (like Pro/cheQ) is not considered very innovative. Yet for IBP, these innovations are beneficial to help physicians to better concentrate on the therapeutic tasks and thus help to improve the quality of performance and patient safety, as shown in Chapter 7 of this thesis and the work done by Wauben et al.[184]. It seems logical that by this achieved reduction of risk sensitive events, the risk of adverse events is also decreased. Yet, the true impact of measures on the occurrence of adverse events and patient safety overall should be investigated further. Other safety measures which have proven their value in other high risk industries, such as scenario-based training, crew resource management (CRM) training, and procedural rehearsal or warming-up prior to the actual performance appear promising for healthcare too[27, 181]. The significance of the implementation process to make safety innovations into a success should also not be underestimated. To overcome the habitual reluctance of people against changes in their ingrained working routines, people should first be fully aware of the need for a safety-focused working routine and the added value of the proposed safety measures. In this, involving end-users in the development or implementation process is beneficial[106, 127].

In healthcare the current focus on safety could prove to be a turning point to bring about a substantial cultural and political shift, just as it happened in aviation. Assertiveness needs to become a more appreciated trait for all healthcare professionals and responsibility and liability regarding patient safety should shift to the whole team. This also means that healthcare professionals should become more self-conscious and no longer resign in the fact that complaining about being highly stressed or fatigues is 'not done'. For example, healthcare professionals should ensure that they are familiar with ergonomic guidelines and adapt their working environment according to these guidelines. For procedures that are highly technology dependent the physician should be knowledgeable on the background of technology facilitating the procedure, its drawbacks, how to apply it appropriately, and be conscious of potential risks if applied otherwise. This applies for example for the use of electrosurgical dissection, which can become a lethal weapon in ignorant hands.

The need for a comprehensive curriculum

VR simulators have proven to be valuable tools to acquire and assess IBP skills (Chapter 3 and Chapter 4). The studies presented in this thesis also added to the knowledge on the relations between different IBP skills (Chapter 3 and Chapter 5) and the influence of specific characteristics of the simulator interface on the performance and acceptance of VR simulators for training and assessment of IBP psychomotor skills (Chapter 6). The next step should be assessment of clinical performance in relation to simulator training. This will show the potential of the VR simulator and form the basis for the development of a comprehensive curriculum to properly train physicians in IBP skills[163]. It is already clear that just having a VR simulator at the trainees' disposal is insufficient to make them train adequately on it[36, 94, 163]. Deliberate psychomotor practise and participation in courses to train and assess IBP skills therefore needs to be enforced and should be embedded in the overall education and training.

First of all, an IBP curriculum should be comprehensive and comprise training in the required cognitive, technical, and judgement skills, but also pay attention to non-technical skills training by including team training and scenario-based training[191]. This holistic approach is important, as it is believed that a skilful performed surgical procedure only depends for about 25% on the technical skills of the physician[68]. The tools used and training approach followed within the curriculum play an important role, they should provide proper and objective feedback on performance and offer well-balanced goal-oriented training. Most of the currently available tools are developed only to train or assess a specific skill or performance of component tasks[67]. However, more and more procedural simulation models are emerging on the market these days. Overall, the complete IBP skills set should be represented in the curriculum; yet, it is no necessity to have them all integrated in one single simulation tool. A smart combination of tools could be used, in which each training modality fits a specific (sub-)learning objective best. It is important that for each task the selected simulation tool matches the training or assessment goals. IBP tasks can differ considerably in relation to the demanded visual-spatial skills, hand-eye coordination, or interaction with the tissue through the IBP interface. In the selection and implementation of the simulation tool these differences and key interaction characteristics should be taken into account. The level of fidelity of simulation tools (as in the visual appearance of the task and its surrounding environment (Chapter 6)) may also vary, as long as the functional characteristics of the interaction with the tissue though the IBP interface are accurately simulated. For training of some IBP skills, for example, it is acceptable to use a simulation tool without haptic feedback, while for other IBP tasks having accurate haptic feedback is crucial, as shown in this thesis for laparoscopic suturing (Chapter 6). And, training of different component tasks for a specific procedure, could take sequentially place on different simulation modalities: learning how to prepare the patient and OR on a desktop computer, dissection of the tissue on a virtual reality simulator, and suturing on an augmented reality simulator. An augmented reality laparoscopy simulator could be used within a simulated OR setting together with an anaesthesia simulation tool to replicate the performance of a specific procedural task with the whole team[4]. This allows simultaneous training and assessment of technical and non-technical skills within a controlled environment in which it is safe to learn from errors. Such combined training might also expose differences in expectations within the team and latent risks related to the IBP equipment.

Due to the complex nature of IBP skills, acquiring them demands extensive repetitive practise[163]. Setting performance requirements on simulators before allowing clinical performance of specific image-based procedures creates some external motivation. However, to secure learning and retain the trainee's interest in the repetitive practise of particularly the basic IBP tasks, the simulated task should also be sufficiently engaging and challenging. The visual appearance of the task and its surrounding environment, or anatomical fidelity, could make an exercise more appealing to medical trainees. However, as they are most accustomed to the visual and tactile appearance and behaviour of human tissue, they can become easily distracted by a deficient representation of the anatomy and tissue behaviour provided by the simulator during a specific exercise, which could affect their performance (Chapter 6). The distribution of and variation in exercises within the curriculum should also be well-considered, as these have also shown to have an impact on the efficacy of learning[109, 163, 178]. Future research should provide more insight in the impact of different factors that relate to contents and the set-up of IBP curricula.

The challenge of criterion-based training and performance assessment

To safeguard the quality of performance and patient safety in IBP, objective assessment of IBP skills and overall performance is key. Instead of accreditation based on the number of performed procedures and/or a semi-subjective evaluation by a preceptor, performance assessment and accreditation should become more criterion-based. Following a criterion-based approach for training will most likely also improve the efficiency and efficacy of IBP curricula and skills assessment[86]. To achieve this goal, more insight is needed in the composition of the skills within the overall IBP skills-set, their mutual interrelation, and how they develop over time and with increasing experience. It is known that the role and impact of some skills and abilities on overall performance can change due to ageing or by increasing levels of experience[89, 138]. Further research is also needed to determine the general shape of the learning curves for IBP (sub-)skills and what could be regarded as appropriate/acceptable criterion or performance thresholds to move to the next level of training or for accreditation to clinically perform a procedure. The thresholds for different types of IBP tasks could also be more divergent than assumed up to now. The currently available performance curve studies mostly describe performance improvement over relatively short training programmes. Even though performance sometimes proved to level out over the course of these brief programmes (as they also did in the some of the studies presented in this thesis), they generally do not provide insight in whether the trainees reached their training end-point. As the overall performance of IBP draws on a variety of skills and abilities, it could well be that before a trainee reaches his training end-point he will pass through multiple plateaus in the performance curve[21]. A better understanding is needed of the proficiency thresholds for individual IBP tasks and the corresponding training end-points for training of these tasks on simulators. More longitudinal studies are therefore considered required, which should also take a broader range of skills and factors that influence learning and IBP performance into account. Transfer of IBP skills acquired preclinical by training on simulation tools to performance in the clinical setting has been evaluated, but only to a limited extent[156]. Instead of performing straightforward randomised controlled studies into the effect of simulation training on clinical performance (which is actually already considered to be unethical), randomised controlled studies should be set up comparing the effect of different curriculum lay-outs.

