FORCE-BASED ASSESSMENT OF TISSUE HANDLING SKILLS TIM HOREMAN

FORCE-BASED ASSESSMENT OF

TISSUE HANDLING SKILLS

Proefschrift

Ter verkrijging van de graad van doctor Aan de Technische Universiteit Delft Op gezag van de Rector Magnificus prof.ir. K.C.A.M. Luyben, Voorzitter van het College voor promoties, In het openbaar te verdedigen op 1 April om 10:00 uur Door

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Title:	Force-Based assessment of Tissue handling skills
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Copyright:	Tim Horeman, Delft, The Netherlands, 2014
Print:	Sieca Repro
ISBN/EAN:	978-94-6186-268-6

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Financial report for the publication of this thesis was provided by The Nederlands Vereniging van Endoscopische Chirurgie (NVEC), MediSHield BV and Bio-Mechanical Department of the TU-Delft.

SUMMARY: FORCE-BASED ASSESSMENT OF TISSUE HANDLING SKILLS

In laparoscopic surgery, special instruments with long and slender shafts are inserted through small incisions in the abdominal wall. A laparoscope is used for a clear vision inside the inflated abdominal cavity while laparoscopic graspers and cutters are used for manipulation of tissue. The use of long instruments makes it difficult to "feel" the force exerted on tissue during manipulation especially when friction factors disturb the force sensation even further. Tissue manipulation plays an important role in surgery and there is relatively little knowledge of forces applied on tissue during surgery. The main objectives of this thesis were to develop force measurement systems to measure the forces during training, to combine motion and force measurements to come to objective assessment of training of basic MIS skills, and finally to develop force feedback systems to improve force application during training.

The first part of this thesis focuses on the force exerted by the instrument tips during placement of surgical sutures. In many educational programs in surgery, the suture task is used to test the technical skills of the trainee. We proved that the force exerted on the suture pad can be recorded without modification of the instruments or suture pad if a 3DOF force sensor is placed under the suture pad in a box trainer. We showed that performance parameters can be calculated from recorded force data to expose skills important for safe tissue handling during suturing. A validation study showed that it is possible to classify participants with an accuracy of 84% if only force parameters are used.

The second part of this thesis describes a method to reduce the tissue handling force of trainees. By generating a virtual arrow in the laparoscopic image that represents the size and direction of the exerted force during suturing in real time, we found that training with well explained visual feedback can help trainees to minimize the interaction force during needle insertion in a box trainer. For training of wound suturing outside the box trainer, we found that colours, representing the exerted force on the tissue, can help trainees to balance forces between the two tensioned threads during knot tying and to improve the quality of the knot. In another study we showed that it is possible to inform the surgeon about the pulling force during surgery if a small and lightweight sensor is used that can be easily attached to the tensioned thread.

The third part of this thesis we integrated the TrEndo and a force platform into ForMoST, a box trainer that measures both tissue handling force as instrument motion. For this box trainer we developed and validated two new bimanual training tasks for training of tissue handling. The validation study performed with novices, intermediates and experts indicated that force parameters are not strongly correlated to motion parameters and that force and motion parameters have similar discriminative power in both tasks. A study performed with novices that received visual force feedback or visual time feedback during training indicated that visual force feedback during training reduces the tissue manipulation force significantly even when a post task is performed that is different from the training task. We showed that training with visual force feedback improves tissue handling skills with no negative effect on task time and instrument motion and that training with visual time feedback improves instrument motion and task time, but does not improve tissue manipulation skills.

This thesis contributes to the field of training of surgical skills in multiple ways. Mechanical force sensors were developed that can be used for training of tissue handling, to find force thresholds for traction on tissues or for safety monitoring during suturing of incisions. It is shown that force parameters that reflect tissue handling or suture tension, can now be used to inform surgeons about the risk of tissue damage while training laparoscopic skills or suturing tissues.

SAMENVATTING: BEOORDELING VAN WEEFSEL-MANIPULATIE VAARDIGHEDEN OP BASIS VAN KRACHTMETINGEN

Bij laparoscopische chirurgie worden speciale instrumenten met een lange en dunne schacht ingebracht door kleine incisies in de onderbuik. Een laparoscoop wordt gebruikt om een helder beeld te krijgen van de binnenkant van de opgeblazen buikholte. Daarbij worden onder andere laparoscopische grijpers en schaartjes gebruikt om weefsels te manipuleren. Het gebruik van lange instrumenten in combinatie met wrijvingsinvloeden bemoeilijkt het inschatten van de kracht die wordt uitgeoefend op de weefsels. Weefselmanipulatie speelt een belangrijke rol in de chirurgie en er is relatief weinig bekend over de krachten die worden uitgeoefend op weefsels gedurende weefselmanipulatie. Het doel van dit proefschrift was het ontwikkelen van krachtmeetsystemen die de krachten meten gedurende het trainen. Het combineren van bewegingsmetingen en krachtmetingen voor het objectief beoordelen van basisvaardigheden voor minimaal invasieve chirurgie tijdens en na het trainen. En het ontwikkelen van krachtterugkoppelingssystemen, opdat het krachtgebruik gedurende trainingen verbetert.

Het eerste deel van dit proefschrift zoemt in op de krachten die worden uitgeoefend door de instrumentbekjes tijdens het plaatsen van een chirurgische hechting. In veel educatieve programma's voor de chirurgie wordt de hechtingstaak gebruikt om de technische vaardigheden van de trainee te testen. We bewezen dat het mogelijk is om de krachten te meten die worden uitgeoefend op de hechttaak tijdens het hechten door een 3 DOF krachtsensor in een trainingsbox onder de hechttaak te plaatsen zonder modificaties aan instrumenten of hechttaak. We demonstreerden dat uit krachtdata prestatiematen kunnen worden berekend die de vaardigheden, die nodig zijn om weefsel veilig te manipuleren, weergeven. Een validiteitstudie toonde aan dat enkel door het gebruik van krachtparameters het mogelijk is de deelnemers te classificeren met een nauwkeurigheid van 84 %.

Het tweede deel van dit proefschrift beschrijft een methode om tijdens weefselmanipulatie de kracht die wordt uitgeoefend op het weefsel te verminderen. We genereerden in het laparoscopisch beeld van een trainingsbox een virtuele pijl, die de grootte en de richting van de uitgeoefende kracht gedurende het hechten weergeeft. Het bleek dat trainen met goed uitgelegde visuele krachtterugkoppeling, trainees kan helpen de interactiekracht te minimaliseren gedurende het plaatsen en doorhalen van de naald. Voor het oefenen van het hechten van wonden buiten de trainingsbox ontdekten we, dat lichtkleuren, die de uitgeoefende kracht op het weefsel weergeven, trainees kunnen helpen de trekkrachten in beide draadeinden in balans te houden bij het aantrekken van de knoop en dat dit kan helpen de kwaliteit van de hechting te verbeteren. In een andere studie lieten we zien dat het mogelijk is de chirurg te informeren over de trekkracht met een kleine lichtgewichtsensor die eenvoudig aan de gespannen draad is te bevestigen.

In het derde deel van dit proefschrift voegen we de TrEndo en een krachtmeetplateau samen in ForMoST, een trainingsbox die zowel de weefselmanipulatiekrachten als instrumentbewegingen meet. Voor deze trainingsbox ontwikkelden en valideerden we twee nieuwe tweehandige trainingstaken om weefselmanipulatie te trainen. Het validiteitonderzoek uitgevoerd met beginners, gevorderden en experts gaf weer, dat er geen duidelijke correlatie is tussen kracht- en bewegingsparameters en dat kracht- en bewegingsparameters een vergelijkbaar onderscheidend vermogen hebben in beide taken. Een studie met beginners die visuele krachtterugkoppeling of visuele tijdterugkoppeling ontvingen gedurende de training, liet zien dat visuele krachtterugkoppeling tijdens het trainen de weefselmanipulatiekracht vermindert zelfs als een nameting wordt uitgevoerd op een alternatieve trainingstaak. We vonden dat door het trainen met visuele krachtterugkoppeling de weefselmanipulatiekrachten vermindert zonder negatieve effecten op de taaktijd en de instrumentbewegingen. Daarnaast zagen we dat het trainen met visuele tijdterugkoppeling de taaktijd verkort en instrumentbewegingen verbetert, maar niet de weefselmanipulatiekrachten vermindert.

Dit proefschrift is in verschillende opzichten een bijdrage op het gebied van de training van chirurgische vaardigheden. Verschillende mechanische krachtsensors zijn ontwikkeld die men kan gebruiken voor het trainen van weefselmanipulatie, het vinden van de toelaatbare trekkracht op verschillende weefsel voor het trainen van weefselmanipulatie, of voor het veilig monitoren van de draadspanning gedurende het hechten van een incisie. Het toont aan, dat krachtparameters die weefselmanipulatie of hechtingsspanning weergeven nu kunnen worden gebruikt om chirurgen te informeren over het risico van weefselbeschadiging gedurende het trainen van laparoscopische vaardigheden of het hechten van weefsel. "Excellence is an art won by training and habituation. We do not act rightly because we have virtue or excellence, but we rather have those because we have acted rightly. We are what we repeatedly do. Excellence, then, is not an act but a habit."

Aristotle (384 BC - 322 BC)

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CHAPTER 1 INTRODUCTION



In this chapter laparoscopic surgery is explained and the potential of force sensors in surgical procedures is clarified, the aim of this thesis is stated and the structure is outlined.

1.1 FORCE SENSING IN SURGERY

Resident surgeons learn most of their minimally invasive surgical (MIS) skills while operating on a living patient. However, this way of training is expensive, potentially unsafe, not standardized, and results in a long learning curve [1,2]. Therefore, new training methods that enable residents to learn outside the operating room have been developed. These methods however lack techniques that credit surgeons as technically competent. Mastering MIS skills requires repeated practice. Training modules, such as box-trainers, are available to provide a safe environment for practice. The advantage of box-trainers is that they are not expensive, and that they provide a realistic environment with natural force feedback due to the use of real MIS instruments. However, boxtrainers do not offer any objective feedback about the performance (competence score) [3,4]. Apart from accurate control of instrument motion, surgical skills involve proper force application [5-7]. The grasping forces when manipulating tissue or the forces applied onto wires when suturing, should be well synchronized with the actual motion of the instrument (e.g. to prevent slip). [8,9]. The goal of the work presented in this thesis is to develop methods to measure interaction forces during training and to implement a combination of motion and force analysis in order to come to an objective competence assessment in training of basic MIS skills.

1.2 LAPAROSCOPY

Laparoscopy, or "keyhole surgery" is a minimally invasive approach that allows the surgeon to perform the surgical procedure with minimum tissue damage to the abdominal wall.



Figure 1.1 Long and slender instruments are used in Laparoscopy.

In laparoscopy, the abdominal cavity is inflated with CO₂ gas for a clear view of the organs and free movements of the inserted instruments. In most cases, trocar systems are used to guide the instruments to the inflated abdominal cavity. A trocar system

consists of a hollow tube with a valve and a sharp inner pin that is removed after the trocar is inserted in the abdominal wall. In general, trocar systems are designed to reduce friction between the instrument and the incision and to allow translation and rotation of the instrument shaft while the valve in the trocar tube minimizes gas leakage. The study of Van den Dobbelsteen shows however that the friction in the trocar can vary depending on the valves used [10].

For different laparoscopic procedures, different instrument tips are developed for particular surgical actions such as tissue retraction, dissection, cutting and suturing. Although the tips and handles can have different shapes to fulfil different functions, all instruments have a long slender shaft varying in diameter between 3 and 11 mm. The length of the instrument depends on the intended use and can be as long as 470 mm. In order to "look" inside the abdominal cavity, a laparoscope is required. A laparoscope is a hollow tube with a diameter between 2 and 11 mm that contains a rod lens system. Because of those lenses, a clear image can be transferred from the tip inside the cavity towards the optics on the other side of the tube. From there, a digital camera system processes the images that are displayed on a large screen in the operation theatre.

1.3 TRAINING OF LAPAROSCOPIC SKILLS

Compared with instruments in traditional "open" surgery, the movements that the laparoscopic instruments can make are limited. Since these instruments are guided by trocars through fixed incisions, the Degrees of Freedom (DOF) are reduced from 6 to 4. Besides restriction of DOF's, surgeons also have to deal with poor depth perception due to the 2D view of the inner abdominal cavity that make it difficult to control the insertion depth of the instruments. [11]. In addition, the valve in the trocar creates friction between instrument and trocar and the abdominal wall counteracts all movements of the trocar resulting in a reaction force at the instrument handle [10]. In combination with friction in the instrument during tip actuation there are three forces present fluctuating in magnitude and direction during surgery that disturb the force feedback of the surgeon that controls the instruments.



Figure 1.2 The incision and instruments allow movement with 4 Degrees Of Freedom (DOF).

All those factors make tissue handling in laparoscopy more difficult, hence practice is required for laparoscopic tissue manipulation and intracorporeal suturing. Currently there

are three different methods for inanimate training of laparoscopic skills: Box trainer, Virtual reality trainer and Hybrid trainer

Box Trainer

A Box Trainer (BT) consists of a box with a bottom part holding the training task and a top plate with holes that facilitates different types of trocars through which the laparoscopic camera and all kinds of laparoscopic instruments are inserted. For training, various tasks can be defined in relation to the manipulation of these objects. By practicing those training tasks, trainees aim to improve their skills. Eventually, their skills are examined by an assessment system that can be either subjective (e.g. scoring by checklist manually) or objectively (parameters are measured automatically). In most cases, objective assessment is based on task-time task-errors and written exam assessments.

Virtual Reality trainer

Virtual reality (VR) trainers in laparoscopy are available in many shapes and sizes and can have different functionalities. Furthermore, the virtual environment can differ from highly abstract to a realistic representation of the inner abdomen [12,13]. (Figure 1.3 Left – Simendo, Right-Laparoscopic appendectomy simulator). The choice for rather abstract or realistic virtual feedback depends on the level of consciousness that is trained. For eye-hand coordination, the training environment does not need to reflect an actual inner abdomen.



Figure 1.3 Screen shots of two VR trainers. Left Simendo. Right, Laparoscopic appendectomy simulator. Adapted from [12,13].

Although some manufacturers provide haptic feedback for training in laparoscopy and arthroscopy, studies have shown that the haptic feedback is not realistic [14]. Suture tasks that require fine motoric control with lots of force interaction between instruments, thread and environment seem especially difficult to simulate. In contrast to most BT's, VR systems use objective assessment methods based on instrument motion and time parameters. In many simulators, the influence of each individual parameter depends on the virtual task provided.

Hybrid trainer

For many surgeons and skills lab managers, the costs, diversity of training tasks, objectivity in scoring and realism of instruments are the important factors when a training

system is added to their educational program. The left and middle column of Table 1.1 indicates the positive and negative aspects of BT and VR systems.

VR	BT	HT	
+ Objective assessment	- Subjective assessment	+ Objective assessment	
- Modified instruments	+ Real instruments	+ Real instruments	
- Expensive	+ Affordable	Depending [*]	
- No/unnatural force	+ Natural force	++ Natural force	
feedback	feedback	feedback	

*Influenced by the sensors and options in the software as classification models and augmented feedback.

Resulting from this representation, it can be concluded that a system should be developed that includes the positive aspects of all systems. This Hybrid Trainer (HT) in the right column of Table 1.1 seeks to capture the strengths of both VR and BT by providing an affordable, reliable, realistic training arena with metrics to objectively evaluate performance. Figure 1.4 Left shows a modified box trainer that tries to objectify task scoring with a sensor system that automatically detects errors in peg transferring. Those systems require simple sensors in the tasks and do not track instrument movements [15].



Figure 1.4 Screen shots of two different hybrid trainers. Left, a task that measures if an object is dropped in the right area [15]. Right, the ProMIS, a trainer that tracks instruments with camera systems [16].

Figure 1.4 Right shows a picture of the ProMIS [16], a more advanced training system that besides a fixed camera system under the top plate has no other sensory system in the task itself. In this trainer, one set of cameras is used for tracking of the colour markings on the instrument while another camera is used to transfer the image to the trainee. In a recent version of this system, the image of this camera can be modified with virtual information helping the student to complete the task more efficiently. Unfortunately, one major drawback is the reliability of those systems, if vision is obstructed or instruments are crossed, tracking errors occur.

1.4 PERFORMANCE PARAMETERS FOR OBJECTIVE ASSESSMENT

Which performance parameters are used in the assessment of surgical skills in both physical and virtual training, depends among other things on the sensors generating the input data for analyses and training goals. Performance parameters determine to a great extent the training system's proficiency. Furthermore, they are required to provide evidence for reliability and validity of trainers as an assessment tool [17]. Usually, the performance parameters used in assessment methods include only task-time and error. Table 1.2 shows an overview of parameters currently used for VR, BT and HT [18].

Objective parameters			
Task-time	Total time to perform a task		
Part length Total path followed by a laparoscopic instrument			
Economy of motion	Shortest distance to complete task/ total distance		
Speed	Speed of the instrument tip		
Motion smoothness	Consistency of instrument tip speed		
Instrument Measures for correctness of instrument placement and orientation			
orientation			
Depth perception	Total path length of the tip in the axial direction of the shaft		
Angular path	Sum of all angular paths around the instrument's pivot point		
Angular area	Area between the fastest position occupied by the instrument in the camera		
	plain		
Volume	Angular area x Depth perception		
Force/torque	Force and Torque during instrument-tissue interactions with modified		
	instruments		
Errors	Errors performed during the task		
Idle states	Time periods without instrument movements		
Task repetitions	Number of repetitions required on a task before achieving satisfactory		
	completion		
Collisions, damage to surroundings	Detection of collisions and damage to background tissues		

Table 1.2 Commonly used performance parameters

However, with new developments in instrument tracking, it becomes possible to record more and different types of data during a training session. If force data becomes available, it is likely that when data from instrument motion, instrument-tissue interaction forces and task time are combined into objective parameters, assessment may become more accurate. This thesis focuses on the value of force measurements for objective evaluation of task performance during training of basic minimally invasive surgical skills and suture tasks. Comparable with parameters based on instrument motion and task time, it is likely that parameters based on interaction force can be used to indicate if surgical tasks are performed efficiently. Furthermore, if force parameters are used to inform about the force that is exerted on tissue during manipulation (e.g. stretching pulling spreading or pinching) or wires during suturing, the link to potential tissue rupture and therefore surgical safety is plausible. If force parameters can indicate when tissue manipulation is performed safely, it is desirable to include force tracking in training of surgical skills. Figure 1.5 shows that if performance parameters are used in laparoscopic surgery they mainly reflect efficiency if based on task time. In addition, in repetitive training, task time can indicate how fast the trainee adapts to a new situation. Parameters based on instrument motion can inform about efficiency (e.g. large or short path length to complete a task) and safety risks if used in combination with time information (e.g. high instrument velocities near critical organs or vessels). Since parameters based on interaction force during tissue manipulation or suturing can be linked to tissue damage directly but do not inform about instrument handling if there is no interaction, it is assumed that they inform less about efficiency and more about surgical safety compared with motion parameters.



Figure 1. 5 The solid fields indicate the information that time and motion parameters can contain about efficiency and safety of a surgical action. The hatched field indicates the potential information that force parameters contain.

1.5 SURGERY THROUGH A SINGLE INCISION

Single Port Surgery (SPS) is one of the latest trends in laparoscopy and developed to perform laparoscopic procedure exclusively through one single entry point. Single-incision laparoscopy was developed in order to reduce the invasiveness of traditional laparoscopy for cosmetic reasons.



Figure 1.6 Single Port Surgery (SPS) performed through one single trocar. Adapted from [19].

Where mainly rigid and straight instruments are used in conventional laparoscopy, surgeons use combinations of instrument types in single port surgery [20]. Depending on the laparoscopic procedure, straight, bent, double bent and steerable instruments in single port surgery are used to maximize the working space. Since this single port guides the instruments and the camera, many surgeons use a rigid scope with 30% vision angle to create some sideways distance between camera tip and instrument shafts.



Figure 1.7 single curved (Left) and double curved (Right) instruments for single Port Surgery.

If instruments with a single curved tip as in Figure 1.7 are used in a single port, manipulation requires a crossed configuration. In this case, the surgeon moves the right hand-instrument while feedback from the monitor shows that the left one is moving inside the abdominal cavity, and vice versa. The design of the double-curved hand-instruments as in Figure 1.7 eliminates the crossed configuration, permitting a more natural eye-hand coordination. Consequently, the tip is not always in line with the shaft of the instrument. If tip and shaft are not in line, an additional torque is generated forcing the shaft to rotate if not counteracted at the handle site. Furthermore, since single port instruments have bent shafts, it is difficult to know the exact location and orientation of the shaft if the laparoscope is zoomed in at the tips. In this situation, it is possible that the bent shaft is in contact with other tissue outside the visual triangle of safety influencing the motions of the tip. Due to the bent shafts and changing force configuration at the tip site, tissue handling that is already difficult with multiple access ports and straight laparoscopic instruments, becomes even more complex. Therefore it is expected that not only inexperienced surgeons should train to reach a high safety standard in SPS but also

surgeons that are highly experienced in laparoscopy. To identify if a surgeon is able to perform basic (force) tasks, a measurement system for objective assessment of technical skills should be available that is compatible with these new trends in laparoscopy.

1.6 FORCE TRACKING IN SURGICAL SUTURES

Besides the use of force parameters to indicate poor tissue handling in box trainers for laparoscopy training, they can also be used to inform about dangerous interaction forces in real surgical procedures [5]. If the exerted force is too low, a satisfying result is never reached. If the force is too high, tissues or structures are simply damaged. Due to the interposition of instruments it is difficult for surgeons to estimate the applied force on the tissue under all circumstances. Therefore, force sensors incorporated in instruments or between cables or threads can provide valuable real time information about the risk on excessive force that cause tissue damage.

Feedback of suture tension

For some suture applications the tension in the tissue during the healing process and not the actual applied force on the tissue at time of surgery is of interest (Figure 1.8). For these sutures the ideal tension in the threads (or sometimes metal wires) is still unclear. Some surgeons use high forces during suturing to create as much contact between the wound edges as possible while other surgeons suture with lower force in order to minimize necrosis of the tissue around the tightened loops of the sutures [21,22]. One reason why an ideal suture tension is not yet established is that there are no methods available to measure the tension in the thread of loops of the suture that do not compromise the geometry of the suture [23]. For good comparison of suture methods, the tension in the thread should be known immediately after suturing and during the healing process of the wound.



Figure 1.8 Trade-off between loop tension (FL) and contact between wound edges (x). Loops with high thread tension give good contact between wound edges but can cut through tissue or stop blood flow in the surrounding tissue. Loops with low thread tension can result in poor wound closure.

To achieve this, small sensors that measure the tension in a suture loop should be developed. If the force applied by the surgeon is also known during suturing, the relation between applied force, loop tension and healing process can be determined and the most efficient suture method and pulling force can be established.

1.7 OBJECTIVES

There is relatively little knowledge of forces applied on tissue during surgery, however they play an important role in surgical safety and tissue healing. Therefore, the main objectives of this thesis are:

- > To develop force measurement systems to measure the forces during training.
- To implement a combination of motion and force analysis to come to objective assessment in training of basic MIS skills.
- > To develop force feedback systems to improve force application during training.

1.8 THESIS OUTLINE

In Chapter 2 a simple force measurement method was developed based on a platform that measures all forces and torques exerted by laparoscopic instruments on the training task. This affordable simple and small force platform is based on a plug and play optical USB mouse and could therefore be used in most standard box trainers. In Chapter 3 the force platform was used to classify skill levels of Novices and Experts indicating that the device can be used to assess the skills of a subject. To provide some relevant answers to the question whether there are potential risks involved if procedures are performed according to the relatively new single port approach, the force platform was used in Chapter 4 to identify the difference between conventional and single port laparoscopy in terms of tissue manipulation force. Furthermore in the same chapter, the impact of limited instrument motion on the learning curve of 24 students was indicated and the instrument configuration preference of both groups was compared. In Chapter 5 the question was raised if force information can be used for training as well as skills assessment. Many hours of force measurements on sutures in porcine organs provided us with enough data to link the force output of the force platform to actual tissue damage during suturing on different organs. To investigate if peak force warnings based on actual tissue properties could prevent tissue damage, we conducted experiments with different types of visual force feedback in a setting for laparoscopic surgery in Chapter 6 and open surgery in Chapter 7. In line with results from the R.E.P.A.I.R group of the Erasmus MC, the results of Chapter 7 showed that force control in open wound suturing proved difficult for some inexperienced surgeons. In Chapter 8 a new collaboration between TU-Delft and Erasmus MC resulted in the development of two force sensor systems used to identify the relation between stitch tension and pulling force measurement. Based on those developments, a simple and effective tool was developed that can be used inside the Operation Room to warn the surgeon of excessive pulling forces in critical wound closure. Evaluating the results from our first force platform and

experiments, we concluded that there is some room for improvement of the used training tasks and force measurement method. In Chapter 9 we developed a new force sensor that allows accurate force measurements even when forces are exerted further away from the sensor's midpoint. For this new sensor we developed a new set of dynamic position tasks that can only be completed with two hands. After analysing the differences between Novices, Intermediates and Experts with the help of new and existing force, motion and time parameters we learned that skills discrimination with an accuracy up to 100% can be possible. With the training tasks of Chapter 9, a study was started in Chapter 10 to investigate the influence of visual feedback of performance time on the learning curve. The unique aspect of this study was that the training task was completely different from the task used to measure effects in the post test. This study indicated that visual force feedback during training improves basic tissue handling skills without negative effects on instrument movements or task time. In Chapter 11 a discussion was started evaluating the outcomes of the different studies. Furthermore, other fields of application for the force sensors are mentioned and suggestions made over how to further develop the classification methods if more complex tasks are used.

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CHAPTER 2 FORCE MEASUREMENT PLATFORM FOR TRAINING AND ASSESSMENT OF LAPAROSCOPIC SKILLS

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Surgical Endoscopy, volume 24, issue 12, pages 3102-3108



In literature, all available force data recorded during laparoscopic tissue handling was generated by modified instruments. In this chapter a force platform is introduced based on a simple 6DOF mouse that can be placed under a training task in a box trainer. Custom made software was written to measure and record the force that is exerted on this platform and to provide objective performance feedback based on the recorded tissue handling force.

ABSTRACT

Background

To improve endoscopic surgical skills, an increasing number of surgical residents practice on box or Virtual-Reality (VR) trainers. Current training is mainly focused on hand-eye coordination. Training methods that focus on applying the right amount of force are not yet available.

Methods

The aim of this project is to develop a system to measure forces and torques during laparoscopic training tasks as well as the development of force parameters that assess tissue manipulation tasks. The force and torque measurement range of the developed force platform is 0-4 N, and 1 Nm (torque), respectively. To show the potential of the developed force platform, a pilot study was conducted in which 5 surgeons experienced in intracorporeal suturing and 5 Novices performed a suture task in a box trainer.

Results

During the pilot study, the maximum and mean absolute nonzero force that the Novice used were 4.7 N (SD 1.3 N) and 2.1 N (SD 0.6 N) respectively. With a maximum force of 2.6 N (SD 0.4 N) and mean nonzero force of 0.9 N (SD 0.3 N), the force exerted by the Experts was significantly lower.

Conclusions

The designed platform is easy to build, affordable, and accurate and sensitive enough to reflect the most important differences in e.g. maximal force, mean force, and standard deviation. Furthermore, the compact design makes it possible to use the force platform in most box trainers.

2.1 INTRODUCTION

The use of minimally invasive techniques in medicine is rapidly increasing and offers the patient many advantages compared to open surgery. Because of the increasing complexity of minimally invasive procedures, effective and affordable training tools are required to improve the endoscopic skills of surgical trainees. New trainings tools such as box-trainers equipped with motion detection [1,2] or virtual reality trainers [3,4] have been developed to enable trainees to practice outside the operation room and to objectively assess their skills. Current assessment focuses mainly on the efficiency of instrument movements and task (completion) time in basic grasping and positioning tasks. However, there is also a need for objective assessment of performance in delicate tasks such as tissue handling and suturing [5,6]. During these tasks high forces can cause serious tissue damage, therefore monitoring other parameters (i.e. the interaction force between tools and tissue) is essential for proper assessment of endoscopic skills. When box trainers are equipped with force sensing technology, information about interaction force and torque can be used to train delicate tasks that require adequate force control. If trainees use these training tasks and assessment methods to train tissue handling skills in laboratory setting before operating on a patient, the risks of tissue damage can be reduced. The present research consists of two parts. The first objective is to develop a simple and low-cost force platform system that measures force and torque applied on tissue with standard laparoscopic tools inside a standard box trainer. The second objective is to illustrate the potential of the developed platform by measuring the difference in performance of one Novice and one Expert during a simple needle driving task.

Requirements

The design of a platform that measures forces and moments generated between instruments and tissue, should meet the following requirements:

- 1. Measurement of forces in 3 directions (X,Y,Z)
- 2. Measurement of moments around the X, Y, and Z axis
- 3. Device fits in different standard box-trainers with minimal modifications of the training setup
- 4. Multiple training tasks can be trained with the device
- 5. Plug and play and compatible with all standard computer operating systems
- 6. Low cost, robust, and easy to assemble
- 7. Accuracy 10 % of range
- 8. Able to measure frequencies up to 20 Hz [7]
- 9. Force and torque range should be adjustable for different trainings tasks
- 10. The platform must be able to measure forces and torques up to 12N and 0,7Nm [8-11]

Based on these requirements, a prototype was made that makes use of a commercially available 6D mouse (Space Navigator, 3Dconnexion GmbH, Seefeld, Germany). This mouse is typically used to move objects in a three-dimensional virtual environment. The

potential of the prototype for performance evaluation in laparoscopic tasks was investigated in a pilot study.

Opto-electronic 6D mouse

The Space Navigator is a USB device that can be read with standard communication protocols as used by Windows®. In Figure 2.1, a schematic exploded view of the Space Navigator itself is presented. Relative movements and position of the table are determined by optoelectronic components installed inside the Space Navigator. Basically, 3 bundles of infra-red light are created with 3 pairs of LED's mounted on a Printed Circuit Board (PCB) (1). With a triangular plastic block (2) with slit diagraph (3), placed over the LED's (4), the 3 bundles are reshaped into 3 x 2 light paths. The light paths are detected by 3 light detecting components (8), installed on a second PCB (5). Both PCB's are connected by small springs (6) that allow independent movement in all directions.



Figure 2.1 Schematic exploded view of the SpaceNavigator (adapted from Patent EP1850210).

2.2 MATERIALS AND METHODS

Software

Software was written in C++ to record rotation and translation vectors at a rate of 60 Hz. The data was saved in arbitrary units together with a time vector. To compute the force in Newton and torque in Newton per mm for further analysis, the relationship between the measurements and the applied forces was determined by calibrating the force platform.

