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A Hybrid Box Trainer for Training of Technical Skills in Laparoendoscopic Single Site Surgery (LESS)

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Challenge the future

Abstract

Conventional laparoscopic surgery (CLS) is performed through multiple (3-4) small incisions in the abdomen, whereas laparoendoscopic single site surgery (LESS) uses only one single entry point for all the instruments. The approach of LESS has already been applied in multiple disciplines and is gaining increasing popularity mainly due to its improved cosmesis result. Despite LESS shares some similarities with CLS such as impaired depth perception and disturbed tactile feedback; it may poses other technical challenges and demands not seen in CLS. Comparisons between these two approaches so far are merely post-operative results and laboratory comparison mostly using time and error as metrics. Furthermore, only a few existing training systems address force-related measurements and thus there is a need to examine the difference in tissue handling and abdominal force between LESS and CLS.

The goal of this thesis was to design a hybrid trainer that can quantitatively measure the LESS performance on the account of force and motion, and to investigate the difference between LESS and CLS, finally to propose novel metrics based on measurements for future research. A novel two-axis force measurement mechanism consist of hall effect sensors has been developed and incorporated in the box trainer, which measures the abdominal force the instrument exerted on the abdominal wall in a range of 0-15 N with an accuracy of 0.1N. Tissue manipulation force is measured by a force platform in three axes in a range of 0-20N with an accuracy of 0.1N. And acceleration of instrument handle is measured with 3-axis MEMS accelerometers. Experiment involving 22 novices and 2 experts has been conducted to test the hypotheses whether significant differences exist between CLS and LESS in maximum abdominal force, maximum tissue manipulation force and maximum acceleration during task performance.

The development of hybrid box trainer for LESS-specific training shows high potential for future training courses with an emphasis on both force and motion. The results also contribute to future development on the consensus of objective assessment metrics used in surgical training. Maximum tissue manipulation force applied in LESS configuration is significantly higher than that in CLS ($p<0.01$). A significant difference ($p<0.01$) is found in the maximum abdominal manipulation force between CLS and LESS configuration in a task that involves constant tractive force on the instrument. and maximum abdominal force. The maximum acceleration of the left handle is significantly higher in the LESS session than in the CLS ($p<0.01$), but not on the right handle ($p=0.48$).

Content

1 Introduction

1.1 Background

Over the past decade, training for surgical skills has evolved from traditional apprenticeship model in the operating room (OR) to training programs outside the OR. More and more hospitals are equipped with physical or/and virtual training facilities such as box trainer, hybrid trainer and virtual reality (VR) simulator. Surgeons now have the opportunity to train and assess their technical skills in a laboratory setting. These new training methods outside the OR provide a less stressed and less expensive environment for practicing technical skills without compromising the patient's safety due to an increased operation time or increased risk of tissue damage. Despite the fact that many training simulators are now commercially available, new methods for tracking of instruments (Loukas, 2013), mimicking of tissues using artificial phantoms (Fábry, 2013) and simulating the haptic sensations (Våpenstad, 2013) are still in the development.

The need for training and assessing in conventional laparoscopic surgery (CLS) was recognized from the presence of a high complication rate and long learning curves in initial trials (Moore, 1995). In addition, the skills required in laparoscopy can hardly be transferred from training in open surgery (Aggarwal, 2004). Impaired hand-eye coordination, lack of depth perception, poor haptic feedback, difficulties with handling of long instrument and the presence of a fulcrum effect are challenges that require technical skills that cannot gain effectively from observations alone, but from hands on practice and repetition. In Netherlands, the Dutch Society for Simulation in Healthcare (DSSH) has already promoted nationwide implementation of proficiency-based training curricular (Schreuder, 2011).

Laparoendoscopic single site surgery (LESS) has received much attention in recent years. This advanced approach allows surgeons to perform surgical tasks through a single port of entry instead of multiple entry points. LESS provides patients with improved cosmesis result compared to CLS (Stroup, 2010) and has already been applied in several surgical procedures such as cholecystectomy, appendectomy and gastric sleeve resection, etc. (Fransen, 2012). Yet questions arise as to whether there is technical difference between LESS and CLS and whether LESS-specific training is needed. Both in-vivo and ex-vivo experiments have been conducted to compare LESS and CLS. In-vivo experiments take into account of the operation time, conversion rate (i.e. LESS converted to CLS, CLS converted to open), post-operative complication rate, hospital stay, pain etc. Ex-vivo experiments are carried out in laboratory settings and mainly use pre-defined metrics. On the one hand, some claims that no significant difference was found in the performance of a group of 20 novices after training in the two approaches (Fransen, 2012); on the other hand, some concluded that LESS requires a different mind and skill set from CLS, and LESS-specific training is needed (Santos, 2011, Alevizos, 2012). According to Laparoendoscopic Single-site Surgery Consortium for Assessment and Research's (LESSCAR) whitepaper 2009, 'technology development and training cannot necessarily be extrapolated from existing resources for laparoscopic surgery and must be addressed specifically for LESS'.

Object assessment of performance is essential to effective technical skills training in all systems. Traditional assessment has limited evaluation parameters such as total time, errors and end-product analysis, which on the one hand has been validated for evaluation of basic technical skills in laparoscopy (i.e. Fundamentals of Laparoscopic Surgery), on the other hand does not provide any information on the motion or force performance of the trainee. The metrics used for quantitative assessment has been extensively studied in recent years with the introduction of sensory system sand virtual reality simulation (Stefanidis, 2009). A division can be made between motion-related and force-related metrics. Motion-related metrics such as path length and motion smoothness are widely used and validated (Oropesa, 2011) in training system if motion tracking devices are integrated to track the movements of both instruments. Force-related metrics have also been studied in CLS training and validated in suturing tasks, such as force/torque magnitude and peak force in tissue manipulation (Rosen, 2001, Horeman, 2010). Metrics defined in a novel way and reflect different aspects can be complementary to the existing metrics in the assessment of the training system, used for further classification and to provide formative feedback to trainees.

1.2 Problem Statement

Problems within current training and assessing of surgical skills in LESS lie in three aspects: the type of training, skill set different from CLS, and the metrics used in the assessment.

As mentioned above, box trainer and VR simulator can both be used for training purposes. But there are some problems with these two training modalities. Most box trainers lack quantitative measurement tools. Without sensors, box trainer itself cannot provide objective assessment or give direct feedback on motion and force performance. VR simulator, on the other hand, can provide objective assessment on the motion and time, since the measurement system comes inherently in the simulator. But VR simulators cannot provide realistic haptic feedback, which is considered necessary in the performance of force-related tasks (i.e. suturing) (Botden, 2008, Panait, 2009). Some may argue that now advanced VR simulators are equipped with actuators that can simulate haptic sensations in the form of vibrations and resistance on the instrument. However, its level of realism is limited in the lack of accurate modeling of trocar site resistance, instrument clashes, and distorted force feedback (Dankelman, 2008), particularly for the purpose of LESS training. There are also problems with directly modifying the measurement system used in CLS training. Some of the measurement systems are not widely available; the size of which is bulky and will interfere with the surgical technique; sensory system cannot be easily integrated into LESS-specific training.

In discussions of the technical difference between LESS and CLS, analytical comparisons or conclusions found in literature were seldom supported by quantitative measurement data. Moreover, most of the studies conducting training experiments use time and error parameters to assess the performance and give limited information on the quality of the motion and force (Oropesa, 2012). When carefully scrutinized, the task used in some studies lacks a sufficient level of realism or complexity that may lead to results that cannot be linked to real practice.

There has been a lot of research carried on in the definition of metrics used as objective assessment. Ritter 2007, Stefanidis, 2009, and Oropesa 2012 have provided thorough reviews on the metrics used in assessment of laparoscopic surgical skills, most emphasizing the importance and usefulness of motion-related metrics such as path length and economy of movements. However, the basic idea of using tissue manipulation force data in the process of training is new and is not systematically investigated yet. Studies focus on applying the right amount of interaction force between instruments and tissue is scare in literature (Richards, 2000, Rosen, 2003, Horeman, 2012, Singapogu, 2012). With the fact that a large percentage (55%) of surgical errors (tissue damage) are caused by the over-application of force (Tang, 2005), training simulator that addresses force controlling skills and research that investigates the force applied on tissue and incision will be of great importance to lower the risk of injury.

1.3 Thesis Goal

The first goal of this thesis is to design and prototype a hybrid trainer with measurement systems that can record instrument motions and the forces exerted on the training task and abdominal wall in both CLS and LESS configuration.

The second goal is to find time, motion-related and force-related parameters that reflect the most important differences in tissue handling and instrument motions based on the developed sensory systems.

The third goal is a research goal of finding the difference between CLS and LESS based on trocar force, tissue interaction force and instrument motion.

2 Materials and Methods

The materials and methods section is divided into two parts. The first part discusses the overall design of the hybrid trainer. In this part, theoretical model for LESS operation (Section 2.1.1) is elaborated; physical quantities that are aimed to measure (Section 2.1.2) are specified; design requirements (Section 2.1.3) are stated; and concepts for measurement (Section 2.1.4) are elaborated. Eventually, the prototyping (Section 2.1.5) and calibrating process (Section 2.1.6) of the hybrid trainer are presented.

The second part focuses on the design of experiments. Experiments are conducted in order to test the hypotheses associated with the stated problems. This part involves hypotheses statement, subject selection criteria, surgical equipment choices, design of training tasks, and experimental protocol.

2.1 Design of Hybrid Trainer

2.1.1 Theoretical Model

In this subsection, a combination of instrument motion model and summary of source of friction during LESS operation is given such that a theoretical analysis from mechanical perspective can be provided, and the basis for the following measurement can be set.

