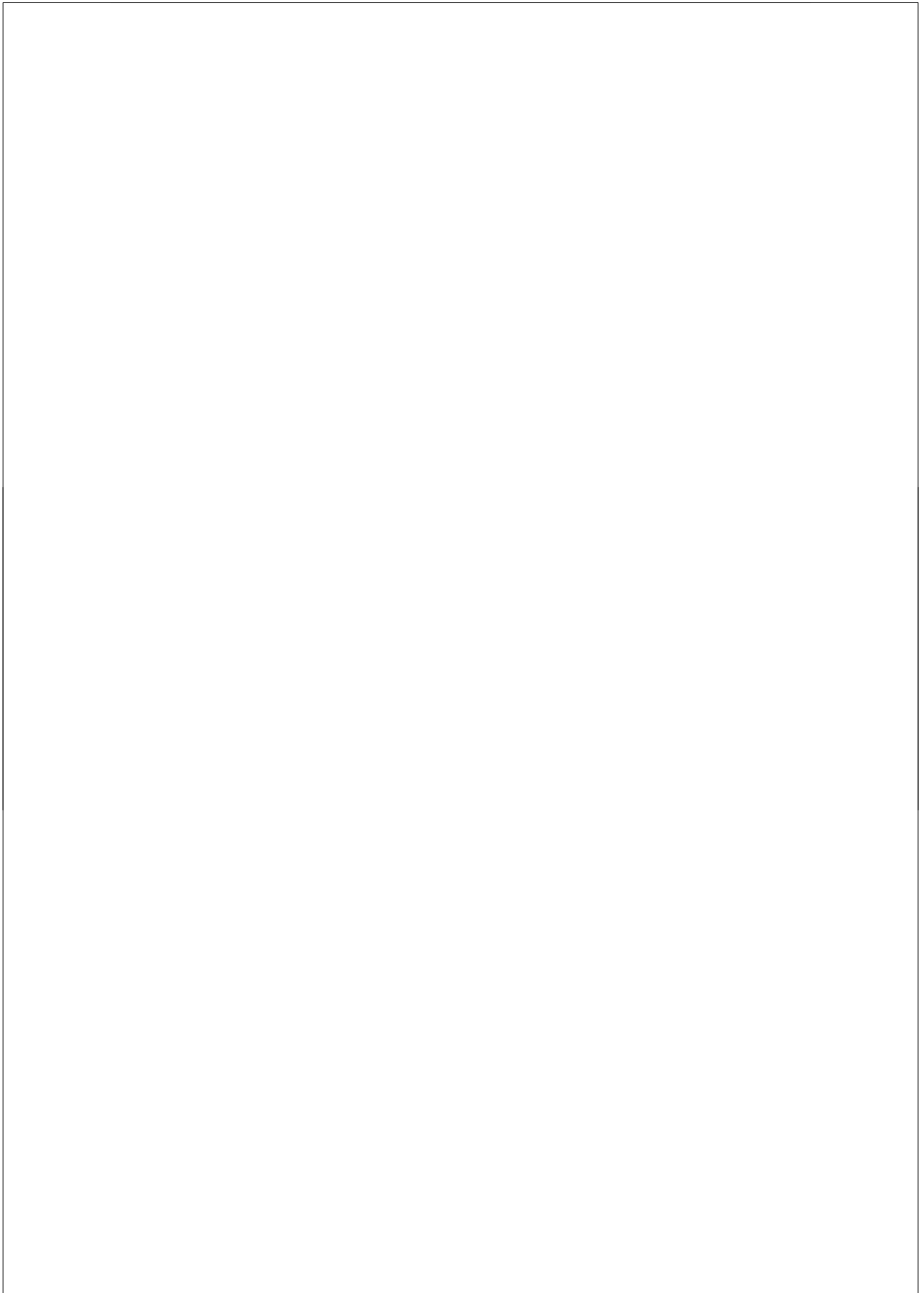


Augmented Reality Simulation for Laparoscopic Training

Realistic haptic feedback & meaningful assessment



Augmented Reality Simulation for Laparoscopic Training

Realistic haptic feedback & meaningful assessment

Proefschrift

ter verkrijging van de graad van doctor
aan de Technische Universiteit Delft,
op gezag van de Rector Magnificus prof. dr. ir. J.T. Fokkema,
voorzitter van het College voor Promoties,
in het openbaar te verdedigen op woensdag 1 april 2009 om 10.00 uur

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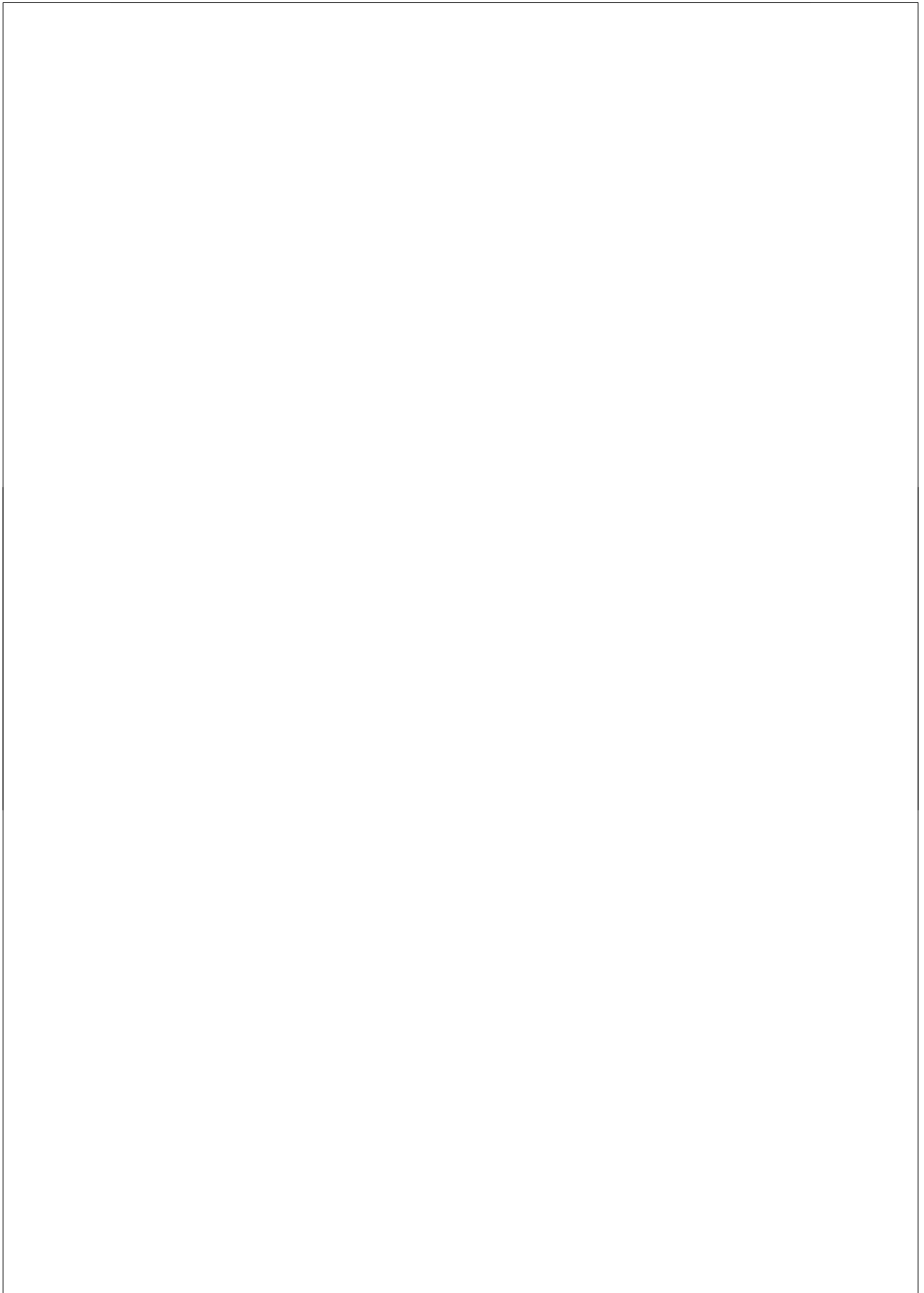
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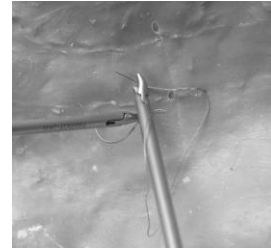
Sonja Buzink

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Chapter 1



General introduction and outline of thesis

Sanne M.B.I. Botden

Introduction

Minimally invasive surgery is often used for several surgical procedures in the last decade. Laparoscopic procedures represent the ‘gold standard’ for e.g. cholecystectomy, anti-reflux and bariatric surgery. The advantages of the minimally invasive approach over the conventional approach, which have been demonstrated for a number of other operations, are limited access trauma due to smaller incisions, shorter hospital stay, and decreased postoperative pain.

Laparoscopic surgery is more complex than open surgery and requires a new set of skills that are specific for this kind of surgery. The surgeon has to become proficient in handling the new instruments, the considerable loss of haptic feedback, dealing with the counter-intuitive manipulation of the instruments (Fulcrum effect), and the two-dimensional (2-D) representation of the three-dimensional (3-D) operating field [1-3]. To take advantage of this minimally invasive approach, skilled and well trained surgeons should perform the procedures. It is difficult and time consuming to teach these skills to the surgeons in training by apprenticeship. There is general consensus amongst most surgeons that education in laparoscopic surgery should be intensified and that there should be an assessment of the skills of the surgeons in training, before they start to perform a laparoscopic procedure in the clinical setting [4-10]. This way improvement and efficiency of the quality of care can be achieved. Therefore it is widely accepted that training in laparoscopic surgery must begin already outside the operating theatre [11].

The goal of simulator training is to master the specific skills needed for laparoscopic surgery and gain proficiency in component tasks of procedures. Currently, expertise in laparoscopy is still mainly assessed based on the number and type of clinical laparoscopic procedures performed (clinically-based expertise) [5,12]. However, it is important to realise that the nature of different laparoscopic skills like tissue manipulation and navigation with an angled laparoscope differ considerably and that the required eye-hand coordination partly relies on different visual-spatial and psychomotor abilities [13]. This is not only the fact for the difference between tissue manipulation and camera navigation [13], but also for laparoscopic suturing skills. The latter skills are a lot more advanced than the previous mentioned basic skills. Therefore it is necessary to focus on all skills that have to be mastered separately, before the trainee is allowed to apply them during a complex laparoscopic procedure. For this purpose, both box trainers, Virtual and Augmented Reality simulators could play an important role in fulfilling the desire for objective proficiency assessment and in accomplishing a shift towards criterion-based training [5,7,12,14,15].

Traditional box trainers contain realistic haptic feedback during the practice, but lack objective assessment of the performance, if there are no observers to assess the performance. However, when an observer is providing the assessment of the performance a certain degree of objectivity can be obtained, providing it is a trained objective observer. While VR simulators provide explanations of the skills and an objective assessment at the end of the performance (without an observer), they are lacking realistic haptic feedback [11]. Augmented Reality simulators, however, have the advantages of the realistic haptic feedback of the traditional box trainers and the objective assessment of the VR simulators.

Haptic feedback is the combination of tactile perception and kinaesthetic perception. Tactile perception is the perception of pressure, vibration and texture (also called discriminative touch), and relies on different kinds of receptors in the skin. During laparoscopic surgery, however, the hands (skin) of the surgeon are not in direct contact with the tissue, but indirectly through instruments, which are inserted in the abdomen through trocars. This additionally causes frictions to the instruments, and results in a significantly reduced tactile perception of the haptic feedback during the manipulation of the tissue, compared to open surgery. The kinaesthetic perception (through muscle tendon and joint sensory receptors) gives information to the surgeon on the position of the instrument in the abdomen. This can also be seen on the screen during the procedure, but is also important when the instrument is not in the visual field. The level of haptic feedback is believed to play a role in generating a correct mental reference model [16,17]. It has been previously proven that realistic haptic feedback is important in the training of laparoscopic suturing, and results in a better skills transfer to the trainee [9,18,19]. To produce realistic tissue and instrument behaviour during the training setting it is important to have the proper information about the mechanical properties of the organs. This is, however, very difficult to achieve, because solid organs, hollow organs, sick and healthy tissue behave different when manipulated [17]. There are some Virtual Reality simulators on the market with haptic feedback, but the quality of this feedback is not satisfactory [15].

Chapter 1

This thesis describes the advantages of the Augmented Reality laparoscopic simulator for the training of laparoscopic surgery. The main research questions were based on the importance of haptic feedback during the laparoscopic suturing training and the need for a meaningful feedback to guide the trainee through their own learning curve.

The first chapters of this thesis focus on the Augmented Reality simulators available and the whether they are a valid training tool. Following, the importance of haptic feedback in laparoscopic suturing training is research and with that the possible additive value of Virtual Reality. In the next chapters a new suturing module has been developed and then researched whether a trainee could learn laparoscopic suturing skills adequately without the guidance of an expert observer. This thesis is finalized with the development of an artificial model of the human upper abdomen, to train the laparoscopic Nissen Fundoplication. The objective of this last study was whether this artificial model would be an adequate replacement for the procedural training on animal tissue models.

Outline of this thesis

In **chapter 2** the Augmented Reality laparoscopic simulation is reviewed and presents the current developments in this simulation technique, and the available simulators.

Chapter 3 addresses the face validity of the ProMIS, an Augmented Reality laparoscopic simulator, as a tool for training suturing skills in laparoscopic surgery.

In **chapter 4** the face, expert and referent validity of the ProMIS Augmented Reality laparoscopic simulator has been described for two different laparoscopic skills: the translocation and suturing tasks.

In **chapter 5** a comparison was made between the ProMIS Augmented Reality laparoscopic simulator and the LapSim Virtual Reality simulator for the basic and the more advanced suturing skills. The comparison was outlined on both the opinion of the participants as the construct validity of both simulator systems.

Chapter 6 presents the importance of haptic feedback in laparoscopic suturing simulation and the additive of Virtual Reality simulation in gaining these advanced laparoscopic skills. For this purpose we compared laparoscopic suturing training on only traditional box trainers with training with the combination of a Virtual Reality simulator.

During the research of this thesis, we have developed a new assessment method for laparoscopic suturing on the ProMIS Augmented Reality simulator. In **chapter 7** not only the validity of this module is described, but also the necessity for meaningful measurements to assess laparoscopic suturing skills during the training.

In **chapter 8** the performance curve of novice trainees was researched on the adapted suturing module, with the newly developed assessment method, on the ProMIS Augmented Reality simulator.

Chapter 9 presents the development of an artificial model of the upper abdomen for the training of the laparoscopic Nissen Fundoplication procedure.

In **chapter 10** this developed model for the laparoscopic Nissen Fundoplication training was validated and compared with animal tissue models.

In **chapter 11** the found results of the studies are elaborated in the discussion. This is followed by ideas for future developments.

Chapter 12 gives a summary and the conclusions of this thesis in both English and Dutch.

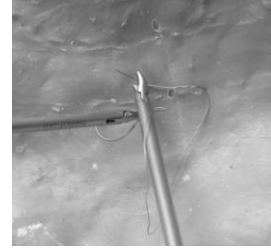
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Chapter 1

Chapter 2



What is going on in Augmented Reality Simulation in Laparoscopic Surgery?

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Abstract

Background

To prevent unnecessary errors and adverse results of laparoscopic surgery, proper training is of paramount importance. A safe way to train surgeons for laparoscopic skills is simulation. For this purpose traditional box trainers are often used, however they lack objective assessment of performance. Virtual Reality laparoscopic simulators assess the performance, but lack realistic haptic feedback. Augmented Reality (AR) combines a Virtual Reality (VR) setting with real physical materials, instruments and feedback. This article presents the current developments in Augmented Reality laparoscopic simulation.

Methods

Pubmed searches were performed to identify articles regarding surgical simulation and Augmented Reality. Identified companies manufacturing an AR laparoscopic simulator received the same questionnaire referring to the features of the simulator.

Results

Seven simulators that fitted the definition of Augmented Reality were identified during the literature search. Five of the approached manufacturers returned a completed questionnaire, of which one simulator appeared to be VR and was therefore not applicable for this review.

Conclusion

Several Augmented Reality simulators have been developed over the past few years and they are improving rapidly. We recommend the development of AR laparoscopic simulators for component tasks of procedural training. AR simulators should be implemented in the current laparoscopic training curricula, and in particular for laparoscopic suturing training.

Introduction

Minimally invasive surgery (MIS) has been accepted world wide as the main treatment for many various pathologies, because of the known advantages over the open procedure. However, performing laparoscopic procedures demands very specific capabilities of the surgeon, which can only be gained through extensive training [1]. To master these skills, the trainee needs to develop an understanding of the spatial relationship and the related hand manoeuvres required to manipulate instruments and tissue in a two-dimensional video rendering of a three-dimensional operation field. Developing these skills before entering an operating room enables a more focused and efficient performance, which minimizes time in the operating room and enhances patient safety [2,3]. For this purpose multiple surgical simulation systems became available to train the laparoscopic skills prior to performing the actual surgery in the clinical setting.

The different kinds of simulators used for training purposes are: the traditional box trainers, Virtual Reality (VR) and Augmented Reality (AR) simulators. Traditional box trainers have realistic haptic feedback during the procedures, but an expert observer must be on hand to assess the performance. VR simulators provide explanations of the tasks to be practiced and an objective assessment of the performance; however they lack realistic haptic feedback. AR simulators retain realistic haptic feedback and provide an objective assessment of the performance of the trainee.

Previous studies [4-8] have shown that realistic haptic feedback is fundamental for good laparoscopic training and results in significantly improved skills transfer to the trainee compared to training without haptic feedback [4,5]. A simulation system that provides unbiased and objective assessment of performance (rather than just speed) could help training, complement knowledge-based examinations, and provide a benchmark for certification [1].

Augmented Reality laparoscopic simulators provide both realistic haptic feedback and objective assessment of the performance. By retaining both of these important training properties in this simulator system, these could be a potent training tools for the current surgical training curricula. Therefore this study provides an overview over the Augmented Reality simulation technique and the available simulators.

Methods

Pubmed searches were performed to identify articles with combinations of the following key words: ‘laparoscopic’, ‘simulation’, ‘trainers’, ‘Augmented Reality’, and ‘hybrid’. Further articles were obtained by manually searching the reference lists of the identified papers.

The identified companies or research groups that we found to have produced an Augmented Reality laparoscopic simulator were asked to participate in this study. They each received the same questionnaire asking for a description and features of their Augmented Reality laparoscopic simulator. The items in the questionnaire covered: features, modules and tested skills, properties for assessments, haptic (force) feedback, most important aspects, and shortcomings. The final part of the questionnaire contained questions on the validation of their simulator and the costs of the hardware and software.

Results

Simulators

Seven simulators that fitted the definition of Augmented Reality were identified during the literature search. All of the corresponding manufacturers or research groups were approached to complete the questionnaire, asking them to cooperate with this study and inform us about the features of their simulator. Five of the approached producers returned a completed questionnaire; one simulator appeared to be VR and was therefore not applicable for this overview. The results of the returned questionnaire are stated as an overview in Tables 1 and 2.

ProMIS

ProMIS combines the virtual and real worlds in the same system: users learn, practice and measure their proficiency with real instruments on physical and virtual models. It comprises a number of modules designed to develop and evaluate surgical proficiency. The simulator comprises a ‘mannequin-type’ bodyform linked to a laptop computer (running Windows XP). Inside the bodyform, a vision-tracking system enables tracking and measuring of the real surgical instruments (and hand movements) within the bodyform. By marking each instrument, the vision tracking system can identify the position, direction and velocity of left instrument, right instrument and camera at any time. There is an unlimited degree of freedom and tactile feedback while performing the tasks. The training modules may be physical tasks

on ‘trays’, VR tasks or a combination of both. Real instruments, trocars and port placement are used on physical tissue.

The metrics and assessment (Tables 1 and 2) presented are based on data gathered by the tracking cameras. There are learner and group management tools to follow the progress of the trainee.

The core ‘bodyform’ unit has a inner and outer molded torso casings, between which a model ‘skin’ is placed. There is a sliding drawer on the front side for the placement of the trays. A universal serial burse (USB) foot pedal is used during the performance of the task, to go on to the next step. The base has the option to tilt, enabling the bodyform to be tilted forwards and backwards up to 45°. The Dell XPS laptop computer, connected to the ProMIS bodyform, runs Windows XP, and has a 15” screen or equivalent, with a hard-drive of at least 60GB, 1GB random-access memory (RAM), and 6800 GFORCE TOGO graphics card.

CELTS

The computer-enhanced laparoscopic training system (CELTS) is a prototype laparoscopic surgery simulator that uses real instruments, real video display and laparoscopic light sources with synthetic skin and task trays to permit highly realistic practice of basic surgical skills. Since instruments and displays are real, actual suturing can be performed without the need to create software models of suture or needle behaviour, for instance. An embedded metrics algorithm automatically scores each user for both right and left hand on five critical indicators of surgical skills.

A five point graphical scale of trainee performance compared to expert performance, using an automatic integral algorithm. The database is infinitely expandable so statistical variation/reliability improve with each use. The performance is measured longitudinally using trainee log-in data and all performance data can be transmitted wirelessly to faculty mentor using integral transmissions hardware.

LTS3e

The LTS3-e (LTS) is a relatively low cost Augmented Reality simulator capable of training and assessment of technical laparoscopic skills of Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Fundamentals of Laparoscopy (FLS) program. The LTS3-e is essentially an electronic evolution of McGill inanimate system for training and evaluation of laparoscopic skills (MISTELS) and offers a few more tasks. It provides validated physical reality exercises assessed electronically with validated McGill metrics. The system possesses sensors embedded in physical modules, which capture performance data, permitting computer based electronic scoring. The software can store user information and compare

Chapter 2

performances over time. The transportable unit (dimensions 50 x 37 x 27cm, weight 15kg) consists of an enclosure containing a built-in PC (running Windows XP Professional, Pentium processor, 100gb hard drive, DVD-RW drive, 120-240 VAC power), video display (15" screen, 1024x768 display), electronic carousel, digital video camera, cold light illuminator, DVD, and wireless keyboard. The LTS also has a tensiometer to verify knot security with a disruptive force of 1 kg in one of the suturing exercises.

Blue DRAGON

The Blue DRAGON (University of Washington, Seattle, WA, USA) is a system for acquiring the kinematics and the dynamics of two endoscopic tools along with the visual view of the surgical scene. This is an assessment method for the performance when training in a realistic setting, e.g. on a box trainer, animal model or clinical setting. The assessment of the performance is based on the placement of the instrument and the tool-tissue interaction during the task. This research group has recently produced a new prototype of simulator system, Red Dragon [9], which is not only for the simulation of laparoscopic skills, but can also be used for the assessment in the clinical setting. This simulator has not yet been validated, but will be commercially available, produced by Simulab, under the name of 'Edge'.

The assessment of the Blue Dragon is based on the Markov Model [10-18], decomposing a surgical task in symmetric finite-states (28 states) where the left and the right hands are represented by 14 states each. These states correspond to a fundamental tool-tissue interaction based on the tool kinematics and associated with unique force, torque and velocities signatures. These measurements are given at the end of the performance as an overview in a table or as a three-dimensional (3-D) graphic of the path travelled by the instruments. In addition to the data acquisition, the synchronized view of the surgical scene is incorporated into a graphical user interface displaying the data in real time.

The Blue Dragon includes two four-bar passive mechanisms attached to real laparoscopic tools, translating the laparoscopic tool's rotation in the ports. These mechanisms are equipped with three classes of sensors: position sensors (multi turn potentiometers - Midori America Corp.) for measuring the positions, orientations and translation of the two tools attached to them. In addition, two linear potentiometer (Penny & Giles Controls Ltd.) measure the laparoscopic handle and tool tip angles, during the performance. Three-axis force/torque sensors (ATIMini sensor) are located at the proximal end of the laparoscopic tools' shaft, and inserted into the tools' handles providing binary indication of any tool-tissue contact.

Table 1 Features of the Augmented Reality simulators						
Modules and tasks of the simulator:		Basic skills:	ProMIS	Blue Dragon	CELTS	LTS3e
	Modules and tasks of the simulator:	○ Navigation/coordination	X	X	X	X
		○ Touching	X	X	X	X
		○ Grasping	X	X	X	X
		○ Stretching/traction	X	X	X	X
		○ Translocation	X	X	-	X
		○ Other:		All laparoscopic skills can be measured		
		Advanced skills:				
		○ Clip application	X	X	-*	-
		○ Transection/cutting	X	X	-*	X
		○ Dissection	X	X	-*	-
○ Diathermia	X	X	-	-		
○ Suturing	X	X	X	X		
○ Knot tying	X	X	X	X		
○ Other:	Hand-assisted/laparoscopic colectomy	All procedural component tasks	Cannulation			

Table 1 (continued)
Features of the Augmented Reality simulators

Recorded Parameters	ProMIS	Blue Dragon	CELTS	LTS3e
- Time - Path length - Smoothness - Economy of movement - Errors - Other:	- X - X - X - X - X - Hand dominance	- X - X - X - - - Tool/tissue interaction Opening/ closing of instrument	- X - X - X - X - - Instrument orientation, ambidexterity	- X - - - - X
Feedback: - Progression curve of recorded parameters - Real playback of the task - Virtual playback of the task - Other:	- X - X - X	- - - - Overview of measurements	- X - -	

Table 1 (continued) Features of the Augmented Reality simulators		ProMIS	Blue Dragon	CELTS	LTS3e
Need for observer	o Is there an 'expert' observer needed for evaluation of the performance of the tasks?	No	No	No	Yes
	o An 'expert' observer is only needed for feedback/help with problems?	Yes	Yes	Yes	Yes
	o Trainees can train and evaluate modules without an 'expert' observer.	Yes	Yes	Yes	Yes
	Instructions:				
	o Written instruction of the task on the screen	Yes	No	No	Yes
	o Demonstration video	Yes	Yes	No	Yes
	o Spoken instruction during the task	Yes	No	No	No
	o Guiding lines on the screen during the task	Yes	No	No	No
	o Other:	Animation to illustrate the Task			
Validation	Is the simulator completely validated	Yes	Yes	No	Under research
	- If not, what part is?				

Table 1: Features of the Augmented Reality simulator according to their manufacturers

* Clipping and transection could be performed with small changes to the simulated skin, but are not part of the original skills set.

** Blue dragon is not commercially available, but the Red Dragon, an improved prototype of this simulator, will be commercially available as 'Edge', produced by Simulab.

Table 2: Assessment method and important aspects					
	ProMIS	Blue Dragon	CELTS	LTS3e	
Assessment	Time	Markov Model:	Time	McGill metrics	
	Path Length	Force	Ambidexterity		
	Economy of Movement	Tension	Instrument		
	Hand Dominance	Velocity	orientation,		
	Task-specific errors		Economy of motion		
	Self-assessment form				
Most important aspects	Combination of physical reality and virtual reality in the same unit.	Objective assessment of MIS skills using the Markov Model	Automatically record performance	Realistic physical exercises	
	Enables real instruments and real haptics		Use of real instruments	Knot integrity exercise using electronic tensiometer	
	Can adapt to a curriculum		Allowing knot to be assessed		
Shortcomings	None	No progression curve of the performance assessment	No commercial partner to date	Absence of anatomical representations	

Table 2: Assessment methods and important aspect of the Augmented Reality simulator according to their manufacturers

Discussion

Augmented Reality laparoscopic simulation

Augmented Reality is a term also used in diagnostic and treatment techniques, where an overlay of the anatomy can be given, or visual cues of specific landmarks, which were previously scanned with computer tomography (CT) or magnetic resonance imaging (MRI). In this study we focus only on Augmented Reality in laparoscopic simulation.

Physical Reality (Box trainer)	Augmented Reality	Virtual Reality
Advantages • Realistic haptic feedback • Cost-effective	Advantages • Realistic haptic feedback • Objective assessment of performance • Interactivity	Advantages • Objective assessment of performance • Interactivity
Disadvantages • Subjective assessment • Lack of interactivity	Disadvantages • Lack of assessment protocol	Disadvantages • Lack of realistic haptic feedback • Lack of assessment protocol

Figure 1: Properties of the different simulation techniques used in laparoscopic training.

Augmented Reality is the essential link connecting the virtual world with the real world. Virtual information is added to the real world. Augmented Reality rose from the need to exploit optimally virtual data coming from simulations. Augmented Reality simulation is the combination of physical (real) and Virtual Reality in one system (Figure 1). This enhancement of the physical training in laparoscopic simulation can be accomplished with overlays of anatomical representations or by objective assessment at the end of the performance. Another approach to Augmented Reality is the visual pathway of the instruments which can be shown during a playback of the performance.

A major advantage of the AR laparoscopic simulator over the VR simulators is that it allows the trainee to use the same instruments that are currently used in the operating room. The

simulator provides realistic haptic feedback because of the hybrid mannequin environment the trainee is working in, which is absent in VR systems. This simulator offers a physically realistic training environment that is based on real instruments interacting with real objects. The physical task is combined with demonstration videos on the screen, and the performance of the trainee is recorded for subsequent replay. Because AR simulators are a learning system on their own, there is no need for an expert laparoscopic surgeon to be on the scene to guide the trainee. Therefore AR simulation is a good way for trainees to practise their laparoscopic skills in their free time.

Validation of AR simulators

Multiple studies [19-23] have been published validating the effectiveness of ProMIS in training and assessing laparoscopic skill. The ProMIS has shown construct validity for orientation, dissection, and basic suturing tasks in several independent studies [20,22,23]. The face validity has also been shown in the study by Botden et al. [24], in which the surgeons give favourable ratings to the suturing module, with regards to realism and haptic feedback. Other articles have been published using the ProMIS in general skills acquisition [25] and comparing ProMIS AR with VR simulation [22]. In the comparison of AR with VR laparoscopic suturing [22], the ProMIS AR simulator was preferred by far over the VR simulator to train suturing skills. The study by Nerula et al. researched the assessment system of the ProMIS simulator for assessing the skills with robotic instruments [19]. This shows the wide variety of teaching laparoscopic skills the ProMIS can be used for.

The CELTS simulator has not been validated thoroughly, because the focus of this research group is on the development and improvement of new simulator systems. However, several studies have been published introducing the CELTS laparoscopic simulator, showing construct and some face validity [26-29]. Maithel et al. showed construct validity of the CELTS by comparing the assessment of the performances of junior and senior residents. They concluded that computer-enhanced video trainers (Augmented Reality) may offer an improved interface while incorporating useful multidimensional metrics, but that further work is needed to establish standards for appropriate skills assessment methods and performance levels for using these simulators [26,27]. Stylopoulos et al. concluded from their studies that the CELTS provided educational feedback by identifying key factors, such as depth perception, smoothness of motion and instrument orientation, which contributed to the overall score. Assessment based on these parameters could distinguish the trainee from the expert [28,29].

Currently, no studies been published on the LTS-3e laparoscopic simulator, because the validation research is still in progress.

There are several studies [10,11,13-16,18] showing the usability of the Markov Model during laparoscopic training, using the Blue Dragon laparoscopic simulator. Rosen et al. have researched the Markov Model within the assessment system extensively and concluded that the major differences between the different skills levels were shown in terms of types of tool-tissue interactions being used, transitions between tool-tissue interactions being applied by each hand, the time spent performing each tool-tissue interaction, overall completion time, and the variable force/torque magnitudes being applied by the subjects through the laparoscopic instruments [10,15-17].

Benefits of Augmented Reality simulation

As shown in this overview, several types of Augmented Reality simulators currently are on the market, ranging from relatively simple 'box trainers' with a separate assessment method to more advanced simulators with demonstration videos, overlays during the performance and the essential assessment of the performance. Still there are improvements that could be made to make these simulator systems more suitable and complete to implement in the current training curricula for laparoscopy. Demonstration videos and providing formative feedback during the training could help surgical residents more to train their laparoscopic skills. In the current training on the traditional box trainers an expert observer must be on hand to provide feedback and assess the performance. Both VR and AR systems provide objective measurements of the performance, but lack meaningful assessment protocols. However, AR simulators additionally offer realistic haptic feedback. For laparoscopic suturing training, for example, AR is the best choice for a simulation system, as haptic feedback during practice is mandatory for good skills transfer to the trainee [7,30-33], and providing feedback will guide and motivate trainees to practice these difficult laparoscopic skills until they have reached specific goals [34-37].

