In-vivo Force Sensing during Laparoscopic Sacrocolpopexy Vaginal Vault Manipulation

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Abstract – *Context:* During laparoscopic sacrocolpopexy vaginal vault prolapse is repaired by restoring the anatomical state of the vagina with a surgical mesh. A vaginal manipulator is placed inside the vagina to provide proper exposure to the surgeon for fixation of the mesh on the vaginal surface and vault by laparoscopy. Vaginal vault manipulation is done manually by an assistant and long operation times lead to fatigue, inconsistent application of tensioning forces and possibly vaginal rupture. This work describes a novel force sensor designed to be integrated in a vaginal manipulator to measure interaction forces between the vaginal vault and the manipulator. *Content:* The sensor is characterized and tested in lab-environment. After receiving ethics committee approval two first-in-woman studies have been conducted. Both the force and pose of the instrument were recorded. *Conclusions:* The force sensor showed to be suited to measure vaginal vault interaction forces and will be embedded in a robotic system for vaginal vault manipulation. Up to now, no previous research has quantified these interaction forces. Quantifying these forces and providing feedback cues to the surgeon is of particular interest, especially as a means to avoid vaginal rupture due to over-tensioning. A total of thirty interventions will be recorded.

Keywords: clinical trial; force sensing; laparoscopic sacrocolpopexy; minimally invasive surgery; pose tracking.

1. Introduction

Pelvic organ prolapse (POP) is defined as any abnormal descent of pelvic organs (bladder, uterus, rectum or small bowel) and occurs in up to 50% of parous women in their forties,¹ half of them being symptomatic.² Structural damage to the supporting ligaments and muscles of the pelvic organs leading to POP is mainly caused by vaginal delivery and age,³ followed by overweight.⁴ Often POP can be treated by the vaginal route, e.g. with a pessary and pelvic floor rehabilitation.⁵ However, when the top of the vagina prolapses, it is better repaired by an abdominal approach.

1.1. Sacrocolpopexy via Laparoscopy or Laparotomy?

In sacrocolpopexy (SC) the anatomical position of the vaginal vault and/or cervix is restored by suturing a surgical mesh to the vaginal cuff or cervix and variable portions of

the anterior and posterior vagina, and by connecting the other end of the mesh to the anterior longitudinal ligament over the sacrum. This has been shown to be the most effective approach to treat apical vaginal defects.^{6,7}

When SC is performed in a minimally invasive way, it is called laparoscopic sacrocolpopexy (LSCP), which is the conventional procedure nowadays. During LSCP the mesh is attached with long, slender instruments that are inserted through cannulas in the abdominal wall. Three to four incisions (one for every cannula) of approximately 1 cm are made to provide access to the surgical site. At least three people are needed to perform the intervention: a surgeon who uses two instruments to dissect tissue and suture the mesh; a first assistant who positions the laparoscope and controls a third instrument (e.g. graspers); and a second assistant who operates a *vaginal manipulator* to position and tension the vaginal vault so that it is properly exposed to the surgeon during dissection of excess tissue and mesh-attachment. There is level-I evidence that LSCP yields as good anatomical and subjective outcomes as the same operation by laparotomy,⁸ an open surgery where a large ab-

dominal incision is made. Important benefits of LSCP over laparotomy are a lower morbidity rate, reduced blood loss, less postoperative pain, a shorter revalidation time and better aesthetic results.⁹

Despite being beneficial for the patient, LSCP suffers from technical drawbacks associated with minimally invasive surgery (MIS). Loss of direct sight on the patient's internals, an unstable camera view¹⁰ and limited haptic feedback make a steep learning curve¹¹ and lead to long operation times (224 minutes on average⁷). About 60 cases are needed for an experienced laparoscopist to perform LSCP as safe and quick as an experienced surgeon.¹² The need for three people around the operation table limits the available workspace, which forces the operating staff to take on non-ergonomic postures for long periods of time.

As a consequence, surgeons frequently report discomfort in neck and upper extremities as well as high stress levels.¹³ The vaginal vault manipulating assistant positions the vaginal vault based on verbal instructions of the surgeon, but there is often miscommunication due to their different orientation with respect to the patient. This and fatigue causes vaginal vault positioning- and tensioning errors which take time to correct and further increase operation time. Thereby, over-tensioning the vaginal wall might cause vaginal rupture which leads to heavy bleeding and further complicates the surgery.^{14,15}

1.2. Gathering Design Requirements for Robot-Assisted Sacrocolpopexy

To overcome the technical difficulties of LSCP while avoiding the medical drawbacks of laparotomy, robot-assisted surgery (RAS) has gained a lot of popularity in the field of POP surgery.¹³

Given the critical nature of vaginal vault tensioning, the output force and force controllability would form major requirements for a robotic system designed for vaginal vault manipulation. There is little known about the vaginal vault interaction forces during LSCP surgery, so proper force quantification is needed.

