EDUCATION

Face and construct validity of virtual reality simulation of laparoscopic gynecologic surgery

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OBJECTIVE: The objective of the study was to validate virtual reality simulation in assessing laparoscopic skills in gynecology by establishing the extent of realism of the simulation to the actual task (face validity) and the degree to which the results of the test one uses reflects the subject tested (construct validity).

STUDY DESIGN: Subjects (n = 56) were divided into 3 groups: novices (n = 15), intermediates (n = 20), and experts (n = 21). Participants completed 3 repetitions of a training program consisting of 4 basic skills and 3 gynecologic procedural simulations. The performance was compared between groups using a post hoc Student *t* test with the Bonferroni technique. Face validity was determined by using a questionnaire of 27 statements.

RESULTS: Resulting from the questionnaire, the opinion about the realism and training capacities of the tasks was favorable among all groups. The degree of prior laparoscopic experience was reflected in the outcome performance parameters of the tasks. Experts achieved significant better scores on specific parameters.

CONCLUSION: The results of this study indicate acceptance and thus face validity of the system among both reference (novice, intermediate) and expert group. There is a significant difference between subjects with different laparoscopic experience and thereby construct validity for the laparoscopic simulator could be established.

Key words: gynecology, laparoscopy, LapSim, surgical training, virtual reality

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Laparoscopy is a widely used operation technique in gynecology. In The Netherlands all gynecologists should be able to perform basic laparoscopic procedures (diagnostic laparoscopy, ectopic pregnancy, salphingo-oophorectomy) at the end of their training. The advantages of minimal access surgery have been proven repetitively and comprise less pain, shorter hospital stay, and faster recovery.[1]

With the growing use of laparoscopy, it is important to realize that the laparoscopic technique requires different skills compared with open surgical procedures. It requires distinct psychomotor abilities, hand-eye coordination, and depth perception. At present residents-in-training for gynecologists are learning most of the specific laparoscopic skills in the operating room. There is no consensus or agreement on the method with which to learn and measure laparoscopic performance. Virtual reality simulation could provide a safe and objective method to support residents in training, the basic skills of laparoscopy before performing surgery in the operating room.

Virtual reality trainers are widely used in the airline industry and the military.[2] Simulation provides the opportunity to expose trainees to infrequent experienced or risky procedures. A simulator can create a safe, controlled, and standardized environment to practice specific skills and could be able to objectively measure the performance of a subject. Besides training, simulators are capable to assess the skills of a subject in training simultaneously.

There is growing interest in the potential role for medical simulation in gynecology[2] and particularly the potential role of the virtual reality[3] because the traditional box trainers and animal models require human monitored evaluation, which makes them subjective, expensive, and time consuming. In the last few years, several basic and more advanced virtual reality laparoscopic simulators were developed and validated.[4,5] The LapSim laparoscopic surgical simulator (Surgical Science Ltd, Gothenburg, Sweden) is a system designed to simulate basic and advanced laparoscopic tasks in a virtual environment that closely resembles an operative field.[4,5]

With increasing interest in simulation programs, it is important to investigate the validation of a surgical simulator. Validity is defined as "the property of being true, correct, and in conformity with reality." For the surgical simulator, this means does it measure what it is designed to measure?

Validation is comprised of a number of principles. To accomplish the different parts of validation, several benchmarks have been developed to assess the validity of a testing instrument. These include face validity, content validity, con-