A 4-DOF theoretical model that identifies possible motions associated with instrument manipulation in LESS was elaborated (Figure 1 (1)). This model uses standard straight laparoscopic instrument for illustration, which is modelled as a rigid bar with defined length and shaft diameter. Figure 1 illustrates the insertion of the instrument into the abdominal wall to reach the target tissue.

Similar to that in CLS, in LESS the surgeon is able to move the instrument in four degree of freedom (4-DOF) and the movements can be defined as; translation (1st DOF), rotation (2nd DOF) of the instrument around its axis, left-right (3rd DOF) and forward-backward (4th DOF) rotation of the instrument around the incision point. The other degree of freedom is constrained by the pivot point where the instrument is inserted into the abdomen through the trocar. This motion model applies to all instruments inserted through the single port.

In most cases, a single port device has three to four channels: one for the laparoscope and the others left for other hand instruments. Although a same total number of instruments can be inserted in single port device as in CLS, empirical evidence suggests that the multi-channel trocar does not allow the same range of motion for one instrument as the conventional trocar used in CLS does, or requires higher effort to reach the same range of motion than that required in conventional trocar, especially when all channels of the single port device are in use. In addition, the movement of each instrument is at the same time constrained by the other instruments and by the port itself.

Apart from modelling all possible instrument motions and its limitations, forces experienced by the instrument were also demonstrated. In laparoscopy, surgeon's haptic sensations are weaker than in open surgery, but the surgeon can still perceive haptic sensation through the instrument as they touch the trocar, the abdominal wall, the organ, and other physical objects within the surgical environment (Bholat, 1999). During operation, the instrument will experience friction from different sources. These friction forces were modelled in Figure 1(2).

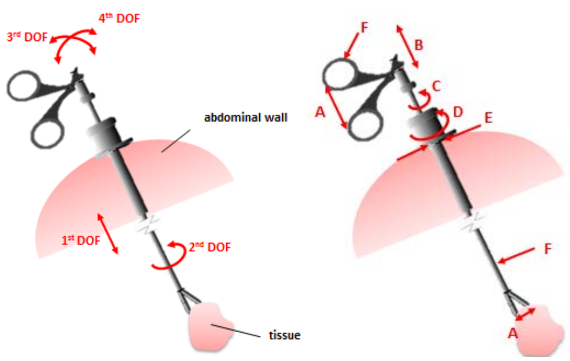


Figure 1 (1) left: 4-DOF theoretical model of instrument movement, (2) right: Source of friction during operation (A: instrument mechanism, B: in the trocar during instrument axial translation, C: in the trocar during instrument rotation, D: in the abdominal wall during trocar rotation, E: in the abdominal wall during trocar horizontal translation, F: internal and external instrument clashes)

The first source that influences the haptic feedback is the friction between the actuation rod and shaft of the instrument (A in figure 1(2)) during the motion of the jaws, which is inherently in the instrument mechanism. Due to this friction, the ratio between the grip force in the tip of the instrument and the grip force in the handle is always smaller than one. And the ratio changes with the opening and closing of jaws.

The second source (B,C in figure 1(2)) is found in the trocar when an instrument is in contact with the trocar valve. According to Van den Dobbelsteen et al, friction between the instrument and the trocar valve range from 0.25 N to 3.0 N; and this value varies greatly between different instrument and different trocar. The friction is also subject to the relative movement velocity between instrument shaft and trocar, and the movement direction. The friction magnitude can be reduced either by changing the properties of the sealing cap or by lubricating the instruments (van den Dobbelsteen, 2007).

The third source that influences haptic feedback is the abdominal wall (D,E in figure 1(2)). During operation, the trocar is placed in the patient's abdominal wall. The interface between the trocar and the abdominal wall is acts as a pivot point that resists any rotational movement of the instrument. Moreover, due to the contact pressure between trocar shaft and instrument after rotation of the instrument around the incision, extra friction is created during axial instrument movement. Unlike the interface between instrument and trocar, the resistance of the abdominal wall (skin, subcutaneous fat, facial and muscular layers) can vary due to non-isotropic biomechanical properties. Rotational movements of trocar are especially hindered by the stiffness of the abdominal wall. The counteracting torque created around the trocar in the incision can range up to 0.7 Nm according to angle and direction of tilt (Picod et al. 2005).

Other sources (F in figure 1(2)) such as instrument clashes happen both inside and outside the abdominal cavity, negatively affect surgeon's performance (Horeman, 2012).

2.1.2 Measurement

In order to design and prototype a measurement system, the required physical parameters are first determined in this section. These parameters include tissue manipulation force, abdominal force and 3-axis acceleration of instrument handle.

Tissue manipulation force

In CLS as well as in LESS, the surgeon interacts with internal organs through a set of standard mechanical instruments (e.g. forceps, curved needle scissors) that can be inserted through trocars. During the performance of a surgical task, there is frequent occurrence of interaction between instrument and organs. This interaction can be categorized into three types as illustrated in Figure 2. First there is the pulling/stretching force; secondary the pushing/pressing force; and finally the pinching force (with or without torsion). The pinching force is highly depending on the type of forceps used while the pulling and pushing forces are independent from the type of forceps used. Whereas Prior studies have shown the relationship between pinch force and tissue damage (Heijnsdijk, 2004), high pulling and pushing force that can lead to tissue damage is under studied. Therefore, the tissue manipulation force in this thesis describes the pulling and pushing force during interaction with the manipulated object. Moreover, the tissue manipulation in this study is assumed to be a contact force without torques.

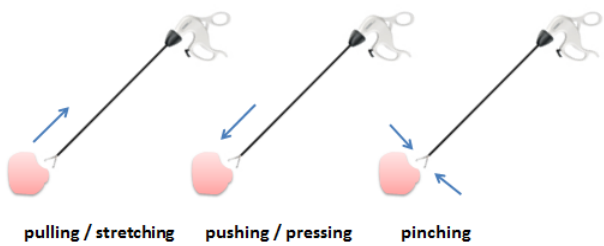


Figure 2 Interaction between instrument and tissue

Abdominal force

In Figure 3, the abdominal force that the trocar exerted on the abdominal wall during instrument manipulation is illustrated. The trocar accommodates one instrument in CLS; while in the case of LESS, the single port device accommodates all the instruments. In both cases, the trocar is acting as pivot point that has close interaction with the abdominal wall. Both rotation and horizontal translation of the single port device are constrained by the abdominal wall due to its high stiffness.

A former study (Horeman, 2012) has found that the level of force exerted on the abdominal wall during surgery is rather high. Whether the abdominal force is important to be considered during LESS training is not known yet. Here in this thesis, abdominal force will be measured in both LESS and CLS configurations.

Three-axis Acceleration of Instrument Handle

During operation, surgeons move the instrument on one end (handle) to obtain certain motion on the other end (instrument tip). Acceleration is one of the kinematic characteristics of this motion, indicating the rate of change of velocity with respect to time. Due to design requirements and final concept choice (in Section 2.1.3, 2.1.4), 3-axis acceleration for both instruments are measured as an indication of instrument motion (Figure 4), the parameters derived from 3-axis acceleration will be elaborated in Section 2.1.4.

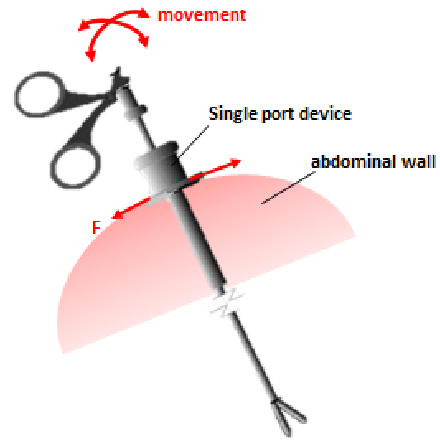


Figure 3 abdominal force exerted on the trocar

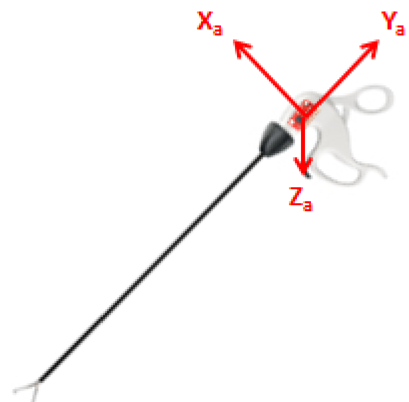


Figure 4 accelerometer installed on the instrument handle (Xa, Ya, Za represent local coordinates of accelerometer, with Ya and instrument shaft mounted on the same direction)

2.1.3 Requirements

On account of the fact that a hybrid trainer is a united system, key requirements including range and accuracy of measurement, sampling frequency and user interface are discussed in this section. A summary table giving an overview of all requirements and their corresponding technical quantification is given in Appendix I.

Requirements on Framework

According to Cesanek and Horeman, the framework of a hybrid trainer should combine real instruments and physical training models with computer monitoring for post processing, thus offering objective software-generated evaluation of task performance while retaining the features of a simple box trainer (Cesanek, 2008, Horeman, 2008).

Requirements on Force Measurement

According to De Visser et al., the average pulling force applied by surgeons to stretch pig's colon for dissection is 2.5 N and the maximum pulling force is 5 N (De Visser, 2002). Recent study has shown that the maximum interaction force during training process can be up to 8 N (Horeman, 2012). Therefore, based on previous results, it is expected that the tissue manipulation forces generated during both experts and novices' performance can be up to 10 N. A measurement accuracy of ±0.1 N should be sufficient enough to measure delicate training task that involves tissue manipulation.

