Virtual reality training and equipment handling in laparoscopic surgery

Emiel Gesina Gerardus Verdaasdonk

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Voor mijn moeder en vader

TABLE OF CONTENTS

Chapter 1

Introduction

INTRODUCTION

Laparoscopic surgery

Laparoscopic surgery (keyhole surgery, minimally invasive surgery or endoscopic surgery) is one of the biggest innovations in surgery of the 20th century. In laparoscopic surgery the surgeon performs the procedure through small incisions in the abdominal wall while watching a video monitor. Laparoscopic surgery has important benefits for patients compared to conventional surgery such as reduced pain, reduced hospital stay and quicker return to normal physical activities [1-4]. However, the skills needed for this technique differ fundamentally from open or conventional surgery. In particular the psychomotor skills to control and operate the instruments differ from the conventional knife, dissectors and scissors. It takes relatively more time to master these skills to compensate for the disturbed hand-eye coordination [5-8], the loss of direct contact with the operation field [9, 10], the problems with reduced depth perception [11], the use of a 2-D image of a 3-D environment on a monitor [12,13], working with long instruments and the reduced force feedback from the tissue. In addition, the introduction of sophisticated technical equipment in laparoscopic surgery has made the surgical environment more complex. New problems are encountered in the domain of man-machine interaction during these high-tech procedures, creating opportunities for errors or incidents to occur.

The learning curve and training of surgeons

Traditionally, training of young surgeons predominantly takes place in the operating room (OR) on patients, under careful supervision of an experienced surgeon. For centuries, this apprenticeship model (learning on the job) has proven to be effective. However, the introduction of minimally invasive surgery, and the limitations of this technique as described above, made surgeons realize that new training strategies were needed.

In surgery, the “learning curve” is usually defined as the decline of total operative time and reduction of operative complications [14-16]. In literature it is assumed that a surgeon is experienced when operative time and numbers of complications have stabilized. Although these are important parameters, they offer only limited insight into the actual increase in experience and the task performance quality of surgeons [17]. Every surgeon experiences his or her own learning curve while learning a new procedure or skill. However, learning on patients, and the inevitable occurrence of human errors while learning, raises ethical questions. Besides the ethical issues there are also other important constraints that have made the OR become a less than ideal place for surgical training.

The modern hospital demands efficient use of operation capacity and equipment, but training in the operation room is expensive and time consuming [18, 19]. Recently, working hours for all medical trainees have been reduced, although the number of years to become a specialist is maintained. Under the new working hour directive in Europe the workweek has been reduced from 60 hours to a maximally of 56 hours per week (in 2009: an maximum of 48 hours per week) [20], and in the United States [21] the standard workweek for physicians in training has been reduced from more than 100 to 80 hours per week.

In addition, there is a demand from society and governments for objective and transparent quality criteria for surgeons and other specialists. Patients demand qualified and experienced surgeons to operate on them. Nevertheless, qualification in the Netherlands and most other countries worldwide relies more on successful attendance and on job experience (6 years of surgical training), than on clear reliable and objective criteria. Finding objective criteria for judging good surgical technique is difficult and needs further investigation [22].

Training solely according to the apprenticeship model is no longer considered acceptable in laparoscopic surgery, although the benefits of this model, in which the master controls the quality, should be preserved [23-28]. Clearly, effective training devices are needed to train young surgeons outside the operation room where patient safety is not at risk.

Current training methods and devices

Most training institutions have adopted basic laparoscopic training courses for surgical trainees. These courses take two or more days and consist of lectures, laparoscopy videos and, most importantly, laparoscopic psychomotor skills training. Throughout the world different training models are used to train the motor skills, such as human cadavers, animal models, mechanical box trainers, and, more recently, virtual reality simulators. The ultimate aim of these simulation models is to shorten the learning curve of the trainee in the real job by providing a safe environment without any risks for patients.

Human cadavers offer accurate anatomy but lack important physiological features. Animal models such as porcine are widely used in laparoscopic training courses [29-33]. Although they are considered to simulate the human physiological features and tissue characteristic well, the anatomy differs from humans. They are relatively expensive, can not be used for multiple repetitions and are forbidden in some countries. When the time consuming training of basic psychomotor skills are considered, animal and human cadaver models seem less efficient to use as primary training model.

Mechanical box trainers can be used for unlimited practice with real instruments and equipment. Training programs consisting of various drills to improve laparoscopic motor skills have been developed and validated [34-41]. However, the main disadvantage of box trainers is the lack of automated performance assessment. Objective assessment is important for feedback to the trainee and progress tracking for the educators.

More recently, virtually reality (VR) simulators have emerged and have become attractive tools for laparoscopic training [28,42,43]. The interest in surgical VR simulators has been stimulated by the obvious parallels of laparoscopic surgery with the airline industry with its reputation for safety and its commitment to lifelong training. VR simulators or computer-based simulation provides objective feedback automatically which allows trainers and educators to assess performance and monitor progress. Several VR simulators have been developed and the evidence showing validity is growing [44]. Studies show that laparoscopic VR simulators can measure motor skills objectively and that structural training improves the task performance during laparoscopic procedures in patients and animal models [43-48]. However, laparoscopic skill training remains a challenge in surgical education for several reasons. One of the reasons may be the high system requirements and the relatively high initial costs of VR simulators [49]. Hence, there is a need for an affordable, robust and effective simulator. Secondly, simulators have not been structurally incorporated into the surgical curriculum. The effects of training and how to relate the measurement of the simulator to actual skills are not yet fully understood. Therefore, this has to be studied and developed further [50].

The SIMENDO (DelltaTech, Rotterdam, the Netherlands) is a recently developed simulator (5,000 to 9,000 euro for software and hardware), aimed to train hand-eye coordination motor skills for endoscopic surgery. The simulator is based on the principles and insight derived from previous research by Wentink at Delft University of Technology [8]. The design provides an easy to use plug and play system, employing abstract tasks and measuring performance of the trainee automatically with various parameters. However, for effective use in a surgical curriculum, the tasks and metrics incorporated in this new simulator have to be assessed and validated. In addition, this research potentially provides new insights in laparoscopic skills training and feedback for further improvement of the simulator itself. Figure 1 shows a diagram of the research, development and further validation of the simulator.

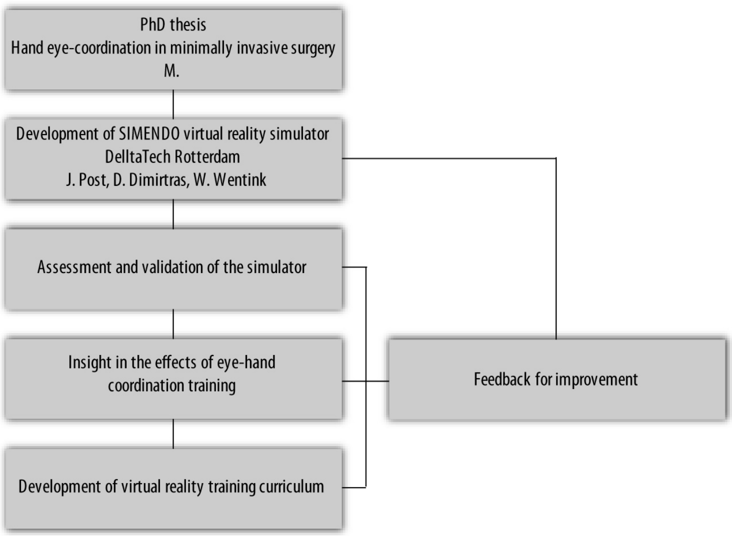

Figure 1. Research and development diagram for the validation of SIMENDO simulator

Standardisation and safety in surgery

In health care in general, but in surgery specifically, patient safety and the role of human error are increasingly receiving attention. The media and several scientific reports emphasized the occurrence of human error in medicine [51, 52]. The operating room is the most common site for the occurrence of adverse events (i.e. errors with serious consequences that could have been prevented) [51, 53]. The OR is a complex and high risk environment, but the factors contributing to medical errors within this context are poorly understood.

Currently, comparable surgical procedures may be performed differently at different hospitals, and even between doctors within one hospital [54]. The laparoscopic equipment and instruments used also differ between and within hospitals. There is a lack of clear and standardized protocols of how equipment should be used and how certain surgical procedures should be performed precisely.

Several authors call upon a systematic approach to identify the mechanisms behind the occurrence of medical errors in surgery and development of strategies to prevent them [55-59]. Inspired by the successful approaches in other high risk environments (such as aviation, chemical and nuclear industry) the incorporation of the following strategies is proposed:

- standardisation of the surgical process, equipment, instruments and task performance
- the use of checklists, protocols for emergency, decision support
- analysing data of errors and incidents (use monitoring systems, "black-box")
- acknowledgement of human factors and adopting a safety culture (insight in the effects of fatigue, stress, communication failures)
- enhanced training (simple and complex simulators, communication, team training, Crew Resource Management))

Standardization of endoscopic surgical operations and its execution are essential for the procurement and maintenance of quality assurance in endoscopic surgical practice [60]. For example in laparoscopic cholecystectomy, the guideline to dissect the triangle of Calot (Critical View of Safety as described by Strasberg [61, 62]) can help reduce errors.

The usefulness of checklists is clear and they are widely used in aviation and complex industries. However, they are rarely used in medical practice and surgery, at least not formally. Checklists could be used to check the availability and functioning of equipment in the operation room before the procedure starts, or for critical surgical steps. Nevertheless, the development and introduction of a checklist is not a simple task. Questions have to be addressed about the design, requirements and the use of a checklist (as a step-by-step "cookbook approach", expert decision support or as a backup procedure).

The establishment of procedural standardisation and checklist use can potentially enhance surgical training and development of effective training tools. It will help define the training objectives and training needs more accurately, which allows development of structured education.

In line with the checklist approach another approach started in surgery some years ago. This is the analysis of errors and incidents, based on the task analysis by observation (video monitoring) [17,63-66]. However, structured detailed monitoring of surgical performance and processes using video monitoring (the black box) is far from standard. Currently, it is only used to conduct research with specific goals. There is no infrastructure as exists in aviation to investigate incidents based on video monitoring on a large scale. Legal and privacy problems have to be addressed as well. Most importantly, incident and task analysis of surgical procedures is still in its infancy.

Surgical educators, healthcare managers and the government are aware of the importance of human factors in medical error. In literature, several reports outline the influences of fatigue and stress on performance and decision making [67-71]. Other reports point out the importance of team communication and the effects of communication failures [72, 73]. However, investigation of these factors is complex and many questions remain unanswered. Furthermore, when they are identified they have to be incorporated in medical training which requires a revision of the current curriculum.

Enhanced training strategies, incorporating the use of checklists, acknowledgement of human factors, as well as proficient communication are still to be developed. For this, much is to be investigated, studied, determined and developed.

PROBLEM STATEMENT AND OBJECTIVES OF THIS THESIS

With the worldwide adoption of laparoscopic surgery into daily practice, this technique has become an integral part of the general surgical curriculum. However, the psychomotor skills needed for this technique differ fundamentally from those needed for open or conventional surgery.

The time-consuming practice on patients, and the inevitable occurrence of human errors while learning, raises ethical questions. Surgical educators have now realised that skills training outside the operation room is required before operating on patients. This has become even more important due to the increased financial constraints in health care, the reduced working hours of medical trainees and the societal demand to develop quality criteria for medical specialists.

Various solutions for laparoscopic skills training exist, but they often do not offer objective assessment or are relatively expensive. Furthermore, the training effects of VR simulators are still not fully understood, and educators are reluctant to structurally adopt VR simulators into the surgical curricula on a large scale. Currently, there is a need for an affordable device for laparoscopic skills training, which produces valid and objective measurements that can be incorporated into a surgical curriculum.

The introduction of new technical equipment needed for laparoscopic surgery has made the operation room (OR) complex. The influence and consequences of this new equipment on the man-machine interaction have received little attention. Insight in the present needs and problems during training of laparoscopic surgery is required.

This PhD thesis has two main objectives:

- Validation of a new VR simulator for laparoscopic psychomotor skills training in order to incorporate the simulator effectively into the surgical curriculum.
- Determination of the current problems and needs encountered during training of laparoscopic surgery in the operation room in order to develop methods to improve safety and efficiency

OUTLINE OF THE THESIS

This thesis consists of two parts, covering both main objectives stated above. The first part describes the validation process and results of VR simulator SIMENDO (DelltaTech, Delft, the Netherlands). Also, different strategies are offered to incorporate skills training into the surgical curriculum.

PART I Validation of the SIMENDO virtual reality simulator

Chapter 2 describes the first validation results of the SIMENDO simulator.

Chapter 3 describes the construct validity of the SIMENDO. This study assesses the learning curve of four groups of subjects with different experience levels in laparoscopic surgery.

Chapter 4 presents a study with the SIMENDO, determining the effect of two different training schedules: training with short breaks on one single day versus an equal amount of training spread out over several days.

Chapter 5 presents a randomized controlled trial to determine the effect of laparoscopic knot-tying training on the VR simulator in a realistic laparoscopic environment.

Chapter 6 shows the role of performance criteria in order to incorporate laparoscopic psychomotor skills training into a structured surgical curriculum.

Chapter 7 describes the results of a national competition with the SIMENDO simulator and the potential of "serious gaming" in surgical training.

The second part presents the results of an assessment of the problems with the laparoscopic equipment, based on video captured observations. In addition, the effect of a checklist is studied as a solution for the existing problems.

PART II Current problems and needs during laparoscopic surgery in the operating room

Chapter 8 describes the incidence of problems with the technical equipment in routine laparoscopic cholecystectomies.

Chapter 9 outlines the requirements and format of a checklist in order to improve the safety of surgical processes.

Chapter 10 describes a study determining the effect of a perioperative checklist in order to decrease problems with laparoscopic technical equipment.

Chapter 11 outlines a summary of the results of a communication analysis during the dissection phase of a laparoscopic cholecystectomy.

Chapter 12, presents the conclusions this thesis. Furthermore, a general discussion, recommendations and potential directions for future research are provided.

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Chapter 2

Validation of a new and simple virtual reality simulator for training of basic endoscopic skills: the SIMENDO

E.G.G. Verdaasdonk[1,2], L.P.S Stassen [1,2], L.J. Monteny [1], J.Dankelman [1]

1 Department of BioMechanical Engineering, Faculty of Mechanical, Maritime & Materials Engineering, Delft University of Technology, Delft, the Netherlands
2 Department of Surgery, Reinier de Graaf Group, Delft, the Netherlands

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ABSTRACT

Background: The aim of this study was to establish content, face, concurrent and the first step of construct validity of a new simulator, the SIMENDO, in order to determine its usefulness for training basic endoscopic skills.

Methods: The validation started with an explanation of the goals, content and features of the simulator (content validity). Then, participants from eight different medical centres consisting of experts ($\geq$100 laparoscopic procedures performed) and surgical trainees (<100) were informed on the goals and received a "hands-on tour" on the VR trainer. Subsequently, they were asked to answer 28 structured questions about the simulator (face validity). Ratings were scored on a scale from 1 (very bad/useless) to 5 (excellent/very useful). Additional comments could be given as well. Furthermore, two experiments were conducted. In experiment 1, aimed at establishing concurrent validity, the training effect of a single handed hand-eye coordination task in the simulator was compared with a similar task in a conventional box-trainer, and with a control group receiving no training. In experiment 2 (first step of construct validity) the total score of task-time, collisions and path length of 3 consecutive runs in the simulator was compared, between experts (>100 endoscopic procedures) and novices (no experience).

Results: A total of 75 participants (36 expert surgeons and 39 surgical trainees) filled out the questionnaire. Usefulness of tasks, features, and movement realism were scored between a mean value of 3.3 for depth perception and 4.3 for appreciation of training with the instrument. There were no significant differences between the mean values of the scores given by the experts and surgical trainees. In response to statements, 81% considered this VR trainer generally useful for training endoscopic techniques to residents, and 83% agreed that the simulator was useful to train hand-eye coordination. In experiment 1, the training effect for the single-handed task showed no significant difference between the conventional trainer and the VR simulator (concurrent validity). In experiment 2, experts scored significantly better than novices on all parameters used (construct validity).

Conclusion: Content, face-, and concurrent validity of the SIMENDO are established. The simulator is considered useful for training eye-hand coordination for endoscopic surgery. The evaluated task could discriminate between the skills of experienced surgeons and novices, giving the first indication of construct validity.

INTRODUCTION

Since the introduction of the laparoscopic cholecystectomy, opinions in medical society about training of minimally invasive surgical skills have changed. There is consensus that surgical training should be structured and assessment of skills should be introduced to ensure safe and high quality treatment [1-4]. Training in the operation room (OR) is time consuming [5,6] and exposing the patient to relatively inexperienced surgical residents is potentially unsafe. Furthermore, recently reduced working hours for residents in the Netherlands and other countries, have reduced time available for practical training of procedures in the OR. Training surgeons according to the apprenticeship model only, is no longer acceptable [7,8]. Therefore most teaching hospitals have adopted training courses, prior to training in the OR. During these courses, surgical residents train with box trainers, virtual reality (VR) trainers or animal models. VR-simulators can provide a challenging, safe and controlled environment to master the basic skills needed to perform laparoscopic surgery [9-12]. Other advantages are objective automatic scoring of performance, and the possibility of unlimited repetitions of training situations.

Several VR-simulators for training of laparoscopic techniques and procedures have been developed [13,14]. Surgeons receiving VR simulator training show significantly improved performance in the OR as compared to those in control groups, measured in task time and errors [15]. However, the use of VR simulators in training hospitals is limited. This may be partly due to their high cost, the extensive system requirements, and their relatively immobile characteristics. In this context, there is an increasing interest for effective, mobile, basic and thereby affordable VR training tools for endoscopic techniques outside the OR. The SIMENDO (Delltatech, Rotterdam, the Netherlands) is a new VR-trainer, developed to specifically meet these demands. The training tasks in the simulator are based on thorough assessment and research of hand-eye coordination during laparoscopic surgery [16].

Prior to implementation of a new training tool in a curriculum, evaluation and validation of the tool and its parameters is mandatory. Subjective approaches to validation include content, and face validity. Content validity is generally defined as "an estimate of the validity of a testing instrument based on a description of the contents of the test items" or a judgement about what domains the instrument trains e.g. psychomotor skills or anatomy [17,18]. Therefore, content validation is more a summation of contents of the device under study then an actual study. Face validity refers to whether the model resembles the task it is based upon and addresses the questions to what extent the instrument simulates what it is supposed to represent and whether it is considered useful for training [3,17-19]. Most studies compare the opinions of experts with those of non- experts. In concurrent validity, the relationship between the test scores on the trainer under evaluation and the scores achieved on another instrument purporting to measure the same construct are compared [17]. Construct validity can be defined as "evaluating a testing instrument based on the degree to which the test items identify the quality, ability, or trait it was designed to measure" [17]. This is usually done by measuring performance in 2 groups who are hypothesized to differ in the skill being measured by the instrument, e.g. experienced surgeons and novices [20-22].

The aim of the present study was to establish content-, face- and concurrent validity and perform the first step of construct validity of the SIMENDO, thereby determining its usefulness for training basic endoscopic skills.

METHODS AND MATERIALS

The system: hardware and system requirements

The SIMENDO (Simulator for endoscopy) consists of one instrument handle on a box weighing 1.0 kg and measuring 10 by 10 by 40 cm in length and height (Figure 1). The software is integrated in the system and provides "plug and play" connectability via an USB port. Users of this simulator do not need to install additional software to be able to practice with the instrument. Each PC with a Microsoft® Windows® XP operating system is directly accessible for the simulator. Minimal computer requirements are a 722 mHz processor, 128MB RAM, a standard graphical card (nVidia Geforce 4™) and Microsoft® Office® software (with Access® Database).

Figure 1. Left: the SIMENDO connected to the PC via USB-port. Right: two exercises: piling up of cylinders and clipping of a vessel

Content validation

The exercises in the training program are designed to train hand-eye coordination using abstract tasks without force feedback. The training program (SIMENDO version 1.0.0*)* in the simulator starts with a short theoretical explanation of the difficulties a surgeon faces during endoscopic procedures. The goal is to train non-expert subjects the skills needed to deal with specific characteristics of endoscopic surgery such as the fulcrum effect, the use of long instruments, hampered depth perception, scaling of instruments and misorientation. During the explanation the user is asked to manipulate a virtual endoscope and instruments to demonstrate misorientation during laparoscopic surgery [16]. After this the user can choose between four different tasks: piling up of cylinders (Figure 1), manipulation of a 30^o endoscope, clipping an artery and dissecting a gall bladder. Also, a game is available called “catch the needles”, in which the skills described are practised. All the tasks, except the “30^o endoscope”, can be performed at three different levels. In each level, the angle between the endoscope and the instrument is increased (augmented misorientation). Besides these levels, the user can change the distance and the angle between the instrument and endoscope in any direction.

Time needed to complete the task and the number of errors are automatically measured and displayed. The errors are predefined as collisions with non-target structures and the inappropriate placing of a clip or the dropping of it. It is also possible to track movements and measure the path length of the instruments. The user can alter the settings for each task, such as the entry positions of instruments and camera.

Face validation

Participants

Expert surgeons and surgical trainees from eight different hospitals in the Netherlands, were visited and introduced to the simulator, between 1 October and 30 November 2004. In this study an “expert surgeon” was defined as having performed $\geq$100 endoscopic procedures and a “surgical trainee” as having performed less than that. The introduction to the simulator consisted of an explanation of the goals of the training system and a hands-on tour through all the components of the program. Subsequently, the participants were asked to give their opinion about the training system by filling in a questionnaire.

Questionnaire

All participants were asked for their age, gender, position held in the hospital and experience with endoscopic surgery in years and number of procedures. The opinions of the expert and trainee groups were evaluated with 28 questions about the SIMENDO. The questions were adapted from a questionnaire previously used in a study on face validation of another VR trainer [19]. The first section of the questionnaire entailed five questions about the first impression, design, and user-friendliness of the simulator. The second section contained eight questions about the training capacities of the simulator. The questions in the first two sections had to be answered by rewarding a mark on an ordinal scale, ranging from 1 (very bad / useless) to 5 (excellent / very useful). In the third section, the participants were asked for their comments and suggestions to improve the simulator in three open-ended questions. In addition, one question was posed about the price of the simulator and two questions about the willingness to train with the system. The final section presented nine general statements about the suitability to train surgical residents with the simulator. These statements had to be answered with "agree", "disagree" or "no opinion". Participants could give additional comments on all the questions.

Concurrent validity

To establish concurrent validity, an experiment was conducted to compare performance results after training with the simulator, training with a conventional laparoscopic box trainer, and without training (control group).

Experiment 1

Twenty-four students (12 male, 12 female) with no previous experience in surgery participated. They all performed a pre-test consisting of a single handed positioning task in a box trainer. In this task 10 points had to be touched with a laparoscopic grasper. When a non-target surrounding was accidentally touched a short signal sounded. Then, they were randomized into 3 groups of 8 subjects each, using sealed envelopes. The first group received training in a box trainer, the second in the VR trainer and the third group received no training at all. The training in the box group consisted of dropping 3 cubes in holes without touching the surroundings. A similar task was performed in the VR trainer ("drop the balls" task). Both groups repeated the training task 18 times. After the training all participants performed a post-test task which was identical to the pre-test positioning task. During the pre-test and post-test, the time and errors (defined as collisions with non-target environment) were measured.

Construct validity

In order to evaluate construct validity it was tested whether the measured parameters of a task in the VR trainer (time, collision and path length) could discriminate between experienced surgeons ($\geq$100 endoscopic procedures) and novices (no experience with endoscopic surgery).

Experiment 2

The first step of construct validation was performed with 5 experienced surgeons ($\geq$100 endoscopic procedures) and 20 novices (no experience with endoscopic surgery). They each performed 3 runs of a single-handed exercise in the VR trainer under study. The same VR task was used as in experiment 1 ("drop the balls"). Time, collisions and path length were measured and saved in the database of the simulator. Data of 3 consecutive runs were summated for each individual and for each separate parameter. Results were compared between the experienced surgeons and novice group.

Statistics

Data were analysed using SPSS® (version 11.0). Differences between the calculated mean scores of the expert and non-expert groups were analysed with the Kolmongorov-Smirnov test (two sided) for the five-point ordinal scale. The Fisher Exact Test (two-sided) was used to compare differences between the groups on the responses "agree" versus "disagree".

The 2-tailed Mann-Whitney U test was used to analyse differences between the non-parametric data of the groups in Experiment 1 and 2.

RESULTS

Face validity

Participants

In total, 75 surgeons and surgical trainees from eight different hospitals (three academic hospitals and five large community training hospitals) participated in this study.

The "expert" (36/75) and "surgical trainee" (39/75) groups consisted of medical specialists and residents from the departments of surgery, gynaecology, urology and orthopaedic surgery. Table 1 shows the characteristics of the participants. The majority of all the participants, 72% (54/75), worked in general surgery. Figure 2 shows the distribution of participants as a function of the number of endoscopic procedures performed.

Table 1. Characteristics of participants

Group	Total		Experts	Novices
total n (male: female)	75 (52:23)		36 (30:6)	39 (22:17)
median age (range)	33 (24-59)		42 (31-58)	30 (24-59)
Specialities of participants	Total n (%)		Experts n	Novices n
general surgery	54	(72.0)	22	32
gynaecology	13	(17.3)	7	5
urology	4	(5.3)	3	1
others	4	(5.3)	3	1
Total	75	(100.0)	36	39

Table 2. Results ratings (1 = very bad/useless and 5= excellent / very useful)

What is your opinion about …	Total	Experts		Novices		
	mean	mean	SD	mean	SD	P-value [a]
first impression						
appearance and design of the instrument	4.0	3.9	0.7	4.1	0.6	0.41
appearance and design of the software	3.9	4.0	0.7	3.9	0.6	1.00
realism of simulated movements	3.5	3.6	0.8	3.5	0.7	0.98
user-friendliness of the instrument	4.0	4.1	0.6	4.0	0.7	1.00
appreciation of training with the instrument	4.3	4.1	0.9	4.5	0.7	0.34
training capacities						
training of basic endoscopic procedures	4.0	4.0	0.9	4.0	0.7	1.00
training of hand-eye coordination	4.3	4.4	0.6	4.3	0.6	0.99
training of depth perception	3.3	3.1	1.2	3.4	0.9	0.55
tasks						
piling up cylinders	3.8	3.9	0.8	3.7	0.9	0.27
movements with a 30º endoscope	3.9	4.0	0.8	3.7	0.9	0.71
clipping a vein	3.9	4.0	0.9	3.9	0.9	1.00
dissecting the gall bladder	3.2	3.4	0.9	3.0	1.1	0.43
catching the needles	3.7	3.6	1.1	3.7	1.1	1.00

[a] *Komongorov- Smirnov test, two sided, Expert versus Novice group.*

First impression

Table 2 shows the mean values of the scores for the first impression of the simulator. Most values tend to be good (4), except for the correlation between the movements of the hand and the screen. The highest mean score of 4.3 was given for the appreciation of training with the device. No significant differences were found between the expert surgeons and the surgical trainee group.

Training capacities and tasks

The training capacity of endoscopic procedures in general, and most of the tasks were rated good, with a mean score around 4. The highest score in the category training capacities was given to training of hand-eye coordination (4.3). Training of depth perception received a relatively low score (3.3). The task “dissection of the gallbladder” was not considered specifically useful as indicated by a mean score of 3.2. Table 3 provides the results of the statements. In response to the statements, 81% considered the SIMENDO useful for training of endoscopic techniques to residents in general and 83% agreed that the simulator was useful to train hand-eye coordination. Of all the participants, 91% believed that it was useful for training within the hospital and 77% also believed that the simulator was useful for training at home. Most expert surgeons (75%) indicated that the simulator could become useful for measuring skills for endoscopic procedures. Only 40% of the trainee group agreed with this statement.

Table 3. Results statements

Statement: "the Simendo……"		Total %	Expert %	Novice %	P-value
…is a useful instrument to train endoscopic techniques to residents.	Agree	81.3	92.7	72.8	0.05
	Disagree	14.7	5.6	23.1	
	No opinion	4.0	3.8	5.1	
…can become a useful instrument to train endoscopic techniques to residents.	Agree	92.0	88.9	94.9	0.19
	Disagree	6.7	11.1	2.6	
	No opinion	1.3	0.0	2.6	
…is a useful instrument to train basic skills in endoscopic surgery.	Agree	74.7	77.8	71.8	0.52
	Disagree	14.7	11.1	17.9	
	No opinion	10.7	11.1	10.3	
…can become a useful instrument to train basic skills in endoscopic surgery.	Agree	90.5	86.1	94.7	0.05
	Disagree	6.8	13.9	0.0	
	No opinion	2.7	0.0	5.3	
…is a useful instrument to train hand-eye coordination.	Agree	83.8	88.2	97.4	0.67
	Disagree	7.4	5.9	8.8	
	No opinion	8.8	5.9	11.8	
…can become a useful instrument to train hand-eye coordination.	Agree	86.6	82.9	90.6	0.20
	Disagree	9.0	14.3	3.1	
	No opinion	4.5	2.9	6.3	
…is appropriate to train at home.	Agree	77.0	77.1	76.9	1.00
	Disagree	16.2	17.1	15.4	
	No opinion	6.8	5.7	7.7	
…is appropriate to train at the hospital.	Agree	90.5	91.4	89.7	0.62
	Disagree	5.4	2.9	7.7	
	No opinion	4.1	5.7	2.6	
…can become a useful instrument to measure the performance of laparoscopic procedures	Agree	56.8	75.0	39.5	0.13
	Disagree	20.3	16.7	23.7	
	No opinion	23.0	8.3	36.8	

Fisher Exact Test (2-sided) for agree vs disagree for responses from Expert vs Novices.

Other comments

In response to the open questions, 30 of the participants indicated a preference for a two or three handed simulator to train with, 23 advised on additional tasks, 14 respondents suggested to include a suturing/knotting task and nine would like to have tactile feedback added to the system. In response to the question what aspects were especially liked or disliked, 13 participants stated that they liked the simplicity of the system. Eleven participants made a comment about poor depth perception and eight disliked the fact that there was no force feedback in the device. 75% of the participating surgeons responded that the current price of the simulator was reasonable and that they would like to have the device in their hospital (Table 4).

Table 4. Results other questions

		Total %	Expert %	Novice %	P-value
Would you like to train with the Simendo?	yes	72.6	57.1	86.8	0.01
	no	19.2	31.4	7.9	
	no opinion	8.2	11.4	5.3	
Would you like to have the Simendo in your hospital?	yes	81.3	75.0	87.2	0.79
	no	8.0	11.1	5.1	
	only if	10.7	13.9	7.7	
What do you think of the price?	to high	25.3	27.8	23.1	0.40
	reasonable	74.7	72.2	76.9	
	to low	0.0	0.0	0.0	

Fisher Exact Test (2-sided) for yes vs no, and to high vs reasonable for responses from Experts vs Novices.

Concurrent validity

There were no significant differences between the performance scores of the three groups in the pre-test task. Figure 3 and 4 shows the results of the pre-test and post-test tasks. After training, time to complete the task improved in the VR group by 33% and in the box group by 42%, which was both significantly higher than in the non-training group (improvement by 15%) (Mann-Whitney U test *p=0.021*, *p=0.001*, respectively). The number of collisions decreased in the both trained groups (VR and box), but this difference was not significant as compared to the non-trained group (Table 4).

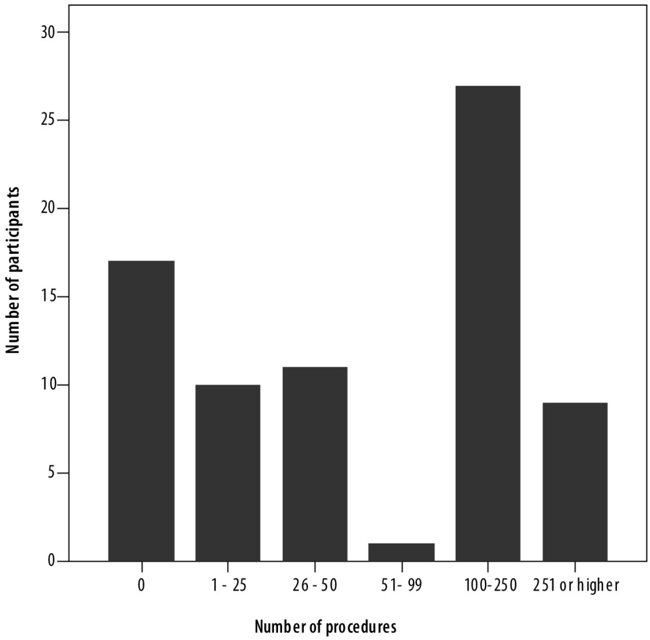

Figure 2. Distribution of participants as function of number of endoscopic procedures performed

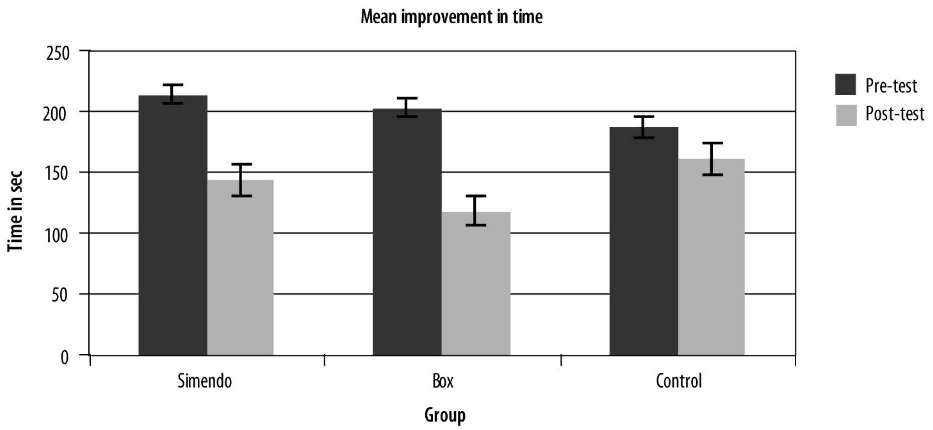

Figure 3. Mean improvement in time after training: SIMENDO (33%) vs Control (15%) *p = 0.021*, Box (42%) vs Control (15%) *p = 0.001*

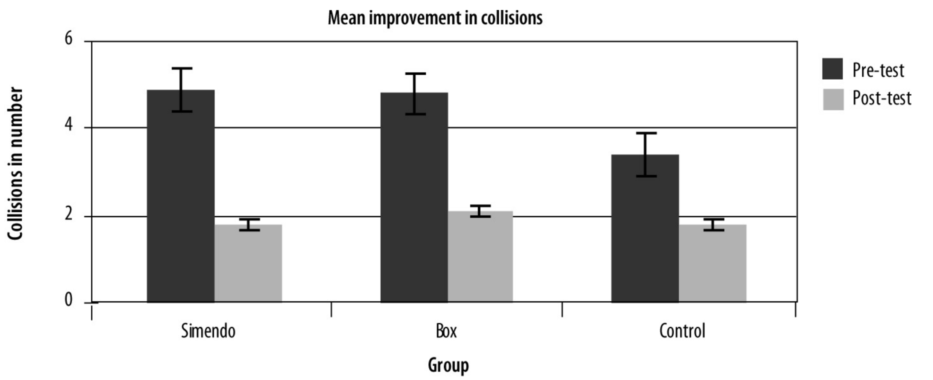

Figure 4. Mean improvement in collisions after training: SIMENDO (64%) vs Control (48%) Not Significant, Box (55%) vs Control (48%) Not Significant

Construct validity

Figure 5 gives the results for time, collisions and path length. The boxes show the median scores of the parameters over 3 consecutive runs of one exercise for each group. The performance of experts was significantly better than of the novices on all parameters. The task-time was shorter (median 102.7 seconds, range 46.7-126.7 sec versus 149.2 seconds, range 79.6-290 sec) *p=0.008*), the number of collisions less (median 3, range 1-8 versus 8.5, range 1-21 *p=0.038*), and the total path length shorter (median 80.1, range 50.2-95.3 versus 94.0, range 77.9-163.6, *p=0.025*).

