



Face-, expert, and referent validity of the Xitact LS500 Laparoscopy Simulator

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Abstract

Background: This study was undertaken to establish face-, expert, and referent validity of the Xitact LS500; a virtual reality laparoscopic cholecystectomy simulator.

Methods: A four-page, 20-item structured questionnaire was presented to 120 surgeons attending a surgical convention. Participants received an instructed hands-on “tour” on the Xitact simulator. Data were analyzed according to the level of experience of the surgeon, resulting in an “expert group opinion” of 87 surgeons and a “referent group opinion” of 33 surgeons.

Results: The majority of respondents believe Xitact has the potential to become a useful tool in teaching (93.1%) and measuring performance assessment (79.3%) in laparoscopic cholecystectomy. Expert- and referent-group opinion does not differ significantly on any of the presented statements. The opinion regarding the realism of the virtual laparoscopic cholecystectomy environment is favorable among both groups, although it is considered not yet perfect. The “haptic feedback” sensation of the Xitact is a parameter that needs further development.

Conclusions: Both expert- and referent surgeons value Xitact to be an important and useful tool in the laparoscopic teaching setting. Further studies need to be performed to establish the construct validity of the simulator (e.g., to what extent is the simulator logically encompassed into a theoretical framework of acquiring skills, needed for the laparoscopic cholecystectomy) to measure shortening of learning curves on the laparoscopic cholecystectomy procedure, and ultimately to justify its use in the surgical curriculum.

Key words: Surgical skills — Surgical simulation — Virtual reality — Laparoscopy — Objective assessment

For some time, laparoscopic cholecystectomy has replaced the open cholecystectomy as treatment-of-choice for symptomatic cholelithiasis. Skills needed to perform laparoscopic cholecystectomy correctly cannot be ex-

trapolated from skills acquired from performing the open procedure, since the laparoscopic technique requires distinct psychomotor abilities, hand–eye coordination, and different skills than those needed for the open procedure. At present, residents-in-training are introduced to the procedure mainly by classical surgical apprenticeship, that is, by guided hands-on operating room experience. However, there are no existing standards that must be met by a surgeon to practice this technique safely [13]. Moreover, there is no agreement whatsoever on the method or the means with which to measure laparoscopic performance objectively.

It is inevitable for surgeons learning a certain surgical procedure to go through a learning curve. Acquiring laparoscopic surgical skills involves initial learning and further refinement of cognitive and psychomotor skills [2]. Related to the acquisition of such skills are performance errors. These errors will occur less often only when surgeons become more skilled, i.e., toward the end of the individual learning curve. In current medical practice, it is not only a challenge but merely a necessity to shorten learning curves safely in order to diminish avoidable errors in the clinical setting. Practice on patients is no longer considered acceptable. The Senate of Surgery of Great Britain and Ireland have declared that no surgeon should undertake any operative procedure unless competent to do so [9]. This statement is in dispute with the classical surgical apprenticeship model. One way to shortcut the learning curve safely *outside* the clinical setting is by means of creating an alternative, equally informative and effective teaching setting. The surgical skills laboratory may play an important role in the acquisition of skills in minimal access surgery, and surgical curricula should contain a laparoscopic skills training program [8, 12]. Such a training setting requires a stimulating, tension-free environment that must be highly similar to the actual working environment, and, most importantly, the surgical community itself must be willing to adopt its concept.

New technologies, such as virtual reality surgical simulators and objective methods of assessment, are powerful instruments that could improve a physician's

competence and overall quality of patient care if validated and implemented properly. Ongoing improvements in this technology suggest an important role for virtual reality and simulation in surgical education and training [6]. Virtual reality simulators ideally present a computer-generated “natural” representation of an environment allowing sensory (sound, sight, and touch) interaction. Other high-risk professions, such as in the field of aviation, aerospace, maritime, military, and nuclear energy, have been using such simulators for the purpose of training difficult and demanding tasks. In doing so, these industries have reduced errors to nearly zero. Since 1955, examination on a flight simulator has been required by the aviation industry and military as a component for certification and annual recertification. Currently, all military and commercial pilots must train and be certified in their technical skills on a flight simulator specific for the aircraft they will fly [11]. Although simulation and objective assessment methods for medical and surgical procedures are in their infancy, new technologies are challenging and gaining rapid interest in the surgical community. Virtual reality computer simulation of laparoscopic procedures is an era that is developing fast. The very nature of laparoscopic surgery makes it likely to benefit from developments in virtual reality and telepresence technology [3].

