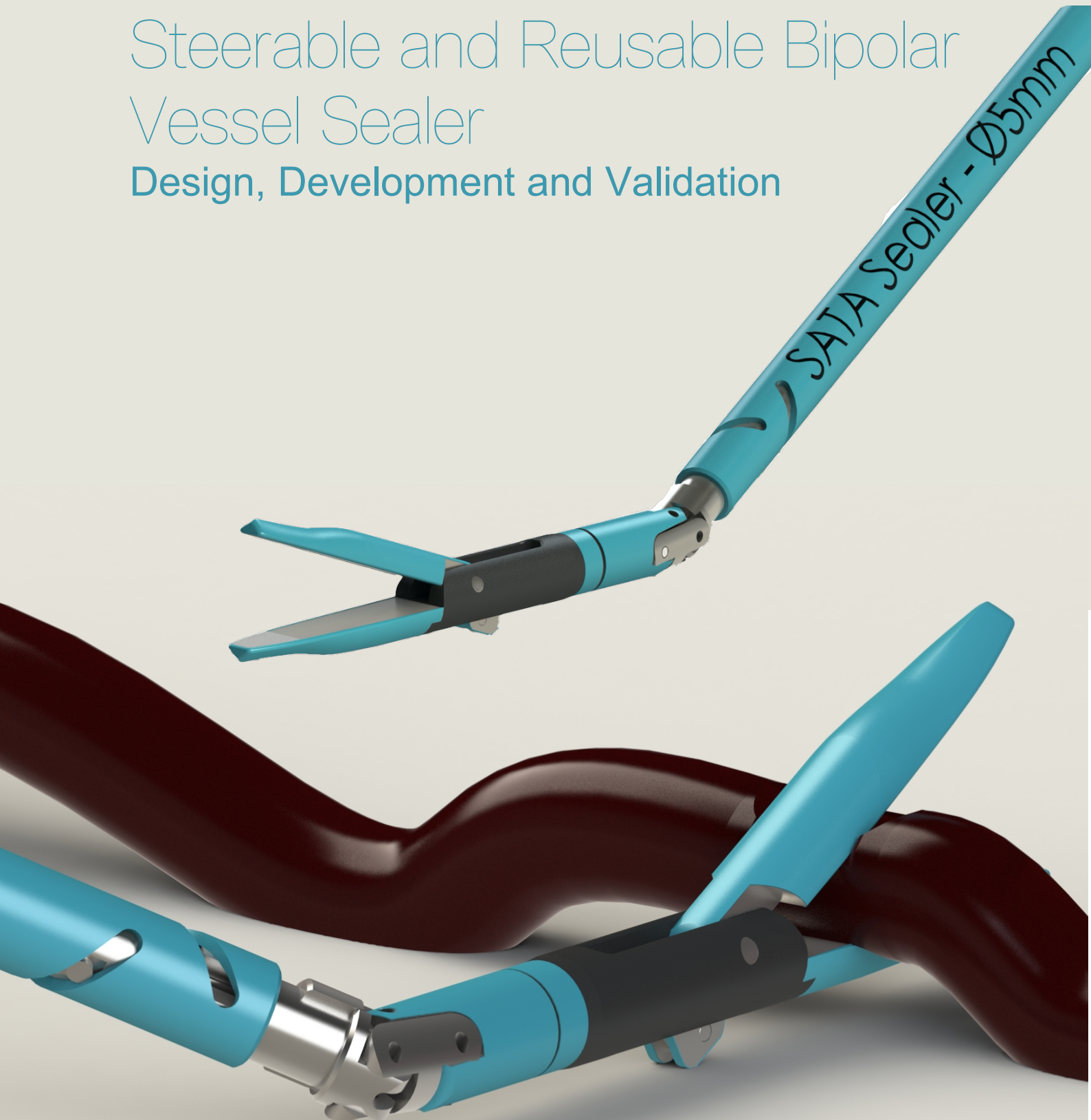


Steerable and Reusable Bipolar Vessel Sealer

Design, Development and Validation



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By

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Abstract

A new radical design approach arose from the need to develop a bipolar electrosurgical instrument that is modular and cleanable, thus reusable and therefore suitable for low- and middle-income countries (LMICs). Advanced Bipolar Vessel Sealer (BVS) instruments that are currently on the market cannot be cleaned or maintained well and are therefore most often sold as disposables. Especially in LMICs it is a significant financial burden for hospitals. This possibly leads to the re-use of single-use intended instruments which in turn jeopardizes patient safety. Simultaneously, designing a reusable instrument fits well in the transition to a more circular and sustainable society. To perform advanced laparoscopic surgery with cleanable and affordable electrosurgical instruments, a new design approach is needed. A first phase was initiated by the creation of a cable less steering principle called Shaft Actuated Tip Articulation (SATA) mechanism [6]. Unfortunately, by adding electrically conductive wires to a SATA instrument it loses its modularity and thus cleanability, precisely for which the SATA technology offered a solution in the first place. In addition, there are no non-robotically controlled and reusable BVS instruments with two DOFs available on the market. By being steerable, the user of the instrument is able to deliver a higher quality seal as well as to seal more difficult-to-reach blood vessels and tissue.

In this thesis project the goal is to redesign a SATA instrument which sustains bipolar vessel sealing and thus designing a BVS that is easy to clean, easily disinfected and sterilized and which is reusable for a vast amount of surgical procedures.

Ideas have been gained by analysing the SATA mechanism and studying commonly used BVS devices. A systematic selection procedure based on the design requirements has resulted in a winning concept for the conduction of electricity through the SATA instrument. For the design of the tip, determining factors were elaborated on, including the construction of the open and close mechanism and the force transmission ratio between the required seal force on the blood vessel or tissue and the necessary tensile force in the core of the instrument.

The most critical components of the final model have been identified and evaluated by means of FEM simulations and an experiment. The FEM simulations of the tip components show that the design is satisfactory and that a safety factor of ~ 1.5 has been achieved. This means that these components do not fail due to normal use and they have a long lifespan as well. In the experiment a flexible nitinol guidewire with Teflon coating was tested for wear by pulling the guidewire through an angled SATA hinge. After some necessary adjustments and additions to the design of the BVS, the results were improved but not optimal.

The outcome of this project is a good basis for the BVS design where the steerability has been maintained as well as the modularity and cleanability. The reusability depending on the flexible coating around the core needs to be further investigated and improved.

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*Philip de Haes
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1 Introduction

In this chapter the motive for a new design of a Reusable Steerable Bipolar Vessel Sealer is introduced. With the most important criteria that it becomes a steerable and reusable instrument for which SATA technology is implemented.

Also, an overview of the design process is presented as well as various (design) methods for creating ideas, concepts and evaluation of the final model.

1.1 Problem definition

The need for designing a new Bipolar Vessel Sealer arises from the use of laparoscopic instruments in developing areas, where the use of disposable instruments is often not financially feasible and simultaneously the possibilities for cleaning and sterilizing instruments are limited. Minimally invasive surgery has many advantages over open surgery, which is particularly important in developing areas. In addition, a reusable instrument designed for highly developed areas can actually contribute to more circularity in the field of surgical instruments and a sustainable healthcare industry.

1.1.1 Laparoscopy in developing countries

Particularly in developed countries, many surgical procedures are preferably performed through minimally invasive surgery (MIS). Decreased blood loss, reduced risk of infection, less postoperative pain and shorter hospital stay are some known advantages of MIS over open surgery [7-10]. The benefits of MIS over open surgery are perhaps even more important in low- and middle-income countries (LMICs), where access to clean water and sanitary living conditions are much more limited and blood banks are scarce [11]. There are however significant barriers to the uptake of MIS in LMICs, high cost of equipment and instruments, difficult sterilisation procedures and lack of training are just a few of the challenges.

Over the years a wide variety of laparoscopic instruments have been designed to be used during MIS. While some instruments are reusable, often laparoscopic instruments are intended for single use and should therefore be disposed after each procedure to avoid complex sterilisation and ensure patient safety [12]. Unfortunately, in LMICs in particular, there is no guarantee that single-use instruments will actually be used only once because this is often not feasible [13].

One essential instrument that is used during MIS is a Bipolar Vessel Sealer (BVS). This laparoscopic device uses a lower intensity radio-frequency (RF) bipolar current together with an accurate tissue clamping force to seal blood vessels and other tissues. In bipolar configuration both jaws in the tip of the instrument are electrodes, one active and one return. Figure 1-1 shows an example of such a bipolar vessel sealer.

From this problem the idea arose to design an instrument that is modular, cleanable and thus reusable and therefore suitable for use in LMICs. Such an instrument may offer a solution to guarantee patient safety and the quality of MIS procedures in a cost-effective manner.



Figure 1-1 Left: LigaSure Bipolar Vessel Sealer © Covidien [14]. One of the most described bipolar vessel sealers in the literature. Right: Animation of a vessel being clamped between the jaws of the LigaSure device .

1.1.2 Sustainable circular instruments

Furthermore, designing a reusable BVS fits well in the transition to a more circular society. The global healthcare sector is rapidly growing due to ageing populations, population expansion and new developing markets [15]. Therefore, the use of medical instruments is increasing and more and more waste is being created. On average, the amount of waste created per (hospital) patient each day in the US is 8.4 kg [16]. In European countries, such as France (3.3 kg) and Germany (3.6 kg), less than half of the US waste is created. Mass consumption and an exponential growth in the use of disposables have a negative effect on the costs and availability of raw materials. This causes a growing demand in circularity for sustainable surgery and a sustainable healthcare industry.

1.1.3 Bipolar vessel sealing

To elaborate the choice for bipolar configuration, the distinctions between monopolar and bipolar configurations in electrosurgical instruments are briefly explained here, see Figure 1-2. In monopolar configuration, one electrode is located in the tip of the instrument while the other electrode is located elsewhere on the patient's body [17]. This means that the current runs through the patient's body.

In bipolar configuration both the active and return electrodes are located in the tip of the electrosurgical instrument [17], see Figure 1-1 and Figure 1-2. This means that only the grasped tissue between the tip is included in the electrical circuit and the affected tissue will thereby close the electric circuit. Typical effects on the tissues are cutting, coagulation and vessel sealing, depending on the power setting. Moreover, bipolar configuration requires a voltage of ~300V [18], whereas monopolar configuration requires voltages of >1000V. For bipolar coagulation a power output of ~50W is necessary [17-19], whereas monopolar configuration requires a power output between 120-300W. For these reasons bipolar configuration is considered to be safer in use and less harmful to the patients [19].

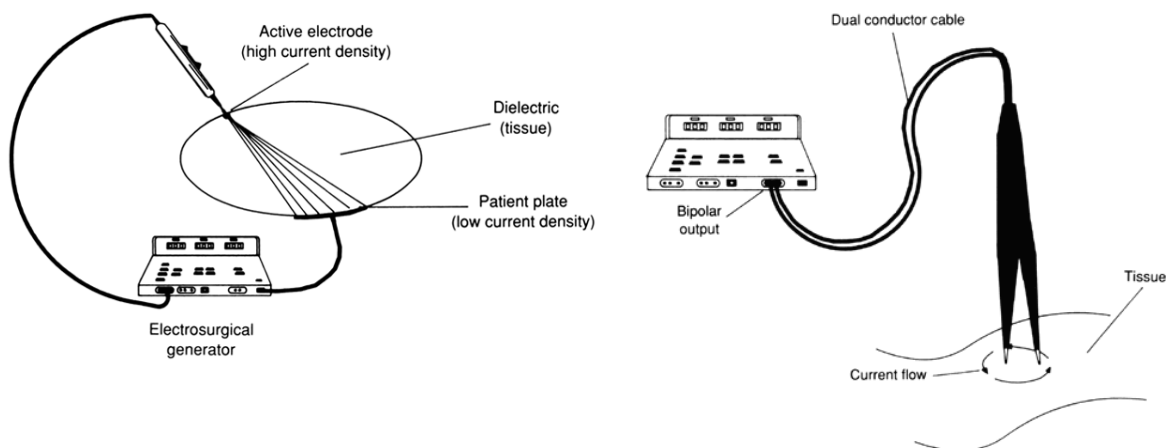


Figure 1-2, Electrosurgery configurations. Left: monopolar configuration, current runs through the patient's body. Right: bipolar configuration, only the tissue between the jaws is affected [20].

1.1.4 Tip Articulation

A steerable vessel sealer offers more reachability to harder to reach tissues, better tissue alignment and reduces the need for using grasping and manipulation tools. This enables the surgeon to seal vessels and tissues easier and more precise which improves the seal quality.

With the introduction of Shaft Actuated Tip Articulation (SATA) technology [6], a cableless, steerable laparoscopic grasping instrument is already designed. Simultaneously, SATA fulfils the need of being modular and cleanable, see Figure 1-3. By being cableless and modular, SATA instruments are easily assembled and disassembled to allow thorough cleaning and sterilisation. At the same time, low-tech cleaning methods are sufficient for this process [6].

SATA offers two DOFs namely; left and right 'yaw' motion and 'roll' motion along its longitudinal axis as shown in Figure 1-3. In comparison, current non-robotic bipolar vessel sealers often do not have more than one DOF in tip movement (steerable) and instruments that do have more than one DOF are intended for single use, i.e. not reusable.

Because of the features that SATA instruments offer, it was decided to implement this technology in the design of a steerable and reusable BVS. In the new design, the SATA instrument will form the basis. However, current SATA technology is not directly compatible with electrosurgical instruments because the addition of electrical wires will affect the modularity and steerability. For this reason, an alternative must be found to replace conventional electrical wires and to conduct electricity using the various modular components of the instrument.

Prior to the design project, a literature research into conductive and insulative coatings was conducted to identify coatings that could possibly be used and implemented into the design of a SATA instrument [21]. The use of strategically applied ceramic insulative coatings can be a solution for replacing conventional electrical wires, allowing the SATA instrument to maintain its modularity and thus cleanability and reusability [21].

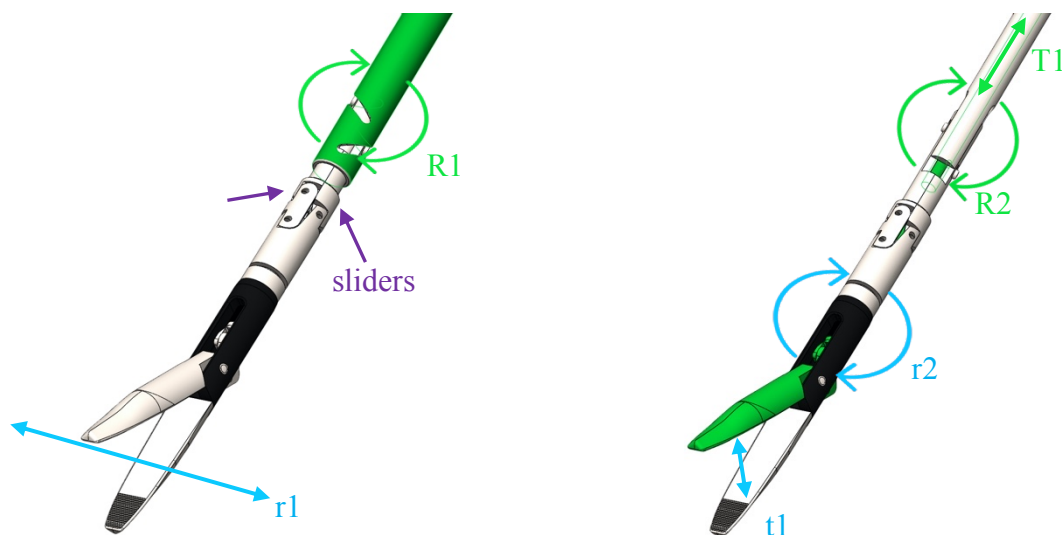


Figure 1-3, SATA two DOFs BVS instrument and tip, principles of tip actuation. Left: Sideways articulation ($r1$) is accomplished by rotation of the outer axis shaft ($R1$), which drives the sliders. Right: Tip rotation ($r2$) and opening ($t1$) are accomplished by rotation ($R2$) or translation ($T3$) of the inner axis shaft.

1.1.5 Design goal

Bipolar vessel sealers are generally designed as single use products, while there is a demand for affordable and reusable instruments, both from an economic and sustainable point of view. Although there is a reusable BVS available, the KLS Martin MarSeal, it is not steerable and expensive. In addition, there are no non-robotically controlled BVS instruments with two DOFs available on the market. By being steerable, the user of the instrument is able to deliver a higher quality seal as well as the ability to seal more difficult-to-reach blood vessels and tissue.

In this project, a SATA instrument will be redesigned such that it enables bipolar vessel sealing and a new tip will be designed that fits the SATA BVS instrument. To achieve this, options to guide electricity in two directions through the SATA instrument are explored and drawn into concepts. Separate concepts have been drawn up for the tip. The tip should facilitate the bi-directional conduction of electricity and serve as a housing for the open and close mechanism

of the jaws. The latter has a strong influence on the design of the tip. The instrument is developed and the most critical parts of the design are identified and evaluated.

The design goal states:

“ Design a Steerable and Reusable Bipolar Vessel Sealer that is modular, easily disinfected and sterilised and which is reusable for at least thirty surgical procedures whilst maintaining its functionality and assuring patient safety. ”

1.1.6 Thesis outline

This report details the design, development and validation of a Steerable and Reusable Bipolar Vessel Sealer. After the introduction on the thesis topic, the problem definition and setting up the design goal, the project's methodology is presented in Chapter 1. Additional pre-research is conducted and described in Chapter 2, followed by a list of design requirements. The conceptual design phase is shown in Chapter 3. Chapter 4 covers technical design details and a CAD model is presented. The new BVS design is evaluated in two ways therefore, in Chapter 5, the CAD model is evaluated through Finite Element Method (FEM) simulations and Chapter 6 describes the experimental evaluation of the core and its coating. The outcomes of this thesis project are discussed in Chapter 7.

1.2 Design Methodology

After defining the problem and setting up the design goal, a number of steps have been taken to work towards the end product of this thesis project. The steps are distributed over three design phases as shown in the flowchart in Figure 1-4 [22]. In iterative manner, the design steps have been completed repeatedly in order to optimize the product.

The first phase is the Analysis, this includes the problem definition, background information, the design goal and preliminary research. Both the background information and preliminary research, and known clinical functioning prerequisites have been used to specify the design requirements.

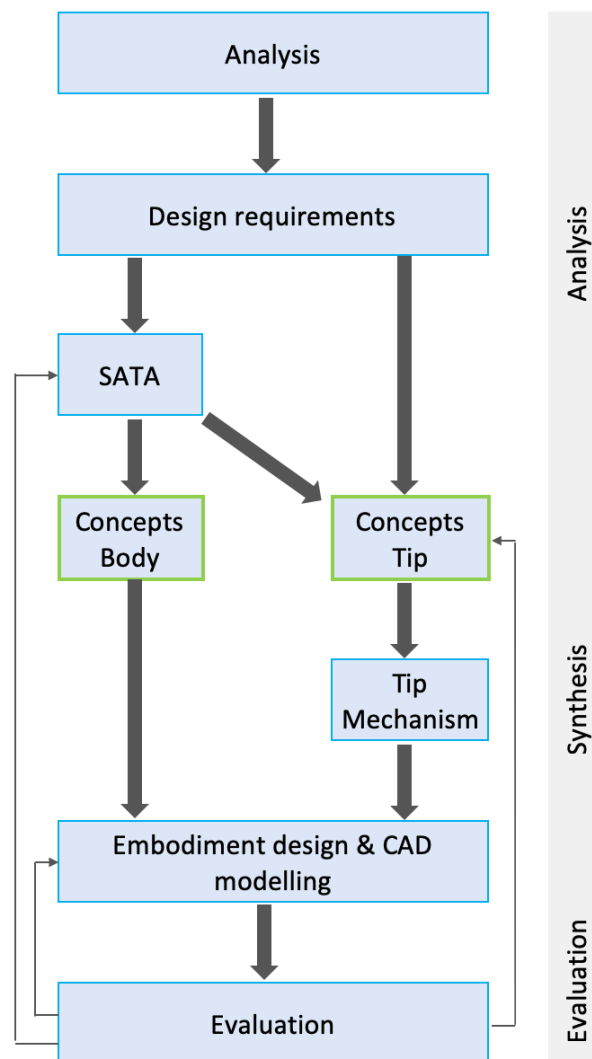


Figure 1-4, Flow chart design process. The three initial design phases are: analysis, synthesis and evaluation. To go from design goal to end product, a cycle of the three phases is formed which results in an iterative process. Marked in green are the two sections of the instrument that are separately developed.

Various aspects of bipolar laparoscopic instruments currently on the market are explored through preliminary research, which has yielded some insights that have been used to create concepts and optimise the design. Because SATA technology was implemented in the design, an early step in this phase was to analyse the SATA mechanism at component level.

In the second phase, the synthesis, ideas are generated and converted into concepts and solutions. Concepts for the body of the instrument and concepts for the tip are designed independently, as each of these component groups require a different approach. The Braindrawing method was used to generate ideas for the body of the SATA instrument. For this method the question is asked; 'How to' conduct electricity in two directions through each of the SATA components? [23]. Ideas are structured in a morphological chart and then compiled as concepts. Concept evaluation and selection is done using Harris profiles [23].

Creating the tip and selecting a suitable design requires a more detailed approach because the configuration of the open and close mechanism of the jaws (to be chosen) strongly determines the design of the tip. Ideas and configurations have been obtained by reverse engineering methods, which are also included in the morphological chart. Selection of the open and close mechanism of the tip is based on calculations. Subsequently, for some specific tip components design solutions were evaluated using Harris profiles. In the final step of the synthesis phase, the embodiment design, the winning concepts of the instrument body and tip are merged and developed into a detailed CAD model.

As part of the evaluation phase, the design is iteratively optimized during the CAD modelling using FEM simulations. Ultimately, the final design is evaluated on two areas (see Figure 1-5):

- 1) The final tip design is assessed for lifespan (reusability) by simulating repeated loading on the tip components in FEM (von Mises stress). The obtained stress results are combined with heavy use of the instrument during surgery (number of cycles) in fatigue prognosis graphs in Chapter 5.
- 2) The most critical component is tested for wear (reusability) in a small experiment in Chapter 6.

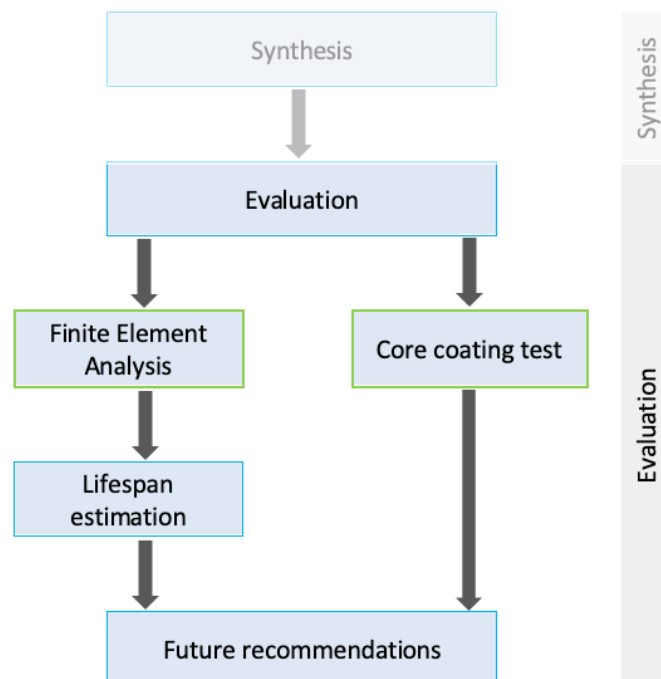


Figure 1-5, Overview Evaluation phase. Marked in green are the two areas on which the design will be evaluated.

2 Background

This Chapter includes additional research conducted prior to the design phase. Through this research, some useful insights on the design of bipolar instruments are obtained.

The design requirements are presented in this chapter as well.

2.1 Gathering insights

Prior to the design phase, useful insights were obtained through a visit to the Central Sterile Supply Department (CSSD) at the Leids Universitair Medisch Centrum (LUMC), retrieving hands-on instruments from van Straten Medical, studying literature on commonly used bipolar instruments, a breakdown of two commonly used bipolar instruments and design standards for designing medical devices [24]. Furthermore, the model of the SATA mechanism that is being redesigned is shown.

2.1.1 Field research

In addition to usage in the operating room, processes such as; manual and automated cleaning, checking instruments for possible defects, sterilisation, transport and storage are actions that the instrument is subjected to. To a certain extent, all these processes cause wear and degradation to the instrument. Figure 2-1, Figure 2-2 and Figure 2-3 show images of these processes.

Dutch CSSDs work according to the RIVM standards and regulations for cleaning and sterilising medical devices and instruments. This includes manual brushing and cleaning, washing and disinfecting, (visual) inspections of instruments, sterilisation and storage. Nowadays, steam sterilisation is the most commonly used method for sterilisation of medical devices [25] and for laparoscopic instruments sterilisation is done for three minutes at 134°C. Another frequently used method is ethylene oxide (EO). However, EO is toxic, explosive and extensive precautions are required when using this method. Therefore, EO has disappeared from most hospitals e.g. Dutch hospitals do not make use of EO sterilisers [25].



Figure 2-1, Aesculap bipolar grasper. Additional protection is used to cover the relatively vulnerable tip of the instrument during storage.

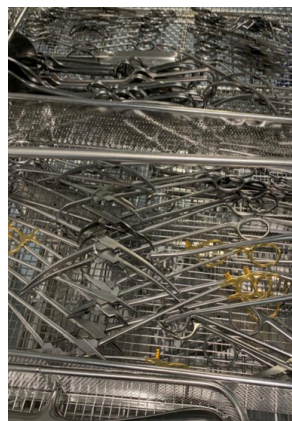


Figure 2-2, Set of instruments in a tray. Instruments are carefully placed in trays during washing, sterilization and storage processes.



Figure 2-3, Insulation testing. Using a PTU6 pinhole detector the CSSD staff can easily check the electrical insulating components for insulation failure.

Hands-on reusable and non-reusable (laparoscopic) instruments are retrieved from the 'Circulaire Instrumentbeheer' project at van Straten Medical. This project is focussing on revising instruments and reusing hospital waste materials for new instruments. As can be seen in Figure 2-4, a large number of used instruments was available to investigate due to the current disposal economy of medical instruments in the Netherlands. The investigated instruments provide various options for conducting electricity as well as different mechanisms to open and close the jaws. A variety of electrical insulating materials is encountered and insulating material differences between reusable and non-reusable instruments was exposed.



Figure 2-4, Instrument recycle bin at van Straten Medical. Many instruments are thrown away every day e.g. because they are (partly) damaged, single-use products or (partly) worn out.

2.1.2 Additional literature research

Before starting the design of a new BVS, it is useful to investigate which instruments are commonly used; have good functionalities; and are reusable. Even more interesting is to see whether there are existing design problems with these commonly used instruments and if there are existing solutions to these problems.

The use of bipolar vessel sealers has been extensively described in the literature and comparisons between devices from different manufacturers are made [26-30]. For example, research into the differences in functionality between types of bipolar vessel sealers, the quality and efficiency of the different devices (e.g. the seal time, burst pressure, seal strength, sealed vessel sizes, thermal spread, etc.). Instruments that are most often mentioned are: LigaSure (Medtronic, Minneapolis, MN), ENSEAL (Ethicon Endo-Surgery, Cincinnati, OH) and Gyrus PKS (Gyrus-ACMI, Maple Grove, MA), probably because these are frequently used.

The above-mentioned instruments are all intended for single use. However, literature can be found in which the reusability of these instruments is determined [31], particularly focussing on functionality after the instruments went through several cleaning and sterilisation procedures. Gardeweg et al. (2019), studied the effect of multiple use and sterilisation on the performance of multiple bipolar vessel sealing devices. They compared the disposable LigaSure and Caiman (Braun-Aesculap, Tuttlingen, Germany) with the reusable MarSeal (KLS Martin, Tuttlingen, Germany). After a limited number of cycles and sterilisation procedures, the seals created with the disposable devices were very similar to those produced by the reusable device. Only one Caiman device was damaged following sterilisation. A similar study was conducted by Klar et al. (2011), in which they also compared the disposable LigaSure with the reusable MarSeal device. No significant differences in functionality was measured. However, they found that the mean sealing time was significantly shorter with the use of the reusable device [32].

The reuse of instruments does not seem to have a negative effect on their functionalities. By constructing the new BVS instrument with materials suitable for cleaning and sterilisation, it is expected that all functionalities will be retained. This short research has shown that there are a number of instruments that are widely used in practice. From these instruments it has been derived which open and close mechanisms of the jaws exist, what jaw lengths are common and what options for conducting bipolar electricity are currently applied.

2.1.3 Reverse engineering

Based on the prior mentioned research two instruments were chosen for further investigation, the LigaSure Blunt Tip vessel sealer (non-reusable) and the AdTec (Aesculap, Tuttlingen,

Germany) bipolar instruments (reusable). Furthermore, the Storz RoBi (Karl Storz, Tuttlingen, Germany) has been investigated because these are also reusable bipolar instruments.

AdTec bipolar instruments are reusable and use ceramic materials for electrical insulation. The use of ceramic materials is particularly interesting because these types of materials were found to be suitable implementation in the new BVS design [21]. However, LUMC's CSSD specialist explained that although the instruments are reusable, in practice they can only be reused to a limited extent. The ceramic materials in the tip of the instruments, which provide electrical insulation, are frequently damaged during surgical procedures. A possible cause for this is the 'clogging' of the hinges in the tip by human tissue, which can lead to ceramic particles breaking off during articulation of the jaws.



Figure 2-5, AdTec instrument(s). Left: sketch of an exploded view of the instrument. The ceramic insulation layers are coloured in cyan. Right: various reusable AdTec instruments with different functionalities [33]. The ceramic material is coloured blue. Note that these are bipolar laparoscopic instruments, but not specifically vessel sealers.

Figure 2-5, shows a variety of AdTec instruments (right) and a sketch of an exploded view of such instrument (left). As shown in the sketch, the insulated pulley cable (core) is connected to the 'butterfly' hinge. For convenience we call this the active (+) electrode. One of the jaws is directly connected to the hinge and thus part of the active electrode (+). The other jaw is indirectly connected to the hinge, there is a ceramic layer in between, and thus (-) or return electrode. The latter jaw continuously makes contact with the tip housing and in turn the tip housing is connected to the shaft, thus part of the return electrode (-). Ceramic insulating inserts prevent short circuiting between the jaw open and close mechanism and tip housing.

Another instrument that was investigated is the LigaSure Blunt Tip BVS. This is a single use intended device that uses electrical wires to conduct electricity to and from the tip of the instrument. Interesting are the 'sockets' that are placed over the jaws. Each of the sockets is connected to one of the wires, thus forming an active (+) electrode and return electrode (-). The outer layers of the socket consist of insulating materials and prevents electricity to leak to the other stainless-steel components or the patient. The tip open and close mechanism is commonly used for laparoscopic instruments, see Figure 2-6. In this case, the core pulls a pin that is guided through diagonal cut outs in the jaw (proximal side). Because the cut out is diagonal, it initiates the jaws to open when the core is pushed or the jaws to close when the core is pulled.

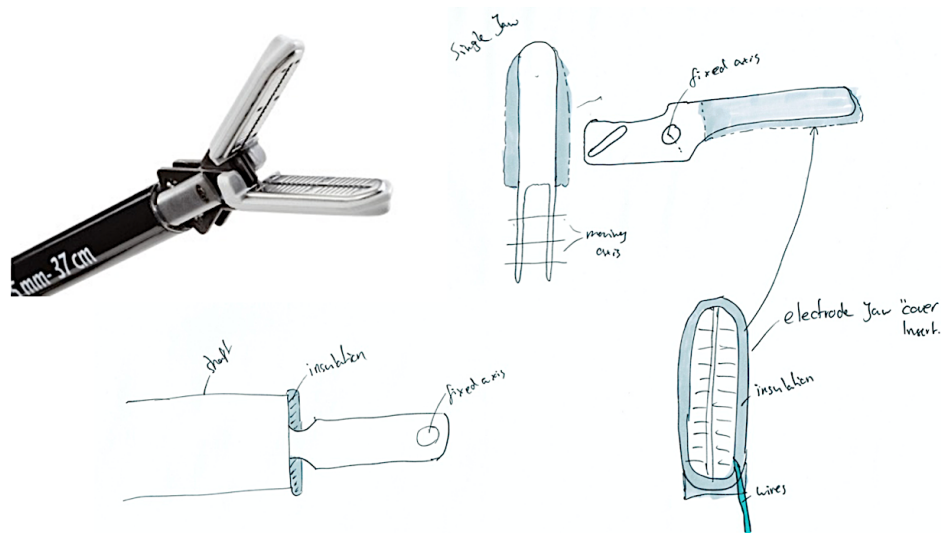


Figure 2-6, LigaSure Blunt Tip. Top left: LigaSure Blunt Tip length sealing length 20mm. Sketch: Grey areas represent electrical insulating materials. The jaws have a fixed hinge axis and open and close motions are initiated by pushing or pulling the core that is connected to the diagonal cut out.

2.1.4 Exploded view SATA

A CAD model of a laparoscopic SATA instrument is taken apart and an exploded view of the instrument is given in Figure 2-7. The current tip has been omitted because it is not suitable for bipolar electrosurgical purposes. Redesigning the handle is beyond the scope of this thesis project.

Part VII has threads on the distal end (nut side) to which the tip (bolt side) is attached. Part III is the rigid part of the core. Construction of the remaining core section, which connects the rigid core to the tip, is determined later in this report.

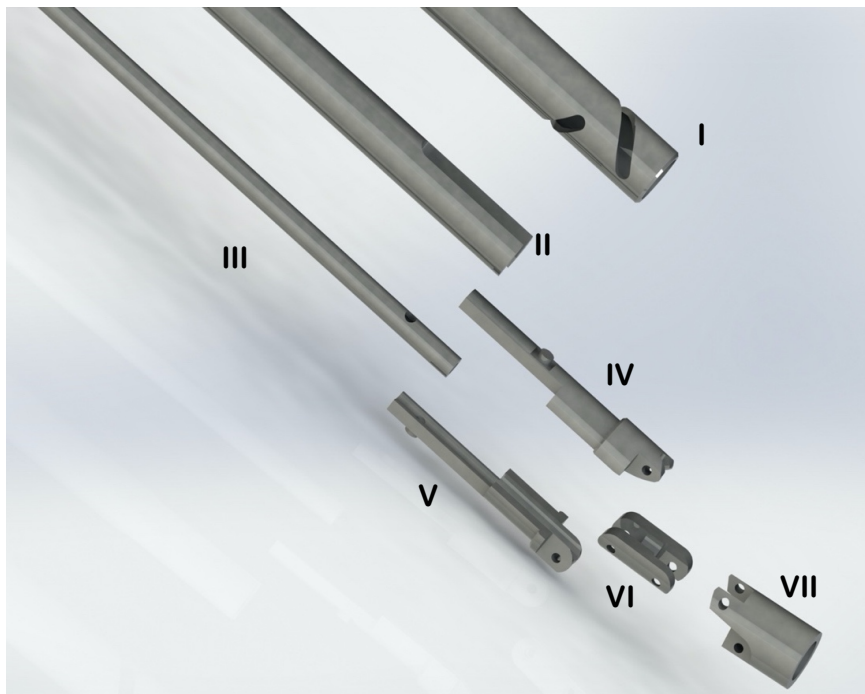


Figure 2-7, Exploded view SATA hinge mechanism. I = external axis shaft, II = mid axis shaft, III = internal axis shaft / core, IV = slider 1, V = slider 2, VI = h-hinge, VII = tip base. CAD model by [34]

2.2 Design requirements

Developing a Reusable and Steerable BVS that fulfils the design goal demands a list of requirements. Medical instruments must be compliant with known clinical functioning prerequisites. If necessary, the requirements are backed up by literature, manufacturer datasheets, anatomical boundaries and knowledge obtained by consulting engineers and medical staff. Assessment of the concepts and evaluation of the final design is done according to this list.

The instrument should...

Performance

1. ...distinguish itself from conventional bipolar vessel sealers by being reusable, steerable and modular.
2. ...be steerable. The instrument must retain the two degrees of freedom similar to current SATA mechanisms [35].
3. ...seal vessels and coagulate tissue in bipolar configuration.
4. ...seal blood vessels and bundles of tissue up to 7 mm in diameter [36].
5. ...be able to apply a uniformly distributed compression of 20N in magnitude with the jaws [37].
6. ...be able to grasp and manipulate vessels and tissue. Therefore, the jaws of the tip must be able to deliver a pinching force of at least 7N to prevent tissue slipping, when the instrument is not articulated [38-40].
7. ...be designed such that conventional electrical wires are not used for conducting electricity from and to the jaws.
8. ...have limited additional components with respect to the current SATA devices [34].
9. ...be user friendly.

Reusability

10. ...be able to be reused repeatedly.
11. ...Applied forces on the instrument during usage must not cause component failure or cause (permanent) deformation.
12. ...be reusable for a minimum of thirty surgical procedures. The performance of the instrument must therefore remain consistent up to 30 procedures. (A procedure includes: use by surgeon, disassembling and cleaning, instrument quality inspection, sterilization, storage and handling by others) [38].
13. ...allow partial replacement of components in the event of damage at component level. In this way, there is no need to purchase completely new instruments.
14. ...be robust. The design and materials must be chosen in such a way that wear and degradation is prevented as much as possible. Because it is a reusable bipolar vessel sealer, the instrument must be resistant to heat, chemicals and corrosion.

Cleanability

15. ...be modular to allow easy cleaning. This also means the number of steps to disassemble the instrument should be low [38].
16. ...not consist of components that cannot be inspected or cleaned [38].
17. ...be sterilisable according to international standards for sterilisation of health care products ISO 11737-2. Therefore, the instrument must be build out of autoclavable components [38].
18. ...be able to be assembled by a single person in less than 110 seconds [35].
19. ...be able to be disassembled by a single person in less than 110 seconds [35].

Dimensions

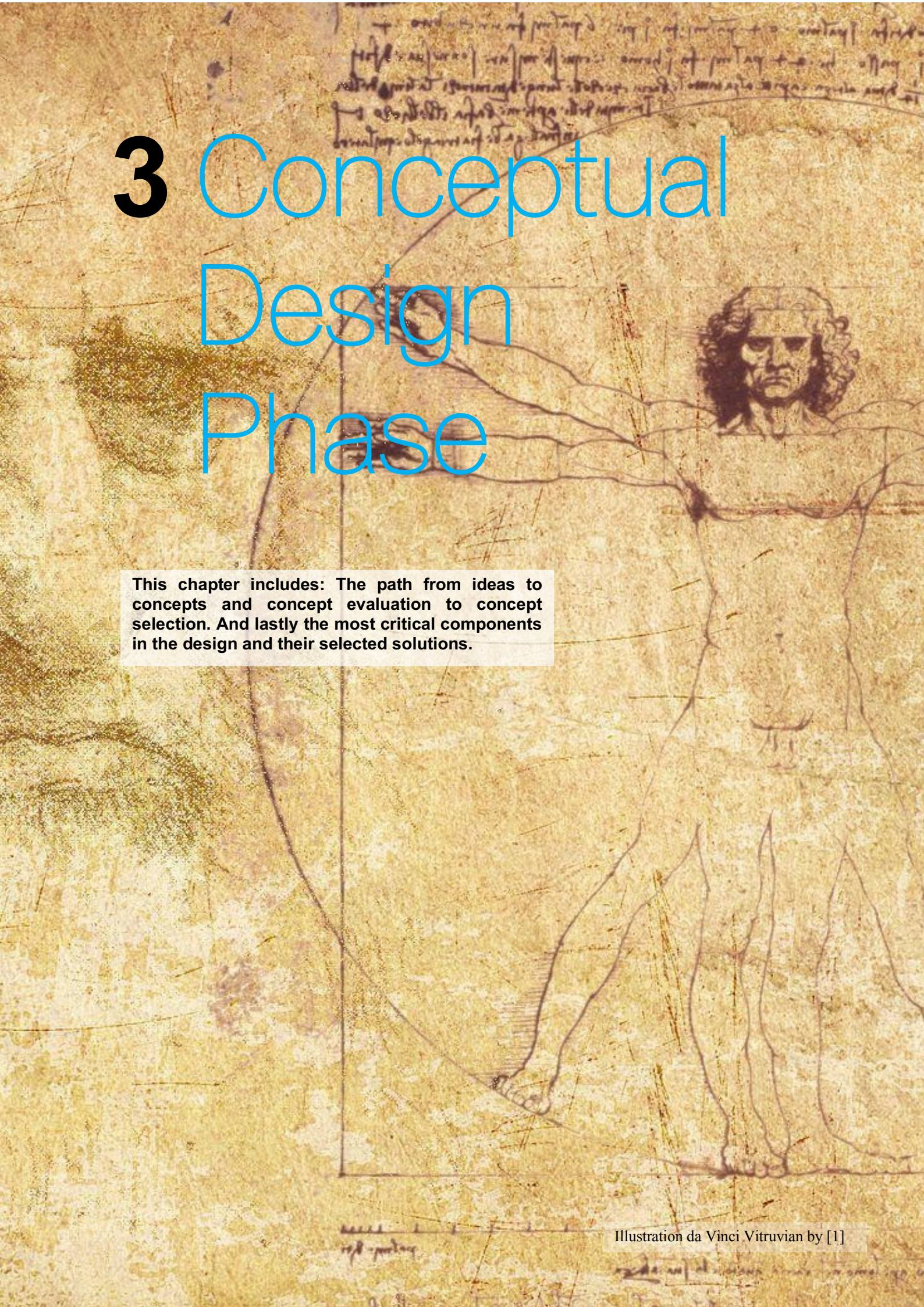
20. ...have fitting dimensions for a 5 mm laparoscopic instrument.

21. ...allow for a jaw opening angle greater than 45 degrees [39].
22. ...fit most standard trocars for 5 mm instruments and the outer diameter should be less than 5.3 mm [41].
23. ...have similar size as conventional laparoscopic instruments, thus Shaft + tip length >330mm [38].

Safety

24. ...be safe in use for the patient and operator.
25. ...prevent leakage of electricity by using electrically insulating coatings.
26. ...prevent collateral tissue damage by using electrically insulating coatings
27. ...be biocompatible. Materials used should not be harmful to the patient, cause inflammatory or allergic reactions to the body's tissue.

3 Conceptual Design Phase



This chapter includes: The path from ideas to concepts and concept evaluation to concept selection. And lastly the most critical components in the design and their selected solutions.

3.1 Conceptualisation

In this section, an overview of the design steps in the synthesis phase are presented as well as ideas and concepts generation for the new steerable and reusable BVS and a Morphological chart.

3.1.1 Overview design steps synthesis phase

The flowchart below in Figure 3-1, shows all the steps of the synthesis phase included in Chapter 3. In Chapter 3, a clear division is made between creating and evaluating concepts for the body of the instrument and concepts for the tip. For some critical components of both the instrument body and the tip, a more in-depth concept solution step and selection has been made. The instrument body and tip are then merged and further elaborated in the embodiment section in Chapter 4.

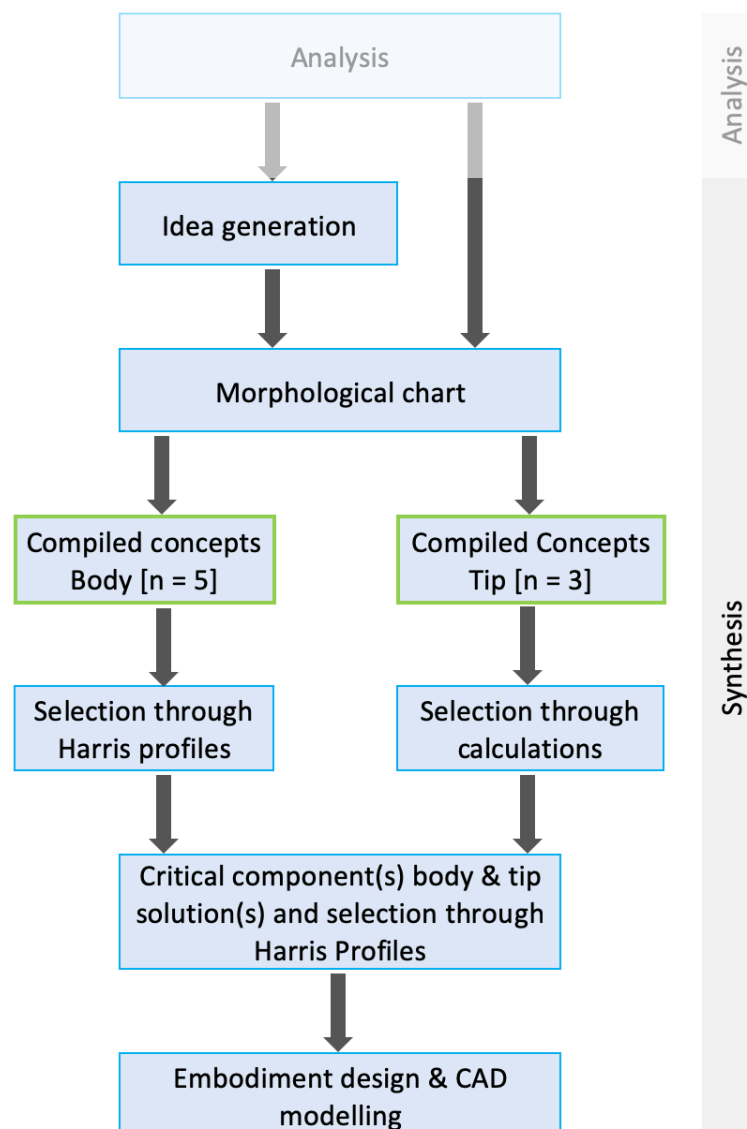


Figure 3-1, Flow chart conceptual design phase (Synthesis phase). Marked in green are the two sections of the instrument that are separately developed.

3.1.2 Idea generation

An exploded view of a laparoscopic SATA instrument is given in Figure 2-7, in the previous Chapter. Ideas for transferring bi-directional electricity through each of the components are generated using the Braindrawing method, see Figure 3-2. The resulted Braindrawing sketches are implemented in the Morphological chart on the next page.

