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Simple and highly efficient laparoscopic training methods

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Für Asmaa und Dana

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Abbreviations:

ABS	American Board of Surgery
COPD	Chronic obstructive pulmonary disease
FLS	Fundamentals of Laparoscopic Surgery
HD	High Definition
LMICs	Low- and middle-income countries
NOTES	Natural orifice transluminal endoscopic surgery
RCTs	Randomized controlled trial
SAGES	The Society of American Gastrointestinal and Endoscopic Surgeons
SEM	Standard error of the mean
2D	Two-dimensional
3D	Three-dimensional

1. Introduction

1.1 Background and history of laparoscopic surgery

Laparoscopic surgery, or laparoscopic-assisted resection, is a modern surgical technique that is done with the aid of a laparoscope [1]. A laparoscope is a thin, tube-like instrument having a light source and a lens for viewing the tissue at the end of the scope. The laparoscope can also have a tool near the lens which can be used to remove tissue for later medical inspection under a microscope [2]. In 1901, Georg Kelling, a German surgeon specialized in gastrointestinal physiology and anatomy, performed the first laparoscopic surgery using a Nitze cystoscope. He performed the surgery on a dog, and he coined the term Celioscopy to describe his procedure [3].

The word laparoscopy is derived from the term “laparo”, an affix derived from Greek where it means flank or abdominal wall, and “scopy”, which basically means observing or viewing [4].

1.2 Laparoscopic equipment

The first step of laparoscopic surgery is the establishment of a pneumoperitoneum. Therefor a cannula is inserted through the abdominal wall, and the abdominal cavity is filled with gas or air. Later, the abdominal content is observed and examined with an illuminated telescope [5]. Laparoscopic procedures use very small incisions, usually not more than 0.5–2 cm, in order to gain approach to the operating field [6].

Laparoscopic instruments consist of many pieces of equipment. The “Veress needle” is a spring-loaded needle. It is used to create a pneumoperitoneum before insertion of the so-called trocars. The trocars consist of an obturator, a cannula, and a seal. They are placed through the abdominal wall. When the cannula is removed, they function as a portal for other instruments to access the abdomen. Trocars are available in different diameters (5–12 mm) and materials (metal for multiple use or plastic for single use) [7].

CO₂ gas is used to establish a pneumoperitoneum. It is used because it is non-combustible, cheap, and soluble (which is important to prevent air embolisms) [8].

The optical equipment consists of a light source and an endoscope with an optic camera in front. The light source is attached directly to the endoscope to provide light during

the operation. The image from the camera is transmitted to a monitor in front of the surgeon. The optic of the endoscope is a very important element to make a safe operation. Usually, the operator's assistant handles the camera position, to provide optimal view of the operating field [9].

Finally, there are the most sophisticated laparoscopic surgical instruments, which include all types of instruments, such as forceps, scissors, clips, retractors, electrocautery instruments, graspers, bowel clamps, special instruments to grasp the intestine, and staplers for intestinal resections. In addition, laparoscopy instruments for aspiration and irrigation, as well as organ extraction devices are used [10,11].

1.3 Characteristics and advantages of minimal invasive surgery

Compared to conventional surgeries, laparoscopic operations provide many advantages for patients. To begin with, the length of the hospital stay is significantly shorter after laparoscopic surgery [12]. Also, the scars are much smaller due to the small incision, which means less pain and better cosmetic results. Additionally, the recovery and healing process is faster, again due to the smaller incisions. Therefore, the patient can return to daily activities earlier than after conventional open surgeries [13]. Last but not least, minimal invasive surgery has less risks of postoperative adhesions or postoperative bleeding [14].

Consistent with the above advantages, many studies reported that laparoscopic surgeries have better quality of life outcomes for patients than open surgeries. Velanovich and colleagues conducted a prospective study in the USA. They compared the quality of life outcome between open and laparoscopic surgery. The study included cholecystectomy, splenectomy, hernioplasty, and oesophageal surgeries. The authors considered many factors including physical, emotional, and mental health, as well as pain, vitality, social functioning, and general health. A total of one hundred patients were investigated. The results showed that laparoscopic surgeries had better quality of life outcomes than open surgeries for cholecystectomy, splenectomy, and oesophageal surgery. However, an open hernioplasty had at least as good health outcomes as an laparoscopic repair [15].

Another study was done comparing the clinical outcomes between laparoscopic and open colon resection in colon cancer surgery [16]. In this study, the researchers collected all data between 2009 and 2013. Some of the points that were evaluated were operative outcomes, postoperative recovery, and early and late events. The results showed significant reductions of the length of hospital stays and bleeding in laparoscopic resection. Also showed faster recovery of bowel function in laparoscopic colon resection [16].

1.4 Contraindications of laparoscopic surgery

There are some contraindications of laparoscopy. These include uncorrectable coagulopathy, the so-called frozen abdomen (massive adhesion between the abdominal viscera and the abdominal wall), intestinal obstruction with massive abdominal distension, severe cardiac dysfunction, concomitant disease requiring laparotomy, retinal detachment, severe COPD, and marked increased intracranial pressure. Other relative contraindications are pregnancy in the last term, extensive previous abdominal operations, portal hypertension, and severe liver disease [17,18,19,20].

1.5 Complications of laparoscopic surgery

Extra-peritoneal gas insufflation is one of the most occurring complications of laparoscopic surgeries [20]. It can cause subcutaneous emphysema and result in hypercarbia and acidosis. However, establishing the pneumoperitoneum by using a Veress needles helps to prevent such complication.

Trocar hernia is another complication that might occur postoperatively. For that reason, the surgeon must close the abdominal wall fascia after finishing the procedure [21].

Vascular injury and intestinal injury are also serious complications. Adhesions or acute infections increase the rate of accidental injury of intra-abdominal organs or vessels [22]. Therefore, the surgeon must be very careful and aware of the anatomy of the region being operated. For instance, by inserting trocars in the lower abdominal wall, there is a risk to injure the inferior epigastric artery. In fact, injury of the common bile duct is one of the major complications of laparoscopic cholecystectomy [23]. Hence, teaching the anatomical landmarks in laparoscopic surgery is very essential to prevent abdominal injuries.

Advantages and disadvantages minimally invasive surgery are summarized in Table 1.

Table 1: Summary of advantages and disadvantages of minimally invasive surgery

Advantages:	Disadvantages:
Minimal trauma to skin, muscles, organs	Needs special training and experience
Less postoperative pain	Impaired touch sensation
Reduced infection rate	Sometimes longer duration of surgery
Short hospital stays	Not suitable for all patients
Quick recovery	Not suitable for all operation techniques
Smaller incisions; better cosmetic appearance	Risks of organs and vessels injuries
Minimal postoperative adhesions	
Minimal bleeding intraoperatively	
Better view for the surgeon in narrow cavities	

1.6 New techniques in minimal invasive surgery

Initially laparoscopic surgery was performed using direct view into the abdomen with optical lenses. Thereafter, when optical systems were developed, the view to the abdominal cavity was transferred by a camera to a 2D screen. Newest techniques allow a 3D view on the optical screen, transferred with high resolution 3D camera [24]. Surgeons lose some of the natural depth perception and accuracy when transferring from open surgery to 2D laparoscopic surgery [25]. Using 3D laparoscopic devices gives the surgeon a better view, which means more accurate work and less complications [26].

Several companies started to come up with new concepts and creations in regard to laparoscopic surgery. In Single-port laparoscopic surgery, the surgeon enters the abdomen through one incision, most likely through the umbilicus (for the best cosmetic

result). Through this one port, the optic system (e.g. endoscope with camera) and the surgical instruments are penetrated [27]. This type of laparoscopic operation is feasible only in selected cases.

Further developments are laparoscopic robotic surgery [28] and natural orifice transluminal endoscopic surgery (NOTES) [29].

Robotic surgical devices allow a surgeon at a console to operate through remote-controlled robotic arms, which may facilitate the performance of laparoscopic procedures. This technique allows greater accuracy and better visualization compared to standard laparoscopic surgery [28].

In NOTES, natural orifices are used to enter the body without skin incisions. Approaches include transvaginal, transoesophageal, transurethral, transnasal, or transcolic. Without skin incision, there are no risks of incisional hernia. Examples of using NOTES procedures in general surgery are transvaginal cholecystectomy and transoral thyroidectomy [30,31,32].

1.7 Challenges of laparoscopic surgery

Since laparoscopy was introduced many years ago, the technique quickly found its way to surgical routine in industrialized countries. Today, surgery cannot possibly be imagined without laparoscopy, and a large number of patients benefit from the advantages of minimal invasive surgery.

Laparoscopic surgery is different from open surgery. For the surgeon, many new challenges are present in laparoscopy. Therefore, gaining experience needs special training. Surgeons need to learn how to enter the abdomen laparoscopically. The sight to the operation field through an endoscope is different from the sight in conventional surgery. In laparoscopy, the view field is limited and depends on the assistants' camera guidance. The cameras magnification offers a detailed image, often better than in conventional surgery. Understanding the anatomy is the key for safe surgery. Surgeons have to learn how to deal with anatomical variants. Therefore, there are anatomical challenges in addition to procedural and training challenges [33]. In laparoscopy surgeons cannot act as in open surgery because of the limited movement fields. Trocar positions play an important role in effective usage of the instrument during the

operation. Surgeons need to learn how to act with laparoscopic instruments in certain places and how to react in special situations only by using laparoscopic instruments.

Also the surgical approach differs if a certain procedure is performed laparoscopically. Cholecystectomy is a good example of different concepts in laparoscopic surgery compared to open surgery. For the open cholecystectomy, the abdomen is entered by the subcostal Kocher incisions and the gallbladder is removed using the anterograde technique. In laparoscopic surgery, the abdomen is entered through four small incisions, and the gallbladder is removed using the retrograde technique (Fig. 1).

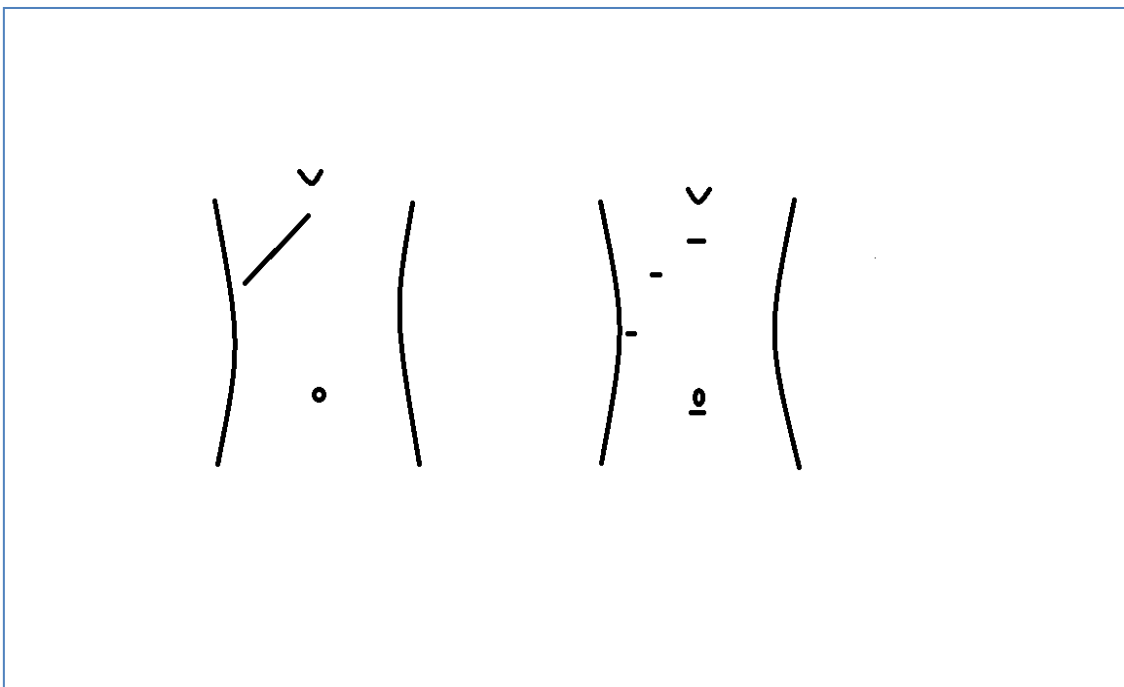


Fig. 1: An example of differences between skin incisions in cholecystectomy using classic open surgery (left) and laparoscopy (right).

