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Defining parameters for objective assessment of technical skills in a transanal purse string suture

Master thesis

TU Delft

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Defining parameters for objective assessment of technical skills in a transanal purse string suture

By

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Summary

Total Mesorectal Excision is the recommended curative surgical treatment for most cases of rectal cancer that exceed multiple layers of the bowel. For some cases a laparoscopic approach is difficult to perform. In cases of highly obese patients, or a specifically distal laying tumor. The tumor is then difficult to reach because of the funneling shape of the pelvis. This creates difficulties for the surgeon resulting for higher risk of damaging nerves and surrounding organs. For these cases a transanal approach is introduced where part of the procedure is performed using Transanal Minimally Invasive Surgery: Transanal Total Mesorectal Excision (TaTME). A key step in TaTME is the transanal purse string suture which is used to close the distal stump of the rectum before starting full thickness incision. When the suture is not performed correctly it creates a risk of contamination of bowel fluids into the abdominal cavity. Currently training of the procedure is done through proctoring and a two-day introductory course with OR-observation and cadaveric training. No box trainers that allow objective assessment of skills are currently available for this specific task. This goal of this thesis is to find parameters that might contain construct validity for expertise for a transanal purse string suture.

Several force-based parameters are selected for analysis. To obtain the goal a novel measurement system is designed according to a set of requirements. The system measures forces exerted on the entrance port for the instruments as well as tissue interaction forces. A pilot study is done after which improvements in the device and test protocol are implemented. Last a construct validity study is performed at VU medical center in Amsterdam.

Two groups participated in the study: novice (n=7) and experts (n=3). Expertise was determined using a questionnaire at the beginning of testing. Less than ten purse string sutures performed are considered novice, more than 50 are considered expert for this study. Promising results are found for tissue interaction forces. Novices apply higher and longer peaks of force. This correlates to observed difficulties in positioning the needle correctly before incision. Experts create a smooth motion by interchanging the needle between instruments. Interesting results are obtained for portal forces along the long axis of the port, in other words box in- and outward. It is seen that the resultant force shifts from a mostly pulling force for novice to a pushing force for experts. This can be a sign of incorrect instruments handling and must be researched further for its function as a parameter for objective skill assessment. Furthermore, internal moments about x-axis and y-axis show interesting results. Where the moment about the y follows a clear sinusoid for both novices and experts, this is not the case for the moment about the x-axis. It is very likely that this is due to the interference of the scope. Significant differences are found for Mx.min, Mx.mean, and Mx.pos. It is suggested that the moment about the x-axis can also be a good indicator for instrument handling skills

The novel measurement system designed for this study can be used to give insight in instrument handling behavior when performing a transanal purse string suture. It has the unique feature to assess internal moments in a single-port setting, which is not applied in skill assessment in laparoscopy yet.

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– The most important relationship during your thesis is with ~~yourself~~ your work spouse –

1. Introduction

1.1. Rectal cancer

The human bowel system consists of multiple parts with various functions. The rectum is the last 10 to 15 centimeters of the large intestine and stand in direct connection with the anus. The rectum acts as a storage site for feces before defecation. According to the Integraal Kankercentrum Nederland the incidence of rectal carcinoma in the Netherlands in 2016 was 4027 (preliminary number), which is about one third of colorectal related cancer cases. Colorectal cancer being one of the three leading causes of death (WHO, 2018) in the US, shows that this number should cause great concern regarding rectal cancer.

1.2. Treatment

Along with radiotherapy and chemotherapy the Total Mesorectal Excision (TME), first described by R. Heald in 1982, has long been the main treatment for curative treatment for some stage I and most stage II and III rectal cancer.[1,2] Heald first linked the influence of the mesorectum to cancer recurrence. Ever since it has been the golden standard for curative treatment of rectal cancer. As seen in Figure 1 the rectum is surrounded by a layer of tissue all around, this tissue is called the mesorectum and holds blood vessels and lymph nodes. When the cancer has grown through the layers of the rectum, and into the mesorectum the TME is a necessary step to take in order to collect all surrounding lymph nodes.

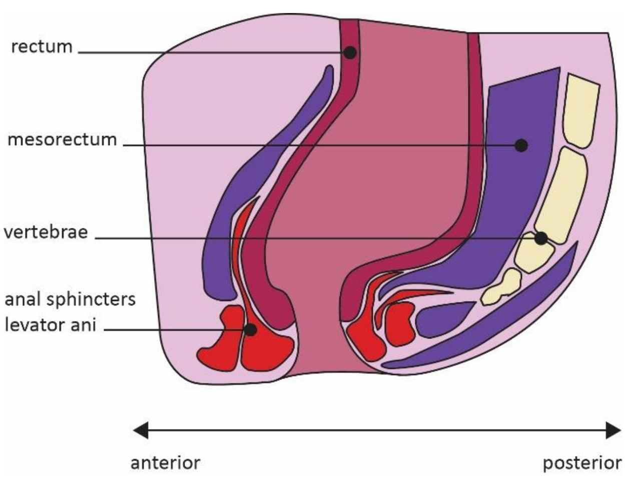


Figure 1 Simplified schematic representation of section of human pelvic area.

As stated before, in TME the complete rectum and surrounding mesorectum is collected. This has long been done laparoscopically, through multiple incisions in the abdomen. However, this approach has its limitations in some situations. Firstly, obesity causes significant challenges in all types of laparoscopic surgery regarding workspace and operating time.[3] Also the location of the carcinoma adds to the level of difficulty in a laparoscopic approach. When the cancer is situated more distally (lower, closer to the anal canal) it becomes more difficult to reach due to the funneling shape of the pelvis.[4] For these reasons a novel method for TME has been introduced. TaTME is a hybrid approach with both an ‘abdominal’ and a ‘transanal’ surgical team (Figure 2). Transanal procedures like Transanal Endoscopic Microsurgery (TEM) and Transanal Minimally Invasive surgery (TAMIS) have before only been used for less invasive surgeries like polyp removal (Stage 0 cancers).[5,6] TaTME aims to broaden the scope of transanal surgery. As the name implies, the rectum is approached via the anus using a specially developed port, GelPoint Path transanal access platform (Applied Medical, Rancha Margarita, CA, USA). This port makes the procedure comparable to single site laparoscopic surgery.[7] The rationale is that when the more distal carcinoma is approached transanally it is easier for the surgeon to preserve surrounding tissue. A step by step description of the procedure can be found in Appendix B. The procedure is currently in clinical trial, and preliminary results shows that the hybrid approach does not have compromising results, nor a better clinical outcome, compared to the full laparoscopic approach.[8–11]

Figure 2 Trans-anal approach in TME. At the bottom the trans-anal team is seen working using the GelPoint Path. Above the entrance points for the abdominal team are visible. The screen shows the view from the transanal laparoscope. (www.rectalcancersurgery.eu)

1.3. Crucial steps in TaTME

Observation during surgery and wet lab training (Appendix C) and conversation with Dr. J. Tuynman gave insight in the challenges for this procedure. Two aspects of the procedure stand out. Because of the bottom-up approach, the surgeon as a different view on the anatomical planes and landmarks involved in this surgery.[12] This can cause for even the more experienced laparoscopic surgeon to ‘get lost’ during the procedure. This creates the risk of dissecting too much tissue. This can result in damage to the prostate or uterus, surrounding nerve bundles, blood vessels or levator ani muscle.[13]

Then there is the purse string suture (hence referred to as ‘the suture’), which is applied in different stages of the procedure. The suture strings the suture thread 360° around the bowel after which it is tightened. The suture can be compared to the thread in an old fashioned simple rucksack (Figure 3), hence the name.

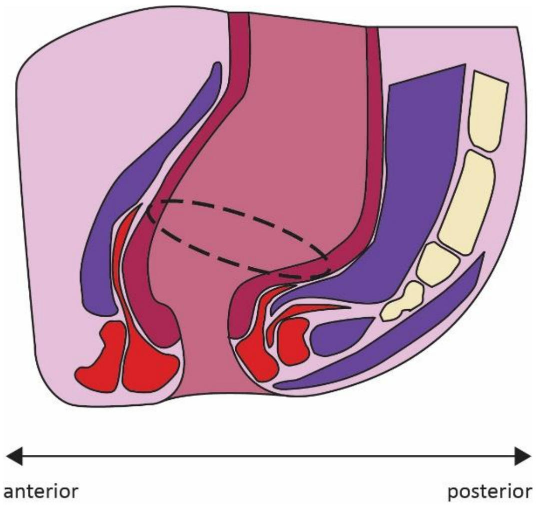
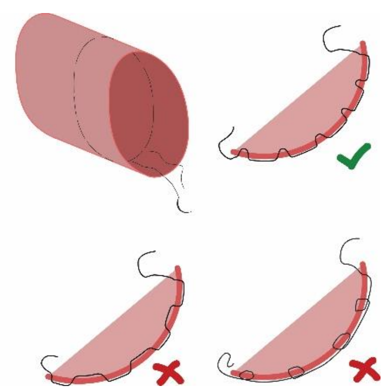


Figure 3 Left: section view of the rectum with a purse string suture. Right: analogy with a stringed backpack.

A crucial use of the suture is during the beginning of the transanal phase of the procedure. The suture is used to tie the rectum distally of the cancer, about 3cm above the anal canal. When the suture is tied, and the internal stump is rinsed with iodine the resection can be started. If the suture is not placed and executed correctly there is a risk of contaminating the abdominal cavity with bowel content. Correct execution of the suture means about 10 to 15 stitches, and little tilting as seen in Figure 4.[14]



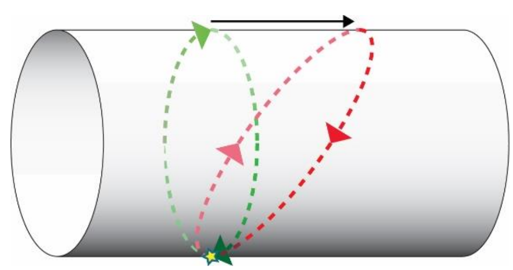


Figure 4 Left: correct execution of the purse string suture. Right: (wrongly) tilting of the suture.

Because of the ‘single port’ approach, the 360° workaround, narrow working space, and the necessity for correct execution this suture can be challenging even for experienced laparoscopic surgeons.

1.4. Education and assessment

The procedure is taught only to surgeons that are already specialist in a field of laparoscopic surgery. Through proctoring in own hospital, the specialists are prepared to pick up the procedure themselves. The first encounter with the procedure often is the TaTME course. This course is designed to give a first introduction to the procedure, teach what is needed for proper implementation and focusses on pitfalls. It consists of lectures, observation in the OR and interactive wet-lab training where the entire (transanal part) of the procedure is performed on cadavers in duo's. The participants are judged; however, the course is mostly designed as an introduction opposed to (skill) training. Although the risks of the procedure and the need for proper training is known, current education is mostly done in a clinical setting.[15] Besides that, the small bit of cadaveric training that is done consists of little strict and still subjective assessment.[16,17]

An extensive literature study showed that training on box trainers is done extensively for general laparoscopy and mostly for simple tasks.[18] There is a gap when it comes to more procedural tasks or specific types of surgery, like a single port approach. Horeman et al. previously discussed the importance of tissue interaction forces in laparoscopic skill assessment.[19] Furthermore, Rodrigues et al. showed that forces on the abdominal wall differ significantly in single port surgery compared to multiport laparoscopic surgery.[20] Furthermore, metrics for objective assessment of skills has been previously researched again this is not done for this type of (single port) procedure.[18] The attempt to fill this gap brings the goal of this study.

1.5. Research question and study objective

For this study it has been chosen to focus on the transanal purse string suture in a scope of objective skill assessment. Which gives the following research question:

What are **potential parameters**

for the **objective assessment** of skills

in a **transanal purse string suture**?

While a wide variety of metrics have potential value (Appendix D) it is decided to focus on forces applied when performing this suture. First the tissue interaction forces will be researched. Second the forces and moments of the port will be studied since this is a novel measurement site in this field of research.

To examine this first a setup will be build that is able to measure forces in all three directions in the access port, as well as tissue interaction forces applied when suturing. After which a construct validity study will be done. Here novice and experts in the field of transanal purse string sutures will be partake in a study to determine if the proposed metrics show construct validity for expertise.

2. Design

2.1. Requirements

Functionality

The system should allow for the application of multiple transanal purse string sutures before needing to change the specimen practiced on. The system should provide measurements of forces applied on the access port as well as tissue interaction forces, collecting data onto a laptop. With this data the proposed parameters for assessment can be calculated (Chapter 3 – Parameters). Force measurements in the port must be at least up to 15N. This threshold is set according to previous research on forces on the abdominal forces in single port laparoscopic surgery.[21] Furthermore, the system should allow for video recording for subjective data analysis.

Use environment

The setup needs to be used in a dry-lab environment. This way, when further developed as box trainer, the setup can be used outside of hospital and at home. The specimen should therefore be chosen adequately. Also, the system must be an addition to the LapStar box trainer (Camtronics, Son (Eindhoven), NL). This box trainer is currently used for laparoscopic skills training and research at VUmc.

Realism

The GelPoint Path access port must be used. Also, the specimen needs to be insufflated. This is needed to create space in the lumen, and if the specimen is not insufflated the material will flutter and this will diminish the ability to perform a proper purse string suture. Clamping and stretching the specimen will not be sufficient, since this will interfere with the tissue interaction force measurements. Furthermore a 30° laparoscope must be used.

Usability

The specimen should be easily interchangeable in between runs. The design should be lightweight since the LapStar box trainer is designed as a portable take-home training system.

Table 1 Summary of design requirements

Criteria	Specific requirements
Functionality	Multiple purse string sutures per specimen Force measurements (x, y and z) in anal port up to 15N Tissue interaction force measurements Video recording
Use environment	Addition to LapStar box trainer Use in dry-lab
Realism	Application of GelPoint Path transanal access platform Allow insufflation of lumen Use of 30° laparoscope High fidelity specimen
Usability	Easy attachment and detachment of bowel specimen Light weight

2.2. General idea

The LapStar box trainer (Figure 5 Left) will be adjusted to allow access from the front of the box. According a predetermined coordinate system mapped to the patient (Figure 5 Right) a suspension for a dummy bowel (Lifelike Biotissue, London, ON, Canada) will be designed (Figure 6). In this suspension force measurements are done in the port site (Figure 6, left, A). To be able to measure these forces a novel system must be developed. This system will allow for motion of the port in 5 degrees of freedom (DOF): translation in x, y and z, and rotation about x and y (Figure 6 right). Tissue interaction forces will be measured at the back (Figure 6 left, B). To measure tissue interaction forces the ForceTrap (Medishield, Delft, NL) device is used. A rigid connection to the hookup point must therefore be designed.

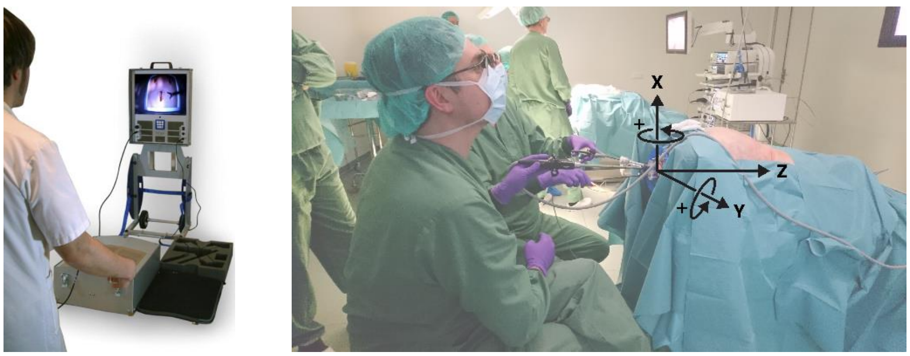


Figure 5 Left: LapStar box trainer
Right: Chosen coordinate system mapped on the patient

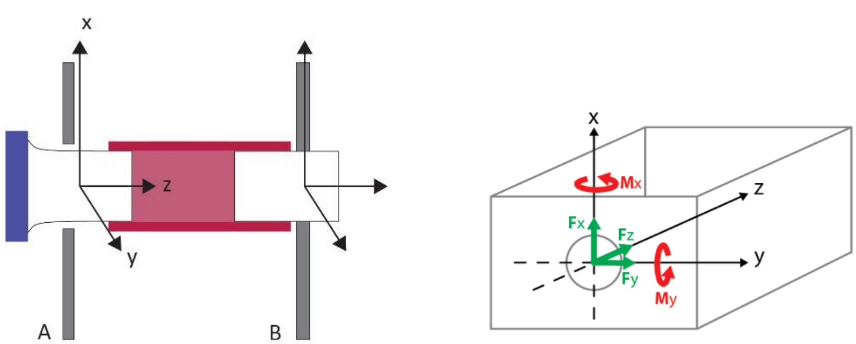


Figure 6 Left: Suspension of the dummy bowel and the two locations of measurements
Right: Coordinate system and measured parameters in the port in the trainer configuration

2.3. Measurement system access port

Conceptual design

For measurements at the port site it is decided to combine two existing and previously validated systems. First is the single port measurement system (Figure 7, Left) as part of a graduation project of Siyu Sun in 2013.[22] This project compared in plane forces exerted in abdominal wall for multiport and single port surgery. It consists of two rings that move separately from each other in-plane. Deflection is measured using hall effect sensors and magnets.

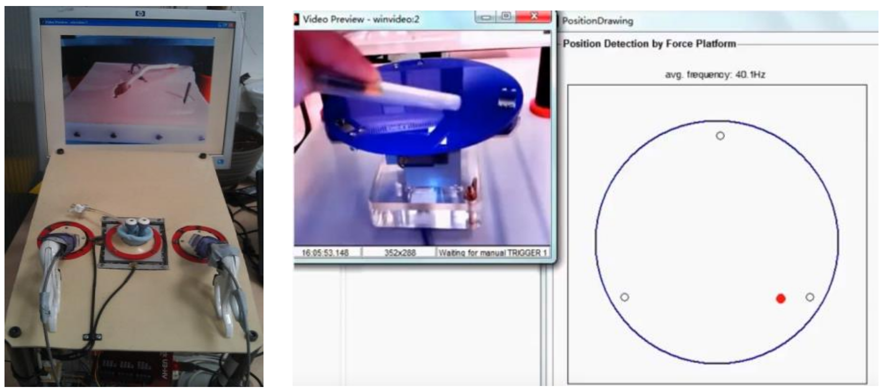
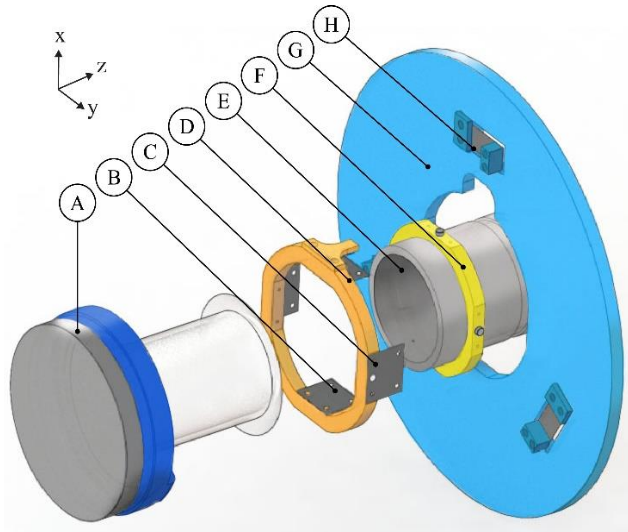


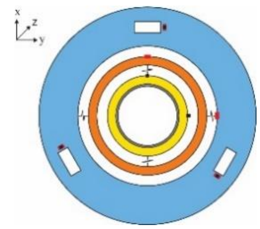
Figure 7 Left: System for measurement of abdominal forces (Horeman et al. 2015)
Right: Force-location platform
(screenshot Youtube, https://www.youtube.com/watch?v=N63hWAyqAbA)

For force measurements inward and out of the port, a force-location platform from the same study is taken as a starting point (Figure 7, right). A plate with three in plane blade springs gives freedom of motion in one direction. The system creates the opportunity to measure an exerted force perpendicular to the plate, and because of the triangulation of the sensors it will be possible to determine moments about the x and y axis of the port. Combining these two systems creates motion in 5 degrees of freedom (DOF) of the port: translation along x, y and z, and rotation about x and y (Figure 7, right).

The starting point of the port is the GelPoint Path anal access port (Figure 8, A). The port is rigidly fixated into a tube to create direct transfer of forces (Figure 8, CDG). This setup creates the ability of translational motion in two degrees of freedom along x and y (Figure 9, AB).

The other 3DOF (translation along the z-axis, and rotation about x and y) are created by a triangulated blade spring construction on the base plate (Figure 8, GH). This base plate is mounted to the interior of the LapStar. The GelPoint Path will exit at the front of the box.





A GelPoint Path anal access port
B Springs motion x-direction
C Springs motion y-direction
D Ring motion y-direction
E Fixation tube for GelPoint Path
F Ring motion x-direction
G Plate motion z-direction
H Springs motion z-direction

Figure 8 Main components of the port measurements system.

