Detachable Steerable Clip Applier for Dissection of ITA Branches

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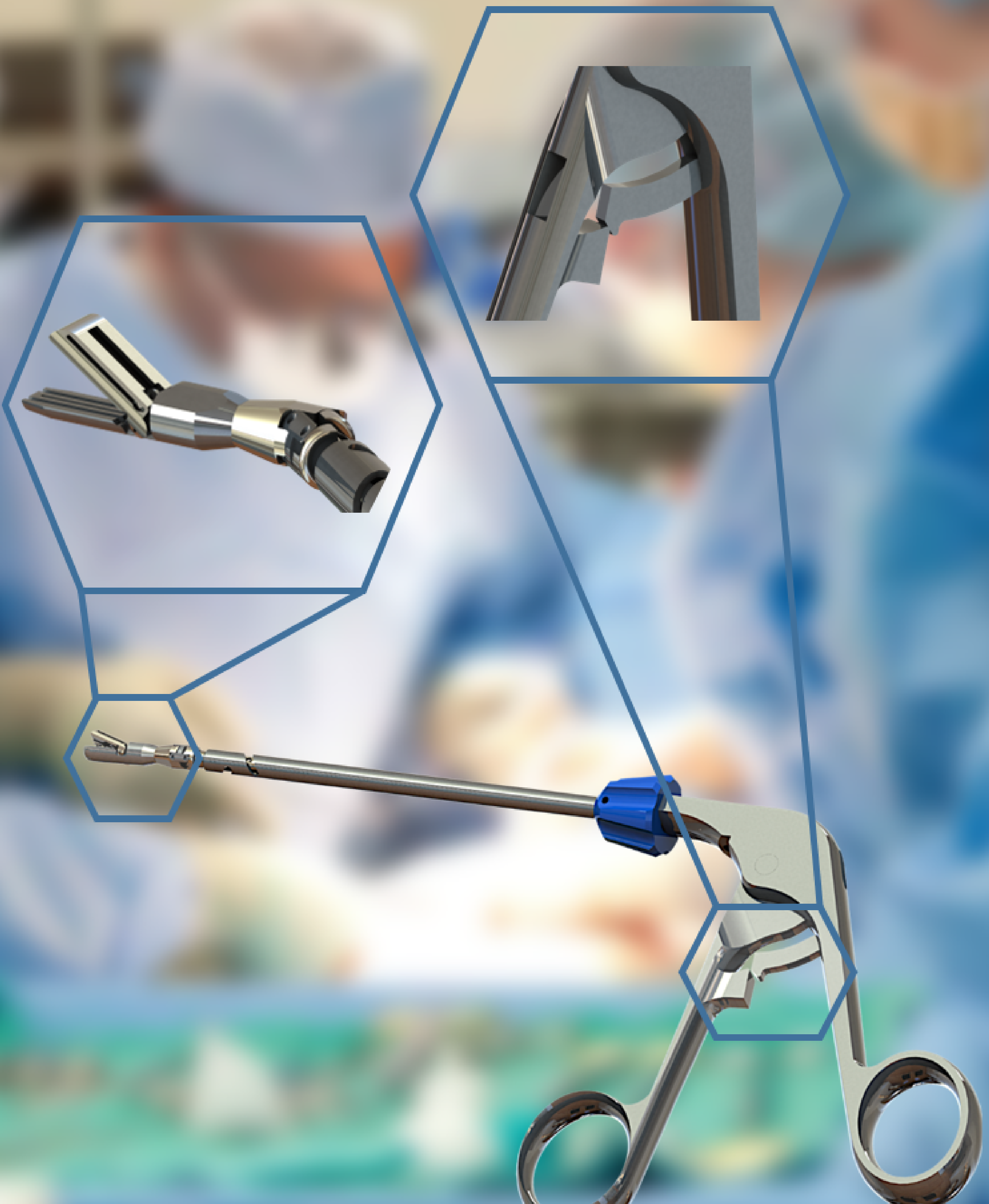

Detachable Steerable Clip Applier for Dissection of ITA Branches

by

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Master of Science Thesis

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Abstract

The internal thoracic artery (ITA) is increasingly being recognized as the best conduit for replacement of diseased coronary arteries. As the ITA is the main blood supply for the sternum, harvesting this artery causes a drop in blood flow, increasing the risk of failing to heal, and risking deep sternal wound infection. Current methods of harvesting the ITA are time consuming, and due to hidden arteries the manoeuvrability of the surgeon is limited.

In this project the goal is to develop a new instrument for branch sealing and dissection, that increases the maneuverability, minimizes damage to surrounding tissue while being more time efficient.

A systematical selection process resulted in the solutions for some of the sub-functions, whereas two sub-functions required more thorough analysis and evaluation. Concept selection for the sub-function *Tip-Articulation* a more in-depth analysis and experimental evaluation (n=19). The selection of the sub-function *Handle-Mechanism* is done by analysis of proven concepts, choices are based on the requirements that resulted from consultation with an experienced surgeon from LUMC, literature study, and supervision of experienced medical instrument engineers. A preliminary headroom analysis is done, resulting in an estimated drop of 64.45% for the duration of sealing and dissecting of branches with a relatively bigger diameter. Further research should specifically be aimed on the further development of the chosen concepts.

ACKNOWLEDGEMENTS

This graduation project would not have been possible without the support of many people. I wish to express my gratefulness to my supervisors. First of all to Tim Horeman (Surge-On Medical), for my graduation project I was planing on developing a new instrument to improve the process of harvesting the ITA, despite being busy with supervision of many graduation project you were willing to supporting me with the develop of this device. By my reckoning, we had a very good balance in the freedom you gave me and the good advise and steering you provided to keep me on track to aim at the essential goals. Jenny Dankelman (TU Delft), who assisted in realizing a research project at SIMIT in Shanghai. Furthermore, she helped me through the early stages of defining the subject, and all the invaluable support and guidance that followed. My third supervisor has been Rob de Lind van Wijngaarden (LUMC), having him as a supervisor was of immense value. He was always willing to help me out with all the questions, and provided the opportunity to attend CABG-surgeries at the LUMC.

Most importantly, I want to express my gratitude to my parents and to my sister. They have experienced all the stages of my study. Since the beginning they have provided me with support and encouragement, making it possible for me to achieve all the goals and experiences.

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1

Introduction

1.1. Coronary Heart Disease

According to the WHO, cardiovascular diseases (CVDs) are the number one cause of death globally. CVDs are heart and blood vessel disorders, form which in 2015 an estimated 17.7 million people died. From this group an estimated 40% were caused by coronary heart diseases (CHD)[1]. CHD is a disease to the vessels that provide the heart muscle with blood. Epidemiological evidence has indicated that since the 1960s the rate has steadily been dropping. Despite its decline, the burden remains high in developed countries, and is rising in developing countries [2]. In the Netherlands, cardiovascular conditions are no longer the leading killer of adults. However, the morbidity remains huge with 400,000 hospitalizations for cardiovascular disease annually [3]. Multiple factors have had their influence on this reduction over the past decades, such as smoking and hypertension[4], but also the technological innovation has improved the possibilities for revascularization [5]. The two available methods for revascularization are; Percutaneous coronary intervention (PCI), which involves the placement of intracoronary stents, and coronary artery bypass graft (CABG) surgery.

1.2. Coronary Artery Bypass Graft

Coronary artery bypass grafting surgery is an open-heart surgery in which a section of a blood vessel is grafted to the coronary artery to bypass a narrowed or blocked section to restore the blood provision to the heart muscle. For CABG-surgery there are three types of grafts that can be used, i.e. radial artery, great saphenous vein, and the internal thoracic artery (ITA). It has been stated by several authors that the ITA provides the best long term results [6, 7]. According to studies the use of this artery increases survival and reduces incidence of recurrent angina, late myocardial infarction, and repeat coronary intervention which is associated with significant higher mortality and morbidity [6, 8–11]. Nevertheless, the ITA does also have limiting characteristics as it can be prone to increased and persistent postoperative pain[12–14]. ITA harvesting can be time consuming, especially if this is performed bilaterally. Other symptoms associated to the ITA harvesting are vasospasm and hypoperfusion in the early postoperative period [15, 16]. An impaired sternal perfusion; causing delayed wound healing, and sternal wound infections (SWI) are risks that can occur after CABG surgery using the ITA [17–21]. Mediastinitis, also known as deep sternal wound infection (DSWI), occurs in 0.4% to 5.0% of patients undergoing CABG surgery, depending on the varying reports, and are associated with longer stays in the intensive care, increased duration of hospitalization [22, 23]. This extra treatment has an undesired impact on the patients Quality of Life (QoL), and has been associated with a significantly higher mortality rate [23, 24]. Additionally, the treatment and management of this group of patients due to extended hospitalization lead to growing costs that is approximately a threefold of patients without these complications [25].

1.3. APPROACH

Ordinary design project usually starts with a design assignment followed by analyzing and defining the 'hidden' design problems. The case for this project differs from the ordinary as there was no problem stated by anybody. After the author attended a surgery the focus was set on improving the dissection of the ITA. The information collected with the literature study and an interview with a cardiothoracic surgeon helped understanding the process of harvesting the ITA. In section 1.3.1 a brief clinical perspective is provided as background information before defining the problems and determining the design goal for this project.

1.3.1. CLINICAL PERSPECTIVE

The human body consists of a right and left ITA which both can be used for a CABG surgery, the procedure that uses both these arteries is known as bilateral internal thoracic artery (BITA). The ITA originates from the subclavian artery and descends at a short distance to the sternal margin. Along the way several branches arise, the arteries that supply blood to the skin, sternum and pectoral muscle and are therefore the most relevant for this project are the perforating, sternal and intercostal branches. These 3 arteries are recurrent in the upper 5 intercostal spaces and arise either separate, or due to anatomical variation as a common trunk, see Table 1.1. An example of such a common trunk, or so called 'collaterals', is depicted in Figure 1.1. These common trunk's are of great interest as they are potentially very convenient when preserving the blood flow after all the branches have been dissected from the ITA. In the example of Figure 1.1, preservation of the trunk in ITA dissection can provide flow to the sternal branch through the connection of the anterior intercostal artery with the posterior intercostal branch, this will be elaborated further at a later stage [27, 28].

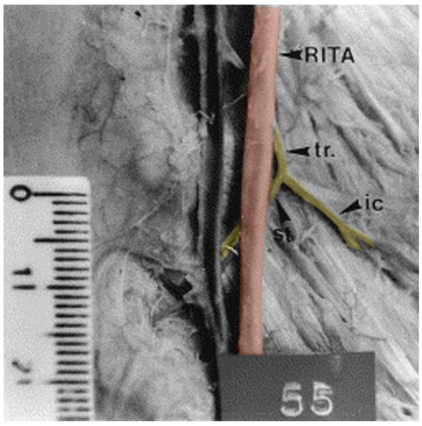


Figure 1.1: A sternal branch (st) and anterior intercostal branch (ic) arising as a common trunk (tr) form the right internal thoracic artery (RITA). The illustration is modified from [26]

As mentioned earlier, there are several grafts that can be used as a bypass. If it is decided to use the ITA for CABG-surgery the procedure starts with a median sternotomy, which is a procedure in which a vertical incision is made along the sternum after which the sternum itself is divided.

When the ITA is located there are two established harvesting techniques to choose from; pedicled and skeletonized. The pedicled technique generates a rim of tissue of 1-2cm around the ITA. Whereas the skeletonization solely yields the artery [23, 29]. Cunningham *et al.* noted that pedicled BITA and skeletonized BITA relatively have an incidence of 6.9% and 1.5% of sternal wound infection [30]. The explanation for this is that the pedicled technique harms the common trunks, whereas skeletonization of the ITA has the potential to preserve the collateral blood flow, essential to lower the risk of infection and other problems due to devascularization. Downsides related to the skeletonization technique are the risks, as it is more traumatic to the arterial wall, the risk of damaging the artery increases. Skeletonized ITA harvesting has been associated with early graft failure, intraluminal thrombus formation, and inflammation due to triggering of the inflammatory cascade [31].

Table 1.1: Mean number of ITA branches, n=50. L, Left; R, Right, ITA Internal Thoracic Artery. Modified from [32].

Type of branch	LITA	RITA
Sternal	5.1	5.9
Perforating	4.8	1.9
Intercostal	6.8	5.7
Common trunks	3.1	3.2

During this procedure it is key to prevent to damage the ITA as it is very sensitive. To prevent stenosis of the ITA the surgeon holds its distance with the instruments that is used for dissection, as most of the instruments are known to cause damage to surrounding tissue [33–36]. This is especially the case, when using electrosurgery which is the most popular technique nowadays. This method can harm surrounding tissue.

The information that needs to stand out from this section is that the preservation of the common trunks can preserve collateral blood flow reducing the risk of SWI. The instruments that are being used nowadays have a double negative impact on the chance of this blood flow preservation. Firstly, the damage to surrounding tissue can damage the common trunk. Secondly, because of the damage to surrounding tissue the surgeon has to dissect the branch at a safe distance from the origin which decreases the chance of preserving the common trunk.

1.3.2. CURRENT TECHNIQUES

Over the years the procedure, method and instruments used for harvesting the ITA have frequently been the subject of comparative studies. The four most commonly applied instruments to dissect branches are described in the following part.

NON-ENERGETIC

The use of clip or suture ligation have been overtaken by electrosurgery in the procedure of division and coagulation of vascular structures. This is especially the case in laparoscopic operations. As for open surgery, the use of clips for haemostatic purpose is quite user-friendly and seals are applied by mechanical compression, posing little risk to surrounding tissue when applied correctly. However, for ITA dissection these devices can be experienced as bulky in the areas where the surgeon has limited manoeuvrability. The clips are made of titanium or polymers. The polymer clip is characterized by the toothed grasping surface and that slipping is prevented by locking.

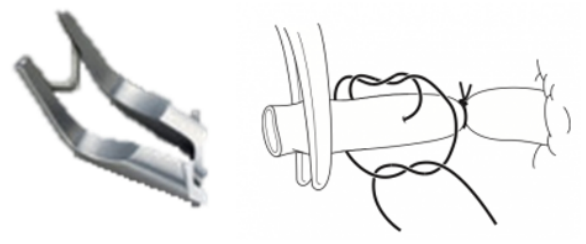


Figure 1.2: Left, example of clip. Right, ligation of vessel by suturing.

MONOPOLAR ELECTROSURGERY

Traditional high radio-frequency (RF) monopolar (MP) electrosurgery is a single cutting electrode using alternating current in which the circuit is comprised of; a generator, an active electrode, the patient, and the return electrode. It usually consists of a hand switching pencil with a Teflon coated blade and generator. Unfortunately this method is not very precise in dissection due to erratic electricity, creating burns on surrounding tissues [37].

BIPOLAR ELECTROSURGERY

A bipolar (BP) RF electrosurgery differs from the MP RF electrosurgery as both the active electrode and return electrode functions are performed at the site of surgery. Therefore, the electrical circuit is minimized to the tissue grasped by this device. It applies high current and low voltage to the vessel, causing denaturation of the collagen and elastin proteins in the vessel wall.

Figure 1.3: Left monopolar electrosurgery. Right, bipolar electrosurgery.

ULTRASONIC SURGERY

Instead of using electrical current the ultrasonic coagulation technique relies on the mechanical vibrations. This ultrasonic energy caused by ultrasound transducers oscillates longitudinally against non-vibrating pad, and thus denaturizes proteins by mechanically breaking the hydrogen bonds in proteins. It is suggested that it produces minimal lateral thermal tissue damage as it controls blood flow by forming coagulum at low temperatures, ranging from 50 °C to 100 °C [38].

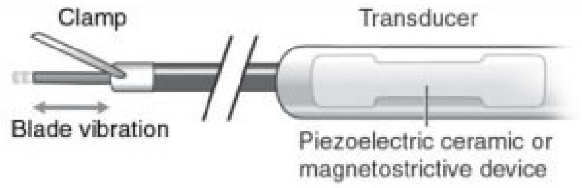


Figure 1.4: ultrasonic device with tip section and actuator section. Image is adapted from [39]

1.3.3. PROBLEM

Achieving a desirable outcome with a CABG-surgery is dependent on variable factors. Nonetheless, harvesting a graft properly is essential in his procedure. As this project aims on the surgeries that desire to use the ITA as the conduit of choice, the plan is to look into the problems for this procedure. Harvesting the ITA is a delicate procedure with multiple risk factors and challenging aspects. The problems stated here are a collection of observations, experiences and data based on attending CABG-surgeries, interview with cardiothoracic surgeon and literature study [40, 41]. In order to give structure to the problems a summation of the problems are placed in a flowchart. If the upper problems in the flowchart are solved, the subsequent boxes are automatically solved as well. A summation of problems when harvesting the ITA are presented in Figure 1.6.

The idea for this project started after attending a CABG-surgery, the procedure of harvesting the ITA was experienced as time consuming, detaching all the branches consumed a noteworthy amount of actions. In section 1.3.1 it was mentioned the ITA had three types of branches that are relevant for this project, as these branches are recurrent in the upper 5 intercostal spaces there are 15 branches to dissect. To dissect one of these branches two or three actions are needed, meaning that the instrument needs to be switched every single time. Having to switch instruments 45 times for one ITA, not to mention when both the ITA's are harvested, seemed striking and has potential to be improved. The interview with dr. Rob de Lind van Wijngaarden, a cardiothoracic surgeon, gave rise to a problem experienced by the practitioner, i.e. a limitation of maneuverability. The patients thorax restricts the reachability of some of the branches forcing the surgeon to apply excessively high forces on the surrounding tissue in order to position the instrument properly, this can lead to chronic wrist pain to the surgeon [42].

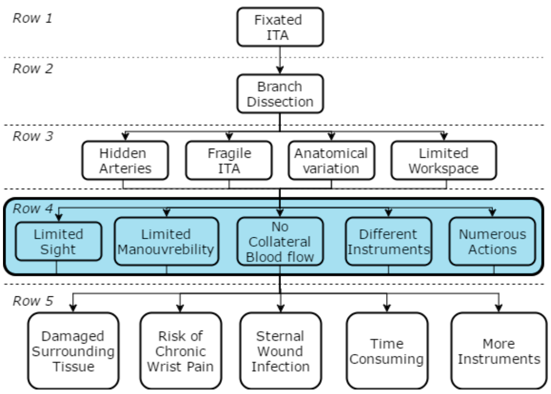


Figure 1.5: A flowchart subsequently linking problems related to harvesting the ITA.

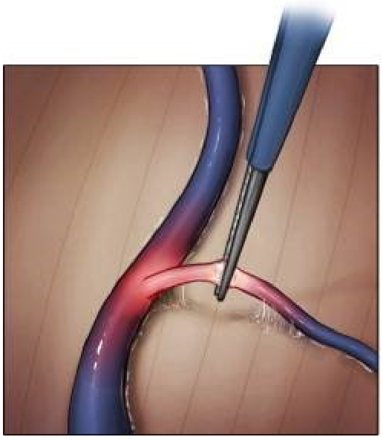


Figure 1.6: Visual explanation of thermal spread. Standard application of bipolar energy to a side branch during dissection potentially created thermal effect beyond the intended area. Adapted from [43]

A conclusion from the literature study is that the anatomical variation of the common trunks has the potential of maintaining the collateral circulation to the sternum and therefore causing the incidence of related infection risks to drop.