One of the prospects of computer-based simulator for IBP was that, amongst others, trainees would require substantially less feedback of experienced physicians to learn about their mistakes and how to improve their performance, as the simulator can keep track of the performance of the trainee and provides feedback upon the performance[5]. Most simulators however only provide summative feedback after completion of the task; during the performance of the task commonly only general remarks or tips are provided. Thus, experienced physicians are still needed to observe the task performance and instruct trainees on how to best improve the execution of the task. Even though the objective recording of performance is still regarded as major distinguishing feature of computer-based simulation over traditional box trainers, the main assessment parameters used by these systems and the summative feedback they present are still under debate[165]. To be perceived as representative for the true level of skills the feedback should be clinically relevant, comprehensible, and presented within a suitable context. Presenting raw numbers or only a pass/fail notification as summative feedback should be avoided, as these alone do not provide sufficient insight in the quality of performance and the elements of the task one should focus on to improve performance. Preferably the performance should be presented alongside references such as the optimal level of performance, the demanded criterion, or preceding performances of the same task by the trainee himself, peers, and/or experts. The customary, easy to measure parameters such as time and total instrument path length should at least be accompanied by scores related to error and the quality of performance. Computer-based simulators are able to produce loads of data upon each task performance; however, only the surface has been scratched in regard to which aspects of the performance represent the skills level best. Comparison of simulator output of distinctly different expertise levels tells something about the validity of the simulator and is useful to roughly estimate individual performances. However, most simulators have much more difficulty distinguishing between physicians who are regarded as intermediately or very experienced. And, we should question whether it is fair to apply the same performance parameters and performance analysis for both training and assessment purposes. Learning could be concentrated in different skill areas along the various stages of the overall IBP learning curve. Also the requirements in relation to the characteristics of the simulation tool could differ between training or assessment purposes. Therefore, more research is needed to identify better distinguishing characteristics of performance for all the different IBP tasks. These are likely to be found deeper under the surface of the performance; most likely in the details of the instrument movements and interaction with the tissue. And, as the interpretation of the on-screen visual information is a key component in the hand-eye coordination in IBP, it might be worth it to look also outside the box and expand the area in which performance parameters are measured. Elements such as eye-gaze pattern, mental workload, dealing with distractions, and muscle strain could be interesting for inclusion in the equation as well[30, 76, 133, 151].

In the development and validation of IBP simulation tools, expert IBP physicians have played an important and often directive role. When performing a task on the skill-based level however, one is not always aware or able to describe in detail what information is used during the performance of the task[134]. Thus, the skilfulness and vast experience of the experts involved in research and design of IBP simulators does not necessarily warrant that they are able to transfer to the designers the key characteristics of their interaction with the IBP interface. In addition, to identify a design or learning related problem, analyse it, or create a fitting solution to such a problem each requires different set of expertise. Hence, it is important that design and evaluation of simulation tools is done by multidisciplinary teams involving also educationalists, cognitive psychologists, and user-interface design engineers.

Bringing the worlds of the skillslab and clinical practise closer together

The healthcare field will keep evolving, new technologies will enter the OR over and over again, and healthcare professionals will never be finished learning. Before, medical training and assessment of performance of physicians after they completed medical school was an integral part of the clinical practise and based on the Halstedian residency-based master-apprenticeship system. Currently, due to medicolegal, ethical, and socio-economic considerations more and more elements of medical training and performance assessment tend to be pulled out of the clinical setting into the skillslab, to be dealt with one after the other. For now and into the near future, part of the education and training of healthcare professionals will still have to take place in the clinical setting with patients. There they learn to combine their newly acquired or updated skills and put them into practise as active member of the surgical team. Simulation technology is not yet advanced enough to offer a similar combination and diversity of cases (anatomical and pathophysiological) under comparable conditions. Simultaneously, the demand for better registration of clinical performance to secure quality of care, by means of developing and implementing so-called black boxes (like flight-data recorders in aviation), is gaining momentum too. This would involve real-time registration of different elements of the procedure by making video-clips for example, in addition to the traditional operative notes which are written post-operatively by the physician. Such a recording system can contribute to more objective operative notes and faster post-operative detection of errors leading to enhanced patient care[184]. Much can also be learned this way about the factors that affect the quality of performance and patient safety. This knowledge can subsequently be included in the skillslab training. And more directly, it provides means for post-operative team debriefing and reflection on performance, leading to imporved work routines and enhanced safety awareness. Ultimately, we envisage that this will lead to a new equilibrium in training and assessment of IBP skills and performance, in which the skillslab will take a more central role, closely intertwined with clinical practice, just as it occurs in other high risk industries. It will not only have a role to acquire new skills, but also to rehearse prior to performance and to recurrently check whether they are still at the appropriate level or need an update.

8.3 Clinical implications of this work

The outcomes of this research has influenced the clinical practice already in several ways. The insights gained by the simulator studies have lead to enhancement and enrichment of the courses teaching IBP skills provided by, at least, the Centre for Knowledge and Skills of the Catharina Hospital Eindhoven. This goes beyond the specific tools and programmes used in the existing courses. For example, the Centre for Knowledge and Skills of the Catharina Hospital Eindhoven now also offers several numbers of well attended courses per year on ‘Safe practice in the OR’ in which other members of the surgical team besides surgeons, such as OR nurses, are trained in basic psychomotor skills for laparoscopy amongst others, such as angled laparoscope navigation and basic instrument manipulation. This means that this work helped to provide many healthcare professionals improve their IBP skills by training on simulators in a skillslab so that they are better prepared to perform their work in the clinical setting.

