Technische Universiteit Delft

Balanced forces

Design of a magnetically balanced compliant grasper

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TUDelft

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Design of a magnetically balanced compliant grasper

by

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This thesis is confidential and cannot be made public until November 25, 2023.

TU Delft

Preface

Before you lies the thesis with the title *'Balancing forces - Design of a magnetically balanced compliant grasper'*. This work is focussed on preventing tissue damage by improving laparoscopic instrument haptic feedback. It is the completion of my Master Mechanical Engineering and the product and result of a year long work. Also, it marks the accumulation of two of my biggest passions: be a humble blessing to the people around me, and technological innovation. May the reader take pleasure in reading my thesis.

This thesis is written by me, but a lot of people contributed in some way to it. I would like to thank my supervisors, for their excellent guidance and support during my graduation process. Tim Horeman, you gave me the opportunity to work on this amazing project. Throughout the process, you were of great value with your advice and guidance, which were both very practical and scientifically sound. Jenny Dankelman and Ásþór Tryggvi Steinþórsson, the same goes for you. Roelf Postema, thank you for your clinical input in this project, without it this thesis would not be as relevant to the clinical reality as it is now. Thanks to Dimitri Kuznetsov for his advice on prototype design and production. I am looking forward to work together with all of the aforementioned people during my PhD.

I would like to thank my 'lab buddies', who were always keen to discuss the issues I was dealing with. Especially Alicja, thank you for the many conversations we had together over a good cup of coffee. Special thanks to my friends in Katwijk, who were always interested in the work I did. Your encouragement and advice was of great value.

Special thanks to my mother, sister, brothers, brother- and sisters-in-law, nephews and nieces, who motivated me throughout the whole process. Whenever I lost sight of a positive outcome, you always encouraged me to go on. In this place, I also want to thank my father, even though he is in a better place now. But, together with my mother, his wisdom, love and interest in technology made me who I am today, both as a person and as an engineer. I know you are proud of me.

Above all, I thank God for both the work He gave me to do and the strength to finish it. May it be a blessing to this world.

J. W. A. Klok
Katwijk aan Zee, November 2019

Glossary

Term	Definition
axisymmetric	Symmetric about an axis of rotation (e.g. revolved about an axis).
compliant	Being able to deform in order to perform or serve a certain functionally.
end effector	Functional tip of an instrument.
handle	Part of an instrument which is gripped by the user to control the instrument and actuate its end effector.
monolithic	Functional element of an instrument, which consists of only one part.
neutral position	Positional state of the compliant grasper with no elastic energy (1), and subsequent position of the instrument's push-pull rod, defined as $x = 0$ (2).
SD	standard deviation

Quantity	Unit	Definition
c_{corr}	-	Correction constant to translate a axisymmetric magnetics problem to a non-axisymmetric one.
F_b	N	Balancing mechanism output force, measured at the push-pull rod.
F_c	N	Elastic deformation forces of the compliant grasper, measured at the push-pull rod.
F_e	N	Sum of all operation forces perceived/experienced at the handle-side of an instrument
F_{err}	N	Balancing error or residue force
F_f	N	Friction forces
F_h	N	Compliant handle forces
F_i	N	Combined internal elastic forces acting in the laporoscopic instrument
F_{rest}	N	See F_{err}
F_{st}	N	Sensitivity threshold
F_t	N	Tissue forces
k_b	N/m	Balancing mechanism stiffness, measured at the push-pull rod.
k_c	N/m	Compliant grasper stiffness, measured at the push-pull rod.
l_{con}	mm	Length of the connector between the pre-bent leaf spring and the push-pull rod.
$\vec{M}$	$J/(T \cdot m^3)$	Constant magnetisation of a permanent magnet.
R_b	-	Balancing force relative to compliant force.
V_{model}	l	The summed volume of the modelled magnets.
V_{true}	l	The summed volume of the magnets.
x	m	Longitudinal push-pull rod displacement relative to its neutral position.
η	-	Mechanical efficiency
ϕ	rad	Connector angle relative to neutral position

Summary

In the last decades, laparoscopic or minimally invasive surgery (MIS) has seen a lot of development. For the patient, laparoscopic surgery has many benefits. However, for surgeons this is not the case. For example, laparoscopic grasper design is poor, with links and joints causing play and hysteresis while performing surgical tasks such as grasping and palpating. Also, mechanical efficiency of conventional laparoscopic graspers is relatively low, ranging between 8% and 42%. This impedes haptic feedback, resulting in the surgeon being insufficiently able to perceive the amount of tissue forces that he or she is exerting. Therefore, a surgeon might misjudge the amount of force he or she is applying on tissue, resulting in more tissue damage, slip and mental stress on the surgeon.

In the past years, a mechanical solution has been developed to mitigate these issues. The conventional grasper tip has been redesigned to a monolithic and compliant grasper. Also, a compliant balancing mechanism was designed, to cancel out undesired elastic grasper tip forces. However, this compliant balancer was not a viable solution, because it was very temperature sensitive in its functionality. In an earlier internship project by the author of this thesis, a different solution was proposed: a magnetic balancing mechanism. Therefore, the design goal of this thesis is: to design a laparoscopic instrument with a monolithic compliant grasper, with the forces generated by the elastic deformation of the compliant grasper and other parts statically balanced by a magnetic balancing mechanism, in such a way that the elastic forces experienced by the user during actuation of the grasper are minimized.

Starting from this goal, design requirements were stated. Most importantly, the balancing forces should be at least 80% and should not exceed 100% of all internal elastic forces for the whole motion range of the grasper tip, to ensure significant balancing. To this end, the force-displacement curve of the compliant grasper tip was measured. Also, the design should be ergonomic, facilitating the resting position of the surgeon's hand while performing surgical tasks, and optimized for the preservation of haptic feedback. Measures for reuse and reprocessing should be taken into account as well.

Several concept solutions were proposed, to fulfil the design goal. The best rated concept was chosen to be converted into a detailed prototype design. This design consists of the already existing compliant grasper tip, balanced by an axial magnet configuration for balancing, exerting a sufficient balancing force to the push pull rod. The handle features a tweezers grip, with finger rings for optimal preservation of haptic feedback.

The novel instrument validation was twofold: first, a technical validation regarding the balancing requirement was performed. This was done by determining the balancing force, using a linear stage with a force sensor. After a redesign of the handle, the balancing force was between 80% and 100% for the whole range of motion of the grasper tip. Mechanical efficiency was 95% for the grasper tip, 96% for the magnetic balancing and 43% for the whole novel instrument. This means that, although the total mechanical efficiency is not as high as expected, the balancing force requirement is met. Second, the instrument sensitivity was measured. Sensitivity is defined as the lowest force level of a loaded laparoscopic grasper where an increase can be perceived, by using only haptic feedback at the handle. This was measured during a controlled comparison ($n = 25$) between the novel instrument, a low quality laparoscopic grasper and a high quality laparoscopic grasper. It turned out that on average, the novel instrument enables the user to perceive a force difference at a lower force level compared to the low and high quality laparoscopic graspers. Therefore, it can be concluded that the novel instrument has a higher sensitivity, and a better preservation of haptic feedback.

It can be concluded that the design goal and its requirements have been met by the compliant laparoscopic grasper. However, for future prototype versions, improvements should be made to the ergonomics and modularity of the design. Also, validation should be focussed more on the clinical context of the instrument.

Contents

I

Initiation

1

Introduction

1.1. Background

In the last decades, laparoscopic or minimally invasive surgery (MIS) has seen a lot of development. There has been a tremendous increase of both the absolute number of MIS procedures and different procedure types. For patients, MIS has several advantages compared to open surgery, such as a smaller chance of complications, shorter post-operative hospital stay and recovery, less pain and less visible scars. However, surgeons performing MIS experience more physical difficulties, pain and injuries compared to open surgery, because MIS is physically and mentally more demanding. The difference (and the cause of many ergonomic problems) between open and laparoscopic surgery can all be led to the fact that with laparoscopic surgery, the intra-abdominal tissue is only manipulated using an intermediate instrument, in contrast with open surgery where palpation of tissue with the hands is possible as well. The lack of this possibility decreases the quality of force feedback that a surgeon can obtain from its own actions. This, in combination with high pressures at the end effector [1], creates a risk of unintended tissue damage.

Several factors contribute to the loss of quality of force feedback. First, most laparoscopic instruments are not designed for optimal haptic feedback to the surgeon's hand. Conventional pistol type instrument handles are controlled by the anterior side of the middle phalanxes, whereas the density of tactile receptors (and thus tactile sensitivity) is much higher at the distal phalanxes [2]. Moreover, instrument mechanisms and handles have poor force transmission. In a study, the mechanical efficiency was measured of several commonly used laparoscopic instruments. This efficiency was defined as the ratio between the output energy when the jaws are opened as a result of a certain preloading and the input energy supplied to the instrument when the jaws are closing:

$$\eta = \frac{E_{open}}{E_{close}} \tag{1.1}$$

Figure 1.1: Typical laparoscopic grasper tip, with links and joints causing friction, play and hysteresis.

The study showed that mechanical efficiency ranged from 8% to 42%. This means that over a opening and closing cycle, more than half of the input energy is lost. Also transmission of forces is varying significantly over the working range [3]. This is the case because conventional laparoscopic instruments utilize a set of pin joints and links combined in a mechanism to transfer control forces from the handle to the end effector (Figure 1.1). The connecting parts of this mechanism can be seen as sliding bearings, which need some play to be

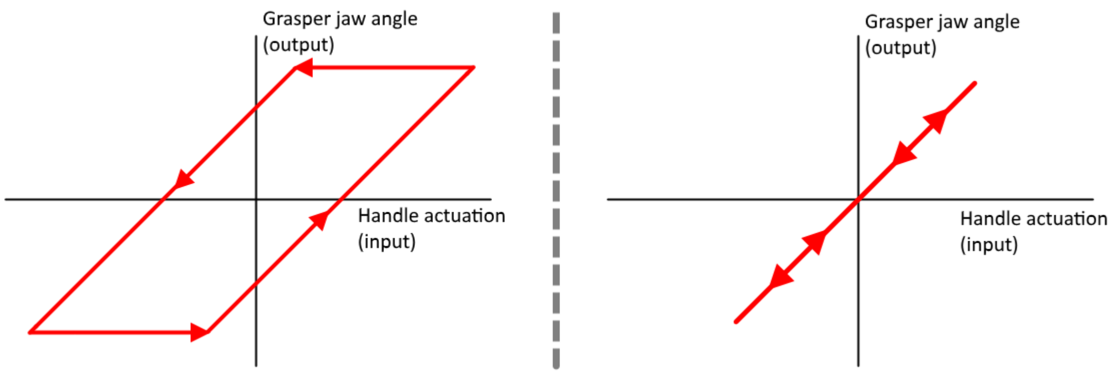


Figure 1.3: Schematic non-quantitative representation a hysteresis loop in a conventional laparoscopic grasper and with low mechanical efficiency (left), and an ideal grasper with no hysteresis and a mechanical efficiency of 100% (right).

able to rotate relative to each other without too much friction. This play is very limited, because of the small size of the mechanism. However, the large arm of an instrument handle greatly increases the play perceived by the surgeon, causing hysteresis between the handle actuation by the surgeon (input) and grasper jaw angle (output) (Figure 1.3). Due to this, the surgeon has to rely for the most part on visual feedback to determine whether the applied force on the handle is being applied to the targeted tissue, or whether the instrument is still in the range of the play.

Mechanical efficiency (as defined earlier in this paragraph) can be used to quantify the amount of hysteresis. The input and output energy of the instrument can be calculated by determining the work done by the instrument during opening and closing respectively. An ideal grasper would have a mechanical efficiency of 100%.

Studies have shown that laparoscopic surgery can benefit from improved haptic feedback, resulting in less tissue forces while performing surgical tasks, leading to less tissue damage [4, 5]. The force reflecting operation instrument (FROI) is an instrument being developed, that augments force feedback through sensors and powered resistance system in the instrument handle. However, this adds a lot of complexity and costs to the instrument. Nevertheless, it can be concluded that laparoscopic surgery can benefit greatly from improved perception of forces and haptic feedback. For example, a surgeon might misjudge the amount of force he or she is applying on tissue, and subsequently apply a force that is either too low or too high, resulting in more tissue damage, slip and mental stress on the surgeon.

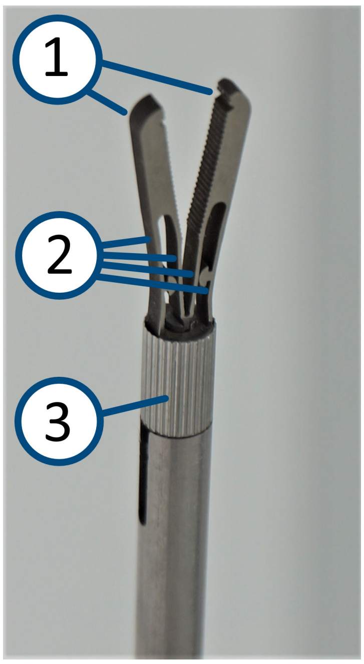


Figure 1.2: Overview of the already designed laparoscopic grasper tip, with the grasper jaws (1), the leaf springs (2) and the ShapeLock mounting interface (3).

Although friction is limited due to the play in the link mechanism of a conventional laparoscopic grasper, it is still present. A study showed that larger friction forces (in the study caused by the contact between instrument and trocar) increase the force perception threshold [6], thus increasing the difficulty for surgeons to detect small changes in applied tissue force, not only for trocar-instrument interaction but also for friction in the instrument itself. This is especially relevant when operating on delicate tissue, where small forces applied on the tissue are often required.

These factors all contribute to the fact that for tasks which require precise dosing of forces, the quality of force feedback of conventional laparoscopic graspers is insufficient. In an ideal laparoscopic setting, surgeons should only experience forces applied by the instrument on the patient's tissue, and not any type of force that is internal to the instrument:

$$F_{e,ideal} = F_t \tag{1.2}$$

With $F_{e,ideal}$ the ideal experienced feedback force and F_t the actual force exerted on the tissue. However, from the previous section it has become clear that in reality, the experienced force is:

$$F_e = F_t + F_f \tag{1.3}$$

With F_f the undesired internal friction forces. Part of this friction is caused by the sliders, joints and links in the grasper tip. In the past years, a mechanical solution has been developed to mitigate these issues. The conventional grasper with joints and links has been redesigned to a monolithic and compliant grasper. It is shaped as such that three parts or regions can be discriminated (see Figure 1.2): Grasper jaws (1), which are the instrument's functional elements and are used to grasp tissue, the leaf springs (2), that allow the jaws to open and close, and the ShapeLock mounting interface (3), which facilitates a hysteresis free connection to the rest of the instrument. The compliant grasper has the following advantages over the conventional grasper:

- It consists of only one part, which means that there is virtually no play and hysteresis;
- there are almost no friction losses in the grasper;
- lastly, it has less cavities and dead spaces, which means that the compliant grasper is easier to clean and sterilize.

However, despite solving the problem of hysteresis and friction, the compliant grasper introduces another problem: the grasper opens and closes its jaws by deforming the leaf spring part. This elastic deformation requires elastic energy, which can be added to the grasper by exerting a force on the instrument handle, delivered by the push-pull rod connected to the grasper. Thus, similar to the friction forces with the conventional grasper, the surgeon still needs to exert a force to the handle that is not exerted to the tissue. As the handle is the interface which gives both tissue force feedback and deformation forces, the surgeon can not discriminate between these two forces. The force experienced by the surgeon through the handle is the sum of tissue and deformation forces, as well as (probably negligible[1]) friction forces:

$$F_e = F_t + F_c + F_f \tag{1.4}$$

With F_e the experienced feedback force, F_t the actual force exerted on the tissue, F_c the force caused by the deformation of the compliant grasper and F_f the friction forces in the instrument, respectively. Like the aforementioned friction forces, the deformation forces 'contaminate' the tissue forces, so the initial issue that was to be solved by compliant graspers is replaced with the same issue, albeit from a different source.

From earlier tests it is clear that the compliant tip deformation forces range from approximately $-15N$ to $15N$, measured at the push-pull rod. Tissue forces on laparoscopic graspers range from $0N$ to $45N$[2]. Consequently, deformation forces might contribute a significant part of the forces needed op control the grasper. Apart from the aforementioned 'contamination' of tissue forces, this also increases the physical stress on the surgeon, which is already high[3].

Forces resulting from elastic deformation are an inherent characteristic of monolithic compliant graspers. So, the issue can not be solved by a redesign of the compliant grasper tip itself. To solve this newly created issue, an additional mechanism is needed that neutralizes the deformation forces. The seesaw analogy can be used to illustrate this. At one end of the seesaw, the deformation forces create an unbalance. In order to level this seesaw again, an equal and opposite balancing force is needed. In the case of the compliant grasper, this

[1] Although the grasper is almost frictionless, the rest of the instrument is not. In any case, F_f with a compliant grasper will be significantly smaller compared to a conventional grasper.
[2] For a more elaborate overview on the topic tissue forces, see Paragraph 4.3.
[3] See Chapter 3.

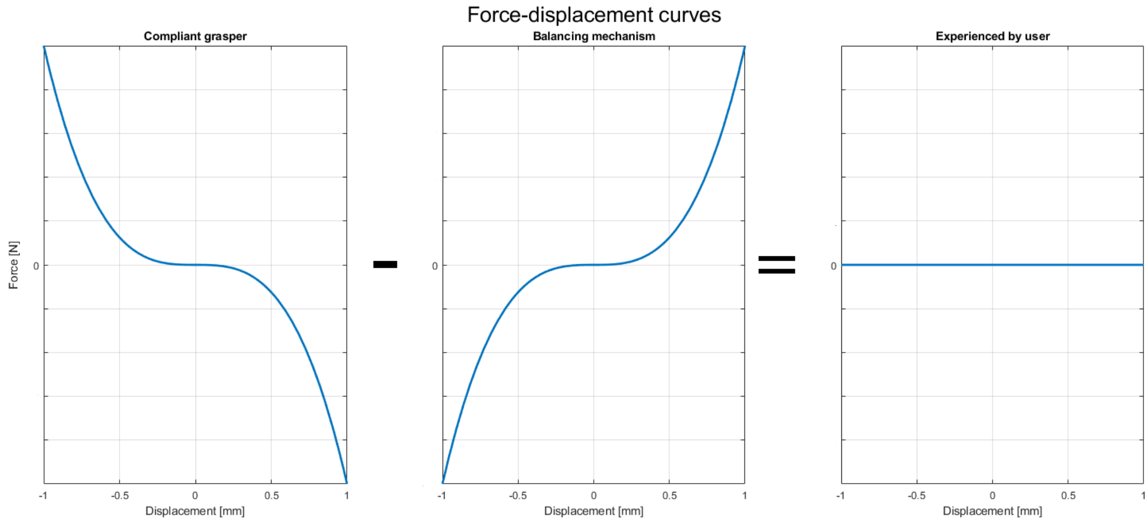


Figure 1.4: Qualitative graphical interpretation of ideal balancing behaviour, resulting in zero compliant forces experienced by the instrument user ($F(x) = 0$). The quantitative validation of the compliant grasper force-displacement curve is subject of Chapter 4, respectively.

balancing force F_b can be applied to the push-pull rod or the handle. Mathematically, the deformation forces F_c can be modelled as a spring with a variable spring constant dependent on the push-pull displacement x:

$$F_c(x) = -k_c(x)x \tag{1.5}$$

Note that all forces in equations 1.5 to 1.10 are exerted in the longitudinal direction of the push pull rod. When the goal is to only feed the tissue forces F_t for a certain x to the surgeon, then the following has to hold:

$$F_c(x) + F_b(x) + F_t = F_t \tag{1.6}$$

This is only valid if:

$$F_c(x) + F_b(x) = 0 \tag{1.7}$$

$$F_c(x) = -F_b(x) \tag{1.8}$$

$$-k_c(x)x = -(-k_b(x)\,x) \tag{1.9}$$

$$k_c(x) = -k_b(x) \tag{1.10}$$

Again, this is all relative to the push-pull rod. So, the instrument is fully balanced when the spring constant of the balancing mechanism $k_b(x)$ is equal and opposite of the spring constant $k_c(x)$. When Equation 1.8 is true, the force-displacement diagrams of the deformation and balancing forces on the push-pull rod are examined (see Figure 1.4), it can be seen that the required balancing mechanism behaves like an inverted spring: when x is increasing, the balancing force is exerted in the direction of x, instead of the opposite in case of a conventional spring. This means that in the longitudinal direction of the push-pull rod, the required balancing mechanism is on its own an unstable system.

In the past, there have been different attempts to balance a compliant grasper [7–11]. They proved that the concept of static balancing has the potential to balance a compliant grasper. However, they were not optimized for clinical use, because they were intended as proof of concept and were deemed either too complex, bulky and hard to clean in order to integrate into a laparoscopic instrument feasible for clinical use. Because of the cost of this instrument, it should be reusable and thus it should be suitable for treatment in the hospital's central sterilisation departments (CSD). This also increases the stress on the complex mechanism. They all share the same basic principle: a compliant element (usually a leaf spring) is connected with a pretension

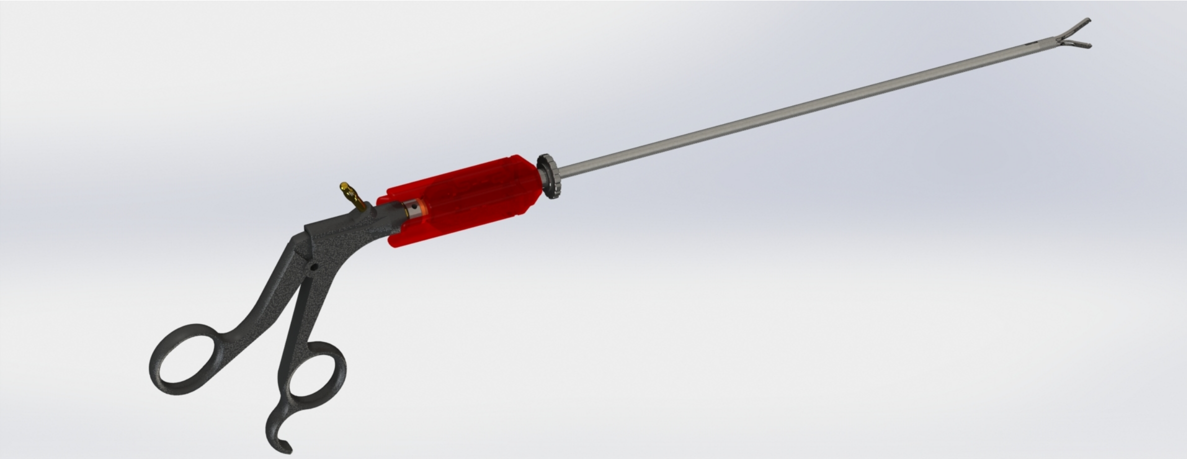


Figure 1.5: Balanced compliant laparoscopic graspers with a pistol type handle (top) and a tweezers handle (bottom).

to a rigid element, which is perpendicular at $x = 0mm$ to the compliant element and connected at the other end to the push-pull rod (Figure 1.6).

The rigid element is only allowed to translate in the x direction and is allowed to rotate. When the push-pull rod is in neutral position ($x = 0$), the deformation force is perpendicular to the push-pull rod, resulting in zero balancing force. When the push-pull rod is moved in the x direction, the rigid element is rotated, and then the deformation force in the pre-bent leaf spring is transferred to a force F_b in the x direction, exerted to the push-pull rod. The magnitude of F_b is dependent on the pretension of the leaf spring and the angle of rotation of the rigid element:

$$F_b = F_{pre} \tan(\phi) \tag{1.11}$$

$$\phi = \sin^{-1}\left(\frac{x}{l_{con}}\right) \tag{1.12}$$

Combining and simplifying these results, the following force-displacement relation is obtained:

$$F_b = F_{pre} \frac{x}{l_{con}\sqrt{1-\left(\frac{x}{l_{con}}\right)^2}} \tag{1.13}$$

Based on this compliant balancing mechanism, there is some unpublished work by Tim Horeman at the Delft University of Technology, which applied this principle to two laparoscopic instruments: one with a pistol type handle, and one with a tweezers handle (see Figure 1.5). During an earlier internship, the author of this thesis worked on the compliant balancing mechanism and its (curved) leaf spring. The results of the functional tests were mixed but not satisfying, because the deformation forces were only balanced for a small part. Also, the balancing mechanism was very temperature sensitive. Around a temperature of $0°C$, balancing was appropriate but at higher temperatures the balancing forces were much less. It can be concluded that in its current form, static balancing using a preloaded compliant mechanism is not a viable solution, because it is too sensitive for external influences and tolerance variations.

Therefore, a different solution was proposed during this internship. When the compliant balancing mechanism was analysed, it became clear that the issue with this mechanism was the physical connection between the leaf spring and the push-pull rod. This connector rod transfers the bending force of the leaf spring to the push-pull rod. In order to work properly, the connector rod has to move smoothly with the amount of friction as low as possible. However, with the bending stress that exceeded the limits of the material, friction and insufficient dimensional tolerances were impeding the function of the mechanism. Also, the connector rod was clamped between the leaf spring and the push-pull rod, to minimize friction, but this also increases the amount of play of the connector rod relative to the leaf spring and the push-pull rod, further decreasing the accuracy of the mechanism. This led to the conclusion that the connector rod should be made redundant. Therefore, a way to transfer balancing forces without physical connection to the push-pull rod was searched. This is possible using a magnetic force field. Since the balancing mechanism should work without an external power source, permanent magnets are deemed to be a feasible solution direction.

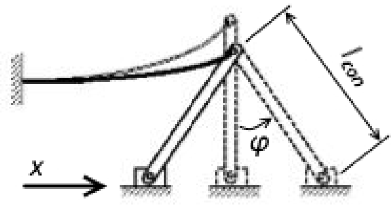


Figure 1.6: Basic model of a compliant balancing mechanism (adapted from Herder et al. (2008))

1.2. Design goal

The goal of this master thesis is to design a laparoscopic instrument with a monolithic compliant grasper, with the forces generated by the elastic deformation of the compliant grasper and other parts statically balanced by a magnetic balancing mechanism, in such a way that the elastic forces experienced by the user during actuation of the grasper are minimized.

1.3. Thesis scope

In order to reach this goal, the following steps will be taken. First, a set of requirements will be formulated. To this end and among other things, the force-displacement characteristics of the compliant grasper will be determined. Based on the outcome, feasible magnet configurations are determined that are able to balance the compliant grasper, using the Finite Element Method Magnetics (FEMM) software. These magnet configurations are used to develop global design concepts, aiming to integrate the magnetic balancing mechanism in the instrument shaft or handle.

During this design phase an instrument handle is designed as well, using results from the literature study on handle ergonomics in Chapter 3. However, the main goal is to integrate a magnetic balancing mechanism into a laparoscopic grasper with a compliant end effector.

Next, the design concepts will be rated according a predetermined set of criteria, based on the requirements. The best rated concept will be developed further, and a detailed prototype design will be created. This prototype will be built, and it will be validated through a technical performance test, a haptic feedback study and a user experience questionnaire, complemented by an expert opinion.

1.4. Reading guide

In this introduction, the background and global outline of this thesis is given. The next chapter, offers a deeper understanding of balancing mechanisms and an overview of the relevant physics of permanent magnets, as well as a preliminary balancing proof of concept acting as a state of the art for magnetic balancing mechanisms. In chapter 3 an overview of the relation between ergonomics and laparoscopic instruments is given. It is followed by chapter 4, where the process of determination of the force-displacement grasper is laid out and the results are presented. In chapter 5, a list of the requirements and their respective background is given. Based on that, design concepts are proposed in chapter 6. Also concept choice is documented in this chapter. The final prototype design is described in 7.

If only the results are of the readers interest, it is best to read chapter 8 and 9 for the validation and discussion of the final prototype (and for further reference also chapter 7). The conclusion and key recommendations can be found in chapter 10.

2

State of the art: static balancing

Before one can go forward in this design process, and design a compliant grasper with a balancing mechanism, a thorough understanding of static balancing systems is needed. In this chapter, the underlying principles are laid out, using literature and working examples.

2.1. Static balancing

In Chapter 1, the term static balancing was already introduced. In general, the purpose of static balancing is to achieve a static equilibrium for a system that would show undesired mechanical behaviour without any balancing. This is done by adding a potential energy source to a system, which adds as much potential energy as it would loose (or adds) during actuation without static balancing.

Static balancing is applied for several reasons: For example, energy consumption during actuation of a system can be decreased significantly. Also, potential energy sources that 'contaminate' haptic feedback and interfere the interaction between an object and its manipulator, can be filtered out. This is the case with the compliant grasper. Herder (2001) identified several arguments and benefits for static balancing: Compensation of undesired forces, energy-free motion, full energy exchange, improved information transmission, elimination of backlash, zero stiffness and inherent safety [13].

Figure 2.1: A spring balanced desk lamp, with its balancer springs near the base[12].

In this paragraph, an overview of static balancing mechanisms is given. The oldest and most basic balancing mechanism is the *counterweight balancing* mechanism. Detailed descriptions date back to ancient Greek times [14]. Also nowadays, counterweights are used in a lot of different constructions and mechanisms, such as bridges, construction cranes, sailing boat keels et cetera. Mechanisms with multiple degrees of freedom can be balanced as well [15, 16]. As long as the moment arms of the mechanism's weights and counterweights are dimensioned correctly, in theory perfect static equilibrium can be achieved.

Another way of balancing a system is by adding *balancer springs*, thus adding an internal spring force. This is often applied in order to cancel out gravitational forces on a mass and create a 'weightless' system [17]. In practice, this is used in desktop lamps [12] (Figure 2.1), but also lifting aids for disabled people [18]. Like counterweight balancing mechanisms, multiple DOF systems can be balanced as well [19].

2.2. Proof of concept

2.2.1. Introduction

Before this graduation project started, the author of this thesis created a proof of concept, where it was investigated whether a pair of magnets, that are moving relatively from each other on the same longitudinal axis, can actually provide the force-displacement curve characteristics that is needed at this scale. Also, a magnet force model is needed to determine the required magnet size and other properties. In the following sections, the method and results of the tested proof of concept are given. To test the limits of the model, a non-axisymmetric problem was created (Figure 2.2).

2.2.2. Methods

The magnets were dimensioned using Finite Elements Method Magnetics (FEMM). This computer program uses FEA to compute the magnetic field lines of magnets, using geometric and physical model parameters. The workflow of FEMM is as following (see also 2.3a and b):

1. Draw the magnet shapes and supporting structures.
2. Assign material parameters.
3. Set the FEA parameters for meshing and computing.
4. Run the solver and obtain the calculated magnetic field.
5. In the magnetic field to compute (by integration) the magnetic forces exerted by and on the modelled magnets.
6. Repeat this for the complete range of motion of x.

To decrease computing time, an axisymmetric problem was defined, and using FEMM and Matlab an estimation of the true (non)-axisymmetric forces was made. This estimation is needed because the axisymmetric FEMM model can only work with full ring magnets. Since the experimental setup does have a ring-shaped arrangement of ten cylindrical magnets instead of a ring magnet, a correction is needed. The magnetic moment of a small permanent magnet is a measure for its strength, and is [20]:

$$\vec{m} = \int_V \vec{M} dV \tag{2.1}$$

With $\vec{M}$ the constant magnetization. It can be concluded that the force exerted by a magnet is proportional with the magnet volume, so the following correction factor was used:

$$c_{corr} = V_{true}/V_{model} \tag{2.2}$$

$$F_{corr} = c_{corr} F_{model} \tag{2.3}$$

With V_{true} the summed volume of the cylindrical magnets and V_{model} the volume of the modelled push-pull ring magnet.

The model was machined at the Biomechanical workshop at 3mE and tested on the linear stage. Neodymium ring and cylinder magnets with respective grade N42 and N48 were bonded to their respective parts in the experimental set up, for specifications see Appendix A. The ring magnet was placed such that its magnetiziation was in line with the longitudinal axis (axial), and the small cylinder magnets were placed with their magnetization in the radial direction. The proof of principle was tested (n=44) at the linear stage described in [21]

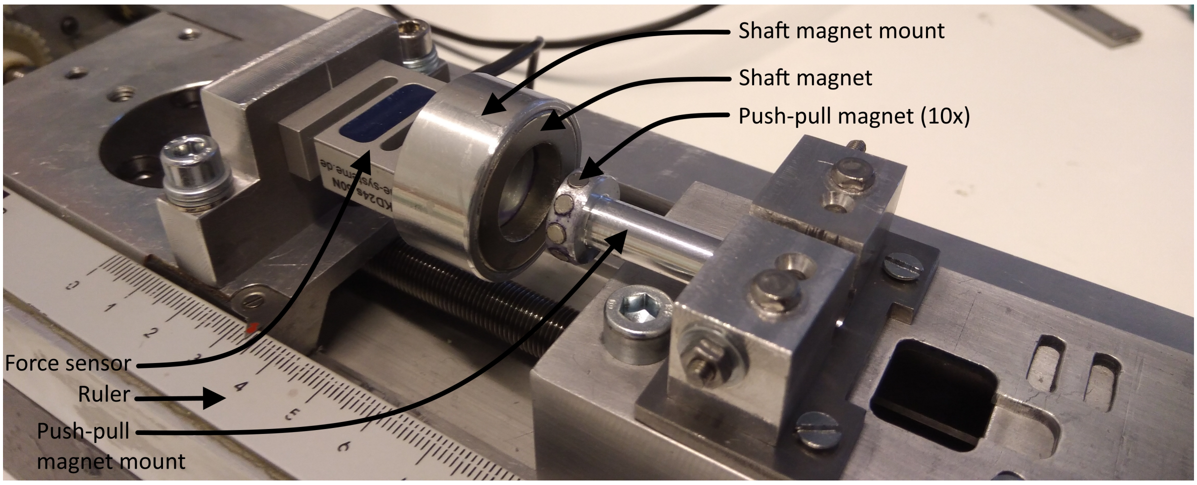


Figure 2.2: Experimental set up with linear stage, shaft magnet (ring shape) and 10 push-pull rod magnets (small cylinder shape).

