The design, production and validation of a force limiting mechanism in a laparoscopic instrument

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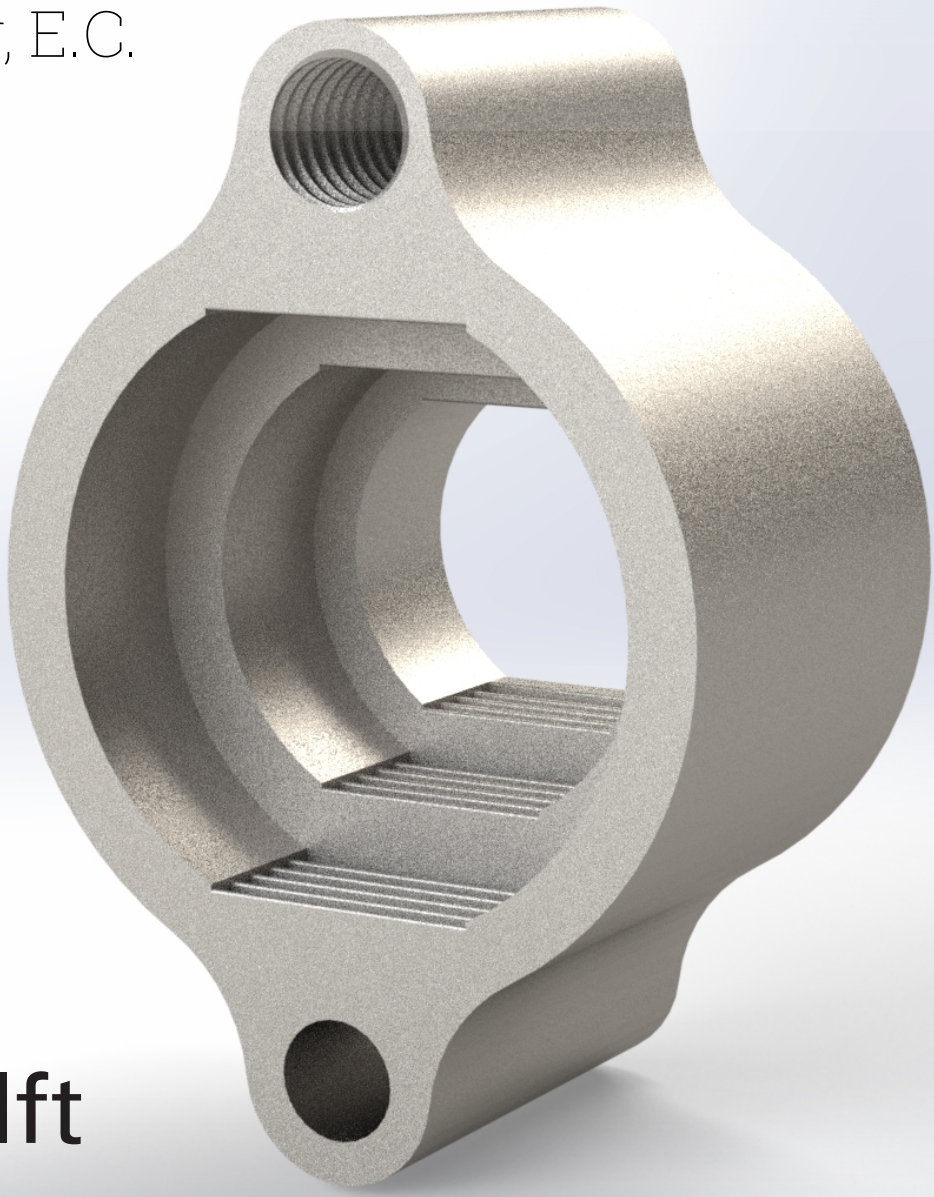

TU Delft

The design, production and validation of a force limiting mechanism in a laparoscopic instrument

by

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TU Delft

PREFACE

In November 2021, I worked in the communication department of the faculty of Mechanical, Maritime and Materials Engineering at TU Delft. As part of my responsibilities, I conducted interviews with students and faculty members to learn about the various aspects of the faculty. As a result, I connected with Ir. Ing. J.W.A. Klok, who worked on improving medical devices within the Minimally Invasive Surgery and Interventional Techniques laboratory (MISIT lab). As someone who had maintained an interest in the medical aspects of Mechanical Engineering during my Mechanical Engineering bachelor's degree, I chose Biomechanical Design as my master's degree. Therefore, the projects that Ir. Ing. J.W.A. Klok was working on immediately took my attention. Following my expression of interest in the project, he suggested a master project that involved the implementation of a force limiting mechanism in a laparoscopic instrument. I chose this project because it had a mechanical engineering focus and also involved medical aspects, which interested me. I enjoyed completing my master's thesis, despite facing some obstacles along the way. Nonetheless, I am proud of the end results I achieved.

I would like to express my gratitude to my supervisors, Dr. Ir. Ing. T. Horeman and Ir. Ing. J.W.A. Klok, for their invaluable guidance, feedback, and suggestions throughout my master's thesis. Additionally, I found my regular meetings with Ir. Ing. J.W.A. Klok particularly beneficial as he provided me with technical and motivational support, allowing me to feel comfortable discussing any challenges or problems I faced during the thesis, which made me more confident in my work.

In addition, I would like to express my gratitude to D.T. de Nijs, R. van Antwerpen, and S.P. van Veldhoven from Inloop Werkplaats Medewerkers (IWM) for their contribution to the development of the components in my design. I am particularly grateful to D.T. de Nijs and R. van Antwerpen not only for their professional assistance but also for the friendship we formed during my master's thesis. Furthermore, I would like to extend my gratitude to L. Roessen and M. Pelle from Dienst Elektronische en Mechanische Ontwikkeling (DEMO) and K.A. Kamman from Reactor Institute Delft (RID) for their invaluable assistance with the two most complex components of my design.

I would also like to express my appreciation to Jacques Brenkman for his assistance with the electronics involved in my validation process. Despite my limited knowledge in this area, Jacques was very helpful in getting me started. Given that he had just begun working at the faculty, I am certain that he will be an asset to both students and staff. Besides that, I would thank Dr. G.P. van der Schelling for giving me the chance to watch a laparoscopic surgery live and elaborate my knowledge further from a different perspective.

Throughout this project, I collaborated with Yannick Smits. I am really grateful about all the good collaboration we had with each other and the friendship we have now. He helped me to stay motivated and to see certain problems from a different perspective.

Lastly, I would like to express my gratitude to my fellow students, Pim Schrijvershof and Anna Graell Collado, as well as my friends and family. Additionally, I want to give a special thanks to my significant other, Martin van der Schelling, for his support throughout my master's thesis. His encouragement and belief in me were invaluable, especially during moments when I lacked confidence in myself.

The way to get started is to quit talking and begin doing. - Walt Disney

Eva Schlösser, Delft, June 2023

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***Abstract*— Laparoscopic surgery uses small incisions and a camera for abdominal or pelvic operations, with benefits such as shorter recovery time and hospital stay. However, reduced surgeon hand-eye coordination and feedback can lead to excessive applied force and potential tissue damage. Haptic and visual feedback systems have been developed for laparoscopic surgery, and their benefits for various laparoscopic tasks have been demonstrated. Although force feedback systems have been extensively studied, there is a dearth of research on force limiting mechanisms in laparoscopic surgery. Nonetheless, incorporating force limiting mechanisms could help prevent complications caused by excessive applied force by the user. This paper presents the design, production and validation of a force limiting mechanism in a laparoscopic instrument, to prevent tissue damage due to excessive applied force by the surgeon. A design method was conducted, which comprised a functional analysis and a design process. Subsequently, a force limiting mechanism was designed and manufactured using various techniques. To validate the mechanical performance, the force in the forceps F_{pinch} and the force in the rod F_{rod} of the laparoscopic instrument were measured. This was carried out under three conditions with the force limiting mechanism set at 10 N, 20 N, and 40 N for F_{pinch}. To validate pre-clinical performance, twenty novices performed a crossover study. Participants performed a basic laparoscopic task by grasping a Floral foam object under two conditions: with and without the force limiting mechanism. The relative depth and the slippages of the Floral foam object was computed after each trial. The mechanical validation results showed that for the instrument with the force limiting mechanism, F_{pinch} remained constant at 0.5 N and 2.0 N, while F_{rod} increased. The pre-clinical validation revealed a significant difference in relative depth between the two instruments. The laparoscopic instrument with the force limiting mechanism was superior compared to the laparoscopic instrument without the force limiting mechanism ($p<0.001$), as less force was transferred by the force limiting mechanism. Additionally, no difference was found between the two instruments in slippages (p=0.068). It can be concluded that a force limiting mechanism in a laparoscopic instrument has been successfully designed and validated and can prevent tissue damage by blocking the excessive applied force by the surgeon. However, further improvement is required to overcome limitations in the design. Moreover, the design has to be tested in various (pre-)clinical settings in order to improve the validity and reliability of the design. Additionally, implementing the force limiting mechanism in robotic surgery should also be considered.**

***Keywords*—** Laparoscopy, Laparoscopic surgery, Laparoscopic instrument, Force, Limit, Mechanism

1. Introduction

Healthcare plays a significant role for the quality of living. Hence, technology is always progressing and new tools and techniques are constantly developed with goal to reduce the invasiveness of surgeries. One such example is a laparoscopic surgery, which is an operation performed in the abdomen or pelvis using only small incisions with the aid of a camera. A laparoscopic surgery offers many advantages over a conventional open surgery, including smaller incisions, resulting in decreased hospital stay, cost and recovery time for the patient [1], [2]. In addition, many procedures are now accomplished with laparoscopic surgery that traditionally were performed in a conventional open surgery [1], [2]. However, certain risks and complications may arise from laparoscopic surgery due to reduced hand-eye coordination, depth perception and haptic feedback available for the surgeon. This can lead to excessive applied force by the surgeon on the laparoscopic instrument, potentially causing damage to tissue, such as perforation or puncturing [3]. In order to reduce risks and complications, haptic and visual feedback systems have been developed for laparoscopic surgery. Multiple studies have demonstrated the benefits of visual force feedback for various laparoscopic tasks. These studies have revealed a reduction in the maximum applied force by the user when visual force feedback was utilized [4]–[9]. Similarly, studies have also shown that tactile force feedback provides benefits for different laparoscopic tasks, resulting in a decrease in force parameters when tactile force feedback was present [10]–[12]. Furthermore, the combination of both visual and haptic feedback has been found to reduce force parameters during laparoscopic surgery [13]. Although force feedback systems have been extensively studied, only a few articles have focused on force limiting mechanisms. Alleblas et al. developed a force reflecting operation instrument (FROI) that incorporates a mechanical brake, which activates when the surgeon applies maximum force on the instrument [14]. Implementing force limiting mechanisms in addition to force feedback could help prevent complications resulting from excessive applied force by the user. Moreover, a mechanical brake could prevent tissue damage by blocking the applied force when the surgeon is unaware of the feedback being given.

Designing such a mechanism poses several challenges, including creating a mechanical break in the required dimensions and implementing the design in clinical use, as the applied force that causes tissue damage varies. Therefore, the objective of this paper is:

The design, production and validation of a force limiting mechanism in a laparoscopic instrument, to prevent tissue damage due to excessive applied force by the surgeon.

This paper will provide an in-depth analysis of the steps taken in order to answer the objective of this paper and elaborates further on the studies of T. Horeman et al. [15] and R. Miedema [16]. The next Chapter 2 elaborates on the background of the laparoscopic instrument, focusing on its design and force transmissions. Chapter

3 describes the design method that was used, including a functional analysis, a design progress, an elaboration and the mechanical and pre-clinical validation of the design. Chapter 4 provides results from the mechanical and pre-clinical validations. Chapter 5 contains a discussion and recommendations for further research. The last Chapter 6 will give the conclusion of the paper. Finally, the acknowledgments, references and the appendices are presented.

2. Background

Figures 1 and 2 illustrate a laparoscopic instrument, consisting of a shaft (labeled as 1), a rod (labeled as 2), a handle (labeled as 3), and forceps (labeled as 4). When the surgeon closes the handle, the forceps close and grasp the tissue, exerting a pinching force on the tissue. Different factors influence the allowable pinching force which causes complications to tissues [17]–[24]. On main factor is the design of the closing mechanism of the forceps of the laparoscopic instrument. Designs with both a parallel closing mechanism and a scissor-like closing mechanism exist within laparoscopic surgery [17]–[21]. In contrast with a parallel closing mechanism, a scissor-like closing mechanism shows a non-homogeneous pressure distribution, which means that the proximal part of the hinge receives higher stresses than the distal part. Therefore, the allowable pinching force is dependent on the point of contact on the forceps [19]. There are several other factors that affect the allowable pinching force, including the the duration of grasping and the type of tissue [18]–[20]. Surgeons are advised to avoid exerting excessive pressure on the tissue and prolonging the grasping time, as such actions can increase the risk of complications on tissues. For instance, the allowable pinching force for a 60-second grasp can be 22 N, whereas for a 30-second grasp, it can be 46 N [18]. Furthermore, the material properties and thickness of tissues in the body differ, as the pressure distribution decreases when the material hardness increases [19], [20]. This results in a difference in allowable pinching force per tissue. Another main factor is the design of the surfaces of the forceps. The forceps of the laparoscopic instrument have to exert a pinching force which is not too high to cause complications, but is high enough to prevent slipping. However, the surfaces designs of forceps vary and therefore the allowable pinching force also varies [17], [22]–[24]. Forceps can have flat, hemispherical, or fenestrated surfaces. A flat surface can exert an allowable pinching force of 40 N, while a surface with hemispheres or fenestrations can exert a lower pinching force of 20 N and 5 N, respectively [17]. Hence, the range of allowable pinching force varies from 5 N to 40 N.