Augmented Reality simulation has great potential in the training of component tasks of procedural training, especially for procedures which require realistic haptic feedback during training. Such procedures are bariatric surgery and colon surgery, in which anastomoses are frequently made and therefore suturing skills are necessary.

Cost efficacy

The costs of both the hardware platform and the software of an AR simulator are comparable to the costs of a VR simulator, as VR simulators have become less expensive over recent years. This results in the tendency for the costs of AR and VR simulator systems to equalize. The costs of an AR simulator can be divided in three parts: the hardware platform, the software packages, and consumables on which to practise the tasks. Both AR and VR

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simulators offer package deals for several software modules together with the corresponding hardware and, for AR, consumables. In AR, however, the costs of the consumables vary considerably, depending on the module for which they are designed, ranging from suturing tissue to abdominal landscapes for colon surgery. Therefore, the costs of an AR simulator strongly depend on the modules one desires to practise in the laparoscopic training curricula.

Conclusion

Several Augmented Reality simulators have been developed over the recent years, and they are improving rapidly. The advantage of AR over VR is that they offer the realistic haptic feedback, like traditional box trainers, while additionally providing objective assessment of the performance. Our recommendation for the future is the development of Augmented Reality laparoscopic simulators for component tasks of procedural training, such as laparoscopic suturing, and improvement of the assessment methods. For basic skills, however, VR has previously been proven a valid training method.

Augmented Reality simulators are a potent new modality laparoscopic simulator system that should be implemented in the current laparoscopic training curricula.

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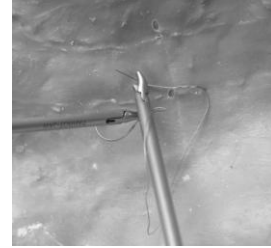
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Face validity study of the ProMIS Augmented Reality laparoscopic suturing simulator

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Abstract

Background:

To prevent unnecessary mistakes and avoidable complications in laparoscopic surgery, there has to be proper training. A safe way to train surgeons for laparoscopy is simulation. This study addresses the face validity of ProMIS, an Augmented Reality laparoscopic simulator, as a tool for training suturing skills in laparoscopic surgery.

Methods:

A two-paged, twelve-item structured questionnaire, using a five-point-Likert scale, was presented to 50 surgeons/ surgical residents. The participants were allotted to two groups: an 'expert' (>50 procedures; N=23) and a 'referent' group (<50 procedures; N=27). Non-parametric statistics were used to determine statistical significant differences.

Results:

General consensus existed in both 'expert' and 'referent' groups, delineating ProMIS as a useful tool in teaching suturing skills surgeons/ surgical residents (mean $\pm$ standard deviation, score 4.91 ± 0.42 and 4.93 ± 0.38 respectively) with regard to realism, haptic (tactile) feedback and suturing techniques. Statistical significant differences in opinion regarding the ergonomics and design of ProMIS between the 'expert' and 'referent' groups existed.

Conclusions:

The ProMIS Augmented Reality laparoscopic simulator is regarded as a useful tool in laparoscopic training in both 'expert' and 'referent' groups. However, statistical significant differences in opinion were present between experts and novices with regards to ergonomics and design of ProMIS.

Background

To take the advantage of minimally invasive surgery (MIS), there must be skilled surgeons able to perform these procedures. Currently, consensus is established on the fact that training in MIS should be intensified, and assessment of surgeons' skills is mandatory for ensuring high-quality endoscopic patient treatment [1]. Moreover, stated is that training in laparoscopic surgery should be performed mainly outside the operating room [2,3]. Continued advances in computer technology combined with the growing need for training in advanced laparoscopic skills outside the operating room, have led to exponential growth and development of Virtual Reality (VR) simulators dedicated to training in the medical profession [1-7].

The use of simulation in surgical training curricula is becoming more widely accepted, for a variety of reasons, such as objective assessment [2,3]. Objective assessment of performance is a prerequisite needed in the learning process of the resident, as well as for legitimate formative assessment. Therefore, it is essential to provide formative feedback during training, although current laparoscopic video training lacks this ability. The ProMIS Augmented Reality (AR) laparoscopic simulator (Figure 1) retains the benefits of a conventional video trainer, such as the realistic haptic (tactile) feedback, but it also generates objective measures of performance, similar to VR simulators [8].

Augmented Reality is the ideal combination of physical and Virtual Reality in one system. Real instruments, which are modified by means of tags on the tips, are tracked by the system to measure the performance of each task. This process results in the objective assessment of the real physical tasks performed by the trainees.

The value of a novel teaching tool such as ProMIS can only be assessed if acceptance exists within the group of experienced laparoscopic surgeons (expert opinion), as well as among potential trainees (referent opinion). An important step in establishing the validity of any new technological equipment is the concept of face validity [4]. The aim of this study was to validate the ProMIS AR laparoscopic suturing simulator as a realistic training tool for laparoscopic suturing and knot-tying.

Methods

Subjects

Fifty surgeons and surgical residents without any previous knowledge of, or exposure to this simulator were introduced to the ProMIS AR laparoscopic suturing simulator. Eighteen participants were questioned during the 3rd congress of the 'Nederlandse vereniging voor endoscopische chirurgie' NVEC (Dutch association of endoscopic surgery). Thirty-two participants were from different surgical departments in the teaching hospital, Catharina Hospital in Eindhoven, the Netherlands.

The participants were allotted to two groups based on their individual experience with laparoscopic surgery, which resulted in an 'expert group' (> 50 laparoscopic procedures; N=23) and a 'referent group' (<50 laparoscopic procedures; N=27).

Protocol

Before starting the suturing task, all participants were given an 'instruction tour' to familiarize them with the ProMIS laparoscopic simulator. This explanation was standardized and the same for each participant. After familiarization, the participants completed the following suturing task: by using a physical tissue model with real suturing materials, the user had to pick up and orient the needle in the needle-holder in the proper position, followed by placing the sutures in the opposing tissue. Subsequently, an intracorporeal 'surgeon's' knot had to be tied. Before both parts of the suturing tasks there a demonstration video was shown and step-by-step explanation during the task was provided on the simulator.

When the participants completed the task, they were asked to complete the questionnaire regarding the ProMIS AR laparoscopic simulator.

Questionnaire

The questionnaire consisted of a two-paged, twelve-item structured questionnaire. The first part of the questionnaire addressed the demographics and surgical laparoscopic experience, to divide the participants in the two groups. Group A (referent group) that had less than 50 laparoscopic procedure experience, and group B (expert group) that had done more than 50 laparoscopic procedures. The second part consisted of questions concerning visual scene, haptic feedback, material and instruments, surgical techniques, usefulness of simulator, design and ergonomics of the simulator. These properties of the simulator were graded on a five-point-Likert scale, in which 1 represented 'not realistic/ not good/ not useful', 3 for 'neutral' and 5 for 'very realistic/ good/ useful'.

Finally, eight statements concerning the usefulness of the simulator in terms of training/teaching capacities were questioned. The participants filled out whether they agreed or disagreed with the statements; there also was the option to fill out 'I do not know'. The questionnaire ended with an open question that requested missing elements of the ProMIS AR laparoscopic simulator.

Equipment

The ProMIS Augmented Reality simulator (Haptica, Dublin, Ireland) (Figure 1) was used in this study, which was based on a Sony Vaio portable notebook computer with a 2.80-GHz Intel Pentium 4 processor running Windows XP Home Edition with 512 MB RAM and a 30 GB hard drive. The laparoscopic interface consisted of a torso shaped mannequin (29" length x 20" wide x 9" deep), with a black neoprene cover, connected to the notebook with a standard four-pin 1394 IEEE digital cable. The mannequin contained three separate camera tracking systems, arranged to identify any instrument inside the simulator from three different angles. The left and right cameras were positioned to capture instrument motion looking in caudal direction of the left and right sides of the mannequin, respectively. The Lapro camera was positioned at the pubic symphysis of the mannequin, looking cephalad and served as the main viewing camera displayed on the computer screen for subjects when performing tasks on the simulator. The camera tracking systems captured instrument motion with Cartesian coordinates in the x, y and z planes at the average rate of 30 frames per second (fps). The distal end of the laparoscopic instrument shaft was covered with two pieces of yellow electrical tape to serve as a reference point for the camera tracking system; therefore, it accepted a broad range of instrument types. Instrument movement was recorded and stored in distinct sections, based on the time the tips of the instrument were detected until they were removed from the mannequin. The notebook was positioned so that the participant had the screen placed at eye level and the mannequin was placed at a standard height for performing the laparoscopic tasks.

Before each task there is the option of a demonstration video and step-by-step instruction.

The ProMIS simulator has a real and virtual playback of the instrument movement available. Several parameters can be evaluated at the end of a task and are also memorized in graphics for reviewing, peer comparison, and other purposes. The parameters recorded are time (seconds), path length (mm), and smoothness; these were memorized for each used instrument individually, and could be evaluated for every step of the tasks.

There are several modules and tasks that can be done to practice basic and more advanced skills. For this study we only use module 4: Suturing and intra-corporal knot-tying (Figure 2).



Figure 1: ProMIS Augmented Reality Laparoscopic simulator (Haptica, Dublin, Ireland), with needle-holders (Karl Storz, Tutlingen, Germany) and versaport trocars 5mm (Tyco Auto Suture, New Haven, USA)

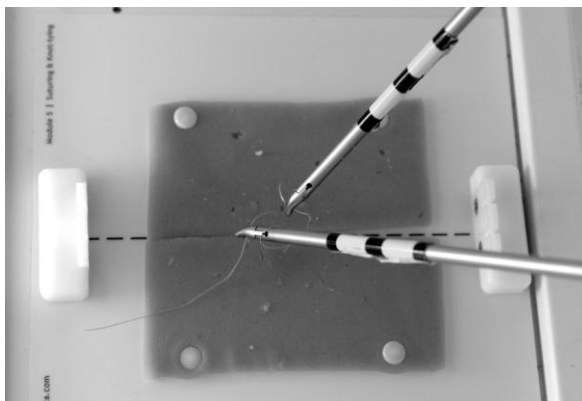


Figure 2: ProMIS Augmented Reality simulator: 'Suturing' task. The needle-holders (Karl Storz, Tutlingen, Germany) are marked with the black-yellow tags on the shaft, to enable video-tracking.

Statistics

The data were collected and analyzed using the Statistical Package for the Social Sciences (SPSS) version 9.0 (SPSS Inc., Chicago, Illinois). Non-parametric statistics were used to determine statistical significant differences.

Results

Demographics

Fifty surgeons and surgical residents without previous knowledge or exposure to the apparatus were introduced to the AR laparoscopic suturing simulator ProMIS and participated in this study. The mean age of the participants was 35 years, (range: 22-60 years). Eleven females (22%) and 39 males (78%) participated in the study. Of all participants 42% were qualified specialist, 4% were 6th year, 4% were 5th year, 4% were 4th year, 4% were 3rd year, 10% were 2nd year and 32% were 1st year residents. All participated were allotted to two groups based on the number of laparoscopic procedures they had performed, which resulted in an “expert group” (> 50 laparoscopic procedures; N=23) and a “referent group” (<50 laparoscopic procedures; N=27).

Face Validity

As seen in Table 1, there was general consensus in both ‘expert’ and ‘referent’ groups, which delineated ProMIS as a useful tool for teaching of suturing skills to surgeons/ surgical residents (mean 4.91 and 4.93 respectively). Eighty-four percent of all participants rate the aspect of the global realism of the Augmented Reality laparoscopic suturing task as realistic to very realistic (score 4 or 5 on the five-point Likert scale).

The general opinion on haptic feedback of the ProMIS AR laparoscopic suturing task was high, with experts who rated this feature with a mean of 4.69 on the five-point Likert scale (Table 2). Almost all participating surgeons and surgical residents (95%) indicated it to be very important to use real suturing thread and laparoscopic instruments instead of Virtual Reality. This tensile character of the ProMIS was regarded very important to learn laparoscopic suturing and knot-tying skills.

The ‘ergonomics and design’ (Table 3) scored less in comparison to the other features asked in the questionnaire, mainly regarding overall ergonomics and placement of the trocars. The main remark on the ergonomic features was that the height of the simulator was not optimal for the performance. The simulator was placed on a fixed table; therefore, it was not possible to position the mannequin at the height and in an angle in which one normally perform in the

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operating room. Therefore the instruments were not in the optimal position and it was more difficult to work inside the trocars. Another comment given by the experts regarding the ergonomics was that they wanted a hand-held laparoscope, instead of the fixed cameras installed in the simulator. They were used to change the view of the operating field, in the clinical setting, but this feature of the simulator was not use in this study.

Table 1: Realism of ProMIS	Expert (N=23)	Referent (N=27)
	<i>Mean (Standard deviation)</i>	
Global realism	4.65 (0.98)	4.48 (1.19)
Importance of true needle	4.91 (0.42)	4.85 (0.53)
Importance of true instruments	4.91 (0.43)	4.85 (0.53)
Realism of thread	4.91 (0.42)	4.78 (0.85)
Realism of instruments	4.65 (0.98)	4.56 (1.01)

Table 2: Haptic feedback	Expert (N=23)	Referent (N=27)
	<i>Mean (Standard deviation)</i>	
Haptic sensation of tissue	4.45 (1.10)	3.96 (1.17)
Resistance of needle	4.64 (0.79)	4.57 (0.84)
Orient needle and place sutures	4.82 (0.59)	4.54 (0.86)
Knot-tying	4.83 (0.58)	4.92 (0.39)

Table 3: Design & Ergonomics	Expert (N=23)	Referent (N=27)
	<i>Mean (Standard deviation)</i>	
Design of simulator	4.30 (0.97)	3.89 (1.50)
Overall ergonomics	3.82 (1.47)	3.96 (1.29)
Trocar placement	3.91 (1.60)	3.81 (1.49)
Movement of instruments	4.27 (1.32)	4.33 (1.11)

Training capacities

As presented in Table 4 most respondents (98%) believed it was important to train residents, by use of simulators such as the ProMIS AR laparoscopic simulator, before operating on patients. Also, 96% of them believed laparoscopic suturing should be an integral part of skills training for the residents in a surgical (sub)specialism. Of the respondents 90% believed it was important to monitor the progress of laparoscopic skills of surgeons in

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training throughout their residency. As shown in table 4, 92% of the respondents believed the ProMIS AR simulator could become a useful instrument for measuring performance in laparoscopic suturing. The majority of the respondents (88%) believed recording the procedure and feedback possibly will enhance future performance. Eighty-four percent was of the opinion that ProMIS was a useful instrument for measuring performance in laparoscopic suturing. All experts agreed that the ProMIS AR laparoscopic simulator provided a user-friendly environment for training laparoscopic suturing skills.

Table 4: Statements on training capacities	Expert (N=23)			Referent (N=27)		
	Agree	Disagree	No opinion	Agree	Disagree	No opinion
Good to train surgical residents on ProMIS	100%	0%	0%	96.3%	3.7%	0%
Good to monitor progress skills	91.3%	4.4%	4.4%	81.5%	14.8%	3.7%
Recording of the procedures is positive	91.3%	0%	8.7%	74.0%	3.7%	22.2%
Feedback enhances the performance	95.5%	0%	4.5%	81.5%	3.7%	14.8%
ProMIS is a useful training tool	95.6%	0%	4.4%	74.1%	3.7%	22.2%
ProMIS will become a useful training tool	91.3%	0%	8.7%	92.6%	0%	7.4%
ProMIS has a user friendly instrument	100%	0%	0%	88.9%	3.7%	7.4%

Suitability of ProMIS related to the surgical curriculum

The ProMIS AR laparoscopic simulator was considered to be of use in all stages of the surgical curriculum, but would be most useful for training of residents (96%) and surgical specialist (86%). The ProMIS simulator also was regarded to be of value in terms of enhancing laparoscopic skills by 76% of the respondents (Table 5).

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Table 5: Opinion on training properties	Expert (N=23)	Referent (N=27)
	Mean (Standard deviation)	
Medical student training	4.13 (1.46)	3.89 (1.50)
Surgical resident training	4.91 (0.42)	4.93 (0.38)
Surgical specialist training	4.57 (1.04)	4.70 (0.91)
Overall laparoscopic ability enhancing	4.55 (1.06)	4.46 (1.07)

Discussion

There is a growing need for laparoscopic skills training, for which simulation is demonstrated to be a potent training instrument [9]. Establishing the validity of these simulators is mandatory for legitimate implementation in laparoscopic training curricula of high quality. It is important for these simulators to be as realistic as possible to ensure the quality of the surgical training and, thus safety of the patients [4]. In this study, investigation of the face validity of the suturing module of the ProMIS Augmented Reality laparoscopic simulator disclosed a highly favourable agreement among all participants considering the realism of training with this simulator.

The face validity of this study was based on a group of ‘experts’, who had performed more than 50 independent laparoscopic procedures (N=23) and a group of less and inexperienced persons, who performed less 50 laparoscopic procedures, referred as the ‘referent’ group (N=27).

Feedback/ Assessment

Training on a simulator provides the trainee with the opportunity to learn in a multimodality step-way approach and offers repetitive practice of laparoscopic skills, in a safe environment. An essential benefit of the ProMIS AR laparoscopic simulator was that the trainee received formative feedback at the end of each task, which could be cognitively implemented and used during the remaining training period. Learning curves are constructed, based on the trainee’s results. These diagrams can be used to facilitate specific training and directions for use in laparoscopic training programs [10].

To be an effective training tool, a simulator has to provide metrics that are meaningful and informative to the trainee. To use the parameter ‘time’ sole feedback parameter is therefore unwise because a laparoscopic surgeon can be fast tying an improper knot, while a surgical resident may take his or her time, producing qualitatively proper knots. Therefore, in knot-tying simulation, in addition to ‘time’, other more meaningful metrics must be recorded, such

as economy of movement, path length and smoothness. Economy of movement is defined as the recorded path length compared with a calculated optimal path length. Smoothness is calculated by the directions and accelerations in the movement of the instruments. The trainee receives the result of these metrics immediately after each knot-tying task. Thus performance status can be interpreted directly and cognitively processed. Next, ProMIS offers a playback function, with or without visual representation through a line plotting the knot-tying 'path' made. The trainee can actually see what he/ she has done, and the suture and knot can be tested on strength and quality, because of the physical component of the ProMIS AR laparoscopic simulator.

In this study there was a general positive agreement (especially among experienced laparoscopists) that the ProMIS AR laparoscopic simulator is useful tool for the training of laparoscopic skills. The feedback of the simulator was regarded as useful for recording progression of the skills of the trainees as well.

Threats to the face validity

First of all, the opinion may be influenced by the individual attention given to the respondent during his/ her performance, and favourable responses may occur due to this attention. This so-called 'Hawthorne-effect' is partially accounted for by giving the same amount of attention to both respondent groups, so uniformity of the over-all opinion is not affected by differences in attention [11]. Another effect that must be mentioned, is that the respondents' opinion was influenced by their own performance. It could be that responders with a low performance score blame the material or the simulator, instead of attributing their unsuccessful performance internally.

Augmented Reality features

The simulation of surgical operations is a complex issue, especially with respect to advanced laparoscopic techniques. Virtual Reality laparoscopic simulators that offer ample computing power and proper procedural software to perform (fairly) realistic simulations have only been available recently. Nevertheless different 'species' of laparoscopic simulators are under development. Several studies have been carried out on different surgical simulators to examine training behaviour [12-15], all focusing on the same core question: Are the skills acquired through VR training transferable to realistic procedures in the operating theatre? All but one of these studies use non-procedural VR training in assessing this question [16]. Although these studies lack power and metrics are patchy, outcomes are favourable for VR trainee residents performing in the operating room. The transferability of skills from simulators to physical reality is major, but remains questionable for most VR laparoscopic

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simulators. Currently, no studies are available that specifically assess training of laparoscopic suturing and knot-tying.

Another advantage of the ProMIS AR laparoscopic simulator over the conventional VR simulators is that it allows the trainee to use whatever instruments that are currently used in their operating room. The simulator provides realistic haptic feedback because of the hybrid mannequin the trainee is really working in, in contrast to conventional VR systems. Offering a physically realistic training environment that is based on real instruments that interact with real objects, is it to be expected that performance results on knot-tying will be unsurpassed by conventional VR suturing training.

Conclusions

The ProMIS Augmented Reality laparoscopic simulator is a hybrid simulator, that offers qualities derived from the VR environment as well as from the physical environment. This makes the simulator of value in teaching and measuring technical skills fundamental to the performance of more advanced laparoscopic surgery tasks, such as suturing and knot-tying.

In this study, ProMIS was regarded as a useful tool for laparoscopic training by both expert and referent group. This is highly confirmative for the assumption that the suturing and knot-tying module of the ProMIS simulator is a novelty in skills trainers, which offers a high potential for laparoscopic training curricula. To maximize the educational benefit of simulation in technical skills, simulators such as the ProMIS Augmented Reality laparoscopic simulator should be embedded within a carefully designed, multidimensional, educational laparoscopic surgical curriculum.

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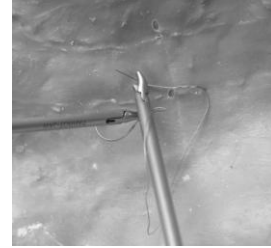
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Chapter 3

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ProMIS Augmented Reality training of laparoscopic procedures: Face, expert and referent validity

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Abstract

Background

Conventional video trainers lack the ability to assess the trainee objectively, but offer modalities that are often missing in VR simulation, such as realistic haptic feedback. The ProMIS Augmented Reality laparoscopic simulator retains the benefits of a traditional box trainer, by using original laparoscopic instruments and tactile tasks, but additionally generates objective measures of performance.

Methods

Eighty-five participants performed a ‘basic skills’ and ‘suturing & knot-tying’ task on ProMIS after which they filled out a questionnaire regarding realism, haptics and didactic value of the simulator, on a five-point-Likert scale. The participants were allotted to three groups: ‘expert’ (>50 procedures and >5 sutures; N=27), ‘intermediate’ (<50 procedures and <5 sutures; N=28) and ‘novice’ (no experience N=30).

Results

General consensus among all participants, particularly the experts, was that ProMIS is a useful tool for training (mean 4.67, standard deviation (SD) 0.48). It was considered very realistic (mean 4.43, SD 0.66), with good haptics (mean 4.08, SD 0.97) and didactic value (mean 4.10, SD 0.65).

Conclusions

This study established the face, expert and referent validity of the ProMIS AR simulator for ‘basic skills’ and ‘suturing and knot-tying’ tasks. ProMIS was considered a good tool for training in laparoscopic skills for surgical residents and surgeons.

Introduction

There is consensus that training in minimally invasive surgery should be intensified and that the assessment of the surgeons' skills should be introduced to ensure high-quality treatment [1,2]. Continued advances in computer technology combined with the growing need for training in advanced laparoscopic skills outside the operating room, have led to exponential growth and development of a variety of medically oriented Virtual Reality (VR) simulators [3-8]. The use of simulation in surgical training curricula is becoming more widely accepted, for several reasons [2-5]. First, simulator training is known to enhance the acquisition of laparoscopic skills [1,2,9-13]. Second, validated VR simulators are able to provide objective assessment and feedback of all the subjects' performance [2,5], allowing for continuous skill refinement. And finally, two randomised, controlled, double-blinded clinical trials have demonstrated that the clinical performance of subject receiving VR training is better than that of control subjects, who received no prior training [1,14]. Objective assessment of the performance is fundamental in order to provide formative feedback during training, though current laparoscopic video training is lacking this ability. To assess the performance on the traditional box trainers a scoring system has been developed in the form of the Fundamentals in Laparoscopic Surgery (FLS) [15]. However an expert observer is still needed to assess the performance of the trainee.

The ProMIS Augmented Reality (AR) laparoscopic simulator retains the benefit of a video trainer, such as the realistic haptic feedback, by using the same laparoscopic instruments as in the clinical setting and tactile tasks, and additionally generates objective measures of performance, similar to VR simulators [16]. 'Haptic feedback' is the phenomenon of tactile or force feedback a person experiences when manipulating a needle and thread. This is of importance, because resistance of the instruments and force/ torque applied tissue also pertain to 'haptics'.

Augmented Reality is the combination of physical and Virtual Reality simulation in one system. The laparoscopic instruments are tracked by the system to measure the performance of each task. This results in the objective assessment of the real physical tasks performed by the trainees.

As is apparent from the EAES consensus guidelines from Carter et al [5], there is a need for validation of the assessments of the simulators, before including them into training curricula [2]. The face validity addresses the acceptance of both experts and non-experts (referent group) of the simulator as a potent training tool and the representation of the clinical setting. In this study the face validity of the ProMIS AR laparoscopic simulator is investigated.

Materials and Methods

Subjects

The participants were tested within a period of two months (May-June 2006) at the ‘Year congress of Dutch Surgical Society 2006’, Veldhoven, the Netherlands (N=44), the Catharina Hospital Eindhoven (N=34), and at the ISCOMS (International Student Congress Of Medical Sciences) 2006, Groningen, The Netherlands (N=12). The participants were allotted to three groups based on their laparoscopic experience: ‘Experts’, who had done more than 50 laparoscopic procedures and at least 5 laparoscopic sutures in the clinical setting; ‘Intermediates’, who had performed less than 50 procedures and less than 5 sutures; And ‘Novices’ who had not done procedures themselves, but had at least seen some procedures, to ensure a reference point to the clinical setting.

Questionnaire

The questionnaire used in this study, was based on questionnaires previously used in validation studies in our research centre [17,18], and consisted of two parts. The first part dealt with the demographics and laparoscopic (simulator) experience of participants. The second part consisted of multiple questions concerning the realism, didactic value and haptic feedback of the simulator.

All questions were rated on a five-point Likert scale, in which 1 stood for not true/ realistic/ useful and 5 for very true/ realistic/ useful, 3 was considered neutral.

Equipment

In this study the ProMIS Augmented Reality (AR) simulator (Haptica, Dublin, Ireland) (Figure 1) was used and validated. The laparoscopic interface consisted of a torso shaped mannequin (29” length x 20” wide x 9” deep), with a black neoprene cover, connected to a notebook with a standard four-pin 1394 IEEE digital cable. The mannequin contained three separate camera tracking systems, arranged to identify any instrument inside the simulator from three different angles. The camera tracking systems captured instrument motion with Cartesian coordinates in the x, y and z planes at the average rate of 30 frames per second (fps). The distal end of the laparoscopic instrument shaft was covered with two pieces of yellow electrical tape to serve as a reference point for the camera tracking system; therefore it accepted a broad range of instrument types. Instrument movement was recorded and stored in distinct sections, based on the time the tips of the instrument are detected until they were removed from the mannequin. The data from the simulator was processed using a portable notebook computer (Sony Vaio, 2.80-GHz Intel Pentium 4 processor, running Windows XP

Home Edition with 512 MB RAM and a 30 GB hard drive). The notebook was positioned so that the participant had the screen placed just below eye level and the mannequin was placed at a standard ergonomic height for performing the laparoscopic tasks.

The simulator records 'time', 'path length' and 'smoothness of movement' (through changes in instrument velocity and changes in direction), during each separate task within the training module. After completion of the task, ProMIS provided statistics on the screen. In addition, a full video and virtual playback of the trainee's performance were saved. Different trays may be placed in the mannequin for each task, such as the suturing pads for the suture and knot tying task. For the translocation task the endograsps 5mm (Tyco Auto Suture, New Haven, USA) were used and for the suturing tasks the needle-holders (Karl Storz, Tutlingen Germany) with Tyco Polysorb 3-0 suturing needle and thread (Figure 2). The sutures were placed on a 1 cm thick suturing pad, which is normally used in traditional box trainers

Protocol

The participants commenced the study by filling out the first part of the questionnaire. Subsequently all participants received the same introduction of the simulator, with the aid of an informative poster. Information was given about the various training modules available and feedback provided by the simulators, as well as the tasks to be performed within the scope of this study. The simulator displayed a demonstration video previous to the task and step-by-step explanations were given during the performance. Next, the participants performed the translocation task (Figure 3), followed by the 'suturing and knot-tying' task (Figure 4). After finishing both tasks, the participants completed the remaining part of the questionnaire. A maximum time limit of five minutes was allotted for the translocation task and ten minutes for the suturing and knot-tying task (five minutes for placing the suture and five for tying the knot), because surgical residents are generally expected to be able to perform such a task easily within this time.

Data analysis

The data were processed and analyzed with the Statistical Package for the Social Sciences (SPSS) version 13.0 using parametric tests. Data on the difference of opinion between the groups was analyzed with the ANOVA test. A level of $p \leq 0.05$ was considered statistically significant.



Figure 1: ProMIS Augmented Reality Laparoscopic Simulator (Haptica, Dublin Ireland)

Figure 2: Needle-holders (Karl Storz, Tuttingen, Germany) obtained from the operating room, which can be used in the mannequin for the suturing task. The black-yellow markings on the shaft are to enable video-tracking.



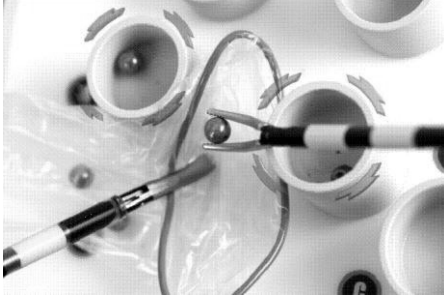


Figure 3: Translocation task

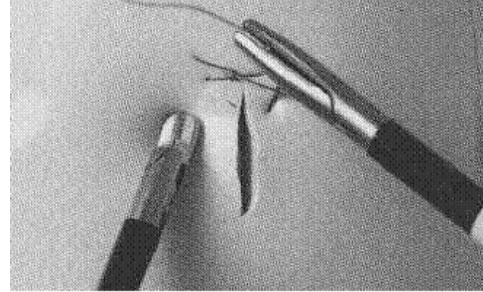


Figure 4: Suturing task

Results

Demographics & Experience

A total of 85 subjects participated in this study, of which 27 ‘experts’, 28 ‘intermediates’ and 30 ‘novices’. The three groups were not homogenous in all demographic aspects (Table 1). The expert and intermediate groups contained relatively more male participants (92.6% and 85.7% respectively). Among the novices there were more females (63.3%). Most of the participants were right-handed (96.7%). The age differences were also considerably between the groups (Table 1).

Issues about the clinical and non clinical laparoscopic experience are stated in Table 2. The intermediates had the most experience on laparoscopic simulators, and may be explained because simulators are recently started to be employed in the training curricula of surgical residents. The training environments used by some of the participants were VR simulators and inanimate box trainers. The ProMIS simulator was only previously tried by seven participants.

Face validity

There was no significant difference in opinion found between the three groups concerning the questioned features of the tasks of the ProMIS laparoscopic simulator (Table 3). The realism of the ProMIS was considered good to excellent by all participants, especially regarding needle and thread. From the experts 81.5 % considered the ProMIS as a good to perfect representation (scoring four and five on the five-point Likert scale) of the clinical setting. The haptic sensations during the manipulating of the tissue was regarded as less realistic than the other parameters related to suturing by all participants, but was still

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regarded as good to excellent by 69.0% of the participants. Of all participants 82.8% regarded the resistance of the needle and thread as realistic to extremely realistic.

Table 1: Demographic features of the participants	Experts (N=27)	Intermediates (N=28)	Novices (N=30)	Total (N=85)	p-value
Median age (years) (range)	45 (30)	32 (25)	23 (21)	33 (43)	<0.001
Education					
- Intern	0	0	27	27	
- Surgical resident	2	19	1	22	
- Other Resident	0	4	2	6	
- Surgeon	25	4	0	29	
- Other specialist	0	1	0	1	

Table 1: Differences between the ages in the three groups was calculated with the ANOVA test. A p-value <0.05 was considered a significant difference.