Mechanical components

To use the Space Navigator as a 6D force platform in box trainers, the allowable range of forces needs to be increased. Increased stiffness in all directions is required to measure forces over 2 N without limiting the movement of the cap. This is accomplished by adding 3 springs around the Space Navigator (Figure 2.2). On one side the springs are

connected to the table (i.e. the upper plate) that is mounted on the cap of the Space Navigator. On the other side, the springs are connected to a base plate fixed on the housing of the Space Navigator. Small adjustments in the position and orientation of all individual springs, with respect to the base plate and table, is possible by repositioning of the spring holders with the three star screws at the top and 3 Allen screws at the base plate (Figure 2.3). If springs with a stiffness of 14 N/mm are used, a force range of 12 N is easily reached. For the first needle driving tests a lower force range of 6 N is sufficient. Therefore, springs with 4N/mm stiffness are used to maximize the resolution



Figure 2.2 Left: force platform built from mechanical components. Right: modified SpaceNavigator that is fixed between base plate and table.

Calibration

Calibration was accomplished with standardized weights of 50, 100, 250 and 500 g. A frame from mechanical components was built to exert well defined forces and torques, in all directions, to the centre of the platform table. During the force calibration of each axis, the load on the platform was increased from -650 till 650 g in steps of 50 g. The Torque on the platform was increased from -1.08 till 1.08 Nm with steps of 98,1 \cdot 10⁻³ Nm. Each axis was calibrated 3 times. After calibration, regression lines were added to the platform output data of each individual axis.



Figure 2.3 Vector representation of example non-selective manipulation

Accuracy

The forces applied during calibration result in force and torque vectors with components in three orthogonal axes (X, Y and Z). During calibration, the output error is determined for every individual axis. However, if the force or torque vector is spanned between two or three axes, each individual translation along, or rotation around, one axis can influence the force-output or torque-output relation of the other axis. To determine a general value for the accuracy of the platform, a series of tests were conducted. During the first test series, three different forces of 0.981 N, 1.962 N and 2.943 N are exerted in line with the 8 direction vectors (Figure 2.4, Q1 to Q8). During the second test series, three different torque values of 0.384, 0.256 and 0.28 Nm are exerted around the 8 direction vectors (Q1 to Q8). During both tests, each measurement was repeated 3 times.



Figure 2.4 Direction of applied force and torque during testing.

Pilot study - Needle driving task

A pilot study in which subjects performed a needle driving task was undertaken to investigate the potential of the force platform. The task was conducted inside a training box (Figure 2.5, right) equipped with two 5-mm and one 11-mm trocars (Endopath XCEL, Johnson & Johnson), 2 needle drivers (B Braun) and one laparoscopic camera. Artificial tissue, imitating the skin and fat layers (Professional Skin Pad, Mk 2, Limbs & Things, Bristol, United Kingdom), was fixed on the force platform. On top of the artificial tissue, the point of insertion and direction were marked by two lines (Figure 2.5 Left). The line thickness was 2 mm and the distance between the two lines was 9 mm. The test group (n=10) consisted of five surgeons who had performed at least 50 laparoscopic sutures during surgery and five Novices without hands on experience in laparoscopic surgery or training. All subjects were asked to pick up a needle (Vicryl 3-0 SH plus 26 mm, Ethicon, Johnson & Johnson) with the needle driver and to insert it at the right line on the tissue. Secondly, the subjects were asked to drive the needle, in the desired direction, through the tissue and to remove it completely at the location of the left line. If a subject was not able to insert the needle at the right line or to remove it at the left line, the measurement was removed from the database and the subject was asked to

try it again. All subjects were asked to complete the needle driving task two times. During the test, no feedback was given to the subjects.

For each subject we determined the maximum absolute force and the mean absolute nonzero force. We defined the mean absolute nonzero force as the force averaged across all samples during which force was exerted so that the resulting measure is based only on the periods of time were interaction took place. To determine whether the results obtained for the experienced surgeons differed from the data from the Novices we performed Students t-tests (SPSS 17.0) to compare the group means. Also, striking differences in force signatures were further investigated. In addition, we asked one Novice and one Expert to perform the needle driving task four times instead of two. This was done to see if learning effects occur within a small amount of repetitions.



Figure 2.5 Left: force platform with artificial skin tissue. Right: test setup with Box trainer, trocars, laparoscope, needle holders, and force platform.

2.3 Results

Calibration

The maximal force range per axis is determined by the linearity of the force platform output. As soon as the moving parts are out of boundary and motion is restricted, the force platform output becomes highly nonlinear and unpredictable. Within working range, the output of the force platform is linear. For torque applied around the X and Y axis, the output is linear. However, if torque is applied around the Z axis, the output is quadratic. Table 2.1 presents the regression lines and R-square values for the fitted data of each axis. The positive mean sensor output and output errors (\pm Standard Deviation, SD), together with linear fitted regression lines are presented in Figure 2.5. The Absolute negative force and torque range is comparable with the positive range.

Table 2.1 Regression lines and R square values

Force calibration			
Axis	Lin. Reg. Line	\mathbb{R}^2	
х	Fx >0 SO=0,0275 ·Fx -10,647	0.9999	
	Fx <0 SO =0,0222·Fx +13,192	0.9988	
у	Fy >0 SO =0,0688·Fy -12,267	0.9941	
	Fy <0 SO =0,0688·Fy +12,267	0.9987	
Z	Fz >0 SO =0,0587·Fz -19,643	0.9907	
	Fz <0 SO =10,0596·Fz-1,0238	0.9981	
	Torque calibration		
Axis	Lin. Reg. Line	\mathbb{R}^2	
х	Mx >0 SO=0,2787·Mx-34,242	0.9971	
	Mx <0 SO=0,2787·Mx +20,637	0.9975	
у	My >0 SO=0,3194·My-10,246	0.9994	
	My <0 SO=0,2932·My+8,897	0.9928	
Z	$Mz > 0$ SO=0,0004· Mz^2 +0,8467· Mz +55,898	0.9996	
	$Mz < 0$ SO=-0,0002· Mz^2 +0,5051· Mz +17,135	0.9954	

 $\mathbf{F} = \mathbf{Force} [\mathbf{10}^{-3}\mathbf{N}]$

M =Moment [10⁻³ Nm]

SO = Platform output [arbitrary units]

 R^2 = square of the sample correlation coefficient between the observed and modeled (predicted) data values

Accuracy

In Figure 2.6 the results of the force and torque accuracy tests are presented. Three horizontal lines indicate the desired value.



Figure 2.6 Mean ± standard deviation (SD) sensor output in arbitrary units and regression lines for a positive force and torque range.



Figure 2.7 Mean \pm standard deviation (SD) sensor output during test run 1–3. Q1 to Q8 represent the direction vectors of the applied force and torque as described in the "Materials and methods" section.

Sensitivity

A threshold, below which all data is discarded, prevents the untouched 3D connexion mouse from drifting. Until this threshold displacement is reached, the output values are zero. The threshold displacement together with the stiffness of the installed spring determines the threshold force and torque. Therefore, a stiffer set of springs increases the measurement range as well as the threshold value. In the force platform with a suitable measurement range for suture tasks, threshold values of 0.7 N for the Z axis and 0.5 N for the X and Y axis were found. Furthermore, the torque threshold values were determined on 0.02 Nm for the Z axis and 0.03 Nm for the X and Y axis.

Pilot study - Needle driving task

It took the surgeons 17.8 s (SD 2.1 s) and the Novice 29.4 s (SD 3.7 s) to complete the task. Before the surgeon and Novices inserted the needle into the artificial tissue, a clear difference between orientation and position of the needle inside the needle driver was visible. After inserting the needle-tip, both subjects used different strategies to drive the needle through the tissue. The surgeon used mostly rotation (R) of the needle around an imaginary rotation point (Figure 2.8A) whereas the Novice used rotation (R) as well as 8translation (X,Y) (Figure 2.8B).



Figure 2.8 Observed difference in needle driving between Expert (A) and Novice (B). R is rotation around needle centre point, X is translation parallel to X-axis, Y is translation parallel to Y-axis.



Figure 2.9 Absolute force exerted on artificial tissue (A). 3D representation of force exerted on artificial tissue (B).

Furthermore, unlike most surgeons, all Novices pressed the needle driver against the tissue during the task. A force graph and 3D force signature of the best performing surgeon and Novice are presented in Figure 2.9A, B. The absolute nonzero mean force and maximal force of all subjects, measured during the needle driving task, are presented in Figure 2.10. The force graphs of a Novice and surgeon that performed the needle driving task four times are presented in Figure 2.10. The maximum and mean absolute nonzero force used by the Novices was on average 4.7 N (SD 1.3) and 2.1 N (SD 0.6) respectively. For the surgeons, the average maximum force (2.6 N, SD 0.4 N) and the average mean force (0.9 N, SD 0.3) were much lower. The Student t-tests showed that there was a significant difference between the two groups of subjects for both depend variables (Mean nonzero force: t=4.3, p<0.005, Maximum force: t = 3.6, p<0.017).



Figure 2.10 Differences between Experts and Novices in performance. Each data point represents the averaged value over two measurements of one subject.



Figure 2.11 Force graphs of a Novice and surgeon that performed the needle driving task four times.

2.4 DISCUSSION

The developed force platform has a mean accuracy for measuring forces of 0.1 N (SD 0.073) and 0.02 Nm (SD 0.016) for measuring torques. This makes the force platform suitable for almost any delicate training task that involves tissue manipulation. However, if forces are exerted at a position further as 60 mm from the midpoint of the force platform table, the mean output error can increase to 10 % of range. To account for larger deviations from the midpoint, the platform can be used in combination with endoscopic box trainer tools that track motion, such as TrEndo [1]. If the position of the tip of the instrument with respect to the force platform midpoint is known, the accuracy can be improved.

The potential of the developed force platform for assessment in laparoscopic tasks was evaluated in a needle driving task. During the needle driving experiment only the force was measured and analyzed. Since the needle is inserted directly above the Platform midpoint, the internal torque is negligible. For other tasks, depending on the dimensions of the task and required accuracy, torque measurements could be highly relevant for performance evaluation.

From our observations during the needle drive experiment it became clear that the needle driving strategy and performance speed had a great influence on the outcome of time dependent parameters. Thus, if force parameters are used for assessment of the subject, it is important to take into account that occasionally there is no interaction between instruments and tissue. In this study we therefore excluded all zero force values when computing a performance measure as the mean force. Other observations suggest that it may be possible to use force measurements to reveal a learning curve (Figure 2.11). However, a larger test group and more measurements per subject are needed before it is possible to determine which force parameters are representative for dexterous performance.

Force and torque information in training tasks

In the present study we evaluated performance in a needle driving task. However, potentially any training task, used to practice laparoscopic skills, can be mounted on the force platform just like the suture task used in the pilot study. Box trainers equipped with the force platform can provide students and instructors with objective information about interaction forces and torques for more effective training and assessment.

With respect to training an important question remains how to present the torque and force data to the student in real-time (Figure 2.12). When tasks are performed inside a laparoscopic box trainer, the resident's attention is directed to the monitor. Further, the complexity of the task may make it difficult to detect whether the proper amount of forces is applied. If the platform is used for well-defined simple tasks, it should be possible to find an effective method of providing force feedback during training. One option is to use this same monitor to display torque and force information. Another option is to use sounds to indicate, for example, that the exerted torque or force exceeds a stored maximum value.



Figure 2.12 Schematic diagram of a resident during training on box trainer equipped with a force platform.

2.5 CONCLUSION

An easy to use 6D platform was developed to measure force and torque in three directions during performance of endoscopic tasks inside box trainers. The low cost prize of the components and the compact design of the platform make it suitable for a broad range of training tasks purposes. The platform requires no modifications of instruments or box trainer. The developed software runs on a laptop or desktop system with a standard operating system. The first prototype, designed for delicate tasks in laparoscopy, measured forces and torques with a mean accuracy of 0,1N (SD 0,07) and 0,02Nm (SD 0,016) respectively. Unfortunately, due to the threshold in the hardware of the mouse, forces less than 0,7N and torques less than 0,03Nm are not detected. However, a pilot needle driving test conducted by five surgeons and five Novices indicated that the platform is accurate and sensitive enough to reflect the most important differences in performance.

Acknowledgments

The authors would like to thank the Bio Mechanical Engineering (BME) technicians of the Delft University of Technology and Skills lab technicians of the Leiden University Medical Centre for help in manufacturing and testing the force platform. They thank all students, surgeons and gynaecologists for participating in this study and providing practical information about surgical training tasks and box trainers.
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CHAPTER 3 FORCE PARAMETERS FOR SKILLS ASSESSMENT IN LAPAROSCOPY

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IEEE Transactions on Haptics, volume 5, issue 4, pages 312-322



In this chapter a comparative study is described with subjects that performed an intracorporeal suture task in a box trainer with integrated force platform. It shows that differences between experts and novices in tissue handling skills can be exposed with force parameters.

ABSTRACT

background

When equipped with motion and force sensors, box-trainers can be good alternatives for relatively expensive Virtual Reality (VR) trainers. As in VR trainers, the sensors in a box trainer could provide the trainee with objective information about his performance. Recently, multiple tracking systems were developed for classification of participants based on motion and time parameters.

Methods

The aim of this study is the development of force parameters that reflect the trainee's performance in a suture task. Our second goal is to investigate if the level of the participant's skills can be classified as Experts or Novice level. In the experiment, Experts (n=11) and Novices (n=21) performed a two-handed needle driving and knot tying task on artificial tissue inside a box trainer. The tissue was mounted on the Force platform that was used to measure the force, which the subject applied on the tissue in three directions. We evaluated the potential of 16 different performance parameters, related to the magnitude, direction and variability of applied forces, to distinguish between different levels of surgical expertise.

Results

Nine of the parameters showed significant differences between Experts and Novices. Principal Component Analysis was used to convert these nine partly correlating parameters, such as peak force, mean force and main direction of force, into two uncorrelated variables. By performing a Leave-One-Out-Cross Validation with Linear Discriminant Analysis on each participants' score on these two variables, it was possible to correctly classify 84% of all participants as an Expert or Novice.

Conclusion

We conclude that force measurements in a box trainer can be used to classify the level of performance of trainees and can contribute to objective assessment of suture skills.

3.1 INTRODUCTION

Due to the complexity of minimally invasive procedures, objective and affordable training tools are required to train and assess the skills of students in surgery. Currently, simple training boxes are slowly replaced by Virtual Reality (VR) or box-trainers that measure time and instrument motion [1]. The main goal of these training systems is to provide trainees with objective information about their performance. However, next to instrument motion and time, the measurement of force exerted on tissue seems to capture important information about the surgeon's laparoscopic skills [2,3]. Especially when surgery is performed on delicate tissue the chance on tissue damage due to the use of excessive force should be minimized. Selecting the proper tissue manipulation force based on what can be felt at the handle is however complicated by disturbances of the instrument-tissue interaction forces [4-6].

To teach trainees to interpret the felt forces when dealing with tissue, objective performance feedback should be provided to the trainee about the resulting forces at the tip. Today, researchers experiment with different modified instruments that provide force information to the surgeon or trainee [7]. However, without proper knowledge of the task requirements and validated performance metrics, those systems cannot determine whether trainees perform as expected. In other words, if feedback is used in a training system, the trainee can only learn from this training system if a clear frame of reference exists.

In the past, several researchers have been successful in classifying different levels of Expertise on the basis of a variety of performance measures. Chmarra et al [8] looked at the performance of participants during four basic endoscopic eye hand coordination tasks. Using several motion and time parameters, these authors were able to classify 74% of all Novices, Intermediates and Experts correctly. Richards et al. [9] and Rosen et al. [10] used force/torque information from a modified laparoscopic grasper with 6DOF force sensor between handle and shaft in combination with video information for state analysis and decomposition of surgical tasks. After decomposition, different surgical actions were analyzed in Markov models for skills classification. Their studies show that force parameters after task decomposition can distinguish Expert from Novices with 80% success. The results of Rosen et al. [9] and Chmarra et al. [8] show that highly reliable classification is feasible and can contribute to objective skills evaluation. However, the performance measures used in these studies require special tracking tools or video images to determine the instrument actions (e.g. translation, rotation, grasping), or even special modified instruments to acquire force and torque measurements [9,11,12]. Further, the inclusion of motion parameters in the classification method makes the approach less suitable for judging the safety of exerted forces during tissue manipulation.

In a previous study we found that Experts apply significantly less force on tissue during a suture task in a box trainer [13]. Such data can easily be obtained without modifications of the surgical tools and is presumably more relevant for evaluation of tissue manipulation skills. In the current study we investigate whether parameters that are exclusively related to the instrument-tissue interaction forces, can be used for reliable classification of different Expert levels. A detailed analysis of the magnitude and direction of applied forces was performed to develop new force parameters for objective evaluation of the trainee's performance. The first objective of the study is to see if significant differences in force application can be found between Experts and Novices during a suturing task performed in a box-trainer. The second objective is to see if force parameters alone can be used to determine the level of skills of the trainee. If such an approach is adequate, training and assessment in hospitals, skills labs or even at home becomes more efficient and effective.

3.2 MATERIALS AND METHODS

Participants

31 participants with different levels of experience in laparoscopy participated in the experiment. The participants were divided into two groups, Experts (n=11) and Novices (n=21). The first group consisted of surgeons and gynaecologists that performed over 100 laparoscopic procedures. The Novices in the second group consisted of first and second year medical students with no experience in laparoscopic surgery or laparoscopic training. Each participant was asked to answer a short questionnaire detailing information about prior experience in laparoscopy. All of the participants were right-handed.

Suture Task and protocol

The participants performed a two-handed suturing task inside a box trainer equipped with two five millimetre trocars and one 11 millimetre trocar (Endopath XCEL, Johnson & Johnson), two needle holders (B Braun, Durogrip TC, PL407R) and a laparoscopic camera. Inside the box trainer, artificial skin (Professional Skin Pad, Mk 2, Limbs & Things, Bristol, United Kingdom) was mounted on a 3DOF force measuring Platform with a custom made aluminium holder (Figure 3.2, Left). At the centre of the artificial skin, two parallel lines were drawn at nine millimetre distance from each other. A 26 mm Vicryl 3-0 needle from Ethicon (Johnson & Johnson) was used to conduct the suture task. The training box was covered with paper and the laparoscope was used for visualization of the suture task on a monitor. Before the measurements started, a video was shown and a schematic overview was provided to the Novices to explain how to make the suture.

Figure 3.1 shows the type of suture with three knots that is used in this study. In the first phase of a single measurement, the participant was asked to insert a needle at the right line and to guide it through the tissue as close as possible towards the left line using their right hand. The left hand was then used to remove the needle at the left line. If the needle was not inserted correctly, a new measurement was started for the next attempt and all recorded data was deleted

If the participant did not succeed within five attempts the participant was removed from the study. In the second phase the participant made three knots. If necessary, participants received additional verbal instructions during the knot tying phase until three successful knots were made. Data from Novices that were not able to tie three knots was removed from this study. All participants were asked to repeat the complete sequence three times in a row with a maximum break of 10 minutes in between. For both phases of the task, the participant was not limited in time.

Before every measurement, the needle was positioned inside the needle holder by the experimenter so that the starting conditions were the same across participants and trials. Since not all participants had previous experience with the type of needle pushers used in this study, each participant had the opportunity to manipulate the buttons and handle for five minutes outside the training box before the start of the first measurement.



Figure 3.1 Suture task needle driving with three knots.

Force measurement setup

To measure the forces that were applied on the artificial tissue we made use of a custom made Force Platform. This Force Platform consists of a 6DOF mouse (Space Navigator, 3Dconnexion) combined with three adjustable coil springs [13].



Figure 3.2 Overview of the experimental setup. Left: close up of artificial tissue mounted on top of a 3DOF Force platform. Right: the box trainer in which the force platform was placed. A laparoscope is used for visualization of the suture task on a monitor. The box was covered with paper during all measurements.

The Space Navigator, developed for 3D navigation in virtual environments, is a USB device of which the output can be read with standard communication protocols as used by Windows[®]. The device measures the changes in position and orientation of the Space Navigator's cap relative to its bottom due to user applied forces. The magnitude of these changes is determined by optoelectronic components installed inside the Space Navigator. The Space Navigator was designed for minimal actuation force during use. Without modification, the maximum horizontal and vertical cap displacement of 3 mm is reached if forces over two Newton are exerted. To increase this force range to 14 Newton, three relatively stiff springs were placed around the Space Navigator to counteract displacements of the cap. The Force Platform was assembled according to Figure 3.3. On one side the springs are connected to the table that is mounted on the cap of the Space Navigator. On the other side, the springs are connected to a base plate fixed on the housing of the Space Navigator. To compute the force in Newton for further analysis, the relationship between the sensor output and the applied forces was determined by calibrating the X, Y and Z displacements of the Force Platform. Calibration was accomplished with standardized weights resulting in forces of 0.5, 1, 2.5 and 5 Newton placed inside a weight holder that hangs freely on a thin cable. A frame from mechanical components and two low friction pulleys was built to guide the cable in horizontal or vertical directions

If loaded with weights, the cable exerts well defined pulling forces, in any desired direction, to the centre of the platform table. During the force calibration of the two directions of each axis, the load on the platform was increased from 0 to 14 Newton in steps of 0.5 Newton. After calibration, regression lines were used to find the formula that expresses the platform output of each axis in force. Finally, a spring balance was used to exert forces in different directions on the Force Platform to check if the exerted force resembles the absolute force as calculated from the calibrated sensor output [13]. In the current configuration, the sensor has an accuracy of 0.2 Newton.



Figure 3.3 Force sensor housing with adjustable springs (A and B) that is fixed to the 3D mouse cap and base plate. If assembled, the force required to move the table and cap in X, Y or Z depends on the stiffness of the springs. The calibration axis X, Y or Z are determined by the Space Navigator's hardware.

Custom made software was written in C++ to record the sensor output to a computer at a sample frequency of 60 Hz. To mark specific events during a measurement, the software allowed the experimenter to press a button in the user interface. The timestamp of these button presses were recorded alongside the sensor data and used to distinguish the different phases (e.g. needle driving part and three different knot tying parts) when analyzing the data.

The Force platform with suturing task on top (Figure 3.2, Left) was locked inside a ring that was fixed to the bottom of the box trainer. This ensured that the sensor's position and orientation never changed with respect to the trocar entry ports during the different measurements. The Force platform was positioned underneath the task area so that it did not obstruct the motions of the instruments in any way. The task conditions were therefore the same as in a normal training setting.

Force parameters and data analysis

In total 16 different force parameters were chosen to evaluate the application of forces by the participants (Table 3.1). These parameters are related to the magnitude and direction of applied forces or to the variability thereof. Due to the different task requirements in the needle driving and knot tying phases in a suture task, not all force parameters are suitable performance measures for both phases of the suture task.

For the needle driving phase and knot tying phase, the forces over time for all three directions, Fx, Fy and Fz, were obtained from the recorded data. The X, Y, and Z axis of the force were defined relative to the Force platform. Based on Fx, Fy, and Fz we calculated the mean force parameters (e.g. meanFx, meanFy and meanFz). Furthermore, we calculated the mean absolute force parameter, maximal absolute force parameter and standard deviation (e.g. meanabsforceNZ, maxabsforce and STDabsforce) from the square root of Fx, Fy and Fz.

During the knot tying phase only, it is expected that force peaks occur when the threads are stretched to tighten the knot. Figure 3.4 shows an example of the absolute force in time during needle driving, the first phase, and knot tying, the second phase, of the task. The highest absolute force peak itself was defined as the period with the highest absolute force between t1 and t2 during the knot tying phase.

force peak =
$$\int_{t_1}^{t_2} |F| dt$$

(Eq. 3.1)

F = Absolute force $t_1 =$ Starting time of absolute force peak $t_2 =$ Stoping time of absolute force peak



Figure 3.4 Representation of the absolute force over time during needle-driving and knot-tying phase. The hatched rectangle indicates the area where the highest mean absolute peak force between t1 and t2 is found in the knot tying phase. The height of the dashed rectangle indicates the mean absolute force between t1 and t2. The boxed values represent the mean Fx, Fy and Fz during the force peak.

The starting time t₁ was defined as the point in time the measured absolute force became higher as 0.1 Newton. The stopping time t₂ was defined as the first moment after t1 the absolute force became less than 0.2 N again. Due to the sensor accuracy of 0.1 N sensor outputs less than 0.2 N were neglected for the determination of t1. During the highest absolute force peak, the mean Fx, mean Fy and mean Fz components (e.g. forcepeak-meanFx, forcepeak-meanFy, forcepeak-meanFz) should indicate in which direction the threads are pulled at the moment a knot is tightened.



Figure 3.5 Phase 1: ellipsoid (transparent) representing the variability in forces in 3D when a needle is pushed from line A to Line B through artificial tissue. Phase 2: ellipsoid (transparent) representing the variability in forces in 3D during the knot tying phase. In both ellipsoids, the thick arrows represent the standard deviations (PC1,PC2,PC3) of the forces along the Principal axes of the ellipsoid.

To determine the main direction of applied forces (that not necessarily coincides with the X, Y, of Z axis), the variability in forces was presented graphically as projections of oriented ellipsoids in 3D (Figure 3.5). In Figure 3.6, Fx-local, Fy-local and Fz-local are the three principal axes of the ellipsoid. PC1, PC2 and PC3 are the standard deviations of the force along those principal axes and define the shape of the ellipsoid. The lengths of PC1, PC2 and PC3 and orientations (Fx-local, Fy-local and Fz-local) were determined using Principal Component Analysis (PCA) software (princom.m, Matlab 2008b). PCA is a mathematical procedure that uses an orthogonal transformation to convert a set of observations of possibly correlated variables into a set of values of uncorrelated variables called principal components [14].

All analyses were performed for the needle driving phase and knot tying phase, separately. To evaluate whether there were differences between Experts and Novices in the main direction of force application the orientation of the largest principal component (PC1) was determined. This orientation was defined by the parameter Alpha, the rotation in the horizontal plane and parameter Beta, the rotation in the vertical plane.



Figure 3.6 3D variability in forces. The black dots represent the force in the global coordinate system (Fx,Fy,Fz). The light grey ellipsoid is fitted on the force data and the orientation of PC1 along Fx-local is defined by Alpha α and Beta β. PC2 and PC3 are not showed in the figure.

The main direction of force application can only be specified when PC1 is significantly larger than the other components. For instance, when the ellipsoid has the shape of a ball or disk, Alpha and Beta cannot be defined accurately. To evaluate the uniqueness of the principal components, the likelihood criterion [15] of the principal components was determined with:

$$\chi^{2} = -(N-1)\sum_{i} \ln l_{i} + (N-1)r \ln \frac{\sum_{i} l_{i}}{r} < \chi^{2}_{\alpha,r}$$

$$\chi^{2} = \text{Likelihood criterion} \qquad (Eq. 3.2)$$

$$\chi^{2} = \text{Likelihood criterion} \qquad (Eq. 3.2)$$

$$r = \text{Number of eigenvalues} = 2$$

$$N = \text{Number of samples}$$

$$l_{i} = \text{The } r = 2 \text{ eigenvalues being compared for a given}$$

$$covariance matrix (i = 1-2 \text{ or } i=2-3).$$

The likelihood criterion was calculated for the two largest standard deviations PC1 and PC2 of the ellipsoid (Figure 3.5). Only ellipsoids with a likelihood criterion higher than 5.99 were taken into account. To get an estimate of the variability in the forces independent from the direction of force we calculated the volume of the ellipsoids. The "volume" parameter was calculated with [16]:

$$V = \frac{4}{3}\pi(PC1 \cdot PC2 \cdot PC3)$$

(Eq. 3.3)

V = volume PC1= standard deviation of force along Fx-local PC2= standard deviation of force along Fy-local PC3= standard deviation of force along Fz-local

Some studies suggest that completion time seems a suitable parameter for discriminating between Experts and Novices [8,17,18]. However, since completion time does not provide information about the exerted forces or the quality of the performed task, it is left out of the classification. If compared to force parameters, the performance time can provide useful information for further research and is therefore presented in Table 3.1

LDA based classification

To classify participants into groups with different performance levels Linear Discriminate Analysis (LDA) is being used. LDA searches for a linear combination of features that separate two classes of objects. The LDA analysis in this study uses force data from Experts and Novices with known levels of experience. The method was applied to see if it is possible to classify a participant as Expert or Novice based on his/her force behavior. A similar approach was used by Chmarra et al [8] for determination of the skills level of residents based on performance time and motion parameters. The following subsections explain the steps taken to increase the discrimination power of the LDA and to give insight information about the correlation between parameters.

Parameter selection with student-T-test

A total of 16 force parameters were identified that could be suitable to determine the differences between groups (Table 3.1). However, LDA limits the number of possible parameters for classification of a participant to only two (Figure 3.8). To reduce the number of parameters we first determined for each of the different parameters whether the group means obtained for the experienced surgeons differed from the group means from the Novices using student T-tests (SPSS 17.0). A probability $p < \alpha$ ($\alpha = 0.05$) was

considered to be statistically significant. The difference between Experts and Novices on the parameters in the coloured fields of Table 3.1 were found to be not significant and these parameters were therefore removed from the further analysis.

Correlation matrices

Next, using only significant parameters, correlation matrixes of the force parameters were calculated. A correlation matrix shows which parameters are inter-related and which are independent from each other. Correlation between parameters gives useful information about the use of particular force parameters for feedback to the trainee. For example, If hypothetically all defined parameters are for 100 % correlated to the "Max force" parameter, trainees only need to learn to minimize the maximal exerted force on the tissue to reach the Expert skills level. Furthermore, only if groups of correlated parameters are found, the use of Principal Component Analysis (PCA) is effective.

Principal Component Analysis

For each group of highly correlated parameters in the correlation matrix, Principal Component Analysis (PCA) was used to find new parameters that represent the group of correlated parameters as good as possible. To illustrate, the example in Figure 3.7 shows how two highly correlated parameters, Par.A and Par.B can be expressed by the new parameter Par. D. In this study, the PCA analysis was used to calculate new principal components for the significant parameters of both suture phases in Table 3.1 (princom.m, Matlab 2008b). PCA orders the newly calculated principal components based on the amount of variance they explain. The first PC explains the most variance while the succeeding PC's explain the rest of the variance in decreasing order. For this study we sum up the number of PC's from top down until a minimum of 75% of the total variance in the data is explained. Since the variance of the used parameters is extremely heterogeneous (i.e. values differ from 0.01, STD 0.3 Newton to 213 STD 55 Degrees), all data was first normalized before PCA was applied. The data of each force parameter for each of the two suture phases was normalized according to:

$$Z = \frac{x - \mu}{\sigma}$$

Z = standard force parameter score μ = the mean force parameter value (Eq. 3.4)

- x = raw force parameter score to be standardized
- σ = the standard deviation of force parameter

Classifier

The principal components that explain minimal 75% of the variance and the data from the participants are now used as input for the classifier (classify.m, MATLAB 2008b). The classifier now determines the borderline between the Novice and Expert data group.