Fig. 1. A laparoscopic instrument which is used during laparoscopic surgery.

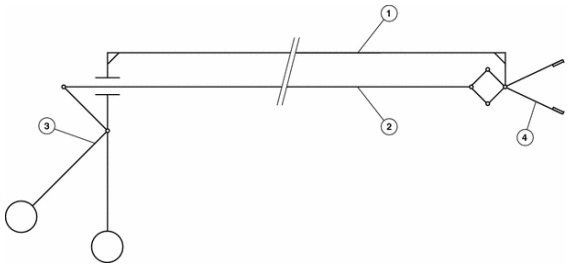


Fig. 2. Schematic representation of a laparoscopic instrument. (1) shaft, (2) rod, (3) handle, (4) forceps [25].

Also the way the forces are transferred from the surgeon towards the forceps of the laparoscopic instrument play an important factor. A laparoscopic instrument has two main force transmissions: One between the handle and the rod, and one between the rod and the forceps. This paper will focus on the transmission between the rod and the forceps. The transmission between the forceps and rod for a laparoscopic instrument is seen in equation 1. Here, F_{pinch} is the pinching force exerted by the forceps of the laparoscopic instrument, F_{rod} the force in the rod of the laparoscopic instrument and the force transmission coefficient λ, which is dependent on the angle α of the forceps as is seen in equation 2, assuming a scissor-like closing mechanism of the laparoscopic instrument [25].

$$F_{\mathrm{pinch}} = 0.5\lambda F_{\mathrm{rod}} \tag{1}$$

$$\lambda = 0.015\alpha + 0.296 \tag{2}$$

This paper elaborates on the paper of R. Miedema [16]. In this paper a component called the Shaftlock is designed. The Shaftlock is a compliant element and is implemented between the rod and the handle of the laparoscopic instrument and undergoes a displacement proportional to the magnitude of F_{rod}. The transmission ratio between F_{rod} and the displacements of the Shaftlock are discussed more elaborately in the paper of R. Miedema and in Appendix A. Combining equation 1 and 2, and the results of the paper of Miedema, it is possible to design a force limiting mechanism that can be implemented in a laparoscopic instrument.

3. Design method

3.1 Functional analysis

The first step of the design method is the functional analysis. Consisting of four functional requirements that the design has to fulfill in order to obtain the objective for this paper. In addition, to ensure the overall quality of the design, four performance criteria have also been established.

3.1.1 Functional requirements:

- *The force limiting mechanism should block the pinching force in the forceps of the laparoscopic instrument at 10 N, 20 N and 40 N.*
  Blocking the pinching force in the forceps at 10 N, 20 N and 40 N through the force limiting mechanism allows to prevent tissue damage. The three different force levels are selected to consider the difference in allowable pinching force during laparoscopic surgery as was elaborated in Chapter 2 [17]–[24].
- *The force limiting mechanism should be adjustable by the user.*
  By adjusting the force levels of the force limiting mechanism during surgery, clinical performance has the potential to be improved. This is due to the fact that laparoscopic surgery involves grasping various types of tissues with different properties, hence the allowable pinching force varies [17]–[24].
- *The force limiting mechanism should be detachable from the laparoscopic instrument.*
  Detaching the force limiting mechanism will allow the laparoscopic instrument to function also as a laparoscopic instrument without Shaftlock or force limiting mechanism.
- *The force limiting mechanism should be maintained and reused.*
  The Central Sterilization Department (CSD) is responsible for processing, sterilizing, and quality-controlling all sterile supplies and equipment used on patient care units. Thus, the force limiting mechanism must withstand CSD's sterilization and disinfection techniques.

3.1.2 Performance criteria:

- *The force limiting mechanism should be low in weight.* The weight should be as less than 130 g in order to provide the surgeon with optimal ergonomics and not lower the functionality and freedom of movement of the whole instrument. The laparoscopic instrument weighs 120 g.
- *The force limiting mechanism should be low in dimensions.* The outer dimensions of the force limiting mechanism should be less than 45 mm in order to provide the surgeon with optimal ergonomics, stability and visibility.
- *The force limiting mechanism should be reusable.* The force limiting mechanism should be reusable for every trial of the pre-clinical experiment in ensure the durability of the design and for consistency in all measurements.
- *The force limiting mechanism should be safe for users.* The force limiting mechanism must be approved by the Human Research Ethics Committee (HREC) at the Technical University of Delft before testing can begin. The HREC examines all the potential risks that may arise during testing, such as participant discomfort, and evaluates how the risk are mitigated.

3.2 Morphological scheme

To design a force limiting mechanism in a laparoscopic instrument, a morphological scheme has been created for the first three functional requirements. The scheme illustrates various potential solutions aimed at satisfying these requirements and is seen in Figure 3.

The first functional requirement contains that the force limiting mechanism should block the pinching force in the forceps of the laparoscopic instrument, meaning that the pinching force F_{pinch} in the forceps of the laparoscopic has to remain constant with increasing F_{rod}. In Appendix A it is elaborated that when F_{pinch} has a value of 10 N, 20 N and 40 N, the corresponding values of F_{rod} are 18 N, 35 N and 70 N respectively for a 20 degree angle of one forcep. The end tips of the Shaftlock component displace 1.5 mm, 3.0 mm and 5.0 mm for these values of F_{pinch} and F_{rod}. Hence, by locking the displacement of the end tips of the Shaftlock component, the transmission ratio between F_{rod} and F_{pinch} can be effectively prevented. In other words, if the end tips of the Shaftlock are unable to move, the value of F_{pinch} will remain constant with increasing F_{rod}. Figure 3 displays three varieties of lock mechanisms which can be added on the end tips of the Shaftlock: snapfit lock, crosscut teeth, and rip teeth. A snapfit lock use protrusions and recesses to interlock components, creating a secure and tight fit. Crosscut teeth have a triangular shape and can obstruct movement in one axis. Conversely, rip teeth have a rectilinear triangular shape that can obstruct movement in two axes.

The second functional requirement contains that the force limiting mechanism should be adjustable by the user. Two main solutions have been explored and are visible in Figure 3: a spring and a rotational mechanism. The spring mechanism can be used like the spring mechanism in an umbrella. When the spring is stretched it locks itself into place. When the user releases the tension on the spring, the spring unlocks itself and displaces. A rotational mechanism can be used to transfer rotational motion into linear motion of a component, allowing the component to change position.

The third functional requirement contains that the force limiting mechanism should be detachable by the user. Therefore, a detachable enclosure component is required to assemble and protect all the components. One side of the enclosure components should be fixed to the handle of the laparoscopic instrument and the other side on the rod of the laparoscopic instrument. Figure 3 presents two approaches for obtaining an enclosure component: a rectangular enclosure component and a cylindrical enclosure component. A cylindrical enclosure component ensures protection against buckling, deformation, and other stresses. Moreover, it also provides high structural integrity and is easier to fabricate, as well as being more space-efficient. On the other hand, the rectangular component may be more straightforward to use when incorporating the mechanism to adjust the force levels.

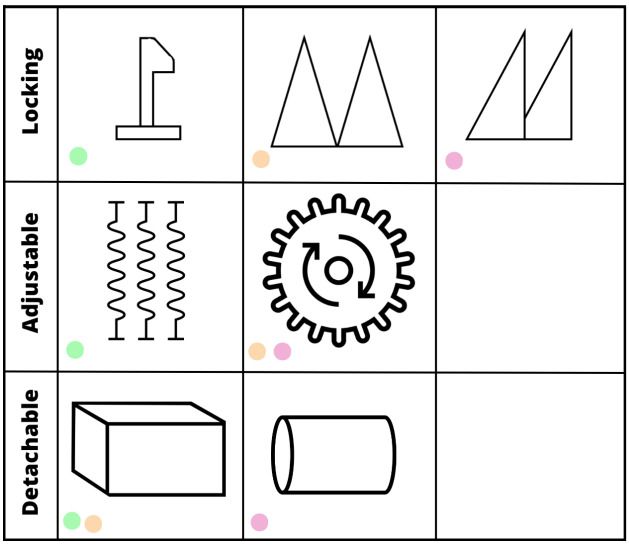


Fig. 3. Morphological scheme for the first three functional requirements. [1,1] Snapfit lock, [1,2] Crosscut teeth, [1,3] Rip teeth, [2,1] Spring mechanism, [2,2] Rotational mechanism, [3,1] Rectangular enclosure component, [3,2] Cylinder enclosure component.

3.3 Concept selection

Three conceptual designs have been depicted, each representing potential solutions aimed at satisfying the first three functional requirements as illustrated in Figure 3. The most promising concept has been chosen for further elaboration, employing a Harris profile based on the performance criteria outlined in Table I.

- *Green concept*: The green concept (GC) is a combination of the green dots in Figure 3 and is shown in Figure 4. It aims to secure the ends tips of the Shaftlock using a snapfit lock. The force levels can be adjusted in the x direction by a spring mechanism that is aligned with the laparoscopic instrument. The components are implemented within a rectangular single enclosure component.

- *Orange concept*: The orange concept (OC) is a combination of the orange dots in Figure 3 and is shown in Figure 5. The orange concept involves locking the end tips of the Shaftlock using crosscut teeth and the force levels can be adjust in the z direction via a rotational mechanism. The components are implemented in a single rectangular enclosure component.

- *Pink concept*: The pink concept (PC) is a combination of the pink dots in Figure 3 and is shown in Figure 6. The pink concept focuses on locking the end tips of the Shaftlock through rip teeth. The force levels can be adjust in the x direction using a rotational mechanism aligned with the laparoscopic instrument. The components are implemented in a cylindrical enclosure component.

Table I displays the Harris profile, which assesses the three concepts according to performance criteria assigned with weight factors. This table provides a comprehensive overview of the different concepts, with weight factors assigned values of 1, 2, or 3, and the concepts scaled on a range of -2, -1, +1, and +2. The total score of the concepts is presented in the last row of the table.

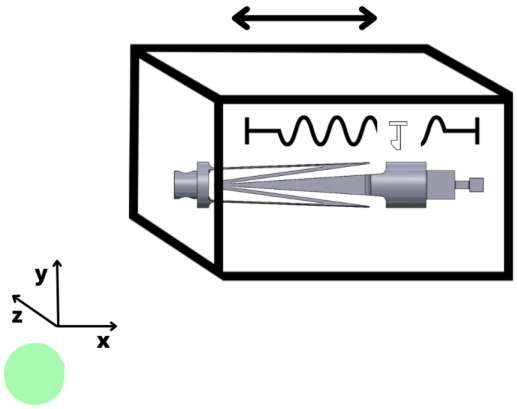


Fig. 4. Green concept (GC): A snapfit lock is used to lock the displacement of the end tips of the Shaftlock. The force levels can be adjust via a spring mechanism in the x direction of the laparoscopic instrument.

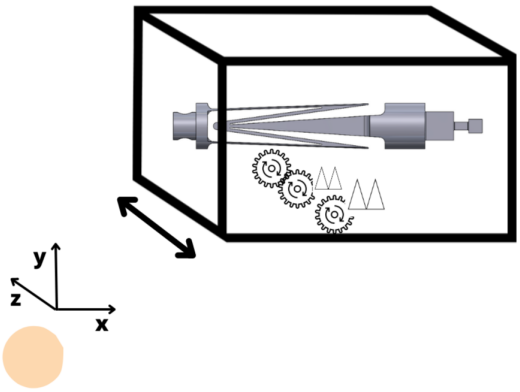


Fig. 5. Orange concept (OC): Crosscut teeth are used to lock the displacement of the end tips of the Shaftlock. The force levels can be adjust via rotational mechanism in the z direction of the laparoscopic instrument.

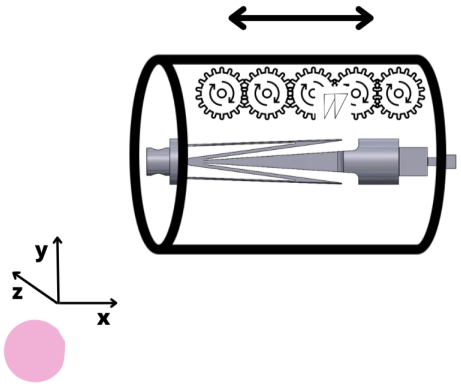


Fig. 6. Pink concept (PC): Rip teeth are used to lock the displacement of the end tips of the Shaftlock. The force levels can be adjust via rotational mechanism in the x direction of the laparoscopic instrument.

TABLE I
HARRIS PROFILE. GREEN CONCEPT (GC), ORANGE CONCEPT (OC), PINK CONCEPT (PC).

Performance criteria	Weight factor	GC	OC	PC
The force limiting mechanism should be low in weight	1	-1	+1	+2
The force limiting mechanism should be low in dimensions	2	-2	-1	+2
The force limiting mechanism should be reusable	2	-1	+1	+1
The force limiting mechanism should be safe for useres	3	+1	+2	+2
Total		-4	+7	+14

The green concept received negative scores in the first, second, and third performance criteria due to the requirement of compliant components for unlocking in the snap-fit lock. There were also challenges associated with the precise assembly of springs in the spring mechanism, particularly when working with small dimensions. However, the green concept scored positively in terms of user safety. Overall, the green concept obtained a score of -4. The orange concept received a negative score in the second performance criteria because the force levels transferred in the z direction, which did not align with the laparoscopic instrument, resulting in larger dimensions. However, the orange concept scored positively in terms of weight, reusability, and user safety. Overall, the orange concept obtained a score of +7. The third concept demonstrated positive scores across all performance criteria. This can be attributed to the alignment of the rotational mechanism with the instrument and the use of a cylindrical-shaped enclosure component, which contributed to reduced weight and dimensions. Additionally, the use of robust materials for the rip teeth allowed for reusability and ensured user safety. The third concept received an overall positive score of +14 and was chosen for further development.