Generally laparoscopy demands visuospatial and motor skills, which have to be learned *ex vivo*. The main challenge for novice laparoscopists is the absence of the third dimension in visual perception, as well as the narrowed depth perception in the predominantly used 2D imaging systems 34][. Handling of laparoscopic instruments has to be subject to training as well, but normally causes few problems.

1.8 Laparoscopic skills training

Laparoscopic training is usually undertaken by means of in vitro models (so-called box trainers or laparoscopic simulators), animal models, and virtual reality simulators [35]. All of these training models require expensive equipment and a certain infrastructure, making laparoscopic training a problem for virtually all surgeons around the world. In Germany, not all hospitals are able to provide their own laparoscopic training centres [36]. Therefore, most surgeons have access to laparoscopic training exclusively via special training courses. These courses are costly in terms of time and money. Moreover, the efficiency of the short-course format is questionable [37]. Individual training or consolidation of recently learned skills is not feasible.

In low- and middle-income countries (LMICs), the situation is even worse. In addition to the challenge of funding the laparoscopic equipment and technical support, LMICs often lack a functional medical infrastructure. Moreover, surgical training is rarely structured and monitored [38]. However, the advantages of minimal invasive surgery are of vital importance in particular in LMICs where sanitation, access to clean water, and blood preservation are often limited, and where most families do not have the resources to bridge non-productive times. During the past decades, there have been promising efforts to introduce and establish laparoscopic techniques in LMICs, and numerous ingenious strategies to deal with limited resources have been published [39,40]. Training opportunities and the availability of trained staff are major problems in LMICs, so that minimal invasive surgery remains far from being a daily routine in developing countries [41].

Laparoscopic beginners require skill learning by observation, theoretical learning, and practice. Training using virtual reality simulation or simple boxes may improve the skills in short time, however continues training is an important factor [42,43]. In terms of practice, the most important challenges in 2D laparoscopy are needle holding in the proper position, suturing, and moving of sharp instruments in the three-dimensional space in absence of a third dimension [44]. For the training of basic laparoscopic

techniques, such as suturing and manipulating instruments, surgeons can rely on dry labs without accurate anatomical environments [45]. Low-cost training boxes are often used to obtain these basic skills. Certain surgical procedures can be trained with the help of animal organs. For example, pig gallbladder-liver complexes are used routinely for the training of laparoscopic cholecystectomies [46]. Even more complicated procedures additionally require special models, realized by virtual reality simulations. However, these are associated with high costs [47].

1.9 Evaluation of the training success

The most commonly used tools to evaluate the progress in surgical skills acquisition are learning curves. Learning curves illustrate the increase in learning with increasing experience. In surgery, the number of cases that a surgeon needs to perform a certain procedure with guaranteed success defines the learning curve. Learning curves help to predict how long it takes to master a certain procedure with a certain quality. They are used to monitor the increase of individual proficiency and to compare the efficiency of training models and programs. In the assessment of laparoscopic techniques acquisition the learning curve is frequently set by markers like operating time, morbidity, conversion rate, instrument changing, and the occurrence of postoperative complications [48].

The turning point of the learning curve, accordingly the number of procedures or training sessions that have to be performed before certain levels of competence is reached, naturally depends on individual abilities and the procedure. Studies assessing laparoscopic colorectal resections describe that it takes approximately 30 procedures until operating time, intraoperative complications and conversion rate decrease [49].

Learning of laparoscopic surgical skills can be obtained through training using laparoscopic trainers, which are provided in laparoscopic training courses. The primary aim of these courses is gaining the essential laparoscopic skills and the different operational techniques [50]. Training is the most important factor to improve laparoscopy skills, which are naturally difficult to be learned *in situ* in the operating rooms. Different studies showed that box trainers have a positive effect and play a role in improving the surgical skills of residents. These studies showed that the learning curve of laparoscopic procedures improves when simple box trainers are used for basic

skills acquisition [51,52,53]. The evidence behind such conclusions comes from many indicators used to assess the improvement of surgeons' laparoscopy skills, including operation time, instrument changing, occurrence of postoperative complications, and conversion from laparoscopic to open surgery. Improvement in surgical skills result in quick and appropriate reactions by surgeons, less errors, and fewer complications [54].

1.10 Laparoscopy in Germany

In Germany, the use of laparoscopic techniques is currently common in most abdominal surgeries, even in oncologic resections. There are many training centres, helping to gain the skills necessary for these surgeries. In fact, training in Germany is essential, and major hospitals have their own training centres. Small hospitals usually send their residents to obtain basic and advanced techniques in courses offered by specialized training centres [55].

1.11 Laparoscopy in Yemen

There are multiple factors that make minimally invasive surgeries difficult to become the standard in low-income countries. In particular, social, economic, and training challenges play important roles [56,57].

My parents originate from Yemen, they moved to Saudi Arabia in 1970. After starting my specialization in general surgery in Germany, I visited Yemen occasionally. In December 2012 I visited Yemen together with my German mentor Professor Dr. Glatzle. This visit was organized by Mr. Abdulla Bugshan, a businessman, who campaigns for education and health care. Mr. Abdulla Bugshan is the owner of a charity hospital in the south of Yemen, he sponsored the Hadramout University in 2010-2012 and funds the specialisation and qualification of physicians, originated from Yemen. The goal of our Yemen visit in 2012 was to implement a training program for laparoscopic surgery for surgical residents in Yemen. Thanks to the advocacy of Mr. Abdulla Bugshan we gained insights into the medical system in Yemen during our visit. In 2012 the health care system in Yemen was organized through the Ministry of health of Yemen, there was no insurance system. A number of University hospitals, predominantly governmental-financed provided the basic health care. There service was free for

patients. There were also private hospitals, where patients had to pay for the treatment. In general, as a poor country, the health care system in Yemen was underfunded and dependent on financial support from other countries.

Our journey led us to two different hospitals. The Bugshan Hospital in Hadramaut Valley is managed privately. The Hadramaut region is located in the southern part of Yemen. Mukalla City, the capital of Hadramaut, has about 300,000 inhabitants. Mr. Abdullah Bugshan is the owner of the hospital and provided insights about the state of laparoscopic surgeries and training in his institution. The hospital has two operating rooms with one of them being dedicated for laparoscopic surgeries. Mr. Bugshan informed us about the hospital strategy and the problems that it faces. There are laparoscopic devices available, but there is no trained local team. Once a month teams of laparoscopic surgeons come from Europe or Saudi Arabia to perform some of the elective operations.

In summary, the local problems are:

- There are no adequately trained teams. External surgeons are invited to perform the laparoscopic operations.
- No local teams are available to train the beginners, and there is a complete absence of training centres or courses.
- There is a complete absence of continuing education even for established surgeons.

The second hospital we visited was the public Ibn Sina Hospital, belonging to the Hadramaut College of Medicine. There, the head of the Faculty of Medicine, Professor Ali Batarfi demonstrated the operating theatres and discussed features and problems of laparoscopic surgery in the institution (Fig. 2, 3). The university hospital has only one laparoscopic surgery unit on its disposal, used sometimes in urological procedures (always in the presence of trained urological consultants). During our visit, the device was no longer used because of technical defects and the absence of a maintenance team that could repair it. As a result of this situation, the open cholecystectomy is the standard procedure to remove the gallbladder. Moreover, there were no laparoscopic training opportunities.

To summarize the challenges of laparoscopy in this hospital, which is a representative example of a public hospital in a low-income country, are the following:

- Absence of facilities and infrastructure.
- Absence of sponsoring companies with consequent maintenance problems.
- Absence of financial resources to acquire and maintain laparoscopic devices and instruments.
- Absence of continuing education even for established surgeons.



Fig. 2: Picture in Hadramaut University. From right to left Khaled Bajaeifer, Prof. Dr. Glatzle, Prof. Dr. Batarfi, medical staff members in Hadramaut University Hospital.



Fig. 3: Visiting Ibn Sina Hadramaut University Hospital Labs. From left to right Prof. Batarfi, Khaled Bajaeifer, Prof. Dr. Glatzle, medical student.

Inspired by the impressions of our visit to Yemen, we planned to organize continuous training courses for laparoscopic skills and procedures in the city of Hadramaut. Mr. Bugshan gave us his permission to offer these courses in his hospital, as a service for local surgeons and medical students, and in coordination with the University of Hadramaut. One particularly important goal was to implement a study to evaluate the effects of different training methods on surgical performance. Unfortunately, the political situation in Yemen became insecure, and our project was stopped. For that reason, we performed the evaluation of laparoscopic training methods at the University of Tübingen in Germany instead.

1.12 Scientific objectives

1. Is it possible to design and develop a low cost but high quality laparoscopic box trainer complying several requirements:
 - Durability and simple maintenance allowing a long- term use in laparoscopic training courses.
 - Suitability for direct vision to the training field as well as 2D laparoscopy to allow a wide field of application.
 - Suitability for the use with and without electrical supplies to allow the training of laparoscopic skills as well as laparoscopic procedures.
 - Suitability for dry lab skills training as well as training of laparoscopic procedures by means of animal organs.
2. Is a structured training in this box trainer effective?
3. Is a training program allowing intermittently direct view to the training site more effective than training exclusively performed with 2D vision?

2. Materials and Methods

2.1 Materials and instruments used in this study

In this study, laparoscopic instruments, electrical devices, surgical instruments, and also solid pieces for development of a trainer box were used.

2.1.1 Laparoscopic instruments

- 2x R.Wolf needle holder (8393.941, Knittlingen, Germany)
- 2x Xcel Ethicon 12mm trocars (Ethicon, Nordstedt, Germany)
- 2x Dexide 10mm trocars (6240.10, Vygon ,Aachen, Germany)
- 1x Mersilene® suture 3-0, EH7350/Ethicon, 36 mm needle, 11 cm, green (Ethicon, Nordstedt, Germany)
- 1x Mersilene® suture 2-0, EH7350/Ethicon, 36 mm needle, 26 cm, green (Ethicon, Nordstedt, Germany)
- Electrocautery hook instrument (37370 DL, KARL STORZ, Tuttlingen, Germany)

2.1.2 Electrical devices

- Florescent lamp (Hi Lite GmbH) (Toom Baumarkt, Tübingen, Germany)
- Web camera (Rollei HD) (Mediamarkt, Tübingen, Germany)
- HD screen (Acer 26) (Mediamarkt,Tübingen, Germany)
- Erbotom ACC 450 electrocautery device (ERBE, Tübingen, Germany)

2.1.3 Other materials

- Metal tray 30 cm x 15 cm (Gastronom box)
- Transparent glass 30 cm x 15 cm (Toom Baumarkt, Tübingen)
- Opaque glass (Toom Baumarkt, Tübingen)
- Cylindrical sponge (4 x 8 cm), lumen (2 x 2 cm) (simulator of soft tissue for the trocar entry) (Toom Baumarkt, Tübingen)
- 4x plastic clamps (Toom Baumarkt, Tübingen)
- 2x camera holder (short and long) (Rollei) (Mediamarkt, Tübingen, Germany)

2.1.4 The materials of the training tasks

- Wood board 15 x 15 cm (tasks board) (Toom Baumarkt, Tübingen)
- Two containers (4 cm diameter, 0.5 cm height); 8x small different shapes solid pieces (beads) (Toom Baumarkt, Tübingen)
- 11x metal loops (0.5 cm diameter), anchored in a wavy line (Toom Baumarkt, Tübingen)
- 4x fitting slots (0.7 cm diameter, 1 cm depth); 4x metal cylinders (Toom Baumarkt, Tübingen)
- Allevyn® 7.5 x 7.5 cm (Smith & Nephew, Hamburg, Germany)

2.2. Methods

2.2.1 Study design

A prospective *ex vivo* study was performed, designed as a two-armed, single blinded and randomized controlled trial.

The substance of the trial was the comparison of two different training methods of basic laparoscopic skills. The training course comprised four tasks:

- Task 1: Beads in different shapes had to be transferred from one container to another.
- Task 2: Metal loops in wavy lines had to be passed with a surgical suture.
- Task 3: Metal cylinders had to be placed into fitting slots
- Task 4: Surgical knots had to be tied.

Before starting the training, participants were shown a video clip explaining and demonstrating four laparoscopic tasks (Fig. 5–8: (1) bead transfer, (2) needle guidance, (3) placement of cylinders, and (4) intracorporeal knot). The students had to perform five training cycles. Every cycle comprised the four tasks. The students had to perform task 1 to task 4 which represent one cycle. Once one training cycle was finished (task 1 to 4), the students had a break of 10 minutes before the next cycle was performed. All participations started the first training cycle with task 1 using the 2D imaging system. After that, the students were randomized and into two groups stratified on performance time, unknowing that a randomization was done. Group A completed the training using the 2D imaging system. Group B performed the first, third, and fifth training cycle using the 2D imaging system. In the second and fourth cycles, the opaque lid of the box was removed permitting direct view to the training site. The four tasks were realized one after another, beginning with task 1, followed by tasks 2, 3, and 4. All participants performed the whole training curriculum in a single session (see Fig.4).

