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Design and Validation of a Novel and Cost-Effective Animal Tissue Model for Training Laparoscopic Adhesiolysis and Mesh Repair of an Incisional Hernia

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Abstract

Objectives: To design and validate a new and cost-effective animal tissue training model for practicing laparoscopic adhesiolysis and mesh repair of an incisional hernia.

Methods and Materials: A laparoscopic training box is mounted with neoprene, which simulates the anterior abdominal wall. The greater curve of a porcine stomach is dissected out and a small circular defect is cut out of the double-layered stomach, this represents the hernial defect. Porcine omentum is stapled around the defect in the stomach, and this represents the adhesions around the incisional hernia.

A Prolene mesh is inserted into the simulated peritoneal cavity under laparoscopic vision and tacked to the anterior abdominal wall.

Face, content, and construct validity of the model was carried out using a 5-point Likert scale questionnaire, and comparison in task performance between course delegates and experts was made using observational and clinical human reliability analysis.

Results: A total of 33 course delegates and 8 expert surgeons were recruited to this study from June 2016 to June 2017. Of the 33 course delegates, 24 were male and 9 were female, with age ranges 27-48 years. Course delegates had between 2 years and 9 years of laparoscopic experience. The mean score on specific feature of the anatomy and colour, sensation of texture, maintenance of pneumoperitoneum and adhesiolysis and mesh fixation was 4.12 ± 0.78, 4.00 ± 0.79, 4.73 ± 0.52, 4.12 ± 0.78 and 4.61 ± 0.56 respectively in the course delegates group, and 4.38 ± 0.52, 4.25 ± 0.71, 4.25 ± 0.71, 4.75 ± 0.46 and 4.75 ± 0.46 respectively in the expert surgeon group on a scale of 1 (unrealistic) and 5 (very realistic).

Conclusion: A newly designed restructured animal tissue model for training laparoscopic adhesiolysis and mesh repair of an incisional hernia is reported. Validation studies on the model demonstrate that this is a very realistic and effective model for skills training in laparoscopic adhesiolysis and mesh repair of an incisional hernia.

As a result of this laparoscopic training model course delegates reported that they had gained transferrable operating skills and increased confidence in the performance of laparoscopic adhesiolysis and incisional hernia repair with mesh.

This training model is an effective and cost-efficient laparoscopic training simulator.

Keywords: Animal tissue model; Simulation training; Training model validity; Laparoscopic adhesiolysis; Incisional hernia repair

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Competences

Practice-based Learning and Development; Medical knowledge; Patient care; Simulated surgical training.

Introduction

Laparoscopy has become the standard approach for many conditions in most surgical specialities [1]. This development has been driven by the desire for less surgical trauma, faster post-operative recovery, shorter hospital stay, and better cosmetic results [2].

It is evident however that laparoscopic surgery is associated with a longer operating time and a higher rate of surgical complications during the learning curve of the trainee surgeon. This has been verified in many studies within the surgical sub-specialities [3-6]. However, the reduction of working hours introduced by the European Working Time Directive (EWTD) and the dissolution of the traditional 'firm' structure have significantly reduced surgical training time and mentorship making it difficult for trainees to perform a sufficient number of procedures to attain competence in these complex procedures to achieve safe and independent practice [7]. The technical skills required for laparoscopic surgery are fundamentally different from those for traditional open surgery, leading to a prolonged learning curve. The primary obstacles in learning laparoscopic surgery are psychomotor and perceptual. The unique nature of laparoscopic surgery combined with an increasing focus on patients' safety and rights, the present reduction in working hours, and concerns over costs of operating theatre time are factors that challenge the traditional surgical approach and contribute to a growing need for novel methods in the training of laparoscopic surgeons [8]. Virtual reality simulation has the potential to offer important advantages in the area of training for new skills and procedures. Perhaps one of the most compelling driving forces for the integration of simulation into surgical training is the ethical imperative of providing patients with the best care. Although it is understood that trainees will eventually develop technical skills by treating patients, patients should not be subjected to the possibility of harm when other training methods are available for skills acquisition [9].

Simulation ensures that some practice has taken place before trainees treat real patients [10]. Simulation also allows for alternative ways to acquire skills within the constraints of working time restrictions and reduced clinical exposure. Simulators are available at any time to be utilized, making them flexible for training. Simulation can also provide a means for both trainee surgeons and consultant surgeons to acquire the necessary skills to incorporate new surgical technologies and innovation into their surgical repertoire. In addition simulation allows scope for error and the ability to allow trainees to learn the consequences of error [11]. Animal training models have been widely used for laparoscopic surgical skills training [12]. When designing and developing such a model, the following factors should be considered [13]: (1) the model should be as realistic as possible to simulate the anatomy and pathology involved in the procedure; (2) skills learnt on the model can be transferred to the operating theatre; (3) the final result of the performance can be made available for inspection and feedback; (4) the model has the ability to distinguish the experience of surgeons; and (5) production of the model is cost-effective and simple to allow it to be massively reproduced for a group of participants.