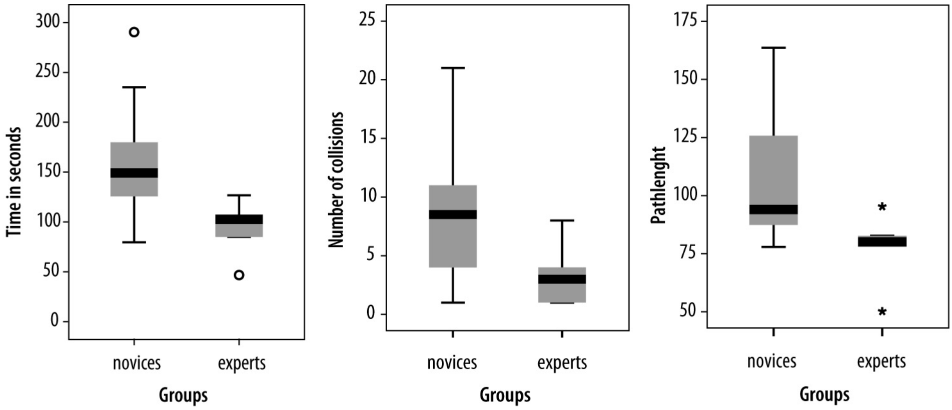

Figure 5. Box and whisker plots for simulation scores of Experienced and Novices for total time, collisions and path length. Boxes represent interquartile range, bars medians and whiskers the range excluding outliers. Circles represent outliers and asterisks extreme outliers

DISCUSSION

The results of this study show that experts and surgical trainees believe that the VR trainer under study is a useful tool to train hand-eye coordination and basic endoscopic skills for inexperienced surgeons. Comparable reduction of time to complete an exercise is achieved with training in a conventional trainer (box trainer) and the VR trainer. Furthermore, experts outperform novices in the current VR trainer.

Structured training and assessment of surgical skills before entering the operation room and performing a procedure on a real patient is an important issue in present surgical education [8,9]. VR is considered a valuable training method for laparoscopic skills [23] and assessment tool for objective evaluation of skills levels of trainees [22,24,25]. Previous studies have shown positive effects of VR training on psychomotor skills during real laparoscopic tasks [14,24, 26-29]. Only the extent to which this training should take place remains a point of discussion [30].

Unfortunately, VR simulators tend to be costly which limits their usefulness. Another disadvantage is their relative immobility. According to most surgeons the SIMENDO could also be used at home. Flexible, mobile training systems are especially interesting as several studies indicate that VR training is likely to be successful when the training schedule is intermittent, rather than condensed into a shorter period of extensive practice [31,32]. Such a schedule is most easy to implement when the simulator is easily accessible, e.g. in every teaching hospital or even at home. Advanced VR trainers can play an important role in condensed skills and assessment courses in large educational centres. Reinforcement of basic skills, such as hand-eye coordination, that diminishes over time if not trained frequently, can take place using simpler simulators. The SIMENDO is a VR simulator that is meant to be low priced and mobile and especially suitable for training basic skills. It can be used in a structured and gradual fashion over several intervals before the trainee takes part in more advanced courses. An advantage of VR trainers in general is that, in contrast to other simple simulators such as box trainers, improvement of performance during training is automatically recorded by registration of several parameters in a database without the need of direct observation by a researcher or faculty member. If necessary, a supervising surgeon can easily review the “learning curve” of the trainee in the simulator afterwards.

In general, the conceptual tasks received higher scores than the task that tries to resemble an anatomical structure: “dissection of the gallbladder”. Apparently, training by means of simplified anatomical structures in this simulator is not considered very useful. Some respondents advised implementation of force feedback and adding of a suturing or knotting task. Currently, force feedback is not the focus of this training device, because the role and implications of force feedback in laparoscopic surgery are not clear [33]. Furthermore, improving the realism of the simulation of anatomical structures, modelling of a suturing of knotting task or adding of force feedback will increase cost considerably by demands on the software. Such expansion of the software would reduce the simplicity of the system and this in combination with the increased cost would exceed two primary goals of this simulator: to supply a simple, plug and play and affordable VR trainer. In addition, there is evidence that the training of conceptual tasks in VR already improves performance during laparoscopic cholecystectomy in the operation room [15].

Although care was taken to optimise the design of this study, face-validity contains weaknesses as it is based upon opinions. In order to reduce this weakness, questions were adapted from a previously used questionnaire [19]. However, systemic errors can originate from the questionnaire: for example, the interpretation of questions can differ among the subjects because of suboptimal formulations. Also, the enthusiasm of the presenters or the attractiveness of a new training system can bias the answers.

In addition to their opinion on validity as a training device, the participants were also asked whether the simulator could become a useful device for measuring skills in endoscopic procedures. Interestingly, in contrast to the expert surgeons, the non-expert group tended to disagree with this statement or had no opinion on this item. This may be explained by the fact that trainees are not familiar with the measurement possibilities of VR-devices in general or they may dislike the idea of accepting metrics for assessment of their performance.

Experiment 1 showed that the reduction of the time to complete the exercise was significantly higher in both trained groups compared to the control group; this was not the case for the number of collisions. Probably, it was easy to learn to avoid collisions with the environment in the pre-test task, allowing for a low collision level of the control group in the post-test task.

Further studies are needed to determine the measuring capacity of the SIMENDO, and its usefulness for assessment and training of basic endoscopic skills of surgical trainees in the surgical curriculum. Improvements of the simulator, such as the possibility of training with two or more simulated instruments and more tasks with better depth perception, are currently being carried out and evaluated.

CONCLUSION

This study showed that both expert and non-expert surgeons considered the SIMENDO to be a useful virtual reality-training device for hand-eye coordination and basic endoscopic surgical skills.

The learning effect for a simple hand-eye coordination task is comparable to the effect in the box trainer. Parameters of this task can discriminate between groups of experienced and inexperienced subjects in the hand-eye coordination skills for endoscopic surgery.

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Chapter 3

Construct validity and assessment of the learning curve for the SIMENDO endoscopic simulator

E.G.G. Verdaasdonk[1,2], L.P.S Stassen[1,2], M.P. Schijven[3], J.Dankelman[1]

1 Department of BioMechanical Engineering, Faculty of Mechanical, Maritime & Materials Engineering, Delft University of Technology, Delft, the Netherlands
2 Department of Surgery, Reinier de Graaf Group, Delft, the Netherlands
3 Department of Surgery, University Medical Centre Utrecht, Utrecht, the Netherlands

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ABSTRACT

Background: The SIMENDO is an affordable virtual reality (VR) simulator designed to train basic psychomotor skills for endoscopic surgery. This study aimed first to establish construct validity by determining which of the parameters can discriminate groups with different experience levels, and second to establish the extent to which training is useful by determining when inexperienced groups reach expert level.

Methods: The study participants were divided into four groups according to their experience with endoscopic procedures: experienced group (group A, >50 procedures performed, n=15); intermediate group (B, >1 and <50 procedures, n=18); endoscope navigation group (C, endoscope navigation experience) n=14); and novice group (D, no endoscopic experience, n=14). Each participant performed three repetitions of six consecutive exercises. The parameters studied were task time, path length of the instruments and number of errors (collisions). Some participants continued training up to 10 repetitions to get insight in the learning curve.

Results: Group A (expert) outperformed all other groups (B, C and D) in terms of total median task time ($p<0.05$), groups C and D in path length, and group D in terms of collision frequency in the first two repetitions. Group B (intermediate) outperformed group D (novice) in total time and endoscope path length for all repetitions, and group C (camera navigation group) outperformed group D (novices) in the first repetition. Less experienced groups D and C did not reach expert level within 10 repetitions for the task time, and group B after the eighth repetition ($p<0.05$).

Conclusion: The study was able to established construct validity for the training program in the simulator under study. The learning curve revealed that training with this simulator is useful for subjects without or limited endoscopic experience. Furthermore, previous endoscopic camera navigation already improves motor skills to more than the basic level.

INTRODUCTION

Endoscopic virtual reality (VR) trainers have become an attractive and valuable tool for training surgeons in a nonpatient environment. The aim of a simulator is to shorten the learning curve of the trainee in the real job.

The SIMENDO (DelltaTech, Rotterdam, the Netherlands) is a recently developed affordable simulator (5-8 k euro software and hardware), aimed at training hand-eye co-ordination motor skills needed to perform endoscopic surgery. This simulator is designed to provide an easy-to-use plug-and-play system for surgical trainees. It features abstract tasks and simultaneously measures the performance of subjects using various parameters for objective assessment. However, for practical and effective use in the surgical curriculum, tasks and metrics incorporated in the simulator need to be tested for objectivity and reliability. Consequently, each new training device must be assessed and validated.

In literature, the validation of training tools and their effectiveness are described using different theoretical models, but exact definitions vary among different authors [1-3]. One important step in evaluating new training tools is to assess construct validity. Construct validity refers to the concept that the studied novelty (e.g. the SIMENDO VR simulator) measures the quality, ability or trait it was designed to measure. Therefore, the metrics or parameters assessed must be related to the level of the performer’s experience. This is usually accomplished by measuring performance in two or more groups that differ in the precise skills being measured by the instrument. For example, practising endoscopic surgeons should outperform inexperienced trainees. Construct validity has been established for several other VR-simulators [4].

In addition to the construct validity study the learning curves of groups with different experience levels were assessed. This is essential because learning curves determine the training capabilities of the simulator. We propose a theoretical model regarding the requirements of the measured learning curve for the different parameters. A learning curve can be defined as the relationship between the parameter measured through training repetitions.

The model we propose is graphically displayed in Figure 1. In the model, it is assumed that the parameters such as task time, errors and path length will decrease as experience is gained. The curve indicated by line 1, characterizes the ideal learning curve for experts using the simulator. Theoretically, there should be no learning effect for experts, because they already poses the ability measured (displayed here as a horizontal line). However, simulation is, per definition, a deduction of a realistic situation. Therefore, in practice, curve 2 represents the expert learning curve more accurately. Curve 3 characterises the learning curve for novices. Due to novices’ lack of experience with the tasks simulated, their curve height is indicative for the performance difference between novices and experts. Obviously, the novices’ curve (3) should approach the expert curve in due time. Furthermore, the novices’ curve should approach gradually and not too quickly. Tasks mastered within a few repetitions have limited training usefulness. The area between curves 2 and 3 represents the task complexity and the effectiveness of the simulator. Hence, the larger the area between curve 2 and 3 the more difficult the task or tasks trained in the simulator.

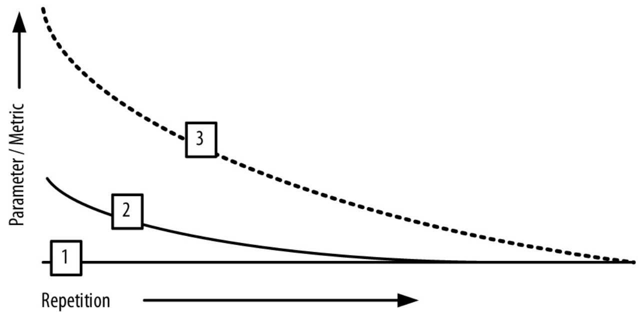

Figure 1. Theoretical concept for the learning curve of simulator parameter assessment.(1) The "theoretical" learning curve for experts in a ideal simulation model, (2) the actual measured learning curve of the experts, (3) the learning curve for novices or non experienced subjects

The current study aimed first to establish construct validity by determining whether the parameters measured for the SIMENDO simulator can discriminate groups with various experience levels, and second to establish to what extent training is useful by determining when inexperienced groups reach expert level.

METHODS

Participants

Participants were divided into four groups, according to their experience with endoscopic surgery:

- *Group A – experienced:* more than 50 endoscopic procedures performed
- *Group B – intermediates:* 1 to 50 endoscopic procedures performed
- *Group C – endoscope navigation:* experienced only in endoscopic camera assistance during endoscopic surgery
- *Group D – novices:* no experience in endoscopic surgery whatsoever.

Material and techniques

For this study, the SIMENDO virtual reality simulator for endoscopic skills was used. This simulator consists of a software interface with several training exercises and two hardware instruments. The two instruments were connected with a Universal Serial Bus (USB) plug to a standard PC or laptop (Figure 2). Previously, the usefulness and face validity of this simulator with a single instrument was studied [5]. In the current study, six training exercises from SimSoft (Delltatech, Delft, The Netherlands) 1.0 software were included. Table 1 describes the goals and the content of exercises used. In all exercises two instruments were used, except for the first exercise (drop the balls). Two exercises (drop the balls, stretch) were executed in the same virtual environment with alternating endoscopic camera position. Impressions of the exercises used in this study corresponding to the descriptions in Table 1 are given in Figure 2.

All participants performed 3 repetitions of the six consecutive exercises described in Table 1. One repetition consisted of the performance of exercise 1 to 6 without scheduled breaks, except to switch from one to the other exercise. In the second repetition the participants repeated the same set of exercises from 1 to 6 end so on.

Most of the participants (see detailed description in the Results section) continued training for learning curve assessment, and performed a total of 10 repetitions. A break was scheduled of 5 minutes after the fifth repetition. The training took place in a quiet room in the presence of an observer. Participants received a written instruction in which they were instructed not to speak during task execution.

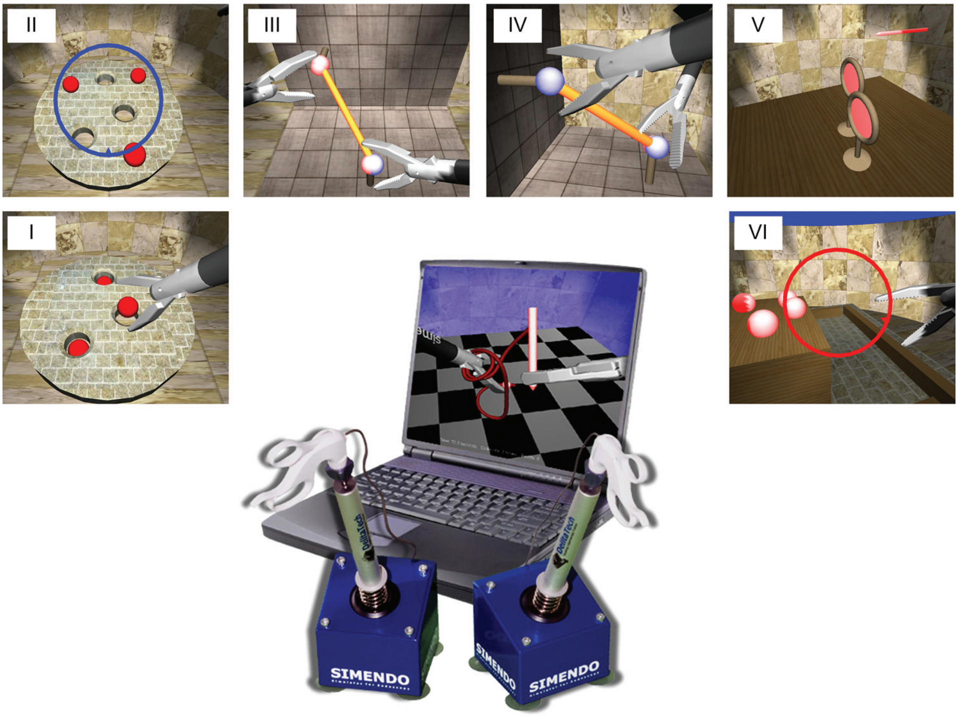

Figure 2. SIMENDO simulator for endoscopic surgery. The two instruments are connected to a laptop via USB. The numbers of the 6 exercises correspond with the description in Table 1.

Table 1. Description of exercises used

Exercise name	Exercise description	Exercise goal
I. Drop the balls, one instrument	Dropping of three balls into holes with right hand only	Basic coordination
II. Drop the balls, two instruments	Dropping of three balls into holes with camera in the left hand and instrument in the right hand	Basic coordination with use of camera
III. Ring and Needle	Putting a needle trough 2 rings (both hands)	Fine coordination and positioning
IV. Stretch easy (endoscope 0^o)	Stretching a tube in correct direction and length with camera between instruments (both hands)	Easy stretching and co-ordination
V. Stretch difficult (endoscope 90^o)	Stretching a tube in correct direction and length with camera from the left (90^o) (both hands)	Difficult stretching and co-ordination
VI. 30^o endoscope handling	Putting 4 balls on a box with in the left hand a 30^o endoscope and in the right hand a grasping instrument	Coordination of instrument with 30^o camera

Parameter assessment

The following outcome parameters were automatically generated during tasks performance: task time, collisions of instruments with non-target objects, and total path length for the right and left instruments. Furthermore, the percentage of time the instrument tip was centred in the endoscope and endoscope path length was measured in two exercises: drop the balls with endoscope navigation and 30-degree endoscope. Task time is measured in seconds, collisions in number and path length in arbitrary units (AU).

The parameters of the six different exercises were summed for each repetition. Then parameter totals per repetition (total task time, total collision etc) were created. After that, the exercises were analysed individually, in which case, parameters were not summated.

Data were analysed with Statistical Package of Social Software (SPSS) version 12.0. The Mann Whitney-U test for parametric data was used to analyse statistical differences between the scores of the groups with different level of experience. Statistical significance was considered when p was less than 0.05. Values are presented as median (range) unless stated otherwise.

RESULTS

Construct validation

The 61 participants were divided into four groups by level of clinical endoscopic experience as previously defined. This resulted in the following groups:

- *Group A – experienced* (n=15): median of more than 100 endoscopic procedures performed
- *Group B – intermediates* (n=18): median of 10 (range 1-30) endoscopic procedures performed
- *Group C – endoscope navigation* (n=14): median of 30 (range 1-40) endoscope navigation procedures performed
- *Group D – novices* (n=14): n o endoscopic experience.

The results for total task time, number of collisions, endoscope and right instrument path length, in three consecutive repetitions are given in Figure 3.

Compared to the expert group, the total task time of the less experienced group (B, C, and D) was significantly longer. Right instrument and endoscope path length of the novices and endoscope navigation group (C, D) also were longer. More collisions and a longer left instrument path length in the first two repetitions were found in group D. As compared with the intermediate group (B), endoscope and right instrument path length were longer in group D. Compared to the endoscope navigation group (group C), longer tasks times and longer path length were found in group D, but this was only significant in the first repetition.

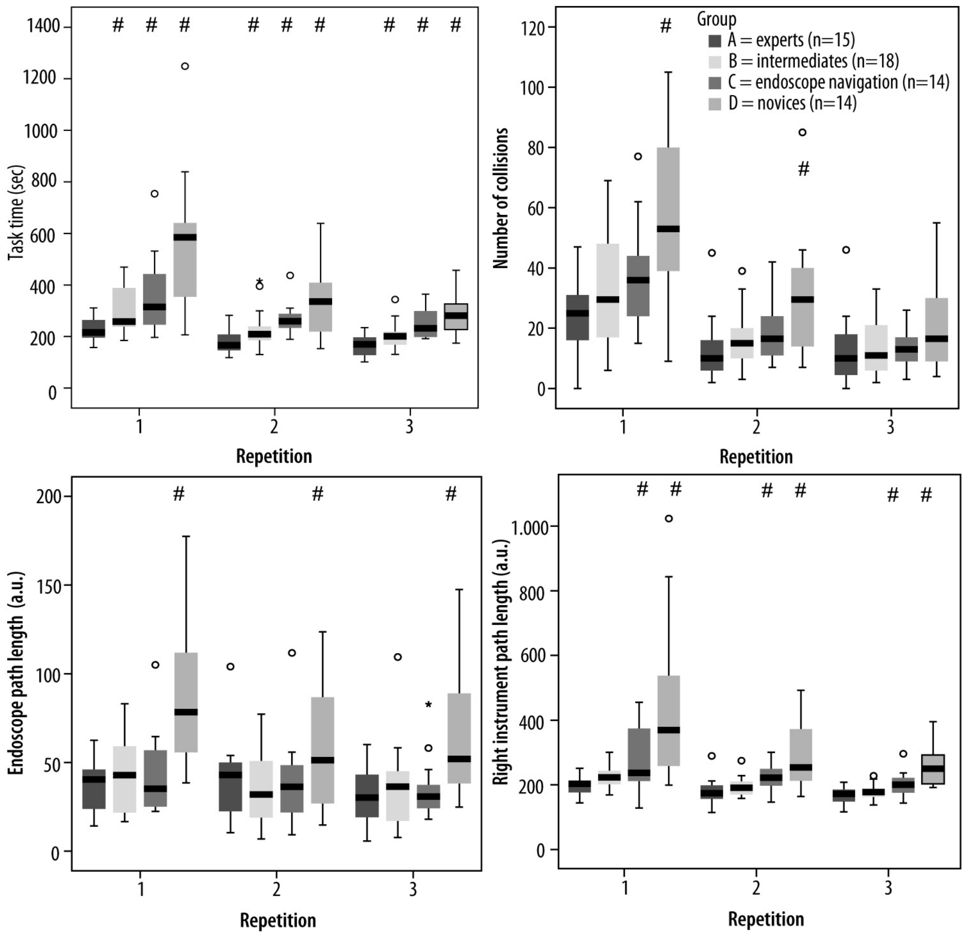

Figure 3. Box plot diagrams for total task time, collisions, endoscope path length and right instrument path length, for 3 consecutive training repetitions. The borders of the boxes represent the 25th (lower border) and 75th percentile (upper border) and the horizontal line the median. The rounds are outliers (o) defined as 1.5 times dispersed from the box borders. The stars (*) represent the extreme outliers, defined as 3 times dispersed from the box borders. The symbol (#) above the boxes represent a significant difference ($P<0.05$) between groups B, C or D and group A (the expert group).

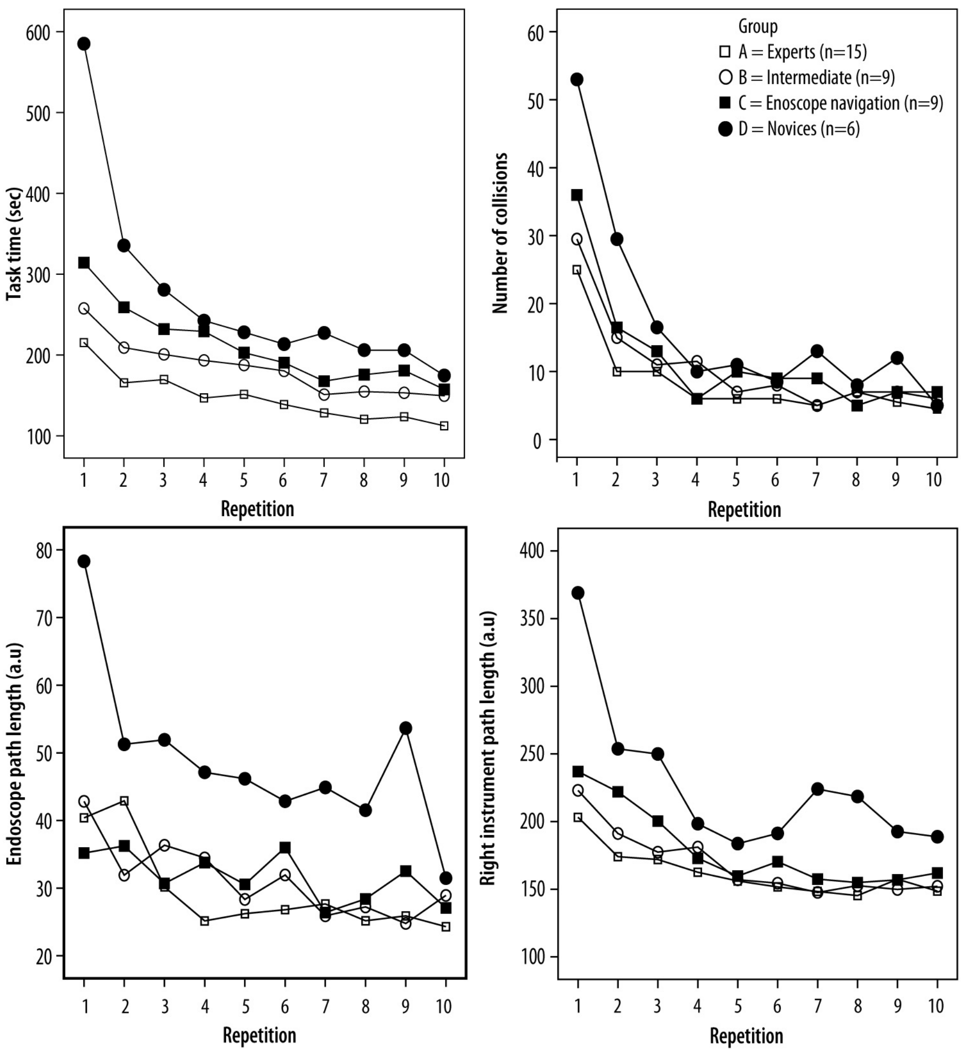

Figure 4. Learning curves of total median task time, number of collisions, endoscope and right instrument path length for the four groups performing 10 repetitions. The details are given in the text.

Individual tasks

Subsequently, the scores were analyzed for each exercise separately. In this case, the parameters of the different exercise were not summed for each repetition. The task time was significantly longer for the novices (group D) than for the experts (group A) in all six exercises, and in three out of six exercises (drop the balls with camera, stretch difficult and ring & needle) for the endoscope navigation group (group C). Right instrument length was longer for novices (group

D) in all tasks except the two stretch exercises, and for the endoscopic navigation group (group C) only in the ring and needle exercise.

In addition, novices had significantly more collisions compared than experts (group A) in drop the balls with camera and ring and needle, but not for all repetitions.

Finally, there were no significant differences between experts (group A) and intermediates (group B) in the individual exercises.

Learning curves

In 49 participants the learning curves for each parameter was assessed. All experienced participants (group A, n=15) and some of the other groups (intermediate group B, n=9; endoscope navigation group C, n=9; and novices group D, n=6) continued the training up to 10 repetitions. The results of the learning curve for total task time, right instrument path length and number of collisions are shown in Figure 4.

Compared with the expert group, the novices and the camera navigation groups had a significantly longer total task time up to the 10th repetition, and the intermediate group up to the 8th. In the novices the endoscope and right instrument path length also were longer than in the expert group up to the 10th repetition ($p < 0.05$).

Table 2 shows the mean of the parameters for the first and the 10th repetition for experts and novices. Note that the difference is diminished between expert and novice group in the 10th repetition. Furthermore, mean and standard deviation decrease in the novice group from the 1st to the 10th repetition.

Table 2. Expert and novice parameter scores for the first and 10th repetition.

Parameter	Repetition	Expert group		Novice group		*P-value* [a]
		mean	SD	mean	SD	
Task time (seconds)	1	230.9	47.3	635.0	364.1	< 0.001
	10	118.3	22.9	182.5	61.0	0.032
Collisions (number)	1	25.5	13.3	51.5	13.0	0.010
	10	7.1	6.0	7.7	5.3	NS
Endoscope path length (a.u.)	1	36.9	14.8	98.4	53.8	<0.001
	10	23.3	8.2	42.4	21.9	0.032
Right instrument path length (a.u.)	1	197.1	32.3	468.0	289.5	0.002
	10	144.0	20.2	203.6	52.7	0.005
Left instrument path length (a.u.)	1	65.5	18.3	148.5	82.0	0.003
	10	42.4	7.4	56.7	14.6	NS

SD, standard deviation, NS, not significant, a.u., arbitrary units

[a] *Two tailed Mann-Whitney U test, for Expert group versus Novices group*

DISCUSSION

The first goal of this study was to establish construct validity for the SIMENDO simulator. The results show that the parameters combined with the exercises in the simulator can be related to various levels of laparoscopic experience. Three studied parameters (task time, endoscope path length and right instrument path length) were able to measure relevant differences over consecutive repetitions for the whole training program and also for some individual tasks. Instrument collisions with the virtual environment as a parameter for error and accuracy can discriminate between novice and experienced subjects only in the beginning of the training (first two repetitions). The learning curve assessment showed that inexperienced groups approached the expert group level by repetitive training. Required practice to achieve expert level was related to previous experience.

The time and path length parameters of the learning curve fit in the theoretical model, proposed in the introduction (Figure 1). The learning curve in the expert group for these parameters is lower and more flat, and the difference with inexperienced groups is great. Analysis of task time along the learning curve shows a significant difference between the groups, even beyond the 10th repetition. The curve shapes indicate that experts adapt fast to the tasks and inexperienced participants encounter a substantial learning effect.

Strong discriminative ability between levels of experience for time and path length parameters is also observed in other simulators [3,6-11]. The results in this study suggest that the tasks mimic psychomotor skills needed for endoscopic surgery. In this experiment none of the inexperienced groups (novices and endoscope navigation groups) do fully approach expert level for all parameters. The profound initial difference between the groups and the gradual converging of their learning curves support a substantial training capacity of the device.

In contrast to task time and path length, the learning curve for collisions is also short for the inexperienced groups, and therefore does not fit the theoretical model.

Including error assessment in performance outcome of training devices is imperative because programs that fail to consider objective assessments of accuracy may overestimate endoscopic proficiency [12]. Rapid "flooring" of error score is also seen in other studies [7]. Apparently, indeed controlled instrument movements avoiding collisions are aptitudes mastered fast.

An interesting question is whether the collision parameter in the studied simulator is acceptable as an outcome parameter for accuracy. As a discriminative parameter for experience level it is not very powerful. However, the SIMENDO aims on training basic dexterity in endoscopic instrument handling (eye-hand co-ordination) and not procedural or anatomical rules, instrument-tissue interaction or knowledge important for tissue handling. Tissue handling requires a high level of accuracy, but for general psychomotor skills training in a basic simulator a low discriminative power is adequate. Additionally, inexperienced subjects still needed more time to accomplish the tasks with the same collision number as experts did. Theoretically, a skilled person is recognised by his ability to perform accurately, effectively and efficiently. In fact, such an observation is clear to anyone who reflects on the difference between their beginner and practiced performance in situations as learning how to play a musical instrument or learning how to drive a car. Experienced endoscopic surgeons have the ability to combine accuracy (low errors or collisions), effectiveness (short path length) and efficiency (time) well, whereas novices do not yet have that ability. Therefore, the combination of several parameters should be used as criterion-based training goals for inexperienced trainees and not time or path length alone.

Naturally, performance varies between individuals. This variance is represented by the standard deviation in the groups (Table 2). The variance between individuals was greater in the inexperienced novices than the experienced group and decreased throughout the training. This observation has also been reported by others [13]. Initially, some inexperienced participants seem to have a more natural dexterity than others in their group. However, in the experienced group, all participants possess a certain level of dexterity (i.e. a psychomotor skills) developed by their work as an endoscopic surgeon.

Despite the large initial differences, attenuation of interindividual performance outcomes occurred (i.e. inexperienced individuals tended to converge to a similar level). According to Ackerman [14], attenuation of variance during task learning indicates shift from a cognitive conscious process to a more automatic unconscious cognitive process. This is a typical characteristic of motor tasks such psychomotor skills required in endoscopic surgery. If the trained tasks required predominantly conscious cognitive processes (applying rules, interpreting new situations) only small improvement is seen in the beginning of the curve, but the difference on interindividual level (e.g. the standard deviation) does not change much throughout training. As expected, standard deviation did change which indicates primarily motor skill training in the simulator.

The endoscope navigation group outperformed the novice group by a shorter task time and endoscope path length. Endoscope navigation experience during real laparoscopic procedures improved objective measurable psychomotor skills in the simulator. Despite the substantial number of procedures assisted in this group (median 30 procedures), quite a bit of additional training was needed to approach expert level in the simulator. It could be assumed that endoscope navigation does only improve very specific psychomotor skills, not general dexterity for endoscopic surgery.

Although endoscope navigation may seem to be an easy task, it is, however, of utmost importance, because it directly influences the performance of the operating surgeon. Consequently, the simulator should also be used to train novice in specific endoscope navigational skills.

The SIMENDO simulator is designed to train basic eye-hand coordination necessary for performing endoscopic surgery. The results in this study suggest that the abstract tasks featured in the simulation, indeed train the basic motor skills needed to perform endoscopic surgery. These outcomes cannot be related directly to enhanced operative performance, but most likely the SIMENDO will shorten the learning curve of basic psychomotor skills required in the operating room. Training motor skills outside the OR will facilitate incorporation of these skills on a more automatically level and consequently reduce the mental load in the actual job [15]. The trainee then can concentrate on other aspects of the procedure such as anatomy and procedural steps. As a result, this will increase safety and save expensive operating room training time.

The implication of the learning curve data is that the SIMENDO can be highly effective for novices and surgical trainees with limited endoscopic experience. Its implementation at the beginning of a surgical curriculum, as criterion-based licensing of basic psychomotor skills, just before animal training or previous to the first 10 endoscopic procedures, would seem to be most beneficial. Probably, it would also enhance skills maintenance. There is, however, no evidence yet supporting a role for high stake examination in surgical trainees.

Future research should aim at determining the usefulness of the SIMENDO simulator for recruitment and selection and its position among other validated simulators. Randomized controlled trails with VR simulators such as MIST VR [16] and LapSim [17] have shown transfer of skills to the operating room. To determine the position of SIMENDO, the next step should be a comparative study (concurrent validity) with one of these simulators.

CONCLUSION

This study established construct validity for the SIMENDO. The learning curve showed that the SIMENDO training is useful for subjects with no or limited endoscopic experience. Furthermore, endoscopic camera navigation during real procedures already improves laparoscopic psychomotor skills to more than the basic level.

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Chapter 4

The influence of different training schedules on the learning of psychomotor skills for endoscopic surgery

E.G.G. Verdaasdonk[1,2], L.P.S. Stassen[1,2], R.P.J. van Wijk[1], J. Dankelman[1]

1 Department of BioMechanical Engineering, Faculty of Mechanical, Maritime & Materials Engineering, Delft University of Technology, Delft, the Netherlands
2 Department of Surgery, Reinier de Graaf Group, Delft, the Netherlands

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ABSTRACT

Background: Psychomotor skills for endoscopic surgery can be trained with virtual reality simulators. Distributed training is more effective than massed training, but it is unclear if distributed training over several days is more effective than distributed training within 1 day. This study aimed to determine which of these two options is the most effective for training endoscopic psychomotor skills.

