Methodologies for the analysis, design and evaluation of laparoscopic surgical simulators

Universidad Politécnica de Madrid

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Methodologies for the analysis, design and evaluation of laparoscopic surgical simulators

On addressing optimal design of virtual reality simulators

Pablo Lamata de la Orden

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Tél. 32 10 47 33 78
Fax 32 10 45 73 50
duc@ciaco.com

A Patricia

A mis padres, Félix y Pilar, y a mi hermana Laura

Summary

Laparoscopy is now a surgical technique practiced in surgical routine. One of its main drawbacks is the long traineeship period required to acquire all necessary skills and to accommodate to the laparoscopic environment. There is a crescent pressure to have transparent training programs, with objective metrics of surgical skill. Virtual reality (VR) simulators are a valuable and valid solution for surgical training and skills assessment.

Several VR simulators for surgical training can be found in the market. The idea of using these means for training surgeons was introduced in 1993, the first prototype was developed in 1997 and the acceptance of its validity as a training tool has arrived in 2002. Concept is valid, and clinical research is now being conducted towards the design of proficiency-based training curriculum with the determination of proficiency levels to establish benchmark criteria, or even the validity of using simulators for trainees' selection. Serious efforts are being made towards the construction of high fidelity systems for surgical training and skills assessment. But little is known about the actual requirements of these simulators in order to be effective training tools. There are doubts about the better efficiency of VR compared to physical trainers.

Therefore the problem addressed in this PhD thesis is how to offer an effective and efficient VR means of training in laparoscopic surgery. And more focused to the design of the simulator, the question is to determine what makes it a useful didactic tool. This biomedical engineer PhD work is conceived to be a bridge between surgical training needs and VR simulation technologies in order to arrive to an optimum simulator. Three different methodological approaches are

taken to face the design of an optimal surgical simulator: (1) The development of a conceptual framework for the analysis, design and validation of simulation technologies (Chapter IV), (2) the study of sensorial capabilities in order to clarify simulation requirements and the need of force feedback (Chapter V), and (3) the design of a surgical simulator for laparoscopic training adapting methodologies for defining specifications, following content validity sessions with mattern experts, and applying lessons learned in the former two approaches (Chapter VI).

Therefore, Chapter IV proposes a taxonomy of didactic resources in VR simulation, what is used to compare different laparoscopic simulators using a pre-defined criterion. VR didactic resources are defined and classified in three main categories based upon the extent to which simulators: 1) emulate reality (fidelity resources); 2) exploit computer capabilities such as new ways of interaction and guidance (teaching resources); 3) measure performance and deliver feedback (assessment resources). Results show how advanced laparoscopic VR simulators have a fidelity similar to that of box trainers with ex-vivo organs (59% and 62% respectively), and how the maximum use of teaching resources is found to be 57% (MIST-VR "suture 3.0" and LapMentor) and of assessment resources is 69% (Reach-In Lap Trainer). Proposed conceptual framework contributes to the definition of simulation requirements and offers guidelines to formulate hypotheses about the importance of different didactic resources. It also provides a methodology to compare simulators and set standards by which emerging technologies can be judged.

Chapter V analyses laparoscopic perception of pulling forces under a triple approach: (1) a perceptual characterisation (2) a study of the in-vivo interaction forces and the ex-vivo biomechanical properties and (3) the development of a force feedback model for simulation. A methodology for surgeon sensory interaction characterization has been defined. Results have identified a "haptic memory" skill recalled with the identification of a tissue and not the expected "visual haptics", a kind of sensorial substitution. Surgeons are able to perceive tissue consistency and distinguish between four strength levels at least. This sensorial information is mainly based in tactile information, what indicates that VR simulators need haptic devices with force feedback capability if consistency information is to be delivered. Objective parameters of forces and biomechanical properties are obtained in order to elucidate which are the factors more important in consistency perception. A logarithmic law of tissue consistency perception has been outlined. Finally all data are gathered and a model of consistency perception is developed. It defines the concept of fixation grade. The other main factor is the kind of tissue. Diffuse logic algorithms are suggested for its implementation.

Finally, Chapter VI proposes a didactic design for a laparoscopic virtual simulator structured in two main packages, one of “basic skills” to be applied to any laparoscopic procedure, and second an example of a procedural simulator centred in the Nissen fundoplication. They have been partially implemented by the SINERGIA Spanish Research Network (G03/135, 2003-2007). Esential skills for laparoscopic surgery are translated into seven didactic units regarding the capabilities of VR technologies. On the other hand, training needs for Nissen procedural skills are defined with adapted Hierarchical Task Analysis (HTA) techniques. Simulation specifications include three steps of this analysis, which are selected due to its critical importance or their special required motor skills. A validation strategy is divided in two steps, an iterative content validity study during simulation construction and a characterization of proficiency levels. Proposed didactic designs are the result of several content validity sessions with experts in surgery and education. Nevertheless, no results of the characterization of proficiency levels are provided. The value of each didactic exercise has been discussed, finding grounds that support the choice of a VR simulator for surgical training.

The present PhD work does not include experimental data about the effectiveness and efficiency of proposed didactic design of a laparoscopic VR simulator. Nevertheless there might be enough evidence in the literature about the validity of a VR simulator for surgical training and skills’ assessment, and this might be generalised to proposed didactic design. Main PhD contributions are: (1) The conceptual framework for the analysis, design and validation of surgical simulators, what is a new viewpoint that aims to clarify thinking, to guide research efforts and to focus development travail; (2) A simple model of pulling interaction forces for its simulation, (3) A methodology for studying laparoscopic sensory interaction; (4) The clarification of the hypothetical “visual haptics” skill in perceiving pulling

forces, a kind of sensory substitution, which has been revealed to be more a “sensorial haptic memory” developed with experience; (5) Didactic designs of a “basic skills” and a “Nissen” VR simulators for laparoscopic training. Several future research approaches are suggested towards an effective and efficient surgical training, like the use of proposed conceptual framework for defining an optimum simulation, the definition of the what has been called the set of Surgical Driving Signals, or the improvement of the didactic value of a simulator with a “smart instructor” feature based in teaching and assessment VR didactic resources and in adaptive contents to users’ needs. Finally, a glimpse over the future of Surgery driven by technical research is provided.

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Chapter I: Introduction

"*Laparoscopic surgery has had a significant impact on all surgical disciplines and is now firmly embedded in routine surgical practice*" [Cuschieri 05]. One of the main drawbacks of this technique is that surgeons require a long traineeship period to acquire all necessary skills and to accommodate to the laparoscopic environment. Physical inanimate models placed in *box trainers* are the most spread mean of training. There is a crescent pressure to have transparent training programs, with objective metrics of surgical skill, and with alternatives that might be used at any time. Virtual reality (VR) simulators are a valuable and valid solution for surgical training and skills assessment.

Nowadays new VR simulation technologies are developed, and serious efforts are being made towards the construction of high fidelity systems for surgical training and skills assessment. But little is known about the actual requirements of simulators in order to be effective training tools. There are doubts about the better efficiency of VR compared to physical trainers. Therefore the problem addressed in this PhD thesis is how to offer an effective and efficient VR means of training in laparoscopic surgery. And more focused to the design of the simulator, the question is to determine what makes it a useful didactic tool.

Three different methodological approaches are taken to face the design of an optimal surgical simulator: (1) The development of a conceptual framework for the analysis, design and validation of simulation technologies (Chapter IV), (2) the study of sensorial capabilities in order to clarify simulation requirements and the need of force feedback (Chapter V), and (3) the design of a surgical simulator for laparoscopic training adapting methodologies for defining specifications and applying lessons learned in the former two approaches (Chapter VI).

VR simulation for laparoscopic training and skills assessment

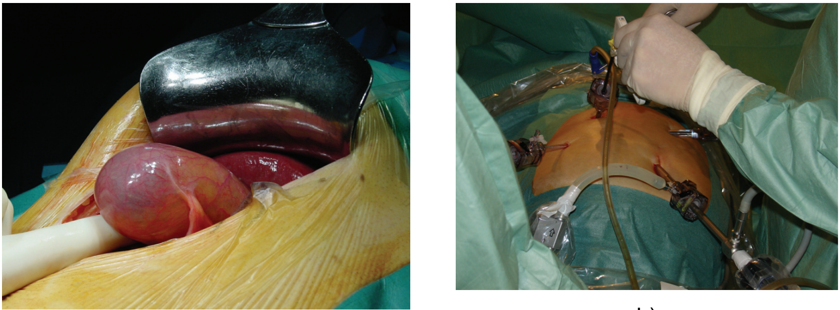
Laparoscopy, the most common minimally invasive surgical technique, has bursted into the operating theatre since twenty years ago [Cuschieri 05]. Its use has spread to almost all surgical services at hospitals among all over the world. It is already the recommended technique in many procedures, like the cholecystectomy, displacing open surgery. Laparoscopy is also becoming the standard technique for other pathologies, like those associated with anti-reflux diseases, colon and rectum among others [Cuschieri 06].

The bursting of this technology with its new concepts and skills has caught unaware many surgical practitioners from the services of hospitals. Whereas some surgeons have made an additional effort to adapt to this new technology, others have rejected it and have lost the opportunity. This change from open to minimally invasive surgical techniques is spreading over surgical procedures and specialities. Today there is no doubt that laparoscopic skills are a principal component of the education of the new surgical residents, and that minimal access is the present and, together with robotics, the future of surgery.

Laparoscopic surgery has very important advantages over open surgery (see Fig. 1). It minimizes tissue trauma and suffering, which leads to short recovery times and cost reduction. It also has lower incidence of wound infections and better cosmetic outcomes. However it presents some technical difficulties due to the limited workspace of the surgeon. Therefore surgeons require a long traineeship period to acquire all necessary skills and to accommodate to the laparoscopic environment.

Traditional training is based in gaining operative experience through "supervised trial and error" on real patients, which is called the Halsted method. This approach is undermined by ethical and practical reasons, it's opportunistic, stressful, and it has constraints on available time, fears, costs and concerns of trainees not getting the degree [Reznick 93;Kneebone 03;Driscoll 04;Feldman 04;Grober 04].

In 1993 Reznick arose the discussion about where operative skills should be taught [Reznick 93], and nowadays there is a spread consensus about it: there is a clear necessity of acquiring technical surgical skills outside the operating room [Haluck 01;Maran 03]. Moreover there is a lack of standards to train and accredit surgeons. There is no standardised curriculum of training, no accepted consensus of how skills and knowledge have to be transferred.



a) b)

Fig. 1: Open (a) vs. laparoscopic (b) approach of a cholecystectomy.

There is a **crescent pressure to have transparent training programs**, with objective metrics of surgical skill and alternatives that might be used at any time [Kneebone 03]. Virtual reality (VR) simulators are a valuable tool for training and skills' assessment [Gallagher 03c]. Skills learnt with simple VR laparoscopic simulators can be transferred to the Operating Room (OR) environment [Seymour 02;Grantcharov 04]. One recent meta-analysis has concluded that VR training reduces time and errors, and that it is a valid tool to differentiate expertise levels [Haque 06]. The main goal of every surgeon is to improve patient's safety, and surgical simulators can play a main role for it [Feldman 04].

How to offer an effective and efficient training

Nowadays new VR simulation technologies are developed, and serious efforts are being made towards the construction of high fidelity systems for surgical training and skills assessment. But little is known about the actual requirements of simulators in order to be effective and efficient training tools [Dankelman 05]. There are doubts about the better efficiency of VR compared to physical trainers [Munz 04].

The development of the first VR simulator in 1997 [Wilson 97] has had to wait five years to see the first validation results, which have been considered a landmark [Seymour 02]. Now that we have the "proof of concept" clear it's a time to reconsider the optimal design of simulators looking for the best training effectiveness.

Therefore the question is how to offer an optimum training in laparoscopic surgery. And more focused to the design of the simulator, the problem is to determine what makes it a useful didactic tool. This problem has four different dimensions (see Fig. 2):

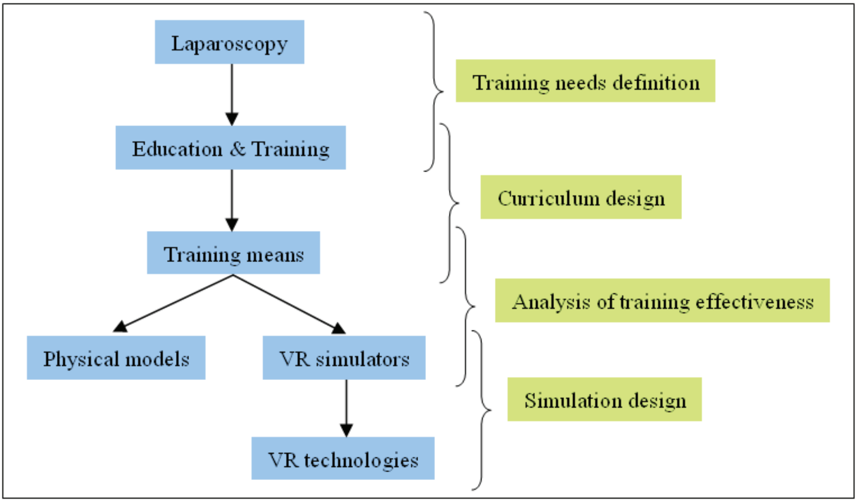


Fig. 2: Conceptual map of the four dimensions of the problem of the effective and efficient acquisition of laparoscopic skills.

- **Training objectives definition**. Objectives and needs of laparoscopic training still have to be agreed [Wentink 03], and these constitute the main requirements in VR simulation design. The definition of what is a competent surgeon and what has to be taught is also crucial [Satava 03b], but a concise and quantitative definition desirable for surgical simulation design is still lacking.
- **Curriculum design**. It has to be determined which training needs are to be covered with VR simulators in competition with other means like box trainers or animal models. Moreover, training is not only a matter of the means used, but also the learning curriculum developed. It has to be ideally based on proficiency levels rather than time-based criterions. There are conditions that should be satisfied in order to offer an efficient training.
- **Analysis of the training effectiveness**. Simulators aim to teach skills to surgeons, and these skills need to be tracked along training so as to have objective data to compare different tools and make a right choice for the training curriculum. Surgical skills assessment is a hot research topic and some proposals are beginning to be accepted like OSATS, MISTELS, or ICSAD [Aggarwal 04]. Even VR simulators have demonstrated its validity in assessing surgical skill [Gallagher 03c]. Nevertheless there is no consensus on how to measure the outcomes of a training tool, there is a need of a “training effectiveness” metric to evaluate simulators. There isn’t a gold-standard training method to compare alternatives, and validation studies are long and costly.
- **Simulation design**. VR simulation of living organs is a really complex task. Current technologies offer limited realism [Liu 03]. A critical issue in the design of simulators for medical training is the relationship between technology and training effectiveness [Kneebone 03;Anastakis 03;Basdogan 04]. A key concern is the level of fidelity necessary for proper training [Liu 03]. Studies are needed to clarify these aspects, serious consideration must be given to the human-factor strengths and limitations of surgeons [Gallagher 03b].

Problem statement: optimal simulator design

The scope is centred on the simulation design, the fourth of defined dimensions of the question of how to provide an effective and efficient laparoscopic training as explained in former section. **The aim is to develop an optimum VR simulator for laparoscopic training**. In other words, this PhD work is conceived to be a bridge between surgical training needs and VR simulation technologies in order to reach an optimum simulator (see Fig. 3).

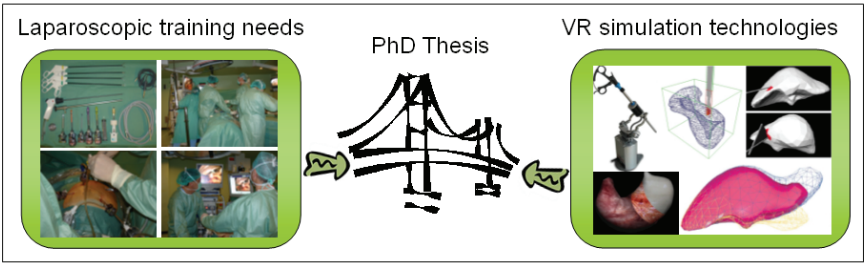


Fig. 3: Representation of the aim of this PhD work, "to be a bridge between training needs and simulation technologies".

VR technologies offer very interesting advantages, but they are also mined by some limitations in the realism. The design of a simulator needs a deep understanding of them, and to answer questions like "which are the resources offered by VR that can enhance training?", "what's useful in a VR simulator?", "which are its actual advantages over other training means?", "which are the laparoscopic training needs to be covered by a VR means?", and "what is the required degree of fidelity in simulation?"

A deep comprehension of laparoscopic training needs is essential to address these issues. This problem is also related with the study of human factors in surgery. The acquisition of laparoscopic skills involves some unconscious operations in which several perceptual, sensitive, motor and cognitive processes are involved. It is also necessary to answer questions like "which sensorial information use surgeons?", "how sensitive are they?", "what is the role of force feedback in surgical training?" This is much related with the definition of the required degree of simulation fidelity.

Justification for the research

There is a need of surgical training outside the OR, and VR simulators are beginning to play an important role on it. Research faced in this thesis aims for optimal training tools in laparoscopic surgery, which has clear benefits for both patients and the health system.

Existing VR simulators are being introduced in training programs and some curricula are being developed with them [Aggarwal 06]. But little is known about the actual requirements of simulators in order to be effective and efficient training tools [Dankelman 05]. Despite their clear potential advantages, there are doubts about the better efficacy of VR compared to physical trainers [Munz 04;Maithel 06]. They finally have a high cost that hinders them to be accessible for many surgical departments at hospitals. This research wants to find the essential components of these systems and to arrive to an effective design affordable by every institution that wants to teach surgical practitioners and to take advantage of the benefits of VR technologies.

This research aims also to contribute for the development of simulation technologies by determining the relevant aspects to be enhanced. Some work is conducted to the definition of specifications of haptic interfaces for specific surgical manoeuvres. The challenge of surgical simulation for training is to deliver a program that requires “zero operating time training”, what is the case of aviation [Wentink 03].

Methodological approach

Three different approaches are taken to face the design of an optimal surgical simulator (see Fig. 4):

- The development of a **conceptual framework** for the analysis, design and validation of simulation technologies (Chapter IV). The basis for this framework is to conceive a surgical simulator as a training means to meet different didactic objectives, a means that can be built making use of a wide range of resources available in VR technologies. This framework is applied and several commercial laparoscopic simulators are analysed, which is the starting point of a discussion about the relevance of each didactic resource for surgical training. An optimum design will be possible once the effectiveness of the different didactic resources has been assessed.

- The study of **human factors**, specifically the study of sensorial capabilities in order to clarify simulation requirements and the need of force feedback (Chapter V). The idea is to identify what visual and tactile information is perceived and how it is useful for the surgeon. This approach was already identified in [Tendick 00]. Methodologies for sensory interaction analysis are developed and surgical gestures studied. The final aim is to build perceptual models that clarify the required level of realism.
- The **design of a surgical simulator** for laparoscopic training (Chapter VI). Methodologies for defining specifications are adapted, studying surgical training objectives and lessons learned in the former two approaches and from the state of the art. It is assessed which didactic resources are more convenient to meet selected training objectives.

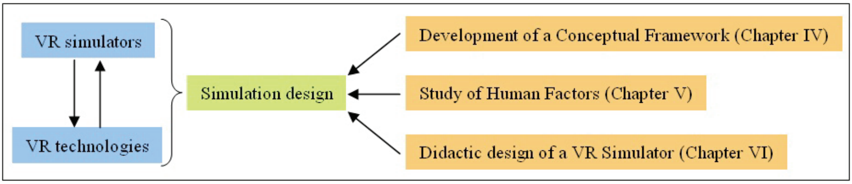


Fig. 4: The three approaches taken for the optimum design of a laparoscopic simulator.

Structure of thesis and framework

The structure of the present thesis is therefore changed from the traditional sections (literature review, hypothesis, material and methods, results, discussion and conclusion). A literature review about the field of VR simulation for surgical training is provided in Chapter II. Objectives and hypotheses are then raised in Chapter III. But then the work is splitted in the three independent chapters introduced before and shown in Fig. 4. A joint discussion and concluding remarks are presented in Chapter VII.

Present PhD thesis has been developed within the “Technologies for Surgical and Planning Simulation of Minimally Invasive Surgery” research activity of the “Grupo de Bioingeniería y Telemedicina” research centre (GBT), Universidad Politécnica de Madrid. GBT is working in two main projects in this topic: 1) SINERGIA- Spanish Collaborative Network (G03/135, 2003-2007), funded by the national Ministry of Health & Education through the *Instituto de Salud Carlos III,* in which GBT is the main project promoter and responsible of Technical Direction; and 2) SIMILAR Network of Excellence (FP6-507609), funded by the IV European Union Research Framework. This PhD work has also been possible thanks to a FPU-Formación de Personal Universitario grant (AP2002-2558, 2003-2007) funded by the Spanish Ministry of Science and Education.

The SINERGIA consortium is composed of 11 technical and clinical research centres specialized on biomedical engineering, biomechanics, computer graphics, virtual reality, imaging processing and minimally invasive surgery. The final goal of the network is the creation of a new and effective laparoscopic simulator for surgical training. Proposed didactic design of Chapter VI has been the roadmap of this SINERGIA consortium. A very close collaboration with the *Centro de Cirugía de Mínima Invasión* (CCMI, www.ccmi.es) of Cáceres has been essential for addressing such design. Development efforts of proposed simulation specifications has been coordinated with other three research centres, Medical Image Computing Laboratory (MedICLab, www.ci2b. upv.es/mediclab/) of Valencia whose former experience and departing VR simulator prototype [Monserrat 03] has been very valuable , *Laboratorio de Procesamiento de la Imagen* (LPI, www.lpi.tel.uva.es/lpi) of Valladolid, and *Centro de Tecnología Médica* (CTM, www.ctm.ulpgc.es/) of Las Palmas de Gran Canaria. It has been also extremely valuable the collaboration with the *Instituto Biomecánico de Valencia* (IBV, www.ibv.org) for addressing the study of biomechanical properties of four selected abdominal tissues in the study conducted in Chapter V.

The PhD work has also been benefited by the collaboration of GBT with the Dept. of Surgical Oncology and Technology of the Imperial College of London (www.doc.ic.ac.uk/vip/sot) through an internship. Specifically, this collaboration has generated a key contribution in the development of the work of Chapter IV.

Chapter II: State of the art

Surgical simulation could be as old as surgery. Almost any means used for training outside the operating room can be considered as a simulator with a certain level of fidelity. Today several and different kinds of simulators for surgical training can be found in the market. The idea of using VR simulators for training surgeons was introduced in 1993, the first prototype was developed in 1997 and the acceptance of its validity as a training tool has arrived in 2002. Concept is valid, and clinical research is now being conducted towards the design of proficiency-based training curriculum with the determination of proficiency levels to establish benchmark criteria, or even the validity of using simulators for trainees' selection.

Therefore the field of VR simulation for laparoscopic training is brand new. The long way to get a valid and reliable tool for training and surgical skills assessment is surrounded by several fields of knowledge: (1) Virtual reality technologies used to build a simulator, like biomechanical models, collision detection and handling algorithms, graphic technologies or haptic interfaces; (2) Medicine and surgery: what laparoscopy is and how it has to be performed, definition of what a competent surgeon is, which training needs exist, which relevant metrics can evaluate surgical skills, etc; (3) Cognitive and educational science to study how surgeons learn, how skills can be assessed, the validation of training and assessment tools, factors that can enhance training or performance, etc.

VR simulation technologies have a limited realism; it is currently impossible to model a precise interaction in a virtual surgical theatre in real time. Nevertheless this is not necessary for surgical training and skills assessment, as several studies have shown. This lack of realism is one of the reasons of the slow acceptance that these training means are having. It has been demonstrated how skills are transferred to the operating room, but this seems not to be enough for the introduction of these technologies in surgical training programs.

Introduction

The idea of using VR simulators for training surgeons was introduced in 1993 [Satava 93], and the first prototype was developed in 1997 [Wilson 97]. The acceptance of its validity as a training tool has arrived with a randomised double-blinded study [Seymour 02]. Concept is valid, and clinical research is now being conducted towards the design of proficiency-based training curriculum with the determination of proficiency levels to establish benchmark criteria [Satava 03a;Stefanidis 05;Brunner 05], or even the validity of using simulators for trainees selection [Gettman 03;Windsor 05].

Therefore the field of VR simulation for laparoscopic training is brand new. The long way to get a valid and reliable tool for training and surgical skills assessment is surrounded by several fields of knowledge, as explained in the following section. This introduction section presents also some basic concepts related to the simulation design, the aim of present work.

Related research fields

The design of a laparoscopic surgical simulator as a training or skills assessment tool is related with three main knowledge fields, as seen in Fig. 5:

- Virtual reality technologies used to build the simulator, like the biomechanical model, collision detection and handling algorithms, graphic technologies and haptic interfaces (see section 0 “VR Simulation technologies” of this chapter).
- Medicine and surgery: what is laparoscopy and how it has to be performed, definition of what is a competent surgeon, which are the training needs, which are the relevant metrics to evaluate a surgeon… (See sections 0 “Laparoscopic surgery” and 0 “Objectives and needs definition” of this chapter).
- Cognitive and educational science to study how surgeons learn, how skills can be assessed, the validation of training and assessment tools, factors that can enhance performance… (See sections 0 “How surgeons learn?” and 0 “How surgical skills are assessed?”).

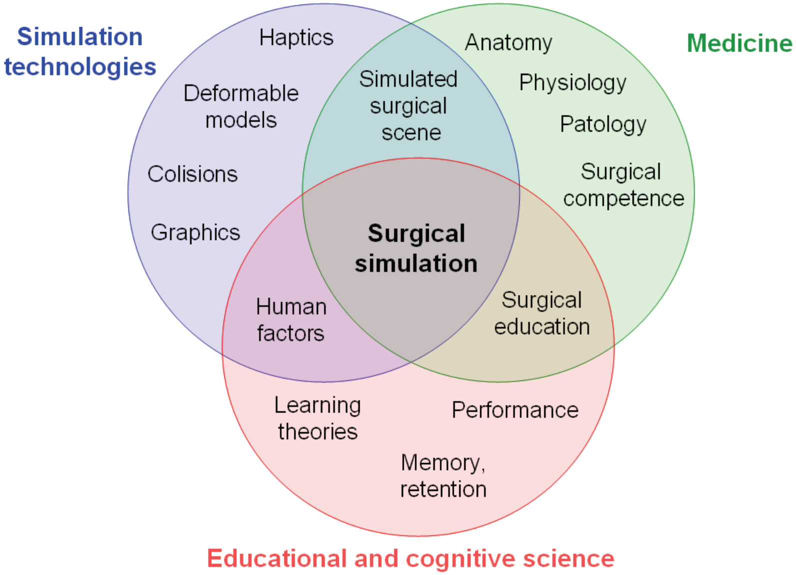


Fig. 5: Related research fields - figure adapted from [Liu 02].

Simulation design: requirements and specifications

How to address the design and development of a surgical simulator? The literature offers some books, guidelines and works that can help in this issue. An interesting and quite complete approach is offered in the "Verification Validation & Accreditation Recommended Practices Guide-RPG" that can be freely accessed through the internet. This RPG systematise the methodology for the development, verification and validation of simulation and modelling. Our interest is focused on the aspects of the Modeling&Simulation Development/Preparation process that helps to provide some basic concepts. This process is a small part of the big picture of the framework presented by the RPG [VV&A RPG 04].

The development process of new simulations has four main stages: (1) Requirements definition, (2) Development of the conceptual model, (3) Specifications design and (4) Implement and test. **Requirements** are the aspects that a simulation should satisfy, objectives that should be met, aspects of the problem that should be addressed. The developer's way of translating the requirements into a detailed design framework is the **conceptual model** shown in Fig. 6 [VV&A RPG 00]. It is a set of entities, actions, tasks, processes and interactions that describe how the developer understands what is to be represented by the simulation, and it is therefore the means by which simulation requirements can be transformed into simulation **specifications** that then drive simulation implementation design. Simulation requirements and conceptual model development are a classic "chicken-egg" pair, they each stimulate and derive from the other.

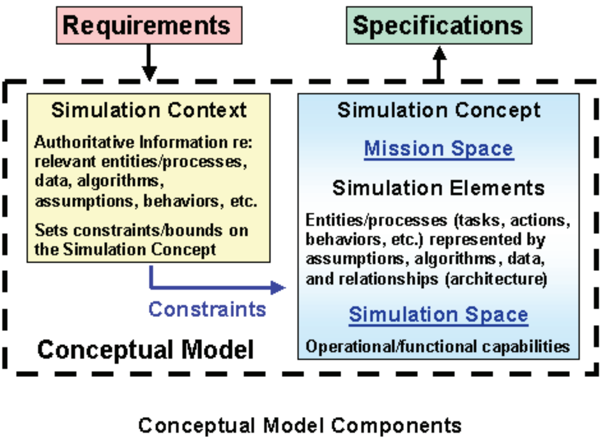


Fig. 6: Simulation conceptual model, taken from [VV&A RPG 00].

This chapter is structured following this process of building a simulator. Section 0 is focused on the first stage, the understanding of the requirements of a surgical simulator. Section 0 presents different means to meet the requirements, different simulators and means of surgical training and skills assessment, paying special attention on the added value of VR technologies and its acceptance. Finally, section 0 deals with the issue of how to arrive to the simulation specifications, something closely related with the definition of the simulation fidelity and the understanding of the human factors in laparoscopic simulation. The chapter is finished with some concluding remarks.

Requirements: laparoscopic training and skills assessment

The design of a surgical simulator begins with the definition of the requirements, that is, what the system is built for. In the field of surgical education there are two main aims to be addressed by a virtual reality simulator: surgical training in a safe environment and objective skills assessment. This section provides knowledge about laparoscopy surgical technique and its need of better training methods.

There is a third objective that a VR simulator may face: trainees' selection. Some authors have recently stated that results with simulators will help trainees to make an appropriate career decision [Gettman 03;Schijven 04b;Windsor 05]. A simulator for this aim can be seen as an assessment tool but, instead of directed to acquire surgical skills, directed to innate abilities. There is not a clear border between these two concepts, between what is innate and what can be acquired. Therefore this work will not enter in this discussion and will be centred on the field of skills assessment and not on the aim of trainees' selection.

Laparoscopic surgery

The first reported laparoscopic cholecystectomy was performed in 1987 [Litynski 99], almost 20 years ago. The benefits of this radical change in the surgical technique were hidden at the beginning because there were several complications and drawbacks reported caused by the poor training received by surgeons. But today this approach is the 'gold standard' technique in several procedures like cholecystectomy, and is spreading among other pathologies.

Laparoscopic technique (see Fig. 7 and Fig. 8) is a surgical approach in which the patient is operated through small incisions made at the abdominal wall using specialised tools and a camera called endoscope. The abdominal wall is inflated before the intervention in order to create what is called the pneumoperitoneum, the surgical workspace. Special gates, called trocars, are placed at the incisions of the wall in order to keep the pressure of the pneumoperitoneum and to prevent damage by the introduction and extraction of laparoscopic tools. These tools have a long axis of about twenty centimetres to reach the different organs and tissues inside the pneumoperitoneum. The endoscope, also introduced by a trocar, illuminates the surgical scene and captures the images, which are sent to a monitor or other kind of display.

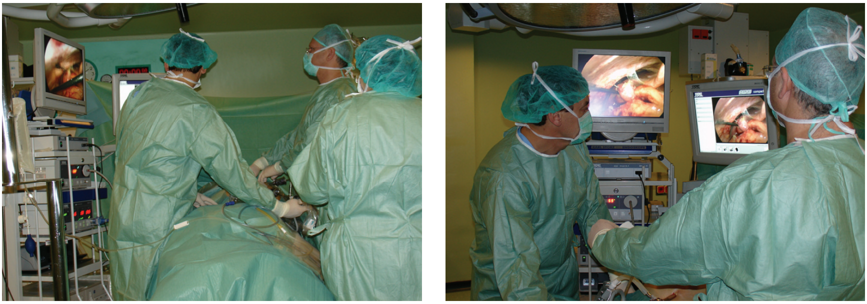
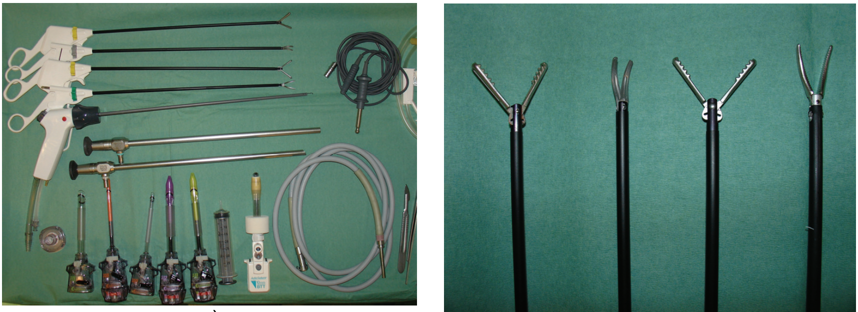


Fig. 7: Laparoscopic operating theatre.



a) b)

Fig. 8: Laparoscopic instrumental: (a) a complete set, with four different tools, an electrocautery hook, two endoscopes of 0º and 30º, six trocars, and different light and electric wires; and (b) detail of the end tips of the four tools: two graspers, a scissors and a dissector.

Therefore surgeons change radically the way of performing surgery when moving from open to laparoscopic surgery. They don't have a direct vision of the scene, whereas an indirect one captured by the endoscope. This makes depth perception much more difficult. Moreover the endoscope is usually manipulated by an assistant, who require some coordination and communication skills. Tools are much longer and haptic information is strongly decreased. And finally manipulation is counter-intuitive because of the fulcrum effect [Gallagher 03b], the inversion of movements due to the pivot point of the trocar. These differences are displayed with block diagrams comparing open and laparoscopic surgery in Fig. 9 and Fig. 10.

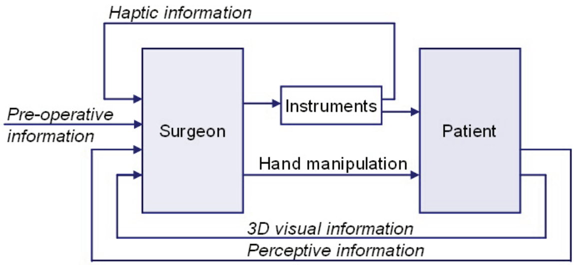


Fig. 9: Block diagrams of laparoscopic surgery – adapted from [Stassen 01]

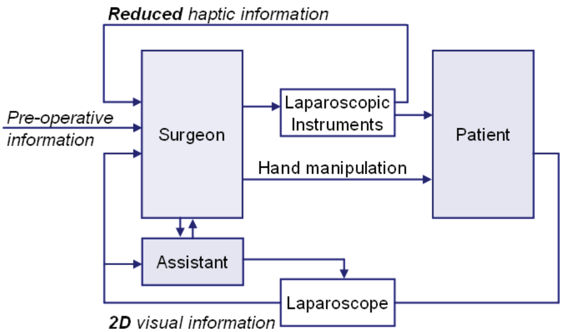


Fig. 10: Block diagrams of laparoscopic surgery – adapted from [Stassen 01]

Advantages and drawbacks of laparoscopic surgery

The basic characteristic of laparoscopic surgery is its trade-off between trauma and difficulty [Stassen 01]: it is far more complicated, and delivers important benefits to the patient.

The main benefits are the reduction of tissue trauma caused to the patient, a better cosmetic result, fewer post-operative complications, less pain and recovery time and a cost reduction in the health service. There is also an important advantage for the surgeon with the use of an endoscope and laparoscopic tools: the better access to small and deep anatomical areas, which are seen with a much higher detail than in an open approach. An example is the access to the hiatus in the operation of anti-reflux diseases (for more details see section 0 of Chapter VI, page 163).

On the other hand, drawbacks arise from the limited workspace and perception of the surgeon. There is no direct vision of the operating field and there is a need to acquire new skills to coordinate hand and eye movements. Tool manipulation is besides affected by the fulcrum effect and the degrees of freedom are limited to six as seen in Fig. 11: insertion /withdrawal, pitch, yaw, opening/closing grasp, torsion and tip torsion. Other difficulty is that the endoscope is not controlled by the surgeon, whereas by an assistant, which makes orientation in the laparoscopic space more difficult. Finally, surgeons have limited haptic information due to the long axis of tools and the degradation caused in trocars [Picod 05].

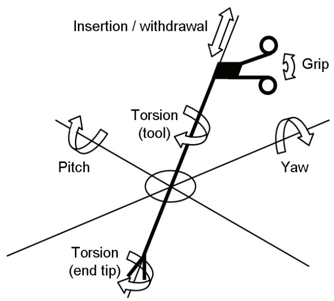


Fig. 11: Degrees of freedom of laparoscopic tools.

Laparoscopic skills

Surgeons moving from open to laparoscopic surgery have to develop new skills due to the limited interaction of laparoscopy and the use of specialised tools. It has been argued that some skills are innate and that these should be used in a selection process prior to the training of valid candidates [Gettman 03]. Another open question is the distinction of what is a skill, a task and a procedure [Satava 03a]. Regardless of these discussions the main laparoscopic skills that a surgeon coming from open surgery should develop are outlined next.

- **Visual spatial perception**: information displayed in a laparoscopic monitor is in 2D, whereas open surgery delivers a direct 3D vision. Surgeons have to learn how to perceive the visual spatial information from the laparoscopic scene.
- **Haptic perception**: haptic information is almost lost in a laparoscopic environment due to the long axis of tools and to the friction in trocars. However there are some tactile cues in surgery that have to be learnt in order to manipulate tissues and organs delicately. This skill is very subjective and hard to be systematically trained.
- **Camera navigation**: it has to be learnt how to navigate in the anatomy of the patient using an endoscope. Surgical laparoscopic scene looks different compared to open surgery: it displays tissues and organs with variable size, and an endoscope offers new points of view of the anatomy. Surgeons have to adapt to this new visual interface and know its new potentials.
- **Hand-eye coordination**: sight and haptic information are no longer concurrent, laparoscopic surgical scene is not displayed in the same place where the hands and tools are. Surgeons have to learn how to coordinate movements in this situation and to overcome the counter-intuitive behaviour of movements caused by the fulcrum effect.
- **Grasping and pulling**: the manipulation of laparoscopic tools involves learning how to grasp and pull tissues steadily and delicately.

- **Coordination of both hands** to manipulate and transfer objects is also important, and a requisite for more complex skills.
- **Cutting and dissection**: these two surgical manoeuvres have to be adapted to a laparoscopic environment. The basic skill to be acquired is the coordination of a right tissue exposure of the left tool with a delicate and controlled cut or dissection gesture with the right tool.
- **Suturing**: intracorporeal suturing requires some special skills to be performed. The main difficulty compared to open surgery is the reduction of the degrees of freedom in the movements of the tools. This makes the confection of the knot a difficult task due to the slippery behaviour of the suturing thread.

How surgeons learn?

It is clear that the laparoscopic technique needs some special skills to be acquired, but how do surgeons learn them? Fifteen years ago, in the introduction of laparoscopy, traditional halstedian method was used, which was underpinned by the higher rates of complications found [Deziel 93]. Nowadays it is widely accepted that laparoscopic training must be done outside the operating room, but there is no “gold-standard” training program.

Available surgical education and training programs

Surgical practitioners that want to acquire laparoscopic skills have basically three alternatives: be a “lucky resident”, make several intensive training programs or find their own way. Surgical departments usually offer to residents a gradual training period of several years with different opportunities of practise in real patients, and sometimes they provide with some training means like box trainers or animal models. This approach is opportunistic, and provides the training mainly in the operating room.

Intensive training programs of 2-3 days, the second alternative, are offered by specialised centres, and they have a strong demand. The success of this form of training is now evident from the large number of laparoscopic courses available worldwide [Aggarwal 04]. An excellent example of this methodology is the training workshops and courses offered by the Minimally Invasive Surgery Centre of Cáceres (Spain), whose didactic paradigm is based in a four-levels training pyramid (see Fig. 12).

Fig. 12: Training model followed by the Minimally Invasive Surgery Centre of Cáceres (Spain), which shows a four levelled structure: (1) basic and advanced skills with box trainers and VR simulators, (2) anatomical protocols and advanced skills with animal models, (3) advanced procedural skills with tele-surgical procedures and (4) practice in the operation room.

