VALIDATION STUDY OF AR GYNAE ENDOTRAINER

DR NUR HIDAYAH BINTI MOHD FAUZI

Dissertation Submitted in Partial Fulfilment

of the Requirement for Degree of Master of Medicine

(Obstetrics and Gynaecology)

SCHOOL OF MEDICAL SCIENCES
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ACKNOWLEDGEMENT

BISMILLAHIRRAHMANIRRAHIM

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ABSTRAK

Latar Belakang:

Di dalam bidang ginekologi, kaedah laparoskopi merupakan pilihan dalam pelbagai jenis rawatan pembedahan kerana ianya dianggap selamat dan berkesan. Walau bagaimanapun, pembedahan laparoskopi memerlukan kemahiran yang tersendiri dan berbeza dengan kemahiran yang diperlukan di dalam pembedahan laparotomi. Untuk mendapatkan kemahiran tersebut, seorang pakar bedah memerlukan latihan yang spesifik. Tujuan kajian ini dilakukan adalah untuk memvalidasi *AR Gynae endotrainer*, sebuah alat simulasi laparoskopi mudah alih yang digunakan di dalam latihan laparoskopi ginekologi, sebagai sebuah alat simulasi yang setanding dengan produk bertaraf antarabangsa iaitu *Karl Storz SZABO-BERCI-SACKIER laparoscopic trainer*.

Metodologi:

Sebuah kajian prospektif telah dijalankan untuk membandingkan *AR Gynae endotrainer* dengan *Karl Storz SZABO-BERCI-SACKIER laparoscopic trainer* sebagai sebuah alat simulasi untuk melatih kemahiran di dalam laparoskopi ginekologi. Para peserta ditugaskan untuk melakukan dua tugasan dengan menggunakan kedua-dua alat *endotrainer* tersebut. Kesemua peserta kemudian membuat penilaian ke atas prestasi kedua-dua *endotrainer* dengan menggunakan kaedah soal selidik dengan membandingkan: reka-bentuk, penempatan alat laparoskopi, kebolehlihatan, ergonomik, triangulasi pergerakan, kesan fulkrum, persepsi kedalaman, kedwicekatan, sumber latihan dan sumber pengajaran. Markah keseluruhan didefinisikan sebagai nilai median yang diperoleh. Kebolehan dan masa yang diambil untuk menyiapkan tugasan yang diberi menggunakan kedua-dua *endotrainer* juga dibandingkan. Sejumlah 26 peserta terlibat di dalam kajian ini termasuk 13 pelajar sarjana dari Jabatan

Obstetrik & Ginekologi dan 13 pelajar sarjana dari Jabatan Pembedahan, Hospital Universiti Sains Malaysia (HUSM), Kelantan, Malaysia.

Keputusan:

AR Gynae endotrainer menunjukkan prestasi yang lebih baik berbanding *Karl Storz endotrainer* di dalam 5 daripada 10 kriteria yang dinilai di dalam soal selidik. Markah keseluruhan yang diperoleh oleh *AR Gynae endotrainer* (median 3.98) adalah setanding dengan *Karl Storz endotrainer* (median 3.91) (p=0.519). Markah penilaian ke atas *AR Gynae endotrainer* adalah ketara lebih tinggi bagi kriteria reka-bentuk (p=0.003) dan sumber pengajaran (p=0.032). Kesemua peserta berjaya menyiapkan kedua-dua tugasan menggunakan kedua-dua alat *endotrainer*. Masa yang diambil untuk menyiapkan kesemua tugasan adalah setanding bagi kedua-dua *endotrainer*. *AR Gynae endotrainer* juga adalah jauh lebih murah.

Konklusi:

AR Gynae endotrainer merupakan sebuah alat latihan simulasi laparoskopi ginekologi yang senang digunakan dan lebih jimat serta setanding dengan *Karl Storz SZABO-BERCI-SACKIER laparoscopic trainer* yang merupakan produk bertaraf antarabangsa.

ABSTRACT

Background:

In gynaecology, laparoscopy is the choice of treatment for a lot of procedures as it is considered safe and effective. However, laparoscopic surgery requires skills that are different from those required for open surgery. In order to acquire the skills, a surgeon needs specific training. The aim of this study was to validate the AR Gynae endotrainer, a new mobile laparoscopic simulator, as a comparable box trainer for gynaecology laparoscopic training, comparing it with the well-established Karl Storz SZABO-BERCI-SACKIER laparoscopic trainer.

Methodology:

A randomized prospective crossover study was designed to compare AR Gynae endotrainer versus Karl Storz SZABO-BERCI-SACKIER laparoscopic trainer as a tool for training gynaecology laparoscopic skills. Participants were assigned to perform two specially designed tasks used for laparoscopic training using both endotrainers. All subjects evaluated both simulators concerning their performance by the use of a questionnaire comparing: design, ports placement, visibility, ergonomics, triangulation of movement, fulcrum effect, depth perception, ambidexterity, resources for training and resources for teaching. The overall score was defined as the median value obtained. The ability and time taken for participants to complete the tasks using both endotrainers were also compared. A total of 26 participants were enrolled in this study, including 13 Masters's students from the Department of Obstetrics & Gynaecology and 13 Masters's students from the Department of Surgery, Hospital Universiti Sains Malaysia (HUSM), Kelantan, Malaysia.