Leave-One-Out-Cross-Validation

For a reliable impression of the number of participants that can be correctly classified based on the data, Leave-One-Out-Cross-Validation (LOOCV) software is written in

Matlab. For each LOOCV case, the training set consists of the data of 31 participants while the data of one participant is selected as a test case. The data of all participants is used once as test case resulting in 31 LOOCV cases. During each LOOCV case, the skills level of the test case is predicted based on its location in respect to the border line as determined by the LDA (Figure 3.8). Since the real experience level of each test case is known, the predicted outcome of each LOOCV cases indicates how reliable new participants are classified based on the used data set and force parameters. A more detailed description of LOOCV for classification can be found in Chmarra et al [8].



Figure 3.7 Hypothetical correlation between parameters. Par.A and Par.B are highly correlated (92%) and can be expressed by Par.D. Furthermore, Par.B and Par.C are not correlated (17%) and cannot be expressed in a single new parameter.

To determine which part of the suture task can be used best for classification, the classification method was used separately for the needle driving phase, the knot tying phase and both phases combined.

3.3 Results

Each participant performed the needle driving phase and knot tying phase 3 times. The averaged outcome per parameter is used for all calculations. The results for each force parameter including mean value, is listed in Table 3.1. For parameters that show significant differences, the results from all participants are presented in Figure 3.11.

Needle driving phase

The parameters that show significant differences in the needle driving phase are depicted in the first and second row of Figure 3.11. All Experts (n=11) were able to insert and remove the needle at the desired locations at the first attempt. Of the Novices (n=21), only 32% was able to complete this phase at the first attempt. The other 68% was able to complete the driving phase within the five attempts. Only data of successful attempts was used in the analysis.



Figure 3.8 Hypothetical example of a single LOOCV case. PC1st stands for largest principal component. PC2nd stands for second largest principal component. The participants are indicated by triangles. The round dot is a participant that is left out of the training data and used as test case. The border line splits the Expert area from the Novice area and is recalculated in the Linear Discriminant Analysis for every single LOOCV case.

The mean maxabsforce and mean meanabsforceNZ found in the Novice group were 4.5 N (STD 1.3) and 1.6 N (STD 0.6) respectively. With a mean maxabsforce of 2.7 N (STD 0.4) and mean meanabsforceNZ of 0.9 N (STD 0.3), the force exerted by the Experts is significantly lower. It took the Experts 21 (STD 6) seconds and the Novices 56 (STD 30) seconds to complete the task. The mean volume of the ellipsoid, that was computed from the standard deviations along its axes, was considerably higher in the Novice group (1.5 (STD 1.3)) when compared with the Expert group (0.5 (STD 0.4)). Looking at the orientation of the ellipsoids, a mean value of 224° (STD 39°) for Alpha was found in the Expert group. With a mean value of 176° (STD 57°) for Alpha, the ellipsoids in the Novice group were much further rotated around the Z axis. A less clear difference was found for the rotation in the vertical plane. A mean value for Beta of 237° (STD 63°) was found for the Expert group and a mean value of 181° (STD 95°) was found for the Novice group. Since all likelihood criteria were higher than 5.99, the orientation was defined reliably for all ellipsoids.

	Experts			Novices			
parameter	Needle driving	Knot tying	Needle driving	Knot			
	Phase 1	Phase 2	Phase 1	tying			
	Mean(SD)	Mean(SD)	Mean(SD)	Phase 2			
				Mean(SD)			
meanabsforceNZ	0.02(0.22)	0.40(0.10)	1 (1(0 (0))	0.47(0.10)			
[N]	0.93(0.32)	0.42(0.18)	1.64(0.62)	0.4/(0.18)			
maxabsforce [N]	2.66(0.63)	2.67(0.97)	4.50(1.07)	4.31(1.24)			
STDabsforce [N]	0.72(0.18)	0.38(0.15)	1.21(0.44)	0.44(0.17)			
meanFx [N]	0.34(0.26)	-0.04(0.07)	0.49(0.48)	-0.02(0.03)			
meanFy [N]	0.01(0.34)	-0.03(0.05)	0.09(0.94)	-0.02(0.04)			
meanFz [N]	0.30(0.30)	0.02(0.12)	0.34(0.30)	0.03(0.05)			
Volume [N]	0.46(0.35)	0.04(0.04)	1.47(1.35)	0.05(0.05)			
PC1 [N]	0.72(0.18)	0.35(0.16)	1.22(0.45)	0.38(0.16)			
PC2 [N]	0.45(0.14)	0.17(0.06)	0.61(0.19)	0.21(0.08)			
PC3 [N]	0.23(0.06)	0.09(0.04)	0.37(0.12)	0.14(0.06)			
alpha_ellipsoid							
[deg]	224(39)	170(82)	177(57)	213(55)			
beta_ellipsoid	220((2))	100(60)	101(00)	106(40)			
[deg]	238(63)	180(60)	181(96)	196(48)			
forcepeak [Ns]	-	4.61(7,32)	-	15.47(10.49)			
forcepeak -meanFx							
[N]	-	-0.11(0.35)	-	-0.20(0.49)			
forcepeak -meanFy							
[N]	-	-0.12(0.28)	-	-0.17(0.50)			
Forcepeak-							
meanFz [N]	-	0.24(0.66)	-	-0.24(0.64)			
Time [s]*	21(7)	95(36)	56(30)	446(184)			

 Table 3.1 Parameter results. The grey fields contain only non-significant force parameters.

* Only for comparison, not used in calculations

Knot tying phase

The parameters that show significant differences in the knot tying phase are depicted in the third row of Figure 3.11. All Experts (n=11) were able to complete the knot tying phase of the task at the first attempt. Due to time constraints, 5 Novices (n=21) did not finish the complete task and stopped after the needle driving phase. All other participants were able to tie all knots according to the instructions given. The average of 2.7 N (STD 1.2) for the maxabsforce parameter in the Expert group is significantly lower than the average value obtained for the Novice group (4.3 N, STD 0.9). The mean meanabsforceNZ is with 0.4 N (STD 0.1) in the Expert and 0.5 N (STD 0.2) in the Novice group not significantly different between groups. It takes the Experts on average 95 (STD 36) seconds and the Novice 446 (STD 184) seconds to complete this task. The

maximal force peak as product of the time and pulling force is with a mean value of 6.7 Ns (STD 7.7) in the Expert group significant lower as in the Novice group. (15.4 Ns (STD 10.5)). Looking at the distribution of the pulling force on the threads in the direction of PC3, the averaged standard deviation found in the Expert group is with 0.01 N (STD 0.4) significantly lower as in the Novice group (0.14 N, (STD 0.6)). None of the other pre-defined parameters were significantly different between groups.

Classification.

The correlation matrices created for the needle driving phase and the two phases together suggested that the parameters maxabsforce, meanabsforceNZ, PC1, PC2, PC3 and volume (from ellipsoid) from the needle driving phase were strongly correlated. Moreover, the correlation matrix of both groups together shows that the group of strongly correlated parameters from the needle driving phase seems also correlated with the forcepeak parameter from the correlation matrix of the knot tying phase. Also from the needle driving phase, the angles Alpha and Beta, who define the ellipsoid orientation, are only highly correlated to each other. Finally, the PC3, maxabsforce and forcepeak parameter from the knot tying phase are also highly correlated. The correlation matrix taken from the parameters of phase one and two together performed best in the LOOCV and is shown in Table 3.2.

parameters parameters	s that sh s are indi	ow signi cated wit	ficant dif h the diff	fferences ferent gr	betweei ey areas.	n Exper	ts and N	Novices. (Correlate	d grou	ups of
	P1- Mean	P1-Max	P1-STD	P1-	P1-	P1-	P1-	P1-	P1-	P2-	P2-

Table 3.2 Pearson Correlation matrix (multiplied by 100 for convenience) calculated from all

	Mean absforce NZ	P1-Max absforce	P1-STD absforce	P1- STDFX local	P1- STDFY local	P1- STDFZ local	P1- volume	P1- Alpha ellipsoid	P1- Beta ellipsoid	P2- force peak	P2- maxabs force
P1-											
maxabsforce	83										
P1-STD											
absforce	96	87									
P1-PC1											
	96	85	99								
P1-PC2	04	72	05	04							
D1 DC2	04	15	83	04							
PI-PC3	75	82	78	76	84						
P1-volume											
	82	77	89	89	88	87					
P1-alpha-											
ellipsoid	-55	-47	-54	-50	-37	-33	-36				
P1-beta-											
ellipsoid	-41	-30	-42	-42	-25	-22	-25	70			
P2-											
forcepeak	61	58	59	63	50	46	48	-14	-37		
P2-											
maxabsforce	53	68	58	60	49	47	43	-29	-40	75	
P2-PC3											
	41	50	42	46	34	42	34	-10	-35	84	78



Figure 3.9 Shows the results of the Linear Discriminant Analysis with Leave–One–Out-Cross-Validations on the significant parameters from the first phase, second phase and both phases together.

For all three groups, the Principal component analysis indicate that at least 75% (e.g. 78% in phase 1, 75% in phase 2 and 91% for phase 1 and 2 combined) of the data's variance is explained by the first two new principal components. The Leave–One–Out-Cross-Validation as performed on the two largest principal components indicates that 78%, 81% and 84% of the Experts and Novices were correctly classified in respectively the first phase, second phase and both phases combined (Figure 3.9). Figure 3.10 shows the linear borderline between the Expert and Novice group based on a LDA performed on the two principal components calculated from the significant parameters only.

3.4 DISCUSSION

Needle driving phase

In line with our previous study [13] and the VR suture study of O'Toole [18], we found that the Novice group applied a higher maximum and mean force than the Expert group. These results also matched our observations throughout the experiment. It was clear that most Novices used much more force than required for the needle to cut through the artificial material.

Leave-One-Out-Cross-Validation results



Figure 3.10 Differences between Novices and Experts based on all significant parameters from phase 1 and 2 combined. PC1st and PC2nd are first and second largest principal components as found after principal component analyses. The borderline shows the border between the different areas of each group.

Looking at the distribution of the force inside both groups, the distribution of the mean force required to drive the needle in the desired direction (meanFx) is comparable between groups. Only small forces are expected perpendicular to the direction the needle is pushed. Except for two outliers, the meanFy values found in the Expert group indicate that all Experts behaved similarly and none used excessive force in the Y direction. In the Novice group however, the mean force varied from -2N to +1.8N. The relatively large variation in magnitude of forces in the Y direction in this group may be explained by friction in the training setup. In the X and Z direction, a large part of the movements can be accomplished by rotation of the needle pusher around its pivot point. Movements in the Y direction are mainly accomplished by axial displacement of the needle holder in the trocar. If, for example, the needle is pushed into the artificial tissue and moved excessively in the Y direction before the instrument handle is released, the friction in the trocar and elastic disc prevent the instrument from moving back to its starting position and a "force-offset" is created.

Since the force-offset is a result of the force-equilibrium between Force-platform springs and trocar valve or elastic disk, nothing is felt at the handle. Since Novices use more force to accomplish the task, the risk on a force offset that influences the meanFy parameter is higher. A second explanation is found in limitations in depth perception. Earlier studies indicate that instrument movements in the direction of the optical axis are difficult to estimate [20, 21]. Presumably, limitations in depth perception make it difficult for untrained eyes to detect unintentional needle displacements in the Y direction. Since needle displacements result in force, a limitation in depth perception could influence the meanFy parameter.

The ellipsoid volume and standard deviations in exerted forces are possibly related to the participant's control of movement direction. If the needle is pushed with a constant force in one direction through the material, the standard deviations are near zero and the ellipsoid volume is small. Especially the direction of the largest principal component (PC1) and the size of the ellipsoid volumes indicate that a large part of the Novices used multiple movements to manipulate the needle through the artificial tissue. The needle is locked inside the needle holder with an angle of 90 degrees with respect to the needle holder shaft.

Due to the configuration of the holes and dimensions of the box trainer, the needle describes an angle of 230 degrees with respect to the positive X axis in the horizontal plane at the moment of insertion (Figure 3.12). If forces are exerted in the direction of the needle, the ellipsoid's largest principal component should aim in the same direction as the needle tip. With Alpha values close to 230 degrees (mean 224°,STD 39°) in the Expert group, it seems that Experts are able to manipulate the needle more efficiently through the artificial material than Novices (mean 176°,STD 57°). Beta does not depend on the location of the trocar relative to the location of the suture area and an ideal value cannot be determined in advance.



Figure 3.11 Needle driving phase and knot tying phase results. The Experts in group 1 are indicated with a "O" mark (n=11) and the Novices in group 2 are indicated with "X" mark (n=16). Each measurement point represents the averaged value of 3 measurements from one participant. The horizontal lines indicate were the mean value is found. Significant differences are indicated by P values. Time was not used for classification.

Knot tying phase

The maximum force in the Novices group is significantly higher compared with the Expert group. However, the low mean force in X, Y and Z direction in both groups indicates that the high absolute forces only occurred during short periods of time. The significant difference in maximal force peak between groups confirms that Novices not only use more force to secure the knot but also that the force is exerted for a longer period of time.



Figure 3.12 Idealized needle driving behaviour. The force is mainly exerted in the same direction as the needle. In this case, the needle tip and largest principal component (PC1) point in the same direction.

During the maximal forcepeak, the mean force in this phase shows in which direction the threads pull on the artificial tissue. The meanFZ- forcepeak value suggests that Novices tend to pull on the threads in the –Z direction while tightening the knot whereas Experts tend to push in the +Z direction. The meanFX- forcepeak and meanFY-forcepeak value's showed no indication of specific differences between groups.

Compared with the volumes calculated in the needle driving phase, the volumes calculated during knot tying are much smaller. The reason can be that interaction takes place through threads without direct contact between instrument and tissue. A thread under tension transmits only force in the direction of the thread to the tissue. If the tip pulls on a thread, only the movements in the axial direction of the thread results in a reaction force in the artificial tissue. All other movements of the tip are not counteracted and do not add "volume" to the ellipsoid.

Classification

The LOOCV method performed on the principal components based on all significant parameters correctly classified 84% of all participants and can therefore help to determine the skills of trainees. Besides the fact that the two phases of the suture task are completely different, combining the significant force parameters of both phases gives the best results. Figure 3.9 also indicates that the number of correct classifications in the needle drive phase is slightly lower than for the knot tying phase. This is rather counter-intuitive since more parameters show significant differences in the needle drive phase compared to the knot tying phase. An explanation can be found in the LOOCV itself. The LOOCV gives only a prediction of the success rate which is not 100% accurate. When, as can be seen in Figure 3.10, three Experts are on the border between groups, minor changes can cause some fluctuations in LOOCV outcome.

In a complementary study, Chmarra et al. used the LOOCV method to distinguish between Experts, Novices and Intermediates on the basis of an analysis of their instrument motions in 4 different laparoscopic tasks [8]. These authors showed that 74% of all participants in the study could be correctly classified using task time and motion parameters.

It should be noticed that the Principal component analysis requires that all input data is normally distributed. To test whether this was so, we performed a normality test (SPSS 17.0 with Shapiro-Wilk analysis) on the data of each parameter in both parts of the suture task. Distributions with a probability $p < \alpha$ ($\alpha=0.05$) were considered to be not normally distributed. The results indicate that for the beta ellipsoid parameter this was not the case in both experimental groups. To determine the contribution of this parameter to our results and, therefore, the possible influence of a violation of the assumption of normality for this parameter on the results, we repeated the analysis while excluding the beta ellipsoid parameter. In this case the PCA and LOOCV analysis performed on phase 1 and phase 2 combined resulted in the correct classification of 82% of the Experts, 76% of the Novices and 77% of the total number of subjects.

Our results show that objective assessment of trainees can be improved further when the force parameters that were used in the current study are incorporated in the classification analysis. If the suture task is performed correctly, the Force Platform does not measure any activity during the knot tying phase. In this phase, additional motion tracking of the instruments could be useful to monitor the skills in knot tying. Therefore, the combining of forces sensors with motion tracking could result in even a higher discriminating power. Possibly, discriminating power can also be improved when data from Experts and Novices is obtained in a more realistic environment. One may question whether it is legitimate to use data from surgeons as Expert data if a task is offered in a box trainer that does not match the surgeon's natural environment during surgery. The performance of Experts on artificial tissue in a box does not necessarily reflect their manipulations of real tissue. Increased discriminating power may therefore also be achieved with the use of high fidelity VR simulators. Further studies are necessary to distinguish between different specialisms in surgery since it is likely that not all tissues and situations require equal delicacy in handling force. For example, it is possible that specialists in gastrointestinal surgery perform different from gynaecologic surgeons on a suture tasks such as used in this study. If the Force platform is used for advanced training in a particular surgical action or even procedure, the training data must come from Experts experienced in that particular field of Expertise.

Besides the use of force parameters as assessment measure after post processing, some force parameters can also be used to provide real time force information to the trainee. If, in case of a needle driving task, the amount of force depends on the tissue handling strategy, real time force information can help guiding the trainee towards the preferred strategy. For instance, the presence of high forces during needle driving implies that the curvature of the needle is not used adequately during insertion or removal. Also, when a horizontal reaction force is measured during the knot tying phase, there is an imbalance between the forces applied with the two individual instruments. Further, the threads are not correctly stretched in a horizontal direction when forces in vertical directions are present during knot tying. In all of these examples real time force information could be used to make the student adapt his/her behaviour.

Studies of Kitagawa and Reiley [3,7] indicate that visual force information during robotic surgery was associated with lower suture breakage rates, peak applied forces, and standard deviations of applied forces during a surgical suture task. If feedback is given, correlation matrices can also help us to choose what kind of force information should be provided to the trainee. In this study the matrices suggest that two groups of parameters are highly correlated to the maxabsforce in Phase 1 and Phase 2. Only the direction of the ellipsoid seems independent from the maxabsforce. Based on these results, further research should indicate if trainees perform better on all force parameters after being trained on minimizing the magnitude of force and applying force in the correct direction.

3.5 CONCLUSION

Our needle driving study confirms that experience has influence on the suture force during a laparoscopic suture task. The maximal absolute force and time clearly discriminate between the two different levels of experience during both suture phases. The mean force and the force variability (e.g. Ellipsoid volume and direction) discriminate between groups in the needle driving part of the task.

The LOOCV method performed on the principal components based on all significant parameters correctly classified 84% of all participants and can therefore be used to improve objective assessment of trainees.

Acknowledgments

The authors would like to thank the Bio Mechanical Engineering (BME) technicians of the Delft University of Technology for help in designing and manufacturing the box trainer with Force platform. They thank all surgeons and gynaecologists for taking interest in this study and providing practical information about suturing in minimally invasive procedures. Finally, the authors like to express special thanks to Gert-Jan Hultzer en René Rodenburg from the skills lab of the Leiden University Medical Centre for providing us with all the instruments, materials and facilities necessary.

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CHAPTER 4 THE INFLUENCE OF INSTRUMENT CONFIGURATION ON TISSUE HANDLING FORCE IN LAPAROSCOPY

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Surgical Innovation, volume 20, issue 3, pages 260-267.



Single access surgery requires different skills compared with conventional laparoscopy. The results in this chapter show the relation between tissue handling force and the distance between two manipulated instruments. The results in this study also indicate that the choice for the preferred instrument configuration is not necessarily based on differences in instrument handling complexity.

ABSTRACT

Background

Single access surgery is one of the latest trends in laparoscopy. Since instruments enter the abdominal cavity through only one incision, the position of the instruments relative to each other is different compared to conventional laparoscopy. Changes in instrument configuration may increase task complexity and therefore affect tissue handling skills.

Methods

The aim of this study is to determine if a relation exists between instrument configuration and tissue interaction force in a artificial tissue manipulation task A study was performed to investigate the differences in manipulation force between a Single Port (SP) and Two Port (TP) instrument configuration in a standard box trainer. A force platform was placed in the box trainer and used to measure the pulling forces and trial time. Twenty-eight medical students with no previous experience in laparoscopic surgery were divided into two equal groups. Group 1 trained the task 6 times with the TP configuration and subsequently performed 6 trials with the SP configuration. Group 2 used the configurations in opposite order. For both groups, the learning curves of the maximum force and task time were compared. Time and maximum pulling/pinching forces were significantly different between the two instrument configurations.

Results

In both groups, the participants significantly used more force in the SP configuration than in the TP configuration (means (std); Group 1: 11.1(2.5)N vs. 8.1(2.2)N, Group 2: 9.0(2.7)N vs 6.6(2.3)N).

Conclusion

The force data indicates that the increased complexity in instrument handling with straight instruments in a SP configuration increases the tissue manipulation force. Furthermore, the tissue handling skills of Novices that mastered the task with the TP configuration decreased after switching to the SP configuration.

4.1 INTRODUCTION

In minimally invasive surgery, instrument motion is limited to translations and rotations at the incision point. In single access surgery, where all instruments and laparoscope are inserted through one incision, contact between instrument shafts and instrument handles limits the freedom of movement of the surgeon even more. Some studies suggest that those limitations in movements result in longer operation time due to increased complexity [1-4]. In studies focusing on skills comparison in box trainers, similar results are found [5,6]. No studies were found that investigated the influence of the single access surgery technique on tissue handling. However, there are reasons to assume that tissue handling is more difficult in single access surgery. In standard laparoscopy, a large workspace can be realized by retracting the instruments or by rotating the instruments away from each other. However, Figure 4.1 shows that in a single access surgery configuration the surgeon is forced to cross the instruments in order to obtain sufficient distance between instruments tips.



Figure 4.1 Left; In single access surgery, instruments must cross in order to increase the working distance between tips. Right; In standard laparoscopy, Instruments can be retracted or rotated around their pivot point to increase the working distance between tips.

Continuous surface contact between shafts results in friction during movements disturbing the tactile feedback at the handles. Distorted tactile feedback could also influence the force control required for safe manipulation of tissue. Figure 4.2 shows that the risk of continuous shaft contact between the two instrument shafts is higher in single access surgery due to the minimum space between handles.

In order to prevent instrument handle interaction and to increase the working area in the abdominal cavity the surgeon can choose either to cross the shafts of the straight instruments or to use special pre-bended instruments [6]. However, the increased complexity in handling the instruments is likely to increase the mental task load as well [7]. Therefore, besides instrument collisions and distorted tactile feedback, an increased mental task load could also influence the tissue handling skills of the surgeon in a negative way.



Figure 4.2 Single access surgery in Box-trainer; Instrument shafts (Left) and handles or hands (Right) are likely to collide.

Studies objectives

The main objective of this study is to investigate the influence of standard TP instrument configuration and SP instrument configuration on the tissue handling skills. The maximum tissue manipulation force and trial time are recorded during each trial and represent the tissue manipulation skills in this study. The second objective of this study is to determine how Novices evaluate the difficulty of both configurations after training and which factors influence this evaluation. In the experiment, we used identical instruments in both configurations to ensure that possible performance differences are only caused by the position of the entrée ports of the instruments.

4.2 MATERIALS AND METHODS

Participants

The total test group consisted of 28 first and second year medical students recruited from Leiden University Medical Centre without hands-on experience in laparoscopic surgery or training. The participants were randomly assigned to one of the two experimental groups.

Experimental setup

A Force Platform was developed consisting of a force sensor to measure time and force in laparoscopic box trainers ranging from 0 to 10 N in 3 dimensions with an accuracy of 0.1 N and a measurement frequency of 60 Hz [11]. A webcam (Logitech,webcam C600) was used to capture images of the workspace of the instruments. Figure 4.3 shows the setup built from a modified standard box trainer that is commonly used in laparoscopic training. To allow the use of a SILSTM port, an extra entree was made between the two existing entrees.



Figure 4.3 Training setup; A standard box trainer modified for SP and equipped with Force Platform (below right) to measure all forces exerted on the training task.

A tissue manipulation task made from artificial tissue was mounted on top of the Force Platform. All forces that are exerted with the straight laparoscopic instruments on the artificial tissue are measured with the Force Platform and stored on a computer. Figure 4.4 shows how the webcam, tissue manipulation task and Force Platform are fixed inside the modified box trainer.



Figure 4.4 Inside view of modified box trainer; A fixed USB camera with LED lights was used to obtain the video images during training. A custom made silicone training task is fixed on top of the Force Platform.

A battery powered light sources with three white LED were placed under the top plate of the box to create a small light beam on the place of interest on the training task. Comparable with real laparoscopic camera systems, the light beam creates a more realistic vision inside the box trainer. For both experimental configurations, SP and TP, two standard laparoscopic forceps were used (Ethicon Endo-Surgery, Johnson &Johnson). To guide the instruments in the SP configuration, a soft plastic single incision trocar (SILSTM trocar, Covidien Surgical, Norwalk, CT, USA) was used. For the TP configuration, two 5mm trocars (Endopath, Ethicon Johnson &Johnson) were used.

Software

A user interface was built in Matlab® to display the camera image inside a separate screen while data was recorded from the Force platform at a rate of 30 Hz. The data is saved in arbitrary units together with a time vector. Since the relation between the force sensor output and the applied forces in Newton is known after calibration, the output is computed in Newton [11]. The forces over time for all three directions, Fx, Fy and Fz, were obtained from the recorded data. The X, Y, and Z axis of the force were defined relative to the Force platform. Based on Fx, Fy, and Fz, we calculated the mean absolute force, from the square root of Fx, Fy and Fz. The Max. absolute force was considered as the maximum value in the absolute force vector.

Training task

A custom made silicone training task was fixed on the Force Platform (Figure 4.5). This task was based on actions identified in a number of "WebSurg" videos about single access procedures [12]. The training task involves a worm-like string of silicone that has to be navigated through a small ring (Phase A) and precisely hooked on a pin (Phase B). During Phase A, the loose end of the artificial tissue needs to be carefully positioned inside the laparoscopic gripper before it can be navigated through the ring. Similar actions are found during tissue dissection. In tissue dissection, one laparoscopic gripper is used for the positioning of tissue inside the view of the camera. The orientation of the tissue inside the gripper is crucial to achieve a straight cut at the desired location. Part B of the task, precise navigation of tissue under tractive force, can be recognized in surgery during laparoscopic sterilization. In female sterilization, the ovarian tube needs to be positioned perpendicular to the laparoscopic camera and stretched for precise placement of a clip or ring. Compared with stretching the "worm" before placing it over a small pin in our task, placement of a clip on a stretched ovarian tube requires precise alignment of instruments and tissue. During this two handed action, it is essential that the tractive force, generated by one instrument, stays low and constant even if the clip is applied by the other instrument.

To mimic blocking of view by organs and connective tissue, the ring and pin are partially hidden under a highly elastic silicone layer. To reach the ring and pin, the silicone layer needs to be pressed downwards. In order to complete the task efficiently, cooperation between both instruments is required at all times. To ensure that the tissue handling complexity of the task represents the surgical actions in SAS sufficiently, 6 experienced surgeons (practicing in Italy or the Netherlands) were asked to try the training task and to give their opinion.

Figure 4.5 shows the task before and after it was completed. All students were asked to navigate the head of the silicone "worm" through the ring. The task was finished after the tissue was stretched and the end of the tissue was placed with its hole over a pin.



Figure 4.5 Left; The silicone training task at the beginning of the session. Right; The silicone training task at the end of the session. The head of the "worm" is navigated through the ring (A). After stretching, the head of the "worm" is pushed over a pin (B).

Procedure

In the experiment, each participant was asked to pick up the head of the worm-like tissue and to navigate it through the ring with one instrument. As soon as the head of the tissue passed the ring, a mark was given in the software. From here, the participant was asked to stretch the tissue as gentle as possible to hook the opening over the pin. All students were told that the artificial material is delicate and should be handled with care. The tissue handling task was performed 12 times during a single measurement session (Figure 4.6). Students that exceeded a trial time of 15 minutes at the first attempt were excluded from the study.

To investigate the influence of the skills learned during task performance with the TP configuration on task performance with the SP configuration and vice versa each students was asked to perform 6 trials according to one technique followed by 6 trials according to the other technique.

In previous experiments we found that, for relatively simple tasks, possible learning effects stabilize after 6 training sessions [10-12]. Therefore, all participants were asked to train for a minimum of 6 trials before starting the experiment. To get familiar with the handles and functionality of the instruments, the instruments were given 5 minutes prior to the start of the training session.

After the training session, the students from both groups were asked to rate the 1st, 6th, 7th, and 12th trial of the training session on a scoring list. A mark of "one" was considered as very difficult and "ten" as very easy. Finally, all students were asked which configuration (e.g. TP or SP) they preferred. For the students that preferred the SP configuration above the TP configuration, the difference in tissue handling performance was determined to investigate if their preference is reflected in the tissue handling force of performance time.

The differences in manipulation force and task time for the 6th and 12th trial were analysed with a two-tailed ANOVA-test (SPSS, version 16). A p-value less than 0.05 was taken as a significant difference.



Figure 4.6 Schematic overview of the training session. Instruments are given to all students 5 minutes before the training starts. Group 1 starts to train according to the TP technique. Group 2 starts to train according to the SP. After the 6th trial the techniques are exchanged for the last six trials. All students were randomly assigned to the groups. The students that exceeded a trial time of 15 minutes during the first trial (pre-test 1) were excluded from the session.

4.3 RESULTS

To ensure that the complexity of the task represents the surgical actions in single access surgery sufficiently, six experienced surgeons were asked to try the training task and to give their opinion. Five surgeons judged the task complexity to be comparable to what they experience in actual single access surgery. However, in actual surgery two of these surgeons make use of bended instruments and one of them used one straight instrument instead of two straight instruments. Three surgeons indicated to use a 30 degrees scope in real practice. On average, it took the six surgeons 71s (std 29) to complete the task.

Study outcome

Two students of Group 2 that started with the SP configuration exceeded the maximum allowable trial time of 15 minutes and were excluded from the study. From the 26 students five students reported that the SP configuration was easier than the TP configuration. Table 4.1 shows how difficult the 1st, 6th, 7th and 12th trials were rated. These results show that the order in which the configurations are mastered has a significant effect on the score for the last trial of the SP configuration (p = 0.042).

Student	Start	Two Po	ort (TP)	Single P	Preference	
number		Laparoscopy		Laparo		
(group 1)		1 st trial 6 th trial		7 th trial	12 th trial	
1	TP	7	9	2	7	TP
2	TP	3	8	2	6	TP
3	TP	7	8	6	7	TP
4	TP	6	8	3	5	TP
5	TP	6	8	5	7	TP
6	TP	4	7	1	5	TP
7	TP	5	8	3	5	TP
8	TP	6	8	2	7	TP
9	TP	1	6	1	3	TP
10	TP	3	7	2	6	TP
11	TP	8	9	3	6	TP
12	TP	4	8	3	6	TP
avera	ged					
sco	re	5.0 (std 2.0)	7.8 (std 0.8)	2.8 (std 1.5)	5.8 (std 1.2)	TP
Student	Start	Two Port (TP)		Single P	ort (SP)	Preference
number		Laparoscopy		Laparo	scopy	
(group 2)		7 th trial	12 th trial	1 st trial	1 st trial 6 th trial	
1	SP	5	7	7	7	SP
2	SP	6	8	4	6	TP
3	SP	2	9	3	9	SP
4	SP	5	8	3	9	SP
5	SP	6	9	4	7	TP
6	SP	4	6	1	3	TP
7	SP	8	7	2	4	TP
8	SP	7	9	2	8	TP
9	SP	2	8	2	8	TP
10	SP	4	6	1 9		SP
11	SP	6	8	4	8	TP
12	SP	4	8	2	7	TP
13	SP	1	5	3	8	SP
14	SP	4	8	2	7	TP
avera	aed	-				
score		4.6 (std 2.0)	7.6 (std 1.2)	28 (std 16)	7 1 (std 1 8)	TP

Table 4.1 Overview of the scores given to the first and last trial of each technique. The start column shows the surgical technique that was started with. The preference column shows which technique was preferred after the training.

