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Design of the Bent On Site Steerable (BOSS) Clip Applier

Technische Universiteit Delft

Delft University of Technology

Challenge the future

Design of the Bent On Site Steerable (BOSS) Clip Applier

By

B.J.M. de Ruiter

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This thesis is confidential and cannot be made public until May 18, 2020.

Preface

From my childhood onwards I have a deep fascination for nature and everything around me. I find everything interesting and making a choice to follow a specific educational path was therefore difficult. I postponed the commitment of a specific path as long as possible and in the meantime, I tried to learn as much of everything as possible. There was however one constant, the drive to question everything, come up with new ideas and create something. When the time came to choose a study, the choice fell on mechanical engineering since I could still diverse in every direction if I wanted to. When I had to pick a master after my bachelor everything fell into place. In the master program of BioMechanical Design, I could combine most of my interests. Since nature intrigues me and has a head start of several million years of optimization and evolution, I have followed the Bio-Inspired Technology track. During this specialization I discovered that subjects such as surgical instruments, health technology and prosthetics are fascinating and offer a chance to satisfy my eagerness to make a difference and help people.

This project is the result of several years of gaining the knowledge and skill to give form to my countless ideas. This thesis describes the design of an instrument that can help surgeons to achieve faster and better results in minimally invasive operations by bypassing conventional sutures and clip appliers and is called: ” Design of the Bent On Site Steerable (BOSS) Clip applier”. This paper is the final submission for the degree of Master of Science in Mechanical Engineering at the Delft University of Technology.

First of all, I would like to thank Tim Horeman for the opportunity and freedom to do this project. I encountered you several times during my bachelor and in the beginning of my masters and it is no coincidence I came to you for my graduation project. You could always find time in your busy schedule to meet me and offered me the believe that I had something worth pursuing and gave me advice, guidance and confidence at the right moments. It is just a pleasure to work with you and I have learned many things from you, especially outside the context of my thesis. I would also like to thank Tomas Lenssen for all the sparring sessions, help when I got stuck and the talks about other projects that we did in our free time and Jenny Dankelman for her feedback during my literature research and thesis.

There are also people that left their imprint on me outside this project such as Jo Spronck and Stefan Lampaert for which I would like to thank them. I encountered you in fly by moments throughout my time at the university but mainly in the time that you supervised the successful journal publication I did with Laurens Krijgsman and Jelle Boots of my bachelor thesis during my graduation project in the journal “Tribology International, Volume 129, pages 46-54”. It was a great experience that I would not have missed. Jo, you excited me and gave me positive energy in every meeting and every moment were your criticism would normally burn someone to the ground. Stefan, I could appreciate your level-headed ness and seemingly endless confidence during the bachelor thesis and the publication that followed which fueled the drive to create something substantial and take away stress and keep everything fun at the same time.

Last but not least, I would like to thank everyone who supported me during my studies, my family and friends for their support during some challenging times and in particular Laurens Krijgsman and Bart Stolk. Bart, I met you at the first day of my masters and it was always a joy to work together, not only on study related matters, but also on other projects. I met Laurens in the bachelor by chance and since then we were inseparable and worked together as much as possible. I enjoyed studying together, but more over I enjoyed al the talks we had and projects such as the 3D-printer we designed and build in our leisure time. I wouldn’t mis it for the world and I hope that I get the opportunity to work with you guys in the future again.

I wish everyone a lot of reading pleasure!

B.J.M. de Ruiter

Delft, May 2020

Contents

Abstract

The shift from open surgery with one large incision to less invasive techniques with multiple small incisions brings benefits such as less trauma, less scar formation and a faster recovery for the patient. However, in minimally invasive surgery (MIS), surgeons struggle with basic tasks such as applying sutures and tying nots. Clip appliers have been developed to take away the need to apply sutures. From the literature research preceding this thesis and a state-of-the-art investigation, it turned out that current clip appliers do not combine simultaneous steerability and the ability to apply multiple clips. Reaching the surgical site can be difficult or impossible with conventional non-steerable clip appliers, and the reinsertion of a clip applier after every clip application is time consuming and can lead to damage to the instrumentation and patient. The goal of this thesis is to develop a reusable minimally invasive steerable clip applier that can bend clips at the surgical site to close ducts and cuts during laparoscopic procedures.

Design requirements and obstacle points are determined for the laparoscopic instrument components by taking the SATA mechanism as a starting point in the design process. Possible solutions to the obstacle points are gathered in a morphological chart that is used to come up with six distinct concepts.

A concept choice is made by experimentally finding the required torque to cut and bend a titanium clip and by verifying the ability of concepts to reach this torque by creating a simplified instrument tip on the same scale as the to be designed tip. The worst-case required torque to cut and bend a medium sized titanium clip of 0.5 by 0.8 mm turned out to be 0.6 Nm and 0.03 Nm respectively. During this experimentation it became clear that clips should be supported over the whole length and not just at the ends during the bending process to secure appropriate closing and compression. Several experiments are performed to find a cutting blade attachment that could transmit the worst-case cutting torque while remaining as bendable as possible.

The concept in which the clips are formed in the tip by cutting off a piece of titanium wire and then bent into a clip turned out to be the most promising because it has a theoretically unlimited number of clips at the implantation site without a cartridge, is sterilizable, relatively easy to fabricate due to its simplicity, and can be modified to produce clips with other dimensions. The concept is 3D printed on a 500% scale to verify functionality. This prototype showed that a revision of the actuation mechanism was required and that a few minor alterations could make the instrument easier to sterilize. 3D printing the new design on a 500% scale verified the functionality. The final functional prototype is also 3D printed at a 200% scale, which is the smallest scale that could be achieved with the available resources. The experiments showed that all the required actions could be performed and the prototypes showed that the mechanism functions as required. It is therefore achieved to design a Bend On Site Steerable (BOSS) clip applier that can make and bend clips in the tip from a continuous titanium wire. The instrument is easy to disassemble and sterilize due to the simple design and the small amount of parts. This simple design makes it also possible to make adjustments so that other sizes and shapes of clips can be made.

1 Introduction

1.1 Introduction to minimally invasive clip applying

The shift from open surgery with one large incision to less invasive techniques with multiple small incisions brings benefits. The patient experiences less trauma, less scar formation and a faster recovery. However, since the introduction of minimally invasive surgery (MIS), surgeons struggle with basic tasks such as applying sutures and tying nots. Minimally invasive surgery deprives the surgeon from a straight field of view and creates a distance between the hands of the surgeon and the surgical site (Figure 1).

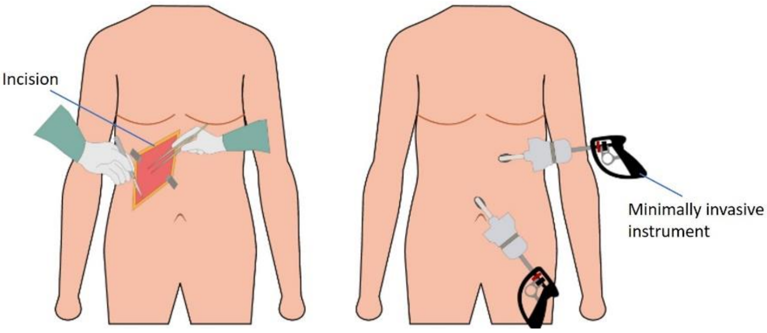


Figure 1: Shift from open towards minimal invasive surgery (MIS).

Operating with non-steerable instruments leads to scaling and mirroring of the surgeon's hand movement, a restricted workspace and loss of touch feedback and dexterity [1]. Therefore, making a suture with a long minimally invasive instrument often takes a relative long time and can lead to increased blood loss of the patient and prolonged operation times. Ergonomic inconveniences can cause fatigue, musculoskeletal disorders and irritation by the surgeon [2], leading to a decreased performance. Ergonomic inconveniences can therefore be harmful for both the patient and the surgeon.

Steerable minimally invasive instruments such as steerable graspers have been developed to facilitate operative tasks like suturing by overcoming the problems of small workspaces, low dexterity and poor maneuverability. Mainly in robotic surgery, steerable devices have shown their value. Although more than 17 steerable handhelds are entering the market of advanced laparoscopic surgery, not many of them are properly validated [3].

Nevertheless, placing sutures and tying knots remains a complex, difficult and time-consuming procedure due to the loss of tactile feedback when working with minimally invasive instruments. Endoscopic clip appliers have been developed to diminish the need for sutures as they can apply clips to areas that need to be closed such as the gallbladder, appendix or veins. The main benefits of endoscopic clip appliers compared to traditional suturing are the ease of use, closure time reduction [4], higher leak pressures and comparable or even better wound healing as they can preserve luminal endothelial lining, decrease fibrin deposition, and preserve luminal morphology [5]–[7].

1.2 State-of-the-art in clip appliers

In general, laparoscopic instruments consist of a handle, a shaft and an end effector with a possible steerable section incorporated throughout the shaft or between the shaft and the end effector (Figure 2).

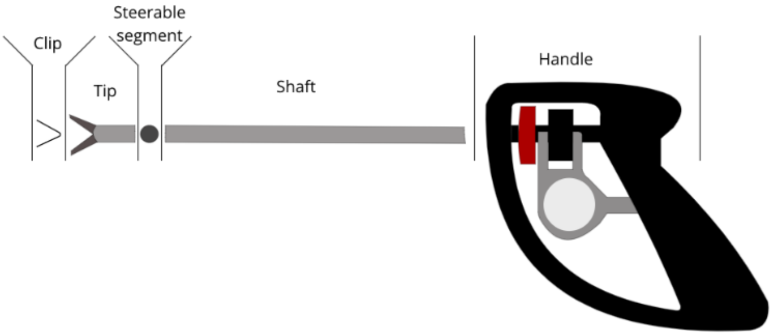


Figure 2: Standard buildup of laparoscopic steerable instruments.

Most developed clip appliers are straight, rigid and therefore non-steerable, allowing only a straight approach of the surgical site. This makes it nearly impossible to apply clips comfortably in any other orientation than straight ahead of the instrument's insertion point. Figure 3 shows inconveniences of rigid non-steerable instruments such as patient deformation and collision of the instruments or trocars when the instruments have to reach a surgical site not straight ahead of the instrument's point of insertion.

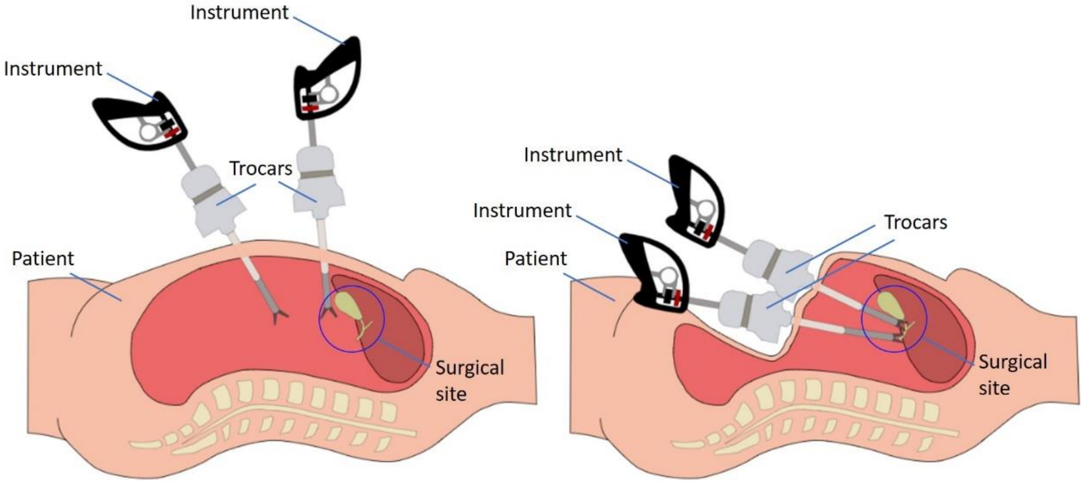


Figure 3: Inconveniences encountered with rigid non-steerable instruments such as collision and patient deformation.

Clip appliers must be steerable to comfortably align the tip of the instrument with the tissue and apply clips in any orientation (Figure 4).

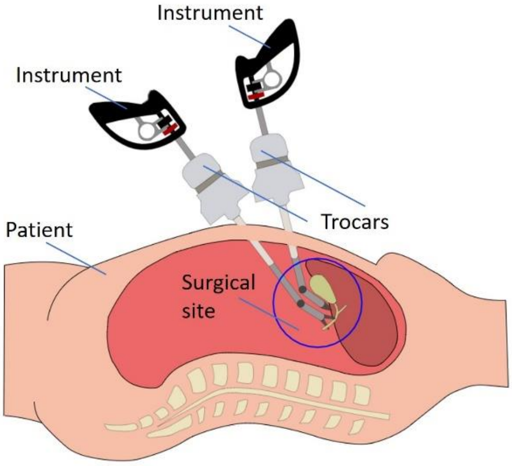


Figure 4: Easier orientation and alignment with steerable instrument.

Preceding this thesis, a literature review was performed, using the web of science database, regarding functionality tested steerable instruments developed in the past decade. This literature review retrieved 69 distinct steerable instruments among which the Shaft Actuation Tip Articulation (SATA) mechanism (developed by Surge-On Medical). This SATA mechanism can perform a steering action by means of an actuation by tubes, allowing the instrument to articulate while remaining stiff. It can handle relatively high forces and is fully sterilizable [8]. The SATA mechanism consists of multiple tubes with a relatively large open inner lumen that can be used to transport the materials required to form the clips (Figure 5).

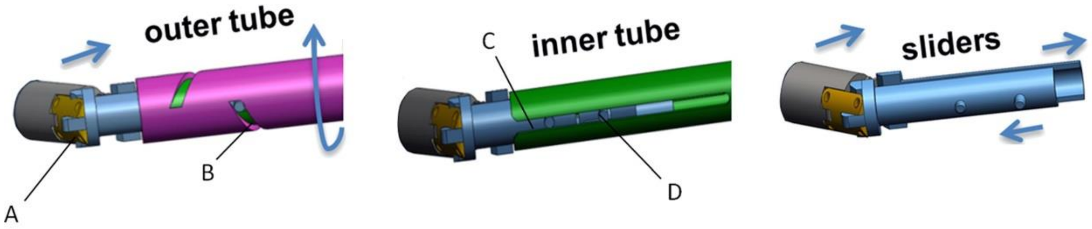


Figure 5: Working mechanism of the SATA principle, retrieved from [8].

Clip appliers that can apply one clip at a time have to be extracted from the patient to insert a new clip in the instrument's jaws before it can be reinserted. Removing and reinserting a device brings risks of infection and damage to the patient. The instrument can also get damaged or can damage other instruments. The reinserted instrument must be maneuvered back to the surgical site which is often a difficult, tedious and time-consuming procedure.

With cartridges, clips can be applied without removing the instrument from the patient to insert a new clip in the jaws after each clip application. Therefore, non-steerable clip appliers can harbor a cartridge with clips, which is often located within the shaft of the instrument [9]–[15], to overcome reinsertion problems. Steerable clip appliers do not have cartridges due to restricted space and feed through difficulties [16]–[19]. However, clip appliers do exist with a cartridge and a flexible shaft [20] or with a cartridge at the distal side of the steerable mechanism [21], [22]. Flexible non-steerable clip appliers cannot be actively maneuvered to the correct application site. Clip appliers with the cartridge at the distal side of the steering mechanism, do not have the problem of clip feed through or restricted space, because the whole rigid cartridge mechanism is simply moved to the distal side of an articulating hinge. This does not really solve the exclusion between a steerable device or one with a cartridge. Instead, it creates a bulky and difficult to steer instrument because all the clips are located between the jaws and the hinge (Figure 6).

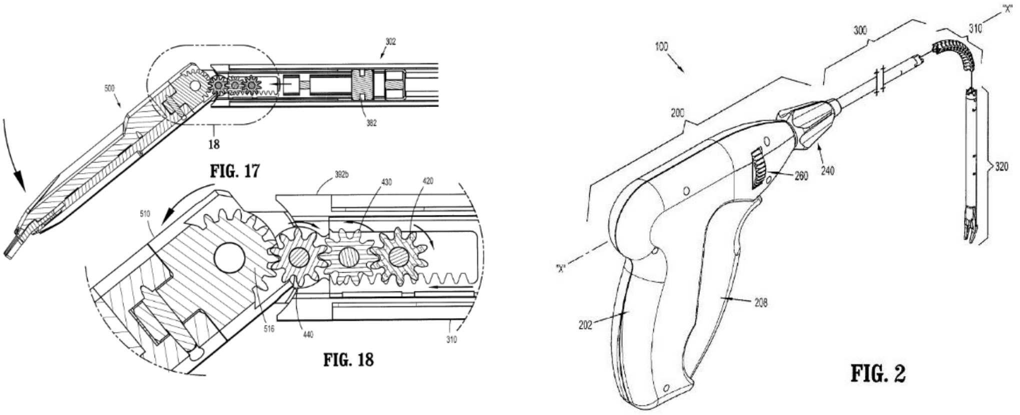


Figure 6: Left: drawing of the device as presented in [21]*, Right: drawing of device as presented in [22]*

The benefit of a device that can be easily steered to apply clips in any direction and orientation brings therefore the downside of losing the benefits of a cartridge and this trade-in is not desired.

Cartridges contain a certain number of clips that is almost never the amount that is needed and clip appliers with a cartridge are often not reusable due to the hard to clean cartridge system. Clip appliers with excess clips after the surgery are thrown away and a new clip applier must be opened if the cartridge gets empty during the surgery, resulting in high operation costs. Cholecystectomy, for example, is more and more performed in a laparoscopic manner and extensive use is made of clip appliers in these procedures. The cost per laparoscopic cholecystectomy procedure of a disposable set of instruments can be up to 19 times higher than the cost per procedure of a reusable set of instruments [23],[24]. The price of a reusable instrument is generally higher than the price of a disposable one as a reusable one can be used for a certain number of operations. The price per operation will therefore be lower compared to a disposable one. This, however, means that a reusable instrument must survive a certain amount of procedures without breaking down and must be fully sterilizable between operations to prevent infection of patients.

It is most likely that making an instrument reusable can have major economic and environmental advantages and can make it more attractive for a hospital to use it compared to a disposable instrument [25]. If a device is reusable, most of the time it does not contain a cartridge since the system behind these cartridges is so complicated that sterilization is not possible.

1.3 Problem definition

A steerable, sterilizable, intuitively to use and cheap clip applier with sufficient number of clips is the ideal. However, such an instrument is not developed in literature nor patents yet. There are no clip appliers that can solve all the problems of a limited workspace, poor clip alignment and excessive time needed to apply a clip. A good designed clip applier should overcome those problems and minimize the risk of infecting the patient, improve the workflow and reduce the cost per operation. To try to fill this gap, the first point of action is to find a better alternative for the above-mentioned cartridges suited for a steerable reusable clip applier since they can cause the instrument to become bulky, disposable and non-steerable.

1.4 Research goal

To develop a reusable minimally invasive instrument that can be steered and can apply the required number of clips once inserted, a device will be designed that uses the SATA mechanism and can form surgical clips at the surgical site before application. By forming the clips at the surgical site when they are needed, the instrument does not have to be retracted from the patient and there is always a clip at hand to use, reducing the infection and damage risk and time needed to close a duct or cut. The simplicity of the SATA mechanism will benefit the design. A device with the above-mentioned capabilities will lower the threshold of using it and will lead to higher quality clip placement, shorter operation times, easier instrument handling and lower operational costs. The goal of this thesis is therefore to develop a reusable minimally invasive Bend On Site Steerable clip applier, or in short BOSS clip applier. A schematic representation of a procedure with such a device can be seen below in Figure 7.

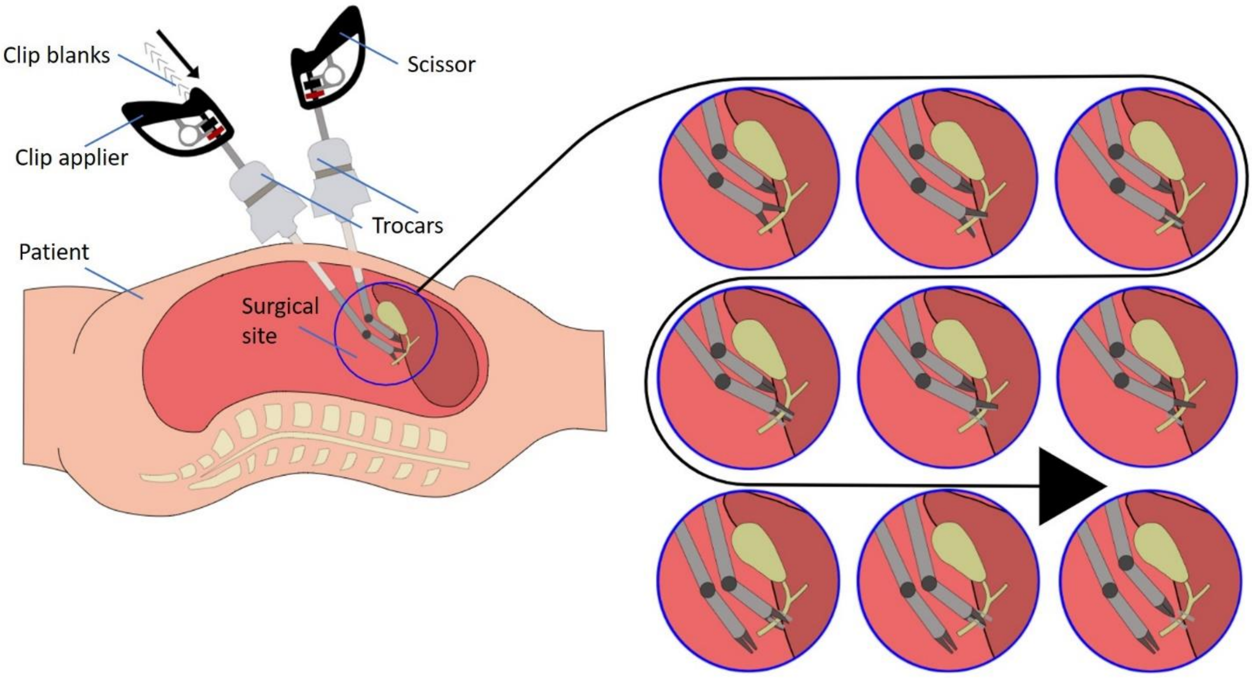


Figure 7: Schematic representation of a surgical procedure with a device that can steer and has sufficient clip blanks.

1.5 Thesis layout

This report has the following structure to guide the design process. First, requirements are gathered in chapter 2 by looking at what each specific part of the instrument must be able to do. Once it is clear what the device must be able to do, obstacle points that will be encountered during the use of the instrument are formulated. All the possible solution to these obstacle points are gathered in a morphological chart. From this morphological chart concepts are formulated and presented in chapter 3. Key factors of the to be designed instrument and specific aspects of these concepts are tested experimentally in chapter 4 to get sufficient information to evaluate the concepts in chapter 5 and pick the most promising one. The most promising concept is worked out completely in chapter 6 and a first prototype is made to check for functionality, manufacturability and possible design improvements. With the issues obtained in chapter 6, the instrument is redesigned in chapter 7 to come to a final design. This final design is evaluated by linking the information from the calculations and experiments obtained in chapter 4 to the final design. The whole design process is discussed in chapter 8 and is concluded in chapter 9. Finally, recommendations for future work are given in chapter 10.

2 Design requirements

2.1 Instrument components

In developing a steerable clip applier that can bend the clips on site or in short, a Bend On Site Steerable (BOSS) clip applier many obstacles will have to be resolved. There are a couple of main challenges that have to be overcome. One must find a way of guiding the clip material -that is to be bend- through the instrument and get it in the place where it will be formed in the eventual clip. Then the material must be formed into a clip and positioned in the right orientation so that it can be clipped. Finally, the device must close the formed clip in a suitable way. This all must be done in a safe and reliable manner. To create an instrument that has the desired functions and capabilities, it must fulfill a set of requirements.

The reusable BOSS clip applier that will be developed, consists out of a few major components, which can be seen in Figure 2 above. Steerable clip appliers consist from the distal to the proximal end of the device of a clip, tip, steerable segment, shaft and handle, with the clips, or clip blanks, possibly passing all these components. The handle allows the surgeon to control the instrument. The shaft forms the connection between the part of the instrument outside and inside the patient. A steerable segment connects the shaft to the tip, but in some instruments the shaft and steerable segment are integrated and form one steerable section. The tip is the part of the instrument that can perform a certain task, specific to that instrument, such as being able to handle and apply a clip in the case of a clip applier. Each component has separate design specifications and requirements. Below, the requirements for each part of the instrument will be discussed first and then listed in order from the distal to the proximal end of the instrument. Finally, there will be a group of requirements that are not specific to a certain component, but concern multiple components or the whole device.

2.1.1 Clip requirements

To form the clips at the surgical site, the clip material has to be transported to the instruments tip. Since the device is to be minimally invasive the dimensions and space available to enable this transportation of clip material will be small and the wanted steerability of the device will complicate this transportation even further. Nowadays, most surgical procedures are done with U or V shaped clips made from titanium wire. Although there are many different sized and shaped clips available, the standardized and commercially available medium size V shaped titanium clips of approximately 7 mm are used to design this instrument because they are the simplest and most commonly used. Unfolded, these clips will have a length of 14 mm, a width of 0.8 mm and a thickness of 0.5 mm. The large size V shaped clips are commonly used in instruments with a larger diameter and the small size clips could be considered as not representative for the ought diameter of the instrument. The medium size V shaped clips are therefore a good starting point for a new instrument. The clip has to be as simple as possible, meaning that is must have a simple shape and as few components as possible. Then the focus of the design can lie on getting a functional instrument without the clip unnecessarily complicating matters. In summary, the clip requirements are:

- Clip must be as simple as possible by having a simple shape and minimal number of components.
- Clip material must be supplied to the tip through the instrument
- Instrument must be able to apply V shaped titanium clips of 7 mm

2.1.2 Tip requirements

The tip at the distal end of the instrument is the part that eventually compresses the clips onto the tissue. Therefore, the tip must be able to harbor a clip and must apply enough force to clamp and compress the clip. To get the clip inside the tip, without retracting the instrument from the patient and inserting the clip from the outside, the clip material must enter the tip from the proximal instrument end. The tip must be as short and nimble as possible to improve maneuverability for the surgeon as the tip is the part between the steerable segment and the tissue of the patient. The surgeon must also be able to see if there is a clip in the tip and where and in what orientation the tip is at all times. In summary, the tip requirements are:

- Complete tip must be as short as possible to improve steerability and consequently accuracy
- Tip orientation must be trackable and distinguishable with a standard endoscope, making the process visually inspectable

2.1.3 Steerability requirements

A steerable instrument is defined in this thesis as an instrument that has one or multiple articulating joints or can follow a curved path. This means that the to be developed instrument must at least have one articulating joint that can actively be controlled. Making the instrument steerable will majorly improve the usability of the device. Not only does the reachable space become larger, but also the ability to approach an application site from another direction will improve the instruments usability and the surgeon's performance, leading to a better surgical result. Normal straight instruments have four spatial Degrees of Freedom (DoF) around the point of insertion. The reduction of 6 DoF (free movement in 3D space with a rigid instrument) to 4 DoF (movement of rigid instrument restricted by the point of insertion) hinders the surgeons in their range of motion (Figure 8).

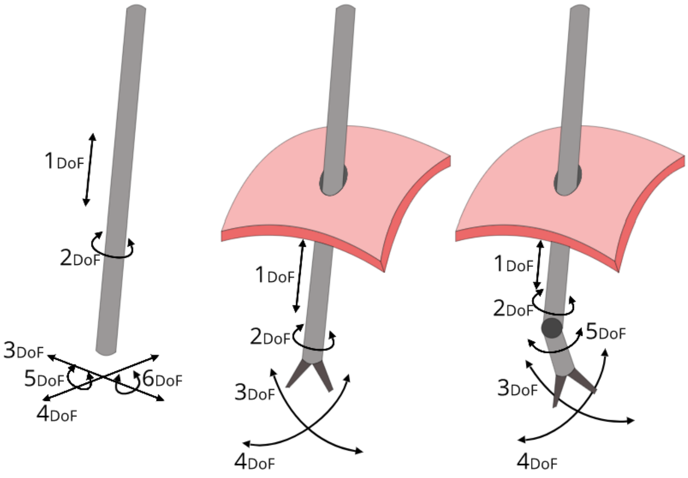


Figure 8: Degrees of Freedom for different situation.

Steerable instruments require at least one extra DoF compared to straight rigid instruments to improve the instrument's range of motion and increase the workspace of the surgeon. Steerable instruments need a section that facilitates additional shaft articulation and axial tip rotation to increase the number of DoF. According to the definition of a steerable instrument, the BOSS clip applier must have at least one articulating joint or can follow a curved path to be called steerable. To keep the start of this design process as simple as possible, only one degree of freedom (DoF) or one articulating joint will be incorporated. The addition of this single DoF will increase the reach of the tool and allows for tip orientation. The SATA mechanism will be used and acts as the steerable segment. It has one articulating joint with a maximum bending angle of around 60°. This high bending angle is one of the main reasons to use the SATA mechanism along with its ability to deliver and withstand high forces. The mechanism showed in mechanical strength tests that it does not get damaged by pressing it three times with a force of 100N or a tangential load of 20N [8]. In summary, the steerability requirements are:

- Instrument must articulate in at least 1 DOF
- Instrument must bend, hold the bend and withstand perturbations
- Instrument can make a bend of minimally 60°

2.1.4 Shaft requirements

The shaft is a relatively simple part of the instrument that connects the steerable segment to the handle. Ideally, the foreseen minimally invasive instrument can be used with standard trocars. There are different sizes of trocars and the larger the trocar, the larger the required incision. To keep the shaft diameter as low as possible while allowing a little bit of designing space, the choice is made to design an instrument that can work in a trocar for 8 mm instruments since the commonly used and commercially available clip appliers with a cartridge range from 5 to 12 mm [26]–[29]. This also means that the steering section and tip are connected to a maximally 8 mm large shaft. This shaft should have an inner lumen to provide a space large enough to feed through the material used to form the clips and guide the driving mechanism that opens and closes the jaws of the tip. We chose to work with the SATA mechanism as it allows for the use of a lumen with a large diameter. In summary, the shaft requirements are:

- Instrument must be inserted through a trocar not larger than 8 mm
- Instrument must be able to transport clip material and harbor driving mechanism inside the shaft

2.1.5 Handle requirements

The handle is the part that the surgeon holds and can use to manipulate the instrument. The handle must provide the opportunity to control the instrument with one hand so that the other hand can be used to control another instrument to manipulate the surgical site. The surgeon must be able to feed through, load and fire a clip by solely operating the handle. Further requirements concern the ergonomics of the handle to make sure that it is comfortable to hold and intuitive and simple to use, meaning as minimal action required as possible. The main focus of this thesis will be on designing the part of the instrument that is located inside the patient during the operation. Therefore, there will not be looked into the design and ergonomics of the handle. Nevertheless, the handle functions and bare minimum requirements are kept in mind to provide the simplest and best possible options of actuation. In summary, the handle requirements are:

- The device must require no more than daily hand force to operate
- The instrument must require as few actions as possible to fire a clip
- The insertion, movement and rotation of the instrument and firing of the clip must be able to do with one hand
- The device must be ergonomically to operate

2.1.6 Reusability requirements

Reusability is a requirement that is highly desirable for any instrument [23]–[25], [30], [31] and that has a significant imprint on the design of a steerable reusable clip applier. To sterilize an instrument every part or group of parts has to be cleanable. To achieve this, all surfaces have to be accessible to scrub or flush them and all parts have to be able to withstand the high temperatures and/or other circumstances encountered in sterilization processes. Reusability is important because the costs per procedure are most likely lower compared to single-use instruments. Moreover, less medical waste is produced making it more sustainable [3]. This is another motivation why the SATA mechanism is chosen as a basis, since this mechanism is designed to be sterilizable. To make sure the overall instrument ends up being reusable, not only the SATA mechanism must be sterilizable. Every component or group of components of the instrument must be cleanable and sterilizable. There should be no hidden spaces that cannot be reached during the cleaning. Therefore, it is desirable that the instrument can be effortlessly disassembled before cleaning and sterilization and easily reassembled afterwards. This way all the surfaces and spaces are accessible while keeping the effort and with that the costs of cleaning the device to a minimum. In summary, the reusability requirements are:

- Instrument must withstand sterilization processes
- The products life span should be as long as possible
- The device must be robust enough to be handled, disassembled and transported to and from the sterilization
- The device must have a finish that is compatible with sterilization processes
- The used materials must withstand sterilization processes
- The focus must lie on a sustainable design with minimal maintenance
- The instrument must function for a certain number of times as a reusable instrument

2.1.7 Non-component specific requirements

Finally, there are several requirements that the instrument will have to fulfil, but that cannot be appointment to one specific or any instrument part. The purpose of a clip applier is to apply a clip to an area that has to be sealed and this sealing has to be reliable. To achieve reliable sealing, the clip has to be closed completely and the tip must be able to compress the clip with excessive force without dislocating or misaligning the clip. The formation, alignment and compression of the clip must be able to be stopped by the surgeon if necessary, to adjust something or abort the clip application. Further should the device not be dependent on, or hindered by factors of the environment to perform these tasks. Finally, it is important that the device can be manufactured and that the device itself and the used materials are safe for the patient and surgeon. In summary, the non-component specific requirements are:

- Instrument must apply reliable sealing
    - close clip completely
    - provide excessive compression force
    - Proper alignment
- The device must be able to be stopped at certain intervals
- All movements should be mechanically actuated without the use of external factors or forces
- Instrument must function under influence of bodily fluids
    - Fluids may not cause to much friction
    - Fluids may not cause heat generation
    - Fluids may not cause visual obstruction
- The instrument must be able to be manufactured by standard instrument makers, meaning that it should be able to be made by people with an education for high precision small mechanics fabrication with standard high precision manufacturing machines
- Instrument and used materials must be biocompatible
- The instrument must be safe for patient without any sharp edges or attachments
- The instrument must be safe for surgeon without any sharp edges or attachments

2.2 Requirements summery

Now that is established which requirements the parts of the instrument and the overall instrument will have to fulfill, a complete list with all the requirements can be put together. This list is composed using among others the Pugh's checklist and can be found below.

