Université de Montréal

Teaching and evaluating basic laparoscopic surgical skills by simulation : Where are we at?

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Résumé (français)

Titre: Teaching and evaluating basic laparoscopic surgical skills by simulation : Where are we at? / L'enseignement et l'évaluation des techniques chirurgicales de base en laparoscopie par simulation: Où en sommes-nous?

La laparoscopie requiert une coordination visuomotrice et une perception de profondeur aiguisées rendant difficile son enseignement par les méthodes traditionnelles. Puisque l'entraînement sur simulateur requiert un investissement considérable en temps et équipement, il est important de prouver sa valeur.

Le LTS 2000-ISM60 est un simulateur physique de laparoscopie amélioré par un système informatisé. Le MISTELS est le simulateur physique considéré comme l'étalon d'or.

Une étude prospective multicentrique a été conduite. Son but était de valider le LTS et de comparer sa performance face au MISTELS et le degré de satisfaction des utilisateurs.

Les participants provenant de la chirurgie générale, de la gynécologie et de l'urologie ont été classés selon leur expérience laparoscopique.

Le LTS possède une capacité discriminatoire du niveau de performance comparable au MISTELS. Un plus haut degré de satisfaction a été retrouvé avec LTS, ceci pourrait justifier son utilisation comme outil d'enseignement et d'évaluation pour les spécialités chirurgicales.

<u>Mots clés</u>: Simulateur physique, habiletés techniques de laparoscopie, enseignement chirurgical.

Résumé (anglais)

Title: Teaching and evaluating basic laparoscopic surgical skills by simulation: Where are we at?

Laparoscopy requires ambidexterity, eye-hand coordination and depth perception. Those technical skills are difficult to teach with traditional methods. Since simulator training requires an investment in both equipment and time, it is important to justify this investment by providing proof of the value of simulators.

The LTS 2000-ISM60 is a computer enhanced video-laparoscopic training system. The MISTELS is considered as the gold standard of physical simulators.

A prospective multicentric study was conducted. The purpose was to validate LTS and to correlate its scoring performance to MISTELS. The users' degree of satisfaction was compared.

The participants (students, residents, fellows and attending) from surgery, gynaecology and urology were classified in groups based on laparoscopic experience.

LTS has a comparable discriminating capability for level of performance to MISTELS according to laparoscopic experience. The higher degree of satisfaction attributed to LTS could justify its use as a training and assessment tool for surgical specialties.

<u>Key words</u>: Physical simulator, laparoscopy, surgical teaching.

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LIST OF ABBREVIATIONS:

ACGE:	Accreditation Council for Gynecologic Endoscopy
A:	Attending
CD:	Compact Disc
F:	Fellow
FLS:	Fundamental of Laparoscopic Surgery
ICC:	Intraclass Correlation
ITER:	In-Training Evaluation Report
LTS-ISM60:	Laparoscopic Training Simulator-Interactive Sensory Module
MISTELS:	McGill Inanimate System for Training and Evaluation of Laparoscopic Skills
MS:	Medical Student
OR:	Operating Room
OSCE:	Oral Structured Clinical Examination
OSATS:	Objective Structured Assessment of Technical Skills
PGY:	Post-Graduate Year
SAGES:	Society of Gastrointestinal and Endoscopic Surgeons
VR:	Virtual Reality

Teaching and evaluating basic laparoscopic surgical skills by simulation : Where are we at?

Article included: How to choose the right physical laparoscopic simulator? LTS2000-ISM60 compared to MISTELS: Validation, correlation and user's satisfaction.

INTRODUCTION

In the domain of aviation, simulation as a learning tool has been present for decades. It is well implemented and is particularly used to train pilots, especially to avoid common mistakes that happen during training, to practice dangerous potential situations and to evaluate pilots' capacities prior to the end of their training. This was made an international priority in order to maximise aeronautical security and benefit passengers. Aeronautical mistakes can be disastrous so are surgical mistakes. It is essential to be able to learn and develop surgical skills in a well organized teaching environment with simulated scenarios of surgical situations.[1]

We all enter medicine without knowing what to expect. Without knowing the amount of constant efforts, incessant public pressure and expectancies, diminishing resources and the ongoing feeling that we must do more with less everyday. Surgeons are no different from other physicians. When entering residency, the future surgeon, be it general, orthopaedic, gynaecological or urologic does not foresee acting in a godly manner, but he does want to excel in his profession.

NEED FOR TRAINING

A surgeon must learn to operate safely and skilfully.[2,3] Traditionally, surgical teaching has been a hands-on training experience with the experienced surgeon teaching the novice how to perform a surgical maneuver.[4] The famous "see one, do one, teach one", the Halsted' s method[5] of teaching, is still a true adage frequently used. However, nowadays, with reduced resident's work time, this method may bring about important potential problems. It has been shown that the operating room is not the ideal environment to teach, especially to novices, due to time, cost constraints and medico-legal concerns.[2,3,4,6] A study by D.J. Scott and collaborators[7] did find that the patient's morbidity and costs were more elevated as a consequence of increased time used in the operation room (OR) and that of material. Moreover, on a day-to-day basis, the surgical exposition or the variety of cases is quite random and the residents must be exposed to all types and kinds of surgery to progress. Some types of surgeries can be missed because they never happen during the time they were in training.

The domains of surgery and high level training sports like tennis or baseball share several commonalities. For example, timing and precision are important to successful actions and decisions. Surgery is not a sport, but from a performance perspective, the operation in surgery is analogous to the game of tennis or baseball.[8] Unlike professional or collegiate baseball players, surgical residents are surgical novices when they are recruited. While they may enter the OR in those early years, most are technically unprepared to participate in a manner that is meaningful to their training.[8]

There are other reasons to explain why the residents can not learn efficiently expected technical skills in the OR. The unpredictable task constraints, which require decision-making to occur simultaneously with action. The limited number of trials within a single, or across several surgical procedures, creates frustration for the teacher and the learner. The motivational climate of an environment dedicated to patient care is, appropriately, outcome-oriented. The motivational climate needed for skill development is task-oriented.[8]

Time is obviously an important outcome, and perhaps requiring surgical novices to work through their speed-and-accuracy trade-offs outside the OR could save time and expense. Although there are challenges, there is much that we can feasibly do to affect our trainees' greater and earlier accumulation of practice.

DELIBERATE PRACTICE

Research in a variety of domains has described the not escapable role of deliberate practice in the acquisition of expert performance. These findings are relevant to surgical expertise, and identify the need for extensive, and deliberate practice in developing skills. Deliberate practice refers to activities that are designed for the purpose of improving performance. These are separate from work activities or services rendered for pay or any others activities directly motivated by external rewards. This definition excludes the work of the operating room from deliberate practice activities. Deliberate practice is highly structured, includes feedback about performances and results, and provides for frequent, repeated experiences for a learner to systematically correct performance weaknesses. Batting practice and fielding practice are examples of deliberate practice.[8] Deliberate practice requires learner dedication. Deliberate practice for surgical residents includes drill and practice. Drill and practice are repetitive and can be boring. Sessions need to be scheduled, and easy access to materials, equipment, and models is necessary. A model taken from teaching literature in physical education supplies a helpful guide for designing deliberate practice sessions in surgery.[9] The following four sequences and their application to surgery are progressing from simple to complex to facilitate the learning of motor skills:

> *"1) Informing tasks are used as an introduction of a new skill such as an instructor's verbal description, pictures or diagrams, and live or video-taped demonstration".*
>
> *"2) Extending tasks refer to increasing or decreasing the level of difficulty of a motor task. A classic example of an extension of a basic surgical skill is the use of bi-coloured lace in learning to tie knots. The extension of many surgical skills can be accomplished by modifying equipment (i.e. adding gloves or grease), increasing or decreasing work space, using non-dominant hand, breaking skills into parts, closing eyes, timing tasks, or dividing learner attention (i.e. recitation of procedure, answering questions, solving clinical problems)".*
>
> *"3) Refining tasks are designed to hone skill quality. Feedback about a learner's performance and their results are crucial to development in refining tasks. The appropriate use of accurate and brief cues helps to shape learner performance".*
>
> *"4) Applying tasks refer to the use of the skill in its authentic or "real life" setting. In surgery, this would include animate or inanimate models, simulators and the OR".*[9]

This model encourages an approach that is aimed at maximizing the potential of the trainees. An approach that focuses on a stable and maximal level of performance, instead of a minimally acceptable level of performance, that the truncated old adage "see one, do one" reinforces.

Skills that permit competence and mastery in laparoscopic (closed) procedures are not directly derivative from skills used in open surgery.[10] Unfortunately, despite the context of reduced resident's work hours, we are now teaching residents at least two ways (closed and open) of performing each procedure, essentially doubling the skills that have to be learned and mastered over a five-year residency.

ERA OF LAPAROSCOPY

Throughout the 1960's and 1970's, laparoscopy became a vital part of gynaecological practice. Despite these technological advances, it was not until after 1986, following the development of a video computer chip that allowed the magnification and projection of images onto television screens, that the techniques of laparoscopic surgery truly became integrated into another discipline: general surgery. The first laparoscopic cholecystectomy performed on a human patient was done in 1987 by the French physician Mouret. The rapid acceptance of the technique of laparoscopic surgery by the medical population is unparalleled in surgical history. It has changed the field of general surgery more drastically and more rapidly than any other surgical milestone.[11]

Laparoscopic surgery affords opportunities for access and surgical manipulation that may replace traditional surgical approaches and permit new ones previously impossible because of mechanical, anatomical or physiological considerations. The concept of minimally invasive surgery applies to thoracic, gynaecological, head and neck surgery, orthopaedics, or any other field where the size of the incisions and the degree of injury to the patient can be minimized with advanced techniques and equipment.[12] Compared with traditional open surgery, laparoscopy requires a surgeon to perform tasks within a two-dimensional videoscopic image of the operative field in which only the tips of the instruments are visible. Laparoscopic instruments are longer than traditional instruments and the surgeon's hands are therefore far removed from the working ends of the instruments. The directional movements of the surgeon's hand result in contrary deflections of the working end of the laparoscopic instrument, creating a disparity between visual and proprioceptive feedback known as the "fulcrum effect".[10] As a consequence of the last characteristics, laparoscopic instruments provide only muted tactile feedback. Obviously, laparoscopic techniques require psycho-motor abilities that are not innate or part of everyday life. The learning curve is steep and the variables described above impact the laparoscopic novice until he learns to adjust through extensive psychomotor practice. When considering all these factors, it seems obvious that laparoscopy requires a different method of teaching and learning.

Besides all that, there are the intraoperative complications. For example, in general surgery, the bile duct injuries have increased with the introduction of laparoscopic cholecystectomy. This added risk is expected to decline as the surgeon's experience in laparoscopic surgery increases. Approximately 20 per cent of all complications and 30 per cent of bile duct injuries were attributable to surgeons who had performed 200 or fewer cholecystectomies in the previous 5 years.[10]

Surgeons who teach and train basic and advanced laparoscopic procedures must now help to develop methods of training and evaluation that truly established procedural based competency. Some tools are available and a number of new ones are being developed. It is up to physicians educators to maximize their potential and set the standards of excellence.[12] At the same time, surgical organizations are calling for methods to ensure the maintenance of skills, advance surgical training, and to credential surgeons as technically competent. Accordingly, the development of standardized training curricula remains an urgent and important agenda, particularly for minimal invasive surgery.

PARTICULARITY OF THE GYNAECOLOGY SPECIALTY

What is particular about gynaecology? The gynaecologists were laparoscopic pioneers and now, they lag behind the general surgeons in the matter of laparoscopic training. Results of a survey in United States indicate that 69% of obstetrics and gynecology residency programs have implemented a formal laparoscopy training curriculum, use more than one method to train their residents, and involve almost half of their faculty on average in training residents to perform laparoscopic surgery.[13,14] However, it was estimated that less than half of Canadian obstetrics and gynaecology programs have a formal laparoscopy training curriculum.

Exposition to different gynaecological interventions is variable and as a result, skills and expertise can vary greatly, depending upon the type and number of cases in which a resident participates.[15,16] The last decade brought new non surgical treatments for the management of many benign gynaecological problems such as dysfunctional uterine bleeding and dysmenorrhea. It is only after a conservative medical treatment has been amply tried that surgery is offered. As a consequence, the number of surgeries was considerably reduced as well as the exposition provided to residents. It reinforces even more the need for a well organized environment outside the O.R. where residents can learn and practice basic skills, pursue their acquisition of skills towards more advanced tasks and be prepared for real case scenarios.

NEED FOR SIMULATION AND SKILLS LAB

Simulation can be described as an exercise that reproduces or emulates, under artificial conditions, components of surgical procedures that are likely to occur under normal circumstances.[4] A good simulation represents a simplified reality and needs not to include every possible small details[17] or to reproduce anatomy with high fidelity.[18] Unlike real patients, simulators are available at any time to fit curriculum needs to allow for a standardized experience that can be duplicated.[19] Surgical skills, that require repeated practice to master, lend themselves well to simulation.