Table 2: Laparoscopic experience of the participants	Experts (N=27)	Intermediates (N=28)	Novices (N=30)	Total (N=85)
Procedures				
median (range)				
- Seen	500 (2920)	100 (290)	8 (50)	75 (3000)
- Camera handling	200 (1470)	50 (250)	0 (20)	40 (1500)
- Assisted	200 (960)	50 (150)	0 (30)	40 (1000)
Simulator				
- No	8	6	22	36
- 1-2 times	7	7	7	21
- 2-5 times	4	8	1	13
- >5 times	8	7	0	15

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Table 3:	Experts	Intermediates	Novices	Total	p-value
Opinion on realism and haptic feedback of ProMIS	(N=27)	(N=28)	(N=30)	(N=85)	
	Mean (standard deviation)				
	Median (range)				
<i>General</i>					
- Global impression	4.07 (0.62)	4.07 (0.60)	4.13 (0.63)	4.09 (0.61)	0.910
	4 (2)	4 (3)	4 (2)	4 (3)	
- Movement of instruments	4.27 (0.78)	4.21 (0.63)	4.37 (0.45)	4.29 (0.69)	0.698
	4 (2)	4 (2)	4 (2)	4 (2)	
<i>Translocation</i>					
- Global impression	3.85 (0.86)	4.00 (0.61)	3.93 (0.70)	3.93 (0.73)	0.755
	4 (4)	4 (3)	4 (3)	4 (4)	
- Haptic sensation material	3.93 (1.07)	4.14 (0.80)	4.17 (0.99)	4.08 (0.96)	0.590
	4 (4)	4 (3)	4 (4)	4 (4)	
- Resistance & movement of instruments	4.07 (0.83)	4.25 (0.65)	4.33 (0.66)	4.22 (0.71)	0.385
	4 (3)	4 (2)	4 (2)	4 (3)	
<i>Suturing</i>					
- Global impression	4.12 (0.71)	4.32 (0.61)	4.03 (0.63)	4.16 (0.65)	0.237
	4 (2)	4 (2)	4 (2)	4 (2)	
- Realism needle & thread	4.37 (0.79)	4.39 (0.63)	4.52 (0.57)	4.43 (0.66)	0.674
	5 (2)	4 (2)	5 (2)	5 (2)	
- Tying of knots	4.37 (0.63)	4.29 (0.71)	4.13 (0.86)	4.26 (0.74)	0.477
	4 (2)	4 (2)	4 (3)	4 (3)	
- Pulling tight of thread	4.33 (0.73)	4.32 (0.55)	4.13 (0.73)	4.26 (0.68)	0.453
	4 (2)	4 (2)	4 (2)	4 (2)	
- Movement of thread	4.46 (0.58)	4.18 (0.77)	4.27 (0.64)	4.30 (0.67)	0.292
	4,5 (2)	4 (2)	4 (2)	4 (2)	
- Haptic sensation tissue	3.89 (0.89)	3.89 (0.69)	3.93 (0.83)	3.91 (0.88)	0.973
	4 (3)	4 (3)	4 (3)	4 (3)	
- Resistance needle & thread	4.19 (0.74)	4.07 (0.60)	4.17 (0.75)	4.14 (0.69)	0.809
	4 (3)	4 (2)	4 (2)	4 (3)	

Table 3: Differences in opinion between the three groups were calculated with the ANOVA test. A p-value <0.05 was considered a significant difference.

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Didactic value

Regarding the value of the simulator, differences in opinion, between the three groups, were found on the properties of the demonstration videos ($p=0.004$ and $p=0.055$, respectively). As outlined in Table 4, the ratings of the intermediate group was lower on these features, whereas the experts were more satisfied. The novices remarked the need of demonstration videos and additional explanation on the task to be performed. In contrast, the intermediates were eager to complete the procedure fast and therefore often showed impatience to watch the whole demonstration video.

The ProMIS surgical simulator scores high as a good training tool for training of surgical residents (Table 5), with little variance in opinion. Of the experts 66.7% were of the opinion that the ProMIS AR simulator was excellent for training laparoscopic skills to surgical residents. And half of them thought the simulator to be very useful for the training of surgical specialists. The difference in opinion between the groups, on the statement ‘the ProMIS is a good training tool for training of interns’, was significant ($p=0.010$) (Table 5). Novices (which were mostly surgical interns) scored this feature higher than experts and intermediates. The novices, in particular, enjoyed the practice on the simulator, but the experts and intermediates agreed that it is not useful to learn laparoscopic skills to surgical interns.

Discussion

Augmented Reality features

The simulation of surgical operations, particularly for Virtual Reality, is very complex, especially when referring to laparoscopic techniques. VR simulators with enough computing power, tailored hardware and software programmes to perform (fairly) realistic simulations have become available only for the past few years. Several studies have been carried out on different surgical simulators to examine their training capacities [19-22]. For learning new skills it is important that trainees receive demonstrations, explanation and feedback. This is a feature VR simulators offer additionally to those provided by traditional box trainers. The ProMIS Augmented Reality simulator contains these VR features, while retaining the benefits of a realistic environment. Multiple studies [3,8,9,19] have shown that haptic feedback is a valuable feature for good laparoscopic training. The ProMIS AR simulator offers a physically realistic training environment that is based on real instruments interacting with real objects, creating realistic haptic feedback, which is absent in VR simulators.

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Table 4: Opinion on usefulness of ProMIS	Experts (N=27)	Intermediates (N=28)	Novices (N=30)	Total (N=85)	p-value
	Mean (standard deviation)				
	Median (range)				
Explanation of each task	4.41 (0.50) 4 (1)	4.18 (0.67) 4 (2)	4.50 (0.68) 5 (2)	4.36 (0.63) 4 (3)	0.142
Demonstration videos					
- Usefulness	4.30 (0.54) 4 (2)	4.14 (0.70) 4 (2)	4.67 (0.55) 5 (2)	4.38 (0.64) 4 (2)	0.004
- Clearance	4.41 (0.57) 4 (2)	4.18 (0.67) 4 (2)	4.57 (0.57) 5 (2)	4.39 (0.62) 4 (2)	0.055
Feedback after task					
- Usefulness	4.04 (0.71) 4 (2)	4.00 (0.72) 4 (3)	4.14 (0.79) 4 (3)	4.06 (0.74) 4 (3)	0.767
- Clearance	3.93 (0.78) 4 (3)	3.75 (0.80) 4 (3)	3.76 (0.83) 4 (3)	3.81 (0.80) 4 (3)	0.660

Table 4: Differences in opinion between the three groups was calculated with the ANOVA test. A p -value <0.05 was considered a significant difference.

Table 5: Opinion on didactic value	Expert (N=27)	Intermediates (N=28)	Novices (N=30)	Total (N=85)	p-value
	Mean (standard deviation)				
	Median (range)				
Training interns	3.50 (1.30) 4 (4)	2.89 (1.31) 3 (4)	3.93 (1.17) 4 (4)	3.46 (1.32) 3 (4)	0.010
Training surgical residents	4.67 (0.48) 5 (1)	4.57 (0.57) 5 (2)	4.30 (0.95) 4,5 (4)	4.51 (0.72) 5 (4)	0.131
Training surgeons	4.37 (0.74) 5 (2)	4.39 (0.56) 4 (2)	4.43 (0.82) 5 (2)	4.39 (0.71) 5 (2)	0.910
Improving laparoscopic skills	4.37 (0.74) 5 (2)	4.39 (0.79) 5 (3)	4.47 (0.72) 5 (2)	4.39 (0.75) 5 (3)	0.879
ProMIS learns proper skills	4.19 (0.68) 4 (2)	3.93 (0.72) 4 (2)	4.23 (0.57) 4 (2)	4.12 (0.66) 4 (2)	0.176

Table 5: Differences in opinion between the three groups was calculated with the ANOVA test. A p -value <0.05 was considered a significant difference.

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Face validity

The realism and haptic feedback are important features that distinguish Augmented Reality from the Virtual Reality simulators. The participants from the current study considered these aspects of the ProMIS AR simulator as good to excellent, in particular for the suturing module. The experts rated the realism with a mean of 4.37 on the five-point-Likert scale, which indicates a very realistic representation of clinical suturing and knot tying skills. The suturing material was regarded as less realistic, but this can be adjusted to individual preference for this simulator. For this study we have used the suturing pads, which have been successfully used in box trainers at our skills lab for several years. However, not much is known about the realism of the haptic feedback they provide. In some VR simulators, the virtual instruments change as needed for the procedure, but the material is fixed in the software. The aspect of a realistic environment and haptic feedback is still questionable in VR simulators [23]. Overall, all participants regarded the ProMIS laparoscopic simulator as a good to excellent representation of the clinical setting, by both the experienced as the non experienced groups. This establishes the face validity of this simulator.

Novice trainees need explanation and demonstration videos on the procedure to be performed. In contrast, more skilled trainees know the procedures, and only need the physical practice. They often considered the step-by-step explanation, which could block the view of the instruments, as a nuisance. The experts, however, were of the opinion that these explanations were a good teaching method for novice trainees. In this study all participants regarded the ProMIS AR laparoscopic simulator as an excellent training tool for the main target group (surgical residents).

Didactic value

The ProMIS AR simulator gave several measurements as feedback to assess the performance: 'Time', 'Smoothness' and 'Path length', which were shown on the screen at the end of the performance. It was tempting for the participants to focus on the time instead of concentrating on the other measurements shown on the screen. 'Time' as a sole measurement might not be the best criterion to grade the trainee on. The primary issue is that the correct technique is used, whereas time is a secondary issue

Studies concerning construct validity have been performed on the ProMIS laparoscopic simulator using several modules, but in particular the suturing tasks [7]. From these studies, we know that the ProMIS can determine the level of skills of the participants, by means of the parameters measured. This is an important aspect for implementing the ProMIS AR simulator as a potent training tool in the current training curricula. Next, it is a valuable tool

for gaining and improving laparoscopic skills by interval practising, once a certain level of skill is obtained.

Limitations

There were some limitations to this study. The major part of the participants participated on a voluntary basis during a congress. The study took place in a separate room and the researcher made sure there were as little observers as possible to avoid bias in both the performance and the opinion of the participants. The time to practice on the simulator was limited and in total 30 minutes were spent on the simulator on average. This was including the explanations, demonstrations videos and performing the tasks. If a participant was of the opinion that a question could not be answered, based on the lack of experience on the simulator, they received the opportunity to gain the appropriate experience to form their opinion.

The limitations of this Augmented Reality simulator are the measurements used to base the assessment of the performance on. 'Time', 'Path length' and 'Smoothness' do give an impression of the skills level of the trainee [7], but they do not provide formative feedback on how to improve the skills and which part of the task or procedure has to be practiced more extensively.

Conclusion

In this study the face, expert and referent validity of the ProMIS Augmented Reality laparoscopic simulator was established for the basic skills, by means of the translocation task, and the suturing and knot-tying skills. All-over ratings about ProMIS's realism was favourable and uniform among both the teaching group (surgeons) as the user group (surgical residents in training). ProMIS is therefore considered as a valuable tool in training laparoscopic skills to both surgical residents and surgeons.

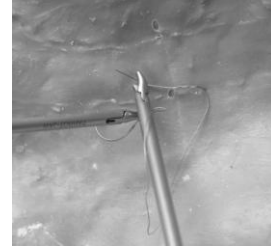
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Chapter 4

Chapter 5



Augmented vs. Virtual Reality laparoscopic simulation: What is the difference?

*A comparison of the ProMIS Augmented Reality
laparoscopic simulator versus LapSim Virtual Reality
laparoscopic simulator*

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Abstract

Background

Virtual Reality (VR) is an emerging new modality for laparoscopic skills training, however, most simulators lack realistic haptic feedback. Augmented Reality (AR) is a new laparoscopic simulation system offering a combination of physical objects and VR simulation. Laparoscopic instruments are used within an hybrid mannequin on tissue or objects, while using video tracking. This study is designed to assess the difference in realism, haptic feedback and didactic value between AR and VR laparoscopic simulation.

Methods

The ProMIS AR and LapSim VR simulators were used in this study. The participants performed a basic skills task and a suturing task on both simulators, after which they filled out a questionnaire about their demographics and their opinion of both simulators, scored on a five-point-Likert scale. The participants were allotted to three groups depending on their experience: ‘experts’, ‘intermediates’, ‘novices’. Statistically significant differences were calculated with the paired t-test.

Results

There was general consensus in all groups that the ProMIS AR laparoscopic simulator was more realistic than the LapSim VR laparoscopic simulator in both the basic skills task (mean 4.22 and 2.18, respectively, $p < 0.001$) as well as the suturing task (mean 4.15 and 1.85, respectively, $p < 0.001$). The ProMIS was regarded as having better haptic feedback (mean 3.92 and 1.92, respectively, $p < 0.001$) and as being more useful for training of surgical residents (mean 4.51 and 2.94, respectively, $p < 0.001$).

Conclusions

In comparison with the VR simulator, the AR laparoscopic simulator was regarded by all participants as a better simulator for laparoscopic skills training on all tested features.

Background

There is consensus that education in minimally invasive surgery should be intensified and that more objective assessment of surgeons' skills should be introduced to ensure high-quality treatment [1]. The growing need for training in advanced laparoscopic skills outside the operating room and continued advances in computer technology have led to growing interest in the development of Virtual Reality (VR) simulators [2,3]. Another simulator system is the Augmented Reality (AR), which refers to systems that merges computer graphics and real imagery into a single, coherent perception of an enhanced world around the user. This means that the images one can see on the screen of the simulator is comprised of a real video image overlaid with a graphics image. This can, for example, be used for directional explanation.

According to various studies [2-4] haptic (tactile) feedback is fundamental for good laparoscopic training and results in significantly improved skills transfer to the trainee, compared with training without haptic feedback [2]. Augmented Reality laparoscopic simulators have realistic haptic feedback because the operator practices on real objects or tissue using surgical laparoscopic instruments. Objective assessment of performance is fundamental in order to provide formative feedback during training, though conventional box trainers lack this ability. Augmented Reality laparoscopic simulators retain the benefits of a box trainer, such as the realistic haptic feedback, but additionally generates objective measures of performance, similar to VR simulators [1].

This study focused on training, simulation, and skills assessment in laparoscopic surgery. Because of the importance of both haptic feedback and objective assessment, we compared the ProMIS (Haptica) AR laparoscopic simulator with the LapSim (Surgical Sciences) VR laparoscopic simulator. Issues such as realism, didactic value, haptic feedback, and user acceptance were validated by participants. The purpose of this study was to evaluate which training system is of more value in training curricula for surgical residents in laparoscopic skills training.

We hypothesized that as a training tool for laparoscopic surgery, the ProMIS Augmented Reality simulator would be better evaluated by the participants than the LapSim Virtual Reality simulator.

Methods & Materials

Subjects

In total, 90 participants took part in this study. Forty-four participants were tested during the 'Year Congress of the Dutch Surgical Society 2006', Veldhoven; thirty-four participants in the Catharina Hospital, Eindhoven; and twelve participants were tested at the International Student Congress Of Medical Sciences (ISCOMS) 2006, Groningen, The Netherlands. The participants were allotted to three groups based on their clinical laparoscopic experience: the 'experts', who performed more than 100 clinical laparoscopic procedures, the 'intermediates', less than 100 clinical laparoscopic procedures and the 'novices', who had no laparoscopic experience at all.

Equipment

ProMIS Augmented Reality simulator

The ProMIS Augmented Reality simulator (Haptica, Dublin, Ireland) (Figure 1), was used in this study. A torso shaped mannequin (737mm long x 508mm wide x 229mm deep), with a black neoprene cover, contained an instrument tracking system, by means of three cameras, arranged to identify any instrument inside the simulator from three different angles. The left and right cameras were positioned to capture instrument motion, looking in caudal direction of the left and right sides of the mannequin, respectively. The laparoscopic camera was positioned at the pubic symphysis of the mannequin, looking cephalad and provided the endoscopic image on the screen.

The camera tracking system captured instrument motion with Cartesian coordinates in the x, y, and z planes at the average rate of 30 frames per second (fps). The laparoscopic instruments of choice (Figures 1 and 2) were marked with two rings of yellow electrical tape at the distal end of the shaft, at a fixed distance, to serve as a reference point for the camera tracking system (Figure 2). For data collection and video imaging display, a Sony Vaio portable notebook computer was used (with a 2.80-GHz Intel Pentium 4 processor running Windows XP Home Edition).

The simulator recorded time, instrument path length, and smoothness of movement (through changes in instrument velocity and changes in direction) for each instrument (right and left hand) during each separate task within the training module. After completion of the task, ProMIS AR provided measurements and statistics on each performed task and module. In

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addition a full video and virtual playback of the trainee's performance were saved, reviewed, and evaluated.

Different trays may be placed in the mannequin for each task, like the suturing pads for the 'suture and knot-tying' tasks. In this study 1 cm thick suturing pads were used, which are used regularly in traditional box trainers.

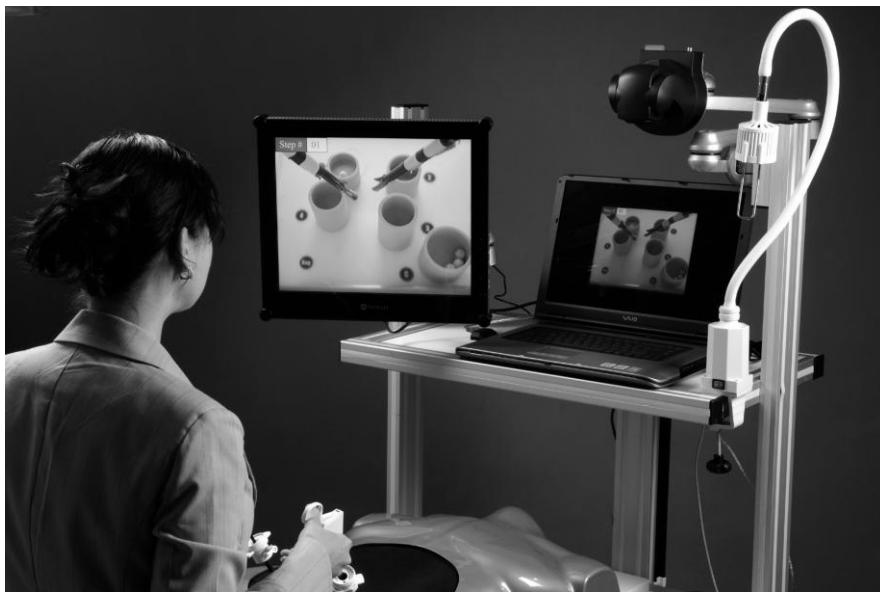


Figure 1: ProMIS Augmented Reality laparoscopic simulator (Haptica), with 5-mm endograsps and 5- and 10-mm versaport trocars (Tyco Auto Suture, New Haven, CT, USA)



Figure 2. The needle holders (Karl Storz, Tutlingen, Germany) are marked with the black-yellow tags on the shaft to enable video tracking.

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LapSim Virtual Reality simulator

The LapSim virtual reality simulator (Surgical Sciences) (Figure 3) is a PC-based surgical trainer for laparoscopic skills. This simulator used a Dell Precision desktop computer (with a 1.5 GHz dual processor systems, Vidia Quadro2EX 32 MB graphics card and running Windows 2000) on a 17-inch, CRT monitor. The VR laparoscopic instruments (Immersion Medical, San Jose, CA, USA) consisted of two handles with sensors using a five-degree-of-freedom tracking system for each instrument. The image on the monitor was a computer generated virtual reality representation of laparoscopic tasks. The software version used in this study was Basic Skills 3.0.

Parameters recorded by the simulator were time, instrument path length, tissue damage, overall score, and a pass/fail score. These parameters were calculated by means of tracking of each instrument handles.



Figure 3: LapSim Virtual Reality laparoscopic simulator (Surgical Sciences)

Questionnaire

The participants were asked to fill out a questionnaire, which consisted of three parts: the first part referred to demographics and laparoscopic and/ or simulator experience. The second part referred to realism, didactic value, haptic feedback, and usefulness of the ProMIS AR simulator. The feature 'didactic value' referred to the additional didactic value of a curriculum with this simulator implemented in it. The last part was on realism, didactic value, haptic feedback, and usefulness of the LapSim VR simulator. The latter two parts had to be answered on a five-point-Likert scale. The questionnaire ended with an open-ended question for general remarks on both simulators.

Protocol

The participants commenced by filling out the first part of the questionnaire. Subsequently, all participants received an introduction about both simulators by means of posters with a short verbal explanation. Information was given about the various training modules available and about the feedback provided by the simulators. Furthermore, the tasks to be performed on both simulators within the scope of this study were clarified. A demonstration video was additionally shown on the ProMIS AR and an instruction text on the LapSim VR before each task. The order in which the participants encountered the simulators was systemically altered (at random), to avoid possible carry-over effects. The participants first performed the translocation task, followed by the suturing task(s) (Figures 4-7). After completing the tasks on one of the simulators, the participants filled out the corresponding part of the questionnaire. They then performed the equivalent tasks on the other simulator, followed by the last part of the questionnaire.

A maximum time limit of three minutes for the translocation task on the LapSim and five minutes for the remaining tasks was used, as trained surgeons are expected to be able to perform such a task easily within this time.

The data (Table 1) recorded by the simulators was extracted to compare the construct validity of both simulators.

Data analysis

All data are processed and analyzed using Statistical Package for the Social Sciences (SPSS) version 13.0. Statistically significant differences in the opinion about these two simulators were calculated with the paired t-test. The significant differences in the level of skills extracted from the simulators between the three groups were calculated with the Kruskal-Wallis test, a p-value of <0.05 was considered a statistically significant difference.



Figure 4: Translocation task ProMIS AR simulator

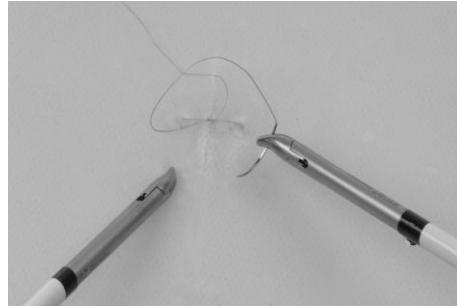


Figure 5: Suturing task ProMIS AR simulator



Figure 6: Translocation task simulator



Figure 7: Suturing task LapSim VR LapSim VR simulator

Results

Demographics

A total of 90 subjects participated in this study, of which 30 ‘experts’, 30 ‘intermediates’ and 30 ‘novices’. The three groups were not homogenous in all demographic aspects. The expert and intermediate groups contained relatively more male participants (76.7% and 93.3%, respectively), whereas amongst the novices, there were more female participants (63.3%). This can be explained by the fact that in the tested population, the gender division was not equal either. Most of the participants were right-handed (96.7%), which was equally divided in all groups. The age difference was considerably between the groups (Table 2).

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The experts all had laparoscopic suturing experience in the clinical setting, (with 56% more than 20 times), more than half of the intermediate group had some suturing experience, and none of the novices had any experience at all (Table 3). All experts and intermediates had assisted on laparoscopic procedures before, while some novices had not even seen a laparoscopic procedure (Table 3). Most intermediates had prior experience on laparoscopic simulators such as VR systems and box trainers as these are nowadays used in training curricula.

Table 1:	ProMIS	LapSim
Modules and parameters used for this study		
Modules	- Instrument handling (translocation)	- Lifting and Grasping (translocation)
	- Suturing & knot-tying	- Suturing & knot-tying
Recorded Parameters	- Time (sec)	- Time (sec)
	- Path length (mm)	- Pass/ Fail (P/F)
	- Smoothness	- Score (%)
		- Path length (mm)
		- Tissue damage

Table 2:	Experts	Intermediates	Novices	Total
Demographics of the participants	(N=30)	(N=30)	(N=30)	(N=90)
Mean age (<i>SD</i>)	45y (7.49)	31y (3.02)	24y (4.51)	33,91y (10.27)
(min-max)	(28-64)	(28-46)	(21-42)	(21-64)
Education				
- Intern	0	0	27	27
- Surgical resident	1	23	1	25
- Other Resident	0	5	2	7
- Surgeon	29	1	0	30
- Other specialist	0	1	0	1

SD: standard deviation

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Table 3: Laparoscopic experience of the participants	Experts (N=30)	Intermediates (N=30)	Novices (N=30)	Total (N=90)
Suturing in clinical setting				
- 0 times	2	14	30	46
- 1-5 times	3	9	0	12
- 5-20 times	8	5	0	13
- >20 times	17	2	0	19
Procedures (mean; min-max)				
- Seen	672 (100-3000)	103 (10-300)	11 (0-50)	252 (0-3000)
- Camera handling	302 (50-1500)	56 (0-250)	2 (0-20)	115 (0-1500)
- Assisted	271 (50-1000)	52 (0-200)	2 (0-30)	103 (0-1000)
Simulator				
- No	10	4	22	36
- 1-2 times	6	8	7	21
- 2-5 times	5	8	1	14
- >5 times	9	10	0	19

Realism & haptic feedback

As presented in Table 4 there was a significant difference in opinion of the participants with regard to features of the two simulator systems. Overall, the ProMIS AR scored higher on all aspects than the LapSim VR laparoscopic simulator, with a p-value <0.001.

The expert group rated the ‘resistance of needle and thread’ on the LapSim VR as not good, with a mean of 1.57. Of all the participants 83.4% judged the ‘haptic sensations’ and 88.9% the ‘resistance and movements of the instruments’ in the ProMIS AR translocations task as good to excellent (4 resp. 5 on the Likert scale). These features from the LapSim VR scored badly to very badly in 62.2% and 67.8% of the respondents respectively (1 and 2 on the Likert scale, respectively) (Table 4).

On the suturing features the ProMIS AR was rated 2,0 points higher on average than the LapSim VR. The suturing task of the ProMIS AR is considered very realistic by 53.3% of the experts in contrast to 0% for the LapSim VR. The ‘haptic sensation’ and ‘resistance of

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needle and thread' of this task were rated 4 or 5 in 70% and 83.3% of the respondents, respectively, on the ProMIS AR and only 4.4% and 6.6% of the respondents, respectively, gave a good rating for the LapSim VR simulator (Table 4).

On the ProMIS AR, 'haptic sensations of the tissue' was regarded by all participants as less than the other features questioned, but it was still regarded as quite good (mean 3.92). The mean rating remained 2.0 point higher than the rating on the LapSim VR (mean 1.92).

Table 4: Difference in opinion on ProMIS and LapSim	ProMIS	LapSim	p-value ^a
	Mean (standard deviation)		
Translocation			
- Haptics	4.10 (0.94)	2.26 (1.07)	<0.001
- Instrument movement	4.22 (0.70)	2.18 (1.02)	<0.001
Suturing			
- Realism	4.43 (0.66)	2.49 (1.07)	<0.001
- Haptics tissue	3.92 (0.80)	1.92 (0.92)	<0.001
- Resistance needle & thread	4.15 (0.71)	1.84 (0.93)	<0.001

^a Statistical significant differences are calculated with the paired t-test, a $p < 0.05$ was considered a significant difference.

Training properties

The training properties of both simulators were also part of this study. On the didactic value the ProMIS AR scored higher than the LapSim VR by all participants (Table 5). The 'ProMIS AR simulator as a training tool for surgical residents' scored 4.67 in the expert group and 4.30 in the novice group. The LapSim VR simulator was scored 2.67 and 3.03, respectively, by the same groups for this feature. Of the experts, 66.7% considered the ProMIS AR a very good 'tool for training laparoscopic skills to surgical residents', contrary to 3.3% for the LapSim VR. On the learning properties of the simulators, 83.3% of the experts indicated that the 'ProMIS AR can teach trainees the proper skills', whereas 13.3% stated that the LapSim VR could serve this purpose.

The opinion on the LapSim VR was divided amongst all participants, which is demonstrated by the wide standard deviations in Table 5. In general, the rating of LapSim VR by the novice group was higher compared with the ratings by the intermediate and expert groups. This can be explained because the novice group consisted mainly of interns, who have not seen, assisted with, or handled a laparoscopic camera before.

Table 5: Difference in Training properties of the ProMIS and LapSim	ProMIS	LapSim	p-value ^a
	Mean (standard deviation)		
Training surgical residents	4.51 (0.71)	2.94 (1.11)	<0.001
Training surgeons	4.38 (0.70)	2.52 (1.09)	<0.001
Learning proper skills	4.08 (0.65)	2.86 (1.01)	<0.001
Simulator appeals to me	4.17 (0.71)	2.59 (1.18)	<0.001

^a Statistical significant differences are calculated with the paired t-test, a $p < 0.05$ was considered a significant difference.

Therefore they had no reference point from which to compare the laparoscopic simulators nor to judge on realism. Especially in this group, one may observe a difference between the part of the group that started the study on the LapSim VR first and the other part that started first on the ProMIS AR. But the general opinion on the open-ended question after completion of the training session was that the ProMIS AR simulator was much more realistic and a better training system than the LapSim VR simulator

Differences in construct validity

The current study enabled collection of the parameters recorded by both simulators, which are presented in Tables 6 and 7. To assess the significance of the parameters and determine the skills level, the Kruskal-Wallis test was used. In all tasks, investigated in this study a time limit of 300 seconds on each task of the ProMIS AR ('translocation', 'needle handling' and 'knot-tying') was used. On the LapSim VR, a limit was set at 180 seconds (30 second for each handling) for the 'translocation' task and 300 seconds for the 'suturing and knot-tying' task. On the ProMIS AR simulator, time has shown to be a significant parameter to determine the level of skills for both 'translocation' and 'suturing' skills ($p < 0.001$), on the LapSim VR, there were no significant differences found in this parameter.

'Smoothness' was calculated on the ProMIS AR by the directions and accelerations in the instruments movement. From the results depicted in Table 6, one can conclude that all measured parameters on the ProMIS AR are significant to determine the level of skills ($p < 0.01$), except for the 'left path length' of the 'suturing' task. On the other hand, all parameters measured on the LapSim VR were not significant for establishing construct validity, except for the 'tissue damage' on the 'suturing' task ($p = 0.009$).

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Table 6: Construct validity of the ProMIS.		Expert (N=30)	Novice (N=30)	p-value ^a
Translocation	Time (sec)	122.13	195.98	<0.001
	Path length (mm)			
	- Left	248.57	309.62	0.010
	- Right	243.28	373.99	<0.001
	Smoothness (mm)			
	- Left	411.50	717.73	<0.001
Suturing	- Right	409.63	695.40	0.001
	Time (sec)	357.30	562.17	<0.001
	Path length (mm)			
	- Left	1112.72	1220.98	0.104
	- Right	1068.44	1624.92	<0.001
	Smoothness (mm)			
	- Left	1135.13	1911.70	<0.001
	- Right	1247.07	1998.47	<0.001

The data in this table represent the mean value.

^a Statistical significant differences are calculated with the Kruskal Wallis test, a $p < 0.05$ was considered a significant difference. There was a time limit used of 300 sec on the translocation task and 600 sec on the suturing task.

Discussion

Implementation of simulators into training curricula of surgeons is of paramount importance, and it progressively gains acceptance [5,6]. The impact of the use of simulators is strongly dependent on the correct choice of the system to be used and should be based upon the outcome of validation studies.⁷ Validation should provide information indicating the usefulness of the chosen system in general and should in particular indicate which system should be used in which training and/or curriculum. Data on (face) validation of the LapSim Virtual Reality laparoscopic simulator (VR) and the ProMIS Augmented Reality (AR) laparoscopic simulator are relatively scarce [2,5,7-10].

Table 7: Construct validity of the LapSim		Expert (N=30)	Novice (N=30)	p-value ^a
Translocation	Time (sec)	119.03	128.31	0.209
	Score (%)	60.13	52.97	0.164
	Path length (mm)			
	- Left	225.21	220.27	0.525
	- Right	193.57	200.17	0.416
	Tissue damage (mm)	3717.25	4501.65	0.086
Suturing	Time (sec)	281.15	300.04	0.128
	Score (%)	90.17	89.50	0.507
	Path length (mm)			
	- Left	319.46	283.98	0.243
	- Right	509.22	470.51	0.264
	Tissue damage (mm)	5707.62	10178.00	0.009

The data in this table represent the mean value.