Analyzing the process of dissecting the ITA from branches clarifies that there is little room to dwell over the worry of preserving the common trunk. The two main factors are the fact that the used instruments are known to cause damage to surrounding tissue. The second factor is the fact that the main objective for the surgeons is to harvest a healthy ITA. A logical consequence is that the exact location of dissection takes place at a safe distance from the origin of the branch. Considering the main objective of the surgeon, the common trunk will most likely be destroyed in order to harvest the ITA safely, see Figure 1.1.

This is a summation of the related problem concerning different stakeholders that are affected by a CABG-surgery. The most worrying problem and probably at the same time the hardest to solve is the prevalence of SWI. This problem eventually increases the duration of the hospitalization, is life threatening, has an impact on the Quality of Life (QoL) and increase the related costs.

1.3.4. DESIGN GOAL

Users have not come to a consensus regarding the method to use for harvesting the ITA. Designing a medical device to harvest this artery is a complex procedure as many factors play a role. For a device to become the instrument of choice it would have to be coping with achieving excellent results on haemostatis by preventing energy to transfer to surrounding tissue when sealing and dissecting a branch and ensuring it is capable of withstanding the pressure. But there are more factors that play a role when looking for the best solution. The ITA must be protected in the process, it must be achieved with low rate of complications, no side branch bleeding, influence prevalence of sternal infection and chest wall pain. Less clinically affected factors must as well be kept in mind when looking for the best method. This relates to the ease-of-use, time efficiency, costs and individual surgeon's level of experience required for proper use of device. Once the optimum of all the factors come together in one device the goal is reached.

In this project an instrument will be developed, this instrument will be an alternative device that solves multiple of the problems stated in section 1.3.3. To give structure to the problems a flowchart was set up. It is desirable to solve the highest problems in the figure as that will prevent the subsequently linked problems or consequences of happening. The problems in row 4 of Figure 1.6 was set as the goal to solve in this project. Translating these problems into goals creates the following design goal for this project:

A new device is to be developed that will be able to seal and dissect branches of the ITA. The device should be steerable and cause minimal damage to the surrounding tissue while limiting the number of actions/instruments that are required for dissection of branches.

---

2 METHODOLOGY

2.1. CONTENT OF THESIS

The proces of developing an instrument is a cycle that works from a goal to the product. This process is, as Roozenburg and Eekels put it, "an iterative 'trial and error'-process, whereas the knowledge about the problem and the device spirals into a higher level" [40]. To achieve the goals set up for this project the steps that were taken can be grouped into four phases, these phases are shown in the diagram depicted in Figure 2.1.

The first phase is the *Analysis*, the project starts with a case from which the problems must be inventoried, background research is being done to specify criteria for the final concept. These criteria state the characteristics of the instrument but also the requirements that are expected by the stakeholders.

In both the *Synthesis* phases ideas and solutions are created. *Synthesis I* focuses more on freely developing concepts through brainstorming and selecting ideas for sub-functions by setting goals with the *S.M.A.R.T.* method, structuring with a morphological map and evaluating concepts with *Harris* profiles. Whereas *Synthesis II* is the detailing of the concepts with technical drawings and modelling.

In the *Evaluation* phase the final concepts are tested with experiments and possible redesigned before settling on a final design [40].

This project was initiated after attending a CABG-surgery and wanting to improve the process of harvesting the ITA. In the previous chapter analysis was done on the clinical perspective, the problems were inventoried and the goal of this project was set up. This chapter will continue on the analysis phase by introducing the stakeholders and specifying the requirements that the device should fulfill. With a function analysis an abstract description of the medical instrument will be given out of which the sub-functions arise. Tackling these sub-functions separately will provide a broad range of solution, by using a morphological scheme the best combinations are put together creating the final concepts.

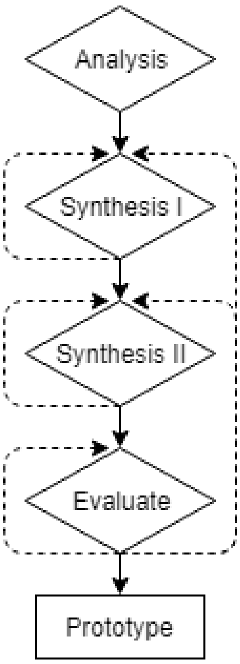


Figure 2.1: Methodical diagram of the engineering design process.

2.2. STAKEHOLDERS

In this section we introduce all the participants that take part in the use or development of the instrument. They are considered as they all have specific problems, expectations, and relation with the instrument.

Target

The *Target* in this project are the patients. During the CABG-surgery they undergo the whole procedure and the main goal of this project will lead to a better procedure by becoming more time-efficient, minimizing damage to surrounding tissue and improve the outcome of the operation by dropping the incidence of SWI caused by CABG surgery.

User

The *User* in this aspect is the cardiothoracic surgeon. They are the specialists that will be using the instrument during the surgery. Harvesting the ITA is not a new procedure and the instrument is not meant to differ a lot from the current procedure. Existing concepts will be evaluated and merged into the novel device. Consultation is done with dr. Rob de Lind van Wijngaarden, a specialist at the LUMC.

Hospital

There are two reasons why the *Hospitals* are an important party to consider. Firstly, they are in charge of sterilizing the reusable instrument. This means they have requirements and expectations when considering to implement a new instrument for their surgeries. Secondly, if patients are detected with SWI the hospital will have to provide additional care. This includes much higher risks for the patient, but also a threefold of related costs when compared to the average cabg-surgery.

Manufacturers

The development of this instrument has been done as a graduation project for the Delft University of Technology and the company Surge-On Medical. They each have their input and expectations related to this project which will be implemented and considered during the project.

2.3. FUNCTION ANALYSIS

To generate possible solutions an analytic-systematic approach was used. This choice was made as this method gives structure to the problem and in order to create the desired concept, varying sub-solutions are combined.

The concrete function description of the device should fulfill the set design goal. To achieve this, the design goal is disintegrated into main and sub-functions. The abstract main function description of the device is visualized in the blackbox, Figure 2.2. This abstract representation is further divided into sub-function allowing to systematically tackle the challenges that are encountered out of the design goal. Figure 2.3 categorizes four sub-functions that ideally, when put together realize the goal that is pursued in this project.

Figure 2.2: Blackbox visualization of the function description.

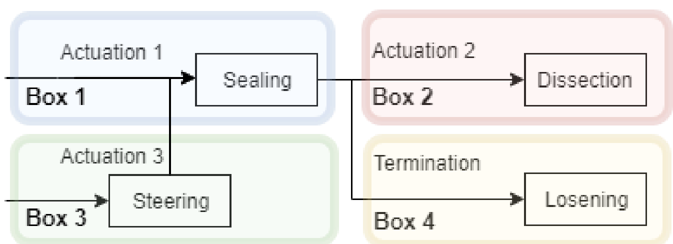


Figure 2.3: Function description of the medical instrument split up in sub-functions.

Two methods came into use in the process of systematically creating creative concepts for the sub-functions. Firstly, sorting the sub-functions based on on priority, as one sub-solution creates additional requirements for the remaining sub-functions. Secondly, by using reverse engineering, a method in which the components of existing solutions are accurately examined to extract knowledge or design information to reproduce and find the most suitable solutions fitting the requirements of this project.

2.4. LIST OF REQUIREMENTS

Developing an instrument that will fulfill the goal and suitbale for CABG-surgery demands a list of requirements. This has been set up and used to quantitatively assess the concepts needed for the selection process to create desired final concept. The requirements are based on the Phug's checklist, assumptions, interview with cardiothoracic surgeon and literature study [40, 41]. The requirements have developed and further specified in later phases of the development process. At the end of the list of requirements a list of criteria has been set up to focus and keep track on the constraints that this project has.

Performance:

1. The user should be able to know what he is doing at the location of the work surface.
2. The instrument must be able to dissect a varying diameter of branches.
3. The instrument must apply reliable sealing.
4. The instrument makes it easier for the surgeon to grasp branches that are difficult to reach with current method.
5. The surgeon must still be able to do the procedure accurately.
6. The instrument is steerable and able to hold the set angle when forces are applied in to use the instrument.

Time:

7. The instrument must work to comparable speed to the used instruments, or more time efficient.

Safety:

8. The instrument and application should reduce the amount of damage to surrounding tissue (especially the ITA).
9. The use of the instrument must be safe of the operators.
10. The use of the instrument must be safe for the patient.
11. The surgeon must have the opportunity to stop and interfere the procedure.
12. The device will only divide if the user commands so.
13. The instrument must not cause an undesired reaction to the body.

Cleaning:

14. The instrument must fulfill the requirements within the standard sterilization process. These include visual inspection, easy accessible shafts, simple cleaning and executed in a few steps. Let small parts stay attached, and make sure that surfaces are flat and smooth if possible. Tight fitting of moving parts is not favourable as it obstructs flowing water. [44]
15. The materials should be able to withstand the environment of the sterilization process.

Product life span:

16. The instrument must be able to be reused repeatedly.
17. The instrument can be reused for at least X amount of dissection.
18. The transport and storage of the instrument in the hospital must not cause extra hazards.
19. If the instrument has a problem it can be replaced partially to keep costs lower than buying a complete new device.
20. There is no need of an expert for a proper maintenance and preparation of the instrument. These steps are self-evident.

Costs:

21. The costs of the instrument must be able to compete with existing instruments.

Dimensions:

22. The dimensions are such that it must be able to be used in open heart surgery.

Ergonomics:

23. The instrument is usable in the position the surgeon is operating.
24. Design so the P5 till P95 of the user population can use it.

Environment:

25. Applied forces on the instrument during procedure must not cause deformation or have impact on the desired result.

Appearance:

26. The design must remain simple and intuitive to assure effortless implementation in the procedure.

List of Criteria

- Recourse's to create a solution are limited.
- This project is a graduation project, therefor the time-span to reach the goal is tight.
- Feasibility.
- Chance of success.
- The expertise that is available.
- The acceptance by the people that are involved.

3

CONCEPT SELECTION

In section 2.3 the essence of the new instrument is described by splitting it up in sub-function. A visualization of the function split-up is presented in Figure 2.3. In this chapter these and additional sub-functions are presented and with a systematical approach, *Morphological scheme & Harris-profile*, this will yield the best solutions. The solutions will be analyzed and adapted further in order to yield the ideal concept for every sub-function.

3.1. MORPHOLOGICAL SCHEME

The systematical method of developing solutions for sub-functions is done by evaluating a broad selection of existing concepts. Structure is broad to this process with a morphological scheme. Table 3.1 shows for all the six sub-functions the variety of concept that will be analyzed. Although, it was pre-defined that the sub-function *Steerable* was established by using the SATA mechanism. Therefore, this sub-function has only one possible concept presented in the morphological scheme. As for the sub-function *Handle*, it was devided into a section regarding the design, and a section for the interacting mechanism that will be incorporate. The six sub-functions set up for this project are the following:

- Sealing
- Dissection
- Steering
- Tip-closure
- Handle
- Clips

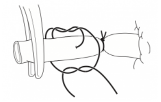
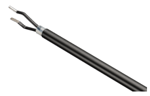
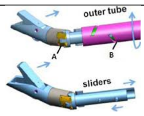
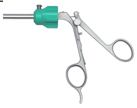
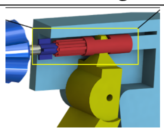
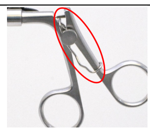
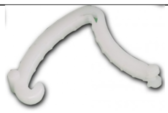
3.2. MULTI-CRITERIA ANALYSIS

In this section each sub-function will be elaborated, and systematically potential solutions are ranked. Ranking of the existing solutions is achieved involving relevant criteria and requirements. If applicable, goals of the sub-functions are set up with the *S.M.A.R.T.-method*. Structuring the selection process is done by using the *Harris-profile*. This is a way to visualize the strengths and weaknesses of different concepts. First of all, a list of requirements that are important for the sub-function is defined. The requirements are given a weight by ranking it with an estimated adequate weight from [1-3], with 3 being the highest weight that can be given to the most important requirements. Rating each concept for all the requirement will be the next step, ranging from [1-5]. A summation of the scores for all the requirements for each concept makes it executable to systematically compare concepts. Making it suitable for evaluating concepts and decision making.

3.2.1. SEALING AND DISSECTION

As mentioned in section 1.3.2, the four most common tools used for dissection are monopolar (MP) electrosurgery, bipolar (BP) electrosurgery, ultrasonic energy, and the combination of clips with cutting or MP/BP.

Table 3.1: Morphological scheme with all the sub-functions.

Functions \ Solutions	1	2	3	4	5
Sealing	 Suture	 Clip	 MP EC	 BP EC	 Ultrasonic
Dissection	 MP EC	 BP EC	 Ultrasonic	 Surgical Blade	 Laser
Steering	 SATA				
Tip-closure	 2-Hinge	 Scissor Linkage	 Pull in	 Single-Slide	 Single-Hinge
	 Overtube	 Cut-out			
Handle design	 Housing	 Open			
Handle mechanism	 Rotating Cam	 Leaf spring	 Deformation	 Switch	 Counter force
	 Rack	 Ratchet	 Loading		
Clips	 Double shank	 Polymer	 Triangle	 Chevron	 Aneurysm

The energetic treatments for branch dissection, such as electrosurgery and ultrasonic surgery, are known to cause damage to surrounding tissue due to the dispersion of high temperature. The mechanism with the lowest damage to surrounding tissue is the application of surgical clips. This mechanism also showed significantly higher mean burst pressure when compared to monopolar electrosurgery and ultrasonic coagulation with the Harmonic Scalpel in an evaluation experiment for the strength of side-branch sealing [37]. Therefore, energy-driven techniques did not fulfill the requirements and the surgical clips in combination with a surgical cutting blade are the most suitable techniques in order to combine sealing and dissecting.

BLADE

For the sub-function of dissecting the blood vessels a range of concepts are labeled as not applicable as there has been chosen to reduce damage to surrounding tissue by using non-energetic methods for the 'sealing' sub-function. The concept that remains to achieve the sub-functions of dissecting is the use of a blade or a similar mechanism of a slicing sharp edged concept. This is a common technique as it is often combined with electrosurgey devices such as MP or BP. As this concept has been proven to be suitable for the goal of dissecting it is applied in the development process of this project. Noteworthy, the risk related to the use of a blade is the fact that the sharpness diminishes when used. This problem will not be incorporated in the design process of this project, but it is to be kept in mind that it is important to ensure proper dissection by either replacing that part by making the blade disposable, or making it possible to sharpen the blade or any other solution that meets the expectation of dissecting the vessel.

Table 3.2: Harris profile of the concepts for sealing a blood vessel. Clips; surgical clips, MP; monopolar electrosurgery, BP; bipolar electrosurgery, US; ultrasonic surgery. On the left the requirements with next to it the weight that is given to that requirement. Rest of matrix are the ratings and scores for the concepts. Bottom shows the final score for each concept.

Sealing	*Weight*	Clips		MP		BP		US	
Requirements	[1-3]	rating	score	rating	score	rating	score	rating	score
Quality sealing	3	5	15	2	6	4	12	5	15
Proven concept	2	4	8	2	6	3	6	4	8
Surrounding tissue	3	5	15	3	3	3	9	4	12
Knows to surgeon	1	2	5	5	5	5	5	3	3
8mm ø	2	3	6	3	6	4	8	3	6
Time efficiency	3	2	6	5	15	3	9	3	9
Complexity	2	5	10	3	6	2	4	2	4
Feasibility	2	5	10	3	6	3	6	2	4
Total Score		**75**		**51**		**59**		**61**	

3.2.2. STEERING MECHANISM

It was stated by the cardiothoracic surgeon, dr. Rob de Lind van Wijngaarden, that the maneuverability is limited when attempting to seal some of the superior branches. This results is applying excessive high forces on the patients thorax as this is restricting the surgeons work space. A second theoretical beneficial application of the steerable instrument is the possibility of accurately choosing the exact spot of sealing and dissection as close as possible to the origin of the branch, improving the possibility of preserving the collateral blood flow. The steering mechanism should provide the tip one rotational degree of freedom (DoF), ranging between -50 and 50 deg, while the hinge mechanism is rigid and accessible for sterilization. The most suitable steering mechanism that is used for this project is provided by Surgeon Medical. The novel steering mechanism, namely the Shaft Actuated Tip Articulation Design (SATA), can be used to build simple and intuitive instruments. Therefore, this mechanism is more advantageous than available hinges, which often aim on maximizing range of motion, minimizing components/the total concept, or creating multiple degrees of freedom [45–49].

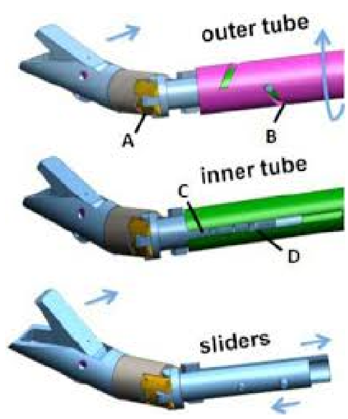


Figure 3.1: The technique that SATA used works with several principles. Steering is actuated by rotation of the outer tube, resulting in articulation of part A, the hinge [44].

Figure 3.1 shows that the sideways rotation of the tip is actuated by a rotation of the outer tube, through the middle there is still space for components to realizing translational motion making it possible to apply forces over the hinge mechanism [44].

3.2.3. TIP-CLOSURE

ANALYSIS

Out of the morphological scheme seven concept arise, theses concepts are analyzed and evaluated for the selection process. The seven concepts are schematically visualized in Figure 3.2. Image I represents the *2-Hinge*, both hinges are connected with two separate rigid bodies. The arrow indicates the motion that will make the hinges to open, stretching the rigid bodies to align parallel to each other. This brings the hinges together and ensures the jaws are in the closed phase.
Image II is the *Single-Slide* concept, used for the Steerable Punch by Surge-On Medical. This concept has one articulating jaw and is controlled by the sliding of the rounded contact surfaces. This concept pivots around the rotation point that is connected to the fixed lower jaw.
The *Scissor Linkage* is schematically represented in image III. This linkage consists of two rigid bodies that are connected at the pivots point, making both jaws to articulate.
Image IV is the *Cut-out* concept, this mechanical linkage has two elongated jaws that go beyond the pivot point, and a body that can move straight. This later body is connected to the cut outs, if this component moves it slides through the cut outs and induces the rotation of the jaws.
The *Single Hinge* has a pivot point connected to the fixed jaw, the arrow indicates the pushing and pulling force acting upon the articulating jaws. This will induce the rotational motion of the upper jaw.
Image VI and VII is a visualization of the *Pull-in* concept. The outer tube depicted here is fixed, as the tip is pulled in the contact with the outer tube will increase the potential energy, this energy is acting on the rigid body of the jaws and forcing it to deform. As long as the relation between the applied stress, Young's modulus, and strain, stay in the elastic range the body will deform back to the original shape.
The principle visualizing the *Overtube* with image VII is similar to image VI. The jaws close due to the deformation of the rigid body, the difference lies in the component that is controlled to open or close the jaws. In image VII the outer tube is moved and the jaws are fixed in position and only deform.

