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Laparoscopic Surgical Skills are Significantly Improved by the Use of a Portable Laparoscopic Simulator: Results of a Randomized Controlled Trial

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Abstract
Background There is growing evidence that training on virtual reality simulators leads to improved performance in the animate and human operating room. However, they are expensive, have a limited availability, and involve complex systems. Portable simulators are significantly cheaper, more user-friendly, and are flexible systems that are more suited to a surgical trainee's busy schedule. The use of portable surgical simulators to train skills and reduce errors has never been evaluated in prospective, randomized clinical settings. The objective of this study was to determine if training on the portable Integrated Laparoscopic Simulator leads to improved performance of core laparoscopic skills.
Methods Core laparoscopic skills were identified by five experienced laparoscopic surgeons and modeled into two exercises and three basic tasks. Twenty surgically naive medical students had baseline laparoscopic skills assessed on a fixed simulator. Participants were randomized to either 14 h training on a portable laparoscopic simulator over a 3 week period, or control with no training. At 3 weeks two expert laparoscopic surgeons blinded to the allocation of participants assessed their pre- and post-intervention performances recorded on a CD-ROM. The outcome measures included time to complete and global rating scores of clipping and dissection tasks.
Results No differences were observed in baseline skills level between the two groups. The intervention group had better quality of scissors dissection ($p = 0.0038$) and improved clipping skills ($p = 0.0051$), and they took less time to accomplish the tasks ($p = 0.0099$) in comparison to control.
Conclusions Training on the portable Integrated Laparoscopic Simulator significantly improved core laparoscopic skills in medical students with no prior experience.

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Introduction

Minimally invasive surgery, in particular laparoscopy, has become the standard of care in many areas of surgical practice [1–4]. Significant patient benefits attributed to laparoscopy have led to increasing indications for this approach, even for complex surgical procedures [2]. The learning curve for laparoscopic skills is steep because of the complex psychomotor skills involved, the two-dimensional views, and mechanical constraints of the instruments, which are vastly different from those employed in traditional open surgery [3]. Recognizing these specialized requirements highlights the importance of incorporating laparoscopic skills training in the surgical curriculum for the surgeon's training and the patients' safety. Surgical trainees commit twice as many errors as an experienced surgeon, and introduction of surgical simulation in training programs may shorten the learning curve [4, 5].

Simulation-based training has long provided the framework for training in many other complex, high-risk professions (i.e., nuclear power, aviation, and the military), with the goal of minimizing risk and maximizing safety [6]. In surgical training, the situation seems even more complicated because of multiple external factors: the European Working Time Directive, increasing costs of operating room time, ethics of learning basic skills on patients, and patient safety. This has stimulated interest in learning laparoscopy skills in a laboratory setting (skill centers) and subsequently transferring them into actual surgical procedures carried out on patients [3, 7, 8]. This requires a significant investment in surgical simulators. There has already been a considerable amount of research into virtual reality simulators (Lapmentor, MIST VR Promis, SIMENDO, or LapSim) that have led to improved performance in both the animate [9–13] and human operating rooms [6–8, 10–14]. However, virtual simulation training has limitations that have slowed its clinical implementation. There are resource-derived constraints, such as trainees' busy schedules, over-sophisticated systems, limited availability, and the considerable cost implications [15].

Portable laparoscopic simulators could enhance the adoption of simulation-based training as they are less expensive, moveable, user-friendly, and flexible systems. Their role and introduction into surgical curricula has not yet been defined, and there are few validated study programs to date. The present study aimed to evaluate the role of a portable laparoscopic simulator (iSIM) in enhancing laparoscopic skills acquisition.

Methods

Twenty medical students with no previous laparoscopic experience were recruited into the study following informed consent between 1 August and 31 October 2010. The participants were invited to take part in the study by email addressed to their medical school email inboxes. A first-come, first-recruitment offer policy was adopted. The sample size was calculated based on previous studies on virtual reality surgical simulation [16–18]. The structure and flow of the participants through the trial is illustrated in Fig. 1a.

Identification of core laparoscopic skills and modeling of tasks

Five expert laparoscopic surgeons well recognized and reputed in their field (had experience of more than 200 laparoscopic procedures, teach and train on a minimum of one urology speciality specific laparoscopic courses) identified 10 basic laparoscopic skills necessary for education, training, and procedure-based learning purpose (Table 1). The skills were identified after watching videos of a range of simple and complex laparoscopic procedures. A Delphi process was used to achieve agreement between the experts in scoring tasks and skills required for laparoscopic execution of a procedure (Fig. 1b). The experts remained unaware of each other's decisions. The following definitions of consensus were established before data analysis:

- Consensus that task should be retained: >80 of experts scored the task >8
- Consensus that task should be excluded: >80 % experts scored the task <5
- No consensus: task failed to meet either of the above criteria

These skills were modeled into two exercises, a scissors dissection task and a clipping task (Fig. 2).