^a Statistical significant differences are calculated with the Kruskal Wallis test, a $p < 0.05$ was considered a significant difference. There was a time limit used of 180 sec on the translocation task and 300 sec on the suturing task

Various devices are used to aid training in laparoscopic skills. These devices range from simple box trainers to sophisticated VR trainers. Whereas VR trainers may have some advantages, most participants of such studies feel that inanimate box trainers help more, are more interesting, and are preferred over VR trainers if only one trainer is allowed [11]. This opinion is supported by the outcome of the current study, as all the participants favour a non-VR environment, with the real instruments used on physical objects, like in traditional box trainers. In the tasks investigated in this study the VR features of the ProMIS AR simulator were not used, which are present for some modules (e.g. orientation and diathermia), so the video images are similar to those of box trainers.

Various studies have indicated that haptic (force) feedback is very important in laparoscopic simulation and increases the effectiveness of VR training systems [12-14]. But this is also one of the most controversial issues in VR laparoscopic simulators design, because it is very difficult and complicated to incorporate realistic haptic feedback into these systems [12]. For AR haptics, this is not an issue because of the nature of the system. The outcome of the

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current study allows the conclusion that ProMIS AR has far better feedback during performance of the tasks compared to LapSim VR.

Apparently ProMIS AR offers a good alternative to VR laparoscopic simulation, as it retains the benefits of VR and additionally offers more realistic haptic feedback. As shown in Tables 4 and 5, the ProMIS AR simulator was rated higher than the LapSim VR simulator on realism, haptic features, and didactic value.

In this study, the subject-expectancy effect was encountered, which is the influence of the individual performance on the opinion on the simulators. For example, on the LapSim VR simulator, when the participants had to perform the 'suturing and knot-tying' task, the majority of the participants (in all groups) were not able to pass the needle through the tissue and therefore could not tie any knots. This annoyed most of them and was noticeable when they had to fill out the questionnaire. On the ProMIS AR, these suturing skills were tested separately, which caused less frustrations.

The outcome of the current study indicates that the construct validity on the translocation and suturing tasks of the ProMIS AR laparoscopic simulator adequately distinguishes between the experts and the novices. Other studies have shown equal results on the construct validity of this simulator [2,15]. This cannot be stated for the LapSim VR laparoscopic simulator, which only shows construct validity on the 'tissue damage' of the 'suturing task' (Table 6). Previous studies [8,10,16-18] on the construct validity of the LapSim show conflicting results: only a few parameters were to show construct [16,17], or only when the most (attending surgeons) and least experienced (interns) are compared [8]. One study [10] even concluded that novices tended to have a better performance compared with the experienced laparoscopists during their first exposure to the LapSim.

To be an effective training tool, the simulator must provide metrics that are meaningful and informative to the trainee. 'Time of performance' as a sole parameter might not be the best criterion on which to grade the trainee. The primary issue is that the correct technique is used and that a tight knot is made, whereas 'time of performance' is a secondary issue. Therefore, it is important to evaluate other metrics recorded by the simulator. In the ProMIS AR simulator the other parameters, such as 'path length' and 'smoothness', give a better impression of the performance and are shown to have a construct validity.

The only measured parameter from the LapSim VR, with construct validity, is 'tissue damage', but this is not sufficient as a sole metric upon which to base the assessment of the level of skills of the trainee.

This study specifically shows that the ProMIS Augmented Reality laparoscopic simulator has a better construct validity and is therefore better as a training tool concerning feedback recordings than the LapSim Virtual Reality laparoscopic simulator.

Conclusion

The outcome of this study allows us to conclude that the ProMIS Augmented Reality laparoscopic simulator is regarded as a better tool for training of surgical residents than the LapSim Virtual Reality laparoscopic simulator on the limited number of tasks tested. The reason for this outcome is, in our opinion, that Augmented Reality offers better realism, haptic feedback, didactic value, and construct validity than does Virtual Reality, and it also gives useful feedback to determine the skills level of the trainee. It is recommendable to implement the ProMIS Augmented Reality laparoscopic simulator in the training curricula in laparoscopic skills for surgical residents. The place of this simulator in the curricula is in the beginning of the surgical residency, at the cholecystectomy level. It is of importance that the surgical residents not only learn basic laparoscopic skills at this level, but also suturing skills for when they, for example, need to tie the cystic duct when perforations occur in the clinical setting.

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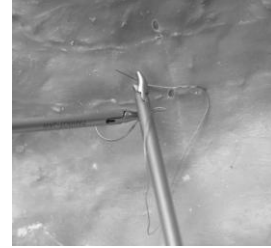
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Chapter 5

Chapter 6



The importance of haptic feedback in laparoscopic suturing training and the additive value of Virtual Reality simulation

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Abstract

Introduction

Previous studies on difference between physical, Augmented and Virtual Reality simulation state that haptic feedback is an important feature in laparoscopic suturing simulation. Objective assessment is important to improve skills during training. This study focuses on the additive value of VR simulation for laparoscopic suturing training.

Methods

All participants of several European Association for Endoscopic Surgery (EAES) approved laparoscopic skills courses (N=45) filled out a questionnaire on their opinion on laparoscopic suturing training. Additionally, participants with little or no laparoscopic suturing experience were allotted to two groups: A (N=10), who started training on the box trainer and subsequently the VR simulator (SimSurgery), and B (N=10), who began on the VR simulator followed by the box. Finally, suturing and knot-tying skills were assessed by an expert observer, using a standard evaluation form (eight items on a five-point-Likert scale). The same was done after the initial training on the box in group A, as a control.

Statistically significant differences were calculated with the independent-sample t-test and the paired t-test.

Results

The total score of group A was higher than both group B and control (means 30.80, 27.60, and 28.20 respectively), but not significantly. The only tendency to a significant difference between groups A and B was found in 'taking proper bites' (means 4.10 versus 3.60, $p=0.054$). All the participants scored the features of the box trainer significantly higher than those of the VR simulator ($p<0.001$), and 46.7% was of opinion that the box alone would be sufficient for laparoscopic suturing training.

Conclusion

From this study we can conclude that VR simulation does not have a significant additional value in laparoscopic suturing training, over traditional box trainers. One should consider that the future development in VR simulation should focus on basic skills and component tasks of procedural training in laparoscopic surgery, rather than laparoscopic suturing.

Background

Extensive practice is of major importance to becoming a skilled laparoscopic surgeon. Traditionally, surgeons have gained their skills hands-on in the operating room under supervision of expert surgeons. The skills needed for laparoscopic surgery are unique and differ from those used during open surgery and therefore necessitate a different training approach. Preclinical practice using inanimate models such as box trainers or Virtual Reality (VR) simulators increases psychomotor skills and translates into improved performance in the operating room [1]. For this reason, the use of simulation in surgical training curricula is becoming more widely accepted. Objective assessment of performance is fundamental to provide formative feedback during training, allowing for continuous skill refinement. Traditional box trainers have been criticized for being unrealistic in presented exercises and for the lack of any form of objective assessment [2]. However, most VR simulators do provide objective assessment and feedback, but lack haptic feedback.

A number of studies [3-5] have shown that haptic feedback is of importance for adequate laparoscopic training, in particular for laparoscopic suturing. The term ‘haptic feedback’ refers to the combination of tactile feedback through sensory skin receptors, and kinesthetic feedback through muscle, tendons and joint sensory receptors. Especially for laparoscopic suturing skills it is important that the participants experience haptic feedback when performing the task. Several key aspects of learning these skills involve refined interaction with tissue and suturing materials, which most likely demands a more sophisticated level of feedback than can be obtained by visual feedback alone. Haptic feedback results in significantly improved skills transfer to the trainee, compared with training without haptic feedback [2]. In general, it is assumed that high fidelity simulations with haptic feedback imply better training effects and a better transfer of skills to the clinical setting [6]. However, realistic haptic feedback during laparoscopic training is currently lacking in VR simulators.

The degree of actual realism of a simulation varies depending on the hardware and software capabilities of a simulator [7]. Because of limited computing power, most VR simulator systems generally only represent a part of the physical environment. This means that certain limitations have to be accepted for any simulation (e.g. suturing and knot tying). If accepted, this results in simplified representations of organs, which do not behave like they do in the clinical setting (e.g. inadequate haptic feedback, limited visual details, etcetera) [7].

Various studies [1,7-11] have been performed comparing traditional box trainers with VR simulators for laparoscopic training, most of which focussed on basic laparoscopic skills. Only the study by Avgerinos et al concluded that for the intracorporeal knot-tying task there was no statistically significant difference in the score measures between the two simulator

systems [8]. They all additionally conclude that further studies are needed to establish which simulation technique is more effective for training [1,7,9-11].

At this point, the available studies do not provide similar results, and also have not shown significant differences between the two laparoscopic training approaches [7,10,11]. This study therefore focuses on the importance of haptic feedback and the additive value of Virtual Reality simulation in laparoscopic suturing training versus traditional box trainers.

Methods & Materials

This study took place during several laparoscopic skills courses in the Catharina Hospital Eindhoven, the Netherlands, and the Academic Hospital of Al Ain, United Arab Emirates, from November 2006 till January 2007. The study has two arms: one investigating the opinions of 45 persons attending five laparoscopic skills courses, and another testing the performance of trainees (N=20) on laparoscopic suturing after different types of training. For the study we used traditional box trainers, VR simulators and questionnaires.

Equipment

Two types of laparoscopic simulators were used in this study: VR simulators and traditional box trainers.

Traditional box trainer

The traditional box trainers we used (Figure 1) were composed of a box inside which the laparoscopic suturing task were performed on a foam suturing pad (Limbs & Things Limited, Bristol, United Kingdom), a Telepac system (Karl-Storz Endoscope, Tuttlingen, Germany) and an additional video monitor (Neovo X17a). The Endoscope, camera and laparoscopic needle holders that were used are from Karl Storz.

VR simulators

Two SimSurgery VR simulator systems were used in this study. Both VR simulator systems ran the SimPort software (SEP 1.04.3 SimSurgery, Oslo, Norway). However, their hardware platform differed: one VR simulator system incorporated the SimPack platform (SimSurgery, Oslo, Norway) (Figure 2), while the other system made use of two Xitact HTP Instrument Ports (Xitact/Mentice SA, Morges, Switzerland) (Figure 3).

The SimPort software package used in this study contained various training modules, including exercises related to specific laparoscopic skills, techniques, or procedures. Current

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training modules included camera navigation, instrument manipulation, dissection, suturing, and haemostasis. For this study only a selection of tasks from the suturing module was used: ‘Two handed stitch with traction’, ‘Realistic surgeons knot’, ‘Realistic interrupted suture’ and ‘Realistic free knot’ (Figure 4). Even though the Xitact HTP Instrument Ports in one of the simulator systems was capable to provide haptic feedback, the SimSurgery software did not support these haptic features. The settings of the force sensors were adjusted to compensate the forces of inserting the instruments. The tasks performed on both VR simulator systems selected for this study were therefore all without haptics.



Figure 1: Traditional box trainer, containing a foam suturing pad (Limbs & Things Limited, Bristol, United Kingdom), a Telepac system with endoscope (Karl-Storz Endoscope, Tuttlingen, Germany), video monitor (Neovo X17a) and needle holders (Karl-Storz Tuttlingen, Germany).



Figure 2: SimSurgery (SEP 1.04.3 SimSurgery, Oslo, Norway) Virtual Reality laparoscopic simulator with the SurgicalSim Education Platform (SEP) (SimSurgery, Oslo, Norway).



Figure 3: Xitact HTP Instrument Ports

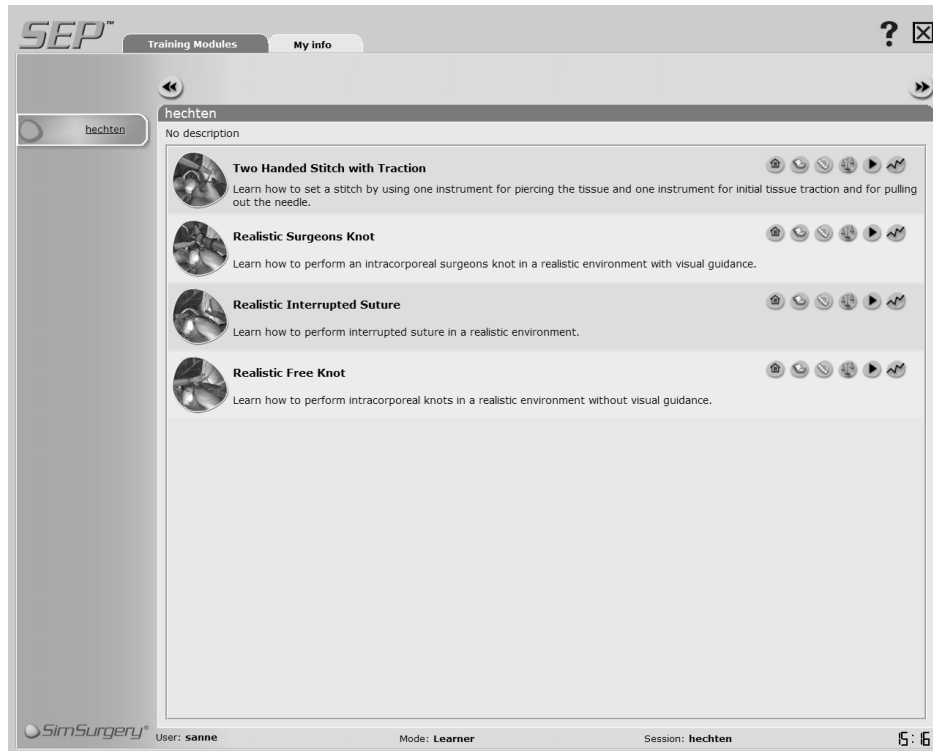


Figure 4: These modules are used for the suturing (Xitact/Mentice SA, Morges, Switzerland). training during the session on the SimSurgery VR simulator in this study.

Subjects

In total 45 participants were involved in the study regarding the opinion on both simulator systems, of which 20 people participated in the Netherlands and 25 in the United Arab Emirates. Some laparoscopic experience was mandatory prior to participation to ensure a reference point to the clinical setting. Laparoscopic suturing experience was an exclusion criterion for the participation in the arm involving the assessment of the suturing and knot tying skills. The participants in the Netherlands were surgical and gynaecology residents, who participated in laparoscopic skills courses as part of their residency. The participants from the United Arab Emirates also participated in a course for laparoscopic skills.

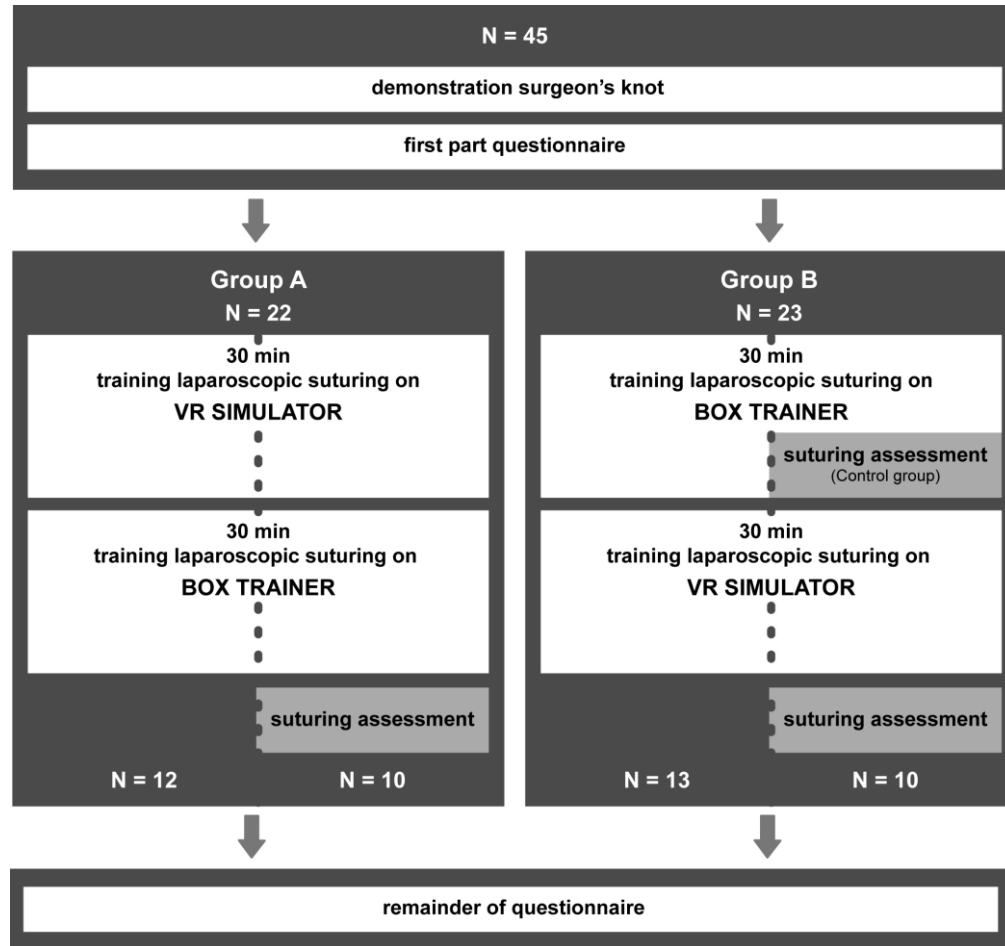


Figure 5: This is the overview of the protocol of the study of all participants (N=45)

Protocol

Before starting the training sessions on either of the simulators, all participants (N=45) filled out the first part of the questionnaire containing questions on demographics and laparoscopic experience. A general introduction of the simulators was given, followed by a demonstration and explanation of the laparoscopic ‘surgeon’s knot’ by an expert. Next, all participants were randomly and blinded divided into two equal sized groups: Group A started with a training session on the traditional box trainer for half an hour followed by a session on the SimSurgery VR simulator for half an hour; Group B started with the same session on the SimSurgery VR simulator, followed by the session on the traditional box trainer (Figure 5)

Performance of suturing skills

The assessment of the performance was only tested in the Netherlands (Figure 5); this subgroup is represented in the Figure and Table as Group Anl (N=10) and Bnl (N=10). These participants (N=20) accomplished the full training course, after which one 'suturing and knot tying task' was assessed by an expert laparoscopist, on the traditional box trainer. The assessment of the skills was done using a standard evaluation form, which consisted of eight items scored on five-point-Likert scale. Table 1 presents a summary of the scoring of the assessment criteria examined by the expert observer. The criteria 'Quality (strength) of knot' was tested by the objective observer by taking out the suturing pad with the tied knot and pulling the thread, to observe if the knot was tight and secured. The expert observers had done more than 100 clinical laparoscopic procedures and had extensive laparoscopic suturing experience. The participants of both group Anl (N=10) and Bnl (N=10) were equally divided between two objective expert observers, to avoid inter-examiner differences.

The control group was gathered from the data of the assessment of group Anl (N=10), after the initial half hour training session on the box trainer (Figure 5).

Opinion of the participants

After finishing the training sessions, all participants (N=45) were asked to fill out the questionnaire regarding their opinion on the simulators used in the study and their role in laparoscopic suturing training.

Questionnaire

The questionnaire used in this study consisted of three parts. The first part was about the demographics and prior laparoscopic and simulator experience of the trainees. In the second part, questions were asked regarding the realism and haptic feedback of both simulators. These questions were answered on a five-point Likert scale. The last part consisted of questions concerning the preferences of the trainees regarding laparoscopic suturing training.

Statistics

All data were processed and analyzed using Statistical Package for the Social Sciences (SPSS) 13.0. Statistically significant differences in opinion regarding the two simulators were calculated with the paired *t*-test. The significant differences between the examined final knots were calculated with the Independent-Sample *t*-test.

Results

Demographics

All 45 participants who attended the laparoscopic skills courses completed the training sessions on both simulators and filled out the questionnaire. This overall group (N=45) consisted of 48.9% residents of surgical specialties, 46.7% surgical specialists, and 4.4% surgical interns (in their last year of training). The participants from the Netherlands (N=20) were surgical residents and gynaecology residents. The male:female ratio was equally divided in both groups (2:1). None of these 20 participants had any clinical laparoscopic suturing experience. Of the 25 participants from the United Arab Emirates, 23.3% had limited clinical experience with laparoscopic suturing, and 13.9% had more experience. All participants (N=45) had some experience with laparoscopic procedures (32.6% had done more than 50 clinical laparoscopic procedures). Only 11.6% had prior experience (more than twice) on laparoscopic simulators such as VR systems and box trainers.

Performance of the suturing skills

Table 1 presents the scoring on the assessment criteria examined by the expert observer of the participants of the Netherlands (Groups Anl, N=10 and Bnl, N=10). The criterion 'Quality (strength) of knot' both group Anl (mean 3.90) and Bnl (mean 3.80) was scored slightly better than the control (mean 3.60), but these differences were not significant ($p=0.563$ and $p=0.641$, respectively). When the scores of the eight criteria were summed, group Anl (which started on the traditional box trainer) had a mean of 30.80, group Bnl (which started on the VR simulator) of 27.60 and the control group of 28.20. Group Anl did score higher on the summed value and on most other criteria, but these differences were not significant. As shown in table 1, only the scores on 'Taking proper bites of the suturing pad, during suturing', had a tendency towards a significant difference between group Anl and Bnl (means: group Anl=4.10, group Bnl=3.60, $p=0.054$).

Opinion of the participants

As presented in Table 2, there was a significant difference in opinion of the participants with regard to realism and haptic feedback between the two simulator systems used for this study. Overall, the traditional box trainer scored higher on all aspects than the SimSurgery VR laparoscopic simulator ($p < 0.001$).

The highest mean score for the VR simulator was given for 'global impression' (3.00), but this is a neutral opinion on the five-point Likert scale. This feature scored a mean 3.95 for the box trainer, which is low compared to the other ratings for this simulator (Table 2). For

Table 1: Scoring of the final laparoscopic knot	Group Anl (N=10)	Group Bnl (N=10)	Control (N=10)	p-value Anl vs control	p-value Bnl vs control	p-value Anl vs Bnl
	Mean (Standard deviation)					
Positioning of needle in needle holder	3.80 (0.63)	3.30 (0.68)	3.30 (0.82)	0.145	1.000	0.105
Running needle through suturing pad	3.90 (0.57)	3.60 (0.52)	3.60 (0.52)	0.232	1.000	0.232
Taking proper bites of the suturing pad, during suturing	4.10 (0.57)	3.60 (0.52)	3.90 (0.57)	0.441	0.232	0.054
Throwing thread around needle holder	3.50 (1.08)	3.10 (0.99)	3.20 (1.14)	0.552	0.836	0.400
Pulling tight of the thread	3.70 (0.95)	3.20 (0.79)	3.70 (0.95)	1.000	0.216	0.216
Tying a correct 'surgical knot'	3.50 (1.08)	3.50 (0.85)	3.20 (0.92)	0.512	0.458	1.000
Quality (strength) of knot (test by pulling on knot)	3.90 (0.99)	3.80 (0.44)	3.60 (1.27)	0.563	0.641	0.773
Global evaluation of Performance	3.90 (0.88)	3.50 (0.71)	3.70 (0.68)	0.574	0.526	0.276
Summation of scores	30.80 (5.69)	27.60 (3.89)	28.20 (5.14)	0.298	0.772	0.160

This is the scoring table of the assessment of the performance of the participants in The Netherlands (N=20).

These training properties are rated on a five-point Likert scale in which: 1: 'Poorly', 2: 'Needs more training', 3: 'Acceptable', 4: 'good' and 5: 'Excellent'. Significant differences are calculated with the Independent-Samples t-test.

Table 2: Opinion on laparoscopic suturing simulators	VR simulator	Traditional box	p-value
	SimSurgery	trainer	
	Mean (Standard deviation)		
Global impression	3.00 (0.89)	3.95 (0.89)	<0.001
Movement of the instruments	2.83 (1.09)	4.37 (0.66)	<0.001
Realism of needle and thread	2.75 (1.06)	4.53 (0.75)	<0.001
Tying of the knots	2.75 (1.03)	4.53 (0.64)	<0.001
Pulling tight of the suturing thread	2.68 (1.08)	4.34 (0.79)	<0.001
Movement of the suturing thread	2.71 (0.93)	4.34 (0.91)	<0.001
Haptic sensations of the tissue	1.98 (1.11)	3.83 (1.16)	<0.001
Resistance of needle and thread	1.93 (1.08)	4.17 (0.80)	<0.001

These are the opinions of all participants (N=45) on the stated features and are rated on a five-point Likert scale. Significant differences are calculated with the paired t-test.

‘realism of needle and thread’, more than 64% of the participants rated this feature as ‘excellent’ on the traditional box trainer. However, the VR simulator has a mean of 2.75 on this feature, with a standard deviation of 1.06. For the VR simulator all standard deviations are between 0.89 and 1.11, which implies that the opinion on the features of this simulator is divided amongst the participants. The standard deviation of the opinion of the box trainer is lower, except for ‘haptic sensation of the tissue’, for which the opinion is also more controversial. For the VR simulator, the features ‘haptic sensations of the tissue’ and ‘resistance of needle and thread’ are regarded as ‘absolutely unrealistic’ by 41.5% and 48.8% of the participants, respectively. On these same features the traditional box trainer was rated as ‘good’ by 29.8% and 42.2% respectively and ‘excellent’ by 33.3% and 35.6% respectively. There were no significant differences in the opinions between the participants of the Netherlands and the participants of the United Arab Emirates.

Of all participants, 53.3% preferred to practice on the VR simulator first, followed by the traditional box trainer, while 37.8% preferred to start on the box trainer (Figure 6). On the question of whether it is necessary to use both simulator systems for laparoscopic suturing training (Figure 7) 53.3% of the participants believed that they are both necessary for a proper training whereas 46.7% believed that the traditional box trainer alone would suffice for the training. The answers on these questions were equally divided between groups A and B. The opinion regarding these questions was not influenced by the order in which the participants followed the suturing training.

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Preference of order to practice laparoscopic suturing skills

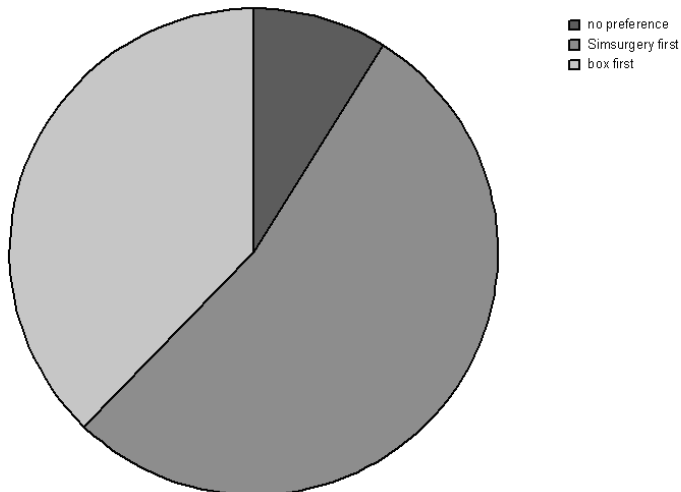


Figure 6: 53.3% of the participants preferred to practice on the VR (SimSurgery) simulator first and then on the traditional box trainer, whereas 37.8% preferred to start their training on the traditional box trainer. However, 8.9% of the participants did not have a preference for either order.

Is it necessary to use both VR and box trainers during a laparoscopic suturing training program?

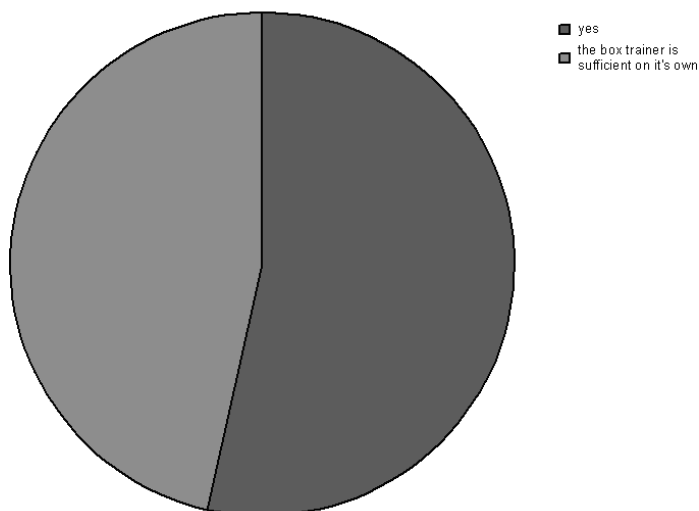


Figure 7: The possible answers on this question were: 'yes', 'only box trainer', 'only VR suturing module (no preference)' or 'only SimSurgery simulator'. 53.3% were of the opinion that both simulator systems were necessary, while 46.7% thought the box trainer would be sufficient on its own.

Discussion

Importance of objective assessment

To be an effective educational tool, the metrics provided by a VR simulator must provide meaningful information to the trainee [12]. ‘Time’, ‘tip trajectory’, and ‘smoothness’ are often used in VR simulation and can provide a much more precise and comprehensive evaluation of basic laparoscopic skills than can be measured by timing drills in box trainers. The benefits include an objective analysis of errors and economy of motion; two parameters that can not be assessed accurately by an observer [13]. However these metrics are not necessarily the most valuable proxies to assess the performance of the trainee. The SimSurgery VR simulator uses various measurements to assess each performance, such as ‘time’ and ‘tip trajectory’ (motion analysis); it additionally records various types of errors made during the performance. When the same task is performed more than once, a performance curve will be visualized for each task repetition. This can be used by the trainees and faculty to monitor their performance and progression and aim remedial training to correct specific deficiencies [13]. An essential tenet of educational theory is that learning should be accompanied by evaluation for both formative (feedback) and summative (final assessment) purposes. This feedback can be used to create dedicated learning programs to enhance skills specifically in the areas that are deficient, and to verify that a required skill level has been attained [12].

The feedback after each performance provided by most VR simulators could motivate the trainees to practise their skills more extensively, until they have reached their goal. Providing feedback and setting goals tends to motivate trainees more, compared with a self-directed group [14]. With a traditional box trainer, the feedback is subjective and an expert needs to be on hand to assess the performance, making it more difficult to set specific goals [15].

One downfall of the assessment method used by VR simulators is that they often oversimplify and only provide a feedback on the performance of the whole task. For example, when the repetitions within a repetitive task are in a random order, it is possible that there is a slight difference in difficulty within the task. The variation in difficulty can make the performance scores appear lower (or higher) than the previous, because this difference in complexity is not compensated in the presented feedback. In our study for example, we found that when a participant did not immediately grab the needle properly at the start of the procedure, it became almost impossible to complete the task. The overall performance turned out much lower, while performing in their normal performance curve, during subsequent sub-tasks within the exercise. A general remark of the participants was

that the feedback given by the VR simulator was not representative for their skills; the participants felt that they were better evaluated by an expert observer.

The participants of this study did not appreciate the benefit of the objective feedback of the VR simulator over the benefits of the traditional box trainer. They preferred the box trainer for laparoscopic suturing training. Similar results were also found in the study of Stefanidis et al [9], who compared a VR simulator with a box trainer. They did not find significant differences in the ratings regarding the ability to provide performance feedback to the trainee, despite the ability of VR simulator to provide additional performance metrics and 'red outs'.