Performance
- Clip must be as simple as possible
- Clip material must be supplied to the tip through the instrument
- Instrument must be able to transport clip material and harbor driving mechanism inside the shaft
- Complete tip must be as short as possible to improve steerability and consequently accuracy
- Instrument must articulate in at least 1 DOF
- Instrument must bend, hold the bend and withstand perturbations
- Instrument can make a bend of minimally 50°
- Instrument must apply reliable sealing
    - close clip completely
    - provide excessive compression force
    - Proper alignment
- Tip orientation must be trackable and distinguishable with a standard endoscope, making the process visually inspectable
- Instrument must be able to apply V shaped titanium clips of 7 mm

Environment
- Instrument must be inserted through a trocar not larger than 8 mm
- Instrument must be biocompatible
- Instrument must function under influence of bodily fluids
    - Fluids may not cause to much friction
    - Fluids may not cause heat generation
    - Fluids may not cause visual obstruction
- Instrument must withstand sterilization processes

Life in service
- The products life span should be as long as possible

Transportation
- The device must be robust enough to be handled, disassembled and transported to and from the sterilization

Manufacturing facilities
- The instrument must be able to be manufactured by standard instrument makers, meaning that it should be able to be made by people with an education for high precision small mechanics fabrication with standard high precision manufacturing machines

Aesthetic appearance and finish
- The device must have a finish that is compatible with sterilization processes

Materials
- The used materials must be biocompatible.
- The used materials must withstand sterilization processes

Product life span
- The focus must lie on a sustainable design with minimal maintenance
- The instrument must function for a certain number of times as a reusable instrument

Ergonomics
- The device must require no more than daily hand force to operate
- The instrument must require as few actions as possible to fire a clip
- The insertion, movement and rotation of the instrument and firing of the clip must be able to do with one hand
- The device must be ergonomically to operate

Quality and reliability
- All movements should be mechanically actuated without the use of external factors or forces

Safety
- The device must be able to be stopped at certain intervals
- The instrument must be safe for patient without any sharp edges or attachments
- The instrument must be safe for surgeon without any sharp edges or attachments

If the requirements above are fore filled an instrument will be developed that can perform the key tasks. It can guide the clip blanks through the steerable section to the place where they will be bend. These clip blanks will be formed into clips and positioned in the right orientation so that they can be clipped. Finally, the device is able to close the formed clips and compress them, all in a safe and reliable manner.

3 Conceptual design

3.1 Solutions to obstacle points

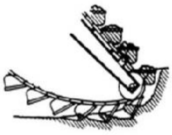
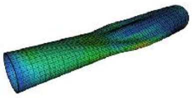
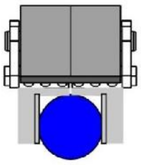
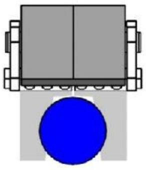
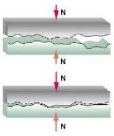
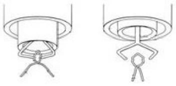
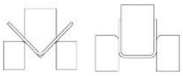
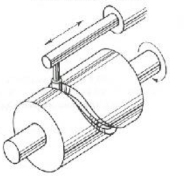
Now that all the requirements are clearly presented, the obstacle points that are encountered during the in use taking and regular use of the instrument are presented below in chronological order. The main obstacle points are indicated with a dash and sub problems are subsequently presented with an empty circle. A set of possible solutions for every obstacle point is given and indicated with a dot. This set of possible solutions for every obstacle point is iteratively compiled and presented below.

- Smoothly get clip material through instrument without getting it stuck
    - Get clip material into and out of instrument
        - Preloaded cartridge
        - Loadable cartridge
        - No cartridge and continuous wire cut at site
        - String with attached pieces of wire
    - Get clip material through bending section and into tip
        - Nitinol tube inner lining
        - Coil spring inner lining
        - Plastic tube inner lining
        - Continuous wire cut at site
- Single out one clip blank and hold the others in place
    - Lever mechanism
    - Valve
    - Close off passage by bending
    - Continuous wire cut at site
    - Push through
- Hold the clip material in the jaws without letting it fall out
    - Friction
    - Shape lock
    - Extra grippers
    - Hook
    - One-way lock
- Initiate clip bending
    - Retractable wedge
    - Already bent
    - bending jaws
    - Retractable hook
    - Rotating cam
- Compress clip
    - Jaw bending
    - Overtube
    - Retractable jaws
    - Sliding wedge
- Release clip without opening
    - Slide
    - Extra space
    - Gripper release
    - One-way lock
    - Friction release

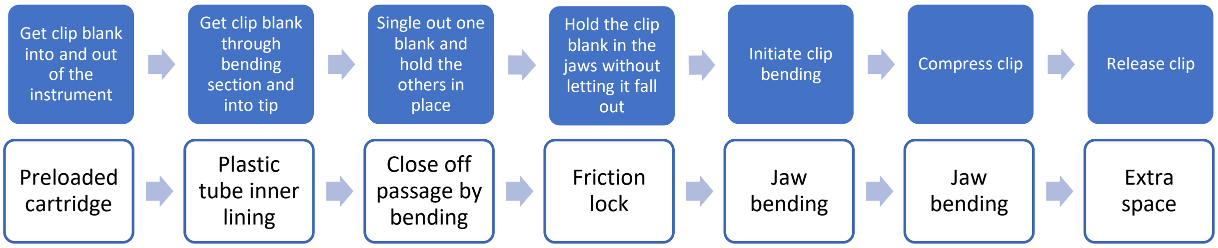
The solutions presented above are gathered in a morphological chart along with a set of possible clip shapes that can be seen in Tabel 1 on the next page. These possible solutions must be tested against a set of boundary conditions to see if they are valuable solutions. This set of boundary conditions consists of the requirements and wishes presented in the chapter of Design requirements.

Using this morphological chart, six concepts are formulated. These concepts are worked out to the point that it becomes clear if the concept is promising or not. In the next section, the concepts are discussed and their working principles is explained and showed through a visual step guide. A workflow chart mentioning the obstacle points, as used to construct the morphological chart, and the for that concept used solutions will be shown in the blue and white boxes respectively. This way a visual overview is made to see which solutions are used and in what order they will be encountered.

Tabel 1: Morphological chart.

		Solutions				
		1	2	3	4	5
Obstacle points	Get clip material into and out of	Preloaded cartridge 	Loadable cartridge 	Continuous wire cut at site 	String with attached pieces of wire 	
	Get clip material through bending section and into tip	Nitinol tube inner lining 	Coil spring inner lining 	Plastic tube inner lining 	Continuous wire cut at site 	
	Single out one clip blank and hold the others in place	Lever mechanism 	Valve 	Close off passage by bending 	Continuous wire cut at site 	Push through 
	Hold the clip blank in the jaws without letting it fall out	Friction 	Shape lock 	Extra grippers 	Hook 	One-way lock 
	Release clip without opening	Friction release Slide 	Extra space	Gripper release 	Hook 	
	Initiate clip bending	Retractable wedge 	Already bent 	Shape lock in bending jaws 	Retractable hook 	Rotating cam 
	Compress clip	Jaw bending with multi hinge, single hinge or no hinge (compliant, monolithic) 	Overtube 	Retractable jaws 	Sliding wedge 	
	Type of clip	Triangle 	Chevron 	Double shank 	Already bent clip 	

3.2 Concept 1



The first step in the flowchart is the way the clip blank gets into and out of the instrument. To solve this first obstacle point, a preloaded cartridge is chosen in concept 1 to get the clip blanks into the instrument. To prevent the clip blanks from getting stuck and get them through the bending section and into the tip, a plastic tube inner lining is used. After one clip blank is loaded, the rest of the clip blanks are held in place by bending the articulating joint of the instrument so that the passage is closed.

The initial idea was to hold the loaded clip blank in the tip by means of a shape lock. Although the shape lock could allow the transporting wire to pass while placing a clip in the jaws (Figure 9), the shape lock at the end of the jaws is around the wire, causing the two parts of the clip not to become in contact with each other. On top of that, the clip should be moved out of the shape lock to remove it after compression. This is not desirable because visibility is low and some of the to be clipped tissues are delicate and will be compliant to the pushing force, leaving the clip in the shape lock.

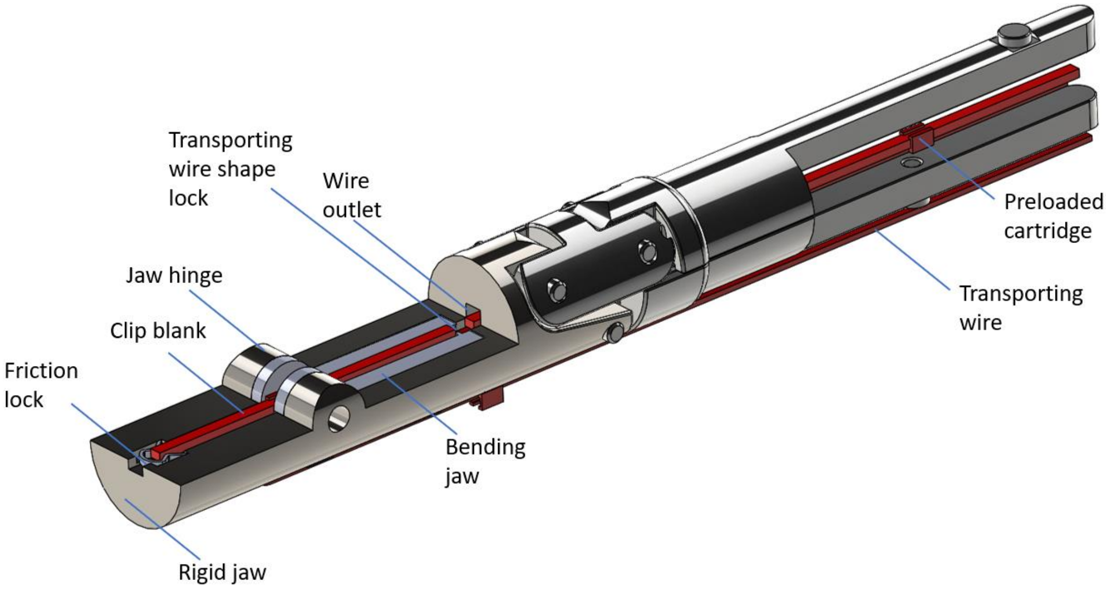
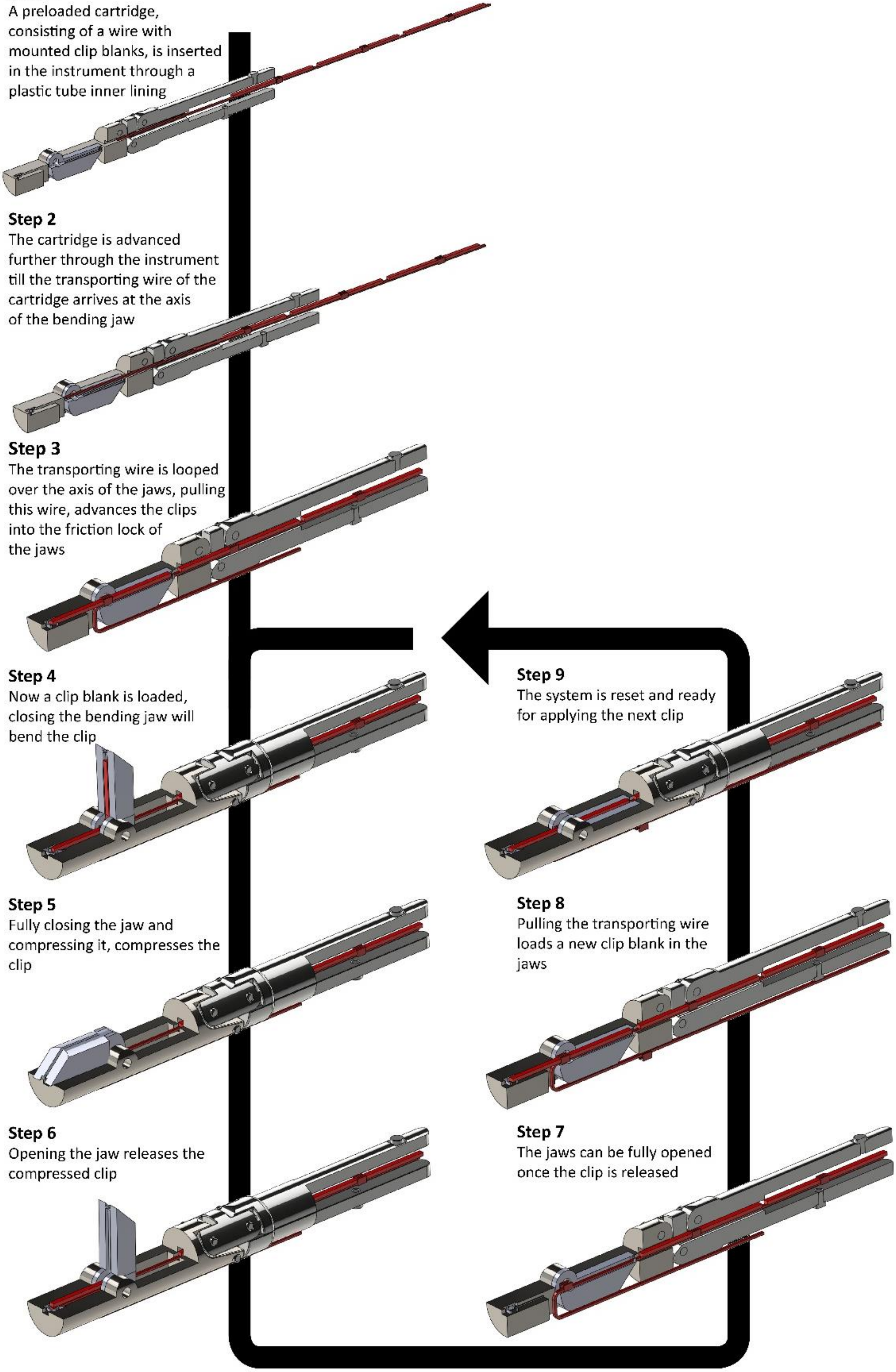


Figure 9: Schematic representation of concept 1.

Therefore, a friction lock is designed, instead of a shape lock, that will exert just enough force to hold the wire in place during the bending process. Once the clip blank is in the friction lock, the uncompressed clip can still be maneuvered to its application site. Once in the right orientation, the clip can be fully bent and compressed by closing the jaws. Finally, the clip can be released by letting the compressed clip enter extra space in the jaws and opening the jaws.

This first concept makes use of a preloaded cartridge which consists of a wire with mounted clip blanks at equal intervals as can be seen in Figure 9 above and Figure 10 on the next page. This cartridge gets inserted in the instrument and a plastic tube inner lining makes sure that the clip blanks do not get stuck inside. This plastic tube inner lining provides at the same time a way for closing of the passage when the instrument is steered so that no more clip blanks can get out. To load a clip blank into the jaws, the string to which the clip blanks are mounted is pulled over an axle so that the clip blank proceeds forward into a spring that works as a friction lock to hold the clip blank in place as can be seen in Figure 10. Pulling the transporting wire a bit further causes the clip blank to be located in the lock and peel off from the transporting wire. At this point one clip blank is loaded in the jaws and the clip can be folded through bending the jaw by pulling the jaw actuation cable incorporated in the jaw hinge. By fully bending the jaw and compressing it, the clip gets compressed. To release the clip at this point, the jaws of the instrument must be opened. Now the instrument must be straightened again so that the transporting wire can be pulled and a new clip blank can be loaded in the jaws.



Step 1
A preloaded cartridge, consisting of a wire with mounted clip blanks, is inserted in the instrument through a plastic tube inner lining

Step 2
The cartridge is advanced further through the instrument till the transporting wire of the cartridge arrives at the axis of the bending jaw

Step 3
The transporting wire is looped over the axis of the jaws, pulling this wire, advances the clips into the friction lock of the jaws

Step 4
Now a clip blank is loaded, closing the bending jaw will bend the clip

Step 5
Fully closing the jaw and compressing it, compresses the clip

Step 6
Opening the jaw releases the compressed clip

Step 7
The jaws can be fully opened once the clip is released

Step 8
Pulling the transporting wire loads a new clip blank in the jaws

Step 9
The system is reset and ready for applying the next clip

Figure 10: Schematic representation of the working principle of concept 1.

3.3 Concept 2

Get clip blank into and out of the instrument	Get clip blank through bending section and into tip	Single out one blank and hold the others in place	Hold the clip blank in the jaws without letting it fall out	Initiate clip bending	Compress clip	Release clip
Preloaded cartridge	Coil spring inner lining	Cartridge placement	Friction lock	Retractable hook	Bending jaws	Friction release

In this concept, a preloaded cartridge is used in which the clip blanks are firmly secured to a carrier to get the clip blanks into and out of the instrument. The clip blanks are guided with a coil spring inner lining through the bending section to solve the obstacle point of getting the clip blank through the bending section and into the tip. Since the clip blanks are secured to the cartridge carrier, singling out one blank can be done by careful feed through and placement of the cartridge carrier. After one blank is proceeded into the tip, this blank is held in place by means of friction. This secure holding is required so that retraction of the transporting wire (hook) will initiate clip bending. After correct orientation of the clip in the body, full clip compression is achieved by full jaw closure. To release the clip, the jaws are opened and the friction holding is released.

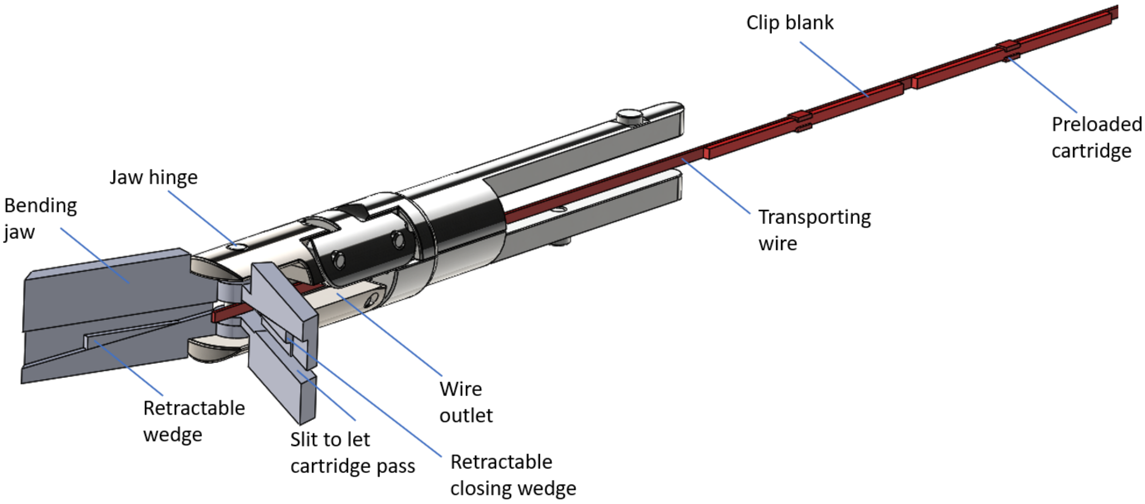
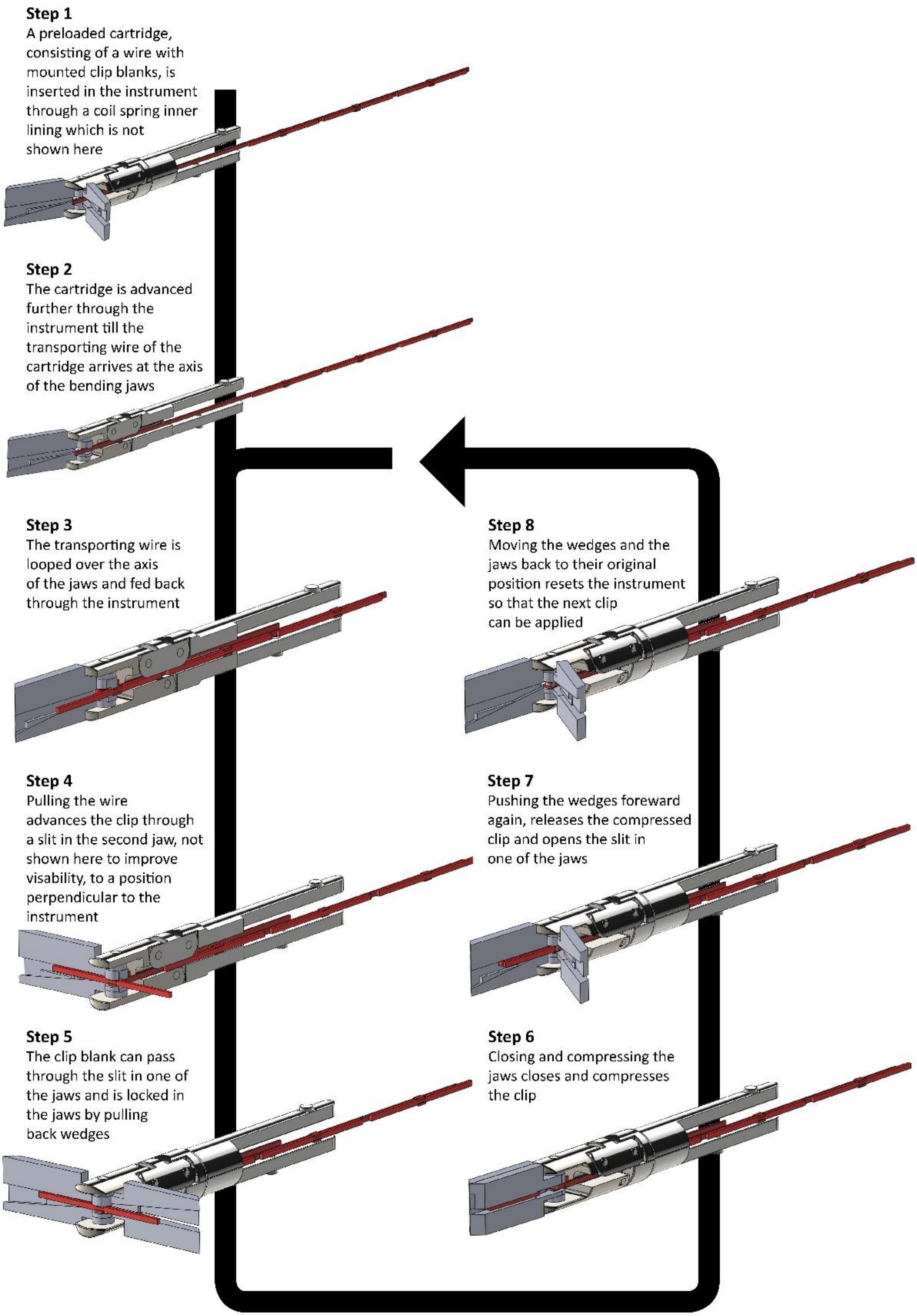


Figure 11: Schematic representation of concept 2.

As can be seen in Figure 11 above and Figure 12 on the next page, this concept makes use of a string with attached clip blanks the same as in concept 1. However, here a single clip blank can be rotated over an axis by pulling the string. This way a clip can be moved into a position perpendicular to the instrument, which is beneficial to initiate bending (Figure 12). A coil spring inner lining is used to prevent the clip blanks from getting stuck while maintaining the flexibility of the instrument. The process of singling out one clip blank is done by pulling the clip blank string till a clip is firmly secure in the friction lock in the jaws. The initial wire bending can be accomplished by using a retractable hook which is actually the attachment point of the string to the clip blank. This string is pulled back over the axle, placing the clip in the jaws. By pulling it further the clip blank gets an initial slight bend before the connection breaks and the next clip blank can be moved to the right position. By pulling a "closing" cable, incorporated in the jaw hinge mechanism, a second jaw will close, the clip can be bent further and moved to the target location for application. Compressing the jaws compresses the clip, after which release of the friction wedges releases the compressed clip. The axle over which the cartridge runs can get in the way of the bending point of the clip making in necessary for the clip to slide forward to complete the compression. At the side of the instrument a slot is made (wire outlet) through which the clip can rotate. The second jaw must also have a slot through which the blank can enter the jaw, after which this entrance slot is closed with a wedge that also holds the clip blank in place by means of friction. In Figure 11 above and Figure 12 on the next page, this second jaw is shown with the entrance slot and the wedge that will have the function of closing this entrance slot and clamping the clip blank.



Step 1
A preloaded cartridge, consisting of a wire with mounted clip blanks, is inserted in the instrument through a coil spring inner lining which is not shown here

Step 2
The cartridge is advanced further through the instrument till the transporting wire of the cartridge arrives at the axis of the bending jaws

Step 3
The transporting wire is looped over the axis of the jaws and fed back through the instrument

Step 4
Pulling the wire advances the clip through a slit in the second jaw, not shown here to improve visability, to a position perpendicular to the instrument

Step 5
The clip blank can pass through the slit in one of the jaws and is locked in the jaws by pulling back wedges

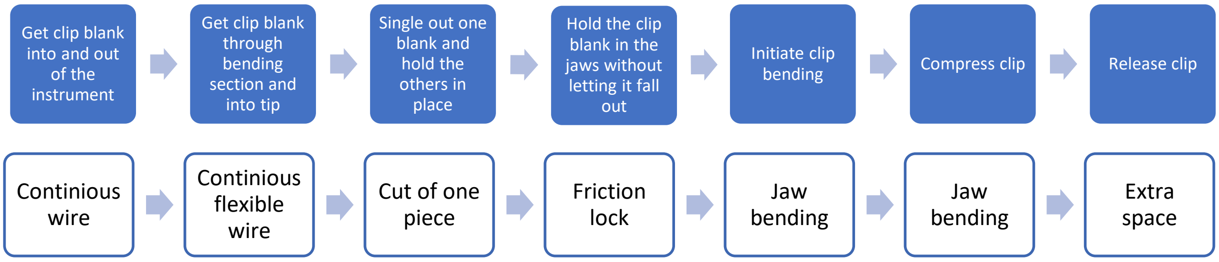
Step 6
Closing and compressing the jaws closes and compresses the clip

Step 7
Pushing the wedges foreward again, releases the compressed clip and opens the slit in one of the jaws

Step 8
Moving the wedges and the jaws back to their original position resets the instrument so that the next clip can be applied

Figure 12: Schematic representation of the working principle of concept 2.

3.4 Concept 3



In concept 3 a continuous wire is used to get the clip blank into and out of the instrument. Therefore, there is no need for a cartridge. This continuous wire can be directly inserted in the instrument to get the clip blank through the bending section and into the tip. The continuous wire can be inserted through a straightened instrument after which a clip blank can be created by cutting of one piece. The clip blank is held in place by a friction lock to pre-form a clip. Since the wire is stuck in the jaws, starting to rotate one jaw causes bending of the clip blank. At this point the clip can be moved and orientated to the desired application site in the body. Full clip compression is achieved by fully closing the jaws. At this point, the fully compressed clip can be released from its friction lock. Opening the jaws will release the clip without opening it.

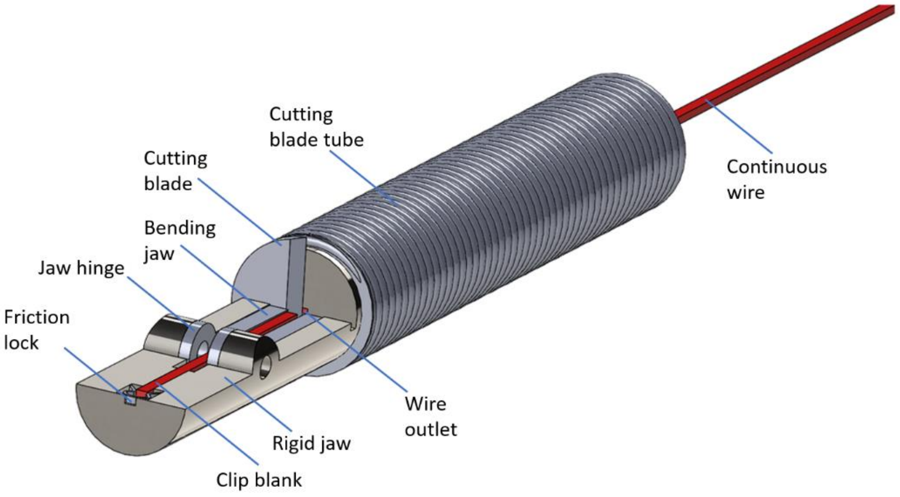
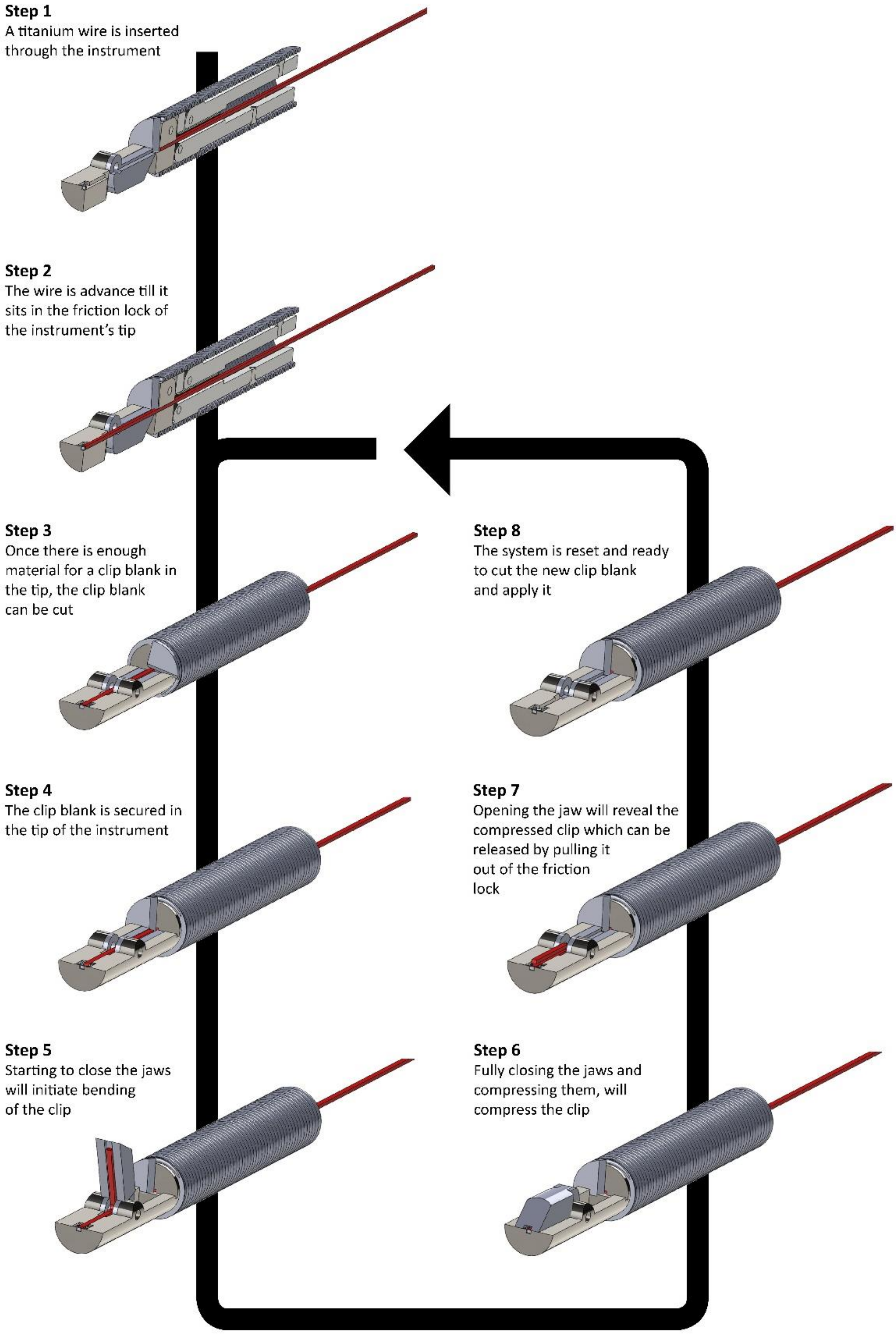


Figure 13: Schematic representation of concept 3.