Methods: Students with no endoscopic experience were randomly assigned to either distributed training on three consecutive days (Group A, n=10) or distributed training within one day (Group B, n=10). For this study the SIMENDO virtual reality simulator for endoscopic skills was used. Training involved 12 repetitions of three different exercises (drop balls, needle manipulation, 30°-endoscope) in differently distributed training schedules. All the participants performed a post-training test (post-test) for the trained tasks, 7 days after the training. The parameters measured were time, non-target environment collisions and instrument path length.

Results: There were no significant differences between the groups in the first training session for all the parameters. In the post-test, group A (training over several days) performed 18.7% faster than group B (training on 1 day) (p=0.013). The collision and path length scores for group A did not differ significantly from the scores for group B.

Conclusion: The distributed group trained over several days was faster, with the same number of errors and instrument path length used. Psychomotor skill training for endoscopic surgery distributed on several days is superior to training on 1 day.

INTRODUCTION

In recent years, training of psychomotor skills for endoscopic surgery has been shifted from the operation theatre to the skills laboratory. To overcome the difficulties in endoscopy such as disturbed hand-eye coordination, visual feedback from a three (3D) environment dimensional to a 2D monitor, and working with long instruments, the surgeon has to practice. Several studies have shown that virtual reality (VR) simulators are useful and valid tools for training psychomotor skills, such as hand-eye coordination [1-6]. Currently, the training of these skills generally is undertaken in structured courses during one or two days and continues inside the clinic. With the reduced trainee working hours and increased pressure on the use of health care facilities, training time needs to be used efficiently. It is therefore important to know how long students should train, when they should train, and what the influence is of different training schedules on the performance.

The effect of different training schedules with respect to its distribution has been studied in other fields such as psychology and neuroscience [7-9]. Distributed training refers to a practice schedule in which periods of training are interspersed with rest periods; massed practice refers to a continuous block of training. Meta-analytic reviews indicate that distributed training results in a better retention of motor skills than massed training. However, the review authors [9] also state that the magnitude of the distributed practice effect depends highly on the tasks trained. Furthermore, the skills studied in the mentioned review involve simple motor behaviour and not the less intuitive skills involved in endoscopic surgery (e.g. disturbed eye-hand coordination). Only one study, by Macky [10], found that distributed endoscopic motor skills training with short breaks (several minutes) is superior to massed training (no breaks) within one single day. However, it is not clear if distributed training on several days is more effective than distributed training over one single day. Furthermore, it is unclear whether the effect can already be measured at the end of the training, or whether it is only measurable after several days.

Evidence from a neurological study showed that one night of sleep after training motor skills enhanced the activity of motor areas in the brain [11]. This would suggest that sleep can enhance the learning effect of motor skills needed to perform endoscopic surgery.

The goal of the study was to determine the most effective schedule for training psychomotor skills to perform endoscopic surgery using a VR simulator: distributed training over several days versus distributed training on 1 day.

METHODS

Students who had no prior experience with endoscopic surgery or endoscopic skills training were recruited from the Faculty of Medicine and Health Sciences of the Erasmus University of Rotterdam and the Delft University of Technology. These students were randomly assigned to two groups of 10 subjects each: group A (training over several days) and group B (training on 1 day with short breaks).

All participants filled out a questionnaire about their personal characteristics (age, gender, dominant hand and educational background), prior experience (VR games and musical instruments), motivation to participate (rating scale of 1 to 10), and dexterity (self-rated on a scale of 1 to 10) in terms of how they would perform (performance prediction) on the simulator. In the rating scales used, 1 was considered the lowest and 10 the highest score for own motivation, dexterity, and performance prediction.

For this study, the SIMENDO VR-simulator (Delltatech, Rotterdam, the Netherlands) was used. Previously, face- and content validity of this simulator was established for the single instrument exercises, and the first results for construct validity were shown [12]. It is a low fidelity VR simulator, developed to train basic endoscopic skills such as eye-hand coordination with the use of abstract tasks. The hardware of the simulator, in this study, consists of two separate instruments that are connected to a laptop with a USB cable. The 15.4-inch screen was placed on a table in front of the participant behind the hardware of the simulator. The training took place in a quiet room and was observed by one or two researcher.

Participants were trained with the following tasks: drop the balls (picking and placing three balls in holes with one instrument in the right hand), the ring (passing a needle through two rings with two instruments, one in each hand) and 30-degree endoscope handling (picking and placing four balls on a box with an instrument in the right and a camera in the left hand). The parameters measured were: time to complete the task (seconds), collisions of instruments with non-target environment (number) and the path length of the right and left instrument (arbitrary units).

The training for group A consisted of 12 repetitions divided over three consecutive days. Thus, each day, a training session of 4 repetitions was performed. Group B performed 12 repetitions within a single day. After each session of four repetitions, the group B participants had a 15-minute break. Figure 1 displays the training schedules for both groups. Each repetition was measured and automatically stored in a Microsoft Access 2002 database connected to the simulator software.

A post-training test (post-test) was performed 7 days after the training. For this test, the same tasks performed in the training were used and measured for one repetition. The total number of repetitions (n=12), and the interval between the end of the last training session and the post-test (7 days) were equal for the two groups.

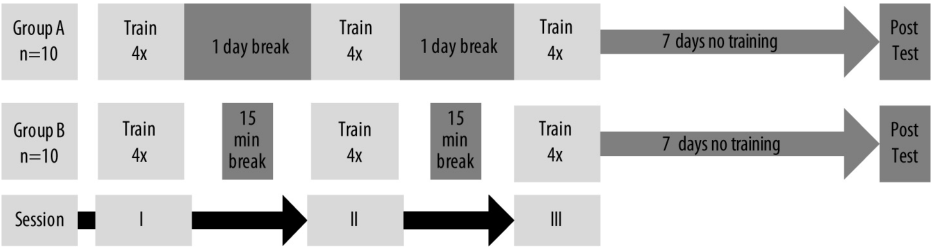

Figure 1. Training schedule for group A (distributed training over several days) and group B (distributed training on one day)

Statistics and calculations

The answers on the questionnaires were compared for both groups. The parameter scores of all the tasks were summated for each repetition and analyzed. Subsequently, the parameter scores also were analyzed for each task separately per repetition and compared between the two groups. Differences between groups were tested for statistical significance using the Mann-Whitney U test for non-parametric data.

RESULTS

Table 1 shows the results for the answers to the questionnaire. There were no differences between the characteristics and the ratings of two groups.

Table 1. Characteristics of the participants for group A (training on several days) and group B (training on one day).

Groups **Characteristic**	**Group A**	**Group B**
General		
Median age in years (range)	21(19-27)	21(19-25)
Male : Female	6:4	6:4
Left hand dominance (n)	2	2
Medical background (n)	8	8
Prior experience		
Some experience with VR games (n)	4	7
Playing a musical instrument (n)	6	5
Motivation to learn skills for endoscopic surgery self rating*		
Median rate (range)	8 (8-10)	8 (8-10)
Dexterity self rating*		
Median rate (range)	7 (7-10)	6.5 (5-9)
Performance prediction self rating*		
Median rate (range)	6 (6-7)	6 (6-7)

** Rating on a scale of 1 to 10 in which 1 was lowest and 10 the highest score*

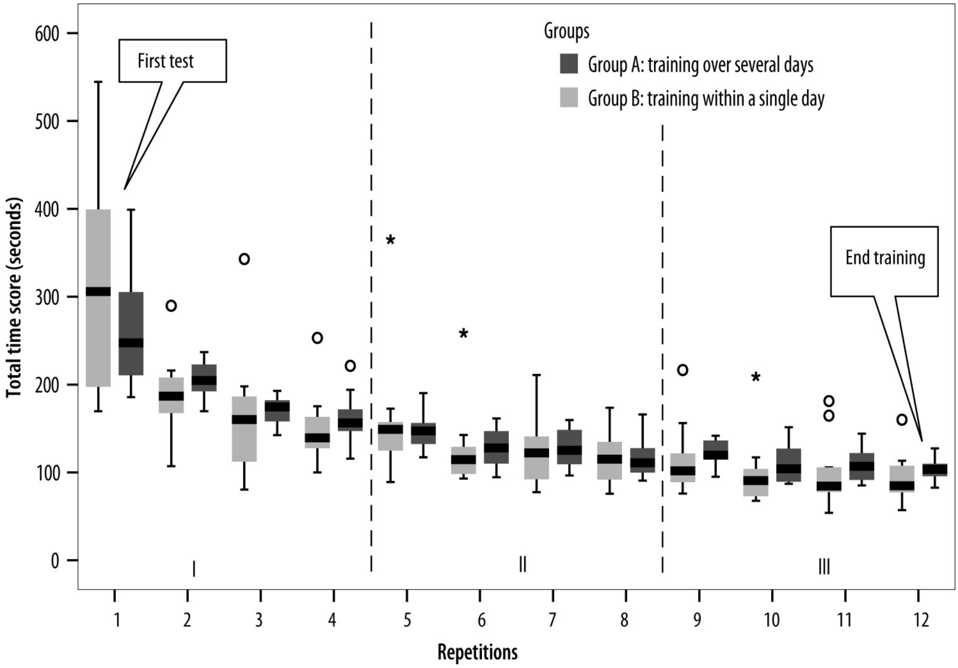

Figure 2. Box plots of time scores summed for all three tasks showing the difference between groups A (training over several days) and B (training within a single day). The boxes represent the interquartile range. The bars medians and the whiskers represent the first percentile range excluding outliers. The circles represent outliers, and the asterisks represent extreme outliers. Roman numerals I, II and III correspond to the training schedule in Figure 1.

Figure 2 shows the results in box-plots of the total time score (seconds) for all three tasks summated per repetition for both groups. Figure 3 shows the results in the end of the training (end-training) and post-test results with respect to time (seconds).

Table 2 presents the total scores for the first training cycle, the end of the training, and post-test. In the post-test, group A (training over several days) performed 18.7% faster than group B (training on 1 day) (p=0.013). Group A tended to make fewer collisions, and had a shorter path length for the right instrument and longer for left instrument, but these scores did not differ significantly from group B.

Comparing of the medians for each of the summated parameter scores between the training sessions showed no significant differences within the groups between repetition 4 to 5, and repetition 8 to 9. Between these repetitions both groups received a period of no training: 20 to 24 hours for group A and 15 minutes for group B.

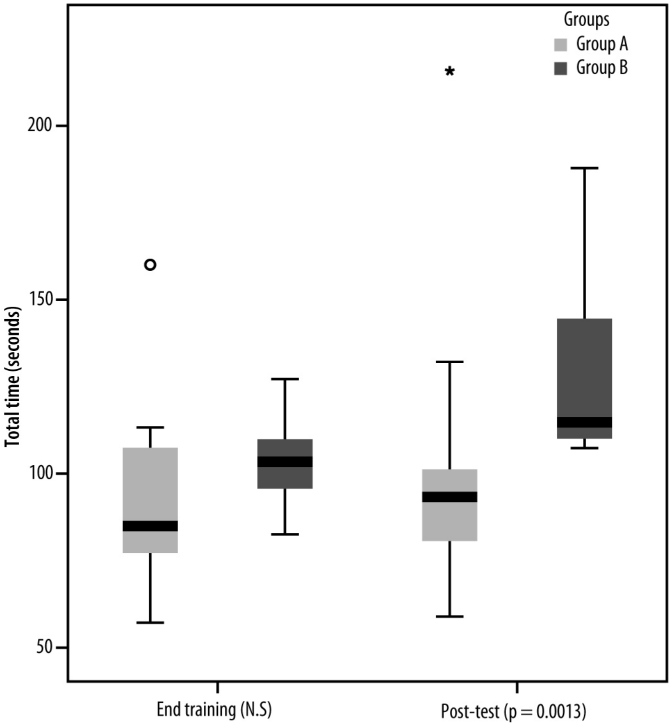

Figure 3. Total time scores of group A (training over several days) and B (training within a single day) for the end training and after 7 days of no training on the posttraining test (posttest)

Table 2. Median scores in the post-training test (post-test) of all tasks summated.

Parameter (medians)		Group A	Group B	Relative (%) difference group A vs B‡	*P-value*
Time (seconds)	first test	305.9	247.5	23.6	Ns
	end-training	85.0	103.0	-17.5	Ns
	post-test	93.3	114.8	-18.7	0.013
Collisions (number)	first test	16.0	13.0	23.1	Ns
	end-training	3.0	4.0	-25.5	Ns
	post-test	4.0	4.5	-11.1	Ns
Path length Right(AU)*	first test	64.2	77.9	-17.6	Ns
	end-training	51.8	48.6	6.5	Ns
	post-test	50.3	52.9	-5.0	Ns
Path length Left (AU)*	first test	32.1	33.8	-5.3	Ns
	end-training	18.3	16.5	10.9	Ns
	post-test	20.7	19.2	7.8	Ns

** AU = Arbitrary Units*

‡ (Score group A - score group B) / score group B 100% = Relative difference*

First test: summated scores on the first training session

End-training: summated scores of the 12th training session

Post-test: summated scores of test 7 days after the 12th training session

Analyses of the scores for each task separately showed that the time score significantly differed between the groups for drop the balls (p=0.023), and the ring (p=0.049), but not for the 30° endoscope (Figure 4a-c). Furthermore, other parameter scores (collisions and path length) did not differ significantly.

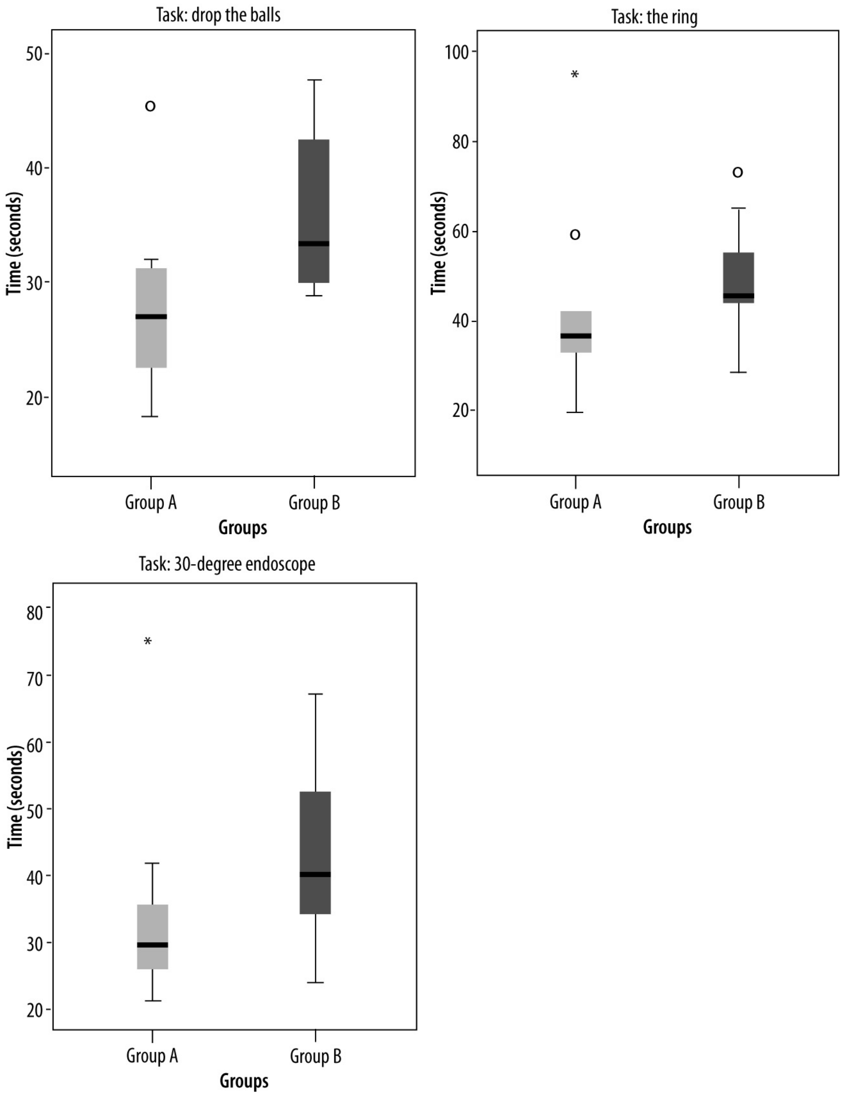

Figure 4. Difference in time scores on the posttraining test between groups A (training on several days) and B (training on 1 day) after 7 days of no training for the following tasks: dropt the balls (A<B; p=0.023), the ring (A<B; $p=0.049$), 30°endoscope (A<B, nonsignificant difference)

DISCUSSION

In the current study, the time scores show that the group training over several days was 18.7% faster compared to subjects training within a single day when tested, 7 days after the last training session. There were no statistically significant differences between the groups in other performance scores such as collisions and path length.

Although it is a common adage that "practice makes perfect", recent studies suggest that training alone is not the only determinant of motor skills learning. Time taken between two repetitions also seems to have an important influence. Evidence from general motor skills research and endoscopic psychomotor skills , have demonstrated that distributed training is superior to massed training [8,10].

Skills acquisition is defined by the gain in performance during the training itself, during either in distributed or massed schedules. The degree to which an acquired skill is retained over the passage of time is called *skill retention* [13]. The phenomenon of performance continuation in a stable state (permanent retention) or even improvement after training has ended is known as *consolidation*.

Other studies have shown that significant gains in motor performance are apparent in both speed and accuracy when measured 24 hours after training, even with no further training during the intervening interval [14,15]. The process of consolidation assumes long-term neurophysiologic changes that allow for the relatively permanent retention of learned behaviour [16].

There is no clear explanation for why distributed training tends to be more effective and enhances consolidation, but it seems that during the rest periods, changes take place in the brain. It is known that motor skill improvement is sleep dependent [11,17] and that rest results in better consolidation. Apparently, the brain needs rest periods to store learned motor skills adequately and to prevent fatigue or possible effects of boredom**.** This may have important implications for the learning of psychomotor skills needed to perform endoscopic surgery. However, these findings apply for learning direct motor skills (e.g., tapping of fingers) and differ partly findings that apply for the learning psychomotor skills for endoscopic surgery.

In our study there was no significant improvement of performance scores between the training blocks in the two training schedules. Neither short nor long breaks enhanced performance significantly during acquisition. Also, no difference in performance gain was found within the groups measured at the end of the training (end-training). However, in the post-training test (post-test), 7 days after the last training, showed that performance time had increased slightly for both groups. Nevertheless, the increase in group B was significantly greater than in group A (i.e., group A was faster than group B). Thus, training including breaks of a night of sleep improves retention for performance time.

No significant difference was observed regarding the number of collisions and path length score between both groups. The exact reason for this remains unclear. The most likely reason concerning the collisions would seem a cognitive component in learning to avoid non target structures. In the simulator used, each time a collisions occurs the user is directly warned by a sound. The direct sound warning was used as a reminder to subjects that they should work carefully and also as an alternative to force feedback within this simulator. As a consequence, the subjects quickly learn to reduce the collisions and seem to pay less attention to the other parameters. Although both groups had the same number of collision and had the same path length, the distributed group (group A) performed the exercises faster. Therefore, training scheduled over several days is preferable for training of endoscopic psychomotor skills.

An alternative explanation could be that the participants did not have enough training repetitions, and therefore were not completely out of their learning-curve. Krakauer [18], using a cursor dexterity task on a computer screen in which trainees did not see their hands, found that more initial training resulted in better retention. Hence, more repetitions of the tasks before the post test could have increased the difference between group A and B. The study of Krakauer also showed that a longer time interval between the repetitions (acquisition) than 24 hours was less effective.

With respect to path length, the decrease in score after 7 days was less than for time and collisions (Table 2). Trainees inexperienced in endoscopic techniques tended to make a lot of inadequate movements, especially in the beginning of the training. However, the acquisition in term of path length occurs relatively fast and had good retention. Hence, the most effective manner to bring the instrument from one place to the other is learned fast and more easily stored in the motor memory.

The study results support the use of a training schedule distributed over several days for the training of endoscopic motor skills. However, for practical reasons training lasting more than two days or more is not always possible. Most "non-university" training hospitals lack adequate training equipment or structural organisation of such training sessions frequently interferes with the busy clinical setting. Our results showed that performance scores decreased up to 19% within a week. Taking into account that motor skills for endoscopic surgery may decrease to 81% within a month [19], if not used frequently, trainees should be advised to perform their first procedure at least within one week after the course or receive training aimed on maintenance of their motor skills.

A paradigm shift to strictly criterion based training (i.e. a trainee should show competence by passing certain scores in the simulation) to the application of a training schedule that results in optimal skills retention over time seems warranted. The next step in research should be to investigate what the effect is of distributed training schedules is on long-term retention and consolidation of endoscopic motor skills.

CONCLUSION

The group with training over several days was faster, with the same number of errors and instrument path length used. Psychomotor skill training for endoscopic surgery distributed over several days is superior to training within 1 day. Further research should focus on studying the long-term effects of distributed psychomotor skills training.

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Chapter 5

Transfer validity of laparoscopic knot-tying training on a VR simulator to a realistic environment: a randomized controlled trial

E.G.G. Verdaasdonk [1,2], J. Dankelman [1], J.F. Lange [3], L.P.S. Stassen [1,2]

1 Department of BioMechanical Engineering, Faculty of Mechanical, Marine and Materials Engineering, Delft University of Technology, Delft, the Netherlands
2 Department of Surgery, Reinier de Graaf Group, Delft, the Netherlands
3 Department of Surgery, Erasmus Medical Center Rotterdam, Rotterdam, the Netherlands

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ABSTRACT

Background: Laparoscopic suturing is one of the most difficult tasks in endoscopic surgery, requiring extensive training. The aim of this study was to determine the transfer validity of knot-tying training on a virtual reality (VR) simulator to a realistic laparoscopic environment.

Methods: Twenty surgical trainees underwent basic eye-hand coordination training on a VR simulator (SIMENDO, DelltaTech, Rotterdam, the Netherlands) until predefined performance criteria were met. Then, they were randomised into two groups. Group A (experimental group) received additional training with the knot-tying module on the simulator during which they had to tie a double laparoscopic knot 10 times. Group B (controls) did not receive additional manual training.

Within a week the participants tied a double knot in the abdominal cavity of an anaesthetised porcine model. Their performance was captured on digital video and coded. Objective analysis parameters were: time taken to tie the knot and number of predefined errors made. Subjective assessments were also made by two laparoscopic surgeons using a global rating list with a five-point Likert scale.

Results: Trainees in group A (n=9) were significantly faster than the controls (n=10), with a median of 262 versus 374 seconds (*p=0.034*). Group A made a significantly lower number of errors than the controls (median of 24 versus 36 errors, *p=0.030)*. Subjective assessments by the laparoscopic experts did not show any significant differences in economy of movement and erroneous behaviour between the two groups.

Conclusion: Surgical trainees who received knot-tying training on the VR simulator were faster and made fewer errors than the controls. The VR module is a useful tool to train laparoscopic knot-tying. Opportunities arose to improve simulator-based instruction that might enhance future training.

INTRODUCTION

Laparoscopic suturing and intra-corporeal knot-tying are among the most difficult tasks that involve eye-hand coordination skills and the knowledge of the correct steps. Proficiency in laparoscopic suturing is an important requirement for surgeons who want to perform advanced laparoscopic procedures. Figert et al. [1] demonstrated that experience with open surgical techniques could not be transferred to laparoscopic knot tying techniques and concluded that specific training is needed to develop laparoscopic knot tying skills.

Training hospitals throughout the world are becoming increasingly aware that governments have reduced the working hours of medical trainees. Solutions to shorten training time, reduce cost, increase safety and potentially improve patient outcome, lie within specially developed training tools that can be used in a safe and controlled environment outside the operating theatre. However, new training models should be validated before they can be effectively and safely incorporated into the curriculum. This is particularly important when the trained behaviour is becoming more complex and involves more procedural knowledge such as in laparoscopic suturing.

In the literature, several studies analysed how laparoscopic suturing performance was affected by video instruction [2], dedicated courses [3,4], mechanical box trainers [5-7], suture material [8] and assisting devices [9]. These studies showed different outcomes, or were performed in a non-randomised setting, or lacked statistical significance.

Two studies on laparoscopic knot-tying on a box simulator did not show any significant differences between the effect of a short dedicated course (lecturing, video instruction and proctoring) and instruction with an instruction manual [3], or between instruction and passive observation [2]. One large, but non-randomized study showed significant improvement in intracorporeal suturing after skills training with basic drills on a box trainer [7]. Another study, that compared four different training strategies for laparoscopic suturing, also found that the trainees who performed basic drills on a VR or on a box trainer had a better performance than the control group. Performance was evaluated by assessing the learning curve of 10 intra-corporal knot placements on foam in a box trainer. Only one randomized controlled trial showed that structured suturing course on a box trainer led to positive skills transfer to the laparoscopic environment on a porcine model [6]. In summary, several studies have been conducted on suture training, but the effect of VR simulator training with on performance in an anatomically realistic environment has not been studied in a randomised trial yet. Thus, there is little evidence that specific suturing or knot-tying skills learned during VR training transfers to the real task.

The aim of this study was to determine whether knot-tying training on a VR simulator led to the transfer of skills to a realistic environment (anaesthetised porcine model). Furthermore, it was hypothesized that additional manual training on the simulator would be more effective than repeated video viewing of the knot-tying procedure on the VR simulator.

METHODS

Description of the training system

In this study the SIMENDO VR simulator (DelltaTech, Rotterdam, the Netherlands) was used. Originally, the simulator was designed to train eye-hand coordination skills using abstract tasks such as camera navigation and basic drills such as "pick and place" tasks. Recently, a knot-tying module has also been added (Figure 1). Driving the needle trough "the tissue" has not been included in this module.

The knot-tying module consists of three separate steps in which the user learns how to tie a double surgical knot. In the first step, a knot has to be tied with a single throw of the tread around the left or the right instrument. In the next step, two single knots have to be tied in opposite directions. Thirdly, a double surgical knot has to be tied with an additional securing knot. A demonstration video clip can be viewed of each step of the simulated knot-tying procedure described above.

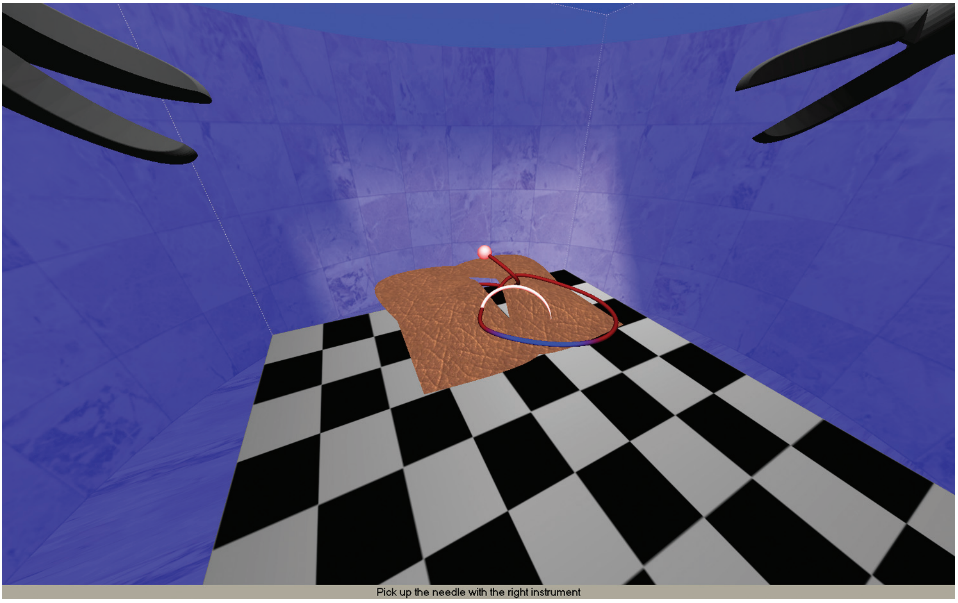

Figure 1. Image of knot-tying module in VR simulator

Study subjects

First and second year surgical trainees who enrolled for laparoscopic basic skills course volunteered to take part in the trial after basic motor skills training on the virtual reality simulator. The laparoscopic course consists of lectures, multi-media training and one day "hands-on" training on an anaesthetised porcine model. Normally, suturing is not part of the course goals. Subjects with experience in laparoscopic knot-tying or suturing (on a laboratory model VR or Box models, or in the operation theatre), were excluded. All participants gave written informed consent and understood the study conditions, and exclusion criteria. They were not informed about the primary endpoints of the trial.

Study design and training protocol

Figure 2 shows a flow diagram of the study. All participants underwent eye-hand coordination training with basic drills on the SIMENDO simulator until pre-defined performance criteria were met. Six tasks from the beginner module of SimSoft 1.0 were used. These tasks have been described and studied previously [10]. Each participant was given as much training as needed to achieve the defined performance level. Subsequently, they were randomized into two groups using closed envelopes. In group A (experimental group), all the exercises in the knot-tying module were made available to the participants including video instruction on how to tie the double surgical knot on the simulator to enable them to train voluntarily. The experimental group were obligated to tie double surgical knot on the laparoscopic VR simulator at least 10 times. Group B (control group), did not receive any further manual VR training. Instead they viewed three consecutive video demonstrations of the VR knot-tying procedure on the simulator.

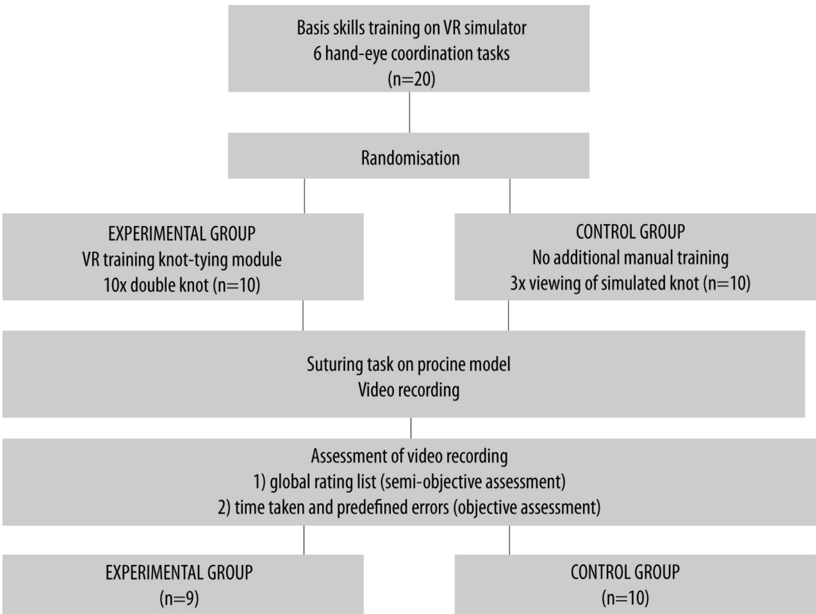

Figure 2. Flow diagram of the study

Performance and assessment on the porcine model

Within a week after participating in group A or group B all trainees had to tie a double laparoscopic knot on an anaesthetised porcine model. The entire performance in the animal model was recorded digitally and coded for each individual. The time taken to drive the needle through the tissue was measured separately from the time taken to tie the knot.

Objective error assessments were made using a modified list from Figert et al. [1] (Table 1). Additionally, subjective assessments were made independently by two expert laparoscopic surgeons (>1000 laparoscopic procedures performed and extensive laparoscopic suturing experience) using a global rating scale adapted from Grantcharov et al. [11] (Table 2). The ratings given by each expert on the subcategories: economy of movement (unnecessary movements and confidence of movements) and error assessment (respect for tissue and precision of the knot-tying technique) were summated and then compared. The experts were blinded to the training status of the participants.

Statistical methods

Data were analysed using the SPSS 12.01 (SPSS, Chicago, Illisnois, USA) software package. Differences in the objective and semi-objective measurements between the two groups were analysed using the Mann-Whitney-U test for non-parametric data.

The level of agreement between the semi-objective assessments made by the two experts was estimated by Cohen's κ coefficient. $P<0.05$ was considered to be statistically significant.

Table 1. Global rating scale to assess laparoscopic knot-tying (adapted from Grantcharov et al. [11])

Economy of movements	**1**	**2**	**3**	**4**	**5**
Unnecessary movements	Clear economy of movements and maximum efficiency		Some unnecessary movement		Many unnecessary movement
	1	2	3	4	5
Confidence of movements	Fluent movement with instruments		Competent use of instruments, but occasionally stiff or awkward		Repeated tentative awkward or inappropriate movement with instruments
Error assessment	1	2	3	4	5
Respect for tissue	Consistently handled tissue appropriately with minimal damage		Handled tissue carefully, but occasionally caused inadvertent damage		Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments
	1	2	3	4	5
Precision of knot tying technique	Fluent secure and correct technique in all stages of knot-tying		Careful technique with occasional errors		Imprecise, wrong technique to approach knot-tying

Table 2. Objective quantification of errors during laparoscopic knot-tying (adapted from Figert et al. [1])

	Group A (experimental) n=10	Group B (control) n=10	*P-value* [a]
No. of times	Median (range)	Median (range)	
1. Instrument-to-instrument needle transfer	1 (0-2)	3 (0-6)	0.071
2. Instrument-to-instrument suture transfer	0 (0-2)	0 (0-4)	0.607
3. Needle dropped	1(0-3)	3 (0-8)	0.027
4. Suture dropped	2 (0-8)	4 (0-9)	0.097
5. Suture fell off the instrument	0 (0-2)	1 (0-4)	0.142
6. Attempted loops	4 (0-10)	4 (0-18)	0.743
7. Instruments out of field of vision	12 (1-23)	15 (3-26)	0.487
8. Needle tip touched the tissue	1 (0-4)	5 (1-10)	0.012
9. Successive new attempts at knot-tying	0	0 (0-1)	0.343
10. Not tightening the knot	0	0	1.000
11. Not completing the knot	0	0 (0-1)	0.343
12. Double loop in knot	0 (0-2)	1 (0-2)	0.477
Total error score	24 (10-40)	36 (17-54)	0.030
Total time taken to drive the needle through the tissue (seconds)	118 (60-510)	203 (70-647)	0.253
Total time taken to tie knot (seconds)	262 (69-406)	374 (169-600)	0.034

[a] *Mann-Whitney U test (two-tailed)*

RESULTS

After randomisation, there were 10 surgical trainees in each group (Figure 2). Each group comprised 3 women and 7 men.

The video recording of one of the participants in group A (experimental group) failed during the knot-tying task on the porcine model, so this person had to be excluded. After the suture performance in the porcine model one participant from group A was excluded due to video recording problems.

Figure 3a shows the box-plot of the time taken to tie the knot. The experimental (group A, n=9) tied the knot 30% faster than the controls (group B, n=10) (p=0.034) and they made a significantly lower number of errors (33%) than the control group (median 24, range 17-54 versus 36, range 10-40; p=0.030). Figure 3b shows a box plot of the number of errors in the two groups Table 2 shows the details of the number of errors and the time taken to tie the knot. The experimental group dropped the needle a lower number of times and made less frequent unnecessary contact with the tip of the needle against the tissue than the control group ($p<0.05$). There were no statistically significant differences in the other error items and time taken to drive the needle through the tissue between the two groups.