Systems like the da Vinci[®] Surgical System (Intuitive Surgical, Sunnyvale, United States) foresee no force feedback so their use in vaginal vault manipulation is doubtful. The ViKY Uterine Positioner[™] (Endocontrol, La Tronche, France) is used for both uterus and vaginal vault manipulation, but was initially designed as a laparoscope positioner, and therefore has difficulties manipulating heavy loads.¹⁶ It also has no force control capability to prevent over-tensioning.

With the final goal of developing a system that takes over the fatiguing task of vaginal vault manipulation and thereby improving surgical outcomes,^{13,17} this work reports on the development of technology to measure forces intra-operatively. Analysis of the recorded data allows for definition of design requirements for vaginal vault manipulating robots, such as force range, the required workspace and allowable space occupancy. In the future, this force sensing

technology can be embedded in a robotic system for vaginal vault manipulation to provide force -feedback and -control.

To characterize the vaginal vault manipulation task, a *force sensor* (Fig. 1) has been developed which can quantify contact forces between the vaginal wall and the vaginal manipulator.

Figure 1: Force sensor attached to vaginal manipulator to measure interaction forces with the vaginal vault during LSCP. The sensor can measure forces in three degrees of freedom, according to the visualized coordinate system. A light but stiff polyetheretherketone (PEEK) housing (beige plastic) protects the sensing structures and provides easy handling. The assistant holds the device at the polyphenylsulfone (PPSU) grip (black plastic) when screwing in the vaginal manipulator so that there is no torque transmitted to the sensing structures, which might damage them. During surgery, a sterile plastic cover/drape is placed between the non-sterile force sensor and the vaginal manipulator to maintain the sterile barrier.

When asked to describe the required tensioning force, clinicians indicated a weight of 0.5 kg (≈ 5 N) radial to the axis of the manipulator (y-axis and z-axis on Fig. 1) and 2 kg (≈ 20 N) along the axis of the manipulator (x-axis on Fig. 1) when pushing the instrument deeper in the patient's body. Thus, after inclusion of a safety margin, the sensor's force range was chosen to be ± 10 N for the y- and z-axis and ± 30 N for the x-axis. During vaginal vault manipulation no interaction torques on the manipulator's head are to be expected since the vaginal wall is only able to apply a force load on one side of the manipulator's head at once. Interaction torques along the shaft of the instrument are expected to be limited due to compensation of the assistant. They are not measured here because it would require estimation of the point of contact between the shaft and the tissue, which makes the recording setup a lot more complicated. The force sensor is characterized in lab-environment before being used in an *in-vivo clinical trial*.

A shortened version of the conventional vaginal manipulator is made with a screw thread at the end to connect it to the force sensor. The total length including the handle portion is equal to the length of the original instrument. The handle portion is somewhat larger than the original handle as it houses the force sensor. With 50 mm outer diameter it has been designed with a comfortable grip such that it allows easy handling as was confirmed by the op-

erators before and after surgery. The manipulator itself is the only part that comes in contact with the patient's internals so it is made out of biocompatible stainless steel 304. This is the same material as the original manipulator used in the hospital. During surgery, a plastic cover/drape is placed between the non-sterile force sensor and the sterile manipulator, as shown in Fig. 1.

2. Vaginal Vault Force Sensing

Forces during vaginal vault manipulation are probably larger than those exerted on the laparoscopic instruments, which vary over ± 20 N,¹⁸ but little is known about the exact amount or direction.

To obtain information on force amplitude and direction, an isometric structure is attached to the vaginal manipulator that is equally sensitive to forces in all directions. Since the expected axial (x-direction) forces are relatively large, the structure has to be made robust so that a force range of ± 30 N can be measured. The sensing elements are placed at the instrument handle so that all electronics stay outside the patient's body. This is convenient for guaranteeing electrical safety and to avoid complex sterilization approaches which might damage the sensor. The strain gauge circuits are applied with an electrically isolating glue (X280 cold curing adhesive, Hottinger Baldwin Messtechnik GmbH, Germany) so that no current is transmitted to the stainless steel cross structures. Additionally, the vaginal manipulator is galvanically separated from the cross structures by a polyetheretherketone (PEEK) connection piece. The structure must also be light-weight, easily attachable to the vaginal manipulator in a sterile way during surgery and not affect the manipulation task itself.