Finally, there are also available tools for autonomous training, like the "Fundamentals of Laparoscopic Surgery" offered by the SAGES-Society of American Gastrointestinal and Endoscopic Surgeons [SAGES 05]. A practising box with an instructions´ CD can be easily acquired and be a means for auto training. There is also a net of examination centres in USA for certification purposes. A short description of this programme can be found in [Fried 04a]. Finally several surgeons have to find its own way and develop home-made solutions in order to gain practise with laparoscopic tools. An example is a box trainer built with a web cam and a personal computer [Chung 05]. Summarising, training of laparoscopic surgeons is nowadays characterised as opportunistic, inefficient and still with some risk to patients.

Learning theories and models

Some theoretical background is important for facing an optimal simulation design for training. The main **theories about adult learning** could be the behavioural, the humanist, the constructivist and the cognitive, which are short reviewed in [Kneebone 03]. A basic concept close to the behavioural current and applied to the learning of a surgical task is highlighted: learning is a progressive process with three phases: (1) cognitive –learn the steps, (2) associative –learn to make the steps and (3) autonomous –automate actions. More information about a theory-based conceptual framework for creating links between task-based practice and clinical practice can be found in [Kneebone 04].

But there's something that might be more important than these theories for the design of a simulator: the **taxonomies of learning objectives**. The reason is simply the need of clarify which objectives should be covered with a simulator and which not in comparison to other learning means. After a review over some of them, two have been selected because of its apparent better relation and application to surgical learning. These are the Bloom taxonomy [Bloom 56] and the Rasmussen model [Rasmussen 83]. **Bloom taxonomy** states that there are three categories of objectives of learning: knowledge, skills and attitudes. Knowledge refers to cognitive aspects, the assimilation and transformation of information, skills to psychomotor competences and attitudes to the growth in feelings or emotional areas. Attitudes in surgery refers to how knowledge and skill are combined in the care of patients [Kneebone 03]. In this way, skills would be the main objective of a virtual reality surgical simulator. Expertise in these skills can only be gained by sustained deliberate practice over many years [Kneebone 03], therefore the training of skills is an objective big enough to justify the design and use of simulators. But, of course, learning objectives of a VR simulator around knowledge or attitudes shouldn't be forgotten.

On the other hand the **Rasmussen model** distinguishes between skill-based, rule-based and knowledge-based learning objectives. The skill level refers to the acquisition of autonomous behaviours, the rule level to the application of stored rules to the execution of procedures, and the knowledge level to the development of solutions to new problems.

An interesting application to learning in minimally invasive surgery is presented in [Wentink 03], and it's also used as a framework to analyse difficulties and challenges in [Stassen 01].

One last definition to be done is the distinction between declarative and procedural knowledge, which is clearly stated in [Liu 03]: "**Declarative knowledge** refers to **'**knowing what to do'. It is explicit knowledge of facts, such as anatomic landmarks during a procedure or physiological effects of surgery. This knowledge can be assessed easily via a quiz or recognition tasks. **Procedural knowledge** refers to 'knowing how to do'. It is explicit knowledge of how to perform a procedure, such as the sequence of navigation of landmarks or the rules of proper use of an instrument. It can be expressed verbally, although it may depend on nonverbal (such as visual or haptic) information. Traditionally it is tested verbally, but it could be assessed instead in simulation by testing the user's proper performance of the intended procedure". In this way, a surgical simulator is oriented to the learning of procedural knowledge.

Effective learning

How can an effective learning be provided? This question has been raised in many domains and much research has been done trying to answer it. And this is much related to the design of an optimal simulator. Some basic didactic criterions are next recompiled [Gagné 85; Reznick 93;Regehr 96;Guest 01;Schijven 03b;Kneebone 04; Issenberg 05].

Users of a surgical simulator are adults, and they follow the principle of the "need of learning". They have to understand the value of training, objectives should be clearly stated like in a list of operations a resident should be competent in doing by the end of the training session/program. In other words, the approach should be **self-directed and centred on the learner**.

Constructive feedback is what really differentiates simple practice and learning. It must be directed and followed by the trainee reflection. Performance criteria and metrics should be defined before, and they have to be adapted to the level of the trainee. These metrics should be representative enough of the whole learning objective. Moreover, good assessment methods ensure that the objectives of the programme are being met. Finally, offering the opportunity of correcting errors is very instructive.

There are several aspects of the **curriculum design** to be taken into account in the design of a surgical simulator. It has been clearly stated that distributed practice is better than intensive training. Training is more effective when it is focused on a problem or task, and when it is contextualised. It's also important to offer a wide range of levels of difficulty and clinical experiences (patients and pathologies).

Finally there are several **internal conditions** for effective learning. Trainees should be motivated, a simple repetition of a task is inefficient without the reinforcement of the aim to learn and enhance skills. Straightforward repetition of a task, such as occurs during everyday work, is ineffective unless it is underpinned by a drive to learn and to improve. Practice is better without mental or physical fatigue and without the stress of "having the life of a patient in your hands": a safe environment like a simulator allows focusing the attention on learning more than in the patient's safety.

Finally, and as a conclusion of this section, the main remarks from an interesting meta-analysis studying the features and uses of high-fidelity medical simulations that lead to effective learning [Issenberg 05] are outlined. This study has found that the most important features of simulation-based medical education reported by reviewed articles are: providing feedback (47% of articles), repetitive practice (39% of articles), curriculum integration (25% of articles), range of difficulty level (14% of articles), multiple learning strategies (11% of articles), capture clinical variation (11% of articles), controlled environment (9% of articles) and individualized learning (9% of articles). It is also important to note that only 3% of articles provided evidence for the direct correlation of simulation validity with effective learning.

How surgical skills are assessed?

Surgical skills assessment is an emergent research field with a lot of work conducted to define relevant metrics of surgical performance [Kneebone 03]. It is very important for giving constructive feedback to trainees and to structuralize learning [Moorthy 03]. Surgical credential is a very interesting goal being pursued, since it would give a very important value to training programs. Learning would be much more effective since participants would improve their skills up to a competency level that guarantee a good surgical practice in the operating room. This would have a great attractive both for trainees and for learning institutions.

Nevertheless the science of assessing surgical skills has been characterised as “being in its infancy” [Darzi 01]. Nowadays it is based in techniques which are subjective and little reliable [Moorthy 03]. Physical and virtual simulators are tools that offer a means to assess surgical skills, but there is little evidence of its ability of predicting surgical performance in the operating room. The main three difficulties are pointed in [Feldman 04]: (1) the lack of universally accepted metrics, (2) the variety of simulators with different levels of validity and reproducibility and (3) the different levels of experience of users and the little sample size in the validation studies done.

Despite these research efforts, practice of surgical evaluation of novice practicioners is currently based in the subjective judgement of the expert that is tutoring them under the traditional Halsted method. In other words, there is no objective metric introduced in the surgical theatre.

Methods for surgical skill assessment

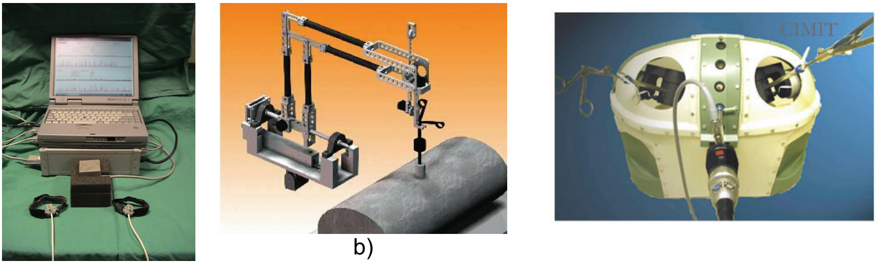
Three studies can be found in the recent literature that give an overview about the methods for surgical skill assessment [Moorthy 03;Aggarwal 04;Feldman 04]. It is also important to highlight a relevant article in this field [Reznick 93] which provided a basis in this field of skills assessment. The main ideas are outlined in this section.

The most extended method is a **direct observation by experts** and annotation in what is call an ITER- *In Training Evaluation Report*. Information gathered in these reports is a score list of several aspects of surgical competence (knowledge, communication skills, professionalism, technical skills). This method lacks reproducibility and fails in the assessment of technical skills. Direct observation can be improved with the incorporation of specific and predefined criteria, which is the main idea of the OSATS, *objective structured assessment of technical skill*. It combines a set of *checklists* and global ratings. This is probably the best method, but it requires a high cost in time and resources.

Recent works have developed **dexterity analysis systems**, such as ICSAD- *Imperial College Surgical Assessment Device* shown in Fig. 13 [Datta 02] and ADEPT- *Advanced Dundee Endoscopic Psychomotor Trainer* [Francis 02]. These systems use electromagnetic [Sokollik 04], optical or mechanical, like the Blue Dragon shown in Fig. 13 [Rosen 02a], tracking sensors to evaluate the movements made by the surgeon. There are also studies that try to find evaluation metrics in the force profiles made by surgeons. The information of forces and movements can be analysed with attractive methods like Markov Hidden Models [Rosen 02b].

There are **physical simulators** that offer simple task which can be analysed easily and allow skills assessment. Some examples are the *Southwestern Center for Minimally Invasive Surgery Task*, the "*Rosser" Tasks*, the MISTELS (*McGill Inanimate System for Training and Evaluation of Laparoscopic Skills*) or the CELTS shown in Fig. 13 [Stylopoulos 03]. These systems have two main advantages: they allow an evaluation off-line and they can be combined with some tracking system and provide information of the movements of the surgeon.

Virtual reality simulators are also valid tools for surgical skill assessment. They are effective in the evaluation of basic skills, but they could evaluate a whole procedure in the near future. The possibility of providing instantaneous constructive feedback is one of their main advantages.



b)

a)

c)

Fig. 13: Three alternatives to acquire objective dexterity data: (a) the ICSAD from the Imperial College of London, (b) the Blue Dragon from the University of Washington, and (c) the CELTS computer-enhanced physical simulator.

A good evaluation tool

An evaluation tool must satisfy these four conditions [Feldman 04]:

- **Reliability**: a measure of precision. Values of performance metrics from the same trainee in different days, without training between them, or acquired by different observers must be similar. It is measured with a value between 0 and 1: 0 means that the tool is not reliable at all, 0.5 indicates an acceptable reliability and 0.8 is considered a good level.
- **Validity**: it questions if an evaluation test measures what it is intended to. It provides the confidence that can be given to the inferences made about the surgeons being evaluated. Validation process must be transparent and robust enough
- Capability of provide **constructive feedback** to the user to indicate the aspects that have to be enhanced.
- The ideal instrument would be feasible, comprehensive, flexible, timely, accountable, and relevant.

Objectives and needs definition

The design of a VR surgical simulation begins with the definition of the objectives sought with it, the needs that it is intended to cover. As explained in Chapter I, this is one the first dimension of the problem of the optimal surgical training (see Fig. 2 in pag. 15): objectives and needs of laparoscopic training and the definition of what is a competent surgeon still have to be agreed [Wentink 03;Satava 03b].

It is surprising to realise that definition and classification of surgical abilities, skills, task and procedures is nowadays an ongoing work [Satava 03a]. And in the distinction between ability and skill there is an important consequence: ability is innate, and a skill is what can be trained and acquired. The discussion about how to use simulators, which are the target users of the system and who and how decides the criterion level of the task is open [Satava 03a]. Following some of the learning theories explained in a former section, VR simulators are seen as a means limited to train basic skills [Driscoll 04] or to skill-based didactic objectives [Wentink 03] (see Fig. 14).

The didactic fundament of simulators is hardly explained in the literature. Ideally, cognitive and technical task analysis by end-users should be obtained before the simulator is created [Champion 03]. An example of this kind of analysis can be found in [MacKenzie 01]. Another important issue is that the definition of objectives should be integrated in a complete laparoscopic training program and not isolated [Satava 01]. Finally, an ideal educational tool would be adapted perfectly to the needs of surgical practitioners. The identification of the individual needs is a complicated task. In this line an interesting framework to adapt training curriculum to the needs of clinical practice is proposed in [Kneebone 04].

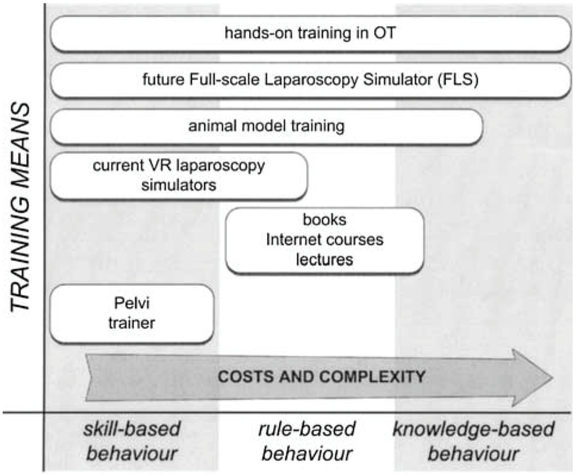


Fig. 14: Utility of different training means by [Wentink 03]

In the case of commercial simulators, MIST-VR was developed following an ergonomic task analysis [Wilson 97;Stone 04], but no information about this analysis has been found. The other simulators offer two kinds of didactic approaches: (1) a set of simple tasks, “basic skill” packages, to practice and acquire identified laparoscopic skills like those described in section 0; and (2) the simulation of different surgical procedures to learn theirs different steps or practise theirs critical steps.

The second main application of VR surgical simulators is skills assessment. Nevertheless, the definition of what is a competent surgeon, what would be the final goal of an educational process, and how to assess competence is a controversial issue. Some efforts have been done trying to take some steps, like the definition of the six components of surgical competence [Satava 03b]: Knowledge, patient care, interpersonal and communication skills, practice-based learning and improvement, professionalism, and systems-based practice. Nevertheless it is not clear which attributes of surgical practise has more importance for the benefits of the patient [Jha 01]. And the great difficulty is to define criteria to judge who is and who is not a competent surgeon.

The means: VR surgical simulators

As seen in the former two sections there is a need of laparoscopic training outside the operating room, and skills assessment is a desired objective by the surgical community. VR surgical simulation is a means to meet these didactic requirements, but not the only one. An overview of different training simulators is provided in section 0. Nevertheless VR technologies, described in section 0, offer an added value for training and skills assessment, as explained in section 0. Despite these advantages and some positive validation results, the introduction of VR simulators in training programs is still small, what is analysed in section 0.

Kinds of simulators

Surgical simulation could be as old as surgery. Almost any means used for training outside the operating room can be considered as a simulator with a certain level of fidelity. A piece of meat used for training a suture could be an example. Or an orange that have to be peeled off delicately. “Simulation can be defined as a device or exercise that enables the participant to reproduce or represent, under test conditions, phenomena that are likely to occur in actual performance” [Krummel 98]. Today several and different kinds of simulators for surgical training can be found in the market. Two works recently published give interesting overviews over them [Kneebone 03;Maran 03].The main ideas are explained in this section.

Simulators are classified depending on the materials used for building them as physical, virtual or hybrid (see Fig. 15). **Physical simulators**, also called box trainers, model-based simulators [Kneebone 03], video trainers [Hamilton 02] or pelvi trainers [Wentink 03], use different materials for building training models like the following: simple seeds and wires set for completing a task; advanced anatomical reproductions, whose technology is quite advanced and provides realistic and cheap models [Kneebone 03]; whole body mannequins; etc. Examples of these simulators with a structured training curricula can be found in [Derossis 98] and [Scott 00].

a) b) c)

Fig. 15: Kinds of simulators depending on the materials used: a) Physical simulator b) VR simulator c) ProMis, a commercial hybrid simulator.

These physical trainers are easily introduced in training programs, and they have found positive validity results [Rosser 97;Anastakis 99;Scott 00;Aggarwal 04]. Surgeons are exposed to real conditions, and they can explore and get used to the limited human-machine interface of laparoscopy [Jha 01]. Moreover advanced simulation can reproduce a whole surgical theatre, offering ways of interpersonal skills training [Jha 01]. However the main limitation is that they do not provide either skill assessment or constructive feedback to the trainee. They usually offer isolated parts of the human anatomy making it difficult to deliver an illusion of reality [Kneebone 03]. Moreover these educational means can be expensive, as they use expensive real laparoscopic tools like the endoscope or plastic anatomical reproductions that are individually cheap (around 80€) but expensive if they are used intensively. The problem of cost can be partially solved by using with cheap resources like a webcam and a personal computer [Chung 05], which offers a very interesting cost-benefit relationship.

Animal models are also used for training. Pigs or dogs are introduced in operating theatres and trainees practice on them. These models have a very high fidelity, but are mined by economical and ethical reasons. A good example of the proper use of this training means is the pyramidal tranining curricula designed by the Minimally Invasive Surgery Centre of Cáceres (see Fig. 12).

On the other hand **virtual reality simulators** are built with the resources offered by computers and interface devices. Laparoscopy can be trained with basically three components: a haptic interface that behaves like laparoscopic tools, a monitor that shows the surgical scene and a computer that manage these two interfaces and the virtual models of tissues, organs and tools. More details about the VR technologies can be found in section 0. The first VR product was the MIST-VR, which is the most thoroughly validated [Driscoll 04] with clear results of how skills are transferred to the operating room [Seymour 02;Grantcharov 04]. More details about commercial products, the value of these simulators, their technologies and their validation and acceptance can be found in following sections of this chapter. A quick overview of laparoscopic VR simulators can be found in [Schijven 03b].

A more detailed state of the art [Kneebone 03] presents a taxonomy adapted from [Satava 01] that classify VR simulators depending on the complexity of the task or procedure being simulated: (1) precision placement systems normally used by undergraduate students; (2) simple manipulation tasks like the manipulation of the endoscope [Korndorffer, Jr. 04]; (3) complex manipulation simulators like MIST-VR (Mentice AB, Goteborg, Sweden) or LapSim (Surgical Science, Goteborg, Sweden); or (4) integrated procedures like the cholecystectomy offered by LapMentor (Simbinox, Lod, Israel).

VR simulators have been also classified depending on the degree of development in three generations [Satava 96]. First prototypes allowed navigation through virtual reconstructions from anatomy of the patient, the second generation is offering mechanical interaction with organs, and the next generation will reflect the physiological behaviour of a virtual patient.

Finally **hybrid simulators** are built with physical materials and are enhanced with some interface enrichment like motion tracking devices, augmented reality features, etc. A good example is ProMIS (Haptica, Dublin, Ireland), which uses real tools which are optically tracked.

VR laparoscopic commercial simulators and prototypes

There have been many research projects and efforts to build laparoscopic surgical simulators during the last ten years. This section provides an overview on the resulting commercial products.

MIST-VR (Mentice Inc, Göteborg, Sweden). This is the first developed simulator [Wilson 97]. It offers an interesting abstract simplification of the laparoscopic workspace with a very low degree of fidelity. Nevertheless it has proved to be a valid tool both for training [Seymour 02] and for skills assessment [Grantcharov 01].

http://www.mentice.com/

LapSim (Surgical Science Ltd, Göteborg, Sweden). This simulator offers a simplified laparoscopic environment to train the basic skills, and some specialised and complex scenarios to learn surgical procedures like the cholecystectomy.

http://www.surgical-science.com

ProMis (Haptica, Dublin, Ireland). This is a hybrid simulator that uses real laparoscopic tools for both physical and virtual tasks. Two cameras make an optical tracking of tools, which is used for the virtual tasks. The last release of the simulator incorporates some interesting augmented reality features to guide the physical tasks.

http://www.haptica.com

Vest-One (Select-IT, Bremen, Germany). This is the result of the KISMET project of the Karlsruhe University, which led to the foundation of Select-IT. The simulator incorporates force feedback and a set of basic task together with a rough simulation of the cholecystectomy.

http://www.select-it.de

Reachin Laparoscopic Trainer-RLT (Reach-In, Stockholm, Sweden). It is one of the first laparoscopic simulators that incorporate force feedback capability with the Laparoscopic Surgical Workstation (Immersion Medical Inc, Gaithersburg, MD, USA). It also offers an interesting option, Forceback^{TM}, in which haptic devices reproduce previously recorded movements.

http://www.reachin.se

Xitact LS500 (Xitact, Morges, Switzerland): It offers force feedback capability with its own designed haptic device mounted on its own platform.

http://www.xitact.com

LapMentor (Simbionix, Lod, Israel). This is the most advanced system nowadays. It has just incorporated a suture module into its basic skills package. This is the only simulator that offers pathological conditions in standard surgical procedures like the cholecystectomy.

http://www.simbionix.com

SEP (SimSurgery, Oslo, Norway). This is one of the newest development, with a new haptic interface paradigm: the use of electromagnetic trackers attached to physical tools. It hasn't force feedback, and it incorporates some new exercises in the basic skills package, like an interesting dissection.

http://www.simsurgery.no

SIMENDO (DeltaTech, Delft, The Netherlands). It offers its own compact haptic interface called TrEndo [Chmarra 06], and it is oriented to the training of basic skills following an abstract conception of the working space, as MIST-VR does. It has recently obtained its first validity results [Verdaasdonk 06].

http://www.delltatech.nl

The added value of VR surgical simulation

VR simulators also called computer-based, offer immediate advantages in surgical training over traditional physical systems.

- **Availability**: a trainee can practise at any time he wants it. There is no need of specialised and not easily accessible equipment like the endoscope.
- **Evaluation capability**: it is possible to follow the progress of the trainee through his learning curve. VR simulators offer a wide range of metrics for objective skill assessment. This is leading to proficiency-based training curriculum [Gallagher 05;Korndorffer, Jr. 05].
- **Directed and immediate constructive feedback**, what enhances both individual and collaborative learning [Kneebone 03]. This has been recently identified as the most important factor that leads to an effective training [Issenberg 05].
- **Autonomy**: a trainee can practise without supervision.
- **Cost reduction** mainly by the suppression of a supervisor behind the trainee [Jha 01].

There are also some potential benefits that have not been completely developed by VR technologies in conjunction with surgical research:

- **Any procedure.** It will be very interesting that surgical simulators could offer all laparoscopic procedures, allowing trainees to practise any of them and evolve in their learning curve [Jha 01]. In anaesthesia simulation there is a great value in the presentation of uncommon but critical scenarios in which a rapid response is needed [Gaba 88]. Nevertheless only certain steps and almost only the cholecystectomy are present in commercial products.
- **Specificity** to the training needs of each trainee [Kneebone 03]. The difficulty is to identify these needs, as explained in former section 0, but ideally VR simulation can offer different degrees of difficulty that can be tuned for each trainee: tasks under demand [Holzman 98]

- **Accreditation process.** The evaluation capability of VR simulators could lead to the definition of accreditation levels in surgical technical skills. This is a very ambitious objective, but current simulators lacks evidence to predict surgical performance in the operating room [Feldman 04]
- **Generalization** of laparoscopic training to every surgeon. The main difficulty is the high costs that commercial VR simulators have, from about 25.000 €.
- **Operation rehearsal**, what is the possibility of performing a virtual operation on a reconstruction of a real patient prior to the real surgical procedure. This involves the acquisition of MR and CT image studies, the introduction of specific biomechanical properties and the simulation of a whole procedure, what is currently a challenge.
- **Surgical investigation.** This refers to the possibility of investigating new ways and techniques of performing surgery in a virtual patient. This is nowadays quite futuristic.

Finally, there are some benefits shared with other simulators. First, there are **no ethical concerns** regarding to the safety of patients or animals. On the other hand a controlled and safe environment allows the trainee to **focus his attention in his learning process** and in critical aspects, not only on the safety of a patient [Jha 01]. Undesirable interferences are minimised [Holzman 98]. This also allows making errors and learning from them. Learning is on a whole enhanced from the theory to the practice [Maran 03].

Nevertheless VR simulators have several drawbacks. The main one is the **limited interactivity** offered by virtual organs and tissues compared to the real ones, what mines the high expectations of surgeons. There is a compromise between visual realism and interaction capability due to the limited computational power [Kneebone 03]. Users may therefore be unable to “suspend disbelief”, may treat the simulation only as a game of even act in a cavalier fashion knowing that the simulator is not a real patient [Jha 01]. Other potential risks are the possibility of acquiring inappropriate behaviours (**negative training**) or developing a false sense of security in skills that could lead to harm [Jha 01].

These benefits and drawbacks of VR simulators are conducting currently to three different applications of this technology, quite related between each others: surgical training, skill assessment and trainees selection. The validation of these ideas and its acceptance are explained in section 0.

VR Simulation technologies

How is a VR laparoscopic simulator built? Which are the different technologies needed? Simulating an operating scene is very complex, and very much more complicated than flight simulation. The main difference is the great difficulty of modelling living organs and the interaction with them in real time: visual update rate must be around 25Hz, and haptic update rate around 300Hz [Burdea 96;Delingette 98]. These issues are addressed in this section. An interesting overview about surgical simulation technologies can be found in [Liu 03].

As introduced in section 0, there are basically three elements in a laparoscopic simulator: a **haptic interface** that behaves like laparoscopic tools, a **monitor** that shows the surgical scene and a computer that manages these two interfaces and the virtual models of tissues, organs and tools. The software running in the computer has four main modules (see Fig. 16): (1) the **biomechanical model** that calculates the deformation and the behaviour of the organ in the virtual scene, (2) the **collision module**, which calculates the interaction between the virtual models and handles this information to other modules, (3) a **graphic motor** that renders the geometry in the visual device (screen), and (4) a **haptic motor**, which reads the positions of the haptic device and returns the haptic forces to the user. Sometimes some of these modules are integrated, like a biomechanical which integrates the collision detection [Gibson 98]. Details about these modules are provided in following sections.

The second basic concept in simulation is the **“simulation loop”**. An emulated real-time behaviour is emulated by the repetition of a cycle that controls the surgical scene. A generic simulation loop would make four principal steps: (1) read the positions of the tools represented by the haptic device, (2) detect the collisions between the elements in the scene and calculates the response of these collisions, (3) calculate de deformation and topological changes of organs and tissues with the deformable models that represents them and (4) display the new geometry and the reaction forces resulted from the deformation process. The **time step** is defined as the time taken to complete a simulation loop.

Therefore "real-time" means therefore that the simulation loop should be done 300 times per second for having a good haptic interactivity, or at least 25 times for a visual rendering. Due to the big difference between these two update rates, it wouldn't be efficient to build a simulation system running so fast to satisfy both at the same time as presented in [Cotin 99]. This is the reason why simulation has usually two loops, the haptic one and the visual one [Cavusoglu 00;Picinbono 02b].

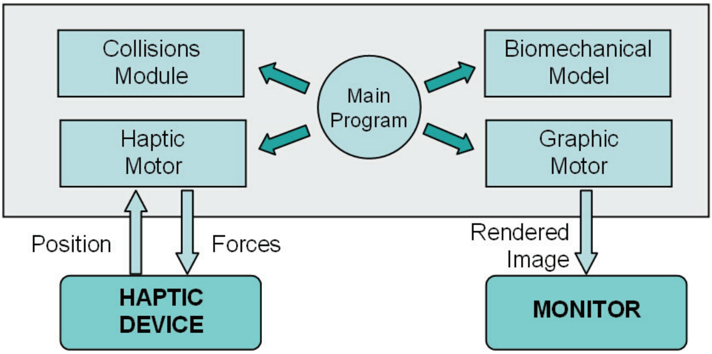


Fig. 16: The main generic modules of a laparoscopic surgical simulator.

Biomechanical modelling

Developing realistic biomechanical models has centred much research during the last years. This has been the core of the research around surgical simulation. A recent and interesting review on the topic can be found in [Meier 05], which concludes that "*At present, there does not yet exist an optimum deformable model that complies with all the different requirements of surgery simulation*".

The problem is that these requirements for a biomechanical model for surgical simulation are really restrictive. They are, ordered by importance, speed, robustness, satisfaction with the visual result and precision [Bro-Nielsen 98]. The challenge is to simulate a realistic biomechanical behaviour in real time. A visual update rate of 25Hz means that a simulation loop lasts 10ms. This is the meaning of real time: calculi in less than 10ms. Therefore there is a trade-off between precision (more complexity) and speed (less complexity).

Deformable models are classified in two main groups [Meier 05]: **heuristic and based in continuum mechanics**. The first group takes the hypothesis that the behaviour of living tissues is too complex to be simulated in real time. Examples are the mass-spring models (see Fig. 17) or the linked volumes. The second group is based in the concepts of the continuum mechanics but simplified in a right manner to simulate the biomechanical behaviour of organs. The finite element model (FEM) is a good example of this second group (see Fig. 18).

Biomechanical modelling is a difficult issue due to several reasons:

Acquisition and incorporation of real biomechanical properties. The fist step is to build experimental settings to acquire the parameters of living tissues, what is a very difficult issue [Lamata 03]. The incorporation of these properties into the biomechanical model is not trivial, moreover in heuristic models [Meier 05].

Tissue characteristics. There are some features of human tissues that makes them difficult to be modelled: (1) Anisotropy, what has been introduced already in FEM [Picinbono 00]; (2) Incompressibility: tissues are composed basically by water, and can be considered cuasi-incompressibles, what usually leads to instability problems [Picinbono 02a]; (3) non-linearity, already introduced in FEM [Picinbono 02a]; (4) high variability of mechanical properties between users, age, disease conditions…

There are cuts, dissections, tearing… in the surgical proceeding that have to be simulated. These actions mean that the model must be able to change its topology, making it impossible to have precalculations to speed-up the simulation. Heuristic approach is more suitable to allow these changes [Voß 99], but there are some solutions developed for a FEM model [Picinbono 00].

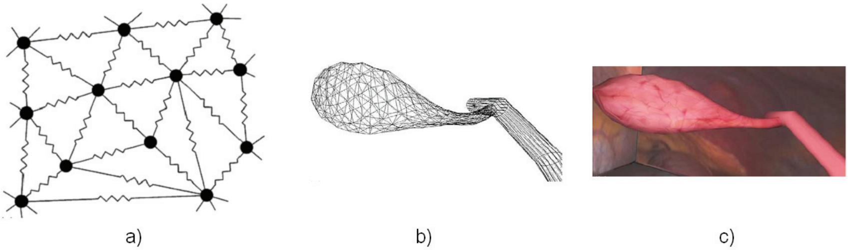


Fig. 17: Mass-spring biomechanical modeling. (a) Superficial network of masses and springs, the constitutive elements, (b) a gallbladder build with a network of masses and springs; (c) the rendered image in a surgical simulator. Figures taken from [Meier 05].

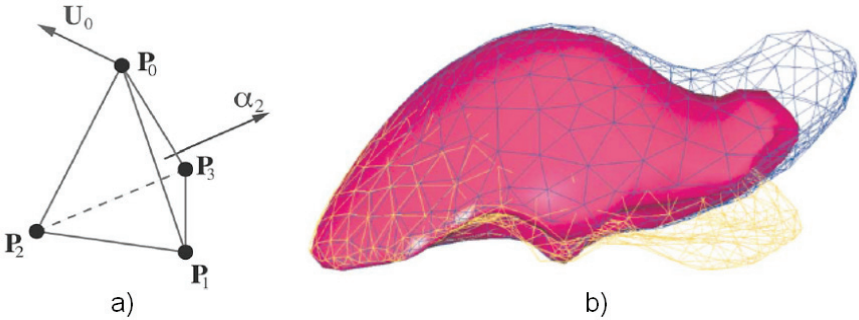


Fig. 18: FEM biomechanical modeling. a) A finite element, the basic component; (b) a liver simulated with this approach. Both figures are taken from [Picinbono 03].

This complex problem is therefore addressed taking some simplifications. The most common is to assume a linear elasticity that is valid for small deformations (small means about a 10% of the size of the organ) [Cotin 00]. This means that any force applied to the model causes an instantaneous deformation proportional to the load, and that the model returns to its rest position once the force is stopped. One of the main drawbacks of this simplification, besides its worse realism, is that a linear model is not invariant to rotation, what can leads to anomalous deformations [Picinbono 02a]. The second simplification is to reduce the requirements of the model, making it unable for topological changes allowing precalculations, adapting them to the expected behaviour in every surgical scenario… This makes them very specific. Other simplifications are to assume homogeneity and isotropy, because the loss of realism is not big if these two conditions are assumed in the biomechanical properties of tissues [Monserrat 01].

Collision detection and handing

Collision module is responsible for detecting overlapping volumes (collision detection) and handling the collision information to other modules (collision handling). Little specific research is found in the literature of surgical simulation about it, whereas this is a very productive field in the area of computer animation [Teschner 05b]. It is usually dealt together with the biomechanical model or with the calculi of the haptic response. An interesting recent overview about collision detection methods can be found in [Teschner 05b] and in [Muñoz Moreno 04].

Collision detection is usually addressed with a coarse remodelling of the objects present in the scene in order to reduce the complexity of calculi. One simple alternative is to define the boundary boxes of objects, and detect if there is any overlapping between them (see Fig. 19a). Another important concept related to the detection of collisions is the time step of the simulation: collisions are detected in discrete instants of time separated a certain number of milliseconds, the time step. Detecting collisions of a surgical tool, a long bar that can moves fast, requires a dynamic approach regarding the region swapped by this tool (see Fig. 19b).

There are three main types of collisions in surgical simulation: tool-tissue, tissue-tissue and tool-tool. Focus of research has been made into the first of them, and it has found quite interesting solutions [Forest 04]. Tool-tool interactions require very advanced haptic interfaces to deliver a good force response to the collision of two rigid objects, as explained in the following section. Finally, interactions between deformable models require a very high computational cost [Delingette 98]. In summary, there are several technical challenges in the solution of collision detection and handling for VR surgical simulation.

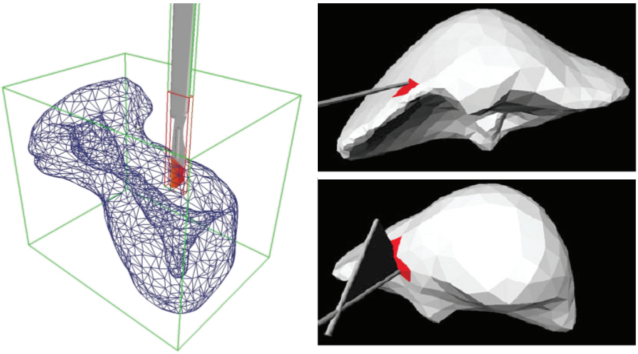
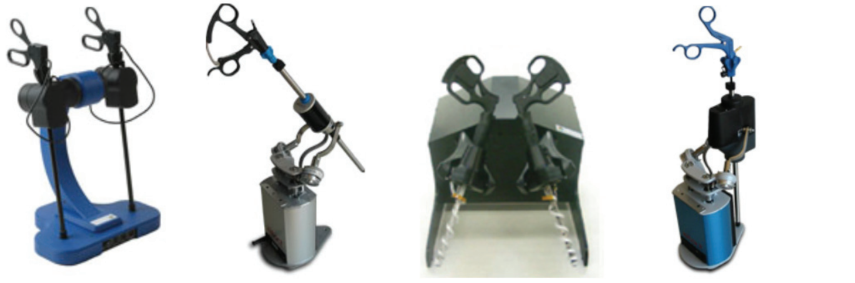


Fig. 19: Collision detection in surgical simulation. (a) Boundary boxes surrounding both an organ (green) and a tool (red). Image is taken from [Teschner 05a]; (b) Upper: detection in a single time step; Lower: dynamic detection regarding the position of the surgical tool at the beginning and at the end of a time step (images taken from [Teschner 05b]).

Haptic interfaces and force feedback

Technology for tactile simulation is much more immature than the visual displays. One of the main reasons is the critical requirement of a minimum update rate of 300Hz, much more restrictive than the visual one. Haptic devices have some limitations in workspace and realism that sometimes hinders the simulation value. One of the basic features of them is that the stiffer the material being simulated, the more difficult to provide a continuous haptic stimuli. An interesting overview about haptic technologies in minimally invasive surgery can be found in [Basdogan 04], and more details about the technology itself in [Biggs 02]. Available commercial haptic devices for laparoscopic surgery are shown in Fig. 20.

Haptic rendering is not only a good haptic device, but an algorithm for the calculation of interacting forces. There are several approaches for obtaining these forces. The first option is to use the biomechanical model. Heuristic ones are said to provide haptic experiences less intuitive [Delingette 98], and have some instability problems. Biomechanical models based on the continuum mechanics simulate forces with physical realism [Delingette 98], but they are computationally expensive. The second option is a geometrical constraint force calculation, to generate a force proportional to the penetration depth of the tool, as done in the buffer model of [Balaniuk 00], what is criticised to be not realistic enough in [Picinbono 00]. The third option is to extrapolate the result of the biomechanical models from the visual update rate to the haptic one, as done in [Picinbono 02b].



a) b) c) d)

Fig. 20: Commercial haptic devices. Non force feedback alternatives: a) Laparoscopic Virtual Interface (Immersion Medical Inc., Gaithersburg, MD, USA); b) Instrument Tracking Port (Xitact S.A., Morges, Switzerland). And devices with force feedback: c) Laparoscopic Surgical Workstation (Immersion Medical Inc., Gaithersburg, MD, USA) d) Instrument Haptic Port (Xitact S.A., Morges, Switzerland)

Visual rendering

The world of computer graphics has experienced a great advance during the last years due to the strong demand of video-games. Personal computers are now easily equipped with advanced and powerful graphics cards that enable a great visualization of complex scenarios. And there are many open-source software libraries that enable the construction of visualization systems. Therefore the visual rendering of the surgical scene in a surgical simulator is a problem solved with existing and available tools. A good result can be obtained with standard libraries and techniques. Some advances are directed to photorealistic rendering [Stoyanov 03] and to the simulation of fumes and bleeding [Zatonyi 03;Agarwal 03].

Validation and acceptance

There is not a clear answer about the acceptance of VR simulators. It has been demonstrated how skills are transferred to the operating room [Seymour 02;Grantcharov 04], but this seems not to be enough for the introduction of these technologies in surgical training programs.

Some authors defend that VR simulation offers attractive advantages and that it is becoming established. It offers task-based practice allowing novices to acquire basic skills before they are "let loose" on patients [Kneebone 04]. Moreover, although it is still in its infancy, simulation as a means of objective skills assessment is well recognised [Duffy 04].

But other authors argue that there are still doubts about the efficiency of this alternative against other training means like simple box trainers [Munz 04]. These box trainers are perceived by trainees to help more and to be more interesting [Madan 05]. It's also said that animal simulators are effective and efficient, and the best option until the arrival of better VR simulators [Wentink 03]. Another factor is the high cost of VR surgical simulations, around 25.000 €. Other reasons for the slow acceptance by the medical community are discussed in [Liu 03]:

> "*Despite the potential of such simulators, acceptance by the medical community has been slow. Physicians are familiar and comfortable with the current teaching model. They also remain largely unaware of simulation's potential. One reason has been the lack of clinical studies. There is little information comparing the training efficacy of simulators with current teaching models. More validation studies are needed to increase adoption of simulation technology by the medical community*"

This is the reason why validation has focused research attention in laparoscopic training among the last years [Gallagher 03a]. One of its main difficulties is the tension between development and validation: when a simulation technology is obtaining validation results, new technical improvements have appeared, coming back to the starting point, and validation is never finished this way… [Kneebone 03] Other common errors arise from the lack of scientific methodology [Gallagher 03a].

The validation of an educational tool, what a surgical simulator is, is a common problem in many domains. Nevertheless, there is a lack of an acceptable evaluation methodology [Feinstein 01]. Validation is a long and complex process, and it can be taken in many different ways depending on the aspect of simulation that is being studied, on the simulation itself and on its aim [Whitney 99]. Definition of the different validation strategies is presented in the following section based on the work of some American associations [American Psychological Association (APA) 74], which is summarised in [Gallagher 03a], and on different recent journal articles [Schijven 02;Moorthy 03;Schijven 03a;Feldman 04]. After the presentation of these validation concepts, a short review of validation studies is provided next.

Validation strategies

As explained before, a surgical simulator can be designed with two main aims: for surgical training or for the assessment of technical surgical skills. Both aspects are much related, as training effectiveness is assessed by monitoring how surgeons improve their surgical skills. Despite this close relationship, validation strategies have been decomposed in these two features. This distinction is not usually made at the literature.

- **Simulator as a skill assessment tool**

A simulator can be an examination tool for surgeons. Then it incorporates representative tasks of different technical skills, with different evaluation metrics defined to assess the performance of surgeons. When a simulator is designed to assess technical surgical skills it must be reliable, valid and feasible. Then it will be an examination tool to be used with confidence [Aggarwal 04].

Reliability is a measure of the consistency of a test, the extent to which the assessment tool delivers the same results when used repeatedly under similar conditions. It supposes no learning between the two tests. It is measured by a reliability coefficient, which is a quantitative expression of the reliability of the tests and ranges between 0 and 1. A good reliability coefficient has been approximated as values >0.8. Although lower values (i.e., <0.7) have been reported, they are generally frowned on in the behavioural sciences. Other useful measures of reliability are α, coefficient α, Cronbach's α, or internal consistency [Gallagher 03a]. Two different aspects are involved:

- **Inter-rater Reliability:** it determines the extent to which two different evaluators (raters) give the same score in a test made by a user. Example: two surgeons evaluate a student performing a simulated procedure and both agree on the overall performance score ($p > 0.80$). This feature has little interest in simulators when they automatically acquire the evaluation metrics, like Virtual Reality simulators.
- **Test-retest Reliability:** it determines the extent to which two different tests made by the same person in two different times give the same result. Example: students are tested twice on the same test and get equivalent scores each time.

