

Ergonomic Factors during Laparoscopic Surgery Training

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Ergonomic Factors during Laparoscopic Surgery Training

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Being superficially different is the goal of so many of the products we see . . .
rather than trying to innovate and genuinely taking the time, investing the
resources and caring enough to try and make something better.

– Jonathan Ive, Product designer

It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change.

– Charles Darwin, Naturalist

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CHAPTER 1 INTRODUCTION

In this chapter the background, problem definition, aim, research approach and questions of the PhD project titled "Ergonomic Factors During the Laparoscopic Surgery Training" will be described. In addition, the outline of the thesis is also included.

1.1 Laparoscopy

Minimally invasive surgery (MIS), also called minimal access, endoscopic or keyhole surgery, is a universally accepted way of surgery in the past two decades. These kinds of procedures are performed through small incisions in the skin, or through the natural orifice of the human body which is been called natural orifice transluminal endoscopic surgery (NOTES). There are many types of MIS procedures, one of which is laparoscopy. Laparoscopy covers the procedures in the abdominal cavity. During a laparoscopic procedure, the abdomen of the patient is inflated with carbon dioxide (CO₂) to create a workspace for the surgeon. Through small incisions, trocars are placed to enter the abdominal cavity. Via these trocars long and thin laparoscopic instruments and an endoscope is introduced. The endoscope illuminates the surgical field and captures the surgical image, while long and thin instruments are used to manipulate the tissue (Lomanto, Iyer et al. 2006; Fullum, Ladapo et al. 2010). (Figure 1.1)

The first laparoscopic cholecystectomy (gallbladder removal) was performed by Dr. Erich Mühe in Germany in September of 1985 (Blum and Adams 2011). This important breakthrough changed the modern surgery, and the laparoscopic cholecystectomy has become a widely accepted technique. Nowadays between 75% and 95% of all cholecystectomies are performed with laparoscopy (Tang and Cuschieri 2006; Sakpal, Bindra et al. 2010).

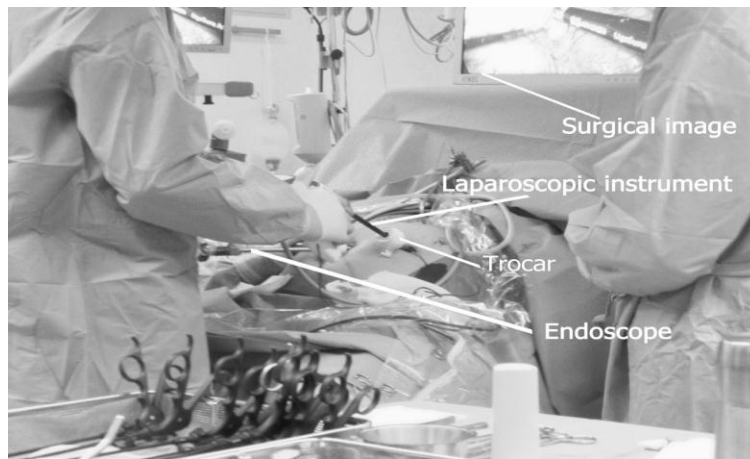


Figure 1.1 Laparoscope and long thin instruments.

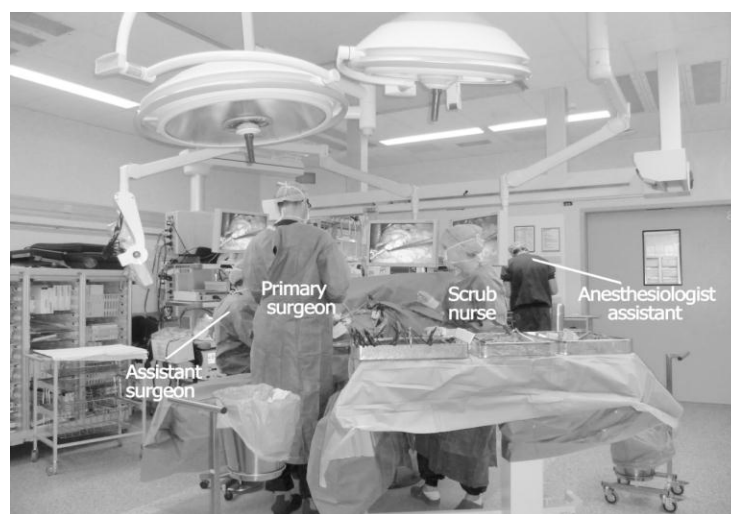


Figure 1.2 MIS Surgical team.

With the introduction of MIS procedure, the patient benefits of less pain, a rapidly recovering and a shorter stay in the hospital. However, this technique challenges the surgeons in many ways and therefore increases the risk for errors and complication (Dankelman, Wentink et al. 2003; Oomen, Hoekstra et al. 2010). Moreover, the surgeons encounter a great number of ergonomic problems during a laparoscopic procedure since ergonomic guidelines are not always applied in the operating room (OR) (Wauben, Veelen et al. 2006).

One of the aspects which makes laparoscopic surgery challenging is that a two dimension image representation of a three dimensional surgical field and loss of depth perception because of performing the procedure via a monitor. During open surgery, surgeons can see and touch the surgical field directly, so there is a three dimensional direct vision and tactile feedback while during laparoscopic surgery this transmission of information is missing. Moreover, since the surgeon manipulates the tissue by long and thin laparoscopic instruments, they are missing the tactile feedback. The indirect vision through an endoscope and the indirect manipulation of

tissue are the main causes of perception problems, which can be divided into disturbed hand-eye coordination, reduced depth perception, and reduced haptic feedback (van Veelen, Nederlof et al. 2003; Albayrak, Kazemier et al. 2004; Wauben, Veelen et al. 2006; Supe, Kulkarni et al. 2010) (Figure1.2). Next to this perception problem, surgeons have a static body posture during a major part of a procedure causing physical discomfort.(Supe, Kulkarni et al. 2010) In addition, the OR is a multidisciplinary work environment which involves collaboration among the surgeon(s), anesthetist, nurses, and other medical staff. Team members are jointly responsible for the patient care and patient safety, while they have different multiple tasks to perform. Different tasks and activities in a team may interfere with one another, which turns the OR into a cooperative and complex work environment (Jakimowicz and Jakimowicz 2011; Pape 2011).

1.2 Surgical simulation in laparoscopy

The OR environment is such complex that it can be compared to high-risk industries, such as aviation, military and nuclear industry. However, simulation in the high-risk industries, especially in aviation has been shown a positive improvement of the safety. Especially, inexperienced pilots are more likely to learn effectively within a simple simulation training environment than to be placed in an actual cockpit to fly, where the complexity of instrumentation and the pressure to perform perfectly can be overwhelming(Dunkin, Adrales et al. 2007). Lessons learned from the aviation could contribute to improve patient safety in the OR. In order to acquire surgical skills without decrease patient safety, the interaction with the surgical instruments and equipment requires extensive training (Jakimowicz and Jakimowicz 2011). Therefore inspired by similar efforts in the domain of aviation and military, surgical simulation is widely used to train surgical trainees from basic tasks to cognitive demanding tasks.

Surgical training consists of developing cognitive, clinical, and technical skills, the latter being traditionally acquired through supervisory (Satava, Gallagher et al. 2003). However, receiving full training “on the job” is not always possible because of patient safety and restrictions of resident working hour. This situation led to use of models, cadavers, and animals to replicate surgical situations and, more recently, the development of surgical skills centers or laboratories (Anastakis, Wanzel et al. 2003). Therefore, alternative training methods must be provided to the surgical trainees within validated training curricula (Torkington, Smith et al. 2000). These validated surgical training curricula allow surgical trainees to practice in a safe and controlled preclinical environment before operating on patients. These curricula may employ simple box trainers, virtual reality simulators and augmented reality simulators (Botden, Buzink et al. 2007)(figure 1.3). These surgical

simulators offer verities of surgical tasks from basic to simulated full complex procedures (Figure 1.4).

The traditional box trainers are commonly used for the training of basic laparoscopic surgical skills (figure 1.3), basically such a training device consists of a box with physical objects in it and, in that box the surgical trainee can practice various skills and tasks, such as the eye-hand coordination and camera navigation. The contents of the box vary from simple objects to animal organs and synthetically produced organs depending on the training. Box trainers are highly versatile, relatively inexpensive and offer physical objects manipulation for surgical trainees, which makes them attractive for laparoscopic trainings purposes. However, a disadvantage of a box trainer is the objective way of assessment of the performance, and mostly the physical objects are not representing the characteristic of real tissue. Therefore in order to offer the surgical trainees a more realistic anatomical structure, Virtual Reality (VR) systems are developed.

VR systems are more complex than box trainers using three dimensional (3D) computer-generated imaging in combination with replicated laparoscopic instruments. VR simulators allow the surgical trainee to overcome psychomotor learning curve by repetitive training scenarios, integration of didactic modalities, and objective assessment of outcome parameters (Botden, Buzink et al. 2007; Seymour 2008). Since the surgical trainees interact with virtual objects no realistic haptic feedback is available when manipulating. Some development is going on to integrate force feedback system into these simulators, but it is not optimal yet, and the cost price is fairly high due to the innovative technical components (Munz, Kumar et al. 2004).

In order to overcome the lack of haptic feedback of VR systems, Augmented Reality (AR) simulators are developed. AR systems combine physical objects (models) with computer data. Like with training on box trainers the structures can be inorganic (artificial) or made from organic (living or cadaver) materials. Due to the physical structures used, AR simulators have haptic feedback.(Botden and Jakimowicz 2009) AR simulators include a video tracking system. This system tracks equipment paths, the procedure time e.g. with this data performances can be measured and validated. AR system uniquely enables users to interact with virtual and physical models in the same unit while providing accurate, comprehensive feedback on performance (Weidenbach, Wick et al. 2000; Lapeer, Chen et al. 2004). Several studies have shown that surgical simulators improve surgical skills,(Torkington, Smith et al. 2000; Schijven and Bemelman 2011) and thus these skills acquired through simulators would be transfer to the OR (Seymour 2008; Sturm, Windsor et al. 2008).

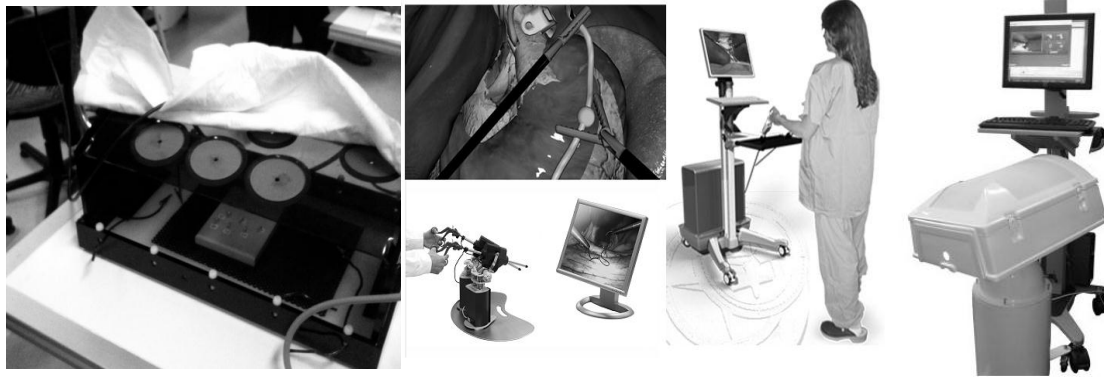


Figure1.3 Box trainer (left), VR simulator (middle) and AR simulator (right).

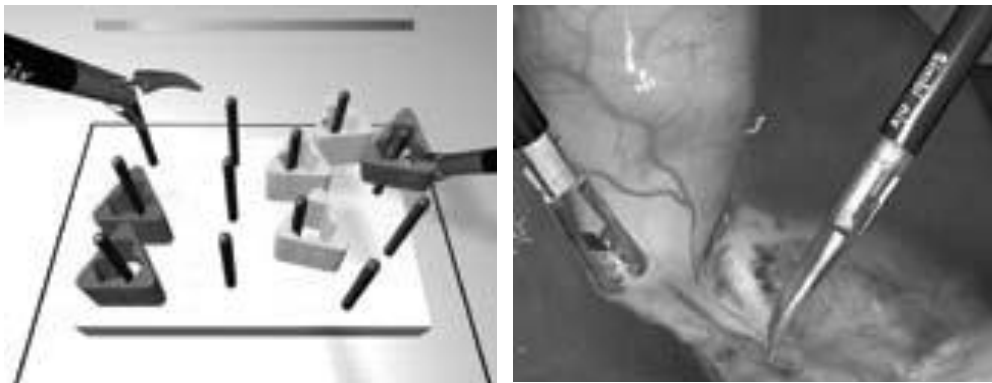


Figure1.4. Basic surgical task (left) and full procedure task (right).

Transfer of surgical skills from isolated training to the real and complicated setting of OR is perceived as cognitively demanding by inexperienced surgeons (Prabhu, Smith et al. 2010). This transfer needs to be smoothened to decrease the social and cognitive overload in the OR. Therefore more environmental factors of the OR should be integrated in the training setting (Gallagher, Ritter et al. 2005).

There are already a lot of studies done to investigate the ergonomic factors during real laparoscopic procedures, and even the guidelines were defined, such as the optimal working posture of the surgeons, the position of the monitors, the optimal operating surface height and so on. However, these guidelines are not implemented in the surgical simulators and training settings and little research is done on the effect of ergonomic settings on task performance. This gap obstructs the transfer of surgical skills from surgical training to real OR performance.

1.3 Aim

The aim of this thesis is to define an optimal laparoscopic surgery training environment to meet the reality of laparoscopic surgery in the OR, and thus to improve the training efficiency.

To achieve this aim the following questions are formulated:

What are the ergonomic problems during the laparoscopic procedure and laparoscopic training?

How do the ergonomic problems of the training setting affect the simulation task?

How to design a portable ergonomic simulator for the surgeons to improve ergonomic consciousness?

How to investigate the intra-operative interference during the surgical procedure and thus to improve the immersive surgical training setting?

1.4 Research approach

In order to achieve the objective of this thesis, the following research approach is used in subsequent chapters. Chapter 2 investigates the influence of ergonomic factors on laparoscopic surgery training based on **an experimental setting in a skills lab**. Chapter 3 employs the research methods of **literature review** and **observation** to investigate the products and problems in laparoscopic surgery training in the skills lab. Chapter 4 employs the **participatory design (PD) approach** to develop a portable ergonomic laparoscopic (Ergo-Lap) simulator for the surgeons to practice basic and advanced laparoscopic skills. In Chapter 5, the face, content and construct validity of the portable Ergo-Lap simulator are evaluated according to **experimental test**. Chapter 6 investigates the face validity of the Ergo-Lap simulator for single incision laparoscopy skills training. In Chapter 7 a **systematic literature review** of the intra-operative interference in the OR is carried out to summarize the effects of distracted events on the surgical performance. Participatory design is an approach which involves the user into the design process, to make sure the designed product meets the user's specific needs (Namioka and Rao 1996).

During this PhD research, the above mentioned research approaches are performed to explore the field, and thus to meet the training demands of the surgical trainees.

1.5 Outline of thesis

This PhD thesis is based on published or submitted articles. Figure 1.5 shows a schematic view of the chapters. The thesis consists 8 chapters which can be divided into 3 parts. Chapter 1 describes the context of the research, research question and aim.

Part A focuses on ergonomic factors during laparoscopic surgery and training. Chapter 2 investigates the ergonomic factors that can influence the task

performance. Chapter 3 presents the products and problems in laparoscopic surgery training, including a case study of design a surgical training table for the skills lab.

Part B focuses on design and validation of a portable ergonomic laparoscopic simulator (Ergo-Lap simulator). In Chapter 4, the design of the Ergo-Lap simulator is described. In chapter 5, face, content and construct validity of the Ergo-Lap simulator is evaluated. Chapter 6 evaluates the face validity of the Ergo-Lap simulator for training basic single port surgery skills.

Part C focuses on the distractions during the laparoscopy procedure. Chapter 7 presents the intra-operative interference in the OR. Finally, the results of this thesis are discussed and recommendations for future research are described in the last chapter.

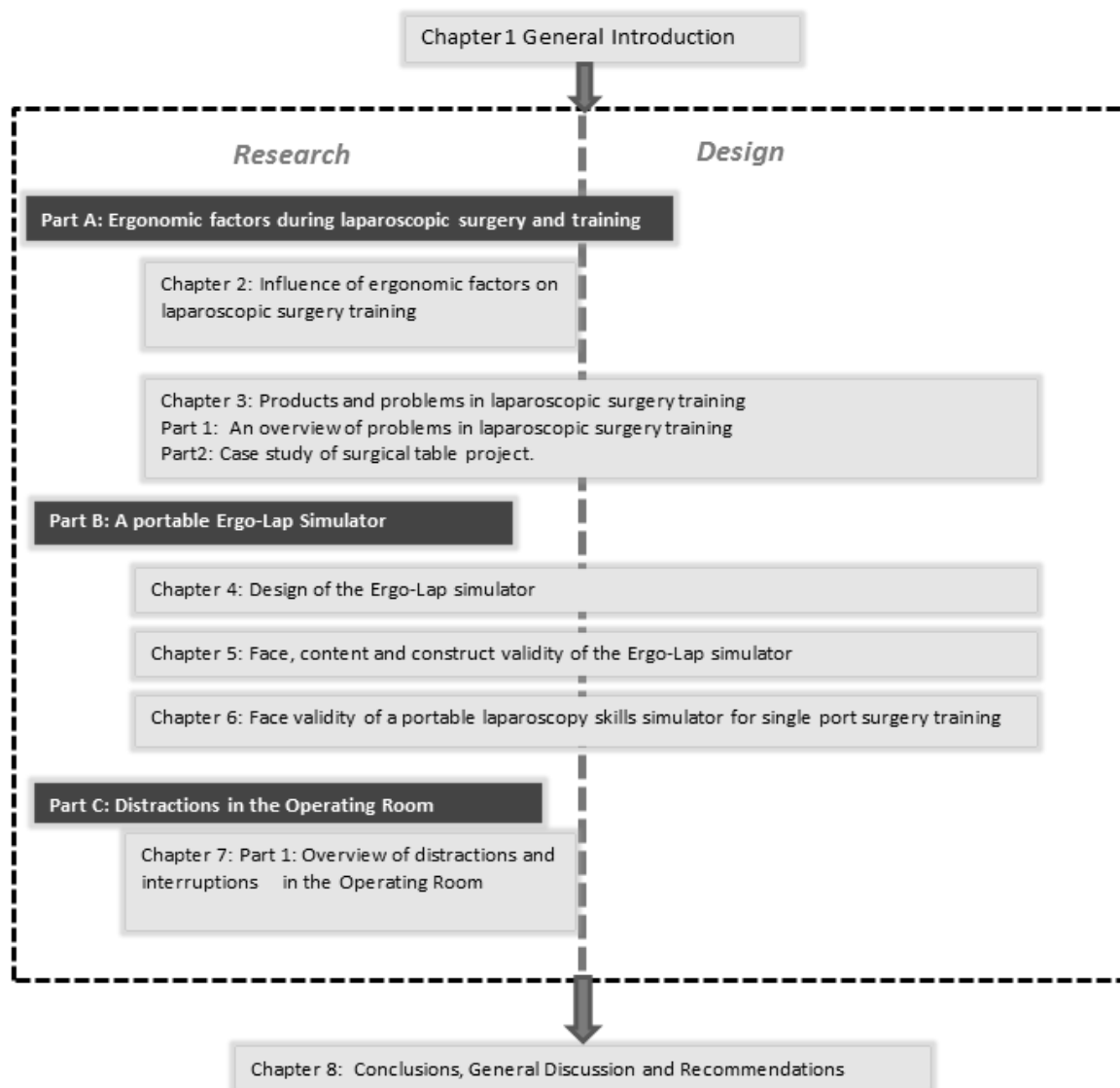


Figure 1.5 Outline of the thesis.



PART A

This part mainly focuses on ergonomic factors during laparoscopic procedure and surgical training. Chapter 2 investigates the ergonomic factors that can influence the task performance. Chapter 3 presents the products and problems in laparoscopic surgery training, including a case study of design a surgical training table for the skills lab.



CHAPTER 2 INFLUENCE OF ERGONOMIC FACTORS ON LAPAROSCOPIC SURGERY TRAINING

This chapter evaluates the effect of ergonomic factors on task performance and trainee posture during laparoscopic surgery training. Twenty subjects without any laparoscopic experience were allotted to 2 groups. Group 1 was trained under the optimal ergonomic simulation setting according to current ergonomic guidelines (Condition A). Group 2 was trained under non-optimal ergonomic simulation setting that often can be observed during training in a skills lab (Condition B). Both groups performed two tasks under Condition A and B. Posture analysis showed that subjects can keep a much more neutral posture under Condition A than under Condition B ($p < 0.001$). The subjects experienced less joint excursion and less discomfort in their necks, shoulders, and arms under Condition A. Significant differences of task performance showed that the group trained under the optimal ergonomic setting performed significantly better than that the group trained under non-optimal setting ($p = 0.005$ for task 1, $p = 0.032$ for task 2). It can be concluded that surgeons learning skills are affected by the ergonomics of simulation setting.

This chapter is mainly based on the following article:

D. J. Xiao, Jack.Jakimowicz, A.Albayrak, R.H.M.Goossens. Ergonomic factors on task performance in laparoscopic surgery training. *Applied Ergonomics* (May 2012), 43 (3), pg. 548-553

2.1 Introduction

In the last two decades minimally invasive surgery (MIS) has been gaining in acceptance and popularity. Laparoscopic cholecystectomy became a golden standard procedure with proven benefits (Kaya, Moran et al. 2008; Matern 2009). However, drawbacks of the laparoscopic approach such as lack of tactile perception and limited degree of freedom for manipulating the instruments remain. Therefore, proper design of the instruments and operating room layout has now become more critical in order to avoid fatigue and human errors. The ergonomic factors are thus of increasingly importance for MIS (Berguer 2006).

Safe performance of laparoscopic surgical procedure requires adequate training preferably in a well-equipped skills lab, within a structural training curriculum. Current states of simulation training in surgery and listing of available modalities have recently been presented (Jakimowicz and Fingerhut 2009; Jakimowicz and Jakimowicz 2011).

Box trainers are highly versatile, relatively inexpensive and offer realistic haptic feedback and are thus attractive for laparoscopic trainings purposes. Basically such a training device consist of a box in which physical objects (like artificial organs) are positioned. The trainee can practice various skills and tasks, such as the eye-hand coordination and camera navigation (Botden, Torab et al. 2008).

Depending on the type of training, a variety of objects can be positioned in the box. Novice trainees start practicing by positioning beans; while more advanced trainees perform procedures on artificial, living or cadaver organs/ tissues. Lights, instruments and medical appliances can be used to simulate the clinical operating room as good as possible. Because the trainee is practicing on physical structures it is valuable to use the standard clinical instruments so as to experience and train the haptic feedback. For this reason, it is meaningful to investigate the ergonomic factors of the simulation setting with box trainer, with an eye for further improvements of existing modalities.

It is common that many simulation setups in skills labs are sub-optimal from an ergonomic point of view, such as table height that cannot be adjusted, monitors that cannot properly be positioned. Also, the workspace and the target location cannot assure a certain range of intra-corporal/extra-corporal instrument length ratio. Last but not least, the optical axis-to-target view angle is often randomly chosen.

In this research, two performance conditions were set for training and testing subjects. One was an optimal ergonomic condition according to literatures (Hanna, Shimi et al. 1997; Emam, Hanna et al. 2000; Matern, Waller et al. 2001; Berquer, Smith et al. 2002), and the other was a non-optimal ergonomic condition that can often be observed in the skills lab. The goal of this study is to investigate the influence of ergonomic factors on task performance during laparoscopic training with a box trainer, and to evaluate the trainee posture under these two conditions.

2.2 Materials and methods

2.2.1 Equipment Setup

A COVIDIEN box trainer equipped with one adjustable camera (WatecWAT-240 VIVID) was used to capture the inside image. Two shadowless LED lamps inside were used as light source, and two holes ($D=10\text{mm}$) in the top cover were used as entrance port. The optical axis-to-target view angle could be set by user.

Two adjustable tables were used: one for adjusting the monitor height, the other for adjusting the operating surface height. A monitor (Acer AL1732) was used to display the inside image. Three cameras (SONY Handycam Hi8) were placed in front, left and right side at an angle of 90 degrees of each subject, to record their actions. Images of these three cameras and one adjustable digital camera used as a 0° angled endoscope were mixed with a Digital Color Quad Processor (Conpon SC-CQPDVR (V1) KIT1) and connected with a desktop. Figure 2.1 shows the position of cameras.

Two experiment conditions were considered. Group 1 was trained under optimal ergonomic simulation setting according to current ergonomic guidelines (Wauben, Veelen et al. 2006; Zehetner, Kaltenbacher et al. 2006) (Marcos, Seitz et al. 2006), i.e. Condition A. Group 2 was trained under non-optimal simulation setting as often be able to observed in a skills lab simulation setting (Condition B). Figure 2.2 shows an awkward posture of a surgeon during a training course. She has to lift her arms to perform task although she already stand on steps. Also the extra-corporal instrument length was longer than the intra-corporal length.

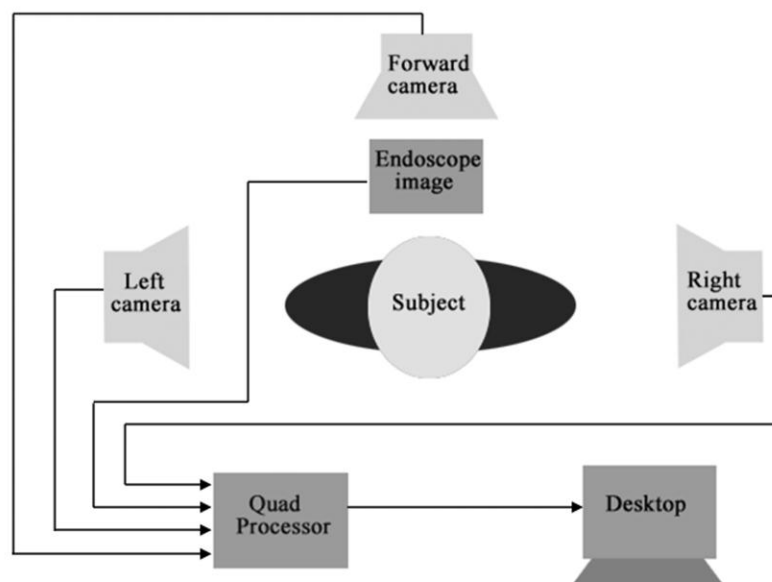


Figure 2.1 Schematic diagram set up of cameras. Three cameras were used to record joints angle, one inside camera was used as endoscope to record inside images.



Figure 2.2 Awkward posture during training course.

Figure 2.3 (left) shows the optimal ergonomic simulation setting (Condition A). The ergonomically optimal monitor position was set as Condition A according to various sources in literatures (Hanna, Shimi et al. 1997; Jaschinski, Heuer et al. 1998; Turville, Psihogios et al. 1998; Burgess-Limerick, Mon-Williams et al. 2000; Emam, Hanna et al. 2000; Matern, Waller et al. 2001; Berquer, Smith et al. 2002). The monitor was at a distance of 0.6m apart from the subjects' eyes. The monitor height (from the middle of the screen to the ground) was between the operating surface and eye level height, and the monitor was inclined (to a maximum of 15 degrees) as preferred by the subjects. The optimal operating surface height was 80% of the elbow height and the table was positioned in 20° tilt (van Veelen, Kazemier et al. 2002). The optical axis was perpendicular to the target plane ($\beta=90^\circ$) (Hanna and Cuschieri 1999; Hanna and Cuschieri 2008). The intra-corporal instrument length was longer than the extra-corporal length (intra-corporal /extra-corporal ratio >1) (Emam, Hanna et al. 2000). Under this condition, every trainee can keep a neutral posture when performing the task.

Figure 2.3 (right) shows a non-optimal ergonomic simulation setting that can often be observed during training in skills labs (Condition B). The monitor was at a distance of 100cm apart from the subjects. The monitor height is 1.1 times of the eye level height. The operating surface height was set equal to the elbow height, and the table was horizontally positioned. The optical axis-to-target view angle was 45°. The intra-corporal instrument length was shorter than the extra-corporal instrument length (intra-corporal/extra-corporal ratio <1). Under this condition, every trainee was performing the task in an awkward posture. The middle of figure 2.5 shows an awkward posture of one trainee when performing task, He has to raise his shoulder and elbows to manipulate the instruments, this could cause serve discomfort after a few minutes.

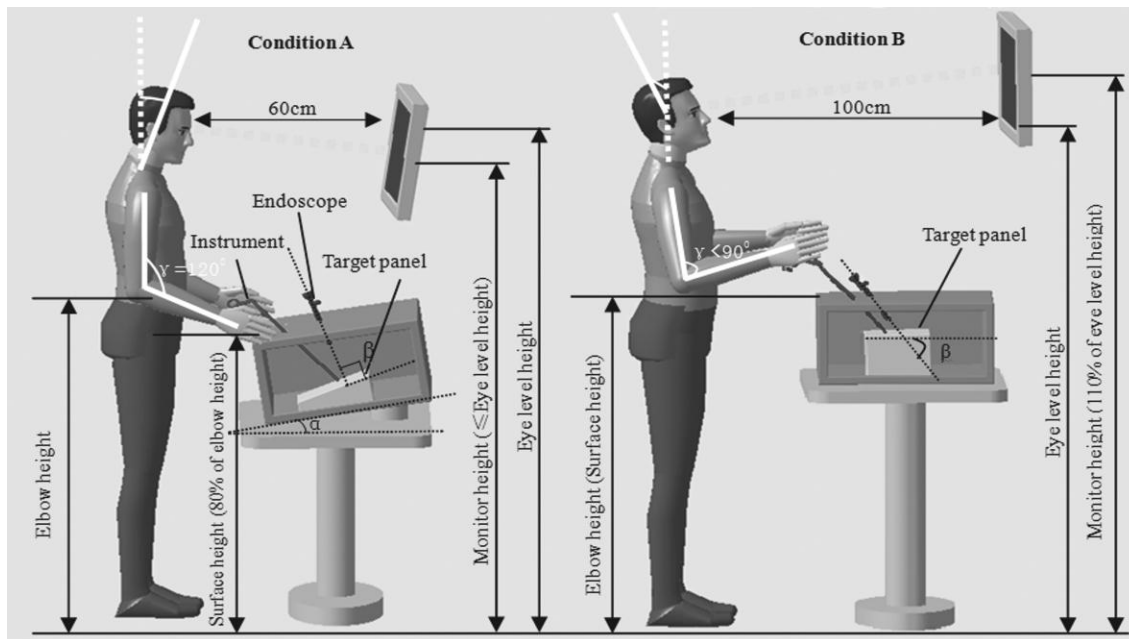


Figure 2.3 Optimal ergonomic simulation setting (Condition A, left); I.e. the distance of the monitor is proper; the operating surface is set as 80% of elbow height; the optical axis was perpendicular to the target plane; box is tilt as an angle of 20° .

Non-optimal ergonomic simulation setting (Condition B, right). I.e. the distance of the monitor is too far and higher than eye level; the operating surface is set as elbow height; the optical axis-to-target view angle was 45° .

2.2.2 Subjects and Tasks

Experienced laparoscopic surgeons who have adapted to a certain work posture were excluded from this study. Twenty subjects (9 males and 11 females) aged from 22 to 31 without laparoscopic experiences were allotted into two groups (Group 1 and 2). Their body height (9 males body height: $179\text{cm} \pm 6\text{cm}$; 11 females body height: $167\text{cm} \pm 9\text{cm}$), eye-level and elbow height were measured. Every subject had to perform two tasks.

In task 1 laparoscopic suturing was simulated by threading tiny tubes (Matern, et al., 2005). Several tiny plastic tubes with a diameter of 5mm were sequentially stringed with a curved needle using two needle holders (26173 KL, Karl Storz, Germany). The number of tubes stringed by every subject in 5 minutes was counted.

Task 2 was supplied by COVIDIEN. The suture (polypore 2-0) was threaded through 8 eyelets on a training block with a curved needle using two needle carriers. The suture path was indicated by the arrows. The completion time and the number of incorrect actions were recorded. Here the incorrect actions included needle dropping, ring missing and wrong suturing direction.