Importance of haptic feedback

A surgeon must be able to identify tissue properties and handle tissue in a safe manner [6]. Challenges facing the laparoscopic surgeon include the loss of haptic (tactile) feedback due to the interposition of long instruments between the surgeon's hand and the tissue. To compensate for the compromised haptics, the surgeon has to relay on visual input from the operating field [9]. However with laparoscopic surgery, there is a loss of important depth cues due to the use of a two-dimensional display monitor. Another disadvantage of laparoscopic surgery is the 'fulcrum-effect' created by the insertion of the instruments through the abdominal wall, which causes the instrument tips to move in the opposite direction as the surgeon's hand [13]. Because of these additional mental translations and counter intuitive interactions, it is important that laparoscopic skills are practiced extensively before application in the clinical setting. During laparoscopic procedures the major part of the haptic feedback is lost. However, the little haptic feedback that remains is valuable and it is, therefore, important that the simulator system provides haptic feedback, preferably as optimal as possible. A disadvantage of the majority of VR simulators is the absence of haptic feedback to the surgeon [13].

Shortly after its introduction, laparoscopic surgery was associated with a high complication rate. The term 'performance curve' was introduced to refer to the number of operations a surgeon has to perform to reach an expertise level with an acceptable complication rate [7]. Further studies showed that even experienced laparoscopic surgeons had to go through a performance curve again when they had to learn a new laparoscopic procedure or technique [7], such as laparoscopic suturing. Data from previous studies suggests that training up to a predetermined level on a box trainer suture model provides trainees with skills that translate into improved clinical performance [13,16]. It has been reported that haptic feedback is very important in laparoscopic simulation and that it can shorten the first part of the performance

curve [6], increasing the effectiveness of laparoscopic training [17-19]. Currently though, this is also one of the most controversial issues in VR laparoscopic simulator design, as it is very complicated to incorporate realistic haptic feedback into VR systems [17]. In particular for laparoscopic suturing training, because of the interactions between instruments, needle, thread, and tissue, it is important that haptic sensations during the simulation is as optimal as possible, but this has not yet been achieved in VR simulation.

One advantage of the traditional box trainers over most VR simulators is that it provides the haptic feedback that is absent in most VR systems. Additionally, it allows the trainee to use whatever instruments he or she prefers to use in the operating room, and they are less expensive [12]. While VR trainers may have some advantages, most participants of studies on this topic feel that traditional box trainers help them more, are more interesting, and are preferred over VR trainers if only one trainer is allowed [20]. This opinion is supported by the outcome of our study, as is shown in Figure 7. The participants favoured the box trainers, which involved the use of real needle-holders and interaction with real needle, thread, and suturing pad, over the suturing module of the VR simulator. As shown in Table 2, the traditional box trainer is rated higher than the SimSurgery VR simulator on both realism and haptic features.

It is important to note that our results do not imply that VR simulator systems are not suitable for training in laparoscopy in general, or for basic skills or component tasks of procedural training in laparoscopy. Previous studies have proven the value of VR simulation without haptics for several types of laparoscopic training [2,4,21,22]. This study does show, however, that for laparoscopic suturing, haptic feedback is considered a necessity, and that training on box trainers is preferable over VR simulator systems, until these are also capable to provide sufficient haptic feedback.

There were no significant differences between the ratings of the assessment after laparoscopic suturing training on only a traditional box trainer (control) or the combination with a VR simulator (Groups Anl and Bnl); neither could we find an optimal order in which the training should be followed to master the laparoscopic suturing skills. Group Anl, which started on the box trainer followed by the VR simulator, had the highest summative score, but was still not significantly higher than either Group Bnl and the control group. From these results we can state that VR simulation in the current form does not have an additional value to traditional box trainers in laparoscopic suturing training.

Conclusions

The outcome of this study allows us to conclude that there was no significant difference in outcome between laparoscopic suturing training on a traditional box trainer alone or in combination with a Virtual Reality laparoscopic simulator. While an important advantage of VR is objective assessment of the performance, the participants of the current study preferred the traditional box trainer over the VR simulator. Therefore we can state that we did not find an additional value of Virtual Reality simulation to traditional box trainers in laparoscopic suturing training. One should consider that the future development in VR simulation should focus on basic skills and component tasks of procedural training in laparoscopic surgery, rather than on laparoscopic suturing.

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Chapter 7



Meaningful Assessment method of laparoscopic suturing training in Augmented Reality

Sanne M.B.I. Botden, Ignace H.J.T. de Hingh, Jack J. Jakimowicz

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Abstract

Background

To be an effective training tool, a laparoscopic simulator has to provide metrics that are meaningful and informative to the trainee. Time, path length and smoothness are often used parameters, but are not very informative on the quality of the performance. This study aims to validate a newly developed assessment method for laparoscopic suturing on the ProMIS Augmented Reality simulator, and compares it with scores of objective observers.

Methods

Twenty-four participants practised their suturing skills on the Augmented Reality suturing module: experienced participants (n=10), >50 clinical laparoscopic suturing experience; and novice participants (n=14), without laparoscopic experience. The performances were recorded and assessed by two unrelated observers and compared with the assessment scores. The assessment score was a calculation of 'time spent in the correct area' and 'quality (strength) of the knot'. To test the accuracy of the individual assessment parameters, we compared these with each other.

Results

The experienced participants had significantly higher performance scores than the novice participants in the 'beginner level' mode (mean 95.73 versus 60.89, standard deviation 2.63 versus 17.09, $p < 0.001$, independent t-test). The performance scores of the assessment method (n=43) correlated significantly with the scorings of the objective observers (Spearman's rho 0.672 $p < 0.001$).

The parameter 'time spent in correct area' had a calculated significant correlation with the strength of the knot (n=229, Spearman's rho 0.257, $p < 0.001$), but this was clinically irrelevant.

Conclusion

This assessment method is a valid tool for objectively assessing laparoscopic suturing skills. Although assessment parameters can correlate, to provide informative feedback it is important to combine meaningful measurements in the assessment of suturing skills.

Background

Nowadays, simulation is used in a more structured way during surgical training. Objective assessment of the performance, provided by Virtual and Augmented Reality simulators, is fundamental for continuous skill refinement [1,2]. Additionally haptic feedback is important for adequate skills training in minimally invasive surgery and in particular for laparoscopic suturing [3-6]. In general, it is assumed that realistic simulations with haptic feedback provide better training outcomes and better transfer of skills to the clinical setting [7]. A study by Aggarwal et al showed that training with haptic feedback results in significantly improved skills transfer to the trainee, compared to training without haptic feedback [8]. However, realistic haptic feedback during laparoscopic training is lacking in most of the Virtual Reality simulators.

Professional organizations have recently recognized the need to assess surgical performance objectively. To be an effective tool, the simulator has to provide metrics that are meaningful and informative to the trainee. Time is a frequently used parameter, but appears not be the best solution as a sole measurement [8]. For example in laparoscopic suturing, a surgeon can be really fast, but ties the worst knots imaginable, while a surgical resident takes three times as long, but achieves qualitatively optimal knots. This is also observed in clinical laparoscopic procedures, where time as a surrogate parameter for proficiency is not sufficient [9]. There are other parameters, such as path length and smoothness, recorded by most simulators, but these are not informative either. Smoothness is defined as the recorded path length compared with a calculated optimal path length. This will give an indication of the global performance of the trainee, but does not provide any information of the performed procedure or sutures. Therefore it is important that an assessment module is developed for specific skills, such as suturing.

Surgical skills training models should be reliable and valid to become incorporated into an objective structured clinical assessment, which could be used to assess individual development and allow progression through a training programme [10]. Currently, no such laparoscopic suturing and knot tying modules with realistic haptic feedback exist. In this study we have validated a new suturing module for the ProMIS v2.0 Augmented Reality simulator (Haptica, Dublin), using an assessment with meaningful measurements.

Methods & Materials

Subjects

Twenty-four participants were allotted to two groups based on their clinical laparoscopic suturing experience: Experienced (N=10), >50 laparoscopic procedures and clinical laparoscopic suturing experience; Novices (N=14), no previous laparoscopic experience, pretrained for basic laparoscopic skills and to get acquainted with the fulcrum effect on the MIST-VR. All participants were tested from January to June 2008, at the Catharina Hospital Eindhoven, the Netherlands.

Equipment

In this study we used the ProMIS v2.0 Augmented Reality (AR) simulator (Haptica, Dublin, Ireland). The laparoscopic interface consists of a torso shaped mannequin (29" length x 20" wide x 9" deep), with a skin coloured cover, which is connected to a notebook (Dell, XPS M1710). The mannequin contains three separate camera tracking systems, arranged to identify any instrument inside the simulator from three different angles. The camera tracking systems capture instrument motion with Cartesian coordinates in the x, y and z planes at the average rate of 30 frames per second (fps). The distal end of the laparoscopic instrument shaft is covered with two pieces of yellow electrical tape to serve as a reference point for the camera tracking system; therefore it accepts a broad range of instrument types. Instrument movement is recorded and stored in distinct sections, based on the time the tips of the instrument are detected until they are removed from the mannequin. The notebook was positioned so that the participant had the screen placed just below eye level and the mannequin was placed at a standard ergonomic height for performing the laparoscopic tasks. The simulator records 'time', 'path length' and 'smoothness of movement' (through changes in instrument velocity and changes in direction), during each separate task within the training module. After completion of the task, ProMIS provides statistics on the screen. In addition, a full video and virtual playback of the trainee's performance are saved. Different trays may be placed in the mannequin for each task, such as the suturing pads for the suture and knot tying task. During the training the 26173 KL and 26173 KAL KOH macro needle-holders (Karl Storz, Tuttingen Germany) with Syneture (Covidien) Polysorb 3-0 suturing needle and thread were used.

Questionnaire

The questionnaire used to research the face validity in this study consisted of three parts. The first part was about the demographics and laparoscopic and simulator experience of the trainees. In the second part, questions were asked regarding the realism and didactic value of the suturing module of the ProMIS V2.0 laparoscopic simulators. These questions were answered on a five-point Likert scale. The final questions asked the opinion of the participants on the size of the dome in the module and preference of simulation technique for practicing laparoscopic suturing skills.

Informed consent was signed by all participants, to state that they voluntarily participated in this study.

Evaluation form

Two independent expert observers rated the performances of the participants by means of a standard evaluation form, which consisted of seven items, scored on a five point Likert scale. This was to research the concurrent validity of the model, as these standard evaluation forms, are used in the thoroughly validated FLS (Fundamentals of Laparoscopic Surgery) to assess the suturing performance. The following items were used: 'position of the needle in the needle holder', 'running the needle through the suturing pad', 'taking proper bites of the suturing pad, while doing the suture', 'throwing the thread around the needle holder', 'pulling the thread tight in the proper direction', 'tying a correct surgeon's knot', 'global evaluation of the performance'. Both observers were experienced with laparoscopic suturing and knot-tying using the same technique as in the module.

Protocol

All participants (both the experienced and novice) started the suturing module in the beginner level and performed two runs of the task. Only the scorings of the second run were recorded for the construct validity, to avoid bias in the scorings because of unfamiliarity with the simulator and module. The novice participants practiced their suturing skills more extensively on this module as part of a training, of which the baseline knot and the knots at both the individual and average performance curve were also used for this study. The scorings of the assessment method were compared with the scores of two independent expert observers. They observed the video recordings of the performances and scored them by means of the evaluation form.

After finishing the session, all participants filled out the questionnaire regarding their opinion on this adapted suturing module and the assessment method, to evaluate the face validity of the module.

Statistics

The data were processed and analyzed with the Statistical Package for the Social Sciences (SPSS) version 13.0. Data on differences of opinion between the groups were analyzed with the independent t-test. The performance scores of the two experience levels were compared using the independent t-test. To visualize the correlation between the performance scores of the assessment method and the scorings of the objective observers the Spearman's rho was used. The inter-observer reliability was calculated with the Cronbach's alpha. A p-value of ≤ 0.05 was considered statistically significant.

Results

Suturing module

The standardized suturing technique for the surgeon's knot was used as previously described by Hanna et al. [11]. This suturing and knot-tying technique is divided into several steps. The step-by-step approach of this suturing module was build with guidance, by means of a dome and an arrow, to pull the knot tight in the proper direction. The assessment method of this module is based on the placing of the instruments. When throwing the thread around the needle-holder, the instruments have to be inside the dome, but when pulling the knot tight, the pulling instrument can move outside the dome (following the direction of the guiding arrow), but the instrument holding the tail end has to stay inside the dome (Figures 1-4). The outcome of this assessment method is presented at the end of the performance as a calculation of the percentage of the time spent in the correct area for each step and strength of the knot. If there is an error made (e.g. taking an instrument out of the dome during knot tying) the dome will turn bright blue, until the error is restored. This error percentage is shown in the assessment parameter: 'time spent in the correct area'. The second assessment parameter used in the assessment score is the strength (quality) of the knot, which was tested by cutting the suture out of the suturing pad and pulling at the cut ends with a tension meter. This showed whether the knot would slip or brake when pulling at it with at least 25 Newton, which a correct 'surgeon's knot' should be able to endure [11,12].

The suturing module is divided into three difficulty levels, in which the dome is the largest in the beginner level and the smallest in the advanced level. The size dome of the middle level is comparable to the area available for suturing the crura or common bile duct in the clinical setting.

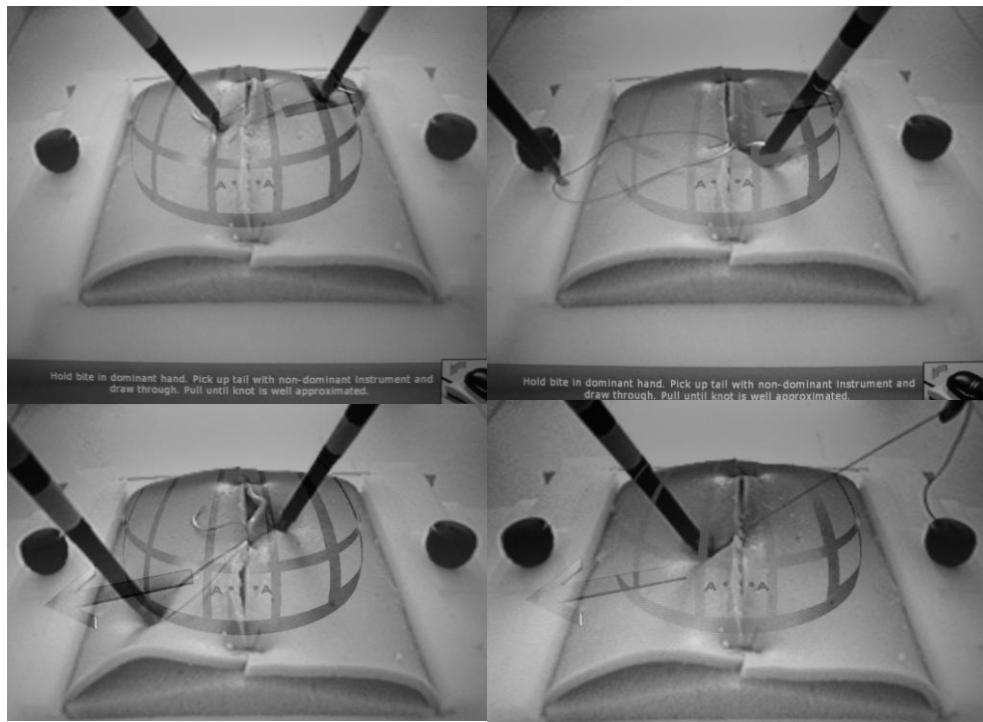


Figure 1-4: The dome is a simulated area in which the trainee has to stay in during the knot-tying. When pulling the knot tight in the proper direction there is a guidance arrow to guide the correct direction to tie a surgeon's knot. The proper instrument can come out of the dome in the guided direction during this step. When the knot is pulled tight in the wrong direction, or the instrument with the tail-end comes out of the dome, the dome will turn bright blue, until the error is restored.

Validity of suturing module

The experienced participants scored significantly better in the 'beginner level' mode, according to the assessment method than the novice participants (mean 95.73 versus 60.89) (Table 1). For the separate assessment parameters, 'time spent in correct area' and 'strength of knot', the experienced participants also scored significantly higher.

When asking the participants about the properties of this suturing simulator, the haptic sensations were rated good to excellent by the majority (Table 2). The demonstration videos before the task were considered good for the training (mean 4.35), while the videos during the performance were rated as less useful (mean 3.21). The experienced participants even

rated the step-by-step videos with a mean of 2.60, which is significantly worse than the novice participants ($p=0.001$). The size of the dome in the ‘beginner level’ mode was rated as good for training by sixteen participants, while six were of the opinion that it was too small and two did not have an opinion on this matter. When asked them about the representation of the performance by the assessment scores eighteen were of the opinion that it was a good representation, two thought it was too high, one that it was too low, and three had no opinion. The suturing module was rated as a good to excellent training tool for the training of laparoscopic suturing to surgical residents (mean 4.50).

Table 1: Differences in performance scores	Experienced participants (n=10)	Novice Participants (n=14)	p-value
	<i>Mean (Standard deviation)</i>		
Total score assessment method	95.73 (2.63)	60.89 (17.09)	<0.001
‘Time spent in correct area’	91.46 (5.25)	68.93 (19.09)	0.001
‘Strength of knot’	100.00 (0.00)	53.57 (23.73)	<0.001
Performance score objective observers	26.73 (3.34)	11.69 (3.63)	<0.001

Table 1: The differences between the scorings of the two experience levels are calculated with the independent t-test. A p-value < 0.05 is considered a significant difference.

Assessment method

The performance scores of the assessment method were compared with the scorings of the same performances (n=43) rated by the objective observers (on the standard evaluation form) and showed a significant correlation (Spearman’s rho 0.672), with an inter-observer reliability of 0.96 (Cronbach’s alpha). The scoring of the observers did also correlate significantly with both the ‘time spent in the correct area’ and the ‘strength of the knot’ (Table 3).

When comparing the separate assessment parameters (Table 4), there were strong correlations between the total assessment scores and both the ‘time spend in the correct area’ and the ‘strength of the knot’ (n=229, Spearman’s rho 0.719 and 0.830 respectively), which were based on the fact that the assessment score is made up from these assessment parameters. The parameter ‘time spent in correct area’ had some correlation with the strength of the knot (Spearman’s rho 0.257), but as is seen in Figure 5 no relevance from this calculated correlation can be made, therefore a rho of <0.4 could not be seen as a relevant correlation. The secondary parameter time also showed a significant calculated correlation

Meaningful assessment method for laparoscopic suturing

with the assessment score and the separate assessment parameters, but as is clear from Figures 6-8, the time to complete the suture does not give a good impression of the primary assessment score.

Table 2: Opinion on assessment method	Experienced Group (n=10)	Novice Group (n=14)	Total group (N=24)
	<i>Mean (standard deviation)</i>		
Realism of needle and thread	4.40 (0.84)	4.43 (0.65)	4.42 (0.72)
Tying of the knots	4.50 (0.71)	3.93 (0.91)	4.17 (0.87)
Movement of the suturing thread	4.30 (0.82)	4.07 (0.83)	4.17 (0.82)
Resistance of needle and thread	4.40 (0.84)	3.86 (0.77)	4.08 (0.83)
Utility of the demonstration video before the task	4.22 (0.83)	4.43 (0.76)	4.35 (0.78)
Utility of the demonstration video's during the task	2.60 (1.26)	3.64 (1.00)	3.21 (1.21)
Utility of the dome as a guidance during the performance	3.30 (1.42)	3.71 (0.91)	3.54 (1.14)
Utility of feedback of the performance	3.30 (1.06)	3.85 (0.56)	3.61 (0.84)
Training tool for surgical residents	4.30 (0.82)	4.46 (0.66)	4.39 (0.72)
Training tool for surgeons	4.20 (1.03)	3.92 (0.76)	4.04 (0.88)

Table 2: The opinion of the participants on the suturing module and assessment method is shown here, the differences are calculated with the independent t-test, with $p < 0.05$ considered to indicate a significant difference. There were only significant differences found between the two groups on the property 'utility of demonstration videos during the performance' ($p = 0.035$).

Table 3: Correlation between performance scores and objective observers	Correlation with objective observers	Significance
Total score assessment method	0.672	at 0.01 level (two-tailed)
‘Time spent in correct area’	0.573	at 0.01 level (two-tailed)
‘Strength of knot’	0.566	at 0.01 level (two-tailed)

Table 3: Correlation between the scores of the assessment method and the performance scores graded by the objective observers, for all baseline knots and the knots at the top of the performance curve of the novice participants (N=43). The significance is calculated with Spearman’s rho.

Table 4: Correlation between assessment parameters	Total score assessment method	‘Time spent in correct area’	‘Strength of knot’	Total time of performance
Total score assessment method	-	0.719**	0.830**	-0.259**
‘Time spent in correct area’	0.719**	-	0.257**	-0.286**
‘Strength of knot’	0.830**	0.257**	-	-0.158*
Total time of performance	-0.259**	-0.286**	-0.158*	-

Table 4: Correlation between assessment parameters for all performances of the beginner level of the suturing module (N=229). The correlations are calculated with Spearman’s rho.

** Correlation is significant at the 0.01 level (two-tailed)

* Correlation is significant at the 0.05 level (two-tailed)

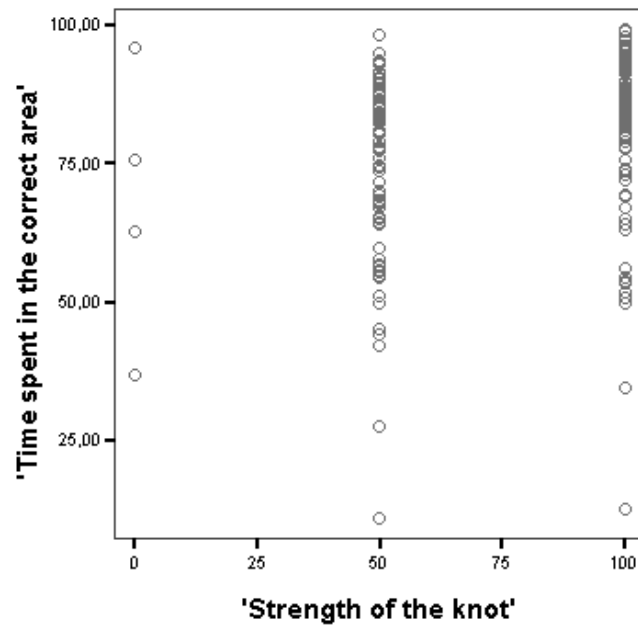


Figure 5: Scatter plots of the correlation between the 'strength of the knot' and the 'time spent in the correct area' during the suturing training (n=229), which showed a calculated significant correlation, but this figure shows no clinical relevant correlation.

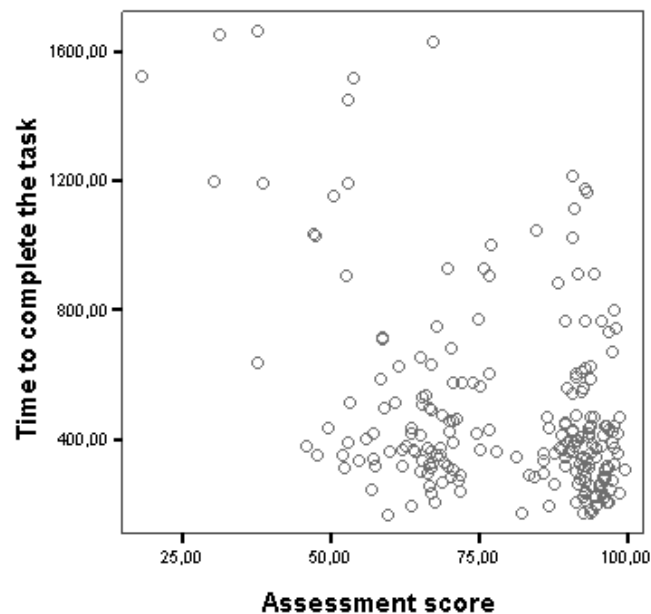


Figure 6: Scatter plots of the correlation between the assessment scores and the time to complete the task (n=229), which showed a calculated significant correlation, but this figure shows no clinical relevant correlation.

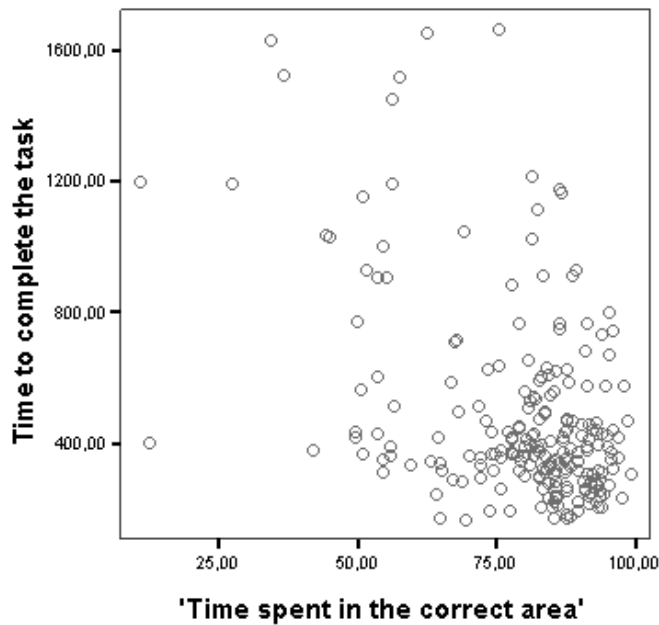


Figure 7: Scatter plots of the correlation between the time to complete the task and the 'time spent in the correct area' during the performance (n= 229), which showed a calculated significant correlation, but this figure shows no clinical relevant correlation.

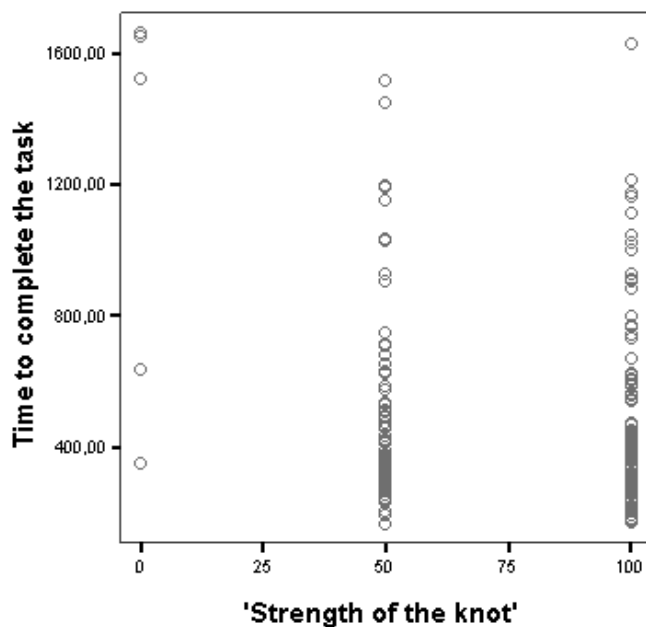


Figure 8: Scatter plots of the correlation between the time to complete the task and the 'strength of the knot' (n=229), which showed a calculated significant correlation, but this figure shows no clinical relevant correlation.

Discussion

Augmented Reality

Augmented Reality is the combination of physical and Virtual Reality in one system. Real instruments, which are modified by means of coloured tags on the tips, are video-tracked by the system to measure the performance of the tasks. This results in the objective assessment of the real physical tasks performed by the trainees, and thus in an objective scoring of that performance.

A major advantage of the ProMIS AR laparoscopic simulator over the computer-based VR simulators is that it allows the trainee to use the same instruments that are currently used in the operating room. The simulator provides realistic haptic feedback because of the hybrid mannequin environment the trainee is working in, which is absent in Virtual Reality systems. This simulator offers a physically realistic training environment that is based on real instruments interacting with real objects. This physical character is regarded very important to learn laparoscopic suturing and knot-tying skills. The participants of the current study also appreciated the realistic haptic feedback of the Augmented Reality as shown in Table 2.

Meaningful feedback

When learning laparoscopic skills, which are distinctive motor skills acquisitions, it is essential to provide feedback to stimulate the learning process [13]. A previous study of Porte et al. [14] demonstrated that information about motion efficiency in the form of number of movement made during the learning of knot-tying skills, with or without expert derived criterion, was not as valuable to the learning process as expert feedback. Presumably, the feedback given by the experts was more understandable to the trainees than the feedback of time, path length and economy of movement. This type of feedback is referred as extrinsic feedback, which should guide and motivate trainees to reach their performance goals [14, 15]. But to motivate trainees to practice their skills, this extrinsic feedback has to be meaningful and informative, which can be in the form of expert feedback. However intense extrinsic feedback can hinder learning during the early stages of skills acquisition, by inhibiting the intrinsic learning strategies [15]. Therefore meaningful feedback at the end of each task, in the form of ‘time spent in the correct area’ per step and quality of the knot, is more meaningful than motion efficiency and should hinder the trainee less during the training than would expert feedback. Other extrinsic feedback that could guide trainees is demonstration videos before and during the training, which are also provided in this suturing module.

To provide informative feedback it is important that meaningful measurements, such as 'time spent in correct area' and the 'strength of the knot', are combined, because focusing on only one is not sufficient to improve the skills. There are some correlations between these measurements, but it is clear that in individual cases the separate measurements individually do not give a proper assessment of the performance. These significant correlations could be based on the large number of knots used for these calculations. The correlation between the assessment measurements has to be clinically relevant and a correlation coefficient of <0.4 could not be considered a clinically relevant correlation. Time does not show a clinically relevant correlation with any of the assessment measurements, and nor do 'time spent in the correct area' and 'strength of knot' (Table 4). Whereas a calculation from these two measurements gives a good impression of the suturing skills, when compared with the ratings of the objective observers.

Assessment method

To determine the end point of the training of suturing skills it is important to know what the trainee is doing and which path has been travelled to get to the final knot. Parameters such as time, path length and smoothness do not tell you anything about the exact movements that are made within the mannequin to get to that final knot. Therefore it is important to create a three dimensional 'space', which the trainee has to stay in, while he is throwing the thread around the needle-holder. This 'space' is imagined as a dome (a cage on the suturing ground), based on the average suturing path travelled by experienced laparoscopic surgeons. The physical dimensions of the dome are derived from the measurements of experienced laparoscopic surgeons, when suturing the crura or common bile duct. This is also the ideal space to stay in during the suturing, which makes the handling of the instruments and throwing the thread around the needle the easiest. Additionally, it is important that the surgical resident learns to suture in a confined space, because in the clinical setting there is always the chance of puncturing the liver or spleen during the suturing.

One of the measurements in the assessment score is calculated from is the quality of the tied knot ('strength of knot') which provides a reliable assessment of the security of the knot [11,12] and is considered the most important factor in tying a knot.

Another major advantage of the dome and guidance arrows during the training is the fact that the suturing procedure is divided into steps, to show the trainee precisely and unequivocally how to perform the suture correctly [2]. The dome (Figure 1-4) itself is only for the path of throwing the thread over the needle-holder. When the thread has to be pulled tight, the trainee has to come out of the dome in the proper direction, which is calculated from the ideal path of the experts. It is important that the trainee only pulls on the needle end of the

thread and only with the proper hand, in the correct direction to create a surgeon's knot. With this dome, the length of the tail end can also be assessed, as the instrument holding the tail end, has to stay inside the dome, while pulling the knot tight.

The performance scores of the assessment method showed significant differences between the two experience groups and therefore demonstrates the construct validity [16]. As shown in the tables there is significant correlation between the scorings of the assessment method and the scorings of the objective observers, which demonstrate the concurrent validity [16] of the developed assessment method for laparoscopic suturing training.

Limitations

The group of experienced participants is smaller than the novice group, which can be attributed by the fact that there were fewer experienced surgeons available to enter in this study. Because the novice participants have tied sixteen knots each (of which three assessed by the objective observers), there were enough runs of the task on the suturing module to calculate correlations between the assessment parameters and with the scorings of the objective observers.

The quality of the visual feedback on the screen was not optimal and in combination with the projection of the dome over the instruments on the screen, the participants (both experienced and novice) regarded the dome sometimes as a nuisance, because of the lack of vision of the needle and tread during the performance. Therefore the quality of the camera should be improved, as should the way of visualizing the dome on the screen, in stead of an overlay over the instruments and suturing material. There is also room for improvement in the step-by-step demonstration video's and spoken guidance, as these were properties of the module that could not be adapted. The demonstration video shown at the beginning of the training was constructed for this study and not part of the suturing module. The step-by-step videos were also rated as less useful during the training, with a significantly worse rating by the experienced participants. This can be explained by the fact that they are useful in the beginning of the learning process, but not when the steps of the procedures are clear to the trainee. The demonstration video with the proper steps, shown before the training, was rated better by the experienced participants of the study than the step-by-step videos (mean 4.22 versus 2.60).