A model developed has to be realistic, appropriate, and effective as a teaching and training tool, and it should also possess the ability to distinguish surgeons' experience. Thus validation of reliability and effectiveness remains critical [14-16].

Methods and Materials

Design and preparation of the restructured animal tissue model

Porcine stomach and omentum were collected from a local abattoir that was fully registered under the standard regulations stipulated by the meat industry and follows strict ethical guidelines.

Figure 1: Laparoscopic training box mounted with neoprene pneumoperitoneum.

Figure 2: Laparoscopic adhesiolysis using the Harmonic scalpel.

A laparoscopic training box, a 10 mm 30 degree laparoscope, 3 ports (2 mm x 11 mm and 1 mm x 5 mm), a Prolene mesh, a 1-0 Vicryl suture, a ruler and a marker pen and chalk, a laparoscopic tacking device, 2 x laparoscopic graspers, hook diathermy or a laparoscopic Harmonic scalpel, 4 x mosquito forceps, a 10 mm syringe, normal saline, a needle, a laparoscopic stack, laparoscopic and external scissors and a suture retriever are required to perform the simulated laparoscopic adhesiolysis and mesh repair of an incisional hernia.

The laparoscopic training box was mounted with neoprene, which simulates the anterior abdominal wall. The neoprene on the laparoscopic trainer creates an air tight seal and therefore maintains a pneumoperitoneum when created (Figure 1). The greater curve of a porcine stomach is dissected out and a small circular defect is cut out of one layer of the double-layered stomach, this represents the hernial defect. Porcine omentum is stapled around the defect in the stomach, and this replicates the adhesions around the incisional hernia.

An experienced consultant general and colorectal surgeon provided close supervision and instruction during the construction of the simulated model.

The cost of making a complete laparoscopic simulation model was approximately £50, which included labour and materials.

Use of the animal tissue model for laparoscopic adhesiolysis and mesh repair of an incisional hernia

Course delegates insert an 11 mm laparoscopic port and gain pneumoperitoneum in a standard fashion. Diagnostic laparoscopy is then performed and the other 11 mm port and the 5mm port are inserted under direct vision. A laparoscopic adhesiolysis is undertaken where the omental adhesions around the hernia defect are taken down using hook diathermy, the Harmonic scalpel or laparoscopic scissors (Figure 2).

When the omental adhesions have been removed, the hernia defect becomes apparent. The diameter of the defect is measured with the ruler and its dimensions marked externally with the chalk, before cutting a piece of prosthetic mesh to size, using the ruler and marker pen for accuracy. Four stay sutures are inserted into the corners of the mesh with the 1-0 Vicryl suture.

The mesh is then rolled and inserted via the 11 mm port and unrolled within the simulated peritoneal cavity under laparoscopic vision. The stay sutures are used to approximate the mesh to the anterior abdominal wall internally, drawn out through the abdomen using the suture retriever and held in place using the mosquito forceps. The mesh is then tacked to the anterior abdominal wall using the laparoscopic tacking device (Figures 3 and 4).

Transverse abdominis plane (TAP) blocks are then sited under laparoscopic vision, and the ports are removed under vision.

Face and content validity

A clear announcement of voluntary participation was made to the course delegates, and who gave consent before participating in the study.

Criteria for validity were defined based on the definition and recommendation that are commonly used for validity testing for laparoscopic models and simulators [14-16].

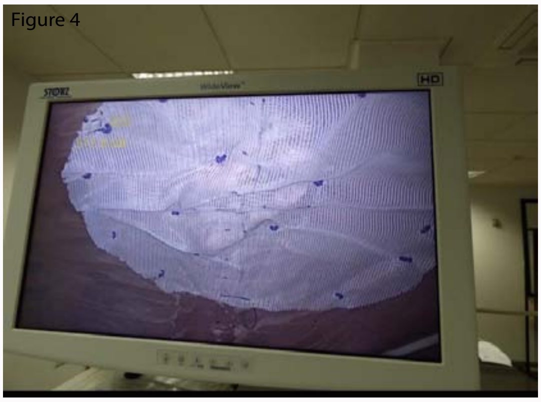
Face validity relates to the degree of realism of the simulator in relation to the real anatomy and setup, whereas content validity involves the measurement of the appropriateness of the simulator as an effective modality [14].

A structured questionnaire was designed for face and content validity of the laparoscopic simulator based on subjective assessment by both participants and experts.

At the end of the course, all participants and experts completed this questionnaire to assess the validity of the model for laparoscopic adhesiolysis and hernia repair training [13].

