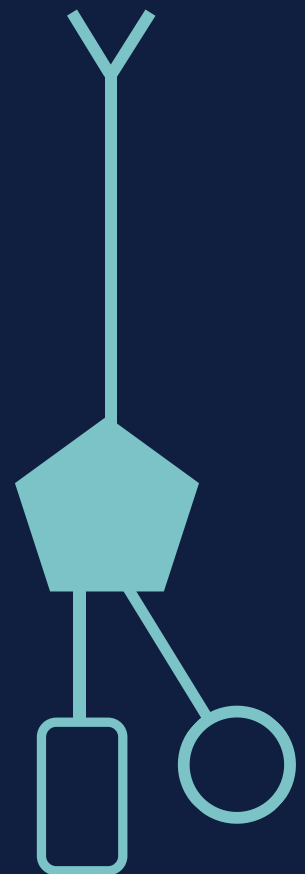


DESIGN OF A NOVEL
LAPAROSCOPIC
INSTRUMENT
WITH COMBINED
FUNCTIONALITY OF A
GRASPER & NEEDLE
HOLDER



Design of a novel laparoscopic instrument with combined functionality of a grasper & needle holder

by

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to obtain the degree of Master of Science in Mechanical Engineering
at the Delft University of Technology,
to be defended publicly on Thursday April 29, 2021 at 14:00.

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*“Read it with sorrow and you will feel hate.
Read it with anger and you will feel vengeful.
Read it with paranoia and you will feel confusion.
Read it with empathy and you will feel compassion.
Read it with love and you will feel flattery.
Read it with hope and you will feel positive.
Read it with humour and you will feel joy.
Read it with God and you will feel the truth.
Read it without bias and you will feel peace.
Don't read it at all and you will not feel a thing.”*

- Shannon L. Alder

Acknowledgements

I wish to express my sincere gratitude to Dr. Tim Horeman for providing me with the opportunity to work on this immensely interesting project. I would also like to thank him for his guidance, his critique and for sharing his immense knowledge in the field of medical instruments, which made it possible for me to successfully complete this project. He always motivated me to maintain the quality of the project and work hard. I would also like to express my deepest regard to my Mr. Tomas Lenssen; without his patient guidance, enthusiastic encouragement and attention to detail, this thesis project would not have been fruitful. I wholeheartedly thank him for his support, encouragement and for guiding me in the right direction at every step of my project. Additionally, I would like to thank Dr. Jenny Dankelman for her feedback and support.

I would like to thank my friends for their support throughout my journey in Delft. My life in Delft would have been very different and difficult without them, especially in the challenging period of the coronavirus pandemic. I am extremely grateful for their constant encouragement and for always being there for me.

I also wish to thank my brother, Abhinav for being a role model for me and for being supportive at every step, the good and the bad. His guidance throughout my education has been unparalleled and he deserves a lot of credit for what I have achieved. Lastly, I would like to thank my parents. Their support, even though from afar has meant the world to me and has been my encouragement to keep going day in day out. I would like to dedicate this thesis to them, the pillars of my life.

*Dhruv Gulhar
Delft, April 2021*

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Abstract

Laparoscopy involves the use of various instruments for performing different functions. As a consequence, time is spent in exchanging the various instruments, adding to the overall operation time. In order to reduce this overall operation time and solve this problem, the number of instrument exchanges need to be reduced. Reducing the number of instrument changes would also lead to fewer disruptions in the choreography of the surgery and decrease costs related to purchase of instrument and their cleaning.

Therefore, in this project, the goal is to develop an instrument with the combined functions of a grasper and a needle holder, to reduce the need of instrument exchanges for performing 2 functions.

The requirements for the instrument were decided on the basis of the sub functions to be performed. Conceptual solutions were then generated to perform the desired sub-functions and systematically compared to obtain a final concept. This final concept was detailed regarding the various mechanisms in the instrument and the distinct assemblies it contains. The force model of these mechanisms were used to theoretically validate the working principles using the required force to be generated. A physical validation of the working principles was also obtained by 3D prints. Further work and research should be done to develop a working prototype of the instrument to validate the functionality of the complete instrument.

1

Introduction

This chapter briefly elaborates on the background of laparoscopic procedures and laparoscopic instruments. Following this, the analysis is done of the problem followed by the design goal of the project. The chapter also explains the approach followed for the project. At the end of the chapter, the structure of the thesis is given.

1.1. Background

1.1.1. Laparoscopy

Endoscopic surgery, also known as keyhole surgery or minimally invasive surgery(MIS) is a surgical procedure that requires the use of special endoscopic tools by the surgeon to operate. Laparoscopic surgery, one of the types of endoscopic surgery is about performing surgical operations in the abdomen and requires the insertion of the tools in the abdominal cavity of the patient through the abdominal wall. During the surgical procedure, there is no direct contact with tissue and there is also an absence of a direct vision of the site of operation. The procedure is performed by manipulation of tissue using tools that are handled from outside the patient's body. A laparoscope is inserted inside the cavity through an incision which has a camera inside it that helps in the visualisation of the operative site. The view of the operative site is usually captured on a 2-D monitor for the surgeons to see[Cao et al., 1996].

During the last couple of decades, surgical medicine has been heavily influenced by minimally invasive surgery. Developments in minimally invasive surgery have led to the replacement of certain conventional procedures by minimally invasive procedures. It has also encouraged surgeons to reassess conventional procedure with respect to perioperative parameters. Minimally invasive surgery procedures are now in routine use and further developments are being carried out. For example, developments regarding the thickness of the instruments for better cosmetic results, or developments in robotic surgery or telesurgery allow more precision with the help of computer-aided methods[Fuchs, 2002].

1.1.2. Laparoscopic instruments

There are a variety of tools used in laparoscopy like imaging devices, gas insufflators, ports of entrance and mechanical instruments. To elaborate on the instruments used in laparoscopic procedures, the example of 2 instruments has been taken: a grasper and a needle

holder. These two instruments would also be discussed in detail in later sections as these are the instruments in consideration for the project

State of the art graspers are made of 3 major components: the end effector or the jaws which is at one end of the instrument and grasps the tissue, the shaft via which the instrument is inserted inside the body and the actuator mechanism (a lever or handle in case of a manually operated grasper) which is located at the proximal end of the instrument. Figure 1.1 shows a laparoscopic grasper and the 3 components. The lever mechanism is located outside the body of the patient and the user exerts a force on the lever mechanism to obtain an open-close action on the jaws located inside the body of the patient. The force is usually transferred through the shaft mechanism via the relative movement of components. The shaft is composed of an inner rod and an outer sheath. These two members are connected to different and distinct components of the instrument to enable relative movement for the eventual closing and opening of the jaws [Farin and Bachar, 2014] [Koc et al., 2017].

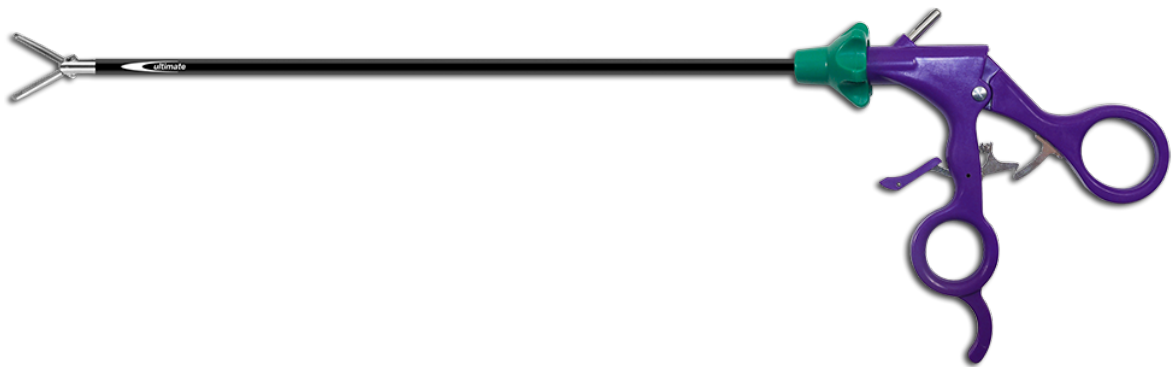


Figure 1.1: Laparoscopic Grasper; from right to left: the handle, shaft and end effector

During laparoscopic procedures, often there is a need to repair or remove some sort of tissue from the site of operation inside the body. Sometimes, a closure is also needed on the tissue being operated upon. These closures are usually performed by surgical clips or staples, conventional needles & sutures or some other forms of suitable closure. The use of needles and sutures has a significant advantage in the process of performing sutures, although the process also poses some difficulties because of limited access. To grip a needle to perform the closure, a needle holder is used to hold the needle securely inside the jaws of the instrument and hence perform the suturing process [Li, 1995]. A conventional needle holder can be seen in Figure 1.2.



Figure 1.2: Laparoscopic Needle Holder

1.2. Problem Analysis

Laparoscopy involves the use of a variety of instruments for various functions. A consequence of using multiple instruments during a laparoscopic procedure is the exchange of these instruments when required. A significant amount of time is spent in exchanging instruments, which causes delays and interruptions in the surgical flow [Den Boer et al., 2001] [Sjoerdsma et al., 2000] [Zheng et al., 2008] [Geryane et al., 2004]. During this exchange of instruments, sometimes time is lost in grabbing the wrong instrument [Joice et al., 1998]. The increase in operation time caused due to unnecessary instrument exchanges also leads to increased mental and physical workload on surgeons [HM Goossens, 2001].

To solve this problem, the number of instrument exchanges in a surgical procedure needs to be reduced. Reducing the number of instrument exchange in surgical procedure also means there are fewer disruptions in the choreography of the procedure [Sutton et al., 2010]. Along with reducing instrument exchanges, reducing the overall number of instruments used in a surgery also has benefits concerning costs. A reduced number of instruments would reduce the purchase costs associated with a surgery [DesCôteaux et al., 1996] [Kim et al., 2020]. Reducing the number of instruments used would also reduce the subsequent costs for cleaning and sterilization. Cleaning costs are the cost associated with the hourly wage of personnel and the cleaning material purchased [Schaer et al., 1995] [Demoulin et al., 1996]. The total sterilisation costs depend on the number of instruments to be sterilised and therefore reducing the number of instruments used would reduce the total cost [Slater et al., 2009].

Reduction of the operation room time as a consequence of lesser instrument exchange would mean lesser mental and physical workload on the surgeon; lesser physical workload would reduce chances of a chronic occupation injury [Miller et al., 2009]. One way of reducing instrument exchanges is by combining the functions of 2 or more instruments so that the need for exchanging these instruments is eradicated. A combination of instrument functions would help in reducing instrument exchange time and avoid unnecessary disruptions caused in the flow of the surgery.

Time motion analyses of surgical procedures have revealed that certain 2, 3 or 4 instrument exchange cycles exist in the exchange of surgical instruments. For example, in a 3 instrument exchange cycle, 3 instruments are used one after the other with a probability of exchange. One such instrument cycle in the analysis by Mehta et al. [2002] is of a laparoscopic suturing device and a laparoscopic grasper. During the procedure of Nissen fundoplication, the probability of exchange of a mechanical suturing device after an atraumatic grasper was 32.1% i.e. 9 times out of 28 times a mechanical suturing device was used after an atraumatic grasper. Furthermore, the instrument cycle exists because the probability of exchange of the atraumatic grasper being used again after the mechanical suturing device is 66.7% i.e. 10 times out of 15, the atraumatic grasper was used after the mechanical suturing device. A representation can be seen in Figure 1.3

Additionally, the mechanical function of a grasper and needle holder has a similar mechanical end effect. Both instruments have an open & close action where through the application of forces, a target object is held between the jaws [Cao et al., 1996]. Therefore, this provides a summary of the problem that exists, the similarity between the mentioned instruments and their relationship with respect to the exchange cycle makes them potential candidates for the combination of functions. An analysis of the instruments along with the

design goal of this project is presented in the next section.

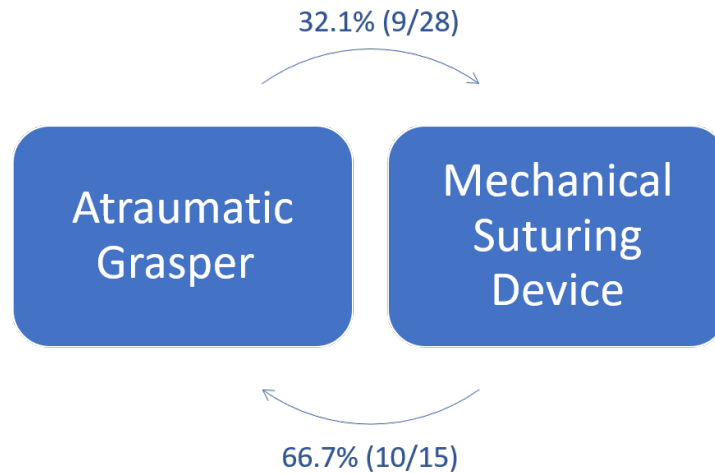


Figure 1.3: Probability of exchange (number of exchanges) for the 2-instrument cycle of a grasper and a suturing device

1.3. Design goal

The functioning of a grasper and needle holder has already been explained in Section 1.1.2. To proceed further, various aspects of the instruments need to be analyzed in order to combine their functions. There are certain areas that a needle holder and a grasper can be compared on for a better understanding of how these instruments function and what all areas would need careful consideration while defining requirements and designing potential conceptual solutions:

- **Force generation:** The laparoscopic grasper is used to manipulate or move tissues or organs during surgery. As there is an absence of haptic feedback in the state of the art graspers, surgeons have to be careful while applying force as excessive force would lead to damaging the tissue. On the other hand, in a needle holder, the requirement is only to generate sufficient force at the tip so that the needle can be secured to perform the suturing procedure. Therefore, attention isn't paid to the amount of forces exerted at the tip as long as they are enough.
- **End effector:** In the case of the state of the art graspers, the end effector which is the tip at the distal end of the instrument comes in various forms and dimensions. Graspers can be atraumatic, traumatic, dissectors or fenestrated with different types of mechanisms which make both jaws of the instrument open equally from the middle. Needle holders usually have a simple end effector with a single hinge mechanism that keeps one jaw stationary and moves the other.
- **Control at handle:** In a grasper, the tip is used to grab and move the tissue, therefore more control is required at the handle in terms of the input motion of the handle being converted to the output motion at the tip. The tip of a grasper is also needed to open and close multiple times and hence would require a handle that can perform

this repetitive motion. In the case of a needle holder, state of the art instruments are simply used to close the handle and lock them with sufficient handle force as long as the needle is needed to be secured between the jaws. This also points to the fact that more force resolution is desired in the case of a grasper as it needs more control, whereas, in the case of a needle holder, lesser force resolution is satisfactory as long as sufficient forces are generated at the end effector.

In this project, an instrument will be developed to solve the problem discussed in the previous section by combining the functions of a grasper and a needle holder. Therefore, after analysing the problem, analysing the instruments in consideration and answering all the relevant questions, the design goal of the project was defined:

To design a novel laparoscopic instrument with combined mechanical functions of a grasper and a needle holder

1.4. Approach & Methodology

The approach and methodology used for this project can be explained through the V-model. The V-model which was initially published in 1993 by Bröhl [1993] for software application, has found its way into the development of technical systems [Gräßler et al., 2018]. The V-model was then adapted for mechatronic systems and explained in the VDI guideline 2206 [Gausemeier and Moehring, 2002].

The V-model from the VDI guideline 2206 was adopted for the design process in this project. In Figure 1.4, the V model can be seen, in which the design and development process is divided into 3 main components: the system design, the domain-specific design and the system integration.