As for the abdominal force, a study in the configuration of LESS has shown that the abdominal force can reach a maximum of 12 N when using the conventional straight instruments during a navigation and tissue manipulation task (Horeman, 2012). For robustness reasons, the system should be able to measure a range of abdominal force from 0 to 15 N, with ±0.1 N measurement accuracy.

Requirements on Acceleration Measurement

Since the range of acceleration of instrument movement during surgical training is absent in literature, it was determined in a preliminary experiment. An accelerometer with two selectable measurement ranges of ±1.5g and ±6g is used (MMA7361L, Freescale Semiconductor, Inc., 2008). It is observed that a range of ±1.5g is sufficient for highest acceleration during normal operation. When the range of acceleration is determined, configuration with higher sensitivity is chosen.

At the same time, the physical presence of the sensor should not alter the hand motion. Furthermore, to prevent that the added mass influences the measured inertia, and for an application like the human hand movement (Stiles, 1967), the accelerometer sensor is required to be extremely small in size and light weight.

Sampling Frequency

The frequency range of hand tremor is 9-25Hz (Stiles, 1967) and normal human oscillatory hand gestures typically lie in the interval between 0.3 Hz and 4.5 Hz (Xiong, 2006), which is much lower than the tremor frequency. Since we like to measure both gestures and tremors if they occur and we like to eliminate any aliasing effects, the sampling frequency for motion tracking system should be set on 50 Hz.

Video update frequency

It is commonly acknowledged that time delays can bring distraction to the trainee due to unnatural visualization during fast instrument movements (Leslie, 1966, Stroosma, 2007). Because of the possible negative impact on the performance, the distraction needs to be avoided by minimizing the time delay to a level that the trainee will not recognize it. According to previous research conclusions, a minimum frequency of 30 Hz should be kept to allow realistic video updating of instrument movements (Zhuang, 2000).

Feedback on performance

Objective formative assessment is a crucial component in the training of new surgical skills, because it can provides direct feedback, describes the learning process or learning curve and allows comparison between individuals or system. Therefore objective formative assessment should be part of the new hybrid trainer. The direct feedback of the new hybrid trainer should be provided in visual form in the graphical user interface. The details of a graphical user interface designed in MATLAB are provided in Appendix III.

Cost

One of the disadvantages of existing computer-aided training tools is their high cost (provided in Table 2). In the design process, the cost of sensors used as well as modification effort should be taken into consideration To keep the costs for the hospital as low as possible the used sensors should be commonly used and not to exceed 600 euro. The cheapest system that fulfills all the requirements should be chosen.

Table 1 Cost of existing training system (Schijven, 2003)

Trainer	Category	Price (euro)
LapSim	VR	39,000
MIST	VR	16,000-25,000
Simbionix	VR	90,000
Xitact	VR	110,000
FLS	BT	600-2000

2.1.4 Conceptual Design

In this part, the conceptual design chosen for the three measurements - tissue manipulation force, abdominal force and handle acceleration - are discussed in combination with decisions made on framework of hybrid trainer, sensor choices for force and acceleration measurement.

Framework of hybrid trainer

The hybrid trainer developed in this thesis is in the form of a box trainer. The size of the box is approximately the size of abdominal cavity. The top of the box is covered with an opaque membrane to prevent direct view on the workspace. Three circular holes are made on the top board, leaving room for trocar ports and abdominal force measurement mechanism in both CLS and LESS configurations. A camera is fixed inside the box at a fixed angle in order to provide a top view to the workspace. Due to the fact that slippage of the box or any movement of the box during measurement will add extra noise to the measured signal, friction pads are added on the bottom of the box. A monitor is needed to display the image captured by the camera, and it is placed above the trainer on an ergonomic height that enables an intuitive and comfortable stand for the trainee.

Sensor Choice for Force Measurement

There are many ways and sensors available to measure force. The final choice is based on multiple factors, including size, weight, range of measurement, sensibility and output voltage range. For the matched range of measurement, sensibility and output voltage range, there are multiple options to fulfill these requirements. For these sensors, the question whether the sensor can be incorporated into a mechanism that fit the space of hybrid trainer is highly important. Table 2 gives an overview of these sensors.

The hall effect sensor is chosen to measure the force for its compact size, relative affordable price, the accuracy and sensitivity. The principle of hall effect sensor is that the hall element responds with an output voltage proportional to the magnetic field strength. According to the data sheet of the hall effect sensor (HONEYWELL S&C – SS49E – IC, Linear, TO-92-3), within the range between the sensor and magnet around 3mm, the accuracy can reach up to 0.0019mm/bit, which is desirable for limited space incorporation. Accordingly, a disc magnet(Neodymium disc magnet, Eclipes N700-RB) with diameter of 3mm is used to establish magnetic field from a distance.

Table 2 Comparison table of different sensors used for force measurement

Sensor	Accuracy	Size	Time delay
Hall effect sensor	0.0019mm/bit	Diameter 4mm, thickness 1 mm	No
Load cell	0.25N/bit	100lbs	No
flexiforce	+/- 3%	0.2 mm × 14 mm × 25mm	5ms
Optical sensor	0,51 mm sq leads	2,24 mm × 1,57 mm × 3,18 mm	No

Sensor Choice for Acceleration Measurement

An accelerometer with higher bandwidth can be chosen to cover the entire bandwidth for normal instrument motion. However, the sensitivity of such a sensor at ±1.5g is much lower (200mV/g @ ±6g) compared with the 3-axis MEMS accelerometer (800mV/g @± 1.5g). Therefore, although it covers not the entire bandwidth, this sensor is used to fulfill the requirements listed in Section 2.1.3.

Specifics of the MEMS sensor are given in Table 3. With this sensor, the acceleration experienced by the sensor and anything attached to it can be measured directly.

Table 3 Specifics of accelerometer sensor MMA7361L

Parameter	Value
number of axes	3
maximum acceleration amplitude	±1.5 g
sensitivity	800mV/g
nonlinearity	±1% FSO
maximum acceleration damage	± 5000 g
supply voltage	3.6V
temperature range	-40 to +125 °C
weight	5 gram

* Here g is used as a unit for acceleration, which is equal to standard gravity.

Force Platform

A novel force platform ForceTRAP v2 is designed and manufactured in the MISIT lab of TU Delft and has been used to fulfill the requirements on measurement of tissue-instrument interaction force. The novel ForceTRAP v2 was developed on the basis of a previous version (Horeman, 2010), which is compact enough to fit in the framework of the hybrid trainer (with the height being 9 cm, and inner surface area being 64 cm^2). The ForceTRAP v2 is fixated by four screws on the bottom base of the hybrid trainer so that it kept relative static with reference to the hybrid trainer.

The ForceTRAP v2 is capable of measuring force ranging from 0 to 15 N along three orthogonal axes x, y and z axis. The base of ForceTRAP v2 contains two pairs of hall effect sensors and magnets to measure the x and y movements respectively. Three spring blades with hall effect sensors are used to measure displacements in the z direction. A decoupling mechanism was designed and placed in the base of the platform so that measurement in x and y axis remained independent. Three hall effect sensors and magnets for the measurements in the z axis were fixed underneath the top plate and base near by the spring blades. The sensors are positioned on the vertices of an equilateral triangle, as illustrated in figure x.

Each pair of sensor and magnet can measure force in two opposite directions. Assume the initial distance between the sensor and the magnet is the equilibrium, a positive value was detected since a greater hall effect was obtained when the distance decreases between sensor and magnet. Vice versa the output increases when this distance increased.

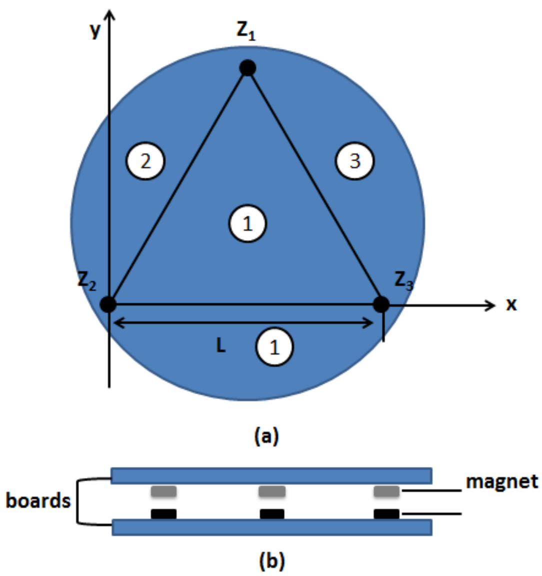


Figure 5 (a) Horizontal (plane x-y) illustration of positions of sensors that measure displacement in z direction (denoted as z_1, z_2, z_3), (b) front view of hall effect sensor and magnet pairs placed in distance

In order to measure force in the horizontal plane, two pairs of hall sensor and magnet are needed. Given the angle between each pair is designed to be $\frac{\pi}{2}$, the magnitude of absolute force in the horizontal plane (denoted as F_{xy}) equals to the vector sum of force in x and y axis (denoted as F_x and F_y respectively). The formula is:

$$\left|F_{xy}\right| = \sqrt{F_x^{\ 2} + F_y^{\ 2}}$$

Because there are three sensors to measure displacements along the z axis, theoretically the absolute force in vertical plane F_z is the vector sum of all three forces:

$$\vec{F}_z = \vec{F}_{z_1} + \vec{F}_{z_2} + \vec{F}_{z_3},$$

where F_{z_1}, F_{z_2} and F_{z_3} represent force calculated from three sensors along the z axis respectively. When F_z is positive, the tissue manipulation force is pushing force; when F_z is negative, the tissue manipulation force is pulling force.

