The influence of laparoscopic handle design parameters on the haptic perception of variable tissue stiffness

Latifa Lesmana Hardjo

TU Delft Delft University of Technology

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by

Latifa Lesmana Hardjo

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Thesis committee:	Dr. ir. T. Horeman,	TU Delft, Chair
	Ir. J.W. Klok,	TU Delft, Daily Supervisor
	Dr. ir. J.J. van den Dobbelsteen	TU Delft

Cover: High quality Laparoscopic Grasper, Laparoscopic instruments Forceps Hangzhou Kangsheng Medical Equipment Co., Ltd. (Modified)

TU Delft

PREFACE

It is an understatement to say that this project has not gone the way that I had imagined. Obtaining an auto-immune disease at the start of the process has had great implications for the trajectory of my graduation project. Often, I have had to prioritize my health over my academic ambitions. Sometimes, the work had to be paused for weeks in a row. As I had no experience with these kinds of struggles, it was difficult to plan ahead and to decide the level of workload for each moment. Especially due to this particular situation, I would like to thank my supervisors, Tim Horeman and Jan-Willem Klok, for their support, flexibility and patience. But also for the inspiring meetings we have had. Challenging me when it was possible, but also letting go of high expectations when it was not, has really made me feel supported. I have learned a lot and I feel proud of the results we have achieved.

I would like to thank my family and friends for the support during the difficult times and for the celebrations of each small victory in the process. I feel immense gratitude for the people around me.

Although it was a long and hard process to write my thesis, I have always enjoyed working on the subject of medical device development. Contributing to an enhanced safety and performance in the medical field gives me a great sense of fulfillment. With this project finished, and with my improved health, I look forward to new challenges in the future.

Latifa Lesmana Hardjo, Amsterdam, August 2022

Abstract

Stiffness perception in laparoscopic surgery has an important role in achieving appropriate tissue manipulation. The need for haptic feedback to perceive tissue stiffness and the reduce in haptic feedback when using laparoscopic instruments suggest an inability to sufficiently experience stiffness perception during laparoscopic surgeries. Better understanding of the perception of tissue stiffness could contribute to the development of better laparoscopic instruments. A stiffness ranking task has been performed with 16 participants, to study the influence of force transmission ratio, contact area and grasping strategy on the haptic perception of variable tissue stiffness. Using a newly developed set of laparoscopic grasper handles varying in the chosen independent variables, being the force transmission ratio and contact area, the participants performed multiple grasps with each grasper handle on a randomized order of tissue samples with three different stiffness levels and ranked them according to the perceived level of stiffness. Force measurements were done during the task and a survey was conducted afterwards. The results indicate that force transmission ratio and contact area do not influence the haptic perception of variable tissue stiffness. In terms of grasping strategy, a lower force exertion is shown to be desirable for perceiving the variable tissue stiffness, while the amount of grasps per tissue sample have not shown to influence the perception. Future studies with larger sample sizes might indicate a difference between high and low force transmission ratios. It is concluded that future designs of laparoscopic grasper handles might not be restricted in terms of force transmission ratio and contact area requirements when a greater haptic perception is aimed at. More haptic perception of variable tissue stiffness is gained in the surgical domain of applying the appropriate grasping strategies.

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The influence of laparoscopic handle design parameters and grasping strategy on the haptic perception of variable tissue stiffness

Latifa Lesmana Hardjo (4305450)

I. INTRODUCTION

Innovations in medical technology have led to the development of laparoscopic surgery in the operating room. To perform a laparoscopic surgery, instruments are placed through small orifices in the abdominal wall to perceive and manipulate the abdominal tissue. The operating field is shown on a screen with the use of a laparoscope (see Figure 1) and the tissue is manipulated with the use of long thin instruments [1][2]. Problems have been reported when performing laparoscopic surgeries, such as a limited depth perception, disturbed hand-eye coordination and reduced haptic feedback [1][2][3][4][5]. The loss of haptic feedback is the largest contributor to surgical errors caused by misperception or misidentification [1].

Fig. 1: The operating field during a laparoscopic surgery is shown on a screen with the use of a laparoscope and the tissue is manipulated with the use of long thin instruments.

Stiffness is one of the properties best perceived through haptic feedback [6]. Stiffness perception is important in laparoscopic surgery to discriminate healthy versus abnormal tissues, identify organs, interact with tissues and to control the instruments [1][5][7][8]. It is necessary for a range of clinical applications, such as to detect subtle lesions like common duct stones and liver lesions, differentiate benign from malignant tissue, palpate arteries and lymph nodes, retract delicate tissue for preservation and localise small and visually indetectable tumours [9][10][11]. The need for haptic feedback to perceive tissue stiffness and the reduce in haptic feedback when using laparoscopic instruments suggest an inability to appropriately experience stiffness perception during laparoscopic surgeries. Better understanding of the perception of tissue stiffness could contribute to the development of better laparoscopic instruments.

A. Haptic feedback

Haptic feedback is the perception of haptic information when interacting with an object or the environment through sense of touch. It can be divided into information on texture, vibration and pressure, called tactile feedback, or on position, movement and force, called kinaesthetic feedback [1][12]. Haptic interaction with different types of tissues contributes to the development of a mental image and memory of the targeted tissue [4]. The surgeon learns how to handle, interpret or predict the reaction of the tissue, which is valuable when performing tissue manipulation. During surgery, haptic information is used to discriminate healthy versus abnormal tissues, identify organs, interact with tissues and to control the instruments [1][5][7][8].

Although haptic feedback is necessary during surgery, it is only present in limited amounts and the haptic feedback which is present represents a combination of forces caused by the interaction of the instrument with the organs, the friction between the instrument and the trocar port, resistance of the abdominal wall during the movement, the effects of the surgeon on the instrument and the activation of the instrument mechanism (see Figure 2) [5][7][13].

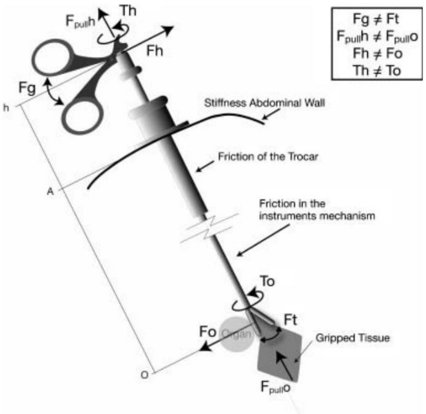

Fig. 2: Distortion factors during instrument-tissue interaction using a laparoscopic grasper.

B. Stiffness perception in laparoscopic surgery

Stiffness is the physical property which describes the extent an object resists deformation in response to an applied force and is typically measured in MegaPascal [MPa]. In literature, the term stiffness is often used interchangeably with the terms consistency, softness and compliance [6][14][15]. Stiffness perception involves both kinaesthetic and tactile haptic feedback. Kinaesthetic information on position, velocity and force is perceived through the muscles, joints and tendons, while the tactile information on pressure and indentation is sensed through the mechanoreceptors in the finger pads [16]. The received haptic information from the nervous system is integrated in the brain to estimate the stiffness [17].

During surgery, it is important to perceive the tissue stiffness, as it determines the magnitude of force required to appropriately manipulate the tissue [4][17]. Surgeons examine tissue characteristics with the use of the palpation technique [16][11][18][19]. In traditional open surgery, surgeons are able to feel the structure, shape and consistency of tissues, as they are able to directly touch the tissues [2], while in laparoscopic surgery, surgeons are only able to touch the tissues indirectly with the use of long thin instruments, such as a grasper, seen in Figure 3. The only way of estimating the force at the instrument tip is by perceiving the force interaction through the instrument handle. In a study by Perreault and Cao, it was described that with the available laparoscopic graspers, only 50 percent of trained participants and 30 percent of untrained participants were able to sort materials with different stiffness and damping characteristics [1].

C. Grasping strategies in laparoscopic surgery

In everyday interactions, people use exploratory movements with the hands to assess the stiffness of surrounding objects. Most typically, this is done by performing multiple indentations with the fingers on the surface, which can be seen as pressing, squeezing or tapping an object [15][16]. In laparoscopic surgery, less is known regarding the strategies to assess the stiffness of objects. Literature studies which describe grasping strategies in laparoscopic surgery are mainly focused on limiting the occurance of tissue slippage and damage [20].

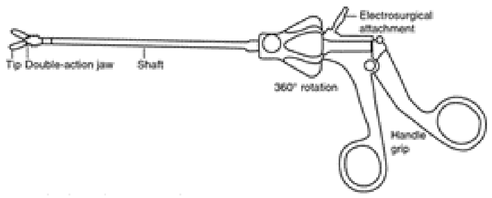

Fig. 3: A Laparoscopic grasper. The grasper tip is actuated by grasping the handle grip, which creates a linear movement in the shaft, and therefore actuates the double-action jaw at the grasper tip.

There has been less reported about behavioral grasping strategies regarding force exertion, grasping movements and grasping durations, with the exception of the force thresholds where slippage and damage occurs [4][21][22], insufficient force exertion slowing down task completion [23] or the difference between forces applied by experts and novices [23][24]. Barrie et al. have described that grasping with high pressures and for prolonged periods of time should be avoided to prevent tissue slippage and damage [21]. From a surgical perspective, studies have described strategies for safe grasping of vulnerable organs, but without including the force requirements involved [25]. Grasping force application strategies have not been extensively studied with regard to haptic perception or stiffness perception in grasping.

D. Relevant stiffness range

To illustrate the range of tissue stiffness relevant for laparoscopic surgery, studies have been reviewed which have performed stiffness measurements on animal and human tissue. Carter et al. have done ex-vivo measurements on pig organs and in-vivo measurements on human organs. It is one of the very few studies where tissue characteristiscs of abdominal organs were measured in living humans. The elastic modulus of pig spleen was measured to be 0.11 MPa and pig liver to be 4.0 MPa. Pig organ tissue is closely related to human organ tissue. In the human tissue, the mean elastic modulus of the right lobe of a healthy liver was measured to be 0.27 MPa, while in a diseased liver it was measured to be 0.74 MPa, which is a three times higher stiffness level [26]. Walraevens et al. have used a non-destructive in vitro method to measure the mechanical properties of healthy and calcified aortic pig tissues, which are relevant when treating atherosclerosis through laparoscopic surgery. Healthy porcine aortic tissue was measured to have an elastic modulus of 0.15 MPa, while calcified porcine and human aortic tissues had an elastic moduli of respectively 0.23 MPa and 0.33 MPa [27].

To also illustrate the range in interaction forces to be perceived, studies have been reviewed which have performed interaction force measurements during tissue manipulation. The systematic review by Golahmadi et al. reported that, in general surgery, epithelial tissue requires on average a force of 3.8 N (with a mean max force of 9.7 N) for tissue manipulation and muscle tissue requires a force of 4.1 N (with a mean max force of 6.7 N) [23]. Picod et al. measured the interaction force with a palpating rod on several abdominal organs of three pig models. The average interaction forces measured ranged from 0.5 N to 10 N in the pelvic wall, 0.4 to 3.5 N in the bladder and 0.2 to 6 N in the ovaries. Overall, the authors conclude that the force range in a laparoscopic gesture is at the very most 0.1 to 10 N [28]. Another study concluded this range to be 0.5 to 12 N [29]. Heijnsdijk et al. have described the mean perforation force in the large bowel to be 13.5 N, which can be regarded as a safety margin [21][30].

The stiffness range which is likely to be relevant to perceive in laparoscopic surgery is approximately 0.1 to 4.0 MPa and the relevant range of interaction force to be used is approximately 0.1 to 12 N.

E. Problem definition

In each laparoscopic surgery, there is a presence of various tissues with different characteristics such as tissue stiffness. The tissue stiffness is valuable for the surgeon to perceive as this determines the amount of force required to appropriately manipulate the tissue [4]. As the haptic feedback experienced when using laparoscopic instruments is limited, it is questioned if the surgeon is sufficiently able to interpret the tissue stiffness and to perceive a variable tissue stiffness. The design of the instrument handle and the behavioral strategies during grasping are factors which possibly contribute to a limited haptic perception.

The independent variables used in this study are chosen to be the force transmission ratio and contact area. It is described how an unequal force transmission in the grasper mechanism can be caused by a low mechanical efficiency, which contributes to a reduce in haptic feedback [30][31] and that the force transmission ratio should ideally be constant through the cycle of opening and closing the instrument [3]. Although some studies have reported on the influence of force transmission ratio on the performance of laparoscopic instruments, the force transmission ratio has not been extensively studied with regard to the haptic perception in laparoscopic surgery. Therefore, it is chosen to include force transmission ratio as an independent variable in this study.

A wide variety of laparoscopic handle designs are currently used, which also include a wide variety in the contact area between the handle and the operating hand [32][33][34]. Although the tool handle design has been shown to influence surgical performance, it is still questioned if it also has influence on stiffness perception [35]. In general, contact area cues are important to perceive object stiffness [18]. Different parts of the hand contain different sensory receptors and therefore process different haptic information [1][12][16]. Studies have reported a difference in perceptual abilities and preferences regarding the fingers to use in stiffness discrimination [15]. Because of the perceptual differences in the parts of the hand and the variety of usage in existing handle designs, it is chosen to include contact area as the second independent variable in this study.

Lastly, grasping strategy has been chosen to include as an additional focus in the experimental study, to explore the subject with regard to force exertion, grasping movements and grasping durations. The studies done on laparoscopic grasping focus mostly on tissue slippage and damage prevention and less on the influence on perceptual capabilities.

F. Research question

The research question is studied and answered with the use of an experimental study. In the experiment, the influence of force transmission ratio, contact area and grasping strategy are studied with the use of a stiffness ranking task and force measurements. The research question is formulated as:

What is the influence of contact area, force transmission ratio and grasping strategy on the haptic perception of variable tissue stiffness?

G. Design goal

To perform the experimental study, a set of laparoscopic grasper handles varying in the chosen independent variables needs to be developed. The use of the laparoscopic grasper handles in an experimental study influences the scope of the design phase and the list of requirements for the design of the handles. The handles are required to be used on a reusable and modular grasper which has been made available for this study (see Figure 4) (NYA1027, NanYu, Zhejiang, China). The design and production of the handles is done in the design phase. The design goal is formulated as:

Fig. 4: The baseline grasper with the scissor handle design and a force transmission ratio of 0.17 to be used in this study. For the design process and experimental research, it has been taken apart to enable the use of the shaft, grasper body and grasper tip in combination with the new grasper handle design.

To design and produce multiple laparoscopic grasper handles to be used in an experimental study, focused on the influence of contact area, force transmission ratio and grasping strategy on the haptic perception of variable tissue stiffness.