The two upper and lower graphs of Figure 4.7 display the learning curves of the force and trial time during the 12 trials of Group 1. Group 1 started the session according the TP configuration and switched half way to the SP configuration. During the TP configuration, the learning curve for the maximum force as well as the performance time decreases from 7.5N (std 2.24) and 633s (std 564) to 6.6N (std 2.31) and 114s (std 40) respectively. During the SP configuration, the performance time drops from 379s (std 183) to 199s (std 99) while the maximum force stabilizes around the 9N (std 2.7) on average.



Figure 4.7 Learning curves of the trial time and maximum force of Group 1. Group 1 switched from the TP to the SP technique after the 6th trial. To emphasize any trends, a 2nd order curve was fitted to each graph.

The two upper and lower graphs of Figure 4.8 display the learning curves of the maximum force and trial time during the 12 trials of Group 2. Group 2 started the session according to the SP configuration and switched half way to the TP configuration. During the SP configuration, the learning curve for the maximum force increases from 9.5N (std 2.6) to 11.0N (std 2.5). The performance time decreases from 554s (std 303) to 192s (std 151) respectively. During the SP configuration, the performance time drops from 187s (std 115) to 101s (std 68) while the maximum force slightly drops from 9N (std 1.6) to 7.9N (std 2.2). Figure 4.9 shows the data from the 6th and 12th trials. The maximum force applied on the tissue during the TP configuration was in both groups noticeably lower compared with the SP configuration.

The students in Group 1 applied an averaged maximum force of 9.0 N (std 2.7) with the SP configuration and 6.6 N (std 2.3) with the TP configuration. The students in Group 2 applied an averaged maximum force of 11.0 N (std 2.5) with the SP configuration and 7.9 N (std 2.2) with the TP configuration. The averaged performance time differences between the SP and TP configuration were similar between groups. To understand the influence of the order in which a technique is learned on the tissue manipulation force, the SP and TP force data in Figure 4.9 was combined and averaged for each Group (Figure 4.9, dotted line). The averaged maximum manipulation force in Group 1 was significant lower compared with Group 2. (6.6N std 2.3 vs 9.0N std 2.7). For the five students in Group 2 that preferred the SP configuration above the TP configuration, the difference in tissue handling performance was investigated.



Figure 4.8 Learning curves of the trial time and maximum force of group 2. group 2 switched from the SP to the TP technique after the 6th trial. To emphasize any trends, a 2nd order curve was fitted to each graph.

At the end of the learning curve, the five students exerted a maximum force of 11.5N (std 2.7) with the SP configuration and 7.7N (std 1.9) with the TP configuration. The performance time was lower for the TP configuration compared with the SP configuration (mean/std; 183/150s vs. 78.5/53s).



Figure 4.9 The maximum force (upper graph) and trial time (lower graph) of both groups at the end of each learning curve (e.g. 6th and 12th trial). "-" is the mean value "*" is the TP technique data and " Δ " is the SP. "..." indicate the averaged max force.

4.4 DISCUSSION

A significant higher tissue handling force for the SP configuration compared to TP is found independent from the configuration mastered at first attempt. Moreover, the learning curves suggest that the maximum manipulation force could increase over time during training with the SP configuration. This is in contrast with the slightly decreasing maximum manipulation force over time during training with the TP configuration.

The averaged maximum force data of each group indicate that the order in which both configurations are mastered by the students influences the overall tissue manipulation skills in terms of manipulation force. At the end of the learning curve, the overall averaged tissue manipulation force is significantly lower in the group that started training with the TP configuration compared with the group that started with the SP configuration. Therefore, from the technical point of view, it would be recommendable to master the laparoscopic technique for (new) surgical procedures before any single access technique is applied. Fortunately, this recommendation is in line with the current approach of most surgeons.

The complexity during the task was limited by the use of a fixed USB camera inside the box trainer. However, the use of a real, non-fixed laparoscope inside the SILSTM trocar restricts the movements of the instrument even more. Further increasing the task complexity could therefore result in more contact between instruments and camera, a higher mental load and therefore higher tissue manipulation forces. A follow up study should therefore compare groups with and without 0 degrees and 30 degrees scopes during a SP task.

Since straight instruments in a SP configuration minimize the range of motion and therefore increase the risk of collisions, manufacturers developed curved and double curved instruments. Further studies should indicate if use of curved or double curved instruments in a SP configuration can prevent high tissue handling forces as found in this study.

In all studies that compared single access surgery with standard laparoscopy, parameters based on time are used as objective performance measures [5,6]. The findings in this study suggest that improvements in task time are not linked to improvements in tissue handling skills. These results correlate with our previous work [13]. In this study visual force feedback dramatically reduced the tissue handling force during a conventional laparoscopic suture task. However, the performance time in the group that received visual feedback during training did not differ from the control group that did not received feedback during training. Moreover, the learning curve in Figure 4.8 shows that even the opposite can be true

For the group that started to train with the SP configuration, the task time reduced significantly while the tissue handling skills deteriorated. Those findings need to be considered if only time is used for skills evaluation

For the five students in group 2 (i.e. 3 female, 2 male) that preferred the SP configuration above the TP configuration, the difference in tissue handling performance was investigated. The trial time and Max force differences between techniques are not different from the rest of the students that preferred the TP configuration above the SP configuration. These results indicate that the choice for the preferred technique is not necessarily based on differences in instrument handling complexity. Other factors as personal interest for new technology or the order in which the techniques were mastered
could also influence the choice for a more complex technique. This is in line with the scoring of the SP configuration in Table 4.1. The final SP trial scored significantly higher if the SP configuration was mastered before the TP configuration.

4.5 CONCLUSION

The force data indicates that the increased complexity in instrument handling with straight instruments in a SP configuration increases the tissue manipulation force significantly. Furthermore, the order in which the two different instrument configurations are mastered by the students influences the overall handling force significantly.

Acknowledgment

The authors would like to thank all students, surgeons and gynaecologists for participating in this study. They thank all surgeons from Italy and the Netherlands for providing practical information about surgical suture tasks in box trainers.

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CHAPTER 5 SUTURING ABDOMINAL ORGANS: WHEN DO WE CAUSE TISSUE DAMAGE

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Surgical Endoscopy, volume 26, issue 4, pages 1005-1009



In literature not much can be found about the maximal allowable pulling force on a suture thread during suturing. This chapter provides the results of 80 hours of measurement on multiple fresh porcine organs. The results in this chapter show that each type of tissue has its own individual range of acceptable maximum forces before damage occurs. The thresholds found in this study are used to provide visual force feedback in this thesis.

ABSTRACT

Background

It is generally assumed that safety of tissue manipulations during (laparoscopic) surgery is related to the magnitude of force that is exerted on the tissue. To provide trainees with performance feedback about tissue handling skills it is essential to define objective criteria for judging the safety of applied forces. These criteria should relate the applied forces to the risk of tissue damage to be of clinical relevance. The current experimental study was conducted to determine which tractive forces during suturing cause tissue damage in different types of porcine tissues.

Methods

Tractive forces were applied on 8 different tissue types of 10 different pigs; e.g. fascia, aorta, vena cava, peritoneum, small and large bowels, uterus and fallopian tubes, by placing increasingly higher loads on sutures in the tissue. We determined at what load tissue damage occurred through visual inspection of the tissue. For each tissue sample three consecutive measurements were performed.

Results

The average maximum acceptable force varied between 11.43 N for fascia to 1.25 N for fallopian tubes. The difference in allowable force between the two structures is almost 10 fold. Small bowels can be handled with a tractive force almost 1¹/₂ fold higher than large bowels.

Conclusion

Every tissue type was found to have its own individual range of acceptable maximum forces before visual tissue damage occurs. With the results presented in this study, it is possible to provide clinically relevant and validated feedback to trainees about their tissue handling skills.

5.1 INTRODUCTION

It is well established that basic surgical skills should preferably be trained in a nonclinical setting [1-3]. Especially complex surgical tasks such as performed in laparoscopic procedures place higher demands on the motor skills of the surgeon and require extensive training. This training can be done in box or virtual reality trainers or pig models and is currently mainly focused on time and economy of movements. In clinical practice the gold standard is to manipulate tissue as gentle as possible and only if necessary, because every manipulation or dissection creates tissue reaction. However, the loss of haptic feedback in minimally invasive surgery (MIS), due to resistance inside the trocars and the use of long laparoscopic instruments, hinders the estimation of applied forces in instrument-tissue interaction [4]. This problem translates for example in more difficulties when learning to safely apply force in a laparoscopic grasp than to learn the same with barehanded lifts [6]. To facilitate the training of tissue handling skills a force measurement platform has been developed for the box trainer [7]. This force platform provides the trainees with objective feedback of the forces applied on tissue during a suture task. The pilot study of this article suggests that a Novice can apply forces up to 7 Newton during needle driving [7]. However, information about the applied forces does not have any clinical relevance when it is not related to the in vivo tissue damage. The current study was conducted to determine the difference in strength for different types of fresh post mortal porcine tissue when tractive forces are applied on a single suture.

5.2 METHODS

The amount of tractive force on a suture that causes visually detectable tissue damage was investigated in eight different types of porcine tissues of ten different pigs; fascia, aorta, vena cava, peritoneum, small and large bowels, uterus and fallopian tubes. All porcine tissues were acquired from the slaughter house on request and immediately stored in a physiologic saline solution at a maximum temperature of 7 degrees Celsius to conserve the tissue until the measurements were performed. Measurements were performed within six hours after slaughter.

An experimental setup was built to apply tractive forces on a suture (Figure 5.1). With this setup tractive forces up to a maximum of 13 N could be put on the suture by means of adding weights of 50 grams (approximately 0.5 N) in gradual load steps. During every load step tractive force was applied for 1 minute. Between load steps, the tissue was completely relieved of tractive force, before the next load step was examined (i.e. another.50 grams was added). To minimize the influence of friction in the experimental setup, the cable was guided by two pulleys with special low friction bearings. The example in Figure 5.2 shows the force and rupture graph of a force measurement on a single tissue sample of the large intestine.

Before the measurements started, tissue was prepared and fixed to a plateau (Figure 5.1a), meaning that an ample size tissue sample was taken and hollow structures (aorta, vena cava, bowels etc.) were cut open and laid flat on the plateau.



Figure 5.1 Tissue measurement system build for tractive force measurements. Tissue is fixed on a plateau (1A). Example of how tractive force on a suture is measured (1A-1B).

During opening of the hollow structures (i.e. aorta, vena cava, bowel) the tissue in the suture area was not stretched or grasped to prevent changes in the force characteristics of the tissue. While fixing tissue samples to the plateau, irregularities in the folding of the tissue were smoothened out without causing the tissue to damage. Once the tissue sample was fixed to the plateau it was moistened throughout the measurement with a physiologic saline solution (similar to which it had been stored) to prevent dehydration. Vicryl 3-0 suture packs of Ethicon (with 26 mm round needle) were used to suture. Every suture was placed on a homogenous part of the tissue sample and irregularities such as small blood vessels and fibroid tissue were avoided as much as possible. Three tractive force measurements were performed on every tissue sample. Between two separate measurements a minimum distance of 20 mm was kept so that damage which originated from prior measurements did not influence the current measurement. The distance between the insertion and exit point of the needle was 8 mm at minimum and 11 mm at maximum (Figure 5.1b). The two wires of the suture were knot at a minimum distance of 50 mm measured from the tissue to the knot (Figure 5.1c). For every measurement two values were registered:

- 1. The mass of the load at which the first sign of macroscopic damage was noted.
- 2. The mass of the load at which the tissue sample starts to rupture; rupture was defined as the insertion or exit hole of the suture becoming bigger with a speed of 2 mm per minute.

All measurements were done by two investigators. If one investigator could not clearly determine whether tissue damage started to occur, the other investigator was consulted and a consensus was reached after applying further load steps. In ambiguous cases a blue light was lit underneath the tissue. Using this approach, tissue damage such as small punctures, could reliably be detected through visual inspection (Figure 5.1). A control group was created to determine whether consecutive load steps on one suture during a single measurement would weaken the tissue at the entry and exit point of the suture and therefore influence the results. The control group consisted of 2 separate control measurements performed on every tissue type. For the control measurements tissues were prepared similar to the regular measurements. Sutures were also placed with Vicryl 3-0 packs of Ethicon and in a similar manner to the regular measurements. In opposite to the regular measurements, in the control measurements, each tissue sample was loaded only once. For each of the 8 tissue types, the first tissue sample was loaded with the maximum load as found in the regular measurement with an additional 200 gram. For each following new tissue sample, the total load was decreased with 50 grams. The measurements with decreasing load were repeated till no tissue damage was noticed anymore. Of every measurement, the number of millimetres (starting with 3 millimetres) of rupture were registered.



Force measurement on single large-intestine tissue sample

Figure 5.2 A representation of a force measurement as performed on a single tissue sample of the large-intestine. As the force on the wires increases after each load step, the tissue finally starts to rupture during the 3rd step. During the fourth step the rupture speed exceeds the 2 mm per minute and the measurement is finished.

5.3 RESULTS

The mean tractive force and 95% Confidence Intervals (95% CI) of each of the different types of porcine tissue are displayed in Table 5.1. Figure 5.3 shows box plots of the tractive forces at the first sign of tissue damage and moment of rupture.

		First sign of damage		Rupture		
Tissue type	Ν	Mean Mass [g]	95% CI	Mean Mass [g]	95% CI	
Fascie	30	1143	1070-1216	1183	1120-1247	
Aorta	30	987	911-1062	1107	1044-1170	
Vena Cava	30	523	464-583	637	555-718	
Peritoneum	30	187	163-211	233	202-265	
Large bowel	30	158	136-180	212	188-236	
Small bowel	30	218	196-241	300	274-326	
Uterus	30	297	263-331	365	332-398	
Fallopian tube	30	125	101-149	168	147-189	

Table 5.1 Tissue damage after loading



Figure 5.3 Box plots of the tractive force measurements at the first sign of tissue damage and moment of rupture. On each box, the central mark is the median, the edges of the box are the 25th and 75th percentiles, the whiskers extend to the most extreme data point

Before tissue damage occurred, the highest tractive force could be put on the fascia and the lowest tractive force on the fallopian tube. The difference in allowable force between the two structures is almost 10 fold. Small bowels can be handled with a tractive force almost 1½ fold higher than large bowels.

The results of the control measurements (Table 5.2) are comparable to the results that were obtained when instantly loading the tissue with different masses. These results suggest that consecutive load steps on one suture during a single measurement do not weaken the tissue at the entry en exit point of the suture.

Tissue	Measurement	Mass [g] tissue damage	Mass [g] no tissue damage	
Fascia	1	1300	1200	
	2	1300	1200	
Aorta	1	800	700	
	2	1000	800	
Vena Cava	1	500	400	
	2	600	500	
Peritoneum	1	200	100	
	2	150	100	
Large bowel	1	300	200	
	2	200	100	
Small bowel	1	300	200	
	2	350	300	
Uterus	1	300	250	
	2	500	400	
Fallopian tube	1	100	50	
	2	150	50	

 Table 5.2 Tissue damage after loading control measurements

5.4 DISCUSSION

Every tissue type was found to have its own individual range of acceptable maximum forces before visual tissue damage occurred. The variation of the results is relatively small within individual types of tissue around 1 load step for peritoneum, large and small bowels, uterus and fallopian tube and around 2-3 load steps for vena cava, aorta and fascia. The observed variance in the measurements is presumably mainly due to natural variation between different pigs and tissue samples. As such, the presented data can be used to determine thresholds for feedback about applied forces. With these thresholds, trainees can be provided with clinically relevant information about their performance and use this feedback to adjust their strategy in (laparoscopic) suturing in different type of tissue and therefore mimics the issue of tissue handling. An earlier study shows the development of a laparoscopic training system that visualizes the interaction force during a suture task as a coloured 3D arrow on the monitor [8]. In this particular surgical trainer the data could be used to warn the resident/student in real time if safety thresholds are exceeded during needle driving or knot tying.

Previous studies have investigated tissue damage due to grasping forces [9,10] and compression loads in porcine [11] and human organs [12]. However, tissue damage due to tractive force on sutures has not been studied before. Heijnsdijk et al. [9] studied tissue damage as a result of the pulling forces exerted on porcine bowels using various grasping forceps. The allowable forces reported in this study where higher than found in the current study. This is possibly due to the larger contact area of grasping forceps compared to contact area of the sutures, so that the forces are distributed across a larger part of the tissue. In this study tractive forces on sutures were investigated because suturing is one of the most critical aspects of safe tissue handling and knowledge about allowable forces while suturing is therefore crucial.

A limitation of this study is, however, the use of fresh postmortem porcine tissues. The porcine model was chosen for because it often is used as a training model in surgery. Furthermore, porcine bowels (large and small) have been shown to have comparable tissue characteristics to human bowels [9]. Although the tissue was obtained freshly, postmortem degradation of tissue takes place and could weaken the tissue and to some degree influence our results [11]. The influence of degradation was kept to a minimum by storing the tissue in a physiologic saline solution at a maximum temperature of 7 degrees Celsius and performing the measurements within six hours after slaughter. Another limitation of using postmortem tissue is that there is no bleeding. Whereas bleeding normally is one of the first signs of tissue damage, the investigators in this study depended on macroscopic enlargement of the puncture holes. Although it was attempted to determine tissue damage as precisely as possible, by judgment of two investigators and use of facilitating tools such as the blue light (Figure 5.1), it cannot be guaranteed that certain microscopic tissue damage had not already occurred. In fact it is quite plausible that microscopic tissue damage precedes macroscopic tissue damage and microscopic tissue changes could occur before the load step in which macroscopic tissue damage was noted. However, during surgery the surgeon also dependents on visual judgment of macroscopic changes of the tissue to determine tissue damage, therefore the method used in this study approaches the clinical setting as much as possible.

The measurements were done in load steps with a maximum applied force of 13 N. In some cases, especially with the fascia and aorta measurements, damage did not occur until the load step of 13 N. Hence, the tissue can take on forces above 13 N without the occurrence of macroscopic tissue damage. Because it was determined on forehand that forces above 13 N are not applicable for the training set up, the measurement stopped at 13 N. This distorts the mean and median results of the fascia and aorta, of which the true mean and median values could lie above those given in the presented results. However, this should not be a problem for the thresholds in the proposed training program as training of tissue handling will logically be done with thresholds that lie much lower, such as those of large/small bowels, uterus, fallopian tube or peritoneum.

In this study, the load on the tissues was slowly increased by hand till the tissue was carrying the load on its own (Figure 5.2). This way of tissue loading is different from a fast short jerk on the suture wires. During a fast jerk, the moving instruments and surgeon's arms are instantly stopped by the tensioned wires. This fast deceleration of mass results in very short lasting but high reaction forces in the suture and tissue. Further studies are necessary to determine whether the threshold values found after a slowly increasing load resemble threshold values found after a fast increasing load.

5.5 CONCLUSION

It is evident that training of tissue handling skills in a non-clinical setting is crucial for patient safety. The presented data can be used to establish safety thresholds in skills training models (box trainer) that provide force feedback to the trainee during a suture tasks. With the determined safety thresholds it becomes possible to teach the resident/student to link the disturbed force feedback at the instrument handles to visually perceived tissue deformation.

Acknowledgments

The authors would like to thank Gertjan Hultzer en René Rodenburg from the skills lab of the Leiden University Medical Centre for providing all necessary facilities to perform this study.

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CHAPTER 6 VISUAL FORCE FEEDBACK IN LAPAROSCOPIC TRAINING

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Surgical Endoscopy, volume 26, issue 1, pages 242-248



In this chapter augmented reality force feedback is introduced and it is demonstrated that this type of feedback can help students to improve their needle driving strategy to reduce the force exerted on the needle during insertion and removal.

ABSTRACT

Background

To improve endoscopic surgical skills, an increasing number of surgical residents practice on box or VR trainers. Current training is mainly focused on hand-eye coordination. Training methods that focus on applying the right amount of force are not yet available.

Methods

The aim of this project is to develop a low cost training system that measures the interaction force between tissue and instruments and displays a visual representation of the applied forces inside the camera image. This visual representation continuously informs the subject about the magnitude and the direction of applied forces. To show the potential of the developed training system, a pilot study was conducted in which six Novices performed a needle driving task in a box trainer with visual feedback of the force and six Novices performed the same task without visual feedback of the force. All subjects performed the training task five times and were subsequently tested in a post test without visual feedback.

Results

The subjects that received visual feedback during training exerted on average 1.3N (STD 0.6N) to drive the needle through the tissue during the post test. This value was considerably higher for the group that received no feedback (2.6N, STD 0.9N). The maximum interaction force during the post test is noticeable lower for the feedback group (4.1N, STD 1.1N) compared with that of the control group (8.0N, STD 3.3N).

Conclusions and discussion

The force sensing training system provides us with the unique possibility to objectively assess tissue handling skills in a laboratory setting. The real-time visualization of applied forces during training may facilitate acquiring tissue handling skills in complex laparoscopic tasks and could stimulate proficiency gain curves of trainees. However, larger randomized trials that also include other tasks are necessary to determine whether training with visual feedback about forces reduces the interaction force during laparoscopic surgery.

6.1 INTRODUCTION

In endoscopic surgery, trocar friction, scaling and mirror effects make it difficult to estimate the forces that are exerted at the tip of the instruments during a tissue manipulation task. Due to this distorted haptic feedback, surgeons need to rely on other information sources (e.g. tissue deformation or colour changes) to prevent tissue damage during manipulation of tissue. In training, the role of force feedback is not always unambiguous. Some manufacturers of training simulators incorporate some kind of haptic feedback in their virtual reality trainers [1,2] while others state that haptic feedback in VR is not essential for simple training tasks. For more complex tasks that are often used for skills assessment (i.e. suturing) many studies suggest that force feedback is essential [3-5]. Previous studies show that interaction forces between tissue and needle during needle driving are related to suture depth and quality, while forces applied on the wires during knot tying are related to the quality of the knot [4,5]. Unfortunately, the force feedback provided in most commercial VR trainers is far from optimal and does not yet mimic the feedback as experienced during real laparoscopic surgery [5,6]. A good alternative is the box trainer. In this physical model the haptic feedback at the instrument handles is as real as it is in live surgery. If the interaction force at the tip is fed back to the trainee in a clear and intuitive way, the trainee can learn how the distorted haptic feedback at the instrument handle and colour or shape changes of the tissue are related to the real force applied at the tip. One possibility is to provide continuous feedback about actual forces to the trainee in the form of a visual representation that is integrated in the camera image. However, a potential drawback of visually displayed forces is that the computations that are necessary to integrate the measured forces into a modified camera image will introduce time delays. Many studies suggest that time delays can distract the trainee due to unnatural visualization during fast instrument movements [13-16]. For realistic instrument movements, the total time delay should be kept as small as possible. Further, the screen update frequency should be kept at a minimum 30 Hz [11,12].

The present research consists of two parts. The first objective is to develop a low-cost training system that continuously informs the trainee about the force applied on tissue. The second objective is to investigate the aspects of such visual force feedback. In the experiment, the performance of six Novices that received visual feedback about interaction force is compared with the performance of six Novices that received no feedback during training. A lower magnitude of applied forces during post testing for the first group indicates that Novices can learn to reduce forces based on visual feedback.

6.2 MATERIALS AND METHODS

Hardware

The Force Platform, a force sensor specially developed for force measurements in laparoscopic box trainers, can measure forces from 0 to 10 N in 3 dimensions with a accuracy of 0.1 N and a measurement frequency of 60 Hz [4]. A webcam (Logitech,

webcam C600) was used to capture images of the workspace of the instruments Figure 6.1 shows the latest version of the Force Platform and a standard box trainer that is commonly used in laparoscopic training.



Figure 6.1 Left: standard box for laparoscopic training. Right: New and waterproof version of the Force Platform.

Figure 6.2 shows how the webcam and the Force Platform are fixed inside the modified box trainer. Eight white LED's were placed around the camera lens to create a small light beam. Comparable with real laparoscopic camera systems, the adjustable light beam creates a more realistic vision inside the box trainer.



Figure 6.2 A webcam, light source and new force platform equipped with artificial tissue are fixed inside the custom made box trainer.

Artificial tissue, imitating the skin and fat layers (Professional Skin Pad, Mk 2, Limbs & Things, Bristol, United Kingdom), was fixed on the Force Platform. On top of the artificial tissue, the point of insertion and direction were marked by two lines. The line thickness was 2 mm and the distance between the two lines was 9 mm.

Software

A user interface was built in Matlab® to display the camera image inside a separate screen while data was recorded from the Force platform at a rate of 30 Hz. The data is saved in arbitrary units together with a time vector. Since the relation between the force sensor output and the applied forces in Newton is known after calibration, the output is computed in Newton [4]. Secondary, the user interface allows the user to display an arrow inside the camera image that represents the magnitude and direction of the force as it is exerted on the training task and force platform. Figure 6.3 shows that the offset between the arrow's point of origin and the lower part of the arrow prevents that the work field becomes obstructed by the arrow itself. The linear relation between offset distance and force magnitude increases the intuitively of the provided visual feedback of the force.



Figure 6.3 Arrow representation of the force magnitude and direction. The arrow is displayed as an overlay inside the laparoscopic image. An offset between point of needle insertion and arrow prevents blockage of the view of interest.

If available, information about the maximal allowable interaction force for a particular task can be stored in the user interface. If 75% of the maximal interaction force is reached, the arrow turns from green to yellow. If the maximal interaction force is exceeded, the arrow turns red.

Time delays

To investigate whether the video and Force Platform data processing time is within the defined specifications, additional tests are necessary. Since the process consists of multiple computational steps, multiple time delays are expected. The grey blocks in Figure 6.4 illustrate where processing time is lost before an image is displayed on the screen after it is captured by the camera. In addition, some time is lost before the data from the force platform is interpreted and visualized inside the recorded image from the camera.



Figure 6.4 Time delays in the training system. The coloured blocks show where noticeable processing time is lost during training. The total time delay is determined by a summation of the delays in each individual coloured block in the representation.

An additional video camera was placed on a tripod in front of the training setup. To determine the delay between image capture by the webcam and image presentation on the monitor, an instrument handle was moved as fast as possible towards a marked bar (point A) above the box trainer. The movements of the instrument handle above the box are recorded by the video recorder as well as the indirect instrument motions from the monitor of the webcam. Figure 6.5 shows a picture from the video recorder of the training setup with two marked points. The number of frames between the moment that point A is reached by the instrument handle and the moment the corresponding point B is reached on the monitor of the webcam determines the delay of the video system. This test was repeated for six times while the complete setup, e.g. box, screen and hand is recorded with 30 frames per second. The first three tests were conducted 10 seconds after the system was started. The last three tests were conducted five minutes after the system was started. During those tests, there was no feedback generated from the Force Platform. Since feedback of the force is not always helpful, the delays found in those tests give an indication of the system's processing time if the force feedback option is not used.

Next to the delay in display of the instruments, it is important to determine the time span between sensor loading and the moment the force feedback is displayed on the monitor. This delay is caused by time required to process al video and sensor data before it is visualized on the monitor. To determine this time delay, an instrument was placed in a trocar and pressed with a small constant load of 200 gram on the artificial tissue. With a fast downwards motion, the instrument handle was manually tapped by the experimenter. As a result, the instrument shaft was pressed against the Force Platform and the load that was registered increased. This test was repeated for three times. Again, the first three test were conducted 10 seconds after the system was started while the last three tests were conducted 5 minutes after the system was started. Afterwards, the number of recorded frames between the moment the instrument handle was tapped and the arrow was displayed on the screen was taken as the total time delay of the system.



Figure 6.5 Determination of the total time delay. An additional camera (not in photo) is placed in front of the system that records the instrument movements and monitor simultaneously. After recording, the number of frames can be counted between the moment the real instrument reaches point A and the moment that the displayed instrument reaches the corresponding point B at the screen.

Because the processing time may depend on the processor speed and capabilities of the display adaptor being used, we performed all tests on two different commonly used computer systems to get an impression of the variance in time delays. The first system (PC-1) is a Dell Dual Core E6600 Computer System that operates on 2.4 GHz and has 2 Gigs of ddr2 Ram. For this desktop system an Intel q965/963 express chipset family was used as display adapter. The second system (PC-2) is a HP Intel Core 2 Duo T7700 laptop that operates on 2.4 MHz with 3 Gigs of ddr3 Ram. This laptop is equipped with an ATI mobility Radeon HD 2600 as display adaptor.

Finally, six experienced surgeon were asked to perform a complete suture task on the training system to see if the system delay affected their performance. The knot type in the suture task was not defined so all surgeons were allowed to produce a suture similar as they should use in surgery. From the six experienced surgeons, four performed the task on the training setup with PC-1 and two on the training setup with PC-2. All surgeons were asked to qualify their own work.

Pilot-study - Needle driving task

A pilot study was performed to investigate the potential benefits of visual feedback during a needle driving task. During the task, the participant was asked to pick up a needle (Vicryl 3-0 SH plus 26 mm, Ethicon, Johnson & Johnson) with the needle drivers and to insert it at the right line on the tissue (Figure 6.4). Secondly, the participant was asked to drive the needle, in the desired direction, through the tissue and to remove it completely at the location of the left line. This needle driving task was performed during the pre-test, training session and post-test.

Figure 6.6 illustrates the setup of this pilot study and how the participants were divided over two groups. The total test group consisted of 12 first year medical students without hands-on experience in laparoscopic surgery or training. The participants were randomly assigned to one of the two groups. During training, the participants in the first group received real time visual feedback about the interaction force until they completed the task. The participants in the second group received no visual feedback and thus performed the same task as during the pre- and post-test. During the training session, all participants performed the needle driving task for 5 times.



Figure 6.6 Setup of this pilot study. This illustration shows how the participants were divided over two groups. One group received visual feedback about the interaction forces (VFF) during the training session and one group received no visual feedback.

Each participant performed the pre-test, training session and post-test in chronological order. Before the pre-test started, both groups received general instructions about the needle driving task and all participants were allowed to manipulate and test the instruments. In addition, both groups were told that the artificial material is delicate and should be handled with care. After the pre-test, the first group was explained how the size and direction of the visualized arrow was related to the exerted force. The second group received no extra instructions.