Another common method to establish the reliability is the **split-half method**, for which test items from a single test occasion are split and then the internal consistency of the assessed items is calculated. One of the main problems in the literature with this kind of studies is that researchers and clinicians are too likely to conclude that a reliable test is ipso facto a good test for any purpose they have in mind [Gallagher 03a].

Validity relates to the property of "being true, correct, and in conformity with reality". In testing, the fundamental property of any measuring instrument, device, or test is that it ''measures what it purports to measure''. Therefore, validity is not a simple notion; rather, it is comprised of a number of first principles. The result is that within the testing literature, a number of validation benchmarks have been developed to assess the validity of a test or testing instrument. These include face validity, content validity, construct validity, concurrent validity, discriminate validity, and predictive validity [Gallagher 03a]. There are subjective (face and content) and objective (construct, concurrent, predictive) validity studies:

- **Face validity**: is defined as ''a type of validity that is assessed by having experts reviews the contents of a test to see if it seems appropriate''. Simply stated, experts review the tests to see if they seem appropriate ‘on their face value’. It is a very subjective type of validation and is usually used only during the initial phases of test construction. For example a simulator has face validity when the chosen tasks resemble those that are performed during a surgical task.

- **Content validity**: is defined as ‘‘an estimate of the validity of a testing instrument based on a detailed examination of the contents of the test items’’. Experts perform a detailed examination of the contents of the tests to determine if they are appropriate and situation specific. Establishing content validity is also a largely subjective operation and relies on the judgments of experts about the relevance of the materials used. For example a simulator has content validity when the tasks for measuring psychomotor skills are actually measuring those skills and not anatomic knowledge.
- **Construct validity**: is the degree to which the test captures the hypothetical quality it was designed to measure. A common example is the ability of an assessment tool to differentiate between experts and novices performing a given task [Schijven 03a]. Other approach is to study if surgical skills improve with simulation practice [Feldman 04].
- **Concurrent validity**: is defined as ‘‘the extent to which the test scores and the scores on another instrument purposing to measure the same construct are related’’. When the other instrument is considered a standard or criterion, the validity test is called “**criterion validity**”. **Discriminate validity** is defined as ‘‘an evaluation that reflects the extent to which the scores generated by the assessment tool actually correlate with factors with which they should correlate’’. Therefore it can be understood as a more restrictive construct validity.
- **Predictive validity**: is defined as ‘‘the extent to which the scores on a test are predictive of actual performance’’. An assessment tool used to measure surgical skills will have predictive validity if it predicts who will perform surgical tasks well and who will not.

Currently there is no consensus regarding the optimal assessment tool for laparoscopic procedures, and studies have been focused on construct validity [Aggarwal 04]. All of these validation strategies have merit; however, predictive validity is the one most likely to provide clinically meaningful assessment [Gallagher 03a].

- **Simulator as a training tool**

A simulator can be used as a training tool. It then incorporates representative tasks of different technical skills in a controlled environment. The question is whether this device with its training strategy actually trains or not the skill is supposed to. Several methodologies have been developed to answer this through subjective (face validity) and objective studies (concurrent validity, transfer of skills from VR to OR, learning curves, efficiency metrics).

- **Face validity**: In an interpretation of what is face validity for an assessment tool, validation studies of training tools have been done with this subjective methodology. This concept is then adapted to the degree in which a system emulates real conditions [Moorthy 03]. One example is the study of the Xitact LS500 system [Schijven 02]. These results can be useful at the early stage of design of the simulator.
- **Concurrent validity:** Validity of a tool can be proven when its results are similar to existing validated tools. The training outcome of different simulators has been compared, like the study of MIST-VR and a pelvic trainer that were similar [Kothari 02]. This has even been defined as the last stage in the validation process, in which the training effectiveness of the simulator is assessed [Schijven 03a]
- **Skills transfer from VR to OR** (Operating Room): This is the methodology that can show clinically useful learning results from simulator use. With prospective, randomized and blinded surgical trials novice surgeons are trained in different ways, and results can actually demonstrate how the skills acquired in a simulated environment are transferred to the operating room, to real surgery. In the field of laparoscopic surgery, the MIST-VR simulator has

been recently validated with this kind of studies [Seymour 02;Grantcharov 04], what has been considered as a landmark [Fried 04a].

- **Learning curves**: A learning curve is a plot of the acquisition of skills along time, measured by different metrics like dexterity, time or errors. If these metrics have been shown to be valid (see former section), a learning curve is a proof of how trainees acquire technical skills. For example, simple box trainer (physical simulator) have demonstrated how the learning curve for operator speed is shorter than that for operator accuracy [Smith 01]. The MIST-VR simulator has shown how novice surgeons improved their performance up to the experts level by practising on it [Gallagher 02].
- **Efficiency metrics**: although these haven't been used in surgical simulation, the field of flight aviation has some of them. One is the TER: Transfer Efficiency Ratio. It is a relationship between the hours required to reach a training goal. For example a TER value of 4:1 means that 4 hours in a simulator have the same didactic value that 1 hour of training with a real environment [Munz 04].

Literature review

Validation of simulation technologies for surgical training and skills assessment has focused research during last years [Gallagher 03a]. An example of this effort is the constitution in the summer of 2002 of the *Validation, Metrics an Simulation Committee (VMAS)* which aims to develop a robust scientific methodology to demonstrate the value of a surgical training program based on simulation [Harvey 03].

- **Physical trainers**

Physical trainers (commonly called box trainers) are usually present in surgical training programs. This is a quite straightforward means that every institution can build and afford, and it has found a good acceptance. Some efforts have been done trying to build standardized curricula for novice surgeons, and their validation studies have found a great impact. As an example, the standardized Rosser drills were tested in 150 trainees and demonstrated the incremental acquisition of skill [Rosser 97]. Nevertheless this study had no control group, and the only metric of skill was time, what has been said to be inconsistent [Grober 04]. Another example is the MISTELS physical simulator [Derossis 98], which has demonstrated the transfer of skills to the operating room [Fried 99]. This simulator is said by its creators to be introduced into a large number of academic medical centres across North America [Fried 04b]. One last example is the LTS2000, which has demonstrate its construct validity with 40 users [Fichera 05].

- **VR simulators**

Whereas physical trainers have found easily a place in surgical training programs, VR simulators are asked to demonstrate clearly its validity. An overview of the studies done is provided in Table 1 and Table 2. An interesting issue found is how novice users can even get better evaluation results than expert surgeons, as found in [Ro 05]. There is a familiarization rate to a VR surgical simulator faster for novices than for experienced surgeons [Hassan 05].

One of the questions that could be raised is, validate until when? It has been asserted that "…no industry in which human lives depend on skilled performance has waited for unequivocal proof of the benefits of simulation before embracing it" [Gaba 92].

Simulator as a skill assessment tool

Face validity

Valid?	*Simulator*	*Users*	*Task*	*Reference*
Yes	XitactLS500	87 exp. 33 novel	All	[Schijven 02]

Construct validity

Valid?	*Simulator*	*Users*	*Task*	*Reference*
Yes	MIST-VR	-	-	[Taffinder 98]
Yes	MIST-VR	100 nov 12 exp 12 inexp	6 basic tasks	[Gallagher 04]
Yes	MIST-VR	41	-	[Grantcharov03]
Yes	MIST-VR	36 (12 exp, 12 interm, 12 novel)	-	[Gallagher 02]
Yes	MIST-VR	29 students	-	[Ahlberg 02]
Yes	MIST-VR	30 students	3 basic	[Mcnatt 01]
Weak correlation scores - experience	MIST-VR	36 trainees, 37 students, 16 exp	-	[Paisley 01]
Yes	XitactLS500	37 exp 37 novel	Clip&cut	[Schijven03a]
Yes	XitactLS500	5 exp 5 novel	Clip&cut	[McClusky 03]
No	XitactLS500	50 novel (25+25)	Clip&cut	[Schijven03c]
Yes	LapSim	9 expert 9 novel	Navigation, cut	[Lonroth 03a]
Yes	LapSim	Exp., junior, naive	3 tasks	[Sherman 05]
No at first exposure to simulator.	LapSim	16 experienced, 13 novices	Basic Skill set and Dissection	[Ro 05]
Yes, but time and path metrics only	LapSim	54 of > 50 operats 61 of < 50 operats	Navigat. coord. grasp. cut. clip.	[Langelotz 05]
Yes, more patent in second	LapSim	Expert, intermed, novice	2 times 7 tasks	[Hassan 05]
Yes	LapSim	10 exp, 14 nov	-	[Eriksen 05]
Yes, but only some parameters	LapSim	Students, residents, faculty	10 repetitions of 6 tasks	[Woodrum 06]

Discriminative validity

Valid?	*Simulator*	*Users*	*Task*	*Reference*
A little. Only expert/ novel/ novel with slow learning rate.	MIST-VR	100 nov. 12 exp 12 inexp	6 basic tasks	[Gallagher 04]
Yes, four learning curves	Xitact LS500	33	-	[Schijven 04a]

Concurrent validity

Concurrent with…?	*Simulator*	*Users*	*Task*	*Reference*
Yes, with OR metrics	MIST-VR	14	6 basic	[Grantcharov01]
Yes, with evaluator's scores.	Xitact LS500	61 novel	-	[Gantert 03]
Yes, scores of dominant and non-dominant hand	LapSim	17	Navigation Grasping	[Carter 03]
No, with a 19-point tech. skill form	MIST-VR	89	-	[Paisley 01]

Table 1: Literature review synthesis about validation results of VR simulators considered as skills' assessment tools.

Simulator as a training tool

Face validity

Valid?	*Simulator*	*Users*	*Task*	*Reference*
Yes	Xitact LS500	87 exp. 33 novel	All	[Schijven 02]
Yes	LapMentor	21 >50 operats, 28 <50 operats	All	[Ayodeji 05]

VR to OR transfer study

Valid?	*Simulator*	*Users*	*Task*	*Reference*
Yes	MIST-VR	16 novel (8 + 8)	Diathermy	[Seymour 02]
Yes	MIST-VR	16 novel (8 + 8)	6 basic	[Grantcharov 04]
No	MIST-VR	29 students	-	[Ahlberg 02]
Yes	LapSim	24 novel	-	[Hyltander 02]
Yes	LapSim	16 novel (8 + 8)	Coordination Apendectomy	[Lonroth 03b]

Comparative study: is VR superior, similar or inferior to a box trainer?

Result	*Simulator*	*Users*	*Task*	*Reference*
VR may provide faster automation of fulcrum effect.	MIST-VR	24		[Jordan 00]
They are **similar**	MIST-VR	30 students	-	[Torkington 01]
Not valid (results are wrongly interpreted in the article)	MIST-VR, Rosser drills	(not valid)	(not valid)	[Pearson 02]
Skills transfer from one to other. **VR superior** in transfer to OR.	MIST-VR, SCMIS GEM	50 (25-25)	10 sessions of 30' making 6 basic	[Hamilton 02]
They are **similar** in suture training.	MIST-VR, Yale Skills Course	Students	5 sessions	[Kothari 02]
They are **similar**	LapSim	24 (8 LapSim, 8 box trainer, 8 control)	3 sessions of 30', making 5 basic tasks	[Munz 04]
VR is superior	LapSim, Tower Trainer	46 (17 LapSim, 16 Tower Trainer, 13 control)	4 sessions of 45' making all tasks	[Youngblood 05]
physical more sensitive (construct validity)	MIST-VR and MSITELS	32 students on both simulators	-	[Avgerinos 05]
They are **similar** (construct and face validity)	MIST-VR, Endotower, and CELTS	91	2 repetitions 1 task	[Maithel 06]

Table 2: Literature review synthesis about validation results of VR simulators considered as training tools.

Optimal simulation specifications

Former section has provided a basic understanding about the requirements of a simulator and the value of VR technologies. This last section of this chapter addresses the question of how to design the simulator and how to define its specifications.

The first point is to identify the skills or procedures to be taught, and to develop the training objectives. Then the appropriate training device must be selected [Maran 03]. And if the added value of VR technologies is important for selected objectives, these means should be chosen and not other options like box trainers (see section 0 "Kinds of simulators" in page 41). More information gathered from literature about how to define the contents of the simuator is presented in section 0 "Building a VR simulator" in page 64.

One important point about simulation design was concluded in an international workshop at Standford [Stanford 01]: "*it will never be possible to model a precise interaction in a virtual surgical theatre in real time. Nevertheless the good news is that this is not necessary for surgical training and skills assessment*." Other authors have stated that "*a good simulation represents simplified reality, free of the need to include every possible detail*" [Gorman 00] referring the book of [Jones 80]. This topic of simulation fidelity is further dealt in section 0.

Finally, a good understanding of human factors is necessary to clarify specifications of a simulator. This issue is much related with the fidelity that should be emulated in the virtual environment. Moreover, it is also important to clarify how surgeons interact and how they develop their sensory and motor skills. All this aspects are discussed in section 0.

Building a VR simulator

There are two main approximations to solve a clinical problem [Stassen 01]:

- **Technologically driven approach**, in which engineers shows to the physicians new bright ideas and systems built to aid a doctor. This usually leads to hi-tech instruments that do not satisfy clinical needs.

- **Clinical driven approach**, in which a medical professional requests a solution for a problem. Engineers then analyse the work flow, environment, tasks, procedures… and discuss them to specify the needs and find potential solutions. This is the best approach to lead to real and applicable systems.

Other authors have also underlined the importance of having a clinical driven research in surgical simulation. It has been stated that there is a risk that simulation will be eclipsed by technology and will forget the educational principles [Kneebone 03]. Another example is the discussion in [Maran 03] "*we must not allow technology to drive the educational agenda […]. Any simulator device can only ever be as good as the educational programme in which it is embedded and many simulators are purchased every year and then under-utilised due to lack of educational goals to underpin their use*". Therefore the fist conclusion is that there is a **need of the clinical input** through all the design, construction and validation process of a surgical simulation. Nevertheless it seems that the development cycle of simulators is broken because there is no feedback from users to the creators of the simulator [Kneebone 03].

Simulation fidelity

One of the most controversial issues in simulation specifications is the definition of the required fidelity for surgical training. Fidelity is understood as the level of realism of the emulated environment. Nevertheless there are two senses of this concept, defined by [Hays 89;Maran 03]:

- "**Engineering, or physical fidelity**, is the degree to which the training device or environment replicates the physical characteristics of the real task. Increasing the engineering fidelity inevitably leads to increases in cost and, beyond certain levels, increasing the fidelity of the training device will produce only small improvements in performance over a simpler device."
- **"Psychological or functional fidelity** is the degree to which the skill or skills in the real task are captured in the simulated task". As concluded in [Arnold 02], careful analysis of the complex surgical skills are required, together with the comparison between

real and virtual environments, in order to assess functional fidelity. The difficulty is specifying and predicting the required psychological fidelity on a simulation before its construction.

This section reviews opinions and empirical data about the required degree of fidelity in simulation in order to provide an efficient training.

Opinions about the required fidelity

A surgeon would ask the maximum level of realism for a simulator to be effective [Darzi 01], which might be related with the immersion sensation that he/she expects. Some authors have raised the opinion that the higher fidelity, the more educational capacity in training surgical skills [Schijven 02], and an imperfect fidelity is considered an inhibitory factor to reach an optimum learning [Jha 01]. In the field of assessing technical skills, the validity of observational methods with simulation models is proportional to the realism of the simulation [Reznick 93].

Nevertheless other authors set the level of realism in the point to suspend the disbelief of the participant [Krummel 98]. Hay and Synger have stated that a simulator with a low fidelity can be a good training tool for novel surgeons [Hays 89]. Following this reasoning Maran & Glavin [Maran 03] presents an interesting discussion about the use of different levels of fidelity in simulation in a continuum of training. One of the points raised is that complex training aids are not appropriate where novices are learning the basic skills involved in a task. Finally, some authors thinks that a good simulator represents a simplified reality, and that it does not need to be a precise representation of reality [Hays 89;Feldman 04].

Facts and empirical data

Objective addressing the question of the required fidelity for surgical simulation is quite difficult. There is little available data in the literature, most of it directed to the study of human factors as explained in the following section. It is worth mentioning the work from Gagné started in the fifties and gathered in [Gagné 85]. One of the points raised is that in the case of developing fine motor skills, the simulator should accurately reproduce the movements required to avoid negative transfer.

One of the difficulties in this field is to measure fidelity, to set a scale to rank it. Some efforts have been done, for example comparing the spatial memory of users in virtual and real environments [Mania 03]. In the field of surgical simulation the only measurement is provided through face validity studies [Schijven 02]. A contribution in this issue is done in Chapter IV.

A useful methodological approach is to compare the training effectiveness of simulation models with different degrees of fidelity. This has been done in the field of endourological skills [Matsumoto 02;Grober 04], and the conclusion is clear: not always an increment in fidelity leads to an improvement in teaching capability. The authors also discuss that anatomy does not need to be emulated with a high precision.

Another fact is that high fidelity systems provide more interest and enthusiasm among trainees [Grober 04]. And that a laparoscopic simulator with a low fidelity, the MIST-VR, is a valid tool for surgical training and skills assessment (see section “Validation and acceptance” in page 55). It has even been said that the simplified reality of this simulator makes it more convincing [Kneebone 03].

Conclusion: a continuum of fidelity in training

Therefore there is not a clear answer about the required degree of fidelity for surgical training. The best conclusion is the idea addressed by Maran & Glavin [Maran 03]: the use of different levels of fidelity in simulation in a continuum of training.

There are other authors that present approximately the same idea [Issenberg 05]. Wentink et al. [Wentink 03] split the continuum of training in three stages: skill-based, rule-based and knowledge-based (see Fig. 14 in page 40). They state that a low realism is enough for the first, and that the incorporation of videos and texts is a straightforward way to reach the second stage in training. Nevertheless a very high realism is required for acquiring the knowledge-based behaviour, where the process of decision making has to be trained. Grober et al. [Grober 04] have also speculated analysing their results that the low-fidelity model provided the “key constructs” of the surgical task, which is the basis to elevate their surgical performance through repeated exposure to the high-fidelity model in a second step.

Human factors in laparoscopic VR simulation

Human beings have limitations of the sensory, motor and cognitive system. Knowing and understanding how surgeons interact and develop their skills is an important issue in order to address the design of a surgical simulator. Research is necessary to determine what visual and haptic cues surgeons use, and how sensitive they are [Liu 03].

Laparoscopy is characterised by a loss of sensory stimuli of the surgeon, which leads to the need of developing new skills (a description of it can be found in section 0 “Laparoscopic surgery”). But, how are these skills developed? How is the visual perception of the laparoscopic scene shown in a monitor? This section reviews the literature about human factors in laparoscopic surgery.

Some basic concepts

Two **sensory** channels are mainly involved in a laparoscopic procedure: sight and touch. But sensorial system is not the only involved in the development of skills: our motor and cognitive systems have an important role. The **motor system** is responsible for the active exploration, in which a force commands are followed by perceptions. And processing this information and linking sensations with perceptions and actions is done by our **cognitive system**.

- **Psychophysics**

Psychophysics [Lederman 96] “is a field of experimental psychology that uses specific behavioural methods to determine the relationship between the physical world and people's subjective experience of that world. Psychophysicists conduct scientific experiments that are carefully designed to let them figure out which physical parameter(s) actually determine a subjective perceptual dimension”.

One common parameter for measuring the resolution of a perceptual capability is the JND (Just Noticeable Difference). It is defined as the relative variation of a magnitude necessary for being perceived by the human being. For example, forces perception slowly changing has a 7% of JND [Tan 94]. Other works studying contact forces, viscosity or grating perception can be found in [Moy 00;Allin 02;Biggs 02]. One of the main drawbacks in this kind of studies is the lack of high fidelity haptic technologies with enough precision [Biggs 02].

- **Touch**

Human beings mechanically interact with the physical world through their **touch sense**. This is composed by two main receptors: the **tactile** ones sense temporal variations of force distributions, and the **kinaesthetic** or proprioceptive receptors capture net forces, posture and motion of limb segments [Biggs 02]. This sense makes us having a precise control of our movements, and it has a high resolution. Nevertheless, it is quite vague in the association of stimuli to objects. Whereas we are able to distinguish between two different grain of sand paper, it is very difficult to memorize these grain levels compared to the easiness to make it with colours [MacLean 00].

There are a lot of psychophysic studies in the literature about touch. Only one of them is highlighted as an example: [LaMotte 00], a recent study of how perception is degraded through tools compared to a direct exploration. Authors also discuss how perception is enhanced with an active exploration compared to a passive one. These issues are related to laparoscopy, performed with specialised tools introduced through trocars.

- **Sensory transposition**

It is defined as the feedback from a specific sensation given to the user through a sensory channel different than the expected [Burdea 96]. Users have different degrees of adaptation, different capacities of drawing equivalences between perceptual stimuli and sensations that sometimes require some training. Sensory transposition can be used to provide sensory redundancy in a virtual environment and strengthen the message that is to be transmitted. This helps to perform complex tasks, but with the caution of not generating contradictions or sensory overload that lead to adverse effects [Popescu 00].

There seems to be some sensory transposition in laparoscopy. Visual cues significantly influence stiffness perception [Basdogan 04]. Providing both vision and force feedback leads to better tissue characterization than only vision feedback or only force feedback [Tholey 05]. Some authors have even suggested that surgeons develop a “**visual haptics**” used to modify the strength applied to tissues with only a set of visual cues from deformation of organs, colours and contours [Stylopoulos 03].

Haptics in laparoscopic surgery

This section provides a quick review of the specific literature about the human factors in touch through laparoscopic tools. Determining the role and the need of force feedback in surgical simulation is dealt in an independent subsection.

There is some work studying perceptual parameters like resolution, range of forces and bandwidth. The **range of forces** exerted in laparoscopic surgery. There are some examples of the measurement of frictions in trocars and surgical gestures [Dubois 02;Picod 04;Picod 05]. Rosen et al. have even used force profiles for characterising surgical gestures and analyse performance with the technique of the Hidden Markov Models [Rosen 01;Rosen 02b]. On the other hand an the study of the **resolution** is approached with VR technologies in [Zhang 03], where the hypothesis of the LOD- *Level Of Detail* is raised: there is a level beyond which additional details in haptic realism is not perceived by human beings. And this hypothesis is evaluated with a VR setting varying the resolution of the virtual models. This has led to smoothness levels beyond which differences are no longer significant for human perception. Other studies have found the limits of perception for non-continuous change of force amplitude and frequency in a scissors-grasping handle [Seehusen 01]. Finally, the requirement for the **bandwidth** of the signal with haptic information is set in 1000 Hz, this is the limit with our somatosensorial system to perceive vibrations require up to. An overview of some studies about the influence of the bandwidth can be found in [Popescu 00].

Other group of studies try to assess the qualitative information that haptic information delivers. Despite tactile information is degraded, Bholat et al found how laparoscopic instruments provide with haptic feedback of texture, shape and consistency [Bholat 99]. Dissectors show high variability feedback quality depending on the instrument tested [den Boer 99]. Wagner et al. studied the dissection, and discussed the hypothesis that haptic information has two main benefits: when tissue resistance is big it serves as a protector barrier against tissue damage and as a guide, and when tissue resistance is low it needs a conscious effort to be perceived and be useful [Wagner 02].

- **The role of force feedback (FF) in simulation**

To define the role of FF is one important issue for the design of laparoscopic simulators, it is unknown the degree of its required fidelity for an effective training [Kneebone 03]. Wagner et al. systematically assessed some benefits of haptic feedback for dissection [Wagner 02], and Kim et al. have shown how FF results in a significant improved training transfer in a simple task [Kim 04]. Tendick described a virtual test-bed for training laparoscopic surgical skills, that is used to examine the relative importance of visual and haptic cues [Tendick 00]. Basdogan et al. concluded that integrating haptics into minimally invasive surgical simulation and training seems essential because it involves touching, feeling and manipulating organs through instruments [Basdogan 04]. Two last benefits of force feedback are, on one hand, that it contributes for the presence sensation, and on the other, that it can enhance user performance by imposing movements restrictions for example [Biggs 02].

But on the other hand haptic information does not appear to be essential because of the big magnitude of friction and other interfering forces and torques [Picod 05]. It is also clear that basic skills can be transferred without FF, as MIST-VR has demonstrated [Seymour 02] and some authors have already discussed [Schijven 03b]. And the incorporation of this feature in simulators increases a lot the cost of the system (a non-FF device costs around 6.000€, and a FF device around 24.000€). Therefore the justification of FF in a laparoscopic simulator is not clear.

Visual perception of the laparoscopic scene

When moving from open to laparoscopic surgery it changes, not only the haptic interaction conditions, but also the way the surgical scene is seen. The main differences are two: the change from a real 3D vision to a flat 2D monitor and the magnification of organs and tissues thanks to the endoscope. This section addresses the issues related to the visual perception of the laparoscopic scene, which are overviewed in [Hofmeister 01], and in [Stassen 01].

- **Depth perception**

One controversial question in laparoscopy is the loss of the depth perception caused by the monoscopic view of the surgical scene. There are a substantial number of studies that do not found a clear benefit of stereoscopic view in the endoscopic scene.

Therefore, where is the information about depth? The answer found in [Stassen 01] is that there are two sources of information (referring to [Sheridan 96]): pictorial and parallax cues. Pictorial cues are size, textures, occlusions and overlappings. A shadow is another pictorial cue, but it is not present in laparoscopy due to the fact that the endoscope carries its own light source at the tip. Some work has been done studying the introduction of other light sources, but it has not been very successful [Stassen 01]. Movement parallax, the second cue for depth perception, concerns shifts in the laparoscopic scene introduced by endoscope movements.

In [Hofmeister 01] it is also pointed out that familiarity with anatomic structures plays a critical role, and that surgeons refer the “touch confirmation”, a kind of exploratory movement along the contours of organs, as a means of practical importance to interpret the operative field.

- **The scaling problem**

Surgeons have to adapt to the variable size and appearance of organs displayed in a laparoscopic monitor. Hofmeister et al [Hofmeister 01] discussed how this adaptation take place. They point out two important aspects, the use of the known size of the instruments and the knowledge of the anatomy.

- **Visual-spatial abilities**

Due to the limited visual environment present in laparoscopy several authors have studied how visual-spatial innate abilities influence the acquisition of surgical skills. A very brief overview about this issue can be found in [Anastakis 00], which makes a hard critic to many studies and concludes that further work is needed.

There are several studies which have found a correlation between standard tests of visual-spatial abilities and performance in surgery [Risucci 02;Wanzel 03]. It is very likely that laparoscopic surgery is more dependent on spatial ability than open surgery, because there is less perceptual information available [Tendick 00]. Other interesting work is presented in [Passmore 01], which concludes that the skill of path following is not improved by the various viewing conditions and is significantly worse for side aligned orientations.

Understanding surgical skills in laparoscopy

Finally, this section of human factors in laparoscopy reviews some work conducted to understand different factors that influences the acquisition of surgical skills in laparoscopy.

- Camera manipulation [Tendick 00]. It is studied how surgeons use spatial skills to manipulate a 45º angled laparoscope. Among the results it is interesting to see how some surgeons do not develop the skill despite a big experience.
- Tool orientation [Tendick 00]. The skill to move the end of a tool to a spatial point is studied with a virtual test-bed. Factors discussed are the mental 3D model of the surgeon, the use of the visual cues like texture or illumination variation or the haptic memory. Nevertheless no clear conclusion is reached.
- Palpation [Tholey 03]. Tissue characterization with different sources of information, visual, tactile or both, is compared using a haptic device. It concludes that the combination of information is better than any of both alone, and that tactile information alone is better than visual.
- Grasping [Heijnsdijk 04]. Users are asked to grasp tissues and hold them during a specific time. It concludes that force feedback and visual feedback play a more limited role than expected in the task of grasping tissue with laparoscopic forceps.
- Dissection [Wagner 02]. It studies the effects of FF on a blunt dissection task comparing performance in three feedback conditions in a telerobotic system. They conclude that FF is helpful: the mechanical contrast between the artery and the surrounding tissue constrains the subjects' hand from commanding inappropriate motions that generate large forces.

Overview

Fig. 21 presents an overview of the analysis, design and validation of laparoscopic VR surgical simulators. The problem is decomposed in four levels (green boxes) involving several concepts (blue boxes):

- **Training needs definition**, which departs from the special skills to be developed to overcome the limitations of laparoscopic surgery. The main difficulty is the objective and quantitative description of training objectives [Wentink 03].
- **Training curriculum design**, taking into account training needs, training means, and adult learning theories. Recent work is addressing the construction of curricula based in proficiency levels using VR simulators [Satava 03a;Stefanidis 05;Brunner 05].
- **Analisys of training effectiveness**, what is needed to validate and compare surgical simulators. There is a lack of parameters to measure training outcomes, which is the problem of the assessment of surgical skills and proficiency [Aggarwal 04].
- **Simulation design**, the construction of a solution that meets surgical training needs with VR simulation technologies and taking into account human factors to define the required fidelity.

This can be seen from a designer point of view (red boxes) in two main categories: (1) **requirements** for training or skills' assessment tools and (2) design **specifications** of the simulator. Finally, a gate is left open for **future applications**. Work of present PhD thesis is focused in three aspects of this field:

- **VR technologies**, with the development of a conceptual framework for the analysis, design and validation of simulation technologies (Chapter IV).
- The study of **human factors**, specifically the study of sensorial capabilities in order to clarify simulation requirements and the need of force feedback (Chapter V).
- The **design of a surgical simulator** for laparoscopic training (Chapter VI).

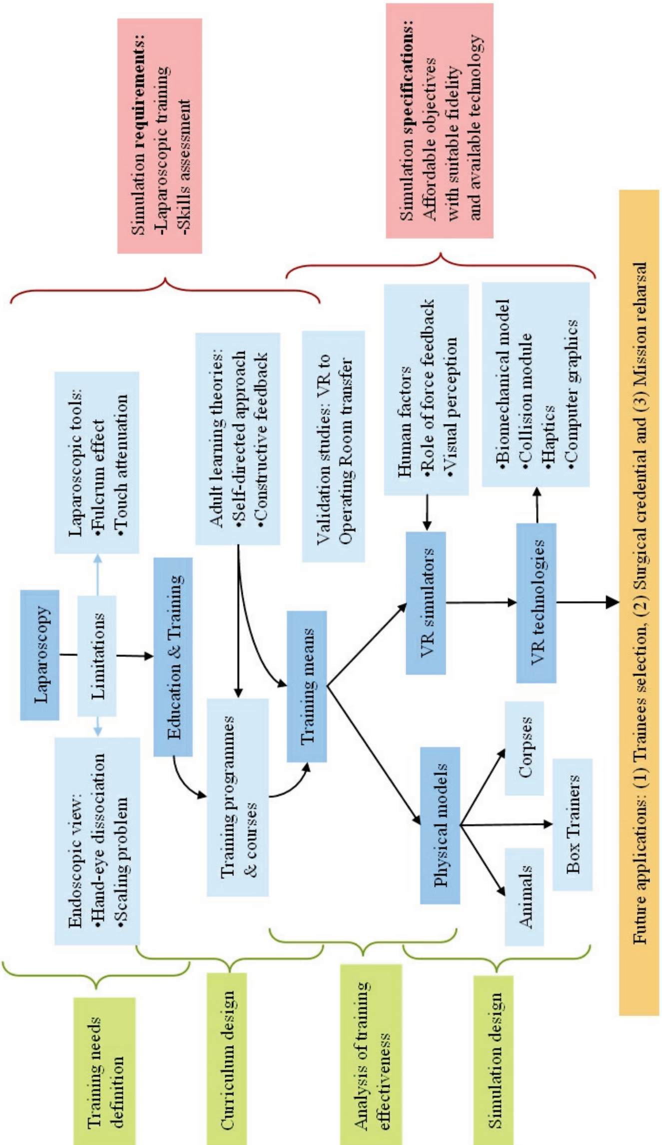


Fig. 21: Conceptual map of the literature review about the design of laparoscopic VR surgical simulators.

Chapter III: Hypotheses and objectives

This biomedical engineer PhD work is conceived to be a bridge between surgical training needs and VR simulation technologies in order to arrive to an optimum simulator. Three areas of contribution for an optimum laparoscopic training based in VR technologies, and several hypotheses and objectives are developed in each of them.

First, it is addressed the development of a taxonomy of VR didactic resources in order to systematise the knowledge of the possibilities and potential value offered by VR technologies for surgical training. This is aimed to be a conceptual framework for the analysis, design and validation of VR simulators, what will contribute for an effective and efficient laparoscopic training based in such simulators.

Second, it is envisaged a perceptual study of laparoscopic pulling forces in order to define simulation fidelity. Several hypotheses about this skill are defined and will be contrasted. The final objective is to develop a model of these interaction forces for a VR surgical simulator, a model with the suitable degree of fidelity.

And third, lessons learned from former areas and a review of existing solutions will be gathered in order to design an optimum VR simulator for laparoscopic training.

Hypotheses

Present PhD work is directed towards the long-term goal of an effective and efficient laparoscopic training based in VR simulators. This problem is addressed at one of its dimensions: how to design an optimum surgical simulator.

This question is first directed at a **conceptual level**, by developing a framework for the analysis, design and validation of such devices. The idea is to develop a taxonomy of *didactic resources* in order to systematise the knowledge of the possibilities and potential value offered by VR technologies for surgical training. Therefore hypotheses at this conceptual level are:

A “A **conceptual framework** for the analysis, design and validation of VR simulators can be built to contribute for an effective and efficient laparoscopic training based in such simulators.”

A.1. “It enables the **analysis** and comparison of such simulators through quantification of the use of different didactic resources to meet similar training objectives.”

A.2. “It allows the definition of **design** specifications systematically driven with a taxonomy of didactic resources.”

A.3. “It offers a **validation** methodology based in the analysis of how the didactic resources have been used.”

A.4. “The taxonomy also enables the **definition of hypothesis** about the importance and value of each of the components defined in the taxonomy. Validation of these hypotheses, assessing the value of each resource, should lead to an **optimum design** of a laparoscopic simulator.”

The problem, the optimum training of laparoscopic surgeons, is approached afterwards at a **human factors’ level**, addressing issues about the perceptual capabilities of surgeons. Tissue consistency perception in a pulling and pushing manoeuvre is studied, and following hypotheses are studied in Chapter V:

B "Laparoscopic surgeons are **able to perceive differences** when assessing tissue consistency depending on the tissue that is being pulled"

C "Tissue consistency perception in laparoscopy is a skill that shows **differences between three expertise groups** of surgeons (novel, intermediate and expert)"

"Evaluation metrics of surgical skill can be defined based in these differences".

D "There is some kind of sensory substitution in tissue consistency perception, which is related with the **"visual haptics"** concept."

E "There is a **grade of fidelity** in a VR surgical simulator beyond which human beings do not perceive differences with an increase of this fidelity."

"A **simple model of pulling interaction forces** in laparoscopic surgery with two or three parameters delivers this level of fidelity."

The design process of an optimum VR laparoscopic simulator is finally addressed in the third stage in this PhD work. It is important to regard that **a VR laparoscopic simulator does not need high levels of fidelity in order to be a valid training tool**. The proof is the transfer of skills from MIST-VR, a laparoscopic simulator with a low fidelity, to the operating room (see section 0 in Chapter II). A hypothesis is developed about the methodology to reach this optimum design:

F "A methodology to reach an optimum VR laparoscopic design should regard the study of several issues: (1) the analysis of validation results of current simulators, (2) an objective and quantitative definition of training objectives and needs, (3) the study of the human factors involved in the interaction and (4) the study of adult learning theories"

Objectives

The goal of this PhD work is to develop an optimum didactic design of VR laparoscopic simulators, which is addressed with three sub-objectives:

1 The construction of a **conceptual framework of the available VR didactic resources** (addressed in Chapter IV), what is envisaged to have utility for the analysis, design and evaluation of surgical simulators. This aims to be a valid tool for the surgical VR simulation community.

   1.1 The analysis and comparison of VR commercial simulators using this framework.

   1.2 The proposal of a **methodological approach for designing an optimal** simulation based in the experimental research towards the assessment of the value of the different didactic resources.

2 The improvement of **understanding of human perceptual capabilities** in laparoscopy for the definition of the required simulation fidelity, what is addressed in Chapter V.

   2.1 The development of a methodology for addressing the study of perceptual skills, trying to determine the relative importance of three components of a perceptual surgical skill: visual cues, haptic information, and previous surgical knowledge and experience.

   2.2 The study of **tissue consistency perception** by laparoscopic surgeons in order to validate several hypotheses about it.

   2.3 The definition of **new laparoscopic evaluation criteria** derived from the understanding of the perceptual skills developed by surgeons.

   2.4 The development of a **perceptual model to be used as a basis for a force feedback algorithm**. This will be addressed by comparing perception with objective parameters which characterise force interaction: interaction force profiles and tissue biomechanical properties.

3 The specification of optimum didactic designs of VR laparoscopic simulators (Chapter VI).

3.1 The proposal of a **methodological approach to define simulation** requirements based in the analysis of surgical procedures. This will be addressed with the use and adaptation of Hierarchical Task Analysis techniques.

3.2 The specification of the didactic **design of a "basic skills"** laparoscopic simulator**.**

3.3 The specification of the **didactic design of a "Nissen"** laparoscopic simulator.

3.4 The proposal of a validation **approach** of VR simulators.

Chapter IV: Conceptual framework for the analysis, design and evaluation of surgical simulators

As explained in Chapter II, few studies have explored the requirements of laparoscopic simulators and the degree of fidelity necessary to be effective educational tools. By identifying which individual didactic resources and combination of resources available in VR simulation technologies are most important for laparoscopic training this chapter aims to develop a conceptual framework for the analysis, design and evaluation of VR simulators.

A study conducted as part of this work proposes a taxonomy of didactic resources in VR simulation and uses it to compare different laparoscopic simulators using a pre-defined criterion. VR didactic resources have been defined and classified in three main categories based upon the extent to which simulators: 1) emulate reality (fidelity resources); 2) exploit computer capabilities such as new ways of interaction and guidance (teaching resources); 3) measure performance and deliver feedback (assessment resources). Advanced laparoscopic VR simulators have a fidelity similar to that of box trainers with ex-vivo organs (59% and 62% respectively). The maximum use of teaching resources was found to be 57% (MIST-VR “suture 3.0” and LapMentor) and of assessment resources was 69% (Reach-In Lap Trainer).

The proposed conceptual framework aims to contribute to the definition of simulation requirements and to offer guidelines to formulate hypotheses about the importance of different didactic resources. It also provides a methodology to compare simulators and set standards by which emerging technologies can be judged.

Introduction

The question being faced is to determine what makes a VR simulator a good and useful training tool. This section presents a conceptual framework to approach it, in which VR simulation is considered as a didactic means to meet different training needs. The basic idea is to classify all capabilities that VR technologies can offer to enhance laparoscopic surgical training, i.e. to classify the *didactic resources* offered by VR simulators.

Proposed concept distinguishes between a simulator's ability to emulate reality (*fidelity resources*); to exploit computer capabilities such as offering new ways of interaction and guidance (*teaching resources*); and to measure performance and deliver feedback (*assessment resources*). The taxonomy provides insight into VR capabilities and limitations, which has been pursued in a recent survey of simulation technologies [Liu 03].

A second step taken in this approach is to study how different laparoscopic simulators make use of didactic resources. This provides quantitative data comparing the *fidelity* and the use of *teaching* and *assessment resources*, which is a contribution towards the need to set standards by which emerging technologies can be judged [Kneebone 03]. This has also allowed refining and validating the proposed conceptual framework.

Finally, literature about training transfer of VR simulators is reviewed and interpreted from the proposed conceptual framework. The objective is to assess the importance of each didactic resource, what would lead to the definition of effective simulation for training. This will be the main focus of the discussion section.