II. MATERIALS AND METHODS

The method for this study includes both the execution of the experimental study and the development of the grasper handles to use in the experimental study. The first part describes the experimental methods applied to study the influence of the chosen independent variables and grasping strategy. The second part describes the design approach used to develop the set of grasper handles.

A. Experimental study

The experiment to study the influence of force transmission ratio, contact area and grasping strategy on the haptic perception of variable tissue stiffness was done using a within-subject design. A total of 16 participants have been acquired using convenience sampling, for which the exclusion criteria was having experience performing any kind of surgical task. Approval of the HREC of the Delft University of Technology was acquired before the start of the experiment. In the experiment, a stiffness ranking task was performed to measure the ability to perceive the variable

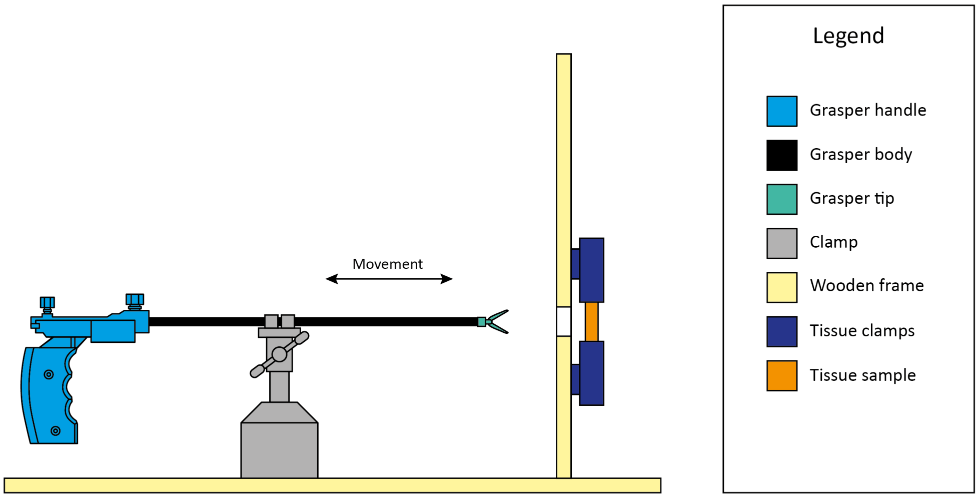

Fig. 5: Schematic side view of the experimental setup. The grasper body is held in the clamp on the bottom plate of the wooden frame. The tissue sample is held by the tissue clamps on the standing plate of the wooden frame. The grasper handle and grasper body can be moved forwards and backwards to place the grasper tip through the hole in the standing plate and onto the tissue sample.

stiffness levels. Also, a force measurement was done during the stiffness ranking task to measure the force exertion and therefore determine the grasping strategy applied. Lastly, a survey was taken in which the confidence of the participants in the stiffness ranking task was determined.

1) Stiffness ranking task: A wooden frame with three slots was used to present the grasper and three silicone samples to the participants (see Figure 5). Pictures of the test setup can be found in Appendix D. A reusable grasper was made available to use in the study (NYA1027, NanYu, Zhejiang, China). The laparoscopic grasper, with the handle removed, was held in the middle of the frame by a rotating clamp, which allowed the grasper to be rotated in the horizontal plane and to be moved towards the three slots. The clamp only held the grasper body, which enabled the replacement of the grasper handles after each round of the experiment without removing the shaft body from the test setup. To remove visual feedback, the three tissue samples were made invisible to the participants by placing them behind the three slots using clamps. Three silicone samples (10x15x60 mm) were casted in three levels of stiffness using silicone rubber of shore hardness (grade A) level 5, level 50 and a combination of the two (Siliconesandmore, Geleen, The Netherlands). This resulted in the soft (1), medium (2) and hard (3) tissue stiffness levels. The developed grasper handles were attached to the grasper body in the clamp, which enabled the grasping of the tissue samples with the different variations in force transmission ratio and contact area.

Before initiating the first round, a practice round was done in which the participant became familiar with holding the grasper handle and actuating the grasper tip. Also, the movements were learned to maneuver the grasper tip towards and into the three sample slots to grasp the tissue samples. Lastly, the soft (1) and hard (3) tissue samples were allowed to be grasped, visibly in front of the wooden frame, to create a baseline mental image of the stiffness levels to be perceived in the task to reduce the occurance of guessing.

A total of six rounds were done with each participant. Each round, a different grasper handle was attached to the grasper body. The order in which the variations were presented for each participant was randomized using a script in Microsoft Excel (Microsoft, Redmond, CA, USA). The grasper handle variations were randomized to limit the influence of a possible learning curve. A tissue sample of each of the three stiffness levels was placed behind the slots, in a randomized order, which was also determined with a script in Microsoft Excel (Microsoft, Redmond, CA, USA). The participant was asked to grasp the samples one by one from left to right and to repeat the movements again from left to right, which created two grasping turns for each sample. The participants had the freedom to grasp each sample as many times and as long as required during each turn. To grasp, the participant was required to move the grasper tip independently from one slot to the next. After grasping all the samples, the participant was asked to write down the perceived order of stiffness levels. The answer form used during the task can be seen in Appendix D.

Afterwards, ranking scores were assigned to the written answers in Microsoft Excel (Microsoft, Redmond, CA, USA). A score of '100' was given to a completely correct given answer. A score of '33' was assigned when only one of the three tissue samples was correctly placed. This was assigned when only the soft (1) or hard (3) tissue sample was placed correctly and the other levels were switched. If only the medium (2) sample was placed correctly, it meant that the soft (1) and hard (3) samples were switched, which was interpreted as guessing and therefore incorrect. A score of '0' was given to a completely incorrect answer.

2) Force measurement: During the stiffness ranking task, the force exertion of the fingertip was measured. This was done with the use of a force sensing resistor (FSR) placed in each grasper handle where the fingertip of the index finger was located (Interlink Electronics, Camarillo, CA, USA). The FSR model 400 with short tails was connected to an Arduino Nano, breadboard, SD Card reader, jumper wires and a 10 KOhm resistor (Arduino.cc, Somerville, MC, USA). The Arduino code and wiring diagram can be found in Appendix B and D. The SD card reader with the micro SD card was used to store the force measurement data during the experiment. Also, a momentary pushbutton connected to the Arduino Nano, was used to indicate when the participant was grasping a tissue sample, to be used in the data processing to organise the data (Hardware1 and electrical store, Shanghai, China). The researcher pushed the button when the participant had the grasper tip located at the first slot and started grasping the tissue sample. The button was pressed until the grasping turn ended and the participant moved the grasper tip to the next slot. The Arduino Nano was connected to a computer where the resistance time graph could be observed in realtime during the experiment. Several force parameters were measured:

- *Total Peaks Non Zero*

  The total amount of grasps measured for each participant. This includes all six rounds. A grasp is defined as an increase in force starting from the minimal force baseline of 0.5 N until the minimal force baseline is reached again. Multiple decreases and increases in force are not defined as multiple grasps unless the minimal force baseline of 0.5 N is reached.

- *Average Peaks Non Zero*

  The average amount of grasps measured for each round of each participant.

- *Maximum Peak force*

  The maximum peak force measured for each participant. This includes all six rounds. The peak force is defined as the maximum force of a grasp.

- *Average Peak force*

  The average peak force measured for each round of each participant. The peak force is defined as the maximum force of a grasp.

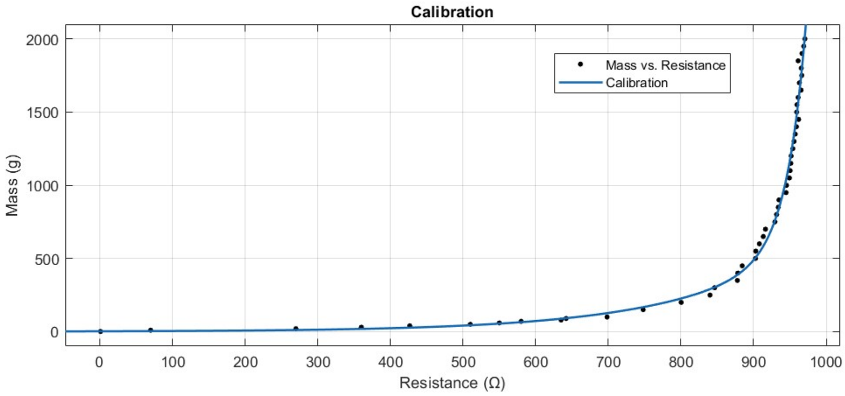

Fig. 6: The results of the sensor calibration. Various weights between 0 an 2000 g have been used to document the corresponding resistance values. The MATLAB Curve Fitting tool has been used to fin an equation which fits the data.

3) Survey: Subjective data was acquired on the confidence of the participants while conducting the stiffness ranking task. The survey was taken with the use of Google Forms and presented on a phone at the end of the experiment (Google, Mountainview, CA, USA). The survey showed the statement, being: "I felt confident about my ranking of the silicone samples". The participants were asked to answer to what degree the statements felt true to them on a 5-point Likert scale, in which 1 stands for "completely not true" and 5 stands for "completely true".

4) Sensor calibration: Sensor calibration of the FSR sensors was performed using one of the force sensing resistors fixated on a scale and by connecting the sensor to an Arduino Nano and computer. Multiple measurements have been done with various weights. From 10 to 100 g, steps of 10 g were used and between 100 and 2000 g, steps of 50 g were used. Each step was measured three times, which were averaged afterwards. The measured data is presented in the calibration graph with the corresponding resistance value (see Figure 6). The Curve Fitting tool of MATLAB R2022a was used to find equation 1, which fits the calibration data (The Mathworks Inc., Natic, MA, USA). This equation was used in Microsoft Excel to convert the measured resistance (Ω) to mass (g) and subsequently to force (N) (Microsoft, Redmond, CA, USA). The coefficients to calculate the mass (f(x)) using the resistance (x) were **a** = 2.47, **b** = 0.0056, **c** = 9.21e-14 and **d** = 0.038.

$$f(x) = ae^{bx} + ce^{dx}$$

(1)

5) Data comparison and statistics: Statistical analyses have been performed using IBM SPSS Statistics 26 (SPSS V26, SPSS, Inc., Chicago, IL). A level of significance of P = 0.05 was used.

B. Design approach

The development of the handle design was done according to the design process described by Roozenburg and Eekels [36]. The complete design cycle consists of the analysis phase, synthesis phase and evaluation phase. An extensive overview of the design process can be found Appendix A. In the analysis phase, literature has been reviewed on the topics of haptic feedback, tissue stiffness, force transmission ratio, contact area and grasping strategies in laparoscopic surgery. It resulted in the formulation of the problem definition, design goal and requirements. In the synthesis phase, solutions to the defined problem were explored and ideas were generated. Using creative brainstorming and problem solving techniques, three concepts have been developed. In the evaluation phase, a final concept was selected and was critically validated using calculations and mechanical validations. The list of requirements had a critical role in each part of the design process. It was used to guide the idea generation in the synthesis phase and to assess the design concepts in the evaluation phase. The total design cycle consisted of an iterative process which was executed multiple times to implement insights gained later in the process and therefore achieve the most valuable results.

1) Requirements: The experimental study has been conducted with the use of a newly developed set of laparoscopic grasper handles, which was made to vary in the chosen design parameters. This influenced the design requirements for the development of the grasper handles. The first two requirements concern the use in an experimental study and the last four requirements concern the functional use of the grasper handles. Although a set of grasper handles was to be developed, the design requirements applied uniformly to each separate grasper handle.

1. Enable a variety in force transmission ratio:
The design of the grasper handle enables a variation in force transmission ratio to use in the experimental study with a range of 0.1 to 0.8.

2. Enable a variety in contact area:
The design of the grasper handle enables a variation in contact area to use in the experimental study. The contact area is defined as the parts of the grasper handle in direct contact with the surface of the hand.

3. Enable actuation of the end effector:
The grasper handle enables the actuation of the end effector, by generating a linear movement of the shaft of the grasper.

4. Connect to the grasping instrument:
The handle is able to be connected and disconnected to the grasping instrument. The connection is able to be established impermanently and in a quick manner.

5. Enable gripping:
The grasper handle is able to be held with one hand.

6. Incorporate ergonomic measures:
The handle is able to be used for the population of Dutch adults, mixed (including both male and female), from P5 to P95.

2) Force transmission ratio: To study the influence of force transmission ratio (FTR), it was required that the grasper handles vary in sufficiently large but relevant transmission ratio differences. As it is currently not reported in literature what the most occurring range of FTR is, the FTR of the baseline grasper was used as a point of reference (FTR = 0.17). Equation 2 shows the relationship between the FTR and the relevant forces Fhandle and Fshaft.

$$FTR = \frac{Fhandle}{Fshaft} \quad (2)$$

A low FTR, such as 0.1 or 0.2, would mean that a grasping force at the handle (Fhandle) would result in a relatively high grasping force at the tip (Fshaft). This creates an amplification of the grasping force. A high FTR, such as 0.4 or 0.8, would result in a grasping force at the tip (Fshaft) which is more equal to the grasping force at the handle (Fhandle). A ratio of 1.0 would result in equal grasping forces at the handle (Fhandle) and the tip (Fshaft). The free body diagrams and the performed calculations are presented in Appendix A. In the concept generation of the design process, a concept has been generated in which the variation in FTR has been established by varying the placement of the hinge on the handle lever. As the distance between the base of the lever and the hinge (called distance L1) and the FTR was found to have a logarithmic relationship (see Figure 7), it was chosen to include FTR values of 0.1, 0.2, 0.4 and 0.8 in this study.

3) Contact area: To study the influence of contact area, it was required that the grasper handles would vary in surface area to actuate the grasper tip. The parts of the hands have different perceptual capabilities and existing grasper handles vary in the usage of these parts [15][32][33][37]. In the concept generation of the design process, a concept has been generated in which the variation in contact area has been established by varying the usage of the hand for actuation. More specifically, to either use both the thumb and index finger to actuate two levers or only use the index finger to actuate one lever.

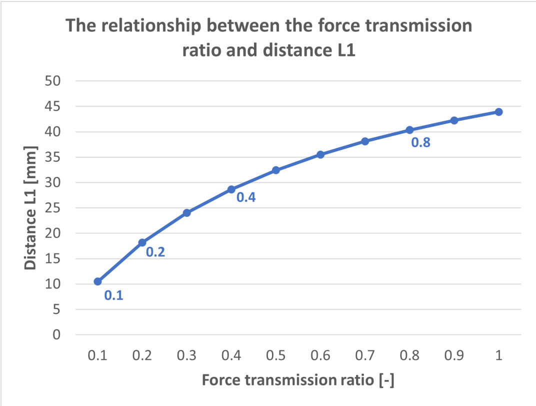

Fig. 7: The relationship between the FTR and the distance L1. The distance L1 is the distance between the hinge and the base of the lever on the grasper handle. The graph shows the four FTR values chosen to include in the study (0.1, 0.2, 0.4 and 0.8) and the corresponding distances of L1.