Braindrawing is done with a group of people (>2). Each participant sketches his/her idea on a piece of paper, and the papers are passed on to each other. Ideas are elaborated on when it passes through numerous participants. [25]

Figure 3-2, Braindrawing method

3.1.3 Morphological chart

The morphological chart was used to summarize the ideas, technologies and design possibilities. Ideas are divided into the following subgroups:

- Ways to conduct electricity
- Conduct through the instrument shaft and core
- Conduct through the slider(s)
- Conduct through the H-hinge
- Conduct through the tip base

And for the tip:

- Tip open and close mechanism
- Jaw electrodes
- Tip housing insulation

Shaft-hinge

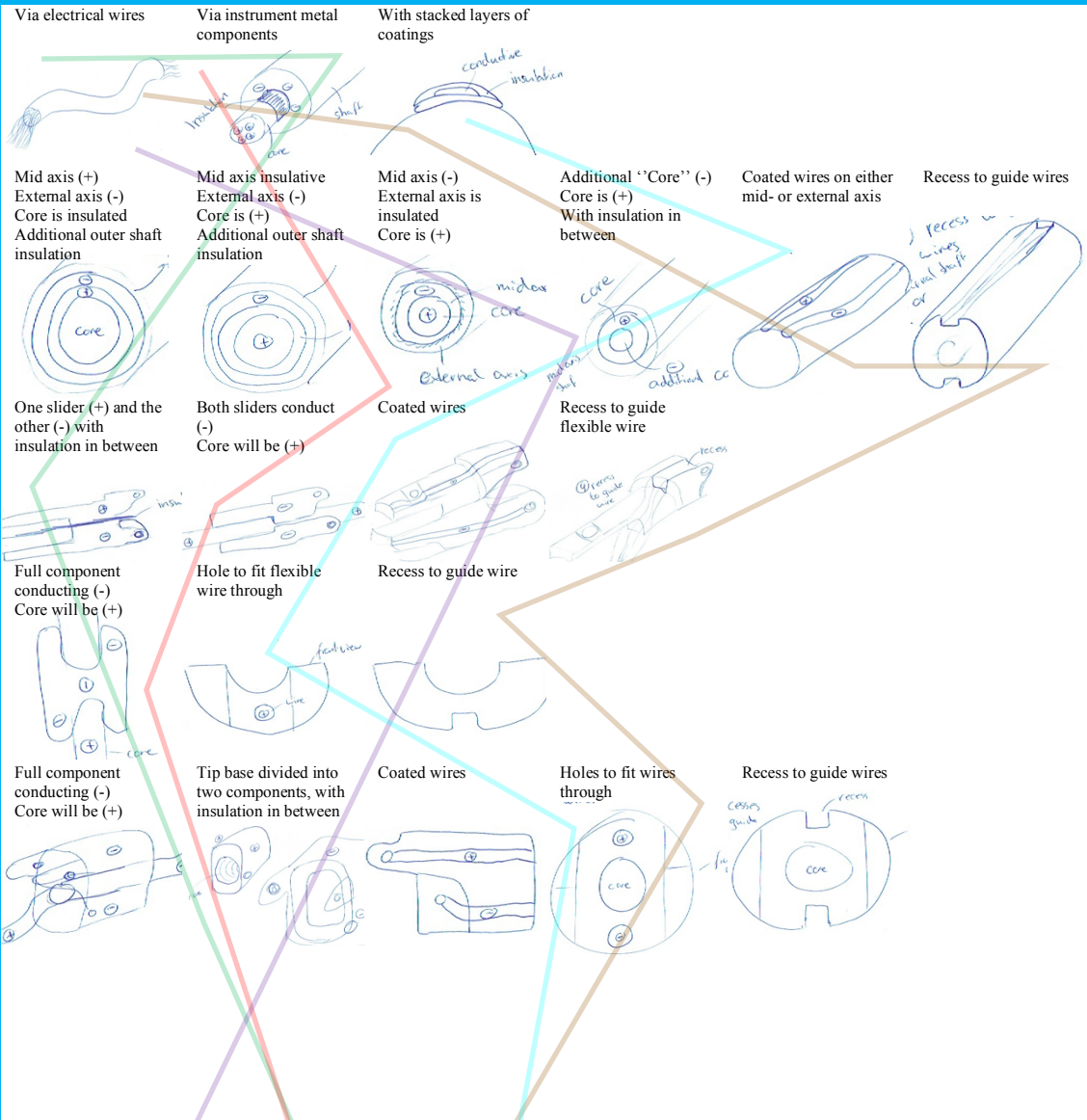
Ways to conduct bipolar electricity

Conduct through shaft + core

Conduct through Slider(s)

Conduct through H-hinge

Conduct through tip base

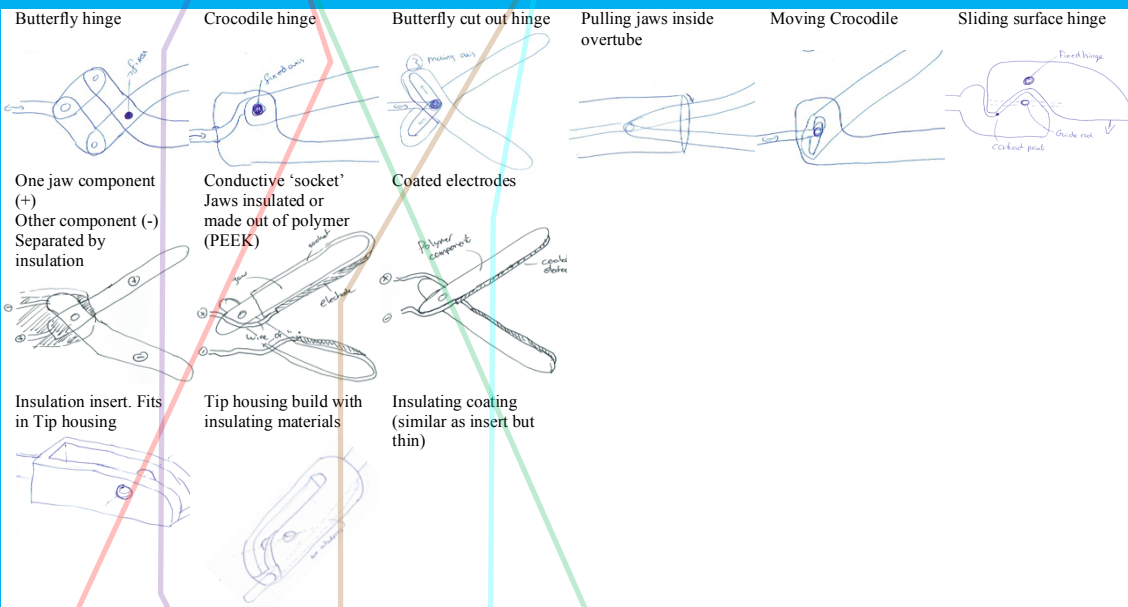


Tip

Tip opening mechanism

Jaw 'electrodes'

Tip insulation



The core model

The double core

External conductor

Coated 'wires'

The twins

3.2 Concepts Instruments body

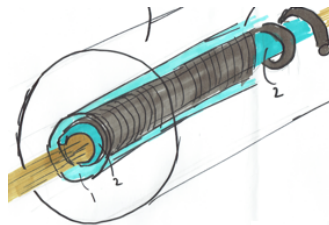
This section covers the creation of concepts that offer a solution to conducting electricity bi-directional through existing SATA components, concept selecting for the instrument body and a more detailed description of the selected concept.

3.2.1 Compiled concepts instrument body

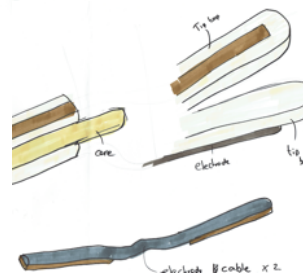
While various combinations are possible, five concepts have been compiled to show the distinctive possible directions, see Appendix 8.1. In each of the concepts, the basis of the instrument is a steerable SATA mechanism. The initial starting point is the creation of an active (+) and return (-) electrode where, if possible, the existing SATA components are part of the electrode(s). Although in a number of concepts the open and close mechanism is part of the electrical circuit, these components are not specifically included in the concepts. Options for the mechanism and concepts for the tip are discussed separately. The complete sketches of the following five concepts are shown in Appendix 8.1 in respective order.

For clarification, within the conceptual drawings, the conductive paths are indicated with (+) sign (active electrode) and (-) sign (return electrode). Bipolar mode uses alternating current (AC), in effect the two paths will alternate (+) and (-), thus they are bi-directional.

Concept 1 – Double core



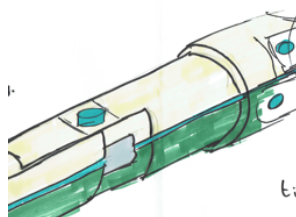
Concept 2 – The external conductor



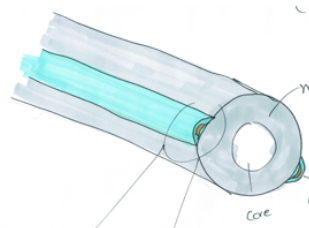
Concept 3 – The core model



Concept 4 – The twins



Concept 5 – Coated 'wires'



3.2.2 Instruments body concept selection

The Harris profile in Table 3-1 provides an overview of the strengths and weaknesses of each concept. The Harris profile is used as reference in decision-making, and helps to determine the best possible design solution for the steerable reusable bipolar vessel sealer. It is important to realise that the assessment is done by the decision maker, thus it is mainly used as a reflective tool to review the concepts and start discussion. The final score should not be taken to literally, but more as an indication of the value of a concept.

The criteria mentioned in the Harris profile are derived from the design requirements. Certain requirements have been clustered for convenience, such as functionality being a cluster of design requirements 2 - 6. For each criteria, the concepts are scored on a scale of -- (-2), - (-1), + (+1), ++ (+2). The total score of each concept is the sum of the pluses and minuses. No weighting factor has been added to the criteria.

The outcome of the Harris profile is decisive, concept 3 'the core model' scores best on most criteria and has an overall score of 14. Most important criteria are the functionality, the reusability and the steerability of the instrument. Moreover, apart from tactically placed electrical insulation, no components need to be added or replaced and only 'minor' adjustments are required compared to the current SATA mechanism. Another factor that strengthens the outcome for this concept is the fact that it uses proven techniques to conduct electricity through the core and other components, which is similar to Aesculap and Storz devices.

Concepts 1 and 2 show potential as well, but these concepts require the addition of several components. Additional components increase costs, possibly complicates cleaning and sterilization and the risk of damaging a component increases, which in turn decreases reusability. Hence, concept 1 and 2 are ranked lower than concept 3. Main reasons for concept 4 and 5 to score low are the vulnerability of insulating layers, the large number of additional components in concept 4 and the predicted complexity of the designs.

Table 3-1, Harris profile. Evaluation and selection of the instrument body concepts.

Instrument Body	1. Double core				2. The external conductor				3. The core model				4. The twins				5. Coated 'wires'			
Criteria cluster	--	-	+	++	--	-	+	++	--	-	+	++	--	-	+	++	--	-	+	++
1 Functionality																				
2 Reusability																				
3 Steerability																				
4 Cleanability																				
5 Sterilisable																				
6 Reduced additional components																				
7 Complexity																				
Total Score	6				6				10				1				3			

3.2.3 Concept of choice instrument body

Concept 3, the core model, has been slightly updated and a more detailed drawing can be seen in Figure 3-3. Electricity will run through the core, open and close mechanism and the upper jaw forming the active (+) electrode, then through the blood vessel or tissue and then back to the generator via the lower jaw and several components of the SATA instrument's mechanism and shaft, forming the return (-) electrode. The core is coated with isolation as well as the external axis shaft, to prevent short circuiting or leakage. The core must be both flexible, to be able to bend within the SATA mechanism, as well as torsional stiff for the rotation of the tip.

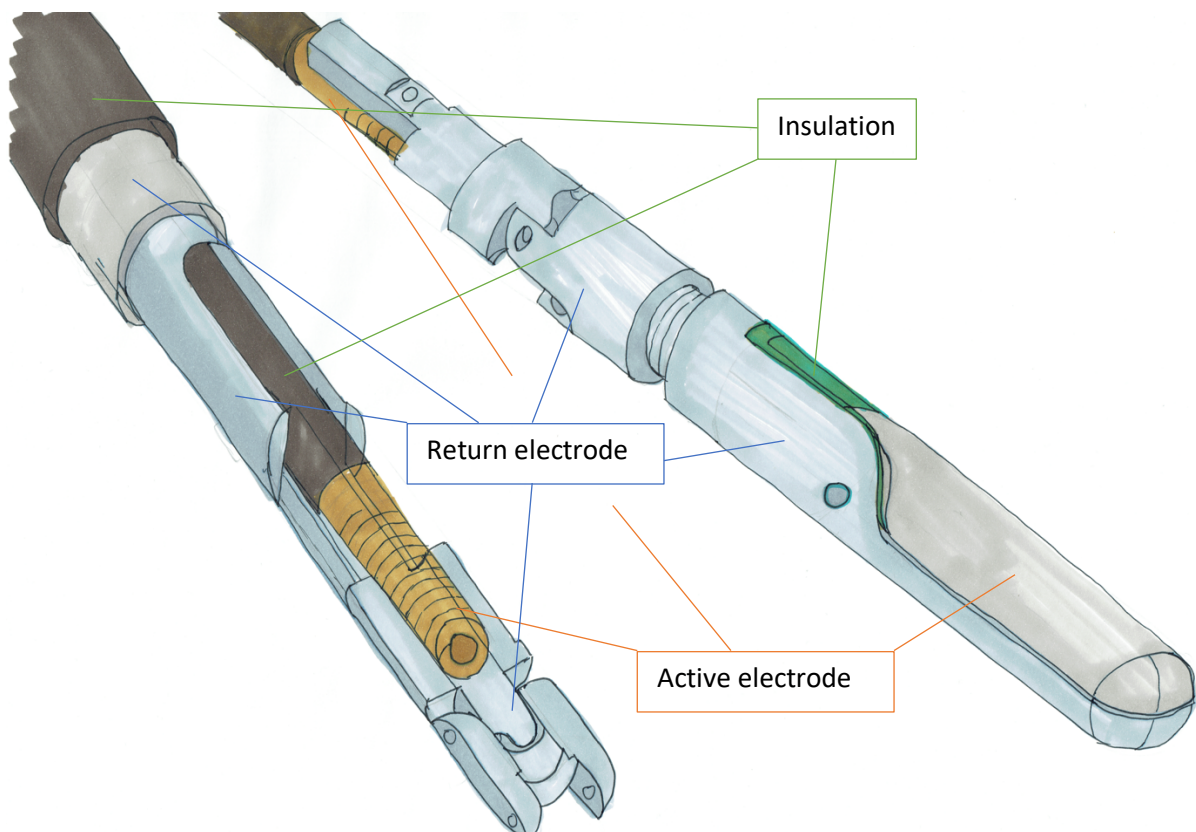


Figure 3-3, Selected concept. Derived from the 'The core model', the winning concept is drawn. Insulating coatings of the core and outer axis shaft are coloured black. The core itself is part of the active electrode and is coloured golden-brown. The blue-grey components are part of the return electrode. Green colour is illustrating is the tip housing insulation (yet to be determined)

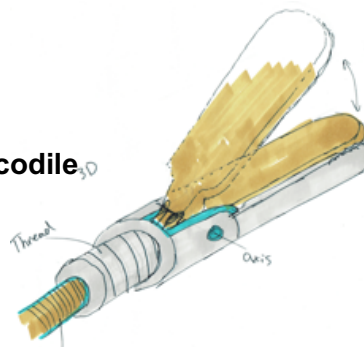
3.3 Concepts BVS Tip

A different approach is required for the creation and selection of tip concepts. For the design of the tip it is important to implement a suitable and fitting open and close mechanism of the jaws and it must be ensured that the tip can function in bipolar configuration.

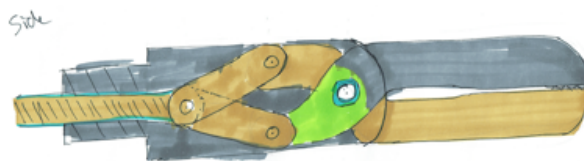
3.3.1 Compiled concepts BVS Tip and corresponding open and close mechanism

Three concepts have been compiled using the morphological chart. It is important that the tip is attached to the SATA mechanism (nut side) by means of a thread (bolt side). The concepts show a number of design solutions for the bipolar conductivity through the tip as well as three different open and close mechanisms. The complete sketches of the three tip concepts are shown in Appendix 8.1 .

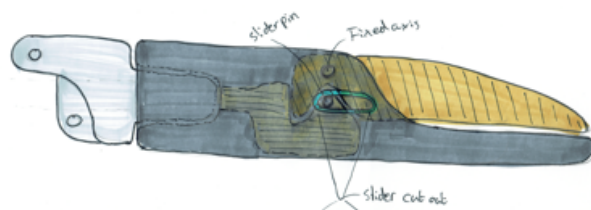
Tip concept 1 – The Crocodile (Mechanism 1)



Tip concept 2 – The Butterfly (Mechanism 2)



Tip concept 3 – The Slider (Mechanism 3)



3.3.2 Tip open and close mechanism comparison through calculations

In the previous sections, the emphasis was on generating concepts showing different solutions for conducting electricity through a SATA instrument and tip. Besides adding bipolar energy, compression of the tissue is important to obtain a good seal, (see requirement 5). The mechanism by which the tip opens and closes plays an important role in obtaining the correct pressure on the tissue.

The ratio in force transmission between the core and the jaws has been determined for each of the three mechanisms. This concerns the ratio between: 1) the tensile force in the core, F_t and 2) the desired force of 20N exerted on the tissue, F_{seal} . A number of assumptions have been made in the calculations to compare the three mechanisms:

- i. F_r and F_t are maximum when the tip is in fully closed position.
- ii. The lever arm length (L_1) depends on the vessel diameter and jaw length, but is set to 12.5 mm for this example.
- iii. The lever arm length (L_2) is set to 4.0 mm.
- iv. Diameter of the instrument is 5 mm. For simplicity L_3 is set at 5 mm, although in reality the hinges require material to be held in place such that $L_3 > 5 / 2$.
- v. Length L_4 is set to 6.0 mm.
- vi. Excluded are: friction, masses and gravity.
- vii. The mechanism must allow a jaw opening of $\Rightarrow 45^\circ$. (requirement 21)

Appendix 8.2 details the calculations for each of the following mechanisms.

Mechanism 1) Scissor mechanism with one link, see Figure 3-4. Well-known instrument manufacturers using a similar type of mechanism are among others: Storz (Storz RoBi), KLS Martin (MarSeal) and Ethicon (ENSEAL).

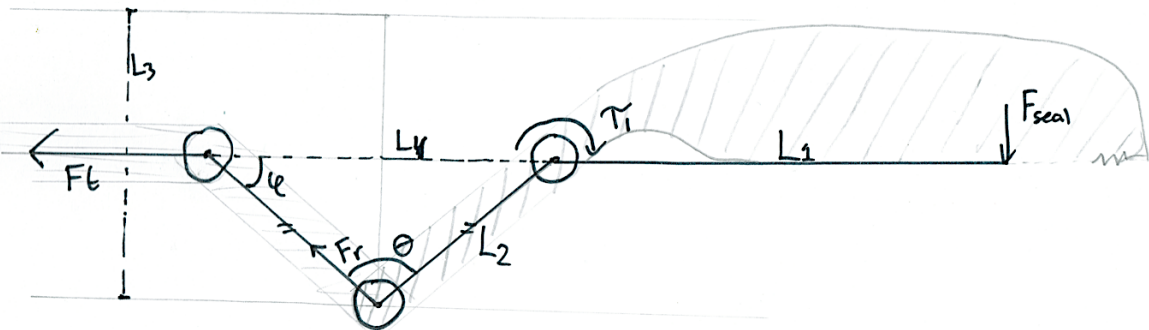


Figure 3-4, Sketch of mechanism 1. By applying F_{seal} we obtain T_1 at the fixed hinge axis. The link has equal length with respect to L_2 .

Following the configuration in the figure above we obtain: $F_r = 63.0\text{N}$, $F_t = 47.2\text{N}$ and the ratio = **0.42**. In other words, to exert a force (F_{seal}) of 20N on the tissue while using the configuration above, a pulling force **$F_t = 47.2\text{N}$** on the core is required.

Mechanism 2) Scissor mechanism with dual link. Well-known instrument manufacturers that use a similar type of mechanism are among others: Aesculap (AdTec) and Storz (Storz RoBi)

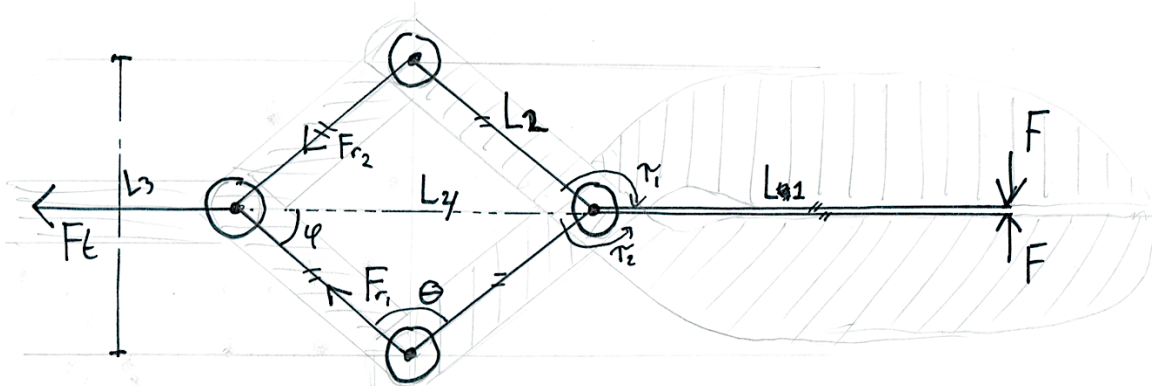


Figure 3-5, Sketch of mechanism 2. Both jaws are able to apply force in this configuration. $F_{seal} = 20\text{N}$ is divided by two, which gives $F = 10\text{N}$. Similarly to the previous calculations for mechanism 1, the torque(s) and forces are determined.

Following the configuration in Figure 3-5 we obtain: $F_{r1} = F_{r2} = 31.5\text{N}$, $F_t = 47.2\text{N}$ and the ratio = **0.42**. In this configuration each jaw exerts a force of 10N on the tissue. Subsequently, the

forces $F_{r(1-2)}$ and $F_{t(1-2)}$ can be calculated for each of the jaws in a similar way as mechanism 1. Adding up F_{t1} and F_{t2} results in the total required tensile force in the core **$F_t = 47.2\text{N}$** .

Mechanism 3) Scissor mechanism without link. The specific mechanism shown in Figure 3-6 is derived from the latest development in SATA instruments. The functionality of this mechanism is comparable to the mechanism applied in the widely used Covedien (LigaSure) instruments. In this configuration the two components, Upper Jaw and Core, are not directly connected by a link. Instead, there is a slide / roll connection between the two parts. When the core is pulled in direction F_t , the jaw closes. When pushed in the opposite direction, the upper jaw opens. By clever designing the contact area of the two components and selecting the right length L_2 and angles θ and ϕ , an optimal force transmission ratio could be obtained. This mechanism requires a slightly different approach compared with the previous two mechanisms. There are no hinged link connections in mechanism 3 and friction plays a crucial role. For the comparison with the previous mechanisms, $L_2 = 4$ and $\theta = 45^\circ$ have been chosen. In addition, $\phi = 40^\circ$ has been chosen. The friction coefficient for steel on steel is 0.57.

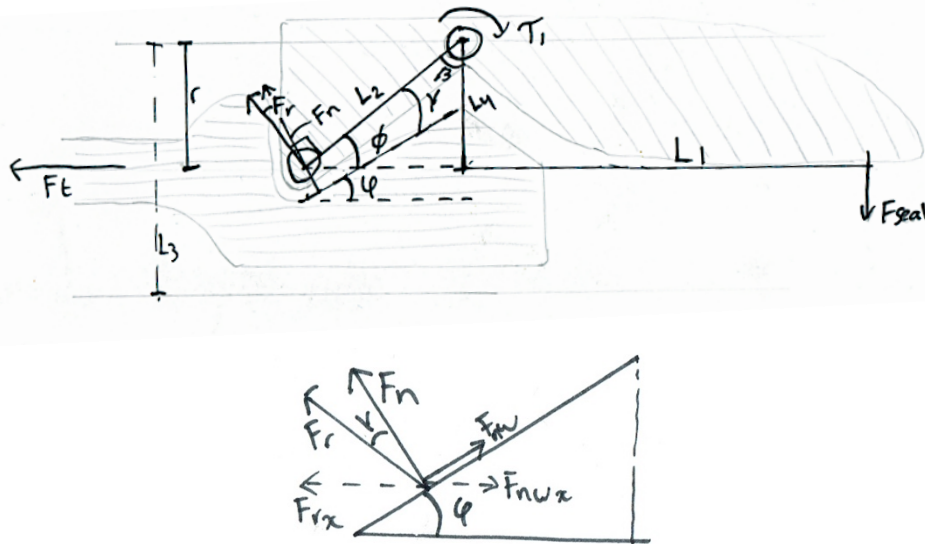


Figure 3-6, Sketch of Mechanism 3, Top. This configuration uses no linkages to connect the Upper jaw and core. Length L_2 and both angles θ and ϕ can be adjusted, and will affect the resulting force F_r and required pulling force F_t . Bottom: sketch used to determine frictional forces.

The calculation in Appendix 8.2 gives an approximation of F_t in this configuration, which is **71.4N** and a ratio of **0.28**. However, the overall dimension of mechanism 3 is shorter compared to mechanism 1 and 2, because no linkages are needed. Thus, there is some room to extend L_2 . Therefore, similar calculations have been done with lengths $L_2 = 5.0\text{ mm}$ and $L_2 = 6.0\text{ mm}$, resulting in forces $F_t = 57.1\text{N}$, ratio = 0.35 and $F_t = 47.6\text{N}$, ratio 0.42 respectively.

Concluding: Assuming equal dimensions of the three mechanisms, all of them show similar force transmission ratios. However, there are some remarks to be made about the assumptions made earlier which ultimately affect the efficiency when the mechanism is implemented into the instruments design:

- i. According to the principle of moments, the ratio approaches 1.0 when length L_2 approaches length L_1 and vice versa. However, a short L_1 is not desirable because it results in a short jaw length. Conversely, a long L_2 is not desirable as it results in an overall long tip body when the jaws are opened.

- ii. In the design, when the tip is closed, each component must be within the required diameter of 5.0 mm. This means that the hinge points, as they are placed in the sketches do not correspond to a realistic design. In other words, distance L3 will be shorter, causing angle θ and length L4 to be greater in mechanism 1 and 2. For mechanism 3 it means that L4 is shorter and θ smaller. It results in an increase of the resulting force F_r and required pulling force F_t .

Points of improvement of the configurations are:

i. Mechanism 1

Point(s) of improvement(s):

- The Upper jaw's axis of rotation can be moved upwards. This allows length L2 to elongate and brings angle θ closer to 90° . Without having to increase the overall dimension of the mechanism, this adjustment can provide a higher force transmission ratio.

Benefit(s):

- Compared to mechanism 2, only one link component is needed reducing the number of hinges.
- Compared to mechanism 2, there is additional room for geometry adjustments (see point of improvement).

ii. Mechanism 2

Point(s) of improvement(s):

- Length L2 could be increased to improve the force transmission ratio, although this will increase length L4 and angle θ as well.

Benefit(s):

- Compared to mechanism 1, half the tensile force (F_r) is applied to each link.
- Compared to mechanism 1, double the angular rotation [degrees] of the jaws with the equal translation [mm] of the core.
- Compared to mechanism 3, allowing a greater angle [degrees] between the jaws (In this comparison, the angular rotation in mechanism 3 cannot be directly translated to translation [mm] of its core).

iii. Mechanism 3

Point(s) of improvement(s):

- Requires complex design of slopes θ and ϕ .

Benefit(s):

- Compared to mechanism 1 – 2, no linkages are needed.
- The number of hinges is reduced to one, although a constrained connection between the lower pulling component and the mechanism housing (i.e. tip body) is added.

A more comprehensive calculation of mechanism 1 and 3 is carried out in section 4.1.3 and Appendix 8.2. respectively. These calculations are more precise and realistic and are used to determine the optimal geometry of the mechanism. Furthermore, the calculations show that mechanism 1 is better suited for implementation in the design because forces F_r and F_t are lower in this configuration.

3.4 Critical components solutions

In this section, the most critical components of the 'core model' concept and tip are identified. Several design directions have been drawn up for each of the critical components. Decision making is again based on clusters of design requirements.

3.4.1 Identifying critical components in design

Design modifications required to convert a SATA instrument into a BVS are primarily aimed at conducting electricity through the instrument. Simultaneously, we can consider these modifications and the associated components as most critical in the new design. This means that the following components are considered critical:

- 1) The core (inner axis shaft): At least part of the component must be flexible so that the tip remains steerable. At the same time, it will act as an active electrode thus requiring a fully surrounding insulating coating, except for the area in direct contact with the link or upper jaw.
- 2) The external axis shaft: The external shaft of the instrument must be insulated to prevent collateral damage. In addition, it must have suitable mechanical and tribological properties.
- 3) The tip housing insulation: In bipolar configuration, an active electrode is connected to one of the jaws and a return electrode to the other. Apart from the sealing surfaces, it is important that the active and return electrode, and therefore also the jaws, are separated from each other by means of an insulating layer.

3.4.2 Design direction selection

Multiple design solutions for each of the critical components are presented and evaluated separately based on the design requirements and the clustered criteria obtained from section 3.2.2. *Please note that the design solutions are independent and can be implemented into the final design in any possible combination.*

Critical component 1: Two solutions for the design of the (partly) flexible core are presented:

- A. Figure 3-7: A stiff rod with attached a ~10 mm long flexible and torsional stiff end section (e.g. torque coil) that allows the core to bend through the SATA steering mechanism, combined with a flexible insulative coating or socket.
- B. Figure 3-8: A stiff rod with attached a ~10 mm long flexible and torsional stiff nitinol end section that allows the core to bend through the SATA steering mechanism, combined with a flexible insulative coating or socket.

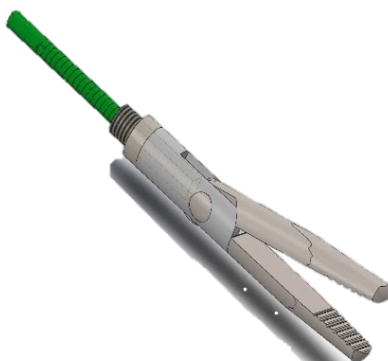


Figure 3-7, **A:** Flexible and torsional stiff stainless-steel coil (green).



Figure 3-8, **B:** Flexible and torsional stiff nitinol rod (black).

In support of Table 3-2, the choice for implementing a Nitinol core is mainly because a coil is expected to be more difficult to clean thoroughly and therefore less suitable for reuse. Furthermore, it is expected that the stainless steel will become permanently deformed over time, and thus losing its functionality.

Table 3-2, Harris profile design solutions for critical component 1.

Critical component 1	1. Stainless steel flex core				2. Nitinol flex core				3.			
Criteria cluster	--	-	+	++	--	-	+	++	--	-	+	++
1 Functionality												
2 Reusability												
3 Steerability												
4 Cleanability												
5 Sterilisable												
6 Reduced additional components												
7 Complexity												
Total Score	2				7							

Critical component 2: Two possible design solutions for insulating the external axis shaft are:

- C. Figure 3-9: Additional external insulation shaft, with a maximum thickness of 0.15 mm. The outer diameter of the shaft will then be 5.3 mm and would just fit through a standard sized trocar. In this case a polymer-based material with a low friction coefficient would be preferred.
- D. Figure 3-10: The external axis shaft is completely covered with a ceramic insulating coating with a thickness >0.15 mm. In this case no additional shafts are necessary.

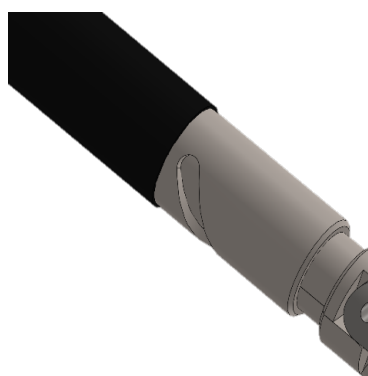


Figure 3-9, C: Additional external insulation shaft (black) with maximum wall thickness of 0.15 mm

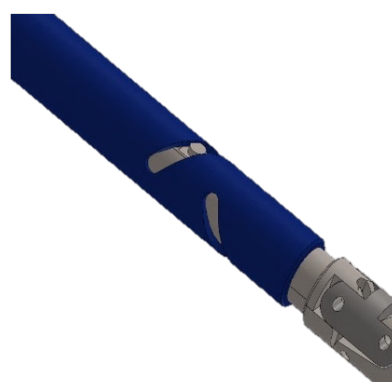


Figure 3-10, D: Coated (ceramic) insulation (blue), covering the entire in- and outside of the external axis shaft. Thickness = ~0.05mm

Table 3-3 shows that neither concept is convincingly better. The choice for a coating instead of an extra shaft is made because this does not require any modifications to the existing SATA components and no extra components are added to the instrument. Nevertheless, more research into potentially suitable coatings needs to be carried out before a final decision can be made, which is not in scope for this thesis project.

Table 3-3, Harris profile design solutions for critical component 2.

Critical component 2	1. Additional insulation shaft				2. Coated external shaft				3.			
Criteria cluster	--	-	+	++	--	-	+	++	--	-	+	++
1 Functionality												
2 Reusability												
3 Steerability												
4 Cleanability												
5 Sterilisable												
6 Reduced additional components												
7 Complexity												
Total Score	6				11							

Critical component 3: There are three proposed solutions to isolate the upper and lower jaws from one another:

- E. Figure 3-11: Insulated insert, could be either polymer or ceramic material. The insert could also be applied as coating. The base of the tip will consist of stainless-steel and the insert ensures that the two electrodes remain separate.
- F. Figure 3-12: Insulated tip body component, preferably polymer material. In this concept, a non-conductive tip housing ensures that the two electrodes are automatically separate. As part of the return electrode, a conductive rod through the tip housing must ensure a closed circuit.
- G. Figure 3-13: Insulated sockets. Because parts of the jaws are constructed with non-conductive materials, the electrodes remain separate.

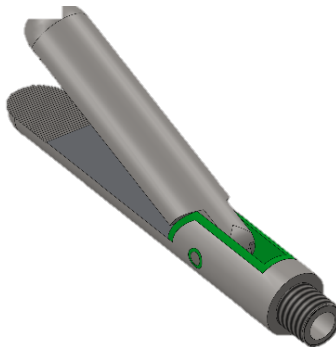


Figure 3-11, Insulated insert, coloured in green.

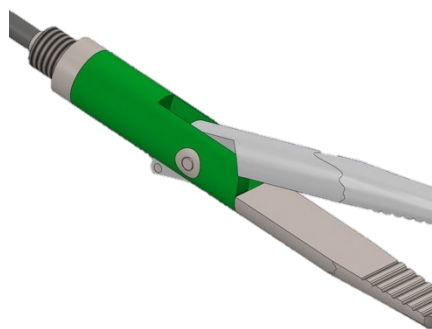


Figure 3-12, Insulated tip body component. (The green component is constructed using non-conductive material.

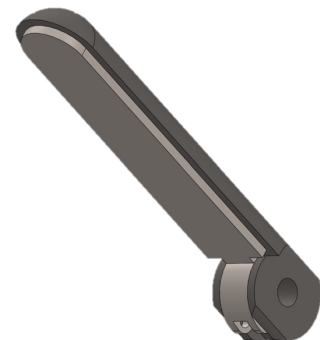


Figure 3-13, Insulated sockets. The black coloured component is constructed using non-conductive material.

No decisive best-suited design solution for critical component 3 is obtained from the Harris profile in Table 3-4. In early design iterations of the tip, all three design solutions were explored. Option 2, a fully insulating tip body was eventually implemented in the final design because this design solution has excellent compatibility with the selected open and close mechanism.

Table 3-4, Harris profile design solutions for critical component 2.

Critical component 3	1. Insulated insert				2. Insulated tip body				3. Insulated sockets			
Criteria cluster	--	-	+	++	--	-	+	++	--	-	+	++
1 Functionality												
2 Reusability												
3 Steerability												
4 Cleanability												
5 Sterilisable												
6 Reduced additional components												
7 Complexity												
Total Score	6				6				0			

3.5 Concept selection summary

The five selected design solutions for the instrument body, the tip and the critical components are presented in the overview below.

Concept 'the core model' has been chosen for conducting bipolar electricity through the instrument body.

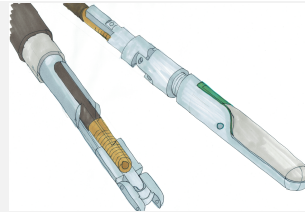


Figure 3-14, 'The core model' selected concept direction

Open and close mechanism 1, 'the crocodile', has been selected to be implemented in the final model.

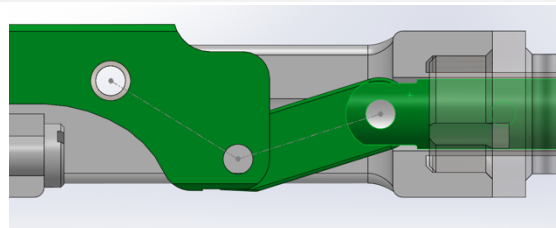


Figure 3-15, 'The Crocodile' selected concept direction

A flexible nitinol core has been selected. As shown in the figure on the right, a piece of nitinol is attached between two stainless steel components that compose the core.

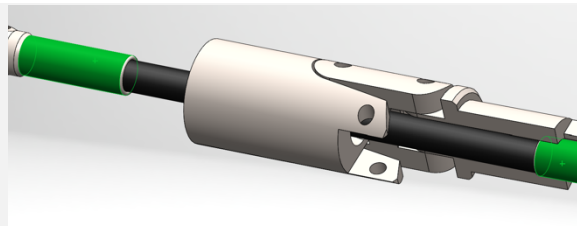


Figure 3-16, 'Flexible Nitinol' rod selected concept direction.

A coating is applied to the outer shaft for electrical insulation. As shown in the figure on the right, this coating can also be applied to the other components for insulation and other functions.



Figure 3-17, 'Coated Insulation' selected concept direction.

To keep the two jaws separated, a tip housing made of PEEK has been chosen. PEEK is a polymer and does not conduct electricity.

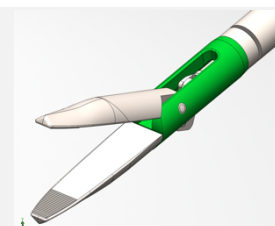


Figure 3-18, 'Insulated tip body' selected concept direction.

4 Embodiment Design

This chapter includes: Technical details such as, law length, hinge pin diameter and material selection. The final geometry for the selected open and close mechanism determined using Matlab.

In the last section, a detailed final CAD model of the steerable and reusable BVS is presented.

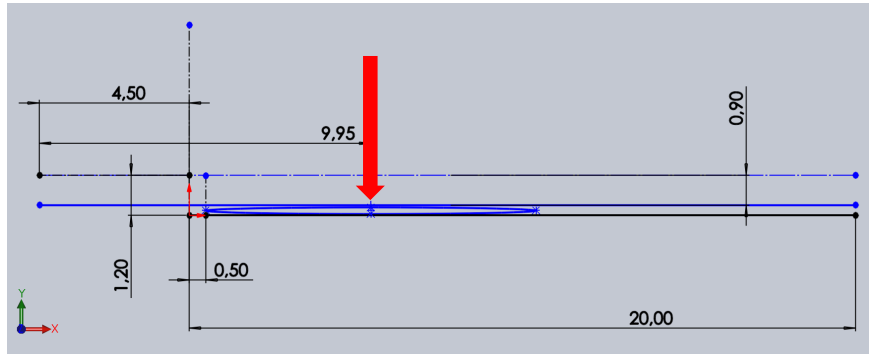


Figure 4-2, Jaws closed with compressed 7mm blood vessel. The point of application of F_{seal} is in the middle of the ellipsoid. Together with an additional safety margin, length $L1$ is 9.95 mm. The red arrow indicates the point of application of F_{seal} .

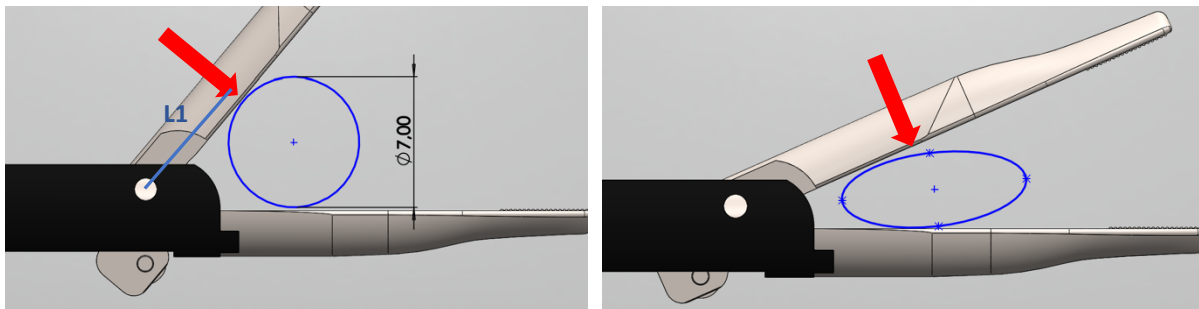


Figure 4-3, Vessels and tissue clamping configuration. Red arrows indicate the point of application of F_{seal} .

4.1.2 Pin shear stress and required axis diameter

In the SATA mechanism there are already some hinge connections, between the sliders, h-hinge and tip base components. The hinges' pin diameter has already been defined for these connections. The required hinge pin diameter(s), related to the open and close mechanism of the tip, are determined in this section. Like all other components of the instrument, the materials used for constructing the pins must meet the design requirements. AISI 316L stainless steel is selected for pins 1,2 and 3, shown in Figure 4-4.

Three hinges have been added in this regard:

1. At T1, the upper jaws' axis of rotation.
2. Connecting the upper jaw and link component.
3. Connecting the link and core.

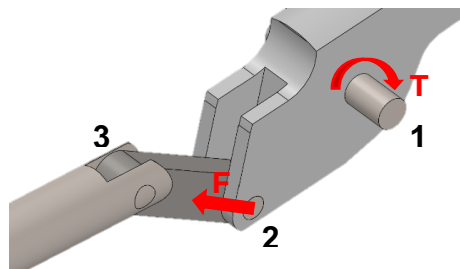
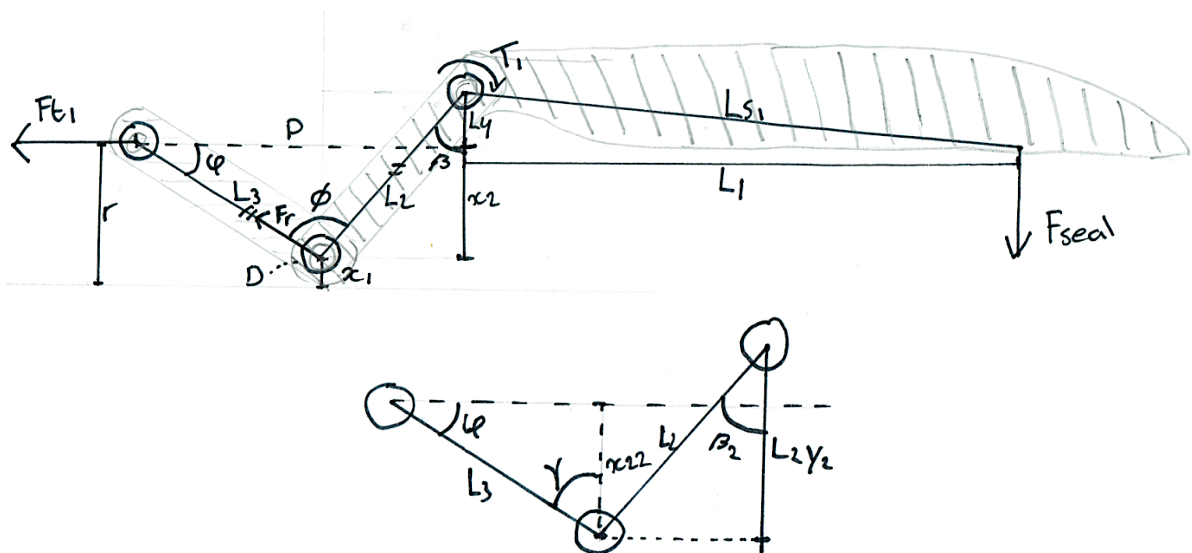


Figure 4-4, Tip hinge mechanism. In this configuration, three hinge pins are required.

Based on the calculations in Appendix 8.2, a pin diameter of 0.9 mm has been chosen. A 316L pin with a diameter of 0.9 mm and 100N applied, results in a maximum shear stress $T_{max} = 157.2$ MPa. This is slightly higher than the allowable shear stress $T = 150$ MPa [43], however this concerns a safety factor of $\sim 3 - 3.5$. In addition, the applied force of 100N is higher than the forces F_r or F_t will be. Therefore, it is unlikely that the shear stress will cause problems when a diameter of 0.9 mm is chosen for the final model.

To determine the most suitable geometry, a script is written in Matlab in which the resulting forces were calculated on a number of additional variables. The simplified version of mechanism 1, from section 3.3.2, has been further elaborated and optimized. Consult Appendix 8.2 for the script and the results. An overview of the geometry to be determined is presented in Figure 4-5. The variables that determine the resulting forces F_r and F_{t1} and the decisive dimensions of the mechanism are:

- It must be emphasised that Fseal does not apply to the most distal end of the jaw, but in the centre of the blood vessel or tissue to be sealed. This means that L1 is not equal to the total length of the jaw.



In the final geometry of the model, a length $L_2 = 4$ mm was selected. In summary this means that:

- 34

- $L2 = 4.0 \text{ mm}$
- $L3 = 4.0 \text{ mm}$
- $L4 = 1.0 \text{ mm}$

The choice for a length $L2$ of 4 mm was made based on the following three points.

1. In fully closed configuration of the jaws ($\beta_2 = \beta + 0^\circ$), the resulting force F_r equals **54.5N**. From Figure 4-6 and Appendix 8.2, it can be observed that as long as the angle between the upper and lower jaw $<30^\circ$, F_r is smaller than 54.5N.
2. Figure 4-7 shows that for all $L2 > 4 \text{ mm}$, F_{t1} is always smaller than F_{t1} in fully closed position of the jaws. **$F_{t1} = 49.7\text{N}$** for $\beta_2 = \beta + 0^\circ$.
3. In principle it is most favourable when the forces F_r and F_t are as low as possible. However, the shortest possible length P is also desirable because this determines the overall length of the tip's housing for the most part. In addition, the required translation of the core is also determined by length P . To reduce wear of the core component and its coating due to translation (friction), the smallest possible translation is desirable. The forces at $L2 = 3.0 \text{ mm}$ or 3.5 mm are higher than at $L2 \Rightarrow 4 \text{ mm}$. All options for length P shorter than length P at $L2 = 4 \text{ mm}$ are therefore excluded.

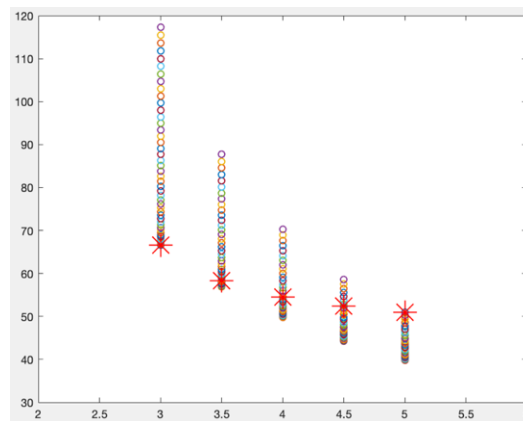


Figure 4-6, $L2$ plotted against F_r . For five different lengths of $L2$, the graph shows the force F_r at closed position of the jaws ($\beta_2 = \beta + 0^\circ$) indicated with a red star *. In Appendix 8.2, all values for F_r are given depending on the angular displacement.

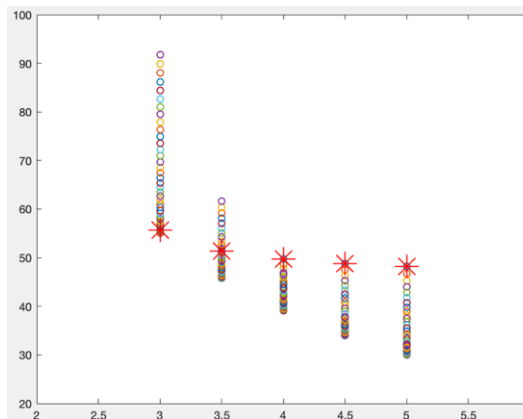


Figure 4-7, $L2$ plotted against F_{t1} . For five different lengths of $L2$, the graph shows the force F_{t1} at closed position of the jaws ($\beta_2 = \beta + 0^\circ$) indicated with a red star *. In Appendix 8.2, all values for F_{t1} are given depending on the angular displacement.

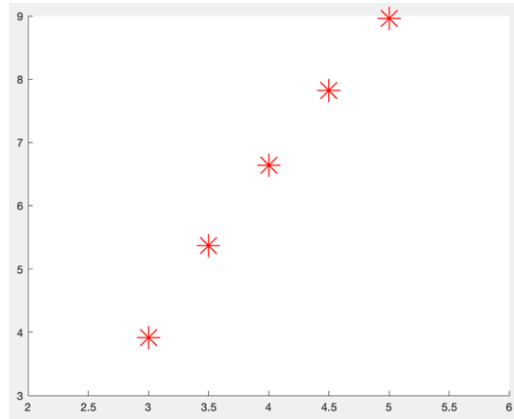


Figure 4-8, L_2 plotted against Length P . Length P gives an indication of the global dimensions of the open and close mechanism. P is measured between the fixed hinge of the upper jaw and the hinge connecting the core with the link, the latter holds for in fully closed position.

L_1 has been determined at **9.95 mm** in the previous paragraph. For simulation purposes in the next chapter, $L_1 = 12.5$ mm was used as well. This results in higher required forces (F_r and F_{t1}) and therefore higher stresses occurring in the simulations. The components of the instrument were assessed based these stresses, among other things.

4.1.4 Grasping forces mechanism 1

Grasping and manipulation tissue or sealing small tissues is possible done with the most distal part of the tip, as illustrated in Figure 4-9. The pinch force necessary to manipulate tissue without slipping or damaging tissue is 3N to 7N [39, 40]. The resulting force F_r and core pulling force F_{t1} for manipulating tissue have been calculated using equal input as in section 4.1.3 and the following modifications:

- $F = 7\text{N}$ (pinch force)
- $L_1 = 25.0$ mm (most distal part of the jaw)

This results in:

- $F_r = 47.9\text{N}$ (for $\beta_2 = \beta + 0^\circ$)
- $F_{t1} = 43.7\text{N}$ (for $\beta_2 = \beta + 0^\circ$)

Calculations for grasping and manipulation of tissues, where a force F_{seal} of 7N must be applied at the most distal point of the tip ($L_1 = 25$ mm), do not result in a higher required tensile force F_t than for sealing with 20N and $L_1 = 12.5$ mm. However, the grasping and manipulation of tissues must be counted as one cycle for determining the lifespan of the components in question, because the forces F_r and F_t are similar in the case of sealing and grasping or manipulation.