(Figure 2.2), using the KD24s 50N force sensor (ME-Meßsysteme GmbH, Germany). The force data of the computed model and machined proof of principle were compared.

2.2.3. Results

Experimental results showed that the experimental force is qualitatively equivalent to the FEMM model (Figure 2.4). If the model data is scaled down to 64%, it matches the experimental data. The calculated volume correction c_{corr}, described in Equation 2.3 is 0.625, which approaches the experiment data (Figure 2.4). The maximum balancer stiffness k_b for this setup is $7N/mm$.

2.2.4. Discussion

From the results of this proof of concept, it can be concluded that FEMM is a reliable tool for modelling magnet force fields and calculating forces. Furthermore, the proof of concept shows that within a limited space envelope with a diameter of approximately $25mm$, magnetic forces of a reasonable order of magnitude can be generated. In the Chapter 4, it will be discovered whether this order of magnitude is sufficient for the static balancing of the compliant grasper tip.

As mentioned in Paragraph 1.1, an important performance indicator of the to-be-designed instrument will be the mechanical efficiency, which is defined as the ratio between the output energy when the jaws are opened as a result of a certain preloading and the input energy supplied to the instrument when the jaws are closing. This can be related to the work W done by the system:

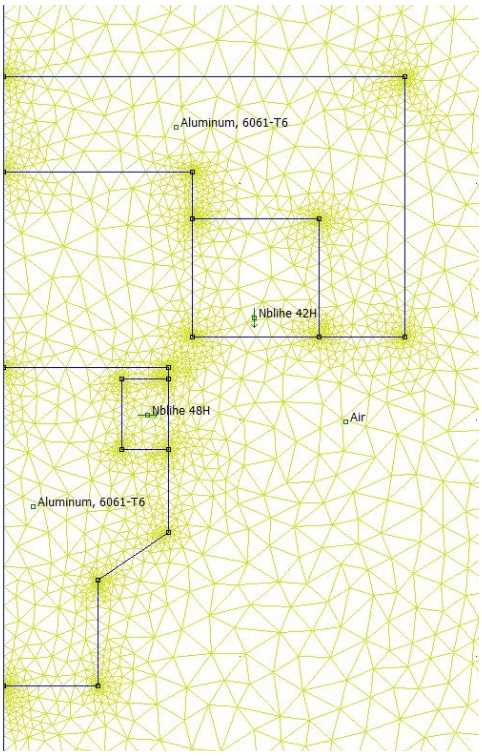
$$\eta = \frac{E_{open}}{E_{close}} = \frac{W_{open}}{W_{close}} \tag{2.4}$$

Furthermore, work can be defined as the integral of the force over a certain path:

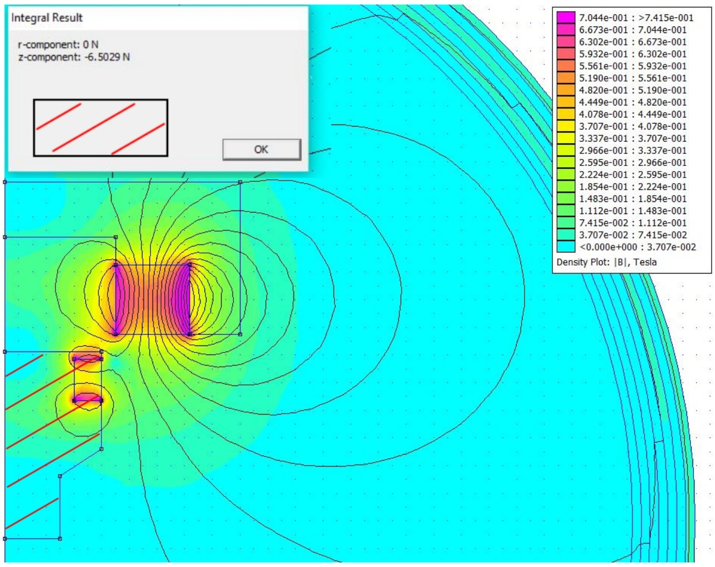
$$W = \int_{x_1}^{x_2} F(x)dx \tag{2.5}$$

With x_1 and x_2 the start and final point of the path, respectively. This means that for the whole or any part of the instrument, the mechanical efficiency is:

$$\eta = \frac{W_{open}}{W_{close}} = \frac{\int_{x_1}^{x_2} F_{open}(x)dx}{\int_{x_2}^{x_1} F_{close}(x)dx} \tag{2.6}$$



(a) Meshed axisymmetric magnet model.



(b) Magnetic field strength of the solved magnet model at a certain position, with integrated forces of the shaded section.

Figure 2.3: FEMM workflow.

Using numerical integration of the data from Figure 2.4, the mechanical efficiency of the magnet movement is $\eta = 96\%$. This is very close to ideal behaviour (100%). Because of the lack of friction, it can be assumed that all similar magnetic balancing mechanisms have such a high mechanical efficiency.

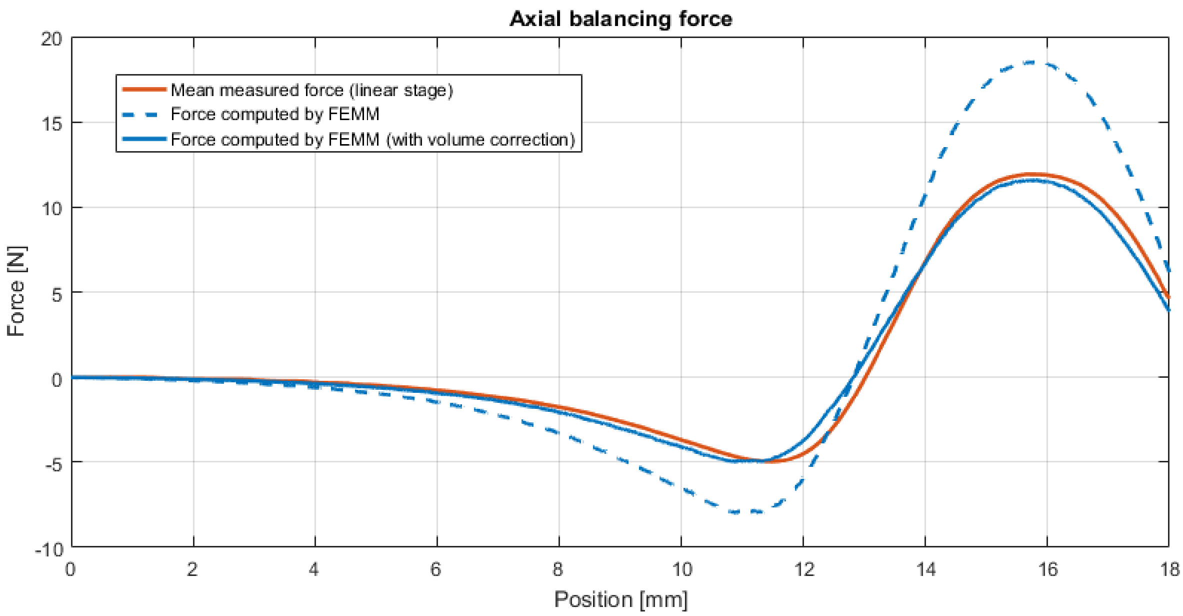


Figure 2.4: Comparison of computed magnetic forces and measured magnetic forces (n=44).

2.3. Closing remarks

In the first paragraph of this chapter, it became clear that static balancing is a useful tool to compensate for undesired forces and energy-free motion. Furthermore, it was investigated whether permanent magnets can provide the force-displacement curve characteristics that are needed at this scale. It can be concluded that this is the case. Also, the FEMM modelling tool is a useful and accurate model to determine the required magnet size and other properties.

3

State of the art: laparoscopic instruments and ergonomics

When it comes to laparoscopic instrument design, the surgeon's comfort is often overlooked. It has been said that laparoscopy has benefited the patient, but not the surgeon [22]. Therefore, prior to this project, a literature search has been conducted aiming to asses the state of the art of ergonomics of laparoscopic instrument handles. In this chapter, a summary is given of that literature review. First, the problem is discussed. Second, the causes are described and last, current solutions are presented, as well as recommendations for ergonomic handle design.

3.1. The problem

As stated in the chapter introduction, laparoscopic surgery has mostly benefited the patient and not the surgeon. In this paragraph, the discomforts related to handle design will be discussed. Only physical discomfort falls within the scope of this review, however it should be kept in mind that mental stress might play a role as well.

3.1.1. History

In the nineties of the previous century, laparoscopic surgery has seen a tremendous increase of both the absolute number of laparoscopic procedures and different procedure types. This led to the demand of various types of new laparoscopic instruments. Since this development was unprecedented, little was known about the implications of the use of laparoscopic instruments on the physical and mental well-being of surgeons. It is hypothesized that the ergonomic aspect was simply neglected due to a plain lack of experience and information. For example, a paper in 1997 stated that "reports of injuries resulting from poor instrument design are uncommon in the literature" [23]. However, in the late nineties scientific literature on this topic started to emerge, as more and more concerns from surgeons were heard, and among others, questionnaires revealed this concern to be widespread [24–26].

3.1.2. Musculoskeletal disorders

Most people do not think of the high physical demand of surgery for surgeons. However, several studies piont out that there is a myriad of discomforts and injuries that comes with the practice of surgery, especially laparoscopic surgery. Studies show that, when comparing open surgery and laparoscopic surgery, the laparoscopic variant requires significantly more muscle effort. Medical staff in the operating room, especially surgeons, do experience physical discomfort of some degree [27]. In a study by Buerger et al. (2003), surgeons performed surgical knot tying both in an open and laparoscopic setting. EMG activity of thenar compartment, the flexor digitorum superficialis, and the deltoid muscles of the dominant arm was measured. It was concluded that EMG activity during laparoscopic knot tying increased with 49% to 60% compared to the open setting. In general, studies have found that laparoscopic surgery is physically more demanding than open surgery, and causes more discomfort [29–34].

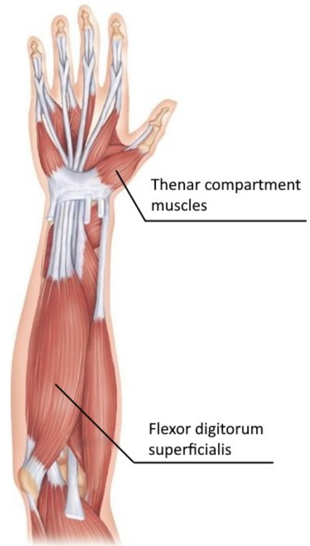


Figure 3.1: Muscles involved in finger movement, of which EMG activities were measured in Buerger et al. (2003). Image adapted from [28].

Musculoskeletal disorders related to laparoscopic surgery have been identified in a systematic review by Stucky et al. (2018). It was concluded that, compared with surgeons performing open surgery, surgeons performing laparoscopic were significantly more likely to experience pain in the neck, arm or shoulder, hands, and legs and experience higher odds of fatigue and numbness [35], caused by awkward joint (wrist, elbow and shoulder) angles and pressure peaks on both fingers and palm due to non-ergonomic handle design [36–42]. Among the surgeon participants of a British survey, 15% suffer from vertebral disc prolapse, with a significant relation between length of practice and numbers of hours worked per week, and the risk of disc prolapse [43]. A survey among 118 Spanish surgeons regarding the use of laparoscopic dissectors and needle holders, reported that two third of the respondents take "uncomfortable or forced posture", like prolonged static postures, and repetitive movements with precision, allegedly causing fatigue, cramp and pain.

A systematic review deemed the prevalence of musculoskeletal disorders among surgeons performing laparoscopic surgery between 22% and 74% [44]. Also in related surgery areas, physical problems are reported and investigated [45–47].

Focussing on the discomforts that laparoscopic surgery is associated with, it can be seen that upper extremity injuries are most prevalent [29, 31, 48–50]. One study investigated the prevalence of upper extremity discomforts experienced by surgeons during laparoscopic surgery [30]. At a conference of the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Task Force on Ergonomics, 149 surgeons completed a questionnaire on whether they experienced pain and/or discomfort in distinct parts of the upper extremity. 8 – 12% experienced pain or discomfort frequently, while less than half of the participants never experienced pain or discomfort. These percentages fall within the prevalence range mentioned earlier. Discomfort and pain was discerned as follows: neck pain, neck stiffness, shoulder/arm pain, shoulder/arm stiffness, hand and wrist pain, hand and wrist stiffness and hand and wrist numbness. The results did not show large discomfort differences between these aforementioned discomfort areas (see Table 3.1). Also the study showed that peak EMG values for thumb, digital extensor and flexor of surgeons during laparoscopic are significantly higher than the respective values for open surgery.

3.2. The cause

There have been numerous attempts to investigate and specify the causes of this problem, which are mainly identified as ergonomic shortcomings in the operation room (OR). More specifically, the predescribed discomforts surgeons encounter are caused by sub-optimal OR table height, poor OR lighting, inconveniently placed monitors, foot pedals and poorly designed instrument handles [36]. Advances in ergonomics have been widely applied in other industries, but have little effect in surgery [51]. Also, to the opinion of a majority of the surgeons this problem is caused by poor handle design in terms of ergonomics [50].

3.2.1. Instrument ergonomics

The difference (and the cause of many ergonomic problems) between open and laparoscopic surgery can all be led to the fact that with laparoscopic surgery, the intra-abdominal tissue is only manipulated using an

	Never (%)	Occasionally (%)	Frequent (%)
Neck pain	41	43	9
Neck stiffness	33	44	18
Shoulder/arm pain	39	43	12
Shoulder/arm stiffness	40	39	11
Hand and wrist pain	45	36	11
Hand and wrist stiffness	43	40	9
Hand and wrist numbness	59	26	8

Table 3.1: Results from the SAGES questionnaire (Berguer et al. 1999)

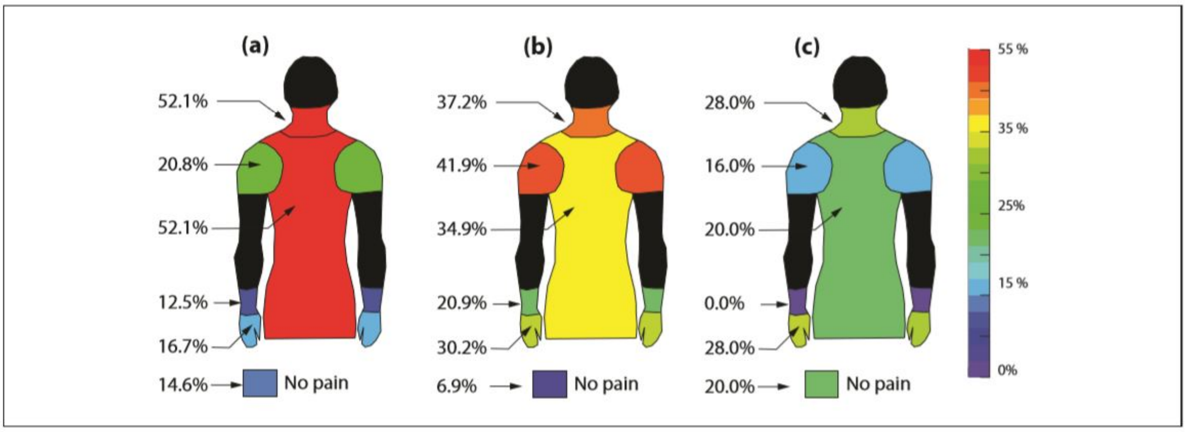


Figure 3.2: Percentage of surgeons sustaining postoperative pain, numbness, or fatigue in various muscle groups according to type of procedure: A. Open surgery. B. Laparoscopic surgery. C. Robotic surgery (Santos-Carreras et al. 2012)

intermediate instrument, in contrast with open surgery where palpation of tissue with the hands is possible. The lack of this possibility constricts the tactile feedback a surgeon can obtain from its own actions. This, in combination with high pressures at the end effector [1], creates a risk of unintended tissue damage. Also, a conventional laparoscopic instrument has only 4 DOF, while a surgeon's hand, which he or she can directly use to manipulate the patient's body and receive feedback, has 36 DOF [52]. Furthermore, with laparoscopic surgery the three-dimensional visual feedback is replaced by a two dimensional video screen, making spatial orientation more difficult [37, 53, 54]. Also, due to pivoting of the instruments about a point in plane with the abdominal wall, the end effector of an laparoscopic instruments moves left if the handle is moved to the right, and vice versa.

The difference between open and laparoscopic surgery can be explained by the ergonomic difficulties that come with laparoscopic instruments. This is also substantiated by a survey among laparoscopic surgeons, which concluded that there is a significant difference between the dominant and non-dominant side regarding physical discomfort during or after laparoscopic surgery [55]. Another survey quiestioned 49 surgeons about their physical discomfort during open, laparoscopic and robotic surgery. It turned out that discomfort related to the hand, wrist and shoulder is most prevalent for laparoscopic surgery (Figure 3.2) [56]. This increases the plausibility of the hypothesis that poor instrument design is the cause of these problems.

3.2.2. Male-female differences

Surgery has (untill about two decades ago) always been a male-dominant area. Therefore, surgery instruments might not be optimized for female hands, possibly causing increased risk physical discomfort for female surgeons. In this paragraph, it is investigated whether this is the case. In a study from 2008, male and

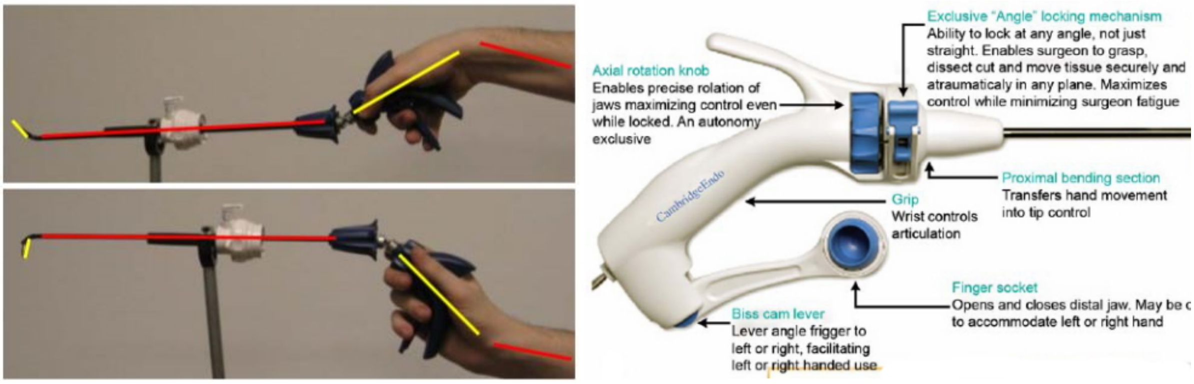


Figure 3.3: Two examples of poor handle design causing extreme wrist excursions (left, Awtar et al. 2009) and unintuitive design (right, Jayasingh 2011).

female surgeons reported their hand glove size, and had to perform certain tasks with laparoscopic instruments. After the tasks, participants were asked to rate the use of the instrument 'easy', 'occasionally awkward', or 'always awkward' to use. The paper concluded that "women were more likely to use two hands and describe these devices as 'always awkward'." In the study, on average female surgeons reported smaller glove sizes than male surgeons, pointing to an average difference in hand size between the two sexes as well [57]. Also, female surgeons reported the need of two-handed operation of laparoscopic instruments more often than men. Therefore, it was concluded that the lower comfort rates of female surgeons can be blamed to the design of laparoscopic handles, which is optimized for bigger (male) hand sizes. In other studies, the same result was concluded [37, 58–65]. However, the latter study also concluded that when compared male and female surgeons with the same hand size, female surgeons reported more discomfort and needed more treatment for injuries of the upper extremity. Therefore, discomforts experienced by female surgeons may not (only) be caused by too large instrument handles, but rather by an increased likelihood of exceeding the maximum hand force that female surgeons can exert without discomfort and injury compared to male surgeons.

3.2.3. Left-handedness

The majority of laparoscopic instruments are not designed for right- or left hand use specifically. Most feature a symmetric handle design. However, some ergonomically shaped are specifically designed. In a survey among left-handed surgeons, it was investigated to what extend left-handedness creates difficulties. It was reported that they often are forced to use instruments designed for the right hand, as 87% of the respondends were offered no left-handed equipment during their training. Also, the surgeons reported that they have difficulty with the handling of several laparoscopic instrument types [66]. Because only 10% of the population is left-handed, it is easy for designers to overlook this group, as producing specifically left-handed instruments is economically less viable for such a small target group.

3.3. The current solutions

There are numerous takes on solving the ergonomic and functional issues of laparoscopic instruments, but none of them have penetrated the market succesfully. This is because while they add to the instrument functionality, they lack in ergonomics. Two examples of this are shown in Figure 3.3. An extensive investigation of this has been written by the author of this thesis [67]. In general, five handle types can be classified (Figure 3.4).

In general, it becomes clear the perfect handle for any specific surgical task has not been developed, and may never be developed [69]. Most studies comparing different handle types show some differences, but almost never a handle type scores best on all measured parameters, such as pain, muscle stress and self-

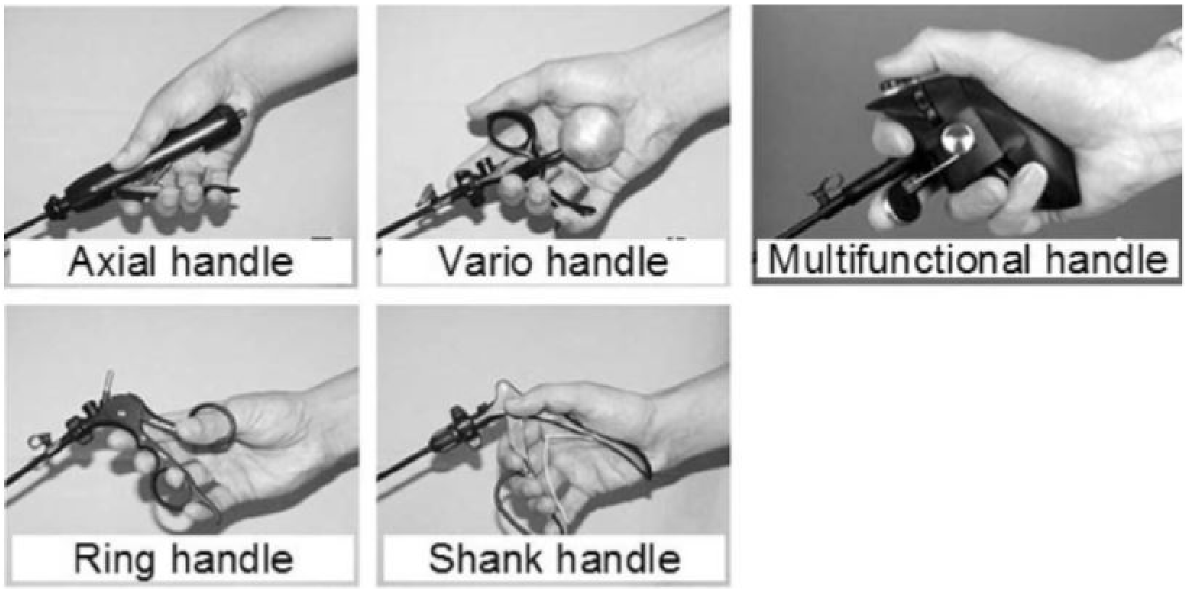


Figure 3.4: Hand postures when holding and manipulating the five different handles: axial handle, vario handle (syringe), multifunctional handle, ring (pistol) handle and shank (palm grip) handle. Adapted from [68].

reported comfort [70]. Not only a handle design depends on objective parameters, but on the surgeons' modus operandi, opinion and preferences as well. Also, task performance of different handle types is often not significantly different, probably because a surgeon will compensate with more effort if an instrument is used that is harder or less comfortable to handle [68, 71, 72]. When designing a laparoscopic instrument, one needs to not only think of technical requirements, but also in terms of emotional comfort and user friendliness [73].

It has been shown that for most surgical tasks, no recommendation for a handle type can be made. When performing different tasks with the same handle, EMG measurements of muscle activity do not differ significantly, other than their amplitudes [68, 74]. On the other hand, muscle activity of different handle types is actually significantly different. However, no handle design could be found where activity of all muscles was reduced compared to other handles. Also it should be kept in mind that different surgeons adapt different holding strategies for the same handle type. This is not always the best way of holding the instrument. So, the handle design should facilitate the intended function and holding strategies of the instrument. Factors that influence the gripping mode are (1) the shape of the object, (2) the size of the object, (3) environmental factors and (4) the task characteristics (5) [75]. For laparoscopic instrument design, the task characteristics are more or less known and the other factors should be designed such that the best suitable gripping mode is encouraged by the handle itself.

While designing a handle, one should be focussing on minimizing extreme wrist, elbow and shoulder joint excursions. The handle should facilitate the resting position of the surgeon's hand while operating [76]. Muscle activity should be minimized. Furthermore, the contact area of the handle with the surgeon's hand should be as large as possible to prevent high pressure areas, especially around areas that exert high forces, such as the fingers. Also, for optimal haptic feedback, preferably the finger tips should be used as the main interface, as they are the most sensitive tactile part of the hand [77]. In conventional laparoscopic instruments, the input-output force transmission of the handle changes when the control angle changes, causing the surgeon to exert unexpected forces on tissue after changing the control angle. Ideally, a linear input-output relation of the instrument should be present. Also, intuitive actuation of the jaw angle should be ensured.

3.4. Closing remarks

In this chapter, an summary of the state of the art on instrument handle design was given. Also recommendations are given, which will be useful when formulating design requirements and during the design of the novel instrument handle.

4

Compliant grasper force-displacement curve

The key functionality of the to be designed instrument is the instrument's ability to balance the elastic deformation forces $F_c(x)$ of the compliant grasper tip. In order to meet this requirement, an equal and opposite balancing force $F_b(x)$ is needed (Paragraph 1.1), provided by a balancing mechanism, and the magnitude of the balancing force should be dependant on the deformation force of the grasper tip:

$$F_b = -F_c \tag{4.1}$$

See also equations 1.5 to 1.10. To balance with the sufficient amount of force, the elastic deformation force F_c of the unloaded compliant grasper tip should be measured. It has been measured before by the Icelandic based company *Reon*, however, these measurements were not suitable for scientific use, so it has been done again. The measuring process is described in this chapter, as well as the results.

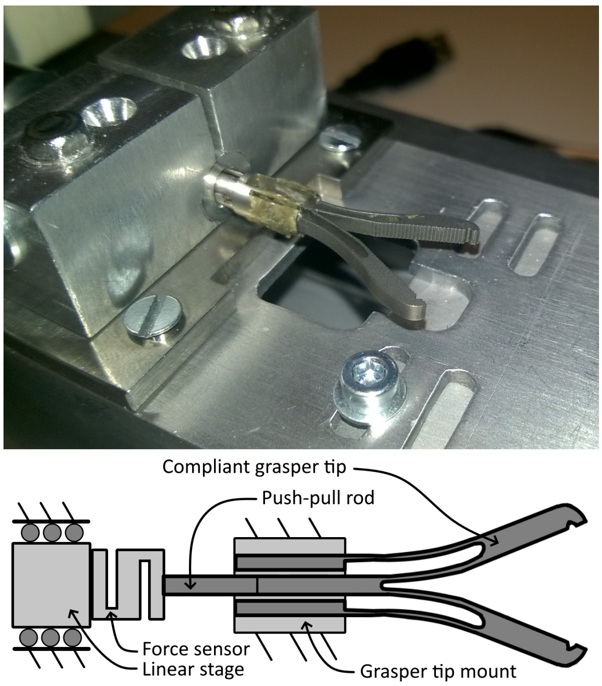


Figure 4.1: Compliant grasper tip force-displacement measurement setup.

4.1. Method

Only one compliant grasper was available for measurement. However, the graspers are produced using high-precision machining techniques. Therefore it can be assumed that in-between variation among these monolithic graspers is very small. Future versions of the grasper tip to be used in the prototype will have small notches on the flexible elements, however this will have no significant effect on the grasper stiffness. The grasper material is Nitinol, which is used because of its super-elastic properties.

For the test, a calibrated linear stage, described in a internship report [21], driven by a 23HSX step-per motor (*McLennan*, United Kingdom) was used. In order to rigidly mount the compliant grasper to the linear stage, custom parts were manufactured (Figure 4.1). Furthermore, the same test set up described in Paragraph 2.2.

First, the maximum push pull rod stroke was measured for an opened to a fully closed grasper and was determined to be $1.2mm$. A fully opened grasper is defined as a jaw tip to tip distance of $16mm$. During the test, the push pull rod was actuated by the linear stage in a reciprocal motion, moving according to:

$$x(t) = \frac{x_{max}}{2\cos\left(\frac{\pi}{t_{period}}t\right)} \tag{4.2}$$

With $x_{max} = 1.2mm$ and $t_{period} = 10s$. The period time was chosen to be this long, to minimize dynamic effects. The experiment was conducted 10 times, each time lasting for 7 periods. A period contains a single back-and-forth motion (from closed to open to closed again), which means that the force displacement curve was measured 70 times. The results were processed and analysed using Matlab. Furthermore the neutral (resting) state $x = 0mm$ of the grasper tip was defined as:

$$F_c(0) = 0N \tag{4.3}$$

When the grasper tip is closed, x is defined to be decreasing, with full closure at $x = -0.75mm$.

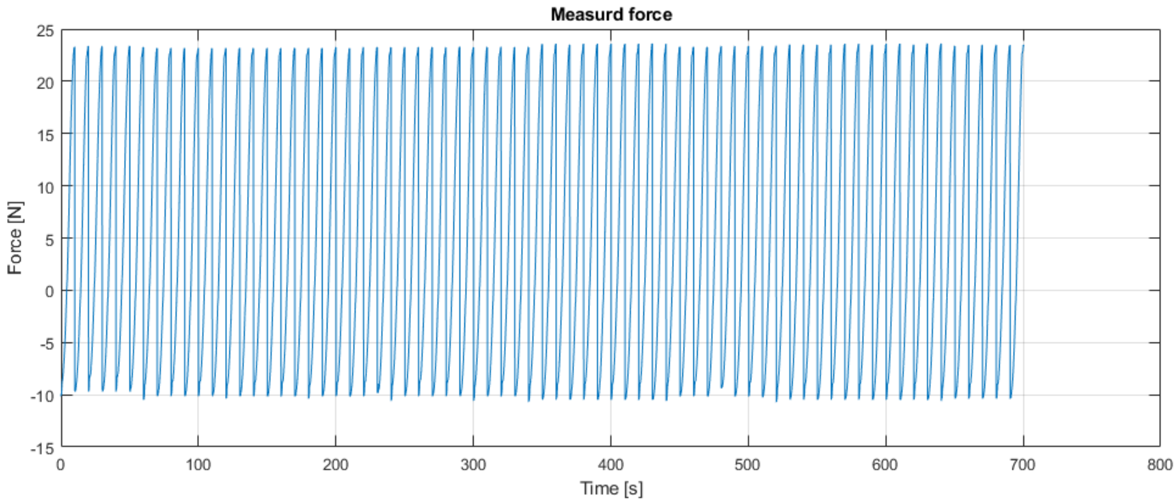


Figure 4.2: Force results ($n = 70$) as function of time.

4.2. Results

The results did not show large variation among the push pull stroke repetitions (Figure 4.2). The force displacement curve is nearly linear over the measured push pull stroke (Figure 4.3a). When the stiffness is calculated from the force displacement curve and a 9-point moving average filter is applied to it, it can be observed that the stiffness is increasing (Figure 4.3b). Due to the characteristics of the imposed sinusoidal velocity function $v(x)$, both velocity and dx approaches zero when the position is near opened or closed. This results in the stiffness differential approaches infinity. This results in unreliable stiffness values (which are greyed out).