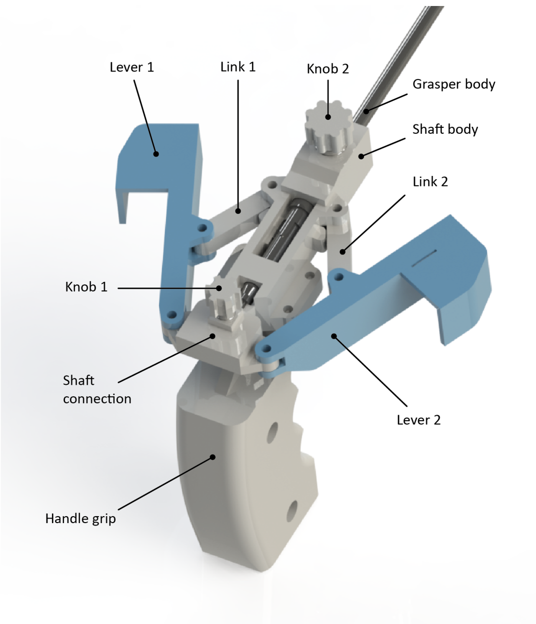

Fig. 8: The final design of the grasper handle including the components.

4) The final set of grasper handles: In Figure 9, the five grasper handle variations are presented. This includes four variations in force transmission ratio and two variations in contact area.

III. RESULTS

The results of the study include the development of the set of laparoscopic grasper handles varying in the chosen independent variables and the results gained in the within-subjects experiment. As the set of developed grasper handles is used in the experiment, the design results are presented before the experimental results. First, the prototype design is elaborated on with the design iterations made and the description of the final grasper handle dimensions. Second, the results of the experiment are presented including the results of the stiffness ranking task, force measurements and survey.

A. Prototype design

A set of five grasper handles have been developed, of which the grasper handles vary in the chosen independent variables. Four handles with the FTR variations 0.1, 0.2, 0.4, 0.8 including the double lever contact area variation and one handle with the FTR variation of 0.2 including the single lever contact area variation. An extensive overview of the design process can be found in Appendix A.

1) Grasper handle design: First, the overall design is presented, which is the same for each handle variation. This can be seen in Figure 8. The handle is able to be connected and disconnected by sliding the handle on the grasper body and by turning two knobs to fixate the handle to the grasper body and the shaft connection to the shaft inside the grasper body. The handle grip can be gripped by the hand while the grasping tip can be actuated by pressing the lever or levers, depending on the handle variation.

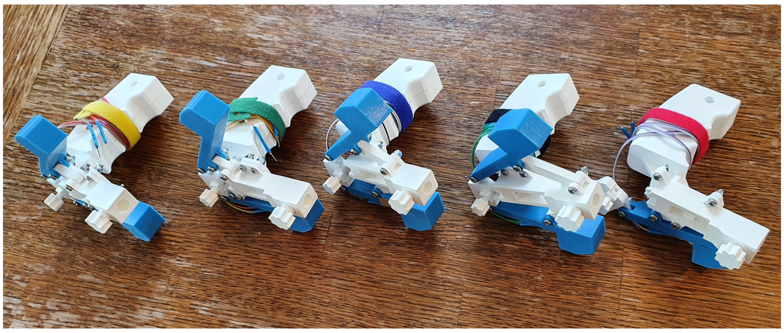

Fig. 9: The final set of grasper handles including five handle design variations. From left to right: the FTR variations 0.1, 0.2, 0.4, 0.8 with the double lever contact area variation, and on the far right, the FTR 0.2 with the single lever contact area variation.

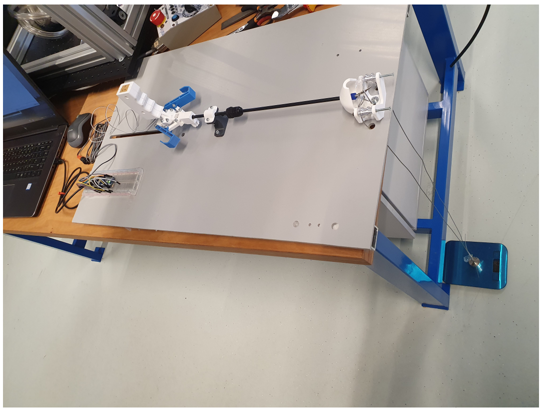

Fig. 10: Setup of the mechanical validation of the grasper handles. The clamped grasper is actuated with varying weights fixed to the grasper tip with the use of steel cables. The weights are placed on a scale below the grasper tip to indicate when the weights are lifted. The mechanical validation is performed by lifting different weigths with the each grasper handle variation.

2) Design iterations: Areas of focus in the design iterations were the reduction in amount of parts, horizontal and axial alignment, establishing a quick and easy connection mechanism to the grasper body, connection of the handle grip and the placement of the sensor. The design iterations can be found in Appendix A. The result is a set of five grasper handles which enable a quick replacement of the handles during the experiment, while establishing control over the grasper tip actuation and facilitating a controlled experiment.

3) Grasper handle dimensions: The dimensions of the varying grasper handles were based on the required variation in FTR. Following the chosen concept, the variations were established by varying the hinge placement in the lever. To ensure the same opening angle for each grasper handle despite the varying hinge placements, the link dimensions have been varied in their length for each handle variation. The calculations for the hinge placement and the link dimensions can be found in Appendix C.1 and C.2.

4) Mechanical validation: The variation in FTR in the grasper handles was mechanically validated by actuating the grasper tip while simultaneously lifting different weights. In the setup, which can be seen in Figure 10, the grasper was placed in the clamp and varying weights were fixed to the grasper tip with the use of steel cables. The weights were placed on a scale below the grasper tip to indicate when the weights were lifted. Weights of 200, 400, 600 and 800 g were used in the validation. The validation resulted in measured FTR values of 0.1, 0.2, 0.5 and 0.8. The measured FTR value of 0.5 in the FTR 0.4 variation was decided to be within acceptable range.

B. Stiffness ranking task

The stiffness ranking task resulted in the participants perceived order of stiffness levels in each experimental round and the assigned ranking scores. The distribution of the average ranking scores of the 16 participants can be seen in Figure 11 and the descriptive statistics are presented in Table I. Figure 12 shows the estimated marginal means for each FTR value. To illustrate what has been measured for each participant, an example of the experimental conditions and assigned ranking scores for one randomly chosen participant is presented in Table II and a characteristic force plot of one force measurement is shown in Figure 13.

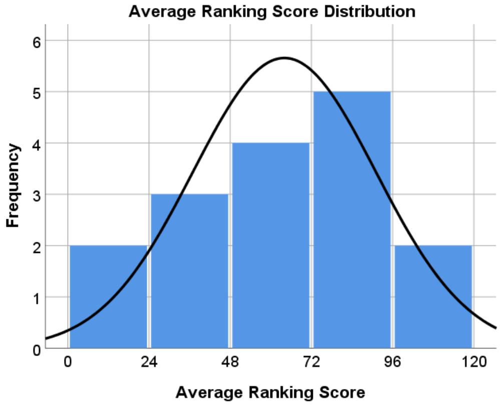

Fig. 11: The distribution of the average ranking scores of the 16 participants (Mean = 64, Std. Dev. = 27.083).

Descriptive statistics

Measure	Mean	Std. deviation	N
Ranking score (FTR 0.1)	64.50	43.044	16
Ranking score (FTR 0.2)	68.75	47.871	16
Ranking score (FTR 0.4)	45.81	50.006	16
Ranking score (FTR 0.8)	58.25	44.771	16

TABLE I: The descriptive statistics of the one-way repeated measures ANOVA performed on the stiffness ranking task results.

1) Force transmission ratio variations: Analyzing the results of the stiffness ranking task using a one-way repeated measures ANOVA results in a statistical difference (P = 0.044) between the

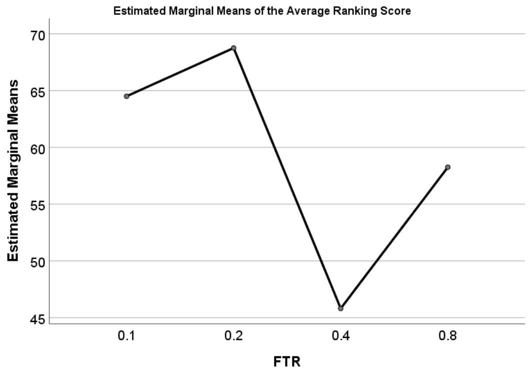

Fig. 12: Estimated marginal means plot of the the one-way repeated measures ANOVA performed on the stiffness ranking task results. A significant difference is found between the FTR values 0.2 and 0.4 (P = 0.044).

ranking scores attained when using the grasper handle with the FTR values of 0.2 and 0.4. No statistical differences were found in the other pairwise comparisons between the FTR values. This can be seen in Table III.

2) Contact area variations: To study the results attained when using the grasper handles with contact area variations, a two sample paired t-test with a one-tailed distribution was used. No statistical differences were found (P = 0.248).

C. Grasping strategy

One-tailed Pearson correlation tests have been done to analyse the correlations between the grasping force metrics (MaxPeakForce, AveragePeakForce, TotalPeaksNonZero and AveragePeaksNonZero) and the stiffness ranking score metric (AverageRankingScore). The correlations are shown in Figure 14. There is a significant correlation found between AveragePeakForce and AverageRankingScore (R = - 0.610, P = 0.006) and there is a significant correlation found between the MaxPeakForce and RankingScore (R = - 0.521, P = 0.019). Both show a moderate to strong negative correlation. There are no significant correlations found between TotalPeaksNonZero and RankingScore (R = 0.252, P = 0.173) and between AveragePeaksNonZero and RankingScore (R = 0.277, P = 0.150).

Ranking score assignment of participant 14								
Round	Handle type	Perceived stiffness ranking			Correct stiffness ranking			Ranking score
1	FTR 0.1 (D)	2	1	3	1	3	2	0
2	FTR 0.4 (D)	2	1	3	2	1	3	100
3	FTR 0.8 (D)	3	2	1	2	3	1	33
4	FTR 0.2 (D)	3	2	1	3	2	1	100
5	FTR 0.2 (D)	1	2	3	1	2	3	100
6	FTR 0.2 (S)	3	2	1	3	2	1	100
Average								72

TABLE II: The ranking score assignment of the stiffness ranking task results of participant 14. The stiffness levels consist of soft (1), medium (2) and hard (3) and are placed in randomized order. The participant scored '100' for four out of six rounds. A score of '0' was assigned for round 1 and a score of '33' for round 3. The average ranking score of the six rounds is 72. The rounds have been done with the FTR variations (FTR 0.1 to 0.8 in randomized order) in the first four rounds and the contact area variations (double levers (D) and single lever (S) in randomized order) in the last two rounds.

Pairwise comparisons						
(I) FTR	(J) FTR	Mean Difference (I-J)	Std. Error	Sig.*	Lower Bound	Upper Bound
0.1	0.2	-4.25	14.558	0.774	-35.28	26.78
	0.4	18.688	14.589	0.22	-12.408	49.783
	0.8	6.25	12.663	0.629	-20.741	33.241
0.2	0.1	4.25	14.558	0.774	-26.78	35.28
	0.4	22.938**	10.423	0.044	0.722	45.153
	0.8	10.5	14.831	0.49	-21.112	42.112
0.4	0.1	-18.687	14.589	0.22	-49.783	12.408
	0.2	-22.937**	10.423	0.044	-45.153	-0.722
	0.8	-12.437	13.93	0.386	-42.128	17.253
0.8	0.1	-6.25	12.663	0.629	-33.241	20.741
	0.2	-10.5	14.831	0.49	-42.112	21.112
	0.4	12.438	13.93	0.386	-17.253	42.128
* = 95% Confidence Interval for Difference. As adjustment for multiple comparisons, the Least Significant Difference is used.						
** = The mean difference is significant at the 0.05 level.						

TABLE III: The pairwise comparisons of the one-way repeated measures ANOVA performed on the stiffness ranking task results, based on the estimated marginal means. The difference between the FTR 0.2 variation and FTR 0.4 variation are significant at the 0.05 level (P = 0.044).

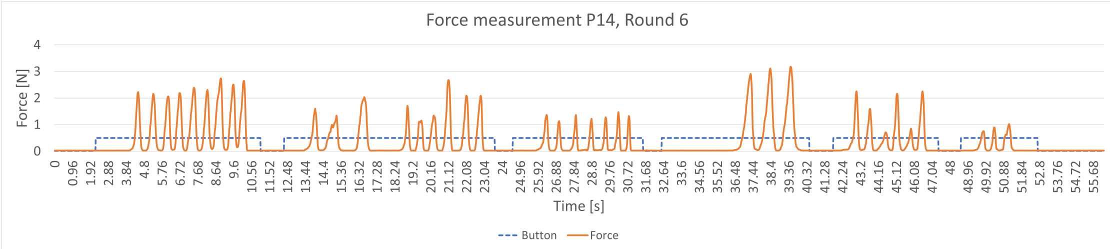

Fig. 13: Grasping force measurement of participant 14. The plot shows round 6 of the stiffness ranking task. For this round, the order of stiffness levels was presented as hard (3), neutral (2), and soft (1). This order was grasped twice using the grasper handle with FTR 0.2 and contact area with one lever (S). The button indicates the placement of the grasper tip on the subsequent stiffness samples. The duration of this round was 55.9 s.