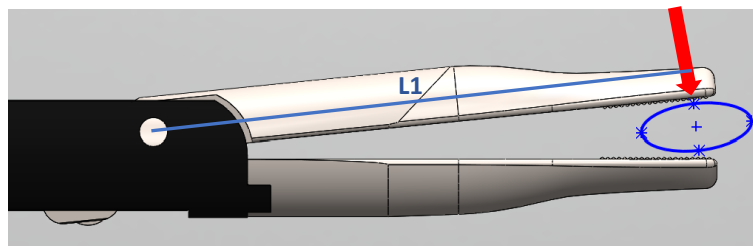


Figure 4-9, Illustration of vessel (blue ellipse) grasping with distal end of the tip. Red arrow indicates the point of application of F .

4.2 Material selection

Material properties play an important role in determining the mechanical configuration and final geometry, for example to calculate the required hinge axis pin diameter. Hence, in this section, some commonly used materials within medical instrument industry have been examined and presented. In addition, for each of the critical components a suitable material is proposed.

4.2.1 Material overview

There are various material types suitable for electrical insulation applications, such as polymers and ceramics. Certainly with the polymers, but also with the ceramics, there are large differences in material properties, which implies the possibility to choose a suitable insulation material for each specific component.

Within the final concept design and its critical components, electrical insulation must be applied in three areas:

1. Surrounding the core
2. Surrounding the external axis shaft.
3. Surrounding the open and close mechanism i.e. active and return electrode components and upper and lower jaws.

A selection of some potentially suitable materials is given in Appendix 8.5. Table 8-4 provides a summary on sterilisation suitability of common polymers and their material properties [44-46]. Polymers that are poor or fairly suitable for steam sterilization are not included in this table. Some common and widely available ceramics are given in Table 8-5 [47].

Lastly, an overview of suitable metals is given in Table 8-6. The highly corrosion resistant 316L stainless steel has been selected for all structural components of the instrument. Nitinol is a special material because it is highly flexible but at the same time a strong material and biocompatible. For these reasons, nitinol is used in, for example, guidewires, needles and medical instruments.

Materials and their properties are obtained from online material databases such as *MatWeb.com* and *MakeltFrom.com*.

Since each component serves a different functionality within the design, thus requiring different material properties, a specific type of insulating layer is desired:

1. Surrounding the core: The core must be flexible and torsion stiff. This is necessary to be able to rotate the tip but at the same time be flexible to bend within the SATA mechanism. Simultaneously, the core translates back and forth to initiate opening and closing of the jaw(s). Therefore, insulation surrounding the core must **be thin, flexible, wear resistant and have a low friction coefficient**.

In the final model, Polytetrafluoroethylene (**PTFE**), also known as Teflon, is selected.

2. Surrounding the external axis shaft: The external axis shaft is a rigid stainless-steel component which rotates around the mid axis shaft. A coating is applied that completely covers the external shaft. In addition, the same insulating coating is applied to the other stainless-steel components, including the external surfaces of the upper and lower jaws. The material selected for the insulating coating must be **wear resistant, impact resistant, scratch resistant, stiff** and a **low friction coefficient** is desired.

In the final model, a **ceramic** coating is applied. *(Note that these ceramic coatings were added for visual purposes only and that they were not included as part of the structures in the FEM simulations.)*

3. Surrounding the tip housing, open and close mechanism, active and return electrode components and upper and lower jaws: The insulating material must be **robust, wear resistant, impact resistant** and provide **structural support**.

In the final model, Polyetheretherketone (**PEEK**), is selected.

Furthermore, it applies to all insulated components and insulation materials that they meet the design requirements on usage and sterilisation. Therefore, materials require the following properties:

- i. Heat resistant
- ii. Corrosion resistant
- iii. Chemical resistant
- iv. Wear resistant
- v. Abrasion resistant
- vi. + mechanical properties as mentioned above

4.3 CAD modelling

Solidworks by Dassault Systèmes has been used to model the Reusable and Steerable Bipolar Vessel Sealer. The SATA mechanism is modified and a new tip design is built from scratch. Furthermore, an overview is given of all instrument components; the materials used; optional manufacturing methods; placement of coatings; and connections between the components.

4.3.1 SATA mechanism modifications

Modifications to the SATA mechanism have been made to allow the core to bend inside the mechanism without the sharp edges and angles causing a kink in the core, see Figure 4-10. The model is assembled in such way that rotations of the outer axis shaft steer the tip left and right as it does in reality. These motions were used to observe and derive the bending angles for experimental purposes in Chapter 6.

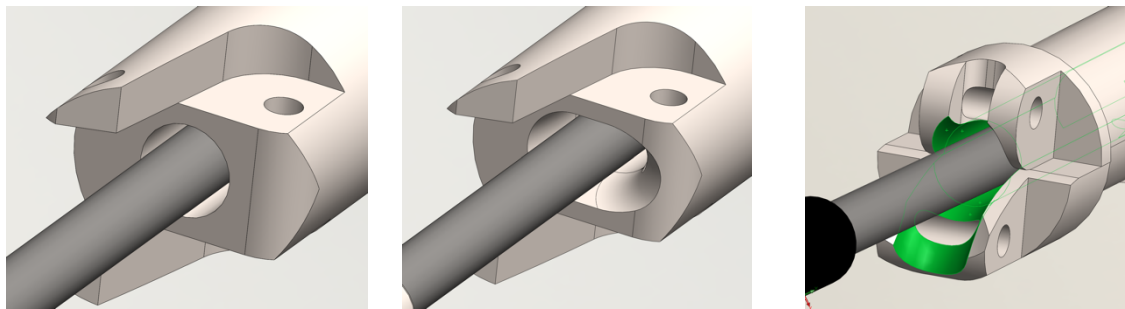


Figure 4-10, Minor SATA modifications. Left: original SATA tip base component with nitinol core (black). Middle: Rounded edges SATA tip base component. Right: Rounded surfaces (green) for both slider components. Rounding off the edges enables the nitinol rod to bend within the SATA hinge without kinking.

4.3.2 Tip design optimisations

Some design iterations arise from new insights, but the vast majority of iterations are based on positive and negative results from FEM analyses. For example, when the occurring von Mises stress were higher than the allowable stresses of the materials used, adjustments to the CAD models were made.

Many design iterations have been done, particularly for the open and close mechanism of the jaws. Since the applied forces are relatively high ($F_r = \sim 55\text{N}$ and $F_t = \sim 50\text{N}$) the resulted stresses in the mechanism components were high as well.

In many cases a higher force has been applied ($F_r = \sim 70\text{N}$ and $F_t \sim 65\text{N}$) than will be the case in reality. As a result, the components have been (re)designed until they reached a Safety Factor (FoS) of > 1.5 . The FoS is calculated according the formula below, this is also the failure criterion that Solidworks simulation software uses to determine the FoS plot.

Safety Factor

$$FoS = \frac{\text{Yield Strength}}{\text{max von Mises stress}}$$

4.3.3 Final model

The winning concept "The Core model" has been modelled into a final design as shown in Figure 4-11 and Figure 4-12. The degrees of freedom of the SATA mechanism are retained. This means that the jaws open and close when the core is pushed or pulled respectively, the tip rotates when the core is rotated and that the tip steers left and right when the outer axis shaft is rotated.



Figure 4-11, Renders of CAD model Steerable and Reusable BVS. Top: BVS body plus tip. Bottom: Sealing a 7 mm blood vessel.

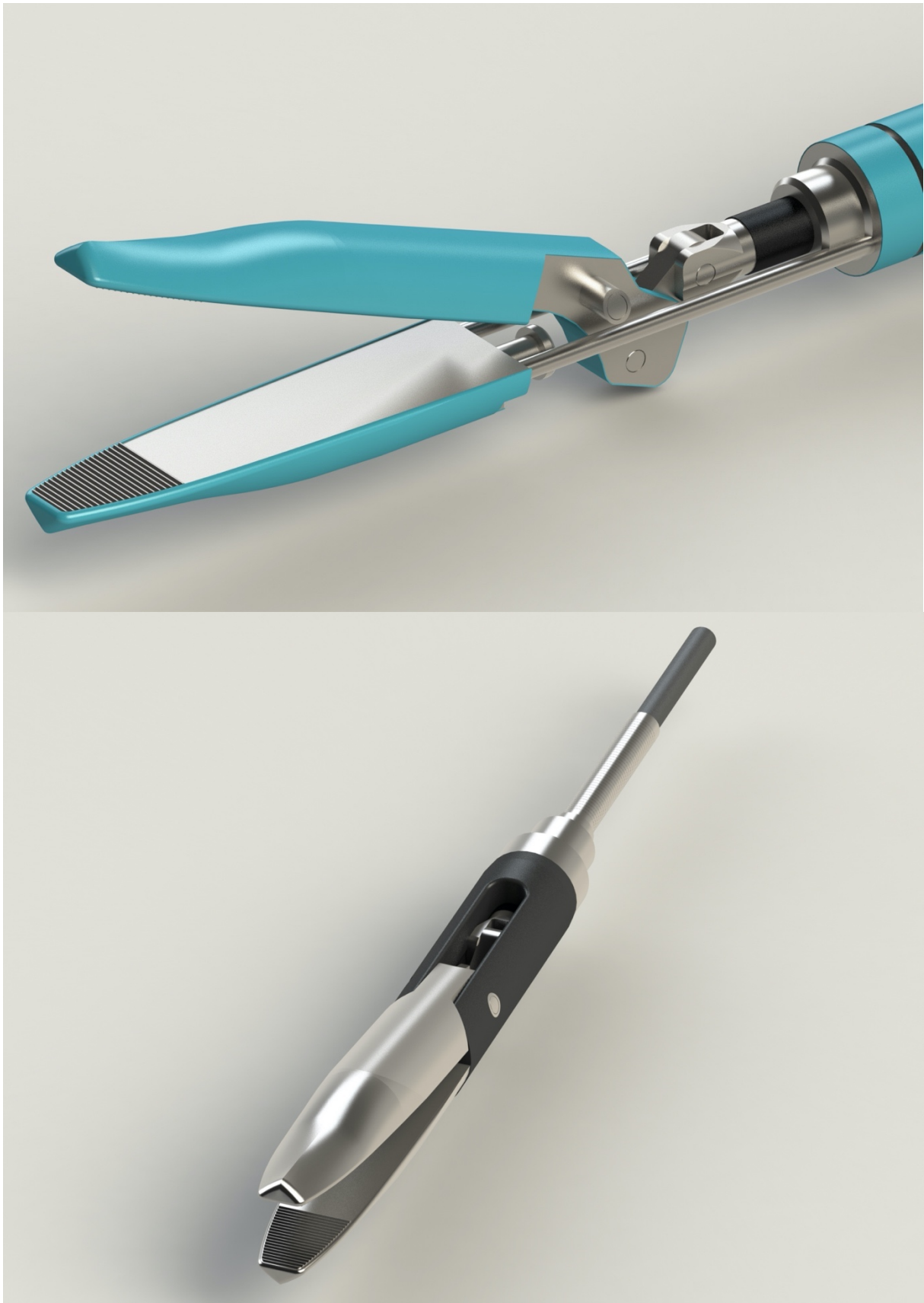


Figure 4-12, Renders of CAD model Steerable and Reusable BVS. Top: New tip design without PEEK base. Bottom: Tip overview without coatings.

The composition of the active and return electrodes is shown in Figure 4-13. Table 8-8 in Appendix 8.6 provides an overview of what components are included in either the active or return electrodes. To achieve distinct electrical paths, electrical insulating (flexible) coatings are applied to the inner axis shaft, nitinol core and NiTiCon component and electrical insulating ceramic coatings are applied to the upper jaw, lower jaw, SS base, tip base, H hinge, sliders high and low and the external axis shaft.

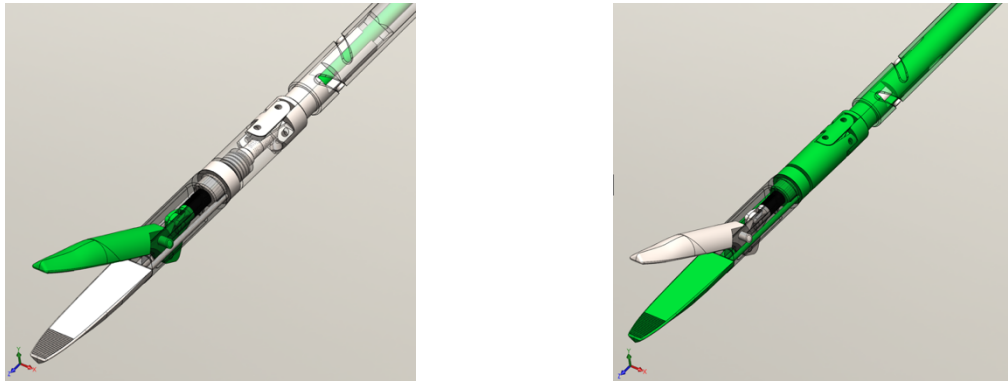


Figure 4-13, Active and Return electrodes. Left: Active electrode components coloured green. Right: Return electrode components coloured green.

Open and close mechanism 1 is implemented in the final design, see Figure 4-14. The maximum angle between both jaws is 50 degrees.

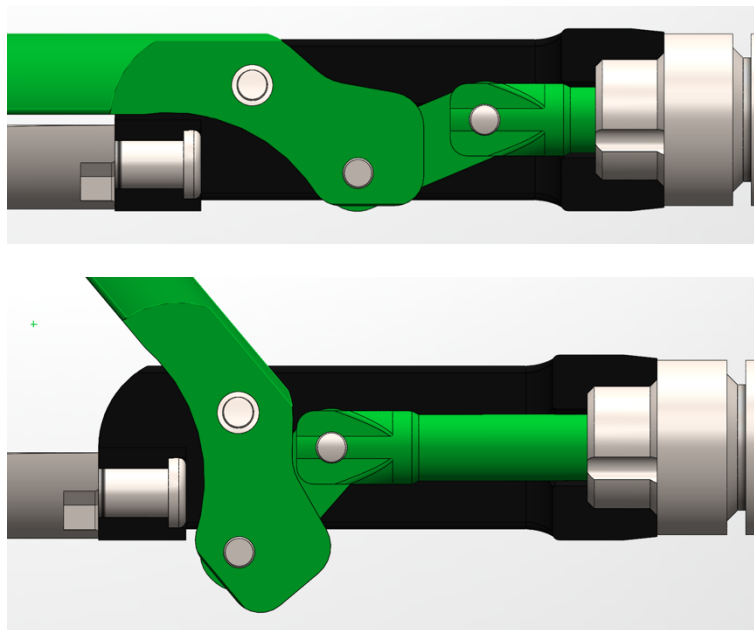


Figure 4-14, Open and close mechanism 1 in CAD. Top: Fully closed position of the jaws. Bottom: Fully opened position of the jaws.

4.3.4 Documentation

All component names, numbers and description are included in Table 8-7 in Appendix 8.6. A distinction is made between the components in the tip and components for the SATA mechanism. For all the components suggested materials have been added in Table 8-9 in Appendix 8.6, as well as possible manufacturing methods and whether the components are coated. An overview of all connections is shown in Table 8-10 in Appendix 8.6. If necessary,

the same connections were included in the setup of the respective FEM simulations in the next section. Connection types are recommended but not definitive. The hinge connections for the open and close mechanism and SATA mechanism are excluded.

The most important connection is the bolt connection between the PEEK tip base component and the lower jaw (nut side), see Figure 4-15. The bolt is 1.4 mm in diameter and provides an axial compression force that pushes the two components together, in addition to absorbing shear stresses. A bolt connection has been chosen because it can be efficiently incorporated into the Solidworks simulation software. This type of connection is not definitive because other solutions are possible.

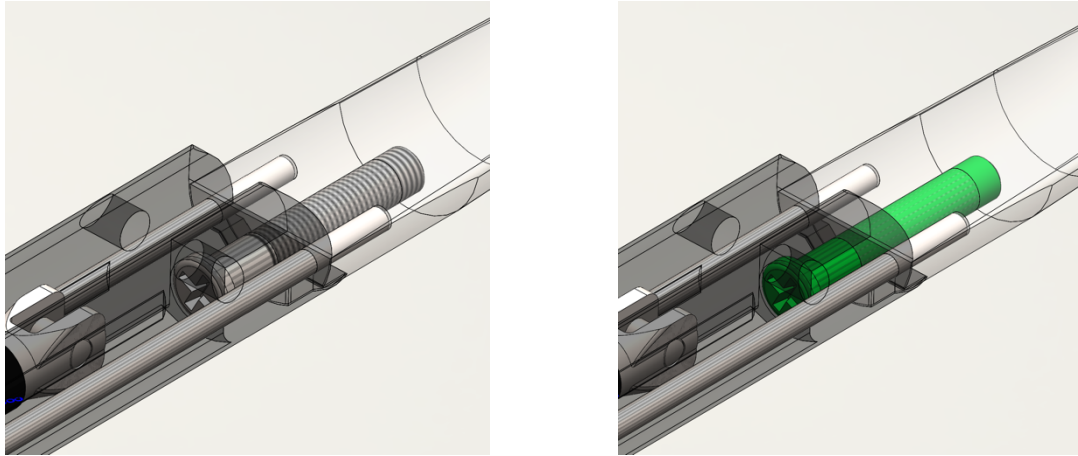
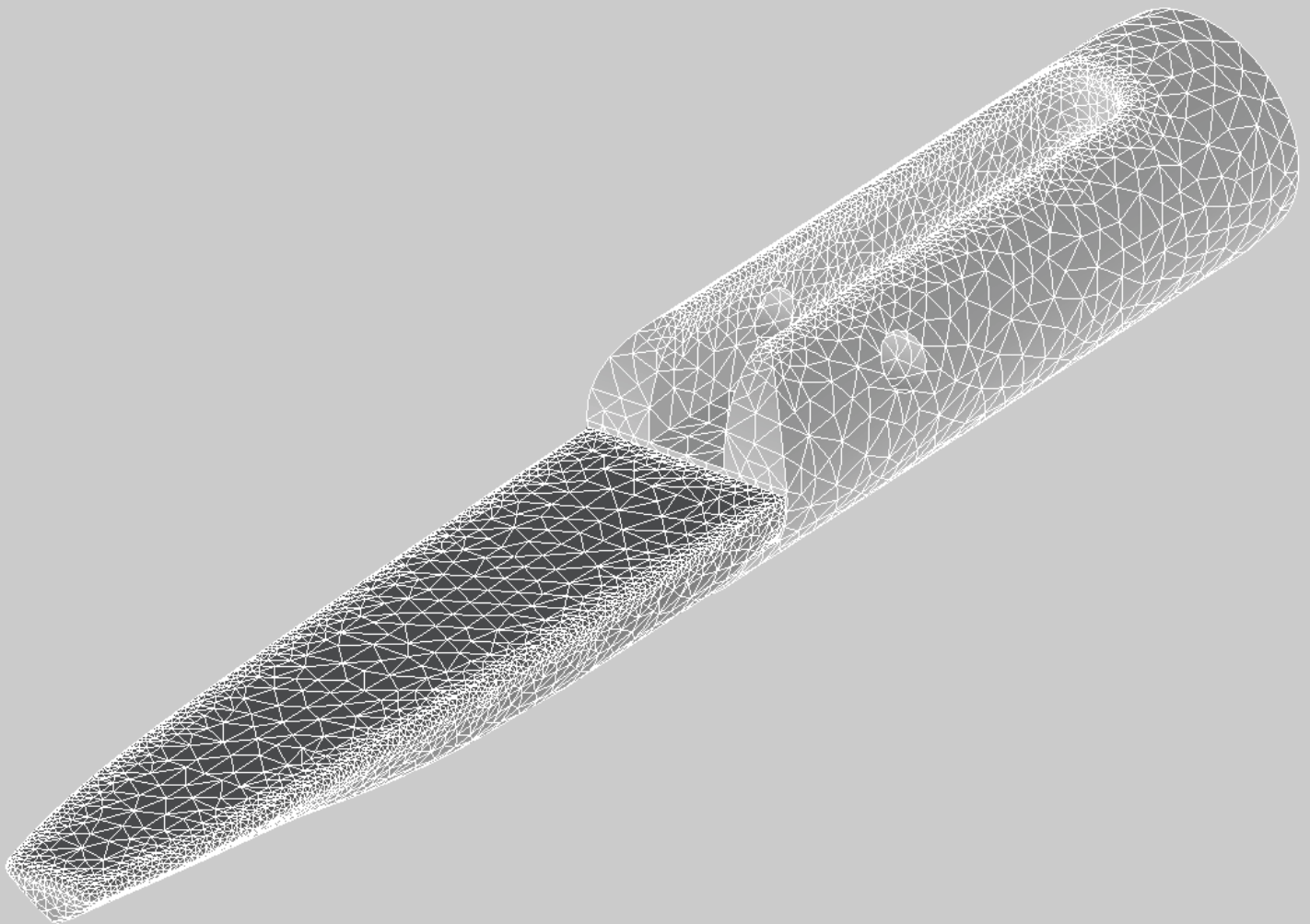


Figure 4-15, Bolt connection between PEEK base and Lower jaw.

5 Design evaluation

This chapter presents the main outcomes of the structural design analysis of the tip components by means of FEM simulations. FEM is also utilized for design iterations and optimizations.



5.1 FEM analysis

Finite element analysis were performed to assess the design of the BVS. Solidworks own simulation (Educational version 2019) software was used for the Finite Element Method (FEM) simulations. The critical tip components that were analysed are the PEEK base (component 2), the Lower jaw (component 3), the Upper jaw (component 4), the Connector (component 5) and the NiTiCon (component 5). Complete FEM reports for each of the components can be found in Appendix 8.6. FEM reports of the same components, but with higher loads, have been added as well to help interpret the results.

5.1.1 FEM analysis of tip components

Four distinct FEM simulations were performed. Each FEM simulation analysis the individual components within an assembly of components. In this way, the von Mises stress, deformation, displacement and Factor of Safety (FoS) for each individual component is determined. Hinge axis pins are treated as rigid objects. The forces applied in the FEM simulations are derived from the forces resulting from the final geometry section 4.1.3.

The simulated components are shown in Table 5-1 below. A complete report of each FEM simulation can be found in Appendix 8.6.

Table 5-1, Components included in FEM simulations

<i>FEM simulation number</i>	<i>Component number(s)</i>	<i>Component name(s)</i>
<i>FEM-1</i>	<i>2 and 3</i>	<i>PEEK base – Lower jaw</i>
<i>FEM-2</i>	<i>4</i>	<i>Upper jaw</i>
<i>FEM-3</i>	<i>5</i>	<i>Connector</i>
<i>FEM-4</i>	<i>6</i>	<i>NiTiCon</i>

5.1.2 FEM-1

Summary:

The most important questions are: Is the bolt connection between the two components strong enough to withstand the applied force and to keep the two components fixed together? Is the PEEK component stiff enough to withstand the uniformly distributed load of 20N on the lower jaw's seal surface?

The bolt connection has a safety factor of 2.8 calculated by Solidworks in the simulation. From this we can conclude that the bolt diameter, length and pre-load are sufficient. The connection between the two components is thus sufficient. The PEEK component shows stress above its yield strength. A fatigue test can determine whether the PEEK component is actually strong enough. Side note, two more stainless steel conductor rods are slid through the PEEK part in reality, which can provide extra rigidity. It is important that a reinforced PEEK is applied, for example glass fiber reinforced PEEK (Carbon fiber PEEK conducts electricity and does not comply), to obtain a higher material yield strength.

Assumptions:

- Both the conductor rods were excluded from this simulation.
- A maximum uniformly distributed compression force of 20N is applied to the seal surface of the lower jaw. To correspond to an L1 of 9.95mm, the force of 20N was not applied as shown in Figure 5-1.

- The contact set(s) between the two components are set to: No penetration and a friction coefficient of 0.3. Although in reality the contacting surfaces will be bonded with adhesives to prevent gap forming.
- For the properties of the bolt connection, see Appendix 8.6.

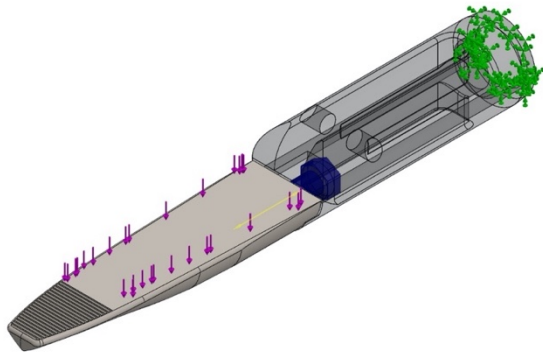


Figure 5-1, Setup FEM-1. Distributed force F_{seal} is applied to the first 15 mm of the lower jaw's surface. Blue coloured is the simulated bolt connector. The PEEK base is fixed at the most proximal surfaces.

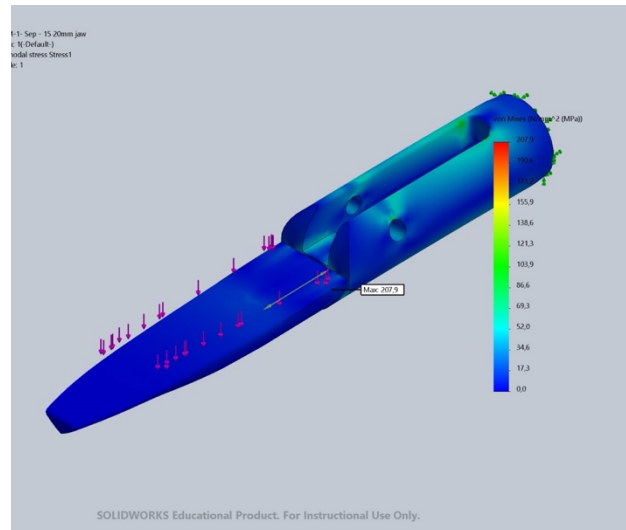


Figure 5-2, FEM-1 von Mises stresses. Maximum stress = 207.9 MPa, occurring in the lower jaw.

The stress and FoS of both parts are determined separately. The maximum stress in the PEEK component was 114.2 MPa, see Figure 5-3. The maximum allowable stress of this specific glass fiber reinforced PEEK is 158 MPa. For a safety factor of > 1.5 , the stress must be below 105 MPa. High stress occurs near the corners around the central cut out, i.e. where the open and close mechanism fits in between. Fatigue test should determine if the component will fail due to fatigue. In reality, the rigidity of the PEEK component is slightly increased by adding the metal conductive rods.

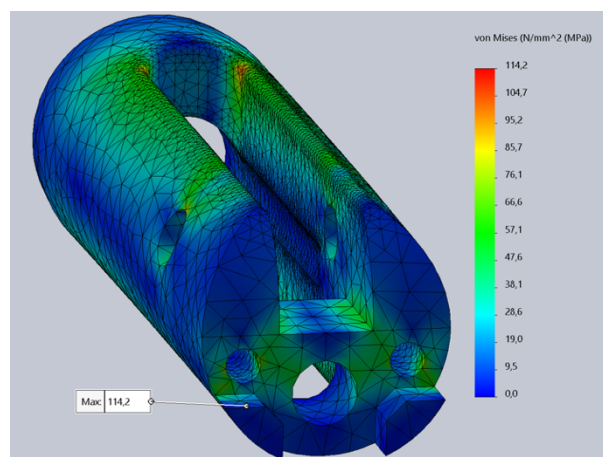


Figure 5-3, FEM-1 von Mises stress PEEK base. Maximum stress is 114.2 MPa.

As with the stainless-steel components in FEM 2, 3 and 4, we see stress concentrations arise in FEM-1 as well. In the case of the lower jaw, the highest stress is 214.3 MPa, see Figure 5-4. below.

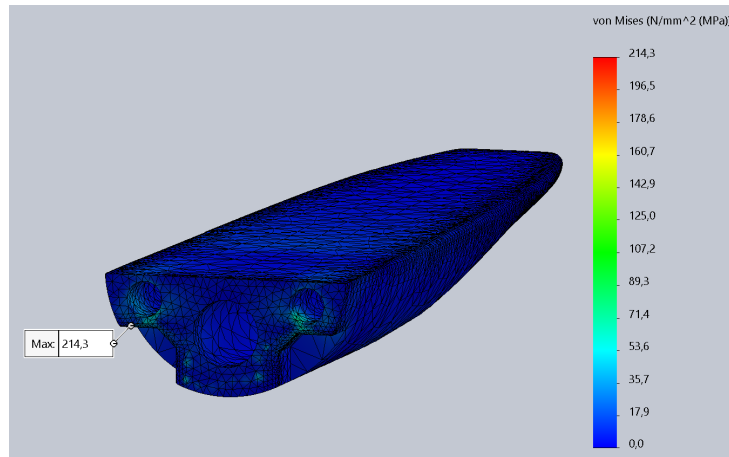


Figure 5-4, FEM-1 von Mises stress lower jaw. Maximum stress is 214.3 MPa.

The calculated FoS for the lower jaw component is below 1.5 due to the high stress concentrations. Figure 5-5 zooms in on these stress concentrations and shows that the high stress only occurs in the superficial row of elements. The stress does not radiate deeper into the material. The surface where the high tensions occur is critical, which is why it is important to investigate whether these stresses can lead to fatigue failure. This is discussed in the next section.

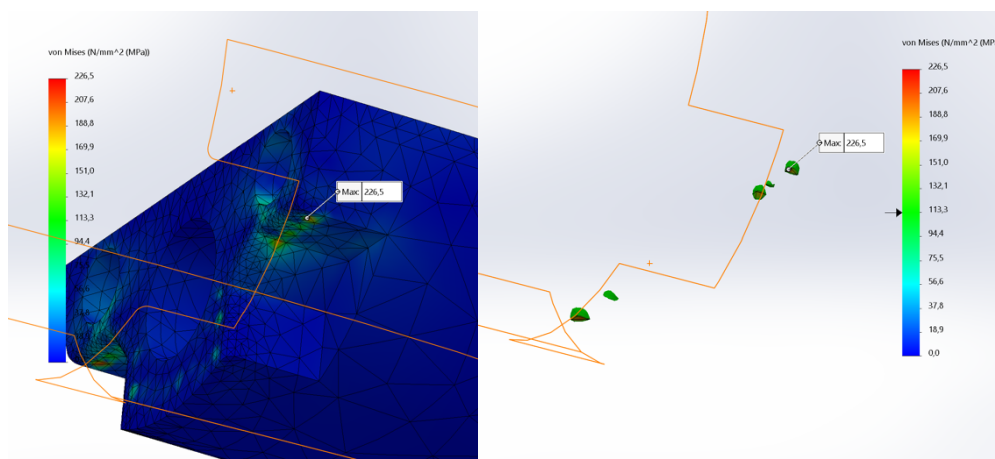


Figure 5-5, Stress concentrations lower jaw. Left: Lower jaw von Mises stress. Right: ISO plot of stress concentrations in the lower jaw. Areas with stress above 113 MPa are shown. Stresses in these two figures are slightly higher due to more complex geometry of the lower jaw in this FEM simulation. However, the results are comparable.

Conclusion FEM-1

Occurring stress in the second row of elements (i.e. near the stress concentrations) are trusted to be accurate. In this case, the stresses are acceptable for the lower jaw component. This is also underlined by the displacement and strain plots. Stress concentrations in the lower jaw component are unlikely to cause fatigue. Fatigue tests must be conducted to determine the lifespan of the PEEK component. A glass-fiber reinforced PEEK material must be chosen to strengthen the material and withstand the stresses. Furthermore, it must be considered that in reality the PEEK component will be reinforced by two metal conductor rods. The bolt connection has a FoS of 2.8 and appears to be a viable solution for connecting the two components. Based on FEM-1 simulation, a uniformly distributed pressure of 20N can be applied to the Lower jaw without damaging the connection between the Lower jaw and PEEK base.

5.1.3 FEM-2

Summary:

This simulation is based on the maximum tensile force (55N) that will be applied to this component, in regards to obtaining the required uniformly distributed seal force (F_{seal}). Higher stresses occur surrounding the hinge axis holes, where the connector component is attached. These stresses are occurring in the first layer of elements and do not radiate deeper into the material. Future fatigue tests could be used to evaluate the stresses near the arched area of the upper jaw.

Assumptions:

For this simulation it is assumed that the instrument jaw is in a fully closed configuration. Therefore a constraint in y-direction (i.e. normal to part of the sealing surface of the Upper jaw) has been applied (Slider / Roller). Figure 5-6 shows the setup of FEM-2. Two rigid hinge axes are applied. The upper rigid hinge axis is constraint with a 'fixed hinge', that is the jaw's axis of rotation. The lower rigid hinge axis has a force (55N) applied to its face which in similar direction as the Connector components longitudinal axis.

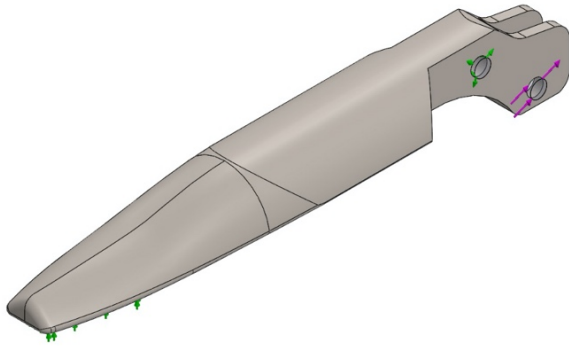


Figure 5-6, Setup FEM Upper jaw

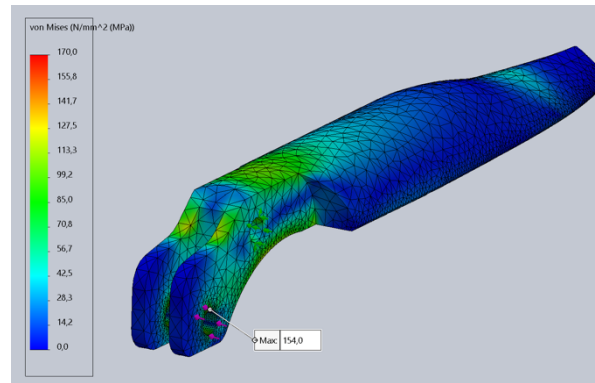


Figure 5-7, von Mises stress FEM-2 Upper jaw.
Maximum stress = 154.0 MPa

As shown in Figure 5-7, the upper jaw's peak stress was 154.0 MPa. This concerns stress concentrations in the surface elements around the holes. However, further analysis indicates that the stresses do not radiate deeper into the material. In addition to the FEM simulation in which a force of 55N was applied, another FEM simulation was performed with an applied force of 69N. The resulting stress concentrations from both simulations are shown below in Figure 5-8 and Figure 5-9. When a force of 69N is applied the peak stress is 193.2 MPa, which is above yield strength of 316L (170 MPa).

Zooming in on Figure 5-8 and Figure 5-9 shows that peak stress occurs in the elements surrounding the holes, see Figure 5-10 and Figure 5-11. The stress plot in Figure 5-10 shows that the stress in the second row of elements is significantly reduced. This also means that the FoS in this row of elements is around 1.5.

Conclusion FEM-2

When a static force of 55N is applied, the stresses that occur are acceptable and the FoS is mostly > 1.5 . When we zoom in on the stress concentrations, we can conclude that they are unlikely to result in material failure. This becomes even more clear when the applied force is amplified to 69N and in particular the stresses within stress concentrations increase. However, these stresses do not radiate deeper into the material. In both cases, fatigue tests should clarify if the component will fail due to fatigue

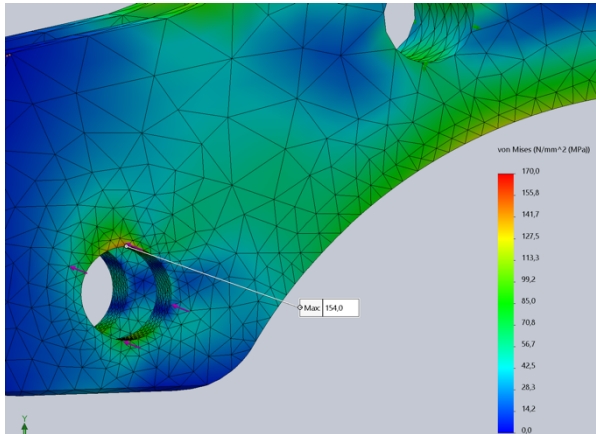


Figure 5-8, Stress concentration surrounding the holes. The applied force F_r was 55N. ($L_1 = 9.95$ mm)

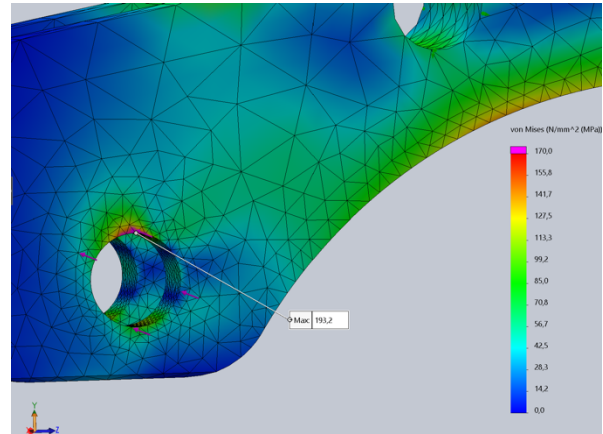


Figure 5-9, Stress concentration surrounding the holes (coloured purple). The applied force F_r was 69N. ($L_1 = 12.5$ mm)

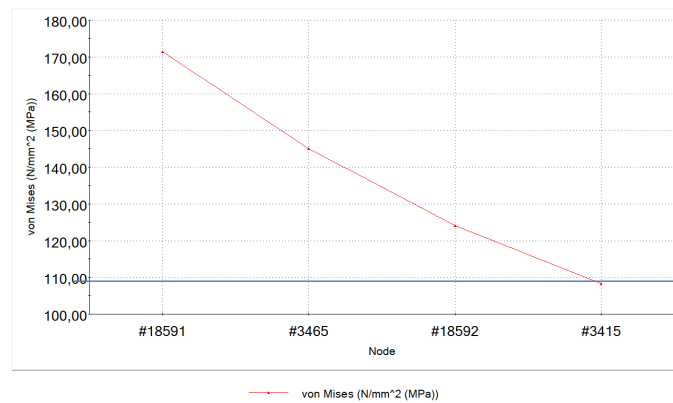


Figure 5-10, Graph of the stress development through the first two rows of elements. Starting point on the left is a node in the middle of the first element. End point to the right is a first node of the third row of elements. The blue line at ~ 113.3 MPa is the boundary for which holds that below the line $FoS > 1.5$

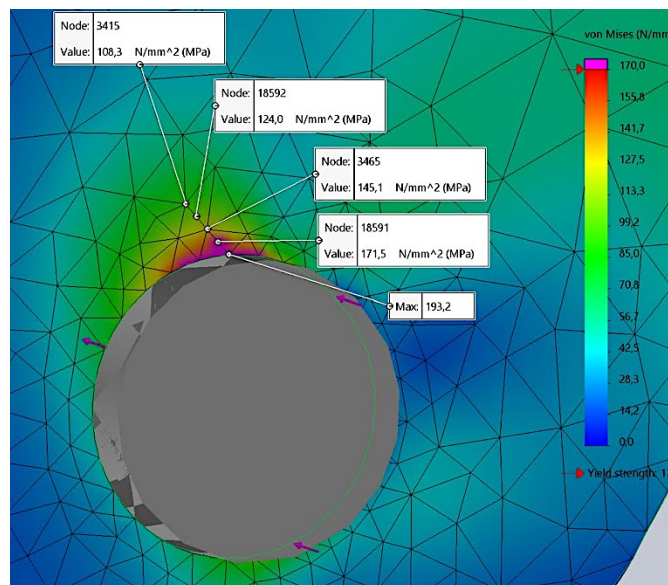


Figure 5-11, Five nodes that show stress degradation. The probe function in Solidworks is used to obtain this figure. The probed notes correspond to the notes in Figure 5-10 above.

5.1.4 FEM-3

Summary:

This simulation is based on the maximum tensile force (55N) that will be applied to this component, in regard of obtaining the required uniformly distributed seal force (F_{seal}). From this simulation it can be concluded that this component has a correct design since the safety factor of > 1.5 applies to most of the component.

Assumptions:

The Connector component links the Upper jaw (4) with the NiTiCon (6) component and has two hinge connections. On both ends a rigid hinge axis is placed. One rigid axis is constrained with a 'fixed hinge', the other rigid axis has a force (55N) applied. Figure 5-12 shows the setup of FEM-3

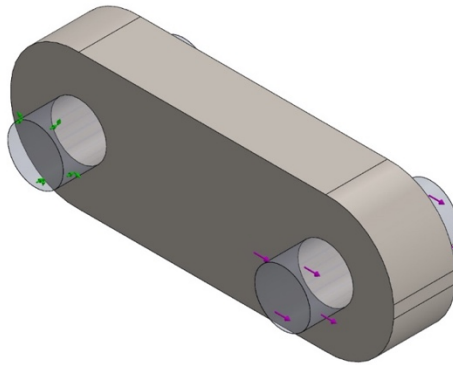


Figure 5-12, Setup FEM-3

Similar to the results from FEM-2, FEM-3 also shows stress concentrations around the holes. However, in the case of the Connector, the stress concentrations are lower. The maximum stress of 135.1 MPa (Figure 5-13) is only 20 MPa above the value of ~ 113 MPa, which is equivalent to a FoS ~ 1.5 . When the applied force is increased to 69N, the peak stress increases to 163.6 MPa, see Figure 5-14. Again, this holds for the areas around the holes.

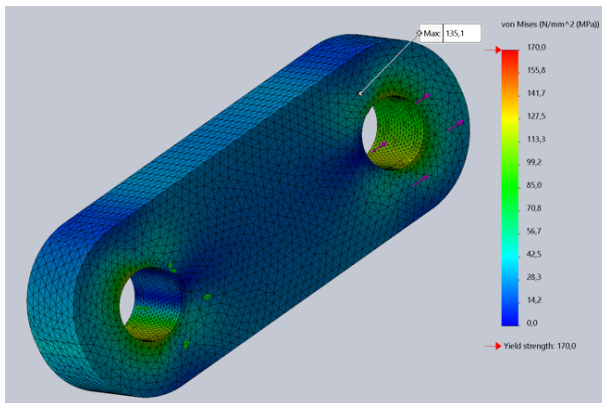


Figure 5-13, von Mises stress FEM-3. Maximum stress = 135.1 MPa. $L1 = 9.95$ mm and $Fr = 55$ N.

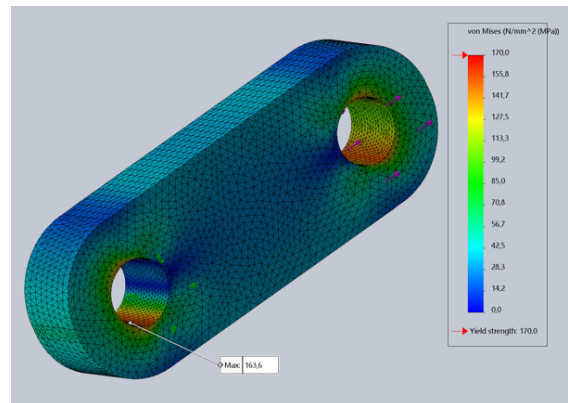


Figure 5-14, von Mises stress FEM-3 with increased applied force. Maximum stress = 163.6 MPa $L1 = 12.5$ mm and $Fr = 55$ N.

Conclusion FEM-3

When a static force of 55N is applied, the stresses that occur are acceptable and the FoS is mostly > 1.5 . Both simulations showed stress levels below yield strength of 316L, which is 170 MPa. Therefore, in both cases the component is unlikely to fail due to material fatigue.

5.1.5 FEM-4

Summary:

This simulation is based on the maximum tensile force (50N) that will be applied to this component, in regard of obtaining the required uniformly distributed seal force (F_{seal}). The NiTiCon component is unlikely to cause problems with the maximum tensile force of 50N applied. Fatigue problems are unlikely to occur since the safety factor of > 1.5 is achieved throughout most of the component.

Assumptions:

The NiTiCon component connects the Nitinol core with the tip open and close mechanism. It is connected to the Connector component, with the two components forming a hinge. Within the simulation setup, a rigid hinge axis constraint with a 'fixed hinge' is placed at this location, see Figure 5-15. The force is attached to the face where normally the Nitinol core is bonded with the NiTiCon component. The applied force 50N is equivalent to force F_t derived from previous calculations.

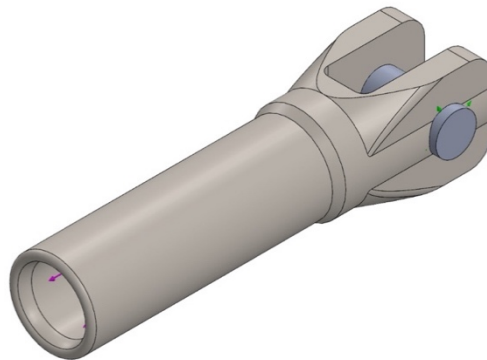


Figure 5-15, Setup FEM-4 NiTiCon.

The results from FEM-4 are consistent with the results from FEM-3. With a force of 50N applied, a FoS of > 1.5 is achieved. An exception are some stress concentrations around the holes, however in these areas the stress 134.6 MPa is acceptable as well, see Figure 5-16. Even when the force is increased to 63N, the peak stress 169.6 MPa remains below the allowable stress of 170 MPa (yield strength 316L), albeit with a small margin, see Figure 5-17.

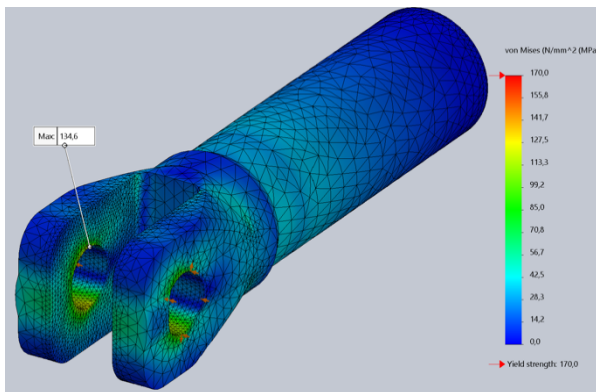


Figure 5-16, von Mises stress FEM-4. Maximum stress = 134.6 MPa. $L1 = 9.95 \text{ mm}$ and $F_t = 50\text{N}$.

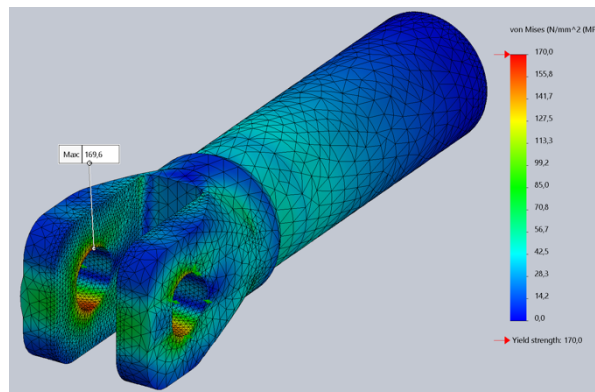


Figure 5-17, von Mises stress FEM-4. Maximum stress = 169.1 MPa. $L1 = 12.5 \text{ mm}$ and $F_t = 63\text{N}$.

Conclusion FEM-4

When a static force of 50N is applied, the stresses that occur are acceptable and the FoS is mostly > 1.5 . Both simulations showed stress levels below yield strength of 316L, which is 170 MPa. Therefore, in both cases the component is unlikely to fail due to material fatigue.

5.2 FEM results interpretation

In the FEM analysis above, static tensile loads were applied to the components and the resulting stresses were determined. In reality, however, the instrument will be dynamically loaded over a large number of cycles. A cycle is defined as a single activation of the BVS. In other words, each time that tissue or vessels are sealed, regardless of the force F_{seal} used, counts as one cycle.

5.2.1 Cycles, material fatigue and estimated lifespan

Design requirement 12 states that an instrument must be reused for at least thirty surgical procedures. The number of cycles in each of these surgical procedures is likely to vary widely because it is dependent on influencing factors such as, type of procedure and experience level of the surgeon. Meeuwssen et al. (2017) investigated the variety of differences in usage of electrosurgical devices. Part of their study focused on the number of activations and activation times of an electrosurgical device during cholecystectomies (these procedures have a relatively standard execution [48]). According to their data [48], the mean number of activations is 102 times and the mean activation time is 2.44 seconds for surgeons, see Figure 5-18.

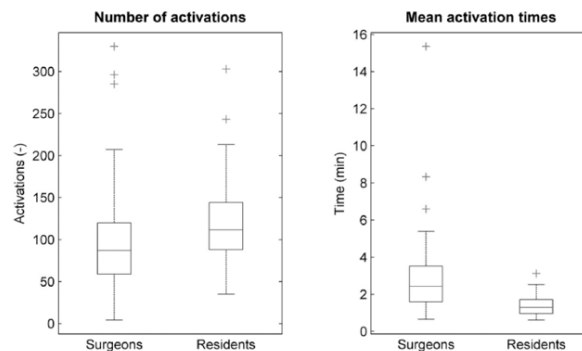


Figure 5-18, Boxplot of number of activations and activation time. Compared were experienced surgeons and residents. The mean number of activations during one procedure was 102.