Logically, the more closely a virtual reality training instrument mimics the realism of the actual procedure in the operating room, the more valid it will be for the acquisition of surgical skill. Any useful surgical virtual reality simulator will need accurate, realistic depiction of detail combined with a high level of sensory interaction. Previous studies have shown potential and interest for virtual reality trainers in the field of laparoscopic surgery in terms of tutoring, training, and assessing skills and performance [2, 4, 5, 7, 9, 10, 14–18]. The Xitact LS500 is the virtual reality laparoscopic simulator under study. The value of a teaching instrument such as the Xitact LS500 can only be assigned if both surgeons who are beyond the learning curve of the procedure under study (expert opinion) as well as the potential trainee (referent opinion) believe in it. An important step in establishing the validity of any new technological equipment is the concept of face validity. Face validity addresses the question: to what extent does the instrument simulate what it is supposed to represent, e.g., the procedure of the laparoscopic cholecystectomy.

The current study focuses on expert and referent face validity of the Xitact LS500 Laparoscopic cholecystectomy simulator.

Methods

Subjects

One hundred and twenty surgeons and surgical residents with no previous knowledge or exposure to the apparatus were introduced to the Xitact LS500.

Eighty-seven participants were questioned at the 87th Annual Clinical Congress of the American College of Surgeons, held 7–12 October in New Orleans, LA. Thirty-three participants were questioned during the International Symposium of Laparoscopic Surgery, held 25–

27 October in Paris, France. All participants were given an instructed “tour” to familiarize them with Xitact LS500, its features, and the laparoscopic cholecystectomy simulation. The “tour” incorporated a hands-on instruction of approximately half an hour by trained instructors. Afterwards, participants were asked to fill in a questionnaire on virtual skills training and testing, and on the experience with the Xitact LS500 laparoscopic cholecystectomy simulation more specifically.

Questionnaire

The questionnaire consisted of a four-page, 20-item survey. Next to participant’s demographics and surgical laparoscopic experience, nine questions concerning the visual scene, haptic feedback, evaluation of location, deformation, movement, surgical techniques, design, and ergonomics of the simulator were presented on a 5-point ordinal answering scale. Value 1 was assigned to “not realistic/good/useful,” value 5 to “very realistic/good/useful.” The usefulness of the simulator in terms of training/teaching capacities was questioned. Also, several open-ended questions concerning missing elements in Xitact, expectations toward virtual reality simulating settings, and need for virtual reality surgical training procedures were proposed. Finally, eight statements concerning Xitact and the need for training by virtual reality were proposed.

Apparatus

The Xitact LS500 Laparoscopy Simulators (Fig. 1) a modular virtual reality training program developed for training and education of a variety of laparoscopic skills. It is a hybrid simulator, combining a physical object (the OpTable, or “virtual abdomen”) with a computer program providing the visual image and haptic feedback.

The program featured and under study is the Laparoscopic Cholecystectomy simulation. The Xitact LS500 is developed and registered by Xitact SA, Lausanne, Switzerland.