4.3. Discussion

It can be concluded that the force-displacement curve of the compliant grasper tip is linear, meaning that it can be statically balanced. From Figure 4.2, it can be seen that there is little to no hysteresis and fatigue,

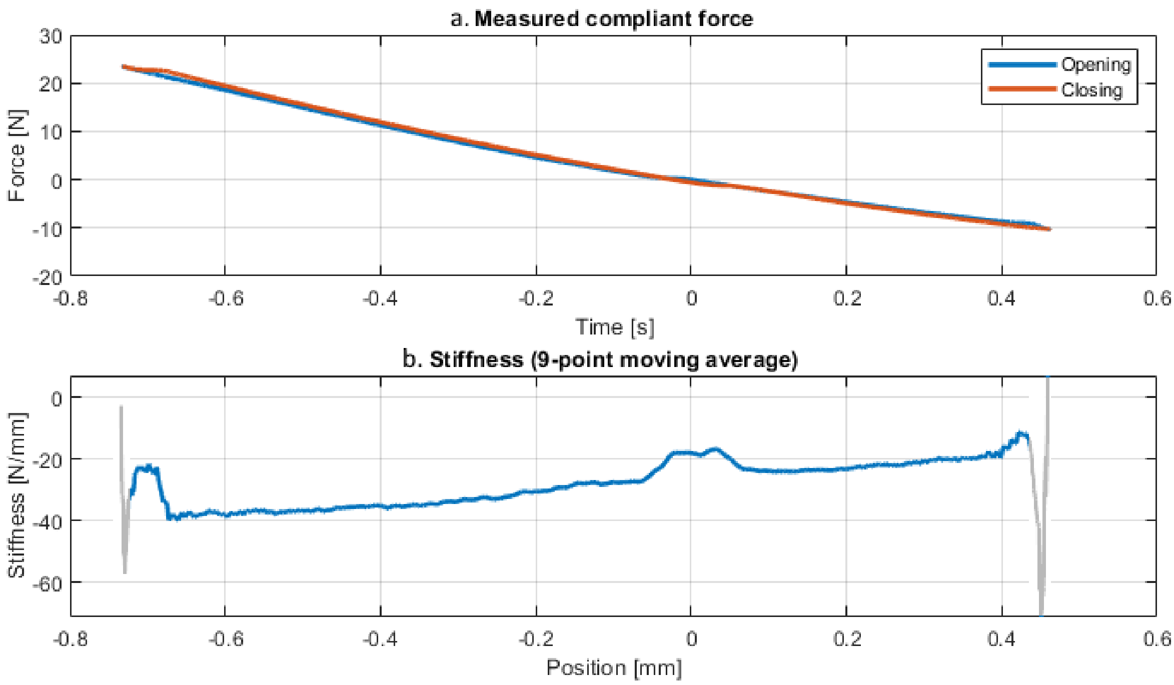


Figure 4.3: a: Force-displacement results (mean, $n = 70$), with separated opening and closing data b. Calculated stiffness.

because the force measurements do not drift from their initial values. It can be concluded that the compliant grasper tip deformation forces are in the same order of magnitude as the tissue forces, as it is shown by [78]. Therefore, a balancing mechanism can significantly improve the force perception of the surgeon while using a compliant laparoscopic instrument. An elaboration on tissue will be given to justify this claim:

Tissue forces are generated at the tip of the instrument. There have been studies aiming to measure these forces. They show that these forces are ranging between $0N$ and $45N$ [79, 80], while one study among 26 surgeons recorded an average force during grasping of $8.52N \pm 2.77N$ [81]. The average of maximum force of each participant during grasping was $24.98N \pm 8.14N$.

In Paragraph 2.2, the mechanical efficiency of any part of the instrument can be calculated according to Equation 2.6. Using numerical integration of the data from Figure 4.3a, the mechanical efficiency of the grasper tip opening and closing cycle is $\eta = 95\%$. Similar to the magnet balancing proof of concept, this is very close to ideal behaviour (100%), implying that there is very little hysteresis in the compliant grasper tip.

4.4. Closing remarks

In this chapter, the force-displacement curve of the compliant grasper tip was measured. These forces are significant relative to tissue forces, and applying a balancing mechanism will be beneficial to improve the force perception of the surgeon.

II

Design

5

Design requirements

Now that the theoretical foundation of this thesis is laid in the background chapters, design requirements can be formulated. In this chapter, all requirements will be stated and explained. Also points of interest or in need of special intention concerning the design are given.

5.1. Functions

From a surgical point of view, the instrument has to perform two functions. The main function of the instrument is *being able to grasp* soft tissue in the abdominal cavity. Secondly, the instrument end effector should be able to *move* both in-and-out and within the abdominal cavity, with the degrees of freedom depicted in Figure 5.1. It should be possible to perform these functions simultaneously.

5.2. Design requirements

In order to perform these functions in a way that the design goal stated in Paragraph 1.2 is satisfied, the prototype should meet the following design requirements.

5.2.1. Magnetic balancing

In Chapter 4, the force-displacement $F_c(x)$ curve of the compliant grasper exerting to the push pull rod was determined. The function of the balancing mechanism is to counter this force with a balancing force $F_b(x)$. Ideally, $F_b(x)$ is equal and opposite to $F_c(x)$. However, as tolerances and magnetic deviations will most likely play a role in the grasper design, one cannot expect to have this ideal balancing behaviour in a practically and economically viable prototype design. Moreover, overbalancing (i.e. $F_b(x) > F_c(x)$) is not desired as well, because then the grasper would always have a tendency to move away from its neutral resting point $x = 0mm$ due to its , becoming an unstable system. Thus, it is important that at any given push-pull rod position x, the balancing force $F_b(x)$ does not exceed the deformation force $F_c(x)$. Taking into account these two considerations and still achieving perceivable balancing behaviour, **the compliant grasper should statically balanced with a maximum underbalancing of** 20%**, but not less than** 0%. This means that:

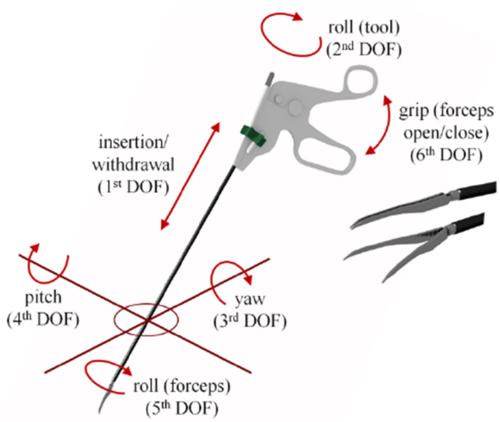


Figure 5.1: Laparoscopic instrument degrees of freedom during surgery.

$$0.8F_c(x) \le F_b(x) < F_c(x) \tag{5.1}$$

Also it should be noted that if, due to design considerations, additional internal forces are generated, then those forces have to be balanced for at least 80% as well. So, more generally, the requirement is:

$$0.8F_i(x) \le F_b(x) < F_i(x) \tag{5.2}$$

With $F_i(x)$ the combined internal elastic forces acting on the push pull rod. Since non-conservative forces like friction force cannot be balanced by any conservative force, it will not be required to balanced these.

5.2.2. Intuitive and comfortable use

The instrument handle should be designed such that wrist joint excursions are minimized. Furthermore, relevant recommendations from the literature study should be taken into account during the design process. General guidelines to aid this process are as follows:

- Since the instrument's key feature is to provide improved haptic feedback, the instrument handle should be designed in a way that it delivers tissue information to the surgeon's hand better than conventional laparoscopic graspers. This will be validated using a force threshold measurement, which is described in Paragraph 8.5.
- During use, the instrument geometry should facilitate and encourage the resting posture of the hand [76]. This will be validated during a by experience questionnaire, described in Paragraph 8.5 as well.

5.2.3. Reusability

Due to the suspected complexity of the to-be-designed instrument, it should be taken into account that the instrument will have to be reusable (or at least parts of it). For single use, the instrument will be too expensive. **Therefore, the instrument should be cleanable and sterilizable.** The end product of this graduation project will only be a working prototype and not a product for clinical use, so cleanability and sterilizability is not an issue for the prototype. However, it is wise to take this already into account for the prototype design. In that way, reusability will not be an issue if next versions of the instrument will be made ready for clinical use. The Food and Drug Administration (FDA) has issued a list of design features that will complicate sufficient cleaning and sterilization [82]:

- Long, narrow interior channels (lumens), including those with internal surfaces that are not smooth, have ridges or sharp angles, or are too small to permit a brush to pass through.
- Hinges.
- Sleeves surrounding rods, blades, activators, inserters.
- Adjacent device surfaces between which debris can be forced or caught during use.
- O-rings.
- Valves that regulate the flow of fluid through a device (stopcocks).
- Devices with these or other design features that cannot be disassembled for reprocessing.
- Serrated edges, acute angles and coils.

In general, there are a few design options when it comes to ease and effectiveness of cleaning and sterilization of narrow lumen and cavities [82, 83]:

- Give cleaning and sterilization personnel the possibility to access and inspect the lumen and cavities.
- Guarantee cleanability for a limited number of use cycles, backed with experimental evidence. In this case, the instrument's use cycle number should be traceable.
- Use female Luer lock flush ports to clean hard-to-reach lumen. Flushing requires a well defined flow path.

- Design in such a way that no dirt is able to enter the lumen.
- Use disposable parts if they are hard to clean.

A evaluation of the design regarding the reprocessing of the to-be-designed instrument can be found in Paragraph 8.7.

5.3. Boundary conditions

Futhermore, there are some boundary conditions for the instrument prototype:

- The already designed monolithic compliant end effector will be used.
- The instrument will not contain any electrically driven components.
- The instrument has a maximum weight of $300grams$.
- Instrument shaft thickness (OD): $5mm$.
- Instrument shaft length: $300mm \pm -20mm$.

5.4. Closing remarks

In this chapter, all information gathered in the Initiation part of this thesis has been synthesized into a set of measurable requirements. In Paragraph 8.8 of the validation chapter, all requirements from this chapter will be evaluated whether they are met or not.

6
Concepts

During the design process, the problem was broken down in different design parts using the design goal, functions and requirements. First, there is the grasper tip itself. It is not the focus of this design process and will not be changed, because the design goal is to balance the current grasper tip version. Changing it would in most cases change the force-displacement curve, already determined in Chapter 4. The rest of the instrument can be divided into the following parts, serving distinct functions (from an engineering viewpoint):

- A balancing mechanism (balancing);
- a control interface (actuation);
- and a locking mechanism (assembly).

All of these three parts are needed to fulfil the purpose of the instrument. One could say that the rotation of the grasper tip is a distinct function as well. However, it is judged that the solution for this function will follow naturally from the choices made in the other three parts, at the end of this chapter and in the description of the final prototype design in the next chapter.

In this chapter, concept sub-solutions will be developed for each of these parts, fulfilling the boundary conditions stated in Paragraph 5.3 and taking into account the design requirements (Paragraph 5.2). The advantages and disadvantages concepts will be discussed as well. Where possible and desirable, these functions will be integrated into each other to simplify the design. At the end of this chapter, the best combination of sub-solutions will be chosen, using Harris profiles.

6.1. Magnetic balancing

The function of the balancer is to cancel out the elastic forces exerted on the push pull rod by the compliant grasper tip. In Chapter 4 the force-displacement curve $F_c(x)$ of the grasper tip has been determined. An equal and opposite balancing force $F_b(x)$ is needed to counteract this force. In this paragraph, permanent magnet configurations are proposed. Like in Paragraph 2.2, the force-displacement curve is computed using the FEMM program, to ensure the right order of magnitude in balancing forces can be achieved with all concepts.

In this paragraph, viable magnet configuration concepts are presented, along with their advantages and disadvantages. These configurations were formulated using the FEMM FEA program. With this program, it was made sure that the force-displacement curve of the configurations are linear, and can yield forces in the order of the elastic deformation forces within a reasonable space envelope. All magnet configurations (Figure 6.1) have the same base principle: one static magnet (set) that is fastened to the instrument housing, exerting a balancing force to a magnet (set) fastened to the movable push pull rod. In this way, the balancing force is exerted to the push pull rod. Note that Figure 6.1 shows 2D depictions of cross sections of the concepts.

Axial: This concepts solely consists of ring magnets. In this configuration, the magnets' planar surfaces are facing each other. Both outer magnets are mounted to the housing, and the inner magnet pair is fastened to the push pull rod.

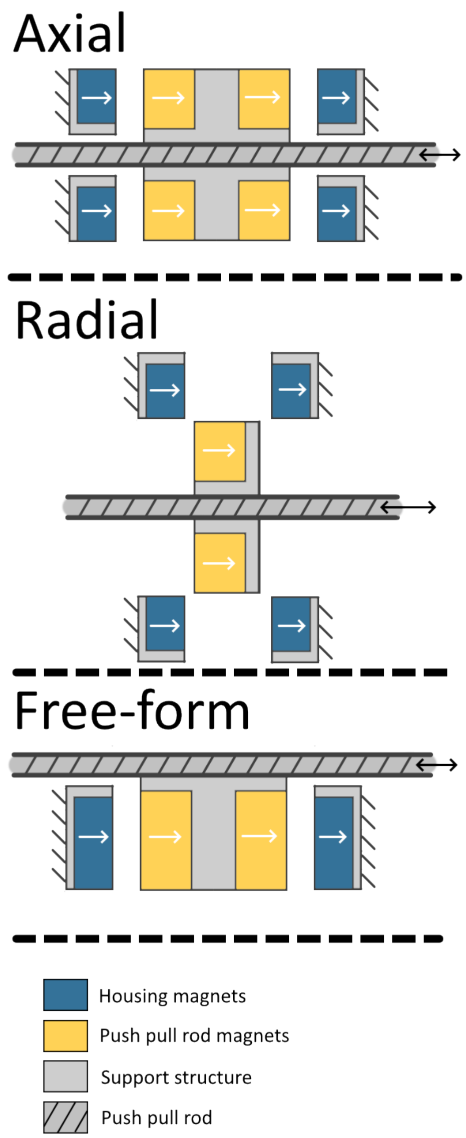


Figure 6.1: Magnets configuration concepts.Note that these are 2D depictions of cross sections of the concepts.

+ Very efficient use of housing space.
+ Efficient use of electromagnetic field, resulting in best possible magnetic force transmission.
+ Axisymmetric design, which results in self-centering behaviour of the push pull rod.
- All magnets are placed in series, so a relatively long housing is needed.
- The push pull rod cannot be removed easily due to the mounted magnets, resulting in limited disassembly options.

Radial: This configuration is very similar to the axial one. Again, it features al ring magnets. However, there is a cardinal difference. The key characteristic of this magnet configuration is that the push pull rod magnets' outer diameter is smaller than the housing magnets' inner diameter. This opens up many options for easy disassembly.

+ The push pull rod magnets' outer diameter is smaller than the housing magnets' inner diameter, so the push pull rod can be taken out relatively easy. This means that disassembly is relatively easy.
+ Axisymmetric design, which results in self-centering behaviour of the push pull rod.
- The electromagnetic field and housing space is not used efficiently, which means that more magnet volume is needed, resulting in a bulkier instrument.
- The magnets slide over each other, introducing the need for a relatively large housing diameter.

Free form: This magnet configuration utilizes block magnets, placed at a distance from the push pull rod. This distance should be as small as possible, lest there be a large moment about the push pull rod. The magnetization direction will be the same as the axial configuration.

+ The balancing mechanism magnets can be placed anywhere in the instrument handle or housing, resulting in a great freedom of design.
+ Efficient use of design space envelope.
- The forces on the push pull rod will not be axisymmetric, introducing great moments about the push pull rod, causing significant friction forces.

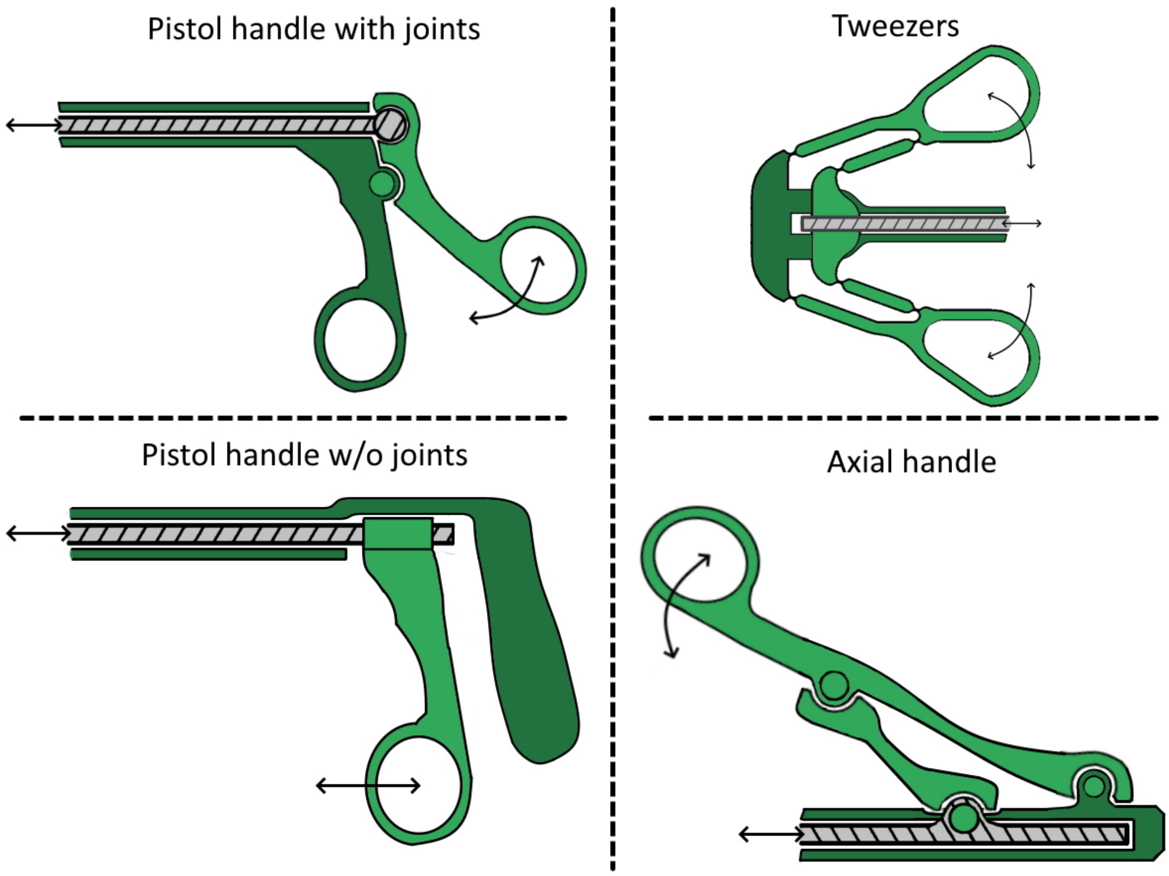


Figure 6.2: Actuation interface concepts. The dark green is the static part of the handle, and the lighter green is the (moving) actuated part.

6.2. Actuation

The instrument's design should facilitate a comfortable and intuitive way to operate. The handle plays an important role in this. It is the main interface through which the surgeon receives haptic feedback. Four concepts for handles have been generated. All concepts are assuming that a push pull rod within a shaft will be used as a rigid connection between the handle and the grasper tip. Drawings of all actuation concepts can be found in Figure 6.2.

Pistol handle with joint: This is the most commonly used handle type for laparoscopic graspers []. The handle features two parts, one static, rigidly connected to the rest of the instrument, and one rotating, which is mounted with a pin joint to the static part. The push pull rod is actuated by and connected to the handle with a ball joint.

+ Surgeons are familiar and experienced with this handle type, which makes for easy adaptation in the field of laparoscopy.
+ Possibilities for cheap mass production, because there are already a lot of jointed pistol handles on the market.
- It features a pin joint and a ball joint, both introducing friction, play and thus hysteresis, reducing mechanical efficiency and haptic feedback.
- Ergonomically poor design, prone to pressure points and facilitating extreme wrist joint excursions.

Pistol handle without joint: This handle is almost the same as the pistol handle with joint. The difference is the movement type of both handle types. The pistol handle without joints is connected rigidly to the push pull rod, instead of a ball joint. This results in a linear motion of the handle.

+ Surgeons are familiar and experienced with this handle type, which makes for easy adaptation in the field of laparoscopy.
+ Rigid connection between handle and push pull rod, resulting in a play- and hysteresis poor handle.
- There is a linear connection between the handle and push pull rod, so there is no magnification of the relatively small push pull rod motion and tissue forces.
- Ergonomically poor design, prone to pressure points, facilitating high muscle stress and extreme wrist joint excursions.

Tweezers handle: This handle's grip is shaped like a tweezers. It features six flexures to produce the desired push pull rod movement. The grasper tip is operated by squeezing the tweezers with the thumb and index finger.

+ The movement of the index finger and thumb is mimicking the grasper tip jaws movement, creating a sensation that the tissue is grasped by those fingers itself.
+ Rigid connection between handle and push pull rod, resulting in a play- and hysteresis poor handle.
+ The most sensitive finger parts (tips) are used to actuate the grasper tip and receive haptic feedback.
+ Symmetric design, exerting only longitudinal forces to the push pull rod, thus minimizing friction.
- Unconventional design.
- The handle flexures exert elastic forces F_h to the push pull rod just like the compliant grasper tip (F_c), which increases the balancing force F_b needed, and thus the magnet volume.

Axial handle: This handle type is used in current laparoscopic instruments as well as the pistol handle, although less common []. It features a thumb or index finger operated lever with pin joints, connected to the push pull rod with a ball joint.

+ Surgeons are somewhat familiar and experienced with this handle type, which makes for easy adaptation in the field of laparoscopy.
+ The most sensitive finger parts (tips) are used to actuate the grasper tip and receive haptic feedback.
- It features a pin joint and a ball joint, both introducing friction, play and thus hysteresis, reducing mechanical efficiency and haptic feedback.
- Ergonomically poor design, facilitating high muscle stress and extreme wrist joint excursions.

6.3. Assembly

One of the requirements for the to-be-designed instrument that reprocessing of the instrument has been taken into account, in such manner that in the future, a market ready version of the instrument is reusable without drastic changes to the prototype design. Therefore, disassembly of the prototype should be possible. Most of the parts can be made easily detachable by choosing the right fit. However, a more challenging part is the connection between the rotating push pull rod and the handle. It is important that this connection is as play-free as possible. Four concepts for this are presented.

Screw-on locking: The push pull rod will be connected to the instrument by an intermediate part, that is screwed to the handle. Rotation of the push pull rod is allowed by the intermediate part due to a circular shape lock.

+ Almost no play.
+ Easy to machine.
- For reprocessing at the CSD, unscrewing the connection is time consuming.

Two part puzzle lock: The push pull rod will consist of two parts, which will fit into each other like a puzzle. A part of the outer shaft will fit over it to lock the parts into place.

+ Almost no play.

+ Intuitive (dis)assembly.
- Relatively complicated to machine.

Nitinol wire: This concept is adapted from the Shaft Actuated Tip Articulation (SATA) instrument. A flexible Nitinol wire, rigidly mounted in the handle, locks the push pull rod in place by falling into a small slot on a intermediate part.

+ Intuitive (dis)assembly.
- The wire needs a relatively large space envelope.

6.4. Final concept selection

In the previous paragraphs, several sub-solution concepts have been discussed. They all are viable solutions to the initial problem. However, the concepts exploit different approaches, which can influence the performance of the design, as described in Chapter 5. Therefore, the sub-solutions that are deemed to perform best on the design requirements will be chosen to be further detailed in a prototype design, and ultimately be produced.

The concept sub-solutions were divided into three parts: balancing, actuation and assembly. Each of these parts will be rated in a Harris profile (a useful tool for concept selection [84]) according to the design requirements. The design requirements that will be used to rank the balancing concepts are:

- Balancing capabilities;
- preservation of haptic feedback;
- comfort and intuitive use;
- reusability (cleanability and sterilization);
- instrument weight (from the boundary conditions).

The (dis)advantages described the in the previous paragraph are used to fill in the Harris profiles.

6.4.1. Magnetic balancing

The best concept for the balancing function is the **axial magnet configuration** (Figure 6.3). This concept both uses the design envelope the most efficient regarding force transmission, and the force field is symmetric in all directions. The free-form configuration is a close second, as it offers more options for disassembly.

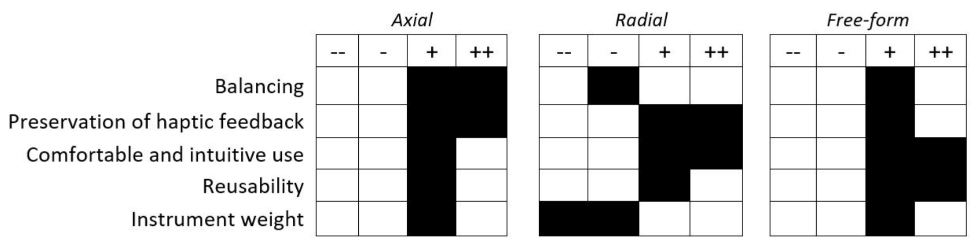


Figure 6.3: Harris profile for the balancing concept selection.

6.4.2. Actuation

The best concept for the actuation function is the **tweezers handle** concept (Figure 6.4). Although it increases the demand of balancing force through the flexures, it can ensure a complete hysteresis free design, preserving the quality of haptic feedback the best of all actuation concepts. Also it shows potential for comfortable use, because it encourages a natural resting state of the hand.

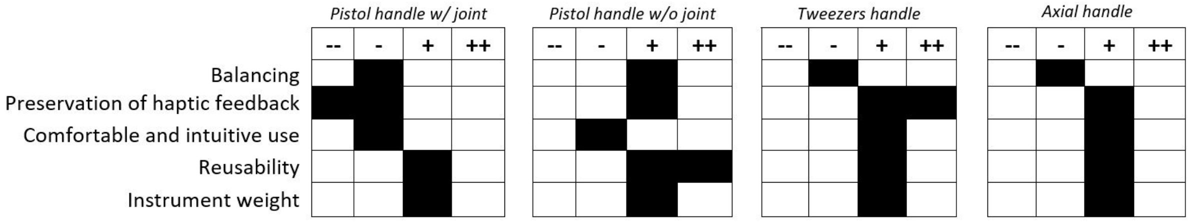


Figure 6.4: Harris profile for the actuation concept selection.

6.4.3. Assembly

The best concept for the assembly function is the two part puzzle lock (Figure 6.5). It is the most intuitive concept to use. However, it has been decided that this concept will not be chosen for the prototype design. Instead, the **screw-on locking** will be incorporated in the prototype design. The reason for this because for progress' sake, the most easy machinable and low-risk assembly concept will be chosen. This choice is based on the fact that the most important part of the prototype (the balancing mechanism) should get the most attention. As the assembly function is less important, an easier-to-design-and-machine solution will be used. Also, unlike the puzzle lock, the screw-on locking can be integrated very easily in the tweezers handle. When the balancing mechanism is working, the design of next versions of the prototype can be more focussed on reusability.

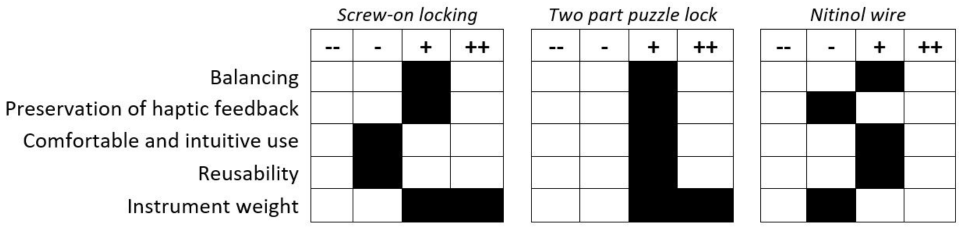


Figure 6.5: Harris profile for the assembly concept selection.

6.5. Closing remarks

In this chapter, concept sub-solutions have been presented. Ultimately, the axial balancing configuration, the tweezers handle and the screw-on locking have been chosen as the best sub-solution combination for the prototype design.

7

Prototype design

In the previous chapter, the best concept combination was chosen. In this chapter, these concepts are integrated into a detailed design. Furthermore, the production of the prototype and subsequent assembly are discussed.

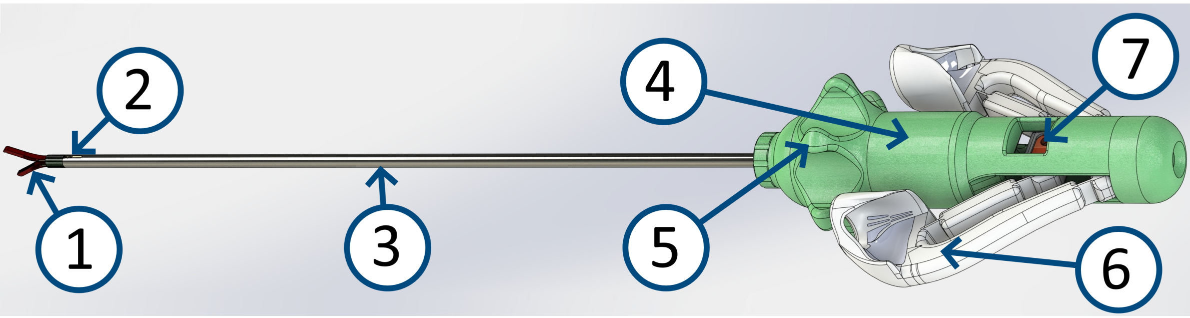


Figure 7.1: Novel instrument design overview, with grasper tip (1), tip locking mechanism (2), shaft (3), balancing mechanism housing (4), rotating interface (5), handle (6) and push pull rod locking (7). Note that the used colors do not represent the final prototype, but are there to easily discriminate between parts in Solidworks.

Figure 7.1 shows a render novel grasper design, with from left to right the grasper tip (1), mounted on the shaft (3) with the already designed ShapeLock technology (2). The stainless steel shaft has an outer diameter of $5mm$ and an inner diameter of $3mm$, to ensure sufficient stiffness. The housing (4), which covers the balancing mechanism, features a rotating knob (5), which enables the user to rotate the jaws while open/close them simultaneously with one hand. The handle (6) is located at the proximal end of the instrument, fastened to the housing and the push pull rod with an intermediate locking part (7). These parts and their respective features will be discussed in the coming paragraphs. More drawing details on the overall design, a cross section view and the individual parts can be found in Appendix B.

7.1. Grasper tip

The grasper tip was already designed prior to this graduation project and its design was not changed, except for the width of the compliant tip, which increased from $1.9mm$ to $2.0mm$. Since the bending stiffness is linear proportional to the width of a beam, this increases the compliant force $F_c(x)$ of the final prototype design with 5% compared to the compliant force measured in Chapter 4.

7.2. Balancing mechanism

As shown in the previous chapter, the optimal magnet configuration with linear force-displacement characteristics $F_b(x)$ is the axial magnet configuration. This is an arrangement of opposite magnetic poles facing each other. In this case, the balancing force will be linear over the whole range. This is optimal for this balancing application, because both the compliant tip force and the handle force is linear as well (Figure 7.4).

Figure 7.2 shows a cross section of the balancer mechanism and the handle integration. The balancer consists of a pair of push pull magnets (1) and housing magnets (2), bonded to their respective magnet mounts (3). The push pull rod magnet mount is fastened to the push pull rod (7) by means of a screw pin (4) at a small angled slot in the push pull rod. In this way, the screw connection does not only utilize friction, but is shape locked as well, ensuring a self centering, play-free connection. The complete balancer mechanism rotates with the grasper tip and shaft, utilizing a rotational sliding bearing (5).

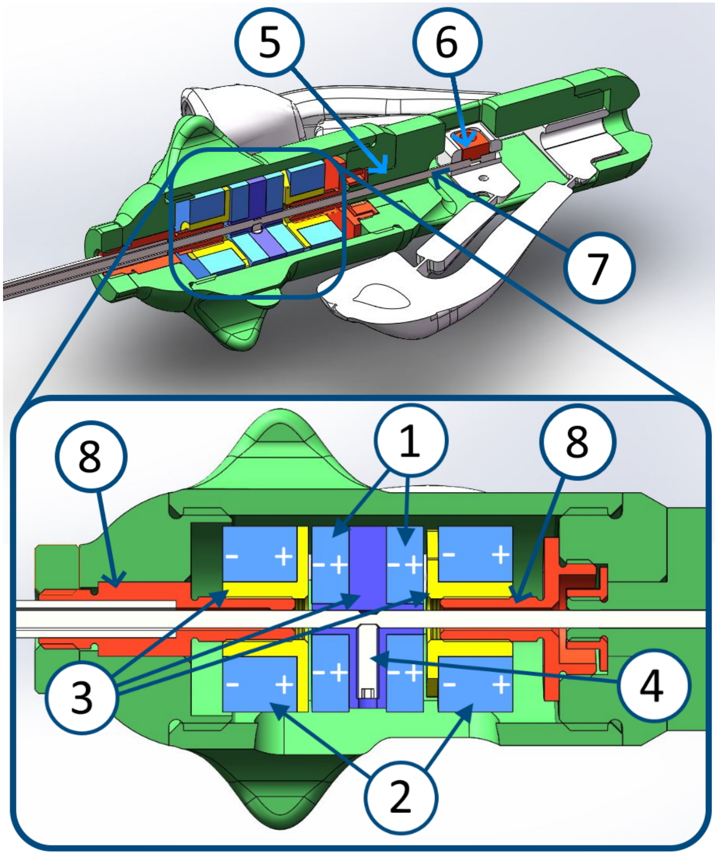


Figure 7.2: Balancing mechanism and handle cross section view, with push pull magnet pair (1), housing magnet pair (2), magnet mounts (3), screw pin (4), grasper rotation joint (5), push pull rod locking (6) and push pull rod (7). The magnetization direction of the magnets are noted with the (+) and (-).