The evaluation of realism on (1) anatomy and colour, (2) sensation of texture and feeling of dissection of the tissues, (3) efficacy and safety of the skills, (4) maintenance of pneumoperitoneum, (5) laparoscopic adhesiolysis, (6) mesh handling and fixation, and (7) fixation of the mesh to the abdominal wall were the end points for assessment of the face validity of the adhesiolysis and hernia repair model (Table 1).

Questions such as 'Is this a useful model for training in laparoscopic adhesiolysis and hernia repair? 'Do you think the skills learnt from this model are transferrable to the operating theatre?' 'Do you feel more confident in performing laparoscopic adhesiolysis and incisional hernia repair after practicing on this model?' 'Do you think this model can be used as a routine training model for lap incisional repair?' were used for content validity.



Figures 3 and 4: The mesh is then tacked to the anterior abdominal wall using the laparoscopic tacking device.

Data collection and statistical analysis

Data was collected using a Likert scale (1 = strongly disagree; 2 = disagree; 3 = neither agree nor disagree; 4 = agree; and 5 = strongly agree) on a standardized anonymous questionnaire. Both course delegates and expert surgeons completed evaluation forms, and analysis of the feedback was performed. Excel (Microsoft Office 2013) and statistical Package for the Social Sciences version 16 were used for data collection and analysis.

Results

Demographics of participants and experts

A total of 33 course delegates were recruited to this study from June 2016 to June 2017. Twenty four of the course delegates were male and 9 were female, with ages ranging from 27 to 48 years. Course delegates had between 2 and 9 years of laparoscopic experience. The expert group consisted of 7 consultant surgeons and a senior registrar with significant experience in laparoscopic surgery, with ages ranging from 35 to 82 years. The expert group had an average of 19.1 ± 6.90 years laparoscopic experience compared to the trainee group who had an average of 4.55 ± 2.22 years of laparoscopic experience.

Course delegates and expert surgeons were recruited to the study on a voluntary basis without any financial interest or other conflicts of interest.

Outcome of face validity of the model

The overall mean satisfaction rate for the training model given by the participants was 4.18 ± 0.77 for port position, 4.12 ± 0.78 for anatomy and colour, 4.00 ± 0.79 for sensation and texture of the tissue, 4.73 ± 0.52 for maintenance of pneumoperitoneum, 4.12 ± 0.78 for laparoscopic adhesiolysis and 4.61 ± 0.56 for mesh handling and

Table 1: Face and content validity parameters measured during the study.

Areas assessed	Expert group scores*	All trainee scores (n=33) Face Validity
Face Validity		
Port position	4.50 ± 0.53	4.18 ± 0.77 p=0.28**
Anatomy and colour	4.38 ± 0.52	4.12 ± 0.78 p=0.39
Sensation and texture of feeling of dissection of tissues	4.25 ± 0.71	4.00 ± 0.79 p=0.42
Efficacy and safety of skills exercise on the model	4.88 ± 0.35	4.48 ± 0.57 p=0.07
Maintenance of pneumoperitoneum	4.25 ± 0.71	4.73 ± 0.52 p=0.04
Laparoscopic adhesiolysis	4.75 ± 0.46	4.12 ± 0.78 p=0.04
Mesh handling and fixation	4.75 ± 0.46	4.61 ± 0.56 p=0.51
Fixation of mesh to abdominal wall	4.25 ± 0.46	4.73 ± 0.52 p=0.02
Content Validity		
Perceived usefulness of model for teaching lap incisional hernia repair	4.63 ± 0.52	4.79 ± 0.42 p=0.35
Perceived transferability of skills from model to operating theatre	4.88 ± 0.35	4.73 ± 0.52 p=0.45
Perceived trainee confidence after using model	4.50 ± 0.53	4.70 ± 0.53 p=0.35
Perceived usefulness of model as part of routine training	5.00 ± 0.00	4.67 ± 0.48 p=0.06
Overall satisfaction with exercise	4.63 ± 0.52	4.79 ± 0.42 p=0.35

*All scores presented as mean ± standard deviation
**P values given for t-test against expert group unless otherwise specified. P <0.05 was considered to be statistically significant

fixation on a scale of 1 (unrealistic/poor) to 5 (very realistic/useful), whereas the experts rated these parameters as 4.50 ± 0.53, 4.38 ± 0.52, 4.25 ± 0.71, 4.25 ± 0.71, 4.75 ± 0.46 and 4.75 ± 0.46 respectively (Table 1).

Content validity

Both participants and experts agreed that this was a very useful and effective model for training in laparoscopic adhesiolysis and mesh repair of an incisional hernia (4.79 ± 0.42 *vs.* 4.63 ± 0.52 respectively (Table 1). The trainees felt that the skills acquired from this model could be transferred to the operating theatre.

