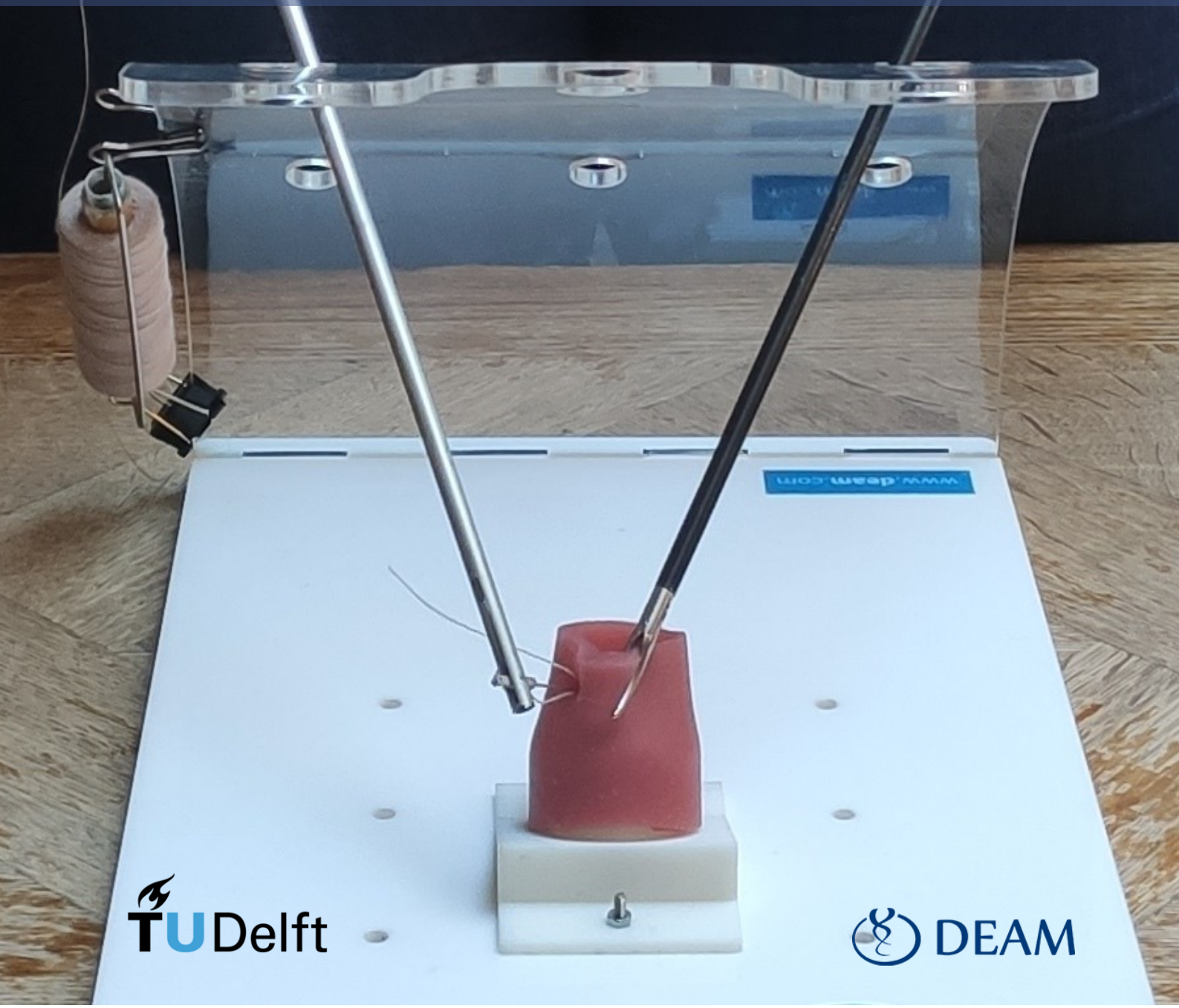
W.R. Beers

Design and development of the Hornet

A new suturing device for laparoscopic surgery



TU Delft

DEAM

Design and development of the Hornet

A new suturing device for laparoscopic surgery

By

W.R. Beers

in partial fulfilment of the requirements for the degree of

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This thesis is confidential and cannot be made public until August 26, 2023.

An electronic version of this thesis is available at http://repository.tudelft.nl/.

Preface

Before you lies the master thesis “Design and development of the Hornet”, the result of a research and development project to design, build, and test a new suturing device for laparoscopic surgery. This thesis was written to fulfil the requirements of the master Biomedical Engineering at the TU Delft.

The project was performed in collaboration with DEAM, a Dutch company that develops and produces steerable medical devices. Before this master thesis, I undertook an internship at DEAM where I worked on a previous prototype of the Hornet. I was excited when DEAM asked me to continue the development of the Hornet for my master thesis, as I enjoyed my experience as an intern at their company.

I would like to express my gratitude to Jules Scheltes, my supervisor from DEAM, for his guidance, feedback, and patience during the development of this new Hornet prototype. He was always available to brainstorm ideas, to help me evaluate a new design, and to prepare for meetings with the consulting gynecologists. I would also like to thank Dr. John van den Dobbelsteen, my supervisor from the TU Delft, for always replying quickly with answers to my questions, and for his patience and understanding when things did not go as planned. My thanks are also extended to the two consulting gynecologists, doctors J. Rhemrev and J. English, for all their input and enthusiastic responses to the new designs. They provided most of the user requirements for the new design, and helped me by giving me the opportunity to attend a few laparoscopic procedures. Finally, I would like to thank all the participants of the user tests for making time to help me evaluate the prototype, and for providing extensive feedback on the design and functioning of the instrument.

W.R. Beers

Delft, August 2021

Abstract

Laparoscopic suturing is one of the most difficult and time-consuming tasks in laparoscopic surgery. The long instrument shafts, two-dimensional view, and limited space for movement make simple actions, such as grasping and manipulating the needle and thread, difficult in the laparoscopic setting. To simplify the suturing process, the Hornet project was started by DEAM. The company was asked by two gynecologists to create a laparoscopic suturing device that simplifies the closure of the vaginal cuff during a total laparoscopic hysterectomy. The first prototypes that were created had promising design elements, but their suturing techniques proved difficult to execute. The modified sewing machine suturing technique was created to solve these issues, resulting in the aim of this thesis: to develop a laparoscopic suturing instrument that uses the modified sewing machine suturing technique to simplify the closure of the vaginal cuff.

A new prototype of the Hornet was designed based on a list of Product Specifications. The needle is fixated to a rotation mechanism in the shaft that allows the user to choose and fixate the angle of the needle. The thread is attached to the needle and can be blocked with a ring on the handle to apply tension to the thread during suturing. The handle has a unique shape, designed to actuate the Hornet's functionalities comfortably. This instrument, Hornet prototype B3, was built and subsequently tested in a series of design verification tests to determine if the design meets the Product Specifications. Additionally, a series of user tests was executed to verify whether the design simplifies the closure of the vaginal cuff. In the tests, the participants placed sutures with both the Hornet and with the regular suturing method. Participants with different levels of suturing and laparoscopic experience were included to determine the effect of experience on the suturing results with the Hornet.

The tests showed that the prototype simplifies the suturing process. All participants were able to place a closed suture with the Hornet, whereas only 43% of the participants placed a closed suture with the regular suturing method. The participants without laparoscopic experience had significantly shorter suturing times with the Hornet compared to regular suturing, indicating that the suturing method with the Hornet is simpler to learn. The participants with laparoscopic experience performed similarly with the Hornet and the regular suturing method, indicating that the first time the Hornet is used gives similar results to experience with regular laparoscopic suturing.

From this research, it can be concluded that the Hornet prototype B3 simplifies the closure of the vaginal cuff when compared to regular suturing. The rotatable needle of the Hornet eliminates the difficult needle manipulations of regular suturing, resulting in faster and simpler suture placement. To further confirm this claim, additional development and testing of the prototype is needed. Some alterations to the prototype design are required to improve its functioning and to ensure that all the product specifications are met. Additional tests are needed to investigate the extent in which the prototype simplifies the suturing process and to determine the learning curve of the Hornet.

Contents

Glossary

Term	Definition
Distal	Defined by Oxford Dictionary as “situated away from the centre of the body or from the point of attachment” [1].
Laparoscopic surgery	A minimally invasive procedure where a camera and instruments enter the abdominal cavity through small incisions, rendering large surgical incisions that can lead to scarring unnecessary.
Proximal	Defined by Oxford Dictionary as “situated nearer to the centre of the body or the point of attachment” [1].
Suture	This word can have two meanings, depending on the context. The word can refer to the thread that is attached to the needle during suturing, or the word can refer to the stitch or row of stitches created during suturing. In this thesis, the word ‘suture’ is used to mean a stitch or row of stitches created during suturing.
Thread	In this thesis, the word ‘thread’ is used as an alternative for the word ‘suture’ to prevent confusion (see ‘suture’ for more information).
Total Laparoscopic Hysterectomy	A laparoscopic procedure where the cervix and uterus are removed.
Vaginal cuff	The vaginal cuff is defined as “the portion of the vaginal vault remaining open to the peritoneum following hysterectomy” [22].

1

Introduction

1.1. Background

1.1.1. Laparoscopy & laparoscopic suturing

Laparoscopic surgery, or laparoscopy, is a form of minimally invasive surgery where a camera and instruments enter the abdominal cavity through small incisions. The abdomen is inflated to provide the surgeon with a working space, and a camera (the laparoscope) provides the surgeon with visuals of the surgical field and the instruments inside the body. The instruments enter the abdominal cavity through trocars placed in small incisions in the abdominal wall. An example of the laparoscopic set-up is shown in Figure 1. The advantages of laparoscopic surgery over open surgery include a reduction in complications, shorter operating times, a reduced hospital stay, and less scarring [2].

Figure 1: A typical lay-out for Laparoscopic surgery. The instruments are operated by the surgeon [right], who views his actions on the monitor. The assistant [left] holds and moves the camera to provide the surgeon with the optimal view. [3]

Laparoscopic suturing is the placement of internal sutures using the laparoscopic setting and tools. Similar to suturing during open surgery, the tools needed for laparoscopic suturing are a needle holder, a grasper (or forceps in open surgery), and a needle with suture thread. The needle and thread are inserted through the trocar, and picked up by the needle holder inside the body. The suture is placed by passing the needle through the tissue using the needle holder and grasper, as shown in Figure 2. The stitch is fixated with a series of knots and the suture is either finished, creating an interrupted suture, or continued, creating a running suture.

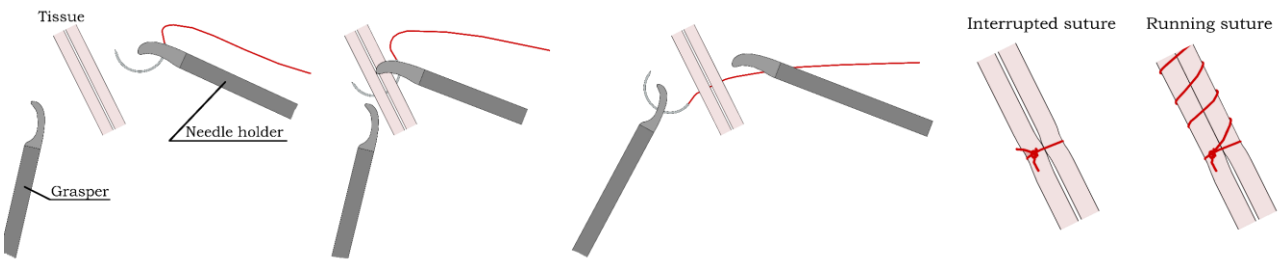


Figure 2: Illustration of the first steps of suture placement [left] and the two types of final sutures [right].

1.1.2. Origin of the Hornet Project

The development of Hornet prototype B3, as presented in this thesis, was in collaboration with DEAM, a Dutch company that develops and produces steerable medical instruments. The Hornet project is one of their current Research and Development projects and was previously worked on by another student from the TU Delft. The project idea originates from the gynecologists Dr. J. Rhemrev and Dr. J. English, hereafter called the *consulting gynecologists*, that frequently collaborate with DEAM on R&D projects. The consulting gynecologists requested an instrument that would simplify the closure of the vaginal cuff during a Total Laparoscopic Hysterectomy (TLH), a laparoscopic procedure where the cervix and uterus are removed. Suturing the vaginal cuff during a TLH is difficult due to the low placement in the abdomen and the small operating field [4], giving the surgeons a limited space to move their instruments. This resulted in the Hornet project, which aims to develop a suturing instrument that makes suture placement in the vaginal cuff easier.

1.1.3. Previous Hornet Prototypes

Two functional prototypes preceded the research in this thesis: prototype B1 and prototype B2, shown in Figure 3 and Figure 4 respectively.

Figure 3: Sideview of Prototype B1, made in Solidworks.

Figure 4: Sideview of Prototype B2, made in Solidworks.

Both prototypes used a similar method to place a suture, shown in Figure 5. For prototype B1, the needle was attached to the distal end of the instrument. The thread, attached to a tube, could be loaded onto the needle to guide it through the tissue. Once through the tissue, the tube is pulled from the needle with a grasper to complete the stitch, and the thread is reloaded onto the needle for the second stitch. This combination of a needle and a tube, however, proved to be too bulky compared to the thread diameter, creating oversized holes in the tissue. For prototype B2, the thread was instead attached to a loose needle. The needle could be loaded into a holder at the distal end of the instrument, allowing the user to easily insert the needle in the tissue. Once through the tissue, the needle is pulled from the holder to complete the stitch, and re-inserted in the instrument for the second stitch.

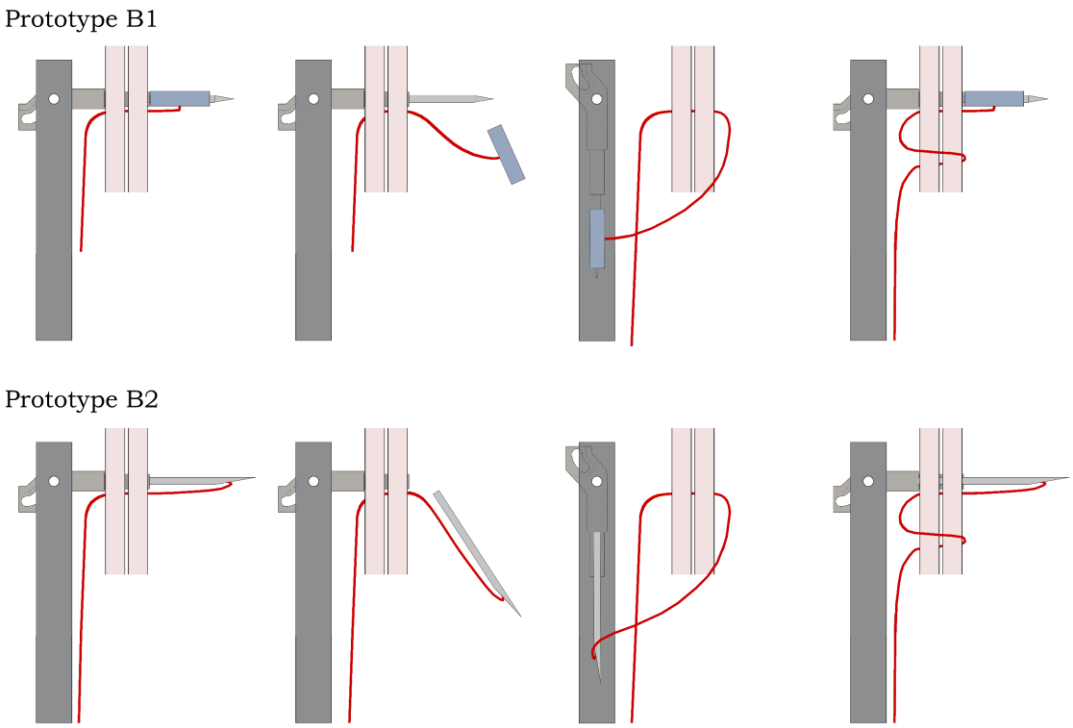


Figure 5: Illustrated depictions of the suturing methods with prototypes B1 and B2.

The prototypes were evaluated by DEAM and the consulting gynecologists. An overview of the user input for development of the new Hornet prototype based on these evaluations is given in Appendix A.

In both prototypes, the needle was attached to a rotation mechanism that allowed the user to change the angle of the needle. This gives the user the ability to align the needle more accurately than is possible when holding a needle with a needle holder. In prototype B1, the needle was fixated in the shaft, taking away the struggles associated with grasping and manipulating the needle with a needle holder [5].

One of the main issues with both prototypes was the difficulty of reloading the tube/needle in the instrument. This required complicated movements with the grasper, which proved difficult in the laparoscopic setting.

1.2. Applicability of a modified sewing machine suturing technique

The evaluation of the previous prototypes showed that the fixation of the needle in the shaft removed the difficulties of grasping, manipulating, and aligning the needle with a needle holder during laparoscopic suturing. The main downside of the previous prototypes, however, was the difficulty of the actions required to complete the suturing process. Fixating the needle with thread in the rotation mechanism removes the reloading issues of the previous prototypes. However, placing a suture with the needle fixated in the instrument requires a new suturing technique where the needle is inserted in the tissue, but not pulled through. This resembles the way a sewing machine creates stitches in fabric.

A sewing machine stitch consists of two threads that are interlocked inside the fabric. The sewing machine technique, when simplified, consists of five steps, illustrated in Figure 6.

1. The needle of the sewing machine is pushed through the fabric
2. A loop formed at the tip of the needle is grabbed by a rotating hook
3. The hook pulls the upper thread (red) around the lower thread (blue)
4. The upper thread is released by the hook
5. The needle pulls back and the stitch is tightened.

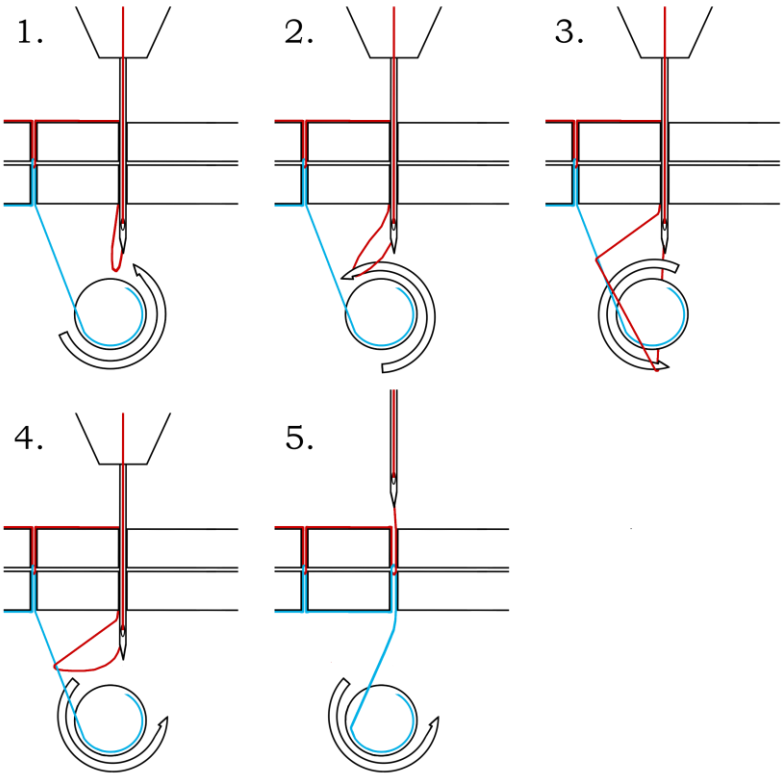


Figure 6: Simplified illustration of the sewing machine technique to place a stitch.

Converting this technique to a laparoscopic suturing technique is simple, as all the actions required can be executed with the Hornet and a grasper. The main difference between the techniques is that the suturing technique will use one thread, instead of two. Translating the steps of the sewing machine stitch to the laparoscopic setting with the Hornet, gives the 'modified sewing machine suturing technique' for the Hornet, illustrated in Figure 7.

1. Push the needle through the tissue
2. Pull back the needle slightly to create a loop
3. Grab the loop with the grasper, and make the loop bigger
4. Move the grasper through the loop and grab the end of the thread
5. Pull the thread through the loop
6. Tighten the stitch by pulling on the Hornet and grasper

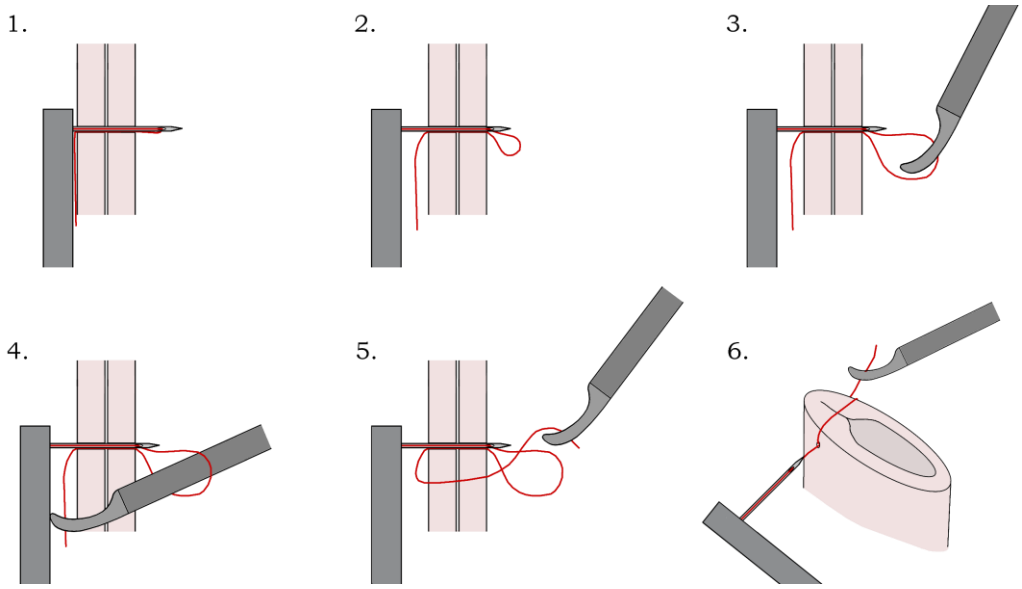


Figure 7: Illustrated depiction of the modified sewing machine suturing technique.

To evaluate the applicability of the suturing technique illustrated in Figure 7 for the closure of the vaginal cuff, silicon models were developed and closed with different suturing methods. These models, shown in Figure 8, were evaluated with the consulting gynecologists. The creation of the vaginal cuff models is described in Appendix Q, and the full evaluation of the closure methods is presented in Appendix R. From this evaluation, it was concluded that the modified sewing machine suturing technique looks promising for closing the vaginal cuff. The technique allows the user to distribute the tension in the suture after each stitch, ensuring that the vaginal cuff is uniformly closed and preventing the suture from loosening while placing a knot.

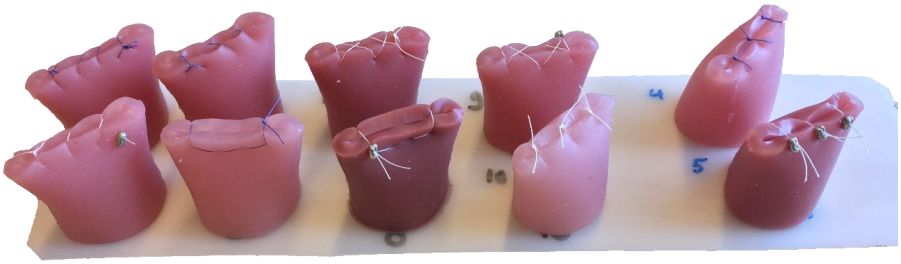


Figure 8: Models of the vaginal cuff with closed with different suture techniques and fastening methods.

1.3. Problem definition and objective

Laparoscopic suturing is widely considered to be one of the most difficult and time-consuming tasks in laparoscopic surgery [6]. Suturing requires many instrument actions that are hindered by the laparoscopic setting. The long shafts of the instruments make them difficult to handle and provide less tactile force feedback than in open surgery [7]. Additionally, the two-dimensional view of the surgical field on the monitor restricts depth perception [8]. Finally, the limited space available in the abdomen, combined with the difficulty to reach certain regions, results in awkward hand positions for the surgeon [9]. These complications make actions that are simple in open surgery, such as grasping and manipulating the needle and thread, difficult in a laparoscopic environment. The Hornet project aims to simplify the laparoscopic suturing and knot tying process by eliminating some of the issues associated with these tasks. Initially, the Hornet will be designed to suture the vaginal cuff, as was requested by the consulting gynecologists. For the new prototype, the aim is to incorporate the modified sewing machine suturing technique in the instrument. The goal of this thesis is therefore:

To develop a laparoscopic suturing instrument that uses the modified sewing machine suturing technique to simplify the closure of the vaginal cuff.

1.4. Approach

The following steps were taken to reach the goal of this thesis.

1. *Specify requirements*
   The Product Specifications for the new prototype were set up based on the evaluations of the previous prototypes, the opinions and wishes of the consulting gynecologists, and the wishes and expertise of DEAM. As the design process progressed, additional Product Specifications were added based on the design choices made. The Product Specifications are presented in *chapter 2*.

2. *Design process*
   During the prototype development, all the aspects of the new prototype were designed. For each component, several concepts were created and evaluated, after which the final components were modelled in SolidWorks. The design process included the creation of the modified sewing machine suturing technique for the Hornet, presented in *section 1.2*. The concepts and final designs of the different components created during the design process are presented in *chapter 3*.

3. *Prototype assembly*
   When the first design of the prototype was finished, the components were created and the Hornet prototype was assembled. After an initial evaluation with the consulting gynecologists, small changes were made to the design to create the final prototype for the user tests. The final prototype is shown *section 3.4*, and a full overview of the assembly of the prototype is given in Appendix J.

4. *Design verification*
   The design of the final prototype was verified with a series of tests, the Design Verification Tests. These tests were used to assess if the prototype meets the Product Specifications. The test designs, results, and discussion of the Design Verifications Tests are given in *chapters 4* and *5*.

5. *User tests*
   The functioning of the prototype, and whether it simplifies the closure of the vaginal cuff, were assessed with a series of user tests. A test protocol and a test set-up were created, and a group of participants was selected. The participants placed sutures with the prototype and the regular suturing method. Their results were used to verify the functioning of the prototype and to assess if the modified sewing machine suturing technique with the Hornet simplified the suturing process. The test designs, results, and discussion of the User Tests are given in *chapters 4* and *5*.

2

Product Specifications

Before the design process started, an initial list of Product Specifications was created. This list was adapted and expanded during the development process. The Product Specifications describe the functional requirements of the instrument in measurable acceptance criteria so that conformity can be proven in the verification tests. Input for these Product Specifications was received from the User Requirements and from choices made during the design process. The final list of Product Specifications is given in Table 1, and their origins are explained in *sections 2.1* and *2.2*. A full overview of the Product Specifications with their acceptance criteria and rationales is presented in Appendix C. The categories of the Product Specifications are based on the main design elements of the new prototype: the rotation mechanism (PS-2), the needle (PS-3), the thread (PS-4), the suturing technique (PS-5), and the handle (PS-6).

Table 1: List of all the Product Specifications, a brief description of their acceptance criteria, and a reference to their origin.

Product specification		Acceptance criteria	Origin
PS-1 : Overall			
PS-1.1	Tip and shaft diameter	Diameter ≤ 5.1 mm.	DEAM
PS-1.2	Working length of shaft (tip to base)	Length between 310 mm and 420 mm.	DEAM
PS-1.3	Hand size (length and width)	All features reachable by hands with length of 15.8-20.6 cm and width of 6.9-9.6 cm.	DEAM
PS-1.4	Single handed use	Usable with a single hand.	Design choice
PS-1.5	Right and left handed use	Usable with either hand.	DEAM
PS-2 : Needle deployment and retraction			
PS-2.1	Needle deployment force	Max force on fingers of 19.3 N.	Design choice
PS-2.2	Angle between needle and shaft	Angles of at least 135° possible.	Consulting gynecologist
PS-2.3	Fixation of the angle between the needle and the shaft	Needle angle fixable at 45°, 90°, and 135°.	Consulting gynecologist
PS-2.4	Automatic needle retraction	Automatic needle retraction when releasing the actuator.	DEAM
PS-3 : Tissue penetration			
PS-3.1	Needle length	Length of 25 +/- 2.0 mm.	Consulting gynecologist
PS-3.2	Needle diameter	Diameter between 0.88 mm & 1.28 mm.	Consulting gynecologist
PS-3.3	Needle sharpness	Puncture force of 2.8 N through stomach tissue.	Consulting gynecologist
PS-4 : Thread specifications			
PS-4.1	Diameter of thread	Diameter between 0.3 mm & 0.5 mm.	Consulting gynecologist
PS-4.2	Thread pliability	Multifilament thread.	Consulting gynecologist
PS-4.3	Working length of thread	Length of at least 23 cm.	Consulting gynecologist
***PS-5 :* Thread manipulation**			
PS-5.1	Thread flow through instrument is unhindered	No accidental blockage of the thread.	Design choice
PS-5.2	Loop formation at the proximal side of the deployed needle	Loop forms at proximal side of the needle.	Design choice
PS-5.3	Thread can be blocked	No slippage of thread during suturing.	Consulting gynecologist
PS-5.4	Length of thread at the tip can be adjusted.	Length of thread can be adjusted.	Consulting gynecologist
PS-5.5	Thread can flow through the NeedleBase	Thread flows through NeedleBase to needle.	Design choice
PS-6 : Handle			
PS-6.1	Reachability of handle features	All features accessible, regardless of handle rotation	Consulting gynecologist
PS-6.2	Simple handle design	All features are necessary and simple.	Consulting gynecologist

2.1. Product Specifications based on User Requirements

Most of the Product Specifications listed in Table 1 were based on the User Requirements. The User Requirements is a list of wishes and requirements that were generated from the evaluations of the previous prototypes, the wishes of the consulting gynecologists and the requirements set by DEAM based on their experience in the field of laparoscopic instrument development. An overview of all the relevant prototype evaluations and wishes from the gynecologists is given in Appendix A. The full list of User Requirements, including their origins and acceptance criteria, is presented in Appendix B. The origins of the Product Specifications based on the User Requirements are described below.

Consulting gynecologists

PS-2.2 & PS-2.3

Evaluation of the previous prototypes has provided insight into the wishes of the consulting gynecologists. The main positive feedback from the consulting gynecologists on the previous prototypes was the ability to adjust the angle of the needle with the Hornet. A feature they missed was the ability to lock the needle at different angles. Additionally, it was requested that the possible needle angles would be increased to reach 135°. In the previous prototypes, the angle had to be maintained by squeezing the handle, putting strain on the user's hand, and could only reach 90°. This resulted in the Product Specifications **PS-2.2** and **PS-2.3**, stating respectively that angles up to 135° should be possible, and that the needle can be fixated at 45°, 90°, and 135°. These three angles were suggested by the consulting gynecologists based on their experience with laparoscopic suturing.

PS-3.1 to PS-4.3

The consulting gynecologists requested a laparoscopic suturing instrument to simplify the closure of the vaginal cuff. This means that the Hornet prototype must be provided with a needle and thread that are suitable for suturing the vaginal cuff with the modified sewing machine suturing technique. Research into suturing the vaginal cuff has resulted in the Product Specifications for the needle length, diameter and sharpness (**PS-3.1**, **PS-3.2**, **PS-3.3**), and the thread diameter, pliability, and length (**PS-4.1**, **PS-4.2**, **PS-4.3**).

PS-5.3 & PS-5.4

Based on their experience with laparoscopic suturing, the consulting gynecologists stated that, to properly place a suture, the instrument should be able to put tension on the thread to tighten the suture and knots. Additionally, the length of the thread at the tip of the needle should be adjustable to ensure that the right amount of thread is available at any time to perform the suturing tasks. This resulted in Product Specification **PS-5.3**, stating that the thread can be blocked, and Product Specification **PS-5.4**, stating that the length of the thread at the tip can be adjusted.

PS-6.1 & PS-6.2

While discussing possible handle shapes, the consulting gynecologists noted that it should be possible to rotate the handle in the hand without losing access to the features on the handle. Furthermore, they stated that the design of the handle should be simple, with as few features as possible, to make the instrument user-friendly. While performing surgery, a user can get easily frustrated when an instrument is difficult or when features do not perform as expected. These requirements resulted in the Product Specifications **PS-6.1** and **PS-6.2** respectively.

DEAM

DEAM has more than 10 years of experience in developing laparoscopic instruments. Based on this experience, DEAM has put forward several Product Specifications.

PS-1.1, PS-1.2, PS-1.3, & PS-1.5

Four of the Product Specifications that were suggested by DEAM, aim to ensure that the Hornet can be used by most users in most laparoscopic set-ups. These specifications are the shaft diameter (**PS-1.1**), the length of

the instrument (**PS-1.2**), the guidelines for the dimensions of the handle based on hand sizes (**PS-1.3**), and the ability to use the instrument left- and right handed (**PS-1.5**).

PS-2.4
The Hornet has a system that allows the needle to be deployed from the shaft. To prevent the needle from accidentally causing damage inside the abdomen while not in use, the needle should retract automatically back in the shaft when the feature that operates this function is released. This requirement was recorded in Product Specification **PS-2.4**.

2.2. Product Specifications based on design choices

Five of the Product Specifications listed in Table 1 were based on choices made during the development of the prototype. In the design processes of the different components of the instrument, choices were made that influenced the design of other components. The requirements obtained from these choices were added to the Product Specifications.

PS-1.4, PS-5.2, & PS-5.5
Three Product Specifications were obtained from the development of the modified sewing machine suturing technique. The first Product Specification, **PS-1.4**, states that the instrument can be operated with a single hand, because a grasper is needed in combination with the Hornet to place a suture. The second Product Specification, **PS-5.2**, states that the loop created during suturing must be formed at the proximal side of the deployed needle. According to the consulting gynecologists, the loop is most accessible when formed at the proximal side of the deployed needle. The third Product Specification, **PS-5.5**, requires the thread to flow through the NeedleBase. For the modified sewing machine suturing technique, the thread needs to pass through the tip of the needle. To ensure that the thread is properly aligned, regardless of the angle of the needle, the thread must be guided through the NeedleBase, in which the needle is fastened (see *section 3.1.1*).

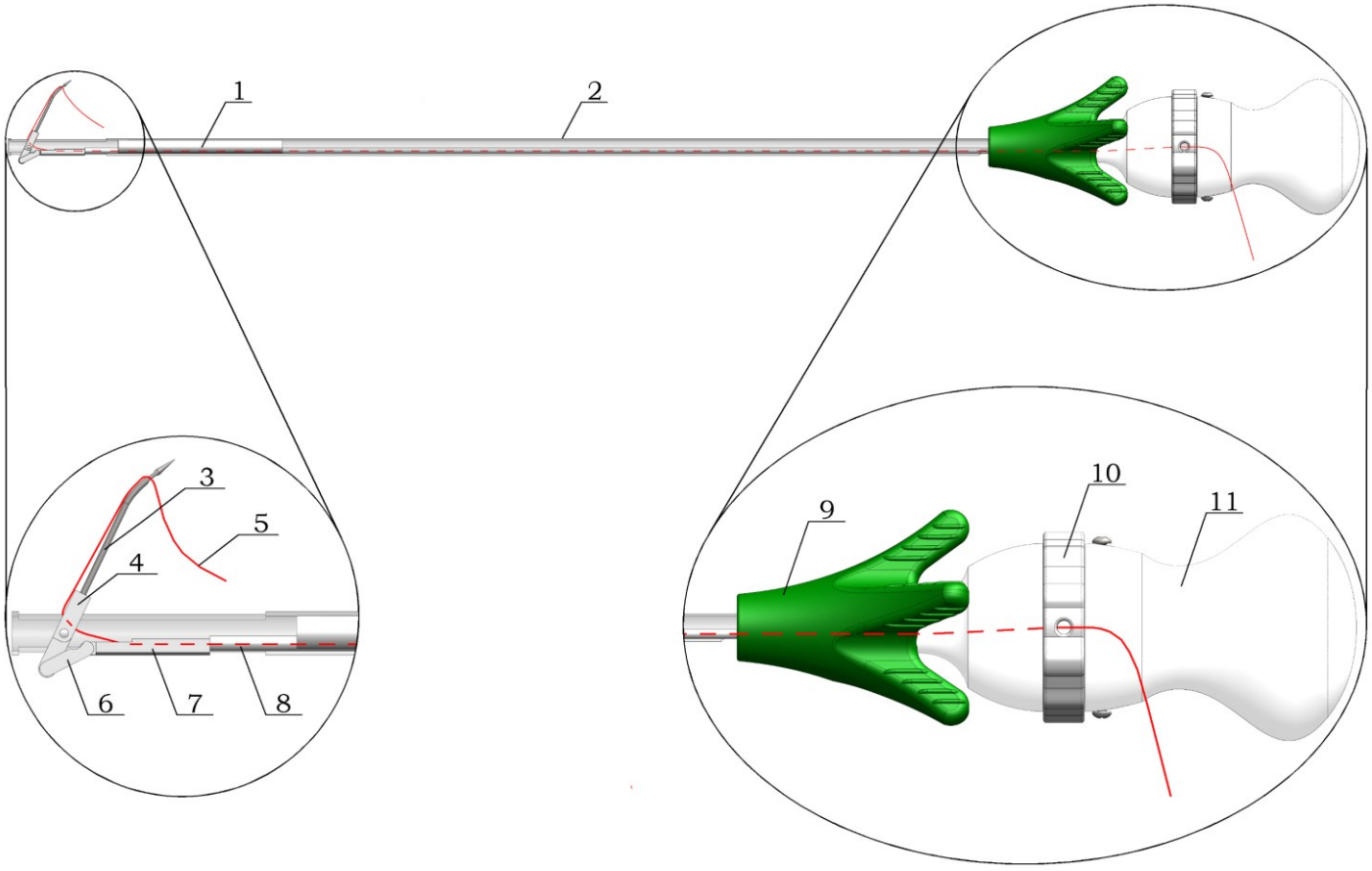
PS-2.1 & PS-5.1
Two Product Specifications resulted from the chosen concepts in the design processes of the Thread System and the Handle. In the design process of the Handle, presented in *section 3.3.2*, the chosen concept for the handle shape included the deployment of the needle by pulling a feature, the NeedleActuator, against a spring. To ensure that most users can deploy the needle comfortably, the forces on the fingers to deploy the needle need to be limited. These force limits were specified in Product Specification **PS-2.1**. During the design process of the Thread System, presented in *section 3.1*, it was decided that the thread would flow through the instrument. This resulted in Product Specification **PS-5.1**, stating that the thread can flow freely through the instrument.

3

Design

During the design process, multiple iterations of the instrument were made. The final design of the Hornet prototype B3 is shown in Figure 9. Short descriptions of the different parts, and references to where they are described in more detail, are given in Table 2.

The rationales behind the designs of each subsystem, including the investigated alternatives, are given in the sections below. The first section, **The Thread System**, describes the flow of the thread through the instrument, and how it influences the shape of the needle and other parts of the instrument. The second section, **The Rotation Mechanism**, describes the mechanism used to hold and deploy the needle. The third section, **The Handle**, describes the designs of the handle as a whole, the actuation of the Rotation Mechanism, and blocking the flow of the thread.



1. PullrodGuide
2. Shaft
3. Needle
4. NeedleBase
5. Thread
6. Hinge
7. PullrodHead
8. Pullrod
9. NeedleActuator
10. SutureRing
11. HandleBase

Figure 9: Final design of the Hornet prototype B3.

Table 2: Short descriptions of the parts shown in Figure 9, and references to the sections with elaborate descriptions.

Part	Short description	Additional information
1. PullrodGuide	A 3D printed component fixated around the Pullrod to prevent the Pullrod moving vertically in the shaft.	Appendix J: Prototype Assembly
2. Shaft	A tube connected to the handle that protects the mechanisms and thread within.	Appendix D: Technical drawings
3. Needle	A bent needle with an eye near the tip, through which the thread flows.	*Section 3.1 – The Thread System*
4. NeedleBase	Holds the needle and can be rotated to deploy the needle out of the shaft.	*Section 3.2 – The Rotation Mechanism*
5. Thread	The thread used to place a suture.	*Section 3.1 – The Thread System*
6. Hinge	Connects the NeedleBase to the PullrodHead.	*Section 3.2 – The Rotation Mechanism*
7. PullrodHead	Connects the Pullrod to the Hinge, and guides the thread from the Pullrod to the NeedleBase.	*Section 3.2 – The Rotation Mechanism*
8. Pullrod	The Pullrod consists of two tubes. The SutureGuide, used to guide the thread through the shaft, and a PullrodStiffener, used to prevent the SutureGuide from kinking.	*Section 3.2 – The Rotation Mechanism*
9. NeedleActuator	The actuator used to deploy the needle and fixate the angle of the needle.	*Section 3.3 –The Handle*
10. SutureRing	The ring used to block the flow of the thread as it exits the handle.	*Section 3.3 –The Handle*
11. HandleBase	The base shape of the handle.	*Section 3.3 –The Handle*

3.1. The Thread System

The Thread System comprises of the flow of the thread through the instrument and its operation. In order make placement of a suture with the Hornet possible, the thread should be able to reach the needle without being accidentally blocked or damaged. In addition, it should be possible to adjust the thread's length and to block the flow of the thread in order to facilitate knot-tying.

3.1.1. Flow of the thread at the needle

The modified sewing machine suturing technique, as described in *section 1.2*, requires the formation of a loop after the first stitch. For this, the thread needs to reach the tip of the needle. The thread can flow either through the needle and exit at the tip, or the thread can flow along the outside of the needle and through an eye at the tip.

Product Specifications

Listed in Table 3 are the relevant Product Specifications for the flow of the thread at the needle.

Table 3: Product Specifications relevant to the flow of the thread at the needle.

Product Specification		Acceptance criteria
PS-5.1	Thread flow through instrument is unhindered	The thread can flow freely through the instrument without accidentally being blocked.
PS-5.2	Loop formation at the proximal side of the deployed needle	When placing a suture, the required loop must form at the proximal side of the needle.

Concepts

Three concepts were created for the flow of the thread at the needle. Each concept guides the thread through the NeedleBase towards the needle to ensure that the thread reaches the needle properly and to prevent the thread getting stuck in the Rotation Mechanism. The different concepts are shown in Figure 10 and described below.

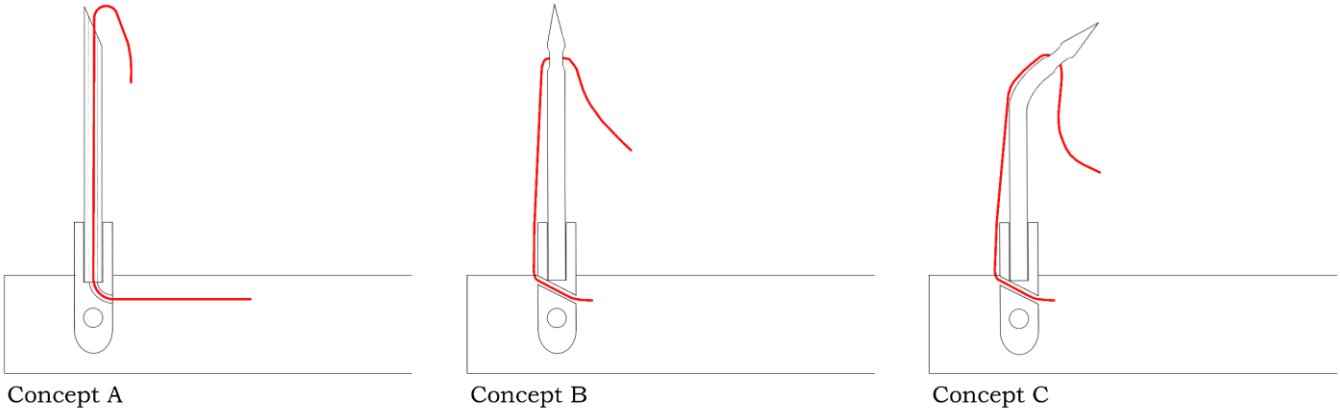


Figure 10: Concepts A, B, and C for the flow of the thread at the needle.

Concept A

In this concept, the thread flows through the NeedleBase into a hollow needle. Figure 10-A shows the flow of the thread through the needle, and Figure 11 shows how the flow of the thread influences the loop formation during suture placement.

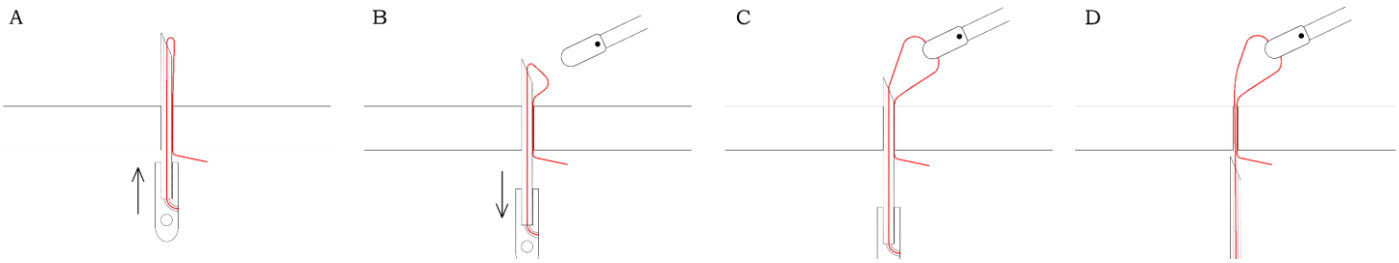


Figure 11: Influence of the flow of the thread on loop formation for Concept A.

Concept B

In this concept, the thread flows along the outside of a solid needle and is attached to the needle through an eye at the tip, as shown in Figure 10-B. In order to ensure that the loop is formed at the proximal side of the needle, the thread is guided through the NeedleBase and flows along the distal side of the needle to the tip. Figure 12 shows how the loop is formed for this concept.

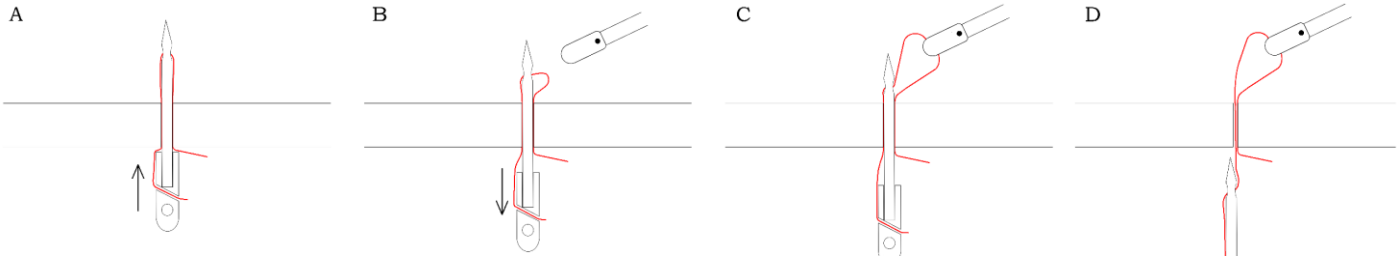


Figure 12: Influence of the flow of the thread on loop formation for Concept B.

Concept C

This concept is similar to concept B, but with a curved needle to make placement of the needle in the tissue easier and to ensure the formation of a graspable loop. The concept design is shown in Figure 10-C. The influence of the curvature of the needle on the loop formation is shown in Figure 13.

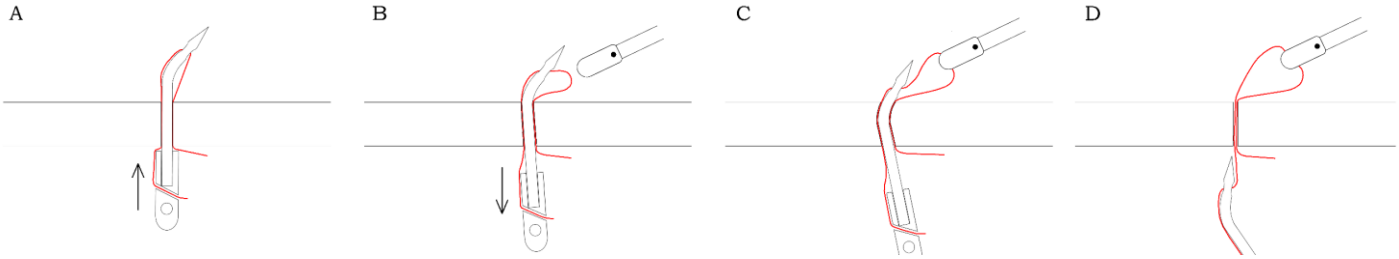


Figure 13: Influence of the flow of the thread on loop formation for Concept C.

Choosing a concept

All three concepts fulfill the relevant Product Specifications for the flow of the thread at the needle as they all allow for the unhindered flow of the thread and facilitate loop creation at the proximal side of the needle.

It was difficult to predict which concept allows for the best and most consistent loop formation during use. The NeedleBase was therefore designed to support all the concepts, see *section 3.2*. After building the prototype, the consulting gynecologists tested the three concepts. Summaries of these tests can be found in Appendix A. Finally, concept C was chosen and implemented in the final prototype for three main reasons:

1. Letting the thread flow along the outside of the needle allowed for better loop formation compared to concept A.
2. The curvature made placement of the needle in the tissue easier compared to the straight needles.
3. With all concepts, loop formation when retracting the needle was not consistent. When no loop was formed, the needle needed to be moved up and down with concepts A and B to force the loop to from to finish the suture. For concept C, however, this was not necessary. The curvature in the needle

creates a ‘pre-loop’, as can be seen in Figure 13-A. This made picking up the thread with the grasper possible, even when no loop was created.

3.1.2. Flow of the thread at the shaft

From the NeedleBase, the thread must be guided towards the handle. The thread can flow either through the shaft or along the outside of the shaft.

Product Specifications

Only one Product Specification is relevant to the flow of the thread at the shaft. This specification is given in Table 4.

Table 4: Product Specification relevant to the flow of the thread at the shaft.

Product Specification		Acceptance criteria
PS-5.1	Thread flow through instrument is unhindered	The thread can flow freely through the instrument without accidentally being blocked.

Concepts

Two concepts were created for the flow of the thread at the shaft. Both concepts and their advantages and disadvantages are described below.

Concept A

The thread flows from the NeedleBase, through the shaft, towards the handle.

Figure 14: Concept A, the flow of the thread through the shaft.

As the thread flows through the shaft, it is protected from accidental damage and soiling during transport and use. However, assembly of the instrument becomes more difficult as the thread has to be guided through the entire system before the instrument is assembled fully.

Concept B

The thread flows from the NeedleBase, out of the shaft, and moves along the shaft towards the handle.

Figure 15: Concept B, the flow of the thread along the outside of the shaft.

Assembly of this concept is easier compared to concept A, as the thread does not have to be guided through the entire instrument. The disadvantage of the thread flowing along the outside of the shaft, however, is that the thread can be damaged or soiled accidentally before or during use. In addition, the dangling thread along the shaft during use can get tangled with the other instruments used during a procedure.

Choosing a concept

Both concepts allow for the thread to move through the instrument unhindered, thus meeting the relevant Product Specification PS-5.1.