A continuous wire is fed through the instrument via an opening at the handle side of the instrument. By pushing the wire forward at the back, the wire proceeds through the instrument until it hits the end of the friction lock, indicating that there is enough wire in the head of the instrument to produce a clip as can be seen in Figure 13 above and Figure 14 on the next page. During the initial insertion of the wire in the instrument, the instrument must be in a straight position to prevent the wire from getting stuck. After the wire has passed all the parts of the joint of the instrument, the wire cannot become stuck anymore since it has no protrusions that can get caught behind bends or other obstacles. To thereafter single out one piece, a part of the continuous wire must be cut off. A flexible tube with a blade at the end, as can be seen in Figure 14, is rotated so that a piece of wire is sheared of. The next step in the process is initiating bending of the clip blank by starting to close the bending jaw, which can also be seen in Figure 14. By further bending the jaw, the clip will be compressed further, until full compression is achieved. The jaw bending is actuated by rods incorporated in the jaw hinge and this process can be interrupted at any moment so that the device with the clip can be orientated correctly to apply the clip at the desired location. To release the clip from the friction lock, the instrument is pushed forward slightly to translate the clip into the extra space in the jaws so that opening of the jaws does not result in opening the clip back up.



Step 1
A titanium wire is inserted through the instrument

Step 2
The wire is advance till it sits in the friction lock of the instrument's tip

Step 3
Once there is enough material for a clip blank in the tip, the clip blank can be cut

Step 4
The clip blank is secured in the tip of the instrument

Step 5
Starting to close the jaws will initiate bending of the clip

Step 6
Fully closing the jaws and compressing them, will compress the clip

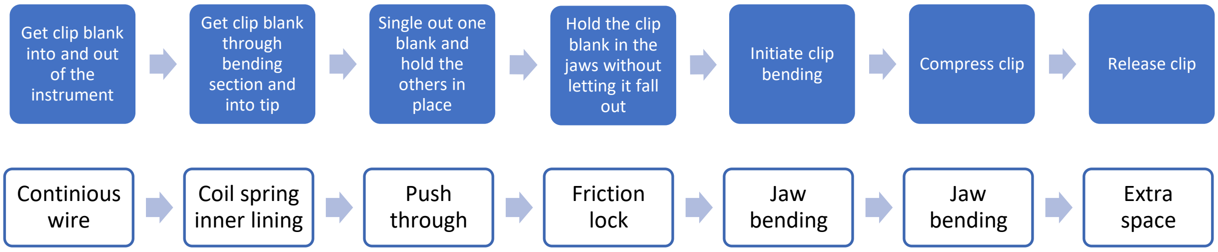
Step 7
Opening the jaw will reveal the compressed clip which can be released by pulling it out of the friction lock

Step 8
The system is reset and ready to cut the new clip blank and apply it

Figure 14: Schematic representation of the working principle of concept 3.

3.5 Concept 4

Since the possible high force transmission over the bending section, in concept 3, could turn out to be unsolvable, a slightly altered concept is discussed here.



As seen before, the first step in the flowchart is the way the clip blank gets into and out of the instrument. The same as in the previous concept, a continuous wire is used in this concept, therefore, there is no need for a cartridge. However, the clip blank is created before the bending section in this concept, making it necessary to transport the clip blank through the bending section and into the tip. A coil spring inner lining will be used to keep the clip blank from getting stuck. The fourth obstacle point, holding the clip blank in the jaws without letting it fall out is solved with a friction lock. Now the bending of the clip can be initiated by starting to bend the jaws. After final orientation, the clip can be compressed by fully compressing the jaws. Opening the jaws and gently pulling the instrument away will release the clip from the friction lock.

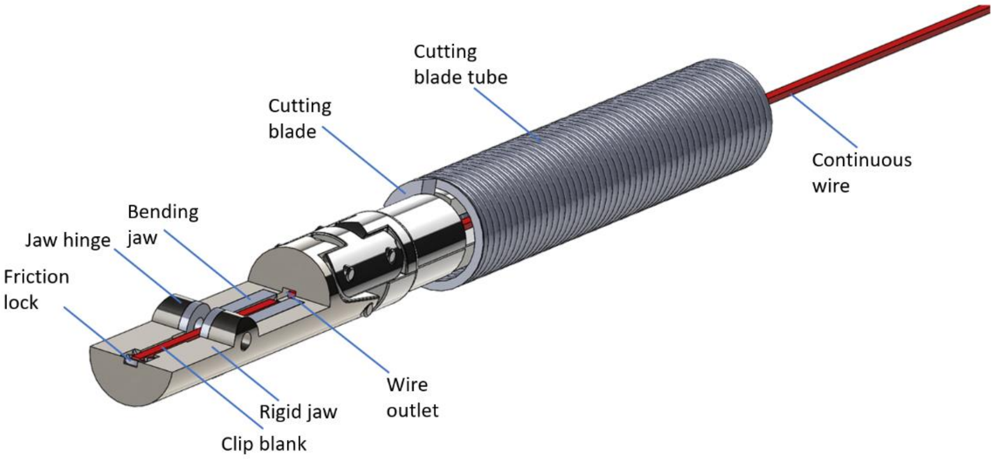
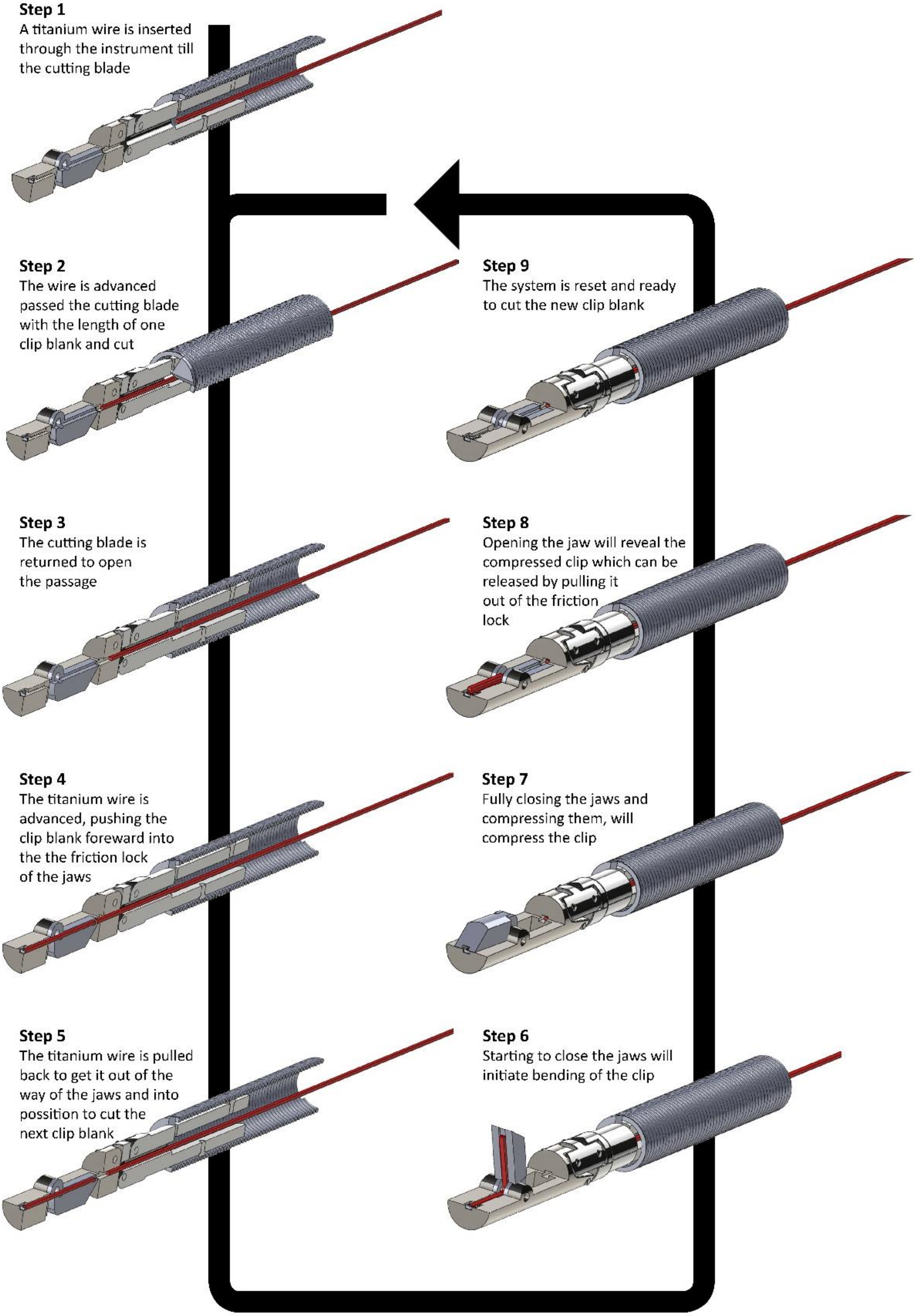


Figure 15: Schematic representation of concept 4.

The friction lock, as seen in the first concept, is also incorporated here. In this concept, the instrument does not have to be in the straight position to insert the wire since a clip blank is created before the bending section. By rotating a rigid tube with a blade at the end, a piece of wire can be cut off that will be the clip blank. By pushing the titanium wire forward, the clip blank can be transported until it is secure in the friction lock as can be seen in Figure 15. After the clip blank is secure, the wire can be pulled back. Now the clip blank is in the instrument's tip, the clip can be bend. By pulling the rods, incorporated in je jaw hinge, the jaws can be actuated. By rotating the jaw, the bending of the clip is initiated, which can be seen in Figure 16 on the next page. Fully rotating the jaw and compressing it will compress the clip completely. Opening the jaws and retracting the instrument will release the clip. Though no cutting force must be transmitted over the bending section in this concept, the design became less elegant and more difficult to control.



Step 1
A titanium wire is inserted through the instrument till the cutting blade

Step 2
The wire is advanced passed the cutting blade with the length of one clip blank and cut

Step 3
The cutting blade is returned to open the passage

Step 4
The titanium wire is advanced, pushing the clip blank foreward into the the friction lock of the jaws

Step 5
The titanium wire is pulled back to get it out of the way of the jaws and into possition to cut the next clip blank

Step 6
Starting to close the jaws will initiate bending of the clip

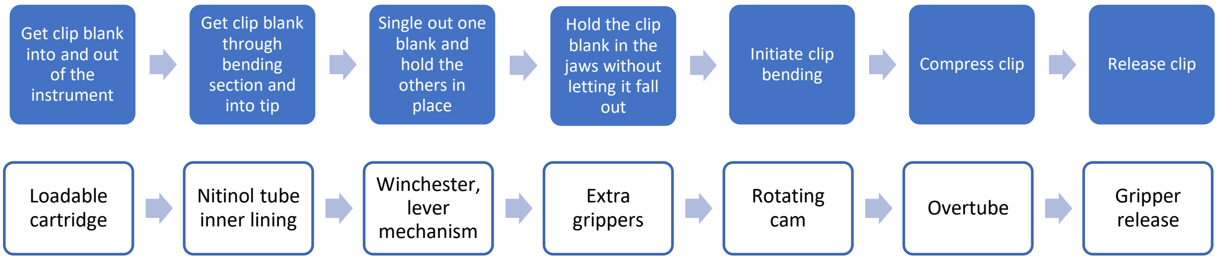
Step 7
Fully closing the jaws and compressing them, will compress the clip

Step 8
Opening the jaw will reveal the compressed clip which can be released by pulling it out of the friction lock

Step 9
The system is reset and ready to cut the new clip blank

Figure 16: Schematic representation of the working principle of concept 4.

3.6 Concept 5



The first obstacle point of this flow chart is solved in this concept by using a loadable cartridge. The already cut clip blanks in the cartridge are guided through the bending section and into the tip by a nitinol tube inner lining so that they do not become stuck inside the instrument. To overcome the third obstacle point in the flow chart, a lever mechanism is used, that transports one clip blank and holds the rest of the cartridge in place at the same time. Extra grippers will grip the clip blank from the lever mechanism and hold it in place so that the clip bending initiation can start. Once the clip is moved to its destination, full clip compression is accomplished by an overtube mechanism. Retracting the overtube and opening the extra grippers will release the clip.

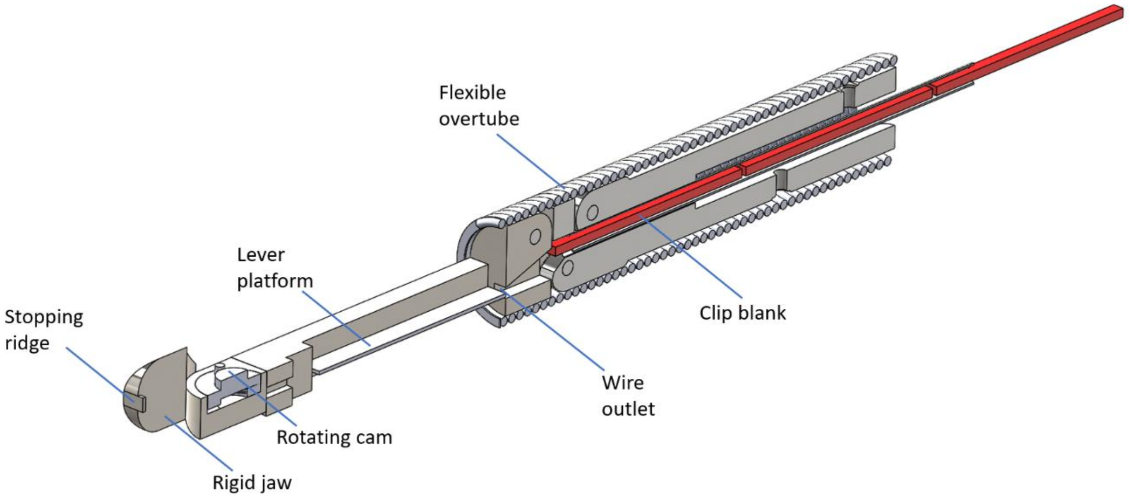
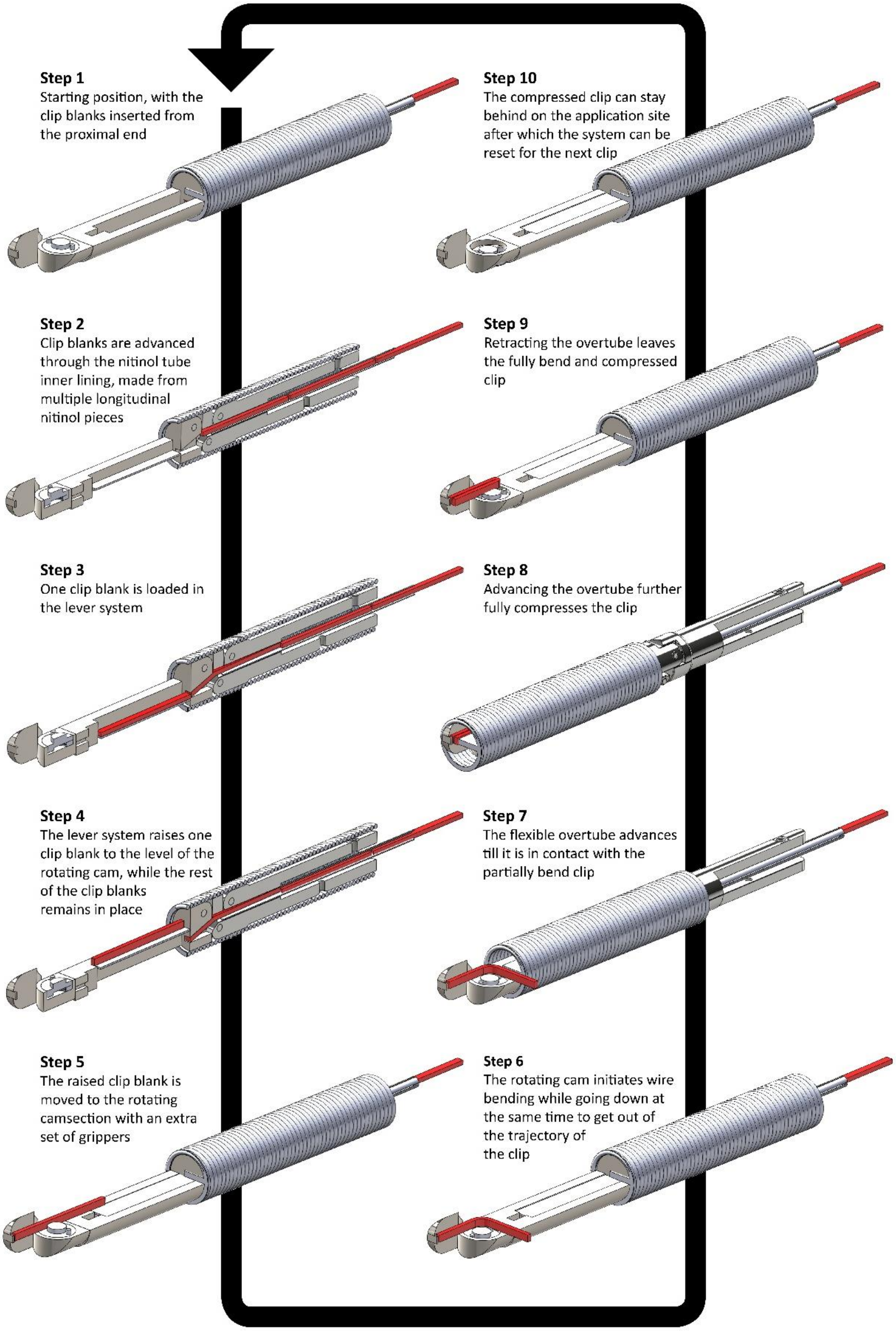


Figure 17: Schematic representation of concept 5.

The concept has a preloaded and reloadable cartridge with straight pieces of wire behind each other in a tube as can be seen in Figure 17 above and Figure 18 on the next page. To prevent the wire from getting stuck when the instrument is bent, a nitinol tube inner lining is used. This inner lining could be made from multiple longitudinal pieces so that they can slide relative to each other to improve bendability. To single out one piece and hold the others is place, a lever system, as can be seen in Figure 18, would be used that brings one piece to a whole other level than the entrance hole and at the same time closes of this entrance hole/ wire outlet. This lever system would be spring loaded and transfers the piece of wire to a set of extra grippers. This concept would use a rotating cam to initiate wire bending. The cam could bend the piece of wire in a desired shape after which it would get out of the trajectory of the clip so that it could be clipped. A flexible overtube could compress the clip firmly after which the extra grippers would release the clip, allowing the clip to stay behind.



Step 1
Starting position, with the clip blanks inserted from the proximal end

Step 2
Clip blanks are advanced through the nitinol tube inner lining, made from multiple longitudinal nitinol pieces

Step 3
One clip blank is loaded in the lever system

Step 4
The lever system raises one clip blank to the level of the rotating cam, while the rest of the clip blanks remains in place

Step 5
The raised clip blank is moved to the rotating camsection with an extra set of grippers

Step 6
The rotating cam initiates wire bending while going down at the same time to get out of the trajectory of the clip

Step 7
The flexible overtube advances till it is in contact with the partially bend clip

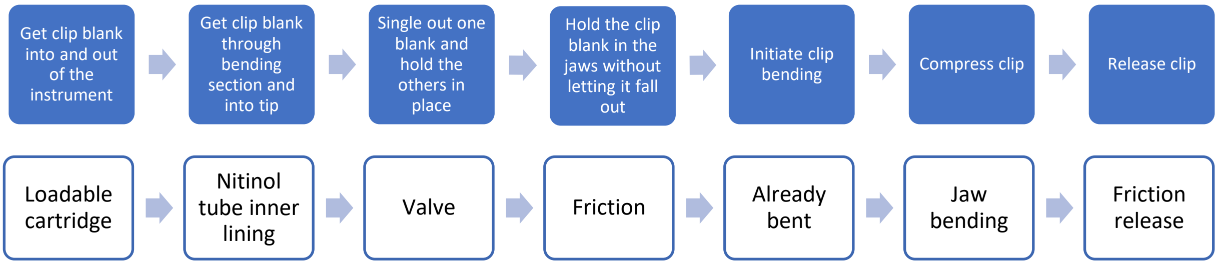
Step 8
Advancing the overtube further fully compresses the clip

Step 9
Retracting the overtube leaves the fully bend and compressed clip

Step 10
The compressed clip can stay behind on the application site after which the system can be reset for the next clip

Figure 18: Schematic representation of the working principle of concept 5.

3.7 Concept 6



To get the clip blanks in the instrument, a loadable cartridge is used loaded with already bent clips. The clip blanks in this cartridge are kept from getting stuck by using a nitinol tube inner lining so that they can get through the bending section and into the tip. A valve is used to solve the third obstacle point in the flow chart. The valve closes after each passing of a clip blank, keeping the rest in place. Friction is used to make sure that the clip blanks are hold firmly in the jaws. Initiating clip bending is not required since the clips are already bent. However, these clips must be opened before they can be applied. Jaw bending is used to open the clips and close them again after they have been positioned correctly. Full closure of the jaws will accomplish clip compression. Finally, to release the clip, the friction that holds the clip in the jaws must be released.

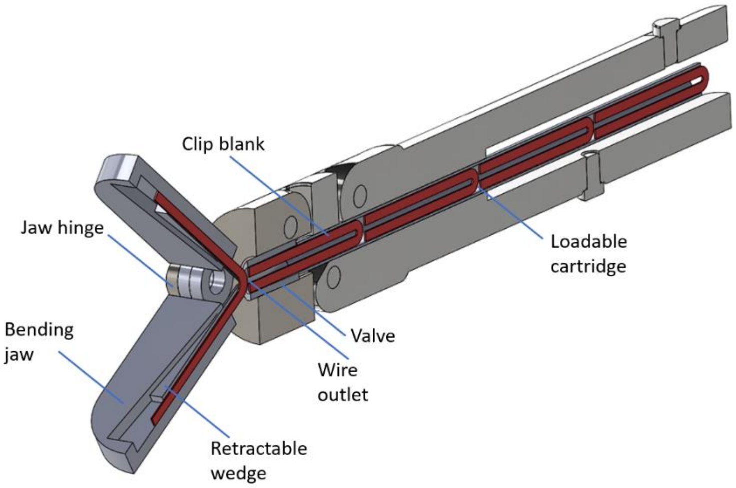
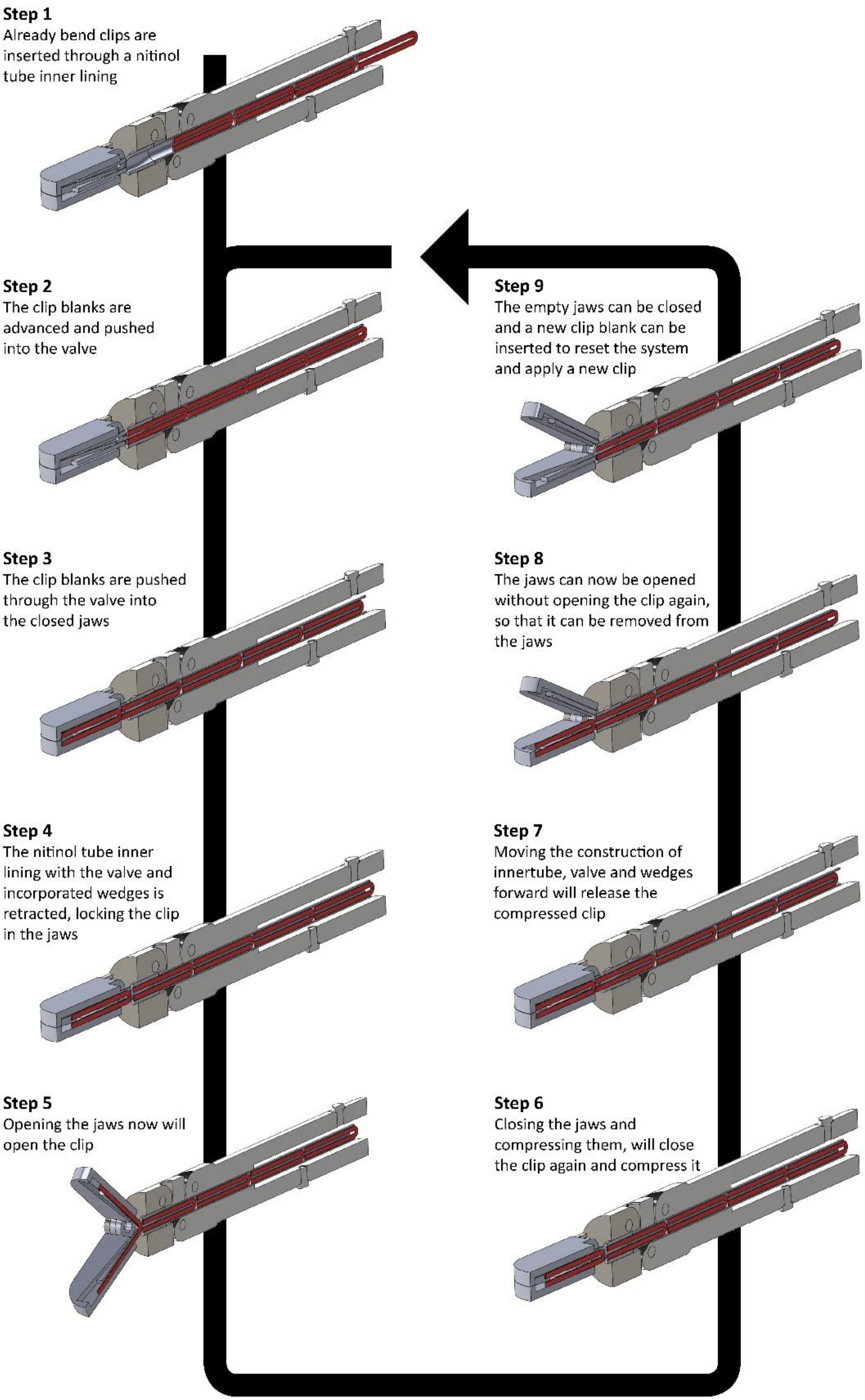


Figure 19: Schematic representation of concept 6.

A loadable cartridge is used in which already bent clips can be inserted that can be pushed behind each other to proceed them through the instrument as can be seen in Figure 19 above and Figure 20 on the next page. A Nitinol tube inner lining is used to prevent the clips from getting stuck in the bending section. In contrast to the plastic tube inner lining from concept 1, this metal inner lining does not close of the passage that easily by bending. Therefore, an elastic valve is used so that one clip blank can be singled out, while holding the rest in the instrument as can be seen in Figure 20. The already bent clip is pushed in the jaws where a wedge can be retracted to hold the clip in place by means of friction. A second jaw will do the same with the other arm of the already bend clip blank. A pair of opening and closing cables is incorporated in the hinge part of the jaws. By pulling the “opening” cable at this point, the jaws with the clip will be opened so that the desired tissue can be placed between the legs of the clip. By closing the jaws again, pulling the “closing” cable, the clip will be closed as well, so that it can be compressed at the desired location. Moving the wedges forward will release the friction lock and enable the clip to be released. Since the dimensions of the instrument under development are so small, parts such as the wedge system or the valve are difficult to manufacture and become hard to assemble. It is therefore desirable to make use of function incorporation so that one part fulfills multiple functions. Connections such as welds or screw connections are better avoided so that the focus lies on monolithic parts.

By incorporating the function of the wedges with the valve, a monolithic part could be made, that has the desired functions, but is easier to manufacture. Therefore, by retracting the innertube with the valve the incorporated wedges are retracted locking the clip blank in place. The connection between the wedge part and the valve part, also guides the clip blank into the jaws.



Step 1
Already bend clips are inserted through a nitinol tube inner lining

Step 2
The clip blanks are advanced and pushed into the valve

Step 3
The clip blanks are pushed through the valve into the closed jaws

Step 4
The nitinol tube inner lining with the valve and incorporated wedges is retracted, locking the clip in the jaws

Step 5
Opening the jaws now will open the clip

Step 6
Closing the jaws and compressing them, will close the clip again and compress it

Step 7
Moving the construction of innertube, valve and wedges forward will release the compressed clip

Step 8
The jaws can now be opened without opening the clip again, so that it can be removed from the jaws

Step 9
The empty jaws can be closed and a new clip blank can be inserted to reset the system and apply a new clip

Figure 20: Schematic representation of the working principle of concept 6.

3.7.1 Monolithic tip design

Concept 6 has a monolithic mechanism to hold the clips in place. An alteration to this concept can be made to see if it is possible to make the whole tip of the instrument monolithic. This can also have a positive effect on the number of required actions.

Instead of having hinged jaws and a monolithic sub system with a valve and wedges it could be convenient to integrate the functions of the sub system into the jaws and make a monolithic tip. A tip design as shown in Figure 21 is actuated by pushing and pulling a central actuation shaft. If the shaft is pushed, the jaws open, if it is pulled, they close. Instead of hinges, flexible beams are used to allow for the bending. In this concept, a set of wedges are connected to the valve that allowed one clip blank to pass through. Pulling this valve backwards, pulls the wedges backwards and locks the clip blank in place so that opening the hinged jaws would open the clip. Since pushing a drive shaft in the monolithic jaws opens the jaws it would be convenient if pushing this shaft also locks the clip in place at the same time. This can be done by using wedges with a reversed slope compared to the ones explained above. When the drive shaft is connected to these wedges and not to the jaws, pushing the drive shaft would result in sliding the wedges forward. When the wedges lock the clip blank in place and cannot slide any further forward, the jaws will open along with the clip. Pulling the drive shaft back, will result in loosening of the wedges until they cannot slide backwards anymore and the jaws will close, compressing the clip blank.

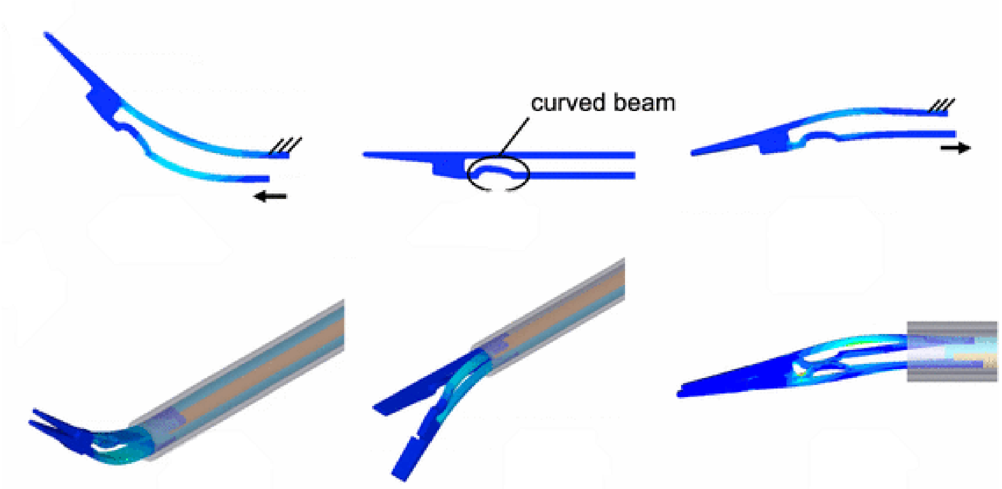


Figure 21: Design of a monolithic tip as described in [32].

4 Conceptual proof of principle evaluation

Since it is not clear which forces the concepts will have to handle, no valuable concept selection can be made yet. Therefore, experiments are performed in this chapter to obtain the necessary information required to make a valuable concept selection. One thing that all the concepts have in common is that they will have to bend and compress the clips. In this chapter tests are performed to see how much force it takes to close and compress the clips. Other experiments are also performed to test aspects specific to certain concepts, such as the cutting of clips, to see if this is possible. With the newly obtained information the concepts can be evaluated and a selection can be made in the next chapter.

