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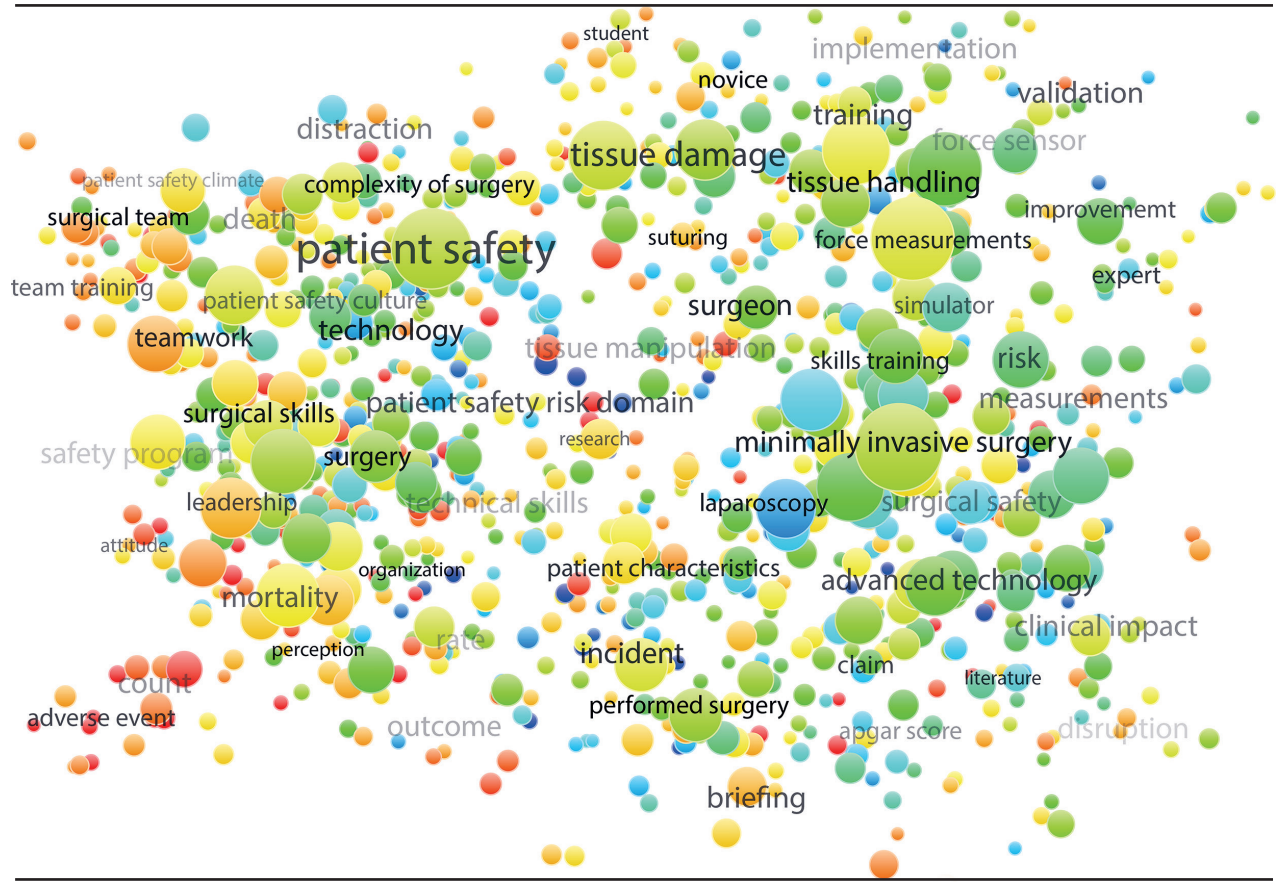


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TOWARDS SAFETY IN MINIMALLY INVASIVE SURGERY

patient safety, tissue handling and trainings aspects



Sharon P. Rodrigues

Towards safety in Minimally Invasive Surgery:

Patient safety, tissue handling and training aspects

Sharon Priscilla Rodrigues

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Patient safety, tissue handling and training aspects

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Towards Safety in Minimally Invasive Surgery:

Patient safety, tissue handling and training aspects

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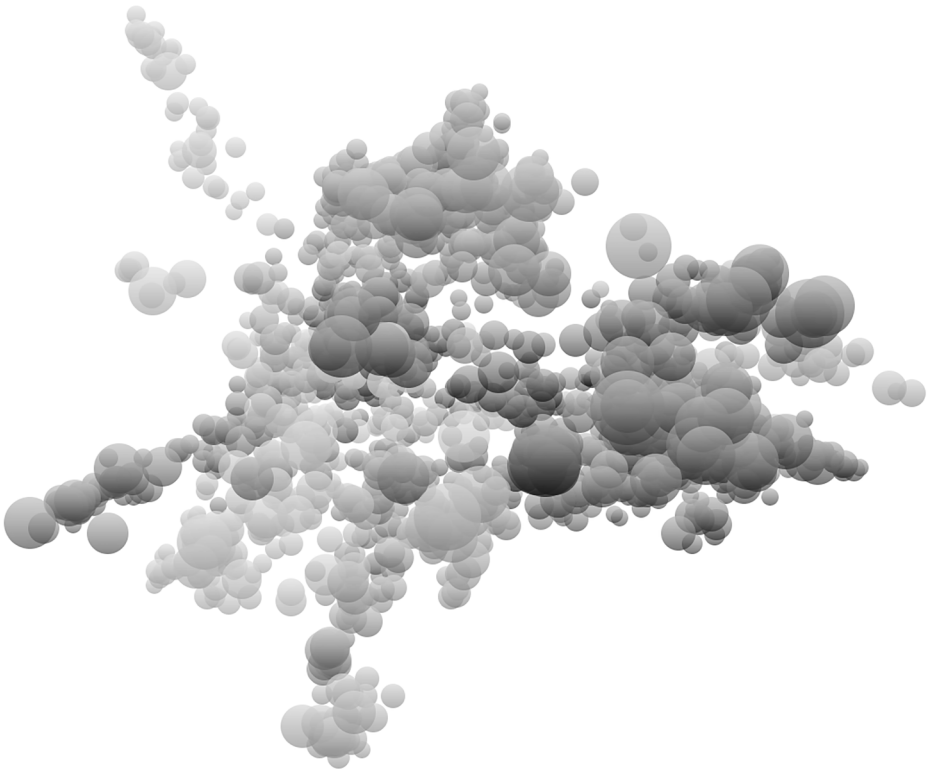
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CHAPTER 1

GENERAL INTRODUCTION



TO ERR IS HUMAN

Ever since the infamous Harvard Medical Practice study, and the report by the Institute of Medicine (IOM) *To Err Is Human: Building a Safer Health System* that followed it, patient safety has become the focus of improvement in healthcare. The IOM report stated that an estimated 44000 to 98000 patients in the US die every year due to medical errors.[1] In April 2007 the results of a Dutch national study assessing the number of hospital adverse events in the Netherlands were presented. This study showed that 5.7% of 1.3 million patients admitted in 2004 encounter an adverse event. In 40% of these patients the adverse event could probably have been prevented.[2] Subsequently in February 2009 the same research group published a study in the Dutch medical journal (NTvG), which showed that in the Netherlands 64% of all hospital related adverse events occur under the responsibility of the surgical specialisms. More than 40% of these adverse events could probably be prevented.[3] Furthermore, a systematic review[4] of eight studies including a total of 74,485 patients showed a median incidence of hospital adverse events of 9.2% with a median percentage of preventability of 43.5%. Of these hospital adverse events 39.6% were related to surgery.

Following the before mentioned Dutch reports, a national safety program has started in the Netherlands in the beginning of 2008: *Voorkom schade, werk veilig*. This program's objective was to reduce the amount of potentially preventable damage due to healthcare by 50% in five years. The report that followed in the end of 2013: *Monitor Zorggerelateerde Schade 2011/2012, Dossieronderzoek in Nederlandse ziekenhuizen*[5] showed a reduction of potentially preventable damage of 30% and a reduction of potentially preventable death of 37% compared to 2004. Not only newly implemented safety programs but also the extensive (media) attention for the issue, lay at the base of this improvement. However, the amount of potentially preventable damage due to medical technology (0.7%) had not reduced compared to previous reports. Minimally invasive surgery, mainly laparoscopy, was still named as one of the most common causes of potentially preventable damage due to medical technology. In general when it comes to damage due to medical technology human factors played a main role.

Patient safety in minimally invasive surgery

The report by the Dutch inspectorate of health care *Risico's minimaal invasieve chirurgie onderschat*[6], published in 2007, directed attention in the Netherlands towards minimally invasive surgery (MIS), especially in advanced procedures. The report emphasized that in addition to the known patient safety risks in the operating room, the technological complexity of MIS increases risks in patient safety. It stated that specific measures are

needed on hospital and national level in order to develop a formal quality system for laparoscopic procedures and thus enhance patient safety.

However, it is not clear what the requirements for such a formal quality system should be. A formal quality system should be verifiable in order to provide an objective form of quality control for hospital staff and government agencies. Therefore patient safety should be objectified. However *patient safety* is a complex, multidimensional concept and cannot be merged together in one measurable parameter. The WHO has long recognized the complexity of the concept patient safety. Since 2005 the WHO assigned a drafting group to develop an International Classification for Patient Safety (ICPS) to facilitate research and communication concerning patient safety. ICPS comprises ten high level classes which include around 600 concepts.[7] The WHO has also developed a patient safety research cycle to structure the research done on this topic. This research cycle describes five areas of patient safety research: (1) measuring harm, (2) understanding causes, (3) identifying solutions, (4) evaluating impact, and (5) translating evidence into safer care. This research cycle makes it possible to classify research. However, so far there is no large scale overview of available literature or different on going developments in patient safety literature available.

Current assessment of patient safety

Currently a comparison between hospitals is often made based on complication and mortality rates, usually normalized for the amount of performed procedures. This indicator can be used to set up a ranking, at which the lowest normalized complication rate represents the best patient safety. Based on these figures a department can benchmark their performance. However, these figures do not indicate which aspects of patient safety should be focused on for improvement. Furthermore, these figures are normalized for the number of performed procedures, but they do not take in account the severity of the procedure and patient characteristics that increase the complexity. Nor do they take in account the experience and skills of the surgical team.

Current patient safety research in surgery

In the operating theatre an area of patient safety research has been focusing on quantifying intra-operative interferences, i.e. surgical flow disruptions. Surgical flow disruptions have been defined as deviations from the natural progressions of an operation.[8] They have the potential to compromise patient safety during the surgery and could potentially lead to near misses.

For instance, Lynch et al[9], conducted an observational study of foot traffic in the OR, they recorded the nature of door movements by subspecialty, time of incision, reason and by personnel type. It was concluded that the rate of OR door movements was remarkably high regardless the surgical specialty. A total of 3071 door movements were recorded during 28 observed surgeries. The total number of door movements ranged from 13 to 316 per surgery (5 to 87 per recorded hour). Perioperative, surgical site infections (SSI) represent a major cause of morbidity and mortality. Frequent opening of the OR door is known to disrupt the airflow system and may compromise the sterile environment of the operating room. Lynch et al. showed that the number of door openings increased in direct proportion to the length of surgery, and that they have an exponential relationship to the number of persons in the OR. Besides their potential to compromise sterility in the OR, door openings and many persons in the OR can be distracting. Therefore, reducing door openings and the number of persons in the OR to an absolute minimum is a potential improvement in patient safety.

Wiegmann et al[8], studied surgical errors and their relationship to several surgical flow disruptions. They observed that disruptions in surgical flow due to problems in teamwork and communication accounted for the greatest percentage of these events (52%). Furthermore those problems are the only surgical flow disruptions with a significant relation to surgical errors. Other surgical flow disruptions they observed were external interruptions (17%), supervisory and training-related distractions (12%), equipment and technological problems (11%) and issues concerning resource access (8%).

Other research groups have also reported communication failures to be an important surgical flow disruptions related to surgical errors and adverse events.[8;10] In fact, communication failures have been reported to occur in approximately 30% of team exchanges. About a third of these communication failures resulted in visible effects that can influence patient safety. [11]

Verdaasdonk et al have studied technical problems, which are especially important in laparoscopy. They investigated the incidence of technical problems during laparoscopic procedures with a video-capturing system. In 87% (N = 26 out of 30) of the procedures, one or more incidents with technical equipment (N = 46) or instruments (N = 9) occurred.[12]

In summary, it appears that patient safety risk domains in the operating room (OR) can be divided into 5 main categories:

1. Social aspects (e.g. teamwork, communication) [13 14]
2. Technological aspects (e.g. instruments, equipment) [12]
3. External aspects (e.g. door movements, irrelevant conversations etc.) [9;15]
4. Functioning (e.g. skills, experience, knowledge) of the OR team members (e.g. surgeon, OR assistant, anaesthesiologist) [8]
5. Organizational aspects (schedules, workload, staffing etc.).

In an attempt to express patient safety in a single number the concept of the *APGAR score* has been used. The APGAR score is a technique to assess the condition of a newborn by the appraisal of five characteristics: respiration, muscle tonus, skin colour, hart rate and irritability. This simple technique was introduced to the world in the fifties by Virginia Apgar and is used at one and five minutes after birth to ensure consistent and systematic assessment of the newborn's condition. With this score a standardized cut off point for the initiation of resuscitation is provided. With the APGAR score Virginia Apgar captured a complex and elusive concept, e.g. the newborn's condition, and expressed it in a number, which could be evaluated and compared. Since the introduction of the APGAR score the quality of obstetrics all over the world changed and maternal and perinatal mortality drastically declined[16]. Atul Gawande and his research group have developed a Surgical Apgar Score (SAS) in which they try to capture the relationship between intraoperative care and surgical outcome[17-19]. SAS is also a ten point score in which a few patient characteristics are appraised. They conclude that the score can be effective in identifying patients at higher- and lower-than average likelihood of major complications. However, with this score they appraise intraoperative patient characteristics, which cannot be influenced or improved. Furthermore, this score focuses on only one patient safety risk domain, e.g. identifying high complication risk.

In the Netherlands research initiatives focusing on patient safety in surgery are rising. For instance a multidisciplinary checklist (SURPASS) is currently being implemented in several clinics in the Netherlands.[20;21] This checklist covers the entire surgical patient pathway of the general surgical patient. Other general checklists, used during a briefing procedure, have already shown to reduce adverse events and communication failures in the OR.[13;22] Technical checklists have shown to reduce the number of technical problems.[23] In literature debriefing has also been mentioned as a potential way to improve patient safety.

The aforementioned report by the Dutch inspectorate of health care *Risico's minimaal invasieve chirurgie onderschat*[6] emphasised that patient safety, especially in laparoscopic surgery, must be improved. Improvements should preferably be based on a systems approach rather than a person approach. However, evidence based research supporting requirements for patient safety improvement methods, is lacking and highly necessary. The current thesis explores aspects of patient safety in laparoscopic surgery based on the aforementioned main categories of risk domains. Since patient safety is such a comprehensive topic, this thesis shall focus on the basics of the main risk domains from a clinical point of view. The risk domains shall be examined in the operating room and an understanding of the impact of MIS on patient safety shall be obtained by comparing the different surgical techniques. However, the fourth risk domain (functioning of the OR team members, e.g. technical skills surgeon) is difficult to objectively assess in a clinical context. It has been shown that surgical skills in part can be objectively assessed in a non-clinical setting such as a skills laboratory. For example objective assessment of time to complete a task[24] and economy of movements[25] are have been shown to be valuable assets. These parameters however do not give sufficient insight one of the most important surgical skills when it comes to patient safety, namely tissue handling. Tissue handling is directly related to patient outcome measurements (e.g. blood loss, adverse events etc.). Therefore to examine the fourth risk domain the focus shall be on tissue handling in a non-clinical setting. Combining these patient safety aspects and risk domains, the main objectives of this thesis are:

- To analyse patient safety risk factors in minimally invasive surgery
- To determine differences in patient safety between minimally invasive surgery and conventional surgery.
- To find ways to train tissue handling skills in a non-clinical setting and thereby improve patient safety in minimally invasive surgery.

OUTLINE OF THE THESIS

The thesis is divided in two parts: part 1 explores patient safety in laparoscopic surgery and part 2 is devoted to the improvement of patient safety in laparoscopic surgery by examining training of tissue handling skills.

Part I Exploring Patient Safety

Patient safety is such a complex multifactorial concept about which has been widely published in recent years, that the amount of scientific literature available on this topic is overwhelming. This makes it difficult to have a good overview of the literature and to see the relations between the different developments that are going on. Therefore **chapter 2** focuses on obtaining a large scale overview of patient safety literature and developments in this topic by using a visualisation technique based on bibliometric data.

In recent years major changes occurred in the perception of patient safety. From a blame culture (the persons-approach) a switch has been made towards a systems-approach.[26] A number of important studies have suggested frameworks of factors that influence patient safety based on the systems-approach to quality and safety in surgery.[27-29] These frameworks were adapted for minimally invasive surgery (Figure 1). In **chapter 3** this framework is validated and the clinical relevance of different patient safety risk factors is examined. **Chapter 4** describes an observational study that measures what goes wrong in laparoscopic surgery based on the above-mentioned framework. The number of events in different risk domains were identified during laparoscopic surgery and compared to the number of events during general surgery.

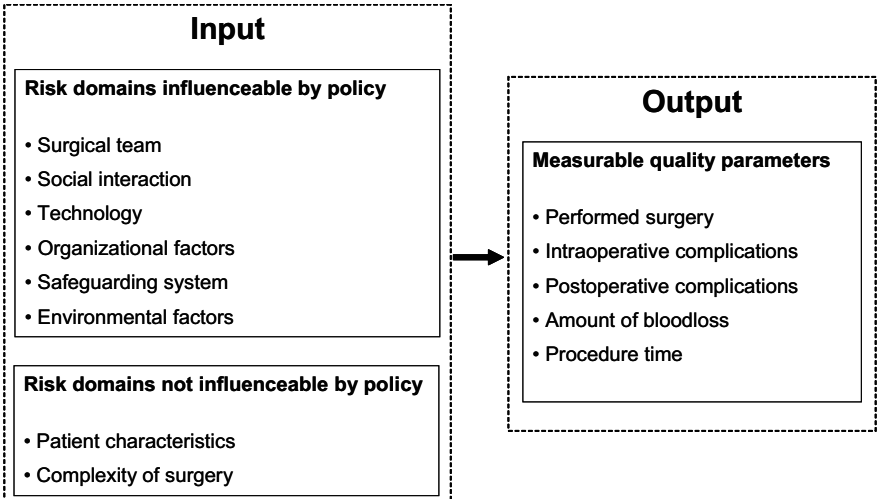


Figure 1. Framework of risk domains explaining patient safety in surgery according to a systems approach.

Part II Training tissue handling skills

The surgical skills of the surgeon, in particular tissue handling skills, are generally assessed as one of the most important and clinically relevant risk factors in surgery. In minimally invasive surgery additional obstacles have to be overcome compared to conventional surgery. Such as loss of depth perception and special orientation due to two dimensional (2-D) vision[30-32], perceived inversion of movement from the handle to the working end of the instrument "the fulcrum effect"[33-35], limited motion freedom and degrees of freedom (DOF's) due to the use of long rigid instruments[32;35] and loss of haptic feedback due to due to resistance inside the trocars[36] and the use of long laparoscopic instruments[37]. All these factors alter the laparoscopic surgeons' tissue handling abilities.

It has been well established that training of basic minimally invasive surgical skills should preferably be done in a non-clinical setting without exposing patients to risks.[38-40] Therefore part two of this thesis focuses on improving the surgeons' tissue handling skills in a laboratory setting.

To objectively assess tissue handling, interaction forces with tissue should be measured. Until now no objective measurement tools are (commercially) available. **Chapter 5** describes the development of a force measurement platform (Delft university of technology, Tim Horeman) that is able to measure these interaction forces and accompanying force parameters for the assessment of tissue handling skills. To assess the clinical impact of this newly developed force measurement platform, several studies were conducted in close collaboration with the Delft University of Technology. To get insight in the clinical relevance of the measured interaction forces an understanding of the amount of force needed to cause tissue damage is necessary. In **chapter 6** the force ranges causing tissue damage are determined in different tissue types. The clinical relevance of tissue handling in laparoscopic surgery is stressed in **chapter 7**, which describes the difference in applied forces during suturing in an open setting versus laparoscopic setting. This chapter examines intra-corporeal as well as extra-corporeal knot tying.

Using feedback on the used interaction forces during a training and the understanding of force limits that cause damage, a trainee can train him or herself on controlling the applied forces and thus tissue handling. In previous studies objective feedback on minimally invasive surgical skills (e.g. economy of movements) has successfully been used for assessment. This feedback is provided after completing a task, i.e. post processing. Providing feedback during the training of a task, i.e. real time feedback can provide the trainee the possibility to adjust their strategy immediately during the training, therefore

making the training more efficient. **Chapter 8** describes the development and validation of an application that provides real time feedback on the applied forces during training. The most efficient training method, i.e. post processing versus real time feedback, is examined in **chapter 9**.

In addition to dealing with diminished haptic feedback laparoscopic surgeons have to interpret a 2D image and translate it into a 3D operating field. Dividing the obstacles that a starting trainee has to overcome in several stages might benefit the trainees' proficiency gain curve. **Chapter 10** explores the effect of training a task in two stages first in an open box trainer without camera, followed by a classical closed box trainer with camera. The proficiency gain curves of this experimental training are compared to the standard training method.

Chapter 11 provides the general discussion of the findings and future perspectives for research. Finally a summary of this thesis is given.

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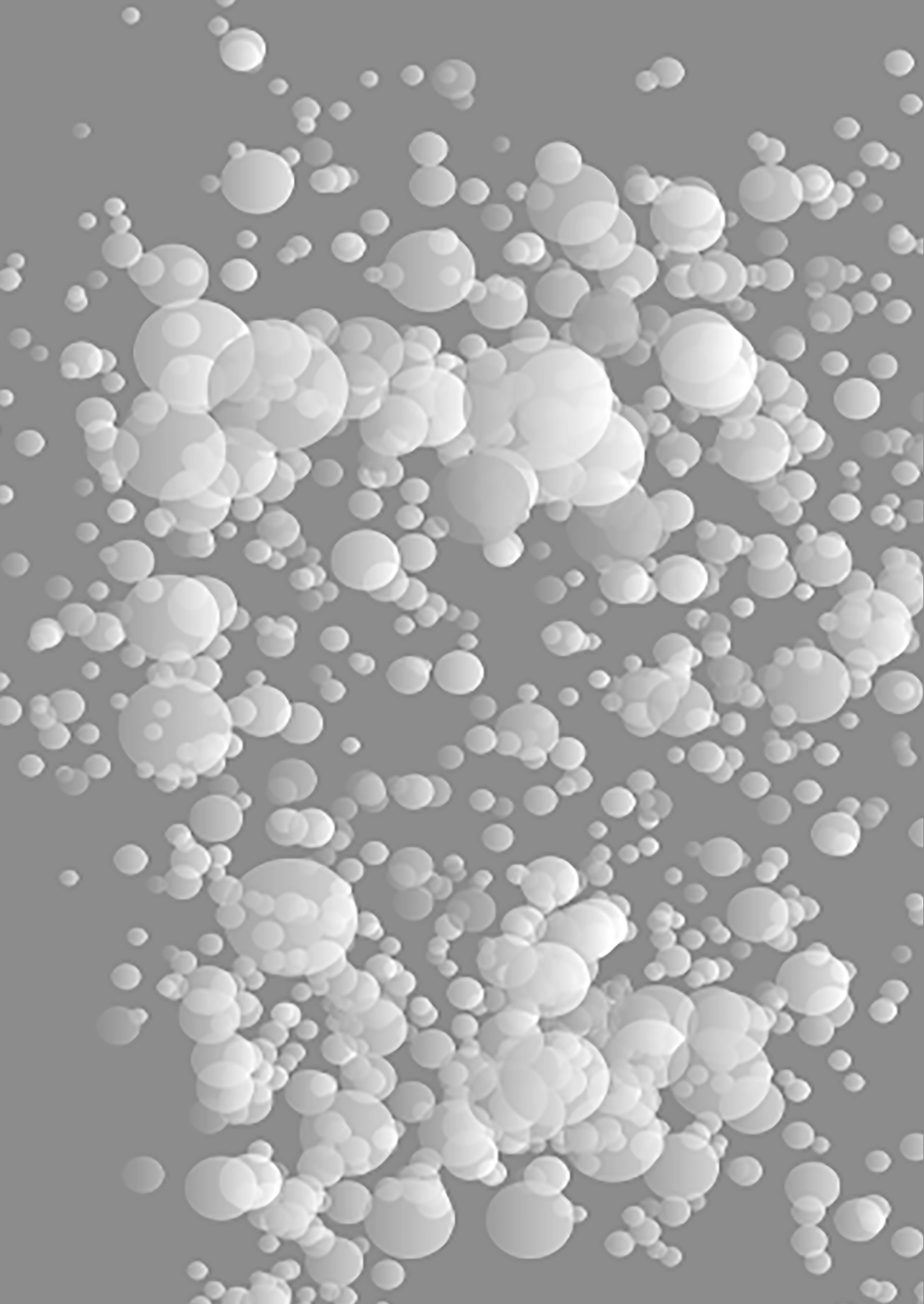
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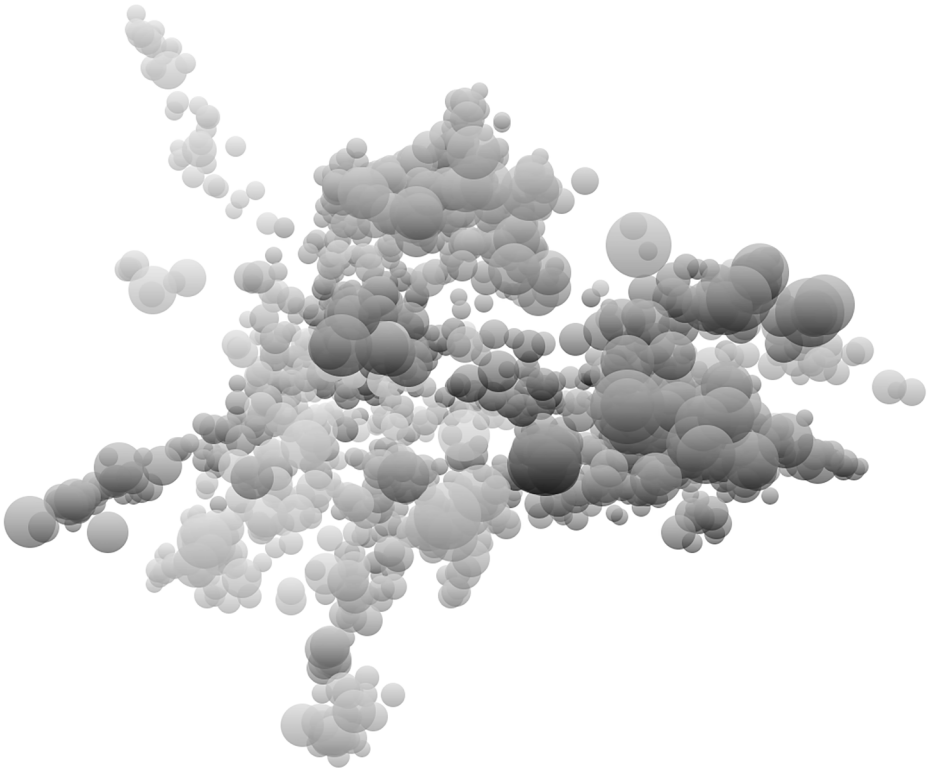
PART I

EXPLORING PATIENT SAFETY

S.P. Rodrigues, N.J. van Eck
L. Waltman, F.W. Jansen.
BMJ Open. 2014 Mar 13;4(3)

CHAPTER 2

MAPPING PATIENT SAFETY: A LARGE-SCALE LITERATURE REVIEW USING BIBLIOMETRIC VISUALISATION TECHNIQUES



ABSTRACT

Background

Even when attention is restricted to a single topic of interest, the amount of scientific literature available is often overwhelming, making it difficult for researchers to have a good overview of the literature and to see relations between different developments. Visualisation techniques based on bibliometric data are helpful in obtaining an overview of the literature on complex research topics, and have been applied here to the topic of patient safety.

Methods

Based on title words and citation relations, publications in the period 2000–2010 related to the topic of patient safety were identified in the Scopus bibliographic database. A visualisation of the most frequently cited patient safety publications was produced based on direct and indirect citation relations between these publications. In addition, terms were extracted from the titles and abstracts of patient safety publications, and a visualisation of the most important terms was created. Furthermore, the main patient safety related topics studied in the literature were identified using a technique for clustering publications and terms.

Results

A total of 8,480 publications were identified, of which the 1,462 most frequently cited ones were included in the visualisation. The publications were clustered into 19 clusters, which in turn were grouped into three main categories: (1) magnitude of patient safety problems (42% of all included publications); (2) patient safety risk factors (31% of all included publications); and (3) implementation of solutions (19% of all included publications). In the visualisation of patient safety related terms, five clusters were identified: (1) medication; (2) measuring harm; (3) patient safety culture; (4) the physician; and (5) training, education and communication. Both the analysis at the level of publications and the analysis at the level of terms indicate an increasing focus on risk factors.

Conclusion

A bibliometric visualisation approach makes it possible to analyse large amounts of literature. This approach can be very useful for improving one's understanding of a complex research topic such as patient safety and for suggesting new research directions

or alternative research priorities. In the case of patient safety research, the approach suggests that more research on implementing patient safety improvement initiatives might be needed.

Strengths and limitations of this study

- This study gives insight in the structure of patient safety literature by analysing a large amount of literature using bibliometric data.
- This approach can be very useful for improving one's understanding of a complex research topic such as patient safety.
- This method of analysing literature may help to suggest new research directions or alternative research priorities. For patient safety research in particular, this method suggests that research on implementing patient safety improvement initiatives receives relatively limited attention.
- However, this method does not give detailed insight in the content of specific publications.

INTRODUCTION

The use of internet has made large amounts of information easily available to researchers worldwide, while at the same time maintaining a structured overview of relevant information has become more and more challenging and time consuming. For many researchers in the biomedical field, PubMed is the search engine of preference. Although very useful for identifying individual publications relevant to one's information needs, search engines such as PubMed offer limited support in obtaining an overview of the structure of the literature on a particular research topic. Researchers need to go through large numbers of publications to find out which streams of literature can be distinguished, how different streams of literature relate to each other, and how literature has developed over time. Obtaining such an overview of the structure of the literature can be an extremely time-consuming process, especially in the case of complex research topics with publications appearing in multiple scientific fields.

An example of such a complex research topic is patient safety. Patient safety is a multi-factorial, multi-dimensional, and cross-disciplinary research topic which gained a lot of attention since the publication of the Institute of Medicine (IOM) report "To Err Is Human: Building a Safer Health System" in 1999. To describe patient safety in a framework, the World Health Organization (WHO) needed approximately 600 concepts (International Classification for Patient Safety).[1] The continuously growing publication rate concerning patient safety and its complex character make it difficult to obtain a comprehensive overview of the patient safety literature. Conventional literature search methods result in an overwhelming amount of patient safety literature, which cannot possibly be assessed manually. For example, an attempt to define "patient safety" with a string of MeSH terms (safety OR "patient safety" OR "Equipment Safety" OR "equipment safety"[mesh] OR "incident prevention" OR "adverse event" OR "adverse events" OR "Accident Prevention" OR "accident prevention"[mesh] OR "safety culture" OR "Medical Errors" OR "medical errors"[mesh] OR "medical error" OR near misses) results in 460,533 publications. Entering "patient safety" alone in PubMed gives 17,556 hits ranging from adverse drug reactions to infection prevention through hand hygiene to safety management systems.

Review articles are available on specific patient safety topics, for example reviews on patient safety in specific specialisms (e.g., anaesthesia, paediatrics, etc.) and reviews on surgical safety (e.g., checklists, communication and teamwork in the operating theatre, etc.). However, to our knowledge, there are no review articles that give a high level view of patient safety. This is due to the multi-factorial, multi-dimensional, and cross-

disciplinary character of the topic. Therefore, insight into the arrangement of patient safety literature is needed to give structure for future (literature) research in this field. Because the conventional approach does not give sufficient insight, an alternative approach is needed. The current study describes an alternative approach of searching, structuring and visualizing large amounts of literature based on bibliographic data and uses this approach to analyse the literature on patient safety.

METHODS

The methods employed in this study originate from the fields of bibliometrics, text mining and information visualisation. From the bibliometrics literature the idea of using citation relations to establish links between publications is borrowed. Text mining literature discusses natural language processing techniques that are used to extract terms from publications. The mapping and visualisation techniques used in this study build on extensive literature in the fields of bibliometrics and information visualisation[2].

First, the data used in this study is discussed. Then the method for delineating patient safety literature as well as the methods for analysing this literature at the level of both publications and terms are discussed.

Data

The current study uses data from the Scopus database. Scopus is a bibliographic database produced by Elsevier that indexes almost 20,000 journals in all scientific disciplines. All journals indexed by PubMed are also covered by Scopus. Scopus is used instead of PubMed because Scopus provides data on the references publications give to other publications. Reference data, which is not available in PubMed, is a crucial element in our approach. Direct access to the raw Scopus data is used (without the need to use the Scopus web interface at www.scopus.com); therefore large quantities of reference data are easily processed.

Delineation of the patient safety literature

Due to the complex nature of the topic "patient safety", delineating the literature on this topic is far from straightforward. The WHO defines patient safety as "the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum", and has used around 600 concepts to describe this wide-ranging definition in more detail.[1] Delineating patient safety literature using criteria based on keywords or MeSH terms did not yield satisfactory results, therefore a more refined two-step approach is

taken.[3;4] First, all publications with "patient safety" in their title are selected, as well as all publications from the following journals with patient safety as their main topic: Joint Commission Journal on Quality and Patient Safety, Joint Commission Perspectives on Patient Safety, Journal of Patient Safety, and Quality and Safety in Health Care. Many relevant publications are still missing after this step, for instance because they were published in general medical journals and do not have "patient safety" in their title. Therefore a second step is needed, in which all publications with at least four citations from or references to publications selected in the first step are identified. Together these two steps yield 8,480 publications in the period 2000–2010, which is the period of analysis. In a random sample of 100 of the 8,480 publications, four publications were not related to patient safety and eight publications were only weakly related.

Analysis at the publication level

To obtain an overview of patient safety literature at publication level, we first assess the relatedness of publications. This is done based on direct and indirect citation relations between publications. Two publications have a direct citation relation if one publication cites the other, and they have an indirect citation relation if they both cite the same publication ('bibliographic coupling'[5]) or are both cited by the same publication ('co-citation'[6]). Bibliographic coupling relations and co-citation relations have equal weight. For each publication, an artificial citation from the publication to itself is created. In this way, a direct citation relation between two publications counts as both a bibliographic coupling relation and a co-citation relation. After assessing the relatedness of publications, a clustering technique is used to identify clusters of closely related publications, following the methodology documented in an earlier paper.[4] This provides a breakdown of the literature into a number of research areas or topics. It is noted that 693 publications cannot be assigned to a cluster. These are publications that have no or almost no citation relations with other publications.