Hardware

The hardware of the Xitact LS500 is a modular system containing:

- *Mtower Monitor Tower.* The Mtower (0.6 m × 1.0 m × 0.4 m, 20 kg) is an independent and freely movable tower that supports a flat panel 18-inch TFT monitor with a resolution of 1280 × 1024 pixels.
- *OpTable Operation Table.* The OpTable-console (0.6 m × 0.7 m × 0.7 m, 50 kg) houses the “abdomen” of the virtual patient, the endoscopic instruments, and the endoscopic camera. Two instruments are mounted in the OpTable, with the possibility of using a virtual third instrument by using a “freeze” software-generated option. The instruments have high-performance Force Feedback with five degrees of freedom, featuring performance, precision, and force feedback on original endoscopic instruments. One endoscope is mounted, with four degrees of freedom, offering several optical axis angles featuring a freeze picture switch combined with adjustable positioning possibilities. The console is topped by an exchangeable port-positioning matrix, enabling various trocar placement possibilities for different procedures. The OpTable’s height is adjustable according to the operator’s height, there is a Trendelenburg capacity, and the OpTable has a connected two-pedal foot switch for simulation of electrosurgical coagulation.
- *Ebox Electronic Box.* The Ebox (0.6 m × 0.7 m × 0.6 m, 25 kg) houses the electronics of the system and is connected to the OpTable. The box includes an industrial personal computer, system memory 512 MB RAM, 20 GB Hard disk. Operating system Microsoft Windows 2000 Professional, CPU Intel Pentium III 1 GHz; video: GeForce II GTS. The electric characteristics of the system include a mains voltage of 100–249 V, 50–60 Hz and a maximum power consumption of 750 W for the entire system.

Software

The following scenes are featured: exposure of the abdominal cavity and the gallbladder region, dissection of Calot’s triangle, clipping and

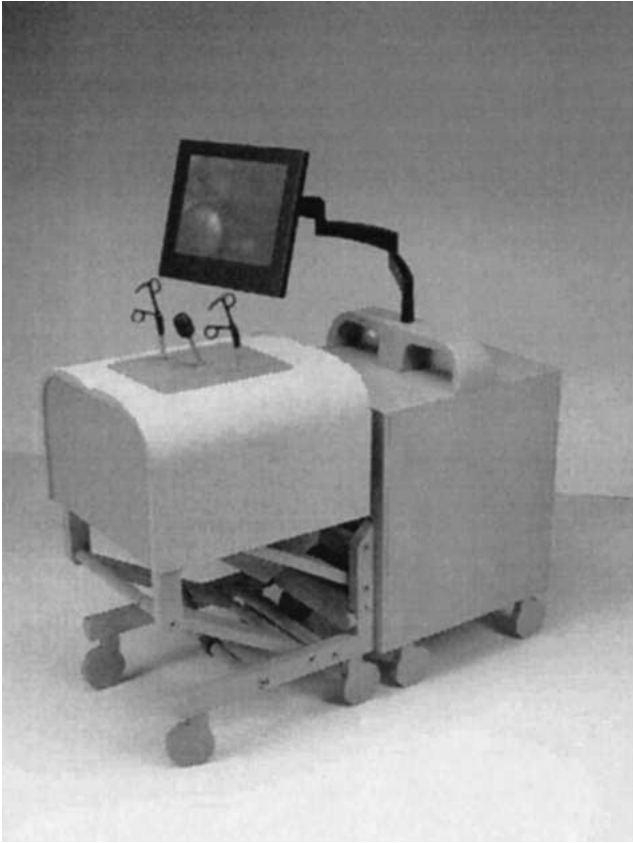


Fig. 1. Xitact hardware.

cutting of the cystic artery and duct. The system incorporates a combination of multimedia elements including text, surgical video clips with voice-over, simulation recordings, and example patient cases. The tasks of the laparoscopic cholecystectomy procedure (insufflation, trocar placement, exploration, clipping, cutting, separation, extraction, and closure) are demonstrated (Fig. 2). The various aspects of the procedure can be assigned and repeated in any desired combination. Different anatomical varieties of Calot's triangle are currently under construction.

Computer

Data recorded by the computer include time per task and error rates (loss of and incorrect placement of clips). Real-time analysis of hand motions to give continuous assessment of skills performance is possible as tool trajectories are recorded.