The four tasks resembled commonly used training tasks, adapted from laparoscopic procedures and abstracted for reproducibility. Each participant trained on his/her own. All skills were performed using two graspers.

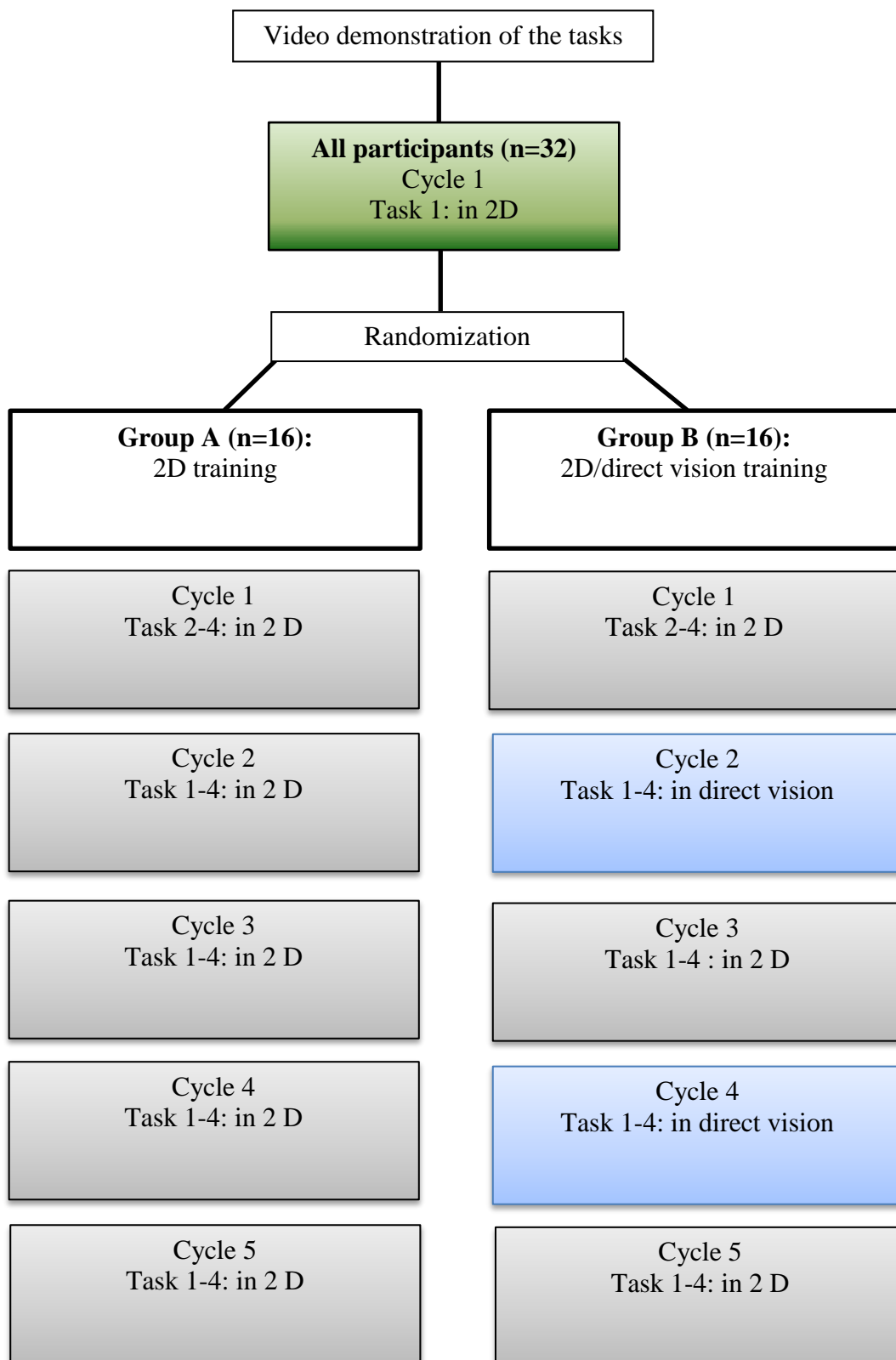


Fig. 4: Training course of the study

2.2.2 Study area

The study was conducted in the Department of General Surgery at the University Hospital of Tübingen. The data were collected in 2015, and the study was previously approved by the local ethical committee of the University of Tübingen by Professor Dr. med. Dieter Luft in 17.10.2013.

2.2.3 Study population and size

Thirty-two laparoscopic novices were enrolled in this study. The participants were medical students aged between 20 and 25 years. The gender distribution of the participants was 18 females and 14 males. They had never used laparoscopic instruments before, never attended laparoscopic training or assisted in laparoscopic procedures (see Table 2). Students participated on a voluntary basis.

Table 2: The characteristics of the participants.

Number	32 medical students
Age	20–25
Gender	18 females (56.3%) and 14 males (43.7%)
Experience	No laparoscopic experience

2.2.4 Sampling technique and randomization

All participants performed task 1 of the first training cycle using 2D imaging system. The time they needed to perform the task was taken. According to this initial performance time, the participants were stratified and randomized into two groups: Group A, performing the whole training using 2D imaging systems, and Group B, permitted to directly view the training site at particular points.

The study was performed as a single-blinded study, so that the students did not realize that they were randomized into two groups. The allocation ratio for the two groups was 1:1.

2.2.5 Training tasks

2.2.5.1 Task 1: bead transfer

In this task (Fig. 5), beads of various shapes were transferred from one container to another. The two containers (4 cm diameter, 0.5 cm height) were fixed in a horizontal position at an interval of 5 cm. Eight beads were placed in the container on the dominant side of the participant. The participants were asked to grasp the beads and transfer them to the container on the non-dominant side. Time was recorded from touching the first bead until dropping the last bead into the second container.



Fig. 5: Task 1: beads transfer.

2.2.5.2 Task 2: needle guidance

In this task (Fig. 6), a surgical suture with a curved needle was guided through a loop course. The course was formed from 11 metal loops (0.5 cm diameter), which were anchored in a wavy line. The task was timed from grasping the needle until it was passed through all loops in a row.

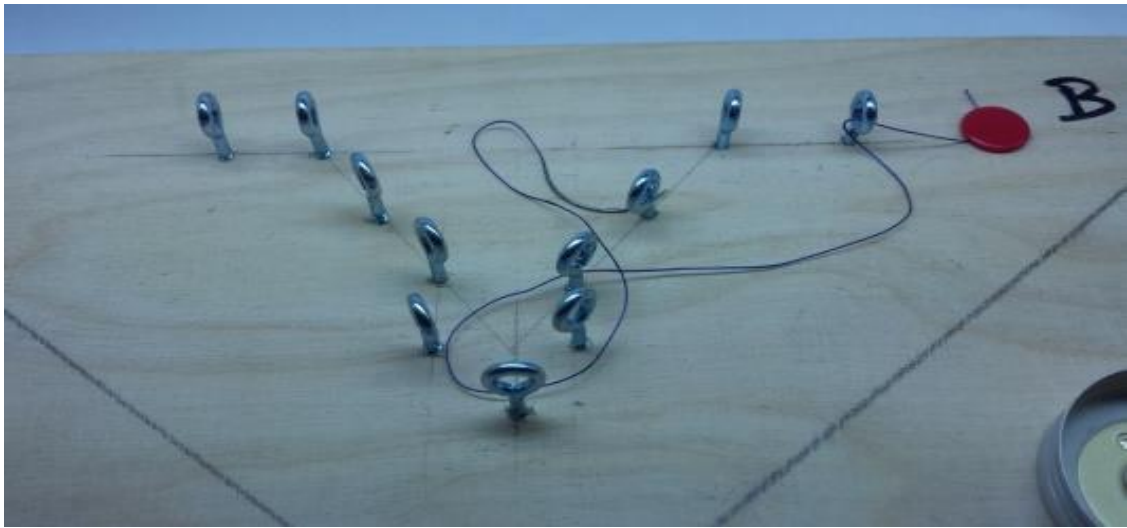


Fig. 6: Task 2: needle guidance.

2.2.5.3 Task 3: placement of cylinders

In this task (Fig. 7), four metal cylinders (0.5 cm diameter, 1.5 cm height) were transferred from a container to four fitting slots (0.7 cm diameter, 1 cm depth) in the bottom plate. Time was recorded from touching the first cylinder until placing the last cylinder into the appropriate slot.



Fig. 7: Task 3: placement of cylinders.

2.2.5.4 Task 4: intracorporeal knot

In this task (Fig. 8), participants were asked to perform an intracorporeal knot (composed of two surgical knots tied in the same direction and a final knot tied in the opposite direction) using a surgical suture on a dressing, which was fixed on the bottom plate. The task was timed from grasping the needle until the knots were completed.

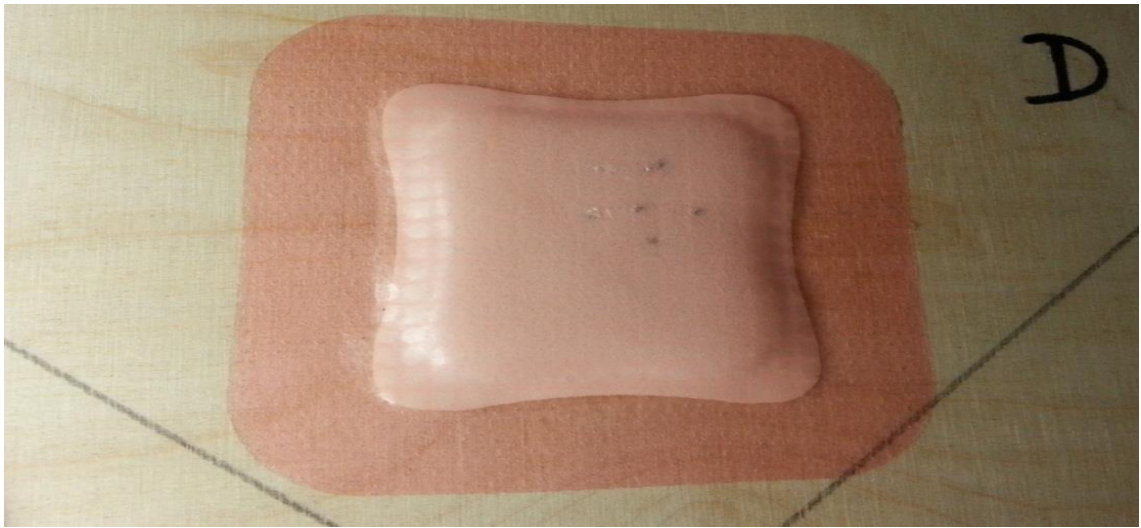


Fig. 8: Task 4: intracorporeal knot.

2.2.6 Data collection and analysis

Observation of the study subjects was conducted by trainers to assess errors and difficulties and to evaluate the performance of the trainees. The training session was always supervised by myself.

Data are presented as mean \pm standard error of the mean (SEM). Differences between the groups were determined by unpaired Student's t-tests, and differences between cycles of training were determined by paired Student's t-tests using the software package of GraphPad Prism 4.0 (San Diego, CA). A p-value of $p \leq 0.05$ was taken as indicating a significant effect.

3. Results

3.1 Construction of the box trainer

A box trainer was developed (Fig. 9, 10) using a metal tray covered by transparent glass and in a second layer by opaque glass. Two ports (12 mm trocars) were placed on the top surface at convenient working angles. The interior of the box was illuminated with a fluorescent lamp. A web camera was fixed on a camera holder in front of the box trainer and connected to an HD screen. The position of the camera was easily movable, so that the box trainer was suitable for training unescorted by an assistant for the camera work. Two laparoscopic graspers were used for training, since these instruments are less expensive in acquisition and could be used multiple times in this *ex vivo* training situation. Total costs for the training box, including monitor, camera, and instruments, were below 400 Euro.

3.2 Construction of the training field for laparoscopic skills training

A wood board was adapted to the inner face of the metal tray. The board was divided in four sectors. One sector for each training task as described in material and methods previously. The board serves as training field in dry lab training.