- **System Design:** The input to the first component are the requirements of the product to be designed. These requirements are defined after the problem analysis and after breaking down the goal of the design problem to be solved. These input requirements also represent what the final product needs to achieve. During the process of system design, conceptual solutions are developed which represent the required characteristics of the future final product. The overall desired function of the product is broken down into sub-functions to facilitate the design process. Suitable solutions to these sub-functions are assigned followed by the evaluation of the overall function of the product. This evaluation is the comparison of various developed concepts according to comparison criteria so that a final solution is selected. During the system design process, to avoid inconsistencies and errors being detected later on this process, the design process has verification steps. These steps make it an iterative process and enable to make changes to either the required characteristics of the future product or to the details of the sub-functions. This design phase verification has not been mentioned in the original VDI guideline. However, in later versions of the V-model, it is acknowledged that requirements cannot be identified and set at once at the beginning of the project. In practice, the requirements can change along the product development process [Neukirchner, 2014] [Gräßler, 2017].

- **Domain-specific design:** In this phase, the selected solution concept is worked out in detail with the necessary calculations of the elaborated design. A comprehensive functional performance is presented with respect to the most critical functions.
- **System Integration:** In this part of the process, the results are integrated regarding various domains and using the validation process, the specified solution is checked with the requirements defined in the beginning. This is done to make sure that the obtained characteristics of the final product are the desired ones. The result of this V-cycle at the end of the system integration process is the final product. In this project and also as mentioned in the VDI guideline, the final product is not the finished and ready to manufacture product, but more of a functional model.

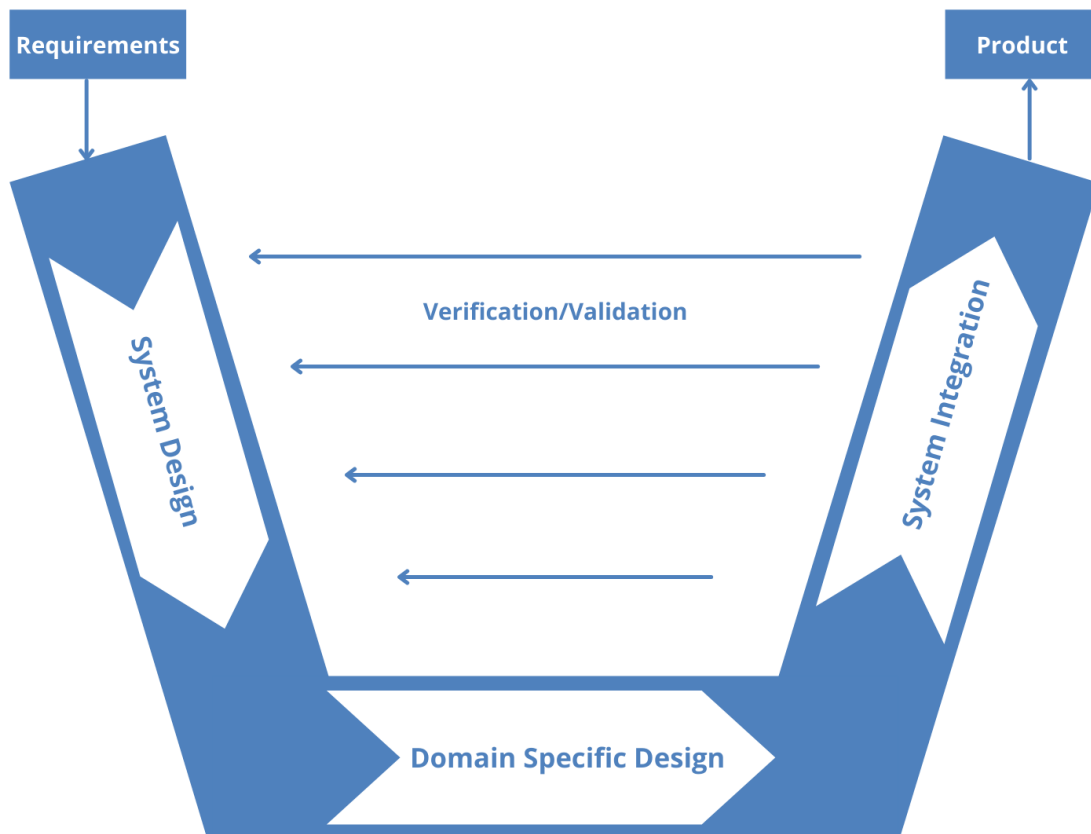


Figure 1.4: V-shaped model for the design process

1.5. Project Outline

According to the methodology discussed in the previous section, the following is the outline of this thesis project:

Chapter 1 covers the introduction and briefly describes the background regarding laparoscopy and the instruments used, the problem analysis and the methodology adopted for this design project.

Chapter 2 contains the design criteria and requirements that the instrument and the concepts have to satisfy.

Chapter 3 explains the important focus areas, the generation of the concepts, and the details of the generated concepts.

Chapter 4 elaborates the features of the various generated concepts and the selection process of the best conceptual solution.

Chapter 5 contains the details of the final design including the design framework and the details of the various mechanisms in the instrument.

Chapter 6 provides the conclusion of the project

And finally, **Chapter 7** is about the general discussion and future scope of this project.

2

Design Criteria

After analyzing the problem, the next step is defining the requirements for the design problem. An important step before the process of system design, as mentioned in the V-model in Section 1.4, is identifying the requirements which are going to affect the process of obtaining conceptual solutions. These requirements should, however, be documented and defined as quantitatively and clearly as possible with the help of the following questions [Pahl and Beitz, 2013]:

- What are the objectives that the proposed solution is expected to satisfy?
- What are the properties that the intended solution should have?
- What are the properties that the intended solution must not have?

In the process of defining the requirements, a clear distinction must be made regarding the demands and wishes. *Demands* are requirements that have to be satisfied under any and all circumstances. If these so-called demands are not met, the concept or the solution is therefore unacceptable for further consideration. *Wishes* on the other hand are requirements that should be considered if it is possible to do so [Pahl and Beitz, 2013].

The process of defining these requirements and eventually using them to compare concepts was an iterative and continuous process as the relevance of some requirements increased with the increase in complexity of the design problem. The requirements will be used to generate concepts and to assess the developed conceptual solutions quantitatively to select the final design. The requirements were selected based on the literature available on design projects for laparoscopic instruments, discussions with supervisors & professors and Phug's checklist [Roozenburg and Eekels, 1995]. Therefore, the demands are the following:

Performance

1. The first performance requirement is that the instrument is able to satisfy the force requirements of a grasper and needle holder. It has been concluded that safe laparoscopic graspers should be able to apply 5N of pull force without the tissue slipping out of the grip of the grasper or being damaged by the tip [Visser et al., 2002]. It has also been experimentally confirmed that an average of 3N pinch force is required to prevent slip at a pull force of 5N [Heijnsdijk et al., 2004a]. For a needle holder, a force of 9N is needed to fixate the needle at the tip [Van Veelen et al., 2003]

2. The instrument should be able to hold a suturing needle between its jaws and lock the handle when required with constant handle force.
3. The instrument has a functional tip that can satisfy the opening angles of each instrument - 55 to 65 degrees for a grasper[Sakes et al., 2018][Bamberg et al., 2006] and 45 degrees for a needle holder[Kode and Cavusoglu, 2007].
4. The instrument can be used by either hand.

Safety

5. The instrument should provide information to the user about the forces applied or the type of function being operated.
6. The instrument should be designed in a way that it has no sharp or moving parts exposed.
7. There should be no electronic components exposed.

Cleaning

8. The instrument should be able to disassemble so that surfaces and spaces are accessible for cleaning and sterilizing with the state of the art processes (flushing of shafts, ultrasonic cleaning, cleaning by vibration followed by autoclaving for sterilization).

Product life span

9. The instrument should be designed for reusability.
10. The major and important components of the instrument should be replaceable.

Dimensions

11. The instrument should fit through a 5mm trocar port.
12. The instrument should have comparable dimensions to the state of the art instruments.

Ergonomics

13. Each function of the instrument should be performed without any extra or special manoeuvres in comparison to current instruments.
14. The desired function of the instrument should be achieved in as few steps as possible.
15. The instrument should offer control at the handle for a repetitive motion when being used as a grasper.

Due to the scope of this project being limited to a graduation project and the complexity of some other design criteria, the requirements mentioned above have been considered more important and therefore prioritized for the design process over some other requirements like material or cost.

After defining the demands that need to be met by the design, the wishes were defined as the following:

- The instrument is able to perform the individual functions equally well as the original instruments.
- The instrument requires minimal hands-on experience by the surgeons
- The instrument should have a simple and intuitive appearance to make the implementation or use of the instrument easy.

3

Concept Generation

Referring back to section 1.3, the next step in the system design process is generating conceptual solutions which are capable of solving the design problem.

One of the most important steps in making concepts that can solve the design problem is breaking down the main function into sub-functions or focus areas. A somewhat complex overall function can be broken down into functions of lower complexity and the combination of these sub-functions then forms a function structure that represents the overall function. The reason why a complex function is broken down into subsequent sub-functions of lower complexity is to [Pahl and Beitz, 2013]:

- Find sub-functions that can help in the process of finding solutions
- Integrate the sub-functions into a clear function structure

3.1. Focus areas

Establishing sub-functions or focus areas can be useful to break down the process of concept generation into smaller steps. These focus areas themselves are not going to provide a solution to the problem but are rather used to obtain more complete solutions. A focus area can be obtained by analyzing the requirements that the final solution has to fulfil. After obtaining these focus areas of the desired instrument, solutions can be found for the various sub-functions and put together in the form of a morphological overview. In this manner, different solutions of each sub-function can be put together to solve the bigger complex problem and obtain the desired design concept.

There are certain focus areas or features which play a direct role in the generation of concepts. Certain focus areas like the type of tip of the instrument or the details of the tip mechanism itself are of relevance but do not directly contribute to the generation of concepts. The tip mechanism and type of tip will be detailed in the final design as per the state of the art mechanisms.

In the case of the design problem being solved in this project, a combination of two functions into one instrument indicates that the resulting new design of the instrument will have to fulfil certain requirements. These requirements have been specified in Chapter 2 as the demands that the instrument needs to meet. From these demands, the focus areas are obtained:

- Force generation in the handle mechanism: The instrument needs to generate sufficient forces so that it can perform both functions sufficiently and therefore the force

generated by the user is a focus area for the generation of concepts. The force generation mechanism not only addresses the mechanism that is used to convert input force to output force but also the type of handle that is being used as these two features are interconnected. The type of handle combines with the force generation mechanism in order to convert the input motion to output motion and is therefore also considered important while generating solutions.

- **Locking mechanism in the handle mechanism:** For using the instrument as a needle holder, the instrument needs to hold a suturing needle between its jaws and lock the handle with constant handle force. Therefore, it is essential for the handle mechanism to have a locking mechanism that can ensure that the designed instrument can be used as a needle holder.
- **Safety feedback in terms of function change:** A requirement regarding the safety of the instrument is that it should provide information to the user about the forces applied or the type of function that is being used. Therefore, the instrument should have a safety feedback mechanism to either inform the user about the forces being applied or prevent them from applying high forces or provide them with information about what function they are using at a particular moment.

Now that the sub-functions have been recognized from the requirements, it is important to consider the schematics of a laparoscopic grasper or needle holder in order to identify how and where these sub-functions can be solved. For that purpose, an example of a laparoscopic grasper is taken, also because it is one of the instruments taken into consideration for the design problem. The schematic representation of a grasper can be seen in Figure 3.1 with the various features.

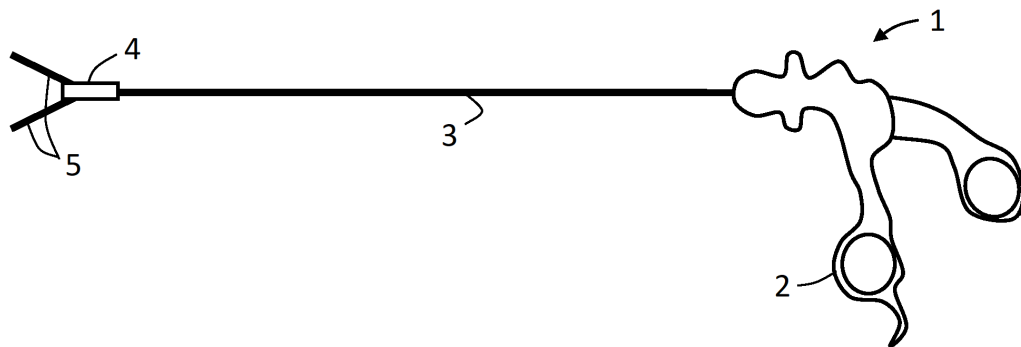


Figure 3.1: Schematic representation of a laparoscopic grasper

The schematic representation is divided into 5 major parts, each of them is going to be significant and contribute towards either the generation of concepts or the final design.

1. Signifies the **type of handle** and the general shape that contains the mechanism which helps to translate the input to the output in the instrument.
2. Signifies the **handle mechanism** by which sufficient force is generated for the desired output action. Therefore, the force-generating mechanism is an important part

of this handle mechanism. In the instrument to be designed in this project, there is a locking mechanism needed because there is a requirement for constant handle force when the instrument is intended to be used as a needle holder. Therefore, the handle mechanism also includes the locking mechanism of the movable handle of the instrument

3. Signifies the **shaft** that accommodates the transmission cable or inner shaft which connects the input to the output.
4. Signifies the **tip mechanism** by which the input force is used to open or close the tip for a desired action.
5. Signifies the **type of tip** used in the instruments since different types of tips have different properties and suitability for actions.

These components of an instrument are essential in the solutions generated to the various sub-functions. For example, the force that is generated by the instrument is not only dependent on the handle mechanism as it generates force but also on the type of handle because that decides how the input motion is converted to output motion.

3.1.1. Force generation

Generating the required force is one of the most important functions of this novel instrument. The two instruments whose functionality is in discussion in this project have a similar action in terms of the action of the tip. The grasper, on one hand, is used to grab and manipulate tissue whereas the needle holder, on the other hand, is used to hold the suturing needle in place so the action of stitching the tissue can be performed effectively.

Grasping, as a function, can be defined as the combination of two actions - pinching and pulling [Westebring-van der Putten et al., 2009]. To make sure that the action of grasping tissue is performed safely, the pinch and pull force which is applied by the instrument should lie in a 'safe area' [de Visser, 2003]. This safe area is defined by the slip line and the damage line, as can be seen in Figure 3.2. However, factors like the jaw properties and mechanical properties of tissues also contribute to safe grasping, apart from the force exerted via the user. In Figure 3.2 it can be seen that the area above the damage line indicates a combination of forces that would damage the tissue and the area below the slip line would indicate a combination of forces that would cause the tissue to slip. Therefore, the safe area defines the combination of forces that ensure safe and efficient grasping [Westebring-van der Putten et al., 2009].

As indicated in Figure 3.2, forces below the slip line will cause the tissue to slip out of the grasper, leading to a delay in the procedure. It is also reported that a majority of the errors associated with graspers involve dropping and tearing the gall bladder in laparoscopic cholecystectomy [Heijnsdijk et al., 2002] [Joice et al., 1998], making it a significant focus point during the design of such a novel surgical instrument.