Results:

A better performance was observed with AR Gynae as compared to Karl Storz endotrainer in 5 out of 10 items evaluated in the questionnaire. Additionally, the overall score of AR Gynae endotrainer (median of 3.98) was comparable to that of Karl Storz endotrainer (median of 3.91) with p=0.519. For the items design and resources for teaching, the evaluation for AR Gynae endotrainer was significantly higher with p-values of 0.003 and 0.032, respectively. All participants were able to complete both tasks using both endotrainers. The time taken to complete both tasks were comparable on both endotrainers. Also, the AR Gynae endotrainer was cheaper.

Conclusions:

The AR Gynae endotrainer was found to be a convenient and cost-effective laparoscopic simulator for gynaecology laparoscopic training and was comparable to the established Karl Storz SZABO-BERCI-SACKIER laparoscopic trainer.

Keywords: Laparoscopy, endotrainer, simulator, minimally invasive surgery.

LIST OF ABBREVIATIONS

MIS	Minimally invasive surgery
BT	Box trainers
VRS	Virtual reality simulators
GESM	Gynaecological Endoscopic Society of Malaysia
O&G	Obstetrics and Gynaecology
USM	Universiti Sains Malaysia
HUSM	Hospital Universiti Sains Malaysia
FLS	Fundamental of Laparoscopic Surgery
SAGES	Society of American Gastrointestinal and Endoscopic Surgeons
MISTELS	McGill Inanimate System for Training and Evaluation of Laparoscopic Skills
MSU	Mobile simulation unit
ESTBS	Endosuture trainer box simulator
SLT	Standard laparoscopic trainer
SPT	Standard pelvic trainer
HKCOG	Hong Kong College of Obstetricians and Gynaecologists
JEPeM	Human Research and Ethics Committee USM

OPERATIONAL DEFINITIONS

Laparoscopy	A type of surgery performed in the abdomen or pelvis using small incisions with the aid of a camera
Minimally Invasive Surgery	Surgical procedure that is performed through tiny incisions instead of a large opening
Endotrainer	A device for healthcare professionals to practice techniques used in endoscopic surgery
Virtual Reality Simulator	Virtual reality systems seek to simulate a surgical procedure in a computer-generated world in order to improve training
Design	Colour, shape, technology and function of an object
Ports Placement	Sites for access to the peritoneal cavity
Visibility	How clearly an image can be seen
Ergonomics	It is the study of the psychological and physical interaction between the users and their tools
Triangulation of Movement	Smooth instrument manipulation along with adequate visualization during laparoscopy
Fulcrum effect	The instrument tips move in the opposite direction to the surgeon's hands around the port site (fulcrum)
Depth Perception	Depth perception is the visual ability to perceive the world in three dimensions and the distance of an object
Ambidexterity	Ability to use the right and left hands equally well

Resources for Training	Physical resources include the training materials and the physical environment for the delivery of formal training
Resources for Teaching	Material that is designed to help facilitate learning and knowledge acquisition

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THESIS

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1.0 INTRODUCTION

Minimally invasive surgery (MIS) has revolutionised surgical care (1). It is often used for several surgical procedures in the last decade. The role of laparoscopic surgery is fast emerging. It represents the 'gold standard', for example, in appendicectomy, cholecystectomy, hernia repair, anti-reflux and bariatric surgery (2). In gynaecology, laparoscopy is the choice of treatment for several procedures, for example, dye test to assess for tubal patency, tubal ligation as one of the sterilisation methods, salphingectomy in ectopic pregnancy, cystectomy, myomectomy as well as hysterectomy in benign cases.

Laparoscopic procedures are considered safe and effective. The implementation of operative laparoscopy has reduced the duration of hospital stay and the convalescence period and has helped improve patient outcomes and enhance recovery after surgery (3,4). Laparoscopy has gone through a series of developmental phases and has become the primary choice as a surgical technique (5).

Although the laparoscopic technique has many benefits, implementation was a challenge. Laparoscopic skills are very different to those used in open surgery and require specific training (6). It is more complex and requires a new set of skills. The surgeon has to become proficient in handling the new instruments with limited range of movement, the considerable loss of depth perception and haptic feedback, dealing with the counter-intuitive manipulation of the instruments (fulcrum effect), and the two-dimensional (2-D) representation of the three-dimensional (3-D) operating field (7,8,9). In order to acquire all of these skills, a surgeon must have continuous training and do many practices.

For a minimally invasive approach, the procedures must be performed by skilled and well-trained surgeons. However, besides the lack of trained endosurgeons to help the amateurs, it is also difficult and time-consuming to teach these skills to the surgeons in training by apprenticeship method (2). It requires longer time to practice and more learning opportunities in clinical practice (10). Limited resources and non-availability of formal animal labs make training in minimal access surgery has always been difficult in developing countries. Thus, simulation training was developed.

During the last few decades, it has been firmly established that laparoscopic skills can be acquired outside the operation theatres using simulators (11). Training can be done on either traditional box trainers (BT) or Virtual Reality Simulators (VRS), which have been shown to be effective methods for providing laparoscopic skills training (12).

Unfortunately, barriers to simulation training – including the need for time to train, unaffordability of conventional endotrainers due to the high prices, and the lack of access – have halted the implementation of simulation training in laparoscopic training programmes. Low accessibility, in particular, has been a constraint. Access to training can be improved by using mobile BT, as this method is affordable, accessible and mobile and therefore allow trainees to train according to their own schedule (13).