A more fine-grained overview of the literature can be obtained using a publication map. A publication map provides a representation of the literature in a two-dimensional space. Publications are located in the map in such a way that the distance between publications gives an indication of their relatedness. The shorter the distance between publications, the stronger their relation. A publication map is constructed of the 1,462 most frequently cited publications within the delineation of the patient safety literature. Each of these publications has been cited at least 20 times. The locations of the publications in the map are determined using the VOS ('visualisation of similarities') mapping technique[7], and a computer program called VOSviewer (www.vosviewer.com)[8]

is used to visualize the map. This program also offers extensive support for exploring the map in an interactive fashion.

In addition to a publication map, a publication cluster map is constructed. Instead of individual publications, this map shows the above-mentioned clusters of publications, thereby providing a more high-level overview of the patient safety literature.

Analysis at the term level

To analyse patient safety literature at term level, we begin by extracting terms from titles and abstracts of publications. This involves three steps. First, a part-of-speech tagger[9] is used to identify nouns and adjectives in the titles and abstracts of publications. Second, nouns and adjectives that belong together are combined into noun phrases. Plural noun phrases are converted into singular ones. In the third step, the 1,000 most relevant noun phrases are selected as terms. The relevance of a noun phrase is assessed based on the degree to which the noun phrase clusters together with other noun phrases.[10] Only noun phrases that occur in at least 15 publications are considered.

The relatedness of terms is determined by counting the number of times terms occur together in the titles and abstracts of publications. The larger the number of co-occurrences of two terms, the stronger their relation. Based on the relatedness of terms, terms are grouped together into clusters and a term map is constructed. A term map works in a similar way as a publication map. Terms are located in a two-dimensional space, and the distance between terms serves as an indication of their relatedness.

Analysis of developments over time

To identify changes in the interest in research topics over time, publication rates are calculated for two time periods, 2000–2005 and 2006–2010. For each cluster of publications and each time period, the number of publications as a percentage of the total number of publications in the time period is determined. Next, for each cluster, a ratio is calculated by dividing the percentage of publications in the period 2006–2010 by the percentage of publications in the period 2000–2005. A ratio above one indicates a relative increase in publications over time, while a ratio below one indicates a relative decrease in publications. To identify changes over time in the terms that are used in the patient safety literature, the mean publication year is calculated for each term. A term's mean publication year indicates whether a term is used more in earlier years or more in later years within the period of analysis.

Table 1. Clusters of publications.

Cluster	Description		Number of publications			Per cent of total		Ratio
			Total	2000–2005	2006–2010			
0	Publications not assigned to a cluster		693	-	-	-	-	-
1	Quality improvement	Patient safety on an organizational/ national level. Including studies concerning implementation of large quality improvement projects.	608	301	307	9.9%	6.5%	0.7
2	Quality improvement	Patient safety on an organizational/ national level. Including studies concerning implementation of large quality improvement projects.	564	203	361	6.7%	7.6%	1.1
3	Incidence of adverse events	Incident reporting and incident prevention. Including articles following the IOM report "to err is human".	844	419	425	13.7%	9.0%	0.7
4	Medication error	Incidence of medication and dosing errors; computerized prescription and smart infusion pumps.	915	340	575	11.1%	12.1%	1.1
5	Training, simulation and communication	Human factors engineering and crew resource management.	913	241	672	7.9%	14.2%	1.8
6	Adverse drug events	Incidence of adverse drug events and drug complications.	735	225	510	7.4%	10.8%	1.5
7	IT support systems	The role of IT support systems in error prevention.	328	155	173	5.1%	3.7%	0.7
8	Culture	Patient safety culture and organizational climate.	410	165	245	5.4%	5.2%	1.0
9	Infection control	Infection control and prevention.	522	153	369	5.0%	7.8%	1.6
10	Medical errors and liability	Medical errors and liability; ethics and disclosure.	283	127	156	4.2%	3.3%	0.8

The ratio of the publication rates for each cluster in the periods 2006–2010 and 2000–2005 is reported in the rightmost column. A ratio above one indicates a relative increase in publications, while a ratio below one indicates a relative decrease in publications. IOM, Institute of Medicine; NICE, National Institute for Health and Care Excellence.

Table 1. Clusters of publications.

Cluster	Description		Number of publications			Per cent of total		Ratio
			Total	2000–2005	2006–2010			
11	Fatigue and work hours	The influence of fatigue; work hours and burn out on patient safety.	224	79	145	2.6%	3.1%	1.2
12	Guidelines (implementation)	Development and implementation of guidelines to improve patient safety. Including NICE guidelines.	200	103	97	3.4%	2.0%	0.6
13	Shared treatment decision making	Including patient preference studies and doctor patient communication.	230	132	98	4.3%	2.1%	0.5
14	Diagnostic errors	Diagnostic errors and clinical decision-making.	152	59	93	1.9%	2.0%	1.0
15	Nursing	Including nurse staffing; job satisfaction; experience and education.	230	104	126	3.4%	2.7%	0.8
16	Laboratory medicine	Including errors and adverse events in transfusion medicine; pathology and clinical laboratory medicine.	181	67	114	2.2%	2.4%	1.1
17	Quantity and quality	Volume as a marker for quality and patient safety in high volume hospitals.	180	74	106	2.4%	2.2%	0.9
18	Anaesthesia	Patient safety and anaesthesia related topics.	131	69	62	2.3%	1.3%	0.6
19	Medical emergency teams	Including criteria for alerting medical emergency teams, early warning, identifying the critically ill patient end evaluation of medical emergency teams.	137	35	102	1.1%	2.2%	1.9
	TOTAL		8480	3051	4736	100%	100%	1.0

The ratio of the publication rates for each cluster in the periods 2006–2010 and 2000–2005 is reported in the rightmost column. A ratio above one indicates a relative increase in publications, while a ratio below one indicates a relative decrease in publications. IOM, Institute of Medicine; NICE, National Institute for Health and Care Excellence.

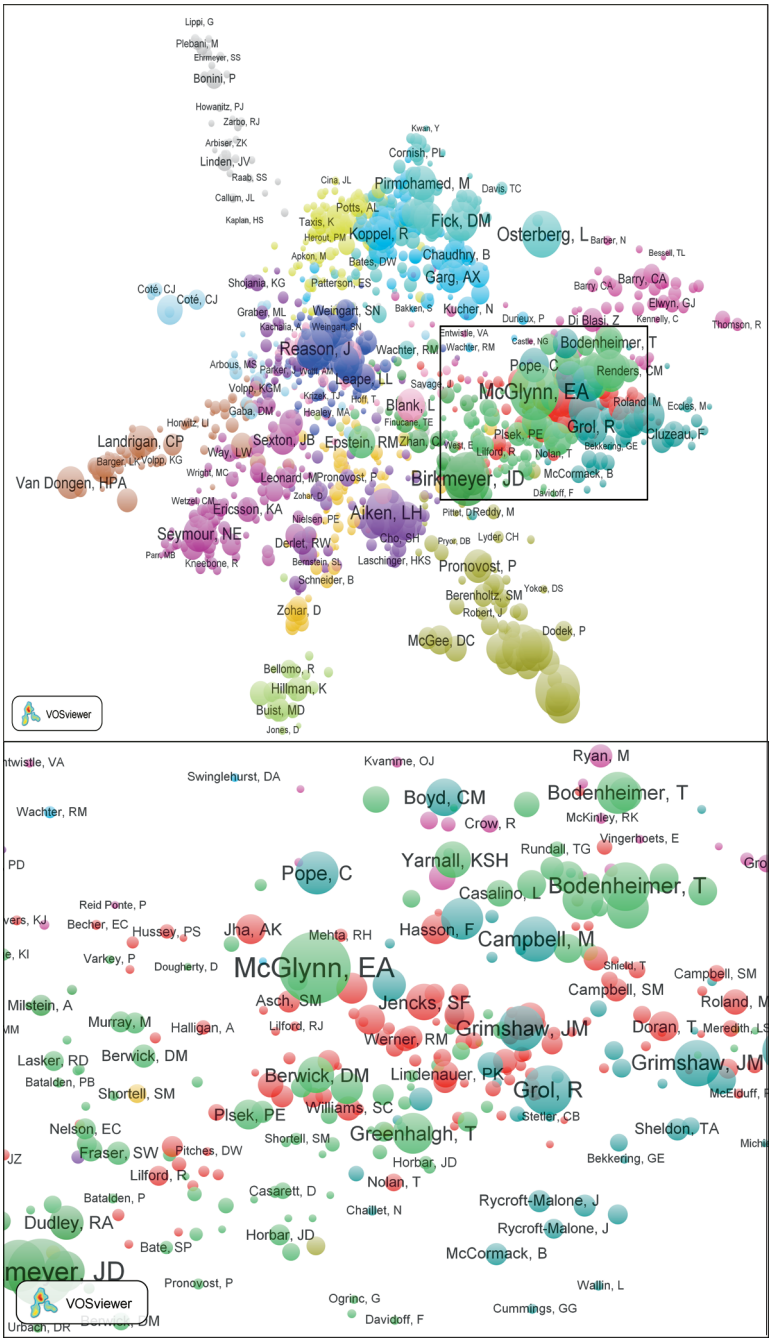


Figure 1 (A) Publication map based on citation relations between frequently cited publications (N=1462). The map shows groups of publications that have been clustered together. Every cluster is shown in a different colour. An interactive version of the map is available online at http://www.vosviewer.com/maps/patient_safety/publications/. (B) Zooming in on clusters 1 (green) and 2 (red), the two clusters that are more intermingled than the other clusters.

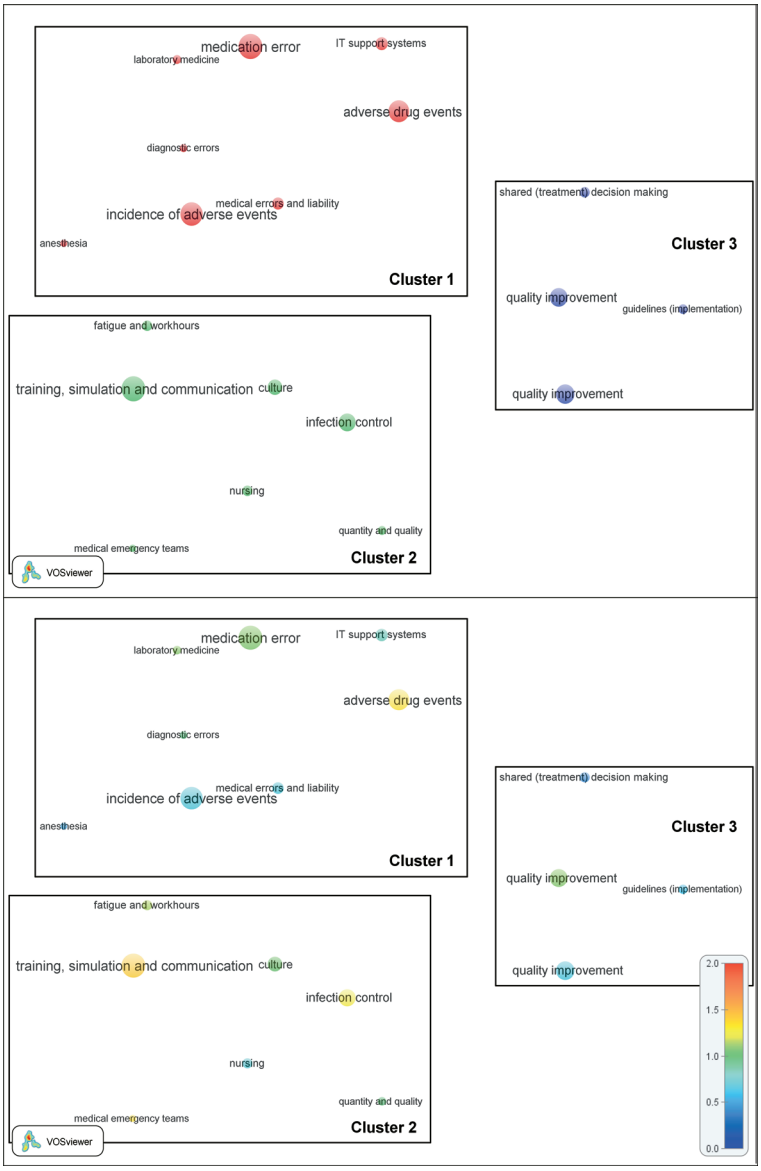


Figure 2 (A) Publication cluster map with colours indicating three main categories of patient safety research. Category 1: research that identifies the magnitude of patient safety problems by measuring and reporting the amount of problems. Category 2: research that focuses on identifying and understanding patient safety risk factors. Category 3: research that focuses on the implementation of solutions. http://www.vosviewer.com/maps/patient_safety/clusters1/. (B) Publication cluster map with colours indicating the trend in a cluster's publication rate. For each cluster, a ratio was calculated by dividing the percentage of publications in the period 2006–2010 by the percentage of publications in the period 2000–2005. A ratio above one indicates a relative increase in publications over time, while a ratio below one indicates a relative decrease in publications. Increases in publication rates can be seen mostly in category 2 (patient safety risk factors). In categories 1 and 3, publication rates tend to decline or are stable. http://www.vosviewer.com/maps/patient_safety/clusters2/.

RESULTS

Publication map

In recapitulation, a total of 8,480 publications were identified of which the 1,462 most frequently cited publications were used to create a publication map (Figure 1a). Interactive versions of all produced maps are available online. The URLs of the interactive maps are provided in the figure captions. Please note that to access the online maps Java needs to be installed on your computer. The publication map illustrates the citation relations between highly cited publications and shows how publications cluster together. The clustering is illustrated in Figure 1 by the use of different colours. The figure generally shows a clear separation of the different colours. The 19 clusters identified by our clustering technique were examined manually to assign an appropriate label to each of them. The labels and descriptions of the content of the clusters are given in Table 1. Clusters 1 and 2 were given the same label because they seem to represent similar types of publications. In the publication map, these two clusters are more intermingled than the others, which is especially well visible when zooming in on the area of the two clusters (Figure 1B).

Publication cluster map

The publication cluster map extracted from the publication map gives a more schematic overview of the 19 clusters of publications (Figure 2a). Using our clustering technique, the 19 clusters can be grouped into three main categories, each of which is indicated by a different colour. Each category represent a field of patient safety research: category 1 represents research that identifies the magnitude of patient safety problems by measuring and reporting the amount of problems, category 2 represents research that focuses on identifying and understanding patient safety risk factors, and category 3 represents research that focuses on the implementation of solutions mostly on an organizational or national level. Category 1 contains the largest number of publications (N = 3,569), representing 42% of all publications included in the analysis, followed by category 2 (N = 2,616), which represents 31% of all publications. Category 3 contains the smallest number of publications (N = 1,602), representing a mere 19% of the total number of publications. Figure 2b shows an increase in publication rates mostly in category 2, the category dealing with research on patient safety risk factors. In both category 1 and category 3, publication rates tend to decline or are stable, with the exception of the cluster on adverse drug events in category 1. The publication rate of this cluster has increased considerably over time (ratio of 1.5). Publication rates and ratios per cluster

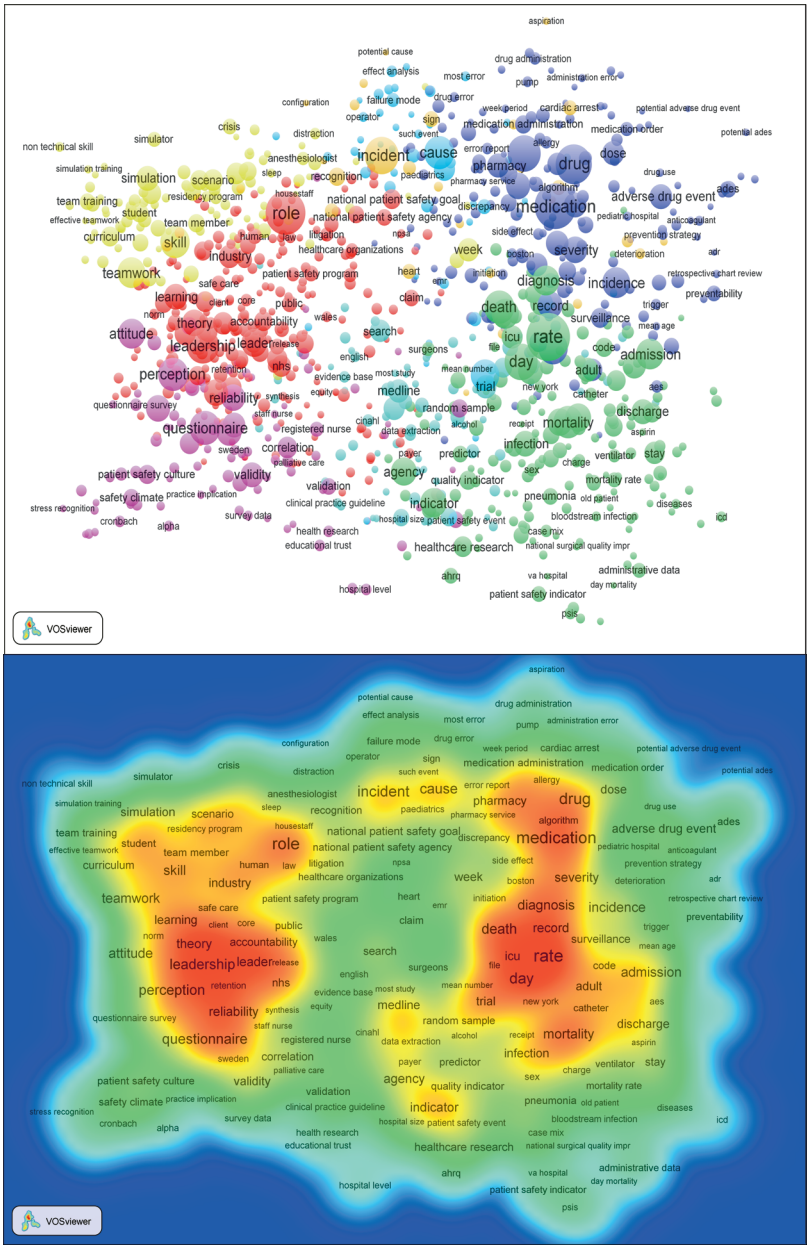
are displayed in Table 1. Notice in Table 1 that the number of publications in the second time period, 2006–2010, is about 55% larger than the number of publications in the first time period, 2000–2005, despite the fact that the first time period covers six years while the second time period covers only five years. Looking at the Scopus database as a whole, the increase in the number of publications between the period 2000–2005 and the period 2006–2010 is less than 20%, so considerably lower than the 55% increase that we find for the patient safety literature.

Term map

The term map (Figure 3a) shows five clusters of terms that are used in patient safety literature. These clusters contain terms concerning: (1) medication; (2) measuring harm; (3) patient safety culture; (4) the physician; and (5) training, education and communication. Figure 3b provides a so-called density visualisation (produced by the VOSviewer software) of the term map. The density visualisation indicates that terms grossly cluster together in two groups, dividing the map in a left and a right side. Terms on the left side of the map tend to be related to patient safety risk factors. In the publication cluster map, these terms are mostly used in category 2. Terms on the right side of the map mostly relate to measurable patient safety outcome parameters. In the publication cluster map, these terms can be found mainly in category 1, the category concerned with studying the magnitude of patient safety problems. Category 3 in the publication cluster map, which is the category that deals with the implementation of solutions, cannot be identified as a separate group of terms in the term map. When the term map is searched for terms relating to category 3, these terms are found mostly in the middle bottom part of the map. In the density visualisation (Figure 3b), this area slightly lights up.

Nevertheless, comparing the publication cluster map and the term map, it seems that research on the implementation of solutions does not have a unique vocabulary of terms that allows it to be distinguished from other types of patient safety research.

Figure 4 shows the same term map as Figure 3, but this time the colour of a term indicates the term's average publication year. Although more scattered than in the publication cluster map (Figure 2b), Figure 4 shows a similar increasing trend in publications related to patient safety risk factors, as the corresponding terms are mostly used in more recent years.



A

B

Figure 3 (A) Term map with colours indicating five clusters of terms: (1) medication (purple); (2) measuring harm (green); (3) patient safety culture (pink); (4) the physician (red) and (5) training, education and communication (yellow). An interactive version of the map is available at http://www.vosviewer.com/maps/patient_safety/terms1/. (B) Density visualisation of the term map. Terms cluster together in two groups, dividing the map in a left and a right side. Terms on the left side tend to be related to patient safety risk factors, while terms on the right side mostly relate to measurable patient safety outcome parameters. An interactive version of the map is available at http://www.vosviewer.com/maps/patient_safety/terms1/.

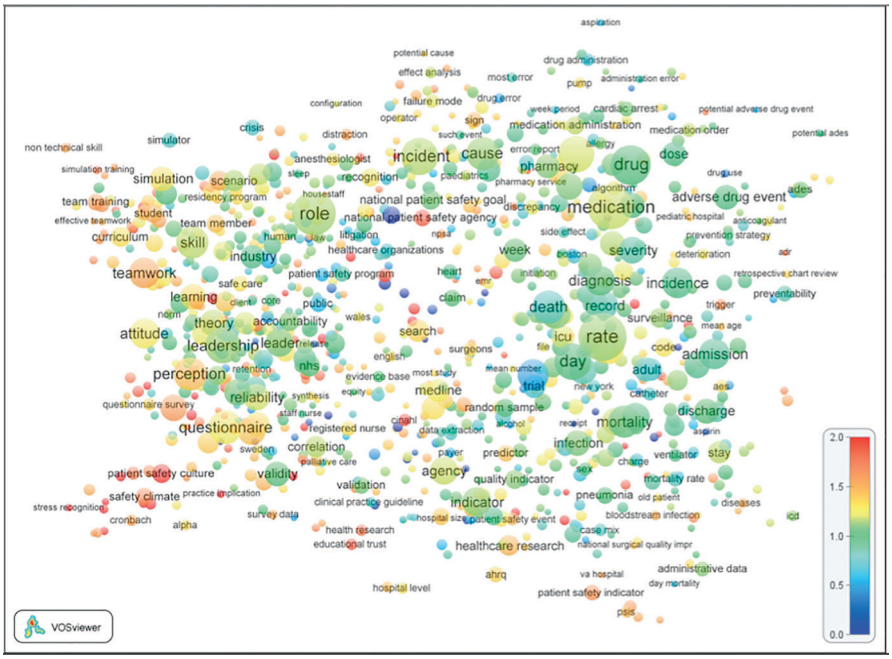


Figure 4 Term map with colours indicating the mean publication year in which a term was used. Terms that are used more towards 2010 are shown in red, while terms that are used more towards 2000 are shown in blue. An increasing trend in publications related to patient safety risk factors can be observed, as the corresponding terms are mostly used in recent years. An interactive version of the map is available at http://www.vosviewer.com/maps/patient_safety/terms2/.

DISCUSSION

When conventional literature research using criteria based on keywords or MeSH terms is unsuccessful due to the complexity and massiveness of the researched topic, analysis based on bibliometric data can give insight into the structure of a research field. There is an extensive body of research on information retrieval techniques that aim to simplify literature search in the biomedical sciences.[11;12] Although our work can be considered related to this line of research, our focus is not so much on retrieving individual scientific publications but more on obtaining a broad overview of the structure of the literature on a particular research topic.[13-16] Our approach seems especially useful when dealing with complex topics that cannot easily be represented by one or a few keywords or MeSH terms.

The present dataset was validated with a random sample of 100 of the 8,480 publications, of which only 4% was not related to patient safety, indicating a good representation of the field. With the clustering process 693 publications could not be assigned to a cluster because they have no or almost no citation relations with other publications. For this

reason these publications are presumed to be of less importance to the field of patient safety. Excluding these publications from the rest of the analysis does not influence the results because only the most highly cited publications are used to create the publication map. It should be noted, however, that for some publications in the Scopus database no data on the references given to other publications is available. Publications for which this is the case are also more likely to be among the 693 publications excluded from the analysis.

The publication cluster map shows that there are three main categories of patient safety literature. The publication rates of the categories are not equally divided. Research into the magnitude of the problem (category 1) is more highly represented and research into implementing solutions (category 3) is less represented. Research focusing on identifying and understanding patient safety risk factors (category 2) is also less represented than research on the magnitude of the problem, although there is an increase in publication rates in this category and therefore further growth can be expected. It is of concern though that a decline in publication rate is observed in the category "implementing solutions", which is a category that already has a relatively small number of publications. This may be considered especially problematic given the fact that improvement in patient safety can only be established by actual implementation of solutions, not only by identifying and understanding flaws in the system.

The three main categories can be divided into 19 clusters each representing an area of patient safety research. The WHO patient safety research cycle describes five areas of patient safety research: 1 measuring harm, 2 understanding causes, 3 identifying solutions, 4 evaluating impact, and 5 translating evidence into safer care.[17] These five areas can be matched quite well to the categories found in the publication cluster map, thereby supporting the clinical validity of the map. Category 1 contains research into area 1 (measuring harm), category 2 contains research into areas 2 and 3 (understanding causes and identifying solutions), and category 3 contains research into areas 4 and 5 (evaluating impact and translating evidence into safer care).

The term map shows a gross division of terms into two sides, outcome parameters (right) and risk factors (left). This resembles a previously described framework of risk domains explaining patient safety in surgery according to a systems approach. This framework depicts patient safety as a balance between risk factors and measurable outcome parameters.[18]

A number of limitations of our analysis need to be mentioned. First, the results of the analysis depend on the approach taken to delineate the patient safety literature. The

use of alternative criteria for identifying patient safety publications might have led to a different view on patient safety literature. Various technical limitations need to be kept in mind as well. The publication map relies on citation relations between publications. Citations are given for a multitude of reasons. Some citations reflect a strong topical relatedness between the citing and the cited publication, but this is not the case for all citations, and we have not been able to distinguish between these different types of citations. In case of the term map, terms may sometimes be ambiguous due to problems with synonyms and homonyms. Furthermore, both the publication and the term map are restricted to a two-dimensional space, which means that they may not always be able to represent the relatedness of publications or terms in the most accurate way. The clusters of publications or terms that were created have the restriction that each publication or term can belong to one cluster only, making it difficult to properly represent publications and terms that relate to multiple topics.

CONCLUSION

In conclusion, large amounts of literature can be analysed using bibliometric data. Visualizing this data using tools such as VOSviewer makes it possible to obtain a broad overview of the structure of the literature on a particular topic of interest. This approach can be very useful for improving one's understanding of a complex research topic such as patient safety. Other complex multidimensional research fields (e.g., technology assessment) can be analysed in a similar way. This method of analysing literature may help to suggest new research directions or alternative research priorities. For patient safety research in particular, this method suggests that research on implementing patient safety improvement initiatives receives relatively limited attention.

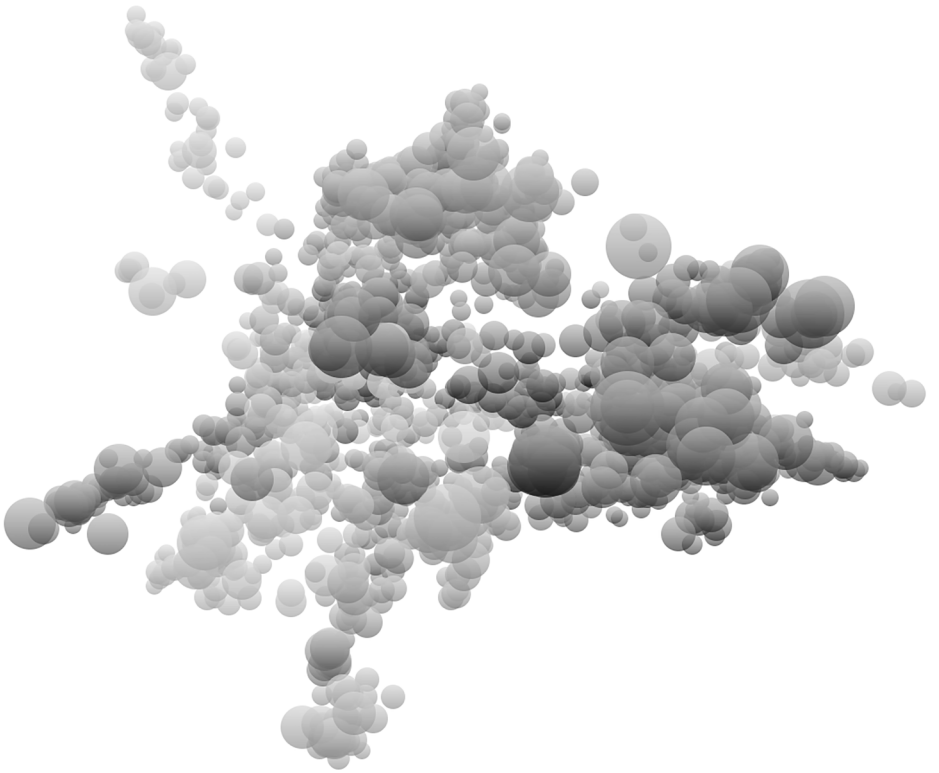
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CHAPTER 3

PATIENT SAFETY RISK FACTORS IN MIS: A VALIDATION STUDY



ABSTRACT

Background

To adapt and validate a patient safety framework for MIS as a first step in understanding the clinical relevance of various PS risk factors in MIS.

Methods

Eight patient safety risk factor domains were identified using frameworks from a systems approach to patient safety. A questionnaire was drafted containing 34 questions. The questionnaire was critically reviewed on clinical relevance and completeness by three experts in the field of patient safety. The questionnaire was distributed among known patient safety experts.

Results

A total of 41 questionnaires were distributed and the response rate was 71%. The intraclass correlation coefficient was 0.42, moderate agreement. The order of influence on patient safety from high to low based on the mean scores of risk domains was: experience surgeon, technical skills surgeon, technology, complications, social interaction, leadership surgeon, blood loss, length of surgery, surgical team, fallibility, patient, safety measures and environment.

Conclusion

This study is an initiative to give insight into clinical relevance of the maze of PS risk factors in MIS. All investigated risk domains were considered to be of noticeable influence on PS. Nevertheless, it is possible to prioritize various risk domains. In fact, experience and technical skills of the surgeon, technology and complications are rated as the most important risk factors, closely followed by social interaction and leadership of the surgeon. Patient, safety measures and environment are rated as the least important risk factors.

INTRODUCTION

Over the past years, society has become more quality driven. Also, in health care, the demand for the highest quality possible has become an important center of attention, especially in the operating room. This urgent request for high quality has made patient safety (PS), as a quality parameter, a very important research topic. Research concerning "patient safety" has expended explosively since 1999 and "patient safety" in the "operating room" has been increasing since 2004. Research concerning "patient safety" combined with "laparoscopy" only recently started to increase, whereas research on "laparoscopy" alone has been increasing fairly stable. All the while, research with the keyword "operating room" as well as the total number of yearly publications has been stable for years.

Recently many PS issues considering minimally invasive surgery (MIS), especially laparoscopy, have been brought to our attention. In The Netherlands, PS issues about MIS (especially laparoscopy) brought to the attention by the Dutch Inspectorate of Healthcare even led to a discussion in the Dutch parliament about the desirability of MIS.[1] Despite the great amount of research about PS and laparoscopy in general, only a few publications concern both items.

In general patient safety is a complex multidimensional concept and the clinical relevance of its various dimensions is not clearly understood. To comprehend the clinical relevance of various PS risk factors in surgery the degree to which a patient is exposed to all of these risk factors during surgery should be studied. Yet studies that try to measure risk factors during surgery usually focus on specific parts of the multidimensional concept. Nonetheless, it has been widely accepted that a wide range of factors influence PS in surgery and a number of important studies[2-5] have addressed this by developing frameworks according to the systems approach to quality and safety in surgery. The aim of this study is to adapt and validate these frameworks for MIS as a first step in understanding the clinical relevance of various PS risk factors in MIS.

METHODS

Existing frameworks that were developed according to a systems approach to quality and safety in surgery[2-5] were adapted for MIS. The adapted framework consisted of the following risk domains:

1. Surgeon: risk factors regarding functioning of the surgeon,
2. Surgical team: risk factors regarding functioning of the scrub or circulating nurse,

3. Technology: risk factors regarding the availability and functioning of technology,
4. Social interaction: risk factors regarding teamwork and communication
5. Environment: risk factors that potentially cause distraction or disruptions of the surgical process,
6. Patient: patient related risk factors,
7. Fallibility: risk factors regarding factors that influence the fallibility of the surgeon,
8. Safety measures: items regarding (compliance of) safety protocols,
9. Result: items regarding the result of the procedure.

For each risk domain risk factors were defined and incorporated in a questionnaire (Table 1). At the end of the questionnaire there was free space for comments on missing risk factors or other issues. The questionnaire was critically reviewed on clinical relevance and completeness by three independent experts, who did not participate in the development of the questionnaire: i.e. the president of the commission on patient safety of the Dutch society of obstetrics and gynaecology, the president of the commission on patient safety of the association of surgeons of the Netherlands who is also a pioneer in MIS and the president of the Dutch society of endoscopic surgery who is also a gynaecologist with a research line in patient safety in MIS. This led to a minor addition to the questionnaire.

Next a sample of international gynaecological PS experts was asked to rate all PS risk factors. A PS expert was defined as a gynaecologist specialized in laparoscopic surgery that had either published on PS related topics and/or is actively involved in a commission on PS. The questionnaire was distributed internationally both directly among PS experts during a gynaecological MIS conference (N = 12) and electronically by email (N = 29). The Risk factors were rated according to their potential impact on PS in MIS on a 6 centimetre Visual Analogue Scale (VAS) with at the endpoints “no impact” and “huge impact”. Because of technological restrictions the electronic version of the VAS was converted to a 13 point scale with, similar to the VAS, at the endpoint 0 “no impact” and at the endpoint 12 “huge impact” and every intermediate point corresponded with half a centimetre on the VAS. For conventional reasons and ease of interpretation, the both scales were converted to a 7 point scale after all data was collected. The mean scores of the VAS and 13 point scale were first analysed separately showing similar results for both rating scales. As such it was decided to combine the two rating scales to report the results of this study.

Data analysis

All data was analysed with SPSS 16.0 software package (SPSS, Chicago, IL, USA).

An overall inter rater agreement was determined for the complete questionnaire with the intraclass correlation coefficient (ICC). The ICC is exactly identical to the weighted kappa with quadratic weights[6], and is an appropriate method to determine an inter rater agreement between multiple raters of multiple questions with a large rating scale as is the case in the current study. The ICC values were interpreted according to Landis and Koch's[7] guidelines for the interpretation of kappa (kappa values < 0 poor; 0 to 0.2 slight, 0.2 to 0.4 fair, 0.4 to 0.6 moderate 0.6 to 0.8 substantial and > 0.8 almost perfect agreement).