After all participants completed the tests, any differences in maximal and mean nonzero force between the groups during the pre- and post-tests were determined with a Students T-Test (SPSS, version 16). A p-value lower than 0.05 was taken as a significant difference. Finally all participants from the group that received feedback were asked if they understood the given feedback and whether it helped them to minimize the applied force.

6.3 **RESULTS**

Time delays

The delays from al tests as conducted on two different computers remained almost constant during the test session. The average delay during all tests was 0.05 (STD 0.02) seconds for PC-1 and 0.04 (STD 0.01) seconds for PC-2. One of the Expert surgeons indicated that he noticed some delay during fast movements on PC-1. However, this surgeon also explained that the noticed delay had no effect on the task itself since suturing requires slow motions. The other five Experts did not mention any delays during or after the suture task. After the task was completed, all surgeons described the quality of their own suture as "good".

Pilot study - Needle driving task

Figure 6.7 display the results from the pre- and post-tests of both groups. The left column represents the group that received visual feedback about the interaction force during training. The right column represents the group that received no feedback about the interaction force during training. The mean absolute nonzero interaction force and maximum interaction force during the post test is noticeably lower for the feedback group (1.3N, STD 0.6N and 2.6N, STD 0.9N) compared to the same parameters measured during the post-test of the control group (4.1N, STD 1.6N and 8N, STD 3.3N). With a mean value of 55.4 (STD 24) seconds and 51.2 (STD 15) seconds, the time to completion in the post-test is comparable for the two groups. All participants from the group that received visual feedback about the interaction force told that they understood what the arrow represented and how its properties related to the exerted interaction force. Four of the six participants told that the arrow helped them to minimize the interaction force during needle driving. From those four participants two explained that the force arrow learned them that removing the curved needle with a rotational movement results in lower forces.



Figure 6.7 Results of the Pilot study. FB Pre: Pre-test of the group that received visual feedback. FB post: Post-test of the group that received visual feedback. Con.Pre: Pre-test of the control group that received no visual feedback. Con.Post: Post-test of control group that received no visual feedback. The "*" indicates that the difference between Pre- and Post-test is significant.

6.4 DISCUSSION

The results from our study show a significant improvement in tissue handling force after training with visual feedback of the force. The group that received visual feedback of the force during training applied on average 68% less force during the post suture test compared with the control group. The maximum force applied during the post test was on average 48% lower for the group that received visual feedback compared with the control group. These results and the subjective judgments of six Expert surgeons suggest that the use of training systems with visual feedback about applied forces has a clear added value for the training of residents.

The results of the pilot study suggest that that visual feedback of the force does reduce the force exerted on the tissue during a suture task. In addition, the visual feedback of the force had an immediate effect on the needle driving strategy of two of the six participants. Based on the feedback the participants learned to use the curvature of the needle during extraction to minimize the exerted forces. Further, the improvement in task completion time was almost similar for the two groups. This could indicate that visualization of the interaction force as an arrow does not influence the complexity of the suture task. This result corresponds with the work of Reiley et al. [17]. This research concluded that visual feedback during robot surgery reduced forces and decreased force inconsistencies among Novice robotic surgeons, although elapsed time and knot quality were unaffected.

The current study was limited to investigating the effect of visual feedback about interaction forces during the needle driving phase of a suture task. Further studies are necessary to determine whether it is possible to teach participants to minimize the interaction forces on tissue during the knot tying phase of the suture task. Also, studies with larger groups of subjects that use longer time periods between post-test and training session are needed to determine whether the reduction of force is temporary or permanent. Furthermore, more research is required to identify other training tasks that can benefit from this type of training.

It is imported to minimize time delays when providing feedback during training. Time delays cause unnatural visualization of motions and may disrupt the motor behaviour of the trainee. In the experiment only one experienced surgeon made a remark about a delay in the display of images at the start of the trial. However, this delay was only noticed for the first two seconds after the system was started. Further investigation of the software confirmed that in the first two seconds, frames are buffered by the camera software. During this initialization process, the delay time increased up to 0.2 seconds. To solve this minor problem, we modified the software to force the application to finish initialization before the task started.

Considering the time delay of the developed training system we found that the delay comparable to or lower than the delays of existing simulators. For professional simulators these delays are in between 45 and 141 ms [14-16]. In the current study, the average delay was 50 ms for PC-1 and 40 ms for PC-2. Since voluntary movements of humans reach a maximum 10 Hz, the computers used in this study are fast enough to generate intuitive feedback [13]. However, if faster and newer computers are used in combination with faster camera systems, delays of less than 0.04 seconds can be reached.

6.5 CONCLUSION

The force sensing training system provides us with the unique possibility to objectively assess tissue handling skills in a laboratory setting. The real-time visualization of applied forces during training may facilitate acquiring tissue handling skills in complex laparoscopic tasks and could stimulate proficiency gain curves of trainees. However, larger randomized trials that also include other tasks are necessary to determine whether training with visual feedback about forces reduces the interaction force during laparoscopic surgery.

Acknowledgment

The authors would like to thank all students, surgeons and gynaecologists for participating in this study. They thank all surgeons and gynaecologists for providing practical information about surgical suture tasks in box trainers.

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CHAPTER 7 VISUAL FORCE FEEDBACK IMPROVES KNOT TYING SECURITY

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Surgical Education, volume 71, issue 1, pages 133-141



From the previous chapter we learned that force feedback with a 3D arrow can reduce the tissue handling force during intracorporal needle driving in a box trainer. In this chapter it

is demonstrated that colour feedback from a force platform equipped with bright LED's can have a similar effect on the extracorporeal suture skills of trainees.

ABSTRACT

Background

Residents in surgical specialties suture multiple wounds in their daily routine and are expected to be able to perform simple sutures without supervision of experienced surgeons. To learn basic suture skills such as needle insertion and knot tying, applying an appropriate magnitude of force in the desired direction is essential. To investigate if training with real time visual force feedback improves the suture skills of Novices, a study was conducted using a training platform that measures all forces exerted on a skin pad, i.e. the ForceTRAP.

Methods

Two groups of Novices were trained on this training platform during a suture task. One group (nov-c) received no visual force feedback during training, whereas the test group (nov-t) trained with visual feedback. The post- and follow-up tests were performed without visual force feedback.

Results

A significant difference in reaction force, (nov-c. mean 2.47N SD \pm 0.62, nov-t. mean 1.79N SD \pm 0.37), suture strength (nov-c. median 25N IQR15, nov-t. median 50N IQR25) and task time (nov-c. mean 109s SD \pm 22, nov-t. mean 134s SD \pm 31) was found between the control and training group of the post-test.

Conclusion

Participants that are trained with visual force feedback produce the most secure knots in the post-test and their suturing results in lower applied forces. Therefore, the results of this study indicate that visual force feedback supports students while learning to insert the needle smoothly, to effectively align the suture threads and to balance the force between instruments during knot tying. However, for long-term learning effects, probably more than one training session is required.

7.1 INTRODUCTION

Suturing is one of the most common methods for wound closure and surgeons suture multiple wounds in their daily routine. Suturing of superficial and deep skin lacerations is considered as one of the most important procedural skills that all surgical residents ought to possess at the start of their medical career [1]. After graduation, doctors are expected to be able to perform simple sutures without supervision of Experts [2]. However, due to the lack of opportunities to practice while in their medical education program, most residents acquire these basic surgical skills when starting to treat patients in practice.

Courses dedicated to practising surgical skills would help Novices to gain surgical experience before their first contact before they treat patients in practice. Such courses will increase confidence, improve performance and reduce the number of beginner's errors [3]. When a suture fails to perform its function, the consequences may be disastrous [4-6]. Bleeding may occur when the suture loop that surrounds a vessel is disrupted. When a suture in an abdominal wound unties or breaks, wound dehiscence and even evisceration may follow [7]. Because of the importance of setting knots of good quality there is a continuing need to improve techniques to teach basic suture skills [8]. The most important criteria for proper wound closure are known: proficiency in speed, precision of hand movements and the firmness of the body of the suture [9].

In a suture, tightness of the loop of the thread determines the pressure on the tissue nearby the wound and therefore the blood supply and drainage of the wound area. As a result, the healing process of the wound is related to the suture itself [10]. A good suture is not too tight to prevent infections and necrosis and not too loose to be unable to press the wound edges together. Furthermore it will not unravel during the recovery of the wound by natural skin movements or accidental manipulation.

Force balance and thread alignment

During needle insertion it is important that the curvature of the needle is followed. A well-controlled force in line with the tip of the needle should push the needle with minimal damage through the tissue. Inadequate needle insertion can result in excessive reaction forces that damage tissue from the inside. Reaction forces during knot tensioning occur due to poor alignment of the threads or a force imbalance between instrument tips while tightening. If the force on the threads during knot tying are not in balance, a reaction force (FR) is generated in the tissue that can result in tissue damage (Figure 7.1-Left). A force imbalance between threads in combination with poor thread alignment indicates that a knot is not properly tensioned increasing the risk on dangerous and weak knots (Figure 7.1-Right). For proposed suture errors, a reaction force (FR) is generated in the tissue that can be measured by a force sensor. During needle insertion a low reaction force is always present. In an ideal knot tying scenario, the measured reaction force remains zero.



Figure 7.1 Two commonly seen errors at the start of a surgical knot. Left; Poor balance of 8N-4N=4N causes a reaction force inside the tissue of 4N. Right- Pour force imbalance in combination with bad thread alignment increases the reaction force even further creating a perfect scenario for dangerous knots.

ForceTRAP with visual force feedback

An increasing number of studies suggest that training with real time visual feedback of instrument motion in Virtual Reality (VR) and Augmented Reality (AR) simulators has a positive effect on learning [11,12]. Moreover, a prior study in laparoscopic needle insertion showed that Novices that were trained with AR feedback of the tissue manipulation force applied less force compared to the control group that received no visual feedback [13]. As a follow up to this study, we developed a force sensor, the ForceTRAP, that incorporates coloured LEDs to signal any imbalance in the forces exerted during tissue manipulation tasks.

In current study, the ForceTRAP is used to provide feedback on three important suture errors that cause high reaction forces in (artificial) tissue. During needle insertion, the student is warned for high forces due to inefficient needle insertion with orange and red lights. During knot tying, the orange or red light warns for a force imbalance between the two tensioned threads or for poor alignment of the two tensioned threads.

The current study investigates the added value of real time visual force feedback on suturing. The main research question is whether training with real time visual force feedback improves the suture skills of Novices.

7.2 MATERIALS AND METHODS

Hardware

The ForceTRAP is based on a previously developed force platform that was validated in two studies on intracorporeal suturing in a box trainer [14,15]. In these studies, a force platform was used to validate the suture task with force parameters. The ForceTRAP uses distance sensors and a microcontroller to determine the deformations of three orthogonally placed parallelograms. Figure 7.2 displays such a parallelogram mechanism which consists of two stiff bars and two spring blades.





To measure deformation of the spring blades in a parallelogram mechanism, hall sensors (hall effect sensor linear, SS495A, HONEYWELL S&C) and magnets were used. If a parallelogram deforms, the spring blades bend which results in a change in distance between hall sensor and magnet. After calibration, the force applied on the parallelogram mechanism can be estimated from the sensor output. The microcontroller uses the sensor output to compute the absolute reaction force and to provide colour feedback via three differently coloured LEDs on the sensor table (Figure 7.3). If the ForceTRAP is connected to a computer, the reaction forces can be recorded at a sample frequency of 100Hz.



Figure 7.3 The ForceTRAP platform with visual force feedback. LEDs are positioned around the task indicating high forces due to incorrect handling.

Artificial tissue can mimic different types of tissue and is often used for training purpose. Because of its constant homogenous structure, artificial skin tissue was used instead of real tissue in order to minimize the influence of differences in tissue specimen and tissue properties on the measurements. Therefore, any difference in performance found is due to differences in technical skills and not to differences in tissue samples.

Accuracy and visual feedback thresholds

Similar to the validated force platform [13-15], the ForceTRAP measures forces from 0N to 20N in three dimensions with an accuracy of 0.1N. In this study, conducted with

identical artificial tissue, needle and thread it was possible to complete a suture task with a maximum force of 1N. Therefore, the provided visual force feedback range should be sufficient to guide the Novice towards this goal. The following feedback threshold values are defined:

- 1. Red, when the reaction force exceeds 2N.
- 2. Orange, when the reaction force is between 1N and 2N.
- 3. Green, the reaction force is between 0.5N and 1N.
- 4. No colour, the reaction force is below 0.5N.

Software

A user interface was built in MATLAB® (MathWorks, Natick, MA) to display the forces in 3 different planes. With this software, a name and number can be given to each measurement, the recording can be started and markers can be assigned to record specific events that occur during the measurement (e.g. slippage of the suture).

Measurement setup

In one task of the suture skills training program of the Leiden University Medical Centre (LUMC), a skin pad is placed on a table with a 1mm thick plastic holder to keep the incision open. The table itself serves as a support to the arms of the trainee. Since the ForceTRAP raises the skin pad 80mm above the table, an 80mm high transparent plastic top plate (A) was manufactured to support the trainee's arms during the suture task instead of the table (Figure 7.4). The top plate is transparent to enable the trainees to see the LEDs of the ForceTRAP. Except for the transparency of the top plate, the starting conditions were similar to those of normal training.

Artificial synthetic tissue pads (B) imitating the skin and fat layers were used for all measurements (Wound Closure Pad - Light, Limbs & Things, Bristol, United Kingdom). Similar as in the regular suture offered at the LUMC, an incision (C) was made of 3mm deep and 75mm long through the longitude of the pad. To minimize a possible effect of insertion location on the results, randomly assigned training numbers were written on the pad (D). Number one represents the pre-test, number seven the posttest and number eight the follow-up test (Figure 7.4- below).

The synthetic skin pad was mounted on the ForceTRAP. A jig (E) with a bending angle of 140 degrees in the middle (Skin Pad Jig Mk2, Limbs & Things, Bristol, United Kingdom) was placed between the ForceTRAP and the skin pad to open the incision by 2 to 3 mm (C), mimicking a real wound that needs to be closed. The pad was then fastened with tie wraps on each end to prevent movement during suturing (Figure 7.4 - below). In the study one set of standard surgical tools and one type of suturing package was used by all Experts and Novices (PremiCron®2xHR26 with tapered needles with polyester, braided, coated, non-absorbable multifilament, 2/0, 90cm, Aesculap, B Braun, Melsungen,Germany).



Figure 7.4 Top; The measurement setup during training with visual force feedback. A-Acrylic glass protection plate for support of the hands. B-artificial skin pad. Below; fixation of the skin pad on a modified jig. C- Incision that opens up to mimic a real wound. D-Eight defined suture locations on the pad. E- Jig under the pad to opens up the incision.

Participants

To evaluate the learning of suturing with and without visual feedback a randomized controlled trial with two groups was chosen. The students were able to contact the authors for participation in the study after an announcement was placed on a dedicated part of the student website of the LUMC. Twenty six students (Novices) within their first

or second year of medical education were assigned to the pre-test group in chronological order, based on the date and time of enrolment. After the pre-test, the function randperm.m in Matlab (MathWorks, Natick, MA) was used for random assigned of the participants to either the group that receives visual force feedback or the control group. All students were Novices in suturing and did not have any previous training in basic surgical skills.

Study design

Figure 7.5 shows an overview of the study design. The first suture after the trial suture is considered as the pre-test. The next five suture tasks were performed during the training phase of the task. The feedback group trained with real time visual feedback on the magnitude of applied forces. The feedback group was instructed to avoid red LEDs as an indication of tissue damage. The control group trained without colour feedback. The visual feedback option was switched off during the pre- and post-test. All participants were requested to return after one month for a follow-up measurement. The purpose was to assess the retention of the suturing skills after the post-test. The suture procedure and test setup in the follow-up measurement and the post-test were equal.



Figure 7.5 The visual force feedback was only switched on during the training phase of the feedback group; during all other phases of the study it was disabled. The forces of the Pre-,post-, and follow-up tests were stored on a laptop.

Procedure

Each student received instructions for approximately ten minutes with standardized and detailed explanation of the interrupted suturing and knot tying technique [16]. Thereafter, a demonstration of the suture task was given prior to the Novice's first suture. During this demonstration the Novices were explained how to avoid tissue rupture or loose knots. Subsequently, each student had the opportunity to test the equipment and tools during a trial suture task in order to become familiar with the material and procedure before the pre-test. All participants were instructed by the same examiner and allowed to ask questions during training only.

Performance measures

Three performance measures were used in this study; maximum absolute reaction force, task time, and suture strength.

Maximum Absolute Reaction Force (MARF) and task time

The MARF is the highest absolute reaction force recorded during the suture task. The absolute reaction force was derived from the recorded forces in the X, Y and Z direction [14,15]. The start of the execution time was taken as the moment that the participant indicated to be ready to start suturing and ended when the free ends of the thread were trimmed to approximately 5 mm length.

Suture strength

To assess the quality of the knots, the tensile strength of the knots was measured with a spring scale of 10N and 50N. A spring scale and wire were used to determine the strength of the knot in the loop of the stitch, used One side of a wire was bended into a small hook while the other side was fixed to a screw in the wall. The hook was used to fix one side of the loop while the other side was pulled with a spring scale. The knots were positioned in the middle of the loop in between the two sides [17-19]. The force on the loop increased approximately 1N per second. The test started with use of the spring scale of 10N. If the knot did not fail, the test was completed with the spring scale of 50N. The maximum measurable suture strength was limited by the maximum value of the spring balance. A minimum required suture strength was defined based on the knot holding capacity as described by Babetty et al. [20]. This factor is used to describe the force that a specified suture can sustain without failing through either the suture breaking or the knot slipping. For a single stitch, the knot holding capacity equals the force required for rupture. Based on the properties of the suture pad used in this study, the knot holding capacity of a dangerous knot is defined as a knot that unties below the suture pad rupture force of 5N or less. If the thread snaps at a knot holding capacity above 45N, while the knot stays intact, the knot is defined as safe and secure.

Statistics

All data was analysed with SPSS statistical software version 17.0 (SPSS, Chicago, IL, USA). Normality testing (Kolmogorov–Smirnov test) was performed to determine whether data were sampled from a Gaussian distribution. For normally distributed data, the one-way analysis of variance (ANOVA) test was used to compare the averages obtained for the control group and test group. Otherwise a Mann-Whitney U test was used for comparison. A *p*-value of < 0.05 was considered to be significant.

7.3 RESULTS

All participants were able to complete the pre-test, training trials and post-test. Due to illness of one participant, the feedback group of the follow-up measurement consisted of 12 instead of 13 participants.

Slipping of the thread from the grasp of the needle holder

During the measurements, it was observed that in three cases the thread slipped out of the needle holder during tightening of the knot. This resulted in a fast jerk motion and a high force on the pad (Figure 7.6-top). Although such errors are related to technical skill, they are presumably not related to the investigated effects of visual force feedback on performance. Therefore, these peak forces were not included in the MARF parameter.

Slipping of the thread out of the grasp occurred during the training session in two cases and in two case during the post measurement. Figure 7.6-top shows how the time period with the large peak was replaced by a time period of equal length using the average reaction force of the complete measurement. After the modification, the MARF parameter was recalculated. In comparison to the slipping of the thread from the grasp in Figure 7.6-top, Figure 7.6-below shows a typical absolute force profile of the first trial of a poorly skilled Novice during suturing.



Figure 7.6 Example of two different force profiles. Top; The slipping of the thread from the grasp during knot-tying results in a high peak in a post measurement. If this accidental error occurs, the large peak is replaced by the averaged force value of the completed measurement. Below; Typical absolute force profile of the first trial of a poorly skilled Novice during suturing.

Pre-test

The data in the pre-test was equally distributed in both groups. There is no significant difference in the MARF parameter, suture strength and task time between the feedback and control group.

Post-test and follow-up-test

The results are presented in Table 7.1 and Figure 7.7. All performance measures (i.e. MARF, suture strength and task time) are significantly different between the groups in the post-test.

	Pre-test		Post-test		Follow-up-test	
parameter	Control group	Feedback group	Control group	Feedback group	Control group	Feedback group
MARF [N] Mean(SD)	2.46(0.93)	2.32(0.65) p>0.05	2.47(0.62)	1.79(0.37) p=0.002	2.58(1.1)	2.02(0.69) p>0.05
Suture strength [N] Median (IQR)*	25(48)	22(48) p>0.05	25(26)	50(25) p=0.046	25(46)	25(40) p>0.05
Task time [s] Mean(SD)	162(51)	181(54) p>0.05	109(22)	134(31) P=0.023	137(39)	143(40) p>0.05

 Table 7.1 Parameter results of the Pre-,Post- and Follow-up tests.

* Not normally distributed, data, shown as median(IQR) instead of mean(SD) with 0N as minimum and 50N as maximum

The MARF found in the post-test was higher for the control group than for the feedback group $(2.47\text{N SD}\pm0.26 \text{ vs. } 1.79 \text{ SD}\pm0.37)(\text{p}=0.002)$. Also, the suture strength was higher for the feedback group than for the control group (50N IQR25 vs. 25N IQR26)(p=0.046). Finally, the control group was quicker in completing the suture task than the feedback group during the post-test (109s SD ±22 vs.134s SD ±31)(p=0.023). No significant differences were found between the groups in the follow-up test.




Figure 7.7 Box plot of the MARF, task time and suture strength in the pre-, post- and follow-up test. For each box: the horizontal black line represents the median and the edges of the box represent the 25th and the 75th percentiles. The box, the upper and lower thin lines represent the range that contains the central 95% of the observations with the maximum and minimum values. Outliers are plotted individually as open circles if the value exceeds 1 SD.

Secure and insecure knots

The threads used in this study break above 50N. The number of secure knots with a tensile strength exceeding 45N during the pre-, post- and follow-up measurements are presented in Figure 7.8. In the post-test, eight out of 13 knots were secure in the feedback group and three out of 13 in the control group. In the follow-up test, the feedback group had five out of 12 secure knots and the control group six out of 13.



Figure 7.8 The number of secure knots in the pre-, post- and follow-up tests.

Figure 7.9 shows the number of dangerous knots in each group. The number of dangerous knots with a tensile strength of less than 5N was comparable between the groups in the pre- and follow-up test (i.e. five out of 13 in pre-test in both groups, and two out of 12 in the feedback group vs. four out of 13 in the control group). In the posttest, a dangerous knot occurred only once out of 13 in the FB group and three out of 13 in the control group.



Figure 7.9 The number of dangerous knots in the pre-, post- and follow-up tests.

7.4 DISCUSSION

In the current study, the results show that immediately after training in simple interrupted suturing with visual force feedback, the applied forces are significantly reduced and that the suture strength is increased. However, these performance improvements also result in a longer task completion time. Without additional training, these differences diminish within four weeks after training.

Learning effects

The Novices that received visual feedback on the force during training where able to decrease the forces with on average 23% below the level of the control group in the post-test without compromising on the quality of the knot (i.e. higher suture strength). This shows that Novices understand, and are able to learn from additional visual force feedback to improve their suture skills. During the training, it was observed that the feedback group devoted more attention to their hand movements, movement of the tissue and thread alignment when the LEDs turned red. This increased awareness may explain the longer task time in the post-test compared to the control group.

Retention of skills

Although the training with visual force feedback resulted in a 23% lower MARF average for the feedback group compared to the control group in the follow-up tests, this difference did not reach significance in the statistical testing. This indicates that a long term learning effect was not established. Possibly the large variability in performance among participants resulted in a too limited power in the test. Within the timeframe of the study, it was only possible to include 26 participants in the experiment. A post-hoc power analysis (sampsizepwr.m, MathWorks, Natick, MA), based on the MARF data (2.6N, SD 1.1N) in the control group of the follow-up test and the average MARF (2.0N) of the Feedback group, showed however that a representative sample size of the population in the follow-up tests should be larger than 42 participants. Nevertheless, even though our study provides no conclusive results on the possible long-term effects of visual feedback, visual feedback is presumably valuable for students with poor force control and limited awareness of the forces exerted on the task. Students that already have good force control will not benefit as much from the visual feedback and a substantial reduction in applied force can therefore not be expected.

Knot quality versus MARF

Even though participants in the feedback group used less force, they did make secure knots during the post-test (Table 7.1). This shows that a lower MARF does not necessarily result in weaker knots. If during knot tensioning the threads are properly aligned and the forces in each of the two threads are opposite but of equal strength, there are no reaction forces present between knot and tissue. In this situation all potential energy is used to tension the knot resulting in a high quality suture.

Suture material versus reaction force

Opposite to our approach in previous research in laparoscopic intracorporeal suturing [14] but in line with the suture training in the LUMC for open wound suturing, the suture pad in the current study was cut and the incision opened. In this configuration the needle is first pushed through one of the wound edges and removed before it passes the second wound edge. Since the contact area is shorter if the two edges of the wound are individually passed, the reaction force is lower compared with suturing on a pad that has no incision and is not bended.

Real tissue is less stiff and deforms considerably during suture errors as poor needle insertion, poor thread alignment or a force imbalances during knot tying. To some degree, deformation of tissue after loading decreases the MARF. Therefore, larger tissue samples are less suitable for teaching of basic surgical suture skills based on force feedback.

Other factors as needle size, and thread material properties (e.g. surface roughness, bending resistance and elasticity) do influence the reaction force to some degree. Despite the match between needle size (26mm) and wound size, a smaller needle cuts less material on its way through the tissue if the curvature is followed. If less cutting force is required the reaction force during needle insertion remains low. The strength of a stitch and behaviour of the thread depend on the suture material. If other incision sizes, tissue materials or suture materials are used on the ForceTRAP it is advisable to re-define the threshold values of the colours. If the colour thresholds are adjusted to the materials used in the educational course, the sensor output is only related to the student's performance and not influenced by unstandardized material properties. Suture data from experienced surgeons can be used to determine the maximal allowable reaction force and therefore colour thresholds of the ForceTRAP.

7.5 CONCLUSION

By training with visual force feedback, Novices can learn how instrument movements during needle insertion and knot tying influence the force exerted on the tissue. Participants that are trained with visual force feedback produce the most secure knots in the post-test and their suturing results in lower applied forces. Therefore, the results of this study indicate that visual force feedback supports students while learning to insert the needle smoothly, to effectively align the suture threads and to balance the force between instruments during knot tying. However, for long-term learning effects, probably more than one training session is required.

Acknowledgment

The authors would like to thank all students, personnel and gynaecologists from the Leiden University Medical Centre for participation in this study. Special thanks to Gert-Jan Hultzer en René Rodenburg of the Skillslab for educating two of the authors in advanced suturing and for providing us with all the instruments, materials and facilities necessary.

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CHAPTER 8 FORCE SENSING IN SURGICAL SUTURES

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PLOS-ONE, volume 8, issue 12, e84466



In this chapter new methods to measure forces acting on a suture thread during suturing on real tissue are introduced. The results show that in a continues suture the force in the thread remains constant up to more than 3 stitches away from the pulled loose end of the suture.

ABSTRACT

Background

The tension in a suture is an important factor in the process of wound healing. If there is too much tension in the suture, the blood flow is restricted and necrosis can occur. If the tension is too low, the incision opens up and cannot heal properly.

Methods

The purpose of this paper is to describe the design and evaluation of the Stitch Force (SF) sensor and the Hook-In Force (HIF) sensor. These sensors were developed to measure the force on a tensioned suture inside a closed incision and to measure the pulling force used to close the incision. The accuracy of both sensors is high enough to determine the relation between the force in the thread of a stitch and the pulling force applied on the suture by the physician. In a pilot study, a continuous suture of 7 stitches was applied on multiple porcine abdomens to study this relationship.

Results

The results show that the max force in the thread of the second stitch drops from 3 (SD 1.2) to 1 (SD 0.3) newton after the 4th stitch was placed. During placement of the 5th, 6th and 7th stitch, the force in the 2nd stitch was not influenced anymore.

Conclusion

This study indicates that in a continues suture the force in the thread remains constant up to more than 3 stitches away from the pulled loose end of the suture. If a force feedback tool is developed specially for suturing during real surgery, the proposed sensors can be used to determine safety threshold for different types of tissue and sutures.

8.1 INTRODUCTION

Suture techniques for abdominal wound closure have been a subject of investigation for a long period of time. The incidences of post-operative complications like incisional hernia and burst abdomen are 2-20% and 1-3% respectively [1,2]. In the high risk patient, incisional hernia rates as high as 38% are found [3]. Although much is known about patient related risk factors, technical factors like suture tension have not been thoroughly investigated. In the process of wound healing, and especially the wound healing after laparotomies, the closing method plays an important role [4]. Besides the suture technique itself, the location of the incision and tension in the suture are factors that influence the quality of the healed incision [5]. Both too high and too low suture tension have a negative effect on wound healing [6-8]. Too high suture tension will lead to ischemia, edema and tissue necrosis, while too low suture tension will lead to wound dehiscence. Several studies were undertaken to determine the relation between the thread tension and the quality of the suture. In a study of Bassini et al. [9], the thread tension was measured using a metallic lamina with strain gauges. Each end of the lamina is attached to one of the wound edges with a holder device that is fixed into the tissue layer. In a study of Cummings et al. [10], a miniature deformable E shaped tensiometer with strain gauges was hooked into a suture to determine the optimal thread tension during the fixation of organs during laparoscopic procedures. The study of Klink at al. [5] shows a technique to measure the tension with a force sensing element that is placed under the knot in a single suture. During knot tying, tension is applied to the suture and force sensing element. After calibration and within some limits, the output of the force sensing element can now be related to the thread tension. Unfortunately, a simple and effective sensor method that does not influence the measured suture tension does not yet exist. Especially in case of multiple stitches in a suture, it is not clear how the force in the first stitch influences the forces applied on following stitches.

The purpose of this paper is to describe the design of two separate force sensors for suture threads. The first sensor can be used to measure the force on a tensioned thread of a stitch inside a closed incision. The second force sensor is developed to hook into the thread at the loose end of a suture to measure the pulling force applied by the physician. By measuring the force applied on those two sensors simultaneously, the relation between the pulling force and the force in one of the stitches of the suture can be determined.

Closing the incision

The "Running" stitch is made with one continuous length of suture material used to close tissue layers which require close approximation, such as the fascia. During each stitch, the needle is driven through both wound edges and tensioned. The thread is then given to the assistant to keep the tensioned thread away from the hands of the surgeon until the surgeon finished the next stitch. Since the tensioned thread is switching hands between surgeon and assistant, a constant pulling force is difficult to maintain.

General system requirements

In a previous study a maximum force of 7 N was measured on suture threads during suturing on a skin pad [11]. If a minimal safety factor of two is used, the new sensors should withstand forces up to 15 N with a working range of 0 to 10 N. Since humans can only control instruments with frequencies not exceeding 12 Hz, the sample frequency of the forces sensors and measurement system should be minimal 24 Hz. In order to investigate the relation between the pulling force on the thread and the force in the stitches placed to close the incision, an accuracy of 0.5 N was assumed to be sufficient.