The efficient functioning of the force mechanism is an important feature in this type of laparoscopic instrument. Due to factors like trocar friction, abdominal wall resistance and mechanical construction of the instrument, the force exerted at the handle of the instrument is not efficiently translated to the tip of the instrument, leading to kinesthetic feedback distortion [Westebring-van der Putten et al., 2008]. Apart from the aforementioned

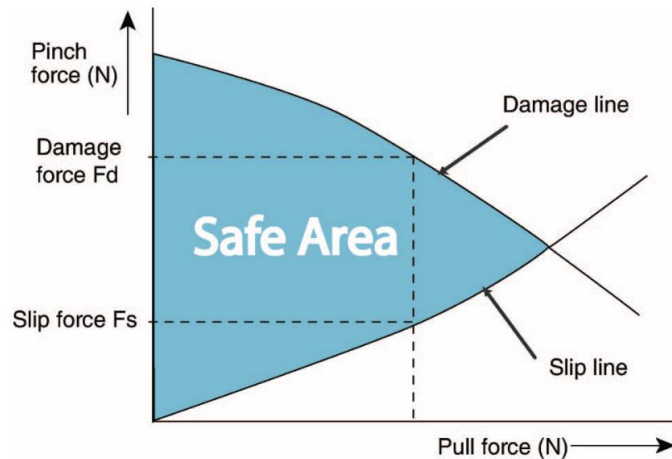


Figure 3.2: Safe area bounded by slip and damage forces [Westebring-van der Putten et al., 2009]

factors, the geometry of the linkages between the various components of the instrument also contributes to force transmission [Van den Dobbelsteen et al., 2012]. The force transmission of the instrument is an important point of consideration also because the relation between the grasping force exerted on the tissue and the input force on the handle is complicated by the non-linearities in the kinematics of the linkages [Payandeh, 1997].

The mechanism of force generation is also critical because the amount of forces needed to perform the 2 distinct functions of manipulating tissue and holding a needle tightly have a different range. When it comes to a grasper, an experiment performed on pig bowel concluded that a pinch force of 3N was sufficient to prevent slip at a pull force of 5N [Heijnsdijk et al., 2004a]. In the case of a needle holder, however, a force of 9N is needed to close the tip of the instrument and fixate the needle for the intended action [Van Veelen et al., 2003].

3.1.2. Locking mechanism of the tip

For maintaining constant force at the handle, there are certain locking mechanisms that exist in the state of the art laparoscopic instruments. These locking mechanisms ensure better ergonomics and lesser fatigue for the user as they don't have to exert a constant handle force at all times. In some cases, when an assistant is needed to hold the instrument with constant handle force to help the surgeon, these locking mechanisms either enable the assistant to help with other tasks or eradicate the need for the assistant. Some locking mechanisms that exist in the handle contain ribs or ridges on each arm member of the handle in the form of a ratchet that locks with the corresponding ridges of the other arm member to lock the handle in position [Cuny et al., 1997].

Similarly, in the case of the novel instrument discussed in this project, there is a requirement to lock the handle with a constant force so that the needle can be held tightly in position while the function of the needle holder is being performed. Depending on the usability of the instrument, the locking mechanism can also be utilised for the function of the grasper if in case a constant handle force is desired while grabbing a tissue, organ or vessel.

3.1.3. Safety feedback

Combining the mechanical functions of the two instruments would also mean that the user is now enabled to apply a higher amount of force when required. In the case of the needle holder, there is a higher force required at the tip than a grasper. A higher force required at the tip would also mean that the user needs to apply higher force at the handle. While it is useful to enable the user to apply these high forces, it is not desired to apply higher forces when manipulating and moving tissues. Damage to the tissue is more likely if the user has more freedom regarding the application of force, because of insufficient feedback in terms of how much force is being applied at the tip. For that purpose, a very critical sub-function is the feedback regarding the safe use of the instrument. To prevent the user from exerting unintended forces, a mechanism that allows giving information back to the user about either the amount of forces being exerted or the type of function that the instrument is performing is going to have an important role. Therefore, one strategy to tackle this would be to limit the amount of force that is being applied at the end effector. When the grasper function is intended, the instrument would be unable to apply a higher amount of forces. Higher force would only be possible to apply via a mechanism like an enabling switch, hence allowing the user to decide when to apply a higher amount of force and when not. This also makes the user aware of the range of force that they are using and makes sure that unintended higher forces are not applied when dealing with delicate tissues. The safety feedback mechanism could also be used to indicate to the user what functions they are using, for example by separate actuation systems. Another strategy to solve the above-mentioned problem could be providing the user feedback about how much force is being exerted. Although preventing the possibility of applying higher force is preferred more than providing feedback, it is important to consider all possibilities systematically in order to develop a complete and efficient instrument.

3.2. Morphological Overview

The morphological overview presented in this section contains various solutions for the sub-functions or focus areas of the instrument in consideration. As mentioned above, the morphological overview only contains solutions to the focus areas that directly contribute to the generation of different concepts. The concepts that are generated from this morphological overview must satisfy the requirements described in Chapter 2 for them to be considered as solutions to the design problem. After the morphological overview is presented, the various generated concepts are detailed in terms of their working principle. This detailing is done up to a point that it answers all questions regarding the sub-functions which the instrument is intended to solve and makes it possible to be compared with other concepts for further selection. It must also be noted that all these concepts are detailed equally in order for the concept comparison to be as transparent and objective as possible.

3.2.1. Interconnection of sub-functions

It is also important to note that the sub-functions and the solutions presented in the morphological overview are also interlinked with each other. For example, a solution that is used to provide safety feedback to the user about the amount of force being applied can


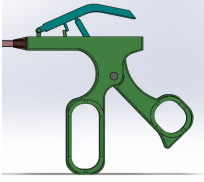



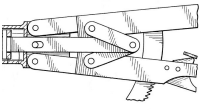
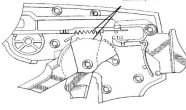
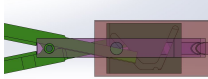
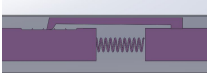
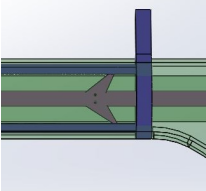

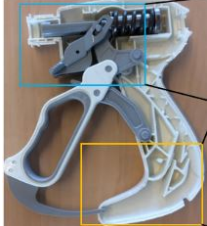

	1	2	3	4
Handle Type	 Scissors	 Scissors+Cylindrical	 Axial	 Levers
Force generation mechanism	 Counter force	 Loading	 Gears	
Safety feedback	 Position control of tip	 Auditory clicks	 Force limiting using compliant mechanism	Separate actuation
Locking mechanism	 Ratchet	 Spring loaded lock	 Confirmation button	

Table 3.1: Morphological Overview

also accommodate a feature for the locking of the handle force. Therefore, it is critical to realise that all the concepts generated might not have independent and distinct solutions for each sub-function. Some solutions for a sub-function also act as a feature to be accommodated and combined with another sub-function via a common solution. In the process of concept generation, it was also noted that certain solutions of sub-functions are more suitable to be linked with a certain other solution in another sub-function. For example, a gear force generation system (rack and pinion) can be used with some handles types but not with an axial handle type because of the input motion given to the handle.

From the overview, it can also be seen that some sub-functions like safety feedback do not have intuitive and already existing general solutions. Solutions to this particular sub-function were generated by taking inspiration from existing instruments and their mechanisms.

3.2.2. Solutions to sub-functions

In the morphological overview, several solutions are presented to the sub-functions. Inevitably, there are more solutions present to a specific sub-function. Therefore, the solutions presented here are chosen to keep in mind the application of the instrument to be designed and the scope of this project.

Handle type

There are four possibilities for the type of handle. The type of handle in the morphological overview has been taken from other types of laparoscopic instruments. Although they might have different applications from the functions being discussed for the instrument in this project, the different types of handles are still relevant to generate innovative solutions. The different types of handles mentioned in the morphological use different types of input motion to generate force at the tip. All of them use a push-pull rod concept with the shaft which makes them suitable for the state of the art tip mechanism as well. Another consideration behind choosing handle types was the control offered by the handle to the user. For example, the state of the art needle holder handle contains a cylindrical grip without finger loops, hence making it unsuitable to be used as a grasper which needs a repetitive motion of the opening and closing of the handle.

- In a survey conducted amongst surgeons by Van Veelen and Meijer [1999], it was seen that 71% of dissectors, graspers and scissors have a pistol grip handle with a scissors model; and 56% of the needle holders and suture graspers have an in-line handle with a cylindrical model. A combination of the two is an in-line scissors model with attributes from both handles and is used in 13% graspers and 23% suturing devices. The summary of this data from this study can be seen in Figure 3.3. Therefore, for the choice of handle types, a scissors model and an axial model is considered.
- For a conventional needle holder, a cylindrical model is used but for a combination of the two, a cylindrical model alone does not offer the control of input motion needed for a grasper. Therefore, a combination of the two is chosen as a solution, for the grip of the cylindrical model and the control offered by the scissors model.
- The lever mechanism is used in clip appliers and offer a closing and opening action of the jaws and is therefore also a relevant solution for the handle type.

Force generation mechanism

- To generate forces, 2 solutions chosen here are from the state of the art instruments. The first solution is the basic and standard solution which is used in the state of the art graspers. It converts the rotational motion of the handle to a sliding motion of the shaft.

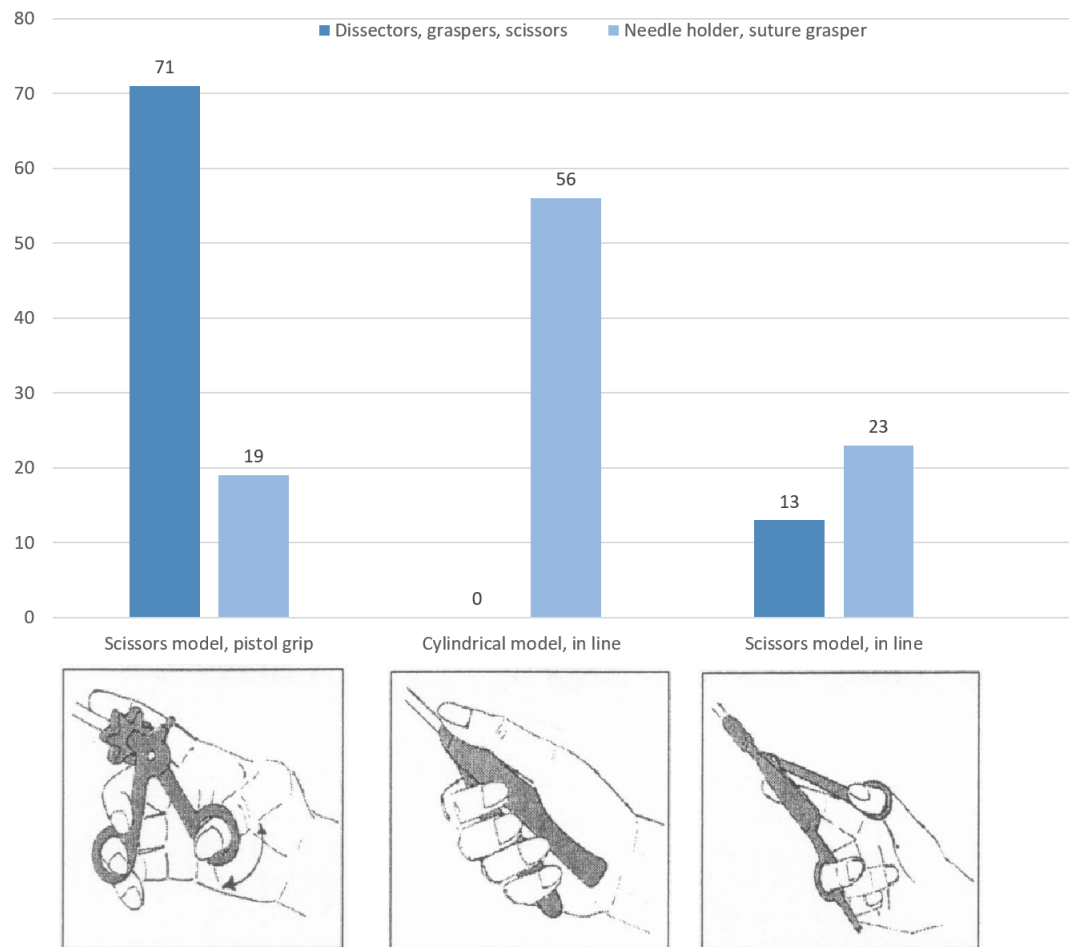


Figure 3.3: Percentages of handle types used in laparoscopy, as surveyed by Van Veelen and Meijer [1999]

- The second solution is the loading mechanism which is primarily used in needle holders. It uses the concept of a slider-crank mechanism where the crank is the handle that is being rotated and via the slider force, the inner shaft of the instrument is moved horizontally.
- The third solution is the gear mechanism that can make use of a rack and pinion mechanism to convert the rotation motion of the handle to linear motion of the inner shaft either for clamping a tissue or for ejecting staples.

Safety feedback

- The first solution presented for providing safety feedback is position control of the tip, therefore manipulating the position to position relation between the handle and the tip to provide information to the user. In position control, the position of the handle is directly related to the position of the tip i.e, the rotation of the handle can be used to control the exact position of the tip at the other end. A v-tip mechanism would be used to separate the two functions according to the position of the tip.
- Auditory clicks, as the name suggests, are audible clicks that inform the user about

the application of higher force. A spring would be attached between two parts of the shaft and when the user exerts force, the extension of the spring would displace the shafts and send the user auditory information through a clicking mechanism.

- Force control is a method or technique used to prohibit the application of a high amount of force by limiting the application of force using a compliant mechanism. When the user exerts force more than a threshold, the compliant mechanism would expand and interact with a fixed component of the shaft to prevent the push-pull motion of the inner cable.
- Separate actuation systems simply have 2 actuation types and therefore remove the chance of confusion regarding the application of high force or instrument use.

Locking mechanism

- The ratchet is the standard state of the art mechanism that involves the interaction of the moving handle piece with the stationary handle piece via cut out ribs and a quick release when the locking function is not needed anymore. This system is used in the state of the art instruments as a locking system because of its easy application and quick release. In some systems, the ratchet can also be disabled and is considered safe because of the interaction with the cut out ribs and the inability to move back.
- The spring-loaded mechanism uses the accumulated tension within the spring to lock a component in a cavity until desired. The advantage of this system is that force can be applied to overcome the initial tension and lock the instrument, like a toggle switch. Since the component gets fixed in the cavity, it is safe and can only be unlocked when the user wants and removes the component from the cavity by toggling the switch back over.
- The confirmation button is a mechanism used to lock the rotation of the component using fixation in the assembly of the handle type using a switch when desired. This system gives the handle no room for movement as it is safely secured and locked in the assembly.

3.3. Concepts

The concepts generated from the morphological overview are presented herein. The sub-functions from the morphological overview and the solution chosen are depicted in the flowchart diagram. While the flowchart diagram shows the individual choices made for each sub-function, an emphasis is also paid on how these choices come together to make the desired conceptual solution. Every conceptual solution is a particular combination of choices from the morphological overview in Section 3.2 and it is important to analyze how the choices for each sub-function work and interact together.