Based on the advantages and disadvantages listed for each concept, it was decided to let the thread flow through the shaft. The protection of the thread was considered to have a higher priority than the ease of the assembly of the instrument. In order to prevent the thread from piling up in the shaft, and to properly guide the thread towards the NeedleBase, it was decided to create a hollow Pullrod through which the thread can flow. Giving the Pullrod this added function allows the thread to be properly guided, without adding another component inside the shaft.

3.1.3. Flow of the thread at the handle

As decided above, the thread reaches the handle through the shaft. The handle has three main functions with respect to the thread system:

1. Storage of the thread
2. Adjusting the length of the thread
3. Blocking the flow of the thread

Each function influences the flow of the thread and how it can be manipulated.

Product Specifications

Table 5 lists the Product Specifications that are relevant to the flow of the thread at the handle.

Table 5: Product Specifications relevant to the flow of the thread at the handle.

Product Specification		Acceptance criteria
PS-4.3	Working length of thread	The working length of the thread should be at least 23 cm.
PS-5.1	Thread flow through instrument is unhindered	The thread can flow freely through the instrument without accidentally being blocked.
PS-5.3	Thread can be blocked	The flow of the thread can be blocked. When blocked, a suture and knot can be placed without the thread slipping.
PS-5.4	Length of thread at the tip can be adjusted	The length of the thread at the tip of the instrument can be adjusted during use.
PS-6.1	Reachability of handle features	All features on the handle can be reached regardless of how the handle is rotated in the hand.
PS-6.2	Simple handle design	All features on the Handle must be necessary and simple to use.

Concepts

The design of the flow of the thread at the handle was subdivided into two steps. The first step is to determine how the thread is stored and how the length of the thread is adjusted. The second step is to decide how the thread is blocked based on the results of the first step.

Step 1: Storage and adjustment of the thread

The instrument should provide enough thread to place a running suture with knot (PS-4.3), and it should be possible to adjust the length of the thread during use (PS-5.4). Additionally, the thread should be able to flow freely through the handle without being blocked accidentally (PS-5.1). The resulting features on the handle needed to store and adjust the thread must be necessary and simple to use (PS-6.2). The thread can be stored either inside or outside the handle. Both storage locations result in a different method of adjusting the length of the thread.

Concepts

Two concepts were designed for the storage and adjustment of the thread. The shape of the handle, as designed in *section 3.3*, was used as a basis for the concepts.

Concept 1A

The thread is stored coiled in the handle, as shown in Figure 16. A knob is added to the outside of the Handle to manually coil the thread during use.

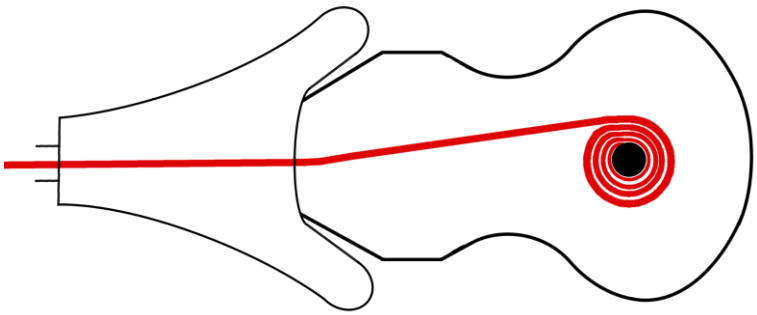


Figure 16: Concept 1A for the storage and adjustment of the thread in the handle.

Storing the thread inside the handle protects the thread from damage and soiling. However, storing the thread inside the handle also limits the length of thread that can be delivered with the instrument as this is limited by the available space inside the handle. In addition, a feature must be added to the handle to coil the thread in order to be able to adjust the length of the thread during use.

Concept 1B

In this concept, shown in Figure 17, the thread exits the handle through an opening and is stored either folded or coiled outside of the handle. Adjustments to the length of the thread during use can be made by hand.

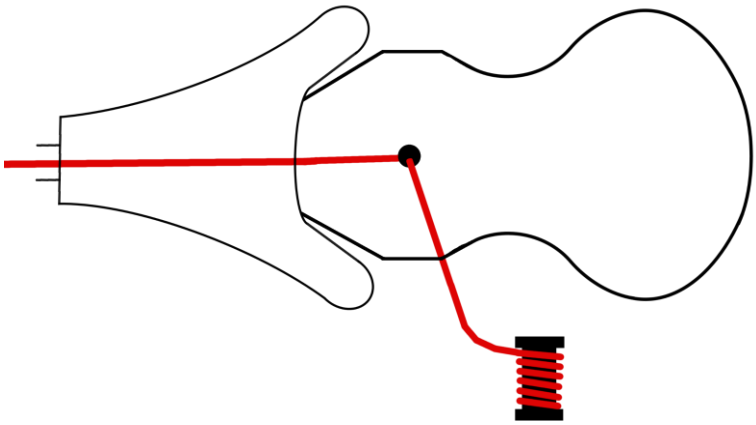


Figure 17: Concept 1B for the storage and adjustment of the thread outside the handle.

No additional feature is needed on the handle, because adjustments to the threads length can be made by hand. In addition, the length of the thread that can be delivered with the instrument is not limited by the dimensions of the instrument. The disadvantage of adjusting the length of the thread by hand is that this

adjustment requires either the surgeon to let go of the supporting instrument (e.g. a grasper), or the help of an assistant.

Choosing a concept

Not all concepts meet the relevant Product Specifications PS-4.3, PS-5.1, PS-5.4, and PS-6.2. An overview of how well a concept meets the Product Specifications is given in Table 6, where green means a specification is met, yellow means a specification can be met with conditions, and red means a specification is not met.

PS-4.3: Working length of thread

Both concepts allow for the thread to be stored with the instrument. Concept 1A has some limitations on the length of thread that can be stored due to the inner dimensions of the handle. This requires the dimensions of the handle to be chosen to allow for the minimum working length of thread of 23 cm to be stored. Concept 1B does not share this problem as the thread is stored outside of the instrument, giving no limitations to the length of the thread that can be delivered with the instrument.

PS-5.1: Thread flow through instrument is unhindered

Both concepts allow for the unhindered flow of the thread through the handle.

PS-5.4: Length of thread at the tip can be adjusted

Both concepts allow for the length of the thread to be adjusted.

PS-6.2: Simple handle design

One of the requests from DEAM and the consulting gynecologists was to keep the operation of the Handle as simple as possible. For concept 1A, a feature is needed on the handle to adjust the length of the thread. Concept 1B, on the other hand, requires no feature to adjust the length of the thread, keeping the design and operation of the Handle simpler.

Table 6: Rating of the different concepts for the flow of the thread at the handle, based on the relevant Product Specifications. Green: specification is met. Yellow: specification can be met with conditions. Red: specification is not met.

Product Specification		Concept 1A	Concept 1B
PS-4.3	Working length of thread		
PS-5.1	Thread flow through instrument is unhindered		
PS-5.4	Length of thread at the tip can be adjusted		
PS-6.2	Simple handle design		

As can be seen in Table 6, concept 1B met all Product Specifications. The main advantage of concept 1B is its simpler handle design. In addition, storing the thread outside of the Handle makes it possible to attach more thread to the instrument. This allows the instrument to be used during procedures where either long or multiple sutures are required without having to adjust or replace the instrument. Because of these advantages, concept 1B was chosen for the storage and adjustment of the thread at the handle.

Step 2: Blocking the flow of the thread

In order to make knot-tying possible with the Hornet, the instrument should be able to put tension on the thread. This requires a feature on the handle that can block and unblock the thread when needed (PS-5.3). Additionally, it should be possible to operate the blocking mechanism of the thread, regardless of how the handle is rotated in the hand (PS-6.1). Instead of designing a construction inside the handle to block the flow of the thread, it was decided to block the thread by utilizing the opening through which the thread exits the handle. Several options to block this opening were considered, resulting in the concepts described below.

Concepts

Three concepts were created for blocking the flow of the thread. The shape of the handle, as designed in *section 3.3*, was used as a basis for the concepts.

Concept 2A

The opening through which the thread exits the handle is blocked with a button, as shown in Figure 18. Pushing the button down closes the opening in the handle with a piece of rubber, thus blocking the flow of the thread. Pushing the button on the opposite side of the handle removes the rubber from the opening, releasing the thread.

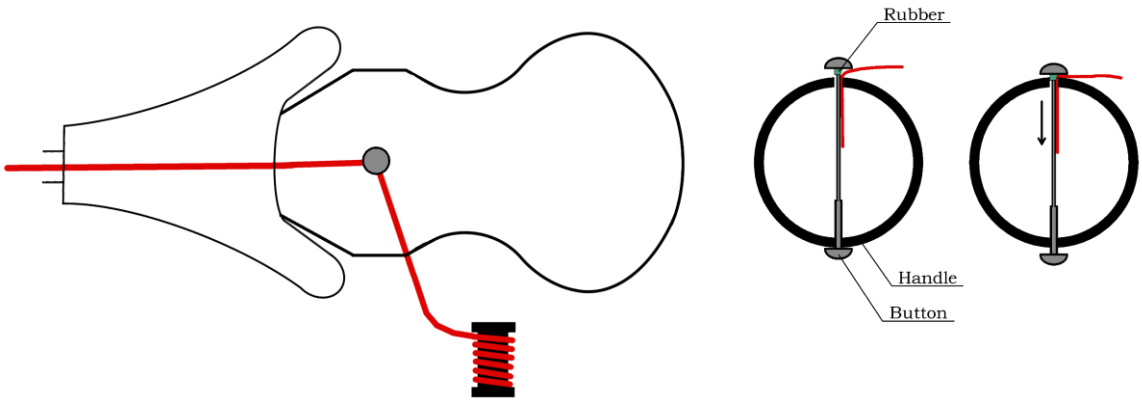


Figure 18: Option 1 for blocking the flow of the thread: a button

Concept 2B

This concept blocks the flow of the thread with a slide, as shown in Figure 19. By pulling the slide towards the proximal side of the handle, a piece of rubber closes the opening in the shaft and blocks the flow of the thread. Pushing the slide towards the distal side of the handle releases the thread.

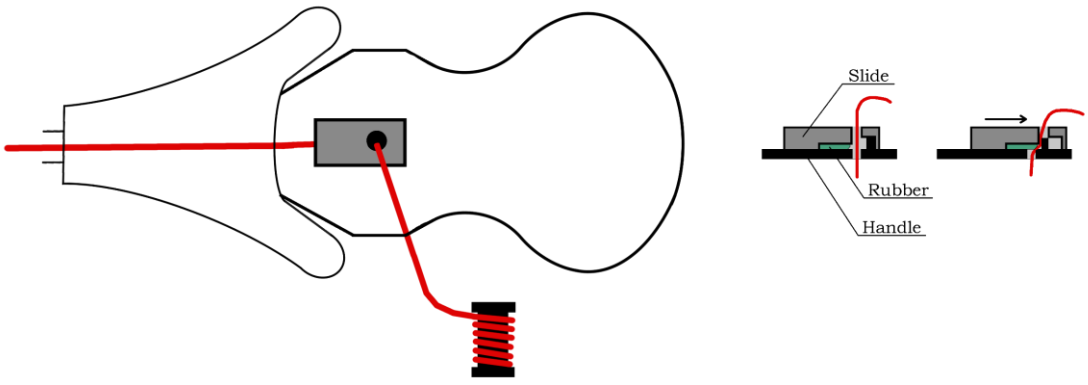


Figure 19: Option 2 for blocking the flow of the thread: a slide.

Concept 2C

This concept uses the same blocking method as described for concept 2B, but implemented in a rotating ring rather than a slide. This concept, shown in Figure 20, allows the user to operate the blocking mechanism, regardless of how the handle is rotated in the hand.

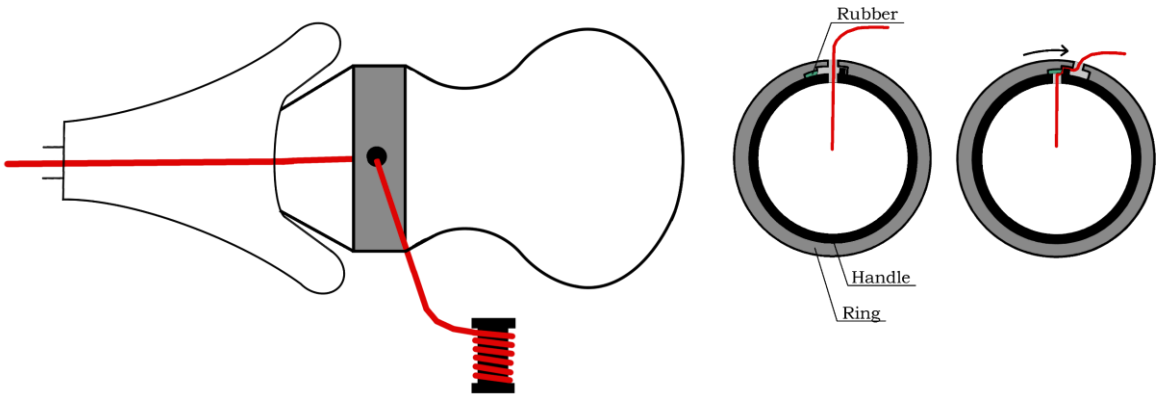


Figure 20: Option 3 for blocking the flow of the thread: a rotating ring.

Choosing a concept

Not all concepts meet the two relevant Product Specifications for blocking the flow of the thread (PS-5.3 and PS-6.1). An overview of how well a concept meets the Product Specifications is given in Table 7, where green indicates that a specification is met, and red indicates that a specification is not met.

PS-5.3: Thread can be blocked

All the concepts meet this Product Specification, as the flow of the thread can be blocked with each method.

PS-6.1: Reachability of handle features

One of the main considerations when choosing a blocking mechanism is that the resulting feature on the handle can be reached, regardless of how the handle is rotated in the hand. Concepts 2A and 2B use a button and a slide respectively to block the flow of the thread. The reachability of these functions depends on how the handle is held. A ring around the handle, as designed in concept 2C, allows the user to rotate the handle in the hand without losing access to the blocking mechanism.

Table 7: Rating of the different concepts for the blocking the thread, based on the relevant Product Specifications. Green: specification is met. Red: specification is not met.

Product Specification		Concept 2A	Concept 2B	Concept 2C
PS-5.3	Thread can be blocked			
PS-6.1	Reachability of handle features			

As only concept 2C met both Product Specifications, the ring was chosen to block the flow of the thread. The final design of this ring, called the SutureRing, is given in the *section 3.3.3*.

3.1.4. Final design of the Thread System

The final design of the flow of the thread through the instrument is shown in Figure 21. The thread enters the instrument through a small opening in the handle that can be closed with a ring to block the flow of the thread. The thread flows through the Pullrod in the shaft towards the tip of the instrument, where it is guided through the NeedleBase and along the distal side of the needle to the needle Tip.

Figure 21: Flow of the thread through the instrument.

3.2. The Rotation Mechanism

The Rotation Mechanism holds the needle and makes deployment of the needle possible. The mechanism consists of the NeedleBase, the Hinge, the PullrodHead, and the Pullrod.

3.2.1. Product Specifications

The function of the Rotation Mechanism is to hold and deploy the needle. To implement this function properly, the design should meet several Product Specifications.

Table 8: Product Specifications relevant to the design of the Rotation Mechanism.

Product Specification		Acceptance criteria
PS-2.2	Angle between needle and shaft	Angles of the needle up to 135° should be possible.
PS-2.3	Fixation of the angle between the needle and the shaft	The needle can be fixated at angles of 45°, 90° and 135°.
PS-5.1	Thread flow through instrument is unhindered	The thread can flow freely through the instrument without accidentally being blocked.
PS-5.5	Thread can flow through the NeedleBase	The thread can flow freely through the NeedleBase to reach the needle.

In addition to the Product Specifications, the design of the NeedleBase in the Rotation Mechanism must accommodate the three concepts for flow of the thread at the needle as presented in the *section 3.1.1.*

3.2.2. Concepts for the Rotation Mechanism

Four concepts were created for the Rotation Mechanism.

Concept A

This concept aims to recreate the Rotation Mechanism of the Hornet prototypes B1 and B2 by reusing their NeedleBase and PullrodHead, shown in Figure 22. This NeedleBase and PullrodHead combination was designed by Koen van Laarhoven while working on the first prototype of the Hornet (Hornet prototype B1) for his thesis [10]. For the Hornet prototype B3, the needle, Pullrod, and other parts will be designed in such a way that they can be attached to the existing NeedleBase and PullrodHead.

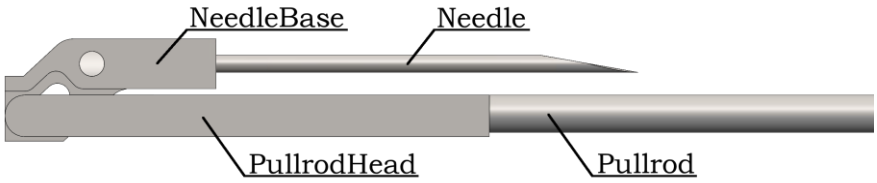


Figure 22: Rotation system from Hornet prototype B2.

The Rotation Mechanism from the Hornet prototypes B1 and B2 rotates the needle by pulling the Pullrod and PullrodHead, allowing the NeedleBase to rotate and deploy the needle out of the shaft. Pushing the Pullrod and PullrodHead forces the needle to retract to the starting position. The operation of the system is illustrated in Figure 23.

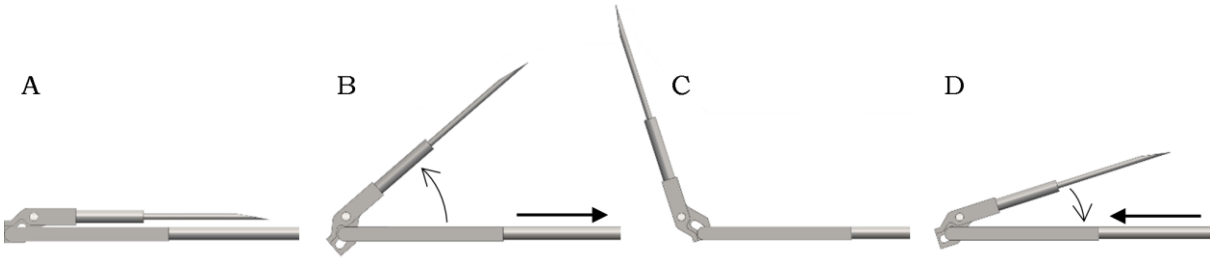


Figure 23: Needle rotation in Hornet prototypes B1 and B2.
A: closed position, B: needle deployment, C: maximum needle angle, D: needle retraction.

Reusing the NeedleBase and PullrodHead has some advantages and disadvantages.

- Advantages:
  - The NeedleBase and PullrodHead have already been designed and produced.
  - The Rotation mechanism works properly. This was demonstrated in the Hornet prototypes B1 and B2.
  - The stiff Pullrod allows the needle to be deployed and secured accurately in several angles.
- Disadvantages:
  - The production technique of the NeedleBase and PullrodHead is not desirable. Both the NeedleBase and PullrodHead consist of metal plates cut to the right shape that are welded together.
  - The NeedleBase and PullrodHead are permanently attached to each other after production, making placement in the prototype difficult.
  - It is not possible for the thread to flow through the NeedleBase since there are no openings in the NeedleBase that facilitate this. Creating these openings post-production is difficult because of the size and material of the NeedleBase.
  - The opening where the needle is fixated is square, making it more difficult to fixate the needle securely and creating the need for fillers in the NeedleBase.
  - The mechanism can only reach angles of the needle up to 107°.

Concept B

This concept is based on the design of the Rotation Mechanism of prototypes B1 and B2. Some changes were made to simplify the shape of the NeedleBase and to allow for the proper line-up of the thread with the NeedleBase.

As decided in *section 3.1*, the thread should flow through a hollow Pullrod towards the NeedleBase where the thread can either flow through the NeedleBase to the opposite side, or enter a hollow needle fastened in the NeedleBase. In the design, shown in Figure 24, the NeedleBase has an opening to allow for the thread to flow through in both ways. The PullrodHead has an opening to allow the thread to flow from the Pullrod towards the NeedleBase. The PullrodHead and NeedleBase are connected using a Hinge to allow for larger needle angles compared to concept A, and to simplify the shape of the NeedleBase.

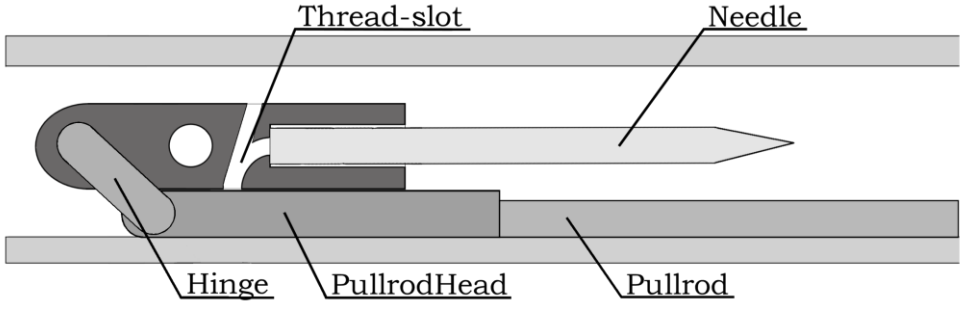


Figure 24: Sketch design of concept B.

This concept has several advantages and disadvantages.

- Advantages:
  - The components can be 3D-printed in stainless steel, simplifying the prototype development.
  - The design consists of three separate components, allowing for simple placement in the prototype, and for changes to be made to the design without replacing the whole mechanism.
  - The needle can be deployed and secured accurately at several angles due to the usage of a stiff Pullrod.
- Disadvantages:
  - From a production perspective, 3D-printing the components is not desirable.

Concept C

In this concept, the needle is attached to a small disk at the distal end of the shaft and rotated using wires. Figure 25 and Figure 26 show the concept sketch and a simple model made to test out the operation of the concept.

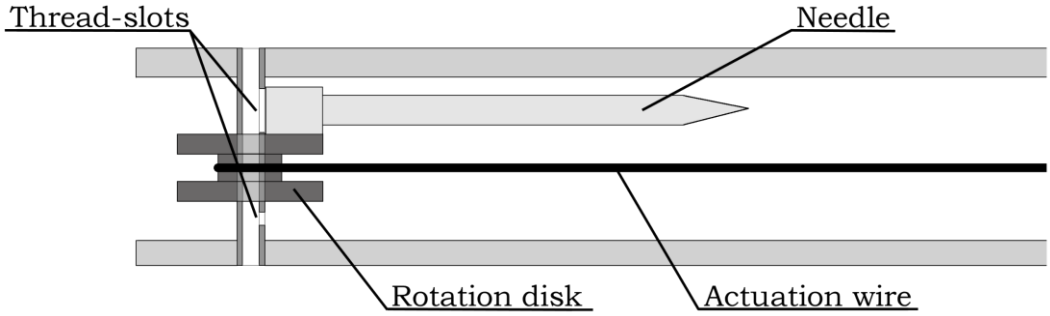


Figure 25: Sketch design of concept C.

Figure 26: Simple prototype model of concept C.

The rotation disk is attached to a hollow axis fixated in the shaft. The needle is attached to the top of the disk, and the disk can be rotated by manipulating two wires as shown in Figure 27. The hollow axis has two small openings, the thread-slots, one below and one just above the rotation disk to allow the thread to flow through the design towards the needle. At the top of the design, the thread can either flow into the needle or flow along the side of the needle.

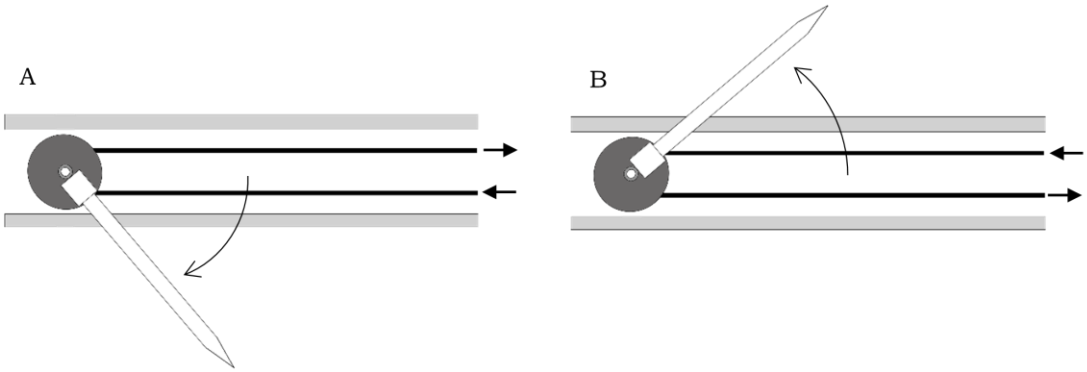


Figure 27: Needle rotation of concept C.

The use of a disk actuated by wires has several advantages and disadvantages.

- Advantages:
  - The needle can be deployed at both sides of the instrument, giving the surgeon more freedom during suturing.
- Disadvantages:
  - Elastic elongation in the wires during use makes it difficult to accurately position the needle and fixate the angle of the needle.
  - The design of the disk becomes complex when all functionalities need to be applied (holding the needle, allowing suture to flow through the system unhindered, smooth rotation of the disk, and attaching the wires for rotation).
  - The thread needs to flow past two sharp corners, hindering its free flow through the system.

Concept D

This concept is a modified version of concept B, where the Pullrod is substituted by wires to rotate the NeedleBase. Wires are attached to the NeedleBase at the top and the bottom, pulling the top-wire deploys the needle and pulling the bottom-wire retracts the needle. This system eliminates the need for a PullrodHead and Hinge. Figure 28 shows the concept sketch for the design and Figure 29 shows a simple model of the concept made with Lego.

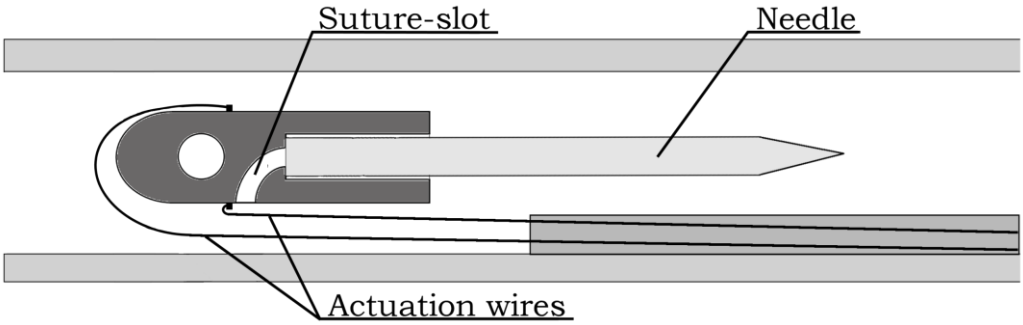


Figure 28: Sketch design of concept D.

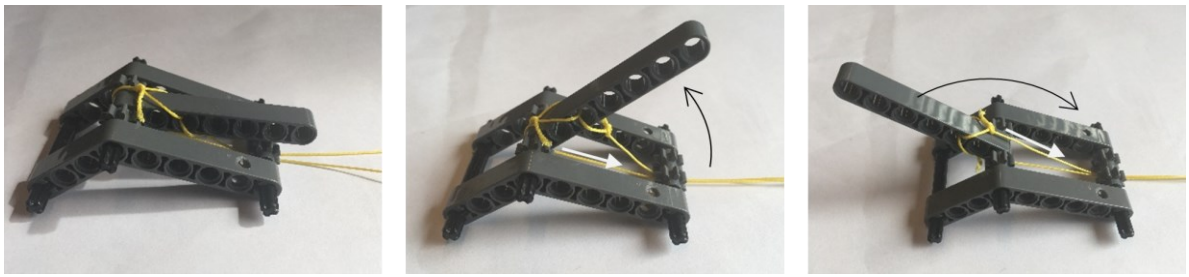


Figure 29: Simple prototype model of concept D made with Lego.

The design of concept D has several advantages and disadvantages.

- Advantages:
  - Only one opening at the distal end of the shaft, where the needle deploys, is needed. Thus reducing the risk of tissue/fluids flowing into the instrument and blocking the mechanisms.
  - The design of the mechanism simplifies the production of the components.
- Disadvantages:
  - Stretch in the wires during use makes it difficult to accurately position the needle and fixate the angle of the needle.
  - The thread can get tangled in the wires during use.

3.2.3. Choosing a concept

To determine a winning concept, each concept is evaluated based on the Product Specifications that are relevant to the Rotation Mechanism. An overview of how well a concept meets the Product Specifications is given in Table 9, where green indicates that a specification is met, yellow indicates that a specification can be met with conditions, and red indicates that a specification is not met.

PS-2.2: The angle between the needle and shaft

Concept A can only reach an angle of 107° due to the fixed design. Concepts B, C, and D can be designed in such a way that the required angle of 135° is reached.

PS-2.3: Fixation of the angle between the needle and the shaft

Concepts A and B use a stiff Pullrod to rotate the NeedleBase. This system has been tested in the Hornet prototypes B1 and B2, showing that using a stiff Pullrod allows the user to choose specific angles without unwanted movement of the needle. Concepts C and D use wires to rotate the NeedleBase. Elastic elongation of the wires during use can make it difficult to accurately position the needle and to fixate the angle of the needle [11].

PS-5.1: Thread flow through the instrument is unhindered

This Product Specification can be met in each concept, depending on the design-choices made. For concepts A, C, and D, facilitating an unhindered flow of the thread will be more difficult than for concept B. Concept A needs a guiding system to guide the thread around the NeedleBase to the needle, without the thread getting stuck in the rotating system. Concept C allows the thread to move through the hollow axis towards the needle. However, this path includes two sharp corners that could hinder the flow of the thread. In concept D, the thread could intertwine with the actuation-wires if the thread in the instrument is not kept tight during use. These problems can all be circumvented, but they require additional parts or elaborate designs. Concept B does not have these problems because the suture can flow straight from the Pullrod, through the NeedleBase to the needle without encountering any obstacles.

PS-5.5: The thread can flow through the NeedleBase

Concepts B, C, and D all allow the thread to flow through the NeedleBase because this feature can be taken into account when designing the NeedleBase. Concept A, however, aims to reuse a previously produced NeedleBase that does not facilitate the flow of thread through the NeedleBase.

Table 9: Rating of the different concepts for the Rotation Mechanism, based on the relevant Product Specifications. Green: specification is met. Yellow: specification can be met with conditions. Red: specification is not met.

Product Specification		Concept A	Concept B	Concept C	Concept D
PS-2.2	Angle between needle and shaft				
PS-2.3	Accurate fixation of the angle between needle and shaft				
PS-5.1	Thread flow through instrument is unhindered				
PS-5.5	Thread can flow through the NeedleBase				

As can be seen in Table 9, concept B scores the best for all Product Specifications and is therefore chosen to be included in Hornet prototype B3.

3.2.4. Final design of the Rotation Mechanism

The final design of the Rotation Mechanism is shown in Figure 30 and Figure 31. The full design process of the Rotation Mechanism is presented in Appendix E.

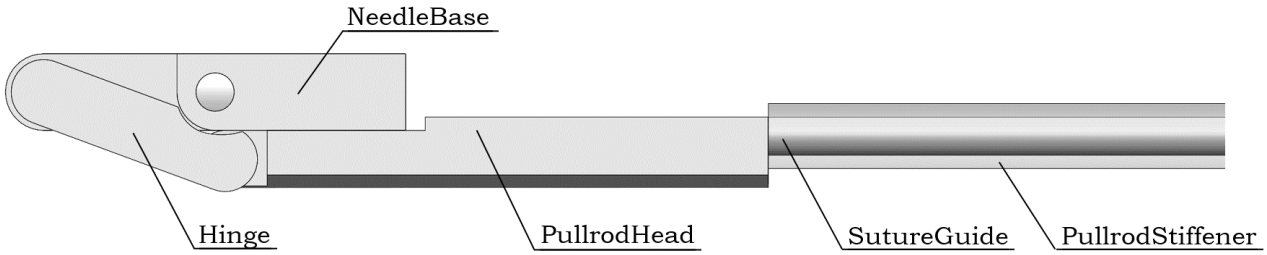


Figure 30: Side view of the Rotation Mechanism for Hornet prototype B3.

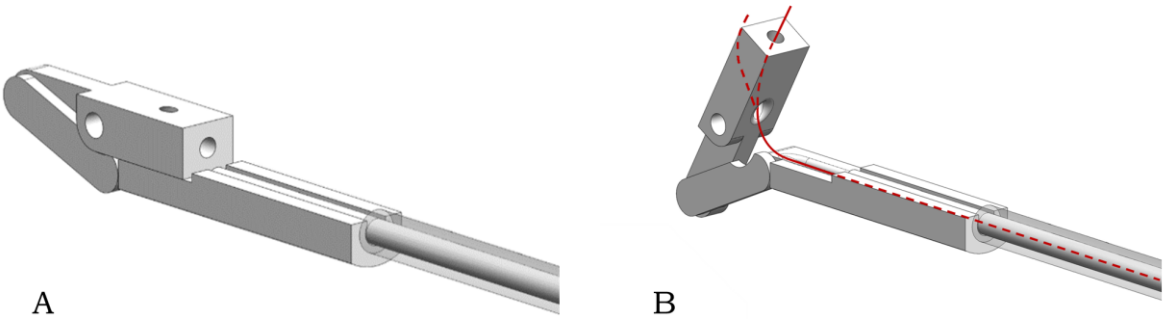


Figure 31: Isometric view of the Rotation Mechanism for prototype B3.
A: folded Rotation Mechanism. B: opened Rotation Mechanism, showing the possible flows of the thread.

The four main components of the Rotation Mechanism are the NeedleBase, the Hinge, the PullrodHead, and the Pullrod. The final designs of the NeedleBase, the Hinge and the PullrodHead are briefly described below. Their complete designs, including dimensions, are presented in Appendix D. The Pullrod consists of the SutureGuide and PullrodStiffener, two simple tubes that did not require a design process apart from dimensioning. The final dimensions of the Pullrod can be found in Appendix D.

NeedleBase

The NeedleBase has been designed to fulfill three main functions:

1. The NeedleBase can hold the needle.
2. The NeedleBase allows for a suture-thread to flow through the NeedleBase.
3. The NeedleBase can be rotated in order to deploy the needle.

Figure 32 presents the design of the NeedleBase and its main elements. The thread-slot, Figure 32-A, is a round opening through which the thread can either flow into the needle or to the opposite side of the NeedleBase. This slot is designed straight to ease post-production corrections with a drill, should the slot be filled with residue or metal shavings during production. The entrance to the thread-slot has been rounded to allow the thread to flow into the NeedleBase smoothly while reducing the chance of damage to the thread.

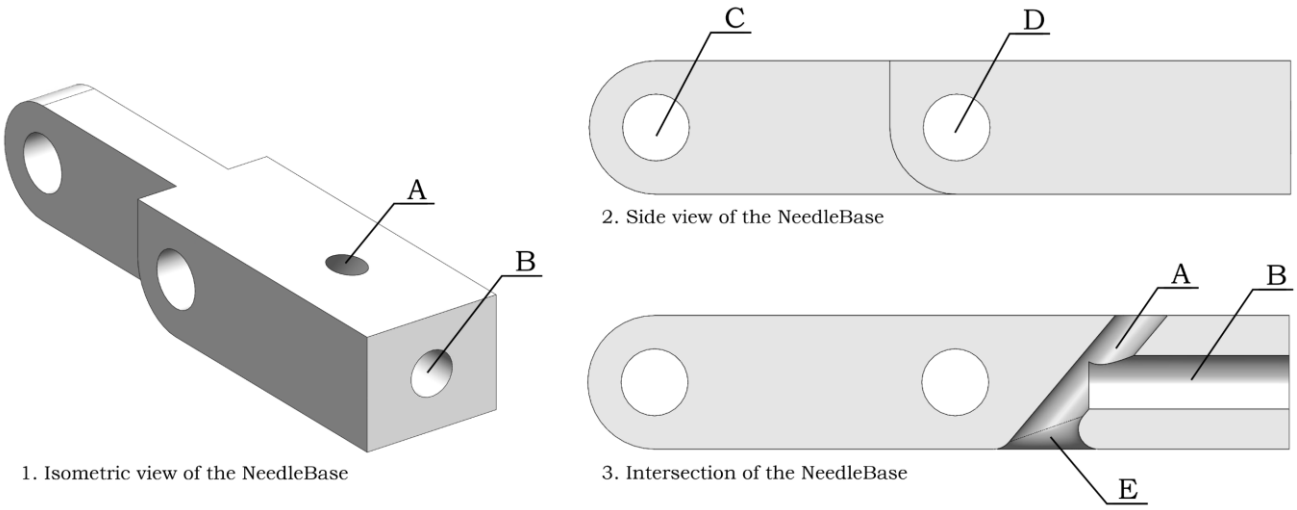


Figure 32: Isometric view (1), Side view (2), and Intersection of the side view (3) of the NeedleBase.
A: Thread-slot, B: Needle-slot, C: Hinge-opening, D: Rotation-opening, E: Thread-slot-entrance

A cut-out is made in the shaft, shown in Figure 33, through which the NeedleBase can deploy the needle. This cut-out supports the NeedleBase when deployed, to prevent the NeedleBase from moving sideways when forces are applied to the needle.

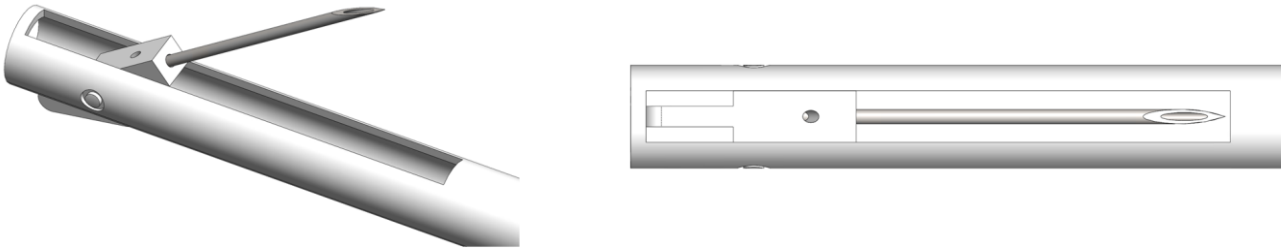


Figure 33: Isometric view (left), and top view (right) of the cut-out for the NeedleBase at the distal end of the shaft.

Hinge

The Hinge has one main function: connecting the PullrodHead to the NeedleBase in such a way that the PullrodHead's horizontal movement results in the rotation of the NeedleBase. The Hinge used in this version of the Rotation Mechanism was originally designed for the LaproFlex, a laparoscopic grasper designed by DEAM.

Figure 34 shows the design of the Hinge. The hinge-gap, Figure 34-A, is a notch made in the original design of the Hinge to make the Hinge fit properly around the NeedleBase, as shown in Figure 30.

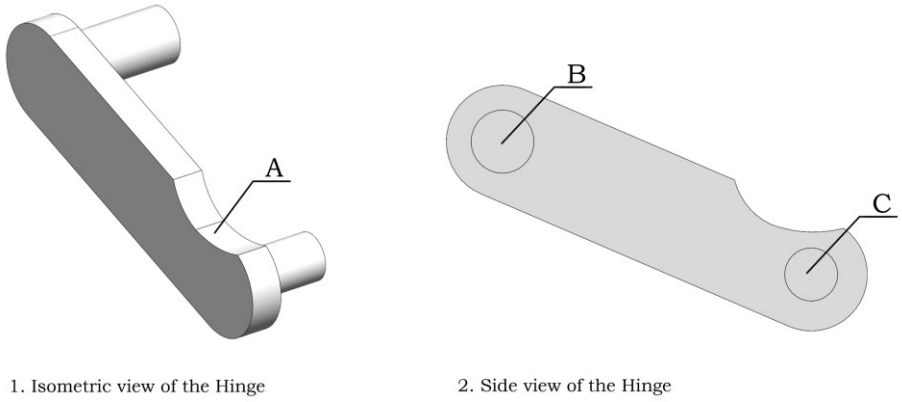


Figure 34: Isometric- and Side view of the Hinge. A: Hinge-gap, B: NeedleBase-pin, C: PullrodHead-pin.

PullrodHead

The PullrodHead has been designed to fulfill two main functions:

1. Allow the thread to flow through the shaft to reach the thread-slot in the NeedleBase.
2. Connect the Rotation Mechanism to the Pullrod.

Figure 35 shows the design of the PullrodHead. The thread-slot, Figure 35-B, is a groove that guides the thread from the SutureGuide towards the thread-slot in the NeedleBase, as shown in Figure 31-B.

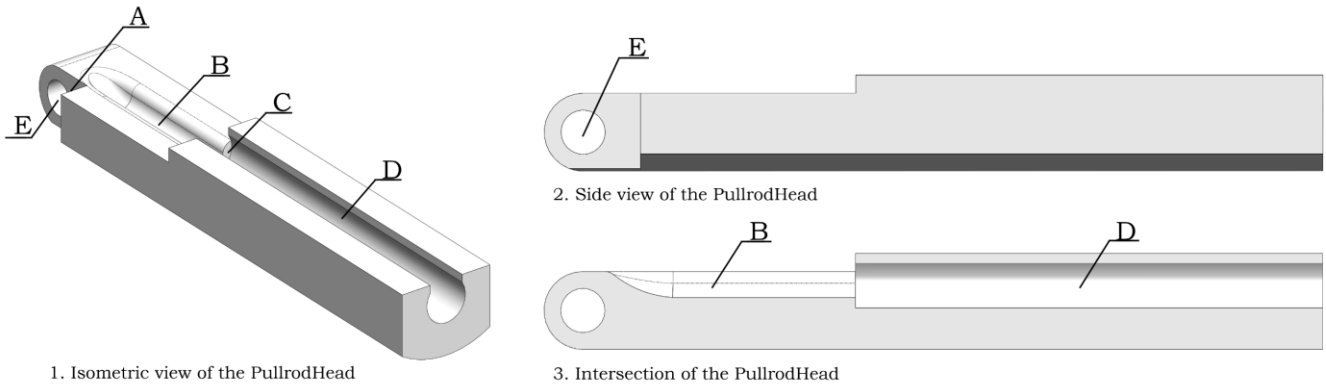


Figure 35: Isometric view (1), Side view (2), and Intersection of the side view (3) of the PullrodHead.
A: Hinge-notch, B: Thread-slot, C: SutureGuide-stop, D: SutureGuide-slot, E: Hinge-opening

A cut-out that fits tightly around the PullrodHead is made in the shaft. This cut-out, shown in Figure 36, ensures that the PullrodHead moves back and forth inside the shaft, without shifting up-, down- or sideways.

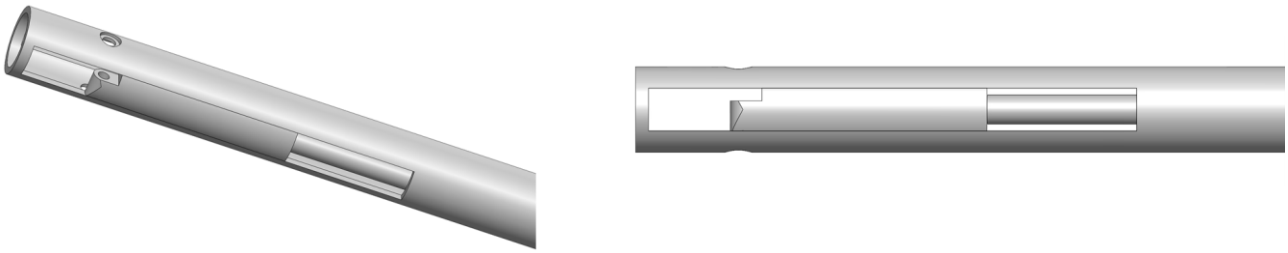


Figure 36: Isometric view (left), and top view (right) of the cut-out for the PullrodHead at the distal end of the shaft.

3.3. The Handle

The handle of the instrument consists of three main parts: the HandleBase, the NeedleActuator, and the SutureRing. First the overall shape of the handle was chosen, after which the specific components were designed.

3.3.1. Product Specifications

The function of the Handle is to hold the instrument and to operate all the features of the instrument (needle deployment, angle fixation, thread blockage). To fulfill these functions, the handle design must satisfy several Product Specifications.

Table 10: Product Specifications relevant to the design of the Handle.

Product Specification		Acceptance criteria
PS-1.3	Hand size (length and width)	All features on the handle can be reached by hands with a length between 15.8 cm and 20.6 cm, and a width between 6.9 cm and 9.6 cm.
PS-1.4	Single handed use	The instrument can be operated during use with a single hand.
PS-1.5	Right and left handed use	Instrument controls can be accessed by the right and left hand.
PS-2.1	Needle deployment force	The force on the fingers to maximally deploy the needle should be less than 19.3 N.
PS-2.3	Fixation of the angle between the needle and the shaft	The needle can be fixated at angles of 45°, 90° and 135°.
PS-2.4	Automatic needle retraction	When releasing the feature on the handle to deploy the needle, the needle should retract automatically.
PS-5.1	Thread flow through instrument is unhindered	The thread can flow freely through the instrument without accidentally being blocked.
PS-5.3	Thread can be blocked	The flow of the thread can be blocked. When blocked, a suture and knot can be placed without the thread slipping.
PS-6.1	Reachability of handle features	All features on the Handle can be reached regardless of how the handle is rotated in the hand.
PS-6.2	Simple handle design	All features on the Handle must be necessary and simple to use.

3.3.2. Determining the shape of the Handle

The shape of the handle influences the design of the components to block the thread and deploy the needle. Before the specific designs of the different components of the handle are created, the overall shape of the handle is chosen.

Concepts

The Hornet aims to replace the needle holder during laparoscopic suturing. The in-line handles attached to laparoscopic needle holders, shown in Figure 37, allow the surgeon to hold the instrument comfortably [12] and to rotate the instrument in their hand during use [13].

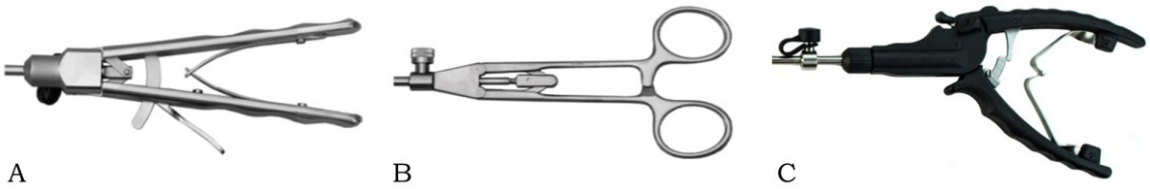


Figure 37: A. Axial Needle Holder handle [14]; B. Ring Needle Holder handle [14]; C. Precise Needle Holder Handle [15]

The relevant Product Specifications for the overall shape of the handle are the hand size (PS-1.3), single handed use (PS-1.4), right and left handed use (PS-1.5), reachability of the handle features (PS-6.1), and a simple handle design (PS-6.2). Two concepts were created for the shape of the handle of the Hornet. Both concepts are presented below.

Concept A

The first concept for the handle shape, shown in Figure 38, is based on the precise needle holder handle shown in Figure 37-C. The shape of the handle was kept, but different functions were assigned to the features on the handle. The angle of the needle is influenced by squeezing and releasing the handle. Fixation of the needle angle is achieved by using the ratchet construction from the original design to lock and unlock the angle. The SutureRing to block the flow of the thread is placed at the tip of the handle as this is the only location where placement of a ring, that can be accessed regardless of how the handle is held, is possible.

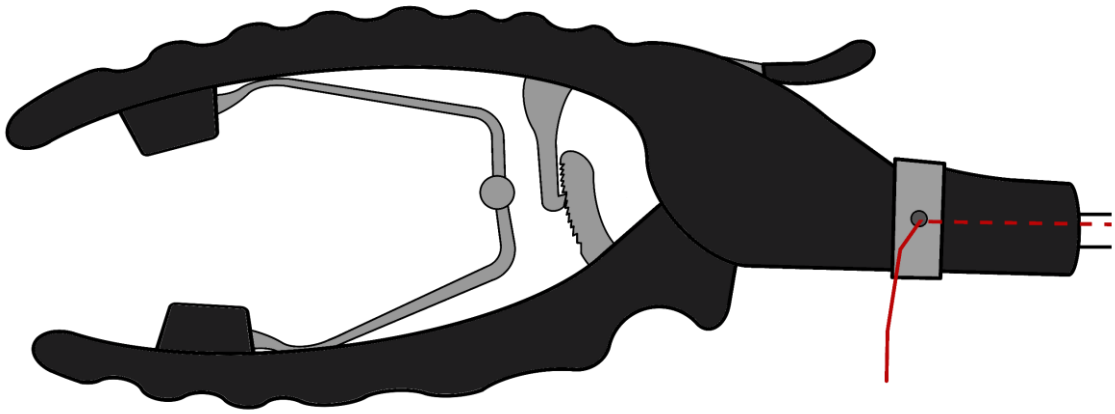


Figure 38: Handle shape design of concept A.

Reusing the shape of an existing needle holder handle has advantages and disadvantages. Surgeons are accustomed to the feel of the handle in their hands, making the instrument pleasant to work with. However, the new functions assigned to the existing mechanisms might cause confusion during use, especially when a surgeon has significant experience with the original handle on which this concept is based.

Concept B

For the second concept, the shapes of the in-line handles were abandoned and a new shape was designed. The pinching force produced by the needle holder to hold the needle is unnecessary in the Hornet because the needle is fixated in the instrument. This allows for different handle shapes, without a pinch function, to be considered.

A symmetric handle shape was designed that lays comfortably in the hand. Figure 39 shows the final design of concept B. The full design process of this handle and its shape is given in Appendix F.

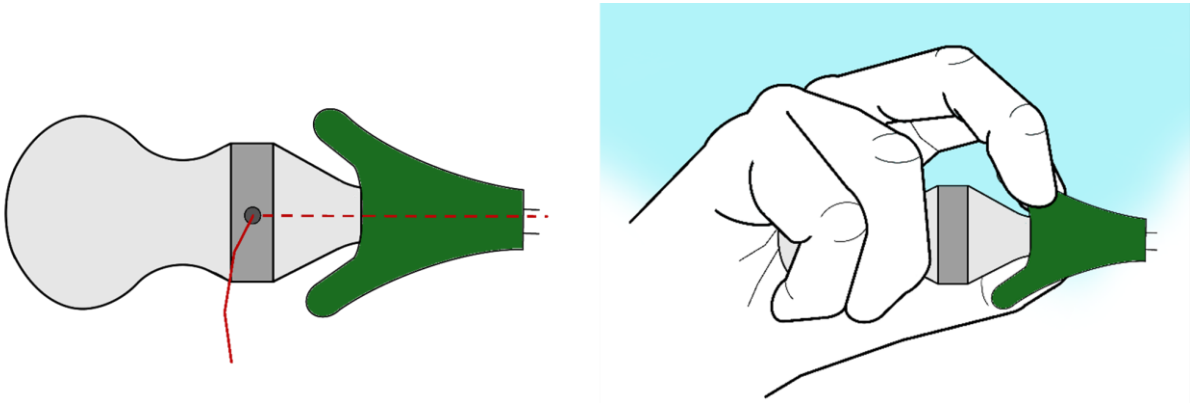


Figure 39: Handle shape design of concept B (Left). Visualization of how the handle shape of concept B is held (Right).