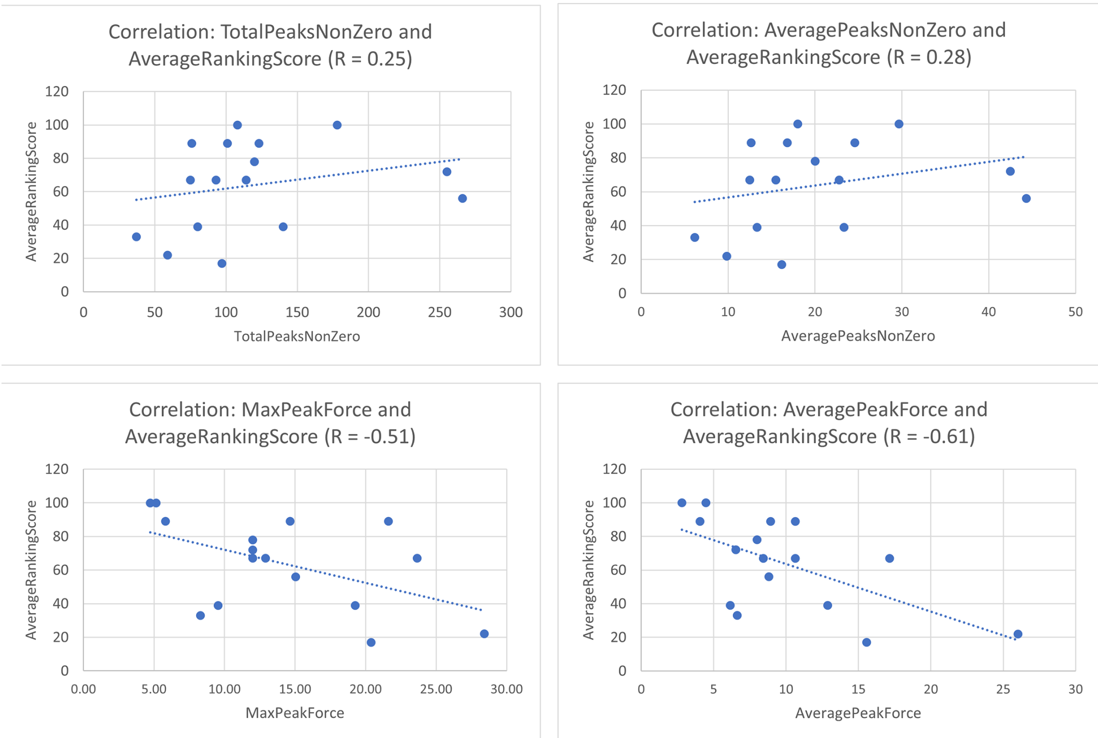

Fig. 14: The correlations between the grasping force metrics (TotalPeaksNonZero, AveragePeaksNonZero, MaxPeakForce and AveragePeakForce, shown on the horizontal axes) and the stiffness ranking score metric (AverageRankingScore, shown on the vertical axes). There is a significant correlation found between AveragePeakForce and AverageRankingScore ($R = -0.610$, $P = 0.006$) and between the MaxPeakForce and AverageRankingScore ($R = -0.521$, $P = 0.019$). Both show a moderate to strong negative correlation.

D. High and low FTR

The means found in the results for the different FTR variations do not show a constant positive or negative slope, but they do show a possible difference between the low FTR values (0.1 and 0.2) and high FTR values (0.4 and 0.8) when grouped together. Analyzing the ranking scores with a two sample paired t-test with a one-tailed distribution results in no significant difference between the groups (P = 0.082). Although not significant, the P-value does show a proximity to the 0.05 level of significance. In this case, if the difference would be significant, it would indicate that a lower amount of FTR would result in a higher average ranking score (mean = 66.625, st. dev. = 44.834), than a high amount of FTR (mean = 52.031, st. dev. = 47.114). The P-value is low enough to imply that a larger sample size might result in a sufficient number of measurements to observe a significant result .

E. Score based differences

To study if a high and low scoring group of participants show different behaviour and therefore different results within this study, a two-way repeated measures ANOVA has been done to study if there would be a difference in ranking scores for each FTR variation if the participants were divided in two groups. The within-subjects factor was chosen to be the FTR variations with four levels and the between-subjects factor was chosen to be the ranking score with two levels (high and low). A participant with an average ranking score of higher than 50 was placed in the high scoring group and lower than 50 in the low scoring group. The analysis shows that there is no significant difference between the FTR levels within each group (P = 0.753). This is also confirmed by the estimated marginal means plot in Figure 15, where the means are different between the groups but not between the FTR levels within the groups.

The same method was applied on the results for the contact area variation. Similar results were found with no significant difference between the contact area levels within the groups (P = 0.418). This is shown in Figure 16. Group wise correlation analyses with one-tailed distributions have been used to study the grasping strategy metrics between the high and low scoring group. No significant difference was found for the maximum peak force and average ranking score within the high scoring group (R = -0.505, P = 0.057) and the low scoring group (R = -0.621, P = 0.132). The same results were found for correlations between the average ranking score and the metrics total peaks non zero in the high scoring group (R = 0.254, P = 0.225) and low scoring group (R = 0.536, P = 0.176) and average peaks non zero in the high scoring group (R = 0.248, P = 0.231) and low scoring group (R = 0.536, P = 0.176). A significant difference was found for the metric average peak force, which has a stronger negative

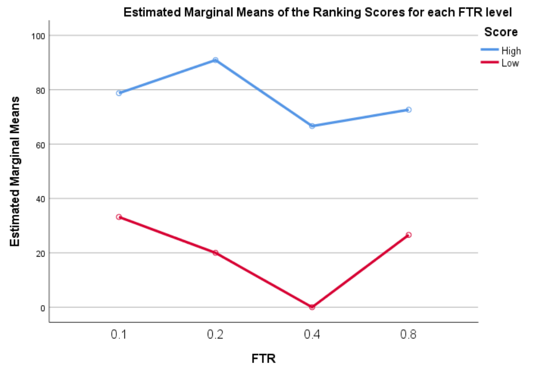

Fig. 15: Estimated marginal means plot as a result from the two-way repeated measures ANOVA performed on the stiffness ranking task results. The subjects are divided in a high and low ranking score group.

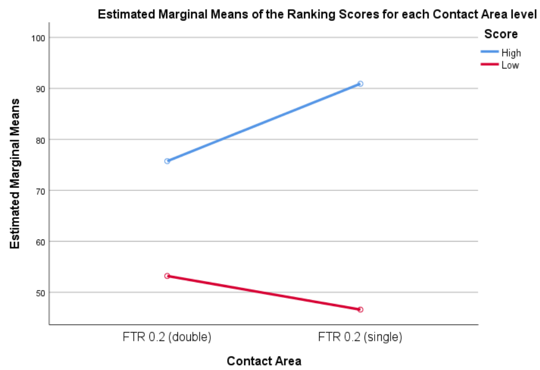

Fig. 16: Estimated marginal means plot as a result from the two-way repeated measures ANOVA performed on the stiffness ranking task results. The subjects are divided in a high and low ranking score group.

correlation with the average ranking score in the low scoring group (R = -0.938, P = 0.009) than in the high scoring group (R = -0.713, P = 0.713). Overall, it can be concluded that it is desirable to exert a low average peak force to attain a high average ranking score and that this has a higher influence when the overall haptic perception of the participant is low.

F. Survey

The distribution of the confidence levels of the 16 participants can be seen in Figure 17. To analyse the correlation between the confidence metric (Confidence) and stiffness ranking score metric (AverageRankingScores), a one-tailed Pearson correlation test has been performed. The correlation graph can be seen in Figure 18. There was no significant correlation found (R = 0.227, P = 0.199).

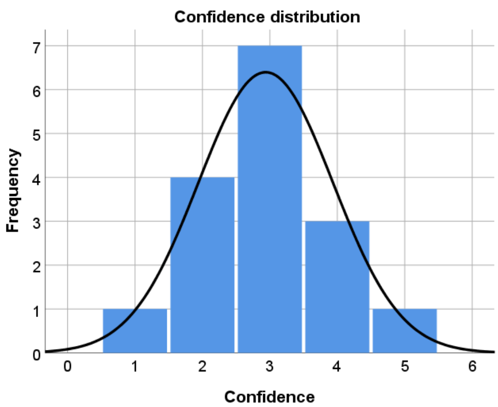

Fig. 17: The distribution of the indicated confidence levels of the 16 participants (Mean = 2.94, Std. Dev = 0.998). In a survey, the statement "I felt confident about my ranking of the silicone samples" was shown. The participants were asked to answer to what degree the statement felt true to them on a 5-point Likert scale, in which 1 stands for "completely not true" and 5 stands for "completely true".

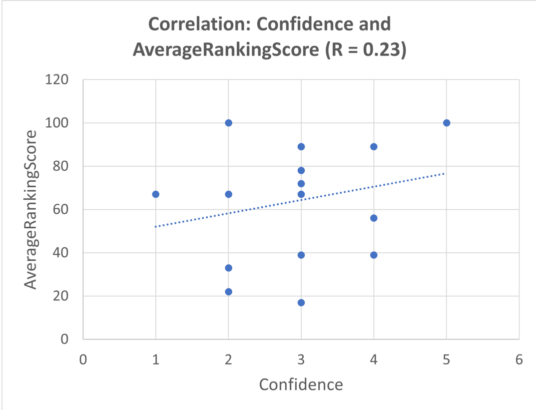

Fig. 18: The correlation between the confidence levels indicated in the survey and the average ranking score of the stiffness ranking task.

IV. DISCUSSION

The results indicate that there is a difference between the FTR values of 0.2 and 0.4, and that a lower average peak force and lower maximum peak force result in higher average ranking scores. It has also been found that contact area and confidence have no influence on the average ranking scores. The results are critically reviewed, based on observed indications, which include the difference in means, the possible required sample size for future studies andthe inconsistency in haptic information. Also, literature is reviewed on the force transmission ratios in other surgical areas and on laparoscopic surgical training.

A. Difference in means

A significant difference in means was found when analyzing the stiffness ranking task results of the FTR variations using a one-way repeated measures ANOVA between the FTR 0.2 and FTR 0.4 variation (P = 0.044). This is explainable by the large difference in means, which was presented in Figure 12. Not finding significant results for the other pairwise comparisons and not seeing a relationship between the estimated marginal means and the FTR values suggest that the finding is less valuable in the search for the influence of FTR on haptic perception.

B. Power analysis

The sample size used for this study (n = 16) was chosen as an arbitrary amount based on an educated guess and was assumed to be sufficient to answer the research question. Ideally, a power analysis would have been done prior to the data collection to compute the required sample size. The small sample size of this study could explain the statistically insignificant results when significant results might have been found with the appropriate sample size. For future studies, the required sample size to have a high probability of correctly rejecting the null hypothesis has been calculated using a power analysis in G*Power. It has been chosen to use the within-subjects analysis of the FTR ranking scores as the indicator, as this was the main focus of the study and presumably requires the highest minimal sample size. With the input parameters chosen, which correspond to the performed study (effect size f = 0.2, alpha = 0.05, power = 0.8, number of groups = 1, number of measurements = 4, correction among repeated measures = 0.5 and nonsphericity correction = 1), it has been calculated that a total sample size of 36 would be required in a future study (n = 36). Performing a within-subjects experimental design has the advantages that the individual differences between the subjects to not influence the outcomes and that there are less subjects needed to perform the experiment to achieve statistical power. It does need to be taken into account that there is a possible learning curve during the experiment.

C. Consistency

In this study, the stiffness ranking task enabled the investigation of the influence of force transmission ratio and contact area, while the force measurements done during the task were used to investigate the influence of grasping strategies. While the participants were asked to grasp the three tissue samples consistently in a certain order, the amount of grasps performed on each sample was allowed to be chosen freely. The advantage of permitting this freedom is the explorative nature of the grasping movements which therefore reveal the strategies chosen by the participants themselves. The disadvantage is the unequal amount of haptic information received, which the participants used for the stiffness ranking task. Controlling the amount of grasps allowed per sample and even the duration of the grasps would result in more reliable results regarding the measured stiffness perception.

D. A broader perspective on force transmission ratio

With regards to the force transmission ratio, the results show that there is no influence on the haptic perception of variable tissue stiffness. There is an indication that lower force transmission might be proven beneficial if more subjects would be included in the study. A lower force transmission would mean that a grasping force at the handle would result in a higher grasping force at the tip, causing the force to be amplified. It has been critically reviewed how this relates to published research if this would be the case.

In literature, force transmission ratio in laparoscopic surgery has mainly been related to the instrument performance, such as preventing tissue slippage, and less to haptic perception [3][31][38][39]. Another application where force transmission plays a role in combination with perception is teleoperative surgery, in which the operator controls the instruments from a remote environment. A study by Boessenkool et al. described how a perfect tracking of forces and positions in the presentation of physical interaction is favorable. This is also called transparency [40]. A perfect tracking of forces could be interpreted as a 1:1 force transmission ratio, which would not be in accordance with the results of this study.

E. Grasping strategy and surgical training

Adequate training and skills assessment directly translates to enhanced patient safety [41]. Surgical training of novices should focus on the improvement of tissue handling skills, which includes reducing the force application, as high force exertion can cause tissue reactions, slippage and damage [42][43][44][45][46]. When selecting the right grasping strategy, it should be taken into account that this also depends on task-related factors such as the stiffness of the tissue. Tissues with different characteristics might require different strategies, which should be included in the laparoscopic curriculum [41].

In terms of grasping strategy, this study has shown that a lower average peak force and lower maximum peak force correlates to a higher average ranking score, and therefore to a higher haptic perception of tissue stiffness. The results of this study correspond to the direction taken in the surgical training of novices to focus on tissue handling skills, which should include reducing the force exertion.

V. CONCLUSION

In this study, force transmission ratio and contact area do not been found to have influence on the haptic perception of variable tissue stiffness. A difference was found between two levels of force transmission ratio, but by not finding significant results between the other FTR levels suggests that the finding is less valuable. In terms of grasping strategy, a low force exertion has been shown to be desirable for perceiving the variable tissue stiffness, while the amount of grasps per tissue sample have not shown a difference in perception results. There are no differences found in the results when low FTR levels and high FTR levels were placed in separate groups or when the participants were organized in low and high scoring groups. Lastly, the perceived confidence was not found to be of influence on the ranking scores. Future studies with larger sample sizes might indicate a difference between high and low force transmission ratios. In future studies focused on the haptic perception of tissue stiffness, it is recommended to restrict the grasping movements of the participants to have consistency in the haptic information received, and to therefore have reliable results regarding the measured stiffness perception. The results of this study regarding the appropriate grasping strategies are in accordance with the direction taken in the laparoscopic skills training of novices which includes reducing the force exertion. It is concluded that future designs of laparoscopic grasper handles might not be restricted in terms of force transmission ratio and contact area requirements when a greater haptic perception is aimed at. More haptic perception of variable tissue stiffness is gained in the surgical domain of applying appropriate grasping strategies.

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APPENDIX

A. DESIGN FILE

1) Introduction: The graduation project consists of the research process of conducting the experimental study and the design process of developing the laparoscopic grasper handles. The two parts have a different focus and consist of different steps. The two parts have been visualized as a research domain and design domain in Figure 19. Because the main focus of the project is to conduct the experimental study, the design domain is secondary to the research domain. As the requirements for the experimental study influence the design requirements for the grasper handles and the design of the grasper handles influences the experimental study, the two parts of the project have to be done in parallel and have to be integrated into one project. An integral approach has been implemented with back and forth adjustments. The model in the design domain is based on the basic design cycle described by Roozenburg and Eekels [36]. This design cycle consists of an iterative process which is executed multiple times to implement new insights and therefore generate the most valuable results. The model in the research domain is based on the experimental design model by Darius and Portier (Darius and Portier, 1999).