Conclusions

The current study shows the construct, concurrent and face validity of the suturing module with the adapted assessment method on the ProMIS laparoscopic simulator. This assessment method is a valid tool for assessing laparoscopic suturing skills objectively. Although assessment parameters can correlate, to provide informative feedback it is important to combine meaningful measurements, e.g. strength of knot, in the assessment of suturing skills. We recommend incorporating simulator systems with an informative assessment method for laparoscopic suturing training, as described and validated in this study, into the training curricula for surgical residents.

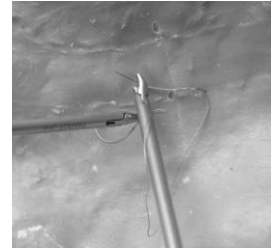
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Chapter 8



Suturing training in Augmented Reality: Gaining proficiency in suturing skills faster

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Abstract

Aims

Providing informative feedback and setting goals tends to motivate trainees to practice more extensively. Augmented Reality (AR) simulators retain the benefit of realistic haptic feedback and additionally generate objective assessment and informative feedback during the training. This study researched the performance curve of the adapted suturing module on the ProMIS AR simulator.

Methods

Eighteen novice participants were pre-trained on the MIST-VR, to become acquainted with laparoscopy. Subsequently, they practiced sixteen knots on the suturing module, of which the assessment scores were recorded to evaluate the gain in laparoscopic suturing skills. The scoring of the assessment method was calculated from the 'time spent in the correct area' during the knot-tying and the quality of the knot.

Both the baseline knot and the knot at the top of the performance curve were assessed by two independent objective observers, by means of a standardized evaluation form, to objectify the gain in suturing skills.

Results

There was a statistically significant difference between the scores of the second knot (mean 72.59, standard deviation (SD) 16.28) and the top of the performance curve (mean 95.82, SD 3.05) ($p < 0.001$, paired t-test). The scoring of the objective observers also differed significantly (means 11.83 and 22.11 respectively, SD 3.37 and 3.89 respectively, $p < 0.001$) (inter-observer reliability Cronbach's $\alpha = 0.96$). The median amount of repetitions to reach the top of the performance curve was eight, which also showed significant differences between both the assessment score (mean 88.14, SD 13.53, $p < 0.001$), and scoring of the objective observers of the second knot (mean 20.51, SD 4.14, $p < 0.001$).

Conclusion

This adapted suturing module on the ProMIS Augmented Reality laparoscopic simulator is a potent tool for gaining laparoscopic suturing skills.

Background

The use of simulation in surgical training curricula is becoming more widely accepted and most Virtual and Augmented Reality simulators are able to provide objective assessment and feedback. Objective assessment of performance is fundamental in order to provide formative feedback during training, allowing for continuous skill refinement [1]. Providing feedback and setting goals tends to motivate trainees to practise their skills more extensively compared to a self directed group [2].

The development of objective measures of operative skill is important to confirm the role of simulators in laparoscopic surgery [3]. For being an effective training tool, the simulator has to provide metrics that are meaningful and informative to the trainee. Professional organizations have recently recognized the need to assess surgical performance objectively [3].

Haptic feedback is fundamental for good laparoscopic training, in particular for laparoscopic suturing [4-6]. Laparoscopic training with haptic feedback results in significantly improved skills transfer to the trainee, compared to training without haptic feedback [3]. Especially for laparoscopic suturing skills it is of importance that the participants have tactile feeling of what they are doing during the procedure. In general, it is assumed that realistic simulations with haptic feedback result in better training effects and better transfer to the clinical setting [7]. Augmented Reality provides realistic haptic feedback, because of the hybrid mannequin environment in which the trainee is working, with real laparoscopic instruments and materials.

To become proficient in laparoscopic skills or procedures, surgeons in training must experience their own learning curve for gaining proficiency. The improvement in skills tends to be more rapid in the first part of the training, and will taper off over time, until a steady state has been reached [8]. In this study we examined the performance curve on suturing skills of trainees with no previous laparoscopic suturing experience to research whether the suturing module of the ProMIS v2.0 Augmented Reality simulator is proficient for training of suturing skills to surgical residents.

Methods & Materials

Subjects

In total eighteen novice participants completed the two day training sessions on the Suturing module of the ProMIS V2.0. All participants were either medical students, during their clinical rotations, or surgical residents. None of the participants had previous clinical laparoscopic experience or any laparoscopic suturing experience.

An informed consent was signed by all participants, to state that they have voluntarily participated in this study.

Equipment

ProMIS V2.0

In this study we used the ProMIS v2.0 Augmented Reality (AR) simulator (Haptica, Dublin, Ireland). The laparoscopic interface consisted of a torso shaped mannequin (29" L x 20" W x 9" D), with a skin coloured cover, which is connected to a notebook (Dell, XPS M1710). The mannequin contained three separate camera tracking systems, arranged to identify any instrument inside the simulator from three different angles. The camera tracking systems captured instrument motion with Cartesian coordinates in the x, y and z planes at the average rate of 30 frames per second (fps). The distal end of the laparoscopic instrument shaft was covered with two pieces of yellow electrical tape to serve as a reference point for the camera tracking system; therefore it accepted a broad range of instrument types. Instrument movement was recorded and stored in distinct sections, based on the time the tips of the instrument was detected until removed from the mannequin. The notebook was positioned so that the participant had the screen placed just below eye level and the mannequin was placed at a standard ergonomic height for performing the laparoscopic tasks.

The simulator recorded 'time', 'path length' and 'smoothness of movement' (through changes in instrument velocity and changes in direction), during each separate task within the training module. After completion of the task, ProMIS provided statistics on the screen. In addition, a full video and virtual playback of the trainee's performance were saved. The suturing pads for the suture and knot tying task were placed inside the mannequin.

Suturing module

For the suturing module used in this study an adapted assessment method was developed, which calculates the assessment scores based on the time spent in the correct area ('dome') and the quality (strength) of the tied knot. The dome itself was only for the path of throwing the thread over the needle-holder. When the thread had to be pulled tight, the instrument had to come out of the dome at a certain point and angle, which was calculated from the ideal path of the experts and guided by an arrow on the screen (Figure 1). It was important that the trainee only pulled on the proper side of the thread and only with the proper hand, in the correct angle to create a surgeon's knot. At the end of the task the assessment score of the performance was shown by means of a percentage per step that was spent in the correct area (Figure 2). The quality (strength) of the knot was tested by cutting the suture out of the suturing pad and pulling at the cut ends with a tension meter. This showed whether the knot would slip or brake when pulled with at least 25 Newton, which a correct 'surgeon's knot' should be able to endure [9].

During the training the 26173 KL and 26173 KAL KOH macro needle-holders (Karl Storz, Tutlingen Germany) with Covidien Polysorb 3-0 suturing needle and thread were used.

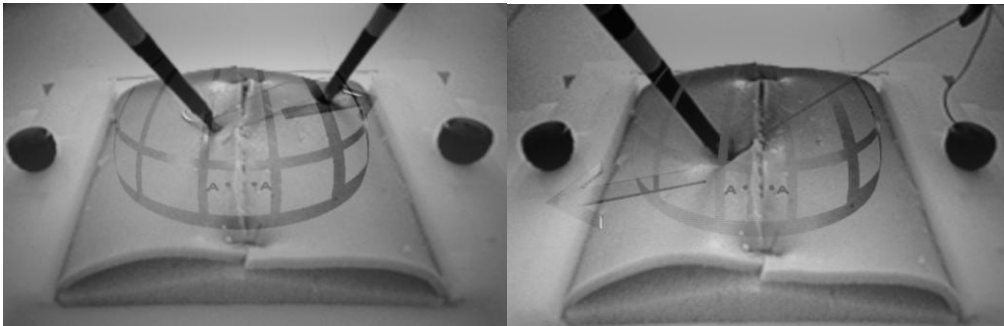


Figure 1 and 2: The dome of the adapted suturing module is visualized on the screen as a guidance and assessment method during the suturing task. When the instruments are inside the proper area, the dome is translucent. The dome and arrow during the suturing task to guide the trainee in the proper direction when pulling the knot tight. The dome turns bright blue when pulling the knot tight in the wrong direction.

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MIST-VR

To practice the basic skills of laparoscopic surgery and become acquainted with the fulcrum effect, the participants practiced four tasks on the well validated MIST-VR laparoscopic simulator. These tasks were: Acquire Place, Withdrawal, Transfer Place and Traversal [4,10-13].

Performance evaluation form

The assessment of the suturing skills of the baseline knot and the final knot were performed by using a standard evaluation form, which consisted of seven items scored on five-point-Likert scale: 1) positioning of needle in needle-holder; 2) running needle through suturing pad; 3) taking proper bites of the suturing pad, while doing the suture; 4) throwing thread around needle-holder; 5) pulling tight of the thread in proper direction; 6) tying a correct 'surgical knot'; 7) global evaluation of performance. For this study we used the summation of these 7 items to compare the performances. Both expert observers have performed more than 500 clinical laparoscopic procedures and have extensive laparoscopic suturing experience, using the same suturing and knot-tying technique.

Protocol

Eighteen novice participants were pre-trained on the MIST-VR, with four basic tasks, before starting the suturing sessions, to become acquainted with the laparoscopic basics and the fulcrum effect. Thereafter, they watched a demonstration video of a laparoscopic surgeons knot. During the training there were step-by-step instruction videos to guide the trainee during the practice, whereas no additional verbal feedback was given on the suturing skills. Then they practiced two knots on the adapted suturing module on the ProMIS V2.0, of which the second one was assessed as the baseline score. The first knot was not used as the baseline to avoid bias in the results, caused by unfamiliarity with both the simulator, instruments and the module; therefore the second run of the suturing task was used as a baseline knot. The second (baseline) knot was also assessed by two independent objective observers, by means of the standard evaluation form. The participants practiced another fourteen knots on the suturing module in two days, in total seven knots on the first day and nine on the second day. After the training session the recorded knots at the top of the individual performance curve and at the overall performance curve (knot seven) were assessed by the objective observers. During the training the assessment scores of the adapted assessment module were gained to evaluate the gain in suturing skills and visualize the learning effect of this suturing module.

Statistics

All data was processed and analysed using Statistical Package for the Social Sciences (SPSS) 13.0. Differences between the performance scores during the training were calculated with ANOVA. The differences between the performance scores at the baseline and at the top of the performance curve were calculated with the paired t-test. Inter-observer reliability was calculated with Cronbach's alpha. A p-value of <0.05 was considered a significant difference.

Results

According to the assessment method, a median of eight repetitions were necessary to reach the top of the performance curve (Figure 3). This is knot seven in the tables and figures, because the first knot was not used in the results to avoid bias. The individual top of the performance curve was compared with the baseline scores which showed a significant difference in the assessment score (mean 72.59 vs. 95.82, $p<0.001$). There was also a significant difference between the assessment scores of the second (baseline) knot and knot seven (mean 72.59 and 88.14 respectively, $p = 0.001$; Table 1). The scores of the 'time spent in the correct area' reached the plateau phase at the seventh knot (Figure 4), and showed a significant improvement during the training ($p<0.001$, ANOVA). The scores of the 'strength of the knot', however, tended to vary during the training session and did not show a significant difference ($p=0.479$, ANOVA), with a dip in the scores at knot six and eleven (Figure 5). Although this was not a primary assessment parameter, there was a significant decrease in the time to complete the knot during the training ($p<0.001$, ANOVA).

The scoring of the objective observers differed significantly for both the knot at the top of the individual performance curve and knot seven, when comparing them with the baseline knot (means 11.83, 22.11 and 20.51 respectively, $p<0.001$; Table 1), with an inter-observer reliability Cronbach's alpha of 0.96.

The scores of the individual assessment parameters 'time spent in the correct area' and 'strength of knot' also showed significant differences between the baseline knot and both the knot at the top of the average and individual performance curve ($p=0.003$, $p=0.004$ and $p<0.001$ respectively; Table 1).

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Table 1: Gaining proficiency in suturing skills	Baseline knot	Knot 7	Knot on Top of individual curve	Baseline vs Knot 7	Baseline vs Top
	Mean (standard deviation)			p-value	
Assessment score	72.59 (16.28)	88.14 (13.53)	95.82 (3.05)	<0.001	<0.001
Score 'time spent in correct area'	76.30 (15.06)	87.39 (12.91)	91.64 (6.11)	0.003	<0.001
Score 'strength of knot'	69.44 (25.08)	88.89 (21.39)	100.00 (0.00)	0.004	<0.001
Objective observer score	11.83 (3.37)	20.51 (4.14)	22.11 (3.89)	<0.001	<0.001

Table 1: Differences were calculated using the paired t-test, a $p < 0.05$ was considered a significant difference. The assessment score is the objectively generated scoring of the assessment score of the suturing module on the ProMIS AR simulator.

Table 2: Mean Assessment score	Baseline knot	Knot 7	Knot in top of individual curve	p-value
	Mean (standard deviation)			
Average abilities (n=13)	64.51 (10.85)	84.75 (14.58)	95.25 (3.27)	Baseline vs knot 7 0.001 Baseline vs top <0.001
Native abilities (n=5)	93.60 (2.60)	96.94 (2.39)	*	0.08

Table 2: Differences were calculated using the paired t-test, a $p < 0.05$ was considered a significant difference.

* Scores of knot seven were the highest scores on the individual performance gain curves of the group with the native abilities

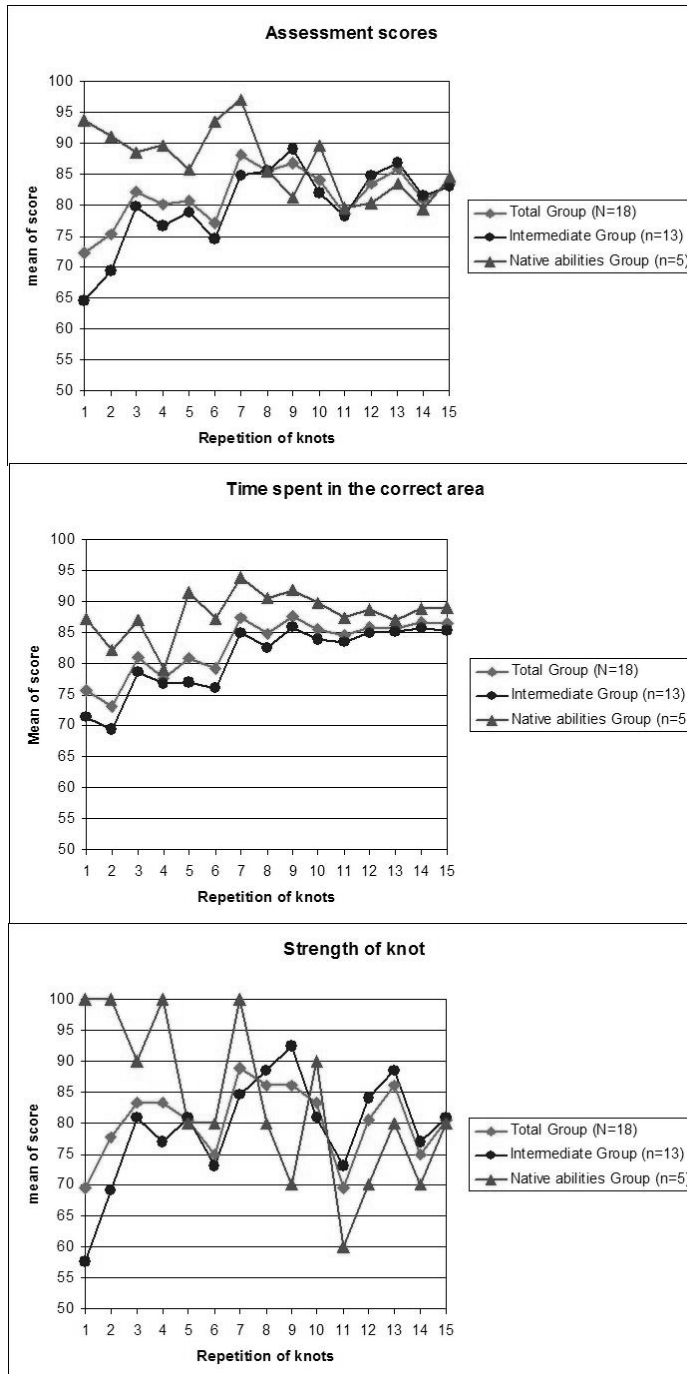


Figure 3: Assessment scores of the suturing module during the suturing training improved significantly: $p=0.008$ for the total group and $p<0.001$ for the intermediate Group (ANOVA). The participants with the native abilities did not show significant differences in their performance ($p=0.602$, ANOVA).

Figure 4: The 'time spent in the correct area' during the suturing training improved significantly: $p<0.001$ for both the total and intermediate Group, but not for the native abilities Group, $p=0.209$ (ANOVA).

Figure 5: The strength of the knot during did not show significant improvement during the training for both the total, intermediate, and native abilities Groups ($p=0.479$, $p=0.105$ and $p=0.104$ respectively, ANOVA).

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Five participants started the training session with high assessment scores and were able to perform a correct surgeon's knot, while staying in the correct area for the major part of the performance. Their assessment scores did not improve significantly during the training ($p=0.602$, ANOVA; Figure 3), nor comparing the baseline knot with the best performance ($p=0.08$, Table 2). The 'time spent in the correct area' did not show a significant improvement during the training session (Figure 4), and neither did the 'strength of the knot', which decreased during the progress of the training (Figure 5). The average group ($n=13$) significantly improved both the assessment score and the 'time spent in the correct area' significantly during the training ($p<0.001$, Figures 3 and 4, Table 2). The strength of the knot did not improve significantly during the training process, because there are a few dips in the curve (Figure 5).

Before the participants started the suturing training, they were all pre-trained on the MST-VR simulator with four basic tasks. The performance scores from these tasks were compared with the scores of the baseline knot, to determine whether there were correlations between the native psychomotor abilities and the native suture and knot tying skills. No significant correlations were found between the basic and suturing skills (Table 3). However, there was a correlation in the performance on the MIST-VR and the time to complete the baseline suture task, but because time is not a primary assessment measurement, no conclusions can be made. Moreover, a significant negative correlation was calculated between the scores of the MIST-VR and the 'time spent in the correct area' during the suturing.

Two participants had major difficulties with the suturing and knot tying skills on the first training day: one was not able to finish the baseline knot and was excluded from the results and the other was able to tie a correct surgeon's knot while staying in the correct area for a respectable part of the performance on the second day.

Table 3: Correlation between basic skills and suturing	Spearman's rho	p-value
Assessment score	-0.185	0.463
'Time spent in the correct area'	-0.479	0.044
'Strength of the knot'	0.099	0.696
Time to complete the performance	0.637	0.004

Table 3: Correlation between the performance on the MIST-VR basic laparoscopic tasks and the laparoscopic suturing performance at the baseline knot, calculated with Spearman's rho. A p-value under 0.05 was considered a significant correlation.

Discussion

The term feedback refers to the return of performance-related information to the performer and can be divided into two major categories: intrinsic feedback and extrinsic feedback [14,15]. Intrinsic feedback consists of performance-related information available directly to the sensory system, like haptic feedback and visual cues of the instrument movement during the task [14,15]. Extrinsic feedback is performance-related information provided by an external source and has two important roles: 1) to facilitate achievement of the performance goal, by providing information about the degree of success thus far, and about the various components involved in achieving that performance goal [15]; and 2) extrinsic feedback should motivate the trainee to continue to strive toward the achievement of that goal [14]. To motivate trainees to practice their skills this extrinsic feedback should be meaningful and informative [15]. Previous studies have shown that, while extrinsic feedback can provide insight into actions and consequences of the actions, they can also inhibit intrinsic learning strategies and the development of problem solving abilities [14].

Stefanidis et al. [14] suggested a trend toward faster achievement of simulator proficiency with the incorporation of frequent video tutorial viewing. Providing video demonstrations before and during the training, as used in this study, has been shown to lead to superior training [14].

It is important that trainees understand the extrinsic feedback that is provided, to translate this in improvement of the skills. Often used parameters, such as time and path length, are not readily transferable to informative feedback to the trainee, and can not be used to effectively improve laparoscopic suturing skills.

In this study the strength of the knot was tested, which provided informative extrinsic feedback of the performance, as a proper tied knot is the performance goal in laparoscopic suturing training. The 'time spent in the correct area' was another measurement used to calculate the performance score from and was shown on the screen after each performance. The trainee was able to see the most problematic part of the knot-tying and what could be done to achieve an optimal knot.

There was a dip in the performance at knots six and eleven (Figure 3). Knot six was the last knot on the first day of the training, in which the participants complained of tiredness and were not focussed anymore. Knot eleven was the fifth knot of the second training day. On this second day, knot tying improved more than expected for most participants, which result in losing focus and concentration. Too intense practice in one day may exhaust a trainee, influencing the performance negatively. This could potentially cause a loss of motivation and negative extrinsic feedback to the trainee. Therefore the recommendation to spread out the

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laparoscopic training over several days or reduce the amount of sutures to be made in one session seems to be justified. The first knot on the second day (knot seven) was the best knot on average presumably because the participants had the opportunity to recapitulate both the intrinsic and extrinsic feedback given to them overnight and regain their concentration.

It has been indicated that learning can be enhanced when trainees have the opportunity to practice with progressively increasing levels of difficulty [10,16,17]. In this study all participants remained in the ‘beginner level’ mode during the training. However, three difficulty levels are available, which have been developed to motivate trainees to practice their skills extensively until they have reached the advanced skills level. For the participants with a native ability in laparoscopic suturing, an ‘advanced level’ mode could be an option to increase their motivation. The performance scores in the ‘beginner level’ mode decreased during the training; if the participants had trained in the more challenging ‘intermediate level’ mode they would have remained focussed to perform with their best capabilities. Existence of a relationship between cognitive abilities and skills acquisition in the early phase of learning new surgical skills has been debated, but these correlations appear to decline when the procedure becomes routine [18,19]. This could be another explanation for the high performance scores in the first runs of the task and the decrease in the scores at the end of the training. However, the pre-training on the MIST-VR does not show a correlation with the scores of the baseline knot, which should otherwise visualize the native psychomotor abilities of the trainee.

Conclusion

This adapted suturing module on the ProMIS Augmented Reality laparoscopic simulator is a potent tool for the training of laparoscopic suturing skills to surgical residents. The trainees in this study needed just seven repetitions on average to reach the top of the performance curve. There were statistically significant differences in both the scoring of this assessment method and in the scorings by the objective observers, when comparing the baseline knot with the top of the performance curve.

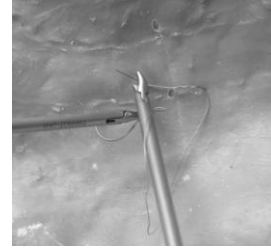
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Chapter 9



Developing a realistic model for the laparoscopic Nissen Fundoplication

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Jack J. Jakimowicz

Submitted

Abstract

Introduction

A realistic model is developed for the laparoscopic Nissen Fundoplication (anti-reflux surgery), which simulates the human anatomy realistically, and could reduce the use of animal tissue models. This article elaborates the designing process of this model and the development process to create the abdominal organs with realistic haptic feedback.

Method

Before developing the artificial tissue, the mechanical characteristics of the tissue were examined and the material that resembled this the closest was used to create the separate organs. The haptic feedback of the intra-abdominal organs is made up of several variables, which can be divided in three main groups: tissue, geometry and context. The stress–strain curves of the different tissues were researched and compared with the properties of industrial materials to find the best material to use for the production of the organs

Results

The aspects that are of influence on the haptic feedback as determined above are used to select the most promising material groups to develop the organs and base from. These aspects were: E-modulus, density, coefficient of friction, sensitivity to tearing, wall thickness, and shelf life.

Silicone and latex materials were the most promising materials to mimic tissue based on these criteria. The connections of the organs to the surface and other simulated tissue were made of velvet rope, to be changeable in the model.

Conclusion

As a result of the development process a reusable modular model of the upper abdomen anatomy was created for the training of laparoscopic procedures, such as the Nissen fundoplication.

Introduction

Laparoscopic surgery is a rapidly growing field, due to the advantages for the patient and cost benefits, but it brings a lot of challenges to the surgeon [1,2]. Common complications are tissue damage leading to haemorrhage or organ perforation, due to using excessive force, uncontrolled movements or movements that are outside the view of the camera [3-5]. The outcomes of laparoscopic surgery can be improved with extensive training, good training facilities, and smart technical solutions. Despite of a broad range of laparoscopic training systems, from box trainers with animal tissue to Virtual Reality simulators [6], there is room for improvement in the training and assessment process of laparoscopic procedures outside the clinical setting [7].

The haptic feedback (which refers to sensing and manipulation of objects through touch) in open surgery differs significantly from the haptic feedback received during laparoscopic surgery [2]. The haptic feedback is decreased in laparoscopic surgery, but not absent. Together with the visual cues on the screen, the haptic feedback received through the instruments give information on the surface texture, shape, and elasticity of the organs and tissues [2,8]. The haptic feedback during a laparoscopic procedure will never be exactly the same, because the context (use of various instruments and trocars, and individual variance between patients) will be different [2,9]. Training with haptic feedback can help trainees to understand the interfering components and learn to estimate their influence on the feedback they receive. It has been shown in previous studies that the training of laparoscopic suturing with haptic feedback is more effective and preferred over training without realistic haptic feedback [10-14]

When haptic feedback is available during the exploration of the three-dimensional (3-D) objects, individuals develop more understanding of the 3-D operating field than when only visual feedback is available [15]. One aspect of haptic feedback is active manipulation that adds the element of choice, control, and conscious movements, which makes learning more engaging and motivating to trainees [15,16]. The models of haptic object-exploration developed by Klatzky and Lederman (1993) suggest that procedural knowledge of what to do and information acquired 'on line' during exploration both contribute to the fidelity and precision of haptic perception [17].

When looking at the training materials that are currently used for procedural laparoscopic training [7,18] two major problems are encountered. Firstly, to simulate realistic haptic feedback the VR simulators are not sufficient [10,14], therefore animal tissue models are used for the training of laparoscopic procedures. The draw back of animal tissue models is not only the difference from human anatomy, but of more importance are the risk of

infections and the growing attention for animal rights. The latter objection has led to increased costs and new legislations which complicate the use of animals for training purposes. The second problem during the training of laparoscopic procedures is the assessment of the performance. This is currently still done by an expert observer during the training course, however this is subjective and costly [10]. An objective assessment based on standardized steps and error scores, in which there is no need for an expert observer, is good to monitor the progression of the trainee, until they have reached the performance goals.

Laparoscopic suturing is an advanced laparoscopic skill, which can be used in several procedures. To develop a model suited to elevate the suturing training to a higher level, the Nissen fundoplication was chosen. This is a procedure used to treat gastro-oesophageal reflux disease (GERD), and requires suturing under tension in several planes. It is of paramount importance to train these skills before performing them in the clinical setting. As discussed before, VR lacks realistic haptic feedback, which is of paramount importance in laparoscopic suturing training [10,14], and does not serve a purpose in suturing training. For this purpose a realistic model was developed for the laparoscopic Nissen Fundoplication, which simulates the human anatomy realistically, and could minimize the use of animal tissue models. This article elaborates the designing process of this model and the development process to create the abdominal organs and tissue with realistic haptic feedback.

Materials & Methods

Model

Before developing the model and artificial organs for the Nissen fundoplication, the human anatomy was gathered from a 3-D representation of full body CT-scans, to obtain the correct measurements of the organs to be created. Next, the mechanical characteristics of the tissue were examined and the material that resembled this the closest was used to produce the separate organs. The model included the parts that are important for the training of the fundoplication in both visual and tactile aspect. This means that all the anatomical structures that can be seen or touched during the execution of the procedure were integrated in the model (Table 1). If an organ was not important on the progress of the procedure and the acquisition of skills by the trainee, or could not be mimicked realistically, it was not integrated in the model.

The most important aspect in the development of the model was the choice of material to use for the production. To realize a product that can compete with the use of animal tissue models, it is of great importance that the material will be perceived as realistic. This is when

the properties closely approach the properties of real human tissue. However, human and animal tissue are very complicated material that consist of several layers and therefore the properties depend on the amount of layers, the layer thickness, the orientation of muscular fibres, moisture level, temperature, etc. For example the stomach wall is comprised of Tunica mucosa, Tela submucosa, Tunica muscularis, Tela subserosa, and Tunica serosa (from inner layer to outer layer). There is very limited information on the mechanical properties of abdominal tissue, which made it challenging to develop the organs for this model resembling realistic properties.

Material selection

The haptic feedback of the intra-abdominal organs consists of several variables [19], which can be divided in three main groups: tissue, geometry and context (Figure 1) [8]. The mechanical properties of the tissue are of great influence on the haptic feedback, and consist of several aspects [20]. Firstly the E-modulus (Young's modulus of Elasticity) is a measure for the rigidity of the material. A high modulus means that the material has a high resistance against deformation. Another important aspect is the density of the material that is used for the simulated tissue. When lifting or pulling at the artificial tissue or organs gravity will partly determine the size of the haptic feedback. If a material with a much lower density than the actual organ is chosen, the volume of the simulated organ should be much larger to match the weight and haptic feedback of the actual organ. This will inevitable result in changed dimensions or wall thickness, two aspects that can not be adjusted without compromising an accurate feedback. The hardness of the material is together with the E-modulus important for the behaviour of the material. The material used for the simulated organs and tissue should not be sensitive to tearing, at least not more than the actual tissue, as this diminishes the haptic feedback. When during suturing of the wrap, for example, the stomach would tear, it gives a different haptic (and visual) feedback than in a clinical setting, and would make an objective assessment impossible. For artificial tissue another important aspect is the shelf live, as material can deteriorate over time, which can change the properties of the simulated tissue and therefore the haptic feedback. However, a simulated model with a long shelf live can be used over a long period of time, while animal tissue models can only be used once.

Organ	Important aspect for model
Stomach	- With part oesophagus entering the mediastinum - Flexible enough for a floppy wrap - Able to suture without tearing - Quality of the wrap should be able to be evaluated (objective assessment)
Crura	- Able to suture without tearing - Quality of the closing of the crura should be able to be evaluated (objective assessment)
Liver	- Must be able to be retracted, or already in retracted position
Spleen	- Must be able to connect short gastric vessels (vasa brevia) to
Greater omentum	- With gastro-phrenic ligament and short gastric vessels - Able to dissect using ultrasonic dissection or equivalent option
Lesser omentum	- Possibility of adding vagus nerve and left gastric artery - Able to dissect without tearing

Table 1: Important aspects of organs and tissue in the model for performing the laparoscopic Nissen fundoplication.

Geometry is the second variable which influences the haptic feedback of the model. The size and shape of the artificial organs have to be accurate to perform the procedure as realistic as possible. When for example the fundus of the stomach is too small the wrap cannot be made, which makes it impossible to perform a Nissen fundoplication on the model. The wall thickness is another aspect that is important in the haptic feedback, as shown in Figure 1. Also when suturing the wrap the wall of the stomach should be in the same range of size as an actual stomach to produce a proper floppy wrap.

The context refers to the rate of connectivity and method of the connection of the organs to the connecting tissue. In the model the force that is needed to detach a simulated organ from the surface is the rate of connectivity. The method of connection between moveable parts in the model, e.g. stomach and omentum, also influence the haptic feedback. When the connection is too rigid a much larger force than in the clinical setting is needed to dissect the tissues from each other, or maybe the wrap can not be made.