The handle is designed to be symmetric, making rotation of the handle in the hand simple. The spherical end of the design fits comfortably in the palm of the hand, and the curves along the handle allow for the little finger and ring finger to comfortably wrap around the handle to hold it, as can be seen in Figure 39. This shape allows the middle finger, index finger, and thumb to operate the two functionalities on the handle, described below.

1. The SutureRing, designed to block the flow of the thread, is placed in such a way on the handle that it can be operated with the thumb.
2. A separate component, the NeedleActuator, is added to the HandleBase to deploy and lock the needle. Pulling the NeedleActuator back against a spring deploys the needle, and rotating the NeedleActuator locks the angle of the needle. The design of the NeedleActuator is based on the design of DEAM's Roticulator, which is part of DEAM's handle for the Laprofix, because this shape allows the NeedleActuator to be operated with two fingers. This was confirmed by testing the Roticulator on a mock-up of the handle, shown in Figure 40. An added bonus of using the Roticulator, according to DEAM, is the creation of a DEAM-line where all DEAM's instruments have matching designs.

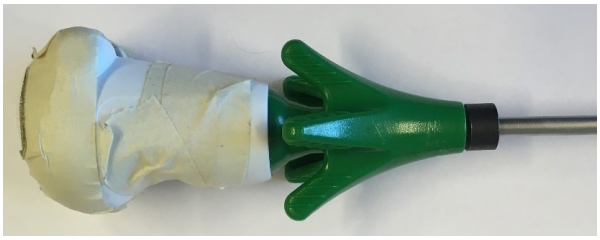


Figure 40: Model of the handle shape to test the usability of the Roticulator (the green component).

Choosing a handle shape

Before choosing a concept for the shape of the handle, both concepts are rated based on the relevant Product Specifications. Table 11 gives an overview of how well a concept meets the Product Specifications.

PS-1.3: hand size (length and width)

All the components on the handle are reachable for most hand sizes. Concept B's handle shape is designed in such a way that most hand sizes can hold it. The features are placed close to each other to make them accessible and simple to operate while holding the handle. Concept A is based on an existing handle shape. It can be assumed that the original shape and features are designed in such a way that most hands can operate the handle comfortably. However, the shape of the handle forces the ring to block the flow of the thread to be added near the tip of the handle. This makes it difficult to reach the ring during use without having to adjust the hand's position on the handle, making actuation of the ring less comfortable.

PS-1.4: single handed use

Both concepts are designed to be used with a single hand.

PS-1.5: right and left handed use

Both concepts can be used with either the right or left hand without losing access to the different features of the handle.

PS-6.1: reachability of handle features

It should be possible to operate all features on the handle, regardless of how the handle is rotated in the hand. Both concepts can be rotated in the hand without losing access to the different features on the handle, thus meeting the product specification.

PS-6.2: simple handle design

A 'simple handle design' is considered to have as few features as possible without losing functionality of the instrument. The basic functions of the handle are the deployment of the needle, locking the needle angle, and blocking the flow of the thread. Both concepts contain the three basic functions. For concept A, all three functions are actuated using separate features. The needle is deployed by squeezing the handle, the angle is fixed by operating the ratchet and the thread is blocked using a ring near the tip of the handle. Concept B only has two features to actuate the three functions. The thread is blocked using a ring on the handle, and both the deployment and fixation of the needle are operated by the NeedleActuator. Combining these two functions in one actuator allows the user to place a suture without having to shift the hand back and forth between features on the handle, putting less strain on the user's hand.

Table 11: Rating of the different concepts for the handle shape, based on the relevant Product Specifications. Green: specification is met. Yellow: specification can be met with conditions.

Product Specification		Concept A	Concept B
PS-1.3	Hand size (length and width)		
PS-1.4	Single handed use		
PS-1.5	Right and left handed use		
PS-6.1	Reachability of handle features		
PS-6.2	Simple handle design		

Both concepts meet all relevant Product Specifications, although for concept A this can results in less comfortable hand-positions during use. Eventually, concept B was chosen as the shape of the handle for three main reasons:

1. **The design is simple and symmetric.**
   The round shape of concept B, in combination with the lack of asymmetric protrusions (as is part of the design of concept A), allows the handle to be easily rotated in the hand without losing functionality.
2. **Compact design**
   Concept B has only two functionalities on the handle to actuate the three different functions, whereas concept A has three features. In addition, the features of concept B are placed closer together compared to concept A, allowing for better access to the features without creating uncomfortable hand-positions.
3. **DEAM-line**
   Concept B allows for the creation of a DEAM-line.

3.3.3. Handle Components

The chosen handle shape consists of three components. The first component is the HandleBase. This is the main body of the handle, to which the other components are attached. The other two components, the NeedleActuator and SutureRing, are used to actuate the three functionalities of the handle. The NeedleActuator is used to deploy and lock the needle, and the SutureRing is used to block the flow of the thread.

The HandleBase

The HandleBase has a symmetric shape that is designed to lay comfortably in the hand during use. The overall shape of the handle was designed empirically by creating clay models of the handle shape that were evaluated by employees of DEAM. The full design process of the HandleBase is given in Appendix F.

After designing the overall shape, the specific dimensions were determined. In order to assure that most users can hold and operate the handle comfortably, the dimensions of the design are based on the common hand sizes presented in Greiner T.M.'s report on the Hand Anthropometry of U.S. Army Personnel [16]. From this report, the 5th-percentile dimensions of the female hand (the lower limit) and the 95th-percentile dimensions of the male hand (the upper limit) are used to determine the dimensions of the HandleBase.

Both the lower- and upper limit hand sizes must be able to hold the handle and reach the NeedleActuator and SutureRing. The four main dimensions that are influenced by the size of the hand are shown in Figure 41.

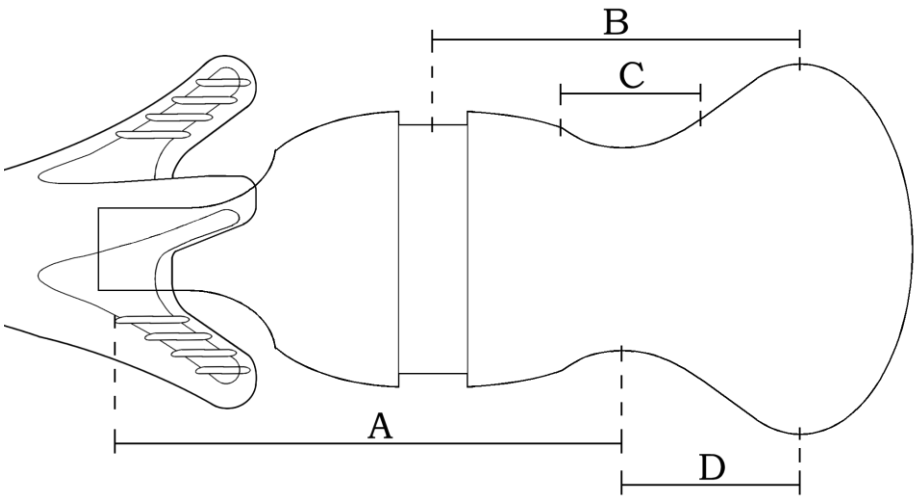


Figure 41: The basic design of the HandleBase and the main dimensions influenced by the hand sizes of users (A-D).

For each of the dimensions in Figure 41, it was determined which finger influences the dimension and whether the upper or lower limit is leading. Figure 42 shows the hand positions and fingers that influence each dimension, and gives the anatomical names of the relevant fingers as referenced in Greiner's report [16].

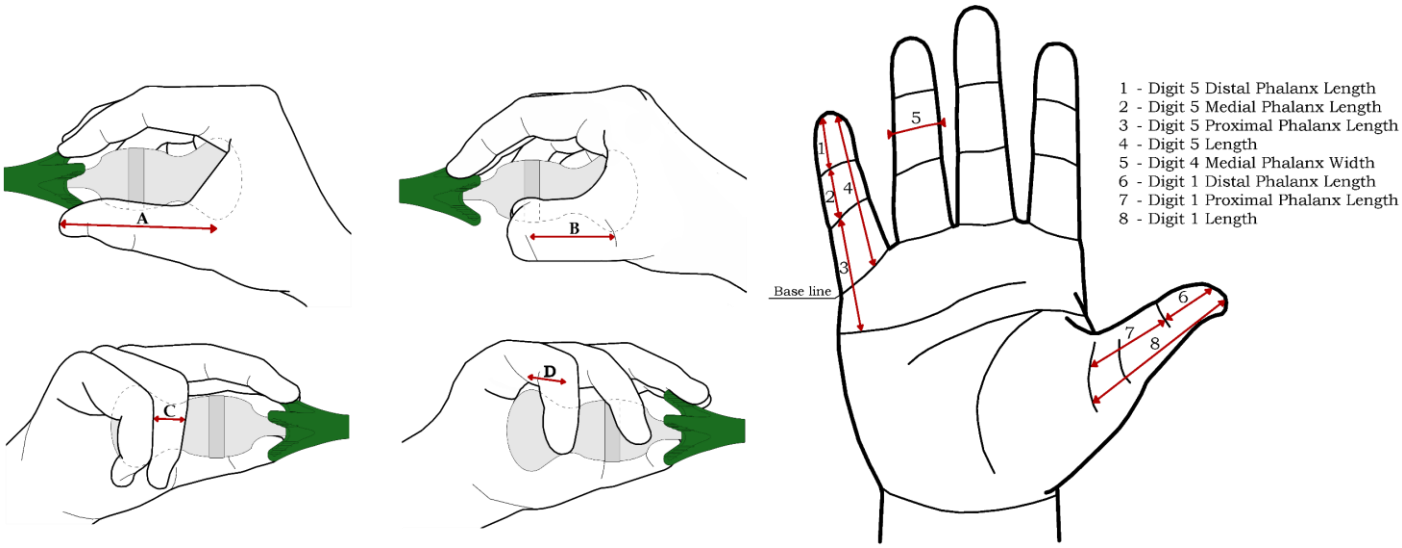


Figure 42: Left – Hand positions to determine each dimension presented in Figure 41. Right – Anatomical names of the relevant finger sections for the handle shape [16].

A. Dimension A is determined by the length of the thumb (Figure 42-8). For this dimension, the lower limit is leading to ensure that every hand can reach the NeedleActuator.
B. Dimension B is determined by the length of the proximal phalanx of the thumb (Figure 42-7). This length assumes the thumb to be flexed to the maximum, as shown in Figure 42-B. Shorter thumbs can stretch to reach the SutureRing, but larger thumbs cannot flex more than designed, the upper limit is therefore leading for this dimension.
C. Dimension C can be either determined by the ring finger or little finger, as can be seen in Figure 42-C and -D. Because thinner fingers can fit inside a larger hollow, but larger fingers cannot fit inside a hollow that is too narrow, the upper limit is leading. Dimension C is therefore determined by the width of the medial phalanx of the ring finger (Figure 42-5).
D. Dimension D is determined by the length of the proximal phalanx of the little finger (Figure 42-3) up to the base of the finger. The upper limit is leading to make sure that larger hands can bend their little finger around the handle.

The lengths and widths of the corresponding hand-sections were determined using Greiner's report [16]. Table 12 gives the calculations used for each dimension, and presents the resulting dimension values. The full dimensions of the HandleBase are presented in Appendix D.

Table 12: Calculations and values for the dimensions presented in Figure 41.

Dimension		Calculation	Dimension Value [mm]
A -	Digit 1	Digit 1 Length	55.8
B -	Digit 1 Proximal Phalanx	Digit 1 Length – Digit 1 Distal Phalanx	38.5
C -	Digit 4 Medial Phalanx Width	Digit 4 Medial Phalanx width	16.2
D -	Digit 5 Proximal Phalanx up to the base line	Digit 5 Length – Digit 5 Distal & Medial Phalanx Link Lengths	19.4

The NeedleActuator

The final design of the NeedleActuator is shown in Figure 43.

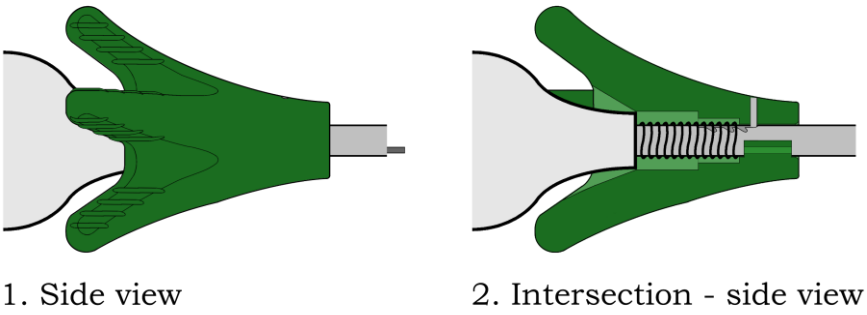


Figure 43: Final design of the NeedleActuator.

Figure 44 illustrates how the NeedleActuator deploys and locks the needle. The NeedleActuator is placed around the shaft and is separated from the HandleBase with a spring. The spring forces the NeedleActuator in its 'home' position, keeping the needle retracted inside the shaft. Pulling the NeedleActuator against the spring deploys the needle. The angle of the needle can then be locked by rotating the NeedleActuator sideways into premade angle-slots in the shaft.

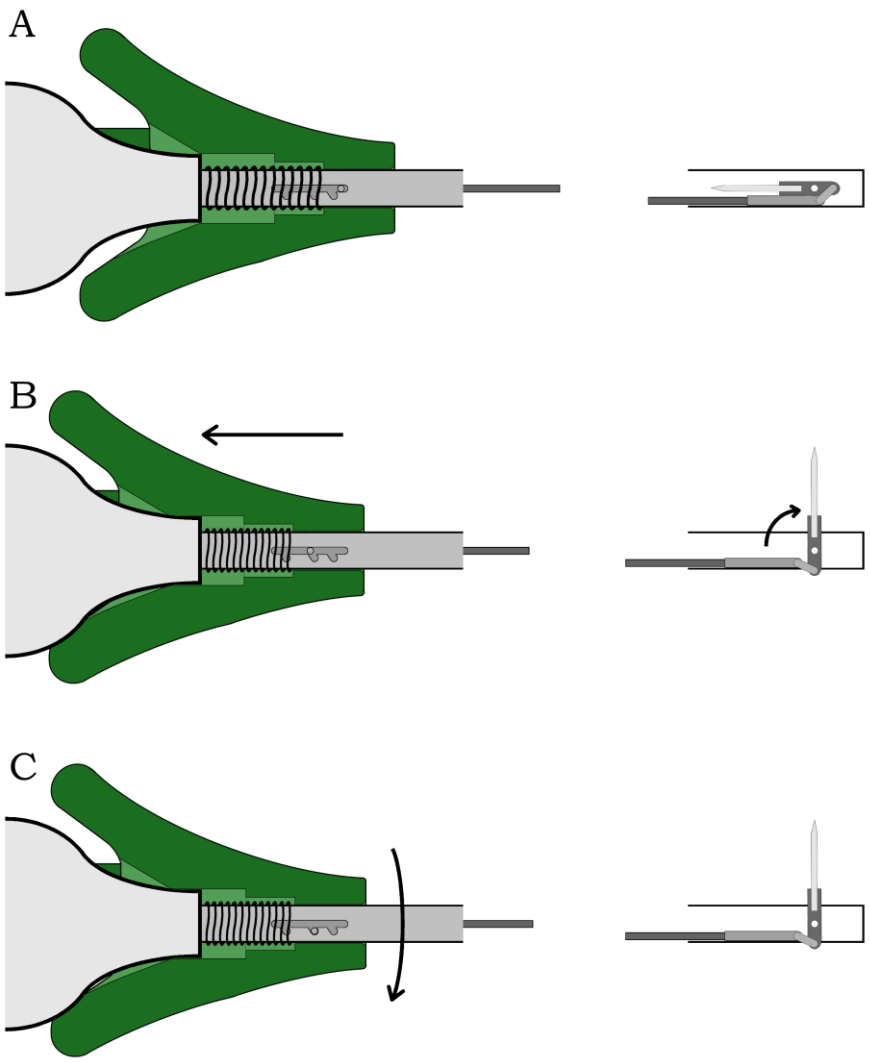


Figure 44: Operation of the NeedleActuator to deploy and lock the needle. A - 'home' position of the NeedleActuator. B – Pulling back the NeedleActuator deploys the needle. C – Rotating the NeedleActuator locks the angle of the needle.

Design elements of the NeedleActuator

Figure 45 presents the different elements of the design of the NeedleActuator. These elements are discussed in more detail below.

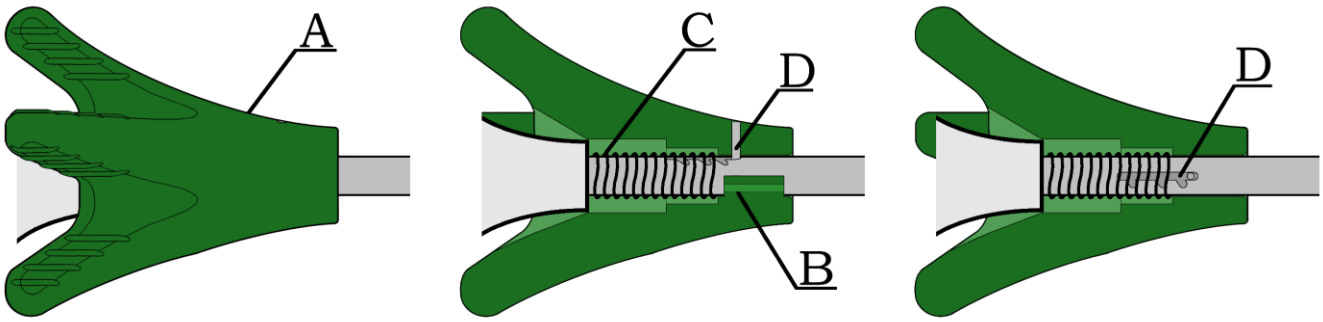


Figure 45: Side view and intersections of the NeedleActuator. A – NeedleActuator shape. B – Pullrod connection. C – Spring. D – Locking Axis.

A. NeedleActuator shape

As stated in the description of concept B for the handle shape (*section 3.3.2.*), the shape of the NeedleActuator is based on the Roticulator of DEAM's handle for the Laprofix. Use of the Laprofix and tests with the Roticulator on a mock-up handle have proven that the outer shape of the Roticulator is easy to grab and can be manipulated with two fingers. The outer design of the Roticulator was re-used for the Hornet, but the inner design was altered to better serve the functions of the Hornet. The transformation of the design of the Roticulator to the design of the NeedleActuator is given in Appendix G.

B. Pullrod connection

In order to be able to deploy the needle, the NeedleActuator should be connected to the Pullrod. This connection must allow the thread to pass freely through it to ensure that the thread reaches the handle unobstructed, as required by Product Specification PS-5.1. Connecting the Pullrod, which is inside the shaft, to the NeedleActuator, located outside the shaft, requires an opening in the shaft through which this connection can move and rotate. This opening in the shaft is shown in Figure 46.

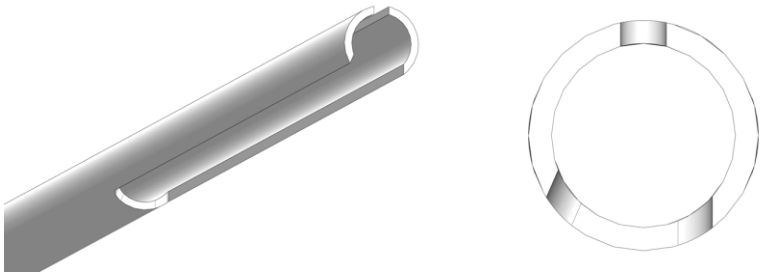


Figure 46: Isometric view (left), and front view (right) of the cut-out for the Pullrod connection at the proximal end of the shaft.

C. Spring

Product Specification PS-2.4 states that, when the NeedleActuator is released, the needle should retract automatically. This can be accomplished by adding a spring in between the NeedleActuator and the HandleBase that forces the NeedleActuator in the 'home' position. No specific calculations for the spring were executed at this point. Instead, several springs with the proper diameter were selected from DEAM's workshop. Through empirical research, the stiffness of these springs was determined and a suitable spring was chosen for the prototype.

D. Locking Axis

To fixate the angle of the needle, inspiration was taken from the shifter plate found in cars. The Locking Axis, fixated in the NeedleActuator, functions as the gear stick and moves through a slot in the shaft with multiple notches for the different needle angles. The shape of this slot and the resulting cut-out in the shaft are shown in Figure 47. The calculations that determined the dimensions of the slot are given in Appendix H.

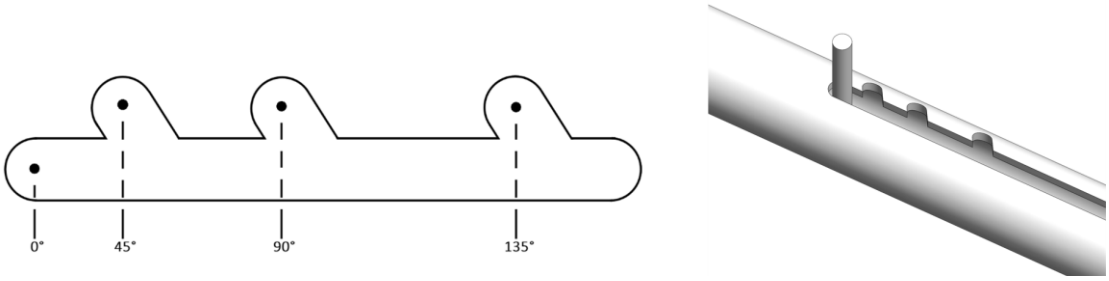


Figure 47: The shape of the 'shifter-plate' -slot (left), and the isometric view of the cut-out for the locking axis at the proximal end of the shaft (right).

The SutureRing

The final design of the SutureRing is shown in Figure 48.

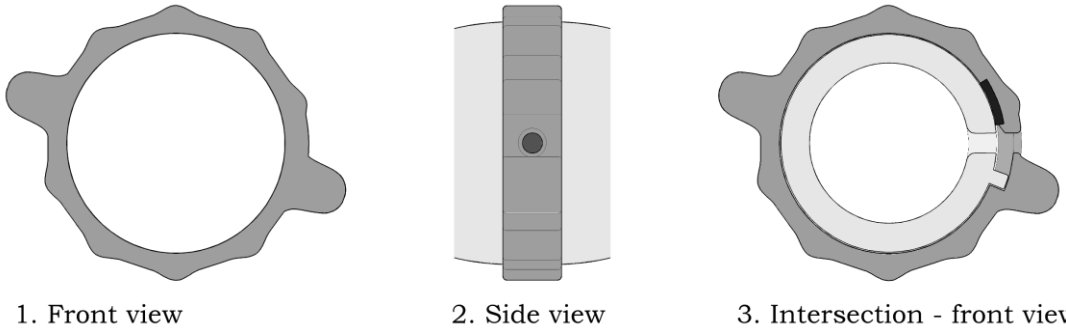


Figure 48: Final design of the SutureRing. 1 - front view of the SutureRing. 2 – side view of the SutureRing and part of the HandleBase. 3 – intersection of the front view of the SutureRing and HandleBase.

Figure 49 illustrates how the SutureRing blocks the flow of the thread as it exits the handle. The SutureRing is placed around the HandleBase. When in its opened position, the SutureRing allows the thread to flow freely through the instrument. Rotating the SutureRing blocks the flow of the thread. The blocking mechanism is a combination of two blocking methods: blocking the thread by sliding a piece of rubber over the opening in the handle, and blocking the thread by pinching the thread in between the SutureRing and a protrusion on the handle. This combination ensures that the thread is blocked properly and does not slip during use.

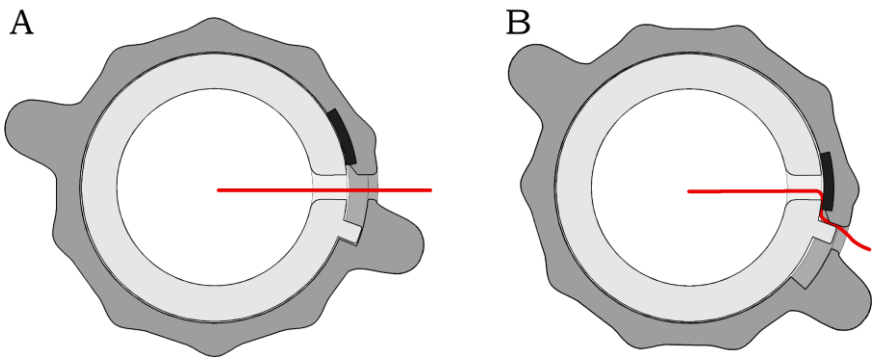


Figure 49: Operation of the SutureRing to block the flow of the thread. A – flow of thread is not blocked. B – SutureRing is rotated and the flow of the thread is blocked.

Design elements of the SutureRing

The different elements of the design of the SutureRing are presented in Figure 50. These elements are discussed in more detail below. The full design process of the SutureRing is presented in Appendix I.

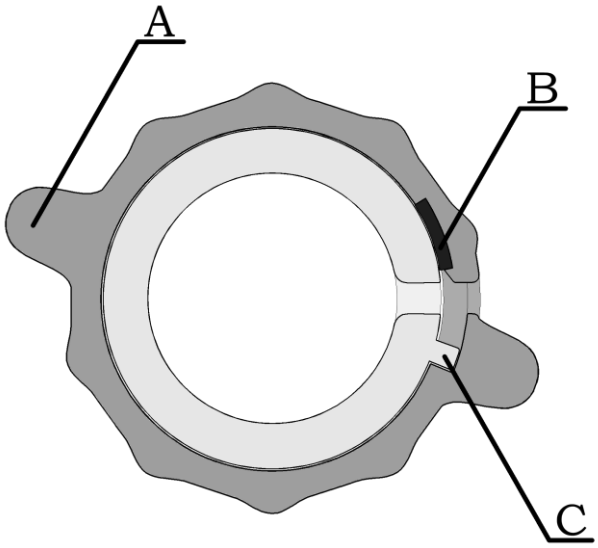


Figure 50: Intersection of the sideview of the SutureRing. A – Wings. B – Rubber. C – Handle protrusion.

A. Wings

The wings, large ridges on either side of the ring, were added to make rotation of the ring easier for the user. The ridges provide the user with a large, easy to feel, surface to press against when rotating the ring, making it easier to block the flow of the thread without having to look at the handle.

B. Rubber

The piece of rubber secured on the inside of the SutureRing is used to block the flow of the thread. In addition, this piece of rubber provides the friction needed to prevent the ring from opening/closing on its own.

C. Handle protrusion

The small protrusion on the HandleBase next to the opening in the HandleBase guides the movement of the ring and stops the rotation of the ring. In addition, the protrusion provides the second blocking of the thread, pinching the thread between the protrusion and the SutureRing, when the SutureRing is closed.

3.3.4. Final Handle Design

The final design of the Handle, with all its components, is shown in Figure 51.

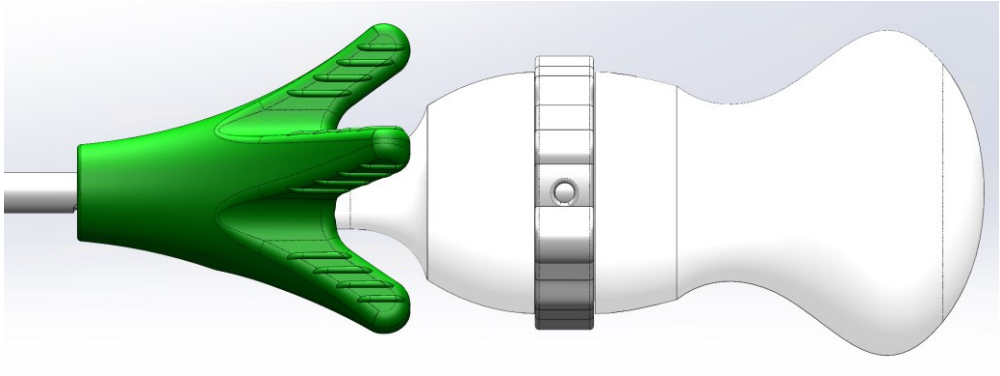


Figure 51: Side view of the final design of the Handle for Hornet prototype B3.

The final designs of the different components are given in Figure 52, Figure 53, and Figure 54. As can be seen in Figure 52-right, the HandleBase has been split into two parts, the HandleBaseFront and HandleBaseBack. The two parts are connected with two screws and can be separated to make placement of the SutureRing around the HandleBase possible. The dimensions of the different components are given in Appendix D.

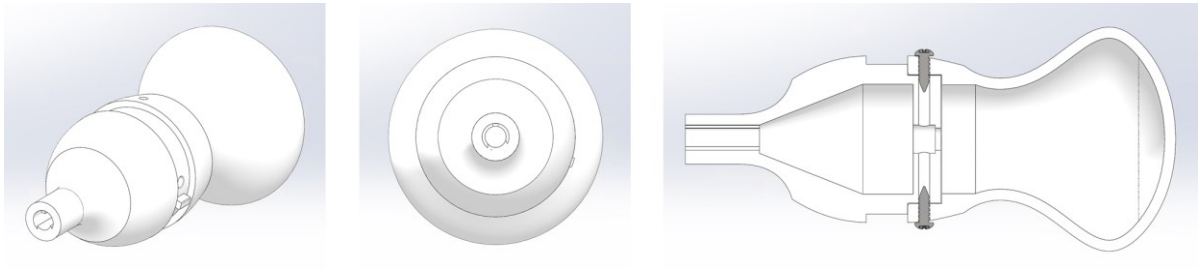


Figure 52: Isometric view (left), front view (middle), and the intersection of the side view (right) of the HandleBase.

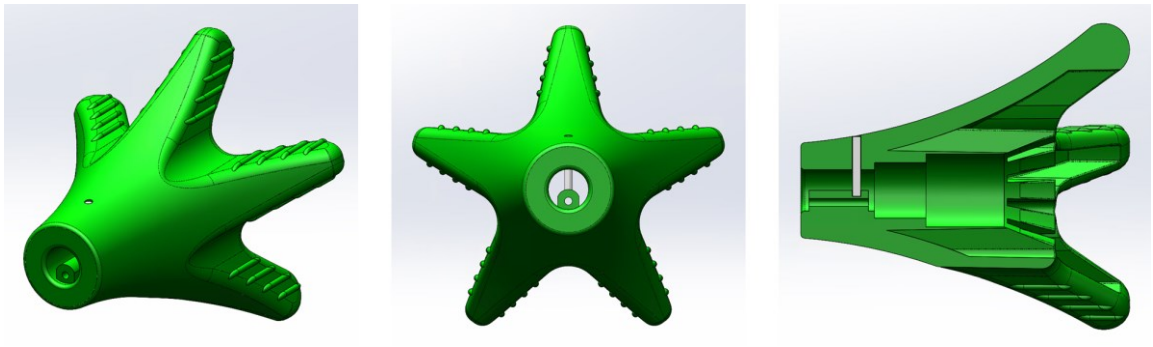


Figure 53: Isometric view (left), front view (middle), and the intersection of the side view (right) of the NeedleActuator.

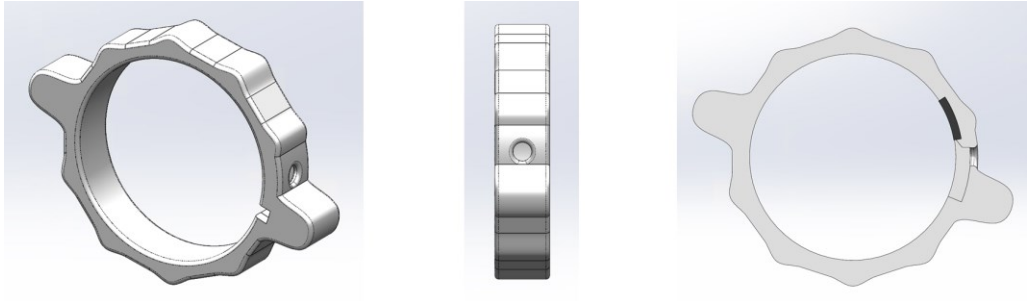


Figure 54: Isometric view (left), side view (middle), and the intersection front view (right) of the SutureRing.

3.4. The Prototype

Based on the designs created during the design process, a prototype was built. The final prototype is shown in Figure 55. The production of the parts and the assembly of the prototype are described in Appendix J.

Figure 55: Images of the final Hornet prototype B3, used in the User Tests.

4

Testing & Results

In order to assess the prototype, several tests were conducted. Design Verification Tests were carried out to see whether the Product Specifications are met. The usability of the instrument was tested with a series of User Tests. The setup of these tests is described in the *sections 4.1 - Design Verification Tests* and *4.2 - User Tests* respectively. The results of all the tests performed can be found in *section 4.3 - Results*.

4.1. Design Verification Tests

The Design Verification Tests are the tests performed to verify that the Product Specifications are met. Three different verification methods were used. A Product Specification can be verified either with a measurement, by observation, or with the user questionnaire. The method used depends on the acceptance criterium of the Product Specification.

4.1.1. Measurements

An overview of the Product Specifications that were verified with measurements is given in Table 13.

Table 13: The Product Specifications that are verified with a measurement.

Product Specification		Acceptance criteria
PS-1.1	Tip and shaft diameter	Diameter ≤ 5.1 mm.
PS-1.2	Working length of shaft (tip to base)	Length between 310 mm and 420 mm.
PS-2.1	Needle deployment force	The force on the fingers to maximally deploy the needle should be less than 19.3 N.
PS-2.2	Angle between needle and shaft	Angles up to 135° should be possible.
PS-2.3	Fixation of the angle between needle the shaft	The needle can be fixated at angles of 45°, 90° and 135°.
PS-3.1	Needle length	Length from the base to the needle tip 25 +/- 2.0 mm.
PS-3.2	Needle diameter	The diameter of the needle between 0.88 mm & 1.28 mm.
PS-4.1	Diameter of thread	Diameter of thread between 0.3 mm and 0.5 mm.

For most of these Product Specifications, the verification was a simple measurement of the length, diameter, or angle of (part of) the instrument. Visualizations and descriptions of these measurements are given in Appendix K. Product Specification PS-2.1, however, required a specific setup to properly measure the relevant forces.

Setup to validate PS-2.1

For Product Specification PS-2.1, the force on the fingers to maximally deploy the needle should be less than 19.3 N. The setup shown in Figure 56 was created to measure the force that needs to be exerted on the NeedleActuator to deploy the needle.

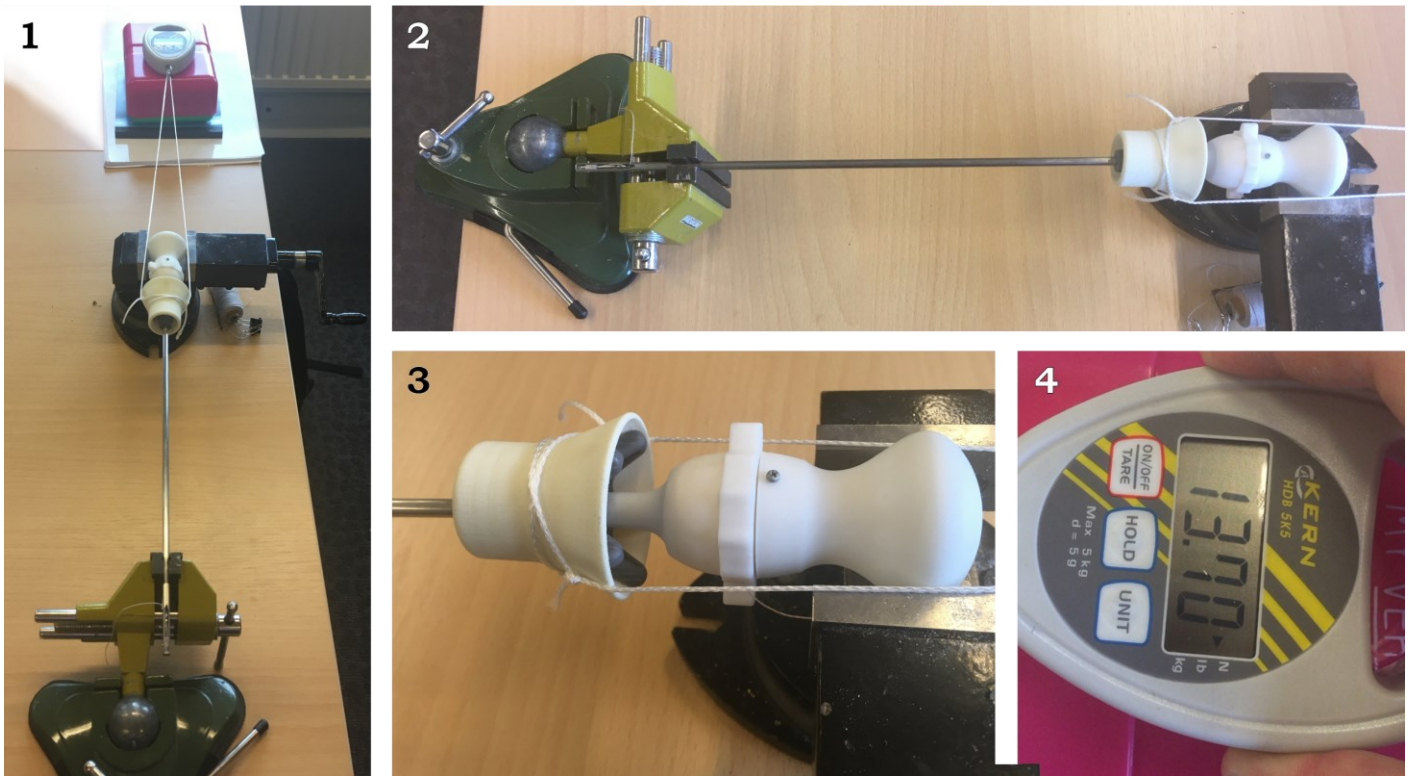


Figure 56: Test-setup to measure the force exerted on the NeedleActuator to deploy the needle.
1: Overview of the test-setup. 2: Top-view of the instrument in the setup. 3: Close-up of the cap over the NeedleActuator. 4: Close-up of the scale with the measured force in Newton.

In Figure 56, the instrument is fixated horizontally and a cap is placed over the NeedleActuator. A hanging scale is attached to the cap and placed horizontally in line with the instrument. By pulling back the scale, the NeedleActuator slides towards the handle, deploying the needle.

The test was performed six times. For each run, the force at the maximum deployment of the needle was recorded. The recorded forces can be found in Appendix K.

4.1.2. Observation

Several Product Specifications can be verified by observing the design or functioning of the prototype. The verification by observation was performed both before the User Tests by inspecting the prototype, and during the User Tests by observing how the participants used the instrument. The Product Specifications that are verified by observation are presented in Table 14.

Table 14: The Product Specifications that are verified by observation.

Product Specification		Acceptance criteria
PS-1.4	Single handed use	The instrument can be operated during use with a single hand.
PS-2.4	Automatic needle retraction	When releasing the feature on the handle to deploy the needle, the needle should retract automatically.

Product Specification		Acceptance criteria
PS-4.3	Working length of thread	The working length of the thread should be at least 23 cm.
PS-5.1	Thread flow through instrument is unhindered	The thread can flow freely through the instrument without accidentally being blocked.
PS-5.2	Loop formation at the proximal side of the deployed needle	When placing a suture, the required loop must form at the proximal side of the needle.
PS-5.4	Length of thread at the tip can be adjusted	The length of the thread at the tip of the instrument can be adjusted during use.
PS-5.5	Thread can flow through the NeedleBase	The thread can flow freely through the NeedleBase to reach the needle.

4.1.3. User Questionnaire

The Product Specifications that needed verification by users were verified with questions added to the questionnaire given to the participants of the User Tests. Table 15 gives an overview of the Product Specifications verified with the questionnaire. The full questionnaire given to the participants of the User Tests can be found in Appendix L.

Table 15: The Product Specifications that can be verified with a user questionnaire.

Product Specification		Acceptance criteria
PS-1.3	Hand size (length and width)	All features on the handle are reachable by hands with a length between 15.8 cm and 20.6 cm, and a width between 6.9 cm and 9.6 cm.
PS-1.5	Right and left handed use	Instrument controls can be accessed by the right and left hand.
PS-5.3	Thread can be blocked	The flow of the thread can be blocked. When blocked, a suture and knot can be placed without the thread slipping.
PS-6.1	Reachability of handle features	All features on the Handle can be reached regardless of how the handle is rotated in the hand.
PS-6.2	Simple handle design	All features on the Handle must be necessary and simple to use.

4.1.4. No Verification

Prototype B3 of the Hornet, as presented in this thesis, was made to demonstrate the functioning and usability of the instrument and is not meant to be used in clinical trials. Once the functioning and usability have been proven, DEAM will continue the design process of the Hornet to create a prototype that conforms with the international standards and requirements for medical instruments. Two of the Product Specifications drawn up at the start of this project cannot be verified at this stage of the prototype development. These Product Specifications are given in Table 16.

Table 16: The Product Specifications that are not verified at this stage.

Product Specification		Acceptance criteria	Why not verified
PS-3.3	Needle sharpness	Needle has a puncture force of at least 2.8 N through the body of the stomach.	Cannot be verified at this stage because the needle used for the prototype is not a certified surgical needle but a sewing-machine needle. A suitable, surgical, needle will be selected for future prototypes meant for clinical testing.
PS-4.2	Thread pliability	Thread should be a multifilament suture.	Cannot be verified at this stage because the thread used for the prototype is regular sewing thread with similar dimensions, instead of certified suture. Certified suture is expensive, especially in the quantities used in this prototype, and will therefore only be added once a prototype suitable for clinical trials is created.

4.2. User Tests

The usability of the new Hornet prototype was tested with a series of User Tests. This section describes the design and setup of the tests, the results of the User Tests are presented in the *section 4.3.2*.

4.2.1. Objectives and expected outcome

The main goal behind the development of the Hornet, as presented in *section 1.3 – Problem definition and objective*, is to simplify laparoscopic suture placement and fixation, with a focus on closing the vaginal cuff during a hysterectomy. The User Tests were used to determine whether this goal is achieved, giving the main objective of the User Tests:

To determine whether the Hornet simplifies laparoscopic suture placement and fixation.

The Hornet removes some of the known issues with regular suturing. This includes grasping the needle, positioning the needle in the tissue, and keeping tension on the suture during knot-tying. Removal of these issues should simplify suture placement and fixation. It was therefore expected that the participants, regardless of their experience with suturing and laparoscopic procedures, perform better with the Hornet compared to the regular suturing method.

In addition to the main objective, the User Tests were used to collect the opinions of the participants on the overall usability and design of the Hornet.

4.2.2. Scope

The simplification of laparoscopic suturing is not directly quantifiable. In the User Tests, this simplification is represented by the time it takes to place and secure a suture. Each participant was asked to place and secure two single stitches. One stitch with the regular suturing method, and one stitch with the Hornet. The time it took a participant to place a stitch was recorded and compared to see whether the Hornet makes suture placement faster, and therefore simpler.

Participants with different levels of experience were chosen for the User Tests to determine whether the participant's level of experience with suturing and laparoscopic procedures has an influence on their performance with the Hornet. Participants without any suturing or laparoscopic experience were also included in the User Tests to see if suturing with the Hornet is easier to learn than regular suturing.

Suturing experience implies a proficiency with regular suturing techniques. It is expected that participants with suturing experience will show a smaller difference in suturing times between the regular method and the Hornet method compared to the participants without any suturing experience.

4.2.3. Participants

Fourteen people participated in the User Tests. The chosen participants were split into three groups based on their experience with suturing and laparoscopy. The first group, the Experts, consisted of three medical professionals (two gynecologists and one urologist) with both suturing and laparoscopic experience. The second group, the Intermediates, consisted of three medical professionals (a general practitioner, an ophthalmologist, and a veterinarian) with suturing experience but without any laparoscopic experience. The third group, the Novices, consisted of eight non-medical participants without any suturing or laparoscopic experience.

4.2.4. Test Setup

The tests were performed in a lapro-trainer provided by DEAM, shown in Figure 57. For each participant, a silicon model of the vaginal cuff was placed in the center of the trainer. Appendix Q shows how these models were made.

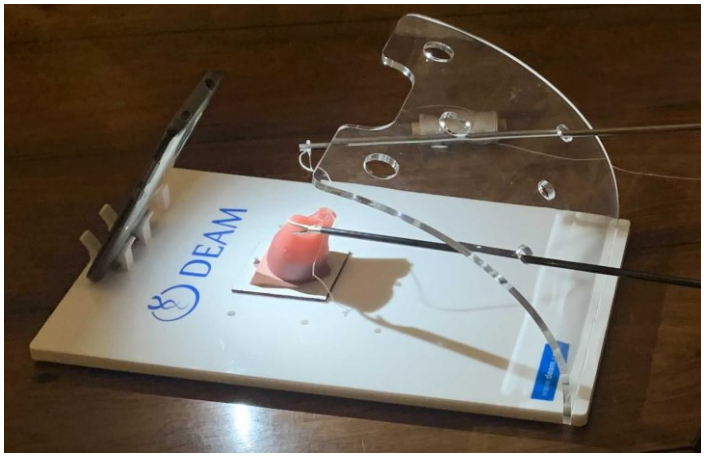


Figure 57: Lapro-trainer from DEAM with a silicon vaginal cuff model, the instruments for the Hornet method and a phone for extra lighting.

Two sets of instruments were used during the tests. The first set, for the regular suturing method, consisted of a grasper, a needle holder, and a needle with thread. The second set, for the Hornet method, consisted of a grasper and the Hornet. Both sets are shown in Figure 58.

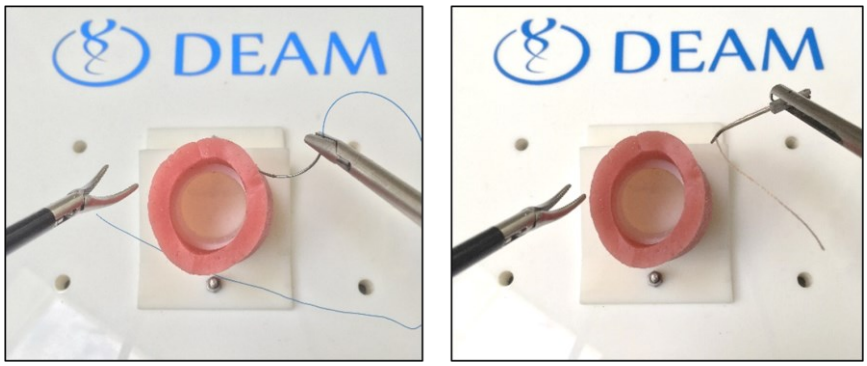


Figure 58: Left – instrument set (needle holder, grasper, and needle with thread) for regular suturing method. Right – instrument set (Hornet and grasper) for Hornet method.

The tests were recorded using two cameras. The first camera, shown left in Figure 59, is a Yi-Action camera that was focused on the vaginal cuff model and its surrounding area to film the suture placement time and

instrument movements. The second camera, shown right in Figure 59, is a laptop camera that was focused on the user (without filming the face for privacy reasons) to monitor the hand and arm movements during the test. All sound during the test was recorded. Each participant was asked in advance if they agreed to the recording of their voice and movements.

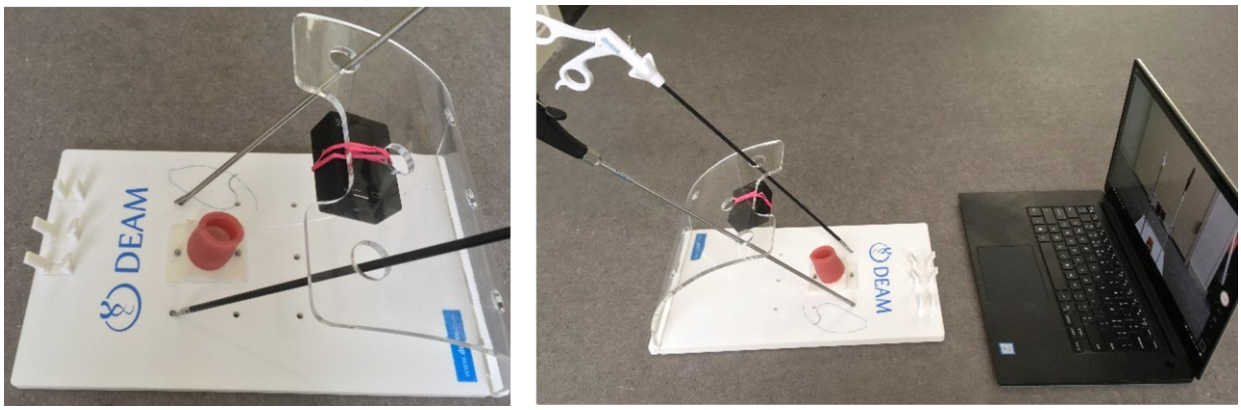


Figure 59: Left – position of the Yi-Action camera in the lapro-trainer to film the vaginal cuff model and instrument movements. Right – position of the Laptop with respect to the lapro-trainer to film the hand and arm movements of the participant.

4.2.5. Test procedure

Each test session with a participant had the following structure:

1. Participant signs a Non-Disclosure Agreement.
2. A general introduction to the project is given, including an explanation of the test setup and the goal of the user tests.
3. The first method is demonstrated.
4. The participant places and secures a single stitch using the first method.
5. Photos of the stitch are made.
6. The second method is demonstrated.
7. The participant places and secures a single stitch using the second method.
8. Photos of the stitch are made, and the silicon models are labelled.

The executions of both the regular suturing method and the Hornet method, as demonstrated during the User Tests, are illustrated in Appendix N.

None of the participants were given training with the methods before the test started. The Novice and Intermediate participants had no experience with laparoscopic procedures or tests in laparoscopic trainers before entering the User Tests. This inexperience could influence the suturing times of the first method used in their test procedure, as they would need to get used to the laparoscopic set-up. To prevent a bias in the results of the first method used, half of the participants of the Intermediate and Novice groups started with the regular suturing method and the other half started with the Hornet method. The Expert participants were exempted from this division, as they all had extensive experience with the laparoscopic set-up.

All comments made by the participants during the sessions were recorded and written down for later reference. After each test session, a questionnaire was given to the user to collect their opinions of the prototype, and to validate the Product Specifications, as described in *section 4.1.3*. A copy of the questionnaire is given in Appendix L.

4.2.6. Time Measurements

During each test session, the performance of the participant was recorded. With these recordings, the suturing times of the participants were determined. For each suturing method, two time measurements were made:

1. The time it takes the participant to carry out the full procedure of placing and securing a single stitch in the silicon model.
2. The time it takes the participant to properly align the needle with the tissue for the first stitch.

The first time measurement was to compare the overall speed of suture placement with the Hornet to regular suturing. The second time measurement was to see if the Hornet solved the needle grasping and alignment issues associated with regular suturing.

When determining the suturing times from the recordings, several guidelines were chosen for starting and stopping the time measurements to ensure that the measurements were comparable. For the regular suturing method, the time measurements were started when the needle driver first touched the thread or needle. For the Hornet method, the measurements were started when the needle was deployed out of the shaft. For both methods, the time measurements for the needle alignment were stopped when the needle tip was positioned against the tissue for insertion, and the measurements for the full procedure were stopped when the final throw of the knot to secure the stitch was tightened.