In a recent article published by the New England Journal of Medicine[20], Reznick described all the recent changes of technical skills training in the 21st century. He concluded:

> *"In summary, the report card on simulation, while not definitely positive, does suggest that it is an important addition to the training arsenal. The*

> *effectiveness of simulation training has been demonstrated primarily for lower-level learners, with a positive effect demonstrated for both laparoscopic and open procedures".*

The goal of a laparoscopic simulator is to provide the opportunity to learn and practice ***basic*** skills in a relaxed environment to attain a basic level of technical ability that can be transferred from the laboratory to the operating environment. Surgical simulation and skills training also offer the possibility to teach and practice ***advanced*** skills outside of the operating room environment before attempting them on living patients. Simulation training can be as straight forward as using real instruments and video equipment to manipulate simulated "tissue" in a box trainer. Newer systems enable the development of comprehensive curricula and full procedural simulations.[12]

It is recommended for each surgical task to repeat at least 30 to 35 times to maximize the positive effects.[7] Other studies[21,22,23,24] reported that an intense training improves video-eye-hand coordination and is translated by an improved performance for beginning surgical residents. It should then be favoured to use the surgical simulators at the beginning of the process of acquisition of surgical skills. The experience demonstrates that simulation is a valuable teaching tool not only for medical students and residents but also for surgeons of different degrees of expertise. For example, Scott and al in 2001 indicated in the "American Journal of Surgery" that surgeons without experience are the one who benefits more from this formation.[25]

A survey was mailed to 253 general surgery program directors to determine the perceived value, prevalence, equipment, types of training, supervision, and costs of the skills labs. Eighty-eight percent of responders consider skills labs effective in improving operating room performance; however, only 55% have skills labs.[17,26]

SIMULATORS

In the area of laparoscopic surgery, simulators fall into three broad categories: **physical** simulators in which the task is generally performed in a trainer box under videoscopic guidance with actual surgical instruments; **computer-based** simulators, in which the task is performed in a "virtual" environment and **hybrid** simulators which combine features from both categories. The tasks range from basic, such as peg manipulation, to more complex, such as laparoscopic suturing. The metrics also range from simple (time to complete a task) to complex (motion analysis).[2,3] Simulation models are becoming more and more sophisticated.

The physical simulator or box trainer uses real surgical instruments and equipment including video monitors, cameras, and laparoscopes. Tactile feedback is limited, as it is in laparoscopic surgery, by the instruments used. The drills developed lack the face validity offered by other systems (virtual); the instruments may be real, but the "tissues" are clearly not. However, the feel of the instruments on the surfaces of tissue, the pressure on closing a handle, and the compliance of compressed structures evoke feedback sensations called haptics. The sensory feedback is one of the important attribute of the box trainer simulator. Low acquisition cost is another key attribute of these devices.

The McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) is a physical simulator and has been extensively studied and validated in almost all points of view.[2,3,6] MISTELS is part now of the Fundamental of Laparoscopic Surgery (FLS) program (CD-ROM educational tool, training drills for the box trainer and a final exam) instituted by the Society of Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES is currently recommending that all senior residents in general surgery demonstrate laparoscopic skills competency by taking this exam offered in only six North American testing centers. The need to take a box trainer-based exam at a specialized center is a major disadvantage of this system. The measurement of performance and objective evaluation of skills, or metrics, requires an independent teacher/evaluator.[12,22, 27] The same way you need a proctor if you are going to use a system for certification. Obviously, training and practice sessions can take place in the absence or in the presence of a teacher/mentor.

Virtual reality surgical simulators are the latest and most promising development in the area of surgical simulation. Many of these simulators provide a more believable practice environment than traditional box trainers, hence providing higher face validity. Objective measurements such as the time to complete a task, economy of hand motion, dexterity, and instrument path length can be easily used as assessment tools to document the progress of laparoscopic skills. Software's updates can be adjusted to create more difficult tasks or to provide new drills or procedures.[12] In an attempt to replicate the biggest advantage of box trainers and make the simulations as real as possible, several simulators now offer built in haptics, or force feedback as an option contributing to the higher cost of those devices. Currently, MIST-VR and LapSim have been the most widely used and studied.

An important aspect of a valid training system is that novices show an improvement of their skills over time. This has been demonstrated in multiples studies done with MISTELS, and more recently, with the VR-simulators.[21,22,23,24] The question arises: Is the virtual reality simulator superior to the physical simulator? They were compared to some extent [13,15,28] but for now, it is agreed that even with the options of motion analysis and upgrading software, their purchase at high costs may not be justified for every simulation center except in a well-organized research context. Haptics are still very primitive and inflexible in term of equipment and the systems are themselves not intuitive. There seems to be a learning curve just to understand how the system works or to deal with some technical difficulties associated to the VR simulator itself. Also, residents can learn shortcuts and bad habits that give them good score.[3]
A conference was given in 2004 by Fried, his comments were:

> "It may not be that pertinent or easily understandable for a resident to know that its path length is not right. It is probably more useful to know that he has trouble with depth perception and than to go practice on a physical simulator".[3]

LTS

The Laparoscopic Training Simulator (LTS) 2000 is a portable physical simulator[29,30] derived from MISTELS and improved by integrating computer-based electronic scoring, interactive user feedback and digital capture of performance data.[28,31] Ten laparoscopic tasks are available: five for testing coordination skills, four for assessing suturing skills, and one for evaluating cutting skills. In other words, five activities were added to the five of the MISTELS system on suggestion of laparoscopic experts, conferring some content validity (defined later in the text). LTS is introducing an automatic electronic scoring system. Indeed, the system possesses physical sensors embedded in each module permitting the capture of specific signals according to the task involved. The simulator innovates by offering a tensiometer entitled to verify knot tightness with a disruptive force of 1kg. Accordingly, the LTS system by its unique computerized components will render the utilization of simulator more user friendly by requiring less scoring manipulation and by permitting an individual feedback after each task and at any moment for reference or comparison. The system does not need an evaluator for drills and practices but eventually for a more formal evaluation, an independent evaluator is necessary.

THE RIGHT SIMULATOR

The elaboration of a computerized surgical simulator is a long, demanding and costly process in a technical point of view. It has to incorporate and integrate all the competencies and complementary capacities of engineers, surgeons, researchers and educators. Once the teaching tool created, the next step is proving aspects of validity and reliability.

An instrument is **valid** when it measures what it was intended to measure.

a) Subjective approaches to validity are *face validity* (an expert is asked to judge whether, on the face of it, the instrument seems to assess the desired qualities) and *content validity* (is a judgment about whether the instruments encompasses all the relevant domains). The evaluation of *content* validity is determining if the simulator is offering an adequate and precise practice for all required competencies to realize a surgical technique. Only surgeons with the required expertise can judged the content validity.[2]
b) Objective approaches are the *criterion validity* (to see the degree of correlation). *Concurrent validity* means comparing the new and old measurement tool. The expected degree of correlation is in the range of 0,4 to 0,8. *Predictive validity* means the extent to which the measurement tool predicts future performance.

When there is no gold standard, evidence for *construct validity* is sought. This is usually done by measuring performance in two groups who are hypothesized to differ in the skill being measured by the instrument.[2]

An instrument is **reliable** when it measures something in a reproducible manner.

a) *Intrinsic reliability* or split halves correlates the performance of subjects on one half of the test compared with the other half.

b) *Interobserver reliability* is the degree of agreement between two different observers. *Intraobserver reliability* means the agreement between observations made by the same rater on two different occasions.

c) *Test-retest reliability* is observations made on the same subject on two separate occasions.

For a test assessing aspects of clinical competence like a surgical simulator, in which the cost of misclassification is high, a reliability at or higher than 0,8 is reasonable.[2]

In his recent study, Reznick also strongly suggests that surgical educators need to incorporate meaningful assessment into residency programs, using rigorous, reliable, and regular means of assessment for all relevant surgical skills[20].

EVALUATION OF LAPAROSCOPIC SKILLS

Despite the importance of surgical skills for surgical competency, according to recent survey, 25% of surgical programs do not evaluate the surgical skills of their residents. More specifically, less than 1% of obstetrics and gynaecology residencies actually test the technical skills of their residents.[28] In Canada and in United States, there is no standardized structured evaluation of gynaecology residents' technical skills when they graduate. The Royal College of Physicians and Surgeons of Canada stated:

> *''The (obstetrics and gynaecology) program **must** provide the College with a final in-training evaluation report for each resident who has successfully completed the residency. This report **must** represent the views of faculty members directly involved in the resident's education and not be the opinion of a single evaluator. It **must** reflect the final status of the resident and not be a summary or average of the entire residency".*[33]

There is now a set of predefined objectives (Can MEDS)[33] in which we can find a description of which surgeries a graduate resident should be competent for. But no formal structure of evaluation is yet provided. The actual ITER format includes a single global rating scale for technical skills evaluation which is offering 4 options: excellent, good, acceptable or fail. This scale is supposed to be used at the end of each surgical rotation. Minimal or no comments on surgical abilities are included in the final ITER presented to the Royal College committee at the final exams. There is no formal technical or practical evaluation at the end of the formation or at anytime before starting the solo practice in most if not all of Canadian gynaecology programs.

Would go on a plane driven by a pilot with a license acquired without a practice exam?

The ITER type of evaluation of residents' surgical skills is usually performed by subjective faculty assessment. The assessment is typically performed at the end of the rotation and is based on the recollection of how the resident performed during that rotation. This type of assessment has been shown to have poor reliability/validity[34] and is often biased by factors other than technical skills. For example, the "effect of central tendency" meaning that untrained evaluator will omit the extremities of the evaluating scale or the "halo effect" when a trainee is judged according to other qualities he had or have shown in the past.[15,16]

Once in solo practice, there is no requirements to document continuing skill competency, again putting surgical professions in stark contrast to commercial airline pilots who undergo extensive and continually updated certification.

Surgical skills evaluations (in training and final) are as important as the training itself. Standard objective measures to evaluate correctly the surgical skills of residents are missing. For all those reasons, surgical simulators were generally judged as useful to introduce anatomical varieties, adverse events simulation and the capacity to quantify some surgical abilities or to evaluate some aspects of surgical competency. As such, simulators essentially test dexterity or basic skills acquisition and not the other aspects of surgical competency, such as knowledge and judgment. They do not simulate the wide variety of scenarios seen in "real" surgery.[34] However, when basic skills are mastered, the learning curve is well climbed up and all the other elements defining surgical competency have a base to be built on.

As said by Aggarwal in December 2006[35]:

> *"Simulation allows for risk-free training in technical skills. For the first time, a proficiency-based curriculum can make the actual level skill rather than a predetermined period of time the primary factor in physicians' progression up the training ladder, ensuring that patients are cared for by doctors with expertise in the procedures they perform."*

To form a surgeon in any specialty, to make an expert out of a resident, or to render someone competent is the principal mandate of a surgical residency program. When it comes to the judicious choice of pedagogical tools for teaching and evaluation, are the actual teachers as critical or informed as we think they should be? To invest in a simulator, in the elaboration of a skills lab and to develop a laparoscopic teaching curriculum are enormous responsibilities for a teaching institution.

The following multicentric study gives an example of how to evaluate and to choose the right teaching tool for the particular needs of a surgical curriculum. The validity and reliability of the LTS2000-ISM60 were sought in three Canadian university centers across three surgical specialties.

ABSTRACT

ARTICLE (FRANÇAIS)

Titre : Comment choisir le bon simulateur physique de laparoscopie? LTS 2000-ISM60 comparé au MISTELS: validation, corrélation et niveau de satisfaction des utilisateurs

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Contexte: La laparoscopie requiert une ambidextérité, une coordination visuomotrice et une perception de profondeur aiguisées rendant difficile son enseignement par les méthodes pédagogiques traditionnelles de chirurgie ouverte. Puisque l'entraînement sur simulateur requiert un investissement considérable en temps et en équipement, il est important de prouver la valeur de celui-ci. Le LTS 2000-ISM60 est un simulateur physique de laparoscopie amélioré par un système informatisé. Le MISTELS est le simulateur physique considéré comme l'étalon d'or. Le but de l'étude était de valider le LTS et de comparer sa performance de pointage (capacité discriminatoire) au MISTELS ainsi que le degré de satisfaction des utilisateurs.

Méthodologie: L'étude s'est déroulée dans trois centres universitaires canadiens: Montréal, McGill et Dalhousie. Les participants (n=123) étaient des externes, résidents, fellows et patrons provenant de la chirurgie générale, de l'obstétrique gynécologie et de l'urologie. Ils ont été classés selon une estimation de leur expérience en laparoscopie: novices, intermédiaires, compétents et experts. 123 ont effectué le LTS et 73 ont fait aussi le MISTELS. Ils ont rempli un questionnaire de satisfaction après chaque performance.

Résultats: LTS a démontré une progression du pointage avec le niveau d'expérience laparoscopique (p=0,000). Une corrélation satisfaisante a été retrouvé entre LTS et MISTELS (0,79). Le niveau de satisfaction était plus grand avec LTS.

Conclusion: LTS possède une capacité discriminatoire du niveau de performance comparable au MISTELS selon le niveau d'expérience laparoscopique. Un plus haut degré de satisfaction a été retrouvé avec LTS, ce qui pourrait justifier son utilisation comme outil d'enseignement et d'évaluation pour les spécialités chirurgicales.

Mots clés: Simulateur physique, habiletés techniques de laparoscopie, enseignement chirurgical.

ARTICLE (ENGLISH)

Title : How to choose the right physical laparoscopic simulator? LTS2000-ISM60 compared to MISTELS: validation, correlation and user's satisfaction.

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Background: The LTS 2000-ISM60 is a computer enhanced video-laparoscopic training system. The purpose is to validate LTS and to correlate its scoring performance to MISTELS considered as the gold standard of physical simulators. To invest in a simulator is a large responsibility for a teaching institution.

Methods: Participants (n=123) were medical students, residents, fellows and attending from surgery, gynaecology and urology. They were classified in groups based on laparoscopic experience: novices, intermediates, competents and experts. 123 were tested on LTS and 73 on both LTS and MISTELS. A satisfaction questionnaire was filled after each performance.

Results: LTS showed a progression of total scores with level of laparoscopic experience (p=0,000). Good correlation was found between LTS and MISTELS (0,79). Level of satisfaction was highest with LTS.

Conclusion: LTS has a comparable discriminating capability for level of performance to MISTELS according to laparoscopic experience. The higher degree of satisfaction attributed to LTS could justify its use as a training and assessment tool for surgical specialties.

Key words: Physical simulator, laparoscopy, surgical teaching.