2) Design goal: The use of the laparoscopic grasper handles in an experimental study influences the scope of the design phase and the list of requirements for the design of the handles. To answer the research question, the experimental study is conducted with the use of a set of laparoscopic grasper handles, which vary in the chosen independent variables. The handles are required to be used on a reusable and modular grasper which has been made available for this study (NYA1027, NanYu, Zhejiang, China). The complete design cycle consists of the analysis phase, synthesis phase and evaluation phase. This design cycle consists of an iterative process which is executed multiple times to implement insights gained later in the process and to achieve the best results. The list of requirements is used to give direction to the idea generation in the synthesis phase and to assess the design concepts when selecting the most valuable results in the evaluation phase. Before constructing the list of requirements, the functions and ergonomics are explored, as the results of these explorations are included in the list of requirements. The design goal is formulated as:

To design and produce multiple laparoscopic grasper handles to be used in an experimental study, focused on the influence of contact area, force transmission ratio and grasping strategy on the haptic perception of variable tissue stiffness.

3) Existing designs: The instrument handles are the direct contact area between the hands and the instruments. As this is the only way of receiving haptic feedback in laparoscopic surgery, it is relevant to review the existing designs which have been reported in literature. There is a wide variety of handle designs available for laparoscopic instruments. Most handles are designed for multifunctionality as one type of instrument handle design may be used for a variety of manipulation tasks [33]. Laparoscopic instruments are designed as multifunctional to reduce the amount of times the tools are removed and inserted, which reduces the risk of infection, but also requires more skills from the surgeon to handle more complex tools [47]. The types of handle designs which are found in literature can be seen in Figure 20. The handle designs are clustered into seven groups: the pistol grip, scissor handle, pencil handle, axial handle, shank handle, horizontal handle and alternative handle, based on the groups described by Van Veelen et al. and Matern et al. [33][32].

4) Functions: The functions of the grasper handle can be divided into functions regarding the product use and functions regarding the use in the experimental study. These functions are included in the list of requirements. The functions are also used in the synthesis phase when developing the Morphological map to generate the design concepts.

Functions regarding the use in an experimental study:

1. Enable a variety in contact area

2. Enable a variety in force transmission ratio

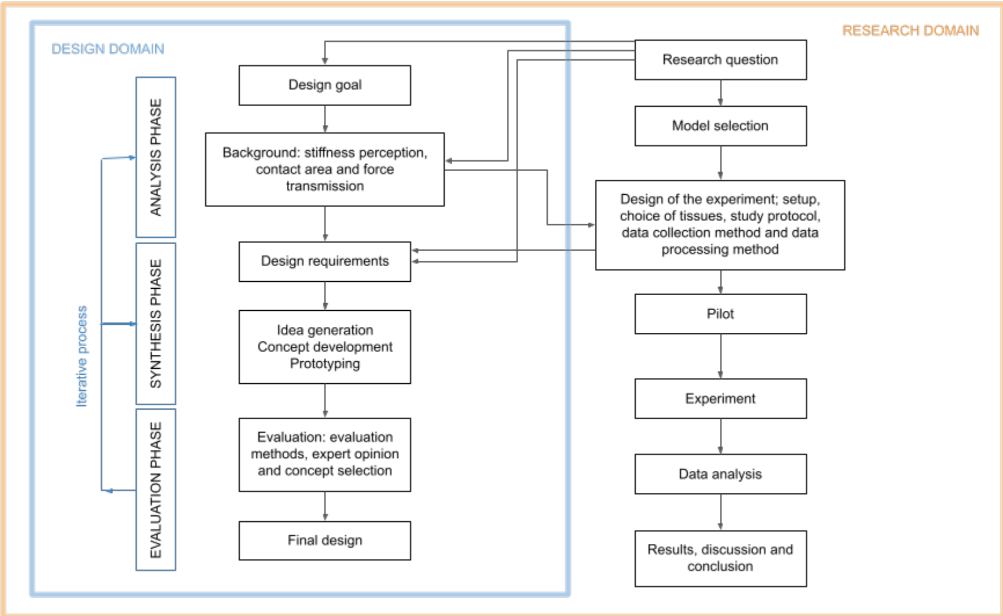

Fig. 19: Schematic view of the parts of the graduation project divided into a design and research domain. The arrows represent the influence of parts on different parts of the project. The design domain is integrated into the research domain.

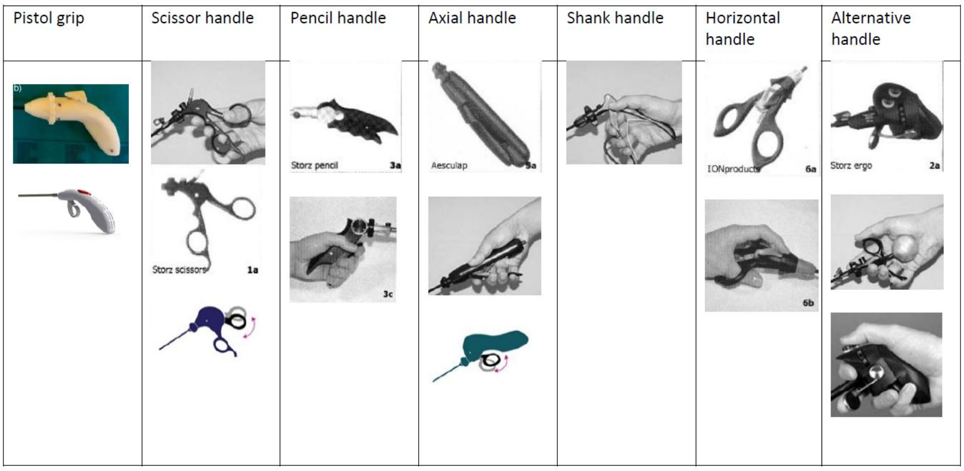

Fig. 20: Laparoscopic handle designs clustered into seven groups: the pistol grip, scissor handle, pencil handle, axial handle, shank handle, horizontal handle and alternative handle.

Functions regarding the product use:

3. Enable gripping

4. Enable actuation of the end effector

5. Connect to the grasping instrument

5) Ergonomics: When designing the grasper handle, hand measures have been taken into account. The anthropometric database DINED is used as the source of the statistical information of these measures. The population to focus the design on is chosen to be Dutch adults, mixed (including both males and females). To enable the use for a large amount of users, the data is included from the fifth percentile to the ninety fifth percentile (P5 to P95). The measures taken into account are shown in Table IV.

Measures	Number of measure	P5	P95
Hand width (without thumb) (mm)	1	71	97
Hand length (mm)	2	163	209
Grip circumference (mm)	3	108	150
Hand thickness (mm)	4	14	34
Forefinger breadth (mm)	5	13	19
Thumb breadth (mm)	6	18	24
Length pointing finger (mm)	7	64*	80*

TABLE IV: Ergonomic measures of both female and male Dutch adults between 20 and 30 years old, taken from DINED. (* = measures used from the population Dutch female and male students between 17 and 27 year old.)

6) Design requirements: The list of requirements describes the aspects of the design which are influenced by the design goal, the functional requirements and the ergonomic requirements. The experimental study is conducted with the use of a newly developed set of laparoscopic grasper handles, which is made to vary in the chosen independent variables. This influences the design requirements for the development of the grasper handles. The first two requirements concern the use in an experimental study and the last four requirements concern the functional use of the grasper handles. Although a set of grasper handles is to be developed, the design requirements apply uniformly to each separate grasper handle.

1. Enable a variety in force transmission ratio:
The design of the grasper handle enables a variation in force transmission ratio to use in the experimental study with a range of 0.1 to 0.8 N.

2. Enable a variety in contact area:
The design of the grasper handle enables a variation in contact area to use in the experimental study. The contact area is defined as the parts of the the grasper handle in direct contact with the surface of the hand.

3. Enable actuation of the end effector:
The grasper handle enables the actuation of the end effector, by generating a linear movement of the shaft of the grasper.

4. Connect to the grasping instrument:
The handle is able to be connected and disconnected to the grasping instrument. The connection is able to be established impermanently and in a quick manner.

5. Enable gripping:
The grasper handle is able to be held with one hand.

6. Incorporate ergonomic measures:
The handle is able to be used for the population of Dutch adults, mixed (including both male and female), from P5 to P95.

7) Idea generation: To generate ideas, the brainstorm method of "How to's" has been used. This method is described in the Delft Design Guide and by Roozenburg and Eekels [36][48]. The results can be found in Appendix D. In this method, the design problem has been divided into subproblems. The subproblems correspond to the defined functions. As the product needs to have these functions, each function is defined as a separate subproblem which needs to be solved by a part of the product. This method results in a large amount of solutions which can be combined to form design concepts.

The solutions of the brainstorm method have been incorporated in a morphological map. The morphological map is a method by Roozenburg and Eekels to generate design concepts [36][48]. Concepts were generated by combining the solutions to the different subproblems. The map can be found in Appendix D.

8) Concepts: The results of the idea generation have been integrated to develop three concepts which each propose a solution to achieve the formulated design goal.

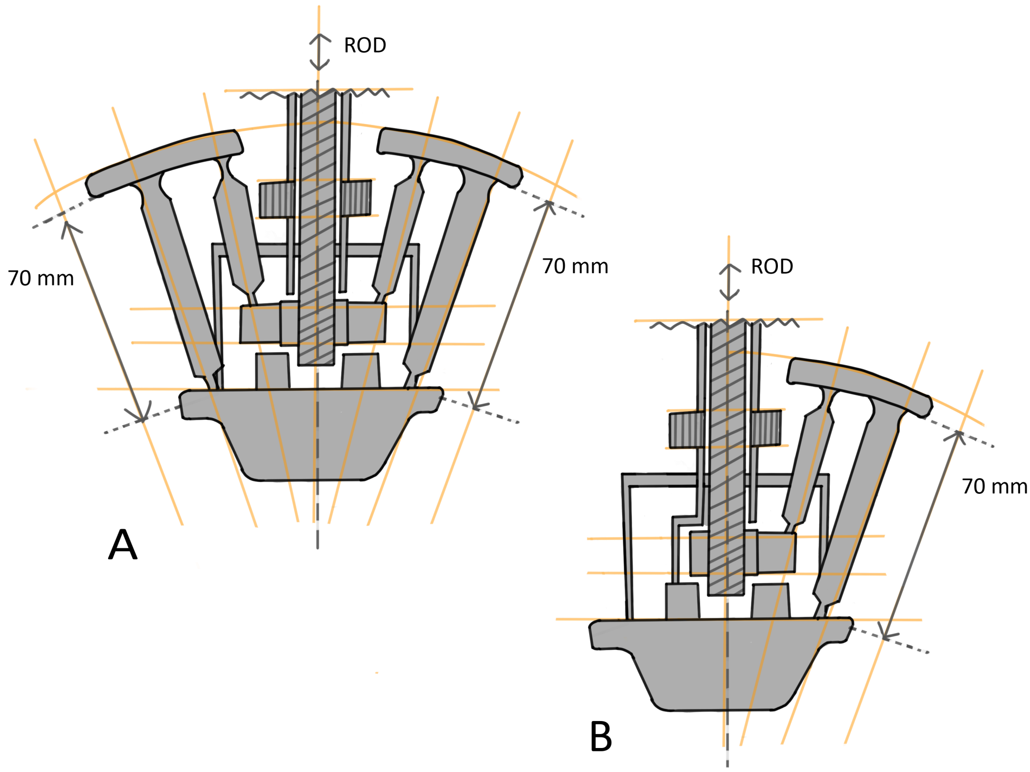

Fig. 21: Concept 1: The moving hinge. This can be actuated using the index finger and thumb (A) or by only using the index finger (B).

Concept 1: The moving hinge

The first concept has a mechanism like a pincet and is similar to a horizontal handle (see Figure 21). Pushing on the lever creates a linear movement in the shaft, which actuates the grasper tip. The FTR can be varied by placing the hinge on the lever on a varying distance from the shaft axis. The contact area can be varied by actuating the grasper tip with either the index finger and thumb (A) or with only the index finger (B). The lever is 70 mm to accommodate with the length of the index finger and thumb, following the ergonomic requirements. The parts of the hand which are not used in actuation, hold the handle grip for stability.

Concept 2: The articulating handle

The second concept has a mechanism like a scissor pistol grip. It can be seen in Figure 22. It is manipulated with the ring finger or multiple fingers in the ring handle and is held with the hand palm and thumb on the other side. The FTR can be varied by placing the ring for the manipulation closer or further away from the articulating joint. The contact area can be varied by requiring only the ring finger or multiple fingers for actuation. The lever is 70 mm long to accommodate the placement of multiple fingers next to eachother. The other side is 100 mm to accommodate the placement of the handpalm or thumb for stability.

Concept 3: The modular spring

The third concept is shaped like an axial handle. It can be seen in Figure 23. The grasper jaws can be opened by pressing both levers. At the end of the shaft rod, a spring is placed which opens the jaws again when the grip on the lever is loosened. The FTR can be varied by replacing the end of the

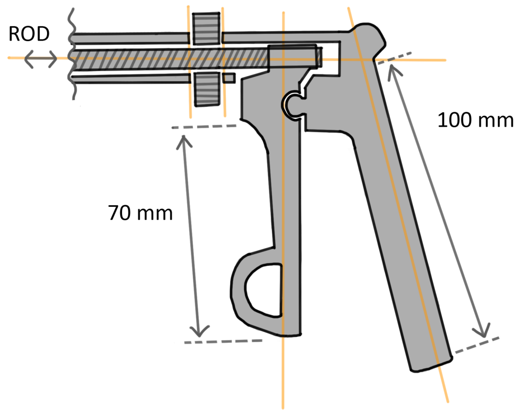

Fig. 22: Concept 2: The articulating handle.

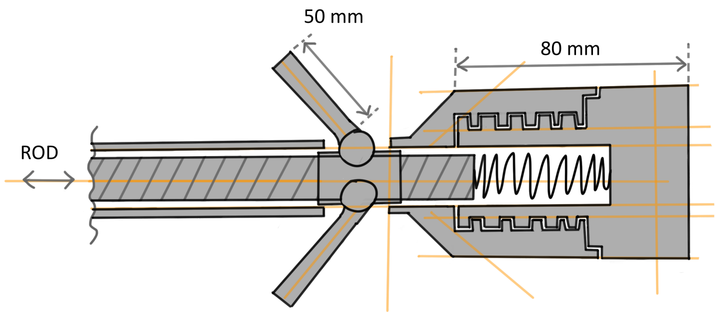

Fig. 23: Concept 3: The modular spring.

handle with a different spring attached. Different springs can be attached which contain varying spring constants and therefore require varying amount of actuation forces. The contact area can be varied by having a different surface roughness on the handle lever. The handle grip is 80 mm long to accommodate the width of the handpalm and the levers are 50 mm long to enable the placement of part of the indexfinger and thumb.