3.3 Training without electrical devices.

By abstaining from the opaque glass, the box trainer was suitable for training without light source and camera. Positioned in a well-lit room, the transparent cover of the box permits direct view into the box.



Fig. 9: Laparoscopic box trainer using the transparent lid for direct view to the training field. The camera, fixed with a camera holder in front of the box, transmits additionally a 2D image to the screen.

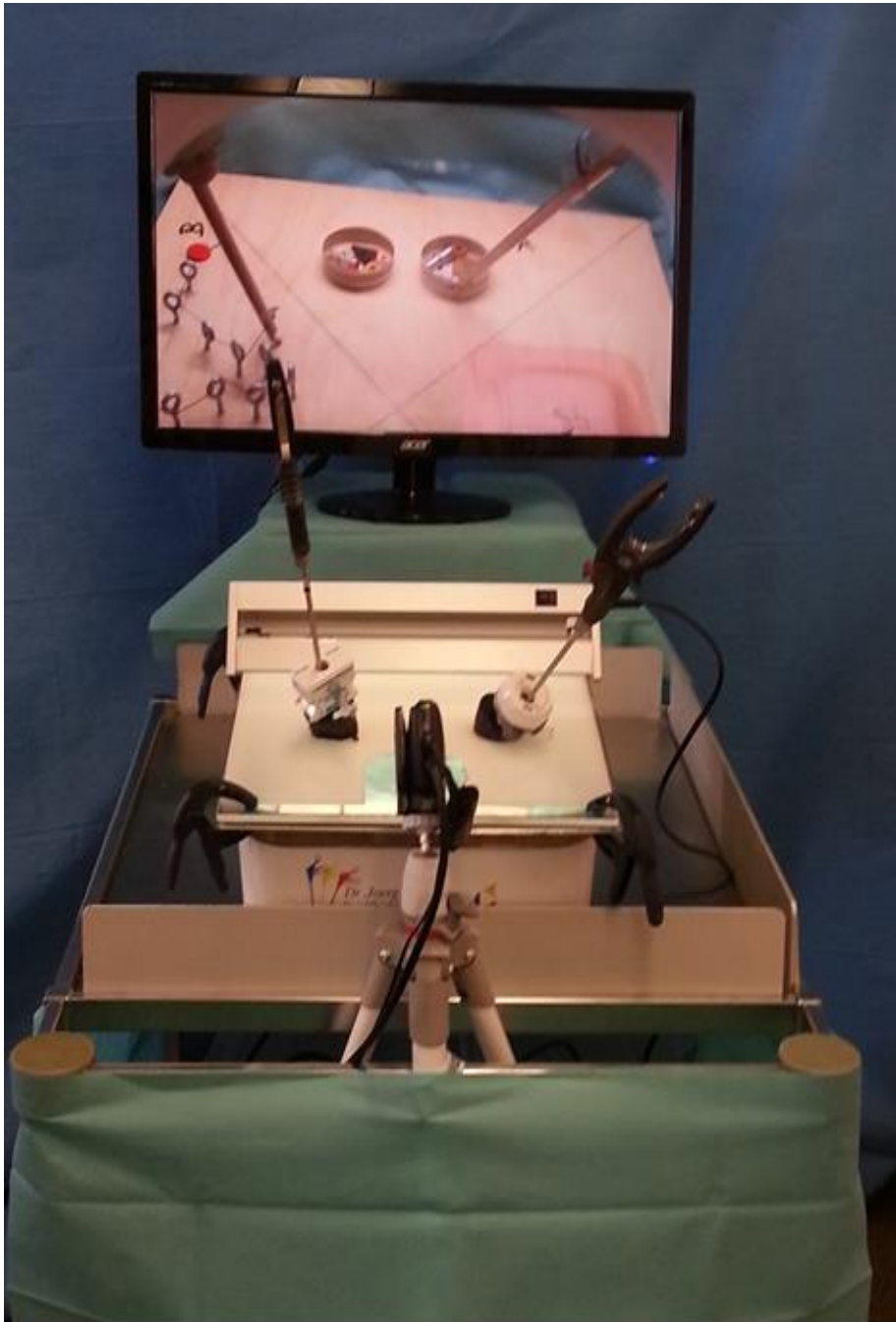


Fig. 10: Laparoscopic box trainer using the opaque lid to prevent direct view to the training field. The opaque lid is fixed on top of the transparent lid using four plastic clamps.

3.4 Wet lab Training: laparoscopic cholecystectomy

The training box was adapted to the requirements of the wet lab training. The stainless steel container was easy to clean and sanitize. Furthermore, the material permits the use of electrocautery.

The box trainer was tested for training of the laparoscopic cholecystectomy on goat gallbladder-liver complexes. The procedure was performed without an assistant for the camera work. A camera fixed in front of the training box, provided sufficient sight to the operation field (Fig. 11, 12).

The liver-tissue is very soft and highly perfused, the wall of the gallbladder very thin. Best practice for cholecystectomy requests the use of an electrocautery hook for excavation of the gallbladder. Training of the procedure on goat organ packages in the box trainer was adapted to this standard and the gallbladder was excavated by means of an electrocautery hook.

Other organ packages, for example the gut, can be placed into the box trainer as well. That made the box trainer suitable for the training of numerous procedures.



Fig. 11: Training of laparoscopic cholecystectomy on goat gallbladder-liver complexes in a wet lab setting. The procedure is performed using an electrocautery hook.



Fig. 12: The setting during laparoscopic cholecystectomy training on goat gallbladder-liver complexes. The box trainer is suitable for installation at home.

3.5 Tasks outcomes

3.5.1 Outcomes of the first cycle of task 1 (bead transfer)

All 32 participants performed the first cycle of task 1 (bead transfer) using 2D laparoscopy. The mean time participants needed to perform this first challenge was 104s. The 25% percentile was 78s, the 75% percentile 116s.

On the basis of the results in the first training cycle of task 1, participants were stratified and randomized into two groups. Stratification was used to generate two almost equal groups regarding performance time. The characteristics of the two groups are listed in Table 3.

Table 3: The characteristics of the two groups after randomization

	Group A: 2D training	Group B: 2D/ direct vision training
Number	16 medical students	16 medical students
Age	20–25	20–25
Gender	7 females and 9 males	11 females and 5 males
Time needed to perform cycle 1 of task1	104.6 ± 16s	103.8 ± 5s

3.5.2 Outcomes in the simple tasks

3.5.2.1 Bead transfer

The time that novice laparoscopists needed to accomplish task 1 decreased significantly between the first and fifth cycle in both groups (group A: Fig. 13, task 1: cycle 1 vs. cycle 5: 105s ± 16 vs. 72s ± 6; $p \leq 0.05$; group B: Fig. 14, task 1: cycle 1 vs. cycle 5: 104s ± 5 vs. 70s ± 7; $p \leq 0.05$). In group A the performance time between the first and the last cycle of training declined by 31%. In group B the performance time declined by 33% between cycle 1 and cycle 5.

The performance time was the fastest when participants were allowed to glance directly to the training site (group B in cycles 2 and 4: 47% and 56% decline compared to cycle 1). Neither group A nor group B reached the performance time of the three dimensional training (cycle 2 and 4, group B) in the fifth cycle of 2D training (Fig 13, 14).

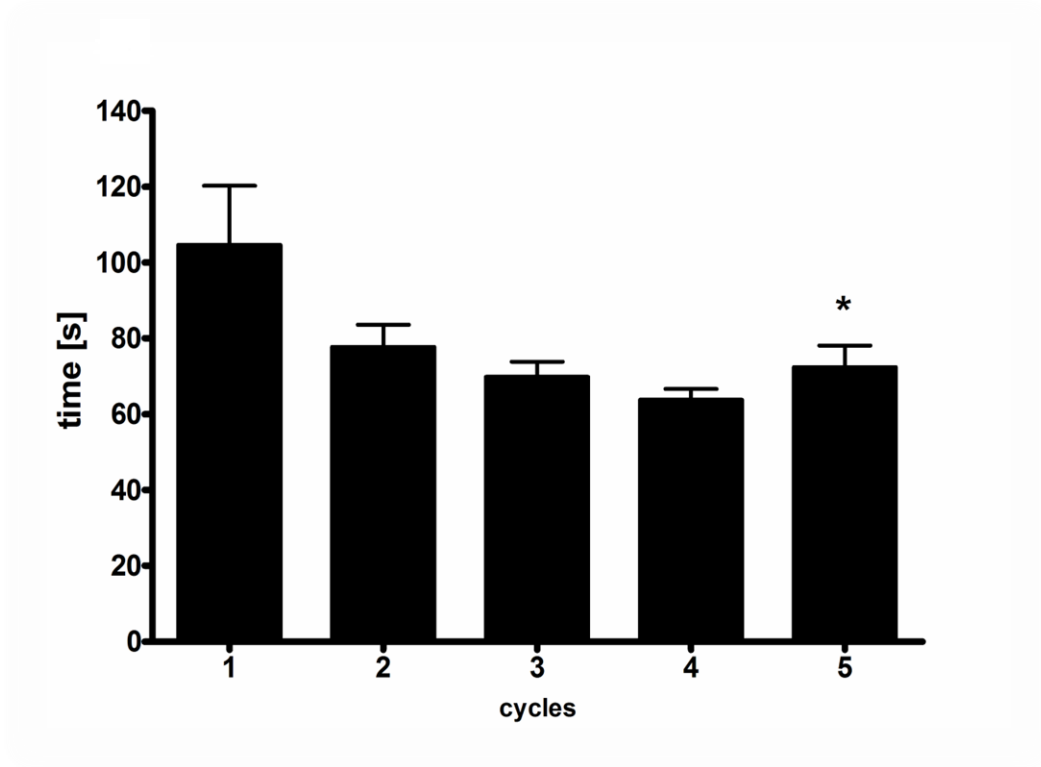


Fig. 13: Outcome measure bead transfer (task 1): Group A using 2D imaging systems.

* $p \leq 0.05$; cycle 1 vs. cycle 5 of group A

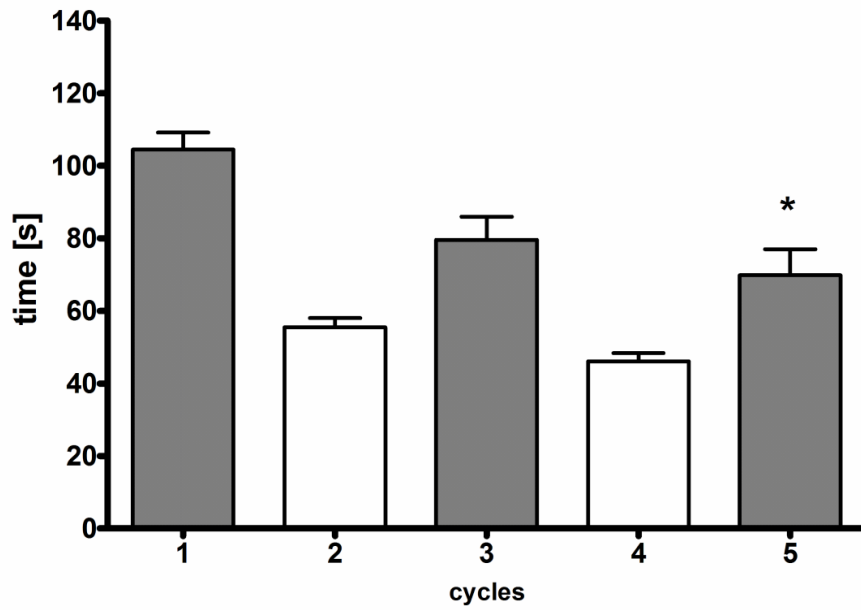


Fig. 14: Outcome measure bead transfer (task 1): Group B using 2D imaging systems in cycles 1, 3, 5 (grey bars) and additional direct view to the training site in cycles 2 and 4 (white bars).

* $p \leq 0.05$; cycle 1 vs. cycle 5 of group B.

Comparison of the time that both groups needed to complete the fifth cycle of task 1 revealed no difference between group A and group B (Fig. 15, task 1: group A vs. group B, $72s \pm 6$ vs. $70s \pm 7$).