The rings and base plate are equipped with hall effect sensors model SS495A (Honeywell, Fresport, USA) and magnets (D=3mm, thickness 2mm). Hall effect sensors have the property to change voltage output according to the magnetic field they are positioned in. As the magnetic field around a magnet changes when getting closer to the pole, this phenomenon is used in this construction. As seen in Figure 9 the spring blades allow one direction of motion per sensor (red block). The relationship between distance to the magnet and voltage output is not linear. Therefore, calibration to the exerted force and voltage output is necessary, see Chapter 4 - Calibration.

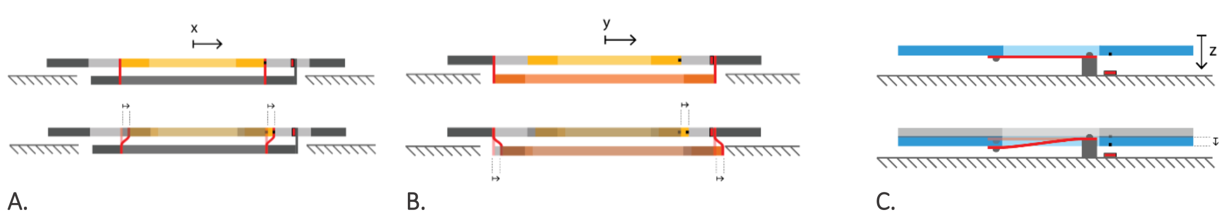


Figure 9 Motion allowed by spring blades for x and y configuration (A, B) and z-direction (C).

Materialization

It is chosen to use mostly aluminum for production of the parts, because of its lightweight characteristics. Most fabrication is done at DEMO, TU Delft. Post-processing such as tapping is done manually at the 3mE workshop. A summary of the production is seen in Table 2 and technical drawings of all parts can be found in Appendix E. Figure 10 shows the port side when assembled, including the rubber dilator part of the GelPoint Path. More imagery can be found in Appendix H.

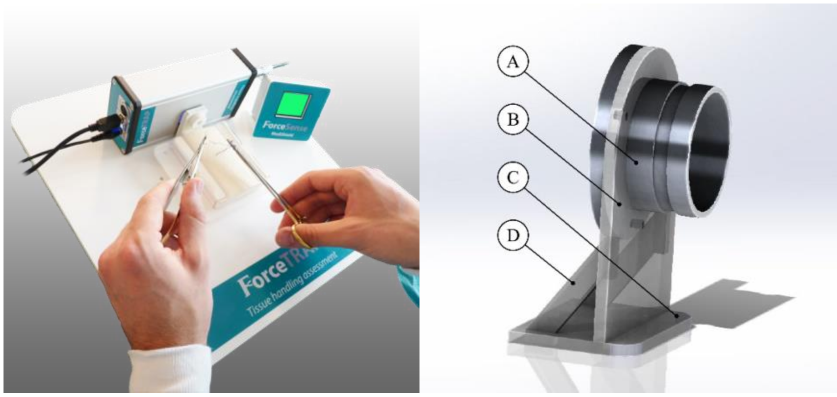
Table 2 Summary of production methods port

Part	Material	Fabrication	Location
Ring motion x	Aluminum 7075	Water cutting	DEMO
		Tapping	3mE workshop
Ring motin y	Aluminium 7075	Water cutting	DEMO
		Tapping	3mE workshop
Base plate	Aluminium 7075	Water cutting	DEMO
		Tapping	3mE workshop
Fixation tube	?	Turning	3mE workshop
Blade springs	Spring steel	Laser cutting	DEMO

Figure 10 **Components of port assembled.**
Left: outside, attachment for GelPoint Path.
Right: inside, front attachment points for dummy bowel

2.4. Coupling ForceTrap

Alike the port fixation tube, a tube is created for connection of the back of the dummy bowel (Figure 11). This is connected to a triangulated fixation that connects directly to the ForceTrap measuring system. Detailed technical drawings can be found in Appendix F.



A – connection tube for bowel
B – vertical part
C – horizontal part
D – diagonal support for stiffness

Figure 11 Left: ForceTrap measurement device
Right: Connection part for bowel

Similar production techniques are used as for the port system. A summary can be seen in Table 3.

Table 3 Summary of production methods ForceTRAP connection

Part	Material	Fabrication	Location
A	?	Turning Tapping	3mE workshop
B	Perspex	Laser cutting	Misit Lab
C	Perspex	Laser cutting	Misit Lab
D	Perspex	Laser cutting	Misit Lab

2.5. Full design

The sensors are read using a LabJack U3 data acquisition device (LabJack corporation, Lakewood, CO, USA). With this device, and electrical circuit integrated the setup is complete as seen in Figure 12. The dummy bowel is suspended in between a portal measurement system and the ForceTrap. Four cables leave the box: power supply for both the ForceTrap and the portal sensors and two USB cables to the laptop.

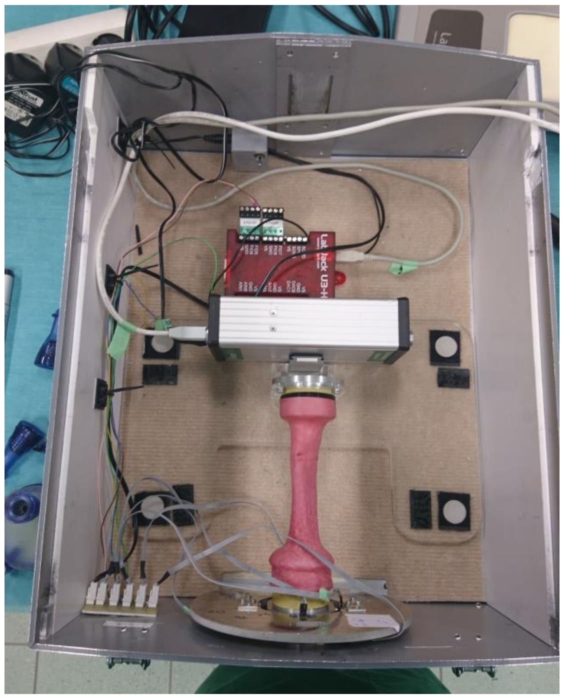


Figure 12 complete system

2.6. Pilot

The goal of this pilot study is gather preliminary data to determine if the metrics show promising results. Also, subjective feedback on the content and construction of the simulator is obtained.

Methods and materials

Logistics

The pilot is performed at the TaTME course of VU Medical Centre. Present at this course are usually about 4 experts in the TaTME procedure, and 10 participating surgeons. The participants in the course are expected to have extensive experience in laparoscopic surgery, but not in single port and transanal surgery. They come to the course to learn about how to perform, and implement the TaTME procedure at their hospital.

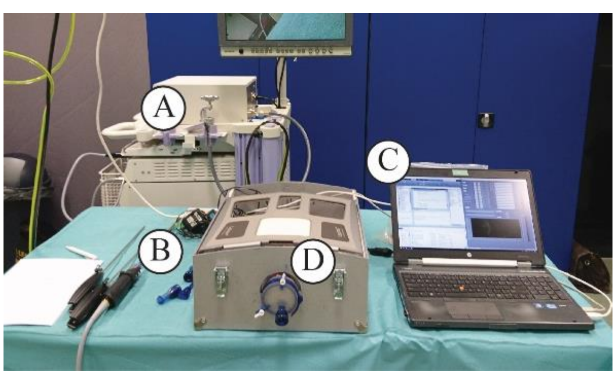
Participants

All participants fill out a questionnaire to determine their level of experience. Participants who have performed less than 10 purse string sutures are considered novice, at more than 50 purse string sutures participants are considered expert (Appendix J).

Protocol

Participants are asked to perform a purse string suture, starting posterior and suturing counter clockwise ending after the last stitch so no knot tying and tightening is involved. Novice is asked to perform the purse string to the best of their knowledge, no tips or hints will be given to prevent bias. All participants will be handed a new suture set to dismiss bias due to a blunt needle.

Because the software (MATLAB script, Appendix I) to read the ForceTrap requires a set time for the measurement. This is set to 300 seconds for novice, and 180 seconds for expert measurements. Port data is obtained through Labjack software LJStreamUD (LabJack Corporation, Lakewood, CO, USA). Data is synchronized by applying a tick to port z1 and ForceTrap x-direction at the point of the first stitch. Labjack stream is stopped after the last stitch, and afterwards data from ForceTrap is cut to that end moment and the pre-tick data is cut as well.
Two groups will be compared in this pilot. First are the novices and experts. Second is the difference between novice before and after the course.



A – laparoscopy tower.
B – laparoscope, instruments.
C – Laptop for data collection
D – novel measurement system.

Figure 13 Pilot test setup.

Execution – visual

Results and interpretation

Data

Two groups, experts (n=4) and novice pre (n=7) successfully finished the task. Trends in maximum, mean and SD of the applied force on the sensors Z1, Z2 and Z3 can be seen between novice and experts (Appendix L). Less is seen for the minimum applied force. This might be because the sensors and magnets are not positioned in the right range. The fact that trends are seen in measurements of Z1, Z3 and Z3 show the potential for different instrument handling for experts and novices. Not only do the magnitudes of the forces change, the mean values for Fz1 and Fz3 seem to shift direction, implying a change in direction of the internal moment.

Comparing raw data of one novice and one expert participant also shows interesting differences. Participant 7, Figure 14, for example creates very high results, often exceeding threshold, of sensor Z1, while almost ‘ignoring’ sensor Z2 and Z3. This implies that this participant is hanging in the port, pushing down with the instruments, as seen in

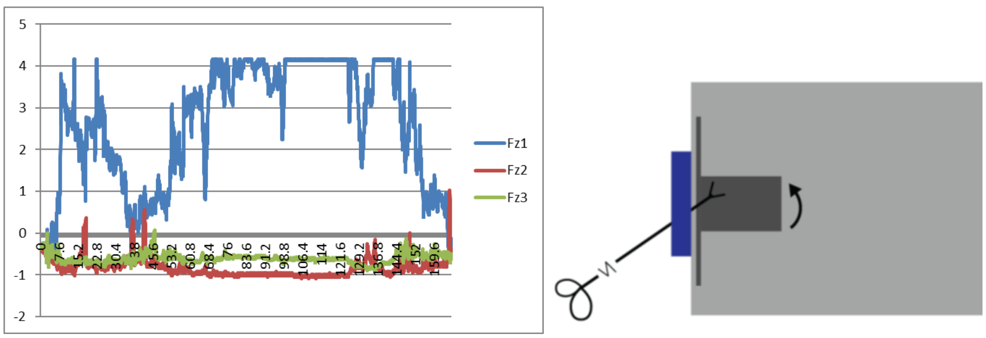


Figure 14 pilot - raw data for Z1, Z2 and Z3 of one novice participant

This behavior stands in great contrast to that of an expert (Figure 15). It is seen that motion is lot more divided over the three sensors. This indicates that experts make more efficient use of the 3D space. Also, the maximum outputs are a lot lower (a factor 2) than with novice.

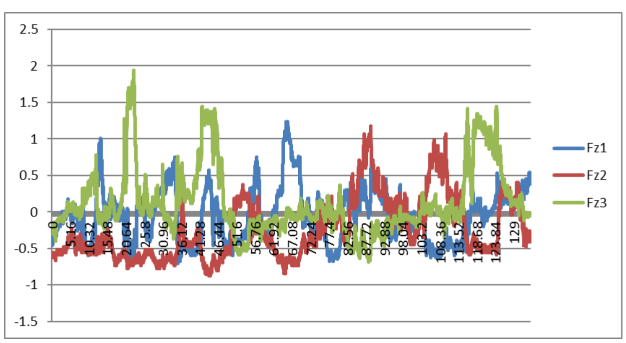


Figure 15 pilot - raw data of Z1, Z2 and Z3 of one expert participant

Observation of the participants whilst performing the task suggests the large impact that the laparoscopist has on the measurements. Since the laparoscope is hold steady mostly, it can be experienced as a ‘boring’ task. Because of this the laparoscopist looks for a comfortable way to hold the scope, and keeps it in that position most of the time. This has influence on the measurements, especially if this resting position is exceeding the threshold of the sensors. Therefore, it is best to approach this exercise as a team-effort and correct for this matter in experimental design and hypotheses formulation.

Clinical expert feedback

Various aspects about the box trainer are mentioned during the day. First and foremost is the realism of the dummy bowel. It is too small in diameter. It is almost 3cm in diameter where an insufflated rectum can become about 6cm diameter. Texture of the dummy is sufficient in realism. Another advantage of the dummy is the fact that the stitches go all the way through, and this way it can be easily viewed if they are applied correctly and in a straight plane. Experts would rather use a cadaver dummy, for example calf's intestine, instead of a synthetic dummy bowel, even though this means that the box cannot be used outside of a wet lab. They believe this part of realism weighs stronger than the possibility of use in a dry lab.

The realism of interaction with the port is high. Primarily because the use of the GelPoint Path. Yet also because the maneuverability within the suspension. An expert is used to flexibility of the port within the anal canal. The stiffness of the springs adds to the realism within the trainer.

Discussion

Limitations

The timer for Tissue Interaction Force data collection added greatly to the inefficiency of the measurements. The software also often did not start the measurement properly after which the program had to be restarted. This added to both inefficiency of the day and annoyance of the participant. Bugs in the software need to be fixed, or a different approach to data collection from the ForceTrap system should be used in further measurements.

Although the use of a tick at the beginning of the measurements turned out to be a sufficient way to synchronize data afterwards, the actual synchronization was very time consuming. Ideally the data is collected in one system.

The dummy bowel specimen was not elastic and therefore it was difficult to attach it to the measurement platforms. The specimen easily broke and because of that no novice post-training measurements could be done. For further research the possibility of using calf's bowel as a specimen will be considered.

Conclusion

Promising results are found in terms of tilting the port about the x and y directions. Also, task time shows to decrease significantly for experts compared to novice. Realism of the trainer is high according to expert opinions.

Adjustments to the system will be made regarding stiffness of the springs for Z1, Z2 and Z3. Stiffness will be adjusted so the scope of the measurements will be more efficient. Same holds for springs for X and Y. These will be made less stiff to allow more motion and therefore hopefully better measurements. The rest of the box will be adjusted to allow for use of a calf's intestine as a specimen.

2.7. Improvements to setup

Range X, Y

The fact that x and y did not show any results is because of the scope in which the magnet can move towards the sensor. This can either be improved by changing the characteristics of the springs, or reduce the space at starting position between the magnet and the sensor. Changing the starting position between the magnet and the sensor means that the size of all base parts should be changed, which will cost a lot of time. It is therefore chosen to change the characteristics of the blade springs. Changing the stiffness of the springs can be done by changing their thickness, or the length of the spring, as seen in equation (1) and (2). Changing the length (l) will have a larger impact than changing the thickness (h) of the spring since this can be done in a matter of mm while thickness of the springs can only vary from 0.1mm to 0.3mm.

$$\delta_{max} = \frac{Pl^3}{3EI} \tag{1}$$

$$I = \frac{bh^3}{12} \tag{2}$$

P = applied load
E = E-modulus of elasticity (spring steel: 206 GPa)
l = length spring
b = width spring
h = thickness spring
I = area moment of inertia

Range Z

Measurements in Z1, Z2 and Z3 often reached threshold levels during the pilot study. Therefore, it is considered to stiffen these springs such that the measurements will keep within range. Because of the fixed size of the notch in the plate, it is chosen to stiffen the z-springs by increasing the thickness (equation 2, h). This way it is possible to decrease stiffness without having to spend time for fabrication of a new base plate. Available thickness of spring steel is 0.10mm, 0.15mm, 0.25mm and 0.30mm. Best of these will be chosen in a trial and error manner.

Specimen

The specimen used in the pilot was too small. Only 23 mm inner diameter, where a human rectum ranges from 40mm to 60mm. Especially when insufflated. Other models have been considered but none would suffice for the needs of this study. Experts requested the use of calf’s colon. Because it resembles the human rectum in size and structured and is already used as a dummy during the TaTME course to practice the first couple of purse string sutures on. Using animal tissue in the test setup comes with some drawbacks. First the setup is not initially built for easy cleaning. And second the homogeneity of animal tissue cannot be assured between, but also within specimen. This creates extra inaccuracies in the measurements. Despite the drawbacks of the use of calf’s colon in this study regarding hygiene, the lack of proper dummies pushed to choose it still. For the next measurements the box will therefore be wrapped in plastic to reduce contact of the tissue with the trainer.

Protocol

During the pilot it was noticed that TaTME really is a team effort. Extreme measurements in the port are often also caused by the scope operator. Therefor the hypotheses will be adjusted accordingly. Participants will hence be judged as a team instead of only by experience of the instrument handler. An extra question will be added to the questionnaire regarding experience with a scope. Having used a scope less than 20 times will be considered novice, more than 20 will be considered expert. Keeping the combinations of a team even will hopefully minimize influence of scope usage on the measurements. The ForceTrap (tissue forces measurements) will henceforth be done using the online software by Medishield. This will take out the set timer that was needed when using Matlab and therefore improve efficiency of the measurements.

3. Parameters

3.1. Port

In the access port two categories of parameters will be studied: forces applied to the port by the instruments and internal moments in the system created by the instruments (Figure 16). Different characteristics of each parameter will be studied: minimal value, maximum value, mean, standard deviation (SD). NOTE: because of mechanical failure of the springs for X and Y, only the resultant force for Z (Fz) will be studied further.

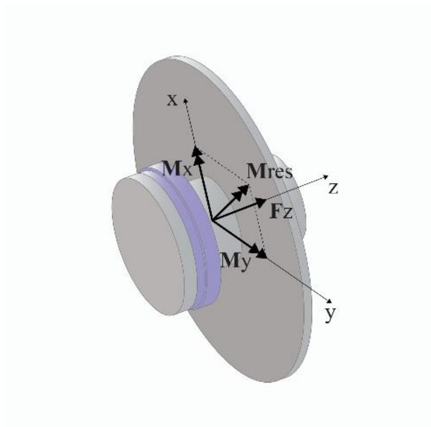


Figure 16 Parameters studied in access port.

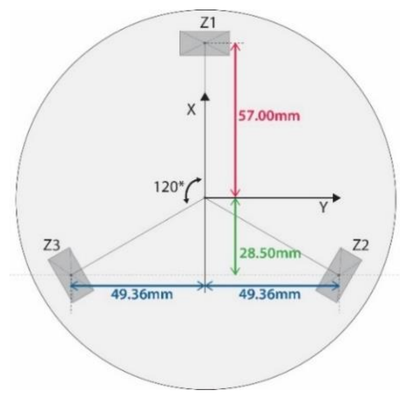


Figure 17 Dimensions of Z sensors

The internal moments are calculated according to the dimensions shown in Figure 17, using the following equations:

$$M_z\ [Nm] = \ 49.36 \cdot 10^{-3}(F_{z1} - F_{z2}) \tag{3}$$

$$M_y[Nm] = 28.5 \cdot 10^{-3}(F_{z2} + F_{z3}\ ) - (57 \cdot 10^{-3}M_{z1}) \tag{4}$$

$$M_{res}[Nm] = \sqrt{M_x^2 + M_y^2} \tag{5}$$

The resultant force in Z is calculated by:

$$F_z\ [N] = F_{z1} + F_{z2} + F_{z3} \tag{6}$$

Regarding Fz, Mx and My also the ratio between a positive and negative output will be studied. In other words: how much task time is spent pushing the port inwards (Fz.pos) our pulling it outwards (Fz.neg), or applying torque right (Mx.pos), left (Mx.neg), down (My.neg) or up (My.pos).

3.2. Suture

At the suture site tissue interaction forces (Fft) will be studied using the ForceTrap measuring platform. Only the resultant tissue interaction force (Table 4) will be studied since the Medishield software does not allow differentiation between x, y and z.

3.3. Summary

A total of 12 unique parameters will be studied. Of these parameters various characteristics are studied, such as minimal value, maxiumum, mean, standard deviation and ratios. This results in a total of 34 metrics to be studied. A summary can be seen in Table 4.

Table 4 Summary of potential parameters for objective assessment

Type	Parameter	Characteristic
	Task time	-
Tissue interaction force	Fft	max, mean, SD
Portal forces	Fz	min, max, mean, SD
	Fz.pos	ratio, mean, SD
	Fz.neg	mean, SD
Portal moments	Mx	min, max, mean, SD
	Mx.pos	ratio, mean, SD
	Mx.neg	mean, SD
	My	min, max, mean, SD
	My.pos	ratio, mean, SD
	My.neg	mean, SD
	M.res	max, mean, SD

4. Calibration Z

Due to mechanical failure of the blade springs (Appendix Q) of X and Y just the sensors for Z have been calibrated.

4.1. Methods

Rationale

The measured output of the hall sensors is in Volt, and does not have a linear relation to the distance to the magnet. It is assumed that the force needed for the deflection of the spring blade stands linearly to the force needed to do so. Because of the circular symmetry of the sensors on the plate, the forces will be distributed evenly over them, as seen in Figure 18.

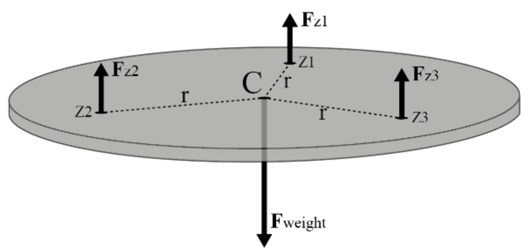


Figure 18 Force distribution over sensors Z1, Z2 and Z3.