CONTRIBUTION OF AUTHORS:

Principal author:

Andrée Sansregret : She was the principal author and the principal investigator of this multicentric study. She developed the entire protocol. She made it conformed for the approval of five ethical boards. She organized the three testing centers and visited them to assure the conformity between centers. She contacted the key persons and made the publicity for the enrolment. Finally, she proceeded to the analysis of data in collaboration with the statistician and to the redaction of the article once the statistics available.

ANDRÉE SANSREGRET	____________________	___________
Name of the student	Signature	Date

Co-authors:

Gerald Fried: He was the principal investigator at University McGill and contributed to the review and creation of the protocol, the recruitment of participants at McGill and the review of this article. He was also the co-director of the master.

Dennis Klassen: He was the principal investigator at University of Dalhousie. He contributed to the organization of the study, to the recruitment of participants and to the review of the article.

Maryse Lagacé: She was the research coordinator of this multicentric study, she helped in the redaction of the protocol and to prepare documents for the approval of ethics committee. She helped for the recruitment in all centers and she tested 95% of the participants. She also reviewed the final article.

Robert Gagnon: He participated in the redaction of the protocol and he analyzed the data with the statistic tools planned at the beginning. He also reviewed the final article.

Harrith Hasson: He participated in the elaboration of the protocol, the recruitment of the investigating centers and he reviewed the final article.

Bernard Charlin: He participated in the elaboration of the protocol, he reviewed all the steps and the organization of this multicentric study. He helped in the coordination of testing centers and to develop strategies for recruitment. He reviewed and participated in the redaction of the final article. He was the principal co-director of the master.

ARTICLE

BACKGROUND:

In general surgery, gynaecology and urology, laparoscopic surgery is widely used. It has created an obstacle to the traditional teaching of surgical skills. Laparoscopic tasks are performed in a sometimes disorienting, two-dimensional, video-controlled environment.[1] Laparoscopy requires ambidexterity, eye-hand coordination, and depth perception. These characteristics of minimally invasive surgery do not conform to the "see one, do one, teach one" model of apprenticeship prevalent in medical education.[2,3] An opportunity for training in laparoscopy outside the operating room would allow the trainee to acquire these skills in a safe and relaxed environment.[3,4,5,6,7,8] Since simulator training requires an investment in both the equipment and time required for training, it is important that this investment be justified by providing proof of the value of simulators.[3,4] An inanimate simulator has to be portable, reproducible and flexible. It also has to be easy to administer, give the maximum feedback information to the user, and induce participants' satisfaction.

MISTELS

The MISTELS system (McGill Inanimate System for Training and Evaluation of Laparoscopic Skills) has previously demonstrated to assess and to score objectively basic laparoscopic skills by a series of structured tasks in a trainer box under video guidance. According to its psychometric qualities assessed in several published studies, it appears as the current gold standard of physical simulators for laparoscopy.[3,10,14,15,16,17,18,19] MISTELS' content validity was confirmed through an inquiry on the pertinence of the chosen tasks involving 44 experienced laparoscopic surgeons and using global rating scales. The scoring performance of the simulator was assessed and participants' scores improved progressively with level of training (n=215, p<0,0001), and residents followed over time improved their scores (n=24, p<0,0001). These results constitute evidences of construct validity.[4,10,17,18] MISTELS was shown to discriminate between competent and non competent laparoscopic surgeons, and as such can be used to evaluate an individual's skill set.[17] MISTELS was also shown to be reliable (interrater and test-retest reliabilities of 0,889 and 0,991 respectively and internal consistency at 0.86[21]). The MISTELS qualities have been demonstrated in general surgery. The methodology of its validity studies was based on the level of training or the academic years to rank performance, but an intermediate effect of performance[20] (PGY 5 scoring better than laparoscopic surgeons) was seen on two occasions.[10,17] This effect is not completely explained by the facts that PGY5 residents may have had more opportunities to practice on the MISTELS or that they perform laparoscopic surgeries almost daily throughout their chief resident year.[20] Perhaps, it is a learning effect to earlier exposition to simulators compared to surgeons or to a quicker response to videogames gadgets because of a generation gap.

Because timing of exposition to laparoscopic surgery and timing of surgical skills teaching activities can vary considerably in residency across specialties and universities, we think that using an estimation of laparoscopic experience to classify the participants rather than the level of formation will be more accurate and can eliminate the intermediate effect described previously.

LTS

The Laparoscopic Training Simulator (LTS) 2000 is a portable physical simulator[22,23] based on MISTELS and improved by integrating computer-based electronic scoring, interactive user feedback and digital capture of performance data.[24] Ten laparoscopic tasks are available: five for testing coordination skills, four for assessing suturing skills, and one for evaluating cutting skills. Five activities were taken from the MISTELS system and five were added on suggestion of laparoscopic experts. Hasson and al in 2001 found that training with this new simulator resulted in significant improvement of laparoscopic skills of all 11 tested physicians. Their post test score after an average of 5,9 hours spent on practice improved (range 2 to 23) regardless of previous level of experience.[23] LTS 2000 system was also tested on 45 practicing laparoscopists in general surgery and gynaecology. LTS 2000 was shown to detect levels of laparoscopic expertise. A progression on the learning curve on the simulator was seen at intermediate levels (3 PGY-3) after clinical exposition (1 month) to advanced laparoscopic procedures.[25] These are interesting described properties building the simulator's validity. Still, LTS is expensive when compared with a physical training box such as MISTELS. A comparison with MISTELS is important to detect differences justifying the high investments (concurrent validity). There is also a need for LTS to prove some aspects of reliability (interrater, test-retest and internal consistency). There is a basic comparison of the two simulators.

TABLEAU I CHARACTERISTICS OF BOTH SIMULATORS

SIMULATORS	**MISTELS**	**LTS2000**
# Tasks	5	10
# testing coordination skills	1	5
# assessing suturing skills	3	4
# evaluating cutting skills	1	1
Tensiometer		X
Cannulation task		X
ADVANTAGES		
Cost	1 500USD	18 800USD
Electronic scoring		X
Interactive user feedback		X
Digital capture of performance		X
Portable	X	X

This multicentric multidisciplinary prospective study was undertaken to document the construct validity and the reliability of the LTS simulator. The scoring performance of LTS and MISTELS were compared (concurrent validity) as well as the participants' satisfaction level after their performance on the simulators.

METHODS

Equipment:

The McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) is a bench model simulator that includes 5 tasks in an inanimate box. Performance is scored for speed and precision. The tasks are designed to provide practice on specific laparoscopic skills such as bimanual dexterity, suturing and cutting. The simulator consists of a laparoscopic trainer box measuring 40 x 30 x 19,5cm, covered by an opaque membrane. Two 12 mm trocars are placed through the membrane at convenient working angles on either side of the 10 mm zero degree laparoscope. Four alligator clips within the simulator are used to suspend materials for certain exercises. The laparoscope and camera are mounted on a stand at a fixed focal length. This enables the examinee to work independently. The optical system consists of the laparoscope, camera, light source and video monitor. The video monitor is placed in line with the operator. An instructor is present to standardize the testing, ensure placement of models for the tasks, timing of the test and calculation of penalties and scores.

The laparoscopic training system 2000 with interactive sensory module 60 (LTS) is an inanimate physical simulator with the same format as the MISTELS but offering an automatic electronic scoring system. The system possesses physical sensors embedded in each module permitting these advantages. Ten tasks are presented in a carrousel and scored for speed (time) and precision (penalties). A tensiometer verify knot tightness with a disruptive force of 2,5 lbs (1 kg). For the purpose of the study, set up conditions were standardized across centers. They include configuration of the floor mat (including height), position of the ISM60 carousel on the mat, position of the primary and secondary trocars, camera type and light source. A stand-alone camera and external light source are fixed in the box. An instructor is present to standardize the testing during the study although every task can either be manually or automatically started and ended.

Subjects:

This study was undertaken within three surgical specialities (general surgery, gynaecology and urology) of three Canadian universities: University of Montreal (principal investigating center), McGill University, and University of Dalhousie in Halifax. Those universities reflect the population diversity of the country and show a particular interest in innovating surgical teaching techniques. The candidates were medical students, residents, fellows and attending with varying degrees of previous experience in laparoscopic surgery.

All participations were voluntary. The obtained results were coded and kept confidential. None of the obtained information during this study was used to evaluate competency or technical ability of residents or physicians. The information will never be available or transmissible to program or department directors.

In each center, a co-investigator and a research assistant were identified to recruit an equal number of candidates from each of the three surgical specialties. The testing was supervised by the research assistant only, to avoid ethical issues. The principal investigator (Montreal) was responsible to set the conditions to ensure the homogeneity of testing and procedures across the centers. Each center collected the data and transferred them to the principal investigating center of the study.

Each center was asked to provide a minimum of 12 participants per speciality distributed equally by academic level (table 2). Each center was also asked to recruit 4 medical students. Therefore, each center had to test a minimum of 40 candidates.

TABLEAU II NUMBER OF PARTICIPANTS PER ACADEMIC YEAR IN EACH SPECIALTY

ACADEMIC LEVEL	GENERAL SURGERY	GYNAECOLOGY	UROLOGY	TOTAL PER CENTER
PGY1-2	3	3	3	9
PGY3-5	3	3	3	9
Fellow	3	3	3	9
Attending	3	3	3	9
TOTAL PER SPECIALTY	12	12	12	36
Medical student				4

Total: 40 participants per center

The participants were divided into four groups based on estimated level of experience (questionnaire in appendice F), as defined by the ACGE (Accreditation Council for Gynecologic Endoscopy) for gynaecology and SAGES (Society of American Gastrointestinal Endoscopic Surgeons) for general surgery. This classification separates the participants using a combination of the quantity of interventions done (levels 1 to 3) and then by the intervention complexity to attain the level 4. Complexity here is defined as the difficulty of the surgery itself or its requirements for high technical abilities and experience (see appendice F).

1) Novice: a) with no previous experience in laparoscopy,
b) who have done up to 5 laparoscopic procedures;
2) Intermediate: who have done 6-49 laparoscopic procedures.
3) Competent: who have done 50 or more standard laparoscopic procedures.

4) Expert: who have performed 50 or more advanced procedures.

The needed number of participants was calculated from data obtained in a previous study comparing two simulators including the MISTELS (the five tasks shared with LTS and the same scoring system).[26] It was expected that the number of participants would give enough power (80%) to detect significant difference of at least 15% (320 points on a maximum of 2100) between categories at the alpha level of 5%. To answer our objectives, a minimum of 30 participants per category (novice, intermediate, competent and expert) were needed (n=120). It was easier to recruit participants by academic level rather than by laparoscopic experience level. Indeed, we roughly estimated that by getting equally distributed participants by academic level, we would get enough subjects in each experience level. At mid-study, data were analyzed. The correlation between the simulators was found to be >0,80. Thereafter only LTS was tested to facilitate recruitment (less testing time).

Research design/procedures

The study was conducted over a 12 month time period.

1) A demographic questionnaire was answered by each participant and automatically entered in the computer. A specific and validated questionnaire evaluating the laparoscopic experience was filled by each participant (see appendice F). Each participant had a unique identifying number consisting of digits identifying the center, the specialty and the order of participation (to avoid ethical issues).

2) A demonstration CD of LTS was shown to all candidates prior to initial testing. The CD demonstrates guidelines for performing each structured task. The participant was then prompted to perform the peg transfer task (#1) to gain familiarity with the simulator and this was followed by testing the same task. Each task or group of related tasks was again demonstrated by playing the CD prior to performing the exercise. An average of 60 minutes was expected for

each participant to complete the 10 tasks. Each task has a predetermined maximal execution time, when all spend the final mark is 0.

3) In each center, the participants were asked to perform tasks of the MISTELS physical simulator. MISTELS was done after the LTS simulator. Considering its greater number of tasks (n=10) it was assumed that a potential superior learning effect would be observed with the LTS. A cross-over study was not planned since the differential learning effect of both procedures could have introduced methodological difficulties, and could have led to data with which it would have been difficult to separate the effect of learning from the true differences between both instruments. Again our primary goal was to demonstrate the construct validity of LTS and its concurrent validity when compared to MISTELS, it did not required a cross-over design. The participants were asked to perform on both simulators within two weeks without additional exposition to any simulator to minimize an external practice effect. An average of 40-60 minutes was expected to complete the 5 tasks on the MISTELS.

Outcome Measures:

4) The final scores of the LTS 2000 ISM-60 were automatically entered on an Excel sheet database. The MISTELS scores were recorded manually on the same program.
5) An immediate and automatic feedback was available after each task on the LTS (time required, number of penalties and score), a similar, but verbal feedback was given after each MISTELS tasks.
6) A satisfaction questionnaire was filled by each candidate after its performance on each simulator (see figure # G). In this post performance questionnaire, the candidates' satisfaction intensity was estimated with a visual analog scale ranging from "Useless" to "Fantastic". The visual analog scale is regarded as a good tool to evaluate subjective feelings[27]. An additional open question was collecting reasons why their university should get this simulator.

Statistical Analysis:

1) Assessment of construct validity of the LTS simulator

Variables: the global score is the sum of each task score (10). An ANOVA analysis was used to evaluate differences between the four experience categories defined earlier and the eight levels of training (medical student to attending). A posteriori testing was used to identify differences between the categories and the levels. A value of $P < 0{,}05$ was considered significant.

2) Assessment of reliability of LTS simulator: Cronbach's alpha was calculated as a measure of internal consistency of tasks to demonstrate reliability of the instrument.

3) Assessing the concordance between the two simulators:

a) The mean total scores of all tasks of both simulators were correlated (10 tasks and 5 tasks).

b) The LTS 2000 scores and the MISTELS scores for the five identical tasks were correlated.

c) The five unique tasks (added tasks) of the LTS were correlated with the five common (known) tasks of MISTELS (5 tasks and 5 tasks).

d) A comparison was done between the five coordination tasks (1,2,3,4,5) and the three sutures tasks (7,8,9).