For each PS risk factor domain (containing a number of separate risk factors) internal consistency was determined using Cronbach's alpha. If internal consistency of a PS risk factor domain was accepted (Cronbach's alpha > 0.7)[8] further analysis was performed for that domain as a whole. If internal consistency was insufficient (Cronbach's alpha < 0.7), further analysis was performed for every risk factor separately. Mean scores and 95% confidence intervals (95% CI) were calculated per PS risk domain (or single risk factors if internal consistency was insufficient) and plotted. Statistical significant difference between PS risk domains was determined with one-way analysis of variance (ANOVA) and Bonferroni post hoc analysis (p-value < 0.05).

RESULTS

A total of 41 questionnaires were distributed of which 29 were completed and returned, resulting in a response rate of 71%. Out of the 29 questionnaires 28 were filled in completely and 1 incomplete (5 items at the last page were not completed).

Agreement over the complete questionnaire was moderate (ICC = 0.42). The internal consistency of PS risk domains surgical team, technology, social interaction, environment, patient, fallibility and safety measures were all acceptable (Cronbach's alpha >0.7) (Table 2). The PS risk domains surgeon and result did not reach sufficient internal consistency (Cronbach's alpha 0.54 and 0.14, respectively) and therefore further analysis was done for every risk factor separately. ANOVA analysis showed significant differences between groups ($p < .001$). Further analysis with Bonferroni post hoc test will be described in more detail below.

Table 1. Categorization of risk factors

Risk domains	Risk factors
Surgeon	Experience of the surgeon
	Technical skills of the surgeon
	Leadership of the surgeon
Surgical team	Qualified staffing
	Experience of the scrub nurse
	Scrub nurse's knowledge of the procedure
	Experience of the circulating nurse
Technology	All instruments are present
	All instruments work properly
	It is known how to handle all instruments
	All equipment is present
	All equipment works properly
	The OR team knows how to handle all equipment
	The surgeons knows how to handle all equipment
Social interaction	Communication between OR team members
	Failure of professional communication
	Communication of important issues at shift changes
	Collaboration between OR team members
Environment	Disruptions of the surgical process
	Distractions (e.g. questions not relating to the patient)
	Number of people in the OR
Patient	Patient's BMI
	Patient's ASA score
	Previous surgeries
Fallibility	Time of day surgery takes place (e.g. daytime, night time)
	Workload
	Number of procedure (e.g. first or last of that day)
	Fatigue
Safety measures	Universal safety protocols
	Briefing according to WHO checklist
	Compliance of safety measures (protocol)
Result	Intraoperative complications
	Amount of blood loss
	Length of surgery

BMI, body mass index; OR, operating room; ASA score, American Society of Anaesthesiologists Physical Status Scores.

Table 2. Cronbach's alpha per risk domain		
Patient safety risk domain		**Cronbach's alpha**
1	Surgeon	0,54
2	Surgical team	0,74
3	Technology	0,90
4	Social interaction	0,81
5	Environment	0,78
6	Patient	0,70
7	Fallibility	0,72
8	Safety measures	0,93
9	Result	0,14

Mean ratings and 95% CI's are plotted in Figure 1. This figure illustrates the relative importance of the PS risk factor domains towards each other and shows that on average the experience and technical skills of the surgeon are rated highest (6.6, SD 0.5 and 6.6, SD 0.7, respectively), whereas leadership of the surgeon was rated significantly less important (mean 5.4, SD 1.2). Although all risk factors are rated relatively high (right side of the 7 point scale), the mean rating of the PS risk domain environment (3.9, SD 1.5) is significantly lower than all other risk domains except for the mean rating of patient and safety measures (4.5, SD 1.5 and 4.4 SD 1.5, respectively). Both technology and social interaction are rated among the most important risk domains (mean 5.9, SD 1.1 and mean 5.5, SD 1.0, respectively). Within the risk domain result, length of surgery and blood loss were rated relatively lower (mean 5.0, SD 1.3 and mean 5.0, SD 1.2 respectively) than complications (mean 5.9, SD 1.2), although not significant. On average the risk domains surgical team (mean 4.9, SD 1.3), fallibility (mean 4.9, SD 1.3), patient and safety measures did not differ significantly.

There were no missing risk factors reported in the free space section. There were a few comments, which will be further discussed in the next section.

DISCUSSION

In this study an adapted framework of PS risk factors in MIS was validated as a first step in understanding the clinical relevance of various PS risk factors in MIS. All investigated risk domains were rated of noticeable influence on PS, confirming the multidimensionality of the concept PS. This also implies that in order to completely assess PS in MIS, all of the proposed risk factors should be considered.

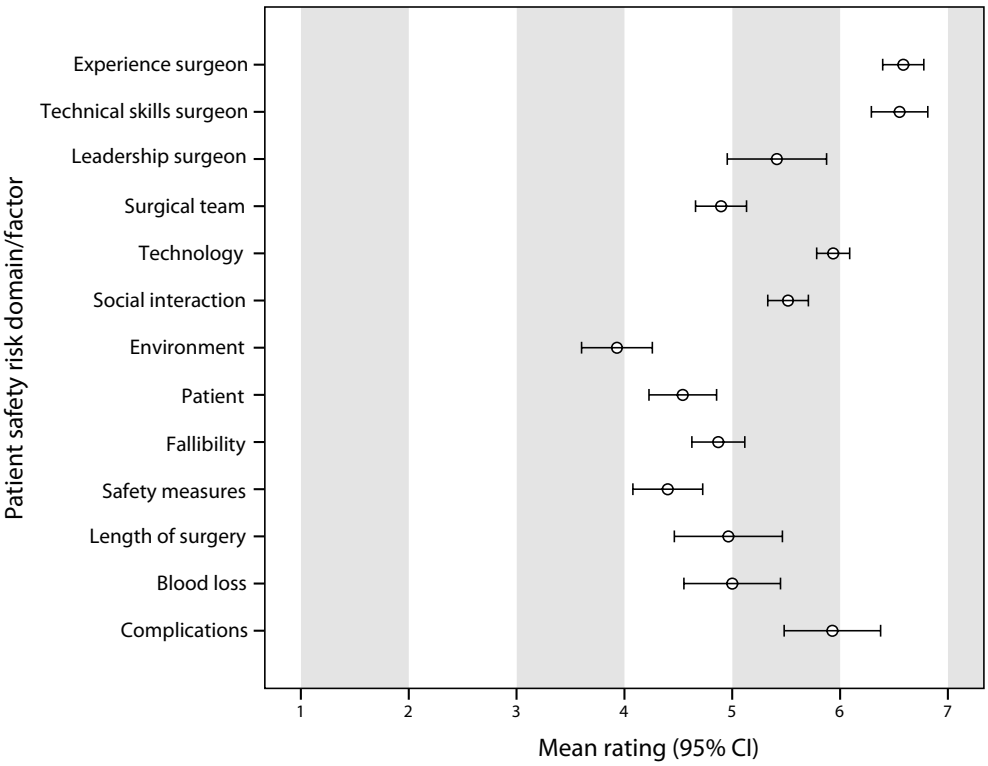


Figure 1. Mean scores and 95% confidence interval (95% CI) per risk domain.

The results of this study should be interpreted carefully. The selection of PS experts comprises only gynaecologists who specialize in MIS; therefore the results can only be interpreted as valid for gynaecological MIS. Further research is needed to examine whether these results can be extrapolated to other specialisms and whether other professionals that participate in MIS (i.e. anaesthesiologists and OR nurses) share this opinion. Furthermore, it should be taken into account that there are differences in agreement on the importance of various risk factors. This is illustrated by the differences in width of the 95% CI of mean (Figure 1). A small 95% CI should be interpreted as strong agreement and a wide 95% CI should be interpreted as weak agreement. As such, agreement on the importance of technology, experience of the surgeon, and social interaction is strongest and therefore the average rating can be interpreted as more reliable than the average rating of length of surgery, leadership of the surgeon, complications and blood loss, of which the 95% CI's are wider (e.g. agreement is less strong). Yet overall agreement of the complete questionnaire was moderate (ICC = 0.42) and the widest 95% CI is 1,0 point wide. Together with the response rate of 71%, this is considered satisfactory.

The free space section in the questionnaire gave experts the possibility to comment on the questionnaire. There were no missing risk factors reported, however there were a few relevant comments made. There was one comment on the importance of the first assistant's experience by directly affecting safety and by adding experience to a difficult procedure. We agree, however we considered this as part of the qualified staff. Another expert commented that the 13 point scale in the electronic version of the questionnaire, gives to much choice and could lead to clustering of the answers in the middle of the scale. Because of software restrictions converting the VAS to a Likert-type scale for the electronic questionnaire was imperative. We chose to let every half a centimetre on the VAS correspond to a point on the Likert-type scale, hence the origin of the 13 point scale. Furthermore, the results show an arrangement of the risk domains in given rating, therefore it can be stated that clustering of the answers due to the large scale is no issue in the current questionnaire.

It is possible to prioritize certain risk domains over others. As such, experience and technical skills of the surgeon, technology and complications have the highest ratings, closely followed by social interaction and leadership of the surgeon. The use of advanced technology in MIS easily explains the experts' view on the importance of good functioning instruments and equipment. The magnitude of technology related problems during MIS has previously been illustrated in several studies.[9,10] Also in gynaecological MIS procedures many technology related problems, with potentially dangerous consequences, have been observed.[11] In these studies, technology related incidents mainly led to delay and extra work. The importance of technology in MIS is supported by the fact that the experts rate this domain among the most important risk domains in MIS. Surgeons could be facilitated in the optimal use of advanced technology in laparoscopic operating units by checklists. Checklists have already been shown to improve the use of the available technology and reduce technology related incidents[9,12]. Problems in social interaction (such as communication and teamwork) have also been shown to occur frequently during surgery.[13,14] For example, communicational difficulties have been reported to occur in approximately 30% of team exchanges.[13] About a third of these communicational failures resulted in visible effects that can influence PS.[14] The importance of social interaction for PS in MIS is supported by the fact that the experts also rate this domain among the most important risk domains in MIS.

Many studies concerning PS in the operating room have been focusing on disruptions and distractions from the surgical process (environment) because they are believed to influence the surgeon's concentration or are perceived as stressful events.[15–20] Remarkably the experts rated this risk domain (environment) as the least influential of all risk

domains. The results of an observational study are in line with the experts opinion as they found frequent disruptions however the stressfulness of disruptions were least severe compared to other (e.g. technical) incidents.[16]

CONCLUSION

This study is an initiative to give insight into clinical relevance of the maze of PS risk factors in MIS. All investigated risk domains were considered to be of noticeable influence on PS. Nevertheless, it is possible to prioritize various risk domains. In fact, experience and technical skills of the surgeon, technology and complications are rated as the most important risk factors, closely followed by social interaction and leadership of the surgeon. Patient safety measures and environment are rated as the least important risk factors.

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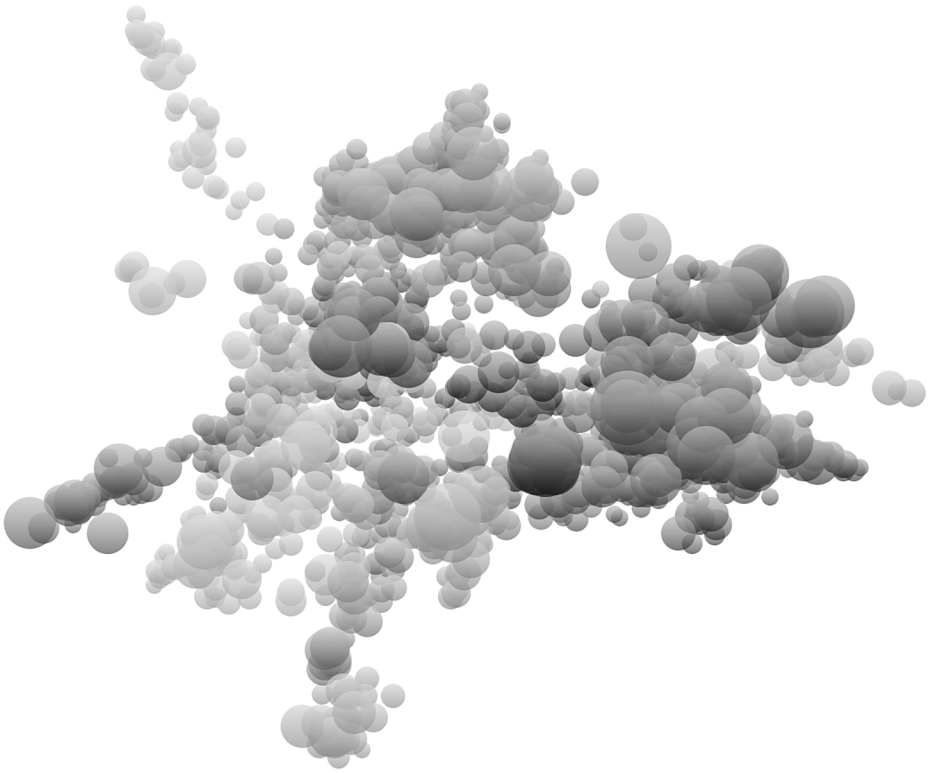
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CHAPTER 4

RISK FACTORS OF PATIENT SAFETY: MINIMALLY INVASIVE SURGERY VERSUS CONVENTIONAL SURGERY



ABSTRACT

Background

To identify the frequency of events of the different patient safety risk domains during minimally invasive surgery (MIS) and conventional surgery (CS).

Methods

A convenience sample of gynaecological MIS and CS was observed. Events were observed and categorized in one of the predefined patient safety risk domains.

Results

A total of 53 procedures were observed, 26 CS and 27 MIS procedures. General characteristics were comparable. A large amount of environment events were observed (on average one every 2.5 minutes). Technical events and events of organizational nature occurred more often in MIS than in CS ($p < 0.01$ and $p < 0.01$). The relative risk for the occurrence of one or more technical events in MIS compared to CS was 1.7, and 4.1 for two or more technical events. There was no relation between time out according to protocol and the occurrence of the different types of patient safety related events.

Conclusion

The technological complexity inherent in MIS makes this type of surgery more prone to technology related problems than CS, even in a specially designed minimally invasive surgical suite. A regular time out procedure developed for CS lacks the necessary attention for the complex technology used in MIS and is therefore insufficient for briefing MIS procedures. Incorporating a specially designed technology checklist in a regular briefing protocol could be a solution to decrease the number of events in MIS.

INTRODUCTION

Ever since the Harvard Medical Practice study and the report by the Institute of Medicine (IOM) "To Err Is Human: Building a Safer Health System" that followed it, patient safety (PS) has become a major focus of improvement in healthcare. It is widely known that the IOM report stated that an estimate 44,000 to 98,000 patients in the US die every year due to medical errors.[1] In the Netherlands the results of a national study assessing the number of hospital adverse events were presented in 2007. This study showed that 5.7% of 1.3 million patients admitted in 2004 encounter an adverse event. In 40% of these patients the adverse event could probably have been prevented.[2] This high percentage of preventability is confirmed in a systematic review[3], including eight studies with a total of 74,485 patients. This study showed a median incidence of hospital adverse events of 9.2% with a median percentage of preventability of 43.5%. Of these hospital adverse events 39.6% were OR-related.

In 2007 the report by the Dutch inspectorate of healthcare[4] emphasized that the complexity of minimally invasive surgery (MIS) further increases risks in PS. However, the mechanism through which PS in MIS is more compromised compared to conventional surgery (CS) remains unclear. In order to understand this mechanism, differences in PS between the two types of surgery should be investigated according to the systems approach. This approach to quality and safety in surgery is required to obtain insight on causes of errors and has a much larger effect on PS than the person approach.[5] A number of important studies have suggested frameworks of factors that influence PS based on the systems approach.[6-8] These frameworks were adapted to explain PS in surgery in several risk domains and measurable quality outcome parameters (Figure 1). With this observational study we aim to identify differences in PS risk factors between MIS and CS according to the systems approach.

METHODS

Case selection

A convenience sample of gynaecological MIS and CS performed at the Leiden University Medical Center, the Netherlands, was observed. CS performed in an operating room (OR) with regular OR settings were observed. MIS procedures performed only in a minimally invasive surgical suite especially designed for laparoscopy (in this case OR-1, Karl Storz) were included because these suites were especially designed to facilitate MIS.[9,10] In this study MIS only comprised laparoscopies. MIS was stratified based on the level of difficulty according to the guidelines of the Royal College of Obstetricians

and Gynaecologists.[11] RCOG levels range from level one procedures, which are basic laparoscopic procedures (e.g. diagnostic laparoscopy and sterilization), to level three, which are advanced laparoscopic procedures (e.g. total laparoscopic hysterectomy). The procedures that could not be classified as MIS were classified as CS.

Categorization system

The adapted framework that explains PS in several risk domains and measurable quality outcome parameters (Figure 1) was the basis for the observations in this study. In order to objectively assess the risk domains in the framework, every risk domain should be quantified. This quantification and further categorization of the observations is explained in Table 1.

The categorization was tested in a pilot study during a period of three weeks. During this pilot random gynaecological surgical procedures were observed according to the categorization. After every procedure individual surgical team members evaluated the procedure with the researcher to determine the feasibility of the categorization. Next the categorization was critically reviewed on clinical relevance and completeness by a board of three independent experts (all authorities in the field of PS and MIS representing the department of surgery, gynaecology and PS in general). The final categorization system is shown in Table 1; it consists of a number of risk domains that have to be quantified during the observations (e.g. social interaction, technology, safeguarding system, organization and environment). This was achieved by observing the number of events that can be categorized in those risk domains.

Events

Events were defined as occurrences that potentially increase risks and therefore compromise PS, either directly or indirectly.

Observations

Observation of events during a surgical procedure started with the time out and ended when the last suture was placed. The total observational time (from time out till the last suture) as well as total procedure time (from first incisions till last suture) was recorded. Furthermore the risk domains that were not quantified by events and the other outcome parameters of the procedure were recorded as defined in Table 1.

Data collection

Data collection was performed by an independent observer that had not been involved in the development of the categorization to ensure objective assessment of the risk domains. This observer was required to have ample knowledge of medical processes, however without knowledge of the specific procedures that had to be observed. Therefore a medical student with 4 years of medical training was selected to be the observer. The observer attended gynaecological surgical procedures during a training period of three weeks prior to the study to obtain familiarity with these procedures. In this period the observer learned to recognize deviations from standard procedure as events and to code events according to the categorization.

Data analysis

All data was analysed with SPSS 16.0 software package (SPSS, Chicago, IL, USA). Differences in frequency of events, experience of surgical team members and length of surgery between MIS and CS were assessed with the independent samples t-test. Differences in categorical data (e.g. patient characteristics) were assessed with chi-square test.

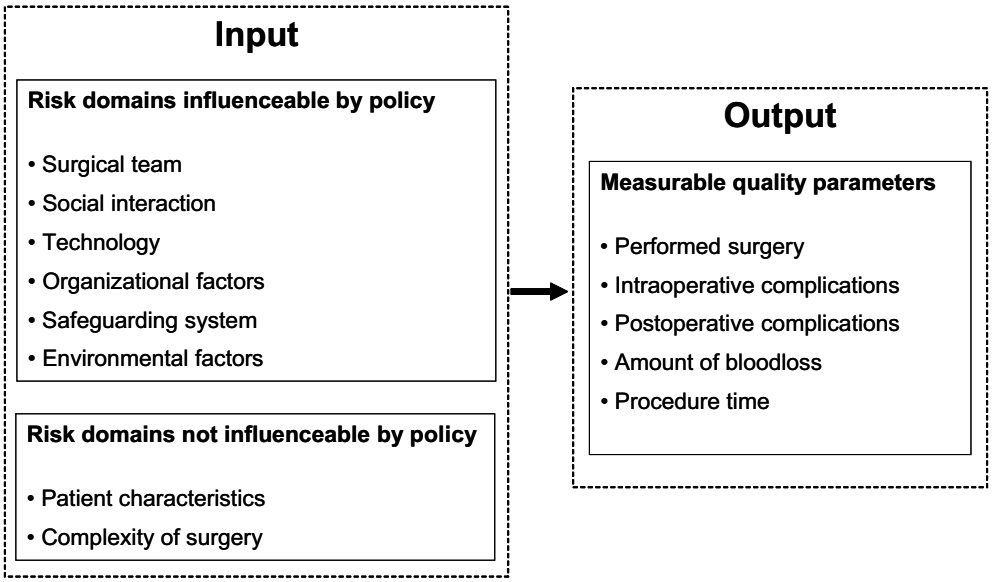


Figure 1. Framework of risk domains explaining patient safety in surgery accoding to a systems approach.

Table 1. Framework to which observations are categorized

Risk domain	Influencing factor	Observation (quantity)
Input		
Surgical team	Knowledge and experience of individual team member	Experience of every individual team member defined as an estimation of the number of similar procedures previously performed
Social interaction	Verbal and nonverbal communication	Events concerning verbal miscommunication
	Teamwork	Events concerning teamwork
Technology	The availability and functioning of equipment and instruments	Events concerning the presence or correct positioning of instruments or equipment
		Events concerning the functioning of instruments or equipment
Organization	Staffing and planning	Adequate scheduling
		Adequate staffing
	Availability of recourses	Availability of supplies
		Availability of technological items
Safeguarding system	Compliance of policies adapted for patient safety	Correct execution of the time out procedure
Environment	Case irrelevant disturbing factors	Door movements
		Telephone calls
		Pager calls
		Radio use
		Case irrelevant conversation
Patient characteristics	Condition of the patient	ASA score
		Body mass index (BMI)
Complexity of surgery	Level of difficulty of the surgery	MIS: type of procedure which can be categorized in RCOG levels
		CS: type of procedure
Output		
Performed procedure		Was the procedure performed as intended?
Intraoperative complication		Intraoperative complications?
Postoperative complication		Postoperative complications up to 6 weeks postoperative.[23]
Blood loss		Amount of blood loss
Procedure time		Total observational AND intraoperative procedure time

ASA, American Society of Anaesthesiologists Physical Status Scores.; BMI, body mass index; MIS, minimally invasive surgery; RCOG, Royal college of obstetricians and gynaecologists; CS, conventional surgery.

RESULTS

General characteristics

A total of 53 procedures were observed, 26 CS and 27 MIS procedures. The CS comprised 5 laparotomies for benign indication, 5 laparotomies for malign indication, 9 vaginal hysterectomies of which 4 were combined with prolapse surgery, 6 vulva surgeries and 1 cervical procedure. The MIS comprised of 10 RCOG level one procedures, 11 level two procedures and 6 level three procedures.

The mean total observational time, as well as the mean total procedure time were comparable for MIS and CS (1h29 vs. 1h52 and 1h19 vs. 1h44 respectively). The mean experience of the surgical team members did not differ between MIS and CS. Patients BMI and ASA score were both comparable between MIS and CS (Table 2).

Events

Total counts of observed events are displayed in Table 2. Between 75% and 100% of events occurred intra-operatively as illustrated in Figure 2. The greatest part of observed events was categorized under environment (MIS vs. CS respectively 90 % vs. 97%). Of these events door movements were observed most, respectively 81% in MIS (n = 925) and 80% in CS (n= 1275). All observed events were checked for a correlation with the length of surgery, which was found in telephone calls and door movements ($R2 = 0.71$ and 0.74 respectively). There was one door movement every 154 sec in MIS and one every 140 sec in CS and one telephone call every 20 minutes in both MIS and CS. When all environment events are combined, on average one event was observed every 125 sec during MIS and every 111 sec during CS. Of these observed environment events 8.8% are noted as disturbing by the surgeon in MIS and 17.6% in CS.

MIS vs. CS

When comparing the frequency of the different types of events in MIS to CS, there was no difference found between environment and social events. Except for disturbance of the radio, this was noted more often during CS ($p < 0.01$). Technical events and events of organizational nature occurred more often in MIS than in CS ($p < 0.01$ and $p < 0.01$) (Table 2).

Of all events with a technical nature observed during MIS, 49% (n = 34) were problems with the positioning of equipment or instruments. Problems with the functioning of

equipment or instruments accounted for 28% (n = 19). In CS 33% (n = 6) of the observed events of technical nature were positional and 28% (n = 5) were problems with functioning. Of the 13 problems of organizational nature that were observed during MIS, 8 involved the unavailability of instruments at the time of surgery. The other organizational problems were a result of inadequate staffing.

Relative risk

The relative risk calculated for the occurrence of one or more events of technical nature in MIS compared to CS was 1.7. The relative risk of having 2 or more technical problems during MIS compared to CS was 4.1. For organizational problems the relative risk could not be calculated because none occurred during CS.

Time out

The time out protocol used in the observed clinic is similar to the time out protocol developed by the world health organization (WHO).[12] In 74% of the MIS procedures the time out proceeded according to this protocol vs. 50% in CS. In one MIS procedure and in 5 CS procedures, there was no time out at all. However no relation between a time out procedure according to the protocol and the occurrence of different types of PS related events was observed.

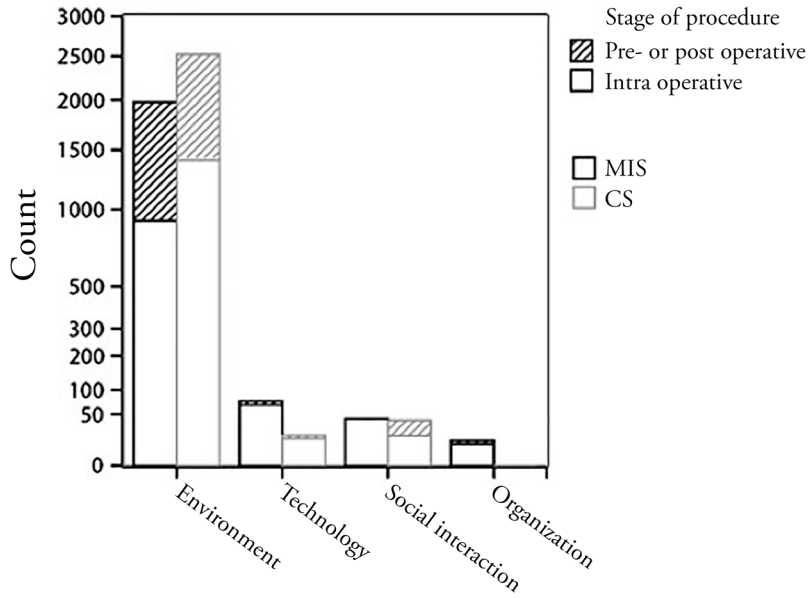


Figure 2. Total counts of observed events in minimally invasive surgery (MIS) and conventional surgery (CS). The striped part represents the share of events that occurred pre- or postoperatively, and the white part represents the share of events that occurred intraoperative.

Table 2. Count of events during the total observational time.

		MIS (n = 27)			CS (n = 26)				MIS vs CS
Risk domain		**Count**	**Max count**	**Mean**	**Count**	**Max count**	**Mean**	**Total**	**P value**
Environment	Total	1145	114	0.48*	1594	208	0.54*	2739	NS
	Door movements	925	90	0.39*	1275	174	0.43*	1812	NS
	Telephone	112	11	0.05*	165	28	0.05*	268	NS
	Beeper	41	8	1.52	77	13	2.96	118	NS
	Radio	9	2	0.33	20	2	0.77	29	p = < 0.01
	Case irrelevant conversation	58	11	2.15	57	9	2.19	115	NS
Technical	Total	69	8	2.56	18	3	0.69	87	p = < 0.01
	Equipment	45	6	1.67	11	2	0.42	56	p = < 0.01
	Instruments	24	2	0.89	7	3	0.12	31	p = < 0.01
Social	Total	43	9	1.59	27	8	1.04	70	NS
	Communication	34	7	1.26	22	7	0.85	56	NS
	Teamwork	9	2	0.33	5	1	0.19	14	NS
Organizational	Total	13	3	0.48	0	0	0.00	13	p = < 0.01

MIS, minimally invasive surgery; CS, conventional surgery; Count; total count of all procedures, Max count; highest count reached during one procedure. Mean, per procedure (count divided by number of procedures) if there was no correlation between count and procedure time; *per minute if there was a correlation between count and procedure time (count divided by procedure time)

DISCUSSION

Differences in PS related events between conventional surgery and minimally invasive surgery can be explained by the use of advanced technology as an essential part of MIS. This is in line with the statement made by the Dutch Inspectorate of healthcare, that the (technical) complexity of MIS further increases risks in PS compared to CS. A previous study has already shown that a great amount of technical events tend to occur during laparoscopic procedures. In fact, in 87% (26 out of 30) of the observed laparoscopic procedures, one or more incidents with technical equipment (N = 46) or instruments (N = 9) occurred.[13] Surgeons might be aware of the implications of new technology on PS. However, to our knowledge a detailed description of the consequences of technology on events that occur in the OR has never been made. Our data show that the majority of the organizational events (62%) were also technology related; more specifically, they were related to the preparation of the technological aspect of MIS (missing instruments or equipment). Altogether, it appears to be the advanced technology added to surgery that in particular hinders PS in MIS when this surgical approach is compared to the conventional approach.

Although general briefing checklists have been proven to reduce morbidity and mortality in surgery,[12,14] the results of this study suggest that in MIS a different approach is required. The fact that a time out according to protocol is not correlated to a lower frequency of events leads us to speculate that a general briefing procedure such as the checklist of the WHO is insufficient for the preparation of MIS. Since the most important difference in events between MIS and CS is the frequency of technology related events, indicates that more attention is needed for technology during the briefing. An adequate solution which has already been proven to reduce the number of technical events in MIS, is the use of a standardized checklist especially designed for MIS.[15] Such a checklist could be incorporated in the general WHO briefing in case of MIS.

This study reports an astonishing amount of environment events occurring around every 2 minutes in both MIS and CS. Consisting mostly of door movements (one very 2.5 min), with the potential risk of surgical site infections. High frequencies of door movements have been reported before, namely 13 till 316 times per surgery (5 to 87 per recorded hour).[16] Similar to what we have seen in the present study, the observed door movements increased in direct proportion to the length of surgery and were also related to the number of persons in the OR. It is remarkable that the bulk of environment events are not observed to be disturbing or distracting to the senior surgeon, as 8.8% of all observed environment events combined are disturbing in MIS and 17.6% in CS. The

reason for this could be that experienced surgeons learned to block distracting events and remain concentrated[17] combined with the fact that most environment events do not occur during critical moments. However the effect of environment events should not be underestimated. Especially the performance of inexperienced surgeons or residents could be influenced by distraction, as shown in a previous study[18].

Social factors such as communication and teamwork have been shown to be important risk factors in PS. In fact, optimizing teamwork in order to reduce error stands at the basis of a whole new era of research: Crew Resource Management. Communicational difficulties have previously been reported to occur in approximately 30% of team exchanges.[19] About a third of the communicational failures resulted in visible effects that can influence PS.[20] In the current study however, the frequency of the observed social events is very low compared to those previous reports. The most obvious reason could be an underestimation of the true quantity of these events. The previously published studies only focused on communicational (or teamwork) events, reporting also small social mishaps, whereas this study also focused on technical, organizational and environmental events. The social events reported in this study must have been prominently present and therefore more prone to influence safety than small social mishaps, which might not have any influence at all. Furthermore, since observations of both MIS and CS were done by the same observer, a comparable (under)estimation is expected for both types of surgery and a relative comparison remains possible. Hence it can be stated that there is no difference in the amount of observed events of social nature between MIS and CS.

Another observational study investigated different types of surgical flow disruptions during cardiac surgery, showing that the greatest amount observed surgical flow disruptions were of social nature (52%).[21] This is in contrast to our observations in MIS, in which the highest percentage of events are disturbing environment events (44.7%), followed by events of technical nature (30.5%). Events of social nature accounted for only 19% of the observed events. In CS the highest percentage of observed events were disturbing environment events (86.2%) followed by events of social nature (8.3%). Technical events during cardiac surgery accounted for 5.5% of the events. Hence, the outcome is highly procedure dependent.

A pitfall of all observational studies is observational bias. It was attempted to reduce observational bias by selecting an independent researcher to perform the observations. Ideally more than one observer should have observed all procedures to test for inter rater agreement. However, this would crowd the operating room, as observations were done in academic hospital where also professionals in training (students, nurses, interns and

residents) attend surgical procedures, and that is not in the interest of PS. Furthermore, it is well recognized that the Hawthorne effect (the awareness of being observed alters the way a person behaves)[22] takes place. Taking this in consideration, the most accurate method to perform observations of surgical procedures is probably with some sort of black box in which video and audio recordings are made. Than less influence of the Hawthorne effect and multiple independent observations would be possible.

CONCLUSION

A large number of events have been observed during both MIS and CS. The technological complexity inherent in MIS makes this type of surgery more prone to technology related events than CS, even in a specially designed minimally invasive surgical suite. A regular time out procedure as used for CS lacks the necessary attention for the complex technology which is used in MIS and is therefore insufficient for briefing MIS procedures. Incorporating a specially designed technology checklist in a regular briefing protocol could be a solution to decrease the number of events in MIS.