There are few training centres for minimally invasive surgery, specifically in gynaecology worldwide. In Malaysia, the Gynaecological Endoscopic Society of Malaysia (GESM) is an official representative body for gynaecologists in Malaysia with a special interest in gynaecology endoscopy and minimally invasive gynaecology surgery. However, until now, we do not yet have our own proper laparoscopic training centre.

Gynaecologists who are interested to further in minimally invasive gynaecology surgery need to be sent out for training in outside countries, i.e. the United Kingdom, India and Taiwan.

As an initiative to help more gynaecology trainees get the chance for laparoscopic training, five lecturers from the Department of Obstetrics and Gynaecology (O&G), School of Medical Sciences, Universiti Sains Malaysia (USM), Kelantan, Malaysia have collaborated to produce AR Gynae endotrainer.

AR Gynae endotrainer is an example of a mobile box trainer that was invented specifically for the practice of laparoscopy surgery in gynaecology. It is the first of its kind invented locally in Malaysia.

This AR Gynae endotrainer was designed to mimic the patients' abdomen instead of the usual training box available. The ports are placed as in actual laparoscopy gynaecology surgery in real patients. This will help the gynaecologists in their learning curve to achieve their basic skills without putting unnecessary risks to patients. It was invented with the intention of making it available to gynaecologists who are interested in learning laparoscopic skills at an affordable price.

AR Gynae endotrainer is made from fibreglass. Its shape is very special – it mimics a real patient's abdomen in laparoscopy surgery which is inflated and distended. It is a one-piece product, relatively small and very light, thus portable and can easily be carried anywhere. The size is about 49cm x 35cm x 24cm, and it weighs only 2kg. There are two ipsilateral ports on each side (right and left) and one suprapubic port placed 12cm from the

pubic bone area. Each port's hole is covered with a round rubber clip. Distance between the ports is 8 to 10 cm. It has a fixed camera and LED light inside positioned at the umbilical site. It just needs to be connected to a laptop with a front camera and ready to be used. No electrical power supply is needed. AR Gynae endotrainer comes with a specially designed board with different exercises used for practice. The board is inserted inside the "abdomen" through a door placed at the lower part of the endotrainer. It is very cheap and affordable. It costs about RM 2,000 (Fig. 1,2,3).