In total, a large number of healthcare professionals with varying levels of expertise from different hospitals participated in our simulator studies. Besides novices, also many experienced physicians who perform image-based procedures on a daily basis in the clinical practise took part. Some only performed a small number of tasks; others took part in a training programme. For all applies that their participation and the feedback provided by the simulator gave additional insight in their skills level for a specific IBP task. On several occasions, this turned out to be quite confronting for the physician or medical trainee in question, when their simulator performance was not matching their expectation. This probably did have an impact on their opinion of realism or didactic value of the system (see the discussion Chapter 3.1). More importantly however, it also made those experienced participants aware of the gap between their own perceived and actual skill level or, for the medical trainees, made them rethink their intended career path.

This work also had a direct impact on the performance of IBP in the clinical practise. The observations during laparoscopic surgical procedures to analyse risk sensitive events in the cart-based and integrated OR settings exposed that the tools/systems provided by the integrated OR system were not fully used. After installation, the protocols to prepare the OR for laparoscopic surgery had not been altered accordingly. The Pro/cheQ procedural checklist tool enforced the operating room nurses and surgeons to use some of the main functions of the integrated OR, due to which they became aware of the systems functions and potential. When the test period for Pro/cheQ ended, part of its effect lasted. The study into risk sensitive events and the added value of the integrated OR and Pro/cheQ also impacted the attitudes of the OR staff towards the use of checklists and the need to create a safety culture. Within the followed user-participatory design approach all members of the OR team in our hospital had the opportunity to actively contribute to the functionalities and content of the Pro/cheQ tool. For our study, this helped to overcome the habitual reluctance of people when a new element needs to be implemented in an existing workflow. In addition, it made clear to all of the healthcare professionals working in the OR that patient safety needs to be improved and that the safety awareness needs to be increased, with the understanding that to this end some sort of checklist would need to be implemented. The Pro/cheQ tool was specifically developed for the laparoscopic cholecystectomies performed in an integrated laparoscopy OR setting. There was also a need for a more general checklist and time-out procedure, which could be used also for other types of surgery and in other OR settings. Besides benefiting from the results of our study, as in the set-up and content of Pro/cheQ, the responsible quality management team could also profit from the increased awareness and a diminished general reluctance to the use of checklists.

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Summary

Worldwide, it is estimated that about 10% of patients admitted to the hospital suffer from injuries caused by medical error. Within the hospital, the operating room (OR) has been identified as the most common site for medical errors, of which many are regarded as preventable. In recent years less invasive approaches of treatment have become available for a broad range of surgical procedures. Technical innovations allow physicians to perform surgery through small incisions or natural body orifices, by making use of imaging equipment to visualise the operating field. These so-called image-based procedures (IBP) involve all types of medical procedures that enable therapeutic intervention by minimal access while the physician intra-operatively perceives the operating area in real-time, though indirectly, through the use of imaging equipment. Some examples of image-based procedures are laparoscopy, flexible gastrointestinal endoscopy, and endovascular surgery. Many factors are of influence on patient safety and the outcome of surgery. The performance of IBP comprises several factors that endanger the quality of performance and patient safety more than the performance of traditional open procedures does. The image-based performance of surgical procedures brought a lot of additional and new technology into the OR. As a consequence, it considerably changed the interaction of the surgeon with the operating field and also the interaction within the surgical team. In IBP, the equipment and instruments forms the interface between the surgical team and the operating field and the dependence on the equipment to perform the surgical procedure effectively, efficiently, and above all safely is much higher. The enforced dependability on and interaction with IBP equipment and instruments results in an increased mental and physical workload for the surgical team which subsequently increases the level of fatigue and reduces the focus on the execution of the surgical procedure.

This thesis focuses on improving patient safety in image-based procedures by better safeguarding the quality of performance of physicians performing these procedures. Key elements in ensuring quality of performance of IBP are the level of proficiency of the physician performing the procedure and the interaction with the operating field via the IBP interface. To allow physicians to perform procedures image-based such that they can focus on the therapeutic tasks rather than on the interaction with the IBP interface, the gap between the preferred and actual level of proficiency of the physician should first of

all be diminished by means of preclinical training. The main objective in this thesis therefore is to investigate the use of simulation tools for preclinical enhancement of the proficiency of physician in specific psychomotor skills required to perform IBP. Second, the influence of the remaining gap on the physician's quality of performance should be bridged by improving the IBP workflow and interaction with IBP interfaces within the clinical environment. In this thesis the influence of some tools that aspire to achieve this goal is also evaluated. The overall field of IBP is too extensive to cover completely within this project; therefore, laparoscopy and flexible gastrointestinal endoscopy were selected as representative IBP types.

In **Chapter 2**, a brief historic overview is given of the development of image-based medical procedures and a categorisation of the overall field of IBP is provided, based on the role of the interface and the interaction characteristics of the different procedures. The human factors and ergonomic issues affecting the performance of IBP and the training and assessment of IBP-related skills are concisely discussed. In example for laparoscopy, where the fixed minimal access of the instruments, positioning of the dedicated equipment around the operating table, and limitations to instrument design are the main causes of physical inconvenience and complaints for the surgical team. IBP often also pose considerable cognitive and sensorial ergonomic challenges. To manipulate the instruments, the physician often requires additional spatial perception skills, as they have to interpret the two-dimensional on-screen information of the three-dimensional operating field and mentally translate the required movement of the instrument into an appropriate, frequently counterintuitive manual input.

By tradition, surgical training is based on the Halstedian model (a residency-based master-apprenticeship system) and accreditation is based on the number of procedures performed and the semi-subjective evaluation of an expert surgeon. In addition to general medico-legal and ethical concerns for patient safety, new work time restrictions, such as the European Working Time Directives (EWTD), have raised the need for preclinical training and objective assessment of proficiency. Furthermore, the master-apprenticeship model proved not to be adequate for IBP, amongst others due to the indirect interaction with the operating field, not allowing learning the nuances and consequences of actions by observation of an expert at work, and the fact that senior physicians are not necessarily as experienced in IBP as they are in open procedures. Virtual reality (VR) simulators could provide an effective alternative for clinical training of laparoscopy and flexible gastrointestinal endoscopy skills and can additionally fulfil the growing need for objective proficiency assessment. The overall potential, general value, and construct of VR simulators have already been proven for these surgical techniques. In **Chapter 3** of this thesis, the validity of the SEP VR simulator (SimSurgery AS, Oslo, Norway) to train and assess the performance on angled laparoscope navigation and bimanual tissue manipulation are established. Also, the relation between performances on the bimanual tissue manipulation task and laparoscope navigation task was studied. The results of our studies show that the SEP VR simulator is a valid and valuable tool to assess and train in both of these skills. Medical trainees can significantly improve their skills in those tasks by training on the SEP VR simulator following a relative brief training programme. At the end of the training programme, the performances of the novices on both tasks were of the same level as the performances of experienced laparoscopists. Comparison of the performance scores within and between the two tasks revealed that there is an obvious trend between the scores on the time to accomplish the bimanual tissue manipulation task or angled laparoscope navigation task and the total tip trajectory for the same task, in general and within the groups of novices and experienced laparoscopists. A correlation was not always found between the performances on the two tasks though, which suggests that clinically-based expertise in tissue manipulation does not automatically entail skilfulness in angled laparoscope navigation and vice versa. Training and assessment of basic laparoscopic skills should thus focus on these tasks independently.