3.3.1. Concept 1

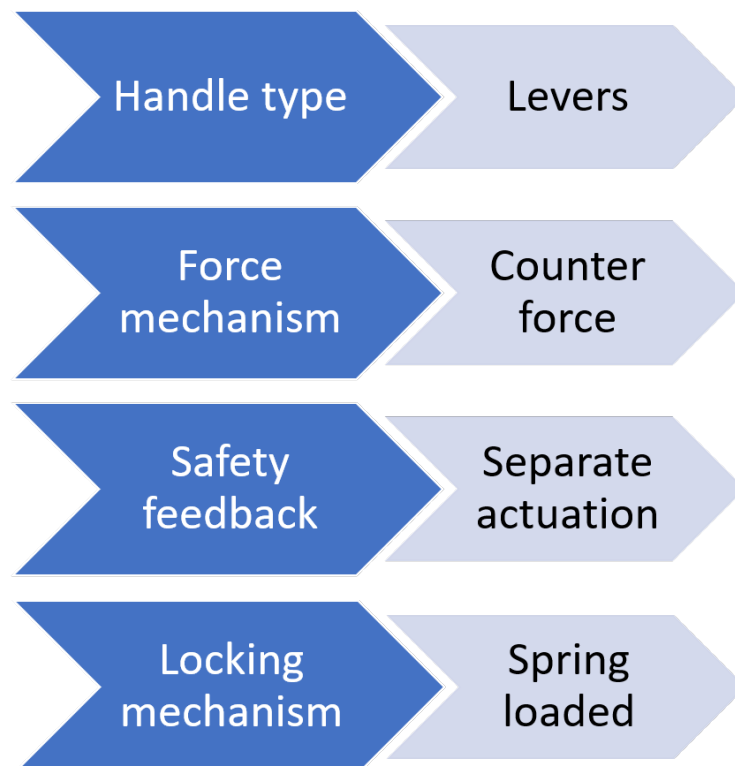


Figure 3.4: Flowchart diagram depicting choices in concept 1

The idea behind this concept was to use 2 separate levers for 2 functions of the instrument. The conversion of input force to output force would be done via the counter force mechanism which converts the rotation of the lever to translation movement of the shaft which is connected to the tip mechanism, as can be seen in Figure 3.4. Using two different levers would mean that the two distinct functions can be performed safely without confusion. For a certain force requirement at the tip mechanism, changing the length of the moment arm at the handle would change the required force at the arm since the shaft force is dependent on the length of the arm and the input handle force. The force mechanism possible for this type of actuation is the counter force mechanism, and the amount of force will be controlled by the 2 different levers.

For the function of the needle holder, the tip also needs to be locked with some constant handle force so that the needle can be held in place. For that purpose, a spring-loaded

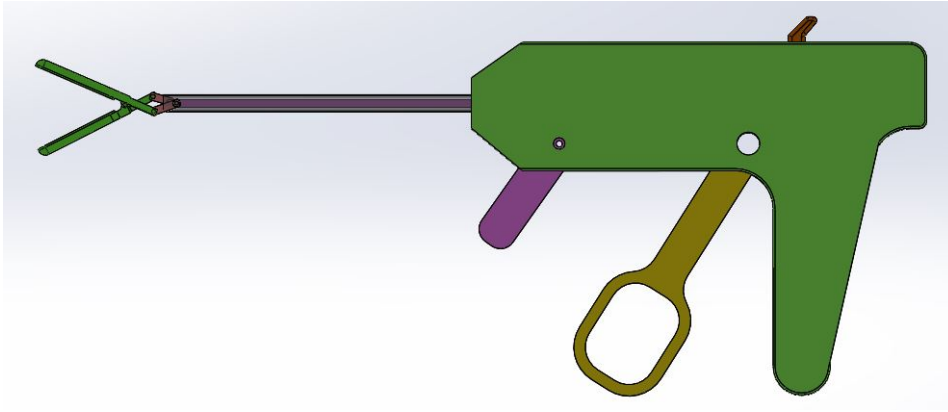


Figure 3.5: CAD model of Concept 1

mechanism that uses the tension of the spring and movement of the lever toggles over a component in a cavity so it cannot be reversed unless the user wishes. The tension in the spring will therefore be used to lock the needle in position. Coupling this particular locking mechanism with the lever handle type is beneficial since ergonomically it will be easier to simply move the lever with some initial force until the tension in the spring is released and the component fits into the cavity. The lever can then be left untouched and the user can simply grip the instrument to perform the suturing function.

3.3.2. Concept 2

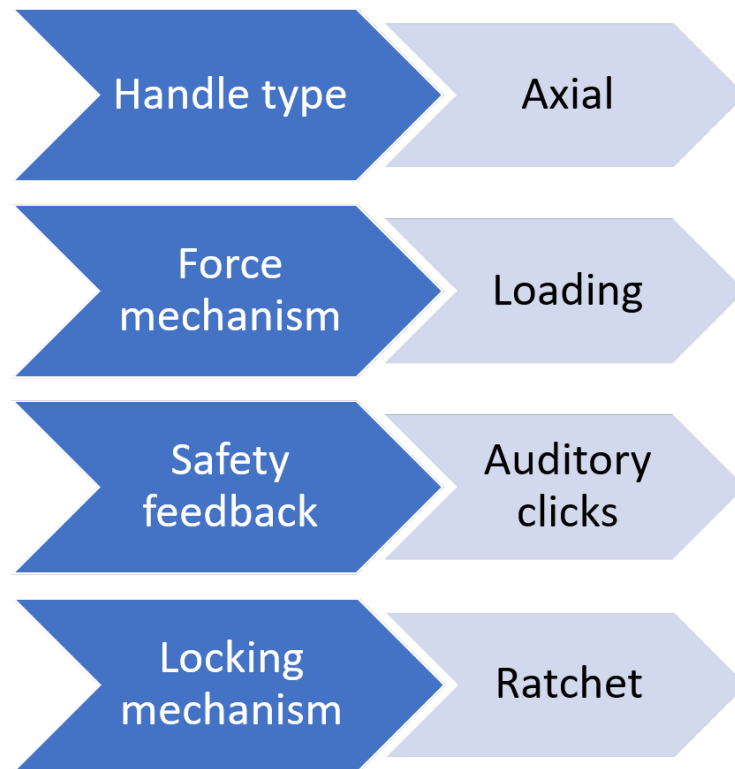


Figure 3.6: Flowchart diagram depicting choices in concept 2

This concept uses the axial type handle along with the loading force mechanism which converts input force to output force. The motivation behind this kind of handle comes from the fact that for a grasper, the user needs the scissors-type loops to carefully open and close the tip while pinching and pulling tissue, and while operating the instrument as a needle holder, the user needs to grip the instrument securely like a pistol grip and perform the suturing operation with sufficient ease of use. The safety feedback is provided via auditory clicks. The principle behind this safety mechanism is that the user should be informed via auditory information that they are either applying more force or using a different function of the instrument. The input force is given at the handle, and the output is received at the beak, so to activate a force feedback mechanism, it would have to be positioned between the input at the handle and the output at the tip.

For generating a force feedback mechanism for this concept, a spring is fitted between 2 components of the shaft with a lever attached to one shaft component. It can be seen in Figure 3.7 that 1 & 3 are the two shaft components and 2 represents the spring between them. 4 is the component attached to 3 that is going to provide the auditory clicks as feedback. In the case of higher application of force, the spring with sufficient stiffness is going to get elongated as it is directly proportional to the applied force, thus increasing the linear distance between shaft component 1 & 3. After a certain increase in distance, component 4 is going to cross over the cut-outs or ribs in component 1, hence making an auditory clicking sound which is going to inform the user of higher application of force.

Since the axial type handle is used in this concept and the user is always in control of the amount of force applied, the ratchet locking mechanism would work well with the choice

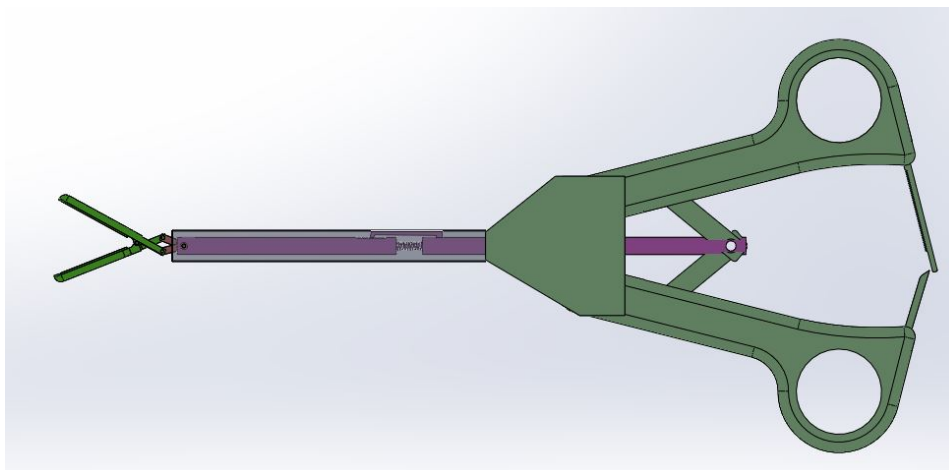


Figure 3.7: CAD model of Concept 2

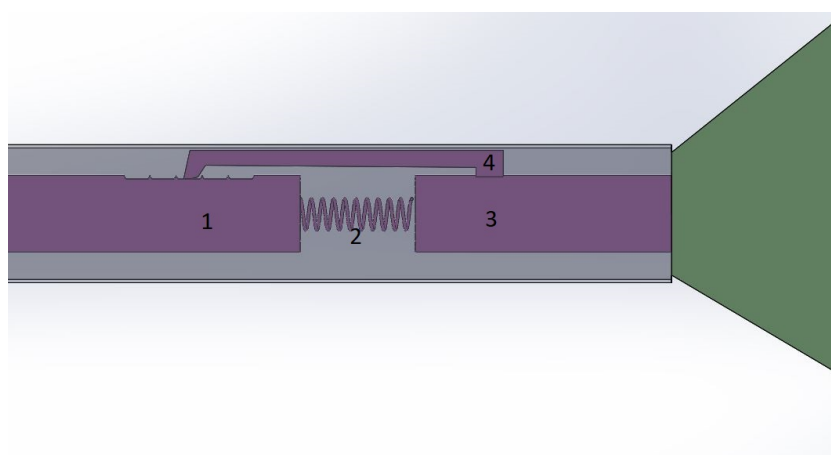


Figure 3.8: Spring mechanism for auditory safety feedback

of handle type. The user can choose to lock the instrument whenever there is a need for constant handle force. The unlocking can be done by disengaging the component which interacts with the locking component in the other handle. In case of the instrument being used as a grasper, the ratchet can also be deactivated completely and the auditory clicks can be used for safety indication. When the instrument is used as a needle holder, the auditory clicks can be ignored and the ratchet can be put into place to lock the handle after the needle is gripped tightly into the tip of the instrument.

3.3.3. Concept 3

This concept uses the scissors-type handle with the counter force mechanism so that the opening and closing of the tip can be facilitated with the opening and closing of the handle. The safety mechanism used in this concept is based on the principle of position control. The position of the tip is going to be used as feedback to the surgeon about the type of function being performed. For controlling the position of the tip, a guided channel is used as the tip mechanism as shown in Figure 3.10. The working principle behind this guided channel is that one section of the guided channel is going to be used as the grasper and the other for the function of the needle holder. The needle holder function is going to be

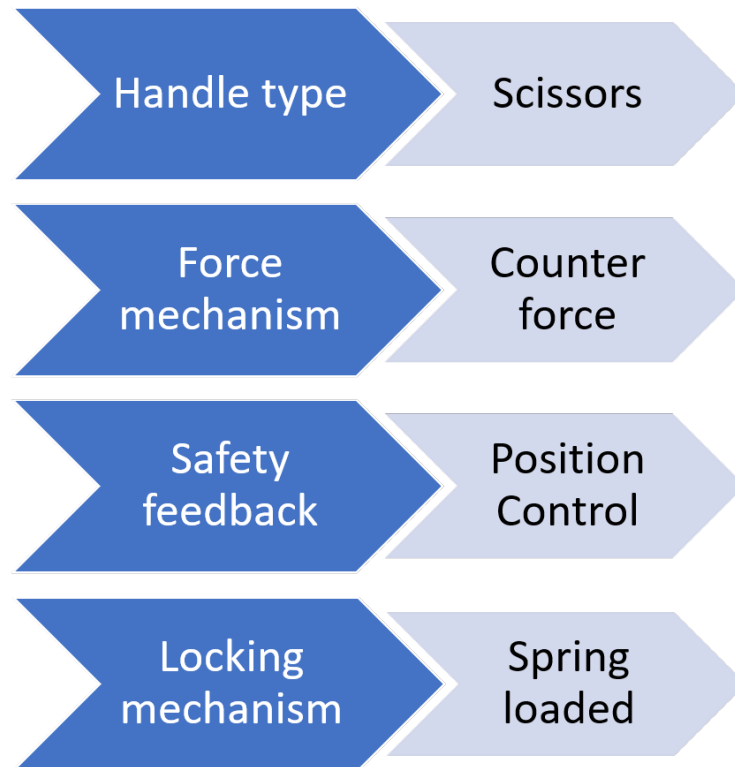


Figure 3.9: Flowchart diagram depicting choices in concept 3

activated when the inner shaft translates so that the levers of the tip shift to the other region of the guided channel and the tip is shut close. A more detailed description of the guided channel is represented below.

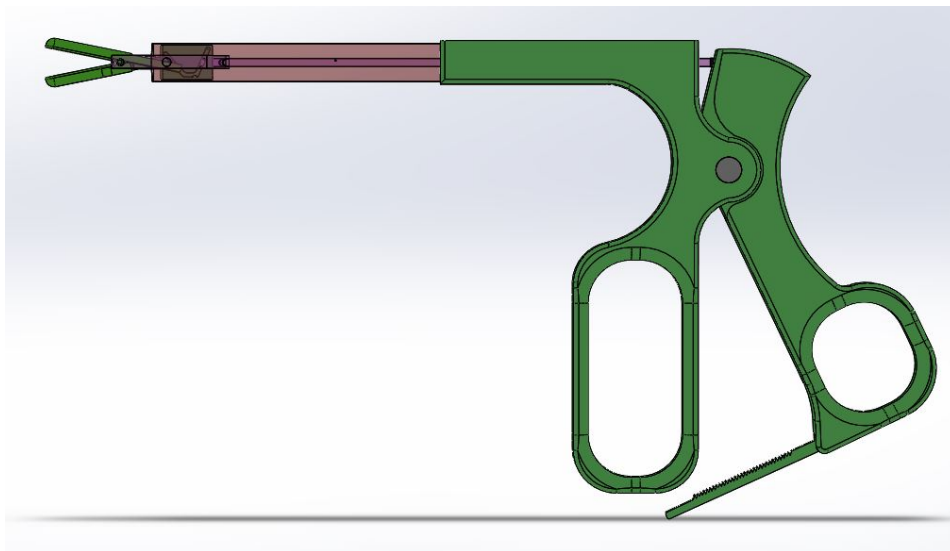


Figure 3.10: CAD model of concept 3

As it can be seen in Figure 3.10, the guided channel consists of a v-shaped cavity. There is a constant elastic force that is going to push the beak towards the horizontal right direction. The left portion of the cavity is for the function of the grasper, and the right portion is for the

needle holder. The tip is closed when the right end of the tip (marked by A) is at positions 1 and 3. Therefore, for the grasper function, the resting position of the beak will be at position 2, with the tip open. In order to close the beak, the user will have to exert force and move A towards position 1. When it is needed to switch to the needle holder function, component A of the tip will have to move from position 2 and overcome the bump in the cavity. This bump in the figure is to give an idea about the resting position. The final detailed version would however be more secure. As soon as component A does that, the elastic force of the spring is going to push it to position 3, where the tip will be in its extreme closed position. In case of a needle being between the tip, component A of the tip might not reach the end position 3, but it will be able to grip the needle in the required position as per appropriate spring tension being applied at it. A spring-loaded locking mechanism is chosen for this concept since there is an elastic force used in the cavity to push component A of the beak towards the horizontal right direction. Therefore the tension in the spring can be used to make sure that when the switch to the function happens, a component of the locking mechanism can be locked into a cavity and the needle can be held in its place until the user wants to release it.