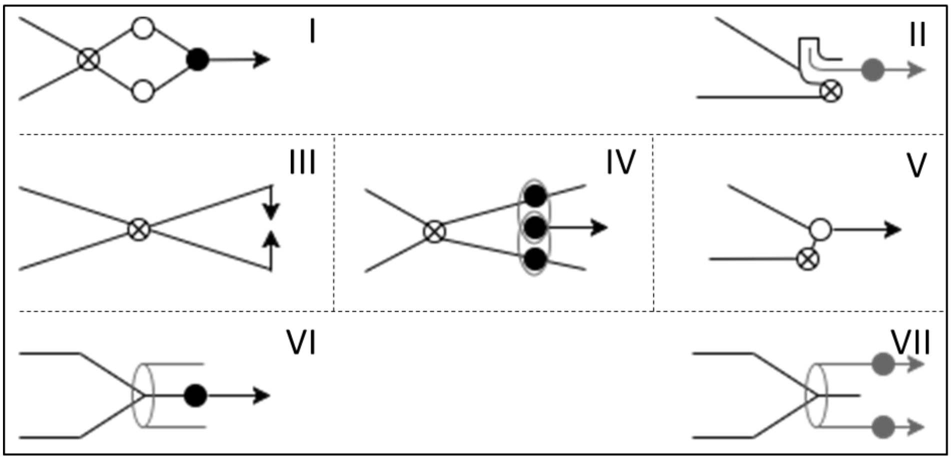


Figure 3.2: A schematic of the mechanical systems used for controlling the jaws at the tip. The jaws are in all the images depicted on the left side, the right is the direction of the shaft and handle. Image I is the 2-Hinge concept. Image II us the Single-Slide concept. Image III is the Scissor linkage Image IV is the Cut-out concept. Image V is the Single Hinge concept. Image VI is the Pull-in concept. Image VII is the Overtube concept.

SELECTION

Selection of the sub-function of closing the jaws of the tip is of great importance as variable function will be coming together here. Meaning a broader amount of requirements will have to be considered. Requirements for the development of a suitable tip-closing mechanism can be categorized in four groups. The first category is *Geometry*, this process will have to yield a mechanism that meets the expectation of fitting within a diameter of 8mm, the tip length may not surpass a length of 25mm.
The second category is *Incorporation*, the sub-functions that is elaborated here will be the component that ensures the transferal of translational motion into a compressing displacement of the jaws of the tip. This must be controlled with one translational motion, this motion must be in the direction of the tip as the function that follows after closing will be controlling the dissecting-function. Moreover, the mechanism that will be doing all this will be in connection with the SATA steering component.
The third category is not to be undermined as this device is designed to be reusable, referring to the category *Sterilization*.
The fourth category is *Feasibility*, function as a guardian angle to ensure that the goals will be achieved within the limited time and resources.
Setting requirements for the development of a tip, specific for this application was done in collaboration with the clinical expert dr. Rob de Lind van Wijngaarden, resulting in the selection process structured in Table 3.3. From this table we can conclude there is a clear that the *Single-Slide* and *One-Hinge* score the highest, followed at some distance by the *Overtube* and *Cut-out* concepts. These four concepts were chosen to analyze, adapt, and advance further in Chapter 4 and 5.

Table 3.3: Harris profile of the concepts for closing the jaws of the tip. At the top, seven concepts that are compared. On the left the requirements with next to it the weight that is given to that requirement. Rest of matrix are the ratings and scores for the concepts. Bottom shows the final score for each concept.

Tip-closure	*Weight*	2-Hinge		Scissor		Pull-in		Slide		1-Hinge		Overtube		Cut-out	
Requirements	[1-3]	R	S	R	S	R	S	R	S	R	S	R	S	R	S
Proven concept	2	4	8	5	10	3	6	4	8	5	10	4	8	4	8
Transferring energy	2	3	6	5	10	3	6	3	6	3	6	3	6	3	6
Dissection	3	3	9	2	6	2	6	1	3	4	12	4	12	4	12
Steering	2	4	8	1	2	3	6	3	6	3	6	3	6	3	6
1 translational controlled	2	3	6	1	2	3	6	3	6	3	6	3	6	3	6
Pushing actuation	3	1	3	1	3	1	3	5	15	5	15	5	15	5	15
Length tip	3	2	6	3	9	1	3	4	12	4	12	2	6	2	6
8 mm ø	3	2	6	2	6	4	12	4	12	4	12	4	12	2	6
Complexity [parts]	3	1	3	4	12	3	9	4	12	4	12	3	9	4	12
Sterilization	3	3	9	3	9	3	9	4	12	3	9	3	9	3	9
Simplicity	2	2	4	3	6	2	4	3	6	4	8	2	4	3	6
Feasibility	2	2	4	3	6	2	4	4	8	4	8	3	6	3	6
	Total Score	**72**		**81**		**74**		**108**		**116**		**99**		**98**	

3.2.4. HANDLE

HANDLE DESIGN

Designing a housing around the mechanism is simply put, creating additional protection. Protection of both users and internal mechanism. Therefore, this concept is recurrent in many medical instruments with varying mechanisms to control the position and locking of the jaws. Implementing these designs inside of the handle means it will withhold unwanted interruption or destruction by the user, but it will also withhold or hinder both the accomplishment and control of proper sterilization. Hence the fact that complex internal design in medical devices are commonly used for disposable instruments. Benefits of placing the handle mechanisms inside the housing are clear. Aspects such as the sterilization, cutting costs, and saving material on the other hand, score better with handles that have an *Open* design. Therefore, the concept of *Open* Handle design was preferred over the use the *Housing* concept.

For the sub-function *Handle Design* an ideal aesthetic and ergonomic design is deliberately left out. This project is to be accomplished within a set period and the resources are limited. Thence, priority was given to functions that are involved in this project. Therefore, proven concepts were able to be used as demonstrator to complete the instrument. Nonetheless, there are requirements that are to be kept mind when selecting suitable handle designs. Starting of with application oriented, during the procedure of harvesting the ITA the instrument will be coming in contact with the opposing side of the opening of the thorax. The chosen *Handle* design must cope with the circumstance and not cause damage to the surgeon or patient's thorax. Furthermore, the requirements for a suitable *Handle* that arise from other sub-functions will be considered as leading factors for selecting a suitable *Handle* design.

HANDLE MECHANISM

The design goal that was stated in section 1.3.4 mentions limiting the numbers of action and/or instruments. This refers to the sub-functions of sealing and dissecting that currently often is achieved with multiple instruments. In this project this will be transformed by merging actions, leading to additional concerns. This section takes these additional concerns into account. In Table 3.4 all the relevant requirements are listed and matched with an estimated adequate weight. From this table we can conclude that the *Deformation* and *Internal* concepts stand out, followed by the *Switch* and *Ratchet*. In a later phase this sub-function will be elaborated further.

Table 3.4: Harris profile of the concepts for splitting the actuation of sealing and dissecting. On the left the requirements with next to it the weight that is given to that requirement. Rest of matrix are the ratings and scores for the concepts. Bottom shows the final score for each concept.

Handle	*Weight*	Rotate Cam		Leaf Spring		Deformation		Switch		Counterforce		Rack		Ratchet		Loading	
Requirements	[1-3]	R	S	R	S	R	S	R	S	R	S	R	S	R	S	R	S
Separate action	3	5	15	3	9	4	12	4	12	3	9	3	9	3	9	2	6
Dissect after sealing	3	5	15	2	6	5	15	5	15	3	9	4	12	2	6	3	12
Safe for surgeon	2	5	10	3	6	3	6	4	8	3	6	4	8	4	8	3	6
Surrounding tissue	2	5	10	3	6	3	6	4	8	4	8	3	6	3	6	2	4
Not fragile	1	4	4	4	4	3	3	3	3	3	3	?3	3	4	4	4	4
Proven Concept	3	4	12	2	6	3	9	1	3	1	3	1	3	4	12	3	9
Prevent semi-compressing	1	2	2	2	2	3	3	3	3	2	2	4	4	2	2	2	2
Prevent semi-dissection	1	3	3	2	2	3	3	3	3	2	2	4	4	4	4	2	2
Intuitive	2	3	6	3	6	5	10	4	8	2	4	3	6	3	6	3	6
Time efficient	2	4	8	4	8	4	8	3	6	4	8	3	6	4	8	4	8
Linked actuation's	3	4	12	3	9	4	12	5	15	3	9	2	6	4	12	3	9
Sterilization	3	1	3	4	12	4	12	2	6	3	9	2	6	3	9	1	2
Complexity [parts]	2	2	4	3	6	4	8	2	4	3	6	3	6	3	6	1	2
Feasibility	2	4	8	2	4	4	8	3	6	2	4	1	2	2	4	2	4
Total Score		**112**		**86**		**115**		**100**		**82**		**81**		**96**		**74**	

3.2.5. CLIPS

A *Harris-profile* was used to ensure several requirements are taken into account when making a selection. For example the quality of the sealing with a certain clip, this reliability must be significant as that is one of the main goals of the final concept. The *Harris-profile* is presented in Table 3.5.
From this table we can conclude that the concept that stands out is the Chevron shaped concept. The polymer concept comes in second, followed by the 2-Shank. No decisive decision will be made based on this profile as none of these concepts have been developed with the intention to place two of them parallel to each other in the jaws of a single instrument. For future work, it is highly recommended to take the top three concepts into account when developing a suitable clip. In the development of a clip suitable for the device of this project it is to be kept in mind that the following requirements are incorporated:

- The geometry has restrictions as the clip may not stick out of the tip-mechanism, due to the fact that a dissection blade will be passing along the clip.
- In an interview with dr. Rob de Lind van Wijngaarden the problem of dislodgement was stated as recurrent and preferably solved. This is the case with the use of WECK® HORIZON™metal ligation system.
- This project aims on the dissection of branches of the ITA, meaning an estimated 15 branches that are to be dissected. Therefore, reloading the jaw with a new clip may not cause too much hazard.
- During the dissection of the ITA branches every blood vessel demands a sealing on both sides of the specific location of dissection. A suggestion is to consider the possibility of linking two clips, similar as the 2-Shank concept, but the connecting piece is to be made from a different material that can be split during dissection.

In order to achieve the development of a suitable clip it is recommended to combine the pros of the three top concepts, possibly yielding the ideal clip mechanism for the device that is developed in this project.
As for this project, the development will continue based on the proven concept of the WECK® HORIZON™metal ligation system.

Table 3.5: Harris profile of the concepts for sealing a blood vessel. At the top, 5 concepts that are compared. On the left the requirements with next to it the weight that is given to that requirement. Rest of matrix are the ratings and scores for the concepts. Bottom shows the final score for each concept.

Clips	*Weight*	2 Shank		Polymer		Triangle		Chevron		Aneurysm	
Requirements	[1-3]	rating	score	rating	score	rating	score	rating	score	rating	score
Quality seal	3	5	15	5	15	2	6	4	12	5	15
8mm ø	3	3	9	4	12	5	15	5	15	1	3
Proven concept	2	4	8	4	8	2	4	5	10	4	8
Stays in jaw	3	4	12	5	15	1	3	3	9	5	15
Varying size	2	4	8	4	8	4	8	4	8	4	8
Complexity	2	2	4	2	4	5	10	5	10	2	4
Feasibility	2	3	6	3	6	4	8	4	8	3	6
Total Score		**62**		**68**		**54**		**72**		**59**	

3.3. CONCLUSION

In this chapter the function of the final concept is split up in several sub-functions. Systematically, each of these functions were analyzed, and existing solutions were compared in order to yield the most suitable sub-solutions. A recap of the concepts that will proceed into next phase of analysis, synthesis and development are described in the following part.

SEALING & DISSECTION

The concept for sealing that resulted with the highest score is the surgical clip. This is a trusted method and provides high quality sealing. In contrast to energy driven techniques, this concept does not cause damage to surrounding tissue due to thermal spread. A leading criteria for the selection of the concept for *Dissection* is similar to that of the *Sealing* sub-function. Namely, the dispersion of heat to surrounding tissue as a result of using energy driven techniques. Therefore, the use of a sharp edged concept, similar to the surgical cutting blade, will be incorporated in further phases of the instrument development.

STEERING

The mechanism that will ensure the set requirements regarding the sub-function of *Steering* is pre-defined to be established with the SATA technique.

TIP-CLOSURE

The top four concepts for this sub-function consists of the *One-Jaw*; characteristic for this mechanism is the articulation of a single jaw that is controlled with a fixed connection to a pushing component that is arises out of the shaft.
The *Punch* is similar to the *1-Jaw* as far as the number of articulating jaws is concerned. The difference lies in the connection between the articulating jaw and component that arises from the shaft and transfers the force that controls the jaw. The connection for this concept consists of two circular cut-outs in these two components that create a rotation of the jaw by overlapping during motion.
In third comes the *Overtube*; a tip mechanism wherein an outer tube slides over the two jaws, that ensures motion of the jaws.
The *Cut-out* concept controls the motion of the tip by specific cut-out in the jaws.
These concepts will be analyzed, adapted and evaluated in Chapters 4 and 5 in order to select the perfect concepts for the final design.

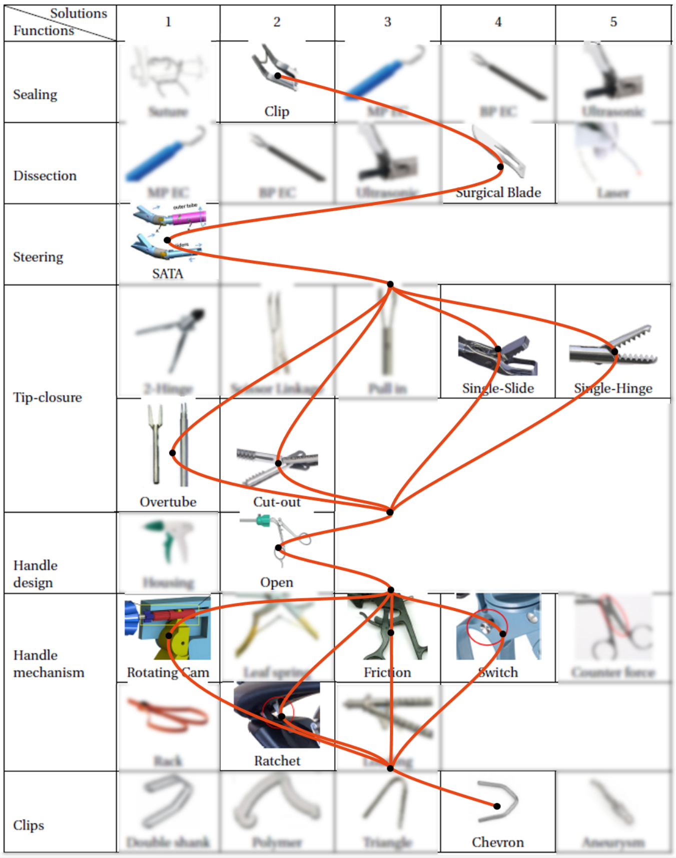


Figure 3.3: The concepts that are selected to proceed into the next phase of analysis and development.

HANDLE

The *Handle* sub-function focuses on the mechanism that separates the actuation of sealing and dissecting. The following four concepts will be further analyzed and adapted in Chapter 6 before making final concept selection to incorporate in the final design; *Deformation, Rotating Cam, Confirmation, Hooked.*

CLIPS

The development of the ideal clip is not part of this project. The *Chevron* concept is selected as the proven concept that will function as demonstrator. For future work it would be interesting to look into the development of a clip specific for the instrument that is being developed with this project.

4
Tip Synthesis

Out of the previous section four concepts were selected to develop further into concepts to that could be evaluated further. In this chapter the concepts of the tip are further analyzed and where possible/necessary adapted .

4.1. One-Jaw

Weill-Blakesley, RUDOLF

The mechanism that first is analyzed is the *One-Jaw*, a basic mechanical joint in a medical instrument. The instrument that was used as example is a laminectomy forceps developed by RUDOLF. In Figure 4.1 the handle is marked with the orange label A, the actuation is initiated here manually, which ensures the translation of the upper shaft. In this figure the most right images visualize the two states of the joint.

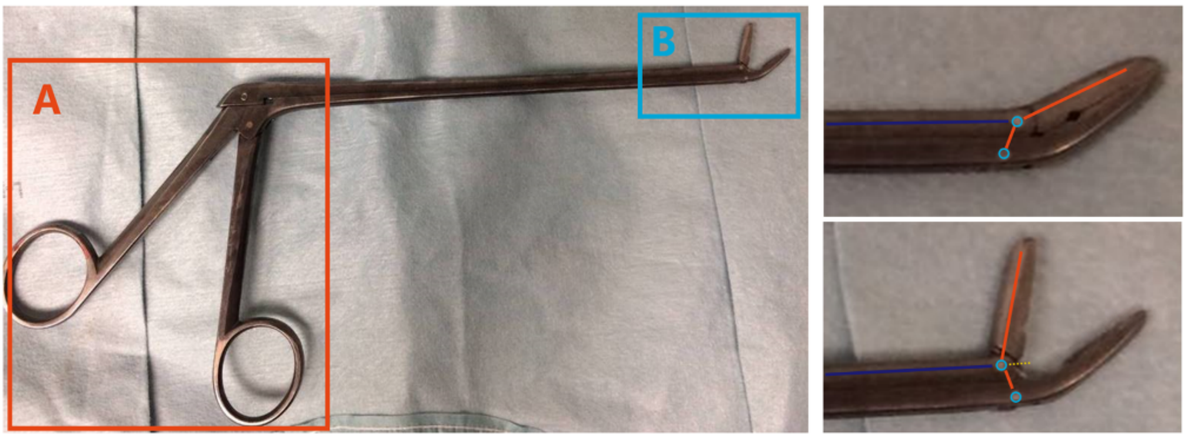


Figure 4.1: Laminectomy forceps with a mechanical hinge joint mechanisms at the tip that is controlled with a translational motion. Most right two pictures depict the two states of the linkage tip.

The simplicity of this mechanism inspired to create a concept that would maintain its simplicity. The concept that arose from the RUDOLF is depicted in Figure 4.2. The top left image in this Figure clearly shows the main components. The yellow component controls the tip by moving in linear direction of the shaft, a bar through the hole of this component transfers the force onto the articulating jaw, depicted in red. Because of the cutout in the red component the tip will close, the next step would be a second actuation to initiate the dissection of the clamped vessel.