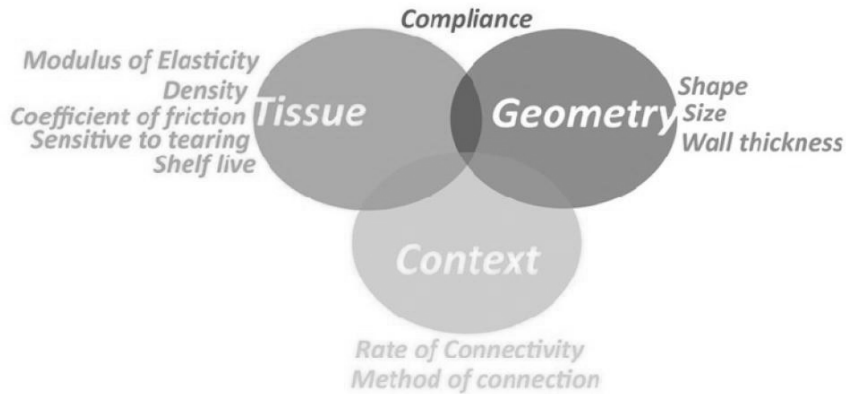


Figure 1: This figure shows the important variables and aspects, with their inner relations that influence the haptic feedback of the tissue and organs in the model.

To visualize the E-modulus the stress–strain curves of the different tissues were researched and compared with the properties of industrial materials to find the best material to use for the production of the organs (Figure 2). The stress-strain curve is a graphical representation of the relationship between stress and strain on a tissue that is obtained by testing. Stress is described as the force applied to a specific surface area. Strain is defined as the amount of deformation of the test piece compared to its original length. Every material has its own stress-strain curve. Based on the stress strain curve materials can be grouped and some characteristics can be derived from the shape of the curve. The E-modulus corresponds to the slope of the linear segment in the stress-strain curve. The area under the linear segment indicates the elastic deformation of the material.

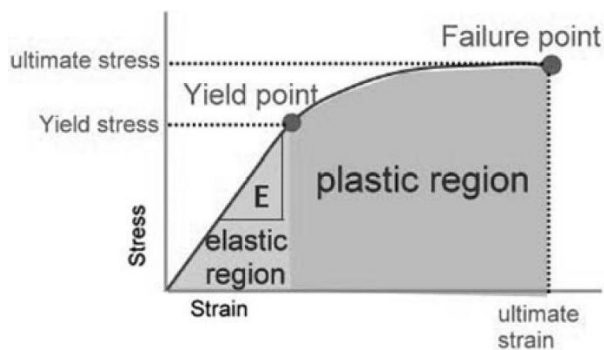


Figure 2: This is the stress-strain curve with the corresponding characteristics of different materials.

Results

The aspects influencing the haptic feedback, as determined above, were used to select the most promising material groups to develop the organs and base. These aspects were: E-modulus, density, coefficient of friction, sensitivity to tearing, wall thickness, and shelf life. The most challenging and most important organ to produce for this model was the stomach, of which the E-modulus was calculated from the stress-strain curve derived from the porcine stomach (E-modulus of 0.3-0.6 MPa) (Figure 3). It was assumed that for the application in the model the begin section of the curve would be the most interesting, because the forces used in laparoscopic surgery are very low and small deviations will be noticed better. Therefore the initial E-modulus (between 2 and 4% elongation) was measured by calculating the slope between 2% and 4% strain on the curve (Figure 3). In retrospect, when looking at the course of the stress-strain curve of the silicone materials and the tissue it would have been more accurate to measure the E-modulus over a strain of 10-40%. This is because the curve of the porcine tissue was very steep in the beginning, while between a strain of 10-40% strain the E-modulus did not change so rapidly. This insight, however, did not change the conclusions of the tests and was therefore not repeated to obtain the E-modulus at different points on the curve.

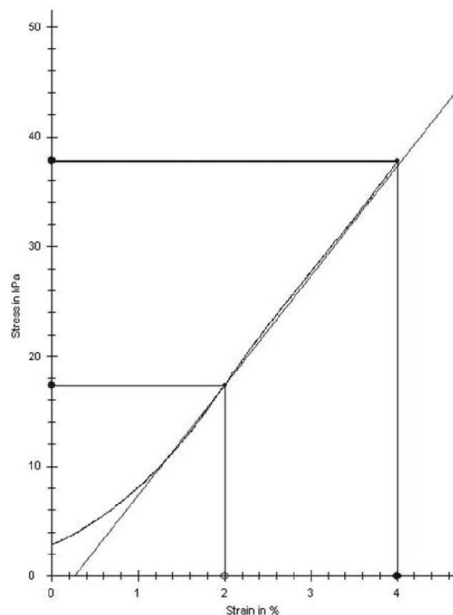


Figure 3: The initial E-modulus of porcine tissue, calculated between 2-4% strain on the tissue.

The initial E-Modulus of tissue was similar to that of undiluted silicon rubbers. However the undiluted silicon material did not have the correct compliance to mimic the behaviour of flexible tissue. The stomach wall with thickness 3 mm and an E-modulus of approximately 0,5 MPa adapted its form to underlying structures, while the silicone rubber with a thickness of 3 mm and E-modulus of 0,5 MPa was a rigid plate and not easily deformable. The silicone rubbers with 30% silicone oil approached the flexible behaviour of tissue, but had a very low E-modulus compared to tissue, therefore it deformed too easily. To come to a suitable material that could mimic tissue different materials were combined. Fibres are often used to increase the tensile strength and E-modulus of soft materials. For this purpose an open fabric with relatively large meshes was used in the form of elastic bandages, the inner layer of the stomach wall, with eurosil orange with 30% silicone oil as the outer layer of the stomach wall. This however did influence the elasticity of the stomach wall, which was too rigid and therefore made it difficult to create the wrap properly. The fabric layer did prevent tearing of the tissue during the creation of the wrap and the suturing of it, which could happen when using only silicones.

The density of the stomach wall should be approximately 1.06g/cm^3 [19]. The coefficient of friction of latex and silicone gels resembled the smooth and moisturized surface area of the human tissue the closest, which would produce the most realistic haptic feedback during the suturing. This is important for both the stomach and the crura. For the suturing and handling of the tissue, it is also important that the tissue does not tear during the procedure. The crura are two muscle straps, which were simulated from silicone rubber and were solid enough to create the proper sutures under tension, to pull both crura together during the procedure.

The shelf life of the model with the tissue is also important to produce a cost effective model. Latex can deteriorate, depending on environmental circumstances, but this can be controlled by adding preservatives. The silicones used nowadays also have a much longer shelf life than ten years ago.

Silicone and latex materials were the most promising materials to mimic tissue based on the criteria used. They were suitable because they have a density that approaches tissue, are easy to process, can be soft and flexible and are commonly available. When silicone is used the resistance to tearing is a point of attention. After some experiments with different silicone rubbers and latex, silicone turned out to be a more promising material, because it is easy to process and the properties of the material can be tuned. Latex has a very long curing time compared to silicone rubbers, and is more sensitive to shrinkage. It is also more difficult to find the right ingredients and concentration to soften the latex. The connections of the organs to the surface and other artificial tissue were made of velvet rope, so they were replaceable in

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the model. Table 2 shows the material selections of the organs and tissue used to develop the model. Figure 4 shows the model when used for the training of the laparoscopic Nissen Fundoplication. Because a few parts (omentum and peritoneal layer over crura) have to be replaced after each training, all the parts were connected together in a way that they can be replaced easily.

Individual part of artificial model	Selected materials
Base	- Low temperature thermoplastic splinting material - Wooden box - Clips - Velcrow
Stomach	- Eurosil silicone rubber orange 10 - Silicone oil - Elastic bandage - Velcrow - Push buttons
Oesophagus (attached to stomach)	- Eurosil silicone rubber orange 10 - Silicone oil - Elastic bandage
Omentum (with short gastric vessels)	- Polyservice silicone rubber (vessels) - Red & blue pigment (vessels) - Latex (omentum) - Velcrow - Push buttons
Crura	- Polyservice silicone rubber - Red & brown pigment - Velcrow
Spleen	- Eurosil silicone rubber - Silicone oil - Brown pigment
Liver	- Polyservice latex - Red & blue & green pigment
Phreno-esophageal ligament	- Polyservice latex

Table 2: For each organ and tissue to be simulated in the model the material is chosen which resembled the human haptic feedback and visual aspects the closest.

Discussion

While many studies have investigated the human perception of force (and weight), almost all are concerned with the magnitude of forces, but not the direction. However, there is no doubt that force directions are important in describing the overall shape, friction, and viscosity of an object [21]. Therefore, it is important that during the training of procedures the trainee receives the proper haptic feedback to realize the shape of the organ. This kind of haptic feedback is extremely difficult to develop in Virtual Reality (VR) simulators [22], but when using real tissue, like in Augmented Reality (AR), this important aspect is already been accounted for.

This is why it is important to develop a realistic model, which will give the proper haptic feedback in the proper direction to the trainee, to implement in an AR simulator. Currently, procedures like the laparoscopic Nissen Fundoplication are often trained in animal tissue models or live animals, but they do not provide any assessment of the procedure. This can be provided by an AR simulator, additionally to the realistic haptic feedback and step-by-step guidance during the training.

The first challenge of the development of this model was to create the organs realistically, in order to perform a laparoscopic Nissen Fundoplication on it. For this purpose various materials were researched to select the best choice for the various organs and tissue to be simulated. The stomach was the most challenging organ to create, because the haptic feedback should be as realistic as possible to create a proper wrap. Therefore the stomach wall was build up from two parts: an inner layer with fabric and an outer layer with silicone rubber. However this still lead to a stomach wall that was still a bit too rigid to create a proper wrap. The crural closure in this procedure is under tension, therefore a proper crura had to be created in which the trainee has to suture under tension to achieve a proper crural adoption, like in the clinical setting.

To guarantee a proper training it is important that the training tools are of sufficient quality [18], but it is equally important that the trainee is motivated to keep training until the skills and procedures are mastered. The motivation of the trainee will depend partially on the attraction and realism of the model to the trainees, but secondly also on unrelated aspects. For example whether the training is mandatory or voluntary can influences the motivation. The anatomy of the model for the Nissen Fundoplication is realistic as it mimics the human anatomy, because it is based on 3-D imaging of human CT-scans. In animal models the anatomy differs a lot from the human anatomy, which makes it more difficult to learn the proper steps of the Nissen Fundoplication. However, the dissection of the tissue can be simulated more realistically on animal tissue models, as this could not be created realistic in

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the model. In animal tissue models the anatomy can be divers as in the clinical setting, which makes it more difficult to rate a performance objectively. The Nissen model represents the normal human anatomy, but it is possible to create anatomic variation to make it more challenging to the trainee. One example is a variation in the length of the short gastric vessels and the position of the vagal nerve and hepatic branch in the lesser omentum. They could be simulated less obvious, because this can be various in the clinical setting as well.

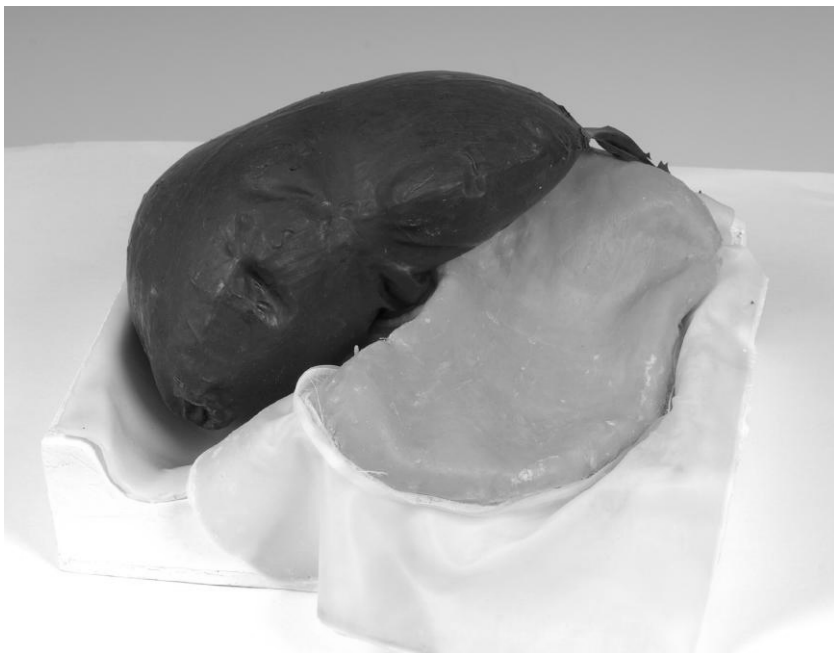


Figure 4: The model for the Nissen Fundoplication, as an overview picture. During the training the model is placed inside a traditional box trainer and the liver should be held up, to show the operating field.

Developing a realistic model for the Nissen fundoplication

A comparison was made between the use of animal tissue models and the model of the upper abdomen, which is presented in Table 3. This is to show the advantages and disadvantages of the different training models and the potency of the development of this model. As can be seen from this Table, the model has many advantages over the animal tissue model, however for the dissection of tissue and recognizing different tissues and organs, the animal tissue model is a good option. But the characteristics of animal tissue models differ significantly from live tissue [20].

Table 3:	Animal tissue model	Artificial model
Advantages and disadvantages of the training models		
Advantages	- Realistic visual aspects - Approaching realistic haptic feedback*	- Representation of human anatomy - Unlimited preservation - Easy to obtain - Fixed costs - Possibility to integrate assessment method - Approaching realistic haptic feedback
Disadvantages	- Different from human anatomy - Limited preservation - Difficult to obtain - Increasing costs, due to legislation - Risk of infections - No possibility integrate assessment method	- Abstracted anatomy and visual aspects

Table 3: Comparison of animal tissue models and the developed model.

** The characteristics of animal tissue is significantly different from live tissue [20].*

Conclusion

As a result of the development process a reusable modular model of the upper abdomen anatomy was created, applicable for the training of procedural training, such as laparoscopic Nissen Fundoplication. The model offers the opportunity to practice the procedure with a better representation for the human anatomy in comparison to animal tissue models.

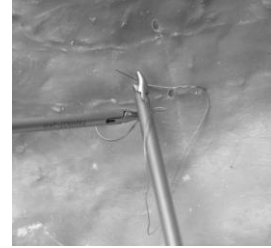
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Chapter 10



Training of the laparoscopic Nissen Fundoplication on an artificial model: Replacing animal tissue models?

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Jack J. Jakimowicz

Submitted

Abstract

Introduction

An artificial model for the upper abdomen was developed, as an alternative for the often used animal tissue models, to bridge the early learning curve in the clinical setting, to a safe environment. The goal of this study was to develop a reusable model with relatively low costs, as a good training tool for the laparoscopic Nissen Fundoplication.

Method

From artificial organs and tissue an anatomical representation for the human upper abdomen was developed for the training of the laparoscopic Nissen Fundoplication. Following, the participants and tutors of an EAES (European Association for Endoscopic Surgery) Upper gastro-intestinal surgery course (N=20) evaluated the realism, haptic feedback and training properties of the model, and compared it with animal tissue models.

Results

The main difference in opinion between the two training models was seen in the properties of the stomach. The wrapping of the stomach of the artificial model was rated significantly lower than the stomach of the animal tissue model (mean 3.6 vs 4.2, $p=0.010$). The main critics on the stomach of the artificial model was that it was too rigid to make a proper wrap. The suturing of the stomach wall, however, was regarded as fairly realistic (mean 3.6). The crura were rated better on the artificial model (mean 4.3) than on the animal tissue (4.0), although, this was not significant. The participants regarded the model as a good to excellent (mean 4.3) training tool.

Conclusion

This newly developed model is regarded as a good training tool for the laparoscopic Nissen Fundoplication procedure. It is cheaper, more durable and readily available to train on and can therefore be used in every training centre. The stomach of this model, however, still needs improvement, because it is too rigid to make the wrap.

Introduction

Laparoscopic Nissen Fundoplication has been shown to be safe and as effective as open Fundoplication [1-6], and has become the preferred surgical option [1,2]. However, there have also been reports on the unique complications of the laparoscopic approach, compared to the open Nissen Fundoplication, such as esophageal perforation, acute para-esophageal herniation, stenosis of the esophageal hiatus and pneumothorax [6-8]. Also a higher re-operation rate was reported at the early stages of the laparoscopic approach, which decreased with increasing experience [5,7,9]

Laparoscopic Fundoplication requires the ability to perform an operation in multiple planes within a three-dimensional environment on two-dimensional visual feedback. The acquisition of these skills, along with the need to acquire facility with new instruments, suturing techniques, and new technological devices are challenges in performing a safe and effective operation [1,7].

A learning curve of twenty procedures per surgeon individually has been previously established for laparoscopic Fundoplication [1,7,10], although it is recognized that individuals may progress at different rates. Various factors may influence the length of a learning curve and its consequences to patients [7]. Important indicators on the learning curve for laparoscopic surgery are the conversion rate and operative complications. By examining individual experiences, it is apparent that problems were most likely during the first five procedures performed by individual surgeons [7], with a rate of 24-55% at the beginning of the learning curve [1,4,7,9]. Complications, re-operations, and conversion rates declined to approximately 10% during the next 15-25 procedures, with little further improvement beyond this point [7]. Most conversions during the first twenty cases were for technical reasons, such as adequately dissecting the posterior "window" behind the oesophagus, the division of the short gastric vessels and fundal mobilization, closure of the diaphragmatic crura, and suture of the fundoplication [1]. Once these steps were learned, conversion rates remained low (2%-10%) [1,5,7,9,10].

Currently, animal tissue models are used regularly in skills centres to train the laparoscopic procedures, such as the Nissen Fundoplication, outside the clinical setting [11,12]. The animal organs are prepared and preserved until they are used for practice. However, these animals are usually specially bred for these purposes and therefore expensive. In a few selected centres, they still practice their procedural skills on live animals, but because of ethical objections and high costs these are not used frequently.

To have an alternative for the animal tissue models, an anatomical model of the upper abdomen was developed to train the laparoscopic Nissen Fundoplication. This can be combined with an instruction video and step-by-step demonstration videos, to bridge the early learning curve in the clinical setting, to a safe environment. The goal of this study was to develop a reusable model with relatively low costs, which can be used as a training tool for the laparoscopic Nissen Fundoplication.

Materials & Methods

Artificial model

Before developing the organs the mechanical characteristics of the tissue were examined, and the material that resembled the characteristics the closest was used to produce the separate organs. The physical proportions of the organs were derived from three-dimensional imaging of a CT-scan of the human anatomy, to resemble the clinical setting closely. The model included the parts that are important for the training of the laparoscopic Nissen Fundoplication in both visual and tactile aspects. This meant that all anatomical structures that could be either seen or touched during the execution of the procedure were integrated in the model. If an organ could not be mimicked realistically, or did not have a significant influence on the training of the procedure, it was excluded from the model. The model (Figures 1 and 2) included: the stomach with omentum minor and major and the short gastric vessels (vasa brevia) attached to it; esophagus attached to stomach, which entered the mediastinum through the opening between the crura; the crura was covered with a peritoneal layer, which had to be dissected to free the esophagus; the liver had to be held up by a liver-retractor to visualize the operating field; and the spleen, to which the short gastric vessels were connected. The connections between the different organs were either by velcro, pins or buttons, to make it easy and fast to replace the disposable parts (peritoneal layer over crura and omentum with short gastric vessels). The stomach and crura could be used 15-20 times, but the peritoneal layer and omentum were replaced after every practice.

Training module

The procedure of the laparoscopic Nissen Fundoplication [1,6,13,14] was divided into steps, to determine the importance of each step to be trained preclinical. The ability to perform these steps of the procedure on the model and the importance of each steps, together with the limitations of the model itself, concluded in four component tasks, which could be trained on the model (Figure 4).

Training of the Nissen Fundoplication on an artificial model



Figure 1: The artificial model for the Nissen Fundoplication, in which the liver held up to show the operating field



Figure 2: The vision of the artificial model, when shown on the screen during the performance of the Nissen Fundoplication. The liver is being held up by a liver retractor.

Protocol

After the model was developed and the procedure was divided into the component tasks, the participants were asked to complete the selected tasks on the model, which was placed in a box trainer. Before the start of the training the participants were shown an introduction video and before each task a step-by-step demonstration video of the corresponding part of the procedure to be performed.

After performing the procedure on the model, the participants filled out the questionnaire to evaluate the realism and haptic sensations of the artificial organs and the anatomical model as a training environment for the laparoscopic Nissen Fundoplication. The target group also

practiced the laparoscopic Nissen Fundoplication on a validated animal tissue model [15] as part of an upper gastro-intestinal surgery course at the Cuschieri skills centre, Dundee, Scotland (Figure 3). The experienced surgeons all had previous experience with training on animal tissue models. Next, the participants gave their preference on the training of this procedure on either this model or the still often used animal tissue models.

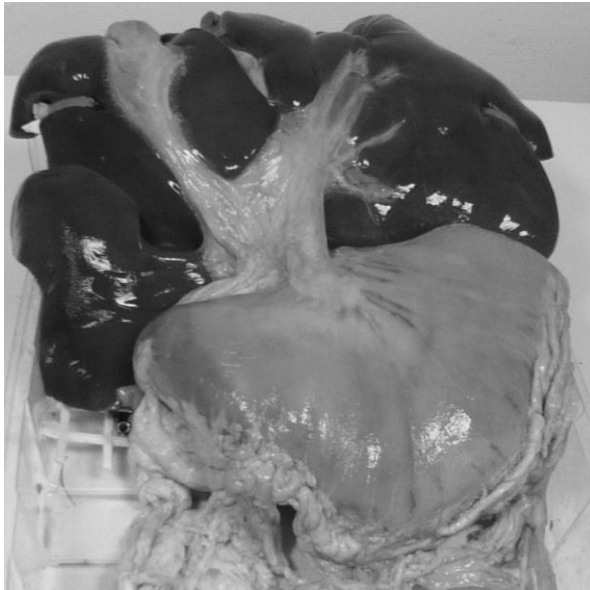


Figure 3: The animal tissue model as used in the Upper gastro-intestinal Surgery course [15].

Subjects

Both the participants and tutors of the EAES (European Association of Endoscopic Surgery) Upper gastro-intestinal surgery course at the Cuschieri skills centre, Dundee, Scotland, from 23-26 September 2008, completed this study (N=20). The participants of the course first received the initial training on the animal tissue models, after which they practiced on this model, to have a reference point. The tutors were all experienced with laparoscopic suturing, the Nissen Fundoplication procedure and the use of animal tissue models.

Questionnaire

The questionnaire used to evaluate the model was divided in four parts. The first part on demographics and laparoscopic experience; The second part contained questions about the realism and haptic feedback on both the model and animal tissue models, rated on a five-point Likert scale; The third part was on the training properties of the model and whether it would serve as a proper training for the Nissen Fundoplication. In the last part the opinion on the separate organs was asked, with regards to visual aspects and haptic feedback. The

questionnaire was completed with an open-ended question for remarks and improvements on the model and tasks.

Statistics

All data was processed and analysed using SPSS (Statistical Package for the Social Sciences) 13.0. A statistically significant differences ($\alpha = 0.05$) in opinion between the model and animal tissue model were set on a difference in the rating of at least 0.7 points, on the five point Likert scale, with a maximum standard deviation of 0.90 and a power of 80%. This calculated to a sample size of twenty subjects.

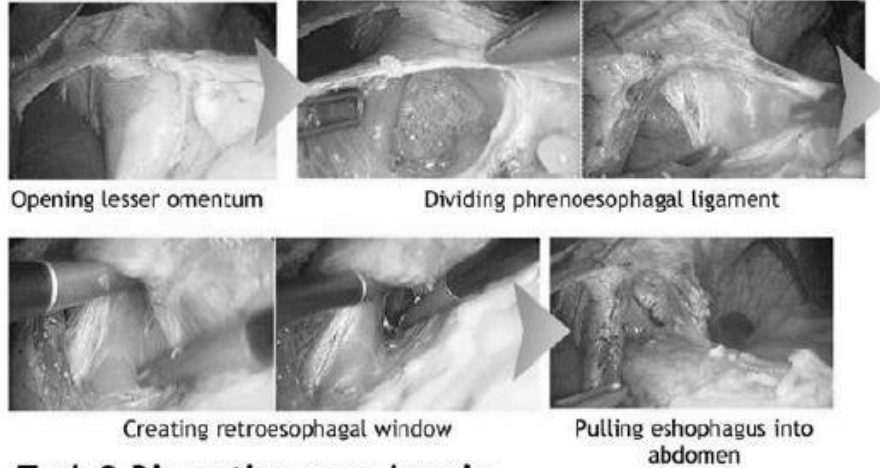
The results of the properties of the model, not compared to the animal tissue model, are compared with the null hypothesis of a neutral opinion on the model (mean 3.0). A p value of under 0.05 shows a significantly better or worse opinion than a neutral opinion on the model.

Results

Figure 4 shows the four complement tasks that could be practiced on the model by the participants. In the first task the lesser omentum had to be opened, then the phreno-esophageal ligament had to be divided to free both the left and right crus, following, the esophagus had to be totally free and the participant should be able to pull it into the abdomen. In the next step the short gastric vessels (vasa brevia) had to be dissected, to ensure that the fundus would be mobile enough to make the wrap. Therefore, also the gastrophrenic attachment had to be dissected. In the third task the crura had to be sutured with two thumb knots. Then the wrap could be made, which had to be closed with three sutures to make a proper wrap around the esophagus. The end points of the procedure were the proper closure of the crura with two sutures and the wrap, which was not too tight, closed with three sutures over a length of 1.5-2.0 cm.

All participants had experience with laparoscopic procedures, and seventeen also with general upper gastro-intestinal procedures. All had previous experience with laparoscopic suturing, either in the clinical setting or in box trainers. Twelve participants had previous experience with the laparoscopic Nissen Fundoplication and eight had not. However, there were no significant differences found in the ratings on the model between these two groups. Table 1 shows the difference in opinion of the participants between this artificial model and animal tissue model. The main difference in opinion between the two training models is seen in the properties of the stomach. The stomach of the artificial model was rated significantly lower than the stomach of the animal tissue model. The main critics on the stomach of the

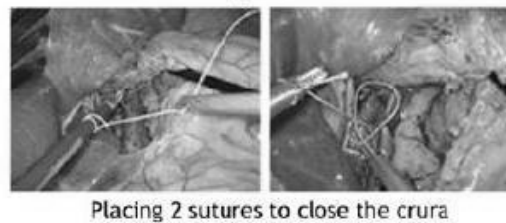
Task 1 Dissecting the crura



Task 2 Dissecting vasa brevia



Task 3 Suturing the crura



Task 4 Creating the wrap

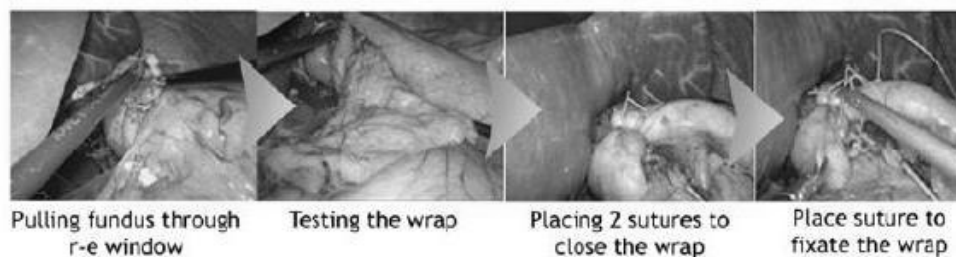


Figure 4: The four complement tasks of the Nissen Fundoplication that could be performed on the artificial model.

Training of the Nissen Fundoplication on an artificial model

artificial model was that it was too rigid, the fundus was not flexible enough to make a proper wrap. The suturing of the stomach wall however, was regarded as fairly realistic (mean 3.6, Table 2). The creation of the retro-esophageal window was also regarded as significantly less on the artificial model than on the animal tissue model (Table 1). The crura was rated better on this model than on the animal tissue model, however this was not significantly (Table 1).

The properties of the crura were rated as realistic (means 3.8-4.0), which is a significant better result, compared to a neutral opinion. The other organs in the model were also rated by the participants: the omentum was rated a 2.6 on visual appearances and flexibility ($p=0.042$ respectively 0.025) and a 2.5 on haptic feedback ($p=0.014$), the main remark was that it did not look realistic and should be more transparent, but that it was not essential for the model and served its' purpose. The liver was rated with a mean of 3.25 ($p=0.287$), the spleen 3.5 ($p=0.009$) and the esophagus 3.6 ($p=0.012$).

Table 1: Ratings on the complement tasks of the Nissen fundoplication	Artificial	Animal tissue	p-value
	model	models	
	Mean (<i>standard deviation</i>)		
Task 1:			
- Dissecting lesser omentum	3.3 (<i>0.79</i>)	3.2 (<i>1.04</i>)	0.649
- Dissecting phreno-esophageal ligament	3.4 (<i>0.75</i>)	3.5 (<i>1.00</i>)	0.606
- Creating retro-esophageal window	3.2 (<i>0.83</i>)	3.7 (<i>0.92</i>)	0.014
Task 2:			
- Dissecting vasa brevia	3.2 (<i>0.82</i>)	3.4 (<i>1.09</i>)	0.834
- Freeing the gastro-phrenic ligament	3.3 (<i>0.81</i>)	3.3 (<i>0.95</i>)	0.806
Task 3:			
- Suturing of the crura	4.3 (<i>0.55</i>)	4.0 (<i>0.86</i>)	0.234
- Bringing crura together	4.3 (<i>0.57</i>)	4.1 (<i>0.64</i>)	0.104
Task 4:			
- Pulling fundus through retro-esophageal window	3.2 (<i>1.23</i>)	4.1 (<i>0.61</i>)	0.004
- Creating the wrap	3.6 (<i>0.89</i>)	4.2 (<i>0.75</i>)	0.010

Table 1: These are the ratings of the artificial model and the animal tissue model for the laparoscopic Nissen Fundoplication given by the participants (N=20. They were rated on a five-point-Likert scale, in which 1 is really unrealistic, 3 neutral, and 5 very realistic. The p-value was calculated with the paired t-test, a $p<0.05$ was considered a statistically significant difference.

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The general remarks given at the end of the questionnaire were: (very) good (n=10), effective model (n=2), excellent for training (n=1), very nice (n=1), anatomy is superior to animal tissue models (n=1).

When asking about the potential as a training tool for the Nissen Fundoplication to surgical residents, the model was rated good to excellent (mean 4.3) and as a replacement for the animal tissue model, it was rated with a mean of 3.5 (Table 3). On the question if the participants thought this model was a proper trainer for the laparoscopic Nissen Fundoplication, fifteen participants felt it was a proper training instrument.

Table 2: properties of organs in artificial model	Rating	p-value
	Mean (standard deviation)	
Stomach		
- Shape	3.8 (0.61)	<0.001
- Size	3.8 (0.70)	<0.001
- Flexibility of stomach wall	2.3 (0.87)	0.002
- Haptic feedback of stomach wall in grasper	2.7 (0.98)	0.186
- Haptic feedback during suturing	3.6 (0.83)	0.008
Crura		
- Shape	3.9 (0.64)	<0.001
- Size	4.0 (0.46)	<0.001
- Haptic feedback during suturing	3.8 (0.72)	<0.001

Table 2: This table shows the rating of the several properties of the organs of the artificial model, given by the participants (N=20). This was rated on a five-point-Likert scale in which 1 is really unrealistic, 3 neutral, and 5 very realistic. The p-values were calculated with the one-sample t-test, when comparing the rating to the neutral opinion of 3.0, a $p < 0.05$ was considered a statistically significant difference.

Training of the Nissen Fundoplication on an artificial model

Table 3: Training properties of artificial model	Rating	p-value
	Mean (standard deviation)	
Training tool for surgical residents	4.3 (0.57)	<0.001
Training tool for surgeons	3.6 (1.00)	0.014
Replacing the animal tissue model	3.5 (0.76)	0.016
Replacing animals under anaesthesia	2.9 (1.15)	0.695

Table 3: These are the rating of the training properties of the artificial model for the laparoscopic Nissen Fundoplication given by the participants (N=20), rated on the five-point-Likert scale. The p-values were calculated with the one sample t-test, when comparing the rating to the neutral opinion of 3.0, a $p < 0.05$ was considered a statistically significant difference.