Taxonomy of didactic resources in laparoscopic VR

The first step requires the definition of a working taxonomy. Based on existing literature and the wealth of experience in combined research teams (surgery, simulation and computing) the following didactic resources taxonomy is proposed:

a) *Fidelity resources*. Simulators endeavour to create environments which approximate reality, and the different aspects of the *fidelity* employed in this reconstruction of the real world are the first category of didactic resources. This engineering or physical fidelity is “the degree to which the training device or environment replicates the physical characteristics of the real task”. This contrasts with psychological or functional fidelity, “the degree to which the skill or skills in the real task are captured in the simulated task” [Maran 03]. Fidelity resources are employed to set different degrees of realism to the *surgical setting*, to the *mechanical interactivity* and to the *physiopathological behaviour*. These three subcategories have been defined inspired in the three generations of VR simulators described in [Delingette 98].

b) *Teaching resources.* VR simulators also offer features unique to a computer simulated environment that can enhance training. These include cues and instructions given to the user to guide a task, or features to manage a training program. These teaching resources have been classified as *guiding features* and *managing features*.

c) *Assessment resources* offer *evaluation metrics* to assess performance and follow up progress, and ways to deliver *constructive feedback* to the user.

The proposed complete taxonomy of didactic resources in VR is shown in Table 3, and a description of each category is presented in the following sections.

Taxonomy of didactic resources				Examples of each resource
Fidelity resources	Surgical setting	Surgical scene	Anatomy	Different shapes (geometry), resolution
			Textures	Organ textures, photorealism
			Illumination	Endoscope light, specularity, shades…
			Visualization	Mono/stereoscopic display, 0º/30º endoscope…
		Instrum.	Handling	Physical handle, right workspace and layout, no frictions
			Correspond.	Right tools size and correspondence in the scene
	Mechanic. interaction	Collisions		Overlapping detection. No crossing
		Deformations		Biomechanical behaviour
		Topological changes		Cutting, dissection, tearing…
		Interaction forces		Tissue consistency, cut or stitch resistance…
	Physiopat. behaviour	Fluids		Bleeding …
		Movements		Breath, circulatory system, digestive system
		Pathological conditions		Tumours …
		Other variables		ECG, arterial pressure…
Teaching resources	Guiding features	Procedur. guides	Instruction	Dialog boxes (read or listened), Instructional video
			Visual cues	Coloured regions, arrows, transparent anatomy
			Tactile	Haptic guide, augmented forces…
		Interaction indicators	Collision	Change of colour
			Top. changes	Grasp release instead of tearing, cutting…
			Forces	Colour code, growing semitransparent sphere
	Managing features	Edition tools		Courses design , users classes, web-interfaced …
		Teacher tools		Results viewing, remote tutoring…
Assessm. resources	Evaluation metrics	Performance		Global assessment, state analysis…
		Errors		Tissue damage or tension, faulty to touch, bleeding…
		Movement		Path length, economy of movements…
		Time		To complete procedure, to recover from errors…
		Forces		Grasping, pulling or separation forces
	Construct. feedback	Summative		Graphical figure with metrics, playback function…
		Formative		Procedural advice or ways to say “wrong way”

Table 3: Didactic resources of VR endoscopic simulation.

Fidelity resources

A laparoscopic virtual environment can be decomposed in three levels. First, a *surgical setting* that has two elements with which a surgeon interacts: a visual interface displaying the *surgical scene*, the abdominal cavity of the patient, and the *laparoscopic instruments* that are handled. The second level involves all the *mechanical interactions* performed in a surgical procedure, classified from an engineering point of view: *collisions*, *deformations*, *topological changes* and *forces*. Other aspects related to the behaviour of the human organism are devised in a third level as *physiopathological* components, for example blood or breathing movements.

Surgical setting

The realism of the abdominal cavity captured by a virtual endoscope depends on the shape and resolution of the 3D models (*anatomy*), the *textures*, the rendering effects that builds the *illumination* and the *visual interface* that presents the surgical scene.

A picture of the human abdominal cavity taken with a real endoscope has the highest realism. On the other hand, a simple interpretation of the workspace with basic geometries (as offered by MIST-VR, Mentice AB, Sweden), has the lowest realism of the surgical scene (see Fig. 22 and Table 4). Medical image studies, MR for example, of anatomical structures can be used to build organ geometries and reach a high degree of realism. One of the latest improvements has been a method for generating a virtual pneumoperitoneum, i.e. the inflated abdominal cavity used as the workspace in laparoscopy [Kitasaka 04].

Although 3D models should have enough resolution to offer a continuous and smooth shape, objects show sharp artificial edges when resolution is low. This parameter is closely related to interactivity, as explained later. On the other hand, geometries can be rendered with plain colours or with organ *textures* with different degrees of realism.

The simulation of the endoscopic light, shades and even specularity effects are other *illumination* resources. Finally, several *visual interfaces* may be used to display the surgical scene, as simple computer monitors or even advanced stereoscopic glasses.

Nevertheless the benefit of stereoscopic visualization in laparoscopic surgery hasn't been clearly revealed [Hofmeister 01]. This is the reason why this fidelity resource hasn't been ranked in Table 4.

Laparoscopic *instruments* are simulated through their visual models on the screen and physically through the use of specialised haptic devices like those shown in Fig. 20 in page 54. Haptic devices should have a natural handling of the tool, without artificial frictions or inertias. . It is also convenient to have the possibility to position them freely in order to have the right layout. These features, together with the workspace, are components of the *handling fidelity*.

Fidelity resources			0	5	10
Surgical setting	Surgical scene	Anatomy	Basic geometries Artificial edges	Organ simplifications Some irregularities	Patient specific organs Continuous shape
		Textures	Plain colours	Rough organ textures	Real textures
		Illumination	Diffuse	Punctual endoscopic light	Like real[a]
	Instrum.	Handling	Strong limitations[a]	Some limitations[b]	Like a real tool
		Correspon.	No calibrated	Tracking problems	Right correspondence
Mechanic interaction	Collisions		Objects cross	Some crossing	No crossing
	Deformations		None or instable	Some limitation	All organs, realistic
	Topological changes		None or instable	Some approximation	Like reality
	Interaction forces		None	Basic force information	Perceived like real
Physiopat. behaviour	Fluids		None	Some approximation	Like reality
	Movements		None	Some approximation	Like reality
	Pathological conditions		None	Some approximation	Like reality
	Other variables		None	Some approximation	Like reality

Table 4: Fidelity scale definition from 0 to 10 in its different aspects. [a] Real illumination "last effects": specularity, changes in light intensity with bleeding. [b] Limitations in handling are friction, inertia, and a limited workspace

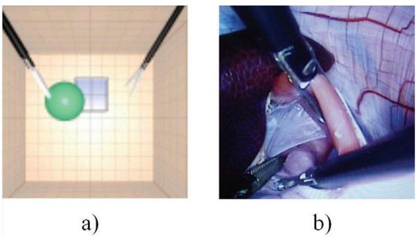


Fig. 22: Different levels of realism of the surgical scene: a) the lowest level with simple geometries (MIST-VR); b) the highest level, a real endoscopic image.

Laparoscopic surgical tools have several degrees of freedom (DOF’s) in their movements, and haptic devices should have enough reach in all of them so as to offer a natural workspace (Fig. 11 in page 29 shows the six DOF’s of a laparoscopic tool). On the other hand, 3D visual models of tools need a right size and a right *correspondence* inside the surgical scene with the physical handles. Movements’ tracking needs enough resolution to offer a continuous and smooth displacement and a right correspondence. A bad correspondence leads, for example, to a situation in which the physical tools collide with each others before they do in the virtual scene. All the aspects related to the function and interactions of each instrument are components of the mechanical fidelity, as explained in next section. The graphical realism of instruments is part of the realism of the *surgical scene*.

Mechanical interaction

Four different components have been considered as part of *mechanical interaction* fidelity: *collisions*, *deformations*, *topological changes* and *interaction forces*. The first step in a mechanical interaction is always a collision, when two objects come into contact. These objects can deform or move, and surgeons make incisions, perform dissection, insert sutures, etc. These are manoeuvres that involve topological changes in the structure of organs and tissues. Interaction forces of these actions may be delivered to the user. The update rate of the visual and haptic displays is a basic parameter to assess mechanical fidelity. It measures the number of times tactile or visual feedback information is updated per second. Based on human perception limits, the lower update rate thresholds are set to 25 Hz for the visual feedback (calculation of deformations and new organ shapes to be displayed) and to 1 KHz for the haptic feedback (calculation of forces) in order to offer a continuous interaction stimuli [Liu 03]. This is the most difficult specification to meet by a surgical simulator, which has to be computational efficient in order to offer a realistic behaviour.

Overlapping volumes between objects, or *collisions*, must be detected. Although seemingly trivial, this issue is in fact very important. There are three kinds of collisions: tool-organ, tool-tool, and organ-organ. Much computational power is required to check if there are overlapping regions between geometries in a whole surgical scene. A good haptic interface is needed to provide a good collision response between rigid objects like two tools. Another difficulty is “collision handling”, the interpretation and use of data returned by the collision detection mechanism. In current research, algorithms are been developed to provide a better interaction [Forest 04]. Another challenging problem is ensuring that the collision detection between deformable objects can be performed in real time. When the collision detection algorithm fails, objects behave in an unrealistic way crossing each other without any interaction.

Tissues and organs should deform in a realistic way when they are manipulated. A biomechanical model is used to calculate *deformations* taking into account how objects collide, their biomechanical properties and their state. This is the core component of a simulator, and the one that requires more computational power. Sometimes these models become unstable, and objects deform by oscillating or vibrating in a complete unrealistic way. A further difficulty is the measurement of biomechanical properties of organs [Liu 03], whose behaviour is very complex (viscoelastic, non linear, anisotropic…).

Topological changes, such as cutting, tearing, dissection, stapling and suturing, are another difficult issue to be addressed. The structure of objects changes in real time and so does the mechanical relationship between different parts of the object. A biomechanical model subdivides geometries in elements as nodes or tetrahedra, and changes in this structure are difficult to be processed in real time when using a realistic model such as the Finite Element Method- FEM [Liu 03]. Nevertheless, recent advances are proposing solutions to this problem [Vigneron 04].

Haptic devices sense movements from the user and only some (see Fig. 20 in page 54) deliver *interaction forces* with different degrees of realism. Forces can be obtained in two principal ways: with an independent and local force model [Forest 04], or interpolating data obtained by the global biomechanical models used for deformation calculation [Picinbono 02b]. The main difficulty is to deliver continuous and stable forces during tissue manipulation since the update rate needs to be very high (1 KHz). Forces should also be delivered in all required DOF’s (see Fig. 2), and have neither instabilities nor artificial vibrations. Haptic devices should have a good resolution in displayed forces, and should be mechanically transparent [Basdogan 04].

Resolution of geometries is another critical parameter in simulation. If resolution is low, organs show artificial edges and shapes when deformations or topological changes take place. If resolution is high, computational power demand rises too much to be provided. Adaptive resolution techniques have been proposed to partially solve this and enhance the mechanical interaction [Wu 01]. Due to the very complex behaviour of living tissues, simplifications are made to reduce the computational cost, which is the main bottleneck in surgical simulation. Therefore it is usual to set the interactivity features for each object in a virtual scene, i.e., to specify if objects are inactive, collide but not deform or collide and also deform. The alternative is to wait for the improvement in computational power, which follows the Moore law.

Physiopathological fidelity

Depending on the training objectives, surgical simulators should emulate not only mechanical interactions, but also physiology and functionality of the human body. Such modelling is important in order to recreate bleeding of tissues during surgical interventions, or to model breath movements. Four subcategories have been considered: *fluids*, *movements*, *pathological conditions* and *other variables* (some examples of each one are shown in Table 3).

These aspects have all been inadequately explored in the field of laparoscopic surgical simulation. Nevertheless some simulators incorporate “bleeding special effects” that emulate the complex behaviour of this fluid. Red dynamic textures mapped to organs, particle systems [Agarwal 03] or fluid dynamic approaches [Zatonyi 03] are some examples. Realistic enough simulation of pathological conditions for training is one of the future trends in laparoscopic VR simulation.

Teaching resources

A computer simulated environment offers different possibilities that can enhance a training process. It may have *guiding features* like *procedural guides* that tell the user what to do and how to do it using visual cues, or i*nteraction indicators*, which are sensorial or cognitive substitutions done to cope with certain interaction limitations that might be even more didactic. On the other hand, it may have *managing features*, resources used for editing a course or tutoring a trainee.

Guiding features

Procedural guides are any type of information a VR simulator offers to a user in order to guide the surgical procedure, i.e. instructions of what to do and how to do it. These may be visual e.g. coloured regions that indicate a target point, arrows that show the right direction of a movement, transparent anatomy that reinforces some cognitive concepts, 3D lines that indicate the path to follow [Passmore 01] or any kind of representation from any virtual point of view. Simulators with a force feedback (FF) capability can also offer haptic aids, allowing trainees to feel the forces exerted by an expert displayed as a haptic guide [Feygin 02] of the procedure. This is called “Forceback function” in the Reachin Laparoscopic Trainer-RLT (Reach-In, Stockholm, Sweden). A computer-assisted simulator can also display simple written or spoken instructions that refer to the surgical task itself (“hold the needle by the coloured region”), or to a complementary laparoscopic manoeuvre like “stop bleeding” or “clean endoscope”. Moreover, before any task, some preliminary instruction can be given, with a video, a description of the task, a description of the anatomy or even a description of the errors. All these components, to varying extents, can make the simulator a virtual teacher with whom the trainee can work independently.

Virtual simulation makes use of different sensorial or cognitive substitutions to cope with interaction limitations or to provide important didactic information. These have been called *interaction indicators*. For example, it has been demonstrated how visual feedback can provide continuous force information in a knot tying procedure [Kitagawa 04]. Collision information may be also efficiently delivered with some changes in colour when the object is touched, tearing can be substituted by a simple grasp release, and “warning colours” may emulate tissue harm. These features can also provide constructive formative feedback as explained later.

Managing features

A VR simulator can be quite versatile, thanks to several managing features. Trainees at different levels of expertise have different training needs, and different strategies can be employed to meet them. Different levels of task difficulty and different sets of tasks may be assigned to different user classes. It is also possible to do all this remotely via a web-enabled tool. These aspects have been considered as *Edition Tools* (see Table 3).

Finally, *Teacher Tools* make tutoring an easier task. A VR simulator can offer the possibility of viewing the result (evaluation metrics or the recorded procedure itself) and viewing comparative analyses between users or sessions. Some simulators offer even the possibility of remote tutoring.

Assessment resources

One of the greatest potential advantages of virtual reality simulators is constructive and objective feedback. This can take two forms: *instantaneous* feedback, when a user makes an error and the simulator reflects it (formative), and *end of task* feedback, when a user reviews his final score based on different evaluation metrics (summative). This score should tell the user on which aspects he has to further improve by showing, for example, a comparison with a standard proficient surgeon. Movements and actions are tracked and analysed to provide this summative feedback.

Formative feedback is usually delivered by the use of *interaction indicators*. For example, if objects turn red when they are wrongly grasped or pulled, this can be used as a metaphor for “wrong way”. The same meaning can be delivered if objects only interact when they are correctly manipulated (although collisions are detected, no deformation is made). And when an object is released automatically can mean that it has been stretched too much.

Nevertheless it is very difficult to assess how a surgeon performs, and the field of objective assessment of surgical skill is of great current interest [Aggarwal 04]. These metrics have been categorised depending on the aspect they aim to evaluate: performance, errors, movements, time or forces (see Table 3).

Analysis and comparison of laparoscopic simulators

Several laparoscopic simulators are currently available. These range from simple box trainers with standardized tasks to advanced VR simulators. All of them are designed to train laparoscopic skills, but they make use of different didactic resources. This section makes use of our proposed taxonomy to study these differences.

Materials and methods

The following VR simulators were considered for the study: “Basic Skills” package and “Suture 3.0” of MIST-VR (Mentice AB, Göteborg, Sweden), “Basic Skills 2.0” package, “Dissection” and “Gynaecologic” modules, these last two considered together, of LapSim (Surgical Science Ltd, Göteborg, Sweden), virtual tasks of ProMis (Haptica, Dublin, Ireland), Reachin Laparoscopic Trainer-RLT (Reach-In, Stockholm, Sweden), and LapMentor (Simbionix, Israel). In addition, two generic box trainers are studied, one with physical objects and the other with ex-vivo organs. The study was done in the dept of Surgical Oncology and Technology (Imperial College of London) between July and December of 2004, posterior simulators’ software updates were not considered.

Proposed taxonomy of didactic resources in laparoscopic VR has been applied in the following way. Fidelity resources were compared quantitatively, taking into account all factors involved following the criterion defined with the taxonomy (see Table 4). Each fidelity component was studied and ranked on a scale of 0 to 10 by three experts in laparoscopic VR simulation (two surgeons researching with simulation technologies and an engineer in the field) who have significant “hands on” experience with all simulators (more than 10 hours in each of them). While a larger number of experts might be desirable, it is difficult to find individuals who are sufficiently experienced with all the systems under consideration. A cronbach’s alpha reliability analysis is made between assessors’ scores.

A consensus with an arithmetic mean of the three valorisations was reached. Values were averaged in a percentage for each level of subcategories: for example, *surgical setting* fidelity is the mean between the realism of *instruments* and *surgical scene*, and this last is the average of the score in *textures*, *illumination*, and *anatomy*, which is decomposed in *shape* and *resolution*.

Finally, the global fidelity percentage was the average between the realism of the three main subcategories: *surgical setting*, *mechanical interaction* and *physiopathological behaviour*. An average score of VR simulation technologies was reached with the arithmetic mean of the seven VR simulators.

Teaching and assessment resources were only ranked as “used” or “not used”, since definition of a scale addressing them is not straightforward. The chosen VR simulators were studied and an average use of these resources was calculated for each subcategory and for a global percentage of use. In this way, every resource has the same relative importance. In the study of assessment resources, metrics were classified into several categories defined inside the five groups (performance, errors, movements, time or forces). Each metric of every simulator was then assigned to one of these categories.

Results

Fig. 23 outlines the main results of the comparison. Scores given to the fidelity resources employed with average percentages are shown in Table 5. Cronbach’s alpha between the three assessor’s scores is 0.8027. The use of teaching and assessment resources is presented in Table 6 and Table 7 respectively.

Simulation fidelity ranges from 18% of MIST-VR “basic skills” to 62% of box trainers with ex-vivo organs (see Table 5). LapMentor is the VR simulator with the highest fidelity, 59%, a better value than the 48% of box trainers with simple objects and very close to the 62% of ex-vivo organs. 100% fidelity is present at the operating room (OR). Box trainers offer a high realism in *surgical setting* and *mechanical interaction*, but lack any *physiopathological feature*. VR simulation has different degrees of realism, and there are some categories in which an average score fails: deformations, tearing, interaction forces and all physiopathological behaviour features (scores 4.3, 3.0, 2.1 and 1.3 respectively, see Table 5).

The most representative fidelity features of each simulator are outlined next. MIST-VR “basic skills” (18% fidelity) follows a unique approach: it presents an abstract concept of the abdominal surgical workspace composed by basic geometries, and it only allows an extremely simple interaction.

Virtual tasks of ProMis (24% fidelity) have even less interactivity and lack some movement tracking (low *correspondence* score), but they present a high realism of surgical setting with a good abdominal cavity model and the use of real laparoscopic tools.

MIST-VR “Suture 3.0” (38% fidelity) and LapSim “basic skills 2.0” (40% fidelity) allow some basic mechanical interactions with objects resembling living tissues or organs. MIST-VR “Suture 3.0” also provides some force feedback with growing semitransparent spheres (a kind of *interaction indicator*), whereas LapSim “basic skills 2.0” simulates some bleeding effects.

Reach-In Lap Trainer (44% fidelity) incorporates force feedback capability, but its haptic device introduces frictions and inertias (lower *handling* fidelity). It also provides a better mechanical interactivity, some bleeding effects and a complete anatomy in cholecystectomy tasks.

LapSim “Dis/Gyn” (48% fidelity) and LapMentor (58% fidelity) increase physiopathological fidelity with pathological conditions in some tasks and present a fairly good surgical setting realism with the anatomy of different procedures. LapMentor delivers force feedback with its own haptic device and has the highest fidelity scores in almost every category.

Finally, although box trainers do not have any physiopathological feature, they have a perfect handling and illumination. Objects commonly used are seeds (48% fidelity), which are not organs or tissues (low *shape* and *texture* score). Ex-vivo organs (62% fidelity) are isolated from an abdominal cavity and have a slightly different mechanical behaviour than living tissues.

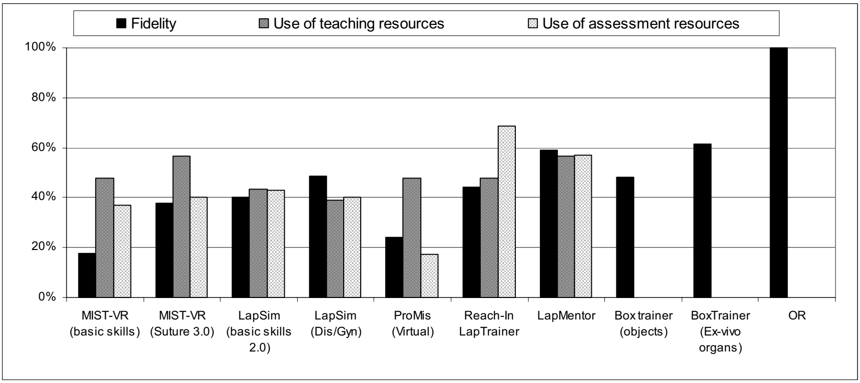


Fig. 23: Fidelity and use of teaching and assessment resources by laparoscopic simulators.

The use of *teaching resources* by laparoscopic VR simulators ranges from 39% (LapSim “Dis/Gyn”) to 57% (MIST-VR “suture 3.0” and LapMentor) of defined possibilities. A “complete simulator” that uses all defined resources would have a score of 100%. *Interaction indicators* are used more by simulators with limited fidelity. MIST-VR for example employs a grasp release as an indicator of an excessive deformation applied to objects (tearing), changes in colour as indicators of collisions, growing semitransparent spheres as forces and changes in colour as indicator of an excessive force applied to a thread or a tissue. Advanced simulators do not need to make use of these resources in order to cope with fidelity limitations, but they may use them to provide some formative feedback (indicating a wrong or correct action).

Procedural guides, the other type of *guiding features*, are mainly instructions to explain to the trainee what to do and colours to indicate target points or areas. None of the simulators presents semitransparent anatomy, a previous 3D animation of the anatomy, paths to follow or forces constraining movements, what are aspects that could be explored in future designs. Generally speaking all these *guiding resources* might have not aroused enough attention in the development and acceptability of simulators. Finally, every simulator offers some *managing features* like users classes and courses design tools.

The use of *assessment resources* ranges from 17% (Virtual tasks of ProMis) to 69% (Reach-In Lap Trainer). A 100% of use would mean that the simulator make use of all defined resources. Simulators with only one or a few surgical procedures simulated, like MIST-VR Suture 3.0 or the virtual tasks of ProMis, have smaller score since some metrics are specific for each procedure. Metrics commonly used by simulators are time, path length and a set of errors relevant to the task.

An abstract approach taken by MIST-VR leads to basic metrics of motor skills, like “closed entry” (a collision with a closed grasper) or “diathermy tip removed”. On the other hand, Reach-In Lap Trainer assesses trainee performance in a higher level of significance with metrics like “uncontrolled dissection” or “diathermy without stretching”. *Summative constructive feedback* is delivered by all simulators by displaying the score acquired in each metric, and many of them have a playback function.

But none of them conclude which skills need to be improved or offers the possibility of viewing any movements pattern or state analysis like the one proposed by Rosen et al. [Rosen 02b]. *Formative feedback* is mainly given with interaction indicators as colours, and only Reach-In Lap Trainer offers dialog boxes that tell the trainee what errors are done, errors with a high level of significance according to defined metrics, as a way of procedural advice.

Fidelity resources				MIST-VR (basic skills)	MIST-VR (Suture 3.0)	LapSim (basic skills 2.0)	LapSim (Dis/Gyn)	ProMis (Virtual)	Reach-In LapTrainer	LapMentor	Box trainer (objects)	BoxTrainer (Ex-vivo organs)	VR average
Surgical setting	Surgical scene	Anatomy	Shape	0.0	4.7	4.3	7.5	6.5	6.0	8.0	0.0	6.5	5.3
			Resolution	9.0	6.5	6.7	6.6	7.0	6.0	7.7	10	10	7.1
		Textures		0.0	5.0	5.0	6.4	6.0	5.0	8.0	1.5	9.0	5.1
		Illumination		1.3	5.0	4.3	6.3	7.5	4.5	8.5	10	10	5.3
	Instruments	Handling		7.3[a]	7.3[a]	7.3[a]	7.3[a]	10	5.5[b]	5.5[b]	10	10	7.3
		Visual correspondence		5.1	8.1	8.6	8.6	4.5	8.9	9.3	10	10	7.6
	Fidelity of surgical setting:			**41%**	**65%**	**65%**	**73%**	**70%**	**62%**	**78%**	**78%**	**95%**	**65%**
Mechanical interaction	Collisions			3.0	5.3	6.0	5.9	1.0	7.0	6.5	10	10	5.0
	Deformations			1.0	6.0	4.7	6.5	0.0	5.5	6.3	5.0	7.5	4.3
	Topological changes	Cutting		NA	NA	4.7	6.8	NA	4.0	7.0	6.5	9.0	5.6
		Dissection		NA	NA	NA	6.2	NA	5.0	7.3	4.5	9.0	6.2
		Tearing		1.0	2.5	3.3	3.2	0.0	4.5	6.5	4.5	9.0	3.0
		Stapling		NA	NA	3.3	7.5	NA125	8.0	7.0	7.5	9.5	6.5
		Suturing		NA	8.0	6.0	4.8	NA	NA	NA	7.5	9.0	6.3
		Cauterization		1.0	NA	5.3	8.0	NA	4.0	8.0	5.0	10	5.3
	Interaction forces			0.0	3.0	0.0	0.0	0.0	5.5	6.0	6.0	9.0	2.1
	Total mechanical fidelity:			**13%**	**49%**	**38%**	**46%**	**3%**	**58%**	**65%**	**67%**	**89%**	**39%**
Physiopathological behaviour	Fluids	Bleeding		0.0	0.0	5.7	6.8	0.0	5.0	8.0	0.0	0.0	3.6
	Movements			0.0	0.0	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.2
	Pathological conditions			0.0	0.0	0.0	3.4	0.0	0.0	6.0	0.0	0.0	1.3
	Other variables			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Total physiopathological fidelity:			**0%**	**0%**	**18%**	**26%**	**0%**	**13%**	**35%**	**0%**	**0%**	**13%**
	Total simulation fidelity:			**18%**	**38%**	**40%**	**48%**	**24%**	**44%**	**59%**	**48%**	**62%**	**39%**

Table 5: Fidelity study of VR and physical laparoscopic simulators. Last column contains an average score for VR simulation technology. Each cell shows the score (0 to 10) in each category of fidelity resources according to the definition of Table 4. NA: Not Applicable . [a]Handling score of the LIE. [b]Handling score of the LSW.

Teaching resources					MIST-VR (basic skills)	MIST-VR (Suture 3.0)	LapSim (basic skills 2.0)	LapSim (Dis/Gyn)	ProMis (Virtual)	Reach-In LapTrainer	LapMentor
Guiding features	Procedural guides	Visual aids	Coloured regions: target point		●	●	●	●	●	●	●
			Arrows		○	●	○	○	●	○	●
			Transparent anatomy		○	○	○	○	○	○	○
			Path to follow		○	○	○	○	○	○	○
			Virtual view (other point of view)		○	○	○	●	●	○	●
		Tactile aids	Forceback function		○	○	○	○	○	●	○
			Forces constraining movements		○	○	○	○	○	○	○
		Instructions	Previous	Instruction video	●	●	○	○	○	●	●
				Description of task	●	●	●	●	●	●	●
				3D animation of anatomy	○	○	○	○	○	○	○
				Description of errors	●	●	○	○	●	○	●
			On the fly	Written dialog boxes	○	○	●	●	○	●	●
				Voice instructions	○	○	○	○	●	○	○
	Interaction indicators	Collision	Colours		●	●	●	○	●	●	●
		Top. Changes	Tearing: grasp release		●	○	○	○	○	○	○
		Forces	Growing sphere		○	●	○	○	○	○	○
			Colours		○	●	●	○	○	○	●
Managing features	Edition tools	Courses design, users classes…			●	●	●	●	●	●	●
		Degrees of difficulty			●	●	●	●	●	●	●
		(Web-interfaced)			○	○	○	○	○	●	○
	Teacher tools	Single results viewing			●	●	●	●	●	●	●
		Comparative results viewing			●	●	●	●	●	●	●
		Remote tutoring			●	●	●	●	○	○	○
	Total teaching resources:				**48%**	**57%**	**43%**	**39%**	**48%**	**48%**	**57%**

Table 6: Use of teaching resources by laparoscopic VR simulators. ●: used, ○: not used.

Assessment resources			MIST-VR (basic skills)	MIST-VR (Suture 3.0)	LapSim (basic skills 2.0)	LapSim (Dis/Gyn)	ProMis (Virtual)	Reach-In LapTrainer	LapMentor
Metrics of performance	Global score		●	●	●	●	○	●	●
	Goals / misses	Completed transfers, visualized targets, cuts, clips or knots made…	○	○	●	●	●	●	●
	Accuracy	Grasp, cut or clip distance (mm). Dissected volume (%)	○	○	●	●	○	○	●
	Economy	Efficiency. Economy of Diathermy, clips, cutting manoeuvres…	●	○	●	●	○	●	●
Metrics of safety, errors	Simple tool manipulation	Collision: Closed entry, wrong collisions (tool non-target…)	●	●	○	○	○	●	○
		Grasping: In wrong place	○	●	○	○	○	●	○
		Pulling: Ducts ripped, max stretch, correct retract. (%), overstretch	○	○	●	●	○	○	●
		Pushing: Number of wrong pushes, maximum wrong push	○	○	●	○	○	●	○
		Holding: Tool not held steadily. Specific in diathermy.	●	●	○	○	○	○	○
		Releasing: Object dropped	●	●	●	○	○	●	●
	Complex tool manipulation	Not bimanual	○	○	○	○	○	●	○
		Unexpected step (tool use or stitch)	○	●	○	○	○	○	○
		Cutting: wrong position, wrong angle or tissue damaged by scissors	○	○	○	○	○	●	●
		Clipping: wrong number of clips. Badly placed clips: wrong	○	○	●	●	○	●	●
		Diathermy: Tissues damaged (number and severity)	●	○	○	●	○	○	●
		Dissection: without stretching tissue, too much or uncontrolled	○	○	○	●	○	●	●
		Suturing: Ripped stitches, thread overstretch, failed adjust needle…	○	●	●	●	○	○	○
	Camera manipulation	Collision: Camera touches tissue	○	○	○	○	○	●	○
		Tool moved when not in view	○	○	○	○	○	●	○
		Maintaining horizontal view	○	○	○	○	○	○	●
	Complications	Blood loss, non-cauterized bleeding	○	○	●	●	○	○	●
		Possible damage to vital structures / perforations / convert to open	○	○	○	○	○	○	●
Metrics of movement	Path length / num.	Linear or angular. Global or left/right hand. Tool or camera.	○	○	●	●	●	●	●
	Economy	Economy (efficiency) of movements, ideal path length	●	●	○	○	○	●	●
	Speed	Of tools or camera	○	○	○	○	○	●	●
	Smoothness		○	○	○	○	●	○	○
Metrics of time	Global		●	●	●	●	●	●	●
	Touching	Time touching / not touching	○	○	○	○	○	●	○
	Timeout	Not enough time to completion	●	●	●	○	○	●	○
Constructive feedback	Summative	Playback function	●	●	○	○	●	●	●
		Metrics view	●	●	●	●	●	●	●
		Movement patterns view	○	○	○	○	○	○	○
	Formative	"Wrong way" Colours	●	●	●	●	○	●	●
		"Wrong way" No interaction	●	●	○	○	○	●	○
		Procedural advice	○	○	○	○	○	●	○
		Total use of assessment resources:	**37%**	**40%**	**43%**	**40%**	**17%**	**69%**	**57%**

Table 7: Use of assessment resources by VR laparoscopic simulators. ●: used, ○: not used.

Methodological approach for designing an optimal simulation

The analysis made in present chapter shows that there isn't a clear answer of what's the optimal design of a training tool. This section aims to provide a methodological approach for addressing it. The basic idea is that **an optimum VR surgical simulator for surgical training will be designed with the suitable combination of VR didactic resources** (see hypothesis A.4 in page 79). Therefore the value and importance of each of these didactic resources should be assessed.

Regarding the taxonomy of didactic resources there are three main directions in the design of a simulator, which can be taken independently or in a combined fashion (see Fig. 24): (1) the improvement of VR technologies for providing a better fidelity, (2) the enhancing of simulation by augmenting the surgical scene for providing a guidance, and (3) the development of evaluation metrics for giving a constructive feedback to the trainee. The question is therefore to assess the value of these three features, and the individual contribution of each didactic resource.

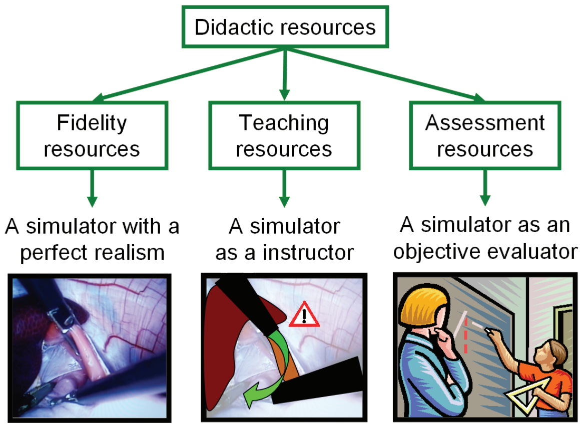


Fig. 24: The three conceptions of a VR surgical simulator driven by the use of different didactic resources.

A simulator is built and designed for a given purpose, a given training objective. This is the first issue to be regarded, a crucial didactic resource for training a certain skill can be something useless for another skill. Therefore, once training objectives are defined the importance of each didactic resource should be assessed. Ideally an expert in the field would be able to make a good judgement about it, but it is difficult to define in “a priori” manner such a hidden knowledge. An experimental methodology could be the only alternative, next sections addresses it.

Building research hypotheses

The conceptual framework conceiving VR simulators as a training means built with several didactic resources is used to develop hypotheses about which is the optimal simulator design. The aim is to assess the importance of each didactic resource.

One of the first questions is to find the relationship between fidelity and training effectiveness. It would be really useful to assess how an increment in the realism of a simulation enhances or not the didactic capability. Fig. 25 shows a hypothetical line that relates these two variables. Several experiments could be conducted to figure out the real shape of this relationship. Some specific hypotheses could be:

- “An increase of fidelity does not imply an increase in training effectiveness”.
- “A low degree of fidelity is enough to provide a good training effectiveness. It could even be the most efficient alternative”.
- “The incorporation of force feedback in simulation delivers an increase of training effectiveness in laparoscopic training”.
- “The stress present in real operating theatres decreases the training effectiveness”.

Another interesting set of hypotheses deals with the importance and use of teaching and assessment resources. Some of these ideas can be expressed graphically has shown in Fig. 26. It could be contrasted if:

- "Teaching and assessment resources can substitute a teacher behind the surgical trainee"
- "MIST-VR Suture 3.0 package used by a trainee alone has a training effectiveness similar to a physical simulator (video trainer) with a tutor"
- "MIST-VR Suture 3.0 package used by a trainee alone is similar with a LapSim with the feedback from a tutor"
- "Teaching and assessment resources can overcome some lack of fidelity and result in an even more didactic simulator"
- "A guided training strategy with constructive feedback in VR can enhance suture training outcome beyond that of physical trainers despite some fidelity limitations"
- "Suture training in VR is enhanced with a guided training strategy focusing the fidelity resources on pre-defined ways of interaction compared to a non-guided one"
- "Growing semitransparent spheres are a good forces substitution in suture training".

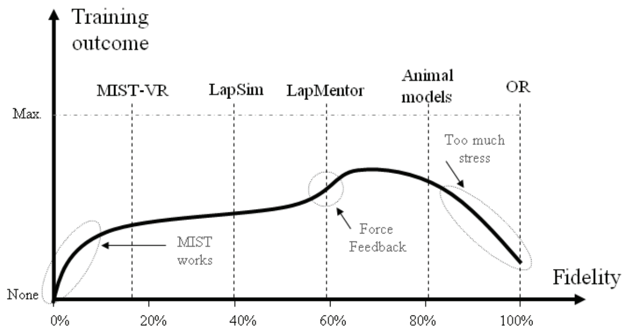


Fig. 25: Hypothetical relationship between simulation fidelity and training outcome. It reflects how a low-fidelity simulator (MIST-VR) is valid for the transfer of skills to the OR [Seymour 02;Grantcharov 04]. It also shows how training effectiveness could be enhanced by the incorporation of force feedback and could be decreased with the stress present in the OR.

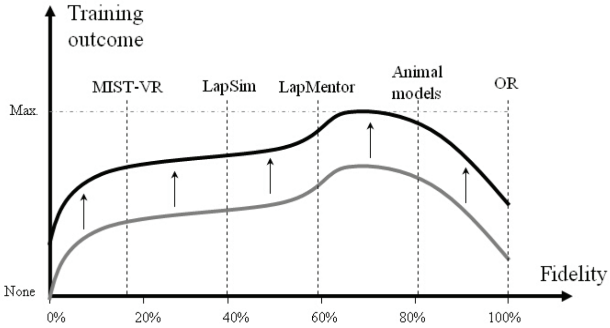


Fig. 26: Hypothetical increase of training effectiveness with the incorporation of teaching and assessment resources

Designing experimental methods

The objective is to assess the importance of different didactic resources in surgical training and to validate the hypotheses raised in former section. Suggested methodological approach is the use of **randomized controlled trials**, the study of how trainees acquire different skills in a simulator with or without the studied didactic resource. Blinded pre-tests and post-test of surgical skill assess how trainees improve in each of the two experimental conditions, allowing its comparison. This is shown in Fig. 27.

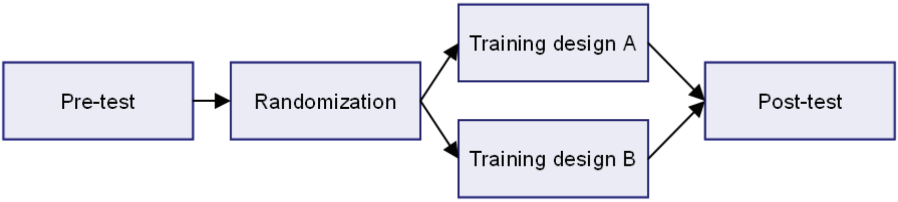


Fig. 27: Randomized controlled trials suggested as experimental design for assessing the importance of different didactic resources. Differences between pre-tests and post-tests deliver the information about training outcome.

A complete study would measure how surgeons acquire all laparoscopic skills in a training program. Nevertheless it can be focused on a specific surgical skill so as to shorten the experimental time and cost. Several issues about the experimental design are dealt next.

Measuring simulation fidelity

When comparing two training means, two simulators designed with different didactic resources, it’s important to characterise these didactic resources in a precise manner. Section 0 of this chapter has presented the measurement and comparison of the use of didactic resources in commercial laparoscopic simulators. But detailed analyses are needed if the study is focused on a specific surgical skill.

As an example, the analysis of fidelity resources is adapted to a “Clip and Cut” task. Categories of fidelity resources from proposed conceptual framework are adapted to what is present in a clip & cut task. This means that only the aspects related to this task are going to be taken into account. Besides, these categories are pondered by setting a maximum score on them, as shown in Table 8. Four simulators are used for comparison in this example (see Fig. 28): MIST-VR (Mentice AB, Göteborg, Sweden), LapSim (Surgical Science Ltd, Göteborg, Sweden), ProMis (Haptica, Dublin, Ireland), and an animal vein set in a physical simulator. “Clip & Cut” task in ProMis is offered with physical plastic cables.

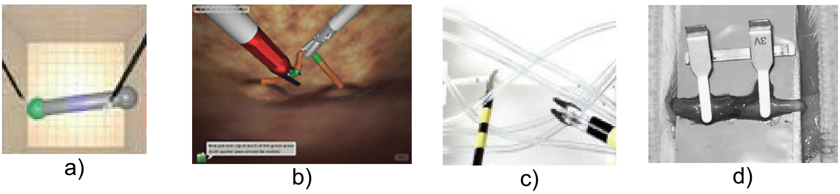


Fig. 28: Simulation models for a “Clip & Cut” task. a) “SCStretch clip” in MIST-VR; b) “Clip Applying” in LapSim; c) "Clip Application" in ProMIS; and d) an anesthetized rat vas deferens (taken from [Grober 04]).