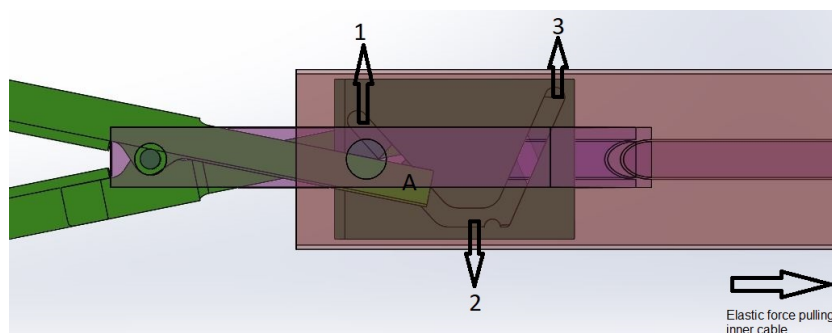


Figure 3.11: V-shaped cavity

The motivation behind the change of function in this concept is focused on opening the tip more than a certain angle is because the range of angle that is required for a standard grasper. The standard range for a grasper is 55 to 65 degrees and therefore opening it more than an angle more than 65 degrees would be outside its normal range of angles.

A scissors-type handle is used for this concept and combined with the other features as this guided channel type of safety feedback would require control in the hands of the user in terms of position to position control. The position of the handle controls the direct position of the tip and in turn the functional change as well. Therefore, a handle type is chosen that can offer control to the user.

3.3.4. Concept 4



Figure 3.12: Flowchart diagram depicting choices in concept 4

A combination of two types of handles is used in this concept since two functions are intended to be performed by the instrument. The standard handle for a grasper is the scissors type and the state of the art for a needle holder handle is the cylindrical grip handle, therefore a handle type that ergonomically combines the two is the handle type choice, as can be seen in Figure 3.12. Therefore, the force mechanism for this concept would be a combination of the loading mechanism and the counter force mechanism. As a result of the two different types of handle types and force mechanism, the safety feedback for this concept is in the form of separate actuation. Since there are two different types of actuations, the distinction in the input of force is quite clear. Each handle mechanism has a different mechanical efficiency and can also be designed to have different force resolution in terms of the input to output motion. The locking mechanism for the function of the needle holder when the needle needs to be locked between the tip is chosen to be ratchet mechanism as handle type of the needle holder function is the pistol handle, which is the state of the art and a ratchet mechanism is suitable for this handle type.

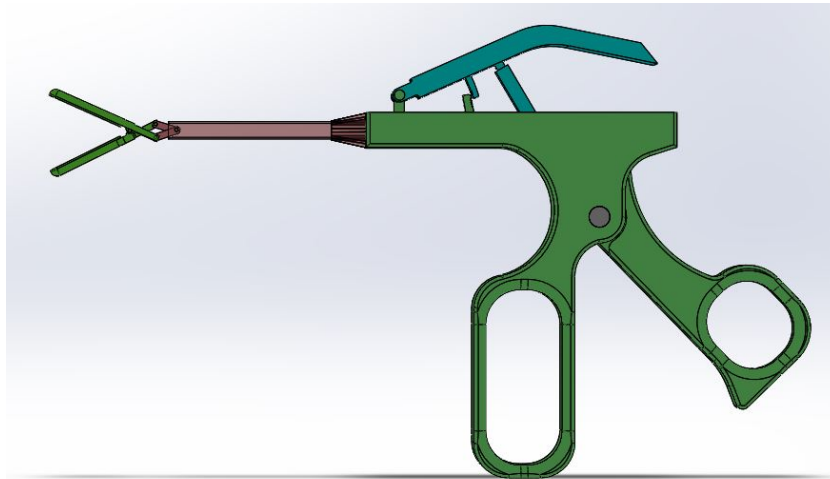


Figure 3.13: CAD model of concept 4

3.3.5. Concept 5

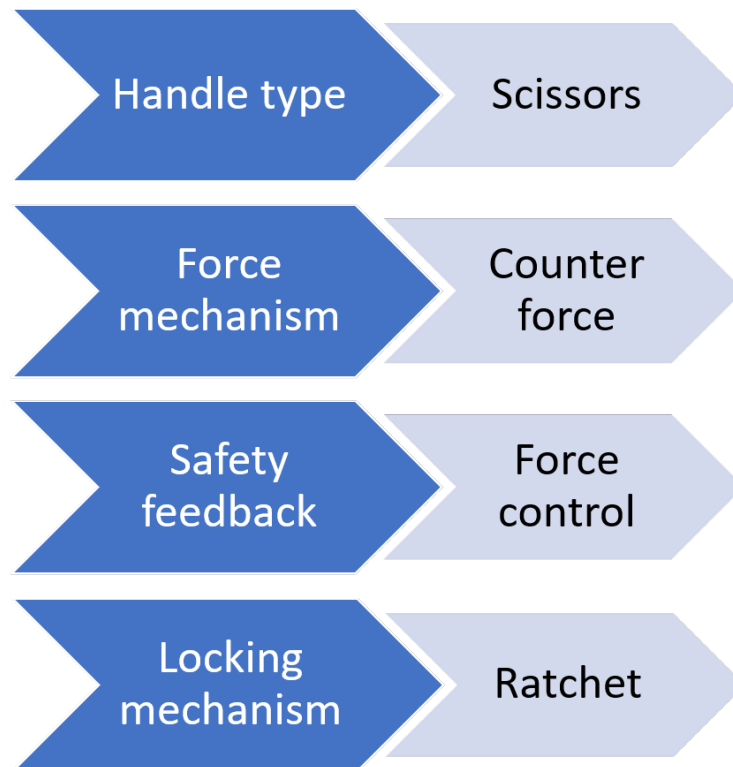


Figure 3.14: Flowchart diagram depicting choices in concept 5

The idea behind this concept is based on the concept of force control. The concept uses a scissors handle type with a counter force mechanism. This concept uses the force control method as a safety mechanism but focuses on the prevention of high amounts of force rather than simply providing feedback on the application of force. Therefore, an effective force control mechanism would stop the user from applying more force than is intended for that function, in this case, the function of a grasper. Similar to concept 2, safety feedback would have to be positioned between the handle and the tip.

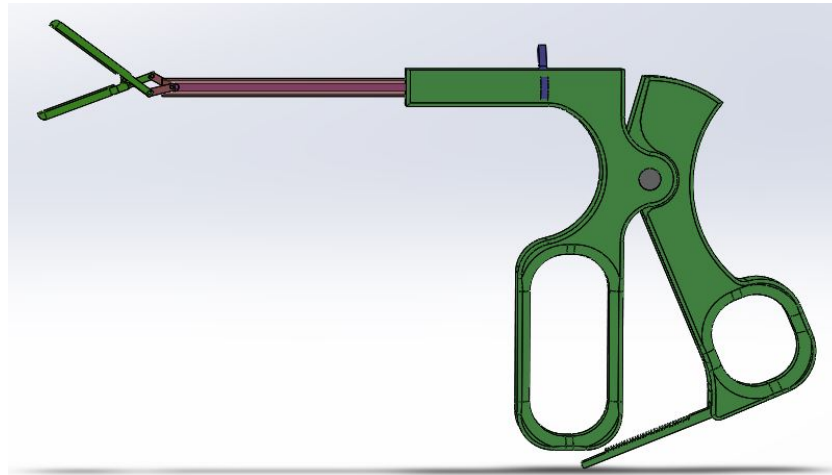


Figure 3.15: CAD model of concept 5

For this concept, a force control mechanism is designed using a compliant mechanism as can be seen in Figure 3.16. The mechanism consists of a flap that is present in the inner shaft that would get activated after a certain threshold of force is crossed. Once activated, the flap would be in contact with the safety switch, fit onto a slot and prevent the shaft from being displaced any further. The slot is located on the inner side of the switch.

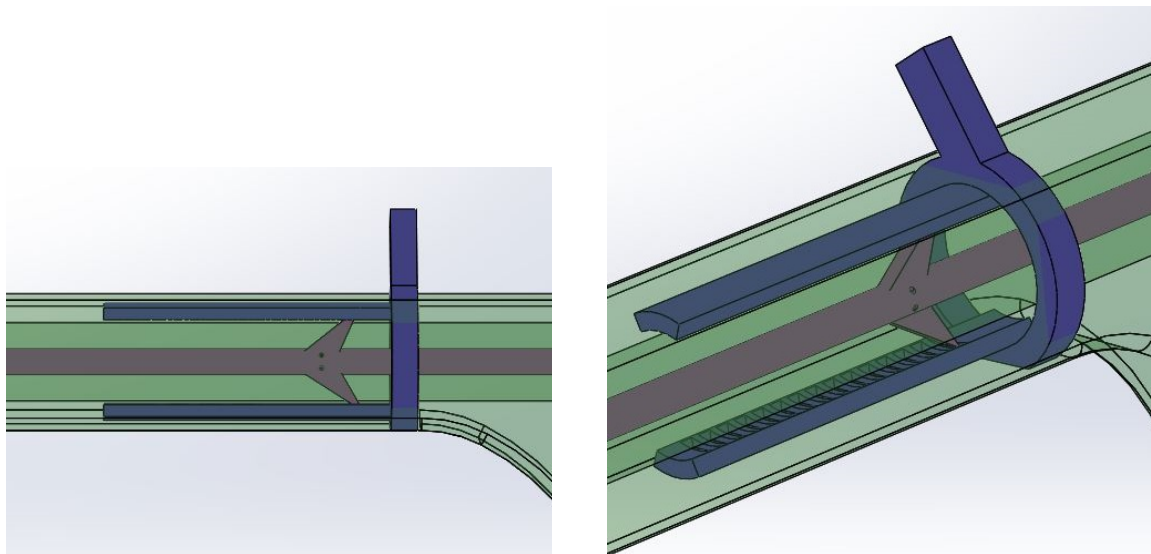


Figure 3.16: Compliant mechanism for force control

To enable the use of a needle holder and to stop the prevention of higher application of force, the switch will have to be moved. Moving the switch will make sure that the component of the switch that was earlier coming in contact with the compliant flap mechanism is no longer in its original position and therefore does not restrict its movement anymore. This will make sure that even when more force is applied, the flap gets activated after a certain force threshold is crossed, but the absence of the switch component in its original position would mean that the linear movement of the shaft is free and hence higher force can come into play. When the switch is turned off and the instrument is to be used as a

needle holder, the handle will still need to be locked with constant handle force to lock the needle inside the tip. Since the concept makes use of a scissors-type handle, a ratchet mechanism is a suitable fit for a locking mechanism.

3.3.6. Concept 6

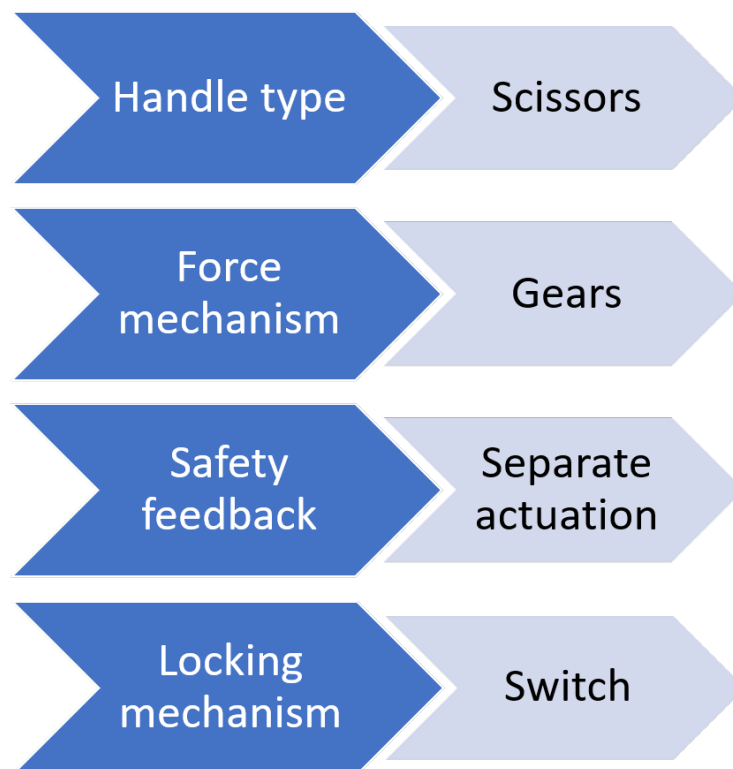


Figure 3.17: Flowchart diagram depicting choices in concept 6

This concept uses gears as the mechanism to generate force - specifically a rack and pinion mechanism. A scissors-type handle is used so that the rotation of the scissors handle can be converted into linear motion of the shaft by using a rack and pinion mechanism. The concept also uses two different gear combinations. For the function of the grasper, a lesser average force is required at the shaft than a needle holder function. Therefore, a gear combination is chosen with two pinion gears of different diameters. The tangential force available from a rack and pinion mechanism is inversely proportional to the diameter of the pinion. Therefore, a smaller diameter pinion is chosen for the needle holder function.

The switch of these gear systems would take place by moving the rotating handle laterally and locking it in a functional position. Therefore, the same handle is used for both functions but each function has a separate actuation system, which will in turn act as a safety mechanism. While making this switch to another function, a form of visual feedback can also be provided to the user about what function is active. The locking of the handle would be done by a confirmation switch mechanism. The locking mechanism would require the handle to be shifted one more level laterally and hence lock the handle in the assembly of the handle. This would make sure that constant force can be applied and the shaft can be prevented from moving when the instrument is used as a needle holder. A confirmation switch can be used to block the lateral position of the handle inside the cavity and

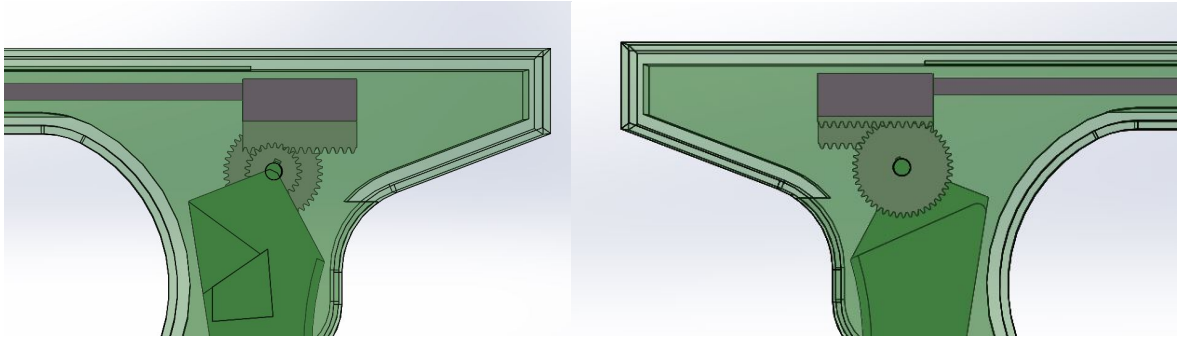


Figure 3.18: Gear arrangement of concept 6

make sure that the handle does not move unless the switch is disengaged.

4

Concept Evaluation

After generating conceptual solutions, the next step is to evaluate and compare concepts to select the best design. In this chapter, the concepts are evaluated first with respect to their individual features and then compared with each other. After a comprehensive evaluation, a decision is made to select which concept is going to be detailed in the last stage.