ACKNOWLEDGMENTS

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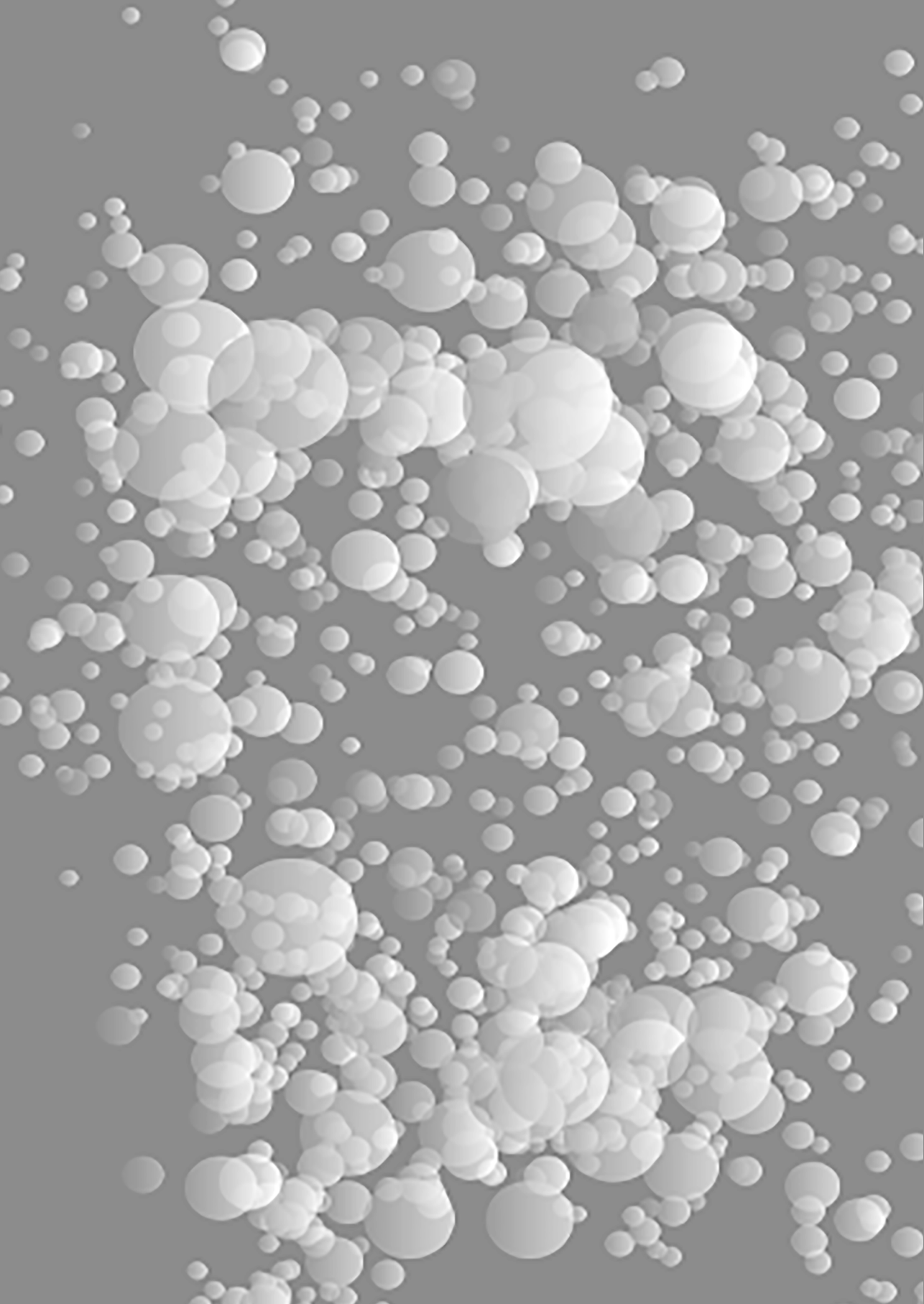
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PART II

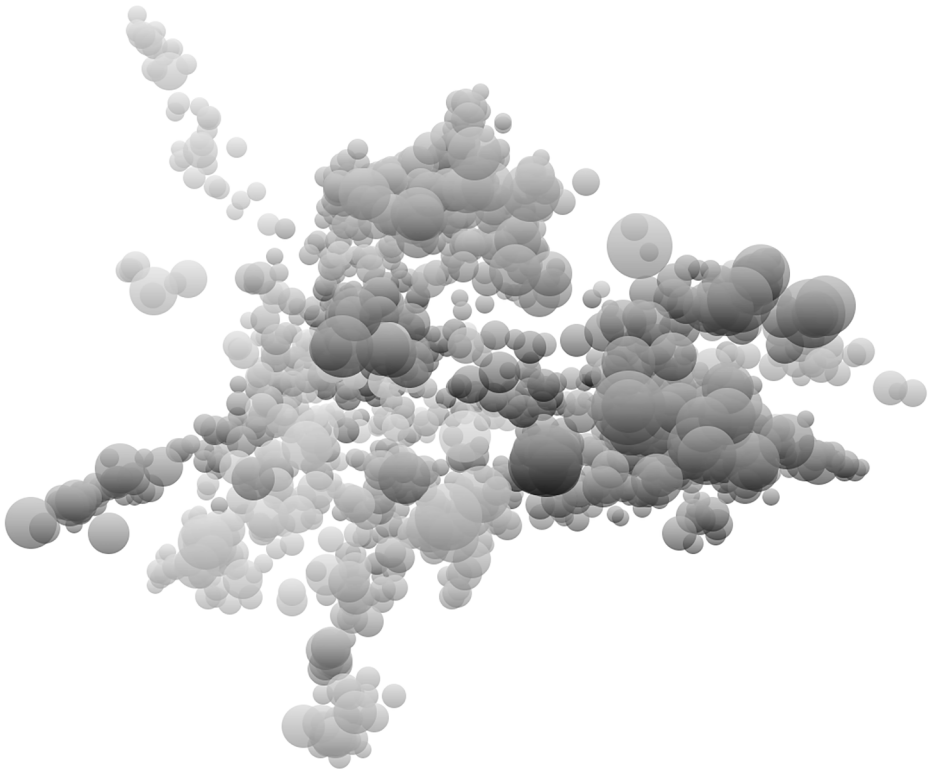
TRAINING TISSUE HANDLING SKILLS

T. Horeman, S.P. Rodrigues, F.W. Jansen,
J. Dankelman, J.J. van den Dobbelsteen.

Adapted from:
Force measurement platform for training and assessment of laparoscopic skills.
Surgical Endoscopy 2010 Dec;24(12):3102-8
&
Force parameters for skills assessment in laparoscopy.
IEEE Transactions on Haptics 2012 Nov;5(4):312-322

CHAPTER 5

FORCE MEASUREMENT PLATFORM FOR TRAINING AND ASSESSMENT OF LAPAROSCOPIC SKILLS



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 construct validity of the developed force platform, a study was conducted in which 11 surgeons experienced in intracorporeal suturing and 21 Novices performed a suture task on artificial tissue in a box trainer. The tissue was mounted on the Force platform that was used to measure the force 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.

Results

A force measurement was developed which has a mean accuracy for measuring forces and torques of 0.1 N (SD 0.073) and 0.02 Nm (SD 0.016), respectively. In the validation study nine of the parameters showed significant differences between Experts and Novices. In general the force exerted by the Experts was significantly lower than the force exerted by Novices.

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. Force measurements in a box trainer can be used to classify the level of performance of trainees and can contribute to objective assessment of suturing skills.

INTRODUCTION

The use of minimally invasive techniques is rapidly increasing and offers the patient many advantages compared to conventional 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. To this extend a simple and low-cost force platform system that measures force and torque applied on tissue with standard laparoscopic tools to place inside a standard box trainer was developed by T. Horeman, Delft University of technology. This chapter in short describes the development of the force measurement platform and the clinical validation.

DEVELOPMENT OF THE FORCE MEASUREMENT PLATFORM

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 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.

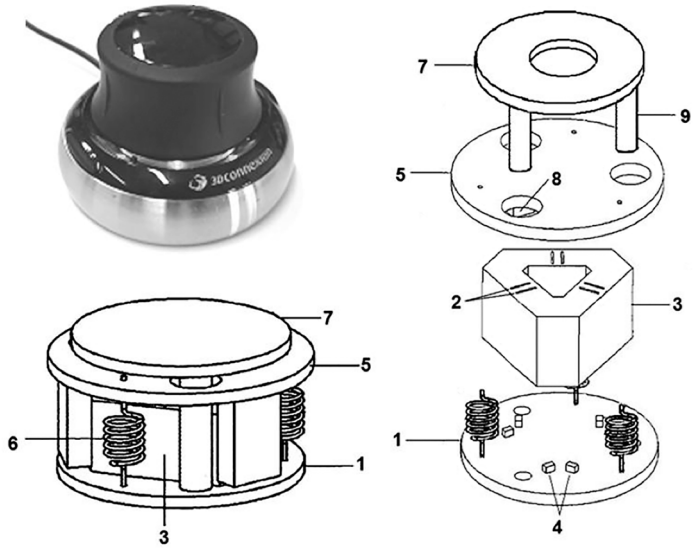


Figure 1. Schematic exploded view of the SpaceNavigator (adapted from Patent EP1850210).

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). 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. 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

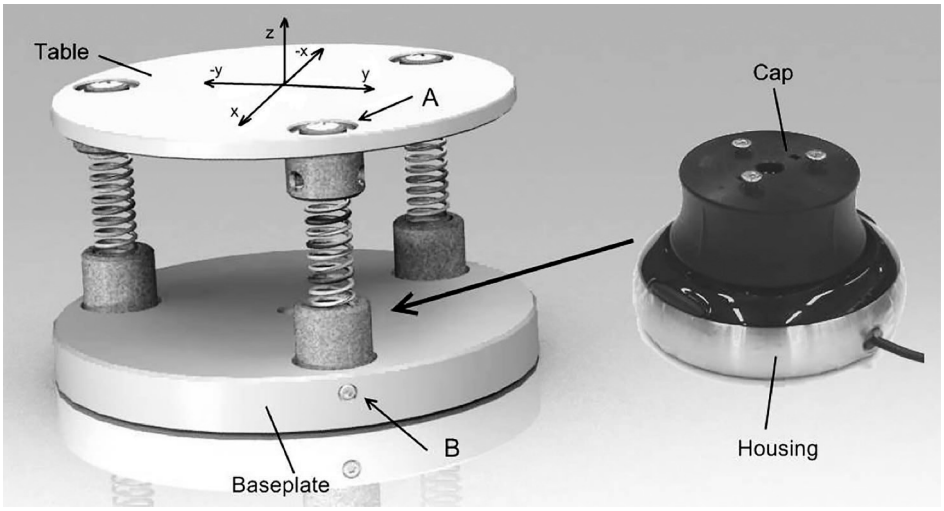


Figure 2. Left: force platform built from mechanical components. Right: modified SpaceNavigator that is fixed between base plate and table.

Calibration and accuracy

The calibration and accuracy are described in more detail in the publication by Horeman.[12] 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.

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 3, 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 3, 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.

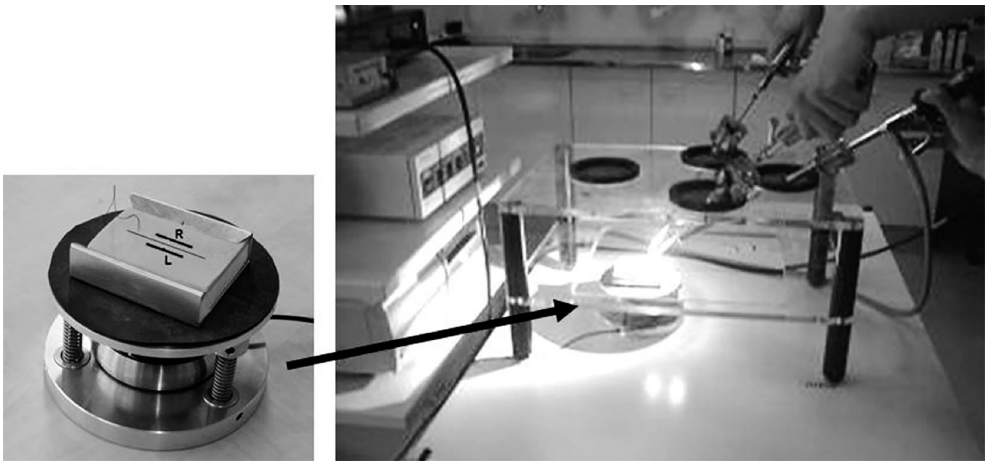


Figure 3. Left: force platform with artificial skin tissue. Right: test setup with Box trainer, trocars, laparoscope, needle holders, and force platform.

Results 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 4A) whereas the Novice used rotation (R) as well as translation (X,Y) (Figure 4B).

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 5A, B.

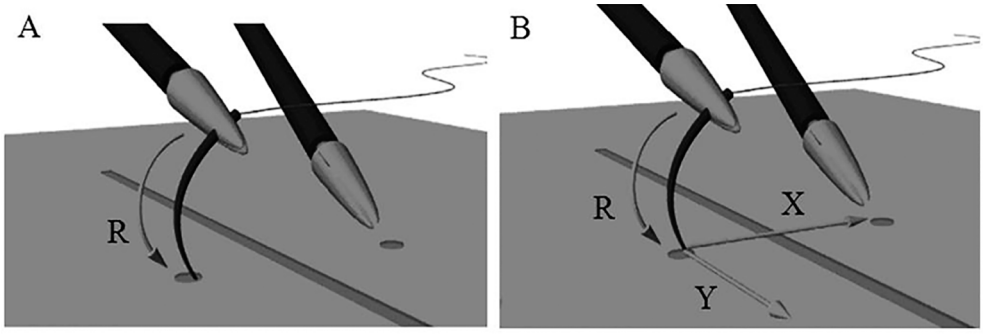


Figure 4. Observed difference in needle driving between Expert (A) and Novice (B). R is rotation around needle centre point, X is translation parallel to X-axis, Y is translation parallel to Y-axis.

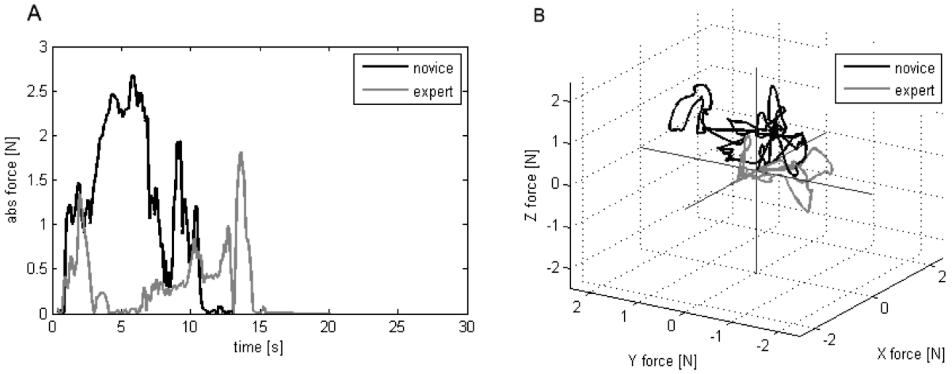


Figure 5. Absolute force exerted on artificial tissue (A). 3D representation of force exerted on artificial tissue (B).

The absolute nonzero mean force and maximal force of all subjects, measured during the needle driving task, are presented in Figure 6. The force graphs of a Novice and surgeon that performed the needle driving task four times are presented in Figure 7. 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: $t = 3.6$, $p<0.017$).

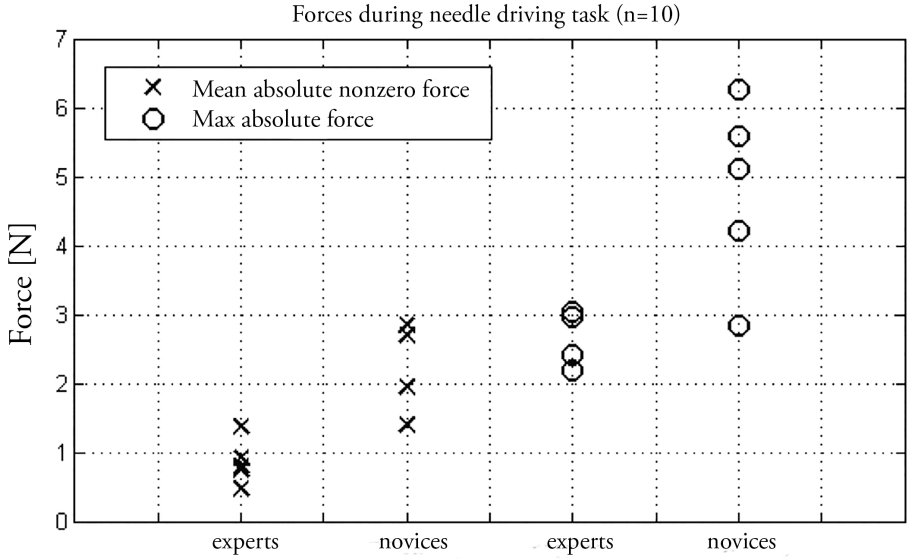


Figure 6. Differences between Experts and Novices in performance. Each data point represents the averaged value over two measurements of one subject.

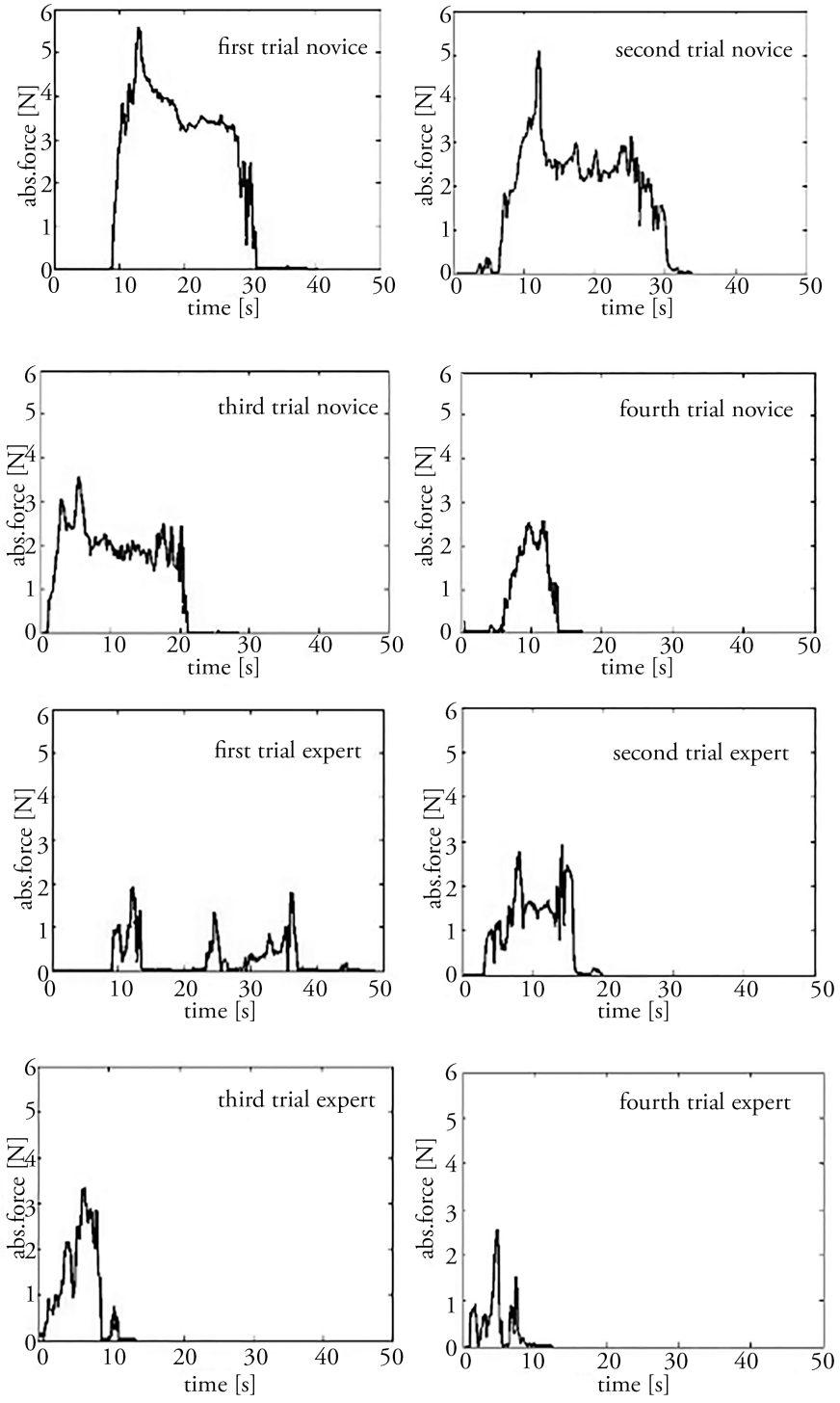


Figure 7. Force graphs of a Novice and surgeon that performed the needle driving task four times.

VALIDATION

Validation of the force measurement platform was established by determining if significant differences in force application can be found between Experts and Novices during a suturing task, which is performed in a box-trainer.

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 were 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 set up with a force measurement platform as described above (Figure 4). A 26 mm Vicryl 3-0 needle from Ethicon (Johnson & Johnson) was used to conduct the suture task. 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 8 shows the type of suture with a three throw knot 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 a three throw square knot. 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 drivers 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.

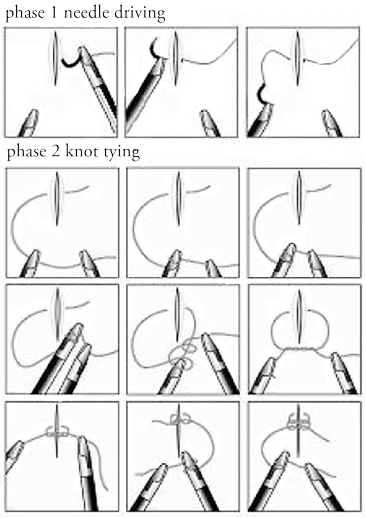


Figure 8. Suture task, which consists of needle driving, followed a three-throw square knot.

Force parameters and data analysis

In total 16 different force parameters were chosen to evaluate the application of forces by the participants (Table 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, it is expected that force peaks occur when the threads are stretched to tighten the knot. Figure 9 shows an example of the absolute force in time during needle driving (first phase) and knot tying (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.

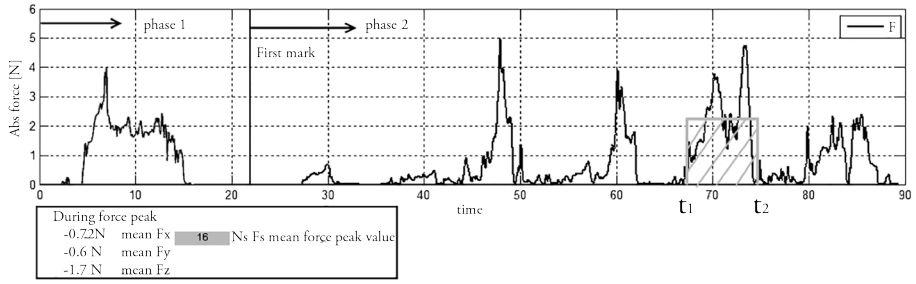


Figure 9. Representation of the absolute force over time during needle-driving and knot-tying phase. The hatched rectangle indicates the area where the highest mean absolute peak force between t1 and t2 is found in the knot tying phase. The height of the dashed rectangle indicates the mean absolute force 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 0.1 N again.

Due to the sensor accuracy of 0.1 N sensor outputs less than 0.1 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.

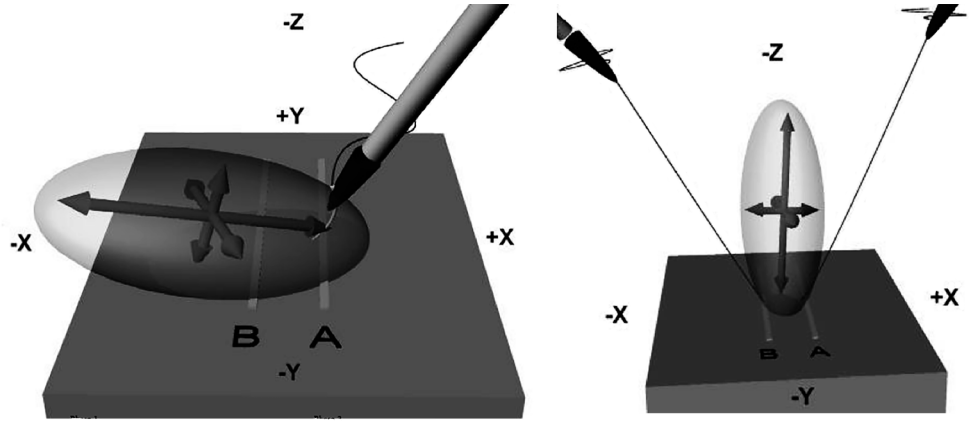


Figure 10. Phase 1: ellipsoid (transparent) representing the variability in forces in 3D when a needle is pushed from line A to Line B through artificial tissue. Phase 2: ellipsoid (transparent) representing the variability in forces in 3D during the knot tying phase. In both ellipsoids, the thick arrows 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 10). In Figure 11 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.

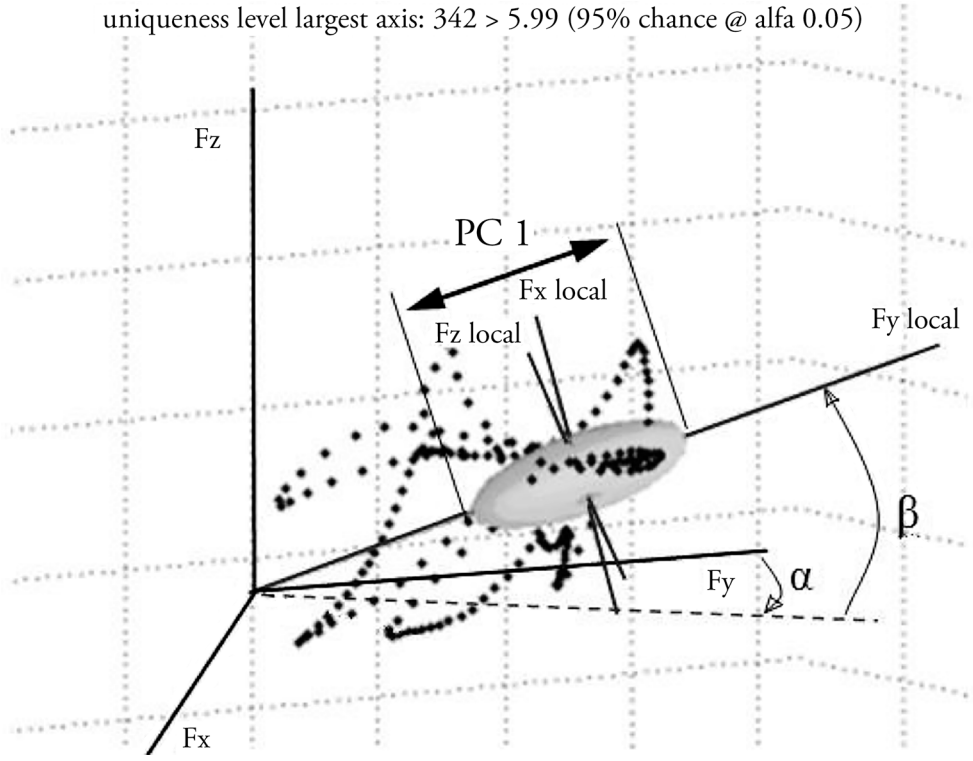


Figure 11. 3D variability in forces. The dots represent the force in the global coordinate system (Fx,Fy,Fz). The green ellipsoid is fitted on the force data and the orientation of PC1 along Fx-local is defined by Alpha and Beta. PC2 and PC3 are not shown in the figure.

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[13] of the principal components was determined with:

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

χ^2 = Likelihood criterion
α = The probability of error = 0,05
r = Number of eigenvaleus = 2
N = Number of samples
l_i = The r =2 eigenvalues being compared for a given covariance matrix (i =1-2 or i=2-3).

The likelihood criterion was calculated for the two largest standard deviations PC1 and PC2 of the ellipsoid (Figure 10). 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[14]:

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

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.[15-17] 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. When compared to force parameters, the performance time can provide useful information for further research and is therefore presented in Table 1.

Statistical analyses

A total of 16 force parameters were identified that could be suitable to determine the differences between groups (Table 1). We determined for each of the different parameters whether the group means of the experienced surgeons differed from the group means from the Novices using student T-tests (SPSS 17.0). A probability $p < 0.05$ was considered to be statistically significant. The difference between Experts and Novices on the parameters in the coloured fields of Table 1 were not significant.

RESULTS VALIDATION

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 1. For parameters that show significant differences, the results from all participants are presented in Figure 12.

Needle driving phase

The parameters that show significant differences in the needle driving phase are depicted in the first and second row of Figure 12. 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.

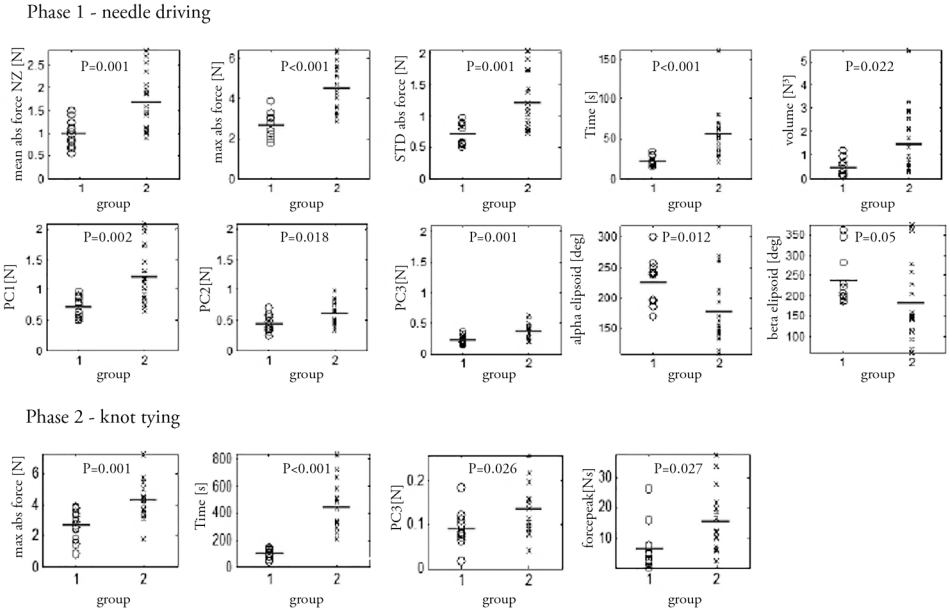


Figure 12. Needle driving phase and knot tying phase results. The Experts in group 1 are indicated with a "O" mark (n=11) and the Novices in group 2 are indicated with "X" mark (n=16). Each measurement point represents the averaged value of 3 measurements from one participant. The horizontal lines indicate were the mean value is found. Significant differences are indicated by P values. Time was not used for classification.

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 224^0 (STD 39^0) for Alpha was found in the Expert group. With a mean value of 176^0 (STD 57^0) 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 237^0 (STD 63^0) was found for the Expert group and a mean value of 181^0 (STD 95^0) was found for the Novice group. Since all likelihood criteria were higher than 5.99, the orientation was defined reliably for all ellipsoids.

Knot tying phase

The parameters that show significant differences in the knot tying phase are depicted in the third row of Figure 12. 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 Novices 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.

Table 1. Parameter results.

	Experts		Novices	
	Needle driving Phase 1	Knot tying Phase 2	Needle driving Phase 1	Knot tying Phase 2
Parameter	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
MeanabsforceNZ [N]	0,93(0,32)	0,42(0,18)	1,64(0,62)	0,47(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 [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)

The grey fields contain only non-significant force parameters. * Only for comparison, not used in the calculations.

DISCUSSION

A force platform was developed that can measure interaction forces with tissue in a nonclinical setting with a mean accuracy for measuring forces of 0.1 N (SD 0.073) and 0.02 Nm (SD 0.016) for measuring torques.

Needle driving phase

In line with the pilot study 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.

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. Because 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.[19, 20] 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 13). 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 224^0, STD 39^0) in the Expert group, it seems that Experts are able to manipulate the needle more efficiently through the artificial material than Novices (mean 176^0, STD 57^0). 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.

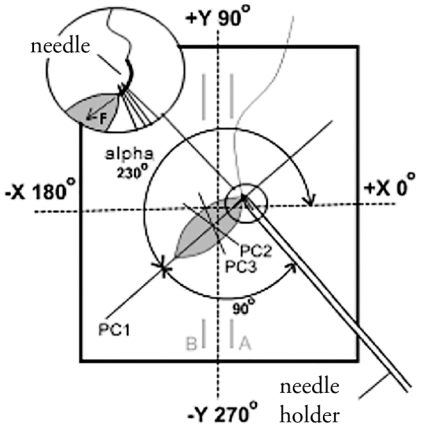


Figure 13. Idealized needle driving behaviour. The force is mainly exerted in the same direction as the needle. In this case, the needle tip and largest principal component (PC1) point in the same direction.

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.

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

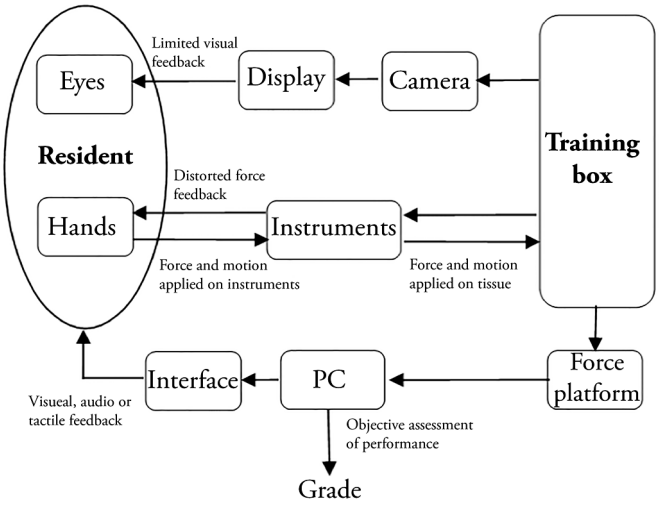


Figure 14. Schematic diagram of a resident during training on box trainer equipped with a force platform.

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.

Force and torque information in training tasks

In the present study we evaluated performance in a suturing task. However, potentially any training task, used to practice laparoscopic skills, can be mounted on the force platform. 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 14). 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.

CONCLUSION

A force measurement was developed to measure force and torque in three directions during performance of endoscopic tasks inside box trainers. The validation study indicates construct validity of the force measurement platform. Experience influences the applied interaction forces during the laparoscopic suturing 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.

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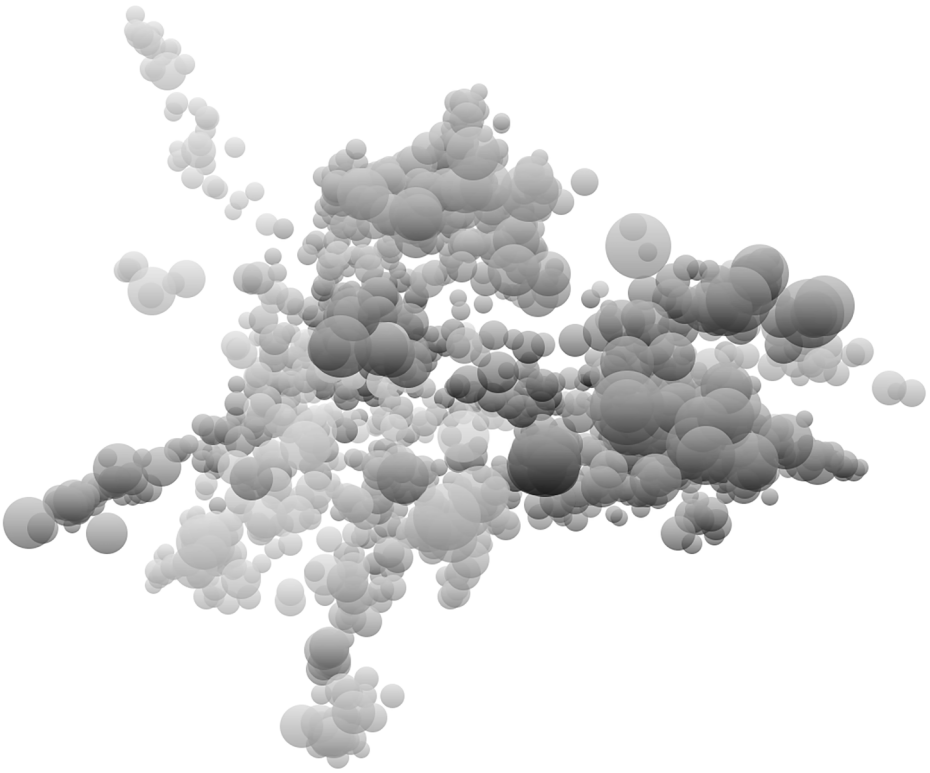
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Surgical Endoscopy 2012 Apr;26(4):1005-1009

CHAPTER 6

SUTURING INTRA-ABDOMINAL ORGANS: WHEN DO WE CAUSE TISSUE DAMAGE?