In agreement with Derossis (Derossis et al., 1998), a timing score was defined based on the completion time and a cutoff time of 900 seconds. A timing score can then be calculated by:

$$\text{Timing score} = 900 [\text{s}] - \text{completion time} [\text{s}] \quad (1)$$

The performance of task 2 was evaluated by the timing score and the penalty score. The penalty score was obtained by the sum of the points for incorrect actions: 10 point for each needle dropping and ring missing, 5 point for each wrong suturing direction. The total score can then be given by:

$$\text{Total score} = \text{timing score} - \text{penalty score} \quad (2)$$

The performance is in direct proportion to the total score in this method. In other words, a task with a certain completion time and fewer mistakes gains a higher score than that with more mistakes.

2.2.3 Experiment procedure

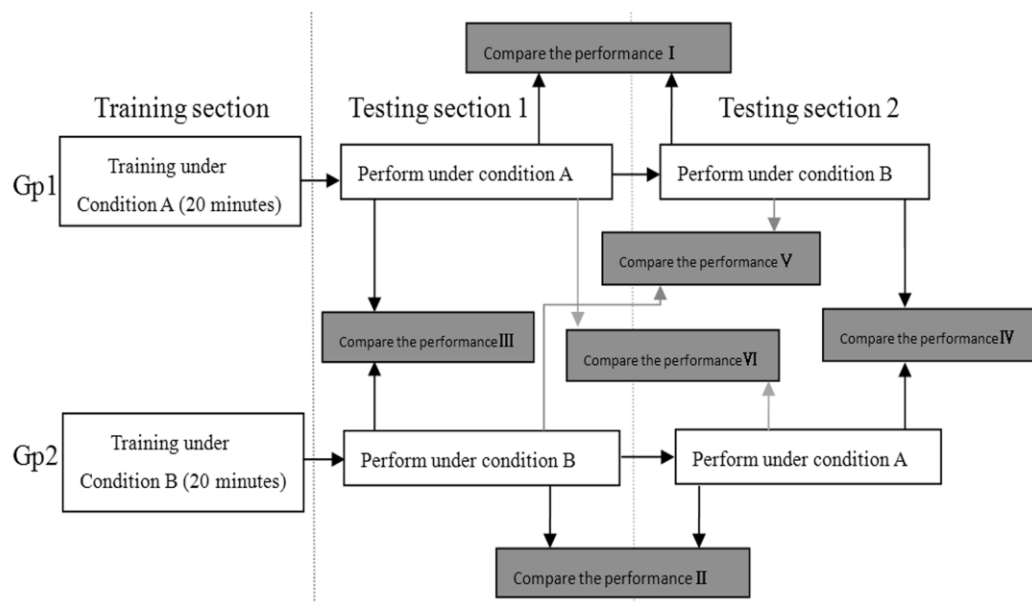


Figure 2.4 Scheme of experiment procedure.

Figure 2.4 shows the experiment procedure. Group 1 was trained with the box trainer under Condition A. Their performance was first assessed under the optimal ergonomic setting (G1A), then under the non-optimal ergonomic setting (G1B).

Group 2 was trained with the box trainer under Condition B. Their performance was first assessed under a non-optimal simulation setting (G2B), then under an optimal ergonomic simulation setting (G2A), as illustrated in Figure 2.3. This testing sequence was specifically chosen in order that the subjects could not recognize the obvious difference of training setting and testing setting.

Every trainee had to perform task 1 and task 2, and the performance of task 1 and task 2 were analyzed respectively. The data were processed using SPSS17.0 software, parametric t-test. The performance difference between Group 1 and 2 were analyzed with the independent t test (III,IV,V,VI). The performance difference of each group under Condition A and B was studied with the paired t-test (I and II). The statistical significance level was set at $\alpha = 0.05$.

2.2.4 Questionnaire and Video Analysis

After the subjects finished the tasks, they were asked to fill in a questionnaire asking them how much physical discomfort in their necks, shoulders and arms they experienced during the test. All questions were rated by a 5-point Likert scale, where points 1-5 stand for no discomfort, mild, moderate, serious and severe discomfort, respectively.



Figure 2.5 Measurement of joint angle and optimal posture of a surgeon

Before the subjects performed tasks, markers were put on their wrists, elbows, shoulders and heads (figure 2.5). According to the position of these markers, joint angles can be measured with MB-ruler on computer screen. The MB-ruler is a triangular screen ruler able to measure angles on the screen (<http://www.markus-bader.de>). It was used to measure the joint angles based on the markers (figure 2.5) at an interval of 5s for a period of 5 min per subject (60 measurements of per part per subject). The angle was then compared to the neutral posture. The right side of figure 2.5 shows an ideal posture for the MIS surgeon according to literatures (Matern and Waller 1999; Veelen 2003). The arms are slightly abducted, retroverted, and rotated inward at shoulder level (abduction $< 30^\circ$). The elbows are bent at about 90° - 120° flexion. This position leads to the maximal strength to be applied for a maximal time. The head is slightly flexed with an angle between 15° - 45° . The video data were processed with the software SPSS17.0 using non-

parametric Wilcoxon signed rank test. The statistical significance level was set at $\alpha = 0.05$.

2.3 Results

2.3.1 Results of task performance

The performance of task 1 was scored by the number of the stringed tubes (Figure 2.6). The mean score of G1A was significantly higher than that of G2B ($p=0.005$ III), and no significant differences ($p=0.615$ IV) were found between G1B and G2A. In addition, both Group 1 and 2 had better performance under Condition A than under Condition B and the mean score showed significant difference ($p=0.025$ and $p=0.001$).

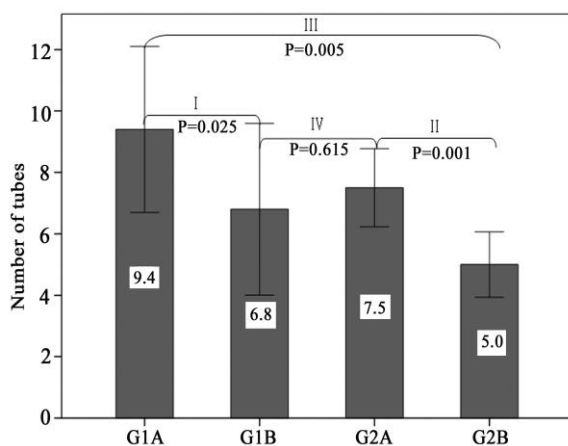


Figure 2.6 Performance of Group 1 and Group 2 under Condition A and B (task 1). The difference between G1A and G2B was significant (independent t-test, $p=0.005$); a significant difference between G1A and G1B (paired t-test, $p=0.025$), or G2A and G2B (paired t-test, $p=0.001$); there was no significant difference between G1B and G2A ($p=0.615$).

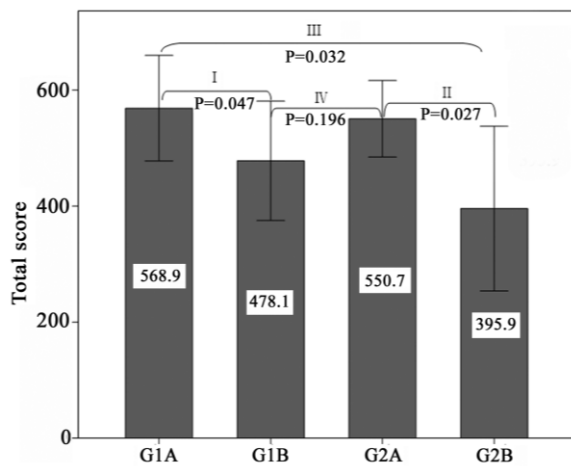


Figure 2.7 Performance of Group 1 and 2 under Condition A and B (task2). The difference between G1A and G2B was significant (independent t-test, $p=0.032$); a significant difference between G1A and G1B (paired t-test, $p=0.047$), or G2A and G2B (paired t-test, $p=0.027$); there was no significant difference between G1B and G2A (independent t-test, $p=0.196$).

The performance of task2 was scored by the timing score and the penalty score according to Eq. (1) (Figure 2.7). The mean score of G1A was higher than that of G2B ($p=0.032$ III). There were no significant differences between G1B and G2A ($p=0.196$ IV), but better performance under Condition A was observed. Both Group

1 and Group 2 performed better under Condition A than under condition B. The mean score were significantly different ($p=0.047$ and $p=0.027$, respectively).

2.3.2 Results of questionnaire

The physical discomfort of the neck, shoulder and arm were rated from 1 (no discomfort) to 5 (severe discomfort). Table 2.1 showed the answers of the subjects. Under Condition A, the subjects who experienced discomfort of their necks, shoulders and arms, comprised 40%, 50%, 60% of the total subjects, respectively. In contrast, the percentages under Condition B were 90%, 100%, 100%,

		Number of Subjects				
		No discomfort	Mild	Moderate	Serious	Severe discomfort
Neck	Con. A	12	7	1	0	0
	Con. B	2	9	6	3	0
Shoulder	Con. A	10	5	3	2	0
	Con. B	0	3	7	6	4
Arm	Con. A	8	10	2	0	0
	Con. B	0	6	6	5	3

respectively.

Table 2.1. Outcome of twenty subjects experience different extent of physical discomfort in their neck, shoulder and arm.

As shown in Table 2.2, the number of the subjects who rated their discomfort of body parts under Condition B higher than that under Condition A. Higher mean indicated that the subjects experienced much more physical discomfort. Significant differences of discomfort extent under both conditions were found ($p=0.0004$, $p=0.0002$ and $p=0.0005$, respectively). It is shown that the subjects preferred Condition A to Condition B.

Table 2.2. The extent of joint discomfort.

	Condition A		Condition B		<i>p</i> value ^a
	Mean(SD)	Median(Range)	Mean(SD)	Median(Range)	
Neck	1.45 (0.605)	1.00 (1-3)	2.50 (0.889)	2.00 (1-4)	0.0004
Shoulder	1.85 (1.040)	1.50 (1-4)	3.55 (0.999)	3.50 (2-5)	0.0002
Arms	1.90 (0.641)	2.00 (1-3)	3.25 (1.070)	3.00 (2-5)	0.0005

^aWilcoxon signed rank test

2.3.3 Results of posture analysis

The posture analysis was implemented for task 1 under Condition A and B respectively. The results of the video analysis of the neck, shoulder and arm were shown in table 2.3. Much more neutral joint positions were recorded under

Condition A than under Condition B. It can be seen that the head flexion/extension were considerably more neutral under Condition A than under Condition B ($p=0.0008$). The shoulder abduction was also more neutral under Condition A (left shoulder $p=0.0009$, right shoulder $p=0.0001$). Significant differences of elbows flexion were recorded (left arm $p=0.0004$, right arm $p=0.0003$). The results were in agreement with the questionnaire.

Table 2.3. Percentage of neutral posture. (Twenty subjects' head flexion, shoulder abduction, and elbow flexion were measured.)

	Head flexion/extension	Shoulder abduction		Elbow flexion	
		Left	Right	Left	Right
Condition A	83.2%	92.6%	92.9%	96.8%	84.2%
Condition B	1.8%	26.1%	25.2%	58.6%	41.8%

2.4 Discussion

Various studies have investigated the role of ergonomic factors in the operating room, but very limited research focused on the ergonomic simulation setting during training in a skills lab. Nevertheless, non-optimal ergonomic simulation setting can usually be observed in a skills lab. Therefore, it is imperative to study whether and how the ergonomic simulation setting in the skills lab can influence the task performance.

The results of this study showed that the task performance of the subjects was influenced by two different conditions, and the ergonomic factors of the skills lab affected the training efficiency. The analysis of the result is given as following (I-VI represent the performance comparison of performance in figure 2.4).

(1) *Different testing condition within groups* (I and II). Significant differences between G1A and G1B (I: $p=0.025$ for task 1, $p=0.047$ for task 2), and between G2A and G2B (II: $p=0.001$ for task 1, $p=0.027$ for task 2) were found. These differences reveal that the subjects show better performance under the optimal ergonomic condition than under the non-optimal condition. Similar results were found in different literatures. In the study of Hanna (Hanna and Cuschieri 1999), ten surgeons carried out a standard task with the optical axis of the endoscope subtending 90° , 75° , 60° and 45° to the target surface. The best task performance was obtained when the optical axis of the endoscope was perpendicular to the target plane. A study of Emma (Emam, Hanna et al. 2000) investigated the effect of 3 intra-corporeal-extracorporeal instrument length ratios (2:1; 1:1; 1:2) on efficiency and quality of intra-corporeal surgeon's knot. The result showed that

intra-corporeal/extracorporeal instrument length ratio below 1.0 degrades task performance

The difference between this study and other studies is that the setup of this study was a simulation of all ergonomic factors together. The results are consistent with those expected and indicate that the ergonomic factors play a vital role in evaluation of the task performance.

(2) *Different testing condition between groups (III and IV).* Significant differences between G1A and G2B were found (III: $p=0.005$ for task 1, $p=0.032$ for task 2). These differences showed that the optimal ergonomic setting leads to better performance. Insignificant differences between G1B and G2A (IV: $p=0.615$ for task 1, $p=0.196$ for task 2) were observed. The reason is that the training condition of Group 1 was better than that of Group 2, as a result, the performance of Group 1 under non-optimal condition was not worse than that of Group 2 under the optimal condition. It was concluded that the optimal ergonomic training condition is benefit for trainee to learn skills.

(3) *Same testing condition between groups (V and VI).* Statistically no significant differences between G1A and G2A (V: $p=0.167$ for task 1, $p=0.719$ for task 2), and between G1B and G2B (VI: $p=0.200$ for task 1, $p=0.303$ for task 2) were found. It was indicated that Group 1 and Group 2 were trained under the optimal condition and non-optimal condition respectively, and their performance was not significantly different under same condition. However, a better performance trend of group 1 was found. The authors deduced that the difference was insignificant because of the limitation of this study. It is therefore revealed that difference in ergonomic setting does not necessarily lead to a distinction of performance in the case of the simple tasks and the relatively short training time. Besides, the use of the subjects is also a main influential factor affecting the experiment outcome. The subjects are not medical students and thus cannot be really focused and professional in the experiment. As a result of this, the more complicated tasks should be predesigned and the medical students should be selected for further research.

The results of video analysis show that subjects hold more neutral posture under Condition A than under Condition B. These findings also agreed with the results of the questionnaire. Under Condition A, the subjects experienced less joint excursion and less discomfort of their necks, shoulders, and arms. It is demonstrated that the physical complaints can be remarkably reduced using the optimal simulation setting. The results of this study are in line with these literatures who defined the current guidelines (Hanna and Cuschieri 1999; Emam, Hanna et al. 2000; Matern, Waller et al. 2001; Berquer, Smith et al. 2002; Marcos, Seitz et al. 2006; Wauben, Veelen et al. 2006). In a study of Kaya (Kaya, Moran et al. 2008), eighty-two participants who performed video endoscopic surgeries assessed various problems ranged from

32% to 72% owing to poor ergonomic conditions. The authors suggested that the problems encountered by the staff during video endoscopic surgery and the poor ergonomic conditions of the operating room affect the productivity of the surgical team and the safety and efficiency of the surgery. Therefore redesigning of the instruments and the operating room is required. In this study, the optimal ergonomic simulation setting is thus recommended for use in the skills lab. It can help the surgeons to realize the importance of ergonomic factors during laparoscopy procedure which they already knew during training.

This study is the first step to analyze the effect of ergonomic conditions on the task performance during surgical training. Optimal ergonomic guidelines for laparoscopic surgery have been defined by many researchers, but why the non-ergonomic settings still existed in operating room and skills lab is a grand question. This question deserves related research to contemplate. In the authors' view, it is meaningful to improve surgeons' ergonomic consciousness by training. Also redesigning of instruments and surgical simulators are required.

The next step will continue to investigate the ergonomic factors during surgical training through more complicated tasks and longer training time. In addition more factors that should be included in the training conditions, in order to make the training condition in a skills lab more close to the real operating room environment.

2.5 Conclusions

This study shows that the optimal ergonomic simulation setting leads to better task performance. And optimal and non-optimal training setting have different learning effects on trainees' skill learning. Training under the present optimal ergonomic condition can reduce the physical discomfort and thus, improve the task performance.

Posture analysis showed that the subjects held a much more neutral posture under optimal ergonomic condition. The subjects had less joint excursion and experienced less discomfort in their neck, shoulders, and arms. Optimal ergonomic simulation setting as described in this study should be recommended in skills lab during training.

2.6 Acknowledgments

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CHAPTER 3 ERGONOMIC PROBLEMS IN LAPAROSCOPIC SURGERY TRAINING & CASE STUDY

Simulation-based training is generally recognized and pays an increasingly important role in training and education of medical specialists, not only in minimally invasive surgery but also in other technology dependent procedures. It offers a unique opportunity to acquire mandatory skills for safe performance of respective procedures.

However, the ergonomic factors of simulators and simulation settings in skills labs have been grossly overlooked. In this study ergonomic factors that can influence training efficiency in several aspects are investigated. This by adopting the ergonomic guidelines for the OR and MIS procedures, performing observations in the OR and in the training centers as well as interviewing expert surgeons on their opinion of the optimal ergonomic setting in general and of skills lab. The aim of this chapter is to create an overview of requirements for optimal ergonomically set up of the training simulator and skills lab, thus bridging the gap between training environment and the OR.

A case study of designing a surgical training table is discussed. The aim of this case study is to improve the design of a surgical training table, and thus to design an optimal table to meet multiple training requirements, especially for the laparoscopy surgical training.

This chapter is based on the following article and report:

D. J. Xiao, A. Albayrak, R.H.M. Goossens, Jack J. Jakimowicz (2011). Training the Surgeons in an Ergonomic Way --- Reduce the Gap between Laparoscopic Simulation and Procedure. Conference Proceeding of HEPS.

Report of Surgical Training Table (2013) as part of Advanced Embodiment Design course at Delft University of Technology. Michiel van Schelven, Marcel van de Pol, Puck Bos, Sandra Lup, Myra Vreede, Michèle de Reus

3.1 Ergonomic problems in laparoscopic surgery training

3.1.1 Introduction

Two decades since its introduction laparoscopic surgery/minimal invasive surgery became a viable, safe and beneficial alternative for large number of open surgery procedures (Berguer 2006). However, it also brings new challenges for the surgeons due to technical drawbacks. Main limitation are well recognized: long rigid instruments introduced through fixed entry point restricting freedom of movement from 6 to 4 degrees, fulcrum effect, magnification of natural hand tremor, limited tactile feedback, two dimensional image of a 3d operative environment and limited side view of operation field. These drawbacks of minimal invasive surgery attribute to a long learning curve and necessitate adequate and intense training program particularly for surgeons in training to guarantee safety and quality of performance.

Intense training programs are however difficult to implement in view of existing (socio-economic) changes, for example the introduction of the European Work Time Directive reducing working hours and therefor limiting the opportunity to train in a clinical setting. Therefore it can be concluded that learning new skills in the OR on patients is no longer the best option, neither for the patient nor for the surgical trainee (Dankelman and Di Lorenzo 2005; Aggarwal and Darzi 2006). A primary aim for trainees is to gain and assess skills through repeated practice in a safe environment, before allowing them to operate upon real patient in the OR. In the course of the last decades, many new methods and materials for training surgeons became available. Several laparoscopic simulators are currently available on the market, and they can roughly be categorized as box trainers, virtual reality simulator systems, and augmented reality simulator systems (Dunkin, Adrales et al. 2007).

Box trainers are relatively inexpensive and provide the experience of haptic feedback in contrast to non-haptic virtual reality (VR) simulators (Botden, Buzink et al. 2008; Bahsoun, Malik et al. 2013). Some VR simulation systems do however provide computer generated haptic feedback nowadays. VR simulators offer the possibility to train psychomotor skills using software, varying from simulating basic laparoscopic exercises to simple surgical tasks toward full operative procedures.

These systems allow repeated practice of standardized tasks and provide unbiased and objective measurements of laparoscopic performance. By using repetitive VR training, a substantial part of the individual learning curve can be overcome before practicing on real patients (Sutherland, Middleton et al. 2006). Augmented Reality is composed of a combination of real-world and computer generated imaging (data). Such systems combine physical objects with virtual reality image. Like with training

on box trainers the structures can be artificial or made from organic (living or cadaver) materials (Dunkin, Adrales et al. 2007).

These different kinds of surgical simulators play an important role in surgical training. They are implemented into training curricula and at surgical skills labs. However the surgical trainees still have to face ergonomic problems during the training. The aim of this chapter is to investigate ergonomic factors during laparoscopic surgical training in lab setting.

3.1.2 Ergonomic factors during laparoscopic surgical training

A number of studies generate ergonomic guidelines on the setting of the OR (Ramon Berguer 1999; Vereczkel, Bubb et al. 2003; van Veelen, Jakimowicz et al. 2004; Berguer 2006; Wauben, Veelen et al. 2006; Zehetner, Kaltenbacher et al. 2006; Det, Meijerink et al. 2009; Sutton and Park 2012). However, these guidelines are not generally applied in hospitals all over the world probably due to the limited attention paid to the ergonomic settings in general. The skills lab facilities often do not comply with the actual generally accepted ergonomic settings of the workspace (see figure 3.1(a) and (b)) and therefore do not condition the trainee in adapting according the ergonomic guidelines in real life OR.



Figure 3.1 (a)

(b)

(c)

3.1.2.1 Ideal working posture for laparoscopic surgeons

Figure 3.1(c) shows an optimal posture for a laparoscopic surgeon regarding the ergonomic guidelines. (van Veelen, Kazemier et al. 2002; Zehetner, Kaltenbacher et al. 2006) The head is bent forward at the angle of a slight nod within 15-45°. Increased bending of the head and neck over a long period of time should be avoided because it may result in tension and pain of the neck muscles. The arms can be held at an elbow angle within 90-120° for a long period of time (Matern and Waller 1999). The favorable working angle between two instruments for stitching

and knotting is 60° (Hanna and Cuschieri 2008). The forearm is in its neutral rotating position between pro- and supination. From this position, any possible grip can be performed fast and easily (Wauben 2010).

Proper and comfortable postures can not only minimize the risk of musculoskeletal injuries to the operator, but also can improve the task performance (Matern 2003). According to this study, the performance of laparoscopic surgery improves when the ideal body posture for laparoscopic surgery is considered (Matern 2003). However, there are also several factors in laparoscopic surgery which can hinder the surgeon to adopt an ergonomic body posture. These factors are listed below.

3.1.2.2 Position of monitor

Because the surgeon views the surgical field through a visual display for long period of time, the position of the monitor is very important for a comfortable posture. Therefore monitors in the OR are often positioned correctly but during the training session in a skills lab, the monitor position is still non-optimal which is incompatible with the recommended neck position. However, video display devices that are mounted on flexible booms allow the surgeon to alter the vertical position of the monitor to obtain the ideal angle between eye level and the monitor both in OR and skills lab, as described above (Figure1c). So it is necessary to improve surgeon's ergonomic consciousness during training.

3.1.2.3 Operating Table Height

A proper adjustment of operating table is very important during laparoscopic surgery to enable the surgeon to keep an ideal upright standing posture. Ergonomically, the angle between the lower and upper arm should be between 90° and 120° as described above. The lowest height of tables used in skills labs is approximately the height of a standard desk, which is too high for laparoscopic surgery training. This may bring height related problems in some cases, and trainees with small posture may need to elevate their arms or stand on one or more foot stoles to achieve the proper operating height, which is very uncomfortable,. See figure 3.2. The small area available for trainees' feet on a stole limits their movements, and quite often the foot switch of elector surgery or other energized devices used during surgery falls off.

3.1.2.4 Selection of laparoscopic instruments

Beside the operating surface level and monitor position, the design of the instruments handle influences the position of the hand. The surgeon needs to squeeze harder, bend the wrists more, and hold their arm higher when using laparoscopic instruments compared to open instruments. These factors, together,

can produce substantial hand and shoulder fatigue and discomfort during laparoscopic surgery (Supe, Kulkarni et al. 2010). To perform laparoscopic surgery, often different kinds of handles attached to different types of instruments are used. (See figure 3.3) Ring handles are suitable for one-handed manipulation of two instrument functions, opening/closing and rotation of the effector. The pistol handles are suited for combining multifunction, such as irrigation, suctioning and coagulation (Matern and Waller 1999).



Figure 3.2. A small trainee is standing on stools

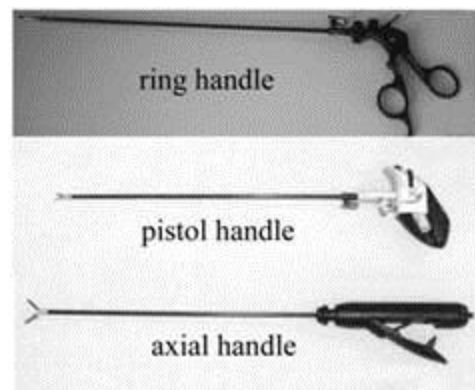


Figure 3.3. Three different laparoscopic handles

3.1.2.5 Port placement and target location



Figure 3.4. Improper manipulation angle

Proper trocar ports location can ease the performance of a laparoscopic procedure and its execution time. For bimanual tasks, manipulation, azimuth and elevation angles govern optimal port sites (Hanna and Cuschieri 2008). During the training with a simulator, by choosing a proper port placement and target location, the optimal working angle can be achieved. However, trainees neglect this important aspect, or the simulators are designed in such a way that cannot ensure a proper port placement and target location. For instance, in left of figure 3.4 shows a

situation where the manipulation angle is more than 100° , and the elevation angle is almost 90° . This kind of condition should be avoided.

3.1.3 Requirements of simulators

Laparoscopic simulators range from simple box trainers with standardized tasks to advanced VR simulators. They use different didactic resources to train laparoscopic skills. Researchers still need to agree upon objectives, needs, and means of training, (Lamata P Fau - Gomez, Gomez Ej Fau - Bello et al. ; Wentink, Stassen et al. 2003) and these agreements should also constitute the main requirements of a simulator design according to ergonomic guidelines.

3.1.3.1 Improving ergonomic setting

A properly designed simulator interface can be beneficial for surgeons to understand the importance of the ergonomic factors during surgical training, and thus improve the consciousness of performing in an ergonomic setting. From an experienced surgeon's point of view, the adjustment of the operating surface level of the simulator, monitor position should be very easy, which can ensure comfortable posture of the surgeon during the procedure. In addition if the target location or port placement can be easily adjusted as well, the ideal manipulation angle of the instruments will be easily achieved.

3.1.3.2 Increasing the realism

The often-quoted criticism is that surgical simulators lack "fidelity," or are not truly lifelike. For many VR simulators, researchers are developing new simulation technologies and making serious efforts towards the construction of high-fidelity systems, such as a vivid anatomy, textures, and tissue deformation and bleeding. However, most VR simulators use the modified instruments to interact with virtual objects, and thus the force feedback is lost, which can be a disadvantage during the performance of some tasks of VR simulators. Although, some of the VR systems already provide some degree of computer generated haptic, it is widely believed that a higher fidelity in simulation will improve training by providing an engaging effective training environment (Darzi A Fau - Datta, Datta V Fau - Mackay et al.). Researchers have their own way to increase realism of low-cost physical trainers. Louise Hull et al (Louise Hull and Roger Kneebone 2010) enhanced the realism of a laparoscopic box trainer by using a simple, inexpensive method. The abdominal cavity images were printed onto a laminated card that lined the bottom and sides of the box-trainer cavity. Incorporating this technique in the training of laparoscopic skills is an inexpensive means of emulating surgical reality that may enhance the engagement of the learner in simulation. In addition, vivid artificial organs can be good substitutes for real animal organs to practice surgical skills.

3.1.3.3 The importance of assessment

Assessment of any task performed on a simulator, together with meaningful feedback, is a vital part of the learning process, which can stimulate trainees to keep learning. For the VR simulators, the computer system registers performance parameters for each task to score performance: time, error parameters, and economy of motion parameters (Eriksen and Grantcharov 2005). For the augmented reality simulators, a camera tracking system is used to record and calculate the path length of the instruments, motion smoothness during task performing as objective assessment, and observation of an expert as subjective evaluation. Refer to simple box trainer, and the performances are mainly scored subjectively by expert surgeons.

3.1.4 Conclusion for the review

Simulation-based training in surgery can provide an immersed, safe training environment for the surgical trainees without risk to harm patients. However, the gap between skills lab and real OR environment is not yet overcome. On the other hand, fortunately the skills acquired during simulation training in the skills lab are applicable to the performance in the OR. There is undoubtedly need for simulation training in skills lab using both simulators and an environment/skills lab setting that fulfill basic ergonomic guidelines.

Within this PhD research many design proposals are made to improve the training setting of the laparoscopic surgery. A portable ergonomic laparoscopic surgical simulator (Ergo-Lap Simulator) was developed. The design and validation of the Ergo-Lap Simulator is discussed in chapter 4, 5 and 6 of this thesis.

In this chapter, an ergonomic surgical training table was selected as a design case will be discussed.

3.2 Case study: A newly designed surgical training table

This case study is based on an assignment of Advanced Embodiment Design (AED). The AED course followed by the students of the Integrated Product Design (IPD) master program at the Faculty of Industrial Design Engineering at Delft University of Technology. In this course, a team of 6 students tackle an embodiment design assignment from a company (figure 3.5). The assignment of case study here is cooperated with Catharina Hospital Eindhoven. The assignment was to design a surgical training table for the skills lab and to offer an improvement in the ergonomic posture of the users. This assignment started with analysis of the requirements, on which the team focused on during the design process.



Figure 3.5 Design team

3.2.1 Analysis phase

The assignment is to define and design a surgical training table for the skills lab in Catharina Hospital, in Eindhoven. As a teaching hospital, a wide range of techniques are taught and practiced in the skills lab of Catharina Hospital. The new designed table should meet the ergonomic requirements, which are listed in the defined requirements for the designated users. Because of a wide variety of users (nurses, nurse practitioners, surgeons), the table has to be strongly versatile, in order to offer correct and ergonomic training conditions to all of the users.

The surgical training table was divided into separate parts, in order to have a better overview of the requirements for each element: table top, attachment poles, attachments, wheels system and facilitative modules.

3.2.1.1 Define requirements

Based on the analysis of the assignment a list of main requirements were created.

(1) Ability to place different training components on the product

The training components are essential for conducting the training on the surgical training table. Various training modules can be attached on the table, depending on the type of training. For example, basic skills trainings, dissection tools and boards are placed on the table, and for laparoscopic trainings simulation modules and screens are needed.

(2) Ability to clean easily

The surgical training table is used in a clinical environment. Even though the table does not contact with the patients, cleaning is still an important aspect that was considered during the design process. It was decided that, in order to be easily

cleaned, the table should not contain holes, rims or small orifices where dirt particles can gather.

(3) Ability to adjust the table height for Dutch percentile P1-P99 length of users

The users of the surgical training table may have various anthropometric measurements. It is important that all the users have an ergonomic posture during their training, both for basic trainings that involve sitting around the table, and for laparoscopic trainings that involve standing. Multiple parts of the table should be adjustable, in order to offer the most ergonomic positions for users with a stature between 1.50 and 1.99m. These parts are the table top, the attachment poles, and the tray.

(4) Accommodate a rolling support for comfortable movement

The surgical training table is usually located in the skills lab. On some occasions the table needs to be moved in a storage room. This is why having a rolling support is an important aspect that was taken into account during the design process. The rolling system has several requirements, concerning the brakes and security aspects.

(5) Accommodate placing of at least 2 HD screens

During the laparoscopic training, the users observe their procedures on one or two screens, depending on the type of techniques being practiced.

(6) Accommodate placing of at least 2 adjustable light sources

During the basic skills trainings four people are sitting around the table, working on delicate procedures, like stitching, suturing, dissection of animal organs etc. For all these procedures, a good source of light is needed. This is why the table should accommodate at least two light sources, preferably one light source for each person.

(7) Accommodate hanging at least 4 liquid substances at the same time

During the basic skills trainings there are various techniques that require hanging liquid substances, such as applying the IV. This is why having the possibility to hang fluid bags is important for having realistic trainings.