The reliability of both instruments was estimated using Cronbach's alpha as described above. The Pearson correlation coefficient with intraclass correlation (ICC) was calculated for the task and total raw scores to compare resident performance between simulators. In order to control for the possible effect of the LTS on the performance of the MISTELS, ranks of residents on each instruments was correlated. A value of $p < 0{,}05$ was considered significant.

4) Assessment of participants' satisfaction level on both simulators:

Satisfaction appraisal was done by a visual analog scale (range [0 - 100]). Means were compared using ANOVA tests.

5) Assessment of the influence of the demographic characteristics on the score performance. The following variables were analyzed to measure a possible effect on the score performance:
   - age, gender, handedness (right, left, ambidextrous),
   - specialty: gynaecology, urology, surgery,
   - level of experience: medical student, PGY 1,2,3,4,5, fellow, attending,
   - previous simulator training: approximate number of hours on a physical simulator, or a virtual simulator.

Linear regression was used to assess the relationship between performance and those demographic data obtained.

Process for ethics approval

The institutional review board approvals were obtained from University of Montreal (from 3 hospitals), from McGill University and from Halifax. The consent form was provided and approved in both French and English (appendices B & C).

RESULTS

Population

Finally, 123 subjects were recruited, from three specialties (general surgery, gynaecology and urology) at different levels of formation. At University of Montreal, the 78 participants tested were 11 junior residents (PGY1-2), 20 senior residents (PGY 3-5), 9 fellows and 29 attending and 9 medical students. At University McGill, 24 subjects were tested. The results were obtained from 8 junior residents, 12 senior residents, 1 fellow and 3 attending. Lastly, at University of Dalhousie, 21 participants were recruited. The results came from 6 junior residents, 8 senior residents, 3 attending and 4 medical students. All three specialties were represented across the three participating university centers: 30 participants were recruited from general surgery, 59 from gynaecology and 21 from urology. The participants were distributed almost equally among the four levels of experience: 23 novices, 34 intermediaries, 36 competents and 30 experts. All the participants were tested on LTS, 73 on both LTS and MISTELS.

No potential subjects explicitly refused to participate but many did not found time in their schedule to perform the testing (3 potential informed subjects to get 1 finally tested).

Construct validity of the LTS simulator

There was a significant progression of the scores according to level of laparoscopic experience (novice, intermediate, competent, expert) (p=0,000) (table III and figure 1). A difference was found between novices and experts (p=0,000), between novices and competents (p=0,006) and between intermediaries and experts (p=0,006). A significant progression was also revealed with the level of formation (medical student, PGY1, PGY2, PGY3, PGY4, PGY5, fellow, attending) (p=0,000). When grouping levels of formation, we found a difference in between groups (p=0,001): the juniors (MS, PGY1) and the seniors (PGY2,3,4) (p=0,000) and the juniors and the experts (PGY5,F,A) (p=0,000) (table IV). As shown in those tables, the scores obtained on MISTELS are comparable to LTS in terms of progression among levels of experience and formation.

TABLEAU III SCORING PERFORMANCE ACCORDING TO LEVEL OF EXPERIENCE

Level of experience	Novices (N)	Intermediaries (I)	Competents (C)	Experts (E)	Statistical significance	Post hoc test results
Score LTS (n)	567,3 (23)	764,4 (34)	841,4 (36)	1022,3 (30)	0,000	N<E;N<C; I<E
Score MISTELS (n)	45,2 (17)	55,8 (24)	59,1 (19)	74,6 (13)	0,001	N<E;I<E

TABLEAU IV SCORING PERFORMANCE ACCORDING TO LEVELS OF FORMATION

Grouped level of formation	Juniors (J) (MS, PGY1)	Seniors (S) (PGY2,3,4)	Experts (E) (PGY5,F,A)	Statistical significance	Post hoc test results
Score LTS (n)	597,0 (25)	902,8 (42)	972,8 (56)	0,000	J<S;J<E
Score MISTELS (n)	40,5 (16)	61,9 (28)	63,5 (28)	0,001	J<S;J<E

Reliability of LTS simulator

Cronbach's alpha for the 10 tasks was evaluated at **0,68**.

Concordance (concurrent validity) between the two simulators:

A correlation of 0,79 was found between the total scores of performance of LTS compared to MISTELS (see figure 2). The Pearson correlation coefficient with intraclass correlation (ICC) was calculated at **0,79** IC[0,68-0,86] (p=0,000) for total raw scores to compare resident performance between simulators.

A comparison was done between the 5 coordination tasks (1,2,3,4,5) and the three sutures tasks (7,8,9). It has been advanced that coordination skills might be easier to acquire in certain individual (have an innate component) compared to sutures skills that would be mastered only with deliberate practice[25]. When comparing the mean of the two groups according to level of experience, the progression is steeper (p<0,000) with coordination tasks (experts much better) compared to the flatter progression with sutures tasks (p=0,074) (figure #3). The correlation between the 10 tasks of LTS to the 5 of MISTELS was also evaluated (table V). Both series of skills have good correlation with total scores (0,58).

TABLEAU V CORRELATION OF THE PHYSICAL SIMULATORS' SCORES ACCORDING TO TASKS

	LTS total	**LTS common**	**LTS unique**
MISTELS total	0,82	0,78	0,72
LTS unique	0,77	0,58	
LTS common	0,97		

Participants' satisfaction level on both simulators

The mean level of satisfaction was 75,9 for LTS and 70,4 for MISTELS (P=0,012).

These are examples of general comments about simulation training and about both simulators:

> *"1) About **simulation**: We are under trained for laparoscopy. It will increase our skills in laparoscopy. We don't get enough exposure in OR. We shouldn't be practicing basic laparoscopic skills in OR setting".*
>
> *"2) About **LTS**: To improve laparoscopic skills for the resident. Excellent measure of skills. Fun to work with. I like the computer assisted evaluation. Fun and improves your skills simultaneously".*
>
> *"3) About **MISTELS**: Good to teach laparoscopic basics. Cheap, practical, realistic, portable. Material tends to break easily (penrose drain, etc) and this influences technique. Tasks were simple but required coordination. The simplicity made the tasks more enjoyable for me on this simulator than the LTS. Great for practice".*

Influence of the demographic characteristics on the score performance:

The multivariate analysis demonstrated a variation of total mean scores only according to the **specialty**, to the **age** and to the **training** with LTS. An interaction probably exists between age and training, but only the effect of the specialty stayed when controlling for this interaction. The general surgery specialty had better overall total scores than the two other specialties. A higher degree of exposition in residency to laparoscopic surgery and to physical simulators was depicted in our demographic data in general surgery, especially at McGill.

FIGURE 1 PERFORMANCE ON LTS VS EXPERIENCE

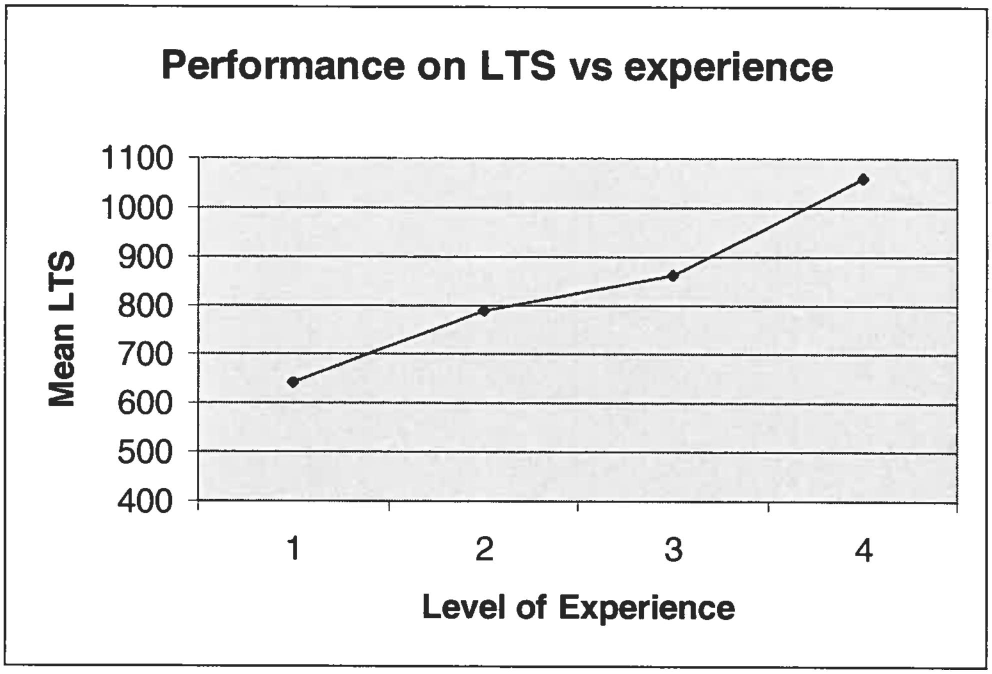


FIGURE 2 CORRELATION BETWEEN LTS AND MISTELS

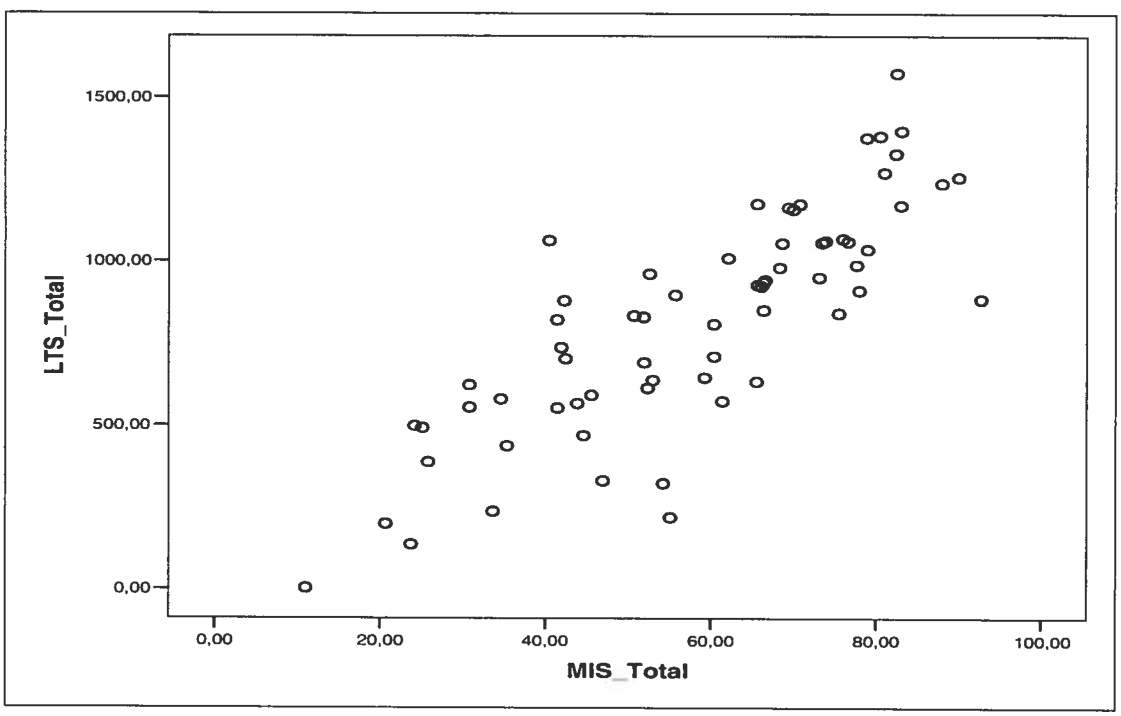
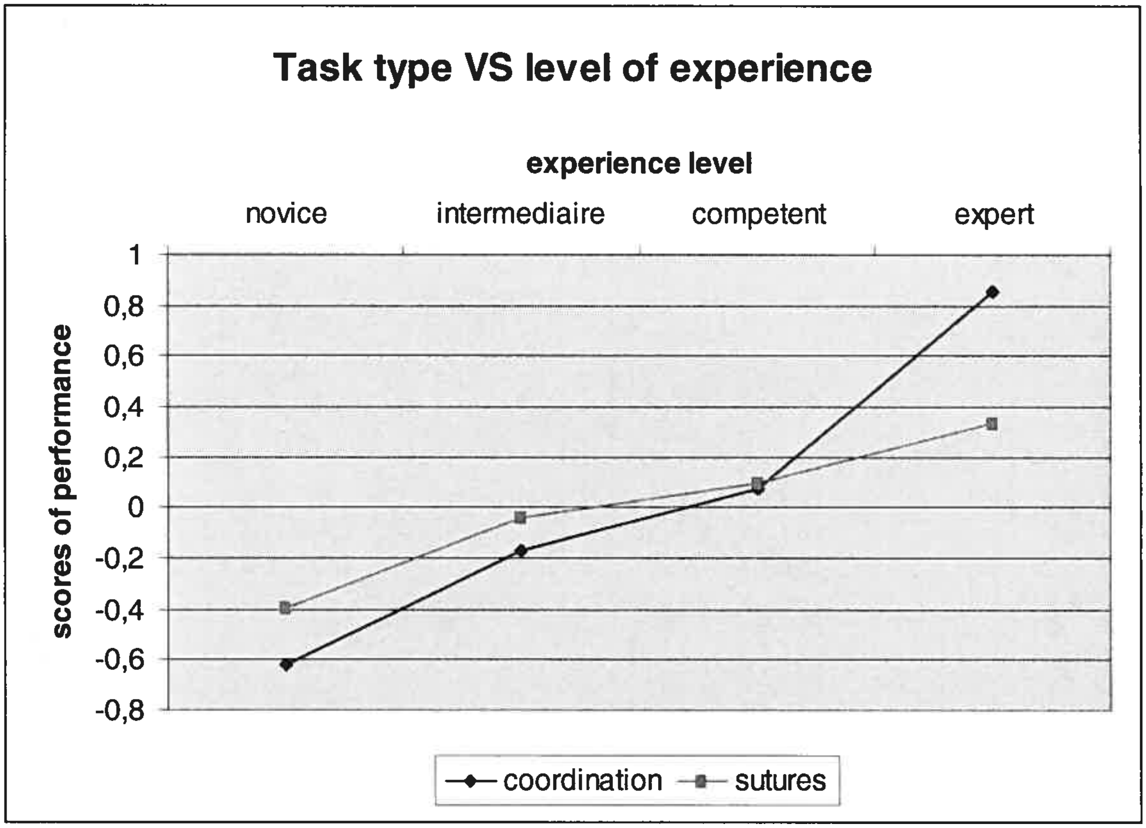