Fig. 1 AR Gynae endotrainer

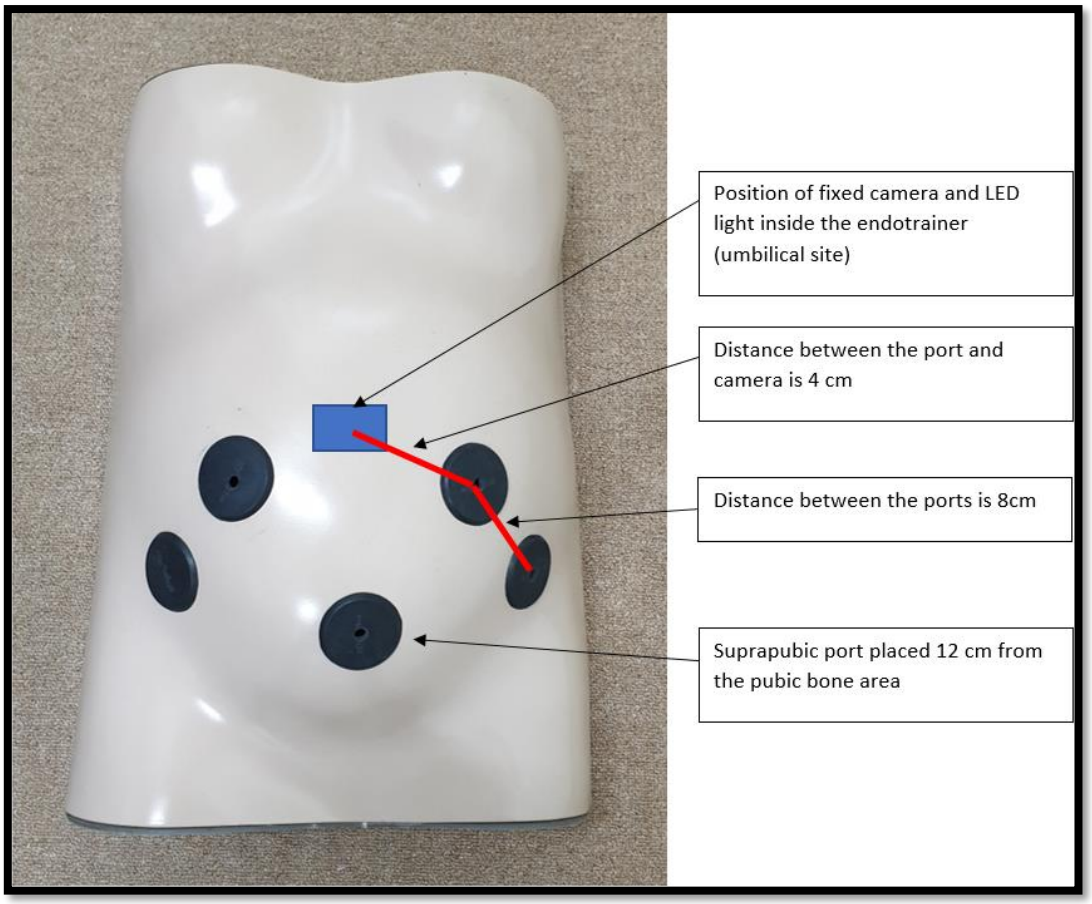

Fig. 2 Ports placement in AR Gynae endotrainer

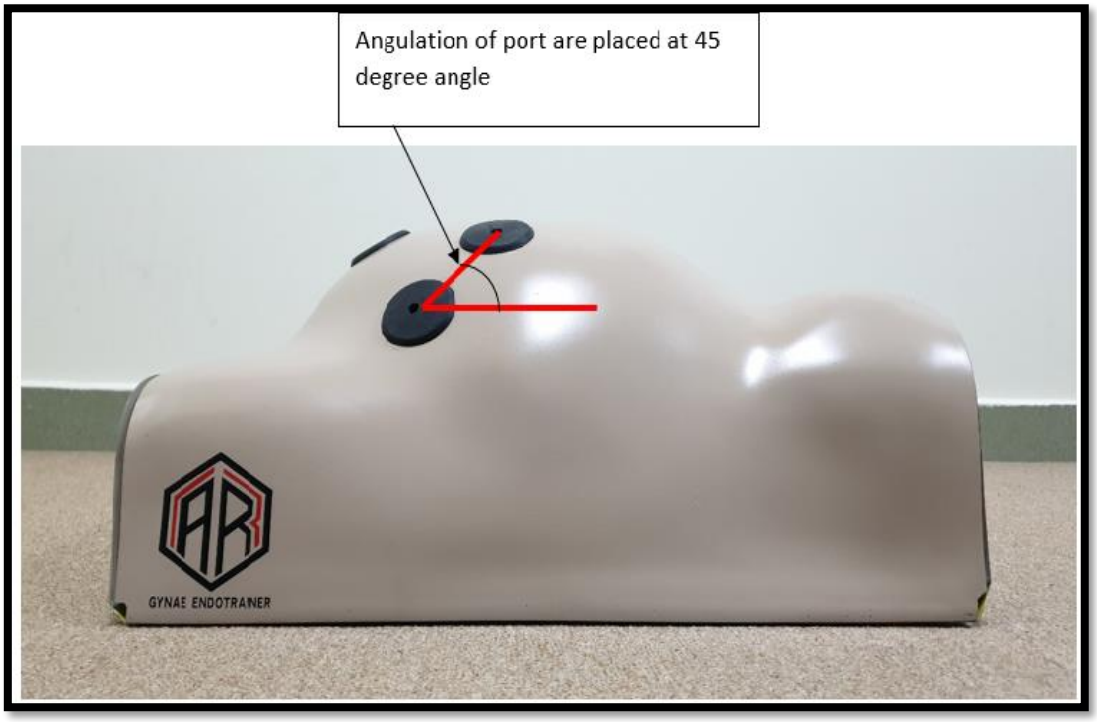

Fig. 3 Angulation of port

There are few tasks designed for AR Gynae endotrainer, and they are inspired by the tasks used in the Fundamental of Laparoscopic Surgery (FLS) simulator. The FLS simulator, which was developed by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), uses five tasks designed by Dr Gerald Fried for the FLS Program, which are Peg Transfer, Pattern Cutting, Endoloop Placement, Extracorporeal Suturing and Intracorporeal Suturing. These tasks are based on the McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) program developed at McGill University and have been extensively tested to ensure that they reflect those technical skills that are fundamental to the performance of laparoscopic surgery (14,15,16)

One of the tasks in the FLS program is "Peg Transfer" (Fig. 4). This task is used to develop eye-hand coordination, depth perception as well as visual-spatial perception in a monocular viewing system. It also develops coordinated use of dominant and non-dominant hands (ambidexterity), a skill proven to translate into better intracorporeal suturing skills (17).

In this task, six pegs are placed on the left side of the pegboard. The pegs need to be lifted with a grasper first in the non-dominant (i.e. left) hand and transfer the object midair to the dominant hand. Then, the pegs will be placed on the right side of the board. Once all six pegs have been transferred, the process is reversed. Each peg is lifted using the dominant (i.e. right) hand from the right side of the pegboard, transferred midair to the left hand and placed on the left side of the board.

Two tasks used in AR Gynae endotrainer - “Beans Transfer” and “Bands Transfer” are specially designed based on this task (Fig. 5,6). In the 'Beans Transfer' task, two types of

beans, 10 of each type, are mixed together and placed in a container in the middle of the training board. The beans need to be transferred into two separate containers on the board according to their types using atraumatic graspers. Both hands need to be used alternately.

While in the 'Bands Transfer' task, two different colour bands, 10 of each colour, are mixed together and placed in the middle of the training board. The bands need to be transferred into two polls on the board according to the colour of the bands using atraumatic graspers. Both hands need to be used alternately.