Recordings of "economy of movement" for the performer are currently under construction.

Statistics

Data were analyzed using the Statistical Package for the Social Sciences, version 9.0.

Results

Demographics

One hundred and twenty surgeons participated in this study, originating from 19 different countries. Fifty percent of them are inhabitants of the United States, and

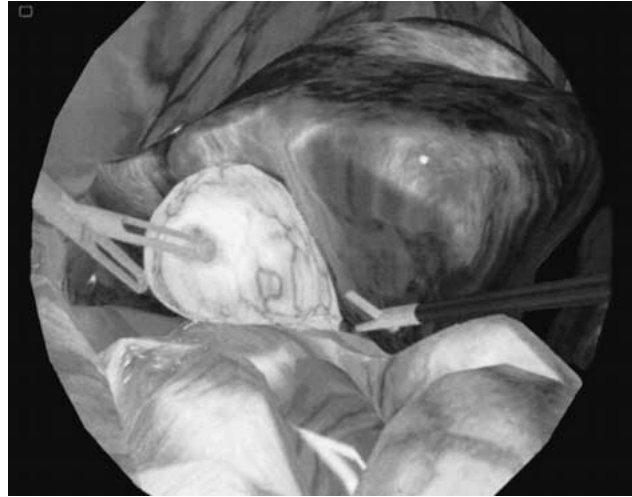


Fig. 2. Xitact scenery.

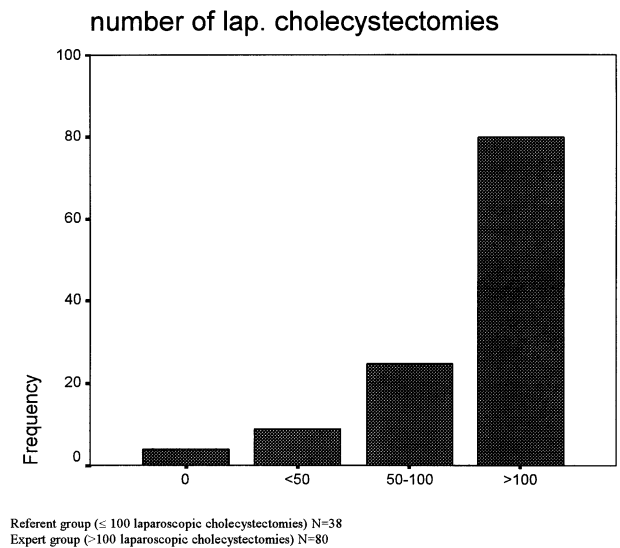


Fig. 3. Number of laparoscopic cholecystectomies.

17% are inhabitants of France. The mean age of the participants is 44 years, ranging from 24 to 88 years of age. There are 13 females in the study (10.8%) and 107 males (89.2%). Dexterity results in 7.6% left-handedness, 76.3% right-handedness, and 16.1% ambidexterity. Of all participants, 96.6% are working as general surgeons, 0.8% as gynecologists, 0.8% as thoracic surgeons, and 1.7% are from other occupations. Of all participants, 65.8% are qualified specialists, 10.3% are in their sixth year of training, 9.4% are in the fifth year of training, 4.3% are in the fourth year of training, 7.7% are in the third year of training, and 2.6% are in the second year of training.

Figure 3 represents the number of laparoscopic cholecystectomies performed by the participants. Thirty-eight respondents have performed fewer than or equal to 100 laparoscopic cholecystectomies. This group of respondents is considered to be the "referent group." Eighty respondents have performed more than 100 laparoscopic cholecystectomies, and this group is considered to be the "expert group."