Multiplying the mean number of activations/cycles (102) with the minimum amount of surgical procedures (30), results in a total cycle number of 3060. In other words, each BVS must at least withstand a minimum of 3060 cycles without any fatigue failure occurring. In the worst-case scenario, the instrument is activated >200 times during thirty procedures, resulting in a total of 6000 cycles.

Material fatigue is normally determined by experimental tensile and bending tests. However, the possible occurrence of fatigue failure can also be derived from fatigue diagrams, also known as S-N curves shown in Figure 5-19 and Figure 5-20. S-N curves are different for each material type, in this case the S-N curve of 316L stainless steel is shown.

For each component the possible fatigue failure is derived from the S-N curves depending on the material used for the component in question, the stresses that occur in the respective FEM analysis and the number of cycles determined above. Two S-N curves (Figure 5-19 and Figure 5-20) for AISI 316L stainless steel were obtained from randomly selected articles as material databases provided limited or inaccessible information.

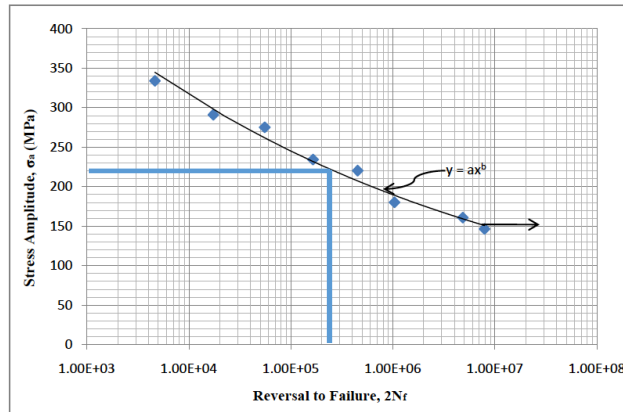


Figure 5-19, S-N curve 316L [49]. In their paper, Mohammad et al. (2012) characterized the fatigue life of austenitic stainless steel 316L at room temperatures and subjected to variable loading. Mechanical properties of their 316L: YS = 332 MPa, UTS = 673 MPa, E modulus = 165 GPa.

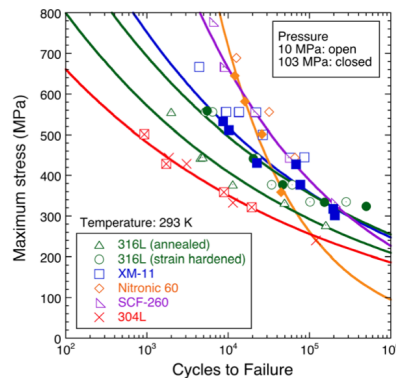


Figure 5-20, S-N curve 316L annealed [50]. Marchi et al. (2015) measured the fatigue life of a variety of austenitic stainless steels in hydrogen environments. The figure above show the results in room temperature and a gaseous pressure of 10 and 103 MPa. Material properties: YS = 280 MPa, UTS = 562 MPa

To estimate the lifespan of the various components (and thus the instrument itself), the S-N curve is approached in a different way. The specific peak stress obtained from the component's FEM analysis is entered in the S-N curve on the y-axis, see Figure 5-19. From this point on the y-axis, a horizontal line can be drawn to determine if fatigue failure occurs. If so, the estimated number of cycles (x-axis) after which fatigue failure occurs is determined by drawing a vertical line.

If the peak stresses are too low, no fatigue failure will occur. This holds for components 5 (Connector) and 6 (NiTiCon). The highest peak stresses were obtained in FEM-1, where the lower jaw shows stress concentrations of ~214 MPa. The lower jaw's fatigue life is estimated at 350.000 cycles according Figure 5-19 and $>10^6$ cycles according Figure 5-20. Second highest stresses were obtained in FEM-2, the upper jaw. Peak stresses of ~193 MPa occurred. Both well exceed the required lifespan (cycles), thus is it concluded that the components will not fail due to fatigue.

Eventually it must be taken into consideration that there are other factors that can affect the fatigue life, such as corrosion and temperature.

6 Core coating evaluation

This chapter presents the main outcomes of the evaluation test for the Core with a Teflon coating.

6.1 Experimental design

An experiment is conducted to measure the durability of a Nitinol Alloy guide wire with PTFE coating pulled through various SATA hinges. The experiment was conducted in the form of several pilots. In this way it can be quickly determined whether the design solution is feasible and what should be considered in future research and future designs.

6.1.1 Reasoning for conducting an experiment

The partially flexible inner axis shaft (core) is considered one of the most critical components in the design of the Steerable and Reusable BVS. The core consists of a 316L stainless steel rod combined with a flexible part of Nitinol Alloy. The core needs to be entirely covered with an insulating coating for electrical insulation as it also serves as the active electrode.

Applying a uniformly distributed pressure of 20N on a 7.0 mm blood vessel requires a maximum tensile force F_t of 50N applied on the core, see section 4.1.3. The Steerable BVS has a sideways articulation range of roughly 140 degrees. Therefore, the flexible part of the core must bend at an angle of 70 degrees left and 70 degrees right. Simultaneously, the core needs to be able to rotate along its longitudinal axis: 90 degrees left and 90 degrees right. As a requirement for the reusable BVS, the core must be reusable for at least thirty surgical procedures (see design requirement 12). Therefore, it is important that the electrical insulation is sufficient at all times and no defects occur on the coating, in this case PTFE. Insulation failure could cause short circuiting, which leads to malfunctioning of the BVS and possible collateral tissue damage.

For this experiment a kink resistant Nitinol guidewire with a low friction hydrophilic PTFE coating is selected. The goal of this experiment is to get a better understanding of the durability of a PTFE coating.

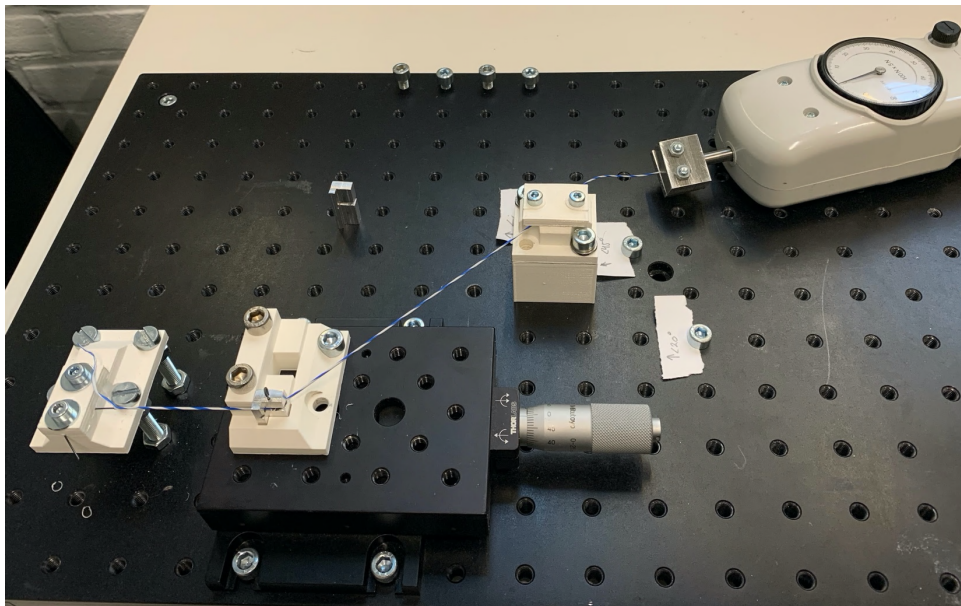


Figure 6-1, Full test setup. The guidewire (core) is currently clamped, under preload, on both ends. The core is always clamped on the left (distal / tip) end. Then the guidewire runs through the mimicked SATA hinge, with either 45 or 70 degrees as a fixed angle. The linear stage is moved 4 mm to the left, simulating a full jaw closure movement. On the right side (proximal / handle), the guidewire is attached to the force gauge.

6.1.2 Materials & methods

A complete initial test setup is provided in Figure 6-1, using this set up pilot 1 has been performed. An adjustment to this set up has been made for pilot 2 and 3, see Figure 6-2. Further details about the instruments, equipment and other materials used are provided in this section.

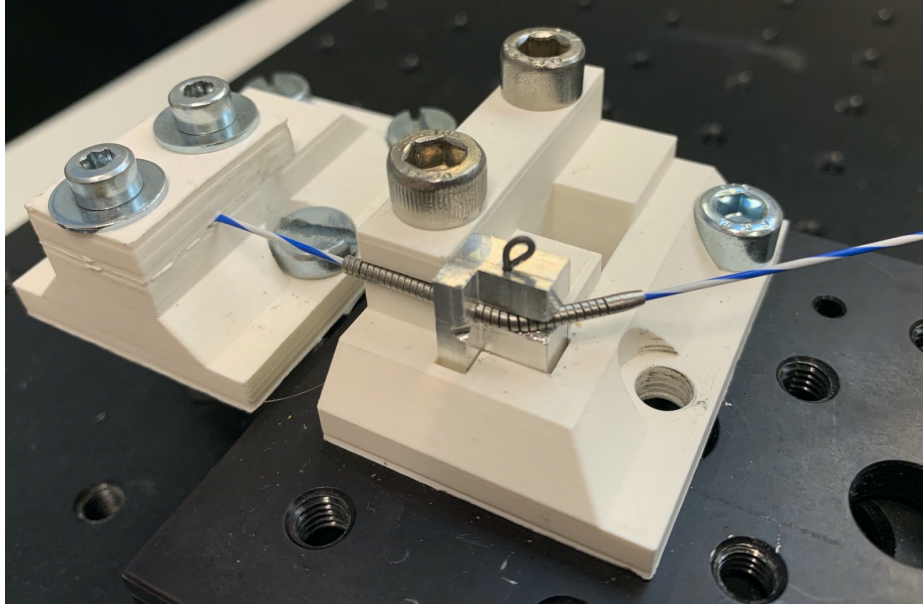


Figure 6-2, Additional stainless steel flexible overtube.

Instruments & equipment

- A 5 mm laparoscopic SATA instrument by Surge-On Medical, Delft, Holland was used to provide the CAD models of the steerable mechanism.
- A Bavarian Wire guidewire manufactured by Medi-Globe GmbH, Achenmühle, Germany consist of Nitinol Alloy cores with PTFE coating. For this experiment a core diameter of 0.889 mm (including the coating) and a total length of 2600 mm was chosen, see Figure 6-3. The guide wire was cut into specimens with lengths of 300 mm.
- A handheld mechanical force gauge by Chatillon, was used to establish and maintain the preload/ applied load.
- A digital multimeter by STREX was used to measure the resistance.
- A linear translation stage by Thorlabs, Newton, US, was used to precisely mimic the linear travel distance the core makes during a full open-to-close movement of the jaws.

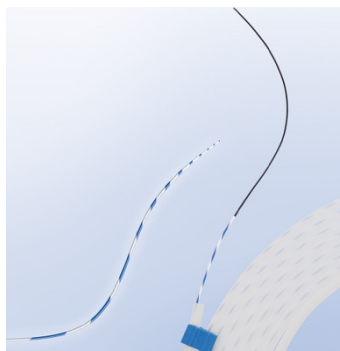


Figure 6-3, Nitinol guidewire with PTFE coating. Obtained from Medi-Globe. The coating thickness is around 0.05 mm.

Materials

- From a SATA instrument 3D CAD file, two steering angles were defined and corresponding surfaces were extracted. Based on these surfaces, two aluminium blocks have been milled that mimic the SATA instrument under angle during the experiment, see Figure 6-4.
- The 'angle block' housing and core clamps are 3D printed out of PLA.



Figure 6-4, Aluminium 'angle blocks'. Left: 45 degrees angle at **slider High** side with hinge axis pin. Right: 70 degrees angle at **slider low** and H hinge side. There is no interference of the hinge pin while steering in this direction.

Experimental design

Two types of variables are distinguished, namely dependent and independent variables.

The initial *electrical resistance* is the dependent variable. The resistance is measured between the Nitinol core and the aluminium angle block, see Figure 6-5. When a resistance is registered by the multimeter, it means that the insulating PTFE coating has failed. I.e. current is leaking between the nitinol core and the aluminium angle block.

The independent variables are: the *angles* of the SATA mechanism (45° and 70°), *preload* of the core (20N – 60N) and *linear translation* of the core (4 mm).

Three distinctive pilots were conducted:

Pilot 1)

In this setup, the guidewire is pulled directly through the aluminium 'angle blocks'. In practice, this means that the guidewire contacts the aluminium at one or two points. These contact points are considered critical points, around which the PTFE coated nitinol guidewire bends and where it is expected that most of the coating's wear occurs.

Pilot 2)

The wear on the coating can be reduced by adding a flexible torque coil to the hinge. The torque coil, through which the guidewire is pulled, ensures that the forces on the guidewire are better distributed. In this case, the critical contact points from the previous setup have been replaced by a larger contact area. When using a correct torque coil, the guidewire bends through a constant radius instead of a sharp angle. For this pilot, a stainless-steel flat torque coil was used.

Pilot 3)

Building on pilot 2, pilot 3 was used to investigate after how many repeated cycles damage occurs to the PTFE coating under certain conditions.

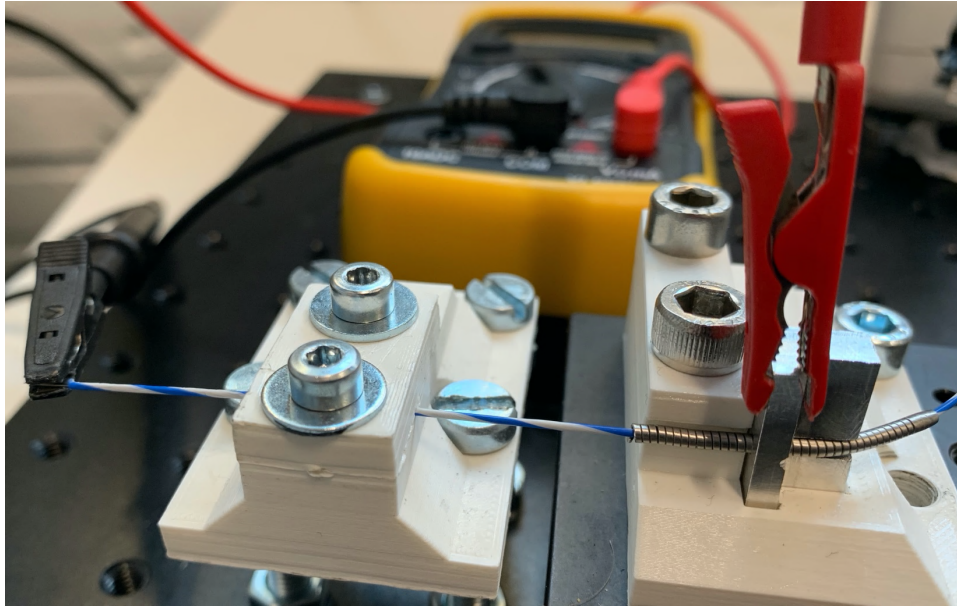


Figure 6-5, Multimeter set-up configuration. The multimeter measures resistance or continuity between the distal end of the guidewire and (only in case of insulation failure) the aluminium 'angle block'.

Protocol

Ideally, the preload or applied load builds up to a maximum of ~50N when the linear stage moves from 0 mm to 4.0 mm. In reality, the required pulling force (F_t) also increases until 50N during the closing of the jaw, i.e. compressing blood vessels or tissues. The required F_t reaches its maximum in fully closed position and thus after a linear translation of 4.0 mm. However, in the current test setup, it was decided to apply a preload immediately and to keep it constant during the translation of the linear stage.

Sealing a blood vessel is considered as one cycle. A cycle is defined as: the complete closing of the jaws, which requires a core translation of 4.0 mm and a constant load during the cycle. Irrespective of the pilots and specimen, experimental cycles were done according the protocol outlined in Table 6-1.

A variety of pulling forces is applied. Approximately 50N corresponds to the force required to apply compression of 20N with the jaws, however, the effect of lower and higher forces has also been studied.

Table 6-1, Protocol for one experimental cycle to evaluate the Nitinol PTFE coated guidewire.

<i>Step:</i>	<i>1</i>	<i>Select the desired 'angle block' and slide it into its fixed position</i>
	<i>2</i>	<i>Set the linear stage to 0 mm</i>
	<i>3</i>	<i>Stick the specimen through both the 'angle block' and clamp and screw tight the clamp</i>
	<i>4</i>	<i>Set the multimeter to continuity test mode (audio cue) or resistance mode and connect the red and black electrodes to the nitinol and aluminium 'angle block'</i>
	<i>5</i>	<i>Check if the force gauge is calibrated at zero, pull in the corresponding angle direction and manually apply a force of ~50N</i>
	<i>6</i>	<i>Maintain the tensile force whilst moving the linear stage 4 mm</i>
	<i>7</i>	<i>Release applied force and return the linear stage to its starting position</i>
	<i>8</i>	<i>Repeat the cycle until the multimeter registrates a resistance or continuity</i>

6.1.3 Results

Three pilots have been conducted. The outcomes are showcased in Table 6-2, Table 6-3 and Table 6-4, for pilots 1, 2 and 3 respectively.

Pilot 1)

In the first pilot a total of six cycles have been conducted. After step 6 (see protocol), the guidewire was clamped on both ends, thus maintaining the applied load, before measuring the resistance.

Table 6-2, Results Pilot 1.

<i>Cycle #</i>	<i>Force [N]</i>	<i>Angle [degrees]</i>	<i>Linear movement [mm]</i>	<i>Insulation failure</i>	<i>Visual damage</i>	<i>Note</i>
1	55	70	4	Yes	Yes	
2	40	70	4	Yes	Yes	
3	20	70	4	Yes	Yes	
4	55	45	4	Yes	Yes	
5	60	45	0	Yes	Yes	<i>Damaged without linear movement. Only preload</i>
6	15	70	4	Yes	Yes	

Insulation failure was measured after each cycle in pilot. The damage was also observed visually after each cycle. Figure 6-6, shows the visual damage after the first cycle. The coating is teared off over a length comparable to the 4 mm linear translation. After applying the preload of 60N at the start of cycle 5 insulation failure occurred immediately, see Figure 6-7.

- *After 1 consecutive cycle (6)*
- *Pulling force ~ 15N*
- *Angle 70 degrees*
- *4 mm translation*

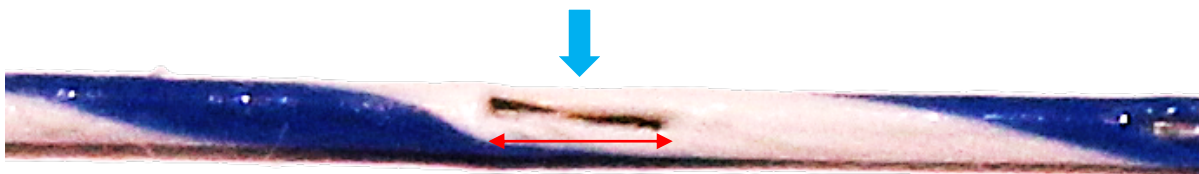


Figure 6-6, Coating damage pilot 1, cycle 6.

- *After 1 consecutive cycle (5)*
- *Pulling force ~ 45N*
- *Angle 45 degrees*
- *No translation*

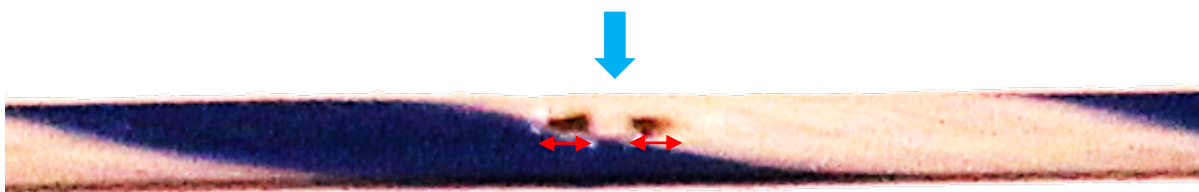


Figure 6-7, Coating damage pilot 1, cycle 5.

Pilot 2)

After adding an overtube to the test setup, a second pilot containing eight cycles was conducted.

Table 6-3, Results pilot 2.

<i>Cycle #</i>	<i>Force [N]</i>	<i>Angle [degrees]</i>	<i>Linear movement [mm]</i>	<i>Insulation failure</i>	<i>Visual damage</i>	<i>Note</i>
1	55	70	4	No	-	
2	55	70	4	Yes	Yes	
3	55	45	4	No	-	
4	55	45	4	No	-	
5	60	45	5	No	-	
6	55	70	4	Yes	Yes	Damage from previous cycle
7	50	70	4	No	-	
8	55	70	4	Yes	Yes	

Cycle 2 and 8 caused insulation failure and showed visual damage, see Figure 6-8 below.

- After 1 consecutive cycle (2)
- Pulling force ~ 55N
- Angle 70 degrees
- 4 mm translation

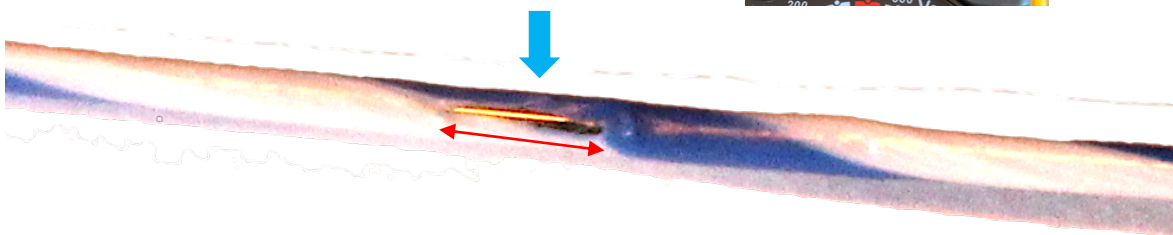


Figure 6-8, Coating damage pilot 2, cycle 2. Multimeter detects current and measures a resistance.

Pilot 3)

Pilot 3 consists of five runs of cycles. A total of fifty-four cycles were performed. The multimeter was connected continuously and set to continuity. The results Table 6-4 showcases after how many cycles the multimeter detects a closed circuit, thus insulation failure.

Table 6-4, Results pilot 3. Durability measurement of PTFE coated Nitinol guidewire.

<i>Run #</i>	<i>Force [N]</i>	<i>Angle [degrees]</i>	<i>Linear movement [mm]</i>	<i>Insulation failure</i>	<i>Visual damage</i>	<i>Note</i>
1	50	45a	4 x 4	Yes	Yes	During 4th cycle insulation failure occurred
2	50	70-	11 x 4	Yes	Yes	At the end of the 11th cycle insulation failure occurred
3.1	50	45-	10 x 4	No	-	
3.2	55	45-	10 x 4	No	Yes	Deformed coating, near rupture

3.3	45	45-	7 x 4	Yes	Yes	During the 27th cycle insulation failure occurred
4	50	45a	5 x 4	Yes	Yes	Similar to run 1, no improvement
5	60	70-	7 x 4	Yes	Yes	Increased force compared to run 2, decreased cycles

- After 20 consecutive cycles
- Pulling force ~ 50N
- Angle 45 degrees (without pin)
- 4 mm translation (each cycle)

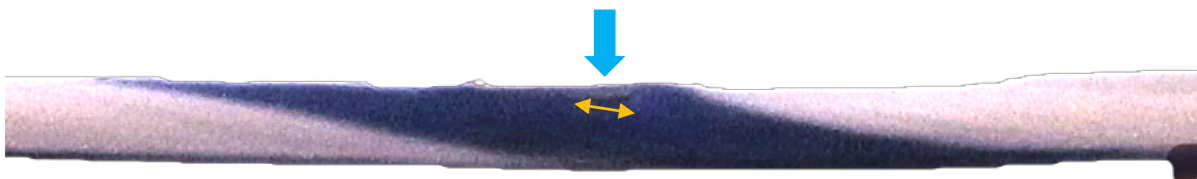


Figure 6-9, Coating wear near rupture during run 3.2. Yellow arrow indicates area where coating has suffered severe wear. Insulation was sufficient not to measure a closed circuit with the multimeter. (The multimeter displays 1., when there is no current flowing).

- After 27 consecutive cycles
- Pulling force ~ 50N
- Angle 45 degrees (without pin)
- 4 mm translation (each cycle)

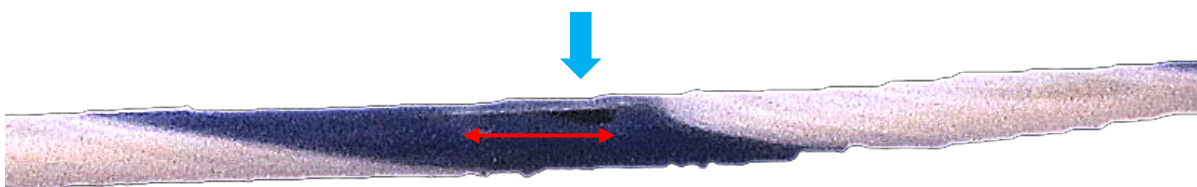


Figure 6-10, Insulation failure during run 3.3. Multimeter detected insulation failure during the 7th cycle in run 3.3. This was after 27 consecutive cycles.

6.1.4 Discussion

Interpreting the results

In the model of the BVS, the core is one of the most critical components because it actuates the open and close mechanism of the jaws and simultaneously acts as part of the active electrode. Since Nitinol has already proven itself to be a suitable material for components requiring torsional stiffness and flexibility, finding a coating that provides the electrical insulation is the challenge.

The setup for Pilot 1 was initially designed for a larger experiment in which the coating was extensively tested under different conditions, such as different angular positions of the SATA

hinge and variable tensile forces and rotations of the core. This type of PTFE coating is very suitable for its application in guidewires, but unlikely to be applicable in a BVS under the circumstances as applied in pilot 1. The PTFE coating is hydrophilic and engineered to provide low friction, however, this makes the material soft and prone to wear and rupturing.

The two contact points over which the coating scrapes combined with the applied tensile force results in immediate damage of the PTFE coating upon translation. Even without translation, as in pilot 1, cycle 5, the coating already ruptures due to the applied force. In this case, the coating cracked at the point where it contacts the axis shaft. Also applied forces (15N), much lower than the required tensile forces (50N), caused damage to the coating.

Another possible cause for coating damage in pilot 1 is that the aluminium blocks possibly contain sharp edges that cut into the coating. The blocks are milled in a conventional way and finished with a file to round of the edges. The complete exclusion of sharp edges does not seem feasible with simple conventional mass production machines.

In any case, the coating must be resistant to sharp edges in order to function, and that is not the case with the current PTFE coating. A possible solution to protect the guidewire and coating was tested in pilot 2 and 3. By using a flexible metal overtube, the coating is protected against sharp edges and also the critical contact points are replaced by a larger contact surface. On the other hand, the bend radius slightly increases and more force is required to steer the tip.

Instead of an extensive experiment, a second and third pilot were conducted to investigate the effect of an overtube. The results of pilot 2 were much more promising than those of pilot 1, with the exception of a sharp angle at 70 degrees.

In pilot 3 the resistance was continuously measured and the multimeter beeps when a closed circuit is detected. This eliminated the need to clamp the guidewire on the proximal side in between cycles. Because the cycles could now be carried out faster in succession, a more dynamic load was created. Although the same type of guidewire, i.e. PTFE coating, was still used, the results from pilot 3 are much more promising than those from pilot 1.

Run three (pilot 3) showed the most promising results. An angle of 45 degrees was chosen, but without inserting the hinge pin. The force applied was ~50N. No visible damage was seen after the first set of ten cycles. At the end of the second run, the coating was noticeably deformed, but there was no insulation failure as can be observed in Figure 6-9. During the third set, the coating eventually ruptured in cycle 7, see Figure 6-10.

In pilot 3, damage to the insulation occurs relatively fast at an angle of 45 degrees with hinge axis pin compared to cycles where the hinge axis pin is removed. Because the pin lies partly in the path of the core, this inevitably forms a critical point where the guidewire will bend and kink. Even after adding an overtube, damage to the PTFE coating occurs much quicker at this specific point. As expected, damage occurs comparatively faster when the angle is 70 degrees than with an angle of 45 degrees without a hinge axis pin.

Recommendations

First and strongly recommended is using an overtube. The geometry of a SATA hinge determines the bending radius and the bending points or contact points over which the core is pulled. In the current SATA mechanism, the contact points are different for the slider-high side and slider-low + h-hinge side. In addition, the contact points shift depending on the angle that the steerable tip makes at that specific moment. By using an overtube, the core will be pulled over a contact area instead of contact points as mentioned before. The contact surface provides a more uniformly distributed load on the core and the bending radius that the core has to make through the SATA hinge is larger and more constant.

The second recommendation is to conduct more research into overtube options and selecting the most suitable overtube. For example, in terms of tube or coil shape, there are many options to choose from such as, round, flat, single layer, multilayer et cetera, see Figure 6-11 below. Furthermore, there are various material options available such as stainless steel and nitinol. Using an overtube will make the SATA hinge mechanism stiffer. In other words, more force is required to steer the tip left and right. 3N to 5N was required to bend the overtube plus nitinol guidewire as used in the experiment. At last, there are also options for applying an insulating coating to the overtube itself.

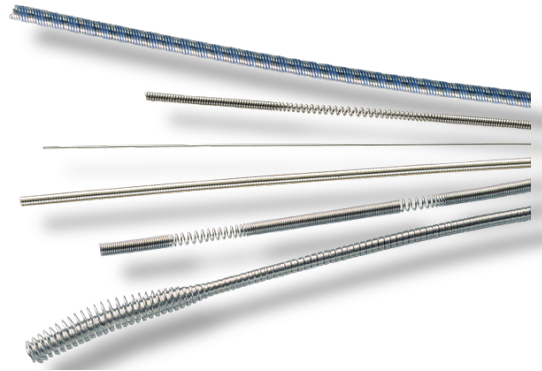


Figure 6-11, Examples of wire coil overtubes to illustrate the variety in shapes [51].

As previously indicated, the PTFE coating on the guidewire is most likely unsuitable for the application in which it was used during this experiment, thus for use as insulating coating on the core of the BVS. On the other hand, PTFE has been specifically chosen because this material appears to be suitable based on its material properties, see Appendix 8.5. The advice is to look for a more wear-resistant PTFE coating as well as for replacement materials and materials with similar material properties to those of PTFE. For examples of substitute materials Appendix 8.5 can be consulted.

From pilot 3 it has become clear that the contact point between the guidewire and hinge axis pin is a critical point where the coating easily ruptures, despite using an overtube. As an increasingly angular displacement is made by the SATA hinge, the pin gradually moves into the path of the core. This particularly concerns the *slider High* side of the instrument. It must be investigated whether the pin, and thus the pivot point, can be moved so that it makes little or no contact with the core during instrument steering.

6.1.5 Conclusion core coating test

In the current setup, the PTFE coating on the nitinol guidewire is not suitable for application on the core of a BVS. This PTFE coating is fragile and will probably wear out quickly due to the sharp corners that the core must make through the SATA hinge. Based on the results of the pilots, it is strongly recommended to use an overtube. This overtube must in any case be flexible, must offer protection to the core and will provide a larger radius around which the core will bend. A critical look should be taken at the placement of the hinge axis pin. In the current SATA model, the pin forms a critical bending point on which the coating ruptures. Research must be conducted into wear-resistant PTFE coatings that fit within the current dimensions of the BVS design. In addition, other materials may be suitable as a substitute for PTFE.

7 Discussion



7.1 General discussion

After selecting the most suitable concept, shaping the model and executing several design iterations, a Steerable and Reusable BVS was developed. The evaluation of the BVS model was done based FEM simulations and a pilot study was set up to test the most critical component, the core. In this chapter, the design process and outcomes are discussed, future recommendations are provided and the final conclusion of the thesis project is given.

7.1.1 Design of a Steerable and Reusable Bipolar Vessel Sealer

The first part of the project design goal was to develop a BVS that is modular, easy to clean and sterilised and therefore reusable. SATA provides the basis for the instrument that is steerable and optimized for reusability. Therefore, the second part of the design goal was to implement the functionalities of a BVS into a SATA instrument to obtain a BVS that is steerable and reusable. To achieve the design goal, modifications to the SATA instrument have been made in order to safely conduct electricity from and to the tip. In addition, a new tip has been designed that is inspired by existing BVS on the market. The tip fits seamlessly onto a SATA instrument whilst maintain its steerable functionalities and reusability.

Because SATA instruments are already reusable and steerable, during the conceptual design phase of the instruments body, particular focus was placed on the various options for conducting electricity to and from the tip. Through Harris profiles the resulting concepts were evaluated based on the design requirements. In this phase it was assumed that all concepts were compatible with the requirements of being a BVS. For this reason, the functional requirements for a BVS are clustered under one criteria heading; functionality. As a result, the differences in ratings are mainly due to other criteria, such as the introduction of additional required components, complexity of the concepts, manufacturability and the expected lifespan. The concept choice and resulting model show that a SATA instrument can be redesigned such that it meets all the functionality requirements of a steerable and reusable BVS. By excluding the use of electrical wires or other additional components, the modularity of the SATA instrument is fully maintained. As a result, the new instrument will distinguish itself from products currently available on the market.

Initially there was no clear winning concept for the tip because A number of aspects needed to be investigated further, such as the insulating layers and the open and closing mechanism of the jaws. A proven principle has been chosen for the tip insulation, i.e. making the complete tip housing from PEEK. On grounds of current research into ceramic coatings [21], it cannot be substantiated whether their use as an insulating layer or insert between the upper and lower jaws is suitable. However, extensive research into ceramic materials for tip insulation is not within the scope of this project. Decisive for the tip design was the choice for the open and close mechanism 1. It must be noted that in calculations for mechanism 1 and 3 not all forces were taken into account, such as frictional forces in the hinges or forces in y-direction. How much effect these forces have on the required tensile forces can be investigated further. In addition to more satisfactory results obtained through calculations, it was found during design iterations that mechanism 1 was readily implementable in the design of the tip. On the contrary, problems arose with the implementation of mechanism 3 because its construction would interfere with the conductive rods running through the PEEK component. Furthermore, to obtain the appropriate tensile force F_t in mechanism 3, a relatively complex design of the sliding surfaces of the upper jaw and the translating pulling block is required.

For calculating the required tensile force F_t in the core, the distance (L_1) between the rotation point of the upper jaw and the point of application of the sealing force F_{seal} has the biggest influence. First, the method used to determine L_1 and F_{t1} is based on a rather extreme schematic configuration. Although sealing blood vessels up to 7 mm is seen as a benchmark

for BVS instruments by manufacturers [36], a blood vessel with a diameter of 7 mm is in most cases larger than the vessels and tissues that are sealed in practice. The compression force F_{seal} of 20N is a maximum required to seal a blood vessel of 7 mm in diameter. For smaller tissues a $F_{seal} < 20N$ may be sufficient to obtain a high quality seal [37]. Furthermore, a blood vessel is never perfectly round and often branches of vessels are sealed as well. Nevertheless, using this extreme configuration as a reference will contribute to strengthening the components more than would be required in practice. Second, an additional safety factor was obtained by introducing forces based on length $L1 = 12.5$ mm. Although in reality it is assumed that the user of the instrument will most likely clamp the blood vessels as proximally as possible between the jaws, for which $L1$ corresponds to a length of 9.95 mm for a 7 mm vessel. However, higher forces obtained with $L1 = 12.5$ were applied during FEM simulations to optimise the design. In short, both the extreme configuration and the extended $L1$ lead to a higher safety factor. And thus a stronger design in which misuse will less likely to lead to instrument failure.

Another important point of attention is that due to friction and bending of the Nitinol core by the SATA hinge, the actual tensile forces on the core are expected to be slightly higher than the tensile force F_t as previously calculated. However, this strongly depends on the final design with overtube and the choice for PTFE or a substitute material as an insulating coating. It is therefore not included in this report.

In the final model, particular attention was paid to robustness, minimal additional components, preservation of modularity, steerability and functionality. Looking at the design of the tip, decisions were made that are not necessarily final. For example, a bolted connection between the PEEK component and the lower jaw was selected because this type of connection is easy to analyse with FEM in SolidWorks simulation software. Other connections are also possible, such as, pin and weld connections or even over-moulding of the PEEK. Furthermore, the connection between the conductive rods, the lower jaw and the steel part of the tip housing (SS base) is not definite. By tightening the conductive rods under tension, the lower jaw can be pressed against the PEEK component. This would make the bolted connection redundant.

In the model the coatings are indicated with a blue colour. The coatings must primarily serve for electrical insulation, but can also provide an anti-stick layer around the jaws. Although the coatings are included in the model and in previous literature research a number of possibly suitable coatings have been defined, the study and selection of a coating is not part of the thesis project.

7.1.2 Validation of the design of a Steerable and Reusable Bipolar Vessel Sealer

The validation of the design was done in two ways: 1) By performing stress calculations and simulations of some tip components using FEM in SolidWorks and by approximating the expected lifespan of these tip components. 2) By studying the wear of a PTFE coating on a Nitinol wire, which is seen as the most critical component in the new BVS.

FEM simulations have been performed continuously during the design iterations of the tip. In these simulations, the components of the tip and in particular the open and close mechanism are engineered such that they obtained a safety factor of > 1.5 . If a safety factor > 1.0 is present, the maximum stresses are always lower than the permissible yield stresses of the material. In this case it is very unlikely that fatigue will occur and the life span is $> 1.0 \cdot 10^6$ cycles. Concerning the stainless-steel components in the tip, the expected lifespan is much longer than the required lifespan of the components. Therefore, it is assumed that the design is strong enough.

For the PEEK component the highest stresses are 114 MPa with a Fseal of 20N on a blood vessel of 7 mm. The tensile strength of unreinforced PEEK is known to be close to 100 MPa. The use of unreinforced PEEK will consequently have a safety factor of < 1.0 and is therefore not recommended. The solution is a 30% glass-fibre reinforced PEEK. This material offers a higher tensile strength of up to 160 MPa, a higher stiffness and is therefore more suitable for structural purposes. Just like normal PEEK, glass-fibre reinforced PEEK is also suitable for injection moulding, extrusion and machining and its properties such as wear resistance, chemical resistance and sterilisation-ability make this material suitable for healthcare applications, such as a BVS.

The feasibility of the concept in which the core is part of the active electrode falls or stands on the insulating coating around the core. The conclusions of the experiment in which a nitinol guidewire with PTFE coating was tested for wear have already been discussed in chapter 6. It should be emphasized that, despite the promising (improved) results of using an overtube, insulation failure of the coating after 27 cycles is far from satisfactory for a reusable instrument. In fact, 27 cycles are not even sufficient for the duration of a single surgical procedure, i.e. > 100 cycles.

7.1.3 Recommendations

Research into a more wear-resistant PTFE coating or a replacement material is strictly necessary. The main purpose of the currently tested PTFE coating on the guidewire is to achieve the lowest possible friction, but the guidewire has a completely different application than the core with a PTFE coating in the design of a BMS. Although low friction of the insulation layer around the core in the BVS is also desirable, this is not the most important function. Low friction between the core and other components can also be achieved by coating the other components with, for example, a ceramic coating that also has a low coefficient of friction. It is also possible to choose a replacement material for PTFE, whereby these materials are in any case wear-resistant, highly flexible, electrically insulating and sterilisable.

There are various options for the overtube in terms of shape and material. Initially, a suitable overtube must be sought and tested which is compatible with the current SATA mechanism design. Figure 7-1 shows an example of an overtube incorporated in the BVS CAD design. It is essential to test the overtube in combination with a more wear-resistant insulating coating. Furthermore, it is possible to make the overtube part of the steering mechanism. For example, the overtube can be attached to the stainless steel part of the core (inner shaft axis) and the stainless steel part of the tip (SS base). In this way, additional torsional stiffness which is required to rotate the tip around its longitudinal axis is provided.

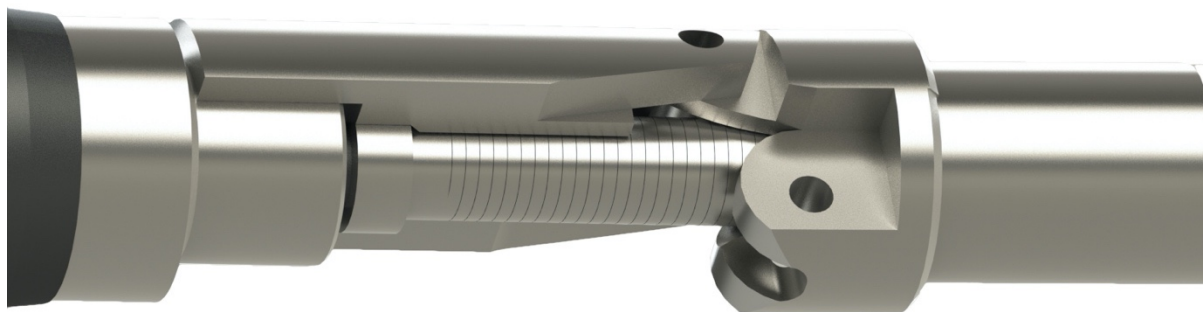


Figure 7-1, Stainless steel overtube. A cross section of the SATA tip base component containing an overtube of 2 mm in diameter and a length of ~10 mm. The component is not fixed but held in place by the screw component of the tip (SS base), the SATA tip base and both sliders. This ensures that the modularity is retained and cleaning is accessible. Furthermore, the component can easily be replaced when necessary.

The pilot experiments showed that at one side of the instrument the axis pin of the SATA hinge crosses the path of the core when the SATA hinge is articulated. In effect, the pin presses against the overtube and creates a point load instead of an evenly distributed load. Simultaneously, the bending radius of the overtube and thus the core is very small when the SATA hinge is articulated to this side of the device. It is recommended to re-design the SATA mechanism in such a way that the bending radius is increased and the pin is no longer crossing the path of the core when the SATA hinge is articulated.

As indicated earlier, more research is needed into the exact composition and deposition methods of the ceramic electrically insulating coatings and their properties in practice. A possible area of this research could be aimed at searching for coatings that both insulate and provide an anti-stick layer. An anti-stick layer ensures that coagulated tissue does not stick to the jaws very easily and reduces the chance of tissue clogging. As a results, the seal quality remains higher during the surgical procedure and it furthermore it provides extra ease of use.

This thesis focuses on the shafts of a SATA instrument and the tip. In the future, modifications to the current design of the SATA handle will be necessary to enable the electricity to pass through the handle and for connecting the instrument to a bipolar electrosurgical generator. Furthermore, the mechanical design of the handle is key to ensure that the pulling force on the core is limited and not much higher than the calculated pulling force F_t , thus preventing any damage.

7.1.4 Conclusion

The design goal for this thesis project was to develop and evaluate a novel Steerable and Reusable Bipolar Vessel Sealer incorporated into an instrument with Shaft Actuated Tip Articulation technology. With the introduction of a reusable instrument, costs in particular must be reduced to ensure that this type of laparoscopic instrument becomes more accessible for use in low- and middle-income settings. In addition, reusable instruments contribute to sustainable surgery and thus a sustainable healthcare.

The results were achieved by redesigning a SATA instrument and making it suitable for Bipolar vessel sealing. The design requirements are derived from the functional principles of a BVS, the requirements for instruments to be reusable and the requirements that hold for SATA instruments. Where possible, existing components of the SATA instrument are part of the active and return electrodes and together with a new tip design, this ensures a closed circuit when tissues and blood vessels are clamped by the jaws. Strategically applied insulating coatings prevent short circuiting and collateral tissue damage. Simultaneously, an ideal uniformly distributed pressure of 20N can be applied on the tissue. All together, these properties ensure that the final model meets the requirements of functioning as a BVS

The new design of the tip is as simple and robust as possible and fits seamlessly into the existing SATA instruments. Limited additional components are introduced by the new design and the modularity is retained. Used materials are suitable for repeated cleaning, disinfection and sterilization cycles. Therefore, the current design has the potential to be reused for many surgical procedures and thus, after further development, an instrument will be delivered that indirectly contributes to reducing costs and making healthcare more sustainable.

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8 Appendixes



8.1 Concept sketches

Concept 1 – Double core

Description

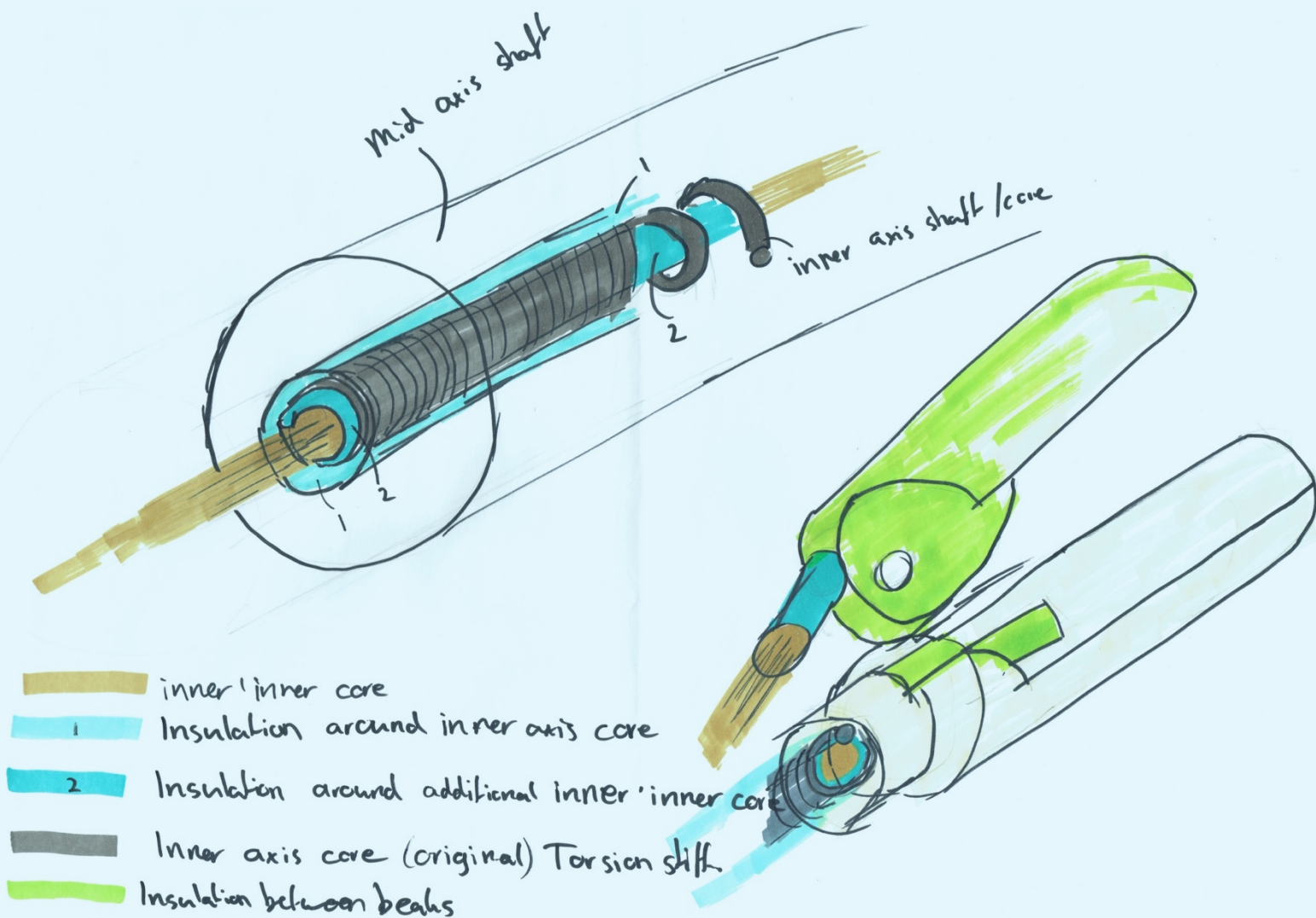
An additional $\varnothing$ 1mm flexible and conductive core is inserted into the original core. The additional core is coated with insulation to prevent short circuiting. In this concept, the original core will conduct electricity as well. Therefore it will be coated with electrical insulating to prevent short circuiting and direct contact to the other stainless-steel components of the instrument. One of the cores is connected to the upper jaw and the other core is connected to the lower jaw.