Fidelity components				MIST-VR	LapSim	ProMis	Rat vas	Max*
Surgical setting	Surgical scene	Anatomy	Shape	3	8	9	10	10
			Resolut	5	3	5	5	5
		Textures		0	3	0	5	5
		Illumination		3	3	3	5	5
	Instrum.	Handling		4	4	5	5	5
		Correspondence		5	5	5	5	5
Mechanic interact.	Collisions			5	8	10	10	10
	Deformations			2	5	8	10	10
	Topological changes	Cutting		0	3	8	5	5
		Tearing		0	3	4	5	5
		Stapling		0	5	7	5	5
	Forces			0	0	7	8	10
Physiopat behaviour	Fluids	Blood		0	5	0	8	10
	Movements			0	0	0	5	5
	TOTAL FIDELITY:			**28%**	**58%**	**75%**	**96%**	**95**

Table 8: Fidelity assessment and comparison of the “Clip & Cut” task from different VR and physical simulators. *: maximum score in each category used to ponder the importance of different issues (Max of 10 has a double importance compared to a Max of 5)

Pre-tests and post-tests: need of a “training outcome” metric

This is one difficult issue in the design of the experiment: to define the “training outcome” metric. Trainees improve their skills using a simulator, but how much they do? How to compare the amount of skill acquisition? Suggested double-blinded methodology starts and ends with a test that tries to assess surgical skill, how to measure it? This field of surgical skill assessment is still lacking much research [Aggarwal 04] in order to obtain a standardized and accepted assessment method. For example, some authors have assessed operative errors in a porcine model as relevant metrics for these tests [Seymour 02].

Once relevant metrics have been defined it would be very interesting to combine them in a joint scale from 0 to 100. A 0 value would reflect that nothing has been learnt, and a 100 score would mean that the trainee has acquired the skill thoroughly. This would allow **characterizing the training need** of each trainee at the beginning of the learning program, and the amount of skill acquisition at the end of it, making comparison between training methods possible. Therefore an **“optimum”** way of learning would be defined as the training method which has the fastest learning curve measured with the "training outcome" metric.

But definition of such a metric is a very ambitious goal that needs the agreement of surgical experts and colleges after concluding experimental results. It is much more difficult if the metric tries to ponder all the skills in laparoscopic globally. The following section shows an example of how to approach the construction of this metric focusing in suturing training.

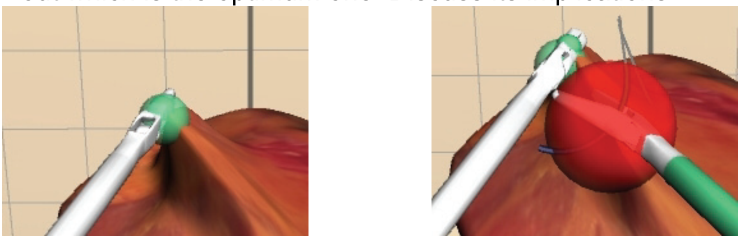
Example: study of the importance of different resources in suture training

The objectives for this study are:

- Assess the importance the mechanical fidelity by comparing the training outcome of three different fidelity levels.
- Assess the importance of a set of teaching resources, one of them the growing semitransparent spheres as a substitute of forces (see Fig. 29).

Secondary objectives:

- Discuss if a growing sphere is a good substitute for forces.
- Compare the results of the different experimental groups and find out which is the optimum one. Discuss its implications.



a) b)

Fig. 29: Growing semitransparent spheres, a virtual enhancing feature used as a force feedback substitution. Screen captures from the commercial simulator MIST-VR.

Material and methods

Four experimental groups are defined; trainees would be randomised among them:

- Group 1 (G1): Low fidelity (LF) and no teaching resources (nCR). This could be a LapSim suture task.
- Group 2 (G2): Medium fidelity (MF) and no teaching resources (nCR). This could be a modified MIST-VR suture task, in which the teaching resources would be deactivated.
- Group 3 (G3): Medium fidelity (MF) and teaching resources (CR). This could be a MIST-VR suture task, which has growing semitransparent spheres and a set of visual aids to guide the trainee in the suture.
- Group 4 (G4): Control, high fidelity (HF) and no teaching resources (nCR). This could be a physical trainer with an animal tissue to be sutured, which has a perfect mechanical fidelity and no teaching resources.

A 100% fidelity is supposed for the animal tissue set in a box trainer, the training mean for the control group (G4). The two candidates for G1, G2 and G3 are MIST-VR and LapSim, whose fidelity needs to be assessed. This issue, together with the definition of the training outcome metric, is dealt in following sections.

Assessing simulation fidelity

Suture requires many of the skills learned before to be performed, there are some difficult manoeuvres that a surgeon must practice many times to perform an intracorporeal knot fast and secure. Suture thread is very slippery when handled with laparoscopic tools, and there is a reduced workspace. Physical behaviour of the thread and its interactions with tools and organs should have a high degree of fidelity. Moreover, tactile information seems to be useful to perform the stitch in the tissue and to stretch the thread when tying the knot [Bethea 04]. All these requirements make the simulation of the suture a very difficult task. Only modelling thread behaviour is an open research field [Lenoir 04], and there are also difficult issues to be solved with collisions and interaction between thread and tools.

Nevertheless two commercial simulators offer acceptable approximations to this task. LapSim presents a very good immersive sensation, thanks to a video played on a kind of sheet in the background, but lacks some functionality and fidelity. MIST-VR offers a guided program (12 tasks) to learn the technique with an acceptable fidelity. None of them offers force feedback.

Fidelity aspects studied are model for the thread, thread-tool interactions, needle-tool interactions, stitching and knotting. The result of the analysis is presented in Table 9. **LapSim suturing has a fidelity of 40% and MIST-VR of 58%**. Categories of fidelity resources from proposed conceptual framework (section 2 in this chapter) are again adapted to the specific task, suture. And different maximum values for each category are defined to ponder relative importance between them. Following paragraphs explain in more detail the valorisations given for each category:

- **Model for the thread**: LapSim uses a discrete biomechanical model composed by nodes tied one to the following. The graphical model is simply some cylinders superimposed to the joints between these nodes, as it can be seen when the curvature of the thread is big. It shows some instabilities (vibrations) apparently when the thread collide with itself and has big curvature. On a whole it shows a slow behaviour that seems a little unrealistic. On the other hand suture thread presented in a MIST-VR behaves in a quite realistic manner, without discontinuities and instabilities. It calculates and describes the shape of a curve, given curve property parameters and external constraints, with a function named “SimCurve”.

- **Thread-tool interactions**: The small size of a thread makes very difficult to simulate its contacts and interactions. One strategy followed by both simulators is to apply an extra security collision volume around thread and tools, i.e. there is a region surrounding these objects that can not be occupied by any other object. Despite this solution some collisions are not detected, and sometimes the thread crosses itself or tools. This problem seems to be more frequent in LapSim.

			Max	LapSim		MIST-VR	
Surgical setting	Surgical scene	Thread model	10	Geometric discontinuities	6	Quite smooth and realistic	9
		Wound model	5	Only a surface	1	An approximation	3
	Instruments	Handling	5	Normal handling	2	Needle holder handling	5
		Corresp.	5	Correct	5	Correct	5
Mechanical interaction	Collisions		10	Almost everything. Big security region.	8	Guided interactivity. Small security region	6
	Deformations	Thread behaviour	10	A bit slow. Some instabilities	5	More realistic. Some instabilities	7
		Knoting fidelity	10	Some slippery behaviour	7	Some slippery behaviour	7
	Top. changes	Incision	10	Quite artificial	2	Quite realistic	8
		Removing needle	10	Little control of it	2	Along needle curve	8
	Forces		20	None	0	None	0
Physiopat. Behaviour	Blood		5	Rough approximation	2	None	0
		TOTAL	**100**		**40%**		**58%**

Table 9: Fidelity assessment and comparison of the “suturing” task LapSim and MIST-VR simulators.

- **Needle-tool interaction**: The interaction of two rigid objects is an open research field, as it is very difficult to deal with collisions and resulting forces. Without FF, this interaction is even less realistic as it is lost one important source of information: the strength used to grasp the needle. Anyway haptic devices are still not mature enough to deliver forces with such high frequency bandwidth as what is required in the interaction of two metal objects. One important aspect to be simulated is the needle adjustment in order to hold it in the right manner to begin the stitch (right angulations and grasp). Only MIST-VR makes it possible either by pulling the thread or pushing the needle with the other tool. On the other hand LapSim do not allow changing the inclination of the needle, and it simulates a virtual behaviour of the needle in which it tends to a vertical position. None of them simulate the interaction when both tools hold the needle, as it is impossible without FF.

- **Stitching (needle-organ interaction)**: LapSim only offers the possibility of stitching a surface, and might lack some fidelity in its mechanical behaviour. Needle hooks the surface even if it slide backwards, and it is difficult to say when the needle comes out again from the tissue after having introduced it. There is no necessity of making a right movement when stitching the tissue with the needle, i.e. a round movement according to needle curvature. Moreover, no control is made on the stitching-in and stitching-out points. MIST-VR offers a much better solution to this interaction problem. It makes an approximation to the problem of stitching two different sides of an injury. Stitching points are showed to the user and controlled. Finally, interaction force is simulated with a growing semitransparent sphere which indicates the user to move the needle through the tissue right.

- **Knotting**: This is probably the most difficult step in an intracorporeal suture. Surgeons must learn the task of winding the slippery thread around the instrument shaft and not to lose it when grasping the other end of the thread. Finally, a right tension should be applied to the knot. Both LapSim and MIST-VR have a good approximation to this step, but only MIST-VR offers some control of forces by turning thread red when it is stretched too much.

Defining a “Suturing training metric”

The experimental design needs a metric to assess how trainees improve their skills; it needs a “suturing training metric”. It is necessary to define parameters relevant that reflects the proficiency in the suturing skill. A short review of the literature is done looking for these evaluation metrics. The search criteria are to find either validation studies of suturing training tools or analysis of suturing skills metrics.

Results of the four selected articles are summarised in Table 10. After studying them, a first design of the “suturing training metric” is defined by:

- Time [Kothari 02]. Nevertheless this metric alone is not consistent [Grober 04].
- Accuracy: distance to marked entry and exit points [Bergamaschi 00].
- Coordination: directed to two aspects, the assessment of the interstitch time [Moody 03] and the acquisition of movements and path length with devices like the ISCAD [Darzi 02]
- Quality and symmetry assessed by an observer with questionnaires and checklists [Moody 03]

Difficulties

The experimental design explained is mined by some difficulties and limitations, which have prevented it from being carried out. Ordered by relevance these are:

- To have all training means available. It has not been possible to have the simulator for the G2, a MIST-VR without teaching resources: the simulation itself is limited to the guided interaction by teaching resources, and deactivating them makes the simulation not intuitive and even unreal. And a study with G1 (LapSim), G2 (MIST-VR) and G3 (physical simulator) would only be a comparison between three different training means, but no clear conclusions about the hypotheses raised could be found.
- To define a metric of suturing skills. As reviewed in the literature, it is difficult to find differences statistically relevant in some of the parameters. The issue of evaluating suturing skills is still lacking a sensitive and relevant set of metrics.
- To assess simulation fidelity in a rigorous manner. The fidelity analysis is limited by the subjective valorisation of one observer. The definition of the pondering of the different factors should also find the consensus of more experts.

Metric	Result	n	Reference
Time	Reduced after training with a MIST-VR (39 ± 21%) or a Yale Lap. Skills Course (30 ± 21%)	24	[Kothari 02]
Error: mm from markers of stitching	Differences between teaching strategies: instruction or passive observation.	6	[Bergamaschi 00]
Goal-directed actions, regardless goal is achieved.	No differences.		
Non–goal-directed actions (failure hand–eye coordin.)	No differences.		
Time (min)	No differences.		
Tissue damage (mm): lacerations from excess force	No differences.		
Dexterity: Movements (n)	No differences adding noise or music.	12	[Moorthy 04]
Dexterity: Path length (cm)			
NPMs: executed movements that did not achieve a goal			
Global rating: components of the task rated on a 5-point Likert scale			
Accuracy: distance to marked entry and exit points			
Knot quality: visual check of throws being squared and that the knot being secured			
Time (s)			
Stitch completion time (s)	No differences.	9	[Moody 03]
Interstitch time (s): Coordination	Differences between nurses and junior or senior surgeons		
Mean peak force (mV)	No differences.		
Bimanual coordination (state analysis)	Differences between nurses and junior or senior surgeons		
Quality (subjective)	Differences between nurses and junior or senior surgeons		
Symmetry (subjective)	Differences between nurses and junior or senior surgeons		

Table 10: Suturing skill metrics in different studies found in the literature.

Discussion

A taxonomy of the resources available in laparoscopic VR simulation has been presented, which offers a conceptual framework for the analysis, design and evaluation of VR simulators in the context of surgical training. The taxonomy developed has allowed a comparison between VR simulations. The intention has been to identify and define clear criteria for effective simulation.

Followed framework of didactic resources has been an attempt to make a step further in the conception of a surgical simulator. These systems are not only an emulation of reality like described in [Delingette 98], but they also offer teaching and assessment resources as described, with their correspondent potential values and utilities.

Scope and limitations of the taxonomy

The scope of this taxonomy is limited to what an isolated VR simulator can offer regardless of other factors in surgical training. As such, it requires further development to take into account not only simulator design, but also curriculum structure, training strategies (e.g. “shaping”, “fading” or “chaining” [Gallagher 05]) and wider issues related to the context in which real life surgical skills are acquired [Kneebone 03]. These include the collaboration of other people (eg. assistant, teacher, other team member) within the simulation. Despite all these desirable future extensions, our proposed taxonomy is a starting point which can be generalised from laparoscopy to other surgical techniques, or focused on a specific surgical skill like laparoscopic suturing.

While the proposed taxonomy is applicable to any type of endoscopic VR simulation, the work presented here discusses simulations of procedures in the abdominal cavity since most commercially available simulators focus on them. It has been also shown how the fidelity study can be focused onto specific surgical skills, like suturing (see section 0).

Setting standards to compare simulators

There are many interrelated issues that influence the outcome of a training programme for surgical residents, like the training opportunities and conditions, the training curriculum, etc (see Chapter II). These factors also influence in the validation and comparison of surgical simulators. The aim of present work has been to focus the comparison into the technical details, into the use of the didactic resources of VR technologies.

Therefore proposed taxonomy has been used to compare how commercially available laparoscopic simulators make use of different didactic resources to meet similar training objectives. One recent overview with qualitative information is available [Schijven 03b], but the data presented is not enough to satisfy the need to set standards by which emerging technologies can be judged. The hierarchical definition of fidelity resources and a criteria ranked from 0 to 10 (see Table 4) has allowed a systematic and quantitative comparison between simulators in terms of their engineering fidelity. The hierarchical averaging of scores for comparison has been chosen as it is one valid logical option, but it could be improved with a more suitable justification. Another future extension would be studying and comparing the psychological fidelity instead of the engineering fidelity, what would be more relevant for the transfer of training. Nevertheless, measuring the degree to which skills in the real task are captured in simulated tasks is a difficult issue. One last challenge is to compare objectively the quality and usefulness of teaching and assessment resources which have been only described as “used” or “not used”. Therefore the scope of the comparison results of these two categories of resources should not be considered as a criterion to say that a simulator is better or worse, it is simply that a simulator use more or less those compared resources.

The issue of fidelity in virtual environments and assessment metrics has been addressed recently [Mania 03]. Some approaches have been done in laparoscopic VR simulation asking users to rank the realism of different issues in face validity studies [Schijven 02;Schijven 03a], but no objective criteria and no reference values were provided. Another recent study has compared deformable models in terms of computations, topology changes handling and biomechanical realism

[Meier 05]. Our proposed approach has assessed fidelity of different simulators comparing them both to box trainers and to the operating room. Reliability between assessor's was high (Cronbach's alpha = 0.8), which indicates that the methodology is consistent. We found that advanced VR simulators can have a fidelity similar to box trainers with ex-vivo organs (59% and 62% respectively). VR fidelity is more limited in deformations, tearing, interaction forces and all physiopathological behaviour features (average score of VR fails, see Table 5), which is in concordance with the conclusions of the review of Liu et al. [Liu 03].

Simulators design strategies

Developed conceptual framework is a new viewpoint over surgical simulators; it serves as a **taxonomy of specifications**. Approaches to simulator design can be identified after studying how laparoscopic simulators make use of different didactic resources. The simplest one is an **abstract conception** of the surgical workspace focusing attention on the basic psychomotor skills that have to be developed by the trainee, identified with an ergonomic task analysis [Stone 04]. MIST-VR "basic skills" was designed in this way, with an extremely simple interaction, almost no deformation and useful interaction indicators.

The second approach aims at simulating a virtual patient with a **perfect realism**, which is normally requested by surgeons. Force feedback is incorporated, organs are more realistic and interaction is enhanced. This is the trend usually followed by research institutions and companies, a trend lead by LapMentor as the simulator with the highest fidelity in almost every field (see Table 5).

But there is one last approach that might have a great potential: to enhance a simulator with a "**virtual instructor**" who guides the trainee through the procedure and delivers constructive feedback. Simulators make use of teaching and assessment resources that build this "virtual instructor" capability. MIST-VR "Suture 3.0", which has the highest use of teaching resources together with LapMentor (57%), offers an interesting guided interaction to teach trainees stitching and knotting skills. Reach-In Lap Trainer, which has the highest use of assessment resources (69%), gives feedback about surgical performance not with low significant measurements like time or movements, whereas with what could be the advice of a surgical expert, with messages like “too much tissue bitten”. The value of these types of resources has not yet been properly studied.

The value of each resource for an optimum design

A central issue that the proposed taxonomy tries to address is the optimal design of a VR laparoscopic simulator for training surgeons. This question has been focused to the assessment of the value of each didactic resource proposed in the conceptual framework. In this way several research hypotheses have been developed, and a methodological approach to contrast them has been proposed (see section “Methodological approach for designing an optimal simulation” of Chapter IV). Once these hypotheses are answered it will be defined an effective and efficient design.

Nevertheless there is an important difficulty in this approach, the definition of a “training outcome” metric. The big challenge of characterising such metric involving surgical experts leads to consider the possibility that it will never be possible to assess training differences with enough sensibility. It has to be regarded that currently it is even difficult to assess differences between box trainers and VR simulators [Munz 04;Maithel 06]. Nevertheless the conception of a surgical simulator as a training means built with didactic resources is simply useful to analyse and interpret current validation studies. Moreover, it can clarify thinking in design processes and towards an efficient research efforts direction.

There are data in the literature that can be interpreted from the point of view of the proposed conceptual framework. However, there are little studies centred on specific resources. Some examples are the analysis of the role of force feedback (see section 0 “Human factors in laparoscopic VR simulation” in Chapter II) or the study of the relevance of providing constructive feedback [Gonzalez 04]. As explained in former sections, another determinate data is that it has been shown how the psychomotor skills acquired with a very simple simulator, MIST-VR, are transferred to the OR [Seymour 02;Grantcharov 04].

On the other hand the added value of more advanced simulators with the incorporation of more fidelity resources seems not to be so clear. A comparison of training outcomes between LapSim “basic skills 2.0” and a box trainer with physical objects has not revealed any substantial advantage of one system over the other [Munz 04]. Grober et al. concluded that surgical skills training on low-fidelity bench models appears to be as effective as high-fidelity model training for the acquisition of microsurgical technical skill [Grober 04].

The value of teaching and evaluation resources has caught less attention in the scientific community. A couple of examples are a specific study of the relevance of providing constructive feedback [Gonzalez 04] and the determination of how a colour code can substitute force feedback [Kitagawa 05]. A implicit result of MIST-VR [Seymour 02;Grantcharov 04] is the validity of using interaction metaphors to avoid the interaction with rigid objects, what overcomes its low use of fidelity resources. More research is needed to clarify the value of these resources for surgical training.

Simulator design is also an important factor for the motivation of trainees and the degree to which they perceive it as a good training tool, what could be called “the individual face validity”. A “fun” character such as that present in the *precision and speed* task in LapSim “basic skills 2.0” might be a very important feature in order to motivate trainees.

Similar questions can be raised about the importance of each resource to assess surgical skills. It has been said that “the validity of a test must be considered proportional to the realism of the simulation“ [Schijven 04a], but MIST-VR has been shown to be a valid tool to test surgical skills [Gallagher 04]. Assessment resources are useful not only for providing constructive feedback, but also for the desirable goal of surgical credential. Value depends on the definition of metrics for skill assessment, on the extent to which the metric reflects relevant information about surgical competence. Nevertheless it is very difficult to assess how a surgeon performs, and the field of objective assessment of surgical skill is of great current interest [Aggarwal 04].

Conclusion

In conclusion, it has been presented a taxonomy of VR didactic resources as a first step towards the systematic definition of simulation specifications, hoping to clarify thinking in this rapidly moving field and focus research in critical aspects. It has served as basis for a comparison between different simulators, a contribution towards definition of standards by which VR emerging technologies can be judged.

This conceptual framework can be used to produce research hypotheses alongside experimental analysis. Nevertheless, there is a big challenge to be addressed, the definition of a “training outcome” metric. Further work is needed to assess the importance of different didactic resources in the search of an optimum simulator design.

Chapter V: Tissue consistency perception analysis and modelling

This chapter addresses the study of human factors in laparoscopy for the definition of the required simulation fidelity. Consistency perception is the capability chosen and it is analysed with a triple approach: (1) a perceptual characterisation (2) a study of the in-vivo interaction forces and the ex-vivo biomechanical properties and (3) the development of a force feedback model for simulation.

A methodology for surgeon sensory interaction characterization has been defined and applied trying to determine the relative importance of three components of a perceptual surgical skill: visual cues, haptic information, and previous surgical knowledge and experience. Results have identified a “haptic memory” skill recalled with the identification of a tissue and not the expected “visual haptics”, a kind of sensorial substitution. Surgeons are able to perceive tissue consistency and distinguish between four strength levels at least. This sensorial information is mainly based in tactile information, what indicates that VR simulators need haptic devices with force feedback capability if consistency information is to be delivered.

Objective parameters of forces and biomechanical properties are obtained in order to elucidate which are the factors more important in consistency perception. First, interaction forces are acquired in-vivo with a grasper equipped with a Force/Torque sensor. Second, biomechanical properties of tissues are assessed ex-vivo with a mechanical testing machine. A logarithmic law of tissue consistency perception has been outlined. Finally all data are gathered and a model of consistency perception is developed. It defines the concept of *fixation grade*. The other main factor is the kind of tissue. Diffuse logic algorithms are suggested for its implementation.

Introduction

The design of a VR laparoscopic simulator needs a deep understanding of the human factors related to this interaction paradigm. How surgeons perceive the laparoscopic operating theatre? Do they develop special perceptual, sensorial or cognitive skills? These are questions not easily addressed, related to unconscious processes of human beings.

The central question that this chapter addresses is “what is the required degree of fidelity in simulation?” Two definitions of fidelity limits are stated in order to answer it (see Fig. 30). The idea is to differentiate between what is not possible to be perceived (no need to be simulated) what can be perceived (it is convenient to be simulated but it does not require a high fidelity) and what is perceived and useful for the surgical procedure (it needs the highest degree of fidelity).

First, the ***Perceptual Fidelity Boundary*** is defined as the edge of our perceptual capabilities. It confines those aspects of the physical reality that are perceived by human beings. Interaction in laparoscopic theatre has to be characterized in order to define this boundary. And second, a ***Utile Fidelity Boundary*** encloses those perceived aspects of reality that are actually used by surgeons to guide an operation. Cognitive studies should be performed to clarify which are these pieces of information gathered from perception. These are the aspects that should have the highest degree of realism. Moreover, virtual reality techniques could be used in the training process to teach a user how to recognize the sensorial stimuli and employ them.

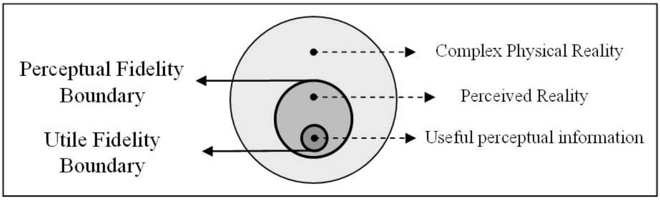


Fig. 30: Conceptual graph of the *Perceptual* and *Utile Fidelity Boundaries*, which are based on human perceptual and cognitive capabilities.

Little effort has been done towards understanding the perceptual-motor and cognitive processes that contribute to laparoscopic surgical skills learning [Tendick 00]. The entire area of haptic abilities and their role in the fundamental abilities (psychomotor, visiospatial, an perceptual) needs more research [Satava 03a]. This field of research is also interesting for the identification of haptic interfaces improvements and for the use of illusions to fool the human user (sensory substitutions) [Biggs 02].

Therefore this chapter addresses the study of human factors in laparoscopy for the definition of the required simulation fidelity. A perceptual capability is chosen and it is analysed with a triple approach: (1) a perceptual characterisation (2) a study of the interaction forces and biomechanical parameters and (3) the development of a force feedback model for simulation with a definition of the *Perceptual Fidelity Boundary*. Chosen capability is tissue consistency perception, since it is important for a surgeon to perform surgical procedures delicately and to not damage tissues.

Tissue consistency perception analysis

A methodology is proposed to characterize sensory interaction in the laparoscopic theatre which pursues to determine the relative importance of three different components of perceptual surgical skills: medical experience and knowledge, force feedback and visual feedback. A similar approach has been done studying tissue grasping [Heijnsdijk 04]. A cognitive study has also been performed, in which users tried to identify different tissues with either visual or tactile information.

Material and Methods

An experimental method has been defined to analyze tissue consistency perception by laparoscopic surgeons. Tissue consistency is here understood as the resistance felt against the penetration (pushing) and withdrawal (pulling) of a grasper holding the tissue. It is measured by a scale from 0 to 10: value 0 corresponds to movements with an empty grasper, and value 10 corresponds to a grasper holding a rigid structure as a ligament in its bone junction.

The experiment has a secondary objective: to study how surgeons are able to identify different tissues with visual or tactile information. Confidence in answers is also asked.

Users

The experimental study was performed in two sessions within two different training workshops in laparoscopic surgery course organized by the MISC (Minimally Invasive Surgery Centre) of Cáceres (Spain). These two training workshops had a time span of six months between each other. A total of 29 different surgeons were enrolled in the study, classified as novel, intermediate and expert depending on their laparoscopic surgical experience (see Table 11). This experience is ranked from 0 (no experience) to 5 (expert). Values between 0 to 2 corresponds to surgeons that have assisted in some surgical laparoscopic procedures, between 3 to 4 corresponds to some real experience like 25 cholecystectomies, and 5 corresponds to an expert user (professor in the training workshop) who has made more than 50 cholecystectomies and fundoplications.

	# users in Session 1	# users in session 2	# total	Mean experience
Novel	10	-	10	0.4 ± 0.8
Intermediate	-	10	10	2.7 ± 1.16
Expert	5	7*	12	5

Table 11: Users enrolled in the study in the two sessions. Experience in laparoscopy is ranked from 0 (no experience) to 5 (expert). *3 expert users repeated.

Method

The experiment has four stages in which surgeons are asked to assess tissue consistency with the 0-10 defined scale. It is initiated by a simple questionnaire (Q) with a written description of different tissues being grasped. In the second and third stages surgeons assess tissue consistency using either visual information (VI) or tactile information (TI) respectively. They are also asked to identify the tissue being pulled in these VI and TI stages. Last, surgeons perform the task of penetration and withdrawal of the grasper in a normal fashion, using both visual and tactile information (VTI) for consistency assessment. At the end of each stage users are also asked to rank their confidence in consistency assessment as low, medium or high.

Ten different tissues (t1-t10, see Table 12) are studied in the questionnaire (Q stage). Most of these tissues have been selected because they are manipulated during Nissen fundoplication. The description of the scenes is made as precise and close to the experiences of VI, TI and VTI stages as possible. Therefore the surgeon is bidden to imagine a pig model, what is used in following stages, and rank the consistency of tissues taking into account possible surrounding attached organs.

Tissue #		Tissue description
t1	*	Diaphragmatic crus, once it has been dissected
t2	*	Esophagus hold close to cardia
t3	*	Fundus, holding all the stomach mass
t4	*	Greater omentum, hold at the free end
t5		Stomach hold at the pylorus
t6		Esophagus hold with a Penrose drain
t7		Fat tissue (lesser omentum)
t8		Fundus, closing the wrapping of the fundoplication
t9		Small intestine
t10		Large intestine

Table 12: Different tissues ranked by its consistency in the questionnaire. * indicates tissues whose consistency is assessed in all experimental stages (Q, VI, TI and VTI) and also studied in detail with the acquisition of objective parameters (interactiiomechanical properties, see section 0)issue biomechanical properties.

In VI stage users view four 10-second laparoscopic recordings corresponding to four tissues being pulled and pushed repeatedly. These tissues are t1-t4 (see Table 12) and are also the tissues considered in the following experimental stages. Video recordings have been acquired in the same pig model in which TI and VTI stages are performed. Fig. 31 shows a frame of each sequence from the first session. Surgeons are asked to identify the tissue (users do not know a priori which structures are present in the video) after seeing each video and before ranking consistency.

During TI stage users perform pulling and pushing manoeuvres without seeing the laparoscopic monitor. Four graspers (Endo-Clinch II, AutoSuture, CT) are set holding the four tissues defined (t1-t4) of the pig model. Each grasper is labelled (A-D) in a blind fashion to the user, who does not know what he is holding. A supervisor controls that no damage is produced in the tissue during this blind manipulation, and users are requested to proceed with caution and delicacy. After ranking consistency surgeons are asked to identify these tissues with two different aids, labelled as TI(11) and TI(4). TI(11) refers to eleven possibilities offered to choose between them after feeling the consistency of each tissue. These possibilities are the ten tissues described for Q stage (see Table 12) and a grasper holding nothing. And at the end of TI stage the four tissues are revealed (t1-t4) to users, who have to associate them with each of the four graspers (A-D); this is TI(4).

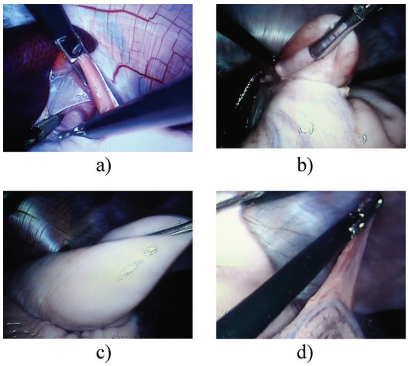


Fig. 31. Different frames of the recordings for the VI stage. a) t1, b) t2, c) t3, d) t4.

In the VTI stage, the last one, surgeons operate laparoscopic graspers in a normal fashion on the pig. Both in this stage and in the former the order of the grasper is set randomly. And these stages are preceded by a scale familiarization protocol: users feel with their hand what ‘0’, ‘5’ and ‘10’ are by pulling three graspers holding nothing, 250g and a fix structure respectively. This correspondence was set taking into account the logarithmic law of human perception and the range of forces expected (10N [Picod 05]). Masses are not rigidly fixed to the grasper, whereas with elastic gum in order to offer a continuous stimulus to the user when pulling the grasper.

Q and VI stages are performed consecutively at the beginning of the training workshop with all users simultaneously in 15 minutes, time enough to write down the answers to the different questions. TI and VTI stages are executed consecutively on the pig model during one morning of the training workshop, each user individually in about another 15 minutes. The experimental set is built in an isolated operating theatre to avoid distractions in user's attention. Surgeons are guided through the different steps by an interviewer without any pressure and with time enough to consider answers and to avoid drifts and interferences between questions.

Statistical analysis

32 sessions with 29 different surgeons are performed (see Table 11). In each session a surgeon assess 10 tissue consistencies in Q, and 4 in each of the rest stages (VI, TI and VTI). This sample size is chosen to detect a 10 percent difference in tissue consistency perception with a power of 80 percent and a two-tailed level of significance of 0,05. Three predictive variables are considered: group of user (novel, intermediate or expert), experimental stage (Q, VI, TI and VTI) and tissue (t1-t10, see Table 12). The end point semiquantitative variable is the tissue consistency, measured with the analogical sensorial scale from 0 to 10.

Factorial ANOVA tests with different factors are used as the statistical tool to find statistical differences between the factors involved in consistency perception. First, tissue consistency in Q stage depends on the tissue (t1-t10) and on the group of users. A factorial ANOVA test with these two factors is performed to study the effect of them. Second, tissues t1-t4 are studied in all the four stages. Thus, the stage factor is included in the ANOVA test to study the behaviour of consistency perception. Normal distribution and homocedasticity are in the data (K-S Normality test and equality of variances F-test). To compare the four different experimental stages, considered as four methods to assess consistency, a regression analysis is made between each couple of stages. VTI is considered as the reference method. Coefficient of determination (R^2) is calculated as a measure of agreement between the stages. Software used was StatView 5.01 (SAS institute Inc., Cary, NC).

Results

Consistency assessment

Expert, intermediate and novel surgeons assessed tissue consistency in different experimental stages. In the questionnaire (Q stage) a total of ten different tissues (t1-t10) have been ranked as shown in Fig. 32. Answers covered the range 0-10 of the scale defined, and had some differences between surgeons. In the ANOVA test studying the two factors in tissue consistency perception in the Q setting “tissue” was a determinant factor ($p<0.0001$), and so was the “group of users” ($p = 0.0011$). No interaction was found between these two factors ($p = 0.6262$).

Tissue consistency of four different tissues (t1-t4) was assessed with only their previous knowledge (Q), with visual information (VI), with tactile information (TI) and with both visual and tactile information (VTI) as shown in Fig. 33. Some indicia of sensory combination have been found in the perception of several tissues, where different visual (VI) and tactile (TI) information seem to be combined by different users in VTI stage. For example, t2 by expert surgeons was assessed on an average as 5.6 in VI, 7.0 in TI and 6.6 in VTI. Nevertheless very little differences have been found between TI and VTI stage in t1 or t4.

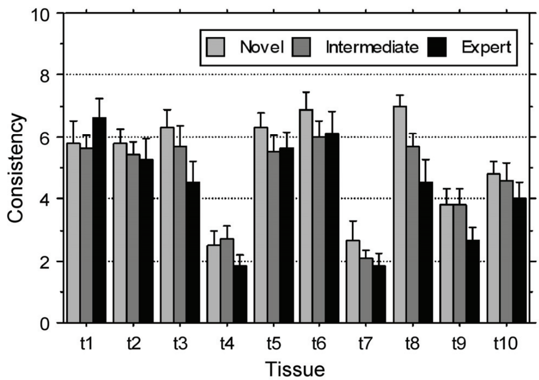


Fig. 32. Tissue consistency ranked in the questionnaire (Q stage) of tissues t1-t10 by novel, intermediate and expert laparoscopic surgeons (error bars show standard deviation).

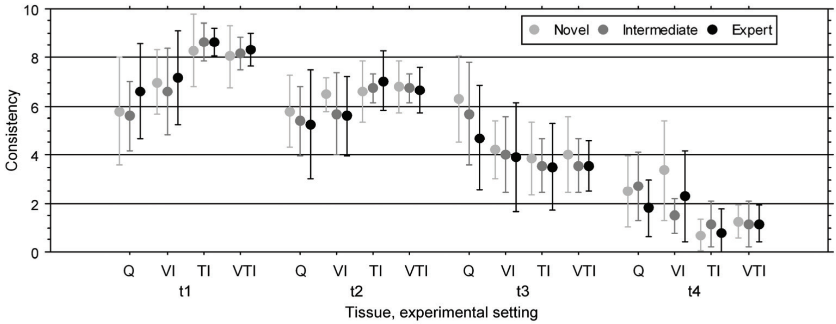


Fig. 33. Consistency valorisations in the four experimental stages (Q, VI, TI, VTI) and of tissues t1-t4 by novel, intermediate and expert laparoscopic surgeons (error bars show standard deviation).

The average consistency values of the four tissues, in each experimental stage and by each group of users are shown in Table 13. Standard deviations of values given for each tissue in each experimental stage by all users are presented in Table 14 with its averages. VTI, considered as the reference stage because of its complete laparoscopic interactivity, has the lowest value (sd = 0.94).

In the ANOVA test studying the three factors studied in tissue consistency perception, "tissue" has been found as a determinant factor ($p<0.0001$), and interrelation has been found between "tissue" and "stage" ($p<0.001$). Neither "stage" ($p = 0.822$) nor "group of users" ($p = 0.289$) were determinant factors, and no other interrelation was found. Regression lines Q-VTI, VI-VTI and TI-VTI are shown in Fig. 34, and the determination coefficient (R^2) between each couple of experimental stages by each group of users is computed and plotted in Fig. 35.

Confidence

Confidence in consistency assessment is quantified from 0 to 5: low (0), medium (2.5) and high (5). Results from the different groups of surgeons are shown in Fig. 36. Confidence in Q stage was not asked in the first session of the study; therefore this variable is missing for novel surgeons, and has only 7 users in the group of expert surgeons.

Tissue identification

Different right tissue identifications rates were obtained by users (expert, intermediate and novel surgeons) in three conditions (TI, TI(4), VI), as shown in Fig. 37. The average right identification rate was 35.7% when users used the tactile information and a list of eleven possibilities (TI), 77.0% when the tactile information is associated with four possibilities- (TI4), and 77.9% when the visual information is used (VI).

A)	Tissue Consistency (all users, all stages)	t1 (n=128) 7.45 ± 1.71	t2 (n=128) 6.25 ± 1.41	t3 (n=128) 4.21 ± 1.79	t4 (n=128) 1.65 ± 1.40
B)	Stage Consistency (t1-t4, all users)	Q (n=128) 4.85 ± 2.30	VI (n=128) 4.84 ± 2.39	TI (n=128) 4.96 ± 3.16	VTI (n=128) 4.95 ± 2.89
C)	Group of users Consistency (t1-t4, all stages)	Novel (n=160) 5.05 ± 2.62	Interm. (n=160) 4.81 ± 2.61	Expert (n=192) 4.83 ± 2.87	

Table 13: A) Average consistency (mean ± sd) for each tissue (t1, t2, t3 and t4) by all users in all stages; B) Average consistency (mean ± sd) in each stage (Q, TI, VI, VTI) for tissues t1-t4 and by all users; C) Average consistency (mean ± sd) by each group of users (novel, intermediate, expert) for tissues t1-t4 and in all stages.

	t1 (n=128)	t2 (n=128)	t3 (n=128)	t4 (n=128)	Mean (n=4)
Q (n=128)	1,888	1,730	2,063	1,351	1,76
VI (n=128)	1,668	1,437	1,679	1,744	1,63
TI (n=128)	0,978	1,053	1,476	0,871	1,09
VTI (n=128)	0,879	0,871	1,223	0,770	0,94
Mean (n=4)	1,35	1,27	1,61	1,18	

Table 14. Standard deviations in consistency assessment by all surgeons for each tissue in each experimental stage. The last row presents the mean standard deviation for each tissue, and the last column the mean for each experimental stage.

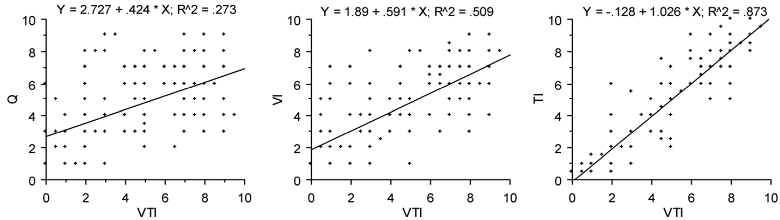


Fig. 34. Regression plots of each of the three first experimental stage (Q, VI, TI) with VTI considering all the users together. Each regression analysis is done with a total of 128 points.

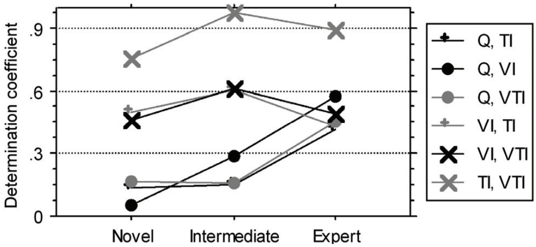


Fig. 35. Line bar chart of the determination coefficient (R^2) in the linear regression between each couple of stages by novel, intermediate and expert laparoscopic surgeons.

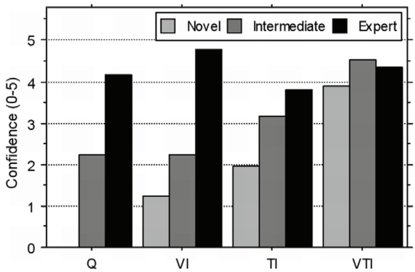


Fig. 36: Confidence (from 0 to 5) in all stages by different users (error bars show standard deviation).