Table 1. Xitact rating (1; not realistic, to 5; very realistic)

	Total Mean	Referent group ≤ 100		Expert group > 100		<i>p</i> -value ^a <i>N</i> -33/ <i>N</i> -87
		Mean	SD	Mean	SD	
Global realism of the virtual laparoscopic cholecystectomy environment in Xitact	3.42	3.47	0.83	3.38	0.99	1.00
Visual realism	3.59	3.66	0.75	3.56	0.76	0.878
Reality of haptic feedback (tactile sensation) of organs/structures	3.07	2.98	1.00	3.09	0.87	0.680
Position/location of organs/structures relative to each other	3.93	4.03	0.73	3.87	0.78	0.928
Reality of deformation organs/structures upon grasping or manipulating	3.38	3.34	0.84	3.41	0.73	0.922
Reality of movement of organs/structures upon grasping or manipulating	3.49	3.50	0.93	3.48	0.85	1.000
Reality of exposure using laparoscopic instruments	3.88	4.09	0.74	3.78	0.87	0.713
Reality of clipping	3.92	3.97	0.84	3.91	0.83	1.000
Reality of cutting	3.98	4.03	0.81	3.94	0.78	1.000
Reality of dissection	3.30	3.29	1.15	3.30	1.25	1.000
Reality of diathermia	3.62	3.53	1.06	3.67	1.16	0.908
Design of simulator	4.00	4.03	0.65	4.00	0.66	1.000
Overall ergonomics	3.87	4.03	0.63	3.81	0.77	0.688
Trocard port placement	3.93	4.00	0.78	3.91	0.86	1.000
Freedom of movement of instruments	3.87	4.00	0.77	3.81	0.88	0.836
Force feedback while interacting with organs	3.33	3.42	1.20	3.27	1.06	0.995

^a Kolmogorov–Smirnov test, two-sided, group ≤ 100 laparoscopic cholecystectomies vs group > 100 laparoscopic cholecystectomies

Face validity

Table 1 refers to the similarity of the Xitact laparoscopic cholecystectomy environment to surgeons' actual experience with or perception toward clinical laparoscopic cholecystectomy.

Expert opinion is represented by surgeons having performed more than 100 laparoscopic cholecystectomies, referent opinion by surgeons having performed fewer than 100. Compared to the overall mean ("Total mean"), the expert opinion tends to be more conservative. Nevertheless, overall opinion about Xitact is favorable, with the item's visual realism, position/location, reality of exposure, clipping, cutting, and diathermia scoring above 3.5. The exterior of the apparatus resembles the actual working situation quite well, with scores approaching 4.0 (design of simulator, overall ergonomics, trocar port placement, freedom of movement of instruments). The reality of the haptic feedback, as represented by "reality of haptic feedback" and "force feedback while interacting with organs," is considered to be not very realistic. Referent and expert group are uniform in their opinion on presented questions.

Training capacities

Almost all respondents believe it is necessary to participate in a basic laparoscopic skills course before operating on patients (94%); in fact, experts feel this even more strongly (96.2%) (Table 2). Respondents feel it is important to train surgical residents using laparoscopic virtual reality settings such as Xitact (83.6%). Again, experts agree even more so (87.3%), but groups do not differ significantly in their opinion (FET 0.199). High ratings are obtained for the statement that Xitact could become a useful tool in teaching laparoscopic chole-

cystectomy (93.1% agree), and the referent group is particularly enthusiastic (97.3% agree). Respondents also believe Xitact provides a user-friendly environment for training of laparoscopic skills (89.6%). Many respondents feel Xitact is already useful (67.2%), but more respondents believe it could *become* a useful tool (79.3%) in measuring performance assessment in laparoscopic procedures. Related to this, is the potential of Xitact to monitor individual progress. Respondents believe Xitact to be an important instrument (81.2%) to monitor progress.

In summary, the majority of respondents believe and agree Xitact could become a useful tool in teaching and monitoring progress in laparoscopic cholecystectomy.

Suitability of Xitact related to the surgical curriculum

Xitact is considered to be of use in all stages of the surgical curriculum and thereafter. Xitact is considered to be most useful for surgical residents-in-training, especially by the referent group themselves (4.40) (Table 3).

Xitact is considered to be of value in terms of error reduction and skills enhancement.