Therefore, the following equation holds:

$$^1/_3\, F_{weight} = F_{Z1} = F_{Z2} = F_{Z3} \tag{7}$$

Setup and Protocol

A force is applied to the setup using weights in steps of 0.1kg (0.981N) for 30 seconds. The average voltage measured is taken as the corresponding voltage to the force applied to the spring. This step is repeated up from -2.5 kg to +2kg. To ensure application of a force in line with the z-axis a socket is designed (Figure 19, Appendix G). Also, an insert is designed to ensure central alignment of the weight into the port (Figure 19, right).

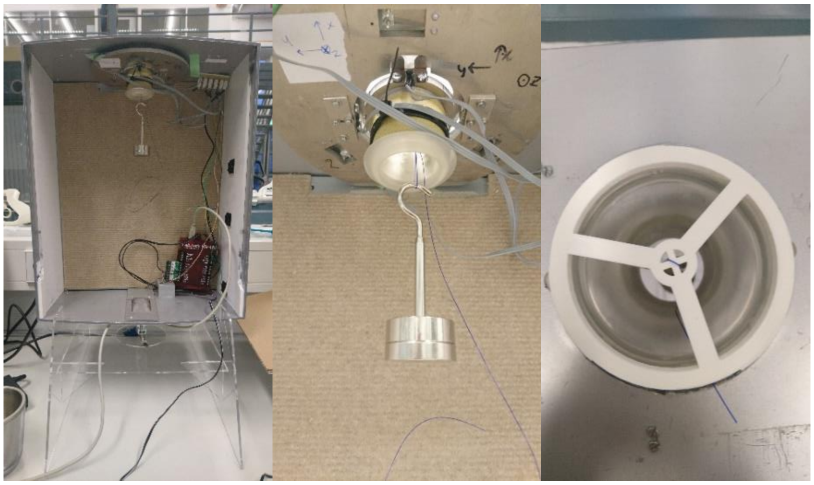


Figure 19 **Calibration setup.**
Left: trainer on socket
Middle: suspension of weights
Right: element for central alignment of the suspension

Data processing

A detailed list of the calibration data can be found in Appendix O. Figure 20 shows a plot of the raw calibration data.

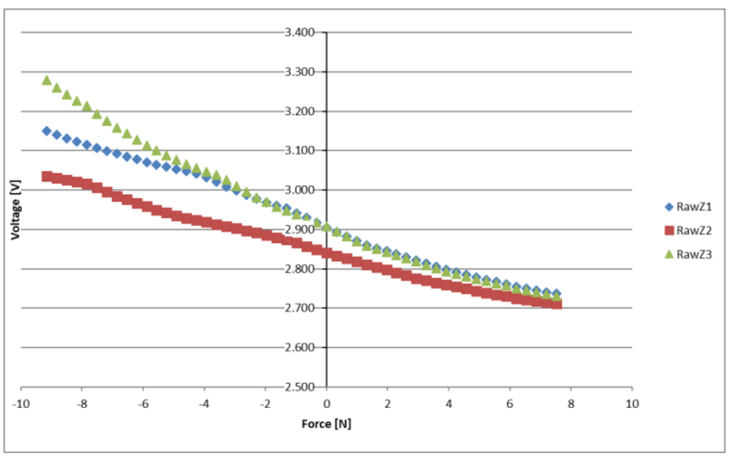


Figure 20 Raw calibration data

The measured voltage and applied force are not linearly dependent. Therefore, a trendline is plotted using MS Excel. A second-degree polynomial (equation 8) proved to give the best fit in this range.

$$y = (c_2 \cdot x^2) + (c_1 \cdot x^2) + b \tag{8}$$

The fitted polynomials for Z1, Z2 and Z3 are seen below. How the constants for all three equations are obtained can be found in Appendix P.

$$V_{z1} = (0.0001 * F^2) - (0.0263 * F) + 2.9095 \tag{9}$$

$$V_{z2} = (0.0003 * F^2) - (0.0198 * F) + 2.8382 \tag{10}$$

$$V_{z3} = (0.0010 * F^2) - (0.0311 * F) + 2.9030 \tag{11}$$

These equations however, are voltage output as a function of applied force. In the study the opposite is needed: applied force as a function of measured output voltage. Therefore, the inverse of three equations is needed to calculate the applied force from the measured voltage output.

4.2. Results

Taking the inverse of the three second-degree polynomials results in the following equations that allow calculation of applied force given an output voltage, equation 9, 10 and 11. These equations are used to map the obtained voltage output data to the force applied by the used during the construct validity study.

$$F_{Z1} = 125.9 - 1.07 \cdot 10^{-3}\sqrt{V * 8.37 \cdot 10^{9} - 1.05 \cdot 10^{10}} \quad 2.5 \leq x \leq 4.9 \tag{12}$$

$$F_{Z2} = 39.8 - 3.48 \cdot 10^{-4}\sqrt{V * 3.32 \cdot 10^{10} - 8.10 \cdot 10^{10}} \quad 2.5 \leq x \leq 3.2 \tag{13}$$

$$F_{Z3} = 15.16 - 4.88 \cdot 10^{-5}\sqrt{V * 4.09 \cdot 10^{11} - 1.09 \cdot 10^{12}} \quad 2.5 \leq x \leq 4.1 \tag{14}$$

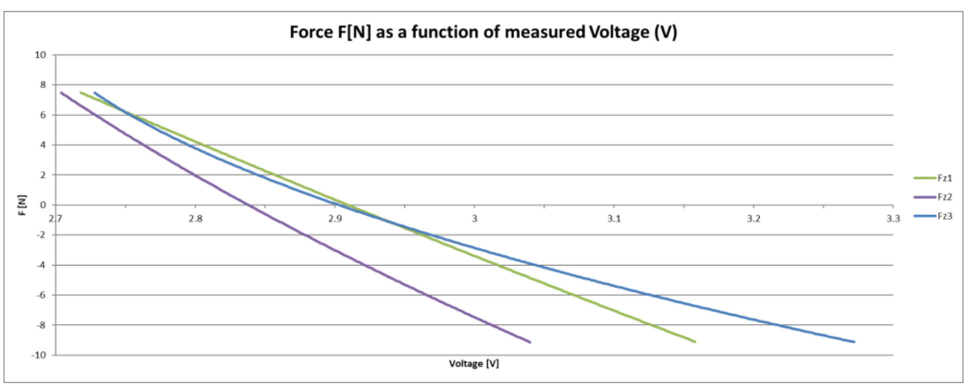


Figure 21 Plot of F(V)

Note that there is a range of output voltage set for these functions (Figure 21). This is because the trend line is only fitted for the data obtained in the calibration (-2.5 to 2kg). Anything predicted outside of these measurements is unpredictable and can therefore not be used for the construct validity study.

5. Construct validity

5.1. Methods and materials

Setup

Participants will work on the previously described test setup. A calf's colon is used as specimen, the setup will therefore be wrapped in cling foil to prevent contamination. Every participant is handed a new suture set to ensure same sharpness of the needle for every participant. A 30° laparoscope (Olympus, Tokyo, Japan). Regular linear laparoscopic instruments are used: scissors, curved grasper and needle driver. Data is collected on a laptop using LJStreamUD (LabJack Corporation, Lakewood, CO, USA), and a MS Surface (Microsoft, Redmond, WA, USA) using ForceTrap software (Medishield, Delft, NL).

Participants

Participants are recruited at the TaTME course of 31 January and 1 February 2018. Subjects are grouped by to experience with a transanal purse string suture. Participants with experience of 0 to 10 purse string sutures are considered novices, those with experience of more than 50 transanal purse string sutures are considered expert. Intermediate (11-50 sutures) participants are excluded from this study. Furthermore, the experience of the laparoscopist is considered. A laparoscopist with experience with a 30-degree scope of more than 20 times is considered and expert, less experienced are considered novice. This information will be obtained through a questionnaire prior to the training.

Task

A full purse string suture consists of running the suture 360° along the wall of the bowel, with the last stitch overlapping the first to ensure full circumference of the bowel. Then the suture is pulled tight, closing the lumen, and tied with a surgical knot. For this study the participants are asked to perform only the suture part of the task. This is done to ensure that the measurements are influenced by only the suture part and data is interpreted correctly.

Protocol

Before participation each participant is asked to fill in a questionnaire regarding their experience in various aspects of laparoscopic surgery. Participants are all clearly instructed before starting the measurements. They are specifically asked to start the suture at the bottom (6 on a clock) and work clockwise. It is emphasized not to tighten the suture and not to tie a knot. Both measurements systems are started before the participant starts the suture. A tic is given to both measurement systems at of the first stitch to allow data synchronization of the data afterwards.

Data analysis

Data is obtained in .txt files with two different programs. The online environment of the ForceTrap for tissue interaction data, and LJStreamUD for port data. The data is afterwards imported in MS excel 2016 for visualization and manual synchronization.

Statistical analysis is done in SPSS Statistics 24 (IBM, North Castle, NY, USA). First a Kolmogorov-Smirnov test for normality will be done. Then a paired samples T-test between the novice group before and after the course and two independent samples T-test between the different novice groups and expert group will be done. Comparison of the novice groups with experts will be interpreted as preliminary results because of the low sample size of the expert group.

Execution – visual

5.2. Results

Two groups are defined based on the questionnaire: Novice (n=7), experts (n=3). All participants where right-handed males. One novice participant performed the Suture counterclockwise, pre- and post-training. Two groups of laparoscopy expertise are defined based on the questionnaire. All novice surgeons were accompanied by an expert laparoscopist. The expert surgeons were accompanied by a novice laparoscopist. Appendices T-Y contain scatter plots of the distributions of all parameters per experimental group.

Data distribution

Kolmogorov-Smirnov tests for normality showed that data for Fz.SD and Time was not normally distributed for novice pre-training. The same holds for Fz.pos.mean in novice post-training. The sample size of experts is too small to determine normality of the data.

Paired samples T-test

Paired samples T-test comparing novice pre- and post-training showed significant changes for some characteristics of Fz in the port (Figure 5) minimum (-4.1, 6, $p<0.01$), mean (-5.3, 6, $p<0.01$), positive-negative ratio (Fz.pos) (-6.0, 6, $p<0.01$), Fz.neg.mean (-3.3, 6, $p=0.2$) and Fz.neg.SD (3.1, 6, $p=0.02$). Also The moment about x (Figure 6) showed significant differences for some characteristics: minimum (Mx.min) (2.8,6,$p=0.03$), mean (Mx.mean) (2.5,6,$p=0.05$), positive-negative ratio (Mx.pos) (3.7,6,$p=0.01$) Mx.neg (-3.7,6,$p=0.01$), Mx.neg.mean (3.7,6,$p=0.01$), Mx.neg.SD (-2.8,6=0.03).

Independent samples T-test

Both novice pre-training and novice post-training are compared to experts in this study. Expert sample size was very small (n=3), so no real statistical conclusions can be drawn from the analysis. A summary is seen in Table 5.

Table 5 Summary of significant findings

Parameter	PRE-POST	PRE-EXP	POST-EXP
Fz.min	**		
Fz.mean	**	(***)	(**)
Fz.pos	***	(***)	(**)
Fz.neg.mean	**	(**)	
Fz.neg.SD	*	(**)	
Mx.min	*		
Mx.mean	*		
Mx.pos	*		
Mx.neg.mean	*		
Mx.neg.SD	*		
My.neg.SD			(**)
Mres.SD			(**)
Fft.SD		(*)	
Time			(**)

* $p<0.05$, ** $p<0.01$, *** $p<0.001$, ( ) indicates that statistical analysis has been done but power was low because of low expert group size

5.3. Discussion

Most important results

The most notable results seen are first the changes in the mean force applied to the port, and the ratio of this force being positive or negative. Furthermore, the lack of difference in task time is an interesting observation. Also, the observation that significant changes in moment about the x-axis (vertical) are noticed but not about the y-axis (horizontal). Last the fact that task time did not change significantly is noteworthy.

Task time

According to pilot results it is expected that task time will be higher for novice than experts. Post hoc power analysis shows that power of the study is very low ($1-\beta<0.2$). Also, the novice pre-training data is not normally distributed. Observation of the scatter plot (**Fout! Verwijzingsbron niet gevonden.**) does show a decline for novice post-training to experts as expected. When considering the one high measurement in novice pre-training as an outlier, task time even seems to go up slightly in the novice post measurement. This might be an effect of showing off in the first round to complete the task fast. Another possible explanation is the presence of experts during the post measurements, which might have created more caution in novices' behavior and therefore slowing them down. It can also be a learning effect of the training day. It is possible that novices are a lot more aware of their actions during the second run, trying to apply the just learned techniques properly which causes a decline in their task time. A follow up study with these participants could give more insight in this learning curve when the taught techniques become more

Tissue interaction force (suture site)

Previous research suggests that tissue interaction force is a valid assessment parameter for skills assessment in surgical tasks.[23,24] Although a trend is observed in the obtained the power of this study is too low ($1-\beta<0.2$) to observe statistically significant results for the maximum and mean tissue interaction force (Fft, Appendix X). Fft.SD however does show a significant decline between novice pre-training and experts. It is expected that with a higher sample size and strict protocol this data can become more interesting as an assessment metric.

When observing the raw data however, interesting differences can be seen. Figure 22 shows the raw data of three novice and three experts. Force peaks applied by novice are longer (les 'spiky') than those of experts. This also correlates to the observed techniques used by experts compared to difficulties for novice to correctly insert the needle through the tissue. Experts are seen to actively transfer the needle between the instruments, creating one smooth motion, having the needle directly in the right plane for insertion. Novice do not use this technique yet which causes them to 'poke' the tissue multiple times before actually setting a stitch. This causes them to apply a force on the tissue for a longer period than experts. This behavior can be interesting as a measure of instrument handling skills.

Horeman et al.[20] showed that tissue damage appears quite quickly in porcine intestines when pulling a suture. The thresholds for the first sign of damage (1.3N, dotted line), and actual rupture (1.8N, full line) are visualized in Figure 22. Novice participants exceed these forces a lot more than experts do. This shows that practicing this suture outside of the OR is highly recommended.

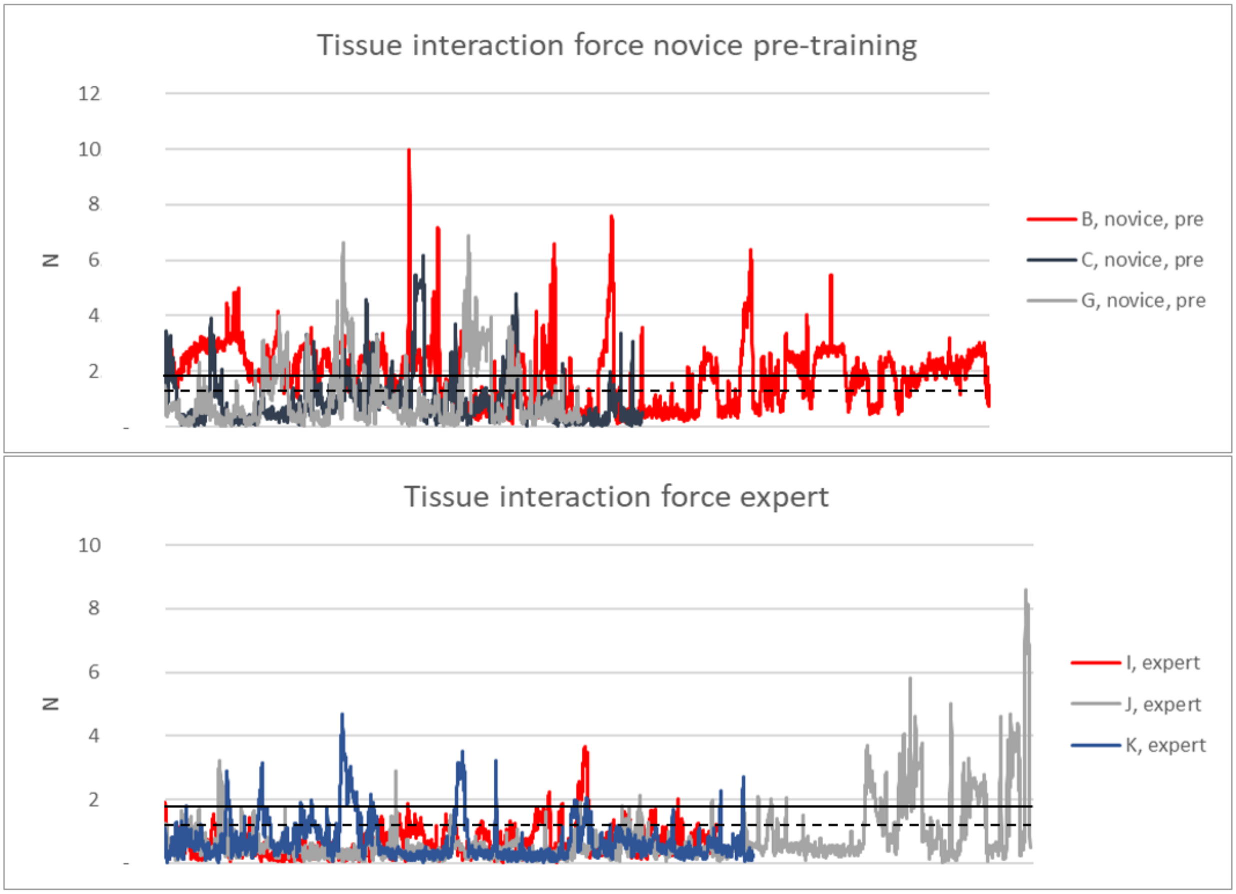


Figure 22 Raw data plots of tissue interaction force of novice pre-training (above) and experts (below). The lines indicate critical values where tissue damage appears in a porcine large bowel.

Fz (port site)

The mean resultant force (Fz.mean, Appendix T) on the port applied box inwards is significantly higher for experts than for novice both pre and post training. It even shifts from negative, which implies a pulling motion on the port, to a positive value, which implies a pushing force on the port. This is also observed in the ratio between a pulling and pushing force during the task (Fz.pos, Appendix T). This shows that the expert group exerted a pushing force 60% to 90% of the time, where for novice pre-training this was the direct opposite, namely only 10% to 40% of the time. This suggests that there is a different in instrument handling between experts and novice that makes for novice to pull on the port more than experts. It is possible that this is caused by difficulties in instrument handling by novice behind the port (inside the lumen). The instruments are not always entirely visible through the laparoscope, which can cause collision of instruments going unnoticed by the operating surgeon.

These collisions might be a cause for clamping the instruments in the port and when put in motion, instead of having them run through the trocar smoothly, pulling the entire port towards the surgeon. There are no previous studies, however there is a possibility that applied force correlates to clinical outcome in regarding anal function. The clear changes in behavior, however, can be of value for objective assessment of expertise. More extensive research is needed to determine the relevance.

Internal moments (port site)

Because of 360° motion that is made when performing the suture, it is expected that the internal moments in the port will shift according to the position of the instruments at a certain moment. Because participants were asked to all perform the suture clockwise, a specific change in moments is expected as seen in. This distinguishing shape is in the raw data seen in My, but less for Mx. It is possible that this is effect is due to input of the laparoscopist. Because they are operating side by side through the one port is possible that the scope, which is held steady, inhibits rotation of the port around the x-axis. The fact that it is the negative moment makes sense since the laparoscopist is sitting to the right of the surgeon, therefore keeping a steady force in the positive x direction, counteracting the negative moment. Also, the scope is positioned 'through' the y-axis, therefore not influencing the moment about it. Taking a closer look at Figure 23 shows that in phase D the suture is being placed in the right side of the bowel. This is also the side where the scope enters the lumen. Comparing the phases in Figure 23 and Figure 24 suggests that interference of the scope with the instruments causes these changes in behavior about the x-axis. This can therefore be a potential measure for efficient instrument use during the suture.

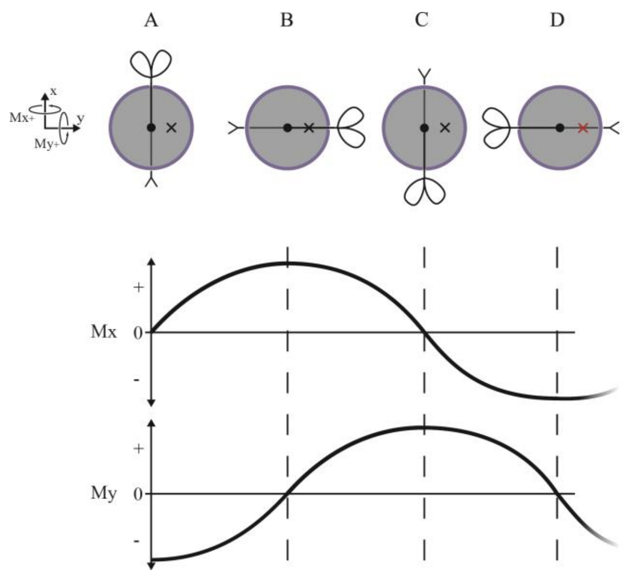


Figure 23 Expected change of internal moments during the suture. Above images represent the front-view of the GelPoint Path with an instrument inserted. Starting the suture at the bottom (A) continuing clockwise (B to D). The X marks the location of the laparoscopist.