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. To be of clinical relevance, these criteria should relate the applied forces to the risk of tissue damage. This 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 eight different tissue types (fascia, aorta, vena cava, peritoneum, small and large bowel, uterus, and fallopian tube) of 10 different pigs by placing increasingly higher loads on sutures in the tissue. We determined the load when tissue damage occurred through visual inspection. 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 tube. The difference in allowable force between these two structures is almost tenfold. Small bowel can be handled with a tractive force almost 1.5-fold higher than large bowel.

Conclusions

Each 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.

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 those 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 movement. In clinical practice, the gold standard is to manipulate tissue as gently 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, 5]. This problem translates, for example, into more difficulties when learning to safely apply force in a laparoscopic grasp than to learn the same with barehanded lifts[6]. To facilitate training of tissue-handling skills, a force measurement platform has been developed for the box trainer[7]. This force platform provides the trainee with objective feedback of the forces applied on tissue during a suture task. The pilot study of this article suggested that a novice can apply forces up to 7 N during needle driving[7]. However, information about the applied forces does not have any clinical relevance if not related to in vivo tissue damage. The current study was conducted to determine the difference in strength for different types of fresh post mortem porcine tissue when tractive forces are applied on a single suture.

METHODS

The amount of tractive force on a suture that causes visually detectable tissue damage was investigated in eight different types of porcine tissue (fascia, aorta, vena cava, peritoneum, small and large bowel, uterus, and fallopian tube) in 10 different pigs. All porcine tissues were acquired from a slaughterhouse on request and immediately stored in physiologic saline solution at maximum temperature of 70C to conserve the tissue until the measurements were performed.

Measurements were performed within 6 h after slaughter. An experimental setup was built to apply tractive forces on a suture (Figure 1). With this setup, tractive forces up to a maximum of 13 N could be placed on the suture by means of adding weights of 50 g (approximately 0.5 N) in gradual load steps. During every load step tractive force was applied for 1 min. Between load steps, the tissue was completely relieved of tractive force before the next load step was examined (i.e., another 50 g was added). To minimize the influence of friction in the experimental setup, the cable was guided by two pulleys with

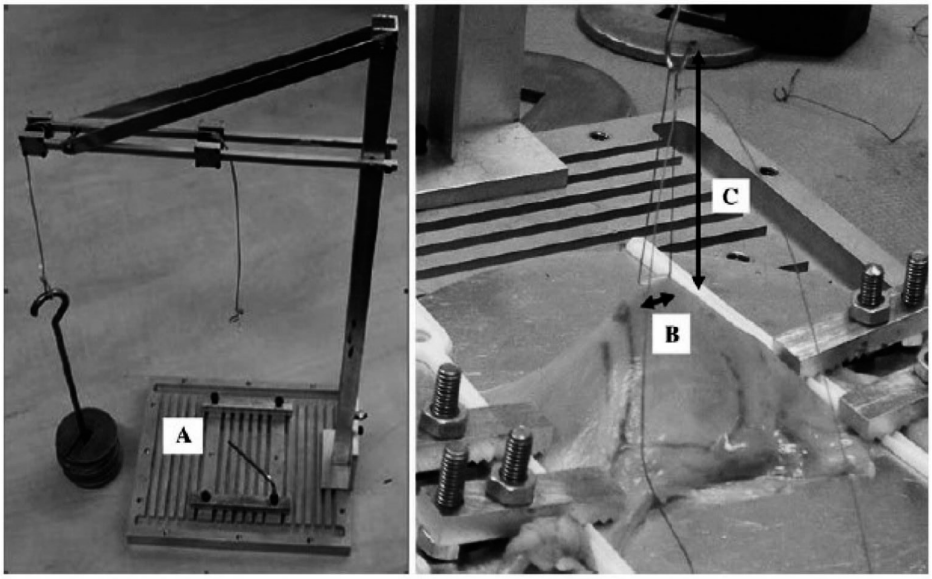


Figure 1. Tissue measurement system built for tractive force measurements. Tissue can be fixed on the plateau (A). Example of how the suture width (B) and height (C) are standardized before the force measurement starts.

special low-friction bearings. The example in Figure 2 shows the force and rupture graph of a force measurement on a single tissue sample of large intestine.

Before the measurements started, tissue was prepared and fixed to a plateau (Figure 1A), meaning that an ample size tissue sample was taken and hollow structures (aorta, vena cava, bowel, etc.) were cut open and laid flat on the plateau. 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 tissue damage. Once the tissue sample was fixed to the plateau, it was moistened throughout the measurement with physiologic saline solution (similar to that in 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 homogeneous 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.

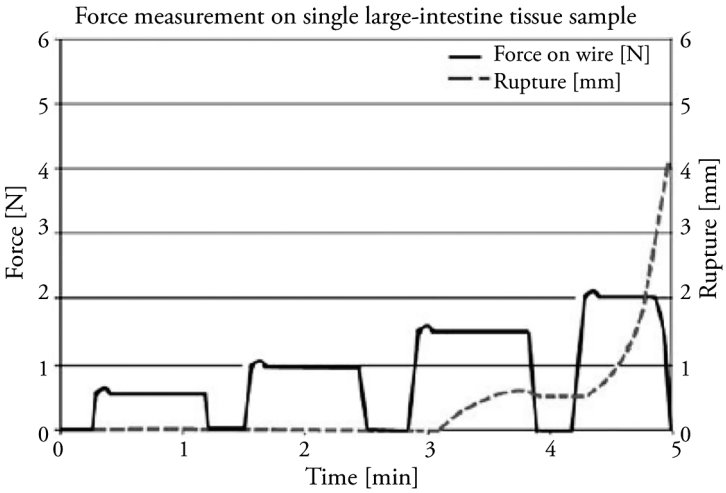


Figure 2. Representation of a force measurement as performed on a single tissue sample of large intestine. As the force on the wires increases after each load step, the tissue finally starts to rupture during the third step. During the fourth step, the rupture speed exceeds 2mm/min and the measurement is finished.

The distance between the insertion and exit point of the needle was 8 mm at minimum and 11 mm at maximum (Figure 1B). The two wires of the suture were knotted at a minimum distance of 50 mm measured from the tissue to the knot (Figure 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 started to rupture; rupture was defined as the insertion or exit hole of the suture becoming larger at a speed of 2 mm/min.

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 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 two separate control measurements performed on every tissue type. For the control measurements, tissues were prepared similarly 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 contrast to the regular measurements, in the control measurements, each tissue sample

was loaded only once. For each of the eight tissue types, the first tissue sample was loaded with the maximum load as found in the regular measurement with an additional 200 g. For each following new tissue sample, the total load was decreased by 50 g. The measurements with decreasing load were repeated until no tissue damage was noticed anymore. For every measurement, the number of millimetres (starting with 3 mm) of rupture was registered.

Table 1. Tissue damage after loading

		First sign of tissue damage		**Rupture**	
Tissue type	N	Mean weight (gr)	95% CI	Mean weight (gr)	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

RESULTS

The mean tractive force and 95% confidence intervals (CI) for each of the different types of porcine tissue are displayed in Table 1. Figure 3 shows boxplots of the tractive forces at the first sign of tissue damage and moment of rupture. Before tissue damage occurred, the highest tractive force could be put on fascia and the lowest tractive force on fallopian tube. The difference in allowable force between these two structures is almost tenfold. Small bowel can be handled with a tractive force almost 1.5-fold higher than large bowel. The results of the control measurements (Table 2) were comparable to the results 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 or exit point of the suture.

Table 2. Tissue damage after leading: control measurements

Tissue type	Measurement	Weight (gr) tissue damage	Weight (gr) 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

DISCUSSION

Each tissue type was found to have its own individual range of acceptable maximum forces before visual tissue damage occurred. The variation of the results was relatively small within individual types of tissue, being around one load step for peritoneum, large and small bowel, uterus, and fallopian tube and around two or three 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, therefore mimicking the issue of tissue handling. An earlier study showed the development of a laparoscopic training system that visualizes the interaction force during a suture task as a coloured three-dimensional (3D) arrow on a 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 that study were higher than found in the current study. This is possibly due to the larger contact area of grasping forceps compared with the 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 post mortem porcine tissues. The porcine model was chosen because it is often used as a training model in surgery. Furthermore, porcine bowel (large and small) has been shown to have comparable tissue characteristics to human bowel[9]. Although the tissue was freshly obtained, post mortem 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 physiologic saline solution at a maximum temperature of 7^0C and performing the measurements within 6 h after slaughter. Another limitation of using post mortem 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 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 that microscopic tissue changes could occur before the load step at which macroscopic tissue damage was noted. However, during surgery, the surgeon also depends 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 even at 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 beforehand that forces above 13 N are not applicable for the training setup, the measurement stopped at 13 N. This distorts the mean and median results for fascia and aorta, for 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 bowel, uterus, fallopian tube, or peritoneum.

In this study, the load on the tissues was slowly increased by hand until the tissue was carrying the load on its own (Figure 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.

CONCLUSIONS

It is evident that training of tissue-handling skills in a nonclinical 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.

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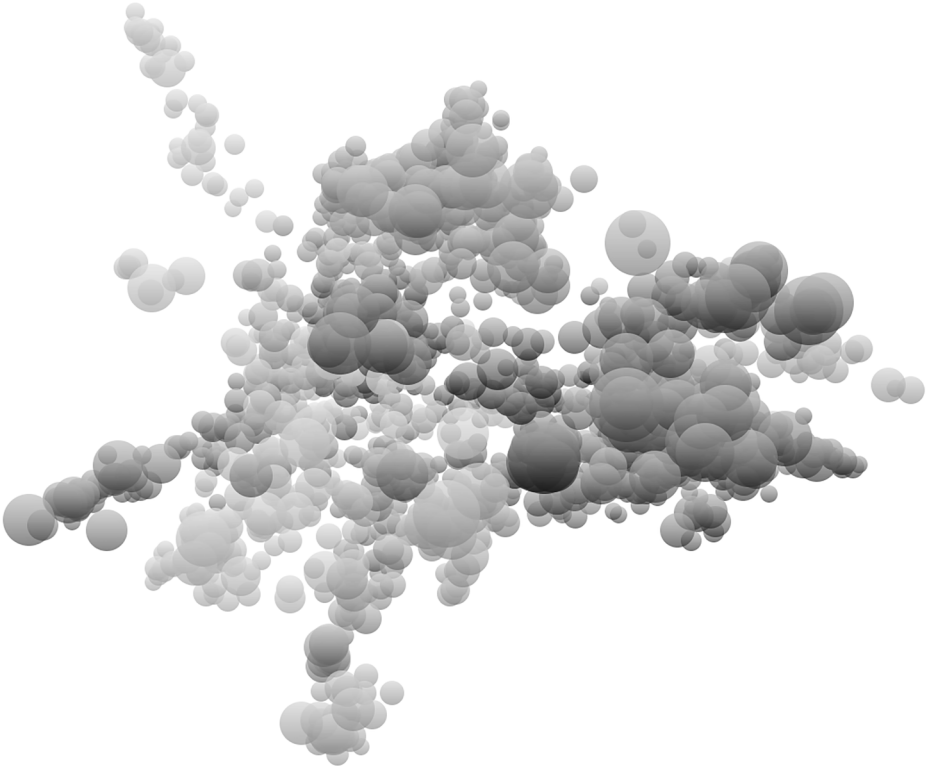
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CHAPTER 7

TYING DIFFERENT KNOTS: WHAT FORCES DO WE USE?



ABSTRACT

Background

To determine differences in applied interaction forces between conventional open surgery and laparoscopic surgery during suturing in a non-clinical setting.

Methods

In a laparoscopic box trainer set-up experts performed two intracorporeal and two extracorporeal sutures on an artificial skin model. They performed two instrument-tie knots and two one hand square knots in a similar conventional training set-up. Time and forces exerted on the model were measured. Sutures are divided in a needle driving phase (Phase 1) and knot tying phase (Phase 2).

Results

Phase 1: Force values in laparoscopic suturing are significantly higher than in conventional suturing, except for the force volume of the extracorporeal suture versus the one hand square knot. Phase 2: The mean non-zero and maximum force during the intracorporeal knot are significantly higher than during the instrument-tie knot. The mean and maximum force during the extracorporeal knot are significantly higher than during the one hand square knot. Laparoscopic suturing takes longer time than conventional suturing.

Conclusion

Expert surgeons apply significantly higher forces during laparoscopic surgery compared to conventional surgery even though the same strategy is used. Presumably, aspects such as the limited visual, haptic feedback, and movement possibilities hampers surgeons' ability to assess the applied interaction forces. Therefore it can be useful to provide additional force feedback about the applied interaction forces during training in nonclinical settings.

INTRODUCTION

Complex surgical tasks such as performed in laparoscopic procedures place higher demands on the motor skills of the surgeon and require extensive training. Training of basic laparoscopic skills should preferably be done in a non-clinical setting[1-3], for example in box or virtual reality trainers or on animal models. Even though tissue handling is regarded as one of the most essential skills when it comes to patient safety in minimally invasive surgery (MIS)[4], current basic laparoscopic skills training mainly focuses on time and economy of movements. Resistance inside the trocars[5] and the use of long laparoscopic instruments[6] cause a loss of haptic feedback in MIS and hinder the surgeons estimation of applied forces in instrument-tissue interaction. Problems with estimating applied instrument-tissue interaction forces can for instance result in more difficulty in learning how to safely apply force on a laparoscopic grasp, compared to learning the same with barehanded lifts.[7] To overcome these difficulties more attention is needed for the training of instrument-tissue interaction, i.e. tissue handling. The importance of haptic feedback in the early training phase of skills acquisition has also been shown in previous studies.[8,9] To facilitate the training of tissue handling skills a force measurement platform[10] has been developed for the box trainer model, which enables providing trainees objective feedback about the forces applied on manipulated objects (e.g. tissue). These force measurements can inform us about the mean and maximum forces which are being used during a task such as intracorporeal or extracorporeal suturing. Information about the applied forces can be related to tissue damage so thresholds can be set for training purposes.[11] To illustrate the importance of the loss of haptic feedback in MIS, this study aims to determine the difference between conventional open surgery and laparoscopic surgery in applied interaction forces during suturing in a non-clinical setting. The consequences of these differences on different suturing tasks and the trainee are discussed.

METHODS

Participants

Experts in the field of laparoscopic surgery were asked to perform four different suturing tasks in two different experimental set-ups. An expert in laparoscopic surgery was defined as a surgeon, gynaecologist or urologist that had performed over 100 advanced laparoscopic procedures.

Experimental set-up

To simulate laparoscopic surgery a box trainer model equipped with two 5 mm trocars and one 11 mm trocar (Endopath XCEL, Johnson & Johnson), two needle holders (B Braun, Durogrip TC, PL407R) and a laparoscopic camera was used. Inside the box trainer, artificial skin tissue (Professional Skin Pad, Mk 2, Limbs & Things, Bristol, United Kingdom) was mounted on a 3 degrees of freedom force measuring platform with a custom made aluminum holder (Figure 1).[10] At the centre of the artificial skin model, two parallel lines were drawn at 8 mm distance from each other to mimic the incision that is sutured. To simulate a conventional surgical set-up, the box trainer was removed leaving only the artificial skin model mounted on the force measurement platform.

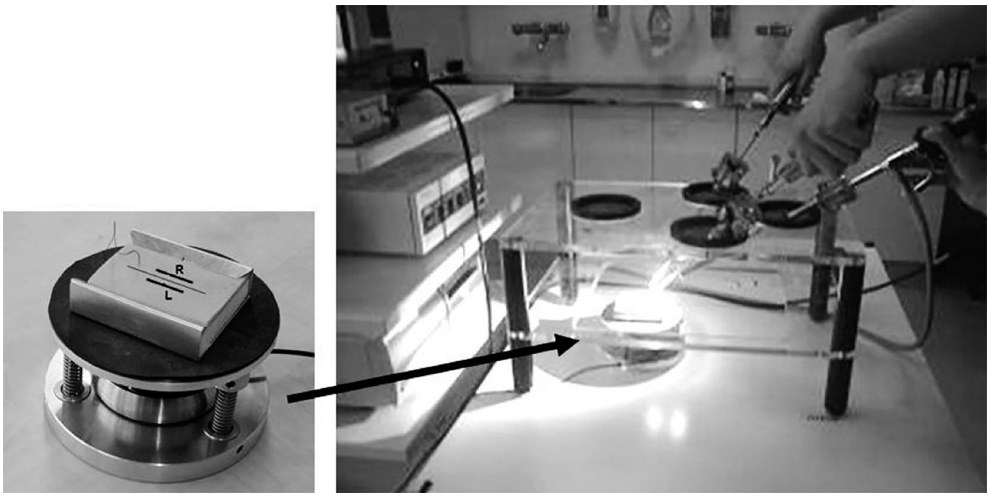


Figure 1. Training set-up. On the left the force measurement platform is shown as it is used in the conventional surgical set up. On the right the laparoscopic box trainer model is shown.

Suture task

In the laparoscopic set-up experts were asked to perform two intracorporeal and two extracorporeal sutures. In the conventional training set-up, experts were asked to perform two instrument-tie knots and two one hand square knots. It was reasoned that the intracorporeal suture best resembles the instrument-tie knot and that the extracorporeal suture best resembles the one hand square knot.

Figure 2 shows the intracorporeal suture with three throws that is used in this study. The instrument-tie knot is completely similar except for using conventional surgical instruments instead of laparoscopic needle drivers.

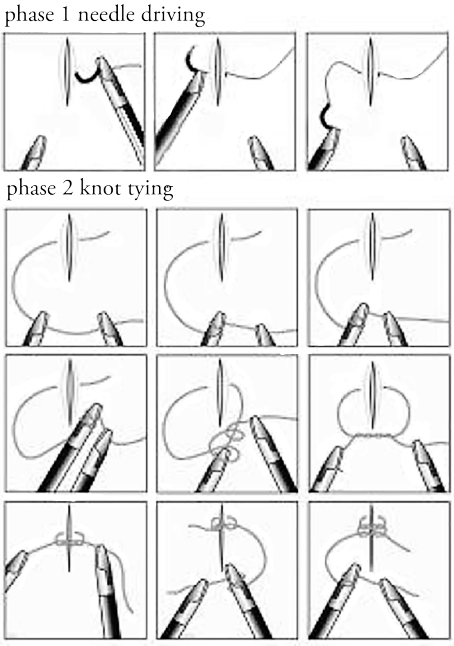


Figure 2. Step by step overview of the suture task performed each trial. During Phase 1 the needle is driven through the artificial tissue in a pre-marked area. During Phase 2 a standardized three throw square knot is formed.

Figure 3 shows the one hand square knot with three throws that is used in this study. For the extracorporeal knot, after Phase 1 both threads are pulled through a trocar after which a one hand square knot (Figure 3) is tied extracorporeal. After every throw a knot pusher is used to tighten the knot. A 26 mm Vicryl 3-0 needle from Ethicon (Johnson & Johnson) was used to conduct all suture tasks.

Phase 1

In the first phase (Phase 1) of a single measurement, the expert 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.

Phase 2

In the second phase (Phase 2), the expert made either one of the requested knots.

Since not all experts had previous experience with the type of laparoscopic needle drivers used in this study, each expert had the opportunity to manipulate the buttons and handle for a minute outside the training box before the start of the first measurement. This way they could get familiar with the instrument. Before the first measurement all experts were instructed that they were suturing fragile tissue such as bowels.

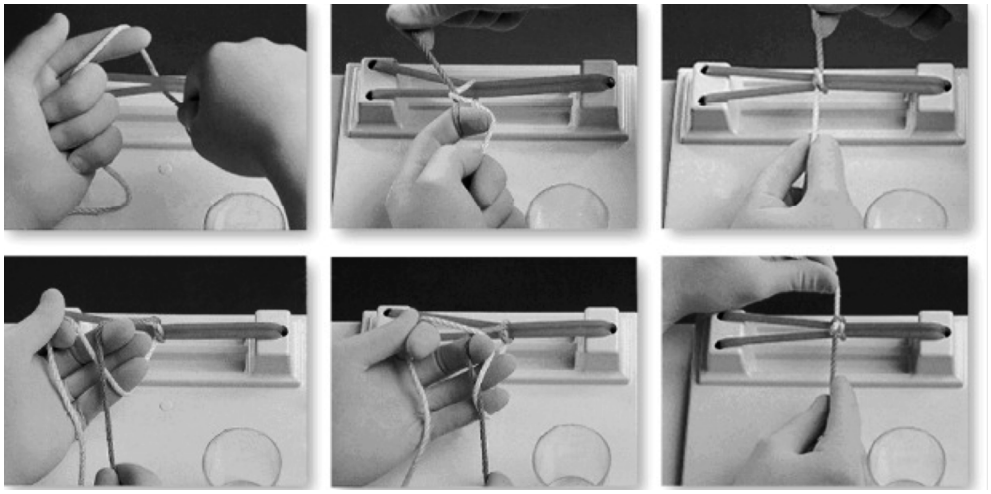


Figure 3. The one hand square knot consisting of three throws. After the second throw a third throw with the same formation as the first throw is formed.

Outcome measures

A force measurement platform, developed at Delft University of Technology, was used to measure the interaction forces and time to perform a task as described by Horeman et al.[10] We chose to analyse the mean force used during a task as well as the mean force non-zero. For the mean force non-zero the period of time that there is no force (force < 0.1 N) applied is deleted from the data.[12] Furthermore we analysed the maximum force and the time used to complete the task. Finally we chose to analyse the force volume, which is calculated as the volume of an ellipsoid around the standard deviations of force in the three axes. This parameter was chosen because it represents the variability in which interaction forces are applied, i.e. tissue handling. The parameters used are further described in a study by Horeman et al.[12]

Data analysis

All data was analysed with SPSS 16.0 software package (SPSS, Chicago, IL, USA). For all parameters differences between the different type knots were determined with a one-way analysis of variance (ANOVA) and Bonferroni post hoc analysis.

RESULTS

A total of ten experts participated to the study, all were right handed. Boxplots of the mean force, mean force non-zero, maximum force, force volume and time to complete Phase 1 of the task are shown in Figure 4. The boxplots of Phase 2 are shown in Figure 5. All knots were completed appropriately according to a visual assessment by the experimenter. The time to complete the full task, both Phase 1 and 2, is shown in Figure 6.

Intracorporeal knot versus Extracorporeal knot

There were no significant differences measured in interaction forces applied during the intracorporeal knot versus extracorporeal knot in Phase 1. In Phase 2 the mean force was higher during extracorporeal knotting. However the mean force non-zero was comparable. There were no other significant differences in interaction forces used during Phase 2.

Instrument-tie knot versus One hand square knot

There were no significant differences in interaction forces applied during the one handed square knot versus the instrument-tie knot in Phase 1 nor Phase 2.

Intracorporeal knot versus Instrument-tie knot

The interaction forces measured during Phase 1 of the intracorporeal knot are significantly higher than in the instrument-tie knot. During Phase 2 the mean force is not significantly higher in the intracorporeal knot, although the mean force non-zero is. The maximum force and the time to complete the exercise are both significantly higher in the intracorporeal knot. The difference in force volume in Phase 2 is not significant.

Extracorporeal versus One hand square knot

The mean force, mean force non-zero, maximum force and time used during Phase 1 is significantly higher in the extracorporeal knot versus the one hand square knot. The volume in Phase 1 of the extracorporeal knot seems higher, however this is not significant. In Phase 2 the mean force, maximum force and time to complete the task was significantly higher in the extracorporeal knot. The mean force non-zero and volume are not significantly.

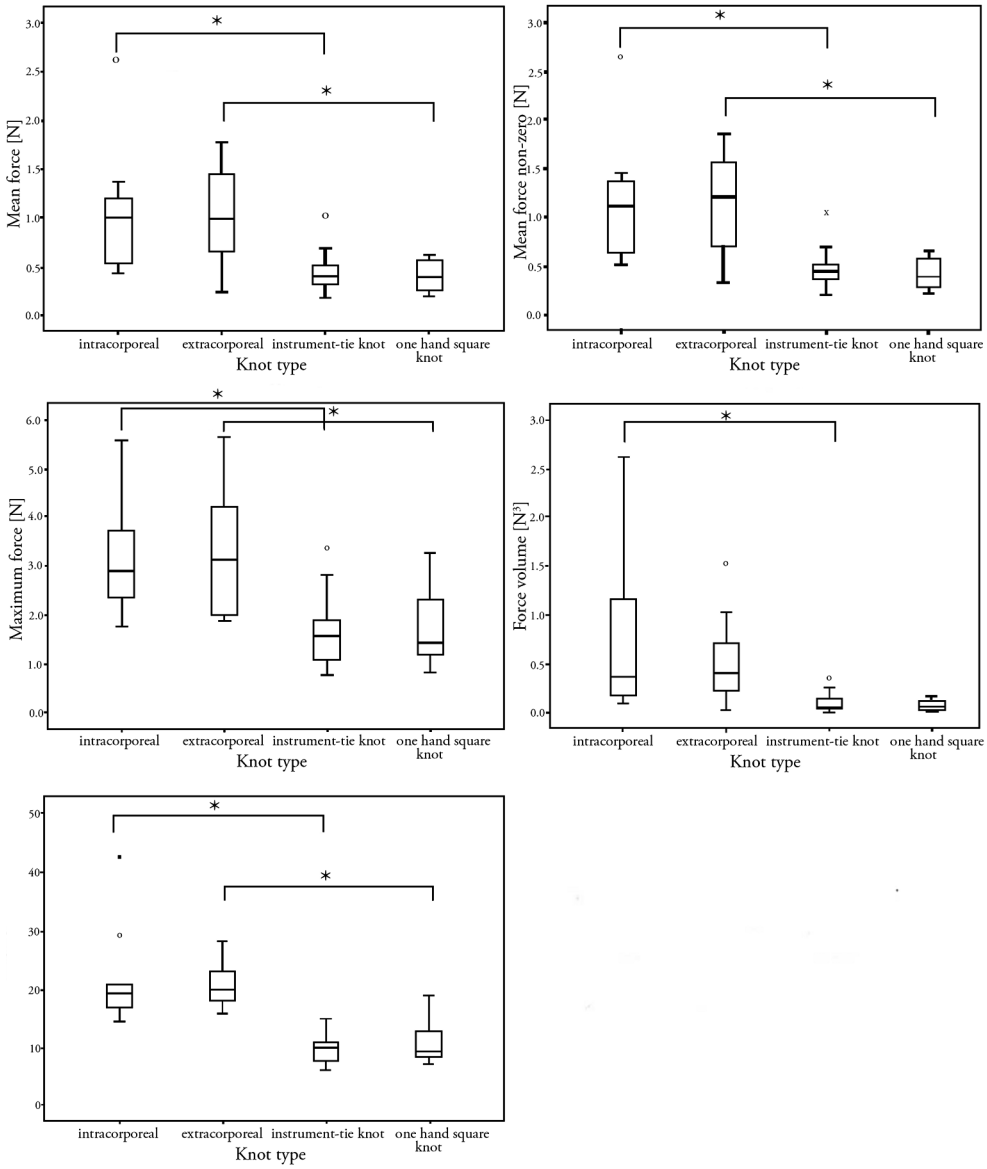


Figure 4. Boxplots of the interaction forces and time used during phase 1 of the different types of knots. Ten experts each performed two sutures of every knot type. Statistical analysis is done with the one-way analysis of variance (ANOVA) and Bonferroni post hoc analysis; * = $p < 0.05$.

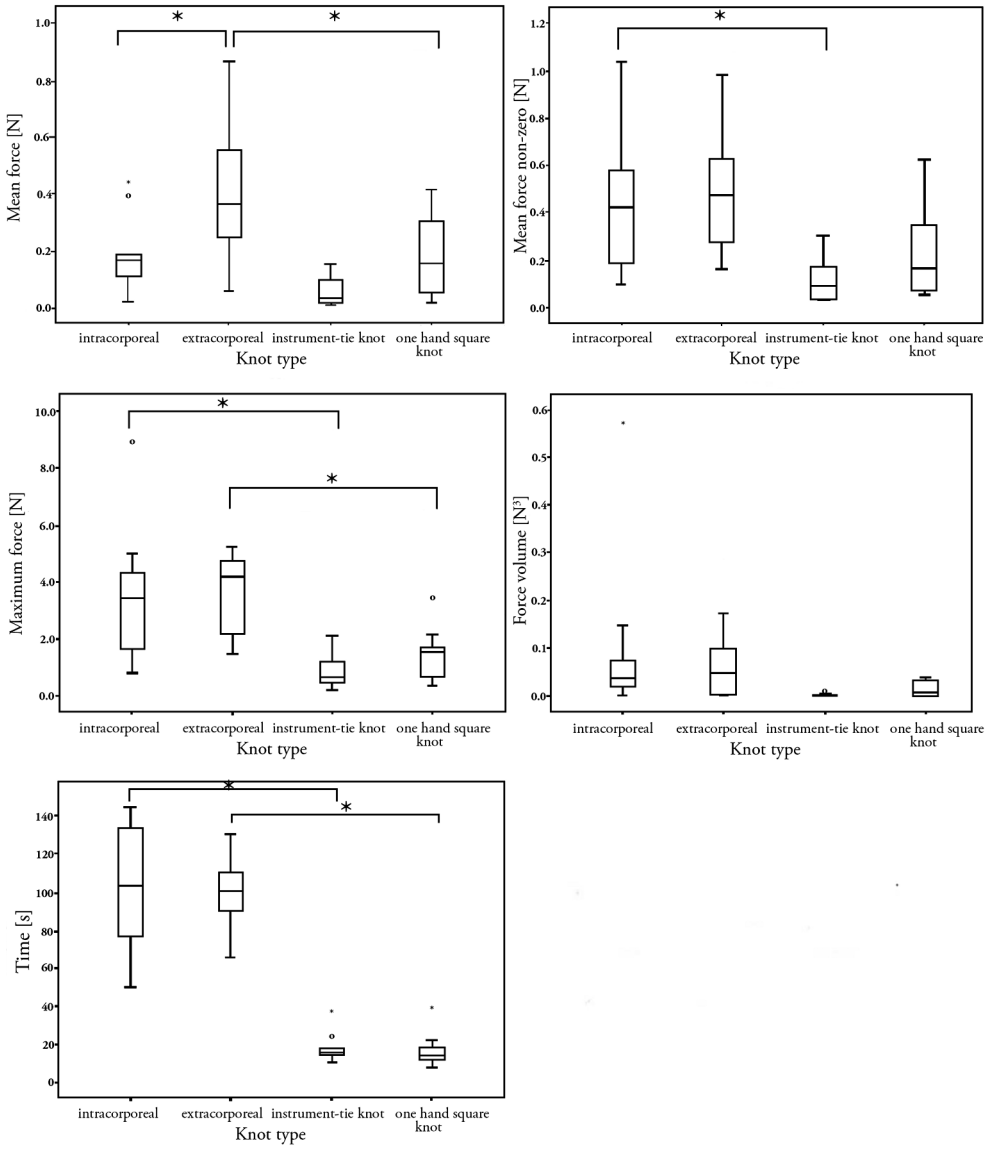


Figure 5. Boxplots of the interaction forces and time used during Phase 2 of the different types of knots. Ten experts each performed two sutures of every knot type. Statistical analysis is done with the one-way analysis of variance (ANOVA) and Bonferroni post hoc analysis; * = $p < 0.05$.

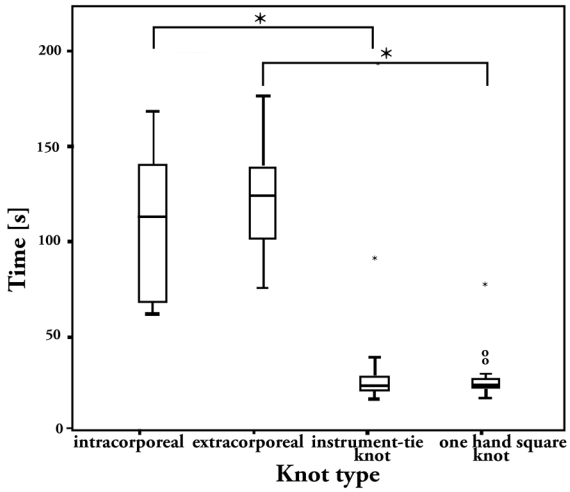


Figure 6. Time to complete the full suturing task (both Phase 1 and 2). Statistical analysis is done with one-way analysis of variance (ANOVA) and Bonferroni post hoc analysis; * = $p < 0.05$.

DISCUSSION

The forces applied during laparoscopic suturing are generally higher than during conventional surgery. This counts for both intracorporeal as well as extracorporeal knot tying. Furthermore laparoscopic suturing takes longer time than conventional suturing.

There are almost no differences in used forces between the two different laparoscopic knots. The higher mean force in Phase 2 during the extracorporeal knot tying can be explained by the fact that extracorporeal knot tying involves continuous traction on the threads. During intracorporeal knot-tying force is only applied during the tightening of the ligature. This is supported by the fact that the mean force non-zero is not different. There were no differences in applied forces between the two different conventional surgical knots. Therefore, it can be assumed that the method of surgery (conventional or laparoscopic) and not the type of surgical knot is the main cause of differences in applied forces.

In general the force values in the laparoscopic set-up were higher than those in the conventional set-up. This is most probably the result of several known complicating factors in MIS, such as the loss of haptic feedback due to resistance inside the trocars[5] and the use of long laparoscopic instruments[6]. Furthermore, limited motion freedom and degrees of freedom (DOF's) due to the use of long rigid instruments[13,14] hamper the surgeon's ability to assess applied forces. Factors such as loss of depth perception and special orientation due to two dimensional (2-D) vision[13,15,16] and perceived inversion of

movement from the handle to the working end of the instrument (fulcrum effect)[14,17,18] are also complicating factors, however they are expected to be of less influence since expert surgeons are known to adjust to these difficulties. Still, visual feedback in the non-clinical setting completely differs from visual feedback in the clinical setting. Although the non-clinical set-up simulates the laparoscopic surgery as realistically as possible by using a real camera and real instruments, visual feedback such as changes in tissue colour or bleeding are not provided. Therefore it is more difficult for the surgeon to adjust his or her strategy when it comes to tissue handling. Furthermore, the artificial skin mounted on the force measurement platform simulates skin and thus logically more resistance is experienced during the needle driving phase (Phase 1) compared to intra-abdominal structures. Higher resistance of the artificial tissue also influences the amount of force needed to drive the needle through. Because the same artificial skin model is used for all suturing tasks, the same bias can be expected in the laparoscopic as well as the conventional set-up. A comparison between the two will still give valuable information on this matter.

A strikingly higher amount of force, especially maximum force, is used in the laparoscopic set-up compared to the conventional set-up. During Phase 1 as much as 1.5 N and during Phase 2 even 2.65 N. In both cases on average the maximum amount of force in the laparoscopic set-up exceeds the range for tissue damage to occur in most intra-abdominal tissues. For example a study using porcine tissue to determine when tissue damage occurs showed that small intestines start to damage at 1,6 N and rupture at 2.1 N, whereas large intestine start to damage at 2.2 N and rupture at 3.0 N.11 Porcine bowels (large and small) have been shown to have comparable tissue characteristics to human bowels.[19] Even though the tissue characteristics of the used artificial tissue influence the necessary forces needed to drive the needle through the tissue during Phase 1 could explain a high force baseline, the same artificial tissue was used for all types of sutures and therefore does not explain a relative difference found in maximum applied forces between the different examined surgical strategies. Furthermore the tissue characteristics of the artificial tissue do not influence the forces needed during the knot tying phase.