Discussion

A Nissen Fundoplication prevents the occurrence of transient lower oesophageal sphincter relaxation [3,5,14], it even increases the distal esophageal sphincter to a height three times the pre-operative levels. This new 360 degrees high-pressure zone restores the competence of the esophago-gastric junction, thus eliminating both acid and non-acid gastro-oesophageal reflux [3,14]. With regards to reflux control there is no difference between the laparoscopic and the open procedure. However, the complication of persistent severe dysphagia has been reported to be higher in the laparoscopic procedure, compared to the open procedure [2,6,14]. Both the length and tightness of the Fundoplication [2,6,16], and the division of the short gastric vessels [6] play a part in this complication. This model allows training and objective assessment of the essential technical skills of crural closure and creating a wrap around the esophagus, to minimize these kinds of complications in the clinical setting.

Animal tissue models and live animals are used quite regularly to train procedures before performing them on patients [11,12]. However, as stated in the statements of the American College of Surgeons, only as many animals as necessary should be used; Any pain or distress animals may experience should be minimized or alleviated; And, wherever feasible, alternatives to the use of live animals should be developed and employed [17]. Other drawbacks of animal tissue models are the costs, short preservation period and it can only be used once. Next to this, the haptic feedback of dead tissue is different from living tissue [18]. Another important aspect in animal models is the infection rate, and therefore it cannot be used in hospital settings, only in specialized animal labs. An artificial model, however, with reusable organs and replaceable tissue, that can be used over and over again, is more cost effective. In this model only the peritoneal layer over the crura and the omentum with the

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short gastric vessels have to be replaced after each practice, but the stomach and crura can last for approximately 15-20 procedures. A modular model, as presented in this study, allows the exchange of organs or tissue on demand, which is not the fact in animal tissue models. This way, the costs per training can stay low and is therefore accessible for all training centres and hospitals. This model is also easier to preserve, has a better scent than animal tissue models, is portable and can be used in any skills centre that has at least one box trainer.

Limitations

The most important aspect in the development of this model was the material to use for the production. To realize a product that can compete with the use of animal tissue, it is of great importance that the material is perceived as realistic. This is when the properties closely approach the properties of real human tissue. However, human and animal tissue is very complicated material that consists of several layers and, therefore, the properties depend on the amount of layers, the layer thickness, the orientation of muscular layers, moisture level, temperature etc. There is very limited information about the mechanical characteristics of human abdominal tissue, which made it challenging to develop the organs for this model resembling realistic characteristics.

The participants of this study regarded the artificial stomach as less realistic than the stomach in the animal tissue model to make a proper wrap. This was because the artificial stomach was too rigid and the stomach wall was slightly too thick. This aspect should be improved to make the model more suitable for training of the laparoscopic Nissen Fundoplication. Also the colour could be more realistic, as it looked a bit too orange, which made it less realistic, on the screen however it looked less bright (Figures 1 and 2). The haptic feedback during the suturing was regarded as realistic, and this property of the stomach should, therefore, not be changed. The crura were regarded as realistic and most participants preferred to train this task on this Nissen model, instead of an animal tissue model. The human anatomy is quite different from the porcine anatomy, which makes it a different kind of procedure that you are training on the animal tissue model. For practicing the dissection of tissue, which is for example connected to the esophagus, an animal tissue model is regarded as superior, as this was not possible to simulate realistically in this model. The step of dissecting is implemented in the tasks (Figure 4), but in a simplistic form, to learn the sequence of the procedure to the trainee.

In the Middle Eastern countries, animal tissue models cannot be used for training, because of ethical reasons; therefore a model with the proper anatomy could be a good way to train these kind of advanced procedures on.

Conclusion

This new developed artificial model is regarded as a good training tool for the laparoscopic Nissen Fundoplication procedure by the participants of this study. It is cheaper, more durable and readily available to train on and can therefore be used in every training centre. Further improvements on the stomach are necessary, because in the current form it is too rigid to make a proper wrap around the esophagus.

We recommend the development of these models for more laparoscopic procedures, this to replace the animal models, such as porcine cadaver models and pigs under anaesthesia, which are still used in skills centres.

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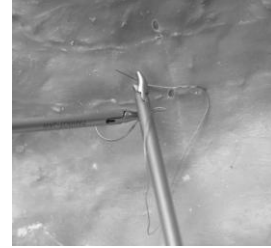
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Chapter 11



Discussion and Future developments

Discussion

Laparoscopy differs from open procedures in the skills that are needed to perform this kind of surgery safely. To take advantage of this minimally invasive approach skilled and well trained surgeons should perform the procedures. However, it is difficult and time consuming to learn these skills to the surgeons in training in the clinical setting. This has also been stated by the Dutch Inspection for Health Care in November 2007. It is stated that laparoscopy is a good surgical approach with a lot of advantages, however, at that moment they were applied to easily. Too many surgeons regarded this technique too optimistic, and underestimated the risks and complications of this approach. From the research of the Inspection there were too many complications that could be accounted for by lack of experience. Therefore, these complications could be reduced by training of surgeons (and surgical residents), and maintaining these skills after the proficiency level has been reached. For this purpose, different kinds of laparoscopic simulators are on the market to train these skills outside the clinical setting, ranging from traditional box trainers, Virtual Reality (VR) and Augmented Reality (AR) simulators. Traditional box trainers contain realistic haptic feedback during the practice, but lack objective assessment of the performance. VR simulators provide explanations of the tasks and an objective assessment at the end of the performance, but they lack realistic haptic feedback. Augmented Reality simulators, however, combined the benefits of the realistic haptic feedback from the traditional box trainers and the objective assessment of the VR simulators.

The first question raised in this thesis was the availability of different Augmented Reality simulators. There were four AR simulators defined and described in chapter 2, of which only two were thoroughly validated. However, from this review it is clear that more research and development is needed to improve these systems for the training purposes. The manufacturer of ProMIS states that there are no shortcomings of their simulator, but as is shown in the following chapters on this AR simulator, several shortcomings have been encountered. Such examples are poor quality of visual feedback on de screen, and poor ergonomics of the hardware. The other manufacturers gave shortcomings such as lacking a performance curve or the absence of anatomical representation. From these AR simulators only the ProMIS was commercially available at the time, therefore the studies described in chapter 3-8 were completed with this simulator system. However, the most promising AR simulator from this review was the Blue Dragon, which enables to measure the laparoscopic skills in both box trainers and animal models. The new AR simulator developed by this research group, the Red Dragon, will be available commercially in the near future. With this simulator system

the skills can be assessed in a box trainer or even in the clinical setting. The parameters measured with this simulator are based on the Markov model and include force, tension and velocity, which will give a good representation of the laparoscopic skills, rather than speed and path length.

As the ProMIS AR simulator was chosen for further research on this training modality, the validity of this simulator had to be established. The experts and referents rated the suturing module as a good training tool and the realistic haptic feedback was regarded as an important factor in the suturing training. To research and validate this simulator more extensively, a second validation study was completed on both the suturing and basic tasks. Both these studies showed that the simulator was regarded as a good training tool, but there were some limitations to this simulator. The ergonomics were not optimal, the demonstration videos and step-by-step videos needed improvements, and the quality of the camera was not optimal, which made the performance more difficult.

Augmented Reality simulator has realistic haptic feedback, which was regarded by both the experts and referent groups in the validity studies as a good feature for the training of laparoscopic suturing. To objectify this, the following studies were completed. First the AR simulator was compared with a VR simulator, which showed that the AR simulator was favoured over the VR simulator. Next to this, the construct validity of the AR simulator was proven, while the VR simulator did not show any construct validity. More important in this study was the fact that hardly any experienced laparoscopic surgeons were able to tie a correct 'surgeon's knot' on this VR simulator. Because the algorithms used in the software of VR simulators that simulate the behaviour of thread are not realistic, it was impossible to tie a correct knot, when using the proper knot-tying technique. Because of the physical character of the AR simulator, this was not an issue. To show the training capacities of VR in laparoscopic suturing training, a VR simulator was compared with box training. This study showed that training on VR possibly has a negative effect on the suturing skills, and when compared with training on the box trainer, the latter is favoured by the trainees. There is no additive value for VR simulation in the training of laparoscopic suturing; therefore they should not be used for this purpose. Because of the lack of proper software for VR suturing training manufacturers of these simulators should not focus on suturing skills, but rather on basic skills and component tasks for procedural training.

The feedback provided by both AR and VR simulators can motivate trainees to train their skills more extensively until they have reached their goals. However, it is important that this feedback is informative and understandable to the trainee. The feedback and assessment

currently provided by these simulators does not give the trainee any adequate information or guidance to help them improve their skills. A trainee cannot improve their suturing skills based on the length of the travelled path or the time to complete the suture, if they do not even know how to complete this suture and knot. Therefore an already existing suturing module on the ProMIS AR simulator was adapted with a dome and arrows to guide trainee during the suturing and knot tying procedure. The assessment of the skills is partially based on this guidance and whether the instruments are in the correct area during the performance. After the performance the assessment scores are shown on the screen to give them step-by-step feedback of the performance. Another important factor in the assessment of suturing skills is the quality of the knot, which is assessed with a tensiometer and calculated through to the assessment score. These two parameters together give a good judgement of the suturing skills and secondly give an informative feedback to improve the skills on. Both the validity of the assessment method and the training capacities of the feedback in this module have been researched and shown to be good for the training purposes. The correlations between assessment parameters have been calculated, and some instances did correlated significantly, but when plotting them in graphics no clinically relevance was shown. This was the fact for all parameters that were compared with each other, because different properties of the skills are measured with each parameter. Therefore it is important that the assessment of the skills is not based on just one parameter, but on several combined. In this assessment method we have combined the quality of the knot with the time spent in the correct area, which showed a clinically relevant correlation with the scoring of two independent observers. It is shown that with an informative feedback system and realistic haptic feedback a trainee can learn laparoscopic suturing individually. Eighteen novice participants practiced their suturing skills on this module, without the guidance of an expert observer, and within eight repetitions they were all able to perform a correct 'surgeon's knot'.

There is still room for improvement in this suturing model and assessment method, because parts of the already existing module on the ProMIS were not accessible for change. If this would be possible an improved suturing module on an AR simulator could be developed, with proper demonstration videos, optimal visual feedback, and three-dimensional overlays of the guidance. Other parameters that could be included in the assessment method are force applied on the tissue and tension of the sutured knot.

This thesis is finalized with the development of an artificial tissue model of the human upper abdomen, to train the laparoscopic Nissen Fundoplication, with the purpose to replace animal tissue models or live animals. The American College of Surgeons have stated that wherever feasible alternatives to the use of animals should be developed and employed. Therefore it is

important that proper models are developed. This is a first model developed for the Nissen Fundoplication, but only the beginning for the development process of other models. This model was regarded as a good training tool and as replacement of animal tissue models, however, there is improvement needed for the stomach, which is still too rigid. This will be finalized in future research, in addition to the development of more artificial models. Following, these models can be used in all training settings, because they are fairly cheap, there is no risk for infections, they are readily usable, and are portable. Another important factor is that it is animal friendly and can also be used in Middle Eastern countries, where animal tissue models cannot be used for training.

The use of models for procedural training can also facilitate the learning process of the standardisation of procedures based on consensus protocols. By integrating a checklist approach to train procedures outside the clinical setting, this will become a standard for each procedure in the clinical setting. This will enhance the patient safety, because these consensus protocols will already be standard to the surgeon, as will be checklists to ensure a safe procedure.

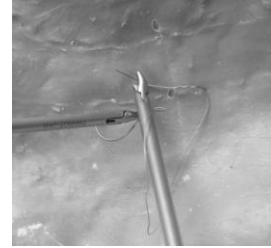
Future developments

Our recommendation for the future is the development of Augmented Reality laparoscopic simulators for component tasks of procedural training, such as laparoscopic suturing. These AR simulators should be implemented in carefully designed training curricula for laparoscopic skills for surgical residents. The place of this simulator system in the curriculum is in the beginning of the surgical residency, at the cholecystectomy level. It is of importance that the surgical residents not only learn basic laparoscopic skills at this level, but also suturing skills for when they e.g. need to tie the cystic duct when perforations occur in the clinical setting. For the latter purpose the developed suturing module with adapted assessment method should be implemented as both a training and assessment tool.

To objectify the performance of procedural training and to guide the trainee in improving their skills and fine tune their procedure, there is a need for an objective assessment method with meaningful feedback. Currently, the observer has stand next to the trainee to guide and assess the performance (subjectively). For both individual training and course based training, objective assessment methods of procedural training would be a solution. Therefore the next step, following this thesis, is to develop an Augmented Reality simulator for the laparoscopic Nissen Fundoplication, based on the developed model, with additionally a tracking system to assess and monitor the progress in the performance. Next to the assessment, there will also be demonstration videos, step-by-step guidance, and instructions to explain the procedure and possible complications and errors that are made to the trainee. The objective assessment of the procedure will be based on both the tracking of the instruments (e.g. travelled path and possible puncturing the liver or spleen) and objective set end points (e.g. two thumb knot sutures to close the crura properly, three sutures to close the wrap, and calibration that the wrap is not too tight or loose).

Following this development, other procedural training on Augmented Reality simulation should be developed for several kinds of laparoscopic procedures. First by adjusting the existing model for the upper abdomen, and next by developing new models. In the development of these models and simulators it is important that design engineers and surgeons work closely together, to represent the clinical setting as optimal as possible. They should provide the opportunity to use all instruments from the operating room, and additionally have a meaningful objective assessment and guidance. These models and AR simulators should be validated before they can be implemented in the training curricula for advanced laparoscopic surgical procedures.

Chapter 12



Summary *Augmented Reality Simulation for Laparoscopic Training*

Summary

Laparoscopy differs from open procedures in the skills that are needed to perform this surgery safely. To take advantage of this minimally invasive approach, skilled and well trained surgeons must perform the procedures. However, it is difficult and time consuming to learn these skills to the surgeons in training in the clinical setting. For this purpose, multiple laparoscopic simulators are on the market to train these skills outside the clinical setting, ranging from traditional box trainers, Virtual Reality (VR) and Augmented Reality (AR) simulators. Traditional box trainers contain realistic haptic feedback during the practice, but lack objective assessment of the performance. While VR simulators have explanations of the skills and an objective assessment at the end of the performance, they are lacking realistic haptic feedback. Augmented Reality simulators however have the benefits of the realistic haptic feedback from the traditional box trainers and the objective assessment of the VR simulators.

This thesis focuses on the Augmented Reality laparoscopic simulator systems. Augmented Reality laparoscopic simulation is a new modality of laparoscopic simulation, next to the frequently used box trainers and Virtual Reality simulators and they are improving rapidly. The advantage of AR over VR is that they retain the realistic haptic feedback as in the traditional box trainers, while additionally providing objective assessment of the performance. **Chapter 2** gives an overview of the Augmented Reality simulators that are developed over the past few years. In this chapter there are several different AR simulators evaluated on their strength and weaknesses. From this it can be concluded that Augmented Reality simulators are a potent new modality laparoscopic simulator system that should be implemented in the current laparoscopic training curricula.

However, before implementing these simulators, they have to be validated thoroughly to show the training capabilities and whether they are a reliable assessment tool. In **Chapter 3 and 4** the face, expert, and referent validity of the ProMIS Augmented Reality simulator have been established. The face validity shows the rate of representation of the simulated tasks to the clinical setting. In both studies the suturing module of this simulator has been regarded as a useful tool for laparoscopic training by both the expert and referent groups. The expert groups consisted of experienced surgeons, who have done at least fifty laparoscopic procedures and had laparoscopic suturing experience. The referent group consisted of medical interns and surgical residents with little or no laparoscopic experience, but are the target group for training purposes. In chapter 4, the translocation task, as a basic skills task, was additionally researched, which was rated favourably as well. In both studies the

ProMIS Augmented Reality simulator was regarded as useful tool for laparoscopic training. The all-over ratings about ProMIS' realism and teaching properties were favourable, and uniform amongst both teaching group (surgeons) as the user group (surgical residents in training). The ProMIS offers a high potential when implemented in laparoscopic training curricula.

In the second part of this thesis several training systems were compared with each other, this to show the most potent training tool. In **Chapter 5** the ProMIS Augmented Reality simulator was compared with the LapSim Virtual Reality simulator on the bimanual tissue manipulation and suturing tasks. The ProMIS AR laparoscopic simulator was regarded as a better tool for training of surgical residents than the LapSim VR laparoscopic simulator, by both the experiences surgeons as the target group. The ProMIS AR was regarded to have a better realism, haptic feedback and didactic value than the LapSim VR. This study also showed that the ProMIS AR had a better construct validity than the LapSim VR on both researched tasks. The construct validity represents the reliability of the assessment tool of the simulator systems, and whether the scorings of the performance correlate with the experience of the participant. In **Chapter 6** the SimSurgery Virtual Reality simulator was compared with a traditional box trainer for the training of laparoscopic suturing and knot tying skills. There were no significant differences in the outcome between laparoscopic suturing training only on a traditional box trainer or on the combination with a Virtual Reality laparoscopic simulator. While an important advantage of Virtual Reality is the objective assessment of the performance, the participants of this study preferred the traditional box trainer over the Virtual Reality simulator. From this study the conclusion could be made that realistic haptic feedback is an important factor for the training of laparoscopic suturing and that there is no place for Virtual Reality in suturing training.

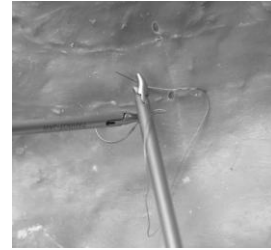
The next part of this PhD research focussed on the development of an adapted suturing module on the ProMIS Augmented Reality laparoscopic simulator with a new assessment method. The reason for developing this new assessment method was that while time, path length, and smoothness are often used parameters in surgical simulators, they do not give a good impression of the performed knot during the suturing training. Additionally they do not give any informative feedback to the trainee, to improve their suturing skills on. The scoring in this assessment method was based on two parameters: 'time spent in the correct area' and 'strength of the knot'. The time spent in the correct area was calculated from the location of the instruments in the simulated abdominal cavity. The ideal location was shown as a cage on the screen, in which the instruments had to stay during the knot tying, this to learn to

suture in a confined space. When pulling the knot tight, the proper instrument could come out of the cage in the proper direction, to make sure a correct surgeon's knot was tied. The second assessment parameter was the strength of the knot, which was calculated by pulling at the ends of the tied knot with a tension meter, to test the security of the knot. In **Chapter 7** this assessment method was validated and compared with the ratings of independent objective observers, and the correlation between the assessment method and parameters was researched. This suturing module with adapted assessment method showed to be a valid tool for objective assessing of laparoscopic suturing skills. Although assessment parameters can correlate, to provide informative feedback it is important to combine meaningful measurements, e.g. strength of knot, in the assessment of suturing skills. The next part of this research was to determine the training capabilities of this module by researching the performance curve of eighteen novice trainees, as described in **Chapter 8**. The trainees needed just eight repetitions on average to reach the top of the performance curve. There were statistically significant differences in both the scorings of this assessment method and in the scorings of the objective observers, when comparing the baseline knot with the top of the performance curve. This study showed that this adapted suturing module on the ProMIS Augmented Reality laparoscopic simulator is a potent tool for the training of laparoscopic suturing skills.

In the last part of this thesis two chapters are dedicated to the development process and validation of an artificial model of the upper abdomen to train the laparoscopic Nissen Fundoplication. The reason for this development is that animal tissue models are used quite regularly to train procedures before performing them in the clinical setting. However, they are expensive, can only be preserved for a short time, and there is a high risk for infectious diseases when using animal tissue models. Additionally, the American College of Surgeons also state that wherever feasible, alternatives to the use of animals should be developed and employed. Therefore, the development of this artificial model, with reusable organs and replaceable tissue, that can be used over and over again, is more cost effective, and therefore, can be used in every training centre. In **Chapter 9** the development process was described, with the selection of the materials for the different organs and tissue, to recreate the upper abdomen realistically. The stomach was the most challenging organ to develop, but also the most important, as the creation of the wrap is crucial for a proper Nissen Fundoplication. The stomach in this model was too rigid to make a proper wrap around the esophagus. The anatomy of the model was based on 3-D imaging of human CT-scans; to mimic the human anatomy realistically. In contrast, animal tissue models differ a lot from the human anatomy, which makes it more difficult to learn the proper steps of the Nissen Fundoplication. This

model offers the opportunity to practice the Nissen Fundoplication with a proper anatomical representation. In **Chapter 10** this artificial model was rated by both experienced surgeons and the target group, during an upper gastro-intestinal surgery course, as a good training tool for the training of the laparoscopic Nissen Fundoplication.

Chapter 12



Samenvatting *Augmented Reality Simulatie voor Laparoscopie Training*

Samenvatting

Laparoscopie verschilt van open procedures wat betreft de vaardigheden die nodig zijn om deze chirurgie veilig uit te voeren. Om het voordeel te nemen uit deze minimaal invasieve aanpak, is het van belang dat de ingrepen worden uitgevoerd door vaardige en getrainde chirurgen. Aangezien het moeilijk en tijdrovend is om deze vaardigheden aan de chirurgen in opleiding te leren in de kliniek, is het van belang dat dit in een simulatie omgeving gebeurt. Daarom zijn er meerdere laparoscopie simulatoren verkrijgbaar om deze vaardigheden aan te leren, zoals de box trainers, Virtual Reality (VR) en Augmented Reality (AR) simulatoren. De box trainers hebben realistische haptische feedback tijdens de training, maar missen een objectieve beoordeling van de vaardigheden. Virtual Reality simulatoren bieden echter een uitleg van de taken en op het einde van de taak een objectieve beoordeling van de vaardigheden, maar deze missen realistische haptische feedback. Dan is er de Augmented Reality simulatie die de voordelen biedt van de realistische haptische feedback van de box trainers met de objectieve beoordeling van de vaardigheden van de VR simulatoren.

Dit proefschrift richt zich op de Augmented Reality laparoscopie simulatoren. Augmented Reality is, naast Virtual Reality (VR) simulatoren en de veel gebruikte traditionele box trainers, een nieuwe manier van laparoscopie simulatie, welke steeds meer wordt ontwikkeld en verbeterd. Het voordeel van AR over VR is dat de realistische haptische feedback, zoals in traditionele box trainers, aanwezig blijft, maar daarnaast wordt er een objectieve beoordeling van de vaardigheden gegeven. **Hoofdstuk 2** geeft een overzicht van de Augmented Reality (AR) simulatoren die over de afgelopen jaren zijn ontwikkeld. In dit hoofdstuk worden verschillende AR simulatoren geëvalueerd op hun sterke en zwakke punten. Hieruit kan geconcludeerd worden dat AR simulatoren een waardevolle nieuwe manier van laparoscopie simulatie zijn en dat deze geïmplementeerd zouden moeten worden in het huidige onderwijs curriculum.

Voordat dergelijke simulatoren geïmplementeerd kunnen worden, moeten zij eerst uitgebreid gevalideerd worden, om aan te tonen dat het goede trainingscapaciteiten heeft en of het een betrouwbare beoordelingsmethode is. In **Hoofdstuk 3 en 4** zijn de face, expert en referentie validiteit van de ProMIS Augmented Reality simulator bepaald. De face validiteit geeft de mate van representatie van de gesimuleerde taak aan de kliniek weer. In beide studies werd de hechtmodule van deze simulator als een bruikbaar instrument beoordeeld voor de training van laparoscopie, door zowel de expert als de referentie groep. De expert groep bestond uit ervaren chirurgen, welke minimaal vijftig laparoscopische procedures hebben verricht en tevens laparoscopische hecht ervaring hebben. De referentie groep bestond uit co-assistenten

en arts-assistenten Chirurgie, met weinig of geen laparoscopische ervaring en zijn tevens de doelgroep als het om training doeleinden gaat. In hoofdstuk 4 werd tevens de translocatie taak, als basisvaardigheid, onderzocht, welke ook positief werd beoordeeld. In beide studies werd the ProMIS Augmented Reality simulator als een bruikbaar instrument voor de training van laparoscopische vaardigheden beoordeeld. De globale beoordeling of het realisme en training eigenschappen van de ProMIS waren positief en uniform over zowel de superviserende groep (ervaren chirurgen) als de doelgroep (arts-assistenten chirurgie). De ProMIS biedt hoge potentie, als deze geïmplementeerd zou worden in de training curricula voor laparoscopie training.

In het tweede deel van dit proefschrift werden verschillende training systemen met elkaar vergeleken, met als doel het meest waardevolle training instrument te vinden. In **hoofdstuk 5** werd de ProMIS Augmented Reality simulator vergeleken met de LapSim Virtual Reality simulator op de bimanuele weefsel manipulatie en hechttaken. De ProMIS AR werd beter beoordeeld dan de LapSim VR simulator voor de onderzochte taken, voor de training van arts-assistenten Chirurgie, door zowel de ervaren chirurgen als de doelgroep. Men vond dat de ProMIS AR de realiteit beter representeerde, met een meer realistische haptische feedback, en hogere didactische waarde had dan de LapSim VR simulator. De construct validiteit geeft de betrouwbaarheid van de objectieve beoordeling van het systeem aan, wanneer deze vergeleken wordt met de ervaring van de proefpersoon. In **Hoofdstuk 6** werd de SimSurgery Virtual Reality simulator vergeleken met de traditionele box trainer voor de training van laparoscopisch hechten en knopen. Er werden geen significante verschillen gevonden tussen de beoordelingen van de deelnemers welke alleen op de box trainer hadden getraind, of in combinatie met de VR simulator. Hoewel objectieve beoordeling van de vaardigheden een belangrijk voordeel van VR is, hadden de deelnemers van deze studie toch de voorkeur voor de traditionele box trainer. Uit deze resultaten kan er geconcludeerd worden dat er geen toegevoegde waarde hebben gevonden van Virtual Reality simulatie boven de traditionele box trainers voor laparoscopische hechttraining.

Het volgende deel van dit promotieonderzoek richtte zich op de ontwikkeling van een aangepaste hechtmodule voor de ProMIS Augmented Reality simulator, met een nieuwe objectieve beoordelingsmethode. De reden voor de ontwikkeling van deze beoordelingsmethode is dat de vaak gebruikte parameters, zoals tijd, padlengte en efficiëntie van beweging, geen goede indruk geven van de uitgevoerde knoop gedurende de hechttraining. De score in deze beoordelingsmethode werd gebaseerd op twee parameters, namelijk 'tijd gespendeerd in het correcte gebied', en 'kwaliteit van de knoop'. De 'tijd

gespendeerd in het correcte gebied' tijdens de uitvoering van de knoop werd berekend vanuit de lokalisatie van de instrumenten in de gesimuleerde buikholte. De ideale plaatsing werd gevisualiseerd op het scherm door middel van een kooi, waar de instrumenten in moeten blijven gedurende de uitvoering, zodat de chirurg leert te hechten in een beperkte ruimte. Wanneer de knoop werd aangetrokken, mocht het juiste instrument in de juiste richting buiten de kooi komen, zodat er een chirurgische knoop werd gelegd. De tweede parameter voor de beoordeling was de kwaliteit van de knoop, die werd berekend door aan beide uiteinden van de knoop te trekken met een krachtmeter, totdat deze brak (een goede knoop) of uit elkaar slipte (slechte knoop). In **Hoofdstuk 7** is deze beoordelingsmethode gevalideerd en vergeleken met de beoordeling van dezelfde oefeningen door twee onafhankelijke observatoren. Daarnaast zijn tevens correlaties tussen de objectieve beoordeling en individuele parameters onderzocht. Hiermee is aangetoond dat deze hechtmodule met aangepaste beoordelingsmethode een valide instrument is voor de objectieve beoordeling van laparoscopische hechtvaardigheden. Ook al kunnen beoordelingsparameters onderling correleren, voor een informatieve feedback is het belangrijk om betekenisvolle parameters, zoals de kwaliteit van de knoop, in de beoordeling van hechtvaardigheden mee te nemen. Het tweede deel van dit onderzoek was het bepalen van de trainingsmogelijkheden van deze module, door het onderzoeken van de prestatiecurve (leercurve) van achttien onervaren deelnemers, zoals beschreven in **Hoofdstuk 8**. De deelnemers hadden gemiddeld slechts acht repetities nodig om de top van de prestatiecurve te bereiken. Er waren statistisch significante verschillen gevonden tussen zowel de scores van deze beoordelingsmethode als de beoordelingen van de objectieve observatoren, wanneer de basis knoop werd vergeleken met de knoop op de top van de prestatiecurve. Deze studie toont aan dat deze aangepaste hechtmodule op de ProMIS AR simulator, een waardevol instrument voor de training van laparoscopisch hechten aan arts-assistenten chirurgie is.

In het laatste deel van dit proefschrift zijn er twee hoofdstukken gewijd aan het ontwikkelingsproces en validatie van een kunstmatig model van de bovenbuik, voor de training van de laparoscopische Nissen Fundoplicatie. De reden voor deze ontwikkelingen is dat modellen van dierlijk weefsel regelmatig worden gebruikt om procedures te trainen, voordat ze worden uitgevoerd in de kliniek. Het nadeel van deze dierlijke modellen is dat zij duur zijn, kunnen slechts voor een beperkte periode bewaard worden en er is een groot risico op infecties. Daarnaast beweert de American College of Surgeons dat, waar mogelijk, alternatieven moeten worden ontwikkeld, voor het gebruik van dierlijke modellen. Daarom is dit kunstmatige model, met herbruikbare organen en vervangbare onderdelen, die meerdere malen gebruikt kunnen worden, voordeliger zijn en kan daarom in elk trainingcentrum

gebruikt kunnen worden. In **hoofdstuk 9** wordt het ontwikkelingsproces van dit kunstmatige model van de bovenbuik beschreven, met daarin de selectie van de verschillende materialen voor de verscheidene organen en weefsels, om de bovenbuik zo realistisch mogelijk te recreëren. De maag was de grootste uitdaging om te creëren, maar tevens het meest belangrijk, aangezien de creatie van de wrap cruciaal is voor een goede Nissen Fundoplicatie. De maag in dit model was te stijf om een goede wrap rondom de oesofagus te maken. De anatomie voor het model voor de Nissen Fundoplicatie was gebaseerd op 3-D beeldvorming van CT-scans, zodat de menselijke anatomie zo goed mogelijk benaderd werd. De anatomie van dierlijk weefsel modellen is echter erg verschillend van de menselijke anatomie, wat het veel moeilijker maakt om de juiste stappen van de Nissen Fundoplicatie hierop aan te leren. Dit kunstmatige model biedt de mogelijkheid om de procedure te oefenen met een goede representatie van de menselijke anatomie. In **Hoofdstuk 10** werd dit kunstmatige model beoordeeld door zowel ervaren chirurgen als de doelgroep, gedurende een bovenste gastro-intestinale chirurgie cursus. Door deze doelgroep werd het model als een goed trainingsinstrument voor het aanleren van de Nissen Fundoplicatie beoordeeld.

Curriculum Vitae

Sanne Botden was born on September 12th in 1983, in Venray, The Netherlands. After accomplishing secondary school at the Raayland College in Venray in 2001, she travelled to Canada and Australia for a year, before starting Medical School in September 2002, at the University of Maastricht. During her study she was active in the student council and Educational Committee of the faculty of Medicine. In 2005 she started her internships in the Catharina hospital Eindhoven, but she also attended an elective internship in general surgery at the Academic Hospital Paramaribo, Surinam for 2 months. During her regular Surgical internship in the Catharina hospital Eindhoven, she started her PhD research in March 2006, with Dr Jakimowicz at the skills centre of the Catharina hospital and in a later stage also at the faculty of Medical Design Engineering at the Technical University of Delft. The major part of the thesis was completed during her internships. She obtained her Medical Degree Cum Laude in January 2008. After which she worked for a half year as a resident (not in training) at the Intensive Care Unit in the Catharina hospital Eindhoven. In august 2008 she started as a resident (not in training) at the Surgical department of the Catharina hospital, where she is currently working.

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Curriculum Vitae

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