The distance between the push pull rod magnet pair and the housing magnet pair determines the magnitude of the balancing force F_b. The closer the magnet pairs are to each other, the higher the balancing force. Because this is the first magnetic balancer version, it is crucial that the distance between the magnet pairs can be adjusted precisely for testing purposes. Therefore, the housing magnet mounts are mounted to the housing hubs (8) by M6 screw thread with a fine pitch of $0.5mm$ instead of the default $1mm$, so the magnets can be adjusted by rotation over the M6 thread. This is needed because the FEMM model shows that even a small change in magnet pair distance already causes a significant balancing force change. With this fine pitch chosen, one is able to adjust the magnet pair distance more precisely for testing purposes. The magnets can be rotated by pushing the dented ring on the magnet mounts, which can be reached through two holes in the balancer housing.

The magnets were chosen according to a few boundary conditions: they should be sterilizable and fit within a housing with a maximum diameter of $30mm$. Also, to minimize the housing volume (and thus the bulkiness of the instrument), the space envelope within the housing should be used as efficiently as possible, leaving a minimum of 'empty' space in the housing.

The balancing mechanism forces were computed using FEMM. The workflow in Paragraph 2.2 was used again to optimize the balancer dimensions and the magnet dimensions in particular. The density plot of the magnetic field is shown in Figure 7.3. Forces were calculated from the magnetic field for the whole range of motion of the grasper tip, shown in Figure 7.4.

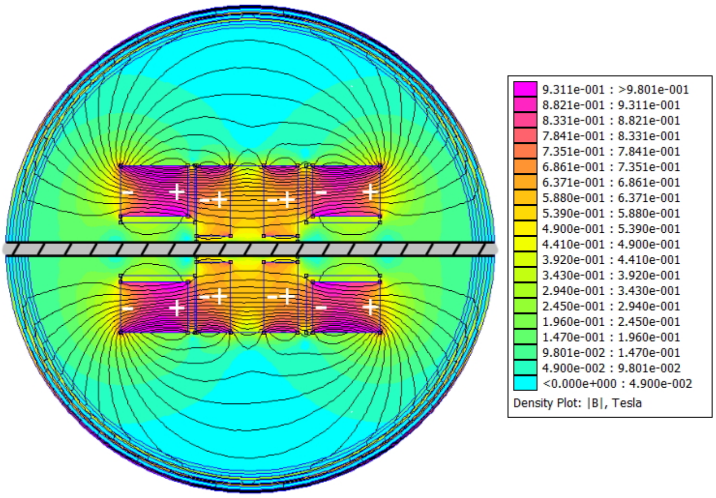


Figure 7.3: Density plot of a cross section of the balancer magnets, with their mounts. The drawn push pull rod has been added after the simulation. The detail view also shows the magnetiziation direction with the (+) and (-).

Only commercially available magnets were considered, because custom magnets are very expensive for such low production volumes (thousands of euros). It turned out that if the magnetization of all magnets is in the same direction, the force is 8% higher compared to a mirrored magnetization, so the first option was chosen (see Figure 7.2). All used magnets have an outer diameter of $25mm$. The magnet material is Neodymium, which is currently the most energy-dense magnet type commercially available. The material grade is N45 and N50 for the push pull rod and housing magnet respectively. See Appendix C for the dimensions and other specifications. The maximum operating temperature is $80°C$. Above this temperature, the magnets will experience irreversible demagnetization. This means that these magnets are not autoclaveable, however they can be sterilized chemically. Also, there are Neodymium magnets with higher working temperature ratings.

Through design choices it was made sure that the push pull rod is exactly in the center of the shaft and housing, by narrowing the housing down to the diameter of the push pull rod at both ends of the housing. This is needed because otherwise, radial forces can occur, decreasing the efficiency of balancing force transmission. By only narrowing the housing for a length of only $2mm$, friction between the housing and push pull rod is minimized.

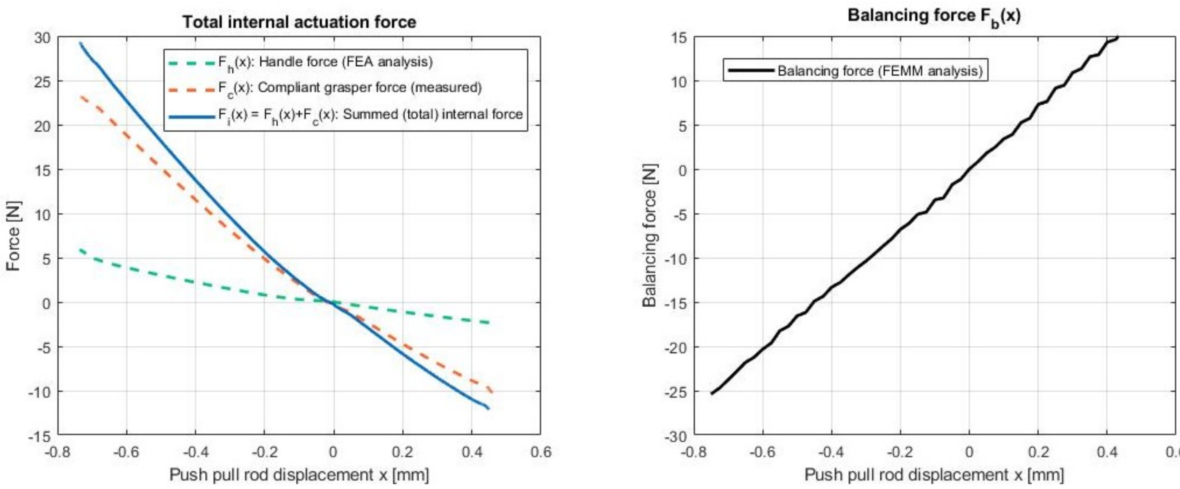


Figure 7.4: a. Summed (total) internal elastic forces F_i of the grasper tip and handle. b. Balancing force F_b obtained from the FEMM simulation.

7.3. Handle

The handle features a tweezers shape (Figure 7.5), stimulating a pinch grip using only the thumb and index finger tips. In this way, the most sensitive parts of the hand [77] will be used to control the instrument and receive feedback. During the final design phase, the handle design evolved from a simple compliant tweezers shape to a more intricate hybrid between angled scissors and the original tweezers (Figure 7.6). The handle consists further of rigid, non-compliant levers and compliant flexures. The non-compliant levers were made wider during the design evolution, because otherwise, the handle does not only bend at the leaf spring parts (which is the intended shape mode), but also at the non-compliant levers. If that is the case, hysteresis would be added to the system, and the input-output relation would become less linear, which is undesired.

The finger rings were added because with a (almost) perfectly balanced grasper, one needs not only to exert a force to close the grasper tip but also to open it. This can now be done by simply spreading the thumb and index finger. In this shape, the fingers mimic the movement of the grasper tip jaws. The small diameter holes of the outer ring ends prohibit the fingers to be put too far into the rings, which constrains the users options for wrong instrument use and encourages the intended use. To facilitate a firm grip, the ring surface bends somewhat inwards.

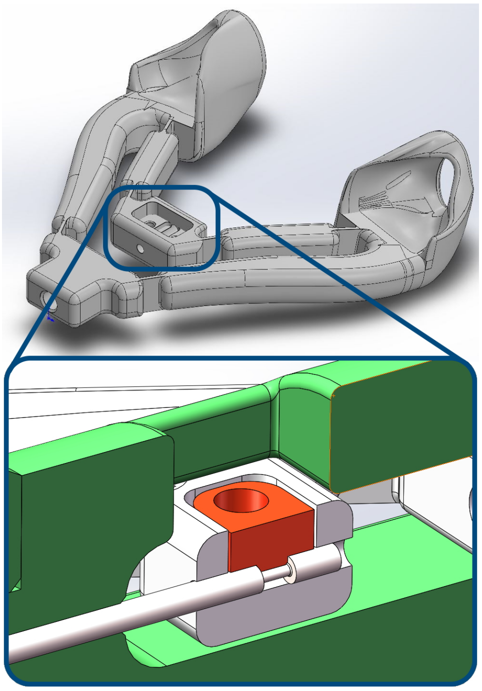


Figure 7.5: Compliant handle design (top), with a cut section of the the locking mechanism for the push pull rod (bottom).

The handle is fastened to the housing with a countersunk M6 screw and to the push pull rod by means of the rod retainer. This retainer uses a geometrical shape lock to ensure tight connection, and is shaped like a half moon at the bottom, falling exactly in place in the designated circular slot of the push pull rod.

The final handle design features flexures, which add to the internal compliant force $F_i(x)$. According to the requirements, the needed balancing force $F_b(x)$ will increase as a result of this. Before a balancing mechanism can be designed, the additional compliant forces exerted by the handle on the push pull rod need to be estimated. This was done using a non-linear *Solidworks Simulation*, imposing a spatial displacement on the handle and computing the subsequent reaction force. The results over the whole range of x can be found in Figure 7.4.

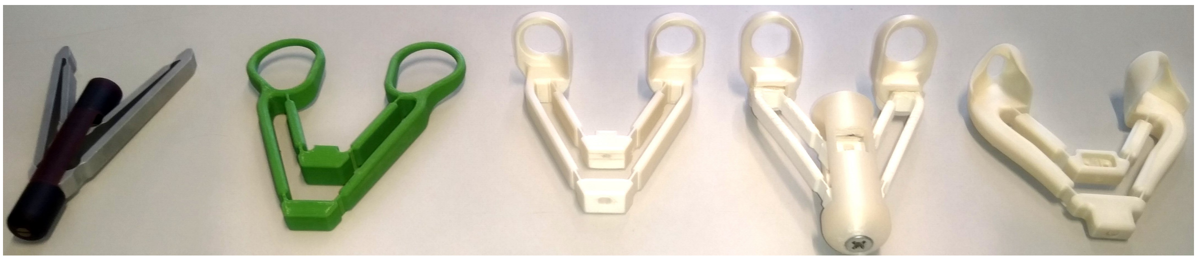


Figure 7.6: Mock-up tweezers handles 3D-printed during the final design phase showing handle design evolution, with the final design on the right.

7.4. Assembly

The assembly of the complete instrument is as follows: first the magnets were glued to their respective mounts with Araldite 2014, as well as the shaft hub to the shaft. Then the assembly of other parts can be done. The grasper tip is assembled (1, see Figure 7.8) and it is mounted to the shaft using the snap fit (2). Then the front parts of the magnet housing can be fastened to the shaft, and one shaft magnet as well (3). Next, the push pull rod magnet assembly with its mount should be screwed on the push pull rod, in a way that the set screw falls in the designated slot on the push pull rod (4). Then the push pull rod is mounted to

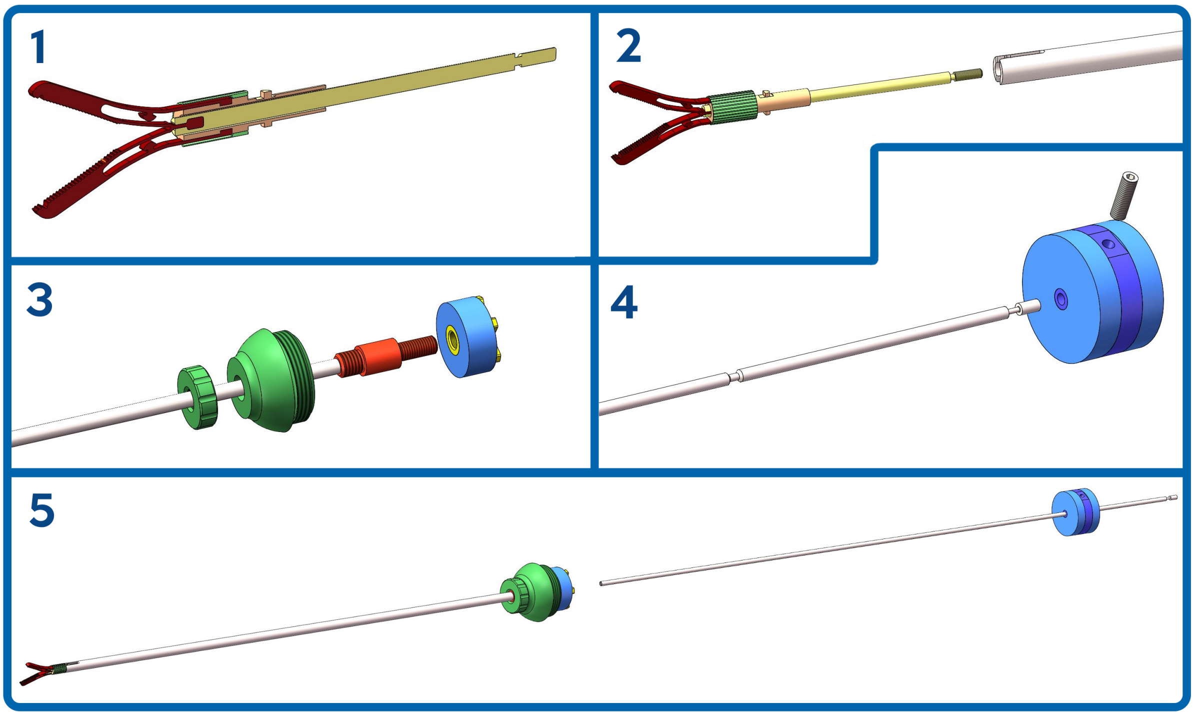


Figure 7.8: Assembly steps 1-5.

the connection rod (5). At this point, one should avoid that the magnets are in direct contact. If they stick to each other, it is difficult to remove them. Also the push pull rod is exerting the magnet forces to the grasper tip, and the excess of forces might cause it to open too much up to the point of breaking the tip flexures.

Next, the back part of the instrument will be assembled. First, housing back has to be mounted on the handle base using the back housing retainer in a way that the housing back is able to rotate freely relative to the handle base. After that, the magnet housing connection can be screwed on together with the second shaft magnet and its mount (6, see Figure 7.7). Now there are two large assemblies: one with the grasper tip, shaft, push pull rod and front part of the magnet housing, and one with the back part of the housing. These assemblies will be fastened to each other, with between them the middle magnet housing (7).

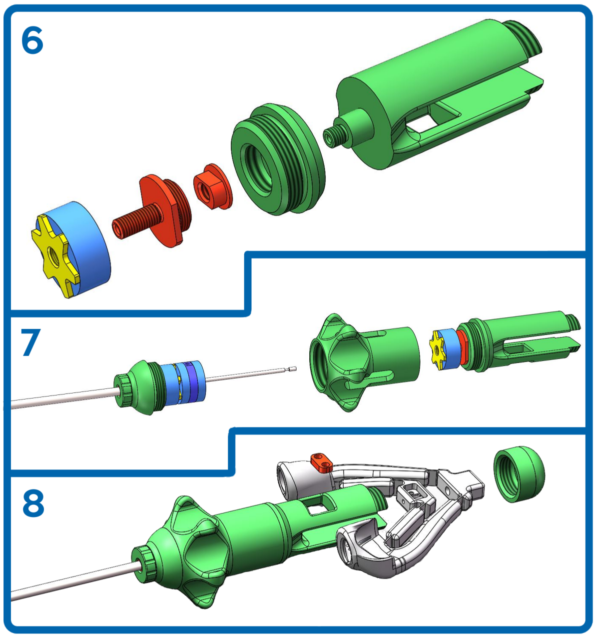


Figure 7.7: Assembly steps 6-8.

After this, the compliant handle can be put on the push pull rod and be secured by the handle base cap and screw. Lastly, the compliant handle is connected to the push pull rod by placing the the rod retainer in the designated slot in the compliant handle (8). Similar to the magnets connected to the push pull rod, the rod retainers shape enables it to geometrically lock into the push pull rod. The rod retainer is fastened to the compliant handle using DIN912 screws.

7.5. Production

All instrument parts were drawn using Solidworks. Crucial dimension tolerances were determined and communicated with the Dienst Elektronische & Mechanische Ontwikkeling (DEMO) workshop. Most of the dimensions were assigned a tolerance according to NEN-ISO 2768-fH, but some needed a more specific tolerance field, for example the shafts and holes. Because production at DEMO took longer than expected, Tim Horeman and the author of this thesis both machined several parts of the instrument at the BioMechanical Engineering workshop. The handle was 3D-printed out of one part with *Formlabs Tough* photo polymer, and resembles the mechanical characteristics of ABS. This reduces production difficulty, because now no handle flexures have to be assembled, which is complicated and time consuming. The possibility of injection moulding has also been investigated, but this turned out too costly at this design phase. More details on this can be find in Appendix D.

All metal parts (except from the grasper tip) were machined from stainless steel (AISI 316). This is the gold standard for medical devices because of its high corrosion resistant characteristics, suitable for autoclave sterilization. The Nitinol grasper tip was wire-EDMed from a plate. This is the best production technique regarding costs and quality. Also it does not add internal stress to the material during production, which is crucial for monolithic compliant systems. It was tried to laser cut the tip, but the small features of the tip could not be cut with the laser cutter at DEMO.

All parts were assembled by the author of this thesis. The magnets were bonded to their respective mounts by Araldite 2014.

7.6. Closing comments

In this chapter, the prototype design, assembly and production was explained in detail.

III

Evaluation

8

Validation

In the previous chapter, the design and production phase has been elaborately described. However, it has yet to be proven whether the instrument meets the design requirements. In this chapter, the instrument will be validated. First the instrument will be evaluated from an engineering point of view, describing the mechanical behaviour during the (first) assembly and subsequent use of the instrument. Design iterations will be described. Also the residual unbalanced force (balancing error) will be measured, to determine the balancing force. Secondly, the clinical relevance of the novel instrument will be evaluated, by comparing it to conventional laparoscopic graspers. Lastly, the chapter will be summarized by the list of design requirements from Chapter 5, each with a note whether they are met or not.

8.1. First assembly

Figure 8.1: A photo taken during the first assembly (step 7 from Figure 7.7).

After all parts were manufactured, they were checked for production errors. All parts were machined up to specifications and tolerances, except for the compliant grasper tips. All tips have a varying outer flexure thickness, consistently having one flexure that is thinner than the other (Figure 8.2). While the nominal thickness is 0.35 mm, the actual flexure thickness varied between 0.12 and 0.20 mm for the thin flexures and between 0.29 mm and 0.39 mm for the thick flexures respectively. The dimensions of the thin flexures are all exceeding the tolerance limits specified in NEN-ISO 2768-fH. The problem was discussed with DEMO and the cause

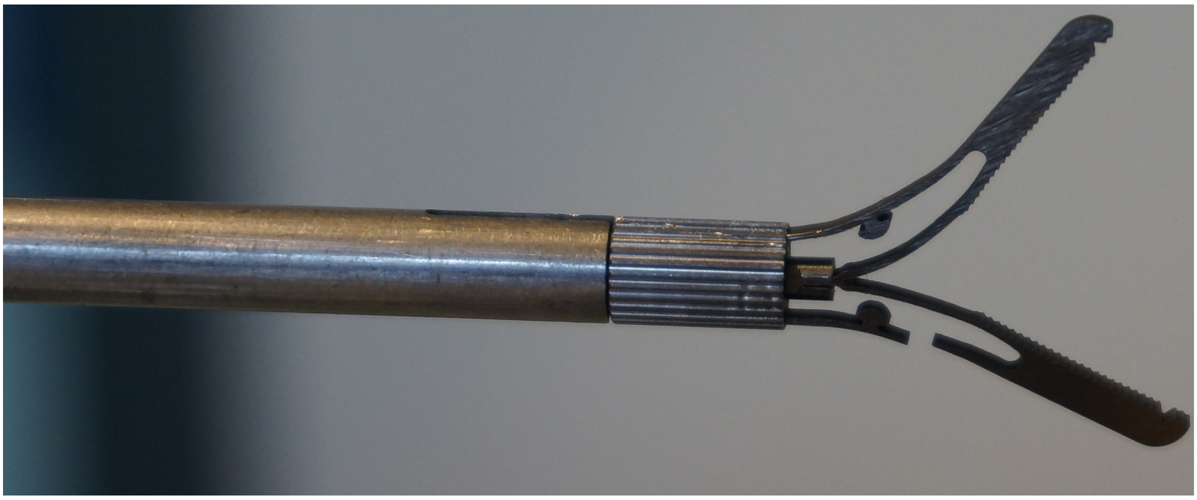


Figure 8.2: The broken tip, which broke at the place where the flexure thickness was not according to the specified dimensions.

was to be found with the small radius slot close to the mushroom shape on the flexure. This causes the EDM wire to slow down, and spark more material than needed. The tip design was changed accordingly, new tips were produced, and all validation was done using the redesigned grasper tips.

The instrument was assembled for the first time. Most parts fitted well together. Only the $2.35mmH7$ hole in the handle mounting was too small to fit the push pull rod without too much friction, so it was bored out to $2.4mm$. Also it was difficult to put the push pull rod through the designated holes in the compliant grasper. However the tight fitting of these holes to the push pull rod is important so it was decided not to bore out these holes. In a next version this should be fixed.

First, the instrument was assembled without the balancing magnets. As expected the instrument functioned, but the actuation of the grasper tip was very stiff, taking a lot of effort and with a strong tendency to go to the tip's neutral position.

It was not complicated to assembly the instruments without the magnets, if the instructions of paragraph 7.4 are followed. However, assembly of the magnets provide a challenge. The easiest way to do assembly step 7 is to carefully adjust the magnets in such a way that during assembly, the magnets cannot touch each other. Otherwise, they are hard to loosen again. The fine pitch of the magnet mounts proved to be helpful in this, as this increases the precision of the adjustment. The forces between the magnets are relatively high (order of $100N$) when they are in close proximity of each other. When the magnets are not handled carefully, it is easy to get wounded by it. The instrument should not be held close to pacemakers or other devices with a high electromagnetic sensitivity.

Figure 8.4: Location of the cupped spring washers that prevent longitudinal hysteresis.

After the instrument was assembled with the balancing magnets, the effort of the hand needed to actuate the grasper tip with the handle felt much smaller compared to the effort needed to do the same without the balancing magnets. This means that the magnet balancing magnet mechanism works as intended. In paragraph 8.3 this is further quantified by determining the balancing error and balancing force.

Despite the strict dimension tolerances, the joint allowing rotation about the longitudinal axis of the instrument showed too much play in the longitudinal direction. This was solved by adding two small cupped spring washers to the rotation shaft (Figure 8.4).

When the instrument was opened from its neutral resting point, there

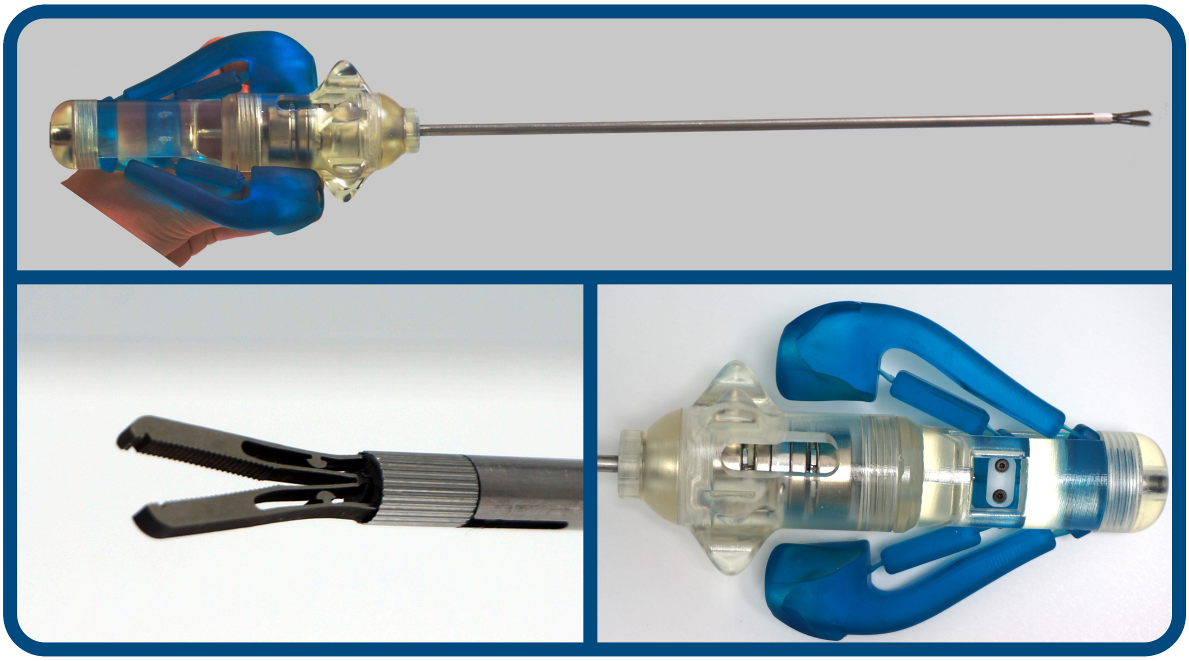


Figure 8.3: The finished instrument after the first assembly.

was a point where the grasper jaws opened by itself, up to a point where
the tip flexures almost broke. This is called overbalancing. This means that at some push pull rod position, $F_b(x) > F_c(x)$ is valid, violating the requirement from Paragraph 5.2.1. In Paragraph 8.3 it will be measured at which value of x the system becomes overbalanced and unstable.

It was noticed that when the grasper shaft and tip were rotated relative to the handle, the magnet adjustment changed, and thus the balancing force. This is because due to the threads on which the magnet mounts and push pull rod are fastened, were not locked.

The instrument weighs 273 grams. This is quite heavy compared to conventional laparoscopic instruments. Related to this is the uncomfortable grip. Because the heavy magnets are placed well beyond the distal point of the hand, the center of gravity of the instrument creates a significant moment about the wrist. In order to hold the instrument, the tweezers grip should be squeezed firmly, and this might influence the control a user has over the grasper tip.

8.2. Expert opinion

An opinion on the balanced instrument was asked from Roelf Postema, a gastrointestinal laparoscopic surgeon with 19 years of experience at the Spijkenisse Medisch Centrum in The Netherlands, researcher at the Vrije Universiteit Medisch Centrum and doctoral researcher at the TU Delft. He was given the instrument at the MISIT lab. He acknowledged the potential of having an hysteresis free instrument in order to improve haptic feedback. However, instrument handle without the grip add-on reduced the added value of the instrument greatly and the surgeon noted that this needs improvement. The root of this problem lies in the fact that without add on, both the control forces of the tip and the gravitational forces caused by the weight of the instrument (holding force) are exerted by the squeezing of the handle tweezers. Also, without the add-on, the user's wrist easily gets into awkward positions during laparoscopic tasks. The surgeon stated that the handle grip add on might solve this problem by separating the working lines of the control force and the holding force.

8.3. Balancing error - original design

8.3.1. Introduction

One of the most important design requirements is the balancing of at least 80% of the internal elastic forces $F_i(x)$. To recall, the balancing requirement is (Equation 5.2):

$$0.8F_i(x) \le F_b(x) < F_i(x) \tag{8.1}$$

The internal elastic forces make up the majority of all internal forces and consist of the compliant tip force $F_c(x)$ and compliant handle force $F_h(x)$. Therefore, the balancing requirement is:

$$0.8\,(F_c(x) + F_h(x)) \le F_b(x) < (F_c(x) + F_h(x)) \tag{8.2}$$

Without the balancing force, it takes a lot of effort of the instrument user to open and close the compliant grasper. With the magnets in correct position, the effort is empirically less. However, it is not zero, which means that the balancing mechanism does not cancel out all internal forces. To check to which extend the balancing requirement from Paragraph 5.2.1 is met, the balancing error $F_c(x)+F_h(x)+F_b(x)$ has to be determined. The following experiment will do this.

The balancing force can be measured using the balancing mechanism as a standalone device. However, it is much more interesting to investigate how it performs within the system of the instrument, because then also the effect of all fits and tolerances and the two compliant systems (tip and handle) can be measured. Validating the balancing mechanism integrated to the rest of the instrument has the consequence that the balancing force cannot be measured directly, because there are other internal forces acting on the mechanism as a whole as well. Only the resultant force on the push pull rod can be measured. This resultant F_{rest} force will be measured in this experiment. It generally consists of the following terms (see Chapter 1 and Glossary for their meaning).

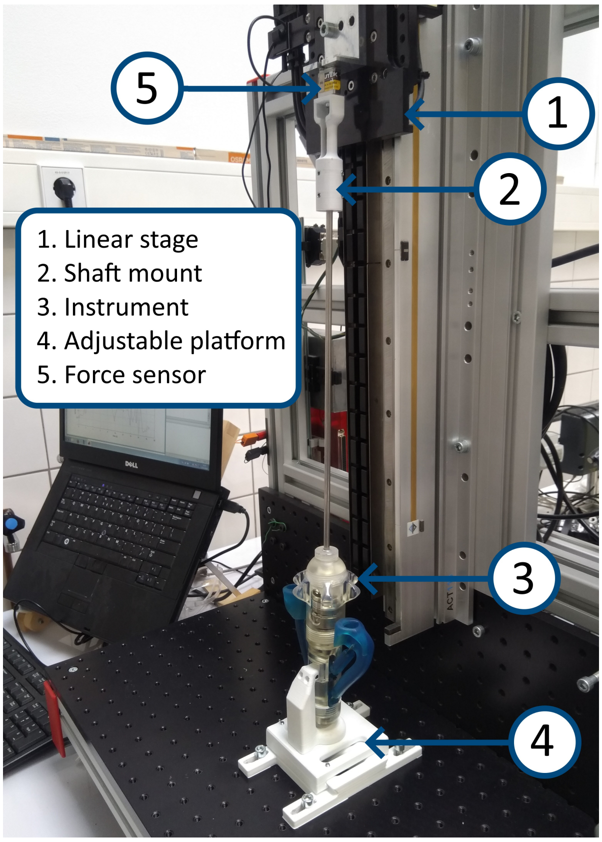


Figure 8.5: Balancing error test setup.

$$F_{rest}(x) = F_c(x) + F_b(x) + F_h(x) + F_t + F_f \tag{8.3}$$

The balancing error will be validated without any external load on the grasper tip, so tissue force F_t can be left out of this equation. Friction force F_f is assumed to be low relative to balancing and compliant forces. The compliant tip and handle forces $F_c(x)$ and $F_h(x)$ are measured (Chapter 4) and computed (Paragraph 7.3), respectively. This leaves room for the definition of the balancing error $F_{err}(x)$, approximated by the to be measured resultant force on the grasper:

$$F_{err}(x) = F_c(x) + F_b(x) + F_h(x) \tag{8.4}$$

$$F_{err}(x) \approx F_{rest}(x) \tag{8.5}$$

With these assumptions, the balancing force generated by the magnets can be calculated:

$$F_b(x) \approx F_{err}(x) - (F_c(x) + F_h(x)) \tag{8.6}$$

8.3.2. Methods

The instrument was clamped at the shaft near the grasper tip to a force sensor *(LSB200, Futek, USA)*, which in turn was mounted to a linear stage (*ACT115 Aerotech, USA)*. The push pull rod was fastened to a 3D-printed adjustable platform, near the compliant handle (see Figure 8.5). This platform, mounted on a static plate, allowed precise positioning of the instrument in the center of the force sensor axis. If the instrument could not be positioned like this, the push pull rod would be pushed against the shaft and housing, creating friction forces that do not exist with normal use.

The magnets were adjusted to ensure optimal balancing. Using the linear stage, the shaft was moved slowly ($0.5mm/s$) relative to the push pull rod, starting from fully closed grasper tip jaws ($x = -0.75mm$) up to the point where the jaws are opened beyond the underbalanced range. This was repeated six times. Data from the linear stage position and force sensor was processed in Matlab.

8.3.3. Results

The maximum measured balancing error was $8.11N$ at $x = -0.75mm$. The grasper tip became unstable and overbalanced (e.g. tended to open by itself) before the neutral point of the grasper tip was reached (at $x_{end} = -0.18mm$, see also Figure 8.6, initial design curve).

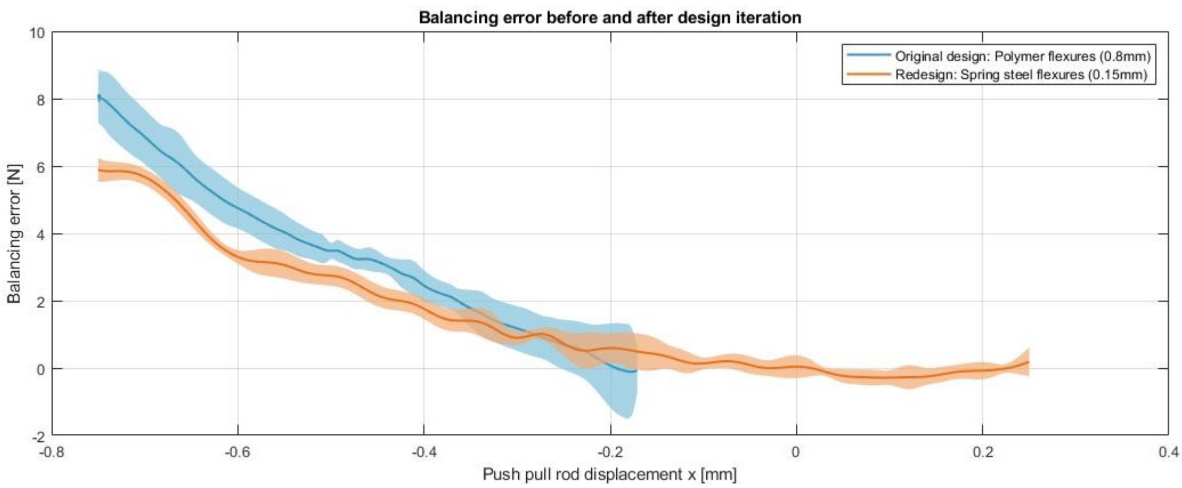


Figure 8.6: Balancing error F_{err} (mean and SD, $n = 6$) before and after replacing the handle flexures, showing mean and standard deviation. Again, $x = 0mm$ at the neutral state and $x = -0.75mm$ at the closed state. This figure contains results from both Paragraph 8.3 and 8.4.