Scissors dissection task (Fig. 2, black circle)

In the scissors dissection exercise, a double-layered latex membrane is attached with tension to a plastic cylinder using an elastic band. The participant is required to carefully dissect between the black lines and separate the triangular shape from its attachments. Any deviation over the lines or damage to the underlying layer of latex was considered an error. This task requires precision and the use of the non-dominant hand to provide traction and position the latex so that the dominant hand can dissect accurately. This task contains nine of the core laparoscopic skills listed in Table 1, except clipping. This task was recorded from start to finish, and the recording was submitted for subsequent analysis.

Clipping task (Fig. 2, white circle)

The participants were asked to select one of the vessels of a synthetic vascular bed and apply two clips, leaving a safe distance between them. To accomplish this, the participant must supinate or pronate both wrists to ensure that both jaws of each clip could be seen prior to applying the clip transversely. This procedure required the subject to use at least nine core laparoscopic skills, except cutting. The procedure was recorded and subsequent analysis of the task performance was carried out.

The Integrated Laparoscopic Simulator (iSIM)

The Integrated Laparoscopic Simulator (iSIM) is a cost-effective portable laparoscopic simulator (£3,000) with a single chip camera system, inbuilt high-definition screen, and recording facility. It displays multiport and single port access, as well as an adaptable skills station (Fig. 3). The simulator takes only a few minutes to set up, is the size of an