Finally, the magnitude of absolute force F in three-dimensional space is calculated as:

$$\left|F\right| = \sqrt{F_{xy}^{\ 2} + F_z^{\ 2}}$$

Apart from measuring the tissue manipulation force, another function developed from the ForceTRAP v2 was to detect the position of the interaction. The position where the instrument interacts with the top plate of ForceTRAP v2 can be determined based on information collected from the three sensors in z axis, if only one instrument is used. If there are two instruments interact with the platform simultaneously, then the sum position can be calculated.

Therefore a function was written in MATLAB using the moment equilibrium theorem developed on the basis of three sensors placed in z direction. In order to be able to detect positions in ①, ② and ③, two rotational matrixes are needed. As it can be seen in Figure 6, angle α and β are need to rotate the (x, y) coordinates to (x', y') and (x'', y'') coordinates respectively, whereas $\alpha = \frac{2}{3}\pi$ and $\beta = \frac{4}{3}\pi$. The rotation matrixes are then defined as:

$$R_1 = \begin{bmatrix} \cos\frac{2\pi}{3} & -\sin\frac{2\pi}{3} \\ \sin\frac{2\pi}{3} & \cos\frac{2\pi}{3} \end{bmatrix}, R_2 = \begin{bmatrix} \cos\frac{4\pi}{3} & -\sin\frac{4\pi}{3} \\ \sin\frac{4\pi}{3} & \cos\frac{4\pi}{3} \end{bmatrix}.$$

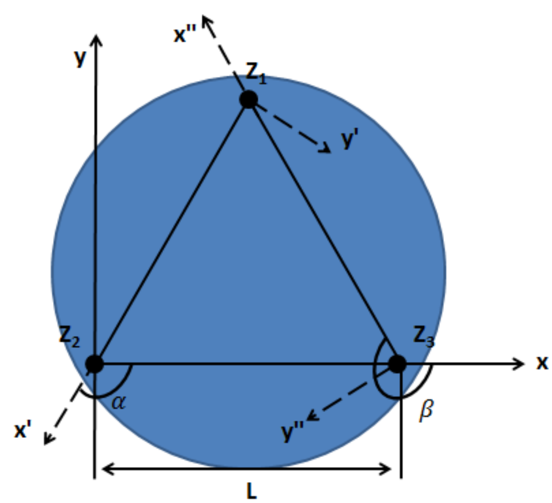


Figure 6 Rotational angles α and β

There are three scenarios:

i. If the forces of each individual sensor are between -0.1 and 0.1, it is assumed that there is no contact between force platform and instrument.

ii. When there is a point contact in area No.1 as marked in Figure 5, the position (x, y) can be derived as following:

$$F_{z_2} > 0, F_{z_3} > 0 \; \square \; F_{z_2} < 0, F_{z_3} < 0$$

$$x = \frac{F_{z1}}{F_{z1}+F_{z2}+F_{z3}} \cdot \frac{1}{2} \cdot L + \frac{F_{z2}}{F_{z2}+F_{z3}} \cdot \left(1 - \frac{F_{z1}}{F_{z1}+F_{z2}+F_{z3}}\right) \cdot L$$

$$y = \frac{F_{z3}}{F_{z1}+F_{z2}+F_{z3}} \cdot \frac{\sqrt{3}}{2} \cdot L$$

iii. When not all three forces are either positive or negative, i.e. the position (x, y) can be derived as following:

If $F_{z_3} < 0, F_{z_1} > 0, F_{z_2} > 0 \; \square \; F_{z_3} > 0, F_{z_1} < 0, F_{z_2} < 0$,

then

$$x_t = \frac{F_{z3}}{F_{z1}+F_{z2}+F_{z3}} \cdot \frac{1}{2} \cdot L + \frac{F_{z1}}{F_{z1}+F_{z2}} \cdot \left(1 - \frac{F_{z3}}{F_{z1}+F_{z2}+F_{z3}}\right) \cdot L$$

$$y_t = \frac{F_{z1}}{F_{z1}+F_{z2}+F_{z3}} \cdot \frac{\sqrt{3}}{2} \cdot L$$

$$\begin{bmatrix} x - L \\ y \end{bmatrix} = R_1 \cdot \begin{bmatrix} x_t \\ y_t \end{bmatrix}$$

If $F_{z_2} < 0, F_{z_1} > 0, F_{z_3} > 0 \; \square \; F_{z_2} > 0, F_{z_1} < 0, F_{z_3} < 0$,

then

$$x_t = \frac{F_{z2}}{F_{z1}+F_{z2}+F_{z3}} \cdot \frac{1}{2} \cdot L + \frac{F_{z3}}{F_{z1}+F_{z3}} \cdot \left(1 - \frac{F_{z2}}{F_{z1}+F_{z2}+F_{z3}}\right) \cdot L$$

$$y_t = \frac{F_{z2}}{F_{z1}+F_{z2}+F_{z3}} \cdot \frac{\sqrt{3}}{2} \cdot L$$

$$\begin{bmatrix} x - \frac{1}{2}L \\ y \end{bmatrix} = R_2 \cdot \begin{bmatrix} x_t \\ y_t \end{bmatrix}$$

Therefore contact position in all cases can be determined from three sensors in z axis.

Abdominal Force Measurement Mechanism

Based on the requirements made in Section 2.1.3, a two-dimensional force measurement system was developed, which consisted of three rings and two sets of spring blades. To measure the movements of the rings, hall effect sensors and magnets were used. In Figure 7, it is showed that the rings are inter connected by spring blades in such a way the rings act as two parallelogram mechanisms. The outer ring is now fixed to the top plate of the training box while the inner ring can move freely parallel to the top plate. Movement of the inner ring perpendicular to the top plate is restricted. According to Figure 7-Right, two pairs of sensors and magnets were used to measure the displacement of the inner ring. The stiffness of the spring blades connecting the rings determines the working range of the sensor. Based on earlier experiments and the most efficient measurement range of the hall sensors, a maximum inner ring displacement of 2 mm was found sufficient when a force of 15 N is applied by a spring balance. After calibration, the sensors were able to measure forces between 0 to 15N parallel to the abdominal plane with an accuracy of 0.1N.

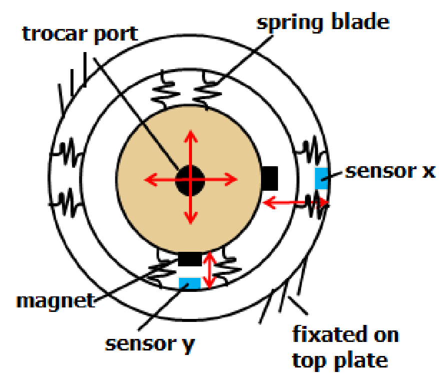


Figure 7 Abdominal force measurement mechanism

Indication of Instrument Motion

One of the main constraints on the instrument motion tracking system design for LESS-specific training is the limited space around and inside the trocar port. Considering the reality of the training, this work put a priority on the employment of real equipment used in surgery. Single port device are used in the trainer because it would be rather difficult to accurately simulate the port device from other models and materials. Once the real port device was used, it left no room for active tracking tools like TrEndo (Chmarra,2010). In other words, the limited space and the necessity to use real surgical device did not allow a gimbal mechanism through which the instruments were inserted and moved. Therefore other options are needed to track the instruments. Two options were found feasible.

<u>Option 1. passive tracking</u>

Contrary to active tracking, passive tracking methods relies on external detection of markers placed on the instrument. (Chmarra,2007). Commonly used passive tracking technologies include image detection, ultrasound and electromagnetic technology. Though passive tracking methods have been used for training and assessment purposes, all require extra laboratory settings (i.e. extra cameras, transducers, electromagnetic field generator, etc.). Also, the displacement of equipment such as cameras will disturb the analysis among subjects or among trails for the same subject. Therefore, Passive tracking methods require the use of extra equipment, which add additional cost to the whole system, and have high requirement on the algorithm and equipment in order to achieve desired robustness. Passive tracking was not found reliable enough to use with LESS.

Option 2. motion measurements at handle

Since there was limitation on the space in the distant part of the instrument that is in the box, it is possible to determine the motion of the tip or shaft of the instrument at instrument handle. For this purposes, mechanical arm has been developed in some systems (Figure 8). However, it is bulky in size, and will bring extra interference to the trainee since it is not easily ignored. The building process will also be considerably complex, and developing a mechanical arm was against the ideal solution of the creation of a portable and simple system.

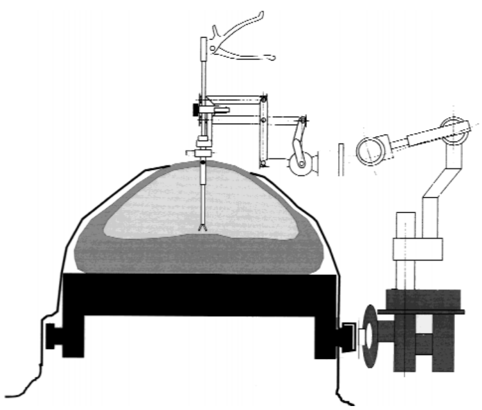


Figure 8 Mechanical tracking of translated motion with endoarm (Schurr, 1999)

As an alternative, small accelerometers can be used to measure the most important instrument motions. According to the definition, sensors attached to the instrument belong to the category of active tracking. As stated above, the ideal place for attachment would be on the instrument handle. The attachment should be in a less noticeable way and should not interfere with the instrument movements. This option was chosen for the prototype of the new hybrid trainer.

Based on acceleration data in three axes, tilt angles with respect to local earth horizontal plane can be calculated.

In Figure 9, accelerometer axes and handle axes are depicted, and it is assumed that the accelerometer axes in the same direction as the handle axes. Pitch angle is defined as the angle between the y axis and the horizontal plane, and the roll angle is defined as the angle between the x axis and the horizontal plane.