Hook-In Force (HIF) Sensor requirements

To prevent changes in the behaviour of the surgeon during the procedure, the sensor should not interfere with the hands of the surgeon. Considering the fast and dynamic actions of the surgeon during suturing, the sensor must be installed and removed easily and quickly within a maximum of 2 seconds. Installed onto the suture thread, the total weight of the force sensor should not exceed 20 gram. This corresponds with a pulling force of 0.2 N when the thread is pulled in vertical direction.

Stitch Force (SF) Sensor requirements

Since two parts of the incision are pressed together by the stitches of the suture, there is no part of the suture that is not in contact with the surrounding tissue. When developing a sensor that measures the force on the suture thread between the contacting wound edges of the incision, the pressure generated by the wound edges should not influence the sensing elements. However, if the influence of the tissue on the sensor cannot be prevented, it should be measurable in order to determine its impact on the sensor's output. Since this sensor is only placed once and remains in position until the incision is entirely closed, the installation and removal time is not critical. However, to prevent too much distortion of the workflow, the maximal installation and removal time is set on maximal 20 seconds.

8.2 Methods

Software

A data recording user interface for the two sensors was built in Matlab (MathWorks,Natick, MA). With this user interface, the recording can be started, stopped and an indicator can be added to the data to mark an important event in time (i.e. procedural error or unexpected event). To monitor the functionality of the sensors at any time during the measurement, two real time force vectors are plotted in the window of the user interface. If one of the sensors fails, this will be noticed. Data from both sensors is combined with a timestamp and recorded at a rate of 60Hz. The resolution was set on 0.88 millivolt per bit since a 12bit analogue digital convertor was used with an input range of 0volt - 3.6volt. The force data in arbitrary units and time data are stored in a text file. Since the relationship between the force sensor output and the applied forces in Newton (N) is known after calibration, the output is computed in Newton [11]. After a measurement is stopped, the user interface allows the user to analyse the recordings and to show force graphs and important parameters as Max force, Mean force, STD of the force, and Force Impulse. A zip file of the complete software package and recorded data

is also available at: www.3me.tudelft.nl/index.php?id=4404, under the section supportive software and data.

HIF Sensor mechanical components

A U shaped deformable force sensor with two spring blades was developed that can easily be placed onto the thread before being tensioned (Figure 8.1). To minimize the risk of damaging threads due to sharp edges, four discs were fabricated to guide the thread. To prevent loosening of the installed HIF sensor, the two discs at the incoming and outgoing side were equipped with an extra silicone ring. Therefore, the thread is pressed between disc and ring ensuring that the HIF sensor stays in place even when the thread is not tensioned.



Figure 8.1 Explanation of the HIF sensor components and schematic view of the forces acting on the end of the spring blades of the HIF sensor; A-plastic discs, B- silicone discs, C-spring blade D-small hall sensor, E-magnet. Since the max. pulling force F, max. torque T and max. distance u are known, the required dimensions of the spring blade can be calculated.

Figure 8.1 shows a schematic drawing of the upper side of the HIF sensor after a pulling force is applied on the thread. The force applied on the thread is counteracted by the spring blade of the HIF sensor. If the thread is loaded, the spring blade deforms (Figure 8.1-u) and the distance between the 2 spring blades increases.

By measuing this distance with a small inductive hall sensor attached to one spring blade (Figure 8.1-D) and a magnet attached to the opposite spring blade (Figure 8.1-E), an output in voltage is generated. The maximal displacement between magnet and hall sensor was defined as 2 mm with a minimum and maxum distance of 1 mm and 3 mm. This is the most sensitive range of the hall sensor. After calibration of the HIF sensor, the pulling force on the thread is related to the output of the hall sensor in volt.

SF sensor mechanical components

In comparison with the HIF sensor, the SF sensor is in continuous contact with the wound edges during the measurements. During closure, pressure is generated between the two wound edges.

If a force sensor with deformable arms is installed in the incision, there is a high risk that the pressure of the wound edges on the sensor predominates the force generated by the tensioned thread. To eliminate the influence of the pressure generated by the wound edges on the sensor, a new type of force measuring concept was developed (Figure 8.2). Instead of measuring the deformation of an actuated arm, the tension in the thread is used to create a torque around a small round tube. In this concept, the real measurement takes place outside the abdominal wall by measuring the torque on the other side of the tube. Therefore, the required space for the measurement inside the incision is minimized to 2.5 mm and only the friction between tube and wound edges for minimal rotations of the tube need to be considered.



Figure 8.2 Explanation of the SF sensor components; A-housing, B- spring blades oriented in a circle, C-Close up of tip with fissure, D-hall sensor and magnet. Due to the force in the thread (F), a torque is created in the tip (T). This torque rotates the shaft in respect of the fixed housing (A). While the spring blades deform, the distance between hall sensor (G) and magnet (E) increases resulting in a change in output signal.

The tip of the tube has a small fissure in the middle in order to place the tip over the thread (Figure 8.2-C). After placement, the sensor is rotated 90 degrees or more before the thread is tensioned. Since the diameter of the tube is constant, the measured forces can be calculated directly after calibration of the sensor. Only if the thread is overlapping after multiple turns, the radius is changing and the output cannot be trusted anymore. If some attention is paid during placement of the tip around the sensor this can be prevented easily. After calibration of the SF sensor, the pulling force on the thread is related to the output of the hall sensor in volt.

Calibration

The sensors were separately calibrated with standardized weights of 50, 100, 250, and 500 gram that where placed on a weight holder with hook. A vertically stretched thread was guided through the tip of the SF sensor and connected to the hook of the weight holder. A camera holder was modified to keep the SF sensor in place. Since there was no need for pulley's to load the sensor, the forces are well defined and not influenced by friction in the setup. The same setup was used to calibrate the HIF sensor. In this setup, the SF sensor was removed and the hooking sensor was installed onto the thread. During the force calibration, the load on the sensors was increased from 0 to 1000 gram in steps of 100 gram. Each sensor output data to determine the relation between output and force on the thread in Newton. The relation between stitch force and sensor output is of a higher order due to a higher order dependency between magnet and hall sensor distance and hall sensor output. Therefore, a second order polynomial was used for the calibration (Rout Square >0.99).

Accuracy

To test the accuracy, both sensors were installed onto a vertically tensioned thread as shown in Figure 8.3. By comparing the force-time curves in one plot, differences in force output can be determined. The thread was loaded with 100 gram, 200 gram, 300 gram and 550 gram.



Figure 8.3 Accuracy test setup. Both sensors are installed in one thread. The left side of the thread is fixated while tension is applied on the other side of the thread with a calibrated spring balance.

Although the rotation of the bar under loading of the HIF sensor is small, it is possible that the wound edges influence the measurement with the SF sensor after sticking to the metal pin while rotating. To determine this influence, the tip of the SF sensor was compressed between two 25 cm2 square pieces of abdominal wall to mimic the wound

edge pressure. The pressure was set on 2 N/mm² and 2.8 N/mm² to mimic an extreme wound edge pressure that normally is not expected in practice. After pressure was applied we rotated the shaft from 0 to 10 degrees (i.e. two times the expected rotation of the SF sensor under maximum thread tension) for three times to record the reaction force resulted from stick-slip effects and friction. If the measured force remains below 0.5 N we consider the influence of stick-slip and friction in our studies negligible.

Experimental validation – setup

Three different square porcine abdominal wall specimens of 300 by 300 mm were used during the experiments. The butcher (Keurslager J. Hoogeveen, Voorschoten, The Netherlands) prepared the samples under supervision of the leading author and gave permission to use these specimen for research. After the abdominal wall was collected from the porcine, they were frozen immediately until the experiments started. The defrosted abdominal walls were clamped between two plates for perfect fixation. During installation of the abdominal wall, sutures on each of the four corners of the abdominal wall were used to stretch the abdominal wall before the plates were pressed together. A hole was cut in the front with a diameter of 200 mm in order to make the incision and to apply the sutures. The incision was 80 mm long and a continuous suture with 7 stitches was used for closure (Figure 8.4). Each abdominal wall was used for two closures. After the first closure, the suture thread was removed and the procedure was repeated for a second time. During the second attempt, the needle was inserted in an undamaged part of the fascia.



Figure 8.4 Experimental validation setup after placement of the last stitch. the SF sensor is installed at the right side of the incision while the HIF sensor is installed on the pulled thread left of the incision.

Experimental validation – procedure

The closure procedure started with a knot in the first stitch. After the needle was driven through both wound edges during the second stitch, the tube of the SF sensor was placed over the exposed thread between the wound edges. Figure 8.5 shows the next step. The sensor is rotated until the tip touches the wound edge at side A. At the moment the tip was rotated half into the wound edge, the SF sensor was fixed inside the holder and the suture was continued until an additional 6 stitches were made. A hinge between holder and sensor allows free movement of the tip parallel to the thread. Therefore, small movements of the incision due to pulling forces on the thread do not result in a reaction force on the tip. This ensures that only the force in the thread is measured.



Figure 8.5 Installation of the SF sensor. The tip is placed over the thread and rotated towards point A until half of the tip is in contact with the tissue.

8.3 RESULTS

Completely assembled but without threads, the mass of the HIF sensor is 16.6 gram and the assembled SF sensor weights without thread 54 grams. The maximum allowable force on the suture thread is 20 N before it damages inside the sensors. The maximum allowable working range of the SF sensor is 0 - 15 N in order to minimize tip rotation after loading and to maintain accuracy. The maximum allowable working range of the HIF sensor is 0 - 20 N before spring blades start to deform permanently. Since the expected normal working forces are much lower the SF and HIF sensor are calibrated with a maximum force of 10 N. In a conventional workshop the production of each sensor used in this study (not optimized for large scale production) took approximately six hours and an additional two hours was required for calibration of the set.

Calibration

Figure 8.6 presents the regression lines and Rout Square values for the averaged data of each sensor. In both cases a 2nd order polynomial seems sufficient for accurate calculation of the force from the sensor output.



Figure 8.6 Calibration graphs of Hook-In with regression lines, R2 fit and 95% CI. Each data point represents the average of 3 measurements per load value.

Accuracy

The measurements indicate that both sensors can easily detect force differences of 0.05 N. The upper graph of Figure 8.7 shows the force graph of the SF and HIF sensor that both measure the force in a single thread (Figure 8.3 for setup). The lower graph shows the difference in output of the sensor during the complete loading cycle. An average error of 0.025 N is found for the complete measurement. The measurements performed to determine the influence of the pressurized abdominal tissue on the rotating tip showed a low reaction force at even the highest pressure (Max. 0.22 N at 2.8 N/mm2).



Figure 8.7 Accuracy of the sensors. Upper graph; the output in Newton from the HIF sensor and SF sensor during one loading cycle. Lower graph; Fdifference indicates the difference between HIF and SF output in newton.

Experimental validation

In real practice it was possible for the surgeon to install the SF sensor within 20 seconds and to remove it within 2 seconds. The HIF sensor can be installed within two seconds after some practice. Placement is easiest if the sensor is held at the aluminium base with the preferred hand and the thread is guided around the four discs with the other hand. Removal from the thread of the HIF sensor took less than one second in all 6 trials. Figure 8.4 shows the setup at the end of the suture. Figure 8.8 shows a plot of the forces acting in the second stitch in the incision (measured by SF) and in the thread 50 mm under the needle (measured by HIF). Figure 8.9 shows that the force in the thread of the 2nd stitch become constant after the 4th and following stitches are placed.



Figure 8.8 Force graphs from the HIF and SF sensors for a continuous suture with 6 stitches. SF output; force in the thread of the second stitch. HIF output; force in the thread 50 mm under the needle. Rectangle; indicator that shows where the highest mean force in the HIF sensor was found.



Figure 8.9 Force graph of averaged force per stitch with SD of all six measurements. The force in the 2nd stitch was measured with the SF sensor and the force in the thread 50 mm under the needle was measured with the HIF sensor. Stitches were placed in the fascia.

8.4 DISCUSSION

In this study two new sensors (SF and HIF) for measuring the forces on sutures were designed, produced and evaluated. Experiments showed that the sensors are robust and accurate enough to measure the pulling and stitch force during suturing and that stick-slip effects and friction between SF tip and wound edges can be neglected.

Experimental validation

We found that due to a relatively high resistance of the tissue in every stitch during placement of the 5th, 6th and 7th stitch, the force in the 2nd stitch was not influenced anymore. This means that when sutures are not pulled through properly after each stitch there will be an imbalance of the divided forces in the wound. The suture with the highest tension on the fascia is most vulnerable for a cut through the fascia or development of necrosis. This means that every stitch should be pulled through with the same strength to lower the risk of wound failure. The remaining thread tension in the second stitch (1.0 N SD 0.6) is in the same force range as the loop tension found in a single stitch placed in the skin and muscle layers after 6 minutes in the study of Klink et al (1.2 N SD 0.5) [5].

The value of force information

With the proposed HIF and SF sensor concepts, objective comparison becomes possible between different types of surgical sutures and suture techniques. Safety thresholds for thread tension can now be determined for different types of tissues. This information can be used for surgical training systems that inform the trainee about risks related to tissue tear during suturing [11-13]. Furthermore, the suturing process can be optimized if the forces acting in the threads are known at all time.

Balancing reaction forces

In the current study only porcine abdomens were used. When the SF sensor concept is used for force measurements in the incision of patients some modifications are necessary. After installation in the tested setup, the hinge between holder and SF sensor allows freedom of movement in only one direction. However, during closure of the incision in living tissue it is likely that the wound moves in multiple directions during respiration or after pulling forces are exerted on the thread. In case of a ridged connection between SF sensor and holder, a reaction force is generated at one side of the SF sensor tip if the wound moves. To prevent reaction forces at the tip, unrestricted 2D movement of the tip is required. A possible solution is presented in Figure 8.10 showing a gimbal mechanism around the sensor that allows free movement of max 20 mm in each direction of the tip.

Towards a practical feedback tool

Extra usability test performed with two surgeons, two residents and two researchers indicated that all test subjects without prior knowledge about the sensors were able to install the SF sensor in 7.8 seconds (SD 7.1) and the HIF sensor in 10.2 seconds (SD 7.5) on a mock-up of the experiment. Moreover, the validation study showed that the installation time can be reduced to a couple of seconds. Therefore this combination of sensors proved useful to determine the relation between the force in the thread of a stitch and the pulling force.



Figure 8.10 SF sensor equipped with two rings that act like a gimbal mechanism to allow movements of max 20 mm of the tip in X and Y direction. The spring blade equations can be found in appendix A.

Although the SF and HIF sensor are useful for research purposes, for training during surgery in the OR, a simple small, light and affordable sensory system with a simple interface is preferable to inform the user about the magnitude of the pulling force. Therefore a new "wheel" sensor was developed that can be laser cut from any suitable relatively stiff medical grade plastic and three machined pins that are fixed in three holes in the wheel. This wheel sensor supports itself between the tensioned threads and is easy to install and remove (Figure 8.11-A,B). Comparable to the SF sensor placement in this study, the fissure in the inner pin of the wheel sensor is placed over the tensioned thread before the wheel is rotated 180 degrees. After rotation, the outer pins are hooked behind the thread. After loading, the inner pin rotates in respect to the two external pins and the spiral shaped bars (C) that connect the inner (D) and external (E) ring of the wheel are pressed outwards. Since the external ring contains the hall effect sensor and the spiral shaped bar the magnet, the pulling force can be related to the output signal of the hall sensor after calibration.

When the control system, power source and feedback source are small enough they can be embedded in the sensor itself. Figure 8.11 shows a prototype of the wheel sensor with embedded feedback system.



Figure 8.11 A simple "wheel" sensor with embedded measurement and feedback system. Left, force exceeds 10 Newton and LED turns red. Right, force is between 8 and 10 Newton and LED turns green. A-Inner pin, B-external pins, C-spiral shaped bar, D-inner ring, E-external ring, F-embedded electronics for force feedback.

The system is controlled by an ATtiny85 micro controller that operates at 100hz and powered by a 3v Lithium battery. The complete prototype of Figure 8.11 has a mass of 11.3 gram. If smd technology with a custom circuit board is used it is estimated that the weight can be reduced to 8 gram. If this feedback sensor is used during training, a green LED indicates a safe working range for the pulling force (Figure 8.11-Right). If the multi-colour LED on the sensor turns red, the sensor warns the surgeon that the pulling force exceeds a predefined threshold (Figure 8.11-Left). In a later phase of development, usability tests and a cost prize calculation should indicate if it is feasible to put this disposable pulling force sensor on the market.

Limitations of this study

We performed 6 series of stitches on three different specimen. Based on visual inspection we chose parts of the prepared fascia that was undamaged to insert the stitch, therefore it is unlikely the first suture placement influences the force measured during the second suture. We recorded the data from the first point of insertion of the needle till the last knot was made before we took the suture out or replaced the specimen. In our study we did not measure the force in the stitch over time. The results of Klink et al. showed a drop of loop tension in single stitches in skin and muscle layers of a rodent model after 60 minutes. Hence it is difficult to estimate whether the drop of the stitch force in the second stitch of Figure 8.9 is caused by a decreasing influence of the pulling force or that tissue relaxation also reduced the stitch force. Therefore, further studies are required to investigate the role of tissue relaxation in continued sutures.

8.5 CONCLUSION

A measurement system is developed that can be used to measure forces in suture threads inside and outside the incision. With the presented force measurement system it becomes possible to relate the thread tension inside sutures to the pulling force applied by the physician. Therefore it enables the comparison of different suture techniques and to determine their impact on wound healing giving insight in one of the oldest surgical procedures. This can lead to a simple hand tool that warns surgeons about excessive forces on suture threads and thereby reduce postoperative complications like incisional hernia and burst abdominal wall.

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CHAPTER 9 ASSESSMENT OF LAPAROSCOPIC SKILLS BASED ON FORCE AND MOTION PARAMETERS

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IEEE Biomedical Engineering, in press



After measuring only the tissue handling force in a box trainer in previous studies, a box trainer that measures both instrument motion and interaction force is introduced in this chapter. The results of the study of this chapter indicate that force and motion parameters are not or minimally correlated when novices and intermediates perform two new dynamic position in this box trainer. A higher correlation is found when experts perform those tasks.

ABSTRACT

Background

Box trainers equipped with sensors may help in acquiring objective information about a trainee's performance while performing training tasks with real instruments. Recently, the motion tracking tool "TrEndo" and force tracking instrument "ForceTRAP" have been combined in a single box trainer, <u>Force and Motion Surgical Trainer</u> (ForMoST). The ForMoST tracks instrument motion and tissue manipulation forces during various training tasks. The main aim of this study is to investigate the added value of force parameters with respect to existing motion and time parameters such as path length, motion volume and task time.

Methods

Two new dynamic positioning tasks were developed for ForMoST that not only requiring adequate motion control but also force control of both instruments for successful completion. Several force and motion parameters were studied in an experiment in which three groups of participants with different experience levels in laparoscopy (i.e. 11 Novices, 19 Intermediates, 12 Experts) completed the two tasks.

Results

In total, ten of the 13 parameters showed a significant difference between groups. Pearson correlations indicated a 34% correlation between force and motion parameters in the Expert group and no correlation in the Novices and Intermediates group. When the data from the significant motion, time and force parameters is used for classification, it is possible to classify the skills level of the participants in this study with 100% accuracy. Furthermore, the force parameters of many individuals in the Intermediate group exceeded the maximum values in the Novice and Expert group.

Conclusion

The relatively high forces used by the Intermediates in combination with the apparent lack of correlation between force and motion parameters argues for the inclusion of training and assessment of force application during tissue handling in future laparoscopic skills training programs.

9.1 INTRODUCTION

During laparoscopic procedures, trocar systems are placed in small incisions in the abdominal wall that guide a variety of long thin instruments into the abdominal cavity. Since long slender instruments are guided through the abdominal wall on a fixed position, the moment arm between incision point and instrument fluctuates during the procedure, the force exerted by the tip on the tissue depends highly on the insertion depth of the instruments. These and other instrument handling difficulties make it essential to train this type of surgical skills before the approach is used in the operation theatre. One common training method for laparoscopic surgery is facilitated by a so-called "boxtrainer". In a box-trainer one can perform training tasks using real laparoscopic instruments. Today, most of the available training tasks focus on improving the trainee's hand eye coordination [1]. Assessment of the trainee's performance can be either subjective when based on the interpretation of the tutor or objective when quantitative measures are used. Objective scoring methods can be based on time, errors, instrument motions or forces exerted on the instruments or training task. In many studies, assessment is based on task errors and task time [2]. In other studies task time in combination with assessment parameters extracted from instrument motions are used for discrimination between Experts Intermediates and Novices [3]. In the work of Rosen et al. and our own previous work it was found that assessment based on interaction force between instrument tip and environment alone give similar results [4-6].

All above-mentioned studies indicate that skills assessment based on motion, force information or performance time is possible. Therefore, the question arises whether a multitude of sensor systems has added value when the discriminating power of force, motion and time parameters is comparable. The studies of Chamarra et al. [3] showed that the correlation of motion parameters such as path length, motion smoothness is high. This indicates that fast performance on a training task likely results in a good motion parameter score which is in line with the opinion of some Experts that measuring task time is sufficient. However, our previous work regarding assessment based on force parameters shows that there is no correlation between force parameters and task time [5,7]. Task time is not representative for force application skills since the score on force parameters can probably not be predicted by the task time. Considering that tissue interaction parameters are, other than motion parameters, indicators for tissue damage and therefore patient safety, monitoring the presence of dangerous excessive forces during training is recommendable.

Although force parameters are not correlated to task time, it is possible that force parameters are correlated to some motion parameters making force sensors obsolete. To determine whether concurrent measurements of force and motion has added value for the assessment of laparoscopic skills we studied time, force and motion parameters in training tasks that represent tissue manipulation in surgery. In order to find differences in tissue and instrument handling between groups with different skills levels, new training tasks are required particularly for training of instrument motion during tissue manipulation. Those standardised tasks should combine the strong aspects of the existing tasks (i.e. delicate position control) and require active control of two hands. Moreover, to mimic real in-vivo situations, force control should be part of the training as well as technical insight of the instrument actions necessary to complete the task efficiently.

The aims of this study

The first goal is to identify whether motion parameters are correlated to force parameters. The second goal is to determine whether a combination of force, time and motion parameters can be used for classification of the skills of a trainee.

9.2 MATERIALS AND METHODS

Participants

Forty two participants with three different levels of experience in laparoscopy participated in the experiment. The participants were divided into three groups, Experts (n=11), Intermediates (n=19) and Novices (n=12). The first group consisted of surgeons and gynaecologists that performed over 100 laparoscopic procedures. The Intermediates in the second group consisted of residents during their specialization in gynaecology. All of them succeeded one or more laparoscopic training sessions in eye hand coordination. To succeed a session, a pipe cleaner task, rubber band task, breads placement task, cutting circle task and intra-corporal knot tying task are completed within a predetermined error score and task time. The group of Novices consisted of first and second year medical students with no experience in laparoscopic surgery or laparoscopic training. Each participant was asked to answer a short questionnaire with detail information about prior experience in laparoscopy. All of the participants were right-handed.

Two new dynamic position tasks

In a previous study on the development of discriminating force parameters a standard suture task was used [5,6]. Suture tasks are commonly used for assessment of performance in the clinic. However, due to the complexity of the task and the small area in which the knot is made it is difficult to relate the measured data to the quality of the performed actions. In the current study we therefore used task decomposition of the suture task and other surgical actions to develop new training tasks tailored to assessment of surgical skills based on force and motion parameters (Figure 9.1).

Task-1, Tissue attachment under traction

This task is made from four different elastic elements with different elastic properties. All elements have equal lengths but the stiffness is different due to differences in shape and thickness. Therefore, good force balance requires that the elements are connected slightly outside the task middle point. If only visual information is used to complete the task and force feedback is mainly ignored, is expected that higher forces are exerted on the task than necessary. Moreover, smart positioning of the elements in both instruments and a good strategy is required for efficient handling. Completion of the task with only one instrument is not possible.

Task-2, Placement of a silicone wire

This task is made from two different elastic elements with different elastic properties. A peace of artificial tissue with two holes at one side is connected to the task's ground plate on the other side. In order to drive the 2 mm thick elastic wire through the holes the

artificial tissue needs to be turned and twisted for proper sight on the task. This is best achieved using both instruments in parallel. Therefore, the use of only one instrument may result in fluctuating traction forces at the tip of the other instrument, especially for someone with limited skills. Completion of this task with only one instrument is not possible.



Figure 9.1 Top: Connection of two vertical and two horizontal flexible elements in Task 1. Bottom: Placement of a silicone wire through two holes in Task 2.

Test protocol

The participants performed two different training tasks inside a box trainer equipped with two five millimetre trocars and one 11 millimetre trocar (Endopath XCEL, Johnson & Johnson), two grippers (Endopath Ethicon Endo-Surgery, Johnson & Johnson) and a USB camera system. Inside the box trainer, one of the two training tasks is mounted on top of a custom-made 3DOF force sensor. The top plate of the training box is non-transparent and the USB camera is used for visualization of the tissue manipulation task on a computer screen. The order in which the tasks were performed was randomized for each participant.

Before the measurements started, a picture was shown to the participants to explain how to complete the two tasks. Figure 9.2 shows the measurement setup in this study. If a problem occurred in the first 2 minutes of the task, a new measurement was started for the next attempt and all recorded data was deleted. If problems occurred after two minutes, the participant was removed from the study. Problems that can occur during the measurements are identified as; breaking of one of four artificial tissues due to excessive forces in Task 1 and falling out of sight of the silicon wire in Task 2. If necessary, participants received additional verbal instructions during the tasks. All participants performed only one of the two tasks in order to prevent learning effects. At the start of Task 2, the wire was positioned on a predefined location in the right upper

corner of the ground plate of the task by the experimenter so that the starting conditions were the same across participants and trials. If it took students more than 15 minutes to complete the task at the first trial, they were excluded from the study and the data was removed.



Figure 9.2 ForMoST system measures force and motion with TrEndo and ForceTRAP. The image of the task is displayed on a computer screen.

Task measurement setup

The TrEndo and new 3D force measurement platform (ForceTRAP) were integrated in a Force and Motion Surgical Trainer (ForMoST). The ForceTRAP is based on three parallel mechanism and uses the optical sensor unit of a commercially available optoelectronic device for sensing [5,6]. Figure 9.3 shows the ForceTRAP as it is placed between the task and bottom plate of the box. In this sensor, the first of three parallelogram mechanism consists of the housing that is connected with two spring blade to a U-profile that can only move in the X direction. On this U-profile, of the second parallelogram is fixed that allows only movement in the Y direction of the opposite U-profile. Finally, a third parallelogram is fixed between the second parallelogram and the optical sensor unit. Together, the three parallelograms allow movement of the optical sensor unit in X,Y and Z and do not allow the sensor unit to rotate in any direction. The calibrated device has an accuracy of 0.1 N and threshold of 0.3N. A more detailed description of the calibration including pictures of the setup and function fitting can be found in a previous study about the force platform [6].



Figure 9.3, Prototype of the 3D ForceTRAP that is fixated between training task and bottom plate of ForMoST. The ForceTRAP is built from three parallelogram mechanisms and components of a 3D connection mouse. The three parallelogram mechanisms prevent rotations around the sensor's midpoint. Therefore, accurate force measurements become possible even if forces are exerted further away from the sensors midpoint.

Custom made software was written in Matlab (2012b) to record the sensor output to a computer at a sample frequency of 30 Hz. A user interface allowed the experimenter to show the different training tasks with description on the training screen, to start and stop the USB video camera and to store data under a predefined filename. Finally, the user interface allows the experimenter to mark specific events during a measurement. The timestamp of these button presses were recorded alongside the sensor data and used to link written remarks to the recorded force and motion data.

To ensure that the sensor's position and orientation did not change during the measurements, the ForceTRAP was fixed to the bottom plate of the box trainer. Since the ForceTRAP 's location is underneath the task area it does not obstruct the motions of the instruments. The task conditions were therefore similar as in a normal training setting.

Performance parameters

To use motion and force information for skills assessment based on classification, performance parameters are required. The nature of a performance parameter depends on the surgical action it needs to reflect in a surgical training task. Seven existing and two new parameters, based on force, motion and time are used to measure performance on the new training tasks. The parameters were chosen partly because of their discriminating power in earlier studies [5,6] and partly based on the opinion of experienced surgeons.

Force related parameters

<u>Max Absolute Force (MAF)</u> – The maximal force found in a trial indicating jerks or punches in instrument-tissue interactions [4].

<u>Mean Absolute Nonzero Force (MANF)</u> – Indicating the averaged mean absolute force of periods during training the absolute force is not nonzero [3].

<u>Force Volume (FV)</u> – Indicating the volume of an ellipsoid spanned around the Standard Deviations (SD) of the force along the three main Principal Components (PC's). The largest SD found in the 3D force defines the orientation of PC1. The second largest SD defines the orientation of PC2 perpendicular to the first. PC3 oriented perpendicular to PC1 and PC2 [5].

$$V = \frac{4}{3}\pi(stdF_{pc1} \cdot stdF_{pc2} \cdot stdF_{pc3})$$

V = volume

 $stdF_{pc1}$ = standard deviation of force along PC1-axis $stdF_{pc2}$ = standard deviation of force along PC2-axis $stdF_{pc3}$ = standard deviation of force along PC3-axis

Motion related parameters

<u>Path Length (PL-Left and PL-Right)</u> - Indicating the length of the 3D instrument tip trajectory and is used as a measure to determine the efficiency of instrument motion for both instruments [5].

<u>Motion Volume (MV-Left and MV-Right</u>) - MV is a measure for the space required by the trainee to complete the task. Different from PL, MV is influenced by the direction the instrument tip moved in a 3D space [5]. For calculation Eq. 9.1 is used with left or right instrument motion data instead of force data.

<u>Mean Distance Between Tips (MDBT)</u> – The mean distance between tips indicates if both instruments are in the area of interest.

$$T2TD = \sqrt{(x_l - x_r)^2 + (y_l - y_r)^2 + (z_l - z_r)^2}$$

dist = absolute distance between two tips

- x_l = position lext tip on local x axis
- x_r = position right tip on local x axis
- y_l = position lext tip on local x axis y_r = position right tip on local x axis
- y_r = position right tip on local x axis z_l = position lext tip on local x axis
- z_l = position right tip on local x axis z_r = position right tip on local x axis

Force and time related parameters

<u>Max Force Area (MFA)</u> - where the MFA parameter indicates the highest measured absolute force, the Max Force Area is defined as the largest period with the highest absolute force between t1 and t2. In earlier work MFA was referred to as force peak [5].