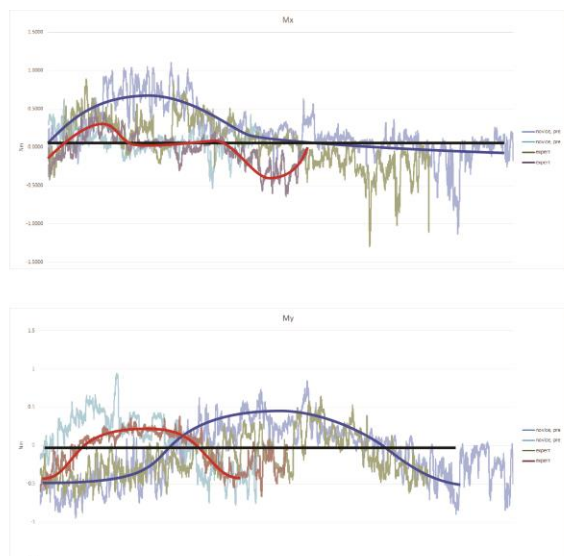


Figure 24 Trajectory of moments about x-axis and y-axis of one expert (red) and one novice pre-training (blue)

Although no significant results are found, the scatter plots of My.min and My.max (Appendix U-V) suggest that rotation about the y-axis will converge to a specific angle of approach with increase in experience. It is likely however that the height of the surgeon's chair or height of the table have an influence on this value of this asymptote. This must be evaluated in a more comprehensive study.

The theory that the laparoscope is a main cause for differences in moments about the two axes, it is interesting to link the experience of the laparoscopist. Two levels of laparoscopist have participated in the teams. All novices were accompanied by someone considered an expert, all experts were accompanied by a novice laparoscopist. The fact that the expert group was accompanied by a novice laparoscopist might explain the slight rise in Mx.min, Mx.max and Mx.mean for experts compared to novice post-training.

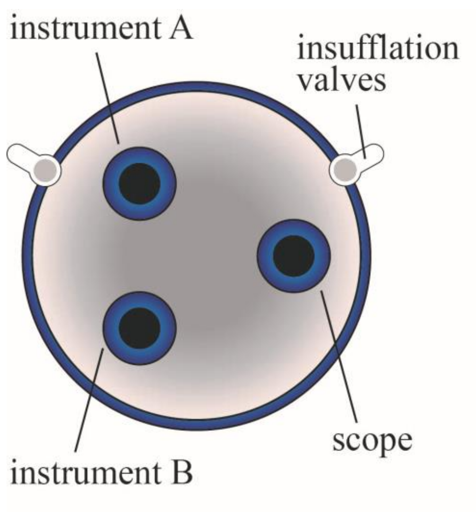


Figure 25 Positioning of instruments and laparoscope in the GelPoint Path transanal access port.

To the knowledge of the author no research has been done into the influence of port handling on clinical outcomes regarding anal function. Fecal incontinence was a concern when first introduced but seems to have little impact on quality of life long after surgery.[25,26,27] The dysfunction that is noted, however is linked mostly to operating time. It can be of interest to assess clinical outcome related to port handling.

5.4. Limitations – construct validity study

In contrast to the dummy bowel used in the pilot study the calf's intestine made it difficult to observe if the suture is being placed neatly in-plane or skewed. Also, the number of stitches is difficult to tell because of the fatty tissue surrounding the specimen. Since these are seemingly important parameters for a sufficient purse string suture (Dr J. Tuynman) it can be considered to develop a way to still observe these aspects. This can for example be done by (post-task / manual) video assessment.

After participant A (intermediate), B, C and D (pre-training novices) the springs in x and y direction of the port buckled. This caused for loss of the two parameters and therefore in-plane forces in the port could not be assessed. However, data collected from sensors Z1, Z2 and Z3, including moment assessment, give seemingly relevant information regarding tool-port interaction. The new metrics defined in terms of internal moments are novel in this field of study and give way for interesting further research.

Only three experts participated in this study. This makes power of the statistical analysis low and outcomes should therefore be interpreted accordingly. Future research should aim for a larger group of expert participants.

A previously performed literature study[18] suggests that actions of the surgeon's body can be of relevance for determining skill level. Since the posture, and hand positioning is much different in TaTME than in general laparoscopy this can also be interesting for future research.

6. Discussion

In this project a novel measurement system for force measurements in a single port laparoscopic setting has been developed and a preliminary construct validity study has been done to identify the relevance of proposed metrics. Most requirements have been met. Live video recording could not be done because this interfered highly with the data acquisition in Matlab. Furthermore, use in dry-lab is not achieved because a calf's colon is eventually used. However, this is because of specific wishes from expert opinions. Because of mechanical failure (Appendix Q) of the blade springs in X and Y force measurements in these directions could not be done. This issue needs to be adjusted if in further research we want to involve these parameters. Although it seems that internal moments in the port can give enough information on instrument handling, and it is unclear what extra information Fx and Fy would give.

Table 6 Summary of requirements and if achieved

Criteria	Specific requirements	Achieved
Functionality	Multiple purse string sutures per specimen	Yes
	Force measurements (x, y and z) in anal port up to 15N	Partly
	Tissue interaction force measurements	Yes
	Video recording	No
Use environment	Addition to LapStar box trainer	Yes
	Use in dry-lab	No*
Realism	Application of GelPoint Path transanal access platform	Yes
	Allow insufflation of lumen	Yes
	Use of 30° laparoscope	Yes
	High fidelity specimen	Yes
Usability	Easy attachment and detachment of bowel specimen	Yes
	Light weight	Yes

* not achieved because requirement is adjusted due to expert wishes

6.1. Relevance for TaTME

It has long been said that training surgical skills outside of the OR is beneficial over usual apprenticeship model.[28,29]Also objective assessment seems feasible when identifying the right metrics for a task.[24,30] Various types of physical box trainers have long been commercially available and used in medical training, and more and more apply objective skill assessment and feedback. However no commercially available single port, not to mention transanal access, trainers that apply this objective assessment are found in literature. [source, lit study]. Keep in mind that TaTME is currently educated in theatre and on cadavers. Also because of the novelty of this procedure gathering knowledge about what makes a good procedure is ongoing and subjective. Therefore, this device can be of value for efficiency and cost effectiveness of training (parts of) TaTME.

Furthermore, the novel measurement port designed for this study gives unique insights in instrument handling behavior in the GelPoint Path because of the configuration of three separate sensors. Parameters regarding the internal moments created in the port site are, to the best knowledge of the writer, not yet examined in terms of objective assessment of instrument handling skills. These parameters cannot be obtained with the ForceTrap that is currently used in the LapStar. This gives it a large benefit for studying technical skills in transanal procedures.

6.2. Future research

This study is currently being continued as a cooperation between TU Delft and VUmc. The aim is to create higher sample sizes, especially for expert participants, to obtain more reliable data for analysis. The eventual goal is to implement this trainer as a standard part of the TaTME course and proctoring period.

The force parameters studied for this project are not the only metrics that have potential for objective assessment of skills. Instrument kinematics data has shown to be a valid tool for skill assessment as well.[18] Although work space is limited is can be interesting to study what motion parameters tell in this single-port approach.

Clinical outcomes in terms of anal function go hand in hand with terms like TEM, TAMIS and TaTME. However, not much is studied about the key causes for better or worse anal function after such surgeries except for duration of the surgery. The outcomes of this study indicate that there is most definitely a difference in port handling between novices and experts. It is interesting to link this behavior to clinical outcomes of actual patients. If the measurements can be done in-operation this data could be linked directly.

6.3. Dot on the horizon

In my opinion the ideal world all the beginning of surgical education will take place outside of the operating room. It will be possible to train all basic procedures and tasks on (realistic) dummies and simulators, or some way not yet thought of at all! At least there will be no need for subjective assessment as all ‘simulators’ make use of an efficient way of data collection and give structured feedback to the trainee. The writer hopes that this research bridges the knowledge gaps one little step more, so eventually these goals will be reached.

7. Conclusion

This project aimed to give answers to the question ‘wat are potential parameters for the objective assessment of skills in a transanal purse string suture?’ A box trainer was designed that allows the application of a transanal purse string suture in a highly realistic environment. The trainer contains a novel measurement port which allows measurement of forces and internal moments in the entrance port. Furthermore, tissue interaction forces at the suture site have been analyzed. A construct validity study was done to determine the potential of a set of force-related parameters for objective assessment of instrument handling skills. Almost all proposed parameters have been analyzed except for in-plane portal forces, due to mechanical failure of the port.

The study showed the potential benefit of analysis of internal moments in the port for instrument handling assessment. Also pushing into, and pulling on the port show to have value in distinguishing between experts and novice.

This project has shown great potential for objective skill assessment in transanal procedures. Continuation of this study is needed to define the parameters in more detail and consider the implications from a clinical perspective.

8. Appendix

A. Stages of rectal cancer

AJCC Stage	Stage grouping	Stage description*
0	Tis N0 M0	The cancer is in its earliest stage. This stage is also known as carcinoma in situ or intramucosal carcinoma (Tis). It has not grown beyond the inner layer (mucosa) of the colon or rectum.
I	T1 or T2 N0 M0	The cancer has grown through the muscularis mucosa into the submucosa (T1), and it may also have grown into the muscularis propria (T2). It has not spread to nearby lymph nodes (N0) or to distant sites (M0).
IIA	T3 N0 M0	The cancer has grown into the outermost layers of the colon or rectum but has not gone through them (T3). It has not reached nearby organs. It has not spread to nearby lymph nodes (N0) or to distant sites (M0).
IIB	T4a N0 M0	The cancer has grown through the wall of the colon or rectum but has not grown into other nearby tissues or organs (T4a). It has not yet spread to nearby lymph nodes (N0) or to distant sites (M0).
IIC	T4b N0 M0	The cancer has grown through the wall of the colon or rectum and is attached to or has grown into other nearby tissues or organs (T4b). It has not yet spread to nearby lymph nodes (N0) or to distant sites (M0).
IIIA	T1 or T2 N1/N1c M0	The cancer has grown through the mucosa into the submucosa (T1), and it may also have grown into the muscularis propria (T2). It has spread to 1 to 3 nearby lymph nodes (N1) or into areas of fat near the lymph nodes but not the nodes themselves (N1c). It has not spread to distant sites (M0).
	OR	
	T1 N2a M0	The cancer has grown through the mucosa into the submucosa (T1). It has spread to 4 to 6 nearby lymph nodes (N2a). It has not spread to distant sites (M0).
IIIB	T3 or T4a, N1/N1c M0	The cancer has grown into the outermost layers of the colon or rectum (T3) or through the visceral peritoneum (T4a) but has not reached nearby organs. It has spread to 1 to 3 nearby lymph nodes (N1a or N1b) or into areas of fat near the lymph nodes but not the nodes themselves (N1c). It has not spread to distant sites (M0).
	OR	
	T2 or T3 N2a M0	The cancer has grown into the muscularis propria (T2) or into the outermost layers of the colon or rectum (T3). It has spread to 4 to 6 nearby lymph nodes (N2a). It has not spread to distant sites (M0).
	OR	
	T1 or T2 N2b M0	The cancer has grown through the mucosa into the submucosa (T1), and it may also have grown into the muscularis propria (T2). It has spread to 7 or more nearby lymph nodes (N2b). It has not spread to distant sites (M0).
IIIC	T4a N2a M0	The cancer has grown through the wall of the colon or rectum (including the visceral peritoneum) but has not reached nearby organs (T4a). It has spread to 4 to 6 nearby lymph nodes (N2a). It has not spread to distant sites (M0).
	OR	
	T3 or T4a N2b M0	The cancer has grown into the outermost layers of the colon or rectum (T3) or through the visceral peritoneum (T4a) but has not reached nearby organs. It has spread to 7 or more nearby lymph nodes (N2b). It has not spread to distant sites (M0).
	OR	
	T4b N1 or N2 M0	The cancer has grown through the wall of the colon or rectum and is attached to or has grown into other nearby tissues or organs (T4b). It has spread to at least one nearby lymph node or into areas of fat near the lymph nodes (N1 or N2). It has not spread to distant sites (M0).
IVA	Any T Any N M1a	The cancer may or may not have grown through the wall of the colon or rectum (Any T). It might or might not have spread to nearby lymph nodes. (Any N). It has spread to 1 distant organ (such as the liver or lung) or distant set of lymph nodes, but not too distant parts of the peritoneum (the lining of the abdominal cavity) (M1a).
IVB	Any T Any N M1b	The cancer might or might not have grown through the wall of the colon or rectum (Any T). It might or might not have spread to nearby lymph nodes (Any N). It has spread to more than 1 distant organ (such as the liver or lung) or distant set of lymph nodes, but not too distant parts of the peritoneum (the lining of the abdominal cavity) (M1b).
IVC	Any T Any N M1c	The cancer might or might not have grown through the wall of the colon or rectum (Any T). It might or might not have spread to nearby lymph nodes (Any N). It has spread to distant parts of the peritoneum (the lining of the abdominal cavity), and may or may not have spread to distant organs or lymph nodes (M1c).

* The following additional categories are not listed in the table above:
TX: Main tumor cannot be assessed due to lack of information.
T0: No evidence of a primary tumor.
NX: Regional lymph nodes cannot be assessed due to lack of information.
https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/staged.html

B. TaTME step by step

Set up

- Bowel preparation
- Profylactic antibiotics
- Lithotomy, both arms alongside
- Rectal lavage on table with betadine
- Equipment set up for abdominal and transanal phase

Abdominal phase; mobilisation

- Splenic flexure take down from medial to lateral (optional step, tailored option) Including ligation of the mesenteric inferior vein
- Medial to lateral sigmoid mobilization
- Identification of the right plane, sure well above ureter
- Ligation of the IMA just above hypogastric plexus (sparing left colic artery)

Abdominal phase rectal dissection

- Circumferential perirectal incision of the peritoneum
- Anterior dissection just until vesicles; denonvillier is spared if oncological safe
- Posterior the first one third of the TME plane
- Lateral identification of the hypogastric nerve bundle; medial to bundle dissection

Transanal part

1. Identification anatomical landmarks; urethra, oscoccygus, length of internal sphincter
2. Lone starr application with 8 elastic retractors
3. Port insertion
4. Laparoscopic or open pursestring
5. TAMIS step 1 circumferential full thickness incision
6. TAMIS step 2 posterior TME plane identification
7. TAMIS stap 3 anterior right plane behind prostate
8. TAMIS stap 4 lateral plane identification
9. TAMIS stap 5 connection with abdominal phase
10. TAMIS stap 6 specimen extraction (transanal of abdominal)
11. TAMIS stap 6 anastomosis (doublepurse string, stapled)
    four types anastomosis

    1. Coloanal intersphincteric
    2. Stapled hemorroidal stapler
    3. Stapled 28-29 mm; abdominal exposure and stapling (drain method)
    4. Stapled 28-29 mm; transanal exposure and stapling (wired method)

C. Observation summary [Dutch]

De periodieke TaTME cursus bestaat uit een dag colleges en OK-observatie en een dag praktijk wet-lab training. De cursus is bedoeld om medisch specialisten (proctologie, colorectale chirurgie, algemene chirurgie) een eerste kennis te laten maken met de procedure, en te inventariseren of het reëel is, en wat er nodig is om de procedure te introduceren in hun ziekenhuis. De cursus trekt medisch specialisten van over de hele wereld.

De eerste dag bestaat uit colleges van verschillende specialisten op het gebied van TaTME, waar voornamelijk wordt gesproken wordt over de eigen ervaring. Vanwege de nieuwheid van de procedure is er nog niet echt een gouden standaard. Daarom wordt er veel gesproken over eigen ervaringen en hoe fouten voorkomen hadden kunnen worden. Het gaat vaak om eenmalige missers. De dag wordt afgesloten met live een operatie bijwonen. Hier wordt veel gepraat door de opererend chirurg, en er is ruimte voor vragen, die worden alleen weinig gesteld.

De tweede dag start weer met colleges, andere sprekers, veel van dezelfde informatie. Dan gaan alle studenten naar de wet-labs waar eerst uitgebreid naar een doorsnede van de bekken wordt gekeken. De anatomische planen worden uitgelicht en risico-locaties. Het grootste deel van de dag wordt doorgebracht in het dierproefcentrum. Waar alle chirurgen in tweetallen het hele trans-anale deel van de procedure kunnen oefenen op een kadaver. Hier is ook een passieve box trainer van Applied Medical aanwezig, met kalfsdarm, waar iedereen eerst driemaal de purse string suture op moet oefenen voor ze de procedure mogen starten.

Sum-up

- Purse string suture vaak benadrukt
  - Hoeveelheid steken (rond de 12)
  - Locatie (+- 3 cm boven einde van anal canal)
  - Door alle lagen van de darm heen.
  - Spiralen
  - Lekken in de buikholte
- Anatomical planes vaak benadrukt
  - Risico om ‘de weg kwijt te raken’ vanwege trans-anale benadering
  - Resectie tot te ver naar achteren, tot voorbij Waldeyer’s fascia.
  - Nerve bundels
  - Rectum en uterus
- De procedure wordt beoordeeld door experts met behulp van een beoordelingsformulier. Maar met de uitkomsten hiervan lijkt weinig te worden gedaan.
- Het beoordelingsformulier treedt niet in detail. Een onderdeel van de procedure wordt aangehaald, en in zijn geheel afgevinkt op een schaal van 1-5.
- Iedereen ‘slaagt’.
- Er wordt veel aandacht besteedt aan anatomie en het belang van anatomische kennis bij deze procedure.
- Bij de colleges worden veel missers aangekaart, en het belang van goede training aangehaald.
- De houding van de handen is anders dan gewone laparoscopie. In plaats uit elkaar zitten de handen zijn ze hier dichtbij en boven elkaar.
- Nadruk op de volgorde van het eerste opensnijden van het rectum (de ‘full thickness incision’). Als je het op een klok zou aflezen zou dat zijn 5, 7, 4, 8, 1, 11, 2, 10, 3, 9. Dus posterior beginnen tot bijna halverwege omhoog, en dan van boven naar beneden. Dat minimaliseert het risico op te ver naar buiten gaan.
- Voor de ‘full thickness incision’’ wordt de plek waar gesneden gaat worden gemarkeerd, ingebrand.
- Een tweede purse string wordt gedaan bij het vastmaken van de stapler voor anastomose. Maar dat gebeurt handmatig, buiten de buik.
- In de purse string is het overpakken van de naald tussen de grijper en de naaldvoerder erg belangrijk. Dan kan je in 1 keer ‘doordraaien’ en hoef je niet te frutselen.
- Spiralen of tilten gebeurt bij de beginners duidelijk
- In de darm bevindt zich een natuurlijke plooi. Het lijkt dat die gevolgd wordt, maar dat kan ook toeval zijn.
- Experts noemen een learning curve van zo’n 30 casus voor de transanale purse string suture