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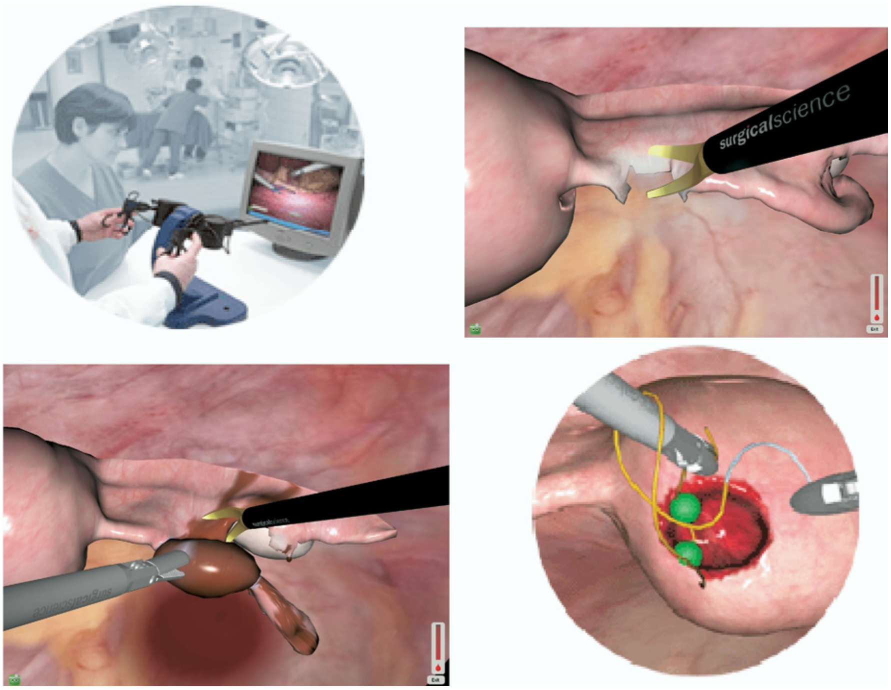
FIGURE 1
The LapSim



The LapSim virtual reality simulator (Surgical Science Ltd, Gothenburg, Sweden), sterilization, salpingectomy, and myoma suturing simulation skill. (pictures provided by Surgical Science Sweden AB)

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struct validity, concurrent validity, discriminate validity, and predictive validity.[4,6,7]

The validation of the virtual reality simulators for training endoscopic surgical skills in surgery has been evaluated repetitively.[8-15] Although some of the training modules on the virtual reality laparoscopic simulators are specially designed to train gynecologists, validation for this surgical specialty has started only recently.[16-18]

This study focused on 2 important types of validity. First, there is the most basic level of validity, face validity (eg, the degree of resemblance between a concept instrument [simulator] and the actual construct [laparoscopic procedure], as judged by a specific target population [both references; novices and experts]) to see whether it seems appropriate.

Second, there is construct validity (eg, the degree of empirical foundation of a concept instrument, based on theoretical constructs).

In practice, this is often based on the presence of a logical difference in outcome between 2 research populations, such as experienced surgeons performing better than inexperienced ones on a certain procedure as set up by the instrument.

The aim of this study was to investigate face and construct validity of the LapSim virtual reality surgical simulator in gynecology.

Materials and Methods

Participants

Gynecologists, residents in training for gynecology, and medical students from the University Medical Centre Utrecht were recruited for voluntary participation. The 56 participants had varying experience in laparoscopic surgery. Three groups were formed based on the laparoscopic experience of the subjects. Group 1 consisted of 15 medical students with no laparoscopic surgical experience (novices), group 2 of 20 residents in training for gynecologist with some laparoscopic experience (performed 10-75 laparoscopic procedures; intermediate), and group 3 consisted of 21 gynecologists and some senior residents who all performed more than 100 laparoscopic procedures (experts). None of the participants had prior experience with the virtual reality simulator.

Equipment

The LapSim consist of an 18 inch TFT monitor and a laparoscopic interface module (Immersion Inc, San Jose, CA) with 2 instruments and a foot switch (Figure 1). The software runs on a dual-processor Pentium IV computer with 256 MB RAM and Geforce graphics card, using Windows XP. The software consists of 2 modules, the LapSim Basic Skills 2.5 and the LapSim Gyn (laparoscopic simulator gynecology) software (Surgical Science Ltd). The Basic Skills 2.5 package consists of 9 different tasks with increasing complexity. The LapSim Gyn simulates parts of 3 procedures: tubal occlusion, salpingectomy in ectopic pregnancy, and the final suturing stage of the myomectomy procedure (Figure 1). The system does not possess haptic feedback.

Face validation

All participants filled in a questionnaire after performing the different skills on the simulator. In addition to the participant's demographics and laparoscopic experience, the questionnaire consisted of 27 statements about the LapSim. The first 11 were about the realism of the simulator and the second 10 about the training capacities of the simulator. These were presented on a 5 point ordinal answering scale (from not realistic/useless to very realistic/very useful). There was 1 statement concerning the lack of haptic feedback. Finally, 5 statements concerning the need for training and assessment by virtual reality were proposed, which could be answered with "agree," "disagree," or "do not know."