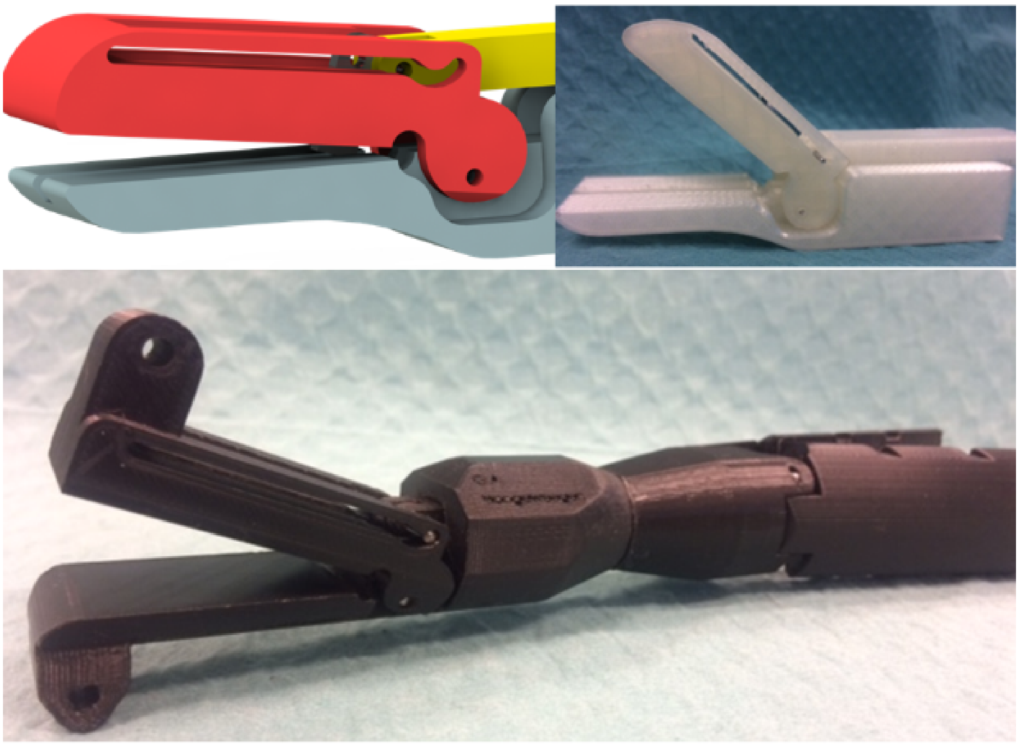


Figure 4.2: (Top left) CAD drawing of tip components. (Top right) 3D-printed concept for mechanical evaluation. (Bottom) Improved concept ready for experimental evaluation.

4.2. PUNCH, SURGE-ON MEDICAL

This concept was developed by Surge-On Medical. Just like the *One-Jaw* from previous section, this concept has a fixed jaw and one articulating jaw. In Figure 4.3 the fixated jaw is shown in purple and labeled with C, whereas the articulating jaw shown in orange has label A. Characteristic for this mechanism is the method of transferring linear motion of cyan component B in Figure 4.3 to articulating jaw A. Right two images in Figure 4.3 show the open and closed stated of the jaw controlled by the cutouts in components A and B.
No adaptation could be made to this mechanism to incorporate with a cutting blade without having to add significantly number of components. The cut-outs control the articulation, but are also restricting factors for further activation of the dissecting sub-function.

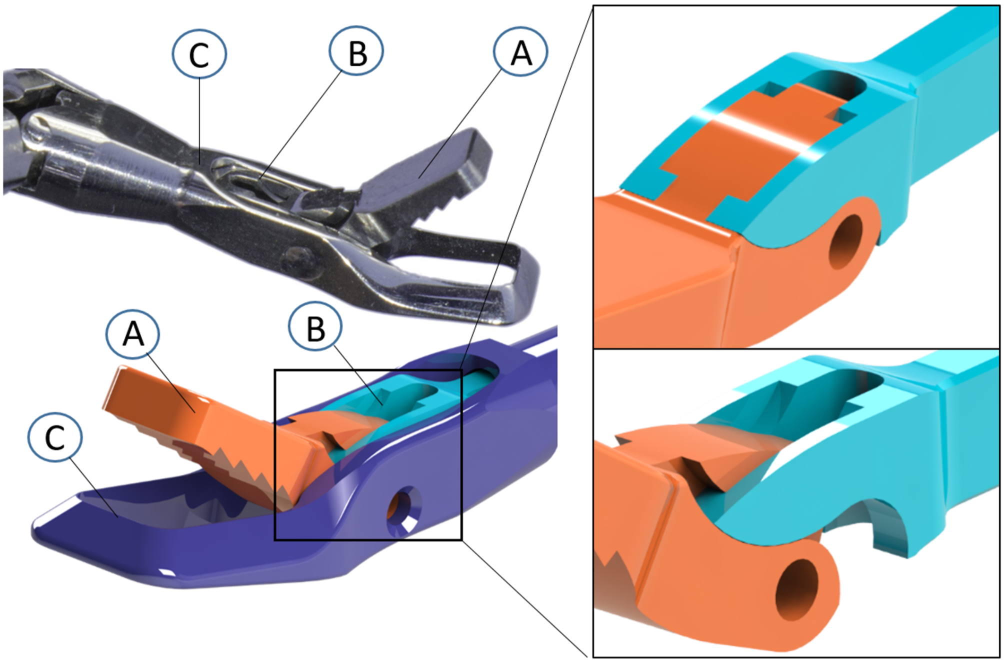


Figure 4.3: The Steerable Punch tip mechanism. (Top left) Picture of Punch with fixated jaw C, articulating jaw A, articulation controller B. (Bottom Left) Render of CAD. (Right two) Focus on articulation components A & B; Top image shows closed state of the tip. Bottom image shows open sate of the tip.

4.3. OVERTUBE

LIGACLIP, ETHICON

The *Ligaclip* is an endoscopic rotating multiple clip applier, and has a mechanism based on compressing two components at the tip with frictional force. In Figure 4.4 essential sections are emphasized, the orange A is the handle for actuation of the medical device. This actuation will drive the cyan marked B segment, the tip. This device is steerable by rotation over the shaft's axis, this rotation is actuated by component C.

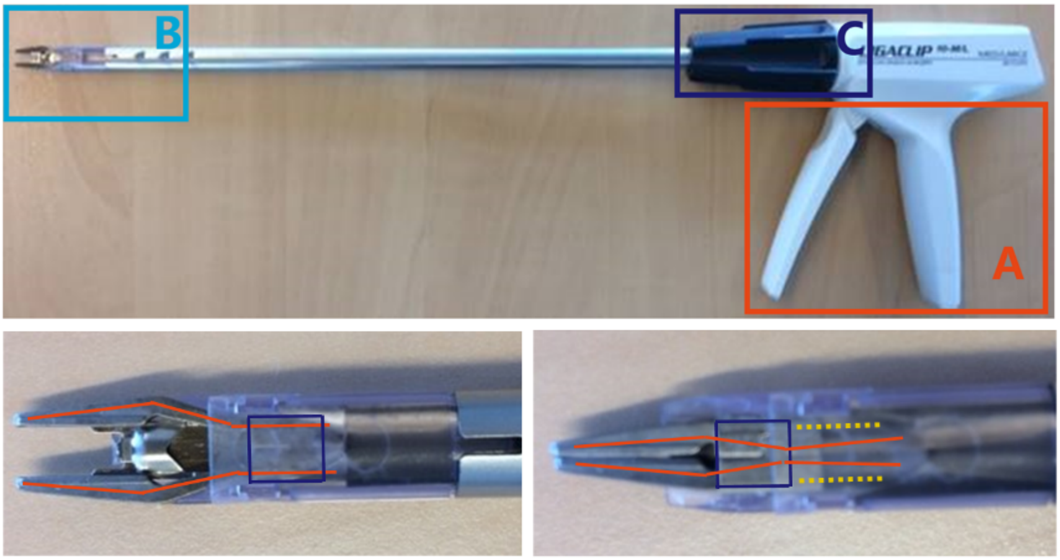


Figure 4.4: Ligaclip with tip closing mechanism relying on frictional force. (Lower two) Purple box moves along the yellow path, contact point of purple component with orange part slides along the inclination forcing the orange jaws to compress.

The compressing feature of this device was the origin to develop the concept that is presented in Figure 4.5. The yellow component can move linear along shafts axis. This movement will express force on the inclination of the red components, resulting in closing motion of the tip.

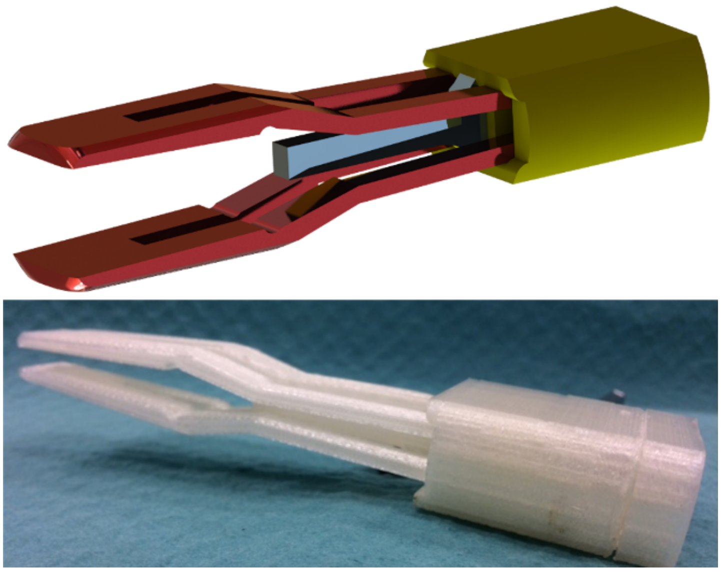


Figure 4.5: Yellow components initiates the motion forcing the red part to compress. Grey part represents the blade that will dissect the vessel.

4.4. CUT-OUT

LIGASURE ATLAS, VALLEYLAB

Similar to the mechanism described in the previous section, there are two jaws at the tip that articulate in order to reach the closed or open state of the tip. The actuation is achieved by pinching the handle (orange A), this causes the purple dot in bottom images in Figure 4.6 to translate backwards towards the handle. The angle between the chosen cut-outs and shafts axis determines the required path length of the purple dot.

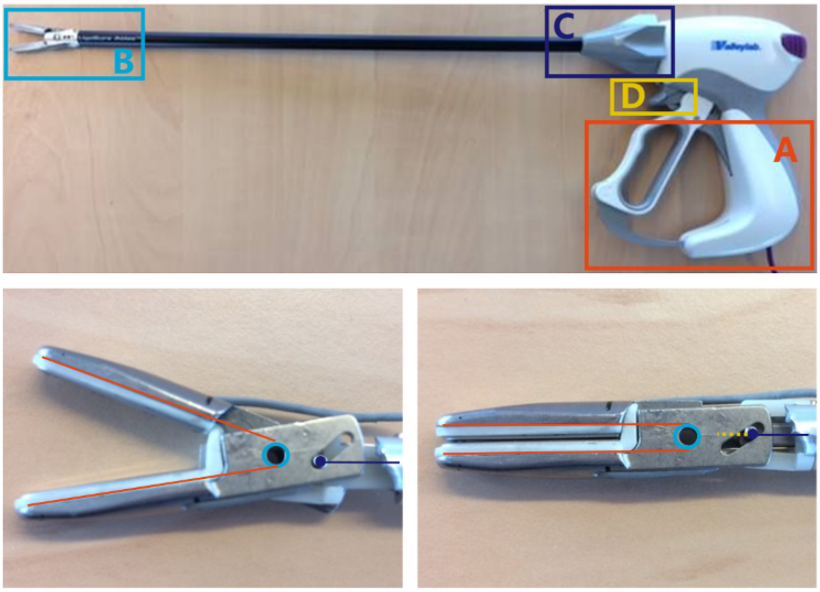


Figure 4.6: (Lower images) Purple component initiates the motion. As a result of the cut-outs, translational motion of the purple dot forces the orange tips to rotate.

The LigaSure Atlas was the starting point for the concept depicted in Figure 4.7. The lower image shows the improved version and consists of four components. As can be seen in both top images in Figure 4.7, both jaw components have a part left from the rotational point between which the blood vessel is to be clamped. The part on the right of the rotational point has the cut-out that makes it possible to translate linear motion into rotation of the jaws. The rotation point in the jaws are held in place by a so called bearer, this component is added and visible in bottom image of Figure 4.7. The linear cut-out in this component guides the pushing part that is located in the center.

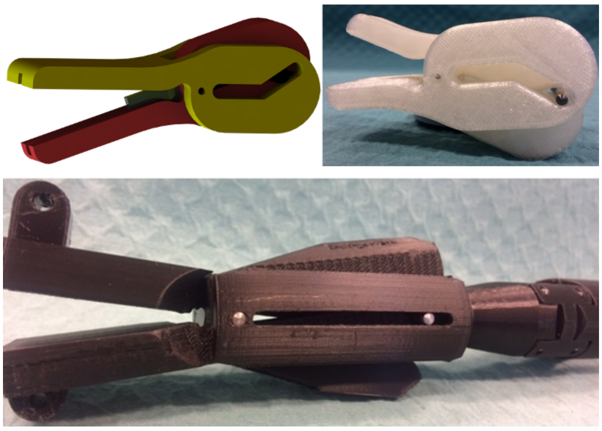


Figure 4.7: (Top left) CAD drawing of tip components. (Top right) 3D-printed concept for mechanical evaluation. (Bottom) Improved concept ready for experimental evaluation.

4.5. DISCUSSION

This chapter started of with four concepts that were to be analyzed, adapted and chosen which concepts will advance to next phase of the development. Section 4.1 analyzed the *One-jaw*, an important adaptation was made to the articulating jaw by including a rounded cut-out to increase the required actuation displacement for closing the tip. This specific rounding effectuates a gradual motion of the articulating jaw.
The *Punch* concept scored high with the *Harris-profile* in section 3.2.3. Looking into the specific function analysis of the interaction of the components it was concluded that it was not possible to incorporate the sub-function *Dissection* with the same components that are characteristic for this design. Therefore the potential of this concept into becoming the ideal mechanism comes to an end.
The third concept that is analyzed is the *Overtube*. This mechanism uses a surrounding tube that is pushed over the elongated jaws enforcing them to compress. To merge this proven concept for applying clips with the sub-function of *Dissection* the cutting blade component is fixated to the outer tube. To realize this it is essential to keep various aspects in mind such as, outer diameter, distance from tip of blade to compressing tube, inclination, fixation method and point. In section 4.3 this concept was adapted for the specific application of this project, resulting in a significantly longer tip. Exactly this considerable length is the break point for this concept and therefore disqualified in the race for becoming the ideal concept.
The last concept is evaluated was named after it's characteristic mechanism, namely the *Cut-out*. This concept has a cut-out that specifies the relation between displacement of actuation component and angular displacement of the jaws. The jaw-components have a mirrored cut-out making the counterparts move synchronously. The cut-out can be split in two sections, the first section is inclined and coordinates the angular displacement. The second section is an elongation of the cut-out. More specifically, a cut-out linear along the axis of the component. Therefore, if the jaws are closed the elongated cut-out is aligned with the shafts axis, making it possible for the linear motion of a blade to slide through the the jaws.

4.6. CONCLUSION

This chapter of the synthesis of the tip mechanism can be rounded up. Section 3.2.3 analyzed and selected the best four concepts with the potential of being implemented in the final design for this project. This chapter starter by analyzing these concepts and incorporate with the requirements relevant for this project. The outcome of this chapter is presented in Figure 4.8, the two concepts that are still in the running of becoming the ideal mechanism for the final design

Figure 4.8: The two concepts that have been analyzed, adapted and advance to next phase of concept selection. (Top) The One-Jaw. (Bottom) The Cut-Out

5

TIP EVALUATION

5.1. INTRODUCTION

In the previous chapter two concepts stood out as the most suitable designs for becoming the mechanism to achieve the goals that were set. Out of these the final concept will be selected that will become the tip mechanism for the proof of concept that will be developed in later chapters. The goal of this experiment is to compare the sealing mechanisms by looking into the physical interaction by applying force to close the jaws .
Data was gathered by measuring the actuation force, linking it to the force measured in the tip of the mechanisms while keeping track of the sealing trajectory. A housing is developed to create constant and equal circumstances for all the trial irrespectively of the concept. The challenge lies in two factors that should be tackled in order to be able to compare the mechanisms. One factor is the difference in number of moving components that make the tip of the concept to seal. For the *One-Jaw* only the upper component make the tip to seal, as for the *Cut-out* concept both components move toward each other. The second factor that creates restrictions to the method of evaluation are the measuring instruments that are either suitable for linear or rotational motion. The housing that is burdened with this task is depicted in Figure 5.1.

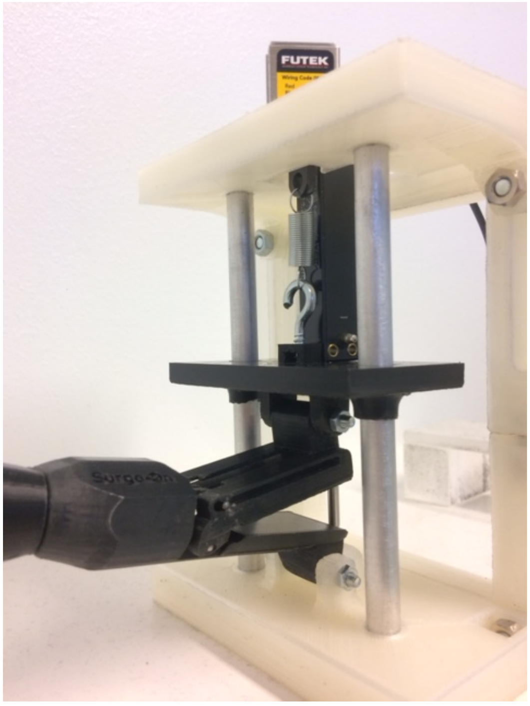


Figure 5.1: Experimental set-up with force sensors, tip mechanism, potentiometer, and sliding table attached to sensor with spring.

5.2. MATERIALS

In order to analyze the mechanical performance of the sealing concepts an experiment is carried out that provides information about the force translation in the two to be compared concepts. The picture shown in Figure 5.1 visualizes the setup of this experiment at *time* = 0.

The schematic experimental setup in Figure 5.2 provides a more clarifying visualization of the system. The actuator here is humanly powered and registered by the first load cell S_1. The second load cell, S_2, is placed at the top, measuring the the forces that act on the sliding table. Determining the location and displacement is done with a liner potentiometer that has a fixated point to the bottom and sliced along with the sliding table, this sensor is depicted as S_3 .