D. List of potential parameters

Port

Forces

Fx
Fy
Fz
Fres

Moments

Mx
My
Mres

Instrument motion

Path length
Velocity
Acceleration
Jerk
Rotation about long axis

Suture

Tissue interaction force

Fx Fx
Fy
Fz

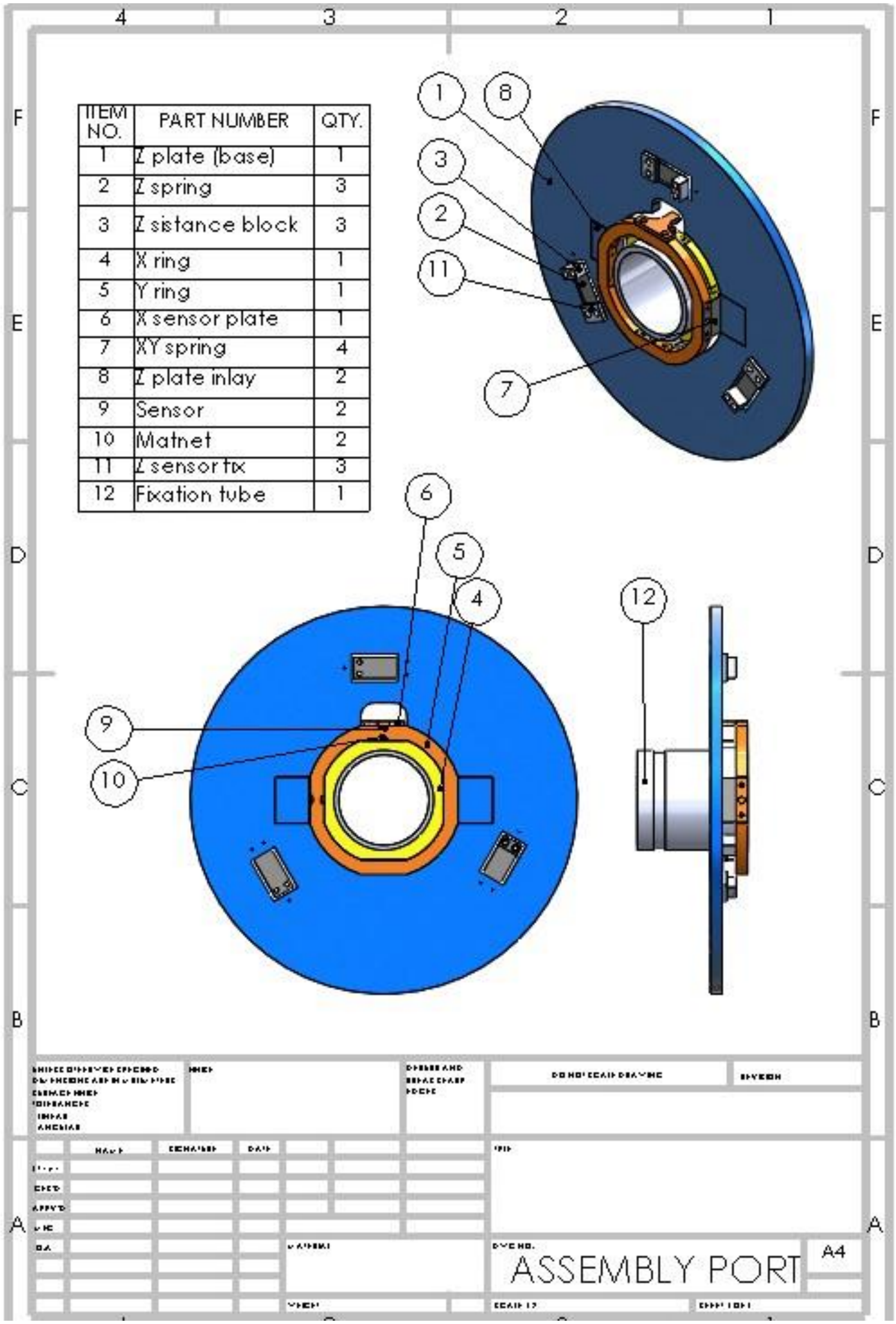
Scores

Number of stitches
Skew on stitch

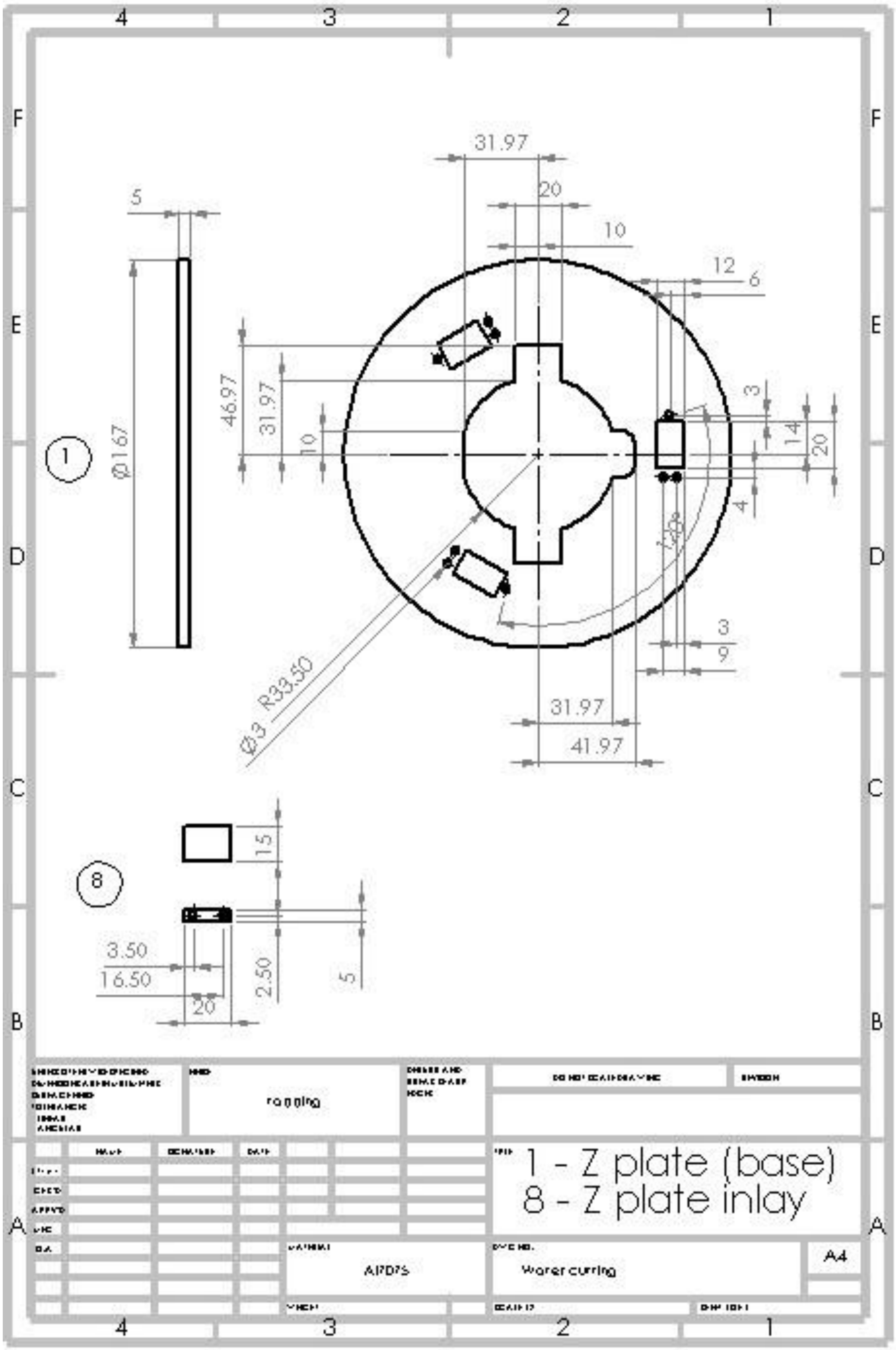
Other

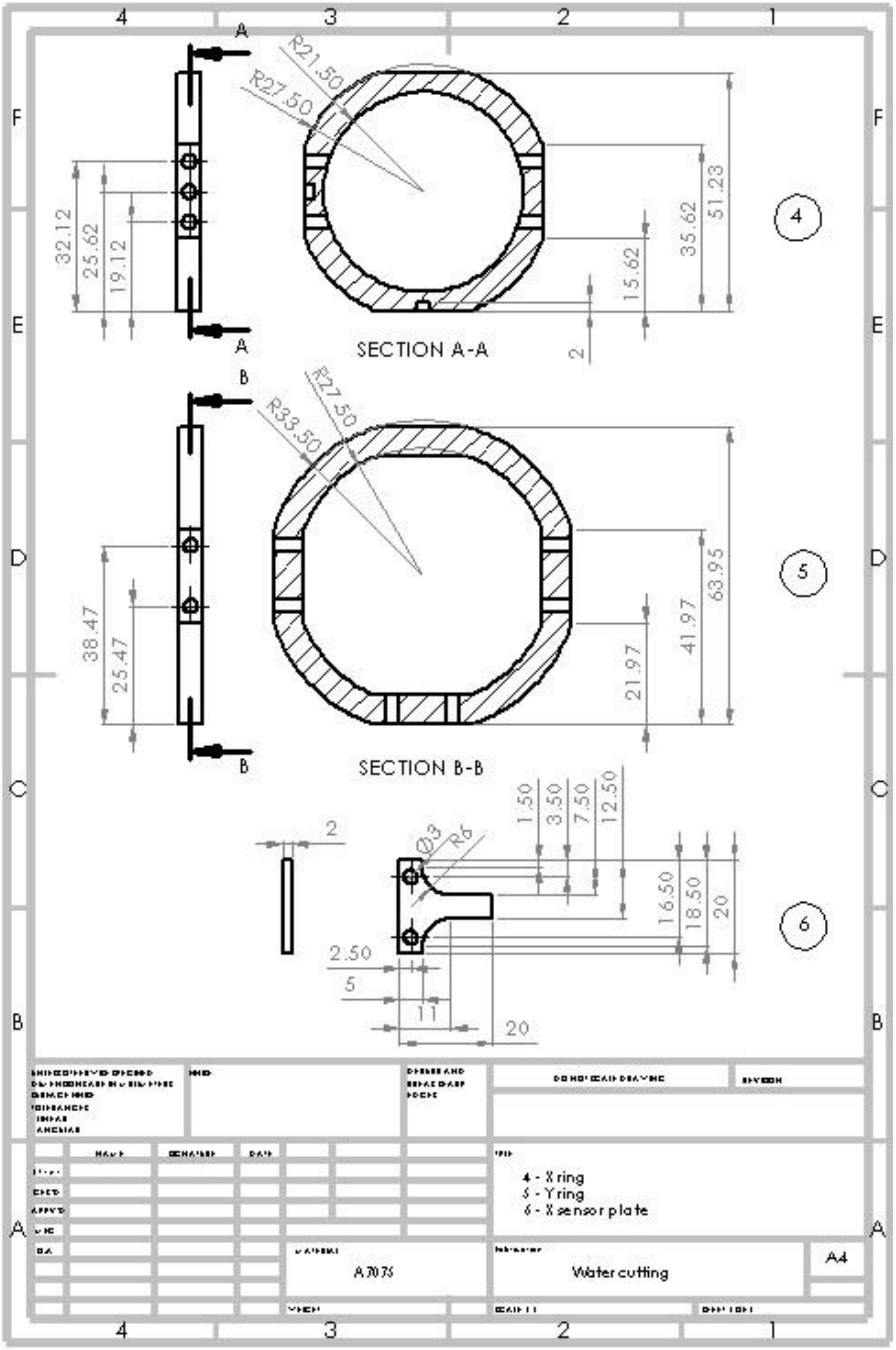
Time

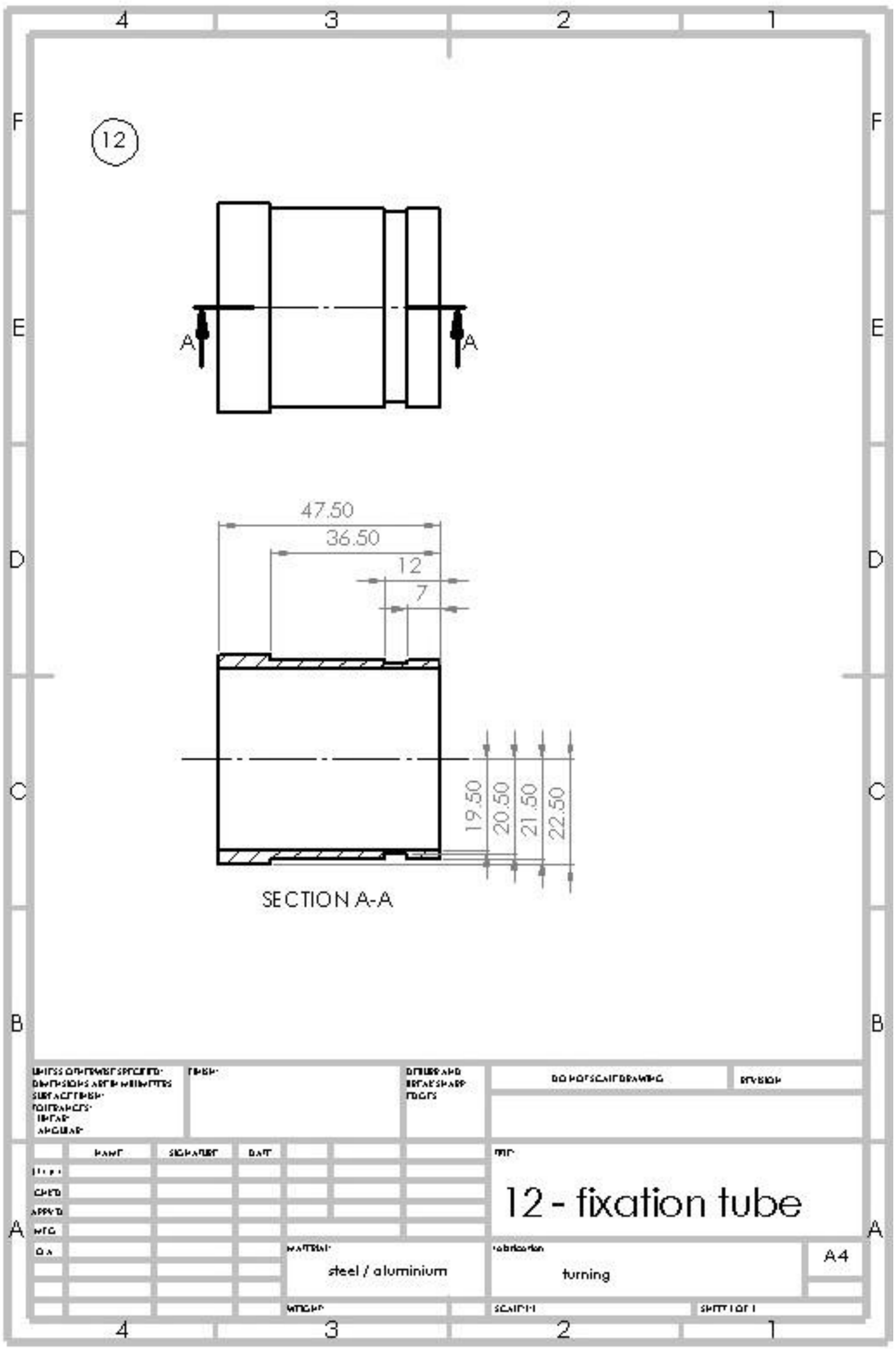
E. Technical drawings - port components

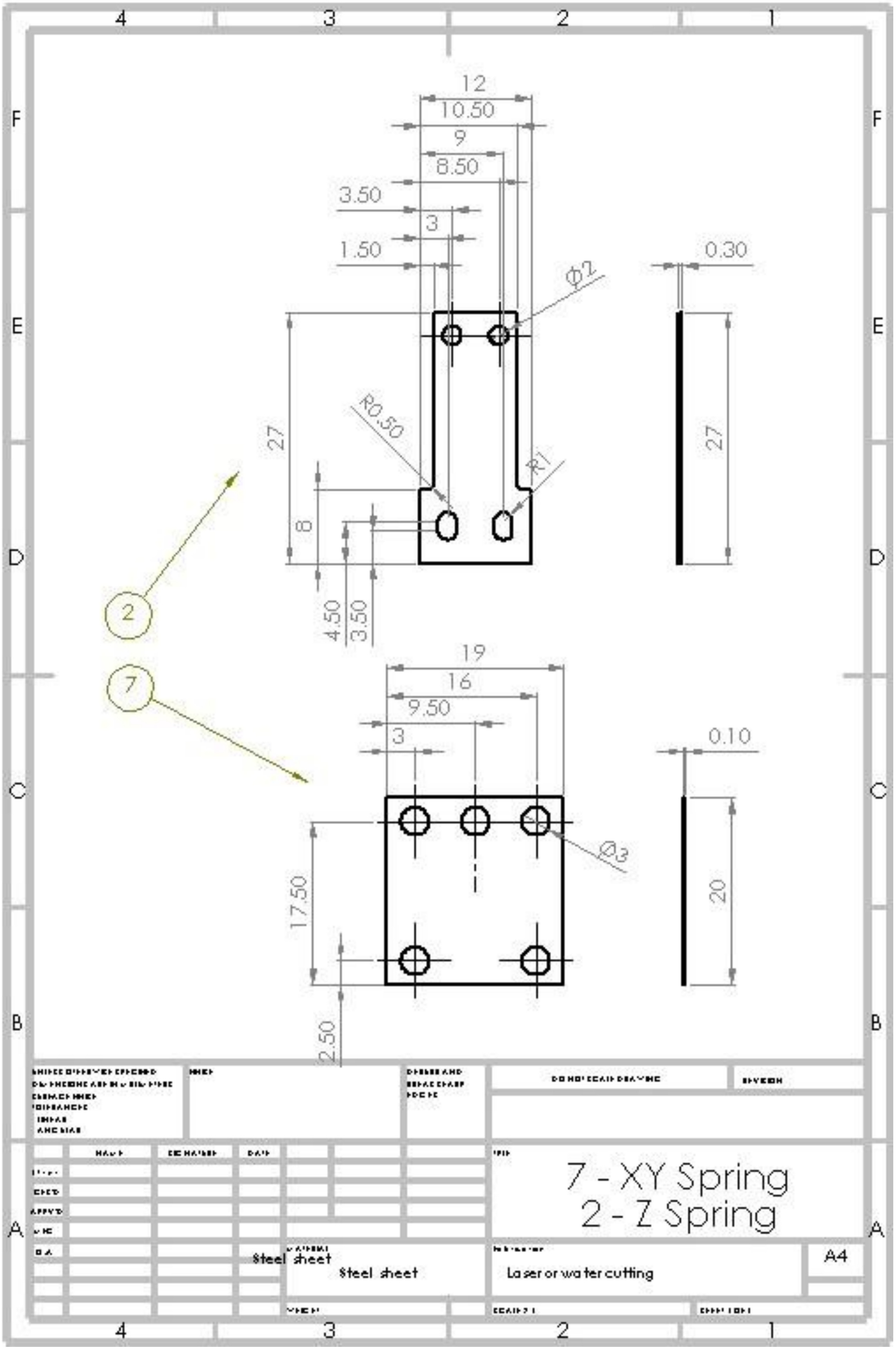


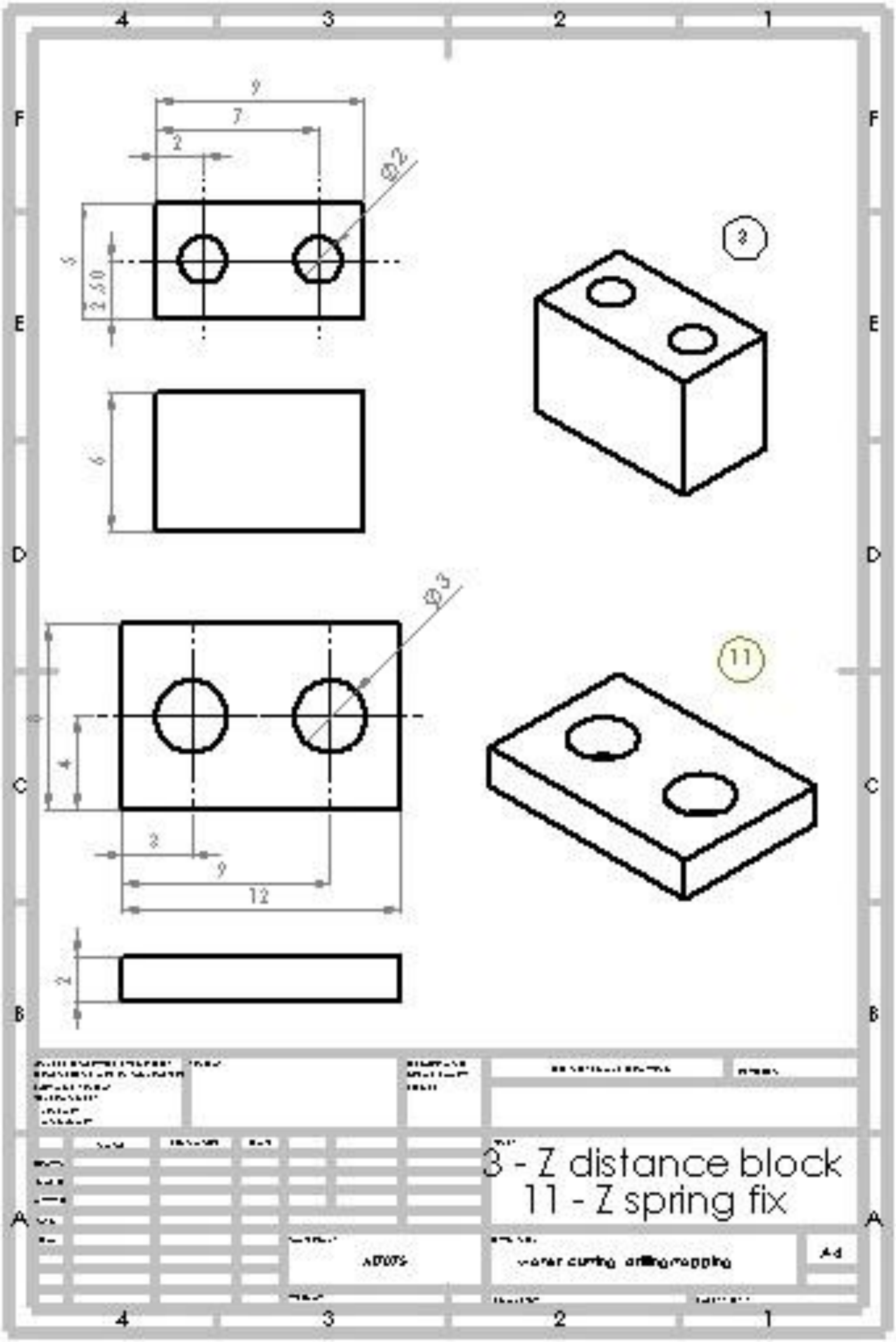
ITEM NO.	PART NUMBER	QTY.
1	Z plate (base)	1
2	Z spring	3
3	Z sistance block	3
4	X ring	1
5	Y ring	1
6	X sensor plate	1
7	XY spring	4
8	Z plate inlay	2
9	Sensor	2
10	Matnet	2
11	Z sensor fix	3
12	Fixation tube	1


31.97
20
10
12
6
5
46.97
31.97
10
3
14
20
4
Ø167
1
R33.50
Ø3
3
9
31.97
41.97
15
8
3.50
16.50
20
2.50
5
1 - Z plate (base)
8 - Z plate inlay
A4
Water curring
AlPD75