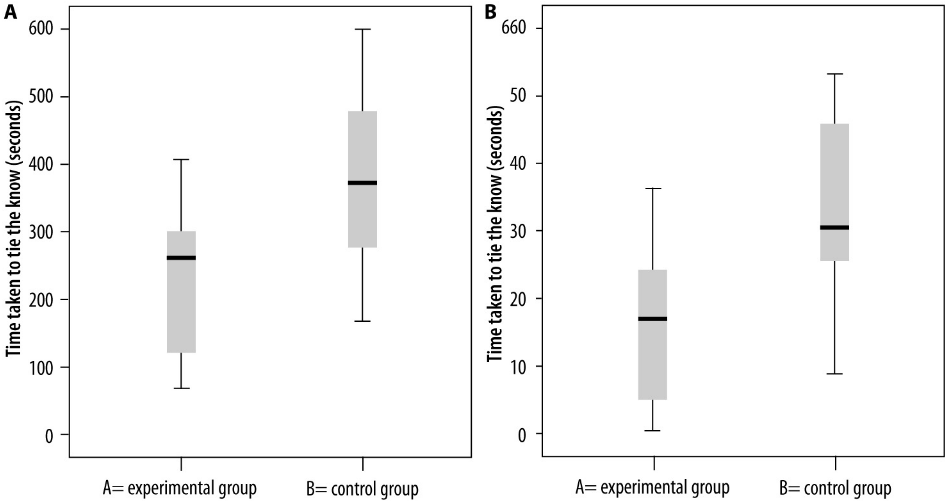

Figure 3. a) total time taken to tie the knot (experimental versus control, *p*=0.034; 3b) error score (experimental versus control, *p*=0.030)

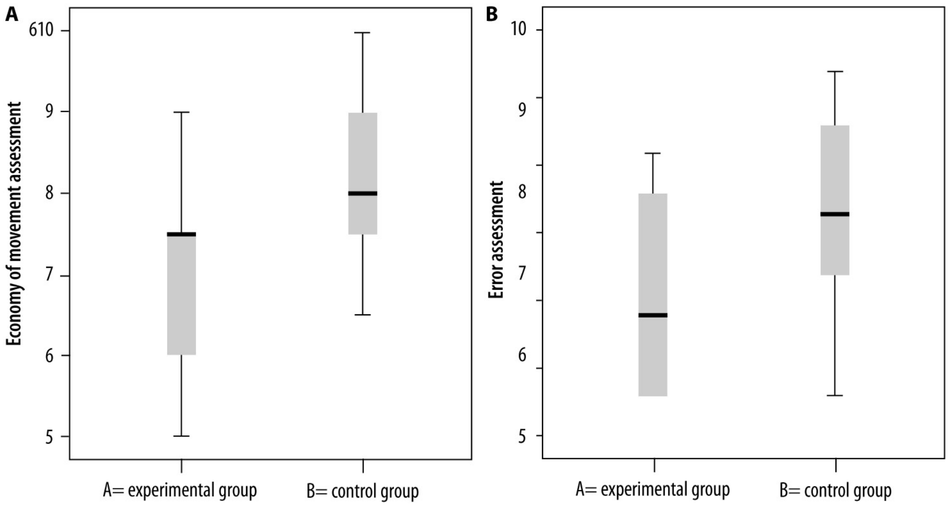

Figure 4. 4a) global rating scale for economy of movement (experimental versus control, p=ns) 4b) global rating scale for error assessment (experimental versus control, p=ns)

Figure 4a and 4b show the assessments based on the global rating list of economy of movement and erroneous behaviour (error assessment), respectively. There were no significant differences in the scores assigned to the groups by the two experts (economy of movement: p=0.114; error assessment: p=0.148). Furthermore, there were no significant correlations between the scores assigned to each participant by the two assessors.

DISCUSSION

This study was designed to determine whether skills acquired during specific knot-tying training on a VR simulator could be transferred to the task in a realistic laparoscopic environment. The participants who received knot-tying training (experimental group) were significantly faster (30%) and made fewer errors (33%) than the controls. The subjective assessments list with a global scale did not show significant differences between the groups.

The outcome of the performance assessment in the real tasks depends strongly on the objectivity and reliability of the method used. Measurement of the time taken to perform the task is very objective and reliable. Besides time, two other assessments methods were made on the basis of global rating scale and a list of objective pre-defined errors.

The global rating scale is a semiobjective assessment method and was originally designed to assess how a surgeon performs a dissection of the gallbladder during a laparoscopic cholecystectomy. Grantcharov used the scale successfully to measure the transfer effect of basic skills training effect on VR simulator with acceptable to good agreement between assessors [11]. In our study, however, the global rating scale did not detect any significant differences between the two groups. There was also insufficient agreement between the ratings assigned to each individual by the two experts. The assessment of the observers was difficult to compare. Therefore, we have to conclude that the global rating list for our study is not a valid and reliable method for knot-tying assessment. Probably, the knot-tying skills and behaviour are too different from the dissection skills. The lack of agreement may have been caused also by differences in opinion about how a double surgical knot should ideally be tied. In our discussions with the expert surgeons, we identified differences in their weighing of the forces used during tightening the knot, their estimations of self-assurance during the knot-tying task, and the adherence to a clear, logical step by step procedure. In addition, the experts had different views on the positioning and manipulation of the needle/needle holder and efficiency of movement. These opinions influenced the assessment.

A more objective method to assess the knot-tying was the method adapted from Figert et al. (Table 2). In this method specific error items were defined. The advantage is that these error items can be easily scored by simply counting them. In contrast with the global rating scale, the specific error list revealed significant and relevant differences. The experimental group clearly made a lower number of errors than the control group. This type of assessment method provides objective measurements of the occurrence of specific behaviour. Such a tool is particularly useful in the present type of research, because it is easy to use and less time-consuming than a global rating scale.

In the present study, the quality of the knot was not assessed. Ritter et al showed that the knot quality with a tensiometer was superior to execution time for assessment of laparoscopic knot-tying performance by experienced surgeons [12]. The objectivity of the assessment could have been further increased if we had determined the quality of the knot as well, for example by determination of the knot quality score. In addition to time and errors used in our study, future research should include also assessment of the knot quality.

During the course of the trial, opportunities for future study and training were identified that can probably lead to profound positive effects of knot-tying training on the VR simulator. Korndorfer indicated that training to reach an expert-based level would most likely enhance the transfer effect to a real situation [6]. For example, evaluations could be made of the effect of longer repetitive toward training more specific performance goals rather than a pre-specified number of repetitions. This way learning can be tailored to the level of the trainee and not to the available time of a course. However, for the purpose of this study the experimental group repeated the double knot at least 10 times, but did not train until specific performance goals were achieved. (e.g., within a certain time frame, path length, etc.). Although the objective assessment method showed a clear benefit from the VR training the laparoscopic experts recommended additional practice before suturing on patients.

The video recording of the knot-tying on the porcine model revealed potential set of cognitive rules and strategies that could be incorporated into the training module. These cognitive rules can be derived from the more serious errors listed with in Table 2. For example, trainees in groups A and B frequently moved their instruments out of the field of vision, which is a dangerous manoeuvre, especially when the instrument is holding a sharp needle. Currently, rules are being implemented in the VR module that obligates trainees to keep their instruments in sight when tying the knot. Another important issue was the number of times the tip accidentally point touched the tissue. On average this occurred five times more often in the control group, but this erroneous behaviour was also seen in the experimental group. Attention should also be paid to the frequently unnecessary transfer of the needle from one instrument to the other. Error parameters can easily be included in the simulator module such that erroneous behaviour as mentioned above has a negative influence on the performance score of the trainee.

An important advantage of VR simulation is the capacity to break complex tasks down in smaller parts or chunks. The first task in the knot-tying module is to complete a single knot with one throw. Then, the exercise advances gradually toward the double knot. Breaking down the task on the simulator was combined with another strategy called backward chaining, which has previously proposed by others to be helpful strategy to learn intracorporeal suturing and knot tying [13]. In backward chaining the exercise starts at the end of a complex task (i.e, the last step the complete task minus 1 step). The reverse single knot is in fact the last step of a double knot. The trainees in experimental group were free in going back and forth in the training module and view short video clips of the knot-tying instruction. The purpose of the video clip instructions was to replace an actual instructor.

In conclusion, the VR simulator under study can provide effective training of knot-tying skills. VR simulator training may maximize the efficiency of instruction from experts, but to achieve safe suturing on patients additional training is recommended. Furthermore, opportunities arose to improve simulator-based instruction that might enhance future training, such as the incorporation of assessment parameters for needle manipulation, respect for tissue and environment.

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Chapter 6

Incorporation of proficiency criteria for basic laparoscopic skills training: how does it work?

E.G.G. Verdaasdonk [1,2], J. Dankelman[1], J.F. Lange[3], L.P.S. Stassen[1,2]

1 Department of BioMechanical Engineering, Faculty of Mechanical, Maritime & Materials Engineering, Delft University of Technology, Delft, the Netherlands
2 Department of Surgery, Reinier de Graaf Group, Delft, the Netherlands
3 Department of Surgery, Erasmus Medical Centre Rotterdam, Rotterdam, the Netherlands

Surgical Endoscopy (in press)

ABSTRACT

Background: It is desirable that surgical trainees are proficient in basic laparoscopic motor skills (eye-hand coordination). The present study evaluated the use of predefined proficiency criteria on a basic virtual reality (VR) simulator in preparation for a laparoscopic course on animal models.

Methods: Twenty-eight surgical trainees who enrolled for a basic laparoscopic course were trained on a basic (VR) simulator until their performance met predefined criteria. Two different criteria were defined, based on the performance of experienced laparoscopic surgeons on the simulator. In the first group (n=10), the criteria were set at the 75th percentile of the laparoscopic surgeons' performance on the simulator and in the second group, at the 50th percentile (n=18). Training time and number of attempts needed until the performance criteria were met were measured.

Results: In the first group, training time needed to pass the test ranged from 29 to 77 minutes (median: 63minutes) with a range of 43 to 90 attempts (median 61 attempts). In the second group, training time ranged from 38 to 180 minutes (median 80 minutes) with a range of 55 to 233 attempts (median 95 attempts). Experience with assisting or performing laparoscopic procedures varied widely and was not correlated with the training time and number of attempts needed to pass the criteria.

Conclusions: The performance criteria for training laparoscopic motor skills on a (VR) simulator resulted in wide variation between surgical trainees in time and number of attempts needed to pass the criteria. This demands training courses with a flexible time span tailored to the individual level of the trainee.

INTRODUCTION

Laparoscopic training courses have become important education tools in the surgical curriculum. Their ultimate aim is to reduce the learning curve of surgeons on actual patients. Most courses take two or more days and consist of lectures, laparoscopy videos and most importantly, motor skills training. Training of laparoscopic motor skills is a central part of these courses.

VR trainers have become attractive and valuable tools to train surgeons in a non-patient, non-animal environment [1,2] and proven effective in learning basic skills that can be transferred to real procedures [3,4]. Especially, the automated assessment, feedback and unlimited use of standardized tasks seem to offer advantages. However, due to new working hour directives of 80 hours per week in the US and 48 hours in Europe by 2011, training courses must not only be effective but also efficient. The learning effect should be maximal while using the least amount of time.

Most training courses employ a fixed duration for training while learning may be highly dependent on individual characteristics such as innate ability, previous experience and motivation. In an optimal training course the available training time should be tailored to the individual level of the trainee. Therefore, proficiency of a given skill should depend on passing a clear criterion rather than an arbitrary amount of time or repetitions. Surgical society has only recently entered the realm of criterion-based training. Standards on which to define training endpoints are receiving attention [5] and some studies indicated the benefits of using preset proficiency criteria [6,7]. Implementation of proficiency criteria may allow trainees to reliably achieve maximal benefit while minimizing unnecessary training [8]. However, the practical consequences of using such endpoints on course design and time schedule are unclear.

The aim of the present study was to assess the consequences of a criterion-based training programme to train basic laparoscopic surgery skills using a VR simulator.

Two different proficiency criteria levels, based on the performance of experienced laparoscopic surgeons, were applied to train eye-hand coordination: easy versus difficult. The feasibility, usefulness and challenge of these levels were evaluated. The potential consequences and difficulties of defining performance criteria for VR simulators for the purpose of recruitment, selection and licensing are discussed.

METHODS

In 2006, all the surgical trainees who enrolled for the basic laparoscopic skills course in Rotterdam (Skills Centre, Erasmus Medical Centre Rotterdam, The Netherlands) were required to achieve a expert-based proficiency criterion on a VR simulator prior to embarking on the animal models. Trainees were allowed to train as long as they needed in their spare time until the proficiency criterion was reached. Training took place within two weeks prior to the training on the animal model.

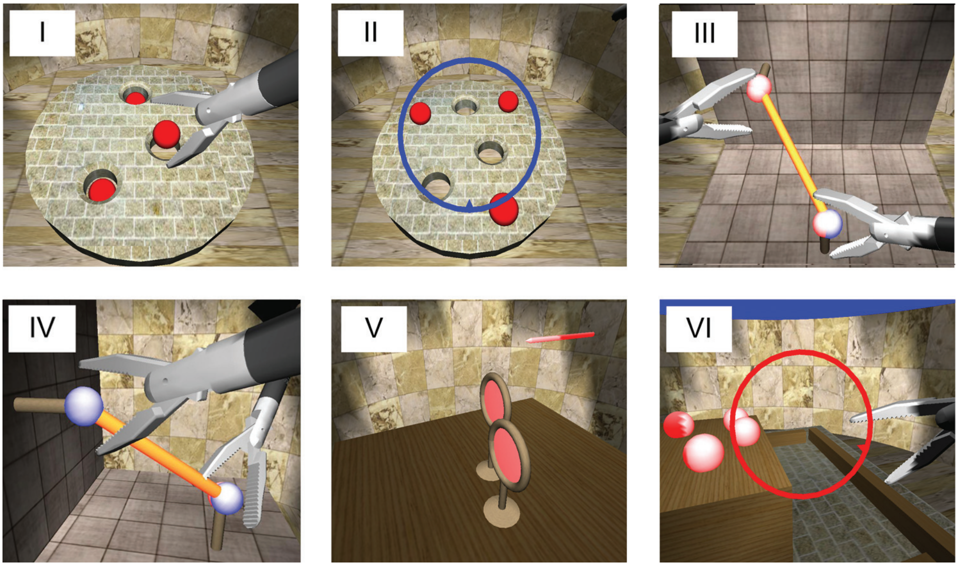

Figure 1. The 6 exercises from the VR simulator, corresponding with the description in Table 1

The SIMENDO® endoscopic simulator (Delltatech, Delft, the Netherlands) was used. This basic simulator aims specifically at eye-hand coordination training applicable to laparoscopic surgery and employs abstract tasks without force feedback [9]. The cost of the simulator hardware and software was about 9,000 euro, excluding the desktop computer. Six tasks were selected from the simulator software SimSoft 1.0 (Delltatech, Rotterdam , the Netherlands) (Table 1 and Figure 1). Measurement parameters were: time to complete the task, collisions with the non-target environment, instrument path length and aiming the endoscope. Correct aim was defined as the percentage of time that the endoscope was centred on tip of the laparoscopic instrument. The proficiency levels were derived from previous work in which the same 6 tasks had been executed by 15 experienced laparoscopic surgeons (>50 laparoscopic procedures performed) [10]. Our proficiency criteria were based on the 5th repetition of the tasks.

Two different proficiency criteria levels were defined. In the first group of 10 trainees (Group 1), the predefined levels were set at the 75th percentile (easy) of the experts' proficiency on the VR simulator. In the second group of 18 trainees (Group 2), the 50th percentile or median (difficult) was employed. Table 1 displays the required values for each task. To pass the test the trainees had to continue training until this level of proficiency was reached in three consecutive repetitions. The total training time (including breaks) and the number of attempts they needed to pass the criteria was measured.

Table 1. Tasks description and results of the two groups with different proficiency criteria levels

Task name	Parameter	Group 1 (75th percentile*)	Group 2 (50th percentile*)
I. Drop the balls (single instrument)	Time (sec)	21	17
	Collision (number)	1	0
	R Path length (a.u.)	24	21
II. Drop the balls & endoscope	Time (sec)	23	18
	Collision (number)	1	0
	R Path length (a.u)	22	19.5
	Endoscope movement (a.u.)	5.5	2.5
	Camera aim (%)	75	75
III. Stretch (no misorientation)	Time (sec)	15	12
	Collision (number)	1	0
	R Path length (a.u.)	11	9
	L Path length (a.u.)	13	11
IV. Stretch (90 degree misorientation)	Time (sec)	25	17
	Collision (number)	1	0
	R Path length (a.u.)	20	14
	L Path length (a.u.)	18	13
V. Ring & Needle	Time (sec)	33	28
	Collision (number)	3	2
	R Path length (a.u.)	28	24
	L Path length (a.u)	22	19.5
VI. 30 degree endoscope & pick and place	Time (sec)	41	33
	Collision (number)	1	0
	R Path length (a.u)	65	61
	Endoscope movement (a.u)	30	23
	Camera aim (%)	75	75

*a.u. = arbitrary unit , * Proficiency level in each group*

The trainees signed an informed consent to use the data for scientific research and they filled in a questionnaire about their previous experience with laparoscopic surgery and laboratory training. After successfully completing the training on the VR simulator, all trainees answered 7 questions about the usefulness, feasibility and challenge of the training at their particular preset proficiency level. Furthermore, they scored the degree of challenge on a scale from 1 (none) to 10 (enormous).

RESULTS

Table 3 shows the median number of attempts (and ranges) needed to pass the preset level per task. The total number of repetitions needed to pass the proficiency level varied also widely between the individual trainees within each groups. In the first group at the 75th percentile level of experts', training time needed to pass the test ranged from 29.4 to 77.1 minutes (median: 63.9 minutes) with a range of 43 to 90 attempts (median 61 attempts). In the second group (50th percentile level), training time ranged from 37.8 to 179.9 minutes (median 80 minutes) with a range of 55 to 233 attempts (median 95 attempts). All the trainees accomplished the predefined criteria.

In Group 1 (75th percentile), the fastest 25% of the trainees needed less than 10 repetitions to pass the criteria for the 30-degree endoscope navigation and delicate needle handling tasks. The slowest 25% needed more than 15 repetitions. In Group 2 (50th percentile), the fastest 25% of the trainees needed less than 14 repetitions to pass the two tasks compared to more than 25 repetitions in the slowest 25% of the trainees in this group.

Experience with assisting with or performing endoscopic procedures (under supervision) and training in laboratories varied widely between the trainees. Table 2 shows the characteristics and experience of the trainees. Figure 2 shows the relationship between the number of endoscopic procedures that the trainees assisted with the number of attempts needed to pass the criteria. No statistically significant correlation was found between these two parameters in either of the groups. There was also no significant correlation between the number of endoscopic procedures performed under supervision by the trainees and the number of attempts (Figure 3). However, none of the trainees who had performed more than two endoscopic procedures needed more than 100 attempts.

The results of the questionnaire, filled in after the training, are shown in Table 4. In the 75th percentile group (Group 1), three out of the 10 participants stated that the criteria were too easy (30%), whereas none of the participants in the 50th percentile group (Group 2) found their level was too easy. The two groups rated the challenge of the training programme with a score of 8.

Table 2. Characteristics of the surgical trainees in Group 1 and Group 2

		Group 1 n=10	**Group 2 n=18**
Male: Female		10:0	12:6
Median age (range)		28.5 (28-30)	29.5 (26-32)
First year of surgical training (n)		5	7
Second year of training (n)		5	11
Previous experience			
Lab training in a Box or VR (n)		3	4
Median number of endoscopic procedures	Assisted	17.5 (5-40)	11 (1-150)
	Partially performed	0.5 (0-8)	0 (0-10)
	Completely performed	0 (0-6)	0.5 (0-15)

Table 3. Number of attempts needed per task to reach the proficiency level for each group

Task description	Group 1 (75th percentile*) Median attempts (range)	Group 2 (50th percentile*) Median attempts (range)
I. Drop the balls (single instrument)	9 (4-18)	17 (5-58)
II. Drop the balls & endoscope	7 (4-22)	13 (3-38)
III. Stretch (normal camera view)	9 (5-13)	11 (4-50)
IV. Stretch (difficult camera view)	6 (3-10)	13 (5-40)
V. Ring & Needle	13 (5-38)	20 (6-88)
VI. 30 degree endoscope & pick and place	13 (7-22)	23 (10-46)
Total attempts	61 (34-90)	95 (55-233)

Group A (n=10) and group B (n=18)

** Proficiency level in each group*

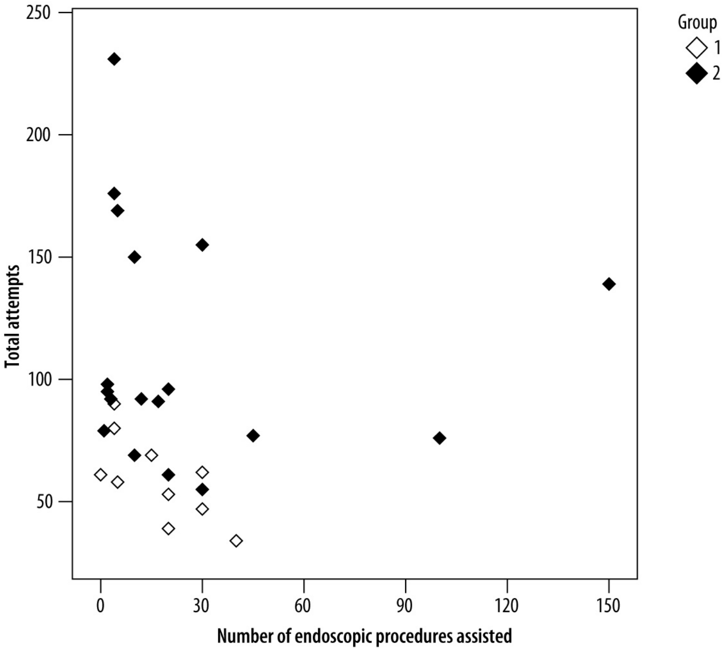

Figure 2. Number of endoscopic procedures assisted and number of attempts in Group 1 (75th percentile) and Group 2 (50th percentile)

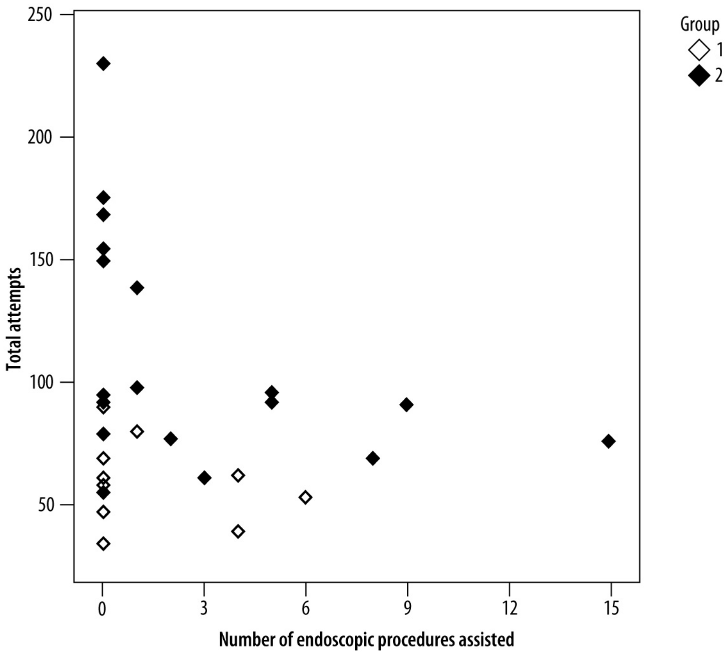

Figure 3. Number of endoscopic procedures performed and number of attempts in Group 1 (75th percentile) and Group 2 (50th percentile)

Table 4. Results of the questionnaire filled out by the participants after the simulator training

Questions		**Group 1 n=10 (75th percentile*)**	**Group 2 n=18 (50th percentile*)**
1. What is your opinion about the competence criteria?	Too difficult	0%	5.5%
	Good	70%	94.5%
	Too easy	30%	0%
2. What is your opinion about training on this simulator in general?	Not useful	0%	0%
	Useful	100%	100%
	No opinion	0%	0%
3. What is your opinion about the tasks?	Poor	0%	0%
	Good	90%	100%
	No opinion	10%	0%
4. What is your opinion about the feedback parameters?	Poor	0%	0%
	Good	90%	94%
	No opinion	10%	6%
5. Is the training challenging? Give a score between 1 and 10 (10 = greatest challenge)		median 8 (range 6-9)	median 8 (range 5-10)
6. Does the simulator training improve the eye-hand coordination of inexperienced trainees?	No	0%	0%
	Yes	100%	100%
	No opinion	0%	0%
7. Is the simulator capable of objectively measuring skills that are important to laparoscopic surgery?	No	0%	0%
	Yes	100%	78%
	No opinion	0%	22%

* Proficiency level in each group

DISCUSSION

The criterion-based motor skills training programme on our VR simulator intended to efficiently prepare surgical trainees for a laparoscopic course on a porcine model. The total number of repetitions needed to pass the proficiency level varied widely between the individual trainees within each group. Some trainees needed up to 4 times more time to pass the test than others.

All the trainees found the training useful and they were able to achieve the predefined criteria, which meant that the set-up had good feasibility. Setting the proficiency criteria at a more difficult level (median expert score, 50th percentile) appeared to be more appropriate than easier setting (75th percentile).

In the literature, there is growing evidence that motor skills training with inanimate VR simulators is valid and improves the performance of actual procedures [11]. However, it is not yet clear how these training models programmes should be standardised and incorporated into the a surgical curriculum. Physical simulators or box trainers have shown to effectively train laparoscopic motor skills as well [12] and competence levels based on performance of experienced laparoscopic surgeons seem suitably challenging for novices [8]. Nevertheless, task time was the only parameter used. Another study successfully trained novices laparoscopic suturing by using an expert performance level, based on time and error assessment [6]. However, the advantage of VR simulators is that performance is measured, stored and displayed automatically. Furthermore, most VR simulators employ several parameters to assess performance, such as task time, collisions with the VR environment, instrument path length and numbers of specifically defined errors. However, there is an ongoing debate about the pass or fail standards of these parameters. In general, the concept of criterion-based training aims to introduce standards that provide surgical educators with strategies to design a transparent and validated training programme. Evaluation of the experimental set-up provides insight into the feasibility of the tasks, the performance criteria and practical issues, such as the duration of training. Several remarks should be made about this new concept of criterion-based skills training.

To validate a criterion-based training programme on a simulator and incorporate it into a structured surgical curriculum the following requirements should be met: 1) the goal of the simulators' training program has to be defined and validated in terms of what skills are actually learned 2) the performance criteria have to be determined based on experienced surgeon performance on the simulation and evaluated to offer trainees a straightforward and challenging exercises 3) inexperienced trainees should be able to meet the criteria, and the consequences of failing to achieve the required criteria level should be made clear beforehand. The student is allowed to progress to more advanced training setting when the criterion is achieved. Students who do not meet the criteria should receive more training, feedback and retest opportunities.

The VR simulator and tasks used in this study aimed specifically at teaching trainees the basic motor skills needed for laparoscopic surgery (e.g. hand-eye coordination). Previous studies showed that the simulator had content and construct validity [9,10]. The VR simulator is a valid model at the beginning of the learning curve in laparoscopic surgery.

Determining performance criteria for VR simulator training is more difficult than it seems. In the literature, there is no consensus on how to define these criteria. Some authors advised a certain number of repetitions that should be performed [13], whereas others recommended the use of pre-set criteria rather than a predetermined training duration or an arbitrary number of repetitions [5,7,14]. When preset criteria and corresponding scores are chosen, the exact scores depend on the researcher and type of simulator. In a study on the MIST-VR [15], the authors remarked that if performance criteria are based on the average scores of experienced laparoscopic surgeons, the level might be too easy. Instead, they recommended using the score of an experienced laparoscopic surgeon who also had extensive experience on the simulator. Aggarwal et al, used the median score achieved by 10 experienced surgeons in two consecutive repetitions, in a study on the LapSim simulator [14].

In the first group the 75th percentile of the expert performance was chosen because the 50th percentile (median) performance scores were expected to be too hard to acquire by the average trainee. However, 30% of the residents considered the 75th percentile too easy. In the next group, only one participant thought the 50th percentile was too difficult. Therefore, the 50th percentile is considered to be more useful.

Introducing criterion-based training motor skills training raises questions about the validity of the criteria for the recruitment and selection purposes of trainees, or (re) licensing of surgeons. Setting the criteria at the median of experts' performance means that per definition, 50% of the experts do not achieve this level either. Therefore, this level can not be used for high stake examination of surgeons (e.g. (re) licensing), but it may be justified for recruitment and selection purposes of inexperienced trainees. Obviously, passing a motor skills test on its own does not guarantee that the individual is competent in all the required domains. Good motor skills are only one of the necessary requirements to become a competent laparoscopic surgeon [16,17]. On the other hand, if a trainee is unable to pass a validated simulation test or demonstrate improvement during training, then a surgical career is questionable. Our results revealed that the current criteria form an efficient means to shape the hand-eye coordination of those who need it and enhance the process of skills acquisition, an essential prerequisite of high standard surgery. Although the SIMENDO® forms a valid model to train subjects with little or no experience with laparoscopic surgery, it seems less suitable for general performance assessment of experienced laparoscopic surgeons for licensing purposes. These, high stake examinations require more complex simulation programmes, or combinations of a battery of different test modules. For example programmes that makes objective evaluations of decisional behaviour, proper reactions on adverse events, anatomical knowledge, etc and thus test competence on a broader scale.

An important practical issue is that the consequences of not passing the test on the simulator must be made clear beforehand. In this study, all the trainees achieved the predefined criteria. Part of the exercise was to train until they met the performance criteria, even if this took a great many training sessions. For future training programmes, it is expected that most surgical trainees will be able to pass the set criteria. This assumption is based on the observation that surgical trainees are highly motivated to learn the required skills and invest the necessary time. In addition, there seems to be natural selection within the surgical population itself. However, this assumption must be considered cautiously, because this might not apply for other simulators and the assessment of subjects with different motivation, interests and backgrounds. Schijven et al [18] found that in clip and cut task on an advanced VR reality simulator, 20% the 30 participants could not improve their performance score sufficiently to obtain proficiency during 30 repetitions. However, not all participants in the study were surgical trainees. The participants comprised of mixed group last year medical students, internal medicine trainees, trainees in the department of anaesthesia and surgical trainees. This might suggest that the selected population of surgical residents, as in our study, are more likely to pass the set criteria. Furthermore, in a study by Brunner et al [5] that used basic exercises on the MIST-VR, indicated that a lengthy learning curve existed for novices, possibly beyond 30 repetitions. In their opinion, performance plateaus may not reliably determine training endpoints [5].

In conclusion, criterion-based training of motor skills on a VR simulator is an efficient, feasible and useful method to prepare surgical trainees for more complex procedures, for example on animal models. Median expert performance scores seemed appropriate as proficiency criteria. The use of the criteria resulted in wide variation between surgical trainees in time and number of attempts needed to pass the criteria. Therefore, it is particularly suitable for the selection of trainees who need more basic motor skills training and providing them enough time to acquire these skills. Consequential, training programs could become more effective if tailored on the individual level. Such flexible courses are currently not common in surgical training.

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Chapter 7

Serious gaming and voluntary laparoscopic skills training: a multicenter study

E.G.G. Verdaasdonk [1,5], J. Dankelman [1], M.P. Schijven [2], J.F. Lange [3], M. Wentink [4], L.P.S. Stassen [1,5]

1 Department of BioMechanical Engineering, Faculty of Mechanical, Marine and Materials Engineering, Delft University of Technology, Delft, the Netherlands
2 Department of Surgery, University Medical Center Utrecht, Utrecht, the Netherlands
3 Department of Surgery, Erasmus Medical Center Rotterdam, Rotterdam, the Netherlands
4 Department of Training and Instruction, TNO Human Factors, Soesterberg, the Netherlands
5 Department of Surgery, Reinier de Graaf Group, Delft, the Netherlands

Submitted

ABSTRACT

Background: This study assesses the issue of voluntary training of a standardized online competition (serious gaming) between surgical residents.

Methods: Surgical residents were invited to join a competition on a virtual reality (VR) simulator for laparoscopic motor skills. A final score was calculated based on the task performance of three exercises and were presented to all the participants through an online database on the Internet. The resident with the best score would win a lap-top computer.

Results: During 3 months, 31 individuals from 7 hospitals participated (22 surgical residents, 3 surgeons and 6 interns). A total of 777 scores were logged in the database. In order to outperform others some participants scheduled themselves voluntary for additional training. More attempts correlated with higher scores.

Conclusions: The serious gaming concept may enhance voluntary skills training. Online data capturing could facilitate monitoring of skills progression in surgical trainees and enhance (VR) simulator validation.

INTRODUCTION

The worldwide adoption of laparoscopic surgery in the daily surgical practice demonstrated that training solely according to the traditional apprenticeship model and learning on the job was no longer acceptable [1,2]. Learning is associated with making mistakes that could harm patients. The awareness that structural training in a safe environment is required prior to embarking on real patients led to a paradigm shift in surgical skills training [3].

Nowadays, some training hospitals have adopted skills labs and various simulation models to train laparoscopic motor skills. Virtual reality (VR) simulators offer trainees unlimited practice, adjusted to their level of skill, in a safe environment without any risks for patients. In addition, computer-based simulation is able to generate objective outcome parameters which can be used for monitoring performance and progress. However, laparoscopic skill training remains a challenge in surgical education. It is reported that voluntary use of a simulation lab leads to minimal participation [4]. The most common reasons expressed for lack of voluntary participation were lack of time and interest. However, deliberate practice is essential for developing skills beyond normal ranges, even for the experienced subjects. This has been shown by Ericson for the domain of professional musicians and top-athletes [5,6].

In order to boost deliberate practice and overcome the motivational barriers we introduced the concept of "serious gaming" in the field of simulator training by introducing a skills competition and a reward for the best performance. There is no single definition for serious games. In general, they cover a broad spectrum of computer-based simulations for training or education in a single or multi-user environment. Serious games are intended to provide an engaging, self-reinforcing context motivating and educating its users. The games often simulate only a part of the real world and realism is not the most important aspect. Serious games are used in various domains such as the military, police, aviation and ship navigation to train personnel in a challenging way [7-10]. Today, numerous examples can be found on the internet. In surgery, computer based simulations are commonly used for laparoscopic skills training, but the potential benefits of a competition have not yet been investigated. The competition element may tackle the voluntary training problem in laparoscopic motor skills training.

In order to induce deliberate practice, the aim of this study was to evaluate the serious gaming effect with an online competition between surgical residents on a laparoscopic VR simulator.

METHODS

Hospitals in the Netherlands were invited to join an online competition with the VR simulator SIMENDO (Delltatech, Rotterdam, the Netherlands). The simulator aims specifically at eye-hand coordination training essential for laparoscopic surgery and employs abstract tasks without force feedback. Previously, several studies proved the simulator had face and construct validity for laparoscopic motor skills training [11,12]. The simulator showed to be able to differentiate between groups with different levels of experience [11].