(Eq 9.1)

(Eq 9.2)

$$\mathbf{MFA} = \int_{t_1}^{t_2} \left| F \right| \, \mathrm{d}t$$

(Eq 9.3)

F = Absolute force $t_1 = Starting time of absolute force peak$ $t_2 = Stoping time of absolute force peak$

Motion and time related parameters

<u>Out of View Time (OVT)</u> – Indicating the time that the instrument tips were not visual on the screen. In this new parameter, the local Z-axis is pointing upwards from the middle of the task. After transformation, the new global Z axis is pointing from the task midpoint towards the midpoint of the camera. The global X axis (Left and right in the box) remains the same while the Y axis is oriented perpendicular to X global and Z global. The total time per instrument the max absolute distance between u (Eq. 9.4) and midpoint of training task is exceeded is a measure for OVT.

$$u = \sqrt{x_{g}^{2} + y_{g}^{2} + z_{g}^{2}}$$
$$u_{\text{max}} - u > 0$$

(Eq 9.4)

u = shortest distance between tip and midpoint on task $u_{max} = max$ alowed shorest ditance between Z axis and u $x_g = position tip in global x coordinates$

 $y_g = position tip in global y coordinates$

 z_g° = position tip in global z coordinates

the visual area between camera and task is shaped like a cone, orienting from the lens. The shape of the area that should not be left by the tip of the instruments is defined as a globe to simplify the algorithm and to minimize calculation power.

Time related parameters

<u>Task-time (T)</u> - Indicating the period of time elapsed between the start of a training and the first second after the task was completed.

Statistical tests

A one-way ANOVA with Bonferroni Post-Hoc test (SPSS 17) was used to determine statistical differences between the experience level of groups. A p-value of less than 0.05 (two tailed) is considered to be significant. In the Pearson correlation matrices (SPSS 17) a correlation between parameters with p<0.05 (two tailed) was considered significant.

Correlation between force and motion parameters

Pearson correlation matrices were used to investigate the relation between all motion and force parameters [4]. If high correlations are found between motion and force parameters, many contacts between tip and tissue are expected. If there are no correlations found, instrument motions are not directly related to the task and partly performed without contact between tip and tissue.

PCA, Classifier and LOOCV

Based on the classification methods used in our earlier study [4], the amount of correctly classified subjects (e.g. Leave-One-Out-Cross-Validation (LOOCV) score) is determined for the Experts versus Novices, Experts versus Intermediates and Intermediates versus Novices. To investigate whether certain combinations of parameter categories (e.g. motion parameters, force parameters or Task-time parameter) give a better LOOCV outcome we determined the LOOCV score for the combination Task-time, force parameters and motion parameters, the combination of force and motion parameters, the combination of Task-time and motion parameters and finally of Task-time and force parameters. Only when at least one significantly different parameter is found for each of the included categories, it is possible to perform the analysis.

Principal Component Analysis

In this study, the PCA analysis was used to calculate new principal components for the significant parameters of both tasks (princom.m, Matlab 2008b). For each group of highly correlated parameters in the correlation matrix, Principal Component Analysis (PCA) was used to find new representative parameters for each group of correlated parameters. PCA orders the newly calculated principal components based on the amount of variance they explain. The first PC explains the most variance whereas the succeeding PC's explain the rest of the variance in decreasing order. For this study we sum up the number of PC's from top down until a minimum of 75% of the total variance in the data is explained. Since the variance of the used parameters is extremely heterogeneous all data was first normalized before PCA was applied. The data of each parameter was normalized according to:

$$Z = \frac{x - \mu}{\sigma}$$

 $\begin{array}{l} Z = standard \mbox{ force parameter score } \\ x = raw \mbox{ force parameter score to be standardized } \\ \mu = the mean \mbox{ force parameter value } \\ \sigma = the standard \mbox{ deviation of force parameter } \end{array}$

(Eq 9.5)

Classifier

The two principal components that explain minimal 75% of the variance of the data from the participants are now used as input for the classifier (classify.m, MATLAB 2008b). The classifier describes the boundary between two groups with different skills levels with use of only two parameters.

Leave-One-Out-Cross-Validation

To obtain the number of participants that can be correctly classified based on the data, a Leave-One-Out-Cross-Validation (LOOCV) program was written in MATLAB 2008b. For each LOOCV case, the training set consists of the data of all minus one participant while the data of that single participant is selected as a test case. The data of all participants is used once as test case resulting in a number of LOOCV cases equal to the amount of participants. During each LOOCV case, the skills level of the test case is

predicted based on its location with respect to the boundary as determined by the LDA. Since the real experience level of each test case is known, the predicted outcome of each LOOCV case can be correct or incorrect. The percentage correctly classified LOOCV cases indicates how reliable new participants are classified based on the used data set and force parameters. A more detailed description of LOOCV for classification can be found in our previous work [5].

9.3 RESULTS

Statistical difference between parameters

All participants were able to complete each of the two tasks within 15 minutes. The results per parameter are represented in Figure 9.4-top for Task 1 and Figure 9.4-below for Task 2. The presence of a p-value in a graph indicates a statistical difference between groups.

Task 1, Tissue connection under traction

For Task 1 the Max Absolute Force, STD force, Task time, Path Length Left and Path Length Right were found to be significantly different between the Novice and Expert group. Between the Intermediate and Expert group, the Max Absolute Force, Task time, Path Length Left, Path Length Right, Max Force Area and Mean Distance Between Tips were found to be significantly different. For none of the parameters significant differences were found between the Intermediate and Novice group.

Task 2 Placement of a silicone wire

For Task 2 the Task time, Path Length Left and Path Length Right and Out of View Time Left were found to be significantly different between the Novice and Expert group. Between the Intermediate and Expert group the Max Absolute Force, Task time and Force Volume, were found to be significantly different. Between the Intermediate and Novice group the Force Volume, Mean Distance Between Tips, Path Length Left, Out of View Time Left and Motion Volume Right were found to be significantly different.

Correlation between force and motion parameters

Figure 9.5 shows the correlation between force, motion parameters and Task-time for the dynamic position task (Task 2). The boxed light grey area in each of the three tables indicates the area where correlating force and motion parameters can be found. The top matrix of Figure 9.5 shows that 12 of the 35 blocks in the boxed light grey area turned dark grey meaning that 37% of the parameters were correlated in the Expert group for Task 2. The lower matrix in Figure 9.4 shows that none of the blocks in the boxed light grey area's turned dark indicating that there is no correlation found between motion and force parameters for Task 2 in the Intermediate group and Novice group. For the tissue connection task (Task 1), 8.6% of the force and motion parameters were correlated in the Novice group and none in the Intermediate and Experts group. Looking at the correlation between Task time and motion parameters a correlation between Task time and motion parameters are correlation between Task time and



the Path Length of the right instrument was found for both tasks in the Intermediate groups, Task 1 in the Expert group and Task 2 in the Novice group.

Figure 9.4 Box plot representation of the parameter results for Task 1 (top) and Task 2 (Below). Each graph represents the results for the Novice, Intermediate and Expert group.



Figure 9.5 Correlation matrices of Experts, Intermediates and Notices for Task 2. A dark grey block indicates correlation between the parameter above and parameter left of the block (p<0.05). If dark grey blocks are present in the boxed light grey area, the motion parameters above the block is correlated to a force parameter left of the block.

PCA, Classifier and LOOCV

Figure 9.6 shows the distribution of Experts and Novices in Task 1 when the first two Principal Components (PC1st and PC2nd) are calculated from the LDA based on the significantly different Max Absolute Force, STD force, Task time, Path Length Left and Path Length Right parameter data. With this dataset it is possible to discriminate between a Novice and Expert level with 100% accuracy. Figure 9.7 shows the distribution of Experts and Novices when the significant different Task time, Path Length Left and Path Length Right and Out of View Time left data is used in Task 2. With this dataset it is possible to discriminate between the Novice and Expert level with 91% accuracy.



Figure 9.6 LDA performed on the Expert and Novice data for Task 1 with all significant parameters. PC1st and PC2nd, largest and second largest principal component in arbitrary units. Magenta line, boarder line as determined by the LDA. In this example 100% of the participants were correctly assigned with the LOOCV.



Figure 9.7 LDA performed on the Expert and Novice data for Task 2 with all significant parameters. PC1st and PC2nd, largest and second largest principal component in arbitrary units. Magenta line, boarder line as determined by the LDA. In this example 91% of the participants were correctly assigned with the LOOCV.

For Task 1 none of the parameters showed significant difference between the Novice and Intermediate groups and therefore the LOOCV was not performed. Since there was no significant difference in motion parameters between the Expert and Intermediate group of Task 2, the LOOCV was performed with the significant different force parameters (e.g. Max Absolute Force and Force Volume) and Task time. Task time was not significantly different between the Novice and Intermediate group. Therefore, a LOOCV was performed with only force and motion parameters (e.g. Force Volume, Mean Distance Between Tips, Path Length Left, Out of View Time Left and Motion Volume Right) and Task time. Table 9.1 shows the outcome of the LOOCV after comparison of different skills levels with different sets of significant parameters.

	Novice- Experts		Intermediates- Experts		Novice- Intermediates	
	Task 1	Task 2	Task 1	Task 2	Task 1	Task 2
Motion	100%	91%	70%	- *1	- *2	- *3
Force						
Task-Time						
Motion	87%	91%	80%	- *1	- *2	77%
Force						
Motion	91%	87%	87%	- *1	- *2	- *3
Task-Time						
Force	100%	91%	87%	76%	- *2	- *3
Task-Time						

Table 9.1 Percentage correctly assigned participants for each combination of groups for both tasks.

*1 There were no significant motion parameters found.

*2 There were no significant parameters found.

*3 Task time parameter was not different between groups.

9.4 DISCUSSION

The aims of this study

The first goal was to identify whether motion parameters are correlated to force parameters in Task 1 and Task 2. The correlation matrices indicated that a correlation between motion and force parameters was found only in the Expert group of Task 2. This argues that motion and time parameters alone cannot be used to asses a student's tissue handling skills.

The second goal was to determine whether a combination of force, time, and motion parameters can be used for classification of the skills of a trainee. Especially with Task 1 that required adequate force control besides motion control, it is possible to distinguish between Novices and Experts with 100% accuracy. For Task 2, it is still possible to discriminate between Intermediates and Experts with accuracies up to 91% and 87% depending on the set of parameters that is used as input for the LOOCV. Interestingly, if motion and force parameters and Task time are used to distinguish between Intermediates and Experts in Task 1, the success rate declines. This can be
explained since there is no correlation between motion and force parameter in the compared groups. Due to the nature of the used PCA, it is possible that the discriminative power of the force and motion parameters counteracts the discriminative power of the Task time parameters when they are not correlated. For each of the part of this study (i.e. new tasks, performance parameters, correlation and classification) the results are discussed in more detail in the following paragraphs.

Discrimination power of tasks

In order to find differences in tissue and instrument handling between groups with different skills levels, new training tasks were developed particularly for training of instrument motion and tissue manipulation. The results indicate that 7 out of 13 parameters were significantly different between skills levels for Task 1 and 8 out of 13 parameters for Task 2. Although the discriminating power of the used parameters is high in this study, Table 9.1 shows that the discrimination power varies over each combination of parameters in each task. Task 1 requires adequate motion and force control and therefore the highest LOOCV outcome was found if force parameters were used in the analysis. The LOOCV for Task 2, which required mainly adequate motion control, gave the best results if motion parameters were part of the analysis. For both tasks, enough parameters were found to be statistically different in order to classify between a Novice or Intermediate level and an Expert level with more than 87% accuracy.

Observations

The Force Volume shows high differences between the Intermediates and Novices as well as Intermediates and Experts in both tasks. In general, a high Force Volume as seen in the Intermediate group, results from fast increasing and decreasing forces (i.e. force spikes) in multiple directions. One explanation for this relatively large difference is that students in the Intermediate group are more convinced about their motion control but less skilled as they may think. Since they are not familiar with these new tasks, the high values in Force Volume could indicate that fast increasing forces result from a slow reaction on unexpected restrictions in movements (i.e. contact with ground plate or stretched tissues). This is supported by the remaining force parameters that show that the results of many Intermediates exceed the results of the novices. As also observed, the Novices seemed imposed by the given instruction to handle all instruments and tissues with great care and move their instruments carefully in order to prevent potential damage to the task. The Experts however have better understanding of the developed training tasks and focus on adequate force and motion control thereby preventing sudden collisions between the solid parts of the tasks and instruments.

Correlation between force and motion parameters

Compared with the Intermediate and Novice group, that showed almost no correlation between force and motion parameters in both tasks, a correlation of 37% for Task 2 was found in the Expert group. In the Expert group of Task 1, no correlation was found between motion and force parameters.

In general, if a high correlation between force and motion occurs, better control is assumed due to more efficient instrument handling and therefore less unintended force exertion during performance. In the Novice and Intermediate group, however, many instrument motions and tissue manipulations are accidental and caused by the unfamiliarity with mirror and scaling effects or depth perception difficulties. Since more instrument motions and tissue manipulations are not intended or not effective, less correlation is found.

For both tasks, higher correlation was expected in the Expert groups compared with the Novice and Intermediate groups. However, this is only partly true since no correlation was found for task-1 in the Expert group. One reason could be that Task 2 was more familiar for the Expert surgeons that all were highly experienced with manipulating tissue. The Experts recognized the step to step approach and created clear vision on the backside of the silicone tissue before the thread was inserted. The Novices and Intermediates basically ignored this first critical step and started to manipulate the tissue without a clear strategy in mind till an opportunity occurred. In other cases some Novices and Intermediates tried to push the thread in the hole without clear vision. Therefore, the clear uniform approach of the surgeons could explain a higher correlation in this task. Compared with the clear uniform approach that was observed in the Expert group during Task 2, more different strategies were used to solve Task 1. This could explain why a high correlation between force and motion parameters was not observed.

Skills classification

The results in Table 9.1 indicate that both tasks can be used to classify the difference in skills levels between Novices and Experts with high accuracy. Compared with the standard tasks used by Chmarra et al. [3] for classification, the new dynamic position task show slightly higher LOOCV results ($\pm 90\%$ versus $\pm 80\%$). If the difference between skills levels become smaller, so is the discrimination power of the used LOOCV method. Looking at the skills levels of the Intermediates in this study, it is still possible to discriminate them from the Expert group with acceptable accuracy but not from the Novice group. Fortunately, for the assessing teacher, it is mainly interesting to know whether an Expert level is reached. If not, additional training is required.

Besides skills level, also the nature of the training task determines the outcome of the LOOCV. In general, the LOOCV outcome for Task 1 is slightly better compared with Task 2. Looking at the individual results of the parameters in figure 9.4, it becomes clear that mainly the force parameters have more discriminative power for Task 1. This task requires well controlled manipulation force for adequate completion whereas Task 2 is performed efficiently when no force is exerted. Since instrument positioning with tissue under traction in Task 1 was not trained by the Intermediates and Novices, adequate force control was found difficult explaining the difference in scoring with Experts on force parameters. Furthermore, all instrument motions (incl. motion errors) with tissue under traction in Task 1 always resulted in force data whereas Task 2 only records force data when motion or manipulation errors occurred. Therefore, the force data of Task 1 gives force parameters with potentially more discriminating power.

Table 9.1 indicates that the discriminating power of the selected parameters is linked to the actual skills levels in a group. For example, where multiple significant different motion parameters were found for the Expert and Novice comparison of Task 1, none were found for Task 2. The force parameters however proved useful for both tasks in this comparison. For further study it is interesting to investigate the discriminative power of standard FLS tasks. When the guidelines and instructions are considered, the results can be compared with other studies performed with the FLS tasks. Although an additional set of tasks was developed especially for the assessment of basic tissue handling during a dynamic position task it is interesting to investigate the discriminative power of the tasks used in FLS when motion and force data is used. Besides the suture tasks, also the circle cutting task requires well controlled traction during cutting. Due to this nature, both the suture task and circle cutting task could reflect important differences in force control during delicate tissue handling.

9.5 CONCLUSION

A new set of dynamic position tasks was developed that requires not only adequate motion control but also sufficient force control for completion with good parameter results. If the data from the motion, time and force parameters are used for classification, it is possible to distinguish the skills level of a novice or expert with an accuracy up to 100%. The relatively high forces used by the intermediates in combination with the apparent lack of correlation between force and motion parameters argues for the inclusion of training and assessment of force application in tissue handling in laparoscopic skills training programs.

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CHAPTER 10 Learning from Visual Force Feedback in box-trainers

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Surgical Endoscopy, accepted for publication



The study in this chapter shows that training with visual force feedback improves tissue handling skills with no negative effect on the task time and instrument motions. Moreover it shows that technical skills learned during training with visual force feedback can be transferable.

ABSTRACT

Background

Currently, Task Time and errors are often used as performance parameters in laparoscopic training. Training with the focus on Task Time improvement alone results in fast, but possibly less controlled instrument movements and therefore sub optimal tissue handling skills.

Methods

25 medical students were randomly assigned in two groups. Both groups performed a tissue manipulation task six times. During this training session the Time Feedback group (n=13) received real time visual feedback of the Task Time. The Force Feedback group (n=12) received real time visual feedback of the tissue manipulation force. After the training sessions, participants in both groups performed an entirely different task without visual feedback. Task Time, force and motion parameters of this post-test were used to compare technical skills of the medical students.

Results

The training data of the group that received force feedback showed a learning curve for the Mean and Max Absolute Force, Max Force Area, Force Volume, Task Time and Path Length of both instruments. The data from the group that received time feedback showed a learning curve for the Max Force, Task Time and Path Length of both instruments. In the post-test the parameters Mean Absolute Force (p=0.039), Max Force (p=0.041) and Force Volume (p=0.009) showed a significant difference in favour of the group that received force feedback.

Conclusion

The learning curves and the post-test indicate that training with visual force feedback improves tissue handling skills with no negative effect on the Task Time and instrument motions. Conventional laparoscopic training with visual time feedback improves instrument motion and Task Time, but does not improve tissue manipulation skills.

10.1 INTRODUCTION

It is well known that laparoscopic surgery presents unique challenges for the surgeon. First, the surgeon has to coordinate three dimensional movements while looking at a two dimensional image. Second, the incisions act as a pivoting point for the instruments since the location of the incisions are fixed. This means that all movements of the instrument tips in the abdominal cavity are in opposite direction to the handle movements outside the abdominal cavity (also known as the fulcrum-effect) [1]. The moment arm between the tip of the instrument and the abdominal wall fluctuates during the procedure. Therefore the forces applied at the tip of the instrument strongly depend on the insertion depth of the instrument. All combined, these difficulties in instrument handling make it important to train psychomotor skills before entering the operating theatre. Besides training on animal models, Virtual Reality (VR) trainers and Box Trainers (BT) are often used to improve the psychomotor skills of medical students and residents.

Objective assessment

Objective parameters based on time and instrument motion are commonly used in training. BTs with sensors that track the motion of instruments [2-8] and tissue manipulation force [9-13] have been proven efficient to assess and train laparoscopic skills. In previous research, a hybrid BT called ForMoST was developed to measure instrument motions and tissue handling force during multiple training tasks [13]. The ForMoST has the ability to train on Task Time, instrument motion and tissue manipulation force simultaneously. Especially if tissues are manipulated under traction, as common in real surgery, force parameters can provide useful information about performance and can provide discrimination between novices and experts with an accuracy between 84% and 100% [12,13].

Real time feedback in training

The Task Time is a clear value that is easy to interpret and therefore easy to improve to an expert level. Hypothetically, if focusing on a better Task Time score, instrument movements become faster and therefore less controlled resulting in poor or dangerous tissue handling if trainees completely disregard the tissue handling force. In order to create awareness about the importance of safe tissue handling, students should be trained with systems that gives real time feedback of the tissue manipulation force. Prior to this study, a study was conducted to show the effects of visual force feedback [11]. This study focused on reducing the applied force on the needle and thread of a suture during a needle insertion task. The results showed that the group that received real time visual force feedback applied on average 68% less force during the post-test without feedback.

Task dependent performance

If the task used in the post-test in which learning effects are measured is not different from the task used during training [10,11], it is possible that the learning effects are mainly task dependent; meaning that effects are not present if other tasks are used or real surgery is performed. Measuring the effects of visual force feedback during training of technical skills in real surgery is difficult since current sensor systems used for objective performance measurements cannot be used in the operating room. Therefore, we conducted a study in which two groups of medical students are trained on one task and

assessed on a different task. In case a transfer of technical skills between these two tasks is present, it is indicated that the obtained technical skills are not task dependent and potentially can be of value during other laparoscopic tasks.

Aim of the study

The aim of this study was to compare the learning effects between training with time as primary feedback, and training with force parameters as primary feedback. Therefore, the main goal of this study is to find an answer to the following two questions:

- 1. How are the force, time and motion parameters influenced during training of basic laparoscopic skills with real time visual feedback of the Task Time?
- 2. How are the force, time and motion parameters influenced during training of basic laparoscopic skills with real time visual feedback of the manipulation force?

10.2 Methods

Participants

Medical students were asked to participate in this study after attending an introduction class for 2^{nd} year students. In this class, 2^{nd} year students get their first introduction into skills training, which consists of 30 minutes of laparoscopy training on a BT. During these 30 minutes of training, students executed a series of validated laparoscopic tasks on a BT. Within this course, students learn to place beads on pins, to cut a circle from a clove spanned over a square of nails, to place an elastic band around a square of nails, to guide a metal pin though a series of aligned hoops and finally to place a suture on a skin pad [14].

In total 25 participants with less than one hour of training and no additional experience in laparoscopic surgery participated in present study. The participants were randomly divided into two groups. The Time Feedback (TF) group consisted of 13 participants (n=13) and the Force Feedback (FF) group consisted of 12 participants (n=12). The TF group consisted of 9 female and 4 male participants and the FF group consisted of 9 female and 3 male participants. Only right handed participants were included in this study. All participants were asked to answered a standardized set of questions about their prior experience regarding laparoscopy. Exclusion criteria for this study were participants who did not complete the first trial of the training session within 45 minutes.

Tasks

In order to investigate the technical skills required for proper tissue handling, two new tasks were developed. The main difference between those new tasks and commonly used tasks for training eye hand coordination, is the use of elastic elements that mimic the properties of real tissues. The construct validity of the tasks used in this study has been established in an earlier study [13].

Task 1 consists of a base plate with four wormlike silicon strips (Figure 10.1). Participants are asked to connect the two sets of silicon strips in a predefined order. A connection is established if the small hook of one tissue is placed in the eyelet of the other. Proper connection is only possible if both instruments work together. Participants are told not to grab the hook or eyelet, to prevent the silicon strips from rupturing.



Figure 10.1 Instructions as provided on the screen to the trainee before training with task 1, tissue connection under traction.

Task 2 consists of a base plate with a silicon flap (Figure 10.2). The silicon flap is connected to the base plate on the left side. There are two holes in the silicon patch. The objective for the participants is to place a silicone two mm thick thread through the two holes at the unconnected side of the flap. This task forces participants to use both instruments. When performed correctly the forces applied in this task are negligible.



Figure 10.2 Instructions as provided on the screen to the trainee before the post-test with task 2 start. Task 2 consists placement of a silicone wire in a silicone flap with holes.

Test setup

In this study the participants performed the two different training tasks inside a modified box trainer (Figure 10.3). The training task is different from the task used in the post-test to measure the effect of visual feedback on task independent technical skills. In the training session task 1 is used. To complete task 1 successfully, some traction is required to connect the loose ends of the silicone strips. The post-test is performed with task 2 (placement of a silicon wire). To complete this task successfully, traction on the task components is not necessary. The box trainer is equipped with the TrEndo system, a force platform and a USB camera for the visualization of the task on a computer screen. The TrEndo consists of two gimbal mechanisms with rotation sensors to measure the rotation of the instruments in the mimicked port site and linear displacement sensors to track the insertion depth of the instruments [6]. The force platform measures all forces in three dimensions that are exerted on the training task during training [10].

Feedback during training

Both groups received visual feedback during training. For the TF group, the elapsed Task Time was shown in digits under the laparoscopic image. Depending on the elapsed time, the letters and digits changed colour from green to orange to red. As long as the indicator was green, the Task Time did not exceed that of the group average of experts. If turned orange, the Task Time did not exceed the group average of intermediates. If turned red, the Task Time exceeded the group average of intermediates. The values were extracted from the validation study of both tasks [13].



Figure 10.3 The setup of the ForMoST system that measures force and motion with ForceTRAP and TrEndo, respectively. The image of the task is displayed on a computer screen.

The FF group received visual force feedback. The visual feedback consists of an arrow (Figure 10.4) that points in the same direction as the applied force. The size of this arrow increases with the exerted force on the tissue. Besides the direction and size, the arrow changes its colour from green to orange to red depending on the safety thresholds of the manipulated tissue. Since the elasticity of the artificial tissue is close of that of uterine tissue, the safety thresholds of uterine tissue were used [15].



Figure 10.4 Example image captured from monitor during training with both feedback modes turned on. In this study the arrow provides information about the size and direction of the tissue manipulation force in the FF group while the time indicator is turned off. The task time indicator gives feedback to the TF group while the tissue manipulation force indicator (arrow) is turned off.

Training protocol

All participants received instructions on how to complete the task. During these instructions a picture was shown to the participants of the FF group and TF group (Figure 10.1 and 10.2). In addition, all participants were told to handle the tissues with care in order to prevent damage of the elastic components and to keep vision on the instruments at all time. The TF group was instructed to improve their performance on the time parameter every repetition. Participants were instructed to aim for a Task Time less than 60 seconds in order to reach an expert level. This expert Task Time for task 1 was established in an earlier study [13]. Participants of the FF group received additional instructions to explain the visual feedback they would encounter in the screen during training. All participants performed task 1 (tissue connection under traction) during the training session with standardized feedback of either the tissue manipulation force or Task Time. After the training session, the tasks were switched during a short break of 10 minutes. Thereafter, all participants were asked to perform the post-test, that consists of executing task 2 (placement of thread in flap) a single time. Before participants started the post-test the image with instructions was opened on the screen (Figure 10.2). After the instructions ended the students were encouraged to use the skills that they obtained during training with: "Please use the skills you just obtained during training to complete this post-test." After the post-test started, general questions regarding the task were answered.

Performance parameters

For this study the performance parameters Maximum Absolute Force, Mean Absolute Force, Force Volume, Maximum Force Area, Task Time, Motion Volume Left and Right, Path Length Left and Right and Mean Distance Between Tips were selected due to their discrimination power or informative character that was demonstrated in earlier work.

<u>Max Absolute Force</u>: The highest absolute force in Newton that was applied on the training task during the measurement [10].

<u>Mean Absolute Force :</u> The mean absolute force applied during measurement in Newton [10].

<u>Force Volume</u>: If the force data is presented in 3D, three principal components can be found indicting the three largest standard deviations of the force. The Force Volume is the volume of an ellipsoid fitted around those three standard deviations [12].

<u>Max Force Area</u>: If the absolute force is presented in time, the Max Force Area indicates the largest surface area under the graph. A force area is created between the moment in time the absolute force becomes larger than zero and the following moment in time the absolute force becomes zero again. Max Force Area units are presented in Newton second and referred to as peak force in earlier research [12].

Task Time: The time needed to complete the task. Task Time is presented in seconds.

Motion Volume Left and Motion Volume Right: If the motion data of a single instrument is presented in 3D, three principal components can be found indicting the three largest standard deviations of the motion. The Motion Volume is the volume of an ellipsoid fitted around those three standard deviations [7]. Motion Volume is presented in mm³.

<u>Path Length Left and Path Length Right:</u> The distance the left and right instrument tip travelled in a confined 3D space after completion of a training task [7]. The distance is presented in meters.

<u>Mean Distance Between Tips:</u> The mean distance between the left and right instrument tips after completion of a training task [13]. The mean distance between tips is presented in millimeters.

Statistical analysis

Statistical tests are used to compare the parameter results of the first trial with the last trial in the training session to determine if learning curves are present in the TF and FF groups. Secondary, the parameter results of the post-tests are used to determine if the data from the FF group is statistically different from the TF group.

To test for a normal distribution, a Shapiro-Wilk test is considered preferable in case a sample size is relatively small (n < 50). The parameter data of the post-test are considered normally distributed when the data of the TF group are normally distributed and the data of the FF group are normally distributed. For all normal distributed parameters an independent-samples T-test is used. For all parameters which do not meet the criteria for normal distribution, a Mann-Whitney U test was used. P<0.05 was considered significant in both cases.

10.3 RESULTS

Each participant was able to finish the first trial within 45 minutes and to perform task 1 six times followed by task 2 which the participants executed once. The Max Absolute Force, Mean Absolute Force, Force Volume, Mean Distance Between Tips, Path Length Left and Motion Volume Left and Right parameters were found to be normally distributed.

Learning curves

The graphs in Figure 10.5 and 10.6 show the training and post-test data of all motion parameters, Task Time and force parameters with a 95% confidence interval. To prove the presence of a learning curve, we tested the first and sixth repetition of the training session. Table 10.1 shows the significant different results of the comparison between first and sixth repetition of training session for the FF and TF group.

In the FF group a significant difference between the first and sixth repetitions of 0.43N (P=0.007) was found for the Mean Abs Force, 3.27N (P=0.001) for the Max Absolute Force, 577sec, (P=0.002) for the Task Time, 73.6Ns (P=0.001) for the Max Force Area, 4.16N³ (P=0.004) for the Force Volume, 4.2 m (P<0.001) for the Path Length of the left instrument and 5.9m, (P=0.002) for the Path Length of the right instrument.

In the TF group a significant difference between the last and first repetitions of 2.56N, (P=0.004) was found for the Max Absolute Force, 325sec (P=0.009) for the Task Time, 3.9m (P=0.019) for the Path Length of the left instrument and 7.96 m (P=0.037) for the Path Length of the right instrument.



Figure 10.5 Learning curves over 6 repetition and post-test scores for Path Length, Motion Volume, Mean Distance Between Tips and Task-time (including the median and 95% Confidence Interval). Significant difference in the post-test was indicated with an "*".



Figure 10.6 Learning curves over 6 repetition and post-test scores for Max Absolute Force, Mean absolute Force, Max Force Area and Force Volume (including the median and 95% Confidence Interval). Significant difference in the post-test was indicated with a "*".

Parameter	Tested difference between R1 and R6				
	Force group		Time group		
	Mean difference	P-value	Mean P-value difference		
Mean Abs. Force	0.43 N	.007	Not significant	>0.05	
Max Abs. Force	3.27 N	.001	2.56 N	.004	
Task time	577.4 s	.002	325.3 s	.001*	
Max Fore Area	73.6 Ns	.001	Not significant	>0.05	
Force Volume	4.16 N^3	.004*	Not significant	>0.05	
Path Length Left	4.2 m	.002*	8.0 m	.037*	
Path Length Right	5.9 m	.000	3.9 m	.019*	

Table 10.1 Comparison between first and last repetition to identify the presence of learning effects.

* data not normally distributed

Statistic difference between groups in post-test

The data of the post-test is used to determine if the parameters from the FF group are different from that of the TF group due to learning effects during training. Table 2 shows that a significant difference was found between the FF and TF group for Mean Absolute Force, Max Absolute Force and Force Volume. No significant differences were found between the FF and TF group in Task Time, Max Force Area, Motion Volume, Path Length Left and Right and Mean Distance Between Tips.

Table 10.2 Parameters that show significant differences between the Time Feedback	k (TF) and Force
Feedback (FF) group in the post-test.	