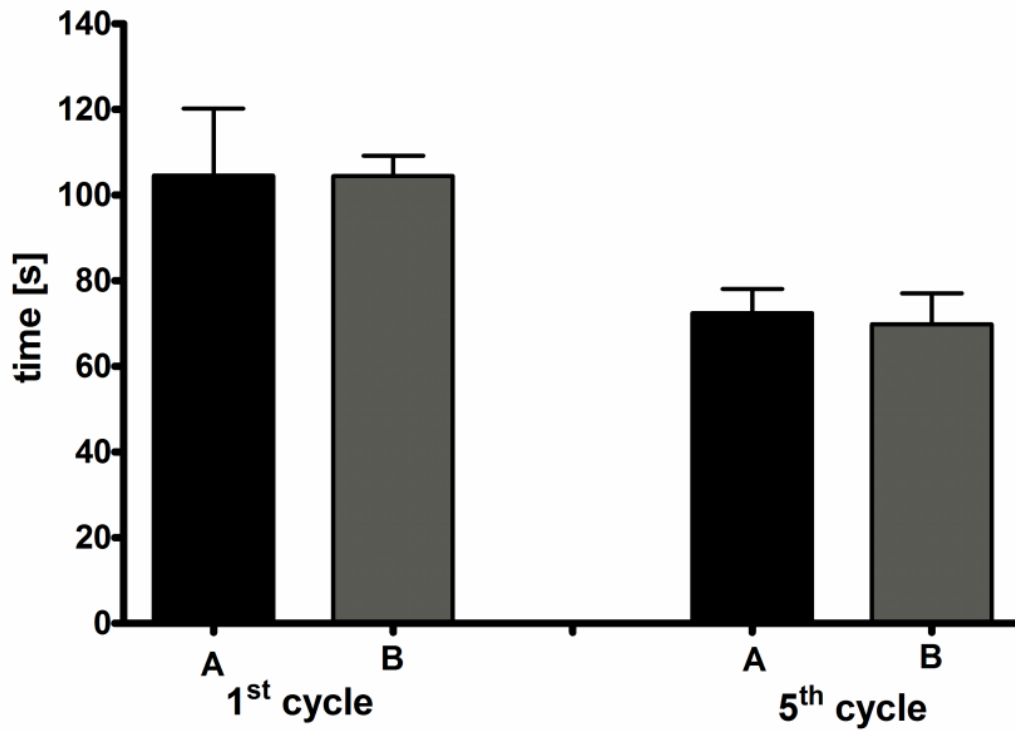


Fig. 15: Bead transfer (task 1): Comparison of the proficiency both groups achieved in cycle 5: Group A, using 2D imaging systems in all cycles of training (black bars). Group B, using 2D imaging systems in cycles 1, 3, 5 and additional direct view to the training site in cycles 2 and 4 (grey bars).

3.5.2.2 Needle guidance

The results that participants achieved performing task 2 (needle guidance) were similar to the results in task 1. Specifically, the time that they needed to accomplish task 2 decreased significantly between the first and fifth cycles in both groups (group A: Fig. 16, task 2: cycle 1 vs. cycle 5: 13 min \pm 1 vs. 8 min \pm 1; $p \leq 0.05$; group B: Fig. 17, task 2: cycle 1 vs. cycle 5: 17 min \pm 2 vs. 7 min \pm 0.5; $p \leq 0.05$).

The time needed to perform task 2 in group A declined 38% between the first and the last cycle of training. In group B the time declined 59% between cycle 1 and cycle 5. The performance time was the fastest when participants were allowed to glance directly to the training site (group B in cycles 2 and 4: 75% and 81% decline compared to cycle 1. Neither group A nor group B reached the performance time of the three dimensional training (cycle 2 and 4, group B) in the fifth cycle of 2D training (Fig 16, 17).

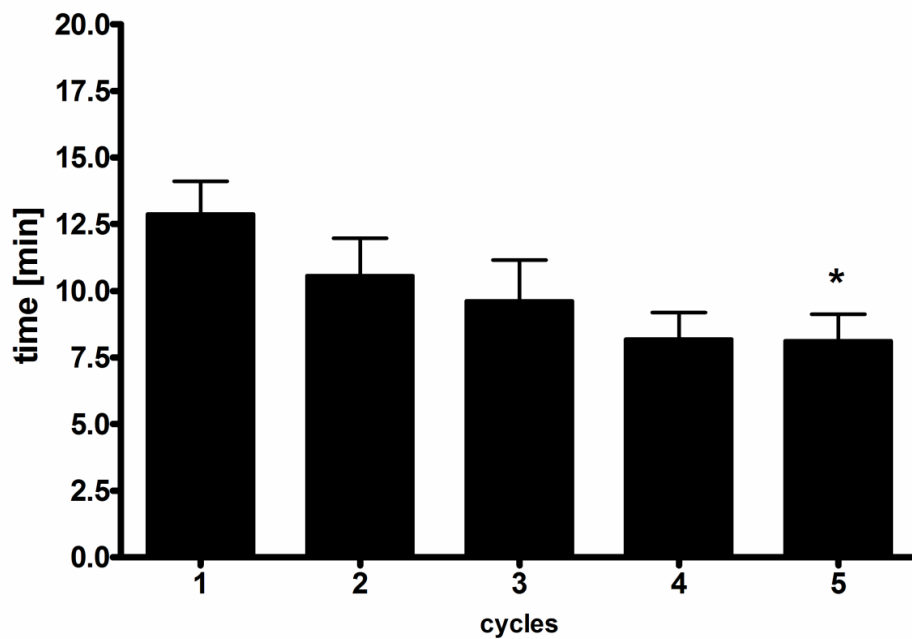


Fig. 16: Outcome measure needle guidance (task 2): Group A using 2D imaging systems.

* $p \leq 0.05$; cycle 1 vs. cycle 5 of group A

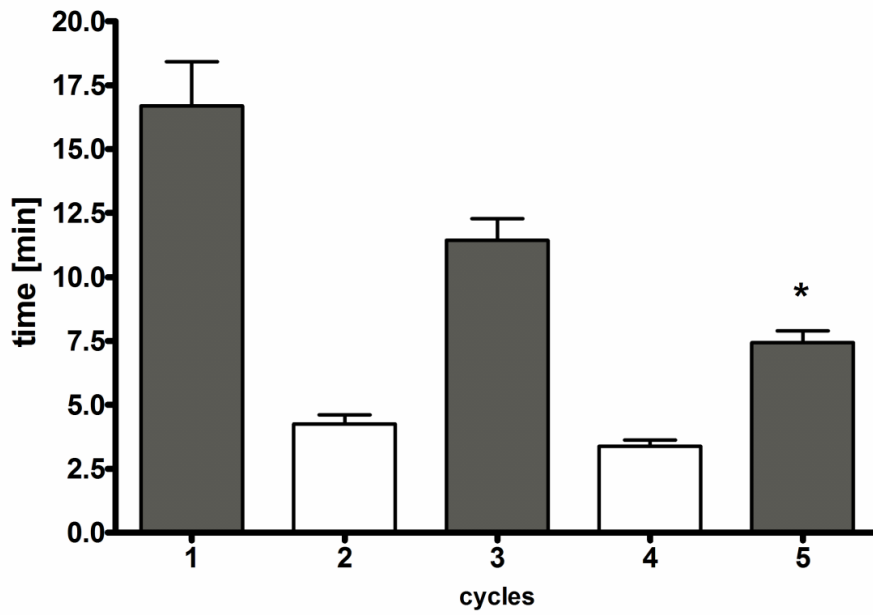


Fig. 17: Outcome measure needle guidance (task 2): Group B using 2D imaging systems in cycles 1, 3, 5 (grey bars) and additional direct view to the training site in cycles 2 and 4 (white bars).

* $p \leq 0.05$; cycle 1 vs. cycle 5 of Group B.

Comparison of the time that both groups needed to complete the fifth cycle of task 2 revealed no difference between group A and group B (Fig.18: group A vs. group B, 8 min \pm 1 vs. 7 min \pm 0.5).

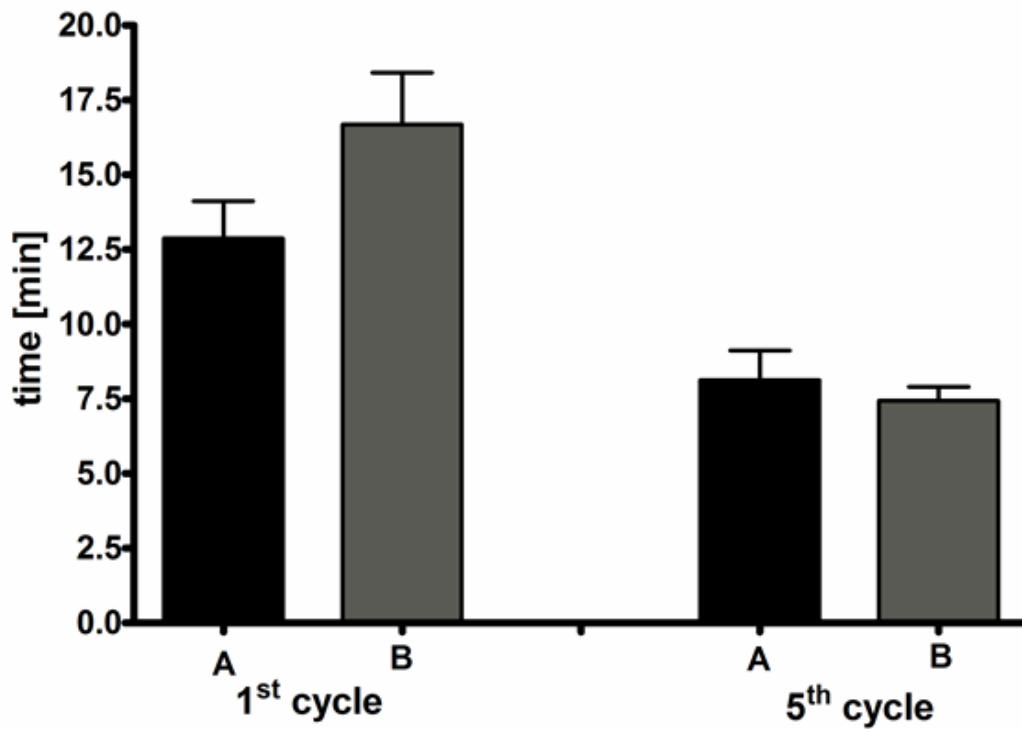


Fig. 18: Needle guidance (task 2): Comparison of the proficiency both groups achieved in cycle 5: Group A, using 2D imaging systems in all cycles of training (black bars). Group B, using 2D imaging systems in cycles 1, 3, 5 and additional direct view to the training site in cycles 2 and 4 (grey bars).

3.5.3 Outcomes of the more complex tasks

The results that novice laparoscopists achieved in task 3 and task 4 differed from task 1 and task 2.

3.5.3.1 Placement of cylinders

Participants of group A could not reduce their performance time from the first to the fifth cycle in task 3 (Fig. 19, task 3: cycle 1 vs. cycle 5: $85s \pm 10$ vs. $93s \pm 30$). In contrast, the time that participants of group B needed to complete the fifth cycle of task 3 was significantly shorter compared to the first cycle (Fig. 20, task 3: cycle 1 vs. cycle 5: $90s \pm 9$ vs. $59s \pm 6$; $p \leq 0.05$). The time needed to perform task 3 in group B declined 34% between the first and the last cycle of training. The performance time was the fastest when participants were allowed to glance directly to the training site (group B in cycles 2 and 4: 41% and 49% decline compared to cycle 1). Group B reached almost the performance time of the three dimensional training (cycle 2 and 4) in the fifth cycle of training (Fig 19, 20).

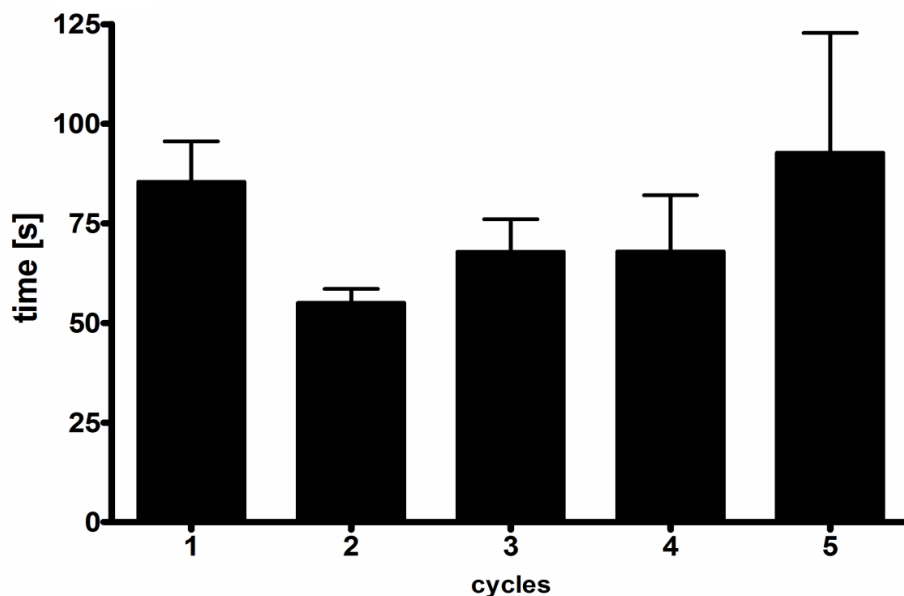


Fig. 19: Outcome measure placement of cylinders (task 3): Group A using 2D imaging systems. Cycle 1 vs. cycle 5 in group A, not significantly different.