Construct validity

The training module evaluated in this study consists of 4 basic skills and 3 gynecologic procedures. The first tasks camera navigation (video 1), instrument

TABLE 1
Results statements: face validity (n = 56)

Questionnaire	Novice, group 1 (n = 15)	Intermediate, group 2 (n = 20)	Expert, group 3 (n = 21)	Total mean	*P* < .05
WHAT DO YOU THINK ABOUT THE REALISM OF . . . (1, NOT REALISTIC, TO 5, VERY REALISTIC)					
Appearance of the instruments	3.86	4.10	3.83	3.94	
Movement of the instruments	3.86	3.70	3.33	3.62	
Freedom of movement of the instruments	3.57	3.45	3.72	3.58	
Function of the instruments	3.71	3.45	3.44	3.52	
Tissue reaction on manipulation	3.14	3.00	2.28	2.79	3 < 2; *P* = .042 3 < 1; *P* = .023
Appearance of organs	3.29	3.15	3.28	3.23	
Appearance of needle and thread (n = 47)	2.86	3.35	2.38	2.87	3 < 2; *P* = .021
Sterilization skill (tuba occlusion)	3.71	3.60	3.11	3.46	
Ectopic pregnancy skill	3.57	3.50	3.22	3.42	
Myoma suturing skill (n = 46)	2.43	2.53	2.33	2.43	
Overall ergonomics	3.36	3.15	3.50	3.33	
WHAT DO YOU THINK ABOUT THE TRAINING CAPACITIES OF . . . (1, USELESS, TO 5, VERY USEFUL)					
Simulator in general	4.43	4.60	4.11	4.38	3 < 2; *P* = .034
Simulator to train hand-eye coordination	4.29	4.55	4.50	4.46	
Simulator to train depth perception	3.71	3.75	2.94	3.46	3 < 2; *P* = .020
Skill: camera navigation	3.64	3.85	3.72	3.75	
Skill: instrument navigation	3.93	3.90	4.06	3.96	
Skill: coordination	4.07	4.00	4.00	4.02	
Skill: sterilization 1 (with clips)	3.93	4.05	3.33	3.77	3 < 2; *P* = .039
Skill: sterilization 2 (with cutting)	4.00	4.15	3.33	3.83	3 < 2; *P* = .008
Skill: ectopic pregnancy	4.21	3.90	3.50	3.85	3 < 1; *P* = .020
Skill: myoma suturing (n = 48)	3.36	3.22	2.81	3.13	
HOW DISTURBING IS THE LACK OF HAPTIC FEEDBACK (1, VERY DISTURBING, TO 5, TOTALLY NOT DISTURBING)					
	2.50	2.50	2.61	2.54	

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navigation (video 2), and the coordination (video 3) task provides basic navigational skills for camera and instrument handling as described by Van Dongen et al[14] and Duffy et al.[8] The final basic task clip applying (video 4), is a complex task in which multiple instruments must be used to cut a vessel between 2 applied clips as described by Larsen et al.[17]

After finishing the 4 basic tasks, participants performed 3 simulations of gynecologic procedures. First was the tubal occlusion (sterilization) procedure (video 5). In a virtual reality environment, both tuba need to be occluded by clips or in a second session by coagulating and cutting the tuba. One hand navigates the camera and the other manipulates an instrument. Available instruments are a grasper, bipolar grasper, diathermic scissors, a suction/rinsing device, and clip applier. Again, performance parameters are measured by the system. The specific task parameters are applied clips, left and right side clip distance, bleeding, and blood loss.