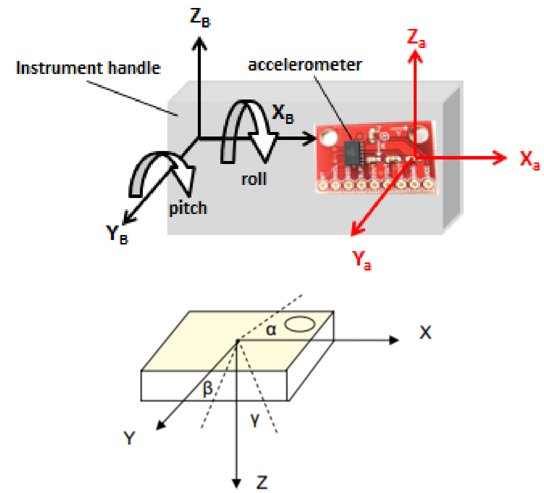


Figure 9 Tilt angle and local coordinates

Tilt angle can be calculated using basic trigonometric equation as follows:

$$\alpha = \arcsin\left(\frac{a_x}{g}\right)$$

$$\beta = \arcsin\left(\frac{a_y}{g}\right)$$

$$\gamma = \arccos\left(\frac{a_z}{g}\right)$$

2.1.5 Prototype

A prototype of the 2D abdominal force measurement mechanism was fabricated and built as a proof of principle. A few hardware modifications were made to the prototyped force platform in order to serve the purpose of training. Software program in MATLAB was written to realize the functions of measuring tissue manipulation force and detecting the position of contacting point with the force platform. Accelerometers were attached to both instrument handles; wires of the accelerometers were placed in a way that did not interfere with hand movement. Mathematical calculations, data acquisition and data processing were carried in MATLAB (R2012b 32 bit). For the dimensional design, SolidWorks (2012 64 bit) was used. Appendix X gives all the technical drawings of all parts of the prototype.

Abdominal force measurement mechanism

As described in Section 2.1.4, the abdominal force measurement mechanism is a 2D force measurement mechanism that consists of three circular rings and four spring blades. The advantage of this 2D mechanism is that the system is able to decouple the forces in two directions. Either two of the three rings are connected by a pair of leaf springs in the opposite side of one axis.

The material chosen for the rings is colored acrylic with high stiffness. The calculation of dimensions of rings is given in Appendix V. The three rings are laser cutted, because the design is two-dimensional, the cutting quality for acrylic is excellent and the laser cutting tolerance of +/- 0.15mm is acceptable with a dimension of ring up to 50mm.

Steel spring blades are used. Leaf springs are widely used for suspension applications. In this application, single steel leaf spring is used for its low cost and easy fabrication. It is suitable for low load forces (up to 15 N) and has reasonably linear working characteristics. The spring constant of leaf springs depends on its dimensions (length, width and thickness). The calculation of thickness is given in Appendix IV.

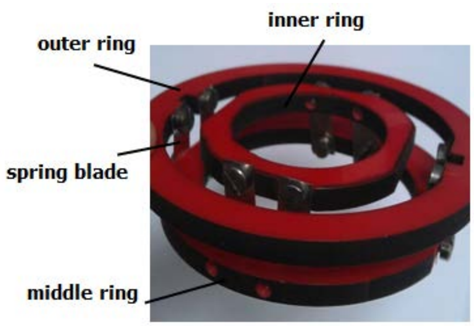


Figure 10 Prototype of abdominal force measurement mechanism

Data Acquisition System

A data acquisition system that consists of 17 analog inputs, two data acquisition boxes (LabJack U3-HV and NI-DAQ USB-6008) and two power sources was built. The two data acquisition boxes are connected to the computer so that the sensor signals are sampled and the result are converted to digital numeric values that can be display and manipulated by the computer. Figure 9 shows the connection of the data acquisition system and more details are given in Appendix II.

2.1.6 Calibration

Abdominal sensors

The goal of calibration is to identify the force-voltage relationship for each sensor. Each sensor is tested in two opposite directions (i.e. towards the magnet and away from the magnet). With the calibration data, the linearity of the sensor can be identified and the abdominal force exerted by the trocar on its surroundings in all directions can be accurately calculated. When the forces in all directions are calculated, the magnitude and direction of the absolute force exerted on the abdominal wall can be calculated using the theoretical model.

Figure 11 Prototype of hybrid trainer

The box trainer was placed on top of a horizontal plane, with extra slippery proof pads to increase static friction and prevent movement of the box trainer. A clamp was fixed on the table with the end of a spring gauge fixed on it. The other end of the spring gauge is hooked on the inner ring of the 2D force mechanism (Figure xx). A ruler was placed on top of the box trainer to keep the spring gauge align with the plane of the box trainer.

Before calibration, the measurement rings were fixated on the top board. The distance between hall effect sensor and magnet has been adjusted to be in the range of 3mm to 7mm based on sensitivity of the hall effect sensor and the stiffness of the spring blades. Force was applied by the spring balance, so that only pulling force was applied. By adjusting the orientation of the box trainer, the direction of the force with respect to the sensor was changed.

In each direction, the range of force in the force-voltage graph was determined between 0 and 10 N. The minimal step was 1N. For each step, 3 measurements were performed for 3 seconds by LABJACK stream software. The average value of each measurement step is calculated and stored in the computer.

All tests were repeated three times. During performing these tests, both sensors were turned on simultaneously.

ForceTRAP v2

The calibration of the X and Y axis of the force platform ForceTRAP v2 is similar to that of abdominal sensors. Spring gauge and clamp were used to apply a standardized force on the sensors. Each axis was tested in two opposite directions (i.e. positive and negative x- and y-axis) from 0 to 10 N with a step of 1N. The force was measured for three times during each step. Data was recorded with LABJACK stream software and the average force was calculated and stored.

For the Z axis calibration, two methods were used. Calibration of the negative z-axis (i.e. pulling) is accomplished with a spring gauge. First the center point was identified as the center point of the equilateral triangle formed by three sensors z_1, z_2 and z_3. Secondly, an adhesive plate was placed on the center point, and a spring gauge was attached to the plate. To keep the spring gauge on a vertical plane, a plumb line and the spring gauge are both clamped in order to establish a reference for vertical direction. Thirdly, the LABJACK stream also displayed the channel of X and Y, indicating if coupling effect occurs.

Calibration of positive z-axis (i.e. pressing) is done with standardized weights of 100g. During the calibration, the load on the platform was increased from 0 g to 1000 g with steps of 100g. Then the load on the platform was decreased from 1000g to 0g in steps of 100g.

The calibration data of all three sensors was recorded with LABJACK stream software.

Accelerometer

When working with accelerometers in the earth's gravitational field, there is always a gravity component as part of the signal. Therefore if the sensor is placed statically, the vector sum of 3-axis component should be equal to the earth's gravity. A simple way of identifying the relationship between signal value and acceleration value can be accomplished by directing each of the three axis of the sensor to the gravitational field. Then the output of the sensor is equal to 1g. According to this method, six stationary positions stated in Appendix VI are used for calibration.

Since the application does not require a tilt-measurement accuracy to be better than 1° when the handles are used, the zero-g level and sensitivity parameters from the datasheet are used to relate the signal output to handle acceleration.

2.2 Design of Experiment

In this section, the design of the experiment performed on the hybrid trainer is explained.

2.2.1 Hypotheses

To investigate the quantitative difference between CLS and LESS, three null hypotheses are proposed:

There isn't a significant difference in the maximum and average trocar force between LESS configuration and CLS configuration.

There isn't a significant difference in the maximum and average interaction force between LESS configuration and CLS configuration.

There isn't a significant difference in the maximum acceleration between LESS configuration and CLS configuration.

2.2.2 Participants

A total of 23 students, and 2 experts participated in the experiment. The students had no former systematic training in laparoscopy and lack real experience in the operating room. Experts included in the experiment are experienced surgeons in conventional laparoscopy and LESS. The order in which the CLS and LESS session were performed in the experiment was randomized for each participant.

2.2.3 Surgical Equipment

In the LESS configuration, the SILS^{TM} port (Covidien Surgical, Norwalk, CT) was used to introduce two instruments into the box. The SILS^{TM} port (Covidien Plc., Ireland) (Figure 1) is a flexible soft-foam port with an approximate shape of cylinder. It is a typical multi-channel device consists of three cannula access channels or lumens, one for the laparoscope and two for standard length 5-mm straight instruments. The required incision length for this device is about 20 mm. In conventional laparoscopic configuration, two standard 5-mm trocars (Endopath, Ethicon Johnson & Johnson) were used. In order to eliminate the influence different instrument have on the experimental results, one set of standard straight surgical graspers (Endopath, Ethicon, Johnson & Johnson) were used for both configurations.

2.2.4 Training Task

Task 1: Transfer and Position (figure 12).A 3d printed task board with pins on top was fixed on a platform inside the box trainer. To complete the task successfully, the subject needs to place three plastic tubes over three pins. The tubes are picked up with the left instrument, then transferred to the right instrument in open space, and finally placed on top of the target pins. This task was modified from validated transfer task in FLS (Fundamentals for Laparoscopic Surgery) box trainer, with an emphasis on precision, eye-hand coordination, dual-hand maneuverability and depth perception. Both time for completion and abdominal force were recorded.