(8) Accommodate placing of sockets for at least 8 components

Almost all the simulation modules used on the surgical training table need electricity power in order to function: lamps, cameras, laparoscopic simulations etc. Having sockets on the table will help avoiding disorganization in the wires and sockets.

(9) Safety requirement

It is essential that the user can work with all the parts of the table in a safe way, without being injured.

3.2.1.2 Target group and context

Target group

The surgical training table has a large number of users with different background educations and anthropometric measurements, perform different kinds of tasks. The main challenge in developing the product was dealing with the ergonomic aspects of the table, because of the wide target group.

Depending on the skills levels, there are various users, like nurses, nurse practitioners and specialists or surgeons. During the development of the table, the variety of users are always taken into account and it was considered essential to make it suitable for users of P1-P99 length, which mean 98% of all users with different anthropometric data.



Figure 3.6. Target group.

Context

The training modules differ in complexity and scenario of usage, depending also on the skills to be practiced. The table is used by nurses, nurse practitioners and specialists. Some training modules that can be placed on the table are as following (Figure 3.7):

- Model arms for training Intra Venous Therapy, model heads and lungs for intubation

- Laparoscopic simulation boxes
- Endoscopic simulation modules
- Dissection boards
- Animal cadaver parts

Besides the simulation modules that are used for the specific parts of the training, other elements need to be placed on the table, in order to complement the functioning of the modules.



Figure 3.7. Different training modules and activities in the skills lab.

- Lights

The lights can be placed in various positions, because of the fixing system and the adjustable arm. The arm allows the user to adjust the position of the light, depending on its position and on the training that is being performed. A table can have multiple lights.

- Screens

Usually the screens are used in the laparoscopic trainings, and are connected to the simulation modules, showing the images that the camera is recording. The position of the screen is essential for the users. The screen can be placed on the tray or can be fixed on an adjustable arm, which allows adjusting the position during the training. A good position of the screen, in regard with the anthropometric features of the user, suggests an ergonomic posture. A table can offer place to multiple screens.

3.2.2 Design process

The design process started with the assignment analysis. Compare to the former surgical training table, several improvements were brought to the first design of the new surgical training table that the client considered to be valuable. The different functionalities of the surgical training table are listed below.

- Height regulation table top

Because of the new power lifts, the table allows the users to have a more ergonomic position while practicing. In the current situation the lowest position of the table top is 700mm, so small surgeons have to use a step in order to get an ergonomic posture. This will no longer be necessary with the new surgical table, because the minimum table top height is 570mm.

- Monitor position

In the new design the boom arm will also be attachable and detachable to the attachment poles so it can also move up and down.

- Mobility

The new design of the surgical training table brings an important improvement in the mobility aspect. A collapsible wheel system is introduced in the design. When the wheels are collapsed, the table can be easily rolled and transported between rooms. When the wheels are up, the table has a larger support surface, which offers it a better stability. Another point that improves mobility is the fact that the table top of the new table is foldable. This makes the whole table smaller and easier to transport and move between rooms.

- Storage

The storage of the new surgical training table can be done in a more efficient way, using less storing space than in the current table. This issue is solved by making the table top side parts foldable.

- Weight

In the new design, the different parts of the table are scaled properly, so they do not weigh more than it is structurally necessary. The aluminium poles are light, but the calculation shows that they can take the weight of the facilitation modules.

- Workspace

The new surgical training table has a considerably larger surface of the workspace, which allows four people to sit around it: two on each side. The design of the poles also makes this possible, because a pole can be turned towards each side of the table, to place the facilitative modules.

3.2.3 Details Design

- Table top

The workspace of the table top consists out of three parts, two side parts and one middle part. These parts are connected to each other via four hinges, two on both sides. (Cross-section shown in Figure 3.8(1)). In each side of the panel two sliders are located which can slide into the middle part when these panels are horizontal (Figure 3.8(2)). The handle for this slider is on the side of the table. The foldable design makes it easier for storage and transportation between different rooms. The side panels can be controlled individually, which makes multiple table set-ups in the Skills lab possible.

- Sliding of the table top

The table top of the new surgical training table can be extended towards the user during laparoscopic trainings. This elongation is only used during this kind of trainings, where certain dimensions are needed to facilitate the module and remain the ergonomic approved distances. The system of this sliding is attached to the attachment part at the top of the lift. Figure 3.8 (3)

- Attachment poles

An adaptation in the design is made to save workspace and fixate training tools freely over the table. This improves the customizability of table and the freedom of the users to place tools on their preferred spot. The curve in the pole is made to provide attaching points for tools above the heads of the user. Here they do not interfere with the movements of the users and makes observation from above possible. The attachment of the lamps with flexible arms to the attachment poles is shown in figure 3.8(4).

- Fixating with clamps

The users will adjust the table to their anthropometric dimensions before they start working on it. The attachment poles, the tray and facilitating tools as the lamp will make use of ring clamps for fixation. These clamps can be easily opened and closed. A picture of the fixating clip supporting the attachment pole at the table top shows the way fixating and loosening the clip works. Figure 3.8(5)

- Lifting system

During the first processing of the design, we chose a scissor lift with a protective case. (Figure 3.8(6)) The scissor lift provides the complete desired travel but might have a bad influence on the safety of the user. The lift is heavy and might cause injury. The casing can also cause several problems, which might result in product failure. After several discussions with the client, the coach and the procurement officer, it was decided to look more into electric lifts. After a long time search in the market, a better and lighter lift solution was found (Figure 3.8(7)). The new lift was applied in the second processing of the design.

The lowest position of the new lift was 60mm higher than the desired set height based on anthropometric data. It was decided to accept this value and choose this lift because the amount of users that would be excluded would be so little and could also still make use of a step. The compact lifting column has a small starting height and a large travel ensuring the large range of positions our design requires because it consists of three movable compartments so it can travel more than its own starting height.



Figure 3.8. Detail design of the surgical table. (1) Cross section. (2) Sliders. (3) Sliding of the table top. (4) Attachment of the lamps. (5) Fixating clip. (6) Scissor lift with a case. (7) Final lift system.

- Design of the Tray

The new tray was fixed between the two poles and the two IV stands which are placed at either end of width of the table top (Figure 3.9). The tray will be fixated on the IV stands with the earlier mentioned clipping system while the attachments poles can be adjusted separately. The tray is made wide enough to store a laptop or a monitor and offered the possibility to adjust the height.

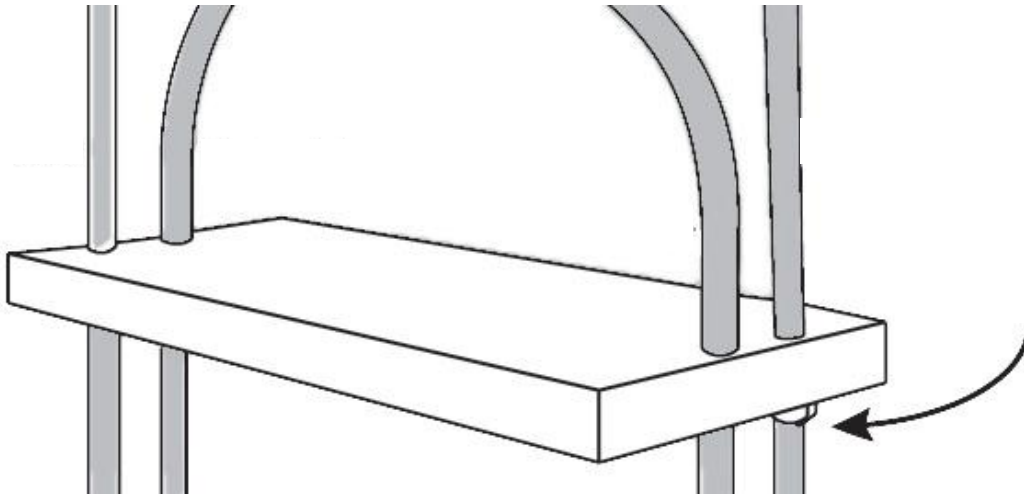


Figure 3.9. Detail design of the tray

3.2.4 Prototype & Evaluation Phase

All the functionalities discussed in the previous chapter is included in the final product proposal. From this final proposal a working prototype is build. The main goal of the evaluation process with the prototype was to validate the self-design parts. This will include the table top folding and sliding system, the sufficient of the lifting system and the adjustment of the attachment poles. All data is gathered using different observation techniques and a questionnaire. During the evaluation session, the participants can share information, comments and feedback. Figure 3.10 showed the prototype.

As a final element, the bottom plate was added to the prototype for easy mobility, and all wooden parts were covered in an extra layer of varnish to make them easy to clean. All electronic components that control the lifts were added, and first executive tests were conducted.

In order to conduct the experiment in a proper manner, a pilot test was carried out in the Faculty of industrial Design Engineering. After the pilot test, a set of conclusions and findings were discussed and small adjustments were made. Three different user tests were carried out in Catharina hospital.

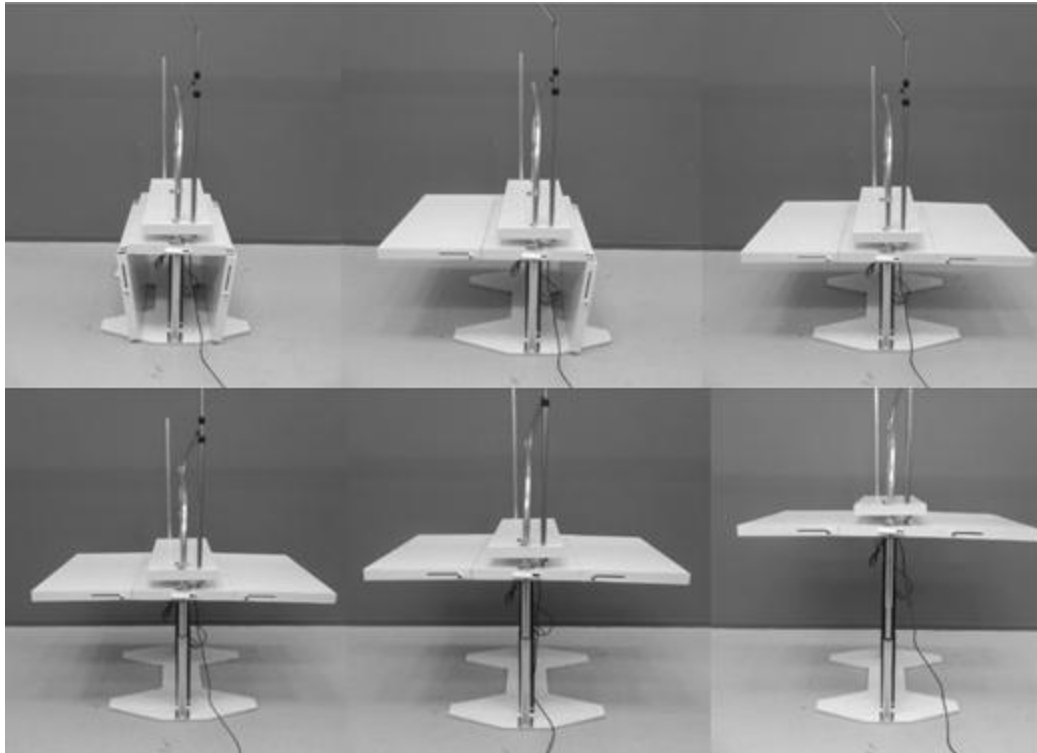


Figure 3.10 Prototype of the surgical table

3.2.4.1 User test 1

Four nurses performed an exam about inserting a needle for intravenous therapy, in a fake arm was observed. In this exam two nurses, one is taking the exam and the other one judges the other nurse stand around the table. Both sides of the table are unfolded (Figure3.11).

The procedure will be done in a standing position. On one of the poles, a lamp is attached. In the beginning of the procedure, the observers told the nurses how the table worked. This is done because they did not want to influence the results of the exam of the nurses. Photos were taken with permission. The researchers had notebooks in order to record the observations of the experiment.

The set-up of the experiment:

Tasks:

1. Set the table in right position
2. Perform the given task (the task of the exam)
3. Fill in the questionnaire

Devices:

- The surgical training table set in the folded position
- One lamp
- Intravenous therapy exam set

Participants:

One male (1.83m), who was the examiner, and four females (1.74, 1.66, 1.89, 1.68) participated in the user test.

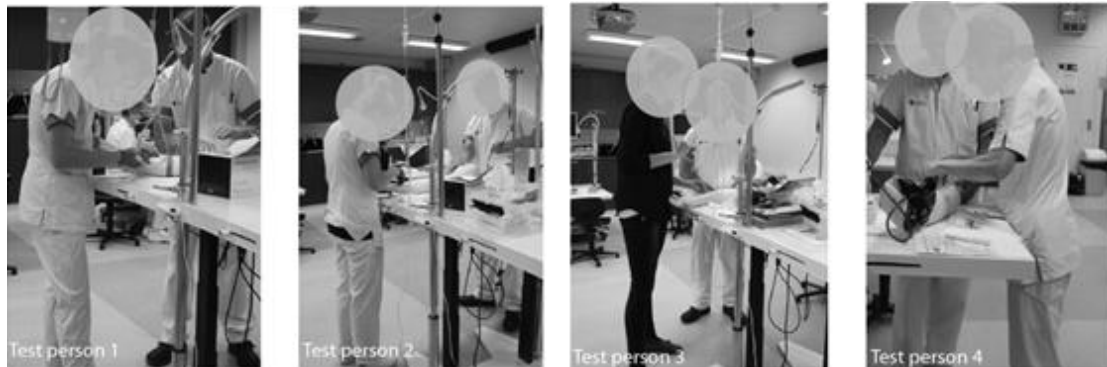


Figure 3.11 User tests 1

Results User test 1

Observations: Before the exam started, it was concluded that the tray in the way, so it was taken off. To have more space to put equipment on, the second table top part was also unfolded. This was perceived as useful. In addition, the height of the table was adjusted on a way, which was comfortable to work at according to the test persons.

We observed that the table was not set in optimal height during the task. In the figure 3.11, It can be seen that the table should be a bit lower for test person 2 and a bit higher for test person 3. When the participants were performing the task, the bottom plate was not included.

Results from questionnaire

The participants were positive about the table. They did not adjust the height of the table, but say the height was already good for them. In addition, the size of the workspace was perceived as wide enough. The big drawback was that the IV stands were too high.

3.2.4.2 User test 2

For the second test, the table was used for performing a laparoscopic task on a box simulator, which was 400 mm high that was positioned on one side of the table top. The screen was positioned on the tray. The researchers had cameras and notebooks in order to record the observations of the experiment (Figure3.12).

Multiple tasks were given to the participants, included unfolding one part of the table top, adjusting the height and adjusting the screen.

The set-up of the experiment contained:

Tasks:

1. Fill in the questionnaire
2. Set the table in the right position
3. Do a laparoscopic training
4. Fill in second part of the questionnaire

Devices:

- the surgical training table set in one folded position
- one lamp
- one screen
- laparoscopic box simulator

Participants:

Three males (1.87m, 1.82m & 1.76m) and one woman (1.73m) participated to the user test.



Figure3.12. User tests 2

Results User test 2

Observations: It seemed that the first and third participants set the table too low, because the elbow angle more than 120° . But they feel it was a comfortable height to work at.

- The lamp was not necessary and not used during the test.

- The screen was too low for the participants.

- The table top could hold the weight of the tools (+- 5 kg) and the screen (+- 3 kg) and still go up and down. Questionnaire: The participants indicate that they were afraid that the poles will be in the way. Especially when moving the tray up and down. Also they thought they maybe will clash their head against the poles.

3.2.4.3 User test 3

The third user test is conducted on a pig heart.

Two persons were sitting at the same side of the table top, working on a pin-up board with a plastic sheet over it. The pig heart will be pinned to the pin-up board.

Multiple tasks were given to the participants, included unfolding one part of the table top, adjusting the height and adjusting the light.

The set-up of the experiment:

Tasks:

1. Set the table in the right position
3. Do the coronary bypass training
4. Fill in the questionnaire

Devices:

- the surgical training table set in unfolded position
- two lamps
- two chairs
- one pin-up board
- plastic sheet cover
- two pigs hearts

Participants:

One man (1.87m) and one woman (1.62m) participated to the user test.

Results User test 3

Results from questionnaire: The participants state that it is clear how the table should be folded and unfolded. Also the height adjustment was clear.

Two persons of different heights were sitting around the table, so the height of the table was for both participants not entirely correct.

The smaller women stated that the height of the poles were right for her, but for the taller men the poles were at face height, which was experienced as unpleasant. It was not clear for the participants how the poles could go higher.

The adjusting of the lamp was easy, but it would not stay steady in one position. The arm could be more rigid.

3.2.4.4 Aesthetic Evaluation

The aesthetics of the table as perceived by the participants is evaluated. The aesthetic value based on the prescribed requirements is defined as: look clinical

and fit in the current skills lab. To make the table fit in the current skills lab, the table should evoke the right feeling at the user. Like medical, technical, professional, robust, subtle, hygienic, simple, durable & safe.

The figure 3.13 below shows how the 11 participants thought about the prototype of the table. The table evokes the right feelings. Compactness was desired, but the results showed in favour of the table being present. However since it is a very widely used surgical training table, making the table look compactness might be very hard.

The factors technical, professional, robust, hygienic, durable and safe are assumed to be lower in the final design. This is because the questionnaire is done about the prototype, which is not built by professionals. Some parts were not made in the prototype; this made it look less professional. (Like for example the collapsing wheels) The table will look more hygienic if it is not painted with a brush and if the finishing of the welds is better done. With a new prototype of the final design a new test should be done, to see if the table still fits all the aesthetic values.

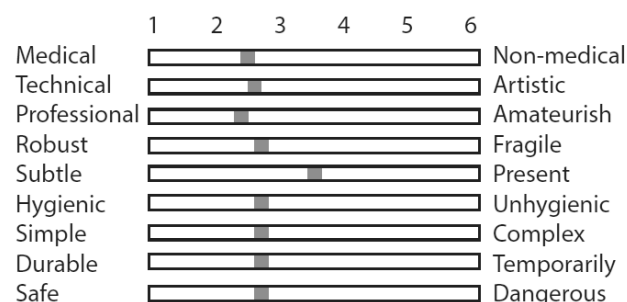


Figure 3.13 Evaluation result of the table

3.2.5 Recommendations for final design & Conclusion

3.2.5.1 Ergonomic sufficiency

The newly designed table can provide a comfortable working height for 10 out of 11 participants. During a sitting task, the table is not low enough for the smallest person (1.62m). In this case, he/she should use the height adjustment of the chair or something under their feet. During a standing task, the table can be adjusted to optimal height for everyone. When using laparoscopic box of 400mm high, the table is not low enough for 6% of the smallest users. This small amount of users should use a stool to stand on. Using a different lift with different height ranges, this would be not a problem anymore. In an ideal situation, this is not necessary, but this new lift has already enormous improvement in the height range and it is exactable that 6%, which will mean users shorter than 1.58m, stand on a stool.

3.2.5.2 Table top part

The foldable design of the table top proved to be a success. With the two sides down, it creates a stable and easily movable object. When one side is folded downwards, the weight of that part creates a counter weight to the weight of the tools placed on the other side part. Also the table can be placed closer to the wall when one of the parts is down, creating a bigger space for the participants and teacher to walk around making them less dependent of the position of their peers.

3.2.5.3 Wheel system

We did not chose wheels collapsing system for this prototype, because this system is already verified in other products. The bottom plate was made of Medium-Density Fiberboard (MDF). A laparoscopic training module was placed on the table during the test at the skills lab. Large sag of the table top was noticed from observational research. The weak connection between the lift and the bottom plate was the main cause for this. A change in the design of the bottom plate is needed because sag of the table top is not desired.

The bottom plate will contact with the floor on a big surface when the wheels are collapsed. The surface is cross-shaped what makes it stable in every direction and still leaves room for the legs while sitting at the table. A visualization of the space underneath the table top for people to sit is shown in Figure 3.14 (1).

The connection between the lift and the bottom plate becomes more part of housing than just a surface connection. Aluminium profiles are used to make a stiff connection between the power lift and the bottom plate. All profiles connected with prefabricated plastic elements to make a stiff construction that surrounds the lifting poles Figure 3.14 (2). These extruded profiles are covered with high pressure laminate (HPL) plate material. In the middle, between the lifting poles, a box is created where the wheels are located. The wheels can lift the whole training table by stepping on the foot pedal on the side of the table. The pedal is controlled and can only follow the shape of the inlet. This system is also used for lifting heavy gymnastic attributes.

3.2.5.4 New design bottom plate

The current table in the Skills lab has a bottom plate made from solid steel. Partially this provides stability because the centre of gravity will be very low to the ground, making the distance it would have to travel to go pass the turning point very large. However, the table only touches the floor by its four wheels. These wheels can all rotate to be able to move the table, but when the wheels turn inward the distance between centre of gravity and turning point greatly decreases, increasing the chance on tumbling over. A wish was to keep the table as light weight as possible to minimize the chance of injuries when turning over, where a

solid steel plate would be very hazardous, but to also design in such a way that tumbling over would not be likely to happen even under conditions of misuse.

The new design is an aluminium frame, holding the wheel collapsing system Figure 3.14 (3) en providing the needed stability when the table is not on its wheels. The bottom plate has a compact and extended position as well Figure 3.14 (4) and 3.14 (5). The holes serve as an unsecure to note that the sides are extendable. The extended version should always be used during any practice. A recommendation would be that the side parts of the table top should be disabled from unfolding to usage position when the legs of the bottom plate are not extended. How this should be done should be determined in a next stage. Figure 3.15 shows the final design.

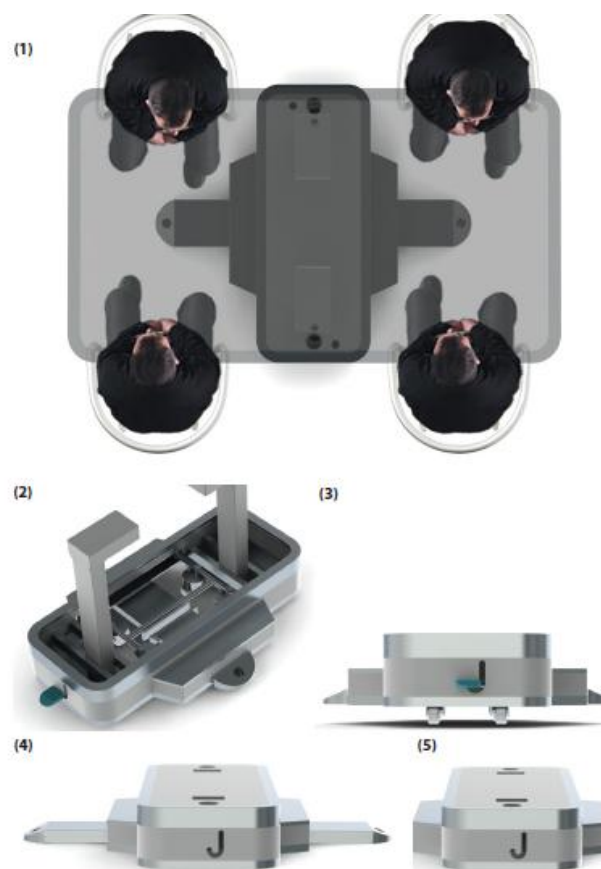


Figure 3.14 Bottom plate.



Figure3.15 Final Design.

3.3 Conclusions

Simulation-based training in surgery can provide an immersed, safe training environment for the surgical trainees without risk to harm patients. However, the gap between skills lab and real OR environment is not yet overcome. In addition, non-ergonomic setting up of the laparoscopic surgical training was still often observed, so the products for the surgical training still need to be well designed. So in this chapter, the case study of an ergonomic surgical training table was described. Although the newly designed table prototype still has some drawbacks and needs to be improved, but it is already a big improvement compared to the table used in the skills lab now. And the recommendations for the final design have been given.



PART B

This part mainly focuses on design and validation of a portable ergonomic laparoscopic simulator (Ergo-Lap simulator). In Chapter 4, the design of the Ergo-Lap simulator is described. In chapter 5, face, content and construct validity of the Ergo-Lap simulator is evaluated. Chapter 6 evaluates the face validity of the Ergo-Lap simulator for training basic single port surgery skills.



CHAPTER 4 DESIGNING OF A PORTABLE ERGONOMIC LAPAROSCOPY SIMULATOR

The cost of laparoscopic simulators restricts the wide use of simulation for training of basic psychomotor skills. This chapter describes the scientifically-based development of an inexpensive and portable Ergonomic Laparoscopic Skills (Ergo-Lap) simulator with multiple tasks.

The design of this Ergo-Lap simulator and related training task panel was based on scientific research regarding the representative skills and the ergonomic guidelines for laparoscopic surgery. A user-centred design approach was followed. Fifty-three surgical participants with variable laparoscopic experience (14 medical students, 27 surgeons in training, and 12 experienced laparoscopic surgeons) performed several tasks on the prototype and gave their feedback by filling out a 5-point scale Likert scale questionnaire.

The results of the usability evaluation showed that the participants regarded the Ergo-Lap simulator as a useful device to practice the basic and advanced skills effectively. Forty-three of the 53 participants indicated they would like to purchase this simulator since it is easy to use and challenge their laparoscopic skills.

This chapter is based on the following article:

Xiao, D., A. Albayrak, J. J. Jakimowicz and R. H. Goossens (2013). A newly designed portable ergonomic laparoscopic skills Ergo-Lap simulator. *Minim Invasive Ther Allied Technol.*

4.1 Introduction

In the last decade both surgeons and patients have increasingly accept laparoscopic surgery. For some of the surgical procedures it became a golden standard. As reported in many studies laparoscopic surgery offers several benefits for patients compared to open surgery (Aggarwal and Darzi 2006; Jakimowicz and Fingerhut 2009; Buzink, Christie et al. 2010). However, the complexity of the technology used in laparoscopy is challenging for surgeons in many ways. One of the main disadvantages is lack of proper tactile perception, disturbed hand-eye coordination, limited degree of freedom for instrument manipulation, etc.(Fraser, Klassen et al. 2003; Westebring-van der Putten, van den Dobbelsteen et al. 2009). Acquiring mandatory skills for performing laparoscopic procedures safely is of paramount importance. Previous studies have shown laparoscopic skills have to be trained intensively to separate the clumsiness from proficiency (Sherman, Feldman et al. 2005; Jakimowicz and Fingerhut 2009).

Many recently published studies have addressed the need of effective training modules for an efficient transfer of laparoscopic skills to the operating room (Cannon-Bowers, Bowers et al. 2010; Brinkman, Buzink et al. 2012). Box trainers and different kinds of simulators are used to achieve proficiency in laparoscopic skills and facilitate the transfer of skills to the OR. Although helpful, majority of these simulators are costly, due to the required and expensive laparoscope and camera (Dunkin, Adrales et al. 2007; Aggarwal, Crochet et al. 2009; Buzink, Goossens et al. 2010). Not every surgical training programme can afford these expensive training devices and therefore new and creative products must be developed to allow surgical trainees to learn and reinforce their laparoscopic skills. According to this line of thought, the so-called homemade box trainers have been developed (Beatty 2005; Al-Abed and Cooper 2009; Al-Kandari, Gill et al. 2011).

Such as the SIMENDO virtual reality trainer (Verdaasdonk, Stassen et al. 2006), which is responsible for a number of basic skills, including suturing, camera navigation and instrument positioning. However, this system costs approximately \$5,000. Besides, the 3-Dmed Minimally Invasive Training System (MITS) provides a simulation of real-time laparoscopic surgery. All of the MITS include Color LCD Monitor, Camera, and Box with Internal Lighting. It is easy to set up, portable, and affordable. The prices of the MITS ranges from \$1,900.00 - \$3,500.00.(<http://www.3-dmed.com>).

However, these training systems are still relative expensive, and thus out of reach of medical students, residents and most practitioners. In addition, they do not provide an ergonomic set up. Several studies have investigated and shown the importance of adequate ergonomic set up of surgical simulation. These studies

searched for proper operating surface height and monitor position, optimal optical axis-to-target view angles, appropriate manipulation angles and proper intra-corporal/extra-corporal instrument length ratio (J.McCormick 1993; Emam, Hanna et al. 2000; Chandrasekera, Donohue et al. 2006). In addition, other studies have discussed the impact of a poor ergonomic set-up during procedures on the physical discomfort that the surgeons experience (Muller and Kuhn 1993; Hanna and Cuschieri 1999; Lee, Haddad et al. 2007; Hanna and Cuschieri 2008). However, the integration of the insights from different studies in one ergonomic skills simulator is still missing.

This study aims to develop an inexpensive Ergo-Lap simulator, which integrates the different insights gathered from previous studies, and so to help surgeons to improve their skills under ergonomic conditions. It incorporated 13 basic and advanced tasks in one task panel. In order to investigate whether these designed tasks can distinguish between different levels of expertise or not, the construct validation of the designed tasks is verified based on the performance scores in a previous study of the authors (Xiao, Jakimowicz et al. 2013). In addition, the simulator is provided with a mobile or static camera allowing multiple angles for individual or dual use. This novel portable Ergo-Lap simulator can be adjusted to fulfil to the ergonomic guidelines and can offer a validated laparoscopic training at home or office.

4.2 Materials and methods

4.2.1 Design approach

During the design process, the user-centred design approach was used. This approach involves the user group throughout the whole design process to help ensure that the product designed meets their requirements (Muller and Kuhn 1993). An experienced surgeon from Catharina Hospital Eindhoven was closely associated with this study. At the beginning of the study, many observations have been done during the training sessions with different kinds of simulators differing from simple box simulators to virtual reality simulators.

An extended literature study, interviews with surgical trainees, and analysis of the current situation has led to different insights and design criteria. Based on these design criteria, a prototype was built. The feasibility of this prototype was assessed by both experienced surgeons and inexperienced surgical trainees, and a questionnaire was used to gain insight into their experience.

4.2.2 Design criteria

The following design criteria were formulated for the development of the Portable Laparoscopic Skills simulator. The simulator should:

Be portable, cheap and easy to transport. It should offer an adjustable work space for different size of instruments since the performance correlated with the fit/match between the length of the instrument and dimension of the work space (Lee, Haddad et al. 2007).

Attain an optimal optical axis-to-target view angle since the best task performance is achieved when the optical axis of the endoscope is perpendicular to the target plane (Hanna and Cuschieri 1999). Attain an optimal manipulation, azimuth and elevation angle. The requirements for these angles were defined as; manipulation angle within the 45° – 75° range and as closed to an ideal angle of 60° as possible with equal azimuth angles (Hanna, Shimi et al. 1997; Chandrasekera, Donohue et al. 2006).

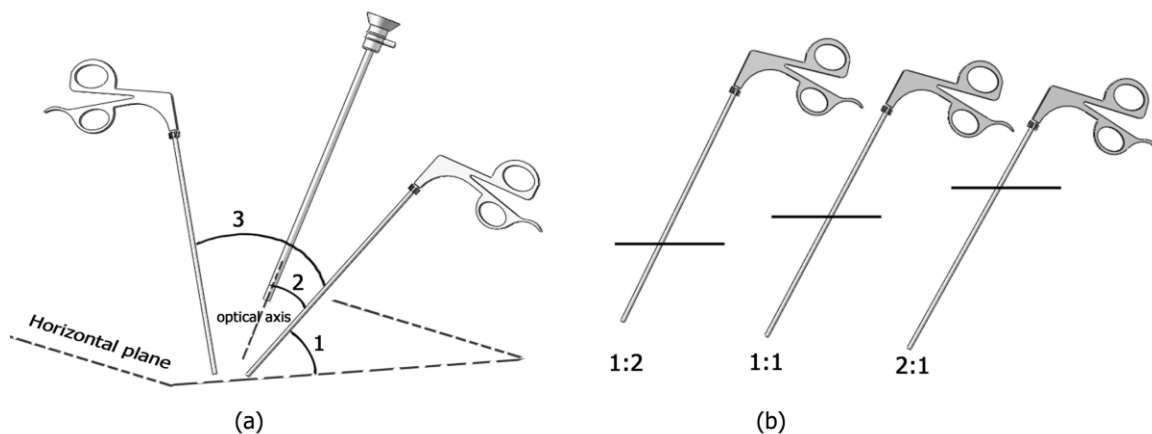


Figure 4.1. (a) Angles govern port placement: 1 elevation angle (the angle between the instrument and the horizontal plane); 2 azimuth angle (angle between instrument and the optical axis of the endoscope); 3 manipulation angle (the angle between two instruments). **(b)** Intra/extracorporeal instrument length ratio.