In **Chapter 4** the validity of the GI Mentor II VR simulator (Simbionix Ltd, Cleveland, USA) for training and assessment of basic flexible lower gastrointestinal endoscopic skills is assessed, using a basic hand-eye coordination task and multiple virtual colonoscopy cases. Our results show that the GI Mentor II simulator offers a convincing realistic representation of colonoscopy and that the simulator can discriminate between performances of endoscopist of different expertise levels. Over four training sessions the novices improved their performances significantly, but their performance did reach the same level as the experienced or expert endoscopists for all performance parameters.

Flexible gastrointestinal endoscopic and laparoscopy are two commonly practised image-based procedures, of which the basic skills can be well trained preclinical using VR simulators. These two IBP have elements in common, such as the use of video as imaging technique. On other elements however, they differ considerably such as the hand-eye coordination and visuomotor translation to manipulate the camera and instruments. Gastrointestinal surgeons are often accustomed to perform both laparoscopy and colonoscopy and the existing assumption is that experience in one of those techniques is of considerable benefit when learning the other. However, the interaction between laparoscopy and flexible gastrointestinal endoscopy skills has hardly been studied. Current trends and novelties in technology and surgical techniques that draw from multiple types of IBP, such as Natural Orifice Transluminal Endoscopic Surgery (NOTES) fusing laparoscopy and flexible gastrointestinal endoscopy, increase the need for knowledge on transfer of skills amongst specialists in both techniques. In **Chapter 5** we explored the influence of colonoscopy training on the performance of basic laparoscopy tasks (and vice versa) by comparing the laparoscopy performances of a group of inexperienced endoscopists who had prior training in colonoscopy with the performances of a group of inexperienced endoscopists without this experience (and vice versa). To this end, medical trainees (inexperienced in IBP) were trained on the GI Mentor II simulator and the SEP simulator following a cross-over study design comprising the same tasks as used for the studies presented in Chapter 3 and Chapter 4. The results imply that training in basic laparoscopy skills does not affect the performance of basic colonoscopy tasks. Training in basic colonoscopy skills appears to have, to a limited extent, a positive influence on the performance of a basic angled laparoscope navigation task. Thus, it can be concluded that psychomotor skills required to perform basic laparoscopy and colonoscopy tasks are not directly interchangeable. It is not necessarily advantageous to have experience in another IBP technique when learning a new IBP technique. Simultaneously, these results also imply that training in basic skills for different IBP does not have to be done consecutively and can be mixed. Training and assessment of IBP-type-specific skills should focus on each type of IBP tasks independently.

Differences in user-interface interaction and hand-eye coordination are not always taken into account when tools for training for different basic IBP tasks are considered. In **Chapter 6** we therefore explored several different elements of the user-interface interaction that could influence the efficacy of training of specific laparoscopic skills on simulation tools. To examine whether the presence of anatomical landmarks is of influence on the performance of angled laparoscope navigation, as claimed by some experienced laparoscopic surgeons participating in the studies presented in Chapter 3, a group of experienced laparoscopic surgeons performed an angled laparoscope task on the SEP simulator in two different virtual environments: the standard SEP abstract environment and a VR environment representing the lower abdomen. The experienced laparoscopic surgeons performed the laparoscope navigation task with significantly better simulator scores in the abstract virtual environment, compared to in the virtual environment with anatomic landmarks. A similar difference was found in a group with inexperienced medical trainees, which means that this influence is not related to the level of experience. Laparoscopic suturing involves refined interaction with tissue and suturing materials, which most likely demands a more sophisticated level of feedback than can be obtained by visual feedback alone. It is therefore suggested that to learn laparoscopic suturing skills adequately, it is important that trainees experience haptic feedback when performing suturing related training tasks. The term 'haptic feedback' refers to the combination of tactile feedback through sensory skin receptors and kinaesthetic feedback through muscle, tendons, and joint sensory receptors. In general, it is also assumed that high-fidelity simulations with haptic feedback imply a better training effect and a better transfer of skills to the clinical setting. However, realistic haptic feedback during laparoscopic training is currently lacking in VR simulators. Therefore, the importance of haptic feedback and the added value of objective performance assessment for laparoscopic suturing training was investigated. To this end, two studies were carried out. In the first, the aim was to evaluate the suturing training provided by a VR simulator and an augmented reality (AR) simulator by having both systems simultaneously tested and their didactic value judged by laparoscopists of different expertise levels. In the second study, the added value of suturing training on a VR simulator besides suturing training on a box trainer was investigated. The results of both studies confirm that to acquire laparoscopic suturing skills realistic haptic feedback is essential. Training of laparoscopic suturing skills should therefore best be performed on a simulation system that provides proper haptic feedback, such as traditional box trainers or augmented reality simulators.

Improving patient safety and quality control in the laparoscopic OR, and partly bridging a potential gap between the preferred and actual level of proficiency of the physician, requires a substantial change in workflow and work routine. Technological innovations such as the integrated OR system have the potential to improve the ergonomics, safety, and efficiency of performing laparoscopic surgery. Pro/cheQ is a digital procedural checklist tool designed to safeguard patient safety and enhance the quality control during laparoscopic surgery by structuring and standardising the preparation of equipment and instruments, time-out moments, recording of intra-operative images, debriefing, and filling out the operation report. To assess the impact of these two promising tools on safeguarding patient safety in the OR, their influence on the number and type of equipment and instrument related risk sensitive events during laparoscopic cholecystectomy (gallbladder removal) was analysed (**Chapter 7**). Using both an integrated OR system and the prototype of the Pro/cheQ tool reduces the occurrence of equipment and instrument related risk sensitive events further than using an integrated OR alone. The type of equipment and instrument related risk sensitive events that occur in cart-based OR, integrated OR and the integrated OR while using the Pro/cheQ tool differs as well. Our study shows that the Pro/cheQ tool supports the workflow in a natural way. The impact of using Pro/cheQ extends beyond the reduction of risk sensitive events, it also raises the general safety awareness and synchronises the mutual understanding of responsibilities and expectations amongst the members of the surgical team. The engagement of the OR staff to value having a safety culture and actively use tools such as the integrated OR and checklist proves to be very important. The implementation process of such tools should therefore be broadly based within the hospital and follow a multifaceted approach.