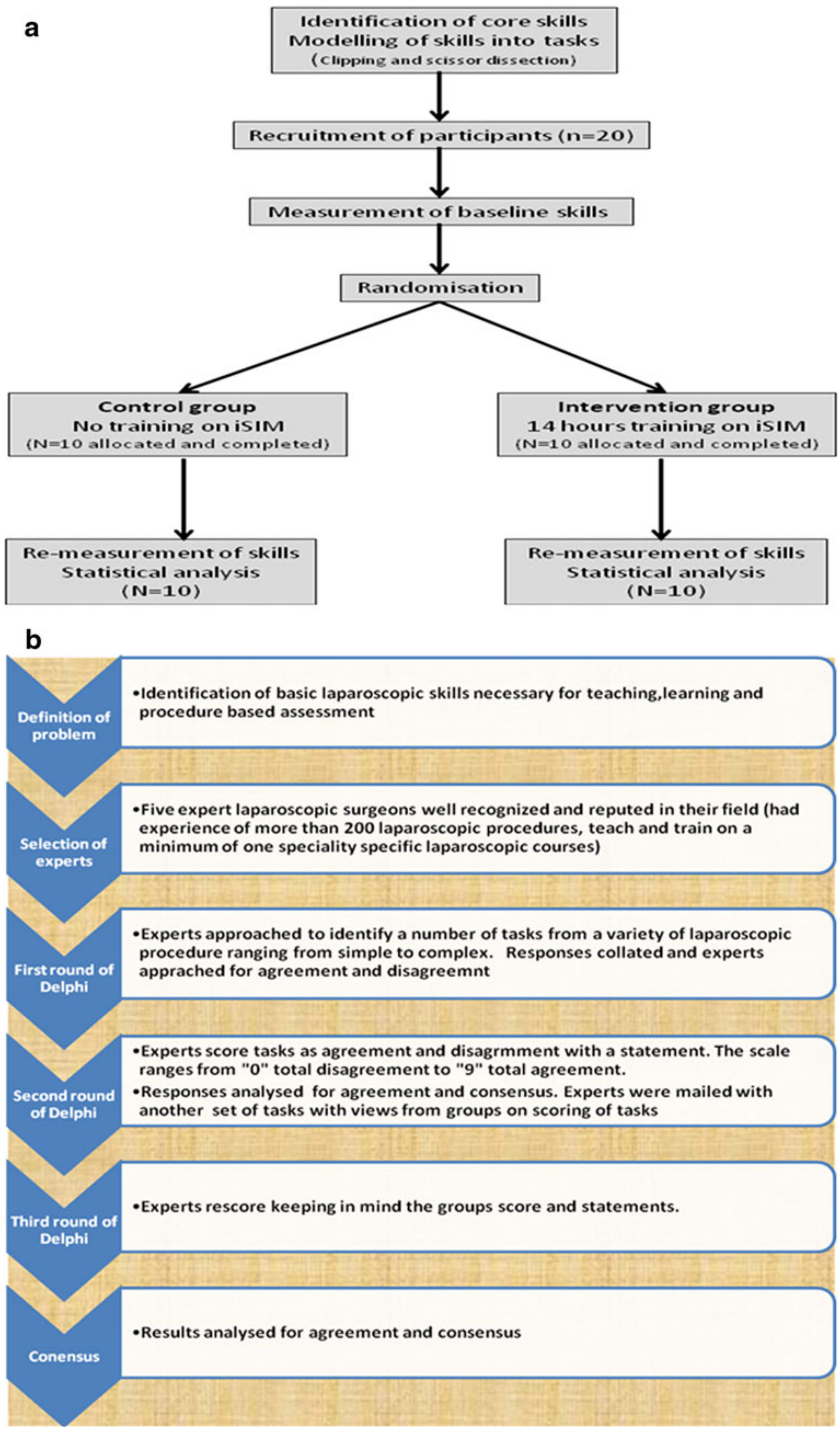

Fig. 1 **a** Structure and flow of participants through the trial. A diagram illustrating the structure and the flow of the participants through the trial (N = number of participants). Integrated Laparoscopic Simulator (iSIM). **b** Delphi process adopted for skills identification and consensus

Table 1 Core laparoscopic skills measured in the trial which were identified by the consensus agreement of five expert laparoscopic surgeons

Core laparoscopic skills	
Retraction of tissue	Dissection of tissue planes
Trajectory of instruments (time and motion)	Flow of procedure and forward planning
Instruments handling	Clipping
Preciseness in tissue handling	Use of non-dominant hand
Cutting	Unnecessary movements

Fig. 2 Model used for Scissors dissection task and Clipping task (Black circle) and clipping task (White circle)

average laptop computer, and is suitable to practice a wide range of core laparoscopic skills (http://www.isurgicals.com).

Baseline assessment of laparoscopic skills

A 10 min introductory presentation (T.J. and B.J.), which included a brief video of the tasks in simulators and in real patients, was given prior to baseline skills assessment on a fixed laparoscopic simulator in the Cuschieri Skills Centre. Standard Storz laparoscopic instruments and a video endoscopic system (KARL STORZ Endovision DCI Endoscopic System, DCI HOPKINS II Laparoscopes. Enlarged view, diameter 10 mm) with a 2-dimensional monitor were used to perform the task. Instruments were introduced into the trainer box with a 60° manipulation angle, an elevation angle of 45°–60°, and equal azimuth angles. Performances for each task was recorded on a computer disk (CD-ROM) and subsequently measured by two expert laparoscopic surgeons (B.T. and G.N.), who used the validated and reliable Objective Structured Assessment of Technical Skills (OSATS) tool [19] (Table 2). Participants were then randomized into intervention and control group using third

Fig. 3 The portable Integrated laparoscopic simulator (iSIM)

party (statistician) computer-generated random numbers. To ensure concealment of allocation, none of the investigators were involved in this process. The investigators involved in the analysis of data and scoring of the tasks were blinded to the details of the participants and performed the evaluation independently.

Progress of intervention and control groups

The intervention group was provided with an instruction sheet and a CD-ROM showing a video of the dissection and clipping tasks being performed by an expert surgeon. They all completed 14 h of practice on the iSIM over a 3 week period. A log book was maintained by an independent person (T.J.) to ensure compliance with the practice. The control group had no access to the portable simulator during this time. At the end of the training period both groups repeated the same tasks on the fixed simulator, and their performances were recorded on CD-ROM. The recorded exercises were again scored with the OSATS tool by independent members of the team (B.T. and G.N.) not associated with the recording process, unaware of group allocation, and each with significant experience using OSATS.

Statistical analysis

Differences between the two groups were assessed with the 2-sample t test and the Mann–Whitney U-test at 1 and 3 weeks to compare the difference in skill levels. Intra-group comparisons were assessed with the paired t test and Wilcoxon matched pairs test at pre- and post-intervention stages to determine the within-group levels of improvement.