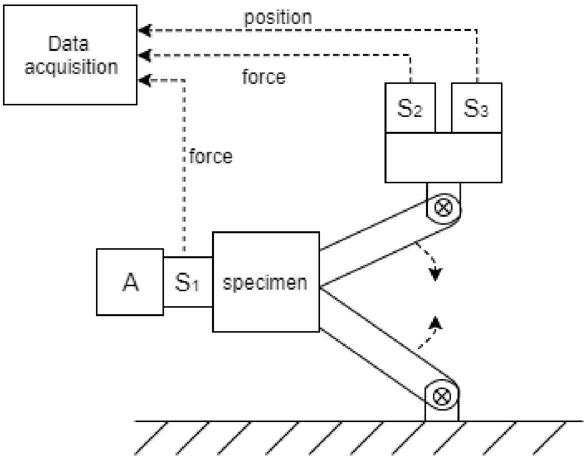


Figure 5.2: Instrumentation diagram showing the measured closing motion of the specimen. (A= manual activation, S1= load cell 22N, S2= load cell, S3= linear potentiometer)

Sensors

The sensor that measures the input force is a Futek miniature S Beam Load Cell, an example sensor is depicted in figure 5.3 with matching amplifier. The load cells and amplifiers convert the amount of exerted force over the load cell into an output in Volt. The sensors are calibrated by applying masses of `m=[0, 200, 400, ..., 1000]` for sensor 1 and sensor 2 with masses `m=[0, 100, 200, ..., 500]`. The corresponding force in newton is calculated with Newton's second law, formula 5.1. These values are put alongside the measured voltage output of the sensors in Table 5.1. A scatter-plot is created with the data for the voltage and newton variables. Formula 5.2 shows the formula for a trendline, in this formula a is the slope and b is the intercept, whereas variable x is the measured voltage yielding the measured force y acting on the sensor. Note that in Figure 5.2 both lines have a R^2=1 indicating a good fit of the line to the data.

$$F = \frac{m \cdot 9.81 m/s^2}{1000} \tag{5.1}$$

$$y = ax + b \tag{5.2}$$

Figure 5.3: The Futek miniature s Beam Load Cell.

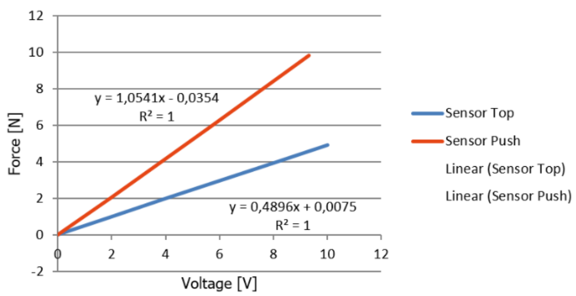


Figure 5.4: Calibration of both sensor visualized in a graph. Sensor push indicating the sensor placed at location of human powered initiation. Sensor Top representing the trendline for the values of the sensor placed to measure the compressing force.

Table 5.1: Table with all the measured valued for calibration

Sensor 1			Sensor 2		
mass	newton	volt	mass	newton	volt
0	0	0	0	0	0
200	1.962	1.91	100	0.981	1.99
400	3.924	3.78	200	1.962	3.96
600	5.886	5.64	300	2.943	5.99
800	7.848	7.47	400	3.924	8.02
1000	9.81	9.32	500	4.905	10

POTENTIOMETER

The potentiometer used in this experimental setup is depicted in Figure 5.5. The outer end of the shaft is fixated whereas the black-housing component is locked into the sliding table proving data of the location and displacement. Th potentiometer is connected to a NI myDAQ USB 6008, using the +5V, GND and AI2 ports.

Figure 5.5: The Sakae linear potentiometer 13FLP100A.

The acquisition of the data is achieved using a NI myDAQ device that is connected to a PC. All the measurements are stored on the PC. Data analysis is preformed using Matlab R2016a software.
Two design concepts are chosen as the specimen to be evaluated in this experimental set-up and arose from Chapter 4.

5.3. METHOD

5.3.1. EXPERIMENTAL DESIGN

The dependent variables in this experiment will be the forces expressed on the moving table and the location of that specific 'table'. The trajectories of the red line in Figure 5.6 is the measured force indicating the required force at actuation point and measured with sensor 1 to close the tip. The blue line represents the compressing force at the outer tip measured with sensor number 2.
The independent variables that determine the difference in these values and ratios is the specimen that is examined. Two specimen will be used in sequence, with each being examined in 19 runs, this allow a total of 38 runs.
The experimental setup illustrated in 5.1 shows the starting position for every run. In order to ensure equal runs and minimize the chance of human error the runs are done according to a protocol.

5.3.2. PROTOCOL

Ideally, higher quality specimen would be used for the runs to minimize friction. It was decided to prepare specimen that could replicate the closing mechanism multiple times. To ensure the correct relation of the measured compressing force acting on the table with the displacement it would be perfected by using a new spring for every run of control whether the spring constant has maintained unchanged. To limit the influence of re-use, unused similar springs were used for each specimen, meaning that both go through the wear of 19 runs during the experiment. Irrespectively of the specimen, the runs were done according the protocol outlined in Table 5.2.

5.3.3. DATA ANALYSIS

During this experiment a sequence of data point is made of the forces acting on the specimen and measured position over time. This acquisition of data will provide information to determine the required forces to initiate and achieve a closing state of the tip in relation to force expressing in opposite direction of the closing motion.
The course of the retrieved data is visualized in Figure 5.6, 5.7. These two plots are an example of one run. Figure 5.6 depicts the measured forces, the red line showing the measured data at the input location of sensor 1. The most left two circles indicate the moment where displacement is initiated based on the displacement noted in Figure 5.7. In this same Figure the most right circle indicated the termination which is also indicated in Figure 5.6.

Table 5.2: Protocol for a run for evaluation of closing mechanics.

1	Determine desired starting point of the upper futek
2	Control whether the slider can freely slide.
3	Place pushing components until almost in contact with futek pushing part.
4	Control if starting value is correct
5	Start measurement.
6	Start moving pushing components.
7	Stop at desired location of pushing component.
8	Retract pushing component
9	Stop measurement.

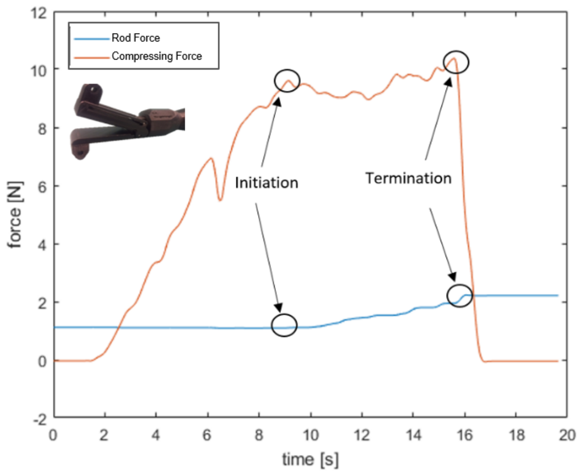


Figure 5.6: Data from an example run with the Single-Hinge concept. The area of interest is between the marked area's Initiation and Termination. This plot shows the output for both the Futek sensors.

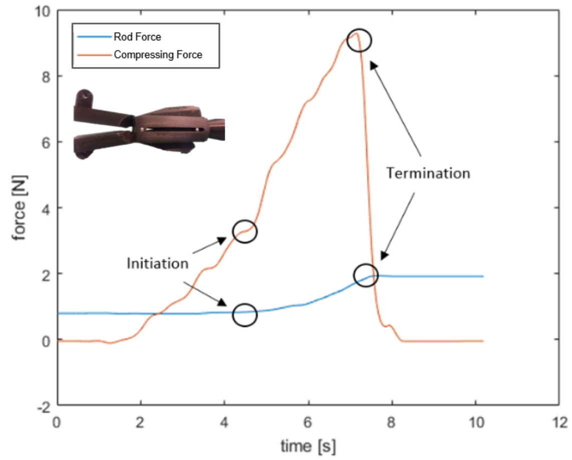


Figure 5.8: Data from an example run with the Cut-Out concept. The area of interest is between the marked area's Initiation and Termination. This plot shows the output for both the Futek sensors.

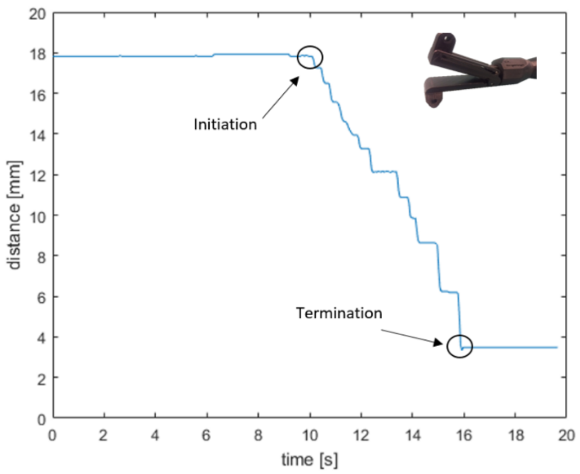


Figure 5.7: The plotted data is the output from the potentiometer during an example run with the Single-Hinge concept. The point labeled with Initiation is the moment the jaws start to close. Label Termination is for when the jaws are closed.

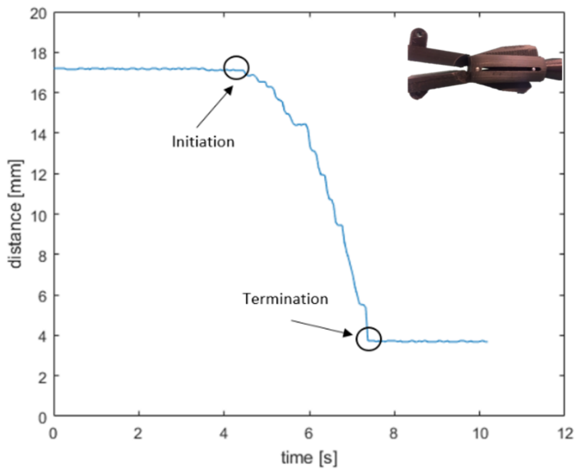


Figure 5.9: The plotted data is the output from the potentiometer during an example run with the Cut-Out concept. The point labeled with Initiation is the moment the jaws start to close. Label Termination is for when the jaws are closed.

5.4. RESULTS

A total of 39 runs have been conducted and included in this Chapter. Te raw data of the characteristic progress of a run with the *One-Jaw* specimen is introduced as an example run in section 5.3.3 with Figures 5.6 and 5.7. The counterpart of this plotted raw data for the *Cut-Out* specimen are visualized in Figure 5.8 and 5.9. Noteworthy is to mention that the circle place in these figures are base on the first change in angel in the graph of the potentiometer. Meaning that the moment of displacement of the 'sliding table' is the exact same moment as of which the values are derived from the graphs with the force values.

Table 5.3: Mean values of force needed for initiation at Time 1 and required mean force at achieving closing state of tip at Time 2.

	Initiation [N]	Termination [N]
Single-Hinge	9.61	9.23
Cut-Out	4.57	8.99

The values of the *Initiation* and *Termination* for all the runs were collected and analyzed to provide a mean value. The mean of these values is presented in

Table 5.3, the distribution of the data collected at *Initiation* and *Termination* is displayed with a boxplot in Figure 5.10.

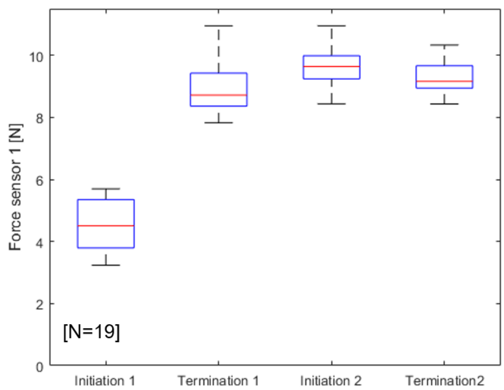


Figure 5.10: Boxplot with values measured at initiation and termination. Two boxplots on the left are based on measurements on concept Cut-Out. Right two, boxplots from measurements from the Single-Hinge concept.

Table 5.4 shows the mean maximum force per specimen and the corresponding boxplot's for the sensor 1 and sensor 2 are shown respectively in Figure 5.11 and 5.12.

Table 5.4: Maximum forces measured with sensor 1 and sensor 2 for both specimen. Values are the mean over 19 runs.

	Sensor 1 [N]	Sensor 2 [N]
Singe-Hinge	10.25	2.32
Cut-Out	9.25	1.94

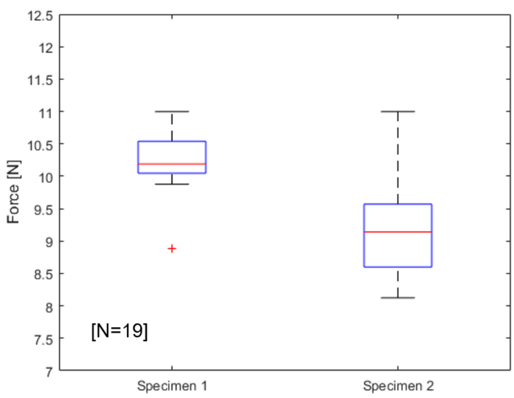


Figure 5.11: Box plot of the maximum force measured at the rod. Specimen 1 representing the Single-Hinge concept. Specimen 2 representing the Cut-Out concept.

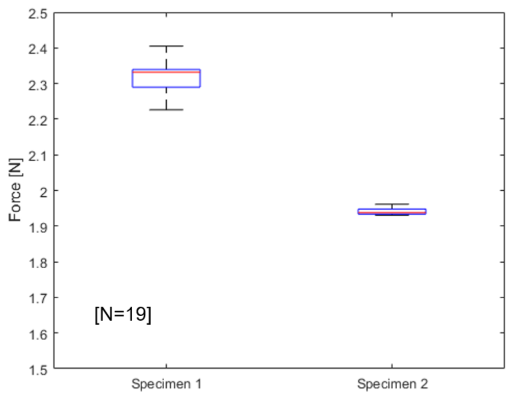


Figure 5.12: Box plot of the maximum force measured at the compressing sensor.. Specimen 1 representing the Single-Hinge concept. Specimen 2 representing the Cut-Out concept.

5.5. DISCUSSION

INTERPRETATION OF THE RESULTS

In the previous section all the information regarding the influence of the measured input force and the compressing force with location was presented. The most important findings can be categorized in **three** subjects. First of all, the required force over time, Figure 5.10 clearly shows that the *Cut-out* has an effect on the required force when comparing the initiation of the closing trajectory with achieving closed state of the tip. Whereas for the *One-Jaw*, the required force that is applied is equal for both the initiation and termination. This finding is noteworthy as this phenomenon will influence the feedback experienced by the user of the final concept.

The second finding to point out is the efficiency of the translation of the force. Table 5.4 already gives a head up that the maximum applied forces and compressing force experienced at the tip of both specimen do not differ from one another that much. This impression is supported and reinforced with the boxplots in Figure 5.11 and 5.12, note the scale of the y-axis.

Thirdly, both specimen reach the position that is determined as 'Termination' shortly after reaching the maximum force, this is clearly visible in in the figure representing the measured forces and distance. After achieving the maximum force it stands out that there is a steep drop is force acting on sensor 1. Explanatory, as both specimen are designed with a cutout making it possible to accomplish the dissection of the vessel that theoretically should be located between the jaws. Meaning, the components translating the actuating force into rotation of the jaws will have an accumulated force of approximately 10 N that suddenly has a drop in resistance. Therefore, the potential energy is transformed to kinetic energy and overshoots.

LIMITATIONS
This experiment has some limitations that could have influenced the validity of the results. First, in the set up design an acting force was overlooked. An earlier version of the set up was designed with a fixated position for the shaft part of the specimen. As one of the specimen has two jaws that will be rotating in order to close the concepts would be having different circumstances during runs and thus not suitable for an comparison experiment. Therefore, the set up was changed into linking the specimen to the experimental housing by creating two similar rotation point for both the specimen. This solved the initial problem, but created the problem of a freely moving shaft of the specimen. The fact that this specimen will have the gravitational force creating an momentum reducing the ability of free sliding for the 'sliding table'. Nevertheless, the runs were completed by increasing the number of runs and providing support to the shaft of the specimen. Furthermore, the specimen are constructed with additive manufacturing. The available technique was not ideal and for future experiments it is preferred to use devices with higher quality.

IN SCOPE OF PROJECT
Putting this research in the scope of this project will point out some essential aspect that need to be considered. Starting of with the transferal of the input force to measured output. To put it in perspective experimental runs were done with WECK® metal ligation clips developed by HORIZON™. These resulted in a measured maximum force of 6N. Therefore, if current circumstance are maintained the input force will have to be increased by a threefold. As the specimen were developed with the purpose to be tested in similar circumstances, neither of the tips has been optimized. This is a step that will have to be undertaken if the choice for the most suitable tip mechanism is made. Furthermore, the results of this experiment provide useful information related to the transferal of input force, these specifications are required for the future steps of doing a finite element analysis (FEA) and considering which material to use. Some commonly used materials are titanium and surgical stainless steels. More specific, austenitic 316 stainless and martensitic 440 and 410 stainless steel.

5.6. CONCLUSION

With the results achieved in this experiment there can be concluded that both concepts do not differ that much in required maximum force and transferal of the input force. Therefore no decisive factor can be pointed out directly from the results. However, an aspect that varies between the concepts and should be elaborated further is the length of the tip. The *Cut-Out* concept requires a significantly longer tip length. Two reasons can be designated for this, the mechanism that transform the lateral actuation into rotation has to be allocated in line with the fixed rotation point. As for the *One-Jaw*, this mechanics can be placed behind, on top, or in front of the rotation point. Additionally, this disadvantage is exacerbated as the mechanism is elongated with a cut out to enable the actuation of the blade through the tip. Resulting in a significantly longer tip. Besides the fact that the user pointed out that the tip should have a maximum length of 25mm, the longer tip length enlarges the momentum. As the final concept is supposed to be steerable a momentum is created if the tip is not aligned with the shaft, increasing the tip length creates a bigger arm. Hence the decisive conclusion of selecting the *One-Jaw* as the concept that is to be implemented in the final concept.

6

Handle Synthesis

In the handle different functions come together. This is the interface for the surgeon to control the separate function incorporated in the device. The goal is to design a single-handed controllable component while remaining simple and intuitive to assure effortless implementation in the procedure.
In section 3.2.4 an explanation was given of the method of establishing the design of the *Handle*. It was stated that the leading factor that will be considered is the selected concept for the sub-function of creating an interference between the activation created with the handle for closing the tip, and the activation with the handle to dissect the vessel.
The top ranked concepts from section 3.2.4 are further analyzed, adapted and advance to a new selection process. This process is supposed to yield the most suitable mechanism that is incorporated in the final design.