Finally, **Chapter 8** summarises all research findings and discusses them in a broader scope. The general discussion re-evaluates issues related to the implementation of safety measures in healthcare, the need for comprehensive curricula to train IBP skills. The challenges related to criterion-based training and assessment are also discussed within this chapter. Some perspectives for further research are presented and the clinical implications of the studies performed are briefly discussed.

Samenvatting

Wereldwijd lopen naar schatting 10% van de patiënten die worden opgenomen in een ziekenhuis letsel op ten gevolge van een medische fout. Binnen het ziekenhuis vinden verhoudingsgewijs de meeste medische fouten plaats in de operatiekamer (OK), waarbij veel van de aldaar gemaakte fouten gezien worden als vermijdbaar. Sinds enkele jaren zijn minder invasieve behandelmethoden beschikbaar voor een breed scala chirurgische ingrepen. Door technologische innovaties kunnen artsen operaties uitvoeren door kleine incisies of natuurlijke lichaamsopeningen, waarbij zij gebruik maken van beeldvormende apparatuur om het operatiegebied te zien. Deze zogenoemde operaties vanaf beeld (image-based procedures - IBP) omvatten alle soorten medische ingrepen die via minimale toegang therapeutische interventie mogelijk maken, waarbij de behandelend arts gedurende de ingreep het operatiegebied real-time, maar indirect, waarneemt met behulp van beeldvormende apparatuur. Enkele voorbeelden van operaties vanaf beeld zijn laparoscopische chirurgie, flexibele gastro-intestinale endoscopie en endovasculaire chirurgie.

Vele factoren zijn van invloed op de patiëntveiligheid en chirurgische uitkomst van een operatie. Het vanaf beeld uitvoeren van een ingreep omvat enkele factoren die de kwaliteit van de ingreep en patiëntveiligheid sneller in gevaar kunnen brengen dan wanneer deze ingreep op de traditionele open wijze zou worden uitgevoerd. De komst van IBP introduceerde een heleboel extra en nieuwe technologie in de OK. Het veranderde tevens drastisch de omgangswijze van de chirurg met het operatiegebied en de interactie binnen het operatieteam. Bij IBP vormt de apparatuur en het instrumentarium de interface tussen het chirurgische team en het operatiegebied. Tegelijkertijd is de afhankelijkheid van deze apparatuur om de ingreep op effectieve, efficiënte, maar vooral ook op veilige wijze uit te voeren groter. Deze afgedwongen afhankelijkheid van en omgang met de benodigde IBP apparatuur resulteert voor het chirurgisch team in een toename van de mentale en fysieke werklast, welke vervolgens leidt tot een toename van de vermoeidheid en een afname van de concentratie op het uitvoeren van de chirurgische interventie.

Dit proefschrift richt zich op het verbeteren van de patiëntveiligheid tijdens operaties vanaf beeld door betere waarborging van de kwaliteit van de prestatie van de behandelend arts. Het vaardigheidsniveau van de arts en zijn omgang met het operatiegebied via de IBP interface zijn van grote invloed op de kwaliteit van IBP. Om het voor artsen mogelijk te maken dat zij zich tijdens het uitvoeren van IBP kunnen concentreren op de therapeutische handelingen, zonder afgeleid te worden door de interactie met de IBP interface, zal eerst de discrepantie tussen het gewenste en het eigenlijke bekwaamheidsniveau van de arts verkleind moeten worden door middel van training buiten de klinische omgeving. In dit proefschrift wordt daarom vooral onderzoek gedaan naar het gebruik van simulatiemiddelen om de bekwaamheid van artsen in IBP-specifieke psycho-motorische vaardigheden te verbeteren. Vervolgens dient de invloed van een eventueel nog aanwezige discrepantie tussen het gewenste en het eigenlijke bekwaamheidsniveau van de arts op zijn klinische prestatie gereduceerd, dan wel overbrugd te worden door verbetering van de workflow en interactie met IBP interfaces. In dit proefschrift wordt daarom tevens de invloed van enkele hiertoe veel belovende instrumenten geëvalueerd. Omdat het binnen dit project niet mogelijk was om het volledige IBP domein te behandelen is gekozen om te focussen op laparoscopische chirurgie en flexibele gastro-intestinale endoscopie als representatieve IBP typen.

In **Hoofdstuk 2** wordt een beknopt historisch overzicht gegeven over hoe het IBP domein zich heeft ontwikkeld. Het biedt tevens een categorisatie van de verschillende typen ingrepen binnen het IBP domein op basis van de rol van de IBP interface en eigenschappen van de interactie van de arts met het operatiegebied en het instrumentarium. In dit hoofdstuk worden ook de invloed van verschillende ergonomische aspecten op het uitvoeren, leren en beoordelen van operaties vanaf beeld besproken. In laparoscopische chirurgie bijvoorbeeld, kunnen de vaste toegangspoorten van de instrumenten, positionering van de apparatuur rondom de operatietafel en beperkingen ten aanzien van instrumentontwerp bij het operatieteam tot lichamelijke ongemakken en kwalen leiden. Tevens brengen IBP verschillende cognitieve en sensorische uitdagingen met zich mee. Het manipuleren van de laparoscopische instrumenten vereist bijvoorbeeld specifieke vaardigheden op het gebied van ruimtelijk inzicht; men moet de tweedimensionale weergave van het driedimensionale operatiegebied op het beeldscherm interpreteren en in gedachten vertalen naar de juiste manipulatie van het instrumentarium, vaak is dit een handeling die tegen de intuïtie ingaat.

De chirurgische opleiding is traditioneel gebaseerd op het Halstediaanse model (meester-gezel principe) en accreditatie vindt plaats op basis van het aantal uitgevoerde operaties en het semi- subjectieve oordeel van een ervaren specialist. Naast enkele algemene medisch juridische en ethische belangen heeft nieuwe wetgeving op het gebied van werktijdbeperking, zoals de European Working Time Directives (EWTD), de behoefte aan preklinisch trainen en objectief beoordelen van bekwaamheid verder vergroot. Het meester-gezel systeem bleek daarnaast ook niet geschikt te zijn voor het overbrengen van specifieke IBP vaardigheden. Dit komt onder andere door de indirecte interactie met het operatiegebied, waardoor men de nuances en gevolgen van bepaalde handelingen niet kan leren door het observeren van ervaren specialisten, en door het feit dat oudere artsen niet altijd even ervaren zijn in IBP als in traditionele open operatie technieken.