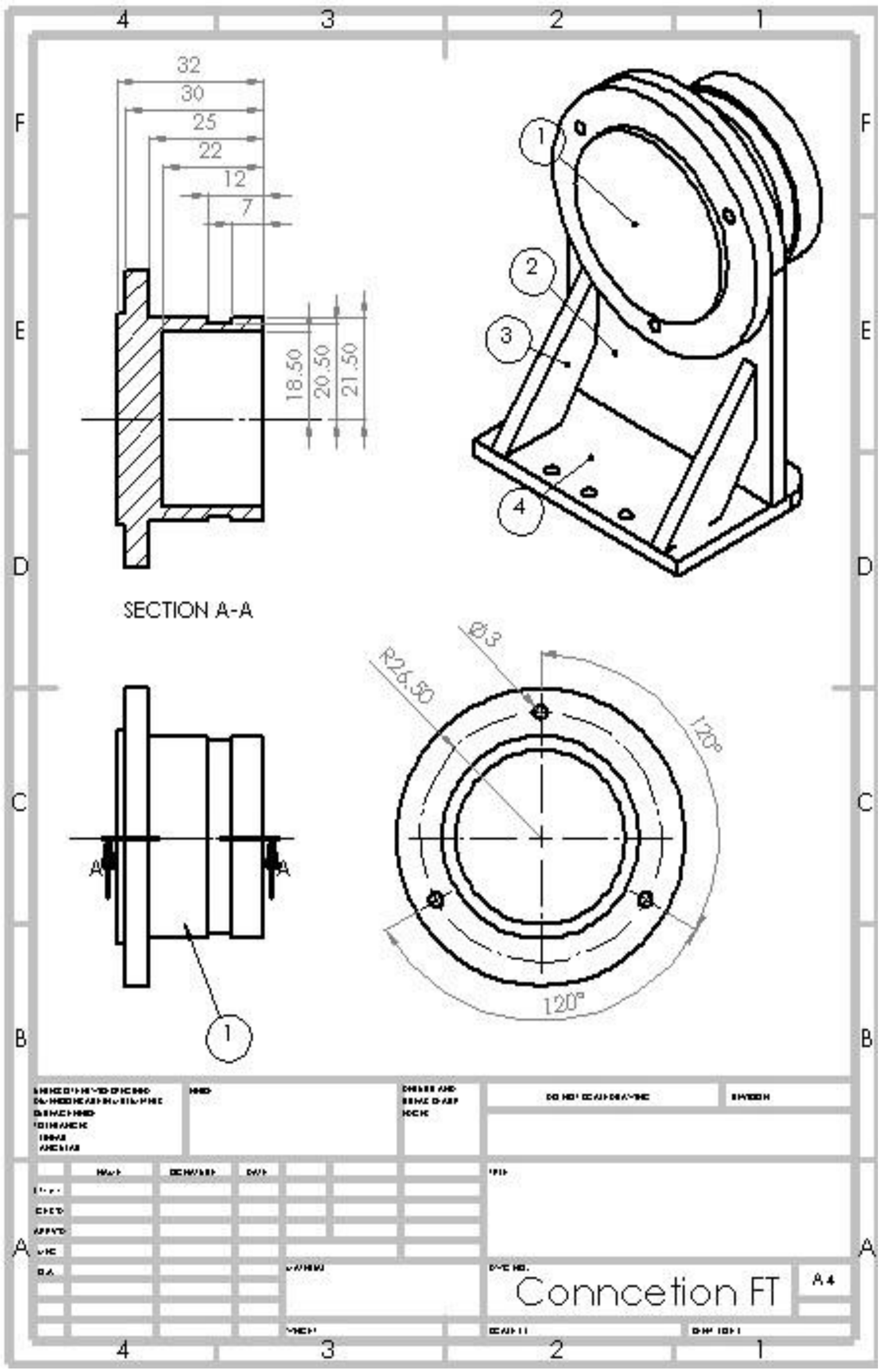

SECTION A-A
R21.50
R27.50
32.12
25.62
19.12
51.23
35.62
15.62
2
SECTION B-B
R27.50
R33.50
38.47
25.47
63.95
41.97
21.97
1.50
3.50
7.50
12.50
Ø3
R6
2
16.50
18.50
20
2.50
5
11
20
4 - X ring
5 - Y ring
6 - X sensor plate
A7075
Water cutting
A4

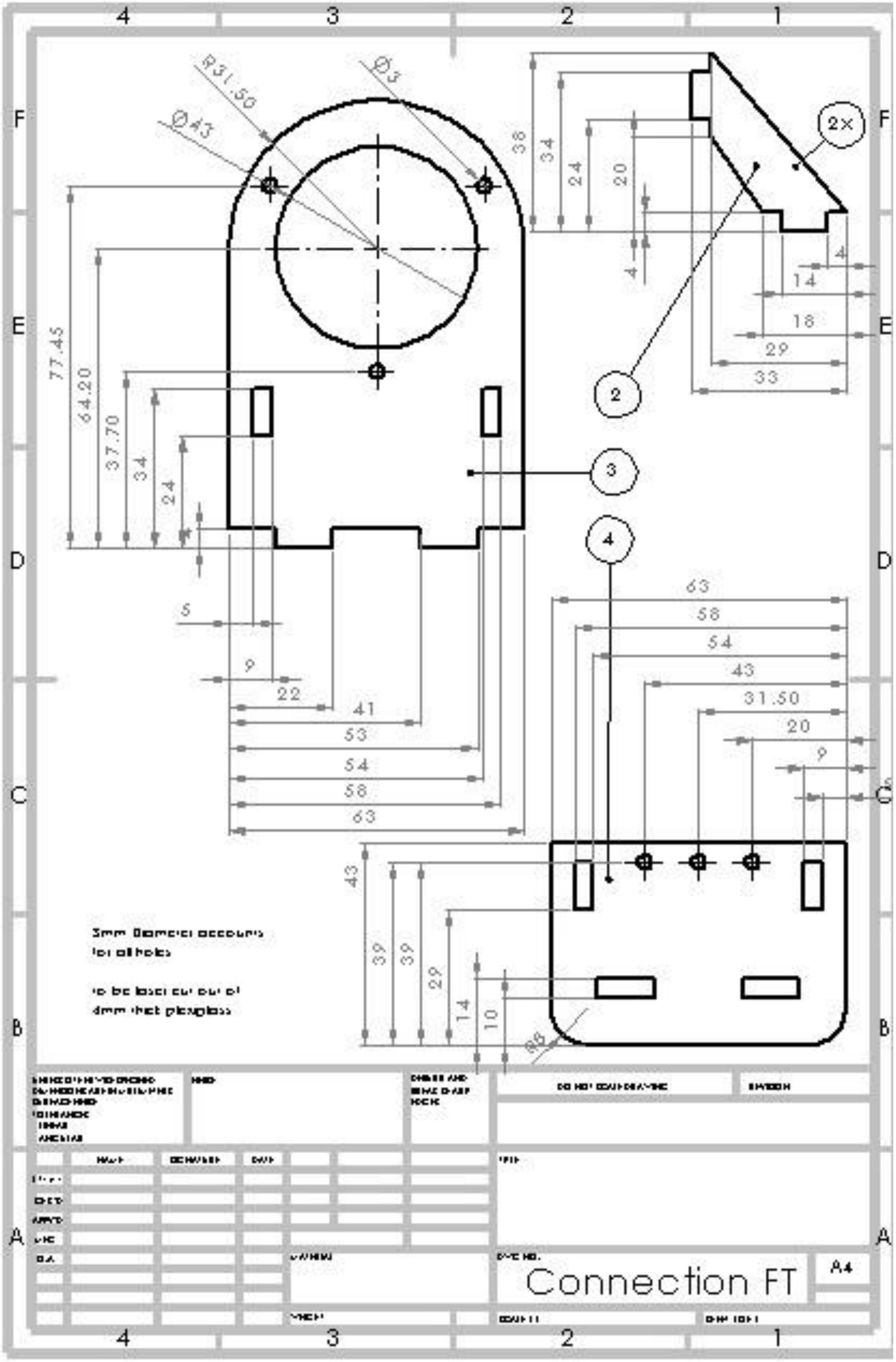

12
A
A
47.50
36.50
12
7
19.50
20.50
21.50
22.50
SECTION A-A
12 - fixation tube
steel / aluminium
turning
A4


12
10.50
9
8.50
3.50
3
1.50
Ø2
0.30
27
R0.50
R1
27
8
4.50
3.50
2
7
19
16
9.50
3
0.10
Ø3
17.50
20
2.50
DO NOT SCALE DRAWING
REVISION
NAME
SIGNATURE
DATE
7 - XY Spring
2 - Z Spring
Steel sheet
Steel sheet
Laser or water cutting
A4

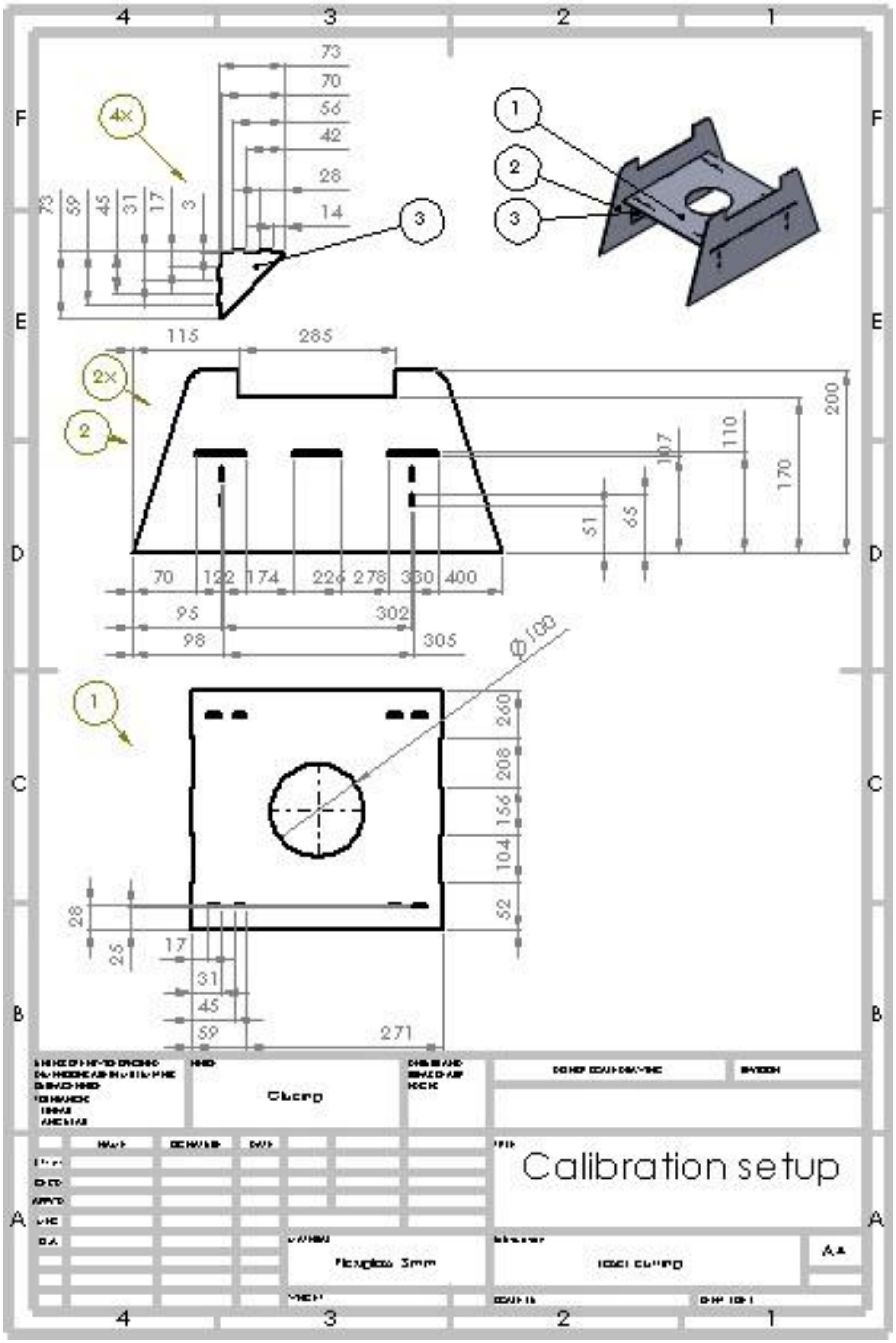

9
7
2
Ø2
5
2.50
6
Ø3
4
3
9
12
2
3
11
3 - Z distance block
11 - Z spring fix
AlZ07S
water cutting drilling/tapping
A4

F. Technical drawings - ForceTRAP connection

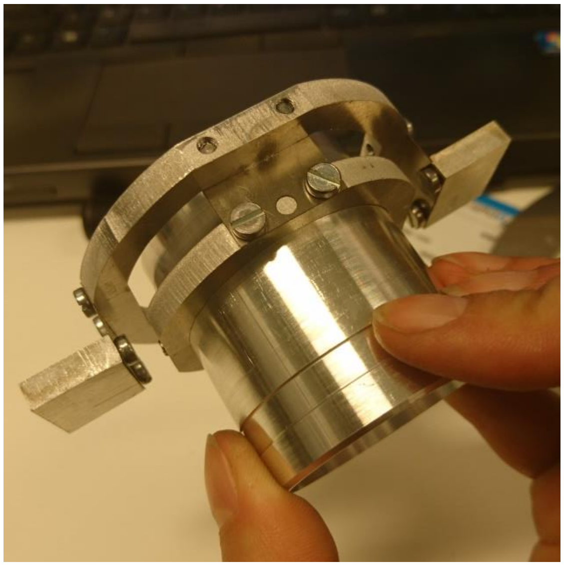


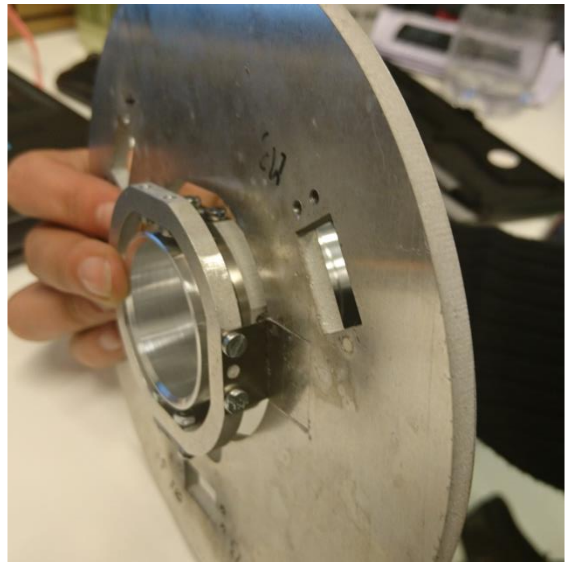

Connection FT
A4

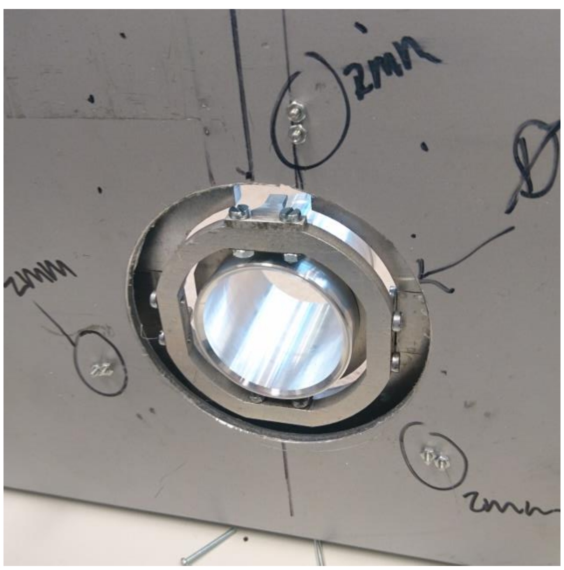
G. Technical drawings - calibration setup



H. Pictures – production and assembly


Rings for motion in x and y, attached to the fixation tube


x-y platform attached to the base plate


Complete design mounted to the wall of the box (view from outside)


Complete design mounted to the wall of the box including silicon tube of GelPoint Path.
(inside view)

I. Pilot – Matlab code ForceTrap

```
clear all; close all; clc

%%

datestamp = datestr(now,'yyyymmdd-HHMMSS');

%%

% ForceTrap serial example
%
% Author: DJ van Gerwen
% Created: 2017 dec 6

% Parameters
recording_time_s = 60;

% Constants
forcetrap_freq_Hz = 50; % Do not change this value

% Close any serial objects inadvertently left open after previous session
%fclose(instrfind);
delete(instrfindall);


% Configure serial port
forcetrap_port = 'COM3';  % Check windows device manager for correct port
serial_obj = serial(forcetrap_port);
%set(serial_obj,'baudrate',57600,'terminator',{'CR/LF','LF'});
set(serial_obj,'baudrate',57600,'terminator','LF');

% Open port
fopen(serial_obj);

% Pausing 5 seconds to let ForceTrap reset
disp('Pausing 5 seconds to let ForceTrap reset...');
pause(5);

try
    % Forcetrap initialization (set idle state)
    fprintf(serial_obj, 'iets');
    message = '';
    while serial_obj.BytesAvailable
        message = fscanf(serial_obj);
    end
    disp(message)

    % Set forcetrap stream state
    flushinput(serial_obj);
    fprintf(serial_obj, 'rec');
```

```
    % Get requested number of data samples from the forcetrap
    number_of_samples = recording_time_s * forcetrap_freq_Hz;
    fprintf(1, 'Recording %u samples at %.0f Hz (approx. %.1f seconds)\n',
number_of_samples, forcetrap_freq_Hz, recording_time_s);
    messages = cell(number_of_samples, 1);
    tic
    for i = 1:number_of_samples
        messages{i} = fscanf(serial_obj);
    end

% Set forcetrap idle state
    fprintf(serial_obj, 'stop');
    flushinput(serial_obj)
    disp('Recording stopped')
    fprintf('Time elapsed: %.1fs\n', toc);
    disp(serial_obj.BytesAvailable)

    % Convert string messages to doubles
    time_s = zeros(number_of_samples, 1);
    force_xyz_N = zeros(number_of_samples, 3);
    for i = 1:number_of_samples
        message_data = str2num(messages{i}(6:end-3)); %#ok<ST2NM>
        time_s(i) = message_data(end)/1000;
        force_xyz_N(i,:) = message_data(end-3:end-1);
    end
    time_s = time_s-time_s(1);

    % Show result
    plot(time_s, force_xyz_N)
    xlabel 'time [s]'
    ylabel 'force [N]'
    legend('F_x','F_y','F_z')

    % Save file

    file_name = sprintf('cali_ft_z_100_%s.mat', datestamp);
    save(file_name, 'time_s', 'force_xyz_N')

catch err
    % Show error info
    disp(err.message)
    disp(err.stack)
end

% Clean up serial object
fclose(serial_obj);
delete(serial_obj);
```

J. Pilot – questionnaire results

Label	Gender	Dexterity	Specialty	Laparoscopic experience in theatre (number of advanced procedures, i.e. any other than lap. Appendectomy, -cholecystectomy, -TEP/TAPP)	Experience with single port surgery	Experience with TaTME procedure	Number of performed transanal purse string sutures	Experience with laparoscopic box trainer
1	M	R	coloproctology	>100	6-10	1-10	1-10	1-10
2	M	R	general surgery	>100	1-5	0	0	1-10
3	F	R	colorectal surgery	51-100	6-10	0	0	11-50
4	M	R	colorectal surgery	51-100	6-10	0	0	0
5	M	R	GE surgery	>100	>20	0	1-10	11-50
6	M	R	GE surgery	>100	>20	11-50	11-50	>100
7	M	R	colorectal surgery	>100	>20	0	0	11-50
8	M	R	colorectal surgery	>100	>20	51-100	51-100	11-50
9	M	R	colorectal surgery	>100	>20	>100	>100	51-100
10	M	R	GI surgery	>100	>20	51-100	51-100	51-100
11	M	R	general surgery	>100	6-10	1-10	1-10	11-50
12	M	L	CR surgery	>100	>20	11-50	11-50	11-50
13	M	R	general surgery	>100	>10	>100	>100	11-50

K. Pilot – descriptive statistics Z

	N	Minimum	Maximum	Mean	Std. Deviation	time
Fz1.1	14499	-.65	2.62	.3649	.46860	290
Fz1.2	13636	-.96	4.17	.8424	1.11780	273
Fz1.3	26700	-.84	4.17	.5485	.83359	534
Fz1.4	14803	-.60	3.75	.5076	.66064	296
Fz1.5	14000	-.70	4.17	.8013	.82463	280
Fz1.6	14300	-.62	4.17	.5211	.66460	286
Fz1.7	8350	-.81	4.17	2.6342	1.46335	167
Fz1.8	5938	-1.09	1.32	-.5693	.45921	119
Fz1.9	6685	-.70	1.23	-.0440	.36539	134
Fz1.10	8954	-.78	1.84	.0322	.40127	179
Fz1.11	9448	-.93	2.44	.2921	.54456	189
Fz1.12	8266	-.90	1.48	-.0839	.45729	165
Fz1.13	6478	-1.02	2.32	-.0025	.55709	130