The second gynecologic procedure is a salpingectomy (video 6). In this procedure

TABLE 2
The statistical significant parameters of each task: construct validity

Task with parameter	Group 1, novice (n = 15)	Group 2, intermediate (n = 20)	Group 3, expert (n = 21)	Significant difference ($P < .05$)
Camera navigation				
Path length (meters)	4.34	4.04	3.32	3 < 1 and 3 < 2
Angular path (degrees)	1720	1556	1223	3 < 1 and 3 < 2
Instrument navigation				
Right instrument time (seconds)	37.8	33.7	30.3	3 < 1
Left instrument time (seconds)	37.1	33.0	29.1	3 < 1
Tissue damage (number times)	3.37	2.78	1.91	3 < 1
Coordination				
Total time	106	104	90	3 < 1 and 3 < 2
Instrument misses (%)	47.0	35.8	22.1	3 < 1
Camera path length	1.68	1.30	1.10	3 < 1
Camera angular path	859	671	563	3 < 1
Clip applying				
No significant parameter				
Sterilization clip				
Total time	79.0	88.8	67.4	3 < 2
Applied clips (number)	2.07	2.70	2.16	3 < 2 and 2 > 1
Right side clip distance (millimeters)	19.7	15.5	18.6	2 < 1 and 2 < 3
Left instrument angular path	191	241	131	3 < 2
Sterilization cut				
Bleeding (mililiters per second)	0.11	0.11	0.04	3 < 2
Ectopic pregnancy				
Total time	384	251	212	3 < 1 and 2 < 1
Blood loss (milliliters)	198	113	86	3 < 1 and 2 < 1
Unremoved diss tissue (number)	0.60	0.31	0	3 < 1
Left instrument path length	3.68	2.80	2.13	3 < 1
Right instrument path length	5.84	4.21	2.73	3 < 1
Right instrument angular path	1082	778	469	3 < 1

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an ectopic pregnancy has to be dissected from the fallopian tube and surrounding membrane using bipolar graspers and/or a diathermic scissor as described by Larsen et al[17] and Aggarwal et al.[16]

The last training task is the closure of the uterine wall cavity after a myomectomy (video 7). With 2 needle holders, a needle, and thread, 3 sutures have to be correctly placed, tightened, and tied. The system measured minimal tissue bite, knot error, and ripped stitched. Maximum time in this study was set for 5 minutes.

After verbal instructions the participants performed 3 repetitions of this training module composed of the 7 different tasks. The first repetition was considered as an familiarization to the virtual reality simulator. The average performance of the second and third repetition was used in the analysis.

Use of statistics

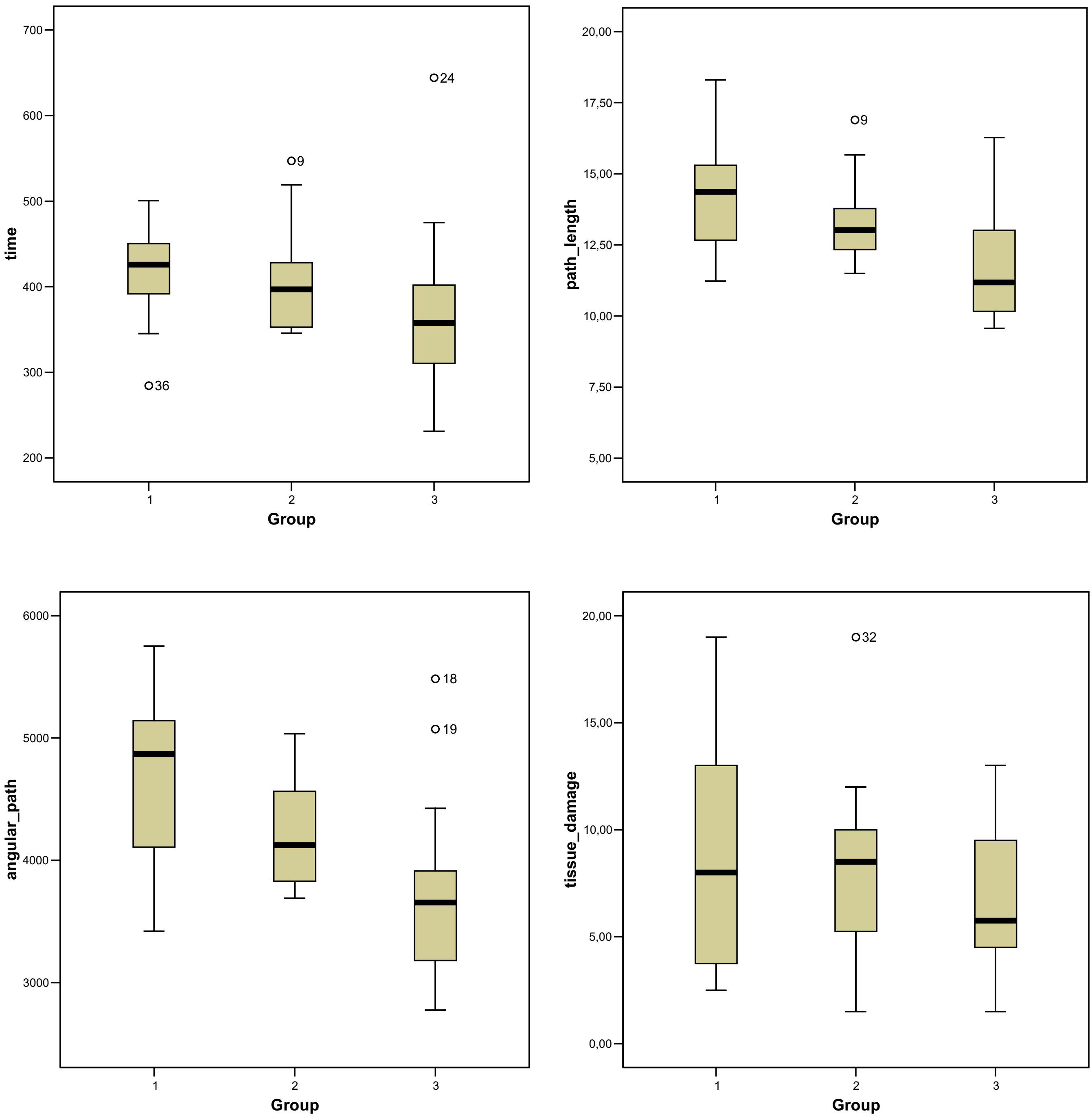
Data were analyzed using the statistical software package SPSS 12.0 (SPSS Inc, Chicago, IL). Analysis of variance was used with post hoc analysis using the Bonferroni test to determine the difference in face and construct validity between the 3 groups. $P < .05$ was considered statistically significant. Values are presented as means unless stated otherwise.