4.2.7. Suture quality

After a participant placed a suture, a picture was taken of the model to assess the quality of the suture. For each participant, the quality of the placed suture was assessed by assigning the suture to one of three categories:

1. Fully open
2. Slightly open
3. Closed

Examples of the three categories are presented in Figure 60. A suture was considered to be closed when the two walls of the vaginal cuff were pushed together. The suture was considered to be slightly open when the two walls of the vaginal cuff were pulled towards each other, but did not touch. The suture was considered to be fully open when the walls of the vaginal cuff were not, or only slightly, pulled towards each other.

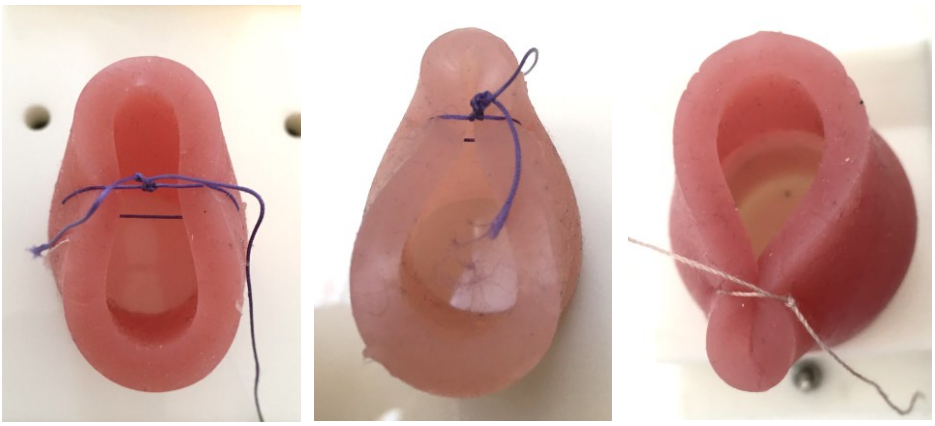


Figure 60: Examples of the three categories for the assessment of the suture quality. Left – fully open. Middle – slightly open. Right – closed.

4.3. Results

The results of both the Design Verification Tests and the User Tests are presented in this section.

4.3.1. Results Design Verification Tests

Most of the Product Specifications that were tested, met the acceptance criteria. Three of the Product Specifications were not met based on the results of the tests. Why these Product Specifications did not meet their acceptance criteria is discussed in *chapter 5,* together with how, and if, this influences the User Test results.

The results of all the Design Verification Tests are shown in Table 17. The green and red highlights indicate respectively which Product Specifications have been met, and which Product Specifications have not been met.

Table 17: Results of the Design Verification Tests. Green: Product Specification is met. Red: Product Specification is not met.

Product Specification		Acceptance criteria	Results
PS-1.1	Tip and shaft diameter	Diameter ≤ 5.1 mm	Shaft diameter = 5.0 mm
PS-1.2	Working length of shaft (tip to base)	Length between 310 mm and 420 mm	Working length = 291 mm
PS-1.3	Hand size (length and width)	All features on the handle can be reached by hands with a length between 15.8 cm and 20.6 cm, and a width between 6.9 cm and 9.6 cm.	All the participants stated that they could reach the features on the handle. The hand dimensions of 86% (12/14) of the participants are within the stated limits.
PS-1.4	Single handed use	The instrument can be operated during use with a single hand.	Once started with the procedure, all participants used the instrument with a single hand.
PS-1.5	Right and left handed use	Instrument controls can be accessed by the right and left hand.	All participants stated they could reach the controls, 2/14 of the participants were lefthanded.
PS-2.1	Needle deployment force	The force on the fingers to maximally deploy the needle should be less than 19.3 N.	The maximum force on the fingers measured is 13.70 N.
PS-2.2	Angle between needle and shaft	Angles up to 135° should be possible.	The largest possible angle is 149°.
PS-2.3	Fixation of the angle between needle and shaft	The needle can be fixated at angles of 45°, 90° and 135°.	The fixed angles are 45°, 92°, and 133°.
PS-2.4	Automatic needle retraction	When releasing the feature on the handle to deploy the needle, the needle should retract automatically.	The needle retracts automatically when the NeedleActuator is released.
PS-3.1	Needle length	The free length of the needle, from the NeedleBase to the tip, is 25 +/- 2.0 mm.	The needle length is 21 mm.
PS-3.2	Needle diameter	The diameter of the needle between 0.88 mm & 1.28 mm.	Needle diameter is 0.89 mm.
PS-4.1	Diameter of thread	Diameter of thread between 0.3 and 0.5 mm	Thread diameter is 0.3 mm.
PS-4.3	Working length of thread	The working length of the thread should be at least 23 cm.	The coil with thread attached to the instrument allows for more than 23 cm of thread.
PS-5.1	Thread flow through instrument is unhindered.	The thread can flow freely through the instrument without accidentally being blocked.	The thread can flow freely through the instrument when the SutureRing is open.
PS-5.2	Loop formation at the proximal side of the deployed needle.	When placing a suture, the required loop must form at the proximal side of the needle.	The loop forms at the proximal side of the needle.
PS-5.3	Thread can be blocked	The flow of the thread can be blocked. When blocked, a suture and knot can be placed without the thread slipping.	The flow of the thread can be blocked sufficiently for suture placement, as stated by all participants of the User Tests.

Product Specification		Acceptance criteria	Results
PS-5.4	Length of thread at the tip can be adjusted.	The length of the thread at the tip of the instrument can be adjusted during use.	The length of the thread can be adjusted by pulling the thread at the handle or at the needle.
PS-5.5	Thread can flow through the NeedleBase	The thread can flow freely through the NeedleBase to reach the needle.	The thread flows through the NeedleBase unhindered.
PS-6.1	Reachability of handle features	All features on the Handle can be reached regardless of how the handle is rotated in the hand.	Both features, the NeedleActuator and SutureRing, could be reached by the participants regardless of the rotation of the Handle in the hand.
PS-6.2	Simple handle design	All features on the Handle must be necessary and simple to use.	All participants stated that the Hornet has a simple, easy to use, design. None of the participants noted in the questionnaire, nor during the tests, that they found features on the handle to be unnecessary.

4.3.2. Results User Tests

The results of the User Tests can be divided into two categories: the results of the suture placements and the results of the questionnaire.

Suture placement results

Fourteen participants performed the test procedure as described in the User Tests section above. During each test session, the performance of the participant was recorded and analyzed. In addition, pictures were taken of the placed sutures, to assess the quality of the placed stitches.

Time measurements

An overview of the measured suturing and needle alignment times is given in Figure 61 and Figure 62 respectively. The individual results of the participants can be found in Appendix O.

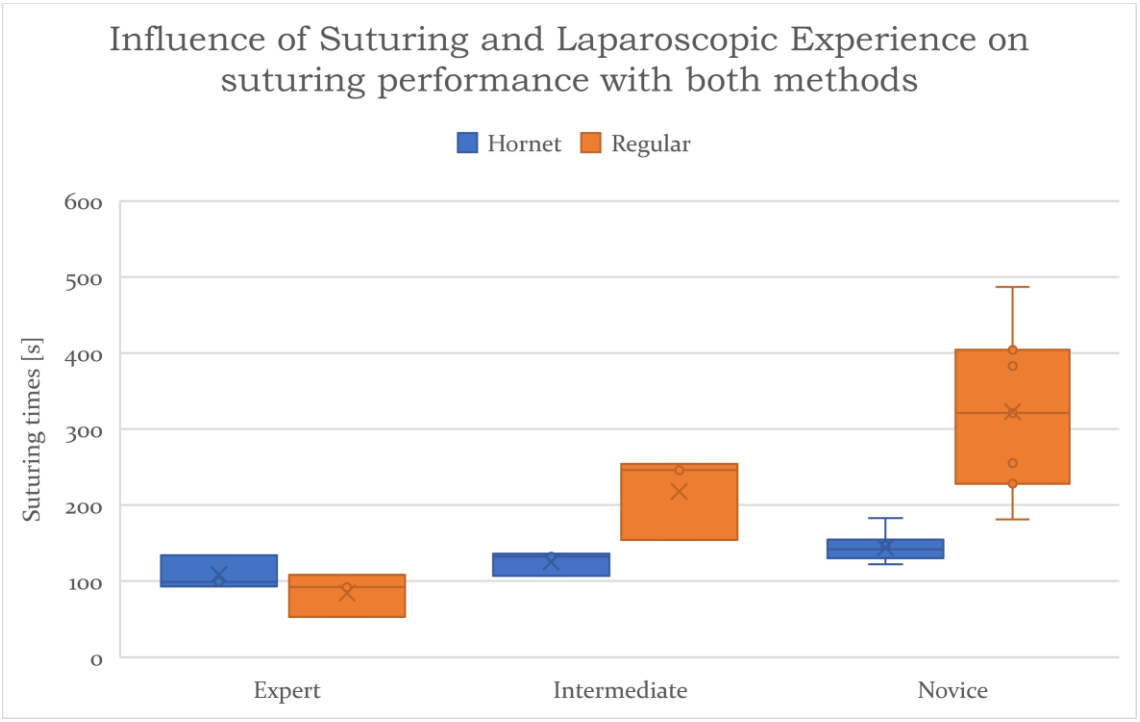


Figure 61: The suturing times of a single stitch with knots with the Hornet and the regular method for participants with different levels of experience.

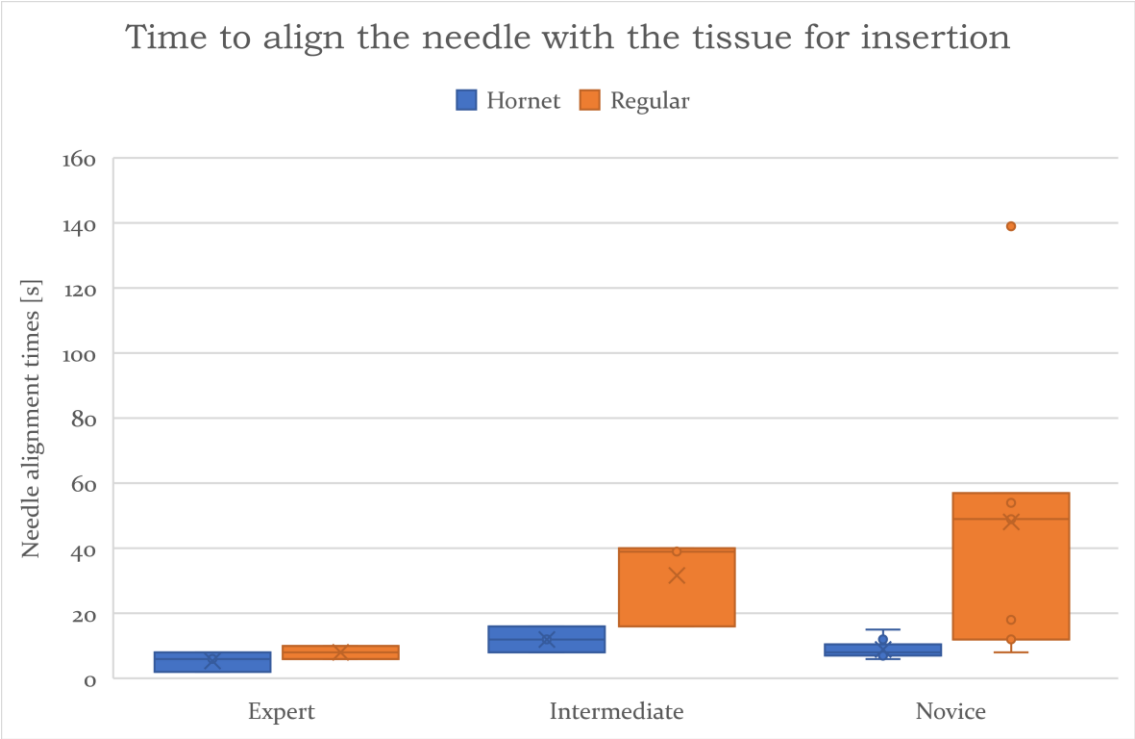


Figure 62: The needle alignment times with the Hornet and the regular method for participants with different levels of experience.

To prevent a bias in the results caused by inexperience with the laparoscopic set-up, six participants (two Intermediates, four Novices) started the test procedure with the regular suturing method, and five participants (one Intermediate, four Novices) started the test procedure with the Hornet method. Figure 63 presents the suturing times per suturing method for both starting method groups.

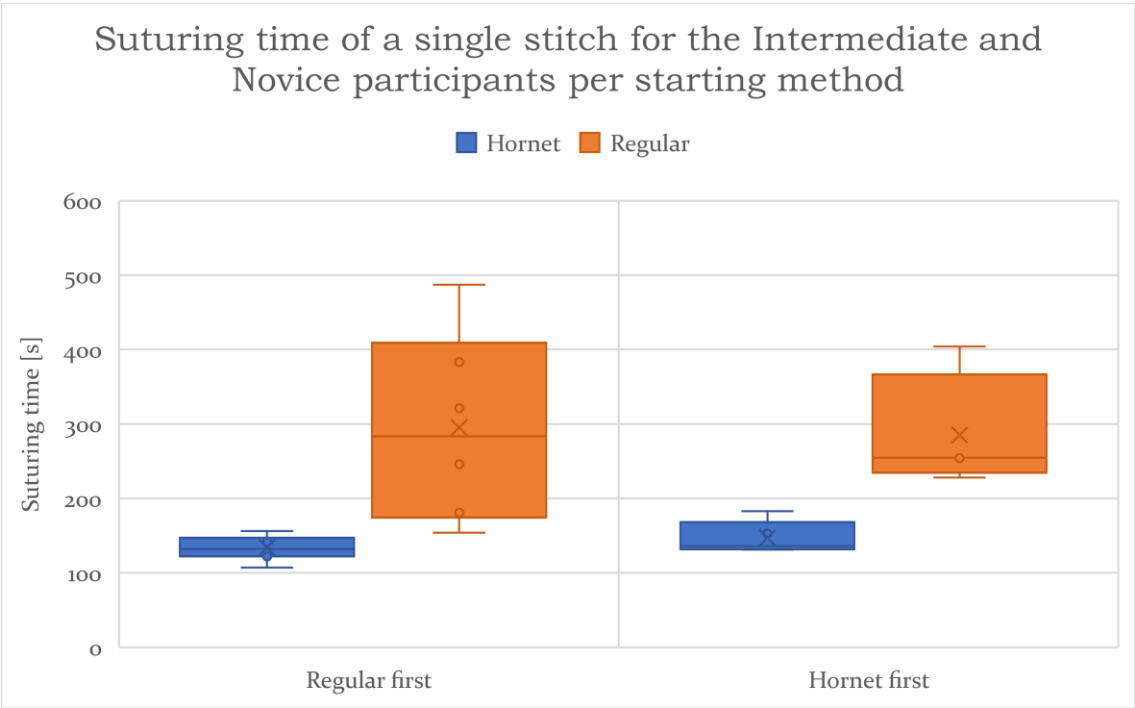


Figure 63: The suturing times to place a single stitch with knots. A division is made between the participants that started with the regular suturing method (Left) and participants that started with the Hornet method (Right).

Suture quality

The sutures placed by the participants were assessed and assigned to one of the three suture quality groups: fully open, slightly open, and closed. The results for all participants are visualized in Figure 64.

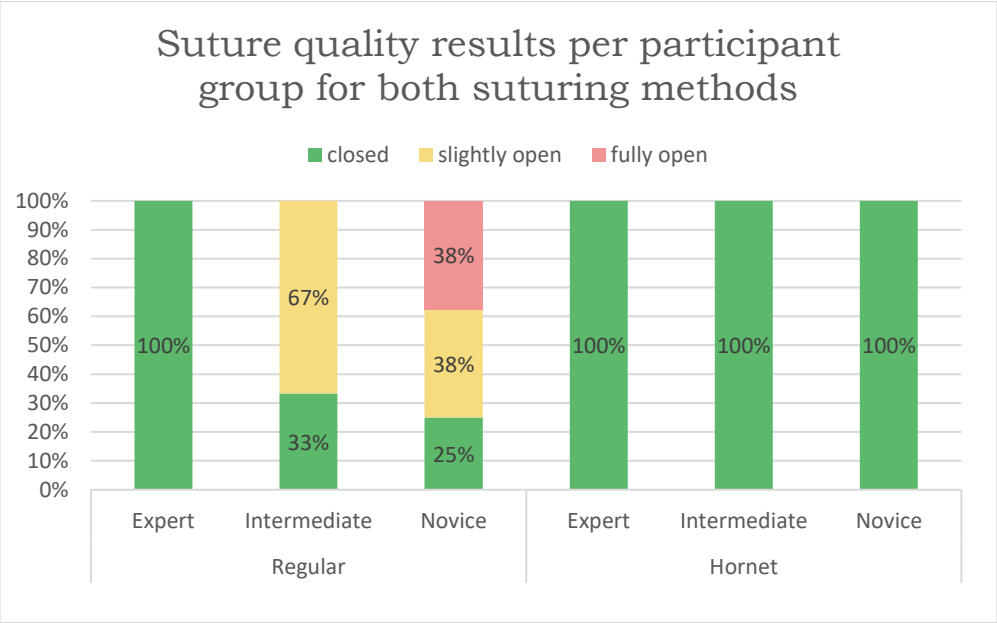


Figure 64: Suture quality of the sutures placed by the participants per participant group and suturing method.

Questionnaire results

After the test, each participant filled out a questionnaire. The full questionnaire can be found in Appendix L, and the answers given by the participants are listed in Appendix M.

The questionnaire focusses on three main categories: the instrument design, the instrument usage, and the suturing technique. The statements in the questionnaire were based on the Product Specifications and questions that arose during the initial evaluation of the prototype with the consulting gynecologists. In addition to answering the statements, the participants were encouraged to give comments on their experience with both the Hornet and the regular suturing method.

Several one-way ANOVA tests were executed to determine whether the answers given in the questionnaire were significantly different per participant group. The tests showed that the responses in the questionnaire by the three participant groups per statement were not significantly different. The scores given by all the participants for each statement are therefore presented together to improve readability. For an overview of the calculated F-statistic values and p-values, see Appendix P.

Instrument design

The scores given by the participants for the statements that are related to the design of the instrument are presented in Figure 65.

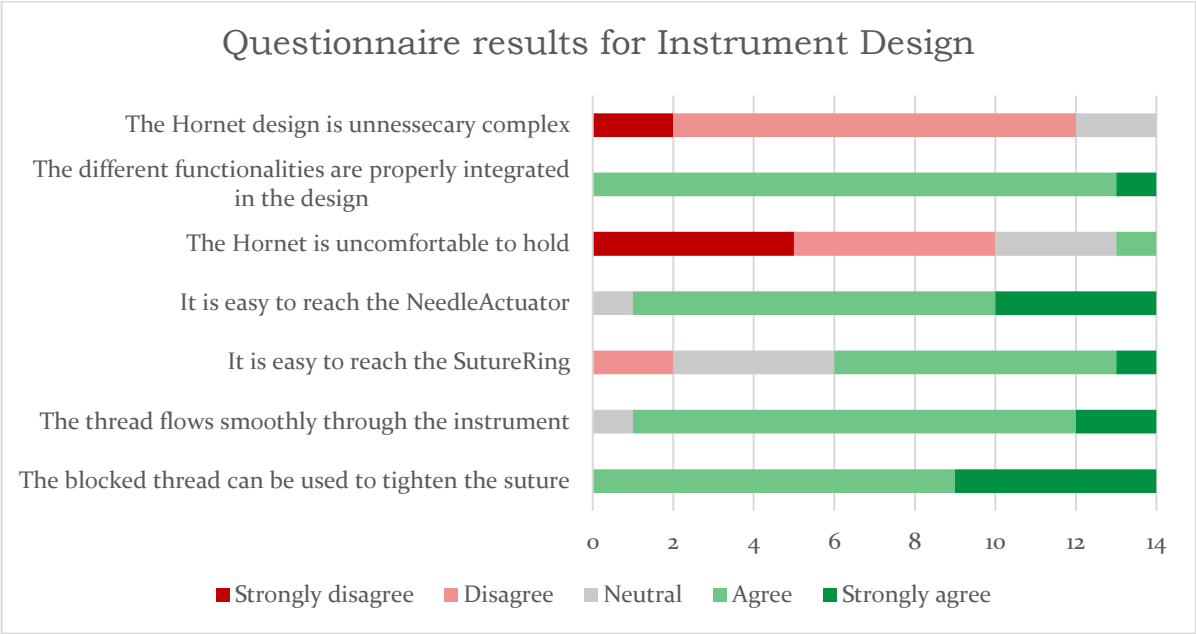


Figure 65: Questionnaire results that focus on the Instrument Design (statements are translated from Dutch).

All participants found the Hornet well designed for its functions. The NeedleActuator could be reached and used comfortably by all participants, and the SutureRing could be reached comfortably by 71% (10/14) of the participants. The other four participants commented that they could reach and use the SutureRing, but found it uncomfortable.

The Hornet was considered comfortable to hold in general by 71% (10/14) of the participants. Two participants stated that they found all laparoscopic handles uncomfortable due to issues with their hands, and two other participants stated that the Hornet handle shape needs some getting used to.

Instrument usage

The scores given by the participants for the statements that are related to the usage of the instrument are presented in Figure 66.

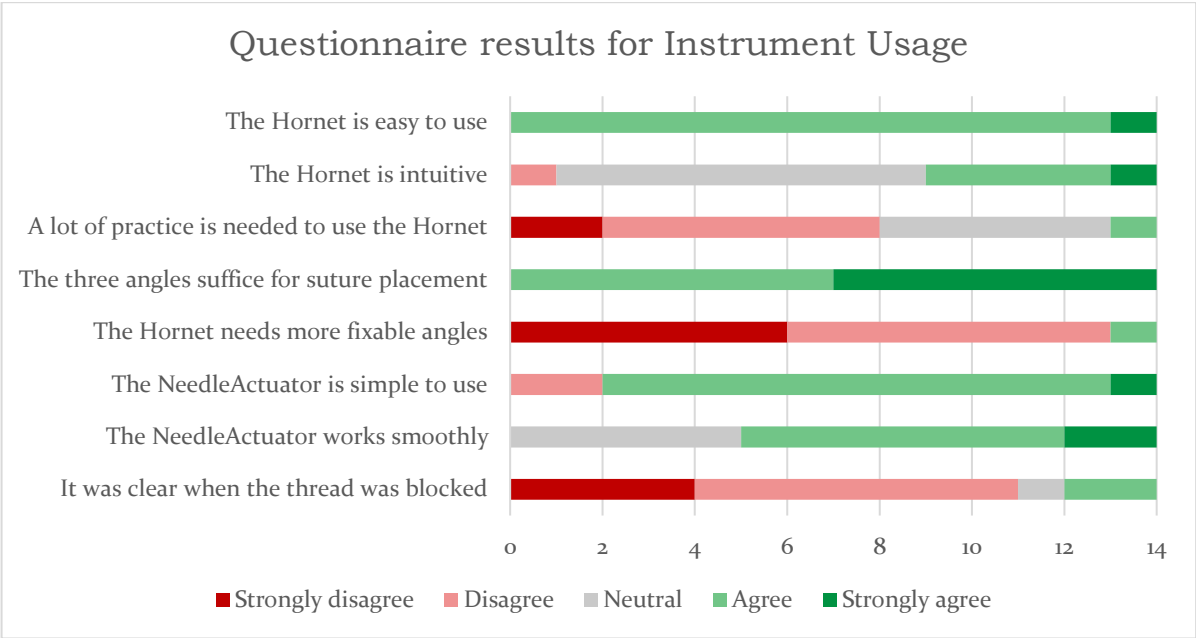


Figure 66: Questionnaire results that focus on the Instrument Usage (statements are translated from Dutch).

All participants found the Hornet easy to use, but several stated that some initial instruction was required to use the functions on the handle. The three angles that can be fixed by the NeedleActuator are considered to be sufficient for suture placement by all participants. However, two participants stated that they would prefer a stepless system, similarly to that of a needle holder, to allow the needle to be fixed at any angle.

Three main comments were made by the participants regarding the use of the SutureRing. Firstly, 57% (8/14) of the participants noted that the rotation of the SutureRing feels counter-intuitive, as it rotates left to block the thread. They did not consider this to be a problem, but stated that it does require some instruction and practice with the Hornet. Secondly, 21% (3/14) of the participants found that when using the SutureRing, the NeedleActuator can rotate accidentally, unlocking and retracting the needle during use. Thirdly, 79% (11/14) of the participants found it difficult to know when the thread was blocked without pulling on the thread, and asked for a visual or audible signal that the thread is blocked or unblocked.

Suturing techniques

Several statements in the questionnaire aimed to survey the participant's opinion about the two suturing methods used during the User Tests. The scores given by the participants for the statements that are related to these suturing techniques are presented in Figure 67.

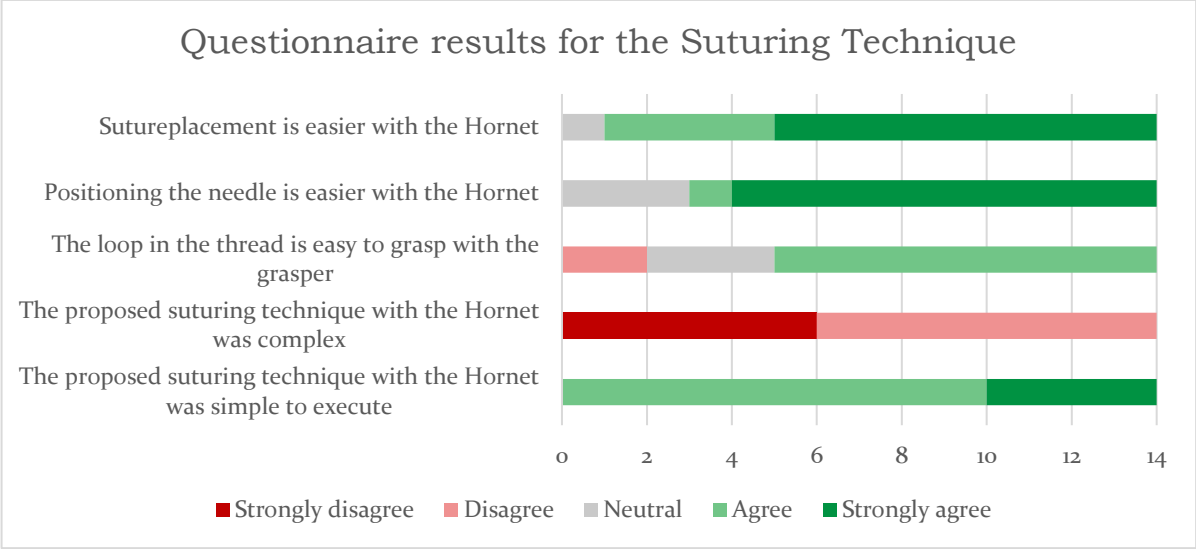


Figure 67: Questionnaire results that focus on the Suturing Techniques (statements are translated from Dutch)

All participants stated that aligning the needle and placing a suture is easier with the Hornet compared to regular suturing. Issues noted with the regular suturing method include the difficulty of grasping, holding on to, and manipulating the needle and thread with a needle holder. According to the participants, the Hornet solves these problems as both the needle and thread are permanently attached to instrument. The participants stated that especially knot-tying was simpler with the Hornet compared to regular suturing. The three Expert participants liked the ability to change the angle of the needle during use, as a needle driver does not allow for the angle of the needle to be changed without dropping the needle.

The modified sewing machine suturing technique with the Hornet was considered by all participants to be simple to execute after some instruction. Grasping the loop was seen as difficult by 14% (2/14) of the participants. Three other participants, that gave a neutral score to the statement, commented that grasping the loop was do-able but seeing it requires some squinting. All five participants, stated that practicing with the Hornet made grasping the loop easier, and they all believed it to be simpler than the thread manipulations needed for regular suturing.

5

Discussion

The goal of this thesis was to "*develop a laparoscopic suturing instrument that uses the modified sewing machine suturing technique to simplify the closure of the vaginal cuff*". To this end a laparoscopic suturing device, the Hornet, was designed, built and tested. The results of these tests, presented in the previous chapter, show that a laparoscopic suturing device was created that can be used to place a suture with the modified sewing machine suturing technique in a model of the vaginal cuff. In this chapter, the main features of the design of the prototype will be compared to existing laparoscopic instruments, and the results of the tests will be analyzed and discussed to determine whether the Hornet simplifies the closure of the vaginal cuff.

5.1. The prototype design

The design of the prototype has three main features that are unique to the Hornet: the deployable needle with fixable angles, the freely adjustable and lockable thread, and the handle shape. There are three laparoscopic instruments available to which the Hornet can be compared: two suturing devices, the Endo Stitch™ by Covidien [17] and the RD180 Device® by LSI Solutions [18], and an implantation device for pacemakers with a hollow, rotatable needle [19].

The first feature unique to the Hornet is the deployable needle. While the implantation device for pacemakers has a deployable needle, and the Endo Stitch and RD180 Device both have needles attached to the instrument, the Hornet is the first suturing instrument with a deployable needle with fixable angles, giving the user more freedom and stability while placing a suture. Additionally, the curved needle of the Hornet has dimensions similar to the regular needles used during laparoscopic procedures, whereas the other instruments have shorter, straight needles, limiting their usability.

The second unique feature is the freely adjustable and lockable thread. The modified sewing machine suturing technique of the Hornet requires the thread to flow freely through the needle tip, allowing the users to adjust the length of the thread during the suturing process to provide more freedom of movement. The Endo Stitch and RD180 Device, on the other hand, are equipped with a fixed length of thread that cannot be altered once the suturing process has started. To tighten the suture and knots, the SutureRing of the Hornet can be used to block the flow of the thread at any time, whereas the other instruments can only tighten the thread under certain conditions, such as holding the needle with both jaws for the Endo Stitch, and repositioning the thread in the shaft for the RD180 Device.

Finally, the handle shape is unique to the Hornet. The rounded, in-line design of the Hornet's handle is different from the axial and pistol grip handles with levers of the needle holders and available laparoscopic suturing devices (see Appendix F). The shape of the handle of the Hornet is designed to lay comfortably in the hand and rotate easily, whereas the pistol grip handles cannot be rotated in the hand, and are known to cause muscle strain in the hand with prolonged use [20, 21].

5.2. Interpretation of the results

Two sets of tests were conducted to test the built prototype, the Design Verification Tests and the User Tests. The results of the different tests, and their implications, are discussed below.

Nine two-sample t-tests for unpaired data were conducted to compare the suture times and needle alignment times of the different participant groups and the two suturing methods. The p-values and significances obtained through these tests are included in the discussion of the User Tests results below. An overview of all t-test results is given in Appendix P.

5.2.1. Interpretation of the Design Verification Tests results

The goal of the Design Verification Tests was to verify the Product Specifications. The results of these tests show that 77% (17/22) of the Product Specifications were met. Two of the Product Specifications were not verified at this stage of the prototype development, as described in the Design Verification Tests section of the previous chapter. The three Product Specifications that did not meet their acceptance criteria are listed below.

- PS-1.2: Working length of shaft (tip to base).
- PS-2.3: Fixation of the angle between needle and shaft.
- PS-3.1: Needle length.

Why these specifications were not met, and whether this has had an influence on the results of the User Tests, was analyzed.

PS-1.2: Working length of shaft (tip to base)

The working length of the shaft is 291 mm, which is shorter than the length required by PS-1.2. Initially, the working length of the shaft met the Product Specification. However, the design of the handle was altered after the shaft for the prototype was produced, resulting in a shorter working length of the shaft. It was decided not to re-make the shaft, as the resulting working length of the prototype was still considered to be sufficient for use in the lapro-trainer. The length of the shaft has had no influence on the results of the User Tests, as none of the participants had any difficulty in reaching the silicon model of the vaginal cuff during their tests.

PS-2.3: Fixation of the angle between needle and shaft

Two of the angles at which the prototype can fixate the needle, deviate by 2° from the angles required by PS-2.3. These slight deviations are likely caused by the slack in the system that allows the needle to move slightly when locked. The results show that these deviations from the preferred angles do not impact the performance with the prototype. All participants of the User Tests stated that the three angles of the prototype were sufficient to place a suture. This includes the two consulting gynecologists that requested the three fixable angles in the User Requirements (see Appendix B).

PS-3.1: Needle length

The length of the needle in the prototype was limited by the length of the available sewing machine needles. This resulted in a shorter needle length than requested by the acceptance criterium of PS-3.1. The two consulting gynecologists stated that a longer needle would improve the formation of a loop, making grasping the loop easier (Ref User Input). This might suggest that the shortness of the needle could have influenced the ability to grasp the loop during the User Tests. During the tests, 36% (5/14) of the participants had some issues with seeing and grasping the loop. It is, however, unclear if these issues were caused by the length of the needle or by other external factors like lighting, eye-sight and the color of the background versus the color of the thread.

5.2.2. Interpretation of the User Tests results

The main goal of the User Tests was to determine whether the Hornet simplifies laparoscopic suture placement and fixation. To prevent a bias in the results, half of the Novice and Intermediate groups started their test procedure with the regular suturing method and the other half started with the Hornet method. The results show that, regardless of which method was used first, there was no significant difference in the suturing times with the regular method (P=.59) or in the suturing times with the Hornet method (P=.38). This suggests that the order in which the two suturing methods were performed did not influence the results of the participants.

Before testing, it was expected that the participants of the User Tests would all perform better with the Hornet method compared to the regular suturing method, regardless of their experience with suturing and laparoscopic procedures. The results show that the Novices benefited the most from the Hornet with significantly faster (P<.001) suturing times with the Hornet (M= 143 s, SD= 20 s) than with regular suturing (M=323 s, SD= 101 s). Similarly, a large difference between the mean suturing times of the Intermediates with the Hornet (M=125 s, SD=16 s) and the regular suturing method (M=218 s, SD=56 s) was be observed. The Intermediates were significantly faster (P=.049) with the Hornet than with the regular suturing method. The Experts, on the other hand, had shorter mean suturing times with the regular method (M=84 s, SD=28 s) than with the Hornet method (M=109 s, SD=22 s). The difference between these mean suturing times, however, were not statistically significant (P=.31). These results show that the Hornet has a positive influence on the suturing time for the participants that are new to laparoscopic procedures.

The suturing performances of the Experts with the regular suturing method (M=84 s, SD=28 s) were significantly faster (P=.02) than the suturing performances of the Intermediates (M=218 s, SD=56 s). This can be attributed to the experience of the Experts with laparoscopic suturing techniques, and to the inexperience of the Intermediates with manipulating a needle and thread at a distance in a laparoscopic environment. This is demonstrated by their mean needle alignment times with the regular suturing method. It took the Intermediates on average four times as long to pick up and align the needle compared to the Experts. These slower needle and thread manipulations could be observed throughout the regular suturing procedures of the Intermediates, causing their overall suture placement to take 2.5 times as long compared to the Experts.

The Novice participants, without any suturing or laparoscopic experience, performed slowest with the regular suturing method. It took the Novices 1.5 times longer than the Intermediates to place and secure a single stitch, and nearly four times longer than the Experts. In the questionnaire and during the test procedures, all the Novice participants voiced their annoyance with holding and manipulating the needle during the regular suturing method. Picking up and aligning the needle took the Novices six times as long as the Experts, due to the Novices frequently dropping the needle or grabbing the thread or needle in the wrong location for proper manipulation. These slower manipulations of the needle and thread, in combination with the awkward movements the Novices made with the instruments, resulted in their long suture placement times with the regular suturing method.

For the Hornet method, the differences in the suturing times between the three groups are smaller. The suturing times of the Novices and the Intermediates with the Hornet do not differ significantly (P=.15). These comparable suturing times of the Novices and Intermediates suggest that a user does not require non-laparoscopic suturing experience to place a suture with the Hornet. Similarly, the Experts were not significantly faster (P=.36) in suturing with the Hornet than the Intermediates. This suggests that laparoscopic experience has no significant influence on the first suture placements of a participant with the Hornet.

The quality of the sutures placed by the different participants was similar for the Hornet, but differed for the regular suturing method. All participants created a closed suture with the Hornet, whereas only 43% (6/14) of the participants created a closed suture with the regular suturing method. The Experts all created closed sutures with the regular suturing method. Of the intermediates, 33.3% (1/3) created a closed suture, and 67,7 % (2/3) created a slightly open suture with the regular suturing method. The Novices performed the least consistent, with 25% (2/8) creating closed sutures, 38% (3/8) creating slightly open sutures, and 38% (3/8) creating fully open sutures with the regular suturing method. The main cause for the open sutures created with the regular suturing method was the difficulty of keeping tension in the thread while placing the knots. The modified sewing machine suturing technique with the Hornet did not have this problem, as the interlocked thread in the tissue, created when the stitch is placed, provides enough friction to keep the suture closed while the knots are placed. The results of the participants indicate that suture placement with the Hornet allows for consistently closed sutures for all participants, whereas the suture quality of the regular suturing method depends on the experience of the user.

The Novice and Intermediate participants all entered the User Tests without any experience with laparoscopic suturing. Their significantly faster results with the Hornet compared to regular suturing, as presented above,

suggest that placing a suture in a laparoscopic environment is easier with the Hornet than with the regular suturing method. The results of the Experts seem to support this statement as their suturing times with the Hornet, without any practice, were similar to their suturing times with the regular suturing technique, with which they are proficient. This is reinforced by the responses of the participants in the questionnaire, where 93% (13/14) of the participants agreed that suture placement is easier with the Hornet compared to the regular suturing method. One of the main reasons that the Hornet is perceived as easier, appears to be the simplification of the suturing process. As noted by the participants, the permanently attached needle in the Hornet eliminates the need for the difficult needle manipulations required during regular suturing. This is supported by the significant shorter (P=.04) needle alignment times of the Novices for the Hornet method (M=9 s, SD= 3 s), compared to the regular suturing method (M=48 s, SD=45 s).

5.3. Limitations

The test set-up for the User Tests limits the comparability of the suturing times of the tests to the suturing times in a clinical setting. The set-up with the lapro-trainer allows the user to look directly at the model and instruments, rather than perceiving them on a monitor. This takes away the problems with depth perception often associated with laparoscopic procedures. Additionally, the orientation and distance of the vaginal cuff model from the entry point of the instruments in the lapro-trainer differs from reality. In the lapro-trainer, both the model and the instruments are properly lined up and visible, which makes approaching the model simpler than it would be in the clinical setting. Although these differences limit the comparability of the suturing times from the test to those from a clinical setting, reliable conclusions can still be drawn by comparing the results of the different participant groups to each other.

The generalizability of the results is limited by the number of participants that took part in the User Tests. Especially the small groups of Experts and Intermediates, although diverse, decrease the power of the conclusions that are drawn. It is beyond the scope of this study to comprehensively and accurately determine the differences in the suturing times between the Hornet method and regular suturing. The goal of this study is to demonstrate the Hornet's potential as a substitute for regular suturing. For this purpose, the small group of participants in this study suffices.

The reliability of the suturing times and needle alignment times are impacted by the nature of the test set-up. The full test procedures were recorded, and the suturing and needle alignment times were taken from these recordings. Determining these time measurements is prone to subjectivity, because some participants took brakes or pauses in the middle of the procedure that needed to be removed from the measurements to get the true time measurements of the suturing methods. These pauses and brakes were mainly present in the test procedures with the Novices, as they often paused to ask questions or to comment on certain aspects of the suturing procedure or the instruments. Giving the participants some time to practice with both methods would have eliminated these brakes, making the obtained time measurements more reliable. Due to the limited available time of some of the participants, however, no practice time was given beforehand to any of the participants to keep the results comparable. The obtained time measurements cannot be used to assign specific suturing times to the groups of participants. However, the general relationships between the results of the different participant groups can be determined.

5.4. Recommendations

Based on the results, discussions, and limitations of the Design Verification Tests and the User Tests, several recommendations for future research and development of the Hornet can be made. The recommendations fall into two categories: recommendations for the design and development of the Hornet, and recommendations for the testing of the Hornet.

5.4.1. Design and development

The length of the shaft of the prototype was shorter than the required length. For future prototypes, the length of the shaft should be lengthened to meet the requirements to ensure that the Hornet can reach all regions in the abdominal cavity. Similarly, the length of the needle was shorter than the required length. It

was unclear whether this has had an influence on the results of the User Tests. However, to improve the loop formation while suturing the vaginal cuff, the needle length of future prototypes should meet the requirements.

While building the prototype of the Hornet, there were some issues with bending the sewing machine needles. While bending the needle, the tip of several needles broke off before the required curvature was reached. In addition, bending the needle seemed to reduce the needle's strength, as several needle tips broke off during use of the instrument. For future prototypes, specifically designed bent needles should be used, rather than bending a straight needle.

Based on the feedback from the participants in the User Tests, several elements on the handle should be redesigned. Firstly, the direction of rotation of the SutureRing should be altered from counter-clockwise to clockwise to make using the SutureRing more intuitive. Secondly, some sort of feedback should be added to the SutureRing that tells the user that the thread is blocked. This could be, for example, an audible click, a visual indication with color, or a tactile ridge. Thirdly, the locking mechanism of the NeedleActuator needs to be more rigid, to prevent the needle from unlocking when the SutureRing is used. Increasing the length of the notches in the 'shifter-plate'-slot might suffice.

5.4.2. Testing of the prototype

To obtain more accurate results that are statistically relevant, a larger group of participants should be used in future studies. Additionally, the participants should be given some time to get acquainted with the test setting and the instruments before the test is conducted. This will give a more accurate portrayal of their results, as no alterations to the measurements need to be made to make the results comparable.

In this research, the quality of the sutures placed by the participants was assessed by observation of the models. This assessment was used to give an indication of the quality of the sutures placed by the different participant groups. A more extensive analysis of the placed sutures should be performed to verify that the sutures placed by the Hornet are of sufficient quality. This could be done by measuring the tension in the thread and the strength of the knots placed.

This study focused on whether the Hornet would simplify suture placement. Future studies might include researching the learning curve of the Hornet compared to regular suturing. A small start has been made during this study by allowing some of the participants that had some extra time to perform the test procedure twice. The interested reader can find the results of these additional tests in Appendix O.

6

Conclusion

The goal of this research was to develop a laparoscopic suturing device that simplifies the suturing of the vaginal cuff by using the modified sewing machine suturing technique. Based on the analysis of the prototype, it can be concluded that a functional suturing instrument, the Hornet prototype B3, is created.

The built prototype uses a modified sewing machine suturing technique. The needle is fixated in a rotation mechanism in the instrument, giving users the opportunity to deploy and fixate the needle, thus simplifying needle alignment and suture placement. The freely adjustable length of the thread at the tip of the needle allows users to adjust the length of the thread while suturing, and the SutureRing allows the user to block the flow of the thread at any time to tighten a suture or knot. The unique handle design of the prototype was considered to be comfortable to hold by most participants when compared to the handles of the needle holder and grasper, although the design of the SutureRing on the handle requires some adjustments to improve its comfort and usability.

The User Tests demonstrated that a user does not require suturing or laparoscopic experience to place a suture with the Hornet. All participants managed to place a suture with the Hornet that closed the vaginal cuff, whereas only 43% of the participants managed to place a closed suture with the regular suturing method. Additionally, the suturing times of the participants showed that placing a suture in the laparoscopic environment is easier with the Hornet than with regular suturing. The rotatable needle of the Hornet eliminates the difficult needle manipulations of regular suturing, resulting in faster suture placement, and the suturing technique simplifies the knot tying process by maintaining tension in the thread.

This research serves as a proof of concept for the development of the Hornet. The evaluation of Hornet prototype B3 showed that the prototype simplifies the closure of the vaginal cuff for users with different levels of suturing experience. Some alterations to improve the functioning of the prototype are required to ensure that all the Product Specifications are met. In addition, further research is needed to assess the quality of the sutures placed with the Hornet, to investigate the extent in which the prototype simplifies the suturing process, and to determine the learning curve of the instrument.

To conclude, the Hornet prototype B3 has important beneficial features such as the deployable needle and the lockable thread, that simplify the suturing process. The use of a rotatable needle makes aligning and manipulation of the needle easier, whereas the blocking of the thread in combination with the Hornet's suturing technique makes it possible to distribute the tension evenly over the suture, simplifying the knot-tying process. These features result in faster suturing times for users with different levels of experience.

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Appendices

Appendix A: User Input Overview

DEAM steerable medical devices

Confidential

Hornet

Document Title	**User Input Overview**
Document ID	**DE_361_UserInputOverview_B3**
Project Phase	**B3**

Table of Contents

1 Scope

Over the years of the design of the Hornet, multiple meetings, interviews, prototypes, and test sessions have taken place. This report gives an overview of all the documented user input that is relevant for the design of the Hornet prototype B3.

2 Meeting overview

Date	Attendees		Subjects discussed
22-07-2017	Designer: User: Supervisor:	K. Laarhoven J. English	Designs Hornet prototype B1
28-03-2018	Designer: User: Supervisor:	K. Laarhoven J. Rhemrev J. Scheltes	Evaluation Hornet prototype B1
19-11-2018	Designer: Supervisor:	W.R. Beers J. Scheltes	Introduction to the Hornet project and problems with prototype B1
22-02-2019	Designer: User: Supervisor:	W.R. Beers J. English J. Rhemrev J. Scheltes W. Peters	Evaluation Hornet prototype B2
04-09-2019	Designer: User: Supervisor:	W.R. Beers J. English J. Rhemrev J. Scheltes W. Peters	Presentation new suture technique Hornet prototype B3
02-10-2019	Designer: User: Supervisor:	W.R. Beers J. English J. Rhemrev J. Scheltes	Handle options Hornet prototype B3

3 Meeting summaries

3.1 22-07-2017

User input from J. English (Gynecologist) for the design of Hornet prototype B1.

#	Requirement	Remarks
1	Thread diameter	3-0 thread is very fine. We even use 0 thread for suturing a vaginal top (0.4mm), the hornet will use a 2-0, 0 or 1 thread
2	Thread type	Use barbs to make suturing easier
3	Thread material	Thread must be resorbable, use a polyglyconate (vycril) or PDS which is stronger
4	Needle diameter	The needle must be at least 0.7 mm and shouldered. The pointy tip only has to slightly stick out of the cylinder to which the suture thread is attached
5	Needle tip	Diamond tip needle splits the tissue, a conical tip pushes it apart and closes easier after the needle has passed
6	Needle strength	Lifting tissue with the needle is a user situation that will never happen in normal use, every surgeon knows that lifting something with a needle is dangerous, keep this in mind when modeling extreme situations
7	Shaft cut-outs	The shaft cut-out must be mirrored to make it suitable for holding the hornet in the right and left hand

3.2 28-03-2018

In this meeting, the designer of the Hornet prototype B1 (K. Laarhoven) presented the prototype to J. Rhemrev (Gynecologist).

During the meeting, several remarks were made with respect to the requirements for the instrument. The remarks were summarized by K. Laarhoven and are shown in the table below.

#	Requirement	Remarks
1	Shaft length	Shaft should be longer (+/- 50mm), it is currently too short. *Shaft length prototype B1: 285 mm*
2	Needle length	Needle should be slightly longer (+/- 5mm) and stick out slightly further out of the cylinder. The shaft could have a small cut-out in which the needle falls. This makes it even more fool-proof for the user to reload the cylinder. *Needle length prototype B1: 13 mm*
3	Thread straightness	During the test the steel wire tended to kink, the Dynema less so. The suture thread should remain free of plastic deformations. Dynema wire was preferred over the steel wire.
4	Handle ergonomics	User made the remark that the handle felt a bit cramped after prolonged use. The bottom half of the handle could be a bit 'higher' to make the fist-grip slightly larger.
5	Needle sharpness	The needle is not sharp enough currently. Surgical diamond tip needle is required.

3.3 19-11-2018

An introduction to the Hornet project by Jules Scheltes. The problems with prototype B1 were explained.

#	Requirement	Remarks
1	Shaft length	The shaft's length of prototype B1 was 285 mm. A length of 300-360 mm is preferred.
2	Needle length	The Needle of prototype B1 consists of 2 parts: an 14 mm long needle with a diameter of 0.7 mm (of which 8 mm is visible), and a 4 mm long filler around the Needle, resulting in a total diameter of 1.0 mm. It is preferred that no filler is needed and the needle has a visible length of 15-17 mm.

3.4 22-02-2019

Hornet prototype B2 was presented to Dr. J. Rhemrev and Dr. J. English. The prototype was then tested to get the opinions of the gynecologists.

#	Requirement	Remarks
1	Needle size	A round-tipped needle must be used when suturing muscle-tissue. Round-tipped needles 'push' apart the tissue without creating an actual hole. When the needle is removed, the tissue shrinks back around the suture. This makes leakage after suturing less likely.
2	Reloading	It is too difficult to reload the needle back into the shaft. It is difficult to properly align the needle with the opening in the shaft. Maybe magnets can be used to attract the needle into the shaft.
3	Needle angles	It is really nice how the needle angle can be changed to properly align the needle.
4	Needle fixation	It would help if the needle was fixated in the shaft. This will remove the need to manipulate the needle with the needle holder (something which is difficult in the laparoscopic setting).

3.5 04-09-2019

As part of the development of the new suturing technique, several models of the vaginal cuff were created and closed with different suturing methods. The consulting gynecologists then were asked to provide their insights on which types of cuff closure were acceptable / the best.

#	Requirement	Remarks
1	Suture method	A clip is the easiest way to secure suture because it is easy to keep the tension in the suture. Clips are expensive. Knot-tying and barbed suture are also good options.
2	Needle vs Suture diameter	It does not matter if the needle has a larger diameter compared to the suture as long as you do not use a cutting needle but a round tipped needle. When the needle is retracted, the tissue 'shrinks' around the suture because it is muscle-tissue. This reduces the chances of leakage.
3	Needle shape	A curved needle makes suturing easier.
4	Knot-tying	The instrument makes it possible to easily manipulate the suture which can help during knot-tying.
5	Needle length	The needle will need to be about 2.5 cm long. If too short, there will not be a big enough loop through which to pull the short end of the thread.

#	Requirement	Remarks
6	Suture technique	Try to design the instrument for a running suture. There is no reason to make interrupted sutures, they are only time-consuming.
7	New suture technique	The new suture technique makes it easy to distribute the tension in the suture.
8	Suture	The end of the suture needs to be reinforced to make it easier to grasp and manipulate
9	Suture	The end of the suture must have a different color to make it easier to see

3.6 02-10-2019

Two different handle designs for the Hornet prototype B3 were presented. Several questions about the handles and their functionalities were asked, resulting in the remarks given in the table below.

The presented handle models were:

Model 1: A standard, rigid inline handle for a needle driver.
Model 2: A handle based on the design of the LaproFix handle.

#	Requirement	Remarks
1	Handle shape	Model 1: The handle is already very functional and can be used in 360 degrees just by changing your hand. Lays better and sturdier in the hand compared to model 2 handle. Model 2: can work if it is fully rigid. Because if there is resistance of the tissue it might bend. The handle itself is fine. The end needs to be rigid.
2	Thread fixation method	A knob or a slide/wheel is preferred for fixating the thread.
3	Angle between needle and shaft	It must be possible to fixate the angle of the needle. The ideal angles are 45° to 135°. The default angle used is 90°, but 45° is a pleasant angle to work with and angles >90° (up to 135°) make it easier to suture in deep pelvis areas.
4	Needle rotation	If the handle can be easily rotated in the hand, there is no need to add a functionality that rotates the needle. Adding this will make the instrument unnecessary complex.
5	Needle length	Needle length is good, it is easy to penetrate through both sides of the vaginal cuff. *Needle length is 17 mm*
6	Suture method	You should be able to use the Hornet with a regular grasper (and not only the LaproFlex) to make the design feasible. With this instrument, the struggle of having to grasp and manipulate a needle in the correct angle with a needle driver disappears.