Both course delegates and experts felt that this model could be used as a routine training model for laparoscopic adhesiolysis and mesh repair of an incisional hernia (4.67 ± 0.48 *vs.* 5.00 ± 0 (Table 1).

Discussion

Virtual reality simulators for laparoscopic surgical skills training are an invaluable training resource [13]. However animal tissue models have been shown to be superior and are the preferred method for surgical trainees to acquire technical skills in laparoscopic surgery when a suitable organ or tissue can be found in an animal [12]. When suitable and realistic anatomy cannot be found naturally, a restructured animal tissue model can become a valuable and effective training resource.

Restructured animal tissue models have been successfully developed and used in a variety of different laparoscopic procedures such as laparoscopic salpingectomy and laparoscopic fundoplication in gynaecological and general surgical training respectively [17,18]. These models have been proven to be realistic, cost-effective, and simple enough to be produced for use in laboratory-based surgical training courses with a large number of surgical trainees [17,18]. In addition when these restructured animal tissue models are used during surgical training courses the final results of the procedures can be assessed, feedback can be given to the trainees, and the exercise can be repeated [17,18].

The materials and methods used to develop this laparoscopic adhesiolysis and incisional hernia repair model with restructured porcine stomach and greater omentum within a laparoscopic training simulating box have been described in detail in this article. The key features that were considered when designing and developing this model were realistic anatomy, effective simulation repetitive practice, feedback on performance, simulator validity, and cost [13].

The aim of this article was that by describing the details of the materials used and methods applied to design and develop this simulated training model, that surgical trainers could replicate this model and integrate it into their training program [19].

There is no doubt that when compared to synthetic training models, animal training models and virtual reality simulators, human cadavers remain the most realistic training model for many laparoscopic and open surgical procedures. It is our recommendation that junior and intermediate surgical trainees acquire basic and intermediate level laparoscopic skills on a restructured animal tissue model before progressing to simulation training on cadavers when they attend advanced laparoscopic training courses.

It is essential to validate a simulator to examine its fidelity, authenticity, and efficiency before it is integrated into a training course [13-16,20-23]. Therefore the face and content validation of this laparoscopic training model was performed.

Expert surgeons found port position, anatomy and colour of the model, sensation and texture of the tissues, efficacy and safety of the skills exercise and mesh handling more realistic than the trainee surgeons but this difference was not statistically significant. However expert surgeons found laparoscopic adhesiolysis on the model more realistic than the course delegates and this difference was statistically significant. This is a positive endorsement of this training tool as expert surgeons with vast experience in laparoscopic surgery found the model realistic and skills acquired during this exercise transferrable to real-life surgery. Expert surgeons found maintenance of pneumoperitoneum and fixation of mesh to the abdominal wall less realistic than the trainee surgeons and these differences were statistically significant (Table 1).

In terms of content validity trainees rated the model more useful for teaching laparoscopic incisional hernia repair than expert surgeons but this difference was not statistically significant. Both trainees and expert surgeons felt that skills acquired with this training tool were highly transferrable and increased confidence was gained in laparoscopic skills as a result of using this training tool, and all agreed that this training model should be integrated into laparoscopic training.

Compared with the other existing training models, the major advantages of this laparoscopic adhesiolysis and mesh repair of an incisional hernia model are: 1) real animal tissue was used; hence tissue planes could be appreciated, tissue handling was on par with real - life laparoscopic surgery, and haptic feedback was present; 2) the relevant anatomy and pathology in the training tool was restructured as closely as possible to real-life anatomy and pathology; 3) real electrosurgery, real equipment and instruments were utilized during the exercise; 4) the final results of the laparoscopic training tool were validated over a one year period with course delegates and independent expert surgeons, and 5) the model was cost effective [17]. The model cost £50 and hence the cost was minimal compared to other simulators [13,17,22]. Despite the high scores achieved from both expert surgeons and trainee surgeons, the major disadvantage of this model is that it did not simulate bleeding that is an essential skill to learn to avoid and manage when it occurs. A potential future improvement in this training model might be to simulate intra-operative bleeding so that the model is more applicable to real life. There was also a lack of objective data to demonstrate whether skills learned on this model could be transferred to improved performance in the operating theatre (criterion validity). Further studies on criterion validity should be conducted if this model is to be used as an assessment tool for the trainees in the future.

Conclusion

A newly designed restructured animal tissue model for training laparoscopic adhesiolysis and mesh repair of an incisional hernia is reported. Validation studies on the model demonstrate that this is a very realistic and effective model for skills training in laparoscopic adhesiolysis and mesh repair of an incisional hernia.

As a result of this laparoscopic training model course delegates reported that they had gained transferrable operating skills and increased confidence in the performance of laparoscopic adhesiolysis and incisional hernia repair with mesh. This training model is an effective and cost-efficient laparoscopic training simulator.

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