4.1. Features of concepts

- **Concept 1:** Concept 1 focuses on the principle of using 2 different levers for 2 distinct functions. While one of the disadvantages of this concept could be the extra number of steps associated with two separate types of actuations, an advantage of this kind of system is the clear distinction of the functions. This removes any chances of confusion for proper use of the instrument. The user is given a clear choice for each function. A feature of this concept also includes a possibility to adjust the length of the levers and the contact point at the inner shaft so that the moment arms can be changed to influence the rotational force required at the handle. Although the possibility of separate actuation offers clarity and distinction, it could also lead to a bulkier assembly of the handle, which in turn might pose challenges in manufacturing and cleaning.
- **Concept 2:** Concept 2 focuses on using elastic force as feedback for the safety mechanism. The advantage of this kind of mechanism is that it is reliable and easy to use. In terms of repeatability, it can offer multiple cycles of use due to its simple design. One of the most important aspects of this concept would be to choose a spring of appropriate stiffness. The axial handle also offers more control than a cylindrical model because of the finger loops. One disadvantage associated with this concept is that the use of this type of safety feedback mechanism is only going to provide auditory information about the application of force. The user is still in control and in case of a mistake, higher forces could still be applied when not intended.
- **Concept 3:** Concept 3 focuses on the control of the position of the tip of the instrument and change functions. The advantage of this concept is the less number of steps required. All actions are done via one handle mechanism. The change of function is based on the fact that there is a range of use for the tip of a grasper and exiting that range can be used to lock the instrument in the required position. The elastic force of the spring in the locking mechanism can be used for the grasper function to keep the

tip open and for the needle holder function, it can be used to close the tip with the required force. The disadvantage, however, with this concept is the detailing required in the tip mechanism. The effective functioning of this concept will only be assured with an accurate design. Additionally, the switch to the needle holder function is possible by a simple action, therefore, increasing the possibility of an unintended switch.

- **Concept 4:** Concept 4 focuses on the combination of the 2 types of actuation for the 2 intended functions of the instrument. The idea is not to make a modular tool by simply putting 2 functions into one instrument but to use the different types of actuations to the benefit of each function. More sensitivity for the movement of the tip is provided for the grasper action as it uses the scissors grip with the finger loops and simple application of force is used for the needle holder through the loading mechanism. The two types of actuation systems are combined in an ergonomic way that would make it easy to operate. The disadvantage of this type of combination is the bulkiness of the design. Additionally, the design is not very ergonomic in terms of the number of steps involved as the user would have to perform separate steps for each function.
- **Concept 5:** Concept 5 focuses on the principle of providing safety feedback via prohibition of force application. The compliant flap in the instrument gets activated after a certain threshold of force is crossed and doesn't allow the user to exert any higher force by engaging with the switch. Intentional disengaging or deactivation of the switch would allow the compliant flap to not engage with the switch even if high forces are applied. Although this concept allows the user to use the instrument as intended, one of the major disadvantages of this concept is the fragility of the compliant mechanism and its possible inability to operate over multiple repeatable cycles. The number of steps to use the instrument for its intended use is also high as engaging and disengaging the switch adds to the basic steps involved in using the instrument.
- **Concept 6:** Concept 6 focuses on the principle of using the high efficiency of gears for its force-generating mechanism. The use of gears also gives the added advantage that different diameter of the pinion gear enables the user to choose the ratio of input torque of the handle to the output force available in the shaft. Reducing the diameter of the pinion gear would mean that more rotational movement of the gear is required to obtain the same desired translation of the shaft. This concept also has a complex design. The accuracy of the gears, their mating action and the shifting of function relies on accurate details of the gear design.

4.2. Concept choice

For selecting the best concept, all the conceptual solutions are compared to each other with respect to certain criteria, which are obtained from the main focus areas of the instrument. The discussion for comparing the concepts according to each criterion is as follows:

- **Force generating mechanism:**

The force-generating mechanism is one of the criteria over which the various concepts were compared. The efficiency of the force-generating mechanism was the focal point of this criteria i.e. the amount of output force generated at the shaft of the

instrument if a given force is applied at the handle. In the concepts discussed above, there is a counter force mechanism, a loading mechanism, a rack and pinion mechanism and a combination of the counter force and axial mechanism. The efficiency of the various mechanisms was calculated via kinematic analysis, considering a constant force being exerted at the handle, F_{handle} .

In the case of a rack and pinion mechanism, the tangential force,

$$F_{shaft} = \frac{2 * T_h}{d}$$

Where T_h is the torque exerted at the handle and d is the diameter of the pinion gear. Here, $T_h = \text{Length of the lever arm} * F_{handle}$. Since there are 2 pinions in concept 6, the shaft force comes out to be 21.38 times the handle force and 11.83 times the handle force for the smaller pinion and bigger pinion respectively.

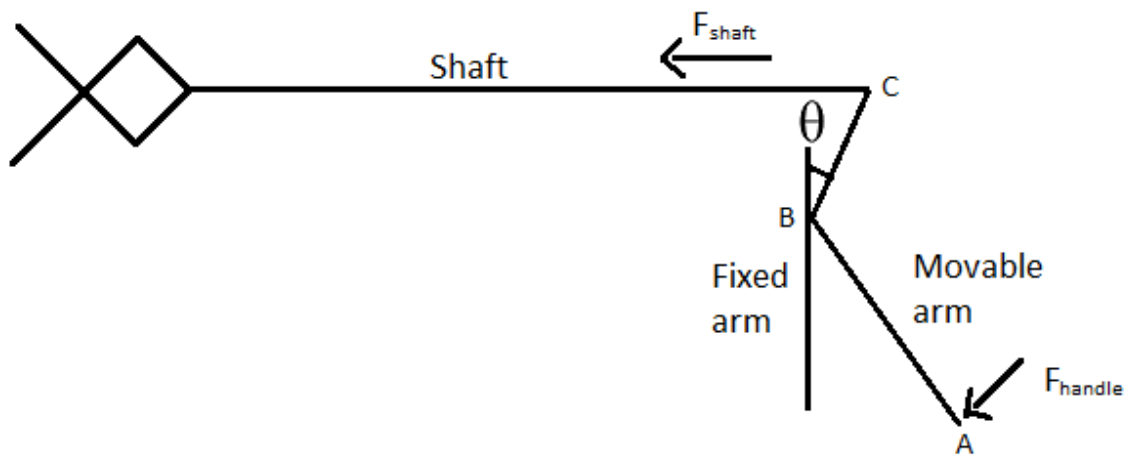


Figure 4.1: Schematic diagram of counter force mechanism

For the counter force mechanism, the schematic diagram can be seen in Figure 4.1. The handle force is applied at point A and the resultant force is along the shaft from point C. The force along the shaft,

$$F_{shaft} = \frac{F_{handle} * AB}{BC * \cos\theta}$$

Therefore the force along the shaft depends on the angle θ . The force was calculated for the 2 extreme positions of the range of motion of the handle. The extreme positions of the handle were calculated by assuming a standard 4 bar linkage as the tip mechanism, for which the extreme angles between the tip are 65° and 0° . The force along the shaft for the angle between the jaws being 65° came out to be 2.35 times the handle force and for the angle between the jaws being 0° , it came out to be 2.5 times the handle force.

For the loading force mechanism, the schematic diagram can be seen in Figure 4.2. The mechanism is similar to a slider-crank mechanism. The crank receives a torque

and there is a horizontal force obtained at the slider. In this case, the crank is the handle lever, AC and the Slider is at point D which is attached to the shaft and gives it a horizontal force of F_{shaft} . F_{shaft} depends on the ratio of the perpendicular distance of points A & B from the pivot point C, as well as the two angles α and β . The shaft force is,

$$F_{shaft} = F_{handle} * \frac{AE}{BF} * \frac{\cos\alpha\cos\beta}{\sin(\alpha + \beta)}$$

As the force obtained on the shaft is a function of the angles, in this case as well the force is calculated for the two extremes positions. The force along the shaft for the angle between the tip jaws being 65° came out to be 3.63 times the handle force and for the angle between the tip jaws being 0° , it came out to be 6.12 times the handle force. Therefore, from the above calculations, it was found out that the rack and pin-

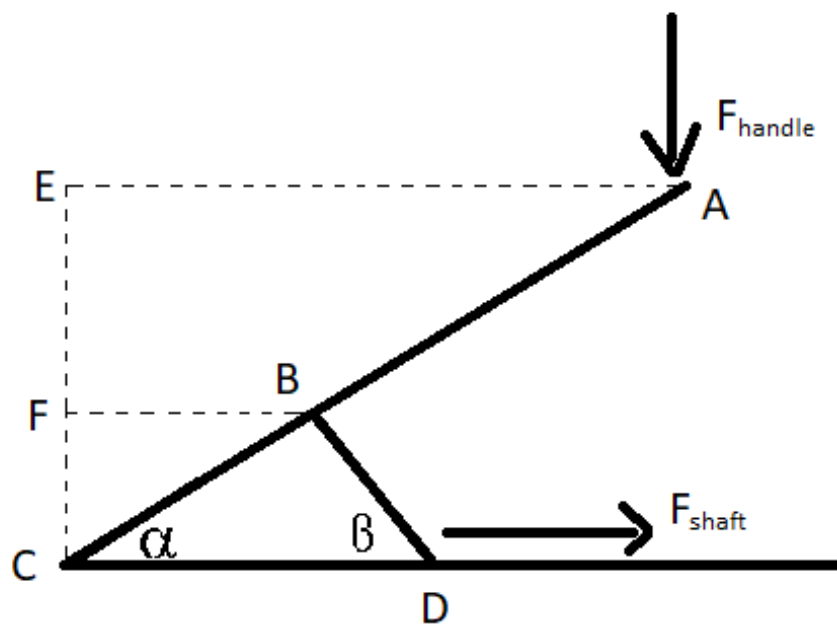


Figure 4.2: Schematic diagram of loading force mechanism

ion mechanism has the highest efficiency, followed by the loading mechanisms and then the counter force mechanism. Therefore in Figure 4.3 it can be seen in the first row of comparison that concept 6 is the best solution followed by concept 2. Concept 4 uses a combination of the counter force and the axial handle and is therefore placed between the two for this estimation.

- **Safety Feedback:** The safety feedback criteria aims at evaluating the various safety feedback mechanism present in the concept and compare them against the others. This criterion focuses on the quality of feedback to the user about the change of function or the application of force. Concept 5 which uses the principle of prohibition of force application is the best when it comes to the safety feedback mechanism as it doesn't allow the user to apply high forces.

Concepts 1,4 and 6 have separate actuation systems so they as a group are second best. But amongst themselves, concept 4 has two separate actuation systems in terms of a scissors handle and a pistol grip on top and the location of needle holder actuation makes it safer than concept 1, where there is a possibility of the needle holder lever being activated unintentionally. Concept 6 has its safety mechanism in terms of the handle shifting gears laterally and therefore has a visual feedback presence in front of the user, making it better than concept 1.

Concepts 2 and 3 provide information to the user about the application of force but do not directly limit the application of force and therefore are as a group, placed last. Amongst themselves, concept 2 provides auditory information to the user after a certain threshold is crossed whereas concept 3 relies on the position of the tip being open for the safety mechanism. The uncertainty with concept 3 is that an unintentional movement of opening the jaws could activate the needle holder even when not desired.

- **Ergonomics (number of steps):** Ergonomics as a criterion is split into two - the number of steps and the ease of use. The number of steps focuses on the number of independent steps it takes to perform all the intended actions by the instrument i.e. the number of steps taken to perform the grasper action, change the function of the instrument, lock the handle for the needle holder function and perform the function. When it comes to this criteria concept 3 takes the least number of steps as it just takes 1 step to change the function of the instrument and the spring-loaded mechanism locks the instrument. Because concept 2 doesn't involve any step in the change of the function because of its auditory safety feedback mechanism, the only step involved is the activation of the locking ratchet for the needle holder. Following this, concept 6 makes 2 lateral steps to change the function and then lock the handle in a required position. Although concept 6 falls lower than concept 2, these steps are not completely independent steps and thus concept 6 is better than concept 1 and 4 where because of the two actuation system, an extra step is needed for function change and then one for locking. In some cases of separate actuation, the user might also choose to use another hand, which in terms of ergonomics is a disadvantage. Concept 5 is the last for this criteria since it has a switch-based safety mechanism; to change functions, the switch needs to be disabled, the ratchet enabled and then the locking of the handle
- **Ergonomics (ease of use):** This criterion focuses on the ease with which the user will use the instrument for its desired purpose. Concept 3 is the best for this criterion and all the intended functions are performed by a conventional motion like in the state of the art grasper and for the change of function, the scissors need to be opened more than a certain angle. It is followed by concept 2 as it involves only the axial handle movements. The grasper action can be performed by a pinching action of the fingers. The feedback happens with the internal mechanism and doesn't require the user to perform any extra manoeuvre and the locking also takes place with the conventional ratchet. Concept 6 comes after these 2 as even though it uses the conventional scissors handle for the actions, it uses the lateral movement of the handle to change functions and then lock the handle. This lateral shifting might require the user to hold the instrument with either another hand while the shifting is done,

or push the hand lever with the thumb while the rest of the hand gives the handle assembly some support. It is an unconventional movement and therefore this concept follows after concept 2 and 3. The rest of the concepts either require the hand to stretch further or the use of 2 hands. For the next concept, concept 5, the switch needs to be deactivated to change function. This might be done with a finger of the hand holding the instrument or with another hand, making it ergonomically less effective than the others. Concept 4 then requires the user to use another part of the instrument when it is intended to be used as a needle holder. For this purpose as well, the user can stretch the thumb and use it or use another hand. And lastly, with concept 1, the lever for the needle holder is placed in front at the distal end of the user and would require the hand to stretch or another hand to use it. The last 3 concepts are graded amongst themselves by the level of discomfort if all are used by only one hand.

- Complexity of design:** This criterion focuses on the complexity of the design and its construction in terms of bulkiness. More detail required for the instrument to work effectively would mean that a higher manufacturing accuracy is desired. For concept 2, the instrument has a simple axial handle with a ratchet. The safety mechanism has a spring that is attached between 2 parts of the shaft and therefore in terms of the complexity of the design of its components, it has a fairly simple design. Concept 4 and 1 are more complex in terms of manufacturability as they have a bulkier handle assembly. Concept 3 is next since even though it is not bulky, it has a complex channel in the tip mechanism that would need to be accurate to work as intended. Concept 6 follows as the accuracy of the gears required for that small a diameter is quite high for the effective engaging and disengaging of the gears, therefore its complexity of design is on the higher side. Concept 5 has the most complex design due to its compliant mechanism. The construction and accuracy of the compliant flap are fundamental in the working principle of the concept as it needs to be activated after a force threshold is crossed.