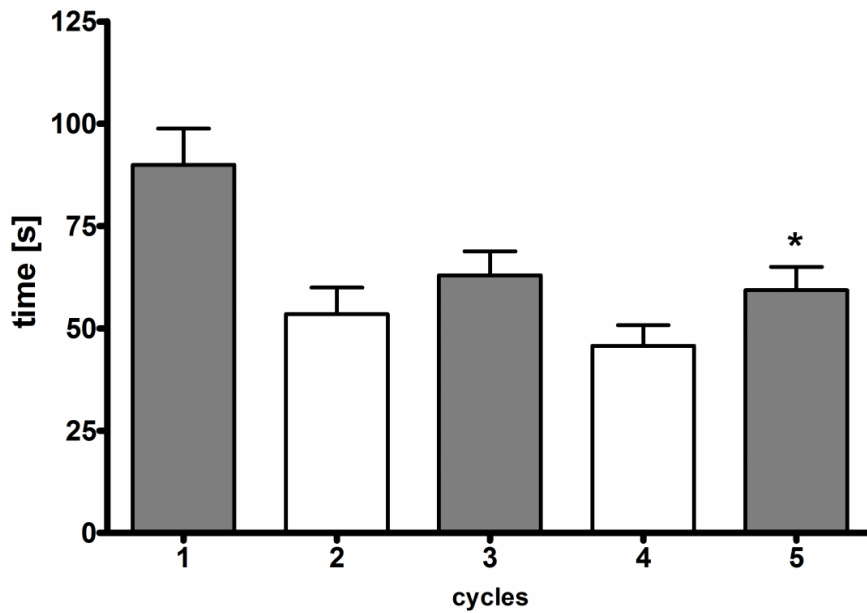


Fig. 20: Outcome measure placement of cylinders (task 3): Group B using 2D imaging systems in cycles 1, 3, 5 (grey bars) and additional direct view to the training site in cycles 2 and 4 (white bars).

* $p \leq 0.05$; cycle 1 vs. cycle 5 in group B.

Comparison of the performance time that both groups needed in the fifth cycle of task 3 revealed that group B accomplished the task almost 40% faster than Group A. However, the difference did not reach statistical significance (Fig. 21: A vs. B, $93s \pm 30$ vs. $59s \pm 6$).

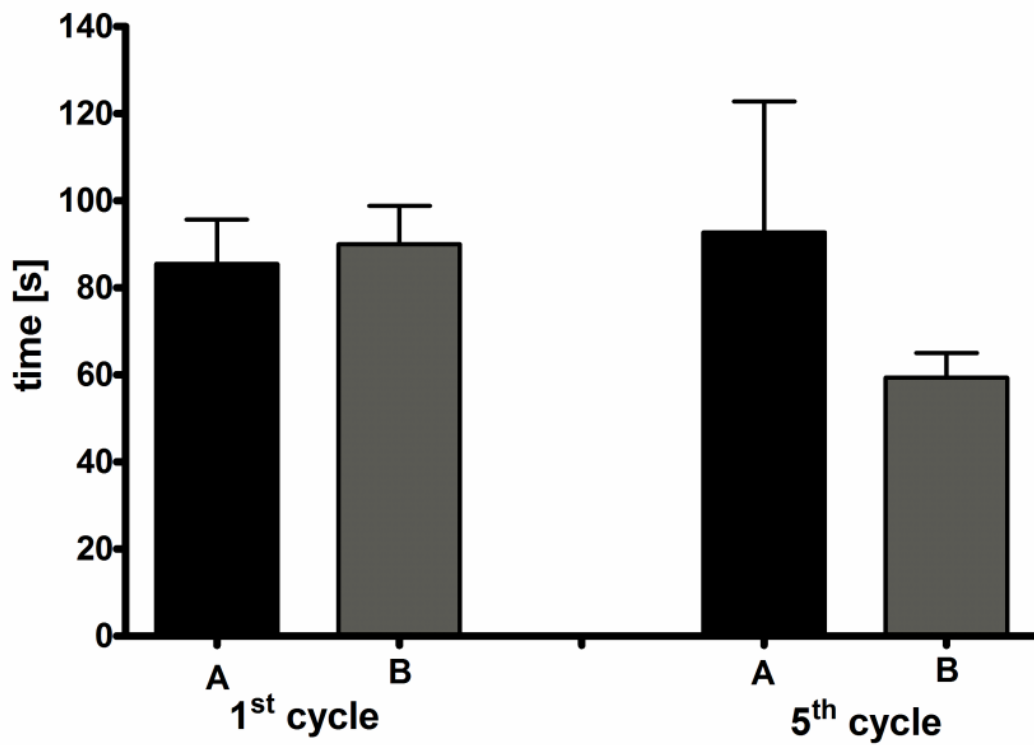


Fig. 21: Placement of cylinders (task 3): Comparison of the proficiency both groups achieved in cycle 5: Group A, using 2D imaging systems in all cycles of training (black bars). Group B, using 2D imaging systems in cycles 1, 3, 5 and additional direct view to the training site in cycles 2 and 4 (grey bars).

3.5.3.2 Intracorporeal knot

Participants of group A could not reduce their performance time from the first to the fifth cycle in task 4 (Fig. 22: cycle 1 vs. cycle 5: 5 min \pm 2 vs. 7 min \pm 2). In contrast, the time that participants of group B needed to complete the fifth cycle of task 4 was significantly shorter compared to the first cycle (Fig. 23: cycle 1 vs. cycle 5: 12 min \pm 2 vs. 3 min \pm 0.3; $p \leq 0.05$). The time needed to perform task 4 in group B declined 75% between the first and the last cycle of training. The performance time was the fastest when participants were allowed to glance directly to the training site (group B in cycles 2 and 4: 73% and 81% decline compared to cycle 1). Group B reached the performance time of the three dimensional training (cycle 2) in the fifth cycle of 2D training.

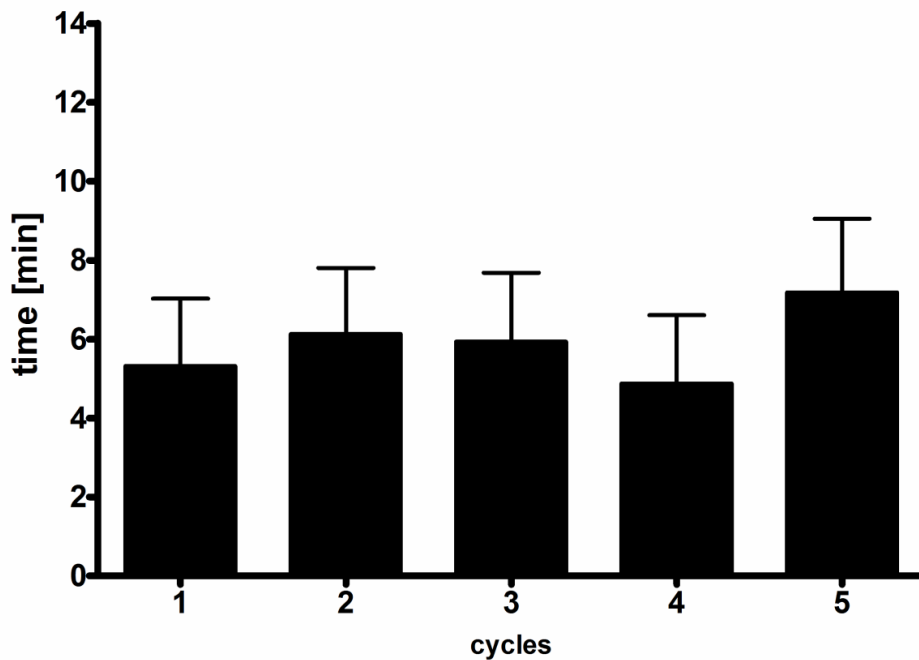


Fig. 22: Outcome measure intracorporeal knot (task 4): Group A using 2D imaging systems. Cycle 1 vs. cycle 5 in group A, not significantly different.

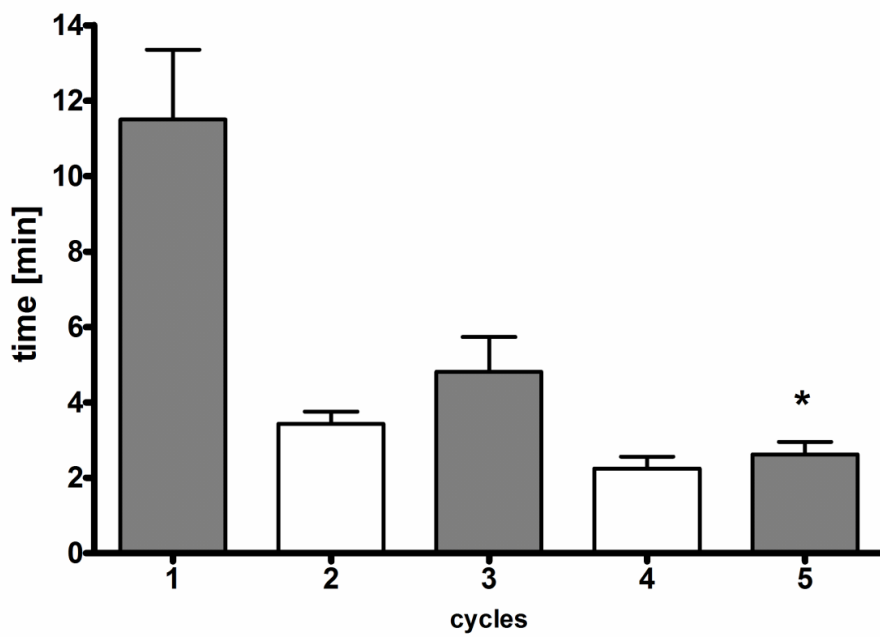


Fig. 23: Outcome measure intracorporeal knot (task 4): Group B using 2D imaging systems in cycles 1, 3, 5 (grey bar) and additional direct view to the training site in cycles 2 and 4 (white bars).

* $p \leq 0.05$; cycle 1 vs. cycle 5 in group B.

Comparison of the performance time that both groups needed in the fifth cycle of task 3 revealed that group B completed the fifth cycle of task 4 significantly faster than group A (Fig. 24: A vs. B, 7 min \pm 2 vs. 3 min \pm 0.3; $p \leq 0.05$).