2.1. Design of the Force Sensor

Fig. 2 shows the implementation where a double-cross structure is attached to the vaginal manipulator. This structure will deform elastically when interaction forces between the vaginal manipulator's head and the vaginal wall occur. The double-cross design adds stiffness in response to radial forces at the manipulator head, but not to axial loading.¹⁹ Thus, isotropic sensitivity for every axis can be obtained by determining the proper distance $|AB|$ between both cross structures. An optimal value for $|AB|$ is found by calculating the bending strain in cross A due to axial load ϵ_A (Fig. 3a),

$$\epsilon_A = \frac{F_{ax}ly}{8EI} \quad (1)$$

the normal strain in cross B due to radial load ϵ_B (Fig. 3b),

$$\epsilon_B = \frac{FL}{|AB|AE} \quad (2)$$

equating them and solving for $|AB|$:

$$\epsilon_A = \epsilon_B \quad (3)$$

$$|AB| = \frac{32LI}{Aly} \quad (4)$$

Which gives a value of 49,8 mm for $|AB|$.
With:

- $A = bh$ cross-sectional area of one beam [m^2].
- $b = 5mm$ width of the beam structures.
- $E = 200GPa$ Young's modulus of stainless steel 304.
- F [N] the total load applied on the manipulator's head, either in axial or radial direction.
- $F_{ax} = \frac{F}{4}$ the axial load per beam (two beams per cross structure) [N].
- $h = 0.8mm$ thickness of the beam structures.
- $I = \frac{bh^3}{12}$ the area moment of inertia of each beam [m^4].
- $l = 24mm$ length of one beam.
- $L = 280mm$ the total length of the manipulator rod, see Fig. 3.
- $y = \frac{h}{2}$ the perpendicular distance to the neutral axis of bending [m].

From (4) one can observe that the distance $|AB|$ for which isotropy is reached is independent of the magnitude of the expected force.

Forces can be measured in three degrees of freedom (DOF), F_x , F_y and F_z , according to the coordinate system of Fig. 2. Each cross structure is equipped with a set of strain gauges to allow decoupled measurement for every axis. Three full Wheatstone bridge circuits are made, where each bridge output represents a force in one of the loading directions.

Figure 2: Double-cross structure attached to the proximal side of the vaginal manipulator and Wheatstone bridge configuration for each measuring axis: x-axis in red; y-axis in blue and z-axis in green. Dotted lines point to the backside of the cross structures.

Fig. 3 sketches the deformation of the double-cross structure for axial (x-axis) and radial (y- or z-axis) loading. The legs of the cross structures bend under radial loading, as a consequence of bending of the manipulator shaft. Based on this deformation pattern, proper strain gauge locations are selected so that the bridge output signal equals zero if the corresponding axis is not loaded. A finite element analysis was conducted to compute the stress/strain distribution for different applied loads. With stainless steel 304 as material for the leaf springs of each cross, an E-modulus of 200 GPa and loads up to 90 N, the stress remained below 203 MPa which is 12 MPa below the limit where plastic deformation occurs. This led to target dimensions of $b = 0.8$ mm, $h = 5$ mm and $l = 24$ mm for the crosses. The housing of the force sensor serves as a mechanical stopper that prevents deformation into the plastic region, which would damage the sensor.

Figure 3: Expected deformation (exaggerated) of cross structures due to a) axial loading and b) radial loading. Strain in bridge B (gauge 5 to 8) cancels out in case of axial loading and strain in bridge A (gauge 1 to 4) cancels out in case of radial loading. Note that gauges 9 to 12 are not visible in this view.