Task 2: Tractive Force Task. The second task was based on WebSurg videos of LESS procedures and designed and validated in a previous study (Horeman, 2013). It consisted of a worm-like silicone string, a small ring and a pin. The ring, pin and one side of the silicone string were fixed on the task board. The ring and pin were partially hidden under a highly elastic silicone layer so as to mimic the blocked view by organs and connective tissue in real scenario. For successful completion, the silicone worm has to be navigated through a ring, and finally hooked on the pin with the hole on the other end of string. Cooperation between instruments in both hands is required at all times in this task. Figure 13 shows the task before and after it was completed. Both time and abdominal force were recorded. The applying force is lower than 4N, and thus comparable with the forces used in laparoscopic surgery (de Visser, 2002)

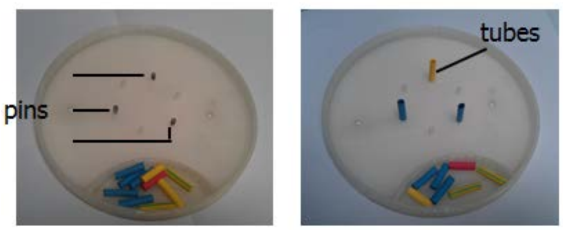


Figure 12 Task 1 grasp, transfer and placement on pin

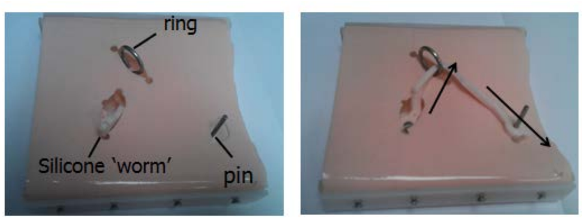


Figure 13 Task 2 grasp, transfer and placement on pin under tractive force

2.2.5 Protocol

The 25 participants were randomly assigned to two groups. The participant was informed of both configurations, and allowed to exercise with the instrument outside the box to get familiar with the usage of the instruments. In group 1, participants started with the CLS configuration for three trials, and then switched to the LESS configuration for the remaining three trials. Between the repetitions there was a short break of 2 minutes. After the first three trials, the participant was asked for finish a questionnaire concerning the frustration level of that configuration. In group 2, participants started with the LESS configuration. Ten subjects performed on task 1 while the remaining nine subject performed all measurements on task 2. The protocol is illustrated in Figure 14.

By dividing subjects into two groups with opposite order of configurations to be trained, the influence of the skills obtained with CLS on LESS and vice versa can be investigated. For each participant, there were two questionnaires (standard NASA Task Load Index) to be answered concerning the task load of the two different configurations.

Table 4 Differences in required skills of the two tasks of this study

demands	task 1	task 2
aiming	√	
precision	√	
hand-eye coordination	√	√
depth perception	√	√
visual-spatial perception	√	√
tactile/haptic feedback	√	√
touching objects	√	√
grasping objects	√	√
moving objects with traction		√
cutting objects		
transferring objects	√	
navigation		√
suturing		

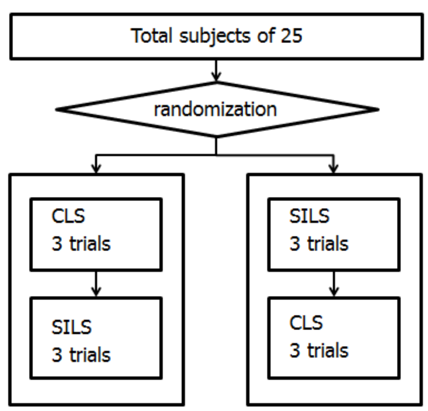


Figure 14 Experiment protocol

2.2.6 Data Analysis

Time and abdominal force were measured for all tasks in all configurations. The abdominal force was calculated based on forces measured by sensors in orthogonal directions and defined as the square roots of

Fx and Fy. The maximum absolute force was considered as the maximum value in the absolute force vector.

All data were processed and analyzed using MATLAB. The statistical differences between the performances in two configurations were calculated with the two-tailed paired t-test. The differences in work load between the two configurations were also summarized. A p-value less than 0.05 was taken to indicate a significant difference.

2.2.7 Metrics

Appendix VII gives an overview of previous defined metrics in literature and the tasks that shown significant difference between groups.

Tissue manipulation force metrics

Forces in three directions are denoted as Fx, Fy, Fz. the x,y,z axis of the force were defined relative to the pressure platform. Based on the three force data series, mean value and maximum value can be calculated. the absolute force value discard the small force values lower than the threshold. Based on the absolute force value, the mean can also be calculated.

Abdominal force-related metrics

The abdominal force F_L and F_R as obtained in the CLS configuration, represents the absolute abdominal force in left and right trocar; F_S as obtained in the LESS configuration, represents the absolute abdominal force in the single port. Similarly, mean force, mean absolute force, maximum force, peak force, and standard deviation can be calculated from the raw data of F_L, F_R and F_S.

Motion-related metrics

The acceleration from gravity allows measurement of tilt of the sensor by identifying which direction is 'down'. By filtering out the external acceleration, the orientation of a three-axis sensor can be calculated from the accelerations on the three accelerometer axes.

3 Results

In this section the calibration results of all sensors are presented. The results of experiment carried to compare CLS and LESS have been presented in the second part, divided in the maximum tissue manipulation force, maximum abdominal force and maximum acceleration in instrument handles, corresponding to the three hypotheses.

3.1 Calibration Results

Table 5 presents the regression equation and R^2 value for the fitted data of each sensor in the abdominal force measurement mechanism and the force platform. The sensor output together with regression lines are presented in Appendix VIII. From the calibration results, it is observed that some sensors are approximate with linear regression, while others are better approximate with second polynomial regression. A $R^2 > 0.99$ is required for all regression equations. Previous work (Wulms, 2013) has shown that non-linear relationship has been found in the hall effect sensors. However, due to the small distance (<4mm) established between the hall effect sensor and the magnet, linear relationship is found sufficient in those sensors, while the calibration of other sensors are sufficient with a second polynomial regression. This is in accordance with previous findings as well (Horeman, 2012). The difference between first and second calibration data was less than 1%.

Table 5 Regression lines and R^2 value of each sensor in each direction

	axis	linear regression line	R^2
left trocar	x	fx>0, y =0.0266x+0.0171	0.9982
		fx<0, y =0.0311x+0.0014	0.9992
	y	fy>0, y= -0.0009x^2 + 0.032x+0.011	0.9996
		fy<0, y= 0.0014x^2+0.0273x+0.0105	0.9989
right trocar	x	fx>0, y = 0.0238x + 0.0049	0.9983
		fx<0, y = 0.0368x - 0.0105	0.9994
	y	fy>0, y=-0.0011x^2+0.0369x+0.0091	0.9996
		fy<0, y = 0.0396x + 0.0021	0.999
single port	x	fx>0, y =0.0002x^2+0.006x+0.0033	0.996
		fx<0, y = 0.0064x - 0.0002	0.9974
	y	fy>0, y =0.0007x^2+0.0065x+0.0087	0.998
		fy<0, y=0.0017x^2+0.0023x+ 0.0102	0.9981
force plat -form	x	fx>0, y=-0.0005x^2+0.0227x- 0.0147	0.9936
		fx<0, y=-0.0003x^2+0.0216x-0.0145	0.9991
	y	fy>0, y=-0.0007x^2+0.0258x-0.0159	0.9994
		fy<0, y=-0.0003x^2+0.0218x-0.0125	0.9987
	z	fz>0, y= -0.0001x^2+0.0223x-0.0123	0.9978
		fz<0, y=0.0005x^2+0.0129x+0.0084	0.9987

The result of accelerometer calibration is shown in Table 6. A good linear regression is found in all axes in both accelerometers (R^2 >0.99), which is in uniform with the indication in the datasheet of MMA7361L.

Table 6 Regression lines and R^2 value of accelerometer in each axis

sensor	linear relationship	R^2
left	ax1 = (x1-1.22956)/0.4595;	0.9941
	ay1 = (y1-1.22631)/0.4585;	0.9991
	az1 = (z1-1.23254)/0.4567;	0.9929
right	ax2 = (x2-1.137911)/0.4497;	0.9955
	ay2 = (y2-1.233991)/0.4566;	0.9998
	az2 = (z2-1.147913)/0.4424;	0.9965

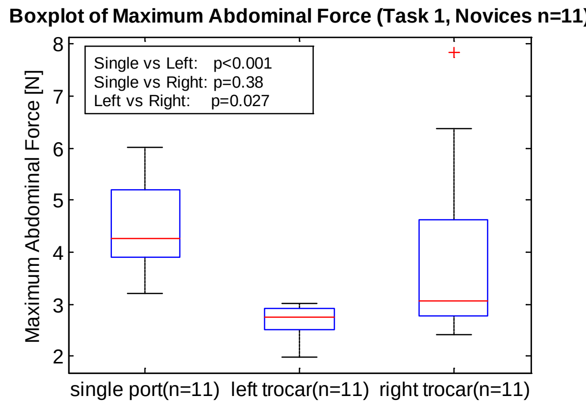
3.2 Experiment Results

In this study, data was collected on 24 participants (22 novices, 2 experts) performing two tasks (each task in two configurations) with a hybrid box trainer. Eleven novices and one expert performed task 1, whereas eleven novices and both experts performed task 2. The starting order of configuration was randomized. Appendix XI shows the results of time, maximum abdominal force and maximum tissue manipulation force divided over both tasks and starting order. Task load preference (lower task load) is also showed for each participant. Of the 24 participants (22 novices and 2 experts), only one student reported a lower task load for the LESS configuration when starting with the CLS configuration followed by the LESS configuration. Overall, the participants reported a lower task load for the CLS session.