Appendix B: User Requirements

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User Requirements

Project	**Hornet**
Document ID	**User Requirements Hornet B3**

1 Use

The Hornet will be used for laparoscopic surgical procedures.

2 User Requirements

The requirements as listed in this document are based on assessments that have been generated over the period of Jan 2015 to Dec 2020. They are based on the User Input Report <Ref 1>, discussions with consulting gynecologists J. Rhemrev and J. English, and the experience of personnel at DEAM, having more than 10 years of experience in the development of laparoscopic instruments.

#	Requirement	Must/ Wish	Acceptance Criteria	Origin	Method to demonstrate conformity
UR-1	**Overall**				
UR-1.1	Fit in standard sized 5mm trocar	M	Should fit at least the top 3 standard trocars	Consulting gynecologists and DEAM.	Determine the inner diameter of commonly used standard trocars and check if the outer diameter of the instrument is smaller.
UR-1.2	Length for use in the abdomen of a normal sized person	M	Able to reach all area's in the abdominal cavity	Logic reasoning based on <Ref 1> and <Ref 2>	Length of shaft from tip till base equal to length of currently available instruments, OR: Determine from anatomy in literature the maximal distance from standard trocar entry to deepest region and check if length of instrument is larger.
UR-1.3	To be used in most regular hand sizes	M	Integrated in the design and successfully validated	Logic reasoning based on <Ref 2>	Check with hand sizes in ergonomic literature, AND/OR: Integrated in the design, validation in user questionnaire. AND / OR: Visual inspection using physical hand model
UR-1.4	Single handed use	W	Integrated in the design and successfully validated	Consulting gynecologists and DEAM.	Integrated in the design, validation in user questionnaire. AND / OR: Visual inspection using physical hand model
UR-1.5	Right and left handed use	W	Instrument is available in a right and left handed version	DEAM	Integrated in the design, validation in user questionnaire, AND/OR:

#	Requirement	Must/ Wish	Acceptance Criteria	Origin	Method to demonstrate conformity
					Visual inspection using physical hand model
UR-1.6	Extension at distal end of the shaft	W	The extension should not hinder the suturing process.	Consulting gynecologists	Measurement of the extension at the distal end of the shaft.
UR-2	**Needle (un)folding**				
UR-2.1	Ergonomically acceptable force on and movement of the lever to fold and unfold the needle	M	Acceptable strain and stress on the fingers to deploy the needle	Logic reasoning based on <Ref 2>	Determine in literature the acceptable movement and force of the fingers and check if the required movement and force of the fingers in the instrument is smaller. AND/OR: Validation in user questionnaire.
UR-2.2	Angles of unfolded needle with respect to shaft adequate enough to place suture.	M	Able to create the needle angles required to place the suture	<Ref 1>	Validation in user questionnaire.
UR-2.3	Fixation of the needle possible at specific angles.	M	Fixate the angle of the needle at 45°, 90° and 135°.	<Ref 1>	Inspection of prototype, AND/OR: Validation in user questionnaire
UR-2.4	Automatic folding of the needle	W	When releasing the lever on the handle, the needle folds	Risk reduction, consulting gynecologists, and DEAM's experience	Visual inspection of prototype, AND/OR: Validation in user questionnaire
UR-3	**Tissue penetration**				
UR-3.1	Needle length long enough to penetrate larger samples of tissue	M	Able to penetrate both walls of the Vaginal Cuff at the same time	Logic reasoning based on <Ref 1>	Equal length as current needle in needle holder AND/OR: Determine in literature the acceptable length and check if the length is comparable. AND/OR: Validation in user questionnaire.
UR-3.2	Needle sharpness	M	Able to insert needle in all suture-able tissues in the abdominal cavity	Logic reasoning based on <Ref 1> and <Ref 2>	Equal sharpness as currently used needles, AND/OR: Validation in user questionnaire.

#	Requirement	Must/ Wish	Acceptance Criteria	Origin	Method to demonstrate conformity
UR-4	**Thread manipulation**				
UR-4.1	Length of thread adequate for easy manipulation	M	Length adequate for knot tying after placing a running suture	Consulting gynecologists	Equal length as current thread AND/OR: Validation in user questionnaire.
UR-4.2	Thread to be free of plastic deformations	W	The thread should be free from plastic deformations during regular use	Logic reasoning based on <Ref 1>	Determine in literature thread types that are known not to plastically deform, AND/OR: Validation in user questionnaire.
UR-4.3	Thread can be blocked	M	The flow of the thread through the instrument can be blocked	Requirement for tightening the knot/suture: consulting gynecologists and DEAM.	Inspection of prototype, AND/OR: Validation in user questionnaire
UR-4.4	Length of thread at tip can be adjusted	W	It is possible to adjust the length of the thread at the tip of the instrument.	Requirement for tightening the knot/suture: consulting gynecologists and DEAM.	Inspection of prototype, AND/OR: Validation in user questionnaire
UR-5	**Handle**				
UR-5.1	Functional usage of the handle in 360 degrees.	W	It should be possible to rotate the handle in the hand without losing access to functionalities.	Consulting gynecologists and DEAM	Physical inspection, AND/OR: Validation in user questionnaire
UR-5.2	Simple handle design	W	The handle should be easy to use with as few functionalities as possible.	Consulting gynecologists	Physical inspection, AND/OR: Validation in user questionnaire

3 Reference Documents

Reference number	Document name
<Ref 1>	DEAM, *DE_361_UserInputOverview_B3*. Amsterdam 2019.
<Ref 2>	Broeders, I.A.M.J. and Kalisingh, S.S.(2009)., *Handboek endoscopische chirurgie*. Bohn Stafleu van Loghum.

Appendix C: Product Specifications

DEAM steerable medical devices

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Product Specifications

Project	**Hornet**
Document ID	**Product Specifications Hornet B3**

1 Scope

This document describes the design input for the design of the Hornet. Input is received from the user requirements and from choices made during the design process.

The product specifications describe the functional requirements of the instrument in measurable acceptance criteria so that conformity can be proven in the verification test. As such the product specifications shown in this document are the baseline for all design verification activities.

2 Product Specifications

Force values identified in the acceptance criteria are assumed to be representative for both the dominant hand and non/ dominant hand. It can be argued that, equal to other activities, the user will apply the dominant hand for the most force requiring tasks.

#	Product specification	Acceptance criteria & rationale	Origin
PS-1	***Overall***		
PS-1.1	Tip and shaft diameter	A: Diameter ≤ 5.1 mm R: Must fit through commonly used standard 5mm Trocar. (<Ref X>, p. 19).	UR-1.1
PS-1.2	Working length of shaft (tip to base)	A: Length between 310 mm and 420 mm R: Length of currently available rigid 5 mm laparoscopic instruments (<Ref 3>, p. 93; <Ref 4>, p.24,31; <Ref 5>, p.14). A length of 285 mm is considered to be too short by J. Rhemrev and J. English (<Ref 1>, p.5).	UR-1.2
PS-1.3	Hand size (length and width)	A: All features on the handle can be reached by hands with a length between 15.8 cm and 20.6 cm, and a width between 6.9 cm and 9.6 cm. R: Length and width of the hand from 5th percentile female to 95th percentile male (<Ref 6>, p. 34, 35).	UR-1.3
PS-1.4	Single handed use	A: The instrument can be operated during use with a single hand R: The instrument is used in combination with another instrument in the other hand, so only one hand is available for the Hornet during the procedure.	UR-1.4

#	Product specification	Acceptance criteria & rationale	Origin
PS-1.5	Right and left handed use	A: Instrument controls can be accessed by the right and left hand. R: This specification gives equal control of the functionalities of the instrument with the right and left hand.	UR-1.5
PS-2	***Needle deployment and retraction***		
PS-2.1	Needle deployment force	A: The force on the fingers to maximally deploy the needle should be less than 19.3 N. R: The sustained thumb-finger palmer grip strength in 5th percentile male is 35 N (<Ref 6>, p. 132). A female has an upper extremities strength of 55% of the male strength. (<Ref 8>, p.133)	UR-2.1
PS-2.2	Angle between needle and shaft	A: Angles of the needle up to 135° should be possible. R: Wish from the consulting gynecologists, described in the User Input (<Ref 12 >, p.5)	UR-2.2
PS-2.3	Fixation of the angle between the needle and the shaft	A: The needle can be fixated at angles of 45°, 90° and 135°. R: Wish from the consulting gynecologists, described in the User Input (<Ref 12 >, p.5).	UR-2.3
PS-2.4	Automatic needle retraction	A: When releasing the feature on the handle to deploy the needle, the needle should retract automatically. R: To prevent the needle from accidentally causing damage inside the abdomen while not in use, the needle should retract automatically back in the shaft when the feature that operates this function is released.	UR-2.4
PS-3	***Tissue penetration***		
PS-3.1	Needle length	A: The free length of the needle, from the NeedleBase to the tip, is 25 +/- 2.0 mm. R: Length needed to penetrate both walls of vaginal cuff (<Ref 13>) with enough extra needle length to perform the suture technique (<Ref 12>, p.4). A length up to 17 mm was considered too short in Prototype B2, the needle needs to be around 25 mm to have enough length to create the loop when put through the vaginal cuff (<Ref 12>, p.5).	UR-3.1
PS-3.2	Needle diameter	A: The diameter of the needle between 0.88 mm & 1.28 mm. R: Commonly used needle for Laparoscopic Hysterectomies: ½ circle, round bodied needle with universal code 2347 with suture size USP 1(<Ref 14>). This code refers to a round bodied needle of 40mm long (<Ref 15>, p.7). The diameters associated with this needle type and suture size are 0.88 – 1.28 mm (<Ref 16>, p. 4,5).	<Ref 12>, based on use of Hornet on the Vaginal Cuff.
PS-3.3	Needle sharpness	A: Needle has a puncture force of at least 2.8 N through the body of the stomach. R: Needle sharpness is determined by the penetration force of the needle (<Ref 21>). Cronin et al (<Ref 22>) found that a new Endo Stitch needle (an existing laparoscopic suture-instrument) has a puncture force of 2.8 +- 0.7 N through the body of the stomach.	UR-3.2
PS-4	***Thread specifications***		
PS-4.1	Diameter of thread	A: Diameter of thread between 0.3 and 0.5 mm R: USP 1 (<Ref 8>, p.692), USP 0 (<Ref 7>, p.119.e2), and USP 2-0 (<Ref 9>, p.1) are commonly used suture sizes for the intended use. USP 1, 0 and 2-0 sutures have a diameter of 0.400-	Based on use of Hornet on the Vaginal Cuff

#	Product specification	Acceptance criteria & rationale	Origin
		0.499 mm, 0.350-0.399 mm, and 0.300-0.339 mm respectively (<Ref 10>).	
PS-4.2	Thread pliability	A: Thread should be a multifilament suture. R: Multifilament suture materials are less likely to plastically deform, easier to handle and better suited to secure knots <Ref 17>).	UR-4.2
PS-4.3	Working length of thread	A: The working length of the thread should be at least 23 cm. R: The ideal thread length for a running suture with a knot is 15-23 cm (<Ref 18>, p. 8).	UR-4.1
PS-5	**Thread manipulation**		
PS-5.1	Thread flow through instrument is unhindered.	A: The thread can flow freely through the instrument without accidentally being blocked. R: In order to place the suture smoothly, the thread must flow freely from the instrument.	Chapter: Thread System
PS-5.2	Loop formation at the proximal side of the deployed needle.	A: When placing a suture, the required loop must form at the proximal side of the needle. R: In order to be able to place a suture using the technique proposed in **Introduction Chapter**, the loop must be accessible to grab with a grasper. According to the consulting surgeons, the loop is most accessible when formed at the proximal side of the deployed needle.	Chapter: Suture Technique
PS-5.3	Thread can be blocked	A: The flow of the thread can be blocked. When blocked, a suture and knot can be placed without the thread slipping. R: The instrument must be able to put enough tension on the thread during suture placement and knot tying to ensure that the suture is placed and secured properly.	UR-4.3
PS-5.4	Length of thread at the tip can be adjusted.	A: The length of the thread at the tip of the instrument can be adjusted during use. R: In order to make suture placement and knot-tying easier, it should be possible to adjust the length of the available thread at the tip of the instrument (<Ref 12>).	UR-4.4
PS-5.5	Thread can flow through the NeedleBase	A: The thread can flow freely through the NeedleBase to reach the Needle. R: To ensure that the thread is always properly aligned with the Needle, regardless of how far the needle is deployed. Guiding the thread through the NeedleBase prevents the thread from getting stuck in the rotation system.	Chapter: Thread System
PS-6	***Handle***		
PS-6.1	Reachability of handle features	A: All features on the Handle can be reached regardless of how the handle is rotated in the hand. R: It is important to be able to rotate the tip of the instrument during laparoscopic procedures in order to be able to accurately reach all tissues in the abdominal cavity. For suturing, the consulting gynecologists prefer to rotate the instrument that holds the needle by rotating the handle in their hands over rotating the tip of the needle using a functionality on the handle (REF USER INPUT). This preference results in the need that all features on the handle must be operable, regardless of how the handle is rotated.	UR-5.1

#	Product specification	Acceptance criteria & rationale	Origin
PS-6.2	Simple handle design	A: All features on the Handle must be necessary and simple to use. R: Operation of the Handle should be as easy as possible to make the instrument user-friendly.	UR-5.2

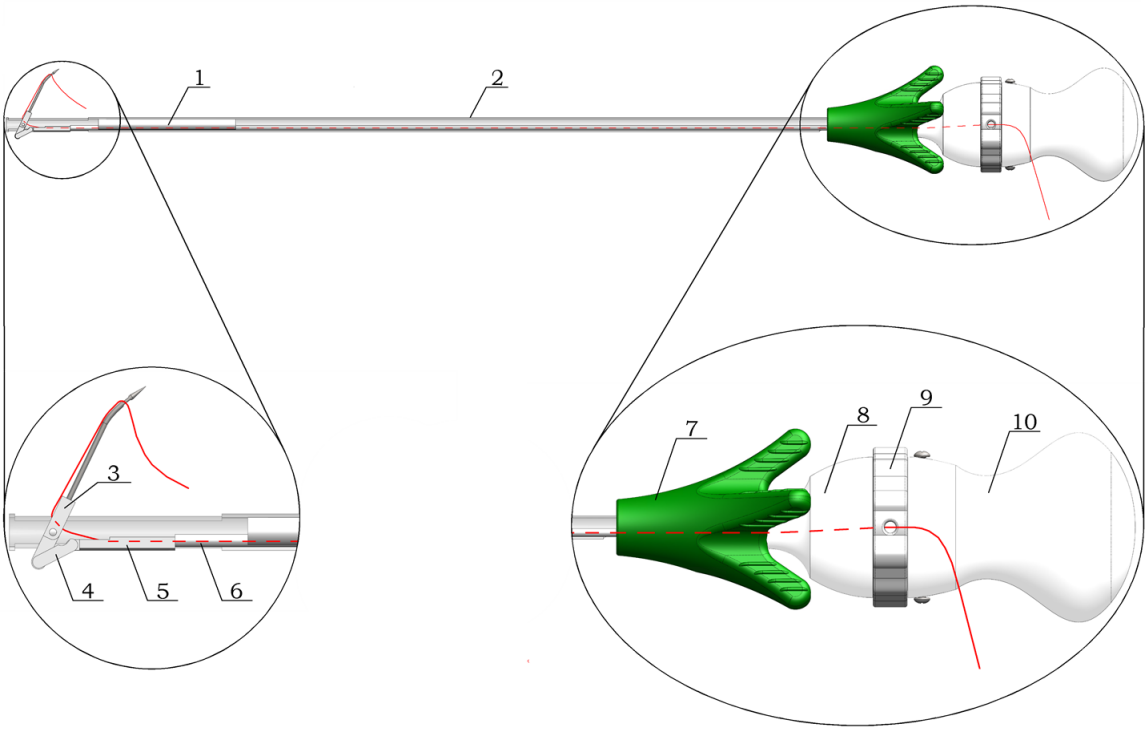
3 References

#	Reference
<Ref 1>	DEAM, *DE_361_UserRequirements_B3.* Amsterdam, 2020 (not published)
<Ref 2>	DEAM, *DE_361_IterativeReview_B1.* Amsterdam, 2018 (not published)
<Ref 3>	Aesculap Inc. (n.d.). *Laparoscopic Instruments product catalog.* Aesculapusa.com. Accessed on March 22, 2021, at: https://www.aesculapusa.com/en/healthcare-professionals/or-solutions/or-solutions-laparoscopic-instruments.html
<Ref 4>	Medtronic. (n.d.). *Access and Instruments product catalog.* Medtronic.com. Accessed on March 22, 2021, at: https://www.medtronic.com/content/dam/covidien/library/us/en/product/hand-instruments-and-ligation/access-instrumentation-products-catalog.pdf
<Ref 5>	Genicon. (n.d.) *Genicon Product Catalog*. Retrieved on March 22, 2021, from: https://pdf.medicalexpo.com/pdf/genicon/full-catalogue/68575-169660.html
<Ref 6>	NASA. (1995). *Man-System Integration Standards (NASA-STD-3000) Revision B.* msis.jsc.nasa.gov. Accessed on March 22, 2021, at: https://msis.jsc.nasa.gov/sections/section03.htm
<Ref 7>	Ucella, S. et al. (2011). Vaginal cuff closure after minimally invasive hysterectomy: our experience and systematic review of the literature. *American Journal of Obstetrics and Gynecology, 205(2),* p. 119e1-119.e12. https://doi.org/10.1016/j.ajog.2011.03.024
<Ref 8>	Kim, S.M. et al. (2018). The use of barbed sutures for vaginal cuff closure during laparoscopic hysterectomy. *Archives of Gynecology and Obstetrics, 297,* p. 691-697. https://doi.org/10.1007/s00404-017-4637-9
<Ref 9>	Herrais, R.J.L. et al (2015). The Use of Barbed Suture for Vaginal Cuff Closure in Total Laparoscopic Hysterectomy. *Obstetrics & Gynecology International Journal, 3(4),* 00088. https://doi.org/10.15406/ogij.2015.03.00088
<Ref 10>	Golnit. (n.d.) *Surgical suture characteristics*. Golnit.com. Accessed on March 23, 2021, at: https://www.golnit.com/suture-characteristics/
<Ref 11>	Broeders, I.A.M.J. and Kalisingh, S.S.(2009). *Handboek endoscopische chirurgie*. Bohn Stafleu van Loghum.
<Ref 12>	DEAM, *DE_361_UserInputOverview_B3*. Amsterdam 2019.
<Ref 13>	LifeLike BioTissue.(2019). *Vaginal Cuff.* Lifelikebiotissue.com. Accessed on August 15, 2019, at: https://lifelikebiotissue.com/shop/obgyn/vaginal-cuff
<Ref 14>	Sankpal, S.R. (2018). *Simplified Laparoscopic Hysterectomy: Practical, Safe and Exonomic Methodology.* Retrieved from: https://www.glowm.com/simplified-laparoscopic-hysterectomy/chapter-9---instrumentation#
<Ref 15>	UNISUR Lifecare Pvt. Ltd. (2021). *Universal Sutures E-Book.* Issuu.com. Accessed on March 23, 2021, at: https://issuu.com/universalsutures/docs/universal_suture_products_catalogue
<Ref 16>	Suturex & Renodex surgical needles. (2021). *Suturex & Renodex Stocklist March 2021* [Brochure]. Retrieved on March 23, 2021, from: https://www.suturex-renodex.com/en/Products/Needles.html#needles-availability-range--surgeries
<Ref 17>	Ratner, D. (2020). *Suturing Techniques Periprocedural Care – Equipment.* Accessed on March 23, 2021, at: https://emedicine.medscape.com/article/1824895-periprocedure#b5

<Ref 18>	Beers, W.R. (2021). *Methods for suture fixation in laparoscopic surgery: A literature review*. (unpublished literature review). TUDelft, Delft.
<Ref 19>	Endocontrol (31-03-2017). *Articulated Needle Holder: JAIMY in General Surgery* [Video]. YouTube. Url: https://www.youtube.com/watch?v=dUvA86tyUkE
<Ref 20>	MIGS_Tips. (22-11-2017). *FLS Skills – Laparoscopic Intracorporeal Suturing: Fundamentals and Tips & Tricks for New Learners* [Video]. YouTube. Url: https://www.youtube.com/watch?v=R5rwEpZaqPk
<Ref 21>	Mecmesin. (2019). *Hypodermic needle sharpness testing.* Mecmesin.com. Accessed on May 10, 2021, at:https://www.mecmesin.com/publications/hypodermic-needle-sharpness-testing
<Ref 22>	Cronin, S., Frecker, M., & Mathew, A. (2007). Puncture force measurements on a porcine stomach. *Gastrointest. Endosc., 65(5),* p.AB294. https://doi.org/10.1016/j.gie.2007.03.688
<Ref 23>	Horeman, T. (2014). *Force-Based assessment of Tissue handling skills*. (phd thesis, TUDelft, Delft, the Netherlands).

Appendix D: Technical drawings

The technical drawings for the parts of the Hornet prototype B3 shown in Figure 68 are given in this appendix. All dimensions in the technical drawings are in millimeters.

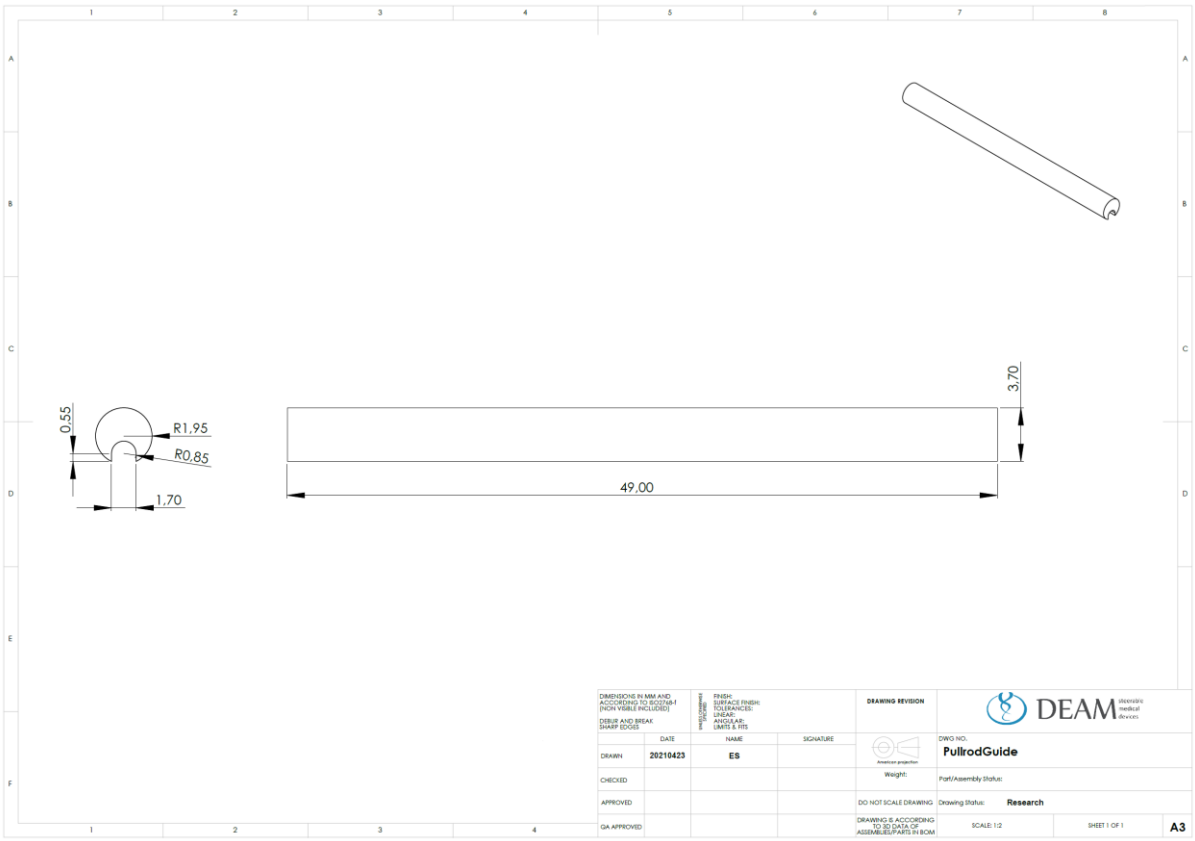


1. PullrodGuide
2. Shaft
3. NeedleBase
4. Hinge
5. PullrodHead
6. Pullrod
7. NeedleActuator
8. HandleBaseFront
9. SutureRing
10. HandleBaseBack

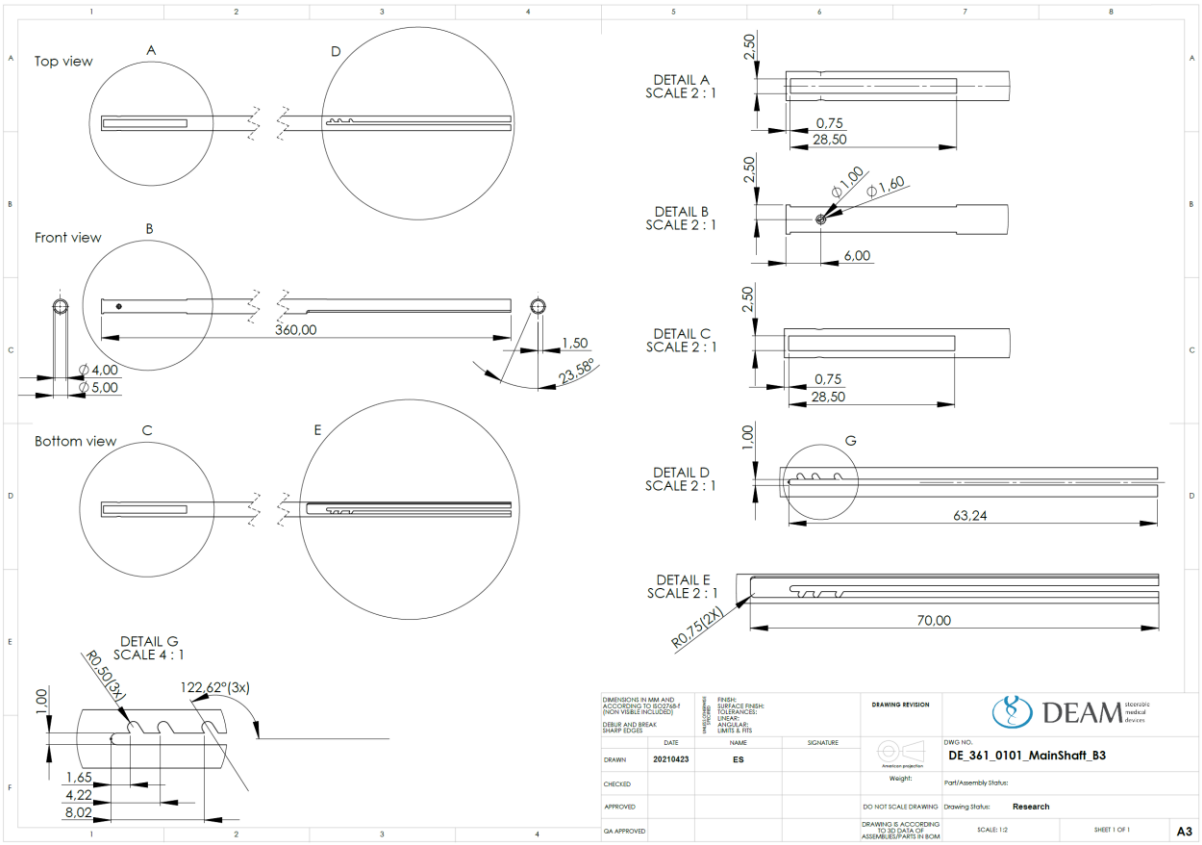
Figure 68: Full Instrument, where parts of which Technical Drawings are presented are labelled.

1. PullrodGuide

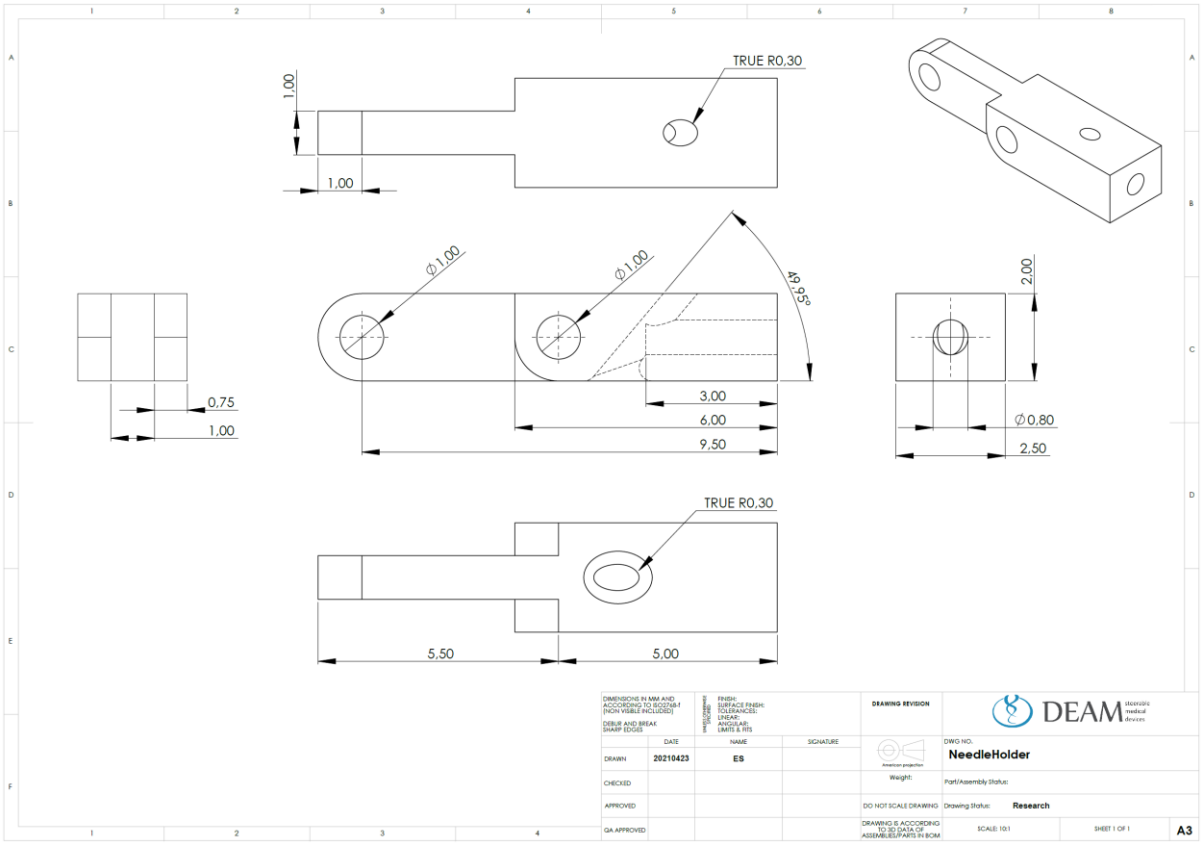
The PullrodGuide is a version of the Needleramp from Hornet Prototype B2 that was modified by hand. There are no technical drawings of the specific PullrodGuides used in the prototypes, but a simplified version with the proper dimensions has been made and is presented below.


0,55
R1,95
R0,85
1,70
3,70
49,00
DEAM
DWG NO.
PullrodGuide
Part/Assembly Status:
Drawing Status: Research
SCALE: 1:2
SHEET 1 OF 1
A3

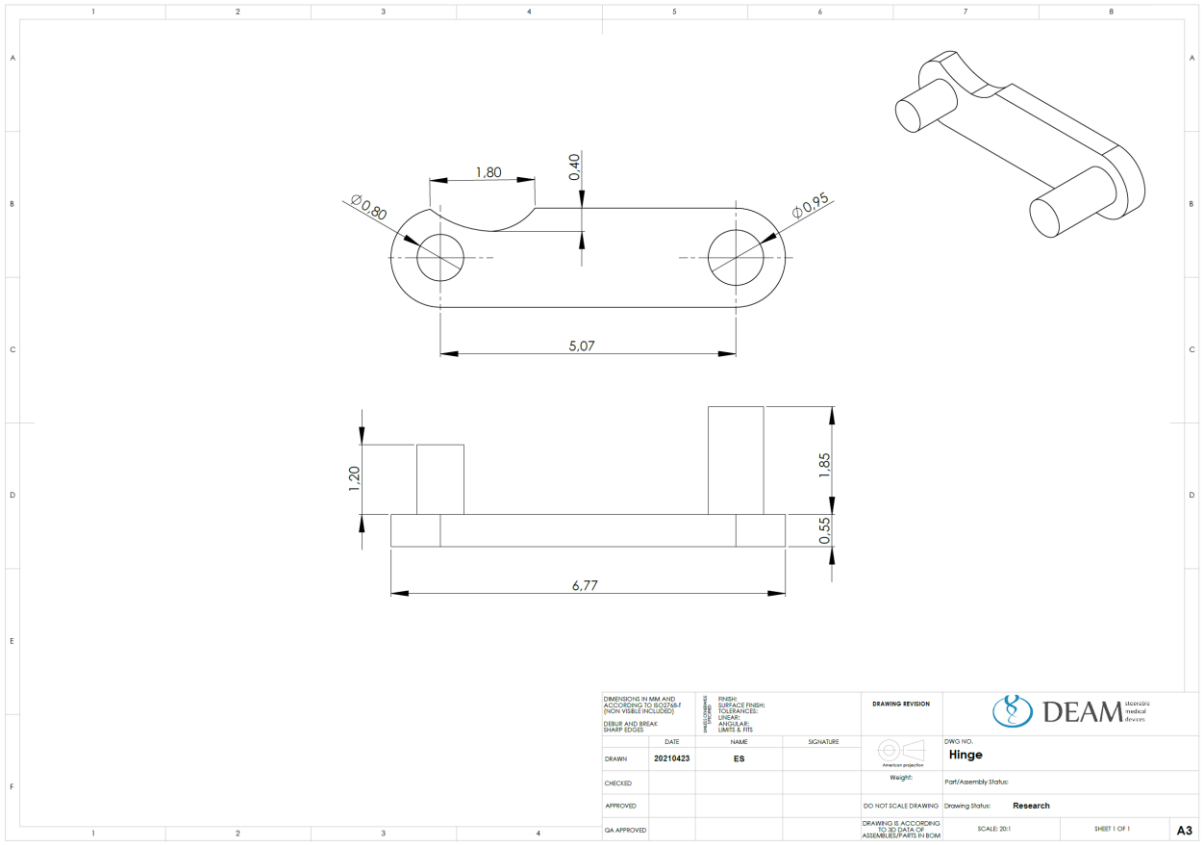
2. Shaft


Top view
A
D
Front view
B
360,00
1,50
23,58°
Ø4,00
Ø5,00
Bottom view
C
E
DETAIL G
SCALE 4 : 1
R0,50(3x)
122,62°(3x)
1,00
1,65
4,22
8,02
DETAIL A
SCALE 2 : 1
2,50
0,75
28,50
DETAIL B
SCALE 2 : 1
Ø1,00
Ø1,60
6,00
DETAIL C
SCALE 2 : 1
DETAIL D
SCALE 2 : 1
G
63,24
DETAIL E
SCALE 2 : 1
70,00
R0,75(2X)
DEAM
DWG NO.
DE_361_0101_MainShaft_B3
Part/Assembly Status:
Drawing Status: Research
SCALE: 1:2
SHEET 1 OF 1
A3

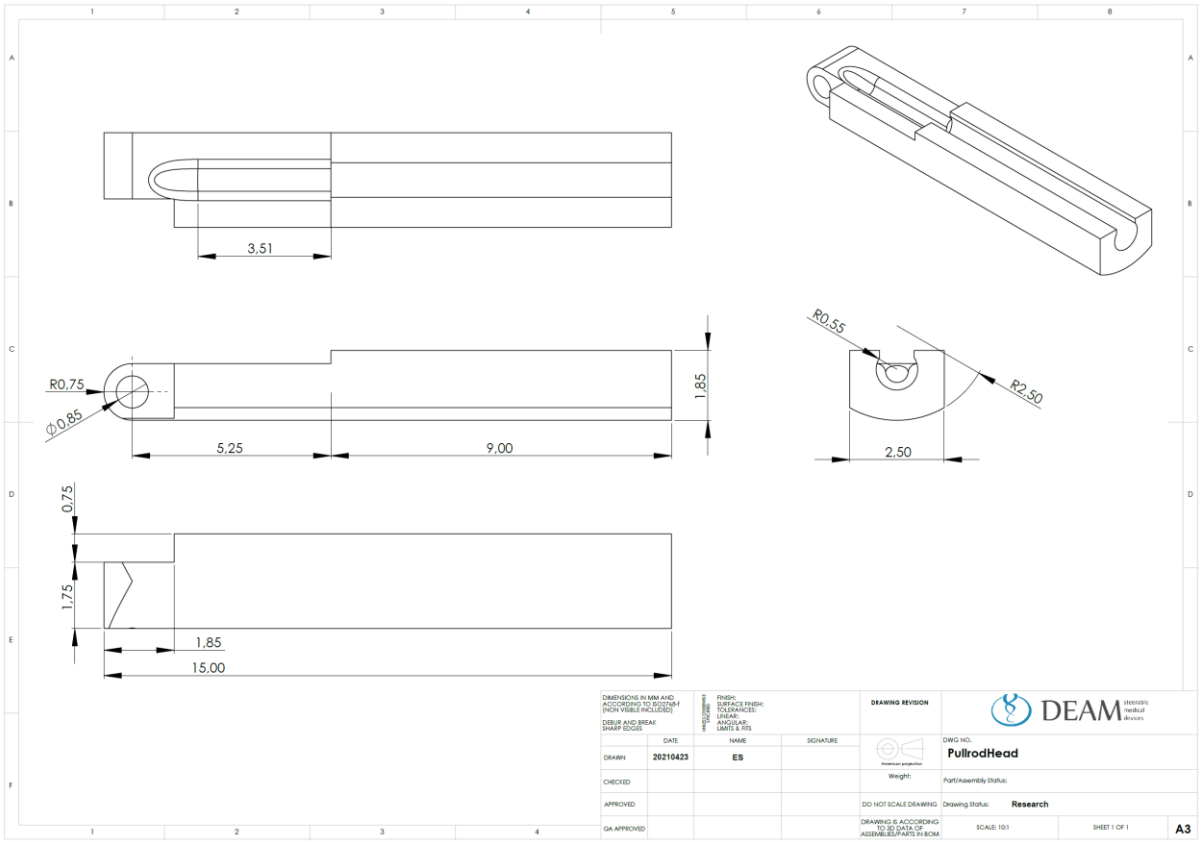
3. NeedleBase



4. Hinge

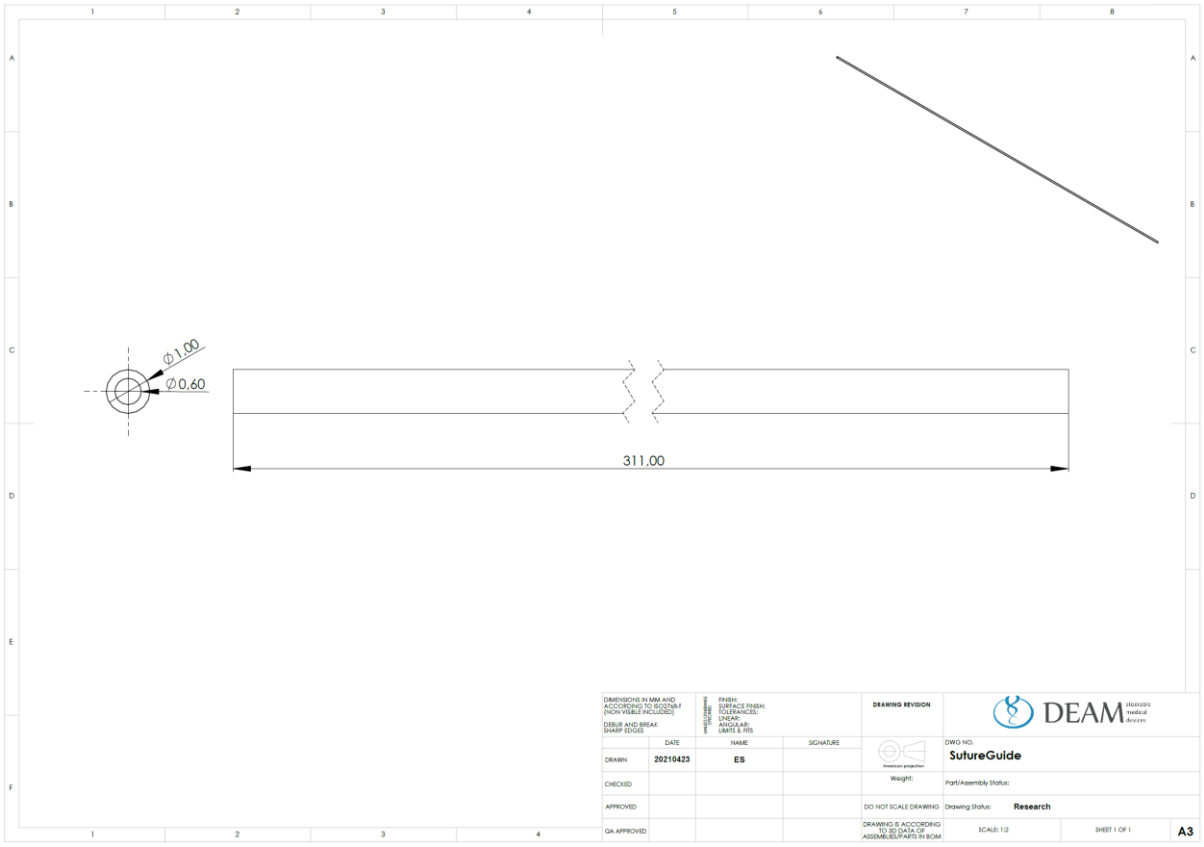


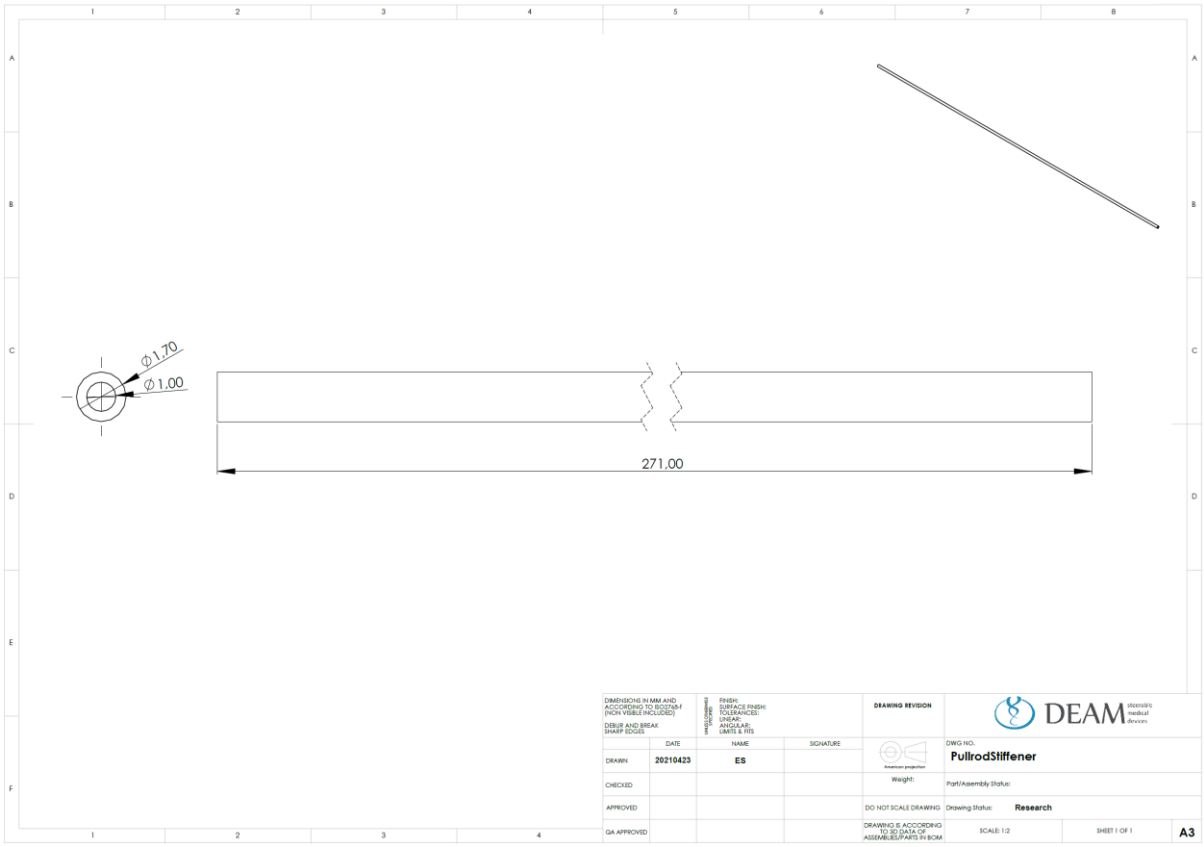
5. PullrodHead



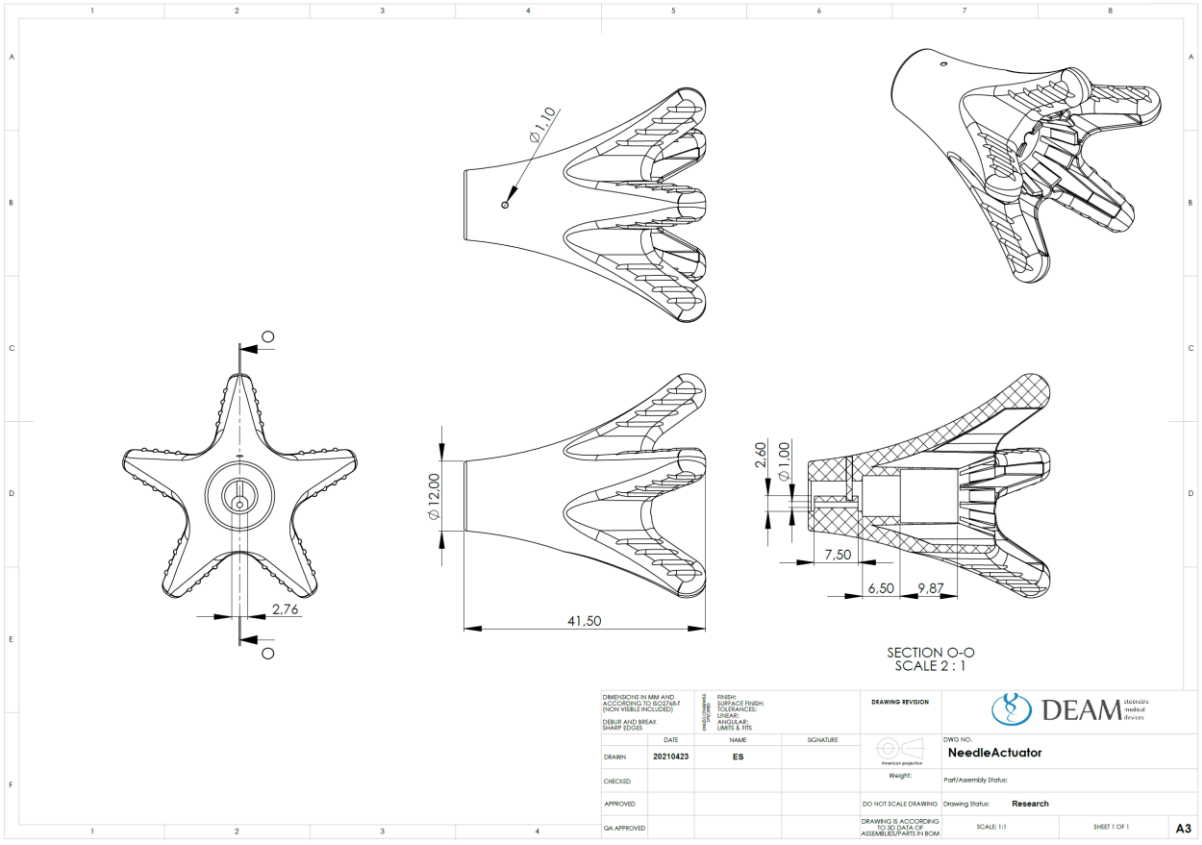
6. Pullrod

The Pullrod consists of the SutureGuide and the PullrodStiffener.