Discussion

Results of this study show a favorable and uniform opinion among both referent and expert groups regarding the face validity of the virtual reality laparoscopic cholecystectomy as presented by Xitact. The term validity means no less and no more than an accurate representation and extrapolation of the results from the research population to the target population under study (internal validity). In our study, there are two

Table 2.

Statement	Disagree	Agree	Do not know	FET ^a
I believe it is necessary for surgical residents-in-training to participate in a basic laparoscopic skills course before operating on patients	5.1% T 8.3% R 3.8% E	94.0% T 88.9% R 96.2% E	0.9% T 2.8% R	0.369
I believe it is important to train surgical residents-in-training using laparoscopic virtual reality settings such as Xitact before operating on patients	11.2% T 17.1% R 8.9% E	83.6% T 74.3% R 87.3% E	5.2% T 8.6% R 3.8% E	0.199
I believe it is important to monitor surgical residents-in-training in their progress on laparoscopic skills throughout their residency by using a laparoscopic virtual reality setting	11.1% T 16.2% R 9.0% E	81.2% T 75.7% R 84.6% E	7.7% T 8.1% R 6.4% E	0.340
I believe Xitact is a useful instrument for measuring performance assessment in laparoscopic procedures	12.9% T 13.5% R 13.0% E	67.2% T 70.3% R 66.2% E	19.8% T 16.2% R 20.8% E	1.000
I believe Xitact could become a useful instrument for measuring performance assessment in laparoscopic procedures	9.5% T 8.1% R 10.4% E	79.3% T 75.7% R 80.5% E	11.2% T 16.2% R 9.1% E	1.000
I believe Xitact provides a user-friendly environment for training laparoscopic skills	4.3% T 6.6% E	89.6% T 91.9% R 88.2% E	6.1% T 8.1% R 5.3% E	0.174
I believe Xitact could become a useful tool in teaching laparoscopic cholecystectomy	0.9% T 1.3% E	93.1% T 97.3% R 90.9% E	6.0% T 2.7% R 7.8% E	1.000
I believe Xitact has potential to be a cost-effective simulator for laparoscopic cholecystectomy	8.8% T 8.6% R 9.2% E	54.9% T 48.6% R 56.6% E	36.3% T 42.9% R 34.2% E	1.000

T, total group, $N = 120$; E, expert group, $N = 87$, R, referent group, $N = 33$

^a Fisher Exact Test, two-sided, group Expert vs Referent group on responses agree vs disagree

target populations, that is, expert (qualified surgeons experienced in laparoscopic cholecystectomy) and referents (surgical trainees). The term face validity refers to the resemblance of a test task to the actual clinical task, in other words: does the task on the apparatus resemble what it claims to resemble? In our study, this means the extent to which the virtual reality laparoscopy on Xitact mimics the reality of the clinical laparoscopic cholecystectomy.

In order to make reliable extrapolations, results must be as free as possible from systemic, nonrandom sources of error or bias.

This opinion, and thus the validity of this study, may be influenced by several systemic sources of bias or adverse evaluation effects [1].

Threats to validity

First, the opinion may be influenced by the individual attention given to the respondent during his or her performance, and favorable responses may occur because of this attention. This so-called "Hawthorne effect" is partially accounted for by giving the same amount of attention to both respondent groups, so uniformity of the overall opinion is not troubled by differences in attention. Furthermore, there is a social

desirability effect apparent by the 100% response rate. No respondent refused to fill out the questionnaire. To what extent referents are just polite or feel obliged to fill in a questionnaire in exchange for a chance to "play" with the simulator is difficult to measure. Again, the instructors displayed no difference in attention to either group. By guaranteeing anonymous use of the responses, researchers aimed for psychological freedom in answering. Another effect that must be mentioned is the "Pygmalion effect," named after Pygmalion, a king figure from ancient Greek mythology, carving a sculpture out of stone so skillfully he fell in love with it. Translated to this setting, it might be that a respondent's opinion was influenced by the mere enthusiasm of Xitact's developers, present at the exhibition and giving the demonstration. And lastly, responses may be favorably influenced by the mere novelty of the apparatus, being attractive because of its premiere at the exhibitions. The referent group may be particularly susceptible to this phenomenon, having being around for less time in the working field of surgery and relatively unprotected against the tempting display of apparatus by the industry. Table 1 does show a slightly more favorable attitude among referents.