The competition consisted of three tasks: pile cylinders, 30-degree endoscope manipulation and drop the balls with boxes. The tasks are short exercises of several minutes, 1 to 4 minutes. Time needed to complete all the tasks depends on experience with laparoscopic surgery and skills training. Normally, these tasks can be performed separately on the simulator (SimSoft 2.0), but for this study they were modified into a "competition module" and had to be performed in a consecutive order. Performance measurement was based on task-time, instrument path length, collisions with non-target environment and errors. The lower the task-time, path length, collisions and errors, the higher the score for each task with a maximum of 10.000. The final score was the calculated average of all three tasks. The final score was automatically sent to an online database (VREST, Enschede, the Netherlands) and directly presented to all the participants on the simulator. The simulator had to be connected to the Internet. The participants received a password by e-mail that allowed them to access the database from any computer connected to the Internet. The database application for the final score presentation was especially built for the study.

To enter the competition, the contestants had to complete a short online registration form and fill out a digital questionnaire concerning age, gender, experience with minimally invasive surgery (MIS), surgical specialty and their motivation to participate. Experience with MIS was defined as performing any laparoscopic procedure. There were four categories: 1) no experience, 2) camera navigation experience, 3) intermediate experience defined as performed less than 50 laparoscopic procedures and 4) experienced participants that performed more than 50 procedures. Concerning the motivation of the participants we asked why they joined the competition. Participants had to choose one out of four options were provided: 1) for fun, 2) they felt obligated, 3) to learn laparoscopic motor skills, or 4) to win the competition. We asked also to rate their motivation to learn laparoscopic motor skills expressed on a scale from 1 (none) to 10 (enormous). Furthermore, participants gave their consent that the data could be used for research. The competition and the preset end date were promoted through short presentations in each participating hospital, posters and press releases. All potential participants were allowed to enter the competition till the end date. The number of attempts per contestant was unlimited. The surgical trainee with the best performance score could win a lap-top computer.

Statistical analysis

The data were analyzed with the Statistical Package for the Social Sciences version 12.0 (SPPS, Chicago, IL) using nonparametric tests. Data on the learning curves was analyzed by the Friedman (nonparametric repeated-measures analyses of variance) test. Comparison between performances of groups was undertaken using the Mann-Whitney *U* Test. A level of $P<0.05$ was considered statistically significant.

RESULTS

Between December 2006 and February 2007, 7 hospitals participated: 3 academic training centers, 4 large regional training hospitals. Thirty-one contestants participated: 22 surgical trainees, 3 surgeons, 6 interns consisting of 23 men (75%) and 8 women (25%). The median age was 30 years (range, 23-56 years). The highest score was 9.88 with 105 attempts and the lowest score was 1.23 with only one attempt. Altogether, the participants trained 79 hours and 20 minutes with a median of 53 minutes (range, 4.4 minutes – 19 hours and 4.5 minutes). Figure 1 displays a pie diagram of the experience with minimally invasive surgery in four categories. Sixteen participants (52%) had performed more than 1 and less than 50 procedures. Figure 2 shows the number of participants by amount training time on the simulator.

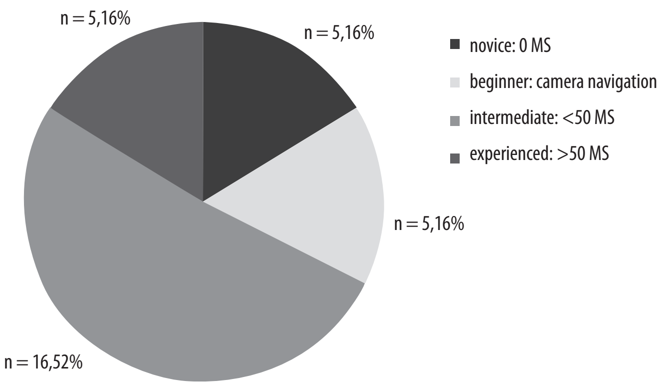

Figure 1: Distribution of participants according to experience with laparoscopic surgery

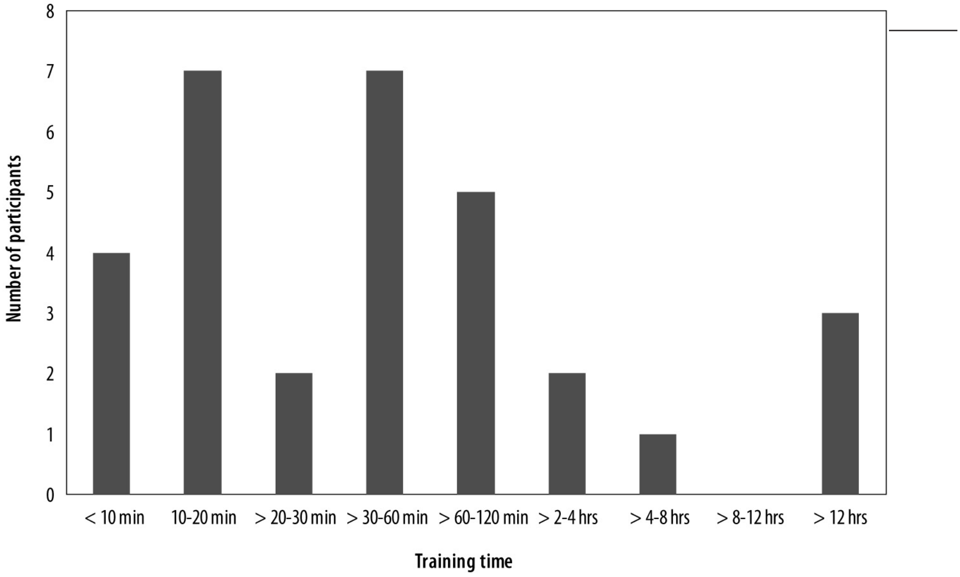

Figure 2: Number of participants by amount training time on the simulator

A total of 777 attempts with a final score were registered in the database. Median number of attempts per participant was 6 (range, 1-212 attempts). Figure 3 shows the median of the scores by the attempts. There were only 5 five participants who performed more than 22 attempts.

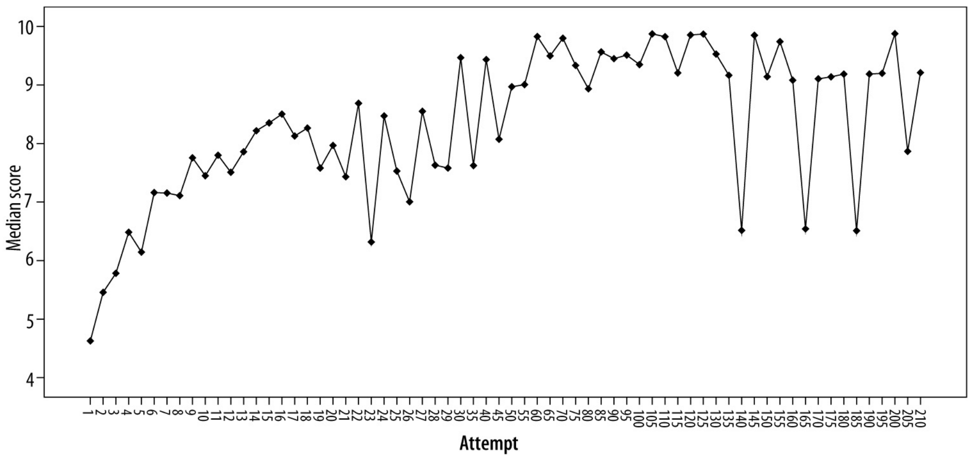

Figure 3: Median scores and attempts

The final score (the highest score a participant reached) was compared with number of total attempts, a higher final scores was associated with a higher number of attempts. Figure 4 shows box plots of the final score versus number of attempts for four groups. More than 30 attempts resulted in a significant higher final score than participants who performed between

10 and 30 attempts (Mann-Whitney U test, P=0.008). There was also a significant difference for the final score between the other groups, except between participants that performed less then 4 attempts and the group that performed between 5 and 9 attempts (P=0.135).

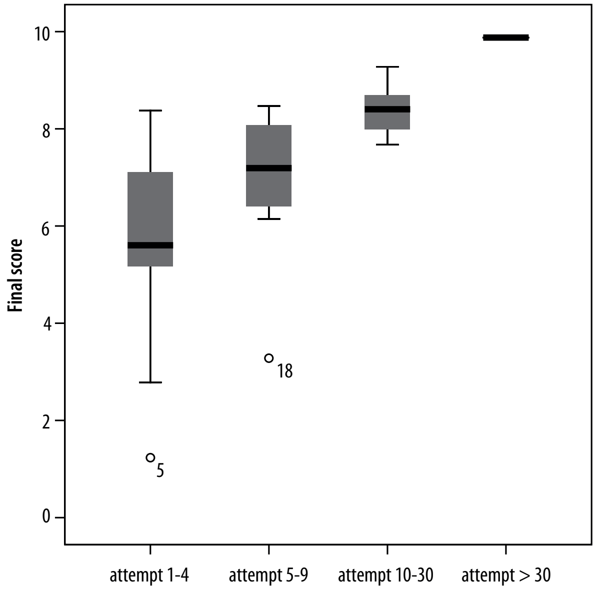

Figure 4: Final score and attempts

Figure 5 shows a bar diagram of the number of participants for each center. Center "C" and center "G" entered the competition 4 weeks later than the others because of technical and organizational difficulties with the internet facilities.

When asked for their motivation to participate in the competition, more than 50% of the contestants stated they wanted to win. The median score of motivation to learn laparoscopic skills as expressed on a scale from 1 (none) to 10 (enormous) was 9 (range, 1-10). The motivation score did not correlate with the final score on the simulator (Pearson Correlation Coefficient was 0.331, p=0.088)

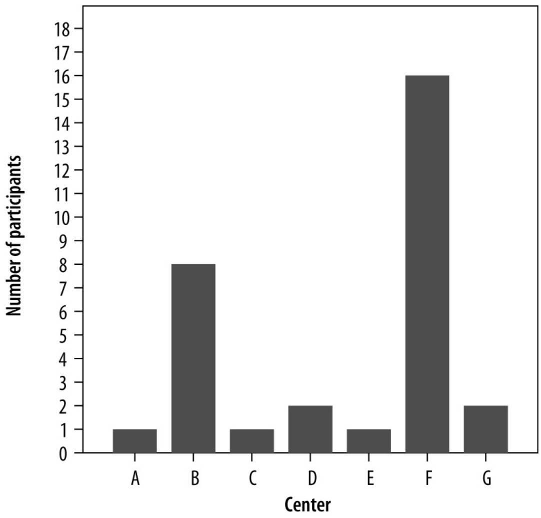

Figure 5: Number of participants and center

DISCUSSION

To our knowledge this is the first study undertaken to explore the effect of a multicenter, online competition with a VR simulator. The term of serious gaming is relatively new in the surgical field and is meant to underline the competition element, engaging features of training and the fact that there was a price to win in addition to existing laparoscopic simulation. The competition on the VR simulators led to deliberate practice and enthusiastic reactions of the participants. In addition, we showed that it is feasible to gather data generated by VR simulators for laparoscopic skills training through an online database.

In the past decade, several VR simulators for laparoscopic skills training have been developed and validated [13]. Studies show that they can reliably asses the skills that are essential for laparoscopic surgery and improve the performance of trainees in real procedures [14, 15]. This effect may further be enhanced by introducing challenging or expert based performance goals [16, 17]. Currently, training criteria for several simulators have been determined [18, 19]. The usual consequence of passing these criteria is that the trainee is allowed to proceed to more advanced training models or performing surgery on patients. However, results from a study with dual task training in which a laparoscopic suturing task had to be performed simultaneously with another visual task, showed that experts and simulator trained individuals outperformed trainees with procedural experience [20]. These results suggests that skill training goes beyond predefined performance levels and would take much longer than most believe. Hence, extensive training seems to be justified. Nevertheless, with the recently reduced workweek for medical trainees there is a problem to fit additional training into a busy training program. Additional training should ideally take place on a voluntary basis, enabling trainees to practice at their own convenience. Furthermore, deliberate practice may enhance skills retention for a longer period [6]. Deliberate practice on simulators in a skills laboratory is difficult, especially for trainees with procedural experience. Motivation is an important, often underestimated, factor in learning new skills and ongoing training.

According to Hutchinson [21] the motivation to learn can be intrinsic (from the trainee) and extrinsic (from external factors). Extrinsic factors are exams, assessments, promotion, financial profits, prolonging registration etc. Intrinsic factors are motivators such improvement of personal achievement (improvement of skills and knowledge), be prepared for new situations, security, but also fun and competition. We can not separate these factors in our study. However, the price to win was an extrinsic factor but the desire to achieve and to win the competition was an intrinsic factor. Both can be considered to enhance deliberate practice. However, one can speculate whether such competition is an attractive factor for everyone.

There are some limitations of this study. There was a remarkable difference in the percentage of participating residents between the centers. This can partly be explained by the fact that two centers entered in the competition later than others due to some technical and organizational difficulties with the internet facilities. Furthermore, in each center it took several weeks before the competition really started and three centers provided clearly less participants than others. The teachers, also mentioned by Hutchinson [21], may have played a role. The enthusiasm of the staff and their periodic encouragement of trainees to join the competition could explain the difference between the centers for a large part. Most of the participants, once taking part in the competition, seem to be really motivated as indicated by the fact that only few trained less than ten minutes. Unfortunately, we do not have data about the trainees who did not participate and the reasons for their choice.

The cardinal question that remains is whether there is a role for the serious gaming concept in surgical training. The high percentage of trainees with laparoscopic procedural experience that joined the competition suggests that especially this category was motivated to participate. The competition element seems useful to attract experienced trainees for additional skills acquisition. This gaming element can easily be added to the existing simulators for laparoscopic motor skills training. The serious gaming concept may be additional to basic laparoscopic skills training in which achieving competence of a basic level, for example until predefined criteria, is mandatory and takes place in the structured setting of a lab. The online data capturing can be helpful to monitor skills acquisition over time and can be used to employ standardized training on a larger scale. The performance of the individual trainee can easily be integrated into a digital portfolio.

For surgery in general, there is a large potential for simulation and serious gaming in training of more complex or cognitive skills such as decision making, diagnosing and learning the steps of common surgical procedures. It is most likely, that in the near future serious games for medical trainees will emerge. In other domains, often heavily funded, such as the military and aviation, this new form of training is already successfully used [7,9]. Since improving quality and patient safety in healthcare by efficient, competence-based training has become a high priority, innovative education methods will surface. Cooperation with the gaming industry, adopting their principles, ideas and technology is important. However, the surgical training community should develop the required content, design the educational curriculum and control the validation.

In conclusion, the use of competition elements on the simulator may enhance the motivation of surgical trainees to train voluntary. Furthermore, data capturing over the Internet could facilitate monitoring of skills progression in surgical trainees and enhance the ongoing validation research of various simulators.

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Chapter 8

Problems with technical equipment during laparoscopic surgery: An observational study

E.G.G. Verdaasdonk[1,2], L.P.S. Stassen[1,2], M. van der Elst[1], T.M. Karsten[1], J. Dankelman[2]

1 Department of Surgery, Reinier de Graaf Group, Delft, the Netherlands
2 Department of BioMechanical Engineering, Faculty of Mechanical, Maritime & Materials Engineering, Delft University of Technology, Delft, the Netherlands

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ABSTRACT

Background*:* This study was designed to investigate the incidence of technical equipment problems during laparoscopic procedures.

Methods: A video-capturing system was used, consisting of an analogue video recorder with three camera image inputs and a microphone. Problems with all technical equipment used by the surgical team such as the insufflator, diathermy apparatus, monitors, light source, camera and camera-unit, endoscope, suction devices and instruments were registered.

Results*:* In total, 30 procedures were randomly videotaped. In 87% (26/30) of the procedures one or more incidents with technical equipment (49 incidents) or instruments (9 incidents) occurred. In 22 incidents (45%) the technical equipment was not correctly positioned or not present at all; in the other 27 (55%) incidents the equipment malfunctioned as a result of a faulty connection (9), a defect (5), or wrong setting of the equipment (3). In 10 (20 %) cases the exact cause of equipment malfunctioning was unclear.

Conclusion: The incidence of problems with laparoscopic technical equipment is high. To prevent such problems, improvement and standardisation of equipment is needed, combined with the incorporation of checklist use before the start of the surgical procedure. Future research should be aimed at development, implementation and evaluation of these measures into the operating room.

INTRODUCTION

The report "To Err is Human, Building a Safer Health System" emphasized the occurrence of errors in medicine [1]. It is estimated that each year at least 44,000 people die due to medical errors in the United States, but this may be as high as 98,000. Thus, even when the lower estimate is used, more people die in one year as a result of a medical error than from motor vehicle incidents.

A common site for adverse events in the hospital is the operating room (OR) [2]. In the study by Leape [2] most of these adverse events were considered preventable. At present, it is unclear what kinds of problems or incidents occur in the OR and what their incidence and impact is. In literature, several authors plea for a systems approach [3-5]. In the system approach it is assumed that adverse effects due to human error will always occur, because to err is human. The causes and solutions should be searched for in the environment e.g. the system. Reason [3] used the system approach to study major adverse events (AE) and accidents such as the nuclear Three Miles Incident. He concluded that seemingly unimportant incidents occur prior to major accidents or adverse events [3]. Prevention of future accidents starts with investigating the occurrence of these incidents in order to design adequate defenses. The "cheese model" after the theory postulated by Reason (Figure 1), clarifies how these defenses in the system can influence the occurrence of adverse events. In complex environments such as the OR several defence mechanisms secure the safety of the patient. Examples include the design of equipment, experience of the personal and the use of certain protocols and OR etiquette. Weaknesses in these defenses clear the road for incidents (represented in the model as holes in the defenses). According to the model, because of effective defences on different levels, not all incidents in the OR lead to adverse events that endanger the patient's health. For this reason, most incidents seem to have no consequence at all, but if all occur at the same time or in sequence, the result can be an adverse event.

The introduction of sophisticated technical equipment in Minimally Invasive Surgery (MIS) has made the surgical environment even more complex. New problems are created in the domain of man-machine interaction during high-tech procedures, thereby creating opportunities for errors or incidents to occur. The problems related to the skills of the surgeon was studied by Sarker et al. [6], but the problems related to mechanical instruments and the technical equipment (the laparoscopic tower and the diathermy), have not been assessed before.

The aim of this observational study, therefore, was to investigate the incidence of technical equipment problems during laparoscopic cholecystectomies in order to develop adequate specific defense strategies. An incident was defined as a problem with the mechanical instruments, or with the positioning, presence or malfunctioning of the technical equipment.

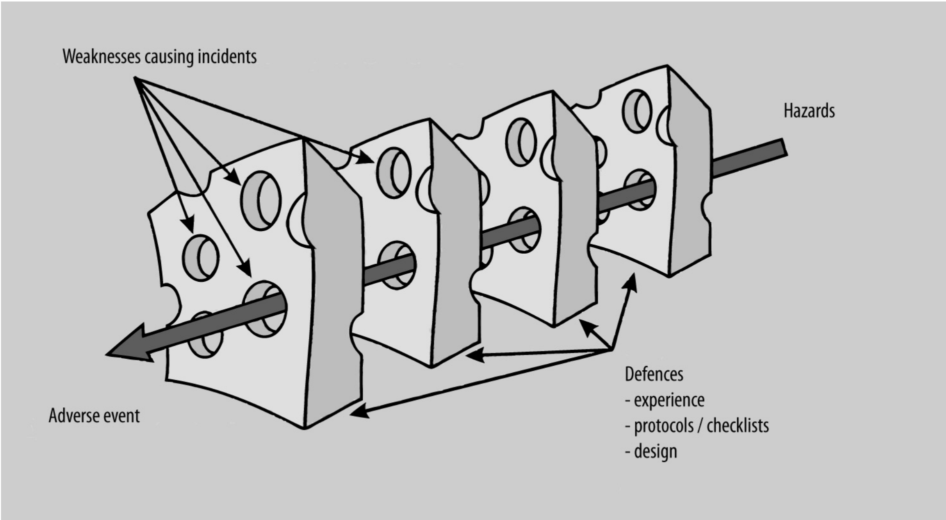

Figure 1. Cheese slices represent defense mechanisms such as hospital organisation (team) experience, checklists / protocols, and equipment design. Holes represent incidents and are weaknesses in these defenses. In a complex environment (such as the OR) incidents may cause a accident trajectory (large arrow) and lead to adverse events.

METHODS AND MATERIALS

To identify risks that might lead to breaches in the OR defense, a video capturing system was used, consisting of an analogue video recorder with 3 camera image inputs and a microphone. The image of the endoscope, an overview of the OR, and an image of the hands of the surgeon were automatically synchronised in one image and recorded. A microphone was placed on the surgeon's head. Between June 2004 and December 2004, laparoscopic cholecystectomies were recorded in the setting of a large non-university training hospital. The standard equipment consisted of a laparoscopic tower trolley and two Sony PVM-Trinitron Colour Video Monitors. Several instruments are placed on the tower, including an insufflator, a xenon light source, a digital 3-chip camera and camera-unit. Separately on another trolley a diathermy apparatus was mounted. Each team consisted of a surgical trainee, a (supervising) surgeon, a scrub nurse and a circulating nurse.

Videotapes were recorded as part of a larger project that aims at improving training of surgical residents in the performance of minimally invasive procedures.

A researcher was present during the recordings of all procedures. Afterwards, the tapes were reviewed and analyzed by the first author (E.G.G.). Procedures converted to open or conventional cholecystectomies were analysed up to removal of the trocars. Problems with technical equipment, such as insufflator, diathermy apparatus, monitors, light source, endoscope or suction device were counted. These problems were divided into two categories: (1) positional (apparatus in the wrong position or not present at all). (2) functional (malfunctioning resulting from wrong setting or connection or due to an unclear cause). Problems with instruments were also counted. Time to solve a problem was counted in seconds and calculated to minutes.

RESULTS

A total of 30 laparoscopic cholecystectomies were recorded and analysed. The participating surgeons consisted of 7 different staff surgeons and 11 surgical trainees. In 20 all procedures (66%), a surgical trainee (resident) initially started the operation, supervised by one of the staff surgeons. A staff surgeon was present in the operating room during each procedure. In 9 out of 20 (45%) procedures, started by a trainee, a partial or total take over by the supervising surgeon occurred. In four procedures, the laparoscopic approach was converted to an open procedure. These were not due to technical problems with the equipment or instrumentation.

In the course of 26 procedures, one or more incidents with technical equipment or instruments were noted. Figure 2 shows the number of procedures by number of problems. A total of 58 incidents were recorded, ranging from 1 to 6 incidents per procedure. In 84% (49/58) there was a problem with the technical equipment only and in 16% (9/58) a problem with the mechanical instruments occurred. Table 1 presents all incidents. Figure 3 displays incident frequencies with the laparoscopic technical equipment only, subdivided by causes. In 45% of the cases (22/49), the laparoscopic equipment either was not present (6/49) or not optimally positioned (16/49). In 55% (27/49) the laparoscopic equipment was malfunctioning. In 9 cases the malfunctioning was due to a faulty connection (twice the monitor, five times the diathermia apparatus and twice the insufflator), and in 3 incidents (once the monitor, and twice the insufflator) due to a wrong setting of the equipment. A defect caused a problem in 5 occasions (3 times of one of the monitors, once the diathermy cable, and once the endoscope). In all these incidents the technical equipment needed readjustments or direct replacement. In 10 cases (20%) the exact cause of equipment malfunctioning remained unclear. These incidents involved interference of diathermy with the image (four times), suboptimal image quality (five times) and once inferior but acceptable light quality. In one occasion, the light quality was adjusted by the hospital technical service, after the procedure.

In 16% (9/58) of all incidents, there was a problem with the mechanical instruments. In one case, the laparoscopic retrieval bag for the gallbladder was not present and 6 times a mechanical instrument was defect and had to be replaced.

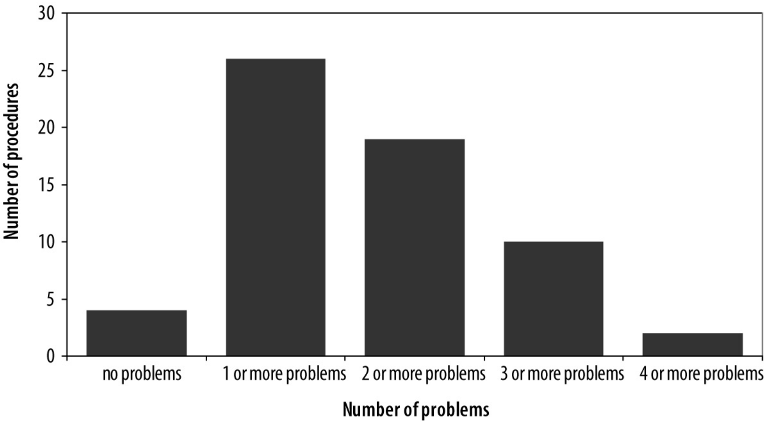

Figure 2. Number of problems by number of procedures

Table 1. Frequency of problems with technical equipment and mechanical instruments

Type of equipment involved	Positional		Malfunction and cause				
	Not present	Not in position	Setting	Connection	Defect	Unclear	Subtotal
Image/monitor	6	7	1	2	3	5	24
Pedals		9					9
Endoscope					1		1
Light source						1	1
Diathermy				5	1	4	10
Insufflator			2	2			4
Instruments	1				6	2	9
Total	7	16	3	9	11	12	58

With each incident, operation time was lost. Total operation time needed to solve the problems (of all the procedures together) was 110 minutes. The median time needed per incident was 1.5 minutes (range 0.2-20.3 minutes). Figure 3 shows the total time lost per procedure. Most problems occurred during the initial phases of the procedure.

All the observed problems caused no direct post operative complications in the patients. All operation reports were reviewed, and none of the above described incidents were mentioned in any of the reports.

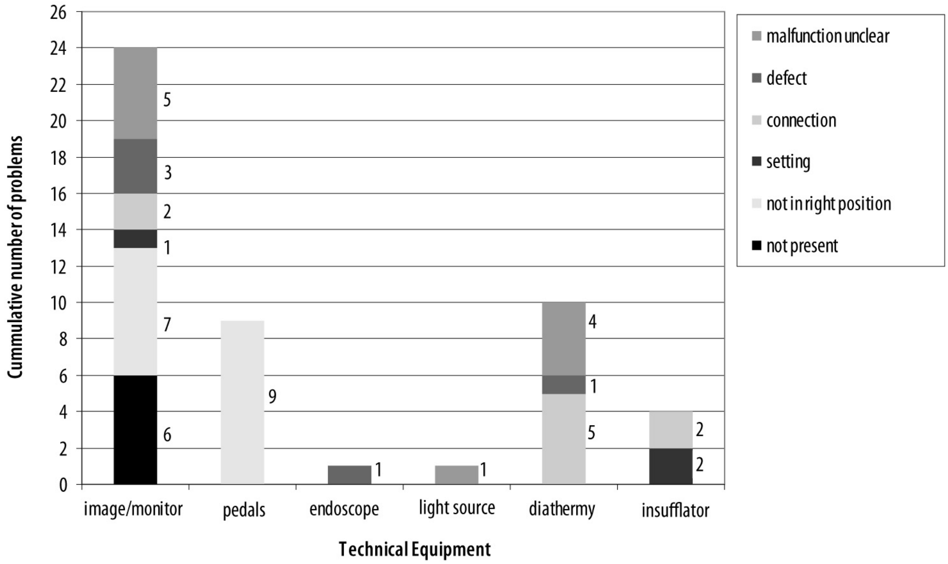

Figure 3. Frequency of incidents with technical equipment, subdivided by causes

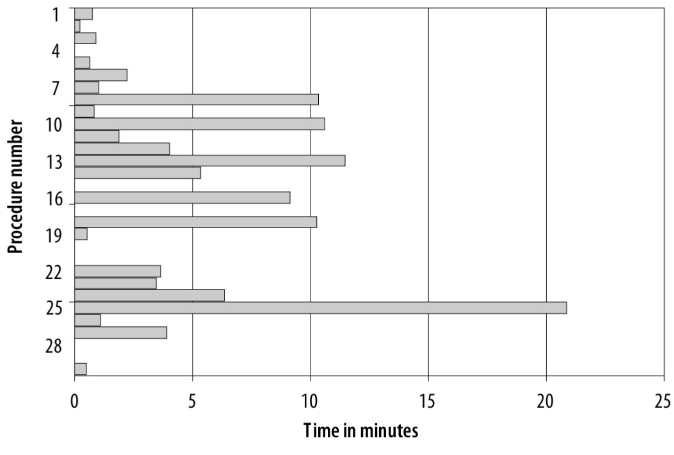

Figure 4. Total time to solve incidents per procedure

DISCUSSION

In 26 out of 30 laparoscopic cholecystectomies analysed, one or more incidents with technical equipment or instruments was documented. These incidents concerned mainly (84%) problems with the technical equipment only. In half of these cases the equipment was malfunctioning, and in 20% of those, the cause of the problem was unclear. In our observations the rate of incidents was high, and in some cases it took a lot of valuable operating time to solve the problem.

Surgical outcome is usually evaluated by the extent to which the pathologic condition has been treated and by morbidity and mortality. These outcome parameters can be affected by factors such as the working environment, the design and the use of technical equipment, communication and team co-ordination [5]. Assessment of all these factors together is complex. Previously, other investigators have looked into surgical skill related factors such as instrument and tissues handling. Such assessment proved feasible and showed a high number of errors, as well [6-9]. The present study focussed on another factor: problems with the use of technical equipment.

At present there is no data available in the literature on the exact incidence of problems with technical equipment. Therefore it is unclear if other hospitals have the same experiences, although when comparable instruments and equipment are used, similar problems can be expected. The laparoscopic cholecystectomy is a well-standardised procedure that is usually used as “educational” for trainees. Nevertheless, even in the presence of an experienced laparoscopic surgeon (supervisor), as was the case in our study, problems with equipment occurred regularly. In more complex laparoscopic procedures, with more instruments and additional equipment, the incident frequency could even be higher.

Incidents with positioning or just the absence (45 %) of necessary equipment in the OR seems to be a problem of a lesser importance than equipment malfunctions. The most common problem relating to missing equipment concerns availability of the second monitor for the assistant. Equipment positioning incidents also often concerned the monitors. In a cramped OR, proper placement of the screens requires thorough planning. In the present study some of the monitors are positioned on trolleys and some on booms. Whatever the mounting system, monitors are generally positioned before the surgeon starts to operate. According to hospital protocol, normally two monitors are used during a laparoscopic cholecystectomy. In our hospital all staff surgeons share the opinion that two monitors are mandatory, both for ergonomic reasons and optimal view. Nevertheless, because of logistic reasons a second monitor was not always present, and repositioning of the monitors, after the surgeon has started the procedure, were also recorded as an incident. One may argue that repositioning a monitor during the procedure is not a problem. However, repositioning equipment during the procedure takes time and draws attention away from the main task i.e. operating on the patient.

Our thorough observations were documented with a specially developed video capturing system, used in earlier studies [10]. Recently, others have started to use video capturing systems, consisting of multiple camera inputs and audio, mostly digital, to monitor performance during open or laparoscopic surgery. An example is the Clinical Data Recorder of Royal College of Surgeons in London (8 camera's and 4 microphones) [5]. Comparable systems are also used in trauma resuscitation settings [11,12]. Published reports show the potential of these systems to investigate surgical performance beyond the traditional clinical outcome. The results will be used to develop and apply strategies that will enhance efficiency and safety of the surgical procedures. In complex working environments, such as nuclear power plants and aviation, these strategies have been in place for some time, with a tremendous positive influence on safety and efficiency. For example, pilots are explicitly trained in using protocols and checklists in solving common problems encountered as they do their job. It is striking that a surgical procedure can be started without a structured check and clearance of all personnel that are actively part of the procedure.

It is of interest that none of observed the incidents of equipment malfunctioning were described in the operation reports. Therefore, the current reporting system cannot be used to analyse these problems. If the organisation wants to learn from these problems another system is needed. Video monitoring is a good option, but there are some difficulties. Use of video-monitoring as a "black box" inside the operation room is, unfortunately, limited, both because later analysis of it is time-consuming and because it reveals weaknesses in the surgical system that may be of legal importance. Such issues will have to be resolved before the use of video recording can become common practice.

The problems with technical equipment analysed in this paper led us to the question why such easy-to-prevent incidents happening at all? A possible conclusion might be that handling of complex technical equipment and solving its problems with it are not a part of the natural domain of doctors and healthcare workers. Classical education and training is focused on solving medical problems of patients asking for knowledge and strategies unrelated to solving problems with technical equipment that a surgeon might encounter during laparoscopic surgery. Nevertheless, the potential risk of these seemingly unimportant incidents is illustrated by the theoretical model of Reason [3,13] who contends that real adverse events are the end result of a spectrum of coinciding incidents (Figure 1). According to Reason these incidents can be caused by active failures or latent conditions. Active failures are unsafe acts committed by people who are in direct contact with the patient or system. Latent conditions arise from decisions made by designers, builders, procedure writers and top-level management.

A number of approaches can be put in place to prevent problems from happening: (1) redesign of the equipment, (2) improvement of training / proficiency checks, 3) use of protocols and checklists.

The redesign of equipment and systems is expensive and a slow process. Nevertheless, there are already systems imbedded in new operating room design that might provide some solutions for problems found in this study. Unfortunately, not many hospitals have the financial resources for OR's of the future. Furthermore, increasing high-tech applications often creates new unforeseen problems.

Proper training to prevent incidents has a large potential. However, training is difficult if there is no clearly accepted protocol of equipment handling. The advantage of training is the opportunity to create a specific and standardised safety culture among OR personnel. Cultural changes are important because medical staff report that error control is important but difficult to discuss and not handled well [14]. It should be noted that training can be time consuming and that knowledge and skills will fade through time. Recurrence training is therefore continuously needed.

The third approach, the use of checklists or protocols, can provide a quick and inexpensive solution for preventing small incidents. At present a specially developed checklist for OR setup and equipment handling is being tested and evaluated in our institute. It is expected that the combination of a relatively short training focussing on the consequent use of equipment checklist will help to decrease the number of incidents.

CONCLUSION

The existence of equipment problems in the operation room (OR) is known, but up to now has not been measured objectively. Observations from the present study revealed that the incidence of problems associated with equipment and the instrumentation during laparoscopic cholecystectomy was strikingly high. To prevent these problems, improvement and standardisation of equipment is needed, ideally in combination with the use of a short checklist before the start of each surgical procedure. Future research should aim at development, implementation and evaluation of these measures into the OR.

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Chapter 9

Requirements for the design and implementation of checklists for surgical processes

E.G.G. Verdaasdonk[1,2], L.P.S. Stassen[1,2], P.P. Widhiasmara[1], J. Dankelman[1]

1 Department of BioMechanical Engineering, Faculty of Mechanical, Marine and Materials Engineering, Delft University of Technology, Delft, the Netherlands
2 Department of Surgery, Reinier de Graaf Group, Delft, the Netherlands

Submitted

ABSTRACT

Background: The use of checklists is a promising strategy to improve patient safety in all kinds of surgical processes, inside and outside the operation room (OR). The aim of this article is to provide requirements and implementation of checklists for surgical processes.