A reasonable elevation angle should be within the range of 30° – 60° . And an ideal range of elevation angle is around 40° – 45° (Fingerhut, Hanna et al. 2010) (Fig. 4.1(a)). Make sure an intra/extracorporeal instrument length ratio (I/E) between 1:1 and 2:1, ideally closed to 1:1 since the I/E below 1.0 degrades task performance and is associated with uncomfortable movement of the elbow and shoulder (Emam, Hanna et al. 2000) (Fig. 4.1(b)). Contain a mobile or fixed camera with at least 1.3 megapixels resolution to capture good quality image. And representing the use of an endoscope of 0° and 30° degree for individual or dual use.

- (1) Contain a light source which is bright enough to fully illuminate the entire working space. The recommended illumination level for video display terminals is in the range of 300 to 500 lx (J.McCormick 1993).
- (2) Allow multiple tasks to meet different training needs and an integrated task panel, which supports these multiple tasks.
- (3) Offer the possibility to record the performance for review purposes.
- (4) Provide internet connection allowing supervision of the trainee.
- (5) Enable competition between two trainees at different locations using internet.

4.2.3 Design process and prototype

The following key components were identified as essential for the construction of this box simulator: a cavity, a camera and display, a light source, task panels and multiple tasks.

Cavity

Based on the formulated design criteria, a calculation was done to define the dimension the box simulator and location of the ports. The height can be adjusted from 12cm to 20cm by four flexible pillars for different size of instrument (Fig.4. 3(a)). The shape of the cover was curved (like the contour of the abdomen) allowing a natural way of interaction. The cover and bottom can be easily connected with six clips to make it folded. The location of the ports was determined by different factors; the manipulation, azimuth, elevation angles, these angles can influence the task performance (Hanna and Cuschieri 2008). Length of the instruments since 3 different lengths are required for patients with different stature; standard (360mm) for most adult patients, short (300 mm) for smaller adults, and mini (200-240 mm) for paediatric patients(Emam, Hanna et al. 2000).

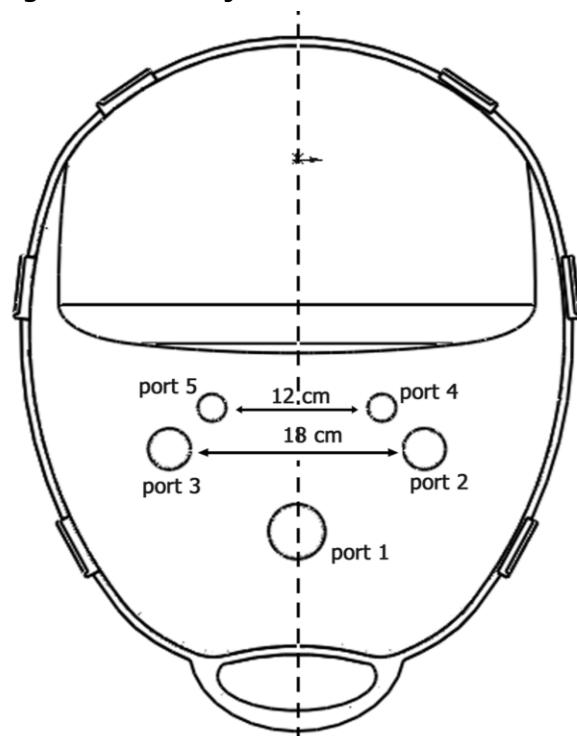


Figure 4.2 Cover of Ergo-Lap simulator.

Based on the different length of instruments, optimal angles mentioned in design criteria (3) and proper I/E ratio mentioned in design criteria (4), five ports were set in the box cover.

Port 1 was for camera and the other ports (ports 2&3, ports 4&5) were for instruments. Port 2&3 and port 4&5 were about 18cm and 12cm apart and equidistant from the midline of the box cover, respectively. In order to keep two equal azimuth angles the camera port is located in the middle of two instruments ports (Figure. 4.2). Ports 2&3 can be used for long instruments (300-360mm) to simulate a procedure with adult patients, and ports 4&5 for short instruments (200-240mm) to simulate a procedure with paediatric patients. By doing so, an optimal manipulation angle around 60° and I/E ratio around 1:1 can be achieved. Actually, it is hard to keep same manipulation angle during the procedure, but it is useful to keep closed to 60° .

A task panel support is integrated in the bottom of the box, which could be fixed in different positions (Fig. 4.3(a)).

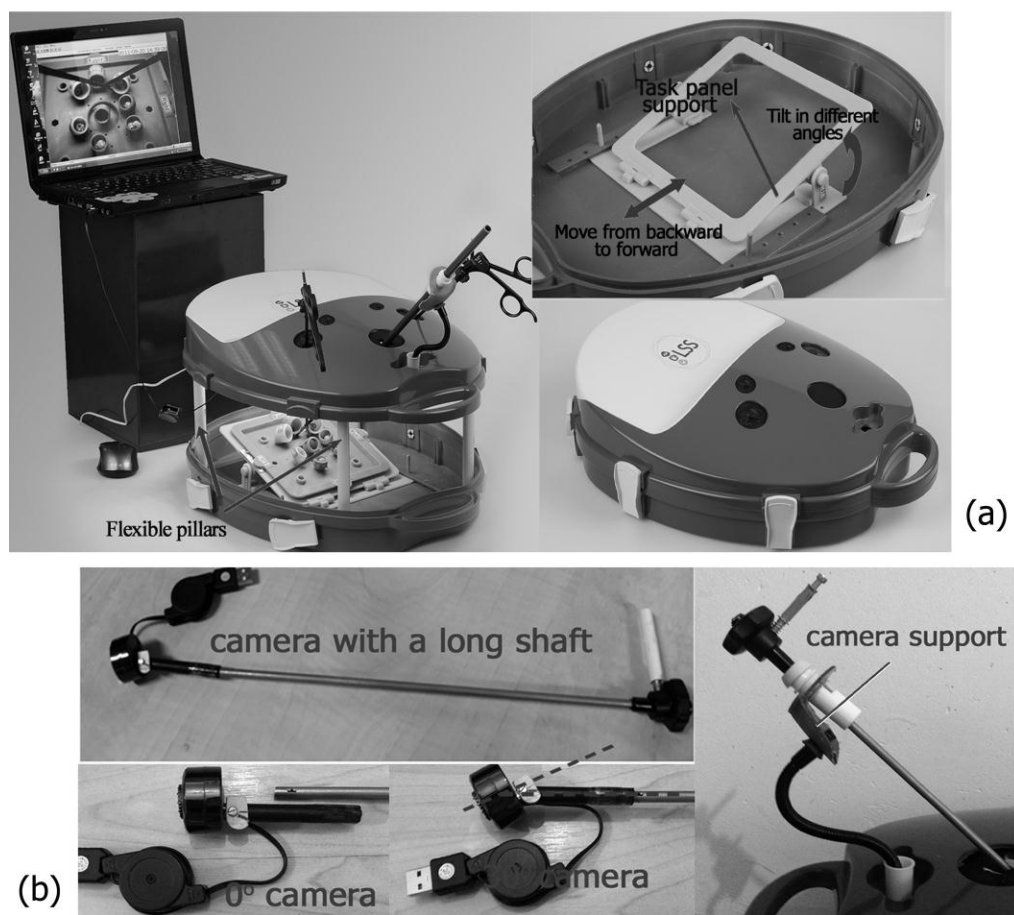


Figure 4.3 (a) Ergo-Lap simulator ready for use (left); the flexible set-up of task panel (upper right); folded Ergo-Lap simulator. (b) Modified webcam.

Light source

As shown in figure 4.3 the enclosure was not closed totally allowing the ambient light insight the box trainer. The amount of light that reach the task panel depends on the power of the light source. The recommended luminance for performing visual task with medium accuracy is around the 500 lx (J.McComick 1993). However, the ambient light entering the work space was below this value and therefore an extra light source was used to fully illuminate the entire working space around the 500 lx Three light strips each with 9 mini light sources were used to meet this requirement. Those strips were easily attached to the ceiling of the box cover.

Camera and displays

In order to provide a reasonable level of detail and clarity, a flexible USB-powered webcam (usb2.0, China) with 12 megapixels, running at 60 frames per seconds was selected and after some adaptation used to achieve the optimal resolution to smooth animation (Figure 4.3(b)). Furthermore, this webcam had an auto-focus and zoom function, so the operator does not need to adjust the camera all the times. To simulate the same manipulation possibilities like the endoscope, the selected mobile webcam was inserted and attached into a metal pipe (5 × 300 millimetres). The other end of the pipe was housed in a cap, which was marked with a pillar to remind the direction of the webcam. When the box trainer is used by one person the webcam can be fixed with a special support to the cover. In addition, the USB-powered webcam can be easily connected to any laptop or desktop. By using the internet two trainees can take part in an online competition in two different locations. A chat software named Tencent QQ (<http://www.imqq.com>) can display both their own and competitors' image in one screen (Figure. 4.4). This can motivate the trainees to carry out an efficient competition. Moreover, the supervisor can conduct a remote guide to the trainees.

Task panel and multiple tasks

In order to reduce the costs, one multiple functional task panel was designed for attaching in total 5 different task clusters varying from basic to advanced. The task panel can be tilted to different angles and moved forward and backward by a support (Figure.4.3(a)). Five different clusters of tasks were designed for the surgical trainees to practice their skills. The first cluster was for camera navigation and object transfer; the second was for training 2D to 3D deception; the third cluster was for training two hands coordination and using proper force to stretch band; the fourth cluster was for passing needle and chenille wire through rings; the fifth cluster was for training advanced laparoscopic skills, such as application of a

ligation loop, knot tying and suturing under tension, dissection and intra-corporeal knot (Figure.4.5).

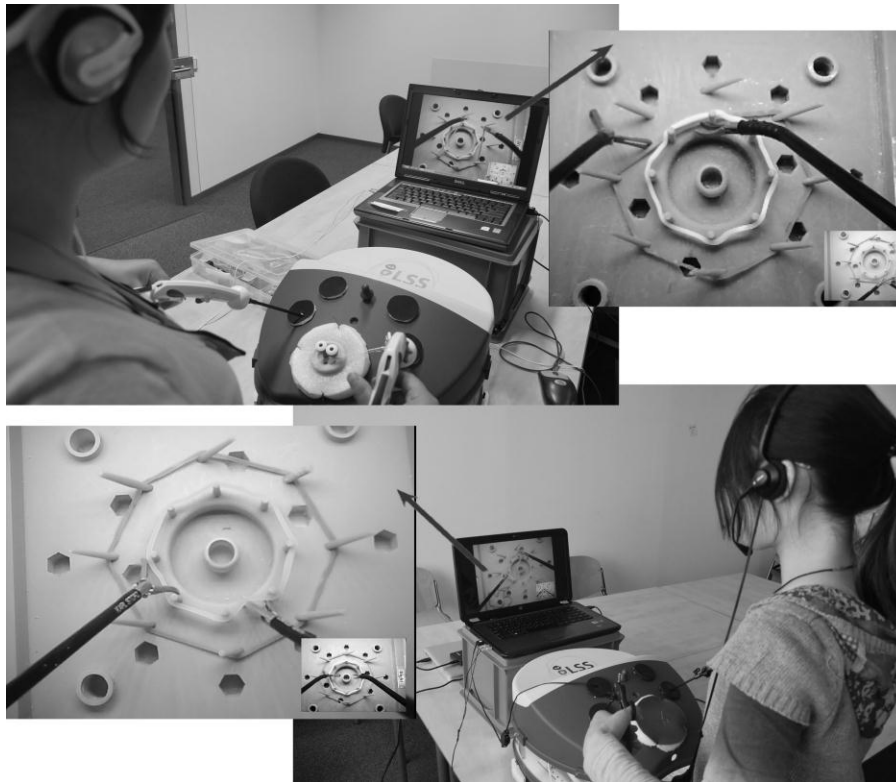


Figure 4.4 Two trainees are carrying out an online competition in two different locations.

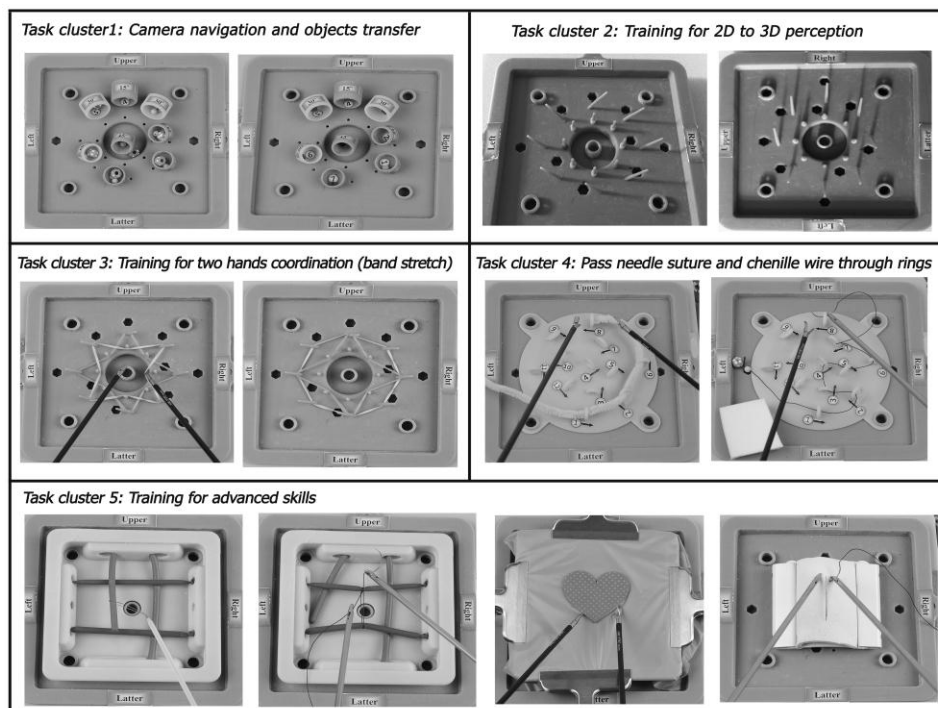


Figure 4.5. Five task clusters.

4.2.4 Participants

In order to test the prototype and get feedback from medical trainees, this Ergo-Lap simulator was brought to two hospitals, Maxima Medical Centre Veldhoven and Catharina Hospital Eindhoven, both in the Netherlands. The participants voluntarily took part in this study during their spare time. In total Fifty-three surgical participants (14 medical students, 27 surgeons in training, and 12 medical experienced laparoscopic surgeons) with variable laparoscopic experience performed several tasks on the designed Ergo-Lap simulator and gave their feedback on this Ergo-Lap simulator by filling out a 5-point Likert scale questionnaire. The participants' awareness of ergonomic factors during laparoscopy procedure was also investigated. Table 1 shows the demographics and ergonomic awareness of the participants.

4.3 Results

The participants' awareness of ergonomic factors during laparoscopic surgery was investigated by a questionnaire (Table 4.1). The results show that majority of the surgical trainees do not realize the importance of the ergonomic factors. Only some of them know these factors theoretically.

The experienced specialist do know the optimal operation surface height, monitor position and optical to target view angle. However, only 50% of them pay attention to the optimal manipulation, azimuth, elevation angle and Intra/extracorporeal instrument length ratio.

Table 4.2 showed the results of the opinion and impression of the participants on the Ergo-Lap simulator. In order to investigate whether different expertise level of participants give different opinions, the participants were divided into Experienced (N=20, >50 clinical laparoscopic procedures) and Novice (N=40, <10 clinical laparoscopic procedures) group according to their clinic laparoscopic experience.

Insignificant differences were found between two groups for all the questions. The attractiveness of the Ergo-Lap simulator was rated from good to excellent (Table 2). Some of the participants said that because of its ergonomic design this simulator remind them easily to consider an ergonomic set up during training. All of the participants found the simulator a useful tool which was easy to use for their skills training.

Furthermore, 43 of the 53 participants would like to purchase this portable simulator since it is easy to use and useful to challenge their laparoscopic skills. Also, 46 of 53 participants would like to recommend this Ergo-Lap simulator to surgical trainees.

Based on the cost of the prototype (\$900 to produce a single prototype, but it can be expected that mass production will be at lower cost), the anticipated price to buy the Ergo-Lap simulator (including the camera and all the task materials) is less than \$500, which is within the expected price ranges stated by 43 of 53 participants (\$300-\$650). Compared to the current available VR simulators, this Ergo-Lap simulator could offer an inexpensive alternative with which trainees can practice basic laparoscopic skills.

Table 4.1. Demographics and experiences of participants and awareness of ergonomic factors during laparoscopic procedures.

		Specialist (N=12)	Surgical Resident (N=27)	Medical Student (N=14)	Totals (n=53)
Age	Mean (\pm SD)	43.83 (\pm 2.97)	30.15 (\pm 0.57)	23.00 (\pm 0.30)	31.36 (\pm 8.94)
	Min-Max	33-61	24-35	21-25	21-61
Experience in Laparoscopic procedures	None	0	9	14	33
	<10	0	8	0	8
	10-50	0	2	0	2
	>50	12	8	0	20
Experience in laparoscopy simulators	None	0	4	14	18
	only briefly	3	7	0	10
	<5h training	1	7	0	8
	\geq 5h training	8	9	0	17
1 Are you aware of the proper operating surface height for laparoscopy surgery?					
No		1	11	14	25
Yes		11	16	0	28
2 Are you aware of the optimal monitor position for laparoscopic surgery?					
No		0	9	14	23
Yes		12	18	0	30
3 Are you aware of optimal to target view angle for laparoscopic surgery?					
No		2	11	14	27
Yes		10	16	0	26
4 Are you aware of the optimal manipulation angle, azimuth angle and elevation angle?					
No		6	13	14	33
Yes		6	14	0	20

5 Are you aware of proper Intra/extracorporeal instrument length ratio?				
No	6	13	14	33
Yes	6	14	0	20

Table 4.2. Opinion and impression of participants about the Ergo-Lap simulator, rated on a 5-point Likert-scale. (1=strongly disagree (very poor), 3=neutral, 5=strongly agree (excellent)).

	Experienced (N=20) Mean (±SD)	Novice (N=33) Mean(±SD)
How would you rate the attractiveness of this Ergo-Lap simulator?	4.00 (±0.65)	4.03(±0.73)
How would you rate this Ergo-Lap simulator for training in an ergonomic way?(e.g. make sure proper manipulation angle, elevation angle and I/E instrument ratio)	3.95(±0.76)	3.79(±0.78)
Do you think this Ergo-Lap simulator is useful to practice basic laparoscopic skills?	4.45(±0.51)	4.36(±0.49)
Did you find this Ergo-Lap simulator easy to use?	4.40(±0.50)	4.55(±0.51)
Do you think having this Ergo-Lap simulator will make you more often practice your laparoscopic skills?	3.70(±1.03)	4.06(±0.79)
Would you like to have such a Ergo-Lap simulator yourself?	3.90(±0.97)	4.15(±0.91)
Would you like to recommend such a Ergo-Lap simulator to others?	4.00(±0.97)	4.15(±0.57)

4.4 Discussion

The use of simulation for skills training outside the operating room has been embraced by surgical societies and had become important part of surgical training. The transferability of simulator-acquired skills to the operating room is well documented(Schijven, Jakimowicz et al. 2005; Jakimowicz and Fingerhut 2009). Despite this evidence, the skills curricula need additional refinement to maximize the benefit to learners(Brinkman, Havermans et al. 2012). Additional issues, such as finding time for skills training in the busy schedule of surgery residents, getting facilities buy-in and support, investing in the required resources, have to be addressed. Even if proper facilities are available, access is restricted by time constraints. Therefore, In order to provide the opportunity for surgical trainees to practice basic skills at home or at the office, several publications describe easy to use homemade simulators from card box or plastic(Keyser, Derossis et al. 2000; Al-Abed and Cooper 2009; Kobayashi, Jamshidi et al. 2011). One of the shortcomings of currently available simulators is their lack of an ergonomic training set-up. The impact of a poor ergonomic set-up on the physical discomfort experienced by surgeon's performing laparoscopic tasks is reported in several studies (Hanna,

Shimi et al. 1997; Hanna and Cuschieri 2008). Moreover, the influence of ergonomic factors on task performance has been investigated in a lab set up (Hanna and Cuschieri 2008; Xiao, Jakimowicz et al. 2012). However, the integration of the insights from different studies in one ergonomic skills simulator is still missing.

Designing and validating a new ergonomic portable laparoscopic skill simulator which integrates the different insights gathered from previous studies was the aim of this study. The Ergo-Lap simulator was designed, at the Technical University of Delft, Faculty of Industrial Design Engineering (FIDE), in compliance with the ergonomic guidelines. Therefore, offering the opportunity for laparoscopic training at home or at the office. Participants rated the Ergo-lap as a useful training tool to practice their laparoscopic skills and improve their awareness of ergonomic factors during training.

In addition, before a surgical simulator can be used to assess surgical skills, its validity must be verified. Construct validity indicates the extent to which the simulator can distinguish between different levels of expertise based on the performance scores (McDougall, Corica et al. 2006). The construct validity of the tasks of this simulator was implemented by 26 novice and 20 experienced trainees in a previous study of the authors. The performance of every trainee was assessed by time duration and number of errors. The result showed that the designed task can distinguish between various levels of laparoscopic expertise (Xiao, Jakimowicz et al. 2013).

Furthermore, most of the task materials of this newly designed Ergo-Lap simulator, such as balls, tubes, bands were cheap and easy to get from super market. An integrated task panel providing multiple training exercises can satisfy the need for practicing basic psychomotor and advanced laparoscopic skills. Moreover, surgical trainees have the unique opportunity to develop their own tasks based on this task panel.

However, there is one concern when it comes to any home-training curriculum: will trainees practise adequately without supervision? To address and solve this problem the Ergo-Lap provides registration of tasks performed and offers the possibility of online-supervision. The recorded materials are of value for feedback and personal assessment. To stimulate trainees an online worldwide competition is possible.

With the Ergo-Lap simulators, surgeons, residents, interns and medical students would have the opportunity to practice basic psychomotor skills, suturing and knot tying and other laparoscopic techniques on their own time. Whether it is at home, the office, in a dedicated training facility or in the operating room lounge, the

portability of the trainer would allow more opportunities to practice than those provided by a fixed institutional virtual reality trainer.

The Ergo-Lap simulator has some limitations. The work space and the location of task panel cannot be adjusted automatically, to reduce the costs of the system the adjustment can be done manually. Another limitation is the task material cannot represent the real tissue, but it is still useful to training laparoscopic skills for trainees to improve their psychomotor skills.

The next step of this research is to develop this prototype also for single port surgery training, and make it adapt for different brand of single port system.

4.5 Conclusion

For laparoscopic skills training, this inexpensive and portable Ergo-Lap simulator with diverse tasks choices offers a flexible training opportunity to help trainees to improve their skills under ergonomic conditions. Also this is an effective alternative for hospitals without a surgical skills lab.

4.6 Acknowledgement

We are very grateful to the involved participants. And thanks Sonja Buzink from Delft University of technology for her good suggestion on developing basic tasks. The authors affirm that they have no conflicts of interest.



CHAPTER 5 FACE, CONTENT AND CONSTRUCT VALIDITY OF A NOVEL PORTABLE ERGONOMIC SIMULATOR FOR BASIC LAPAROSCOPIC SKILLS

The purpose of this chapter was to verify the face and content validity of a new portable Ergonomic Laparoscopic Skills simulator (Ergo-Lap simulator) and to assess the construct validity of the Ergo-Lap simulator in four basic skills tasks.

Forty-six participants were allotted into two groups: a Novice group (N=26, <10 clinical laparoscopic procedures) and an Experienced group (N=20, >50 clinical laparoscopic procedures). Four tasks were evaluated: two different translocation exercises (a basic bimanual exercise and a challenging single-handed exercise), an exercise involving tissue manipulation under tension, and a needle-handling exercise. The Experienced group completed all tasks in less time than the Novice group did ($p < 0.001$, Mann-Whitney U test). The Experienced group also completed Tasks 1, 2, and 4 with fewer errors than the Novice group did ($p < 0.05$).

Of the novice participants, 96% considered that the present Ergo-Lap simulator could encourage more frequent practice of laparoscopic skills. All of the experienced participants confirmed that the Ergo-Lap simulator was easy to use and useful for practicing basic laparoscopic skills in an ergonomic manner. The majority (95%) of these respondents would recommend this simulator to other surgical trainees.

This chapter is based on the following articles:

Xiao, D., J. J. Jakimowicz, A. Albayrak, S. N. Buzink, S. M. B. I. Botden and R. H. M. Goossens Face, Content, and Construct Validity of a Novel Portable Ergonomic Simulator for Basic Laparoscopic Skills. *Journal of Surgical Education*.

5.1 INTRODUCTION

Technique and skills are essential in order to be able to perform laparoscopic procedures safely and effectively. One practical solution for acquiring these skills involves the use of a laparoscopic simulator (Chandrasekera, Donohue et al. 2006). Studies have shown that specialists can improve their clinical performance through dedicated practice of their laparoscopic skills (Barry Issenberg, Mcgaghie et al. 2005).

Several types of simulators are currently being used for training purposes: traditional box trainers, virtual reality (VR), and augmented reality (AR) simulators. These simulators play important roles in surgical education (Botden, Buzink et al. 2007; Botden and Jakimowicz 2009). Several useful yet expensive VR and AR simulators (e.g. Surgical Science AB® LapSim, Simbionix LapMentor™, and CAE Healthcare ProMIS) are commercially available, along with training modules ranging from basic skills to complex laparoscopic procedures, with prices ranging from €1,560 to €70,000 (Dunkin, Adrales et al. 2007; Botden, Buzink et al. 2008). However, these tools are too expensive for many hospitals, particularly in developing countries.

Many medical centers also use inexpensive box trainers for practicing basic and advanced laparoscopic skills, although these tools are somewhat limited in their application. For example, the Karl Storz box trainer with multiple tasks, which has been used in the skills lab of Catharina Hospital Eindhoven, requires a special display, cables, or other cumbersome equipment. Various efforts have been devoted to developing portable box simulators that can improve the convenience and efficiency of surgical training. Examples include the portable FLS box trainer developed by the Fundamentals of Laparoscopic Surgery (FLS) program (Peters, Fried et al. 2004), the mirrored-box simulator produced by Keyser and colleagues (Keyser, Derossis et al. 2000), and the portable trainer assessed by Hruby and colleagues (Hruby, Sprenkle et al. 2008). Several investigations have focused on homemade simulators involving cards or plastic box trainers (Chandrasekera, Donohue et al. 2006; Al-Abed and Cooper 2009; Alfa-Wali and Antoniou 2011; Khine, Leung et al. 2011). These portable box trainers provide convenient and effective alternatives with which trainees can practice basic skills at home or in the office.

One major shortcoming of the simulators that are currently available is that they do not support the ergonomic guidelines for laparoscopic surgery, thus failing to offer an ergonomic training set-up (Hanna and Cuschieri 2008; Xiao, Jakimowicz et al. 2012). According to the studies by Hanna and colleagues, the performance of bimanual tasks could be improved by obtaining an optimal manipulation angle of 60° (with equal azimuth angles) and an optimal elevation angle between 30°–60° (Hanna, Shimi et al. 1997; Chandrasekera, Donohue et al. 2006). Furthermore, according to a study by Emma and colleagues, intra/extracorporeal instrument

length ratios (I/E) below 1.0 cause deterioration in task performance, expand the range of movement at the elbow and shoulder, and increase angular velocity at the shoulder (Emam, Hanna et al. 2000). It is important for trainees to become accustomed to proper ergonomic working conditions, as this can improve task performance and minimize physical discomfort (Xiao, Jakimowicz et al. 2012). Nevertheless, a portable and ergonomically simulator has yet to become available. The authors have developed a new portable Ergonomic Laparoscopic Skills simulator (Ergo-Lap simulator) from a user-centered perspective, following the ergonomic guidelines (Emam, Hanna et al. 2000; Hanna and Cuschieri 2008). Before a surgical simulator can be used to assess surgical skills, its validity must be subjected to rigorous verification (McDougall, Corica et al. 2006; Zhang, Hünnerbein et al. 2008). This study focuses on three basic and valuable forms of validity: construct validity, face validity, and content validity. Construct validity indicates the extent to which the simulator can distinguish between different levels of expertise based on the performance scores. Content validity indicates the extent to which the simulator is able to teach the trainees that which it is intended to teach, as evaluated by experts dedicated to the device. Face validity refers to the relative realism of the simulator, as evaluated by non-experts (McDougall, Corica et al. 2006). This study aims to verify the construct validity of four innovative tasks on the Ergo-Lap simulator for training basic laparoscopic skills, in addition to evaluating the face validity and content validity of this new ergonomic portable simulator.

5.2 Materials and methods

5.2.1 Ergo-Lap simulator

In the context of this study, the Ergo-Lap simulator with multiple tasks is used to train basic laparoscopic skills. Its dimensions are similar to those of a folded briefcase (55cm × 32cm × 12cm), and it can be stored in limited space (figure 5.1). The system weighs 3kg, including the task materials and an integrated handle for easy transportation. The simulator can be connected to a computer, where video software makes it easy to record task performance, thus allowing surgical trainees to evaluate and improve their performance. The physical set-up of the Ergo-Lap simulator can be adjusted to attain an ergonomic setting and adapt to various types of training tasks for a broad range of users (figure 5.1). For example, the task panel can move backward /forward, and it can be tilted at various angles in order to acquire a proper optical axis-to-target viewing angle and an appropriate intra/extra-corporal instrument length ratio. The cover height of the simulator can also be adjusted to create different volumes of the work space. The simulator is accompanied by an instruction manual, which helps trainees to create an optimal ergonomic training set-up for each task.



Figure 5.1 Ergo-Lap simulator: The Ergo-Lap simulator ready for use (left); the flexible arrangement of the task panel allows for ergonomic training conditions (upper right); the Ergo-Lap simulator ready for transportation (bottom right).

	<p>Task 1: Transfer beads</p> <p>Transfer (in random order, using both hands) seven small beads from the side containers to the central container, and transfer the large beads from the side containers to the central pool using two graspers. Transfer all the beads back to the side containers. Dropping a bead counts as an error.</p>
	<p>Task 2: Transfer tubes</p> <p>Transfer the tubes from the inner pillars to the outer pillars with right hand (selecting the tubes in random order), and then transfer the tubes back to the inner pillars with left hand. Dropping a tube counts as an error.</p>
	<p>Task 3: Stretch band</p> <p>Use the grasper to stretch the blue rubber band around the inner pillars, and stretch the yellow band around the outer pillars. And then creat an 8-points star. The slipping of the band counts as an error.</p>
	<p>Task 4: Pass needle suture</p> <p>Pass the needle and suture thread through all the rings using two needle holders, and then slide the bead over the thread and pass it through all the rings. Dropping the needle, missing the ring or passing through the ring in a wrong direction count as errors.</p>

Figure 5.2 Overview of the four Ergo-Lap simulator exercises used in this study.

5.2.2 Tasks and assessment

Four tasks were selected for validation in this study (Figure 5.2). Task 1 (Transfer of balls) was designed to involve the use of graspers and the development of bimanual coordination skills. Task 2 (Transfer of tubes) was designed to involve the use of graspers by the dominant and non-dominant hands, respectively, and to train surgeons to adapt their perceptions from three-dimensions to two dimensions. Task 3 (Band stretch) was designed to develop laparoscopic coordination skills with both hands. The goal of Task 4 (Pass suturing needle and a small ball through rings) was designed to involve the use of needle holders and to develop bimanual coordination skills. In Tasks 1 and 2, any time a ball or tube is dropped, it is counted as an error. In Task 3, any time the band slips or is lost, it is counted as an error. In Task 4, errors are defined as dropping the needle, missing the rings, and passing the needle in the wrong direction. The completion time and error frequency of each task were recorded on video. This video was then used to assess task performance in terms of the completion time and number of errors. To avoid bias according to level of expertise, the observer was blinded to the skill level of the participant performing the tasks.