8.3.4. Discussion

Using Equation 8.6, the balancing force $F_b(x)$ can be calculated. This has been done for the whole range of push pull rod displacement x, as shown in Figure 8.7b. If these results are compared with the combined internal prototype design forces from Figure 7.4 in Chapter 7 (shown again in Figure 8.7a), it can be seen that $F_b(x)$ is by approximate the opposite of the total internal forces, which is required for the static balancing. However, it is important to quantify the sufficiency of the balancing force. Therefore, the design requirement regarding balancing of at least 80% for the whole working range (paragraph 5.2) should be checked. The relative balancing of the instrument, which is the fraction of the balancing forces relative to the total internal forces, can be calculated using:

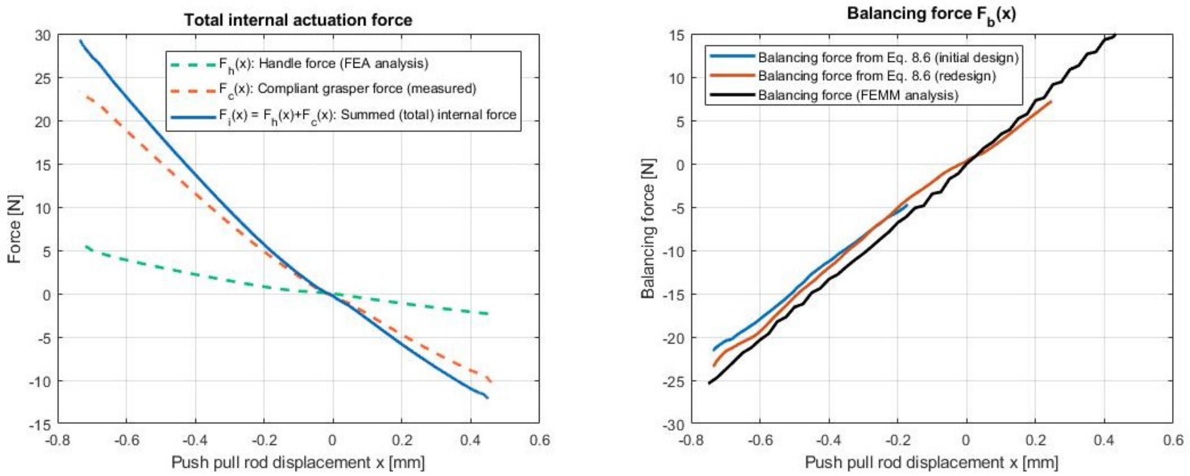


Figure 8.7: a. Preliminary combined internal elastic forces of the grasper tip and handle, earlier shown in Figure 7.4. b. Balancing force $F_b(x)$ as calculated according to Equation 8.6 computed using FEA analysis in Paragraph 7.2.

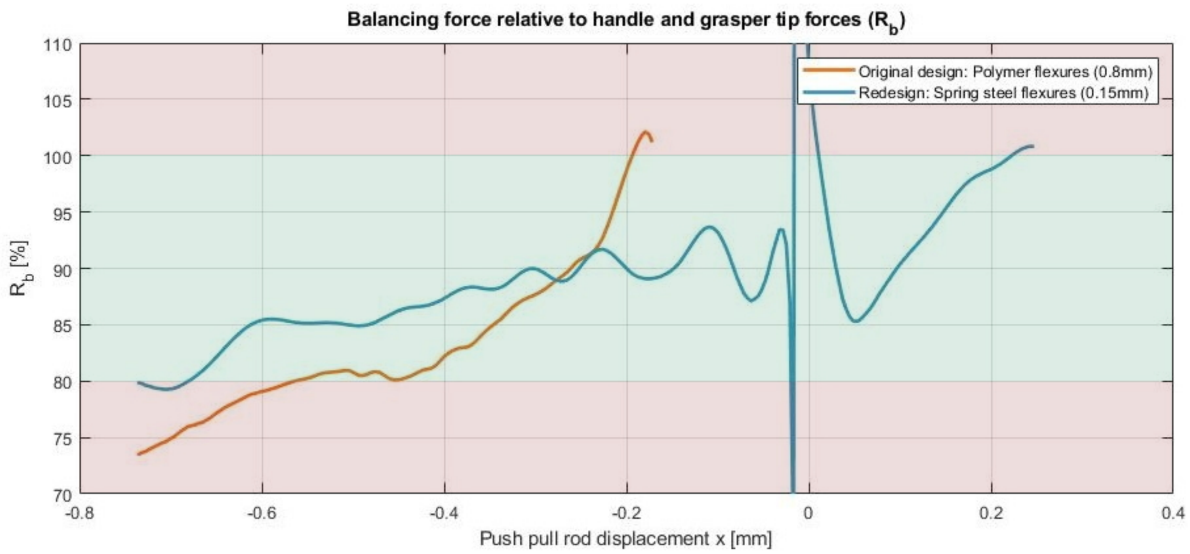


Figure 8.8: Comparison between the mean relative balancing error R_b before and after replacing the handle flexures. This figure contains results from both Paragraph 8.3 and 8.4. The green shaded area indicates the range where the balancing requirement of Equation 8.1 is met.

$$R_b = \frac{F_b(x)}{F_c(x) + F_h(x)} = \frac{F_{b,err}(x) - (F_c(x) + F_h(x))}{F_c(x) + F_h(x)} \tag{8.7}$$

Figure 8.8 (initial design curve) shows the relative balancing. It can be concluded that the relative balancing requirement of at least 80% is not reached for the majority of the working range of x. Note that $x = 0mm$ at the neutral resting state of the grasper tip and $x = -0.75mm$ at the closed state. It is hypothesised that the thick ($0.8mm$) polymer flexures are dissipating some of the elastic energy added to the flexures when they are bended. It should be tested whether a redesign of the handle increases the relative balancing. Therefore, the experiment was redone after a redesign. The results of this are in the next paragraph.

8.4. Balancing error - handle redesign

8.4.1. Introduction

The polymer handle flexures were replaced by spring steel (thickness 0.15mm). This time, not only the force-displacement curve of the grasper tip opening should be measured, but also the subsequent closing. In this way, the hysteresis loop (see also Figure 1.3) can be determined, and subsequently the mechanical efficiency η. This can be used to compare the instrument's mechanical performance to existing data of conventional laparoscopic instruments, reported in [3].

8.4.2. Methods

First, the underbalanced range was determined for the instrument with the redesigned handle, which was $-0.75mm < x < 0.18$. The balancing error test was redone using almost the exact same protocol as the previous test. The only difference is the addition of a closing cycle directly after every opening cycle. The test was repeated six times.

8.4.3. Results

The complete opening and closing cycle can be found in Figure 8.9. However, because the balancing force during closing of the instrument before the redesign was not measured, only the opening balancing error curves will be compared (compare in Figure 8.6, redesign curve). The balancing error of the opening of the instrument with the spring steel flexures was smaller (lower) than the balancing error with polymer flexures. When opening the instrument grapser tip, the relative balancing is higher with the redesign (Figure 8.8, redesign curve). Also the desired underbalanced range (where $80\% < R_b < 100\%$) of push pull rod displacement x was larger with the redesign. Before the redesign, the balanced push pull rod range was $0.57mm$, and after the redesign it is $0.99mm$, an increase of 42%.

In Figure 8.8, close to $x = 0mm$ the relative balancing goes to positive and negative infinity. This is not true to the physical reality, but rather a mathematical consequence of the function R_b (Equation 8.7), where the denominator $F_c(x) + F_h(x)$ goes to zero around $x = 0mm$. This means that close to $x = 0mm$, Equation 8.7 is not reliable.

Because not only opening forces are measured, but also closing forces, a complete force-displacement cycle can be presented (Figure 8.9). From this figure it can already be seen that there is quite some hysteresis in the novel instrument. From the force-displacement cycle data, the mechanical efficiency η of the whole instrument can be calculated, using Equation 2.6:

$$\eta = \frac{W_{open}}{W_{close}} = \frac{\int_{x_1}^{x_2} F_{open}(x)dx}{\int_{x_2}^{x_1} F_{close}(x)dx} \tag{8.8}$$

Just as it has been done with the magnet proof of concept in Chapter 2 and the compliant grasper tip in Chapter 4, numerical integration was used, yielding a total instrument mechanical efficiency of $\eta = 43\%$.

8.4.4. Discussion

The replacement of the flexures in the instrument handle has resulted in a small but significant improvement in balancing. The instrument can now be balanced for more than 80% for the whole range of displacement of x. Moreover, the instrument is (under)balanced over a larger range, and the grasper can be opened more before it is overbalanced and opened by the increasing balancing forces itself. This means that the jaws can be opened further and can grasp larger tissue structures.

Derived from the hysteresis loop (Figure 8.9), the mechanical efficiency of the instrument η is 43%. Following from the high mechanical efficiencies of the compliant grasper tip (95%) and magnetic balancing mechanism (96%), it was expected that the efficiency of the whole instrument was much higher than the ef-

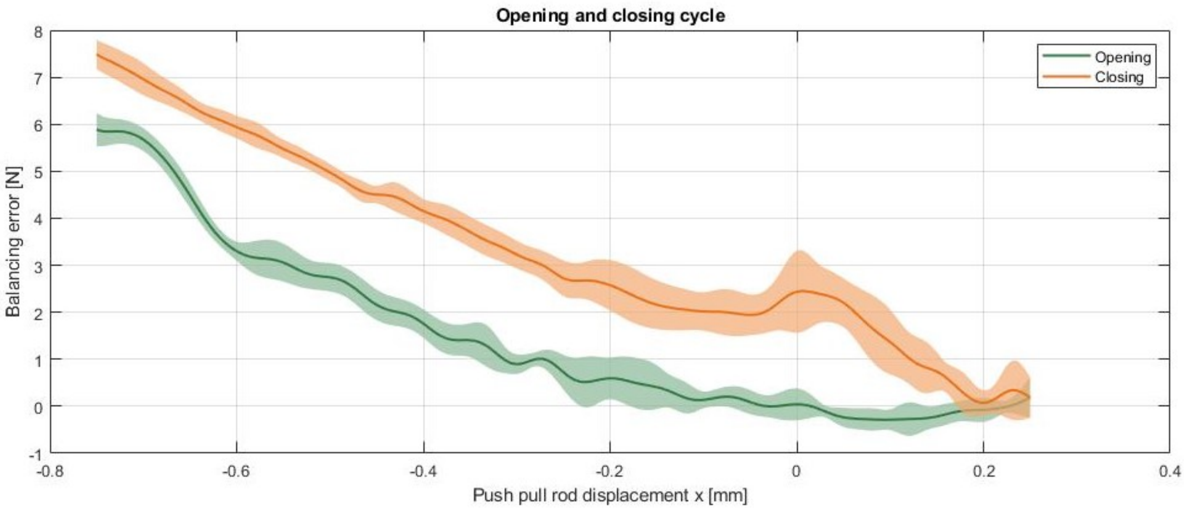


Figure 8.9: Hysteresis loop of F_{err} (mean and SD) for the complete opening and closing cycle (n = 6), with η = 43%.

ficiency of conventional laparoscopic instruments. As described in Paragraph 1.1, the mechanical efficiency of conventional instruments range from 8% to 42%. This means that with a mechanical efficiency of 43%, the novel grasper is performing in this respect just as well as the best conventional instruments. It is hypothesized that the cause of such a low mechanical efficiency is the friction forces present in the novel instrument. This is backed by the fact that the mechanical efficiency of the grasper tip and magnetic balancing mechanism are relatively high. This means that the source of inefficiency has to come from a different instrument part. It is hypothesized that the push pull rod is pushed against the guiding holes at both ends of the magnet housing. Moreover, there might be some radial magnetic forces, causing friction between the push pull rod and guiding holes as well. Also the redesigned handle was not perfectly symmetric, and consequently, moving parts of the handle were sliding against the static housing. Moreover, the mechanical efficiency of the compliant handle part should be measured independently as well. However, having a total mechanical efficiency of 43% is a satisfying starting point to significantly surpass conventional laparoscopic graspers in this respect. When designing the next version of the compliant grasper, one of the main goals should be minimizing friction.

It should also be noted that this and the previous experiment were conducted with only one compliant grasper tip. Therefore nothing is known about the possible variation between grasper tips. However, this variation thought to be low after solving the issue with the large variation in flexure thickness.

From this experiment, it can be concluded that the novel instrument with compliant grasper tip and handle are balanced for more than 80%.

8.5. Quality of haptic feedback validation

8.5.1. Introduction

The main goal of the compliant instrument is to improve the quality of haptic feedback. Already after the first assembly it was stated that the instrument showed little to no hysteresis, compared to conventional laparoscopic graspers. However, another factor that influences haptic feedback, is friction. The combined effect of hysteresis and friction as well as the ergonomic handle design determines largely the quality of haptic feedback. In order to validate the quality of haptic feedback, a comparison between conventional laparoscopic graspers and the compliant grasper is needed. The hypothesis that is being tested in the following experiment is as follows: the quality of haptic feedback of the compliant grasper is higher than a conventional grasper.

Before any validation can take place, a definition of how quality of feedback can be measured must be formulated. Haptic feedback on a laparoscopic grasper can be defined as the resultant force on the hand of the user of that grasper, as a result of a load on the grasper. Moreover, in the case the compliant grasper,

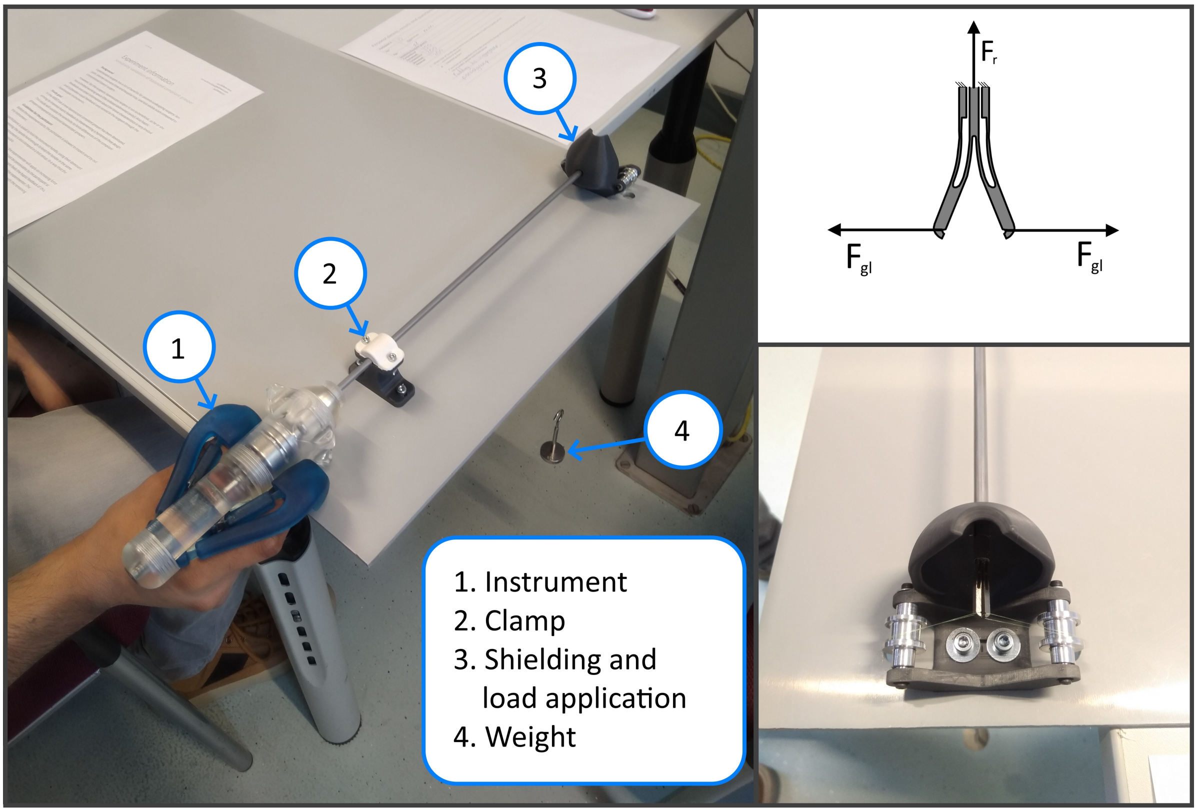


Figure 8.10: Overview of the test setup measuring the instrument sensitivity.

the tissue forces on the grasper are the desired source of haptic feedback. During surgical procedures where it is favourable to be able to perceive small forces, it is important that even these small forces can be discriminated. The instrument should be as sensitive as possible for force differences and perturbations during performance of these type of tasks. A way of comparing laparoscopic graspers in this respect, is to measure the lowest force that can be perceived by the user. The magnitude of this force is highly dependable on the amount of hysteresis and friction in the instrument. Thus, a dependent variable is defined: the sensitivity threshold F_{st}. However, the perceivance of this force is also dependant on the user itself. Therefore, the study should involve human subjects, each with a different view and sensitivity for haptic feedback. The lowest perceivable force (force threshold) of a user is a measure for the sensitivity of the instrument. If a significant difference between the different instruments can be measured for a reasonable amount of subjects, it can be concluded that the quality of haptic feedback differs as well.

8.5.2. Methods

A test setup was design and build, using a base PVC sheet and an instrument clamp. A load was applied using pulleys, a nylon string and calibrated weights of 50 grams each (Figure 8.10). The instruments was clamped in the test setup, in a way that the instrument tip is not visible, to ensure that the participants can only rely on haptic feedback and not for example visual feedback. Three instruments were used in this study: the balanced grasper, and two conventional laparoscopic graspers; a low quality unbranded grasper, and a high quality Aesculap grasper (Figure 8.11).

The participants were given an informed consent (see Appendix E), and after they were allowed to inspect all instruments, the experiment started. Participants were asked to hold the instrument handle, using their dominant hand, squeezing the handle hard enough to keep the handle in the same (almost closed) position. Using weights, an increasing (gravitational) force was applied to the grasper tip. At the start of the experiment there was already a load of 50 grams. The increment of weight was 50 grams as well. As soon as the participant felt the haptic feedback of this load force in the handle, he or she was instructed to notify the experimenter. This load is named and stored as the sensitivity threshold force F_{st}. The experiment ended at this point, and was redone with the remaining instruments. After the sensitivity test of the last instrument, a short questionnaire was given, consisting of two questions:

1. *"Which handle type did you find more comfortable to hold?"* [Possible answers: conventional grip OR tweezers grip OR no preference]
2. *"Can you think of any improvements to the current design of the compliant grasper?" [Open question]*

The answers to the second open question will be categorized. Only categories with 2 or more entries from different participants will be reported.

Before the actual study, a pilot study was conducted with 5 subjects to estimate the needed number of participants, using the Matlab function `sampsizepwr`. Using the mean and standard variation of the pilot study, and assuming a minimal statistical power of 0.9, the minimum number of participants is 12. However, as this is a fairly low number, it was determined that there should be at least 20 participants. Participants were selected according to the following criteria: 18-65 years old, and having no surgical experience. During the actual study 25 participants (16 males, 9 females) performed the experiment. The mean age was 31 (SD 7 years).

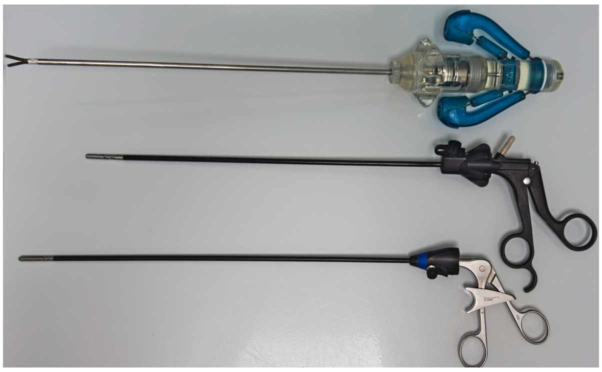


Figure 8.11: Instruments used in the sensitivity measurements. From top to bottom: the novel instrument, the unbranded grasper and the Aesculap grasper.

8.5.3. Results

The sensitivity threshold force was the lowest for the balanced grasper (mean 1.37N, SD 0.44N), followed by the Aesculap grasper (mean 2.15N, SD 0.71N) and the unbranded grasper (mean 2.65N, SD 1.20N). See also Figure 8.12. Comparing the sensitivity threshold forces of the balanced grasper and other graspers separately using two t-tests yielded the following p-values for significance:

- Balanced grasper versus Aesculap grasper: $p = 1.06E-5$
- Balanced grasper versus unbranded grasper: $p = 5.89E-6$

Based on a confidence interval of 95%, it can be concluded that both effects are significant ($p \ll 0.05$). The sensitivity difference between the Aesculap grasper and the unbranded grasper is significant as well ($p = 0.049$), however the statistical power is very low (0.67). The effect of sex is not significant. The answers to the questionnaire showed that 24% percent of preferred the tweezers handle, 68% preferred the conventional handle and 8% had no preference. The answers to the second (open) question mostly addressed the design of the handle and will be discussed in the next subparagraph.

8.5.4. Discussion

In the introduction of this experiment, it has been defined that a lower threshold force can be related to a higher sensitivity to force perturbations of the grasper tip. Figure 8.12 shows that the compliant grasper has a significantly lower threshold force compared to both low and high quality conventional laparoscopic graspers. Thus, it can be concluded that the compliant grasper has a significantly higher quality of haptic feedback and sensitivity to force perturbations during laparoscopic surgery than conventional laparoscopic graspers in general.

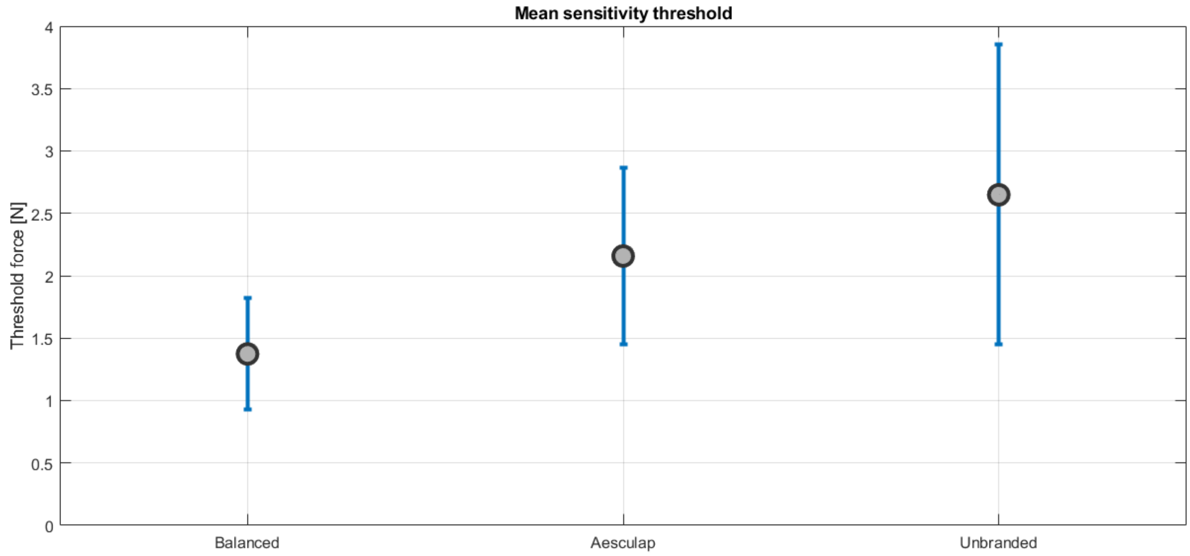


Figure 8.12: Results of the sensitivity threshold measurement of the laparoscopic instruments ($n = 25$) (balanced grasper versus Aesculap grasper: $p = 1.06E-5$, balanced grasper versus unbranded grasper: $p = 5.89E-6$).

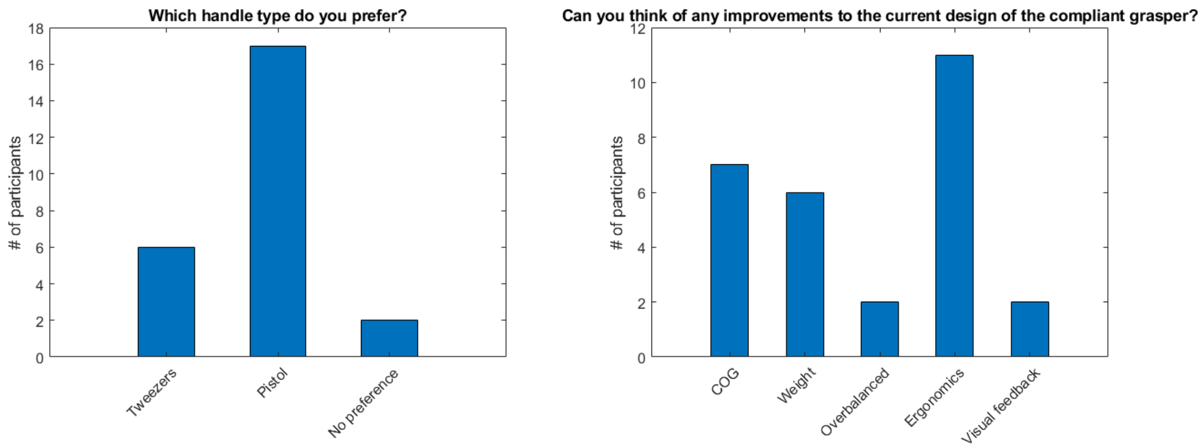


Figure 8.13: Categorized answers to the questionnaire.

During the sensitivity measurements, the quality of haptic feedback of the conventional instruments seemed to depend heavily on stick-slip effects and the way the participants were holding the handle. This was not only experienced by the conductor and participants of this experiment but was later also seen when the standard deviations of sensitivity threshold of the conventional instruments were compared with that of the novel instrument. The standard deviation of the novel instrument is smaller, due to a smaller influence of confounding experiment conditions like hand pressure and interlocking.

The answers to the questionnaire varied widely. They were sorted into the following categories (Figure 8.13):

- Seven participants reported about the center of gravity (COG). All of them mentioned that the COG is too far from the hand, creating a torque about the wrist joint, causing fatigue and discomfort.
- Six participants found the weight to be too much.
- Two participants complained about the unexpected overbalanced opening behaviour of the grasper tip jaws.
- The hand posture and original handle (without the hand grip add on) was deemed uncomfortable by eleven participants.

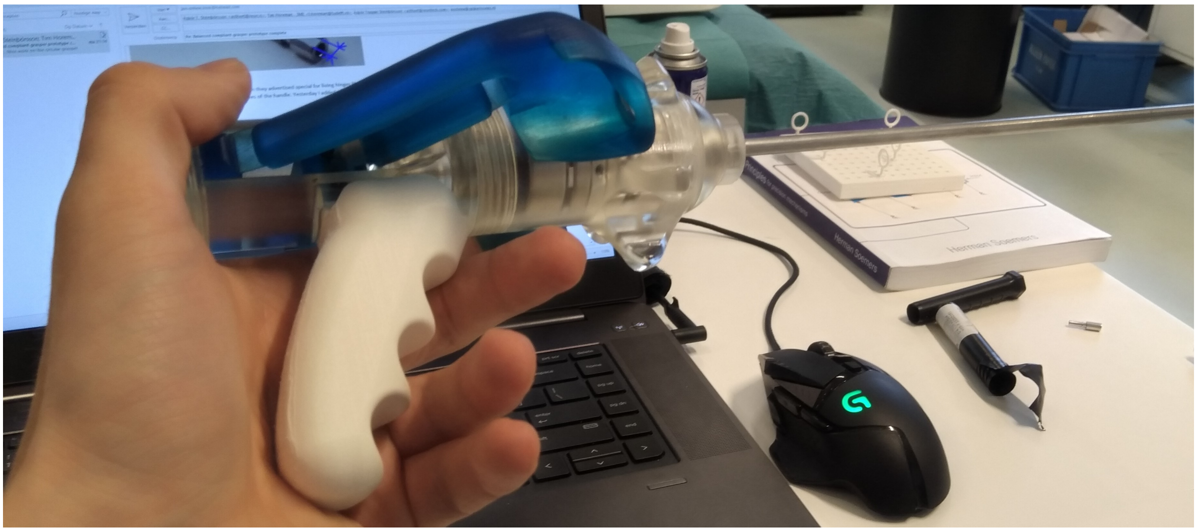


Figure 8.14: Hand grip add on.

- During the experiment, the grasper tip was visually shielded from the participants. In general, this made them insecure about their performance during the test. Two participants actually reported on this, suggesting a visual indication of the opening of the jaws. However this cannot be given because the core idea of the test is to only measure haptic feedback and no visual feedback. During surgery this is not needed as well because then the surgeon has visual feedback on a screen.

8.6. Hand grip

After the pilot test and sensitivity test, the participants were asked how they felt about the comfort and ergonomics of the handle. Unanimously they said that it was not comfortable to hold the instrument in one hand, because it had a tendency to fall out of their hands. This has already been described in the previous paragraph as well. Therefore, an add on hand grip for the handle was designed (Figure 8.14). When mounted to the instrument, the instrument was already much more stable in the hand, because now the weight of the instrument was carried by other fingers than the fingers used to control the tweezers grip. Unfortunately it was not possible to attach it to the instrument for the current validation phase. However in a next version of the instrument, the handle should be redesigned taking into account these findings.

It was also noticed that the handle flexures introduced significant elasticity to the grasper tip control. If the grasper tip is grasping an object or is shut completely, the handle can still be closed more. This is also a form of hysteresis which is not desired, and in a way it decreases the quality of haptic feedback, because one cannot discriminate between the elastic forces of the grasped object and the handle itself.

8.7. Reusability

In Paragraph 5.2.3, it is required that the design of the novel instrument "should be cleanable and sterilizable". This has been taken into account in the design. All instrument parts can be disassembled, and remaining hollow spaces can be reached and flushed easily. When disassembled, the instrument contains no narrow lumen or dead spaces where dirt can build up. However, with the current design, it takes more effort to dis- and reassemble the novel instrument during reprocessing, compared to conventional laparoscopic graspers. Therefore, during development of next versions of the novel grasper design, ease of disassembly should be one of the main design requirements.

8.8. Design requirement evaluation

To conclude and summarize this chapter, all design requirements and boundary conditions are checked in Table 8.1.

Requirement	Condition	Requirement fulfilled?	Paragraph
Balancing	$0.8(F_i) \leq F_b(x) < (F_i)$	Yes, for the push pull rod range of $-0.75 < x < 0.24$.	5.2.1
Intuitive and comfortable use	Provide haptic feedback better than conventional laparoscopic graspers.	Yes, at least for threshold sensitivity.	5.2.2
	Facilitate resting posture of the surgeon's hand	At this point, no, but pistol grip add on shows potential, according to expert opinion and participant questionnaire.	5.2.2
Reusability	Prototype should be designed with measures taken for cleanability and sterilizability in mind.	Yes	5.2.3
Component type	No electronically driven components	Yes	5.3
Weight	$m_{instrument} < 300gram$	Yes, $m_{instrument} = 273gram$	5.3
Shaft dimensions	Outer diameter: $\leq 5mm$, Instrument shaft length: $300mm \pm -20mm$	Yes	5.3

Table 8.1: Design requirements evaluation.

9

Discussion

As made clear in Chapter 1, 2 and 3, the benefits of preserving the quality of haptic feedback in laparoscopic surgery are obvious. It makes the surgeon more aware of the instrument-tissue interaction, which can lead to more precise dosing of forces, preventing unnecessary tissue trauma. Compared with open surgery, laparoscopic surgery in general already takes a leap in preventing tissue damage, which is linked to shorter hospital stay as well. By finetuning laparoscopic instruments for their intended tasks, tissue trauma can be decreased even further. The novel compliant instrument has proved to be a next step in this. Based on the findings in the previous chapter, it can be concluded that the novel compliant grasper improves the quality of haptic feedback compared to both low and high quality conventional laparoscopic graspers.

Laparoscopic surgery can benefit greatly from improved perception of forces and haptic feedback. For example, a surgeon might misjudge the amount of force he or she is applying on tissue, and subsequently apply a force that is either too low or too high, resulting in more tissue damage and mental stress on the surgeon. Also when soft, deformable tissue is pulled, it gets stretched and thus it will become thinner. However, if the opening of the grasper tip does not change accordingly due to the lack of haptic feedback about the changing force on the tissue, the grip force will decrease and slip might occur. If the quality of haptic feedback increases, this would also be beneficial for locating tumours or metastasis. This can be done by grasping suspicious tissue and evaluating the stiffness through haptic feedback. Cancerous tissue is often stiffer compared to healthy tissue, so if smaller differences in grasper tip force and stiffness of haptic feedback can be perceived, tumours can be removed more precisely. With sufficient haptic feedback, it would even be possible to perceive more subtle dynamic processes in a patient like pressure changes in a blood vessel.