Main benefits

- Limited additional components
- Limited design changes with respect to original instrument design
- Safety, only the core is conducting electricity

Disadvantages

- Core is hardly cleanable
- The core will become stiffer
- Core is critical component



Concept 2 – The external conductor

Description

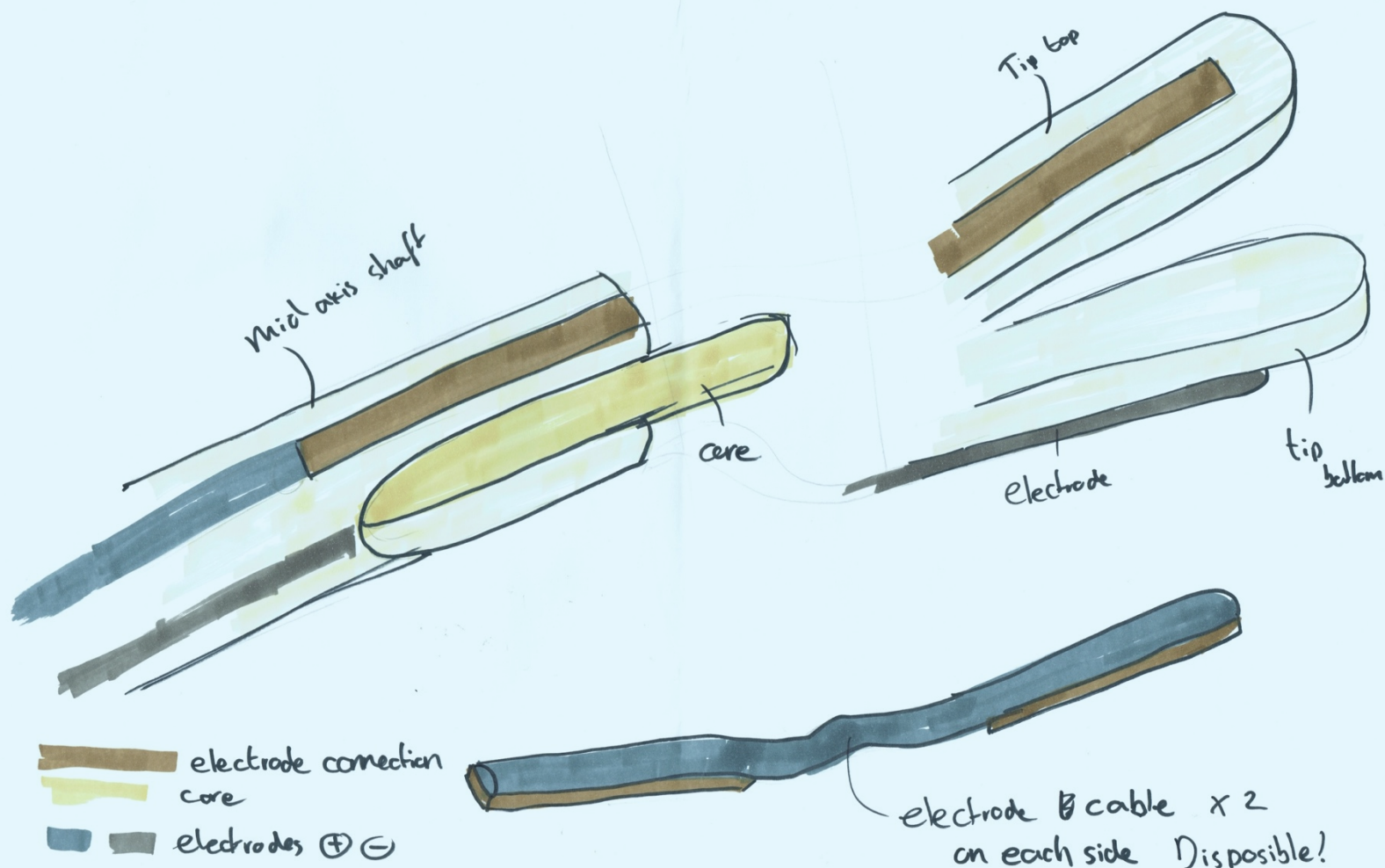
Two short flexible electrical cables (electrodes) are added to the instrument to transfer the electricity directly from the shafts to the tip of the instrument, skipping the SATA hinge. Added to the shaft are either electrical wires or coated electrical wires, to create a (+) and (-) path. The (+) and (-) cables are directly connected to either the upper jaw or lower jaw at the tip of the instrument.

Main benefits

- Additional electrical cable components can be easily replaced
- Easy to clean

Disadvantages

- Critical connections for electrical cables
- 'Loose' components
- Cable electrodes may reduce steerability



Concept 3 – The core model

Description

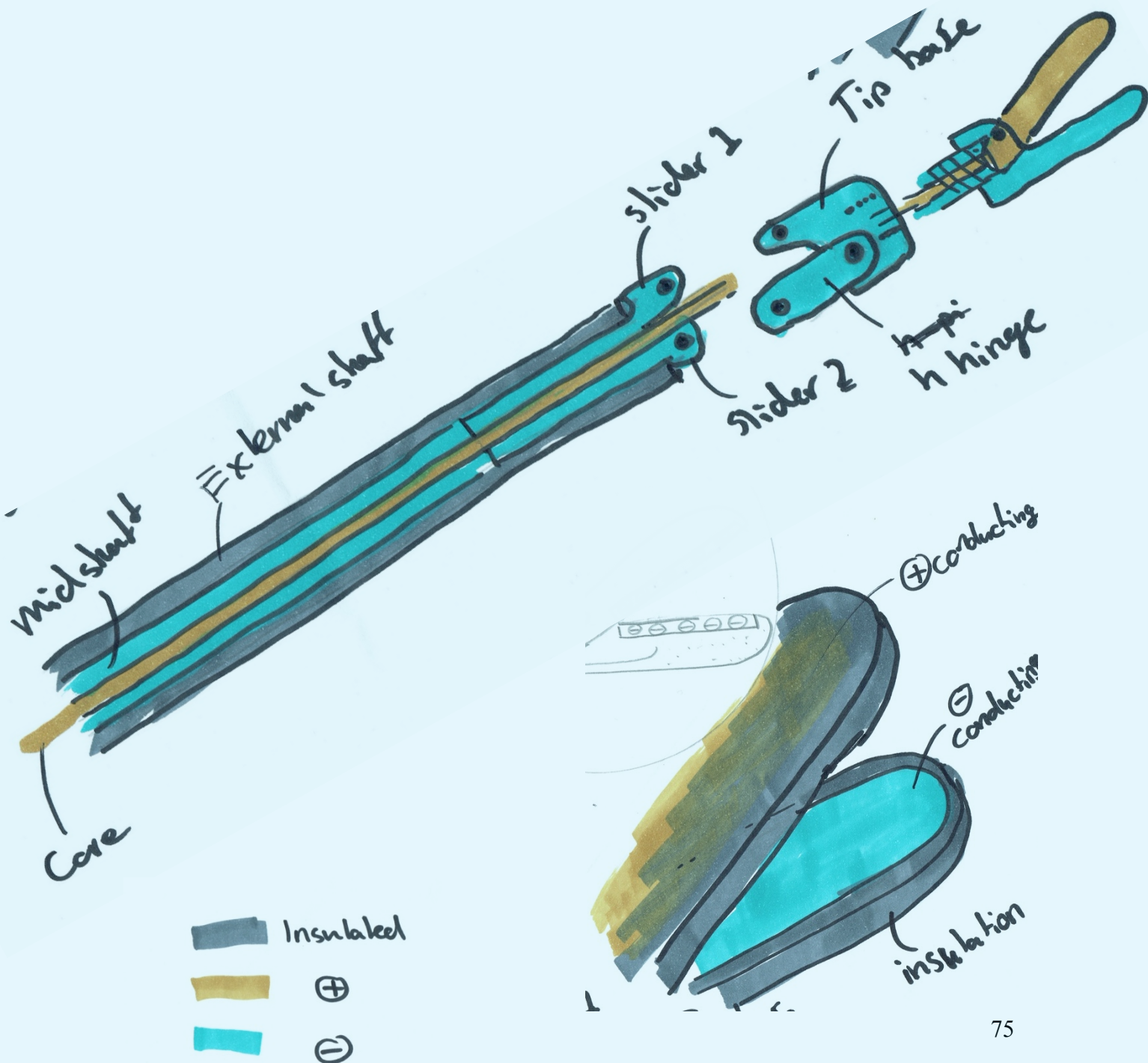
No additional components are added to the instrument. Full steerability and functionality is guaranteed. However, electrical insulation between the core and the other components is needed. The external shaft can be made of fully insulating materials or be coated with insulation materials.

Main benefits

- No additional components needed (excluding insulating coatings)
- Limited design changes with respect to original instrument design
- Proven functionality on both electrically as steerability aspects

Disadvantages

- All components will have to conduct electricity (exempt insulation layers/components)



Concept 4 – The twins

Description

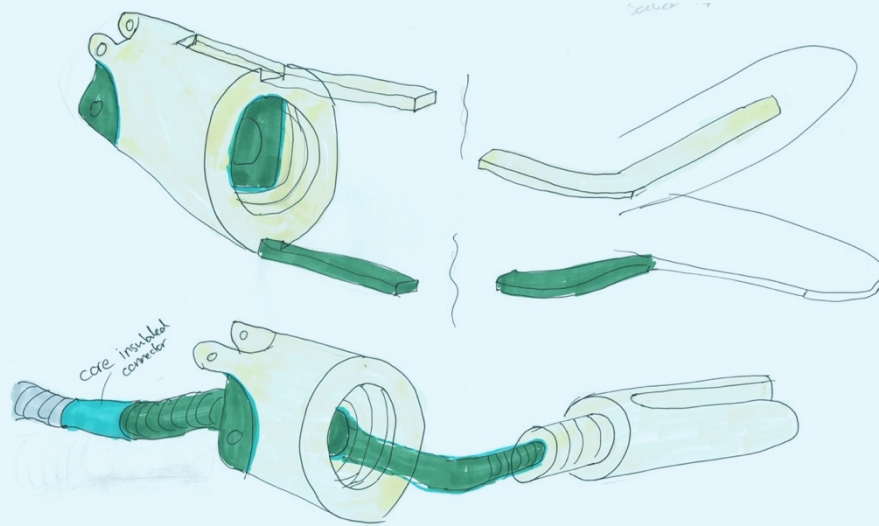
The entire design of the current SATA instrument is split in two. The top components will form the (+) path and the bottom components form the (-) path or vice versa.

Main benefits

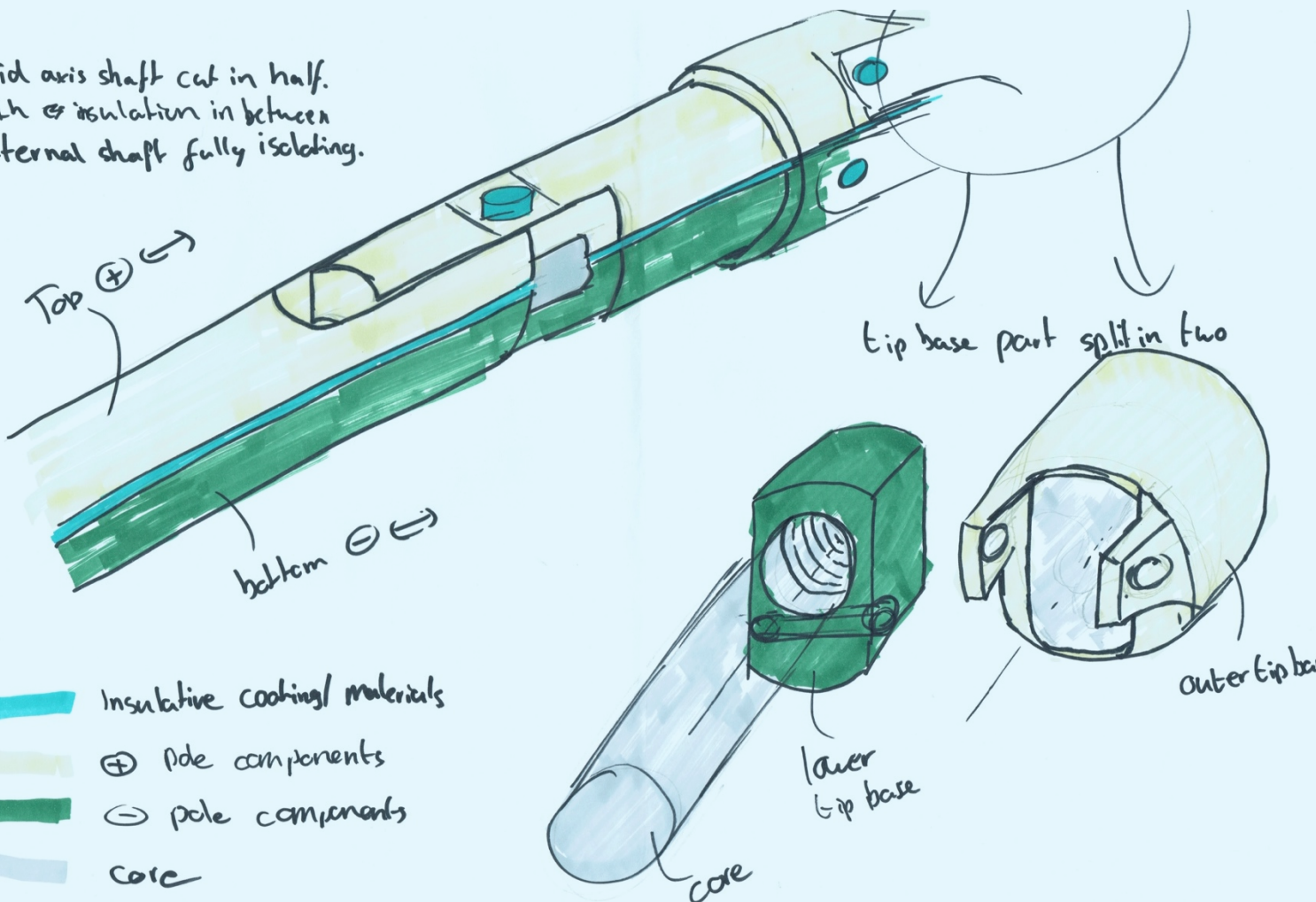
- Cleanability

Disadvantages

- Additional components
- Complex components
- Lifespan of insulation coatings
- Disassembly time
- All components are conducting



Mid axis shaft cut in half.
with insulation in between
External shaft fully isolating.



Concept 5 – Coated 'wires'

Description

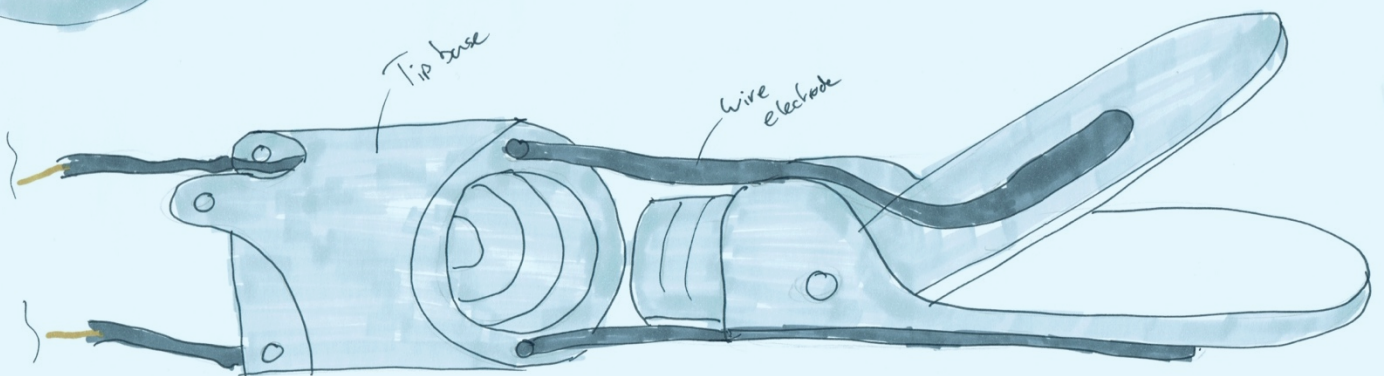
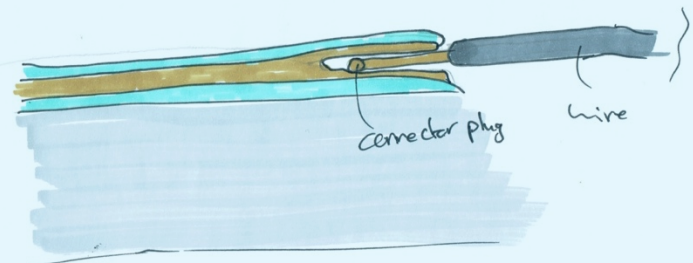
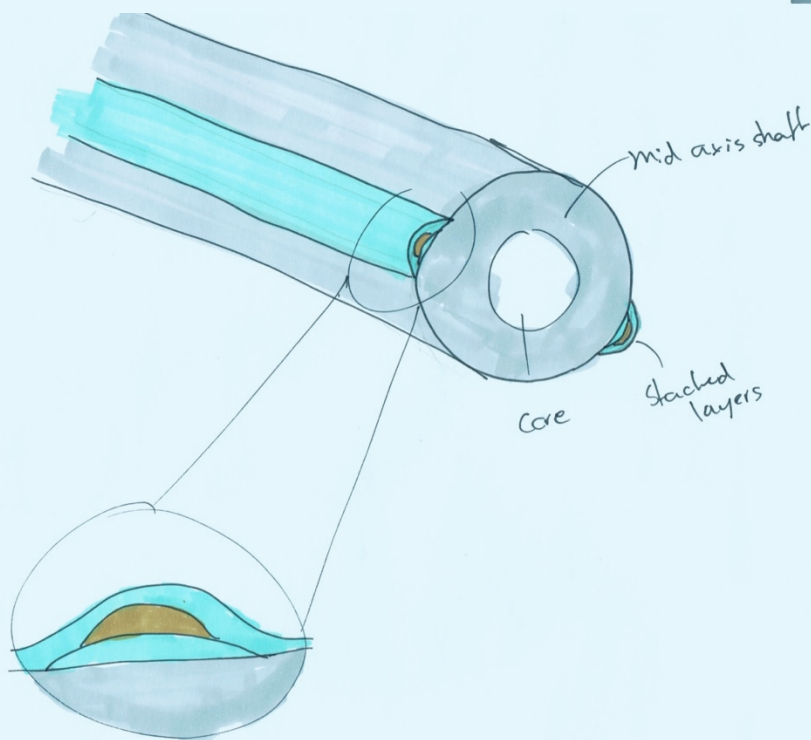
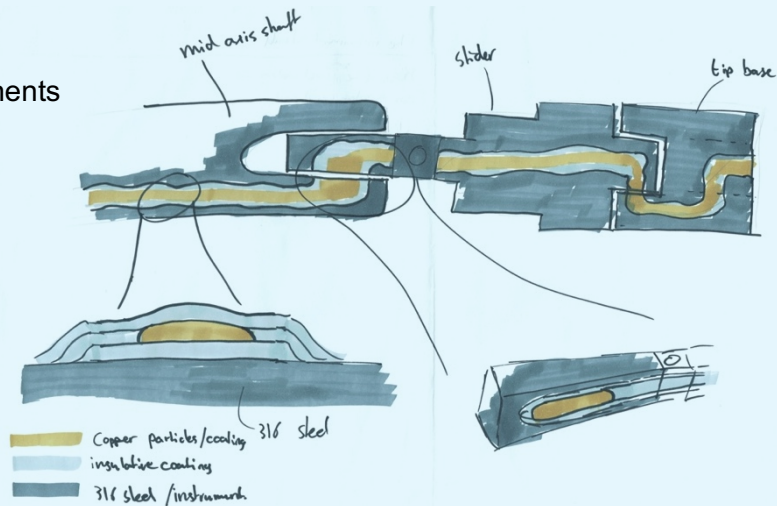
Electrically conductive paths are created by stacking layers of conductive and insulative coatings. Continuous contact between the conductive surfaces of the various components is necessary to keep the circuit closed. A solution to avoid the hinges is the 'external conductor' concept principle.

Main benefits

- Cleanability

Disadvantages

- Complex connections between components
- Lifespan of the coatings
- Insulation failure
- Conductivity through small area's



Tip concept 1 – The crocodile

Description

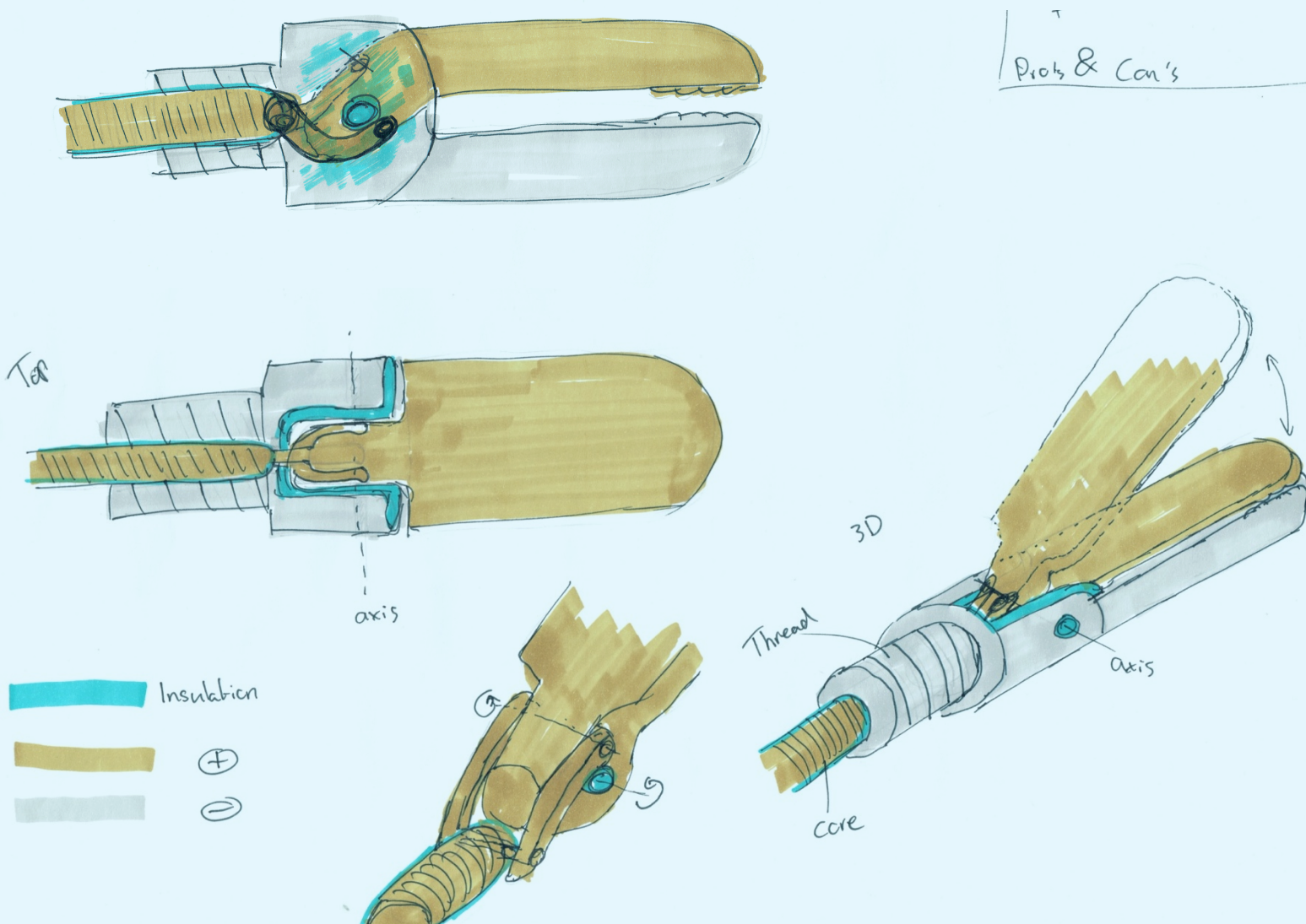
Similar to the 'butterfly' hinge, however the crocodile hinge uses only one link component instead of two. Meaning that only one of the two jaws can articulate. The hinge mechanism, on the other hand, is more robust and the two jaws are easier to insulate from each other. In this tip concept the core is the active electrode (+), in turn the core is connected to the upper jaw via a link. The lower jaw is connected to (part) of the tip housing forming the return electrode (-). By means of an insulating layer or a tip housing (partly) made out of insulating materials the two jaws are separated from each other, preventing short circuiting.

Main benefits

- Robust hinge mechanism
- Reduced tip components
- Well insulated paths
- SATA compatible

Disadvantages

- Only one jaw rotates (allows smaller angular rotation compared to butterfly)



Tip concept 2 – The butterfly

Description

The butterfly mechanism is a commonly used and proven mechanism for opening and closing the jaws of a laparoscopic instrument. In this case, the core is the (+) electrode and is connected to the bottom beak via the hinge's components (light brown). The upper jaw is (-). Although it is connected to the hinge, there is an insulating component in between (green), so that short circuiting is not possible. The upper jaw makes continuous contact with the tip housing, which directs the electricity back through the other components of the instrument (-). The axis, over which both hinges work, is insulated as well. A layer of insulation separates the tip housing and the butterfly mechanism (blue). The core is insulated as well.

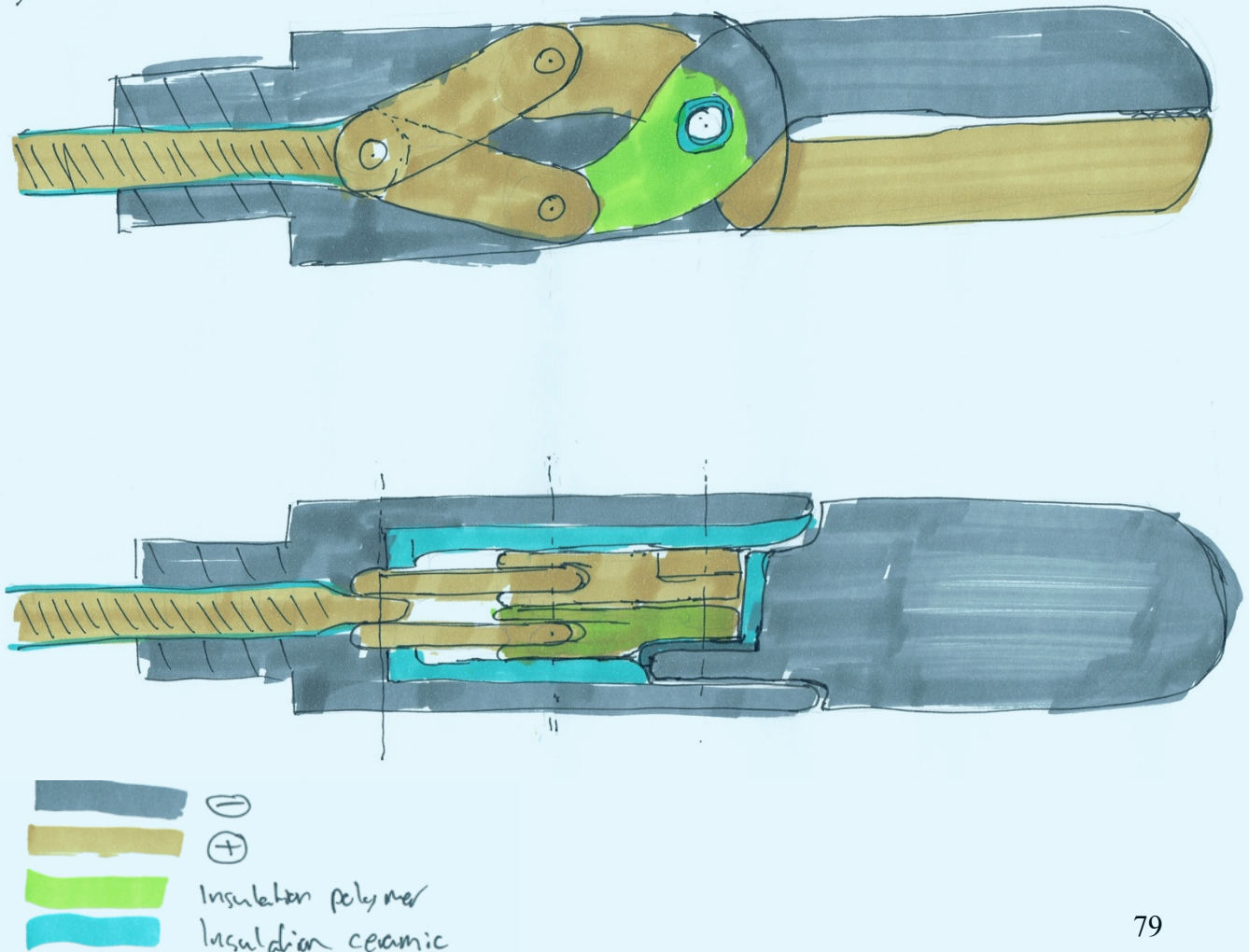
Main benefits

- Proven mechanism
- Little linear movement required to open the tip
- Well insulated paths
- SATA compatible

Disadvantages

- Hinges prone to jam
- Fragile insulating layers

Side



Tip concept 3 – The slider

Description

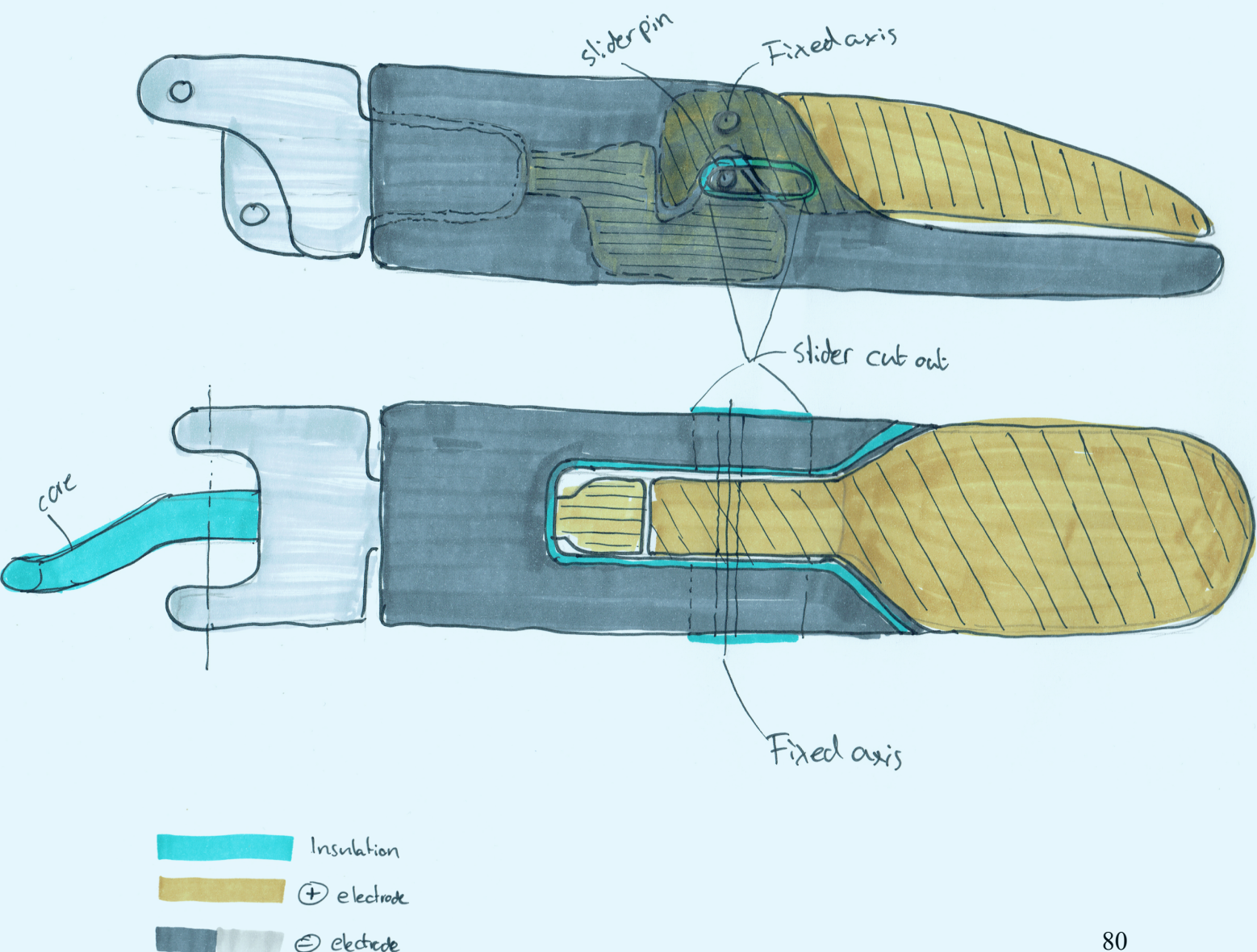
The slider tip provides an open close mechanism with a reduced number of necessary hinges. Pulling the core and applying compression to the blood vessel will ensure contact between the core and upper jaw, thus closing the circuit. An insulating layer must prevent short circuiting between the lower jaw (-) and the core, slider and upper jaw (+). A critical insulating layer is needed separate the lower jaws slider cut out surface and the slider pin. The dimensions and slope of the surface between the slider and upper jaw determines the ratio between applied force on the blood vessel and pulling force.

Main benefits

- Reduced number of mechanism components
- Well insulated paths.
- SATA compatible

Disadvantages

- Cut out in tips body
- Reduced material around fixed hinge axis
- Complex force transmission



8.2 Calculations tip mechanism comparison

The following formulas were used to calculate torque T1 and forces Fr and Ft:

$$\text{Torque [Nmm]} \quad \tau = F * r * \sin(\alpha)$$

$$\text{Torque [Nmm]} \quad T1 = F_{\text{seal}} * L1 * \sin(\alpha)$$

$$\text{Force [N]} \quad F_r = \frac{T1}{\sin(\theta) * L2}$$

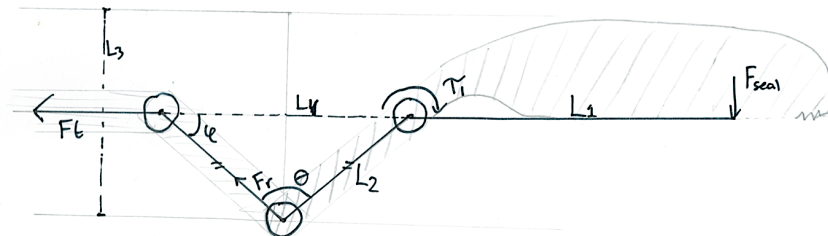
$$\text{Force [N]} \quad F_t = \cos(\varphi) * F_r$$

$$\text{Angle [Degrees]} \quad \angle \theta = 2 * \sin^{-1}\left(\frac{L4/2}{L2}\right)$$

$$\text{Angle [Degrees]} \quad \angle \varphi = \cos^{-1} \frac{L4/2}{L2}$$

$$\text{Force transmission ratio} \quad \eta = \frac{F_{\text{seal}}}{F_t}$$

Mechanism 1) Scissor mechanism with 1 link, see figure blow.



Sketch of mechanism 1. By applying Fseal we obtain T1 at the fixed hinge axis. The link has equal length with respect to L2

Following the configuration in the figure above we obtain:

$$\text{Torque [Nmm]} \quad T1 = 20 * 12.5 * \sin(90)$$

$$T1 = 250 \text{ Nmm}$$

$$\text{Angle [Degrees]} \quad \angle \theta = 2 * \sin^{-1}\left(\frac{3}{4}\right)$$

$$\angle \theta \approx 97.18^\circ$$

$$\text{Force [N]} \quad F_r = \frac{250}{\sin(97.18) * 4}$$

$$F_r \approx 62.99$$

$$\text{Angle [Degrees]} \quad \angle \varphi = \cos^{-1}\left(\frac{3}{4}\right)$$

$$\angle \varphi \approx 41.41^\circ$$

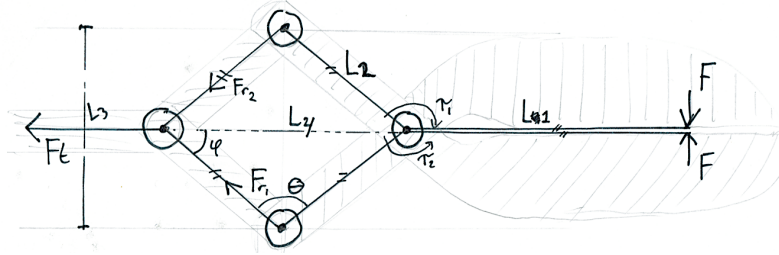
$$\text{Force [N]} \quad F_t = \cos(41.41) * 62.99$$

$$F_t = 47.24$$

$$\text{Ratio} \quad \eta = \frac{20}{47.24} = 0.42$$

If we want to exert a force (Fseal) of 20N on the tissue while using the configuration above, a pulling force **Ft = 47.27N** on the core is required.

Mechanism 2) Scissor mechanism with dual link.



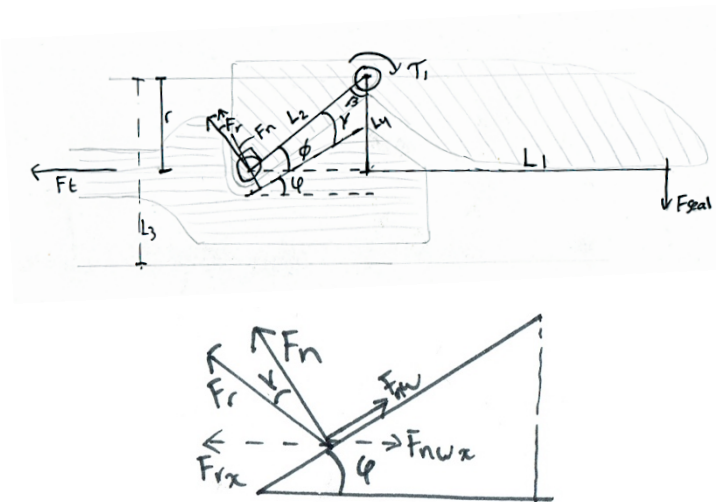
Sketch of mechanism 2. Both jaws are able to apply force in this configuration. $F_{seal} = 20\text{N}$ is divided by two, which gives $F = 10\text{N}$. Similarly to the previous calculations for mechanism 1, the torque(s) and forces are determined.

Following the configuration above in the figure above we obtain:

Torque [Nmm] $T1 = 10 * 12.5 * \sin(90)$ $T1 = 125 \text{ Nmm}$ Angle [Degrees] $\angle\theta = 2 * \sin^{-1}(\frac{3}{4})$ $\angle\theta \approx 97.18^\circ$ Force [N] $Fr = \frac{125}{\sin(97.18) * 4}$ $Fr \approx 31.50$	Angle [Degrees] $\angle\phi = \cos^{-1}(\frac{3}{4})$ $\angle\phi \approx 41.41^\circ$ Force [N] $Ft1 = \cos(41.41) * 31.50$ $Ft = 2 * Ft1$ $Ft = 47.24$ Ratio $\eta = \frac{20}{47.24} = 0.42$
---	--

In this configuration each jaw exerts a force of 10N on the tissue. Subsequently, the forces $Fr(1-2)$ and $Ft(1-2)$ can be calculated for each of the jaws in a similar way as mechanism 1. Adding up $Ft1$ and $Ft2$ results in the total required tensile force in the core **$Ft = 47.25\text{N}$** .

Mechanism 3) Scissor mechanism without link. For the comparison with the previous mechanisms, $L2 = 4$ and $\theta = 45^\circ$ have been chosen. In addition, $\phi = 40^\circ$ has been chosen. Friction coefficient steel on steel is 0.57.



Sketch of Mechanism 3, Top. This configuration uses no linkages to connect the Upper jaw and core. Length $L2$ and both angles θ and ϕ can be adjusted, and will affect the resulting force Fr and required pulling force Ft . Bottom: sketch used to determine frictional forces.

$$\text{Torque [Nmm]} \quad T1 = 20 * 12.5$$

$$T1 = 250.0 \text{ Nmm}$$

$$\text{Angle [Degrees]} \quad \angle \theta \approx 45^\circ$$

$$\text{Angle [Degrees]} \quad \angle \varphi \approx 40^\circ$$

$$\text{Angle [Degrees]} \quad \angle \gamma \approx \theta - \varphi = 5^\circ$$

$$\text{Force [N]} \quad Fr = \frac{250.0}{4}$$

$$Fr = \mathbf{62.50}$$

$$\text{Force [N]} \quad Fn = Fr * \cos \gamma$$

$$Fn = 62.50 * \cos 5^\circ \\ \approx 62.2622$$

$$\text{Force [N]} \quad Fnw = Fn * 0.57$$

$$Fnw = 62.2622 * 0.57 \approx 35.4894$$

$$\text{Force [N]} \quad Fnwx = Fnw * \cos(\varphi)$$

$$Fnwx = 35.4894 * \cos(40) \\ \approx \mathbf{27.19}$$

$$\text{Force [N]} \quad Frx = Fr * \sin(\theta)$$

$$Frx = 62.50 * \sin(45) \approx \mathbf{44.19}$$

$$\text{Force [N]} \quad Ft = \sum Fx = Fnwx + Frx$$

$$Ft = \sum Fx = 27.19 + 44.19 \\ = \mathbf{71.38}$$

$$\text{Ratio} \quad \eta = \frac{20}{71.38} = \mathbf{0.28}$$

The calculation above gives an approximation of Ft in this configuration, in this case **71.38N**. However, if we look at the overall dimensions of mechanism 3 compared with mechanism 1 and 2, mechanism 3 is shorter since no linkage is needed. Thus, there is some room to extend L2. Therefore, similar calculations have been done with lengths L2 = 5 mm and L2 = 6 mm:

$$\text{Force [N]} \quad Fr = \frac{250.0}{\mathbf{5}} = \mathbf{50}$$

$$\text{Force [N]} \quad Ft = \sum Fx = 21.75 + 35.36 \\ = \mathbf{57.10N}$$

$$\text{Ratio} \quad \eta = \frac{20}{57.10} = \mathbf{0.35}$$

$$\text{Force [N]} \quad Fr = \frac{250.0}{\mathbf{6}} \approx \mathbf{41.67}$$

$$\text{Force [N]} \quad Ft = \sum Fx = 18.13 + 29.47 \\ = \mathbf{47.59N}$$

$$\text{Ratio} \quad \eta = \frac{20}{47.59} = \mathbf{0.42}$$

8.3 Hinge pin diameter formulas and calculations

The following formulas are used to determine the appropriate pin diameter(s). All references in this section are to [sections](#) from [Roloff / Matek machine parts](#).

$$\text{Bending moment [Nmm]} (a) \quad M_b = \frac{F * (ts + 2tg)}{8}$$

$$(b) \quad M_b = \frac{F * ts}{8}$$

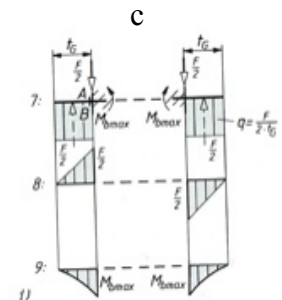
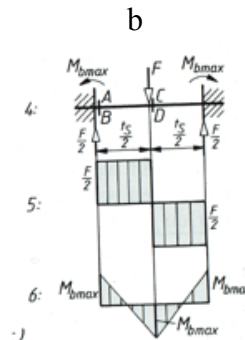
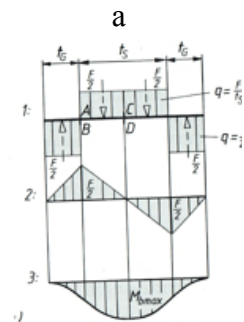
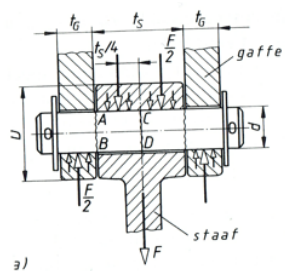
$$(c) \quad M_b = \frac{F * tg}{4}$$

(Section 9.2)

a = Pin has a loose fit in both clevis and rod

b = Pin is fixed in the clevis and has a loose fit in the rod

c = Pin is fixed in the rod and has a loose fit in the clevis



Normalised pin diameter [mm]

$$d = k * \sqrt{\frac{K_a * F}{\sigma_b}}$$

(section 9.2.2)

k = clamping factor

k = 1.6 (a)

k = 1.1 (b)

k = 1.1 (c)

(Table 3-5)

K_a = operating factor

K_a = 1.2 ... **1.5**

(tables 1-1 & 3-11a)

$$\sigma_b = \text{allowable bending stress}$$

$$\sigma_b = R_m = R_{mn} * K_t$$

$$(R_{mn} = \text{Ultimate tensile stress})$$

$$\text{Bending stress [MPa]} \quad \sigma_b = \frac{K_a * M_b}{0.1 * d^3} \leq \bar{\sigma}_b$$

$$\text{Shear stress [MPa]} \quad \tau_{max} = \frac{4}{3} * \frac{K_a * F}{2 * A} \leq \bar{\tau}_a$$

$$A = \text{cross-sectional area pin}$$

$$\bar{\tau}_a = \text{allowable shear stress}$$

The bending moments based on situation a, b and c are determined for a force (Fr or Ft) of **100N**:

$$\text{Bending moment [Nmm]} (a) \quad M_b = \frac{100 * (1 + 2 * 0.5)}{8} = 25$$

$$(b) \quad M_b = \frac{100 * 1}{8} = 12.5$$

$$(c) \quad M_b = \frac{100 * 0.5}{4} = 12.5$$

$$\sigma_b = R_m = R_{mn} * K_t \quad \bar{\sigma}_b = R_m = 520 * 1$$

$$\text{Normalised pin diameter [mm]} (a) \quad d = 1.6 * \sqrt{\frac{1.5 * 100}{520}} = 0.8593 \rightarrow 0.9$$

$$(b - c) \quad d = 1.1 * \sqrt{\frac{1.5 * 100}{520}} = 0.5907 \rightarrow 0.6$$

$$\text{Bending stress [MPa]} (a) \quad \sigma_b = \frac{1.5 * 25}{0.1 * 0.9^3} \leq 520 = \mathbf{514.4}$$

$$(b - c) \quad \sigma_b = \frac{1.5 * 12.5}{0.1 * 0.6^3} \leq 520 = 868.1$$

$$\text{Shear stress [MPa]} (a) \quad \tau_{max} = \frac{4}{3} * \frac{1.5 * 100}{2 * (0.9^3 * \pi/4)} \leq 150 = \mathbf{157.2}$$

$$(b) \quad \tau_{max} = \frac{4}{3} * \frac{1.5 * 100}{2 * (0.6^3 * \pi/4)} \leq 150 = 353.7$$

Based on the results above, a pin diameter of 0.9 mm has been chosen. The bending stress can be reduced to 257 MPa, by choosing installation options b or c. A 316L pin with a diameter of 0.9 mm and 100N applied, results in a maximum shear stress Tmax of 157.2 MPa. This is slightly higher than the allowable T of 150 MPa, however this concerns a safety factor of ~ 3 . 3.5, in addition, the applied force of 100N is higher than the forces Fr or Ft will be. It is unlikely that the shear stress will cause any problems when a diameter of 0.9 mm is chosen for the final model.

8.4 Geometry mechanism 1 Matlab scripts & results and mechanism 3 script.

In theory L_3 can be longer than L_2 , not shorter. This causes the angle θ to increase, which is less favourable for the force transmission ratio in the mechanism. For this reason, L_3 was kept equal to L_2 at all times. In the script **$L_2 = [3: 0.5: 5]$** mm was chosen as input.

The longer L_4 , the longer $L_2 = L_3$ can be without increasing the overall dimensions of the mechanism. However, since the radius of the instrument is 2.5 mm and some length is needed to house the hinge axis et cetera, L_4 can vary between 0 mm and 1 mm. **$L_4 = 1.0$** mm gives favourable results.

All other lengths and angles depend on the above lengths, the radius of the instrument and the diameter of the hinge axis pins.