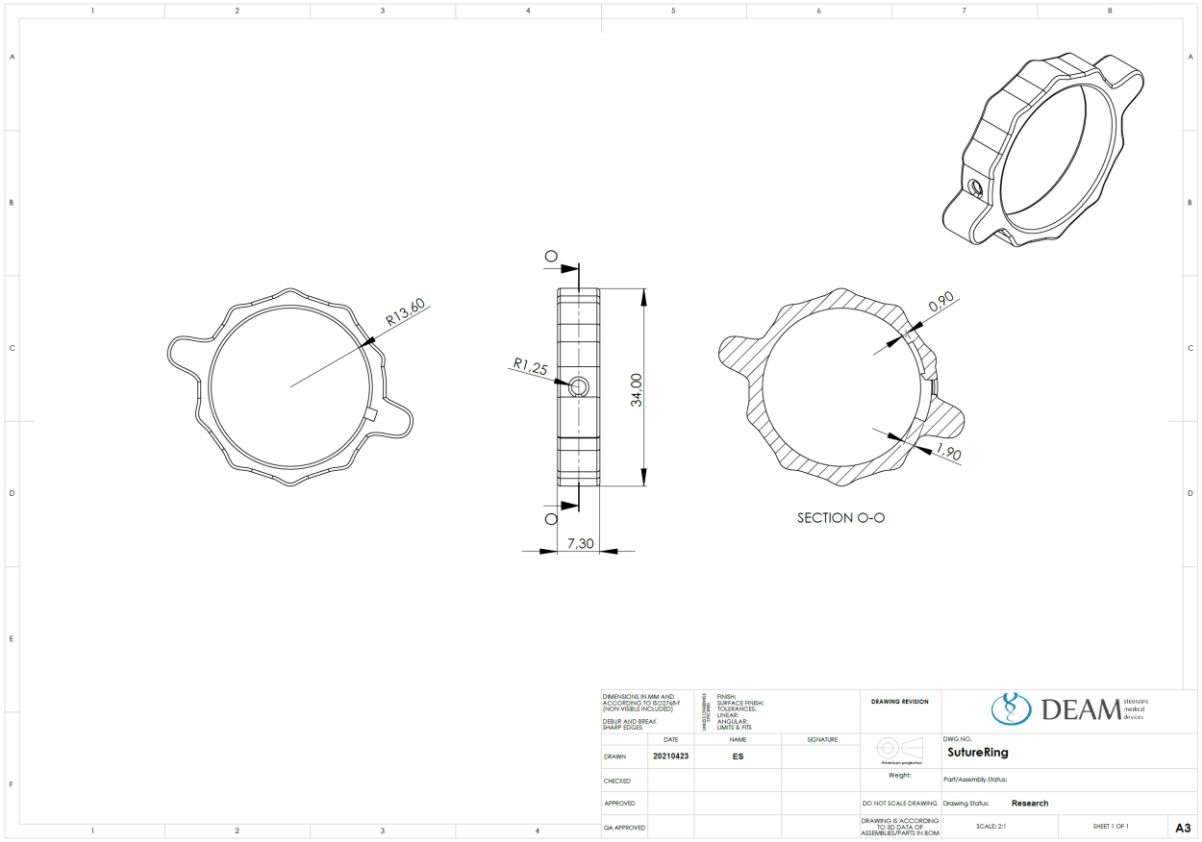




7. NeedleActuator

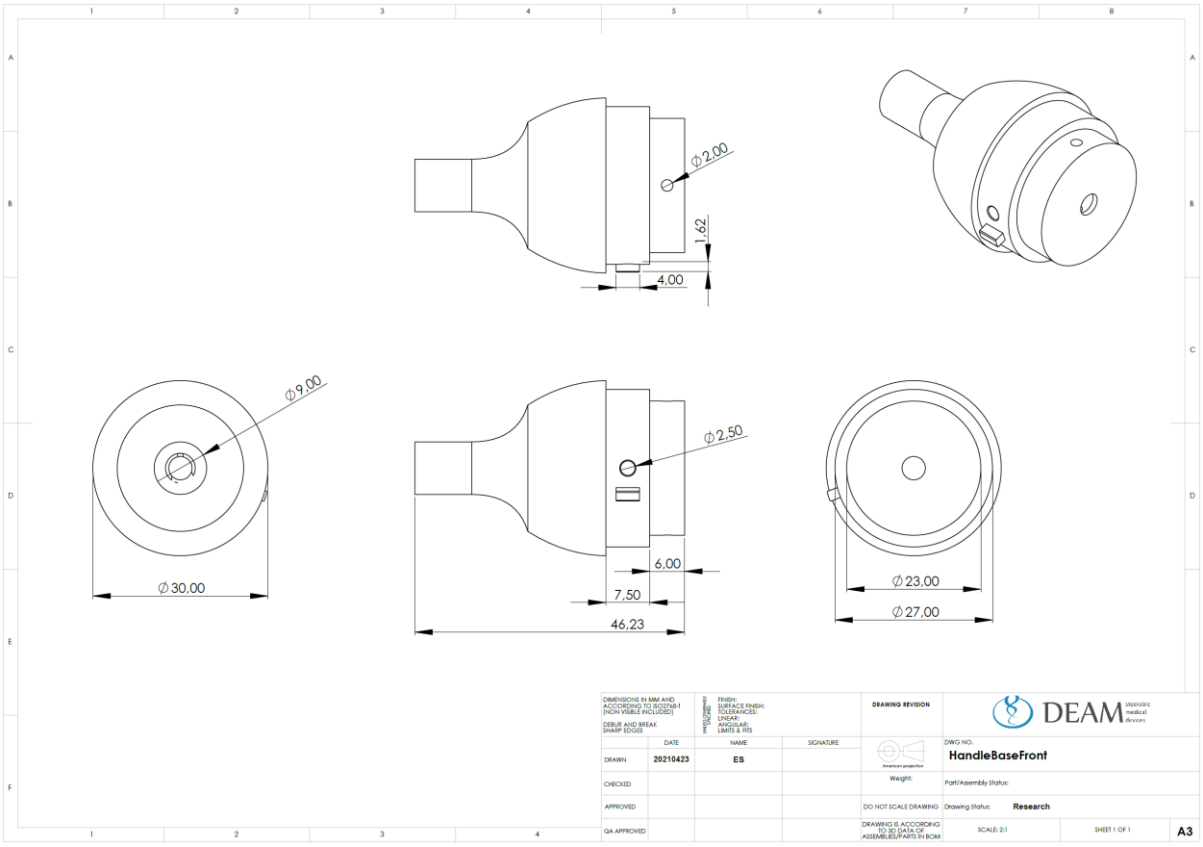


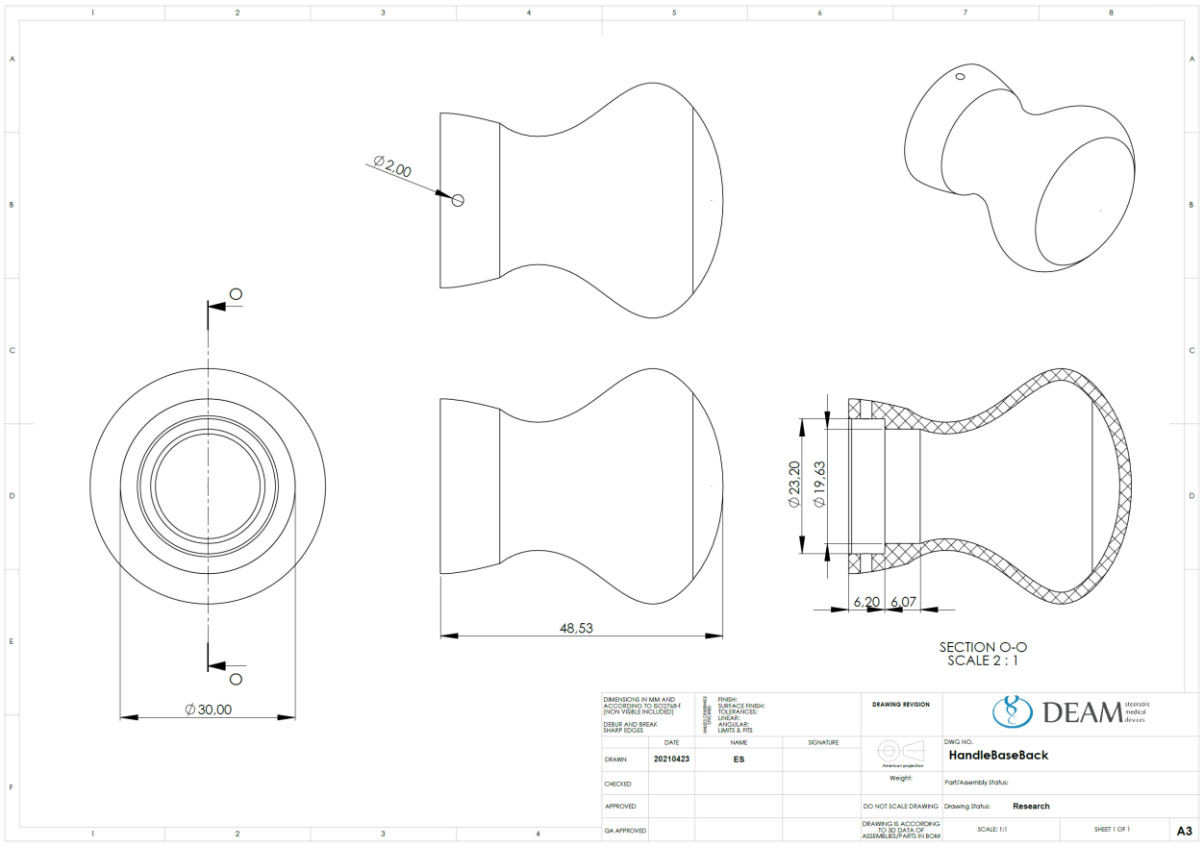
8. SutureRing



9. HandleBase

The HandleBase consists of two components: HandleBaseFront and HandleBaseBack.





DIMENSIONS IN MM AND ACCORDING TO ISO7345-f (NON VISIBLE INCLUDED) DEBUR AND BREAK SHARP EDGES		FINISH: SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR: LIMITS & FITS		DRAWING REVISION	DEAM ideomitic medical devices
	DATE	NAME	SIGNATURE		DWG NO. HandleBaseBack
DRAWN	20210423	ES		American projection	
CHECKED				Weight:	Part/Assembly Status:
APPROVED				DO NOT SCALE DRAWING	Drawing Status: Research
QA APPROVED				DRAWING IS ACCORDING TO 3D DATA OF ASSEMBLIES/PARTS IN BOM	SCALE: 1:1 SHEET 1 OF 1 A3

Appendix E: Rotation Mechanism design process

This appendix describes the main iterations and changes made to the design of the NeedleBase and PullrodHead during the design process.

1. Design prototype B1 / B2

The original design of the rotation mechanism, used in Hornet prototype B1 & B2, was created by Koen van Laarhoven while he worked on his thesis. This rotation mechanism consists of 4 parts:

- NeedleBase
- PullrodHead
- Pullrod
- PullrodStiffener

The NeedleBase and Pullrod are connected to each other during the production process and cannot be separated after production. The Pullrod is fixated in the PullrodHead. To prevent kinking of the Pullrod, the Pullrod is supported with an additional tube called the PullrodStiffener. Figure 69 shows the Rotation Mechanism with needle from prototype B2. Figure 70 gives the isometric views of the two components of the Rotation Mechanism from prototypes B1 and B2.

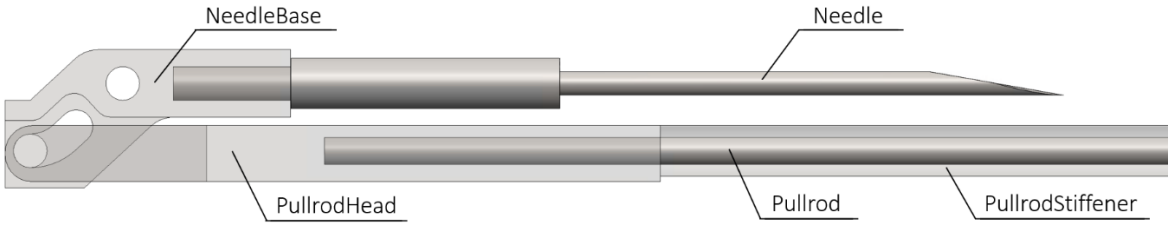


Figure 69: Intersection of side view of the Rotation Mechanism, Pullrod, and needle from prototype B2.

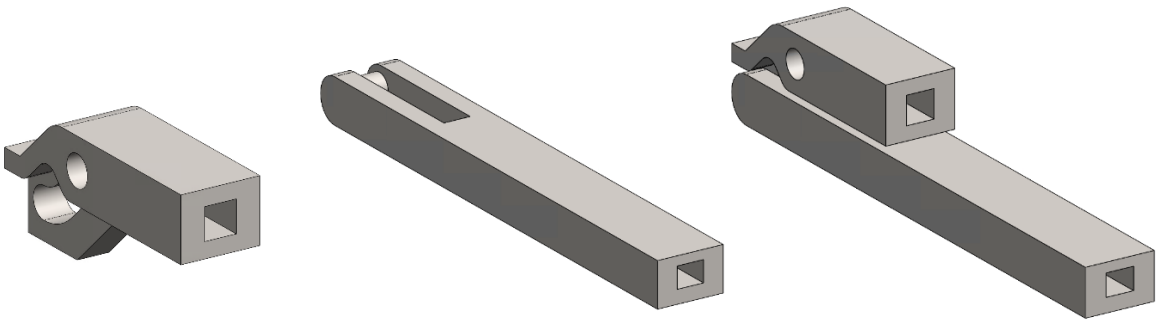
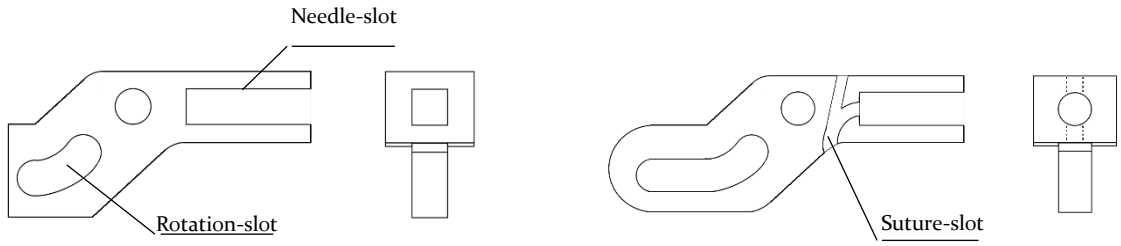


Figure 70: Rotation Mechanism of prototypes B1 and B2. Left – NeedleBase. Middle – PullrodHead. Right – Rotation Mechanism.

2. Initial design for NeedleBase of concept B

The new design of the NeedleBase is based on the NeedleBase from previous prototypes of the Hornet. Changes made to the previous design of the NeedleBase include:

1. The opening for the needle in the NeedleBase and the opening for the Pullrod in the PullrodHead are made circular for a better fit.
2. An opening for the suture-thread to flow through is created in the NeedleBase. This slot allows the thread to either flow through the NeedleBase to the opposite side or to enter a hollow needle fastened in the NeedleBase (See *section 3.1 - The Thread System*). This suture-slot is a straight slot through the NeedleBase to make production and post-production easier. This way, the slot can be easily opened up with a small drill, should the slot be filled with residue from the 3D-printing process.
3. The slot through which the PullrodHead moves is elongated to allow for a larger angle of the deployed needle.

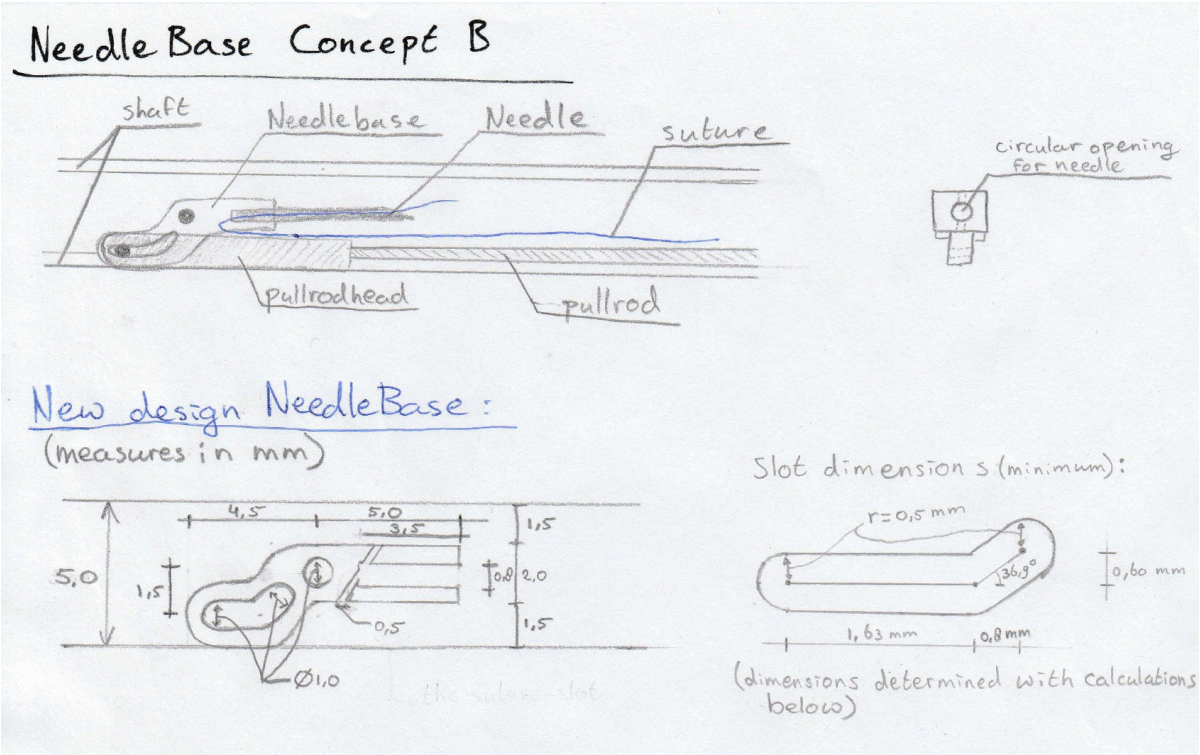


A. NeedleBase design prototype B1/B2

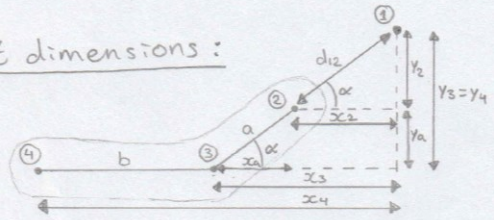
B. NeedleBase design Concept B for prototype B3

Figure 71: The side and front views of the NeedleBase designs for prototype B1/B2 (A) and concept B for prototype B3 (B).

The new design, with estimated dimensions and calculations, is presented in the images below.



Slot dimensions :



①=rotation axis of Needle Base

$x_3 = 2,0$ mm
$y_3 = 1,5$ mm
} Based on previous design Needle Base

$d_{12} \leq 1,5$ mm } the pullrodhead is fixed at a distance of 1,5 mm from ①, when ② rotates around ①, the max. distance may be 1,5 mm, otherwise the pullrodhead can not rotate the NeedleBase without dislodging.

length section a :

$\alpha = \tan^{-1}\left(\frac{y_3}{x_2}\right) = \tan^{-1}\left(\frac{1,5}{2,0}\right) = 36,9°$

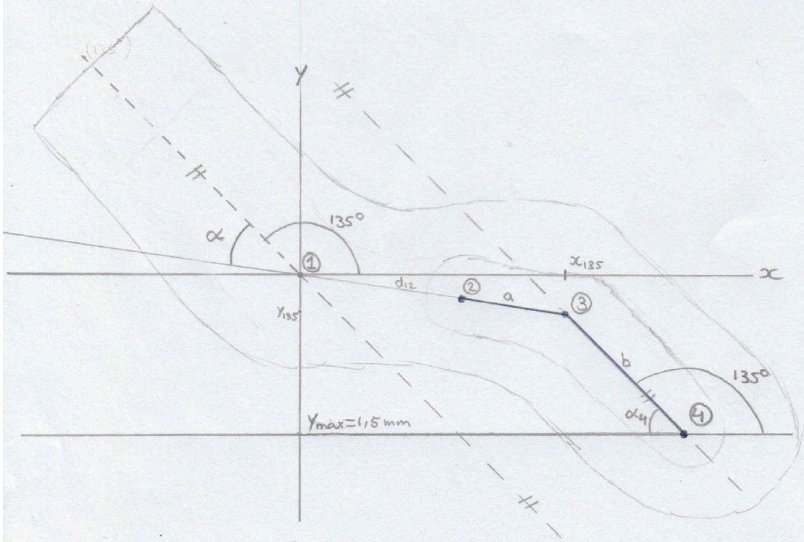
$y_a = y_3 - (\sin(\alpha) \cdot d_{12}) = 1,5 - \sin(36,9) \cdot 1,5 = 0,6$ mm

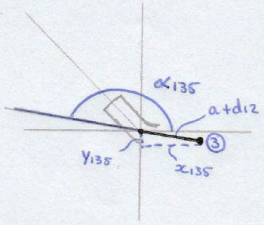
$x_a = x_3 - (\cos(\alpha) \cdot d_{12}) = 2,0 - \cos(36,9) \cdot 1,5 = 0,8$ mm

$a = \sqrt{x_a^2 + y_a^2} = \sqrt{0,8^2 + 0,6^2} = 1,0$ mm

length section b :

The needle must reach angles of 135°, so minimum length for section b is found at 135°





Coördinates of point ③ :

$x_{135} = \cos(180° - \alpha_{135}) \cdot (a + d_{12})$
$= \cos(180° - (135° + \alpha)) \cdot (1,0 + 1,5)$
$= \cos(180° - (135° + 36,9°)) \cdot 2,5$
$= 2,48$ mm

$y_{135} = \sin(180° - \alpha_{135}) \cdot (a + d_{12})$
$= \sin(180° - 171,9°) \cdot 2,5$
$= 0,35$ mm

section b is parallel to the centerline of the Needle /NeedleBase in point ①

$b = (y_{max} - y_{135}) / \sin(\alpha_4)$
$\alpha_4 = 180° - 135° = 45°$
} $b = \frac{(1,5 - 0,35)}{\sin(45°)} = 1,63$ mm

3.

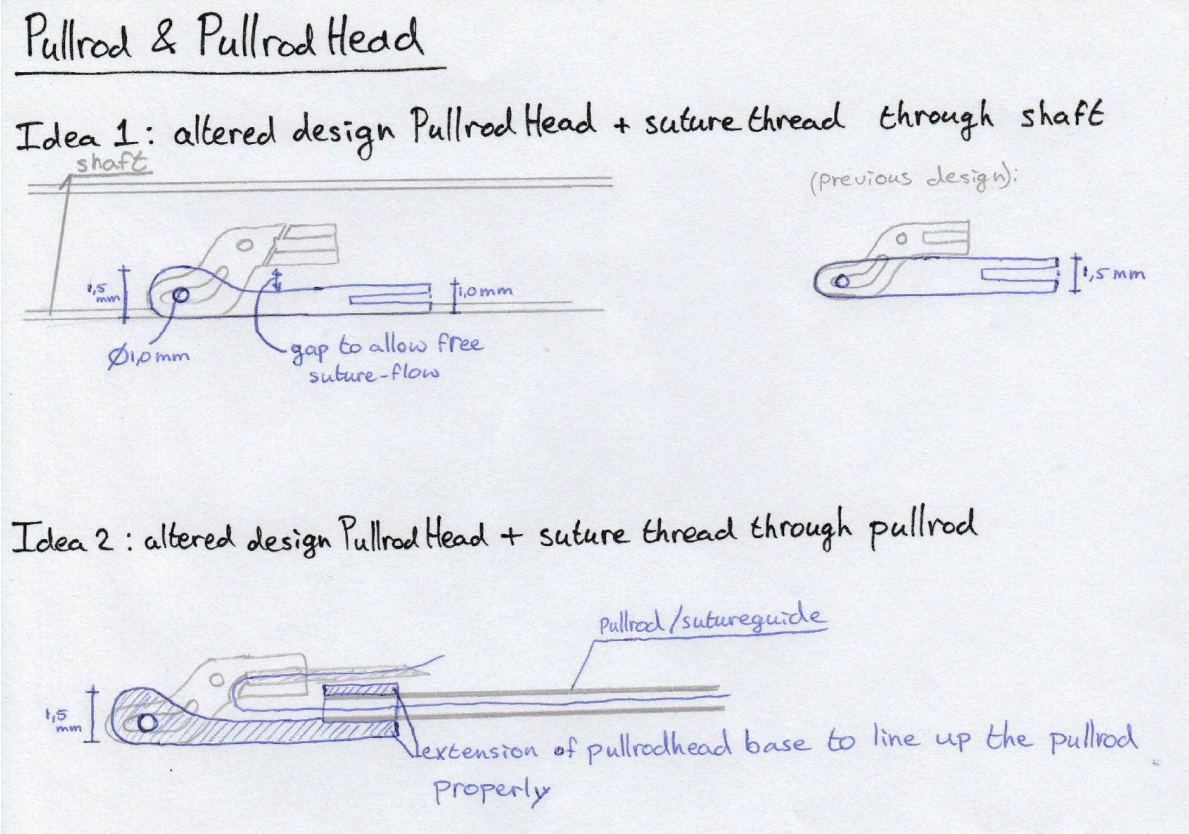
3. Altered designs for the PullrodHead to fit with NeedleBase

The new design of the NeedleBase influences the design of the PullrodHead. Changes made to the previous design of the PullrodHead include:

- The 'base height' of the PullrodHead is smaller (from 1.5 to 1.0 mm) to create space for the suture-thread.
- The distal end of the PullrodHead is kept at a height of 1.5 mm to properly line-up the PullrodHead with the NeedleBase.
- Instead of having the suture-thread flow free through the shaft, the thread flows through the existing Pullrod and is guided towards the NeedleBase by the PullrodHead. The proximal part of the PullrodHead is heightened to allow to suture-thread to flow straight from the Pullrod to the NeedleBase.

Design Concept B

The first idea presented in the image below was discussed with Jules, after which the design of Concept B came to life.



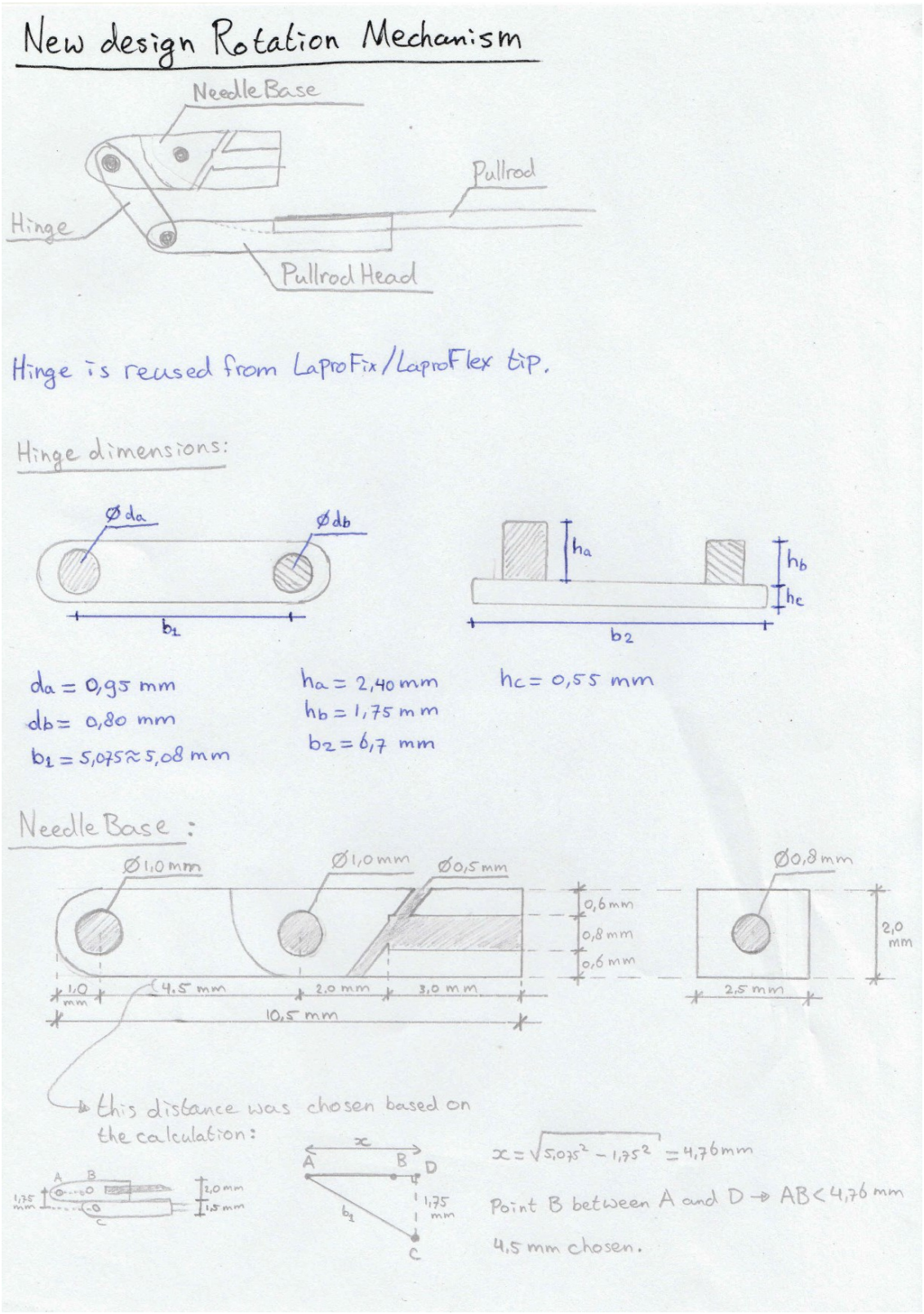
4. Switch to different rotation mechanism with hinge

While working on the designs for the NeedleBase and PullrodHead shown above, it was concluded that the resulting designs would get complex shapes with thin walled structures that are difficult to produce properly and cheaply.

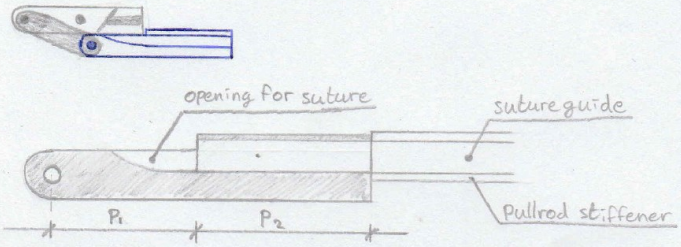
In order to simplify the design, the rotation system was altered. A hinge is added to substitute the PullrodHead-slot in the NeedleBase, allowing for a simpler design of the NeedleBase.

The images below show the design of the main components of the altered Rotation Mechanism. The dimensions for the Hinge are set, since the hinge from the tip of the LaproFlex (an instrument produced by

DEAM) was used. The dimensions for the NeedleBase are based on the previous design of the NeedleBase, with some alterations, additions, and omissions. Most of the dimensions of the PullrodHead are determined while designing the part in SolidWorks and are based on the dimensions of the Hinge, the NeedleBase and the haft.



Pullrod Head & Pullrod:



P_1 and P_2 are chosen while designing the Pullrod Head in Solidworks based on the dimensions of the Needlebase and Hinge in order to get a good fit

Suture guide: Ø = 1,0 mm x 0,2 mm

Pullrod stiffener: Ø = 1,7 mm x 0,3 mm

Appendix F: Design process of Handle shape Concept B

In this appendix, the design process of the handle shape is explained. The structure of the appendix is summarized below:

1. Researching handle shapes
   An overview of the existing handle shapes of laparoscopic instruments.
2. Choosing a basic handle design
   Creating mock-up designs and choosing a basic handle design.
3. Determining handle dimensions
   Determining the dimensions of the HandleBase

1. Researching handle shapes

Before designing a new handle shape for the Hornet, the handle shapes of different laparoscopic instruments were examined to get an idea of the possibilities.

Shank handle

Shank handles can either be in-line, Figure 72-A, or curved, Figure 72-B and -C.

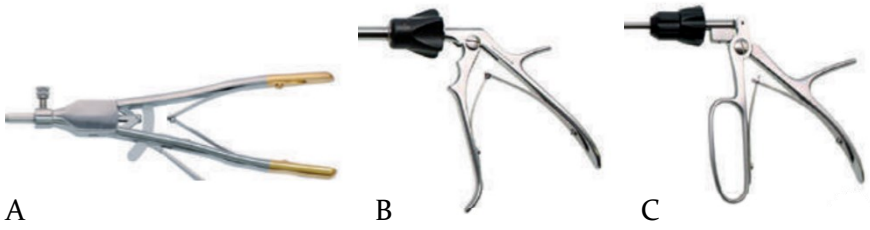


Figure 72: Shank handle shapes. A: in-line, with ratchet [2]. B: curved, without ratchet [2]. C: curved, with ring, without ratchet [2].

Scissor or Ring handle

Scissor, or ring, handles are curved with respect to the shaft and have two rings on the handle.

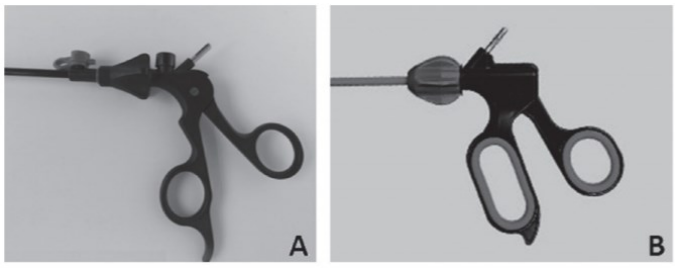


Figure 73: Scissor or Ring handles. A: small rings, B: large ring. [1]

Pistol handle

There are different types of handles with a pistol grip. Three examples are given in Figure 74.

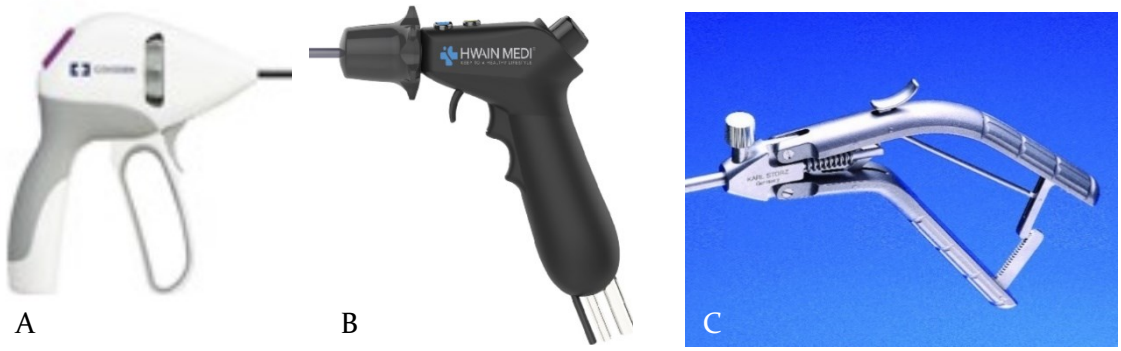


Figure 74: Pistol grip handles. A: complex pistol grip handle with closed lever [6]. B: complex pistol grip handle with open lever [5]. C: simple pistol grip handle with ratchet [4].

Axial handle

There are many different types of axial handles. A few examples are shown in Figure 75.

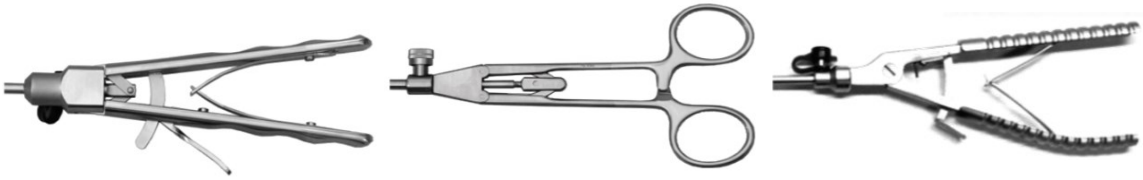


Figure 75: Axial handles. Left: straight handle without rings [3]. Middle: straight handle with rings [3]. Right: curved upwards handle without rings [3].

DEAM handle

The DEAM handle is different from the other handle shapes as it is an inline handle without a conventional handle.

Figure 76: Inline handle of the LaproFix from DEAM [7].

2. Choosing a basic handle shape

The pinching force produced by most handle types above are unnecessary in the Hornet because the needle is fixated in the instrument. This allows for different handle shapes, without a pinch function, to be considered for the second handle concept.

An inline design, without levers, was considered as this would allow for more natural hand positions than the curved handles of for example laparoscopic graspers. DEAM suggested to use the design of the Laprofix handle for the Hornet, as this would allow for the creation of a DEAM-line. Two mock-up instruments were made based on the Laprofix handle. One mock-up copied the design of the handle of the Laprofix, the other

mock-up focused on an inline design without levers. These mock-ups were then assessed to see whether the handle designs would be suitable for the Hornet.

2.1. Mock-up designs

The two mock-up instruments consisted of a shaft in which a needle was fixated. The shafts were then attached to the two mock-up handles based on the Laprofix. These handles were created from the existing Laprofix handles and the intended functionalities were not yet implemented, only simulated.

Mock-up instrument 1: "Laprofix +"

A version of the Laprofix handle with an added feature. The handle design has three main features:

1. Rotation mechanism actuation [actuation of the green "wing" on top of the handle]
2. Blocking the thread [by an added feature, to be designed later]
3. Rotation of the shaft [rotation of the green Roticulator]

The rotation of the shaft is necessary in this design, as the "wing" on top of the handle prevents the user from rotating the handle in the hand while maintaining functionality.

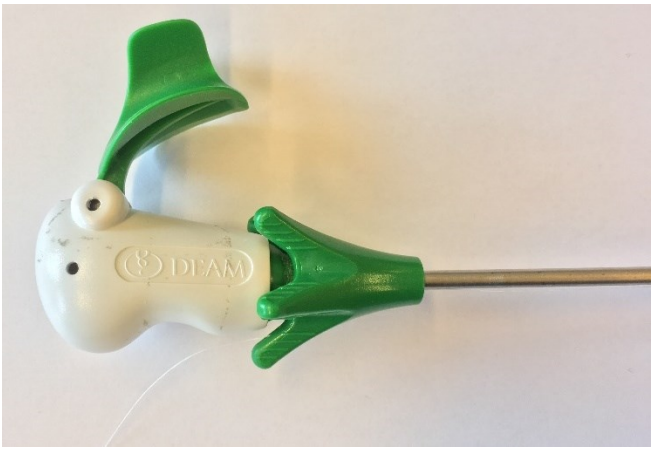


Figure 77: LaproFix + handle. The Roticulator rotates the shaft, the "wing" is used to deploy the needle.

Mock-up instrument 2: "Laprofix –"

A "reduced" version of the Laprofix handle, where the "wing" on top of the handle is removed to create an in-line handle. This allows the instrument to be rotated in the hand. This frees the Roticulator to be used to deploy the needle. The handle has 2 features:

1. Rotation mechanism actuation [the green Roticulator]
2. Blocking the thread [by an added feature, to be designed later]

To deploy the needle, the Roticulator would be pulled towards the HandleBase. A spring placed between the Roticulator and HandleBase provides resistance so the needle can be deployed smoothly.

Figure 78: Laprofix – handle. The Roticulator deploys the needle.

2.2. Evaluating the mock-up designs

Both mock-ups were evaluated by simulating the suturing actions with the instrument in a lapro-trainer. The Laprofix + was not comfortable to place a suture with. The rotatable shaft made it difficult to apply pressure to the tissue without the needle moving away. When the rotation of the shaft was blocked, awkward movements of the hands and arms were needed to properly align the needle with the tissue. Additionally, incorporating the three functionalities in the handle of the Laprofix + will be difficult, as the mechanism to use the "wing" takes up most space in the HandleBase. This leaves no space in the HandleBase to allow the thread to flow through or be stored without being blocked or damaged. Furthermore, the mechanism that rotates the shaft makes it difficult for the thread to move through the shaft towards the handle. The Laprofix, on the other hand, did not share these problems. The handle could be rotated in the hand with ease, and the removal of the "wing" and the rotation of the shaft results in a hollow HandleBase with enough space for the thread to flow through or be stored. For the Laprofix -, the main issue was keeping the needle properly deployed while placing a stitch, as it was tiresome for the fingertips to keep the Roticulator pulled against the spring.

2.3. Chosen handle shape

The chosen basic handle shape was the design of Laprofix -, with some alterations. The main features of the design will be:

- HandleBase: A symmetric handle shape
- NeedleActuator: An actuator for the deployment of the needle [the Roticulator]
- SutureRing: A ring to block the flow of the thread (as decided in the design process of the Thread System)

The basic shape of the HandleBase is simple, this is a symmetric version of the Laprofix handle, as shown in Figure 8.

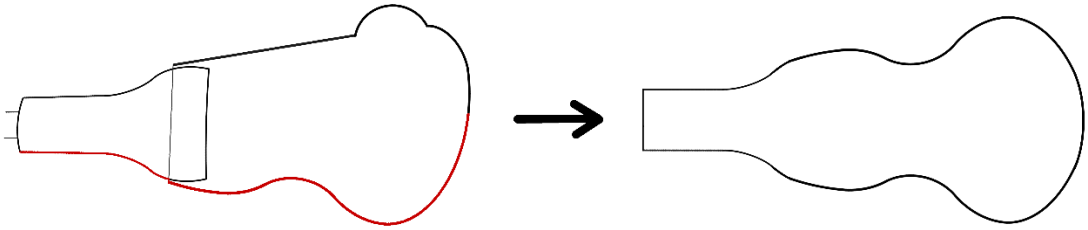


Figure 79: Creation of symmetric handle shape (right) from the highlighted part of the Laprofix handle shape (left).

The exact dimensions of the HandleBase were determined with rapid prototyping. An initial clay model was created with the dimensions from the Laprofix handle. Multiple employees of DEAM have assessed the shape and size of this model, after which the dimensions were slightly altered. The main change was the enlargement of the second bulb to make the handle fit better in the palm of the hand.

The outer shape of the NeedleActuator was kept the same as the dimensions of the Roticulator on the Laprofix handle. The changes made to the inner design of the NeedleActuator is explained in the main Thesis and Appendix B.

The design of the SutureRing is presented in the main thesis and fully explained in Appendix I.

3. Determining handle dimensions

After the overall shape was created, the specific dimensions were determined. In order to assure that most users can hold and operate the handle comfortably, the dimensions of the design are based on the common hand sizes presented in Greiner T.M.'s report on the Hand Anthropometry of U.S. Army Personnel [8]. From this report, the 5th-percentile dimensions of the female hand (the lower limit) and the 95th-percentile dimensions of the male hand (the upper limit) are used to determine the dimensions of the HandleBase.

Both the lower- and upper limit hand sizes must be able to hold the handle and reach the NeedleActuator and SutureRing. The four main dimensions that are influenced by the size of the hand are shown in Figure 80.

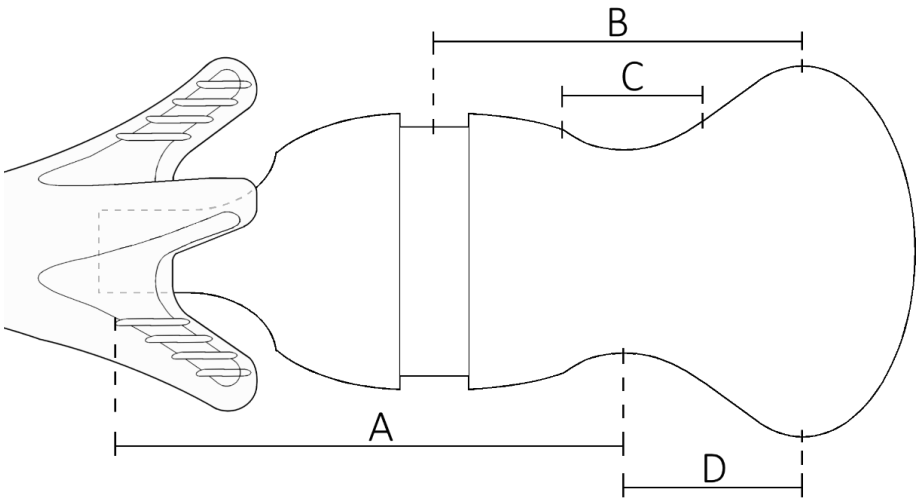


Figure 80: The basic design of the HandleBase and the main dimensions influenced by the handsizes of users (A-D).

For each of the dimensions in Figure 80, it was determined which finger influences the dimension and whether the upper or lower limit is leading. On the left in Figure 81, the hand positions and fingers that influence each dimension are shown. On the right in Figure 81, the anatomical names of the relevant fingers as referenced in Greiner's report [8] are given.

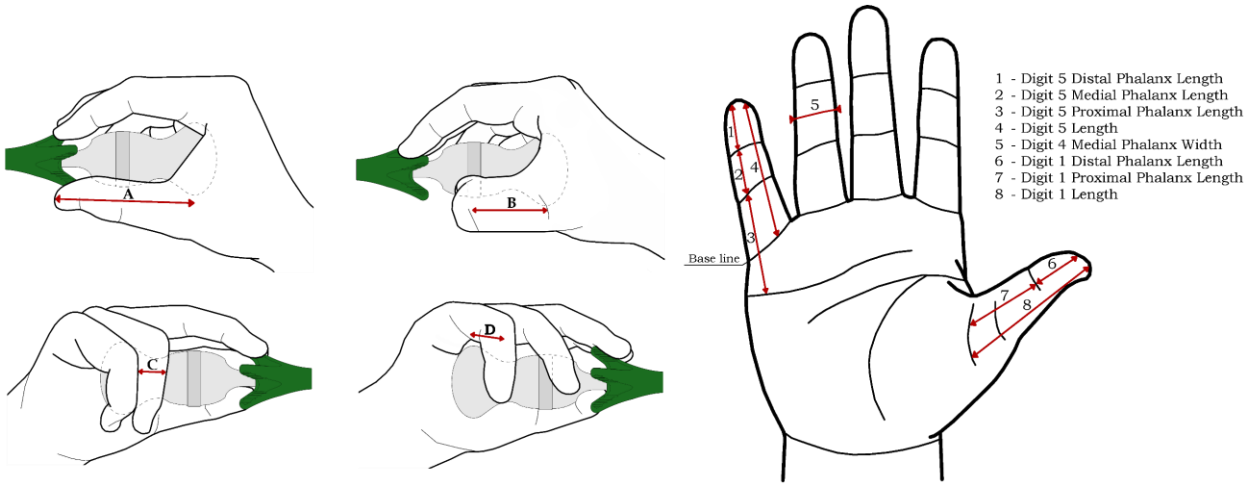


Figure 81: Left – Hand positions to determine each dimension presented in Figure 41. Right – Anatomical names of the relevant finger sections for the handle shape [8].

Dimension A is determined by the length of the thumb. For this dimension, the lower limit is leading to ensure that every hand can reach ensure that every hand can reach the NeedleActuator.

Dimension B is determined by the length of the proximal phalanx of the thumb (Figure 81-7). This length assumes the thumb to be flexed to the maximum, as shown in Figure 81-B. Shorter thumbs can stretch to reach the SutureRing, but larger thumbs cannot flex more than designed, the upper limit is therefore leading for this dimension.

Dimension C can be either determined by the ring finger or little finger, as can be seen in Figure 81-3 and -4. Because thinner fingers can fit inside a larger hollow, but larger fingers cannot fit inside a hollow that is too narrow, the upper limit is leading. Dimension C is therefore determined by the width of the medial phalanx of the ring finger (Figure 81-5).

Dimension D is determined by the length of the proximal phalanx of the little finger (Figure 81-3) up to the base of the finger. The upper limit is leading to make sure that larger hands can bend their little finger around the handle.

The lengths and widths of the corresponding hand-sections were determined using Greiner's report [8]. Table 18 gives the calculations used for each dimension, and presents the resulting dimension values in cm. The full dimensions of the HandleBase are presented in *Appendix D*.

Table 18: Calculations and values for the dimensions presented in Figure 80..

Dimension		Calculation	Dimension Value [cm]
A -	Digit 1	Digit 1 Length	5.58
B -	Digit 1 Proximal Phalanx	Digit 1 Length – Digit 1 Distal Phalanx	3.85
C -	Digit 4 Medial Phalanx Width	Digit 4 Medial Phalanx width	1.62
D -	Digit 5 Proximal Phalanx up to the base line	Digit 5 Length – Digit 5 Distal & Medial Phalanx Link Lengths	1.94

4. Sources

[1] Allbas, C. (1989). Laparoscopic scissor handles [Images]. In *Ergonomics and haptic feedback in minimally invasive surgery* (phd thesis, Radboud Universiteit Nijmegen, Nijmegen, the Netherlands). Retrieved on November 20, 2019, from: http://www.nvec.nl/wp-content/uploads/2018/06/Alleblas-Thesis-Final.pdf

[2] Aequitas-Medical. (n.d.). Laparoscopic handles [Images]. Retrieved on November 20, 2019, from: http://www.aequitas-medical.be/files/tontarra/AQ_Laparo_cat.pdf

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Appendix G: Transformation of LaproFix' s Roticulator to Hornet's NeedleActuator

For the new design of the NeedleActuator, the existing SolidWorks model of the LaproFix' s Roticulator was used. After removing the superfluous elements on the inside of the design, three main elements were added to serve the functions of the NeedleActuator. The elements added are:

1. A connector between the Pullrod and the NeedleActuator
2. An axis to function as the 'gear stick' in the gearbox-slot
3. A cascading notch to surround and guide the spring

The transformation of the Roticulator of the Laprofix to the NeedleActuator for the Hornet is shown in Figure 82.

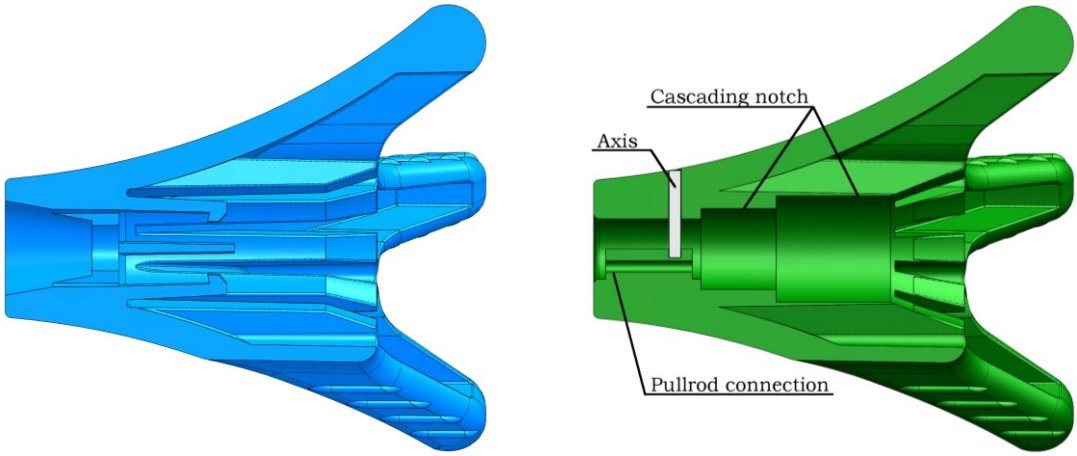


Figure 82: Left – Intersection of LaproFix' s Roticulator. Right – Intersection of Hornet's NeedleActuator.

The rationale behind each added element is given below.

1. A connector between the Pullrod and the NeedleActuator
   The NeedleActuator and the Pullrod need to be connected without blocking the thread that moves through the Pullrod. A protrusion is added to the inside of the NeedleActuator, as shown in Figure 83. This protrusion has a hollow opening in which the Pullrod can be secured without blocking the thread.

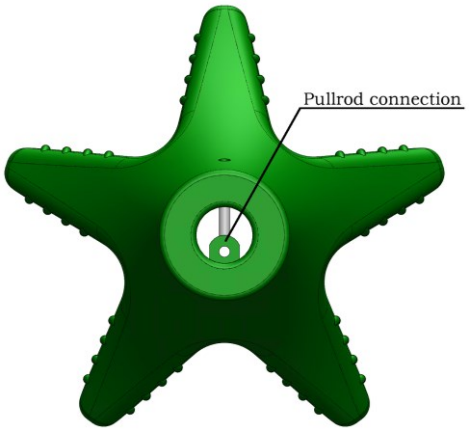


Figure 83: Front view of the Hornet's NeedleActuator, showing the Pullrod connection.

2. An axis to function as the 'gear stick' in the gearbox-slot
   In order to be able to fixate the angle of the needle, a metal axis needs to be added in the NeedleActuator. To make placement of the axis easier, the axis is added near the tip of the NeedleActuator as can be seen in Figure 82. A hole through the top of the NeedleActuator and into the Pullrod-protrusion are used to fixate and support the axis.

3. A cascading notch to guide the spring and support the NeedleActuator

   The spring that forces the needle to retract is positioned inside the NeedleActuator. By pulling the NeedleActuator towards the HandleBase, the spring gets compressed between the NeedleActuator and the HandleBase. To guide and support the spring, a notch that fits the dimensions of the spring is created inside the NeedleActuator. Figure 84-A shows the inner design of the NeedleActuator.