Parameter	group	Mean	Standard deviation	Sig.
Mean Abs. Force (N)	TF	0.791	0.396	.037
	FF	0.514	0.187	
Max Abs. Force (N)	TF	9.329	3.951	.041
	FF	6.676	1.613	
Force Volume (N^3)	TF	3.588	3.401	.009
	FF	0.738	0.510	

* Data not normally distributed

10.4 DISCUSSION

The results indicated a learning curve for Path Length Left and Right, Task Time and all force parameters in the group that received visual force feedback during training. For the group that received time feedback during training, a learning curve was found for the Path Length Left and Right, Task Time and Max Absolute Force parameter. The data from the post-test performed on task 2 showed that the FF group that received force feedback during training performed better on the most important force parameters Mean Absolute Force, Max Absolute Force and Force Volume.

Influence of visual feedback on performance

The results and learning curve of the Task Time parameter in Figure 10.5 indicate that there is no significant difference in Task Time during the sixth repetition of the training session. At the first repetition however, the FF group performed that task approximately 60% slower compared with the TF group. This difference was expected because the participants in the FF group needed some time to get used to the arrow displayed on the screen. Although both groups performed almost similar on the Task Time and motion parameters at the end of the training session, the FF group performed better on the force parameters during training and post-test. This indicates that although the training task 1 is complex, it is possible for students to process the additional virtual 3D arrow on the screen in order to minimize the tissue manipulation force and to improve tissue handling performance.

Since there is no difference in Task Time between the TF group and the FF group at the end of the training session and post-test, it seems better to train residents with visual force feedback as primary feedback source instead of Task Time. As a consequence, training on tissue manipulation force could reduce the amount of tissue damage and complications during or after surgery, without lengthening the procedure time.

Training focused on task-time reduction

If the main focus in standard training is on Task Time reduction during training, only psychomotor skills are trained without much attention to tissue handling. This phenomenon is clearly displayed in the learning curves of the force parameters in Figure 10.6. Although learning effects are present in both groups, the averaged group difference was around two times higher for the Mean and Max Absolute force parameter and seven times higher for the Force Volume in the TF group during training. Moreover, looking at the differences in Confidence Interval in Figure 10.6, it seems that especially the students that show rough tissue handling benefit the most from the feedback.

Transferring tissue manipulation skills between different tasks

Task 2 was used only in the post-test. When performing this task correctly almost no forces are applied, a good score on this task is mainly based on understanding of the instruments, task and resulting strategy. Although participants of both groups applied more force than necessary, it was observed that the participants in the FF group paid more attention to the forces they applied on the tissue. Task 1, that was used during training is different from task 2 since it requires traction (i.e. pulling on the "worms") for successful completion. This implies that the students need to use different skills that were not trained in the post-test. Nevertheless, the results of the post-test show a significant difference in most force parameters. Therefore, our results indicate that basic tissue manipulation skills trained in one type of task are transferrable to another task with a different layout and different objects to manipulate. This corresponds with the results from other studies in which the task used in the post-test was different from the training task, [16-20]. Moreover, two of those studies used surgical procedures on animals to concluded that skills obtained during training with VR or BT are even transferable to real surgery [18-20].

Instrument manipulation skills

None of the motion parameters were significantly different between the FF and TF group in the post-test. Therefore it cannot be concluded that a positive effect on motion parameters can be accomplished by training with force feedback alone. However, the results do strongly suggest that training with visual force feedback has no negative effect on motion parameters and therefore psychomotor skills of the trainees. This implies that improvement in instrument manipulation is mostly based on the amount of training, with or without force feedback. However, it is possible that specific training focused on instrument motion could even further improve instrument handling. Further studies that include an additional group that receives visual feedback of instrument motion alone could indicate the influence of instrument motion feedback with respect to time feedback and force feedback.

Complexity of tasks

During this study it was important to motivate the participants in both groups. Especially in the group that received visual force feedback the first and second task seemed challenging for some novices. Therefore it is important to keep an eye on the participants during the repetitions and motivate them when needed. Motivation occurred by telling the struggling participant that all beginnings are difficult and that eventually everybody learned to perform the task. This motivation was given to three participants in the TF and five in the FF group. Moreover, for future research it is advisable to add a short movie to the introduction that clarifies how the virtual arrow represents the exerted force on the tissue to minimize the difference in Task time at the beginning of the learning curve.

Limitations of this study

Within this study, the impact of two feedback modes were compared by means of parameter outcome in the post-test. The group that received force feedback was not motivated to complete the task as fast as possible. The group that received time feedback was not motivated, apart from the given instructions, to minimize the force at all times. In real training it is likely that an instructor provides incidental feedback to the trainee about the force that is applied based on deformation of tissue. This group was not included in this study. In order to investigate whether visual force feedback during tissue handling is competitive or even better than expert feedback, more research is needed.

10.5 CONCLUSION

The learning curves and the post-test indicate that training with visual force feedback improves tissue handling skills with no negative effect on Task Time and instrument motions. Training with visual time feedback improves instrument motion and Task Time, but does not improve tissue manipulation skills. Therefore, in order to reduce tissue damage and complications to a minimum without lengthening the procedure time, future laparoscopic training should focus on tissue handling skills instead of Task Time reduction. After all, 'first, do no harm', remains the most important principle in medicine [21].

Acknowledgments

The authors would like to thank the BioMechanical Engineering (BME) technicians Arjan van Dijke and Hans Drop of the Delft University of Technology for help in connecting all the electrical components. They thank all surgeons and gynecologists for taking interest in this study and providing practical information about learning effects in training. Finally, the authors like to express special thanks to Gert-Jan Hultzer en René Rodenburg from the skills slab of the Leiden University Medical Center for providing us with all the instruments, materials and facilities necessary.

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CHAPTER 11 DISCUSSION AND RECOMMENDATIONS

TIM HOREMAN



Althought ForMoST has given existance, the search for relevant new tasks and effective training methods that clearly improve surgical skills in the OR has just began. This chapter recapulates the achievements from the previous chapters and provides suggestions to increase the accaptance of ForMoST in training centra.

"I have been impressed with the urgency of doing. Knowing is not enough; we must apply. Being willing is not enough; we must do."

Leonardo da Vinci (1452-1519)

11.1 FORCE MEASUREMENTS IN BOX TRAINERS

The first and second objective of the thesis were to develop a force measurement system to measure forces and to determine the role of force feedback during training of surgical skills. For this the Force and Motion Surgical Trainer (ForMoST) system was developed containing existing instrument tracking sensors and new force tracking sensors for preclinical objective assessment of basic laparoscopic skills. In Figure 11.1, the system is displayed with Trendo's for motion tracking and a force platform for force tracking. For assessment, new motion parameters were developed to inform about the view on instruments and new force parameters were developed to inform about safety in tissue handling. With the new training system, studies were performed to find the most discriminating parameters for the intra and extra corporal suture tasks. Secondly, clinical procedures were analysed to identify a new set of force application tasks that can be used to determine in general the level of surgical experience in tissue handling. For the last objective, a method was developed to provide force feedback to the user and studies were performed to investigate the impact of this feedback on the parameter outcomes and learning curves.



Figure 11.1 The ForMoST training system as developed by MediSHield BV. Left, complete setup with TrEndo's between instruments and top plate and force platform between task and bottom plate. Right, Close-up of force platform with holder containing a suture pad for intracorporeal suturing.

The importance of force measurements in box trainers

There are two main reasons to integrate force sensors in training systems that assess surgical performance. The first reason is to assess important technical skills as instrument handling and tissue handling that are required for safe endoscopic surgery in an objective way. To assess the technical skills of a surgeon in and outside box trainers, OSATS (Objective Structured Assessment of Technical Skills) are used (Figure 11.2). Although the name suggests that objective information is used for assessment, a score is given to each of the items of the OSATS based on the assessing teacher's interpretation of performance [1]. Since the surgeon's "respect for tissue" is considered important for surgical performance, force measurement systems and objective parameters that represent "respect for tissue" should be integrated in training systems [2].

GLOBAL RATING SCALE OF OPERATIVE PERFORMANCE

Please circle the number corresponding to the candidate's performance in each category, irrespective of training level

Respect for Tissue :				
1 Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments	2	3 Careful handling of tissue but occasionally caused inadvertent damage	4	5 Consistently handled tissue appropriately with minimal damage
Time and Motion :				
1	2	3	4	5
Many unnecessary moves		Efficient time/motion but some unneccessary moves		Clear economy of movement and maximum efficiency
Instrument Handling :				
1	2	3	4	5
Repeatedly makes tentative or		Competent use of instruments		Fluid moves with instruments
awkward moves with instruments		but occasionally appeard		and no awkwardness
by inappropriate use of instruments		stiff or awkward		
Knowledge of Instruments :				
1	2	3	4	5
Frequently asked for		Knew names of most		Obviously familiar with the
wrong instrument or used		instruments and used		instruments and their names
inappropriate instrument		appropriate instrument		
Flow of Operation :				
1	2	3	4	5
Frequently stopped operating		Demonstrated some forward		Obviously planned course of
and seemed unsure of next move		planning with reasonable progression of procedure		operation with effortless flow from one move to the next
Use of Assistants :				
1	2	3	4	5
Consistently placed assistants poorly		Appropriate use of assistants		Strategically used assistants
or failed to use assistants		most of time		to the best advantage at all time
Knowledge of Specific Procedure :		192		
1	2	3	4	5
Deficient knowledge. Needed		Knew all important		Demonstrated familiarity with
specific instruction at most steps		steps of operation		all aspects of operation

Figure 11.2 OSATS (Objective Structured Assessment of Technical Skills) are used by hospitals to assess the skills of a surgeon in and outside box trainers. The first question indicates that respect for tissue is considered important in surgery.

A second reason is to increase the power of the skills classification methods used by training systems to assess the trainee. Chmarra et al. showed that motion parameters can be used for classification of the skills of the trainee [3]. In her studies she found that

parameters such as path length, motion smoothness, task time and depth perception showed enough discriminating power to distinguish between novices, intermediates and experts with an accuracy of 74%. From the mentioned parameters, the task-time parameter was most discriminative whereas all other motion parameters are highly correlated to the task time. The studies in this thesis show that important force parameters as maximal force, mean force, force area and force volume do not only have discrimination power but are also not strongly correlated to motion or time parameters in the novice and intermediate groups (Chapter 9). This suggests that force parameters contain unique information about technical skills that cannot be extracted from time and motion parameters alone and are therefore of value during skills assessment. Force measurements in box trainers are therefore useful since the integration of force parameters in classification software can increases the discrimination power and incorporates the assessment of technical skills that reflect tissue handling. With the proposed training systems, novices and intermediates can train tissue handling skills in box trainers without the feedback of experts.

Learning curves of force parameters

Chapter 7 and 10 indicate that, although instrument motion improves naturally during training, tissue handling skills remain constant. Moreover, the outcome of two questionnaires showed that most novices indicated that they improved significantly in performance, even the novices that exerted force on the training task up to three times higher compared to experts. The absence of a clear natural learning curve in force parameters in combination with the high forces that many novices exert on the tasks without notice, are indicators that additional training focussing on the tissue handling force is important in the educational program that needs to be followed before surgery on patients is allowed.

Training of tissue manipulation in curriculum

The data from Chapter 9 show that the tissue handling force of some intermediates exceed the levels of the novices, indicating that the focus on task-time and instrument motion alone during a skills training course can have a negative influence on the tissue handling force. If we calculate the average tip speed for the instruments (e.g. left and right instrument and tasks combined) of Chapter 9 we see that novices move the instruments relatively slow (Table 11.1) and manipulate the task components less delicately compared with the experts. Intermediates however learned to deal with the instruments in a box setting and show faster instrument motions comparable with the experts. However, since intermediates are not trained with a focus on tissue handling they can show the same rough instrument handling as novices. This indicates that tissue handling skills of an intermediate mainly improve after many surgical procedures in which the consequences of rough tissue handling are experiences. In Table 11.1 this is evident from the force parameters of the experts that are two times lower on average compared with the novices and intermediates. Further research is necessary to indicate if tissue handling skills should be trained after novices learned to work with the instruments in a box or that training of instrument handling and tissue handling can be combined in one training session.

Table 11.1 Tip speed and maximum force calculated for the participants of Chapter 9. Intermediates increase their instrument speed while the maximal force during tissue handling remains high. Dark grey; low averaged instrument speed or high average maximum force. Light grey; high averaged instrument speed or low average maximum force.

	Avaraged instrument Speed	Avaraged maximum Force		
	± SD [m/s]	± SD [N]		
novices	8.4±2.7	6.9±2.4		
intermediates	11.1±2	6.8±3.8		
experts	11.9±3.0	3.1±1.5		

Defining force thresholds for assessment

In order to assess technical skills after training, a comparison between the parameter outcome of the trainee and thresholds that are considered "the gold standard" is needed [4]. In most of the presented work the parameter threshold values for training of novices and intermediates were extracted from collected force and motion data from experts that performed tasks on a box trainer. In some situations however, measurements on real tissue can give a more uniform and reliable threshold value since there is no influence of factors as "face validity" and "construct validity" on performed with free weights or spring balances to find solid threshold measures for the maximal allowable pulling force for multiple organs.

In other cases, it is necessary to record the pulling force on tissue in multiple situations during a surgical procedure. In Chapter 8 for example, a set of small custom made sensors was developed and produced to determine the force in the thread of a stitch in relation to the pulling force on the loose end of the thread. Although the force in the stitch is important for the healing process of the wound, only the pulling force can be measured with the force platform of Chapter 7. Hence, with a known relation between stitch force and maximal pulling force on the thread, the pulling force can be used as representative threshold value in trainers to create a solid and reliable stitch.

If artificial tissue is used for training while force thresholds where defined with real tissue, it is important that the mechanical properties of the artificial tissue are comparable to the mechanical properties of the real tissues that were used to determine the thresholds.

11.2 FEEDBACK OF PERFORMANCE

Parameter interpretation

Most parameters were developed especially for classification of technical skills. Therefore, not all qualitative parameters that are effective for discrimination between skills levels are relevant for surgery or can be used to provide constructive feedback to the trainee. Table 11.2 gives an overview of the most discriminating assessment parameters as used in this thesis and parameters that can be important for surgical safety. In the middle column it is indicated how relevant we think the parameter is for safe surgery. The right column indicates how a parameter output can be used to instruct the trainee in general.

Besides a more general instruction based on a single parameter outcome, a combination of parameters outcomes can result in a different more specialized task dependent instruction. Experiments with suture data of Chapter 2 indicated that the position of the instrument tips during tightening of the knot gives valuable information about the knowledge the trainee processes about knot tying. In 68 % of the data it was found that a high peak force value was accompanied by a high tip to tip distance or high distance between tips and suture pad exposing a poor strategy. This combination of outcomes can therefore result in the instruction: "grab the threads a maximum of 30 mm from the knot before tightening" or "keep your tips maximal 1 cm above the pad during tightening". If this type of constructive feedback is used for training in simulators, a deeper understanding of the task supported by practical clinical knowledge is required.

	Relevance for safety	Informative instruction to trainee		
Time parameters				
Task time	Reduction of operation time beneficial for patient	Task time is high, more practice is needed		
Motion parameters				
Part length	Not directly	Try to minimize unnecessary instrument movements		
Speed	Tissue puncture due to overshoot if tip is sharp	Lower your instrument speed		
Depth perception	Risk on accidental contact between tissue and tips	Check your insertion depth		
Motion volume	Not directly	Try to minimize unnecessary instrument movements		
Tip to tip distance	Poor view on instruments. Risk on accidental contact between tissue and tips	Use both hands for task Keep tips close to each other		
Out of view time	Poor view on instruments. Risk on accidental contact between tissue and tips	Keep your instruments in sight		
Force parameters				
Max force	Tissue damage	Forces are too high. Minimize traction during manipulation.		
Mean force	Risk on tissue damage due to pour force control	Too many contact between instruments and tissue. Watch out for unintentional contact with tissue		
Force Volume	Poor force control during interaction	Too much jerks or collisions during manipulation. Lower your instrument speed during manipulation		
Force-Time parame	eters			
Peak force or Max force area	Excessive force during traction	Lower your force during traction. Let instruments work together to minimize tissue tension		

Table 1	11.2 I	Parameter	based	Feedback.
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Real-time feedback of performance

In addition to the use of parameters for skills assessment, Chapter 6, Chapter 7 and Chapter 11 describe methods to inform the trainee about their performance in real time. Although feedback can be given in many different ways (e.g. auditory, visual, tactile), we chose to use the human sensory system most important for the tasks that were performed. By modifying the area visual to the trainee, it was found that the human mind is capable of using additional visual information such as object colour and shape to improve tissue handling to some degree. Even if the feedback option is turned off and the task is changed during the post-tests, most trainees performed better compared with trainees that did not receive additional visual feedback during training. Although our studies indicated that visual feedback reduces the interaction force in suture tasks it remains unclear if similar effects can be found if haptic or auditory feedback is used. Extra visual information in the view of the trainee is easy to observe. However, visual feedback aside the task area (i.e. LED's in Chapter 7) can distract from the task or even block part of the image when an arrow is used as in Chapter 6. This needs to be considered when one wishes to use additional visual feedback during surgery. Real surgery requires continuous focus not exclusively on the surgical action itself but also the surroundings.

Although we found that training with visual feedback has a positive influence on force parameters that represent tissue handling and that training effects were significant even when and the post test was different from the training task, the question remains how feedback improves performance. Although not researched specifically, it seems that when force feedback is used to find the best strategy for a task during training, this strategy is remembered and reproduced during the post test. In case of needle driving in Chapter 6 and 7, this means that novices learn to use the curvature of the needle to their advantage. In case of tissue connection under traction in Chapter 10, novices learn to grasp the artificial tissue near the loose end instead of the middle for easier manoeuvrability of the connective means with less traction. In the Rasmussen model [6], the real time visual feedback in those examples helps novices to choose the right strategy on a skills and knowledge based level upon informing the novices about dangerous forces on a rule based level.

11.3 FUTURE RESEARCH

Clinical validation

We showed that force feedback can teach novices to lower the interaction forces during training on training tasks in a box trainer, However, with the current technology available, it was not possible to proof that surgeons trained on tissue handling specifically apply less force on the tissue compared with surgeons that followed the conventional educational program. Further studies with modified instruments that can measure the tissue manipulation force during surgical procedures on animal models or patients should indicate the efficiency of training with force feedback in box trainers.

Laparoscopy though a single entree port

The ForMoST combines two different measurement systems into one setup. Although highly efficient for skills determination, the system can only track straight instruments in

a conventional two port laparoscopic configuration. Furthermore, TrEndo's add mass and volume to the instruments and therefore change the face and construct validity to some degree. For laparoscopy through a single incision (e.g. single access surgery), with or without curved instruments, TrEndo's cannot be used anymore. A recently developed force tracking platform is able to determines the point of contact based on the ratio of reaction forces in three small force sensors under the table surface. Figure 11.3 shows a working model of the force tracking system inside the recently developed trainer for Single access surgery. Contact between pen and surface (top) results in a red dot at the same location in the user interface (below). This platform is accurate enough to detect writing on its surface and could provide valuable position information if Trendo's cannot be used.

For the studies performed on box trainers in this thesis, force parameters were based on interaction force between instrument tips and training task. According to Chapter 4, single access surgery results in higher tissue interaction forces compared with conventional laparoscopy. Higher forces at the tip are likely to result in higher forces in the abdominal wall that supports the trocar port. If force sensors are placed between trocar port and abdominal wall, further studies should indicate if recordings of the abdominal force contain additional value for training of single access surgery.



Figure 11.3. Position tracking in single access surgery with a new force platform based on the force distribution over minimal three unidirectional force sensors. This platform is accurate enough to track a marker during writing on the plate.

Complex training tasks

After performing the first pilot tests as described in Chapter 2, we came to the conclusion that needle driving and knot tying requires different skills. During needle driving, there is continuous contact between tip and tissue whereas efficient force control is essential in order to drive the needle through the tissue. A theoretically ideal knot however requires no reaction force on the tissue as discussed in Chapter 3 and 8. Differences in force parameter results are mainly useful to identify differences in skill levels when performing an action in the task that requires tissue handling. Hence, the absence of force data can be an important indicator for good instrument motion control during an action that does not

require tissue handling. Therefore, a combination of both measurement systems (e.g. motion and force tracking) is ideal for a suture task when motion and force parameters are calculated for the corresponding actions (e.g. needle driving and knot tightening). By dividing up a task into segments defined by the skills required, a first attempt was made to improve the quality of the parameters that represent instrument or tissue handing.

In case complex tasks are used that contain multiple surgical actions such as cutting, manipulating, and knot tying, it is advisable to determine the parts of the task that generate important data and the parts that mainly generates noise for each parameter. If this is determined from a technical and clinical point of view, evaluation of each separate action with selected parameters can then lead, not only to a more robust classification, but also to more informative feedback.

Learning curve parameters

In order to improve the discrimination robustness further, studies should indicate whether it is effective to incorporate the learning effects for important parameters in the classification. Especially for simple tasks it was observed that experts show a short learning curve that is mainly caused by their need to adopt to the unfamiliar training setup. Restricted by a lack of skills of novices, the learning curve of a novice is longer and less steep.

11.4 CONCLUSION

A new force platform was developed and incorporated in a new Force and Motion Surgical Trainer (ForMoST). Multiple small mechanical sensors were developed that can be used to find force thresholds for training of tissue handling as well as for safety monitoring during suturing of incisions. It is shown that force parameters that reflect tissue handling or suture tension, can now be used to inform surgeons about the risk of tissue damage while training laparoscopic skills or suturing tissues.

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APPENDIX A

Equasion A.1 shows how the deformation u results from F and T in the Hook-in Force sensor. The spring blade deforms and the distance between the 2 spring blades increases. Euler's bending theory for beam elements was used to calculate the thisckness of the spring blades.

$u = \frac{Tl^{2}}{2EI} + \frac{Fl^{3}}{3EI} = \frac{3Tl^{2} + 2Fl^{3}}{6EI}$ $I = \frac{bh^{3}}{12}$ $h = \sqrt[3]{\frac{6Tl^{2} + 4Fl^{3}}{Ebu}}$	(Eq. A.1)
u = max distance of 2 mm	
F = max force in wire of 20N	
T = max torque of 20N x 6 mm	
l = length of spring blade of 14 mm	

I = area moment of inertia

E = elasticity modulus steal of 210 GPa

b = spring blade width of 5 mm

h = hight of spring blade

Equation A.2 shows how the thickness of the spring blades in the Stitch Force sensor was derived from the Euler bending theory for a beam element clamped on one side and with fixed angle on the other side.

$$T_{tip} = 2Fr_{tip}$$

$$F_{sb} = \frac{T_{tip}}{r_{base}n_{blades}}$$

$$u = \frac{F_{sb}l^3}{3EI} - \frac{T_{sb}l^2}{2EI}, \theta = \frac{F_{sb}l^2}{2EI} - \frac{T_{sb}l}{EI} = 0$$

$$u = \frac{F_{sb}l^3}{3EI} - \frac{F_{sb}l^3}{4EI} = \frac{F_{sb}l^3}{12EI}$$

$$I = \frac{bh^3}{12}, h = \sqrt[3]{\frac{F_{sb}l^3}{Ebu}}$$

F = max force in wire of 20N, $F_{sb} = force$ on each springblade

 r_{tip} = radius of tip, r_{base} = radius of baseplate that holds the springblades

n = number of springblades

 T_{tip} = torque on tip, T_{sb} = torque on tip

l =length of spring blade of 15 mm

E = elasticity modulus steal of 210 GPa

b = spring blade width of 6 mm, h = hight of spring blade

(Eq. A.2)

 $[\]theta$ = angle at end of the sprinblade

DANKWOORD

Als eerste bedank ik mijn (co)promotoren Jenny (TU-Delft), John (TU-Delft) en FrankWillem (LUMC). Jenny gaf uitstekend sturing gedurende mijn promotie. Haar deur staat altijd open voor haar collega's, promovendi en studenten. Ik weet dat dat vanuit alle lagen in de organisatie zeer gewaardeerd wordt, zo ook door mij. John dank ik voor zijn professionele ondersteuning en zeer kritische blik op mijn toch wel diverse onderzoeksvoorstellen. FrankWillem zeg ik dank voor de manier waarop hij altijd meedacht met ideeën en vindingen waarvan de werking voor menig clinicus en ook technicus niet altijd te begrijpen is. Het aardige aan FrankWillem is dat hij tijdens overleg niet denkt: "Ach, laat die technische lui maar praten; ik knik wel ja". In de gesprekken die ik met FrankWillem voerde, probeerde hij altijd het wat, hoe en waarom te bevatten.

Het promoveren vindt niet altijd plaats op een roze wolk zoals menig buitenstaander veronderstelt, daarom was ik blij dat ik al het lief en leed kon delen met Dennis, Kirsten, Nick, Arjo, Arjan en Linda. Zij zaten immers allemaal in een soortgelijk schuitje, waardoor we veel steun aan en lol met elkaar hebben gehad. De nodige koffierondjes en tripjes naar de stad die daarbij hoorden waren ook erg gezellig. Dennis zonder jou, als wandelende vraagbaak voor Matlab problemen, was het nooit gelukt met het VER systeem. Bedankt voor je hulp met mijn soms wat "warrige" programmatuur. Arjan, zonder jouw drive om mijn opstellingen altijd te voorzien van Arduino's en mooi gekleurde LED's zouden ze toch minder aansprekend zijn.

Vooral in het begin van mijn promotie heb ik veel tijd doorgebracht met mijn klinische collega Sharon in het LUMC om onderzoek te doen naar de sterkte van weefsels. Gertjan en Renee, die het Skills lab faciliteren hebben er altijd voor gezorgd dat wij ons werk konden doen. Als het nachtwerk werd, wat weleens voorkwam, omdat weefsels vers gemeten moesten worden, stonden er koekjes, koffie en blikjes fris klaar. Daarvoor bedankt mannen. Mijn dank gaat uit naar Berty van het Gyn secretariaat, zij heeft heel wat zaken moeten uitzoeken als we weer iets afwijkends van plan waren.

Als onderzoeker en ondernemer valt het niet altijd mee om belangen gescheiden te houden. Vaak gaat dit goed als er vanuit dit netwerk met een commerciële visie geïnvesteerd wordt om systemen, die zijn ontwikkeld voor mijn onderzoek, te modificeren om dienst te doen als product of trainingsapparaat. Moeilijkheden ontstaan echter wanneer er na een vaak lange tijd van engineering en marketing, mogelijk geld verdiend kan worden en het voor het valoriserende management niet altijd duidelijk is wat de waarde is geweest van de personen of bedrijven die het product echt commercialiseren. Gelukkig waren er altijd mensen om mij heen die zich bewust waren van de moeite die deze stappen kosten. John, Gabrielle, Jenny en Caroline van onze BME afdeling en natuurlijk Stefan van het Transfer Office, bedankt voor jullie heldere kijk op de situatie en het verduidelijken van het belang en de visie van de TU op de momenten dat het nodig was. Dit heeft mij erg geholpen om strategieën te bedenken om zonder belangenverstrengeling voor iedereen een win-win situatie te creëren.

MediShield BV en daarin Klaas, Keerti, Willem, Freek en Erwin wil ik graag bedanken voor het geduld dat zij hebben gehad tijdens de verschillende projecten die liepen met de TU-Delft. Gelukkig dat iedereen bleef geloven in de potentie van de innovaties, ook als er vanuit het niets een partij spontaan besluit concepten van MediShield op de markt te brengen. Arne, Freek, Pieter-Bas, Desi, Mathijs, Frank en Siyu, ik bedank jullie als technische en klinische stagiairs/afstudeerders voor de modellen, simulatoren en producten die jullie in relatief korte tijd hebben gerealiseerd. Het was inspirerend om met jullie te werken. Desi, die als stagiair na een onuitvoerbaar project op het MISIT lab, op mijn SAS project terecht kwam. Al snel bleek dat zij niet met een gewone stage maar met haar Master thesis bezig was. Ondanks dat foutje heeft ze keurig werk geleverd en is ze zelfs nog mee geweest naar een congres in Tel Aviv. Jullie hebben me geleerd dat de ene afstudeerder niet de andere is en dat ik goed op moet letten hoe ik natuurlijke capaciteiten van personen op de juiste manier inzet.

Bijzondere dank gaat uit naar Freek, Frank, Luuk, Anne en Jurriën, voor hun gedreven aanpak. In een relatief korte periode van enkele weken kregen ze het voor elkaar om vanaf een schets, zelf, zonder enige ervaring, werkende prototypes te fabriceren van de meest uiteenlopende systemen en sensoren. Het feit dat ik van de meeste van jullie niet meer afkwam, geeft vertrouwen in mijn begeleiding. Freek en Frank liepen zelfs meerdere stages onder mijn supervisie bij de TU-delft, MediSHield, LUMC en AMC, waarbij er ook nog meerdere nationale en internationale prijzen werden gewonnen.

Ook mijn vrouw, vrienden en alle familie en collega's wil ik bedanken voor hun interesse in mijn activiteiten en Dolf en Corinna voor het nakijken van deze dissertatie. Aan de meeste vrienden, tantes, ooms, nichten en neven was het niet altijd makkelijk uit te leggen wat ik nu precies aan het doen was. Wellicht dat dit boekje eindelijk wat licht zal doen schijnen op mijn activiteiten van de afgelopen jaren.

Als Laatste wil ik Jeroen Luuk bedanken, ons schattige zoontje die geboren is 5 dagen voor ik de laatste hand legde aan dit proefschrift. Hoewel het niet altijd lukte om papa rustig de laatste typefouten uit dit proefschrift te laten halen is het wel weer een stuk gezelliger geworden in huis.



Jeroen Luuk Horeman-Franse geboren op 8-1-2014 om 10:18.

CURRICULUM VITAE

Tim Horeman was born in Haarlem, Holland, in 1980 and started his career in mechanical engineering at the MTS followed by the HTS in 2000 in Alkmaar. In 2004 he received his Engineering degree in the field of Mechatronics after finishing a graduation project at Tyco Healtcare (Phillips) in Petten. In this research project he developed a new container system for radioactive I-131 capsules. Those highly active capsules can now be wrapped, transported, stored and used with a minimum risk on exposure to radiation. After moving to Delft in 2005, Tim received his MSc degree in Biomedical engineering from the Delft University of Technology with specialization in BioMechatronics and minimally invasive surgery and medical safety in 2008. Tim did his PhD research in the Minimally Invasive Surgery and Interventional Technology (MISIT) group of the department of Biomechanical Engineering of the TU-Delft and Gynaecology department of the Leiden medical Centre. During his PhD research he developed novel training systems equipped with force and motion tracking systems that provide feedback to the user. In 2009, Tim founded the company MediShield BV that develops and integrates devices and sensory systems in the medical field. After his PhD research in May 2013, Tim started as project leader on the Steerable Punch project, a collaboration between universities, international and national operating companies that aims on the development, validation and production of a new steerable punch for arthroscopic surgery.

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