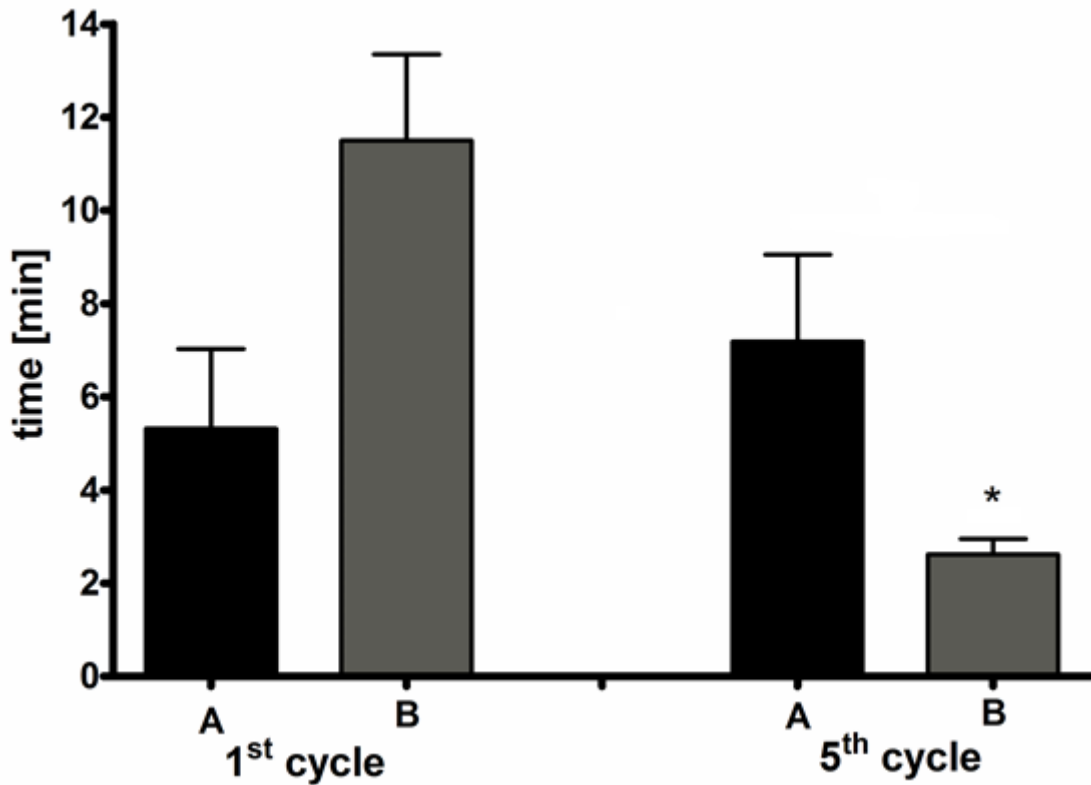


Fig. 24: Intracorporeal knot (task 4): Comparison of the proficiency both groups achieved in cycle 5: Group A, using 2D imaging systems in all cycles of training (black bars). Group B, using 2D imaging systems in cycles 1, 3, 5 and additional direct view to the training site in cycles 2 and 4 (grey bars).

* $p \leq 0.05$; 5th cycle group A vs. 5th cycle group B

4. Discussion

4.1 Training of laparoscopic surgery

The development of minimally invasive surgery using laparoscopic techniques constituted a paradigm shift in the field of surgical procedures. Laparoscopic surgery is associated with less post-operative pain, reduction in surgical wound infections, less hospital stays and quicker return to the daily life activities when compared to conventional open surgery [58]. However, several barriers to the practicing of laparoscopic surgery remain to be present in LMIC [41].

4.1.1 Training of laparoscopic surgery in Yemen

The most important barrier for wide-scale adoption of laparoscopic surgery in LMIC was commonly believed to be the lack of resources. We visited a private hospital and a public hospital in Yemen in 2012. There we experienced, that the fundamental challenge in the hospitals is the lack of laparoscopically trained surgeons and training opportunities. Many cost-analysis studies came to a similar conclusion. The lack of financial resources alone is not the significant barrier of laparoscopic surgery. Therefore, despite the higher cost of post-surgical care in comparison to that after laparoscopic surgeries, traditional open surgeries are still the most prevalent in these countries [59, 60]. Indeed, acquisition of laparoscopic equipment requires considerable capital. Donations of medical equipment might help to overcome this dilemma and are often practiced. But the centerpieces of laparoscopic equipment - the camera system as well as the laparoscopic instruments - need professional maintenance. In high-income countries hospitals keep service contracts with the company which provide the laparoscopic unity. Those maintenance agreements are hardly realizable in low-income countries and are mostly unworkably. We experienced this problem during our visit in the Ibn Sina Hospital in Yemen. The hospital possesses a laparoscopic unit used for urological interventions in the past. But due to a technical defect the unity was out of use when we visited the hospital and there was no perspective to fix the defect. This dilemma might be solved by long-sighted equipment acquisition or donation respectively. It is hardly understandably that spare parts and a certain service are not available in our globalized and digitalized world. The other substantial obstacle of laparoscopic surgery in low income-countries remains to be the lack of surgeons'

training, which has been found to significantly improve the skills of the targeted surgeons [54]. Both hospitals we visited in Yemen, the private Bugshan Hospital as well as the public university hospital Ibn Sina Hospital, had neither laparoscopically trained surgeons nor laparoscopic training devices. Furthermore, there were no cross regional training courses like we are accustomed to in Germany. If laparoscopy is performed, it is practiced by foreign surgeons. Formation of own laparoscopic surgeons does not take place. The human resources are available, but no training opportunities.

4.1.2 Training of laparoscopic surgery in Germany

In the meantime standard procedures like appendectomy, cholecystectomy and herniotomy are predominantly performed laparoscopically in Germany. Those procedures are part of the specialty training in visceral surgery. Candidates for the board certification in visceral surgery have to prove a certain number of them. However, laparoscopic skills training is not mandatory in Germany. There is a broad agreement that laparoscopy skills have to be trained *ex vivo* and teaching laparoscopy exclusively in patients is perceived to be unethically. But there is no obligation to standardized skills training before performing laparoscopy in patients. Other countries, for example the USA, demand special training courses during specialization. Residents of general surgery in the USA have to complete a standardized curriculum to obtain basic laparoscopic skills, the so called “Fundamentals of laparoscopic surgery” (FLS) program. The program was implemented by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Applicants for the board certification in general surgery have to show that they successfully achieved the FLS certification [61]. The adoption of an obligatory curriculum for laparoscopic skills training in Germany is debated but not implemented to date.

4.2 The value of box trainers in laparoscopic skills acquisition

The requirement and usefulness of simulation training in laparoscopy is widely recognized and accepted. Several studies have shown that laparoscopic skills, acquired with the help of training tools, are transferred to the clinical setting. Operating time, operating performance, as well as complication rate benefit from simulation training [37, 45, 54, 62].

The box trainers which are used in dry lab training can be constructed with little effort and low costs. They are effective in training of basic skills such as handling of laparoscopic instruments, suturing and knot tying. Wet lab trainers are suitable for training of certain laparoscopic procedures (e.g. laparoscopic cholecystectomy, appendectomy) in animal organs. Virtual-reality simulators are particularly advantageous for targeted training of special procedures. They are associated with high costs and reduced reality and tactile feedback [35] [40] [63].

Repetition is essential in skill acquisition, but few residents have adequate access to laparoscopic training tools [35, 50]. Installation and maintenance of laparoscopic training centers are expensive endeavors. Furthermore, surgical residents frequently require access to training tools outside normal working hours [37]. In Germany only certified centers for minimally invasive surgery have to provide training facilities. Simple homemade box trainers provide the possibility to overcome this dilemma. They might be installed in the doctors' room, available 24 hours a day for the residents and also maintained by them. Box trainers might also be installed at home, allowing even more flexibility of training.

The advantages of simple box trainers in the education of laparoscopic surgeons have been recognized before. Specifically, the design of homemade laparoscopic trainers has been published by others [52], and the effectiveness of box trainers has been shown [40,51]. In a systematic review of 48 studies, Gravante and colleagues evaluated the achievement of basic and complex laparoscopic skills by means of low-cost box trainers. [52]. The majority of the studies analyzed the acquisition of general skills such as conveying, cutting, and knot tying by novice and moderately experienced surgeons trained with box trainers. The authors found improvement of laparoscopic skills in most

included studies and assume that box trainers are a cost-effective alternative for 2D video trainers.

Also training in animal tissues is important in order to get familiar with tissues similar to human tissues. Many studies found skills acquired in training boxes transferable to the operative field [62]. No training box has been proven to be superior over other boxes. That allows building of boxes according to the targeted skills.

Some authors report very low costs for the construction of their box trainers by using cardboard boxes or simple plastic storage boxes. However, it must be recognized that these materials severely limit the durability of the box and possible fields of applications. Chandrasekera et al. designed a low-cost cardboard box trainer with cut-out top to permit direct vision to the operative field [40]. They compared the box trainer with 2D video-laparoscopy pelvic trainer among third year medical students. The students went through extensive eight cycles of training (3 hours per cycle) on 3 tasks, including sugar cube transfer, mint transfer, and disc cut-out. To reduce stereoscopic vision, the students in the cardboard box group had one eye obscured. The authors report, that the cardboard box group achieved laparoscopic skills in significantly shorter time when compared to students trained on the 2D video trainer. These findings together with our results provide an evidence, that training with direct vision by means of low-cost box trainers might be superior for achieving laparoscopic tasks in comparison to 2D vision in expensive pelvic trainers [40]. As the cost of conventional video trainers could reach \$30,000 and considering efficiency as a combined function of cost and effect, makes us postulate, that our box trainer is more efficient than conventional video trainers.

Clevin et al. validated the effect of a structured training curriculum on a low cost box trainer, constructed from an opaque plastic wash tub. They recruited 16 gynecologic residents who had limited laparoscopic experience and randomized them into an intervention group and a control group. The participants proficiency in camera navigation, instrument navigation, coordination, grasping, lifting and grasping an object, cutting and clip applying were assessed by the computer system of a virtual reality laparoscopic trainer based on objective parameters like time, error, and economy of motion scores two times at an interval of one week. In between, the intervention group

trained three hours on the homemade box trainer. The authors detected a significant greater improvement of the performance scores time, error, and economy of motion in the intervention group compared to participants without training [51]. By using a virtual reality simulator to evaluate the psychomotor performance the study benefits from an objective and unbiased assessment.

Generally, studies show improvement of surgical skills after using trainer boxes or virtual reality simulators. Mohammadi and colleagues evaluated the improvement of accuracy in laparoscopic skill between two groups. One group was trained on a box trainer, the other group on a box trainer and a virtual reality simulator. They did not detect significant differences between both groups in the proficiency achieved [63]. Munz and colleagues came to a similar conclusion when they compared error scores and motion analysis after a three-weeks training course in a box trainer and in a virtual reality simulator respectively. They did not detect significant difference between both groups [64]. Similarly, Stefanidis et al. conducted a study to assess the effect of a proficiency-based simulator training among 20 surgeons in the first academic year [35]. After a median training time of 12 hours and 325 repetitions, they found a 50% improvement in simulator scores. However, they emphasized that installation of this simulator could not be considered as a cost-effective training approach.

The box trainer that we developed possesses novel qualities. It allows a multitude of different types of training. It also permits 2D vision and direct vision to the training field. The corpus of our training box is formed by a metal tray so that it is suitable for training modules and animal tissue as well and furthermore permits the use of electrocautery. Thus, our box can be deployed not only for training of basic laparoscopic skills, but also for training of certain laparoscopic procedures by means of animal tissue (e.g. training of the laparoscopic cholecystectomy by using porcine or goat gallbladder and liver complexes). The possibility to use electrocautery in the box is another major advantage. Handling electrocautery is delicate and should be trained in *ex vivo* models for patient safety.

Participants trained on our box trainer rapidly improved their performance of laparoscopic skills. The average time needed for skills such as “bead transfer” was significantly reduced at the end of training by 31% in the 2D group and by 33% when

participants used 2D laparoscopy and intermittent direct view to the training site. Thus, particularly training of simple tasks on our box trainer, achieved comparable improvement to that of proficiency-based simulator training at much lower costs.

4.3 The impact of stereoscopic vision on the performance of laparoscopy

At the moment, laparoscopic procedures are usually performed with the aid of 2D imaging systems. Even in wealthy states, 3D imaging systems are not available everywhere, and the benefit of 3D laparoscopy for patients is still debated [26]. Novice laparoscopists have to learn how to deal with the absence of the third dimension and the altered depth perception in 2D imaging systems. For most inexperienced laparoscopists, this is the main challenge of laparoscopy. From other studies we know, that the use of 3D imaging systems shortened the time that participants needed to accomplish laparoscopic tasks. 3D imaging systems also improved the performance score in comparison to the use of 2D imaging systems [34,59-65]. Byrn and colleagues detected a significant improvement of performance time and error rate by using 3D imaging in a da Vinci robotic system independently of the participants' surgical experience [34]. Also Tanagho et al. and Storz et al. found a better performance of laparoscopic tasks in 3D laparoscopy compared to 2D laparoscopy by both: experienced laparoscopists and laparoscopic novices [66,67]. Cicione and colleagues as well observed an improvement of performance by 3D laparoscopy. But in their study, laparoscopic naïve participants benefited to a greater extent from the 3D imaging system than experienced laparoscopists [65].