Lastly, the force F_r and F_{t1} will depend on the position of the upper jaw, i.e. the angle between the upper and lower jaw **$[0^\circ: 1: 45^\circ]$** . The forces F_r and F_t are therefore given for all angles $\beta_2 = \beta + [0^\circ: 1: 45^\circ]$.

```
%% Geometry hinge mechanism updates version Mechanism 1
clear all
close all
clc

%% Calculating torque T1 needed for a compression force of 20N on the tissue

F = 20; % [N] seal force

L1 = 9.95; % [mm] length axis of rotation -> Fseal
L4 = 1.0; % [mm] Axis of rotation

L1s = sqrt(L1^2 + L4^2) % lever arm

alpha = 90 + atand(L4/L1); % [degrees] angle between force vector and lever arm.

T1 = L1s * F * sind(alpha) % [Nmm] Torque

%% Setting up geometry (when tip fully closed)

L2 = 3:0.5:5; % [mm]
L3 = L2; % [mm]

D = 0.9; % [mm] hinges pin diameter
x1 = 0.5 * D + 0.4; % [mm] Additional material to house hinge pin.
r = 2.5; % [mm] (radius of instrument)

x2 = r - x1; % [mm]

L2y = x2 + L4; % [mm]

beta = acosd(L2y./L2); % [degrees]

%% Opening jaw range 0 - 45 degrees

angle = [0:1:45].'; % [degrees]
q = ones(46,5);
beta2 = q.*beta - angle; % [degrees] % [degrees] open jaw in steps of 1 degrees rotation in T1

L2y2 = cosd(beta2).*L2; % [mm]
x22 = L2y2 - L4; % [mm]

gamma = acosd(x22./L3); % [degrees]
```

```

theta = beta2+gamma; % [degrees]
phi = asind(x22./L3); % [degrees]

%% Calculating tensile force in connector

% Fr
Fr = T1 ./ (sind(theta).*L2) % [N]

%% Calculating tensile force in core

% Ft1
Ft1 = cosd(phi).*Fr % [N]

%% Distance P is used for reference in the CAD model

% P (distance between hinge axis and core axis)
P = (L2.*sind(beta2)).+(L3.*cosd(phi)) % [mm]

%% Translation of core

%For L2 = 4
trans = P(93) - P(138); % [mm] translation of the core from fully closed to fully opened
position.

%% Arbeit
A = Ft1(:,3) .* trans; % force x distance

A_mean = mean(A) % [Nmm] mean work.

%% Plot Fr
figure(1)
plot(L2,Fr,'o')
xlim([2 6])
hold on
plot(L2(1),Fr(1),'r*','MarkerSize', 20)
hold on
plot(L2(2),Fr(47),'r*','MarkerSize', 20)
hold on
plot(L2(3),Fr(93),'r*','MarkerSize', 20)
hold on
plot(L2(4),Fr(139),'r*','MarkerSize', 20)
hold on
plot(L2(5),Fr(185),'r*','MarkerSize', 20)

%% Plot Ft1
figure(2)
plot(L2,Ft1,'o')
xlim([2 6])
hold on
plot(L2(1),Ft1(1),'r*','MarkerSize', 20)
hold on
plot(L2(2),Ft1(47),'r*','MarkerSize', 20)
hold on
plot(L2(3),Ft1(93),'r*','MarkerSize', 20)
hold on
plot(L2(4),Ft1(139),'r*','MarkerSize', 20)
hold on
plot(L2(5),Ft1(185),'r*','MarkerSize', 20)

%% Plot P
figure(3)
plot(L2,P,'o')
xlim([2 6])
hold on
plot(L2(1),P(1),'r*','MarkerSize', 20)
hold on
plot(L2(2),P(47),'r*','MarkerSize', 20)
hold on
plot(L2(3),P(93),'r*','MarkerSize', 20)
hold on
plot(L2(4),P(139),'r*','MarkerSize', 20)
hold on
plot(L2(5),P(185),'r*','MarkerSize', 20)

```


Table 8-1, Fr Mechanism 1

Fr =

66.6306	58.2739	54.5207	52.3824	51.0159
66.8269	57.9065	53.7826	51.3482	49.7240
67.0712	57.5979	53.1197	50.4093	48.5507
67.3627	57.3456	52.5272	49.5582	47.4848
67.7010	57.1476	52.0008	48.7881	46.5166
68.0854	57.0021	51.5371	48.0931	45.6377
68.5156	56.9073	51.1326	47.4681	44.8408
68.9913	56.8618	50.7846	46.9087	44.1196
69.5120	56.8645	50.4906	46.4107	43.4685
70.0776	56.9142	50.2482	45.9708	42.8825
70.6878	57.0101	50.0556	45.5859	42.3575
71.3424	57.1513	49.9110	45.2532	41.8897
72.0412	57.3372	49.8131	44.9705	41.4758
72.7841	57.5674	49.7605	44.7355	41.1129
73.5709	57.8412	49.7521	44.5465	40.7985
74.4014	58.1585	49.7870	44.4020	40.5303
75.2755	58.5189	49.8645	44.3005	40.3064
76.1930	58.9223	49.9838	44.2409	40.1252
77.1536	59.3685	50.1446	44.2223	39.9851
78.1572	59.8576	50.3463	44.2437	39.8850
79.2034	60.3894	50.5888	44.3045	39.8236
80.2920	60.9641	50.8718	44.4042	39.8003
81.4225	61.5818	51.1952	44.5424	39.8142
82.5947	62.2424	51.5590	44.7188	39.8647
83.8079	62.9461	51.9633	44.9331	39.9513
85.0618	63.6931	52.4081	45.1853	40.0738
86.3557	64.4834	52.8937	45.4754	40.2320
87.6890	65.3172	53.4203	45.8035	40.4256
89.0610	66.1946	53.9881	46.1698	40.6548
90.4709	67.1157	54.5974	46.5744	40.9196
91.9178	68.0805	55.2486	47.0178	41.2201
93.4010	69.0892	55.9420	47.5002	41.5567
94.9193	70.1415	56.6780	48.0220	41.9296
96.4717	71.2376	57.4570	48.5838	42.3392
98.0572	72.3772	58.2793	49.1861	42.7861
99.6745	73.5602	59.1452	49.8292	43.2708
101.3224	74.7864	60.0551	50.5139	43.7938
102.9996	76.0553	61.0093	51.2407	44.3557
104.7048	77.3668	62.0081	52.0101	44.9573
106.4365	78.7202	63.0517	52.8227	45.5992
108.1934	80.1149	64.1402	53.6791	46.2822
109.9738	81.5505	65.2737	54.5798	47.0070
111.7763	83.0261	66.4523	55.5254	47.7744
113.5993	84.5410	67.6760	56.5163	48.5851
115.4411	86.0942	68.9446	57.5529	49.4399
117.3002	87.6847	70.2579	58.6356	50.3394

Table 8-2, Ft Mechanism 1

Ft1 =

55.6475	51.3920	49.6660	48.7341	48.1580
55.4536	50.7132	48.6717	47.4820	46.6762
55.3021	50.0868	47.7471	46.3206	45.3091
55.1923	49.5102	46.8872	45.2422	44.0454
55.1240	48.9811	46.0876	44.2399	42.8752
55.0967	48.4976	45.3446	43.3076	41.7899
55.1104	48.0579	44.6545	42.4400	40.7821
55.1650	47.6604	44.0145	41.6323	39.8452
55.2604	47.3037	43.4216	40.8804	38.9734
55.3969	46.9868	42.8736	40.1805	38.1617
55.5745	46.7085	42.3683	39.5294	37.4056
55.7936	46.4681	41.9037	38.9240	36.7010
56.0544	46.2649	41.4781	38.3619	36.0445
56.3576	46.0982	41.0902	37.8406	35.4329
56.7034	45.9677	40.7385	37.3581	34.8634
57.0924	45.8730	40.4220	36.9126	34.3336
57.5252	45.8139	40.1398	36.5024	33.8412
58.0024	45.7904	39.8909	36.1262	33.3843
58.5247	45.8025	39.6748	35.7826	32.9610
59.0928	45.8502	39.4908	35.4706	32.5700
59.7073	45.9337	39.3386	35.1893	32.2098
60.3690	46.0534	39.2179	34.9378	31.8792
61.0786	46.2097	39.1284	34.7156	31.5772
61.8369	46.4029	39.0701	34.5220	31.3028
62.6445	46.6336	39.0430	34.3566	31.0554
63.5022	46.9025	39.0473	34.2192	30.8343
64.4106	47.2101	39.0830	34.1095	30.6389
65.3704	47.5573	39.1506	34.0274	30.4689
66.3822	47.9447	39.2504	33.9730	30.3239
67.4465	48.3734	39.3829	33.9463	30.2037
68.5639	48.8440	39.5487	33.9475	30.1082
69.7349	49.3577	39.7484	33.9770	30.0375
70.9596	49.9152	39.9827	34.0350	29.9915
72.2386	50.5177	40.2524	34.1221	29.9705
73.5719	51.1660	40.5584	34.2389	29.9747
74.9596	51.8613	40.9016	34.3858	30.0044
76.4019	52.6045	41.2830	34.5637	30.0603
77.8985	53.3966	41.7036	34.7734	30.1426
79.4493	54.2387	42.1646	35.0158	30.2522
81.0540	55.1317	42.6670	35.2918	30.3896
82.7121	56.0765	43.2121	35.6024	30.5557
84.4230	57.0740	43.8011	35.9487	30.7514
86.1862	58.1252	44.4351	36.3320	30.9776
88.0007	59.2306	45.1155	36.7534	31.2353
89.8656	60.3912	45.8434	37.2142	31.5258
91.7799	61.6074	46.6202	37.7158	31.8501

Table 8-3, Distance P Mechanism 1

P =

3.9117	5.3730	6.6401	7.8235	8.9599
3.8492	5.3050	6.5694	7.7513	8.8866
3.7865	5.2361	6.4974	7.6773	8.8111
3.7236	5.1663	6.4240	7.6014	8.7333
3.6606	5.0958	6.3492	7.5237	8.6534
3.5976	5.0245	6.2733	7.4444	8.5713
3.5346	4.9526	6.1961	7.3634	8.4872
3.4716	4.8800	6.1177	7.2807	8.4010
3.4087	4.8068	6.0383	7.1965	8.3129
3.3459	4.7332	5.9578	7.1108	8.2228
3.2833	4.6590	5.8763	7.0237	8.1309
3.2209	4.5845	5.7938	6.9351	8.0371
3.1588	4.5096	5.7105	6.8452	7.9416
3.0970	4.4343	5.6264	6.7541	7.8444
3.0356	4.3589	5.5415	6.6617	7.7456
2.9745	4.2833	5.4559	6.5681	7.6452
2.9139	4.2075	5.3696	6.4735	7.5433
2.8538	4.1316	5.2828	6.3779	7.4399
2.7942	4.0558	5.1955	6.2813	7.3352
2.7351	3.9800	5.1078	6.1838	7.2292
2.6766	3.9043	5.0197	6.0854	7.1220
2.6188	3.8288	4.9312	5.9864	7.0136
2.5616	3.7535	4.8426	5.8866	6.9041
2.5050	3.6785	4.7537	5.7863	6.7936
2.4492	3.6038	4.6648	5.6855	6.6822
2.3942	3.5296	4.5758	5.5842	6.5700
2.3399	3.4557	4.4869	5.4825	6.4570
2.2863	3.3824	4.3981	5.3805	6.3433
2.2336	3.3097	4.3095	5.2784	6.2290
2.1817	3.2376	4.2212	5.1761	6.1142
2.1306	3.1661	4.1332	5.0738	5.9991
2.0804	3.0954	4.0455	4.9715	5.8836
2.0310	3.0254	3.9584	4.8694	5.7678
1.9825	2.9562	3.8718	4.7674	5.6520
1.9348	2.8879	3.7859	4.6658	5.5361
1.8881	2.8205	3.7006	4.5646	5.4203
1.8422	2.7540	3.6161	4.4638	5.3046
1.7972	2.6884	3.5323	4.3636	5.1892
1.7530	2.6239	3.4495	4.2641	5.0742
1.7097	2.5604	3.3676	4.1653	4.9596
1.6673	2.4979	3.2867	4.0673	4.8457
1.6257	2.4365	3.2069	3.9702	4.7323
1.5850	2.3762	3.1282	3.8741	4.6198
1.5451	2.3170	3.0506	3.7790	4.5081
1.5061	2.2589	2.9742	3.6851	4.3974
1.4678	2.2020	2.8991	3.5924	4.2878

Final geometry tip open and close mechanism 3

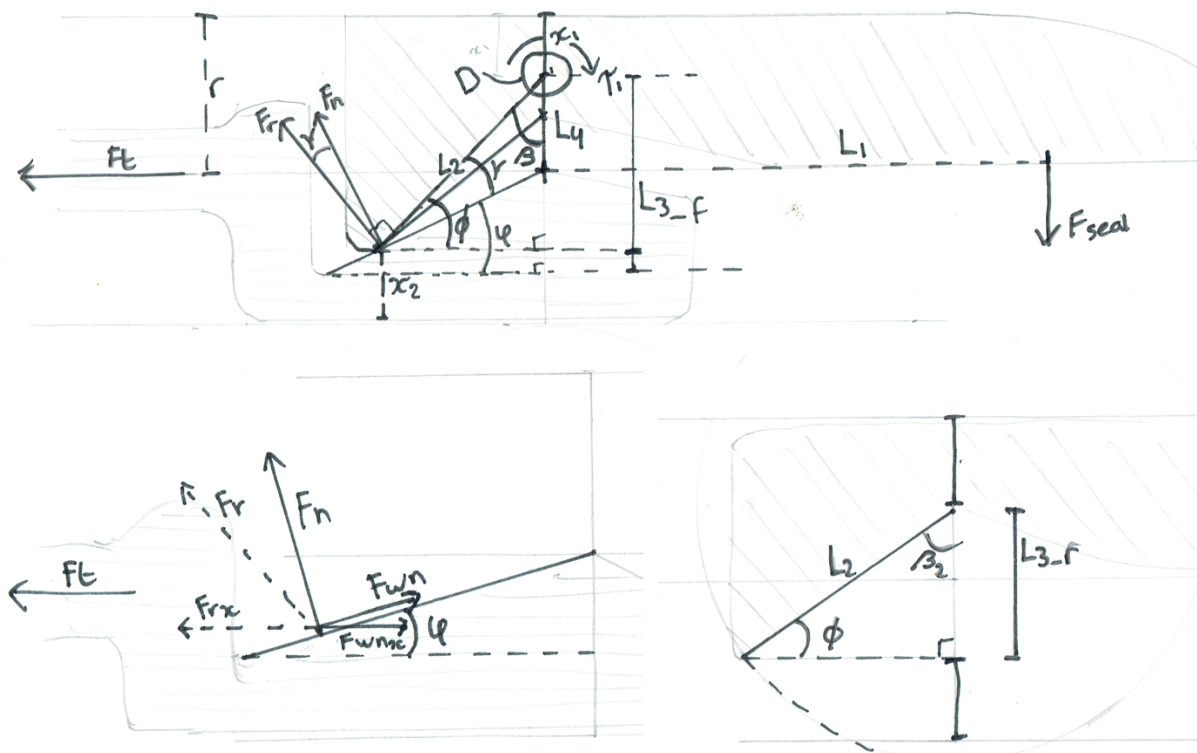
As for mechanism 1, the determination of the geometry for mechanism 3 is further elaborated in Matlab. See Appendix 8.5 on page 94. An overview of the geometry to be determined is given the figure below. The most important variables to determine the resulting force F_r and tensile force F_t are:

- length L_1 [mm]
- Length L_2 [mm]
- Angle θ [degrees]
- Angle ϕ [degrees]

For the comparison with mechanism 1 $F_{\text{seal}} = 20\text{N}$ and $L_1 = 9.95\text{ mm}$ are chosen again. Also constraint lengths x_1 and x_2 , which depend on the diameter of the instrument, have been added. The normal force F_n on the lower pulling block is determined by multiplying F_r with $\sin(\theta - \phi)$. θ and ϕ are variable from $[0^\circ: 1: 50^\circ]$ degrees, where $\phi \leq \theta$.

Again, with this mechanism, the force transmission ratio depends to a large extent on the lever on the right (L_1) and the lever on the left (L_2) with the addition of the friction between the two sliding components. However, length L_2 in this mechanism does not appear to be a free choice, but depends on the dimensions (r , x_1 , x_2 and L_4) that the instrument has to meet. In the most favourable case L_2 has a length of 3.5 mm and the angles θ and ϕ are both 45 degrees. For this setup, the resulting force is **$F_r = 56.8571\text{N}$** and the tensile force **$F_t = 60.0502\text{N}$** .

If we compare mechanism 1 and 3, we see that the tensile force with which the core has to be pulled is higher in mechanism 3 than in mechanism 1. However, the linear translation of the cable is shorter in mechanism 3 than in mechanism 1, namely 2.47 mm versus 3.74 mm respectively.



```

%% Geometry hinge mechanism updates version Mechanism 3
clear all
close all
clc

%% Calculating torque T1 needed for a compression force of 20N on the tissue

F = 20; % [N] seal force

L1 = 9.95; % [mm] Length point of application Fseal on bloodvessel

T1 = F * L1 % [Nmm] Torque

%% Setting up geometry (when tip fully closed)

% length L2
L2 = [2:0.5:7]; % [mm]
%L2 = 3.5;

D = 0.9; % [mm] hinges pin diameter
x1 = 0.5 * D + 1.05; % [mm] Additional material to house hinge pin.
r = 2.5; % [mm] radius of instrument

x2 = 0.0; % [mm] Space for lower pulling part

L3_f = 2*r - x1 - x2; % [mm] maximum check length L2 can be!

%% variables

theta = [0:5:50]'; % [degrees] angle theta
%theta = [1; % [degrees] angle theta
phi = [0:5:50]; % [degrees] Slope of lower pulling part equal or smaller than theta.

%% real L3 and Opening jaw range 0 - 45 degrees
beta = 90 - theta; % [degrees] depending on L2 and theta fully closed position jaws
beta2 = beta - 45; % [degrees] beta after opening jaws 45 degrees.

L3_r = cosd(beta2) .* L2 % [mm] real distance L3

L3_check = L3_f - L3_r % [mm] Must be positive!!! otherwise incorrect geometry.

%% Force Fr
Fr = T1 ./ L2 % [N] %resulting force (slope of theta)

q = ones(11,11);
q_theta = q.*theta; % [creates matrix phi]
q_phi = q.*phi; % [creates matrix phi]

gamma = q_theta - q_phi % [degrees]

%% Normal force
Fn = Fr' .* cosd(gamma) % [N] Normal force (slope of phi)

Fn_theta45 = Fn(4,:) % column for theta = 45 degrees and variable phi and L2 = 3.5
%theta45 = cos(gamma_theta45).*Fr
%% Friction force
Fwn = Fn_theta45 * 0.57; % [N] 0.57 is friction coefficient steel on steel

Fwnx = cosd(phi) .* Fwn % [N] friction force in x direction on slope phi. (phi = 0:5:50)

%% Forces in Fr x direction
q = ones(11,1);
Fr_theta45 = Fr(:,4) % (Fr for L2 = 3.5 and theta = 45)

Frx = Fr_theta45 .* sind(45)
%% Summ of forces in x direction

Ft = Frx + Fwnx % [N]

%% Distance P is used for reference in the CAD model

% P (distance between hinge axis and core axis)
P = sind(beta)*3.5 % for length L2 = 3.5
P2 = sind(beta2)*3.5 % for length L2 = 3.5

%% Translation of core

%For L2 = 4

```



```
trans = P - P2; % [mm] translation of the core from fully closed to fully opened position.  
  
%% Arbeid  
A = Ft' .* trans; % force x distance  
  
A_mean = mean(A) % [Nmm] mean work.
```

8.5 Material properties of polymers, ceramics and stainless steels.

Table 8-4, Polymer materials suitable for medical applications and standard sterilisation procedures

#	Material	Sterilisation		Mechanical properties							Electrical properties		Thermal properties		
		Autoclavable (A)	Other (EO)	Yield tensile strength [MPa]	Ultimate tensile strength [MPa]	Young's modulus [GPa]	Flexural modulus [GPa]	Hardness [Rockwell M]	Elongation at Break [%]	Density [g/cm ³]	Dielectric strength [kV/mm]	Resistivity [ohm*m]	Heat deflection temperature [degrees]	Melting onset [degrees]	Other
	Polyolefins														
1	Polypropylene (PP)	Yes	Yes		23-33	0.9 – 1.1	1.3		12	0.9			50 - 100	150	
	Polystyrene														
2	Polycarbonates (PC)	Yes	Yes	62	66	2.3	2.3	68	110	1.2	15	10 ¹⁶	130		
3	Polyoxymethylene (POM)	Yes	Yes		61	2.8	2.6	80	65	1.4	41	10 ¹⁴	100		
	High-temperature thermoplastics														
4	Polyethersulfone (PES)	Yes	Yes		87	2.6	2.6	88	65	1.4	16	10 ¹⁵	200		
5	Polysulfones (PSU)	Yes	Yes		70	2.5	2.7	69	52	1.2	17	10 ¹⁵	180		
6	Polyetheretherketone (PEEK)	Yes	Yes		97	4.0	3.8	120	43	1.3	20	10 ¹⁴	160	340	Shear strength 50 MPa
7	30% Glass Fiber PEEK	Yes	Yes		160	10	11	120	2.1	1.5	20	10 ¹⁴	300	340	Shear strength 100 MPa
8	Polyphenylene sulphide (PPS)	Yes	Yes		75	3.9		120	11	1.3	28	10 ⁹	130	290	
9	Liquid crystalline polymer (LCP)	Yes	Yes		180	11	9.0		3.0	1.4	33	10 ¹³	240	280	
	Fluoropolymers														
10	Polytetrafluoroethylene (PTFE)		Yes		25	0.45	0.4		300	2.2	14	10 ¹⁸	70	330	
11	Fluorinated ethylene (FEP)	Yes	Yes		20	0.43	0.6		300	2.1	22	10 ¹⁶	50	260	
12	Perfluoro alkoxy (PFA)	Yes	Yes		30		0.7		300	2.2	22	10 ¹⁶	75	300	
13	Ethylene chlorotrifluoroethylene (ECTFE)	Yes	Yes		49	1.6	1.7	92 [R]	230	1.7	18	10 ¹⁴	1	240	
14	Ethylene tetrafluoroethylene (ETFE)	Yes	Yes		46	1.5	1.2		230	1.8	16	10 ¹⁵	50	260	
15	Polyvinyl fluoride (PVF)	Yes	Yes		65			83		1.4			90	230	
16	Polyvinylidene fluoride (PVDF)	Yes	Yes		49	1.1	1.5	110	200	1.8	10	10 ¹²	85	170	

Table 8-5, Some ceramics and their properties.

#	Material	Sterilisation		Mechanical properties						Electrical properties		Other properties		
		Autoclavable (A)	Other (EO)	Fracture toughness [MPa*m ^{1/2}]	Ultimate tensile strength [MPa]	Young's modulus [GPa]	Hardness (knoop)	Poisson's ratio	Density [g/cm ³]	Dielectric strength [kV/mm]	Resistivity [ohm*m]	Thermal Conductivity [W/mK]	Resistance:	Most important material properties: https://www.ceramtec.com
	Oxide-Based Ceramics													
1	Alumina (Al ₂ O ₃) 93-95% purity			3.9	210	270	1120	0.22	3.7	12	10 ¹³	19	Corrosion Wear	-Biocompatible -Low friction -High resistance to wear and corrosion -Excellent mechanical properties
2	Alumina (Al ₂ O ₃) 97-99% purity			4.2	230	310	1290	0.22	3.8	12	10 ¹⁴	24	Corrosion Wear	-Biocompatible -Low friction -High resistance to wear and corrosion -Excellent mechanical properties
3	Zirconia-Toughened Alumina (ZTA)			7.2	290	360	1660	0.24	4.1	8.9	10 ¹³	25		-High toughness -High compressive strength -High hardness -Biocompatible
4	Aluminium Titanate (Al ₂ TiO ₅)			1.0		13	5 GPa (Vickers)		3.2			1.6	Chemical	-High thermal insulation -Low Young's modulus
5	Zirconia (ZrO ₂) TTZ			9.9	410	190	1210	0.29	5.7	7.7	10 ¹¹	2.2		-High thermal insulation -High toughness
	Non-Oxide Ceramics													
6	Aluminium Nitride (AlN)			2.9		330	1160	0.31	2.9	56	10 ¹⁰	96		-High electrical insulation -High thermal conductivity
7	Silicon Nitride (Si ₃ N ₄)			6.2	510	310	1570	0.27	3.2	18	10 ¹²	31	Thermal shock	-High toughness -High flexural strength -High operating temperatures

Table 8-6, Material properties of various stainless steels and Nitinol

#	Material	Sterilisation		Mechanical properties							Electrical properties	Other properties		
		Autoclavable (A)	Other (EO)	Yield tensile strength [MPa]	Ultimate tensile strength [MPa]	Young's modules [GPa]	Hardness [Rockwell B]	Shear strength [MPa]	Poisson's ratio	Density [g/cm ³]	Conductivity S/m	Thermal conductivity [W/mK]	Chemical resistance	Other
	AISI 316 Stainless steel grades										2.6% IACS			
1	Annealed 316 SS			230	570	200	80	400	0.28	7.9	1.5*10 ⁶	15		
2	Cold finished 316 SS			410	520	200	80	350	0.28	7.9	1.5*10 ⁶	15		
3	Hot finished 316 SS			250	580	200	80	420	0.28	7.9	1.5*10 ⁶	15		
4	1/16 – 1/2 Hard 316 SS			350 - 850	660 - 1180	200	80	450 - 690	0.28	7.9	1.5*10 ⁶	15		
	AISI 316L Stainless steel grades										2.6% IACS			
5	Annealed 316L SS			170	530	200	80	370	0.28	7.9	1.5*10 ⁶	15		
6	Cold finished 316L SS			430	700	200	80	470	0.28	7.9	1.5*10 ⁶	15		
7	Hot finished 316L SS			240	570	200	80	410	0.28	7.9	1.5*10 ⁶	15		
8	1/16 – 1/2 Hard 316L SS			350 - 870	670 - 1160	200	80	460 - 690	0.28	7.9	1.5*10 ⁶	15		
	Other Metals													
9	Nitinol Low-Temperature phase			100	754	28			0.30	6.5	1.3*10 ⁶	10		-High corrosion resistance
10	Nitinol High-Strength Superelastic			1280	1450					6.5				- Biocompatible

8.6 CAD Model and design documentation

All component names, numbers and description are included in Table 8-7. A distinction is made between the components in the tip and components for the SATA mechanism. For all the components suggested materials have been added in Table 8-9, as well as possible manufacturing methods and whether the components are coated.

<i>Table 8-7, Components list final model reusable and steerable bipolar vessel sealer.</i>			
<i>Component number</i>	<i>Name component</i>	<i>Component description</i>	<i>Quantity</i>
<i>TIP</i>			
<i>1</i>	<i>PH_4000_v8 – SS base</i>	<i>Threaded tip base bonded with PEEK base</i>	
<i>2</i>	<i>PH_4001_v8 – PEEK base</i>	<i>Polymer tip housing</i>	
<i>3</i>	<i>PH_4002_v8 – Lower jaw</i>	<i>Lower jaw</i>	
<i>4</i>	<i>PH_4003_v8 – Upper jaw</i>	<i>Upper jaw</i>	
<i>5</i>	<i>PH_4004_v8 – Connector</i>	<i>Link between Upper jaw and Core</i>	
<i>6</i>	<i>PH_4005_v8 – NiTiCon</i>	<i>Distal end of the core, to connect Nitinol rod with connector</i>	
<i>7</i>	<i>PH_4006_v8 – Conductor rod</i>	<i>Electrically conductive rods, connecting the Lower jaw with the SS base</i>	<i>II</i>
<i>8</i>	<i>PH_4007_v8 – PIN</i>	<i>Bolt that connects the PEEK base with the Lower jaw</i>	
<i>9</i>	<i>PH_4008_v8 – Axis UJ</i>	<i>The Upper jaw axis</i>	
<i>10</i>	<i>PH_4009_v8 – Axis UJ insert</i>	<i>To hold in place the UJ axis.</i>	
<i>11</i>	<i>PH_4010_v8 – axis pin (2mm)</i>	<i>Axis between Upper jaw and Connector</i>	
<i>12</i>	<i>PH_4011_v8 – axis pin (2mm) round</i>	<i>Axis between Connector and NiTiCon</i>	
<i>13</i>	<i>PH_4012_v8 – Nitinol rod</i>	<i>Flexible part of the core</i>	
<i>14</i>	<i>PH_4013_v8 – Nitinol rod insulation</i>	<i>Flexible insulation for the core</i>	
<i>15</i>	<i>PH_4014_v8 – Overtube</i>	<i>Flexible core protection rod</i>	
<i>16</i>	<i>PH_4015_v8 – PEEK overtube</i>	<i>Additional insulation to prevent short circuiting</i>	
<i>SATA</i>			
<i>17</i>	<i>PH_011 – External axis shaft</i>	<i>Outer shaft with ceramic insulation coating</i>	
<i>18</i>	<i>PH_012 – Mid axis shaft</i>	<i>Middle shaft, housing the core</i>	
<i>19</i>	<i>PH_013 – Inner axis shaft</i>	<i>Core</i>	
<i>20</i>	<i>PH_031 – Tip base_revised_smooth</i>	<i>Threaded base (nut)</i>	
<i>21</i>	<i>PH_032 – H hinge - revised</i>	<i>Connecting the Slider low with tip base</i>	
<i>22</i>	<i>PH_033 – Slider high - revised</i>	<i>Directly connected to the tip base</i>	
<i>23</i>	<i>PH_034 – Slider low - revised</i>	<i>Connected to the H hinge</i>	

24	PH_041 – Slider pin	Slider pin's run through a guided path in the External axis shaft.	II
----	---------------------	--	----

Table 8-8, Components that are part of the active and return electrodes.

(Name and component number)			
Active electrode:		Return electrode:	
Inner axis shaft	19	Lower jaw	3
Nitinol core	13	Conductor rods	7
NiTiCon component	6	SS base	1
Connector	5	Tip base	20
Upper jaw.	4	(Overtube)	15
		H hinge	21
		Slider high	22
		Slider low	23
		Mid axis shaft	18

Table 8-9, Materials, coating and manufacturing methods.

Component number	Material description	Manufacturing method	Coating applied	Coating type
1	Stainless Steel 316L	Extrusion + conventional	Yes	Ceramic insulation
2	30% Glass Fibre reinforced PEEK	Injection moulding, Extrusion		
3	Stainless Steel 316L	Moulding + conventional	Yes	Ceramic insulation + Anti stick
4	Stainless Steel 316L	Moulding + conventional	Yes	Ceramic insulation + Anti stick
5	Hardened Stainless Steel 316L	Extrusion + conventional		
6	Stainless Steel 316L	Extrusion + conventional	Yes	PTFE insulation
7	Hardened Stainless Steel 316L	Extrusion + conventional		
8	Hardened Stainless Steel 316L	Extrusion + conventional		
9	Hardened Stainless Steel 316L	Extrusion + conventional		
10	Hardened Stainless Steel 316L	Extrusion + conventional		
11	Hardened Stainless Steel 316L	Extrusion + conventional		
12	Hardened Stainless Steel 316L	Extrusion + conventional		
13	Nitinol Alloy	Extrusion + conventional	Yes	See component 14
14	PTFE or PVDF			
15	Stainless Steel 316L	Extrusion, laser cut		
16	PEEK	Extrusion + conventional		

17	<i>Stainless Steel 316L</i>	<i>Extrusion + conventional</i>	<i>Yes</i>	<i>Ceramic insulation</i>
18	<i>Stainless Steel 316L</i>	<i>Extrusion + conventional</i>		
19	<i>Stainless Steel 316L</i>	<i>Extrusion + conventional</i>	<i>Yes</i>	<i>Ceramic or polymer</i>
20	<i>Stainless Steel 316L</i>	<i>Extrusion + conventional</i>	<i>Yes</i>	<i>Ceramic insulation</i>
21	<i>Stainless Steel 316L</i>	<i>Extrusion + conventional</i>	<i>Yes</i>	<i>Ceramic insulation</i>
22	<i>Stainless Steel 316L</i>	<i>Extrusion + conventional</i>	<i>Yes</i>	<i>Ceramic insulation</i>
23	<i>Stainless Steel 316L</i>	<i>Extrusion + conventional</i>	<i>Yes</i>	<i>Ceramic insulation</i>
24	<i>Hardened Stainless Steel 316L</i>	<i>Extrusion + conventional</i>	<i>Yes</i>	<i>Ceramic insulation</i>

An overview of all connections is shown in Table 8-10. If necessary, the same connections were included in the setup of the respective FEM simulations in the next section. Connection types are recommended but not definitive. The hinge connections for the open and close mechanism and SATA mechanism are excluded.

Table 8-10, Connections between components.

<i>Connection number</i>	<i>Component A</i>	<i>Component B</i>	<i>Connection type</i>
<i>C1</i>	<i>SS base</i>	<i>PEEK base</i>	<i>Adhesive</i>
<i>C2</i>	<i>PEEK base</i>	<i>Lower jaw</i>	<i>Threaded bolt</i>
<i>C3</i>	<i>PEEK base</i>	<i>Lower jaw</i>	<i>Adhesive</i>
<i>C4 – C5</i>	<i>SS base</i>	<i>Conductor rod</i>	<i>Welding + adhesive</i>
<i>C6 – C7</i>	<i>Lower jaw</i>	<i>Conductor rod</i>	<i>Welding + adhesive</i>
<i>C8 – C9</i>	<i>PEEK base</i>	<i>Axis UJ</i>	<i>Adhesive</i>
<i>C10 – C11</i>	<i>PEEK base</i>	<i>Axis UJ insert</i>	<i>Adhesive</i>
<i>C12</i>	<i>Axis UJ insert</i>	<i>UJ axis</i>	<i>Spot welding</i>
<i>C13</i>	<i>Hinged NiTiCon</i>	<i>Nitinol rod</i>	<i>Heat shrink</i>
<i>C14</i>	<i>Nitinol rod</i>	<i>Inner axis shaft</i>	<i>Heat shrink</i>
<i>C15</i>	<i>Nitinol rod</i>	<i>PEEK overtube</i>	<i>Adhesive</i>
<i>C16</i>	<i>Tip base revised</i>	<i>Overtube</i>	<i>Welding</i>

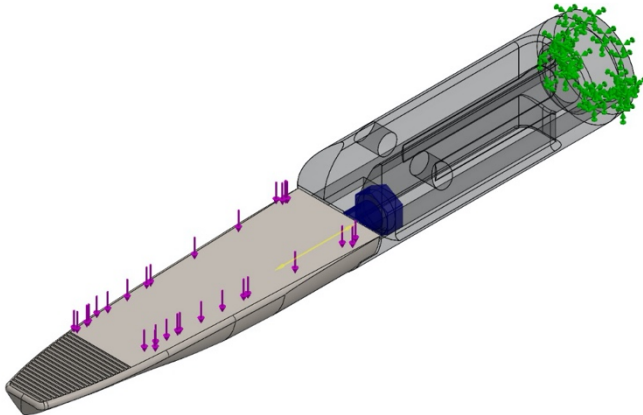
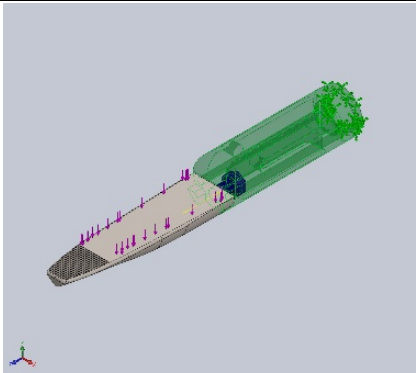
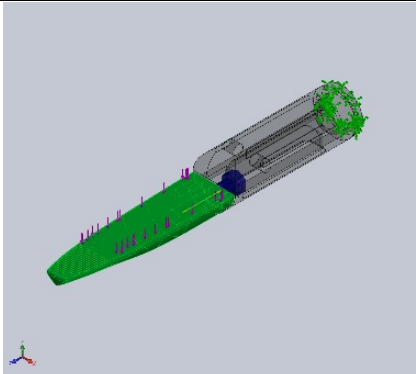
8.7 FEM – reports

FEM - 1

Simulation 1

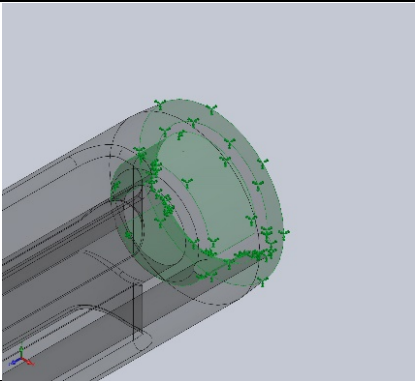
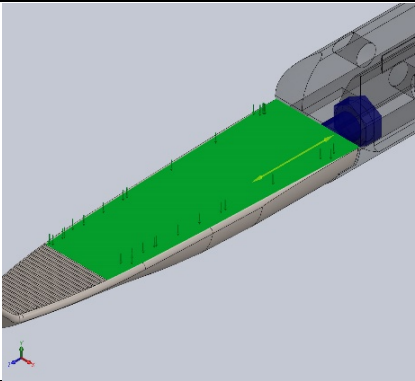
Title:	FEM-1 PEEK base and Lower jaw + Connector bolt	
Author:	Philip de Haes	
Details:	Component No: 2 3 8 Part-file name: PH_4001_v8 – PEEK base Part-file name: PH_4002_v8 – Lower Jaw Assembly CAD-file name: FEM-1 – Sep – 15 20mm jaw Study name: Static 1 Date: 15-09-2020	
Summary:	The most important questions are: Is the bolt connection between the two components strong enough to withstand the applied force. Is the PEEK component stiff enough to withstand the uniformly distributed load of 20N on the lower jaw's seal surface? The bolt connection has a safety factor of 2.8 calculated by Solidworks in the simulation. From this we can conclude that the bolt diameter, length and pre-load are sufficient. The connection between the two components is thus sufficient. The PEEK component will show stresses close to yield. A fatigue test can determine whether the PEEK component is actually strong enough. Side note, 2 more stainless steel conductor rods are slid through the PEEK part in reality, which can provide extra rigidity. It is extremely important that a reinforced PEEK is chosen, for example glass-fiber reinforced PEEK. (Carbon fiber PEEK conducts electricity and does not comply).	
Assumptions:	- Both the conductor rods (Component No:) were excluded from this simulation. - An ideal uniformly distributed compression force of 20 N is applied on the surface of the lower jaw. - The contact set(s) between the two components are set to: No penetration with friction coefficients 0.3. Although in reality the contacting surfaces will be bonded with adhesives to prevent gap forming.	
Study details:	Analysis type: Static Mesh type: Solid Mesh Solver type: FFEPlus (Solidworks default) Large displacement: off	Length/Displacement: mm Temperature: Celsius Angular velocity: Rad/sec Pressure/Stress: MPa

Model Information

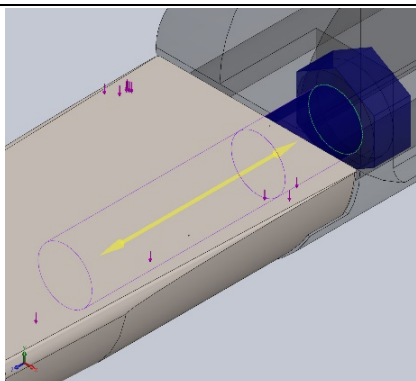
Model:	 			
Solid bodies properties:	 	Mass: 0,000282757 kg Volume: 1,8481e-07 m ³ Density: 1.529,99 kg/m ³ Weight: 0,00277101 N		
	 	Mass: 0,00106567 kg Volume: 1,32761e-07 m ³ Density: 8.027,04 kg/m ³ Weight: 0,0104436 N		
Material Properties:	Component 2 Name: KetaSpire KT-820 GF30 BK95 Model type: Linear Elastic Isotropic Default failure criterion: Unknown Yield strength: 158 N/mm² Tensile strength: 158 N/mm² Compressive strength: 169 N/mm² Elastic modulus: 10.500 N/mm² Poisson's ratio: 0,34		Component 3 Name: AISI Type 316L stainless steel Model type: Linear Elastic Isotropic Default failure criterion: Max von Mises Stress Yield strength: 170 N/mm² Tensile strength: 485 N/mm² Elastic modulus: 200.000 N/mm² Poisson's ratio: 0,265 Mass density: 8,027 g/cm³	

	Mass density: 1,53 g/cm³ Shear modulus: 318,9 N/mm²	Shear modulus: 82.000 N/mm² Thermal expansion coefficient: 1,65e-05 /Kelvin

Loads and Fixtures

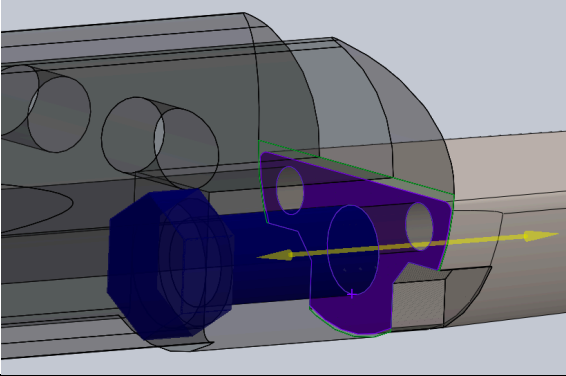
Fixture:						Entities: 4 face(s) Type: Fixed Geometry
Resultant forces:	Components	X	Y	Z	Resultant	
	Reaction Force (N)	-2,08616e-07	20	-1,48416e-05	20	
	Reaction Moment (N*m)	0	0	0	1e-33	
Load:						Entities: 1 face(s) Type: Apply normal force Value: 20 N

Connector Definitions

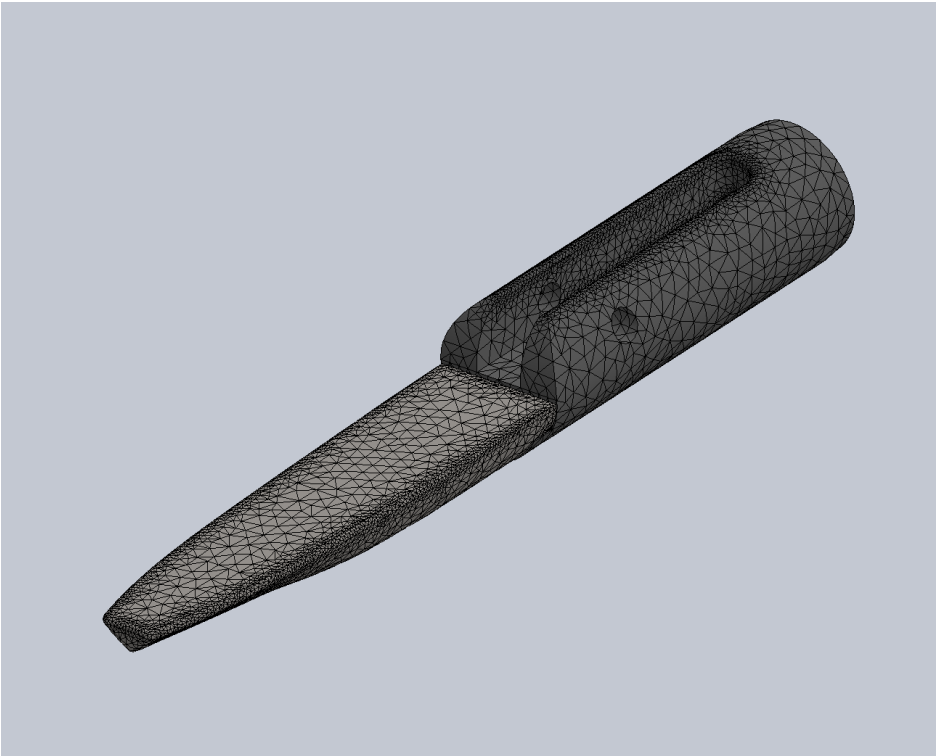
Connector details:						Entities: Type: Head diameter: Nominal shank diameter: Preload (Axial): Young's modulus: Poisson's ratio: 1 edge(s), 2 face(s) Bolt(Head/Nut diameter)(Counterbore screw) 2 mm 1,4 mm 200 2e+11 0,265	Strength details: Bolt Check: OK Calculated FoS: 2,82677 Desired FoS: 2
	Type	X	Y	Z	Resultant		

Connector Forces:	Axial Force (N)	0	0	-200	200
	Shear Force (N)	0,00082981	-0,00098098	0	0,0012849
	Bending moment (N*m)	-3,8716e-06	2,0514e-06	0	4,3815e-06

Contact information

Contact set:					Type: No Penetration contact pair Entities: 2 face(s) Friction Value: 0,3 Advanced: Node to surface
	<i>Entities: All remaining contact faces are set to No Penetration</i>				
Contact/Friction force:	Components	X	Y	Z	Resultant
	Contact Force (N)	0	0	-7,9244	7,9244
	Friction Force (N)	-0,035392	-0,47293	5,9985E-19	0,47425

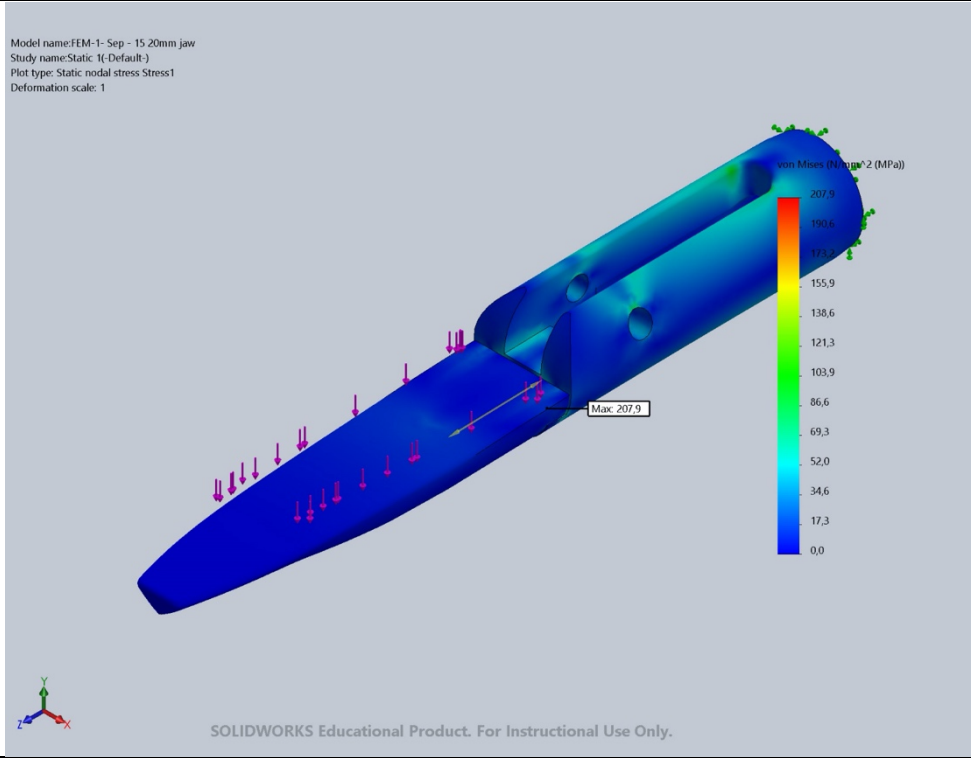
Mesh Details

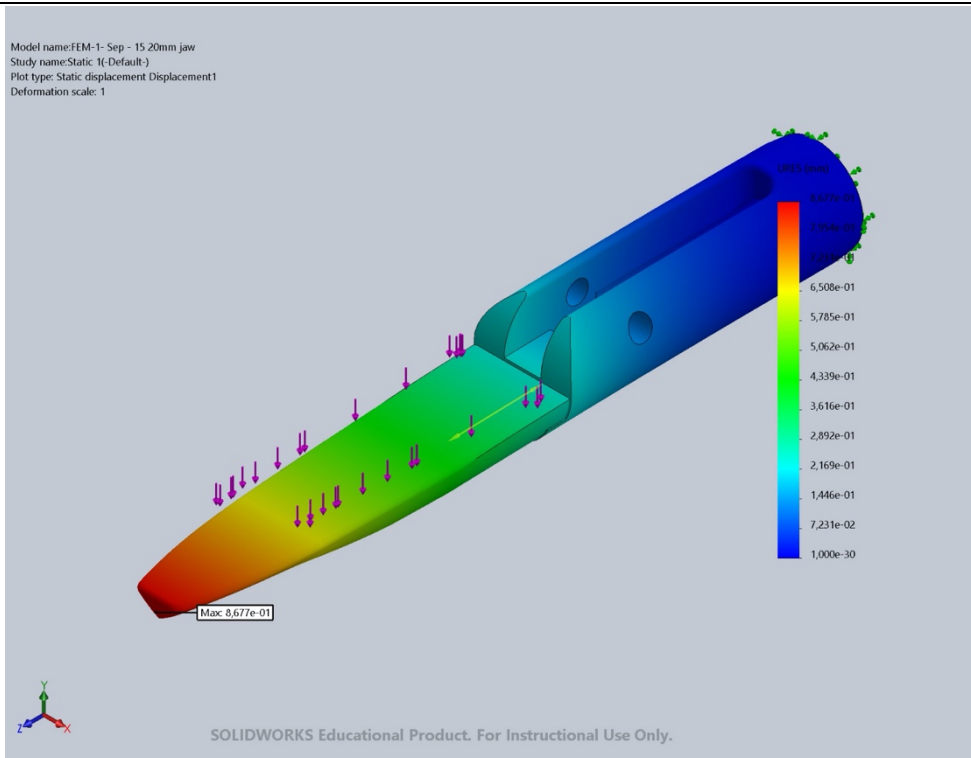
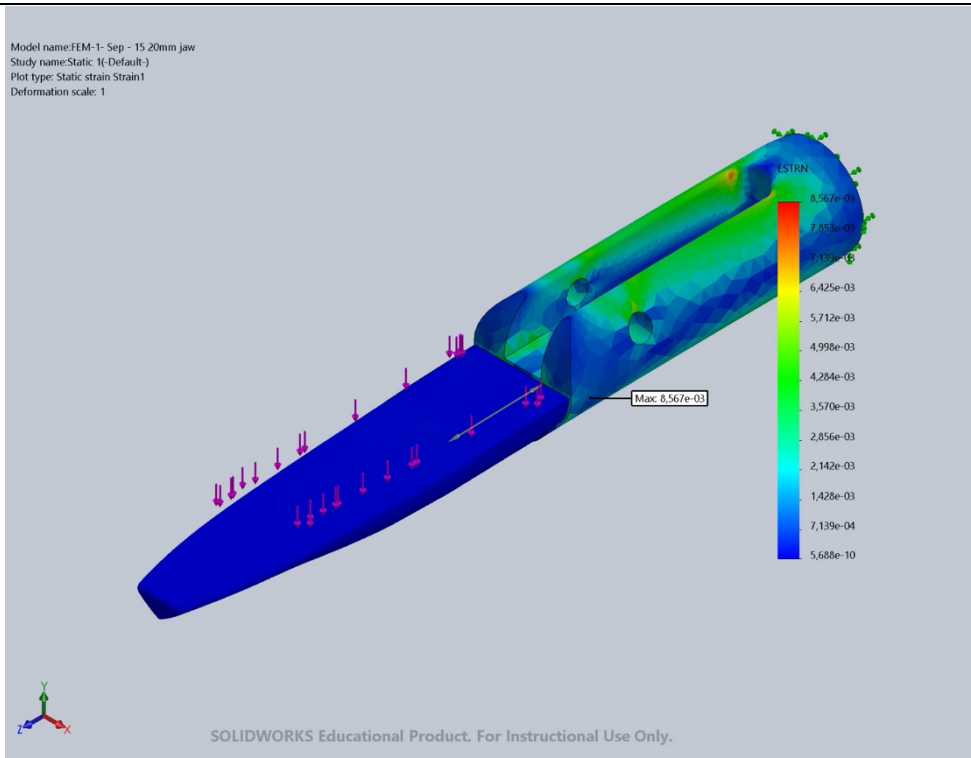
Mesh:				
Mesh information:	Mesh type: Solid mesh Mesher used: Curvature-based mesh Jacobian points: 4 Max element size: 0,680496mm Min element size: 0,136099 mm Mesh Quality: High Total nodes: 103132 Total elements: 63652			Entities: 1 face(s) Units: mm Size: 0,160866 Ratio: 0,160866
Mesh control:				