9) Concept selection: The Harris Profile method is used for the concept selection. The concepts are assessed based on their expected fulfillment of the requirements. The results can be seen in Figure 25. Concept 1 is expected to have the most consistent result regarding the implementation of the varying force transmission ratios, while concept 3 will be relatively difficult to achieve the same results with. The variation of the contact area of concept 3 would suffice, but is

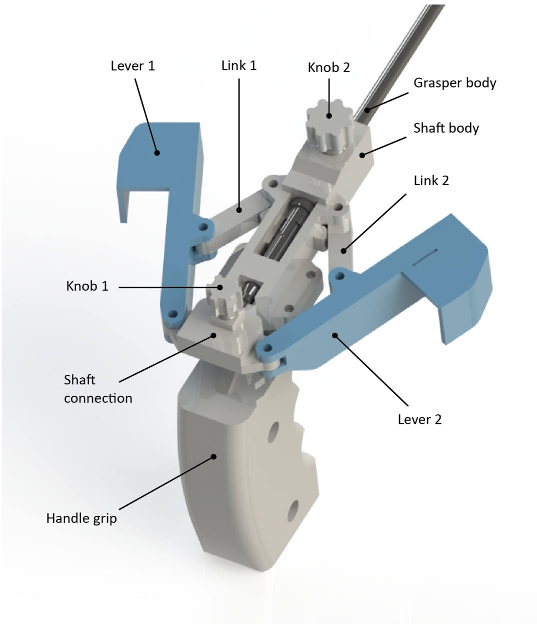

Fig. 24: The final design of the grasper handle including the components.

evaluated as less interesting compared to the other concepts. Concept 3 also shows a less reliable actuation mechanism, with the spring required for actuation, compared to the other actuation mechanisms. Concept 3 could be difficult to connect to the grasper due to the spring placed in the center. Concept 2 has varying lengths in the lever to vary the force transmission ratio, but this is expected to cause problems with regard to correctly gripping the instrument and to conform to ergonomic requirements. This is not expected for concept 1 and concept 3. Concept 1 has the highest score in the Harris Profile and is chosen as the final concept. The final concept design of the grasper handle and the components can be seen in Figure 24.

10) Proof of concept: The final concept consists of the varying hinge placements to vary in the force transmission and the single lever or double lever for actuation to vary in the contact area. The varying hinge placements are accompanied by varying link dimensions to ensure that the opening and closing angles of the handle levers remain the same during actuation for each force transmission ratio variation. The first visual presentation of the final concept can be seen in Figure 39 in Appendix D. Calculations have been done to validate this concept and to determine the appropriate hinge locations and corresponding link dimensions.

Hinge placement calculations: The grasping force at the tip is transmitted along the shaft in the instrument mechanism, through the shaft connection and onto the base of the handle lever. This force (Fshaft) is assumed to be a single vector in the direction of the instrument shaft. This can be seen on the free body diagrams in Figure 27. The force transmission ratio can be expressed as equation 3.

$$FTR = \frac{Fhandle}{Fshaft} \tag{3}$$

To perform the calculations, Fshaft was chosen to be 10 N, as this is a grasping interaction force relevant in laparoscopic tool-tissue interactions. A mathematical model was developed Maple with the force, distance and angle parameters presented in the free body diagrams (Maplesoft, Cybernet Systems Co. ltd., Chiyoda, Japan). The calculations can be found in detail in Appendix C.1 and C.2. The variations in force transmission ratio were chosen to be 0.1, 0.2, 0.4 and 0.8. For each value of FTR, the hinge placement was calculated using the developed mathemetical model and was expressed as the distance L1. L2 could be calculated using the total length of the lever. Equation 4 shows the simplified equation.

$$L1 = \frac{FTR * L2}{sin(\beta)} \tag{4}$$

$$L8 = \frac{L7(L1 * sin(\beta)^2 + L6 * FTR}{FTR * sin(\delta)(L7 + L4)} \tag{5}$$

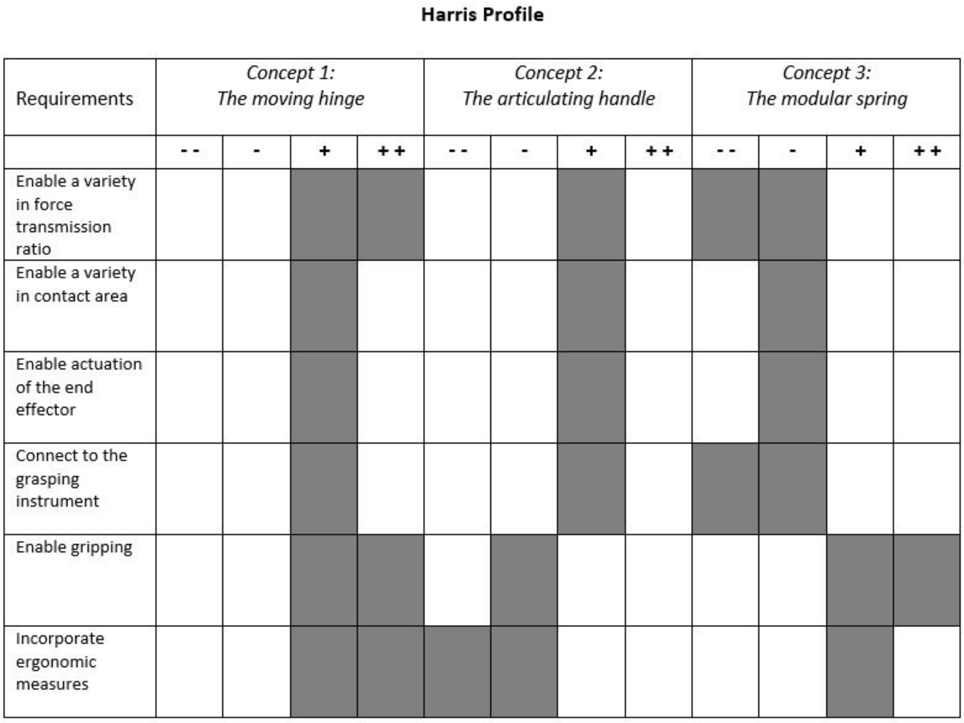

Fig. 25: The Harris Profile used in the concept selection. The concepts are assessed based on their expected fulfillment of the requirements. Concept 1 has the highest score and is chosen as the final concept.

The calculations used for this simplification can be found in Appendix C.1. The distance L1 for the chosen FTR values were found to be 10.48 mm, 18.16 mm, 28.66 mm and 40.32 mm respectively. An overview of the final dimensions is presented in Table V. This means that a higher FTR corresponds to a larger distance L1, and therefore a hinge placement (B) further from the base of the lever (A). This can be seen in Figure 26.

Link dimension calculations: With the use of a 3D printed prototype, the desirable opening angle of the grasper handle was determined, which corresponded to a value of 23.33 degrees for angle Alpha and 39.23 degrees for angle Beta. To ensure the same opening angle for each grasper handle despite the varying hinge placements, the link dimensions have been varied in their length for each handle variation. Using the calculated hinge placements expressed as distance L1, the corresponding link dimensions were calculated. Equation 5 shows the simplified equation.

The calculations used for this simplification can be found in Appendix C.2. The link dimensions for the chosen FTR values were found to be 8.40 mm, 16.10 mm, 25.60 mm and 35.10 mm respectively. An overview of the final dimensions is presented in Table V.

11) Final concept variation dimensions: The dimensions of the final concept varying in force transmission ratio and contact area used to produce the final set of grasper handles are shown in Table V.

12) Prototype iterations: In the design process, design iterations have been applied. This section

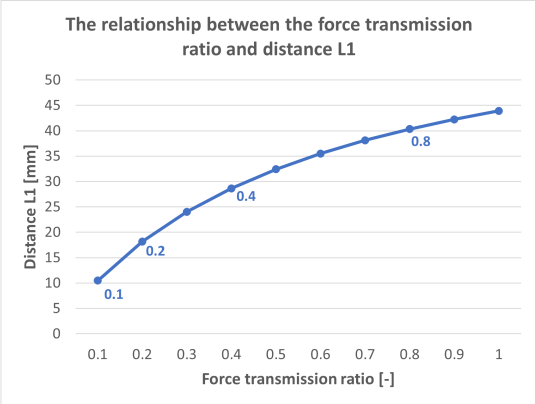

Fig. 26: The relationship between the force transmission ratio and the distance L1. The distance L1 is the distance between the hinge and the base of the lever on the grasper handle. The graph shows the four FTR values chosen to include in the study (0.1, 0.2, 0.4 and 0.8) and the corresponding distances of L1.

Variation in force transmission ratio	Distance L1 (mm)	Distance L8 (mm)
0.1	13.4	8.4
0.2	22.3	16.1
0.4	33.4	25.6
0.8	44.5	35.1

TABLE V: The dimensions of each variation in force transmission ratio. The distance L1 represents the hinge placement and the distance L8 represents the length of the link.)

describes each area of focus within the development of the grasper handles.

Handle connection: Two knobs with screw fittings in the shaft frame (1) and shaft connection (2) allow quick and easy removal and attachment of the handles to the grasper body and shaft. Before using the grasper, the grasper body needs to be sled into the shaft body and the knobs needs to be tightened. While actuating the grasper handle, the knobs prevent the linear movement of the grasper body in the shaft frame and of the shaft in the shaft connection. The knob in the shaft connection (2) not only enables connection, but is also an integral part in the actuation of the grasper tip. The fixation of the end of the shaft when the levers are pressed, results in the movement of the shaft and therefore the grasper tip. The knob is shaped in a way that limits the maximum impression on the shaft, which prevents bending in the shaft. Before this adjustment, there would be friction if the knob was tightly fastened. The connection mechanism contributes greatly to a reduction in execution time for the experiment, as it requires a total of five grasper handle replacements.

Integrated design: In each iterative step, the amount of parts have been reduced. For example, the shaft frame used to consist of three separate parts, joined by small nuts and bolts. Creating a more integrated design results in higher ease of demolding and a shorter production and post-processing time. This was of high importance during the prototyping phase when developing multiple handle variations. It also results in more stability and a higher functionality. For example, the shaft connection was redesigned to only consist of one part and the connecting knob. By consisting of one part, the connection to the shaft was more form fitting and with a more uniform fixation in the entire set of grasper handles.

Horizontal alignment: The first design versions included a high degree of instability in the horizontal plane. As there are six hinges in each grasper handle, the hinges play an important role in the grasping functionality. Designing hinges with a larger surface and with fastening from two sides instead of one resulted in a much higher stability between the levers and the links, between the links and the shaft frame and between the levers and the shaft connection. The higher stability in the horizontal plane contributes to more control of the grasper tip when actuating the grasper levers.

Axial alignment: A connection in the shaft frame has been designed to establish axial alignment when connecting the grasper body and shaft to the grasper handle. During attachment, the

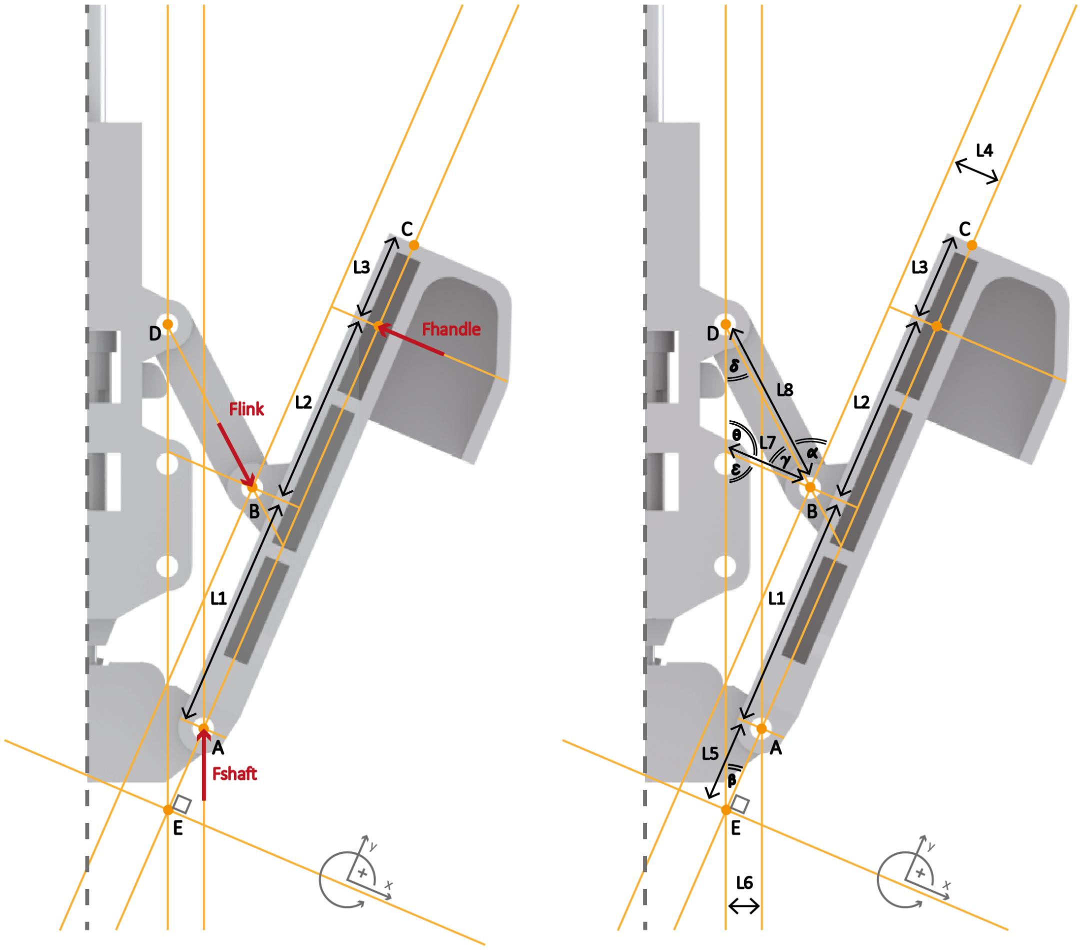

Fig. 27: The free body diagrams of the handle lever. On the left, the relevant forces are shown and on the right the relevant distances and angles are shown.

grasper body slides into the form fitting part. Therefore, the grasper body has the same orientation with regard to the grasper handle during each use.