3.4 Dimensional design

The final design was created using Solidworks 2021 software. The final design, along with its components and their corresponding letters, can be seen in Figures 9 and 10. Figure 7 displays the Shaftlock component (A in Figure 9). To lock the displacement of the end tips of the Shaftlock, rip teeth were added to both ends. Moreover, another component was required to achieve this lock. This led to the development of the Conicoco component (B in Figure 9). The design process of the Conicoco component can be observed in Figure C. Initially, the Conicoco consisted of a conical ring. Subsequently, the Conicoco component was further designed to incorporate rip teeth for the three different force levels of 10 N, 20 N, and 40 N. Additionally, an additional axle (C in Figure 9) was integrated into the Conicoco component to enable rotation of the laparoscopic instrument.

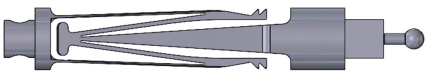


Fig. 7. Shaftlock component in Solidworks 2021.

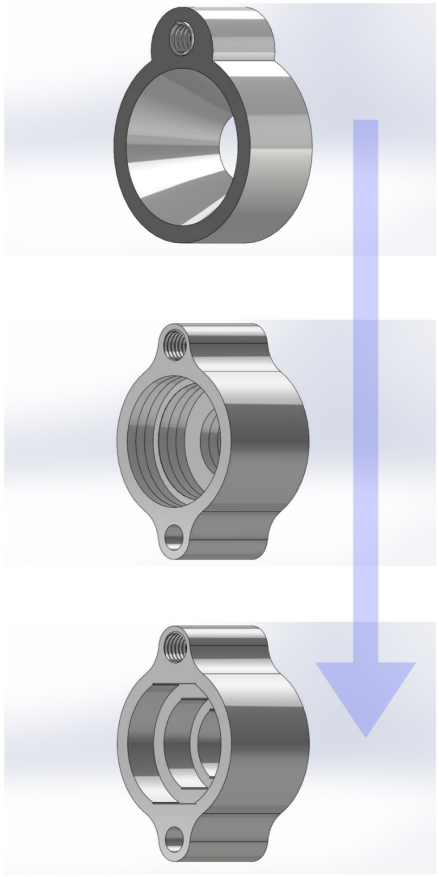


Fig. 8. Design iterations of the Conicoco component. Top: Initial design featuring a conical ring. Middle: Integration of rip teeth and an additional axle. Bottom: Final design of the Conicoco component with horizontal rip teeth positioned on the sides where the end tips of the Shaftlock displace. The height of the rip teeth varies according to the three force levels of 10 N, 20 N, and 40 N.

In order to minimize the unnecessary use of rip teeth, only the sides of the Conicoco component where the end tips of the Shaftlock would displace were equipped with horizontal rows of rip teeth. The height of the rip teeth radius was adjusted to match the three different force levels: 1.5 mm, 3.0 mm, and 5.0 mm respectively (D in Figure 9).

For the first force level of 10 N, there are four rows of rip teeth, while the second and third force levels have five rows. It was considered unnecessary to add a fifth row for the first force level because it would result in insecure locking of one side of the end tips of the Shaftlock. The decision to include additional rows of rip teeth was determined by the maximum displacement of 5 mm in the x direction for the Shaftlock component (refer to Appendix A). The rip teeth have a height of 1.0 mm and an angle of 45 degrees, to accommodate for the displacement of 1.5 mm and to fit the Shaftlock into the smallest diameter of the Conicoco. The edges of both the Shaftlock and Conicoco rip teeth are curved for ease of alignment and engagement. Since the rip teeth of the Shaftlock are made of Nitinol, the rip teeth of the Conicoco must be constructed from a material capable of withstanding the strength of Nitinol, such as stainless steel or aluminum.

To make the force limiting mechanism adjustable in the x direction of the laparoscopic instrument, a screwlead (E in Figures 9 and 10) was chosen. The screwlead is attached to the Conicoco component and translates rotational motion into linear motion, allowing the Conicoco to be moved to the position where the desired force level is achieved by aligning the rip teeth of the Shaftlock with those of the Conicoco component. The screwlead is fixed between the two enclosure components (F/G in Figures 9 and 10). A knob (H in Figures 9 and 10) is attached to the end of the screwlead to allow the surgeon to apply rotational movement for adjusting the desired force level. The enclosure components of the force limiting mechanism design enables visualization of the Conicoco's placement for the desired force level. A more detailed visualization of the placement for the three force levels is presented in Appendix B.

To make the force limiting mechanism detachable from the laparoscopic instrument, a cylindrical shape was chosen for the enclosure components. All the components are assembled within these two enclosure components, which are fixed to the handle of the laparoscopic instrument via a connection piece component (I in Figures 9 and 10) with four screws on one side. This component is synchronized with the handle, so if the laparoscopic instrument rotates, the force limiting mechanism rotates as well. On the other side, the two enclosure components are screwed onto the rod of the laparoscopic instrument via another connection piece (J in Figures 9 and 10).

A more detailed version of the design process can be found in Appendices C and D. Appendix C presents a more detailed design process for the Conicoco component, while Appendix D provides an overview of the entire design process.

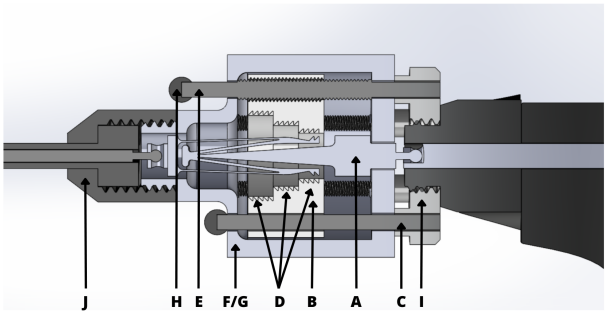


Fig. 9. Section view of the force limiting mechanism in a laparoscopic instrument designed in Solidworks 2021. (A) Shaftlock, (B) Conicoco, (C) Extra axle Conicoco, (D) Rip teeth for the three force levels, (E) Screwlead, (F/G) Two enclosure components, (H) Knob, (I) Connection piece handle, (J) Connection piece rod.

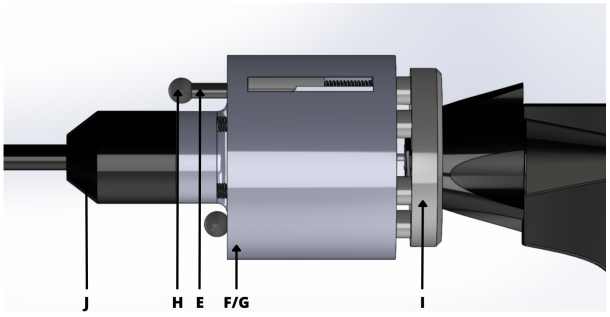


Fig. 10. Side profile view of the force limiting mechanism in a laparoscopic instrument designed in Solidworks 2021. (E) Screwlead, (F/G) Two enclosure components, (H) Knob, (I) Connection piece handle, (J) Connection piece rod.

3.5 Mechanical validation

The mechanical validation will ensure that the design of the force limiting mechanism is performing accurately and to identify any errors or defects in its design. The experiment aimed to measure the transmission ratio between F_{rod} and F_{pinch} for four different Shaftlock conditions in the laparoscopic instrument. The first condition involved measuring the laparoscopic instrument without the Shaftlock and force limiting mechanism, while the other conditions involved measuring the laparoscopic instrument with the Shaftlock and the force limiting mechanism. The second condition evaluated the first force level of 10 N. The third condition evaluated the second force level of 20 N. Finally, the fourth condition evaluated the third force level of 40 N. The purpose of this experiment was to investigate the transmission ratio between F_{rod} to F_{pinch}. The hypothesis stated that the force limiting mechanism impacts the transmission ratio, meaning that F_{pinch} remains constant at 10 N, 20 N, and 40 N, respectively, while F_{rod} increases. Any observed differences in the transmission ratio would suggest that the force limiting mechanism has an effect on the transmission ratio within the laparoscopic instrument. However, if no differences are found, it can be inferred that the force limiting mechanism does not influence the transmission ratio within the instrument.

The setup for the input F_{rod} for the experiment can be seen in Figure 11. To measure F_{rod}, a linear stage (A, B) was fixed onto a board, and a force sensor (C) (LSB200 25lb, FUTEK, USA) was mounted onto the linear stage. A component (D) was designed to connect one end of the force sensor to the rod of the laparoscopic instrument or the Shaftlock component (depending on the experiment condition) at the other end. The rod or the Shaftlock was incorporated into the design (F). By activating the linear stage (A), the rod of the laparoscopic instrument was pulled backwards while the design was held stationary between two barriers (E, G) to restrict its movement. The force sensor measured the input force F_{rod}, which was read using NI LabVIEW 2018 software.

Figures 12 and 13 present the setup used to measure the output force F_{pinch} for both experiments. To obtain F_{pinch}, the rod of the laparoscopic instrument was fixed within a barrier (A), while the forceps of the laparoscopic instrument (B) were set at an open 20-degree angle. This barrier was also secured on the same board used for the input setup. A metal thread (C) was then pulled tightly and fastened onto the forceps at a 2/3 length from the hinge and a fixation component (D) at a 15-degree angle. The fixation component was mounted onto a force sensor (E) (LSB200 10lb, FUTEK, USA), which was fixed onto a linear stage (F). As the input setup increased F_{rod}, the forceps of the instrument attempted to close. However, the metal thread caused the forceps to remain open at the 20-degree angle. As a result, a force was applied to the metal thread and subsequently to the force sensor, which could be measured. Therefore, the value of F_{pinch} could be determined. The output force F_{pinch} was measured with the force sensor and read using the software ControlDesk dSPACE GmbH. It is worth noting that the linear stage (F) remained stationary throughout the experiment. The linear stage was utilized because its setup enabled the measurement of F_{pinch}.

Both force sensors were calibrated before conducting the experiment. Furthermore, the output force sensor was calibrated to account for the force of gravity at the 15-degree angle of the metal thread. The force sensors operated at different frequencies, with the input force sensor functioning at 10 Hz and the output force sensor operating at 1000 Hz. To ensure consistency in the results, corresponding data points were selected.

Five trials were conducted for each condition, each lasting for sixteen seconds. The input force F_{rod} and output force F_{pinch} were measured simultaneously by rotating the handle of the linear stage in the input setup. For the first condition, F_{rod} was increased up to 80 N. For the second, third and fourth condition, F_{rod} was increased up to 65 N, 80 N, and 80 N. After the experiment, an offset of 15 N for F_{rod} was removed. The different values of F_{rod} were selected to avoid causing irreversible damage to the Shaftlock, as was predicted by the Solidworks calculations (Appendix A).

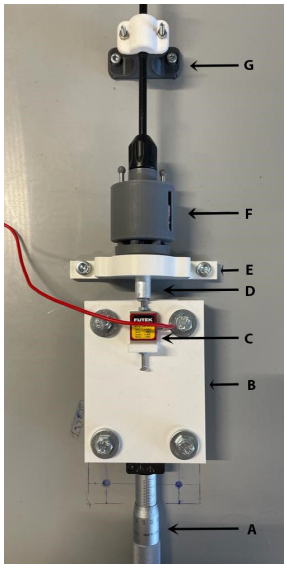


Fig. 11. Setup for the input F_{rod} of the mechanical validation experiment. (A) Linear stage activation, (A, B) Linear stage, (C) Force sensor, (D) Component to attach the force sensor and the rod of the laparoscopic instrument, (E) Barrier, (F) Design of the force limiting mechanism and (G) Barrier.

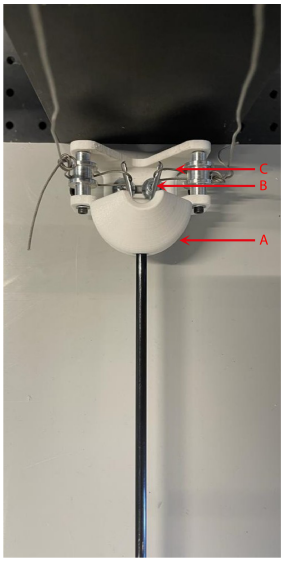


Fig. 12. Setup for the output F_{pinch} of the mechanical validation experiment. (A) Barrier, (B) Forceps of the laparoscopic instrument, (C) Metal thread.

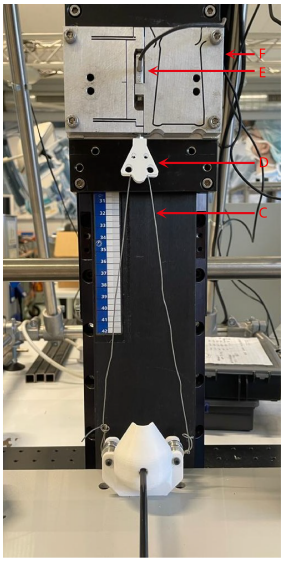


Fig. 13. Setup for the output F_{pinch} of the mechanical validation experiment. (C) Metal thread, (D) Fixation component, (E) Linear stage, (F) Force sensor.

3.6 Pre-clinical validation

Pre-clinical validation is necessary to ensure the safety and effectiveness of the force limiting mechanism before testing it on humans. The objective of this experiment was to determine whether the laparoscopic instrument with the force limiting mechanism would generate a lower pinching force, compared to the laparoscopic instrument without the force limiting mechanism in a pre-clinical setting. The hypothesis states that the laparoscopic instrument with the force limiting mechanism will produce a lower pinching force than the instrument without the force limiting mechanism. The experimental setup is described first, followed by an explanation of the performance parameters used to indicate the pinching force.