5.2.3 Subjects

The Ergo-Lap simulator was brought to two hospitals: the Catharina Hospital Eindhoven and the Máxima Medical Centre, both in the Netherlands. Junior and senior residents, medical interns and laparoscopic specialists were invited to perform several tasks on the Ergo-Lap simulator during the intervals of their work day. The participants were divided into two groups according to their clinical laparoscopic experience: a Novice group, consisting of participants who had performed fewer than 10 clinical laparoscopic procedures, and an Experienced group, comprising participants with clinical experience performing more than 50 laparoscopic procedures. For the basic skills tests, surgeons who had performed more than 50 procedures were assigned to the Experienced group (Aggarwal, Grantcharov et al. 2006) (Buzink, Botden et al. 2009).

5.2.4 Protocol

All participants provided informed consent after having received an explanation of the study design. They completed questionnaires based on demographics and their previous laparoscopic experience. Before performing a task on the simulator, the participants received a general introduction to the Ergo-Lap simulator, as well as standardized instruction, including a video demonstration of each task. Nevertheless, some of the trainees did not have enough time to complete all four of the tasks. This was particularly the case for the experienced participants, who sometimes had to leave in order to treat emergency patients. For this reason, the sequence of the four tasks was randomized for each participant, thereby ensuring that each task was performed by at least 18 participants from each group. The

minimum number of participants needed in each group (17) was determined according to a two-tailed test ($\alpha = 0.05$; power $(1-\beta) = 0.80$), with a fixed effect size of 0.9 (following the study by Livingston and Cassidy) (Livingston and Cassidy 2005; Aggarwal, Grantcharov et al. 2006). This number was increased to 18, in order to compensate for potential attrition.

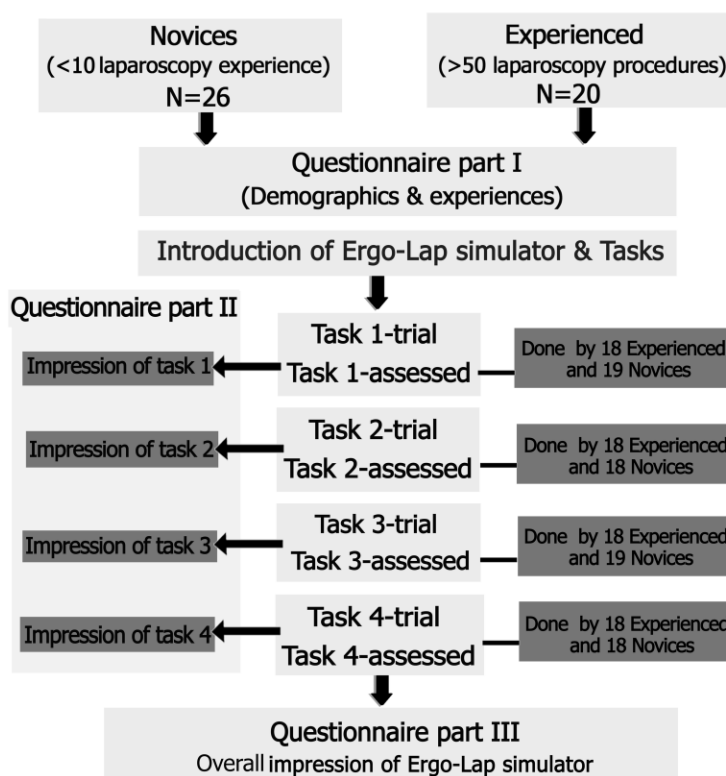


Figure 5.3 Overview of the study protocol.

Figure 5.3 illustrates the process of this study. The participants performed each task twice, with only the score from the second repetition used to evaluate the performance. For Tasks 1, 2, and 3, participants used two graspers (type Karl Storz 33310), and for Task 4, they used two needle holders (type Karl Storz 26173). After finishing each task, the participants completed the questionnaire and evaluated their task performance along a five-point Likert scale (Table 5.1). After performing all of the tasks, the participants completed the last section of the questionnaire, which concerned their overall impressions of the Ergo-Lap simulator. In addition, one item was included in the questionnaire to investigate what the participants would consider a reasonable price for the Ergo-Lap simulator.

5.2.5 Statistical analysis

The completion time and the total number of errors were recorded on video for each task. Comparisons between the Novice and Experienced groups were

performed using the software package SPSS®, version 17.0 (SPSS, Chicago, Illinois, USA). For normally distributed data, the Student t-test was chosen; for all other data, the non-parametric Mann-Whitney U test was used. The significance level was set at $p < 0.05$.

5.3 Results

In all, 46 participants took part in this study: 26 participants were assigned to the Novice group, which ultimately consisted of 14 medical interns and 8 junior surgical residents who had not yet performed any clinical procedures, as well as 4 residents who had performed fewer than 10 clinical procedures. The Experienced group consisted of 20 participants, including 12 surgeons and 8 senior residents, each of whom had performed more than 50 clinical procedures.

5.3.1 Time and error score

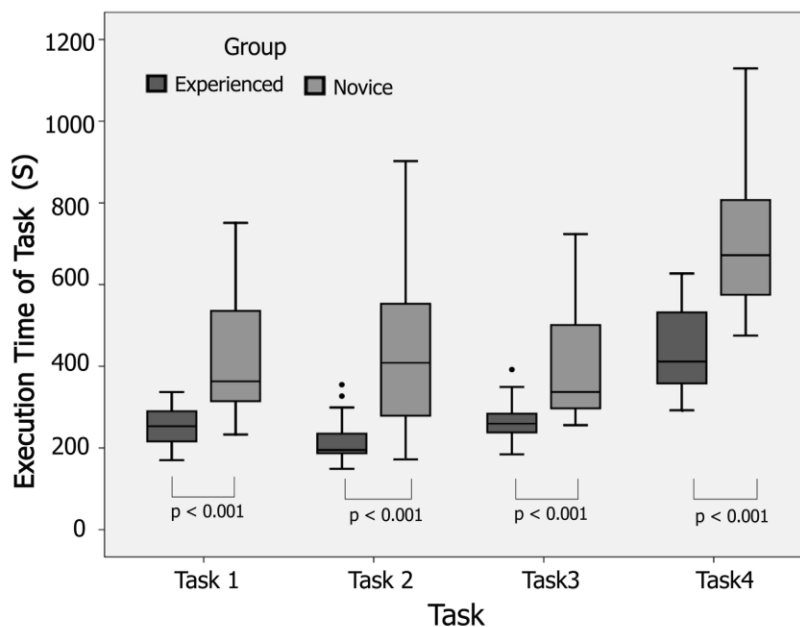


Figure 5.4 Completion time for each task and expertise group. Presented P-values represent significant differences between the two expertise groups for each task (Mann-Whitney U test).

Construct validity was evaluated by comparing the completion times and error frequencies of the Novice and Experienced groups. The normality test was used to analyze each group of data in order to determine whether the Student t-test or the Mann-Whitney U test should be used. As shown in figure 5.4, the Experienced group completed all of the tasks in significantly less time than the Novice group did (Student t-test for Task 1 and 4; Mann-Whitney U test for Task 2 and 3), and they performed Tasks 1, 2, and 4 with significantly fewer errors (Mann-Whitney U test for Task 1 and 4; Student t-test for Task 2), as shown in Figure 5. The results presented in figures 5.4 and figure 5.5 illustrate that the Experienced group's

completion time and error frequency were centralized with a narrow standard deviation, while the results from the Novice group were more scattered.

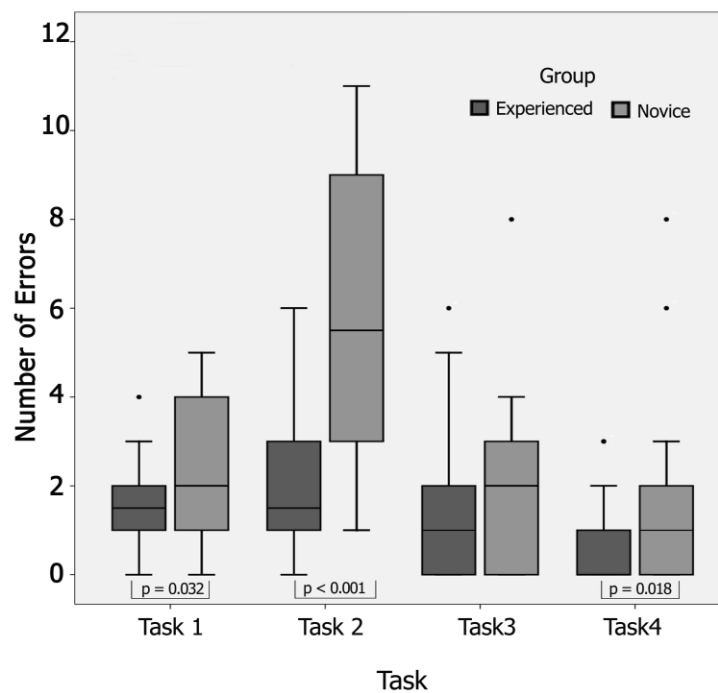


Figure 5.5 Number of errors for each task and expertise group. Presented P-values represent significant differences between the two expertise groups for each task (Mann-Whitney U test and Student t-test; only significant differences are presented).

5.3.2 Participant opinions regarding the tasks

All of the participants rated their global impressions of all four tasks as good to excellent (Table 5.1). Insignificant differences were found between the ratings of the Experienced group and those of the Novice group, with the exception of the item concerning the level of difficulty. The Experienced group rated Task 2 as more difficult than the Novice group did (means of 4.11 and 3.56, respectively; SD of 0.83 and 0.79, respectively; $p < 0.050$). The Novice group rated Task 4 as more difficult than the Experienced group did (means of 4.44 and 3.39, respectively; SD of 0.51 and 1.04, respectively; $p < 0.050$). Tasks 1 and 3 were rated equally difficult by the both groups.

Table 5.1 Participants' overall evaluations of each task, rated along a five-point Likert-scale (1=strongly disagree, 3=neutral, 5=strongly agree).

		Task 1	Task 2	Task 3	Task 4
The task is useful for working with graspers (for Tasks 1, 2, and 3) and needle holders (for Task 4).	Mean	4.14	4.03	3.89	4.33
	(SD)	0.10	0.11	0.13	0.11
The task makes the trainee think about which hand to use (for Task 1)	Mean	4.19			
	(SD)	0.11			
The task is useful for training the ability to shift perception from 3D to 2D (for Task 2).	Mean		4.22		
	(SD)		0.10		
The task is useful for training hand coordination (for Tasks 3 and 4).	Mean			4.13	4.17
	(SD)			0.11	0.12
How difficult do you consider this task?*	Mean	2.92	3.83	3.50	3.92
	(SD)	0.16	0.14	0.13	0.16
Global impression of the task**	Mean	4.08	3.97	4.00	4.11
	(SD)	0.10	0.10	0.11	0.09
Results printed in boldface indicate significant differences.					
*(1=very easy, 3=neutral,5=very difficult), **(1=very poor, 3=neutral,5=excellent)					

5.3.3 Face and content validity of the Ergo-Lap simulator

The face validity of the Ergo-Lap simulator was evaluated by the participants in the Novice group, with 92% rating the simulator's attractiveness as neutral to excellent. In addition, 96% of the Novice participants thought that the present Ergo-Lap simulator could lead to more frequent practice of laparoscopic skills. Furthermore, 92% reported that they would like to purchase the simulator (Table 5.2).

Table 5.2 Face validity of the Ergo-Lap simulator, as assessed by the Novice group (n=26), rated along a five-point Likert-scale (1=strongly disagree [very poor], 3=neutral, 5=strongly agree [excellent]).

	Responses				
	1	2	3	4	5
How would you rate the attractiveness of this Ergo-Lap simulator? n(%)	0	2(8)	1(4)	18(69)	5(19)
Do you think that having this Ergo-Lap simulator would encourage you to practice your laparoscopic skills more often? n(%)	0	1(4)	5(19)	13(50)	7(27)
Would you like to have an Ergo-Lap simulator of your own? n(%)	1(4)	1(4)	2(8)	13(50)	5(34)

The Experienced group was asked several questions in order to assess the content validity of the Ergo-Lap simulator (Table 5.3). All of these participants confirmed that the Ergo-Lap simulator was easy to use and useful for practicing basic laparoscopic skills in an ergonomic fashion. The majority (95%) of these participants said that they would recommend this simulator to other surgical trainees.

Table 5.3 Content validity of the Ergo-Lap simulator, as assessed by the Experienced group (n=20), rated along a five-point Likert-scale. (1=strongly disagree [very poor], 3=neutral, 5=strongly agree [excellent]).

	Responses				
	1	2	3	4	5
How would you rate this Ergo-Lap simulator for training in an ergonomic manner? (e.g., ensuring proper manipulation angle/elevation angle/instrument scaling) n(%)	0	0	6(30)	9(45)	5(25)
Do you consider this Ergo-Lap simulator useful for practicing basic laparoscopic skills? n(%)	0	0	0	11(55)	9(45)
Did you consider this Ergo-Lap simulator easy to use? n(%)	0	0	0	12(60)	8(40)
Would you recommend such an Ergo-Lap simulator to others? n(%)	1(5)	0	3(15)	10(50)	6(30)

We also investigated the price that the participants would consider reasonable for the Ergo-Lap simulator. Of the 46 participants, 23 indicated a range of €400–€600, while 13 indicated a range of €200–€400. The anticipated price for the Ergo-Lap simulator is less than €300, based on the cost of the prototype.

5.4 Discussion

Given that the performance of the Experienced participants was significantly better than was that of the Novice participants, with shorter completion times and fewer errors for all four tasks, we can conclude that these tasks are capable of distinguishing between different levels of expertise.

The participants reported that Tasks 1, 2, and 3 were very useful for training bimanual coordination. The video revealed that, in Task 1, the Experienced group was better aware of which hand should be used to pick up the beads, as the surgical trainees were forced to decide which hand was appropriate for different targets.

In Task 2, the video showed that the Novice group spent much more time aligning the orientation between the tube and the pillar. Participant opinions indicate that

this task is very useful for training the surgeon's ability to adapt their perceptions from 3D to 2D.

The video further showed that, in Task 3, the Novice group spent much more time coordinating two graspers in order to stretch the rubber bands than the Experienced group did. Task 4 involved a total of 12 rings with various orientations. The participants considered this task useful for training surgical trainees to pass and hold the needle properly. In addition, the task using a small ball placed on a suture was also useful for training bimanual coordination. Compared to the tasks designed for other box simulators, the tasks designed for this assessment of the Ergo-Lab simulator were more challenging, and they were more effective in stimulating the trainees to improve and evaluate their performance.

The purpose of the current study was to evaluate the face validity, content validity, and construct validity of the Ergo-Lap simulator system, which includes 13 laparoscopic exercises from basic to advanced tasks. Of the 13 tasks included in the system, the four most innovative were chosen for the first step of the validation process, as they had been designed for basic psychomotor skills. Several researchers have validated laparoscopic simulators that can distinguish the performance scores of different expertise levels, in most cases basing their scores on completion time (Korndorffer Jr, Bellows et al. 2012; Helmy 2009). The use of completion time alone, however, is not sufficient for providing a precise measure of task performance. Other studies have assessed laparoscopic skills in terms of accuracy and speed, although they do not mention the reasoning underlying their calculations (Derossis Md, Fried Md et al. 1998; Fraser, Klassen et al. 2003; Zhang, Hünerbein et al. 2008; Kobayashi, Jamshidi et al. 2011). Although completion time and number of errors are both essential components of an objective assessment of task performance, it is difficult to determine the relative weights for these two indices when constituting the final scores. In this study, the task performance of the participants was graded according to completion time and number of errors.

Various studies have examined the process of learning surgical skills and the optimization of training. Stefanidis²⁸ reported on an investigation of the theoretical framework underlying the acquisition of surgical skills and factors that optimize learning on simulators. Brinkman and colleagues demonstrated that the training of basic laparoscopic skills using single or multiple modalities does not produce different training outcomes (Brinkman, Havermans et al. 2012). It should therefore be possible to acquire basic laparoscopic skills with simple box or home simulators.

The face validity of the Ergo-Lap simulator was evaluated by the Novice group, in which 96% of whom considered that the present Ergo-Lap simulator could increase the frequency of practicing laparoscopic skills. The Expert group rated the content validity of the Ergo-Lap simulator as a useful learning tool that could challenge the

basic skills of surgical trainees. In addition, all of the experienced participants rated the simulator as easy to use (Table 5.3), thus indicating that it could be an easy-to-use training device for surgical trainees.

The compact and easily transportable Ergo-Lap simulator provides opportunities for surgical trainees to practice their laparoscopic skills more conveniently, even at home or in the office. The integrated task panel for multiple training exercises can satisfy the need to practice both basic and advanced laparoscopic skills. The simulator also allows surgical trainees to develop their own exercises based on the panel. In addition, the computer software's recording capability can help trainees to preview previously-recorded performance before starting their training, in addition to helping them perform self-assessments and improve their skills after training. Based on the cost of the prototype, the anticipated price for the Ergo-Lap simulator is less than €300, which is within the expected price ranges stated by 46 participants (€200-€600). Compared to the expensive VR simulators, this Ergo-Lap simulator could offer an inexpensive alternative with which trainees can practice basic laparoscopic skills.

The present Ergo-Lap simulator nevertheless has several limitations that should be considered. First, the task materials do not provide an accurate reflection of the properties of real tissue. In addition, the simulator is not capable of identifying excessive force during the exercise involving the stretching of bands.

The issue of how to motivate surgical trainees to practice their laparoscopic skills voluntarily remains interesting (Stefanidis and Heniford 2009; Verdaasdonk, Dankelman et al. 2009). Surgical trainees could use this webcam-based simulator to initiate an online laparoscopic-skills competition amongst surgical trainees or experts throughout the world. This could also help to make surgical trainees more interested in using the simulator frequently, ultimately helping them to improve their skills. Future studies will involve this simulator in the Laparoscopic Surgical Skills (LSS) training program as a means of encouraging trainees to practice their basic skills before taking the formal course. For example, the Ergo-Lap simulator will be distributed to surgical trainees before the start of the LSS training program. Surgical trainees will not be entitled to register for the LSS training program until they have passed the basic skills test on the Ergo-Lap simulator. This will ensure that trainees can concentrate on advanced skills training using complicated arrangements in the skills lab during the LSS program.

5.5 Conclusions

Although simulation learning can never replace hands-on training, it does provide a safe and cost-effective environment within which surgeons can practice their laparoscopic skills. The novel Ergo-Lap simulator was found to be a useful, effective

and didactic training tool by both the experienced and novice participants in this study.

The four deliberately designed basic tasks were rated as good to excellent for training purposes. They were challenging, and they allowed the simulator to distinguish between different levels of expertise. Moreover, this Ergo-Lap simulator is an inexpensive alternative with which surgical trainees can update their skills in the skills lab, at home, or in the office.

5.6 Acknowledgements

This study was supported by Catharina Hospital Eindhoven and Máxima Medical Centre, Veldhoven. We are very grateful to the participants involved in the study, as well as to Prof. A. Fingerhut for his valuable advice.



CHAPTER 6 FACE VALIDATION OF A PORTABLE ERGONOMIC LAPAROSCOPY SKILLS SIMULATOR FOR SINGLE INCISION LAPAROSCOPY SURGERY TRAINING

In recent years, many efforts have been made to reduce the trauma of surgical access further by the use of single-incision laparoscopic surgery (SILS). The Ergo-Lap simulator was taken to the 20th International Congress of the EAES 2012 in Brussels. During the congress, the simulator was assessed by 13 general surgeons with different SILS experience using a standardized questionnaire to determine the usability of the Ergo-Lap simulator training for basic SILS skills. Eleven of all the 13 participants rated the simulator as an attractive simulator. For the aspects of training in an ergonomics way, twelve of 13 participants rated as good to excellent, due to the work space and task panel location can be adjusted according to the length of instruments. Also, 92% (12 of 13) thought the Ergo-Lap simulator was useful to practice basic SPLS skills. 81% (11 of 13) thought it was very easy to use. For SILS skills training, this inexpensive and portable Ergo-Lap simulator offers a feasible training opportunity to help trainees to practice their SILS skills under ergonomic conditions.

This chapter 6 is based on the following studies:

Xiao, D., A. Albayrak, S. N. Buzink, J. J. Jakimowicz, R. H. M. Goossens Face Validity of a Portable Ergonomic Laparoscopy Skills Simulator for Single incision Laparoscopy Surgery Training. *Surgical Technology International*. Accepted.

6.1 Introduction

The introduction of laparoscopic surgery has revolutionized the surgical approach of various clinical procedures.(Buzink, Christie et al. 2010; Xiao, Jakimowicz et al. 2012) These techniques allow extensive operations to be performed with little trauma, leading to faster postoperative recovery.(Tang, Hou et al. 2012) In recent years, efforts have been made to reduce the trauma of surgical access further by introducing the single-incision laparoscopic surgery (SILS) or scar-less surgery.(Chow, Purkayastha et al. 2010) Although the superiority of SILS procedure compares to multiple incision laparoscopy Surgery (MILS) still needs to be demonstrated,(Santos, Enter et al. 2011) SILS is being increasingly performed on patients.(Canes, Desai et al. 2008; Tang, Hou et al. 2012) However, SILS is associated with a significant learning curve and is more challenging in terms of ergonomics, such as maintenance of sufficient exposure, sustained pneumoperitoneum, adequate retraction, collision between instruments (internal and external), collision between instruments and optics, and limited instrument manipulation and triangulation (Figure 6.1).(Chow, Purkayastha et al. 2010) As a result, many surgeons have to cope with this challenging operating environment through compensatory techniques such as using percutaneous sutures for retraction and employing coaxial, flexible, and articulating instruments to improve triangulation.(Roberts, Solomon et al. 2010; Tang, Hou et al. 2012)

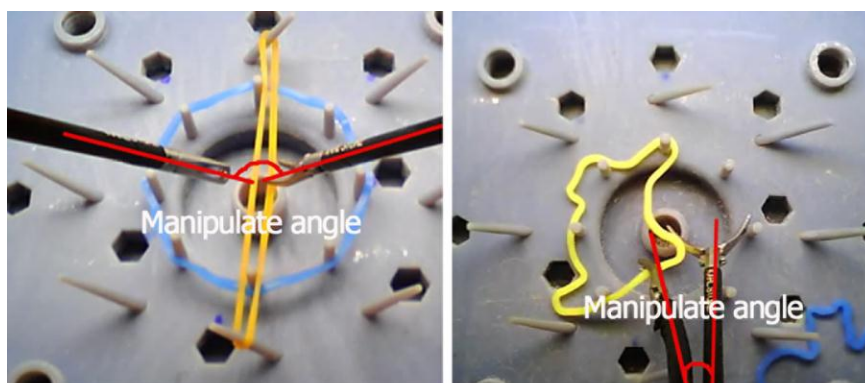


Figure 6.1 Different Manipulate angle of MILS and SILS.

Several groups have reported initial success with SILS procedure,(Kaouk, Haber et al. 2008; Chow, Purkayastha et al. 2010; Curcillo, Wu et al. 2010) the results suggested that SILS is a safe and effective alternative to MILS procedure. However, there is still no consensus on the content of a formal SILS training.(Santos, Enter et al. 2011) Whereas there is consent that surgical training should be structured and assessment of skills should be introduced to ensure safe and high-quality treatment.(Verdaasdonk, Stassen et al. 2006; Brinkman, Havermans et al. 2012) Santos, et al employed surgical simulation to investigate the performance difference between surgeons with SILS experience, and those without. They

concluded that specialized training is necessary in order to practice SILS safely.(Matsumoto, Hamstra et al. 2002; Santos, Enter et al. 2011) However, the specialized program for SILS skills training is still lacking structured validated curriculum. Several studies investigated the feasibility of SILS by modified MILS simulators. However, these modified simulators are not suitable for using different single port devices.(Santos, Enter et al. 2011) We developed a portable ergonomic laparoscopy simulator (Ergo-Lap) for both MILS and SILS training. The usability of the Ergo-Lap simulator for multiple port laparoscopic surgery training had been assessed by 46 surgical trainees. This Ergo-Lap simulator with multiple tasks was rated as a useful and inexpensive training tool that can distinguish between various levels of laparoscopic skills.(Xiao, Jakimowicz et al. 2013) In the traditional validity framework, 'face validity' is defined as the opinion of experts who are knowledgeable about how the target construct is expressed in its relevant contexts.(Andreatta and Gruppen 2009) The aim of this study is to evaluate the face validity of this developed portable Ergo-Lap simulator for SILS skills training.

6.2 Materials and methods

6.2.1 Ergo-Lap simulator

The Ergo-Lap simulator is a portable training tool, which was developed according to ergonomic guidelines (Figure 6.2).(Xiao, Jakimowicz et al. 2012)

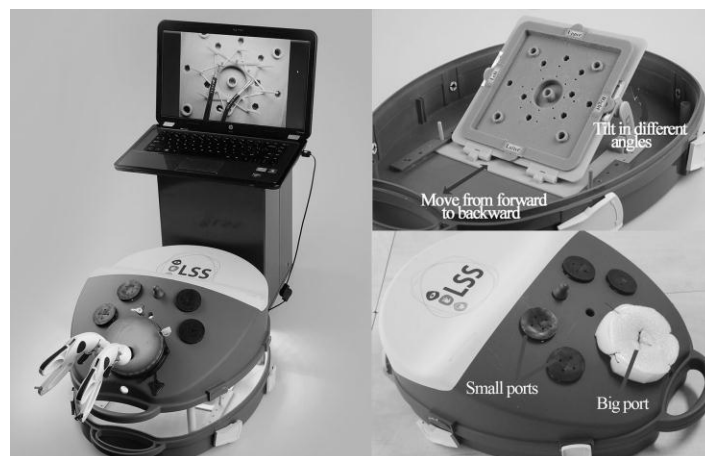


Figure 6.2 Ergo-Lap simulator: The Ergo-Lap simulator ready for use (left); the flexible set-up of the task panel allows for ergonomic training conditions (upper right); the Ergo-Lap simulator ready for transportation (bottom right).

It includes multiple tasks to train basic laparoscopic skills.(Xiao, Albayrak et al. 2013) After the evaluation of the Ergo-Lap simulator for MILS, the cover was adjusted to make the simulator more suitable for SILS training. The simulator cover was redesigned and improved based on the previous prototype of the Ergo-Lap simulator.(Xiao, Jakimowicz et al. 2013) Compared to the previous cover, the new

cover was designed more dome shaped to make sure that the instruments can reach the task panel. The big port in the cover was designed for adapting different single port devices, such as X-zone, Gel port and SILS port (Figure 6.3).



Figure 6.3 Different ports for SILS procedure.

The Ergo-Lap simulator is equipped with a webcam that can record the task performance of the trainee by video software. The physical set-up of the Ergo-Lap simulator is adjustable in height to meet different ergonomic requirements of a broad range of users and offers different types of basic tasks (Figure 6.1). The task panel can be moved backward and forward, and can be tilted under different angles to obtain a proper optical axis-to-target view angle and appropriate intra/extra-corporal instrument length ratio. In addition, the cover of the simulator can be adjusted in height in order to create different volumes of the workspace according to the size of the instruments. For instance, when practicing paediatrics skills with small size instruments, the work space should be smaller. To assist the trainee, an instruction booklet is provided by the simulator to show how to create an optimal ergonomic training set-up for each task.

6.2.2 Participants and tasks

During the 20th EAES congress in Brussels, the simulator was assessed by 13 general surgeons from different countries with different SILS experience using a standardized questionnaire. In this study, we selected the participants who performed more than 50 MILS procedures and at least 1 to 5 SILS procedure as the target subjects for assessing the simulator. Each participant provided informed consent to take part in the study voluntarily and filled out a questionnaire about demographics and their prior experience in laparoscopic and single port procedures. Before performing a task on the simulator, the participants received a standardized instruction and watch a demonstration video of the tasks. And they were allowed to choose one of the three available single port devices (Figure 6.3), Straight (Karl Storz 33310) or curved instruments (Covidien SILS™ Clinch & Covidien SILS™ Dissector) from the package we provided allowing participants to make their choice. The participants were asked to perform two tasks (Figure 6.4).

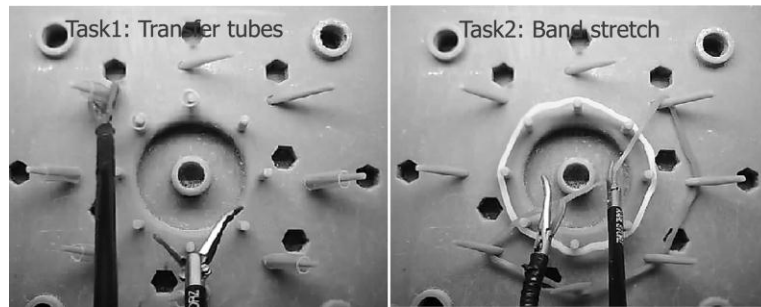


Figure 6.4 Task1 & Task2

Task1 (Transferring tubes according to tilt pillars) was designed for dealing with graspers, and to train surgeons perception from 3 dimensional to 2 dimensional plane. And dropping of a tube was counted as an error for Task1. Task2 (Stretching band) aimed to develop laparoscopic coordination skills with both hands. And slipping of a band was counted as an error for Task2.

6.3 Results

According to the participants' demographics and their prior experience in laparoscopic and single port procedures, three participants with no experience at all of SILS were excluded from the result analysis. The realism and didactic value of the simulator was assessed by 13 male participants (12 specialists and 1 senior residents.) with different levels of experience in SILS and MILS (performed varied from 1 to more than 100 SILS procedures). The demographics and laparoscopy experience of the participants were showed in Table 6.1.

Table 6.1 Demographics and laparoscopy experience of the participants

		Participants (N=13)
Age (year)	Mean (SD)	43
	Min-Max	32-61
MILS experience	10-50	0
	50-100	1
	>100	12
SILS experience	1-5	3
	5-20	0
	20-50	5
	50-100	1
	>100	4

From the questionnaire, each participant has their own commonly used single port device, which is displayed in table 2. From table 6.2, it could be found that 9 of 13 participants selected the single port device that they commonly worked with. But other 4 of 13 participants did not select the one that they familiar with, because these were not available in the setup of our study. The tasks performances of the 13 participants were evaluated by time and number of errors. In order to acquire

an initial relation of performance and SILS experience, the 13 participants were divided into four groups according to their SILS experiences. Figure 6.5 and figure 6.6 show the performance of all participants on Task1 and Task2. From the scatter plot, it can be seen that experienced participants performed the task with less time and less errors compare to the inexperienced ones.