6.1. Rotating Cam

The designed that is developed and analyzed here arose from the principle of a retractable clicking pen. Essential for this construction are the three components and a spring to build up tension. The particular contour of the borders that come in contact with each other decides to which position the tip is moved. This concept is depicted in Figure 6.1. Top left image visualizes the mechanism in the top of a pen. This concept is adapted to work with the requirements for a handle specific for this project. A more clarifying visualization is provided on the right side of the figure. Labels are given to essential components, A is part of the housing and consists of pins to align and guide components B and D. Component B moves in linear direction of the shaft and is able to rotate about its axis. The motions are is controlled by the contact of the cam-cutouts on components A and D. Component D is controlled by the handle, component C. Image I shows the positions in resting phase with open jaws at the tip. Image II shows the position after the first activation of the user, component D is pushed forward up to to point that the wing of component B passes the alignment pin of component A. This is the phase component B rotates into the next position. The second activation is depicted in image III with, label E indicates the rotational displacement of the handle.

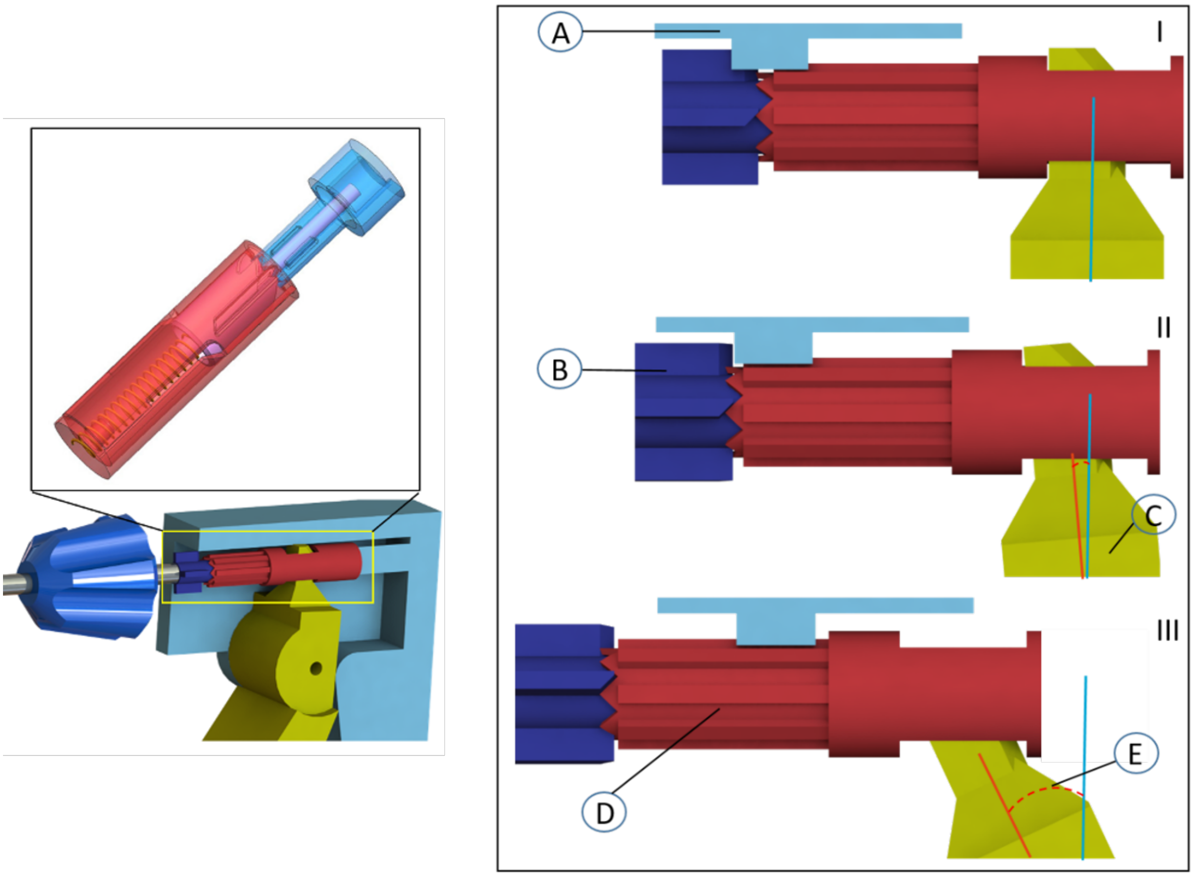


Figure 6.1: (Top) An example of the mechanism in a double-click pen. (Bottom) The retractable pen-mechanism inspired the design of a similar mechanism in the handle components, ensuring the desired position when closing the tip and actuating the dissection motion. The procedure can be terminated by rotating the blue component clockwise. The right three images represent three of the essential phases. Label A is for the housing, label B is for component that rotates due to contact area between cam designs of components A and D. Label C is for the handle. Label D is for the component that moves in linear direction, transferring the motion of the handle to the interacting mechanism. Label E is for the angle the handle has, indicating in which phase of closing it is. Image I is with opened jaws. Image II with closed jaws but no dissection. Image III closed jaws and fully displacement of the blade for dissection.

6.2. RATCHET

two existing internal concepts are analyzed and potentially adapted if possible. An example of an instrument with a ratchet as design to achieve two stated of locking is the AdTec® needle holder by B. Braun Medical with an axial handle, Figure 6.2. The interesting aspect of this instrument for this project is not so much the ergonomics of the axial handle as the ratchet mechanism. This mechanism consists of two essential components that will be clarified next. The image on the right is zoomed in on the pin, this pin can rotate if force is applied, but in resting phase moves back to the exact position that is depicted on the right image. The second essential component of the ratchet mechanism is built into the counterpart of the handle, therefore this is not clearly visible in Figure 6.2. The essence of that part is that it is shaped to create a guiding path for the pin, making it possible to lock in the desired positions and unlock when needed.

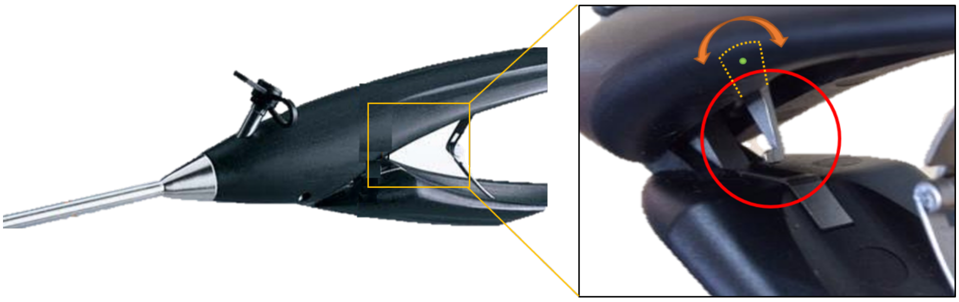


Figure 6.2: The AdTec® needle holder by B. Braun Medical with an axial handle. (Right) Zoomed in on the ratchet mechanism, the circled pin can rotate if force is applied. Build in the counterpart of the handle is the guiding path for the pin if the handle is compressed. Ensuring the handle locks and unlocks.

Although the contours of this concept are not clearly visible with the AdTec, it is still an non-internal design. Therefore, sterilization should be achieved without having to clean the inside of the handle. A comparable ratchet mechanism has been developed by VALLEYLAB, but then internal of the handle. In the next section this concept will be elaborated and clarify the contour of the component that creates the guiding path for the pin.

LIGASURE ATLAS, VALLEYLAB

The LigaSure depicted in Figure 6.3 is an example of triggering mechanism inside the housing. Squeezing the handle will initiate the jaws at the tip to close, at the same time in the handle a trajectory is followed. This so called ratchet-mechanism is shown in the right bottom image with a red dotted line. The accumulated tension with the spring makes the grey pin lock in the cavity, ensuring the tip will not release the vessel until the user pushes the pin out of the cavity to release the lock and therefore terminating the clamping of the jaws. In this specific example there are two handle that only can be squeezed one after another.

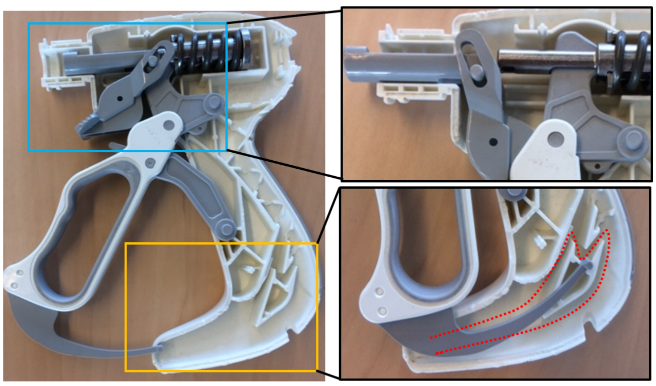


Figure 6.3: Double actuation mechanism in handle of LigaSure Atlas, form VALLEYLAB. (Right top) The second actuation is controlled with a second trigger. (Right bottom) The red dotted line represents the path that the grey component follows. This shape ensures that two motions are needed to open the tip again.

6.3. DEFORMATION

A concept created by Silex Medical was further analyzed and adapted into a possible construction for the separation of the two actuation's required for sealing and dissecting. The proven concept of the Onyx by Silex Medical is depicted in Figure 6.4.

Figure 6.4: Onyx locking mechanism by Silex Medical.

Adapting that concept for the procedure that this project focuses on yield a design that could like something like the image shown in Figure 6.7. This figure shows the three essential phases of the working mechanism of this handle. Phase I is the resting phase in which the jaws are in opened. Actuation by the user will move the handle into phase II, the two pins will collide and notify the user phase II has been established. Phase III can be reached by applying additional force, forcing the pins to slide over each other. Labels A indicate the rotational displacement, whereas label B shows the displacement of the pin that transforms the rotational force into linear motion.

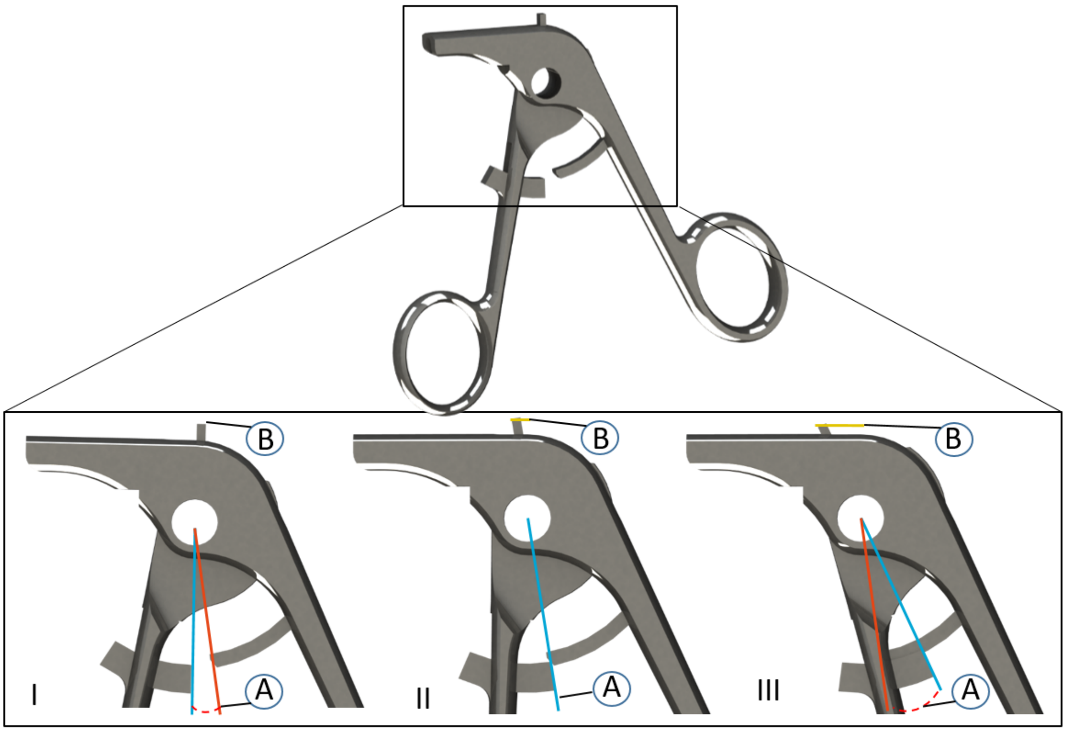


Figure 6.5: Adaptation of the Onyx locking mechanism. Each image indicates one if the three essential phases. Image I is with open jaws. Image II with closed jaws but no dissection. Image III is with closed jaws and fully activation of the blade after the pin has deformed.

6.4. CONFIRMATION

Incorporating a mechanism that forces the surgeon to actively confirm to accept the dissecting phase is of great value if the purpose if to minimize the chance of undesired actuation of dissections.

The Orbitaris bipolar forceps has a handle that rotates independently of the shaft. The surgeon can lock the handle in the desired position by using the pin that goes lateral through the handle. This specific instrument is depicted in Figure 6.6.

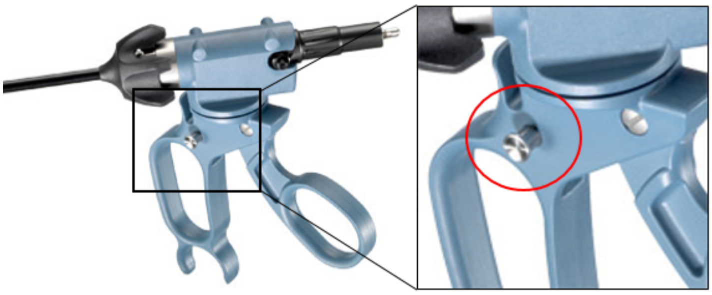


Figure 6.6: ORBITARIS monopolar laparoscopic forceps with a 360 ørotating handle, with lock to maintain rotated position.

Although this principle has been applied to lock the rotation of the handle, a similar method has the potential to be implemented for separating two actuation's within one handle. Various methods can be devised to achieve the requirements for this sub-function. This section limits the development to the principle of using an additional action of the user, rather than designing the best possible use of a button or any other method of unlocking the possibility to proceed to the next actuation. The design to visualize this concept is depicted in Figure 6.7. Three images are depicted in this figure. Image I shows the resting phase wherein the jaws of the tip are open. After the first actuation Image II is reached, in this phase the handle can not be compressed any further because of the blockage created by a knob which has label A. After moving component A the handle can be compressed further to control the dissecting mechanism. Label B is given to the stated of compressing of the handle.

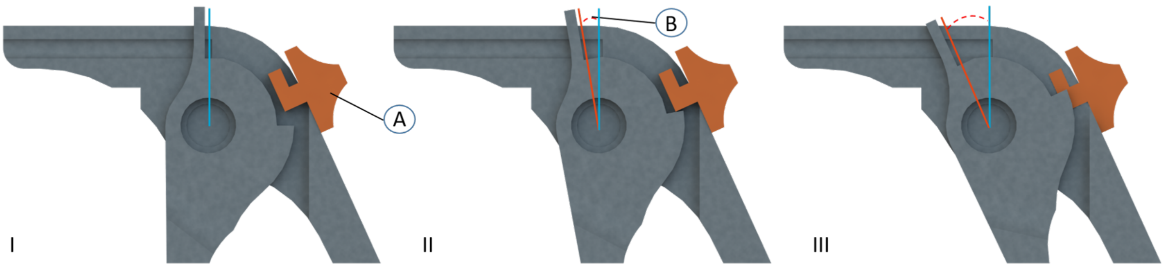


Figure 6.7: Adaptation of the Onyx locking mechanism. Image I is with open jaws. Image II with closed jaws but no dissection. Image III is with closed jaws and fully activation of the blade after the button has been displaced by the user.

6.5. DISCUSSION

In chapter 2 & 3 the problems and goal are decomposed and translated into sub-function. Section 3.2.4 focused on the sub-function of the handle and a systematical selection process yielded four concepts that were to be analyzed further.
The current chapter started of with the *Rotating Cam* concept. This is a concept that has proven to be suitable to repeatedly lock in two phases. This mechanism is adapted to meet the requirements.
The *Ratchet* concept is a design that is suitable for locking and unlocking the handle, and thus the jaws, at fixed position and after the preset path has been followed. Meaning, the red dotted line in the right bottom image in Figure 6.3 shows the path the pin will have to following to lock and unlock. This dotted line has two peaks, it is up to the designer to determine the height of the peaks, and therefore how much the user needs to compress the handle before it is locked. Putting this principle into the scope of this project, will induce the conclusion that this concept is not suitable to be incorporated. Referring to the fact that both peaks will be linked to one of the sub-function. The first peak ensures closing of the jaws, linking the second peak to dissecting. Advantage is that one can only dissect after sealing, but after sealing it is necessary to dissect to open the jaws. The problem that arose can trigger the mind of an engineer to come up with a solution, but it will nevertheless increase the complexity of the concept. Another disadvantageous aspect of this concept is the valley between the two peaks of the dotted red line. To be more specific, the necessity of the user to significantly drop pressure on the handle before being able to start dissecting. This additional action requires a time frame that will accumulate on the total time window required to achieve sealing and dissection.
Section 6.3 aimed on analyzing the method that is being called the *Deformation* concept. Characteristic for this concept are the two pins, each attached to one handle. These pins can be designed to slide alongside up to a desired position where deformation increased the resistance that is experienced by the user. Positioning of this mechanism, on the other hand, can be a bit of a dilemma. Factors playing a role would be the possibility of sterilizing all the areas, the users hand that should be able to work freely without risking damage, the strength of the pins, position is relevant for the risk of being damaged.
The last concept that is considered is named after the requirement of demanding a confirmation. This method separates two activation's and forces the user to actively approve the start of dissection. As mentioned in section 6.4, this can be realized in various ways. Figure 6.7 visualizes one method, wherein an displacement of the orange button by the user is required to go from phase II to phase III. Relating this process to the procedure of sealing and dissecting a blood vessel some disadvantages arise. When using the instrument it will be in close contact with the patients thorax, therefore it can be experienced as problematic if the switch is place on one of the sides. Another downside of placing a switch on a side is the fact that surgeon's can be both left and right handed, therefore the placement will not be equally ergonomically convenient. Besides deciding the location of the switch, incorporating it into the handle will introduce sterilization hazards. The last noteworthy disadvantage is not so surprising considering the name that was given to this concept. Confirmation by actively giving approval means the introduction of the requirement of an additional action of the user. As a goal of this project is to make the procedure more time-efficient, adding an action is undesirable.
Bringing structure to the discussion of the previous section is done with a Harris-profile, Table 6.1. The concept that ends up with the highest score is *Deformation*. Therefore, this concept is chosen to advance into the next phase.

Table 6.1: A Harris-profile to give structure and function as a recap for the discussion.