Ideally, the voltage output for the full Wheatstone bridges (5) reduces to $V_{out,x} = V_{ex}GF\epsilon$, $V_{out,y} = 0$ and $V_{out,z} = 0$ in case of axial loading (Fig. 3a); to $V_{out,x} = 0$, $V_{out,y} = V_{ex}GF\epsilon$ and $V_{out,z} = 0$ in case of radial loading in y-direction (Fig. 3b) and; to $V_{out,x} = 0$, $V_{out,y} = 0$ and $V_{out,z} = V_{ex}GF\epsilon$ in case of radial loading in z-direction (not shown on Fig. 3). Where V_{ex} is the bridge excitation voltage, GF the gauge factor of the strain gauges and ϵ the

induced strain. For sign convention stretching of a strain gauge is given a positive sign $+\epsilon$ and compression of a strain gauge a negative sign $-\epsilon$.

$$\begin{cases} V_{out,x} = V_{ex} \frac{GF}{4} (\epsilon_1 - \epsilon_2 + \epsilon_3 - \epsilon_4) \\ V_{out,y} = V_{ex} \frac{GF}{4} (\epsilon_5 - \epsilon_6 + \epsilon_7 - \epsilon_8) \\ V_{out,z} = V_{ex} \frac{GF}{4} (\epsilon_9 - \epsilon_{10} + \epsilon_{11} - \epsilon_{12}) \end{cases} \quad (5)$$

This inherent decoupled behavior leads to a diagonal 3×3 calibration matrix $\mathbf{K}$ mapping voltages to forces (6). $\mathbf{f}$ and $\mathbf{v}$ are 3×1 column vectors containing the output forces and output voltages respectively.

$$\mathbf{f} = \mathbf{K} \mathbf{v} \quad (6)$$

2.2. Characterization of the Force Sensor

The sensor is characterized by suspending weights on the manipulator's head while clamping it in different orientations so that loads can be applied independently along x-, y-, and z-axis.

The calibration matrix, accuracy, precision and coupling between axes are evaluated by loading each axis stepwise over its calibration force range, which is ± 30 N for the x-axis and ± 10 N for the y- and z-axis. Axial forces (x-axis) are considered to be larger than radial forces (y- and z-axis) since the vaginal manipulator is mainly moved inwards along the center axis of the vaginal vault during tensioning, which causes a bigger axial reaction force of the vaginal tissue compared to radial forces. The average value of 5000 measuring samples (obtained at 1 kHz) is taken at each loading step.

Before calibration the sensor already showed good decoupled behavior, confirming the earlier assumed deformation under radial loading. After multiplying with the calibration matrix

$$\mathbf{K} = \begin{bmatrix} 127 & 0.979 & -0.630 \\ 8.70 & 91.3 & -1.22 \\ 0.963 & 1.33 & 81.1 \end{bmatrix} \times 10^3 \quad (7)$$

the coupling is reduced even more.

One can see that $\mathbf{K}$ indeed resembles a diagonal matrix, although small deviations from the ideal situation are present due to imperfections in manufacturing and assembly. Table 1 shows the remaining force output of the non-loaded axes while a first axis is loaded over its predefined calibration range. This cross-sensitivity is expressed as the average percentage error and is below 6% for every axis.

Table 1: Coupling between axes after calibration expressed as the average percentage error. A reference load is applied stepwise on a first axis over its calibration range. Loading steps are 0 N, 1 N, 2 N, 5 N, 10 N, 15 N, 20 N, 30 N to cover the range of the x-axis and 0 N, 1 N, 2 N, 5 N, 10 N for y- and z-axis, applied in positive and negative direction. For each loading step, the percentage error is calculated as the difference between the force output of a non-loaded axis and the applied load divided by the applied load. The average percentage error is then obtained as the average of the absolute values of each loading step.

	F_x	F_y	F_z
F_x ref	/	5.9%	2.0%
F_y ref	5.8%	/	2.3%
F_z ref	5.4%	0.9%	/

After application of $\mathbf{K}$, the accuracy is calculated as the average error between a known load, applied stepwise over the axis' force range, and the force output reading. As a measure for precision, the standard deviation on the accuracy measurement is used. The obtained accuracy and precision for a full force range, as shown in Table 2, are all below 3%. Fig. 4 shows good linear behavior between the sensor's input and output. As a measure for linearity the Pearson correlation coefficient is calculated for every axis and displayed in Table 2, which indeed shows very good results.

Table 2: Accuracy, precision and maximal error of the force sensor, expressed as a percentage compared to the force range and in newtons. Good linearity is observed for every axis with values that are near to 1.

	Accuracy		Precision		Maximal error		Linearity
	[%]	[N]	[%]	[N]	[%]	[N]	[/]
x	2.73	0.82	1.83	0.55	4.13	1.24	0.99
y	2.66	0.27	1.55	0.16	6.3	0.63	0.99
z	2.63	0.26	1.43	0.14	5.8	0.58	0.99

Figure 4: Relation between the sensor's input and output after calibration.