4.1 Compression experiment

4.1.1 Methods and test setup

For the design of the BOSS clip applier and the eventual evaluation of all the concepts, it is necessary to know what kind of force is required to bend a titanium clip blank after it has been cut. Looking at literature, minimal information can be found. There is some information in literature about the closing force of titanium aneurysm clips, however, since these clips have a significantly different working principle compared to standard V shaped ligating clips, this data is not directly transferable. Due to the little information in literature about titanium alloy clip closing forces, an experimental setup is designed to test the required closing force of titanium clip blanks. To make this experiment representable for the to be designed clip applier, a test setup is made in which clip blanks are tested with the same dimensions as will be used in the real instrument. Using Solidworks, a simple setup is designed that could be 3D printed. This setup can be seen in Figure 22 below.

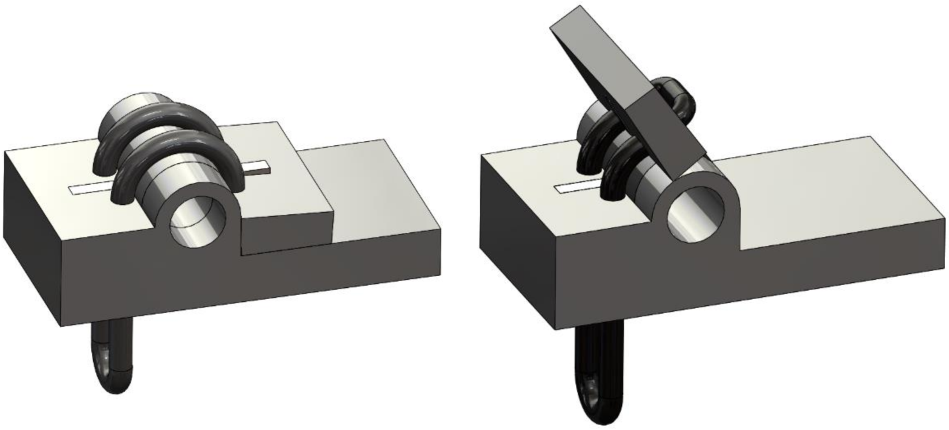


Figure 22: Schematic representation of compression experiment setup.

The setup consists of a movable jaw with a slit to insert half the clip blank and two holes for the wire to pass through and a large bottom jaw with two holes for the wire, a slit to place the other half of the clip blank in, and a larger solid part that extends beyond the movable jaw which can be used to mount the setup in a bench vice.

This setup is a simplified version of what the instrument could look like. A piece of wire could be looped through the four holes and tight in a knot making the need for a complex connection point obsolete. The assembled 3D printed setup with the looped wire and an inserted clip blank, can be seen in Figure 23.

Figure 23: Pictures of compression experiment setup.

The clips that are tested are medium size titanium clips obtained from a cartridge distributed by LocaMed. First a dry run is done, with a push pull force gauge with a capacity of 50 N and a mechanical memory similar to the one shown in Figure 28, since it could be noted that there was quite a bit of resistance in the system. The first couple of runs without a clip blank showed that a force of 5 N was required to close the jaws. This friction force did not decrease when the number of trials increased and therefore this force can be subtracted from the test trials with clip blanks to get the force required to solely close the clip blank.

4.1.2 Results

A total of 9 clip blanks were bend and closed in the experiment. In Tabel 2 below the number of the experiment is shown with the force measured to bend and close the clip, the force required with the initially measured friction force subtracted and the corresponding required bending moment respectively. The wire to close the jaws, passes through holes placed with a distance of 3 mm from the center of the axle. The required bending moment to close the clip blanks is calculated by multiplying the corrected forces with this distance.

Tabel 2: Measurements of the compression experiment.

Experiment nr	1	2	3	4	5	6	7	8	9
Measured force (N)	12	19	16	13	15	15	13	16	16
Corrected force (N)	7	14	11	8	10	10	8	11	11
Required moment (Nm)	0.021	0.042	0.033	0.024	0.03	0.03	0.024	0.033	0.033

The data from Tabel 2 is visually represented in the graph of Figure 24 below. A trendline is drawn and all the trials lie around an average of approximately 0.03 Nm and have a standard deviation of 0.006.

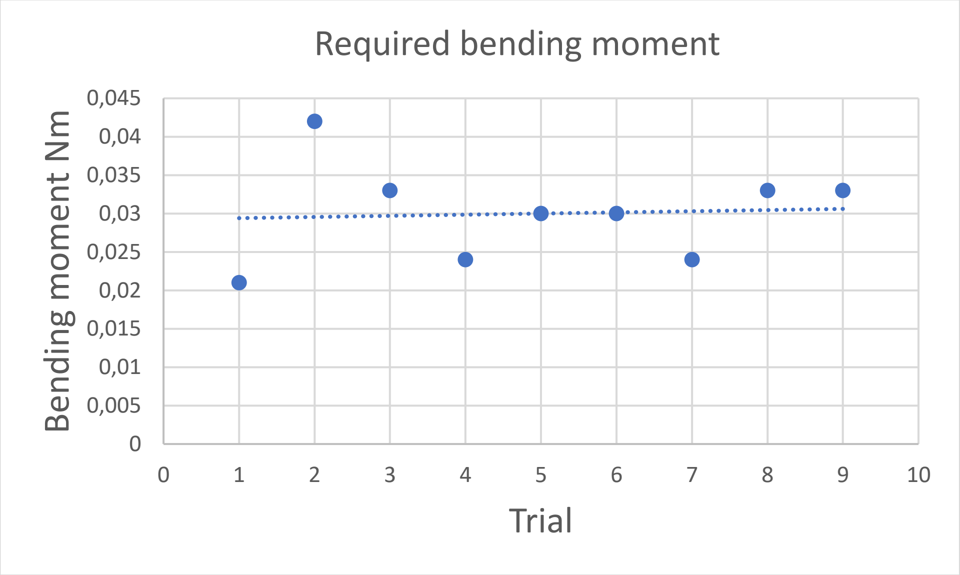


Figure 24: Graph of compression experiment with required bending moment VS trial.

4.1.3 Conclusion and discussion

The experiments showed that an average bending moment of around 0.03 Nm is required to close the clips. The bend clips from the 9 trials can be seen in Figure 25.

Figure 25: Results of the 9 bending trials.

These clips show a couple of things worth noting. First, they have one leg longer than the other, indicating that they have not been bend in the middle. On top of that they all show a belly, which is caused by a lack of support in the middle during bending. These two things coincide since the lack of support in the middle allowed the clip to start to bend on a spot slightly off center. Nevertheless, the legs are parallel and pressed together at the end of most clips, which shows that it is possible to get proper closing when the clip is supported.

To prevent the clips from developing a belly during bending and making sure they are pressed together over the entire distance, it is important that the clip is supported along the whole length during bending and compression. The difference in leg length, as was the case in the experiment has to be prevented in the eventual design by making sure the clip is supported over the entire length except a small spot where the blank has to bend.

4.2 Cutting and torque calculations

One of the main issues with concept 3 and 4, is the question if it is possible at this scale to cut off a piece of titanium wire. To this end, several worst-case scenario calculations are made which are shown below.

To cut a piece of titanium wire, to form a clip blank, a certain amount of force is required. This force depends on the shear strength of the titanium wire and the surface area on which the force acts. The shear strength is a material property while the surface area on which the force acts is a geometrical property. Since all the parts are so small and titanium is a relatively tough material, calculations are made to see which forces act on the parts of the instrument.

The shear strength τ is defined as the applied force divided by the area on which it acts:

$\tau = \frac{F}{A}$ with
τ = shear strength in $\frac{N}{m^2}$ or Pa
F = cutting force in N
A = surface area on which the force acts in m^2

The ultimate shear strength of titanium Ti-6Al-4V grade 5 annealed is 550 Mpa [33]. The surface on which the cutting force acts is the cross-sectional area of the titanium wire. A standard clip, from the commercially available Covidien Endo Clip III 5 mm device, has a cross-sectional area of 0.5 by 0.8 mm, therefore:

$$the\ cross - sectional\ area\ A = B * H = 0.0005 * 0.0008 = 0.0000004 m^2$$

This gives $\tau = \frac{F}{A} => 550 * 10^6 = \frac{F}{0.0000004} => F = 550 * 10^6 * 0.4 * 10^{-6} = 220N$

To calculate the required moment, the following standard formula can be used:

$M = F * r$ with
M = moment in Nm
F = Cutting force in N
r = radius at which the force acts in m

The wire enters the tip through a hole 0.9 mm off center and is cut by rotation of a tube with a blade. With a cutting force F of 220 N at a radius r of 0.9 mm This gives:

$$M = 220 * 0.0009 = 0.198 Nm$$

Therefore, to cut the piece of titanium wire, a moment of 0.198 Nm must be applied.
The tube that delivers this moment, will be loaded under torsion. To see if this tube will fail under the required torsion, the torsional shear of the tube can be calculated. The torsion is a function of the shear strength τ and the gematrical term W_t in the form:

$T = W_t * \tau$ with
$W_t = \frac{\pi}{16} * \frac{D^4 - d^4}{D}$ with
D = outer diameter of the tube in m
d = inner diameter of the tube is m

Assuming a stainless-steel tube will be used to cut the wire, with an inner diameter of 5 mm and an outer diameter of 6 mm the equation becomes:

$$W_t = \frac{\pi}{16} * \frac{D^4 - d^4}{D} = \frac{\pi}{16} * \frac{0.006^4 - 0.005^4}{0.005} = 22 * 10^{-9}$$

$$T = W_t * \tau => 0.198 = 22 * 10^{-9} * \tau => \tau = \frac{0.198}{22 * 10^{-9}} = 9 * 10^6\ Pa = 9\ Mpa$$

4.2.1 Cutting and torque calculations discussion and conclusion

According to the calculations it would take around 0.198 Nm to cut a titanium clip blank from a wire that enters 0.9 mm off center. To validate these calculations and see if they are a close enough approximation of the real situation experiments will have to be performed.

The ultimate shear strength of stainless steel obviously depends on the type of stainless steel, but is for AISI type 304 Stainless Steel around 300 Mpa [34], which shows that the by the tube experienced shear strength of 9 Mpa to cut the titanium wire is well below the ultimate shear strength. Therefore, all the forces required to cut a titanium clip blank are sufficiently low that the instrument should be able to handle them without failing.

In these worst-case calculations, the assumption is made that all the forces are transmitted through a uniform straight tube, however, this is not the case in concept 3. If the wire is cut distal to the SATA mechanism, the forces applied at the proximal end of the SATA mechanism need to be transmitted across the bending section. The question is if a structure can be made or designed that has the ought dimensions and is flexible enough to bend along with the sata mechanism but is stiff enough in torsional direction to transmit the necessary torque to the cutting blade. The possible work around is presented in concept 4 and would be to cut the pieces of wire proximal to the bending section and then transport the clip blank to the distal side. This way the cutting mechanism can remain straight, making it more predictable if it will work. This, however, is at the cost of an extra step of clip blank transportation.

4.3 Cutting experiment

Some of the developed concept use the cutting of titanium wire to create clip blanks just before application at the surgical site. Therefore, the instrument must be capable of cutting the clip blanks with a reasonable amount of force applied to the instrument. In this section the required forces are investigated and the calculations and model of section Cutting and torque calculations are verified with an experimental validation setup.

4.3.1 Methods and test setup

This experimental setup is made with a 1 to 1 model of the concept. A schematic representation of the designed experimental setup can be seen below in Figure 26.

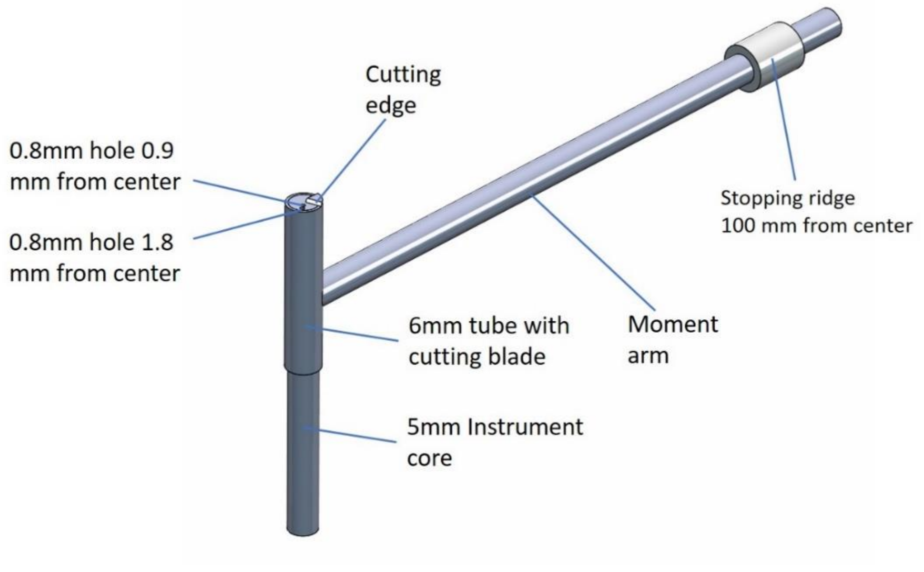


Figure 26: Schematic representation of the cutting experiment.

A simple real sized instrument model will be made consisting of a 5 mm instrument core that will resemble al the tubes and components of the actual instrument. This core will be mounted in a bench vise to secure the entire setup. In this core there are two holes that are placed at 0.9 and 1.8 mm from the center. These holes represent two possible entrance location where the titanium wire can enter the tip of the instrument. These holes have a diameter of 0.8 mm which is exactly big enough to insert the titanium wire. Over this 5 mm instrument core, a tube with an outer diameter of 6 mm is placed that has the cutting blade at the end. This cutting blade has a 45° sharpened cutting edge to cut the wire. To this cutting tube, a moment arm is connected that has a stopping ridge that can be secured at a certain distance from the center, initially this will be 100 mm.

This whole setup is manufactured from silver steel with the help of a lathe and a milling machine. The cutting edge is made by eye with a jewelers file and all the connections are soldered with silver solder. Resulting in the setup as presented in Figure 27 in the next page.

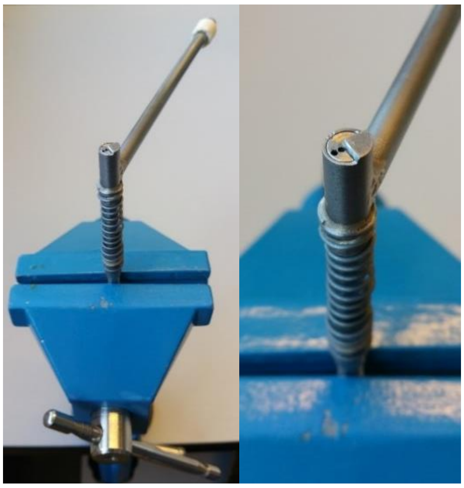


Figure 27: Pictures of cutting experiment setup.

As can be seen in Figure 27, a spring is added to the cutting tube. This spring is used to hold downward tension on the cutting blade to make sure that the blade would not be pushed off when the moment arm is rotated and the titanium is cut. The titanium wire used in this experiment is obtained by straightening a clip from the commercially available Covidien Endo Clip III 5 mm device. This titanium wire has the same cross-sectional area as used in the calculations described earlier, namely 0.5x0.8 mm. After the titanium wire is inserted in a hole, it can be cut. The force is applied on the moment arm with the push pull Force Gauge with a measurement domain of 0-10N presented on the left in Figure 28. The hook of the pulling side of the Force Gauge is placed against the stopping ridge. After inserting the titanium wire, the cutting action could be performed by pulling the gauge. The gauge has a mechanical memory function, meaning that the dial remains at the maximal required force to cut the wire, see the right side of Figure 28. After resetting the whole setup, the measurement could be performed again.

Figure 28: push pull Force Gauge.

4.3.2 Cutting experiment results

Cutting the wire in both the 0.9 mm from center and 1.8 mm from center holes is performed to see if the required force scales linear. Each test is done two times to spot accidental false measurements and prevent systematic errors. These tests are done initially for a moment arm of 100 mm and then for a moment arm of 50 mm by relocating the stopping ridge. This leads to a total of 8 measurements which are listed in Tabel 3 below.

Tabel 3: Measurements of cutting experiment.

	50 mm arm from center		Average	100 mm arm from center		Average
0.9 mm from center	4.3 N	0.22 Nm	0.23 Nm	2.7 N	0.27 Nm	0.29 Nm
	4.7 N	0.24 Nm		3 N	0.3 Nm	
1.8 mm from center	6.6 N	0.33 Nm	0.34 Nm	5.3 N	0.53 Nm	0.57 Nm
	7 N	0.35 Nm		6 N	0.6 Nm	

A visualization of this table can be seen in the graph of Figure 29 in which the required torque for each experiment is presented in chronological order.

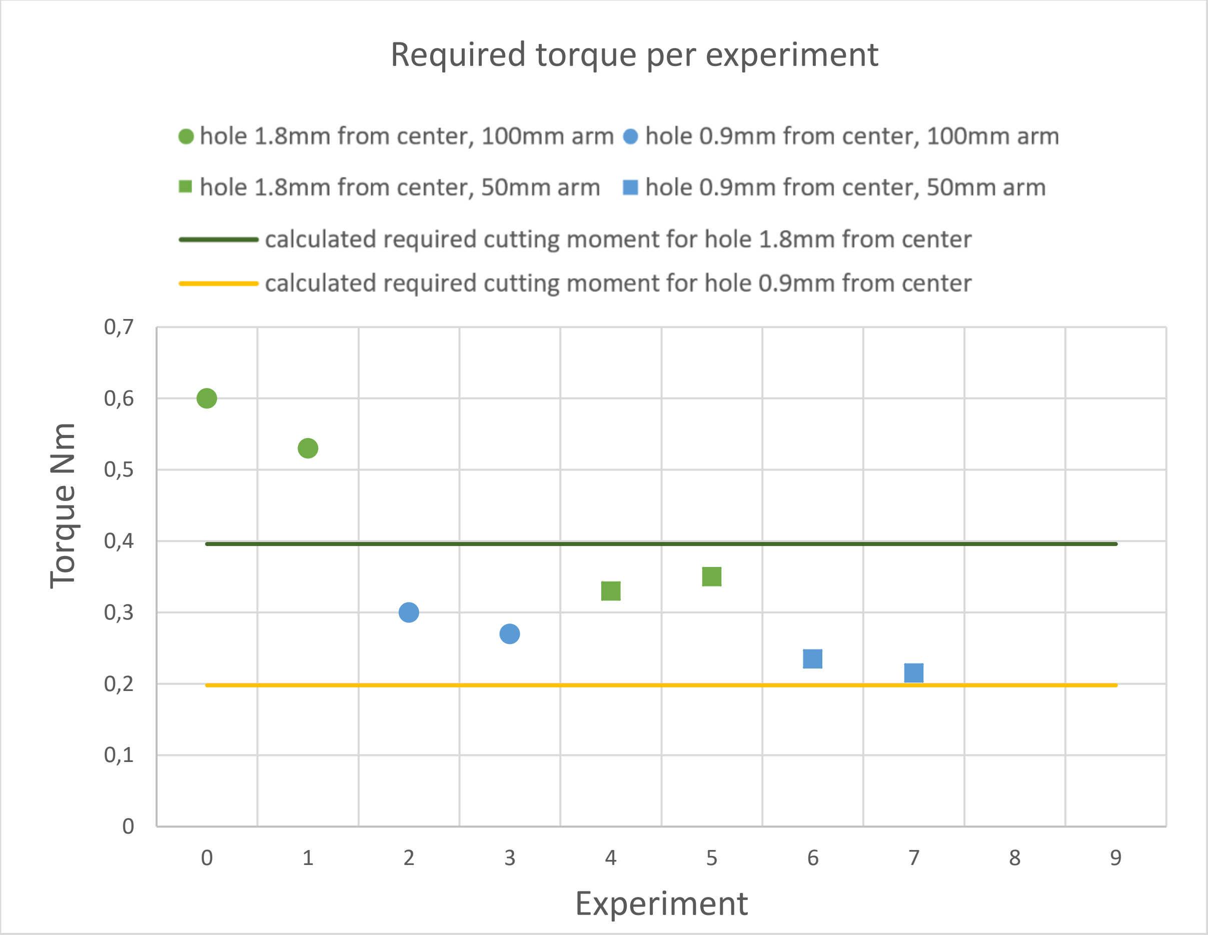


Figure 29: Graph of cutting experiment with required torque VS experiment number.

According to the calculations shown in the section Cutting and torque calculations, a shear force of 220 N would be required to shear off a piece of titanium Ti-6Al-4V grade 5 annealed wire with a cross-section of 0.5x0.8 mm. This would result in a required moment of 220*0.0009=0.198 Nm to cut the wire 0.9 mm from the center and a moment of 220*0.0018=0.396 Nm to cut the wire 1.8 mm from the center. These two values are represented in Figure 29 by the yellow and dark green line respectively. The type of titanium of the used clips in the experiments is unknown. However, the obtained moments are 0.23 Nm and 0.29 Nm for the hole 0.9 mm from the center with a moment arm of 50 mm and 100 mm respectively. For the hole 1.8 mm from the center the obtained moments are 0.34 Nm and 0.57 Nm for the moment arms of 50 mm and 100 mm respectively.

4.3.3 Cutting experiment conclusion and discussion

As can be seen from the results, the force does not behave linear in all cases. For the arm of 100 mm, the moment required to cut the wire in the hole 1.8 mm from the center is around 0.57 Nm and approximately two times as big as the moment of 0.29 Nm required to cut the wire with the same arm in the hole 0.9 mm from the center. However, looking at the measurements of the arm of 50 mm, the moment required to cut the wire 1.8 mm from the center is around 0.34 Nm and is not two times as big, as the moment of 0.23 Nm required to cut the wire at 0.9 mm from the center. When for one entrance hole the measurements of the two arms are compared, it can be seen that although the arm is scaled with a factor of two, the required force does not scale with a factor of two. Nevertheless, the values are in the same range and the obtained values for the two measurements of every combination are close together, giving a good indication of the required force.

The lack of the expected linear relation can be explained by the friction and play within the system. Also, the imperfect cutting edge of the cutting blade has a negative effect on the repeatability and the required force. When the calculations done are compared with the obtained measurements, a reasonable resemblance can be observed. This shows that the calculated and measured moments are in accordance with each other and that the system is indeed able to cut titanium wire at this scale without deformation or failure.

4.4 Torque experiment setup and results

As discussed earlier, the force to cut the wire in concept 3 must be transported from the proximal end of the instrument across the bending section to the distal part of the instrument as can be seen in Figure 30 below.

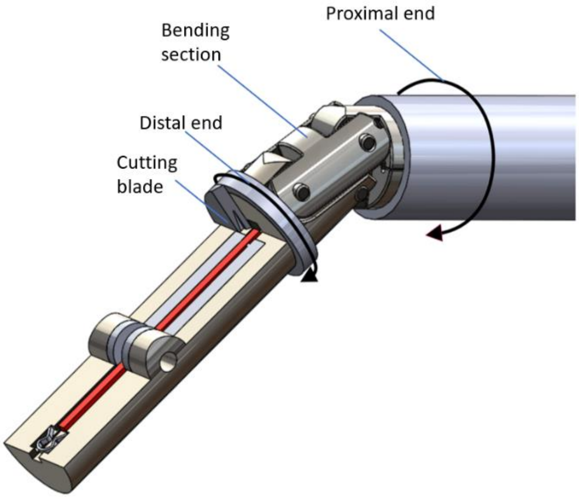


Figure 30: Required force/motion transmission.

This means that there must be a connection between the proximal and distal end that can bend along with the hinges, but can transfer enough torque. From the cutting experiment described above, it can be seen that a torque up to 0.6 Nm must be applied at the tip, which is provided at the handle, depending on the placement of the hole from which the wire emerges and the moment arm used to apply the moment. Since this 0.6 Nm is the highest value, this will be used as a worst-case scenario to select a coupling to transport the moment. Finding a coupling that can transport such a torque while remaining flexible is quite a challenge. As far as known, all the standard solutions available on the market, such as for example bellows, are not usable for the required dimensions. Therefore a few ideas are tested experimentally to see if it is possible to find a suitable solution. First, an ordinary spring is tested to see what kind of moments it can withstand before it starts to deform.

To perform these experiments, the 6DOF Load sensor HEX-70-XH-200N OptoForce 6-Axis F/T Sensor is used with a stand mounted to it that can hold the coupling under testing. The specifications of this sensor are given in Tabel 4 below and the entire setup can be seen in Figure 31.

Tabel 4: Specifications as obtained from [35].

Sensor Type	6-Axis Force/Torque Sensor			
Dimensions	Height x diameter		35 x 70 mm	
Weight	(With built-in adapter plates)		260g	
	Fxy	Fz	Txy	Tz
Nominal Capacity (N.C)	200 N	200 N	20 Nm	13 Nm
Single axis overload	500 %	500 %	300 %	300 %
Signal noise[1] (typical)	0.1 N	0.2 N	0.006 Nm	0.002 Nm

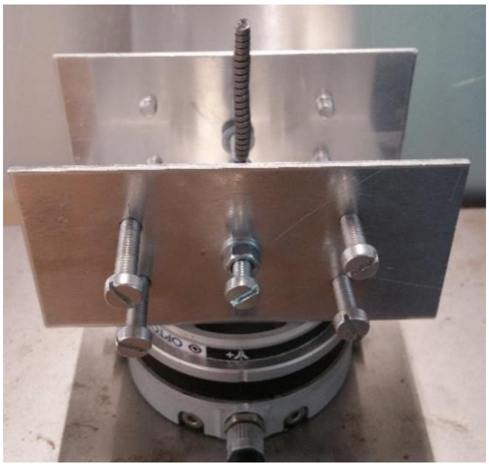


Figure 31: Picture of the torque experiment

Only the torque around the longitudinal axis of the coupling under testing in this orientation is of interest at this moment and this is measured as the torque around the Z or longitudinal axis. A spring is chosen that has closely packed windings so that they will push against each other from the start, instead of after it deforms significantly as would be the case with a loosely wound spring (Figure 32).

Figure 32: Closely packed spring.

Using the setup as described above and the MATLAB code (Appendix A) to process the data, the torque graph of a closely packed spring with outer diameter of 4 mm and inner diameter of 2.7 can be obtained, which is shown below in Figure 33.

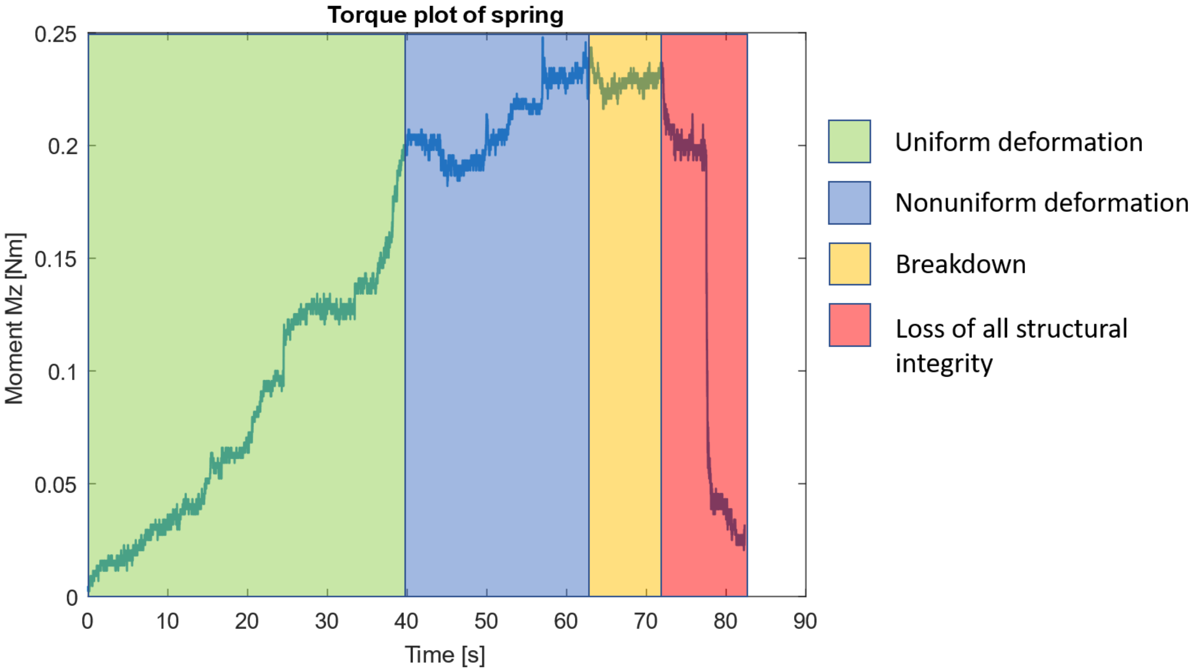


Figure 33: Graph of the torque experiment with the closely packed spring.

As can be seen from this result, this spring can withstand around 0.23 Nm before breakdown. This is well below the worst-case moment of 0.6 Nm. When a moment is applied to the spring, the torque that is transmitted goes up linearly till around 0.2 Nm. However, to reach this point a large rotation must be made as the spring starts to deform immediately. Around 0.2 Nm the spring is not deforming uniformly anymore and starts to buckle. The process of breakdown can be seen from around 60 seconds. From this point, further rotation does not increase the transmitted torque. A final drop begins from 70 seconds with a sudden drop at around 80 seconds where the wire of the spring kinks and the complete structural integrity of the spring is lost.

There are two reasons why an ordinary spring does not work good as a torque coupling as could be seen in the experiment. Applying the torque in the direction in which the spring is wound results in a spring that will get wound closer and closer until the spring binds to the mechanism inside, resulting in a breakdown. Applying the torque in the opposite direction results in the spring unwinding until it buckles, which also results in a breakdown. Since a vital part of the concept's mechanism runs through the inside of the required flexible coupling, turning the spring in the direction of the windings of the spring is not possible since it will bind to the inside mechanism which will cause a breakdown. After insertion of the instrument into the patient, there is more room for the mechanism. This means that it is not necessarily bad if the spring would expand a little bit. This opens perspective to use a spring, with a torque in the direction that would unwind the spring, and an outside tube that is not torsion stiff, but can withstand pressure from the inside. To test this idea, the same spring as used in the previous experiment is used, but with the addition of a plastic tube with an inner diameter of 4 mm and an outer diameter of 5 mm (Figure 34).

Figure 34: Closely packed spring with plastic outer tube.

This tube is placed over the spring and the torsion is applied to the spring in the direction that it would unwind it. This setup is tested and the results can be seen below in the graph of Figure 35.

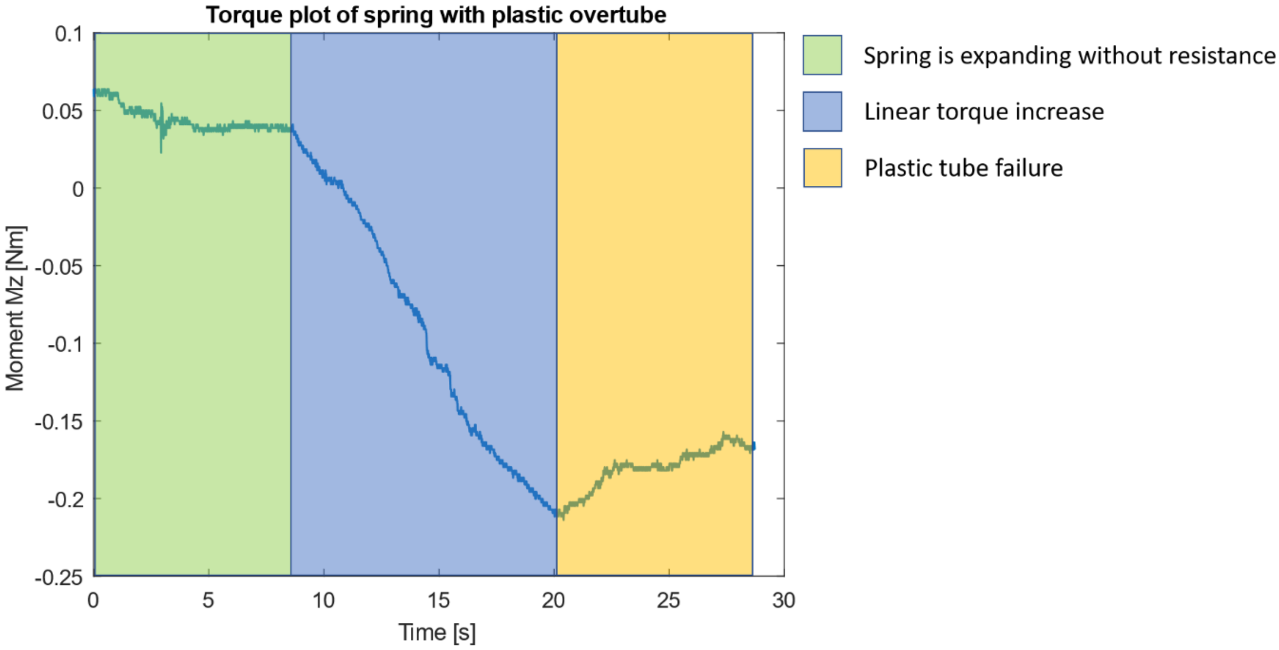


Figure 35: Graph of the torque experiment with the closely packed spring with plastic outer tube.