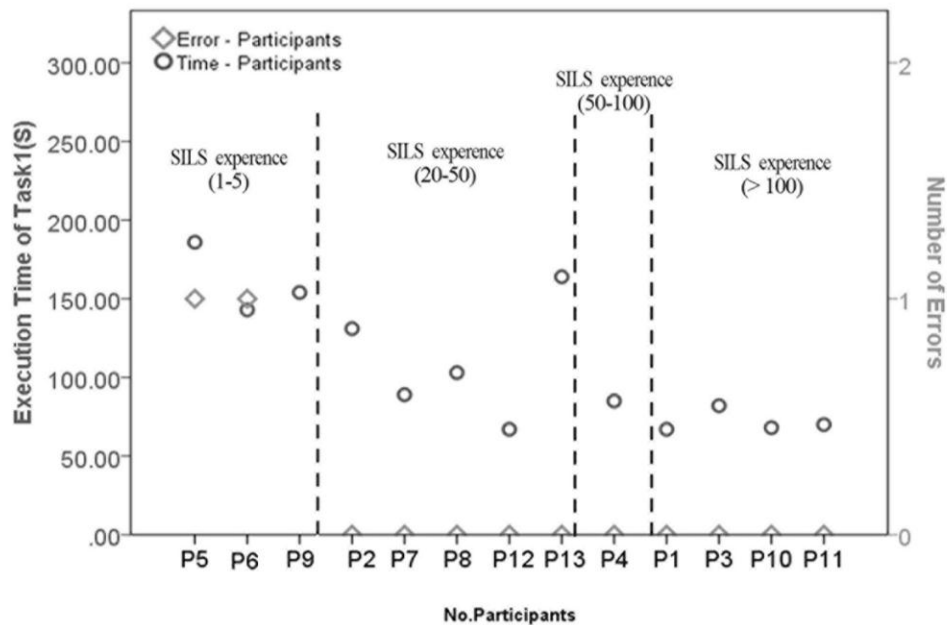


Figure 6.5 Execution Time and number of errors of task1

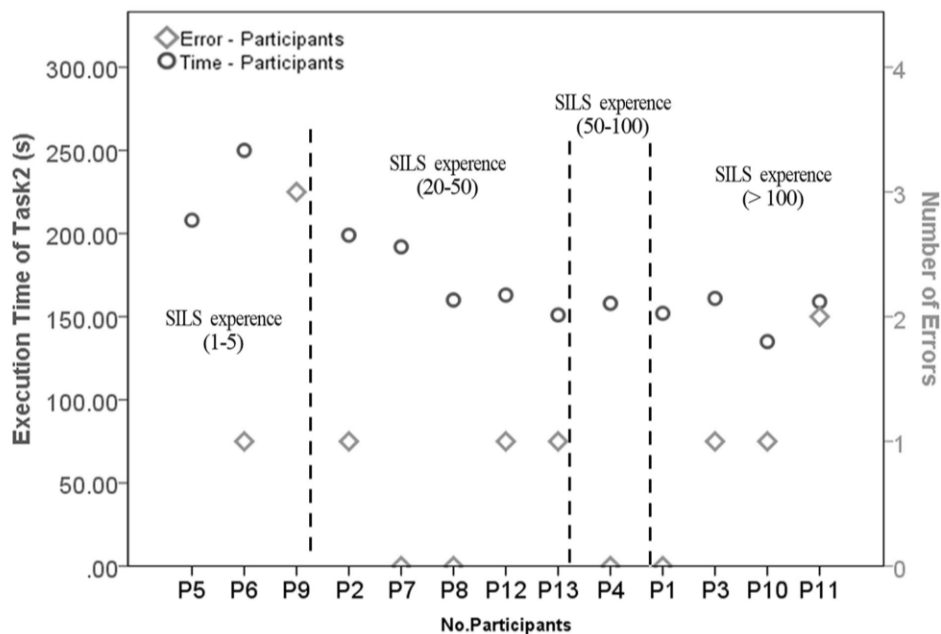


Figure 6.6 Execution Time and number of errors of task 2

Table 6.2 Single port and instruments used by the participants.

Participants	Commonly work with single port device	Single port device used in this study.	Instruments Used in this study
P1	EZ Access (HAKKO Japan)	X-Cone(Karl Storz)	Straight instruments (Karl Storz)
P2	SILS Multiple port (Covidien)	SILS Multiple port (Covidien)	Curved instruments (Covidien)
P3	EZ Access (HAKKO Japan)	SILS Multiple port (Covidien)	Curved instruments (Covidien)
P4	SILS Multiple port (Covidien) & Gel port (Applied Medical)	SILS Multiple port (Covidien)	Straight(Karl Storz) & Curved instruments
P5	Olympus LESS	Gel port (Applied Medical)	Straight instruments (Karl Storz)
P6	X-Cone(Karl Storz) & SILS Multiple port (Covidien)	SILS Multiple port (Covidien)	Straight(Karl Storz) & Curved instruments
P7	SILS Multiple port (Covidien)	SILS Multiple port (Covidien)	Curved instruments (Covidien)
P8	SILS Multiple port (Covidien)	SILS Multiple port (Covidien)	Curved instruments (Covidien)
P9	SILS Multiple port (Covidien)	SILS Multiple port (Covidien)	Curved instruments (Covidien)
P10	X-Cone (Karl Storz) & SILS Multiple port (Covidien) & Gel port (Applied medical)	X-Cone (Karl Storz)	Straight instruments (Karl Storz)
P11	EZ Access (HAKKO Japan)	SILS Multiple port (Covidien)	Curved instruments (Covidien)
P12	X-Cone (Karl Storz)	X-Cone (Karl Storz)	Straight instruments (Karl Storz)
P 13	SILS Multiple port (Covidien)	SILS Multiple port (Covidien)	Curved instruments (Covidien)

Table 6.3 shows the participants' opinion on task 1 and task 2. All participants together rated the global impression of all tasks jointly as good to excellent.

Table 6.4 shows the participants' opinion on this Ergo-Lap simulator. Thirteen participants gave their opinions on the tasks and the simulator by rate 5-point questionnaire. Eleven of the 13 participants rated the simulator as an attractive simulator (Table 6.4). Twelve out of 13 participants found that the simulator offers an ergonomic training setup due to the adjustability of workspace and task panel location according to the length of instruments. Also, 12 of 13 thought the Ergo-Lap simulator was useful to practice basic SILS skills. Eleven of 13 thought it was very easy to use. Twelve of 13 participants considered that this simulator would stimulate them practice SPLS skills more often if they can afford it. Eleven of 13 would like to purchase the simulator and 12 would recommend the Ergo-Lap

simulator to other medical trainees. According to the questionnaire, we concluded that this simulator is a useful tool for training SILS skills.

Table 6.3 Opinion of the participants about two tasks (Task 1 – Transfer Tubes, Task 2 – Band Stretch & Create Stars), rated on a five-point Likert-scale. (1=absolutely not useful, 3=neutral, 5=very useful).

Questions	Task 1 Mean (SD)	Task 2 Mean (SD)
The task is useful to handle with curved grasper	3.92 (0.86)	4.23 (1.01)
The task is useful to train the perception of 3D to 2D. (only for task 1)	3.92 (0.76)	
The task is useful to train bimanual coordination (only for task 2)		4.46(0.97)
Your whole impression of the task	4.07 (0.64)	4.54 (0.66)

Table 6.4 Opinion and impression of participants about the Ergo-Lap simulator, rated on a 5-point Likert-scale. (1=strongly disagree (very poor), 3=neutral, 5=strongly agree (excellent)).

	Mean (\pm SD)
How would you rate the attractiveness of this Ergo-Lap simulator?	4.15 (\pm 0.69)
How would you rate this Ergo-Lap simulator for training in an ergonomic way?(e.g. make sure proper manipulation angle, elevation angle and I/E instrument ratio)	3.92 (\pm 0.64)
Do you think this Ergo-Lap simulator is useful to practice basic single port laparoscopic skills?	4.23 (\pm 0.60)
Did you find this Ergo-Lap simulator easy to use?	4.30 (\pm 0.75)
Do you think having this Ergo-Lap simulator will make you more often practice your single port laparoscopic skills?	4.54 (\pm 0.66)
Would you like to have such an Ergo-Lap simulator yourself?	4.38 (\pm 0.77)
Would you like to recommend such an Ergo-Lap simulator to others?	4.15 (\pm 0.69)

6.4 Discussion

To date, the apparent advantages of the SILS technique have been mainly cosmetic and related to patient satisfaction. However, there still has no evidence show that the SILS cholecystectomy is definitely better than standard multiport laparoscopic cholecystectomy. Although several studies showed that SILS approach is feasible and safe and thus might be used as an alternative technique, this alone does not necessarily justify its useless in surgical practice.(Chow, Purkayastha et al. 2010; Curcillo, Wu et al. 2010; Santos, Enter et al. 2011)

The major difficulty with SILS comes of the need for the surgeon to adapt to the new way of instrumentation and a longer learning curve compare to MILS.(Pereira,

Pereira et al. 2011; Kwasnicki, Aggarwal et al. 2013) For instance, both the long instruments and laparoscope are introduced through the same port and on the same axis, so instruments often interfere with each other not only within the abdomen but also extra-abdominally.(Chow, Purkayastha et al. 2010; Pucher, Sodergren et al. 2013) For alleviating these above difficulties and smooth the SILS instrumentation, new curved instruments were developed. These instruments with increased curvature at the tip and on the shaft significantly aided the dissection of Calot's triangle.(Sanne, Rob et al. 2011)

Santos et al compared the performance of standardized tasks from the modified Fundamentals of Laparoscopic Surgery (FLS) program using either the MILS or the SILS technique. They identified the need for further instrument development and testing, and emphasized the need to develop proper training regulation for surgeons who would like to perform SILS procedures clinically.(Santos, Enter et al. 2011)

Specialized platforms, instruments and training curricula should be developed for inexperienced surgeons who wish to perform SILS. However, a dedicated training simulator in the market is still lacking. Surgical trainees often employ modified MILS simulators for practicing SILS skills.

The Ergo-Lap simulator is developed for both SILS and MILS basic skills training. It can be adapted to different single port devices, such as X-zone, Gel port and SILS port. During the test, we gave participants the opportunity to choose different ports and different instruments freely. In addition, the participants were allowed to change the single port device if they were not satisfied with the devices that they chose at the beginning. This could be an effect way to exclude the prejudice to the Ergo-Lap simulator because of dislike the single port device. A comparative study on the performance of various ports in a surgical simulator has been reported by Brown-Clerk et al, it seems that all current single port devices have certain drawbacks.(Brown-Clerk, Laveaga et al. 2011) In our study, we did not investigate the influence of different single port device on the task performance. In addition, Santos et al compared the effectiveness and learning curves of additional instrument types for SILS training (straight vs. dynamic articulating), there is no differences in SIL scores according to instrument type.(Pereira, Pereira et al. 2011) In this study, we did not investigate the influence of the instrument type on task performance.

During the evaluation process, only the participants who have SILS experience were involved. The task performance was assessed by execution time and number of errors. And the results were displayed by scatter plots (Fig.5 and Fig.6). Although there were only 13 participants, but a slight linear trend was shown that experienced participants performed the tasks with less time and less errors

compare to the inexperienced ones. Although different levels of SILS experienced participants should be involved to evaluate the Ergo-Lap simulator, it indicated that the inexperienced surgical trainees have a potential to improve their SILS skills by practicing on the Ergo-Lap simulator.

Kwasnicki et al compared the skill acquisition and transfer in SILS and MILS, it suggested that dedicated SILC training appears to develop competencies for both SILC and LC, therefore its addition to the early surgical curriculum is likely to extend the access of SILS to patients without reducing MILS skill acquisition.(Kwasnicki, Aggarwal et al. 2013) However, the Ergo-Lap simulator is easy to adjust between SILS and MILS setting, so it should be a proper option for training both SILS and MILS skills in the early stage of laparoscopy training.

This study has limitations: we did not compare the Ergo-Lap simulator with other modified simulators. In addition, we did not involve more different experience levels of participants for the validation. The next step of this study is to evaluate the task performance between different SILS expertise level objectively and therefore to construct content validity of the Ergo-Lap simulator for SILS training.

6.5 Conclusions

For SILS skills training, this inexpensive and portable Ergo-Lap simulator offers a feasible training opportunity to help trainees to practice their SILS skills under ergonomic conditions.

6.6 Acknowledgement

We are very grateful to the involved participants. The authors affirm that they have no conflicts of interest.

PART C

Part C mainly focuses on the distractions during the laparoscopy procedure. Chapter 7 presents the intra-operative interference in the OR and the effect of distractions on task performance.



CHAPTER 7 INTRAOPERATIVE INTERFERENCE IN OPERATION ROOM

The operating room (OR) is a highly complex work environment and high demanding cognitive skills collaboration among surgical team members. Surgeons are subject to various distractions and interruptions that can be detrimental to their task performance and the quality of surgical procedure. The purpose of this study is to review the literature on distractions and interruptions during intraoperative phase of different surgical procedures in both the real OR and skills lab setting.

A systematic literature research was conducted against a set of inclusion criteria. Major databases (Medline, PubMed, Web of Science, and Scopus) were searched to obtain relevant articles. In total, 27 articles were included in this review. Twelve observational studies were carried out during the OR to observe interruptions and distractions during the procedure. In addition, 11 experimental studies employed a surgical simulator with simulated distractions and interruptions to investigate the effect of distracting events on the task performance. And four qualitative studies interviewed the surgical team to investigate the influence of intraoperative distractions on their performance.

Surgeons are facing multiple distractions and interactions during surgery. Most of these can cause stress to the surgeon and may disrupt the surgical flow potentially resulting in adverse events. Thorough analysis of interruptions and the way surgeons cope with them, could potentially contribute to the positive outcome of procedures. Analysis of experimental studies focusing on the effects of disruptions and interrupting events both in the OR and in skills lab setting provide evidence for the need to develop an effective, comprehensive training program in an environment similar to the OR.

This chapter is based on the following systematic literature review:

Xiao D, Albayrak A, Jackimowicz J, Goossens RHM. Intraoperative Interference in Operation Room: A systematic review of the literature. Submitted to Surgical Endoscopy.

7.1 Introduction

The prevalence of Minimally Invasive Surgery (MIS) has been bringing apparent advantages to the patients, such as less blood loss, shorter stay in hospitalization and a rapid recovery. On the other hand, MIS has turned the operating room (OR) into an even more complex environment and high demanding cognitive skills collaboration among anesthetists, nurses, surgeons and other related personnel. This highly complex work environment poses a challenge to optimize the surgical workflow and the performance of the surgical team.(Moorthy, Munz et al. 2004) In the complex OR settings, the clinical specialists have to operate under high levels of stress, such as? I think you mean: in complex surgical procedures with unexpected noise and distractions etc. Under such circumstances, the surgeon does not only have to perform surgical tasks, but manage multiple interferences as well.(Chisholm, Collison et al. 2000; Pape 2011)

The surgical team members are together responsible for patient care, and at the same time they have their own responsibilities and different multiple tasks to perform in shared space in the OR. The different tasks and activities of the surgical members may interfere with one another. And therefore, situations can be occurred with a great number of distractions and interruptions.(Pape 2011)

Several previous researches have also indicated that both the aspects of the physical discomfort and social environment can interfere with the work of surgical teams.(Kant, Jong et al. 1992; Sexton, Thomas et al. 2000) Physical discomfort can arouse muscle fatigue, and miscommunications between surgical team members may disturb the surgical workflow.

Especially new surgical methods, such as minimally invasive surgery introduced considerable ergonomic problems for a range of disciplines in the OR compared to open surgery.(Burgess-Limerick, Mon-Williams et al. 2000; van Veelen, Kazemier et al. 2002; Kaya, Moran et al. 2008) However, there are few studies that have focused primarily on assessing interactions in surgery and there a few that have focused on distraction or interruption in the OR. Previous studies(Moorthy, Munz et al. 2003; Moorthy, Munz et al. 2004) employed operation theater background noise, arithmetic problem, and pop music as the primary distracting sources to demonstrate significant adverse effects on surgical performance under the simulated settings. However, realistic distraction probably have a different impact on surgical performance because they are more likely to be blocked out.(Pluyter, Buzink et al. 2010)

Although the OR is admitted to be a multidisciplinary environment with numerous distractions and interruptions, a purposive designed training programs which provide the trainees to practice various skills in a distracting situation safely, are

still missing. The shortage of systematic training can result in inexperienced surgical trainees poorly prepared for the multiple demands of the OR environment. (Hassan, Weyers et al. 2006)

Motivated by the need to improve team performance and reduce adverse events in surgery, measuring and investigating the effect of interference on surgeons cognitive stress level during operation is necessary to optimize the surgical settings and thus to maintain high surgical performance (Arora, Sevdalis et al. 2010). Next to this, a systematic view is increasingly important to health care, for improving efficiency and patient safety (Healey, Sevdalis et al. 2006). The safety from a systematic perspective can be achieved by improving the interaction among the system components. (Reason 2000; Wilson 2000) There is considerable potential for studying system interactions within the OR in order to highlight weaknesses in the process of care. With the long-term aim of developing effective training systems for surgeons, the purpose of this study is to review the literature on distractions and interruptions during intraoperative phase of different procedures (both MIS and open surgery) in both the real OR and skills lab setting. And this literature review will focus on the following questions: (1) what are the main distractions and interruptions during intraoperative in the OR? (2) What are the methods for measuring distractions and interruptions during this phase? (3) What are the effects of distractions and interruptions on the surgical performance?

7.2 Materials and methods

7.2.1 Data sources and search strategy

Different databases such as the Medline, PubMed, Web of Science, and Scopus were included in the search. The initial search was restricted to English articles with abstracts published in peer-reviewed journals between 1982 and 9th April 2013. Since the first endoscopic appendectomy was performed by a German physician Kurt Semm in 1982 (Blum and Adams 2011). So this year was chosen as a starting point for this literature study.

The search strategy included the following terms with the appropriate combinations: Category 1= "distractions" OR "interruptions" OR "interference" OR "disturbance" AND Category 2= "Laparoscopic procedure" OR "surgical skills" OR "surgical performance" OR "operating room" OR "surgical simulation" OR "surgical education" OR "Intraoperative"

After combining category 1 and category 2, limits were set to restrict studies to those carried out on human subjects and reported in English. An initial screening revealed that many studies were related to anesthesia and preoperative phase of the surgery. Subsequently, the following additional limits were applied: NOT

preoperative, NOT postoperative, NOT anesthesia, NOT patients. A summary of the search results is presented in Table 1. The search generated 3735 references, including some duplicated articles due to parallel searches.

Table 7.1 Summary of searches.

Database	Hits(before limits applied)	Hits (after limits applied)
Medline	817	148
PubMed	845	359
Web of science	807	310
Scopus	1246	338
Total	3715	1152

7.2.2 Inclusion/exclusion criteria

Articles which matched the following criteria were included: (1) a focus on interference during intro-operative procedure in the operating room; (2) experimental research that focuses on distractions in the skills lab; (3) Questionnaire and interview studies with surgeons to investigate distractions during surgical procedure. Review articles that focus on the distractions and non-technique skills were studied only to identify other relevant empirical studies.

7.2.3 Selection process and data extraction

A three-staged process was applied: two reviewers (1) independently identified and screened the search findings for potentially eligible abstracts, (2) examining the abstracts, (3) and summarizing full articles which were selected for further analysis.

In the first stage, two researchers screened all the 1152 titles and abstracts independently to ensure reliability. In case of different of opinion with regard to the selection, this was discussed by the two researchers. If the title or abstract did not provide enough information to meet the Inclusion/exclusion criteria, the article was referred to the next stage of the process.

In the second stage, each abstract and full articles were examined by first researcher independently using the inclusion criteria.

In the third stage, the full texts of the remaining abstracts were evaluated in detail using a standard format (Table 7.1). For quality-assurance purposes, three researchers evaluated the same five articles independently to ensure reliability. Then the first author evaluated all the retrieved articles.

7.2.4 Organization of results

Based on the findings, a categorical description of distractions was constructed. Retrieved articles were classified accordingly. Three categories were identified: (1)

Observation of distractions and interruptions in the OR, (2) experimental studies used surgical simulator to investigate the effects of distractions and interruptions on surgical performance, and (3) questionnaire survey on the influence of distractions and interruptions among the OR staffs. Each article is described using same structure: subjects, methodology and setting, aim, type of distractions and interruptions, measure of distraction, measure of performance, conclusions from the author and quality of evidence.

The level of empirical evidence is based on the Grading of Recommendations Assessment, Development, and Evaluation scale (GRADE)(Balshem, Helfand et al. 2011). The GRADE system is used for authors to describe their findings and reasons in the context of a systematic review or guideline. So the GRADE system can give a general rating of both the level of evidence and the quality of the article. The GRADE rating scale has four categories of quality of evidence: (I) high, (II) moderate, (III) low, and (IV) very low (Balshem, Helfand et al. 2011). The definition of these four different categories is as following:

(I) High: quality evidence implies that the true effect lies close to that the estimate effect of the distraction. The category comprises multicenter random control trials (RCT), one large high-quality multi-center trial.

(II) Moderate: quality evidence implies the true effect is likely to be close to the estimate effect of the distraction, but there is a possibility that it is substantially different. This category consists of one-center RCT, RCT with severe limitations.

(III) Low: quality evidence implies that the true effect may be substantially different from the effect of distraction. This category consists of high-quality qualitative studies, quasi-experimental designs with limitations.

(IV) Very low: quality evidence implies that the true effect is likely to be substantially different from the estimate effect of distraction. This category consists of low-quality qualitative studies (questionnaire survey) with severe limitations (Buljac-Samardzic, Dekker-van Doorn et al. 2010; Tacconelli 2010; Balshem, Helfand et al. 2011).

For rating the quality of evidence, the GRADE guidelines was used, and an extent of adjustment was adapted for this study. Quality evidence level depends on the type of the study (Experimental, observational and questionnaire survey) and methodology (design of the protocol, sample size etc.). The quality level of the retrieved studies was determined by three researchers jointly. Firstly, three authors assessed the same five papers independently and fill in the table 7.1. Studies with different rating scores were discussed jointly to come to an agreement.

7.3 Results

7.3.1 Selected articles

The first stage, 142 abstracts were eligible, 65 duplications were excluded. In total 77 abstracts were left for the second stage.

In the second stage, 77 full articles were read by the first researcher. The search included one review (Arora, Sevdalis et al. 2010) that focused on the impact of stress on surgical performance and one special column (Beyea 2007) about distractions and interruptions in the OR, these two papers were analyzed to identify additional studies, but none were found.

After reading the full articles, 50 articles did not meet the inclusion criteria. Therefore a total of 27 articles included in the third stage for final analysis. The three researchers evaluated the same five articles independently to ensure reliability of the results. Then the first author evaluated all the retrieved articles. The results of the 27 articles are summarized in Table 7.2.

Table 7.2 Characteristics of studies

Authors	Subjects	Methodology and setting	Aim	Distractions and interruptions (OR events/ Simulated OR events)	Measure of distraction	Measure of performance	Conclusions from author	Quality of evidence
(Feuerbacher, Funk et al. 2012)	18 Novice surgeons	Prospective Experimental study, Laboratory setting	To investigate whether distraction and interruption induce errors to the performance of a laparoscopic task by novice surgeons	(1) 4 distractions: (2) 2 interruptions:	Not measure	1.Surgical errors measured by simulator 2.Answer of a memory task	Operating room distractions and interruptions have the potential to cause operative errors in surgical trainees.	(II) moderate: Experiment study with more realistic distractions.
(Gillespie, Chaboyer et al. 2012)	Surgical Team: anesthetic consultant, surgical consultant and/or resident, circulating nurse, scrub nurse, and anesthetic nurse.	Observation of 160 procedures in OR.	To quantify describe intraoperative interruptions and team communication in surgery.	(1) Procedure interruptions. (2) conversational interruptions. (3) miscommunication events.	(1)Type and number of interruption, role of team member interrupted. (2)number and type of miscommunication.	Duration of the surgical procedure.	Interruptions can reduce team members' ability to remain focused, prolong surgery and endanger team members' ability to maintain situation awareness.	(III) low: Big sample size observational study
(Goodell, Cao et al. 2006)	13 surgical residents and medical students.	A surgical skills laboratory	To determine the cognitive distractions on laparoscopic surgical task performance, using a virtual reality simulator.	mental arithmetic problems	Arithmetic error	(1) Time to task completion, (2) errors of Motion. (3) economy of Motion. (4) overall score.	Cognitive distraction has negatively influence on the performance of laparoscopic surgical tasks.	(III) low: Experiment study. Small sample size experimental studies.
(Hassan, Weyers et al. 2006)	12 medical students and 12 inexperienced surgical residents.	A surgical skills laboratory	To investigate the impact of habitual stress-coping strategies on the laparoscopic performance.	Habitual stress-coping strategies.	Rating scale of the questionnaire.	(1) time to task completion. (2)errors of Motion. (3) economy of Motion.	Ineffective stress-coping strategies correlate with poor virtual laparoscopic performance.	(IV) very low: Experiment study: no simulated distractions.

(Healey, Primus et al. 2007)	Surgical team: anesthetist and their nurse, primary surgeon, surgeon's assistant, scrub nurse, and circulating nurse.	Observation of 30 urology procedure in the OR .Use an eight-point ordinal scale to rate the observed salient distraction and interruption.	(1) to measure the frequency of distraction and interruption in a single sample; (2) to identify the source of distraction and interruption; (3) to evaluate noise in the operating theatre with sound pressure measurement.	Case irrelevant conversation, phone, beeper, equipment, procedure, and environment factors, monitor	(1) Frequency of the distracted events (2) eight-point ordinal scale to rate distraction level. (3) duration of the interruption. (4) noise level	Duration of the surgical procedure.	The frequency of events deriving from varying degrees of equipment, procedure and environment problems, telephones, beepers and conversations.	(IV) very low: Small sample size observation study
(Healey, Sevdalis et al. 2006)	50 procedures. Surgical team: anesthetist, Surgeons, nurses and their respective assistants.	Observation of 50 procedures in the OR. Use a 9-point ordinal scale to rate the observed interference.	To observe and record the frequency of distraction and interruption in the operating theatre during the intra-operative phase of surgery.	Case irrelevant conversation, phone, beeper, equipment, procedure, environment, movement of monitor, external staff, noise, rate of door opening.	(1) Frequency of the interference events. (2) eight-point ordinal scale to rate distraction. (3) duration of the interruption. (4) noise level (5) frequency of door opening.	Duration of the surgical procedure.	Measurement of distraction and interruption in the OR is feasible. But the measures need further validation by obtaining agreement to other relevant measures.	(IV) very low: Small sample size observation study
(Hodge and Thompson 1990)	Surgical team and patients	OR observation: A complete operation (radical neck dissection) was recorded for an analysis of the overall noise levels during a typical major surgical procedure.	Sound levels during a typical major operation were measured to identify the main sources of noise in the OR.	Sources of noise: Sucker, diathermy machine, anesthetic alarms, speech, conversation.	Two sound meters	Not measure	(1) During surgery the sources of continuous noise were the sucker and the ventilator. (2) Main sources of intermittent noise included the diathermy machine, anesthetic alarms, and intercom.	(IV) very low: Small sample size observation study

(Conrad, Konuk et al. 2012)	31 novice surgeons	A surgical skills laboratory setting with VR simulator.	To examine the effect of auditory stress and auditory relaxation on laparoscopic motor skill performance in novices and compares these results to the effects of the internal stresses of mental loading.	(1) Stressful auditory stimuli: Dichotic music (2) auditory relaxation: classical music (3) Mental load: arithmetic task	Not measure	(1) Time to completion task (2) task accuracy.	(1) Both task learning and performance is impacted by acoustic stimuli. (2) Listening to relaxing music leads to improved learning of a surgical procedure.	(III) low: Quasi-Experiment study
(Hsu, Man et al. 2008)	31 medical students and 9 experienced laparoscopic surgeons	A surgical skills laboratory setting with Fundamentals of Laparoscopic Surgery (FLS) simulator.	To examine the effect of a cognitive distracting task on the performance of a simple laparoscopic task in relation to the level of surgical experience.	Arithmetic task	(1) Number of arithmetic question. (2) Number of correct answers	(1) Peg transfer score. (2) Number of arithmetic question and number of correct answers.	Effects of a surgical and cognitive dual-task set on performance depended on the experience level of the surgeon.	(III) low: Quasi-Experiment study
(Makama, Ameh et al. 2010)	The OR staff (Nurses, theatre attendants) and users (the Surgeons, anesthetists, and Patients)	Interview study, not in real OR.	To explore the views of staff and users on the acceptability and role of music in the OR.	Music	Not measure	Self-report	Music in the OR can minimize annoyance, prevent distraction, reduce stress and diminish the anxiety of patients, staff and users.	(IV) very low Questionnaire survey
(Meneghetti, Pachev et al. 2012)	Nine surgery residents and 6 experienced laparoscopic surgeons	A surgical skills laboratory setting with VR simulator.	Use dual-task methodology to the assess the laparoscopic surgical skills.	Three auditory-stimulus tasks: (1) Counting "beeps". (2) Selected response. (3) Mental calculations.	(1) reaction time. (2) error rate	(1) time to completion the task. (2) Total number of errors.	(1) The use of dual-task may help trainers to identify which surgical trainees require more preparation before entering the real OR. (2) Experienced surgeons can maintain performance levels on a primary task in the face of distractions.	(III) low: Small sample size experiment study

(Patterson 2012)	The OR staff	Questionnaire survey.	Using an online survey to investigate the situation and opinion on the using of mobile device in OR	Mobile device in the OR.	Not measure	Not measure	(1) personal use of mobile devices in the OR sometimes distracts providers from patient care and potentially endangers patients. (2)Benefits in convenience and communication.	(IV) very low Questionnaire survey
(Pereira, Pereira et al. 2011)	Surgical team	OR observation of 50 cases surgical trama.	(1) To measure the frequency of interruptions and distractions in the trauma operating room. (2) To identify the source of interruptions and distractions in OR. (3)To assess the intensity of sound in decibels (dB) in OR.	(1)Disruption unrelated to the surgical case. (2)Interruption related to surgical. (3)Distraction not related to the case. (4)Distraction-related case (5) Opening doors, (6)Phone/Pager ringing (7)Alarms (8)Noise level. (9)Long surgical procedure (10) Fatigue	Number and duration of interruption and distraction.	Duration of surgical procedure.	Interruptions and distractions are frequent and should be studied by the trauma surgeon to develop prevention strategies and lines of defence to minimize them and reduce their effects.	(IV) very low Small sample size observation
(Persoon, van Putten et al. 2011)	86 medical students	A surgical skills laboratory setting with VR simulator.	To establish the effect of distraction on the performance of cystoscopy and basic endourological tasks.	Answer questions about medical cases.	Two adequate verbal responses the conversation controlled by experimenter.	(1)Number of traumata, (2)number of missed lesions in the bladder and (3) time to completion were measured by the VR simulator.	(1) Distraction during the performance of Endourological skills results in significantly poorer performance. (2)Most students do not realize they are affected by distraction.	(II) moderate: Random control trial experiment study

(Pluyter, Buzink et al. 2010)	12 medical trainees	A surgical skills laboratory setting with VR simulator.	To examine whether such realistic social and technological distracting conditions may influence surgical performance.	(1) Social distraction: combination of music and case irrelevant communication.(2)Technological distraction: non-optimal laparoscope navigation.	Individual differences in cognitive style.	(1) overall task score, (2) task errors, and (3) operating time	Surgical training should involve managing social and technological distracting sources, and integrated technical and nontechnical training.	(II) moderate: Experiment study with more realistic distractions.
(Persoon, Broos et al. 2011)	Surgical team 8 urologists and 7 urology residents	Observation in OR and interview with 8 urologists and 7urology residents	This study aimed (1) to quantify the frequency, nature of distracting events and their effects on performance during endourological procedures and (2) to explore urologists' and residents' perspectives on experienced ill effects due to distracting factors.	Pager, telephone, radio, door movement, equipment, procedure, case-irrelevant communication	Use a seven-point ordinal scale was to measure the level of observed interference.	Self-report of the interviewer.	Equipment problems and communication have the largest impact on the sterile team and regularly interrupt procedures. (2) Distracting stimuli can influence performance negatively and should be minimized.	(II) moderate: Mixed method: big sample size observation and semi structured interview.
(Sevdalis, Healey et al. 2007)	Surgical team	Observation of 48 general surgery procedures in the OR.	(1) To describe the content, initiators and recipients of communication s that intrude or interfere with individual surgical cases. (2) Consider the level at which the surgical team are distracted by these case-	Case irrelevant communication	Use a nine-point scale to rate the level of distraction introduced to the operating theatre by each case irrelevant communicatio n event.	Not measure	(1) Some of the observed CICs contributed to the administration of the OR case-list. (2) This CICs can interfere with highly sensitive work.	(IV) very low Small sample size observation

			irrelevant communications (CICs).					
(Suh, Chien et al. 2010)	Fourteen in medical students and residents.	A surgical skills laboratory setting.	The purpose of this research was to investigate the effect of distraction on robot-assisted surgical skill performance in medical students and residents.	Secondary tasks included distractions: (1) mathematics problems, (2) a decision-making task, (3) a memory task, (4) recorded noise from operating room.	The percentages of correct answers were calculated as scores for three secondary tasks (mathematics problems, decision making and memory)	(1) The time to task completion, (2) speed and the total distance travelled were analysed.	(1) The performance of a robot-assisted surgical task was negatively affected by secondary tasks. (2) Residents with more surgical experience demonstrated a larger attention capacity for multitasking	(III) low: Experiment study with small sample size.
(Szafranski, Kahol et al. 2009)	Fourteen surgical residents.	A surgical skills laboratory setting with simulator.	(1) To introduce realistic noise and distractions in simulated surgical environments and quantify their effects on surgical proficiency, and (2) to quantify the effects, if any, of resident pre-training in noisy conditions.	(1) Ambient noise from an operating room and directed auditory noise. (2) Visual distractions consisted of flashing lights on the simulator screen. (3) Vibration of pagers.	Not measure. Random controlled by experimenter.	(1) Hand and tool movement smoothness (2) Cognitive errors.	Noise and distractions can significantly impede performance of surgical residents, but this effect can be nullified by introduction of noise and distractions in the training environment.	(III) low: Experiment study with small sample size.
(Moorthy, Munz et al. 2004)	Twelve surgeons	A surgical skills laboratory setting with pelvic-trainer.	To objectively evaluate the effect of noise and music on the performance of a complex surgical task.	(1) OR background noise (80-85 dB). (2) Music.	Controlled by experimenter.	(1) Tasks accuracy, (2) knot quality, and (3) number of non purposeful movements.	Surgeons can effectively "block out" noise and music	(III) low: Experiment study with small sample size.

