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Acquiring minimally invasive surgical skills

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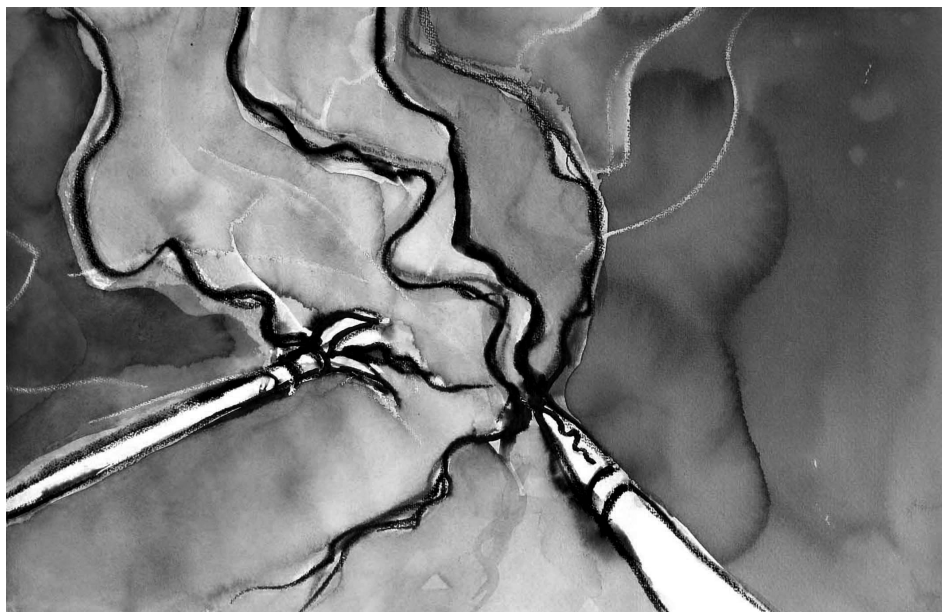
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CHAPTER 1

GENERAL INTRODUCTION



Minimally invasive surgery (MIS) developed due to technological advances in instrumentation along with an appreciation that avoidance of laparotomy may confer advantages for patient recovery such as reduced post-operative pain, shorter hospitalisation, more rapid return to normal activities, and improved cosmetic results.[Darzi et al., 1999] Still, MIS has some different surgical features in comparison with laparotomy. In the first place, the depth perception of the surgeon is reduced because the operation field has to be interpreted from a two dimensional (2D) screen.[Munz et al., 2004] Furthermore, long instruments are inserted through the abdominal wall during laparoscopy. This creates counter intuitive movements with a limited range of motion and results in an distorted hand eye coordination.[Gallagher et al., 1998; Pearson et al., 2002] In the third place, haptic feedback is diminished, because there is no direct contact between the surgeon's gloved hands and the tissue [Bholat et al., 1999]. Finally, camera instability may increase fatigue.[Heemskerk et al., 2006] As a consequence, a surgeon who performs MIS is faced with the challenge to master a different set of technical surgical skills compared to performing a conventional procedure.

Despite the advantages of MIS for patient recovery, this new surgical technique has not been adopted without any trouble. The initial implementation of the laparoscopic cholecystectomy progressed rapidly and has led to an alarming number of significant complications due to inadequately trained and skilled surgeons.[Forde, 1993] These concerns remained after its initial adoption phase, as illustrated by the report published by the Dutch Health Care Inspectorate, entitled "Risks of minimally invasive surgery underestimated".[IGZ 2007] The Inspectorate stated that the actions taken to prevent incidents in MIS were insufficient. Specifically, improvement of the training of MIS skills was demanded, combined with the setting of a certain level of basic endoscopic skills prior to operating on real patients.[Stassen et al., 2010]

Although the obligation for skills training was new with the publication of this report, the importance of basic MIS skills training outside of the OR has long been realized. In 1985, pelvi-trainers were already introduced by Kurt Semm to learn 'how to operate mono-and binocular' and to 'handle the grips of the instruments' (Figure 1).

Unfortunately, no broad implementation of these boxes occurred. However, the following arguments support skills training outside of the OR prior to patient exposure. Firstly, there are ethical concerns about teaching basic skills on a patient, when alternatives are readily available.