The torque in this graph increases in negative direction since we are applying the moment in the opposite direction compared to the measurement above. In this graph it can be noticed that for the first 10 seconds the torque does not increase significantly and that the starting position was not spot on, because the graph does not start at zero, but at a positive torque. In these first seconds, the spring is expanding and does not get resistance of the plastic tube yet. From around 10 seconds the torque increases faster and more linear than in the experiment above. However, from 20 seconds a sudden change can be observed. At this point the plastic tube fails and does no longer resist the expansion of the spring resulting in a sudden decrease in maximum torque. Since the graph starts at 0.05 Nm this setup could withstand a maximum torque of 0.25 Nm before it breaks down. Therefore, this system cannot withstand the target torque of 0.6 Nm, however, it shows that a solution with an outer tube could work when the outer tube can withstand more outward pressure.

With this result in mind a new solution is found with a woven steel wire tube which can be seen in Figure 36. The woven structure causes a part of the structure to be loaded in compression and a part to be loaded in tension when a torque is applied resulting in a relative torsion stiff but flexible structure. A tube that is woven with wire with a diameter of 0.2 mm and an outer diameter of 10 mm is tested with the experimental setup as described above and results in the graph of Figure 37 on the next page.

Figure 36: Steel wire woven tube.

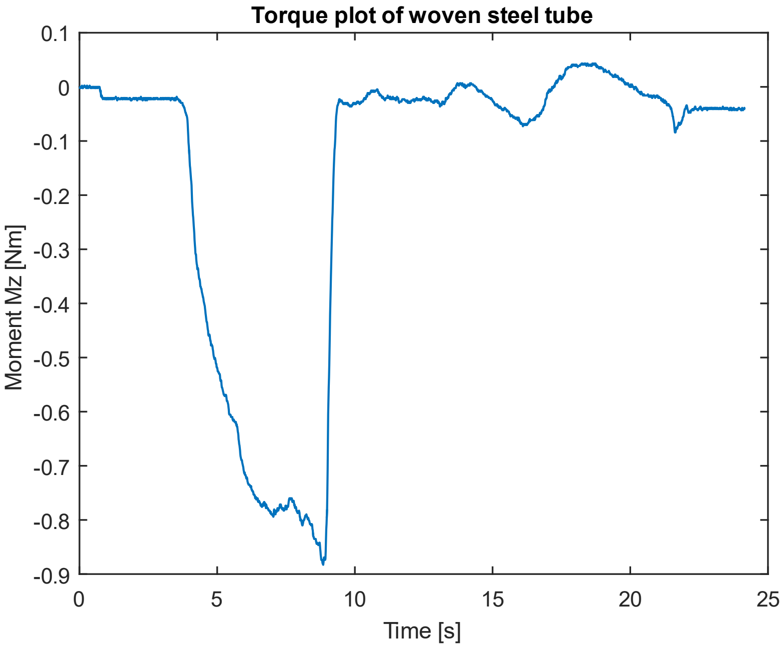


Figure 37: Graph of the torque experiment with the steel wire woven tube.

The woven steel tube is mounted on the force sensor the same way the springs of the previous experiments are mounted. The torque had to be applied to the springs with a clamp, however, because the woven steel tube does not offer much resistance to pressure from the outside the torque was applied by hand which led to a little bit of noise in the measurement at moments where the hand force weakened and the tube slipped. When the moment was applied, starting from around 5 seconds, a steep increase in torque is measured to approximately a torque of 0.8 Nm as can be seen in the graph. At this point the tube slipped and some chatter can be observed. More torque was applied, however, at this point it could be visually observed that the tube started to deform and the torque was released. From this experiment it can be concluded that a torque of 0.6 Nm (the target torque) can be easily achieved and that even higher torques can be transmitted up to 0.9 Nm before slight deformations start to occur.

Directly after the torque measurement a moment around the x and y axis was applied consecutively to achieve a bend of -90° to a +90° angle for both axes. The small fluctuations starting from 10 seconds in the graph above are due to crosstalk from these measurements concerning the required moment to bend this tube from a -90° to a +90° angle. These experiments are performed to get an idea of the required moment to make a bend with this type of tube. The results of this experiment can be seen in the graphs of Figure 38 below. A moment of approximately 0.3 Nm is required to make a sharp 90° bend in either the positive or negative direction.

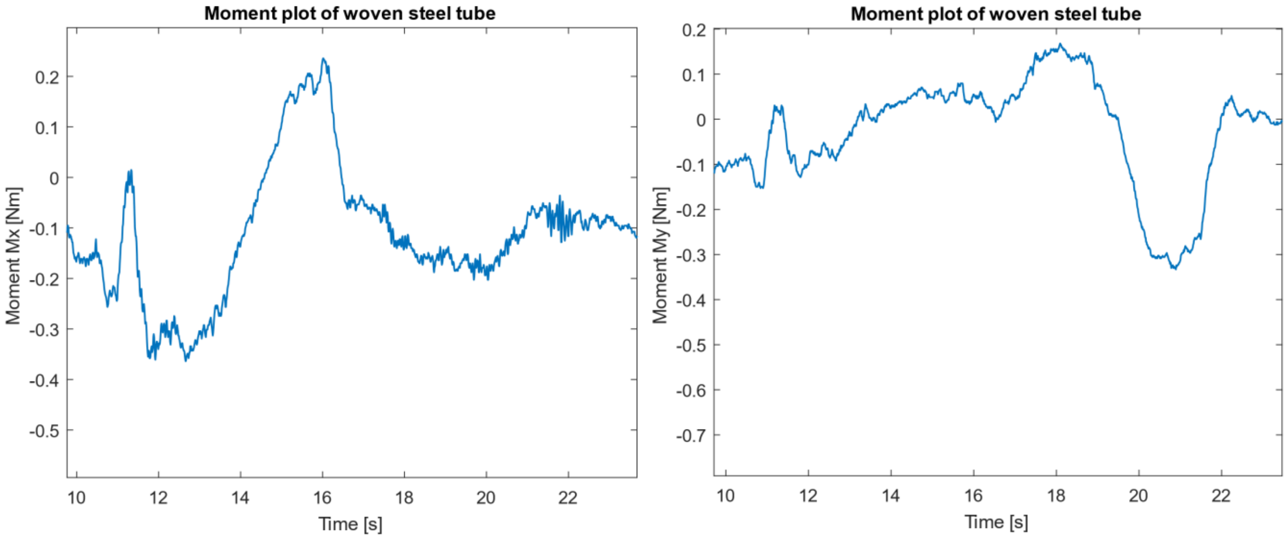


Figure 38: Graph of bending moment Mx VS time and My VS time of woven steel tube.

4.5 Flexible coupling experiment setup and results

Now that a possible suitable solution is found for the flexible coupling that can transmit enough torque without breaking down, it is necessary to see if such a solution can work at the required scale. To this end, a mockup model of the SATA mechanism with the flexible coupling is made and tested for its torque transmitting capabilities and resistance to bending in the steering direction.

The SATA mechanism is imitated with two 5 mm brass rods that are connected in the middle by means of a hinge. A woven stainless-steel tube with a 7.5 mm outer diameter is obtained of which the ends are sealed by a steel press fitting, making it possible to apply the torque to the tube without compromising the integrity of the woven structure by deforming it. These press fittings have an inner hole of 5.1 mm and an outer diameter of 8 mm with the woven structure in between. Two moment arms are made that can be connected to the flexible coupling with a press coupling and one of these arms has a ring (at which weight can be hung) at 75 mm from the center where the flexible coupling is connected. These parts, along with the experimental setup with the weight already applied, can be seen in Figure 39.

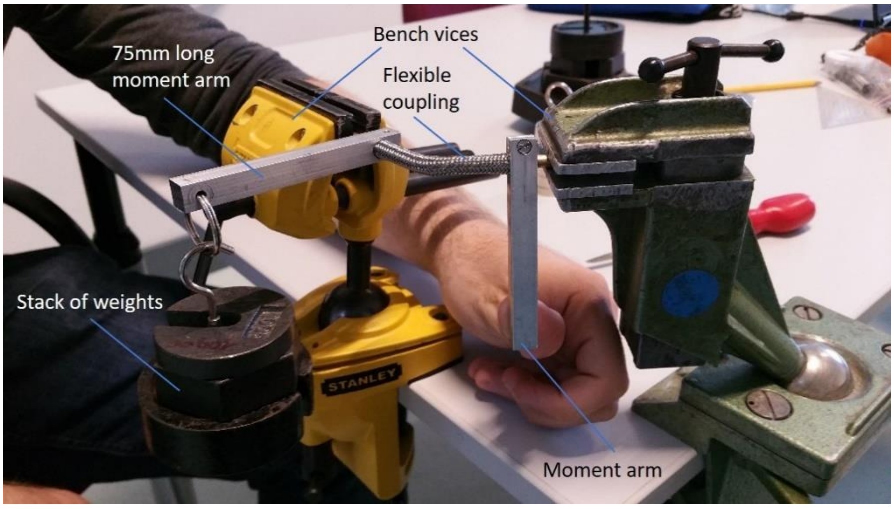


Figure 39: picture of flexible coupling experiment setup.

From the experiment of cutting the titanium wire, a maximum (worst-case scenario) torque of 0.6 Nm was obtained. This corresponds with the moment arm of 75 mm to a weight of 800 grams that must be able to be rotated. As can be seen in Figure 39, the flexible coupling is mounted under an angle. This angle is 60° which corresponds to the maximum bending angle of the SATA mechanism, which would be the worst case to cut the titanium wire. When a weight of 850 gram is applied as is the case in Figure 39, the coupling shows hardly any deformation and is still easy to rotate. This is the case till a weight of 1200 grams, after which the coupling still does not show much deformation, but the press couplings of the moment arms to the flexible coupling start to slip. This means that the coupling could probably withstand even more weight than the 1200 grams if a stronger connection to the moment arms could be realized.

A point of interest is the amount of deformation under a certain load. To test this, the same setup, but with the addition of a protractor, is used as can be seen in Figure 40 below.

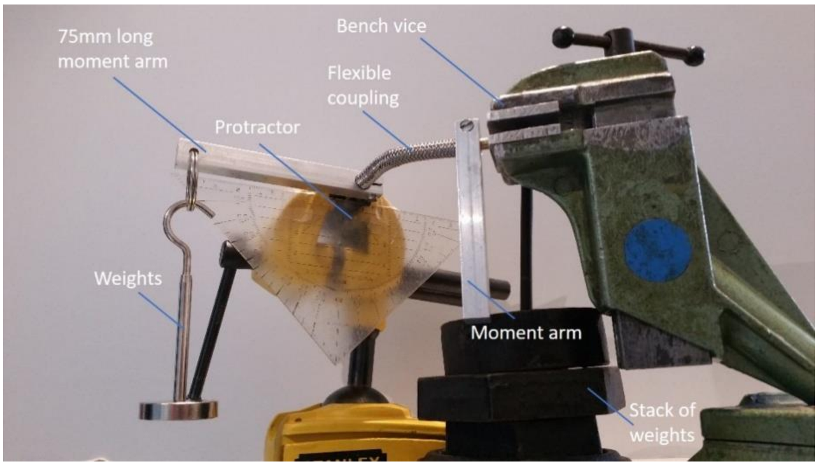


Figure 40: picture of flexible coupling experiment setup with protractor.

The moment arm, to which a moment was applied to rotate the system in the previous experiment, is held in place by a stack of weights. The moment arm with the ring to which the weights are applied is mounted horizontal under 90° to the other arm and is initially set to 0° on the protractor as can be seen in Figure 40. Since the moment arm decreases when the coupling starts to deflect, a correction is applied, giving: $moment\ arm = \cos(\alpha) * 75, with\ \alpha = angular\ displacement$. The graph in Figure 41 below shows the amount of degrees the flexible coupling rotates under a certain torque.

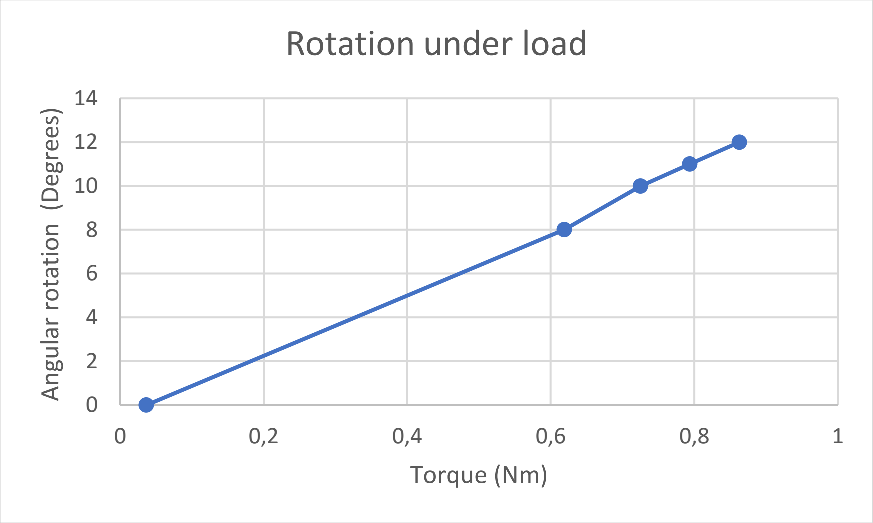


Figure 41: Graph of angular rotation of the flexible coupling vs applied torque.

An almost linear relation can be seen with an increase of 1° every 0.072 Nm. With the worst-case scenario of a required cutting moment of 0.6 Nm, this would result in a rotation of 8.3° before the titanium wire is cut.

Finally, it is investigated how much force is required to bend the structure around the hinge of the simulated SATA mechanism. Ideally the coupling could bend 60° under the application of almost no force. To test this, the rod of the mechanism is mounted under 60° in a vice with the arm to which the weights are applied 40 mm from the hinge. A protractor is also mounted to the vice to keep track of the angular rotation. Figure 42 shows the bending under different weights.

Figure 42: Amount of deflection under load.

Since the moment arm varies with the weight, the moment arm for each weight is calculated using the formula's and Figure 43 below.

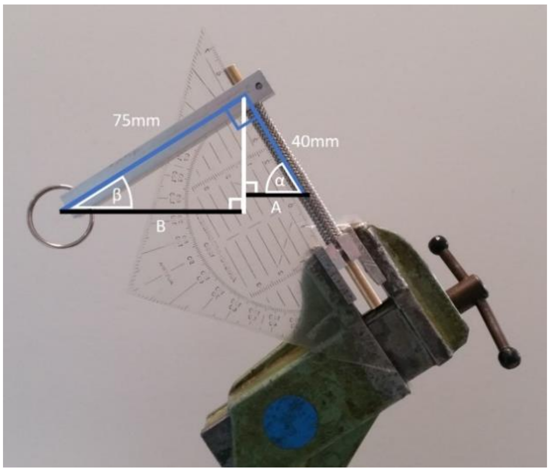


Figure 43: Goniometric representation of experimental setup.

The coupling is put in an angle of 60° relative to a horizontal position at the beginning of the experiment and in this orientation, the coupling is in the 0° position on the protractor. The total moment arm is $A + B$. To calculate A, the following formula can be used $A = \cos(\alpha) * 40, with\ \alpha = 60^{\circ} - angular\ displacement$. To calculate B, goniometri can be used giving $B = \cos(\beta) * 75, with\ \beta = 180^{\circ} - \alpha - 90^{\circ}$. The total moment arm is therefore: $A + B = \cos(\alpha) * 40 + \cos(\beta) * 75 = \cos(60 - angular\ displacement) * 40 + \cos(30 + angular\ displacement) * 75$. The corrected results are represented in the two graphs of Figure 44 and Figure 45 below.

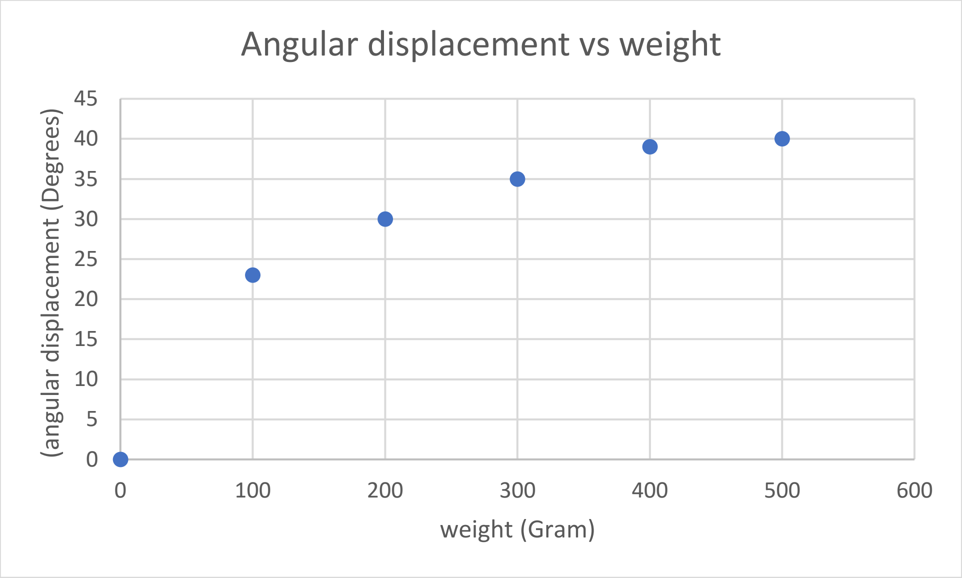


Figure 44: Graph of Angular displacement VS Weight.

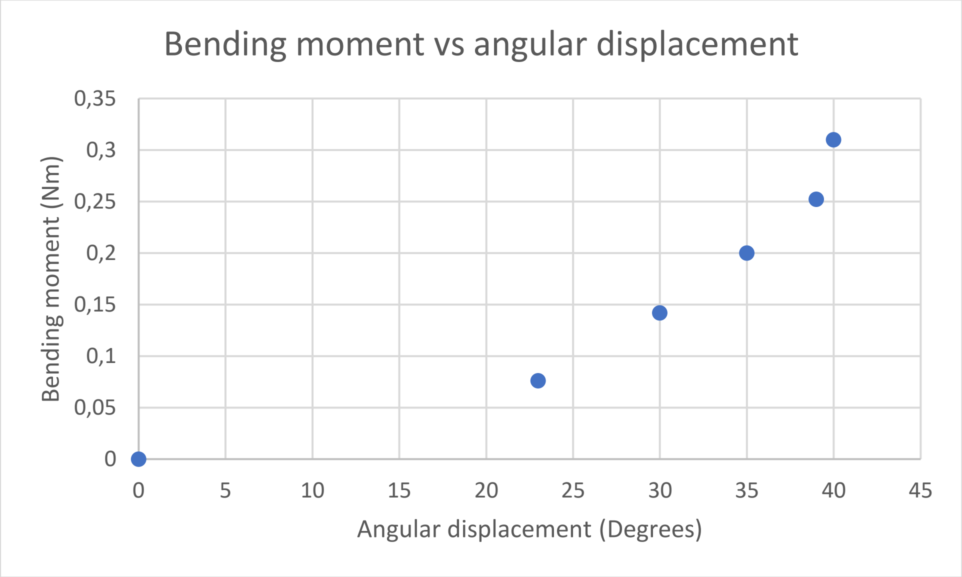


Figure 45: Graph of Bending moment VS Angular displacement.

From this graph it can be seen that an angular displacement of 60° is not achieved with a reasonable load. The first graph flattens at 40° and has the largest rise in the first 100 grams. This means that the structure and dimensions of the coupling increasingly prevent the coupling to achieve the desired bend. The required moment to bend the coupling, represented in the second graph, seems to increase exponentially and is too high to be delivered by the SATA mechanism. However, this flexible coupling is largely over dimensioned as can be seen from the torque experiments, which opens perspective to make changes to the structure to improve bendability.

The torque experiment described in Torque experiment setup and results is performed with the woven steel tube that can be seen on the left of Figure 46a below.

Figure 46a

Figure 46b

Figure 46c

This woven steel tube is a standard high-pressure stainless-steel tube with an outer diameter of 10 mm and a wire diameter of 0.2 mm. The flexible coupling experiment described above is initially performed with the coupling seen on the right side of the 10 mm tube in Figure 46a. This coupling is made by deforming the 10 mm tube to a 6.3 mm inner diameter and apply press fittings on the end to keep it in this shape. Although this coupling could transfer a decent amount of torque, it deformed readily easily. At the place of the hinge, the coupling started to bulge out and rapidly failed as can be seen in Figure 47.

Figure 47: Failing of 10 mm woven steel tube.

Therefore, another tube was obtained as can be seen on the left of Figure 46b. This tube has an outer diameter of 7.5 mm and an inner diameter of 6.3 mm and a wire diameter of 0.2 mm. A coupling is made from this tube without deforming it as can be seen on the right of Figure 46b. This coupling is used in the experiments described above because hardly any deformation could be observed, even under high loads. Because this coupling turned out to be hard to bend and highly over dimensioned, a new woven tube is tested.

This new tube has an outer diameter of 4.5 mm and a wire diameter of 0.1 mm. The coupling is obtained by deforming the tube to 6.3 mm inner diameter and applying press fittings to the ends. Deforming the original tube to get the desired dimensions weakens the structure as we have already seen with the coupling made from the 10 mm outer diameter woven tube. This weakening of the structure also happened by deforming this smaller tube, as can be seen in Figure 48 below.

Figure 48: weakening of 4.5 mm woven steel tube.

The results obtained from performing the same experiment as described above, with the coupling as can be seen in the right of Figure 46c, are presented in the graph of Figure 49 below.

Since the moment arm decreases when the coupling starts to deflect, the same as with the other coupling, the same correction for the moment arm is applied, giving: $moment\ arm = \cos(\alpha) * 75, with\ \alpha = angular\ displacement$. The graph below shows the amount of degrees the flexible coupling rotates under a certain torque.

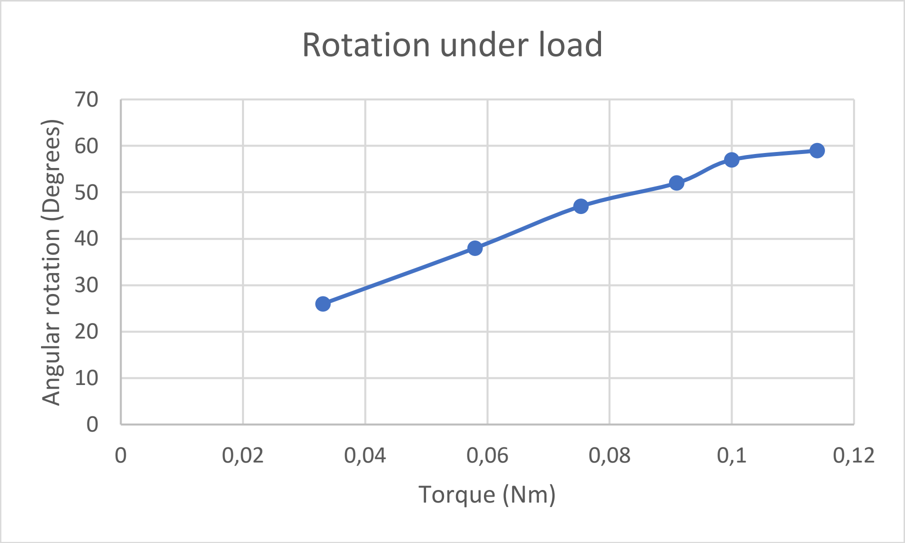


Figure 49: Graph of Angular rotation VS Torque.

An almost linear relation can be seen with an increase of 1° every 0.00193 Nm. With the worst-case scenario of a required cutting moment of 0.6 Nm, this would result in a rotation of 311° before the titanium wire is cut and this is unrealistic. The experiment is aborted at an application of 0.114 Nm since the coupling started to fail and the angular rotation became too large for the coupling to function properly.

The original 4.5 mm tube and the coupling made from it both were very pliable. The force it took to bend the coupling to 60° is so low, that the resolution of the measuring equipment was to coarse to measure it. However, this coupling could only lift 300 grams before it started to deform significantly, which corresponds to a moment of 0.114 Nm which is significantly less than the worst-case scenario of 0.6 Nm. Nevertheless, this experiment confirmed that deforming a woven tube to obtain the desired dimensions undermines the structural integrity and by adjusting the dimensions and wire thickness a coupling could be obtained that has the desired properties. Unfortunately, it was not possible within the scope of this project to obtain a piece of woven tube with the desired properties to test, because this would have to be custom made.

An overview of the results obtained from the experiments is presented below in Tabel 5. Since the desired coupling is not obtained yet, the table gives an indication of the required coupling

Tabel 5: Overview of obtained results from all the flexible coupling experiments.

	Structural integrity	Maximum load obtained from experiment	Bendability	
Standard high-pressure tube of 10 mm (Figure 46a left)	good	0.9 Nm	0.3 Nm for 90°	
Coupling made by deforming standard high-pressure tube of 10 mm (Figure 46a right)	poor	Failed	Failed	
Standard high-pressure tube of 7.5 mm (Figure 46b left)	good	0.9 Nm	0.3 Nm for 40°	
Coupling made from standard high-pressure tube of 7.5 mm (Figure 46b right)	good	0,863 Nm	0.3 Nm for 40°	
Woven steel tube of 4.5 mm (Figure 46c left)	good	N.A.	N.A.	
Coupling made by deforming woven steel tube of 4.5 mm (Figure 46c right)	poor	0,114 Nm	< 0.01 Nm	
Desired flexible coupling	good	0,6 Nm	< 0.4 Nm*	

N.A.: Coupling in this state could not be tested to obtain the values.

* Obtained from [8] by looking at the maximal sideways force that could be resisted at the end of the 20mm tip before damage occurred.

5 Concept evaluation

To make a choice between the concepts the advantages and disadvantages of these concepts have to be known. The advantages and disadvantages of all the concepts will therefore be discussed below.

5.1 Concept advantages and disadvantages

Concept 1 excels in that the premade clip blanks can be simple straight pieces of titanium wire and the overall instrument can be designed such that it is relatively small. A small instrument can be inserted in the patient through a small incision and could be useful in small space situations. The clip blanks however must be mounted on a carrier which makes it less simple than if it were just the clips. Another disadvantage is that the clip carrier return wire runs outside the instrument and must be pulled until a clip is locked in the friction lock, which leads to a large piece of unused carrier before the first clip and a difficult initial feed through.

Concept 2 has simple clip blanks, but a comprehensive clip blank carrier, since the connection strength between the wire and clip blank matters. This connection must be strong enough to start a bend and must break after this initial bend. The system with the wedges is also relatively complicated, which is a con. However, because of this system and the opening at the side of the instrument (wire outlet), the tip length can stay small while simple straight clip blanks can be used.

Concept 3 has a simple clip blank material and is insensitive to jamming after initial feed through while being relatively small. However, the instrument must be in a straight orientation for initial wire insertion. The forces required to cut the titanium clip blanks are sufficiently low for the instrument to handle.

Concept 4 is less elegant than concept 3 it still has a simple source material, no proneness to jamming and a relatively small construction. On top of that, the instrument does not have to be in a straight position for initial wire insertion. However, the cost for an instrument that does not have to be in a straight position for initial wire insertion, is a more difficult actuation process to transport the cut clip blank through the bending section and a more elaborate bending section design to prevent the clip blank from getting stuck.

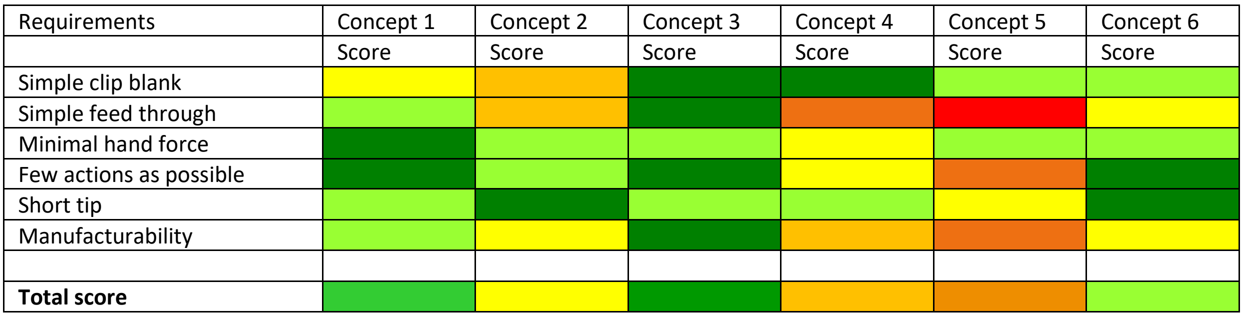
Concept 5 has many challenges in the overall design and its components. The space needed for the lever system to bring up one piece of wire will make the instrument difficult or impossible to handle comfortably, as can be seen in Figure 18. The extra grippers that grip the clip blank once the lever system brings it up, require a considerable amount of space, and the rotating cam is due to its mechanics very difficult to manufacture at such a small scale. One of the requirements is that the tip should be as short as possible to keep the end of the instrument close to the point of rotation. With this concept, this is simply not possible. On top of that it would be difficult to fit all the mechanics needed to operate the lever and rotating cam system into an instrument with the desired dimensions. Therefore, this concept is not desirable as a whole, but also its components, with exception of the flexible overtube, are not suitable solutions to the obstacle points as described in the flow chart.

Concept 6 uses clip blanks that have to be bent beforehand, there is no need for a carrier or difficult feed through, which is a pro of this design. The compactness of this design is another strong benefit. Since the clips are already bent, the tip length can be half that of designs such as concept 4, in which the clip is bend from a straight piece of wire. A disadvantage of this design is the complicated and difficult to manufacture wedge system.

5.2 Concept choice

The choice for the best concept is made with the help of an altered Harris profile. Instead of using a scale from + + to - - as in a normal Harris profile, this altered Harris profile ranks each concept relative to the other concepts depending on certain criteria. These criteria are some of the most important goals and can be seen in the left most column of Tabel 6. Each concept had to live up to the requirements and some of these requirements are black and white, as a figure of speech. These black and white requirements are not mentioned in Tabel 6 since no discussion is possible about them and the concepts had to fulfill them. The requirements used in the altered Harris profile can be seen as targets and the best concept will score the highest on these targets. A color will be appointed to a concept for each target, depending on how good the concept is ought to perform for the given target relative to the other concepts. This way the concept that will perform best for a given requirement will be marked with dark green, the second best will get light green, the third best will get yellow, the fourth best will get orange, the second last will get dark orange and the one that is ought to perform the least for the given goal is marked with red. If two concepts are ought to perform the same for a given target, they will receive the same color.

Tabel 6: Altered Harris Profile.



Requirements	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5	Concept 6
	Score	Score	Score	Score	Score	Score
Simple clip blank	🟨	🟧	🟩	🟩	🟩	🟩
Simple feed through	🟩	🟧	🟩	🟧	🟥	🟨
Minimal hand force	🟩	🟩	🟩	🟨	🟩	🟩
Few actions as possible	🟩	🟩	🟩	🟨	🟧	🟩
Short tip	🟩	🟩	🟩	🟩	🟨	🟩
Manufacturability	🟩	🟨	🟩	🟧	🟧	🟨
Total score	🟩	🟨	🟩	🟧	🟧	🟩

The Harris profile given in Tabel 6 shows that concept 2, 4 and 5 have a significantly lower rating than the other three concepts. The most noticeable difference between concepts 1, 3 and 6 is the type of clip blank material. Concept 1 has the most complicated clip blank material. It does not only need the titanium wire to be cut to length beforehand, but also to be mounted in a carrier with the right clamping force to transport it through the instrument. Concept 6 has the second most complicated clip blank since the clip blanks have to be cut to length and folded before they enter the instrument. Finally, the simplest clip blank can be found in concept 3, because a continuous piece of titanium wire can be fed into the instrument and the instrument will perform all the actions to make the eventual clip. Therefore, the type of clip blank material that is used also affects the complexity of the mechanism and the amount of required force. The feed through of the clip blank material in concept 1 is relatively simple since all the clips are pre mounted on a carrier. By pulling the return lead of this carrier, the blanks are transported through the instrument and a clip blank will be loaded in the jaws. An even simpler feed through can be achieved with the continuous wire since no return lead is required and the wire has no gaps or protrusions where the wire can get caught inside the instrument. Since the already bend clip blanks of concept 6 have no interconnection, these are the most difficult to feed through of the three concepts. The complete monolithic tip design of concept 6 could help in decreasing the number of actions needed to fire a clip. However, since concept 6 uses already bend clip blanks an extra action is required compared to the other two concepts. This extra action entails the opening of the clip before it can be clipped and closed again. This also leads however, to the possibility of a shorter tip. In concept 1 and 3 the tip length has to be minimally two times the length of the clip since the clip enters the tip straightened and is then folded to its final shape. In concept 6 the tip can be shorter since the clip enters the tip in its final shape and does not have to be fully unfolded. With the knowledge from the previous chapter, it became clear that concept 3, the concept with the continuous titanium wire cut at the surgical site, can be manufactured and that it takes very little hand force to perform the required actions.