FIGURE 3 SCORES ON COORDINATION TASKS VS SUTURES TASKS ACCORDING TO LEVEL OF EXPERIENCE



DISCUSSION

Proficient laparoscopic surgery requires a unique subset of surgical skills that deserves special learning. These are not an innate behaviour. One must be able to interpret two-dimensional video input and use this input at varying angles to guide the motion of the hand held instruments. The acquisition of these skills is extremely variable among individuals, but can be very slow, especially when experienced only in an operating setting. The OR environment is a performance setting, not a deliberate environment suitable for skills acquisition. This learning is further slowed for the novice surgeon by unfamiliarity of the anatomy, the operative procedure and the added stress of the operating room. Surgical inexperience combined with laparoscopic inexperience can result in an extremely frustrating situation and create unnecessary anxiety of performance for the resident.[1]

This study had as principal objective to validate a computer enhanced video-laparoscopic system, the LTS 2000-ISM60. It was important to the authors to demonstrate different aspects of validity, construct (capacity of discrimination using scoring performance) and concurrent (correlation of LTS with another physical simulator). MISTELS is one the most studied physical simulator and is considered for the purpose of the present study as the gold standard in its category. The satisfaction's level of participants has been rarely assessed in the past. To measure this variable as a factor of face validity seemed essential.

To invest in a simulator is a large responsibility for a teaching institution. But to effectively train residents in a surgical domain is a demanding mission. Because there are increasing constraints placed on available operating room time, surgeons are in a rush. The patient population of our teaching hospitals is changing. There are increasing fears that medico legal considerations will result in less operative experience for our residents.

A structured laparoscopic training program is what to aim for. The main idea is to provide a practice schedule to residents, to render regular deliberate practice of simple and more complicated tasks easy and accessible even with the heavy workload of residency. It is essential to create opportunities to give feedback and to evaluate the residents on a regular basis.

The LTS is attractive, because like the MISTELS, it is a portable and a user friendly simulator. The LTS can be used in an autonomous fashion, with after tasks feedback and a personal log to compile own results. Because it is also more expensive, a validation, correlation and satisfaction multicentric study of that kind was judged as pertinent.

The authors had the opportunity to test the simulator in three specialties in three different universities increasing our population diversity but rendering the results analysis more extensive.

To assess construct validity, the progression of performance was measured according to levels of formation like it was usually done in previous studies involving surgical skills evaluating tools. Because of the variety of the OR exposition across different programs, universities or provinces, the hypothesis was that by classifying participants by their level of experience, the discriminating capability or construct validity of the simulator could be improved. A statistically significant progression was demonstrated between all the categories except between novices and intermediaries and between competents and experts. For the latter, some reasons were proposed.

First, due to insufficient participants recruited in some categories, especially, in the fellow section (10 instead of 27), it can be presumed that this new classification was not fully evaluated. However, our recruitment did permit to obtain 123 participants and to represent adequately each of the four experience level.

Why did we not succeed in recruiting the desire number of participants according to level of formation? Time-constraint made the recruitment very hard. Residents, fellows and staffs are busy subjects, to keep them away from their duties or their pager for more than an hour is an exploit in itself. Also often, there are not three fellows per specialty, depending of the size of the program. Announcements in grand rounds, posters, letters personally addressed and one on one meeting were done. Once the participants were enrolled, the majority were highly motivated and did well respond to their experience regardless of their previous level of expertise.

Second, the classification in itself should be discussed. For example, it can be argued that some participants classified in the intermediate category should have stayed in novices and that some in the competent category could have been upgraded to experts. When referring to the criteria necessary to be competent (50 or more basic procedures), is performing 100 simple procedures with success can make an expert of you (50 or more advanced procedures)? Recall bias problems concerning the numbers and types of cases done could have also cause misclassification.

A third point is the large importance given to task #9, the intracorporeal knot with knot security testing. It is a all-or-nothing task, meaning that even if you did it quickly and correctly (high score), you loose it all if the knot slipped. It is understandable from an OR reality point of view, that it is essential for a knot to be secure on a bleeding cut vessel. However, LTS is a simulator aiming to teach and to evaluate basic skills. Accordingly, 0 or 400 points makes a huge difference on a score of maximum 2100. When analyzing closely senior residents and staff performances, the task #9 was very discriminating. Often the LTS total score diminished drastically because task #9 was fell. In a number of cases, it did not correlate well with the MISTELS score. It seemed interesting to recalculate a new score by using the score after having tied the knot, before the tension test. Fortunately, those data were kept in the computerized log and were analyzed at the end of recruitment. The scoring process was modified by decreasing the penalty from loosing it all to the removal of 50 points for example. When comparing the modified LTS total score to MISTELS total score, the correlation was 0,76 (compared to 0,79). The construct validity was sought according to the modified LTS score and it stayed the same. No major difference justified a change in task #9 scoring process.

LTS scoring performance correlated well with MISTELS. It was easy to predict since the first was based on the second (5 identical tasks). MISTELS' tasks correlated as well with the tasks unique to LTS.

The comparison done between the 5 coordination tasks (1,2,3,4,5) and the three sutures tasks (7,8,9) did not confirmed previous thoughts that coordination skills might be easier to acquire in certain individual compared to sutures skills[25]. But after a certain degree of experience, the coordination skills seemed to improve faster. Further studies, concerning the acquisition of different types of technical abilities would be needed.

The interpretation of the results was rendered difficult by the enormous variability in the range of results according to university and to specialty. Again, the study involved three centers, three disciplines and nine different programs. The nine programs are not equally exposed to laparoscopic simulators. For example, the residents evolving in the program of surgery at McGill are much more exposed to simulators for practice and research purposes in their training, 10 or more hours on average compared to 0 to 3 hours at Montreal (data taken from our demographic questionnaire). In fact, there obtained results were on average higher.

The trainees' satisfaction level has been assessed in a previous study done by Maden and al[28], comparing LTS2000 to MIST-VR. 83% of students chose LTS 2000 when asked to pick only one trainer. In this present study, satisfaction was higher with LTS on the visual analog scale. LTS was evaluated before having done the MISTELS. It could have possibly influenced the results. It is possible that the results would have been different (higher or lower) if the evaluation would have been done after having performed on both simulators.

In general, for the open question: "Why should your university get this simulator?" The responses were positive to both simulators without pushing towards one or the other. Comments that were coming over and over were: "residents need practice", "they want simulators before hands on surgery", "they want to manipulate instruments and to be introduced to basic exercises in a laparoscopic-like setting". All participants found utility to both simulators. LTS was often chosen over MISTELS for the greater number and variety of tasks as well as the autonomous feedback.

CONCLUSION

This multicentric multidisciplinary prospective study demonstrates the construct validity of the LTS2000-ISM60 simulator. The scoring performance of LTS and MISTELS are comparable. A high level of satisfaction was found with both simulators, slightly higher with LTS. The automatic scoring system and performance logging system are very appealing for an eventual evaluation system and university training program. Depending on their budgets and the quantity of simulators (number of residents) needed, the decision in which one to choose gets easier. Definitely, physical simulators deserve further interests and studies to assess transferability of acquired abilities to the operating room.

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CONCLUSION

The ultimate goal when validating a surgical simulator is to establish that by using this particular tool, simulation becomes a didactical method that improves the security and the competency control of surgeons in general practice.

EVALUATIVE CAPABILITY OF A SIMULATOR

This multicentric study had as main purposes to validate the physical laparoscopic simulator LTS and to compare it to MISTELS, which was considered after extensive literature review (please refer to article), as the gold standard in this category of simulators. LTS showed aspects of validity and reliability but not to the extent it was hoped for. By changing the classification system from "by level of formation" to "by level of experience", and by adding 5 tasks to the validated MISTELS, the goal was to obtain a more convincing construct validity. When comparing the participants' total performance scores obtained on LTS, the four predefined levels of experience were not found to be statistically all distinct from each other like it was hypothesized first. It discriminated well three levels on four: between novices and experts, between novices and competents and between intermediaries and experts.

However, a satisfying concurrent validity was attributed to LTS when compared to MISTELS and interesting isolated data were found through the linear graphic of correlation (figure #3).

Several reasons were proposed for those validation results.

A classification system based on surgical laparoscopic experience is very interesting and promising but as addressed earlier in the article, has some flaws.

Unfortunately, it was found with that system in particular, that misclassification was easy, especially with the component of recall bias (the difficulty to remember number and types of surgeries performed in the past). No range of time was included. For example, were those surgeries performed during their residency 10 years ago or during the past three years? Also, the distinction between competents and experts can be quite subtle. Between those two levels, it is only the complexity of cases that makes the difference.

To prevent misclassification, the best method, though much more time consuming, would have been to examine and count the type of surgeries performed by reviewing surgical protocols of each participant over the last 12 months. The subjects would have been classified according to their estimated number of cases done in the last 5 years (cases in 1 year X 5). The recruitment time frame would have probably been affected and slowed by such logistics across three university centers and their archives.

A combination of the classification by level of formation (academic year) and by level of experience is suggested to permit comparison in between simulators and among other evaluation tools dedicated to technical skills like global rating scales.

To pursue the analysis of the obtained construct validity, the simulator itself needs to be further examined. In that matter, two tasks out of ten deserve further interests.

First, task #9, the intracorporeal knot, which had a maximal obtained score of 411/480 on a maximal obtained total score of 1575/2100 (10 tasks). It corresponds to 26% of the total score. The nature of that task is to tie a secured square knot with a silk suture. As demonstrated in the video, two half knots have to be oppositely thrown to obtain a final square knot. The surgeon knot (special knot to avoid a slipping suture) cannot be used neither a third half knot to improve solidity. In an OR setting, the surgeon usually choose its knot according to his ability or to the amount of knot security needed, which could be different for example, to close a hole on the intestine versus to tie a vessel. When the same task is performed in the LTS simulator, using a surgeon knot or doing a third throw would certainly add solidity to the wanted squared knot. As well, it would probably increase the chance of success on the security tension test. If the participant had the possibility to use whatever knot he wanted or felt comfortable doing, it could have increase his particular task score. It would have probably affect mostly the competent and expert participants' total scores. This assumption is based on figure #3 illustrating the linear correlation between the scoring performance of LTS compared to MISTELS according to level of performance.

As discussed earlier, it can be easily appreciated that some subjects fell out of the field. The results of those subjects were closely looked at without revealing their identity but only disclosing their level of formation and experience. It was shown that a number of participants in the competent or expert categories did very well on the MISTELS (knot tying included), but had average score on the LTS. The latter score seemed to be lower mainly because task #9 was failed, at the tension test. Knowing that it was possible to recalculate task #9 score without the all-or-nothing security testing, the scoring process was modified for analysis purposes. Instead, a 50 points penalty was removed when the knot slipped while the 1kg tension was applied. As expected, a significant augmentation was induced to the total score of those participants. A maximal obtained score of 411/480 on a maximal obtained total score of 1605/2100 (10 tasks) was obtained which still corresponded to 26% of the total score. However, the construct validity or discriminating capability of the entire test stayed the same on final analysis unlike what was anticipated.

In fact, we do still believe that task #9 has to keep a high attributed score because if the trainee succeeds in tying a secure intracorporeal knot, his basic skills are probably well acquired. Task #9 incorporates abilities essential to become proficient in a laparoscopic simulation setting.

The second task to criticize or to scrutinize is task #10, the cutting circle task. This task score is based on the total time required to cut a rigid paper circle and on the precision in cutting correctly around the circle. However, it seemed that if you do the task very quickly and carelessly you get a better score (even with precision penalties applied) than if you do it meticulously. In fact, there is probably not enough time allowed for this task. It was found that if you are skilful but very careful, you may don't get enough time to finish and you get no point.

By revisiting and modifying the given instructions to participants, the time allowed and the scoring system attached to those two tasks, it was presumed that the construct validity could be enhanced. But as said earlier, changing scoring of task #9 was not conclusive.

Apart from those critics, it is still strongly believed according to this multicentric study that LTS has important criteria of a valid simulator. Again, it has shown to have an acceptable discriminating capacity, was well appreciated by the users and is adding an interesting computerized integrating system. Thereby, probably justifying its purchase at its higher cost for those universities that budgets can afford, and certainly justifying further studies.

TRANSLATION OF THOSE CONCLUSIONS INTO OUR MILIEU

Why do we need an acceptable discriminating capability from a physical laparoscopic simulator? Why a surgical department would want to get this kind of physical simulator?

Obviously, a training program must be interested in evaluating their trainees at the beginning of their formation to get their basic score and to classify them. Their basic score can be thereafter used as a guide and a reference. It serves teachers to orient their teaching according to the level of students. It serves to the resident or surgeon in practice to compare himself to a standard of competence or to the level he should be at or should aim for. Then, with organized deliberate practice and by keeping a performance log, each user can monitor his progression and adjust his amount of training according to changing performance score.