Novice participants with no experience in laparoscopic surgery or boxtrainers performed the experiment and had one dominant hand (right). Prior to the experiment, all participants completed an informed consent form, and the Human Research Ethics Committee (HREC) at the Technical University of Delft approved the entire experiment, as documented in Appendix F. To conduct a crossover study, the participants were divided equally into two groups. Group one performed the first four trials without the force limiting mechanism followed by four trials with the force limiting mechanism. Group two performed the opposite, starting four trials with the force limiting mechanism, followed by four trials without the force limiting mechanism. Thus, each participant completed a total of eight trials.

The experiment was conducted using a Lapron Boxtrainer (Lapron Boxtrainer, ForceSense and Amsterdam Skills Centre, The Netherlands). Before the participants began the first trial, they were familiarized with the depth perception of the boxtrainer. The participants were required to transfer a synthetic object from their dominant hand to their non-dominant hand using two laparoscopic instruments. Additionally, they were familiarized with the Floral foam material by practicing applying force to it using the laparoscopic instrument.

For this experiment, a basic laparoscopic task was chosen, which consisted of four steps to be followed for each trial. The task was to transfer the synthetic object from a box located next to the dominant hand to a box located next to the non-dominant hand, as is elaborated in Figures 14 to 17. Participants were instructed to use the full surface area of the forceps to grasp the Floral foam object, and to grasp it along the longitudinal axis of the instrument to prevent the Floral foam from breaking easily when pulled in a different direction. The setup of the boxtrainer from both the outside and inside can be seen in Figures 18 and 19.

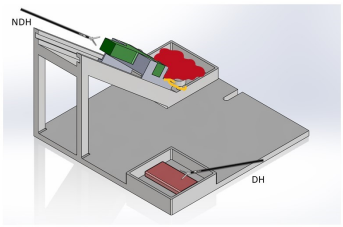


Fig. 14. A laparoscopic instrument is being held in the dominant hand (DH), while the non-dominant hand (NDH) holds the laparoscopic instrument with or without the force limiting mechanism, depending on the group and trial. The task involves transferring a synthetic object from a box located beside the dominant hand to the box located beside the non-dominant hand.

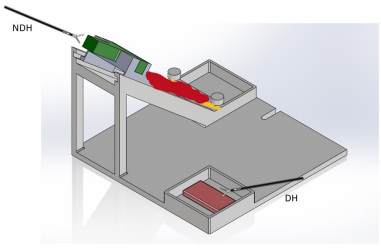


Fig. 15. To make the box located beside the non-dominant hand visible, it was required to grasp the Floral foam object. The Floral foam object was secured in a holder on a rail mechanism, and pulling it caused the holder to move, revealing the box beneath it.

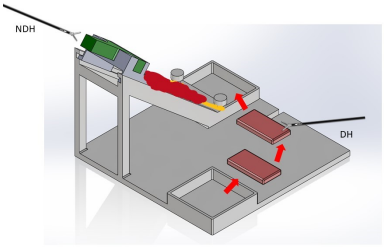


Fig. 16. The next step was to collect the synthetic object that was placed in the box located beside the dominant hand and transfer it to the box located beside the non-dominant hand.

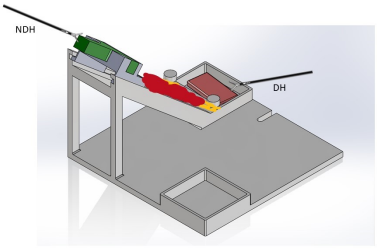


Fig. 17. Once the synthetic object was in the box located beside the non-dominant hand, the trail was completed.

After the experiment, participants were asked to rate on a scale of 1 (not at all) to 5 (very much) whether they experienced difficulty in moving the Floral foam object for both the laparoscopic instrument with and without the force limiting mechanism. Moreover, they were asked to rate on a scale of 1 (too heavy) to 5 (not heavy) the weight for both instruments. For the laparoscopic instrument with the force limiting mechanism, they were also asked to rate on a scale of 1 (no awareness) to 5 (substantial awareness) if they felt a difference in resistance.

The experiment aimed to analyze two performance variables: relative depth (RD) and slippages of the Floral foam object per trial. The amount of slippages during each trial was documented to measure the slippages. To calculate relative depth, the Floral foam object, made from phenol, formaldehyde polymers, surfactants, and wetting agents (Oasis, Praxis, The Netherlands) [26], was used due to its irreversible imprint when force was applied. This imprint becomes more profound with greater force, making it an ideal material for measuring the remaining depth. The Floral foam objects were made using a cutter to ensure consistent dimensions, and the height of each object was 18 mm. Participants held the laparoscopic instrument with or without the force limiting mechanism in their non-dominant hand and grasped the Floral foam object with the forceps, creating an irreversible imprint on the object. The relative depth was calculated using Formula 3, where D represents the initial height of 18 mm of the Floral foam object and d [mm] represents the remaining depth measured. The force limiting mechanism was set at the first force level of 10 N as higher levels could cause the Floral foam to break. When the force caused the Floral foam to break, the relative depth was 100 percent. The cutter and Floral foam object can be seen in Figures 20 and 21, and the relative depth representations is shown in Figures 22 and 23.

$$RD = \frac{(D-d)}{D}100 \tag{3}$$

Fig. 18. The boxtrainer with two laparoscopic instruments. The non-dominant hand held the instrument with or without the force limiting mechanism. The dominant hand held the instrument without the force limiting mechanism.

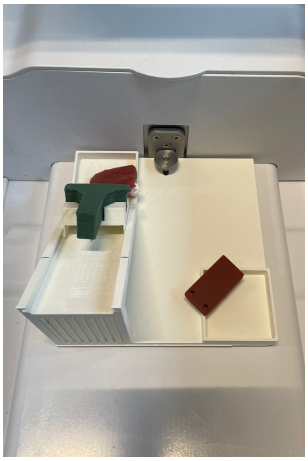


Fig. 19. The experiment setup inside the boxtrainer, with the Floral foam object and synthetic object.

Fig. 20. The cutter that was used to make the Floral foam objects.

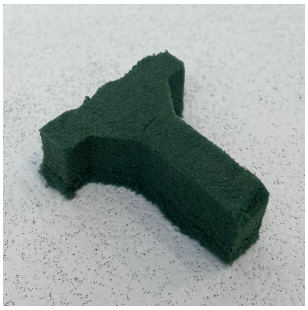


Fig. 21. The Floral foam object which the participants had to grasp with the laparoscopic instrument.

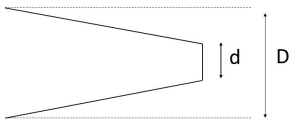


Fig. 22. Schematic representation of the relative depth. D represents the initial height of 18 mm of the Floral foam object and d [mm] represents the remaining depth measured.

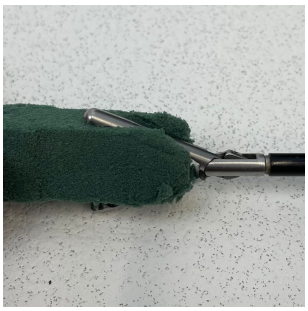


Fig. 23. The forceps of the laparoscopic instrument grasps the Floral foam object.

4. RESULTS

A comprehensive elaboration on the final design will be provided, followed by the presentation of the results from both the mechanical and pre-clinical validation.

4.1 Final design

The prototype of the final design is presented in Figures 24 and 25. Figure 24 shows a section view of the prototype, while Figure 25 depicts the prototype integrated into a laparoscopic instrument. The final design comprises 17 components, including screws and bolts, weighs 82 g and has an outer diameter of 40 mm. Various manufacturing techniques were employed to produce most of the components of the design. Components that did not require any manufacturing techniques, such as screws, were obtained from the Inloop Werkplaats Studenten (IWS) and Inloop Werkplaats Medewerkers (IWM) at the Faculty of Mechanical, Maritime and Materials, Delft University of Technology, or were purchased from a local building supply store. Table II provides an overview of all the components, their materials, and their sources.

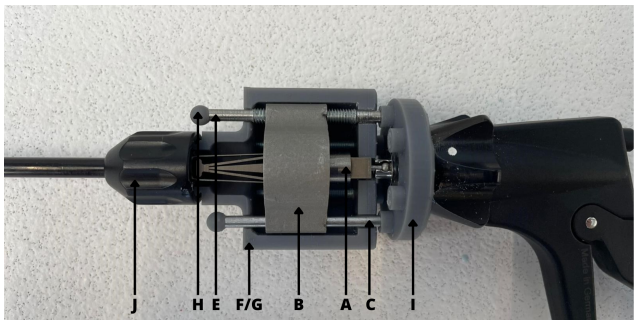


Fig. 24. Section view of the prototype of the force limiting mechanism in a laparoscopic instrument. (A) Shaftlock, (B) Conicoco, (C) Extra axle Conicoco, (E) Screwlead, (F/G) Two enclosure components, (H) Knob, (I) Connection piece handle, (J) Connection piece rod.

- *Wire - Electrical discharge machining:*
  The Shaftlock component is a highly complex design and was manufactured using a technique called Electrical Discharge Machining (EDM), also known as spark machining. This technique employs electrical discharges or sparks to create a desired shape [27]. The process was carried out at the Dienst Elekrtonische en Mechanische Ontwikkeling (DEMO) located at the Delft University of Technology. Nitinol was used to make the Shaftlock, a material that provides a high Yield Stress (approximately 400 MPa). Consequently, the Shaftlock component is stronger and more durable under higher stresses.
- *Selective Laser Melting:*
  The Conicoco component was produced using Selective Laser Melting (SLM), a 3D printing process that fuses metallic powders together (Sisma Mysint 100, Sisma, Italy) [28]. The manufacturing was conducted at the Reactor Institute Delft (RID), located at the Delft University of Technology. The Conicoco component was made from stainless steel. The Conicoco component was also produced from aluminium using a CNC machine, which was less expensive. However, the force levels required different heights in order to produce the component accurately with the CNC machine, resulting in less quality of the component. After comparing the stainless steel EDM-produced Conicoco with the aluminum CNC-produced Conicoco, the stainless steel EDM-produced was chosen for its superior quality.
- *Stereolithography:*
  The two enclosure components, the connection piece component from the two enclosure components to the handle, as well as the knobs, were produced using Stereolithography (SLA), which is a 3D printing technique that uses a UV laser to selectively cure a liquid photopolymer resin layer by layer, creating an object (Formlabs 3, Formlabs, Germany) [28]. The manufacturing process was carried out at the Inloop Werkplaats Medewerkers (IWM) located within the Faculty of Mechanical, Maritime, and Materials at Delft University of Technology, and the components were made from Grey resin.

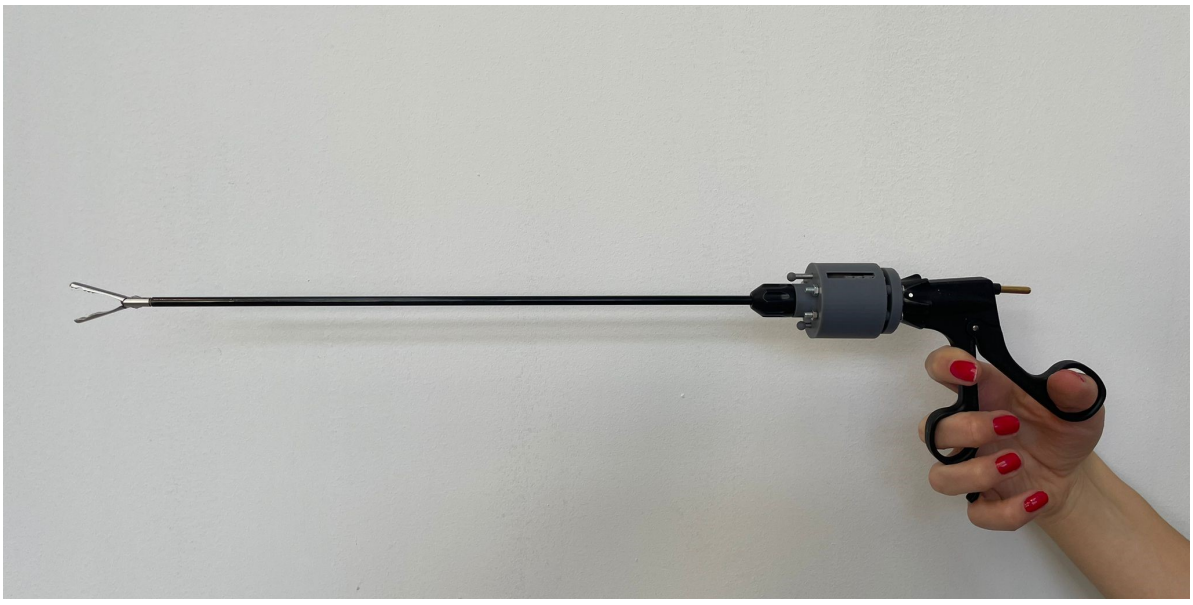
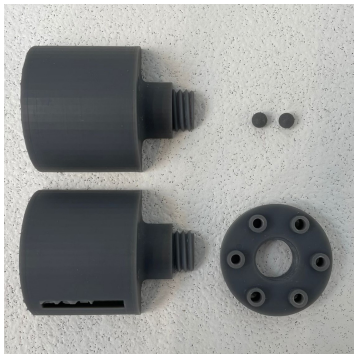
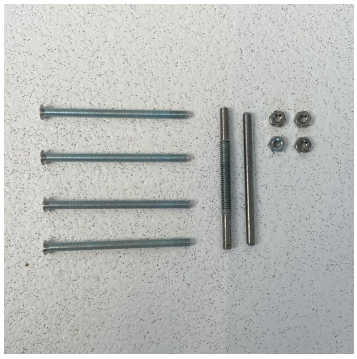


Fig. 25. Prototype of the force limiting mechanism in a laparoscopic instrument.

TABLE II
ALL COMPONENTS, THEIR MATERIAL AND THEIR SOURCE OF THE DESIGN. [1,1] SHAFTLOCK, [2,1] CONICOCO, [3,1] TWO ENCLOSURE COMPONENTS, KNOBS AND CONNECTION PIECE HANDLE, [4,1] SCREWLEAD AND EXTRA AXLE OF CONICOCO, SCREW AND BOLTS.