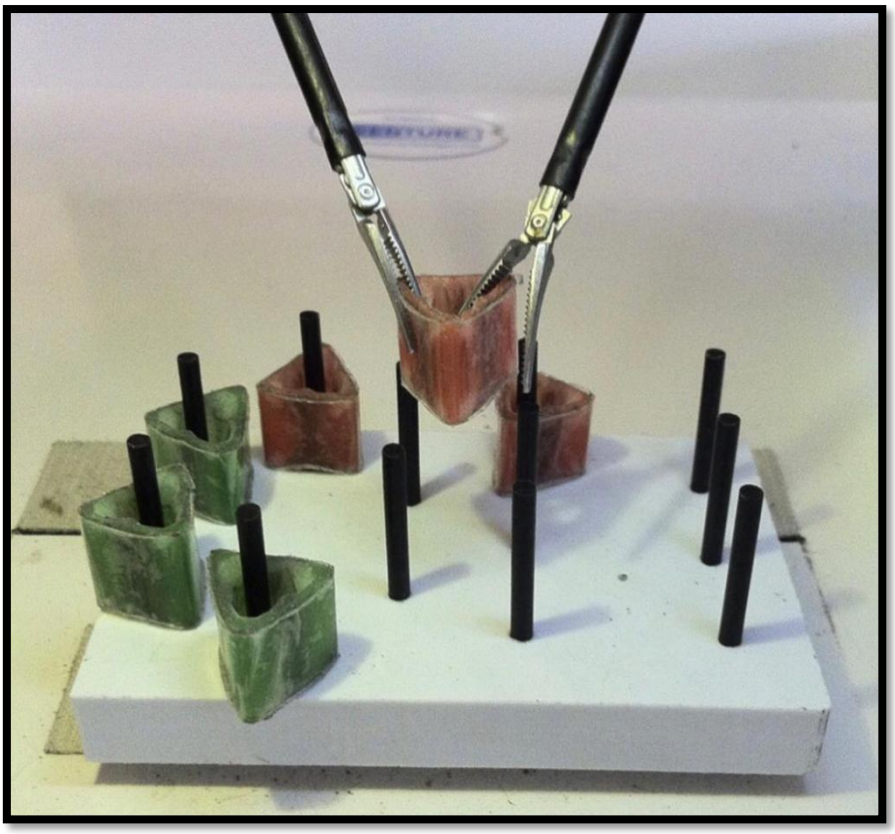

Fig. 4 Peg Transfer

Fig. 5 Beans Transfer

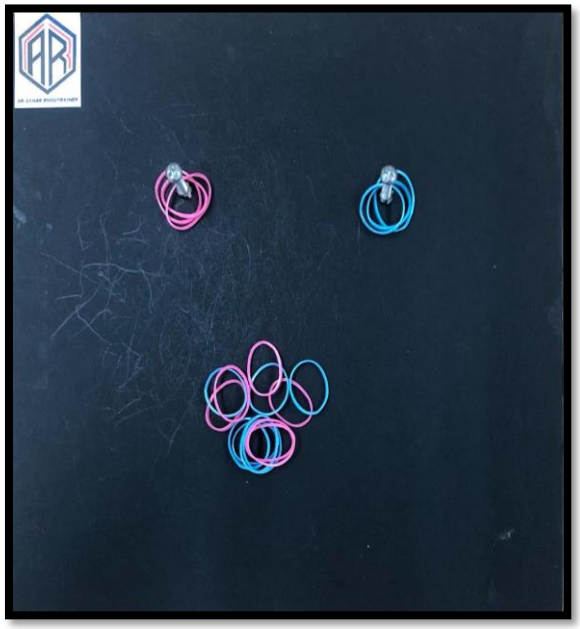

Fig. 6 Bands Transfer

Karl Storz is the leading endoscope manufacturer based in Germany. It has served the world for more than 70 years. It is an established brand and very well known for its advanced technology and quality. Karl Storz had produced endotrainers for different types of surgery, i.e. neurosurgery, otorhinology, cardiovascular and abdominal surgery. One of the endotrainers is SZABO-BERCI-SACKIER laparoscopic trainer, which is used for training laparoscopy in surgery, gynaecology and urology (Fig. 7). It was designed to simulate various laparoscopic procedures, especially the different suturing techniques. It contains diaphragms at the typical puncture sites and a flexible endoscope holder that provides the surgeon with the ability to manipulate instruments with both hands. The endoscope is connected to a compact and portable all-in-one system called TELE PACK X LED that has a high-resolution display and powerful LED light source just like the real one used in the operating room (Fig.8). The exercise board can just be placed inside the endotrainer. The SZABO-BERCI-SACKIER laparoscopic trainer costs about RM12,000. Together with the endoscope and the system, it costs more than RM100,000, according to the local supplier.