The learning process in 2D laparoscopy includes psychomotor skills learning and visuospatial orientation simultaneously. Considering the problems which are caused by the altered depth perception in 2D laparoscopy, we conceived a box trainer that allows both: skills training with a 2D imaging system on the one hand and training with direct view to the training site on the other hand. Thereby our box trainer offers the possibility to overcome the dilemma of the altered depth perception without expensive and delicate 3D camera and monitor. We hypothesized that occasional direct view to the training site raises the efficiency of laparoscopic training, because it helps to deal with the narrowed depth perception and facilitates training of the eye-hand coordination. The results of the 32 novice laparoscopists included in our trial confirmed this hypothesis in parts. The

participants were challenged with a pair of simple tasks (bead transfer and needle guidance) and a pair of complex tasks (placement of cylinders and intracorporeal knot). All participants rapidly improved the performance of simple laparoscopic skills (bead transfer and needle guidance). Comparison of the time that both groups needed to complete the fifth cycle of task 1 and task 2 revealed no difference between group A, who performed the whole training in 2D vision and group B, who trained in 2D vision with intermittent direct view to the training site. A number of surveys compared the performance of laparoscopic tasks with 3D imaging systems and 2D imaging systems. They report that 3D imaging systems improved even the performance of fundamental non-complex tasks [66,67,68]. Apparently 3D imaging simplifies laparoscopy. But the results of our study suggest that learning simple laparoscopic tasks does not benefit from additional stereoscopic vision. Presumably laparoscopic beginners rapidly compensate- to a certain extent- the absence of the third dimension.

However other authors as well as the current study registered that the performance of complex laparoscopic skills benefits from stereoscopic imaging [69,70,71,72]. Students, who performed the whole training using 2D imaging systems, did not achieve advancement in handling complex tasks (placement of cylinders and intracorporeal knot) after five cycles of training. In contrast, participants who performed two training cycles with direct view to the training site significantly improved the performance of complex tasks. These results suggest that intermediate direct view to the training site accelerates the acquisition of advanced laparoscopic skills. Nickel and colleagues published a similar observation. In their study laparoscopic novices accomplished a suturing and knot tying task in 2D vision faster, when they had a previous 3D training [70]. The performance scores of laparoscopic beginners are better in 3D laparoscopy than in 2D laparoscopy. However, the performance worsens when trainees change from the 3D system to the 2D system. Switching from 2D laparoscopy to the 3D system in contrast, improves the performance scores. Using the stereoscopic vision in the early phase of laparoscopic surgical training improves the students surgical skills [73].

In a systematic review Sørensen et al. assessed the effect of 3D imaging on the outcomes of laparoscopy [26]. They included 31 randomized controlled trials in the review; three trials were conducted in a clinical setting, while the majorities (28 trials) were performed in a simulated setting. About two-thirds of the included studies found

an improvement of the performance time and 63% reported a significant decrease of errors with 3D laparoscopy in comparison to 2D laparoscopy [26].

The box trainer we developed with a transparent cover provides direct view to the training site, which is surely better than any advanced 3D technology. Among all trials reviewed by Sørensen and colleagues, no trial found negative effects of 3D viewing on the number of errors during laparoscopy [26]. On the other hand, using advanced 3D systems to visualize the operative field may be associated with eye strain, fatigue, and dizziness [67,71]. In contrast, other authors report, that 3D vision can reduce the cognitive efforts exerted by the surgeon during the operation [67]. Our box provides direct view to a transparent cover. This is more comfortable than 3D imaging systems and presumably caused less eye fatigue than 3D imaging systems. Independently of potentially exhausting 3D technology, participants favor 3D laparoscopy [24, 65]. Kong et al. report that about 54% of the non-experienced and 80% of experienced laparoscopic surgeons preferred 3D over 2D vision [24].

Way and colleagues analyzed 252 bile duct injuries during laparoscopic operations and found that the most common determinant of errors in laparoscopy is the visual inaccuracy due to the lack of the third dimension, which accounts for 97% of all errors [74]. There is a claim that experienced surgeons learned how to manage the absence of the third dimension in laparoscopic surgery. However, some studies report that even experienced laparoscopic surgeons improve their performance by 3D laparoscopy [65,75].

4.4 The efficiency of self-continued training

Access to laparoscopic trainers does not naturally implicate voluntary training and progress in laparoscopic skills performance. Zapf et al. report that 25 percent of american surgical residents who received a commercial box trainer for individual training at home did not use it, although the majority of users evaluated the box trainer favorably [76]. A german survey in 2016 revealed, that the participating residents of visceral surgery used skills labs at their hospitals more frequently when obligated to training. Regular training periodically supervised and analyzed by an expert might be the ideal conception [77].

4.5 Limitation of the study

This study has limitations that have to be considered. We evaluated a small group of laparoscopic novices. However, the group was assembled by laparoscopically naïve students and therefore very homogenous. The participants had to perform the training at a stretch; the protocol provided just 10 min breaks between the cycles. The students needed about two hours for the training session, and one has to assume that increasing fatigue might be a problem for most participants. However, this setup provided very constant conditions and enabled to analyze a very homogenous group. Ensuring a high level of homogeneity was more important for the validity of the study then establishing optimal didactic conditions.

This study did not evaluate the effect of the training on error rate and economy of movements. Reliable registration of these parameters needs sophisticated computer system. As the error rate and economy of movements account for the time needed to complete a certain task, this objectively measurable parameter was focused.

5. Summary

Laparoscopic procedures demand skills, which necessarily have to be trained in *ex vivo* models. The main challenge for novice laparoscopists is the absence of the third dimension and the narrowed depth perception in the predominantly used two-dimensional (2D) imaging systems. Handling of laparoscopic instruments has to be trained as well, but normally causes fewer problems.

In the current study an inexpensive box trainer was developed. The box trainer was designed as a prototype for laparoscopic training courses in Yemen. The training courses were intended to advance laparoscopic surgery in Yemen. Using simple and inexpensive materials a durable box trainer was constructed. The box trainer was suitable for learning and practicing of basal laparoscopic skills in a dry lab setting, as well as the training of laparoscopic procedures in a wet lab setting. Applying electrocautery was practicable as well. The box trainer allowed practicing with direct view to the training field. Additionally the training field could be covered by an opaque lid and by means of a 2D camera and screen it was suitable for training with 2D vision.

A randomized controlled trial was conducted to evaluate if the efficiency of laparoscopic skills training increases when the training curriculum allows direct view to the training site at certain points. 32 medical students devoid of experiences in minimally invasive surgeries were included in the study. The participants were randomized and stratified into two almost equal groups. Group A performed the whole training using a 2D- camera transmitted monitor image. Group B similarly realized cycle 1, 3 and 5 of the training using the 2D imaging systems but was allowed to direct view to the training site in cycle 2 and 4. The curriculum scheduled two simple tasks (bead transfer, needle guidance) and a pair of complex tasks (placement of cylinders, intracorporeal knotting). Performance time was recorded for each task.

The box trainer was well-accepted by the participating laparoscopic novices. Furthermore, participants expeditiously ameliorated their performance of simple laparoscopic skills. In this trial the training of simple laparoscopic skills (bead transfer and needle guidance) did not benefit from additional glances to the training site. The students improved the performance of simple laparoscopic tasks, irrespective of the opportunity to direct view to the training site. However, direct view to the training site

benefited the training of complex laparoscopic skills like placement of cylinders and intracorporeal knots.

Durable box trainers can be self- made at low costs and nevertheless offering multiple training opportunities. Laparoscopic skills training in this simple box trainer is well accepted and effective. Training of complex laparoscopic skills, benefits from the combination of training with a 2D system and intermittent direct view to the training site. Most likely the improvement of the hand-eye coordination under direct view to the training site increases the effectivity of skills training.

6. Conclusion

Continues training of laparoscopic skills is the key to improve proficiency in laparoscopic surgery. Skills training using simple training boxes is effective. Training of complex laparoscopic skills is easier and more effective when it's performed in the combination of training with a 2D system and intermittent three dimensional view of the training site.

Zusammenfassung

Laparoskopische Eingriffe erfordern Fertigkeiten, die idealerweise in *ex vivo* Modellen erlernt werden können. Laparoskopieanfängern bereiten vor allem die fehlende dritte Dimension und die reduzierte Tiefenwahrnehmung in der überwiegend eingesetzten zweidimensionalen Laparoskopie Schwierigkeiten. Auch die Handhabung der laparoskopischen Instrumente muss trainiert werden, dies bereitet in der Regel jedoch weniger Probleme.

In der vorliegenden Arbeit wurde ein kostengünstiger Boxtrainer entwickelt. Der Boxtrainer wurde als Prototyp für Laparoskopie-Trainingskurse für Yemen gestaltet. Mit Hilfe der Trainingskurse sollte die laparoskopische Chirurgie im Yemen gefördert werden. Unter Verwendung einfacher und kostengünstiger Materialien wurde ein langlebiger Boxtrainer konstruiert. Der Boxtrainer eignete sich für das Erlernen und Trainieren basaler laparoskopischer Bewegungsabläufe im sogenannten *dry lab* setting. Es ist aber auch für das Training laparoskopischer Eingriffe im *wet lab* setting geeignet. Auch der Einsatz der Elektrokauterisation war möglich. Der Boxtrainer konnte für das Training mit direkter Sicht auf das Trainingsfeld durch eine transparente Scheibe eingesetzt werden. Durch blickdichte Abdeckung des Trainingsfeldes und den Einsatz einer 2D Kamera und passendem Monitor eignete er sich aber auch für das Laparoskopietraining unter 2D Sicht.

Eine randomisierte, kontrollierte Studie wurde durchgeführt um zu bewerten, ob die Effektivität des Laparoskopietrainings gesteigert werden kann, wenn der Trainingsplan, an bestimmten Punkten, direkte Sicht zum Trainingsfeld vorsieht. In die Studie wurden 32 Medizinstudenten ohne Erfahrungen in der minimalinvasiven Chirurgie eingeschlossen. Die Teilnehmer wurden in zwei annähernd gleiche Gruppen randomisiert und stratifiziert. Die Gruppe A absolvierte das gesamte Training mit Hilfe eines 2D Monitorbildes. Die Gruppe B absolvierte die Trainingszyklen 1, 3 und 5 auf die gleiche Weise, durfte aber während der Trainingszyklen 2 und 4 direkt auf das Trainingsfeld schauen. Der Trainingsplan sah zwei einfache Aufgaben (Transfer kleiner Gegenstände und Führen einer Nadel) und zwei komplexere Aufgaben (Einordnen kleiner Zylinder und intracorporales Knoten) vor. Gemessen wurde die Zeit, bis die Aufgaben erledigt werden.

Der Boxtrainer wurde von den teilnehmenden Laparoskopieanfängern gut angenommen. Zudem verbesserten die Teilnehmer rasch ihre Leistungen bei der Erfüllung der einfachen Trainingsaufgaben. Diese Studie konnte keinen Vorteil für das Training einfacher Laparoskopiefertigkeiten unter direkter Sicht messen. Die Studenten verbesserten ihre Leistungen unabhängig von der Möglichkeit direkt auf das Trainingsfeld zu schauen. Allerdings wirkte sich das Training komplexer Bewegungsabläufe (Einordnen kleiner Zylinder und Intracorporales Knoten) mit zwischenzeitlicher direkter Sicht auf das Trainingsfeld günstig auf den Trainingseffekt aus. So konnte die Zeit, die für die Bewerkstelligung der komplexen Trainingsaufgaben nötig war, innerhalb der fünf Trainingszyklen signifikant reduziert werden. Dagegen konnte die Gruppe die ausschließlich an 2D Monitor trainiert ihre Leistungen bei der Erfüllung komplexer Aufgaben nicht verbessern. Langlebige Boxtrainer können kostengünstig hergestellt werden und trotzdem zahlreiche Trainingsmöglichkeiten bieten. Einfache Boxtrainer zum Training laparoskopischer Fertigkeiten werden gut angenommen und sind effektiv. Die Effektivität des Trainings komplexer laparoskopischer Fertigkeiten kann durch eine Kombination von 2D-Sicht und dreidimensionaler Sicht gesteigert werden. Wahrscheinlich wird diese Steigerung der Trainingseffektivität durch die verbesserte Hand- Auge-Koordination unter dreidimensionaler Sicht zum Trainingsfeld ermöglicht.

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8. Erklärung zum Eigenanteil

Die Arbeit wurde von Khaled Bajaeifer und Professor Dr. Jörg Glatzle konzeptiert. Den Boxtrainer konstruierte Khaled Bajaeifer. Khaled Bajaeifer rekrutierte die Teilnehmer, führte die Studie durch und sammelte die Daten. Die Datenanalyse erfolgte durch Khaled Bajaeifer. Die Interpretation der Data erfolgt durch Khaled Bajaeifer, Dr. med. Friederike Eisner und Professor Dr. med. Jörg Glatzle. Das Manuskript schrieb Khaled Bajaeifer. Die Korrekturen erfolgten durch Dr. med. Friederike Eisner und Professor Dr. med. Jörg Glatzle.

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