Table 2 Objective structured assessment of technical skill instrument (OSATS) [17]

General skill	1	2	3	4	5
Respect for tissue	Frequently used unnecessary force or caused damage by inappropriate use of instruments		Careful handling 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		Economy of movement and maximum efficiency
Instrument handling	Repeatedly makes tentative or awkward moves with instruments		Competent use of instruments although occasionally appeared stiff or awkward		Fluid moves with instruments and no awkwardness
Use of left hand	Consistent poor or failed use of left hand		Good use of left hand most of the time		Strategically used left hand to the best advantage at all times
Flow of operation and forward planning	Frequently stopped operating or needed to discuss next move		Demonstrated ability for forward planning with steady progression of operative procedure		Obviously planned course of operation with effortless flow from one move to the next

Table 3 Demographic data of participants

	Intervention group	Control group
Sex ratio (M:F)	6:4	8:2
Age (years)[a]	23.8 (21–36)	22.2 (21–25)
Handedness (right:left)	9:1	10:0

[a] Values are mean (range)

GraphPad InsTat software (http://www.graphpad.com/quickcalcs/ttest2.cfm) was used for the statistical analysis.

Results

All twenty of the recruited participants completed the study. There was no significant age, gender, or handedness difference between the two groups (Table 3). Consensus following the Delphi process among the experts was achieved in 60, 70, and 80 % in first, second, and third rounds, respectively. On a few tasks there was 100 % consensus. This reflects a high construct and content validity of the process.

Baseline laparoscopic skills

Baseline scores of laparoscopic skills on the fixed simulator did not demonstrate any significant difference between the control group and intervention group for the dissection (*p* value 0. 0731; 95 % confidence interval 3.17–0.17) or clipping task (*p* value 0.507; 95 % confidence interval −2.93 to 1.53) on the 2-sample *t* test (Table 4). In addition, there was no significant difference in the time taken to complete each task (*p* value 0.659; 95 % confidence interval −59.12 to 38.52) 2-sample *t* test and Mann–Whitney *U*-test.

Postintervention assessment of laparoscopic skills (Table 5)

The intervention group had better quality of scissors dissection (*p* value 0.0038; 95 % confidence interval 3.43–14.56), improved clipping skills (*p* value 0.0051; 95 % confidence interval 14.90 to −3.29), and took less time to accomplish the task (*p* value 0.0099; 95 % confidence interval −63.68 to −12.32) in comparison to control on 2-sample *t* test and Mann–Whitney *U*-test. Interestingly,

Table 4 Baseline laparoscopic skills and OSATS scores at baseline in both the groups

Laparoscopic skills	Intervention group Mean (SD)	Control group Mean (SD)	Statistical significance *p* Value (95 % confidence interval)
Scissors handling and dissection (OSATS score)	7.0 (2.26)	5.5 (0.71)	0.0731 (3.17–0.17)
Time taken for dissection task (s)	276.8 (50.57)	292.2 (24.66)	0.402 (−23.04 to 53.84)
Clipping tasks (OSATS score)	7.1 (2.983)	6.4 (1.27)	0.507 (−2.93 to 1.53)
Time taken for clipping task (s)	121.48 (61.48)	110.9 (38.29)	0.659 (−59.12 to 38.52)

Table 5 Post-intervention laparoscopic skills and OSAT scores in the two groups

Laparoscopic skills	Intervention group Mean (SD)	Control group Mean (SD)	Statistical significance p Value (95 % confidence interval)
Scissors handling and dissection (OSATS score)	20.7 (4.08)	11.70 (7.12)	0.0038 (3.43–14.56)
Time taken for dissection task (s)	116.90 (52.02)	221.50 (74.49)	0.0019 (−164.96 to −44.24)
Clipping tasks (OSATS score)	20.80 (3.49)	11.70 (7.67)	0.0051 (14.90 to −3.29)
Time taken for cutting task (s)	54.9 (14.27)	92.90 (35.91)	0.0061 (−63.68 to −12.32)

Table 6 Intra-group analysis of skills in both control and intervention groups

Laparoscopic skills	Intervention group			Control group		
	Baseline score Mean (SD)	End of the study score Mean (SD)	Statistical significance p Value (95 % confidence interval)	Baseline score Mean (SD)	End of the study score Mean (SD)	Statistical significance p Value (95 % confidence interval)
Scissors handling and dissection (OSATS score)	7.0 (2.26)	20.7 (4.08)	<0.0001 (−16.7987 to −10.60)	5.5 (0.71)	11.70 (7.12)	0.0135 (−10.9538 to −1.4462)
Time taken for dissection task (s)	276.8 (50.57)	116.90 (52.02)	<0.0001 (111.6146 to 208.1854)	292.2 (24.66)	221.50 (74.49)	0.0106 (18.5697 to 122.8303)
Clipping tasks (OSATS score)	7.1 (2.983)	20.80 (3.49)	<0.0001 (−16.7489 to −10.6511)	6.4 (1.27)	11.70 (7.67)	0.0449 (−10.4651 to −0.1349)
Time taken for cutting task (s)	121.48 (61.48)	54.9 (14.27)	0.0037 (24.5801 to 108.5799)	110.9 (38.29)	92.90 (35.91)	0.2925 (−16.8757 to 52.8757)

intra-group analysis showed some skills improvement trend in the control group as well (Table 6)