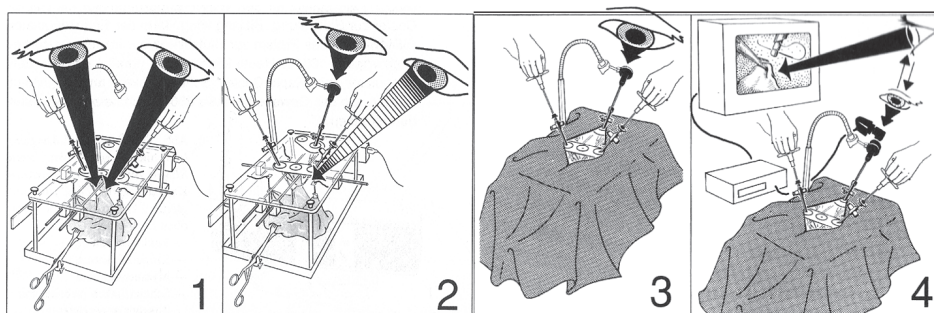


Figure 1. pelvi-trainer as designed by Kurt Semm.

Skills acquired on box trainers [Scott et al., 2000] and virtual reality (VR) trainers [Grantcharov et al., 2004; Seymour et al., 2002] are transferable to surgery on real patients. Moreover, simulator training might bypass the early learning curve, which is known to be associated with an increased rate of complications. [Southern Surgeons Club, 1991] A second argument to support that the OR should not be the predominant learning environment is that surgeons are pressed to be more efficient in the OR due to increasing financial constraints. Thirdly, teaching hospitals are increasingly populated by patients with more serious and complex surgical problems that demand the skills of expert surgeons working at maximum efficiency.[Blanchard et al., 2004; Brolmann et al., 2001] Finally, working hours restrictions leave residents with less opportunities to perform surgical procedures on living humans. Teaching fundamental MIS skills outside of the OR is likely to improve the time trainees spend in the operating theatre because those who have acquired basic surgical skills can focus more thoroughly upon the anatomy, pathology and procedural aspects of actual surgery.[Korndorffer, Jr. et al., 2005c] Therefore, from a teaching perspective, it is more efficient to learn basic surgical skills prior to performing actual surgery.

Consequently, skills laboratories have been set up worldwide in order to train and assess MIS skills outside of the OR. By now, most teaching hospitals have training facilities, or at least access to it elsewhere. However, no guidelines or standards exist yet how to design and use such facilities. This parallels the finding of the Dutch Health Inspectorate that there is no uniformity in MIS training, both in general and between endoscopic professionals (e.g. surgeons, gynaecologists, urologists).[Stassen et al., 2010] In fact, the development of training facilities is often based upon the funder's personal preferences and on the money available, rather than upon scientific evidence of the value for the process to acquire surgical skills. Even, it has been stated that one of the greatest errors in setting up a surgical skills lab, is to purchase the equipment first and then to design a curriculum around it.[MacRae et al., 2008]

Up until now, most research has focused on the available trainers for MIS surgery. The two inanimate simulators are a box trainer and a VR trainer. Within these two categories, many types of simulators have been developed with even more exercises, varying from relatively simple tasks to entire procedures.[Hammoud et al., 2008] Mounting validation studies have been conducted on new exercises in the box or VR trainers. [Kolkman et al., 2008; Schreuder et al., 2011] Validity addresses the concept of whether the test is actually measuring what it was intended to measure.[Feldman et al., 2004b] For example, does the simulator discriminate surgeons of different skill levels, and does the exercise resemble an actual surgical situation? Validity is a prerequisite before exercises are employed in a MIS training program. However, there is no consensus about the optimal type of trainer.[Stefanidis et al., 2009b] Additionally, it is unknown which metrics should be applied for simulator training and assessment purposes, with existing measures varying from simple (time) to the more complex (motion analysis). [Hammoud et al., 2008] Although, evidence is emerging that training should be mandatory,[Hammoud et al., 2008; Kolkman et al., 2007b; Stefanidis et al., 2008] formal curriculum development is lagging behind.

In summary, more evidence is required to identify training resources, exercises and programs which confer the best outcomes in terms of acquiring proficiency in predefined training objectives. The first part of this thesis addresses the questions raised above, and

thereby aims at providing a more solid, scientific basis for the design and the use of MIS training facilities outside of the OR. Future investment should support those training facilities utilizing evidence based training.