Requirements	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5	Concept 6
	2 Moment arms	Spring	V tip	2 actuation	Compliant switch	Gears
Force generation mechanism	Yellow	Green	Yellow	Yellow	Yellow	Green
Safety feedback	Yellow	Red	Red	Green	Green	Yellow
Ergonomics (number of steps)	Yellow	Green	Green	Yellow	Red	Yellow
Ergonomics(ease of use)	Red	Green	Green	Red	Yellow	Yellow
Manufacturability/Simplicity of design	Yellow	Green	Yellow	Green	Red	Red
Total score	Red	Green	Green	Yellow	Red	Yellow

Figure 4.3: Modified Harris profile

The process of selecting the most suitable concept is done by a modified Harris profile. Unlike a conventional Harris profile, the concepts are not judged on a scale of ++ to –, instead, they are given colours relative to each other and ranked as per a criterion. The idea behind this alteration to the system is to make the visualisation more intuitive. The

criteria that are chosen, as can be seen in Figure 4.3 in the first column are either important sub-functions that the concepts have to perform or important considerations that are chosen as criteria for these kinds of design projects. For the process of ranking, the con-






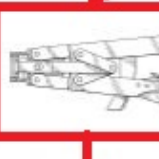

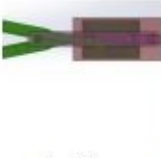

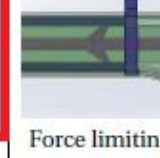



	1	2	3	4
Handle Type	 Scissors	 Scissors+Cylindrical	 Axial	 Levers
Force generation mechanism	 Counter force	 Loading	 Gears	
Safety feedback	 Position control of tip	 Auditory clicks	 Force limiting using compliant mechanism	Separate actuation
Locking mechanism	 Ratchet	 Spring loaded lock	 Confirmation button	

Figure 4.4: Choices of selected concept in morphological overview

cepts are assigned certain colours. The best concept for certain criteria would get assigned the colour dark green, the second-best is assigned light green, followed by the third-best in yellow, the fourth-best in orange, the second to last is assigned the colour red and the last one is denoted by dark red. The assigning of a certain colour makes sure that the grading is relative. Concepts are given the same colour if there is no way of differentiating between them according to a criterion or if they use the same mechanism.

It can be seen from Figure 4.3 that the best concept came out to be Concept 2 with the spring safety mechanism. It can be observed that although the concept scores well in most criteria, it scores considerably lower in the safety feedback criteria. The concept eventually came out to be the best one since all criteria have equal weight in the comparison table. For the design problem in this project where 2 functions are being combined, safety feedback is an important criterion but it must be noted that all the three categories of feedback

considered are sufficient for the instrument. The feedback in this instrument is done by auditory clicks which in itself is a functional choice but in comparison to others, scores lower. Therefore, scoring low in that category does not make this concept undesirable or a solution that is not good enough because of the type of solutions offered for safety feedback.

The final chosen concept, Concept 2, can be seen in Figure 4.4 as per the choices from the morphological overview. This selected concept will be detailed further in the next chapter for design and functional details.

5

Final Design

After making a decision about which conceptual solution is the best on the basis of the criteria, the next step is to develop that conceptual solution into a detailed design. As discussed in section 3.1, there are certain focus areas that will be detailed in this chapter to obtain the detailed design. The design of an instrument can be broken down into designing its various components in detail and then analyzing how they would come together to function as an instrument. This chapter, therefore, presents the design of various components of the instrument in terms of their kinematics and force models along with the various assemblies which depict how many different parts are there in the instrument and how they interact together.

5.1. Design of components

5.1.1. Tip mechanism

The standard state of the art grasper uses a 4 bar rhombus linkage as the tip mechanism. For this instrument, in this subsection, the force calculations are presented that will provide the respective forces that are needed for the instrument and its function as a grasper and needle holder. In this 4 bar linkage, the linear translation of the shaft enables the opening and closing of the tip.

In a study by Van den Dobbelsteen et al. [2012], a force model of the 4 bar linkage is presented with the relation between the shaft force and the opening angle of the tips. The force model from this study is used as a reference in this subsection for the evaluation of the pinch force. For the evaluations, the calculations are done without considering friction forces and it is also assumed that because of the tip geometry being symmetrical, the pinch forces are equal on both sides of the grasper. This force model is also only valid for an idealized grasper with an equal length of links. In Figure 5.1, the schematic representation of the 4 bar linkage is presented.

In Figure 5.1, the forces acting on different points can be seen. The angles described in the figure are changing constantly with the movement of the linkage. The angle β is a summation of a constant angle β_0 and the angle between the tip and the horizontal centerline, θ . Therefore, $\beta = \beta_0 + \theta$. Subsequently, the forces on different points can be calculated.

$$F_a = \frac{F_{shaft}}{2\cos\beta}$$

of β_0 , the value of pinch forces increased for all the values of opening tip angles, hence increasing the value of the force transmission itself. Whereas it would be useful to choose an angle of 50° for β_0 for force transmission, the geometry of the tip assembly does not make it possible for the diameter of the whole assembly to be less than 5mm so that it can be suitable to enter a 5mm trocar port. Therefore an angle of 15° was chosen for β_0 . For an angle of 15° for β_0 , the force transmission λ comes out to be:

$$\lambda = 0.0153\theta + 0.2808 \quad (2)$$

The average absolute error of this approximation came out to be 0.0056 and the standard deviation of 0.0066. Additionally, to visualize this linearization and analyze it even further, a constant shaft force was taken and the pinch force was calculated by the 2 means: by calculations from the force model and by using the force transmission coefficient λ . A constant shaft force of 40N was taken and the resulting pinch forces can be seen in Figure 5.2.

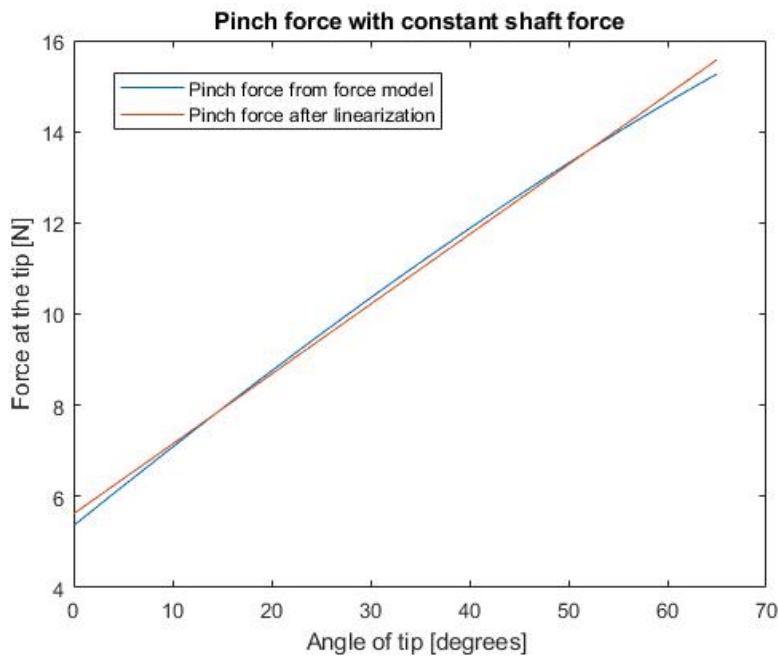


Figure 5.2: Comparison of generated pinch forces by force model & linearization

To visualize the relationship between the different variables and the pinch force, the above-explained formulae were put into MATLAB to obtain graphs between these parameters. It is known that the force required to safely secure the suture needle into a tip is 9N and that the grasper should be able to generate a pinch force of at least 3N. Therefore the maximum requirement of the pinch force of 9N was taken as a constant and the other parameters were obtained.

Figure 5.3 shows the relation between the opening angle of the tip and the required shaft force for a constant pinch force of 9N. It can be seen that the shaft force increases with decreasing opening angle of the tip when a constant pinch force of 9N is needed. This relation can be explained from the fact that if the pinch force is constant, the shaft force is inversely proportional to λ and therefore the opening angle θ of the tip (from (1)).

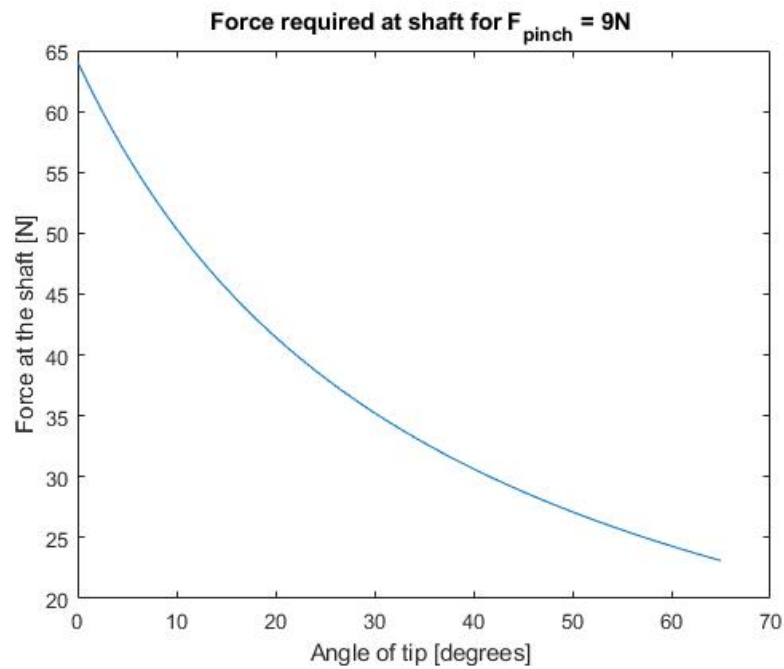


Figure 5.3: Force required at the shaft to maintain constant pinch force of 9N

With the force calculations completed, a CAD model of the tip mechanism was made. The tip assembly consists of 6 components which form the state of the art 4 bar linkage is used which uses 2 hinges and a push-pull rod for actuation. The exploded view of the assembly can be seen in Figure 5.4. 6 is the outer shaft which will also be seen in the handle assembly further in the chapter. 5 is the inner push-pull rod from the safety mechanism assembly. 2 are the tips or the beaks of the tip assembly which are the effective end effectors. 4 is a pivot pin. 3 are articulating levers used in the 4 bar linkage and 1 is another pivot pin used for the beaks.

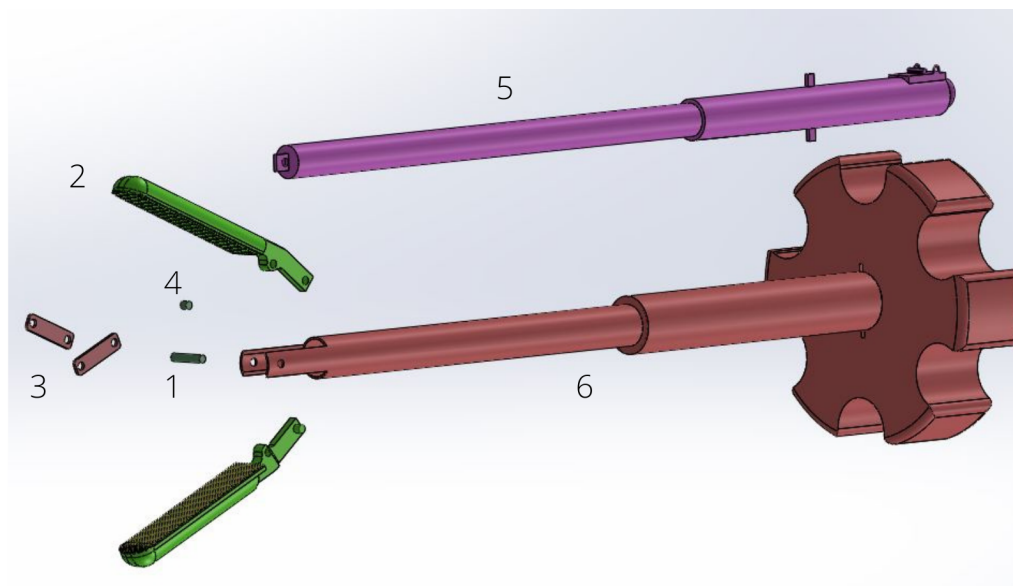


Figure 5.4: Exploded view of the tip assembly

Shaft 5 is placed concentrically inside 6. Articulating levers 3 are attached to 5 using pivot pin 4. The beaks 2 are attached to outer shaft 6 using pivot pin 1. The complete assembly of the tip can be seen in Figure 5.5.

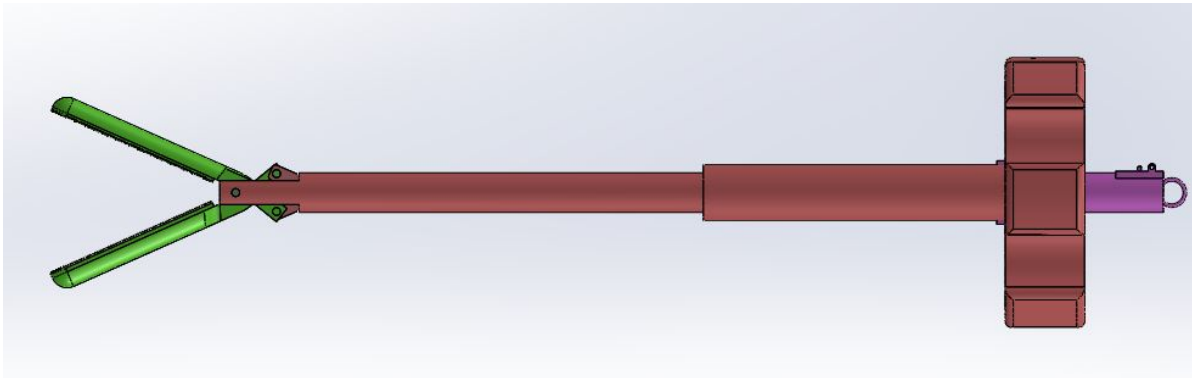


Figure 5.5: Side view of the tip assembly

The beak of the assembly opens up to an angle of 65° as per the requirements of the instrument. The cross-section of the tip that would interact with tissue is 22mm in length and 5mm in width. The details of the tip concerning the shape and surface pattern will be discussed later in this chapter.

5.1.2. Handle Design

The design of the handle is an important feature in the design of the instrument. It is the handle through which the user interacts with the instrument. The user exerts a force on the handle which acts as the input to the instrument and in turn, there is an output seen at the other end of the instrument i.e. at the end effector.

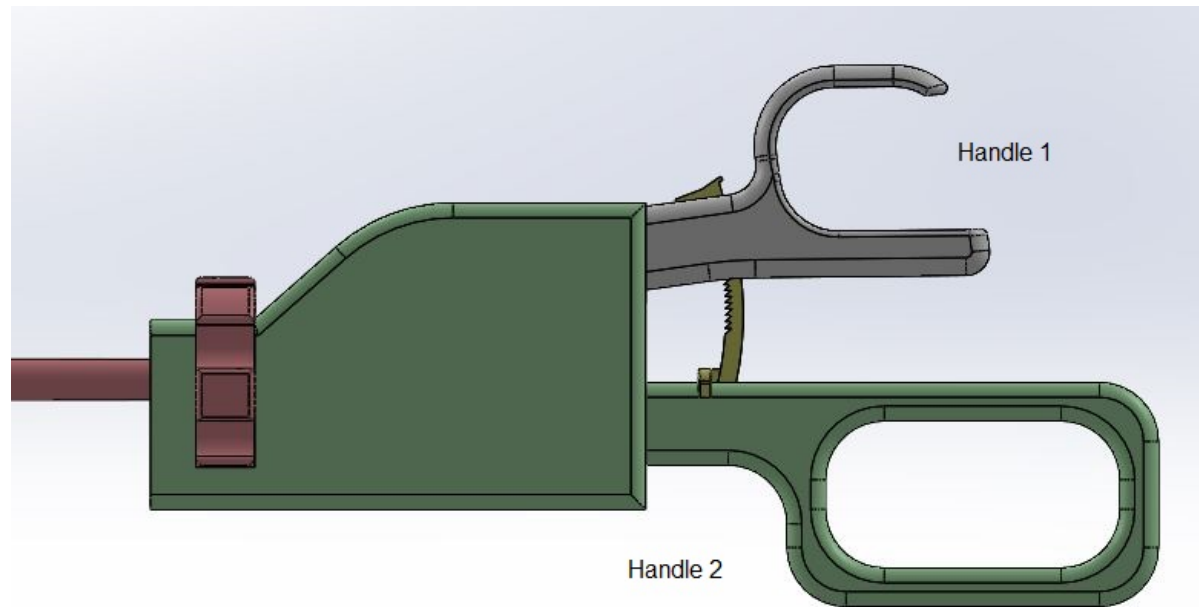


Figure 5.6: CAD model of the handle assembly

In the design of this instrument, the handle mechanism contains two handles, one stationary and one moving, as can be seen in Figure 5.6. Handle 2 is stationary and part of a bigger assembly whereas handle 1 is rotating about a point in the assembly. The intended use of this instrument is through the exertion of force by the thumb on handle 1, inside the loop, while two fingers - the middle finger and the ring finger are in the bigger loop in handle 2. The index finger is left free to interact with the rotation collar which will be discussed further and the 5th (smallest) finger is not used for any operation. The force generation mechanism in the handle is the axial loading mechanism. The force model of the instrument works as a slider-crank mechanism that is converting the rotational force of a rotating handle to a slider or axial force of the shaft. In the force model presented here, the friction forces of the linkages are not considered. Therefore, only kinematic force evaluations are performed.