Handle *Requirements*	*Weight* [1-3]	Rotate Cam rating	Rotate Cam score	Ratchet rating	Ratchet score	Deformation rating	Deformation score	Switch rating	Switch score
Sterilization	2	1	2	3	6	4	8	2	4
Time-efficiency	2	3	6	2	4	4	8	2	4
Safety	2	5	10	4	8	2	4	4	8
Incorporation	1	3	3	4	4	4	4	2	2
In scope of project	3	2	6	2	6	3	9	2	6
	Total Score	**27**		**28**		**33**		**24**	

7

MODELING

7.1. INSTRUCTION

Up to this chapter all the sub-functions were elaborates, and where necessary further analysis and adaptations were made. Concept are scored on requirements and the most suitable concepts are selected. In this chapter these concepts come together to create the final model. Figure 7.1 is a schematic representation of how the sub functions are linked and come together as a final design. Section A represents the tip mechanism and will be elaborated first. Section B consists of the SATA mechanism, the shaft, and part of the handle. Section C will elaborate the mechanism in the handle further.

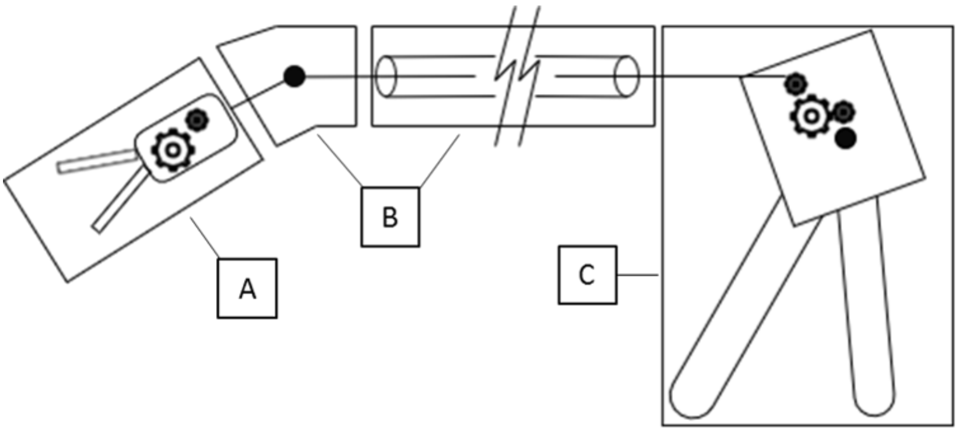


Figure 7.1: Schematic representation of the mechanism in the tip. Section A is the tip which this mechanism, linked to the steering and shaft components, labeled B. Section C is the handle design and mechanism that ensures the separation of actions.

7.2. TIP

During this project the tip mechanisms have thoroughly been analyzed. The *Single Hinge* concept is selected as the most suitable and has been modified to incorporate the actuation of the blade control. In the process of designing the tip a choice has to be made over the pattern of the cut out which will guide the tip to both open and close, and makes the transition possible of jaws-control to blade-control. Figure 7.2 shows the three possibilities for the cut out patterns. The top two images show the schematic representation of a *Single Hinge* concept and a CAD design. The complexity of this lies in the fact of the combination of a rotational motion with a linear motion. The lower jaw is a fixed rigid body, it is connected with the articulating red jaw at a pivot point which is schematically represented with the crossed circle. The articulating jaws is pushed and pulled with the yellow component in image II, and in image I with the black horizontal line. This horizontal line can only move horizontally, and therefore there will be a change is distance between the black dotted contact point and the pivot point. A proper cut out will guide the contact point. The most left column in the table shows three of the states the jaws can be positioned in. The contract point displacement can be place on three locations in relation to the pivot point. Each column represents one is this positions, at the bottom is a schematic representation of the shape that is required to guide the tip.

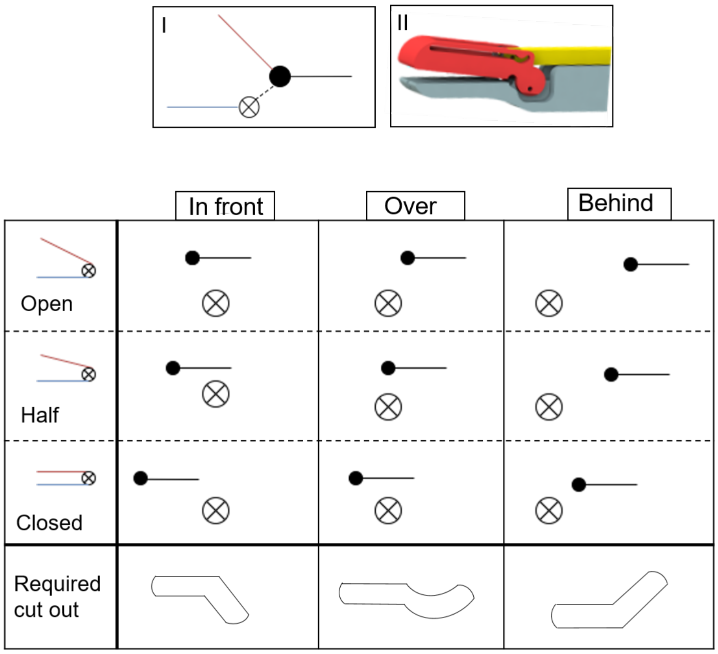


Figure 7.2: Schematic representation of design analysis for placement of the contact point. Top, Image I and II a schematic representation and CAD design of Single Hinge concept. Table, left three of the states the jaws can be in. Position of the contact point between the pushing element and articulating jaw in relation to the pivot point.

A requirement that has been recurrent in the selection process of the tip is the total length of the tip. The length of the tip is defined as the outer point at the end of the tip to the connection with the SATA mechanism. It has previously been stated that it is preferred to reduce this length. Therefore, the positioning of the contact point elaborated in Figure 7.2 is preferably place *Over* the pivot point. This will reduce the required space and still make it possible to actuate the blade. The final CAD design of the tip mechanism is shown in Figure 7.3.

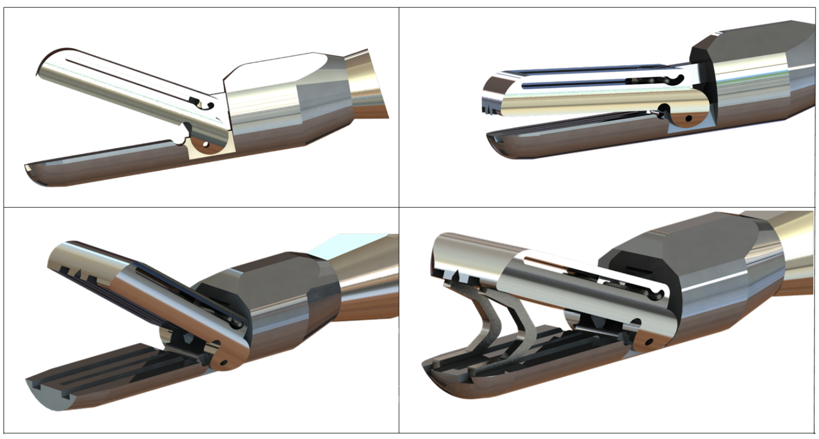


Figure 7.3: Final design of the tip. Top left, side view of opened jaws. Top right, side view of almost closed jaws. Bottom left, isometric view of opened jaws. Bottom right, isometric view of opened jaws with surgical clips.

FINITE ELEMENT ANALYSIS

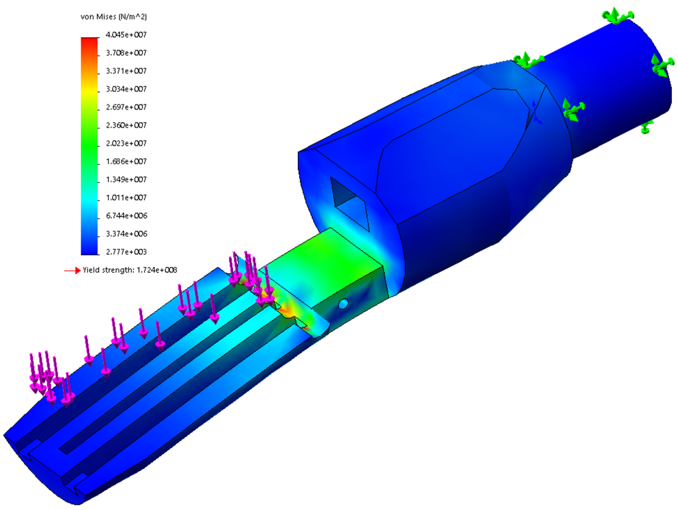


Figure 7.4: Impression of the Finite Element Analysis of the non-articulating jaw, executed in Solidworks. This method is used to evaluate the stress distribution.

Finite Element Analysis (FEA) is performed using Solidworks to evaluate the stress distribution throughout the tip design. In this section two example FEA pictures are shown using stainless steel AISI 316 as selected material. Figure 7.4 shows the von Mises stress in the non-articulating jaw of the tip. Figure 7.5 shows the FEA for the displacement with the acting forces. This method of analysis helps detect the weak spots in the design.

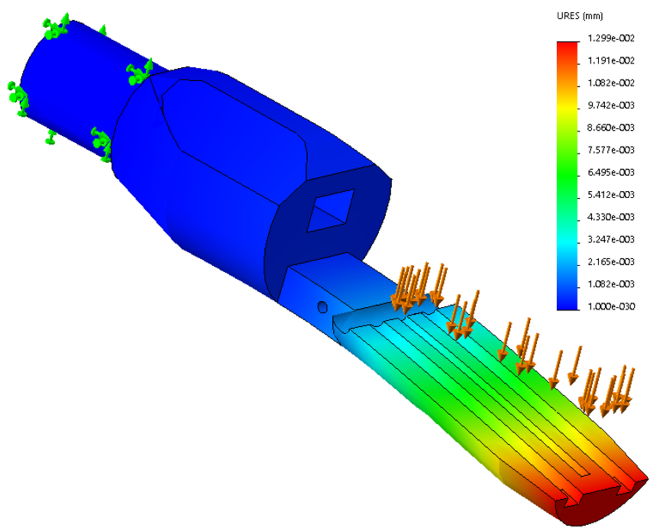


Figure 7.5: Impression of the Finite Element Analysis of the non-articulating jaw, executed in Solidworks. This method is used to evaluate the deformation.

7.3. STEERING

Making the tip steerable has been an important aspect of the instrument design. In consultation with the cardiothoracic surgeon it was defined that the tip should be able to articulate between 50 and -50 degrees in lateral direction. The mechanism that is chosen for this sub function is the Shaft Actuated Tip Articulation Design (SATA). This is a design that is provided by Surge-On Medical. How the mechanism function has been elaborated earlier, but the essence lies in the rotation of the outer tube. Cut outs in this tube guide the two connection components to move laterally of each other in contrary direction. This ensures the hinge to either articulate left or right.

Figure 7.6 shows an exploded view of the essential components in the SATA design. The smaller top four components can be categorized as the hinge parts, the upper one is connected and fixed to the tip design. The left tube is the outer tube that include the cut outs and transfer the rotational motion to lateral motion of the hinge parts. All the components at the bottom are parts that connect the shaft to the handle and allow the user to rotate the tube. The right tube connects the motion that is initiated at the handle by the user, to the tip.

All these components put together form the connection to the handle, the steering wheel, and parts for the hinge to ensure the tip can articulate. The assembly of all these components is shown in Figure 7.7.

Figure 7.6: Exploded view of components from the SATA steering design.

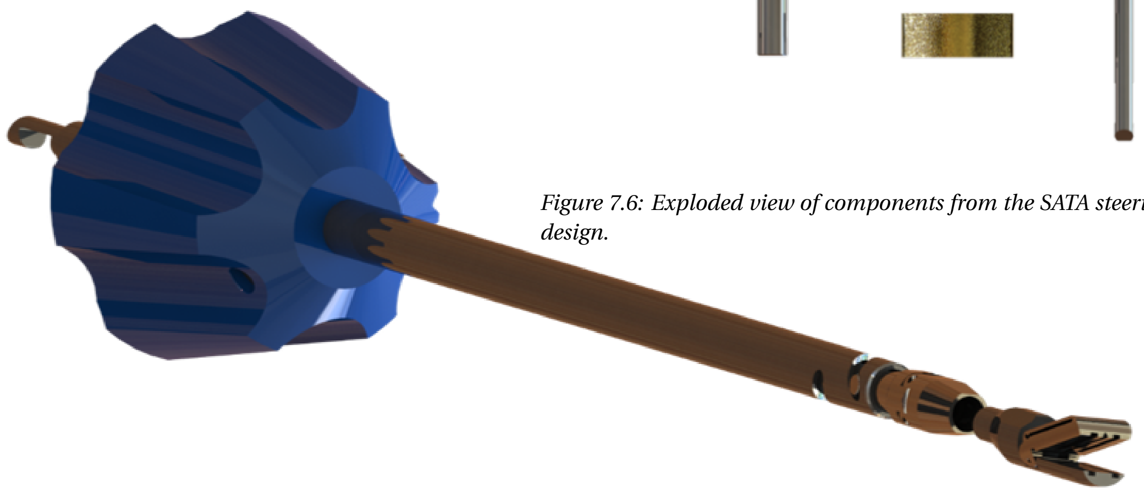


Figure 7.7: Isometric projection of an assembly of the SATA mechanism, the tip components are aligned to indicate the position.

7.4. HANDLE

Chapter 6 evaluated a range of concepts that scored the highest according a Harris profile. The selection of four concepts that had the potential in becoming the concept that is to be implemented in the final design was brought down to the one best concept. Requirements such as sterilization and time efficiency have had an decisive impact on ranking the concepts, yielding the *Deforming* concept. The essence of this principle is that a peak of additive force is required to transit from the sealing phase to the dissecting phase. This is required peak force is visualized in Figure 7.8. The first phase is characterized with a constant required force up to the point that the tip is theoretically closed, a design in the handle will have to ensure that the applied force increases significantly before the the blade is brought into motion. Once the peak is overcome there should not be an accumulated counter force acting on the handles due to the design. These specifications resulted in the following design that is shown in Figure 7.10. The top image shows where the mechanism is placed on the demonstrator handles. Bellow the four images show in chronological order the phases of the interacting mechanisms in the handle from open jaws to closed jaws, and fully displacement of the blade. Specifically Image II, where F_x represents the relatively strong counter force and builds up to the peak force, shows the principle of this deformation concept. Force F_y nearly acts perpendicular on the blue pin initiating deformation. Image III shows the phase of just passing the peak force, the shortened F_x arrow indicated the counter force is dropping, and the required deformation is nearly at its max. Hereafter the counter force as a result of the design is no longer present, up to the end where a stop is built in. This stop also protects the SATA mechanism and blade from repeatedly having the impact of reaching the end phase.

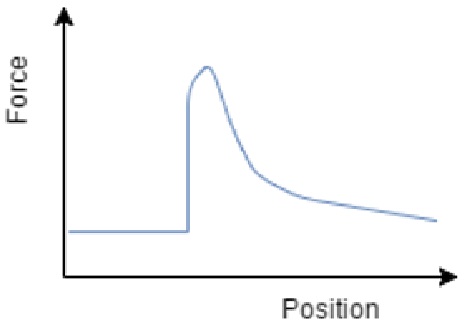


Figure 7.8: The required force input in relation to the position of the articulating handle.

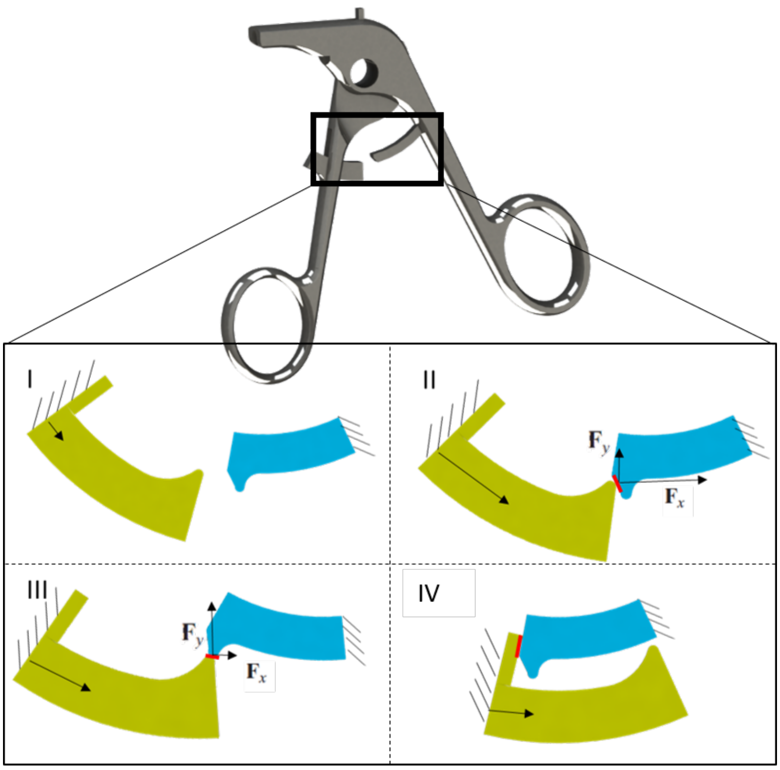


Figure 7.9: The design for the handle mechanism that ensures the user is aware of initiating the phase of dissection. Due to the contact in Image II the pin starts to deform until enough force is applied to continue the process of fully pinching the handles and ensure total displacement of the blade.

7.5. FINAL DESIGN

Figure 7.10: Renders of the final design.

8

PRELIMINARY HEADROOM ANALYSIS

8.1. INTRODUCTION

Ideally, a number of experiment are to be done to achieve the perfect evaluation and validation of the final concept. Due to limited time and resources not everything could be done. For example the validation of a prototype by experiment the use in an environment simulation a median sternotomy with some branches that are problematic to reach. An experiment that can yield results that will strongly validate this device is by having long term result of harvesting various ITA's with various devices and techniques, including the instrument that is developed for this project. The outcome indicating the incidence of sternal wound infection will determine if the preservation of collateral blood flow has an impact on the quality of life (QoL) and related costs. As for this project the aim of validation should be kept realistic and within the constraints that this project has.

Figure 8.1: Harvesting the LITA at the LUMC.

8.1.1. GOAL

A goal of this project is to make the procedure more time efficient. This goal is supposed to be achieved by merging various necessary actions and therefore eliminating repeatedly having to position the instrument and handing over and switching instruments. In this chapter a validation of the time-efficiency is done.

8.1.2. METHOD

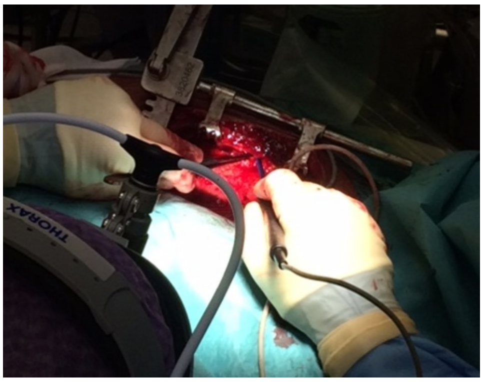


Figure 8.2: Surgeon using MP electrosurgery during the process of harvesting the RIMA.