	N	Minimum	Maximum	Mean	Std. Deviation
Fz2.1	14499	-1.05	1.34	-.3518	.41232
Fz2.2	13636	-1.09	3.94	-.3643	.64685
Fz2.3	26700	-1.12	3.04	-.6240	.26211
Fz2.4	14803	-1.09	2.74	.1507	.73997
Fz2.5	14000	-1.12	.91	-.7150	.16867
Fz2.6	14300	-1.09	1.90	-.4102	.32072
Fz2.7	8350	-1.09	1.02	-.8271	.22074
Fz2.8	5938	-.84	.22	-.5352	.17893
Fz2.9	6685	-.88	1.18	-.2409	.41841
Fz2.10	8954	-.88	.71	-.3119	.33358
Fz2.11	9448	-.84	3.89	.1111	.74615
Fz2.12	8266	-.81	.75	-.4014	.23794
Fz2.13	6478	-1.05	1.54	-.5583	.30326

	N	Minimum	Maximum	Mean	Std. Deviation
Fz1.1	14499	-.65	2.62	.3649	.46860
Fz1.2	13636	-.96	4.17	.8424	1.11780
Fz1.3	26700	-.84	4.17	.5485	.83359
Fz1.4	14803	-.60	3.75	.5076	.66064
Fz1.5	14000	-.70	4.17	.8013	.82463
Fz1.6	14300	-.62	4.17	.5211	.66460
Fz1.7	8350	-.81	4.17	2.6342	1.46335
Fz1.8	5938	-1.09	1.32	-.5693	.45921
Fz1.9	6685	-.70	1.23	-.0440	.36539
Fz1.10	8954	-.78	1.84	.0322	.40127
Fz1.11	9448	-.93	2.44	.2921	.54456
Fz1.12	8266	-.90	1.48	-.0839	.45729
Fz1.13	6478	-1.02	2.32	-.0025	.55709

L. Pilot – independent samples T-test Z

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Time	e.v.a.*	1.252	.292	-2.418	9	.039	-149.35714	61.76204	-289.07258	-9.64171
	e.v.n.aº			-3.180	6.974	.016	-149.35714	46.96259	-260.49072	-38.22357
Fz1_min	e.v.a.	1.477	.255	-1.156	9	.278	-.11321	.09796	-.33482	.10839
	e.v.n.a.			-1.057	4.932	.340	-.11321	.10713	-.38975	.16332
Fz1_max	e.v.a.	1.359	.274	-4.490	9	.002	-1.96393	.43742	-2.95344	-.97441
	e.v.n.a.			-5.070	8.664	.001	-1.96393	.38735	-2.84537	-1.08248
Fz1_mean	e.v.a.	.917	.363	-2.345	9	.044	-1.00176	.42727	-1.96830	-.03521
	e.v.n.a.			-2.967	8.107	.018	-1.00176	.33761	-1.77849	-.22502
Fz1_SD	e.v.a.	3.090	.113	-2.214	9	.054	-.39900	.18024	-.80674	.00874
	e.v.n.a.			-2.897	7.135	.023	-.39900	.13774	-.72345	-.07455
Fz2_min	e.v.a.	.014	.910	2.380	9	.041	.14464	.06078	.00716	.28213
	e.v.n.a.			2.418	6.671	.048	.14464	.05982	.00176	.28752
Fz2_max	e.v.a.	6.856	**.028**	-2.130	9	.062	-1.49893	.70387	-3.09120	.09334
	e.v.n.a.			-2.614	8.726	.029	-1.49893	.57352	-2.80255	-.19531
Fz2_mean	e.v.a.	2.198	.172	-.181	9	.861	-.03723	.20589	-.50300	.42853
	e.v.n.a.			-.224	8.578	.828	-.03723	.16625	-.41616	.34170
Fz2_SD	e.v.a.	9.044	**.015**	-1.110	9	.296	-.14814	.13348	-.45010	.15381
	e.v.n.a.			-1.383	8.461	.202	-.14814	.10713	-.39285	.09657
Fz3_min	e.v.a.	1.477	.255	-1.156	9	.278	-.11321	.09796	-.33482	.10839
	e.v.n.a.			-1.057	4.932	.340	-.11321	.10713	-.38975	.16332
Fz3_max	e.v.a.	1.359	.274	-4.490	9	.002	-1.96393	.43742	-2.95344	-.97441
	e.v.n.a.			-5.070	8.664	.001	-1.96393	.38735	-2.84537	-1.08248
Fz3_mean	e.v.a.	.917	.363	-2.345	9	.044	-1.00176	.42727	-1.96830	-.03521
	e.v.n.a.			-2.967	8.107	.018	-1.00176	.33761	-1.77849	-.22502
Fz3_SD	e.v.a.	3.090	.113	-2.214	9	.054	-.39900	.18024	-.80674	.00874
	e.v.n.a.			-2.897	7.135	.023	-.39900	.13774	-.72345	-.07455

* equal variances assumed

º equal variances not assumed

M. Pilot – descriptive statistics X, Y

	N	Minimum	Maximum	Mean	Std. Deviation
x_1	14499	.850	.870	.85850	.003702
x_2	13636	.848	.876	.85856	.003596
x_3	14499	.843	.874	.85791	.003258
x_4	14499	.849	.870	.85710	.003017
x_5	14000	.846	.877	.85542	.003409
x_6	14300	.844	.875	.85871	.002885
x_7	8350	.834	.864	.85385	.003462
x_8	8350	.834	.864	.85385	.003462
x_9	6685	.852	.871	.86147	.002068
x_10	8954	.852	.866	.86006	.001677
x_11	9448	.846	.866	.85717	.003021
x_12	8266	.854	.874	.86294	.003084
x_13	6478	.854	.873	.86169	.002271
	N	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
y_1	14499	1.060	1.150	1.12348	.009743
y_2	13636	1.087	1.142	1.11632	.006411
y_3	14499	1.050	1.154	1.12172	.006850
y_4	14499	1.083	1.147	1.12008	.006827
y_5	14000	1.092	1.145	1.12077	.005114
y_6	14300	1.092	1.212	1.11916	.005057
y_7	8350	1.076	1.142	1.12137	.007996
y_8	8350	1.076	1.142	1.12137	.007996
y_9	6685	1.101	1.136	1.11772	.004863
y_10	8954	1.104	1.150	1.12582	.005988
y_11	9448	1.082	1.162	1.12636	.008134
y_12	8266	1.101	1.152	1.12508	.004908
y_13	6478	1.113	1.146	1.12907	.005446

N. Pilot – independent samples T-test X, Y

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
x_min	e.v.a.*	1.633	.233	.651	9	.531	.00286	.00439	-.00707	.01278
	e.v.n.aº.			.558	4.182	.605	.00286	.00512	-.01112	.01683
x_max	e.v.a.	.151	.707	-.848	9	.418	-.00250	.00295	-.00917	.00417
	e.v.n.a.			-.890	7.315	.402	-.00250	.00281	-.00909	.00409
x_mean	e.v.a.	2.594	.142	1.461	9	.178	.00234	.00160	-.00128	.00596
	e.v.n.a.			1.196	3.773	.301	.00234	.00195	-.00322	.00789
x_SD	e.v.a.	3.658	.088	-3.170	9	.011	-.00098	.00031	-.00168	-.00028
	e.v.n.a.			-2.472	3.420	.079	-.00098	.00040	-.00216	.00020
y_min	e.v.a.	.012	.915	2.354	9	.043	.02279	.00968	.00089	.04468
	e.v.n.a.			2.326	6.151	.058	.02279	.00979	-.00104	.04661
y_max	e.v.a.	.205	.661	-1.251	9	.242	-.00536	.00428	-.01504	.00433
	e.v.n.a.			-1.324	7.492	.224	-.00536	.00405	-.01480	.00408
y_mean	e.v.a.	2.083	.183	.857	9	.414	.00205	.00239	-.00336	.00747
	e.v.n.a.			.747	4.353	.494	.00205	.00275	-.00534	.00944
y_SD	e.v.a.	.121	.736	-1.354	9	.209	-.00122	.00090	-.00327	.00082
	e.v.n.a.			-1.388	6.856	.209	-.00122	.00088	-.00332	.00087

* equal variances assumed

º equal variances not assumed

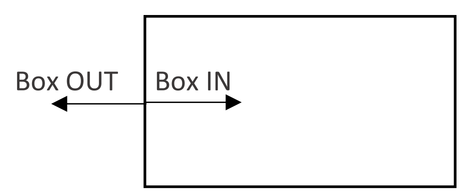
O. Calibration – measurement data

BOX OUT

Total mass applied	**Force per spring**	**Voltage**		
	(m*9.81/3)	Z1	Z2	Z3
m [kg]	**F [N]**	**[V]**	**[V]**	**[V]**
-2,500	-9.156	3.150	3.035	3.279
-2,400	-8.829	3.141	3.030	3.261
-2,300	-8.502	3.131	3.026	3.243
-2,200	-8.175	3.122	3.021	3.226
-2,100	-7.848	3.115	3.016	3.213
-2,000	-7.521	3.107	3.006	3.194
-1,900	-7.194	3.099	2.996	3.176
-1,800	-6.867	3.092	2.985	3.158
-1,700	-6.54	3.085	2.976	3.144
-1,600	-6.213	3.078	2.967	3.127
-1,500	-5.886	3.071	2.958	3.113
-1,400	-5.559	3.064	2.950	3.101
-1,300	-5.232	3.058	2.942	3.089
-1,200	-4.905	3.053	2.935	3.077
-1,100	-4.578	3.048	2.929	3.065
-1,000	-4.251	3.041	2.923	3.055
-0,900	-3.924	3.032	2.918	3.047
-0,800	-3.597	3.020	2.913	3.039
-0,700	-3.27	3.008	2.907	3.026
-0,600	-2.943	2.998	2.902	3.010
-0,500	-2.616	2.987	2.897	2.995
-0,400	-2.289	2.978	2.891	2.981
-0,300	-1.962	2.969	2.886	2.969
-0,200	-1.635	2.961	2.880	2.958
-0,100	-1.308	2.954	2.874	2.948
0	0	2.905	2.841	2.907

BOX IN

Total mass applied	**Force per spring**	**Voltage**		
	(m*9.81/3)	Z1	Z2	Z3
m [kg]	**F [N]**	**[V]**	**[V]**	**[V]**
0,100	1.308	2.860	2.811	2.858
0,200	1.635	2.853	2.804	2.850
0,300	1.962	2.845	2.797	2.843
0,400	2.289	2.838	2.790	2.835
0,500	2.616	2.830	2.783	2.827
0,600	2.943	2.822	2.776	2.818
0,700	3.27	2.813	2.770	2.810
0,800	3.597	2.805	2.764	2.801
0,900	3.924	2.798	2.759	2.793
0,1000	4.251	2.791	2.754	2.787
1,100	4.578	2.785	2.749	2.780
1,200	4.905	2.779	2.744	2.774
1,300	5.232	2.773	2.739	2.769
1,400	5.559	2.767	2.735	2.763
1,500	5.886	2.762	2.730	2.757
1,600	6.213	2.755	2.725	2.750
1,700	6.54	2.750	2.721	2.744
1,800	6.867	2.745	2.718	2.740
1,900	7.194	2.741	2.715	2.735
2,000	7.521	2.737	2.712	2.731



P. Calibration – polynomial constants

Fitting a second-degree polynomial:

$$y = (c_2 * x^2) + (c_1 * x) + b$$

Constants are calculated using MS Excel 2016 using the following functions. Where for ‘y’ the range of voltage data a selected, and for ‘x’ the corresponding range of force data.

$$c_2 := INDEX\left(LINEST\left(y, x^{\{1,2\}}\right), 1\right)$$

$$c_1 = INDEX\left(LINEST\left(y, x^{\{1,2\}}\right), 1,2\right)$$

$$b = INDEX\left(LINEST\left(y, x^{\{1,2\}}\right), 1,3\right)$$

This gives the following constants, and thus equations for Voltage at a certain applied load.

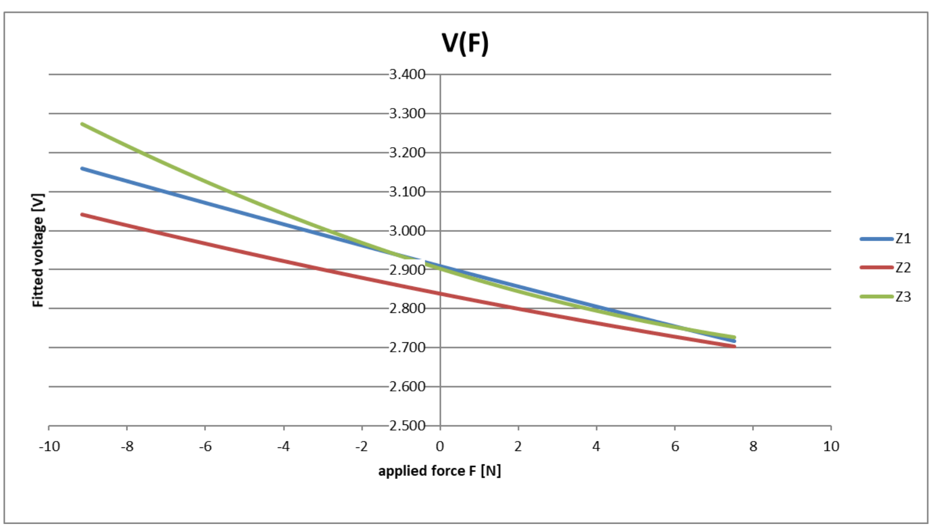
component	z1	z2	z3
c_2	0.0001046	0.0002487	0.0010247
c_1	-0.0263407	-0.0197997	-0.0310623
b	2.9095196	2.8382244	2.9029896

Filling in the constants gives the following equations for Voltage output as a function of applied force. They are plotted below.

$$V_{z1} = (0.0001 * F^2) - (0.0263 * F) + 2.9095$$

$$V_{z2} = (0.0003 * F^2) - (0.0198 * F) + 2.8382$$

$$V_{z3} = (0.0010 * F^2) - (0.0311 * F) + 2.9030$$



Q. Buckling X and Y

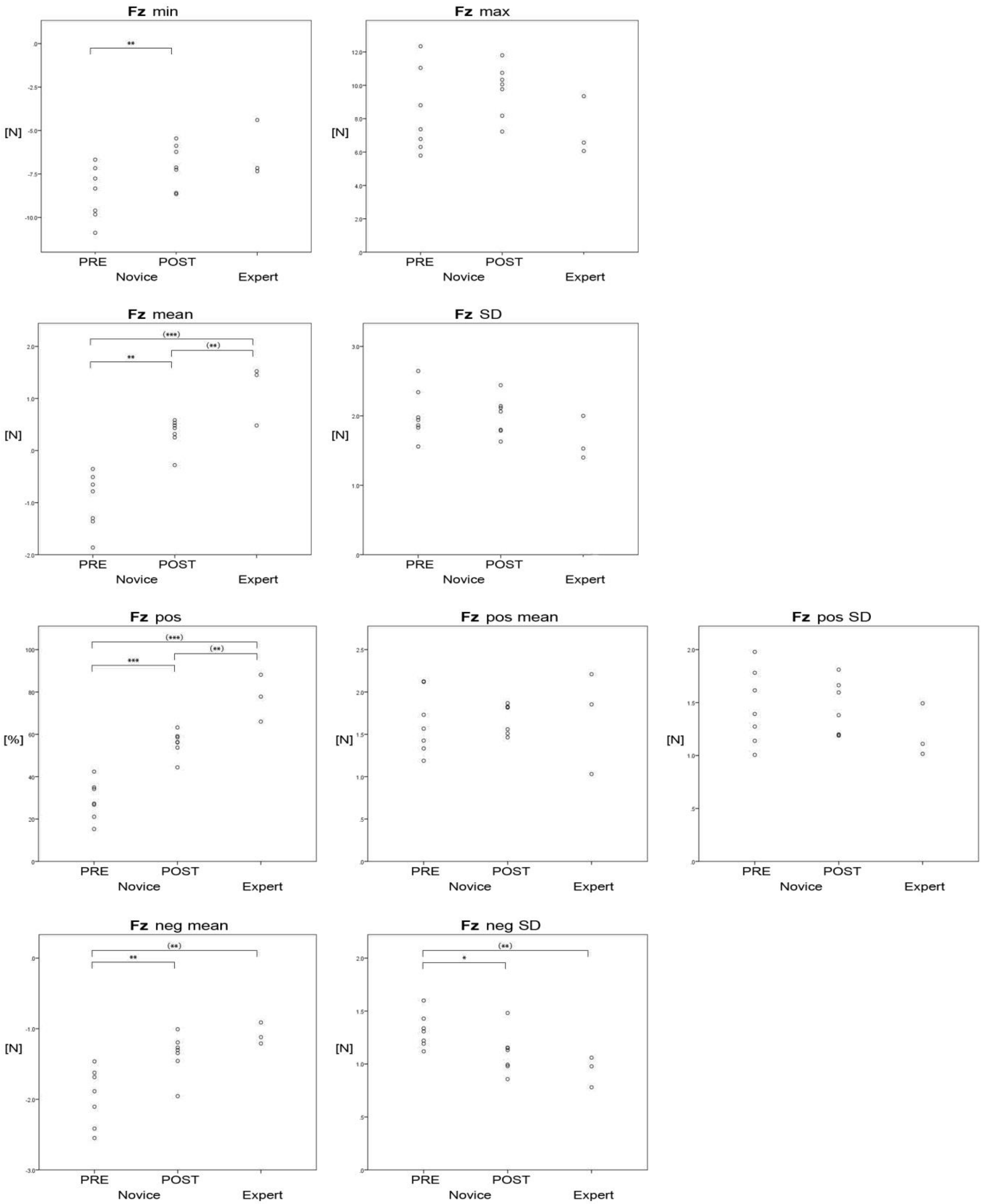
R. Construct validity - questionnaire result

Label	Gender	Dexterity	Specialty	Laparoscopic experience in theatre (number of advanced procedures, i.e. any other than lap. Appendectomy, -cholecystectomy, -TEP/TAPP)	Experience with laparoscopic box trainer	Experience with 30° scope	Experience with single port surgery	Experience with TaTME procedure	Number of performed transanal purse string sutures
1	M	R	coloproctology	11-50	>100	11-20	0	11-50	11-50
2	M	R	general surgery	11-50	>100	11-20	1-10	1-10	11-50
3	F	R	colorectal surgery	11-50	>100	11-20	1-10	0	11-50
4	M	R	colorectal surgery	1-10	>100	0	1-10	1-10	1-10
5	M	R	GE surgery	1-10	>100	11-20	0	0	1-10
6	M	R	GE surgery	1-10	>100	0	0	0	1-10
7	M	R	colorectal surgery	1-10	>100	11-20	0	0	1-10
8	M	R	colorectal surgery	1-10	>100	>20	1-10	1-10	1-10
9	M	R	colorectal surgery	11-50	>100	>20	>100	>100	11-50
10	M	R	GI surgery	11-50	?	>20	>100	>100	11-50
11	M	R	general surgery	51-100	?	>20	>100	>100	51-100
12	M	L	CR surgery	11-50	>100	0	11-50	11-50	11-50
S	M	R				0			
Y	F	R				>20			

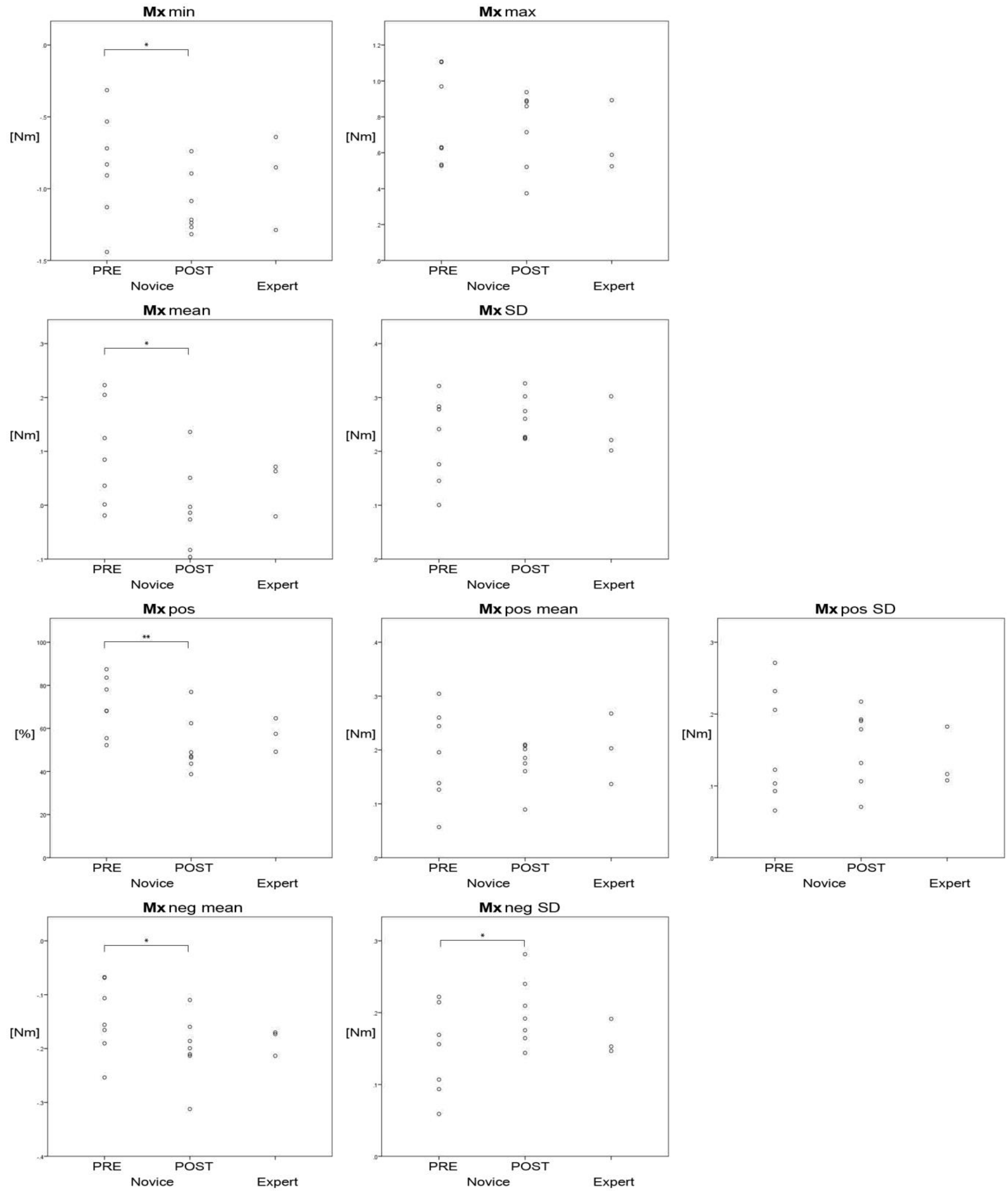
S. Construct validity – team composition