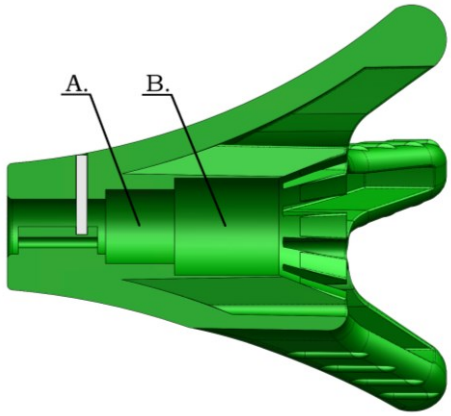
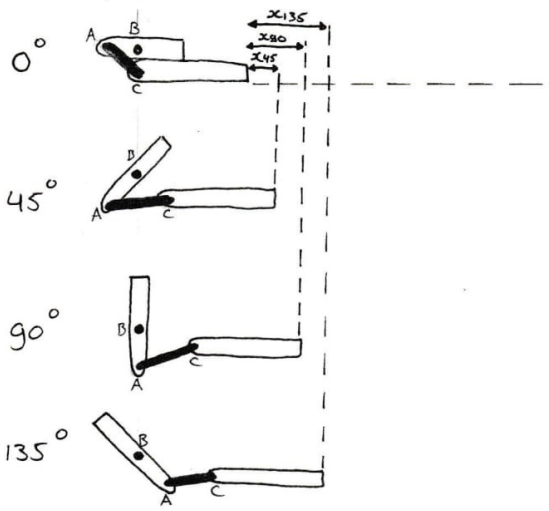
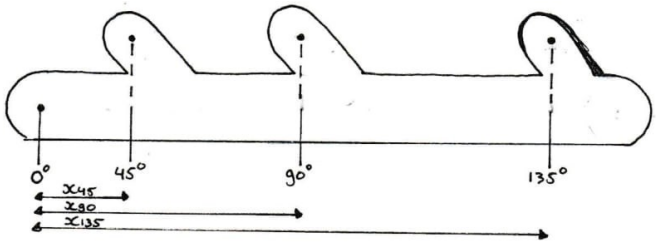


Figure 84: Intersection of Hornet NeedleActuator. A: notch for spring, B: notch for support by the HandleBase.

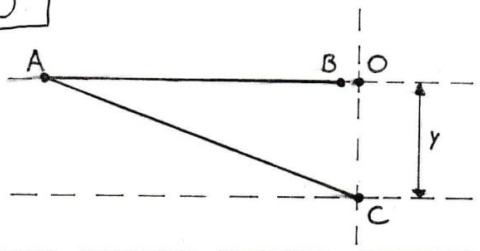
The NeedleActuator moves along the shaft to deploy the needle. In order to make this movement stable, the NeedleActuator needs to be supported both at the tip and in the back. At the tip, the NeedleActuator is supported by the shaft, but in the back the NeedleActuator curves outwards in order to fit around the base of the handle. To give the NeedleActuator the proper support, the tip of the HandleBase is elongated, see *section 3.3* and an extra opening is added to the inside of the NeedleActuator, see Figure 84-B.

Appendix H: Calculations of the shifter-plate slot





0°



Constants:

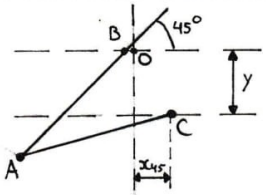
AB = 4,5 mm (distance between Hinge-opening and Rotation-opening)

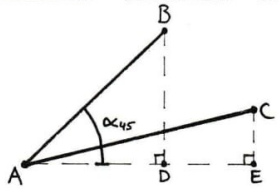
AC = 5,08 mm (length of the Hinge: NeedleBasepin to PullrodHead-pin)

BO = 0,27 mm (horizontal distance between Rotation-opening of the NeedleBase and the Rotation-opening of the PullrodHead)

y = 1,75 mm (fixed distance between the Rotation-opening and the axis of movement of the PullrodHead)

45°





$\alpha_{45} = 45°$

$x_{45} = AE - AD - BO$

$= 4,87 - 3,18 - 0,27$

$\boxed{x_{45} = 1,42 \text{ mm}}$

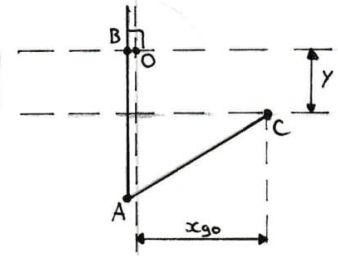
$AD = \cos(45°) \cdot AB = 3,18 \text{ mm}$

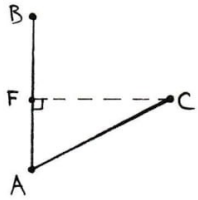
$BD = \sin(45°) \cdot AB = 3,18 \text{ mm}$

$CE = BD - y = 1,43 \text{ mm}$

$AE = \sqrt{AC^2 - CE^2} = 4,87 \text{ mm}$

90°





$x_{90} = CF - BO$

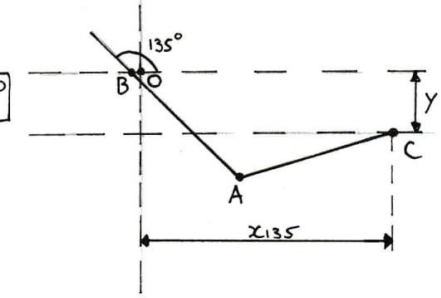
$= 4,27 - 0,27$

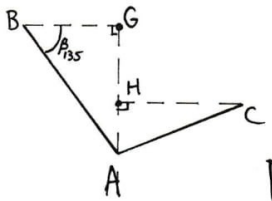
$\boxed{x_{90} = 4,00 \text{ mm}}$

$AF = AB - y = 2,75 \text{ mm}$

$CF = \sqrt{AC^2 - AF^2} = 4,27 \text{ mm}$

135°





$\beta_{135} = 180° - 135° = 45°$

$x_{135} = BG + CH - BO$

$= 3,18 + 4,87 - 0,27$

$\boxed{x_{135} = 7,78 \text{ mm}}$

$BG = \cos(45°) \cdot AB = 3,18 \text{ mm}$

$AG = \sin(45°) \cdot AB = 3,18 \text{ mm}$

$AH = AG - y = 1,43 \text{ mm}$

$CH = \sqrt{AC^2 - AH^2} = 4,87 \text{ mm}$

Appendix I: SutureRing design process

In this appendix, the design process of the SutureRing is presented. First, the blocking mechanism was designed and incorporated in a ring design. The initial design of the ring was printed and tested with the first version of the prototype. Based on some comments from the consulting gynecologists, the ring was slightly altered to create the design as presented in the main thesis.

1. Blocking mechanism

A ring was chosen to block the flow of the thread, because a ring can be accessed no matter how the handle is rotated in the hand. The ring will be rotated to block the thread as it exits the handle. This means that the thread moves freely through an opening in the HandleBase and SutureRing, until the SutureRing is rotated to block the thread.

The thread will be blocked by covering the opening through which the thread exits the HandleBase. In order to provide enough friction to block the thread, without damaging it, a piece of rubber will be moved over the opening in the HandleBase. This blocking method is shown in Figure 85.

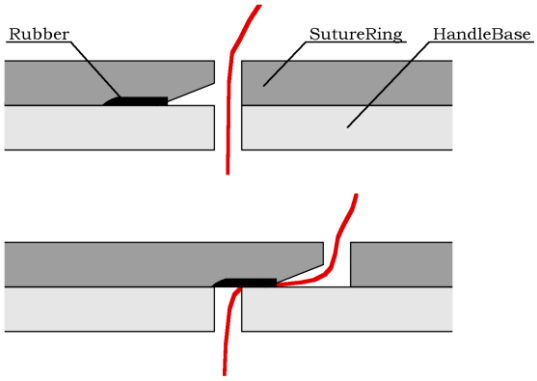


Figure 85: Blocking mechanism with rubber over the opening in the HandleBase.

As can be seen in Figure 85, once the thread is blocked, the end of the thread can still move freely from side to side through the opening of the SutureRing. Building a mockup of this blocking mechanism showed that, when the thread is pulled or moved sideways with force, the thread is pulled through the rubber lock. To ensure that the thread is properly blocked and cannot be accidentally pulled free, a second blocking method is added. The second blocking method blocks the thread by pressing it between the SutureRing and a protrusion on the HandleBase. The combined blocking mechanism is shown in Figure 86.

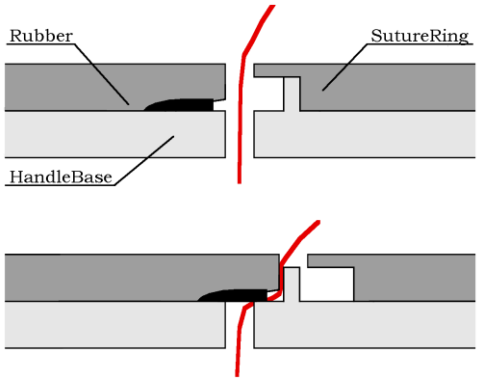


Figure 86: Combined blocking mechanism with rubber over opening in the HandleBase and pinching of the thread.

2. Basic shape of the ring

The blocking mechanism needs to be implemented in the ring. First, the overall shape of the ring is determined, as shown left in Figure 87. The ring has small ribs along the outside to provide grip. A small hole in the ring allows the thread to flow through. Secondly, the blocking mechanism is added to the ring, as

shown on the right in Figure 87. A piece of rubber is fixated in the ring to block the opening in the handle through which the thread flows.

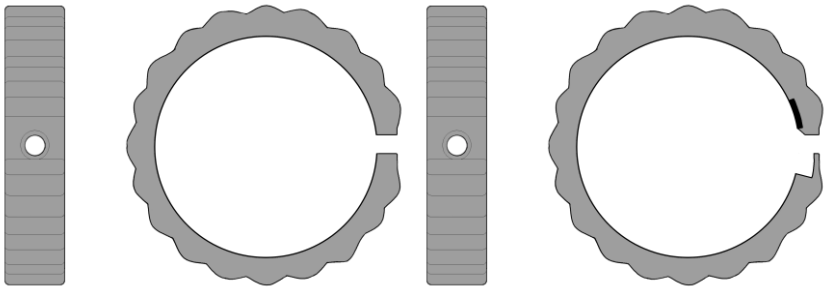


Figure 87: Left - Basic shape of the SutureRing. Left: side view of the ring. Right: intersection of the front view. Right - SutureRing with blocking mechanism incorporated. Left: side view of the ring. Right: intersection of the front view.

To allow the second blocking method as described above, a protrusion on the HandleBase is needed to pinch the thread. The design and placement on the HandleBase of this protrusion is shown in Figure 88.

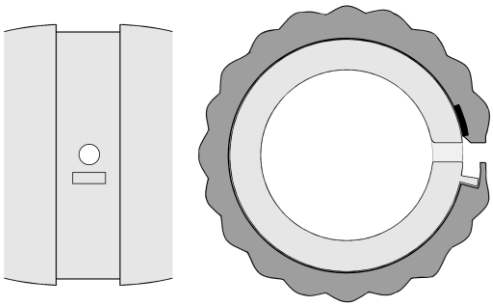


Figure 88: Left – section of the side view of the HandleBase, depicting the protrusion to block the thread. Right: intersection of the front view of the HandleBase and SutureRing.

3. Altered ring design

The ring as designed above was printed with DEAM's 3D-printer and added to the first prototype. This prototype was then tested, which resulted in one main issue with the ring: the ring was difficult to actuate because there was too little grip with the small ribs. The design of the SutureRing was altered to have larger ribs. Additionally, two 'wings', large ridges on either side of the ring, were added to make rotation of the ring easier for the user. The ridges provide the user with a large, easy to feel, surface to press against when rotating the ring, making it easier to block the flow of the thread without having to look at the handle. The new design of the SutureRing is shown in Figure 89.

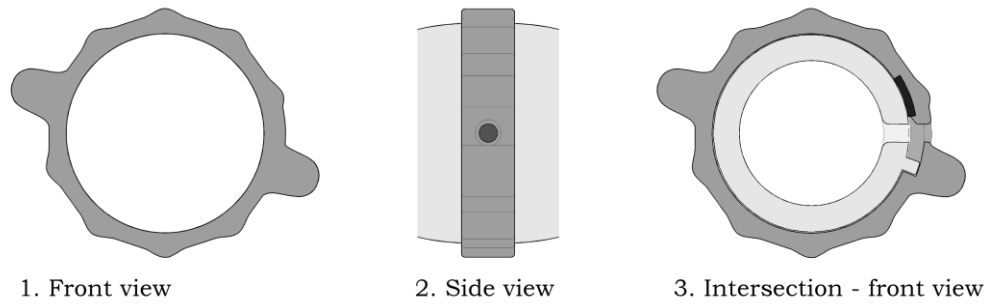


Figure 89: 1 - front view of the SutureRing. 2 – side view of the SutureRing and part of the HandleBase. 3 – intersection of the front view of the SutureRing and HandleBase.

Appendix J: Assembly process Hornet prototype B3

1. Parts overview

For building prototype B3 several parts were bought, made or re-used from previous prototypes.

In the first version of the prototype, the needle was a hollow injection needle. The needle creation of that was eventually used in the final prototype is described at the end of this appendix.

An overview of all the parts and their origin is given in Table 19.

Table 19: List of parts for Hornet prototype B3, and their origin and production process.

Part	Origin	Production process
NeedleBase axis	Make	1.0 – 0.2 mm tube Cut to right length and forced in place
NeedleBase	Ordered	3D-printed by iMaterialize
Needle	Make	Use needle from DEAM, cut to size
Hinge	Re-used	Reused from older version mechanism of Laproflex
PullrodHead	Ordered	3D-printed by iMaterialize
SutureGuide	Make	1.0 – 0.2 mm tube Cut to right length
PullrodStiffener	Make	1.7 – 0.35 mm tube Cut to right length
NeedleActuator	Make	3D-printed by DEAM
NeedleActuatorRod	Make	1.0 mm rod Cut to right length
Shaft	Ordered	Made by DEMO
PullrodGuide	Re-use	Needleramp from prototype B3. There it was used to guide the needle, here it is used to force the PullrodHead in place.
Spring	Re-used	From DEAM's supply
HandleBaseFront	Make	3D-printed by DEAM
SutureRing	Make	3D-printed by DEAM
HandleBaseBack	Make	3D-printed by DEAM
Handle screws	Re-use	From DEAM's supply
Handle axis	Make	1.5 mm tube Cut to the right length
Sewing thread (a substitute for the suture)	Bought	On the spool

2. Assembly process

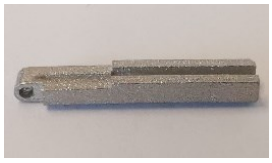
Two prototypes were built. During the initial assembly of the first prototype, some problems were encountered:

- When assembled, the Pullrod tended to move upwards into the shaft, preventing proper flipping of the mechanism. This was caused by the amount of space left in the shaft for the Pullrod to move up and down freely. This problem was solved by adding a 'PullrodGuide' in the shaft, that forces the Pullrod to stay in the bottom half of the shaft. For this part, the Needleramp from prototype B3 was used (slightly adjusted to fit around the 1.7 mm tube).
- The SutureRing had a small print-flaw → the design got mirrored during printing, causing the opening needed to slide the SutureRing on the HandleBaseFront to be on the wrong side. This was fixed by creating a new opening on the right side using a file. One of the three printed SutureRings broke during this process.
- The 3D-printed parts made by DEAM contained some brittle parts:
    - Back of the HandleBaseFront. When pressing the shaft into the HandleBaseTop, it would suddenly slip and hitting the back with force, causing the thin wall to break. This was solved by gluing a circular piece of rubber to the back of the HandleBaseTop that absorbs the force.
    - Inside of the NeedleActuator, the connection with the SutureGuide is brittle and can break during assembly when sideway forces are applied.
    - The front of the HandleBaseFront had small protrusions meant to keep the shaft in place. These were difficult to print, causing some warped prints with a lot of residue stuck in the edges. The protrusions needed to be sanded to the right proportions. When fitting the shaft, some parts of the protrusions broke off, due to the high forces needed to push the shaft in place.
- The springs that were selected for the prototype proved to be too weak to have the preferred effect (automatically flipping the needle back inside the shaft). Another spring was found that worked properly, unfortunately DEAM only had one available. The 'black-threaded' prototype uses this spring, whereas the 'red-threaded' prototype uses the originally intended springs.
- Part of the 3D-printed NeedleBases were printed crooked. Fortunately, this did not provide problems in the functionality of the system.

After the above changes, the assembly steps became:

1. **Preparations**
   Prepare all 3D-printed parts:
   1.1. Sand the rough surfaces
   1.2. Remove protrusions created by supports during printing
   1.3. Drill through the holes to make sure they are the right size.
   1.4. Check whether all parts fit together properly.

2. **Pullrod** [*SutureGuide, PullrodStiffener, PullrodHead*]
   2.1. Create the SutureGuide: cut a tube of Ø 1,0 x 0,20 mm to a length of 311 mm using a Dremel. Sand the edges.
   2.2. Create the PullrodStiffener: cut a tube of Ø 1,7 x 0,35 mm to a length of 271 mm using a Dremel. Sand the edges.
   2.3. Slide the PullrodStiffener over the SutureGuide
   2.4. Place one end of the SutureGuide in the PullrodHead and fixate with some superglue.
   2.5. Glue the PullrodStiffener in place, by adding some glue near the PullrodHead and sliding the PullrodStiffener against it.



3. **Handle** [*SutureRing, HandleBaseFront, HandleBaseBack*]
   3.1. Glue a small piece of rubber in the SutureRing and remove the protruding part.
   3.2. Glue a piece of rubber to the back of the HandleBaseTop
   3.3. Slide the SutureRing on the Handletop

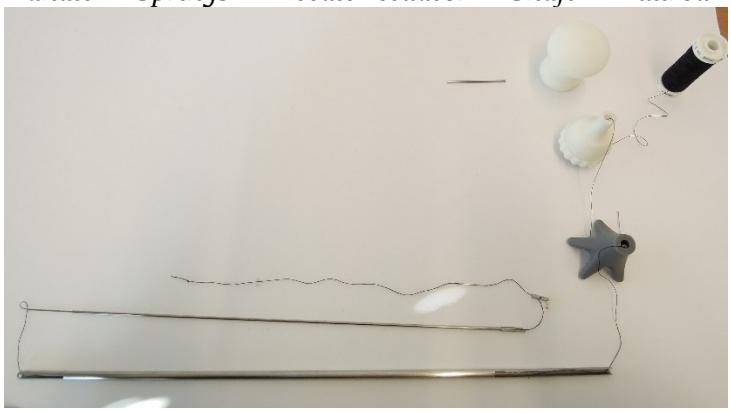
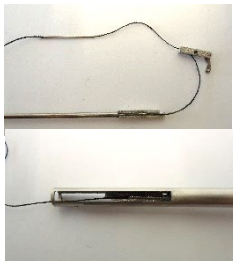
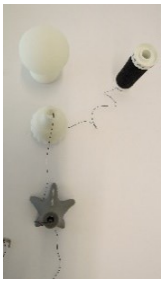

4. **Shaft** [*Shaft, PullrodGuide*]
   4.1. Create the PullrodGuide by modifying the Needleramp from prototype B2 using a Dremel and sanding paper.
   4.2. Glue the PullrodGuide in place in the shaft, just behind the distal protrusion

5. **NeedleActuator** [*NeedleActuator, NeedleActuatorRod*]
   5.1. Place the NeedleActuatorRod (rod, Ø 1,0 mm) in the NeedleActuator.
   5.2. Cut the rod to size using a Dremel. Sand the edges.
   5.3. Glue the NeedleActuatorRod in place.

6. **Needle**
   6.1. Cut a hollow injection needle Ø 0,7 mm to a length of 20 mm using a Dremel. Sand the edges.

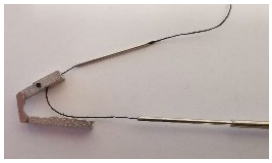
7. **Hinge**
   7.1. Create a small indentation in the side of the hinge to make sure the Rotation Mechanism can properly fit together. Use a Dremel.

8. **Sewing Thread placement**
   8.1. Lay out the parts in order, based on the way the thread moves through the instrument:
   Handle → Springs → NeedleActuator → Shaft → Pullrod → NeedleBase → Needle

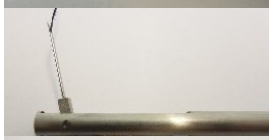




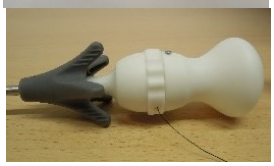
   8.2. Guide the thread through the separate parts of the instrument, starting at the SutureRing. Unwind the thread from the spool as you go. *I pushed the thread through the Pullrod using another rod. I pulled the thread through the NeedleBase and needle by gluing the end of the thread to a stiffer thread that could easily be maneuvered through these parts and then pulling the thread through.*
   8.3. Tie a knot at the end of the thread, after it is pulled through the needle, to prevent the sewing thread from pulling out of the parts.

9. **Assemble the instrument**
   9.1. Attach the NeedleBase to the PullrodHead using the Hinge.



9.2. Carefully slide the Pullrod with the NeedleBase inside the shaft at the distal end and place the PullrodHead in the designated opening at the distal end of the shaft.
9.3. Align the NeedleBase with the distal hole in the shaft for the axis, and secure the NeedleBase in place using the axis.
9.4. Glue the needle in the NeedleBase
9.5. At the proximal end of the shaft, place the NeedleActuator on the shaft.
9.6. Guide the proximal end of the SutureGuide in the designated opening in the NeedleActuator and glue the SutureGuide to the NeedleActuator, making sure the NeedleActuator is pushed up against the PullrodStiffener.
9.7. Place the springs on the proximal part of the shaft, inside the NeedleActuator.
9.8. Guide the shaft inside the handle and pull in place.
9.9. Slide the Handle Axis in place in the HandleBaseFront.
9.10. Place the HandleBaseBack in place and secure using 2 screws.

10. Check-up

10.1. Test if the sewing thread can be moved freely and can be locked
10.2. Test the Needle Rotation Mechanism, check the angles and the smoothness.

3. Alterations to the prototype

After the first test with the consulting gynecologists, some changes were made. The needle was removed using acetone and replaced by a sewing-machine needle from HEMA that was bent in DEAM's workshop (because a bent needle helps with the placement in the tissue and the creation of a suture-loop). The bottom part of the sewing-machine needle was cut off and the needle was glued into the NeedleBase. The thread got a different approach at the NeedleBase too. Instead of being pulled through the needle, the suture was pulled straight through the NeedleBase and through the eye of the needle.

Another alteration was the replacement of the SutureRing with a new SutureRing with 2 distinct protrusions to make actuation of the SutureRing easier (see Appendix I).

Appendix K: Design Verification Tests set-up and results

The Product Specifications that were checked with the Design Verification Tests are listed in Table 20. The Product Specifications PS-3.3 and PS-4.2 were not verified, as explained in the main thesis, and are therefore not included in Table 20.

Table 20: Product Specifications that were checked with the Design Verification Tests.

Product Specification		Acceptance criteria
PS-1.1	Tip and shaft diameter	Diameter ≤ 5.1 mm
PS-1.2	Working length of shaft (tip to base)	Length between 310 mm and 420 mm
PS-1.3	Hand size (length and width)	All features on the handle are reachable by hand with a length between 15.8 cm and 20.6 cm, and a width between 6.9 cm and 9.6 cm.
PS-1.4	Single handed use	The instrument can be operated using a single hand
PS-1.5	Right and left handed use	Instrument controls can be accessed by the right and left hand.
PS-2.1	Needle deployment force	The force on the fingers to maximally deploy the needle should be less than 19.3 N.
PS-2.2	Angle between needle and shaft	Angles up to 135° should be possible.
PS-2.3	Fixation of the angle between needle the shaft	The needle can be fixated at angles of 45°, 90° and 135°.
PS-2.4	Automatic needle retraction	When releasing the feature on the handle to deploy the needle, the needle should retract automatically.
PS-3.1	Needle length	Length from the base to the needle tip 25 +/- 2.0 mm.
PS-3.2	Needle diameter	The diameter of the needle between 0.88 mm & 1.28 mm.
PS-4.1	Diameter of thread	Diameter of thread between 0.3 and 0.5 mm
PS-4.3	Working length of thread	The working length of the thread should be at least 23 cm.
PS-5.1	Thread flow through instrument is unhindered.	The thread can flow freely through the instrument without accidentally being blocked.
PS-5.3	Thread can be blocked	The flow of the thread can be blocked. When blocked, a suture and knot can be placed without the thread slipping.
PS-5.2	Loop formation at the proximal side of the deployed needle.	When placing a suture, the required loop must form at the proximal side of the needle.
PS-5.4	Length of thread at the tip can be adjusted.	The length of the thread at the tip of the instrument can be adjusted during use.
PS-5.5	Thread can flow through the NeedleBase	The thread can flow freely through the NeedleBase to reach the needle.
PS-6.1	Reachability of handle features	All features on the Handle can be reached regardless of how the handle is rotated in the hand.
PS-6.2	Simple handle design	All features on the Handle must be necessary and simple to use.

1. Design Verification Tests setup per Product Specification

For each Product Specification listed in Table 20, the used Design Verification test is described below.

PS-1.1 : Tip and shaft diameter

The diameter of the shaft was measured with a micrometer screw gauge, shown in Figure 90.

Figure 90: A micrometer screw gauge [1]

PS-1.2: Working length of shaft (tip to base)

The working length of the shaft is the length of the instrument that can be inserted in the trocar. This length is from the tip of the instrument to the tip of the NeedleActuator, as shown in Figure 91. This length of the instrument was measured using a ruler.

Figure 91: Working length of the shaft.

PS-1.3: Hand size (length and width)

This Product Specifications states that all the features on the handle can be reached by the most common hand sizes. For each participant, their hand length and width were measured and they were asked whether they could reach the different features on the handle.

The questions in the User Questionnaire related to this Product Specification were: 'the Hornet is comfortable to hold', 'it is easy to reach the NeedleActuator', and 'it is easy to reach the SutureRing'.

The measurements taken of the hands are illustrated in Figure 92, where 420 is the length of the hand and 411 the width of the hand.

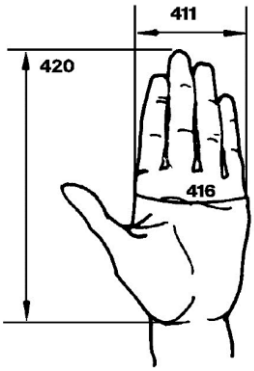


Figure 92: Hand image from NASA's book on Man-Systems integration standards [2]. 411 is the width of the hand. 416 is the circumference of the hand. 420 is the length of the hand.

PS-1.4: Single handed use

Whether the instrument can be operated with a single hand was determined by observing the way the participants used the Hornet during the User Tests.

PS-1.5: Right and left handed use

To assess if the instrument controls can be accessed by both right- and lefthanded users, both the right- and left handed participants of the User Tests were asked whether they could access the instrument controls.

The questions in the User Questionnaire related to this Product Specification were: 'the Hornet is comfortable to hold', 'it is easy to reach the NeedleActuator', and 'it is easy to reach the SutureRing'.

PS-2.1: Needle deployment force

For Product Specification PS-2.1, the force on the fingers to maximally deploy the needle should be less than 19.3 N. The setup shown in Figure 93 was created to measure the force that needs to be exerted on the NeedleActuator to deploy the needle.

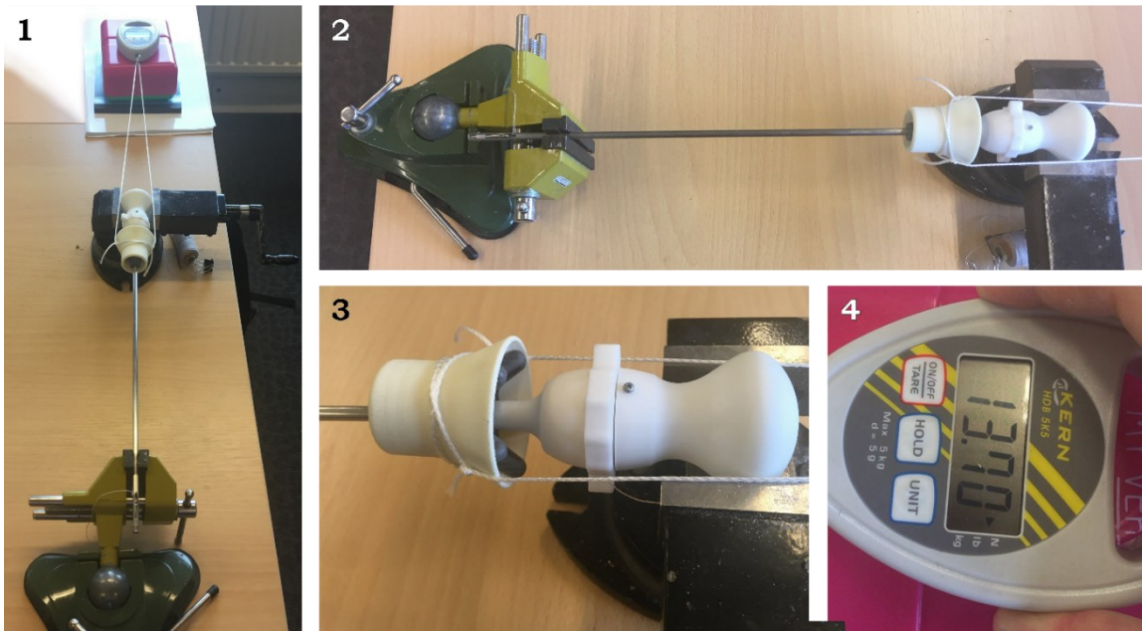


Figure 93: Test-setup to measure the force exerted on the NeedleActuator to deploy the Needle.
1: Overview of the test-setup. 2: Top-view of the instrument in the setup. 3: Close-up of the cap over the NeedleActuator. 4: Close-up of the scale with the highest measured force in Newton.

The instrument is fixated horizontally and a cap is placed over the NeedleActuator. A hanging scale is attached to the cap and placed horizontally in line with the instrument. By pulling back the scale, the NeedleActuator slides towards the handle, deploying the needle.

The test was performed 6 times. For each run, the force at the maximum deployment of the needle was recorded.

PS-2.2: Angle between needle and shaft

To verify if the instrument can reach angles of 135°, the maximum angle of the needle is measure with a digital protractor on a picture that shows the maximum needle angle, as shown in Figure 94.

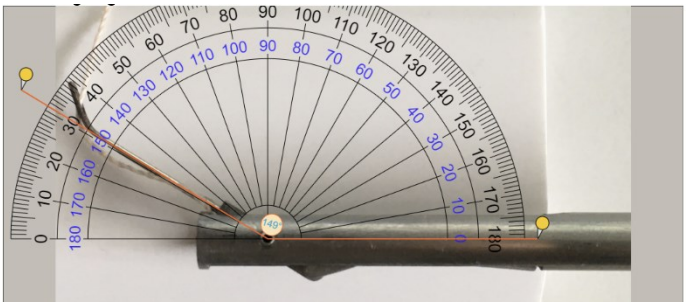


Figure 94: Angle measurement with a digital protractor.

PS-2.3: Fixation of the angle between needle the shaft

To measure the angles of the different fixable needle angles, the needle was locked at the different fixable angles and pictures were taken. The angles were then measured with a digital protractor, similarly to the measurement for PS-2.2.

PS-2.4: Automatic needle retraction

The automatic retraction of the needle was verified by observing the prototype. The NeedleActuator on the prototype was pulled back and released, and it was observed whether the needle automatically retracted back into the shaft.

PS-3.1: Needle length

The length of the needle was measured with a ruler.

PS-3.2: Needle diameter

The diameter of the needle was measured with a micrometer screw gauge, as shown in Figure 90.

PS-4.1: Diameter of thread

The diameter of the thread was measured with a micrometer screw gauge, as shown in Figure 90.

PS-4.3: Working length of thread

The working length of the thread was verified by observation. It was assessed whether the spool of thread contained enough thread to place a suture.

PS-5.1: Thread flow through instrument is unhindered.

The flow of the thread through the instrument was tested by unlocking the SutureRing and pulling on both sides of the thread to see if it could move through the instrument smoothly. This test was done for different needle angles (except the closed position).

PS-5.3: Thread can be blocked

Whether the flow of the thread could be blocked was tested by locking the SutureRing and pulling on both sides of the thread to see if it could move. Whether the blockage of the thread sufficed for suture placement and knot tying was assessed with the User Questionnaire.

The question in the User Questionnaire related to this Product Specification was: ‘the blocked thread can be used to tighten the suture’.

PS-5.2: The loop for suture placement is formed at the proximal side of the deployed needle.

A suture was placed with the prototype to see if the loop at the needle forms at the proximal side of the deployed needle.

PS-5.4: Length of thread at the tip can be adjusted.

The same test as for PS-5.1.

PS-5.5: Thread can flow through the NeedleBase

It is observed whether the thread flows through the NeedleBase.

PS-6.1: Reachability of handle functionalities

The participants of the User Tests were asked whether they could reach all features on the handle while placing a suture.

The questions in the User Questionnaire related to this Product Specification were: ‘it is easy to reach the NeedleActuator’, and ‘it is easy to reach the SutureRing’.

PS-6.2: Simple handle design

The participants of the User Tests were asked their opinion on the features and design of the Hornet.

The questions in the User Questionnaire related to this Product Specification were: 'the design is unnecessary complex', 'the different functionalities are properly integrated in the handle', 'the Hornet is easy to use', 'The NeedleActuator is simple to use', 'It was clear when the thread was blocked'.

2. Design Verification Tests results per Product Specification

For each Product Specification listed in Table 21, the results of the used Design Verification test is described below.

PS-1.1 : Tip and shaft diameter

The diameter of the shaft of the Hornet prototype is 5.0 mm.

PS-1.2: Working length of shaft (tip to base)

The working length of the shaft of the Hornet is 291 mm.

PS-1.3: Hand size (length and width)

The hand dimensions of the participants that provided them are given in Table 21, where green is within the limit, and red is outside the limits given by PS-1.3.

Table 21: Hand dimensions of the participants.

Participant	Expertise group	Hand length [cm]	Hand width [cm]
1	Expert	18.5	8.3
2	Intermediate	20	9.8
3	Intermediate	17.6	8.8
4	Novice	19.8	8.6
5	Novice	19.9	8.5
6	Novice	17.5	6.7
7	Novice	19.5	9.6
8	Novice	17	7.5
9	Novice	18.1	8
10	Novice	19.5	8
11	Novice	18.5	7.5
12	Intermediate	18.5	8.2

The hand dimensions of 86% (10/12) of the participants are within the stated limits. Most participants had a hand length and width within the limit of the acceptance criterium, where only two participants had a deviating hand width. The participants all stated that they could reach the NeedleActuator and SutureRing. Four of the participants found the hand position to reach the SutureRing uncomfortable.

The Hornet was considered comfortable to hold in general by 71% (10/14) of the participants. Two participants stated that they found all laparoscopic handles uncomfortable due to issues with their hands, and two other participants stated that the Hornet handle shape needs some getting used to.

PS-1.4: Single handed use

It was observed that the Hornet could be actuated with a single hand to place a suture. Pulling the thread would have required a second hand. However, none of the participants needed to pull the thread during their tests.

PS-1.5: Right and left handed use

Two participants were left handed, the other participants were right handed. All participants stated that they could reach the controls. Four of the participants, all right handed, found the hand position to reach the SutureRing uncomfortable.

PS-2.1: Needle deployment force

The measured needle deployment forces and the mean, SD, min and max forces are listed in Table 22.

Table 22: Force measurements for the needle deployment force. With the mean, SD, min, and max forces calculated below.

Run	Force at max. deployment [N]
1	12.20
2	13.05
3	12.45
4	13.70
5	13.30
6	13.65
Mean	13.06
SD	0.62
Min	12.20
Max	13.70

PS-2.2: Angle between needle and shaft

The maximum angle between the needle and the shaft is 149°, as shown in Figure 95.

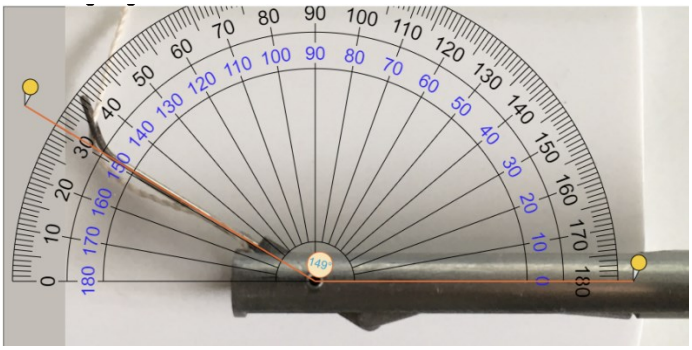


Figure 95: The maximum needle deployment angle of the Hornet.

PS-2.3: fixation of the angle between needle the shaft

The exact angles of the needle when fixed were measured using a digital protractor. Figure 96 shows the results of these measurements.

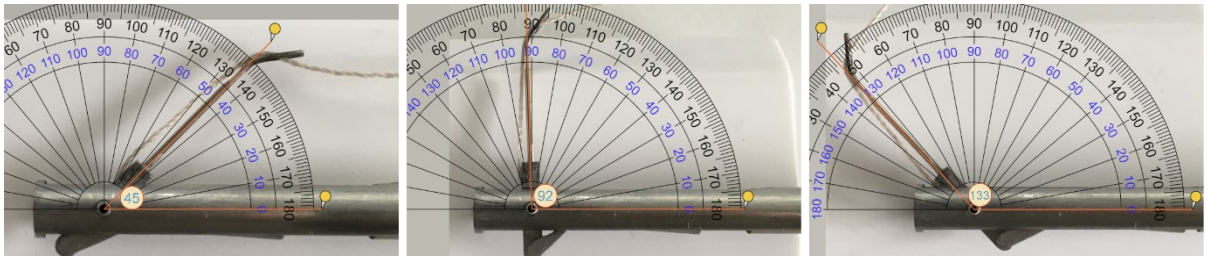


Figure 96: Measurements of fixed needle angles in prototype B3.

The actual fixed needle angles are 45°, 92°, and 133°, instead of the intended angles of 45°, 90°, and 135°. However, the participants of the User Tests stated in the questionnaire that they thought the fixed angles were sufficient and accurate enough to place a suture.

PS-2.4: Automatic needle retraction

The needle is observed to automatically retract into the shaft when the NeedleActuator is released.

PS-3.1: Needle length

The length of the needle is 21 mm.

PS-3.2: Needle diameter

The diameter of the needle 0.89 mm.

PS-4.1: Diameter of thread

The diameter of the thread is 0.3 mm.

PS-4.3: Working length of thread

The working length of the thread is >> 23 cm, as a whole coil of thread is attached to the instrument.

PS-5.1: Thread flow through instrument is unhindered.

The thread is observed to flow freely through the instrument when the SutureRing is open and the needle is deployed.

PS-5.3: Thread can be blocked

The thread can be blocked and this blockage was sufficient for suture placement and knot tying.

PS-5.2: The loop for suture placement is formed at the proximal side of the deployed needle.

The loop was observed to form at the proximal side of the deployed needle.

PS-5.4: Length of thread at the tip can be adjusted.

The length of the thread at the tip could be shortened by pulling the thread at the handle, and lengthened by pulling at the thread near the needle.

PS-5.5: Thread can flow through the NeedleBase

The thread was observed to flow through the NeedleBase without blocking.

PS-6.1: Reachability of handle functionalities

Both features, the NeedleActuator and SutureRing, could be reached by the participants during the entire suturing process.

PS-6.2: Simple handle design

In general, the participants of the User Tests stated in the questionnaire that they thought the Hornet has a simple design that is easy to use. Especially working with the NeedleActuator was considered by the

participants to be intuitive and simple. The SutureRing was considered to be simple to use too, but most participants found it difficult to know when the flow of the thread was blocked without looking at the handle. No participants stated that they believed the features to be unnecessary.

3. Sources

[1] [Image of a micrometer screw gauge]. (n.d.). Retrieved on July 25, 2021, from: https://www.bol.com/be/nl/p/hbm-analoge-buiten-micrometer-50-75-mm-model-2/9200000100859119/

[2] NASA. (1995). *Man-System Integration Standards (NASA-STD-3000) Revision B*. msis.jsc.nasa.gov. Accessed on March 22, 2021, at: https://msis.jsc.nasa.gov/sections/section03.htm

Appendix L: User Questionnaire

Hornet Testprocedure

Document Nummer	
Datum	/ /

Deelnemer

Beroep / Opleiding	
Ervaring met (laparoscopisch) hechten	

Uitgevoerde testprocedure *(in te vullen door Wietske)*

Oefentijd

Instrumenten	**Tijd**
☐ Naaldvoerder + grijper	_____
☐ Hornet + grijper	_____
☐ Hornet + Laproflex	_____
☐ Overig: _____	_____

Uitgevoerde testen

- ☐ A. Lopende hechting met naaldhouder & grijper
- ☐ B. Lopende hechting met Hornet & grijper
- ☐ C. Lopende hechting met Hornet & Laproflex
- ☐ D. Losse hechting (incl. knoop) met naaldhouder & grijper
- ☐ E. Losse hechting (incl. knoop) met Hornet & grijper
- ☐ F. Losse hechting (incl. knoop) met Hornet & Laproflex

Test volgorde: - - - - -

Gebruikte modellen

- ☐ Oefen model(len): _____
- ☐ Oefen vaginatop(pen): _____
- ☐ Test vaginatop: _____

Camera gebruik

- ☐ GoPro (doel: _____)
- ☐ Lange laparoscopische camera (doel: _____)
- ☐ Korte laparoscopische camera (doel: _____)
- ☐ Telefoon camera (doel: _____)

Genomen foto's (deelnemer niet herkenbaar in beeld)

- ☐ Hornet in hand deelnemer
- ☐ Opstelling van de oefening
- ☐ Opstelling van de testen
- ☐ Handhouding(en) deelnemer tijdens oefenen/testen Hornet
- ☐ Resulterende hechting op het model (close-up)
- ☐ Overige fotos: _____

Overige details testprocedure:

_____

_____

Vragenlijst *(in te vullen door de deelnemer)*

Geef aan in hoeverre u het eens bent met de volgende uitspraken. Licht uw antwoord, waar dit voor u van toepassing is, toe.

Algemeen

1. **Ik vind de Hornet makkelijk in het gebruik**

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

2. **Ik vind de Hornet onnodig complex**

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

3. **Ik vind de verschillende functionaliteiten (hoek instellen, hechtdraad bedienen) goed geïntegreerd in het instrument**

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

4. **De Hornet werkt intuïtief**

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

5. **Ik vind de Hornet ongemakkelijk in de hand liggen**

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

6. **Ik had veel oefening nodig voor het gebruik van de Hornet**

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

Hechtingen plaatsen

Het plaatsen van de hechting met de Hornet, vergeleken met de 'standaard' manier.

7. **De Hornet maakt het aanbrengen van de hechting makkelijker**

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

8. **Het positioneren van de naald met de Hornet is makkelijker**

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

9. Het hechtdraad is na de steek goed op te pakken met een grijper

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

10. De voorgestelde hechttechniek met de Hornet was onnodig complex

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

11. De voorgestelde hechttechniek met de Hornet was makkelijk uit te voeren

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

Het Klapsysteem

Het klappen van de naald, het instellen van de hoek van de naald, en de bediening van beide.

12. De in te stellen hoeken zijn voldoende om de hechting te plaatsen

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

13. Ik had graag meer instelbare hoeken gehad

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

14. Het klapsysteem was makkelijk in gebruik

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

15. Het klapsysteem werkte vloeiend

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

16. Ik kon met mijn hand goed bij de bediening van het klapsysteem

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

Het Hechtdraad-systeem

Het verloop van het hechtdraad door het instrument en de bediening daarvan.

17. Het hechtdraadsysteem werkte vloeiend

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

18. Ik kon met mijn hand goed bij de bedieningsring

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

19. Het was duidelijk wanneer het hechtdraad geblokkeerd was

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

20. De blokkering van het hechtdraad was sterk genoeg om de hechting aan te trekken

Erg oneens	Oneens	Niet eens / Niet oneens	Eens	Erg mee eens
O	O	O	O	O

Toelichting: _____

_____

Opmerkingen *(in te vullen door de deelnemer)*

Heeft u nog andere opmerkingen, ideeën, positieve punten, verbeterpunten en/of tips?

Appendix M: User Questionnaire Answers

In this appendix, the answers of the participants of the User Tests to the User Questionnaire are given. The scores per statement and all comments made by the participants, divided by category, are presented. The statements and comments are in Dutch, because the User Questionnaire was in Dutch.

1. Scores for the statements

Statement		Participants													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	Ik vind de Hornet makkelijk in het gebruik	4	4	4	4	4	4	4	4	4	4	5	4	4	4
2	Ik vind de Hornet onnodig complex	2	2	2	2	1	2	2	2	1	2	3	3	2	2
3	Ik vind de verschillende functionaliteiten (hoek instellen, hechtdraad bedienen) goed geïntegreerd in het instrument	4	4	4	4	5	4	4	4	4	4	4	4	4	4
4	De Hornet werkt intuïtief	3	4	4	3	4	3	2	3	5	3	4	3	3	3
5	Ik vind de Hornet ongemakkelijk in de hand liggen	1	2	3	4	1	3	3	2	2	2	2	1	1	2
6	Ik had veel oefening nodig voor het gebruik van de Hornet	3	2	4	1	2	2	2	2	2	3	3	1	3	3
7	De Hornet maakt het aanbrengen van de hechting makkelijker	4	4	5	5	4	4	5	5	5	5	5	3	5	5
8	Het positioneren van de naald met de Hornet is makkelijker	5	3	5	5	5	5	5	3	5	3	5	4	5	5
9	Het hechtdraad is na de steek goed op te pakken met een grijper	4	4	3	4	4	4	3	3	4	2	4	2	4	4
10	De voorgestelde hechttechniek met de Hornet was onnodig complex	2	2	2	2	1	1	1	2	1	1	2	1	2	2
11	De voorgestelde hechttechniek met de Hornet was makkelijk uit te voeren	4	4	4	4	5	4	5	4	5	4	4	5	4	4
12	De in te stellen hoeken zijn voldoende om de hechting te plaatsen	4	4	4	5	4	4	5	5	5	5	4	4	5	5
13	Ik had graag meer instelbare hoeken gehad	1	2	2	2	1	1	1	4	1	1	2	2	2	2
14	Het klapsysteem was makkelijk in gebruik	4	4	4	4	4	4	2	2	5	4	4	4	4	4
15	Het klapsysteem werkte vloeiend	4	3	3	3	5	4	5	4	4	3	3	4	4	4
16	Ik kon met mijn hand goed bij de bediening van het klapsysteem	4	4	3	5	5	4	5	4	4	4	4	5	4	4
17	Het hechtdraadsysteem werkte vloeiend	4	4	4	3	5	4	4	5	4	4	4	4	4	4
18	kon met mijn hand goed bij de bedieningsring	4	4	3	4	4	4	2	5	2	4	4	3	3	3
19	Het was duidelijk wanneer het hechtdraad geblokkeerd was	1	2	4	1	2	3	1	2	2	1	4	2	2	2
20	De blokkering van het hechtdraad was sterk genoeg om de hechting aan te trekken	4	4	5	5	5	4	4	4	5	5	4	4	4	4

2. Comments per category

2.1. Needle rotation & locking mechanism

Participant	Comment
001	Naald kan uit lock schieten
001	Gevoel in linkerhand is anders (voelt verkeerde kant op in eerste instantie)
002	Traploos systeem is makkelijker (dus in elke hoek kunnen stellen, net als bij naalddrijver)
004	Naaldlock vergt wat uitleg
004	Het zou nice zijn als je hem op elke hoek vast kan zetten (is nice als je niet hoeft te zoeken naar de juiste hoek)
005	Het draaien is even wennen en kijken, maar makkelijk te doen met 1 hand zonder te hoeven kijken
005	In te stellen hoeken lijken voldoende, maar is miss anders in een lichaam
005	Het achteruittrekken gaat goed
007	Je neemt het gepruts met de naald weg doordat je met de Hornet de hoek kan instellen
007	Niet een intuitief klapsysteem.
007	De naald moet sterker zijn als hij uitgeklapt is tijdens het aantrekken
008	Werken met de draad is intuitief
008	Het kiezen van de hoek is intuitief
008	Op een fijnere manier hoeken kunnen kiezen (dus niet vast aan deze drie) zal vast iemand helpen. Voor mij was het niet nodig in deze situatie.
008	Klapsysteem werkt wel goed, kan losschieten bij bediening van hechtdraadlock
009	Er waren genoeg hoekopties, meer kan onnodige speling geven
009	Er was nog redelijk wat speling in de hoek (de naald stond niet helemaal vast maar kon wiebelen)
010	De naald geintegreerd in het systeem is nice
011	Het klapsysteem liep een beetje vast, maar kwam door veel gebruik / slijtage
012	Het draaisysteem ging wat stroef en de naald bleef af en toe niet goed vast staan.

2.2. Thread-blocking system

Participant	Comment
001	lockmechanisme is een handigheidje maar contra-intuitief
001	Bij bedienen van het hechtdraad schiet de hoek van de naald snel los
002	Blokkeren van hechtdraad is niet duidelijk omdat het niet te voelen is
004	Feedback wanneer het draad gelockt is ontbreekt (bijv. Trillingen (haptic feedback))
004	Draadlock vergt wat uitleg
005	Het draaien is even wennen, maar makkelijk te doen met 1 hand zonder te hoeven kijken
005	Je merkte pas tijdens het hechten of het draad geblokt was of niet
007	De ring is niet erg intuitief in het gebruik --> je hebt uitleg nodig (de lockrichting is verkeerd om)
007	Er waren genoeg hoek-opties

Participant	Comment
007	Het was onduidelijk wanneer het hechtdraad geblokkeerd was, je merkt dit alleen als je er aan trekt
007	Bij bedienen van het hechtdraad schiet de hoek van de naald snel los
007	Bij bedienen van het hechtdraad en aantrekken knoop beweegt de naald, dit voelt alsof hij kan afbreken
008	Het los/vastzetten van het draadje door te draaien is niet intuïtief
008	Bij het vastzetten/losmaken van de hechtdraad zette ik het klapsysteem vaak los
008	Je moet onthouden of het hechtdraad vastzit of niet. Bij het aantrekken van knopen/draad was het altijd even dubbelchecken of het vast zat of niet
009	Vastzetten van de draad voelt wat onhandig
009	Iets met kleuren kan helpen voor de duidelijkheid van het vastzetten van het locksysteem
010	Het los/vastzetten van de draad was ik soms mee in de war
012	Draaisysteem om vast te stellen voelde onwennig. Is een schuifje niet makkelijker?