A limitation of this study is the small number of experts (N=10), and that experts of different specialisms participated. Experts of different specialisms might have different preferences for certain knotting techniques in clinical practice and might therefore use a specific technique more frequently than others. This could cause group heterogeneity and therefore variance in the results. By only including experts in the laparoscopic field we tried to minimize this influence. The average time to complete the full intracorporeal

suturing tasks was 119 seconds (SD 46 seconds; median 117 seconds, range 61-153 seconds) (Figure 6). A previous validation study showed that experts in laparoscopic surgery perform the intracorporeal knot tying task with an average of 118 seconds (range 50-177 seconds).[20] Therefore it can be concluded that the experts included in the current study performed the intracorporeal suturing task on expert level for the time parameter.

CONCLUSION

In conclusion, expert surgeons apply significantly higher forces during laparoscopic surgery compared to conventional surgery even though the same strategy is used. Aspects such as the limited visual and haptic feedback, and movement possibilities hamper the surgeon's ability to assess the applied interaction forces. Therefore it can be useful to provide additional force feedback about the applied interaction forces during training in nonclinical settings.

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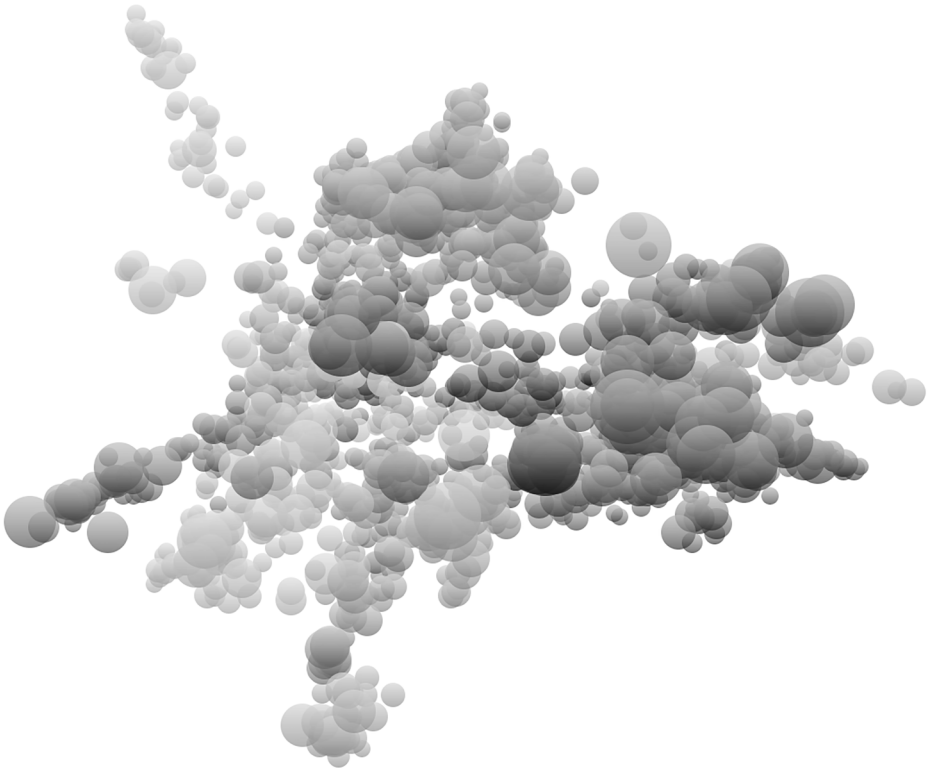
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CHAPTER 8

VISUAL FORCE FEEDBACK IN LAPAROSCOPIC TRAINING



ABSTRACT

Background

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.

Methods

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. 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).

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 visualisation 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.

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

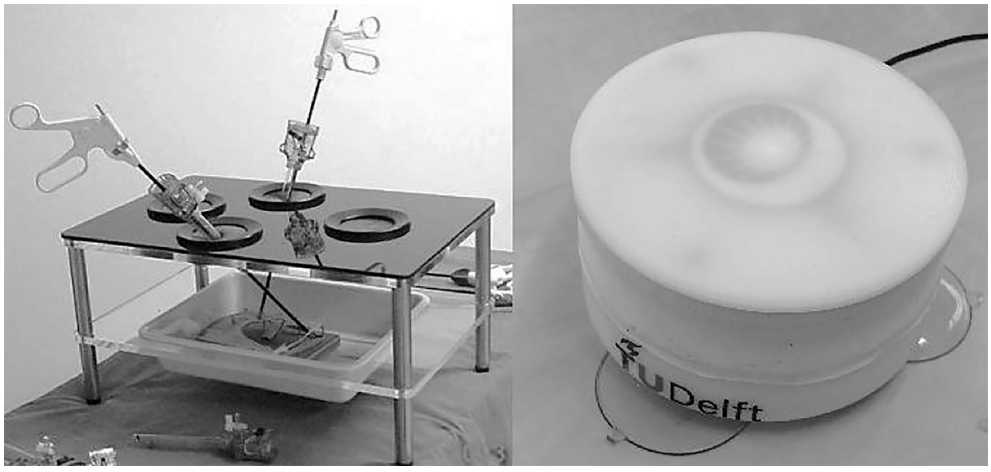


Figure 1. Left: standard box for laparoscopic training. Right: New and waterproof version of the Force Platform.

image will introduce time delays. Many studies suggest that time delays can distract the trainee due to unnatural visualisation 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.

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

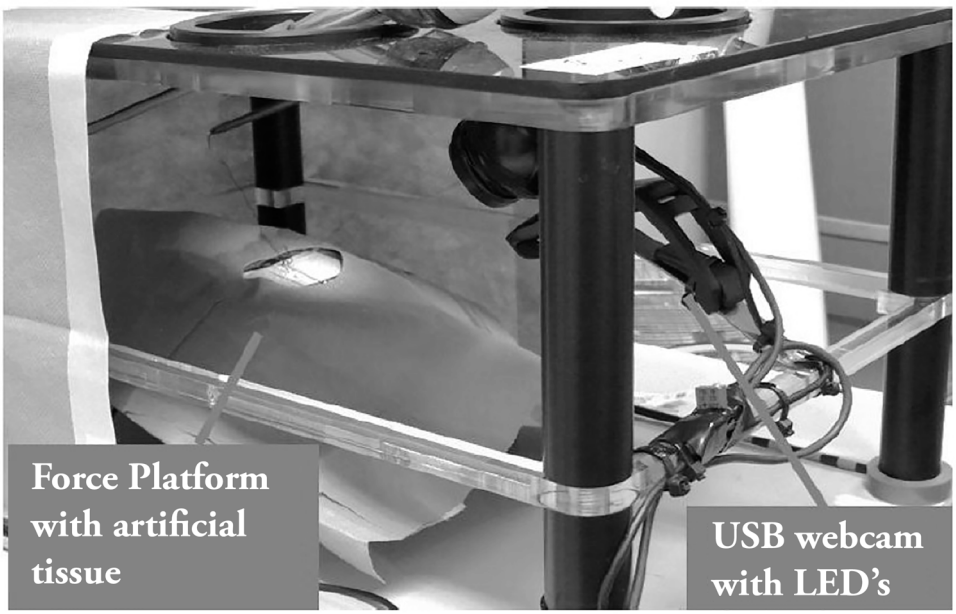


Figure 2. A webcam, light source and new force platform equipped with artificial tissue are fixed inside the custom made box trainer.

1 shows the latest version of the Force Platform and a standard box trainer that is commonly used in laparoscopic training.

Figure 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.

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

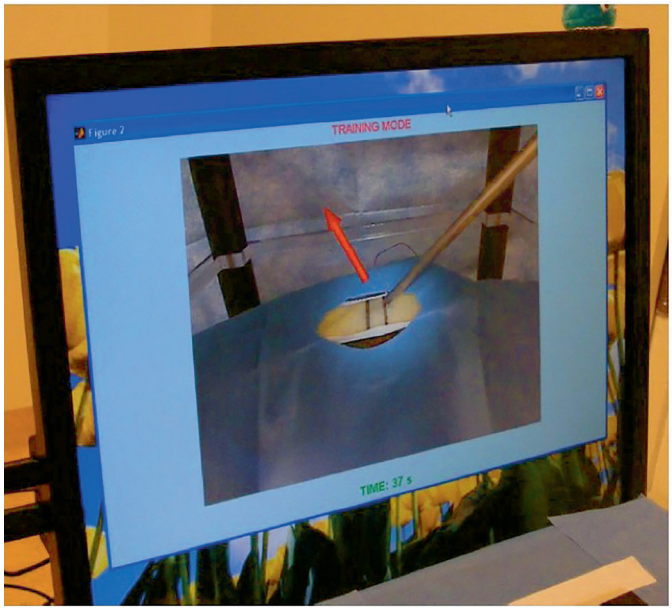


Figure 3. Arrow representation of the force magnitude and direction. The arrow is displayed as an overlay inside the laparoscopic image. An offset between point of needle insertion and arrow prevents blockage of the view of interest.

exerted on the training task and force platform. Figure 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.

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 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.

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 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

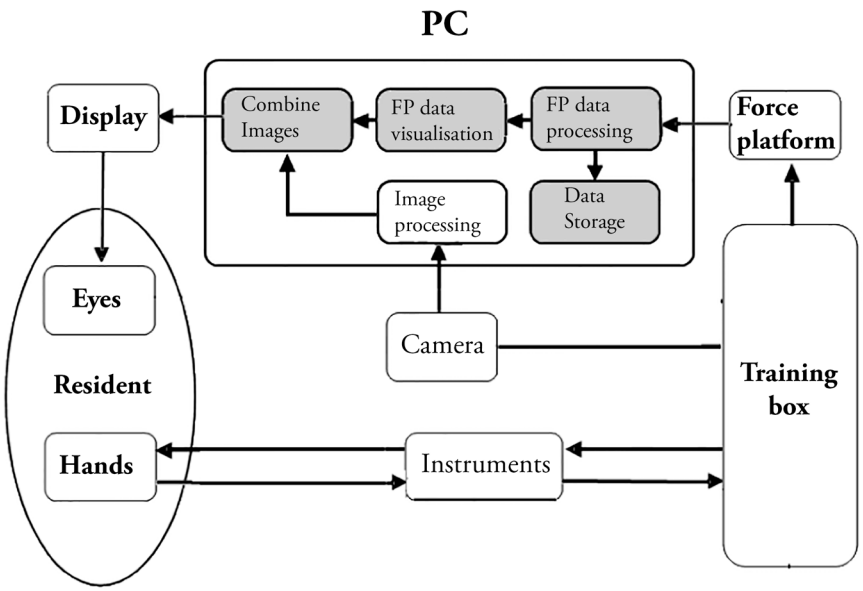


Figure 4. Time delays in the training system. The coloured blocks show where noticeable processing time is lost during training. The total time delay is determined by a summation of the delays in each individual coloured block in the representation.

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. 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.



Figure 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.

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 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 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.

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.

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”.

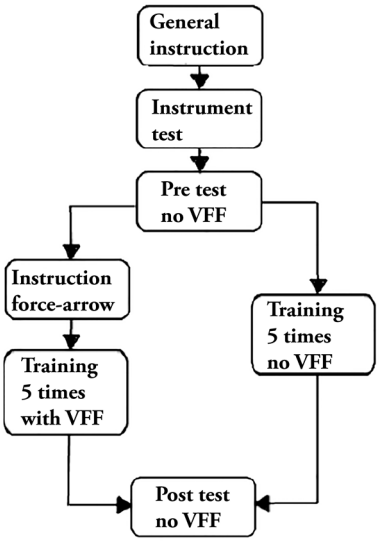


Figure 6. Setup of this pilot study. This illustration shows how the participants were divided over two groups. One group received visual feedback about the interaction forces (VFF) during the training session and one group received no visual feedback.

Pilot study - Needle driving task

Figure 7 displays 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 taught them that removing the curved needle with a rotational movement results in lower forces.

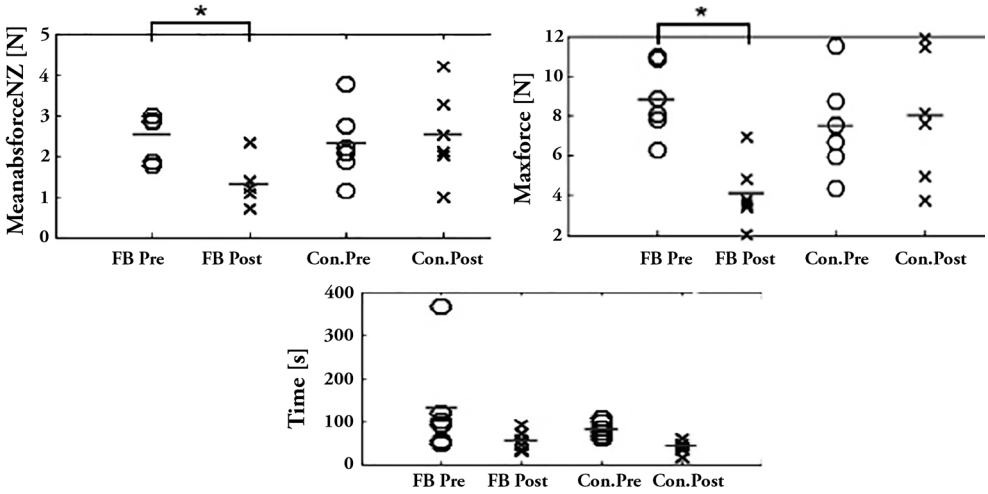


Figure 7. Results of the Pilot study. FB Pre: Pre-test of the group that received visual feedback. FB post: Post-test of the group that received visual feedback. Con.Pre: Pre-test of the control group that received no visual feedback. Con.Post: Post-test of control group that received no visual feedback. The "*" indicates that the difference between Pre- and Post-test is significant.

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 visualisation of 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 visualisation 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.

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 visualisation 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.

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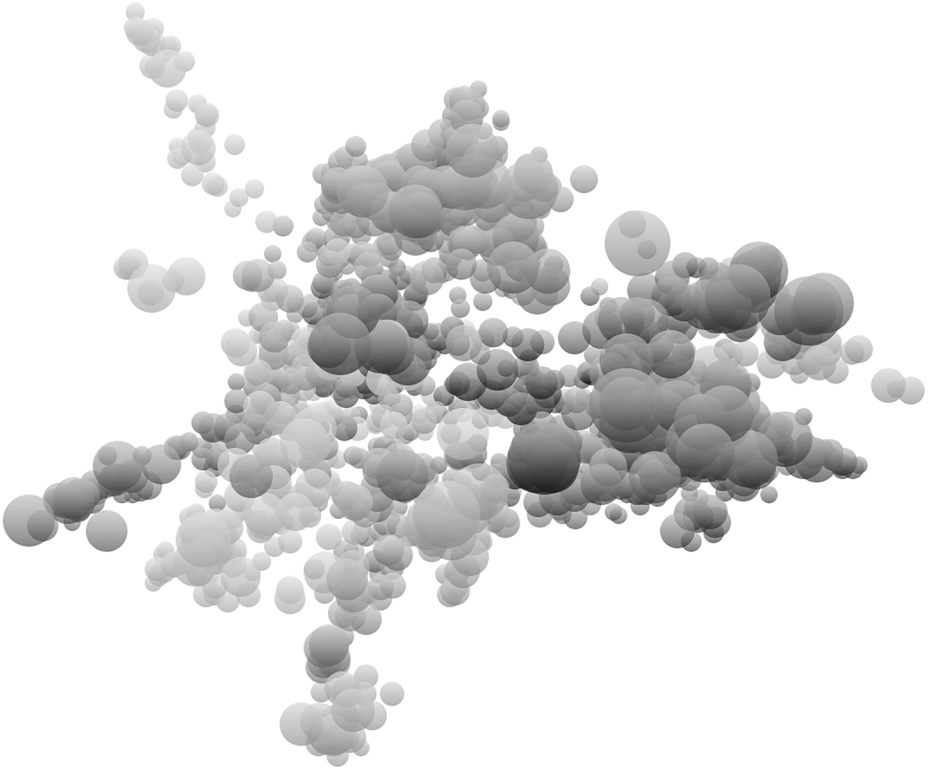
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CHAPTER 9

INFLUENCE OF VISUAL FORCE FEEDBACK ON TISSUE HANDLING IN MINIMALLY INVASIVE SURGERY



ABSTRACT

Background

Force feedback might improve surgical performance during minimally invasive surgery. This study sought to determine whether training with force feedback shortened the tissue-handling learning curve, and examined the influence of real-time visual feedback compared with postprocessing feedback.

Methods

Medical students without experience of minimally invasive surgery were randomized into three groups: real-time force feedback, postprocessing force feedback and no force feedback (control). All performed eight suturing tasks consecutively, of which the first and eighth were the premeasurement and postmeasurement tasks respectively (no feedback). Depending on randomization, either form of feedback was given during the second to seventh task. Time, mean force non-zero and maximum force were measured with a force sensor. Results of the groups were compared with one-way ANOVA, and intragroup improvement using a paired-samples t test.

Results

A total of 72 students took part. Both intervention groups used significantly lower interaction forces than the control group during the knot-tying phase of the postmeasurement task and improved their interaction forces significantly during the knot-tying phase. The form of feedback did not influence its effectiveness.

Conclusion

The tissue-handling skills of medical students improved significantly when they were given force feedback of their performance. This effect was seen mainly during the knot-tying phase of the suturing task.

INTRODUCTION

Basic surgical skills should preferably be developed in a non-clinical setting[1–3]. Complex surgical tasks performed in laparoscopic procedures place higher demands on the motor skills of the surgeon and require extensive training. Objective assessment of basic laparoscopic skills in the laboratory setting has been shown to be possible in box and virtual reality trainers. In box trainers motion-tracking systems provide information about economy of movement[4] and force-sensing systems about tissue-handling skills[5]. In general, this information is analysed and interpreted after completing a task (postprocessing), providing objective assessment (for example at examination) and individualization of the training programme. Individual trainees gain insight into which basic laparoscopic skills are still lacking so that an individual training programme can specifically focus on these areas.

The loss of haptic feedback in minimally invasive surgery, owing to resistance inside the trocars and the use of long laparoscopic instruments, hinders the estimation of applied forces in instrument–tissue interaction[6,7]. A force-sensing system has been developed that gives real-time feedback about the applied interaction force[5,8]. The real-time visualization of applied forces during training seems to facilitate the acquisition of tissue-handling skills for complex laparoscopic tasks[8], but the influence of real-time force feedback on the learning curves of trainees has not been established. Previous studies[7,9] indicated that there was no strong learning curve present in force parameter outcomes when no attention was drawn to the tissue manipulation force. The aim of this study was to determine whether training with real-time visual force feedback or postprocessing force feedback influenced the tissue-handling learning curve.

METHODS

Trainees were first to sixth year medical students with no previous laparoscopic experience. Students with extensive suturing experience were excluded. To show an improvement of 25 per cent in use of forces, the sample size for this study was calculated to be 24 trainees in each group based on the results of a pilot study[8].

Because novices have to adjust to all of the challenges that minimally invasive surgery poses, such as loss of depth perception and spatial orientation owing to two-dimensional vision[10–12], perceived inversion of movement from the handle to the working end of the instrument (fulcrum effect)[13–15], limited motion freedom because of the use of long rigid instruments[12,15] and loss of haptic feedback due to resistance inside the trocars[6], it was speculated that they would have the greatest advantage of training on tissue handling

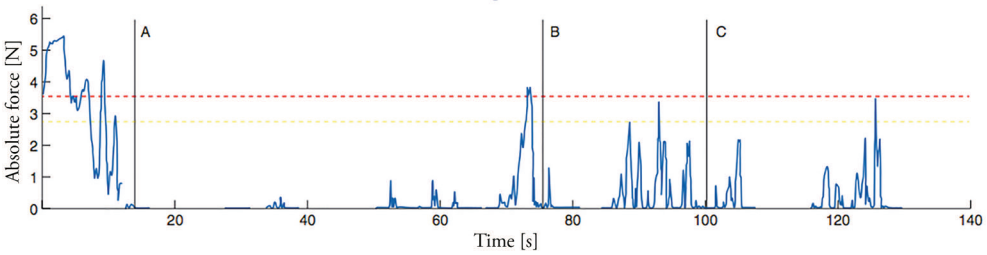


Figure 1. Post processing feedback. The yellow line represents the 75% allowable force limit (2.5 N) and the red line represents the maximal allowable force limit (3.5 N).

after they had had a chance to adjust to the other factors. All participants, therefore, received pretrial training consisting of six suture tasks. No force-related feedback was provided during these pretraining sessions,.

Each participant completed a questionnaire about their personal characteristics (age, sex, dominant hand, year of study), previous experience (games and musical instruments), self-rated dexterity and interest in surgical specialization, measured on a 7-point Likert scale. After the training, they were asked to rate their dexterity and interest in surgical specialization again, and to rate the exercise on level of difficulty and the degree of frustration experienced during the exercise, all on a 7-point Likert scale.

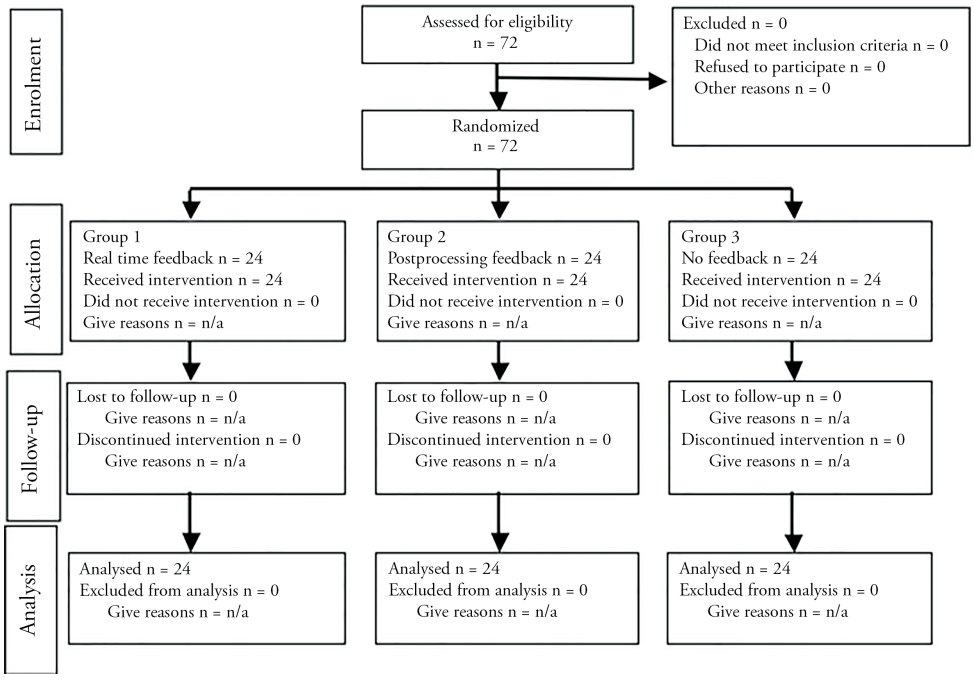


Figure 2. Diagram of randomization.

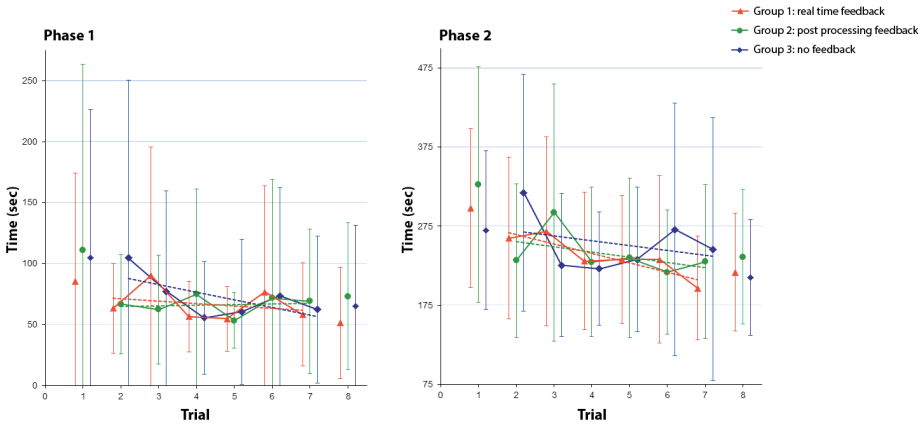


Figure 3. Learning curve for time: a phase 1 and b phase 2. The dotted lines are linear trend lines fitted to the mean data points of training trials 2–7

A similar experimental set-up was used as described in the pilot study[8]. This included a force sensor to measure time and force in laparoscopic box trainers ranging from 0 to 10 N in three dimensions, with an accuracy of 0.1 N and a measurement frequency of 60 Hz. A webcam was used to capture images of the work space of the instruments[8]. A box trainer illuminated to simulate laparoscopic surgery was equipped with two trocars and two needle drivers (Ethicon E705R 5 mm; Johnson & Johnson, Norderstedt, Germany). Artificial tissue (Professional Skin Pad, Mk 2; Limbs & Things, Bristol, UK) was mounted on top of the force platform. All forces exerted by straight laparoscopic instruments on the artificial tissue were measured.

A user interface built in MATLAB displayed the camera image inside a separate screen while data were recorded from the force platform at a rate of 30 Hz. Data were saved in arbitrary units together with a time vector. Because the relationship between the force sensor output and the applied forces in newtons is known after calibration, the output was computed in newtons[5].

Participants were asked to perform a suturing task consisting of two phases: needle-driving and knot-tying. In the first phase, they had to drive a needle (PremiCron® 3/0 braided coated suture with a half-circle round-bodied needle and taper point 26 mm long; B. Braun, Oss, The Netherlands) through the artificial tissue mounted on the force platform, inserting and exiting the needle at predetermined positions (indicated with 2 lines) over a distance of 8 mm. The trainee was then asked to move the left needle driver behind the thread while holding the needle in the right needle driver. The thread was spiralled around the left needle driver twice. With the left needle driver the short end of

the thread had to be grasped and pulled over the artificial tissue. Next, the thread was spiralled once around the right needle driver and pulled into a knot. The last action was repeated at the left needle driver, constructing a three-loop knot.

A video of a knot-tying task was shown twice to participants before the pretrial training and before the trial training. During the pretrial training, they also received explanation of the knot-tying task using a schematic figure. In the pretrial training session students executed a series of six knot-tying tasks. Between a minimum of 1 week and a maximum of 2 months, each trainee received subsequent training in which a series of eight suturing tasks were performed consecutively. Trainees received no feedback during the premeasurement (1st trial) and postmeasurement (8th trial) tasks.

Participants were randomized into three groups. Group 1 received real-time force feedback, whereby an arrow was displayed inside the camera image. The arrow represented the magnitude and direction of the force, and increased in size as greater force was applied. At first the arrow was green (representing allowable force). With an increase to 75 per cent of the allowable force it turned yellow (2.5 N), and when the maximum allowable interaction force was exceeded (3.5 N) it turned red to indicate tissue damage. Trainees received explanation on the interpretation of the arrow as described above before and during the trial.

Group 2 received postprocessing feedback. After performing each single knot-tying task, the trainee received feedback in the form of a graph in which task performance was shown. A yellow line represented the 75 per cent of the allowable force limit (2.5 N), and a red line the maximum allowable force limit (3.5 N) (Fig. 1). Individual results were discussed and the trainee was shown when exerted forces were too high during the training. The trainee was reminded to prevent excessive force during the entire task. Group 3 (control) received no feedback on the applied interaction forces.

The mean time to complete the two separate phases was recorded. Two force parameters were used to describe the results: mean force non-zero and maximum force applied. The mean force non-zero was defined as the force averaged across all time points of the task during which force was exerted so that the resulting measure was based only on the times when interaction with the tissue took place (interaction force more than 0.01 N). Maximum force was the highest force applied during that phase.

Statistical Analyses

Results are reported as mean(s.d.). Statistical analyses were performed using Chi square test and one-way ANOVA for the demographic data, and one-way ANOVA plus Bonferroni post hoc tests for comparisons between the three groups in each phase. Differences between premeasurement (trial 1) and postmeasurement (trial 8) tasks, representing the improvement in a specific parameter, were tested using the paired-samples t test for each group in each phase. $P < 0.050$ was considered statistically significant. Data were analysed by SPSS® version 16.0 (IBM, Armonk, New York, USA).

Table 1. Trainee characteristics

	Real-time feedback (group 1, n = 24)	**Postprocessing feedback (group 2, n = 24)**	**No feedback (group 1, n = 24)**	**P†**
Age (years)	21.3(2.4)	21.3(2.2)	20.7(1.8)	0.536
Sex ratio (M : F)	6 : 18	10 : 14	11 : 13	0.288††
Mean year of study	3.42(1.06)	3.29(1.46)	3.17(1.40)	0.807
Time between pretrial training and trial (months)				
1–2	11	10	10	
< 1	13	14	14	
Interest in a surgical specialization*				
Before training	4.63(1.06)	5.21(1.22)	4.71(1.12)	0.176
After training	4.63(1.10)	5.26(1.01)	5.00(1.03)	0.148
Overall skill*				
Before training	4.50(0.83)	4.42(1.25)	4.54(0.83)	0.906
After training	4.21(0.98)	4.43(1.08)	4.09(1.00)	0.504
Computer skills*	3.75(1.19)	4.12(1.51)	3.96(1.52)	0.657
Difficulty of the training*	5.00(0.83)	5.30(1.02)	5.00(0.91)	0.435
Frustration after the training*	4.25(1.51)	4.61(1.56)	3.61(1.41)	0.078

Values are mean(s.d.), unless indicated otherwise. *Scored on 7-point Likert scale. † One-way ANOVA †† Chi square test.

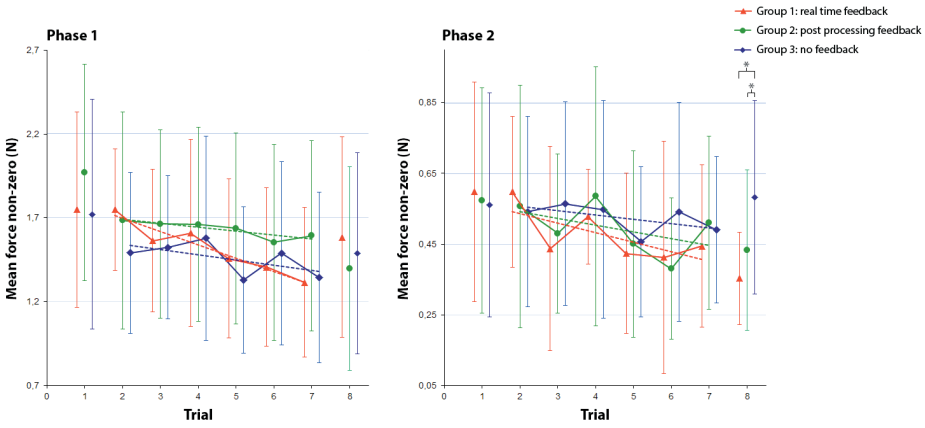


Figure 4. Learning curve for mean force non-zero: a phase 1 and b phase 2. The dotted lines are linear trend lines fitted to the mean data points of training trials 2–7. *P < 0.050 (one-way ANOVA and Bonferroni post hoc test)

RESULTS

A total of 72 students were randomized (Fig. 2). Their baseline characteristics are shown in Table 1. There were no differences between groups, and no difference in performance between men and women. Trainees with a waiting period of more than 1 month between the pretrial training and the trial were divided between the three groups by randomization. There were no significant differences between the three groups at the start of the training (trial 1, premeasurement), either in time or interaction forces.

The mean time, mean force non-zero and mean maximum force during all trials are shown in Figs 3–5. In general, there were no structural differences measured between the three groups during the intervention (trial 2–7). For the postmeasurement task (trial 8), there were no differences in time or interaction forces during the needle-driving phase. In the knot-tying phase of the postmeasurement task, however, the mean force non-zero of both intervention groups (groups 1 and 2) was significantly lower than that in the control group (group 3). The maximum force in group 1 was significantly lower than that in group 3, but was not significantly different between groups 2 and 3. The mean time taken to complete trial 8 was similar in all three groups.

The improvement in group 1 was mainly seen during the knot-tying phase (Table 2), where time as well as all interaction forces improved significantly. During the needle-driving phase, group 1 alone showed a significant improvement in time. The interaction forces in phase 1 did not show any improvement. Group 2 improved significantly in all

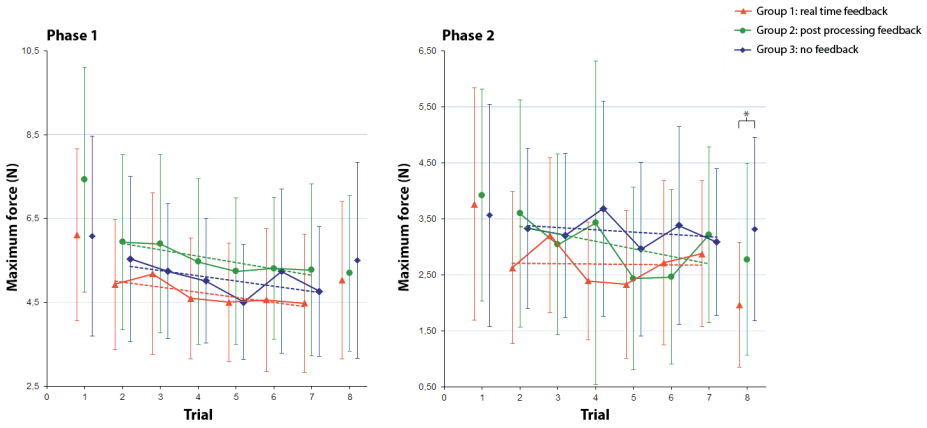


Figure 5. Learning curve for maximum force: a phase 1 and b phase 2. The dotted lines are linear trend lines fitted to the mean data points of training trials 2–7. *P < 0.050 (one-way ANOVA and Bonferroni post hoc test)

parameters during both phases, except for time during the needle-driving phase. Group 3 showed no improvement, except in time during the knot-tying phase.

DISCUSSION

Feedback about interaction forces has been shown to facilitate training of tissue-handling skills in novices[8,9]. The aim of this study was to determine whether training with real-time visual force feedback or postprocessing force feedback influenced the tissue-handling learning curve. Significant differences were found in force parameter outcomes between the pre- and post-tests of the intervention groups that received post-test and real-time feedback during training. There were no meaningful differences in interaction forces between either of the intervention groups and the control group during the training, when feedback was given (trial 2–7).

Data for the training session alone suggest no added value of either type of feedback on interaction forces during training. However, during the knot-tying phase of the postmeasurement, both intervention groups used significantly lower interaction forces than the control group. This improvement by the two intervention groups, not seen in the control group, implies a learning curve in tissue handling based on the given feedback. Despite there being no difference between the two groups, real-time force feedback means that trainees are able to develop tissue-handling skills without the need for a tutor by their side to give instructions.