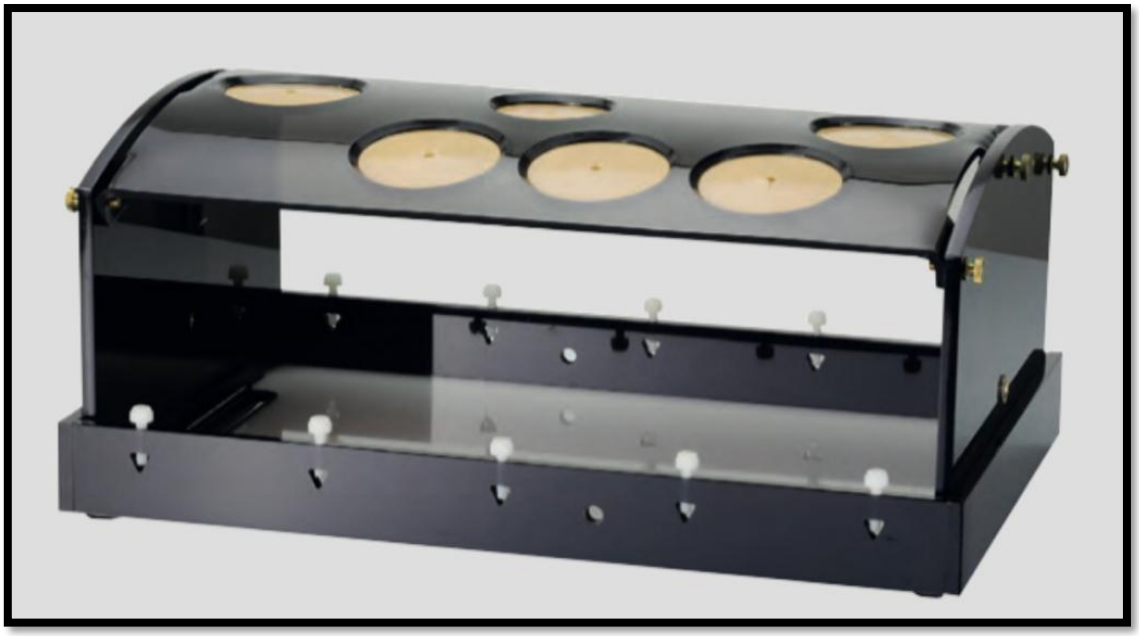

Fig. 7 SZABO-BERCI-SACKIER laparoscopic trainer

Fig. 8 SZABO-BERCI-SACKIER laparoscopic trainer with endoscope held by flexible endoscope holder and connected to TELE PACK X LED system

2.0 LITERATURE REVIEW

LAPAROSCOPY VS LAPAROTOMY

Minimally invasive surgery or laparoscopy has many advantages, i.e. lesser post-operative pain, reduced duration of hospital stay and faster recovery. It has also been proven to be associated with lesser morbidity compared to open surgery or laparotomy.

A study by Walker et al. in 2009, comparing laparoscopy and laparotomy method for comprehensive surgical staging of uterine cancer stage I-IIA showed that comprehensive surgical staging of endometrial cancer could be performed using laparoscopy without increased intra-operative injuries, resulting in less pain and faster recovery, with fewer post-operative complications such as ileus and with shorter hospital stay (18).

An article in the American Journal of Obstetrics and Gynaecology in August 1994 comparing surgical management for patients presenting with pelvic pain who underwent adnexectomy either via laparoscopic or laparotomy concluded that patients who underwent laparoscopic surgery had reduced post-operative pain, short hospitalisation and rapid recovery (19).

Another study held in Canada by Lin et al. on the excision of the ovarian dermoid cyst by laparoscopy and laparotomy proved that hospitalisation time is reduced and recovery is faster in the laparoscopic approach (20).

Another example of morbidity associated with any surgical procedure is adhesion. A study in Sweden looking at adhesion post laparoscopic versus laparotomy salphingotomy for ectopic pregnancy via second look laparoscopy showed that the incidence of adhesions to the affected tube is higher in the laparotomy approach with an increment from 40 per cent to 79 per cent in the laparotomy group compared to 48 per cent to 58 per cent increment in the laparoscopy group (21).

ROLE OF SIMULATORS IN LAPAROSCOPIC TRAINING

However, in order to be able to perform any laparoscopic procedures, a surgeon must have specific skills. Laparoscopic skills are very different to those used in open surgery and require specific training. To train laparoscopic skills to the surgeons in training by apprenticeship method would be very difficult and time-consuming. It requires a longer time to practice and more learning opportunities in clinical practice. Thus, simulation training was developed. It has been proven that laparoscopic skills can be acquired using simulators, either by using a box trainer (BT) or virtual reality simulator (VRS).

A study by Diana L. Diesen et al. in 2011 on 23 novices in laparoscopy surgery who were recruited to participate in a supervised 6-month laparoscopic training program with either BT or VRS showed that there was a significant overall improvement in their surgical skills during an assessment at 0, 2 and 6 months of training with no differences was found between the average score of the BT participants versus the VRS participants (22).

An article in Surgical Endoscopy in 2004 comparing performances after three weeks of training of 24 medical students with no laparoscopic experiences who were randomised

into three groups: LapSim, box trainer, and no training (control) concluded that both trained groups made significant improvements in all parameters and there were no significant differences between the LapSim and BT groups (23).

A study in the United Kingdom in 2012 compared different methods of learning basic laparoscopic skills using BT and VRS and mental training, and one of the conclusions that were made is there were improved learning outcomes on both BT and VRS on several parameters while mental preparation did not prove to be effective in novices learning a new skill (24).

Troncoso-Bacelis et al. in Spain in 2015 held a study to assess the effectiveness of surgeons warming up with an endotrainer before performing laparoscopic cholecystectomy. Sixteen surgeons practised two laparoscopic cholecystectomies, the first with the standard practice with direct entry into the surgery and the second on a different day and with a different patient, with a warm-up of 5min prior to the surgical procedure commencing using LAPA-PRO endotrainer. The study concluded that performing warm-up on a MISTELS system endotrainer before performing laparoscopic cholecystectomy reduces the operating time of surgery for all surgeons (25).

A prospective comparative study to evaluate the impact of laparoscopy simulator training on technical competence during a real surgical procedure was held in France in 2011. The study divided the residents into three groups: Mcgill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) group, training on a simple simulator; LAP Mentor group, training on a virtual simulator; and control group. Each resident was then trained for one month. Initial evaluation and second evaluation post-training were performed.