Methods and Results: The literature on checklist use in the OR was reviewed, based on research in Medline, Pubmed and Google Scholar. Although all studies show positive effects and important benefits such as improved team cohesion, improved awareness of safety issues, and reduction of errors, their number is still limited. Motivation of team members is considered essential for compliance. Currently, there are no general guidelines for checklist design in the surgical field. Based on our own experiences and on guidelines used in the aviation industry, requirements for the checklist design are proposed. The design depends on the checklist purpose, philosophy and method chosen. The methods consist of the "call-do-response" (CDR) and the "do-verify" (DV) method or a combination of both. Advantages and disadvantages of paper versus electronic solutions are discussed. Furthermore, a step by step strategy of how to implement a checklist in the clinical situation is suggested.

Conclusion: The use of structured checklists in surgical processes is most likely to be effective because it standardizes human performance and ensures procedures are followed correctly rather than relying on human memory alone. Several studies present promising and positive first results, providing a solid basis for further investigation. Future research should aim on the effect of various designs and strategies of checklists in order to ensure maximal compliance.

BACKGROUND

Increased complexity of operating room (OR) forces the medical professionals to put more effort in improving surgical safety. The report "To Err is Human, Building a Safer Health System" emphasized the occurrence of errors in medicine [1]. In this report it is estimated that at least 44,000 people die due to medical errors in the US but this number may be as high as 98,000. A recent report, conducted in the Netherlands, revealed that more than 1700 patients die due to medical errors each year [2]. Leape showed that a common site for adverse events in the hospital is the (OR) [3]. In addition, most of these adverse events were considered preventable.

Several reports underlined the importance of Reason's "system approach" in taking measures to reduce adverse events in the hospital instead of the persons' approach [4-8]. According to Reason's theory, safety in complex environments such as OR's relies on multiple system defenses such as the organizational structure, protocols, training of professionals, quality of equipment or technology, etc. When the defenses fail or are flawed an accident is bound to happen. In the system approach the conditions under which individuals work are thoroughly investigated and efforts are made to build strong defenses to avoid human errors or diminish their effects.

In an observational study by Undre et al. [9] of 50 surgical procedures, significant steps were being missed which at the very least eroded safety margins. A frequent failure to check both surgical and anesthetic equipment and a failure to confirm the procedure verbally occurred. In two thirds of the cases delays or changes occurred and in one-eighth of the procedures the patient notes were missing.

Recently, problems related to the technical equipment during Minimally Invasive Surgery (MIS) have been studied [10]. This research showed that, although no adverse events occurred, the incidence of problems with equipment and instruments was strikingly high during routine surgical procedures. Each time an incident occurred the operation flow was obstructed and valuable time was lost. The majority of these problems could have been prevented by correct use and preparation of the equipment, prior to the actual procedure. Besides training of personnel, incorporation of a short checklist before the start of each surgical procedure was recommended. Parallel to the aviation industry, checklist use may be a promising strategy in health care. A checklist could serve as a structural memory aid, helping surgical crews to check and confirm the readiness of the equipment before the operation begins. However, physical appearance and user interaction should be carefully designed so that the checklist serves its purpose. For example, a checklist which is too long, and is difficult to read, or uses ambiguous terminology may have a negative effect on the task performance instead of improving it. On the other hand, if the list is too short and does not incorporate all critical steps it may have no effect at all. Furthermore, a clear strategy to incorporate a checklist in the clinical situation is needed.

The aim of this paper is to provide general requirements for the design and implementation of checklists for surgical processes.

METHODS

The existing literature on checklist use in the operation room was studied. Google Scholar, Medline and Pubmed databases were searched using the search terms 'checklist', 'operating room', "surgery" and "safety". Books or publications in peer reviewed journals between January 1980 and June 2007 were included. Only publications in English language were considered.

Publications included should clearly address 1) the use of the checklist in order to improve quality of care, team communication, patient safety or use of equipment and instruments in the OR, or 2) the effect of a structured checklist in the OR.

After the results of the literature review the general and the physical requirements for the checklist design will be presented. Requirements for the checklist design are based on our own experiences and on guidelines used in the aviation industry. The advantages and disadvantages of paper and electronic checklists are brought to attention. A flow chart, following a number of practical steps, was developed for incorporation of the checklist. Finally, we discuss the broader context of checklist for surgical processes and future research.

RESULTS

The term "checklist" revealed 7429 hits in Pubmed, Medline and 53,200 in Google Scholar. The search was narrowed down by adding "operating room", which resulted in a total of 27 publications in Pubmed, Medline. In Google Scholar, "surgery", "safety" and "protocol" were also added. The search was further narrowed down by only including publications and citations from Medicine, Pharmacology, and Veterinary Science which resulted in 271 hits.

All literature references were manually checked for relevance. Double references were excluded. A total of eight publications were considered relevant to checklist use in the operation room. Cross linking of the references identified eight additional publications and two guidelines from an electronic source. No randomized controlled trials were found.

CHECKLIST USE IN THE OPERATING ROOM

The use of checklists as an evaluation or audit tool is not an entirely new concept in the operation room. In July 2004 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) mandated the Universal Protocol for prevention of wrong site, wrong side, wrong procedure and wrong person surgery for all Joint Commission accredited organizations [11]. The protocol consists of guidelines for a preoperative verification process, marking the operative site and a "time-out" immediately before starting the procedure [12]. During the time out critical information about the patient and the surgical procedure planned is checked by the surgical team members. The goals and the content of JCAHO protocol are stated explicitly. The use of a structured checklist is also recommended. However, criteria for the format of the protocols or checklists are not given. A critical report, conducted before the Universal Protocol was mandated, stated that wrong site surgery is exceedingly rare (1 in 112,994 operations) and hospital protocol design varied significantly [13]. Nevertheless, under optimal conditions the JCAHO protocol could have prevented two third of the examined cases.

Currently, there is limited evidence proving that interventions such as the Universal Protocol are effective [14]. Furthermore, hospitals are facing difficulties in evaluating what the effect is their policy and whether their policy is preventing adverse events.

Lingard (2005) developed a checklist to enhance performance in the operation room and investigated the feasibility of a preoperative checklist as a communication aid between surgical team members. The list was designed by a research team that consisted of experts from various backgrounds, including a communication researcher, cognitive psychologist, nurses, an anesthesiologist, a surgical trainee and research staff. Eighteen surgical procedures were prospectively included in this study. Before each procedure, the surgical team was asked to conduct a discussion according to the checklist. The data collected through observation and interviews showed that the checklist was feasible and provided positive effects on information exchange, addressed educational issues and team cohesion. The surgeons' commitment was particularly important to successful checklist implementation. All participants felt that the checklist completion before set-up of the procedure was optimal. Further research was suggested to determine the sustainability and generalization of checklist intervention and to investigate its impact on patient safety.

With a Safety Attitudes Questionnaire (SAQ), Makary et al. [15] evaluated the impact of operating briefings on coordination of care and risk for wrong-site surgery. The questionnaire was administered before and after initiation of an OR briefing program with a previously developed structured checklist [16]. The results showed that the personnel (surgeons, anesthesiologists, nurses) subjectively perceived a significantly reduced risk for wrong site surgery and improved collaboration. The briefings improved awareness of surgical site and side being operated on. Furthermore, during implementation of the program the quality of the briefings improved. Although the authors acknowledge that their study does not provide evidence that the rate of wrong site surgery decreased, they point out that the SAQ scores may well be associated with clinical improvements and outcome in the OR. Furthermore, the role of a "champion physician" to facilitate development and encourage the briefing protocol was emphasized.

Leonard et al. [17] reported that surgical teams who implemented a perioperative team briefing process at a non-profit hospital in the US achieved positive results. More detailed results were presented by Lawrence [18]. The briefing chart was broken in four sections: surgeon, circulating nurse, scrub nurse and anesthesiologist. Each section member had to elucidate several items in a given case before the surgery. In contrast to Lingard's study the briefing was performed on the moment the patient was anesthetized, because the team members had decided that was the only time they all members are consistently present. Since the briefing process was introduced, wrong site surgeries decreased from 3 to 0, nursing turnover dropped by 16%, and employee satisfaction (measured with Safety Attitudes Questionnaire) increased by 19% [18]. Perceptions of the safety climate in the OR increased from "good" to "outstanding" [18].

Anesthesia is a domain in the OR that has been using checklist as a safety aid for some time. Various checklists have been developed, especially for checking the anesthetic machinery. Studies show that various concepts detect most faults effectively [19-22]. There is also a simulator to train detection of equipment failure [23]. One study showed that an electronic checklist was superior to the standard FDA approved paper checklist list in detecting equipment faults [24]. However, all studies evaluating equipment checklists for anesthetic machinery acknowledges that not always all faults could be detected. Hence, no checklists guarantees 100% accuracy.

Kendell [25] observed the implementation of a safety checklist for anesthesia equipment based on revised guidelines. The observation was conducted in a district general hospital for a period of 6 weeks which resulted in completion of 132 checklists. The checklists detected a fault in the anesthesia equipment in 82.5% of the time. The results underlined the ability of a safety checklist to detect system failures. A constraining factor, mentioned by Kendell [25], is time to complete the checklist. Time governs the willingness and compliance in using checklists. Time consuming checklists can result in failure of checklist completion. Hence, an important consideration in checklist design the length its practicability.

Another study conducted by Hart et al. [26] in the anesthesia field demonstrated the function of a checklist as a memory aid tool. This study investigated the possibility of using a verbal checklist to assist the anesthesiologist administering general anesthesia during Ceasarean delivery. An electronic checklist (voice-controlled) and a high fidelity anesthesia simulator, along with a predetermined scenario were used to collect data. Subject also filled out a questionnaire. Most of the subjects felt that the checklist was useful although only a minority would like to use it in practice. Completion time of the checklist was also mentioned as an important factor to be considered for further implementation. Remarkably, 60% of the participants preferred a written checklist to the verbal checklist. The problem with electronic checklists lies within the technology used to build the interface device. In the study by Hart [25], several subjects had difficulties to understand the voice synthesized by the device, so the written checklist was preferred to the verbal checklist.

The use of a checklist for laparoscopic equipment has been mentioned before. Meijer et al [27] pointed at the potential benefits of checklist for the laparoscopic equipment and described some critical checkpoints. It was also suggested that to ensure proper state and good quality of laparoscopic equipment, preoperative checklist should become a standard. However, explicit design requirements were not described.

In summary, the number of studies about checklist use in the operation room is limited. Several studies present promising and positive first results on improvement of team coherence and the reduction of errors, providing a solid basis for further investigation. Although guidelines for the critical content of some checklists are available, no general guidelines for the development of checklists are provided. Moreover, the requirements for actual checklist design have not been investigated.

CHECKLIST REQUIREMENTS

General purpose of checklists

Checklists are commonly used in the aviation industry. Requirements and guidelines for the checklist design are provided by the Federal Aviation Authorities (FAA) and the Civil Aviation Authority (CAA) on the internet [28-30]. These guidelines provide detailed information about the checklists specifications such as the checklist layout, format, letter fond, physical construction of the document etc.

In healthcare, the most important function of a checklist is to ensure the correct execution of a given procedure or tasks. It forms the first step in standardization of procedural performance. Based on the reviewed literature and on reports from aviation [31, 32] a checklist in the OR should serve the following purposes:

1. as a defense strategy to prevent human errors
2. a memory aid to enhance task performance
3. standardization of the tasks to facilitate team coordination
4. create and maintain a safety culture in the operation room
5. support quality control by hospital management, government and inspectors

Normal, non-normal and emergency checklists

In aviation, checklists are divided into three categories: normal, non-normal (also referred to as abnormal) and emergency checklists. In the medical field a similar differentiation is also important, because it influences the requirements for the final checklist design. In general, the requirements for the normal or routine checklist are less strict than for emergency checklists. Non-normal and emergency checklists must contain each sequential step of a procedure whereas the normal checklist is typically a listing of action items to be performed and do not necessarily represent each procedural step in sequential order.

Checklist philosophy

Deciding which checklist philosophy is followed is important regarding the checklist design and the content that will be included. There are two approaches: the "system engineering" approach and the "human performance" approach. In system engineering approach, all items involved in performing the task or setting the equipment correctly, should be checked. For example, in laparoscopic surgery all instruments on the OR table and all steps to set-up the equipment should be checked. Consequently, this results in a long checklist. From the human performance perspective, a detailed checklist is no guarantee of absolute safety, because it carries the risk that the users fail to use it correctly or choose not to use the list at all. According to this theory, only the "critical items" should be checked to overcome nuisance. An item is considered critical if failure to check it could lead to accidents. Nevertheless, deciding which items are critical is disputable, because accidents research in various high risk environments has shown that small, seemingly unimportant incidents can have disastrous consequences [33]. It is important to consider human capabilities as well as human limitations in designing a checklist. For the medical field in general and surgical processes in specific, the best strategy may be to follow the human performance approach and start with the most essential checks.

Checklist method

Another important choice is the checklist method. Two dominant types can be distinguished: the "call-do-response" (CDR) method and the "do-verify" (DV) method or combinations of these [28-31,34]

The call-do-response (CDR) checklist, also called "do-list" or "challenge-do-response checklist", uses a step-by-step "cookbook" approach [31]. In an aircraft one crew member calls an item before the action is initiated, then taking the action, and then verifying that the action has been accomplished. This method is most effective when one crew member accomplishes the action and another verifies (cross-checks) that the action was taken. This cross-checking between team members keeps all personnel involved and the advantage is that all items are checked in a systematic manner. For non-normal and emergency checklist the CDR method is recommended [30], but it has also been used successfully in normal checklist.

The call-do-response (CDR) method can be translated to the OR during critical steps of the procedure or identifying important "landmark" structures, for example cross-checking of "critical-view of safety" during laparoscopic cholecystectomy (identifying the cystic duct and artery going into the gallbladder) [35]. However, the disadvantage of this method is the rigidity, especially when the list is long. Team members can not perform other tasks at the same time, and once the sequence has been interrupted a skipped item can pass unnoticed [34]. The CDR method fits perfectly into the concept of what is referred to as "time-out procedure". Prior to the surgical procedure, the time-out takes place in which critical items are checked between team members, for example; the name of the patient, site of operation and potential allergies for disinfectants. These safety checks are already used in surgery and several hospitals have already formalized them in their standard protocol.

In the do-verify (DV) method, which is also called "clean-up" method pilots configure an airplane according to memory in variable sequence. Then, the checklist is read to verify that all items have been correctly accomplished. The advantage of this approach are that each individual team member can work independently, which enhances efficiency (quickly performing series of items) and balances the workload between team members. It is the most common used method by commercial airlines [34] and is recommended for normal checklist [30]. The disadvantage of the DV method is the higher risk of items being missed compared to the CDR method.

In the operation room the DV method can be useful for verifying all surgical instruments and for the set-up of the laparoscopic equipment before the start of the procedure.

Design requirements

The checklist requirements recommended for surgical processes are summarized in Table 1. The recommendations are based on the guidelines from the CAA and FAA [28-30]. Furthermore, several other resources recommended by the aviation authorities [31,32,34], combined with our own experience derived from a pilot study with a checklist are used.

The most important requirements for the checklist design are consistency, clarity, and straightforwardness. A checklist should serve a clearly stated purpose and should be used intuitively. Some recommendations are very general and logical such as the robustness and consistency. Others are more specific such as number of checks, binding, font size, font type and spacing.

Checklist solutions

In the commercial aviation industry, many examples are available. This paragraph focuses on the feasibility, advantages and disadvantages of various checklist alternatives for surgical processes. Two major distinctions will be made between types of checklists: the paper and the electronic checklist.

Table 1. Recommended requirements for the design of the surgical checklist

Aspect	Requirement
General	
Consistency	○ Consistent format should be maintained for each checklist, also within hospitals and within surgical procedures ○ Abbreviations should be consistent on all checklists
Quantity	○ At least equal to the number of operating rooms ○ Spare lists
Availability and Accessibility	○ Checklist should be stored in readily accessible location in each operation room
Checklist Variants	○ Specific checklist for each surgical procedure and type of operation, task, or procedure ○ Clear difference between variants (emergency, routine, procedure)
Content and Order	
General	○ Tasks should be presented in list form in a logical, functional or "geographical" flow ○ Maximum of 7 tasks or checks per page is recommended ○ Long procedures should be separated into shorter groups if possible
Critical items	○ Simple mnemonic can be used as an aid ○ Present critical items at the start of the tasks or clearly indicated
Layout and Format	
Content list and Index	○ The content list should follow the same order as the tasks ○ Provided at the front and not exceeding 1 page, if possible ○ An alphabetical index at the ends is recommended
Abbreviation, Phraseology and Brevity	○ Use as few words as possible but understandable and unambiguous ○ Phraseology should be straightforward and in standard medical terms ○ If abbreviation is used, it should be standardized and explained clearly
Start and Finish	○ Tasks and drills must have clearly defined start and finish
Amendments	○ Checklist construction should enable pages or cards to be changed easily for updating purpose ○ Each checklist should contain a record of amendment state, no longer than 1 page ○ Amendment record page should be differentiated from the pages containing the tasks ○ Each amended page should be dated in small print
Figures /Tables	○ Figures, tables should be clearly linked to the tasks
Physical Construction	
Document size and Binding	○ A5 paper size with 50% variance ○ The binding should allow pages to be opened minimum through 180º and ideally up to 360º ,spiral or ring side binding is recommended ○ The binding should be such that all the text on the page can be read
Cover	○ Robust and able to withstand normal handling and cleaning ○ Cover should be easily distinguishable from other pages ○ Applicable surgical procedure should appear on front of cover
Pages and Tabs / Dividers	○ Pages should be able to be cleaned, lamination is recommended ○ Tabs and dividers may be used to assist locating pages
Print Characteristic	
Font type	○ Helvetica, Gill Medium, Arial or Sans Serif are recommended ○ Font type should be consistent throughout the checklist ○ Italics should not be used for tasks ○ Use of italics for comments, notes or supporting information is acceptable
Font size	○ 14pt for heading and 12pt for normal text are recommended ○ A character height-to-weight ratio of 5:3 is recommended
Margins	○ Margins should be at least ¾ inch
Emphasis and differentiation	○ Bold, larger font and underlining are acceptable for emphasis ○ Small dash or bullets in front of individual tasks may be used to aid clarity

Other Typography	○ Vertical spacing between lines should not be less than 25-33% of the overall size of the font ○ Horizontal spacing between characters should be 25% of the overall size and not less than one stroke width ○ Good quality printing should be used
Contrast and color	○ Black text on white or yellow background ○ The reflection percentage of the background should be at least 70% ○ Luminance ration between text and background should be about 1:8 ○ Colored text and pink or red pages are not recommended

Paper checklist

The first and probably the simplest solution is the paper checklist. The most important advantage of the paper checklist is its low technical complexity and high reliability. This form can be made into various sizes according to its purpose. Most of paper based checklist are portable, and thus can be carried around. They are easily produced at relatively low cost, and do not require additional infrastructure or technology for implementation. Furthermore, the paper checklist is highly reliable, because it is independent of power supply, maintenance or computer malfunction. This makes paper checklists very suitable for emergency and abnormal circumstances.

From ergonomics point of view, usually a paper based checklist is also provided with some kind of medium for ease of holding and writing, such as a paper sized cardboard with a clip on it.

It is important to be aware of the fact that paper checklists items in aviation are not marked when completed. They consist of reusable (cardboard or plasticized) lists used by the flight crew to perform important steps of their task. Moreover, checklist use seems to be a second nature for pilots. Their entire training is aimed at correct execution of procedures and checklist use is practiced extensively. Checks are called aloud, recorded by the voice-recorder, and in case of an incident or accident scrutinized for design faults or incorrect execution. This renders the marking of items in this field redundant. However, the disadvantage of reusable paper based checklists without marking is that it has no memory of completed items. Another inherited disadvantage of the paper solution is its inability to be updated automatically if items are revised or new items need to be added.

In surgical care, which is focused on the individual patient, a different strategy may be preferred. A paper based checklist with marking can very well be used in normal circumstances, for example as an integral part of the patients' medical chart. Critical items can be checked prior to a surgical procedure such as allergies, site of the operation, name of the patient, correctness of the indication, sort of procedure, used instruments, expected problems, etc. If preferred, the checklist could be signed by the nurse or surgeon. Checking the items could also serve as a structural briefing of the entire surgical team prior to each procedure. Structural briefing could improve team situational awareness and enhance patient safety.

In summary, the paper based checklist can be used for any circumstance. Because of its low technical requirements, it is easy to use and to implement in the organization. When the checklist is integral part of the patients' medical chart, marking and signing the checklist could solve the problem of missing items or not completing the checklist.

Electronic or computer based checklists

Another type of checklist is an electronic device. A wide variety of electronic devices are available; from small digital handheld devices to a stationary desktop PC. The vocal checklist is a special variation of computer based checklists.

The advantage of electronic checklists is that they can be automatically updated after revisions. An electronic checklist can send and receive information from compatible systems or devices. This feature enhances checklist standardization. The programmable feature and high storage capacity enable multiple checklists to be made and stored in one device. The users can then easily select the appropriate checklist for their task. Automated data capturing for research goals is another valuable feature of electronic checklists. However, initial costs and complexity are increased and electronic devices are susceptible to system malfunction.

The biggest advantage of computer based checklists is the opportunity to feed information regarding the status of the checklist back to the user on. This is called the "feedback loop". The system can alert the user if items have been missed or not completed. Rouse and Rouse already showed in 1982 that pilots made significantly fewer errors using an electronic checklist compared to paper [32, 36]. Completion time, however, was longer for the electronic list, but this could easily be solved with additional training [37]. There are also electronic checklists used in aviation that do not need a human operator. Such a system was evaluated by Palmer and Degani [38]. Several levels of automation can be selected, from full manual check (users complete the checklist items), combined (the system completes the checklist item and subsequently asks for confirmation from the user), and fully automated (the system completes the items without asking for user confirmation).

Several examples of electronic solutions exist. Palmtop displays are small portable electronic devices. They are larger than an adult's hand, capable of processing and storing data, and can be synchronized to a workstation. The storage capacity is smaller than that of a desktop PC.

The Tablet PC is another type of portable device, and although it is larger and heavier than a palmtop display, it has generally better processing capabilities. Moreover, its larger screen provides better display of information. Currently, a company called the Surgical Safety Institute [39] specializes in OR safety and develops checklist software integrated in a Tablet PC. However, the size of this device makes it more difficult for the users to perform other tasks with their hands while working on or holding it. If the users only need a device for a simple checklist, this device could give unnecessary trade offs, especially for cost and portability.

PC's can also be used for checklists. Most modern operation rooms have already a desktop PC installed. Although the immobility can cause limitations it can very well be used for a pre-operative checklist. It requires no additional infrastructure. Moreover, with the increase in use of digital patient records and operation room planning systems in hospitals, a pre-operative checklist could easily be added.

The voice-controlled checklist is a sophistication of the computer based checklists. Currently, several companies provide entire OR concepts including voice-controlled operation of operation equipment, video data management and information resources (e.g. patient records, internet, radiology records etc). However, checklists are not yet included in these concepts. Furthermore, this technology is very new and concerns about reliability should first be addressed before it can be safely used [40].

CHECKLIST DEVELOPMENT

Checklist development and incorporation is a systematic process. Stufflebeam described a general guideline of 12 forward steps for development of a checklist for any particular area [41]. For the development of the surgical checklist these steps were partially adapted and combined with our own experience, resulting in 14 steps (Figure 1).

1) Start checklist development

The first step in checklist development is signaling the need for a checklist solution. In our case a high rate of equipment problems during laparoscopic surgery during routine observations formed the motivation to develop a checklist.

This step can also be used to assign a person or task force to be responsible for managing and directing the checklist development. This could be research fellows, managers or work floor members (e.g. nurses, surgeons etc.).

2) Define checklist purpose

The second step in checklist development is defining the purpose of the checklist. This step should produce a clear definition of the intended use and users of the checklist. Constructing a frequency by consequence table of incidents may be helpful (Figure 3). For example, in our case the purpose of the checklist was to minimize the equipment problem during laparoscopic surgery and the intended users were the scrub nurses. During this step the checklist developers can gather the necessary information by studying the relevant literature or consulting an expert of the related field.

3) Perform task analysis

The next step in the checklist development is performing a task analysis in the area where the checklist implementation should take place. The aim of this step is to gain an insight into the tasks of the potential users. A task analysis can be conducted in several ways such as focus groups, direct observation or video recordings. During focus groups all immediate stakeholders (e.g. representatives of the potential end-users such as nurses, surgeons and managers) discuss the list of activities which are carried out. Recording the tasks in the OR using a video camera will increase objectivity.

4) Make a list of tasks in sequential order

This step is closely related to the task analysis. By presenting the tasks in sequential and logical order, a clear overview of the specific activities of the operators can be achieved. The task analysis report forms the basis of the checklist design.

5) Design checklist concept

In this step, a list of preliminary checkpoints is made based on the previous task analysis report. The end result of this step is a checklist concept. The guidelines and requirements, presented in Table 1, can be used to come to a checklist format that serves its purpose.

6) Review checklist (iteration)

The checklist concept should be reviewed by all stakeholders. Ideally, the stakeholders are representatives of all the end-users (the complete OR team) and managers at the organizational level. The purpose of the review is to give feedback to the checklist developers regarding the adequacy of the checklist concept. If necessary, adjustments can be made during several iterations. The stakeholders should give approval for the checklist concept to be evaluated in the operation room or other environments.

7) Test functionality

During a trial period, the functionality and compatibility of the checklist concept in the task execution are evaluated. During this evaluation process the checklist developers instruct several participants on how to use and complete the checklist. The participants in this case are all the intended end-users. Important information regarding, for example the attitudes of the users toward the checklist, the impact of the checklist on the existing activities and whether the checklist serves its purpose can also be gathered during this step. Methods to collect this information include direct or video observations and structured questionnaires.

8) Checklist approval

Results from the trial period are evaluated by the stakeholders. Final adjustments can be made. Then, the representatives of the stakeholders formally approve the checklist concept.

9) Finalized checklist

The checklist has now been approved and is ready to be distributed among and used by the personnel in their daily work. In the case of a paper (reusable) checklist, this is put in a more durable format to withstand frequent use. In the case of an electronic checklist, the process can be less complicated if during the development phase (step 1 to 8) a paper checklist format is used.

10) Train personnel

In this step, training of all personnel is officially initiated. All personnel are briefed about the implementation of the checklist. In the case of the pre-operative safety checklist for laparoscopic equipment, the scrub nurses specifically are instructed how to use the checklist. The surgeon is instructed to call for the checklist initiation and confirmation of checklist completion. Confirming and cross-checking between different surgical team members ensures proper checklist use.

11) Personnel problem and minor adjustments

Although the checklist has been tested earlier, during the training sessions, some new personnel related problems can be detected. These personnel problem may lead to the changes in the training method or even to checklist revisions. Nevertheless, if the test phase is executed properly these will only be minor adjustments.

12) Implement checklist

After the minor problems have been addressed and solved, the checklist can finally be implemented. During this step, the organization and its people should be briefed with the checklist implementation and receive instructions.

13) Periodically review

Organizations and tasks change constantly because new procedures or instruments are introduced. Therefore, checklists need to be reviewed periodically. The purpose of a periodic review is to evaluate the conformity of the checklist with the regulations. Basically, the time period of a checklist review is arbitrary and based on the needs of the organization, but the review should be conducted at least once a year. In addition, a checklist review should be conducted earlier if major changes in tasks, procedures or equipment occur.

14) Checklist (re)approval

The result of a checklist periodic review should be used to decide whether the checklist is still acceptable until the next review. Approval is granted by one or more representatives of the stakeholders, or someone on the work floor assigned to control the checklist process. If necessary, the list is revised. In the end, checklist development and implementation is a cycle that regularly evaluates the conformity of the checklist with the organization needs and regulations.

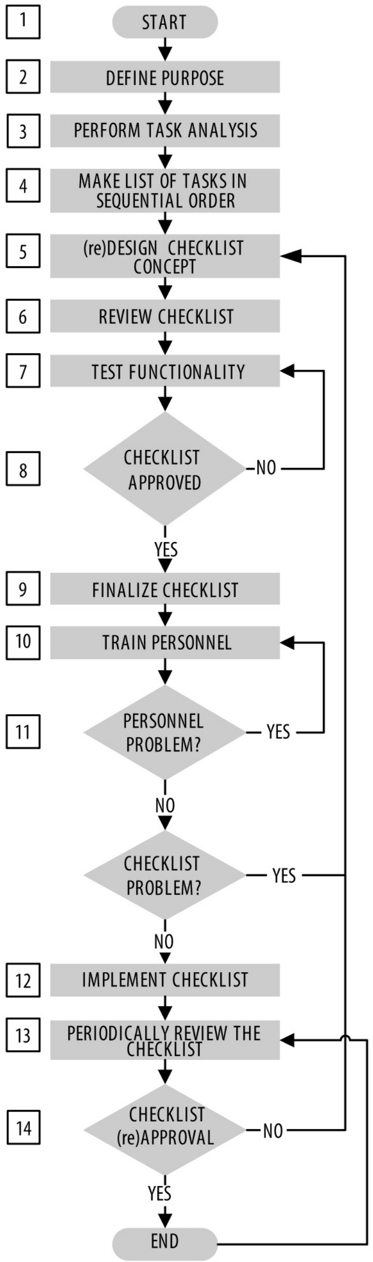

Figure 1. Flow diagram of checklist implementation

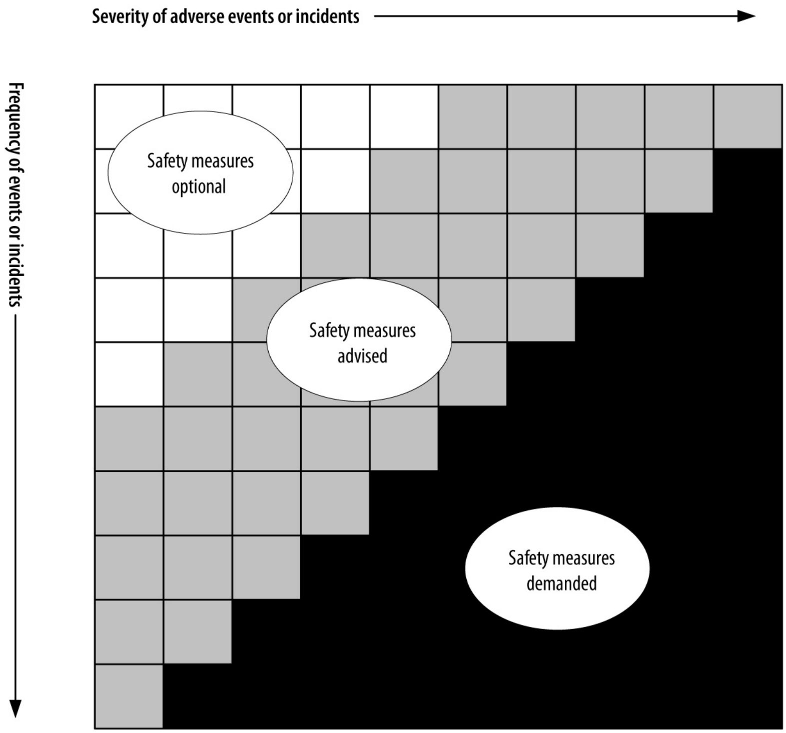

Figure 2. Frequency by consequence table

DISCUSSION AND RECOMMENDATIONS

Checklists as a memory aid in health care are no novelty. However, literature addressing formal use of checklist in the operation room is scarce. Although its purpose and potential seems logical, design of an effective checklist is not a straightforward process. In an effort to formulate design requirements for a surgical checklist, the aviation guidelines proved to be very useful. Nevertheless, further studies are needed that translate the general guidelines, as proposed in this study, into useful tools in daily practice. The ultimate goal is to determine the impact of checklists on the quality of care (e.g. patient safety and efficient workflow).

There is a central role for the medical professionals (surgeons, nurses and managers) in deciding how checklists should be embedded in their environment. They are the end-users and the success of the checklist approach inevitably relies on their motivation and willingness to use it. Therefore, medical professionals should be closely involved in the implementation process. Consensus is needed among medical professionals to decide which processes require a checklist, which items should and which should not be adopted.

It is important to underline that adoption of the checklist approach has several important benefits especially for surgery related healthcare, which should ultimately lead to improved quality. Checklist use itself will enhance the consciousness and positive attitude towards working safely. The importance of team communication is emphasized, because it will become more transparent, structured and standardized. Tasks and responsibilities of each team member are clarified, which will enhance the objectives for team training and also for what is known as Crew Resource Management (CRM). CRM is concerned with cognitive and interpersonal skills needed to manage the surgical procedure in a complex environment and not so much with the technical skills of actually performing the procedure.

In the past, standardization of emergency training such as the Advanced Trauma Live Support (ATLS) has shown to be successful, judging from the large number of physicians trained and number of institutions that have adopted a similar structure [42]. Standardization of tasks, communication and use of equipment may improve reliability of comparing interventional procedures for scientific research and outcomes may become less dependent on the variability of individual surgical team members. However, to guarantee user commitment to checklist the roles and responsibilities of various team members needs to be defined.

The use of checklists could also help the industry to clarify equipment problems and develop effective solutions. How to monitor the effect of the checklist and provide direct feedback to the industry is not clear yet. Furthermore, research to test the benefit of checklists and to improve the (interface) design is needed.

Besides the advantages of checklist use, there are concerns for drawbacks that need to be addressed. Healthcare personnel may be skeptical towards the change in their work routine. Some may argue checklist use may bring it a significant increase in workload. Therefore, it should be made clear that the checklist approach only formalizes tasks that have to be performed anyway. Additional work to complete lists should be kept at a minimum and therefore each checklist should be carefully designed. Furthermore, checklists causing superfluous administration should be avoided. This is, however, no argument against a paper checklist.

Evidently, measurements to increase safety require financial investments and can be costly at first. These costs will, be largely compensated by the improvements in quality of care, in the long run. However, it is not expected that all investments into the checklist can be translated directly into measurable improvements. The effect of checklists is highly dependent on influences of the "safety-culture" within a certain environment. Furthermore, as Calland [4] already suggested, checklists are only one of many strategies to improve quality and institute a safety culture. Strategies such as systematic monitoring of incidents, in-depth accident investigation (root cause analysis), and structural and continued training based on objective assessment, are important as well. In addition, checklists are not watertight in preventing human error or accidents in general. The strength lies within the combination of various safety measurements as mentioned above.

In conclusion, the use of structured checklists in surgical processes is most likely to be effective because it standardizes human performance and ensures procedures are followed correctly rather than relying on human memory alone. Several studies present promising and positive first results, providing a solid basis for further investigation. Future research should aim on the effect of various designs and strategies of checklists in order to ensure maximal compliance.

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Chapter 10

Can a structured checklist prevent problems with laparoscopic equipment?

E.G.G. Verdaasdonk[1,2], L.P.S. Stassen[1,2], W.F. Hoffmann[2], M. van der Elst[2],
J. Dankelman[1]

1 Department of BioMechanical Engineering, Faculty of Mechanical, Maritime & Materials Engineering, Delft University of Technology, Delft, the Netherlands
2 Department of Surgery, Reinier de Graaf Group, Delft, the Netherlands

Submitted

ABSTRACT

Background: A high incidence of problems with the technical equipment is known to occur during routine laparoscopic procedures. Use of a structured checklist of preparatory measures could help to prevent these problems. The study aimed to determine the extent to which a checklist reduced the number of incidents with technical laparoscopic equipment.