Virtual reality (VR) simulatoren kunnen een effectief alternatief bieden voor het trainen van vaardigheden voor laparoscopie en flexibele gastro-intestinale endoscopie buiten de klinische omgeving. VR simulatoren kunnen tevens voorzien in de groeiende behoefte aan objectieve beoordeling van bekwaamheid. Het is bewezen dat het gebruik van VR simulatoren voor training in deze operatietechnieken in beginsel waardevol en nuttig is. In **Hoofdstuk 3** van dit proefschrift wordt de validiteit vastgesteld voor het gebruik van de

SEP VR simulator (SimSurgery AS, Oslo, Norway) voor training in en beoordeling van vaardigheid in laparoscoop navigatie met een 30° optiek en bimanuele weefselmanipulatie. Tevens wordt in dit hoofdstuk de relatie tussen vaardigheid in laparoscoop navigatie met een 30° optiek en vaardigheid in bimanuele weefselmanipulatie onderzocht. De resultaten tonen aan dat de SEP VR simulator een valide en waardevol instrument is om deze beide vaardigheden te trainen, dan wel beoordelen. Jonge artsen in opleiding kunnen hun vaardigheid in deze taken significant verbeteren door een relatief kort trainingsprogramma op de SEP VR simulator te volgen. Aan het einde van het trainingsprogramma is hun prestatieniveau over het algemeen van een vergelijkbaar niveau als die van ervaren laparoscopisch chirurgen. Vergelijking van de prestaties binnen en tussen de twee taken laat zien dat er een duidelijke trend is te onderscheiden tussen de tijd die men nodig heeft om de taak te volbrengen en de totale instrument padlengte voor dezelfde taak, zowel in het algemeen als ook binnen de beginnergroep en groep met ervaren laparoscopisten. Tussen de prestaties in beide taken werd een correlatie echter niet altijd gevonden. Dit impliceert dat klinisch opgebouwde ervaring in weefsel-manipulatie niet automatisch vaardigheid in navigatie met een 30° laparoscoop met zich meebrengt en vice versa. Training in en beoordeling van basale vaardigheden voor laparoscopische chirurgie zou zich daarom op elk van deze taken apart moeten richten.

De validiteit van het gebruik van de GI Mentor II VR simulator (Simbionix Ltd, Cleveland, USA) voor training in en beoordeling van vaardigheid in basale lagere flexibele gastro-intestinale endoscopie taken wordt beoordeeld in **Hoofdstuk 4**. De analyse richt zich daarbij op het uitvoeren van een eenvoudige oog-hand coördinatie taak en meerdere virtuele colonoscopie casussen. De onderzoeksuitkomsten wijzen uit dat de GI Mentor II simulator het uitvoeren van colonoscopie overtuigend realistisch representeert en dat de simulator het onderscheid kan maken tussen endoscopisten van verschillende vaardigheidsniveaus. Over het verloop van vier trainingssessies verbeteren beginners hun prestaties significant, maar zij behalen in deze tijd niet voor alle gemeten parameters het zelfde prestatieniveau als ervaren endoscopisten of experts.

Flexibele gastro-intestinale endoscopie en laparoscopische chirurgie zijn twee veel voorkomende operaties die vanaf beeld worden uitgevoerd waarvoor de basale vaardigheden goed getraind kunnen worden met behulp van VR simulatoren. Deze IBP typen hebben enkele interactie elementen gemeen, zoals het gebruik van video als beeldvormende techniek. Op andere vlakken verschillen deze procedures echter duidelijk, zoals in de oog-hand coördinatie en visuomotorische vertaling voor de manipulatie van de camera en het chirurgisch instrumentarium. Gastro-intestinale chirurgen zijn vaak gewend om zowel laparoscopische ingrepen als ook colonoscopiën uit te voeren. De veel voorkomende veronderstelling is dat men bij het leren van de ene techniek aanzienlijk profijt heeft van ervaring in de andere, en andersom. De wisselwerking tussen vaardigheden voor laparoscopie en flexibele gastro-intestinale endoscopie is echter nauwelijks onderzocht. Huidige trends, technologische innovaties en nieuwe chirurgische technieken die afgeleid zijn van meerdere typen IBP, zoals Natural Orifice Transluminal Endoscopic Surgery (NOTES) waarin laparoscopie en flexibele endoscopie samensmelten, vergroten de behoefte aan kennis op het gebied van vaardigheidsoverdracht tussen IBP typen. Daarom wordt in **Hoofdstuk 5** de invloed van training in colonoscopie op de prestatie in basale laparoscopie taken (en vice versa) onderzocht. Hiertoe zijn de prestaties in laparoscopie taken van een groep onervaren endoscopisten met ervaring in colonoscopie vergeleken met de laparoscopie prestaties van een groep onervaren endoscopisten zonder deze ervaring (en andersom). Jonge artsen in opleiding (zonder IBP ervaring) volgden een trainingsprogramma op de GI Mentor II simulator en the SEP simulator volgens een kruislings opgezet studieprotocol. Het trainingsprogramma omvatte dezelfde taken als die gebruikt werden voor het onderzoek in Hoofdstuk 3 en Hoofdstuk 4. De resultaten impliceren dat training van basale laparoscopie vaardigheden geen invloed heeft op de prestatie in basale colonoscopie taken. Training in basale colonoscopie vaardigheden lijkt van positieve invloed te zijn op de prestatie in basale laparoscopie navigatie, maar slechts in zeer beperkte mate. De conclusie luidt dan ook dat psychomotorische vaardigheden die nodig zijn voor het uitvoeren van basale taken voor laparoscopie en colonoscopie niet direct uitwisselbaar zijn en dat training en beoordeling van IBP specifieke vaardigheden onafhankelijk van elkaar dient te gebeuren. Het hebben van ervaring in de ene IBP techniek levert niet vanzelfsprekend een voordeel op bij het aanleren van een ander type IBP. Tegelijkertijd laten deze resultaten ook zien dat training in basale vaardigheden voor verschillende IBP typen gemixt kan worden en niet noodzakelijkerwijs opeenvolgend hoeft te gebeuren.