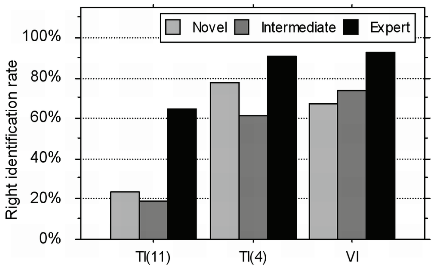


Fig. 37: Right tissue identification rate by different users in TI(11), TI(4) and VI.

Discussion

This experiment has provided interesting data about how tissue consistency is perceived through pulling and pushing forces (TI) and the image of organs being deformed (VI). It has also assessed the influence of mental representations and knowledge built by surgeons (Q). The aim is to provide a deep understanding of this perceptual capability.

Scope and limitations of proposed methodology

The proposed methodology for sensory interaction characterization has been designed to evaluate the relative importance of three components of perceptual surgical skills: haptic information, visual cues, and previous surgical knowledge and experience. The method presented some limitations: it is difficult to find a way to rank perception, and the scale defined to assess consistency was subjective and not familiar for the user. Despite the scale familiarization protocol this might have been a cause of dispersion. On the other hand, sensory stimuli offered to users have reproducibility problems such as tissue consistency fatigue and the need to change grasps from time to time. Friction in trocars has also been a problem, because sometimes it was higher than the resistance of the tissues being pulled. To solve it, tools were wet from time to time to better slide through trocars. Despite all these limitations the methodology has obtained consistent and good results, as shown in different figures and tables.

The high correspondence found between TI and VTI might be explained by an experimental drift due to the temporal proximity between these stages, which were performed consecutively. To avoid this, tissues were randomized and users were asked not to recall answers given in TI stage during VTI. Anyhow there exists the doubt of what would have happen if the order of the experiment would have been TI-VI-VTI instead of VI-TI-VTI.

Influence of surgical knowledge and experience

The first stage of the method (Q) has been designed to evaluate the importance of surgical knowledge and experience. Although users were a little reluctant about it at the beginning, this background allowed them to assign a consistency value to an organ described in a questionnaire (see Fig. 32), and expert surgeons had quite confidence in this stage (see Fig. 36). But the high standard deviation in assessment (VTI, considered as the reference stage because of its complete laparoscopic interactivity, had the lowest standard deviation; see Table 13) and the little agreement with VTI stage ($R^2 = 0.273$, see Fig. 34) indicates that **a description of the chirurgic scene is only a vague information to assess consistency**.

Sensory substitution: The "visual haptics" concept

The concept of visual haptics as a kind of sensory substitution states that surgeons learn to interpret visual information adequately and based upon these cues they sense force despite the lack of force feedback [Stylopoulos 04]. VI stage has been designed to explore the validity of this concept in consistency perception.

Results show how perception with visual information is better compared to Q stage for novel and intermediate laparoscopic surgeons (higher determination coefficient in the regression with VTI, see Fig. 35). But expert surgeons showed a Q-VTI agreement ($R^2 = 0.458$) quite similar to that of VI-VTI ($R^2 = 0.490$), which suggests that **visual cues do not add any information for consistency perception over knowledge and experience**. And the agreement between VI and VTI is still low ($R^2 = 0.509$, see Fig. 34). To some extent, this might have been caused by the big difference found between VI and VTI in t4 in the first session of the experiment (15 users, 5 of them expert, see Table 11). The problem was that the video recording of VI stage shown the omentum being pulled hauling a little the stomach, giving a harder impression. But the analysis made without these data gave $R^2 = 0.534$, which is still low. All these results suggest that **visual information alone is not good enough to assess tissue consistency, even for an expert laparoscopic surgeon**.

Nevertheless a good correlation was found between experience and the Q-VI agreement (see Fig. 35). This suggests the idea that what a surgeon does is to build a mental representation of some different kind of tissue consistencies instead of learning to interpret visual cues. **Thus the "visual haptics" concept is more related with some kind of sensorial memory recalled with the identification of a tissue (with either a read description or a visual picture) and not with the interpretation of visual cues**. This hypothesis is reinforced by another two results: expert laparoscopic surgeons showed a higher VI-Q agreement ($R^2 = 0.573$) than that of VI-VTI ($R^2 = 0.490$), and they had more confidence in VI than in TI when assessing consistency (see Fig. 36) despite TI was much more precise than VI (had more agreement with VTI, see Fig. 35). It seems that surgeons improve their sensory perception capabilities in an early stage after learning to handle and manipulate laparoscopic tools in a right and ergonomic manner (intermediate laparoscopic surgeons showed a better performance than novel, see Fig. 35). But the strong mental representation built after years of experience seems to bring about a lost in attention on visual and tactile stimuli degrading actual consistency perception.

Is there sensory combination?

It has also been evaluated if there is sensory combination between tactile and visual information in consistency perception, comparing VI, TI and VTI. Some indicia have been found in the perception of several tissues, where different visual (VI) and tactile (TI) information seem to be combined by different users in VTI stage. For example, t2 by expert laparoscopic surgeons was assessed on an average as 5.6 in VI, 7.0 in TI and 6.6 in VTI (see Fig. 33). Nevertheless, very little differences have been found between TI and VTI stage in t1-t4, and the agreement between these two stages was the highest ($R^2 = 0.873$, see Fig. 34).

These results suggest that tissue **consistency perception is mainly based in tactile information**. On the other hand expert surgeons felt surprisingly more confident when assessing tissue consistency in VI than when they did in TI (see Fig. 36). This could be much related with the general assumption that the tactile information is almost lost in the laparoscopic theatre. But the fact is that tactile information seems to be the source used by users to feel tissues and rank its consistency. This contradiction between common believe and experimental results was also found by Bholat et al [Bholat 99].

Tissue identification

Tissue identification with either visual or tactile information has also been studied. Despite users were given additional information (TI(11), a list of eleven possibilities), **tactile stimulus is not enough to identify the tissue** (see Fig. 37). On an average, when users were asked to associate four tactile stimuli with four tissues (TI4), they succeeded similarly than they did when asked to identify the tissue shown in a video (VI). Expert laparoscopic surgeons performed much better in this cognitive skill than the other two groups of users.

Is it defined a new evaluation metric?

Another important issue addressed in this study was to determine differences in perception between surgeons with different expertise level, which could be useful to evaluate laparoscopic surgeons. Q stage showed statistically differences between users ($p = 0.0011$, ANOVA test), which were higher in tissues related to stomach (t3 and t8, see Fig. 32) probably because of anatomical differences: pig anatomy has the stomach not fixed to the abdominal cavity as human anatomy does, and novel and intermediate users where not familiar with this. These differences may also be related to the range of forces exerted and felt in open surgery, which should be bigger.

On the other hand **it is difficult to say if the surgeons learn to interpret visual cues or learn to perceive tactile information**. As what was found in a study of grasping [Heijnsdijk 04], experience of surgeons was not a determinant factor when perceiving consistency ($p = 0.289$, ANOVA test). The R^2 factor measuring the VI-VTI or TI-VTI agreements didn't even correlate with the expertise level of surgeons as intermediate surgeons showed a higher agreement than what experts had (0.610, 0.976 for intermediate and 0.490, 0.893 for experts respectively, see Fig. 35). **Tissue identification skills with tactile information could be one interesting metric** to be further studied. As seen before, expert laparoscopic surgeons performed much better in this cognitive skill than the other two groups of users.

One final remark could be raised: the study has been performed with surgeons with different degrees of surgical experience, not with residents. It could be interesting to study if this group of surgical students show differences in these skills.

Force interaction characterization: objective parameters

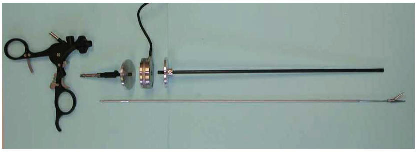
Former section has provided an understanding about the perception of tissue consistency, delivered by pulling and pushing forces. Next step is to measure these forces and to obtain some objective parameters in order to elucidate which factors are more important in consistency perception.

Two experimental designs have been developed to characterise interaction forces in the laparoscopic theatre. First, forces are acquired in-vivo with a grasper equipped with a Force/Torque sensor. Second, biomechanical properties of tissues are assessed ex-vivo with a mechanical testing machine, a work performed by the "*Instituto de Biomecánica de Valencia*" – IBV, Valencia, Spain. Objective results will then be compared to the subjective valorisations and will provide a basis for the elaboration of the force feedback model for simulation, the aim of the next section.

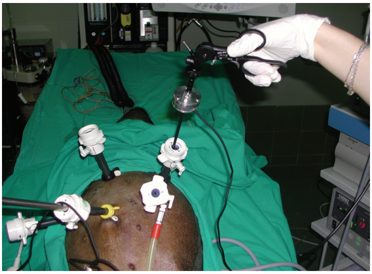
Material and methods

In-vivo interaction forces measurement

This experiment is designed and prepared by GBT [Antolín Fernández 05] and performed in operating rooms of the Minimally Invasive Surgery Centre of Cáceres. A laparoscopic grasper (Click Line, Storz medical, Germany) is equipped with a Force/Torque sensor (Mini40 F/T, ATI, USA) as shown in Fig. 38. This device is similar to that described in [Richards 00;Picod 05]. It can be introduced through a trocar and acquire forces of all degrees of freedom of the laparoscopic tool but grasping. Nevertheless an indirect measure of grasping forces can be taken due to the mechanical transmission of grasping from the handle to the tip of the tool. The transmission is done through the inner metal axis, which is coupled to the outer black tube in which the sensor is attached (see Fig. 38). This is more a limitation than an advantage, because when a grasp is closed it is acquired as a pushing force, i.e., there is a coupling between these two degrees of freedom. Another feature is the total weight of the device, 215g, which is more than double of the grasper alone (85g).



a)



b)

Fig. 38: Device designed to acquire laparoscopic interaction forces. a) Device dismounted in its different components: the black tube has been cut and two metal plates have been designed to fix the F/T sensor. The metal axis is introduced in the black tube and is responsible for the transmission of the grasping movements. b) Device being used in the pig model through a trocar in the forces measurement study.

The device is therefore used in a controlled way, fixing grasping before making pulling and pushing manoeuvres. An experienced laparoscopic surgeon is instructed in this way and performs three repetitions of five consecutive insertion and extraction manoeuvres holding each of the four tissues of the pig model used in former study (t1-t4). In each repetition the tissue is grasped in a different place trying to bite the maximum amount of tissue. Measurements are made on the same pig model that is used for the perceptual experiment. Two parameters are obtained from each force profile: peak to peak value (N) and maximum temporal slope (N/s).

Ex-vivo tissue biomechanical properties assessment

As said before, this experiment is designed and performed by the personnel of the IBV (Instituto Biomecánico de Valencia). A short description of it is given in following paragraphs for a better understanding of the results and discussion sections.Ex-vivo samples are taken from the four studied tissues (t1-t4) and are mechanically characterized with force-displacement graphs.

A universal testing machine SERVOSIS is equipped with a load cell 500 N INTERFACE (see Fig. 39). Tissue portions are taken and prepared following the protocols of the institution, and they are bitten with laparoscopic graspers attached to the testing machine. An extensiometric sensor is mounted in the handle to control the grasping force (see Fig. 40).

Therefore this experimental setup controls the grasping force applied to the handle of the laparoscopic grasper (Fg), the pulling force (F) and the displacement (d). Fg is fixed to three values (47.2 N, 31.4 N, 15.7 N), ranging from a minimum that holds tissues a little consistently to a maximum that shows the beginning of certain damages in the tissues.

A total of 36 trials are made, 3 repetitions with 3 grasping forces for 4 different tissues. A force-displacement graph is obtained in each of the trials (Fig. 41), which is characterized by the stiffness coefficients in two regions, initial (K_1) and final (K_2), the peak force (F_p) and the correspondent distance of this F_p in which tissue is released or torn (d_p).

Fig. 39: SERVOSIS universal testing machine used in the ex-vivo experiment (image given by IBV).

Fig. 40: Experimental setting for the ex-vivo characterization. (image given by IBV).

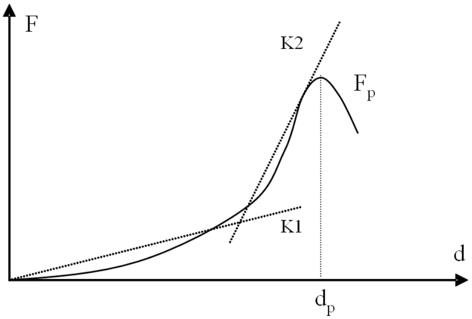


Fig. 41: Force-displacement characteristic curve of a generic tissue with its parameters: initial and final stiffness (K_1, K_2), peak force (F_p), displacement for F_p (d_p). (by IBV).

Results

A set of objective parameters related to the pulling and pushing forces are obtained for each of the four studied tissues. On one hand, in vivo interaction forces are measured and registered in force profiles like those shown in Fig. 42. Two parameters, peak-to-peak value (Vpp) and maximum slope (m) are used to characterize each of the five pulling-pushing cycles of each of the three repetitions. Average values are compared to the subjective assessment of tissue consistency from former section as shown in Table 15. An exponential regression is made between Vpp and VTI perception (see Fig. 43), taking also into consideration values of the protocol for scale familiarization, a 0 value to trocar friction (Vpp=1.4N), a 5 value to a mass of 250gr (Vpp=2.5N) and a 10 value to 1,1Kg (Vpp=11N).

On the other hand the biomechanical characterization study has revealed how grasping force is not a determinant factor in measured parameters (an ANOVA test has not found differences statistically relevant). Table 15 shows the value of the characteristic parameters obtained with the average of the nine trials of each tissue (3 repetitions of 3 grasping forces).

	t1	t2	t3	t4
Subjective perception of tissue consistency:				
TI (0 to 10)	8.8 ± 1.0	7.4 ± 1.1	2.8 ± 1.5	0.8 ± 0.8
VTI (0 to 10)	8.3 ± 0.9	6.7 ± 0.9	3.1 ± 1.2	0.9 ± 0.8
In-vivo interaction forces measurement:				
Vpp (N)	5.8 ± 1.2	3.3 ± 0.6	1.5 ± 0.2	1.6 ± 0.1
M (N/s)	7.4 ± 1.9	3.3 ± 1.1	0.9 ± 0.3	1.0 ± 0.2
†Ex-vivo biomechanical characterization				
K1 (N/mm)	1.23±0.80	0.15±0.02	0.38±0.19	0.22±0.09
K2 (N/mm)	1.35±0.71	0.50±0.18	1.01±0.38	0.31±0.12
dp (mm)	4.02±0.00	10.2±4.19	4.91±3.90	11.9±7.85
Fp (N)	6.25±1.52	6.60±1.20	7.94±2.56	2.13±1.09

Table 15: Results of the subjective perception of tissue consistency and the objective parameters obtained from the interaction forces profiles and the ex-vivo biomechanical characterization. Values shows mean ± standard deviation. †Data given by the IBV.

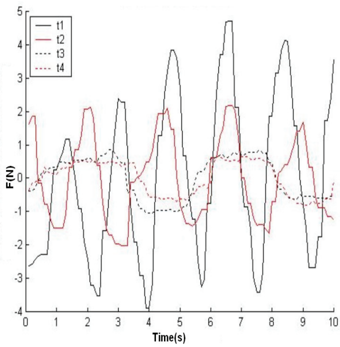


Fig. 42: Interaction force profiles studied for different tissues. Profiles of t3 and t4 are complete, whereas those of t1 and t2 only show the first two pulling and pushing manoeuvres.

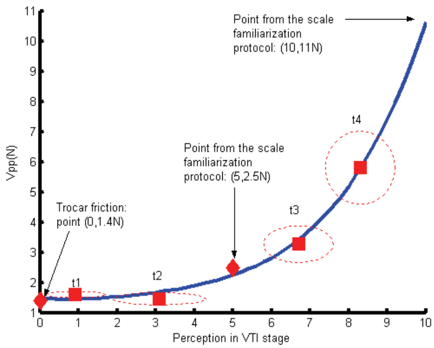


Fig. 43: Logarithmic regression curve between Vpp and subjective perception of tissue consistency in VTI stage. The four ellipsoids reflect the standard deviation of Vpp or consistency valorisations.

Discussion

The objective of this section is the acquisition of objective parameters related to the tissue consistency perception. Two approaches have been taken, the measurement of interaction force profiles and the assessment of the biomechanical properties of four tissues (t1-t4, see Table 12).

Scope and limitations of experiments

There are many variables and factors influencing how forces are produced, like attached organs, point of grasping, factors that change the biomechanical tissue properties (irrigation, disease conditions, age…), and amount of tissue bitten. The complexity of a systematic study would be too high; therefore a simple approach is taken: forces are characterized with temporal profiles acquired in-vivo following a protocol and with tissue biomechanical properties acquired ex-vivo.

The force acquisition device built for the in-vivo study allows characterizing the pulling and pushing interaction forces in a controlled way. Nevertheless the acquisition of forces simultaneously with the perceptual analysis is not possible due to two limiting factors: the coupling of grasping with pushing information and the weight introduced with the F/T sensor, which would distort perception.

The main limitation of the ex-vivo biomechanical characterization is the high dispersion in the results despite followed defined protocol. This is caused by the extremely high sensitivity of tissues to experimental conditions and to the intrinsic variability of biomechanical properties. This is a common problem in this field of research [Carter 01].

Are data comparable?

Ex-vivo stiffness in the initial region (K_1) of t4 has been found to be 1.23 N/mm (see Table 15). This means that a displacement of 1cm produces a force of 12.3 N. Nevertheless in-vivo studies showed the elongation of t4 around 10cm required only 1.6N, what is 100 times smaller. These differences are explained by the distinct experimental conditions as commented before. The in-vivo force measurement has tissues fixed in the abdominal cavity, whereas the ex-vivo tissue characterization has pieces of tissues isolated in a test bed.

Experimental conditions of the two experiments are very different. Therefore results are not straight fully comparable, whereas they are complementary for a better understanding of the behaviour of tissues and the requirements for surgical simulation. It can be concluded that the ex-vivo experiment provides the characteristic isolated tissue stiffness, and the in-vivo measurements add the boundary conditions of the abdominal fixation. This idea will be further explored in the development of the perceptual model, making a first assessment of the influence of the fixation of tissues in the abdominal cavity.

Collected data for a force feedback algorithm

Interaction pulling and pushing forces of four different tissues have been characterized with their peak to peak value and its maximum temporal slope (see Table 15), which can be used as a basis for requirements of a FF algorithm. Force measurements agree with ranges described in the literature [Richards 00;Picod 05].

Another interesting result has been different tear and release thresholds. The ex-vivo trials in which tissue portions were stretched finished with the release of the grasper or the torn of the tissue, determining the peak force (F_p, see Fig. 41 in page 142). t4 has found a tear threshold (2.13N), and the other tissues (t1-t3) have found their correspondent release thresholds (see Table 15). One of the reasons why tissues are released instead of torn is the low efficient transmission of grasping forces between handle and tool tip [Gupta 97], what makes tissue damages more difficult.

Discussion: modelling force perception

The objective of present chapter is the study of human factors in laparoscopy for the definition of the required simulation fidelity, specifically the *Perceptual Fidelity Boundary* (see Fig. 30, page 125). The question has been focused on tissue consistency perception through laparoscopic tools, aiming to understand how pulling and pushing forces are originated and noticed by human senses.

A simple approach has been taken, comparing the subjective perception of four "pulling scenarios" with objective parameters obtained from temporal force profiles of these scenarios and from an ex-vivo biomechanical characterization experiment. Therefore results of former two sections are interpreted and generalised with the construction of a model of the main parameters influencing the perception of pulling and pushing forces.

Scope and limitations of proposed model

The scope of the study is limited to one surgical manoeuvre, pulling. This is one of the most frequent manoeuvres, but not the only one in which force information could be important. Nevertheless pulling enables conceived methodological approach, a straightforward force acquisition and an in-vivo characterization with the device developed. Moreover, it originates force values that are higher than other delicate manoeuvres, what makes it more robust to noise sources in the F/T sensor. Limitations of each of the experimental conditions have been commented in former sections.

Comparing subjective perception with objective data

There are different pieces of information coming from three experimental protocols: a subjective perceptual analysis (section 0), and two objective sources of objective data, in-vivo forces measurement and an ex-vivo tissue characterization (section 0). How can results be interpreted together? Are they comparable? Can human perception be characterised? Are tissues perceived or hindered by trocar frictions?

Are data comparable?

Surgeons performed free pulling and pushing of tissues in the perceptual analysis, whereas in-vivo force profiles belonged to controlled uniform pulling and pushing manoeuvres. This way force profiles were acquired with a uniform velocity, whereas surgeons used different velocities and accelerations to perceive the inertia of the mass held at the end of the tool. Despite this consideration, force profiles are directly comparable to subjective valorisations because they were acquired simultaneously with the second session of the perceptual experiment, with the same pig model and trocars. This means that the peak to peak force value would be a good objective parameter of the “consistency scenario”, because all surgeons roughly reached the same maximum extension. Nevertheless the maximum slope, influenced by inertial aspects, could not be as good.

There are other possible sources of difference, like the point of grasping the tissue or the possible variable conditions of the tissue held in time. Nevertheless their influence should not be relevant, even more with the low resolution that surgeons have shown in consistency valorisations.

Logarithmic perception law

Average perception values and peak-to-peak force parameter are much correlated, as shown in Table 15. Nevertheless perception differences between t3 and t4 have not been explained with force parameters, probably hidden by friction forces which can be up to 3N [Picod 05] or due to the inertial mass that is not registered in force profiles as commented before (t3 is the stomach held by the fundus, and its inertia to changes in velocity could be a difference in its perception compared to t4). Drawing an exponential line relating subjective perception and objective peak-to-peak force it is found a logarithmic shape (see Fig. 43), something common to many sensorial human capabilities.

Friction do not eclipse interaction forces

Results have shown how surgeons are able to distinguish between four different tissue consistencies with only force information. Interaction forces are perceived despite friction, and these forces deliver information about tissue consistency. Device built for the in-vivo experiment acquired a trocar friction force with a maximum value around 0.7 N, which means a peak to peak value of 1.4N. This is similar to what was obtained in t3 and t4 (1.46N and 1.6N respectively, see Table 15). And this trocar friction didn't hinder surgeons to distinguish between t3 and t4. The reason could be the inertia perceived with accelerations caused by surgeons in the perceptual experiment, as commented before.

These results lead to the next hypothesis: **"surgeons are able to differentiate tissues and perceive somesthesic information despite the presence of interfering trocar frictions"**. It seems that surgeons learn to distinguish between friction forces, which are similar in every pulling and pushing manoeuvre, and resulting forces from the interaction with organs. This is opposed to the idea that "*it is unlikely that the operator will be able to discriminate between somesthesic information generated by the organ and that generated by the resistance of the wall*" [Picod 05].

FF requirements: model of force perception

Information gathered in the three experiments is processed in an abstraction process in order to elaborate a model of force perception. This aims to contribute for the definition of the level of fidelity that haptic devices should deliver.

Defining requirements for simulation

This study has provided useful information to determine some requirements for a VR simulator. Surgeons have shown to perceive consistency with mainly tactile information and not with some kind of sensory substitution using visual cues. Therefore, **the VR simulator needs** a haptic device that delivers **force feedback** (FF) to the user, what is in concordance with what Basdogan et al concluded recently [Basdogan 04]. Despite the big amount of friction and other interfering forces and torques [Picod 05] surgeons were able to assess consistency consistently with tactile information.

Results also suggest that surgeons can only feel differences between some levels of forces, and that a simple model for FF calculation in surgical simulation could be enough. Four force levels have been identified corresponding to t1, t2, t3 and t4 (which were statistically different). And the standard deviation in VTI stage, the normal fashion to feel consistency, has been 0.94 in the scale defined from 0 to 10. Therefore **four (or five) levels of forces seem to be enough for the FF model**. Our experience in this study tells us that this FF model can be parameterised depending on basically two variables: the kind of tissue (fat, conjunctive, muscular…), and the degree of fixation to other organs and to the abdominal cavity.

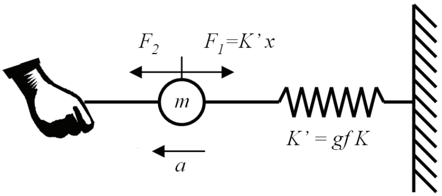
Consistency of t1-t4 tissues has been estimated averaging the answers of expert surgeons in VTI stage (t1: 8.4 ± 0.55, t2: 6.5 ± 1.50, t3: 3.7 ± 0.67, t4: 1.0 ± 0.35, see Fig. 33). These consistency values of VTI stage can be another requirement for the FF model, and a way to validate it by comparing tissue consistency assessment with a real and a virtual environment. Some previous attempts to identify differences in tissue consistency have been made simply classifying them as soft, hard or harder [Hu 04], and this scale is a first effort to take a step forward. The correspondence of these values with actual forces is roughly established by the scale familiarization protocol ('5' for example was set to a grasper holding 250gr, which is a force of 2.5N).

Elaborating the model

The aim is the development of a perceptual model of interaction pulling and pushing forces in a laparoscopic environment. There are many interrelated variables that influencing these forces: the kind of tissue grasped, the anatomical point where the tissue is grasped, the degree of fixation to the abdominal cavity, trocar friction, the individual variability of each subject, the amount of tissue grasped, the grasping force, the conditions of the tissue (healthy, diseased, inflamed…) . Nevertheless human perception is quite rough, what indicates that this problem can be simplified. Therefore the objective is to identify which are the more relevant factors in the generation of pulling and pushing forces.

Results have revealed how surgeons were able to distinguish at least four levels of force intensity, and that trocar friction does not eclipse consistency information. The grade of fixation when holding the tissue with the grasper has not been a determinant factor in an ex-vivo characterization of biomechanical properties; thus, this is a variable that might be not relevant for the model. Another important result is that comparing ex-vivo characterization with in-vivo force profiles it can be noticed how measured stiffness does not correlate with peak-to-peak force values. For example t3 is stiffer than t2, but t2 produced bigger interaction forces than t3 (see Table 15). The grade of fixation of tissues to the abdominal cavity has a big impact in resulting forces.

Therefore, the idea taken is that there are two main factors: the kind of tissue (its stiffness) and the grade of fixation of the tissue to the abdominal cavity. The proposed model is shown in [ec.3]. It indicates that laparoscopic pulling perceived forces (*F*) are a function of the grade of fixation (*gf*), the stiffness of the tissue (*K*), the distance pulled or pushed (*x*), the mass held (*m*) and the resulting acceleration caused to this mass (*a*). The grade of fixation is a no dimensional variable from 0% to 100%. This is a **simple linear elastic model** with an equivalent apparent stiffness *K'=gf K*. Fig. 44 shows a representation of the model, with the equations that rules its behaviour: the second Newton's law [ec.1] is applied to the system in the pulling case.



$$\sum F = m \cdot a$$

$$F_2 - F_1 = m \cdot a$$

$$F_2 = gf \cdot K \cdot x + m \cdot a$$

Fig. 44: Proposed linear elastic model and corresponding equations. F_2 would be the force exerted by user, what is the force perceived with the hand following the third Newton's law (for every action there is an equal and opposite reaction).

Next step is the assessment of the grade of fixation, *gf*. It is defined by the relation between the characteristic tissue stiffness (*K*) and the apparent stiffness found in pulling experiments (*K'*, see Fig. 44). A first approximation is to make estimations for the four studied tissues (t1-t4) with available experimental data. The apparent stiffness (*K'*) is calculated taking the peak force values obtained in-vivo and supposing a linear elastic model. These values are then divided by the displacement made to each of the tissues in the in-vivo study, which was roughly measured in the experiment, as shown in Table 16. This table shows how this *K'* is divided by an estimation of the characteristic stiffness (*K1* taken from the ex-vivo characterization experiment, Table 15) to finally obtain *gf*. The calculation of these values of the grade of fixation shown in Table 16 has not considered the influence of the mass and its inertia. The reason is that movements in the in-vivo experiment were made with a roughly uniform velocity. It can be seen how tissues t1 and t2 show a very high fixation, much bigger than t3 and t4, what it really happens in the porcine abdominal cavity.

	t1	t2	t3	t4
F_{peak} (N)	8.1	4.2	2.3	1.1
d (cm)	1	4	7	10
K' (N/cm) = F_{peak} / d	8.1	1.05	0.33	0.11
K1 (N/cm)	12.3	1.5	3.8	2.2
gf = K'/K1	66%	70%	9%	5%

Table 16: Assessment of the grade of fixation (*gf*) of the four studied tissues. Characteristic tissue stiffness is taken from the ex-vivo experiment (K1, Table 15).

Implementing issues

Due to the low resolution in the human perception of tissue consistency it seems to be appropriate to use algorithms based in diffuse logic. This way tissue stiffness and the degree of fixation could be classified in a discrete number of categories. A first proposal could be:

- Tissue stiffness: High, corresponding to muscular tissues (K≈10N/cm), medium (K≈5N/cm) and low (K≈1N/cm), corresponding to fat tissues.
- Grade of fixation: High (gf≈80%), medium (gf≈50%) or low (gf≈20%).

Other applications

The methodology proposed is also useful to detect limitations in the sensory interaction of the surgeon, which could be used to enhance surgical tools or the laparoscopic technique itself. Results have provided a better understanding about how surgeons learn to adapt to sensory limitations in laparoscopy, which could lead to the elaboration of new training objectives and evaluation metrics to enhance laparoscopy training processes. Nevertheless no clear conclusions have been reached about this issue.

Conclusion

Defined methodology for surgeon sensory interaction characterization has provided consistent and useful results about tissue consistency perception. Statistical differences were found when perceiving consistency depending on the tissue (hypothesis B), but not depending on the expertise level of laparoscopic surgeons (hypothesis C). Nevertheless results suggest that surgeons improve their sensory perception capabilities in an early stage, but also build a mental representation of tissue consistencies after years of experience. This is interpreted to be the “visual haptics” concept (a modified hypothesis D) which could effect a lost in attention on visual and tactile stimuli. It has been assessed the higher importance of tactile stimuli over visual cues in this skill, which suggest that only little sensory substitution might be present.

Surgeons are able to differentiate tissues and perceive somesthesic information despite the presence of interfering trocar frictions. A logarithmic law of tissue consistency perception has been outlined. Results also suggest that VR simulators need haptic devices with force feedback capability if consistency information is to be delivered. Moreover, a simple model with some discrete levels of forces seems to be enough to calculate these forces.

Finally a simple elastic model has been proposed for being incorporated in a surgical simulator. This model is parameterised by two main variables: the kind of tissue and the degree of fixation to other organs or to the abdominal cavity. This model has a reasonable guarantee of offering the level of realism that a surgeon can perceive and differentiate in pulling forces.

Chapter VI: Design of laparoscopic VR simulators and a validation approach

Two didactic designs for laparoscopic VR simulators are proposed with the knowledge of available simulation resources (Chapter IV), and taking into account lessons learned both with the review of the state of the art in Chapter II and the required simulation fidelity in Chapter V. The first one is a “basic skills” simulator designed to train the general laparoscopic skills, and second is an example of a procedural simulator centred in the Nissen fundoplication. They have been partially implemented by the SINERGIA consortium.

Esential skills for laparoscopic surgery constitute the requirements for the “basic skills” package. These are translated into simulation specifications regarding the capabilities of VR technologies. Seven didactic units are defined in the “basic skills” package: hand-eye coordination, camera manipulation, grasping, pulling, cutting, dissection and suturing.

Training needs for procedural skills are analysed in order to define the simulation requirements. Hierarchical Task Analysis (HTA) techniques are adapted and used to systematize the knowledge of what is required to perform a good surgical intervention. Nissen fundoplication, a surgical procedure for anti-reflux diseases, is analysed with this approach. Simulation specifications include three steps of this analysis, which are selected due to its critical importance or their special required motor skills: cruss dissection for esophagus release, window creation and valve creation.

Finally, a validation strategy is divided in two steps, an iterative content validity study during simulation construction and a characterization of proficiency levels. Proposed didactic design is the result of several content validity sessions with experts in surgery and education. Nevertheless, no results of the characterization of proficiency levels are provided. The value of each didactic exercise has been discussed, finding grounds that support the choice of a VR simulator for surgical training.

Introduction

The aim of present PhD is to find an optimum design of a VR laparoscopic simulator for training surgeons. This chapter addresses the construction of a specific didactic design for a training programme. It could be said that this is basically a bioengineering task of how to build a solution that covers certain surgical *training needs* by designing *didactic exercises* with *suitable fidelity* using available *simulation resources*. Chapter IV has provided a framework for the choice of virtual reality didactic resources in the design process. Chapter V has contributed for the better definition of what is the suitable fidelity in surgical training. Finally, this chapter takes the last step: the didactic design of simulation tasks that meet training objectives.

There is little specific literature about how to develop an efficient didactic design of a simulator. It can be found that an ergonomic task analysis was used for the design of the MIST-VR [Stone 04], but without any further detail. In a previous work simulation specifications were divided into perceptual motor skills, spatial skills, and critical steps of surgical procedures [Tendick 00].

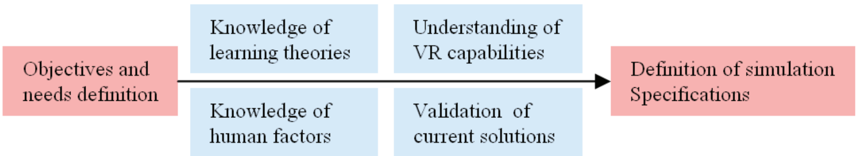


Fig. 45: Process for the definition of simulation specifications.

A logic process for the design specification of a surgical simulator (see Fig. 45) is developed for addressing this issue. It begins then with a clear definition of the training objectives and needs (see section 0, “Objectives and needs definition”, in Chapter II). Afterwards these objectives have to be translated into simulation specifications, regarding the capabilities of simulation technologies and the validation results of current VR simulators. It is also interesting to give heed to adult learning theories and human factors, also reviewed respectively in sections 0 and 0 of Chapter II.

Laparoscopic skills can be divided in two main groups: basic and procedural. The first refers to the fundamental generic skills that are required in laparoscopy, and the second are specific to a surgical procedure (like the cholecystectomy). This division can be found in commercial surgical simulators, and it is followed in this work.

Therefore the approach taken has been the division of the didactic design process in two steps: the systematic definition of training objectives and the definition of specifications for didactic units that meets these objectives. And this has been done for a basic skills simulator (section 0), and an example of a procedural skills trainer, a Nissen simulator (section 0). This chapter also introduces in section 0 a progressive validation approach for the simulator.

Design of a basic skills VR simulator

There are currently several VR laparoscopic simulators in market, all of them offering a "basic skills" package (see section 0 "VR laparoscopic commercial simulators and prototypes" in page 44). This section addresses the rethinking of its didactic design, applying leasons learned and incorporating new contributions.

Simulation requirements: basic training objectives

Laparoscopy requires some basic skills that a surgeon has to acquire. Their definition is quite clear in training programmes of training centres or surgical departments. A general description of them has been presented in section 0 of Chapter II.

Nevertheless these **definitions are vague** for the design of virtual didactic exercises. For example, dissection is a skill that requires a delicate tissue exposure. But, how a good dissection is objectively defined? Which parameters can measure that a dissection is delicate or not? There lacks a characterization of a good surgical manoeuvre, and a definition of when a skill is acquired or when it requires more training. This knowledge is necessary for the specification of a simulator, but it requires a difficult process in order to objectively be acquired.

Simulation specifications: 17 VR didactic exercises

Due to the vague definition of basic skills and their evaluation metrics, explained in former section, didactic design of virtual tasks can be quite heterogeneous among different simulators. Each solution takes a representative exercise of the skill and defines a set of related metrics. Any of these designs might be good, but it is important to keep in mind that there is a risk of building exercises that provides a negative transfer of skills [Gagné 85]. Nevertheless validation studies have not found any negative transfer yet (see review of section 0 “Validation and acceptance” in Chapter II).

A didactic design of a *basic skills simulator* is proposed in this section, which has departed from definition of required skills and from the experience and validation studies of former VR simulators. A total of seven didactic units and their exercises are described in following sections. Several ideas for this design are taken from commercial simulators (MIST-VR, LapSim, LapMentor, SEP, see section 0 “VR laparoscopic commercial simulators and prototypes” in Chapter II) by selecting those validated or interesting exercises. One good example is the task of “Manipulate & Diathermy” from MIST-VR, which has found the better construct validity results in some studies [Grantcharov 01;Grantcharov 03].

A definition of each didactic exercise specifies the training objective, the task to be fulfilled by the user and the set of metrics to evaluate the performance. There are also parameters of the virtual environment that can be changed in order to offer different degrees of difficulty in the task. Fidelity, teaching and assessment resources are involved in these definitions. Details about these exercises are found in Table 17 and Table 18, and a description about them is provided next. This didactic design is the basis for the development of the SINERGIA simulator, the result of a collaborative Research Network funded by the Spanish Health Ministry. Following sections describe each of these units, and some of them include screen captures of the SINERGIA simulator after the implementation of this design.

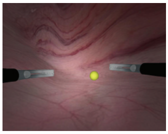
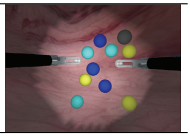
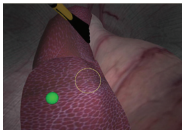
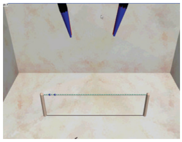
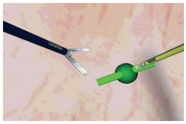
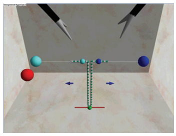
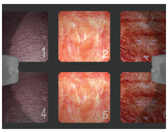
Exercise	Task	Evaluation metrics	Parameters of difficulty	Screen capture
Coordination *similar to those of LapSim or LapMentor*	Touch a set of static balls that appears sequentially in an "organic scene". There is a time limit for each ball.	(1) Time, (2) distance travelled by each tool & efficiency, (3) errors (wrong tool, harm to background), (4) fulfilment.	(1) Size of balls, (2) time limit, (3) number of balls, (4) geometry of "organic scene".	
Speedy coordination *similar to "Precission and speed" (LapSim)*	Touch a set of moving balls that appears all together in an "organic scene". Black balls must be avoided.	(1) Time, (2) distance travelled by each tool, (3) errors (wrong tool, wrong ball, harm to background)	(1) Size of balls, (2) number of balls, (3) geometry of "organic scene".	
Navigation *similar to those of LapSim or LapMentor*	To centre endoscope sight in certain spheres.	(1) Time, (2) distance travelled by each tool & efficiency, (3) errors (collision with anatomy)	(1) Size of spheres, (2) time limit, (3) anatomy complexity and movements.	
Navigation & touch *Original*	Centre endoscope sight in spheres and then lead there a tool.			
Accurate grasping *Original*	Grasp certain points of a thread without causing deformations to it. Grasp area is between a pair of small spheres. There is a time limit.	(1) Time, (2) distance travelled by each tool & efficiency, (3) mistakes when grasping (outside the marked area, with wrong tool) and (4) accuracy	(1) Grasping area size, (2) time limit and (3) *fixed* or *free ends mode*.	
Grasp and transfer *similar to "Transfer & Place" (MIST-VR)*	Grasp a cylinder, transfer to the other tool and release it in a marked area.	(1) Time, (2) distance travelled by each tool, (3) mistakes (wrong transfer, wrong release)	(1) Size of objects, (2) time limit, (3) size of release area	
Coordinated pulling *original*	Grasp thread and pull them following the white path until the big spheres. A "coordination-control bar" provides formative feedback.	(1) Time, (2) distance travelled by tools and (3) coordination.	(1) Different pulling paths, (2) time limit, (3) bar inclination sensibility, (4) bar inclination evaluation threshold.	
Force sensitivity *original*	Grasp and pull different virtual tissue samples and rank its consistency answering a set of comparative questions.	(1) Success rate	(1) Magnitude of difference of stiffness between tissues	

Table 17: First half of the didactic design of the "basic skills" VR simulator: the 8 exercises of the coordination, navigation, grasping and pulling units.