Despite the importance of skills training facilities outside of the OR, the real craft of surgery is obviously transmitted in the OR. Moreover, the decision-making processes and sequels of errors possibly leading to complications cannot be trained with the use of inanimate training models and only partly with the use of animate ones.[Schijven et al., 2004] In fact, in the 100-year-old Halstedian teaching model, the OR was the only place where residents acquired their technical surgical skills. The adage “see one, do one, teach one” was the motto of the surgical training program. Techniques and views were simply handed down from the senior surgeon to the resident until he or she was believed capable of performing surgery independently. The evaluation was coloured by subjectivity.[Darzi et al., 1999] The opinion of the supervising surgeon was practically the only standard that had to be met.[Schijven et al., 2008] This method, also called the *apprenticeship model*, has produced generations of fine technical surgeons.[Haluck et al., 2000] However, it may no longer be optimal with accelerating changes in the health care system: Authority and public demand a safer and more transparent health care system, rather than automatically accepting the proficiency of surgeons. Additionally, specialty training is moving towards more competency based outcome measures rather than being solely based on the training length. To achieve this, more objective external assessments are needed for accurate appraisal in the challenging area of surgical proficiency.[Aggarwal et al., 2004]

Examples of assessment tools for surgical skills are the OSATS (Objective Structured Assessment of Technical Skills) [Martin et al., 1997] and the GOALS (Global Operative Assessment of Laparoscopic Skills) [Vassiliou et al., 2005]. OSATS was developed in Canada and was originally designed to measure technical surgical performance using six stations in a skills laboratory. [Martin et al., 1997] The six stations comprised of the excision of a skin lesion, hand sewn bowel anastomosis, stapled bowel anastomosis, insertion of a T-tube, abdominal wall closure and control of inferior vena cava haemorrhage. The authors established the validity, reliability and feasibility of the general global rating scale of the OSATS for these six tasks. Subsequently, the value of the OSATS has been proven for large scale implementation in obstetrics and gynaecology residency programs, but again it only focused on its use in a laboratory setting. [Goff et al., 2005] However, in the Netherlands this method has been introduced for evaluating surgical skills during real procedures in the OR. This introduction took place in absence of data on the validity of the OSATS in the real surgical setting. Therefore, the second part of this thesis focuses on whether evidence is present to use the OSATS as an intraoperative assessment tool either in conventional and MIS procedures.

OUTLINE OF THE THESIS

As an introduction to the organisation of MIS skills training, **Chapter 2** describes a mandatory nationwide surgical skills course in the Netherlands, with a critical discussion of the current system. As mentioned before, there is no consensus which trainer model should be chosen, especially with constant improvements in trainer models. In VR trainers, the addition of kinematic interaction between laparoscopic instruments and objects is a possible solution to compensate for the lack of haptic feedback. In **chapter 3** we determined whether or not this interaction can replace the haptic feedback that is naturally present in box trainers. A comparison between box and VR trainers is made with respect to acquiring tissue handling skills. Furthermore, both fixed and navigated camera setups are available during simulator training. A navigated camera offers theoretical advantages for the depth perception of the surgeon and allows the practice of navigation skills, whereas a fixed setup allows solitary training. The effect of camera setup on surgical performance is yet unknown. Therefore, three different camera setups are compared in **chapter 4**. As a next step after the choice for a training model, **chapter 5** focuses on the metrics used for training and assessment in a box trainer. In addition to time, three movement analysis parameters are validated for the clinically important knot tying task, by using a tracking device. Regarding the organisation of a skills curriculum, we investigated in **chapter 6** whether the skills acquired during five validated box trainer tasks remain after one year. Skills laboratories have been set up in teaching hospitals all over the world for the training and assessment of MIS skills. However this has been done in the absence of generally accepted standards as to what a MIS skills laboratory should look like and how the training should be conducted. In **chapter 7** an international and consensus based set of quality criteria is developed for a MIS training skills laboratory, including the design of the laboratory and the training curriculum.

Although the OSATS have proved to be valid, feasible and reliable for the use in a laboratory setting, its value for intraoperative use still needs to be established. **Chapter 8** evaluates the validity of this tool for intraoperative use. In addition, more issues relevant to the implementation of the OSATS as an intraoperative assessment tool are studied in **chapter 9**. Firstly, it is determined at which OSATS score a resident is able to perform a certain procedure autonomously. Secondly, the concurrence in the assessment by supervisor and resident is established as a measure of its reliability. Thirdly, the feasibility is investigated by a survey among residents and staff confronted with the tool in daily practice. In **chapter 10**, the OSATS is used as a reference to answer the question as to whether MIS procedures are harder to acquire for the current generation of residents? This answer is found by comparing residents' learning curve for MIS procedures with the curve for conventional surgical procedures.

In **chapter 11** the research results are outlined in a general discussion. This is followed by conclusions and recommendations in **chapter 12**. Finally, in **chapter 13** this thesis is summarized in English and Dutch.