2.3. Handle

Participant	Comment
004	Alle handvatten voelen ongemakkelijk aan
005	De grijper (de pijlpunt) had makkelijker in de hand kunnen liggen
005	Ligging in de hand kan beter
007	De ring waarmee je het draad vastzet zit op een beetje een ongemakkelijke plek. Kon er wel bij maar was ongemakkelijk
008	Je verwacht van het design van de pijlpunt dat het ronddraait en niet perse dat het het hoeksysteem is
008	Je moet je hand verplaatsen om de hechtdraadring te kunnen bedienen, wordt niet echt als een probleem gezien, valt alleen op
009	Wat lastig om met je hand bij de bedieningsring van het hechtdraad te komen
010	Voelt in het begin beetje raar in de hand, maar na even gebruiken niet meer

2.4. Regular suturing

Participant	Comment
004	Hechtdraad oppakken is even kijken maar niet moeilijk
005	Draad pakken is kut, nice van de Hornet dat je het al vasthebt
005	Vervelend om niet altijd genoeg draad te hebben, Hornet lost dit ook op
005	Naald positioneren is lastig
007	het is best een gepruts als de naald los vast hebt
010	De losse naald was een heikelpunt

2.5. Suturing with the Hornet

Participant	Comment
005	Het draadje pakken is nog een beetje lastig, maar na wat oefening wel goed te doen
005	Onduidelijk wanneer het nodig is om het hechtdraad vast te zetten
007	Vooral de eerste stap (positioneren hechtdraad en eerste steek zetten) is sneller
007	hechtdraad oppakken lukte wel maar je moet wel goed mikken en turen
007	De hechttechniek moet uitgelegd worden maar is niet complex, zo was er uitleg nodig bij de 2e en 3e knoop dat het makkelijker is met een uitgeklapte naald
008	De draad zit dicht tegen de naald aan. Maar het is zeker wel te doen.
009	Makkelijker dan conventioneel hechten
010	Het hechtdraad was lastig op te pakken
010	De hechttechniek zelf was vrij makkelijk
011	Het doorhalen van de draad om knopen te leggen ging velen malen makkelijker (en sneller)
012	Het was lastig het lusje op te pakken, dit had misschien ook met het type draad in de Hornet te maken

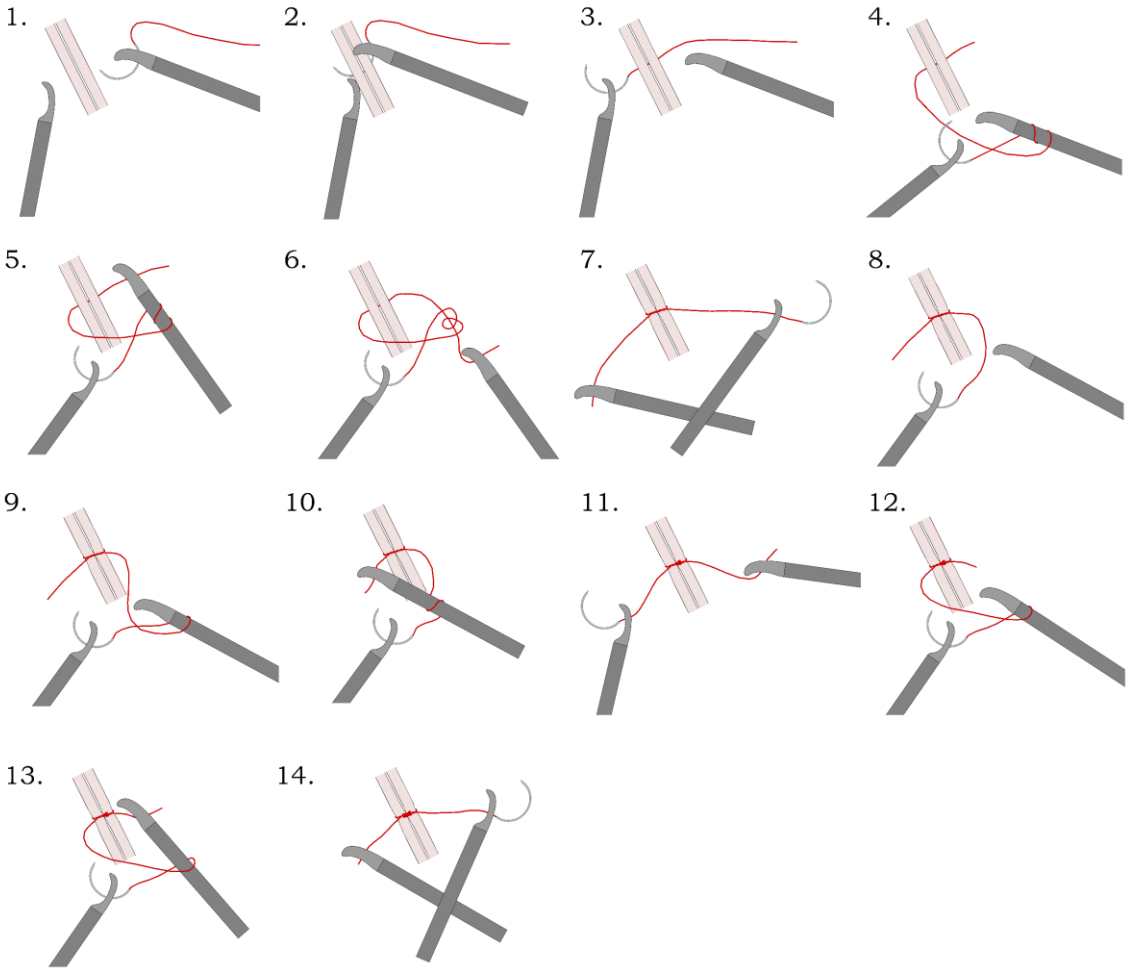
2.6. Possible extra functionalities

Participant	Comment
001	Knip-/Snij-systeem om hechtdraad af te knippen
001	Automatisch oprollen van het hechtdraad

Appendix N: Suturing methods for the User Tests

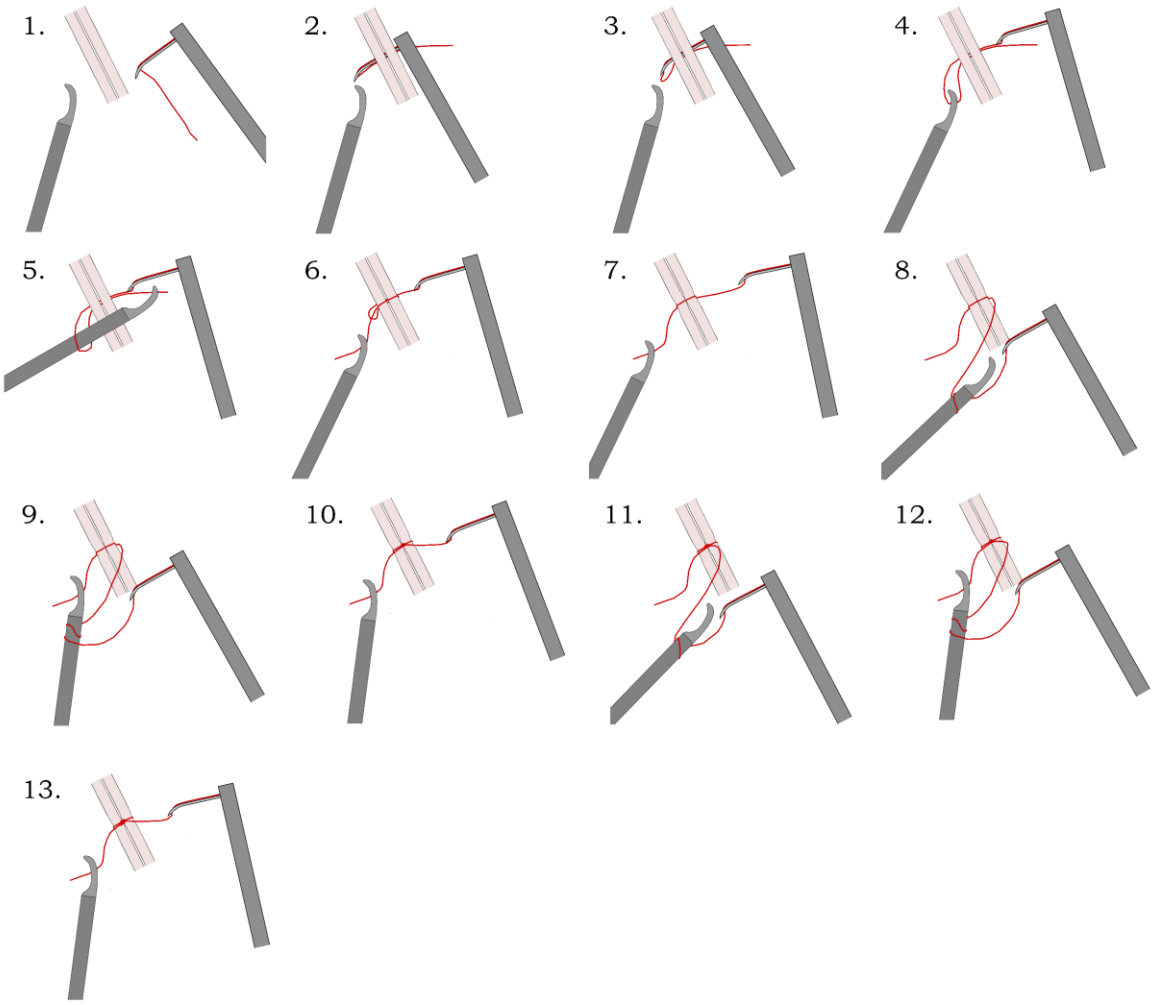
Regular suturing method

1. Pick up the needle with the needle holder
2. Insert needle in the tissue
3. Grab the needle with the grasper
4. Use the grasper to wind the thread around the needle holder, creating 2 loops
5. Grab the end of the thread with the needle holder
6. Pull the end of the thread through the loops created around the needle holder
7. Tighten the first knot
8. Grab the needle with the grasper
9. Use the grasper to wind the thread around the needle holder, creating 1 loop
10. Grab the end of the thread with the needle holder and pull it through the loop
11. Tighten the second knot
12. Grab the needle with the grasper and use the grasper to wind the thread around the needle holder, creating 1 loop
13. Grab the end of the thread with the needle holder and pull it through the loop
14. Tighten the third knot



Hornet suturing method

1. Deploy the needle from the Hornet
2. Insert the needle in the tissue
3. Pull the needle slightly back to create a loop
4. Grab the loop with the grasper and make bigger as you retract the Hornet from the tissue
5. Move the grasper through the loop and grab the loose end of the thread
6. Pull the end of the thread through the loop
7. Tighten the first knot
8. Rotate the needle once around the grasper to create a loop around the grasper
9. Grab the free end of the thread
10. Pull the thread through the loop and tighten the second knot.
11. Rotate the needle once around the grasper to create a loop around the grasper
12. Grab the free end of the thread
13. Pull the thread through the loop and tighten the third knot.



Appendix O: User Test results

This appendix gives the results of all the participants of the User Tests for all their tests.

1. Time measurements

1.1. First use with both methods

Participant	Expertise group	Suture Order	Left- / Right-handed	Suture method	Suturing time [s]	Needle alignment time [s]
1	Expert	Hornet first	Right handed	Hornet	134	8
				Regular	108	7
2	Intermediate	Regular first	Right handed	Hornet	107	16
				Regular	246	39
3	Intermediate	Hornet first	Right handed	Hornet	136	12
				Regular	254	40
4	Novice	Regular first	Left handed	Hornet	152	8
				Regular	487	49
5	Novice	Hornet first	Right handed	Hornet	183	7
				Regular	255	57
6	Novice	Hornet first	Left handed	Hornet	132	7
				Regular	323	48
7	Novice	Regular first	Right handed	Hornet	122	8
				Regular	181	18
8	Novice	Regular first	Right handed	Hornet	142	9
				Regular	321	54
9	Novice	Hornet first	Right handed	Hornet	153	15
				Regular	228	12
10	Novice	Hornet first	Right handed	Hornet	131	6
				Regular	404	139
11	Novice	Regular first	Right handed	Hornet	129	12
				Regular	383	8
12	Intermediate	Regular first	Right handed	Hornet	132	8
				Regular	154	16
13	Expert	Regular first	Right handed	Hornet	99	2
				Regular	92	10
14	Expert	Hornet first	Right handed	Hornet	93	6
				Regular	53	6

1.2. Second use with both methods

Participant	Expertise group	Suture Order	Suture method	Suturing time [s]	Needle alignment time [s]
1	Expert	Hornet first	Hornet	110	10
			Regular	*Only Hornet was used twice*	
5	Novice	Hornet first	Hornet	135	8
			Regular	*Only Hornet was used twice*	
8	Novice	Regular first	Hornet	*Only Regular was used twice*	
			Regular	173	54
10	Novice	Hornet first	Hornet	102	10
			Regular	182	37
12	Intermediate	Regular first	Hornet	106	9
			Regular	134	15

1.3. Means and SDs

	Experts		Intermediates		Novices	
	Regular Mean (SD)	*Hornet* Mean (SD)	*Regular* Mean (SD)	*Hornet* Mean (SD)	*Regular* Mean (SD)	*Hornet* Mean (SD)
Mean suturing time [s]	84 (28)	109 (22)	218 (56)	125 (16)	323 (109)	144 (19)
Mean needle alignment time [s]	8 (2)	5 (3)	32 (14)	12 (4)	48 (45)	9 (3)

1.4. Figures

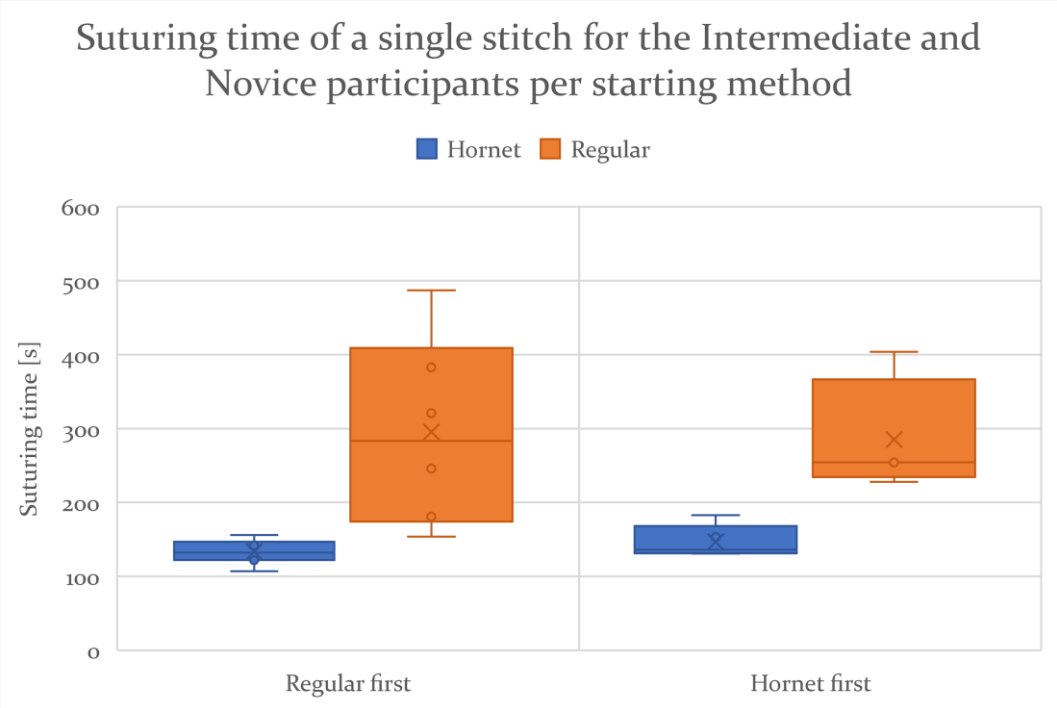


Figure 97: The suturing times to place a single stitch with knots. A division is made between the participants that started with the regular suturing method and participants that started with the Hornet method.

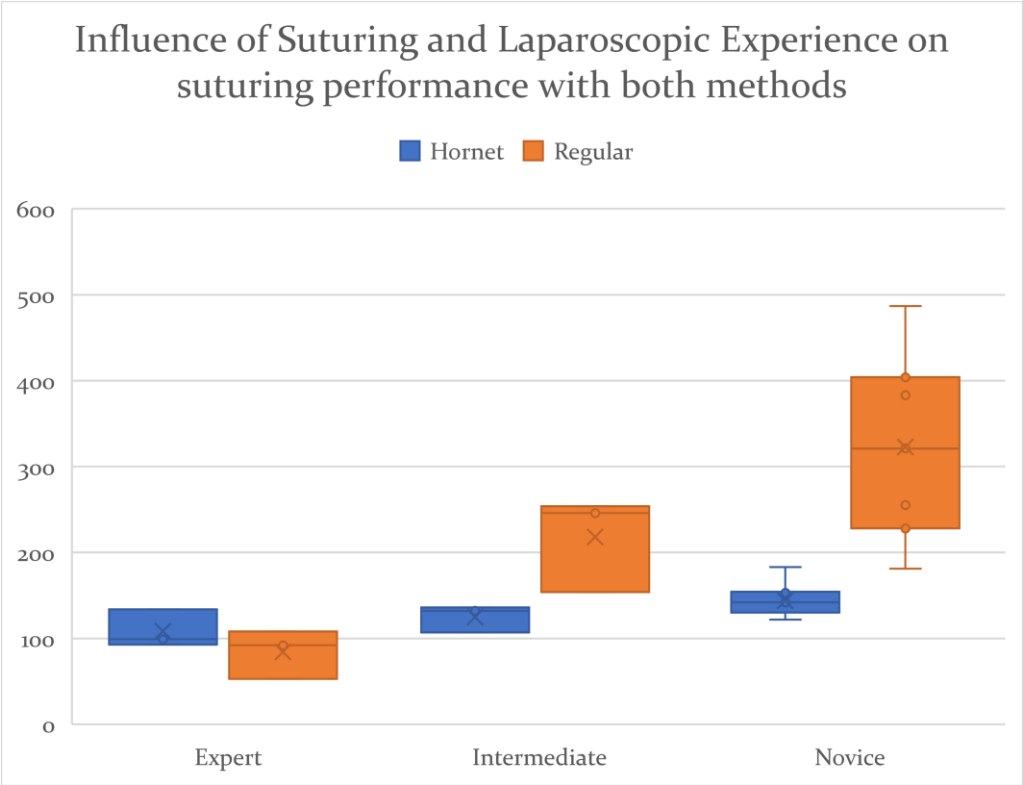


Figure 98: The suturing times of a single stitch with knots with the Hornet and the regular method for participants with different levels of experience.

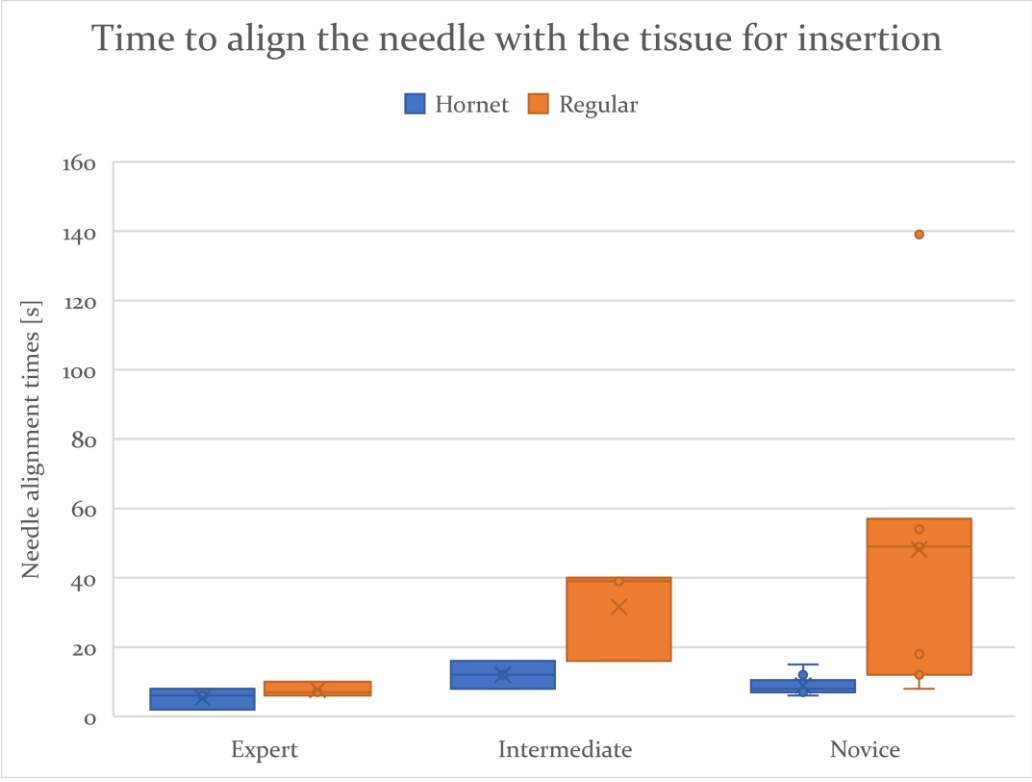


Figure 99: The needle alignment times with the Hornet and the regular method for participants with different levels of experience.

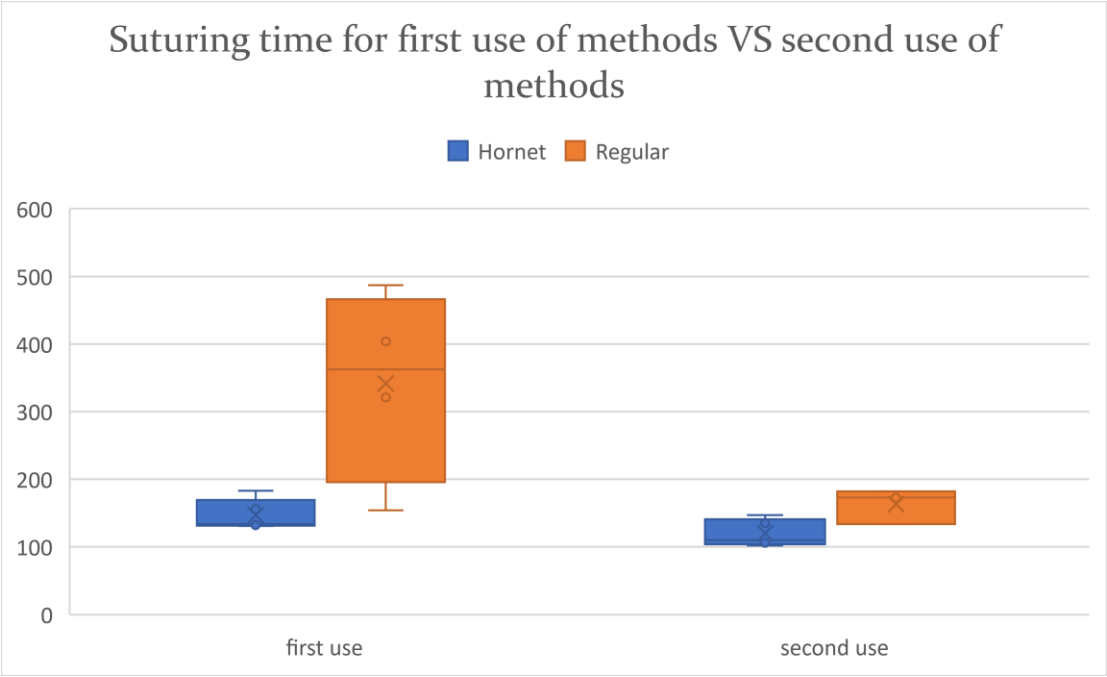


Figure 100: The suturing times for the first use of both methods VS the second use of both methods. Generated with the results of the 5 participants that performed the test procedure twice.

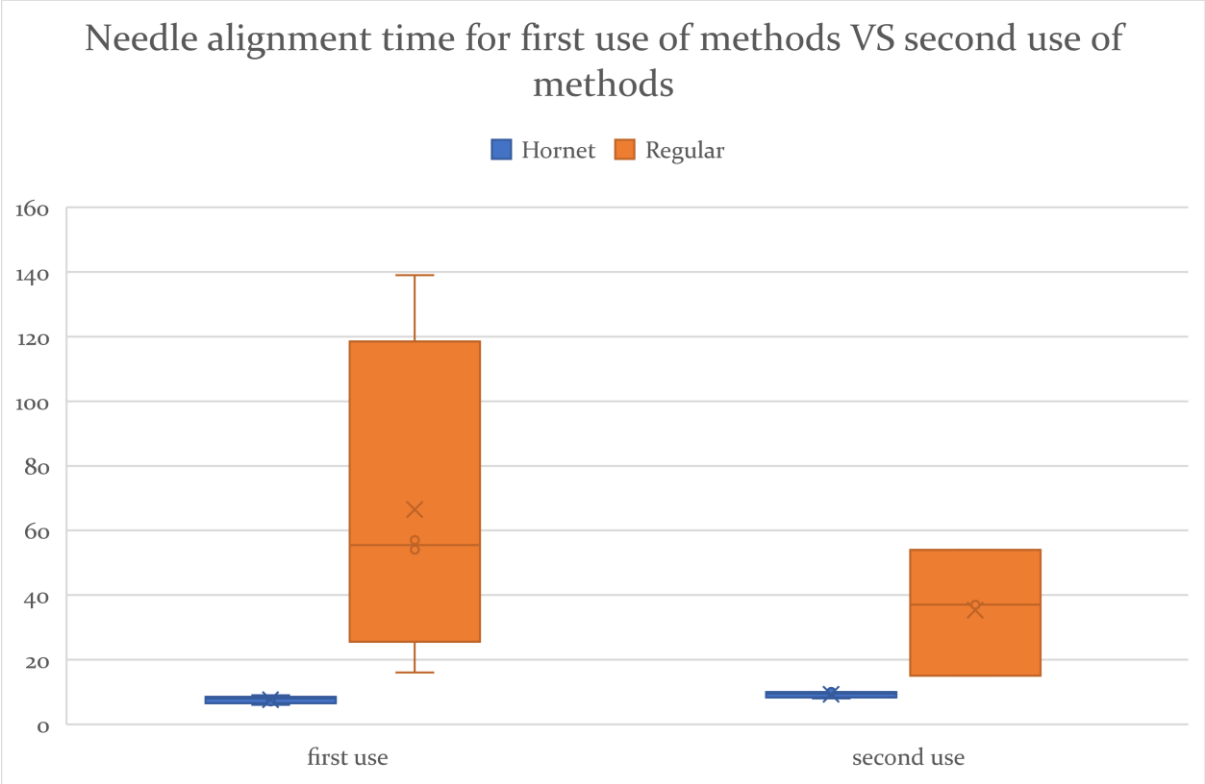


Figure 101: The needle alignment times for the first use of both methods VS the second use of both methods. Generated with the results of the 5 participants that performed the test procedure twice.

2. Suture Quality

Participant	Experience level	Suturing method	Suture quality
1	Expert	Regular suturing method	Closed
		Hornet method	Closed
2	Intermediate	Regular suturing method	Slightly open
		Hornet method	Closed
3	Intermediate	Regular suturing method	Closed
		Hornet method	Closed
4	Novice	Regular suturing method	Slightly open
		Hornet method	Closed
5	Novice	Regular suturing method	Closed
		Hornet method	Closed
6	Novice	Regular suturing method	Slightly open
		Hornet method	Closed
7	Novice	Regular suturing method	Fully open
		Hornet method	Closed
8	Novice	Regular suturing method	Closed
		Hornet method	Closed
9	Novice	Regular suturing method	Fully open
		Hornet method	Closed
10	Novice	Regular suturing method	Slightly open
		Hornet method	Closed
11	Novice	Regular suturing method	Fully open
		Hornet method	Closed
12	Intermediate	Regular suturing method	Slightly open
		Hornet method	Closed
13	Expert	Regular suturing method	Closed
		Hornet method	Closed
14	Expert	Regular suturing method	Closed
		Hornet method	Closed

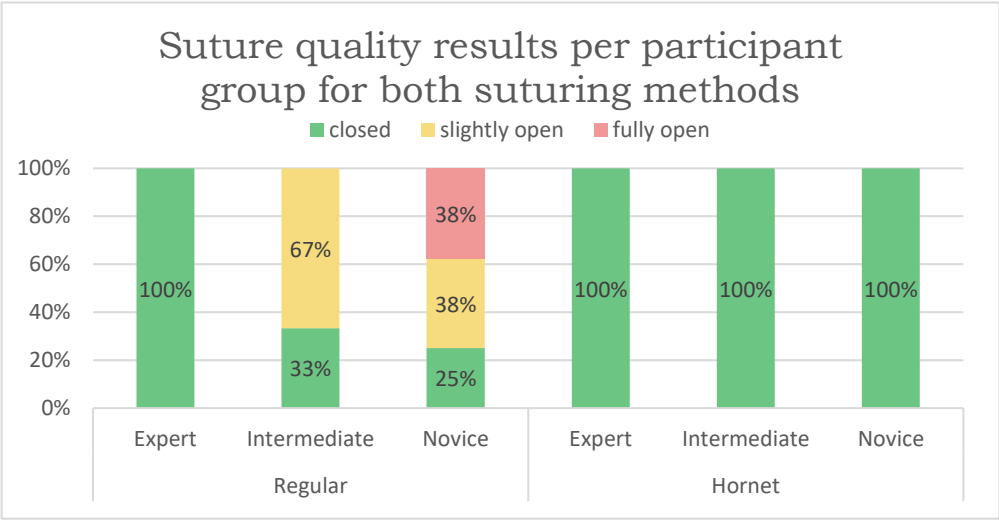


Figure 102: Suture quality of the sutures placed by the participants per participant group and suturing method.

Appendix P: ANOVA & t-test results

This appendix gives the results of the ANOVA tests and t-tests for the main thesis.

1. ANOVA test results

Several one-way ANOVA tests were executed to determine whether the answers given in the questionnaire by the participants are significantly different per participant group.

Table 23 shows the answers given by the participants per statement, with their resulting F-statistic values and p-values. A p-value of $P < .05$ is considered to show a significant difference between the groups, p-values of $P > .05$ suggests that the groups do not differ significantly.

Table 23: ANOVA test results per statement, values generated with online ANOVA-calculators [1], [2].

Statement	Expert scores	Intermediate scores	Novice scores	F-statistic values	p-value	Significantly different?
1	4, 4, 4	4, 4, 4	4, 4, 4, 4, 4, 4, 4, 5	0.33665	0.72127	No significant difference
2	2, 2, 2	2, 2, 3	2, 1, 2, 2, 2, 1, 2, 3	0.71158	0.51213	No significant difference
3	4, 4, 4	4, 4, 4	4, 5, 4, 4, 4, 4, 4, 4	0.33665	0.72127	No significant difference
4	3, 3, 3	4, 4, 3	3, 4, 3, 2, 3, 5, 3, 4	0.56558	0.58371	No significant difference
5	1, 2, 1	2, 3, 1	4, 1, 3, 3, 2, 2, 2, 2	1.53707	0.25783	No significant difference
6	3, 3, 3	2, 4, 1	1, 2, 2, 2, 2, 2, 3, 3	1.2198	0.3323	No significant difference
7	5, 5, 4	4, 5, 3	5, 4, 4, 5, 5, 5, 5, 5	1.66572	0.23338	No significant difference
8	5, 5, 5	3, 5, 4	5, 5, 5, 5, 3, 5, 3, 5	1.03128	0.3886	No significant difference
9	4, 4, 4	4, 3, 2	4, 4, 4, 3, 3, 4, 2, 4	1.37507	0.29307	No significant difference
10	2, 2, 2	2, 2, 1	2, 1, 1, 1, 2, 1, 1, 2	1.91943	0.19273	No significant difference
11	4, 4, 4	4, 4, 5	4, 5, 4, 5, 4, 5, 4, 4	0.68271	0.52542	No significant difference
12	5, 5, 4	4, 4, 4	5, 4, 4, 5, 5, 5, 5, 4	2.07404	0.17207	No significant difference
13	2, 2, 1	2, 2, 2	2, 1, 1, 1, 4, 1, 1, 2	0.20311	0.81918	No significant difference
14	4, 4, 4	4, 4, 4	4, 4, 4, 2, 2, 5, 4, 4	0.33671	0.72122	No significant difference
15	4, 4, 4	3, 3, 4	3, 5, 4, 5, 4, 4, 3, 3	0.80946	0.46994	No significant difference
16	4, 4, 4	4, 3, 5	5, 5, 4, 5, 4, 4, 4, 4	0.68439	0.52464	No significant difference
17	4, 4, 4	4, 4, 4	3, 5, 4, 4, 5, 4, 4, 4	0.10247	0.90345	No significant difference
18	3, 3, 4	4, 3, 3	4, 4, 4, 2, 5, 2, 4, 4	0.17423	0.84238	No significant difference

Statement	Expert scores	Intermediate scores	Novice scores	F-statistic values	p-value	Significantly different?
19	2, 2, 1	2, 4, 2	1, 2, 3, 1, 2, 2, 1, 4	0.77422	0.48464	No significant difference
20	4, 4, 4	4, 5, 4	5, 5, 4, 4, 4, 5, 5, 4	1.1295	0.35797	No significant difference

2. T-test results

Nine two-sample t-tests for unpaired data were conducted to compare the suture and needle alignment times of the different participant groups and the two suturing methods. The p-values and significances obtained through these tests are shown in Table 24. A p-value of $P < .05$ is considered to show a significant difference between the groups, p-values of $P > .05$ suggests that the groups do not differ significantly.

Table 24: t-test results per statement, values calculated with Excel, significance determined with t-table [3].

Comparison made	Compared test results [participant group]	Sample size	Mean [s]	Standard deviation [s]	Variance [s^2]	T	Degrees of freedom	p-value	Significantly different?
For regular suturing times: Hornet first VS regular first	Regular suturing times [Hornet first]	7	229.86	112.82	15083.81	-0.5594	12	0.5862	Not significantly different
	Regular suturing times [Regular first]	7	268.57	135.80	18440.29				
For Hornet suturing times: Hornet first VS regular first	Hornet suturing times [Hornet first]	7	137.43	27.01	729.62	0.90995	12	0.3808	Not significantly different
	Hornet suturing times [Regular first]	7	126.14	18.63	347.14				
Novice's Hornet VS regular suturing times	Hornet suturing times [Novice]	8	143.00	19.58	383.43	-4.9596	14	0.0002	Significantly different
	Regular suturing times [Novice]	8	322.75	100.62	10124.79				
Intermediate's Hornet VS regular suturing times	Hornet suturing times [Intermediate]	3	125.00	15.72	247.00	-2.7893	4	0.0494	Significantly different
	Regular suturing times [Intermediate]	3	218.00	55.57	3088.00				
Expert's Hornet VS regular suturing times	Hornet suturing times [Expert]	3	108.67	22.14	490.33	1.1732	4	0.3058	Not significantly different
	Regular suturing times [Expert]	3	84.33	28.29	800.33				

Comparison made	Compared test results [participant group]	Sample size	Mean [s]	Standard deviation [s]	Variance [s^2]	T	Degrees of freedom	p-value	Significantly different?
Intermediate VS Expert regular suturing times	Regular suturing times [Intermediate]	3	218.00	55.57	3088.00	3.7128	4	0.0206	Significantly different
	Regular suturing times [Expert]	3	84.33	28.29	800.33				
Novice VS Intermediate Hornet suturing times	Hornet suturing times [Novice]	8	143.00	19.58	383.43	1.5771	9	0.1492	Not significantly different
	Hornet suturing times [Intermediate]	3	125.00	15.72	247.00				
Expert VS Intermediate Hornet suturing times	Hornet suturing times [Expert]	3	108.67	22.14	490.33	-1.0418	4	0.3563	Not significantly different
	Hornet suturing times [Intermediate]	3	125.00	15.72	247.00				
Novice's Hornet VS regular needle alignment times	Hornet needle alignment times [Novice]	8	9.00	3.02	9.14	-2.6444	14	0.0192	Significantly different
	Regular needle alignment times [Novice]	8	48.13	41.74	1742.13				

3. Sources

[1] ANOVA Calculator: One-way Analysis of Variance Calculator. (2021, July). Retrieved from: https://goodcalculators.com/one-way-anova-calculator/

[2] One-way ANOVA Calculator. (2021, July). Retrieved from: https://mathcracker.com/one-way-anova

[3] T-table. (2007). Retrieved on July 20, 2021, from: https://www.sjsu.edu/faculty/gerstman/StatPrimer/t-table.pdf

Appendix Q: Vaginal cuff model & holder creation

To demonstrate the modified sewing machine suturing technique and to provide proper models of the vaginal cuff for the participants in the User Tests, models of the vaginal cuff were designed and created. It was decided to create our own models of the vaginal cuff, rather than buying them. Buying the models would have been costly and creating the models at DEAM would allow for more models to be created than would have been possible if the models were bought.

The design and creation of the vaginal cuff models consisted of several steps:

1. Research the shape and dimensions of the vaginal cuff
2. Material selection & production selection
3. Vaginal cuff mold design
4. Vaginal cuff model creation

In addition to the vaginal cuff models, this appendix presents the design of the holder for the vaginal cuff models in the lapro-trainer.

1. Research the shape and dimensions of the vaginal cuff

The dimensions of the vaginal cuff differ slightly per person, making it difficult to find one single dimension. Therefore, the dimensions of an existing vaginal cuff model for practicing closing the vaginal cuff were taken. These dimensions are shown in Figure 103.

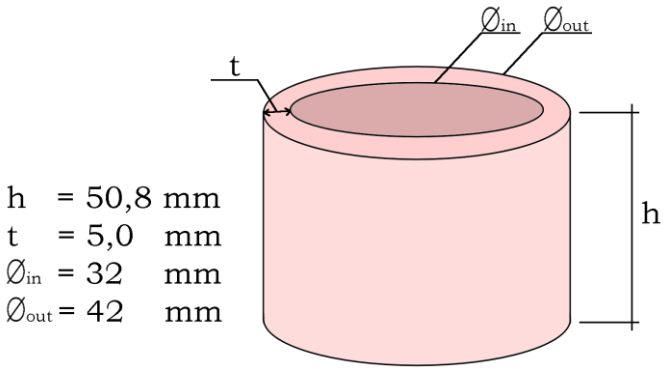


Figure 103: Dimensions of a vaginal cuff model. The dimensions originate from [1]

2. Material selection & production method

Jules Scheltes, co-founder of DEAM and supervisor for this project, suggested to use pourable silicon to create the vaginal cuff. Soft silicon is often used to simulate suture and it can easily be poured into a mold to create models.

The silicon used for the vaginal cuff models was: Smooth-on Exoflex 0030. This silicon rubber creates soft, strong and stretchy models, which fits the intended purpose.

3. Vaginal cuff mold design

To create the vaginal cuff, a mold was designed in SolidWorks and printed by DEAM. The mold, shown in Figure 104, consists of 3 parts to make demolding easy. The outer shell is split in two parts that can lock around the inner column.

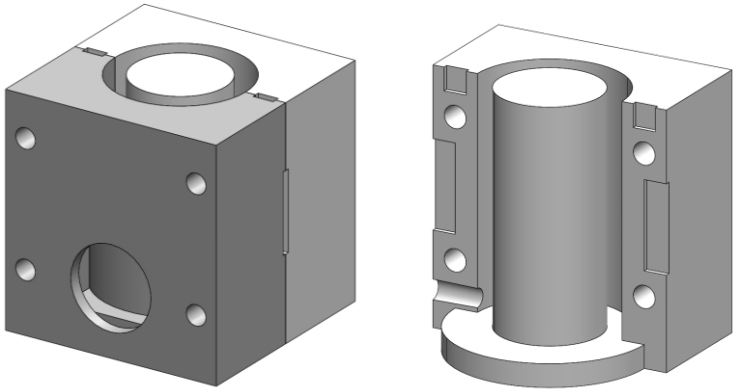


Figure 104: Renders of the vaginal cuff mold made in SolidWorks.

4. Vaginal cuff model creation

The models were created by mixing the silicon and pouring it into the mold. The mold was then placed in an oven at 100 °C for 10 minutes to allow the silicon to harden. After the mold had cooled, the model was taken from the mold and stored.

The created model is shown in Figure 105.

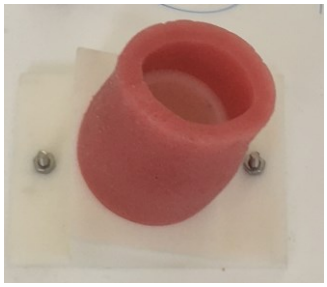


Figure 105: Silicon vaginal cuff model

5. Lapro-trainer holder for vaginal cuff models

To properly position the vaginal cuff models in the lapro-trainer for the user tests, a holder for the models was created. This holder, shown in Figure 106, can be fastened in the holes in the lapro trainer. The holder positions the vaginal cuff model at an angle of °, which was according to the consulting gynecologists a good approximation to the orientation of the vaginal cuff in reality.

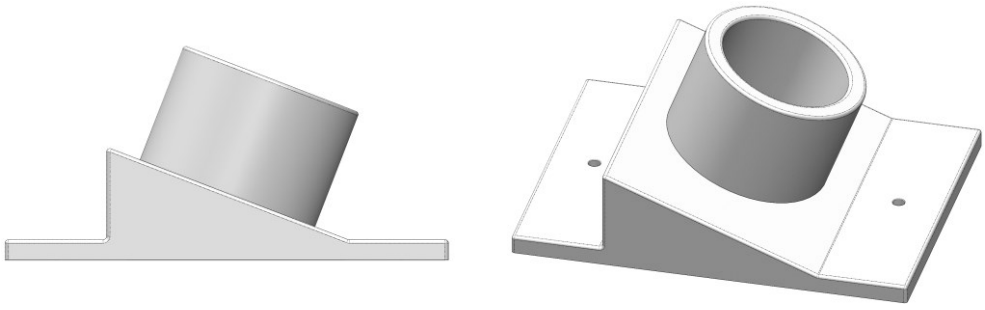


Figure 106: Renders of the vaginal cuff model holder from the SolidWorks file. Left – side view of vaginal cuff model holder. Right – isometric view of vaginal cuff model holder.

6. Sources

[1] 3-D med. (n.d.). *Vaginal Cuff 2" wet*. 3-dmed.com. Retrieved on August 3, 2020, from: https://www.3-dmed.com/product/vaginal-cuff-2-wet/

Appendix R: Evaluation of the vaginal cuff closure options

In order to get a good grasp on how the vagina cuff should be closed, several models of the vagina cuff were made. All models were then closed using different suture techniques. These models were then shown to Jim and Johann, who gave feedback on how to proceed.

1. The Models

Ten models were made. These models can be subdivided into 3 groups based on the fastening method: knots, clips or barbed suture. An overview of all the models can be found in Table 25 and Figure 107.

Table 25: Overview of the suture models and their fastening method

Fastening method	Model number	Suture technique
Knots	1.	Running regular suture
	4.	Interrupted regular suture
	6.	Running modified sewing machine suture type 1
	7.	Running modified sewing machine suture type 2
	10.	Interrupted sewing-suture
Clips	2.	Running suture
	5.	Interrupted suture
	8.	Running modified sewing machine suture type 1
	9.	Running modified sewing machine suture type 2
Barbed suture	3.	Running suture

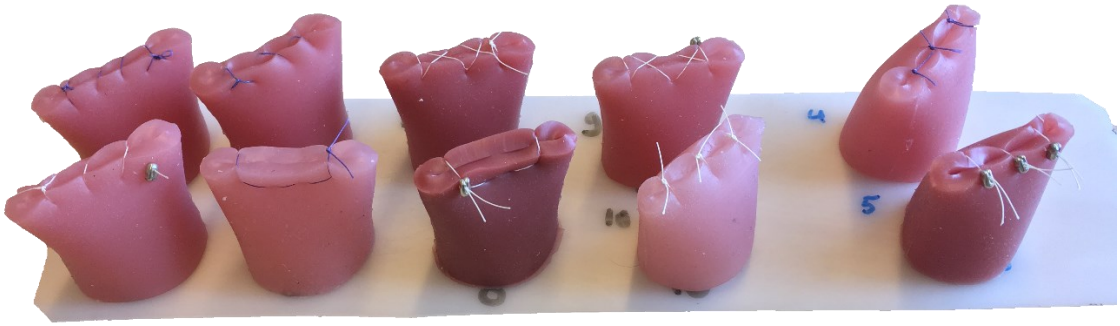


Figure 107: Models of the vaginal cuff with closed with different suture techniques and fastening methods

2. Sutures fastened with knots

Knotting is the standard, most common form of suture fastening. To fasten the suture, a surgical knot was used. This knot consists of a square knot and a reverse half knot with a half knot, as shown in Figure 108.

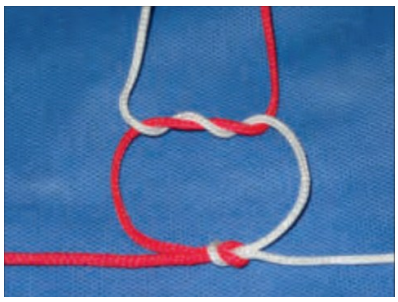


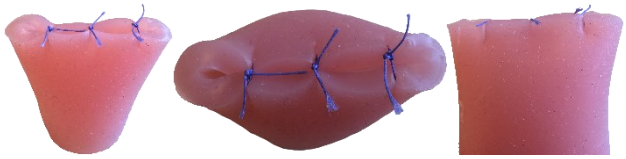
Figure 108: Surgical knot [1]

- Model 1

Characteristics:

- Suture technique: running suture
- Suture type: Vicryl 3-0 suture
- Fastening: 2 surgical knots

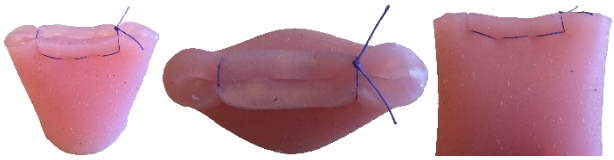
- Model 4



Characteristics:

- Suture technique: interrupted suture
- Suture type: Vicryl 3-0 suture
- Fastening: 3 surgical knots

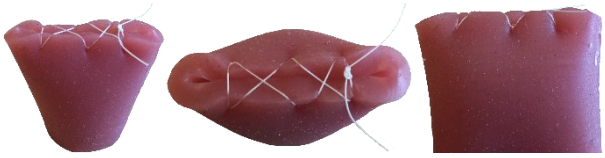
- Model 6



Characteristics:

- Suture technique: running modified sewing machine suture type 1
- Suture type: Vicryl 3-0 suture
- Fastening: 1 surgical knot

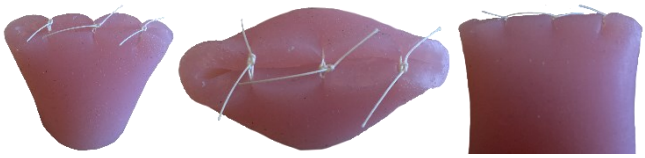
- Model 7



Characteristics:

- Suture technique: running modified sewing machine suture type 2
- Suture type: Vicryl 3-0 suture
- Fastening: 1 surgical knot

- Model 10



Characteristics:

- Suture technique: interrupted sewing-suture
- Suture type: Vicryl 3-0 suture
- Fastening: 3 surgical knots

3. Sutures fastened with clips

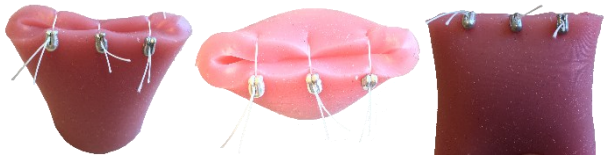
An easier, though more expensive, way to fasten suture is by using clips. For the models, clips available through DEAM were used: insoluble, metal clips that need to be clamped around the suture.

- Model 2

Characteristics:

- Suture technique: running suture
- Suture type: Vicryl 3-0 suture
- Fastening: 1 surgical knot, 1 metal clip

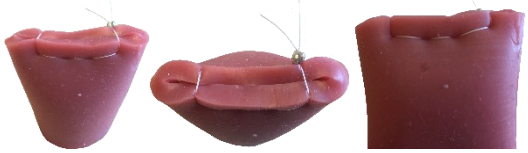
- Model 5



Characteristics:

- Suture technique: interrupted suture
- Suture type: Vicryl 3-0 suture
- Fastening: 3 metal clips

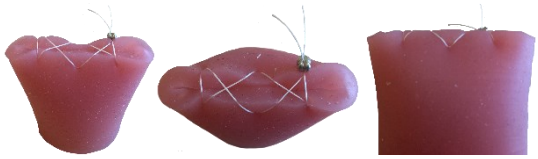
- Model 8



Characteristics:

- Suture technique: running modified sewing machine suture type 1
- Suture type: Vicryl 3-0 suture
- Fastening: 1 metal clip

- Model 9



Characteristics:

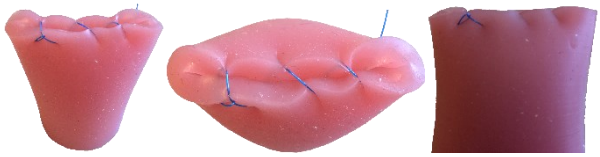
- Suture technique: running modified sewing machine suture type 2

- Suture type: Vicryl 3-0 suture
- Fastening: 1 metal clip

4. Sutures fastened with Barbed suture

Barbed suture contains tiny 'hooks' that grasp into the tissue, preventing the suture from loosening or shifting. This makes tying knots obsolete. Only one model was made using barbed suture since only the running suture is a suitable technique for using barbed suture.

- Model 3



Characteristics:

- Suture technique: running suture
- Suture type: Covidien V-loc 3-0 suture
- Fastening: loop, barbed suture

5. Comments consulting gynecologists

The comments of the consulting gynecologists are listed below, grouped per subject.

5.1. Needle size

It is no problem when the needle has a larger circumference than the suture as long as a round-tipped needle is used instead of a cutting needle when suturing muscle-tissue. A cutting needle cuts the tissue, creating an actual hole. A round-tipped needle 'pushes' the tissue apart, when the needle is removed, the tissue shrinks back around the suture. This makes leakage after suturing less likely.

5.2. Suture technique: interrupted suture

There is no reason to make interrupted sutures, this is only time-consuming.

5.3. Clips

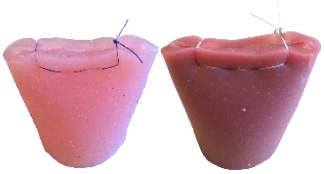
- Clips are the easiest solution for fastening suture since it is easy to retain the tension in the suture while applying the clip.
- Clips are expensive
- Knotting and barbed suture are good fastening methods too.

5.4. Suture technique: modified sewing machine suture

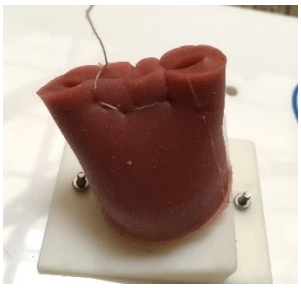
In General

- This suture technique makes it easy to distribute tension in the suture.
- Reinforce the end of the suture + give it a different color. That way it is easy to find, grasp and manipulate the suture through the loop. The end could also be converted into a small flat reinforcement.
- The instrument could help with creating knots because one of the most important parts is holding on to the suture.

Models 6 & 8



- These models are not possible since the edges aren't pushed together. The goal is for the edges to 'stick together' for the healing process to properly work. These models keep the edges parallel from each other, making proper healing very slow/impossible.
- The technique allows the user to distribute the tension in the suture after each stitch, ensuring that the vaginal cuff is uniformly closed
- The technique could work if the needle is not pushed straight through the vaginal cuff. The needle should be pushed under an angle upwards through one side and downwards through the second side, thus pulling the edges against each other. This results in the suture placement as shown on the model below.



This version looks very promising and allows for a quick closure of the vaginal cuff.

Models 7 & 9

- These models seem promising
- It is time consuming to keep moving the needle from one side of the vaginal cuff to the other.

6. Sources

[1] Liceaga, A. and Fernandes, L.F. and Romeo, A. (2013). *Romeo's Gladiator Rule: Knots, stitches and knot tying techniques.* Straub Druck + Medien AG.