Team	Instruments	Scope	gloves	direction	extra	team experience
A	1	S	No	CW		Intermediate
B	2	S	No	CW		Novice
C	3	S	No	CW		Novice
D	4	S	Yes	CW		Novice
E	5	S	Yes	CCW	not finished	Novice
F	6	S	Yes	CW		Novice
G	7	S	Yes	CW		Novice
H	8	S	Yes	CW		Novice
I	9	Y	Yes	CW		Expert
J	10	Y	Yes	CW		Expert
K	11	Y	No	CW		Expert
L	12	Y	No	CW		Intermediate
M	8	P6	Yes	CW	H2	Novice
N	6	P8	Yes	CW	F2	Novice
O	1	P2	Yes	CW		Intermediate
P	2	P5	Yes	CW	B2	Novice
Q	5	P2	Yes	CCW	E2	Novice
R	7	P2	Yes	CW	G2	Novice
S	4	P3	Yes	CW	D2	Novice
T	3	P4	Yes	CW	C2	Novice

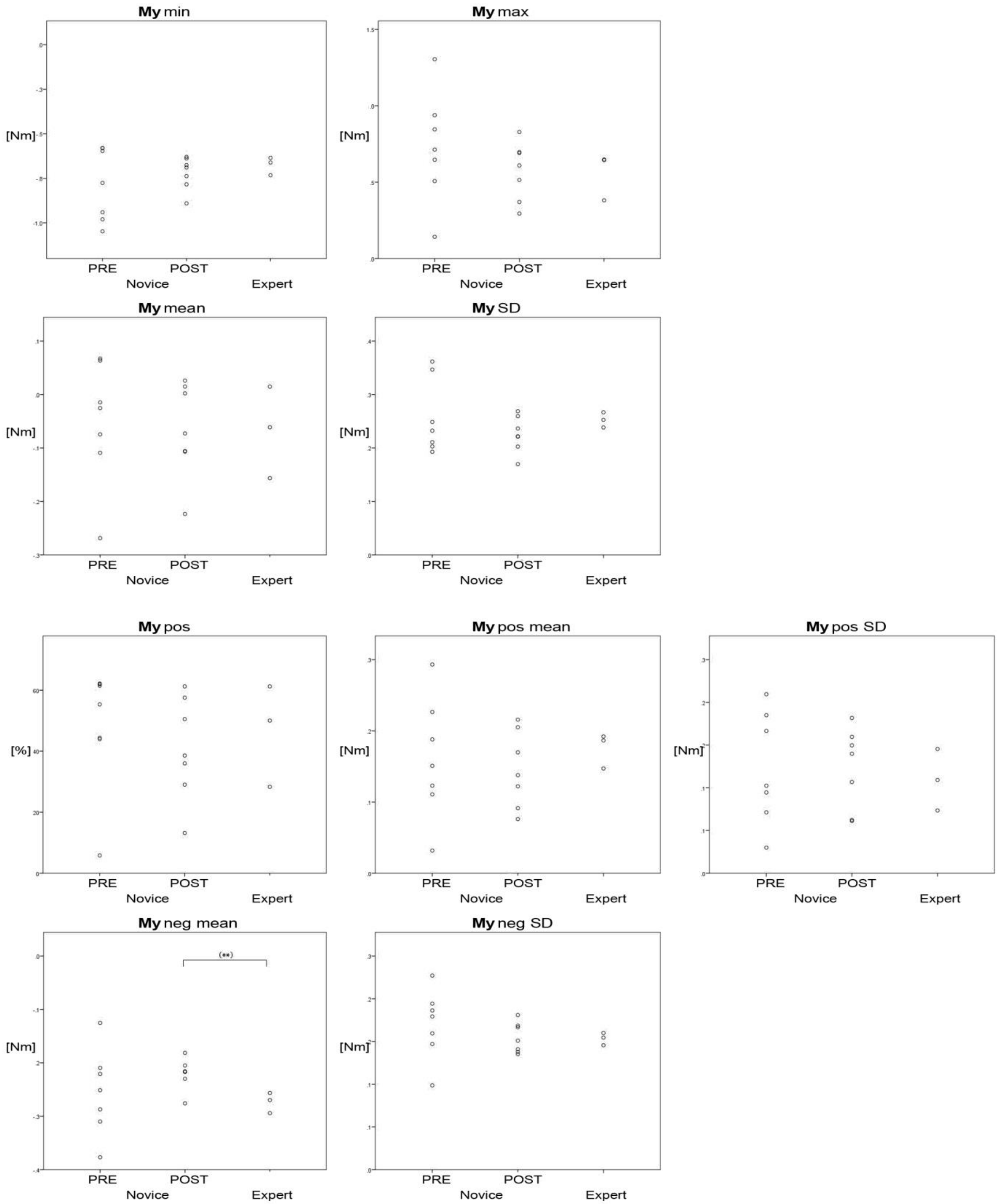
T. Construct validity – scatter plots Fz



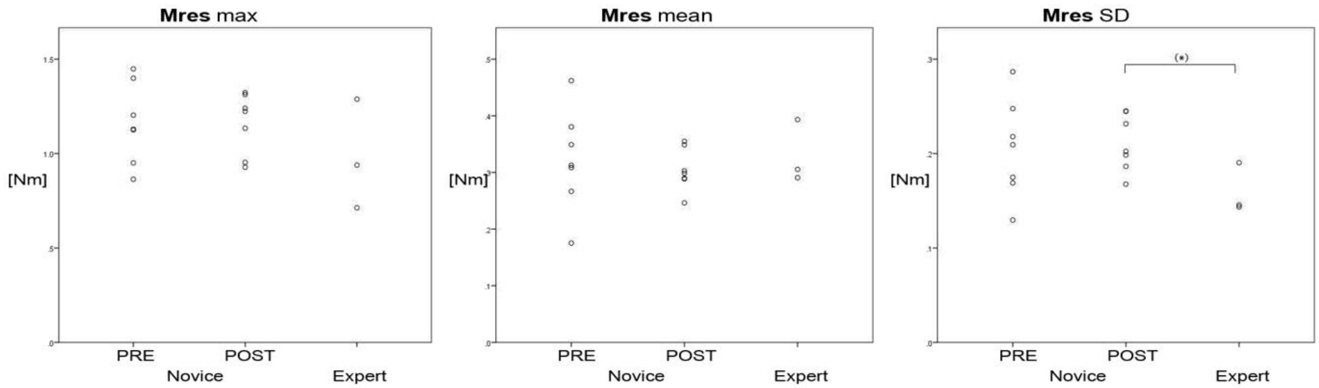
U. Construct validity – scatter plots Mx



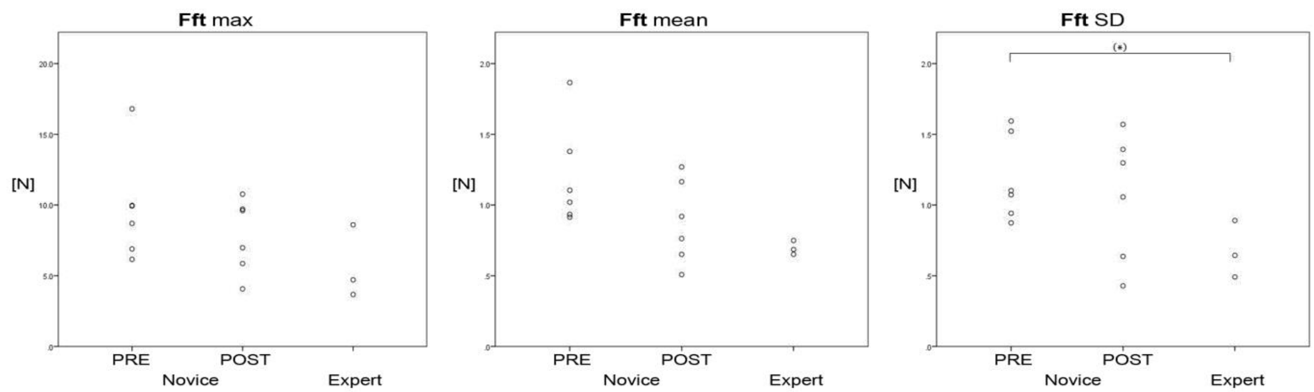
V. Construct validity – scatter plots My



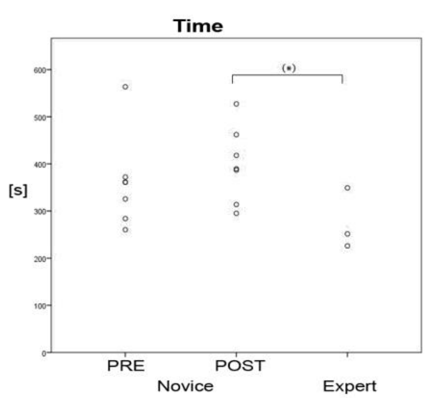
W. Construct validity – scatter plots Mres



X. Construct validity – scatter plots Fft



Y. Construct validity – scatter plots Task time



Z. Construct validity – descriptive statistics

Team	Fz1.pos	Fz2.pos	Fz3.pos	Fres.min	Fz.max	Fz.mean	Fz.SD	Fz.pos	Fz.pos.mean	Fz.pos.SD	Fz.neg	Fz.neg.mean	Fz.neg.SD
B1	50	61	11	-10.8896	11.0445	-1.2982	2.6452	27	2.1248	1.9785	73	-2.5489	1.5994
C1	83	44	7	-9.6069	6.3034	-1.3610	1.9409	21	2.1194	1.7810	79	-2.1055	1.3084
D1	41	78	11	-7.7630	8.8055	-0.5090	1.9786	35	1.4252	1.2733	65	-1.6238	1.1913
E1	36	58	50	-9.8308	12.3407	-0.3532	2.3401	42	1.5667	1.3922	58	-1.8861	1.4285
F1	33	68	32	-7.1741	5.7864	-1.8633	1.8300	15	1.7306	1.6154	85	-2.4141	1.3366
G1	51	53	36	-8.3394	7.3650	-0.6535	1.8635	34	1.1884	1.0057	66	-1.6849	1.2206
H1	34	53	46	-6.6792	6.7805	-0.7831	1.5581	27	1.3330	1.1386	73	-1.4637	1.1194
I	49	63	52	-4.3978	6.5648	1.5244	1.3998	88	1.0315	1.0157	12	-0.9114	0.7802
J	63	69	28	-7.1644	9.3491	1.4506	2.0004	78	1.8534	1.1101	22	-1.2092	1.0599
K	88	36	38	-7.3396	6.0627	0.4811	1.5287	66	2.2092	1.4931	34	-1.1203	0.9779
H2	55	68	35	-5.8814	11.7990	0.5308	2.1410	56	1.8677	1.8106	44	-1.1943	0.9930
F2	76	58	38	-6.2299	7.2286	0.2516	1.7858	54	1.5598	1.1877	46	-1.2672	0.9799
B2	39	63	60	-7.2567	10.7461	0.4322	2.1155	56	1.8189	1.5952	44	-1.3454	1.1513
E2	44	44	50	-8.5950	10.0544	-0.2798	2.4415	44	1.8167	1.6634	56	-1.9549	1.4816
G2	63	47	47	-7.1279	8.1729	0.4837	2.0629	59	1.8255	1.3812	41	-1.4571	1.1315
D2	46	70	54	-5.4580	9.7662	0.5841	1.6292	63	1.5097	1.1997	37	-1.0078	0.8578
C2	70	33	50	-8.6604	10.3309	0.3178	1.7993	59	1.4635	1.1905	41	-1.3020	1.1539

Team	My.min	My.max	My.mean	My.SD	My.pos	My.pos.mean	My.pos.SD	My.neg	My.neg.mean	My.neg.SD
B1	-0.9405	0.8452	-0.1090	0.3617	44	0.2265	0.1665	56	-0.9405	-0.3768
C1	-0.9799	0.1422	-0.2685	0.2029	6	0.0318	0.0299	94	-0.9799	-0.2872
D1	-0.5965	0.7129	-0.0255	0.2109	55	0.1230	0.1024	45	-0.5965	-0.2096
E1	-0.5805	1.3051	0.0672	0.2323	61	0.1879	0.2095	39	-0.5805	-0.1253
F1	-0.7761	0.9387	0.0636	0.3466	62	0.2931	0.1850	38	-0.7761	-0.3101
G1	-1.0477	0.5068	-0.0746	0.2485	44	0.1508	0.0945	56	-1.0477	-0.2513
H1	-0.5804	0.6465	-0.0148	0.1928	62	0.1107	0.0713	38	-0.5804	-0.2208
I	-0.6616	0.3811	-0.0613	0.2383	50	0.1471	0.0735	50	-0.6616	-0.2699
J	-0.7326	0.6447	-0.1565	0.2666	28	0.1920	0.1455	72	-0.7326	-0.2942
K	-0.6348	0.6482	0.0147	0.2526	61	0.1865	0.1092	39	-0.6348	-0.2565
H2	-0.7378	0.3698	-0.1058	0.2026	36	0.0914	0.0624	64	-0.7378	-0.2167
F2	-0.6891	0.6966	0.0148	0.2365	61	0.1698	0.1068	39	-0.6891	-0.2300
B2	-0.6755	0.2947	-0.1066	0.1698	29	0.0761	0.0612	71	-0.6755	-0.1814
E2	-0.7840	0.8282	0.0259	0.2686	58	0.2051	0.1818	42	-0.7840	-0.2168
G2	-0.6386	0.6092	0.0021	0.2594	51	0.2157	0.1497	49	-0.6386	-0.2160
D2	-0.6297	0.6906	-0.0729	0.2212	39	0.1378	0.1596	61	-0.6297	-0.2051
C2	-0.8904	0.5145	-0.2235	0.2217	13	0.1221	0.1399	87	-0.8904	-0.2760

Team	Mres.max	Mres.mean	Mres.SD	Fft.max	Fft.mean	Fft.SD	Time
B1	1.3992	0.4620	0.2867	9.9700	1.8656	1.1021	361.0400
C1	1.2035	0.3805	0.2476	6.1600	0.9331	0.9417	563.3800
D1	1.1257	0.3127	0.2179	9.9300	1.3790	1.5221	325.6000
E1	1.4486	0.3086	0.2093	*			371.8800
F1	0.9504	0.3491	0.1749	8.7000	0.9139	0.8743	361.0400
G1	1.1290	0.2666	0.1688	6.8900	1.0199	1.0724	260.3200
H1	0.8640	0.1753	0.1296	16.8000	1.1042	1.5934	283.9400
I	0.9388	0.3053	0.1457	3.6700	0.6510	0.4912	225.9000
J	1.2879	0.3933	0.1903	8.6000	0.7493	0.8908	349.0400
K	0.7132	0.2907	0.1435	4.7100	0.6854	0.6438	251.5400
H2	1.3230	0.2895	0.2447	9.7100	0.7627	1.0572	418.0000
F2	0.9271	0.3029	0.1864	9.6100	1.2688	1.3933	295.1600
B2	1.2399	0.2462	0.1985	10.7700	1.1648	1.5695	462.0000
E2	1.3122	0.3550	0.2450	*			313.7000
G2	1.1340	0.2985	0.1676	6.9800	0.9192	1.2976	527.2200
D2	0.9530	0.2885	0.2023	4.0700	0.5078	0.4284	389.4200
C2	1.2235	0.3488	0.2315	5.8600	0.6509	0.6370	386.8200

* Data was not collected during pre-training measurement, cannot be compared to post-training measurement. Post-training data is therefore removed from the study for this participant.

AA. Construct validity – paired samples T-test (pre-post)

Paired samples T-test

	Parameter	Not norm.*	p [A]	r [B]	1 – β [C]	Participant Future [D]
1	Fres min		<0.01	0.9		
2	Fres max				0.2	27
3	Fres mean		<0.01	0.9		
4	Fres SD	PRE			0.1	787
5	Fres.pos.max				0.2	27
6	Fres.pos.mean	POST			0.1	787
7	Fres pos SD				0.1	787
8	Fres neg min		<0.01	0.9		
9	Fres neg mean		0.02	0.8		
10	Fres neg SD		0.02	0.8		
11	Fres pos		<0.01	0.9		
12	Fres neg		<0.01	0.9		
13	Fz1 pos				0.2	27
14	Fz2 pos				0.2	27
15	Fz3 pos				0.3	19
16	Mx min		0.03	0.8		
17	Mx max				0.1	787
18	Mx mean		0.049	0.7		
19	Mx SD				0.1	52
20	Mx pos		0.01	0.8		
21	Mx pos max				0.1	787
22	Mx pos mean				0.1	787
23	Mx pos SD				0.1	787
24	Mx neg		0.01			
25	Mx neg min		0.03	0.8		
26	Mx neg mean		0.01			
27	Mx neg SD		0.3			
28	My min				0.1	90
29	My max				0.2	27
30	My mean				0.1	90
31	My SD				0.1	52
32	My pos				0.2	27
33	My pos max				0.2	27
34	My pos mean				0.1	199
35	My pos SD				0.1	787
36	My neg				0.2	27
37	My neg min				0.1	90
38	My neg mean				0.1	52
39	My neg SD				0.1	52
40	Mres max				0.1	787
41	Mres mean				0.1	199
42	Mres SD				0.1	787
43	Fft max				0.2	27
44	Fft mean				0.2	24
45	Fft SD				0.1	199
46	Time	PRE			0.1	90

* Kolmogorov-Smirnov
A significance level
B effect size
C post hoc power analysis
D proposed number of participants in future study to get a power of 1-beta=0.8.

BB. Construct validity – independent samples T-test

			Novice pre-training - Expert				Novice post training - Expert			
	Parameter	**Not norm.***	**p** [A]	**r** [B]	**1 – β** [C]	**Participant Future** [D]	**p**	**r**	**1 – β**	**Participant future**
1	Fres min				0.1	30			0.1	117
2	Fres max				0.1	263			0.2	30
3	Fres mean		<0.01	0.9			<0.05	0.7		
4	Fres SD	PRE			0.1	43			0.2	43
11	Fres pos		<0.01	0.9			<0.01	0.8		
6	Fres.pos.mean	POST			0.1	1047			0.05	-
7	Fres pos SD				0.1	66			0.1	66
9	Fres neg mean		<0.01	0.8					0.2	43
10	Fres neg SD		<0.01	0.8					0.1	66
16	Mx min				0.1	1047			0.1	117
17	Mx max				0.1	263			0.1	263
18	Mx mean				0.1	117			0.1	117
19	Mx SD				0.1	1047			0.1	263
20	Mx pos				0.1	43			0.1	263
22	Mx pos mean				0.1	1047			0.1	117
23	Mx pos SD				0.1	1047			0.1	263
26	Mx neg mean				0.1	117			0.1	1047
27	Mx neg SD				0.1	263			0.1	66
28	My min				0.1	66			0.1	117
29	My max				0.1	117			0.05	-
30	My mean				0.1	1047			0.05	-
31	My SD				0.1	1047			0.1	66
32	My pos				0.1	1047			0.1	263
34	My pos mean				0.1	1047			0.1	263
35	My pos SD				0.1	1047			0.1	22
38	My neg mean				0.1	1047	<0.05	0.7		
39	My neg SD				0.1	263			0.05	-
40	Mres max				0.1	66			0.1	66
41	Mres mean				0.1	1047			0.1	117
42	Mres SD				0.1	66	<0.05	0.7		
43	Fft max				0.1	43			0.1	66
44	Fft mean				0.1	22			0.1	66
45	Fft SD		0.04	0.7					0.2	43
46	Time	PRE			0.1	66	0.049	0.6	0.2	30

* Kolmogorov-Smirnov
A significance level
B effect size
C post hoc power analysis
D proposed number of participants in future study to get power of 1-beta=0.8A group ratio expert-novice of 1:3 is assumed. The smallest group is noted.

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