Maximum Abdominal Force

The distribution of maximum abdominal force applied by the novices in the left, right and single trocar site in task 1 and task 2 and the p-values are represented by box plots in Figure 15. The novices in task 1 applied an average maximum abdominal force of 2.7 N (SD=0.3) at the left trocar site, 4.0 N (SD=1.7) at the right trocar site in the CLS session, and 4.5 N (SD=0.8) at the single port site in the LESS session. In task 2, the novices applied relatively higher maximum abdominal forces at all three trocar sites: 3.3 N (SD=0.8) and 5.8 N (SD=2.1) at the left and right trocar site respectively and 8.4 N (SD=2.0) at the single port site. In both tasks, maximum abdominal force applied in left trocar is much less widely distributed than the others, which implies a general lack of excessive use in left hand instrument. By contrast, maximum abdominal force applied in the right trocar is highly scattered, suggesting its high dependence on the subject's strategy to finish the task.

When comparing the maximum abdominal forces in task 1 regardless of the starting order, it is significantly higher at the single port site in the LESS session than that at the left trocar site in the CLS session (p<0.001). Between single port site and right trocar site no significant difference is found (p = 0.38). From the results of task 2 a significant difference is found between the maximum abdominal force in the LESS session and CLS session (left: p<0.001; right: p=0.007). There is no significant difference between the task time of the CLS session and LESS session in both tasks (task 1: p=0.87; task2: p=0.07).



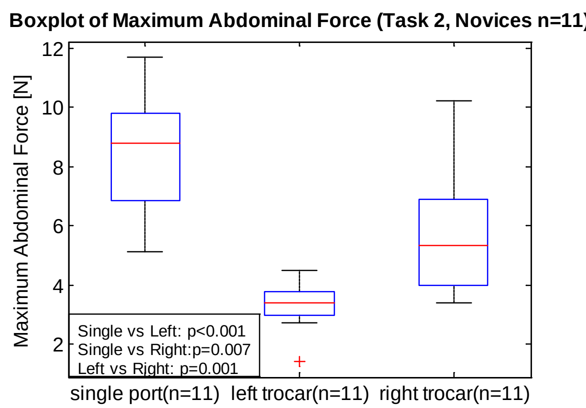


Figure 15 Distribution of maximum abdominal force applied in left, right and single trocar (top: task 1, novices, n=11; bottom: task 2, novices, n=11)

In task 1, the maximum abdominal force applied in the LESS session is noticeably higher compared with the CLS session when starting with the CLS session (left: p<0.001; right: p=0.006). This is not the case in the group starting with the LESS session in task 1 where no significant difference is found between the right trocar site and single port site (p=0.72). In task 2, significant differences are found between the left/right trocar site and single port site in both starting orders, though the p-values are slightly below 0.05.

To understand the influence of the order in which a technique is learned on the abdominal force, the force data in both starting orders are combined and averaged for each order (Figure 16). In task 1, when participants start with LESS session, they seem to apply more widely distributed and higher maximum abdominal force in the right trocar site in CLS configuration than those start with CLS order (p=0.06), though not significant. When starting with CLS session, the influence of starting order on maximum abdominal force applied in LESS configuration is less obvious compared to that in the converse order (Single 1 vs Single 2: p=0.66). This is also similar with task 2, except that the influence of starting with CLS on the maximum abdominal force applied in LESS configuration is more obvious; which is to say, after practicing in CLS, the participants applied a more narrowly distributed and less maximum abdominal force in the single port site. Nevertheless, the influence of starting order on maximum abdominal forces applied in all three trocar forces is not significant in both tasks.

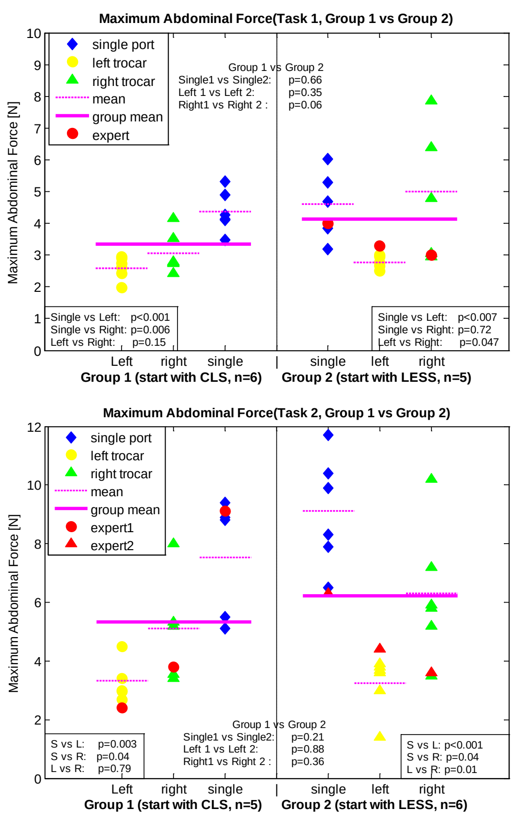


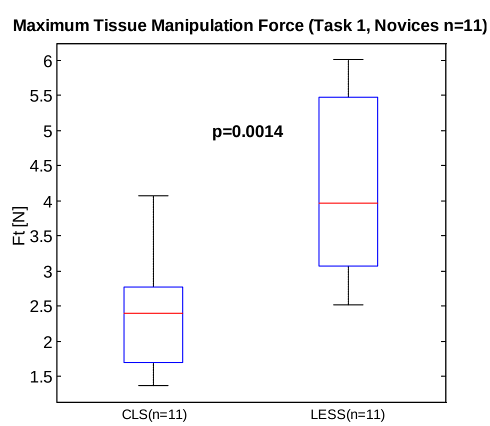
Figure 16 Influence of starting order on maximum abdominal force applied in left, right and single trocar sites (top: task 1, group 1,n=6, group2, n=5; bottom: task 2, group 1, n=5, group 2, n=6)

Tissue Manipulation Force

In CLS session in task 1, a mean tissue manipulation force of 2.4 N (SD=0.9) was applied. In LESS session, this is 4.0 N (SD=1.3). When practicing task 2, a relative high mean tissue manipulation force of 5.6 (SD=1.3) and 10.4(SD=3.6) were applied in CLS and LESS respectively. Significant difference can be found between the results of CLS and LESS sessions in both tasks (task 1, p<0.01; task 2, p<0.01). Figure 17 shows the boxplot of tissue manipulation force in task 1 and task 2.

In task 1, when started with CLS configuration, the maximum tissue manipulation force reaches 1.8 N (SD=0.4) in CLS session and 3.8 N (SD=1.3) in LESS session, where the difference is significant (p<0.01). When started with LESS configuration, this is 3.0 N (SD=0.8) for CLS and 4.3 N (SD=1.4) for LESS session, however, the difference is not significant (p=0.07). In task 2, when started with CLS configuration, the average maximum tissue manipulation force applied in CLS session is 4.5 N (SD=2.0) whereas in LESS session is 8.6 N (SD=4.0),where the difference is not significant in either cases.

The influences of starting order on maximum tissue manipulation force applied in tasks are presented in Figure 18. In task 1, the maximum tissue manipulation forces applied in LESS configuration are similar (p=0.49) in both starting orders; when started with LESS configuration, the maximum tissue manipulation force applied in CLS configuration appears higher than that started with CLS configuration (p=0.01). In task 2, forces in the same configuration are not significant difference with both starting orders (CLS: p =0.1, LESS: p=0.6). However, a small trend can be found in both tasks that maximum tissue manipulation force applied in LESS session is decreased after CLS session, whereas the force applied in CLS session is increased after LESS session.



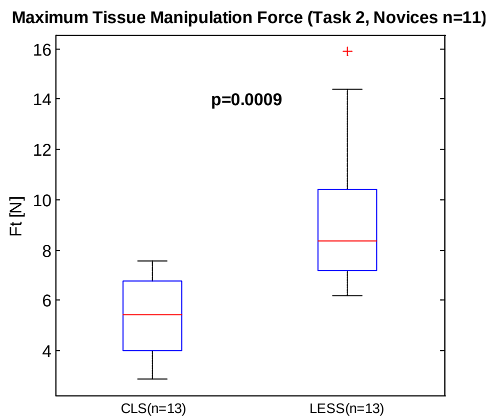


Figure 17 Boxplots of maximum tissue manipulation force in both CLS and LESS configurations in task 1 and task 2

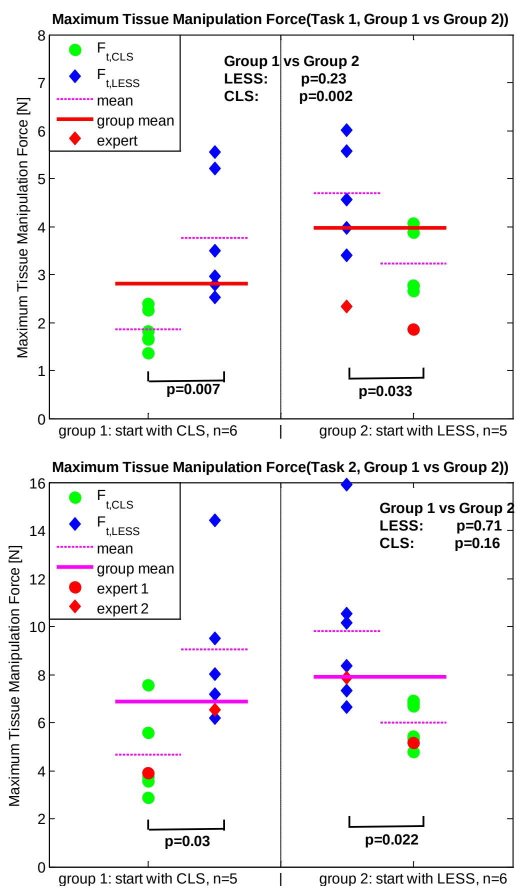


Figure 18 Boxplot of maximal tissue manipulation force task 1 and task 2

Motion

The maximum acceleration of the left and right handle is compared between CLS and LESS for task 2 (Figure 19). A significant difference between CLS and LESS is found in the maximum acceleration of the left handle ($p<0.01$), but not on the right handle LESS ($p=0.48$).