Grip connection: Each variation in force transmission ratio has a different hinge placement on the levers. This is accompanied by a varying length of the links between the levers and the shaft frame, which therefore requires varying hinge placements on the shaft frame. As the grip is also connected to the shaft frame, this connection can only be established in the remaining space on the shaft frame. The variations of grip connections can be seen in the figures.

Sensor placement: Each grasper handle has a sensor placed in the distal part of the lever where the finger pad of the index finger is located. A gap made in the lever facilitates the placement of the round sensor in the lever. For the experiment, it is important to have a uniform sensor placement in the entire set of grasper handles to prevent the occurance of noise and measurement differences.

B. ARDUINO CODE

```
#include <SPI.h>
#include <SD.h>

// Define FSR pin:
#define fsrpin A0
File myFile;

String filename;
long startTime;

int buttonPort = 2;
boolean writing = false;
int index = 10;
char input;

//========================
String Name = "Participant1Round1";
//========================

//Define variable to store sensor readings:
int fsrreading; //Variable to store FSR value

void setup() {

// Begin serial communication at a baud rate of 9600:
  Serial.begin(115200); //(9600);

  Serial.print("Initializing SD card...");

  if (!SD.begin(4)) {
    Serial.println("initialization failed!");
    while (1);
  }

  pinMode(buttonPort, INPUT);
  Serial.println("initialization done.");

}

void loop() {
// Read the FSR pin and store the output as fsrreading:
  fsrreading = analogRead(fsrpin);

 if (Serial.available()) {
  input = Serial.read();
  Serial.println("Input :" + input);

  switch (input) {
    case '0':
    if (writing)
    {
      long duration = millis() - startTime;
      myFile.println("Duration :" + String(duration));
      myFile.close();
      Serial.println("Was written to " + filename);

      writing = false;
    }
    break;

    case '1':
    if (!writing)
    {
      filename = Name + String(index) + ".csv";
      while (SD.exists(filename))
      {
      Serial.println("Skipping. File exist: " + filename);
      index ++;
      filename = Name + String(index) + ".csv";
      }

      myFile = SD.open(filename, FILE_WRITE);
      startTime = millis();
      Serial.println("Writing to " + filename);
      writing = true;
    }
    break;

    }

  }

if (myFile && writing) {
  if(digitalRead(buttonPort))
  {
    myFile.print("0, ");
    Serial.print("0, ");
  }
  else
  {
    myFile.print("250, ");
    Serial.print("250, ");
  }

    myFile.println(fsrreading);
    Serial.println(fsrreading);
}

  delay(20); //Delay 200 ms.
}
```

C. CALCULATIONS

1) Hinge placement calculations: The calculations used to calculate the distance L1, which represents the hinge placement on the lever. The forces, distances and angles correspond to the free body diagrams, presented in Figure 27.

$$FTR = \frac{Fhandle}{Fshaft}$$

$$\overset{+}{\rightarrow}\sum F_x = 0$$

$$\Rightarrow Flink*cos(\alpha) - Fhandle - Fshaft*sin(\beta) = 0$$

$$+\uparrow\sum F_y = 0$$

$$\Rightarrow Fshaft*cos(\beta) - Flink*sin(\alpha) = 0$$

$$\circlearrowleft + \sum M_B = 0$$

$$\Rightarrow Fhandle*L2 - Fshaft - Fshaft*sin(\beta)*L1 = 0$$

$$\Rightarrow L1 = \frac{FTR*L2}{sin(\beta)}$$

2) Link dimension calculations: Using the calculated hinge placements expressed as distance L1, the corresponding link dimensions were calculated. The forces, distances and angles correspond to the free body diagrams, presented in Figure 27.

$$L5 = \frac{L6}{sin(\beta)}$$

$$L7 + L4 = (L2 + L5)*tan(\beta)$$

$$\frac{L7 + L4}{sin(\beta)} = \frac{L2 + L5}{sin(\beta)}$$

$$\theta = 180 - \epsilon$$

$$\delta = 180 - \gamma - \theta$$

$$\frac{L7}{sin(\delta)} = \frac{L8}{sin(\theta)}$$

$$\Rightarrow L8 = \frac{L7(L1*sin(\beta)^2 + L6*FTR}{FTR*sin(\delta)(L7 + L4)}$$

D. SUPPLEMENTARY FILES

The supplementary files include pictures of the experimental test setup, the wiring diagram of the experimental setup, answer form of the stiffness ranking task, How to's of the idea generation phase and the morphological chart.

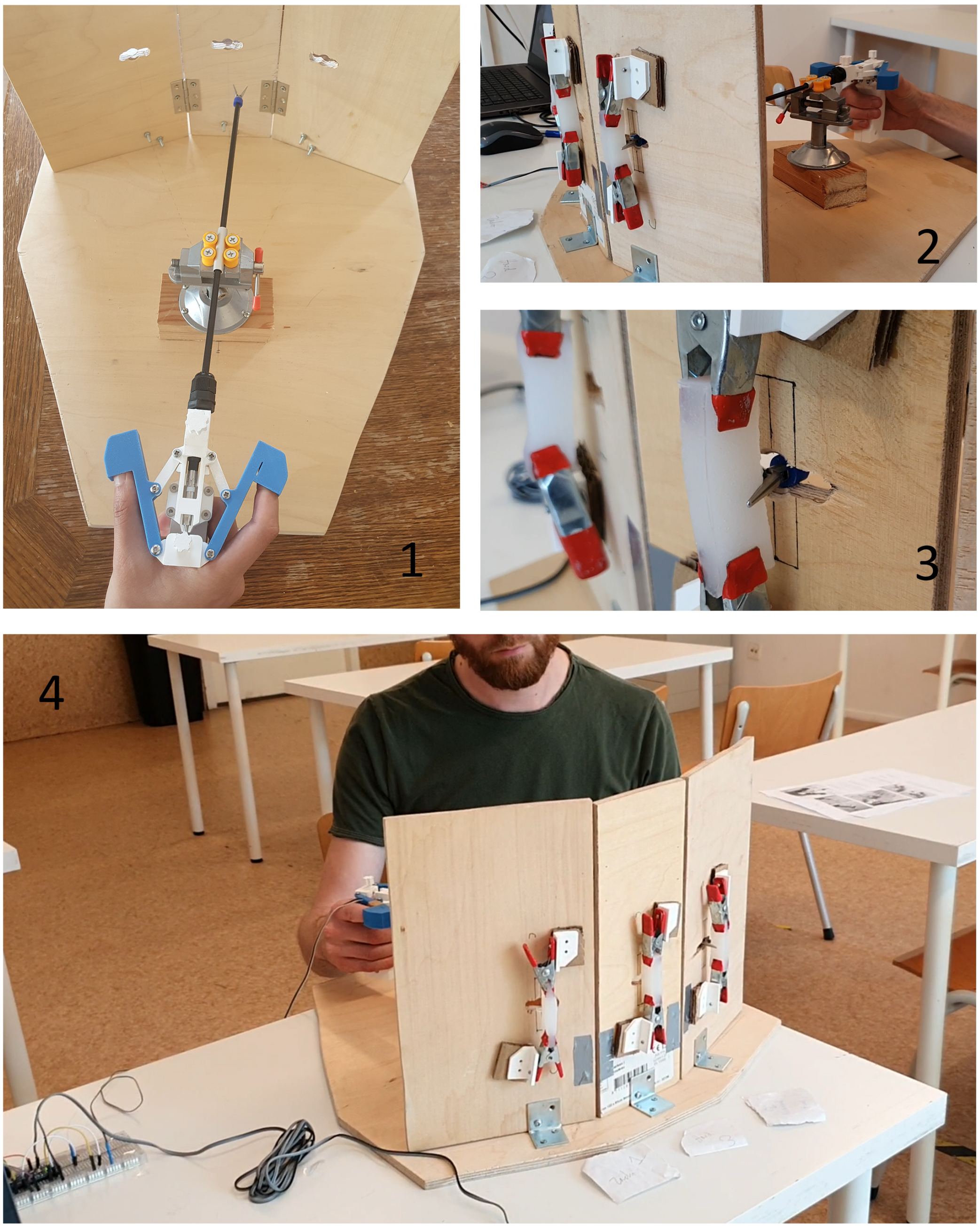

Fig. 28: Pictures of the experimental test setup. (1) Top view of the setup with the grasper held in the clamp and the three slots visible. (2) Side view of the setup with the tissue clamps visible in the back holding the tissue samples. (3) The tissue sample is grasped by the grasper tip. (4) The test setup seen from the back. The participant is holding the grasper and grasping the first tissue sample.

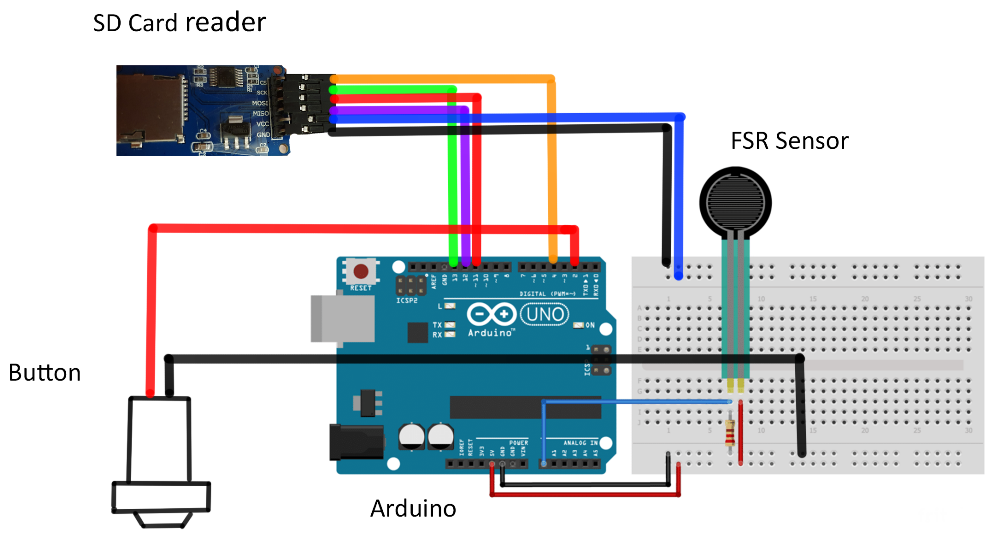

Fig. 29: The wiring diagram. In the actual setup, the jumper wires to the FSR sensor were much longer and the FSR sensor was placed in each grasper handle.

Ranking questionnaire

Please write down the numbers 1, 2 and 3 for the perceived tissue stiffness levels.

The three boxes represent the three sample slots.

Each number occurs one time in each round.

1 = soft, 2 = neutral, 3 = hard

Example	3	1	2
Round 1			
Round 2			
Round 3			
Round 4			
Round 5			
Round 6			

Fig. 30: The answer form used in the stiffness ranking task.

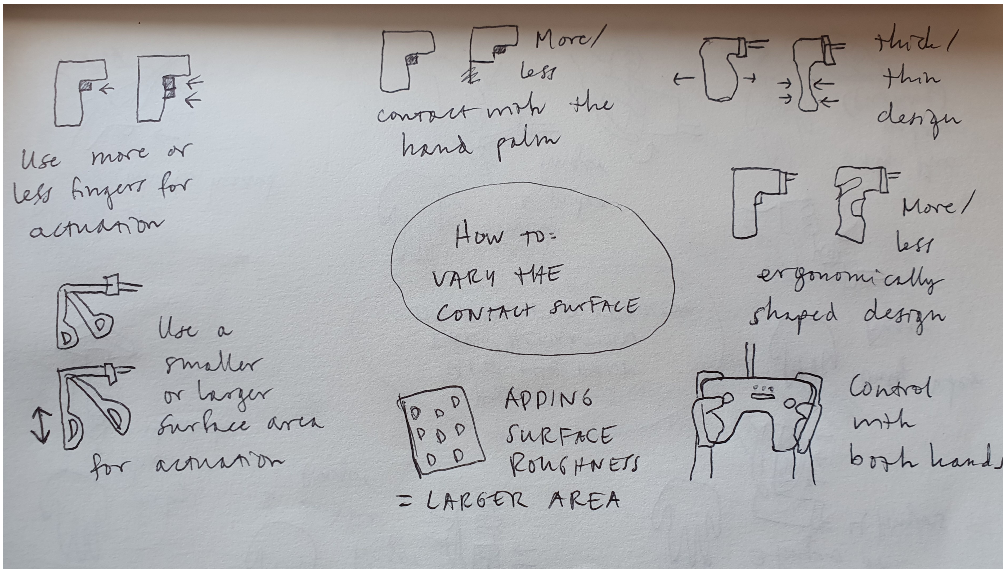

Fig. 31: How to vary the contact surface.

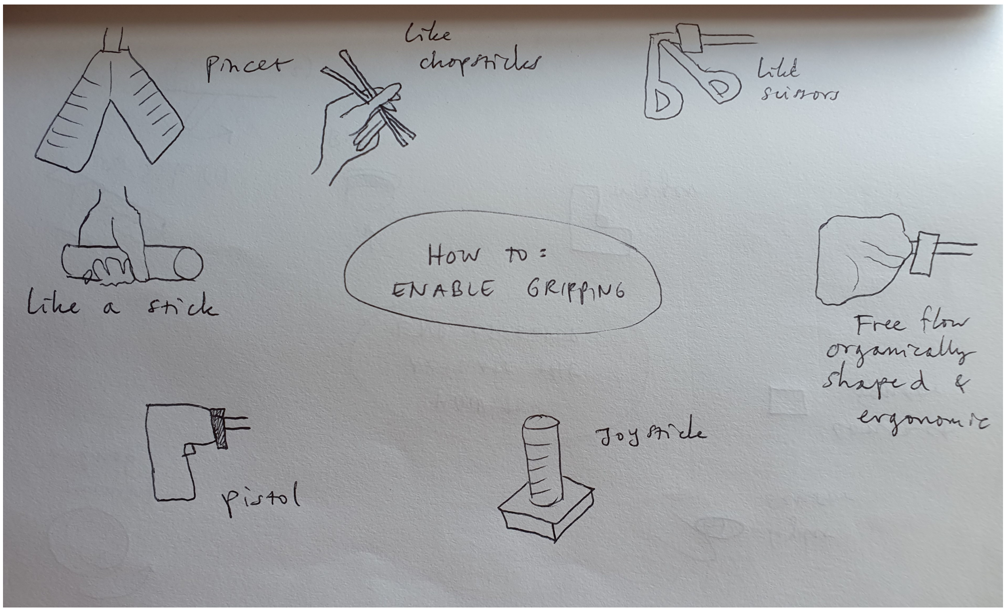

Fig. 32: How to enable gripping.