Discussion

Principal findings

This is the first randomized controlled trial aimed at assessing the role of a portable laparoscopic simulator in improving laparoscopic skills in subjects (novice medical students) with no previous laparoscopic or surgical experience. The results show a significant improvement in the laparoscopic skills defined tasks. The quality of tasks and the time taken to perform them were significantly better in the group with access to the portable simulators and dedicated training. Availability of portable simulators can contribute to laparoscopic skills development, and their use in surgical education can play a significant role, in particular ny providing reinforcement of learning. Our study showed that access to a portable simulator allows repeated practice of standardized laparoscopic surgical steps and reduces the time taken to perform steps with improvement in quality. Participants who had portable simulation-based training before final assessment with validated tools performed better than their counterparts who had no contact with the portable simulator.

There is already evidence that virtual reality (VR) simulation training can lead to an improvement in laparoscopic skills in both the animate [6, 10–13] and human operating room [14, 20–22]. However, surgical trainees' access to VR simulators is restricted by the limited availability of such equipment on current training programs, the considerable cost implications of attending a course, and the time constraints of the trainees' schedule. Portable laparoscopic simulators are less expensive, user-friendly, and flexible. They may provide a more feasible method to improve the acquisition of laparoscopic skills in surgical trainees and have the potential to be easily incorporated into future surgical training programs. This study has demonstrated that the performance of novices was increased significantly after training on the iSIM, which was in line with what has been shown in many VR training studies. Thus, the iSIM could play a significant role in laparoscopic skills acquisition, both for the advantages described above and because it is realistic and cost effective to implement such a device in a surgical department. It could also provide benefit to surgeons with basic and intermediate levels of laparoscopic skills in warming up their skills before they perform an operation on a patient in the operating room, a use suggested previously in a VR simulator study [23]. However, further research needs to be constructed to investigate the impact of such methods.

Generalizability (external validity) of the study

The study was conducted following the CONSORT guidelines [24, 25]. The robust mechanism of task identification by expert and validated tools were used. The tasks were identified by five expert laparoscopic surgeons taking into consideration instrument handling, depth perception, and fine motor control (Table 1). A Delphi process was used with good validity for consensus on the type of tasks. We used OSATS because it is well recognized for its good validity, reliability, and inter-rater reliability when assessing performance using bench models in skills laboratories [19, 26, 27]. Whether basic laparoscopic skills gained by training on a portable laparoscopic simulator can actually improve performance in the human operating room remains to be seen. However, practice on portable simulators could still enhance and re-enforce the skills during laparoscopic surgical training. There is a need for shortening the learning curve of technical skill during training, as this will be a form of quality assurance for the public. An objective assessment is vital because deficiencies in training and performance are hard to rectify without objective feedback [15].

Future research

This study assessed the impact of training on a portable laparoscopic simulator in surgically naive medical students. Therefore the next important step should be to use a large cohort in which to assess the benefits of access to portable laparoscopic simulators to surgical trainees with different levels of training. This would help define the place of a portable simulator in the surgical training curriculum. This could be used as an adjunct to selection of surgical trainees in assessing their spatial perception of tasks during the interview process, as is done in other specialities such as radiology [28] and pathology [29]. In addition, transferability of skills to the operating room and improved patient outcomes (due to training on portable laparoscopic simulators) needs to be determined.

The observation that there was improvement in performance of the controls even after a single use of the stimulator is an interesting one (Table 6). Such findings have potential implications for duration of simulator training required in future research. There is now strong evidence from studies of behaviour in the operating room that failures in non-technical skills are frequently implicated in adverse surgical events and errors [30]. Therefore proficiency in technical skills alone is insufficient to ensure patient safety, and it is imperative that training and assessment in non-technical skills are also incorporated into trainee surgical curricula.

Conclusions

This study demonstrates that training on the portable Integrated Laparoscopic Simulator leads to significant improvement in core laparoscopic skills in medical students with no prior experience.

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