Unfortunately, a gap still exists between improving trainees' technical abilities on a validated simulator which has been demonstrated a number of times[21,22,23,24] and proving that those acquired abilities are transferable to the operating room. Can we justify the purchase of simulation tools for laparoscopic teaching? Does it really improves OR skills? This further aspect will be discussed here.

TRANSFERABILITY OF ACQUIRED SKILLS TO OPERATING ROOM

A number of studies have demonstrated some aspects of transferability, here are one involving a physical simulator (MISTELS' like) and one using a virtual simulator. Researchers in Dallas used modified Rosser Stations (drills using inanimate objects within a box trainer[36]) known collectively as the "Southwestern stations." In 2000, this team documented in a prospected randomized trial that surgical residents who received 5 hours of simulator training scored significantly better when assessed by Reznick's global rating scale (see appendix H and discussion later) of operative performance, compared with controls.[7] This was the first study to establish transferability of skills in the context of real operation (laparoscopic cholecystectomy), which confirmed concurrent validity for this type of skills training.

The next landmark study indicating that skills were indeed transferable to the real operating room setting is commonly known as "VR to OR" ("Virtual Reality to Operating Room") and was published by Seymour and al from Yale University in 2002[38]. Sixteen surgical residents (PGY 1-4) were randomized to either MIST VR (Mentice, Goteborg, Sweden) training until expert criterion levels established by experienced laparoscopists were achieved, or control non-VR-trained. Gallbladder dissection was 29% faster for VR-trained residents. Mean errors were six times less likely to occur in the VR-trained group. It was concluded that the use of VR surgical simulation to reach specific target criteria significantly improved the OR performance of residents during laparoscopic cholecystectomy. Importantly, the VR to OR study introduced the concept of expert-derived proficiency (fully trained, competent: expert[38]) levels consistent with established educational theory regarding skills acquisition.[37, 39]

Traditional training methods require trainees to practice for a arbitrary training duration or numbers of repetitions. Proficiency levels based on expert performance maximize the efficiency and learning, ensuring that all trainees uniformly reach a suitable level of performance prior to curriculum completion.[34,40,41].

IS THERE A USER FRIENDLY OBJECTIVE EVALUATION OF OR SKILLS?

To assess transferability of acquired skills, needed or expected technical skills have to be objectively evaluated in OR first (OR expected proficiency). What kinds of tools are available? How valid in terms of objectivity and expected proficiency are they?

When compared to In Training Evaluation Report (ITER) and procedural logs, evaluation by direct observation seemed at present to be the most valuable way to judge technical abilities.[2] Direct observation is to assess operating room performance of technical skills by using specific, predefined criteria.[42] *Checklists* and *global rating scales* are two tools to evaluate technical surgical skills in an OR setting. *Checklists* are lists of tasks, with 1 mark given if the task is performed correctly and no mark if it is performed incorrectly or not at all (eg, places grasper on fundus of gallbladder). *Global rating scales* are lists of items scored on a scale from 1 to 5, with the use of explicit descriptors at points 1, 3, and 5 (eg, respect for tissue: 1 = frequently used unnecessary force on tissue or caused damage; 5 = consistently handled tissues appropriately with minimal damage)[2,42].

A global rating scale was validated by Reznick and was proven to be reliable (see appendix H).[43] In a study by Martin and al in 1997[44], 20 surgical residents took part in a live animal and bench station (Oral Structured Assessment Technical Skills) using checklists and global rating scales for evaluation. This study suggested that global ratings were a better method of assessment than task-specific checklists. However, both evaluation tools have been used in terms of intraoperative assessment and have been shown to be reliable and valid measures of intraoperative performance.[7,45]

The global rating scale developed by Reznick was modified and revalidated by a recent study conducted by Vassiliou and al at University McGill in general surgery[46]. The Global Operative Assessment of Laparoscopic Skills (GOALS) consisted of a 5-item global rating scale adapted from Reznick's original scale. 21 participants were evaluated during a laparoscopic cholecystectomy. The obtained data indicate that GOALS was feasible, reliable, and valid and supports its use in the training and evaluation of laparoscopic skills.

Direct observation using specific valid and reliable evaluation tools could permit objective scoring or classification of our resident performance. In a context on simulation training, it allows demonstration of improvement after training sessions. Most importantly, it opens the door towards objective technical abilities evaluation at the end of surgical rotation and at the end of residency.

WHAT'S NEXT?

There are no simulation tests or standard accreditation that ends the formation of a gynaecologist, a urologist or a surgeon like it is well established in aviation. There are several reasons to explain this reality. First of all, competency has been defined in a number of different ways in dictionaries, in different disciplines and by different authors. For example, general competency could be simply defined as the capability or the efficiency of performance in a particular discipline.[38] Surgical competency is somewhat different, it could be considered as a multifaceted art. It requires judgment, medical knowledge, professionalism and technical abilities. It is generally believed that almost anyone can acquire basic technical or manual skills of different kinds if they put the time and energy required and if they get appropriate coaching. Interestingly, Fried in one his recent conference said: *''If they don't have basic skills, they will never be competent"* when talking about residents.[3]

Since evaluation of surgical skills has always been done by direct observation without objective measurements, no standard of practice have been established except for litigious cases (unusual or higher rate of complications for a certain physician). For judgment, medical knowledge and professionalism, three entire chapters (with great luck) would have to be written to describe how the actual medical teachers struggled to teach best and evaluate those expected competencies.

Because expected competencies were recently defined by the Royal College of Physicians and Surgeons of Canada, evaluation methods are just in their early development. Hopefully, those methods will include the evaluation of surgical expertise or competency.

In the mean time, how can we translate the above teaching and evaluating surgical tools in our milieu? A description of concrete actions recently taken in our current surgical curriculum, future vision and projects are following.

GYNAECOLOGY SURGICAL TRAINING PROGRAM

From this simulator study, an increasing interest was shown by everyone at University of Montreal. It is now time for the Department of Obstetrics and Gynaecology to implement a standardized laparoscopy training program or at least from a more urgent point of view, to make available simulation tools that all levels of trainees can use. A space was made available and two physical simulators (MISTELS and LTS) are presently available.

For the present, how can we judiciously and efficiently, introduce a training program with reasonable costs in an era of constant cuts in budget on the one side and, on the other side, advanced high technology equipment requirements?

There are examples of formal teaching of surgical skills in obstetrics and gynaecology residency. One of them is at the University of Washington. According to a study conducted by Goff and al in 1999[47], when formal surgical training is given to obstetric-gynecologic residents, their surgical skills improved subjectively and objectively. Indeed, a training program can probably be established in any department but to certain costs. Depending on available budgets, material (animals, surgical models and simulators) and faculty members/teachers time can be evaluated and organized. To convince the faculty members and all the active teachers of my department, the starting point would be to evaluate objectively our residents' current abilities before implementing a new program. We would obtain a baseline measure of our residents' abilities and an indirect measure of the quality of our actual surgical teaching. We would then probably be able to negotiate and justify the higher costs of a new training program.

EVALUATION OF TECHNICAL SKILLS

The same team in Washington developed an Objective Structured Assessment of Technical Skills (OSATS) in obstetrics and gynaecology for open surgery and for laparoscopic surgery.[48,49] They were inspired by Reznick[16] in Toronto who first pioneered this type of objective skills assessment with general surgery residents. Basically, it is a seven-station examination based on the well-know Oral Structured Clinical Examination (OSCE), administered to 24 residents. The test included laparoscopic procedures (salpingostomy, intracorporeal knot tying, closure or port sites) and open abdominal procedures (subcuticular closure, bladder neck suspension, repair of an enterotomy and abdominal wall closure). All tasks were performed using life-like surgical models. Residents were timed and assessed at each station using three methods of scoring: a task-specific checklist, a global rating scale, and a pass/fail grade. Construct validity and reliability were satisfying when scores of each task where analyzed according to the level of formation. General comments about this evaluation were very encouraging:

> *"1) Having a resident operate completely independently, without the usual verbal or physical cues that attending physicians often unconsciously provide residents, is very revealing".*
>
> *"2) This type of testing is very useful because the tasks are standardized and every resident is doing the identical procedure. This allows faculty members to accurately assess if a resident is falling behind his/her peers in technical skills".*

"3) This type of testing can also expose weaknesses in the surgical curriculum and this can heighten faculty awareness about teaching surgical skills".

"4) Residents who fall behind can be identified early for additional instruction and practice".

"5) Testing can provide residents with the self-confidence that they can do a procedure without input from a supervising physician".

"6) Finally, this type of testing could allow surgical educators to be confident that we have trained competent surgeons". [48,49]

An important factor to consider when implementing such a test is again, its cost. The purchase of the material for the first edition was evaluated around 5000 USD by the University of Washington in 2000.[48] This amount included a pelvic (female) trainer, two laparoscopic trainers, abdominal wound closure model and a bowel model. For each exam, thereafter the cost was evaluated at 1000 USD for 16 residents accounting for the models parts that had to be replaced and faculty members time for supervision and organization. Their space used was free. It was estimated to be less costly than using porcine models and as effective.[49] Convincing my department to purchase sophisticated simulation models is feasible but a well organized plan or program is essential. An evaluation setting a baseline of every resident and assessing actual teaching of technical abilities in our department is to my opinion a non avoidable introduction.

PRACTICE ACCORDING TO LEVELS OF FORMATION: IDEAS TO START THE PROGRAM GRADUALLY.

For the *novices* (PGY 1-2), it would be essential that they can practice on physical simulators before having hands on in OR. Two obligatory half-day sessions per year, one supervised and the other not, could be easily and shortly established. Those would introduce the trainee to instruments, laparoscopic environment and trocar entry. The *intermediate* (PGY 3-4) trainees already exposed to clinical OR cases would have the opportunity to come back to simulators on one half-day per year and whenever needed thereafter. After each surgical rotation at all residency levels, a station on a simulator would be created to evaluate some aspects of the resident's progress and to give early on training feedback. The PGY 5 trainee would be offered to practice non exposed techniques or to exercise different procedures according to individual specific needs on one half-day and whenever needed. They would have to attain expert scores levels (proficiency) when provided on simulators available and eventually be tested and obtain laparoscopic skills certification.

Another interesting possibility, is to become a MISTELS evaluating center as part of the (Fundamental Laparoscopic Surgery) FLS program. The University of Montreal could become the first center providing an accreditation in the gynaecology discipline. Junior residents would have to be accredited prior to going further steps or higher levels of training for example.

NEW COLLABORATION BETWEEN PROGRAMS

The three surgical specialties at the University of Montreal showed great interest in trying to collaborate between programs. The three curriculum could synchronize the training of their residents, together or on different schedules. The higher costs caused by the purchase of the simulators could then be assumed by the three specialties.

In addition, by discussing with my colleagues physicians of all the three surgical disciplines (general surgery, gynaecology and urology) who participated in the study, a majority found in those simulators an opportunity to practice in between cases to keep their skills, to perfect them or even to learn new skills or tasks brought by new fellows recruited. An opening for continued surgical education was created (mini fellowships and preceptor ships).

FINAL CONCLUSION:

Teaching and evaluating surgical skills entered a new era. Simulation, evaluation and accreditation are domains in effervescence. Research is well advanced in general surgery; a great deal must still be done in gynaecology and in urology. Teaching methods are available, evaluation tools are being validated, and the training program or curriculum are evolving positively. By choosing carefully our pedagogical instruments, laparoscopy training can be taught and evaluated more effectively in gynaecology at the University of Montreal.

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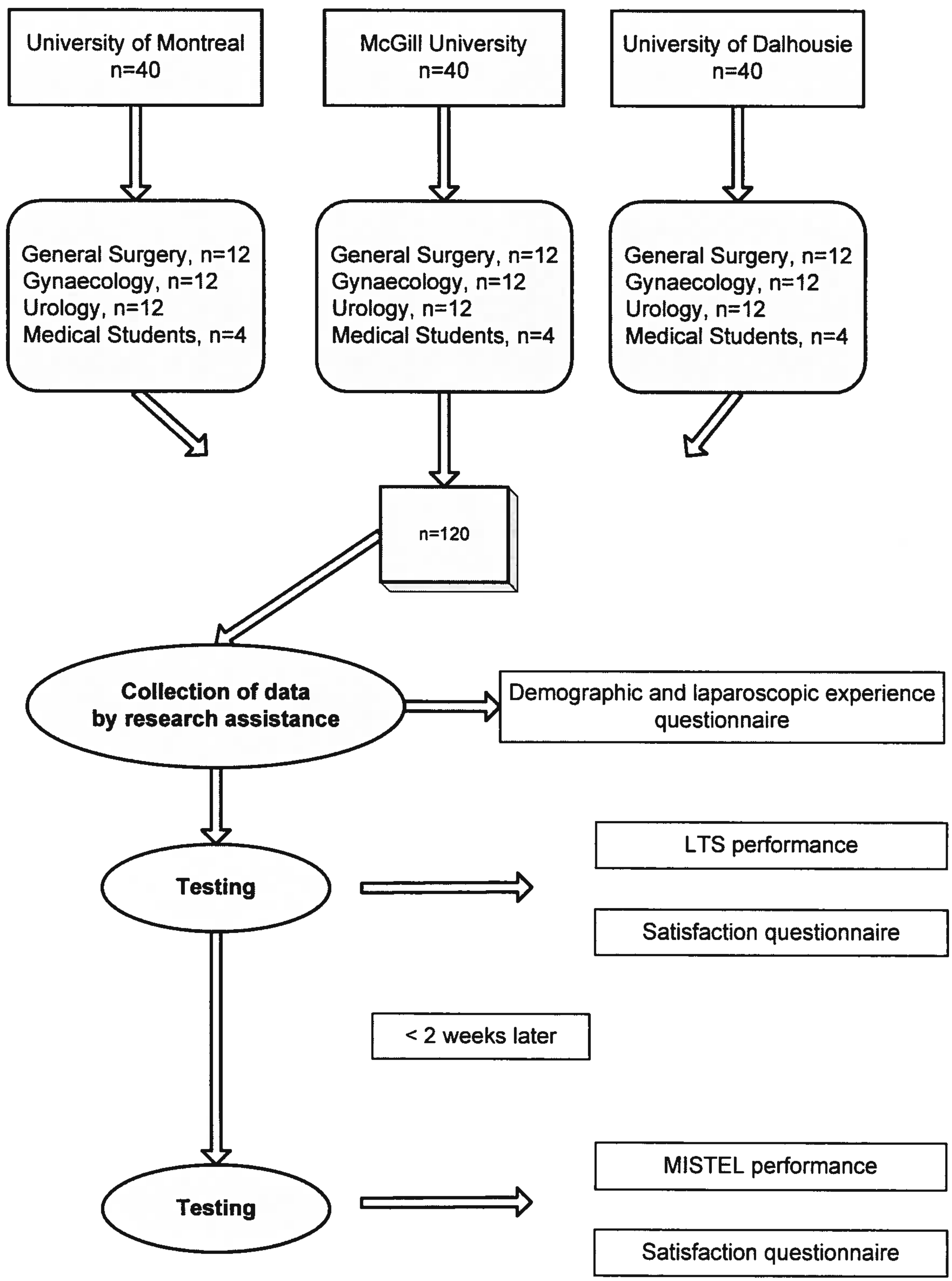
APPENDICES