9.1. Design and production considerations

In general, the novel instrument was well designed and constructed up to specifications. However, there were a number of points which need attention and improvement. In this paragraph these points will be addressed.

Design process. During the final design phase, it was chosen to only simulate the force-displacement curve of the compliant handle. Although non-linear effects were taken into account by the FEA simulation, it still produces less accurate results than a force measurement on a linear stage using the handle prototype. This lack of knowledge resulted in the need for a handle redesign, replacing the flexures. Probably, a preliminary force measurement would bring this need to light much earlier in the process.

Assembly and magnet adjustment. It was noticed that the balancer assembly with the magnets was very cumbersome. It took great effort to both avoid the magnets from sticking to each other, and to adjust the magnets. Also it is difficult to find the correct magnet adjustment, because it has to be adjusted when it is connected in series to the compliant grasper tip and handle, which both influence the setting of the magnets.

Moreover, when the grasper shaft and tip were rotated relative to the handle, the magnet adjustment changed. Therefore in a next prototype, it would be beneficial to be able to adjust the magnets more independently and accurately. This can be achieved by making it possible to first adjust the magnets on conical mounts before mounting the balancing mechanism to the other compliant parts of the instrument. Also the use of spacers between the magnet pairs would be helpful during assembly.

Tweezers grip. In order to hold it firmly in one hand without the add-on, participants of the user test experiment had to squeeze the instrument handle so tight, that their grip became like a power grip, minimizing the benefits of the intended precision grip [76]. Because the balanced grasper is significantly heavier than conventional laparoscopic graspers, it is even more important that the instrument fits well in the users hand and that a precision grip is facilitated by the design. For a next prototype, it is definitely needed to physically separate the holding and actuating function of the grasper handle. An attempt to solve this was already made, using an handle grip add-on, creating a pistol-like handle grip which is to be held by the palm grip. This means that the force needed to hold the instrument is generated by the palm with a quasi power grip, and the force needed to control the grasper this is exerted by the thumb and index finger, facilitating a precision or tweezers grip. This is a promising solution direction and should be investigated in future prototype versions.

Another possible improvement to the hand grip would be removing the leaf springs, which add to the compliant force $F_c(x)$ in the instrument (and thus increases the required $F_b(x)$). It also adds undesired flexibility to the handle which decreases the quality of haptic feedback. If pin joints are chosen for a new prototype, both problems can be solved. However that would introduce play and hysteresis again to the instrument. A possible solution to this might be leaving some of the compliant force in the instrument, which will pre-stress the handle joints a bit, and thus diminish play and hysteresis in this way.

In the broader perspective of the Sensing in Surgery (SiS) project, the question arises whether it is desirable to have a non-conventional instrument handle like the tweezers handle. The aim of the SiS project is to improve haptic feedback through implementation of a compliant grasper. To this end, standardized validation is crucial. So if both grasper tip and instrument handle are different from conventional instruments, and both influence the surgeon's haptic feedback perception, two (design) variables are changed at the same time. This has the result that one cannot discriminate the influence on haptic feedback of the grasper tip and the handle. To be sure of the effect of the grasper tip on haptic feedback, other design aspects such as the handle should be kept the same as conventional instruments.

Grasper tip. The grasper tip can be improved by enlarging the grasping area. This reduces the pressure on the grasped tissue, while maintaining the grasping force, so the haptic feedback will not change. Also, the grasper tip flexures might be optimized to reduce the compliant force $F_c(x)$. In the next version of the prototype, the grasper will be cut out of Nitinol rod of $5mm$ instead of $2mm$ thick plate. This will increase the grasping area anyway. Also the flexures will be cut out in this circular shape. It should be investigated what is the influence on the compliant force. Moreover, this means that the neutral resting state of the grasper tip will be the closed state. This means that the balancing requirement will be one-sided instead of two-sided now. The balancing mechanism has to be redesigned according to these changes.

Reusability. It has been mentioned in the requirements that the instrument should be reusable. As expected, the total cost of the instrument will not be lower than conventional reusable laparoscopic graspers, and thus to be commercially viable product, it has to be reusable indeed. Because there is an overpressure in the peritoneal cavity during a laproscopic surgery, blood will seep into the shaft of the instrument. This means that to be reusable, the instrument should be cleanable in some way. This can either be done by taking the instrument apart, being able to flush the instrument without taking it apart. For future versions of this instrument, it is advised to use a combination of both options: allowing the balancer mechanism to be flushed without the need to take it apart, and applying a detachable grasper tip. This also relates to the recommendation for a modular design with different grasper tip options and add-ons which will be discussed next.

Modularity. The use of a balancing mechanism is not limited to the current grasper shape. If there is the need, other end effectors can be attached as well, using the ShapeLock connection. Also within the SiS project, another solution to prevent tissue damage is proposed as well: the ShaftLock module, which is a pinch force limiter, that fits in the instrument shaft. These all are modules that can be (re)placed without replacing the complete instrument. In this light, also the complete balancing mechanism could be made modular and exchangeable, which also can aid during reprocessing for reuse.

9.2. Purpose and further validation

At the start of this thesis, the goal of designing a compliant laparoscopic grasper was set. However, grasping is a very inclusive term and can be more specified. During discussions with dr. Postema, the cooperating surgeon, it became clear that the grasping function can be subdivided in two categories: at one hand there is surgical preparation, which includes the less subtle grasping, manipulation and tearing of tissue in order to reach and prepare a certain site in the patient's body. The second category is related to the execution of the intended surigical task, like dissecting malicious tissue or checking for metastasis. Here it is important for the surgeon to be able to receive reliable haptic feedback about tissue stiffness and texture. For further validation, it might be investigated whether there is a difference in advantage of the novel instrument over conventional graspers between these two task categories. Then, relevant studies should be designed in order to be able to simulate different task types. In general, it is important that further research should be aimed towards validation of the clinical relevance of the novel instrument. Due to project limitations, the validation task used to measure the quality of haptic feedback in this thesis lacks a relation to the clinical environment and its surgical tasks. To improve this, a few possibilities can be considered:

Clinical relevant tasks and parameters might involve measuring tissue and trocar forces during basic surgical pick-and-place tasks. Performance parameters during surgical tasks can already be easily measured using the ForceSense laparoscopic training system. This system is already used by academic hospitals and medical societies to certify surgeons. For more feedback sensitive tasks like dissecting, it is interesting to measure the quality of haptic feedback regarding mechanical characteristics of tissue and dynamic processes. The general hypothesis to be validated should be: While using the novel compliant instrument, one can discriminate changes and differences between tissue characteristics better than while using a conventional laparoscopic grasper.

A different, more qualitative approach to this can be achieved by comparing tissue damage after performing a certain surgical task. This can be done by trauma assessment of tissue by a pathologist. Probably other (non-biological) materials with similar damage or memory characteristics can be used for this as well.

In this thesis, the focus is on the quality of haptic feedback, the stream of information from the tissue to the surgeon. However, one could also investigate the influence of the quality of control. Because of the decreased hysteresis, the force-displacement curve of the compliant instrument is much more linear than that of a conventional laparoscopic grasper. According to the dr. Postema, this can also be a significant advantage of the compliant grasper.

10
Conclusion

The design goal of this thesis was stated in Paragraph 1.2:

> *The goal of this master thesis is to design a laparoscopic instrument with a monolithic compliant grasper, with the forces generated by the elastic deformation of the compliant grasper and other parts statically balanced by a magnetic balancing mechanism, in such a way that the elastic forces experienced by the user during actuation of the grasper are minimized.*

It can be concluded that the novel compliant grasper described in this thesis improves the quality of haptic feedback compared to conventional laparoscopic graspers. Through technical and sensitivity validation, it became clear that the magnetic static balancer in combination with the compliant is a viable solution, both from an engineering and clinical perspective. This design and study outcome is a promising base for future work. Special attention should be given to the improvement of the instrument ergonomics and modular design. Also, improving clinical relevance and standardisation is crucial for future instrument validation studies.

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A

Test magnet specifications

supermagnete

Data sheet article S-03-02-N

Technical data and application safety

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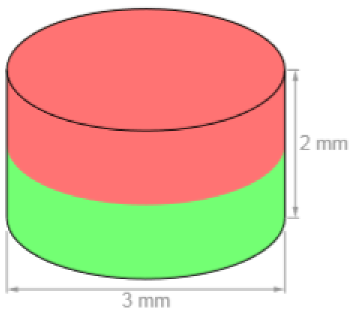
1. Technical information

Article ID	S-03-02-N
Material	NdFeB
Shape	Disc
Diameter	3 mm
Height	2 mm
Tolerance	+/- 0,1 mm
Direction of magnetisation	axial (parallel to height)
Coating	Nickel-plated (Ni-Cu-Ni)
Manufacturing method	sintered
Magnetisation	N48
strength	approx. 300 g (approx. 2,94 N)
Max. working temperature	80°C
Weight	0,1074 g
Curie temperature	310 °C
Residual magnetism Br	13700-14200 G, 1.37-1.42 T
Coercive field strength bHc	10.8-12.5 kOe, 860-995 kA/m
Coercive field strength iHc	≥12 kOe, ≥955 kA/m
Energy product (BxH)max	45-48 MGOe, 358-382 kJ/m³



Pollutant-free according to RoHS Directive 2011/65/EU.

Figure A.1: Cylinder magnets used in the magnetic balancing proof of concept.

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Data sheet article R-27-16-05-N

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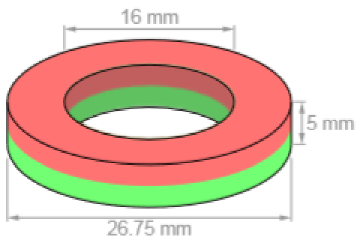
1. Technical information

Article ID	R-27-16-05-N
Material	NdFeB
Shape	Ring
Outer diameter	26,75 mm
Inner diameter	16 mm
Height	5 mm
Tolerance	+/- 0,1 mm
Direction of magnetisation	axial (parallel to height)
Coating	Nickel-plated (Ni-Cu-Ni)
Manufacturing method	sintered
Magnetisation	N42
strength	approx. 11 kg (approx. 108 N)
Max. working temperature	80°C
Weight	13,7157 g
Curie temperature	310 °C
Residual magnetism Br	12900-13200 G, 1.29-1.32 T
Coercive field strength bHc	10.8-12.0 kOe, 860-955 kA/m
Coercive field strength iHc	≥12 kOe, ≥955 kA/m
Energy product (BxH)max	40-42 MGOe, 318-334 kJ/m³



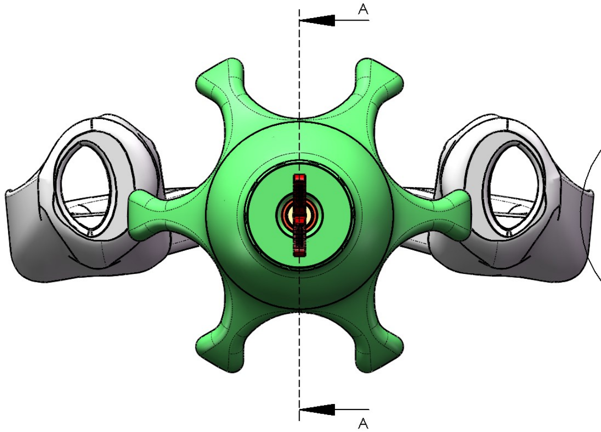
Pollutant-free according to RoHS Directive 2011/65/EU.

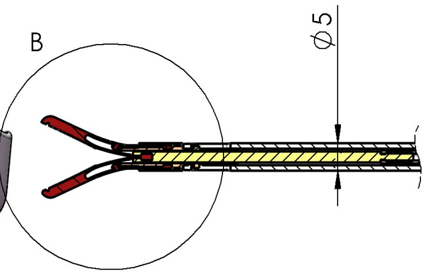
Figure A.2: Ring magnet used in the magnetic balancing proof of concept.

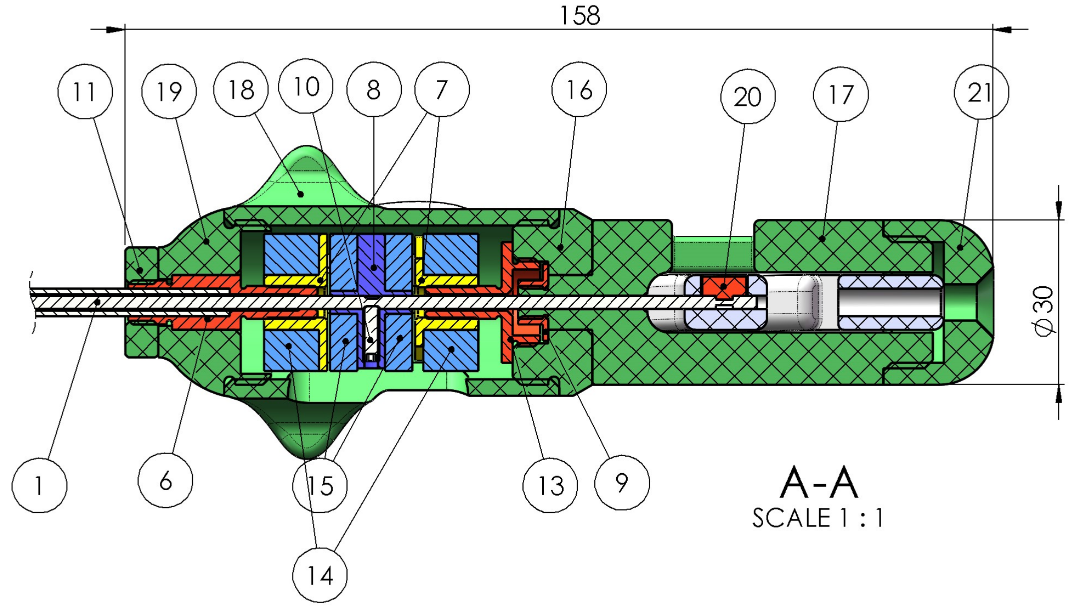
B

Technical drawings

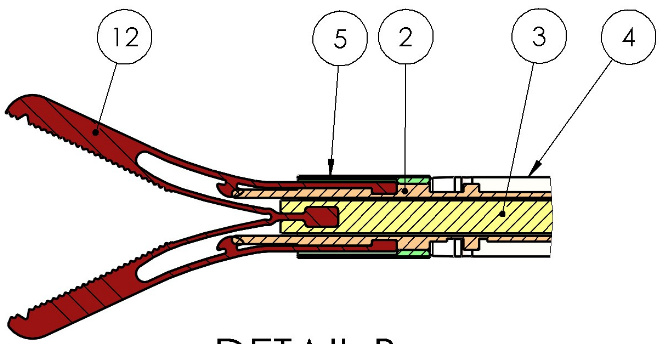
On the next page, an overview of all parts with their respective materials is presented. On the pages thereafter, the technical drawings of all parts.



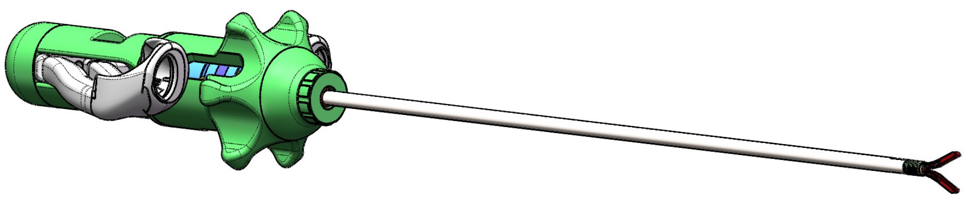




A-A
SCALE 1 : 1

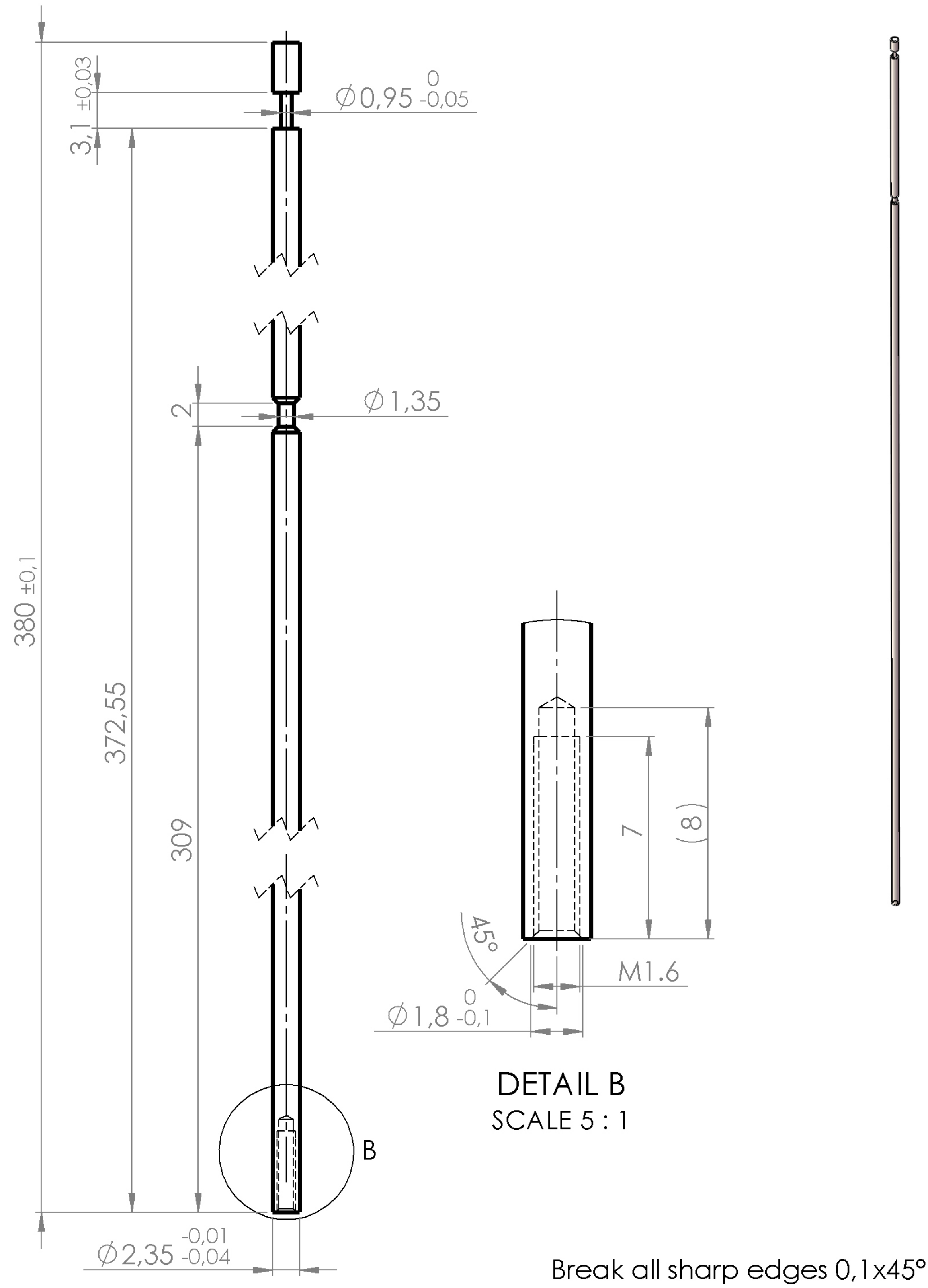


DETAIL B
SCALE 3 : 1

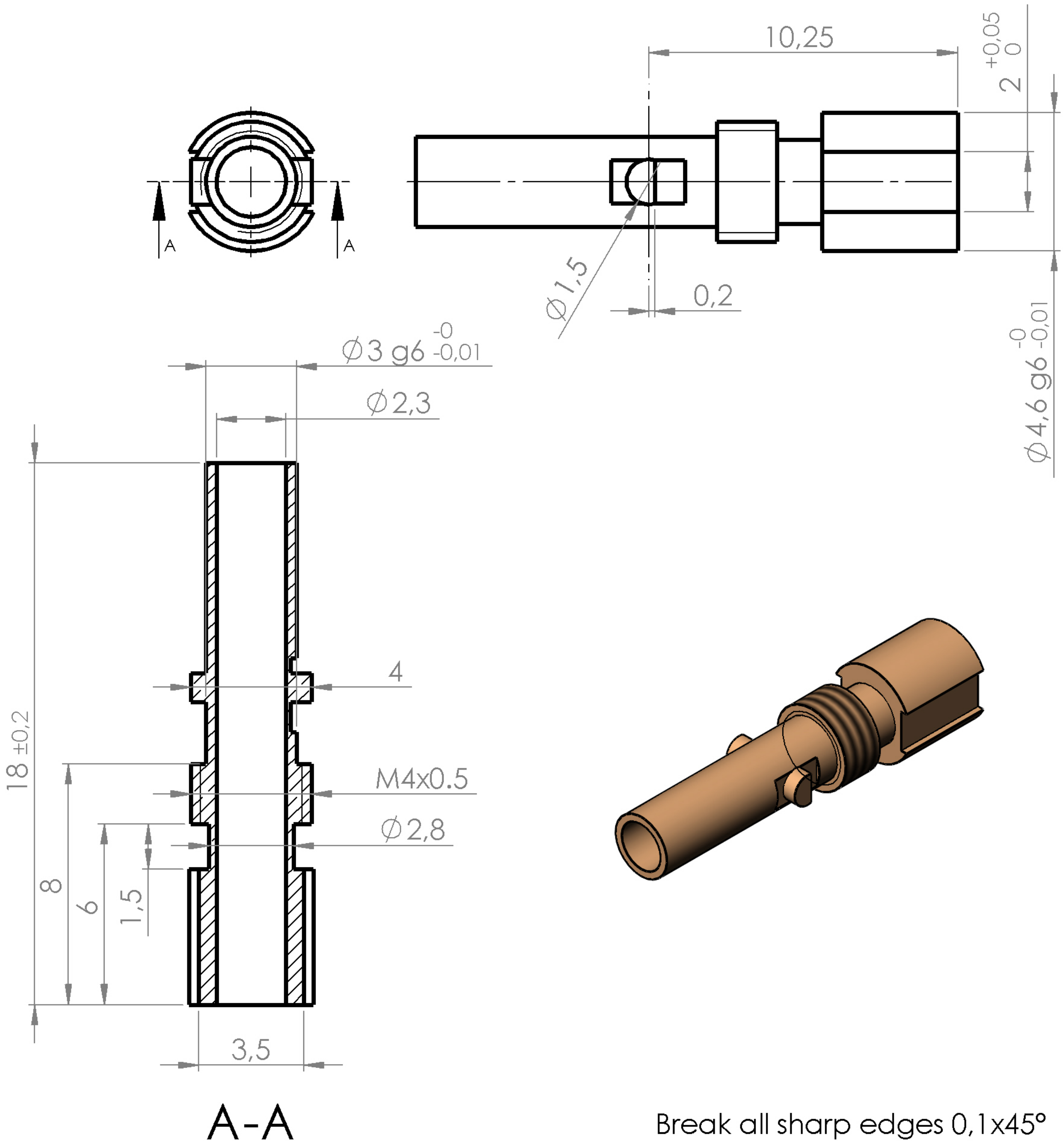


ITEM NO.	PART NUMBER	DESCRIPTION	QTY.	MATERIAL
1	MBG01-M01	Push Pull Rod	1	RVS 316 (1.4401)
2	MBG01-M02	Connection Fork	1	RVS 316 (1.4401)
3	MBG01-M03	Connection Rod	1	RVS 316 (1.4401)
4	MBG01-M04	Outer Shaft	1	RVS 304 (1.4301)
5	MBG01-M05	Tube Fork	1	RVS 316 (1.4401)
6	MBG01-M06	Outer Shaft Hub	1	RVS 316 (1.4401)
7	MBG01-M07	Magnet Mount	2	RVS 316 (1.4401)
8	MBG01-M09	Rod Magnet Mount	1	RVS 316 (1.4401)
9	MBG01-M12	Magnet Housing Retainer	1	RVS 316 (1.4401)
10	MBG01-M16	Rod Pin	1	RVS
11	MBG01-M18	Housing Retainer	1	POM-C
12	MBG01-M19	Compliant Grasper	1	Nitinol
13	MBG01-M20	Magnet Housing Connection	1	RVS 316 (1.4401)
14	MBG01-O02	Rod Magnet	2	RVS 304 (1.4301)
15	MBG01-O08	Ring Magnet	2	RVS 304 (1.4301)
16	MBG01-P10	Magnet Housing Back	1	POM-C
17	MBG01-P11	Handle Base	1	POM-C
18	MBG01-P13	Magnet Housing Mid	1	POM-C
19	MBG01-P14	Magnet Housing Front	1	POM-C
20	MBG01-P17	Rod Retainer	1	POM-C
21	MBG01-P21	Handle Base Cap	1	POM-C
22		Handle	1	
23			1	

Getekend	Jan-Willem Klok	Benaming	Full Assembly		
Controle	D. Kuznetsov				
Datum	22-10-2019	Project	Compliant Grasper		
Status	Vrijgegeven				
Materiaal		Eenheid	Schaal	Tekening nummer	Blad nr.
Aantal	1	mm	1:1	MBG01-S01	1 / 1
TU Delft DEMO			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002	Formaat A3
				Auteursrecht voorbehouden volgens de Wet	

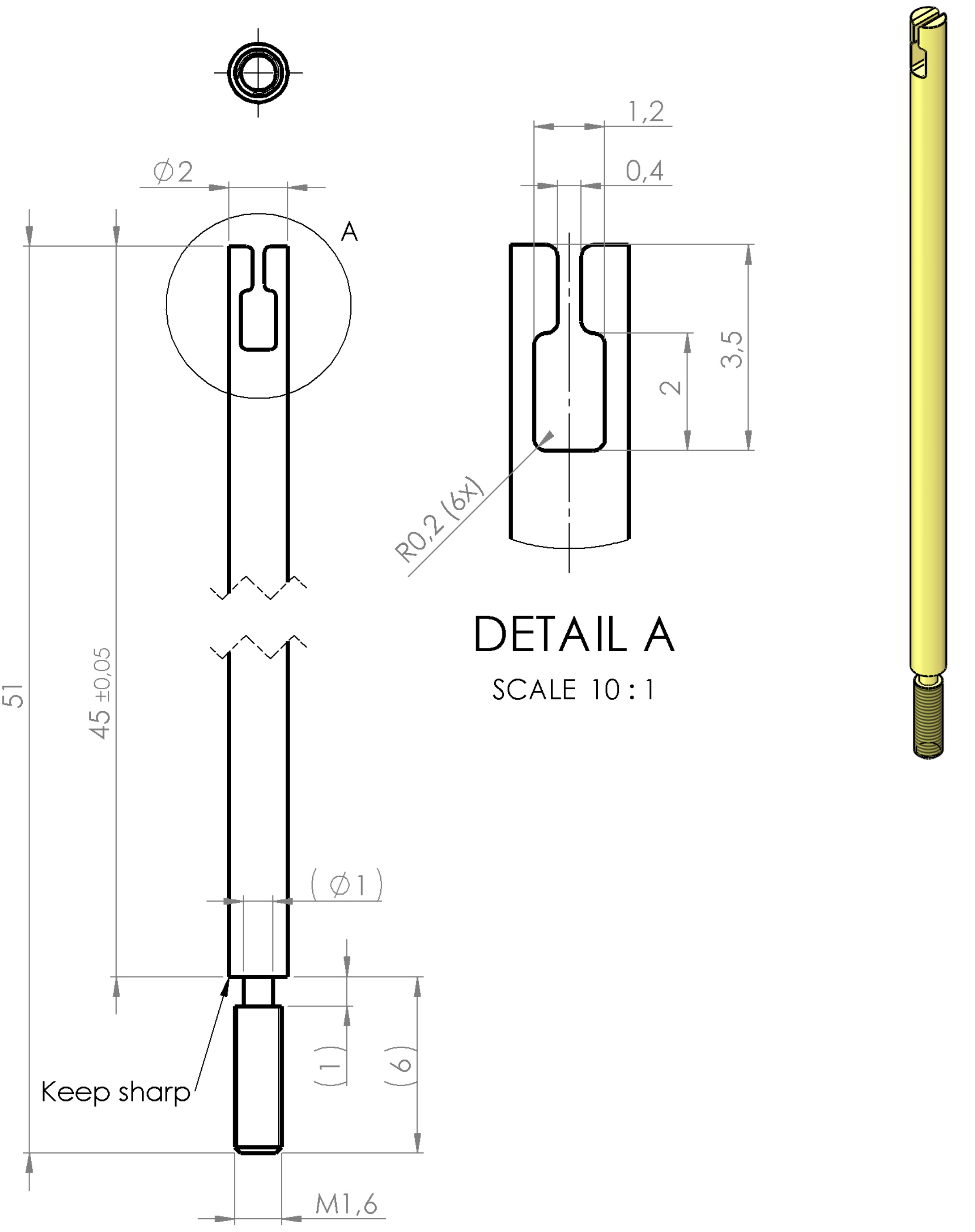


Getekend	Jan-Willem Klok	Benaming Push Pull Rod			
Controle	...				
Datum	21-6-2019	Project Compliant Grasper			
Status	Vrijgegeven				
Materiaal	RVS 316 (1.4401)	Eenheid mm	Schaal 2:1	Tekening nummer MBG01-M01	Blad nr. 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002 Auteursrecht voorbehouden volgens de Wet	Formaat A4



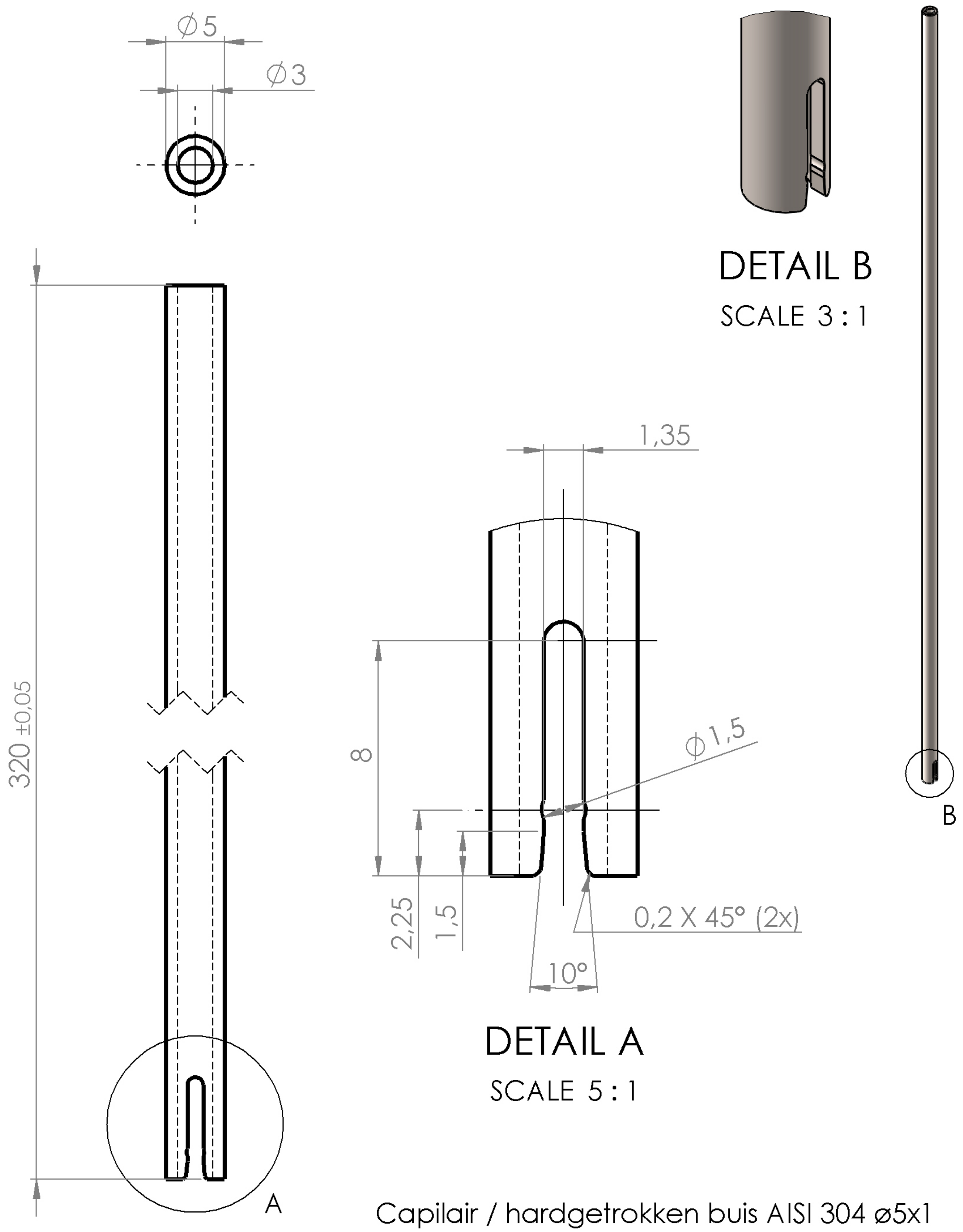
Break all sharp edges 0,1x45°

Getekend	Jan-Willem Klok	Benaming: Connection Fork			
Controle	...				
Datum	26-8-2019	Project: Compliant Grasper			
Status	Vrijgegeven				
Materiaal	RVS 316 (1.4401)	Eenheid: mm	Schaal: 5:1	Tekening nummer: MBG01-M02	Blad nr.: 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002 Auteursrecht voorbehouden volgens de Wet	Formaat: A4