(Sami, Waseem et al. 2012)	Surgical team	Observation in OR: 32 surgical procedure.	To identify and quantify factors causing stress in the OR and evaluate the relationship between these factors and surgeons' stress level.	(1) Technical factors. (2) Patient factors. (3) Team factors. (4) Distractions. (5) Equipment problems. (6) Teaching (7) Personal issues	Surgeons use an eight point scale questionnaire to rate the stress level	Not measure	Certain stressful factors do occur among surgeons in the OR and can increase the potential for errors	(IV) low: Observation study with small sample size
(Wiegmann, ElBardissi et al. 2007)	Surgical team	Observation of 31 cardiac surgery operations.	To study surgical errors and their relationship to surgical flow disruptions in cardiovascular surgery prospectively to understand better the effect of these disruptions on surgical errors and ultimately patient safety.	Flow disruptions include (1) Teamwork or communication failures. (2) Equipment and technology problems, (3) Extraneous interruptions. (4) Training related distractions. (5) Issues in resource accessibility.	Frequency of the disruptions.	Frequency of surgical errors.	(1) Surgical errors increased significantly with increases in flow disruptions. (2) Teamwork/communication failures were the strongest predictor of surgical errors.	(IV) very low: Observation study with small sample size
(Zheng, Martinec et al. 2008)	Surgical team	Video-aided observational of 12 surgical procedures.	To examine disruptive events during laparoscopic surgery using video recording and analysis technologies.	(1) Instrument change. (2) Surgeon position change (3) Nurse duty shift. (4) Conversation. (5) Phone/pager answering. (6) Extraneous interruption.	(1) The frequency and duration of each type of disruptive event were recorded. (2) Events were categorized based on whether or not they delayed the workflow.	Duration of the surgical time.	Categorizing disruptive events and examining their negative impact on the OR time will help to develop methods to eliminate inefficiency inside the OR.	(IV) very low: Observation study with small sample size

Sevdalis, N. et al. (Sevdalis, Forrest et al. 2008)	Surgical team	Questionnaire survey	To report the development of the "Disruptions in Surgery Index" (DiSI): a tool that captures self-perceptions of operating room staff regarding the disruptions that they and their colleagues have to deal with in the operating room.	(1) Bleeps, (2) External noise (3) Loud music (4) People walking in and out of the operating room (5) Temperature (6) Unavailable or not working equipment (7) Irrelevant chatting (8) Language issues	Scale questionnaire	Not measure	DiSI is useful in that it differentiates between the frequency and the severity of disruptions	(IV) very low Questionnaire survey
(Parker, Laviana et al. 2010)	Surgical team	Observation of 22 surgical procedures	to create and validate a practical tool that systematically classified surgical flow disruptions.	(1) Technical issue (2) Case-irrelevant Conversations (3) Pagers/phones (4) Instrument/device not at table (5) miscommunication	(1) Frequency of event type. (2) impact for disruptions (e.g. duration of pause in task, 2 nd task engaged)	Not measure	This surgical flow disruptions tool is an important first step in systematically categorizing and measuring surgical flow disruptions and their impact on patient safety in the operating room	(IV) very low Observational study with small sample size
(Healey, Olsen et al. 2008)	Surgical team	Observation of 22 laparoscopic cholecystectomy procedures	To explore the feasibility of applying two sets of measures to evaluate teamwork and work interference and their relations.	Case irrelevant conversation, phone, beeper, equipment, procedure, environment, movement of monitor, external staff, noise, rate of door opening.	Use a nine-point scale to rate the level of distraction	(1) Used OTAS (Healey, Undre et al. 2004) to measure team performance. (2) Operative duration	Through team-feedback and de-briefing sessions, these methods and measures may serve to raise awareness of performance-shaping factors in teams and enable effective team adaptation.	(III) low: Observational study associated with team performance

(Ullmann, Fodor et al. 2008)	Surgical team	Questionnaire survey of music in the OR	To evaluate the perception of the influence of music on physicians and nurses working in the OR	Music	Not measure	Self-report	Music has a positive effect on the staff working in the operating rooms.	(IV) very low Questionnaire survey
(Healey, Primus et al. 2007)	Surgical team: anesthetist and their nurse, primary surgeon, surgeon's assistant, scrub nurse, and circulating nurse.	Observation of 30 urology procedure in the OR .Use an eight-point ordinal scale to rate the observed salient distraction and interruption.	(1) to measure the frequency of distraction and interruption in a single sample; (2) to identify the source of distraction and interruption; (3) to evaluate noise in the operating theatre with sound pressure measurement.	Case irrelevant conversation, phone, beeper, equipment, procedure, and environment factors, monitor	(1) Frequency of the distracted events (2) eight-point ordinal scale to rate distraction level. (3) duration of the interruption. (4) noise level	Duration of the surgical procedure.	The frequency of events deriving from varying degrees of equipment, procedure and environment problems, telephones, beepers and conversations.	(IV) very low Small sample size observation study

7.3.2 Covered surgical area by included studies

Most of the included articles (27) were prospective observational studies and experimental studies, 12 observational studies were carried out during the OR to observe interruptions and distractions during the procedure.(Hodge and Thompson 1990; Healey, Primus et al. 2007; Sevdalis, Healey et al. 2007; Wiegmann, ElBardissi et al. 2007; Healey, Olsen et al. 2008; Parker, Laviana et al. 2010; Pereira, Pereira et al. 2011; Persoon, Broos et al. 2011; Gillespie, Chaboyer et al. 2012; Sami, Waseem et al. 2012) One of 12 studies was an observation based on recorded intraoperative video (Zheng, Martinec et al. 2008). In addition, 11 experimental studies employed surgical simulator with simulated distractions and interruptions to investigate the effect of distracting events on the task performance. (Moorthy, Munz et al. 2004; Goodell, Cao et al. 2006; Hsu, Man et al. 2008; Szafranski, Kahol et al. 2009; Pluyter, Buzink et al. 2010; Suh, Chien et al. 2010; Persoon, van Putten et al. 2011; Conrad, Konuk et al. 2012; Feuerbacher, Funk et al. 2012; Meneghetti, Pachev et al. 2012) One of 11 experimental studies explored the impact of habitual stress-coping strategies (SVF78 stress-coping questionnaire) on the laparoscopic performance of novices using a virtual reality simulator.(Hassan, Weyers et al. 2006) And four qualitative studies interviewed the surgical team to investigate the influence of intraoperative distractions on their performance with questionnaires.(Sevdalis, Forrest et al. 2008; Ullmann, Fodor et al. 2008; Makama, Ameh et al. 2010; Patterson 2012)

The different surgical procedures researched in the twelve included observational studies were: urology procedure,(Healey, Primus et al. 2007) open surgery and laparoscopic surgery, (Healey, Olsen et al. 2008; Zheng, Martinec et al. 2008; Persoon, Broos et al. 2011) radical neck dissection,(Hodge and Thompson 1990) laparotomy and thoracotomy,(Pereira, Pereira et al. 2011) general surgery,(Sevdalis, Healey et al. 2007; Sami, Waseem et al. 2012) and cardiovascular surgery (Wiegmann, ElBardissi et al. 2007) (Parker, Laviana et al. 2010; Gillespie, Chaboyer et al. 2012)

7.3.3 A note on terminology

Because different terminology is used in the literature to describe the distract events during intraoperative phase, the terminology which is used for this study will be explained. Most of the studies from the literature use the words “distractions” and “interruptions” to describe the events which interfere with the surgical team member from their work.(Moorthy, Munz et al. 2004; Goodell, Cao et al. 2006; Hassan, Weyers et al. 2006; Healey, Primus et al. 2007; Healey, Olsen et al. 2008;

Makama, Ameh et al. 2010; Conrad, Konuk et al. 2012; Feuerbacher, Funk et al. 2012; Gillespie, Chaboyer et al. 2012; Meneghetti, Pachev et al. 2012)

Distraction was defined as the behavior observed when there was diversion of attention during the execution of a primary task and or verbal response to a secondary task related or not related to the primary activity, such as orienting away from a task. Interruption was defined as a distraction resulting in cessation of the main task activity(Healey, Sevdalis et al. 2006).

“Disruptions” of the surgical flow was investigated by two different studies. Wiegmann et al. and Zheng, et al. defined surgical flow disruptions as any issues in teamwork, technology/instruments, training, or the environment that result in deviation from the natural process of an operation, thereby potentially hindering safety.(Wiegmann, ElBardissi et al. 2007; Zheng, Martinec et al. 2008) In this article, we use the distractions and interruptions to represent all the interfered events during intraoperative phase.

7.3.4 Measure of distractions

The noise level of the OR can be measured objectively by a sound meter.(Hodge and Thompson 1990) However, the other distracting events such as case irrelevant communication, visual or auditory disruptions are difficult to be measured during operation. Now there is no optimal objective tool exists for measuring distractions directly and objectively. Several observational studies in the OR measured the distractions and interruptions only by frequency (Wiegmann, ElBardissi et al. 2007; Pereira, Pereira et al. 2011; Gillespie, Chaboyer et al. 2012; Sami, Waseem et al. 2012). Zheng et al.(Zheng, Martinec et al. 2008) measured the disruption by both frequency and duration. But the same distracting events may cause different level of distraction, so other studies measured the distractions by reflecting ordinal levels of team involvement in a distracting or interrupting event. (Healey, Sevdalis et al. 2006; ElBardissi, Wiegmann et al. 2007; Wiegmann, ElBardissi et al. 2007; Sevdalis, Forrest et al. 2008; Parker, Laviana et al. 2010) Because two or more observers measured the distractions jointly, so the inter-rater reliability was also accessed.

For 10 out of 11 experimental studies in the skills lab, the simulated distracting conditions were controlled by the researchers, so the distraction level was kept the same during every distracting condition. However, the individual differences in cognitive style, the irritation for the same distracting condition might differ between trainees.

Hassan, I. et al.(Hassan, Weyers et al. 2006) used SVF78 stress coping questionnaire to assess negative stress (including distractions) coping strategies. Sevdalis, N. et al.(Sevdalis, Forrest et al. 2008) developed the Disruptions in

Surgery Index (DiSI) to assess OR professionals' self-perceptions of disruptions that affect surgical processes. The other two studies (Makama, Ameh et al. 2010; Patterson 2012) used structured questionnaires to investigate the OR staffs' opinion on the music and personal mobile device in the OR.

7.3.5 Categories of observed OR distractions and interruptions and their effects on OR team

Twelve observational studies in the OR investigated the sources of distractions and interruptions and their frequency of occurrence on team performance during surgery. Sources of interruptions included telephone, pager, conversation, equipment, and procedure.(Healey, Sevdalis et al. 2006; Healey, Primus et al. 2007; Zheng, Martinec et al. 2008; Gillespie, Chaboyer et al. 2012) Table 7.3 summarizes the sources and categories of the distractions and interruptions.

Table 7.3 Sources of observed distractions in OR. (Adapted from literatures(Healey, Sevdalis et al. 2006; Healey, Primus et al. 2007; Sevdalis, Healey et al. 2007; Healey, Olsen et al. 2008; Sevdalis, Forrest et al. 2008; Pereira, Pereira et al. 2011; Persoon, Broos et al. 2011; Gillespie, Chaboyer et al. 2012; Sami, Waseem et al. 2012))

Distraction Sources	Definition	examples from literature
Operating room environment (Environmental factors)	Workspace and human-interface problems. (including auditory, visual and sensorial disruption)	Pager-any pager in theatre or next to theatre
		Phone-any phone in or next to the theatre
		Radio-action or response to radio causing distraction
		Alarms
		Music
		Temperature-surgeon complain OR too warm
		Door opening
Technology and instruments (Equipment factor)	Any item of equipment malfunction/not ready.	Clamp for abdomen jammed
		Diathermy off or settings not correct
		Laparoscopic graspers not working
		Failing table adjustment
		Endoscope not working
		Electric point not working
Technical factors	Any skill-based or decision error, misinterpretation of relevant information.	Technical/skill issue
Training and		Unexpected patient issues

	disruptions; training is included due to unfamiliarity of a particular patient.	Complex procedure
		Training and teaching junior team member
		Surgeon leaves to attend a beeper message
Teamwork	Team cohesion, cooperativeness, and familiarity.	Miscommunication
		Coordination
Communications	Any case-irrelevant communications in the OR.	Patient-irrelevant communication
		Procedure-relevant communication
		Irrelevant comment/query by team member Irrelevant comment/query by external staff
		Medical irrelevant communication
		Unclear communications
		Language issues
Others	Any distraction or interruption not including in the above	Duty shift, external visitors, move monitor

An observational study by Healey et al. (Healey, Sevdalis et al. 2006) focused on the distractions and interruptions on surgeons, anaesthetists, and nurses during routine 50 general surgical procedures (open and laparoscopy, from incision to closure). The results indicated that the surgeon group was more frequently distracting, with a total count of 276, compared to the nurse group (213) and anaesthetist group (116). The total counts of events per case ranged from one to 39, with a mean of 13.56 (SE \pm 1.12). The total count of events per case as a proportion of operative time ranged from 0.04 to 0.86 per min, with an average of 0.29 (SE \pm 0.02). Among other distractions and interruptions, those related to communication, equipment, procedures, and the operative environment occurred most commonly and were most visibly disruptive.

In the same study, Sevdalis et al. (Sevdalis, Healey et al. 2007) focused on case-irrelevant conversations across 48 procedures in general surgery. The researchers reported an average of 3.48 case-irrelevant communications (CICs) per surgical procedure. The researchers found that regarding to the absolute frequency of CIC events, surgeons were the most likely initiators and recipients of CICs event. However, not all CIC events introduced the same level of distraction to the OR team. Regarding to the level of distraction CICs, surgeons introduced significantly fewer disruptions than anaesthesiologists or nurses. (Sevdalis, Healey et al. 2007) The researchers indicated that the most distracting communications were those associated with (1) OR equipment/provisions, (2) case-irrelevant patients, (3) irrelevant comments/queries by team staff and external staff, and (4) teaching

junior team members. Similar findings were obtained in urological surgery by Healey et al. (Healey, Primus et al. 2007), the frequency of events and their attached ratings were high, deriving from varying degrees of equipment, procedure and environment problems, and conversations.

An observational study by Wiegmann et al. (Wiegmann, ElBardissi et al. 2007) examined surgical flow interruptions and their relationship to errors in 31 cardiac procedures during intraoperative phase. The result show that flow disruptions consisted of teamwork/communication failures, equipment and technology problems, extraneous interruptions, training-related distractions, and issues in resource accessibility. They recorded 341 disruptive events. Analysis of the results indicated that teamwork/communication accounted for 52% of these events. Of the remaining surgical flow disruptions, 17% of the surgical flow disruptions occurred because external/extraneous interruptions. Equipment and technical difficulties contributed to another 11% of disruptions. Twelve percent of disruptions were related to supervisory/training-related distractions. Finally, issues of resource accessibility accounted for the remaining 8% of the observed events.

An observational study by Gillespie et al. (Gillespie, Chaboyer et al. 2012) assessed the relationship between interruptions, team familiarity, and miscommunications across the 160 surgical procedures (From application of skin preparation to application of final surgical wound dressing). One hundred and seven (66.9%) of the 160 procedures were characterized by interruptions, with a total of 243 interruptions occurring during these procedures. For all 107 procedures, the mean number of interruptions per procedure was 2.3 ± 1.6 (range, 1-9).

Another observational study by Parker et al. (Parker, Laviana et al. 2010) validated an observational tool for assessing surgical flow disruptions and their impact on surgical performance across 10 cardiovascular procedures (between patient entry into the operating room and wound closure). A total of 328 surgical flow disruptions were observed, with an average of 32.8 flow disruptions per case, or 7.1 flow disruptions per hour.

Zheng, Bin et al. carried out a video-aided observational study to examine disruptive events across 12 laparoscopic antireflux surgeries (From insert to withdraw the laparoscope). They observed a total of 114 disruptive events per hour on average. Intraoperative conversations were record with the highest frequency (71 episodes/h) and longest duration (16 min/h). However, only 1% of the conversations delay surgical workflow less than 1 min. The events that generated most surgical delays were instrument change (3.4 min/h). On average, disruptive events performed in the OR caused 4.1 min of delay for each case per hour, corresponding to 6.5% of the procedure time.

Sami, A. et al. (Sami, Waseem et al. 2012) identified 110 stressors from 32 elective surgical procedures. The analysis of the results showed that technical problems most frequently caused stress (16.4%) and personal issues the least often (6.4%). Although teaching and distractions/interruptions were frequently encountered by the OR team, it caused less stress to the surgeons. Technical factors, teamwork, and equipment problems occurred frequently and were also a major contributor to OR stress.

Persoon, MC. et al. (Persoon, Broos et al. 2011) observed 78 procedures in the OR and interviewed 15 surgeons to investigate the effect of distractions during endourological procedures. An average of 20 distracting events were recorded per procedure with a rate of one distracting event every 1.8 min. According to the results, equipment problems and procedure-related and medically irrelevant communication were the most frequently observed causes of interruptions and identified as the most distracting factors by the interviewees.

The quality of evidence of the observational studies varied from (III) low to (IV) very low. Only two studies presented a (III) low quality of evidence. The other OR observational studies only presented very low quality of evidence. Persoon, M.C. et al. (Persoon, Broos et al. 2011) used a mixed method: this study combined a big sample size observation in the OR and a semi structured interview of the surgeons, which was rated as low quality of evidence. The other study performed by Healey, A. N. (Healey, Olsen et al. 2008) measured both the distraction and team performance, and found a negative association between distraction and team performance, so it presented a low quality although the sample size was small compare to other very low quality of evidence OR observational studies.

7.3.6 Simulated abstractions and interruptions in skills lab experiment study

Ten studies employed surgical simulator to investigate the effect of distractions and interruptions on task performance. The simulated distractions and interruptions used in these studies were summarized in table 7.4.

These studies have a common limitations that all the experiments were conducted under controlled laboratory conditions and did not truly replicated the environment and conditions in OR. However these studies demonstrated the effects of distractions and interruptions on surgical performance.

Table 7.4 Categories of distractions used in a surgical skills laboratory setting.

Type of distraction	The control of the simulated distractions
Disturbance of view filed, Phone call , unrelated conversation, noise, a medical question, a personal question	One distracted condition (combined the following 4 distractions and 2 interruptions): (1) Unexpected movement in front of the trainees' field of view. (2) Phone call answered by the observer.(3) An unrelated side conversation between observer and another person. (4) Noise from a dropped metal tray. (5) A medical question: how to deal with a patient who have breathing difficulties. (6) A personal question: why chose the profession. These distractions and interruptions were all initiated by the observer with the timing of distraction occurring at critical decision points during simulated surgical procedure.(Feuerbacher, Funk et al. 2012)
Arithmetic problems	The difficult of arithmetic problems was kept at medium level to ensure sufficient loading of surgeons' cognitive resources, yet not too difficult to prevent performance.(Goodell, Cao et al. 2006)
Dichotic music (auditory stress) Classical music (auditory relaxation) Mental arithmetic tasks	Three distracted conditions: (1)Dichotic music represented two conflicting genres, with one type of music presented in each ear simultaneously. (2)Mental arithmetic tasks played a role as "mental loading". Subjects have to perform standardized arithmetic exercises as soon as possible while completing the task. (3)Subjects were exposure to classical music for auditory relaxation.(Conrad, Konuk et al. 2012)
Answer question about a medical case	The participant was asked a question about a medical case. The conversation continued until two adequate responses had been obtained.(Persoon, van Putten et al. 2011)
Exposure to music, conversation, and non-optimal handling of the laparoscope	One distracted condition (combined the following two distractions): (1)Social distraction: combination of 2 popular songs mixed in parallel with a 30s of case-irrelevant communication. (2)Technological distraction: the laparoscope was manipulated using a standardized protocol to provide a non-optimal laparoscope navigation.(Pluyter, Buzink et al. 2010)
Arithmetic problems	The subjects were asked to answer mathematical questions continuous in one minute, while performing the laparoscopic task. (Hsu, Man et al. 2008)

Secondary tasks: counting beeps, selective responses, and mental arithmetic	<p>Three distracted conditions with three secondary tasks respectively.</p> <p>Task 1: Counting "beeps"—the subject had to respond by stating the number of beeps they heard.</p> <p>Task 2: Selected response</p> <p>Task 3: Mental calculations (Meneghetti, Pachev et al. 2012)</p>
Secondary tasks: mathematics problems, a decision-making task, a memory task, recorded noise from operating room	<p>Four distracted conditions (The order of distraction tasks was also randomized).</p> <p>(1) The decision-making task: verbally answer questions chosen from the Medical College Admission Test problem bank.</p> <p>(2)The memory task: memorization of 10 skeletal muscles of the body, while performing surgical task.</p> <p>(3)Mathematics problems: kept at moderate level to provide sufficient loading of the subjects' cognitive resources.</p> <p>(4)OR noise: Pre-recorded noise (50–90 dB) from OR included patient monitors, suction machines, drill machines and conversations between surgeons and residents.(Suh, Chien et al. 2010)</p>
OR ambient noise and directed auditory noise, vibratory distraction, and visual distractions.	<p>The following three distractions composed one distraction condition.</p> <p>(1)Noise: recorded ambient noise was kept at a 45-dB level and the directed noise varied between 60 dB and 80 dB (through all the session).</p> <p>(2)Vibratory noise distractions: A computer controlled pager for vibratory noise at various time points(random during the session).</p> <p>(3)Visual distractions: flashing lights on the simulator screen (random during the session).(Szafranski, Kahol et al. 2009)</p>
Noise Music	<p>Two distracted conditions:</p> <p>(1)OR back ground noise at 80 to 85dB.(Looped audiotape).</p> <p>(2)Music: an audio compact disk of classical compositions was played. And the decibel level of the music depended on the surgeon's preference.(Moorthy, Munz et al. 2004)</p>

Several studies investigated the effect of distraction and interruptions on task performance of inexperience surgical trainees.(Szafranski, Kahol et al. 2009; Pluyter, Buzink et al. 2010; Persoon, van Putten et al. 2011; Conrad, Konuk et al. 2012; Feuerbacher, Funk et al. 2012; Gillespie, Chaboyer et al. 2012) Feuerbacher, R. L. et al. (Feuerbacher, Funk et al. 2012) found that the realistic distractions and interruptions have the potential to cause operative errors in surgical trainees. Mental distraction and auditory stress negatively affect specific components of surgical learning and performance, and classical music may positively affect surgical memory consolidation.(Conrad, Konuk et al. 2012) For inexperience surgical trainees, distractions can significantly impede their performance, but this effect can be reduced by introduction of distractions in the training situation.(Goodell, Cao et

al. 2006; Szafranski, Kahol et al. 2009; Pluyter, Buzink et al. 2010; Persoon, van Putten et al. 2011) In addition, another study conducted by Moorthy, K. et al.(Moorthy, Munz et al. 2004) indicated that experienced trainees can effectively “block out” noise and music.

Several studies compared the influence of distractions (secondary task) both on novice and experienced trainees.(Hsu, Man et al. 2008; Suh, Chien et al. 2010; Meneghetti, Pachev et al. 2012) Meneghetti, A. T. et al. (Meneghetti, Pachev et al. 2012) adopted dual-task methodology to assess surgical trainees laparoscopic performance on a virtual reality simulator. Participants were asked to perform a primary task while concurrently having to deal with a secondary task. In this study, error rates for novices and experts increased when the distracting secondary tasks were introduced. However, expert surgeons were able to maintain consistently low error rates no matter what type of distraction was encountered. The novices attended to the surgical task at the expense of some aspects of secondary task performance. Hsu et al. demonstrated similar findings.(Hsu, Man et al. 2008) In a robot assistant suture-tying task, Suh, Irene H. et al.(Suh, Chien et al. 2010) also found that the performance of surgical task was negatively affected by secondary distracting tasks both for novice and experienced trainees. However, experienced trainees demonstrated a larger attention capacity for multitasking.

The quality of evidence varied from (II) moderate to (III) low. Three studies presented moderate quality of evidence.(Pluyter, Buzink et al. 2010; Persoon, van Putten et al. 2011; Feuerbacher, Funk et al. 2012) Persoon M.C. et al. carried out a random control trial to investigate the distraction and novice surgical trainees’ performance, and the result showed distractions decreased surgical performance.(Persoon, van Putten et al. 2011) And the other two studies employed more realistic distractions during the experimental setting.(Pluyter, Buzink et al. 2010; Feuerbacher, Funk et al. 2012) Although the sample size of the study was small, they also investigated the influence of individual cognitive style on the level of individual irritation.(Pluyter, Buzink et al. 2010)

7.3.7 Questionnaire survey of distractions

Hassan, I. et al.(Hassan, Weyers et al. 2006) used SVF78 stress coping questionnaire to assess negative stress (including distractions) coping strategies. The result indicated that ineffective stress-coping strategies correlate with poor virtual laparoscopic performance.

Sevdalis, N. et al.(Sevdalis, Forrest et al. 2008) developed the Disruptions in Surgery Index (DiSI) to assess OR professionals’ self-perceptions of disruptions that affect surgical processes. The result of this cross-sectional study showed that surgeons perceived significantly fewer disruptions than anesthesiologists or nurses.

Although OR professionals acknowledged disruptions and their impact, they attributed to error for their colleagues more frequently than for themselves. These studies have been prominent in informing the development of measures that identify the nature and types of interruptions that occur in surgery.

Makama, J. G. et al.(Makama, Ameh et al. 2010) used 162 questionnaires which involved the OR staff and patients to investigate the role of music in the OR. They found that the music played in the OR has immeasurable effects. It can prevent distraction, minimize annoyance, reduce stress and diminish the anxiety of patients, staff and users. Ullmann, Y. et al.(Ullmann, Fodor et al. 2008) had the similar conclusion that music has a positive effect on the staff working in the OR. Another study (Patterson 2012) used structured questionnaires to investigate the OR staffs' opinion personal mobile device in the OR. They concluded that personal use of mobile devices in the OR sometimes distracts providers and potentially endangers patients, however, benefits in convenience and communication. The quality of evidence of all the questionnaire survey studies was rated as a very low quality level (IV).

7.4 Discussion

The OR is such a complex work environment that all the OR staff need to highly cooperate for the patient safety. This makes the OR to be a multidisciplinary work environment. The OR staff not only have to focus on the primary task, but must also cope with secondary tasks due to distracting events. These distracting events experienced by the surgeons may affect their performance, especially for the inexperienced surgeons, and thus play as a potential contributor to the adverse surgical outcome. This review attempted to identify the type of distractions and interruptions during operation, refine methods for measuring distracting events, and detect the effects of distractions on surgical performance. The results show that the distractions and interruptions are difficult to be detected and hard to be measured objectively. However, this review systematically summarized the effects of distracting OR events on surgical performance according to observational OR studies and experimental studies in a laboratory setting. This should be helpful for future research on realistic distractions and surgical performance, and useful as reference for defining a better training curriculum with special attention to team training.

7.4.1 Identified distractions and interruptions (*Distracted events*)

Our first question is: What are the mainly distractions and interruptions during intraoperative phase in the OR? We identified 12 relevant observational studies, which focused on distracting OR events, and 11 experimental studies that employed simulated distracting OR events and cognitive secondary tasks. The detected

distracting OR events are related to OR environment features (such as pagers, phone call, alarms, noise), communications, technical factors, training and procedures. The distractions related to environment factors occurred most frequently, compare to other distractions.

7.4.2 Methods for measure distractions during intraoperative in the OR

Our second question is: What are methods for measuring distractions and interruptions during intraoperative phase? From the retrieved studies, there are mainly two methods to measure the distractions. The first method is performed independently by two or more observers using a standard structured form (including a predefined distracting event categories list) to identify the frequency and source of the distracting events. And rating the level (or severity) of the distracting events with a predefined ordinal rating scale. The inter-rater reliability among different observers was assessed subsequently. However, the predefined ordinal rating scale is differing among different studies.(Parker, Laviana et al. 2010; Persoon, Broos et al. 2011). For example, Healey, A. N. et al.(Healey, Sevdalis et al. 2006) defined the rating scale based upon the relative involvement of the team, whereas Parker, S. H. et al. (Parker, Laviana et al. 2010) define the rating according to the severity of the event such as duration of task cessation.

The second method is that the OR staff using a standard questionnaire to self-report the distracting events that they experienced during the intraoperative phase. In addition, the OR staff need to rate the level of each specific disruption type using a predefined ordinal rating scale.(Sevdalis, Forrest et al. 2008) This subjective rating of events in the OR by those directly involved could be related to observational measures.

Both of these two methods are commonly used for measuring distraction, especially the first method. Neither of these two methods are objective measurement, both of them have limitation. For the first method, the measure was biased because different definition of ordinal scale and different opinion of the observer. However, for the second method, the measurement of distractions is not during the time when the distraction occurred since they need to focus on the operation. Normally the OR staffs were asked to complete the questionnaire at a time and place convenient to them, which demanding to recall the events (Sevdalis, Forrest et al. 2008).

It might be a more reliable way to measure the intraoperative distractions that employ the OR staff themselves to use a predefined ordinal rating scale to rate the distractions based on video recorded cases which they performed.

7.4.3 Effect of distractions and interruptions on surgical performance

Back to the third research question: What are the effects of distractions and interruptions on surgical performance? Actually, few observational studies assessed both distractions and interruptions concurrently. It is not easy to determine the effects of distracting events on surgical performance. Only 5 observational studies identified the relation between distracting events and surgical performance.(Wiegmann, ElBardissi et al. 2007; Healey, Olsen et al. 2008; Parker, Laviana et al. 2010; Persoon, Broos et al. 2011; Gillespie, Chaboyer et al. 2012) The following conclusion can be extracted: (1) The increasing number of intraoperative interruptions will definitely result in the increasing of miscommunications, while the familiarity of the surgical team will reduce the miscommunication. (2) Equipment problems (or technology and instrument) and communication failures (or teamwork factors), and procedure factors during intraoperative phase have the largest impact on the surgical team, increase surgical errors, and regularly interrupt procedures. (3) Case irrelevant conversations generally result in distractions, but not interrupt the surgical flow.

Actually, establishment of the link between distracting events and surgical performance in the OR is difficult, 11 experimental studies employed “controlled experiments” with surgical simulator to gain further understanding of the effects of specific distraction and interruption on surgical performance. The following main conclusion can be extracted:

(1) Cognitive distractions (including mental load and auditory stress) negatively affect novice medical trainees’ task performance (Goodell, Cao et al. 2006; Szafranski, Kahol et al. 2009; Pluyter, Buzink et al. 2010; Persoon, van Putten et al. 2011; Conrad, Konuk et al. 2012; Feuerbacher, Funk et al. 2012). And individual differences in cognitive style appear to influence perceived irritation during performance (Pluyter, Buzink et al. 2010). (2) Surgeons can “block out” noise and music due to the high levels of concentration required for complex surgical task. (Moorthy, Munz et al. 2004) (3) Expert surgeons are capable of maintaining performance levels on a primary task in the face of distractions that may occur in the operating room (Hsu, Man et al. 2008; Suh, Chien et al. 2010; Meneghetti, Pachev et al. 2012).

However, simulated distractions in the skills lab cannot represent the OR environment, simulated task on a surgical simulator cannot represent the surgical procedure. This is the main limitation of the experimental studies.