Table 2 Comparison of premeasurement (trial 1) and postmeasurement (trial 8) results				
	Trial 1*	**Trial 8***	**Improvement (%)**	**P†**
Phase 1: needle-driving				
Group 1				
Time (s)	86(89)	52(46)	40	0.040
Mean force non-zero (N)	1.75(0.58)	1.59(0.60)	–	0.230
Maximum force (N)	6.11(2.04)	5.03(1.87)	–	0.056
Group 2				
Time (s)	111(153)	73(60)	–	0.183
Mean force non-zero (N)	1.97(0.64)	1.40(0.61)	29	0.003
Maximum force (N)	7.43(2.68)	5.19(1.86)	30	0.001
Group 3				
Time (s)	105(121)	65(66)	–	0.258
Mean force non-zero (N)	1.72(0.68)	1.45(0.59)	–	0.136
Maximum force (N)	6.08(2.38)	5.38(2.27)	–	0.258
Phase 2: Knot-tying				
Group 1				
Time (s)	298(101)	218(73)	27	0.003
Mean force non-zero (N)	0.60(0.31)	0.36(0.13)	40	< 0.001
Maximum force (N)	3.76(2.08)	1.96(1.09)	48	< 0.001
Group 2				
Time (s)	328(149)	234(83)	29	0.010
Mean force non-zero (N)	0.57(0.32)	0.41(0.20)	28	0.033
Maximum force (N)	3.92(1.89)	2.59(1.51)	34	0.005
Group 3				
Time (s)	270(100)	210(73)	22	0.019
Mean force non-zero (N)	0.56(0.32)	0.58(0.27)	–	0.717
Maximum force (N)	3.56(1.98)	3.32(1.64)	–	0.614

*Values are mean(s.d.). Group 1, real-time feedback; group 2, postprocessing feedback; group 3, no feedback. †Paired-samples t test.

All participants in this study were surgical novices who received pretrial training in which they performed six intracorporeal sutures without any force-related feedback. This might have influenced the effect seen on the learning curve, leading to an underestimation of the effect of visual force feedback during training. The difference in time between the pretrial training session and the session in this study varied between 1 week and 2 months owing to the capacity of the skills laboratory and limited hours of the instructor who took the measurements during the pretrial training session. Although a previous study[16] showed that tissue-handling skills can diminish after 1 month, randomization

resulted in no differences between the three groups in time between the pretrial training and the study itself, so this effect was likely to be similar in each group.

Before the start of the study it was speculated that the novices should have some insight into the altered depth perception, the fulcrum effect and the use of long, rigid instruments in order for them to be able to focus completely on tissue handling. These are all factors that the novice surgeon must appreciate before tissue handling, so the present experimental design attempted to reproduce this. It is accepted, however, that these factors could influence the trainee's tissue-handling skills. If novices had passed through the steepest part of their learning curve because they had already learned to adjust to depth perception, the fulcrum effect and the use of long, rigid instruments before start of the trial, this would obviously affect the learning curve measured in the present study. It may be that the learning curve for fine-tuning tissue handling is much longer than the eight trials measured in this study. Other studies investigating the learning curves for suturing or knot-tying have identified an exponential decline in knotting time and increase in knot quality, mainly achieved after 20–30 knots[17], and a suturing learning curve that reaches a plateau after 8 days of training, with a total training time per individual of 24 h[18].

Previous studies[19,20] have shown a benefit of short regular training over massed practice for simple as well as complex laparoscopic training tasks. They suggest that in learning difficult skills, such as laparoscopic techniques, cerebral processing saturates rapidly and concentration diminishes. Fatigue then limits further learning. In the present study, novices performed eight suturing tasks consecutively. This protocol might have limited learning owing to fatigue, although the effect should be similar in the three groups.

Based on the pilot study[8] it was expected that there would be a difference in the interaction forces used during the needle-driving phase, in favour of the feedback groups. No relative or absolute differences between the three groups were found, however. The most likely reason is that the task performed in this study (complete suture task) was more complex than the needle-driving task alone used in the pilot study. As needle-driving in this study was only a part of the total task, it seems that trainees were satisfied when the needle had been driven through the tissue successfully and then focused on the more complex knot-tying part of the task. Because the complete suture task requires a larger cognitive component than the needle-driving task alone, it is likely that a greater focus on forces exerted on the needle during the short needle-driving phase results in a greater reduction in force, as shown previously[8]. This suggests that complex tasks should be divided into smaller, simpler tasks, which are trained individually to create optimal

learning circumstances.

Learning motor skills involves cognitive, associative and autonomous stages: the trainee tries to understand different steps of the task; practices the skill, integrating the knowledge of the task into the appropriate motor behaviour; and then the skill is performed without cognitive awareness[21]. Feedback is thought to play a major role in the first two stages, but especially during the associative phase. It is during these stages that real-time visual force feedback should be incorporated into laparoscopic skills training. In the autonomous stage, force parameters could still be measured as ways of assessing the level of the trainee, for example as part of an examination.

Trainees who practise exercises that mimic clinical situations seem to have better clinical outcomes than those who are not trained[22]. Regarding tissue-handling skills specifically, a previous study showed that acquired tissue manipulation skills learned with visual force feedback are transferrable to a different task[9]. Making trainees aware that high exerted forces in a box trainer are related to errors in surgical performance allows them to adjust and improve their technique, and this is likely to be beneficial in clinical surgery. Future research might include other outcome measures related to the strength of the knot, tension of the loop and tear of the tissue as indicators of the quality of the suture performed.

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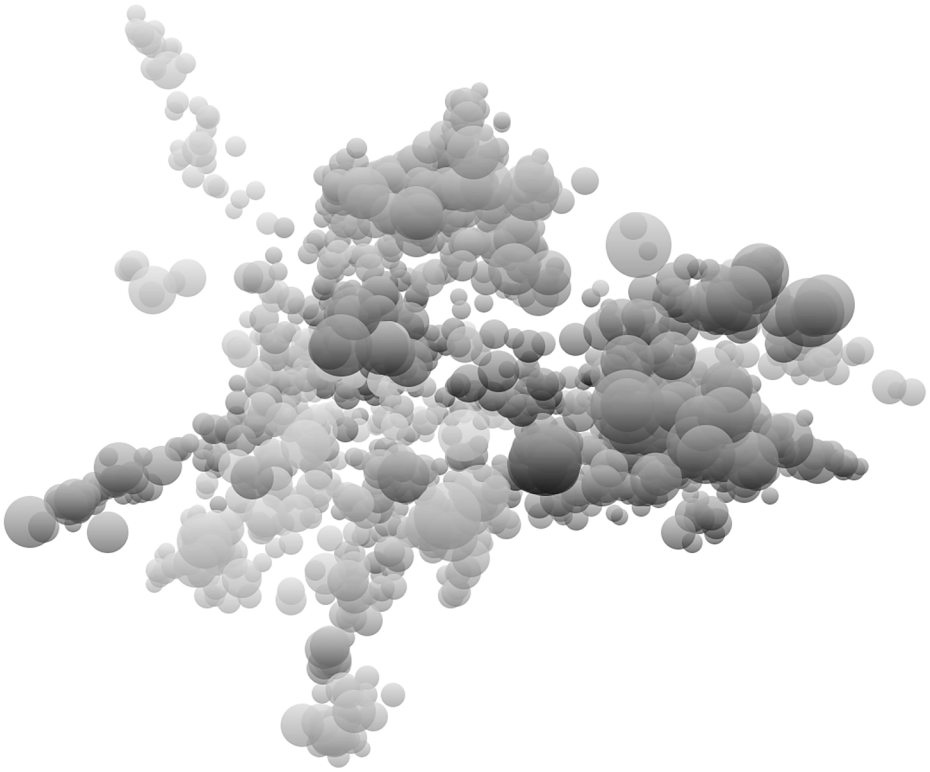
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CHAPTER 10

LAPAROSCOPIC SUTURING LEARNING CURVE: THE 3-D EFFECT



ABSTRACT

Background

The aim of this study is to examine the influence of training under direct (3D) vision prior to training with 2D vision on the learning curve of the laparoscopic suture task.

Methods

Novices were randomized in two groups. Group 1 performed three suturing tasks in a transparent laparoscopic box-trainer under direct vision followed by three suturing tasks in a standard non-transparent laparoscopic box-trainer equipped with a 0° laparoscope. Group 2 performed six suturing tasks in a standard laparoscopic box-trainer. Performance time, motion-analysis parameters (economy of movements) and interaction force parameters (tissue handling) were measured. Participants completed a questionnaire assessing: self-perceived dexterity before and after the training, experienced frustration and the difficulty of the training.

Results

In total 34 participants were included, one was excluded because of incomplete training. Group 1 used significantly less time to complete the total of six tasks (27%). After the training there were no differences in motion or force parameters. Group 2 rated their self-perceived dexterity after the training significantly lower than before the training and also reported significantly higher levels of frustration compared to group 1. Both groups rated the difficulty of the training similar.

Conclusion

Novices benefit from starting their training of difficult basic laparoscopic skills, e.g. suturing, in a transparent box trainer without camera. It takes less time to complete the tasks and they get less frustrated by the training with the same results on their economy of movements and tissue handling skills.

INTRODUCTION

It is well established that the apprenticeship model is insufficient for acquiring minimally invasive surgical (MIS) skills and that basic MIS skills should preferably be trained in a non-clinical setting to ensure patient safety.[1-4] Simulator training programs are widely implemented into surgical, urological and gynaecological resident curricula.[5;6] Some of the challenges that MIS poses to surgeons and surgeons in training are:

- loss of depth perception and special orientation due to two dimensional (2-D) vision[7-9],
- perceived inversion of movement from the handle to the working end of the instrument "the fulcrum effect of the abdominal wall"[10-12],
- loss of haptic feedback due to resistance inside the trocars[13] and the use of long laparoscopic instruments[14],
- limited motion freedom and degrees of freedom (DOF's) due to the use of long rigid instruments[9;12].

It is known that expert MIS surgeons learn to adjust to and compensate for these challenges. But when novices first start training of their basic MIS skills they have to adjust to all these challenges at the same time making acquiring these skills a notoriously difficult task. Lack of training due to lack of time and motivation is a known problem, even though it is generally agreed among residents that simulation training of MIS skills is essential and should be obligatory.[15-17]

Allowing novices to gradually adjust to the challenges MIS poses, by letting them train under direct 3D vision before they switch to 2D vision, could be of benefit both in time consumption and in motivation. In theory the main benefit would be that they do not have to compensate for the lack of depth perception and special orientation at the same time as learning how to manipulate the long rigid instruments and adjusting to the fulcrum effect. Compensating for a lack of depth perception requires the novice to use a variety of 2D cues such as light and shade, relative size of organs, organ interposition, texture gradient, aerial perception and motion parallax.[7] Because the effect is speculated to be more extensive in complex tasks compared to simple tasks we chose to examine the effect of direct 3D vision on the learning curve of the laparoscopic suture task. The aim of this study is to examine the influence of training under direct vision prior to training with 2D vision on the learning curve of the laparoscopic suture task. To this extend we examine the consumed training time, the economy of movements, tissue handling skills and the novice's opinion during the training.

METHODS

Study population

Novices (i.e. first and second year medical students in the preclinical phase of their studies) were recruited by means of advertisement on bulletin boards in the medical faculty of Leiden and in the medical library of the Leiden University Medical Center (LUMC). They participated on a voluntary basis. Students with prior laparoscopic or simulator experience as well as students with prior experience in suturing more than once were excluded. After enrolment, participants completed a questionnaire providing demographic information (i.e. gender, hand dominancy, prior suturing experience, experience in computer gaming, and self-perceived dexterity on a 7 point Likert scale). Novices were randomly assigned to either the intervention or the control group using the website www.randomization.com. In both groups, novices performed one intracorporeal suture task six consecutive times (see detailed description below). The intervention group first performed the training task three times under direct vision in the interventional set up (trial one till three). Following these three interventional trials the novices in the intervention group performed the training task three times in the control set up (trial four till six). The control group performed the training task six times in the control set up (trial one till six).

Training set up

The laparoscopic box trainer was equipped with a TrEndo tracking system[18] for motion analysis and force measurement platform[19] for analysis of interaction forces (Figure 1). Participants used two laparoscopic needle drivers (Ethicon, E705R), one in each hand. Since none of the subjects had previous experience with needle drivers, each subject had the opportunity to manipulate the buttons and handle for 5 minutes outside the training box before the first training task.

Both the intervention group and the control group performed their training task in the same training set up with the mere difference that the intervention group could look through the transparent cover of the box during the intervention. By consequence, the effect of training with 3D vision prior to training under regular conditions can be investigated.

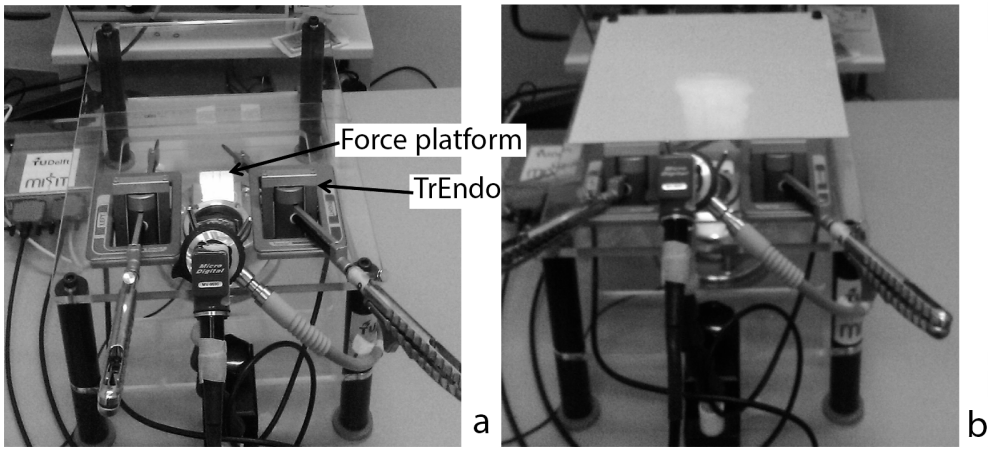


Figure 1. Physical box trainer (LUMC, Leiden). 1a. Experimental (open) set up with transparent top so that the novices could look at the task under direct (3D) vision. 1b. Standard (closed) set up, the transparent top was covered with a non-transparent plate and the image of a 0º scope was presented on a monitor in a fixed position (2D vision).

Task

Prior to training the task, a demonstration video was shown. Then, a step-by-step graphical explanation of the knot tying technique was shown Figure 2. Next, the video was demonstrated again while instructions were given about specific requirements (entry and exit point of the needle, when to use a double and single loop etc.). The training task consisted of the placement of a simple suture followed by tying an intracorporeal knot in a standardized way. The exercise started with the needle (Vicryl 3-0 SH plus 26 mm, Ethicon, Johnson & Johnson) prepositioned in the needle driver and both needle drivers on a pre-marked place (start position). A proper bite (8 mm) has to be taken of the suturing pad in a pre-marked area. After pulling the needle and a substantial part of the thread through, a 3-throw knot was tied. This was done by making a double forward loop, followed by a single reverse loop, and finally a single forward loop. During the training the researcher coached a participant, if necessary, to perform the task correctly and to ensure that every suture was performed in the standardized manner.

For analysis of each trial (six per participant) the suturing task was divided in two phases:

1. Needle driving phase: driving the needle through the artificial tissue
2. Knot tying phase: three throws to tie the knot.

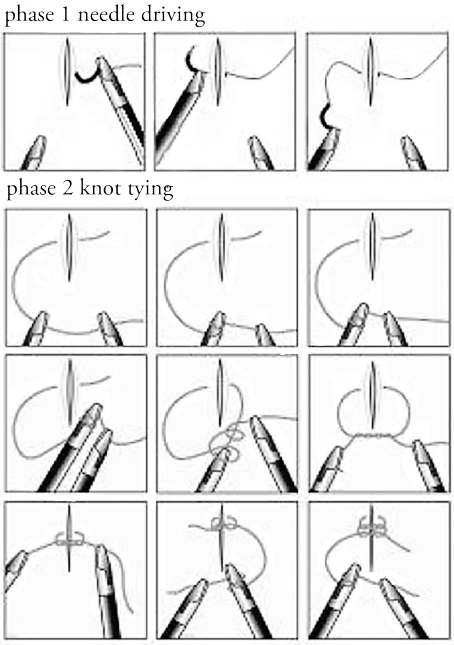


Figure 2. Step by step overview of the suture task performed each trial. During Phase 1 the needle is driven through the artificial tissue in a pre-marked area. During Phase 2 a standardized three throw square knot is formed.

Outcome Measures

During the training session the total time taken to perform each trial was recorded to get insight in the speed at which a trial could be successfully performed. Furthermore, the movements of the tip of the instruments were recorded with the TrEndo tracking device, developed at Delft University of Technology.[18] Consequently, motion-analysis parameters were established of which we decided to analyze the following validated economy of movement parameters[20]:

- Path length: defined as the average length of the curve described by the tip of the right and the left instrument while performing the task (mm). Path length represents the economy of movements.
- Volume: defined as an ellipsoid around the standard deviation of the path length in 3 dimensions for both the right as well as the left instrument (mm^3). Volume represents the precision of movements with less influence of single outliers.

A force measurement platform, developed at Delft University of Technology, was used to measure the maximum force and the mean absolute nonzero force in Newton (N) as described by Horeman et al.[19] Finally we also chose to analyze the volume, which is calculated as the volume of an ellipsoid around the standard deviations in the three axes. This parameter was chosen because it represents the accuracy in which interaction forces are applied, i.e. tissue handling.

All performed tasks were assessed on a three-point scale for:

- correct entry and exit of the needle in the artificial tissue (2 points at exact entry and exit on the predetermined points, 1 point if entry and/or exit point deviated less than 1 mm, 0 points if entry and/or exit deviated more than 1 mm),
- how tight the knot was pulled (2 points for correct tightness, 1 point if the knot was too tight with compression of the artificial tissue or too loose with a margin less than 1 mm, 0 points when the knot was too loose with a margin more than 1 mm),
- slipping of the knot (2 points if for no slipping, 1 point for slipping less than 1 mm, 0 points for slipping more than 1 mm).

After the training participants were asked again to complete a questionnaire in which they assessed self-perceived dexterity after the training and they were asked to rate their experienced frustration and difficulty of the training all on a 7 point Likert scale.

Statistical analysis

Statistical analysis of the data was done with the Statistical Package for Social Sciences (SPSS, version 16.0, Chicago, IL). Proficiency gain curves for time, path length, volume, maximum force, mean absolute non-zero force and force volume are plotted as mean's with 95% CI. Differences in these parameters between the intervention and control group were determined with the independent samples t-test ($p < 0.05$). Differences in suture quality between the two groups were determined with the Chi-square test ($p < 0.05$). Differences in assessed self-perceived dexterity, frustration and difficulty of the training were determined with the independent samples t-test ($p < 0.05$).

RESULTS

Participants

A total of 33 participants were included of which one was excluded because the training was not completed. The demographic information of the two groups is shown in Table 1. There were no differences in gender, hand dominancy, prior suturing experience, experience in computer gaming, and self-perceived dexterity prior to the training.

Table 1. Demographic information of the study population

Characteristic		Group 1 Mean (N=18)	Group 2 Mean (N=14)	*P-value*
Gender (N)	Male	6	7	NS
	Female	12	7	
Age (mean)		21.5	20.5	NS
Hand dominancy (N)	Left	2	2	NS
	Right	16	12	
Prior suturing experience (N)	Yes	4	6	NS
	No	14	8	
Experience in computer gaming (N)	Yes	7	6	NS
	No	11	8	

Time

The proficiency gain curves of time to complete the suturing task for both the needle driving phase and the knot tying phase are shown in Figure 3A and Figure 4A. The figures show that novices in the experimental set up group use significantly less time to complete the needle driving task during trial 3, e.g. the last task in the open box trainer before they switch to a standard box trainer. A significant amount of time is saved during the knot tying phase in the experimental set up. All knot tying tasks in the open box trainer are preformed significantly faster than in the standard box trainer (trail 1-3). In Group 1 the total amount of time spend on performing all six trials ranged between 7 and 23 minutes with a mean of 11 minutes. In Group 2 the total amount of time spend on performing all six trials was significantly higher and ranged between 10 and 26 minutes with a mean of 15 minutes. Group 1 uses 27% less time than Group 2 to perform the full training.

Economy of movements

Figure 3B-E and Figure 4B-E illustrate the proficiency gain curves of the path length and volume of the left and right hand. Differences between in motion parameters, if any, are seen in the first three trails when novices are training in different set ups. These differences are washed out when Group 1 switches from the experimental set up to the standard set up.

Interaction forces

During the first trial novices in the experimental set up use significantly less interaction forces than novices in the standard set up (Figure 3G-H and Figure 4G-H). This is seen in the needle driving phase as well as the knot tying phase. However, except for the maximum force used during trial the needle driving phase of trial 2 there are no differences in interaction forces during trial two till six.

Suture quality

There were no significant differences between the two groups in entry or exit points of the needle, tightness of the knot nor slipping of the knot. There were no differences seen in any trial.

Questionnaire

The average self-perceived dexterity of novices before training was similar in both groups. However, after training the novices that had trained in the standard training set up rated their self-perceived dexterity significantly lower than novices who had trained on the experimental set up. Furthermore, novices that had trained in the standard training set up had experienced significantly higher levels of frustration than novices in who had trained on the experimental set up. Both groups rated the difficulty of the training similar. Mean given rates are shown in Table 2.

Table 2. Results questionnaire

	Group 1	**Group 2**	
Question	Mean (N=18)	Mean (N=14)	*P-value*
Self-perceived dexterity before training (mean)	5,00	4,67	NS
Self-perceived dexterity after training (mean)	4,79	3,94	0,023
Frustration assessed after training (mean)	2,43	4,06	0,003
Difficulty assessed after training (mean)	4,29	4,83	NS

Results of the questionnaire on self preceived dexterity, frustraion and difficulty of the training rated on a 7 point Likert scale.

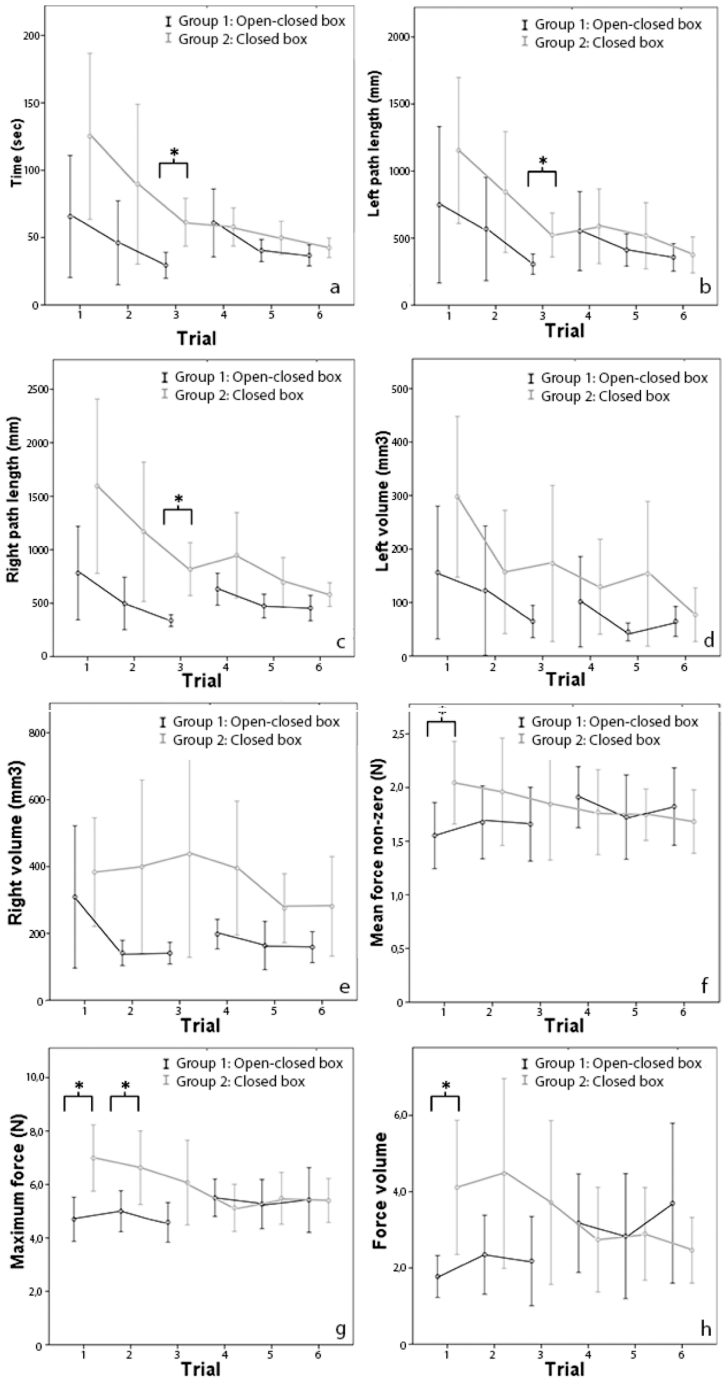


Figure 3. Learning curves of Phase 1, the needle driving phase. In Group 1 trial 3 is the last task in the open box trainer (with transparent top) before they switch to a standard (closed) box trainer. a, Time; b and c, left and right path length; d and e, left and right volume; f, mean force non-zero; g, maximum force; h, force volume; * $P < 0.05$.

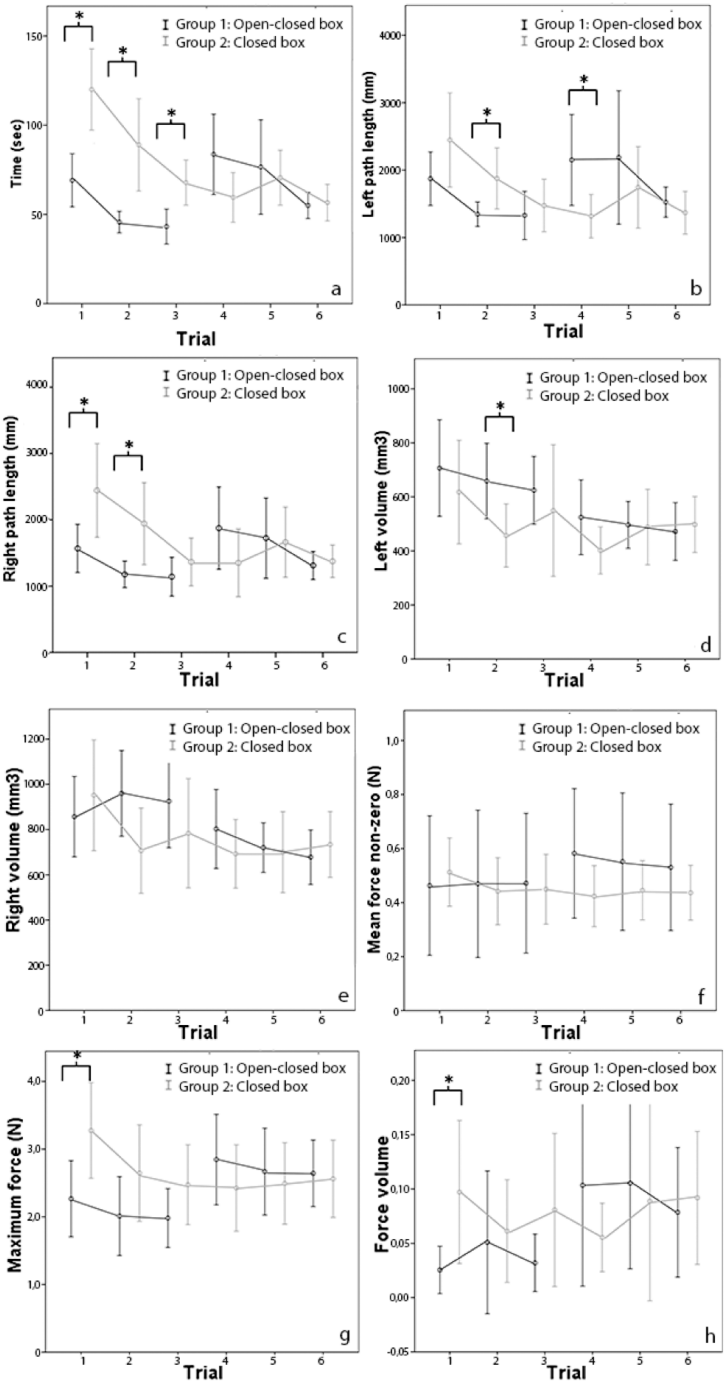


Figure 4. Learning curves of Phase 2, the knot tying phase. In Group 1 trial 3 is the last task in the open box trainer (with transparent top) before they switch to a standard (closed) box trainer. a, time; b and c, left and right path length; d and e, Left and right volume; f, mean force non-zero; g, maximum force; h, Force volume; * $P < 0.05$.

DISCUSSION

Main findings

In standard laparoscopic trainings set ups novices have to adjust to all challenges MIS poses at once. With this study we have shown that by exposing novices to these adjustments in a second stage they save ~27% in time and they rate the training as less frustrating. This could affect novices' motivation for training MIS skills. By allowing them to start their training under direct vision instead of with 2D vision, they do not have to compensate for the lack of depth perception and special orientation at the same time as learning how to manipulate the long rigid instruments and adjusting to the fulcrum effect. As mentioned before, compensating for a lack of depth perception requires specific additional skills from the novice such as the use of a variety of 2D cues such as light and shade, relative size of organs, organ interposition, texture gradient, aerial perception and motion parallax.[7]

Strengths and Limitations

To our knowledge this study is the only study that has investigated the effect of 2D vision in the initial training phase of laparoscopic suturing. With a simple and inexpensive adjustment to a regular laparoscopic box trainer we have shown a positive effect on the laparoscopic suturing learning process of novices. However, a limitation of this study is the relatively small sample size. Therefore we calculated the sample size needed to demonstrate a difference between the two groups for the different parameters (force as well as motion related) during the needle driving phase (Phase 1) as well as the knot tying phase (Phase 2) with a power of 80% and a P-value of 0.05 to demonstrate significance. The sample size needed varies between N = 261 (for Phase 2; left path length) and N = 1.409.518 (for Phase 1; right volume) The very large sample size needed for each parameter suggests that we would not find any differences, even if we would have extended our trial.

Interpretation

It is generally known that motivation for laparoscopic training is inversely related to laparoscopic experience. The motivation to learn can be intrinsic (from the trainee) and extrinsic.[21] The latter are exams, assessments, promotion, financial profits, prolonging registration etc. These factors can be influenced by staff and program directors (e.g., by providing compulsory training time during working hours, inter-individual competitions and feedback). Several studies have focussed mainly on extrinsic motivational factors,

for example van Empel[15] has given trainees complete box trainers to make training at home available. Unfortunately the average time trained at home (298.5 min; SD 383.1 min) was significantly lower than the self-reported desired training time (1687.6 min; SD 1225.9 min). Verdaasdonk[22] found that the competition element stimulated with a price was useful to attract mainly experienced trainees. These studies might suggest a significant role for intrinsic motivational factors. Intrinsic factors are motivators such improvement of personal achievement (improvement of skills and knowledge), be prepared for new situations, security, but also fun and competition. These factors vary per person and are difficult to alter. The fact that novices in the Group 2 (standard set up) rate their self-perceived dexterity after the training significantly lower than before the training together with the higher reported level of frustration in this group might suggest that the training in Group 2 could decrease intrinsic motivation compared to the training in Group 1 (training with direct vision first).

Residents themselves stress the importance of simulation training of MIS skills. In surveys they agree that simulation training is essential and should be obligatory.[15-17] However, voluntary simulation training remains a challenge. Besides a lack of motivation, a lack of time is the most common reported reason for not training.[15-17] This study shows that a considerate amount of time (27%) can be spared by training under direct vision. A study by Hodgson[12], in which they examine the influence of various DOF's of laparoscopic instruments, has also shown that performing tasks under direct vision safes time (22%). This time saving effect was even larger (33%) when in addition to direct vision extra DOF's were added.

When the optimal time is to switch from the experimental set up (3D vision) to the standard set up (2D vision) remains unclear. It can be speculated that most benefit will be gained when a trainee trains under direct vision until they master the skills to adjust to the fulcrum effect, the loss of haptic feedback and to the limited motion freedom and degrees of freedom (DOF's). Since trainees in this study switched to the standard set up after the third trial, we cannot answer this question.

Several studies have shown advantages of 3D camera visualisation over 2D visualisation, mainly in saving time and surgeons preference, while others (using older visualisation techniques) have reported equivalency in task performance.[23] Also the study by Lush[24] has shown that 3D visualisation results in significant improvement in depth perception, special location and precision of surgical performance of basic tasks. However, this effect was not seen in more complex tasks such as suturing. As long as the benefits of 3D visualisation techniques remain unclear, such an expensive new technique has no place

yet in surgical training programs. Providing physical box trainers with a transparent top is a cheap adjustment and because it makes a camera and monitor system unnecessary, it should be possible to provide every starting trainee with their own training set up.

CONCLUSION

In conclusion novices benefit from starting their training of difficult basic laparoscopic skills, such as suturing, in a transparent box trainer under direct vision. It takes them less time and they get less frustrated by the training with the same end result on their economy of movements and tissue handling skills. Furthermore, it is a simple and cheap adjustment to the standard laparoscopic box trainer set up, making it possible to provide trainees with their own training set up for the start of their basic laparoscopic skills training. It would be interesting to examine whether providing trainees with their own adjusted box trainer, for example for home training, benefits the learning curve of their basic MIS skills compared to a conventional trainings program.