Nevertheless, even if these phenomena are of influence, they are not reflected in the outcomes of the study as expressed in the firm uniformity of opinion among

Table 3. Ratings of potential usefulness of Xitact (1; not very useful; to 5; very useful) for various groups

	Total Mean	Referent group ≤ 100		Expert group > 100		<i>p</i> -value ^a <i>N</i> = 33/ <i>N</i> = 87
		Mean	SD	Mean	SD	
Medical student training/education	3.97	4.12	1.02	3.91	1.10	0.889
Surgical residents training/education	4.32	4.40	0.74	4.28	0.79	0.983
Surgical specialist training/continuing education	3.93	4.09	1.11	3.86	1.15	0.937
Overall laparoscopic error reduction	3.86	4.03	1.04	3.78	1.12	0.985
Overall laparoscopic skills enhancement	3.96	4.09	0.98	3.89	1.11	0.999

^a Kolmogorov–Smirnov test, two-sided, group ≤ 100 laparoscopic cholecystectomies versus group > 100 laparoscopic cholecystectomies

both groups. One might expect experts, trained themselves by the classical surgical apprenticeship model, to be conservative in their opinion on novelties. However, this seems not to be the case with Xitact. The eagerness of referents to train with it and the enthusiasm and need for *ex vivo* training modules as expressed by the experts seem to provide an ideal setting for the implementation of this new type of technology.

An important prerequisite for the face validity of Xitact is its haptic potential. Grasping objects without weight, shape, or texture makes a virtual environment ghostly and insubstantial [3]. Touch, however, is one of the most difficult of sensations to mimic in a virtual reality setting. Xitact, providing a haptic sensation and feedback, has a potential that exceeds that of other virtual reality laparoscopic surgery simulators currently available. Not considered very realistic to the clinical laparoscopic situation by the respondents, it is beyond a rudimentary sensation, and this is precisely why Xitact's technology must be considered promising. However, this aspect must be further refined.

The training capacities of Xitact are vast since it is a computer based technology. Xitact, therefore, not only is a skills trainer but can also be seen as a rich source of data which can be used to objectively assess individual improvement in performance and compare performance across peer groups. Hence, its data representation capacity combines a modular training schedule with an underlying basis for constructive feedback and options for a personalized, rational training schedule.

Implementation

The success of the Xitact LS500 simulator will be dependent on a variety of factors. The scenery needs further refinement, especially with respect to the reality of dissection and haptic feedback. Content and construct validity need to be established and are currently under study. As with any training tool, there will be a simulator learning curve that has to be taken into account. The length of this curve is dependent on the quality of the interface for the human–computer interaction and will be determined by the initial learning rate. In order to reflect these rates, the economy of movement as measured by the simulator will be a parameter of utmost importance.

For widespread acceptance of the Xitact by the surgical community, it must be demonstrated that skills

acquired via the Xitact are transferable to the operating room environment. This so-called “virtual reality to operating room study” can only validly be initiated after face-, construct-, and content validity of Xitact are established. Retail costs of the simulator are about \$150,000. A major advantage of the apparatus is the potential to train residents adequately, while reducing the need for (live) animal material with its associated costs and infrastructure. Ultimately, there is justification for purchase when shorter learning curves can be demonstrated by a valid “VR to OR” study. Next, the more surgical modules available (laparoscopic Nissen fundoplication, laparoscopic inguinal hernia, laparoscopic appendectomy, laparoscopic colon surgery, bariatric procedures, and laparoscopic gynecology operations), the more interesting the apparatus will be.

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