As can be seen in Tabel 6, concept 3 comes out best, with the most balanced score and the least negative outliers. This way of choosing a concept gives a good indication of which concept is ought to be the most successful and is worth perusing first. Concept 3 has the most complete package. Concept 1 and 3 have, compared to concept 6 a simpler design. They have fewer precision parts that have to move such as the valve with the wedges as in concept 6 and are therefore ought to be less prone to malfunction and are easier to fabricate. On top of that, concept 3 has the simplest clip blank material. This will help in keeping the cost low, but is also a huge benefit to make the instrument reusable. When the titanium source material is not fully used during an operation, it can be easily sterilized and used in another operation. This could also be the case with more complicated clip blank materials, however, a simple spool of titanium wire is less prone to complications.

6 Final concept

Now that the experiments and the concept evaluation have shown that concept 3 is feasible and most promising, the design can be worked out completely. Certain design aspects have not been paid attention to previously because it would take too much time and it could be assumed with great reasonability that it would not pose big problems. However, attention must be paid to these topics in the final concept because they do concern vital parts of the design. Below the whole design will be discussed and all the choices will be explained.

6.1 Wire channel placement

Concept 3 is based on the main principle that the clips are cut and formed from a continuous piece of wire at the surgical site. The cutting experiments showed that it is possible to cut a titanium clip with the desired instrument and that the required force goes down when the radius where the wire enters the tip goes down. In theory, the wire should enter the head of the instrument through the center, so that the lowest possible force is required to cut the wire. However, in practice it is very difficult to cut the wire when it enters through the center with a rotating knife. A large rotation would be required and all the stress of the cutting action would be concentrated on the outmost tip of the cutting blade. The large rotation would result in a small section of the tip distal to the blade that would be connected to the rest of the tip proximal to the blade, weakening the overall structure of the instrument's tip. A trade-off is made between the required cutting force and the integrity of the tip. This led to the wire entering the tip 1 mm from the center of the tip as can be seen in Figure 50.

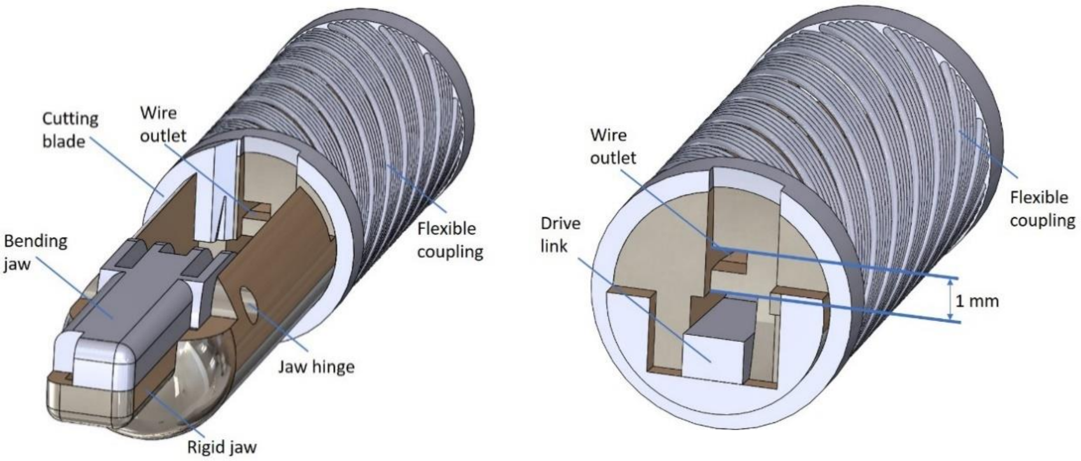


Figure 50: 3D model of tip design with cut through.

Although the design can be modified to allow many shapes and sizes of clip blank material, this first design is based on titanium wire with a cross-section of 0.5x0.8 mm. According to the calculations in concept 3 it would take 220 N to shear of a piece of titanium wire with the given cross-section. The blade starts to touch the material 1 mm from the center of the tip and this will be the worst-case scenario to cut the wire. Therefore, according to the model this would result in a maximum required moment to cut the wire of $220 * 0.001 = 0.22Nm$.

Letting the wire enter the tip off center had certain consequences. An advantage of the SATA mechanism is the relatively large open centric lumen through which items such as the clip blank material can be transported. Because this lumen arrives at the center of the tip, the wire must be directed of center into the tip. If the transport of the wire from the center to the location off center would be by means of a straight hole, the wire would continue in this direction when the wire is pushed through further and would not end up in the friction lock at the far end of the tip as can be seen in Figure 51.

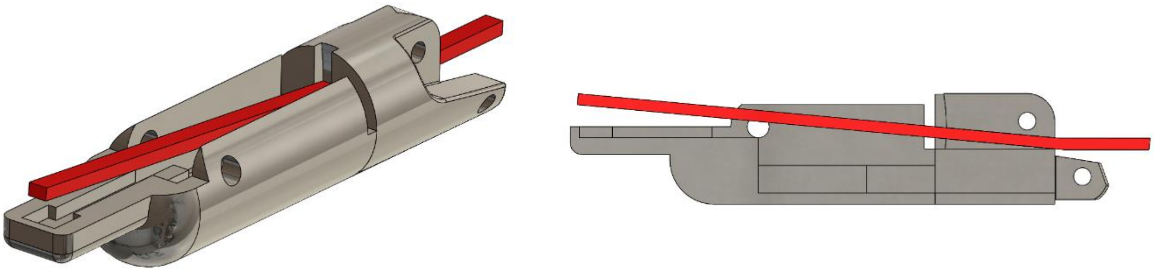


Figure 51: 3D model of tip with cut through of wire transport with straight entrance hole.

To avoid this, a hole with a bend in it is required so that the wire enters the sip in a slight downward direction. However, this makes the manufacturing of the tip more difficult. A benefit of the off-center placement of the clip blank material is that the center remains partially free. This available space can be used to store the mechanism that actuates the jaw. Finally, the whole working platform of the tip is placed off-center with respect to the center of the instrument as can be seen in Figure 52. This could require some getting used to when using the instrument, but it also offers some space in the tip to incorporate the opening and closing mechanism of the jaw.

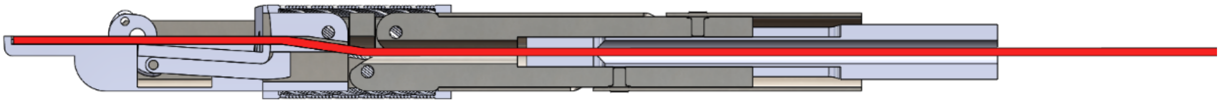


Figure 52: Cut through of instrument with bend wire entrance hole and off-center working platform.

The opening and closing mechanism consist of multiple links connected through hinges. This type of mechanism is chosen, instead of for example a rack and pinion system, because it is relatively simple and fail proof. A two-link mechanism is used as can be seen in Figure 53 because the movable jaw must make a rotation of over 180°. The design has been optimized to maximize the size of these links to ensure its strength. All the available space (created by the off-center jaw placement) is utilized for this opening and closing mechanism.

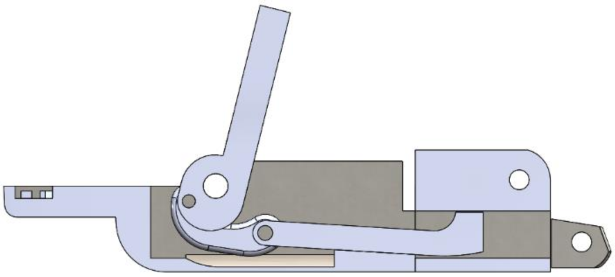


Figure 53: Cut through of link mechanism.

Since the clip blank must pass through the middle of the jaws, the middle of the movable jaw must remain free, meaning that the hinge pin of the jaw must consist of two parts (Figure 54). The link mechanism for the opening and closing of this jaw is seated at either side of the middle so that a symmetric force is exerted on this jaw which maximizes the strength.

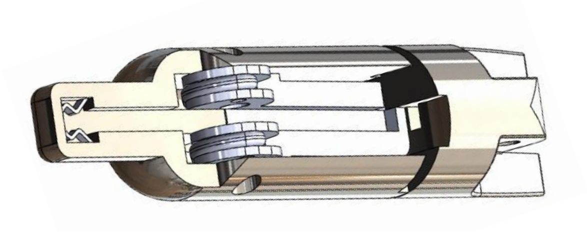


Figure 54: Jaw with free middle part.

The two links at either side of the jaw are connected to one central link, the drive link, that runs beneath the jaw (Figure 55). This link is connected to an actuation cable that runs through the shaft to the handle. This drive link also functions as a stop upon which the movable jaw rests in open position. This way the jaw cannot go beyond a certain point when open so that it can function as an anvil when the wire is cut.

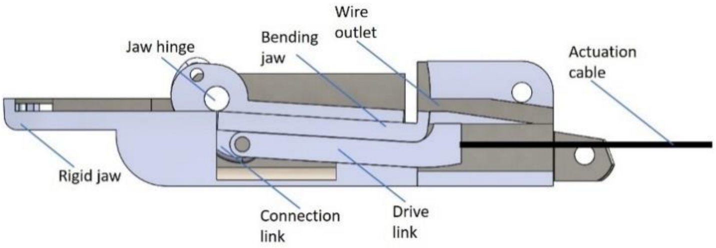


Figure 55: Cut through of the tip with all the links and connections.

6.2 First prototype (5:1 scale-up)

Throughout the design process an eye has been kept on the manufacturability. Especially on the scale in which this instrument will be manufactured, it is important to keep everything as simple as possible. Designing with a 3D modeling software is convenient, but certain aspects could be overlooked rather easily. Therefore, the final concept, as presented above, is 3D printed to check for functionality, manufacturability and possible design improvements. Printing the design resulted in the instrument presented in Figure 56 that is 500% larger than the actual design due to printability.

Figure 56: 3D printed prototype of final concept 500% larger than the original.

6.2.1 First prototype evaluation

This print gave insight into several aspects and possible improvements. The print quickly showed that the combination of the sloped bottom over which the drive link slides and the drive link didn't have the desired effect. During the closing action of the jaw, the drive link and the slope do not stay in contact leading to the drive link tilting up which results in all the hinges ending up on one line which locks up the system. On top of that, a slope, deep inside a hole, would be very difficult to make at this scale (Figure 57).

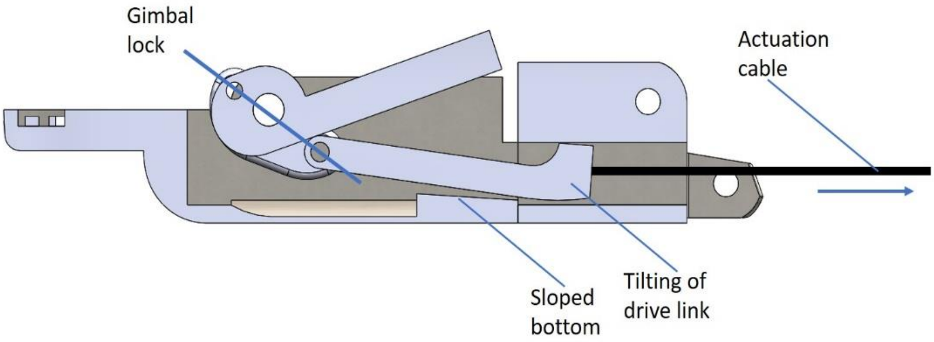


Figure 57: Gimbal lock of the instrument's tip.

Due to the design of the drive link and the angle under which it should operate, the link makes an up and downwards movement when it slides to open and close the jaws (Figure 58). This leads to in-effective use of the available space, the possibility for the drive link to tilt in the shaft and the connection cable to travel the same up and downward path. The drive link was made rectangular since it also acted as a stop upon which the movable jaw could rest when the titanium wire is cut (Figure 55). On retrospect a rectangular drive link is not convenient because a rectangular hole must be made to accommodate the drive link and a rectangular hole is difficult to make, especially on the ought scale.

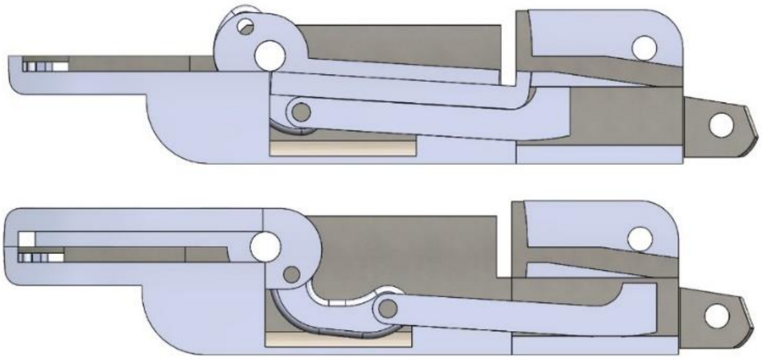


Figure 58: Up and downwards movement of drive link during jaw closure.

7 Final Design

Taking all the issues above into account, the tip is redesigned. The links are altered in such a way that no sliding under an angle is necessary and the drive link can make a straight sliding motion. This eliminates the need for a slope at the bottom of the jaw and the up and downward motion of the drive link during sliding. The drive link is made with a circular cross-section instead of a rectangular one to eliminate the need for a rectangular guidance hole. To prevent the drive link from tilting and letting all the hinges ending up on one line causing gimbal lock, this drive link hole and drive link should have a tight sliding fit. The head of the instrument could now have a flat bottom and a bottom would be necessary to provide counter pressure when the movable jaw rests on the drive link when the wire is cut. Instead, however, stopping ridges have been made on the sides of the head on which the movable jaw can rest during wire cutting to relieve the drive link from this load (Figure 59).

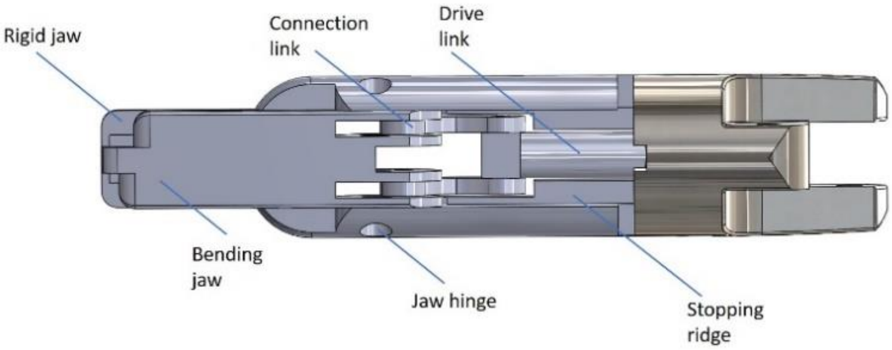


Figure 59: Top view of the tip with stopping ridges.

Since the drive link should have such a fit that it is guided in a straight line, the need for a bottom in the head is removed. Removing the bottom of the head is convenient for several aspects. The head becomes much easier to manufacture. Instead of making a deep hole with tight tolerances, a hole through and through can be made and the head can be worked from two sides. Also, the assembly becomes much easier when the internal linking mechanism can be reached from two sides. Finally, dropping the bottom improves cleanability and sterilizability because there are no hidden surfaces and the linkage mechanism can be easily accessed to flush and clean.

Even though a handle is not designed in this thesis, the handle of the instrument and the way the tip will be actuated is kept in mind throughout the design process. The way the clip blank material is provided to the tip and the way the tip is actuated is kept as simple as possible. This way a handle can be designed in the future with two simple outputs that is then connected to the instruments tip.

The goal is to make the instruments reusable and sterilizable, making the head bottomless helps in this aspect. The SATA mechanism is suited for sterilization due to the ability to be easily disassembled into a few cleanable parts. However, adding the flexible sleeve with the cutting blade over this mechanism complicates this easy disassembly. The flexible sleeve should also be disassembled to be able to be flushed, rinsed and sterilized. To achieve this, the head is redesigned such that it consists out of two parts as can be seen in Figure 60. These two parts can slide into each other and are secured with two screws.

Figure 60: Two parted tip of instrument.

Making the head in this way, resolves several problems. With this design the instrument is easy to disassemble and clean. Unscrewing the two screws enables the front part of the head together with the hinge mechanism to be taken away from the instrument, then the flexible coupling with the blade can be slid off and the rest of the sata mechanism can be disassembled as it was designed to do (Figure 61).

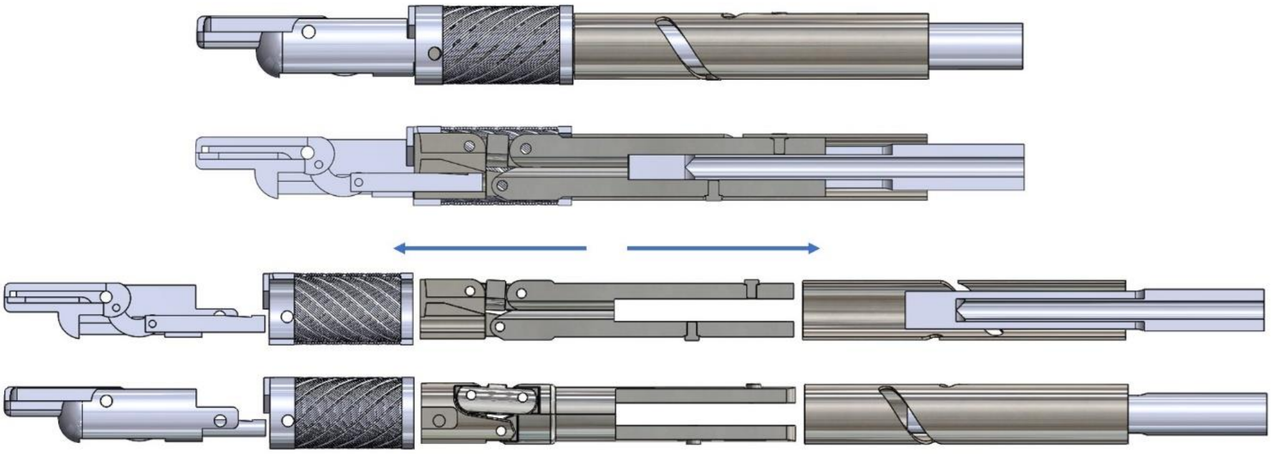


Figure 61: Assembled and disassembled overview of the instrument, with cut throughs.

Another benefit of a head made from two parts is that the blade is secured between the front part of the head and the back part. As observed in the experiments of titanium wire cutting, the blade tends to push itself of when it cuts the wire, leading to bending of the wire instead of cutting it. With the configuration described above, the blade cannot be pushed off, away from the backside of the head, leading to a well guided cut. Finally, the overall assembly of the head is made easy, because all the sub mechanisms can be assembled separately, after which the sub-assemblies can be assembled in the final instrument.

The manufacturing of the head becomes easier due to the two parts. More freedom in tool orientation is possible and tricky areas are easier to reach. One of these tricky areas and hard to manufacture features for example, is the rectangular hole from which the titanium wire enters the head. This hole must be rectangular to ensure the correct orientation of the wire in the head and has approximate dimensions of 0.5 by 0.8 mm. On top of that, it is convenient for this hole to have a funnel like shape so that the titanium wire aligns itself effortlessly with the hole through which it enters the head. Several manufacturing options could be used such as 3D metal printing, square hole drilling and broaching, however, to make such a hole at this scale, wire-edm could be the most successful. Since it is a challenge to make such a hole, it is convenient that the site is better accessible with a two parted head.

7.1 Second prototype (5:1 scale-up)

3D printing the final concept helped in evaluating the motion of the system and gave insights into possible improvements for the final design. To check if these alterations improved the functionality of the instrument, the final design is also prototyped using 3D printing, leading to the prototype presented in Figure 62 which is also printed on a 500% scale.

Figure 62: 3D printed prototype of the final design, 500% larger than the original.

This prototype quickly showed that the improvements had the desired effect and the system functioned smoothly. The 3D printed prototype gives the ability to evaluate the movement of the instrument, however, to evaluate if the instrument can perform the required tasks, some calculations must be made and linked to the obtained values from the performed experiments. As can be seen in Figure 63 on the next page, the titanium wire from which the clip blanks will be made enters the head of the instrument through a hole of which the top is 1 mm from the center of the instrument.

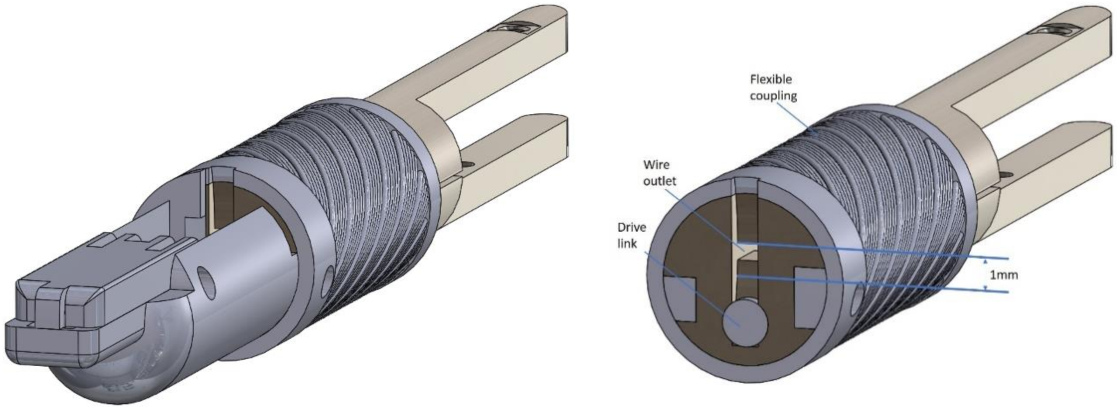


Figure 63: 3D model of tip design with cut through and entrance hole placement.

This means that the blade will have to start the cut 1 mm away from the center of the instrument. The blade will start the cut on the upper left corner of the wire, progressing in a diagonal fashion leading to a lower required force to cut the wire compared to a straight approach (Figure 64).

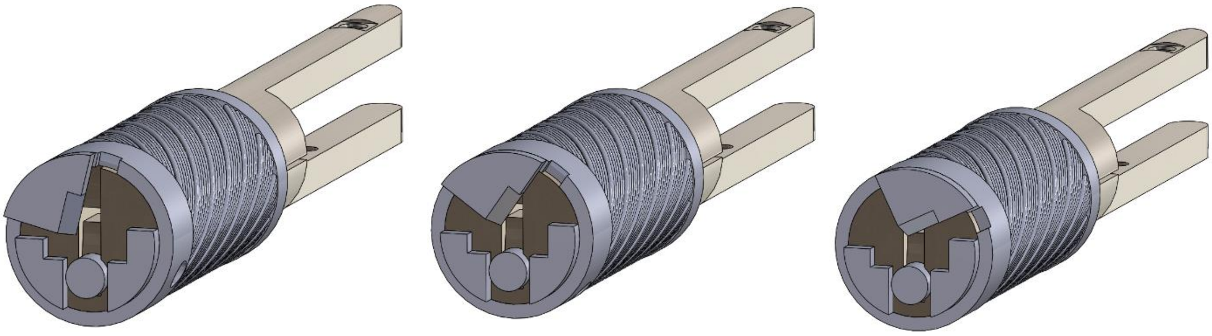


Figure 64: Blade progression during wire cutting.

Nevertheless, a shear force of 220N, as discussed before, will be used to calculate the required moment. With a distance of 1 mm, a moment of $220 * 0.001 = 0.22\ Nm$ will be required to shear of the clip blank from the continious titanium wire. This is well below the assumed worst-case moment of 0.6 Nm that was used to develop a flexible coupling that could transport the required moment over the steerable segment.

7.2 Finite Element Method (FEM) analysis

Now that it is shown that the instrument can move and function smoothly and the required moment can be transported properly, the last part that has to be evaluated is the link mechanism. When closing a clip blank, this link mechanism will experience relative high forces. To evaluate if this system can handle those forces without failing a Finite Element Method (FEM) analysis is made using the model created in Solidworks.

To perform the analysis, a material is appointed to the parts. In this case everything is made from 316 stainless steel. From the experiments with bending the titanium clip blanks, values for the required closing forces are obtained. During this experiment it became clear that in each closing cycle the highest forces are required when the clip is closed all the way and has to be compressed. Therefore, the FEM analysis is performed with the link system in an orientation that resembles the closed position of the instrument as can be seen in Figure 65. From the 9 results of the performed experiments as described in the section of Results of Compression experiment, the highest value after correction for the friction in the setup is 0.042 Nm. The force that is exerted by pulling the drive link backwards is transported by the connection links to the movable jaw that exerts the force on the titanium clip. This process is imitated in the FEM analysis by applying a force on the groove in which the clip blank normally lies that results in a moment of 0.05 Nm. The hinge around which the movable jaw pivots is considered as fixed, as well as the end of the drive link to let the system be in equilibrium.

Performing the analysis in this way, resulted in Figure 65 below. The color scale is adjusted in such a way that red indicates all stresses above the yield strength and a little below to provide a safety margin.

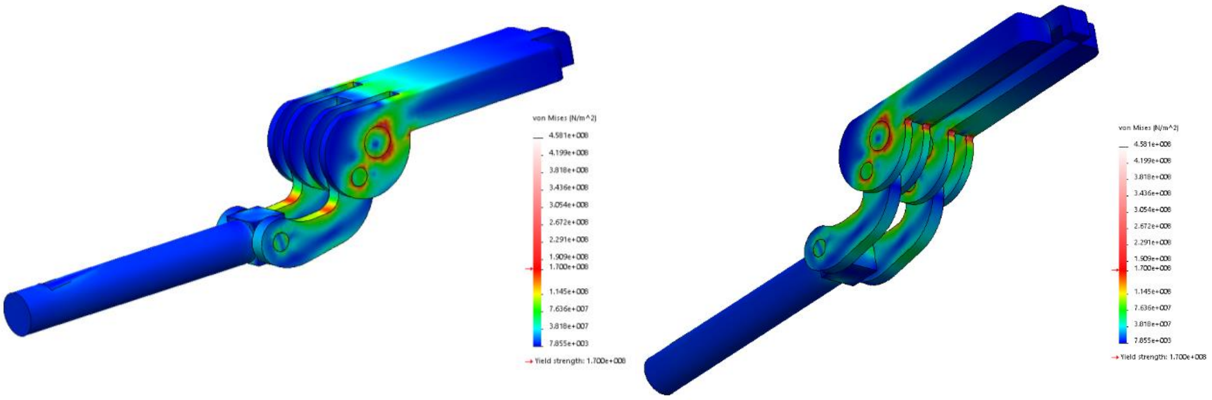


Figure 65: Finite Element Method analysis of clip compression.

In the figures it can be seen that there are certain points that suffer from a stress concentration and are likely to fail when repeatedly subjected to the required forces. The stress concentration around the axes indicate compression and are probably due to the limitations of the program in handling concentrations of stress and will not cause the system to fail.

The other stress concentrations are located in spots in which it makes sense that the stress could be higher there. To make sure that these spots will not become weak points and cause a failure of the instrument, they are adjusted so that they will guide the stresses in a better way. To achieve this, the curve of the connection links is adjusted and sized up to the maximal possible size while maintaining enough clearance to let the system function smoothly. The stress concentration in the corners of the movable jaw is created due to sharp angles there. A fillet is made in these corners to eliminate this stress concentration. Performing the FEM analysis again with the adjusted model gives the results as can be seen in Figure 66 below.

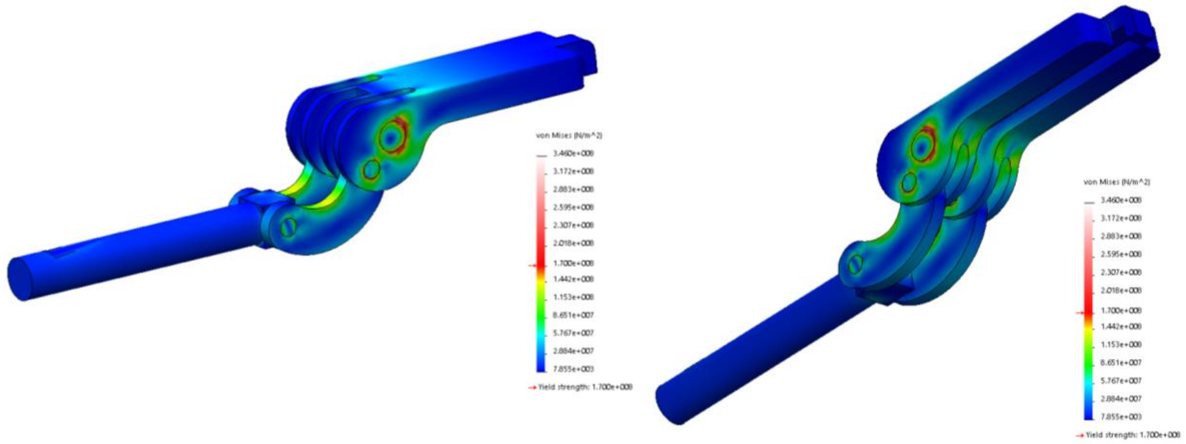


Figure 66: Finite Element Method analysis of clip compression after adjusting stress concentrations.

The adjustments to the design lead to stresses well below the yield strength, indicating that this design should be able to bend and compress the clips without major deformations and failure of the mechanism.

In this model the presence of tissue between the closing jaws when the clip is compressed is not taken into account. The tissues that are normally clipped are very compliant and would not contribute significantly to the required moment. When tissue is seated between the jaws, the force transmission would be slightly different. However, since the simulation is performed with the jaws in the worst possible position, opening the jaws a little bit to let tissue in, would result in a more efficient force transmission, leading to lower stresses in the members of the mechanism. Nevertheless, a moment approximately 20% higher than the highest measured required moment to close a clip is used to perform the simulation to account for unforeseen aspects.

7.3 Final prototype (2:1 scale-up)

Now that is validated that the designed instrument functions properly, a prototype is made that is 200% larger than the original instrument. This is the closest approximation of the eventual instrument that could be achieved with the available resources. This prototype is partially resin printed as can be seen in Figure 67. All the axles and links are made out of steel with the help of a lathe and milling machine.

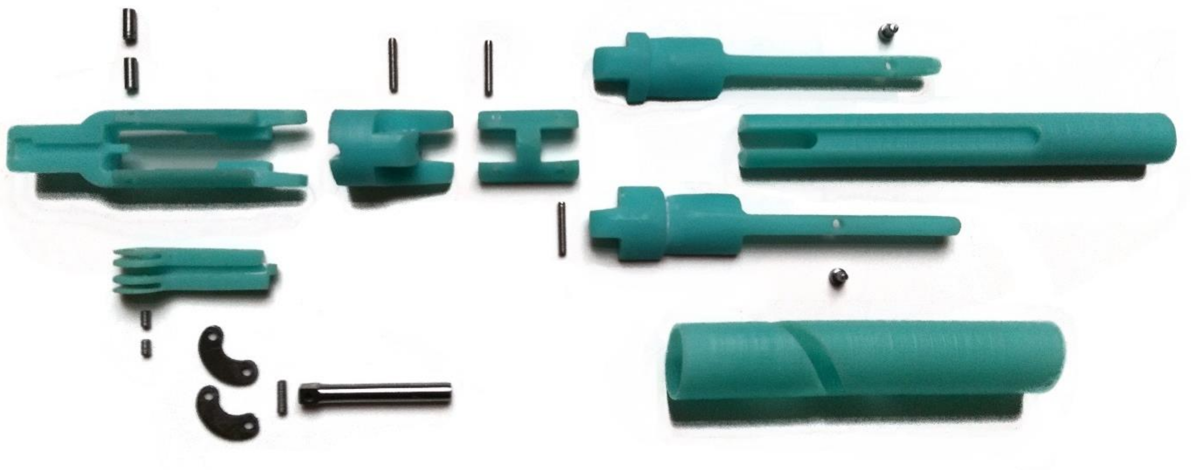


Figure 67: 3D resin printed prototype of the final design, 200% larger than the original.

Even though this instrument is still two times as large as the original system, it gives a better indication of the eventual instrument. The assembled prototype is shown in Figure 68.

Figure 68: 3D printed prototype of the final design, 200% larger than the original.