Component	Material	Component source
	Nitinol	Wire-EDM
	Stainless steel	SLA
	Grey resin	SLM
	Stainless steel	IWS/IWM

.

4.2 Mechanical validation results

The experiment aimed to measure the transmission ratio between F_{rod} and F_{pinch} for four different Shaftlock conditions in the laparoscopic instrument. The results, depicted in Figure 26, show that the transmission ratio between F_{pinch} and F_{rod} varies significantly among the four conditions. The first condition involved measuring the laparoscopic instrument without the Shaftlock and force limiting mechanism, depicted by the green line, while the other conditions involved measuring the laparoscopic instrument with the Shaftlock and the force limiting mechanism. The pink line corresponds to the condition for the first force level of 10 N, the blue line represents the condition for the second force level of 20 N, and the orange line illustrates the condition for the third force level of 40 N.

It is observed that for the first condition the transmission ratio remains constant up to 75 N for F_{rod}, with a corresponding value of 4.4 for F_{pinch}. It is also observed that the Shaftlock component efficiently transfers all the energy from the rod to the forceps of the laparoscopic instrument, without any energy being stored within the Shaftlock component. As the transmission ratio has the same slope as the other conditions.

In the second condition (pink), it is observed that when F_{rod} reaches 27 N, the corresponding value of F_{pinch} remains constant at 0.5 N as F_{rod} increases. However, when F_{rod} reaches 45 N, F_{pinch} begins to increase again till 0.7 N, indicating that F_{pinch} remains constant for an increase of 18 N in F_{rod}. Moreover, the line stops at 50 N, which was the threshold set for F_{rod} to prevent irreversible damage to the Shaftlock component. It should be noted that a modification was made to the test setup after the initial results presented in Appendix E, which involved tightening the bolts more firmly to prevent slippage.

In the third condition (blue), it can be observed that when F_{rod} has a value of 45 N, the corresponding value of F_{pinch} remains constant between 1.7 and 2.0 N as F_{rod} increases by 14 N. Beyond this point, F_{pinch} begins to increase again as F_{rod} increases. When F_{rod} reaches the limit of 65 N, the value of F_{pinch} is 2.8 N.

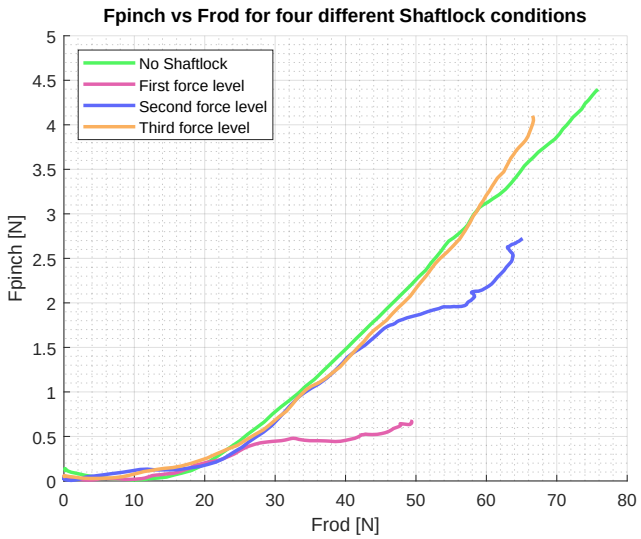


Fig. 26. F_{pinch} vs F_{rod} for four different Shaftlock conditions. The first condition aimed to measure the laparoscopic instrument without the Shaftlock component and the force limiting mechanism (green). The second, third and fourth condition aimed to measure the laparoscopic instrument with the Shaftlock and the force limiting mechanism. The second condition aimed to measure the first force level of 10 N (pink). The third condition aimed to measure the second force level of 20 N (blue). The fourth condition aimed to measure the third force level of 40 N (orange).

In the fourth condition (orange), it is apparent that the transmission ratio between F_{rod} and F_{pinch} remains constant until the threshold value of F_{rod} is reached at 65 N, meaning that F_{pinch} does not remain constant with increasing F_{rod}. It was not possible to increase F_{rod} beyond this point as it could cause permanent damage to the Shaftlock component. Moreover, it is observed, the transmission ratio increases after 60 N, meaning that more force is transferred from F_{rod} to F_{pinch}.

4.3 Pre-clinical validation results

The pre-clinical validation study involved twenty participants, both male and female, between the ages of 17 and 35. They performed a basic laparoscopic task for eight trials. Figure 27 presents the relative depth of the Floral foam object as a percentage per trial per group. Figure 29 shows the relative depth of the Floral foam object for all trials, both with and without the force limiting mechanism. The slippages of the Floral foam object per trial per group are presented in Figure 28. The number of slippages in one trial and the total trials are shown in Figure 30. Finally, the results of the questionnaire's five questions can be seen in Figures 31 to 35.

Figure 27 includes sixteen box-charts showing the relative depth per trial for both groups. The green box-charts represent group 1, while the orange box-charts represent group 2. Group 1 performed the first four trials without the force limiting mechanism followed by four trials with the force limiting mechanism. Group 2 performed the opposite, starting four trials with the force limiting mechanism, followed by four trials without the force limiting mechanism. The x-axis shows the trial number, while the y-axis displays the relative depth as a percentage. When the force applied to the Floral foam caused it to break, the relative depth was 100 percent. The black dotted line between trials 4 and 5 denotes the change in condition of the laparoscopic instrument.

It can be observed that the medians and variations of the relative depth differ between group 1 and group 2 for the first four trials. The medians for group 1 have values between 60 and 85 percent, whereas the medians for group 2 are lower, ranging between 50 and 60 percent. Additionally, the variation for group 1 is 50 percent, while for group 2, the variation is lower at 20 percent. Furthermore, for group 1, the second trial has a higher median of 85 percent compared to the other three trials, which have a median of 60 percent. Additionally, it is observed that the medians and variations of the relative depth differ between group 1 and group 2 for the last four trials. The medians for group 1 have a constant value of 50 percent, while the medians for group 2 are higher, ranging between 55 and 65 percent. Moreover, the variation for group 1 is 20 percent, while the variation for group 2 is higher at 25 percent. It should be noted that the difference in variation between both groups is less than the difference in variation observed between both groups for the first four trials. Furthermore, for group 2, the fifth trial has a higher median of 65 percent compared to the other three trials, which have a median of 55 percent. Moreover, it is worth noting that for the last two trials of both groups, the variation has the same value. Furthermore, it is also observed that some participants reached a relative depth of 100 percent, causing the Floral foam object to break, while performing the task with the force limiting mechanism.

Figure 29 displays two box-charts showing the relative depth of the Floral foam object for all trials with and without the force limiting mechanism. The y-axis shows the relative depth as a percentage, while the x-axis represents the two conditions of the laparoscopic instrument. The left (blue) box-chart shows the results for the laparoscopic instrument without the force limiting mechanism (MEDIAN=61.11, SD=19.98, MIN=33.33, MAX=100.00), while the right (pink) box-chart shows the results for the laparoscopic instrument with the force limiting mechanism (MEDIAN=50.00, SD=15.48, MIN=16.67, MAX=100.00).

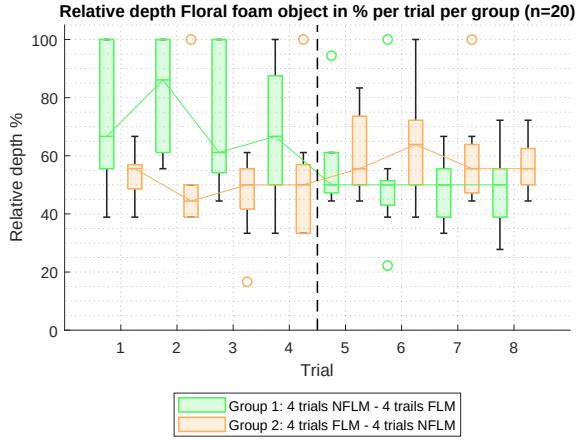


Fig. 27. Relative depth of the Floral foam object in percentages per trial per group. Group 1 (green) performed the first four trials without the force limiting mechanism (NFLM) and the last four trials with the force limiting mechanism (FLM). Group 2 (orange) performed the first four trials with the force limiting mechanism (FLM) and the last four trials without the force limiting mechanism (NFLM).

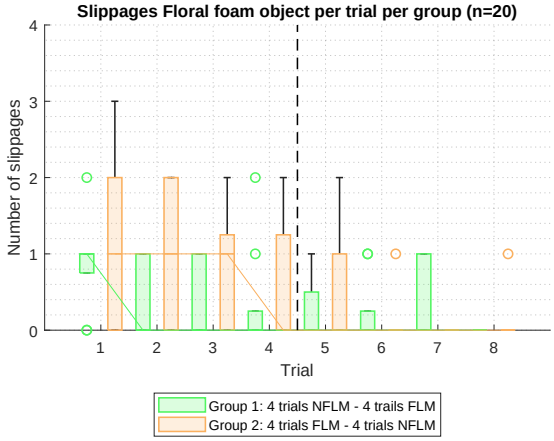


Fig. 28. Slippages of Floral foam object per trial per group. Group 1 (green) performed the first four trials without the force limiting mechanism (NFLM) and the last four trials with the force limiting mechanism (FLM). Group 2 (orange) performed the first four trials with the force limiting mechanism (FLM) and the last four trials without the force limiting mechanism (NFLM).

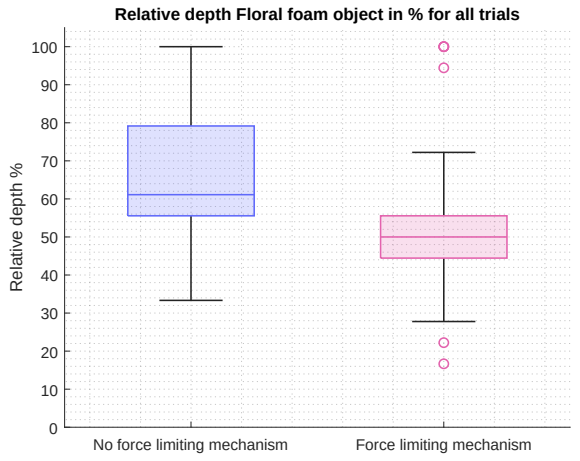


Fig. 29. Relative depth of the Floral foam object in percentages presented in two box-charts. Left (blue): All trials performed without the force limiting mechanism. Median: 61.11 percent. Right (pink): All trials performed with the force limiting mechanism. Median: 50.00 percent.

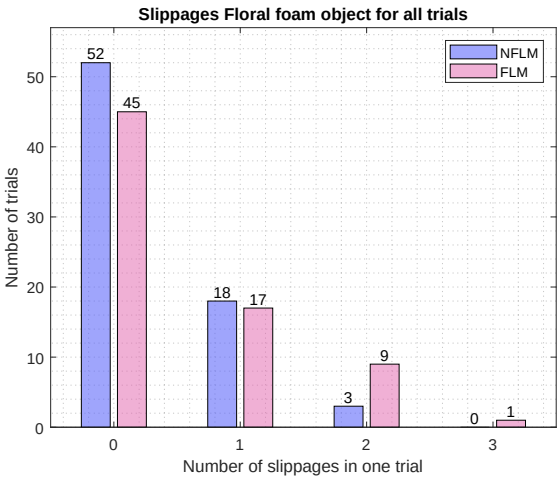


Fig. 30. Slippages Floral foam object for all trials. The number of slippages in one trial on the x-axis and the number of trials on the y-axis. The blue bars present the results without the force limiting mechanism, and the pink bars present the results the with the force limiting mechanism.

It is observed that both the median and variance for the laparoscopic instrument with the force limiting mechanism are lower compared to those without the force limiting mechanism. To assess the statistical significance between the two conditions, a Wilcoxon Signed Ranks Test was conducted on the data using SPSS and Matlab2021b software, which was chosen because the data was non-normally distributed and each participant performed trials in both conditions. Moreover, a Wilcoxon Singed Ranks Test accounts for outliers and small sample sizes. The results of the Wilcoxon Singed Ranks Test showed a significant difference in the relative depth between the two conditions, resulting in a significantly lower relative depth when performing the trials with the force limiting mechanism compared to those without the force limiting mechanism ($p<0.001$).

Figure 28 includes sixteen box-charts showing the slippages per trial for both groups. The green box-charts represent group 1, while the orange box-charts represent group 2. The x-axis shows the trial number, while the y-axis displays the number of slippages. The black dotted line between trials 4 and 5 denotes the change in condition of the laparoscopic instrument. The medians and variations of slippages are observed to differ between group 1 and group 2 for the first four trials. Specifically, the medians for group 1 have an average value of 0, while the medians for group 2 have a higher average of 1. Additionally, the variation for group 1 has a value of 1, whereas for group 2, the variation is 2. For the last four trials, it is noted that the medians and variations of slippages are the same for both groups. The medians for both groups have a constant value of 0, while the variations have a value of 1. However, within the trials, it is observed that group 2 had more variations.

Figure 30 displays eight bars representing the number of slippages in each trial on the x-axis and the number of trials where that number occurred on the y-axis for the two conditions of the laparoscopic instrument. The blue bars represent the laparoscopic instrument without the force limiting mechanism and the pink bars represent the laparoscopic instrument with the force limiting mechanism. The figure reveals that 0 slippages occurred more frequently in the group without the force limiting mechanism than in the group with the force limiting mechanism (52 versus 45). Additionally, two slippages in a single trial were more common in the group with the force limiting mechanism than in the group without it (9 versus 3). Furthermore, the group with the force limiting mechanism experienced three slippages in a single trial, whereas this did not occur in the other group. A Wilcoxon Signed Ranks Test was conducted using SPSS and Matlab2021b software to determine whether there was a statistically significant difference between the two conditions. However, the results indicated that there was no significant difference between the two conditions (p=0.068). Therefore, the laparoscopic instrument with the force limiting mechanism did not have a significant impact on the occurrence of slippages compared to the laparoscopic instrument without the force limiting mechanism.