Remaining noise on the force measurements was reduced with a moving average filter that takes the unweighted mean of 100 previous data samples (obtained at 1 kHz). Table 3 shows standard deviation of the force output signal for a ten minute recording in unloaded state, before and after noise reduction. The filter reduces the noise in every bridge output well below 0.1 N.

Table 3: Standard deviation of the force output signal in unloaded state, recorded before and after noise reduction (unit: N).

	Original signal	Filtered signal
σ_{F_x}	0.289	0.061
σ_{F_y}	0.179	0.053
σ_{F_z}	0.136	0.023

3. Towards a Setup for In-Vivo Force- and Pose- Measurements

After characterization, the force sensor is equipped with a 6DOF tracking probe to record its pose in an electromagnetic field from a field generator (Aurora System, Northern Digital Inc., Canada). Pose tracking is added for three reasons: Firstly, vaginal manipulators are made out of stainless steel because it is a sterilizable and stiff material. This avoids bending of the manipulator's shaft when large forces are applied on its head. Unfortunately this makes for a very heavy device, especially because of the large volume of the manipulator's head. Pose recording allows for gravity compensation by subtracting the influence of the gravitational force F_g , acting on the center of mass of the manipulator, from the total measured force to obtain the interaction force F with the vaginal wall (Fig. 5). Secondly, the workspace of the vaginal manipulator can be visualized together with the corresponding force data, so that the location of large interaction forces with the vaginal vault can be defined. And lastly, it allows for landmarking of the vaginal vault entrance so that its location with respect to the vaginal manipulator can be visualized. This is done by holding the manipulator's head at the vaginal vault entrance after the patient is placed on the operating room (OR) table. The tracking probe is attached at the backside of the force sensor so that it stays within the boundaries of the electromagnetic field during surgery. The pose tracking range of the Aurora System is $500 \text{ mm} \times 500 \text{ mm} \times 500 \text{ mm}$, which is significantly larger than the instrument's range of motion during vaginal vault positioning. When embedded in a robotic device, the pose of the vaginal manipulator can be derived from the robot's joint positions.

Figure 5: 6DOF pose tracking probe attached to the backside of the force sensor. Gravity compensation of the vaginal manipulator is done by transforming the gravitational force F_g from to world frame (x_w, y_w, z_w) to the sensor frame (x_s, y_s, z_s) and subtracting it from the measured force data, thus obtaining the actual interaction force F with the vaginal vault.

3.1. Operating Room Setup and Procedure for Combined Force- and Pose-Recording

The operating staff prefers minimum influence of the study on the normal surgical procedure. An appropriate location for the field generator is found under the sheets that separate the sterile (patient) zone and non-sterile zone (under the OR-table), as shown on Fig. 6. All other recording hardware is placed away from the surgical site, next to the already present OR-equipment. This also avoids EM interference with the surgical tools. The setup is placed in the OR before the start of the surgery, when the patient is not on the OR-table yet. Similarly, the setup is removed after the surgery is finished, when the patient has been moved out of the OR.

Figure 6: Clinical trial setup: The force sensor can be tracked by an electromagnetic field generator. The vaginal vault manipulating assistant sits between the patient's legs as during a normal intervention.

Force data is recorded with a field-programmable gate array (FPGA) (cRIO-9045, National Instruments, United States) and sent to a computer over a User Datagram Protocol (UDP) connection. This computer is also connected with the pose tracking system by Universal Serial Bus (USB). Force and pose data are matched based on timestamps. The recording and data processing is done by using a combination of LabVIEW, Python and Robot Operating System (ROS) software. Fig. 7 shows the data flow diagram.

Figure 7: Data flow diagram: After data acquisition the force- and pose- data are combined based on timestamps.

4. In-vivo Study Results

Two initial clinical studies were conducted. The first patient had a much higher degree of prolapse compared to the second patient. During the first clinical study interaction forces were below 5 N on average with peaks up to 25.48 N, which is mostly within the predefined calibration ranges of ± 30 N and ± 10 N. During the second study forces often reached 20 N in negative x-direction for longer periods of time and exceeded even 40 N in the beginning of the intervention (Fig. 8). However, most of the time they also stayed within range of ± 30 N and ± 10 N. Table 4 summarizes the recorded force data for both studies.