Break all sharp edges 0,1x45°

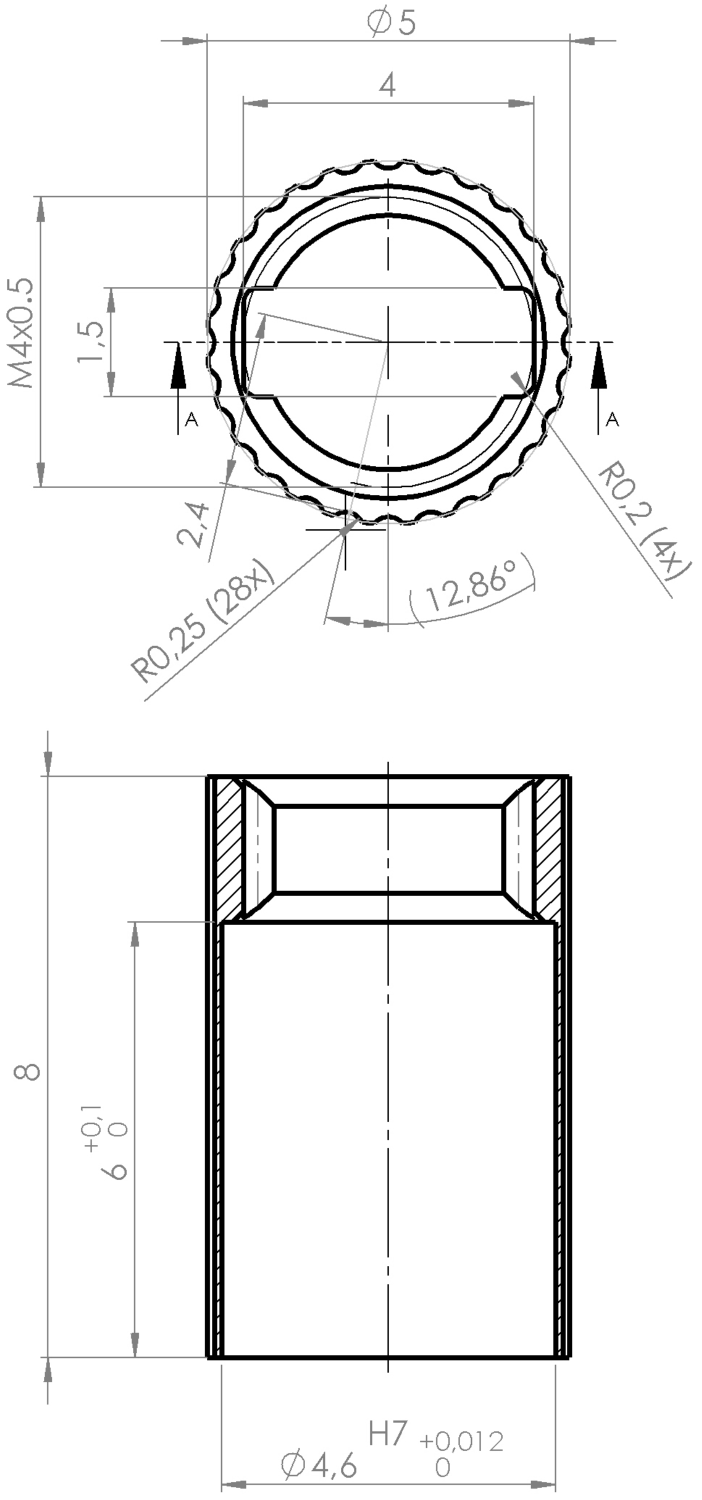
Getekend	Jan-Willem Klok	Benaming: Connection Rod			
Controle	...				
Datum	11-6-2019	Project: Compliant Grasper			
Status	Vrijgegeven				
Materiaal	RVS 316 (1.4401)	Eenheid: mm	Schaal: 5:1	Tekening nummer: MBG01-M03	Blad nr.: 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002	Formaat: A4



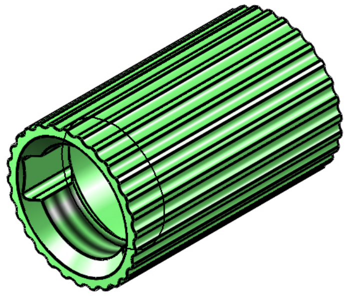
Capilair / hardgetrokken buis AISI 304 ø5x1

Alle scherpe hoeken breken 0,1x45°

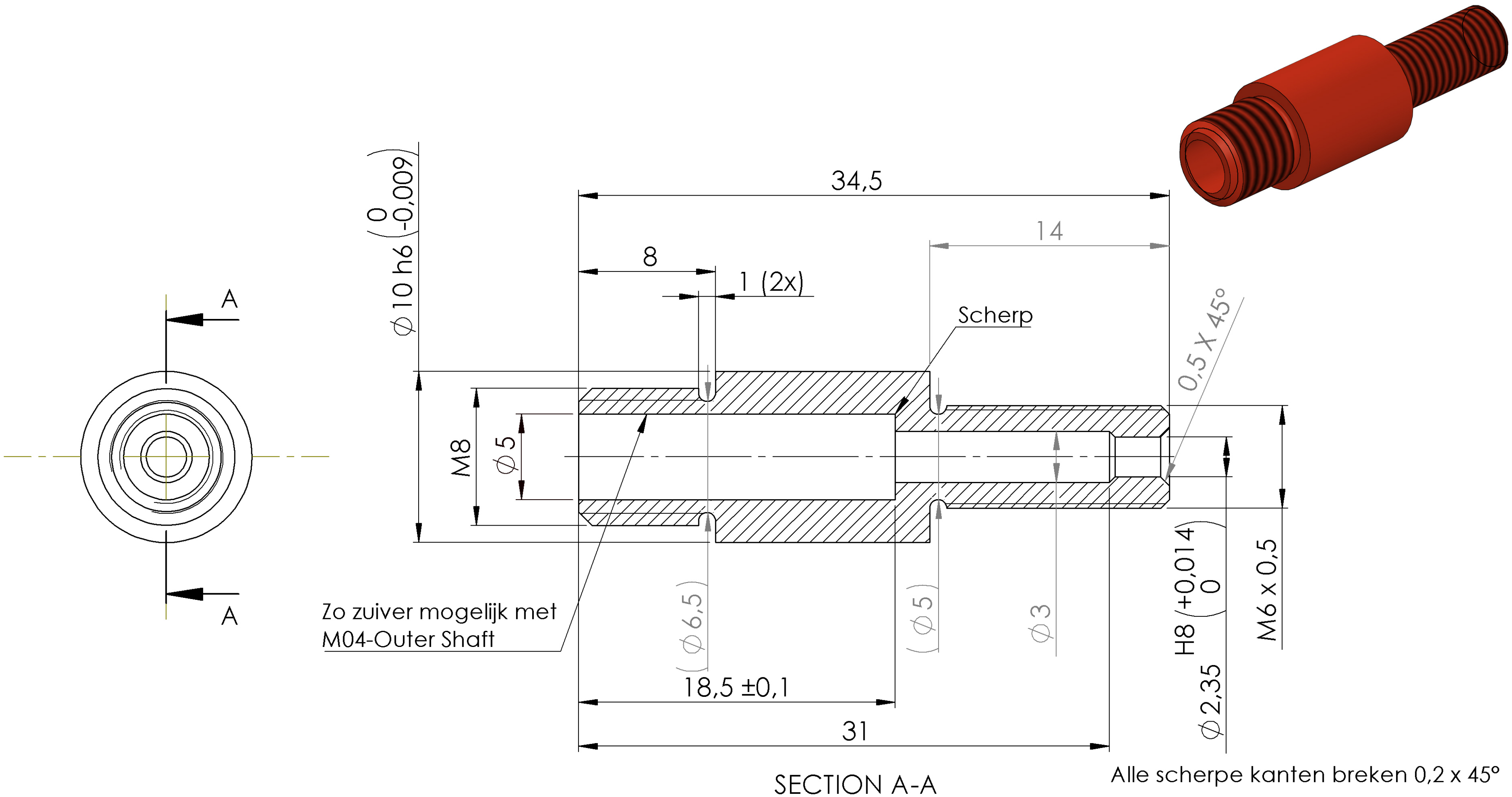
Getekend	Jan-Willem Klok	Benaming: Outer Shaft			
Controle	...				
Datum	11-6-2019	Project: Compliant Grasper			
Status	Vrijgegeven				
Materiaal	RVS 304 (1.4301)	Eenheid: mm	Schaal: 2:1	Tekening nummer: MBG01-M04	Blad nr.: 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- mH Ruwheden volgens NEN-EN-ISO 1302:2002	Formaat A4
				Auteursrecht voorbehouden volgens de Wet	



A-A

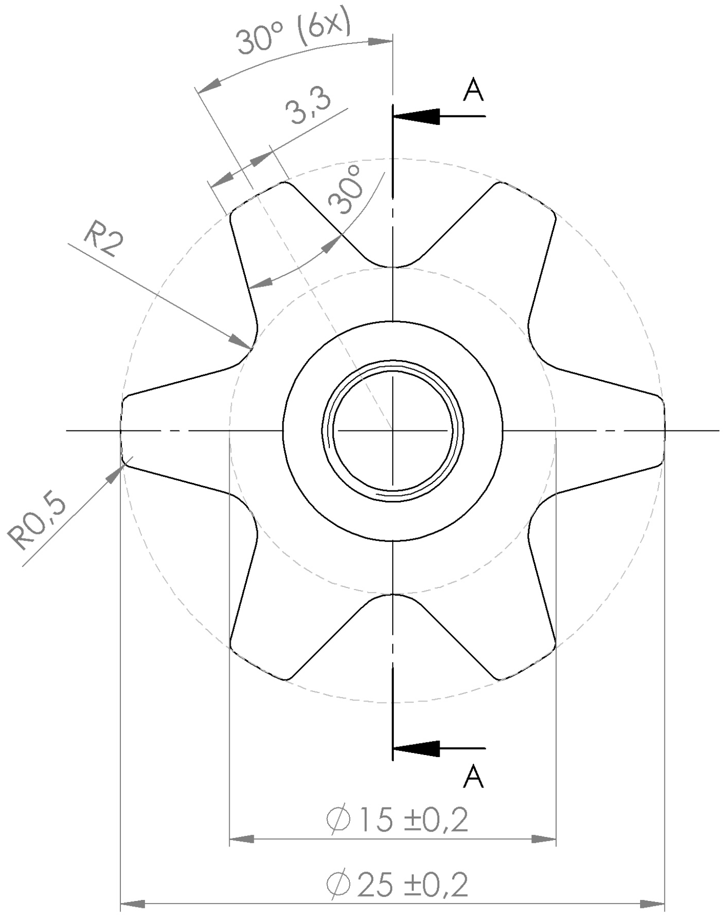


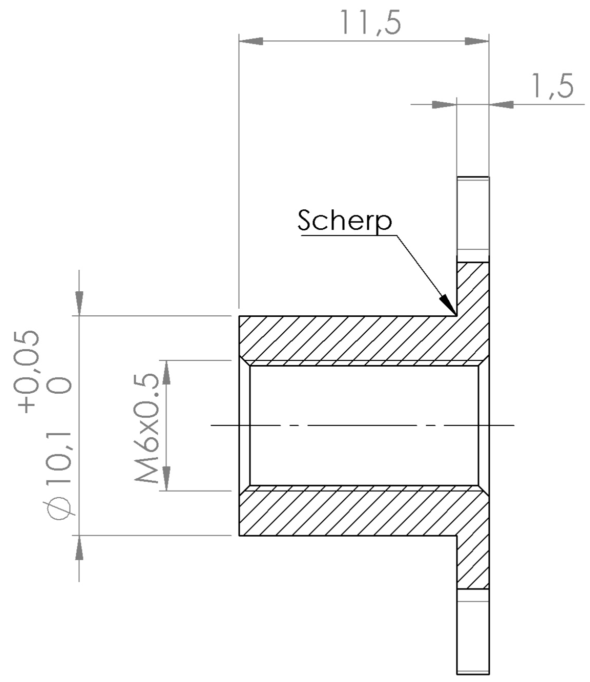
Getekend	Jan-Willem Klok	Benaming Tube Fork			
Controle	...				
Datum	11-6-2019	Project Compliant Grasper			
Status	Vrijgegeven				
Materiaal	RVS 316 (1.4401)	Eenheid mm	Schaal 10:1	Tekening nummer MBG01-M05	Blad nr. 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002 Auteursrecht voorbehouden volgens de Wet	Formaat A4



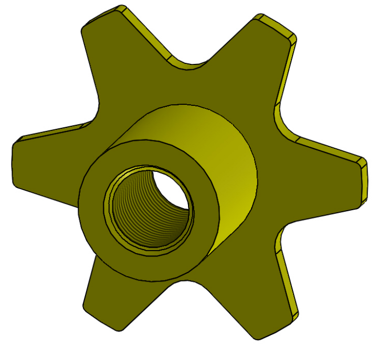
Alle scherpe kanten breken 0,2 x 45°

Getekend	Jan-Willem Klok	Benaming: Outer Shaft Hub			
Controle	D. Kuznetsov				
Datum	11-6-2019	Project: Compliant Grasper			
Status	Concept				
Materiaal	RVS 316 (1.4401)	Eenheid: mm	Schaal: 3:1	Tekening nummer: MBG01-M06	Blad nr.: 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002 Auteursrecht voorbehouden volgens de Wet	Formaat: A4



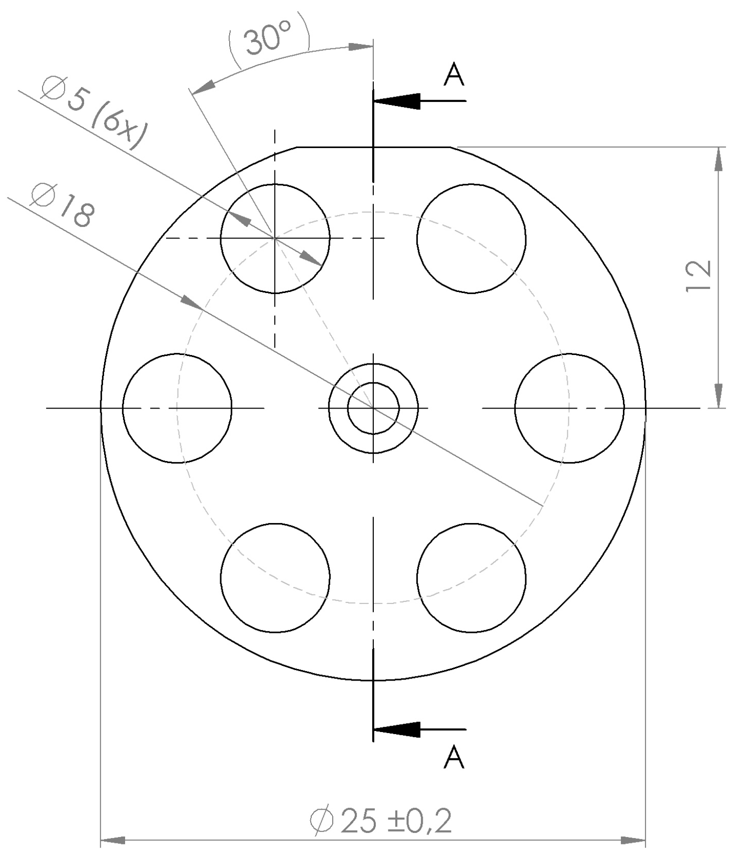


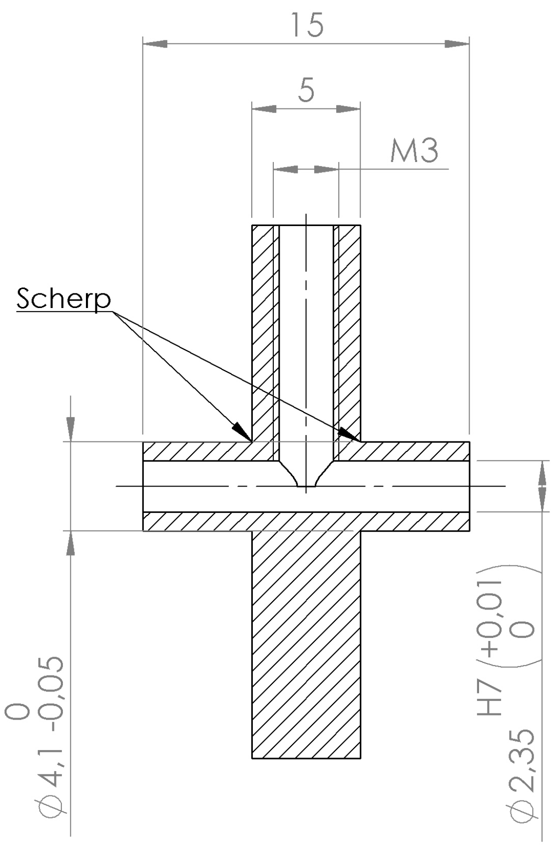
SECTION A-A



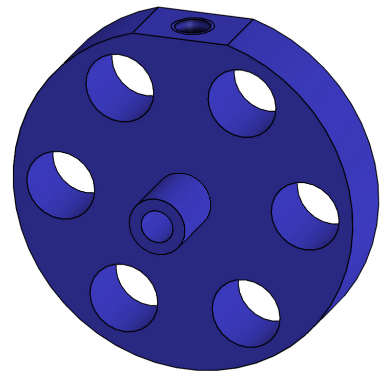
Alle scherpe kanten breken 0,2 x 45°

Getekend	Jan-Willem Klok	Benaming Magnet Mount			
Controle	D. Kuznetsov				
Datum	2-7-2019	Project Compliant Grasper			
Status	Concept				
Materiaal	RVS 316 (1.4401)	Eenheid mm	Schaal 3:1	Tekening nummer MBG01-M07	Blad nr. 1 / 1
Aantal	2				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002 Auteursrecht voorbehouden volgens de Wet	Formaat A4



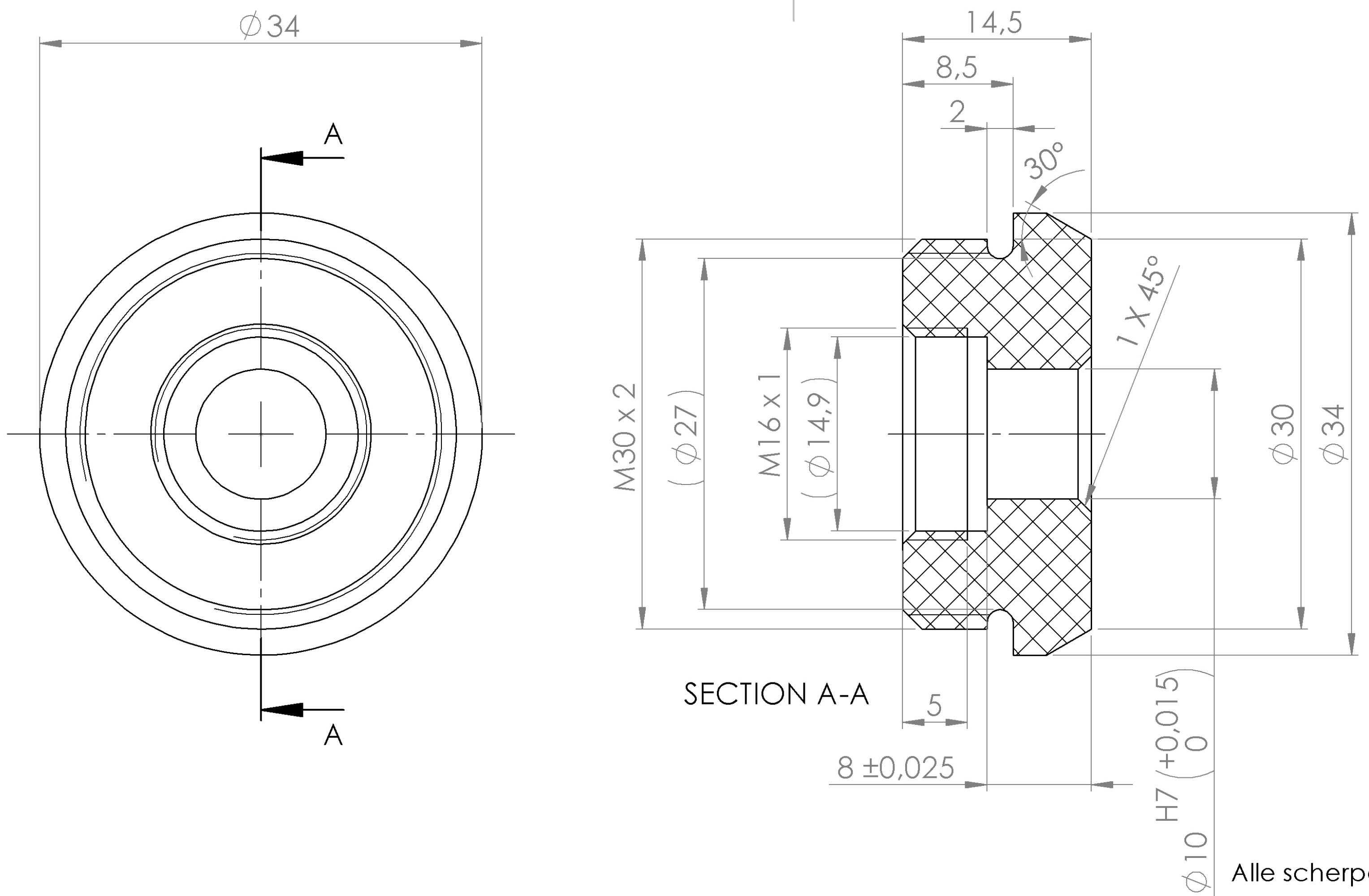


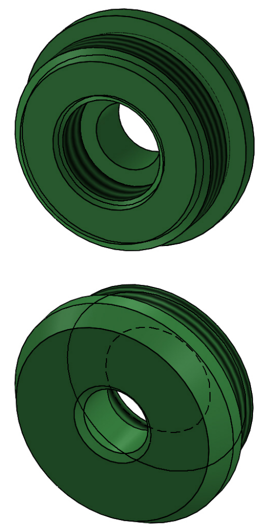
SECTION A-A



Alle scherpe kanten breken 0,2 x 45°

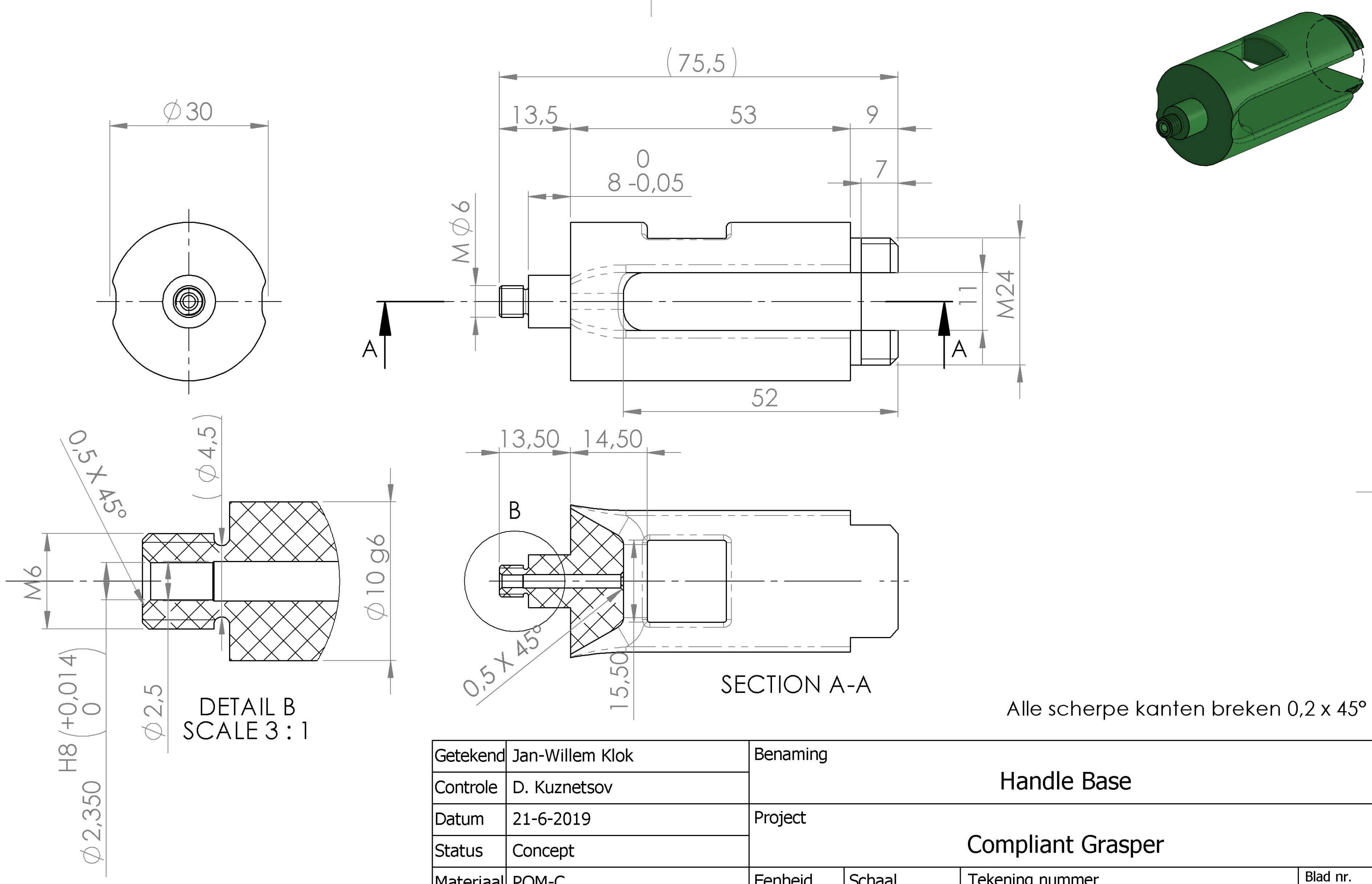
Getekend	Jan-Willem Klok	Benaming: Rod Magnet Mount			
Controle	D. Kuznetsov				
Datum	11-6-2019	Project: Compliant Grasper			
Status	Concept				
Materiaal	RVS 316 (1.4401)	Eenheid	Schaal	Tekening nummer	Blad nr.
Aantal	1	mm	3:1	MBG01-M09	1 / 1
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002	Formaat A4





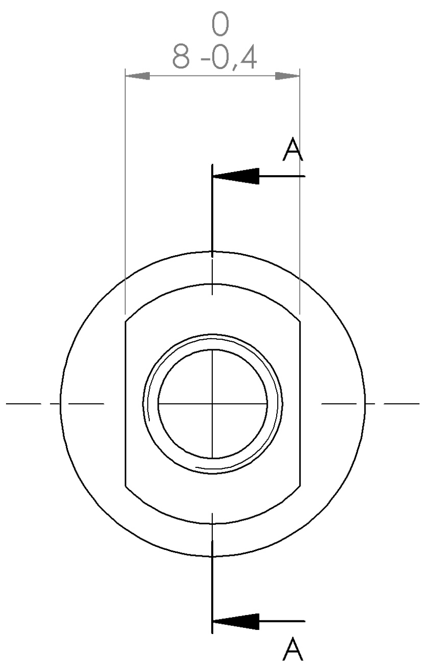
Alle scherpe kanten breken 0,2 x 45°

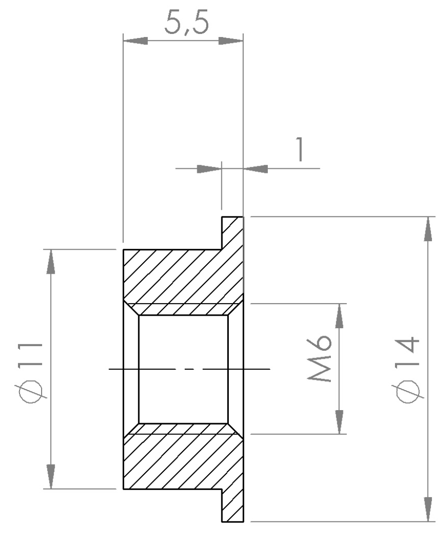
Getekend	Jan-Willem Klok	Benaming Magnet Housing Back			
Controle	D. Kuznetsov				
Datum	11-6-2019	Project Compliant Grasper			
Status	Concept				
Materiaal	POM-C	Eenheid mm	Schaal 2:1	Tekening nummer MBG01-P10	Blad nr. 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002 Auteursrecht voorbehouden volgens de Wet	Formaat A4



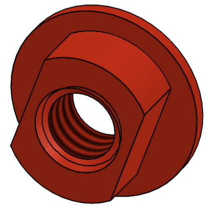
Alle scherpe kanten breken 0,2 x 45°

Getekend	Jan-Willem Klok	Benaming: Handle Base			
Controle	D. Kuznetsov				
Datum	21-6-2019	Project: Compliant Grasper			
Status	Concept				
Materiaal	POM-C	Eenheid	Schaal	Tekening nummer	Blad nr.
Aantal	1	mm	1:1	MBG01-P11	1 / 1
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002	Formaat A4
				Auteursrecht voorbehouden volgens de Wet	