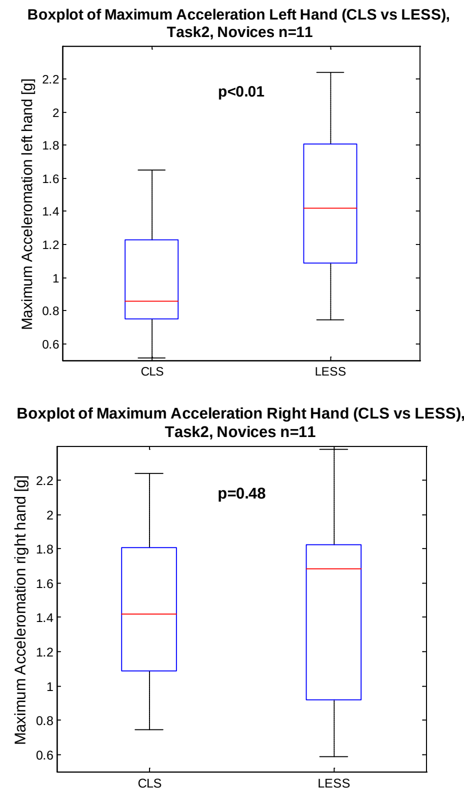


Figure 19 Boxplot of maximum acceleration of left and right handle

4 Discussion

The first goal of this thesis was to develop a hybrid box trainer for training and quantitative measuring of technical skills in laparoendoscopic single site surgery. A hybrid box trainer has been developed with measurement systems that can record instrument motions and the forces exerted on the training task and abdominal wall in both CLS and LESS configurations. The forces exerted by the instruments on the task are measured with a custom three-axis force platform under the task and the forces that are exerted on the abdominal wall are measured with custom two-axis force measurement mechanism. Instrument motion is measured with acceleration sensors fixated in the handle of the instruments. In addition, a user interface is built to start and stop the measurements, to visualize the forces exerted on the force platform and to provide feedback to the subjects after each performance.

The second goal was to find time, force-related parameters and motion-related parameters that reflect the most important differences in tissue handling and instrument motions based on the developed sensory systems. Metrics based on three measurements are developed. A comparison between expert and novices in Appendix XII suggesting that mean absolute force, maximum force, peak force, contact position, mean absolute acceleration, maximum acceleration, range of tilt angle in 3-axis, rate of change of tilt angle in 3-axis might be interesting for future research. Future studies involve more experts in LESS is needed for validation of the newly defined metrics based on tissue manipulation force, abdominal force and acceleration.

The third goal was to identify differences between CLS and LESS based on tissue manipulation force, abdominal force and instrument motion. Experiments involve 22 novices performing two tasks in random starting order (either start with CLS or LESS) have been conducted. The results indicate a quantitative difference between CLS and LESS in force parameters and instrument acceleration. The results also suggest that starting order and type of task have an influence on certain parameters.

Figure 16 indicates that the starting order in which the different instrument configurations are mastered does not necessarily influence the abdominal force at the trocar sites in this crossover study. In task 1, the maximum abdominal force applied in the left and single trocar sites are not affected much by the different starting order (left: $p=0.88$, single: $p=0.21$). In the right trocar, however, a mean difference in maximal trocar force of 1.7 N was found (group 1: 3N (0.6), group 2: 4.7N (2.1)), thought the difference is not significant ($p=0.06$). This may be due to a relatively small *n* in the two groups (5 and 6 each). The result may suggest that when practicing an aiming and precision task (task 1) with LESS configuration first, participants are tending to use right hand instrument more often and less delicately in the following CLS session.

Similar to that in task 1, the starting order in task 2 does not influence the abdominal force at the trocar sites (Figure 16). From the significant difference on maximum abdominal force applied between CLS and LESS session, it is determined that the instrument configuration itself highly influences the abdominal force in a task that involves constant tractive force on the instrument.

Although the results indicate that the average maximum abdominal force applied in the LESS session is significantly higher ($p<0.001$) than that applied in the CLS session in task 2, this is not the case for task 1. One reason can be that task 1 mainly requires accurate position control during the grasping motions and basic movement of the instruments with minimal contact between the tip and the task board. In task 2, however, force control plays an important role since one instrument is constantly under tractive force while the other is used for support and guidance of the silicon-worm. Therefore, this study shows that if straight instruments in a LESS configuration are used for a (surgical) task that require collaboration between two instruments under traction, the force exerted by the trocar on the abdominal wall increases.

Prior work have documented that the average level of maximum tissue manipulation force applied in CLS session is in about 6 N and in LESS session is about 9 N (Horeman, 2012). The experiment results in task 2 suggest a similar range of maximum tissue manipulation force as in prior work. Moreover, the study of Horeman et all found an increased maximum tissue manipulation force in the CLS session after first practicing LESS and a decrease in maximum tissue manipulation force after first practicing CLS (Horeman, 2012). This is similar to the results found in this study. However, due to the difference itself nature of task 1, the experiment results are different from that of Horeman, et al., meaning that tissue manipulation force is in a much lower range.

The possible causes for high tissue manipulation force occur in task 1 can be: hitting due to interference between instruments or lack of tactical feedback for depth; unnecessary pressure against the task board; and confirming the right position of target pins. Similar causes like hitting and unnecessary pressure also cause high tissue manipulation force found in task 2, but the most frequent occurred is caused by the excessive tractive force applied by the novice. This may imply that novices pay too little attention to, or tend to be unaware of the force applied to task/tissue, which potentially lead to unexpected tissue damage during operation.

In the experiments, the position an instrument has contact with the force platform is determined with three sensors in the z-axis, and the acceleration is measured in the handle. However, the accurate motion tracking of the whole instrument is not realized. In cases that there are two instruments in contact with the force platform at the same time and accurate position tracking is desired, the hybrid trainer needs a more accurate motion tracking system such as a mechanical arm or image detection. The question remains if accurate position tracking is necessary or that acceleration information contain enough information about instrument handling skills. It is shown in this study that the maximum acceleration parameter results indicate a significant difference on the left hand comparison between CLS and LESS in favor of the CLS configuration. Further studies should indicate whether a learning curve is present in instrument acceleration during training with LESS. If so, this motion parameter can be used to identify instrument manipulation skills as compliment to parameters such as path length and motion smoothness.

In this study, straight instruments and a $SILS^{TM}$ single port device were used. However, besides standard straight instruments, pre-curved and articulated instruments are now commercially available to overcome the limited range of motion encountered in LESS. Also, besides $SILS^{TM}$ port, different types of multi-channel single port devices are promoted by manufacturers. Further studies are needed to investigate if the type of instrument or the type of single port device will influence the experiment results. Nevertheless, the choice of instrument and single port device often depends on each surgeon's preference. Although all manufacturers claim that their set of instruments is better than others, more research with the newly developed hybrid box trainer is required to indicate if risks occur due to high forces on the abdominal wall or tissues. Moreover, forces exerted by the instruments on the patient are generated by the surgeon's arms. Especially in combination with larger instruments and difficult arm positions common in laparoendoscopic single-site surgery, studies should also focus on the ergonomics of the operating surgeon.

Among previous studies comparing task performance of LESS with that of CLS in laboratory settings, most studies (Botden, 2011, Cox, 2011, Santos, 2011, Fransen, 2012, Miernik, 2012) use only task time and task error as performance measures. The logical deduction behind these studies is that one approach is more (not more) technical challenging if it requires significant (not significant) longer time to finish the same task than the other. However, the specific skills that differentiate the two approaches remain unknown. Recent comparative studies have started to use motion tracking devices such as ICSAD (Kwasnicki, 2013) and ProMIS (Alevizos, 2012) that can be used for both CLS and LESS configurations, with the metrics of path length and motion smoothness defined in each system. Research on force/torque parameters has been focused on laparoscopy (Richards, 2000, Rosen, 2003) but is scare in comparative studies. The findings in this study suggest that better performance in task time are not necessarily guarantee better performance in force-related parameters such as mean and max abdominal force and tissue manipulation force. This study suggests that force has a clinical implication cannot be provided or replaced by total time. Since force is also not predictable from observation, error detected by proctor also cannot reflect the possibility of excessive force applied.

The development of this hybrid trainer equipped with force platform and motion indicators is clinically relevant, especially for the purpose of providing (real time) objective feedback to the trainees during surgical training. This helps to minimize the required training effort to improve patient safety (Horeman, 2012). Moreover, since the research in forces during CLS and LESS are scarce, this work helps to contribute to this field.

For the future application of objective assessment, more data is needed from both LESS experts and novices so as to test the hypothesis that metrics developed is able to distinguish between subjects with different level of LESS skills. Then a classifier can be used to establish a threshold for sufficient performance. In this study, the lack of expert's data is an obstacle. Nonetheless, the data acquired in the experiments of this study can be expended in future research.

5 Conclusion

In this thesis, a hybrid box trainer that can measure tissue manipulation force, abdominal force and acceleration of instrument handle was built. The results indicate that difference between LESS and CLS can be quantitatively measured with regards to tissue manipulation force, abdominal force and acceleration of instrument handling. Three hypotheses are tested, which indicate that there is a significant difference in the maximum tissue manipulation force and abdominal force between LESS configuration and CLS configuration. This work may be a first step towards the validation of force-based LESS-specific training.

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