8 Discussion

8.1 Compression experiment

In the closing experiment, the clips did not close completely over the whole length. This is probably due to the lack of support over the full length of the clip during bending. The test setup is also 3D printed and therefore not as rigid as the eventual stainless-steel version. The friction between and flexibility of the parts of the 3D printed setup can also be assumed to have an influence on the smooth closing of the clips. Although a dry run is performed, to investigate the friction in the setup, the deformation of the setup under the load of bending a clip could increase this friction. This, again, could be considered as a worst-case scenario and therefore valuable for the design process. The eventual real instrument will be made of stainless steel and will consequently be less flexible than the plastic of the 3D print. This will lead to less friction and other losses and will result in a lower required moment to close the clips.

8.2 Cutting experiment

In the experiment of determining the required cutting torque, there were some limitations. The setup used to perform the experiment should resemble a simplified instrument tip. Looking at the dimensions and the overall buildup this is accomplished well. However, this setup had some limitations. First of all, the hole through which the titanium wire emerged was round and did not have the same shape as the wire. This made it possible for the wire to rotate and deform when it was cut, which is unfavorable for cutting. The imperfect cutting edge of the blade also influenced the cutting force. With more appropriate instruments, a better edge could be made which is beneficial for lowering the required cutting force. Another limitation is that the cutting blade wants to push itself away from the part from which the wire emerges when it starts to cut the wire. It is tried to prevent this by attaching a spring to the tube with the cutting blade and keep a downward tension on the whole setup. This made it possible to cut the wire, but has an influence on the required cutting force. In the final design these aspects are taken into account. The push off is solved by locking the blade in position, the cutting blade will have a better cutting edge and the hole from which the wire emerges has the same shape as the wire to prevent rotation of the wire and eventually incorrect closure. The required cutting torque as obtained from the experiments will consequently be higher than the required cutting torque in the eventual real situation. The results from the experiments can be considered as worst-case and are therefore valuable to use in the development of the BOSS clip applier.

When the titanium source wire would be round, rotation of the wire during cutting would not matter. Also, the orientation would no longer be an issue and the hole through which it enters could be round, making it easier to manufacture. However, a round wire has no preferable bending direction which leads to the possibility for misalignment in bending. Since the clips that are available on the market have a rectangular cross-section the choice is made to design the instrument to form clips made from wire with the same rectangular shape.

8.3 Flexible coupling experiment

In the last series of experiments, concerning the flexible coupling, the deformation of the couplings and the connection between the ends of the coupling and the moment arms posed the biggest challenge. This showed that for the eventual instrument a coupling should be made that does not has to be deformed to get the right dimensions. Also, the connection between the flexible coupling and the tube that actuates it, should be one that can withstand the cutting torque plus a safety margin, and will probably not be a press fitting. The results showed however, that most of the couplings started to deform before the press fittings failed. The instance in which the press fitting failed before deformation of the coupling was at such a high torque that the worst-case cutting torque was already achieved. The results from these experiments are therefore not diminished by the press fittings and are valuable to use in the design process.

According to the calculations of the required cutting force and the dimensions of the final design a required cutting torque of 0.22 Nm was obtained. A worst-case cutting torque of 0.6 Nm is used during the design process, however, the eventual cutting torque will be much lower. The experiment with the flexible coupling made from the 4.5 mm outer diameter woven steel tube showed that a torque of 0.114 Nm could be achieved with a large rotational deformation before failing. Taking the properties of the other tested couplings in mind, it becomes clear that a coupling made of a similar woven steel tube without deforming it, will achieve the required specifications.

Finally, at the end of the flexible coupling experiment section, the values for the desired coupling are given. Here it is indicated that the desired coupling should have a bendability below 0.4 Nm. This value however is obtained by looking at the maximal force that could be resisted by statically pressing the tip, of one of the earliest prototypes of a SATA instrument, to a rigid surface. This value will differ from the moment that the SATA mechanism can deliver by actuation due to internal deflection and resistance. It is however a good indication of what kind of moments we are dealing with and newer versions of the SATA mechanism can handle much higher forces.

8.4 Prototype

The working principles of the different mechanisms were successfully proven with the build prototypes. The first prototype quickly showed that the linkage mechanism could use improvements and helped in making the final design. The second prototype worked as desired and showed that the alterations to the design had the desired effect. The mechanism worked properly and that the instrument could be quickly disassembled for easy sterilization. Combined with the results from all the experiments, a result is achieved that shows an instrument that can function and perform the desired actions even in all the worst-case scenarios. The final prototype gave a better insight in the eventual size of the instrument. The 3D printed prototypes are therefore a quick and easy way to check if the design functions as planned and how it will look eventually.

8.5 Final design

In this section the in Design requirements formulated requirements will be discussed and whether or not they are accomplished.

The eventual designed instrument forms V shaped clips of 7mm in the tip out of titanium wire. This clip blank material is extremely simple and is provided to the tip through the instrument. The instrument is also able to harbor the driving mechanism alongside the titanium clip blank material inside the instrument's shaft. This shaft can have such a small diameter that even with the flexible coupling on the outside the overall diameter did not exceed 8mm. The following requirements are therefore met.

- Clip must be as simple as possible
- Clip material must be supplied to the tip through the instrument
- Instrument must be able to transport clip material and harbor driving mechanism inside the shaft
- Instrument must be able to apply V shaped titanium clips of 7 mm
- Instrument must be inserted through a trocar not larger than 8 mm

The tip of the eventual design is not as short as some of the tips of the other concepts as can be seen in the section of Conceptual design. The following requirement concerned the length of the instrument's tip.

- Complete tip must be as short as possible to improve steerability and consequently accuracy

This requirement is for filled, because even though there are concepts with a shorter tip, the final design is superior on many levels compared to these other concepts and the slightly longer tip is a good compromise. The tip has an open structure making it possible to see what is going on during clip application and the tip is able to close the clip completely and can withstand the relatively high forces encountered when the clip is compressed as shown in the sections of Compression experiment and Finite Element Method (FEM) analysis. These forces can easily be delivered by hand without much effort. Therefore, the following requirements are also met.

- Tip orientation must be trackable and distinguishable with a standard endoscope, making the process visually inspectable
- Instrument must apply reliable sealing
    - close clip completely
    - provide excessive compression force
    - Proper alignment
- The device must require no more than daily hand force to operate

The following requirements are met by using the SATA mechanism as the steerable segment. The rest of the instrument is designed in such a way that no limitations are imposed on this steerable section.

- Instrument must articulate in at least 1 DOF
- Instrument must bend, hold the bend and withstand perturbations
- Instrument can make a bend of minimally 50°

Besides the actuation of the SATA mechanism, the instrument requires tree steps to form and apply the clips. The titanium wire has to be pushed forward, the rotation of the blade can then cut of a clip blank after which the clip can be applied by pulling the actuation cable to close the tip. The number of actions required to fire a clip is therefore minimal. The actuation is also completely mechanical and can be stopped at every moment if desired. This way of firing a clip allows the instrument to remain really simple. With a properly designed handle some of these steps such as pushing the wire through and cutting it could be combined making the instrument operable with one hand. The few parts out of which it consists can be easily disassembled which makes sterilization and maintenance easy. These advantages helped this concept to emerge as the best from the evaluation and caused the following requirements to be met.

- The focus must lie on a sustainable design with minimal maintenance
- The instrument must require as few actions as possible to fire a clip
- The insertion, movement and rotation of the instrument and firing of the clip must be able to do with one hand
- The device must be ergonomically to operate
- All movements should be mechanically actuated without the use of external factors or forces
- The device must be able to be stopped at certain intervals

Finally, there is the following list of requirements for which it cannot yet be said whether they have been achieved or not since the instrument is not manufactured and clinically used yet.

- Instrument must be biocompatible
- Instrument must function under influence of bodily fluids
    - Fluids may not cause to much friction
    - Fluids may not cause heat generation
    - Fluids may not cause visual obstruction
- Instrument must withstand sterilization processes
- The products life span should be as long as possible
- The device must be robust enough to be handled, disassembled and transported to and from the sterilization
- The instrument must be able to be manufactured by standard instrument makers, meaning that it should be able to be made by people with an education for high precision small mechanics fabrication with standard high precision manufacturing machines
- The device must have a finish that is compatible with sterilization processes
- The used materials must be biocompatible.
- The used materials must withstand sterilization processes
- The instrument must function for a certain number of times as a reusable instrument
- The instrument must be safe for patient without any sharp edges or attachments
- The instrument must be safe for surgeon without any sharp edges or attachments

The biocompatibility is tried to ensure by using stainless steel throughout the entire design. This stainless steel is also resistant to sterilization processes and the components are designed in such a way that they should be sterilizable and not break during handling, disassembly, sterilization and transport. Considerable effort has been put into designing the instrument in such a way that it can actually be manufactured. This seems to be accomplished well and the prototypes support this notion. Looking at all the requirements and how they are met, the eventual design is really satisfactory and successful.

8.6 Relevance to and impact on field

Since the design of the BOSS clip applier is successful, it could have an impact on the field. Using clips can lead to a comparable or even better surgical result than using hand sown sutures, but require shorter operation times [36], [37]. Clip appliers that can apply multiple clips without the need for reloading, such as the InScope MultiClip applier have shown their ability for good closing and even greater time reduction [38]. The reduction of treatment time and facilitation of work due to the elimination of clip reloading, even in an instrument with only tree clips in the cartridge (ClipMaster3), can have an added value especially in cases with active bleeding [39]. It goes without saying that an instrument like the BOSS clip applier, that can apply numerous clips without the need of reloading or retraction, can be a valuable addition to a surgeon's instrumental arsenal.

Even though clip appliers are cost effective compared to for example vascular staplers [40], the main factor influencing the high total cost of laparoscopic surgery is the high costs of laparoscopic instruments [41]. While factors such as patient outcomes, shorter hospital stay and operation times are all beneficially effected by the use of clip appliers and help lowering the cost of laparoscopic surgery, the high instrumental cost nullifies this. The BOSS clip applier overcomes this problem by being fully reusable and omitting the need for specialized clips.

The BOSS clip applier is designed as a handheld instrument, but can easily be adapted to be used in robotic surgery because of the simple actuation and such an instrument has high potential in robotic surgery [42]. Due to the restricted workspace in minimally invasive surgery, the ability to apply a clip under an angle showed its value early on [43]. Since it was so difficult to obtain a steerable instrument, workarounds have been developed. A set of 6 clip appliers with different angles for example have shown great utility in over 250 surgical trials [44]. Attempts have been made by for example Covidien to develop a steerable clip applier that can apply multiple clips [21] [22] [45], but they have all resulted in bulky and difficult to steer instruments because all the clips are located between the jaws and the hinge. Even clip appliers with a fixed angle are developed to be used in specific instances such as closing of intercavernous sinus bleeding during sellar dural opening in transsphenoidal surgery [46].

Articulating clip appliers such as the OMNIFinger, which is commercially available [16], are popular even though it can only apply one clip at a time since there are no better alternatives. The BOSS clip applier is designed to offer a better alternative and overcome the above mentioned problems, help minimally invasive surgery a step further and instead of expanding the surgeon's instrumental arsenal shrink it by providing an instrument that is modular and combines multiple capabilities.

9 Conclusion

With this thesis it is showed that it is possible to create a functional model of a steerable clip applier that automatically cuts and bends clips from a continuously inserted wire. Besides this unique approach, the instrument is constructed in a way that complete cleaning, inspection and sterilization in the reprocessing phase remains facilitated. Looking at the outcomes of al the experiments, along with the 3D printed prototype, it can be assumed that the final product will function correctly. All the tested aspects showed that they could hold up and work well on their own. Therefore, combining all these parts in a complete instrument will provide a device that can perform the ought functions and will not fail performing the desired tasks. Since the design is kept simple, it is relatively easy to fabricate the instrument and adjust it to specific wishes, such as clip size. The simple clip blank material also provides the possibility to replace it with another material that could offer different properties, Therefore, this thesis provides a versatile and modular instrument of which its working principles are proven.

10 Future work and recommendations

The result of this whole design process is a resin printed prototype 200% larger than the ought instrument. Although this is a successful proof of principle and all the distinct components are tested or simulated, a real scale metal prototype is required to really test the instrument for its functionality. Therefore, making a real scale metal prototype would be one of the first follow-up steps to develop this instrument into a commercially available instrument. With this prototype, bench top tests could be performed and eventually, possibly clinical trials.

Since the developed instrument is so versatile and the clip source material is so simple, the device lends itself perfectly for different clip source materials. It could for example be very interesting to look into the option of using a dissolvable clip source material. The titanium clips that are used nowadays are left indefinitely in the patient. These clips do not react with the body and can generally be left without any problems at the surgical site. However, titanium clips can diminish the quality of CT and MRI images [47] and postoperative clip migration can cause problems leading to the need for clip extraction [48]. Clips such as the Hem-O-Lock are made from polydioxanone [4]. These clips have a specific shape and have a latching system to lock. However, if these clips are provided in a pre-shaped string, they could be cut out and shaped in the tip of the instrument. Another alternative clip source material, that is worth looking into in the future, is for example the magnesium alloy clip material developed in [47] which is safely absorbed by the body after a period of time.

All this considered, the instrument developed in this thesis is very versatile and can be a useful diving board for the further development of multiple instruments.

11 References

[1] P. Breedveld, H. G. Stassen, D. W. Meijer, and J. J. Jakimowicz, “Manipulation in Laparoscopic Surgery : Overview of Impeding Effects and Supporting,” *Laparoendosc. Adv. Surg. Tech.*, vol. 9, no. 6, pp. 469–480, 1999.

[2] R. Berguer, D. L. Forkey, and W. D. Smith, “Ergonomic problems associated with laparoscopic surgery,” *Surg. Endosc.*, vol. 13, pp. 466–468, 1999.

[3] S. F. Hardon, F. Schilder, J. Bonjer, J. Dankelman, and T. Horeman, “A new modular mechanism that allows full detachability and cleaning of steerable laparoscopic instruments,” *Surg. Endosc.*, vol. 33, no. 10, pp. 3484–3493, 2019.

[4] G. Kelling, H. C. Jacobaeus, R. Kortsch, C. Fervers, T. Stolze, and H. Kalk, “Operative (Surgical) Laparoscopy,” in *Biomedical Engineering in Gastrointestinal Surgery*, 2017, pp. 307–309.

[5] K. H. Fuchs and W. Breithaupt, “Transgastric small bowel resection with the new multitasking platform EndoSAMURAI for natural orifice transluminal endoscopic surgery,” *Surg. Endosc. Other Interv. Tech.*, vol. 26, no. 8, pp. 2281–2287, 2012.

[6] E. Pikoulis *et al.*, “Arterial reconstruction with vascular clips is safe and quicker than sutured repair,” *Vascular*, vol. 6, no. 6, pp. 573–578, 1998.

[7] J. W. Lee *et al.*, “Anastomosis of vessels less than 2 mm with the vascular clip system clip applier,” *Journal of Korean Medical Science*, vol. 16, no. 3. pp. 303–308, 2001.

[8] T. Horeman, F. Schilder, M. Aguirre, G. M. M. J. Kerkhoffs, and G. J. M. Tuijthof, “Design and Preliminary Evaluation of a Stiff Steerable Cutter for Arthroscopic Procedures,” *J. Med. Device.*, vol. 9, no. 4, p. 044503, 2015.

[9] M. S. Peyser, D. J. Cuny, D. W. Strauss, S. W. Reed, C. L. Rethy, and E. Aranyi, “Surgical clip applier. U.S. Patent No 5,700,270,” 1997.

[10] D. T. Green, H. Bolanos, D. E. Alesi, and K. E. Toso, “Surgical clip applier. U.S. Patent No 5,591,178,” 1997.

[11] Menges et al, “FOLDING CARTRIDGE FOR A MULTIPLE CLP APPLIER. U.S. Patent No 4,491,133,” 1985.

[12] Burbank III et al., “LIGATING CLIP APPLIER. U.S. Patent No 5,431,668,” 1995.

[13] Ahlberg et al, “MULTIPLECLIP APPLIER APPARATUS AND METHOD. U.S. Patent No 8,529,588 B2,” 2013.

[14] DiGiovanni et al., “MULTIPLE CLIP APPLIER. U.S. Patent No 4,500,024,” 1983.

[15] Shelton IV et al., “REPLACEABLE CLIP CARTRIDGE FOR A CLIP APPLIER. U.S. Patent No 9,649,111 B2,” 2017.

[16] Grena, “OMNIFinger^{TM} Articulating Endoscopic Clip Appliers - Grena Ltd.,” *https://www.grena.co.uk/our-products/ligating-clips/373-omnifinger-appliers*, 2020. .

[17] A. Crockard, “Endoscope device for applying an aneurysm clip. U.S. Patent No 5,174,276,” 1992.

[18] P. Menn, “Articulating Steerable Clip Applier for Laparoscopic Procedures. U.S. Patent No 9,918,715,” 2018.

[19] W. D. Dannaher, “Surgical clip applier with articulation section. U.S. Patent No 9,220,508,” 2015.

[20] K. W. Smith, J. A. Kortenbach, R. Sixto Jr, and C. R. Slater, “Flexible surgical clip applier. U.S. Patent No 6,824,548,” 2004.

[21] K. Whitfield and C. L. Rethy, “Articulating clip applier. U.S. Patent No 8,968,337,” 2015.

[22] K. H. Whitfield and C. L. Rethy, “Articulating endoscopic surgical clip applier. U.S. Patent No 8,403,945,” 2013.

[23] F. D. Daschner, S. Adler, M. Scherrer, and K. D. Ru, “Comparison of economic and environmental impacts between disposable and reusable instruments used for laparoscopic cholecystectomy,” pp. 268–272, 2005.

[24] N. Vasios, M. Verroiotou, G. Komninos, S. Arapoglou, and G. Fragandreas, “Study of the Cost of Mainly Reusable Equipment for Laparo- scopic Cholecystectomy,” *Hell. J. Surg.*, vol. 85, no. 2, pp. 101–104, 2013.

[25] J. Siu, A. G. Hill, and A. D. Maccormick, “Systematic review of reusable versus disposable laparoscopic instruments: costs and safety,” *ANZ J. Surg.*, no. 87, pp. 28–33, 2016.

[26] AppliedMedical, “Epix® Universal Clip Applier.” 2019.

[27] B. Braun, “AESCULAP ® Challenger ® Ti.” .

[28] Genicon, “A Li-Gator Disposable Clip Applier.” 2016.

[29] Ethicon, “Ethicon product catalog.” p. 45, 2018.

[30] E. Yung, M. Gagner, A. Pomp, G. Dakin, L. Milone, and G. Strain, “Cost Comparison of Reusable and Single-Use Ultrasonic Shears for Laparoscopic Bariatric Surgery,” *OBES SURG*, vol. 20, pp. 512–518, 2010.

[31] P. H. Deprez, Y. Horsmans, M. Van Hassel, and P. Hoang, “Disposable versus reusable biopsy forceps : a prospective cost evaluation,” *Gastrointest. Endosc.*, vol. 51, no. 3, pp. 262–265, 2000.

[32] J. Arata *et al.*, “Articulated minimally invasive surgical instrument based on compliant mechanism,” *Int. J. Comput. Assist. Radiol. Surg.*, vol. 10, no. 11, pp. 1837–1843, Nov. 2015.

[33] “Titanium Ti-6Al-4V (Grade 5), Annealed.” .

[34] matweb, “ASM Material Data Sheet,” *http://asm.matweb.com/search/SpecificMaterial.asp?bassnum=mq304a*, 2020. .

[35] Optoforce, “ESCAD_OPTOFORCE_Kraftsensor_Hex-H.” pp. 1–3, 2017.

[36] C. J. Zeebregts and et al, “NONPENETRATING VASCULAR CLIPS FOR SMALL-CALIBER ANASTOMOSIS,” *Microsurgery*, vol. 20, no. March, pp. 131–138, 2000.

[37] F. Catena, M. La Donna, S. Gagliardi, A. Avanzolini, and M. Taffurelli, “Stapled Versus Hand-Sewn Anastomoses in Emergency Intestinal Surgery : Results of a Prospective Randomized Study,” *Surg. Today*, no. 34, pp. 123–126, 2004.

[38] G. S. Raju, I. Ahmed, S. Xiao, and D. Brining, “Controlled trial of immediate endoluminal closure of colon perforations in a porcine model by use of a novel clip device (with videos),” *Gastrointest. Endosc.*, vol. 64, no. 6, pp. 989–997, 2006.

[39] F. Y. Hondo *et al.*, “Endoscopic Therapy with a Novel Multiple Clip Applicator (ClipMaster3) in the Upper and Lower GI-Tract,” *Gastrointest. Endosc.*, vol. 67, no. 5, p. 2008, 2008.

[40] A. Nouralizadeh, A. H. Kashi, and N. Moosanejad, “Vascular Clips Are Safe and a Great Cost-Effective Technique for Arterial and Venous Control in Laparoscopic Nephrectomy : Single-Center Experience,” *Endourology*, vol. 26, no. 8, pp. 1009–1012, 2012.

[41] Ï. Lu, E. O. Hamamci, H. B. M, S. Bostanog, and A. Korkmaz, “Use of Laparoscopic Splenectomy in Developing Countries : Analysis of Cost and Strategies for Reducing Cost,” *Laparoendosc. Adv. Surg. Tech.*, vol. 12, no. 4, pp. 253–259, 2002.

[42] F. A. Buzad *et al.*, “Single-site robotic cholecystectomy : efficiency and cost analysis,” *Med. Robot. Comput. Assist. Surg.*, vol. 9, no. March, pp. 365–370, 2013.

[43] T. Note, S. Suzuki, H. Ohkuma, T. Sekiya, and K. Ebina, “A Flexible Aneurysm Clip Applier,” *Acta Neurochir. (Wien).*, vol. 135, pp. 201–202, 1995.

[44] R. Solomon and T. Fukushima, “New Aneurysm Clip Appliers for ‘Key-Hole’ Neurosurgery,” *Neurosurgery*, vol. 28, no. 3, pp. 474–476, 1991.

[45] K. N. Cloutier *et al.*, “Articulation : A New Innovation to Clip Appliers for Use in Minimally Invasive Surgery,” in *37th Annual Northeast Bioengineering Conference (NEBEC)*, 2011, pp. 1–2.

[46] Y. Hong, S. Chen, S. Guo, J. Yu, Q. Wu, and J. Zhang, “A new technique for management of intercavernous sinus bleeding with titanium clips in transsphenoidal surgery,” *Neurol. India*, vol. 58, no. 6, pp. 2–6, 2020.

[47] Kobe University, “Dissolvable surgical clip , 5 mm in size , made of a magnesium alloy,” *ScienceDaily*, 2015.

[48] G. A. Turini *et al.*, “Intravesical Hemostatic Clip Migration After Robotic Prostatectomy : Case Series and Review of the Literature,” *J. Laparoendosc. Adv. Surg. Tech.*, vol. 26, no. 9, pp. 710–712, 2016.

Appendix A: MATLAB scripts

```
Measurement1 = readtable('woven steel tube');

plotfunction(Measurement1,1)
```

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```
function plotfunction(Measurementdata,plotnumber)
```

Creating plots

```
TimeStamp = Measurementdata.TimeStamp; % aquiring the time from the
measurement data

% Creating a usable timeline expressed in seconds
Time =zeros(length(TimeStamp),1);
for i=1:length(TimeStamp);

   P = str2double(regexp(char(TimeStamp(i,:)),':','split'));
   Time(i,1)= P*[3600;60;1];
end

% letting the timeline start from zero
Timeplot = Time - Time(1);

figure(plotnumber)

% Creating the plot of the torque Mz

% subplot(3,2,1);
Mz =Measurementdata.Tz_Nm_;

plot(Timeplot,Mz,'LineWidth',1)

title('Torque plot of woven steel tube') % title to be changed for every
plot

xlabel('Time [s]')

ylabel('Moment Mz [Nm]')
```

```
% % Rest of the data obtained from the sensor
%
% % Creating the plot of the moment Mx
%
% subplot(3,2,3);
%
% Mx =Measurementdata.Tx_Nm_;
%
% plot(Timeplot,Mx,'LineWidth',1)
%
% title('Moment plot of woven steel tube') % title to be changed for every plot
%
% xlabel('Time [s]')
%
% ylabel('Moment Mx [Nm]')
%
%
% % Creating the plot of the moment My
%
% subplot(3,2,5);
%
% My =Measurementdata.Ty_Nm_;
%
% plot(Timeplot,My,'LineWidth',1)
%
% title('Moment plot of woven steel tube') % title to be changed for every plot
%
% xlabel('Time [s]')
%
% ylabel('Moment My [Nm]')
%
%
% % Creating the plot of the force Fx
%
% subplot(3,2,2);
%
% Fx =Measurementdata.Fx_N_;
%
% plot(Timeplot,Fx,'LineWidth',1)

%title('') % title to be changed for every plot
```

```
%
% xlabel('Time [s]')
%
% ylabel('Force Fx [N]')
%
%
% % Creating the plot of the force Fy
%
% subplot(3,2,4);
%
% Fy =Measurementdata.Fy_N_;
%
% plot(Timeplot,Fy,'LineWidth',1)

%title('') % title to be changed for every plot
%
% xlabel('Time [s]')
%
% ylabel('Force Fy [N]')
%
%
%
% % Creating the plot of the force Fz
%
% subplot(3,2,6);
%
% Fz =Measurementdata.Fz_N_;
%
% plot(Timeplot,Fz,'LineWidth',1)