The results of the questionnaire are presented in Figures 31 to 35. Figures 31 and 32 display the participants' responses to the question regarding the level of difficulty experienced in moving the Floral foam object on a scale of 1 (not at all) to 5 (very much). The participants were asked to rate their experience for both conditions, with and without the force limiting mechanism. The results were similar for both conditions, with 52 percent and 50 percent of participants reporting no difficulty in moving the Floral foam object. Participants who faced challenges mainly cited issues with depth perception in the box trainer, the Floral foam object breaking too quickly, or difficulties in maintaining grip when pulling the Floral foam object further.

Figures 33 and 34 display the participants' responses regarding the weight of the laparoscopic instrument on a scale of 1 (too heavy) to 5 (not heavy). They were asked to rate their experience for both with and without the force limiting mechanism. The majority of participants, 60 percent and 55 percent respectively, did not perceive any difference in weight between the two instruments. However, some participants reported feeling a difference in weight when moving the laparoscopic instrument with increasing motion.

The figure depicting the responses of participants to the question of whether they perceived a difference in resistance when using the laparoscopic instrument with the force limiting mechanism on a scale from 1 (no awareness) to 5 (substantial awareness) is shown in Figure 35. It was found that the majority of participants (63 percent) were not aware of any difference in resistance between the two instruments. However, a small proportion of participants (16 percent) reported feeling a difference in resistance. One participant mentioned that she perceived the Floral foam object slipping more easily and therefore applied more force on it.

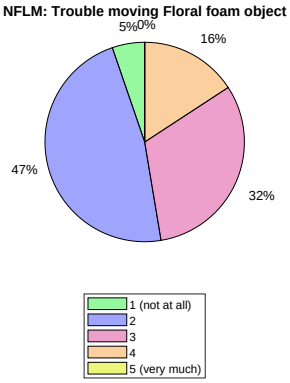


Fig. 31. Responses of the participants to the question of how difficult it was to move the Floral foam object without the force limiting mechanism (NFLM) on a scale of 1 (not at all) to 5 (very much).

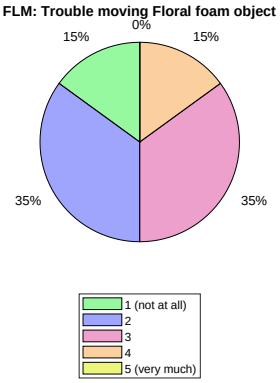


Fig. 32. Responses of the participants to the question of how difficult it was to move the Floral foam object with the force limiting mechanism (FLM) on a scale of 1 (not at all) to 5 (very much).

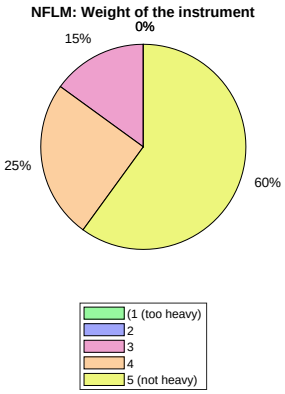


Fig. 33. Responses of the participants to the question about the weight of the instrument without the force limiting mechanism (NFLM) on a scale of 1 (too heavy) to 5 (not heavy).

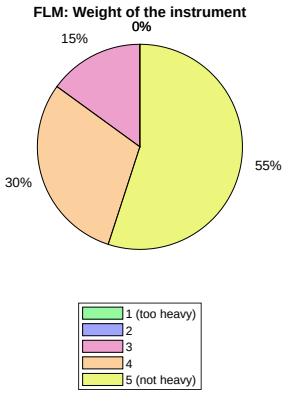


Fig. 34. Responses of the participants to the question about the weight of the instrument with the force limiting mechanism (FLM) on a scale of 1 (too heavy) to 5 (not heavy).

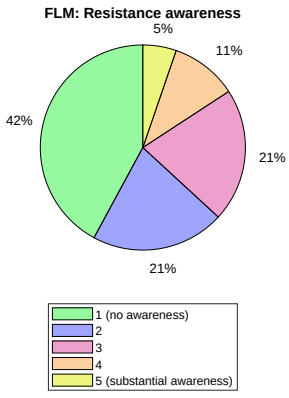


Fig. 35. Responses of the participants to the question of the awareness of a resistance difference with the force limiting mechanism (FLM) on a scale of 1 (no awareness) to 5 (substantial awareness).

5. Discussion

The next chapter discusses the results of the mechanical validation and evaluates whether the functional requirements and the performance criteria have been met. An overview of all the requirements and whether they have been met can be seen in Table III. Subsequently, the results of the pre-clinical validation will be discussed.

5.1 Mechanical components

The mechanical validation results confirmed that the force limiting mechanism does not meet the requirement: *The force limiting mechanism should block the pinching force in the forceps of the laparoscopic instrument at 10 N, 20 N and 40 N.*

The purpose of the first condition in the experiment was to determine the transmission ratio between F_{rod} and F_{pinch} without the Shaftlock component. Figure 26 demonstrates that there is no difference in the transmission ratio between the conditions with and without the Shaftlock component. Therefore, the Shaftlock does not store any energy from the rod but transfers all the energy towards the forceps of the laparoscopic instrument. The purpose of the second, third and fourth condition was to investigate whether the force limiting mechanism for all three force levels affects the transmission ratio between F_{rod} and F_{pinch}, with F_{pinch} being maintained constant at 10 N, 20 N, and 40 N, respectively, while F_{rod} increases. Figure 26 illustrated that, for the first two force levels, F_{pinch} remained constant at 0.5 N and 2.0 N, respectively, as F_{rod} increased.

The observed force levels were not in accordance with the expected values of 10 N, 20 N, and 40 N for F_{pinch}. Specifically, the first force level of 10 N resulted in a constant F_{pinch} of only 0.5 N, whereas the second level of 20 N had a constant F_{pinch} of 2.0 N. Moreover, the third force level did not reach the expected 40 N for F_{pinch} and did not remain constant but instead increased up to 4.4 N. The lower values of F_{pinch} could be attributed to one main reason. The metal thread used to measure F_{pinch} did not cover the entire grasping area of the laparoscopic instrument, but only one point of contact and the three force levels of 10, 20, and 40 N were assumed to be applicable to the entire forcep area. Indicating the whole forcep area, instead of one point of contact, the values of 0.5 N, 2.0 N and 4.4 N will be expected much higher.

Moreover, the observed force levels were not in accordance with the expected values of 18 N, 35 N, and 70 N for F_{rod}. For the first force level, F_{pinch} remained constant at a value of 25 N for F_{rod} instead of 18 N. The second force level remained constant at 45 N instead of 35 N. For the third force level, F_{rod} was likely higher than 70 N. These discrepancies may be due to the fact that the rip teeth did met at the chosen values, but probably did not yet lock which eachother.

In Figure 26, it is evident that, unlike the first force level, the second force level exhibits a shorter constant value for F_{pinch} as F_{rod} increases. This observation can be attributed to the tendency of the two enclosure components in the design to bend under higher forces, which results in the backward pulling of the rod of the laparoscopic instrument.

The absence of a difference in the transmission ratio for the third force level can be attributed to the bending of the design under high forces, similar to what occurred in the second force level. Additionally, it should be noted that applying any additional force to the Shaftlock would have resulted in irreversible damage, as the Shaftlock had already been pulled 10 N beyond the point where irreversible damage could be attributed. Furthermore, Figure 26 also reveals an interesting observation within the third force level, wherein F_{pinch} demonstrates a greater increase when F_{rod} reaches 60 N. This phenomenon can be attributed to the design's tendency to bend under high forces or the occurrence of slippages within the setup during the experiment. It is noteworthy that this particular result occurred precisely at 60 N of F_{rod}. In the end of the experiment, an offset of 15 N for F_{rod} was observed and removed. This indicates that at 60 N of F_{rod}, the Shaftlock experienced a force of 75 N, surpassing the limit of 70 N before irreversible damage occurred to the Shaftlock. This limit could have also contributed to the unexpected behavior of the end tips, which probably failed to displace themselves as anticipated. Given these findings, it is essential to conduct a new experiment specifically designed to evaluate the Nitinol-based Shaftlock under higher forces from 70 N. This would enable accurate calculations of displacements and forces, allowing for a more comprehensive understanding of its performance.

Moreover, some limitations arose within the design of the Conicoco component, which was used for locking the ends tips of the Shaftlock. The first limitation of the design is related to the displacement of the Shaftlock. While the Conicoco was designed based on the assumption of a linear displacement of the end tips of the Shaftlock, in reality, the displacement was not entirely linear and increased with greater force. This deviation is explained in Appendix A. Future research should focus on designing the Conicoco to account for this non linear displacement of the tips of the Shaftlock. The second limitation of the design is related to the complexity of manufacturing the Conicoco component. The Conicoco was manufactured twice, using two different techniques: Selective Laser Melting (SLM) and a CNC machine. While the SLM technique resulted in better quality, it also came at a higher cost. In contrast, using a CNC machine, the Conicoco could be made from aluminum, resulting in less weight and costs. However, not all CNC machines can accommodate the small dimensions of the Conicoco design.

It has been confirmed that the force limiting mechanism is adjustable by the user, thereby fulfilling the requirement that states: *The force limiting mechanism should be adjustable by the user.* However, some limitations have to be stated. The first limitation concerns the locking mechanism of the Conicoco. While the focus was mainly on locking the Shaftlock with the Conicoco, more attention should be given to improving the security of the Conicoco itself. Currently, the Conicoco is locked between the two enclosure components of the design and has an extra axle. However, during the locking of the Shaftlock with the Conicoco, the Conicoco tended to displace itself in the extra axle, resulting in a 1-degree angle movement. One solution could be to make the axle a screw lead. However, it should be noted that both screw leads must rotate at the same frequency to translate the Conicoco correctly. This could be achieved by implementing a gear around the two screws, and the user could then rotate the gear to change the force levels. A limitation related to the usability of the design concerns the visualization of the set force level. Currently, the Conicoco component must be aligned with the required force level, which is done by the user of the instrument and can lead to uncertainties. A design could be implemented with a spring mechanism that can secure the Conicoco for the desired force level. Moreover, it should be clear to the surgeon which force level is required. Although the allowable pinching force is known for different types of forceps [17], it is essential to consider all the factors that arise during laparoscopic surgery. A combination of clinical and communication studies is needed to redesign the manual for the user to know which force level is required in a specific setting.

It has been verified that the force limiting mechanism can be detached from the laparoscopic instrument, thereby satisfying the requirement that states: *The force limiting mechanism should be detachable from the laparoscopic instrument.* However, some limitations have to be stated. The first limitation pertains to the two enclosure components of the design. Small openings were present between these components, which did not provide complete sealing. Moreover, since the components were made of grey resin, they tended to deform under high forces. This issue was addressed by adding an extra ring around the enclosure components and increasing their thickness.

TABLE III
OVERVIEW OF ALL REQUIREMENTS AND THEIR STATUS OF FULFILLMENT

Requirements	Desired values	Observed values	Requirement met
The force limiting mechanism should block the pinching force in the forceps of the laparoscopic instrument at 10 N, 20 N and 40 N	10 N, 20 N, 40 N	0.5 N, 2.0 N, - N	No
The force limiting mechanism should be adjustable by the user	Yes	Yes	Yes
The force limiting mechanism should be detachable from the laparoscopic instrument	Yes	Yes	Yes
The force limiting mechanism should be maintained and reused	Yes	Not all materials	No
The force limiting mechanism should be low in weight	$<$130 g	82 g	Yes
The force limiting mechanism should be low in dimensions	$<$45 mm	40 mm	Yes
The force limiting mechanism should be reusable	160 trials	$>$160 trials	Yes
The force limiting mechanism should be safe for users	Yes	Yes	Yes

However, the most effective solution would be to use a single enclosure component made of a stronger material such as aluminum or stainless steel. Furthermore, a single cylindrical component could be designed where the components could be inserted from the top or the bottom of the cylinder, instead of from the cross-section. The second limitation concerns the connection piece that links the two enclosure components to the laparoscopic instrument's rod. The screw on the enclosure components is made of grey resin, in a redesign the screw should be made of aluminum or stainless steel.

The maintenance and reusability of the force limiting mechanism have not been met because it is unclear if all components of the design can be properly cleaned in the CSD department. The components made from grey resin need to undergo cleaning tests to ensure the safety of the material before their reusability can be confirmed. Additionally, to prevent fluids from entering the instrument, it is necessary to completely close the enclosure components at the visualization area for all three force levels and make it translucent. As a result, the requirement that states; *The force limiting mechanism should be maintained and reused*, is not satisfied.

The force limiting mechanism weighs 82 g, meeting the performance criteria: *The force limiting mechanism should be low in weight.* When implemented into the laparoscopic instrument, it weighs 202 grams. Moreover, participants did not feel a substantial weight difference between the two instruments. It should be noted that the Conicoco component made from stainless steel weighs 28 g, while its aluminum counterpart weighs only 9 g, representing a 68 percent reduction in weight.

The outer diameter of the force limiting mechanism is 40 mm, meeting the performance criteria: *The force limiting mechanism should be low in dimensions.*

The force limiting mechanism has successfully demonstrated reusability throughout all 160 trials of the pre-clinical experiment, satisfying the performance criterion that states: *The force limiting mechanism should be reusable.* The pre-clinical testing allowed the force limiting mechanism to be operated at least 160 times. However, it is important to acknowledge that material fatigue is inevitable, and further research is required to assess the design's lifespan during actual service.