A: PROTOCOL DESIGN



B: CONSENT FORM FOR EDUCATIONAL RESEARCH

How to choose the right physical laparoscopic simulator? LTS2000-ISM60 compared to MISTELS: validation, correlation and user's satisfaction

Investigators: A.Sansregret, MD, GM.Fried, MD, DR. Klassen, MD, HM.Hasson, MD

Institutions: Centre de recherche de l'Hôpital Ste-Justine, Steinberg-Bernstein Centre for Minimally Invasive Surgery at Montreal General Hospital and Queen Elizabeth II Health Sciences Centre

Purpose : The purpose of this study is to assess the construct validity and the reliability of the Laparoscopic Training Simulator (LTS) and to compare its results (5 shared tasks score) to the MISTELS simulator which is a reliable and valid instrument considered like the gold standard of inanimate simulators. Participants' satisfaction level will also be assessed on both simulators.

Procedures: You (student, resident, fellow and attending) will be asked to complete a questionnaire regarding laparoscopic experience, level of training, speciality and program. Then after viewing an instructional video, you will be scored during performance of the 10 tasks of the LTS 2000 ISM-60 simulator. These tasks will be scored for precision and speed using a standardized scoring system.

All the participants will also be asked to perform the MISTELS (McGill Inanimate System for Training and Evaluating Laparoscopic Skills) tasks (5) as well. The results will be analyzed and the construct validity of the LTS simulator, its reliability and its correlation with the MISTELS system will be assessed. Participants' satisfaction will be evaluated after each performance.

Advantages/disadvantages: You will have the opportunity to practice on the LTS simulator after the study has been completed. The main disadvantage is the time required to undergo the LTS (60-90 minutes) and the MISTELS (100-150 minutes).

Confidentiality: The data obtained will be kept confidential. The data will be coded and no name will be available to researchers. No information obtained from the study will be used in any way for evaluation of the skill or competence of the student, resident, fellow or physician. The information will not be available to the program director or department director. Questions may be answered by the investigators listed above.

Voluntary participation: I am aware that participation is voluntary and that refusal to participate or withdrawal from the study at any time will not involve any penalty or prejudice within the residency program.

Consent: I have read the above information and have had the opportunity to have all of my questions answered to my satisfaction. I agree to participate in this study and I have been given a copy of the research information and consent form. I am aware that by signing this form I do not give up any of my legal rights.

______________________	______________________
Signature of Participant	Signature of Investigator
______________________	______________________
Name of Participant	Name of Investigator

Date:______________________

C: PARTICIPANT FRENCH CONSENT FORM

Formulaire d'information et de consentement

TITRE : Projet d'étude en pédagogie médicale : Comment choisir le bon simulateur physique de laparoscopie?
Le LTS 2000-MS60 est comparé au MISTELS : validation, corrélation et niveau de satisfaction des utilisateurs.

CHERCHEUR PRINCIPAL : Andrée Sansregret, md
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BUT DE L'ÉTUDE :
Le but de cette étude est d'évaluer la validité de construit et la fiabilité du simulateur LTS (10 épreuves) et de comparer sa performance de pointage suite à 5 épreuves équivalentes et comparatives avec le simulateur MISTELS (McGill Inanimated System for Training and Evaluating Laparoscopic Skills) qui est un outil reconnu fiable et valide et considéré comme le standard de qualité des simulateurs inanimés. Ces deux simulateurs ont été conçus afin de développer et d'évaluer des habiletés chirurgicales de base en laparoscopie.

NATURE ET DÉROULEMENT DU PROJET :
En tant qu'étudiant (externe), résident junior et senior, fellow ou spécialiste en chirurgie générale, en gynécologie ou en urologie nous vous invitons à participer à ce projet de recherche éducationnel (dans le cadre de la pédagogie médicale).

Nous vous demanderons de compléter un questionnaire indiquant votre expérience pratique en laparoscopie, votre niveau de formation, spécialisation et programme. Suite au visionnement de la bande vidéo éducative et instructive, on vous demandera d'effectuer les 10 épreuves du simulateur LTS2000 ISM-60. Vous serez évalué selon un système de pondération standardisé basé sur la précision et la vitesse d'exécution pour chacune des tâches. Ce premier test vous demandera environ 60 minutes de votre temps.

Au cours des deux semaines qui suivront ce premier test, on vous demandera d'exécuter un deuxième test sur le simulateur de référence MISTELS qui comprendra 5 tâches correspondantes. Cela vous prendra environ 40 à 60 minutes de votre temps. Toutes ces interventions se dérouleront dans votre hôpital. Finalement, on vous demandera de remplir un questionnaire de satisfaction après votre performance sur chacun des simulateurs

L'analyse de ces résultats permettra de déterminer la fiabilité et la validité de conception du simulateur LTS2000, d'établir sa corrélation avec le modèle de référence MISTELS et de déterminer lequel est le plus apprécié par les participants.

Au total environ 120 professionnels et étudiants de 3 centres universitaires Canadiens participeront à cette étude.

AVANTAGES / DÉSAVANTAGES :
Vous aurez l'opportunité de vous exercer à l'utilisation du simulateur LTS après que l'étude soit complétée. Le seul désavantage est le temps requis afin de compléter l'examen.

CONFIDENTIALITÉ :
Les résultats obtenus seront gardés confidentiels et les données seront codées. Vos noms n'apparaîtront nulle part sur le questionnaire. Le chercheur peut décider qu'il est nécessaire de joindre aux données des informations supplémentaires, telles votre âge, sexe ou certaines données académiques sans toutefois que celles-ci permettent de vous identifier.

Les données obtenues ne seront utilisées qu'aux fins du présent projet. Aucune information obtenue au cours de ce projet ne sera utilisée pour évaluer la compétence et la dextérité des médecins ou étudiants. L'information ne sera ni disponible ni transmise aux directeurs de programmes et de départements.
Tous les renseignements obtenus dans le cadre de ce projet de recherche sont confidentiels. Cependant, aux fins de vérifier la saine gestion de la recherche, il est possible qu'un délégué du comité d'éthique de la recherche consulte les données. Par ailleurs, les résultats de cette étude pourront être publiés ou communiqués dans un congrès scientifique mais aucune information ne pouvant vous identifier ne sera dévoilée. Les données (questionnaires et évaluations) seront conservées à l'Hôpital Sainte-Justine sous la responsabilité du Dr. Andrée Sansregret pour une durée de 5 ans, après quoi elles seront détruites.

COMMUNICATION DES RÉSULTATS AUX PARTICIPANT :
Vos résultats personnels (temps, erreurs et pointages) vous seront transmis après chaque tâche par le simulateur LTS. Les mêmes résultats vous seront transmis verbalement par le superviseur après chaque tâche exécutée sur le simulateur MISTELS.

RESPONSABILITÉ DES CHERCHEURS :
En signant ce formulaire de consentement, vous ne renoncez à aucun de vos droits prévus par la loi. De plus, vous ne libérez pas les investigateurs et le promoteur de leur responsabilité légale et professionnelle advenant une situation qui vous causerait préjudice.

PARTICIPATION VOLONTAIRE/ DROIT D'ABANDONNER L'ÉTUDE :
Votre participation à cette étude est entièrement volontaire. Vous pouvez également vous retirer de l'étude à tout moment en faisant connaître votre décision à l'équipe de recherche. Votre refus de participer à l'étude ou de vous y soustraire n'entraînera aucune pénalité, ni aucun préjudice dans votre cursus médical ou votre pratique professionnelle.

INFORMATION ADDITIONNELLE :
Si vous désirez obtenir plus de renseignement concernant l'étude, vous pouvez contacter Maryse Lagacé, coordonnatrice de recherche, au: 514-345-4931 poste: 5747, ou le Dr Andrée Sansregret, investigateur principal, au 514-345-4788.

Pour tout renseignement sur vos droits à titre de participant à ce projet de recherche, vous pouvez contacter la conseillère à la clientèle de l'Hôpital Sainte-Justine, au 514-345-4749.

CONSENTEMENT :

On m'a expliqué la nature et le déroulement du projet de recherche. J'ai pris connaissance du formulaire de consentement et on m'en a remis un exemplaire. J'ai eu l'occasion de poser des questions auxquelles on a répondu. Après réflexion, j'accepte de participer à ce projet de recherche.

____

Nom du participant (Lettres moulées)

____ ______________

Signature du participant Date

____

Nom de la personne ayant obtenu le consentement (Lettres moulées)

____ ______________

Signature Date

ENGAGEMENT DU CHERCHEUR

Le projet de recherche sera décrit au participant ainsi que les modalités de la recherche) répondra à leurs questions et leur expliquera que la participation au projet de recherche est libre et volontaire. L'équipe de recherche s'engage à respecter ce qui a été convenu dans le formulaire de consentement.

____ ______________

Nom du chercheur (Lettres moulées) Date

____ ______________

Signature du chercheur Date

D: LTS DESCRIPTION

LTS 2000 ISM-60 system: It consists of an enclosure with a simulated multilayered abdominal wall and an adjustable floor mat to which various exercise models are attached with Velcro strips. The models are viewed through a stand-alone video camera (camcorder), a light source, a video monitor and VCR. Surgical manipulation of exercise models is carried out with standard laparoscopic instruments directed from strategically located ports. It consists of a rotating sensor platform (carousel) which is attached to the LTS2000 floor mat, as an additional model. The carousel contains 6 modules for performing structured laparoscopy training tasks. Physical sensors are embedded in each module (interactive sensing module (ISM60).

Simulated Laparoscopic Skills

A. Coordination Tasks

These tests for spatial perception and orientation, hand-eye coordination using dominant and non-dominant hands and precise manipulation and targeting.

Task 1: Peg Manipulation and Insertion

Instruments used: 2 rotating curved alligator forceps.

The candidate picks up 1 of 9 pegs from the container with the non-dominant hand, transfers it to the dominant hand and inserts it into a hole.

Scoring Parameter:

Number of pegs	- 6
Starting Point	- initial picking of first peg
Completion Point	- six pegs inserted
Max time	- 300 seconds
Penalties	-10 points deducted for each dropped peg to a maximum of 60 points. This is entered manually as errors occur by clicking or pressing the error button of the software or controller.

Task 2: Ring Manipulation and Guidance using Dominant Hand

Instruments used: 2 rotating curved alligator forceps.

The candidate picks up a conductive ring from its pod with the dominant hand, approaches the free end of the double curved post, mounts the ring over the post and guides it to the bottom, while avoiding contact with the metallic post.

Rotating the jaws of the forceps facilitates achieving circular motion. Once the ring is located at the bottom of the post, the candidate stretches it gently to place its free end around the short metallic post and activate the sensor.

<u>Scoring Parameters</u>:

Number of rings	- 1
Starting Point	- initial picking of ring from its pod.
Completion Point	- ring located around short metallic post, stable for 3 seconds.
Max time	- 120 seconds
Penalties	- 10 points deducted for each ring drop to a maximum of -30 points. Errors entered manually as they occur.
	- 10 points deducted for each second of contact between ring and post, to a maximum of 60 points (calculated electronically).
	- Breaking the ring while stretching it results in a score of zero, as the sensor will not be activated. This penalty is entered after the exercise is completed.

<u>Task 3: Ring Manipulation and Guidance using Non-Dominant Hand</u>
Same as task 2, using the non-dominant hand on the second ring.

<u>Task 4: Ductal Cannulation using Dominant Hand</u>
Instruments used: 2 alligator forceps.
The candidate uses the non-dominant hand to stabilize, elevate and orientate the simulated duct. The dominant hand grasps the flexible rod, introduces it into the duct, threads it through the duct and pulls it from the other end.

<u>Scoring Parameters:</u>

Starting Point	- initial grasping of the duct with the non-dominant hand or grasping of the rod with the dominant hand.
Completion Point	- rod pulled out completely from the opposite end
Max Time	- 100 seconds
Penalties	- 10 point deducted for each dropped rod to a maximum of -20 points. Errors entered manually as they occur.

<u>Task 5: Ductal Cannulation using Non-Dominant Hand</u>
Same as task 4, reversing the role of the two hands. The rod is introduced into the side of the previous exit, using the non-dominant hand.

<u>**B. Suturing and Knot Tying Tasks**</u>

These tasks test for the ability to place and tie suture knots, which require special skills in addition of those of coordination.

<u>Task 6: Lasso Loop Formation</u>
Instruments used: None
Using a long segment of 0 silk suture (90 cm or 36"), the candidate forms a Roeder type loop with 3 suture wraps on the external post. The loop is then tested for sliding.