Methods: A 28-item checklist was developed based on frequently occurring laparoscopic equipment problems during 30 laparoscopic cholecystectomies (Control group). A further 30 procedures were conducted with the checklist (Checklist group). The number and type of incidents with the technical equipment were compared between the groups. All the procedures were recorded using a special audio-video system (black-box).

Results: In the Checklist group, the total number of incidents per procedure was 53% lower than in the Control group (23/30 versus 49/30). The checklist led to fewer incidents of wrong positioning (9/30 versus 22/30), and wrong settings and connections (7/30 versus 12/30) of the equipment. Defects or malfunctions decreased from 15/30 in Control group to 7/30 in the Checklist group. One or more incidents with the equipment occurred in 47% (14/30) of the checklist procedures compared to 87% (26/30) of the control procedures. Median time taken to complete the checklist items was 3.3 minutes (range 1.0-8.3 minutes).

Conclusion: Use of a checklist was feasible and helped to reduce problems with the laparoscopic equipment in the operating room. Future research should aim to implement checklists for different procedures and investigate their effects.

INTRODUCTION

The introduction Minimally Invasive Surgery (MIS) and its sophisticated technical equipment have made the surgical environment more complex. New problems have been created in the domain of man-machine interaction during these high-tech procedures, creating opportunities for errors or incidents to occur. Surgeons are aware of the existence of user problems with the laparoscopic equipment and instruments in their operating theatres [1]. Recently, the occurrence of incidents with the technical equipment has been quantified [2]. These incidents comprised of problems with the mechanical instruments and problems with the technical equipment, for example positioning, absence or malfunctioning. The frequency of incidents was strikingly high: 49 incidents in 26 out of 30 routine laparoscopic cholecystectomies.

A short preoperative checklist based on the concepts used in industry and aviation could help to prevent these problems. Currently, no checklists that specifically aim to structure human interaction with the surgical equipment in the operating room are available. It is unknown whether this approach is feasible and effective.

The aim of this study was to develop a structured preoperative checklist and to determine the feasibility of its use and whether it could help to prevent incidents with laparoscopic equipment during routine laparoscopic procedures.

METHODS

Development of the checklist

A concept checklist was developed based on an incident analysis with the equipment in 30 laparoscopic cholecystectomies (Control group) [2]. Guidelines for aviation checklist design were also taken into consideration [2,3]. The concept checklist was reviewed and adjusted by an expert laparoscopic surgeon and several experienced operating room nurses. In a pilot study with two procedures the concept checklist was tested, adjusted on the basis of errors and inconveniences. The size was brought back from A4 to A5 format and all pages were covered with transparent plastic cover.

Table 1 and Figure 1 show the 28-item checklist that was considered ready for further investigation. The checklist consisted of three parts had to be executed by the circulating operating room nurse. Part 1 comprised the checks necessary prior to the arrival of the patient at the operating room. Part 2 covered the period up to the point when the endoscopic camera was introduced into the abdomen; part 3 had to be executed after the camera had been introduced into the abdomen.

Table 1. Structured checklist of preparatory measures

Part I: Preparation prior to the procedure

☐ Check presence of image on two monitors
No image then:
→ Switch monitors off and on
→ Connect cable (BNC) from “video comp” to first monitor “ input: comp/sos” on back of second monitor
No image then:
→ witch monitors off and on
→ Replace laparoscopic tower without image and report problem

☐ Check the amount of CO2 gas available
(min. 1 green line is sufficient for one standard laparoscopic procedure)
Make sure that:
→ the TEM cable is not connected
→ gas valve is open (turned to the left)

☐ Check whether CO2 filter is present on insufflator
☐ Check whether light source is functioning
Light source defective then:
Replace laparoscopic tower and report problem

Equipment connections & settings
Diathermy ValleyLab Force FX: monopolar
☐ Connect diathermy cable of laparoscopic instrument to coagulation at front port 2
☐ Connect foot switch cable to the back in port 2
☐ Connect disposable patient-plate
☐ Connect diathermy knife (yellow) to “cut/coa” at the front
☐ Set minimal “coagulation” on 35 Watt (lower setting allowed)
☐ Set minimal “cut” on 35 Watt

Note: if diathermy device malfunctions during the procedure
→ First check above items
→ Then replace diathermy cable of laparoscopic instrument
→ Then replace foot switch + cable and report problem
→ Replace diathermy equipment and report problem

Part II: before introduction of 1st trocar

☐ **Equipment set-up**
☐ Place diathermy equipment at foot on right-hand side of the patient
☐ Place footswitch near right foot of surgeon, cable directed along upper side of pillar of the OR table
☐ Place first monitor and laparoscopic equipment tower near right shoulder of the patient
☐ Check with surgeon whether monitor is correctly positioned.
☐ Place second monitor on the left shoulder of the patient
☐ Check with assisting surgeon whether monitor is correctly positioned.
☐ Place suction equipment next to diathermy equipment.

Equipment connections & settings
Monitors
☐ Check again the presence of an image on the monitors
No image then:
→ Switch monitors off and on
→ Connect cable (BNC) from “video comp” to first monitor “input: comp/sos” No image then:
→ Switch monitors off and on
→ Replace laparoscopic tower without image and report problem

Insufflator & light source
☐ Connect light cable to light source
☐ Set light source at 75%, check again the presence monitor image
→ If necessary adjust to 100%
☐ Check that disposable CO2 with filter is connected to insufflator cable
☐ Set maximal insufflator pressure at 14 mmHg
☐ Set minimal insufflation flow at 1.4 L/min

Part III: after introduction of 1st trocar

☐ On indication of surgeon that trocar is correctly placed in the abdomen, set flow at maximal
☐ Perform “white balance”
☐ Focus endoscopic camera
☐ Cross-check with surgeons whether light and colour settings are correct
If colour setting incorrect despite “white balance”
→ Switch monitor off and on and consult the operation team
Colour settings still incorrect then:
→ Adjust settings on monitor
Image to dark:
→ Light source higher
→ Replace light cable. Set source at 75%
→ Replace endoscope
→ Replace camera
→ Postpone procedure, replace laparoscopic tower and report problem
☐ Coat endoscope with anti-condensation fluid

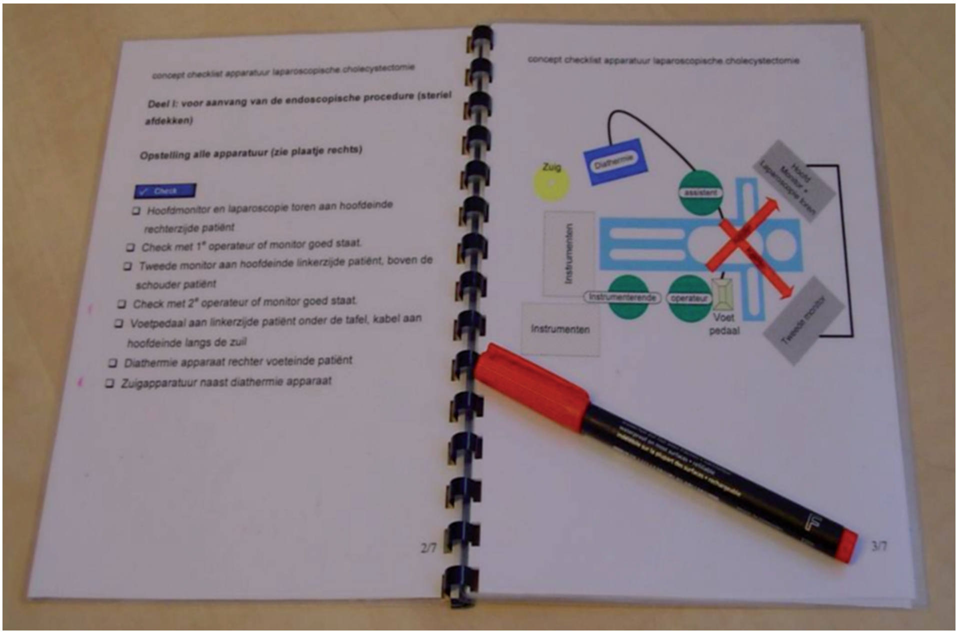

Figure 1. Checklist concept

Study protocol

The study was conducted in the setting of a large non-university training hospital. Our standard laparoscopic equipment consisted of a laparoscopic tower trolley and two Sony PVM-Trinitron Colour Video Monitors. The tower trolley held an insufflator, a xenon light source, a digital 3-chip camera and camera-unit. Diathermy equipment was mounted separately on another trolley. Each team consisted of a surgical trainee, a (supervising) surgeon, a scrub nurse and a circulating nurse. The checklist was used during 30 laparoscopic cholecystectomies (Checklist group). All procedures were recorded using a special audio-video system that consisted of two digital video recorders with 3 camera image inputs and two microphones (Storz, Tuttlingen, Germany). Patients were asked to sign an informed consent form on the day prior to the surgical procedure.

The video material was reviewed and analysed by the first author (E.G.G.). Procedures that needed to be converted to open or conventional cholecystectomies were analysed up to the moment of removal of the trocars.

Assessment method

Incidents with the technical equipment, such as the insufflator, the diathermy equipment, monitors, light source, endoscope or suction unit were were divided into several categories:

position and absence (equipment in the wrong position or not present at all), settings and connection (problems due to wrong settings or connections), and defects and unclear (problems due to a defects or unclear malfunctioning). Problems with the laparoscopic instruments were not included. Time taken to execute the items on the checklist was also measured.

The number of incidents in the Checklist group was compared to the number in the Control group. The Fisher exact test (two-tailed) was used to analyse differences in total number of incidents between the Checklist and the Control group. $P<0.05$ was considered to be statistically significant.

RESULTS

Between June 2004 and December 2004, 30 laparoscopic cholecystectomies without the use of a checklist were recorded and analysed [2]. These procedures formed the Control group. From 1 September 2006 to 30 March 2007 a total of 30 laparoscopic cholecystectomies with the use of checklist were recorded and formed the Checklist group. In the Control group, the surgeons comprised 7 different staff surgeons and 11 surgical trainees. In the Checklist group, the surgeons comprised 6 different staff surgeons and 12 surgical trainees.

In four procedures in the Control group, the laparoscopic approach was converted to an open procedure [2]. These decisions were not due to technical problems with the equipment or instruments. None of the procedures in the Checklist group were converted to an open procedure.

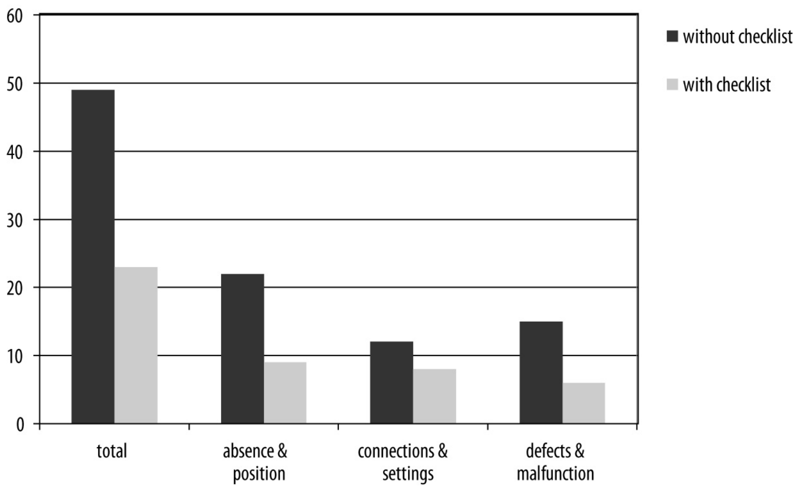

Figure 2. Number of incidents with and without the use of a checklist

In the Checklist group, the total number of incidents per procedure was 53% lower than the Control group (Checklist group 23/30 versus Control group 49/30). Figure 2 displays the number of incidents in the Checklist group and Control group. In the Checklist group there were fewer incidents of wrong positioning of the equipment (9/30 versus 22/30) and wrong settings or connections (7/30 versus 12/30). The number of incidents due to defects or unclear malfunctioning was 7/30 in the Checklist group versus 15/30 in the Control group. Table 2 shows the number of incidents in more detail in relation to the different components of the laparoscopic equipment.

Table 2. Number of incidents with the equipment in the Control group and Checklist group

	Subtotal		**Absence & Position**		**Settings & Connections**		**Defects & Unclear**	
	Control	**Checklist**	**Control**	**Checklist**	**Control**	**Checklist**	**Control**	**Checklist**
Monitor/Image	24	14	13	5	3	3	8	6
Endoscope	1	0					1	
Light source	1	0					1	
Insufflator	4	4			4	3		1
Diathermy	10	1			5	1	5	
Pedals	9	4	9	4				
Total	49	23	22	9	12	7	15	7

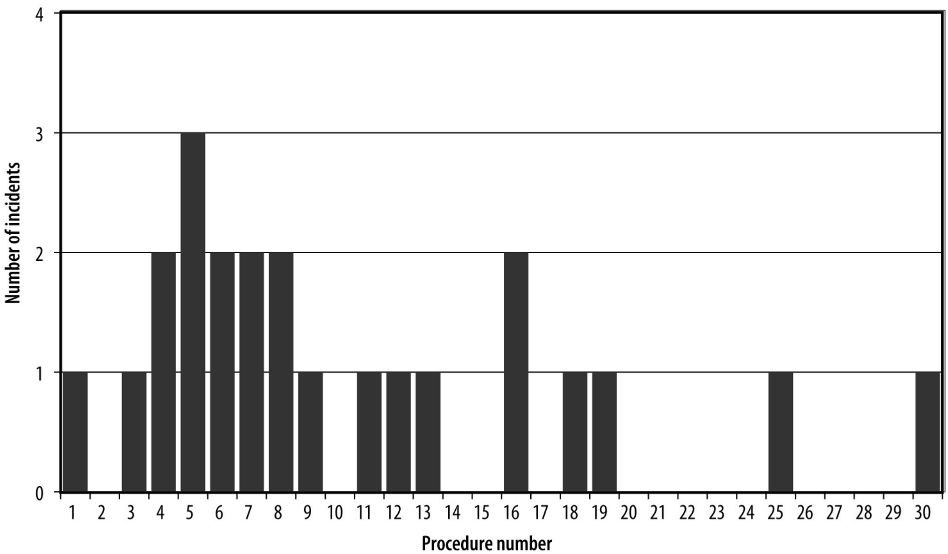

Figure 3. Number of incidents per procedure in the Checklist group

Overall, one or more incidents occurred with the equipment in 47% (14/30) of the procedures in the Checklist group compared to 87% (26/30) in the Control group (*P*=0.003*)*. Furthermore, twice as many incidents occurred in the first 10 procedures of the Checklist group than in the last 20 procedures (Figure 3). None of the problems observed on the recordings caused direct operative complications in the patients.

Median time taken to complete the items on the checklist was 3.3 minutes (range 1.0-8.3 minutes).

DISCUSSION

This is the first study on the effects of a short preoperative structured checklist that specifically aimed to prevent problems with the laparoscopic equipment.

The concept of using a structured checklist prior to a surgical procedure is not completely new in health care. Anaesthesia checklists to prevent machinery problems appeared more than a decade ago. Studies showed that various checklist concepts detected machinery faults in 50-80% [4-6]. The lists or protocols varied between hospitals vary and it was not clear whether some hospitals ever used these lists.

In 2004, the Joint Commission on Accreditation of Health care Organizations (JCAHO) mandated the Universal Protocol to prevent wrong site, wrong procedure and wrong person surgery within all Joint Commission accredited organizations [7]. The protocol consists of guidelines that advise a preoperative verification process, marking of the operative site and "time-out" before starting the procedure [8]. The use of a checklist in the time-out period is especially recommended. The results of the first studies that evaluated the effect of structured checklists were positive and indicated improved safety climate, decreased wrong site surgery, improved personnel satisfaction and better team cohesion [9-11]. However, there were no specific guidelines for the physical design of the checklist.

Although the advantages of checklists seem logical, critics doubt their benefit and still emphasize the disadvantages, such as the extra time needed to complete the list, the extra work and the rigidity of following a specific list. Nevertheless, when safety is the highest priority, the potential benefits should outweigh these disadvantages.

The checklist used in this study led to more than 50% reduction in the number of incidents with the equipment. In a retrospective report by Kwaan [12], two thirds of the wrong site surgeries (8 out of 13) could have been prevented by the correct use of the JCAHO protocol. In the case of wrong side surgery, it is difficult to determine the effect of the Universal Protocol solely on the basis of the decrease in adverse events, because wrong side surgery is extremely rare (1 in 112,994 operations). As was shown in the present study, the checklist could not prevent all incidents with the laparoscopic equipment. In the literature, the studies on checklist for anaesthesia equipment also showed that they could not detect or eliminate all the faults. Therefore, the use of checklist does not guarantee complete safety. However, in this study more than half the incidents were prevented, while with the anaesthesia equipment, even up to 80% were prevented, which cannot be interpreted in any other way than a substantial improvement in the quality of care. Furthermore, the effect of a checklist goes beyond any directly measurable reduction in actual adverse events. In the hectic environment of an operating room, with the constraints and separate priorities of each profession, a standardized checklist provides a structure for communication and performance. Moreover, a checklist enhances consciousness about safety issues and awareness of the importance of preventing human errors. The actual incorporation of checklists in daily practice, however, requires the commitment of all personnel. In general, health care professionals are not used to performing tasks and communicating in a standardized manner. Successful incorporation of a preoperative checklist or time-out, therefore, requires cultural changes. In our study, this "learning curve" effect was illustrated double so many incidents in the first ten procedures as in the last twenty procedures. Personnel needed time to become accustomed to the checklist and realize its usefulness.

Another important factor in successful incorporation of a checklist in the OR , is the cooperation of the surgeon [9,10]. It is considered essential that the checklist initiative is supported by the surgeon. In the study by Markary several "champion physicians" were appointed to ensure the execution of the checklist. This strategy seemed to be effective and it was advised to assign enthusiastic leaders to initiate the protocol.

In the present study, video monitoring was used to observe the level of commitment to the checklist. In addition, a researcher was present during each procedure. This could have slightly influenced the results, because the supervision itself may have enhanced the commitment to the checklist use. However, this influence was present in the Control group and the Checklist group and therefore cannot explain the observed differences.

Once the positive effect of protocols or checklists has been acknowledged, it is important to address the question of how to ensure the use of the checklist and its correct execution. In aviation, correct checklist use is extensively practised during pre-flight training. Furthermore, during the flight the cockpit communication is recorded by the voice-recorder and stored in the black-box. The video monitoring used in the present study can be considered as a black-box and a control mechanism to stimulate adherence. Currently, such video or audio monitoring is not standard in most operating rooms, but this may change in the near future once the legal obstacles have been resolved and the scepticism among specialists has ceased. Further research should focus on the design of reliable and effective interfaces that aim to achieve maximal compliance of the users to the protocols. In addition, other initiatives can be expected to enhance the cultural changes needed to improve patient safety and outcome such as (OR) team training, critical communication exercises and education on how human factors influence performance (Crew Resource Management).

In conclusion, it was feasible to employ a preoperative checklist to help prevent problems with laparoscopic technical equipment in the operating room and there was a considerable reduction in the number of incidents. Future research should aim to find the preferred physical presentation and interfaces for such protocols and to implement checklists for different procedures.

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Chapter 11

Verbal communication analysis during laparoscopic cholecystectomies and the potential for surgical training

ADAPTED FROM

Analysis of verbal communication during teaching in the operating room and the potentials for surgical training

E.M. Blom[1], E.G.G. Verdaasdonk[1,2], L.P.S. Stassen [1,2], H.G. Stassen[1],
P.A. Wieringa[1], J. Dankelman[1]

1 Department of BioMechanical Engineering, Faculty of Mechanical, Maritime & Materials Engineering, Delft University of Technology, Delft, the Netherlands

2 Department of Surgery, Reinier de Graaf Group, Delft, the Netherlands.

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ABSTRACT

In the present study a new classification method was used in order to gain insight in the specific contents of verbal communication processes during training of laparoscopic surgery.

Eight videotaped laparoscopic cholecystectomies were analyzed; two entire procedures and the dissection phase of 6 procedures. The communication was classified in 4 types (commanding, explaining, questioning and miscellaneous) and 9 additional content domains (operation method, location, direction, instrument handling, visualization, anatomy and pathology, general, private, indefinable). For each item a specific thesaurus was defined. The communication events were analyzed and scored according their classification by a researcher, with the help of a special designed software program.

The analyses of the entire procedure showed a high percentage of the "explaining" and high percentages of explaining "operation method", and "anatomy and pathology" content. In the analyses of the dissection phases of six procedures, 60% of the communication events were related to the "explaining" type in combination with high percentage of the "operation method" (27%), "anatomy and pathology (19%) and location (positioning of instruments and tissue interaction).

The classification method is feasible and reflects objectively the verbal communication between supervising surgeon and trainee. The results suggest specific training needs for cognitive skills training and the classification method may contribute to evaluation of different training methods.

BACKGROUND

Surgical trainees gain experience during performance of laparoscopic procedures in the operation room under supervision of an experienced surgeon. However, there has been little insight what is actually taught during this procedural training of surgeons in the operating room. In order to improve training methods and develop new training devices a better understanding of the teaching process in the operating room is needed. Analysis of the communication between the surgeon and the trainee during training may provide this insight.

Analysing cognitive tasks and communication is difficult. Different methods have been developed [1-3]. Hauge et al. [1] described a method aimed at registering teaching behaviour in the OR in order to distinguish between informing, questioning, responding and setting-tone behaviour. Lingard et al. [2] investigated the team communication in the OR to distinguish patterns that suggest team tension which could influence team performance. Guerlain et al. developed an extensive software program to analyse audiovisual data from operation procedures [3]. However, none of their methods are particularly aimed on the content of communication. Therefore, a new classification method developed at the Delft University of Technology was developed. A pilot study showed acceptable inter and intraobserver agreement (70% and 86% respectively) [4].

In the present study the classification method was used in order to gain insight in the specific contents of verbal communication processes during training of laparoscopic surgery.

THE COMMUNICATION CLASSIFICATION METHOD AND THE LAPAROSCOPIC PROCEDURES

Four communication types were distinguished: explaining, commanding, questioning, and miscellaneous communication (Table 1). Additionally, the content of the type of communication was classified and defined in 9 content domains. Various combinations between type and the content domains formed the classification method. In total, the communication was divided into 23 categories. Not all combinations between type and content were possible. For instance a combination of commanding (as type) for anatomy and pathology (as content) doesn't occur. Communication aiming on the transfer of knowledge from a senior surgeon to a surgical trainee was considered as explaining, even if these communication events sounded like commanding. Commands about how to adjust the endoscope were considered commanding visualization in any case.

The analysis was based on videotapes of routine laparoscopic cholecystectomies, captured during a previous study (Chapter eight), using a special video capturing system in combination with a head-mounted microphone for the surgeon. Eight laparoscopic cholecystectomies were analysed. Two entire cholecystectomies and the dissection of 6 procedures were analysed.

The two entire procedures were carried out by a senior surgeon assisted by a surgical trainee. Each procedure was divided into 6 phases: start, dissection, clipping of the duct, separating gallbladder from liver, control of haemostasis, closing of the wounds).

In six of the eight procedures, the dissection phase was analysed. Focusing on this phase seemed indicated as this is the phase in which most manipulations and tissue-instrument interaction takes place, demanding the most intensive communication in the training setting. These procedures were carried out by six different residents supervised by a senior surgeon. The scoring of the communication was facilitated with a software program. (J-video, University of Maryland 2003). This task analysis program was adjusted for the study. Each communication event was manually entered. The number of communication events as well as the classification was registered.

Table 1. The types, content and description of the communication classification

Types	Content domain	Description
Explaining	Operation method	The procedural steps and sequence
Commanding	Anatomy / pathology	Anatomical landmarks, abnormalities
Questioning	Location	Description of where to interact with tissue
Miscellaneous	Direction	In which direction to push or pull tissue
	Instrument handling	Which instruments to use
	Visualisation	Actions with the endoscope
	General	General conversation in relation to the procedure
	Private	Conversation not related to procedure
	Indefinable	Not related to any domain described above

RESULTS

The distribution of the communication classification by the 4 types and 9 content domains is shown in Table 2 in detail. The results of analyses of the two entire procedures show a high percentage of communication of the "explaining type"; 31% for the first procedure and 37% for the second procedure. The trainee in the first procedure had previously assisted two laparoscopic cholecystectomies; the other had assisted more than 10 procedures before and performed two procedures under supervision.

The explaining communication was subdivided by the content. The highest percentages were found for explaining the "operating method" (24% and 33%), anatomy and pathology (29% and 19%). A relatively high percentage of explaining about "instrument handling", was only found in the first procedure (23%).

Table 2. Results by type and content of communication of two laparoscopic cholecystectomies

Types	Content	Procedure 1	Procedure 2
Explaining	Total	31%	37%
	Operation method	24%	33%
	Anatomy / Pathology	29%	19%
	Location	12%	17%
	Direction	4%	7%
	Instrument handling	23%	13%
	Visualisation	4%	2%
	General	4%	9%
Commanding		27%	29%
Questioning		19%	8%
Miscellaneous		23%	25%

In addition to the two entire procedures analysed, the dissection phase of six other laparoscopic procedures was analysed. On average, 60% of the communication during the dissection phase was related to explaining. Experience of trainees varied between 1 to 15 procedures performed under supervision (1, 1, 2, 5, 6, and 15 respectively). The results of the communication analyses aimed at explaining during the dissection phase are shown in Figure 1 and 2. Figure 1 displays the average for each content domain and Figure 2 for each procedure. High percentages were found for the explaining the operation method (27%), anatomy/pathology (19%) and the location were to manipulate the tissue (25%). More detailed results can be found in the original publication [5].

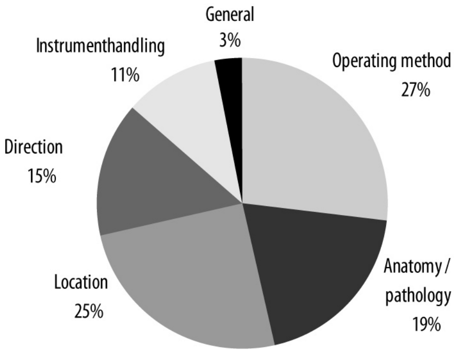

Figure 1. Average distribution of the explaining content during the dissection phase of 6 laparoscopic cholecystectomies.

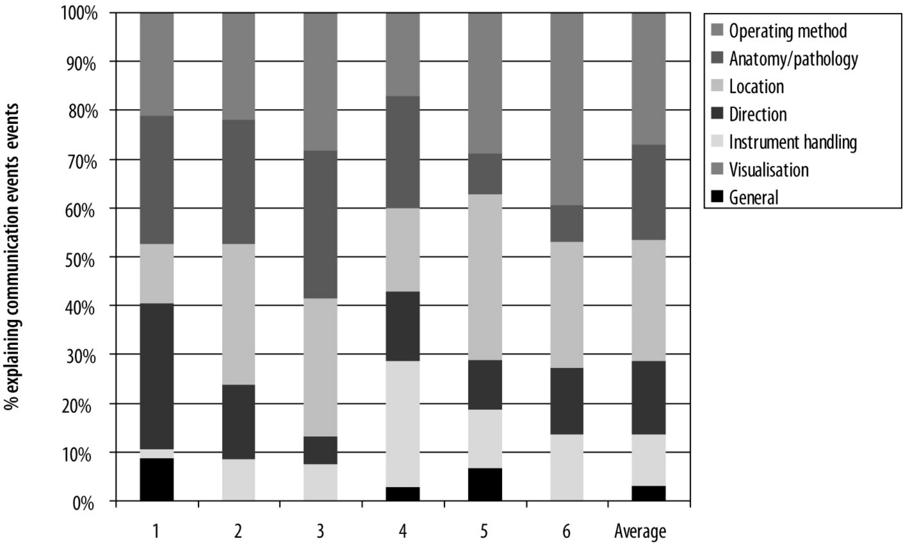

Figure 2. Distribution of explaining content in the dissection phase in 6 laparoscopic cholecystectomies (each procedure in detail)

DISCUSSION AND CONCLUSIONS

The study showed that the used verbal communication classification method is feasible to quantify the topics that are being discussed in the OR. A high percentage of the communication was related to explaining the operation method, anatomy, pathology and instrument handling. Our communication analysis showed that costly operation time is consumed by explaining basic knowledge. Hence, there is a need for cognitive skills training. In order to shorten the intraoperative learning curve, these aspects should be taught before the procedure outside the operating room. Furthermore, the classification method might be useful to measure the effect of cognitive skills training.

The classification method appeared to be feasible, but there are also constraints that need to be addressed. The approach is time consuming. Gathering the data required a special video capturing system and the presence of a research fellow. However, this process may become more automated in the future because of the increasing availability of integrated audio-video systems in the OR. Currently, the videotape analyses required approximately three times the time of the original tape. However, applying the method can be learned quickly, also by researches without specific medical training.

Analysing communication cannot be done without interpretation. Therefore, a strict thesaurus was used to avoid subjective effects as much as possible. In addition, a pilot study in which several observers applied the method showed an acceptable interobserver agreement of 0.7 [4,5]. This seems to provide sufficient reliability to objectify verbal communication in the operating room, which was the goal of the method. If the present method is valid for judgement or high stake assessment of trainees (credentialing, licensing) remains questionable. Currently, the reliability is not high enough. A interobserver agreement higher than 0.8 seems reasonable.

The communication may depend highly on the characteristics of patients, the surgical team, the surgeon's teaching style and experience level of the trainee. The outcome of our analyses may be influenced by specific characteristics within one institute. However, our analyses identified a consistent pattern of communication types and content and seemed less likely to depend on team composition or patient characteristics; for example the high percentage of explaining the procedural methods and anatomy.

The high percentage of explaining anatomy and procedural steps suggests that specific training and assessment of these aspects could shorten the learning curve in the operation room. Currently, there are some training tools aimed on training of this knowledge (CD's, books, WebSurg). However, these training tools are generally not embedded in a structural curriculum in the same way as motor skills training. Moreover, they often lack objective assessment of what is actually learned to the student. Communication analysis can be used to determine the content of the training.

In 25% of the explaining events are aimed at explaining the location of instrument-tissue interaction (Figure 1). In other words; the surgeon guides the trainee through the procedure by describing exactly where to interact with the tissue. This is sometimes complicated and can lead easily to misinterpretation by the receiver (the surgical trainee). The development of a "pointing-tool" is suggested, for example a sterile laser pointer to point on the video monitors. Recently, Stefeles et al evaluated several pointing devices (wireless) that can be used to control equipment in the operating room [6]. With some changes these devices can be used as pointing devices during OR training.

In summary, the classification method for the verbal communication is feasible and objectively reflects the interaction between the supervising surgeon and the trainee.

The method was developed to assess the verbal communication during a laparoscopic cholecystectomy, and although time consuming, the approach may be useful to assess other procedures as well. The results suggest specific training needs for cognitive skills training and the classification method may contribute to evaluation of different training methods.

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Chapter 12

General conclusion, discussion and recommendations

GENERAL CONCLUSION, DISCUSSION AND RECOMMENDATIONS

General conclusions

The first objective of this thesis was the validation of a new virtual reality (VR) simulator for laparoscopic psychomotor skills training in order to incorporate the simulator effectively into the surgical curriculum.

> In this thesis the SIMENDO VR simulator was evaluated. The simulator proved to be valid for training of psychomotor skills in trainees with limited or no experience with laparoscopic surgery. Training laparoscopic skills on a simulator distributed over several days seems better than training on just one day for the same amount of time. Criterion-based training was feasible and successfully incorporated in the surgical curriculum. Laparoscopic knot-tying skills acquired on the simulator are transferable to knot-tying performance in an animal model. The use of competition elements on the simulator may enhance the motivation of surgical trainees to train voluntarily.

The second objective of this thesis was the evaluation of the current problems and needs encountered during training of laparoscopic surgery in the operation room in order to develop methods to improve safety and efficiency of this training environment.

> Problems with the laparoscopic equipment occurred regularly and could partly be prevented with the use of a structured checklist. The design and implementation of checklists in clinical practice needs further investigation. Insight was obtained in the communication during performance of laparoscopic cholecystectomies and provided opportunities for future development of simulators and training methods.

GENERAL DISCUSSION AND RECOMMENDATIONS

Simulators in modern surgical training

Today's surgical education is facing a crisis in training needs: on the one hand the working hours of medical trainees and therefore their experience at the operating table are being reduced; on the other hand, training solely on patients raises ethical questions and is therefore no longer acceptable. In addition, performing laparoscopic surgery requires special motor skills and the need for training this technique outside the operating room has been well recognised [1,2]. There seems to be general consensus in the surgical field that (simulation) training is a prerequisite before performing procedures on patients [3-7]. In the past decade several simulators have been developed and the research on surgical training and assessment flourished [8-12]. In literature several studies provide evidence that simulators are capable of training skills essential for laparoscopic surgery [8,11-15] and improve performance in the operating room [16-19]. As a result, the use of simulators in the modern surgical curriculum has become inevitable. However, many questions remain on which simulator should be used, how and when training should take place, and for how long trainees should practice. There is still some scepticism about the effects of simulator training compared to traditional training methods [20]. Another important topic of discussion is the role of "realism" in laparoscopic simulators. In the next paragraphs these issues will be discussed and directions for future research will be provided.

The role of realism in surgical virtual reality simulators

Realism in virtual reality simulation is not a straightforward issue. Since the introduction of simulators for surgical training, developers strive to create more "realistic" simulators in an effort to provide a full scale surgical simulator in which the trainee can feel, do and anticipate the same as they do in an actual surgical procedure in the operating room. Users and surgical educators often express the feeling that simulators should be more "real", although most of the time it is unclear what is really meant by this statement. However, the question is whether a more "realistic" simulator is necessary to deliver effective surgical training.

To answer this question, several considerations about realism and simulation need to be addressed.

Realism, low and high fidelity simulators

First of all, it is important to understand that simulation per definition is a representation of reality and not reality itself. Behaviours and perceptions of the "real" world are always reproduced to a limited degree. Hence, in simulation reality is always compromised.

Secondly, it is important to define what is meant by realism. There are several ways to describe realism in relation to simulators. In literature, the level of realism in simulators is often referred to as the level of fidelity [21]. High-fidelity simulators reflect the complexity of given task to a very detailed level. In contrast, low-fidelity simulators tend to simplify complex situations and purposefully leave certain details and aspects out. Another useful distinction of fidelity is to consider physical fidelity and functional fidelity [22]. Physical fidelity refers to the degree to which the simulation imitates the visual, auditory, spatial, kinaesthetic, and tactile characteristics present in the real world. In other words, physical fidelity concerns the appearance of the environment. For example, a human bowel in a simulator looks, moves, and feels the same as it does in a human abdomen during a real laparoscopic procedure. Functional fidelity refers to the degree to which the simulation imitates the response to a stimulus from the user such as the reaction of the laparoscopic instruments when grasped, moved, retracted, etc. Virtual reality simulators that use abstract tasks, such as the SIMENDO, have high functional fidelity. The instruments react similar to laparoscopic instruments during surgical procedures, but have low physical fidelity because no internal organs are represented.