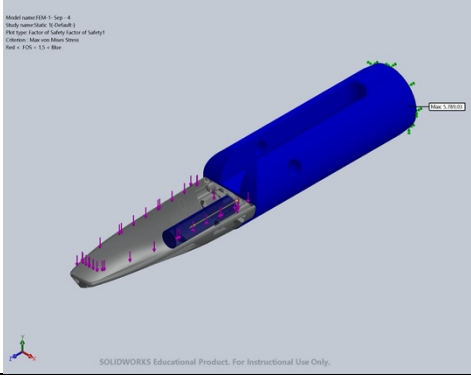
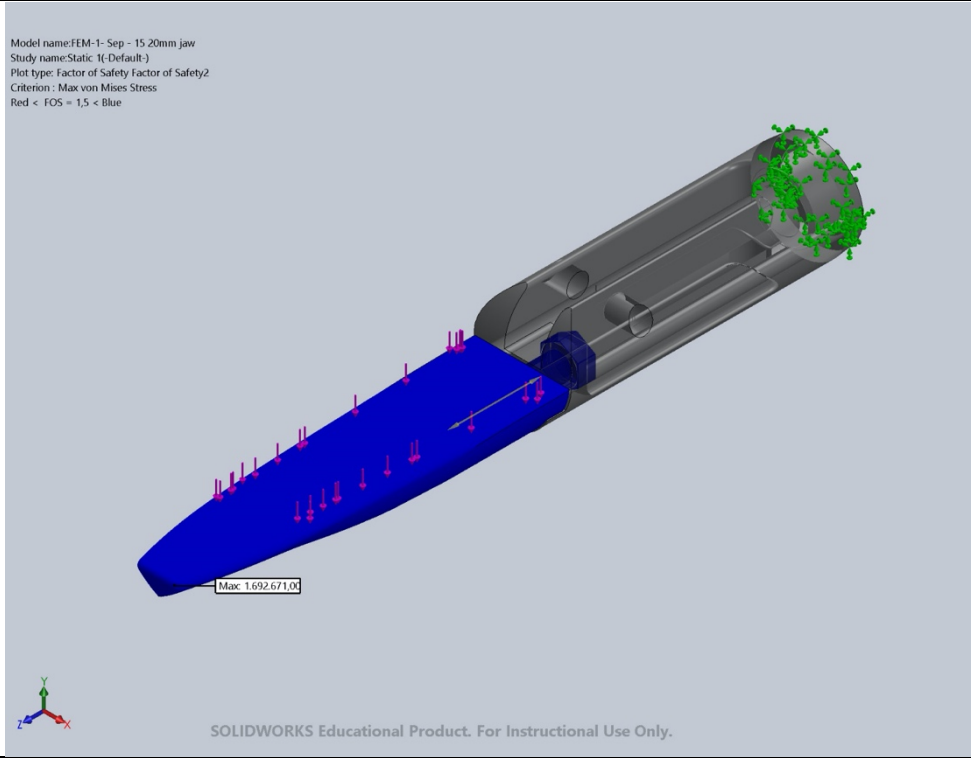
Resultant Forces

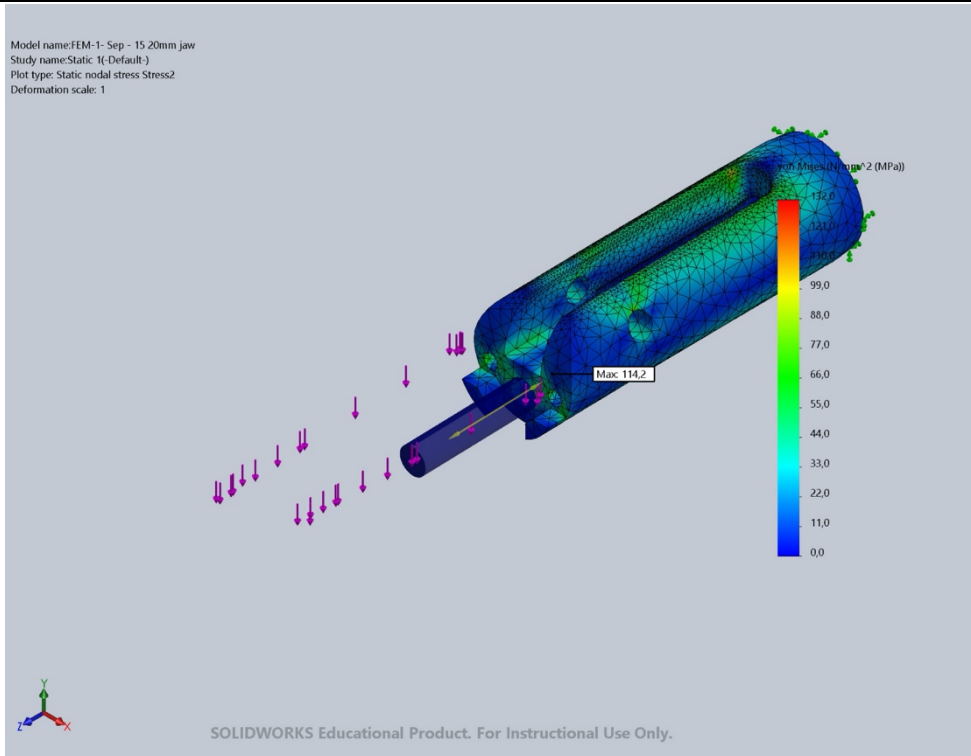
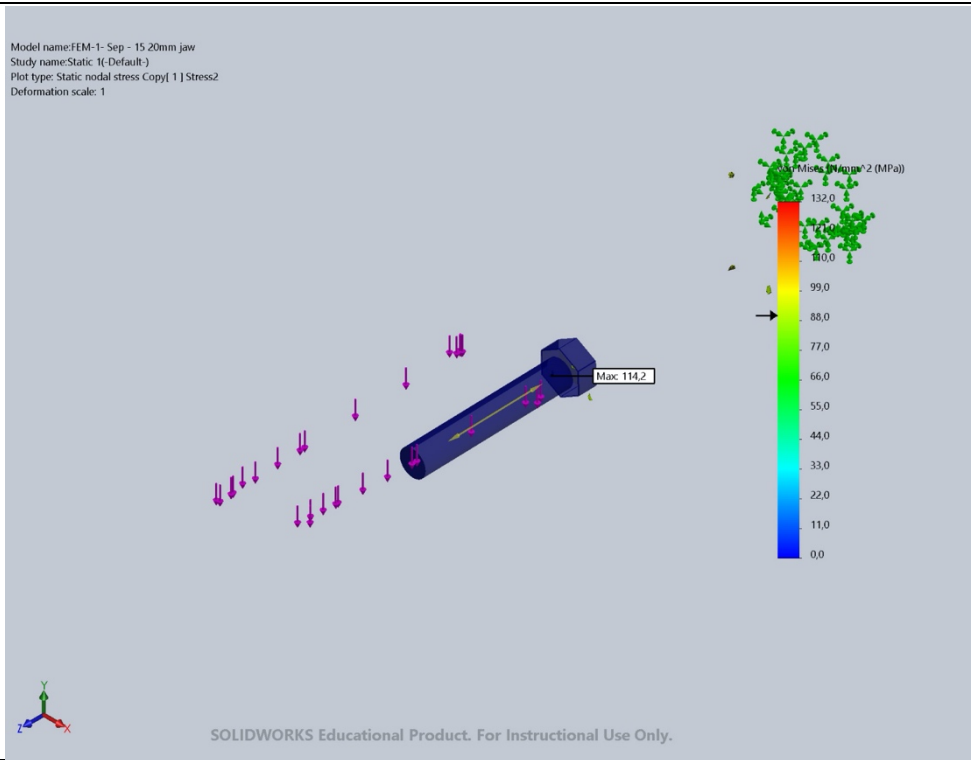
Reaction forces:	Selection set	Units	Sum Xs	Sum Y	Sum Z	Resultant
	Entire model	N	-2,08616e-07	20	-1,48416e-05	20

Study Results

VON: von Mises Stress	Min: 0,0 N/mm ² (MPa) Node: 76741	Max: 207,9 N/mm ² (MPa) Node: 74403
Picture(s)		
Discussion:	The highest stresses are above yield, however they are considered as ‘stress concentrations’ or ‘stress singularities’ and most likely do not cause the materials to yield. They are pointed out and discussed in the sections below.	
URES: Resultant Displacement	Min: 0,000e+00 mm Node: 25	Max: 8,677e-01 mm Node: 73577

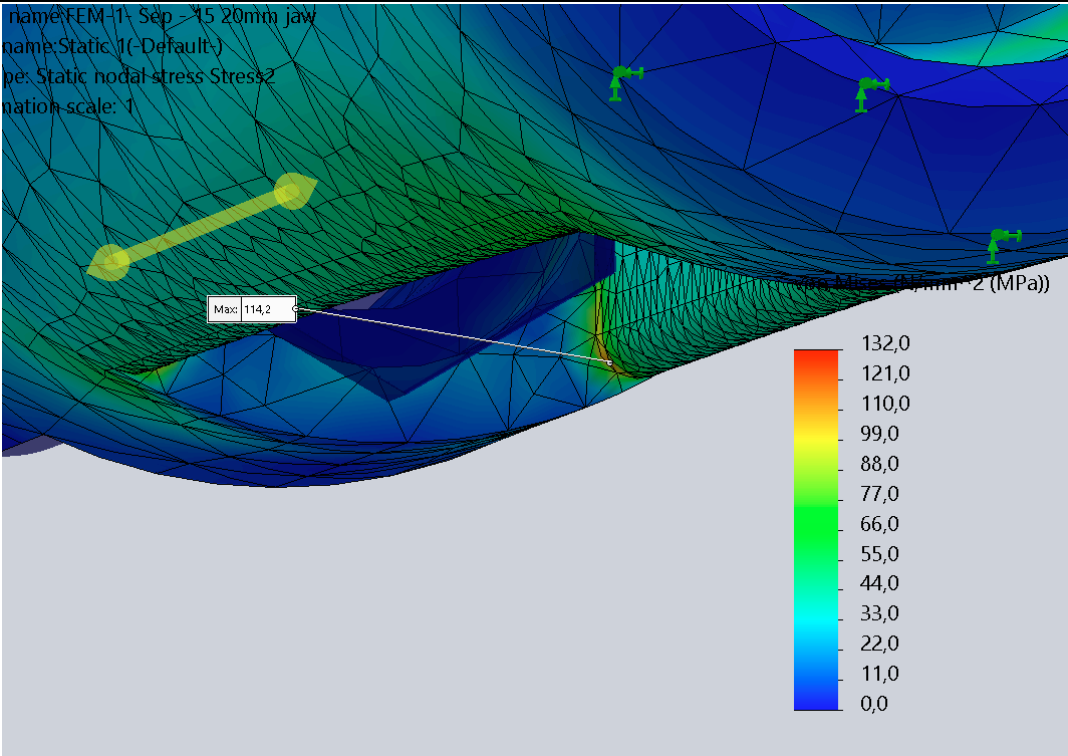
Picture(s)					
Discussion:	Max displacement is acceptable. This is considered as first indication that the model does not yield due to the high stresses.				
ESTRN: Equivalent Strain	<table border="0"> <tr> <td>Min: 5,688e-10</td><td>Max: 8,567e-03</td></tr> <tr> <td>Element: 57343</td><td>Element: 31556</td></tr> </table>	Min: 5,688e-10	Max: 8,567e-03	Element: 57343	Element: 31556
Min: 5,688e-10	Max: 8,567e-03				
Element: 57343	Element: 31556				
Picture(s)					
Discussion:	Max strain is very low.				
Factor of Safety	<table border="0"> <tr> <td>Min: 1,38</td><td>Max: 3.077,96</td></tr> <tr> <td>Node: 26579</td><td>Node: 11512</td></tr> </table>	Min: 1,38	Max: 3.077,96	Node: 26579	Node: 11512
Min: 1,38	Max: 3.077,96				
Node: 26579	Node: 11512				

Picture(s)		
Discussion:	Red areas: FoS < 1.5. Sharp edges consisting of stress concentrations cause the safety factor to be below 1.5 in these areas.	
Factor of Safety	Min: 0,82 Node: 74403	Max: 1.692.671,00 Node: 76741
Picture(s)		
Discussion:	Red areas: FoS < 1.5. Due to high stress concentrations the safety factor cannot be trusted. Stress concentrations are discussed below.	
VON: von Mises Stress Component:	Min: 0,0 N/mm ² (MPa) Node: 76741	Max: 114,2 N/mm ² (MPa) Node: /

Picture(s)	 Model name:FEM-1- Sep - 15 20mm jaw Study name:Static 1(-Default-) Plot type: Static nodal stress Stress2 Deformation scale: 1 Max: 114,2 Von Mises Stress (MPa) 114,2 99,0 88,0 77,0 66,0 55,0 44,0 33,0 22,0 11,0 0,0 SOLIDWORKS Educational Product. For Instructional Use Only.
Discussion:	Maximum stress is 114.2 MPa. The safety factor in this stress areas is below 1.5, however the stresses are still below yield strength.
	 Model name:FEM-1- Sep - 15 20mm jaw Study name:Static 1(-Default-) Plot type: Static nodal stress Copy(1) Stress2 Deformation scale: 1 Max: 114,2 Von Mises Stress (MPa) 132,0 99,0 88,0 77,0 66,0 55,0 44,0 33,0 22,0 11,0 0,0 SOLIDWORKS Educational Product. For Instructional Use Only.
Discussion:	ISO clipping plot shows stress area >90 MPa. They indicate
VON: von Mises Stress Component:	Min: 0,0 N/mm² (MPa) Node: 76741 Max: 207,9 N/mm² (MPa) Node: 74403

Picture(s)	
Discussion:	
Discussion:	ISO clipping plot shows stress area >113MPa. As can be seen, small parts of the top layer of elements show high stress concentrations.

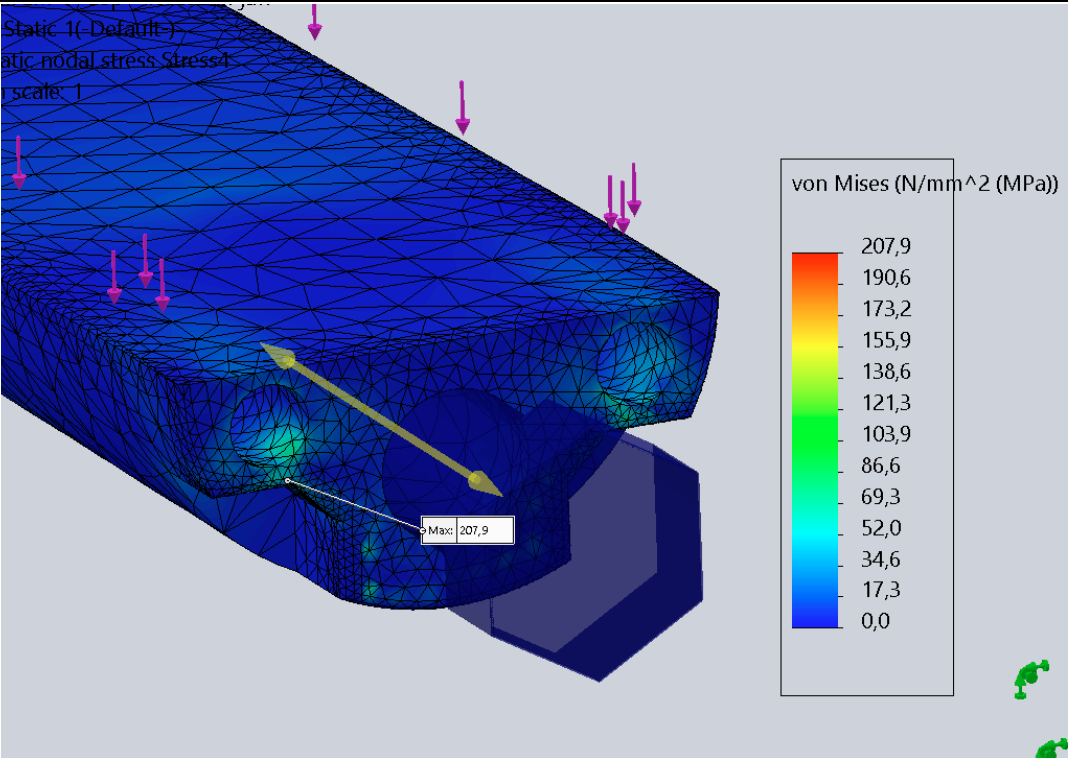
Additional information



Discussion:

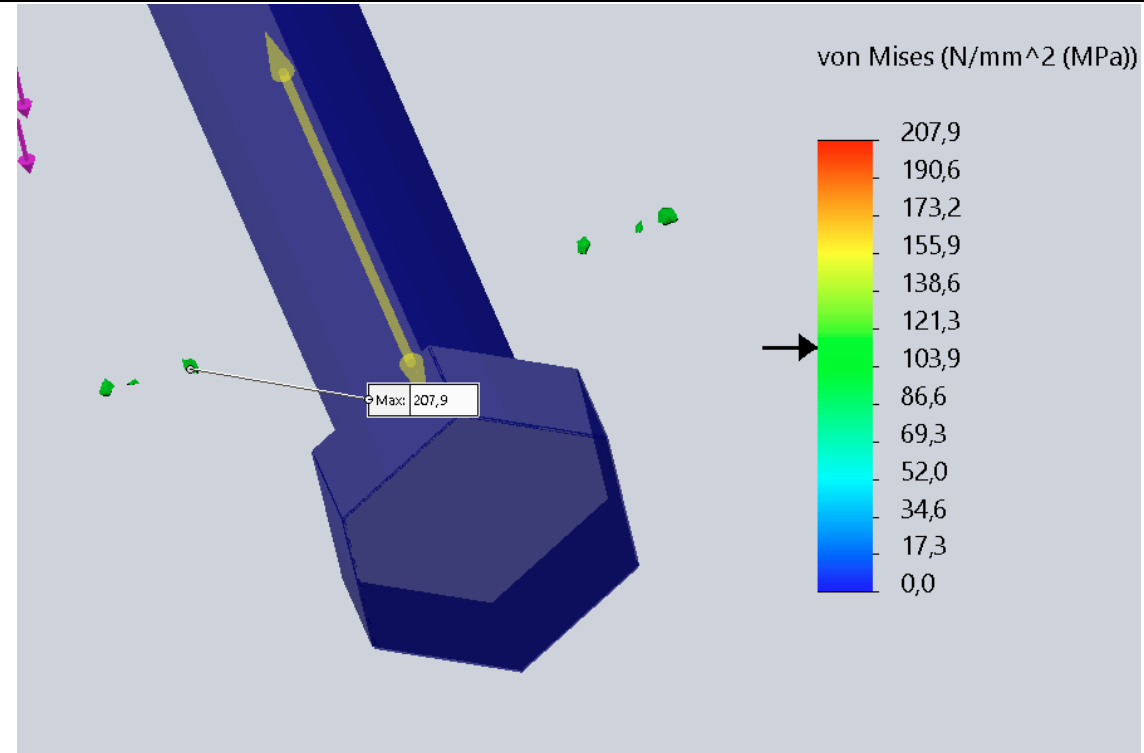
Highest stress occurs near all 4 of these 'sharp' edges in the PEEK base component.

Additional information



Discussion:

Close-up of the stress areas above yield strength.

Additional information	 von Mises (N/mm² (MPa)) 207,9 190,6 173,2 155,9 138,6 121,3 103,9 86,6 69,3 52,0 34,6 17,3 0,0 Max: 207,9
Discussion:	ISO plot shows that only the green coloured (tiny) areas show high stresses. It is very unlikely that these will cause the component to fail due to fatigue.

Study Conclusion

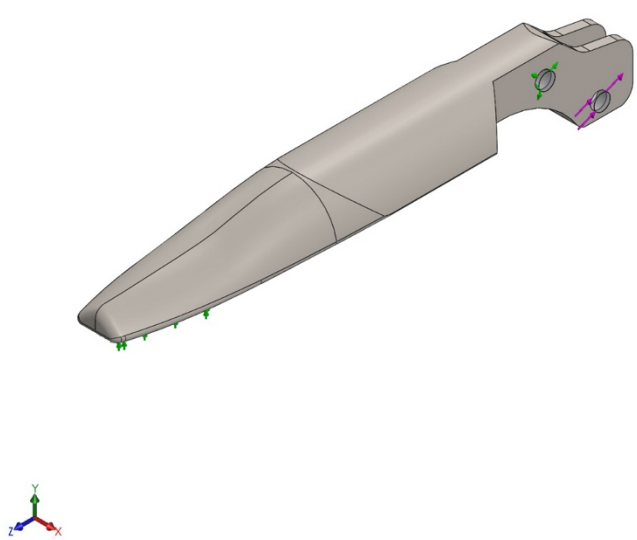
Conclusion:	The stress at some distance from the stress concentrations are trusted, i.e. stresses in the second row of elements behind the stress concentrations. In this case, the stresses are acceptable for the lower jaw component. This is also underlined by the displacement and strain plots. Stress concentrations in the lower jaw component are unlikely to cause fatigue. Fatigue tests must be conducted to determine the lifespan of the PEEK component. A glass fiber reinforced PEEK material must be chosen. However, it must also be considered that in reality the PEEK component will be reinforced by two metal conductor rods. The bolt connection has a FoS of 2.8 and appears to be a viable solution for connecting the two components. Based on FEM-1 simulation, a uniformly distributed pressure of 20N can be applied to the Lower jaw without damaging the connection between the Lower jaw and PEEK base.
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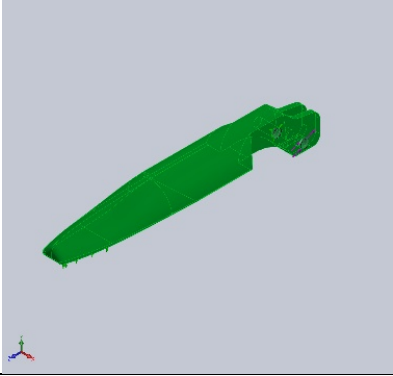
FEM - 2

Simulation 2

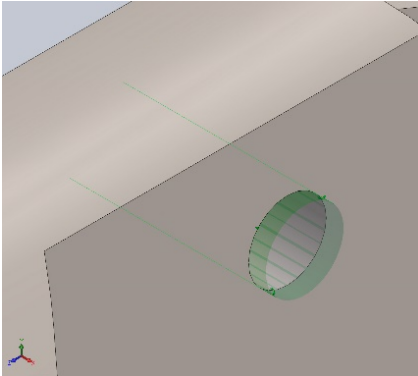
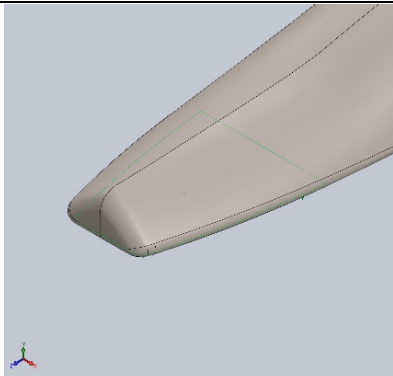
Title:	FEM-2 Upper jaw	
Author:	Philip de Haes	
Details:	Component No: 4 Part-file name: PH_4003_v8 – Upper Jaw CAD-file name: FEM-2 - Sep – 15 – 20mm Jaw Study name: Static 2 L1 = 9_95 mm Date: 15-09-2020	
Summary:	This simulation is based on the maximum tensile force (55 N) that will be applied to this component, regarding the required sealing pressure. Higher stresses occur surrounding the hinge axis holes, where the connector component is attached. These stresses are occurring in the first layer of elements and do not radiate deeper into the material. Future fatigue tests should be done to evaluate the stresses near the arched surface.	
Assumptions:	For this simulation it is assumed that the instrument jaw is in a fully closed configuration. Therefore a constraint in y-direction (i.e. normal to part of the sealing surface of the Upper jaw) has been applied (Slider / Roller). Two rigid hinges axes are applied. The upper rigid hinge axis is constraint with a ‘fixed hinge’, that is the jaw’s axis of rotation. The lower rigid hinge axis has a force (55 N) applied to its face.	
Study details:	Analysis type: Static Mesh type: Mixed Mesh Solver type: FFEPlus (Solidworks default) Large displacement: off	Length/Displacement: mm Temperature: Celsius Angular velocity: Rad/sec Pressure/Stress: MPa

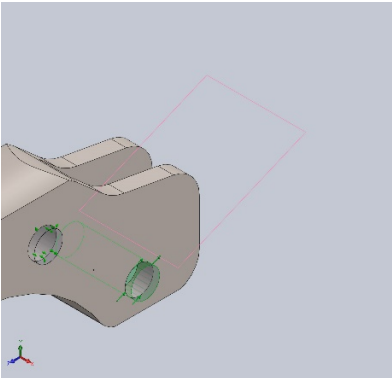
Model Information

Model:	
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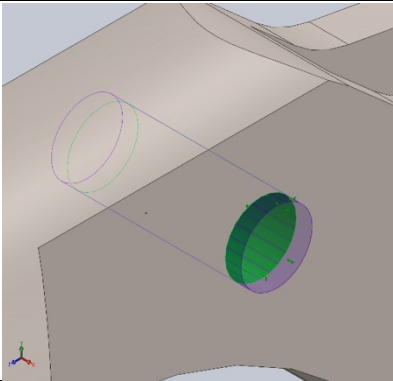
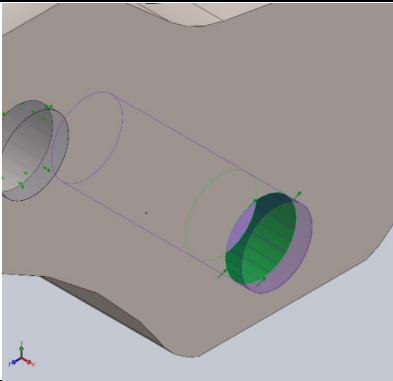
Solid bodies properties:		Mass: 0,00144055 kg Volume: 1,79458e-07 m³ Density: 8.027,24 kg/m³ Weight: 0,0141174 N
Material Properties:	Name: AISI Type 316L stainless steel Model type: Linear Elastic Isotropic Default failure criterion: Max von Mises Stress Yield strength: 170 N/mm² Tensile strength: 485 N/mm² Elastic modulus: 200.000 N/mm² Poisson's ratio: 0,265 Mass density: 8,027 g/cm³ Shear modulus: 82.000 N/mm² Thermal expansion coefficient: 1,65e-05 /Kelvin	

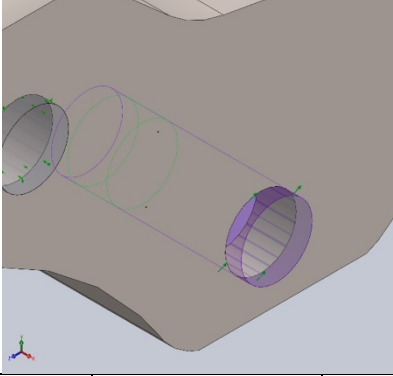
Loads and Fixtures

Fixture:			Entities: 1 face(s) Type: Fixed Hinge		
Resultant forces:	Components	X	Y	Z	Resultant
	Reaction Force (N)	0	0	0	1e-33
	Reaction Moment (N*m)	0	0	0	1e-33
Fixture:			Entities: 1 face(s) Type: Roller/Slider		
Resultant forces:	Components	X	Y	Z	Resultant
	Reaction Force (N)	2.11752e-06	12.3828	-6.7683e-06	12.3828

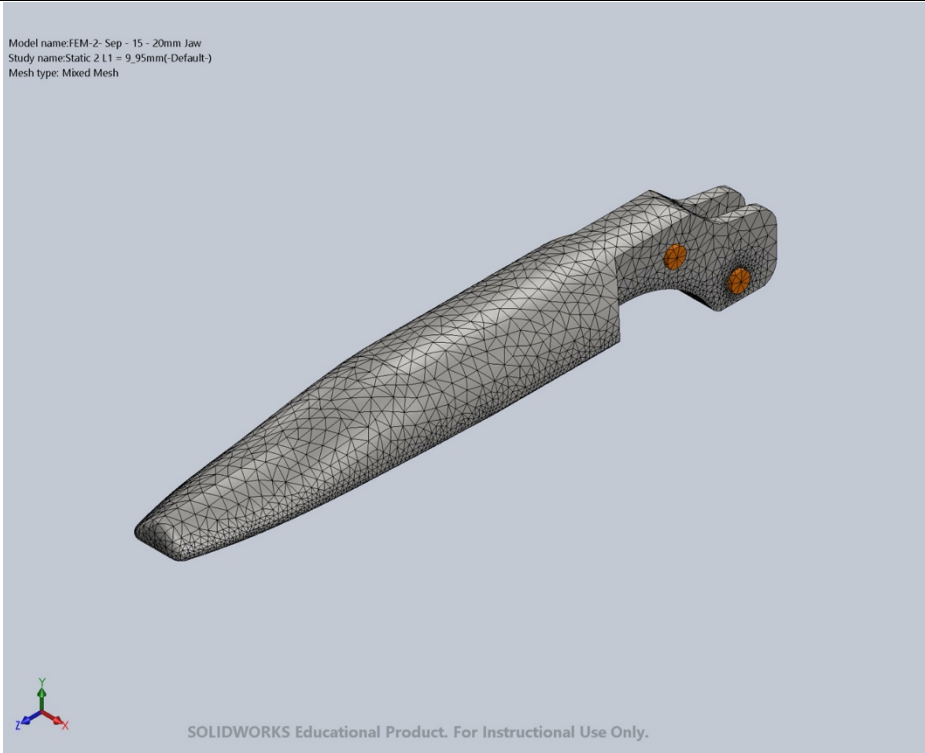
	Reaction Moment (N*m)	0	0	0	1e-33
Load:	 Entities: 1 face(s), 1 plane(s) Reference: Plane2 Type: Apply force Values: 55; ---; --- N Moments: ---; ---; --- N.m				

Contact information

Contact set 1:	 Type: No Penetration contact pair Entities: 2 face(s) Advanced: Node to surface				
Contact/Friction force:	Components	X	Y	Z	Resultant
	Contact Force (N)	2,0708E-17	1,6889E-14	5,2851E-13	5,2878E-13
Contact set 2:	 Type: No Penetration contact pair Entities: 2 face(s) Advanced: Node to surface				
Contact/Friction force:	Components	X	Y	Z	Resultant
	Contact Force (N)	0,0062712	-10,652	25,357	27,503

Contact set 2:					Type: No Penetration contact pair Entities: 2 face(s) Advanced: Node to surface
Contact/Friction force:	Components	X	Y	Z	Resultant
	Contact Force (N)	-0,0062678	-10,658	25,346	27,496

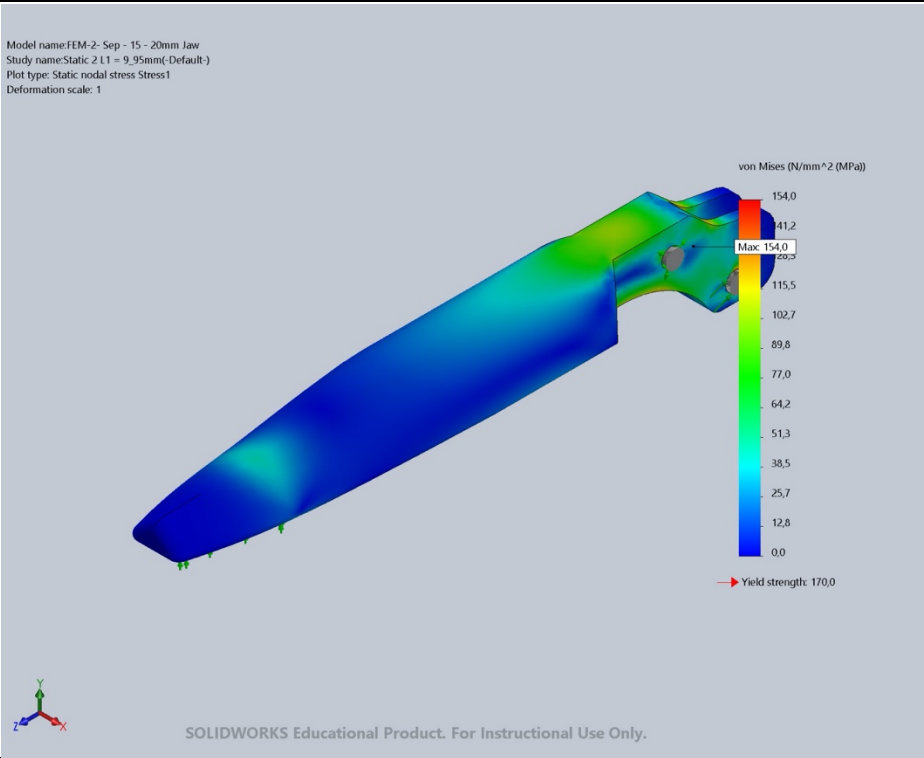
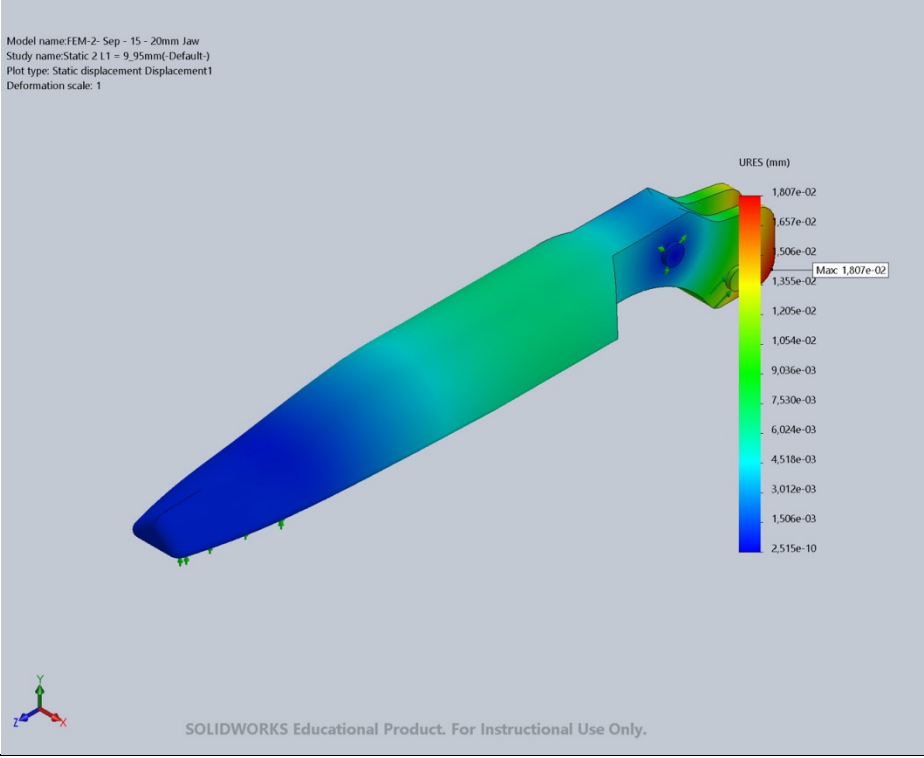
Mesh Details

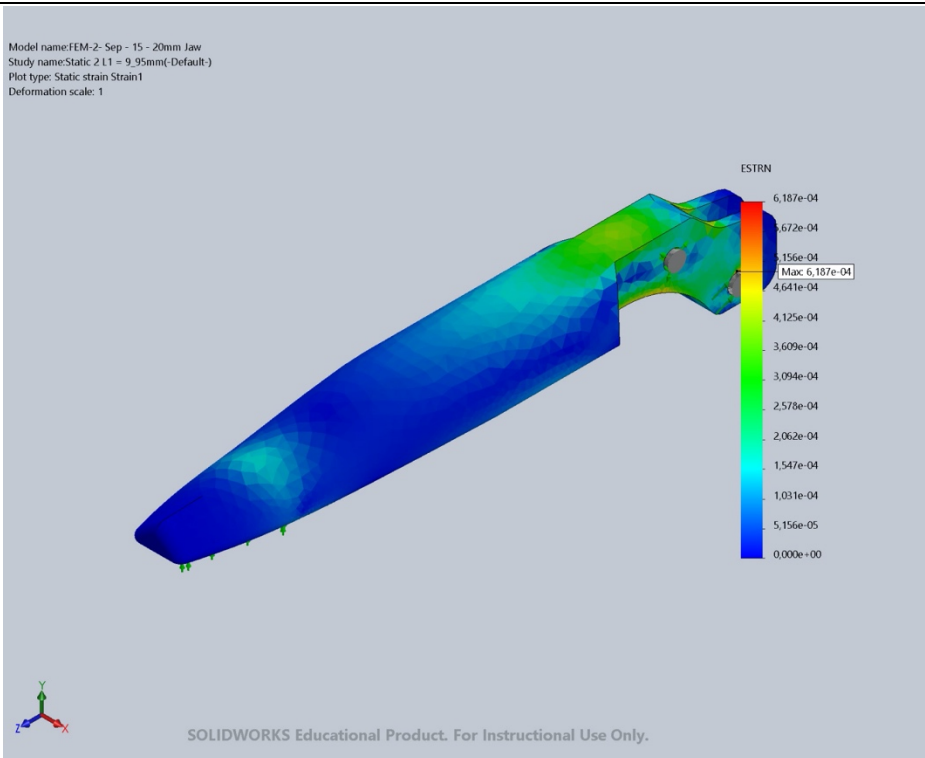
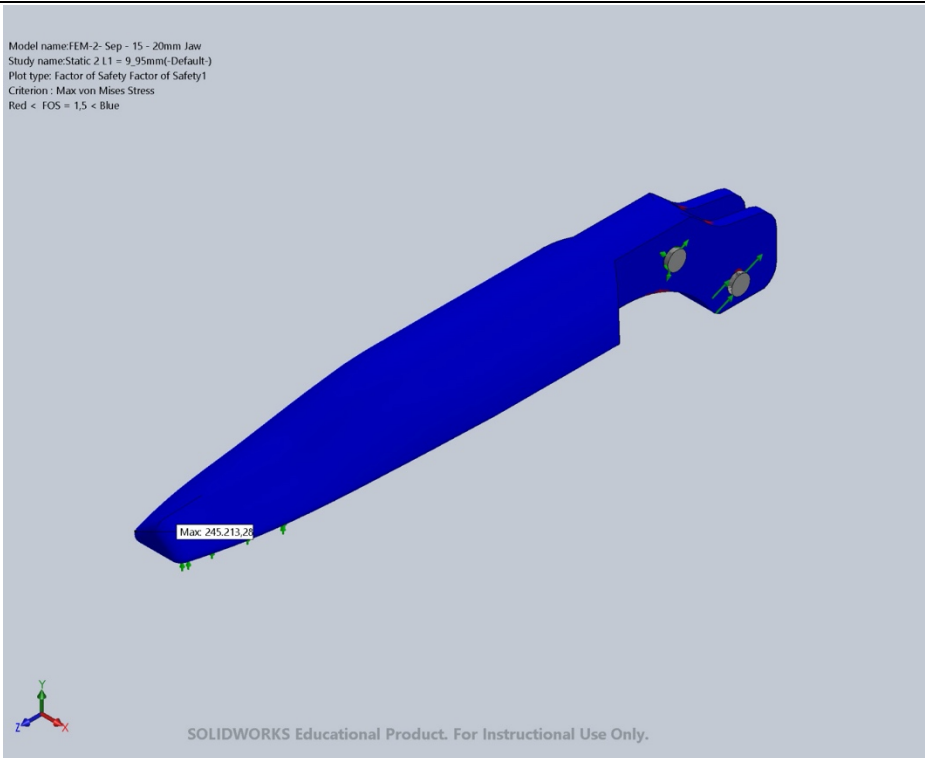
Mesh information:	Model name: FEM-2_Sep - 15 - 20mm Jaw Study name: Static 2 L1 = 9.95mm(-Default-) Mesh type: Mixed Mesh  SOLIDWORKS Educational Product. For Instructional Use Only.	
Mesh information:	Mesh type: Mixed mesh Mesher used: Curvature-based mesh Jacobian points: 4 Max element size: 0,564312 mm Min element size: 0,112862 mm Mesh Quality: High Total nodes: 65345 Total elements: 40553	Entities: 3 face(s) Units: mm Size: 0,141086 Ratio: 0,141086
Mesh Control:		

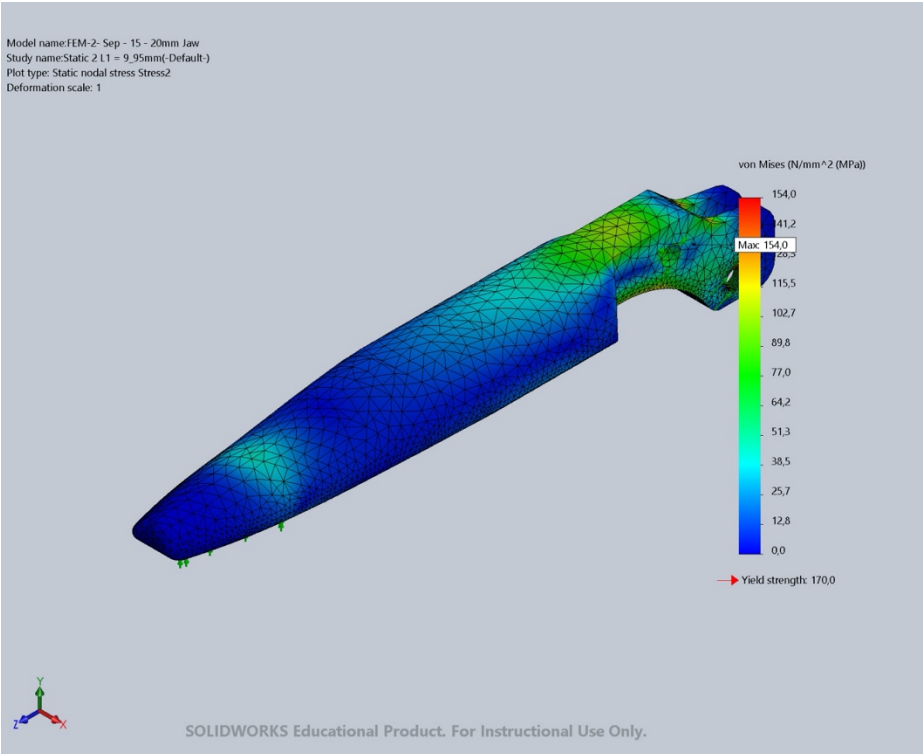
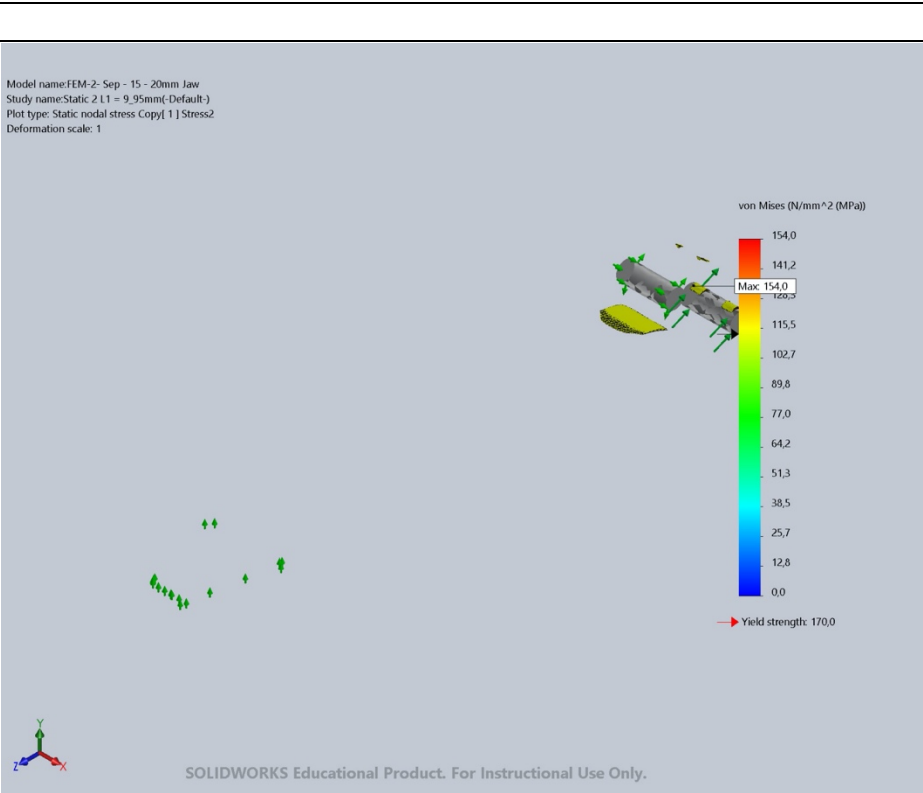
Resultant Forces

Reaction forces:	Selection set	Units	Sum X	Sum Y	Sum Z	Resultant
	Entire model	N	2,11752e-06	12,3828	-6,7683e-06	12,3828
Incorrect values due to use of rigid bodies in simulation. The force is applied on one of the rigid bodies.						

Study Results

VON: von Mises Stress	Min: 0,0 N/mm ² (MPa) Node: 64706	Max: 154,0 N/mm ² (MPa) Node: 437
Picture(s)	Model name:FEM-2- Sep - 15 - 20mm Jaw Study name:Static 2 L1 = 9,95mm(- Default-) Plot type: Static nodal stress Stress1 Deformation scale: 1 	
Discussion:		
URES: Resultant Displacement	Min: 2,515e-10 mm Node: 65111	Max: 1,807e-02 mm Node: 450
Picture(s)	Model name:FEM-2- Sep - 15 - 20mm Jaw Study name:Static 2 L1 = 9,95mm(- Default-) Plot type: Static displacement Displacement1 Deformation scale: 1 	
Discussion:	Max displacement is acceptable.	
ESTRN: Equivalent Strain	Min: 0,000e+00 Element: 40236	Max: 6,187e-04 Element: 11945

Picture(s)	 Model name:FEM-2- Sep - 15 - 20mm Jaw Study name:Static 2 L1 = 9.95mm(- Default-) Plot type: Static strain Strain1 Deformation scale: 1 ESTRN 6.187e-04 6.672e-04 3.156e-04 Max 6.187e-04 4.641e-04 4.125e-04 3.609e-04 3.094e-04 2.578e-04 2.062e-04 1.547e-04 1.031e-04 5.156e-05 0.000e+00 SOLIDWORKS Educational Product. For Instructional Use Only.
Discussion:	Negligible strain. Indication that the model probably doesn't yield.
Factor of Safety	Min: 1,10 Node: 437 Max: 245.213,28 Node: 24883
Picture(s)	 Model name:FEM-2- Sep - 15 - 20mm Jaw Study name:Static 2 L1 = 9.95mm(- Default-) Plot type: Factor of Safety Factor of Safety1 Criterion : Max von Mises Stress Red < FOS = 1.5 < Blue Max: 245.213,28 SOLIDWORKS Educational Product. For Instructional Use Only.
Discussion:	Red areas: FoS <1.5. Critical areas are illustrated in red.