RESULTS

Face validation

Table 1 shows the mean values of the scores for the first 21 statements. The first 11 statements about the realism of the LapSim (Surgical Science Ltd) had a

FIGURE 2
Results of 4 basic skills



Box plots of results of 4 basic skills together. Parameter time (seconds), path length (meters), angular path (degrees), and tissue damage (number of times) are shown.

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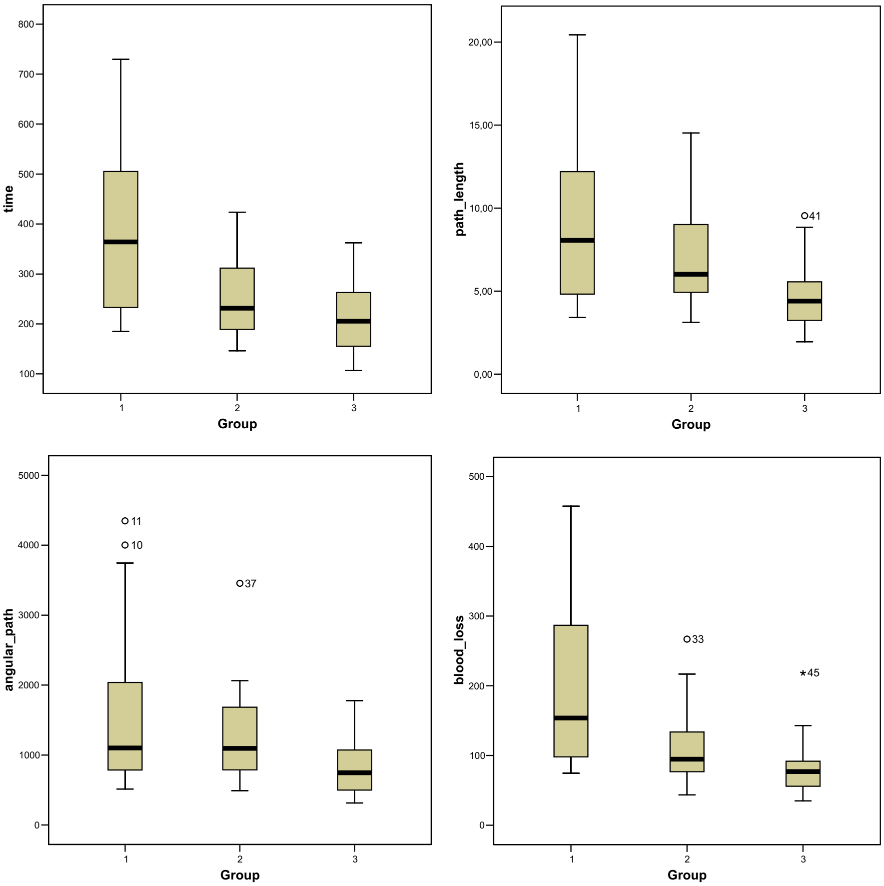
mean score of 3.29. The lowest scores were given for the realism of the myoma suturing skill (2.43), the tissue reaction on manipulation (2.79), and the appearance of needle and thread (2.87). The training capacities of the LapSim (Surgical Science Ltd) were rated higher (mean 3.86), especially for the simulator in general (4.38) and to train hand-eye coordination (4.46). Some answers showed significant differences between the expert and the other 2 groups (Table 1). The overall scores of the experts were lower compared with the scores of the intermediates and novices. The lack of haptic