The force limiting mechanism is approved by the Human Ethics Committee (HREC). Therefore, meeting the performance criteria: *The force limiting mechanism should be safe for users.* However, it should be noted that when experiment changes, a new HREC approval is required.

It was validated that the force limiting mechanism is able to be tested on its mechanical performance and all the functional requirements and performance criteria could be evaluated. However, some limitations to setup of the mechanical validation have to be mentioned.

One limitation of the input setup was the occurrence of slip between the linear stage, the board, and the barriers, which affected the initial results. Tightening the bolts firmly between experiments could prevented the slip from occurring. Another limitation was the method used to pull the rod backward in the input setup, which involved rotating a knob fixed on the linear stage. However, maintaining a consistent rotational speed for every experiment was challenging, and a motor could be added to ensure consistent frequency. Additionally, initiating the entire setup was challenging since both sensors were connected to different computers and had to be started simultaneously. Future research should explore a setup where both input and output are connected to the same computer.

Although some limitations arose during the mechanical validation process, the overall setup represents a promising way to measure the pinching force and the force in the rod of the laparoscopic instrument. Future research is needed to find a way to measure the entire area of the forceps of the laparoscopic instrument and to improve the limitations in the setup. Furthermore, it is possible to determine if the design meets the functional requirements and performance criteria.

5.2 Pre-clinical components

The objective of the pre-clinical experiment was to determine whether the laparoscopic instrument with the force limiting mechanism would generate lower pinching force compared to the laparoscopic instrument without the force limiting mechanism in a pre-clinical setting. Figure 29 shows the box-charts that compare the relative depth of the laparoscopic instrument with and without the force limiting mechanism. As shown, the median and variation of the trials with the force limiting mechanism are lower than those without the force limiting mechanism ($p<0.001$). Therefore, it is confirmed that the force limiting mechanism generates lower pinching force, and the hypothesis is valid.

Figure 27 displays the results of the relative depth for all trials in both group 1 and group 2. Group 1, which started without the force limiting mechanism, had higher median and variation values in the first four trials compared to group 2, who began with the force limiting mechanism. This indicates that the force limiting mechanism had a significant impact on the initial four trials. Interestingly, when the instrument condition was switched for the last four trials, group 1 with the force limiting mechanism had lower median and variation values than group 2 without the force limiting mechanism. However, group 2 still had lower median and variation values than the first four trials of group 1, which suggests a learning effect due to the force limiting mechanism. However, it is important to acknowledge that even with the force limiting mechanism, the Floral foam object still broke in some trials. This can be explained by the fact that when the Floral foam object slipped, some of its material remained stuck on the forceps of the laparoscopic instrument, making it harder to grasp the object again and causing it to become more fragile and prone to breaking.

Another finding from Figure 27 is that for both group 1 and 2, the median relative depth was higher in the second trial without the force limiting mechanism compared to the other three trials without the force limiting mechanism. This could be attributed to participants gaining confidence from a successful first trial and applying more force in the second trial, resulting in breakage and a relative depth of 100 percent for the Floral foam object. However, this trend was not observed in the second trial with the force limiting mechanism in both groups, indicating that the mechanism prevents excessive force due to participant confidence.

The objective of the pre-clinical experiment was to determine whether there would be no difference in slippages between the laparoscopic instrument with the force limiting mechanism and the laparoscopic instrument without the force limiting mechanism in a pre-clinical setting. Figures 28 and 30 show the results of the slippages of the two instruments. The results showed no significant difference between the two instruments (p=0.068), indicating that the force limiting mechanism does not contribute to an increase in slip and that the hypothesis is met. However, both figures show that more slippages occurred with the laparoscopic instrument, although no significant difference was found. This can be explained by the fact that the forceps of the laparoscopic instrument have to exert a high pinching force to prevent slipping, and the force limiting mechanism influence the exerted pinching force.

The results of the questionnaire showed that no difference was found between the two instruments for rating the difficulties of moving the Floral foam object and their weight, indicating that the participants did not feel difference in the instruments. as can be seen in Figures 31 to 34. Figure 35 further supports this finding, as participants were asked to rate their awareness of resistance when using the instrument with the force limiting mechanism. More than half of the participants reported no difference in resistance, suggesting that they did not feel the force limiting mechanism in action. While the force limiting mechanism was designed to remain F_{pinch} at a constant value and not to give force feedback, it is still noteworthy that participants did not were aware of any resistance difference despite the significant improvement in results with its use. This appoint the need for also force feedback systems to be implemented within laparoscopic surgery in order to increase the awareness of the user of the applied force on tissues.

It was validated that the force limiting mechanism is able to be tested on its pre-clinical performance. However, there are some limitations to setup of the validation.

The first limitation pertains to the use of Floral foam object. While this material is helpful in measuring depth, it is also quite fragile. In certain trials, participants unintentionally broke the Floral foam object before the experiment was completed, rendering the trial incomplete. Moreover, if the Floral foam object slipped, some of the material adhered to the forceps of the laparoscopic instrument, making it more challenging to grip the object again due to the removed material. An alternative material could be explored to address this issue. The second limitation relates to the depth perception of the box trainer, which made it challenging for participants to visualize the box where the synthetic object had to be placed. Pulling the Floral foam object after grasping it created the box, but it became more difficult to pull further due to the elastic fixed on its holder. To address this issue, a line was drawn on the setup to guide participants on how far to pull. Another limitation was that participants had difficulty grasping the Floral foam object with the whole surface area of the forceps. To overcome this, participants received feedback on whether they had grasped the object with the whole surface area of the forceps. The final limitation is that the height of the Floral foam objects for the first six participants was not 18 mm as required. To address this issue, the height of the Floral foam objects was checked and adjusted to 18 mm at the beginning of the experiment for the remaining 14 participants. To correct the data for the first six participants, the Floral foam objects with incorrect heights were excluded, resulting in a total of 73 and 72 data points for groups 1 and 2, respectively, and a total of 73 and 72 data points for the laparoscopic instrument without and with the force limiting mechanism, instead of the expected 80 data points for all conditions. However, this did not affect the results.

Some recommendations for further research include exploring the use of multiple materials since the human body contains a wide range of material properties, and without experimenting with other materials, it is uncertain whether the same results will be observed. Moreover, the setup should be tested in a clinical environment to determine the feasibility of using the laparoscopic instrument with the force limiting mechanism in a real surgical setting. Additionally, the design could be implemented in robot-assisted surgery, but further research and design optimization are necessary before this can be achieved.

6. Conclusion

The results showed that the pinching force of the laparoscopic forceps remained constant, while the force in the rod increased when the force limiting mechanism was integrated into the laparoscopic instrument. Furthermore, a pre-clinical experiment demonstrated the effectiveness of the force limiting mechanism, as it led to a significant improvement in performance compared to the laparoscopic instrument without the mechanism.

Our data suggest implementing of a force limiting mechanisms in addition to force feedback could help prevent complications resulting from excessive applied force by the user.

It can be concluded that the force limiting mechanism in a laparoscopic instrument has been successfully designed, produced and validated. However, further research is needed to investigate the limitations of the design and to test it in various (pre-)clinical settings and combining the instrument with a feedback mechanism. This way, tissue damage could be prevented caused by excessive applied force by the surgeon during laparoscopic surgery.

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APPENDIX A
MECHANICAL EVALUATION SHAFTLOCK

R. Miedema's paper [16] presents the design of a compliant component called the Shaftlock, which can be implemented into a laparoscopic instrument. When force is applied, the Shaftlock component undergoes a displacement proportional to the magnitude of the force in the rod of the laparoscopic instrument.

This paper has modified the Shaftlock component by changing the material and adding an oval construction and rip teeth. In R. Miedema's paper, the Shaftlock was made of 7075 T6 Aluminium, while this paper uses Nitinol instead. Nitinol provides a higher yield stress, making it stronger and more durable under higher stresses. The oval construction provides additional protection against buckling, and the ribbed teeth have been added to the two end tips of the Shaftlock component. The modified Shaftlock component can be seen in Figure 36.

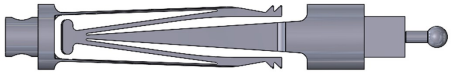

Fig. 36. Shaftlock component in Solidworks 2021. An oval construction and rip teeth on the two end tips are added.

The Shaftlock component, once installed in the laparoscopic instrument, undergoes a 4 mm displacement in the x-direction as the forceps of the instrument open and close. Additionally, the Shaftlock component behaves as a compliant element, resulting in further x-direction displacement due to the force in the rod of the laparoscopic instrument. The relationship between F_{rod} and the displacement of the Shaftlock in the x-direction was studied by R. Miedema [16]. These prescribed x-displacements were used in a non-linear Solidworks 2021 study to determine the maximum y-displacements of the end tips of the Shaftlock component. The displacements were analyzed for F_{rod} values of 18 N, 35 N, and 70 N.

The values of F_{rod} chosen for the study were 18 N, 35 N, and 70 N, which correspond to pinching forces of 10 N, 20 N, and 40 N respectively, applied by the forceps (with an angle of 20 degrees) of the laparoscopic instrument [25].

Using the displacements of the Shaftlock component obtained from the non-linear study in Solidworks 2021, a component can be designed that can effectively lock the end tips of the Shaftlock. The simulation results can be seen in Figure 37.

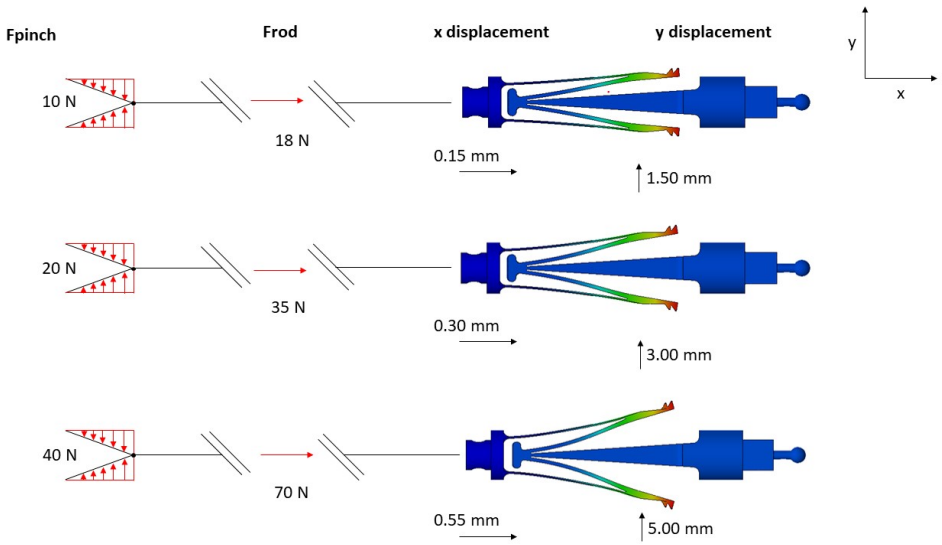

Fig. 37. Displacements of Shaftlock for a pinching force F_{pinch} of 10 N, 20 N and 40 N. The maximum displacements of the ends tips of the Shaftlock in y direction are 1.50 mm, 3.00 mm and 5.00 mm respectively. Simulated in Solidworks 2021.

APPENDIX B
VISUALIZATION THREE FORCE LEVELS

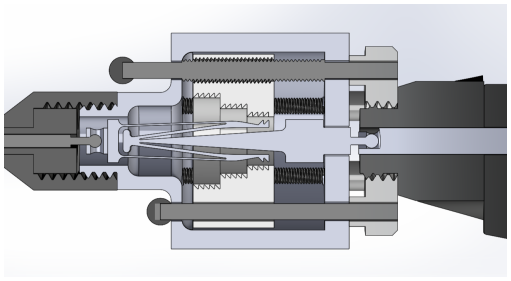

Fig. 38. Cross section of the design in Solidworks 2021 for the first force level of 10 N.

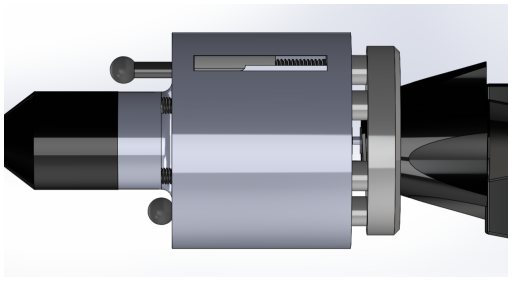

Fig. 39. Side profile view of the design in Solidworks 2021 for the first force level of 10 N.

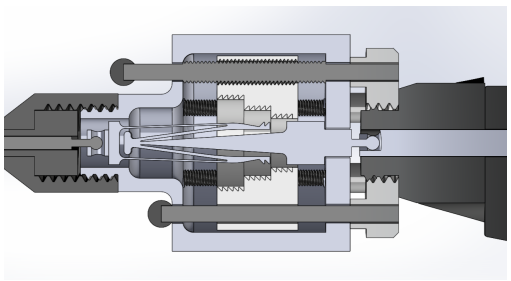

Fig. 40. Cross section of the design in Solidworks 2021 for the first force level of 20 N.

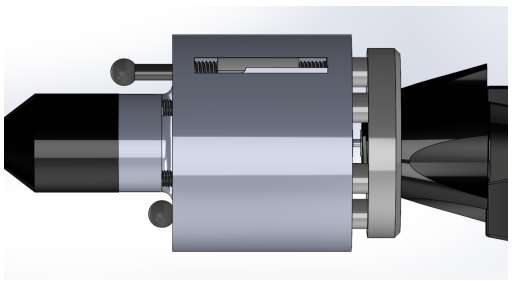

Fig. 41. Side profile view of the design in Solidworks 2021 for the first force level of 20 N.