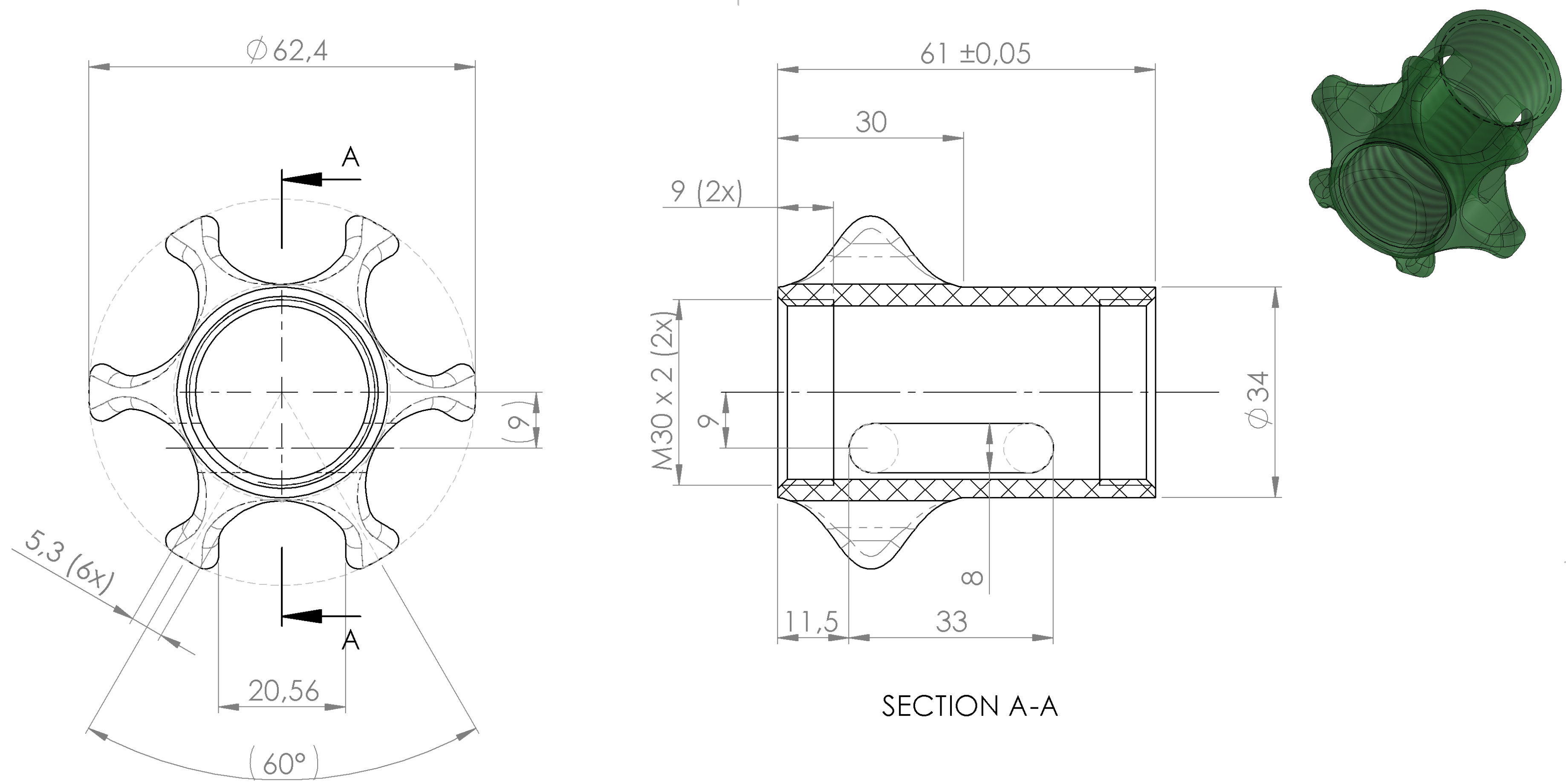


SECTION A-A



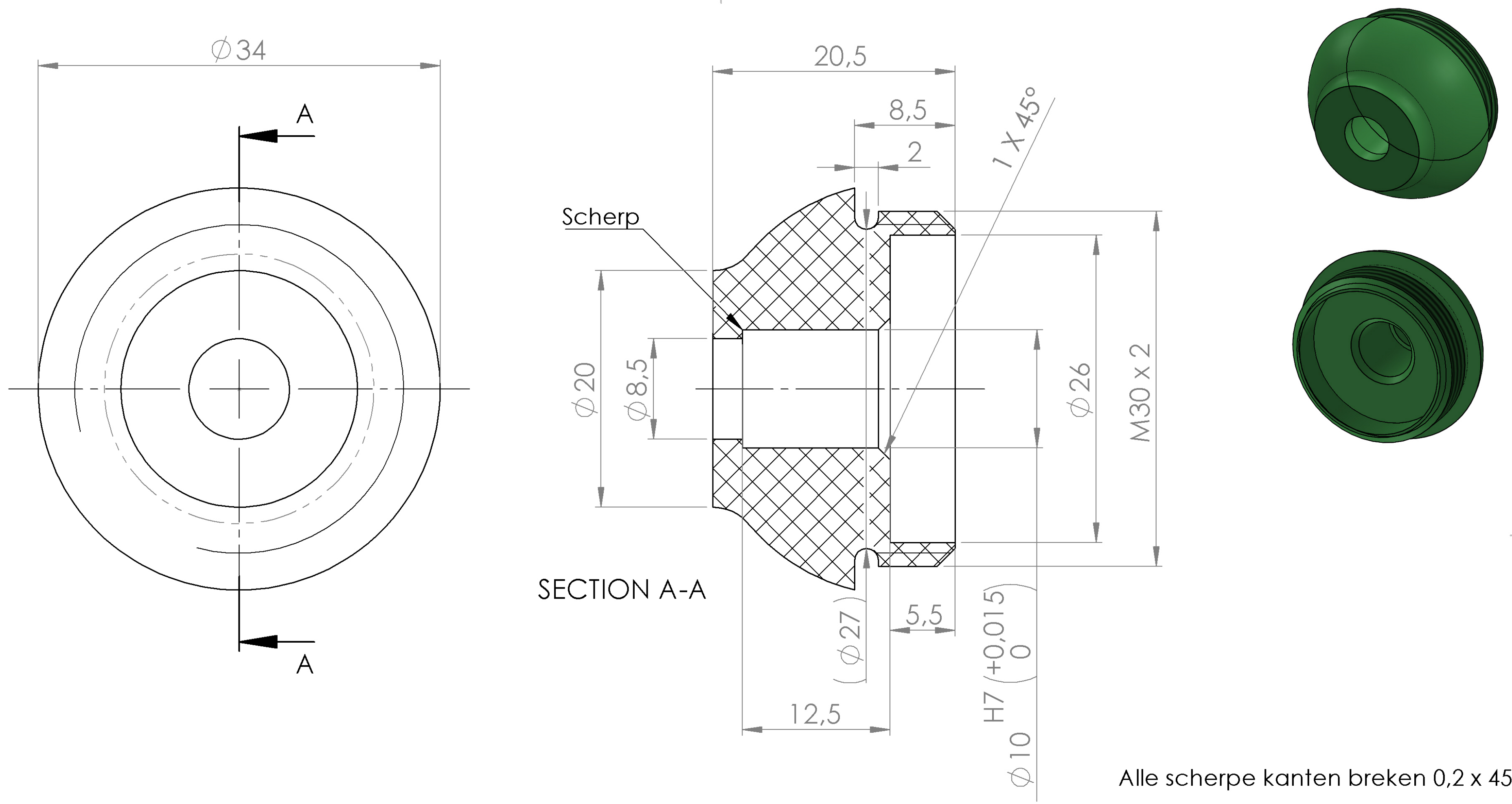
Alle scherpe kanten breken 0,2 x 45°

Getekend	Jan-Willem Klok	Benaming Magnet Housing Retainer			
Controle	D. Kuznetsov				
Datum	11-6-2019	Project Compliant Grasper			
Status	Concept				
Materiaal	RVS 316 (1.4401)	Eenheid mm	Schaal 3:1	Tekening nummer MBG01-M12	Blad nr. 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002 Auteursrecht voorbehouden volgens de Wet	Formaat A4



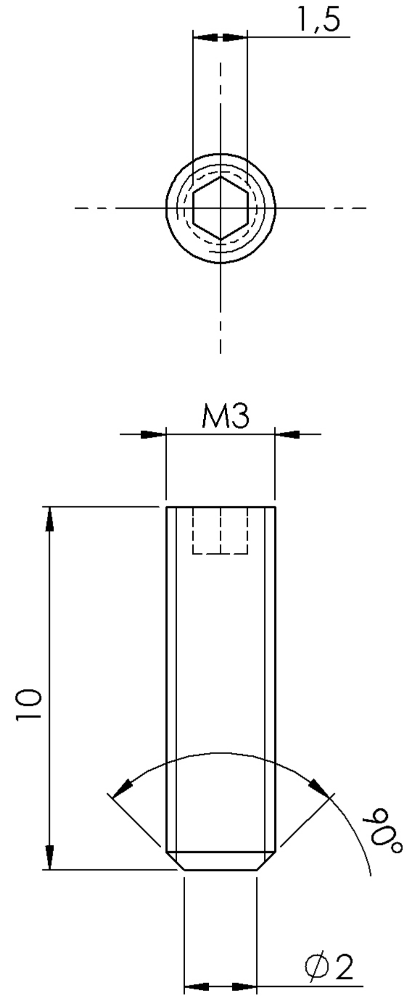
Alle scherpe kanten breken 0,2 x 45°

Getekend	Jan-Willem Klok	Benaming: Magnet Housing Mid			
Controle	D. Kuznetsov				
Datum	11-6-2019	Project: Compliant Grasper			
Status	Concept				
Materiaal	POM-C	Eenheid: mm	Schaal: 1:1	Tekening nummer: MBG01-P13	Blad nr.: 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002 Auteursrecht voorbehouden volgens de Wet	Formaat: A4



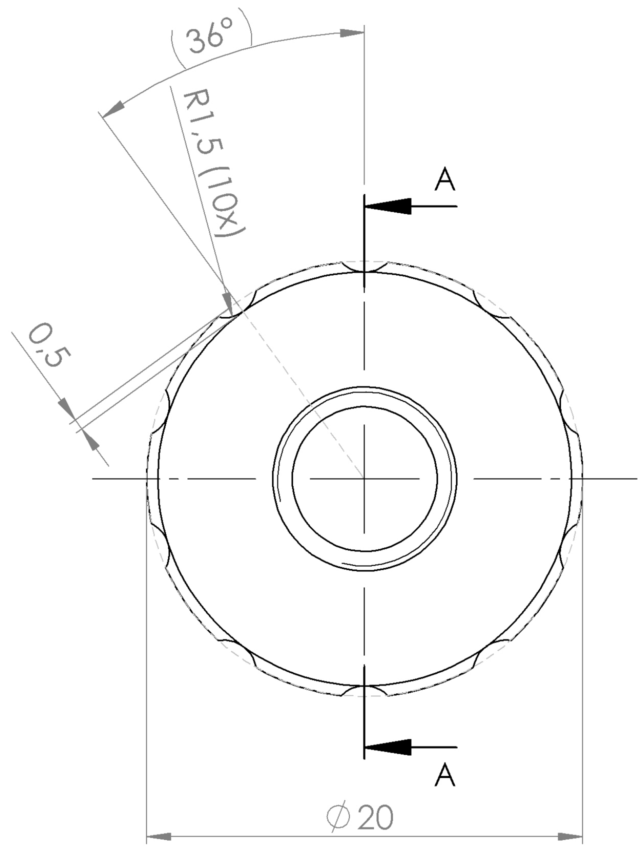
Alle scherpe kanten breken 0,2 x 45°

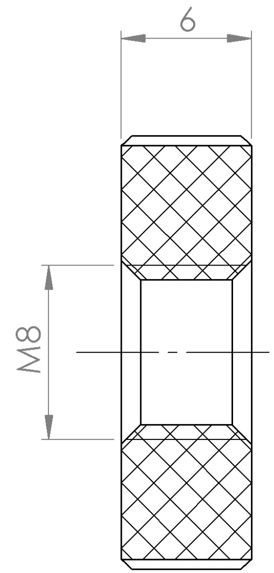
Getekend	Jan-Willem Klok	Benaming: Magnet Housing Front			
Controle	D. Kuznetsov				
Datum	11-6-2019	Project: Compliant Grasper			
Status	Concept				
Materiaal	POM-C	Eenheid	Schaal	Tekening nummer	Blad nr.
Aantal	1	mm	2:1	MBG01-P14	1 / 1
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002	Formaat A4
				Auteursrecht voorbehouden volgens de Wet	



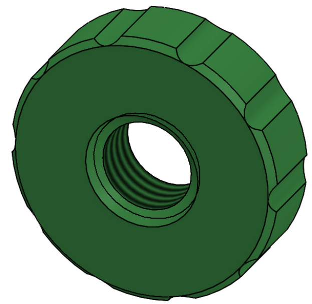
DIN913 M3x10
Stelschroef met binnenzeskant A2
(Fabory nr. 51240.030.010)

Getekend	Jan-Willem Klok	Benaming: Rod Pin			
Controle	D. Kuznetsov				
Datum	11-6-2019	Project: Compliant Grasper			
Status	Vrijgegeven				
Materiaal	RVS	Eenheid: mm	Schaal: 5:1	Tekening nummer: MBG01-M16	Blad nr.: 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768-Ruwheden volgens NEN-EN-ISO 1302:2002	Formaat A4



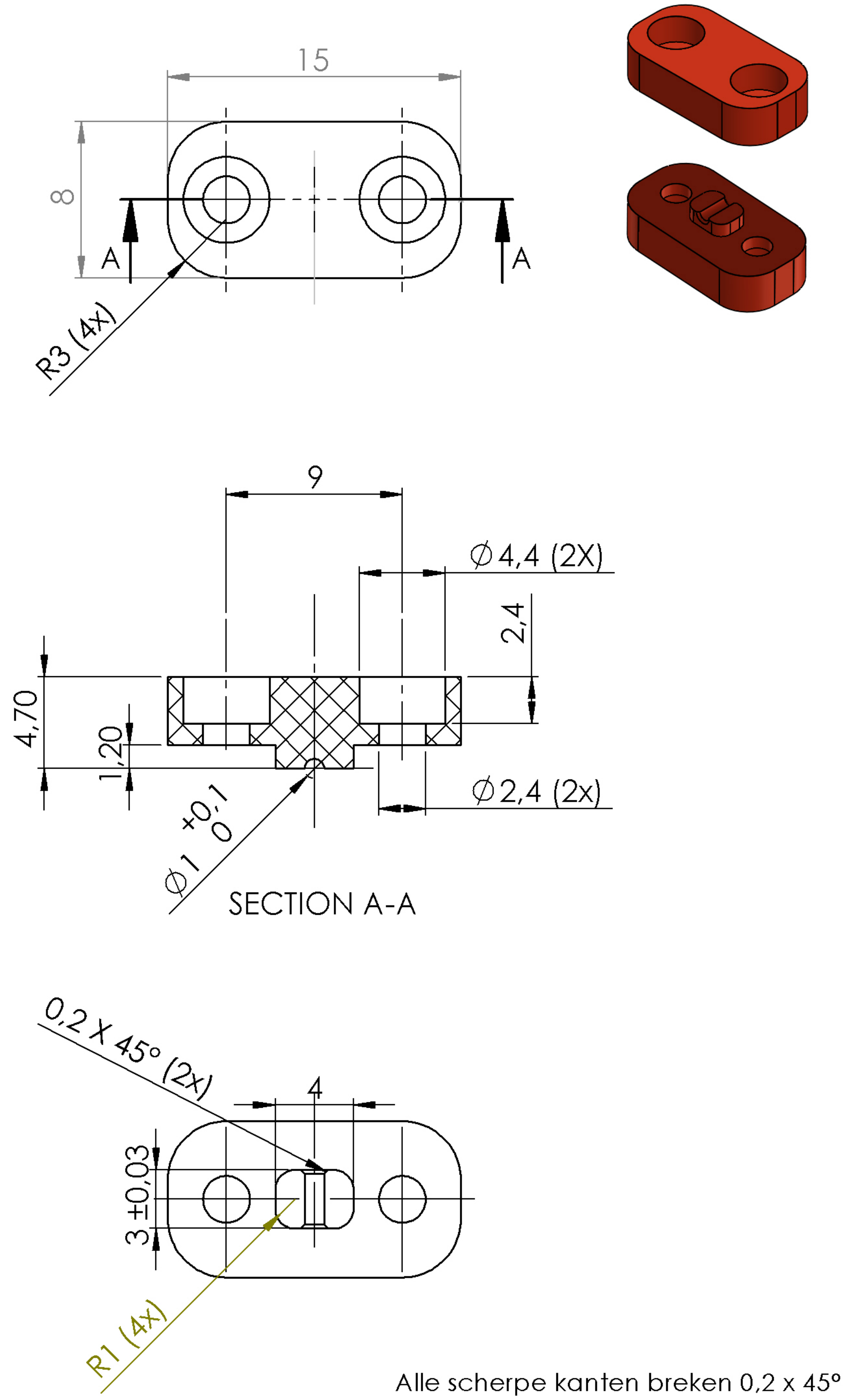


SECTION A-A



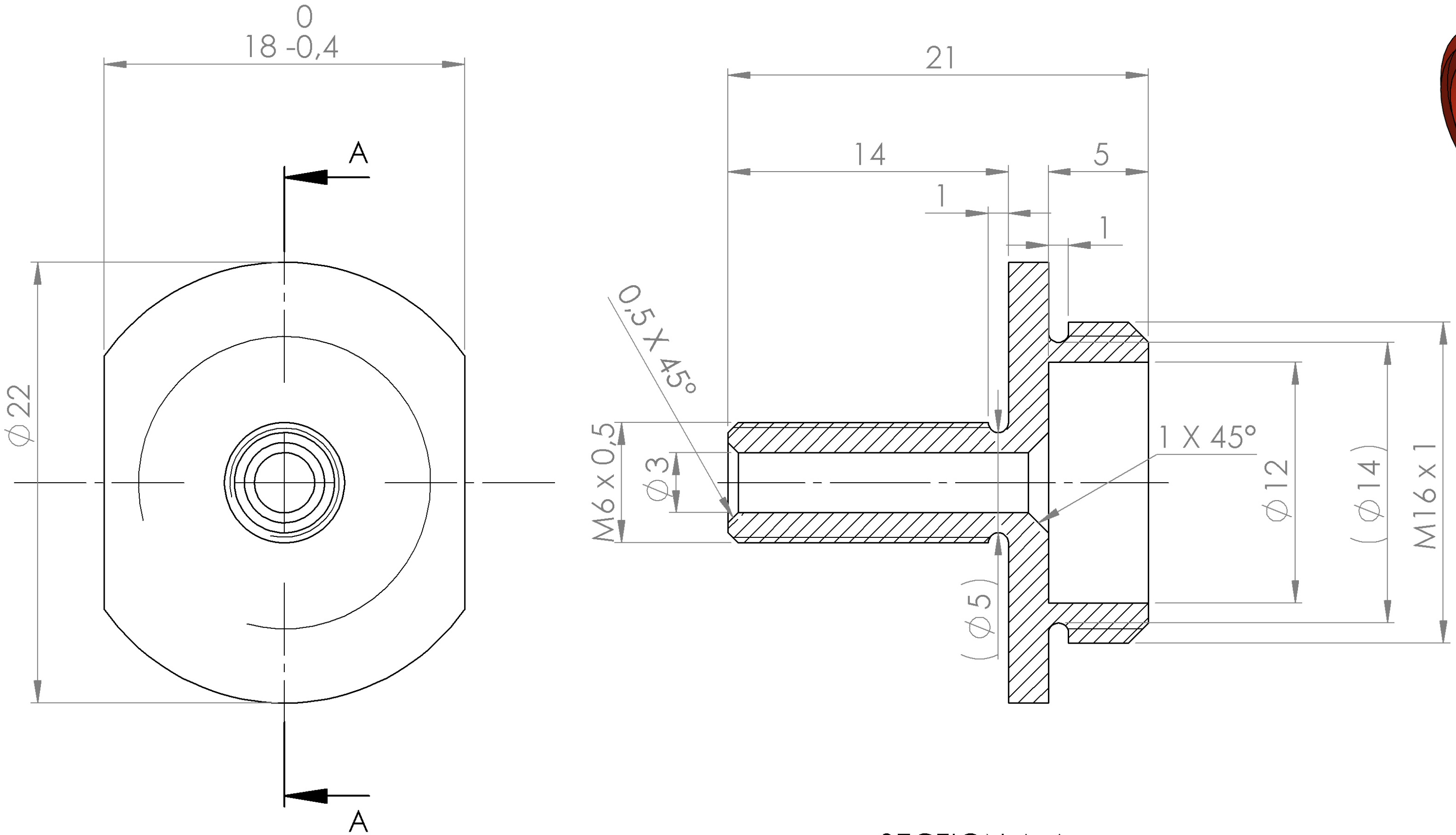
Alle scherpe kanten breken 0,2 x 45°

Getekend	Jan-Willem Klok	Benaming: Housing Retainer			
Controle	D. Kuznetsov				
Datum	11-6-2019	Project: Compliant Grasper			
Status	Concept				
Materiaal	POM-C	Eenheid: mm	Schaal: 3:1	Tekening nummer: MBG01-M18	Blad nr.: 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002 Auteursrecht voorbehouden volgens de Wet	Formaat: A4

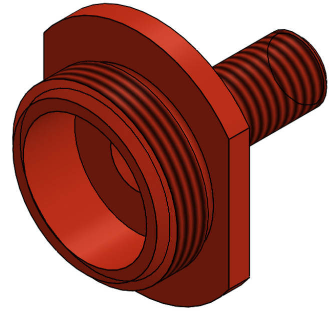


Alle scherpe kanten breken 0,2 x 45°

Getekend	Jan-Willem Klok	Benaming Rod Retainer			
Controle	D. Kuznetsov				
Datum	21-6-2019	Project Compliant Grasper			
Status	Concept				
Materiaal	POM-C	Eenheid mm	Schaal 3:1	Tekening nummer MBG01-P17	Blad nr. 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002 Auteursrecht voorbehouden volgens de Wet	Formaat A4

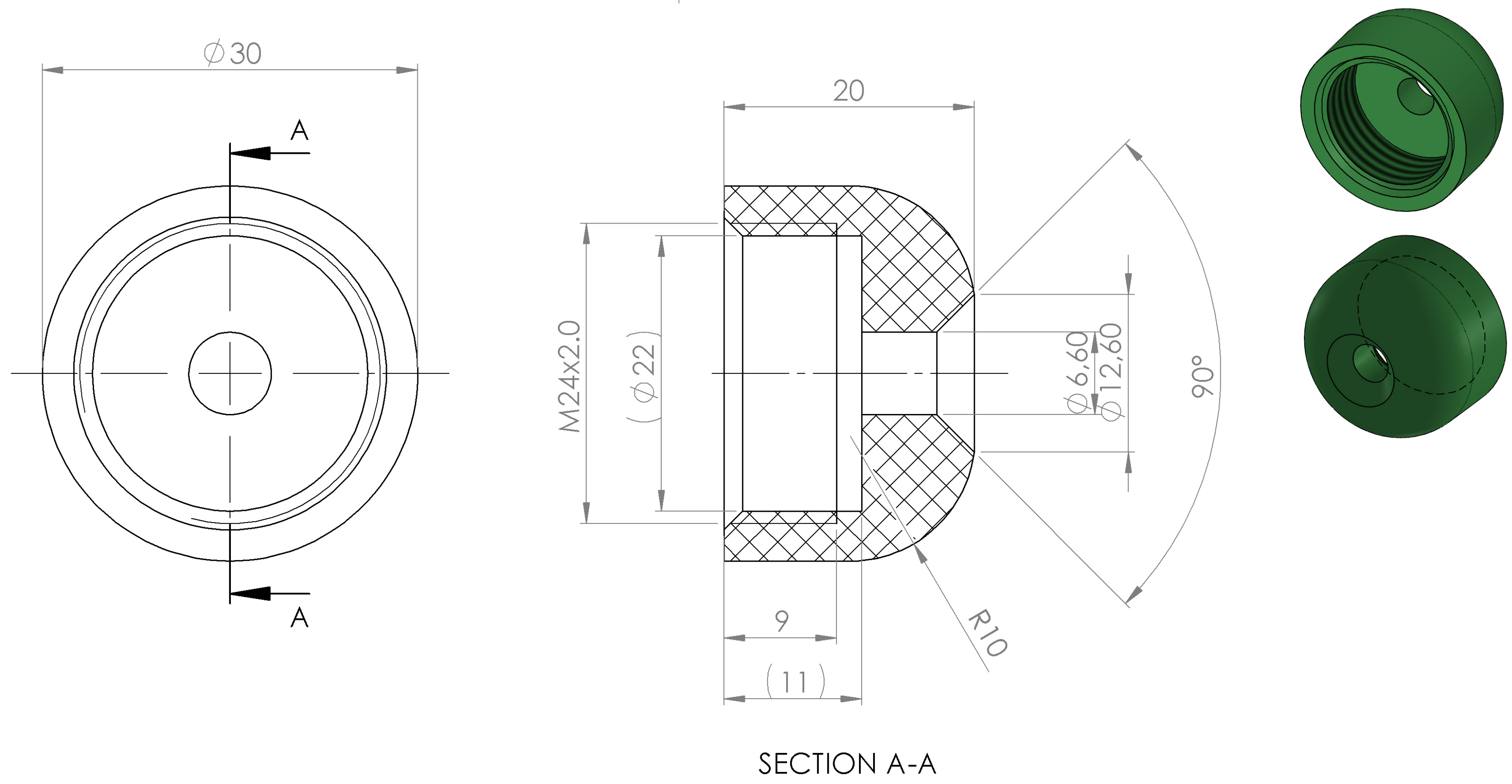


SECTION A-A



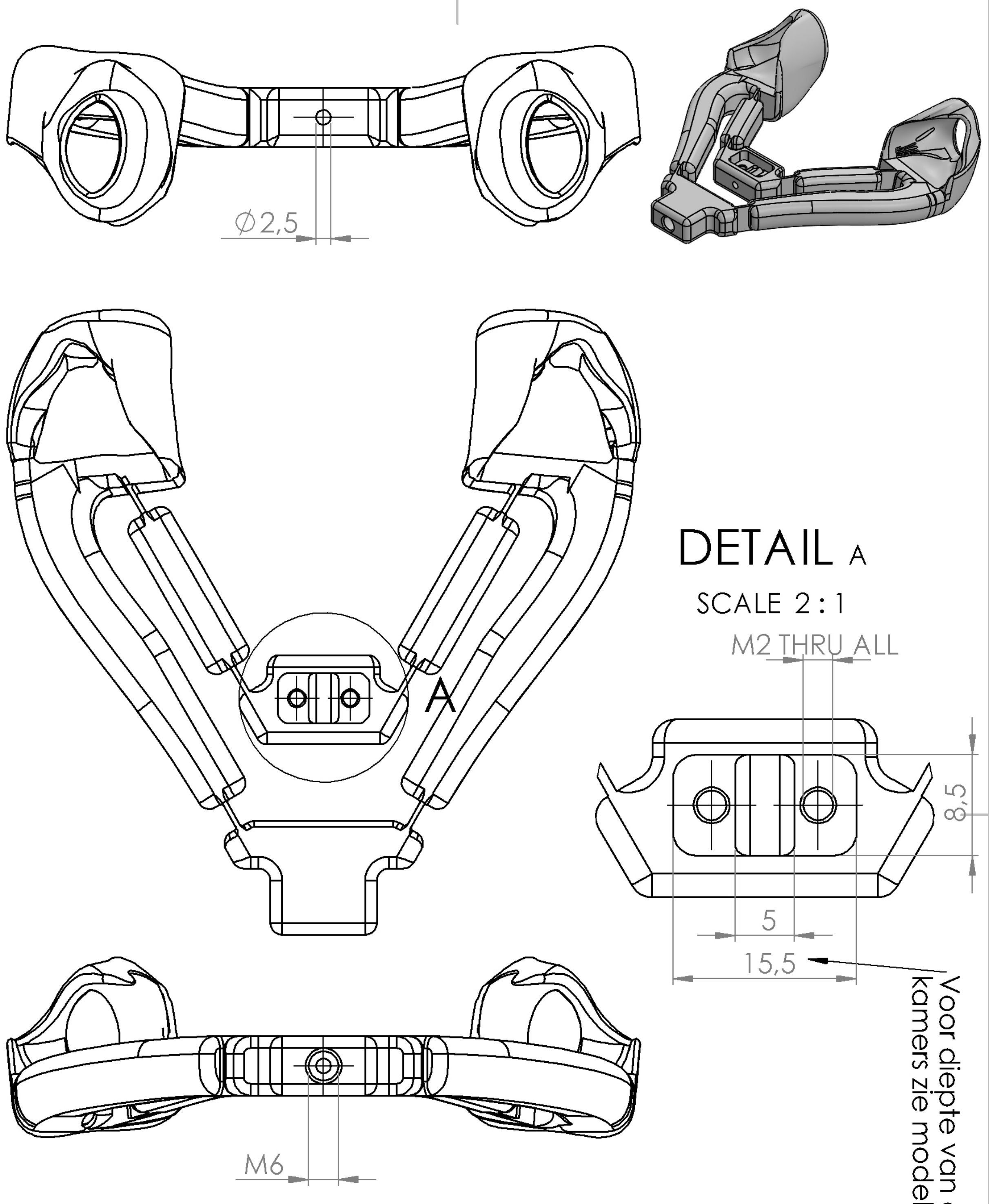
Alle scherpe kanten breken 0,2 x 45°

Getekend	Jan-Willem Klok	Benaming Magnet Housing Connection			
Controle	D. Kuznetsov				
Datum	2-7-2019	Project Compliant Grasper			
Status	Concept				
Materiaal	RVS 316 (1.4401)	Eenheid mm	Schaal 3:1	Tekening nummer MBG01-M20	Blad nr. 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002 Auteursrecht voorbehouden volgens de Wet	Formaat A4



Alle scherpe kanten breken 0,2 x 45°

Getekend	Jan-Willem Klok	Benaming Handle Base Cap			
Controle	D. Kuznetsov				
Datum	11-6-2019	Project Compliant Grasper			
Status	Concept				
Materiaal	POM-C	Eenheid mm	Schaal 2:1	Tekening nummer MBG01-P21	Blad nr. 1 / 1
Aantal	1				
TU Delft DEMO www.demo.tudelft.nl			Ra 3,2 Alle vlakken tenzij anders vermeld	Toleranties volgens NEN-EN-ISO 1101:2013 en NEN-ISO 2768- fH Ruwheden volgens NEN-EN-ISO 1302:2002 Auteursrecht voorbehouden volgens de Wet	Formaat A4



Te printen in Formlabs, materiaal: Engineering Resins: Tough

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:	FINISH:		DEBURR AND BREAK SHARP EDGES	DO NOT SCALE DRAWING	REVISION	
	NAME	SIGNATURE	DATE	TITLE:		
DRAWN						
CHK'D						
APPV'D						
MFG						
Q.A			MATERIAL:	DWG NO. MBG01-S03-CompliantHandle	A4	
			WEIGHT:	SCALE:1:1	SHEET 1 OF 1	

C

Balancing mechanism magnet specifications

supermagnete

Technisch specificatieblad artikel R-25-04-05-N

Technische specificaties en gebruiksveiligheid

Webcraft GmbH
Industriepark 206
78244 Gottmadingen, Duitsland

Telefoon: +49 7731 939 839 1

www.supermagnete.nl
support@supermagnete.nl

1. Technische specificaties

Artikel-ID	R-25-04-05-N
EAN	7640155436861
Materiaal	NdFeB
Vorm	Ring
Buitenste diameter	25 mm
Binnendiameter	4,2 mm
Hoogte	5 mm
Tolerantie	+/- 0,1 mm
Magnetiseringsrichting	axiaal (parallel aan hoogte)
Coating	Vernikkeld (Ni-Cu-Ni)
Productiewijze	gesinterd
Magnetisering	N45
Houdkracht	ca. 9,4 kg (ca. 92,2 N)
Max. gebruikstemperatuur	80°C
Gewicht	18,1267 gr
Curietemperatuur	310 °C
Remanentie Br	13200-13700 G, 1.32-1.37 T
Coërcitieve veldsterkte bHc	10.8-12.5 kOe, 860-995 kA/m
Coërcitieve veldsterkte iHc	≥12 kOe, ≥955 kA/m
Energieproduct (BxH)max	43-45 MGOe, 342-358 kJ/m³

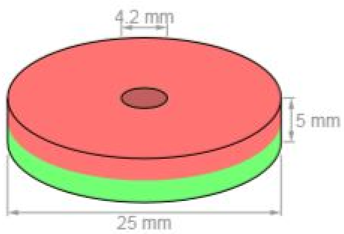


Figure C.1: Push pull rod magnet specification sheet.

Extra informatie

Gewicht	30 g
Afmetingen	10 mm
Model	Ring
Materiaal	Vernikkeld (Ni-Cu-Ni)
Houdkracht (kg)	15
Magnetisering	N50
Magnetiseringsrichting	Axiaal
Maximale gebruikstemperatuur	80
Diameter 1	25
Diameter 2	10
Hoogte 1	10
Volume	4123

Figure C.2: Housing magnet specification sheet.

D

Injection moulding quotation

The prototyping company P3D has an interesting production technique that combines the low costs of complex 3D printed shapes with the series production possibilities of injection molding. A mould is 3D printed, in which the liquid polymer of the end product is cast. This is a relatively low cost option for first series prototype production. However, for the first prototype phase this is too early, because the handle design is still subject to significant changes, requiring a new mould every time. An quotation was requested nonetheless:

PRIM-mould: €1850,-
Starting costs: € 109,-
Unit price for a series of 50 units: € 10,62
Delivery time: 1 week

E

Consent form

11-9-19

Jan-Willem Klok
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0620899101

Experiment information

Sensitivity validation of balanced compliant grasper

Background

Laparoscopic surgery has a lot of benefits for patients undergoing surgery: less pain, shorter recovery time and hospital stay, and less visible scars compared to conventional (open) surgery.

However, for the surgeon, laparoscopic surgery is not so beneficial, as he or she has a limited working space (the inflated abdominal cavity). Also haptic feedback and other information about the tissue characteristics is very limited and is (besides visual feedback) only served to the surgeon through the laparoscopic instruments.

Study goal
In the MISIT lab a new laparoscopic *compliant grasper* has been developed, aiming to improve haptic feedback by implementing a hysteresis-free design. This study will validate the sensitivity to force differences of the compliant grasper compared to traditional laparoscopic graspers.

Guidelines for the participant
Before the experiment starts, the participant is allowed to inspect and try out the instrument.

The participant is asked to hold the instrument handle, using their dominant hand, squeezing the handle hard enough to keep the handle in the same position. The instrument is also clamped in a test setup, in a way that the instrument tip is not visible.

When the participant is ready, the experimenter will apply an increasing force to the instrument tip. This force will not be perceivable by the participant at the start. However, as soon as the participant feels the haptic feedback of this this force in the handle, he or she should notify the experimenter. The experiment will end at this point, and will be redone with the remaining instruments.

11-9-19

Jan-Willem Klok
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0620899101

Consent Form for validation of balanced compliant grasper

Please tick the appropriate boxes	**Yes**	**No**
Taking part in the study		
I have read and understood the study information dated 11-9-2019, or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	O	O
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.	O	O
I understand that taking part in the study involves holding the instrument while weights are being added to the grasper, and reporting when this can be perceived by the participant at the instrument's handle.	O	O
Use of the information in the study		
I understand that information I provide will be used for a graduation report and scientific publications.	O	O
I understand that personal information collected about me that can identify me, such as [e.g. my name], will not be shared beyond the study team.	O	O
I agree that my information can be quoted in research outputs.	O	O
Future use and reuse of the information by others		
I give permission for the data retrieved from this experiment and answers to the questionnaire that I provide to be archived so it can be used for future research and learning.	O	O

Signatures

____________________ ____________________ ________

Name of participant [printed] Signature Date

11-9-19

Jan-Willem Klok
jan-willem.klok@hotmail.com
0620899101

Personal details, results and questionnaire answers

Participant #:	
Sex:	Male/Female
Age:	
Sensitivity threshold (grams):	
Conventional (Unnamed):	
Conventional (Aesculap):	
Balanced:	

1. Which type of handle did you find more comfortable to hold? The handle of the…
   - O ...conventional grasper.
   - O ...balanced grasper.

2. If you have any suggestions that might improve the design of the balanced grasper (grasper tip or handle), please state them below:

………

………

………