FIGURE 3
Results of the ectopic pregnancy skill



Box plots of results of the ectopic pregnancy skill. Parameters time (seconds), path length (meters), angular path (degrees), and blood loss (milliliters) are shown.

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feedback was scored as most disturbing, with scores of 2.61 from the experts vs 2.50 from the intermediate and novice subjects.

The majority of the subjects agreed that the LapSim virtual reality trainer is a useful instrument to train endoscopic techniques to residents, especially hand-eye coordination. Gynecologists were not all convinced that the simulator could measure endoscopic skills for an endoscopic procedure.

Construct validity

The 56 subjects were equally distributed based on level of experience (group 1, n = 15; group 2, n = 20; group 3, n = 21). The mean age in the groups was 25 years (group 1); 32 years (group 2); and 42 years (group 3). From the 56 participants, everyone completed the 3 repetitions of the 7 tasks.

The parameters that showed a significant difference between groups are shown in Table 2. Comparisons between the expert (group 3) and novice (group 1) subjects demonstrated the most significant difference. For most of the basic skills, there was a trend towards better performance on all parameters for group 3 vs group 2 and group 2 vs group 1. Only the basic clip applying skill and the gynecologic sterilization module did not show this trend.

The sterilization simulation showed some significant performance parameters. The greatest difference was found in the ectopic pregnancy procedure. None of the subjects could complete the myoma suturing procedure within the set time limit of 5 minutes. Five of the 56 subjects (9%) were able to tie 1 knot, the other subjects none. From these 5 participants, 4 were from the expert group and 1 from the intermediate group.

Figure 2 shows the performance parameters time, path length, angular path, and tissue damage for the 4 basic skills together. The more experienced the group, the better was the performance. There was a significant difference for path length and angular path between groups 3 and 2 (P = .028 and P = .022, respectively) and between groups 3 and 1 (P = .00 and P = .00, respectively).

The ectopic pregnancy module showed the most distinctive difference in performance between the 3 groups (Figure 3). The experts performed best, followed by the intermediates and novices. In this ectopic pregnancy module, group 1 was significantly slower than group 2 (P = .005) and group 3 (P = .00).

The total path length and angular path were significantly longer in group 1 vs group 3 (P = .003 and P = .010, respectively). The blood loss was significantly more in group 1 than groups 2 (P = .010) and 3 (P = .00). The box plot in Figure 3 also shows that there was less variability in performance in the expert group than the intermediate and novice subjects group.

Comment

The questionnaire demonstrated reasonable face validity. The majority of participants believed the LapSim could become a useful tool in training laparoscopic skills to residents and gynecologists. No other studies that describe face validity of the LapSim virtual reality simulator for the use in gynecology are known.

The LapSim was able to differentiate between subjects with varying laparoscopic experience; the performance of the subjects on the virtual reality simulator was proportional to their laparoscopic experience. Twenty of 82 parameters in different skills were sensitive enough to show a significant difference between the performance of the 3 groups. Although we could confirm the construct validity of the LapSim, there was a difference in the discriminative properties of the skills.