The method of validating is to carry out recordings of the currently applied method for harvesting the ITA. These recordings will include timing and tracking of the actions done by the cardiothoracic surgeon during both LITA and RITA harvesting. At the invitation of dr. Rob de Lind van Wijngaarden the attendance could be realized. Before the procedure started of the process of collecting data is consulted with all attendees in the O.R.. This is necessary as they are involved in the process of handing over and receiving the instruments. The surgeon is asked to point out when the process of harvesting is started. This is the moment of starting the recordings, values are collected for every time a instrument is handed over. The values that are collected include the recordings of time values and actions done by the cardiothoracic surgeon during both LITA and RITA harvesting.

8.2. RESULTS

In the process of harvesting an ITA three steps are undertaken, preparation, branch dissection, and blood drainage. To analyze the recordings the actions are categorized in different manners. First of all the data is categorized per instrument, this is shown in Table 8.1. The instruments that were used by the surgeon are a MP electrosurgery instrument, clip appliers, surgical scissor, blood drainer.

Table 8.1: Data categorized per instrument.

	Monopolar		Clips	Scissor	Drainage
	Branch	Prep			
Times used (n)	20	16	41	6	1
Total duration (s)	339	1097	462	154	132
Duration (s), mean ± SD	16.14 ± 9.17	68.56 ± 59.87	11.27 ± 4.71	25.67 ± 1.21	132
Percentage (%)	16.48	53.33	22.46	7.46	6.42

Secondly all the actions undertaken per branches are put together. There can be concluded that there is quite a variation in the steps taken to dissect a branch. However, data can be analyzed by grouping the actions. In Table 8.2 the data is presented in two groups, a group of branches that is dissected with MP, the other branches are dissected with scissors. Typically the branches with bigger diameter are dissected with scissors. To keep the analysis in the scope of this project the focus is set on the groups related to branch dissection. Therefore the actions related to blood drainage and preparation of the artery are filtered out. The averaged values for the recordings per action per dissection method are presented in Table 8.3.

Table 8.2: The data is grouped per method of dissection. Either MP or scissors. Additionally the number of branches, total duration, and mean duration for accumulated duration of sealing and dissecting is given.

	Branches [n]	Total [s]	Seal & Dissect per branch [s], mean ± SD
MP	15	643	39.79 ± 10.96
Scissor	6	317	52.83 ± 13.08

Table 8.3: All actions related to the dissection of a vessel are grouped related to the method of dissecting, which means group MP and group Scissors. For each of these groups the total number of applied clip and mean duration of application, and duration of dissection is provided.

	Total clips per dissection method [n]	Total MP per dissection method [n]	Clip duration, mean ± SD [s]	Dissection duration, mean ± SD [s]
MP	29	19	10.44 ± 3.84	14.2 ± 3.88
Scissors	12	1	12.5 ± 7.13	25.67 ± 1.21

The recordings have been filtered to yield all the data from the start of sealing a branch to dissecting that branch. The dissection of all recorded branches have been accumulated and are presented in Figure 8.3. To give an impression of the potential of the device that is created in this project the results of the recorded O.R. attendance is compared with an impression of the estimated time required to successfully use the device. The estimated values are presented Table 8.4 and Figure 8.4. The estimated time is build on the fact that actions are merged and the collected data. The estimation was made as accurate as possible by using the average time required for applying a clip, MP electrosurgery device. Scissors are deliberately left out as they require excessively amount of time with the current method, the surgeon has to accurately place the scissor between the clips. This will not be the case with the novel device, hence the decision of not involving its data for calculation of the estimated required time. With the novel device the step from twice sealing and dissecting is minimized, the instrument does not have to be re-positioned accurately at the exact location three times over. Figure 8.4 shows the estimated process of dissecting all the branches. After placing the tip at the desired location the sealing can be placed, this duration is estimated to be equal to the average that was mentioned and explained earlier. The second action would be dissection by only compressing the handle. As can be noted in Figure 8.4 the use of the MP electrosurgery instrument is still recurrent for some branches. The reason for this is the fact that this device was sometimes recorded to be used twice for one branch, an explanation for this would be that it is used for preparation of the branch. As the novel device is not taking over that task it is also added to the estimated duration of dissecting all the branches together.

Table 8.4: Values of estimated duration of use for the new instrument. Values are averaged duration of recorded action with the current method of branch sealing and dissection.

	Seal duration [s], mean ± SD	Dissect [s]	Preperation [s]	Branch finished [s], mean ± SD
Novel device	12.0 ± 4.09	3	6	18.78 ± 6.73

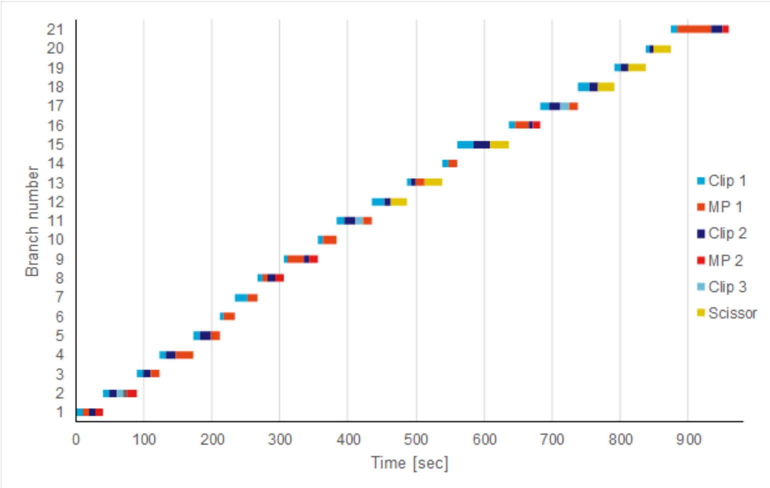


Figure 8.3: Current time course of dissecting a LITA

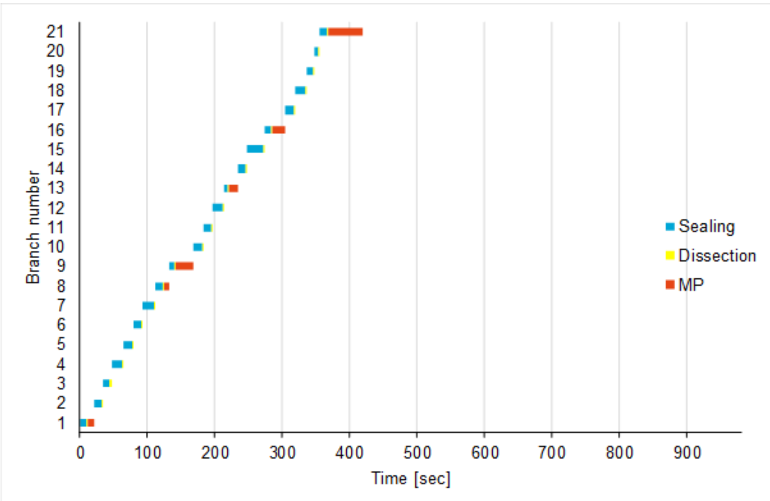


Figure 8.4: Estimated time course of dissecting a LITA

8.3. DISCUSSION

The estimated duration of the novel device can be compared to the collected data. Despite that it is necessary to keep in mind that the results for the novel device are an estimation, a considerable time reduction is accomplished. The result of finishing a branch sealing and dissection withing 19 second, as is mentioned in Table 8.4, is still a big improvement compared to the duration of 39.79 and 52.83 seconds, respectively dissection with MP electrosurgery instrument and scissors. That is a drop of 52.80% in comparison with the more common technique for branches with a smaller diameter, wherefore MP instrument is commonly used, and 64.45% for the bigger branches. The branches with a bigger diameter are not dissected with a MP electrosurgery instrument as the size prevents the vessel to coagulate. Extrapolating these results to the procedure of sealing and dissecting branches that was recorded and depicted in Figure 8.3, results in the estimated duration of the process as is shown in Figure 8.4. Adding the duration of sealing and dissecting for each of the 21 branches count up to a total of 960 seconds. Adding the values for the estimated duration for all 21 branches adds up to 421 seconds. This is a reduction of 539 seconds, meaning 9 minutes are saved in a procedure of harvesting the ITA that is expected to take up to 30 minutes. Out of this data there can be concluded that the goal of making the procedure more time efficient is accomplished.
Despite the promising results shown, it is necessary to temper the expectations as there are various factors that had impact on the results. Due to the circumstances of limited time and resources this could only be done by collecting data of the currently used methods. The process of data collection was done while attending a CABG-surgery where both the LITA and RITA were harvested by different individuals, a junior cardiothoracic surgeon and cardiothoracic surgeon, respectively. As just mentioned, the person harvesting the LITA was during the recordings not yet a classified cardiothoracic surgeon. It may be possible that the resident surgeon was more careful during the procedure and applied more clips that an experienced surgeon would do. Even if it would have been an experienced surgeon, it varies strongly depending on the surgeon what method is use. Roughly said, some surgeons prefer rapidly harvesting the ITA by sweeping all the surrounding tissue away with the use of a MP electrosurgery device, resulting in significantly more damage. Other surgeons give preference to a more careful and precise procedure, over time efficiency. Only if there would be an instrument that could combine accuracy and precision with time efficiency.
Ideally the recordings would have been done with numerous procedures and users. Due to a limitation in time and resources that was not possible, but for future work it is an interesting aspect to keep in mind. Creating a bigger database with correct recording can strongly support the influence the novel device might have. During the recordings for this experiment there was attempted to introduce the participants in the O.R. to the procedure of recordings. Nevertheless, with the current method of switching instrument and using many different instrument within a relatively short period created a situation that could have impaired the recordings. For future work a solution should be created to improve either the sight or hearing of the person responsible of the recordings. Another hazard that was experiences and should not be neglected is that in the current method of recording the moment of handing over an instrument is noted. A suitable method for keeping track on switching instrument, but not for switching actions. Meaning, some instruments can be used for various actions and therefor it is hard to record the moment an action is terminated. To be more specific, the MP electrosurgery instrument can both be used for preparation of a blood vessel, as for sealing and dissecting a blood vessel with a relatively small diameter. Therefore, it can be noted that the surgeon started using a MP instrument for the dissection of a vessel and thereafter started preparing the next branch. According the person making annotations it is all one action if he does not get any visual or audio feedback.

Figure 8.5: Facing towards the camera in the middle is the surgeon during LITA harvesting, sitting on the left facing the camera is the resident surgeon harvesting the radial artery and sealing branches by placing sutures.

9

CONCLUSION

In this project the process of harvesting the ITA is improved by optimizing the process of dissecting time-consuming and difficult to reach branches. The solution is found in the development of a steerable clip applier that in the process can dissect the branch. Making the instrument reusable was one of the goals, resulting in a detachable dissecting steerable clip applier. This instrument is designed with the demands and wishes from an experienced cardiothoracic surgeon, experienced engineers and a literature study. A prototype is developed by systematically analyzing and evaluating all the sub-functions. In this chapter the process and outcomes are discussed, the relevance for the clinical aspect is evaluated, and recommendations for future work are given. The evaluation of the project is brought to an end with a final conclusion.

9.1. GENERAL DISCUSSION

9.1.1. DESIGN PHASE

The choices made in the development of the device are based on the set requirements and conclusions that can be drawn from the analyzes done. During this process the criteria of available resources and limited time span have had their influence. First of all, the chosen method of sealing; the Harris profile for this sub-function indicated that the use of clips would be the most suitable concept for this device. In second comes the relatively new concept, the use of ultrasonic energy. The two main requirements that make the ultrasonic energy come in second are *Complexity* and *Feasibility*. Meaning that it can not be stated that the concept of sealing vessels with clips is the ideal method for this device. Second, the selection process for the concept of closing the jaws started of good. All the concepts were analyzed and ranked with the use of a Harris profile. The concepts that advanced tot he next phase underwent more thorough analysis, resulting in the loss of two concepts. As for the single rounded sliding concepts the articulation of the jaws could not be merged with the actuation of a cutting blade. Therefore, this concept was rightly dismissed. As for the *Overtube* concept, the closing mechanism is based on the technique of deforming a rigid body within the elastic range. This aspect makes the development of such a concept way more complex as the resources for making prototypes for the experiment are limited. The characteristics of developing an *Overtube* concept with polyactic acid, PLA, a plastic filament commonly used with 3D-printing, is that the prints are stiff but brittle, and therefore causing problems to use them for the experiments conducted. Ideally this factor would not be a reason for a concept to be dismissed, but it was necessary regarding the criteria this project has.

Two concepts advanced to the phase that they are further developed in order to assess the transferal of the input forces. Load cells are used to measure pressure at the input and output, and a potentiometer is linked to the mechanism to acquire data of the exact position. This way theory and practice can be compared. As expected, the difference between the two concepts is mainly the increase the ascending required force for the *Cut-Out*, whereas the *One Hinge* concept makes the jaw to articulate at a relatively constant force. Yet both concepts require a maximum input force that is approximately a five-fold of the output force. Although these concepts are yet to be optimized, the proportions resulting from this experiment can be used for Finite Element Analysis, and analysis of suitable materials. Furthermore, the effects of friction on the specimen are ideally eliminated when analyzing the mechanisms. At the end, the experiment showed that the two concepts do not differ that much in maximum force required to fully close the tip. The final decision for the tip

mechanism if based on a broader aspect of the evaluation, namely the implication of the device usage. Tip length can be appointed as decisive factor. A longer tip length is undesirable, considering the area and space available for the tip to move inside the thorax, and the fact that the momentum increases with a longer tip.
In the synthesis phase of the handle the mechanisms of proven concepts are firstly analyzed. Using the Harris profile several concepts arose that advanced to the next phase of further analysis and development. This project aims on merging various actions, but the various aspects such as hidden areas and number of components is to be kept in mind. Therefore, the mechanism in the handle should be able to control the sealing and dissecting components separately, without significantly increasing the complexity. In the process of using a device that both seals and dissects some assumptions are made. In consultation with the cardiothoracic surgeon the process of sealing and dissecting branches is analyzed. That is how there is concluded that there is no need for a locking state of the handle after the clips have been placed. After the surgeon places the clips there must be feedback to ensure clips are closed, and dissection can start. The dissection process may only be initiated after approval, meaning that the chance of dissecting the vessel without awareness of the user must be prevented. The mechanism in the handle should also have the possibility of aborting the process of dissecting if that is desired by the user. The concept that is selected does have the required sub-functions incorporated. A consequence of this concept is that it requires an approval of the user in the form of an increase in the force applied on the handles. This results in an overshoot once the dissecting phase is initiated, increasing the impact on the vessel and potentially thoroughly dissecting the vessel.

9.1.2. BACK TO CLINICAL ASPECT

In chapter 8 an estimation is made of the difference in duration between harvesting method currently applied in the LUMC and the duration required for the new device. Despite the promising potential of making the procedure more time efficient, the expectations should be tempered. The data recordings should be improved and over a larger number of surgeries. The main deficiencies in the current recordings are expected to be occurred in the process of grouping actions, and attending a surgery wherein an above-average amount of clips are placed. This can be explained due to the anatomical variation of the patient, or the surgeon deemed it necessary.
The process of applying two clips to a vessel whereafter it is dissecting is used more commonly than only for the branch dissection of the ITA. The removal of the gall bladder for example is currently done by separately applying two or three clips, after which the vessel is dissected. This is usually a laproscopic intervention, making it more difficult for the surgeon as the conventional two dimensional method lacks depth perception. Merging the use of multiple instruments ensures all the required actions take place at the correct distance from each other, while being nicely aligned.
Another example is the harvest of the saphenous vein, this vein can also be used as a graft for CABG surgery. Various devices and methods exist to seal and dissect the branches, but this novel instrument has the potential of also being used for that purpose. Some existing methods are not accessible for all hospitals because of the costs, an existing method that is accessible and commonly used is by suturing the branches. This process can significantly be accelerated with the new instrument.
It is pointed out that with the current clip appliers surgeons need to have some experience as it is up to the user to decide how much force is applied on the clip. It is recurrent that inexperience's surgeons do not apply enough force on a clip, leading to risks of dislocating the clip and loosening up the sealing. This should not be the case with the new instrument as the blade can only be activated after the jaws have been closed completely.
The steerability of the device has been pointed out to be beneficial specifically for the hidden branches, which at the same time are usually the most cranial branches. Characteristic for these branches is a bigger diameter, therefore require larger size clips and are commonly dissected with scissors instead of electrosurgery instruments.
Besides the fact that some of the arteries are already hidden, the surgeon is faced with the situation whereby a wider opening of the retractor improves and increases the working area. On the other had, studies have shown that widening the sternal retraction and longer bypass time increase the risks of brachial plexus injury [50]. With the use of this new instrument the steerability improves the ability of reaching arteries while opening the sternum as small as possible.

9.1.3. FUTURE WORK

Recommendations for this project for further development is to do research on the following field. In this project the mechanisms for the tip and handle are chosen and defined. Nevertheless, both designs require further development to assure the mechanisms operate as indicated. Meaning the cut out design of the tip requires adaptations and as the handle mechanism relies on the deformation characteristics of the material that is to be chosen material, the design must be adjusted accordingly. The same goes for the aesthetic and ergonomic design of the handle. This section was left out of this project, but in the future it requires attention for proper development of the instrument.

A considerable aspect of the new instrument is the feature of having a detachable tip and shaft. The advantage of this property is the fact that it is beneficial in the sterilization process. To ensure the instrument works properly as a reusable the aspect of a sharp blade must be guaranteed. A solution must be provided in the future to cope with the fact that the sharpness diminished over time if it is used repeatedly. Solutions can be found by replacing the blade over a number of runs, or designing and choosing the material such that the sharpness can be guaranteed.

This project is focused on using surgical clips of the chosen method for sealing blood vessels. Proven concepts showed the possibilities of using both single as double articulating jaws, therefore the design of a clips was estimated to have a lower priority. Nevertheless, this new device is unique by aligning to clips in the jaws and actuating a blade through the middle. Therefore, the design of suitable clips is not to be left out in the future as the instrument must be able to be reloaded in order to reuse for the next blood vessel.

Another aspect that is interesting to consider for future work is the mechanism and possibilities to incorporate ultrasonic surgery in the tip. But as for now, the development of this device should be developed as it has the potential of improving the procedure while keeping the costs low.

9.2. CONCLUSION

The design goal for this study was to develop a method to improve the current technique by making a reusable steerable instrument that is capable of sealing and dissecting a blood vessel. The development resulted in a clip applier that has a blade built in, the handle is designed thus that the user remains in control and actively has to approve the separate actions.

This result is achieved by systematically analyzing and evaluating existing concepts. Setting and adapting the requirements, especially related to sterilization and based on consultation with a cardiothoracic surgeon, resulted in a selection process for the sub-functions that yielded the most suitable concepts.

The project shows that the design goals set for this study is fulfilled, there is potential of making the procedure more time-efficient, reducing the costs, and reducing the prevalence of sternal wound infection, but future research should be performed to improve the current prototype.

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