Bij beschouwingen van simulatie instrumenten voor het trainen van verschillende IBP vaardigheden wordt niet altijd volledig rekening gehouden met aanwezige verschillen in user-interface interactie en oog-hand coördinatie. In **Hoofdstuk 6** worden verschillende onderdelen van de user-interface interactie die van invloed zouden kunnen zijn op de doeltreffendheid van simulatortraining voor enkele specifieke laparoscopie taken onderzocht. Als eerste is de invloed van het al dan niet aanwezig zijn van anatomische herkenningspunten in een simulatieomgeving op de prestaties in een laparoscoop navigatie taak onderzocht. Een groep ervaren laparoscopisch chirurgen voerde derhalve op de SEP simulator een laparoscoop navigatie taak uit met een 30° optiek in twee verschillende virtuele omgevingen: de standaard SEP abstracte virtuele omgeving en een virtuele omgeving met een weergave van de anatomie van de onderbuik. De ervaren laparoscopisch chirurgen voerden de laparoscoop navigatie taak met significant betere simulator scores uit in de abstracte omgeving in vergelijking tot de virtuele omgeving met anatomische herkenningspunten. Een vergelijkbaar verschil werd gevonden in een groep met onervaren artsen, dit betekent dat het gevonden verschil niet afhankelijk is van het ervaringsniveau.

Laparoscopisch hechten vereist geraffineerde omgang met weefsel en hechtmateriaal. Het is aannemelijk dat dit een hoger niveau van feedback vereist dan de feedback die aanwezig is in visuele informatie alleen. Om laparoscopisch hechten adequaat te leren wordt het daarom als belangrijk verondersteld dat men haptische feedback ervaart bij het uitvoeren van aan hechten gerelateerde trainingstaken. De term ‘haptische feedback’ verwijst naar de combinatie van tactiele feedback door sensorische receptoren in de huid en kinesthetische informatie die afgegeven wordt door spieren, pezen en sensorische receptoren in de gewrichten. In het algemeen wordt tevens verondersteld dat zeer waarheidsgetrouwe simulaties met haptische feedback betere trainingsresultaten opleveren en een betere overdracht van vaardigheden naar de klinische omgeving. Het ontbreekt VR simulatoren voor het trainen van laparoscopie vaardigheden momenteel echter vaak aan realistische haptische feedback. Daarom zijn twee studies uitgevoerd naar het belang van haptische feedback en de toegevoegde waarde van objectieve vaardigheidsbeoordeling voor het trainen van laparoscopisch hechten. De eerste studie had tot doel de trainingstaken op een VR simulator en een augmented reality (AR) simulator te evalueren, door de laparoscopisch chirurgen van verschillende expertiseniveaus deze taken op beide systemen te laten uitvoeren en beoordelen op didactische waarde. In de tweede studie is de toegevoegde waarde van hechttraining op een VR simulator naast hechttraining op een box trainer onderzocht. De resultaten van beide studies bevestigen dat voor het verwerven van vaardigheden voor laparoscopisch hechten realistische haptische feedback essentieel is. Voor training van laparoscopische hechtvaardigheden is het daarom aan te raden gebruik te maken van een simulatie systeem dat voorziet in correcte haptische feedback, zoals traditionele box trainers of een AR simulator.

Verbetering van de patiëntveiligheid en kwaliteitscontrole in de laparoscopische OK en het deels overbruggen van de discrepantie tussen het gewenste en het eigenlijke bekwaamheidsniveau van de arts vereist een substantiële aanpassing van workflow en werkroutine. Technologische innovaties zoals geïntegreerde OK systemen hebben het mogelijk gemaakt om de ergonomie, veiligheid en efficiëntie van het uitvoeren van laparoscopische operaties te verbeteren. Pro/cheQ is een digitale procedurele checklist tool die ontwikkeld is om tijdens laparoscopische ingrepen de patiëntveiligheid beter te waarborgen en de kwaliteitscontrole te verbeteren door middel van structurering en standaardisering van de voorbereiding van apparatuur en instrumentarium, time-out momenten, opname van intra-operatieve beelden, debriefing en het invullen van het operatieverslag. Om de invloed van deze twee veelbelovende tools op het waarborgen van de patiënt veiligheid in de OK in te schatten, is in **Hoofdstuk 7** het effect van deze tools op het aantal en type apparatuur- en instrumentarium gerelateerde risico gevoelige gebeurtenissen tijdens laparoscopische cholecystectomie (galblaasverwijdering) geanalyseerd. Het gelijktijdig gebruik van het geïntegreerde OK systeem en het prototype van de Pro/cheQ tool reduceert het aantal apparatuur- en instrumentarium gerelateerde risico gevoelige gebeurtenissen verder dan enkel het gebruik van het geïntegreerde OK systeem. Ook het type apparatuur- en instrumentarium gerelateerde risico gevoelige gebeurtenissen dat zich voordoet verschilt tussen de cart-based OK, geïntegreerde OK en geïntegreerde OK met Pro/cheQ. Het onderzoek laat zien dat de Pro/cheQ tool de workflow op een ongekunstelde wijze ondersteunt. De invloed van Pro/cheQ reikt verder dan de reductie van risico gevoelige gebeurtenissen, het verhoogt ook het algemene veiligheidsbewustzijn en synchroniseert het onderlinge begrip ten aanzien van verantwoordelijkheden en verwachtingen tussen de leden van het operatieteam. De betrokkenheid van het OK personeel in het creëren van een veiligheidscultuur en het actieve gebruik van tools zoals de geïntegreerde OK en Pro/cheQ blijkt zeer belangrijk. Binnen de ziekenhuisorganisatie moet het implementatieproces van dergelijke tools daarom breed gedragen worden.

Ten slotte worden in **Hoofdstuk 8** alle onderzoeksbevindingen samengevat en bediscussieerd. In deze algemene discussie worden enkele aspecten besproken die in verband staan met de implementatie van veiligheidsmaatregelen. In de discussie komen ook de behoefte aan allesomvattende curricula om IBP vaardigheden te trainen en de uitdagingen die gekoppeld zijn aan prestatie gerichte training en beoordeling aan bod. Hierin worden tevens enkele richtingen voor nader onderzoek en productontwikkeling gepresenteerd. Als laatste worden de klinische implicaties van het uitgevoerde onderzoek kort besproken.

About the author

Sonja Buzink was born 25 December 1976 in Haarlem and raised in Zwanenburg, both in the Netherlands. After attending Lyceum Sancta Maria in Haarlem she moved to Delft in 1996 to study Industrial Design Engineering (IDE) at the Delft University of Technology. In the final phase of her study she specialised in the design of products for people and environments with additional ergonomic demands, such as for healthcare. January 2004 Sonja obtained her Master's degree, with distinction, as best MSc IDE graduate of the year, on the development of an assistive product to prevent falling in the toilet environment. Next, she worked as researcher for the Friendly Rest Room consortium at the Faculty of Industrial Design Engineering, Delft University of Technology, investigating several usability aspects of the toilet environment for elderly people.