Additional information	 Model name: FEM-2- Sep - 15 - 20mm Jaw Study name: Static 2 L1 - 9.95mm(- Default-) Plot type: Static nodal stress Stress2 Deformation scale: 1 von Mises (N/mm² (MPa)) Max: 154.0 Yield strength: 170.0 SOLIDWORKS Educational Product. For Instructional Use Only.
Discussion:	In this figure the elements and their stresses are illustrated. High stresses occurred around the holes in the first layer of elements and below the arch. Stress levels are just 15 MPa below yield strength. Fatigue test should be done.
Additional information	 Model name: FEM-2- Sep - 15 - 20mm Jaw Study name: Static 2 L1 - 9.95mm(- Default-) Plot type: Static nodal stress Copy[1] Stress2 Deformation scale: 1 von Mises (N/mm² (MPa)) Max: 154.0 Yield strength: 170.0 SOLIDWORKS Educational Product. For Instructional Use Only.
Discussion:	ISO clipping plot shows stress area >113 MPa, thus areas with a safety factor <1.5. Indicates critical stresses occur only around the holes near the surface.

Study Conclusion

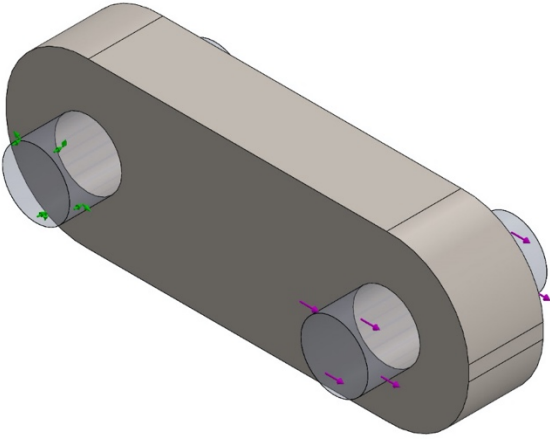
Conclusion:	Higher stresses occur surrounding the hinge axis holes, where the connector component is attached. These stresses are occurring in the first layer of elements and do not radiate deeper into the material. Future fatigue tests should be done to evaluate the stresses near the arched surface.
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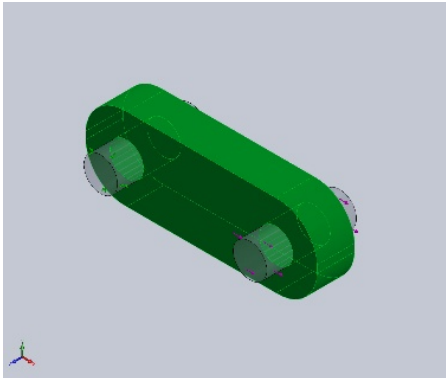
FEM - 3

Simulation 3

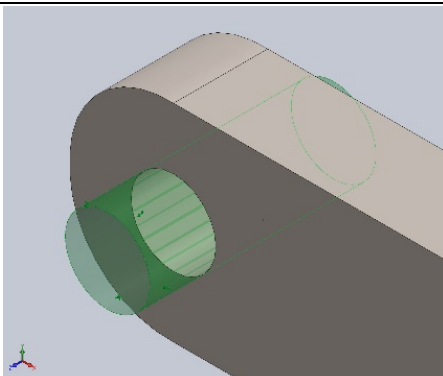
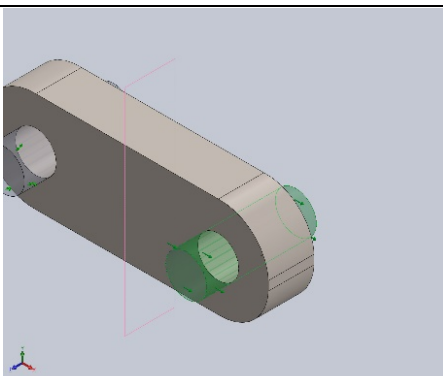
Title:	FEM-3 Connector	
Author:	Philip de Haes	
Details:	Component No: 5 Part-file name: PH_4004_v8 – Connector CAD-file name: FEM -3 – Sep – 15 Study name: Static 2 L1 = 9_95 mm Date: 15-09-2020	
Summary:	This simulation is based on the maximum tensile force (55N) that will be applied to this component, regarding the required sealing pressure. From this simulation it can be concluded that this component has a correct design since the safety factor of > 1.5 applies to most of the component.	
Assumptions:	The Connector component links the Upper jaw (4) with the NiTiCon (6) component and has two hinge connections. On both ends a rigid hinge axis is placed. One rigid axis is constraint with a ‘fixed hinge’, the other rigid axis has a force (55N) applied.	
Study details:	Analysis type: Static Mesh type: Mixed Mesh Solver type: FFEPlus (Solidworks default) Large displacement: off	Length/Displacement: mm Temperature: Celsius Angular velocity: Rad/sec Pressure/Stress: MPa

Model Information

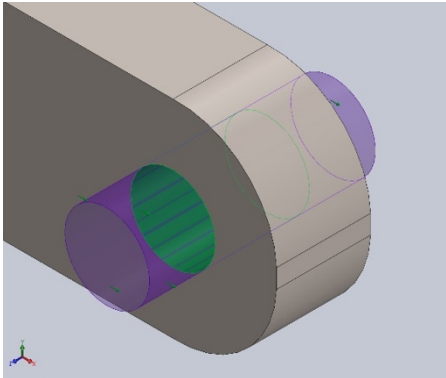
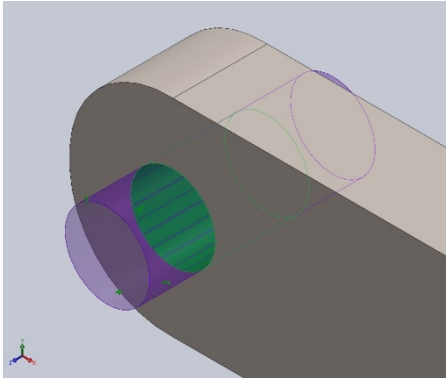
Model:	
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Solid bodies properties:		Mass: 9,17415e-05 kg Volume: 1,14291e-08 m³ Density: 8.027 kg/m³ Weight: 0,000899067 N
Material Properties:	Name: AISI Type 316L stainless steel Model type: Linear Elastic Isotropic Default failure criterion: Max von Mises Stress Yield strength: 170 N/mm² Tensile strength: 485 N/mm² Elastic modulus: 200.000 N/mm² Poisson's ratio: 0,265 Mass density: 8,027 g/cm³ Shear modulus: 82.000 N/mm² Thermal expansion coefficient: 1,65e-05 /Kelvin	

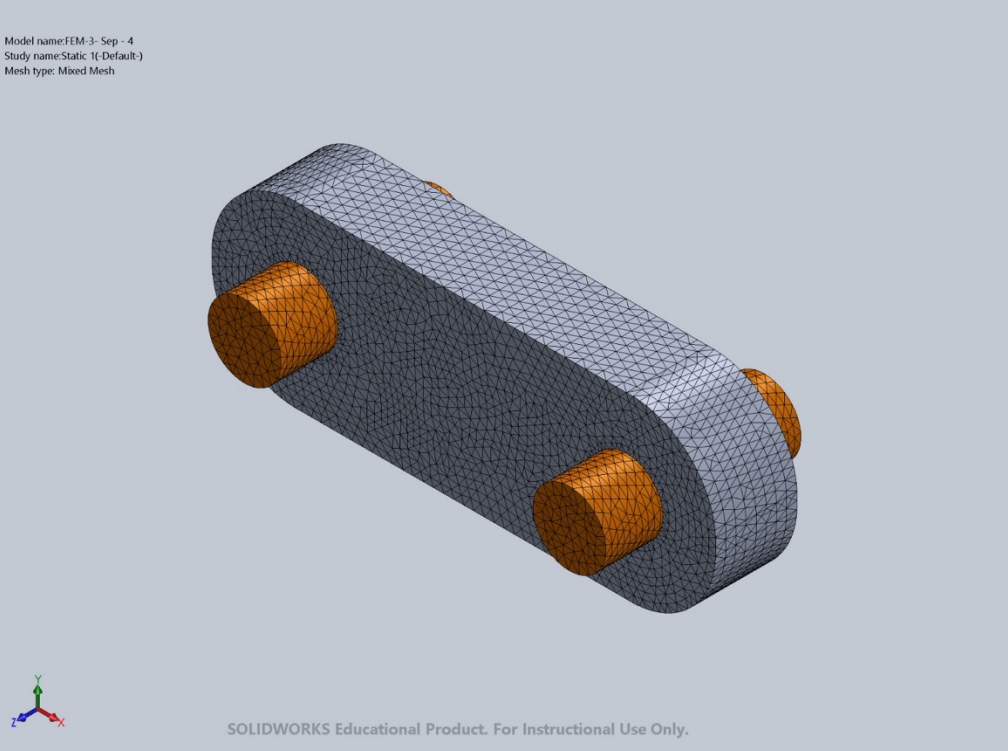
Loads and Fixtures

Fixture:			Entities: 1 face(s) Type: Fixed Hinge		
Resultant forces:	Components	X	Y	Z	Resultant
	Reaction Force (N)	0	0	0	1e-33
	Reaction Moment (N*m)	0	0	0	1e-33
Load:			Entities: 1 face(s), 1 plane(s) Reference: Right Plane Type: Apply force Values: ---; ---; 55 N Moments: ---; ---; --- N.m <i>The force is directed along the longitudinal axis of the connector component.</i>		

Contact information

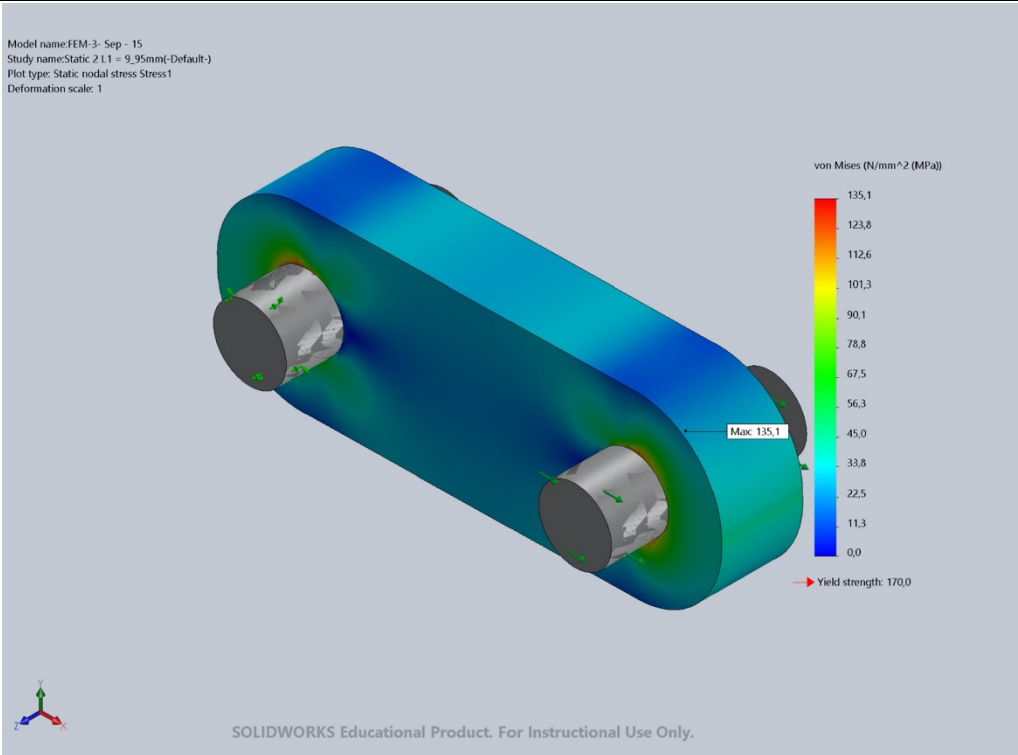
Contact set 1:					Type: No Penetration contact pair Entities: 2 face(s) Advanced: Node to surface
Contact/Friction force:	Components	X	Y	Z	Resultant
	Contact Force (N)	-1,7173E-13	-6,2284E-14	6,7233E-19	1,8268E-13
Contact set 2:					Type: No Penetration contact pair Entities: 2 face(s) Advanced: Node to surface
Contact/Friction force:	Components	X	Y	Z	Resultant
	Contact Force (N)	6,9153E-13	-4,4274E-14	-1,0057E-18	6,9295E-13

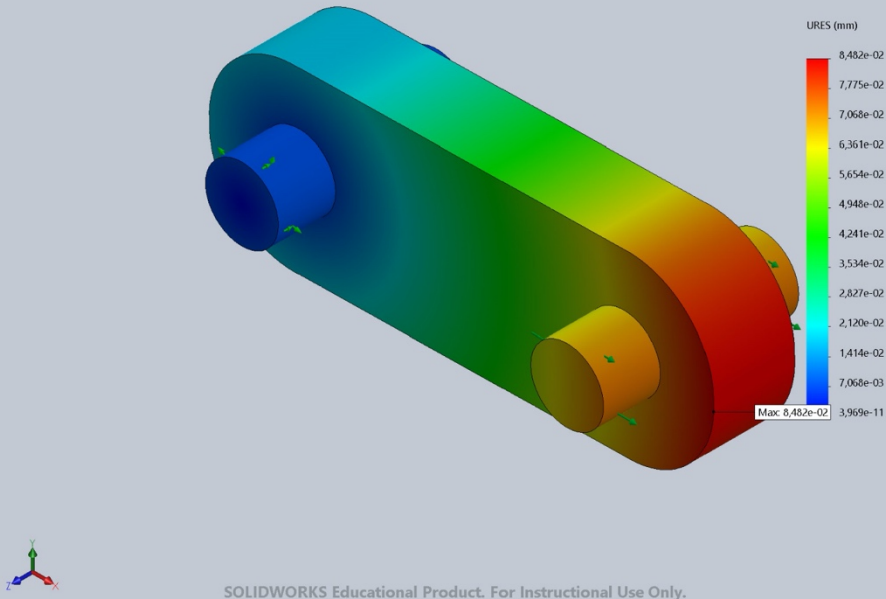
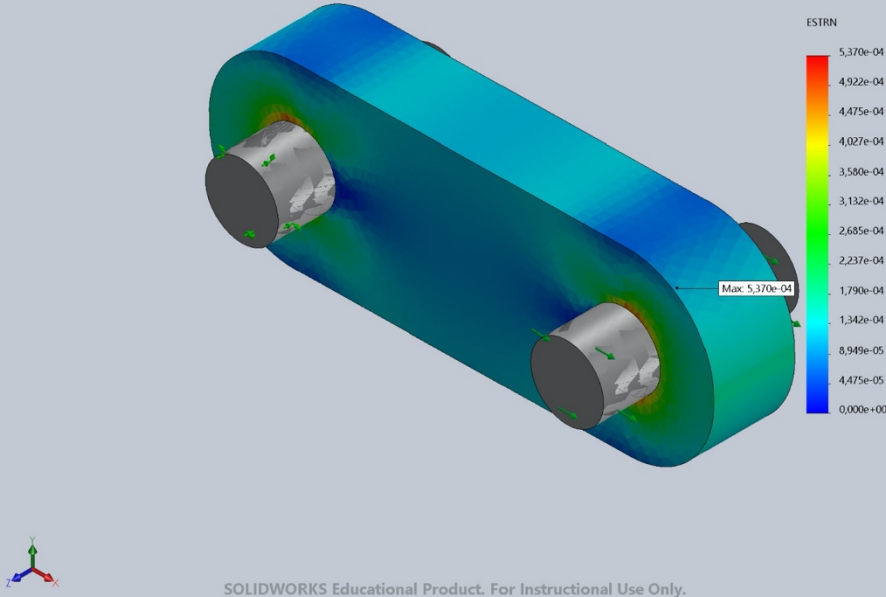
Mesh Details

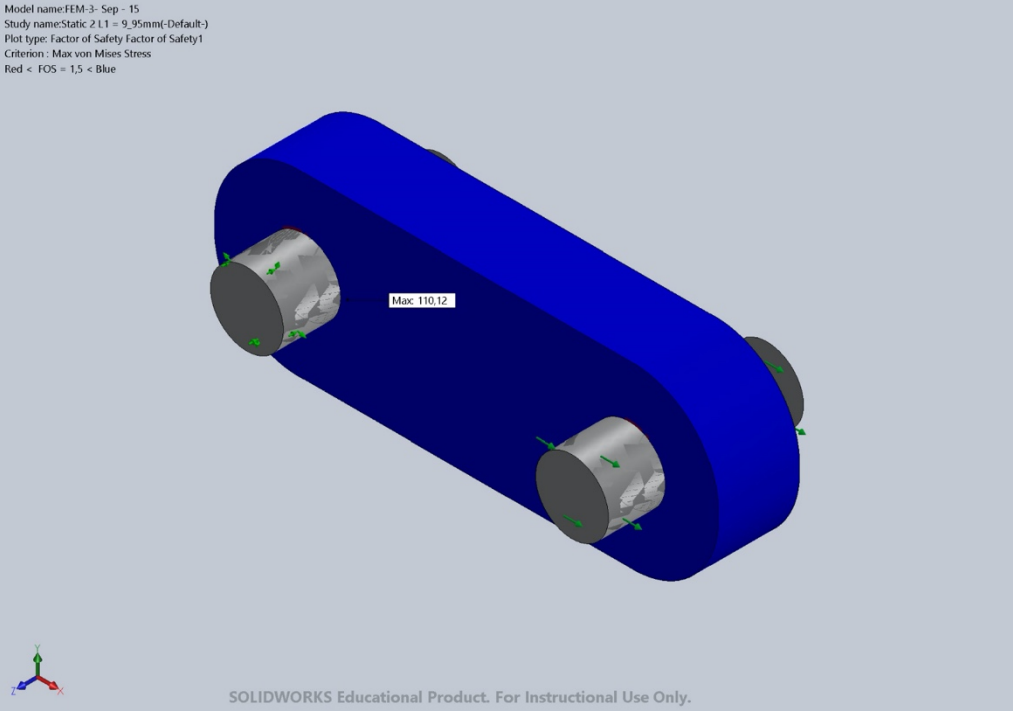
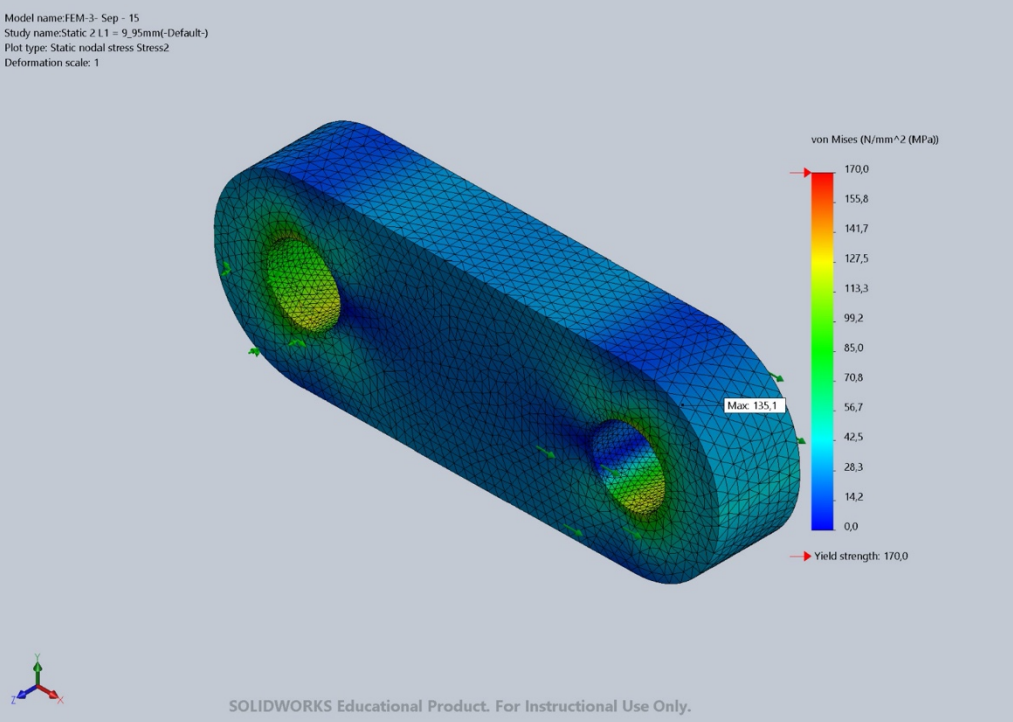
Mesh	Model name: FEM-3 - Sep - 4 Study name: Static 16 (Default) Mesh type: Mixed Mesh  SOLIDWORKS Educational Product. For Instructional Use Only.			
Mesh information:	Mesh type: Mixed mesh Mesher used: Curvature-based mesh		Entities: 2 face(s) Units: mm	

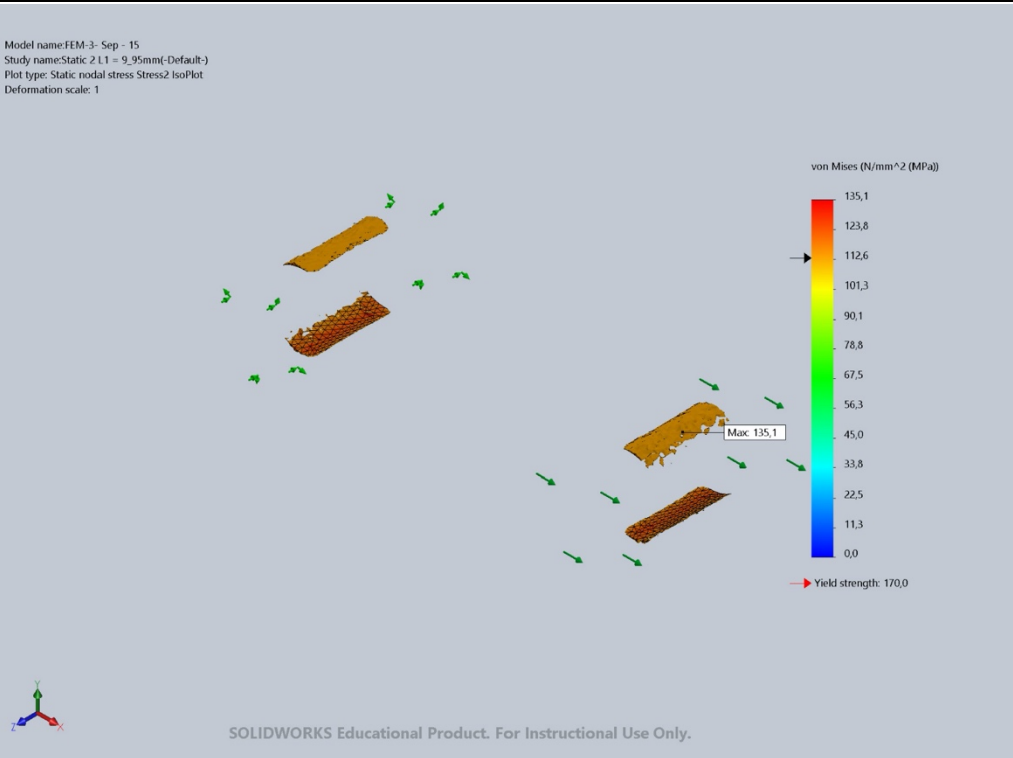
Mesh Control:	Jacobian points: 4 Max element size: 0,123965 mm Min element size: 0,112695 mm Mesh Quality: High Total nodes: 117291 Total elements: 79631	Size: 0,0563476 Ratio: 0,0563476
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Resultant Forces						
Reaction forces:	Selection set	Units	Sum X	Sum Y	Sum Z	Resultant
	Entire model	N	0	0	0	1e-33
Incorrect values due to use of rigid bodies in simulation. The force is applied on one of the rigid bodies.						

Study Results		
VON: von Mises Stress	Min: 0,0 N/mm^2 (MPa) Node: 113720	Max: 135,1 N/mm^2 (MPa) Node: 27085
Picture(s)	Model name:FEM-3- Sep - 15 Study name:Static 2 L1 = 9.95mm(-Default-) Plot type: Static nodal stress Stress1 Deformation scale: 1 	
Discussion:	The highest stress value is just below yield strength. These stresses are discussed below.	
URES: Resultant Displacement	Min: 3,969e-11 mm Node: 115856	Max: 8,482e-02 mm Node: 16

Picture(s)	Model name:FEM-3- Sep - 15 Study name:Static 2 L1 = 9.95mm(-Default-) Plot type: Static displacement Displacement1 Deformation scale: 1  URES (mm) Max: 8.482e-02 SOLIDWORKS Educational Product. For Instructional Use Only.	
Discussion:	Max displacement is acceptable.	
ESTRN: Equivalent Strain	Min: 0,000e+00 Element: 77848	Max: 5,370e-04 Element: 9519
Picture(s)	Model name:FEM-3- Sep - 15 Study name:Static 2 L1 = 9.95mm(-Default-) Plot type: Static strain Strain1 Deformation scale: 1  ESTRN Max: 5,370e-04 SOLIDWORKS Educational Product. For Instructional Use Only.	
Discussion:	Strain is acceptable. Could indicate that material does not yield.	
Factor of Safety	Min: 1,26 Node: 27085	Max: 110,12 Node: 4675

Picture(s)	 Model name:FEM-3- Sep - 15 Study name:Static 2 L1 = 9.95mm(-Default-) Plot type: Factor of Safety Factor of Safety1 Criterion : Max von Mises Stress Red < FoS = 1.5 < Blue Max 110.12 SOLIDWORKS Educational Product. For Instructional Use Only.
Discussion:	Red areas: FoS <1.5. The factor of safety is below 1.5 near the high stress areas.
Additional information	 Model name:FEM-3- Sep - 15 Study name:Static 2 L1 = 9.95mm(-Default-) Plot type: Static nodal stress Stress2 Deformation scale: 1 von Mises (N/mm² (MPa)) Max 135.1 Yield strength: 170.0 SOLIDWORKS Educational Product. For Instructional Use Only.
Discussion:	This figure illustrates the elements that show high stress. Red coloured indicate stresses near yield strength, which is 170 MPa. Higher stresses occur on the surface of the first layer of elements near the hinge holes. However, the stresses in these areas are well below yield strength and show a safety factor just above 1.5.

Additional information	Model name:FEM-3- Sep - 15 Study name:Static 2 L1 = 9.95mm(-Default-) Plot type: Static nodal stress Stress2 IsoPlot Deformation scale: 1  von Mises (N/mm² (MPa)) 135,1 123,8 112,6 101,3 90,1 78,8 67,5 56,3 45,0 33,8 22,5 11,3 0,0 Max 135,1 Yield strength: 170,0 SOLIDWORKS Educational Product. For Instructional Use Only.
Discussion:	ISO clipping plot shows stress area >113 MPa. These are the areas where the safety factor is below 1.5.

Study Conclusion

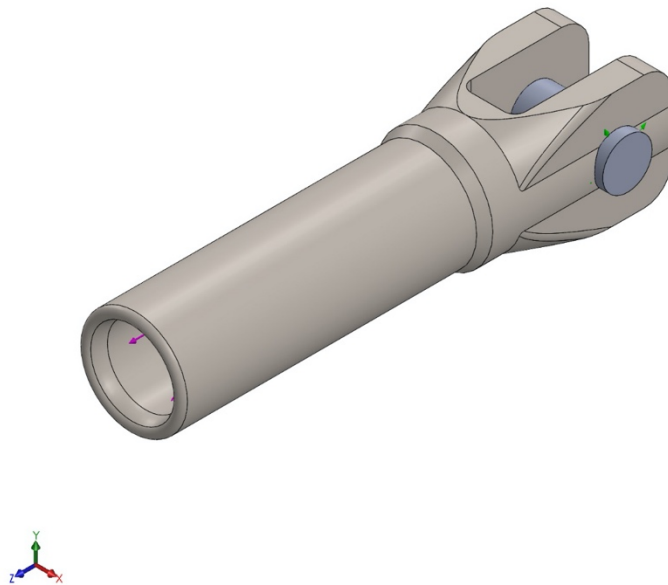
Conclusion:	Disregarding the stress concentrations, the Connector component appears to be strong enough to withstand the maximum applied tensile forces easily. This component is unlikely to cause problems with the maximum tensile force of 55 N applied. Fatigue problems are unlikely to occur since the safety factor of 1.5 is achieved throughout most of the component.
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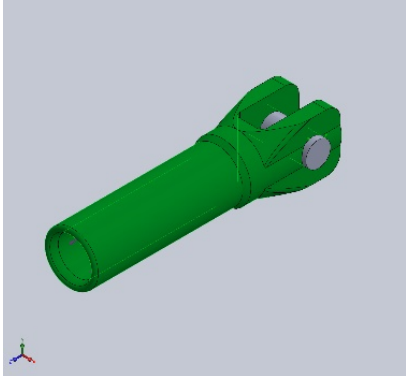
FEM - 4

Simulation 4

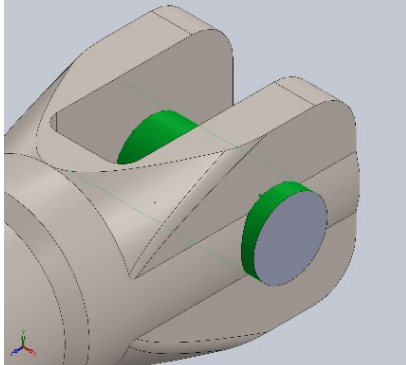
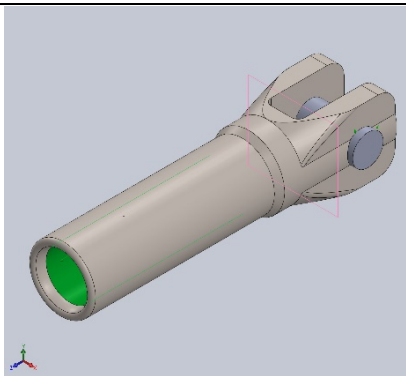
Title:	FEM-4 NiTiCon	
Author:	Philip de Haes	
Details:	Component No: 6 Part-file name: PH_4005_v8 – NiTiCon CAD-file name: FEM-4 - Sep – 15 Study name: Static 3 L1 = 9_95 mm Date: 15-09-2020	
Summary:	The NiTiCon component is unlikely to cause problems with the maximum tensile force of 50 N applied. Fatigue problems are unlikely to occur since the safety factor of 1.5 is achieved throughout most of the component.	
Assumptions:	The NiTiCon component connects the Nitinol core with the tip opening / closing mechanism. It is connected to the Connector component, forming a hinge. A rigid hinge axis constraint with a 'fixed hinge' is placed at this location. The force is attached to the face where normally the Nitinol core is bonded with the NiTiCon component. A force of 50N is applied based on previous calculations.	
Study details:	Analysis type: Static Mesh type: Mixed Mesh Solver type: FFEPlus (Solidworks default) Large displacement: off	Length/Displacement: mm Temperature: Celsius Angular velocity: Rad/sec Pressure/Stress: MPa

Model Information

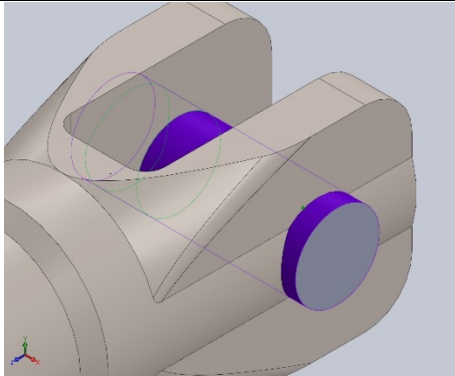
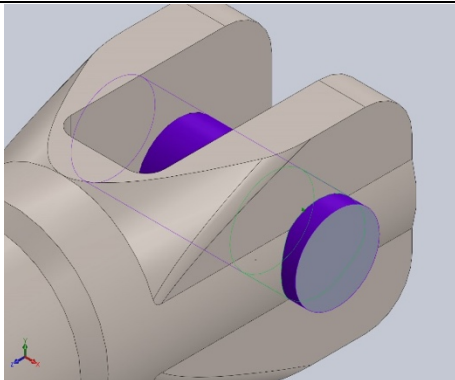
Model:	
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Solid bodies properties:		Mass: 0,000125506 kg Volume: 1,56353e-08 m³ Density: 8.027,1 kg/m³ Weight: 0,00122996 N
Material Properties:	Name: AISI Type 316L stainless steel Model type: Linear Elastic Isotropic Default failure criterion: Max von Mises Stress Yield strength: 170 N/mm² Tensile strength: 485 N/mm² Elastic modulus: 200.000 N/mm² Poisson's ratio: 0,265 Mass density: 8,027 g/cm³ Shear modulus: 82.000 N/mm² Thermal expansion coefficient: 1,65e-05 /Kelvin	

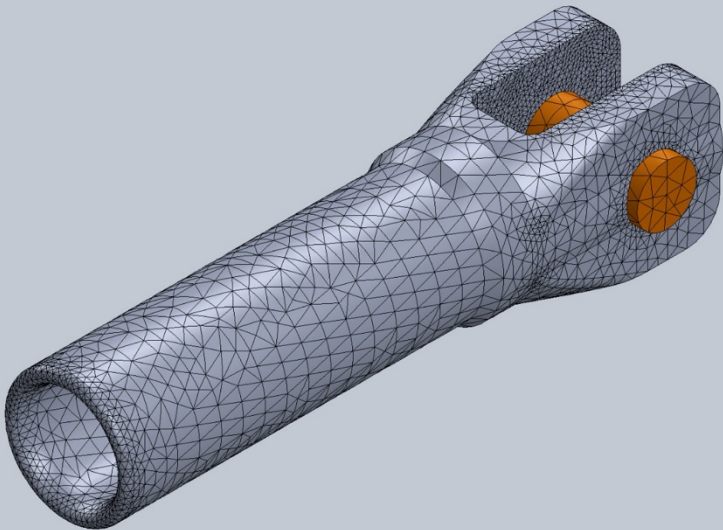
Loads and Fixtures

Fixture:			Entities: 1 face(s) Type: Fixed Hinge		
Resultant forces:	Components	X	Y	Z	Resultant
	Reaction Force (N)	0	0	0	1e-33
	Reaction Moment (N*m)	0	0	0	1e-33
Load:			Entities: 1 face(s), 1 plane(s) Reference: Front Plane Type: Apply force Values: ---; ---; 50 N Moments: ---; ---; --- N.m <i>This component is bonded with a Nitinol core contact the green surface (see figure on the left), similarly to where the force is attached.</i>		

Contact information

Contact set 1:				Type: No Penetration contact pair Entities: 2 face(s) Advanced: Node to surface	
Contact/Friction force:	Components	X	Y	Z	Resultant
	Contact Force (N)	-0,0064517	0,0012558	25,001	25,001
Contact set 2:				Type: No Penetration contact pair Entities: 2 face(s) Advanced: Node to surface	
Contact/Friction force:	Components	X	Y	Z	Resultant
	Contact Force (N)	0,0064517	-0,0010175	24,999	24,999

Mesh Details

Mesh:	Model name:FEM-4- Sep -4 Study name:Static 2 from [Static 1](Default-) Mesh type: Mixed Mesh   SOLIDWORKS Educational Product. For Instructional Use Only.
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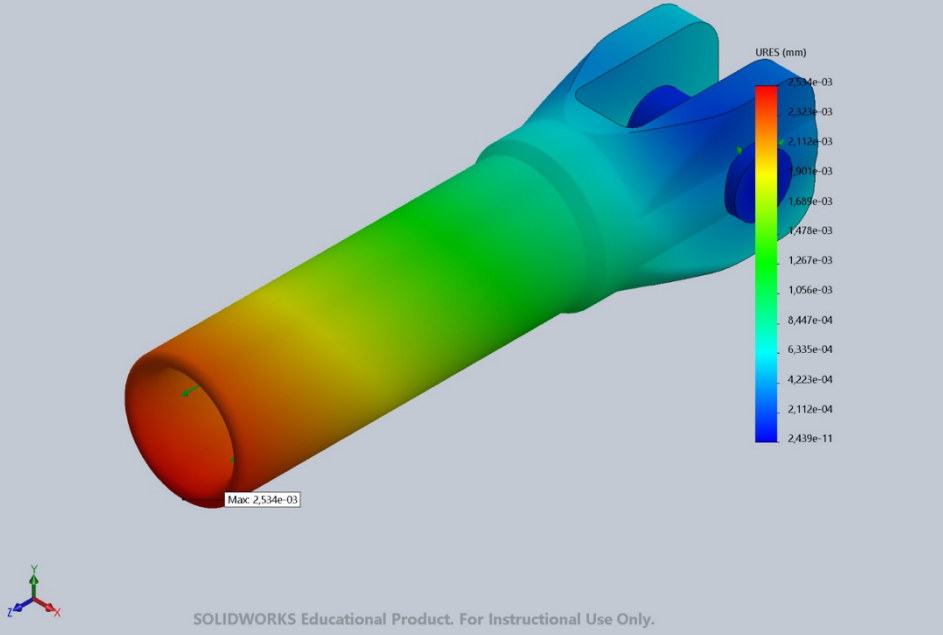
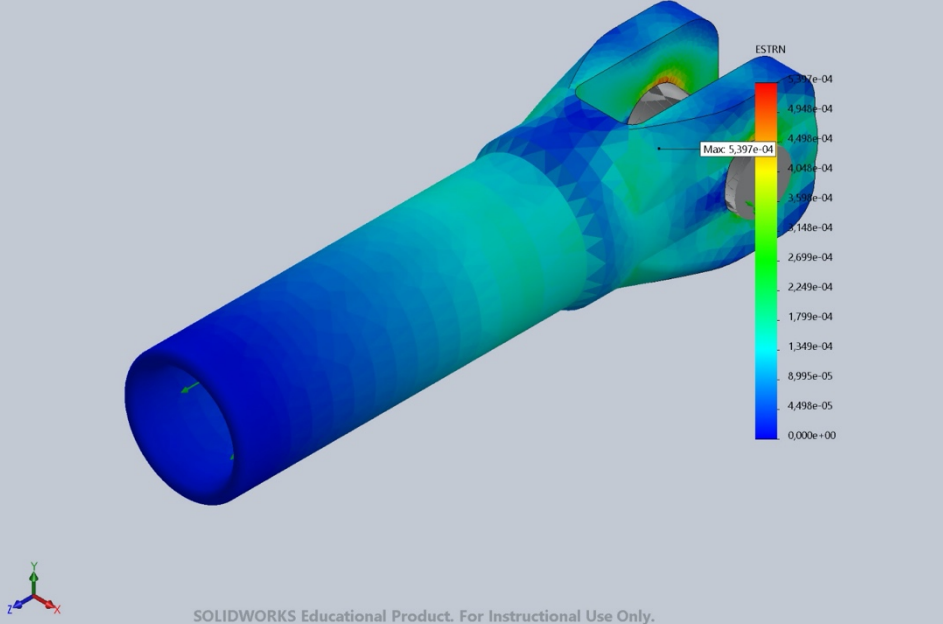
Mesh information:	Mesh type: Mixed mesh Mesher used: Curvature-based mesh Jacobian points: 4	Entities: 4 face(s) Units: mm Size: 0,0639003 Ratio: 0,0639003
Mesh Control:	Max element size: 0,255602 mm Min element size: 0,0511204 mm Mesh Quality: High Total nodes: 84748 Total elements: 54599	

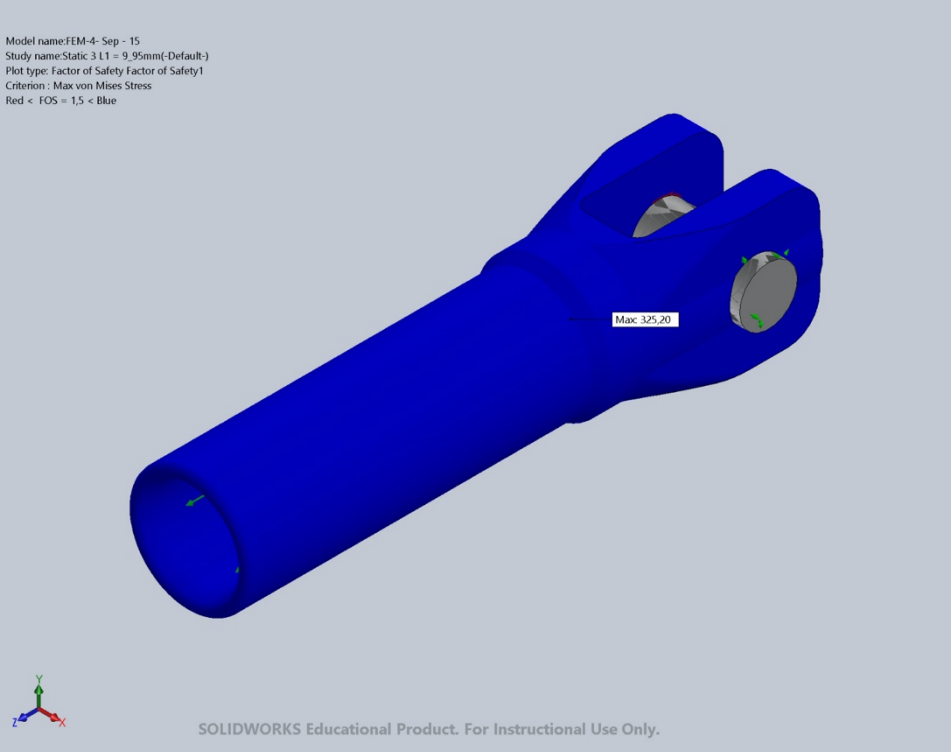
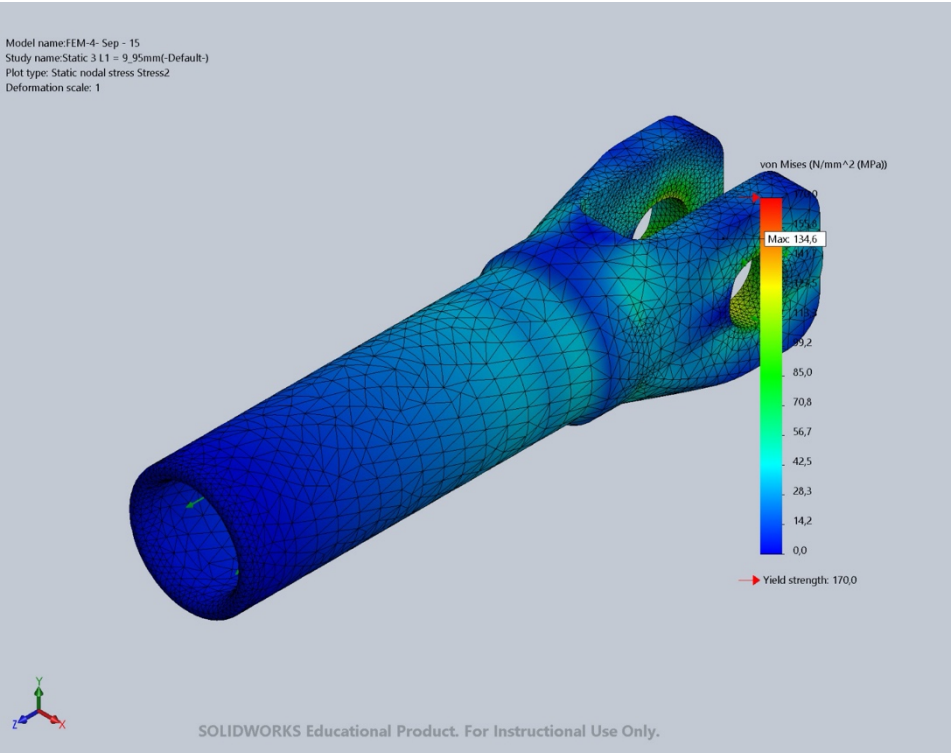
Resultant Forces

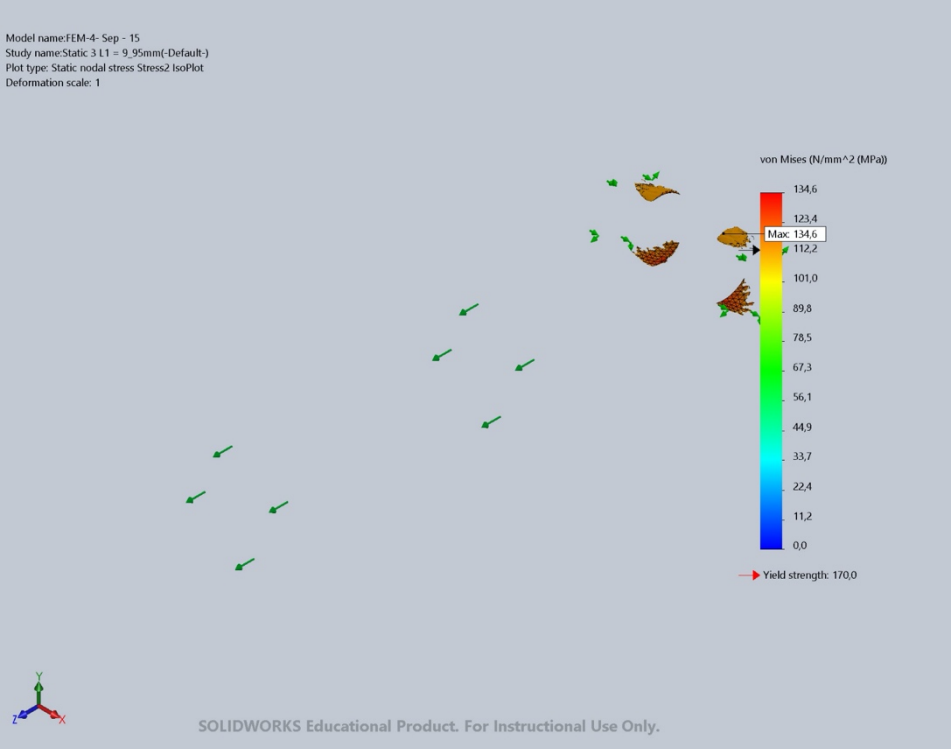
Reaction forces:	Selection set	Units	Sum X	Sum Y	Sum Z	Resultant
	Entire model	N	0	0	0	1e-33

Study Results

VON: von Mises Stress	Min: 0,0 N/mm^2 (MPa) Node: 84299	Max: 134.6 N/mm^2 (MPa) Node: 12717
Picture(s)	Model name:FEM-4- Sep - 15 Study name:Static 3 L1 = 9.95mm(-Default-) Plot type: Static nodal stress Stress1 Deformation scale: 1	
Discussion:		
URES: Resultant Displacement	Min: 2,439e-11 mm Node: 84400	Max: 2,534e-03 mm Node: 5627

Picture(s)	Model name:FEM-4- Sep - 15 Study name:Static 3 L1 = 9.95mm(-Default-) Plot type: Static displacement Displacement1 Deformation scale: 1  URES (mm) 2.534e-03 2.323e-03 2.112e-03 1.901e-03 1.689e-03 1.478e-03 1.267e-03 1.056e-03 8.447e-04 6.335e-04 4.223e-04 2.112e-04 2.439e-11 Max: 2.534e-03 SOLIDWORKS Educational Product. For Instructional Use Only.	
Discussion:	Displacements are acceptable.	
ESTRN: Equivalent Strain	Min: 0,000e+00 Element: 54376	Max: 5,397e-04 Element: 14529
Picture(s)	Model name:FEM-4- Sep - 15 Study name:Static 3 L1 = 9.95mm(-Default-) Plot type: Static strain Strain1 Deformation scale: 1  ESTRN 5.397e-04 4.943e-04 4.489e-04 4.035e-04 3.581e-04 3.127e-04 2.673e-04 2.219e-04 1.765e-04 1.311e-04 8.567e-05 4.013e-05 0.000e+00 Max: 5,397e-04 SOLIDWORKS Educational Product. For Instructional Use Only.	
Discussion:	Strain is acceptable and could indicate that the material doesn't yield.	
Factor of Safety	Min: 1,26 Node: 12717	Max: 325,20 Node: 6034

Picture(s)	
Discussion:	Red areas: FoS < 1.5. Similarly to the stress plot, the red areas indicate high stresses.
Additional information	
Discussion:	This figure illustrates the elements that show high stress. Red coloured indicate stresses near yield strength, which is 170 MPa. No red coloured elements appeared. The maximum stress 134.6 MPa well below 170 MPa.

Additional information	Model name:FEM-4- Sep - 15 Study name:Static 3 L1 = 9.95mm(-Default-) Plot type: Static nodal stress Stress2 IsoPlot Deformation scale: 1 
Discussion:	ISO clipping plot shows stress areas (elements) with a safety factor below 1.5, thus stresses above 113 MPa. This figure shows that the stress does not radiate deeper into the material instead only the a few elements near the surface are affected.

Study Conclusion

Conclusion:	Based on the above results, this component is unlikely to cause problems with the maximum tensile force of 50 N applied. Fatigue problems are unlikely to occur since the safety factor of 1.5 is achieved throughout most of the component.
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