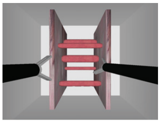
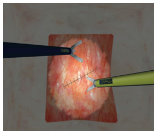
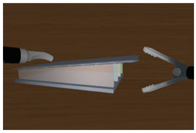
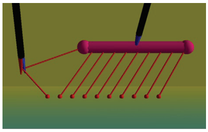
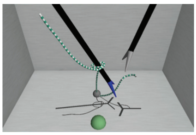
Exercise	Task	Evaluation metrics	Parameters of difficulty	Screen capture
Accurate cutting *Similar to "cutting" (LapSim)*	Cut a set of cylinders in marked lines after pulling them.	(1) Time, (2) distance by tools, (3) cut accuracy (4) errors: lack of tension in exposure, tearing.	(1) Tearing sensibility	
Continuous cutting *Original*	Cut a surface following drawn pattern after exposing it.	(1) Time, (2) distance travelled by tools, (3) cut accuracy (4) errors: lack of tension in exposure, tearing.	(1) Tearing sensibility, (2) complexity of drawn pattern	
Blunt dissection *Original*	Separate two structures joined by three conjunctive layers using dissection manoeuvres with a right tissue exposure, and without harming organs.	(1) Time, (2) distance by tools, (3) errors: harm colliding objects, tearing in exposure, tearing in dissection.	(1) Tearing sensibility	
Cautery coordination *Similar to "Manipulate & Diathermy" (MIST-VR)*	Grasp an object, place it in a spatial region, hold it and cauterize with the other tool marked areas.	(1) time, (2) distance travelled by tools, (3) errors: tear a joint, harm cylinder, harm surface, cautery more than one joint at once.	(1) size of object, (2) size of region where object is held, (3) size of areas to be cauterized	[not available]
Hook dissection *Similar to "Precision Dissection" (LapSim)*	Hook and cautery joints of a cylinder one by one, with a right tension and without harming the cylinder or the surface.	(1) Time, (2) distance by tools, (3) errors: tear a joint, harm cylinder or surface, cautery more than one joint at once.	(1) Tearing sensibility	
Stitching *similar to those offered by SEP MIST-VR, or LapMentor*	Stitch needle through both sides of an open wound after a right exposure.	(1) time, (2) distance travelled by tools, (3) stitching point accuracy, (4) errors: stitch tearing	(1) tearing sensibility	[not available]
Knotting *similar to those offered by SEP MIST-VR, or LapMentor*	Make an intracorporeal knot.	(1) time, (2) distance travelled by tools	(1) thread fixed or not at the wound point, (2) slippery behaviour of thread	

Table 18: Second half of the didactic design of the "basic skills" VR simulator: the 7 exercises of the cutting, dissection and suture units.

Hand-eye coordination unit

The objective of this unit is to learn how to orientate tools in the laparoscopic space and to displace them with precision. Two coordination exercises, "*Coordination*" and "*Speedy Coordination*", are defined to practice and meet this objective. This unit requires a perfect correspondence between physical handles and displayed tools (one of the fidelity components of the surgical setting, see Table 3 in Chapter III). No other critical resource is needed. Teaching resources are used to guide the task: a colour code is defined to indicate if user has to use the right tool (dark blue), the left tool (light blue) or both tools simultaneously (yellow). This code will be common in all exercises.

Orientation unit

This unit offers two exercises, "*Navigation*" and "*Navigation & Touch*", to learn to manipulate the endoscope, the laparoscopic camera, and to orientate it. It is also designed for training of the "blind insertion", a skill that enables surgeons to guide a tool to a right region without seeing it on the monitor. Realistic anatomical models and textures are used to make users familiar with how anatomy is visualised in laparoscopy.

Grasping unit

Once a trainee has learnt to orientate tools with former exercises, this unit addresses grasping of objects. Two exercises are defined for developing (1) the skill of grasping tissues accurately, in a precise point in the 3D space, and (2) a skill of performing coordinated grasping manoeuvres in order to transfer an object.

First exercise, "*Accurate Grasping*", is developed with a virtual thread that has to be grasped and released accurately and delicately. A formative constructive feedback is delivered to the trainee by the result of the interaction with the thread: task is done right when no deformation is caused to the thread after grasping and releasing it (see Fig. 46). This is a challenging issue for the trainee, who can be then further motivated in order to get it, and also allows defining accuracy as the deformation caused to the thread when grasping. Moreover, difficulty of task can be tuned by setting thread ends fixed or not. In a "*fixed ends mode*" the thread will come back to its rest position gradually after being deformed, and in a "*free ends mode*" the thread will fold as the user makes mistakes, making the task more difficult (see Fig. 47). Therefore, strength of this exercise relies in the use of these features, these teaching and assessment resources.

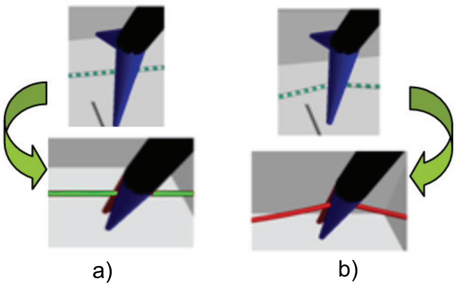


Fig. 46: Constructive feedback of (a) a good grasp, when no deformation is caused, and (b) a bad grasp, when a deformation is caused to the thread.

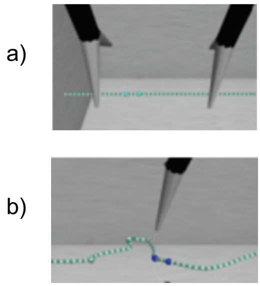


Fig. 47: Accurate grasping task layout at the middle of the exercise with (a) a *fixed ends mode* or a (b) *free ends mode*.

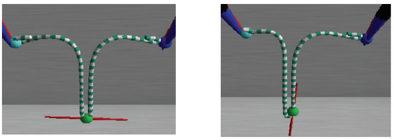
Second exercise, "*Grasp & Transfer*", addresses the coordination skill of transferring objects. Controversy is raised when defining interaction with a rigid object, since its haptic fidelity is a challenging issue. This issue is solved by commercial simulators in two ways, letting a "mechanical transparent" behaviour or presenting only deformable objects in transfer tasks. First option is presented by MIST-VR simulator ("*Transfer Place*", "*Traversal*" and many other tasks) when tools cross objects when they collide with them, and the second is offered by LapSim simulator ("*Grasping*" task), whose design makes use of virtual deformable vertical tube portions. Approach taken is the "mechanical transparent" behaviour, which can be seen as a teaching resource in proposed taxonomy of didactic resources of Chapter IV.

Pulling unit

This fourth unit is addressed to two objectives related to the pulling manoeuvre. The first is learning how to perform a symmetric pulling, what is required when tightening an intracorporeal knot. The second is the acquisition of the sensibility to differentiate tissue consistencies, different resistances of tissues against pulling.

"*Coordinated pulling*" exercise is built using a virtual thread, which provides interesting teaching resources for improving training. The main feature is the incorporation of a "coordination-control bar", a bar attached to the thread that delivers formative constructive feedback to user about the symmetry of pulling (see the red bar of the scene displayed in Fig. 48). This control bar is inclined if user pulls more from one end of thread than form the other. This is also used to define the coordination metric as the percentage of the total path travelled by the "coordination-control bar" in which the bar's inclination is smaller than a given threshold.

"*Force sensitivity*" exercise is designed to train users' sensibility to pulling forces. VR have the strength of enabling controlled and repeatable force stimuli. Different tissue samples with unknown simulated stiffness are offered to trainees, who are asked to answer simple questions like "which is stiffer, tissue 1, tissue 2 or are they the same?"



a) b)

Fig. 48: Constructive feedback given to user (a) when pulling is coordinated, the red bar stays horizontal, and (b) pulling is not coordinated, the red bar inclines to one side.

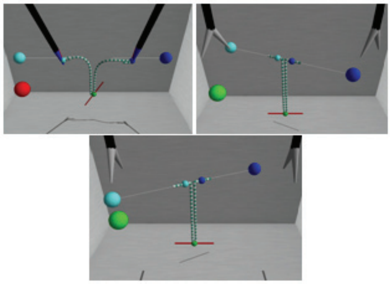


Fig. 49:different pulling directions in the coordinate pulling exercise

Cutting unit

This unit addresses training of cutting skills, stressing the issue of making this manoeuvre with a right tissue exposure, a right tension, and accurately in two exercises. "*Accurate cutting*" requires the coordination of both hands to tighten and cut a set of cylinders.

Teaching resources can be used to inform the user when tissue is been tightened too little (bad cut) or too much (risk of tearing).

A "*Continuous cutting*" following drawn patterns in a virtual canvas is the second exercise. The different orientations and shapes in these patterns are used to cover the different spatial orientations for this task as well as to increase the level of difficulty. Two interesting teaching resources can be used to guide a correct tissue exposure: (1) spheres to indicate the spatial point where the tip of the tool grasping the tissue has to move to, and (2) growing semitransparent spheres as a metaphor of pulling forces, which changes to a red colour when there is a risk of tearing. These resources are already present in the suturing task of the SEP (SimSurgery, Oslo, Norway).

Dissection unit

This unit is designed to train two different ways of dissecting organs: making opening manoeuvres with dissectors or scissors (blunt dissection) and using a cautery hook.

"*Blunt dissection*" offers a controlled virtual environment to practise this skill. There is no anatomical fidelity, whereas geometrical shapes focus trainees' attention on the task. "*Cautery coordination*" is designed to learn to apply diathermy steadily as an intermediate step before the use of the cautery hook. This exercise is adapted from the "Manipulate & Diathermy" task of MIST-VR simulator, which has shown positive and consistent validity results [Grantcharov 01;Grantcharov 03]. Finally, "*Hook dissection*" trains the skill of hooking and pulling small portions of tissue to cautery them. It is designed with an abstract approach like the "Precise dissection" of LapSim.

Suturing unit

This last unit addresses suturing training, the most complex skill of the whole package. It is decomposed in two steps, two exercises: stitching and knotting. The thread should have the more realistic behaviour as possible. Teaching resources are very interesting for guiding the trainee and teaching how to perform tools movements, as currently delivered by commercial suturing packages in SEP, LapMentor or MIST-VR.

Design of a Nissen VR simulator

There is currently no VR laparoscopic simulator offering a traning program for a Nissen fundoplication procedure. Nevertheless several products present a laparoscopic cholicestectomy, like LapMentor, SEP or RLT. The analysis of simulation requirements and definition of specifications is therefore addressed from no other reference than the clinical literature and knowledge.

Simulation requirements: Nissen training objectives

Surgical laparoscopic procedures require specific knowledge and skills developed. These procedures have to be analysed in order to identify and define training objectives. Hierarchical Task Analysis (HTA) techniques are applied and adapted for this purpose. This methodological approach has been taken before to analyse the Nissen fundoplication [MacKenzie 01] and also to develop evaluation metrics for assessing technical skills in a cholecystectomy [Sarker 06].

The main idea is to **systematize the knowledge of what is required to perform a good surgical intervention**. This is done by defining specific fields (goal, errors, applied knowledge and practical advices) in each of the tasks of a conventional hierarchical tree. Each of the steps, each of the tasks, would then be ideally assigned to a training program which uses **the most suitable means**. These means range from VR technologies to box trainers or didactic media like books or videos, since VR technologies might not be the optimum alternative for all purposes.

Therefore a surgical procedure is decomposed in a hierarchical tree of tasks, and each task is defined with four fields:

- Goal: the objective of the task.
- Errors: the mistakes and errors that can be done in the task.
- Applied knowledge: information required to guide the action or prevent errors.
- Practical advices: cues and counsels that can make the task easier.

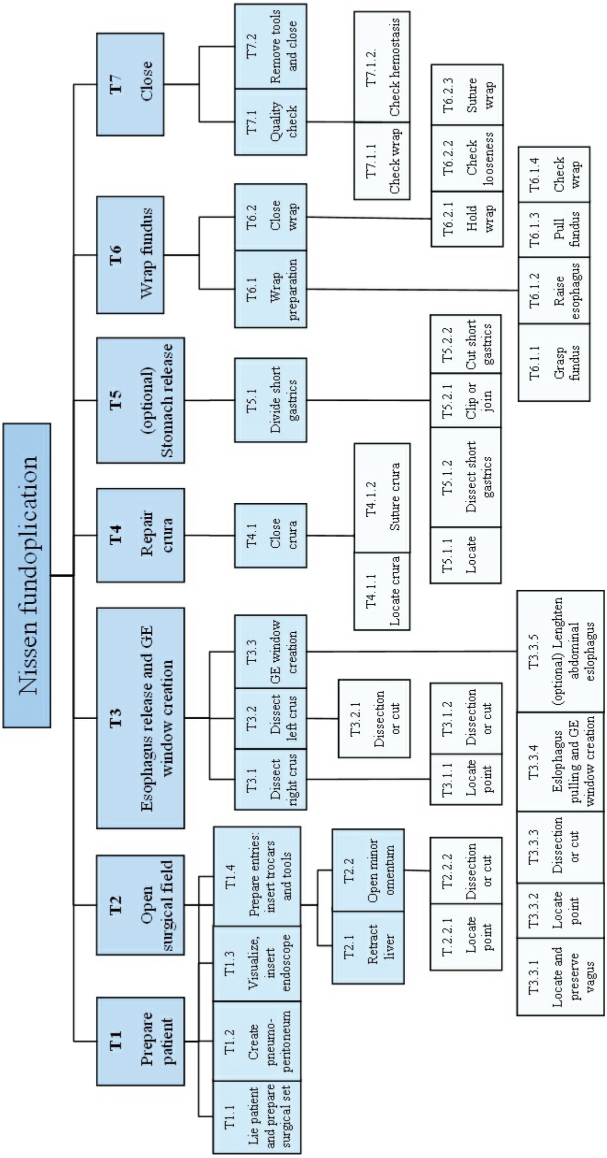


Fig. 50: HTA of Nissen fundoplication.

Nissen fundoplication				
Task	**Goal**	**Errors**	**Applied knowledge**	**Practical advices**
2 Open surgical field				
2.1 Retract liver	Liver not hinders visualization	Liver lacerations (too much force)		
2.2 Open minor omentum		Harm hepatic left aberrant artery	Anatomy: triangle by liver, right crus and hepatic branch of vagus nerve, which has to be preserved	
2.2.1 Locate point		Harm important artery of behind	Entry point: less resistance and more transparent	First exploration better by pulling stomach
2.2.2 Dissection or cut	Hiatus anatomical area is exposed	Crude action, bleeding		Bimanual, good tissue exposure
3 Esophagus release and GE window creation.		Esophagus or gastric perforation. Short vessels bleeding	Esophagus must not be grasped	Stomach is better pulled by grasping epifrenic adipose layer
3.1 Right crus dissect.		Harm posterior vagus nerve.		
3.1.1 Locate point			Start point: bottom part, the crura joint in “V” shape	
3.1.2 Dissect. or cut		Crude action, bleeding	End point: upper crura curved region next left crus	Bimanual, good tissue exposure
3.2 Left crus dissection		Harm posterior vagus nerve. Harm spleen.	Start point: former end point, going to crura joint in “V”	Easier by pulling stomach towards the right leg.
3.2.1 Dissect. or cut	Esophagus is released	Crude action, bleeding	End point: what esophagus allows	Bimanual, good tissue exposure
3.3 GE window creation		Mediastine dissection.		
3.3.1 Locate and preserve vagus nerve	Vagus nerve is preserved next to esophagus.		Anatomy: vagus is between right crus and esophagus	
3.3.2 Locate dissect. point			Point: retroesophagic membrane next crura joint	
3.3.3 Dissection or cut	Retroesofagic tunnel is created	Harm spleen	Direction: follow left crus (what was missing from task 3.2)	(Optional) left tool through tunnel to present cut area
3.3.4 Esoph. pulling and GE window creation	GE window is wide	Harm spleen		Esoph. raised by a vessel-loop allows a good window exposure
3.3.5 Lengthen abdominal esoph. (opt)	Dissected abdominal esophagus has 4 to 6 cm	Neumothorax. Harm posterior vagus nerve.	Direction: esophagus dissection through thorax	

4 Repair crura				
4.1 Close crura				
4.1.1 Locate crura			Anatomy: characteristic crura colour and tension.	Exposure by pulling stomach upwards
4.1.2 Suture	Loose hiatus. Suture with suitable muscular tissue	Harm vein cave in slim patients.	Muscular tissue: too little will tear, too much has risk of harming vein cave.	Better starting in the "V" joint. Opt.: use esophagus probe (Fouche)
5 Stomach release (opt.)				
5.1 Divide short gastrics	Stomach is released	Harm spleen, bleeding		
6 Wrap fundus				
6.1 Wrap preparation			If fundus is thight, it needs further dissection.	
6.1.1 Grasp fundus	Fundus is right grasped		Grasping point: at the middle of the fundus	
6.1.2 Raise esophagus				With a vesse-loop
6.1.3 Pull fundus	Fundus goes through GE window		Quality check: GE window wide enough if fundus is easily moved	
6.1.4 Check wrap	Wrap is correct		Quality check: ok if wrap stands when fundus is released	
6.2 Close wrap				Optional: use esophagus probe (Fouche)
6.2.2 Check looseness			Quality check: 1) grasped wrap is easily moved 2) it is possible to introduce a tool through the wrap.	
6.2.3 Suture wrap	Wrap is sutured		Procedural option: suture point to right crus to prevent wrap migration	
7 Close				
7.1 Quality check				
7.1.1 Check wrap	Wrap is correct			
7.1.2 Hemostasis check	No bleeding and clean scene.			

Table 19: Hierarchical Task Analysis of Nissen fundoplication extended with the specification of the goal, errors, applied knowledge and practical advices of each task. Task 1 and some substeps have been removed to shorten description (these two steps are general). GE: gastroesophagic.

As an example, proposed methodology is applied to a surgical procedure: Nissen fundoplication. Literature is reviewed in order to acquired a deep understanding of it [Usón 99;Morales Conde 03]. One previous HTA [MacKenzie 01] has been found to be an excellent departing point. Analysis' results shown in Fig. 50 and Table 19 have been elaborated in collaboration with expert surgeons.

Simulation specifications: 3 Nissen sub-tasks

The HTA of Nissen fundoplication (Table 19 and Fig. 50) is the starting point for designing didactic exercises. Tasks are reviewed and some of them selected with two criteria: (1) they have a critical importance or (2) they require a special motor skill that should be practiced many times. This selection has led to the choice of the four steps whose simulation specifications are described in following sections.

The objectives of each exercise are: (1) learn the standard procedure (column "Applied knowledge" of Table 19), (2) learn to avoid common errors (column "Errors" of Table 19) and (3) practice the motor skill.

Cruss dissection for esophagus release

This corresponds to tasks 3.1 and 3.2 (see Table 19 and Fig. 50). Simulation specifications are:

- Surgical scene built with: (1) Interactive models of crura and esophagus. Peritoneum and conjunctive tissue surrounds them. Vague nerve is a small cylinder attached to esophagus. Collision detection and handling between them and tools. Therefore simple geometries (bent cylinders) are proposed as the best approach to model crura and esophagus in order to facilitate the work with collisions. (2) Static models of the remaining surgical scene with an efficient collision detection to turn the organ red when touched.
- Teaching resources to guide interaction: regions are highlighted and a semitransparent tool is situated and performing the next step (a short preview animation overlaid on the scene).
- Performance in this exercise is assessed by: (1) time, (2) distance travelled by tools and (3) errors: grasp esophagus, harm vagus nerve, and harm spleen (too much traction).

Window creation

This is the task 3.3 (see Table 19 and Fig. 50), simulation specifications are:

- Virtual surgical scene is built with: (1) interactive models of crura, esophagus and stomach with the same considerations than before in order to enable collision detection and handling between deformable models. (2) Static models of the remaining surgical scene, with a collision colour indication as former exercise.
- Teaching resources are used to guide the trainee. A semitransparent anatomy is offer to the trainee in order to: visualise the vague nerve's location, the conjunctive tissue that has to be dissected, and the wrong direction of dissection that leads to mediastine.
- Performance assessed by: (1) time, (2) distance travelled by tools ad (3) errors: grasp esophagus, mediastinal dissection, harm vague nerve, harm short gastric vessels.

Valve creation

This is the task 6.1 (see Table 19 and Fig. 50), and the simulation specifications are:

- Virtual surgical scene is built with: (1) interactive models of esophagus and stomach' fundus. Special attention should be paid to the collision detection and handling between deformable models, because this task is focused in the interaction between these two organs. (2) Static models of the remaining surgical scene as former exercise.
- Teaching resources are used to teach the trainee the quality indicators of a valve.
- Performance assessed by: (1) time and (2) distance travelled by tools.

Validation approach

There are several validation strategies defined in the literature, and many results of different current surgical simulators (see review of section 0 “Validation and acceptance” in Chapter II). A **two-step validation strategy** is proposed as the better alternative to address this issue for a new didactic design. It consists of small content validity studies with selected surgeons and of extensive studies for defining proficiency levels.

Design process and construction of a surgical simulator is long, and it is convenient to have a close communication with physicians in order to orientate it in the right direction. Validation has to be taken into account in this process since the very beginning, and to assure that the simulator makes sense. This is reached with **Content Validity study sessions** in which experts in surgical training and teaching reviews the didactic design. This constitutes the first progressive stage in the proposed validation strategy. Proposed designs of both a “basic skills” and a “Nissen” laparoscopic VR simulator have passed several content validities studies, which have been performed in individualised interviews with experts in surgical training. The result of these studies is the final version of the didactic design, which has been described in this chapter.

Once the surgical simulator is built, studies can be performed to assess its construct validity or its transfer of skills to the operating room. But the second step is to go directly for what could be the last validation result: the proficiency levels definition. Once stated simulator scores will indicate where trainees are in the learning curve, and the “remaining amount of learning” required finalising the training program and getting the *degree*. This value is desired nowadays, and it is starting to be obtained in recent works [Satava 03a;Stefanidis 05;Brunner 05]. It would be desirable to contribute for this issue as soon as possible, what is another reason for facing proficiency levels characterization directly in this two-step validation approach.

Discussion

This chapter addresses the design specifications of a VR surgical simulation with the definition of didactic exercises and units. Some general aspects and the value of this design are discussed in following sections.

Definition of design specifications of a surgical simulator can be a creative and attractive process. Requirements, training objectives, can be translated into a wide variety of didactic exercises making use of different didactic resources of VR technologies. But this process has to regard the limits of these technologies; it is not possible to simulate everything. A good designer is an expert in understanding both the clinical needs and the VR capabilities.

The division of simulation contents into "basic skills" and "procedural skills" has been adopted from existing simulators in market. The concept of perceptual motor skills presented in [Tendick 00] is included into the "basic skills" package (a good example of training perceptual motor skills is the "*Force sensitivity*" exercise). It might be lacking an accepted and congruent taxonomy of surgical skills that classifies training needs and the contents of a simulator, what was identified in Chapter II (section 0, "Objectives and needs definition").

Developing a "basic skills" optimum curriculum

Definition of simulation requirements, the training objectives to be met, is not as precise as what would be desirable for simulation design, as described in section 0. For example, the objective simulation specification with measurable parameters of what is a "good and delicate dissection" is not straightforward. Unfortunately **there seems not to be a means to address a more objective definition of basic skills and their relevant metrics**. Probably a priori solution is not possible, and only validation studies can make objective this knowledge. In fact, the development and validation of surgical VR simulators is providing a better understanding of the different components of a surgical skill, and a means to characterise and objectively define them.

Therefore one important source of information is the **review of existing solutions** for training basic skills and their validation results.

There are very interesting ideas in VR simulators already in market. Many of them have been included to improve proposed didactic design, like the "Manipulate & Diathermy" task of MIST-VR which has shown the most consistent construct validity results [Grantcharov 01;Grantcharov 03].

Moreover, proposed design is not only a recompilation of ideas already existing in current simulators, but **it also incorporates improvements** like the training of "blind insertion", the use of a virtual thread to train an "*accurate grasping*" and a "*coordinate pulling*" with interesting ways of delivering constructive feedback (see Table 17), the training of the force sensorial capabilities (see the "*Force sensitivity*" exercise), the incorporation of a "continuous *cutting*" following a pattern and a simple model to practice a blunt dissection (see Table 18).

After this general discussion, the **value of each didactic exercise** is debated next.

Hand-eye coordination might be the most basic and important skill. There are many different ways to train it, and every practice with laparoscopic tools improves it. Nevertheless the systematic training of this skill could be desirable in order to be acquired fast and thoroughly. Very simple VR exercises can provide attractive and useful means to practice and to assess learning curves of surgeons. There is no need of high fidelity systems; the only requirement is a precise correspondence between haptics devices and depicted tools in the screen. Computer-enhanced trainers can also provide tools tracking and offer similar features, but they are more bulky. Moreover, VR can offer "dexterity challenges", like the "*Speedy coordination"* task (see Table 17), to continue motivating trainees and improving their skill until levels hypothetically beyond what is gotten in a physical trainer. As a conclusion, this is a skill in which **VR offer a clear value and benefit** over other training means.

Camera manipulation is also a new skill for a surgeon coming from open surgery. VR exercises offer an interactive and attractive way of training, with evaluation metrics that are not possible in physical simulators. Camera manipulation is more complex when using endoscopes with a direction of view angled at 30º, and training of these manoeuvres is more significant. Nevertheless this is not a critical skill for the safety of the patient, and residents usually have a lot of practice acting as assistants in surgical procedures. Therefore the need of training of this skill is quite well covered in current residence periods, making it less relevant for a training curriculum in a VR surgical simulator. **Even so, this is a worthy component** in a VR training curriculum.

Blind insertion is a particular skill not addressed in a simulator before. It is useful to speed a surgical procedure, but it is not critical al all. It could be considered as a secondary skill. It could be even argued that it should be developed and used only by experienced surgeons, since novices are taught that surgical tools can not be moved without visual control. Nevertheless a VR environment can assess the accuracy in which a surgeon insert a tool and reach a point, giving **an interesting means for training** this skill systematically. This is the reason why it has been considered part of the VR training exercises.

Grasping is a skill to be performed **delicately**. Organs and tissues have different harm thresholds, and surgeons should be aware of them. Nevertheless it is very difficult to characterise and model these behaviours, even more to simulate them. This is a skill that should be gained through experience, **not in a VR simulator**. This also refers to the delicateness of the other skills.

But on the other hand grasping has other aspects that can be addressed with a VR simulator. **Grasping accuracy** can be trained and objectively measured, and an added value in delivering constructive feedback has been provided in the "*Accurate grasping*" exercise. This is an example of how **VR didactic resources can find new paradigms and value for training** with the use of VR didactic resources that neither a physical nor a computer-enhanced simulator can offer.

The **coordination** involved in the **transfer of objects** can be effectively trained in a box trainer, but VR adds the value of an objective and immediate evaluation. There is one point to be raised against the transfer of objects in a virtual environment: the lack of realism in the interaction with rigid objects. A physical simulator offers the challenging task of transferring a chickpea or a slippery bean, a clear advantage over a VR one. The conclusion is that this **is a worthy component** in a VR solution, but without a clear advantage over physical alternatives.

Coordinated bi-manual pulling is addressed in a simulator for the fist time. This is a very specific skill required when tightening a knot. Thus, its relevance could be little, but this is not a reason for not including it in a training curriculum. VR assessment resources have provided an **interesting value** by a formative constructive feedback in the "*Coordinated pulling*" exercise.

An exercise for developing **sensitivity to pulling interaction forces** is another contribution of proposed design. Laparoscopic surgeons develop a perceptual skill to feel and perceive haptic information, and the idea is to concentrate trainee's attention trainee on it. Nevertheless this has always been a controversial issue: it is not clear the extent in which the use of these force cues can helps to perform a safe surgical procedure. Construct validity results of this exercise will provide an interesting contribution for this discussion. As a conclusion, this has an **interesting research value**, but its training utility has not been clearly assessed.

The main concept involved in **cutting and dissection** manoeuvres is "tissue exposure", the right presentation of the region to be cut or dissected, what is done with the non-dominant hand. Dominant hand can helps in this presentation with a gentle pushing. This also involves some anatomical knowledge and practical experience with tissues' behaviour and harming thresholds. Simulation of such features requires a fidelity that is hardly possible with current VR technologies. Therefore acquisition of proficiency in these skills might be only possible with real tissues and organs. Nevertheless VR exercises offer a means of practising the motor skills involved in these tasks, specially the coordination between both hands and the cautery foot pedal. This is what is efficiently trained with the "*Manipulate & Diathermy*" task from MIST-VR simulator, what has been incorporated in proposed design. Moreover proposed didactic cutting and dissection units offer an interesting variety of training situations reinforcing aspects like accuracy, adaptability to different cutting directions, practise of blunt dissection or practise with the use of a hook dissector (see Table 18). The conclusion is that the acquisition of proficiency in these skills might not be possible with a VR simulator. Nevertheless VR exercises are **worthy to provide a basis** of them.

Laparoscopic **suturing** is one of the most difficult skills to be acquired by surgeons, training need is big. Physical trainers offer a perfect environment to practice intracorporeal knotting, what is the most complex aspect. On the other hand VR simulators offer very interesting teaching resources to teach spatial concepts and relationships, like how to hold the needle or how to make the loop around the tool, something that is quite difficult to be transmitted in a physical simulator. Another advantage is the possibility of splitting the task in elemental steps, what has proved to be more didactic [Aggarwal 05]. Nevertheless VR thread models lack some realism. This could mean, in the worst case, that a trainee who is proficient in VR suturing would not even be acceptable in real suturing due to the differences in the thread behaviour and the tricks learnt in the VR environment. This discussion is concluded with a partial proposal for a suturing curriculum. An autonomous acquisition of this skill can be done with (1) an intensive session with a VR simulator with two aims: the understanding of suturing spatial manoeuvres with the use of teaching resources and the splitted approach to practise them. Once the trainee has perfectly understood the suturing manoeuvre, he does (2) an extensive practice in a physical trainer. This training means offers a perfect realism in the suturing thread, and there is no more need of guidance of constructive feedback once the trainee has understood the task and how to solve it. A **combined approach with both VR and physical simulators** seems to be the most efficient alternative.

Developing simulators for surgical procedures

What is required for performing a laparoscopic surgical procedure? Well, clearly the surgeon must have a set of basic skills. But, what else has to be trained or learned? What to be included in a VR simulator of surgical procedures?

Methodology used for answering these questions has been the adaptation of hierarchical task analysis techniques for the study of surgical procedures. The aim is to clearly specify the goal, errors, applied knowledge and practical advices of each of the steps of a procedure. This analysis has provided a good comprehension of the process that a trainee has to learn, and has been essential for selecting and designing simulation exercises. Therefore HTA techniques have enabled the definition of training objectives, and even the specification of didactic exercises like those given in section 0 of Chapter VI. Moreover, it has also been used by other researchers for defining evaluation metrics [Sarker 06].

This methodology can be further developed with an efficient representation of procedural alternatives and decision processes. A diagram with the alternatives in the procedure and the criteria for taking each of them would be useful. Nevertheless this knowledge might not be so relevant for specifying exercises for a VR surgical simulator, since this training means is still immature for high stakes objectives like decision making [Wentink 03].

Simulation of a complete surgical procedure is a technical challenge; VR technologies offer a limited realism. The selection of procedural steps to be simulated is necessary to focus development efforts. It has been done based on two criteria, its critical importance or a need of a motor skill. First criteria is common to other approaches in literature for simulation design [Tendick 00], and the second has been raised due to the great value that a VR simulator has in guiding and objective evaluating the acquisition of such motor skills.

It could be argued that simulation specifications of proposed “Nissen package” lacks the level of detail required for defining parameters of a right and proficient realization, like what happened with “basic skills”. As discussed in former section this knowledge is quite fuzzy and only validation studies would lead to a completely objective definition of skills and their relevant metrics.

This discussion is finalised with the crucial question, **is a VR simulator the best training means to learn a laparoscopic procedure?** The lack of biomechanical realism leads to the idea that surgical proficiency can not be acquired with a VR simulator. Nevertheless there are procedural steps and concepts that involve spatial relationships between organs that would be more efficiently taught with the use of teaching resources. For example, the anatomy is partially hidden in the step of “window creation” in a Nissen procedure (see task 3.3 in Table 19), and it can be efficiently shown with transparent textures and highlighting selected regions as proposed in the specifications (see section 0, “Window creation”). The opportunity of practising the procedure with this “augmented virtuality” could have a great value for surgical training.

Therefore a VR simulator is regarded as an interesting training means for the first practices of a surgical procedure. Proficiency could not be reach with it, but the first steps in the learning curve could be taken with the added value of VR didactic resources: a fast and better comprehension of spatial relationships and a fast and better understanding of potential risks and sources of error. This is a hypothesis to be validated in future research.

Implementing a surgical simulator

This chapter has addressed the didactic design of a surgical simulator. It has been said that VR technologies offer limited capabilities in simulating the interaction with living organs (see the review of these technologies in section 0 of Chapter II and the proposed taxonomy of fidelity resources in section 0 of Chapter IV). Therefore the question is, “is it possible to build a surgical simulator as it has been specified in former sections?” Implementation efforts have been taken within the SINERGIA Spanish Collaborative Network.

The answer is yes, but with some difficulties. In the basic skills package there are two technical problems partially solved: simulation of a continuous cutting and simulation of a blunt dissection. A continuous cutting involves a precise collision detection and handling between scissors and tissue. Some surgeons even claim that it is crucial to stroke a tissue before each cut, and a good realism in this manoeuvre would require high resolution models and efficient methods. On the other hand blunt dissection requires both the simulation of conjunctive tissue, those little and feeble joints between organs, and the simulation of how these joints are broken with the opening of a dissector. It can be also argued that suturing thread simulation requires an improvement in its mechanical behaviour. Realism of harm thresholds for the development of delicateness in surgical manoeuvres is an issue that is regarded only as a challenge.

Simulation of surgical procedures like Nissen fundoplication requires besides the solution of another problem: collision detection and handling between deformable models. This can be addressed by modelling organs with a combination of basic geometries. Nevertheless today there is no practical solution, and simulation of such interactions and surgical procedures is a challenge.

And, what about the simulation of interaction forces? Proposed simulation specifications only use them in the "*force sensitivity*" basic task, and a simple fuzzy model is considered to be enough regarding conclusions of Chapter V. An issue to be enhanced is the mechanical design of haptic interfaces in order to make them mechanically transparent and reduce its cost.

Nevertheless, it must be said that simulation technologies have perfectly solved other important aspects. Tracking of tools' movements offers enough resolution, and enables all the surgical evaluation issues related with them. This is the main added value of a computer-enhanced simulator. Interaction with basic geometries, not with organs, is quite well managed, and this is enough for a VR surgical simulator to offer a training value like validation results of MIST-VR has demonstrated [Haque 06]. These two fidelity resources might be enough for training all motor skills involved in laparoscopic surgery.

And it is important to regard the issue of the required fidelity in a simulator in order to be a useful training tool, what was reviewed in section 0 of 0. Implementation of dissection with a cautery hook can be abstracted like the "Manipulate & Diathermy" task of MIST-VR, or it can be simplified with a button joint to the ground with several threads like the "Precision dissection" task of LapSim, or it can be simulated with a high level of realism in a cholecystectomy like the "Lap Chole" task of LapMentor. Are there differences between these training alternatives? Initial motivation of trainees is higher with a realistic environment, is this motivation kept?

Validation approach

There is a great importance in demonstrating that a VR simulator is useful to train surgeons and assess their motor skills. This will affect the acceptance of the simulator. Nevertheless the great amount of validation studies of MIST-VR (see Table 1 and Table 2 in pages 62 and 63 respectively) seems not to be enough for its generalised introduction in surgical training programs. This seems not to be the crucial question.

Therefore proposed validation strategy is directed towards two main objectives: to strength the development process with small content validity studies and to characterize proficiency levels, what could be the most desirable value nowadays. Moreover, construct and other kinds of validity already proven by other current simulators could be considered generalised to every VR simulator to a certain extent. Thus, these *intermediate* validity results are not considered.

Comparative studies of the transfer of skills to the operating room are also desirable. Nevertheless the lack of an objective metric of “training effectiveness” makes the obtaining of concluding results very difficult. This is the reason why this step has not been regarded in proposed validation strategy.

Conclusion

Simulation requirements have been stated after an analysis of surgical training objectives. A HTA technique has been adapted and used for the analysis of a Nissen fundoplication. These requirements have been translated into the specification of a “basic skills” and a “Nissen” training packages of the VR simulator. This design has regarded successfully solutions offered by existing simulators and has contributed with new training tasks. Finally, a validation strategy is proposed to be divided in two steps, an iterative content validity study during simulation construction and a characterization of proficiency levels.

The value of each didactic exercise has been discussed, finding grounds that support the choice of a VR simulator for surgical training. There are nevertheless important questions that remain open for finding an optimum design: a metric to assess the training outcome, the assessment of the importance of simulation fidelity, and some technical challenges in simulating the interaction of living organs.

Chapter VII: Discussion and conclusion

This PhD work has aimed to be a bridge between surgical training needs and VR simulation technologies in order to arrive to an optimum simulator. Despite the fact that the field of VR simulation design could be already mature, three areas of contribution have been identified: (1) the systematization of the knowledge about the didactic resources offered by VR technologies (Chapter IV), (2) the study of human perceptual capabilities in order to define simulation fidelity (Chapter V), and (3) a new didactic design of a laparoscopic simulator (Chapter VI).

Main contributions are: (1) a conceptual framework of VR surgical simulators, a new viewpoint that helps to clarify thinking, to guide research efforts and to focus development travail, whose validity will be stated if scientific community adopts it and exploits its potential; (2) A simple model of pulling interaction forces for its simulation, (3) a methodology for studying laparoscopic sensory interaction; (4) it has been revealed how the hypothetical "visual haptics" skill, a kind of sensory substitution, is more a "sensorial haptic memory" developed with experience; (5) Didactic designs of a "basic skills" and a "Nissen" VR simulators for laparoscopic training.

Several future research approaches are suggested towards an effective and efficient surgical training, like the use of proposed conceptual framework for defining an optimum simulation, the definition of what has been called the set of *Surgical Driving Signals*, or the improvement of the didactic value of a simulator with a "smart instructor" feature based in teaching and assessment VR didactic resources and in adaptive contents to users' needs. Finally, a glimpse over the future of Minimal Invasive Surgery driven by technical research is provided.

Discussion

This section discusses the value of contributions of present PhD work, and the validity of research hypotheses from Chapter III. It is focused first in the methodological approach followed, and then in the three steps taken: the development of the taxonomy of didactic VR resources (Chapter IV), the development of the perceptual model of pulling forces for its simulation (Chapter V), and the didactic design of a laparoscopic simulator (Chapter VI). Finally, several reflections are made about the current and potential value of a VR simulator for surgical training.

A global approach for VR simulation design

This PhD work is conceived to be a bridge between surgical training needs and VR simulation technologies in order to arrive to an optimum simulator. The construction of this bridge starts with a review of related fields, looking for a global view and a methodology for addressing it. This leads to the definition of the **four dimensions of the question of how to offer an optimum training in laparoscopic surgery**: (1) training objectives definition, (2) curriculum design, (3) the analysis of training effectiveness and (4) simulation design (see p. 15, Chapter I). This is **one of the methodological contributions** of present work.

Research is then focused in one of these dimensions, simulation design, what is something realizable and affordable with available resources of present PhD. Analysis of training effectiveness could have a higher interest, but a close coordination with training centres and a big economical support are required. On the other hand, curriculum design and training objectives definition are dimensions too clinical for the engineer background and expertise of the PhD candidate.

There are currently several laparoscopic VR simulators in market; the **field of simulation design could be already mature. However, several areas for contributions are clearly identified**: (1) the development of a taxonomy of VR didactic resources in order to systematise the knowledge of the possibilities and potential value offered by VR technologies for surgical training, (2) the study of human perceptual capabilities in order to define simulation fidelity, and (3) a new didactic design of a laparoscopic simulator which is intended to be better than former ones.

These three areas are addressed in separate chapters. Chapter VI addresses right away the optimum didactic design of a VR simulator for laparoscopic training, applying lessons learned in former chapters. The taxonomy of didactic resources of VR technologies proposed in Chapter IV has been useful for defining simulation specifications, most especially in regarding this training means not only as an imitation of a laparoscopic scenario, but also as a virtual instructor (using teaching resources) or as a smart tool that provides formative feedback (using evaluation resources). On the other hand, a new didactic exercise has been proposed directed to the skill of perceiving pulling forces. This exercise, described in Chapter VI, is based in the knowledge gained with the study of this skill in Chapter V.

Simulation design can be basically faced with two approaches: driven by technology or driven by clinical needs (see section 0). In a certain way this PhD work has taken both approaches **following a biomedical engineer driven approach**: from an in-depth knowledge of clinical needs and requirements, and current technological limintations of VR simulation technologies. The taxonomy of VR didactic resources can be seen as a classification of technology capacities to drive the design of a simulator. Questions like “what is this resource useful for?” or “what can I build with a combination of these resources?” have been raised to guide simulation specification. But the explicit approach taken is clinically driven: it departs from a clear definition of training objectives, looking for the best training means to satisfy them. It is interesting to regard the value of each methodological alternative, but more influence from the clinical approach is convenient.