Spring 2005 she was fortunate to start a PhD project focusing on the role of human-product interaction on patient safety during image-based procedures. This was a joint initiative of the Catharina Hospital Eindhoven and the Faculty of Industrial Design Engineering, partly sponsored by the Scientific Fund of the Catharina Hospital Eindhoven. Next to her research activities, Sonja supervised graduation and research projects of students in Industrial Design Engineering and medical students. As a teacher, she was also involved in several courses on ergonomics and design. Furthermore, she was a member of the organising committee of the IDE PhD day 2007 and the symposium 'Improving patient's safety and quality of performance in surgery' in 2008. During her PhD project, Sonja presented parts of her research at various national and international conferences.

Currently, Sonja is continuing her research on safeguarding patient safety and quality of performance in minimally invasive surgery as a post-doc working on the Laparoscopic Surgical Skills programme for the European Association for Endoscopic Surgery (EAES), for which she was awarded a Fellowship grant by Delft University of Technology and an EAES Research grant.

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Acknowledgments

Over the past years, many people have supported, stimulated and/or inspired me in my work. Some were closely involved for a longer period of time, others just showed interest in my work when I occasionally met them. Without their contribution, this thesis would not have been the same. Therefore, a big ‘Thank you!’ to all of you!

Thank you! Dr. Jakimowicz for initiating this project first of all and arranging funding from the Scientific Fund of the Catharina Hospital. The hospital and world of surgery were unexplored territories for me, but with your help I quickly felt very welcome and at home. Being one of your PhD students opened many doors and created great opportunities to do research. You gave me space to find my own way, even though I sometimes felt that, in the back of your mind, you had a plan thought out for me all along. Your positive and calm mindset, quick feedback, and pragmatic solutions encouraged me to keep going. I am looking forward to continue working with you on the Laparoscopic Surgical Skills programme.

Thank you! Huib for your guidance and scientific support. You kept the end goal, this thesis, in mind throughout this project, making sure we did not go to far astray when I, driven and eager, wanted to set up a new study once again. Within my supervisory team you were the one with a bit more distance to the topic, which often lead to very interesting and insightful discussions. When you reviewed my writings, the margins were always scribbled full with comments and suggestions for improvement. Your focus on quality often made me rethink the set-up of my studies, the statistical analysis of the data and/or presentation of the results, challenging and encouraging me to try to gain even more insight. Thank you for putting up with me whenever I was a bit impatient again to start an experiment or submit an article.

Thank you! Richard for supporting me on a ‘daily’ basis. Whenever I needed to discuss my work, you made time for me to talk things through. In our meetings your nice scribbles and mini drawings often helped a lot to structure things and regain overview. Your positive attitude and constructive criticism gave me a lot of confidence and inspiration. In your support you did not focus on work only, you always informed about life outside work; keeping an eye on my work-life balance as well.

Thank you! Sanne for all the fun we had performing our studies and during the conferences we visited together. When I got to know you, you were a surgical intern with a zeal to obtain a PhD. Now, you have obtained your PhD for quite some time already and you work as a surgical resident. It was great to do so many studies together with you in the Skillslab and other locations we were able to drag ‘our’ simulators to. From you I also learned a lot about the life of Dutch medical interns. The fact that for some people outside the Catharina Hospital it proves very difficult to keep us apart, does say something about the closeness of our work I guess.

Thank you! co-authors and other fellow Skillslab researchers for your contributions and comments which led to various publications and conference presentations. I very much enjoyed our discussions on the use and usefulness of medical simulation and the many dinners we had together in the restaurant of the Catharina Hospital.

Thank you! Cees for being such a rock steady support on which I could always depend. I learned a lot from your hands-on approach and dedication. Countless times your knowledge, experience, and/or creativity saved a simulator experiment from going wrong. You were also most helpful to my students and assisted me greatly in getting them started on the right track. You always had an interesting story to tell over a cup of coffee.

Thank you! to all medical specialists, residents, and medical interns who participated in my studies and their supervisors who allowed them to do so. In particular, I thank the surgeons and surgical residents of the Catharina Hospital, who time after time were willing to take part in yet another simulator experiment and welcomed me or one of my students to observe their work in the operating room. I am grateful to the course directors, in particular Yvonne and Lorna, who made it possible to run several of our studies within or parallel to their laparoscopic courses.

Thank you! colleagues of the Catharina Hospital for welcoming me and my students into your world and for supporting and accommodating our work. In particular, I would like to thank the operating room staff, the audiovisual guys, the people of the department of Education & Research, the medical physicists, and Leonie Claes from the Quality department. Mieke en Harry thank you for the times that I could spent the night at your place and relax after work with a nice cup of tea and a pleasant conversation.

Thank you! Johan for introducing me into the world of scientific research when we worked together on the Friendly Rest Room project. You made me see that it suites me. You repeatedly asked me whether I was sure to not want to do a PhD yet. Still, you informed me about the vacancy for this project. I know that it must have been hard for you to see me change my mind and choose for the challenge of another topic.

Thank you! Industrial Design colleagues for the many moments of reflection during so many lunch, coffee, and tea breaks. Fellow Medisign and DDI colleagues, thank you for your inspiration and sharing of your knowledge and experience. It was great being in a fishbowl together with you.

Thank you! to all the students who contributed to this work directly or indirectly. For you – Noortje, Isabelle, Guido, Kenny, Renate, Lotte, Rob, Eva, Wienke, Menno – it was your graduation project, a research assignment, or an internship. Thank you for providing a fresh look on things and the inspiring ideas you created.

Thank you! to the Scientific Fund and the Executive Board of the Catharina Hospital for supporting my work financially. I am also grateful to the people from industry – Vidar,

Ronald, Jan, Jurjen, Stefan, Raoul, Tal, Fiona – who supported my work and their companies – SimSurgery, Covidien, Karl Storz, Xitact/Mentice, Philips, Simbionix, Haptica – that helped to make some of the studies presented in this thesis possible by unconditionally providing equipment and technical support.

Thank you! dear family, family in-law, and friends for your support and interest in my PhD work, also sometimes called 'studie', 'scriptie' or 'afstuderen'. The refreshing questions you asked at times brought me to new insights and ideas. Fieke and Jasper thank you for undergoing the trial of defense together with me. Pap, mam, broertje, jullie onvoorwaardelijke steun en vertrouwen in alles wat ik doe hebben mij mede tot hier gebracht. Ik ben trots om jullie dochter/zus te zijn!

Dear Dennis, lief, by no means can a 'Thank you!' or any other word cover my gratitude to you! You keep me in balance. You complete me. Without your love, patience, and encouragements I could never have achieved all of this. Sweet little Fabian, your bright smiles and curiosity light up my life and made it a lot easier to finish this thesis.

TU Delft

CATHARINA-ZIEKENHUIS