In the basic skills, the greatest difference between the groups was found in camera navigation, instrument navigation, and coordination. Not all measured parameters are able to show a difference between the groups; this was also found by Woodrum et al.[19] This group used 3 of the 4 basic skills we used in this study (coordination, instrument navigation, and clip applying). Interestingly, our research confirms their results, indicating that time, path length, and angular path are the most discriminative parameters.

In our study, besides time, the coordination skill showed 3 other significant parameters (instrument misses, camera path length, and camera angular path), and the instrument navigation skill showed another significant parameter (tissue damage instead of path length). In this study the clip-applying skill did not show a significant performance parameter, whereas Woodrum et al[19] found 3 parameters (time, incomplete target areas, and blood loss), and Larsen et al[17] also found 3 parameters (time, path length, and angular path) to differentiate significant between the groups.

A possible explanation for the smaller difference between the groups in this skill could be the fact that the task is complex. There are some pitfalls that can contribute to a longer performance of the task. Therefore, 1 short familiarization run might not be enough for a reliable measure of the performance of this task.

It can not be excluded that the study is underpowered because no power calculation was done for hand.

Within the gynecologic procedural simulations, the removal of the ectopic pregnancy discriminates the best, as reflected in outcome performance parameters of the different groups. The ectopic pregnancy simulation also scored best by the experts in the questionnaire about the realism and training capacities of the LapSim. The gynecologic suturing skill was not showing a difference among the groups, simply because none of the participants could finish this exercise in the available time. Probably it was too complicated, especially within the restricted time set of 5 minutes. Furthermore, the graphics of this complicated skill could be improved, especially the view and fluency of the needle and suture itself.

It is important to realize that in this study not all performance parameters measured by the LapSim system were able to differentiate between subjects with different levels of experience. This could possibly be explained by the size of the study or because these parameters might not be valid measures of laparoscopic performance. For procedural tasks one could develop a scoring system that is built on certain clinical relevant performance parameters. In general surgery this was done for the clip and cutting phase of a laparoscopic cholecystectomy.[12]

In the present study, the construct validity of the gynecology module is demonstrated. The myoma suturing skill needs to be improved and investigated, but the removal of the ectopic pregnancy is a valid and realistic simulation of the virtual reality trainer. This is consistent with the findings of other studies.[16,17]

The sterilization simulation showed some significant performance parameters but less than the salpingectomy simulation. In this task on some parameters, the novices performed better than the intermediates. This could be explained by different factors. The sterilization simulation is not very structured. There is no real parameter to determine whether the sterilization is established (clip on the right place or tuba cut completely through?), and the exercise does not stop automatically. Perhaps it was necessary to give the subjects more instructions about this task.

In the last few years, several studies concerning the validation of the basic skills of LapSim for training endoscopic skills have been published by different studies on surgical residents.[8,9,11,13,14,19,20] These studies have shown construct validity for the LapSim virtual reality simulator in general surgery.

In the field of gynecology, Larsen et al[17] showed construct validity for the LapSim simulator. Aggarwal et al[16] showed that virtual reality simulation is useful in the early part of the learning curve for residents who want to learn to perform the salpingectomy for ectopic pregnancy.

An overview of the use of virtual reality trainers in gynecology was recently given by Hart and Karthigasu[21] In concordance with our opinion, they conclude that virtual reality training will become an essential part of clinical training in the near future.

In conclusion, the findings of this study are 1 of the first steps of confirming that virtual reality laparoscopic simulators have great promise in gynecological training. It is an objective and constant system that can measure a trainee's skill level. Virtual reality simulators are still expensive and should be used by all surgical specialties to justify the costs. Implementing them in the different training programs (general surgery, urology, and gynecology) will have additional value, next to the box trainers and hands-on training. Specialized fellowships for laparoscopic surgery are still needed to train advanced competent laparoscopic surgeons.

All the participants in our study thought it was a useful instrument to train eye-hand coordination, and almost all thought it was a useful instrument to train endoscopic skills. Face and construct validity in gynecology are established for this simulator. Further research should be done on the predictive validity of the simulator to show whether training on the simulator predicts better performance in the operating room. ■

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