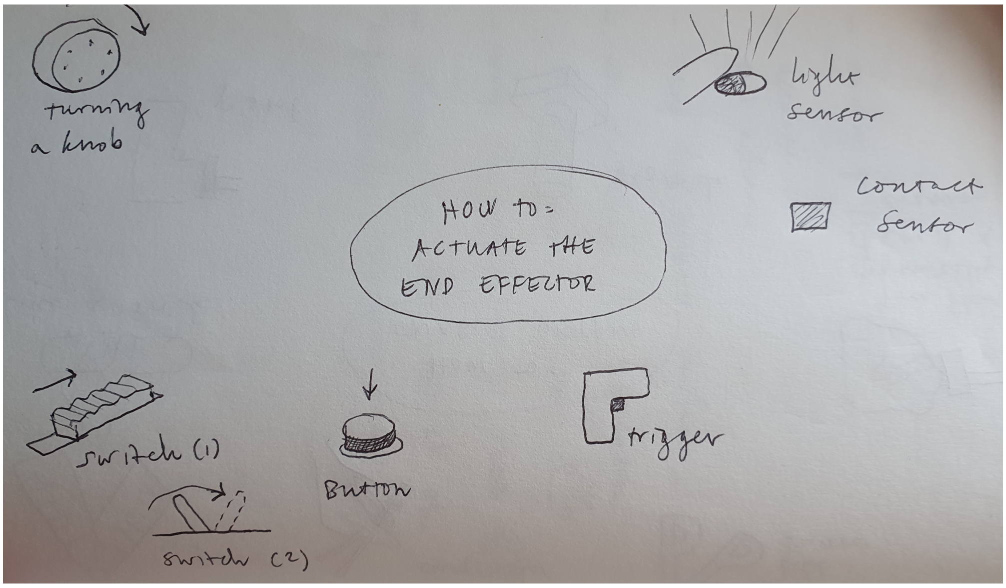

Fig. 33: How to actuate the end effector.

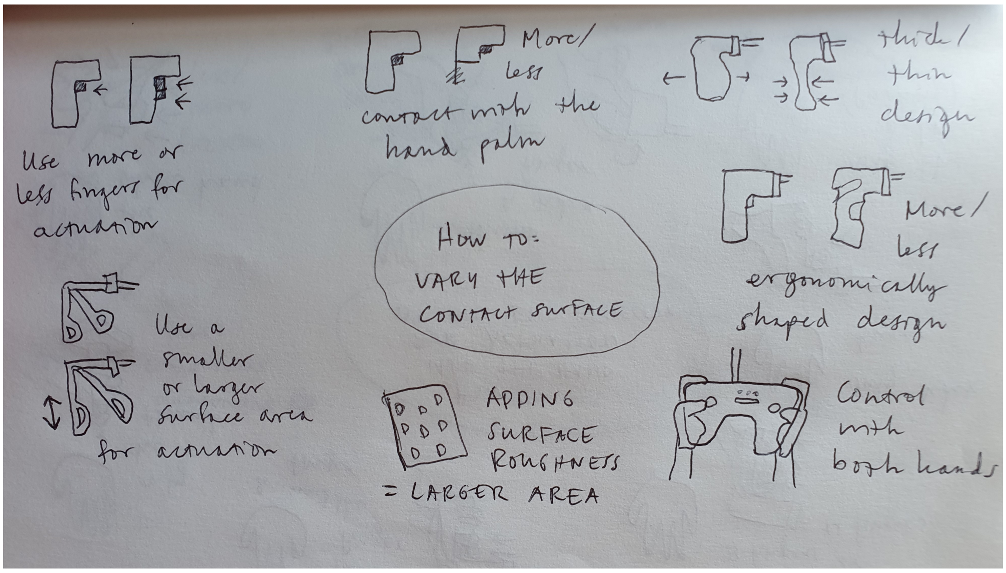

Fig. 34: How to vary the contact surface.

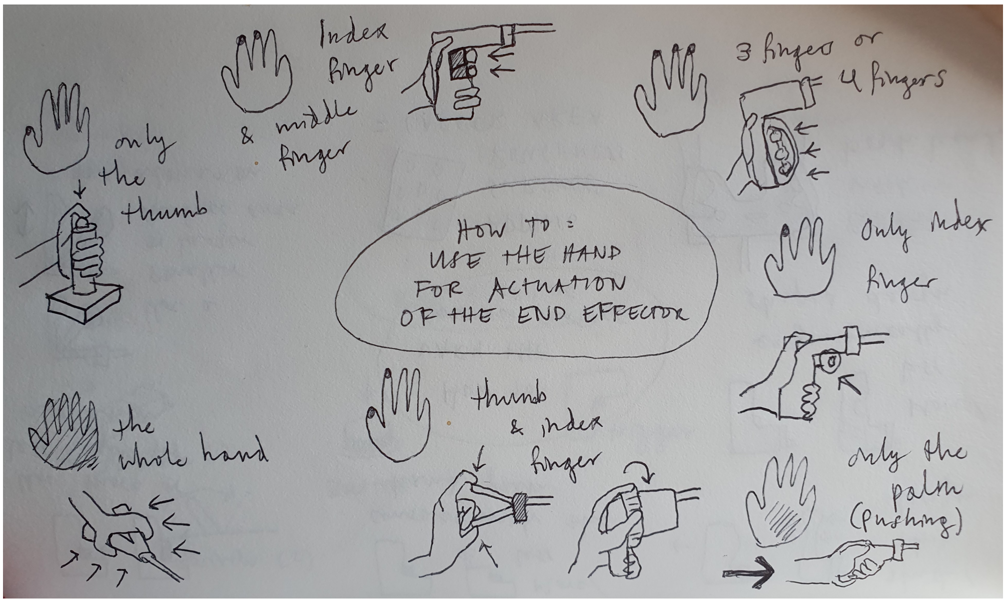

Fig. 35: How to use the hand for actuation of the end effector.

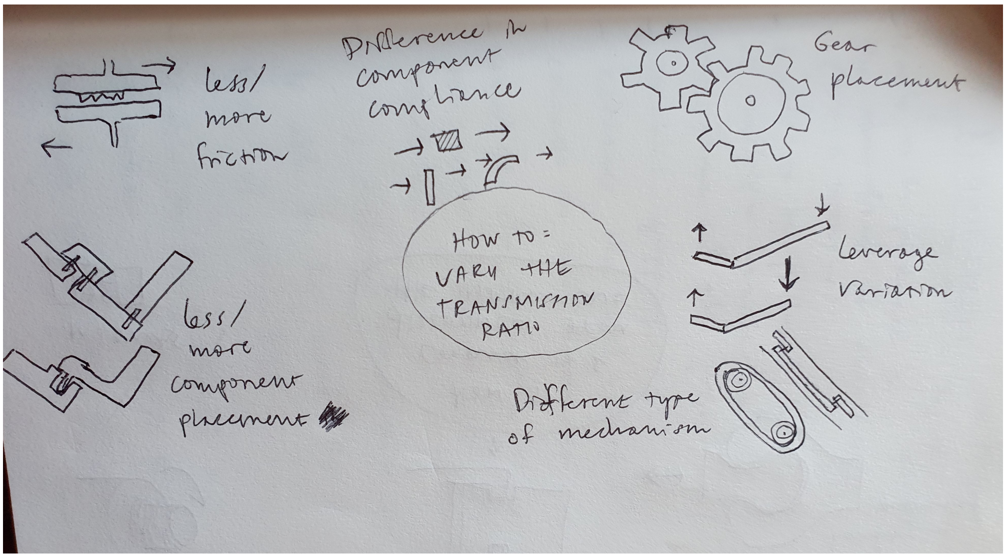

Fig. 36: How to vary the force transmission ratio.

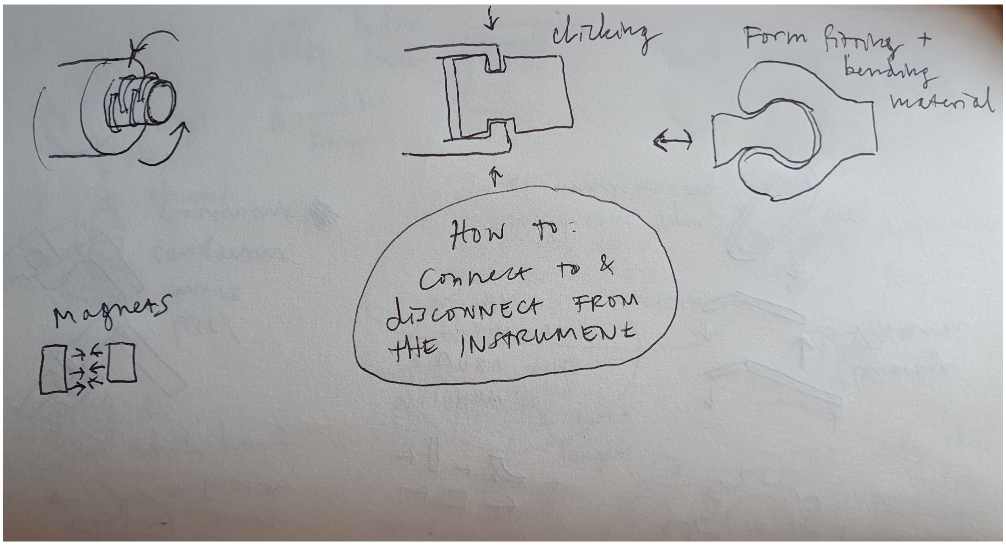

Fig. 37: How to connect to and disconnect from the instrument.

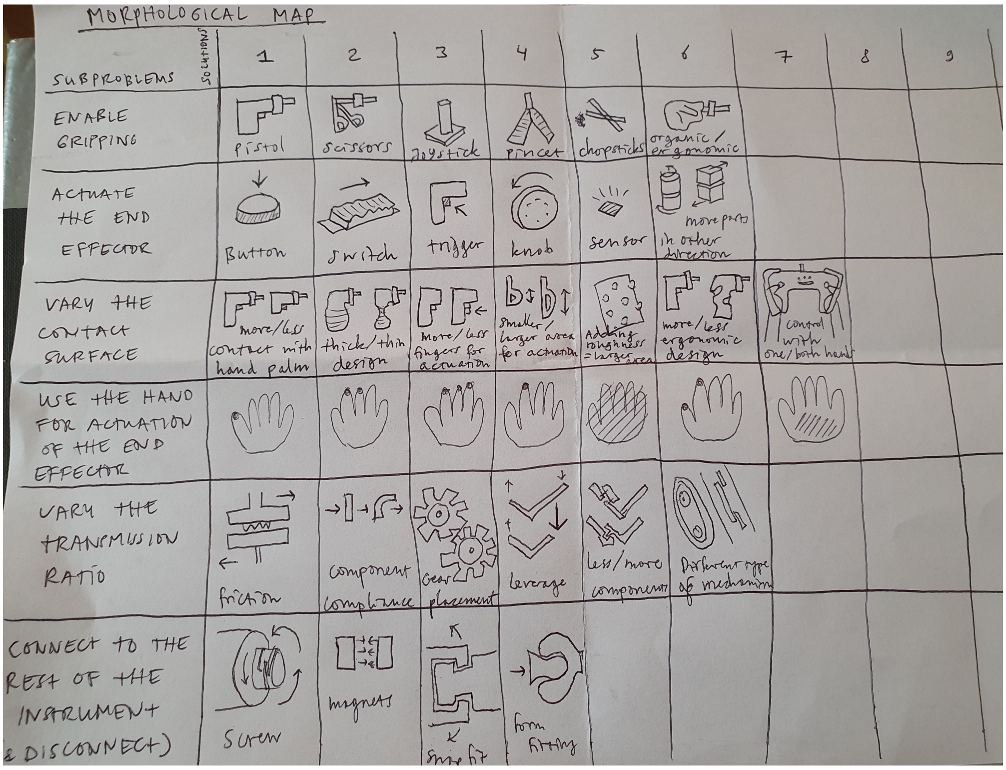

Fig. 38: The morphological map.

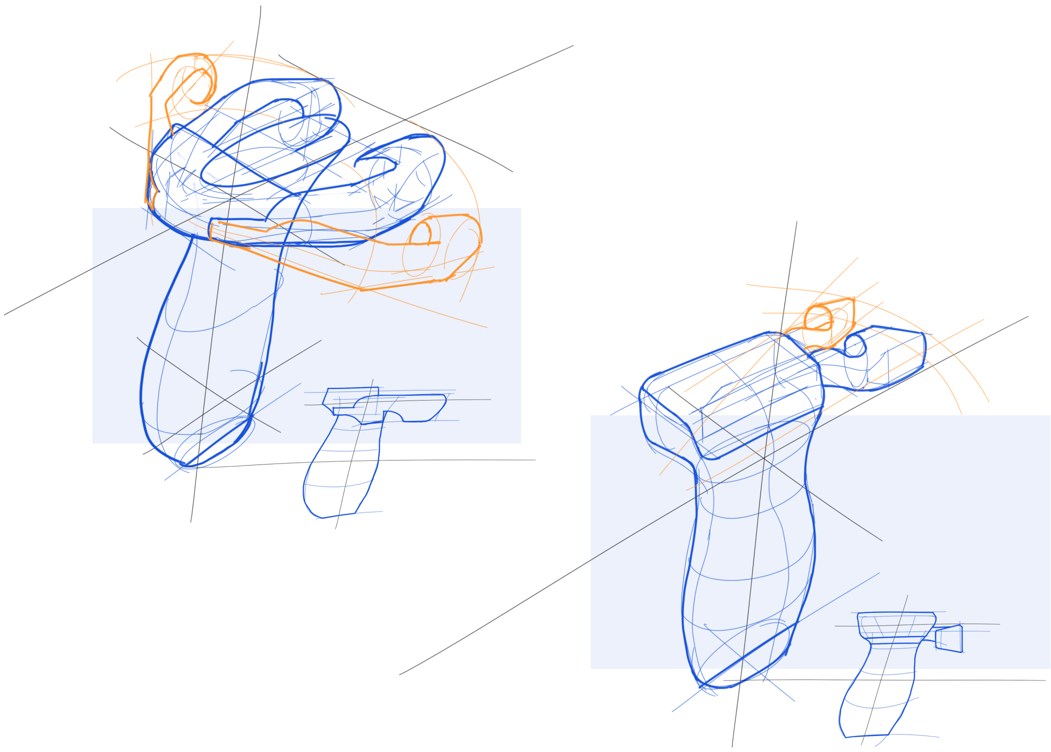

Fig. 39: The first visual representation of the final concept.