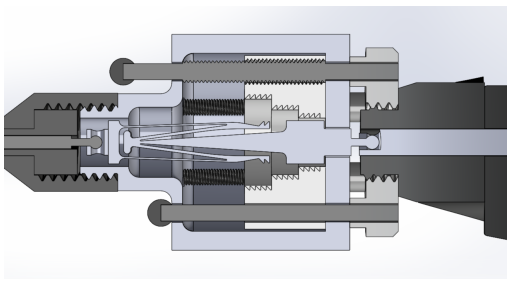

Fig. 42. Cross section of the design in Solidworks 2021 for the first force level of 40 N.

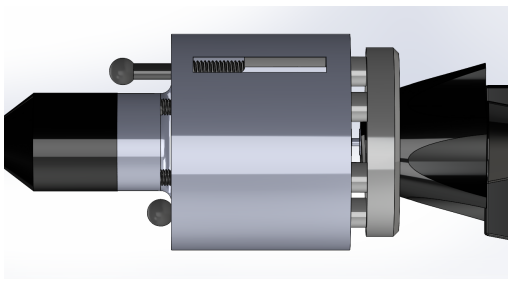

Fig. 43. Side profile view of the design in Solidworks 2021 for the first force level of 40 N.

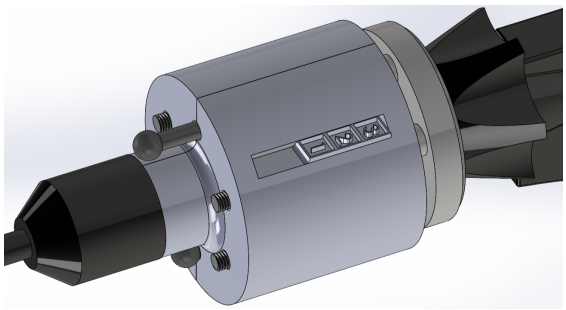

Fig. 44. Side profile view of the design in Solidworks 2021. In order to adjust the desired force level the user can translate the Conicoco to number 1, 2 and 3. Respectively meaning the first, second and third force levels of 10 N, 20 N and 40 N.

APPENDIX C
DESIGN PROGRESS CONICOCO COMPONENT

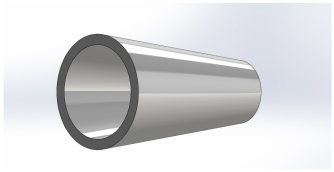

Fig. 45. V1: The first design of the Conicoco featured a basic conical shape with a diminishing diameter as its length increased.

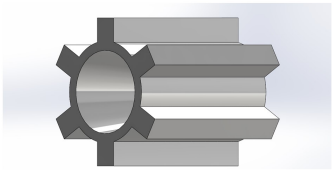

Fig. 46. V2: To modify the force level of the Conicoco, two clamps were added for each level of force.

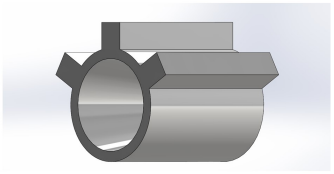

Fig. 47. V3: One clamp was removed for each force level adjustment.

Fig. 48. V4: As the clamps were found to be an inadequate solution for adjusting the force levels, they were removed and replaced with a screwlead at the top of the Conicoco. Additionally, its length was reduced to 10 mm.

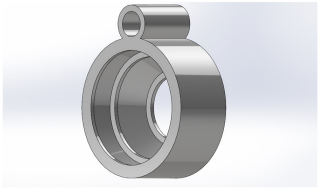

Fig. 49. V5: Three rows of crosscut teeth were implemented into the Conicoco, initially for force levels of 10 N, 30 N, and 50 N. Moreover the screwlead height was changed so it fit in the outside layer of the design.

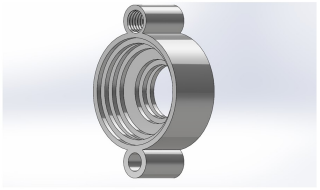

Fig. 50. V6: The angle of the forceps on the laparoscopic instrument affects the location where the teeth of both the Shaftlock and Conicoco will meet. Therefore, more rows of crosscut teeth were added for each force level. An extra axle secures the Conicoco.

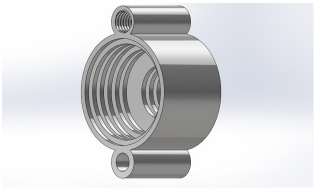

Fig. 51. V7: The length of the Conicoco was extended to 15 mm, resulting in five rows of crosscut teeth for each force level.

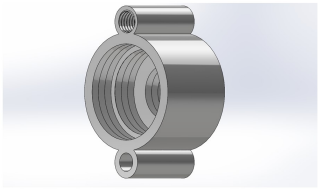

Fig. 52. V8: To prevent both x and y displacements of the Shaftlock, the crosscut teeth were replaced with rip teeth.

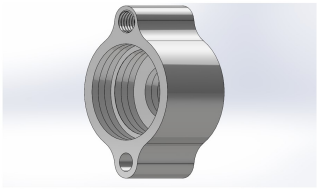

Fig. 53. V9: Fillets were incorporated around the outside layer in order to fabricate the Conicoco.

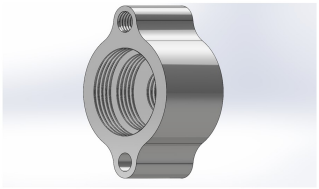

Fig. 54. V10: The height of the rip teeth was adjusted to 1 mm with a 45-degree angle to enable the fabrication of Conicoco. Moreover, the force levels were changed to 10 N, 30 N and 40 N.

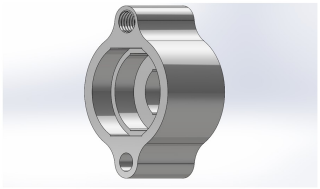

Fig. 55. V11: The rip teeth were removed except for those at the top and bottom of the Conicoco, which were added horizontally.

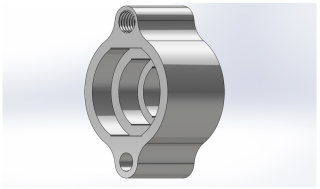

Fig. 56. V12 - Final design: The force levels were modified to 10 N, 20 N, and 40 N, and the smallest diameter was enlarged for easy fitting of the Shaftlock into the Conicoco.

APPENDIX D
DESIGN PROGRESS FORCE LIMITING MECHANISM

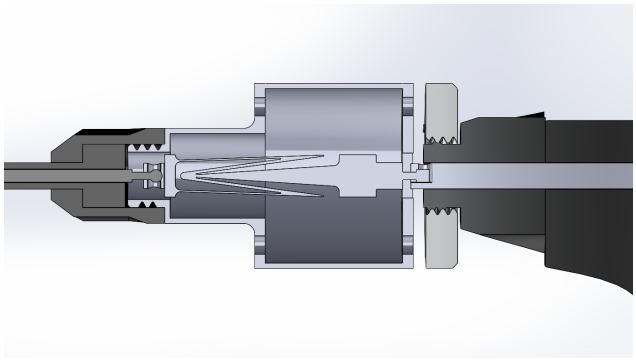

Fig. 57. First version of the design. The Shaftlock component without modifications is implemented in the two enclosure components. One side of the enclosure components is secured to the rod of the laparoscopic instrument with a screw. The other side is not fixed in this version.

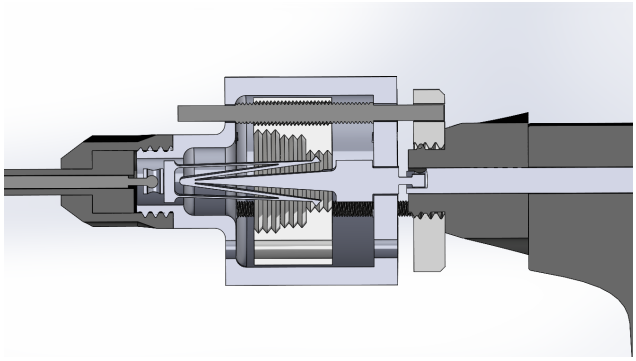

Fig. 58. Second version of the design. The Shaftlock component with the crosscut teeth is implemented in the two enclosure components. Moreover, the eight version the Conicoco and its screwlead is also implemented. The two enclosure components are thicker and the length has been decreased.

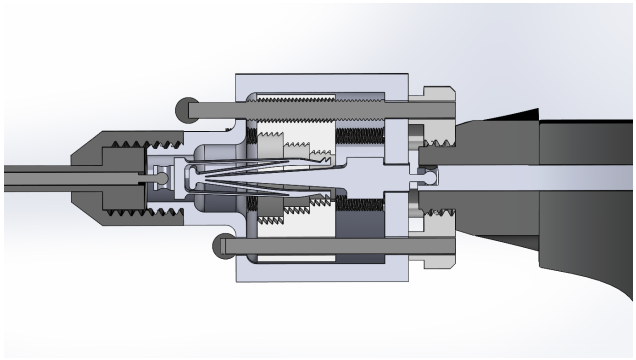

Fig. 59. Third version of the design. The rip teeth have replaced the crosscut teeth on both the Shaftlock and Conicoco components. Additionally, an extra tube has been added to the connection piece component of the two enclosure components in order to prevent bending in the design. Finally, the leading axis has be added.

APPENDIX E
INITIAL RESULTS MECHANICAL VALIDATION

The third experiment aimed to compare F_{pinch} and F_{rod} for two different Shaftlock conditions. The first condition involved using the laparoscopic instrument with the Shaftlock component, while the second added the force limiting mechanism for the first force level of 10 N for F_{pinch}. As shown in Figure 60, there were noticeable differences in the transmission ratio between F_{pinch} and F_{rod} between the two conditions.

In the first condition (orange), the transmission ratio remained constant up to 65 N. However, in the second condition (pink), the transmission displayed differences. Firstly, from 0.2 N of F_{pinch} to 2 N of F_{pinch}, the slope of the transmission ratio was steeper, indicating a more rapid increase in F_{pinch}. Additionally, when F_{rod} reached 60 N, F_{rod} decreased to 22 N without the laparoscopic instrument rod being turned back.

To overcome these discrepancies, which indicated slippage within the test setup, the bolts were tightened more firmly to prevent slippage.

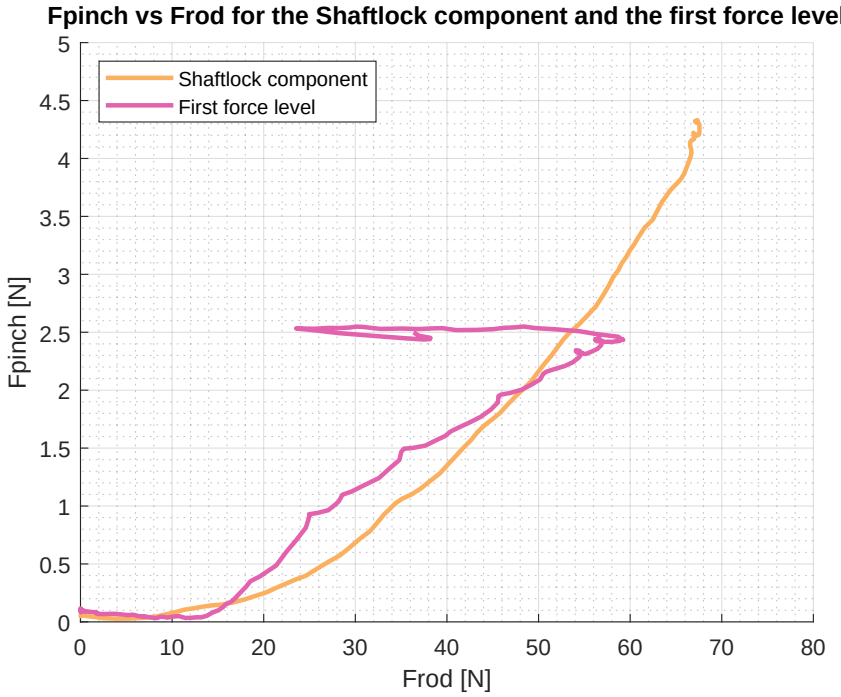

Fig. 60. F_{pinch} vs F_{rod} for two different Shaftlock conditions before modifications in the test setup. The first condition involved using the laparoscopic instrument with the Shaftlock component, while the second added the force limiting mechanism for the first force level of 10 N (pink).

APPENDIX F
HREC APPROVAL

Date 20-Jan-2023
Contact person Dr. Cath Cotton, Policy Advisor Academic Integrity
E-mail c.m.cotton@tudelft.nl

Human Research Ethics Committee
TU Delft
(http://hrec.tudelft.nl/)

Visiting address
Jaffalaan 5 (building 31)
2628 BX Delft

Postal address
P.O. Box 5015 2600 GA Delft
The Netherlands

Ethics Approval Application: The design and integration of a force limiting mechanism in a laparoscopic grasper, consisting of a compliant and a block element in order to prevent excessive forces applied by the surgeon
Applicant: Schlösser, Eva

Dear Eva Schlösser,

It is a pleasure to inform you that your application mentioned above has been approved.

Thanks very much for your submission to the HREC which has been approved. In addition to any specific conditions or notes, the HREC provides the following standard advice to all applicants:

- In light of recent tax changes, we advise that you confirm any proposed remuneration of research subjects with your faculty contract manager before going ahead.
- Please make sure when you carry out your research that you confirm contemporary covid protocols with your faculty HSE advisor.
- Our default advice is not to publish transcripts or transcript summaries, but to retain these privately for specific purposes/checking; and if they are to be made public then only if fully anonymised and the transcript/summary itself approved by participants for specific purpose.
- Where there are collaborating (including funding) partners, appropriate formal agreements including clarity on responsibilities, including data ownership, responsibilities and access, should be in place and that relevant aspects of such agreements (such as access to raw or other data) are clear in the Informed Consent.

Good luck with your research!

Sincerely,

Dr. Ir. U. Pesch
Chair HREC
Faculty of Technology, Policy and Management

Fig. 61. HREC approval