<u>Scoring Parameters:</u>

Starting Point	- crossing suture over external post.
Completion Point	- correct sliding loop formed.
Max Time	- 120 seconds.
Penalties	- Zero score is given if the loop is not formed properly. In this case, the instructor forms the loop and gives it to the trainee to perform Task 7.

<u>Task 7: Lasso Loop Target Cinching</u>

Instruments used: 2 alligator forceps, knot pusher and small hemostat.
The candidate holds the long free end of the suture with the hemostat and brings the pre-formed loop into the simulator. The loop knot should be held with an alligator forceps while being introduced into the port to prevent it from unravelling. Once into the simulated abdomen, the open loop is advanced toward the vertically oriented silastic tube and the silastic tube is pulled into the loop with an alligator forceps. The loop is advanced further and positioned over the pre-marked area. The loop is then tightened by pulling on the suture end attached to the hemostat and cinched with a knot pusher. The suture is not cut.

<u>Scoring Parameters:</u>

Starting Point	- Bringing the open suture loop into the simulator.
Completion Point	- Achieving a predetermined tension within the tube that is maintained for 3 seconds.
Max time	- 180 seconds
Penalties	- 50 points deducted for cinching the knot outside of the 6 mm target area. This penalty is entered manually after the task is completed. Zero score is given if the end point is not achieved.

<u>Task 8: Extracorporeal Knot-tying Around a Horizontal Tube</u>

Instruments used: 2 alligator forceps, knot pusher, scissors, and a small hemostat.

Using a long silk suture segment (90 cm [36"] in length), the surgeon brings the free suture into the simulated abdomen keeping one end outside the simulator captured with a hemostat. The surgeon gently lifts the horizontally oriented silastic tube with one alligator forceps, feeds the free suture under the tube and pulls it gently outside of the abdomen to encircle a simulated artery in the premarked zone. Two suture sides are evened out in length. The candidate forms a flat half hitch outside the simulated abdomen and takes it down to the target area with a knot pusher. The surgeon throws one more half hitch in the same direction so as to make a granny slip-knot. The surgeon slides the hitch downward with the knot pusher and cinches the knot tightly. The suture is then cut.

<u>Scoring Parameters:</u>

Starting Point	- Bringing the suture into the simulated abdomen.
Completion Point	-Achieving a predetermined tension within the tube that is maintained for 3 seconds.
Max time	- 300 seconds.
Penalties	- 50 point deducted for cinching the knot outside of the 6 mm target area. This penalty is entered manually after the task is manually completed. Zero score is given if the end point is not achieved.

<u>Task 9: Placement of Stitch and Testing of Intracorporeal Knot</u>
Instruments used: 2 needle holders (one curved), 2 alligator forceps (one curved), and scissors.

Using a curved or Ski needle swedged on 0 silk suture with a working length of 15 cm, the exercise begins when the candidate first pick up the needle from its pad. The candidate orients the needle properly within the needle holder and takes a full thickness purchase into one side of the simulated incision then the other side within the premarked area.

The candidate makes two half hitches in opposite directions (so as to form a square knot). After the knot is tied, the done button on the controller is pressed or the done button of the software is clicked to activate the tensiometer and test the knot.

<u>Scoring Parameter:</u>

Staring Point	- Picking up the needle from its sponge pad.
Completion Point	- Knot is not loosened with a disruptive force of 2,5 lbs (1 kg) applied to the tensiometer.
Max time	- 480 seconds.
Penalties	- If the knot fails, the score is zero. 50 points deducted if the stitch is placed outside of the marked area. This is entered manually after the exercise is completed.

<u>C. Precise Cutting Task</u>

<u>Task 10: Circle Cutting:</u>
Instruments used: 2 alligator forceps, sharp curved scissors.
The surgeon positions a circle cutting disk on top of the exercise housing, aligns the 3 pins of the housing with matching perforation in the disk and presses the disk paper against the pins until the disk is securely seated at the bottom of the pins.

Using a sharp laparoscopy scissors in the dominant hand and alligator forceps in the non-dominant hand (for traction), the surgeon cuts into the disk paper along one of the yellow passages leading to a yellow circle. The exercise time starts with the initial cut in the disk paper. The paper disk should be cut completely within the yellow circle. Once it is freed, the disk is loosened and removed from the pins using 2 alligator forceps working together. Removal of the disk from the housing represents successful completion of the task. Penalty points are deducted for veering outside or inside the yellow circle.

Scoring Parameters:

Starting Point	- Initial cut in disk paper.
Completion Point	- Removal of the paper disk from the housing.
Max time	- 300 seconds.
Penalties	The inner disk (cut piece) is examined; 5 points are deducted for each color fraction seen outside the yellow zone. The outer disk (remaining piece) is examined; 5 points are deducted for each color fraction seen inside the yellow zone to a maximum of 100 points. This penalty is entered manually after the task is complete

Scoring Procedure

The timing of each task is started manually by pressing the start-reset button of the system controller or by clicking on the start-reset button of the ISM60 software at a specific starting point for each task. For exercises 1 through 5, penalty point for committing errors are deducted as they occur during the performance of the exercise, by clicking on the error button of the ISM60 software or by pressing the error button of the system controller. This results in automatic deductions from the speed score giving an electronic net score at the completion of the exercise (task). Breaking the ring in exercise 2 or 3 results in a net score of zero.

For tasks 6 through 10, penalties are assessed after the exercise is completed. A zero score is given in exercises 6 through 9 if the candidate fails to achieve the end point, regardless of time: a properly formed Roeder loop in task 6, a predetermined tension within the clinched tube (sustained for 3 seconds) in tasks 7 and 8 and a properly constituted square knot that does not unravel with a disruptive force of 1 kg in task 9. If the end point is achieved within the max time, 50 points are deducted for lack of precision: cinching the tube outside of the target area in task 7 and 8 or placing the stitch outside the target area in task 9. In cutting exercise 10, 5 points are deducted for each color fraction noted inside or outside of the identified color-coded zone.

Additional information will be available in the instruction manual (sent with the simulator).

E: MISTELS DESCRIPTION AND QUESTIONNAIRE

McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS): a bench model simulator that includes 5 tasks in an inanimate box. Performance is scored for speed and precision. The tasks are designed to provide practice on specific laparoscopic skills such as bimanual dexterity, suturing and cutting

Description of the simulator

The simulator consists of a laparoscopic trainer box measuring 40 x 30 x 19,5 cm, covered by an opaque membrane. Two 12-mm trocars are placed through the membrane at convenient working angles on either side of the 10-mm zero degree laparoscope. Four alligator clips within the simulator are used to suspend materials for certain exercises. The laparoscope and camera are mounted on a stand at a fixed focal length. This enables the examinee to work independently. The optical system consists of the laparoscope, camera, light source and video monitor. The video monitor is placed in line with the operator.

MISTELS system tasks

Task 1: Pegboard pattern

The operator is required to lift each of six pegs from the pegboard with the left hand, transfer it to the right hand, and place it on another pegboard. This procedure is then reversed. The cut off time is set at 300 seconds. A penalty score is calculated as the percentage of pegs that could not be transferred as a result of being dropped outside the field of view.

Task 2: Pattern cutting

This task requires a 4-cm diameter premarked circular pattern to be cut out of a 10 X 10 cm piece of gauze suspended between alligator clips. The examinee uses a grasper in one hand and places the material under tension while cutting with endoscopic scissors that are held in the other hand. The cut off time is 300 seconds. The penalty score is determined by calculating the percentage area of deviation from a perfect circle.

Task 3: Placement of a ligating loop

This task involves the accurate placement and tightening of a commercially available prettied slip knot on a tubular foam appendage. The procedure involves back loading the ligating loop into a reducer, stabilizing the appendage, accurately and securely setting the knot, and cutting the excess suture. Cut off time is 180 seconds. The penalty score is calculated by measuring the distance (mm) of the loop away from the premarked position. A 50-point penalty is given for any insecure or failed knot.

Task 4 and 5: Intracorporeal and extracorporeal knots

A simple suture is placed through pre-marked points in a longitudinally slit penrose drain. The suture is then tied using either an intracorporeal knot (task 4) or an extracorporeal knot (task 5). Cut off time is 600 seconds for the intracorporeal knot and 420 seconds for the extracorporeal knot. A penalty score is calculated to reflect the accuracy and security of the suture. The penalty score is based on the total distance in mm of deviation from the premarked points and the gap in mm if the suture fails to approximate the slit. Additional points are given based on the security of the knot (0 points for a secure knot, 10 for a slipping knot, and 20 for a knot that comes apart).

Questionnaire: Evaluation of laparoscopic experience

Date: ____________________________

No.: ____________________ (office use)

Specialty: ________________________

please circle response

Gender: Male Female

Age: _______

Level of training: MedSt R1 R2 R3 R4 R5 Fellow Staff

Handedness: R L Ambidextrous

<u>SURVEY OF EXPERIENCE</u>: *Please circle response*

<u>Basic Laparoscopic Procedures:</u>

1) Number of times I have performed a laparoscopic cholecystectomy, Lap ectopic pregnancy:

As surgeon (majority of the case):

Never 1-5 5-10 10-20 20-50 >50

As Assistant:

Never 1-5 5-10 10-20 >20

2) Number of times I have performed a diagnostic laparoscopy, lap tubal ligation, laparoscopic biopsy, laparoscopic adhesiolysis:

As surgeon:

Never 1-5 5-10 10-20 >20

As Assistant

Never 1-5 5-10 10-20 >20

3) Number of times I have performed a laparoscopic appendectomy:

As surgeon:

Never 1-5 5-10 10-20 >20

As Assistant:

Never 1-5 5-10 10-20 >20

Advanced Laparoscopy:

4) Number of times I have performed a Laparoscopic Nissen Fundoplication, Laparoscopic Pyeloplasty (urology):
   As surgeon:
      Never 1-5 5-10 10-20 >20

   As Assistant:
      Never 1-5 5-10 10-20 >20

5) Number of times I have performed a Laparoscopic Splenectomy:
   As Surgeon:
      Never 1-5 5-10 10-20 >20

   As Assistant:
      Never 1-5 5-10 10-20 >20

6) Number of times I have performed a Laparoscopic Bowel Resection:
   As Surgeon:
      Never 1-5 5-10 10-20 >20

   As Assistant:
      Never 1-5 5-10 10-20 >20

7) Number of times I have performed a Laparoscopic Adrenalectomy:
   As Surgeon:
      Never 1-5 5-10 10-20 >20

   As Assistant:
      Never 1-5 5-10 10-20 >20

8) Number of times I have performed a Laparoscopic Nephrectomy, Nephroureterectomy:
   As Surgeon:
      Never 1-5 5-10 10-20 >20

   As Assistant:
      Never 1-5 5-10 10-20 >20

9) Number of times I have performed Laparoscopic Bariatric surgery:
   As Surgeon:
      Never 1-5 5-10 10-20 >20

   As Assistant:
      Never 1-5 5-10 10-20 >20

10) Number of times I have performed Laparoscopic Inguinal/Incisional Hernia Repair:
As Surgeon:
Never 1-5 5-10 10-20 20-50 >50

As Assistant:
Never 1-5 5-10 10-20 >20

11) Number of times I have performed Laparoscopic Prostatectomy, Laparoscopic partial nephrectomy:
As Surgeon:
Never 1-5 5-10 10-20 >20

As Assistant:
Never 1-5 5-10 10-20 >20

12) Number of times I have performed Laparoscopic ovarian cystectomy, oopherectomy, salpingo-oopherectomy, resection of endometrial implants:
As Surgeon:
Never 1-5 5-10 10-20 >20

As Assistant:
Never 1-5 5-10 10-20 >20

13) Number of times I have performed Laparoscopic Myomectomy, Hysterectomy, Lap-assisted vaginal hysterectomy, laparoscopic uterine suspension:
As Surgeon:
Never 1-5 5-10 10-20 >20

As Assistant:
Never 1-5 5-10 10-20 >20

14) Number of times I have performed another advanced procedure:
Please name procedure(s): ______________________________

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As Surgeon:
Never 1-5 5-10 10-20 >20

As Assistant
Never 1-5 5-10 10-20 >20

PREVIOUS SIMULATOR EXPERIENCE:

Approx # hours:

MISTELS_____ LapSim____ MIST-VR ____ Wet lab_____ Other (specify)_____

F: ACGE AND SAGES CLASSIFICATION COMBINED

Basic procedures

General Surgery
-cholecystectomy
-appendectomy

Gynecology
-ectopic pregnancy
-tubal ligation
-diagnostic laparoscopy
-laparoscopic biopsy

Urology
-none

Complex procedures

General Surgery
-Nissen funduplication
-splenectomy
-bowel resection
-adrenalectomy
-bariatric surgery
-inguinal/incisional hernia repair

Urology
-pyeloplasty
-nephrectomy
-partial nephrectomy
-nephroureterectomy
-prostatectomy

Gynecology
-ovarian cystectomy
-oophorectomy
-salpingo-oophorectomy
-resection of endometrial implants
-myomectomy
-hysterectomy
-lap-assisted vaginal hysterectomy
-uterine suspension

G: SATISFACTION QUESTIONNAIRE

How to choose the right physical laparoscopic simulator? LTS2000-ISM60 compared to MISTELS: validation. correlation and user's satisfaction

No.: ______________________
(office use)

1. Please circle the simulator used:

LTS MISTELS

2. Please indicate with an X your level of satisfaction for the simulator used on this visual analog scale:

FANTASTIC

3. Please give the main reason why your university should get this simulator?

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H: GLOBAL ASSESSMENT BY REZNICK

GLOBAL RATING SCALE OF OPERATIVE PERFORMANCE
Please circle the number corresponding to the candidate's performance in each category, irrespective of training level.

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