The results showed that there was a significant improvement in the scores in the MISTELS (P= .042) and LAP Mentor (P = .026) groups and not in the control group (26).

A literature review focusing on BT and VRS was published in the European Journal of Obstetrics & Gynecology and Reproductive Biology in 2019. The author concluded that the traditional approach to surgical training needs to evolve with the integration of novel training tools such as simulators. Inanimate models are safe, easily reproducible, readily available, offer the challenge of unlimited practice to trainees and require no supervision. BT are useful to learn basic laparoscopic skills with inherent advantages in terms of tactile sensation and affordability, whereas VRS have a higher cost, although they are better models to simulate advanced laparoscopic procedures. The majority of scientific evidence confirms a significant improvement in the performance of certain tasks following simulator training (27).

MOBILE VS FIXED SIMULATORS

Besides time constraints, low accessibility has been a barrier to simulation training. This can be improved by using mobile BT as it allows trainees to train according to their own schedule.

A comparative study on the efficacy of laparoscopic skills training in a Mobile Simulation Unit (MSU) compared with a fixed site was done in Australia in 2013. The study showed that participants who received MSU training achieved a significantly higher score in performance skills than their fixed-site counterparts. It was concluded that MSU-delivered laparoscopic simulation training is not inferior to fixed-site training (28).

LOW COST VS EXPENSIVE SIMULATORS

Commercial laparoscopic trainers are sold at a very high price and thus unaffordable for most trainees. Because of that, as an alternative, lots of cheap BT are produced worldwide. It has been proven in several studies that inexpensive, "home-made" BT are also as effective as expensive, high technology commercial BT for laparoscopic training purposes. Most importantly, most of these self-designed BT offer high-quality products at affordable prices.

A study by Mayank Jain et al. in 2009 proved that training on cheap, self-designed hernia BT shows good results and can be used for surgical residents and practising surgeons who are exposed to basic laparoscopic skills. The study assessed 40 candidates who were trained for two days using a self-designed simulator BT for hernia surgery. The result from the study showed significant improvement in the global (10.15 on day 1 and 12.85 on day 2) and task-specific score for transabdominal preperitoneal (TAPP) (3.55 on day 1 and 5.83 on day 2) and intraperitoneal onlay mesh (IPOM) (4.4 on day 1 and 6.4 on day 2) repair of groin and incisional hernia, respectively (29).

Another study published in BMC Surgery in 2018 compared the endosuture trainer box simulator (ESTBS) with the standard laparoscopic trainer (SLT), which is three times more expensive. A total of 37 participants with different levels of laparoscopic expertise were recruited for this study. All participants were required to perform suturing and knot tying tasks using both trainers and then responded to a 10-item questionnaire based on a 5-point Likert scale. It was found a superior performance of ESTBS as compared to SLT concerning to 7 items (triangulation of movement, resistance and resilience of portals, ergonomics and

positioning, technical resources for training, design, technological resources and teaching) and similar performance between the two devices in relation to another 3 items (stereotaxy, fulcrum effect and visibility). The median overall score showed that the overall performance of ESTBS (4, very good) was significantly higher ($P < 0.0001$) than that of SLT (3, good) (30).

A study by Yoon et al. compared a low cost, portable laparoscopic trainer (UCi Trainer) with a standard pelvic trainer (SPT) (Karl Storz, Tuttlingen, Germany). 16 participants were assigned to perform timed peg transfer and intracorporeal knot tying tasks with the UCi Trainer and SPT. The study showed that there was no significant difference between peg transfer and intracorporeal knot tying task scores completed on the UCi Trainer when compared with the SPT. The author concluded that the cost-effective UCi Trainer is a valuable tool for facilitating resident training in laparoscopy (31).

FUNDAMENTALS OF LAPAROSCOPIC SURGERY (FLS)

Specific skills are needed to perform laparoscopic surgery. The limited movement range of the instruments, the loss of depth perception, haptic feedback and the fulcrum effect are among the difficulties faced by the surgeon in laparoscopic surgery. To acquire the skills needed, a surgeon needs specific training. Formal training programmes in basic laparoscopy, such as the Fundamentals of Laparoscopic Surgery (FLS) course and some training programmes in advanced laparoscopy, have proved the transfer of acquired skills to the operating room.

An article in Cirugia Espanola in 2014 on simulation in laparoscopic surgery reviews the most important aspects of simulation in laparoscopic surgery, including the most used simulators and training programmes. The article highlighted the FLS course as a programme designed to teach the basic skills required in laparoscopic surgery and has been validated for and proved its correlation with basic technical skills in the operating room (32).

A study by Scott D.J et al. in 2008 showed a 100% passing rate of certification examination in 21 novice medical students who practised all five FLS tasks over two months period. The study also demonstrated significant improvement in post-testing scores compared with pre-testing scores (33).

Another study in Botswana, Africa, was held to determine the feasibility and impact of a 3-day FLS course. The study that involved 20 surgeons and trainees showed that the mean post-test scores were significantly higher than pre-test scores for each FLS task. The author concluded that the FLS course in a resource-restricted country is feasible and resulted in a significant improvement in FLS technical skills after three days (34).

3.0 RATIONALE OF THE STUDY

To validate AR Gynae endotrainer as a comparable box trainer for gynaecology laparoscopic training, which may help gynaecologists to practise laparoscopic skills at an affordable price.