Not all potentially distracting stimuli seem to have a negative effect on surgical procedures. Makama,J.G. et al.(Makama, Ameh et al. 2010) and Ullmann, Y. et al.(Ullmann, Fodor et al. 2008) evaluated the influence of the music in the OR by questionnaire, they concluded that music can prevent distraction, minimize annoyance and made them more efficient. If used appropriately, classical music

may positively affect surgical memory consolidation, listening to relaxing music leads to improved learning of surgical procedure (Conrad, Konuk et al. 2012).

7.4.4 Implications for surgical training

The effects of Interruptions have been measured in the multidisciplinary work environments using observation tool and self-report methods.(Healey, Primus et al. 2007; Sevдалис, Forrest et al. 2008) Such as in the aviation where certain tasks and activities distract a person from a primary task or interrupt their task momentarily.(Chisholm, Collison et al. 2000) Based on the investigation of the interruptions during these complex work environments, different types of crew resource management (CRM) training system were developed to train multiple task coping skills.(O'Connor, Hörmann et al. 2002; Flin, Martin et al. 2003) The safety of the surgery in the OR can be increased by paying attention to stress and distraction coping skills. So it is important to investigate the distractions and interruptions during the complex OR environment. This knowledge and insights should be implemented in an effective surgical training curriculum.

Experienced surgeons gradually develop the coping strategies to eliminate the influence of distraction through working on the OR.

For some tasks, experienced surgeons can achieve automaticity, which allowed them have more capacity for multiple stimuli during a complex procedure.(Hsu, Man et al. 2008) For training the novice trainees to have more capacity for multiple stimuli such as noises, case irrelevant communications, several training program were developed. For example, using secondary cognitive tasks to disturb their primary task, thus to training their mental capacity. (Kahol, Vankipuram et al. 2009; Persoon, van Putten et al. 2011). While the dual-task training method was proved effectively by these studies.(Kahol, Vankipuram et al. 2009)

However, only dual-task training sole cannot improve the training effectively in a highly cooperative OR environment. According to research, the number of intraoperative interruptions was positive related to the number of miscommunication. While the number of miscommunication was negative related to team familiarity.(Gillespie, Chaboyer et al. 2012) One of the ways for improving team familiarity is to implement team training, especially in a more realistic training environment. While team training in the real OR is effective, but may not practical due to bring the patient safety in danger. Many new training concepts were shown up, such as surgical crisis based training, (Powers, Rehrig et al. 2008) immersive training(Nistor, Allen et al. 2007), and distributed simulation training.(Kneebone, Arora et al. 2010) These concepts have in common that training the surgical team in fully simulated OR with fully simulated surgical procedures, which could make the

surgical training more comprehensively (Moorthy, Munz et al. 2006; Kassab, Tun et al. 2011), and seems to be the main future trend in surgical training.

In addition, according to researches about individual cognitive style, (Pluyter, Buzink et al. 2010; Meneghetti, Pachev et al. 2012) the individual difference in the cognitive style can present different extent of irritation level to the same distraction source. The individual difference should be taken into consideration to provide an optimal training environment.

Nevertheless, it seems that the music in the OR have positive effect on “block” some distractions, so if using probably, music also could be used during training session to improve training efficiency. (Moorthy, Munz et al. 2004; Conrad, Konuk et al. 2012)

7.4.5 Limitations of this study

Several limitations of this study have to be considered. This study was restricted to peer-reviewed articles, not including books and the search was also restricted to a number of key words, and this might exclude some relevant publications. In addition, the quality level of evidence of the retrieved studies varied from moderate to very low, studies with high quality level of evidence is still lacking.

7.5 Conclusion

In spite of limitation this review allows the conclusion that surgeons are facing multiple distractions and interactions during surgery. Most of these can cause stress to the surgeon and may disrupt the surgical flow potentially resulting in adverse events. More attention should be paid to perusing/ studying the role of both disruptions and interruptions in the OR and developing preventive measures to safeguard quality of performance. The outcome of the review implicates the need for improvement of methodology of techniques for measuring and quantifying disrupting events in the OR. Thorough analysis of interruptions and the way surgeons cope with them, could potentially contribute to the positive outcome of procedures. Analysis of experimental studies focusing on the effects of disruptions and interrupting events both in the OR and skills lab setting provide evidence for the need to develop an effective, comprehensive training program in an environment familiar or similar to the OR. This should allow trainees to cope better with distracting conditions and interruptions and improve their performance in the OR.

CHAPTER 8 GENERAL CONCLUSIONS AND DISCUSSION

This chapter recapitulates all research findings and discusses these in a wider range. Factors which are relevant for surgical training efficiency are discussed. The recommendations for the setting up of the skills lab and future research are described.

The overall aim of this thesis is to define optimal ergonomic settings and conditions – an optimal environment for effective training in minimal invasive surgery (MIS). This environment should allow training resembling the reality of laparoscopic surgery in a real OR. In order to achieve this objective, different studies were designed and the results are presented in this thesis.

This thesis is divided into three parts referred to as Part A, Part B and Part C. Part A focuses on the review of ergonomic factors during laparoscopic surgery and training. Part B describes a portable Ergo-Lap simulator and the validation of this simulator with laparoscopic specialist and surgical trainees. Last but not least, Part C focuses on the distractions and interferences during the intraoperative procedure. This part set out a systematic review of literature on the distractions and interferences during surgery.

8.1 Conclusions summarized

The first step in this research was to make an overview of the ergonomic problems encountered by laparoscopic surgeons. In Part A an experimental setting was applied to investigate the influence of ergonomic factors on the laparoscopic tasks in the skills lab (Chapter 2). The result of the experiment indicated that training under improved ergonomic settings not only reduce the physical discomfort for the surgical trainees, but also improve the task performance.

During the laparoscopic training courses in the skills lab, it was observed that the surgical trainees encountered physical discomfort as a result of working in a non-ergonomic setting (Chapter 3). These ergonomic deficiencies prevented the trainees from keeping a comfortable posture during the laparoscopic training. In order to improve their posture and solve ergonomic problems related to the physical work setting, a new surgical training table was developed (Chapter 3).

During the observation in the skills lab, it was found that the time available for the training was limited for the surgical trainees. In addition, we discovered that the trainees did not pay attention to the manipulation angle, elevation angle, and azimuth angle during the training. According to our experimental study (Chapter 2) and recommendations derived from literature, these angles influence the task performance.

To improve the training setting, a portable ergonomic laparoscopic simulator was designed for surgical trainees to practice basic laparoscopic skills at home or in the office. This portable Ergo-Lap simulator, which includes thirteen laparoscopic tasks, was designed according to ergonomic guidelines derived from the literature (Chapter 4). The face, content and construct validity of this Ergo-Lap simulator was assessed by both novice and experienced surgeons. The simulator was evaluated as

an inexpensive alternative for the surgical trainees to update their skills at home or in the office (Chapter 5).

In recent years, efforts have been made to reduce the trauma of surgical access further by introducing the single-incision laparoscopic surgery (SILS). This new approach has the potential to improve postoperative recovery further and to allow potentially “scar-less” surgery (Chow, Purkayastha et al. 2010) (Santos, Enter et al. 2011). SILS is being increasingly performed on patients (Canes, Desai et al. 2008; Tang, Hou et al. 2012). But a proper simulator for the SILS training is still lacking. As a solution for this problem, the Ergo-Lap simulator was developed in such a way that it allows the trainees to train their SILS skills. The face validity of the Ergo-Lap simulator for SILS training was evaluated by thirteen SILS surgical trainees. They evaluated this simulator as a potential tool to practice SILS skills (Chapter 6).

To meet the reality of an OR in a skills lab setting, immersive surgical training becomes more important. In order to define an immersive training environment for laparoscopic training, a literature review was carried out to assess the distractions during the laparoscopic procedure both in real and simulated OR environment (Chapter 7). The result of the review shows the need for improvement of methodology of techniques for measuring and quantifying disrupting events in the OR. Analysis of experimental studies focusing on the effects of disruptions and interrupting events both in the OR and skills lab setting provide evidence for the need to develop an effective, comprehensive training program in an environment familiar or similar to the OR.

8.2 General remarks

Patient safety and quality performance are of paramount importance in healthcare, and therefore the main goal for healthcare professionals. Developments in technology have been playing an important role in improving patient safety. For instance, the MIS technology was developed to reduce operation trauma and to assure quick recovery. This MIS turned the OR into a highly complex and high-tech environment, and increased the physical discomfort and cognitive overload of the surgical team (Det, Meijerink et al. 2009). In order to support the surgical team and to reduce the physical discomfort and cognitive overload, different technologies were developed, such as the use of robotics. At the same time, the set-up of the OR improved. Examples are the height adjustable surgical tables and high-resolution movable monitors. Last but not least, different training curriculum was developed to assist the surgical team to acquire surgical skills out of the OR. However, the surgical training is still not as systematic as other high-risk industry trainings, and the set-up in the skills lab suffers from ergonomic deficiencies. In consequence, the general objective of this thesis is developing an optimal surgical

training and set-up environment for the surgical trainees to improve their skills in an ergonomic and efficient way.

8.2.1 Ergonomics design in the skills lab for laparoscopic procedure training

Specific elements such as monitor position, surgical table height already affect the cognitive and physical demands of the OR environment, but there is ample room for improvement through ergonomic research and application (Sutton and Park 2012). In order to improve surgical trainees' awareness of ergonomic guidelines, and thus to decrease the physical discomfort and to improve training efficiency, the following aspects should be considered during the design of a skills lab.

Table height (or operative surface height of surgical simulator)

The height of surgical training table should be adjustable according to the surgeon's height, when the surgeon is performing a laparoscopic task at the table. A height range allowing an elbow flexion between 90° and 120° should be achieved. The operative surface height of the surgical simulator should also meet the same requirements.

Monitors

From an ergonomic point of view the optimal viewing angle of monitor during laparoscopy is within 15° degrees below the horizontal plane of the eye (gaze-down). This prevents strain and discomfort in the neck. Monitors should be adjustable in height and inclination, to achieve an optimal position. The viewing distance is variable based on the visual acuity of the surgeon, and it should be established to avoid the eye-strain.

Cables and tubes

Usually, surgical training takes place in a skills lab demanding different kind of devices and accessories. The large amount of tubes and wiring etc. present at the skills lab should be organized in such a way to avoid the obstruction of the workflow. A future skills lab should have an optimal cable management system.

Easy to supervisor and objective assessment

It is a well-known phenomenon that an individual performs a skill better when he/she has the knowledge that he/she is observed and assessed. This constitutes the "Hawthorne effect" which scholars have found being present in many scientific assessments of human factors. It is therefore also possible that this effect, of

known-to-be-observed, is present in training situations for ergonomic purposes (Holden 2001).

Laparoscopy is technically challenging and requires a high level of knowledge, dexterity, skills and co-ordination. In the meantime ergonomic skills should not be forgotten. These latter should also be assessed. Such assessment needs to be done unnoticed in order to avoid the bias introduced by the Hawthorne effect. If there is an effective supervise system, which can record trainee's behavior and their task performance without being noticed by the trainees, the trainee's performance can properly be assessed without the "Hawthorne effect" being present.

8.2.2 Cognitive demand training for laparoscopic procedure

The literature review in Chapter 7 revealed that, especially since the widespread use of the MIS, the OR has been turned into a more complex environment. There also a need for a demanding collaboration between the surgical team members and other related personnel. This highly complex work environment brings a challenge to optimize the surgical workflow and the performance of the surgical team (Moorthy, Munz et al. 2004). Under such circumstances, the surgeon does not only have to perform surgical tasks, but also have to manage multiple interferences at the same time (Chisholm, Collison et al. 2000; Pape 2011). These multiple interferences introduce, to a certain extent, a cognitive overload or at least a distraction to the surgeons, especially to inexperienced surgeons. Surgeons are highly capable and effective task performers, both in terms of mental capacity and hand-eye coordination abilities. Since there is a gap between the surgical training setting in the skills lab and the real OR, the technical skills acquired in the skills lab are not adequate for performing a surgical procedure safely. A comprehensive and efficient training environment and program is highly demanded.

Several experimental studies implemented the secondary cognitive tasks (arithmetic problems, answer questions) or simulated distractions (e.g. OR noise, case-irrelevant communication, dichotic music) into the training, to distract the surgical trainees from the primary simulated surgical tasks. The results showed that these secondary cognitive tasks simulated and these distractions influence the novice surgeons' task performance. They increase the time needed to complete the task at hand and increase the number of errors (Goodell, Cao et al. 2006; Szafranski, Kahol et al. 2009; Persoon, van Putten et al. 2011). Experienced surgeons are less affected. They have achieved "automation" in the performance of laparoscopic task and therefore are less affected by cognitive distractions (Hsu, Man et al. 2008). However, surgeons remain to some extent influenced by distractions and interruptions. In the surgical domain, increased awareness about the adverse impacts of distractions and interruptions, combined with effective training, should mitigate the adverse impacts and improve patient safety in the OR.

To improve the strategy of coping with cognitive distractions of the surgical trainee, an effective training program should be developed. Therefore, involving a secondary cognitive task and simulated distractions in the surgical training is a logical way forward. The simulated distractions should be as realistic as possible.

8.3 Research Methodology and limitations in the PhD research

This thesis focuses on setting up an ergonomic laparoscopic surgical training. Different studies with various research methods have been performed. The experiments discussed in chapter 2 are based on a comparison of task performance and arm joints angles under the optimal and non-optimal training set-up. The task performance was assessed by the parameters of time and task error. A screen MB ruler software was used to measure the joint arm angles during the task performing. Although the use of a screen MB ruler to measure the arm joint angles gives a good indication, more information could have been gathered by also using a different measuring tool, such as EMG. That would give additional data on muscle strain during the task performance.

Before a simulator can be integrated into an educational program, it is recommended that its validity should be determined (McDougall 2007). The value of a surgical simulator should be sequentially evaluated following a pyramidal structure with associated complexity and effort of assessment.

The validation of the Ergo-Lap simulator is based on the face, content and constructs validity (Chapter 4, 5 & 6). Although the results showed that the Ergo-Lap simulator can distinguish expertise level of the surgical trainees, these are not compared with other existing box trainers. The concurrent and predictive validity have not been assessed.

Finally, a systematic literature review was carried out to investigate the effects of distractions and interruptions on surgical task performance. The results have been discussed in chapter 7. These results give a good overview and might be a useful reference for further research. However insights could not be supported by data from observations in the OR.

8.4 Recommendations for the future research

Findings from this PhD study generated several recommendations for future research which will be presented in this section.

8.4.1 Implications for surgical training

There is no doubt that new technological developments regarding surgical procedures require a comprehensive surgical training. This comprehensive surgical

training includes several important elements. One of those elements is increasing awareness of the ergonomic setup of the training and establishing the impact of the task performance and physical discomfort. Different studies performed in this thesis show the positive effects of ergonomic training setup improvement. We therefore recommend making the ergonomic awareness and the way of thinking and acting on this matter part of the surgical training curriculum.

Another important element of a comprehensive surgical training is the interface between the reality and the training. Factors like cognitive skills, coping with stress, team cooperation, multi-tasking, dealing with distractions and interruptions during a real surgical procedure should be implemented in the curriculum. The same applies to team training and crisis resource training offered to the whole team. By introducing this to the curriculum, the trainees will be able, in an early stage of their training, to bring the experience gathered in training in an almost real OR setting, to the real OR and benefit thereof.

Recently, nontechnical skills are significantly emphasized as part of modern surgical training (Yule, Flin et al. 2006). Such training in a fully simulated OR with an OR team has been tested successfully (Moorthy, Munz et al. 2006; Undre, Koutantji et al. 2007). According to literature, this is an important new direction for future surgical training. This simulated OR targets a higher level of skills, enabling the surgical trainees not only to perform a surgical task but also to interact in a multidisciplinary healthcare team in a realistic environment. The simulated OR is necessary to investigate the work environment and work distribution in surgical teams more thoroughly. Addressing the issues concerning team performance in surgery is not an easy task for the surgical team in the OR. To describe and measure the patterns of distractions that surgical teams experience is a useful step forward in addressing those concerns. Further development and validation of tools and methods for quantifying the distractions and interruptions in the OR are needed.

8.4.2 Objective assessment of task performance in surgical training

Objective assessment of technical skills and nontechnical skills in the simulated comprehensive surgical training

Objective assessment of the surgical performance plays an important role in surgical training and, in fact, should be fully incorporated in any didactic training course. Besides being useful from a technical point of view, training also motivates the surgical trainees. However, assessing surgical competence objectively is far from easy. Assessment tools have been developed recently, both for technical skills and for nontechnical skills. The validated Objective Structured Assessment of Technical Skills scale (OSATS) (Martin, Regehr et al. 1997) is widely used for

assessing surgeon's technical skills both in OR and simulated surgical task in the skills lab.

For the nontechnical skills assessment, several behavioral marker systems were developed, including Observational Teamwork Assessment for Surgery tool (OTAS) and (Healey, Undre et al. 2004) Communication and Teamwork Skills Assessment (CATs). (Frankel, Gardner et al. 2007) In general, these behavior markers appear to be developed solely on the basis of the surgeons' opinions with a relative lack of supporting empirical research, and most are at an early stage of evolution. (Yule, Flin et al. 2006) Further research is needed to validate and quantify these behavior markers. Objective assessment of surgical performance (both technical and nontechnical) is important for carrying out comprehension crew or crisis resource management training in surgical training.

Objective assessment of technical skill on the surgical simulator

Ethical concerns on patient safety have led to a tendency to bring the training and assessment processes out of the OR as much as possible. Surgical simulators play an important role in acquiring surgical skills for the surgeons without harming the patient. Box trainers have also become popular training tools, offering simple but elementary tasks to develop basic and advanced surgical skills. VR simulators allow controlled training and objective skills' assessment on exercises ranging from simple tasks to complex laparoscopic procedures.

Measurement of performance and delivering feedback are although basic, key aspects of designing a simulator. Time, total path length and economy of movements are considered in general as valid metrics. Quality metrics such as end-product analysis and error count, although much more variable in their definition, are also considered basic for a correct determination of surgical level. Overall, the clinical significance of these metrics has yet to be further determined, and thus thorough validation is required before being adapted to training curricula. Their validation and study are essential research aspects in the development of new objective assessment programs.

VR simulators have some advantages that can add value to the training and assessment of surgical skills. For instance, they are useful for monitoring a surgeon's learning curve, and offer a wide range of metrics which can be applied for objective assessment, both efficiency and quality driven. However, there are also some disadvantages, such as difficult to match with the trainee's demanding schedule, costly and lack of realism and interaction. These might be the reasons of slow implementation of VR simulators. Compared to the VR simulators, portable webcam based box simulators offer more flexible opportunities for surgical trainees to practice basic psychometric skills at home or in the office. The Ergo-Lap

simulator which was developed during this PhD study is a proper alternative for surgical trainees (Chapter 5, 6 & 7). However, this Ergo-Lap simulator cannot provide immediate feedback of the task performance to the trainee. In addition, the task completion time and number of errors have to be scored separately, which limits feedback for the task performance. The assessment system should thus be improved. Improvement could be achieved by recording a standard task video for every task. This video cannot only be used for documentation purposes, but could also be reviewed by an expert for formative and summative feedback.

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SUMMARY

With the introduction of minimally invasive surgery (MIS), the patient experiences the benefits of less pain, a more rapid recovery and a shorter stay in hospital. However, MIS provides many challenges to surgeons and they need extensive training to acquire this new technique. This training consists of developing cognitive, clinical, and technical skills. However, acquiring full training “on the job” is not always possible because of patient safety and restrictions of residents’ working hours. This situation led to the development of surgical skills centers or laboratories. These skills laboratories can offer a protected, mistake-free training environment and validated surgical training curriculum that allows surgical trainees to practice in a safe and controlled preclinical environment before operating on actual patients. In addition, following the example of the aviation and military industries, surgical simulation is now being widely used to train surgical trainees from basic tasks to cognitively demanding tasks.

The overall aim of this thesis is to define the optimal ergonomic settings and conditions needed to provide an optimal environment for effective training in MIS. This environment should allow training resembling actual laparoscopic surgery in a real OR. In order to achieve this, the study included an elaborate literature review, experimental investigation and design cases. This thesis is divided into three parts referred to as Parts A, B and C. Part A (Chapters 2 and 3) focuses on the review of ergonomic factors during laparoscopic surgery and training; Part B (Chapters 4, 5 and 6) describe a portable Ergo-Lap simulator and the validation of this simulator with laparoscopic specialist and surgical trainees. And finally, Part C (Chapter 7) focuses on distractions and interferences during the intro-operative procedure.

Part A deals with ergonomic factors during laparoscopic surgery and training. Chapter 2 investigates ergonomic factors that can influence the task performance,

and evaluates the effect of these ergonomic factors on task performance and trainees' posture during laparoscopic surgery training. Posture analysis showed that subjects can keep a much more neutral posture under optimal conditions than under non-optimal conditions. The subjects experienced less joint excursion and less discomfort in their necks, shoulders, and arms under optimal conditions. Significant differences of task performance showed that the group trained under the optimal ergonomic setting performed significantly better than that the group trained under a non-optimal setting. It can be concluded that surgeons' learning skills are affected by the ergonomics of simulation setting.

Chapter 3 investigates ergonomic factors that can influence surgical training efficiency in several aspects by adopting the ergonomic guidelines for the OR and MIS procedures, performing observations in the OR and in the skills lab as well as interviewing expert surgeons on their opinion of the optimal ergonomic setting in general of skills lab. This chapter also discusses a case study of designing a surgical training table. The aim of this case study is to design an optimal table to meet multiple training requirements, particularly for laparoscopy surgical training.

Part B focuses on design and validation of a portable ergonomic laparoscopic simulator (Ergo-Lap simulator).

Chapter 4 describes the scientifically-based development of an inexpensive and portable multi-task Ergonomic Laparoscopic Skills (Ergo-Lap) simulator. The design of this Ergo-Lap simulator and related training task panel was based on scientific research regarding the representative skills and the ergonomic guidelines for laparoscopic surgery. A user-centred design approach was followed.

Chapter 5 is intended to verify the face and content validity of the new portable Ergonomic Laparoscopic Skills simulator (Ergo-Lap simulator) and to assess the construct validity of the Ergo-Lap simulator in four basic skills tasks. This Ergo-Lap simulator with multiple tasks was rated as a useful training tool that can distinguish between various levels of laparoscopic expertise.

Chapter 6 evaluates the face validity of the Ergo-Lap simulator for training basic single-incision laparoscopic surgical skills (SILS). The Ergo-Lap simulator was taken to the 20th International Congress of the EAES 2012 in Brussels. During the congress, the simulator was assessed by 13 general surgeons with different levels of SILS experience using a standardized questionnaire to determine the usability of the Ergo-Lap simulator training for basic SILS skills. For SILS skills training, this inexpensive and portable Ergo-Lap simulator offers a feasible training opportunity to help trainees to practice their SILS skills.

Part C focuses on distractions during the intra-operative procedure.

Chapter 7 contains a systematic literature search conducted to review the literature on distractions and interruptions during intra-operative phase of different surgical procedures in both the real OR and skills lab setting. In total, 27 articles were included in this review. Twelve observational studies were carried out during the OR to observe interruptions and distractions during the procedure. In addition, 11 experimental studies used a surgical simulator with simulated distractions and interruptions to investigate the effect of distracting events on the task performance. In four qualitative studies the surgical team was interviewed to investigate the influence of intra-operative distractions on their performance. Surgeons face multiple distractions and interactions during surgery, most of which can cause stress to the surgeon and may disrupt the surgical flow, potentially resulting in adverse events. Thorough analysis of interruptions and the way surgeons cope with them could potentially contribute to the positive outcome of procedures. Analysis of experimental studies focusing on the effects of disruptions and interrupting events both in the OR and skills lab setting provide evidence for the need to develop an effective, comprehensive training program in an environment similar to the OR.

Finally, Chapter 8 recapitulates all the research findings and discusses these in a wider range. Factors which are relevant for surgical training efficiency are discussed. The recommendations for the setting up of the skills lab and future research are described.

SAMENVATTING

Door de introductie van minimaal invasieve chirurgie (MIS) zijn de voordelen voor de patiënt, dat hij of zij minder pijn lijdt, dat er sneller herstel is na de operatie en dat men daardoor korter in het ziekenhuis verblijft. Voor de chirurg betekent deze operatietechniek echter dat er een groot aantal nieuwe vaardigheden nodig zijn en dat er een omvangrijk trainingsprogramma moet worden doorlopen alvorens men deze techniek eigen is. De training van een chirurg bestaat uit het ontwikkelen van cognitieve, klinische en technische vaardigheden. Het volledig in de praktijk trainen van deze vaardigheden is niet altijd mogelijk vanwege obstructie van de patiëntveiligheid en blijkt in praktijk moeilijk in te plannen in verband met werktijden. Mede hierdoor zijn er opleidingscentra opgericht waar deze vaardigheden getraind kunnen worden. De opleidingscentra bieden een mogelijkheid om de vaardigheden in een gecontroleerde en veilige omgeving aan te leren, voorafgaand aan het toepassen daarvan op een patiënt in de operatiekamer. Daarnaast worden er in de opleidingscentra computer gesimuleerde situaties aangeboden, vergelijkbaar met de mogelijkheden in het leger en de luchtvaart, om naast de basisvaardigheden ook cognitief gecompliceerdere taken te trainen.

De algemene doelstelling van dit proefschrift is om optimale ergonomische trainingsomstandigheden te definiëren en vervolgens te introduceren in trainingscentra waar minimaal invasieve procedures kunnen worden getraind. Daarbij moeten de omstandigheden zoveel gelijk zijn aan de omstandigheden in de operatiekamer tijdens laparoscopische operaties (dat is één klasse van de minimaal invasieve operaties, namelijk in de buikholte). Met dit doel voor ogen is er een literatuurstudie gedaan, zijn er verschillende experimenten uitgevoerd en werden er nieuwe producten ontworpen. Dit proefschrift is opgedeeld in drie delen, A, B en C. In deel A, dat bestaat uit hoofdstuk 2 en hoofdstuk 3, wordt er een overzicht gemaakt van de ergonomische factoren die een rol spelen bij laparoscopische

chirurgie en training. In deel B, dat bestaat uit hoofdstuk 4, 5 en 6, wordt de, door de auteur ontworpen, compacte Ergo-Lap simulator geïntroduceerd alsook de validatie daarvan met specialisten en chirurgen in opleiding. Tenslotte wordt in deel C, hoofdstuk 7, stilgestaan bij factoren die zorgen voor afleiding en verstoring tijdens de operatie.

In deel A wordt er een overzicht gemaakt van de ergonomische factoren die een rol spelen bij laparoscopische chirurgie en training. In hoofdstuk 2 worden de factoren onderzocht die het uitvoeren van de taken kunnen beïnvloeden en wordt het effect op de houding en taakuitvoer van een aantal van deze factoren in een experimentele setting bestudeerd. Houdingsanalyse laat zien dat de proefpersonen onder optimale ergonomische omstandigheden beter in staat zijn om een goede houding aan te nemen dan onder niet optimale ergonomische omstandigheden. Tijdens de optimale ergonomische omstandigheden hadden de proefpersonen minder extreme gewrichtsuitlagen en ervoeren minder discomfort in hun nek, schouders en armen. De groep die onder optimale ergonomische omstandigheden had getraind liet een significant betere taakuitvoering zien dan de groep die onder niet optimale omstandigheden had getraind. Er werd geconcludeerd dat het aanleren van chirurgische vaardigheden wordt beïnvloed door het al of niet toepassen van ergonomische richtlijnen tijdens de trainingsomstandigheden.

In hoofdstuk 3 wordt het toepassen van ergonomische richtlijnen in de operatiekamer en in de trainingscentra bestudeerd door observaties en interviews met ervaren chirurgen. De ervaren chirurgen werd gevraagd in hoeverre zij dachten dat richtlijnen met betrekking tot optimale ergonomische omstandigheden in de trainingscentra werden toegepast. In een case studie wordt het ontwerp van een speciaal ontwikkelde tafel besproken, die, tijdens het trainen, volledig volgens de ergonomische richtlijnen kunnen worden ingesteld.

In deel B wordt het ontwerp en de validering van een draagbare ergonomische simulator besproken, de Ergo-Lap simulator.

In hoofdstuk 4 wordt het ontwerp en de onderbouwing van een goedkope, draagbare en ergonomische simulator beschreven (de Ergo-Lap simulator), ten behoeve van het trainen van laparoscopische vaardigheden. Het ontwerp van de simulator is gebaseerd op publicaties in de wetenschappelijke literatuur met betrekking tot ergonomische richtlijnen en optimale taken voor training. Daarna is er een user-centered ontwerpmethodiek gevolgd om de simulator daadwerkelijk te kunnen bouwen.

De validiteit van een simulator kan op verschillende niveaus worden bestudeerd. In hoofdstuk 5 wordt de 'face validity' en 'content validity' van de Ergo-Lap simulator geëvalueerd, en wordt de 'construct validity' bij vier basistaken onderzocht. De

Ergo-Lap simulator werd beoordeeld als een nuttige aanvulling op de training, waarmee het mogelijk is onderscheid te maken tussen verschillende expert niveaus.

In hoofdstuk 6 wordt de 'face validity' van de Ergo-Lap simulator bestudeerd ten behoeve van training van vaardigheden ten behoeve van laparoscopische ingrepen middels slechts één incisie SILS (single incision laparoscopic surgery). Op het 20^e Internationale Congres van de EAES (European Association for Endoscopic Surgery) in Brussels werd de Ergo-Lap simulator geëvalueerd door 13 algemene chirurgen met verschillende mate van expertise bij het verrichten van SILS. De simulator werd beoordeeld als geschikt voor het trainen van basis vaardigheden die nodig zijn voor het uitvoeren van SILS procedures.

In deel C wordt stilgestaan bij factoren die zorgen voor afleiding en verstoring tijdens de operatie.

In hoofdstuk 7 is een systematisch literatuuronderzoek gedaan naar studies die de invloed bestuderen van afleidingen en verstoringen tijdens de operatie, bij verschillende chirurgische procedures zowel in de operatiekamer als in een trainingssetting. Er werden 27 artikelen geïnccludeerd. Twaalf daarvan waren observatiestudies die plaatsvonden in de operatiekamer, bij 11 observatiestudies werd een simulator gebruikt, en in de resterende 4 studies werden operatieteams geïnterviewd buiten de operatiekamer. Het werd duidelijk dat er meerdere afleidingen en verstoringen zijn van het operatieproces. De meeste daarvan zorgen voor verhoogde stress en kunnen het werkproces zodanig verstoren dat dit leidt tot fouten. Een analyse van het gedrag dat door afleidingen en verstoringen wordt veroorzaakt en een inbedding daarvan in de trainingssetting zou mogelijk kunnen leiden tot het nog verder verbeteren van de trainingscontext. Het uitgangspunt dat daarbij moet worden gehanteerd is dat – net als bij het toepassen van ergonomische vuistregels – de trainingssituatie zoveel mogelijk lijkt op de daadwerkelijke situatie in de operatiekamer.

Tenslotte worden in hoofdstuk 8 de bevindingen in een ruimere context geplaatst, en worden de factoren besproken die relevant zijn voor het trainen van chirurgen. Het hoofdstuk wordt afgesloten met aanbevelingen voor een toekomstig trainingscentrum en mogelijk toekomstig onderzoek.

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LIST OF PUBLICATIONS

Journal

1. **Xiao DJ**, Albayrak A, Jakimowicz JJ, Goossens RHM (2013). Intra-operative Interference in Operation Room: A systematic review of the literature. Surgical endoscopy. Submitted to Surgical Endoscopy.
2. **Xiao DJ**, Buzink SN, Albayrak A, Jakimowicz JJ, Goossens RHM (2013). Face Validation of a Portable Ergonomic Laparoscopy Skills Simulator for Single-incision Laparoscopic Surgery Training. Surgical Technology International. Accepted for publication.
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2. Xiao.D.J, Albayrak.A, Goossens. R.H.M, Jakimowicz. Jack. A Newly Designed Portable Laparoscopic Trainer Based on Ergonomic Guidelines. Oral Presentation. 20th International Congress of the European Association for Endoscopic Surgery. 20-23 June 2012, Brussels, Belgium.
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4. Xiao.D.J, Albayrak.A, Goossens. R.H.M, Jakimowicz. Jack. Validation Test of the Surgical Simulation Device----Case Study. Third International Conference on Interaction Design. 4-6th December 2013, Xi'an China.