Finally, **the present PhD work does not include experimental data about the effectiveness and efficiency of proposed didactic design** of a laparoscopic VR simulator. Both the approach taken and the contributions made could be too theoretical. There are two main reasons for not having these results. First one is the deficiency in the scientific community of accepted metrics to assess and compare training outcomes. This is in fact a research area in itself towards which several efforts are driven currently and one of the identified dimensions of the problem (see see p. 15, Chapter I). The second reason is the big effort required for building an appropriate comparative experiment. Several issues are required: development resources for building a robust simulator following proposed specifications, economical resources for purchasing current simulators for the comparison, and structural and logistic resources for conducting such experiments involving a cohort of surgical trainees. This has fallen out of reach for current PhD work.

Nevertheless there is evidence in the literature about the validity of a VR simulator for surgical training and skills' assessment. This could be generalised to proposed didactic design, since it has taken those valid concepts and exercises from current laparoscopic simulators. The dimension of this criticism would be then reduced to the comparative results between proposed solution and existing ones. **A new design has been proposed, but it has not been assessed its added value compared to current solutions**.

A framework for comparing simulators and guiding research

The main contribution of Chapter IV is the development of a conceptual framework for the analysis, design and validation of VR surgical simulators. Its main idea is to conceive a VR simulator as a training means that can be build using different combinations of didactic resources offered by VR technologies. This is **a new viewpoint that helps to clarify thinking, to guide research efforts and to focus development travail**.

Several hypotheses about the value of this framework have been developed in Chapter III; discussion about its validity is addressed in coming paragraphs.

*Hypothesis A: "A **conceptual framework** for the analysis, design and validation of VR simulators can be built to contribute for an effective and efficient laparoscopic training based in such simulators."*

This hypothesis is decomposed in its three aspects, in the three uses of proposed conceptual framework. A useful tool for the analysis, design and validation of VR simulators is a contribution for the effective and efficient laparoscopic training, and the validation of each of these three issues will infer the extent of this contribution. Nevertheless **the real validity and utility of this conceptual framework will be stated only if scientific community takes into account potentials of this tool**.

*Hypothesis A.1: "It enables the **analysis** and comparison of such simulators through quantification of the use of different didactic resources to meet similar training objectives."*

TRUE: an analysis and comparison of current laparoscopic simulators has been able with proposed conceptual framework. Results are given in Chapter IV (pp. 95-103), which have led to the identification of three conceptions for a simulator: (1) an abstract representation of the surgical workspace, (2) the search for a perfect fidelity, or (3) a simulator understood as a virtual instructor (see p.118). Nevertheless comparison of the use of didactic resources is currently mainly qualitative. Future work can be conducted towards a psychological fidelity analysis and towards setting criteria to assess the quality and usefulness of teaching and assessment resources.

*Hypothesis A.2: "It allows the definition of **design** specifications systematically driven with a taxonomy of didactic resources."*

TRUE: simulator specifications of the laparoscopic VR simulator proposed in Chapter VI have been driven following the terminology proposed by the taxonomy. The decomposition of simulation capabilities into fidelity, teaching and assessment resources has offered a systematised view of what a simulator can offer in each of its didactic exercises, what is important for ordering and clarifying thinking.

Hypothesis A.3: "It offers a ***validation*** *methodology based in the analysis of how the didactic resources have been used."*

NOT VALIDATED AND TOO AMBITIOUS: the adequate use of didactic resources has not been proven to be a sufficient characteristic in order to validate a surgical simulator. Only the definition of what would be an *adequate use* of didactic resources is a difficult issue. Therefore this hypothesis has been too ambitious for present PhD work, and it is rewritten into a modified hypothesis A.3 "Proposed taxonomy **helps the interpretation of validation results** from simulators that use different resources". When validation studies find differences in the training outcome of a surgical simulator, these differences can be interpreted under the point of view of the use of didactic resources.

Hypothesis A.4: "The taxonomy also enables the ***definition of hypothesis*** *about the importance and value of each of the components defined in the taxonomy. Validation of these hypotheses, assessing the value of each resource, should lead to an* ***optimum design*** *of a laparoscopic simulator."*

TRUE: research hypotheses have been defined, and are given in section "Methodological approach for designing an optimal simulation" of Chapter IV. Proposed conceptual framework is therefore useful to drive simulation validation research in order to find those simulation capabilities more relevant for surgical training. Nevertheless it has been not possible to validate that this methodology leads to an optimum design. This is again something too ambitious for present PhD work. Nevertheless **this hypothesis constitutes the fundamental idea proposed in this PhD for driving the research and development efforts** in this field of laparoscopic training using VR simulation. The main methodological difficulty for this approach is the definition of a "training outcome" metric which has enough sensibility.

A simple model of pulling interaction forces

Work described in Chapter V has conducted to **a simple model of pulling interaction forces**, what is one of its main contributions. This model can be incorporated into a VR surgical simulator, and has a **reasonable guarantee of offering the level of realism that a surgeon can perceive and differentiate**. It has to be noticed that pulling forces are only part of the haptic interaction of a surgeon in the laparoscopic operating field. Besides, further work is convenient in order to identify, not only the *Perceptual Fidelity Boundary* defined by perceptual capabilities, but the *Utile Fidelity Boundary* defined by cognitive capabilities, and which encompasses the useful sensorial information a surgeon actually utilise for performing safe procedures (see Fig. 30 in page 125, the “Conceptual graph of the *Perceptual* and *Utile Fidelity Boundaries,* which are based on human perceptual and cognitive capabilities.”).

This chapter has also provided a **methodological contribution in the study of laparoscopic forces perception**. It is conceived for assessing the relative importance of three different components of perceptual surgical skills: the medical experience and knowledge, the force information and the visual information. A description of proposed methodology is given in Chapter V (pp. 126-131).

Validity of proposed hypotheses about how the perception of pulling interaction forces is and how a model is developed from it are discussed next.

*Hypothesis B: “Laparoscopic surgeons are **able to perceive differences** when assessing tissue consistency depending on the tissue that is being pulled”*

> TRUE: Surgeons have been able to differentiate at least four tissue consistencies when performing pulling manoeuvres. Results are given in Chapter V (pp. 131-135). Moreover, this information has been perceived despite the presence trocar frictions, which were thought to be a eclipsing interference [Picod 05].

Hypothesis C: "Tissue consistency perception in laparoscopy is a skill that shows ***differences between three expertise groups*** *of surgeons (novel, intermediate and expert)"*

> FALSE: No differences in consistency perception between expertise groups were statistically significant (see pp. 131-135).

Hypothesis 0: "Evaluation metrics of surgical skill can be defined based in these differences".

> FALSE: Surgical experience seems not to be related with the skill of differentiating interaction pulling forces.

Nevertheless the cognitive task of identifying a tissue with either visual or tactile information showed differences between the level of expertise (see Fig. 37 in page 134), what should be studied in more detail. **This idea for defining metrics of surgical proficiency based on perceptual skills should be further analysed**, addressing also the studying of other surgical manoeuvres. **This is besides a methodological approach for assessing the value of force feedback**.

Hypothesis D: "There is some kind of sensory substitution in tissue consistency perception, which is related with the ***"visual haptics"*** *concept."*

> FALSE: visual information does not add any additional information for consistency perception over knowledge and experience (see pp. 131-135). Nevertheless, results have suggests the idea that what a surgeon does is to build a mental representation of some different kind of tissue consistencies instead of learning to interpret visual cues.

Thus, **instead of a "visual haptics" concept expert surgeons seems to develop some kind of "haptics memory",** which is recalled with the identification of a tissue (with either a read description or a visual picture) and not with the interpretation of visual cues.

*Hypothesis E: "There is a **grade of fidelity** in a VR surgical simulator beyond which human beings do not perceive differences with an increase of this fidelity."*

REASONABLE, BUT NOT VALIDATED: this has been an assumption taken whose validation has not been addressed. Nevertheless it is something very reasonable, and some results from the literature support it [Zhang 03].

*Hypothesis 0"A **simple model of pulling interaction** forces in laparoscopic surgery with two or three parameters delivers this level of fidelity."*

REASONABLE, BUT NOT VALIDATED: such model has been developed, but no study has been conducted to validate its hypothetical feature of having an adequate level of fidelity. Nevertheless experimental results from the perceptual analysis (first section of Chapter V) and the study of interaction forces (second section of Chapter V) partially support the idea. It seems reasonable to think that there is **no need of more complicated models**.

Is the proposed simulator an optimum?

A didactic design for a VR laparoscopic simulator is proposed in Chapter VI. The aim of current PhD work is to reach an optimum design. So, is this goal attained? Alas, **there is no answer for such question**: there lacks a metric to compare training outcomes between training tools. This is one of the identified dimensions of the problem of how to offer an optimum training in laparoscopic surgery, as already commented in section 0 of this chapter.

Then, could it be said that proposed design is more effective in surgical training than former ones? Unfortunately there is again no answer because of the same reason. **Even differences in training results between box trainers and VR simulators are not clear** [Torkington 01;Kothari 02;Munz 04;Maithel 06] **despite the potential advantages that VR can offer** (see section 0, "The added value of VR surgical simulation", in Chapter II).

The next step lowering validation aspirations of proposed design is to wonder if it is at least valid for laparoscopic training. **This design has been the roadmap of the laparoscopic simulator developed by the SINERGIA Spanish Research Network** (G03/135). It has been therefore partially implemented, and its validation is in process at the time of writing this thesis dissertation. It has passed several iterative content validity studies, but, from the time being, there are no results about its construct validity or about the transfer of skills to the operating room. **Nevertheless construct and other kinds of validity already proven by other current simulators could be considered generalizable** to every VR simulator to a certain extent, as discussed in 0 of Chapter VI. This is even more reasonable in the case of proposed design, which is based into these current solutions and validation studies.

It is **surprising the little discussion in the literature about the design of virtual tasks**. Information about the methodology to define didactic exercises can hardly be found. Present PhD work addresses this issue in a global manner, and tries to clarify the value of a VR approach in training different skills compared to a physical alternative. An important contribution of Chapter VI is therefore the **discussion about the value of addressing training of each individual skill with a VR simulator from an intermediate viewpoint between the clinical need and the technical resources** (see section 0 in this chapter).

Validity of proposed hypothesis to guide the process of designing an optimum laparoscopic surgical training is discussed next.

Hypothesis F, "A methodology to reach an optimum VR laparoscopic design should regard the study of several issues: (1) the analysis of validation results of current simulators, (2) an objective and quantitative definition of training objectives and needs, (3) the study of the human factors involved in the interaction and (4) the study of adult learning theories"

IT SEEMS LOGICAL AND TRUE: this is a hypothesis about the right manner to address the design of a simulator, and the four issues to be studied seem necessary for arriving into an optimum solution. Nevertheless there is not scientific evidence about it.

So, what's the rational use of a VR alternative for surgical training?

This question has been partially answer when wondering about the optimum value of proposed didactic design (discussion of Chapter VI). However this is the key question of this field of research, and will be dealt globally in this section.

The first main idea is that **a VR simulator should not try to offer a complete laparoscopic training programme**. Other training means, like box trainers, might be much more efficient for some skills, like a simple suturing in a foam model. Another example is the use of multimedia material presented in a didactic guide as an attractive and motivating means to learn procedural knowledge and risks in critical steps [Rosser 00]. And a real laparoscopic theatre will always offer those stress conditions that, under certain supervision, have to be learned to be managed.

One crucial question is therefore the selection of the most convenient training means for the different stages and skills in the process of training. There are already some conceptual models that tries to reflect these ideas, like the Rasmussen division into skill-based, rule-based and knowledge-based training goals (see Fig. 14 in page 40). Thus, **the best approach could be a combined use of different training means, not a big effort to simulate a perfect VR environment in order to cover all training needs**.

When a surgeon is talked about a laparoscopic VR simulator, his first image of such system is a perfect emulation of a living patient. This would be a training means that overcomes the lack of realism of box trainers and that enables a "zero operating time training". A surgeon would like to practice complex surgical procedures and even to rehearse an intervention with this ideal tool. **These high expectations constitute one of the biggest barriers for VR simulators to be introduced into training programs**.

The general view formed after this PhD work is that **VR alternative is recommendable for the first stages of training motor and coordination skills, by taking advantage of its assessment and guiding features**. On the other hand, a physical training means might be more suitable for reaching proficiency in the last stages of training, due to the lack of fidelity that a VR option has. An example might be the acquisition of a proficient suturing skill involving the manipulation of a real thread with real interaction forces.

On the other hand, training of procedural knowledge and cognitive skills might follow a similar pattern. VR simulators offer **a very interesting alternative to understand and learn the different tasks and steps of a surgical procedure**, what can be efficiently enhanced with the aid of multimedia didactic material [Rosser 00]. But neither box trainers nor VR simulators have been able to simulate a realistic living organism, what is still a challenge. Last steps in the learning curve have therefore to be taken in an operating room. It is still not possible to have a “zero operating time training”, what is the case of aviation [Wentink 03].

The reality is that, instead of a perfect realism, VR technologies only offer a limited interaction. So, does it make any sense to use VR simulators? The answer is clear: “of course”. **The value of these technologies is not only in the emulation of reality, but also in the use of teaching and evaluation resources** that provide the values of availability and autonomy, the capability of an objective evaluation, the delivery of a directed and immediate constructive feedback, and a cost reduction by the suppression of a supervisor behind the trainee (see section 0 in Chapter II).

The future of VR simulators

There is a clear need of surgical training and objective assessment of skills. VR simulators are beginning to be used to satisfy this need, but it is still a field covered by box trainers. Current tendency seems to be a growing adoption of the VR alternative, but in a rhythm that could be still slow. It could be only a matter of time to convince physicians and expert surgeons of the added value of a VR simulator.

It is important to regard that the most important factor that leads to an effective training is the constructive feedback [Issenberg 05], something that could be efficiently delivered by a VR simulator. Research and development efforts should be focused into the use of these teaching and evaluation resources, and not into a perfect imitation of the operating room. Or in other words**, efforts should be directed towards enhancing the didactic value of the simulator**. Some interesting capabilities are beginning to be risen, like a simulator whose level of difficulty dynamically adapts to the performance of the trainee in order to minimize frustration and optimize learning conditions for all learners [Pham 05].

It is said that validation studies are required for this purpose of convincing surgeons. Nevertheless there are already many of such studies available in the literature (see Table 1 and Table 2 in section 0 of Chapter II), a number that might provide enough evidence of the validity of a VR simulator, as one recent metanalysis has concluded [Haque 06]. The other main regret is the high cost of VR technologies, a VR solution costs around 25.000€. **Immediate future of VR simulators could depend more on developing cheaper solutions than on more validation results**.

Surgical credential is a very desirable goal from the point of view of patients. Governments are beginning to articulate means to address this issue, like the creation in 2001 of the National Board of Medical Examiners in the United States. The opposition of every credential process is the fear from the professional collective of not being accredited. Nevertheless the progressive introduction of these examination and credential processes in the National Health Systems will foster the adoption of VR simulators, which offer a perfect controllable and measurable environment. **This is the vision of the**

long-term use of VR technologies, the credential of surgical technical skills.

There is a force that could be driving this change: the public quality ranking of hospitals or even of doctors. Sensitivity for the need of better training means and programs was motivated at the end fo the twentieth century with the publication of the “Bristol Case” [Senate of Surgery 98] and the “To Err is Human” [Kohn 99], where a better training and objective assessment were claimed for reducing the number of medical errors. Since then, several US states have developed laws establishing mandatory reporting systems, which publicly rank hospitals by the quality of care they provide as determined by the number of errors reported. **The key is encouraging hospitals to move towards the “culture of safety” and to avoid the fear of being evaluated**. It is foreseen a future in which doctors and hospitals will be recognised and even rewarded by insurance companies depending on their clinical outcomes, and a future in which we as patients access the internet to choose our doctor or care institution with the latest quality information [Sadler 06]. Graduates and doctors will then be really sensible for their training programs and their skills proficiency.

VR flight simulators enable currently fulfilling a pilot training program thoroughly, without a single hour of real flight. This is a domain similar to surgery in professional responsibility Surgical simulation will gradually solve its technical and practical challenges and will become a training solution like VR flight simulators.

Conclusions

This PhD work has contributed to the field of VR laparoscopic simulation for training in several issues, which have been ordered following the numbering of objectives in Chapter III:

1 A conceptual framework of the available VR didactic resources has been developed for the analysis, design and validation of surgical simulators. This is a new viewpoint that aims to clarify thinking, to guide research efforts and to focus development travail.

1.1 This framework has enabled the analysis and comparison of VR laparoscopic simulators and a comprehensive definition of design specifications. It also helps the interpretation of validation results from simulators that use different resources.

1.2 A methodology for approaching an optimal simulation design based in such framework has been proposed. It consists basically in the investigation of several research hypotheses about the importance of different didactic resources.

2 Perception of pulling forces in a laparoscopic scenario has been studied and its resolution has been characterised in order to define the required fidelity boundaries in surgical simulation.

2.1 A methodology for studying laparoscopic sensory interaction has been defined and applied for such study. It assesses the relative importance of three components of a perceptual surgical skill: visual cues, haptic information, and previous surgical knowledge and experience.

2.2 Laparoscopic perception of tissue consistency has been characterised: surgeons can differentiate different consistencies; the level of experience is not a relevant factor in this skill; the hypothetical “visual haptics” skill, a kind of sensory substitution, is more a “sensorial haptic memory” developed with experience.

2.3 No evaluation metrics based on perceptual skills have been developed as it was planned: it has been revealed how the ranking of pulling forces does not show differences depending on the surgical expertise.

2.4 A simple perceptual model of pulling forces has been proposed to be a basis for a force feedback algorithm. Two main parameters, the concept of *fixation grade* and the kind of tissue, rule a diffuse logic behaviour. It has a reasonable guarantee of offering the level of realism that a surgeon can perceive and differentiate.

3 Two new didactic designs of VR laparoscopic simulators have been proposed, which are the result of content validity sessions and have been the roadmap of the SINERGIA Spanish Research Network (G03/135). Nevertheless it has not been assessed its added value compared to current solutions, its “optimum” desired feature has been a feature too ambitious to be demonstrated due to the lack of a “training outcome” metric and the high cost and complexity of such study.

3.1 A methodological approach has been proposed to define simulation requirements with the adaptation of Hierarchical Task Analysis techniques. It has enabled the definition of training objectives and design specifications of a Nissen laparoscopic simulator.

3.2 A new “basic skills” VR laparoscopic simulator has been proposed, which has departed from a review of current solutions and the incorporation of new didactic exercises.

3.3 Specifications of a “Nissen” VR laparoscopic simulator has been proposed for the first time, trying to satisfy training needs with available simulation resources.

3.4 A validation approach of a surgical simulator is proposed aiming to be more efficient: it is divided in two steps, an iterative content validity study during simulation construction and a characterization of proficiency levels.

Other contributions of this PhD work are:

- The definition of four dimensions of the scientific problem of how to offer an an efficient and effective laparoscopic training: (1) training objectives definition, (2) curriculum design, (3) the analysis of training effectiveness and (4) simulation design (see section 0 in Chapter I)

- The comprehensive review given in Chapter II of the related fields that surrounds and state of art of the scientific problem.

- The identification of three areas for contributions in the scientific problem, centred into the simulation design: (1) the development of a taxonomy of VR didactic resources, (2) the study of perceptual capabilities in laparoscopy, and (3) the rethinking of the didactic design of VR laparoscopic simulators.

- The definition of two fidelity limits in the analysis of simulation requirements: (1) the *Perceptual Fidelity Boundary* , the edge of our perceptual capabilities, and the *Utile Fidelity Boundary*, which encloses the aspects of reality useful for performing a surgical procedure (see Fig. 30 in page 125).

- A reflection about the current and future value of VR simulators for surgical training, given in section 0 of this chapter. The worth of a VR approach in addressing the training of each basic skill is discussed in section 0 of Chapter VI, and of procedural skills in section 0 of the same chapter. This reflection has taken a bioengineering viewpoint regarding the clinical need and the technical available resources.

Future research

Present PhD work has been focused on the problem of how to train surgeons in an effective and efficient manner. First part of this section identifies areas of improvement in this field, and second part takes a much broader approach, trying to offer a glimpse over all future changes that the advance of technology might introduce in the operating theatre and in Minimal Invasive Surgical (MIS) techniques.

Approaches towards an effective and efficient surgical training

A global conceptual framework

Surgical simulators have been conceived in this PhD as a combination of fidelity, teaching and assessment resources, a combination of VR didactic resources. This framework is therefore focused on "how a simulator is built", but there are many other important factors and issues that influence training outcomes. A global viewpoint regarding all of them would be very interesant, and a direction is suggested for it. **Proposed conceptual framework is proposed to be extended to** other two aspects:

a. **"How the simulator is used"**, involving (1) curricula design: which tasks, which levels of difficulty, number of sessions, time each session, time-based or proficiency based; (2) the environment factors, (3) teacher guidance and feedback regarding the zone of proximal development [Kneebone 04], (4) training strategy [Gallagher 05].

b. **"How the user fits in"**, involving (1) factors in user: innate skills, learning rate and style (trainees that improve faster or trainees that not improve), experience background (both in surgery and in computer games), motivation (a crucial factor [Guest 01]); (2) Perception of simulator: human perception psychophysics factors, personal face validity: perception of the simulator as a worth thing or as a silly computer game; and (3) factors in the simulator: difficulty fitted to clinical need, degree of fidelity to convince the trainee, fun character to motivate the user.

Once this knowledge is organized in a right manner, comparative validation studies could be addressed more systematically, specifying each of the factors that have influenced the training outcome in the experiment. Some review works have critised the disparate of training, and also available data descriving it, that exists in the literature [Haque 06;Sutherland 06].

Analisys of training effectiveness of simulators

Validation studies are performed to assess if skills are acquired or not in simulators. This is one of the dimensions of the problem of surgical training: to measure the training effectiveness is costy and difficult (see section 0 in Chapter I).

This PhD has proposed a methodology for defining an optimum simulator that is based on the assessment of the importance of each didactic resource of VR technologies for surgical training (see section 0, “Methodological approach for designing an optimal simulation”, in Chapter IV). It has provided several research hypotheses that, once experimentally contrasted with randomized controlled trials, will lead to a better way of surgical training. **Further work is therefore necessary for defining which the most important resources in a VR simulator are, and proposed conceptual framework can drive it**. One of the most interesting contributions would be the assessment of the value of both teaching and assessment resources of VR simulators. The main difficulty of this approach, as discussed before, is the development of a metric to assess the training outcome of a simulator and compare the effectiveness of different design alternatives.

Another interesting contribution will be **a metanalysis of current simulation validation studies**. There are several variables to be considered: the experimental design, the specific model of simulator, the tasks offered to trainees, training time, evaluation metrics, expertise of trainees before training… Two recent works in this direction have been already published [Haque 06;Sutherland 06], but analyses are too general due to the lack of comparable information retrieved from reviewed articles. It has also been argued that there is a **lack of use of a right methodology** [Champion 03]. High quality validation results will offer valuable information about which tasks and which simulators provide better validation results.

One last field of research is the **development of better methodologies for comparing and analysing VR simulators**, since randomized controlled trials are a very expensive and slow alternative. This could be driven by the improvement of proposed conceptual framework of VR didactic resources: first, a psychological fidelity analysis, instead of an engineer fidelity approach, will provide a more useful viewpoint about the impact of this resource in training. Second, comparison of teaching and assessment resources should be enhanced by setting criteria to assess its quality and usefulness (see section 0 in Chapter IV). The development of a global framework described in former section will provide also some interesting variables for these comparisons.

Define required level of fidelity in surgical simulation

Another important area of research is the definition of simulation specifications. Whereas flight simulation can be objectively described in terms of forces of handles and the view of a scenario through the cabin, interaction in laparoscopy is far more complicated. **Defining the required level of fidelity in surgical simulation is a challenge**. This involves the controversial issue of defining the role of force feedback in training.The general answer given is that this level of required fidelity raises with the complexity of the skill to be acquired [Maran 03].

Surgical interactions need to be characterised. Interaction forces between surgeons and tissues should be acquired. The key is then to **identify the relevant variables in this interaction in order to build interaction models** like the study described in Chapter V. Proposed methodology of this chapter can be followed and adapted to other laparoscopic gestures in order to define the ***Perceptual Fidelity Boundary*** (see Fig. 30, page 125). And similar methodologies with cognitive analysis instead of with perceptual characterizations can be defined to assess the ***Utile Fidelity Boundary*.** Besides, analogous questions can be rised about the sight, the other principal sensorial channel.

The methodological alternative for defining the required level of simulation fidelty is again to design randomized controlled trials in which users are trained with and without a simulation feature, like described in [Kim 04]. This kind of studies has been included in former section, whereas this section has tried to provide a different approach.

This field of research could have different names, the study of the ergonomy in laparoscopy, or it can be also called the study of human factors. There is an interesting **methodological approach** for addressing the study of human capabilities: the **use of VR simulation technologies**. Characteristics the interaction with objects in a virtual environment can be tuned with no difficulty, and this represents an excellent workbench for conducting experiments. This alternative has the desirable qualities of reproducibility and control, but they could be mined by a lack of realism. This approach has already been taken recently both for addressing the Level of Detail of virtual environments [Zhang 03] and for studying the effect of a degradation in a haptic interface [Brouwer 04]. Pure ergonomical aspects are also studied with VR technologies [Matern 05].

Other interesting approach in this field could be directed towards the **characterization of the tissue damage loads**, already identified in [Liu 03]. This will improve the simulation of the interaction with organs and tissues, and cover the training need of performing manoeuvres with delicacy, without harming tissues. This will also contribute for the definition of the role of force feedback, what could be an important issue for teaching this skill, and for enhancing training processes with the definition of exercises to systematically train and evaluate this skill.

Another contribution would be the **implementation of proposed model of interaction pulling forces**. It should be tuned in order to actually deliver those force magnitudes which have characterised it. Experiments could be then conducted towards the validation of the hypothesis that this model provides enough fidelity in pulling interaction forces.

Human factors towards the understanding of laparoscopic skills

Surgeons develop sensorial and cognitive skills that are difficult to be objectively defined. There is a hidden knowledge that should be made visible. For example, surgeons explain how their tactile sense has a learning curve in laparoscopy: "you can hardly feel anything at the beginning when you are in rigid and bad postures, and you get tired. You get to it when you gradually acquire your surgical skills." But **there lacks an objective and more concise definition of these perceptual and cognitive skills**.

This is a problem very related with the definition of the required level of fidelity described in former section. The perceptual skills will be related with the *Perceptual Fidelity Boundary*, and the cognitive skills with the *Utile Fidelity Boundary*. And the interesting approach is directed towards those skills that an expert surgeon develops more than the study of human perceptual and cognitive capabilities.

Research about this perceptual and cognitive characterization is suggested to be driven by an interesting research hypothesis: **"there are certain *Surgical Driving Signals* a surgeon learns"**. These *Signals* are "perceptual cues which are present in the laparoscopic field and which delivers certain information useful to guide the procedure". These are haptic cues, like certain force intensity when grasping a tissue indicating the presence of a lesion, or visual cues, like a change in the colour of a tissue when it is being pulled too tight. Or they can even be signals that a surgeon has to learn to find, like the identification of a hidden structure by certain surgical manoeuvres. Therefore future work can be conducted in order to define in an objective and quantitative way these *Surgical Driving Signals*.

There are also visual and cognitive skills: a laparoscopic surgeon learns how the anatomy is seen by an endoscope, its variability, and learns to identify the different structures in that *surgical jungle*. **Objective definition of the scope of these visual skills** is another field for contributions. Under the viewpoint of the *Surgical Driving Signals* this would be the characterization of the variability of these *Visual Signals*.

Benefits of this characterization of laparoscopic sensorial and cognitive skills could be: (1) the improvement of surgical training by the design of **specific tasks directed towards the adquisition of characterized skill**s; (2) the enhancement of the objective assessment of surgical proficiency, by the definition of **specific metrics about characterized skills**; (3) the improvement of VR surgical simulation by a better definition of simulation specifications (definition of *Perceptual* and *Utile Fidelity Boundary*); and (4) the basis for augmented reality applications.

This last application conceives a computer assisted surgery in which preoperative models are syncronised and actualised (this could be possible until a certain extent with the movements of surgical tools and with the image captured with the endoscope). This application might have then *the skill* of identifying structures in the image captured by the endoscope, and *the knowledge* of the steps of the procedure where a *Surgical Driving Signal* should be noticed, information that could be pointed out in order to guide the surgeon. In any case, a deep understanding of laparoscopy and required skills is **essential to conceive the aim of augmented reality applications**.

Definition of new objective metrics of surgical skill

The **objective analysis of surgical skills is still lacking much research** [Aggarwal 04] in order to obtain a standardized and accepted assessment methods. This is a well defined field of research, with clear benefits in several issues: (1) the enhancement of surgical training with the development of new constructive feedback features based in these new objective metrics, (2) the improvement of the surgical quality with the definition of rutinary evaluations of surgical practitioners or with the desirable surgical credential process, and (3) the development of the required metric of training effectiveness of simulators, the main difficulty in the comparative studies as discussed before in section 0.

One great potential of a VR environment is the possibility of logging every event or action, the basis for every objective metric of surgical skills. The difficulty is to take these crude parameters and extract from them relevant information with a clinical significance. There is an interesting field of **research in designing VR surgical tasks for assessing surgical skills**, a design directed towards the identification of relevant actions and not towards training. This requires a deep understanding of surgical skills, and probably a model of the interaction in order to provide a meaning to events and actions. There is an interesting work of Rosen et al. which models tools' movements with a Markov Model [Rosen 06]. Similar efforts towards interaction models with higher clinical significance are very interesting.

Skill assessment in VR simulators has a great value, but in the operating room is even more worthful. The difficulty in the surgical theatre is the acquisition of the events and actions, what is straightaway in a VR environment. Force sensors and tracking devices can be attached to surgical tools [Rosen 06], but they hamper the interactivity of surgeons. The ICSAD, for example, is based in electromagnetic sensors that might be less invasive [Datta 02]. An interesting research field is the development of **a system for tracking laparoscopic tools based only in the processing of the conventional endoscopic video sequences**. Potential benefits of such system would be: (1) a non-invasive automatic evaluation system of surgical skills based in the movements made by surgeons, (2) an intesting means of tracking movements in biomechanical characterization experiments like those described in , and (3) a basic component of augmented reality applications, which will require undoubtily the knowledge of the position of surgical tools. These benefits will depend on the accuracy a video processing approach could offer.

Improvement of simulation technologies

The objective of a simulator with a completely realistic interaction is still far away [Kneebone 03]. There is not still a **biomechanical model** that satisfy all the requirements for surgical simulation [Meier 05]. Existing solutions for **collision detection and handling** applied to deformable organs require an unaffordable computational cost: research is needed to provide a realistic interaction [Liu 03]. And these are only aspects of the mechanical interaction, the behaviour of organs. The next step is modelling the natural variability of situations or properties [Wentink 03], together with physiopathological conditions.

The future of MIS driven by technical research

Surgery has experienced the MIS revolution thanks to several technical advances, what else can be expected in the future?

Better training solutions

VR surgical simulators can now be characterised as valid tools for training motor skills, there is evidence that users lessen their time and errors when practising with them [Haque 06]. But there are several potential values that the development of technology might attain:

- Not only motor skills, but cognitive also. A trend to be followed is the aim of **extending the scope of VR simulators from motor skills to cognitive and other non technical aspects of surgical practice** like decision making. The use of multimedia material and interactive paradigms could be a good complement in a VR simulation package that can approach this extension.

- Towards a **"virtual instructor."** The simulation didactic value is more important than simulation fidelity. Following the terminology proposed in the conceptual framework of VR didactic resources, **improvements should be made in the use of teaching and assessment resources in order to improve the didactic value**. Special attention should be paid into the constructive feedback capabilities, which has shown to be the most important factor for an effective training [Issenberg 05]. It can be developed new evaluation metrics related to specific exercises with the analysis of force or path profiles or the result of basic research like that directed towards a better understanding of laparoscopic interaction. It is also very interesting to develop capabilities in order to build a "virtual instructor", a guide into the different contents and during each exercise, several ways of delivering constructive feedback, or even a dynamic difficulty adaptation to the skills level of the trainee [Pham 05].

- Towards a **"zero operating time training,"** in which there is no need of practise in real patients to acquire all surgical skills.

Better solutions for evaluating surgical skills

VR surgical simulators can now be characterised as valid tools for evaluating technical surgical skills, there is evidence that they can clearly differenciate between levels of experience [Haque 06]. There are tracking devices like ICSAD [Datta 02] that provides objective information that can be modelled in order to differenciate levels of expertise [Rosen 06]. But there are several potential values that the development of technology might attain:

- **New objective metrics**, as described before in section 0.
- **Optimal ways of constructive feedback**, one of the most important features in a training system, and a key component in that “virtual instructor” goal of a VR surgical simulator.
- A **“training effectiveness” metric**, something required for comparing different training solutions (see section 0 of this chapter).
- A means for **trainees’ selection**, as it is already been investigated [Gettman 03;Schijven 04b;Windsor 05].
- A means for a **surgical credential process**. This would be the long-term goal of the objective evaluation of surgical skills.

Surgical planning

Technology has enabled virtual planning of surgical interventions through a detailed analysis of image studies of the patient. Information about the particular shape of the anatomy and of tumours is extremely valuable in neurosurgery. But these kind of techniques are starting to evolve to other surgical applications, like liver surgery [Lamade 05]. The value of preoperative planning systems is provided through 3D visualizations and computer-generated proposals of surgical paths and resections.

Computer-assisted surgery, augmented reality

Laparoscopic surgery is performed through the visulization captured by an endoscope. These video sequences could be merged with some kind of information for guiding the surgeon and preventing errors. This is nowadays a reality in craniomaxillofacial surgery, in which computer-aided surgical navigation technology offers substantial improvement regarding esthetic and functional aspects in a range of surgical procedures [Ewers 05]. One of the biggest challenges is the development of a navigation system that could cope with the deformations of non-rigid organs [Lamade 05].

It is also required to define the specification of augmented reality applications, the specific cues and information that is to be delivered to the surgeon. A better understanding of surgical interaction is an approach for it as discussed in section 0 of this chapter.

“In silico” patient model

The concept “in silico” refers to what is performed on computers or via computer simulation. The idea is opposed to the traditional terms of “in vivo” or “in vitro”, and represents a fetching methodological approach to conduct research and investigation.

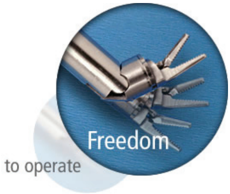
An in silico patient model refers to a complete and extremely realistic virtual model that enables both the rehearsal of a surgical intervention before the real one, and the investigation of new surgical techniques to solve particular diseases. This is an enourmous challenge for current researches in VR technologies.

Advanced laparoscopic systems

Laparoscopy was driven by the introduction of new and long tools in the patient with the visualization captured by an endoscope. Nevertheless its interaction paradigm is quite limited as described in section 0 of Chapter II. There is a new generation of advanced laparoscopic systems to be coming [Heemskerk 06].

Tools can **improve their ergonomic aspects**, and they can provide **more versatile movements**. A very interesting contribution has been done with the development of a tool with one more degree of freedom, the Radius surgical system show in Fig. 51 (Tuebingen Scientific Medical GmbH, Tübingen, Germany) [Heemskerk 06]. Moreover, another application of **VR technologies** is the study and analysis of ergonomic aspects, they have been a **comparison tool** for assessing the convenience of different handles [Matern 05].

a)



b)

Fig. 51: Handle (a) and tip (b) of the Radius surgical system (Tuebingen Scientific Medical GmbH, Tübingen, Germany), which provides a seventh degree of freedom to a laparoscopic tool.

But technology is not only introducing advances in laparoscopic tools, but also allowing **new kinds of minimal invasive surgical approaches**. A great example is the Transanal Endoscopic Microsurgery [Burghardt 05]. Other interesting aspect to be enhanced is the visualization of the surgical scene through high-quality 3-dimensional systems [Heemskerk 06].

And there is a revolution that is coming, the surgical approach with **console-based robot-arm manipulated systems like the daVinci** (Intuitive Surgical, CA, USA). This system delivers several advantages: a much more comfortable interface for the surgeon, a more intuitive and ergonomic handling, a stereoscopic vision, one more degree of freedom in the movements of tools, the scaling of movements enabling tiny and precise movements, and the temblor filtering. Nevertheless it lacks of haptic feedback, it involves a new interaction paradigm that requires the acquisition of new skills, and the system has currently a very high cost (around 2M€). The future of robotic surgery could be the **development of microrobots that perform automatized tasks** like tiny sutures [Morita 05].

Next years will probably provide new and exciting improvements in technology that will drive the future of surgical care.

Glossary and references

Glossary

Ability: the natural state or condition of being capable, aptitude [Satava 03a]. Adaptive capacity, trait or aptitude that a person brings to a given task. Abilities are more fundamental and stable than knowledge and skills.

Declarative knowledge: knowing what to do. It is explicit knowledge of facts, such as anatomic landmarks during a procedure or pathological effects of surgery. This knowledge can be assessed easily via a quiz or recognition tasks.[Liu 03]

Distributed Practice: the arrangement of instructional trials such that responses from several training programs are interspersed between repeated trials of another program.

Effective (learning): quality of ensuring that all training objectives are met [Wentink 03]

Efficient (learning): quality of ensuring that the training means at cost effective and that the required training time is minimized.

Ergonomics (1): is the study of mental and physical capabilities o persons in relation to the demands made upon them by various kinds of work. [Delano 03]

Ergonomics (2): study of work practice and the design of interfaces between people and machines or tools. By applying knowledge from the disciplines of psychology, physiology and engineering, it is possible to improve work performance in terms of speed and accuracy, and reduce the physical and psychological discomfort to the operator [Joice 98].

Fidelity: extent to which the appearance and behaviour of the simulator / simulation match the appearance and behaviour of the simulated system [Maran 03]

Engineering or physical fidelity: is the degree to which the training device or environment replicates the physical characteristics of the real task. Increasing the engineering fidelity of the simulator inevitably leads to increases in cost and, beyond certain levels, increasing the fidelity of the training device will produce only small improvements in performance over a simpler device. [Maran 03].

Psychological or functional fidelity: this is the degree to which the skill or skills in the real task are captured in the simulated task. The level of fidelity required depends on the type of task and stage of training and influences skills transfer [Maran 03].

Fidelity Boundaries: limits that enclose a subset of the features of the physical reality that are used to define simulation requirements in a VR environment - a surgical simulator in the context of this PhD (see Fig. 30 in page 125).

Perceptual Fidelity Boundary: edge that confines those aspects of the physical reality that are perceived by human beings.

Utile Fidelity Boundary: edge that encloses those perceived aspects of reality that are actually used by surgeons to guide an operation. Cognitive studies are required to clarify which are these pieces of information gathered from perception.

Human factors: study, design and evaluation of human-machine systems with an emphasis on human capabilities and limitations as they impact system operation. The goal of human factors is to optimize system performance while maximizing human safety and operational effectiveness. [Delano 03]

Learning curve: the time taken and/or the number of procedures an average surgeon needs to be able to perform a procedure independently with a reasonable outcome [Subramonian 04].

Objective: level of competence that is expected of the trainee after he or she completed the training [Wentink 03]

Performance: refers to the global efficiency with which a complex activity is completed.

Procedure: a series of steps taken to accomplish an end [Satava 03a]

Procedural knowledge: knowing how to do. Explicit knowledge of how to perform a procedure, such as the sequence of navigation of landmarks or the rules of proper use of an instrument. It can be expressed verbally, although it may depend on nonverbal (such as visual or haptic) information. Traditionally it is tested verbally, but it could be assessed instead in simulation by testing the user's proper performance of the intended procedure [Liu 03].

Skill: a developed proficiency or dexterity in some art, craft, or the like [Satava 03a]. Result of applying a specific combination of abilities to a given task.

Task: a piece of work to be done, a difficult or tedious undertaking [Satava 03a]

Verification: process to check that a system is working as it has been designed for. This is a former process that leads to validation stages.

Acronyms

ADEPT: Advanced Dundee Endoscopic Psychomotor Trainer

DOF: degree of freedom, in the movements of a laparoscopic tool for example.

FEM: finite element model

FF: force feedback.

ICSAD: Imperial College Surgical Assessment Device

ITER: In Training Evaluation Report

OR: Operating Room.

OSATS: Objective Structured Assessment of Technical Skill

MIS: Minimally Invasive Surgery.

MISTELS: McGill Inanimate System for Training and Evaluation of Laparoscopic Skills

TER: Transfer efficiency ratio

VR: Virtual Reality

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