4.0 RESEARCH QUESTIONS

1. What is the mean for the marks given by the participants for the below items for both AR Gynae endotrainer and Karl Storz SZABO-BERCI-SACKIER laparoscopic trainer based on the Likert scale?

i. Design
ii. Ports placement
iii. Visibility
iv. Ergonomics
v. Triangulation of movement
vi. Fulcrum effect
vii. Depth perception
viii. Ambidexterity
ix. Resources for training
x. Resources for teaching

2. How many participants were able to complete the designed tasks using both endotrainers?

3. What is the average time taken by the participants to complete the designed tasks using both endotrainers?

5.0 OBJECTIVES

5.1 GENERAL OBJECTIVE

To validate AR Gynae endotrainer as a comparable box trainer for gynaecology laparoscopic training

5.2 SPECIFIC OBJECTIVES

1) To compare the quality of AR Gynae endotrainer with Karl Storz SZABO-BERCI-SACKIER laparoscopic trainer in terms of:

i. Design
ii. Ports placement
iii. Visibility
iv. Ergonomics
v. Triangulation of movement
vi. Fulcrum effect
vii. Depth perception
viii. Ambidexterity
ix. Resources for training
x. Resources for teaching

2) To compare the ability to complete the designed tasks using both endotrainers

3) To compare the average time taken to complete the designed tasks using both endotrainers

6.0 RESEARCH METHODOLOGY

6.1 STUDY DESIGN AND STUDY VENUE

This study was a randomised prospective crossover study. It was conducted at the Department of O&G, HUSM, Kelantan.

6.2 STUDY POPULATION

Masters's students from the Department of O&G and Department of Surgery, HUSM, Kelantan.

6.3 INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria

- Masters's students in the Department of O&G HUSM who are of level 2 and above according to Hong Kong College of Obstetricians and Gynaecologists (HKCOG) criteria of levels of gynaecological laparoscopic surgery
- Masters's students in the Department of Surgery HUSM who may perform basic laparoscopic procedures, i.e. appendicectomy and cholecystectomy

Exclusion criteria

- Novices who have no experience in laparoscopy surgery

6.4 SAMPLE SIZE CALCULATION

The sample size was calculated using Sample Size Calculator version 2.0 by Wan Nor Arifin (http://wnarifin.github.io). For objectives 1 and 3, the sample size was calculated using Two-mean Comparison (paired/crossover) - Hypothesis Testing and Intraclass Correlation Coefficient methods as shown below in Table 1 and Table 2, respectively. For objective 2, the sample size was calculated using Kappa Coefficient method, as shown below in Table 3.

Table 1: Hypothesis Testing method

Standard deviation of difference (σ)	3.000
Expected difference (Δ)	2.000
Significance level (α)	0.050
Power (1-β)	0.800
Drop out	10%
Sample size	18
Sample size (with drop out)	20

Table 2: Intraclass Correlation Coefficient method

Observation/Subject (n)	2
Significance level (α)	0.050
Power (1-β)	0.800
Minimum acceptable reliability (ρ0)	0.70
Expected reliability (ρ1)	0.90
Drop out	10%
Sample size	23

Sample size (with drop out)	26

Table 3: Kappa Coefficient method

Minimum acceptable kappa (k0)	0.30
Expected kappa (k1)	0.90
Proportion of outcome (p)	0.30
Significance level (α)	0.050
Power (1-β)	0.800
Non-centrality parameter	7.849
Drop out	10%
Sample size	23
Sample size (with drop out)	26

From the calculations, the sample size required for this study, including ten per cent drop out, would be **26 participants**.

6.5 SAMPLING METHOD AND SUBJECT RECRUITMENT

A purposive sampling method was used in this study. An advertisement via social media was spread among Masters's students of O&G and Surgery HUSM. The inclusion and exclusion criteria were listed in the advertisement. HKCOG level criteria also were included in the advertisement so that participants could decide their level of competency. Those who fulfilled the criteria and consented to the study had contacted the principal investigator directly. Further explanation had been given by the principal investigator on any enquiry. The first 13 volunteered participants from the O&G department and the first 13 volunteered participants from the Surgery department who fulfilled the study criteria were recruited in this study to

meet the required sample. A suitable date and time for the study session were set. Consent was taken from all participants prior to data collection.

6.6 ETHICAL CONSIDERATIONS

This study was conducted after an ethical clearance had been obtained from the Human Research and Ethics Committee (JEPeM) of the School of Medical Sciences, USM (USM/JEPeM/20120642). The letter of approval was as attached in the appendix.

6.6.1 Vulnerability of the Participants

Participation of participants in this study was entirely voluntary. Recruitment of participants was via an advertisement on social media. There was no compulsion in this study. Prior to the study session, verbal and written consents were taken after participants were satisfied with the explanation given about the study. The data collection form was filled in by the participants separately from the consent form to keep anonymity in this study. Data collection forms were numbered using subject ID, and no personal details such as name were required. Participants might refuse to take part in the study and might withdraw at any point of the study without being discredited. Participants who decided to withdraw from this study did not need to justify their decision and were not required to return the incentives received prior.

6.6.2 Declaration of Conflict of Interest

This study involved Masters's students from the O&G Department HUSM who are also colleagues of the principal investigator and students of the co-investigator of this study. Therefore, to minimise the bias, participants from Surgery Department HUSM were also involved in this study.

6.6.3 Privacy and Confidentiality