Table 4: Clinical trial results: Maximum, average and standard deviation of total force and maximum forces on each axis (unit: N).

	$F_{tot,max}$	μF_{tot}	σF_{tot}	$F_{x,max}$	$F_{y,max}$	$F_{z,max}$
Study 1	25.48	4.41	2.42	21.81	12.46	6.45
Study 2	47.28	10.87	7.36	46.75	17.13	8.83

Fig. 9 visualizes combined force- and pose data where each point in space is color coded to match a force range. A growing force amplitude when the manipulator is inserted further into the vaginal vault is visible during both studies. These periods of high tensioning are marked on Fig. 8 and seem to correspond with the time of mesh attachment to the vagina. Pose data shows that the manipulator head workspace inside the vagina can be confined within a bounding box of 128 mm $\times$ 359 mm $\times$ 180 mm (x,y,z) and 152 mm $\times$ 161 mm $\times$ 107 mm for the first and second study respectively. An area around which the manipulator pivots was observed near the vaginal vault entrance in both cases. Although, a real remote center of motion (RCM), i.e. a fixed pivoting point in space, is absent.

The study did not hinder the intervention in any way. In both studies, the assistant who manipulated the vaginal vault described no difference in body posture or additional fatigue compared to a standard intervention. Setting up

the force sensor, i.e. putting the force sensor in the sterile plastic cover and screwing in the vaginal manipulator, took less than 1 minute. It is worth mentioning that the vaginal vault manipulating assistant during the first intervention was an experienced trainee, while the second assistant was an intern medical student who had little prior practice.

5. Conclusion

A force sensor for measuring vaginal vault interaction forces during LSCP is developed and tested in lab-environment. During characterization the force sensor showed to be suited for measuring interaction forces with the vaginal vault.

After obtaining ethics committee approval, two initial *clinical studies* are conducted to test the *in-vivo* performance of the setup. Interaction forces between the manipulator device and the vaginal vault and the pose of the manipulator device were successfully recorded. In-vivo force data showed that the main loading direction is along the axis of the vaginal manipulator. The force amplitude is raising when the vaginal manipulator is inserted deeper into the vaginal vault. Probably, this is due to the increased resistance to stretching from the vaginal tissue. There is a large difference in force amplitude between both trials. It is hypothesized that this is due to the different degrees of prolapse between both patients where a higher degree of prolapse results in more flexible tissue offering less resistance during vaginal vault positioning. Forces during the second intervention exceeded the ± 30 N range for short periods of time, especially in the beginning of the intervention where a maximal force peak of 47 N was recorded. Given the robustness of the force sensor, as described in 2.1, and its good linearity these large forces can be measured correctly. This was verified in lab-environment after observing the results mentioned above. However, the design requirements concerning stiffness of a vaginal vault manipulating robot and its force sensing capabilities are larger than initially anticipated prior to the study.

The lack of previous experience with vaginal vault manipulation might have led to over-tensioning in the beginning of the second intervention, which was reduced after 15 minutes. Possibly the assistant felt that the applied tension was too high and corrected himself. Also fatigue can be a possible reason of this reduction in force amplitude after 15 minutes.

To draw proper conclusions about the measured data, a total of thirty LSCP interventions will be recorded. We are not aware of similar experiments, hence results of this trial will be of great value for future developments of (robotic) assistive technology for LSCP. On one hand they provide design requirements for robotic systems for LSCP and on the other hand the sensing technology can be embedded in the robotic system itself to provide force-feedback and -control. The currently developed handheld force sensor, as described in this work, can be used for training of surgeons.

Figure 8: Clinical trial results of the first (left) and second (right) study. During the first study interaction forces stay below 30 N, during the second study this limit is exceeded for short periods of time. Periods of high tensioning are marked with letter T and correspond with points of deep insertion on Fig. 9. Except for the first period of study 2, they match with the time of mesh attachment.

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Conflict of Interest

The authors declare that they have no conflict of interest.

Figure 9: Clinical trial results of the first (top) and second (bottom) study. Points in space of the manipulator's head are color coded to match a force range, based on total force. Interaction forces get higher when moving deeper into the vaginal vault. The vaginal vault entrance serves as a pivoting area for the vaginal manipulator.

Ethical approval

All procedures performed in studies involving human par-

ticipants were in accordance with the ethical standards of the institutional and/or national research committee and

with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Clinical Trial Center UZ Leuven has approved this study under number S61346.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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