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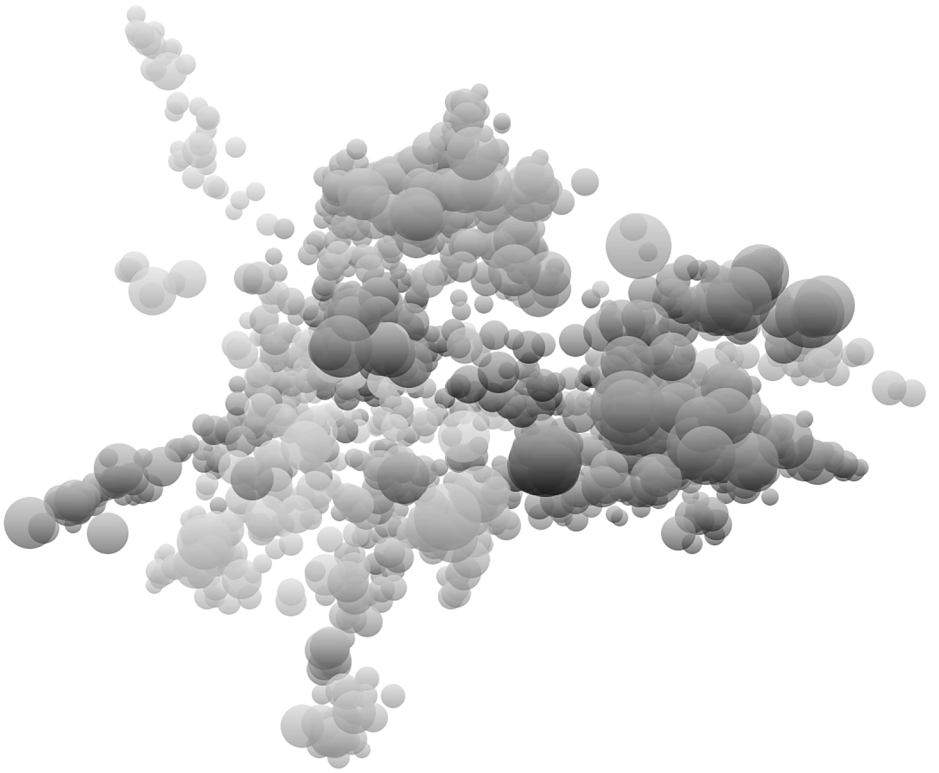
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CHAPTER 11

GENERAL DISCUSSION



DISCUSSION

In surgery, patient safety has become one of the most important quality parameters, especially since society has become more and more quality driven. The 2007 report by the Dutch inspectorate of health care[1] emphasized that the complexity of minimally invasive surgery (MIS), further increases risks in patient safety, more than in conventional surgery. The national report of 2013[2] showed that despite the success of national safety programs, which reduced potentially preventable damage with 30% and potentially preventable death with 37%, the amount of damage related to medical technology remained stable. Yet again MIS was reported as one of the main categories of adverse events related to medical technology. However, many factors potentially contribute to the latter. In this thesis aspects of patient safety in MIS and the accompanying advanced technology are extensively researched.

Exploring patient safety

In order to explore patient safety in laparoscopic surgery, an exact understanding of the meaning of patient safety is inevitable. The continuously growing publication rate on patient safety topics and its complex character make it difficult to obtain a comprehensive overview of the patient safety literature. We used an alternative and relatively unknown method to obtain a large scale overview of patient safety literature and developments on the topic: a visualisation technique based on bibliometric data[3] (**chapter 2**). With this method our focus is not so much on retrieving individual scientific publications but more on obtaining a broad overview of the structure of this literature.[4-6] The results stress the complexity of patient safety as a research topic as the overview contains almost 8500 publications on widespread patient safety issues. These publication could be categorized in 19 clusters which again could be categorized in 3 main categories: 1 magnitude of the problem; 2 identifying and understanding patient safety risk factors; 3 implementation of solutions. Whereas the focus had previously been on illustrating the magnitude of patient safety problems, towards recent years patient safety literature is focusing more on identifying risk factors. Although there is also an extensive body of literature on implementation of solutions to patient safety problems, mainly on organizational or government level, this category is relatively underrepresented compared to the other two categories. A possible development towards research on the implementation of patient safety solutions could be anticipated for as a spinoff from the growing research on identifying and understanding patient safety risk factors, since a logical next step would be to research safety enhancing improvements to these risk factors.

The shift towards research into identifying patient safety risk factors might be explained by the major changes that have occurred in the perception of patient safety, in recent years. From a blame culture (the persons-approach) a switch has been made towards a systems-approach.[7] A number of important studies have suggested frameworks of factors that influence patient safety based on the systems approach to quality and safety in surgery.[8-10] We have adapted these frameworks for minimally invasive surgery which included the following risk domains: experience of the surgeon, technical skills of the surgeon, technology, complications, social interaction, leadership of the surgeon, blood loss, length of surgery, surgical team, fallibility, patient, safety measures and finally environment. We determined the clinical relevance of different patient safety risk factors in this framework in **chapter 3** and clearly showed that in MIS the leadership and technical skills of the surgeon are the most important patient safety risk factors.

Differences between MIS and conventional surgery

The clear differences in safety factors between MIS and conventional surgery in the clinical as well as the non-clinical setting are described in **chapter 4**. The differences in patient safety between these two approaches was measured in an observational study by registering what goes wrong in MIS (laparoscopic) surgery and conventional surgery. The number of events in different risk domains were identified during laparoscopic surgery and compared to the number of events during conventional surgery. Differences in patient safety related events between conventional surgery and MIS could all be explained by the use of advanced technology as an essential part of MIS. The relative risk of encountering one or more events of technical nature during MIS compared to conventional surgery was 1.7 and the relative risk of having two or more technical problems was 4.1. These numbers confirm the previously mentioned 2007 statement by the Dutch inspectorate of health care[1] that the complexity of MIS further increases risks in patient safety. The magnitude of technology related problems during MIS has previously been illustrated in several other studies.[11-13] Also in gynaecological MIS procedures many technology related problems, with potentially dangerous consequences, have been observed.[14] In these studies, technology related incidents mainly led to delay and extra work, e.g. having to retrieve equipment or instruments from another location.

It is generally known that MIS requires different surgical skills than conventional surgery due to the different technique. The consequences of this difference in surgical technique on tissue handling are illustrated in **chapter 7**. This chapter shows the difference in tissue handling during suturing and knot tying in a non-clinical setting using a MIS and conventional approach. We found that interaction forces used during laparoscopic

suturing are generally higher than during conventional surgery. This is most probably the result of limited of haptic feedback in MIS, among others due to resistance inside the trocars[15] and the use of long laparoscopic instruments[16]. However, it has to be noted that in a clinical setting the surgeon also gets information about tissue handling in the form of visual feedback, which in a non-clinical setting lacks. Although the non-clinical set up simulates laparoscopic surgery as realistically as possible by using a real camera and real instruments, visual feedback such as changes in tissue colour or bleeding are not provided. Therefore it is more difficult for the surgeon to adjust his or her strategy when it comes to tissue handling. It can be said that in box-training an alternative to the missing visual feedback could be very valuable.

Training tissue handling skills

As we showed in **chapter 3**, the surgical skills of the surgeon, in particular tissue handling skills, are generally assessed as one of the most important and clinically relevant risk factors in surgery. In MIS additional obstacles have to be overcome compared to conventional surgery. It has been well established that training of basic MIS skills should preferably be done in a non-clinical setting without exposing patients to risks, thus also training of tissue handling.[17-19] From a clinical point of view it is of interest to be able to assess tissue handling in an objective manner. To this extend we describe the development of a force measurement platform (Delft university of technology, Tim Horeman) that measures these interaction forces and accompanying force parameters for the assessment of tissue handling skills (**chapter 5**). This chapter shows that a difference between the expert and novice can be assessed based on the used interaction forces, indicating construct validity. Furthermore, it is shown that interaction forces, in contrary to motion parameters, are not time related and therefore an important missing element to MIS skills training. However these interaction forces alone have no clinical relevance without understanding which forces cause tissue damage. In **chapter 6** we show that of 8 different types of porcine tissue, every tissue type had its own individual range of acceptable maximum forces before visual tissue damage occurred. The porcine model was chosen for because it is often used as a training model in surgery. Furthermore, porcine bowels (large and small) have been shown to have comparable tissue characteristics to human bowels.[20] The presented data can be used to establish safety thresholds in skills training models (Boxtrainer) that provide force feedback to the trainee during suture tasks. This makes training more clinically relevant and also adjustable to the level of the trainee. By adjusting the settings to different tissue types, training becomes more specified, e.g. better developed tissue handling skills are required for suturing bowels compared to suturing the uterus.

As said before **chapter 7** stresses the clinical relevance of tissue handling in laparoscopic surgery. The high interaction forces used during laparoscopic suturing in the non-clinical setting suggest that besides the loss of haptic feedback in MIS, another difficulty plays a role specifically in the non-clinical setting. This could be the altered visual feedback containing information about tissue handling (e.g. changes in tissue colour or bleeding). More visual information about tissue handling could be very valuable during MIS tasks in the non-clinical setting. This information should provide feedback on applied interaction forces during training combined with an understanding of force limits that cause damage. A trainee could train him- or herself on controlling the applied forces by using the feedback to adjust his or her strategy and thus train his or her tissue handling. In previous studies objective feedback on MIS skills (e.g. economy of movements) has already successfully been used for assessment.[21;22] This feedback is provided after completing a task, i.e. post processing. Providing feedback during training of a task, i.e. real time feedback could provide the trainee the possibility to adjust their strategy immediately during the training, therefore making the training more efficient. In **chapter 8** we describe the development and validation of an application that provides real time feedback on the applied forces during training. We found that novices their tissue handling skills improve significantly when they are given force feedback of their performance (**chapter 9**). This effect is seen mainly during the knot-tying phase of the suturing task. Based on this study we could not demonstrate a difference in effectiveness of the form of given feedback, e.g. real time or post processing. When it comes to visual feedback for learning simple motor tasks conflicting reports have been published varying from a negative influence due to adding a distracting component to a positive influence based on the form of visual feedback (e.g. real time versus post processing).[23] For simple motor tasks post processing visual feedback seems more effective than real time feedback, unless real time visual feedback is combined with no feedback or post processing visual feedback in a training program. Real time visual feedback in simple tasks has been reported to give a negative influence on retention of skills. However in complex tasks in different types of sports and physical therapy, real time visual feedback has mainly been reported to be effective. In general it seems that the more complex the task, the more a trainee can benefit from real time visual feedback.[23] Since laparoscopic suturing is considered a complex task in theory trainees would benefit from real time visual feedback of interaction forces. However we did not find a difference between the form of given feedback. Furthermore we did not examine the retention of skills.

The most benefit of visual feedback of force parameters is gained during the first learning phase while learning the general movement pattern. During the second learning phase it is suggested that real time visual feedback should be alternated with no feedback or

post processing feedback for optimal retention of skills.[23] Another important aspect of visual feedback of interaction forces is the design, i.e. the visualisation of the real time feedback. If the design is inappropriate, positive effects are inhibited even though concurrent visual feedback would actually be effective for learning the task.[23] Further research is needed into optimizing the training program alternating real time and post processing feedback and also into the most appropriate design for visual feedback of force. Also the retention of skills after training with visual feedback on interaction forces should be examined.

In addition to dealing with diminished haptic feedback laparoscopic surgeons have to interpret a 2D image and translate it into a 3D operating field. In **chapter 10** we have shown that dividing the obstacles that a starting trainee has to overcome in several stages, is of benefit to the trainee. By starting the training in an open box trainer without camera, later followed by a classical closed box trainer with camera trainees need significantly less time to become as proficient in their basic laparoscopic skills as those who train in a closed box-trainer alone. Besides, the trainees get less frustrated about practicing basic laparoscopic skills this way, which could lead to a positive influence on their motivation for training and therefore indirectly improve patient safety.

FUTURE PERSPECTIVES

The technical complexity of MIS increases the risks in patient safety compared to conventional surgery. With fast on-going advances in technology it is important to keep trace of patient safety whenever new technologies are first implemented. For example, integrated minimally invasive surgical operating rooms, laparoscopic robots and various types of single-port laparoscopy have been implemented in clinics worldwide. More recently, the 3D video imaging is introduced. Not only to give a better view to the surgeon, but it is also commercially launched to compete with robot surgery.[24;25] However, no scientific data are available to support the additional (promised) benefits of these new technologies. Therefore it would be interesting to see if the benefits of all these new technologies outweigh the potential increased risks in patient safety by the introduction of new techniques.

Patient safety rankings based on complication rates and safety scores such as the Surgical Apgar Score are insufficient, because they do not take the complete patient safety framework, such as described in **chapter 3**, in consideration. Driven by the need for higher patient safety standards, a model should be developed for operating room situated MIS procedures in addition to scores such as the SAS score. This model should not focus on one patient safety indicator, but rather incorporate all important variables that influence patient safety (indicators). Furthermore, it should be combined with outcome measures and normalized for severity of the procedure and patient characteristics. **Chapter 3** describes such a framework, which could serve as basis for such a model. This could potentially provide a method for objective evaluation and comparison of patient safety in MIS procedures (a standardized scoring system) and could be used to benchmark patient safety, thereby enable objective quality control for hospital staff and government agencies. After implementation, the model can be used to detect system flaws in risk domains, which need the attention of hospital staff.

A possible model, which might be interesting to use for such a scoring system, is data envelopment analysis (DEA). In this model selected risk domain indicators will be aggregated in one patient safety index. DEA is a nonparametric performance measurement technique that is used to empirically measure productive efficiency of decision-making units (DMU). For each DMU, in this case a MIS procedure, the efficiency is defined as a ratio of the weighted sum of outputs to the weighted sum of inputs. DEA is mainly used in economics to determine the efficiency of a production process if it has a structure of multiple inputs and outputs. Recently it has been applied to benchmark road safety in European countries.[26] It would be interesting to examine

the possibility to use DEA to benchmark patient safety in a similar manner on a smaller scale (since a single procedure is a DMU).

Finally, providing feedback on interaction forces during skills training in a non-clinical setting can facilitate training of tissue handling skills. However, the optimal modus of providing such feedback remains yet unclear. Future research should focus on determining the optimal modus of providing feedback on interaction forces. In case of visual feedback the optimal design of visual feedback should be examined. Furthermore, different training programs starting with real time feedback and later alternating real time and post processing (or no feedback) should be examined, with a focus on retention of skills.

CONCLUSION

Patient safety in MIS is a complex multi-factorial issue that can be explained in a framework based on a systems approach. We found that in this framework, the MIS surgeon has a central role. Because of the use of complex technology in MIS and the difference in surgical skills needed to perform MIS, patients are exposed to additional risks compared to conventional surgery. Therefore special attention is needed for training of MIS skills. In a non-clinical setting tissue interaction forces inform us about a trainee's tissue handling skills. We found that providing feedback on tissue interaction forces during the training of complex tasks has a positive effect on tissue handling skills in MIS. The learning process of MIS tasks requires the novice to overcome multiple obstacles at once. However, simple solutions such as adjusting a conventional box-trainer to provide 3-D vision, can facilitate the initial learning process.

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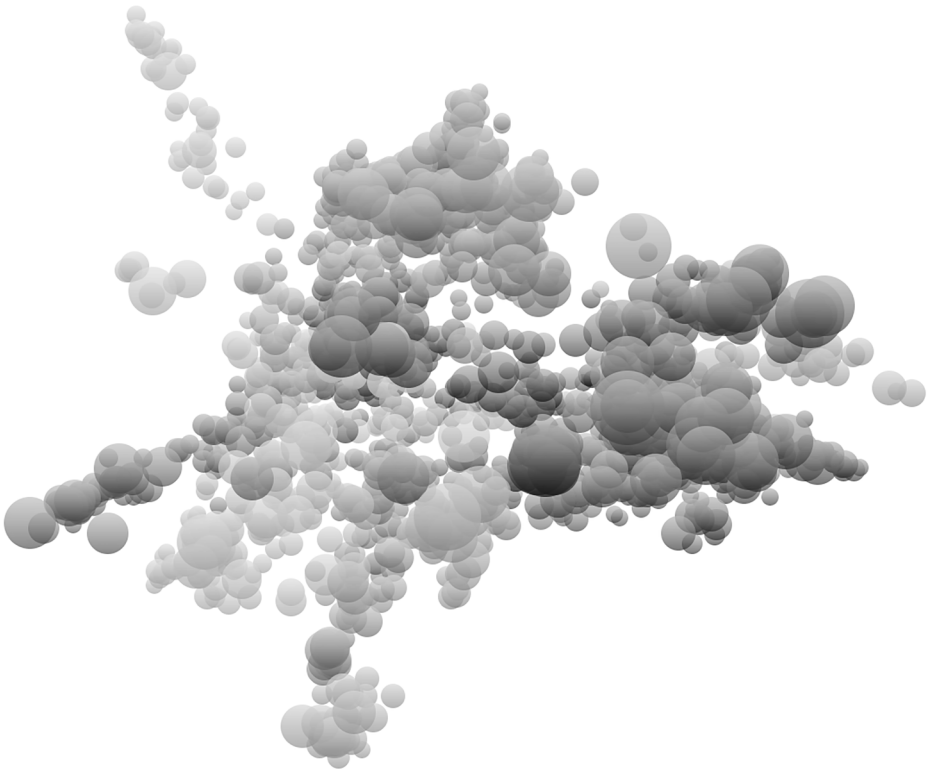
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CHAPTER 12

SUMMARY / SAMENVATTING



SUMMARY

Ever since publication of the report by the *Institute of Medicine (IOM) To Err Is Human: Building a Safer Health System*, patient safety has become the focus of improvement in healthcare. This is confirmed in **chapter 2**, where we show a major increase in publications reporting on patient safety related issues over the last decade. The topic patient safety is so complex and multifactorial that it is difficult to comprehend. To get some insight into the topic we performed a large scale analyses of the literature and we were able to categorize patient safety publications into three main categories: (1) magnitude of patient safety problems, (2) patient safety risk factors and (3) implementation of solutions.

The 2007 report by the Dutch inspectorate of health care directed focus towards patient safety in minimally invasive surgery (MIS). The complexity of MIS increases risks in patient safety more than in conventional surgery (CS). The national report of 2013 showed that despite the success of national safety programs, the amount of damage related to medical technology remained stable. Yet again MIS was reported as one of the main categories of adverse events related to medical technology. There are many potentially contributing factors that lay at the base of the reason why MIS is poses increased risks to patients. In this thesis different aspects of patient safety in MIS and the accompanying advanced technology are extensively researched.

In general patient safety risk domains in the operating room (OR) can be divided into 5 main categories (**chapter 1**):

1. Social aspects (e.g. teamwork, communication)
2. Technological aspects (e.g. instruments, equipment)
3. External aspects (e.g. door movements, irrelevant conversations etc)
4. Functioning (e.g. skills, experience, knowledge) of the OR team members (e.g. surgeon, OR assistant, anaesthesiologist)
5. Organizational aspects (schedules, workload, staffing etc).

In light of this thesis we specifically focused on these risk domains in relation to MIS. We adapted a framework according to a systems approach to include these risk domains. Next we validated the framework among patient safety experts in MIS (**chapter 3**). We found all risk domains are relevant to patient safety, but that technology and technical skills of the surgeon are by far the most relevant. Next the validated framework was used to observe the magnitude of events during MIS en CS (**chapter 4**). We showed that the technological complexity inherent to MIS makes this type of surgery more prone to

technology related problems than CS, even in a specially designed minimally invasive surgical suite. And that regular time out procedures developed for CS lack the necessary attention for the complex technology used in MIS. It is of interest to focus more on the risk domain functioning of the OR team members, especially the technical skills surgeon as this is the most relevant to patient safety. However, it is difficult to objectively assess surgeons' technical skills in a clinical context. It has been shown that surgical skills in part can be objectively assessed in a non-clinical setting such as a skills laboratory. Of all surgical skills, tissue handling can be directly related to patient safety. Therefore the second part of this thesis focuses on training and assessment of the surgeon's tissue handling skills in MIS.

In **chapter 5** we describe the development and of a force measurement platform that measures interaction forces at tip of the instrument. We validated this newly developed force sensor and showed that by measuring interaction forces it is possible to assess the surgeon's tissue handling skills. To better understand the meaning of the measured forces from a clinical point of few we have measured at which forces different tissue types start to damage (**chapter 6**). This is used to set limits on allowable forces during the training of intracorporeal suturing. The need to provide information about applied forces during training of MIS surgical skills is illustrated in **chapter 7**. Here we show that experts use higher interaction forces during suturing in a MIS training set up compared to a CS training set up. This is mainly the result of a loss of haptic feedback and the fact that visual cues to which experts in the clinical situation can adjust their strategy, such as blood loss and tissue colour changes, lack in the non-clinical situation. When provided with information about applied interaction forces during a task, one could use this information instead of other visual clues to adjust the amount of force applied. Therefore in **chapter 8** we describe the real time visualisation of applied interaction forces with a virtual arrow and show the potential benefit of this form of feedback for training tissue handling. In **chapter 9** we further investigate the benefit of real time force feedback compared to post processing feedback and no feedback in the training of intracorporeal suturing. We prove that trainees their tissue handling skills improve significantly when they are given force feedback of their performance. The improvement is mainly seen during the knot tying phase of the suturing task. However we could not demonstrate a difference in effectiveness of the form of given feedback, e.g. real time or post processing.

Besides the loss of haptic feedback in MIS, the altered depth perception and fulcrum effect are challenges that have to be overcome in MIS. Especially novices, without any experience, are hindered by the fact that they have to adjust to many challenges at the

same time, which makes it difficult for them to focus on tissue handling already at the start of their training. In **chapter 10** we examine the influence of training under direct (3D) vision prior to training with 2D vision on the learning curve of the laparoscopic suture task. With this simple and inexpensive adjustment to a box trainer we prove that novices benefit from starting their training of difficult basic laparoscopic skills under 3D vision. It takes them less time to complete the tasks and they get less frustrated by the training with the same results on their economy of movements and tissue handling skills.

In **chapter 11** the results of the aforementioned chapters and future perspectives are discussed. In conclusion patient safety in MIS is a complex multi-factorial issue that can be explained in a framework in which the MIS surgeon has a central role. Because of the use of complex technology in MIS and the difference in surgical skills needed to perform MIS, patients are exposed to additional risks compared to conventional surgery. Therefore special attention is needed for training of MIS skills. Providing feedback on applied forces during the training of complex MIS tasks has a positive effect on tissue handling skills.

SAMENVATTING

Patiëntveiligheid is een belangrijk focus voor kwaliteitsverbetering geworden in de gezondheidszorg sinds de publicatie van het rapport van het *Institute of Medicine (IOM); To Err Is Human: Building a Safer Health System*. Dit wordt bevestigd in **hoofdstuk 2**, waarin wij een enorme stijging in publicaties over patiëntveiligheid constateren in het laatste decennia. Het onderwerp patiëntveiligheid is zo complex en multifactorieel dat het moeilijk te bevatten is. Om meer inzicht te krijgen in het onderwerp hebben wij een grootschalige analyse gedaan van literatuur over patiëntveiligheid. Met deze analyse konden wij publicaties over patiëntveiligheid categoriseren in drie hoofdcategorieën: (1) omvang van patiëntveiligheidsproblemen, (2) patiëntveiligheid risicofactoren en (3) implementatie van oplossingen.

Het in 2007 gepubliceerde rapport van de Inspectie voor de Gezondheidszorg (IGZ) richtte de focus op patiëntveiligheid in minimaal invasieve chirurgie (MIC). De complexiteit van MIC vergroot de risico's voor patiëntveiligheid in vergelijking tot conventionele chirurgie (CC). Het nationale rapport in 2013 toonde aan dat de hoeveelheid schade veroorzaakt door medische technologie stabiel bleef ondanks het succes van nationale veiligheidsprogramma's. Wederom werd MIC genoemd als een van de belangrijkste categorieën voor onbedoelde schade als gevolg van medische technologie. Aan de oorzaak hiervan liggen veel potentieel bijdragende factoren ten grondslag. In dit proefschrift onderzoeken wij verschillende aspecten van patiëntveiligheid in MIC en de geavanceerde technologie inherent aan MIC.

Risicodomeinen met betrekking tot patiëntveiligheid in de operatiekamer (OK) kunnen onderverdeeld worden in 5 categorieën (**hoofdstuk 1**):

1. Sociale aspecten (b.v. teamwork, communicatie)
2. Technologie (b.v. instrumenten, apparatuur)
3. Externe factoren (b.v. deurbewegingen, irrelevante gesprekken etc.)
4. Functioneren (b.v. vaardigheden, ervaring, kennis) van OK teamleden (b.v. chirurg, OK assistent, anesthesioloog)
5. Organisatorische factoren (roosters, werkdruk, bezetting etc.).

In het kader van dit proefschrift hebben wij ons gericht op deze risicodomeinen in relatie tot MIC. Op basis van een systeembenadering hebben wij een raamwerk voor patiëntveiligheid gemaakt die alle risicodomeinen omvat. Dit raamwerk hebben wij gevalideerd onder patiëntveiligheidsexperts binnen de MIC (**hoofdstuk 3**). Wij kwamen

er achter dat alle risicodomeinen in het raamwerk van belang zijn voor patiëntveiligheid, maar dat technologie en de technische vaardigheden van de chirurg in het geval van MIC verreweg het meest relevant zijn. Vervolgens hebben wij het gevalideerde raamwerk gebruikt om de omvang van patiëntveiligheidskwesties tijdens MIC en CC te observeren (**hoofdstuk 4**). Wij toonden aan dat de technische complexiteit inherent aan MIC deze vorm van chirurgie, ten opzichte van CC, bij uitstek gevoelig maakt voor technische problemen. En dat er in de reguliere time out procedure, welke ontwikkeld is voor CC, te weinig aandacht is voor de complexe technologie die gebruikt wordt tijdens MIC. Omdat de technische vaardigheid van de chirurg een van de meest belangrijke risicofactoren in de MIC is, is het interessant om meer gericht naar dit risicodomein te kijken. Het is echter lastig om in een klinische situatie chirurgische vaardigheden objectief te beoordelen. Uit eerder onderzoek is gebleken dat het goed mogelijk is om chirurgische vaardigheden objectief te beoordelen in een niet klinische omgeving zoals een skills laboratorium. Van alle chirurgische vaardigheden is weefselgevoel direct te relateren aan patiëntveiligheid. Om deze reden ligt de focus van het tweede deel van dit proefschrift op het trainen en beoordelen van weefselgevoel in MIC.

In **hoofdstuk 5** beschrijven wij de ontwikkeling van een krachtmeter die interactiekrachten meet. Wij hebben deze krachtmeter gevalideerd en tonen aan dat door het meten van interactiekrachten met kunstweefsels het mogelijk is om het weefselgevoel van de chirurg te beoordelen. Om een beter begrip te krijgen van de betekenis van de gemeten krachten vanuit een klinisch oogpunt hebben we bij verschillende weefsels gemeten bij welke krachten er weefselschade ontstaat (**hoofdstuk 6**). Met deze waardes kunnen grenzen van toegestane krachten tijdens training van laparoscopisch hechten bepaald worden. De behoefte aan informatie over gebruikte krachten tijdens het trainen van MIC vaardigheden wordt bevestigd in **hoofdstuk 7**. In dit hoofdstuk laten we zien dat experts hogere interactiekrachten gebruiken tijdens laparoscopisch hechten in vergelijking tot conventioneel hechten. Dit is met name het gevolg van verminderde haptische feedback en het feit dat visuele aanwijzingen waarop de expert in de klinische situatie zijn of haar strategie kan aanpassen, zoals bloedverlies en veranderingen van kleur van het weefsel, tekortschieten in de niet klinische situatie. Als men informatie over de toegepaste krachten krijgt tijdens de training, zou men hun strategie kunnen aanpassen op basis van deze informatie ter vervanging van de visuele informatie in de klinische situatie. On deze reden beschrijven wij in **hoofdstuk 8** de real time visualisatie van toegepaste interactiekrachten door middel van een pijl en tonen wij potentiele voordeel aan van deze vorm van terugkoppeling voor het trainen van weefselgevoel. In **hoofdstuk 9** onderzoeken wij het voordeel van de real time terugkoppeling ten opzichte van terugkoppeling na het afronden van de taak en geen terugkoppeling tijdens het

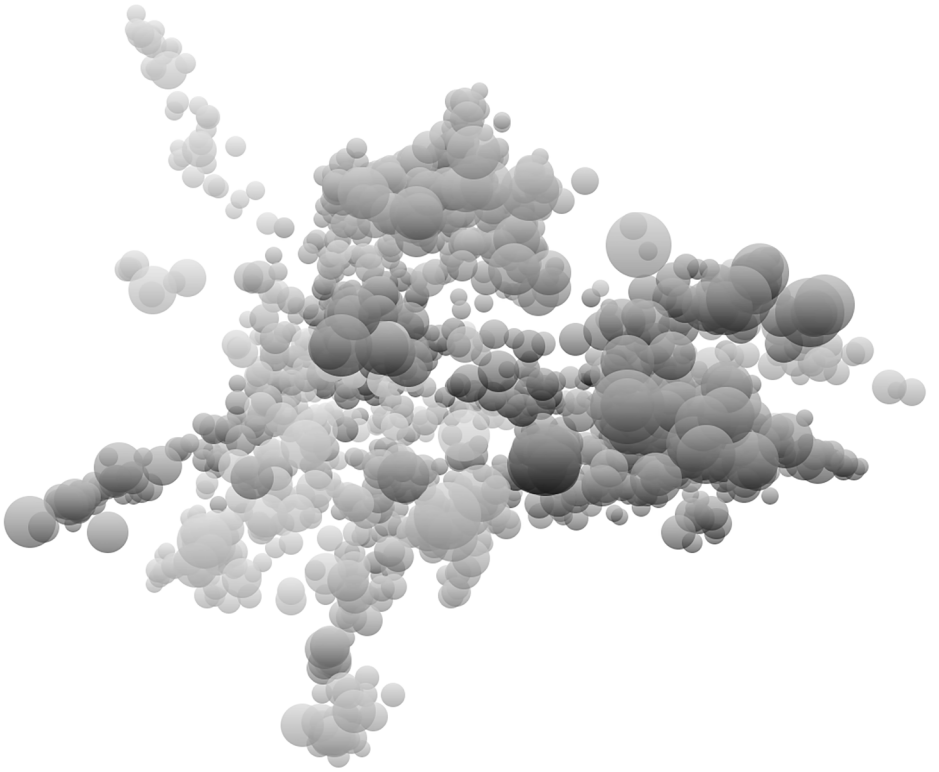
trainen van intracorporeal hechten. Wij tonen aan dat het weefselgevoel van studenten significant verbeterd als zij terugkoppeling krijgen over hun gebruikte interactiekrachten. Deze verbetering zien wij vooral tijdens de knoop fase van de hechttaak. Echter konden wij geen verschil aantonen in de vorm van terugkoppeling (real time of achteraf).

Naast de verminderde haptische feedback in MIC zijn het veranderde diepte inzicht en het "fulcrum effect" belangrijke hindernissen die genomen moeten worden bij het leren van MIC. Met name novicen, zonder enige ervaring, ondervinden moeilijkheden met het feit dat zij zich aan veel verschillende veranderingen tegelijk moeten aanpassen. Hierdoor is het lastig voor novicen om zich aan het begin van de training te richten op weefselgevoel. In **hoofdstuk 10** onderzoeken wij de invloed van trainen onder direct zicht (3D) voorafgaand aan trainen met een camera (2D) op de leercurve van de laparoscopische hechttaak. Met deze simpele en goedkope aanpassing laten wij zien dat novicen er baat bij hebben om training van moeilijke laparoscopische basisvaardigheden te starten onder direct zicht (3D). Deze manier van trainen kost minder tijd en novicen raken minder gefrustreerd met hetzelfde eindresultaat op efficiëntie van beweging en weefselgevoel.

In **hoofdstuk 11** worden de resultaten van de voorgaande hoofdstukken en suggesties voor vervolgonderzoek besproken. Kort samengevat is patiëntveiligheid in MIC een complex multifactorieel onderwerp dat kan worden weergegeven in een raamwerk waarin de chirurg een centrale rol speelt. Patiëntveiligheid komt bij MIC extra in het geding door het gebruik van complexe technologie en de andere benodigde chirurgische vaardigheden om MIC procedures te kunnen uitvoeren. Daarom is extra aandacht nodig voor training van MIC vaardigheden. Het geven van terugkoppeling over gebruikte krachten tijdens training van MIC vaardigheden heeft een positief effect op weefselgevoel.

CHAPTER 13

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LIST OF PUBLICATIONS

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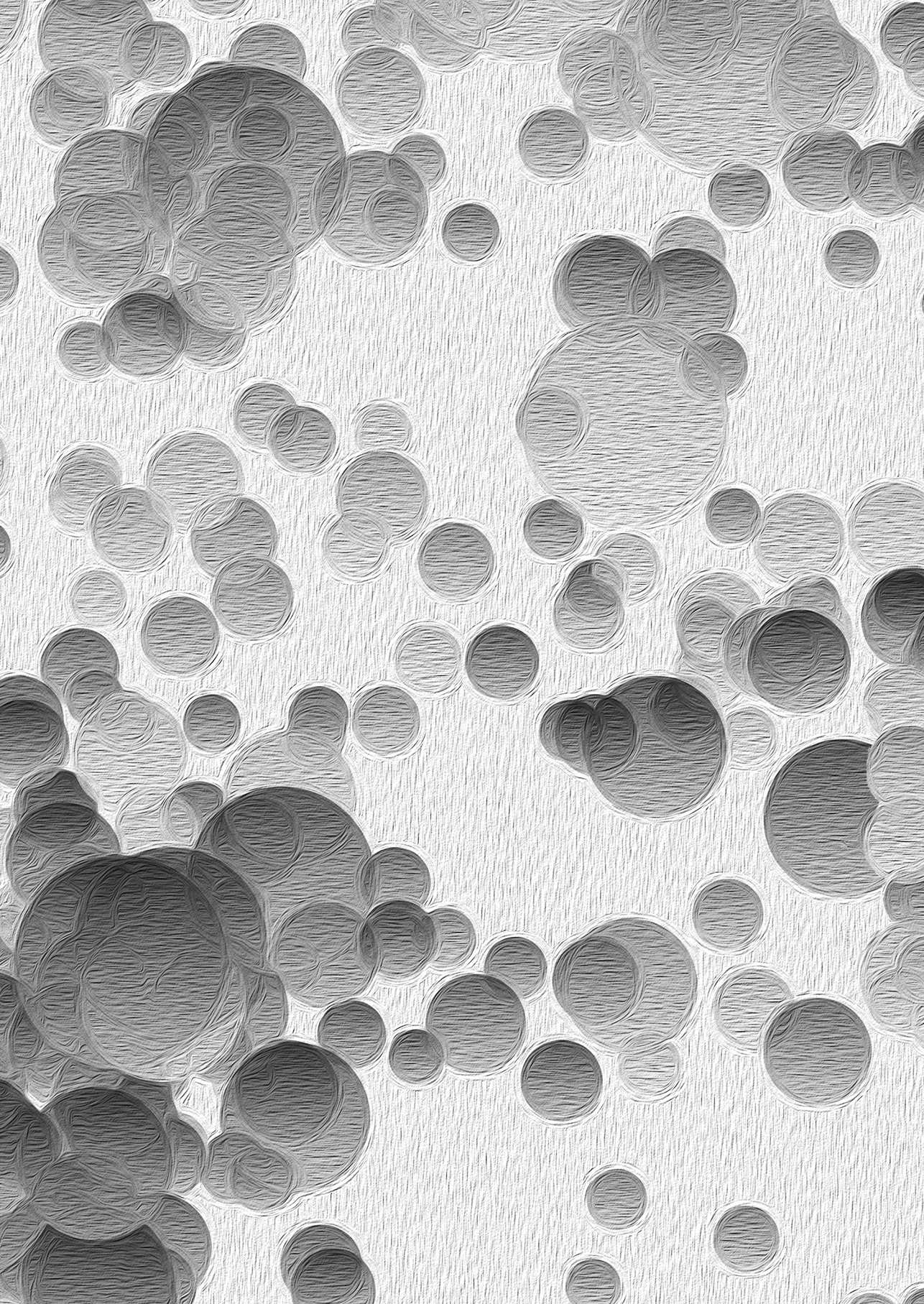
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CURRICULUM VITAE

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Dank!

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