%title('') % title to be changed for every plot
%
% xlabel('Time [s]')
%
% ylabel('Force Fz [N]')
end
```

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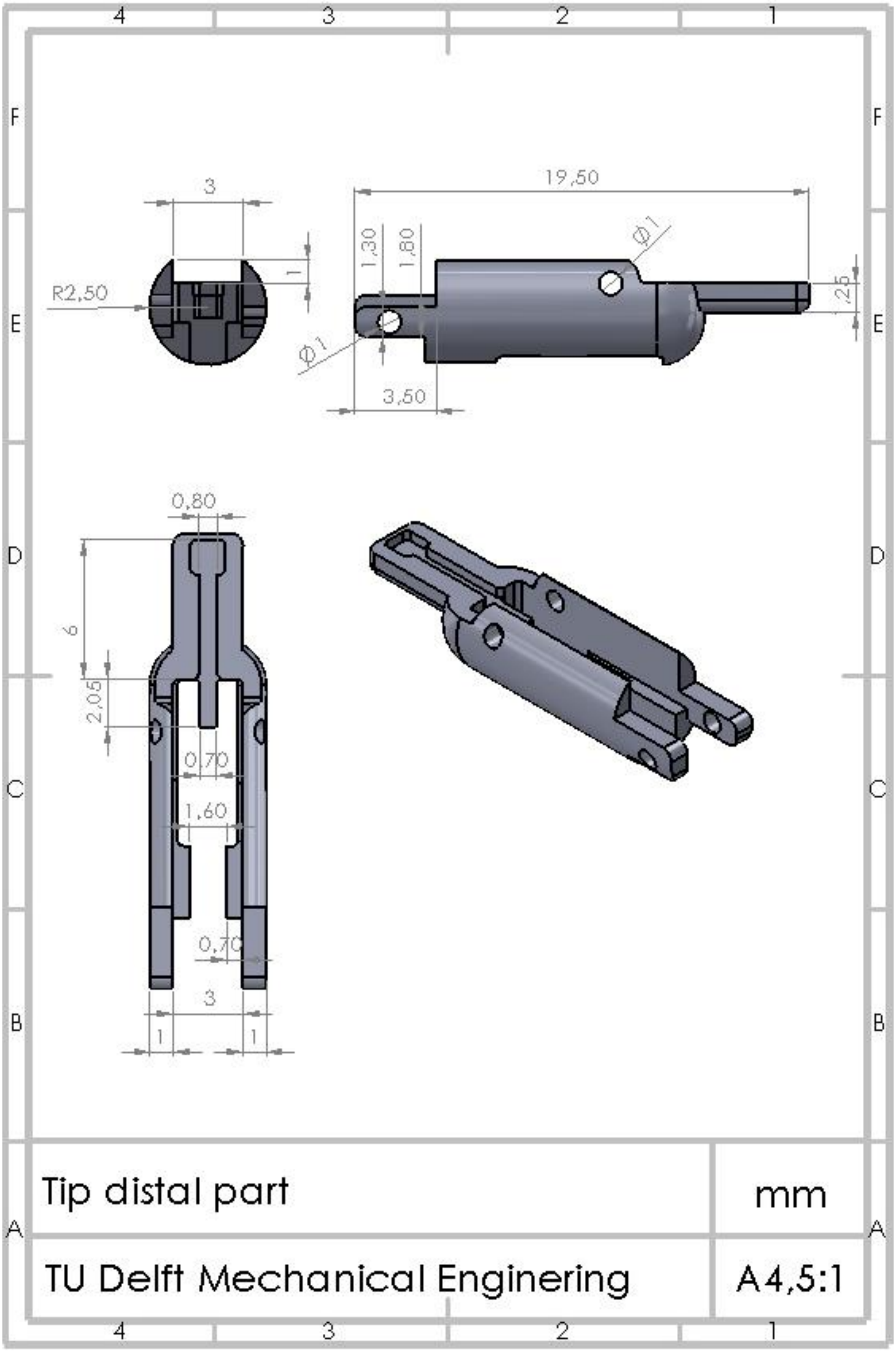
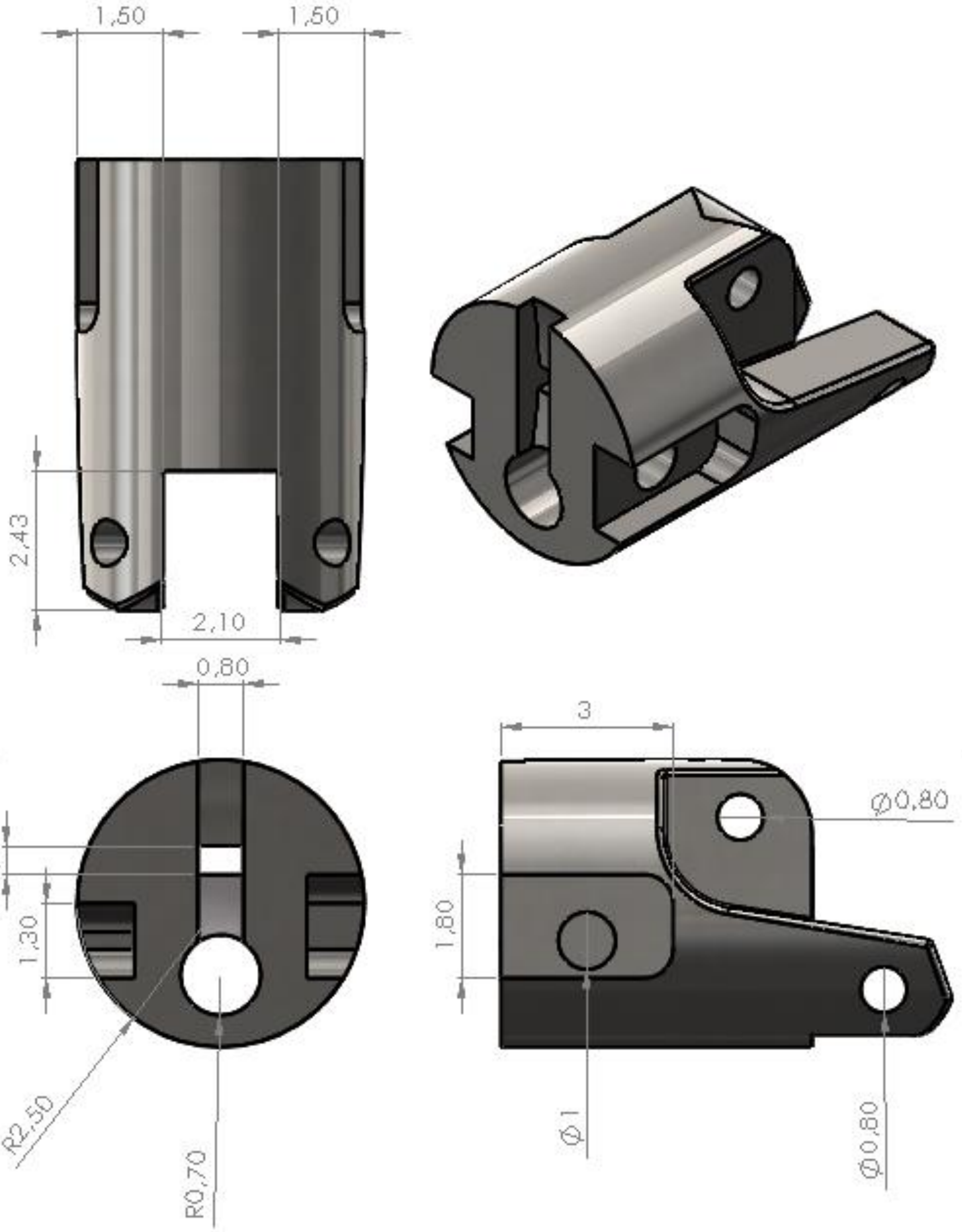
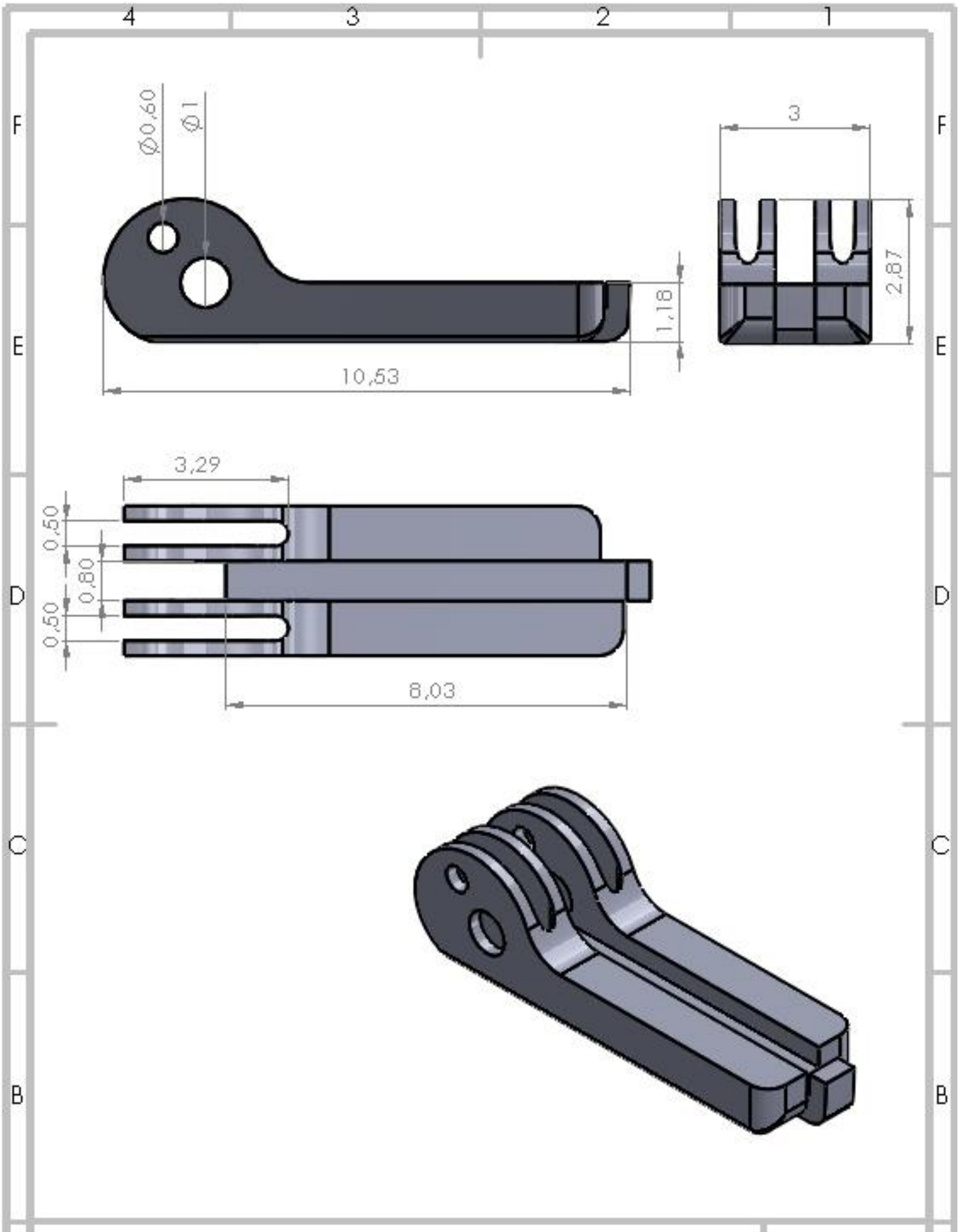
Appendix B: Solidworks drawings





Tip proximal part	mm
TU Delft Mechanical Enginering	A4,10:1

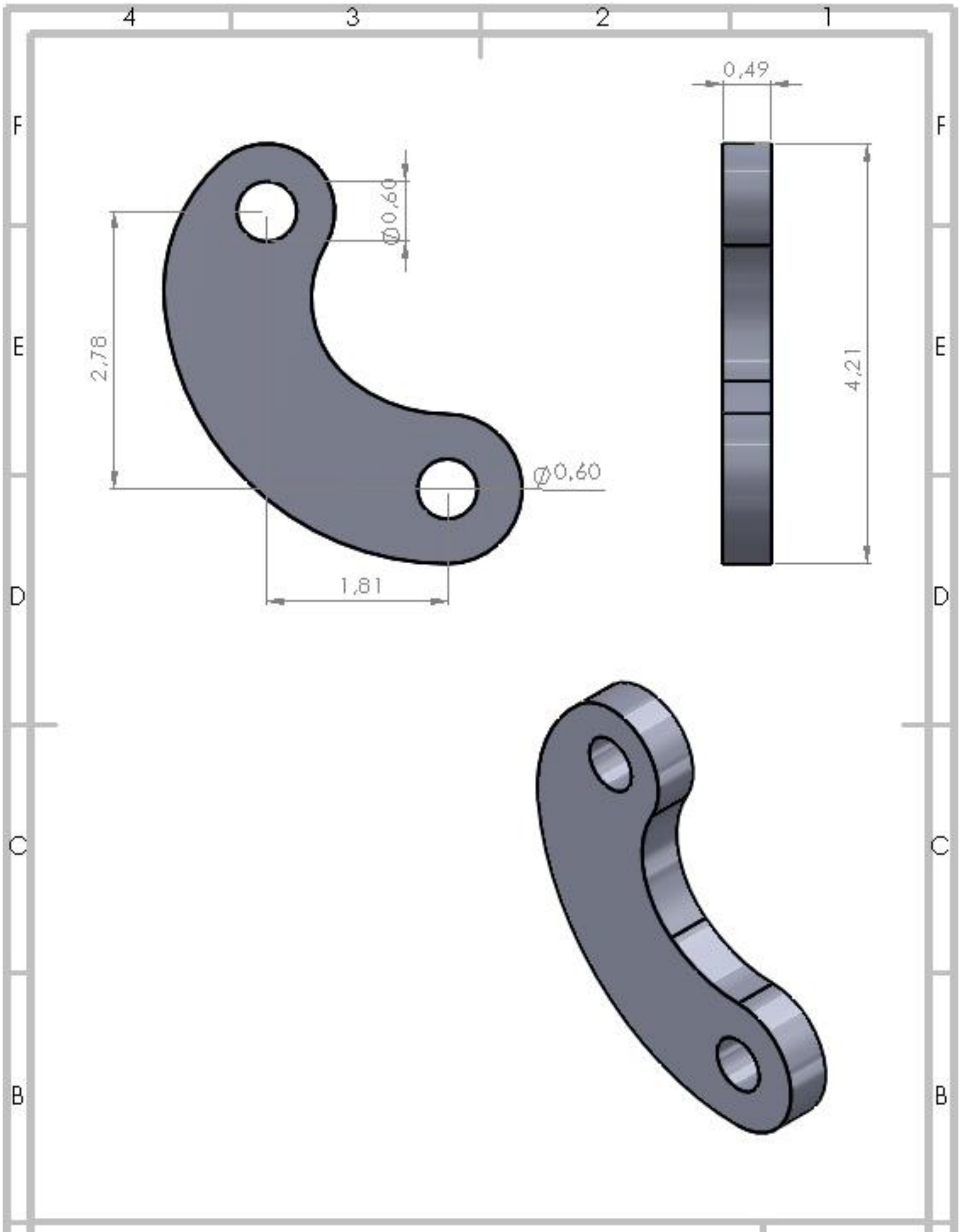


Jaw

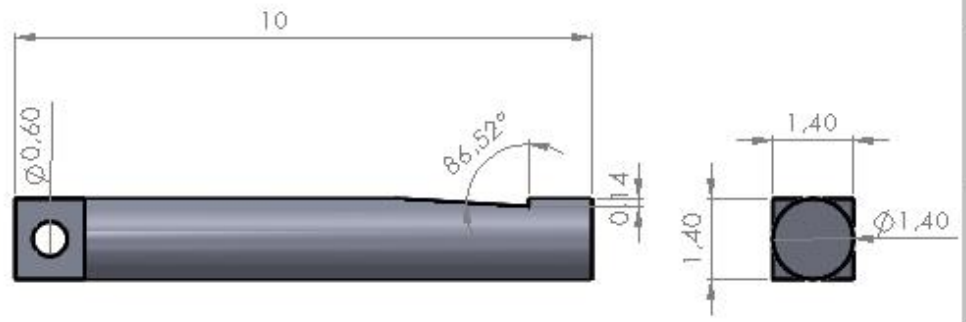
mm

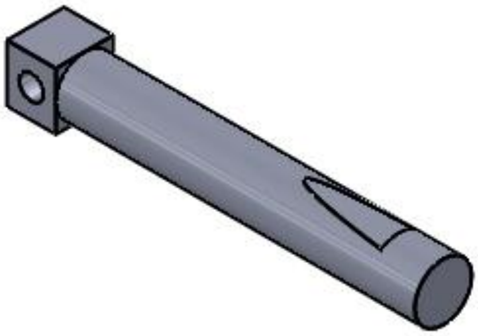
TU Delft Mechanical Enginering

A4,10:1



Link	mm
TU Delft Mechanical Enginering	A4,20:1



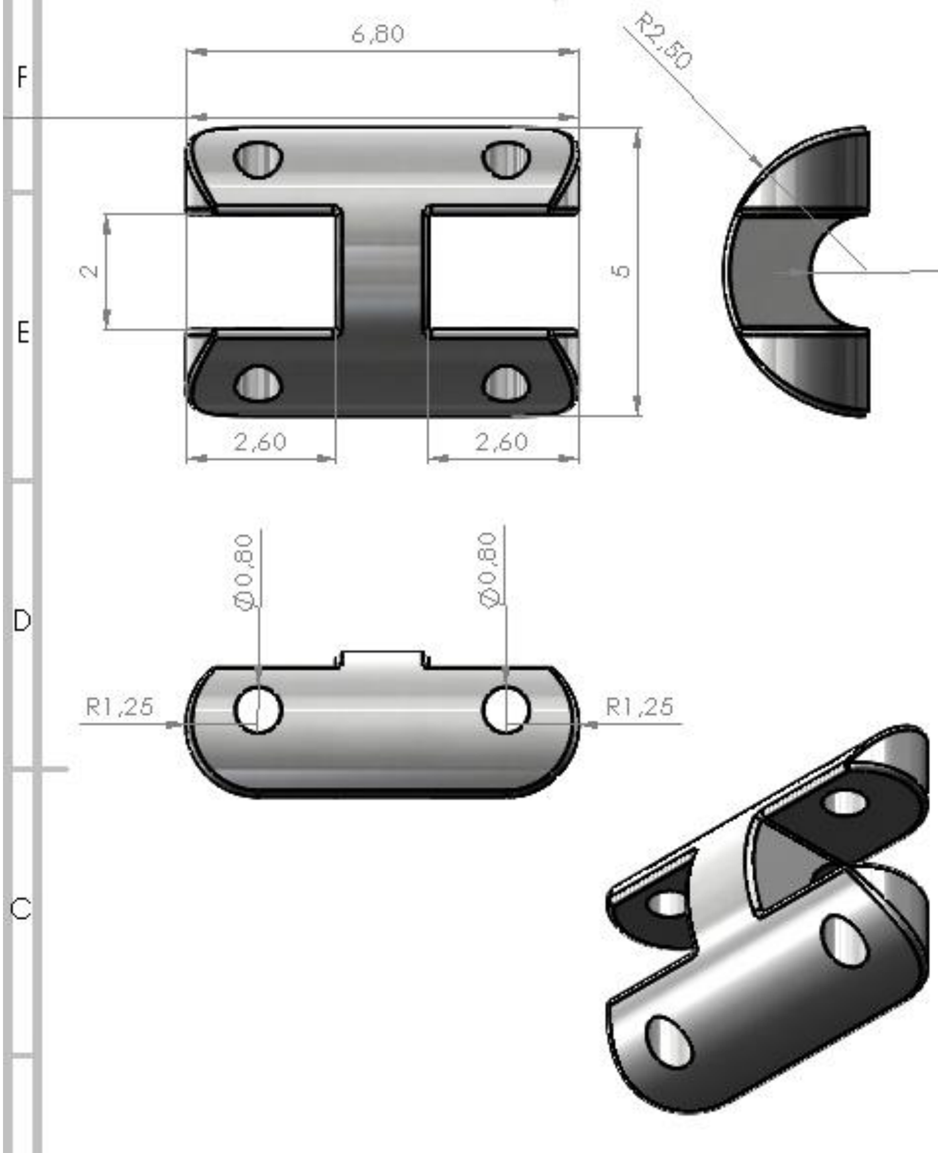


Drive link

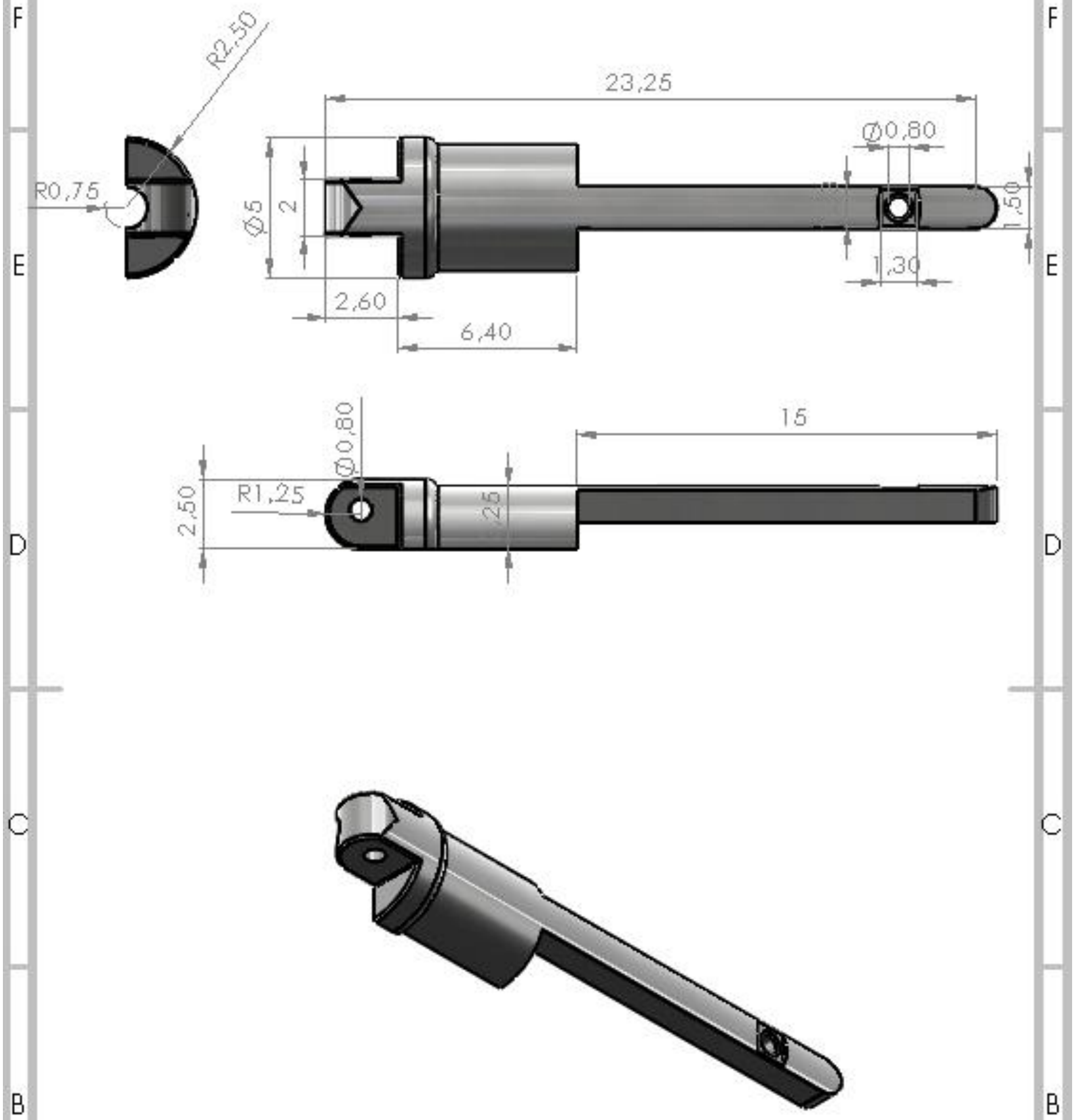
mm

TU Delft Mechanical Enginering

A4,20:1



Hinge	mm
TU Delft Mechanical Enginering	A4,10:1

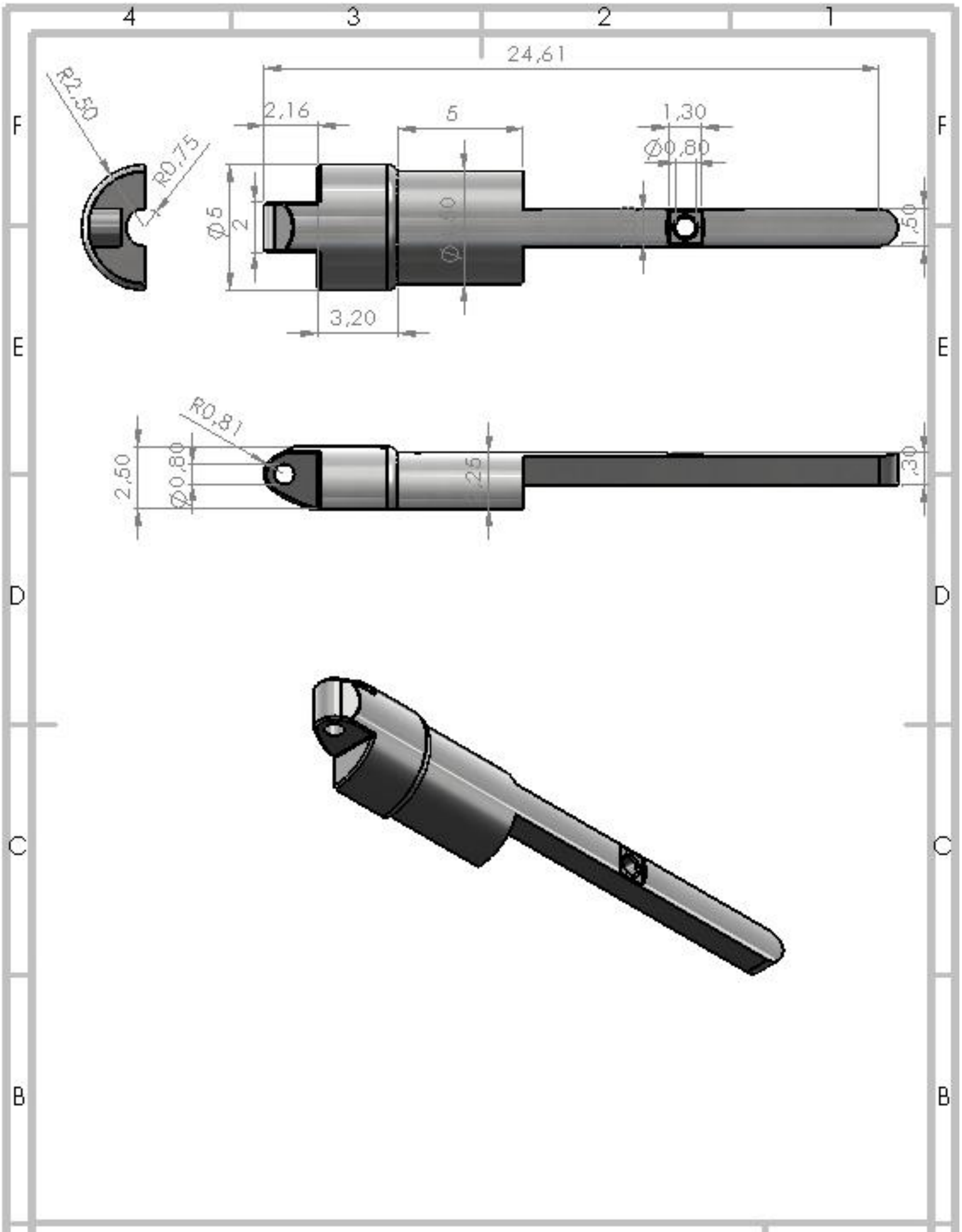


Upper slider

mm

TU Delft Mechanical Enginering

A4,5:1

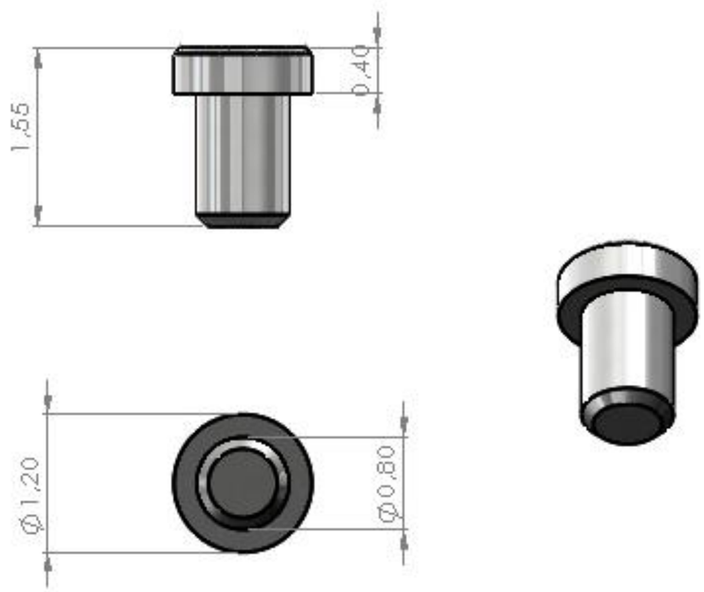


Lower slider

mm

TU Delft Mechanical Enginering

A4,5:1

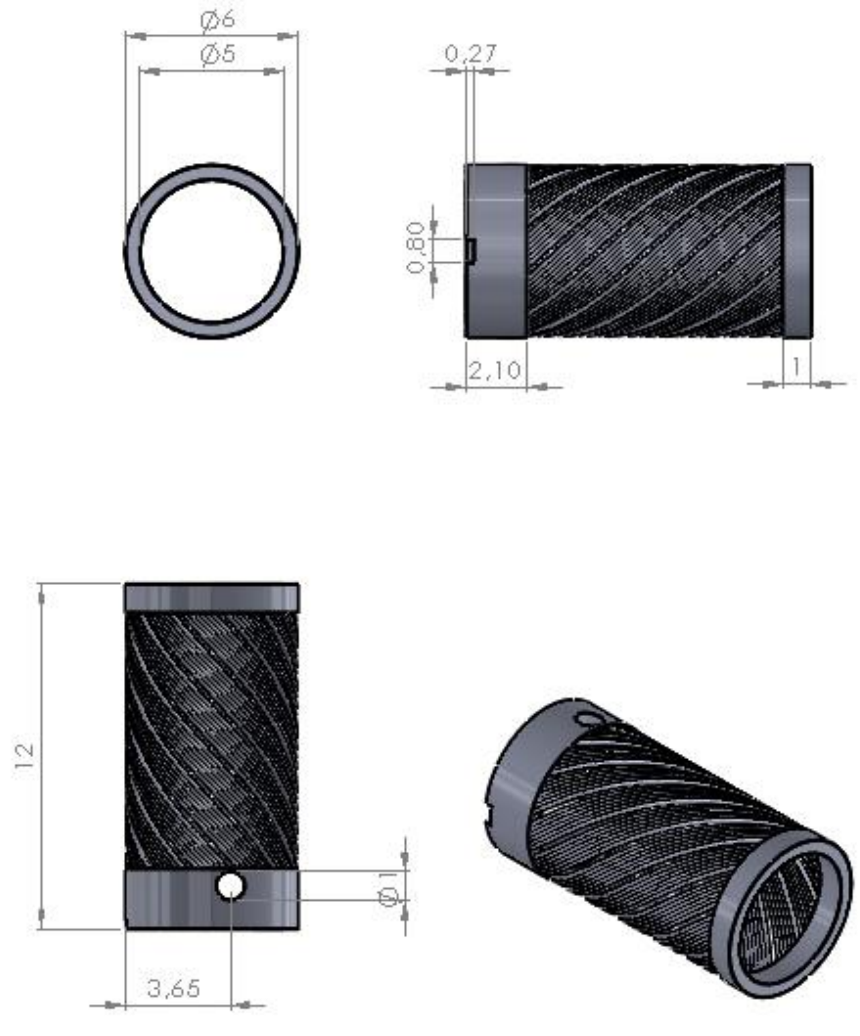


Slider pin

mm

TU Delft Mechanical Enginering

A4,20:1

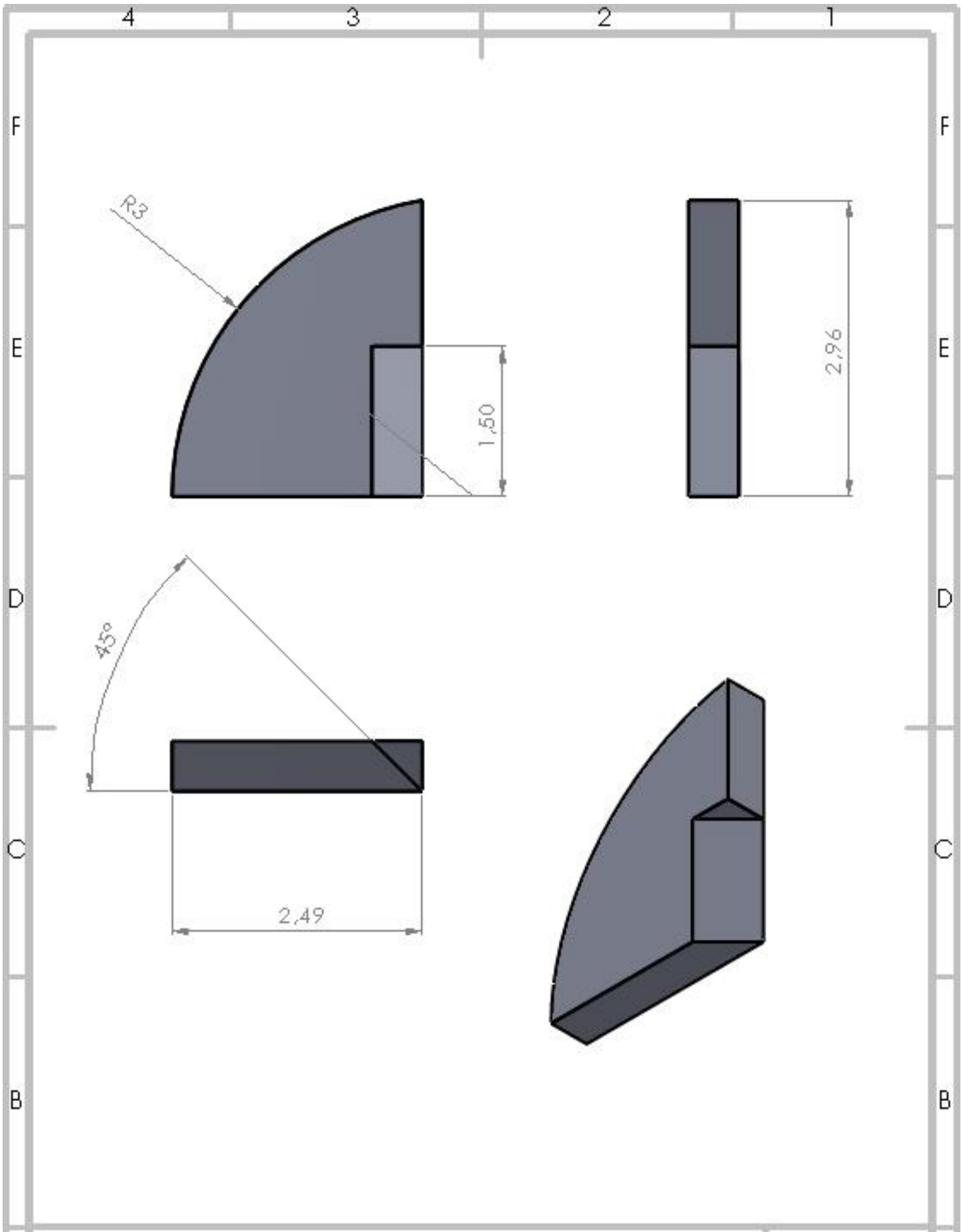


Flexible coupling

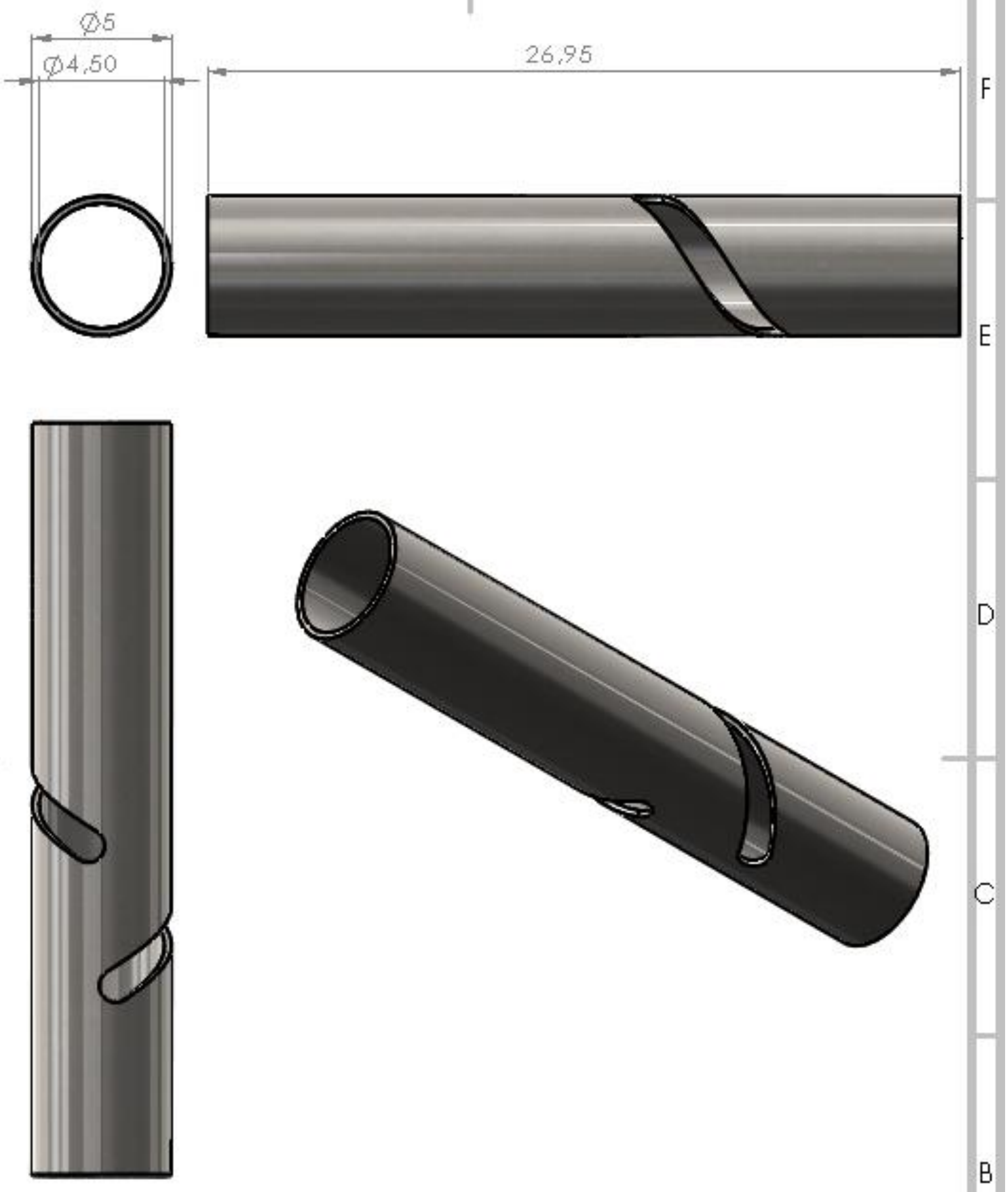
mm

TU Delft Mechanical Enginering

A4,5:1



Cutting blade	mm
TU Delft Mechanical Enginering	A4,20:1



Outer tube	mm
TU Delft Mechanical Enginering	A4,5:1