High functional fidelity is especially important for learning the correct psychomotor skills. In order to learn the correct motor skills, all simulators need high functional fidelity. As presented in this thesis (Chapter 3), there is evidence supporting the effectiveness of high functional fidelity simulators with low physical fidelity for learning psychomotor skills for laparoscopic surgery [11, 9]. Research with other high functional fidelity simulators, for example the MIST-VR, which also uses abstract tasks, shows that this training leads to significant improvement of performance in the operating room [19].

The main reason to develop high physical fidelity simulators is the assumption that they are more effective in transferring simulator-learned skills to the operating room than low physical fidelity simulators. However, there are arguments from the literature that refute this assumption.

The first argument is that evidence from studies on skills training for open or conventional surgery suggests that the skills transferring effect of low physical fidelity mechanical simulators is equivalent to that of high physical fidelity simulators such as animal models [23-25].

Based on results of studies outside the surgical field (aviation), some researchers argue that a realistic environment distracts the trainees during practice, which may act counterproductively when learning a given task [21]. This paradoxical role of physical fidelity would support the strategy to match the simulator to the phase of the trainee. Low physical fidelity simulators would be more appropriate for inexperienced trainees whereas high physical fidelity trainers may be more suitable for advanced learners. However, future research is needed to compare the effect of high versus low physical fidelity simulators on the training of laparoscopic motor skills.

Furthermore, there are two important bottlenecks in the design of high physical fidelity VR simulators: assessment of performance and force feedback.

Assessment of performance

Assessment of performance and how to design a proper assessment protocol is the first bottleneck in the design of high physical fidelity simulators. Automated performance measurement and the subsequently generated feedback is one of the biggest advantages of virtual reality (VR). Interpretation of the measurements in order to provide feedback is complex. Feedback is paramount for learning. However, most currently validated VR simulators use parameters that measure the psychomotor performance of the trainee such as time, path length of the instrument and errors. As a result, the assessment and the feedback provided by the simulator is aimed at improving the psychomotor performance. However, operative skills are clearly a mixture of psychomotor ability, knowledge, judgement, communicative and leadership skills. This is shown by human behaviour models such as Bloom's model of knowledge, skills and attitudes (KSA) [26] and Rasmussen's model of skill, rule and knowledge based behaviour [27,28]. According to these models, all aspects need to be trained in order to perform a given task correctly. Analysis of the verbal communication during laparoscopic procedures performed by inexperienced trainees (Chapter 11) showed a considerable amount of feedback provided by the supervising surgeon in the domains of knowledge and rule based behaviour. Additionally, mental factors such as stress also influence operating performance [29]. Currently, this kind of training and feedback is not incorporated in virtual simulators. In order to provide relevant feedback on knowledge and rule based behaviour, new methods have to be developed to measure this kind of behaviour. Based on the insight of knowledge and rule based behaviour specific assessment protocols can be developed and incorporated in the simulator. Another approach is to use other modalities besides an interactive virtual reality simulator, such as interactive video clips and structured questionnaires. New simulation devices, with different patient centred scenarios are being built [30]. If the goal is to provide more extensive feedback instead of only at psychomotor level, it seems advisable to focus on one of the other domains (rules or knowledge) and not on all domains at once.

Force feedback

The other bottleneck in the design of physical fidelity simulators is the inaccurate force feedback technology (haptics) in commercially available surgical virtual reality simulators. Whereas there may be a high degree of visual and kinaesthetic fidelity of the simulation, e.g. organs look and behave as in a human laparoscopic environment, this may be accompanied by a low degree of force representation. This discrepancy is dangerous, because this may cause learning of improper behaviour (applying incorrect force). When improper behaviour is transferred to the operation room this could negatively influence patient safety.

Simulation of the correct force feedback is rather complex, but the research field is rapidly growing [31-34]. One of the reasons is the lack of input data for the forces that need to be simulated. Many factors influence the forces during laparoscopic surgery such as the resistance in the instruments, the trocars and the characteristics of different types of tissue. Furthermore, although it is evident that the correct forces should be applied during laparoscopic surgery, their role in learning of laparoscopic surgery is not yet fully understood [35]. Future research should provide more insight in the role and influences of force feedback in laparoscopic surgery and its benefit during training. Therefore, virtual reality simulators that include force feedback should be used with caution during training of clinicians. Furthermore, it is advised to use these simulators in a controlled setting, such as carefully designed scientific research.

Curriculum design, VR simulators, and future research

Effective training is not accomplished by solely purchasing an attractive virtual reality simulator, but requires a clear-centred implementation, making sure the technology satisfies the training and assessment needs. The role of a systematic and structurally designed training curriculum is essential. Several theories on learning can be found in literature that may aid the development of effective training programs [36].

Curriculum design

An example of a systematic approach to develop a training curriculum is the instructional system design model (ISD or ID in short) [37]. ID is developed to solve training problems and to improve existing training programs. ID provides the structure to determine who, what, when, where and how to train. Details of this training system will not be described here, but important elements of instructional design (ID) are that the training should be:

- Competence based (job related): the trainee needs to master a required level of knowledge, skill and attitude (KSA).
- Sequential: tasks are provided in a logical order (for example, from simple to complex) and for each training task, the relevant task in the job is shown.
- Tracked: training materials and tools are continuously updated.
- Evaluated: improvement is continuously evaluated and feedback is provided.

Instructional strategies are based on four principles: a) they present relevant information or concepts to be learned; b) they demonstrate the KSA's to be learned; c) they create opportunities for trainees to practice skills; and d) they provide feedback to trainees during (formative feedback) and after practice (summative feedback) [38].

In the Netherlands as well as in many other European countries, the surgical curriculum is rapidly changing. Recently, surgical education has entered the realm of a competence based structure with the adoption of the seven core competences (CanMeds), after the Canadian example. This has been an important and necessary change; however, there are serious consequences for the training methods used. Besides achieving the required experience with surgical procedures, trainees have to go through continuous assessments. Several methods are used to provide assessment in the operation room, at the bedside and during outpatient contacts. These assessments are time consuming and surgical educators struggle with how to intersperse the assessments in their tight clinical schedule.

VR simulators and simulations

For a number of reasons, VR simulators are an attractive tool to be implemented in the modern surgical training curriculum.

Assessment in clinical practice, besides the time management problems mentioned above, may still be biased by factors such as the relationship with the evaluator, the patient, the surgical team etc. Therefore, assessment and coaching or teaching should be separated. This can be provided by the adoption of structured bench station tests [23] or standardized clinical or operating room situations with objective assessors trained to judge performance [39]. For example, Aggarwal [40] described a project in which surgical team training takes place in a simulated operating room. However, this requires investing in trained personnel and thus is expensive and time consuming. Virtual reality simulators can play an important role in structured bench stations for motor skills testing, because of their ability to automatically measure and generate feedback. Furthermore it could reduce the number of educators and assessors when multiple simulators are used simultaneously.

Another advantage of assessment with simulators is to detect underperforming individuals to allow intervention, such as extra training. The study with the criterion based training with SIMENDO showed that some trainees evidently needed more practice training than others to acquire the criteria. However, endoscopic psychomotor skills training concerns only one aspect of competence and knowledge and decisional behaviour needs to be trained as well. In a multi-station testing situation these competences can be assessed and the total performance can be summed up in a final judgement.

Another advantage of the use of VR simulators in the surgical curriculum is that data from measurements can be directly linked to the trainee's portfolio. At present a trainee's progress is mainly documented on paper portfolios, but in the near future digital portfolios will be used. The trainee can practice individually without the continuous need of an instructor and the supervisor can monitor skills progression and maintenance from any place, at any given moment. The online competition with the SIMENDO showed that data capturing through the internet was feasible (Chapter 7).

Future research and use of simulators

Several areas for future research can be determined.

One area of future research is to explore the role of VR simulation as an early recruitment and selection tool. Currently, simulators are used by trainees that have already formally entered the surgical training curriculum. It would be of interest to determine if simulators are useful to recruit and select medical students for surgical training in an early stage. Furthermore, the effect of starting simulator training on a younger age should be investigated.

Low physical fidelity simulators are suitable to start training at an early point in medical education. Medical students should be offered the opportunity to start basic skills training early, in addition to their core curriculum. At that point, they have a less tight educational schedule than surgical trainees during their clinical rotations and could be enrolled in a skills training program. These training programs do not yet exist. Consequentially, universities need to create space in their curricula, hire qualified personnel and build facilities to be able to train students on a large scale and evaluate the long term effects.

Further research is also needed to determine how long trainees should practice on a simulator before they can enter the operating room. On the one hand, training on a simulator should be long enough to be effective. On the other hand, training should not be too long, resulting in tiresome practice, inefficiency of training resources and training time. Using a training program based on expert performance seems very practical, although the exact criteria vary widely depending on the type of simulator and the methods used. Some studies base the training criteria on mean scores performed by experienced laparoscopic surgeons on the simulator. More difficult training criteria do not always result in better operating performance [41]. The number of repetitions to calculate the mean vary between five and eleven [16, 18, 42-45]. Others use a set time frame in which the trainee is allowed to practice on the simulator [18,46], varying from 20 minutes to 10 hours divided over several days or even weeks [17,47, 48].

Another field to be explored is that of skills retention and the effect of recurrent training sessions. Literature on motor skill retention, although limited, shows that motor skills for laparoscopic surgery are retained over several months when not practiced [49]. Dividing training sessions over several days seems to be more effective than training for the same length of time on a single day (Chapter 4). This could have important consequences for curriculum design.

Technology and safety issues

Laparoscopic surgery has had a significant impact on all surgical disciplines and is now firmly embedded in routine surgical practice [50]. The introduction of minimally invasive surgery and other new techniques have made the surgical environment more complex and increasingly dependent on the reliability of its technology. Problems exist in the man-machine interaction during laparoscopic surgical procedures (Chapter 8). They pose a potential hazard to patient safety. Solutions to reduce these risks are specialized training, equipment design and the use of checklists. We described the effect of structured checklist use as well as the general design considerations. However, many questions and challenges remain.

The biggest challenge seems to overcome the scepticism about checklist use within the organisation (e.g. the hospital). This requires a cultural transformation towards safety and a wide understanding of the mechanisms behind human error. Although health care workers are used to protocols in patient treatment, the use of standardized checklists in executing specific tasks is relatively new. The use of checklists in the clinical practice needs further investigation. Standardization of laparoscopic surgical operations and their execution are essential for the procurement and maintenance of quality in laparoscopic surgical practice [51]. In order to induce an effective safety culture, repetitive instruction and education of all personnel on the mechanisms of human error is required.

Further research should aim at developing methods to measure the effect of new safety strategies such as checklists. A successfully used method is the Safety Attitudes Questionnaire (SAQ) (for the SAQ, see also Chapter 9) [52]. However, this is a subjective method and does not measure the number of reduced incidents. Task analysis based on video registration and analysis is an example of a thorough and objective method, but a time consuming one.

As mentioned before, the use of checklists is just one of the methods to achieve safe equipment use (Chapter 9). The design of the equipment is another factor influencing its (safe) use (Chapter 8 and 9). Before clinical trials with new machines or devices are conducted on patients, standardized laboratory test should have provided convincing evidence of the superior or at least equal functionality of the new technology. Currently, no standards are available concerning how new interfaces, equipment or instruments should be tested with regard to their functionality and reliability in the interaction with human operators.

Future research should focus also on functional, ergonomic and safety aspects related to the users (surgeons and nurses). Standards and guidelines must be developed by medical societies, addressing whether training is required to use the new technology and how this training should take place. Although the producers of medical equipment are very helpful in providing instructions, short courses and all kinds of on-demand advice, standardized instruction manuals are rarely available. Furthermore, the acquired skills and knowledge of the user are never objectively tested. Hence, it is not clear what is actually learned and whether the user is qualified to use a specific apparatus.

Introduction of new technology such as the Da Vinci system and the introduction of new techniques such as NOTES (Natural Orifices Trans Endoluminal Surgery) [53] will only increase the need for methods to guarantee safe and accurate use of equipment. With current knowledge of the role of human factors and the occurrence of human errors, development of checklists and standardisation of equipment seems not only wise, but an obligation for every health care professional.

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Summary

Minimally invasive surgery or endoscopic surgery **(Chapter 1)** is one of the most important innovations in surgery of the 20th century. Endoscopic surgery of the abdomen is called laparoscopic surgery. In laparoscopic surgery, the surgeon performs the procedure with long instruments through small incisions in the abdominal wall while watching a video monitor. This type of surgery has important benefits for patients compared to conventional or open surgery such as reduced pain, reduced hospital stay and quicker return to normal physical activities. Despite these advantages, there are also disadvantages. Laparoscopic surgery is more difficult to master and is associated with a longer learning curve than conventional or open surgery. The skills required for laparoscopic surgery are not intuitive. The surgeon needs specific psychomotor skills to control the long instruments through a pivoting point, to compensate for the problems with reduced depth perception because of viewing the 3-D anatomical environment on a 2-D monitor and to compensate for the reduced haptic feedback.

The ethical concerns of training on patients, the reduced working hours for medical trainees, the constantly increasing demands of efficient use of operation capacity and equipment require new, effective and efficient training methods.

Simulation systems, and especially virtual reality (VR) simulators, may provide a solution to the problem. The advantages of VR simulators are the automatic measurement and feedback on performance, the unlimited repetitions of exercises in a challenging and safe training environment. In the last decade, several VR simulators have been developed and studied. However, the training effects of VR simulators are still not fully understood, and educators are reluctant to structurally adopt VR simulators into the surgical curricula on a large scale. Validation of a new VR simulator is essential in order to determine how the simulator should be used in the surgical curriculum.

In collaboration with Delft University of Technology, a new simulator called SIMENDO (DelltaTech, Rotterdam, The Netherlands) has been developed. The SIMENDO is a relatively affordable VR simulator (5000 - 9000 euros) aimed at training basic hand-eye coordination skills needed to perform laparoscopic surgery.

In addition to the need for training of specific psychomotor skills, the introduction of technical equipment for laparoscopy such as a camera system, equipment to insufflate and illuminate the inside of the patient's abdomen, has made the surgical environment more complex. New problems have been introduced in the domain of man-machine interaction, allowing errors or incidents to occur.

The first objective of this thesis is the validation of the VR simulator SIMENDO for the training of laparoscopic psychomotor skills, in order to incorporate this simulator effectively into the surgical curriculum (Part I).

The second objective of this thesis is the determination of the current problems and needs encountered during laparoscopic surgery in the operation room in order to develop methods to improve safety and efficiency (Part II).

PART I : VALIDATION OF THE SIMENDO VR SIMULATOR

Several validation steps can be defined such as the content, face, concurrent, construct validation and the predictive or the transfer validation.

Subjective approaches to validation include content, and face validity. Content validity is generally the description of the content of the domains the instrument tests or trains. The simulator aims at training basic hand-eye coordination skills needed to perform laparoscopic surgery and is designed to provide an easy-to-use plug-and-play system for surgical trainees. It employs various abstract tasks for one or two instruments, and simultaneously measures the subject's performance using various objective parameters for assessment and feedback (time to complete the task, errors, collisions between instrument and environment, aiming of the endoscopic camera, and path length or used trajectory of the instruments). Force feedback is currently not included in the system.

The SIMENDO simulator was subjectively evaluated **(Chapter 2)** by a group of experienced laparoscopic surgeons and a group of surgical trainees, inexperienced with laparoscopic surgery (face validation). The groups considered the SIMENDO to be a useful simulator for the training of hand-eye coordination skills for laparoscopic surgery.

In concurrent validity, the relationship between the test scores on the simulator under evaluation and the scores achieved on another simulator are compared. The learning effect of a simple hand-eye coordination task in the SIMENDO with a single instrument was comparable to the learning effect of a similar task in a box trainer (concurrent validation). In addition, the study revealed clear points for improvement of the VR simulator, such as the improvement of the depth perception, inclusion of more tasks and the possibility to train with two instruments. New tasks were designed and a second instrument was added.

The face, content and concurrent validation was followed by construct validation of the simulator **(Chapter 3)**. Construct validity can be defined as the degree the simulator identifies the quality, ability, or trait it was designed to measure. The parameters of the tasks in the simulator could distinguish groups with different laparoscopic experience levels. The learning curve showed that training on the SIMENDO is useful for subjects with limited or no laparoscopic experience. Furthermore, experience with laparoscopic camera navigation in the operation room improves laparoscopic psychomotor skills to more than the basic level.

Skills acquisition and retention (preservation of skills over longer periods of time) can be influenced by the training schedule used. A study was conducted to evaluate the effects of two different training schedules **(Chapter 4)**; training on one day versus the same amount of training distributed over several days. After one week without practice, the group with distributed training was faster, with a comparable number of errors made and a comparable instrument path length used. Laparoscopic psychomotor training distributed over several days may improve skills retention. Incorporation of the "distribution principle" into laparoscopic skills curricula might enhance the training effectiveness.

In addition to the abstract tasks used so far, a knot-tying module was developed and added to the software of the SIMENDO. In a randomised controlled trial **(Chapter 5)**, subjects that were trained on the VR simulator with the knot-tie module were 30% faster and made 33% fewer errors (transfer or predictive validity) in a laparoscopic animal model, as compared to the control group. Laparoscopic experts recommended additional training after VR training to achieve safe suturing on patients. Opportunities were identified to improve the simulator-based instruction to enhance future training, such as the incorporation of assessment parameters for needle manipulation, respect for tissue and environment.

The next challenge was to structurally incorporate VR simulator into the surgical curriculum. Most training courses employ a fixed duration for training while learning may be highly dependent on individual characteristics such as innate ability, previous experience and motivation. Therefore, proficiency of a given skill should depend on passing a clear criterion rather than an arbitrary amount of time or repetitions. Training programs could become more effective when tailored to the individual level of the trainee. A criterion-based training programme for laparoscopic skills on the VR simulator was designed **(Chapter 6)**. The performances of experienced laparoscopic surgeons were used as criterion. The use of this criterion was feasible and resulted in a wide variation between surgical trainees in the number of attempts needed to pass the criterion. Some trainees needed four times the number of attempts than others did. The study showed that criterion-based training could be a useful method to prepare surgical trainees for more complex training models, for example procedures on animal models.

Despite the available training facilities, skills labs and simulators, laparoscopic skills training remains a challenge in surgical education. Voluntary use of a simulation lab leads to minimal participation, probably because of lack of time or interest. In order to boost deliberate practice and overcome the motivational barriers, the concept of "serious gaming" was introduced in the field of simulator training **(Chapter 7)**. A national on-line competition with a reward for the best performance was initiated. The "serious gaming" concept appeared to be feasible, but there was a considerable difference between the number of trainees of the participating hospitals and a small number trained extensively. The use of INTERNET could facilitate monitoring of skills training of surgical trainees.

PART II: CURRENT PROBLEMS AND NEEDS DURING LAPAROSCOPIC SURGERY IN THE OPERATING ROOM

Analysis of 30 laparoscopic cholecystectomies showed that the incidence of problems with the technical equipment was strikingly high (49 incidents in 30 procedures, only four procedures without technical problems) **(Chapter 8)**. These problems could be prevented by improvement and standardisation of equipment, in combination with the incorporation of a checklist before the start of the procedure.

Checklist use is not a novelty in healthcare, but the design of a checklist for the use in daily practice is not a straightforward process. A literature review on checklist use in the OR showed positive effects of structured checklists on team communication, team cooperation and subjectively perceived safety culture among OR personnel **(Chapter 9)**. Based on our own experience with the laparoscopic equipment problems and based on guidelines from the aviation industry, recommendations were given for a sound checklist design for surgical processes.

A structured checklist was developed to prevent incidents with laparoscopic equipment. The effect of the checklist was studied in 30 laparoscopic cholecystectomies **(Chapter 10)**. The results were compared with the previous 30 procedures without the use of a checklist. In the group with the checklist the number of equipment problems decreased with more than 50%.
To gain insight into the communication content during surgical training in the operation room, a classification method was developed **(Chapter 11)**. The application to the dissection phase of laparoscopic cholecystectomies revealed that communication was mainly focussed on explaining of the operation method (27%), explaining the anatomy (19%), and learning the positioning of the instrument and how to interact with the tissue (25%). The results of the study may be used to specify training needs and to evaluate different training methods.

In conclusion **(Chapter 12)**, in the first of this thesis, a new virtual reality simulator was evaluated. The simulator proved to be valid for training of psychomotor skills in trainees with limited or no experience with laparoscopic surgery. Training laparoscopic skills on a simulator distributed over several days seems better than training on just one day. Criterion-based training was successfully incorporated in the surgical curriculum. Laparoscopic knot-tying skills acquired on the simulator were shown to be transferable to the knot-tying performance on an animal model. The use of competition elements on the simulator may enhance the motivation of surgical trainees to train voluntary.

The second part of this thesis showed that problems with the laparoscopic equipment occur regularly and that these problems partly could be prevented with the use of a structured checklist. Future research should focus on the design of checklists for routine use in the clinical practice. Insight in the communication during performance of laparoscopic cholecystectomies provides opportunities for future development of simulators and training methods.

The conclusion is followed by a general discussion **(Chapter 12)** on the role of realism and several bottlenecks (assessment of performance and force feedback) for the design of future virtual reality simulators. Advantages and future applications of simulators are underlined. Furthermore, recommendations and potential directions for future research in the domain of technology and safety in (laparoscopic) surgery are presented.

Samenvatting

Minimaal-invasieve chirurgie, of endoscopische chirurgie **(Hoofdstuk 1)**, is één van de belangrijkste innovaties in de chirurgie van de 20ste eeuw. Endoscopische chirurgie van de buik wordt ook wel laparoscopische chirurgie genoemd. Bij laparoscopische chirurgie opereert de chirurg met lange instrumenten door kleine incisies in de buik terwijl hij kijkt naar een videomonitor. Dit type chirurgie heeft belangrijke voordelen voor patiënten in vergelijking met conventionele of open chirurgie zoals verminderde pijn, korter ziekenhuisverblijf en snellere terugkeer naar normale fysieke activiteiten. Ondanks deze voordelen zijn er ook nadelen. De vaardigheden voor laparoscopische chirurgie zijn moeilijker aan te leren en zijn geassocieerd met een langere leercurve dan open chirurgie. De vaardigheden die voor laparoscopische chirurgie worden vereist zijn niet intuïtief. De chirurg heeft specifieke psychomotorische vaardigheden nodig om de lange instrumenten scharnierend om een draaipunt te controleren, om te compenseren voor problemen met verminderde dieptewaarneming vanwege het bekijken van de 3-D anatomisch omgeving op een 2-D monitorbeeld en om te compenseren voor de verminderde haptische terugkoppeling.

De ethische aspecten van training op patiënten, de verminderde arbeidstijd voor chirurgen in opleiding, de constant stijgende eisen van efficiënt gebruik van operatiekamercapaciteit en van materiaal vereisen nieuwe, effectieve en efficiënte opleidingsmethodes. Simulatoren en vooral virtual-reality (VR) simulatoren, kunnen een oplossing voor het probleem bieden. De voordelen van VR-simulatoren zijn de automatische meting en terugkoppeling van prestaties en de onbeperkte herhalingen van oefeningen in een uitdagende en veilige opleidingsomgeving. In het laatste decennium zijn verscheidene VR-simulatoren ontwikkeld en onderzocht. Echter, de gevolgen van training met VR-simulatoren worden nog niet volledig begrepen en opleiders aarzelen om VR-simulatoren structureel en op een grote schaal in het chirurgische curriculum in te zetten.

Validatie van een VR-simulator is essentieel om te kunnen bepalen hoe de simulator gebruikt kan worden in het chirurgische curriculum.

In samenwerking met de Technische Universiteit Delft is een nieuwe simulator ontwikkeld, SIMENDO genaamd (DelltaTech, Rotterdam, Nederland). De SIMENDO is een relatief betaalbare VR-simulator (5000 - 9000 euro's), gericht op het trainen van de basale oog-handcoördinatievaardigheden die noodzakelijk zijn voor het uitvoeren van laparoscopische chirurgie.

Naast de behoefte aan training van specifieke psychomotorische vaardigheden, heeft de introductie van technische apparatuur voor laparoscopie zoals een camerasysteem, apparatuur voor insufflatie en voor verlichting van het abdomen van de patiënt, de chirurgische omgeving complexer gemaakt. Er zijn nieuwe problemen geïntroduceerd op het gebied van mens-machine interactie, die fouten of incidenten kunnen veroorzaken.

De eerste doelstelling van dit proefschrift is de validatie van de SIMENDO voor de training van laparoscopische psychomotorische vaardigheden om vervolgens deze simulator op een effectieve manier in het chirurgische curriculum te kunnen integreren (Deel I).

De tweede doelstelling van dit proefschrift is de huidige problemen en behoeften tijdens de training van laparoscopische chirurgie in de operatiekamer te bepalen en daarmee methoden te ontwikkelen die de veiligheid en efficiëntie kunnen verbeteren (Deel II).

DEEL I: DE VALIDATIE VAN DE SIMENDO VIRTUA-REALITYSIMULATOR

Verscheidene validatiestappen kunnen worden onderscheiden zoals de content-, face-, concurrent-, construct- en de predictieve of transfer-validatie.

Subjectieve benaderingen van validatie zijn de content- en face-validatie. Content-validatie is de beschrijving van de inhoud van het instrument en de beschrijving welke domeinen het instrument test of traint b.v. psychomotorische vaardigheden of kennis over anatomie. De simulator is ontworpen om te voorzien in een gemakkelijk en gebruiksklaar "plug-and-play"-systeem voor chirurgen in opleiding. Er wordt gebruik gemaakt van diverse abstracte taken voor één of twee laparoscopische instrumenten. De prestaties van de gebruiker voor beoordeling en terugkoppeling worden gemeten door middel van diverse objectieve parameters (tijd om de taak te voltooien, fouten, botsingen tussen instrument en omgeving, het richten van de endoscoop, en padlengte ofwel de afgelegde weg van de instrumenten).

De simulator SIMENDO werd subjectief geëvalueerd **(Hoofdstuk 2)** door een groep ervaren laparoscopische chirurgen en een groep chirurgische assistenten, onervaren met laparoscopie (face-validatie). Beide groepen waren van mening dat de SIMENDO een nuttige simulator is voor de opleiding van oog-handcoördinatievaardigheden voor laparoscopische chirurgie. In concurrent-validatie, wordt het verband vergeleken tussen de testscores op de simulator met de scores op een andere simulator. Het leereffect van een eenvoudige oog-hand coördinatietaak in SIMENDO met één laparoscopisch instrument was vergelijkbaar met het leereffect van een zelfde soort taak in een boxtrainer (concurrent-validatie). Daarnaast leverde de studie duidelijke verbeterpunten op voor de VR-simulator, zoals de verbetering van dieptewaarneming, meer verschillende taken en de mogelijkheid om te trainen met twee instrumenten. Daarom werd de diepteperceptie verbeterd, werden er nieuwe taken ontworpen en een tweede instrument aan de simulaties toegevoegd.

De face-, content- en concurrent-validatie werden gevolgd door de construct-validatie van de simulator **(Hoofdstuk 3)**. De construct-validatie kan worden gedefinieerd als de mate waarin de simulator de kwaliteit, capaciteit, of eigenschap meet waarvoor de simulator ontworpen is. De parameters van de taken in de simulator kon groepen met verschillende laparoscopische ervaringsniveaus onderscheiden (construct-validatie). De leercurve toonde aan dat de training met de SIMENDO nuttig is voor personen met beperkte of geen laparoscopische ervaring. Verder verbetert ervaring met laparoscopische cameranavigatie in de operatiekamer de laparoscopische psychomotorische vaardigheden boven het basisniveau. In toekomstig validatie-onderzoek, moet elke ervaring van personen met laparoscopische chirurgie worden meegenomen, zelfs als deze beperkt is tot het assisteren bij procedures.

Het verkrijgen en de retentie (behoud van vaardigheden over een langere tijdspanne) van vaardigheden kan beïnvloed worden door het gevolgde trainingsschema. Een studie werd uitgevoerd om de gevolgen van twee verschillende schema's te evalueren **(Hoofdstuk 4)**; training binnen één dag tegenover dezelfde hoeveelheid training over verscheidene dagen verdeeld. Na één week zonder oefening, was de groep met verdeelde training sneller, met een vergelijkbaar aantal fouten en een kleinere? padlengte van de instrumenten. Het behoud van vaardigheden kan verbeterd worden door de laparoscopische psychomotortraining te verdelen over verscheidene dagen. De integratie van het "distributieprincipe" in het laparoscopische curriculum zou derhalve de trainingseffectiviteit kunnen verbeteren.

Naast de abstracte taken, werd een knooptaakmodule ontwikkeld en toegevoegd aan de software van de SIMENDO. In een gerandomiseerde gecontroleerde studie **(Hoofdstuk 5),** waren de personen die op de VR-simulator met de knooptaakmodule werden opgeleid 30% sneller en maakten tot 33% minder fouten (transfer-validatie) in een laparoscopisch diermodel, in vergelijking tot de controlegroep. Laparoscopische experts adviseerden wel extra training na VR-training voordat men veilig in patiënten zou kunnen hechten. Er werden mogelijkheden geïdentificeerd om de simulatortraining te verbeteren, zoals de integratie van beoordelingsparameters voor naaldmanipulatie en de omgang met het weefsel.

De volgende uitdaging was het structureel implementeren van de VR-simulator in het chirurgische curriculum. De meeste trainingscursussen bieden voor iedereen een vooraf vastgestelde trainingsduur aan, terwijl leren in belangrijke mate afhankelijk is van individuele kenmerken zoals aangeboren capaciteiten, eerdere ervaring en motivatie. Behaalde vaardigheid zou daarom moeten afhangen van een duidelijk criterium in plaats van een willekeurige hoeveelheid tijd of hoeveelheid herhalingen. De training zou effectiever kunnen zijn wanneer ze worden aangepast aan het individuele niveau van de assistent-in-opleiding. Een criterium-gebaseerd trainingsprogramma voor laparoscopische vaardigheden op de VR-simulator werd ontworpen **(Hoofdstuk 6)**. De prestaties van ervaren laparoscopische chirurgen werden gebruikt als criterium. Het gebruik van dit criterium bleek uitvoerbaar en resulteerde in een brede variatie tussen chirurgische assistenten in het aantal pogingen om het criterium te behalen. Een criterium-gebaseerde training kan een nuttige methode zijn om chirurgische assistenten voor te bereiden op complexere trainingsmodellen, bijvoorbeeld procedures met diermodellen.

Ondanks de beschikbare opleidingsfaciliteiten, de vaardighedenlaboratoria en de simulators, blijft de laparoscopische vaardigheidstraining een uitdaging in het chirurgisch onderwijs. Het vrijwillige gebruik van een simulatielaboratorium leidt tot minimale participatie, waarschijnlijk wegens gebrek aan tijd of belangstelling. Om vrijwillige training te bevorderen en motivatiebarrières te overbruggen, werd het concept "serious gaming" geïntroduceerd in het gebied van simulatortraining (**Hoofdstuk 7)**. Een landelijke on-line competitie met een beloning voor de beste prestaties werd geïnitieerd. Het concept "serious gaming" bleek uitvoerbaar, maar er was een aanzienlijk verschil tussen het aantal deelnemers van de participerende instelling en een klein aantal trainde extreem langdurig. Het gebruik van INTERNET kan het volgen van vaardigheidstraining van chirurgische opleidingsassistenten vergemakkelijken.

DEEL II: HUIDIGE PROBLEMEN EN BEHOEFTEN VAN LAPAROSCOPISCHE CHIRURGIE IN DE OPERATIEKAMER

Een analyse van 30 laparoscopische cholecystectomiën (galblaasoperaties) toonde aan dat er opvallend veel problemen met de technische apparatuur waren (49 incidenten in 30 procedures, slechts vier procedures zonder technische problemen) **(Hoofdstuk 8)**. Deze problemen zouden kunnen worden voorkomen, door verbetering en standaardisatie van apparatuur, gecombineerd met de integratie van een checklist voorafgaand aan de procedure.

Het gebruik van een checklist is niet nieuw in de gezondheidszorg, maar het ontwerpen van een checklist voor gebruik in de dagelijkse praktijk is geen eenvoudig proces. Een literatuuroverzicht van het gebruik van checklists in de operatiekamer toonde positieve gevolgen op het gebied van communicatie, samenwerking en subjectief-waargenomen veiligheidscultuur voor het chirurgische team **(Hoofdstuk 9)**. Op grond van onze eigen ervaring met de laparoscopische apparatuur en op grond van richtlijnen uit de luchtvaartindustrie, konden aanbevelingen worden gedaan voor het ontwikkelen van een checklist voor chirurgische processen.

Er werd een gestructureerde checklist ontwikkeld om incidenten met laparoscopische apparatuur te voorkomen. Het effect van de checklist werd bestudeerd in 30 laparoscopische cholecystectomiën **(Hoofdstuk 10)**. De resultaten werden vergeleken met de eerdere procedures zonder het gebruik van een checklist. In de groep waarin een checklist werd toegepast, daalde het aantal het aantal problemen met de apparatuur met meer dan 50%.

Om inzicht te krijgen in de communicatie-inhoud tijdens (laparoscopische) chirurgische training in de operatiekamer werd een classificatiemethode ontwikkeld **(Hoofdstuk)**. Toepassing op de dissectiefase van de laparoscopische cholecystectomie liet zien dat de communicatie voornamelijk gericht was op het uitleggen van de operatiemethode (27%), van de anatomie (19%), en op het leren van het plaatsen van instrumenten en het leren het weefsel te manipuleren (25%) . De resultaten van de studie zouden kunnen worden gebruikt om de leerbehoeften te specificeren en verschillende trainingsmethodes te evalueren.

Concluderend **(Hoofdstuk 12)**, in het eerste deel van dit proefschrift werd een nieuwe virtual-realitysimulator geëvalueerd. De simulator bleek valide te zijn voor training van psychomotorische basisvaardigheden van chirurgische assistenten zonder, of met beperkte ervaring met laparoscopische chirurgie. Training van laparoscopische vaardigheden verspreid over verscheidene dagen, lijkt beter te werken dan training op één dag. De criterium-gebaseerde training werd met succes geïntegreerd in het chirurgische curriculum. De knoopvaardigheden die op de simulator worden geleerd zijn overdraagbaar op de knoopprestaties in een diermodel. Het gebruik van competitie-elementen zou kunnen bijdragen aan het motiveren van opleidingsassistenten om vrijwillig te trainen.

In het tweede deel van het proefschrift werd aangetoond dat problemen met laparoscopische apparatuur regelmatig voorkomen en gedeeltelijk kunnen worden voorkomen door het gebruik van een gestructureerde checklist. Toekomstig onderzoek zou zich moeten richten op het ontwerp van checklisten voor routinematig gebruik in de klinische praktijk. Het inzicht in verbale communicatie tijdens laparoscopische procedures biedt mogelijkheden voor het ontwerpen van simulatoren en nieuwe trainingsmethodes.

De conclusie wordt gevolgd door een algemene discussie **(Hoofdstuk 12)** over de rol van realisme en enkele bottlenecks (beoordeling van prestatie en krachtterugkoppeling) voor het ontwerp van toekomstige virtual reality simulators. De voordelen, mogelijke toekomstige toepassingen van simulators worden onderstreept. Verder worden er aanbevelingen gedaan en mogelijke richtingen gegeven voor toekomstig onderzoek op het gebied van technologie en veiligheid in de (laparoscopische) chirurgie.

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