As seen in Figure 5.7, there is a force exerted on the loop at point A in the vertically downward direction. The resultant force is going to be F_{shaft} which will be in the right horizontal direction along CD. Force exerted at point A is going to induce a moment on AC and in turn, exert force at point B. To find out the force at point B, the example of a see-saw can be taken. In the case of a see-saw, force is exerted on one side of the pivot and to calculate the resultant force, the moment equation is equated. In the case of the handle mechanism as well, C is the pivot point and force is being applied at point A. Therefore to calculate the force at point B, the moment equation is equated:

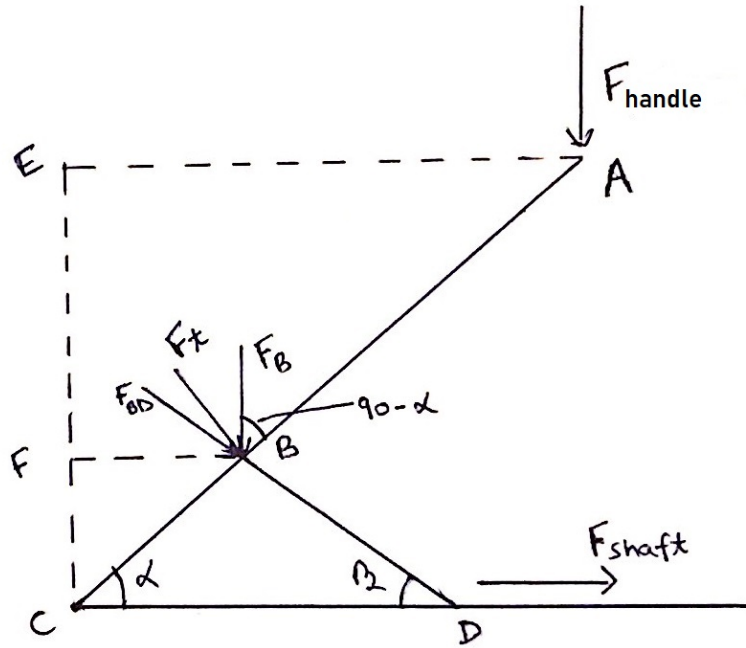


Figure 5.7: Schematic force model of the handle mechanism

$F_{handle} * \text{perpendicular distance from point C} = F_B * \text{perpendicular distance from point C}$

$$F_{handle} * AE = F_B * BF$$

$$\therefore F_B = F_{handle} * \frac{AE}{BF} \quad (3)$$

The force acting vertically downward at point B is going to generate 2 force components, one force component perpendicular to link AC and one force component along with the link AC. Therefore, the vertical component of force

$$F_t = F_B \cdot \sin(90 - \alpha)$$

$$F_t = F_B \cdot \cos \alpha \quad (4)$$

Now, to find out the slider force, the force along link BD (F_{BD}) needs to be determined. The force along BD would also have two force components, one force component perpendicular to link AC and one force component along with the link AC. The perpendicular force component of F_{BD} is equal to the perpendicular component of F_B which is F_t . Therefore,

$$F_t = F_{BD} \cdot \sin(\alpha + \beta)$$

$$\therefore F_{BD} = \frac{F_t}{\sin(\alpha + \beta)}$$

And we know from (4) that $F_t = F_B \cos \alpha$

Hence,

$$F_{BD} = F_B * \frac{\cos \alpha}{\sin(\alpha + \beta)}$$

The force along the shaft, $F_{shaft} = F_{BD} * \cos\beta \implies F_{shaft} = F_B * \frac{\cos\alpha\cos\beta}{\sin(\alpha+\beta)}$

From (3) we know that $F_B = F_{handle} * \frac{AE}{BF}$

$$\therefore F_{shaft} = F_{handle} * \frac{AE}{BF} * \frac{\cos\alpha\cos\beta}{\sin(\alpha+\beta)}$$

From the final equation above we can see that the shaft force depends on the handle force, the geometrical angle of the linkages and the ratio of the perpendicular distances of points A and B. For simplifying the calculations, the ratio of $\frac{AE}{BF}$ is considered as a constant n . The final equation of the force available at the shaft is

$$F_{shaft} = F_{handle} * n * \frac{\cos\alpha\cos\beta}{\sin(\alpha+\beta)} \quad (5)$$

In the case of the handle geometry for this instrument, as seen in Figure 5.6, the value of n comes out to be 4.21. The angles are calculated for the entire range of motion of the instrument for which the tip mechanism will result in the required tip angles. Therefore α ranges from 5.9° to 15.36° and β ranges from 30.2° to 40.92°

Therefore, with the relation from (1) in the previous section, we know that the pinching force of the tip is dependent upon the opening angle of the tip and the shaft force, which in turn is dependent on the angles of the geometrical arrangement of the handle and the handle force as seen above.

Hence, the pinch force is ultimately dependent upon the following variables:

- Opening angle of the tip
- Handle force
- Angles α and β of the geometrical arrangement of the handle

For a required pinch force of 9N, the required shaft forces were obtained in the previous section. Using those shaft forces, the required force at the handle can also be calculated as a function of the opening angle. This would help to understand how much handle force is required for the range of motion of the handle if a constant pinch force of 9N is required. Equation (5) presents the relationship between the handle force, the shaft force and the geometrical angles of the assembly. Using this equation a relationship can be obtained

$$F_{handle} = F_{shaft} * \frac{1}{n} * \frac{\sin(\alpha+\beta)}{\cos\alpha\cos\beta} \quad (6)$$

Using the required shaft forces obtained in the previous section, the handle forces were calculated using equation (6). The relationship is shown in Figure 5.8. It is important to note that as the shaft force depends also on the angle in the geometrical arrangement of the handle, these angles were noted for the extreme positions that generate a tip angle of 0° and 65° , which are the required opening angles of the instrument. Every set of these geometrical angles correspond to an opening angle of the tip, which corresponds to a required shaft force as in Figure 5.3. Therefore, the handle force is obtained from the required shaft force and the angles of the geometrical arrangement of the handle at every instant of the opening tip angle.

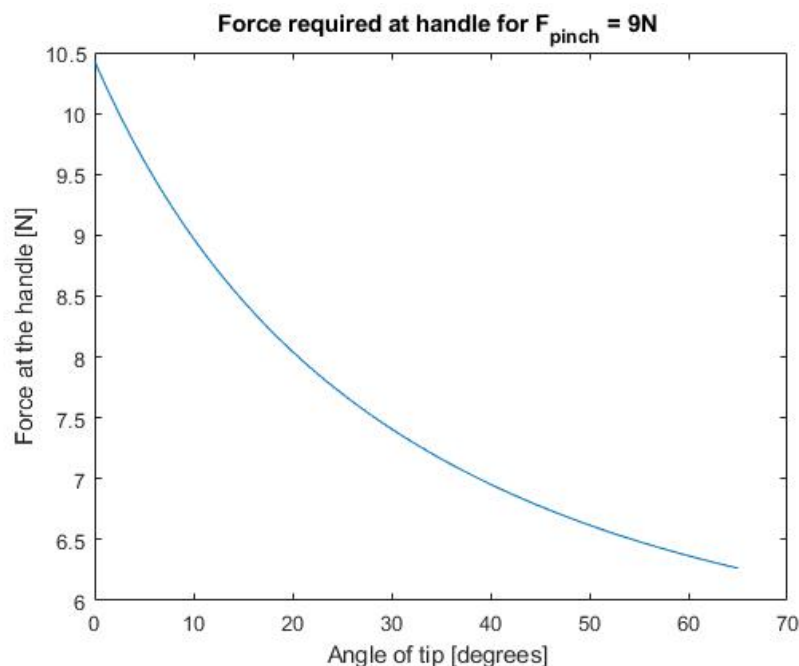


Figure 5.8: Force required at the handle to maintain constant pinch force of 12N

For a constant pinch force of 9N, the maximum handle force required at the handle is 10.45N. From a study done by Westwood et al. [2004] about the force exerted by surgeons at the handle of the instrument while grasping, it was seen that the mean force exerted was 8.52N and the mean maximum force was 24.98N. Therefore, this maximum required force of 10.45N falls near the average force used by surgeons for a grasper, and well under the mean maximum force. In another study done by Van Veelen et al. [2003], certain ergonomic guidelines regarding a needle holder were established. One of the guidelines stated that the required closing force at the handle should not be more than 15N, which is satisfied by the maximum required force for this instrument.

The design of the handle mechanism consists of various parts interacting with each other to generate the required motion and force in the shaft. The handle assembly consists of 8 different parts as can be seen in the exploded view of the handle assembly in Figure 5.9. 12 & 7b are the two parts of the handle that the user holds. Since 7b is a stationary handle, it is incorporated with the housing 7a to make it into a big base: 7. The housing is split into two halves, the other half is 7c. This is done so that the other components can be secured inside the housing and the two halves can be assembled thereafter. The assembling of the two parts can happen in any way known in the start of the art. For example, alignment pins, snap-like interfaces, adhesive ports, etc. can be utilized either alone or in combination for assembly purposes. 6 is the outer shaft of the instrument along with the rotating collar. 10 is the lever of the locking mechanism. 11 is the engaging element of the locking mechanism. 8 are two articulating levers and finally, 9 is a pivot pin.

12 interacts with 7a via a cylindrical extrusion in 7a which acts as the pivot for 12 to rotate. 6 consists of the shaft which is concentric to the hole in 7a and the rotation wheel fits in the slot in 7a. 10 is attached to 7b via a cylindrical extrusion in 7b which acts as a pivot for 10 to rotate in the locking mechanism. For assembly purposes, component 7 would be made in two halves so that the required components can be slotted in their re-

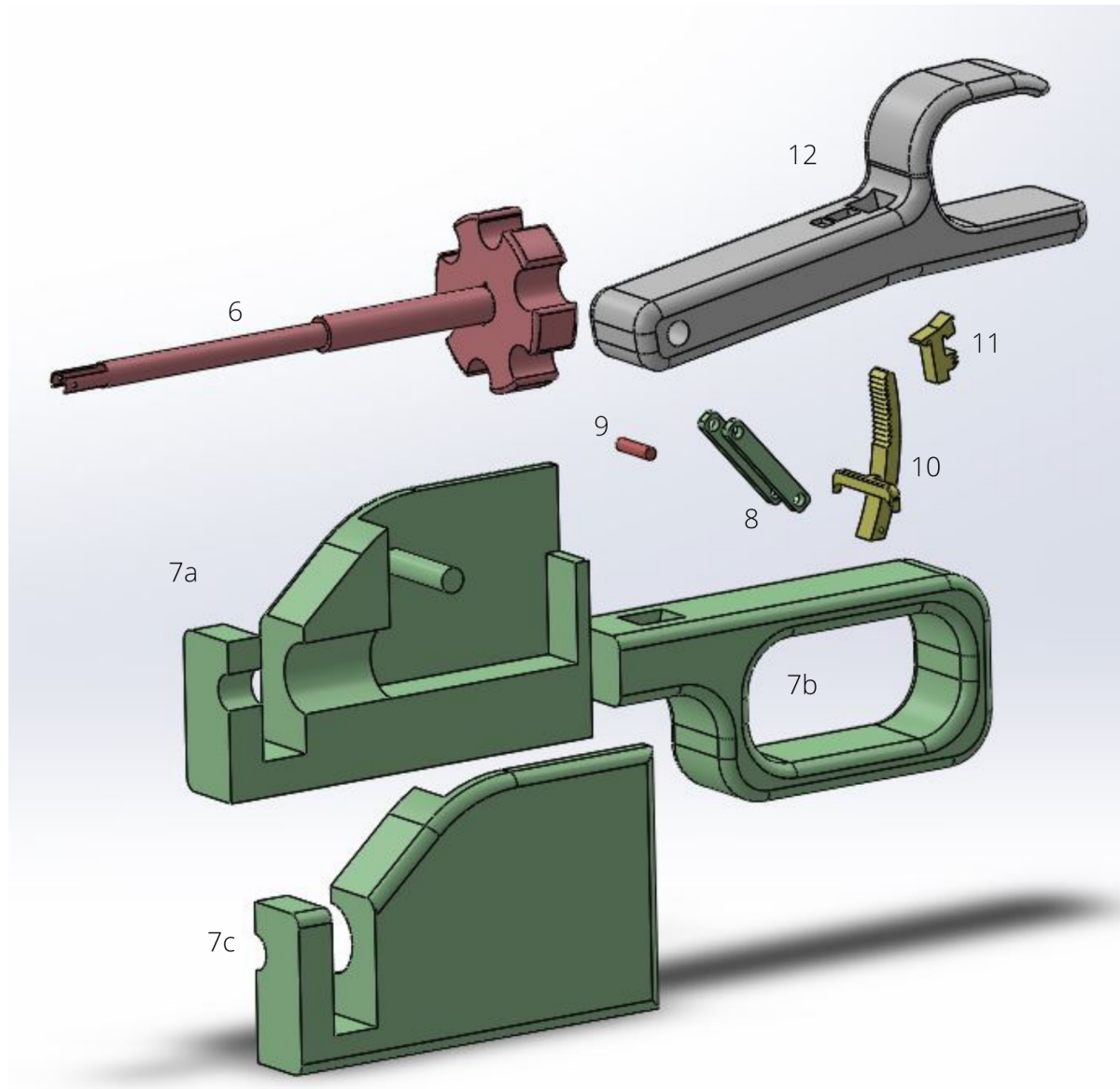


Figure 5.9: Exploded view of handle assembly

spective places and then the two halves joined together. 11 is a snap-fit component that is fit inside 12 in the hollow extrusion to interact with 10 in the locking mechanism, which will be explained later in the chapter. The two levers of 8 interact with 12 via a cylindrical extrusion in 12 through which they pivot. The other end of 8 interacts with the shaft of the instrument via pivot pin 9. The interaction of 8 with the shaft will be shown properly in the safety mechanism assembly. The side view of the handle assembly can be seen in Figure 5.10 where all the components come together to make the assembly.

The selected concept has an axial in-line model which has finger loops like the scissors model and a holding position of a cylindrical model. The user interacts with the instrument by inserting the middle and ring finger in the stationary handle and operating the instrument with the thumb in the upper open loop. The loops of the instrument have been de-

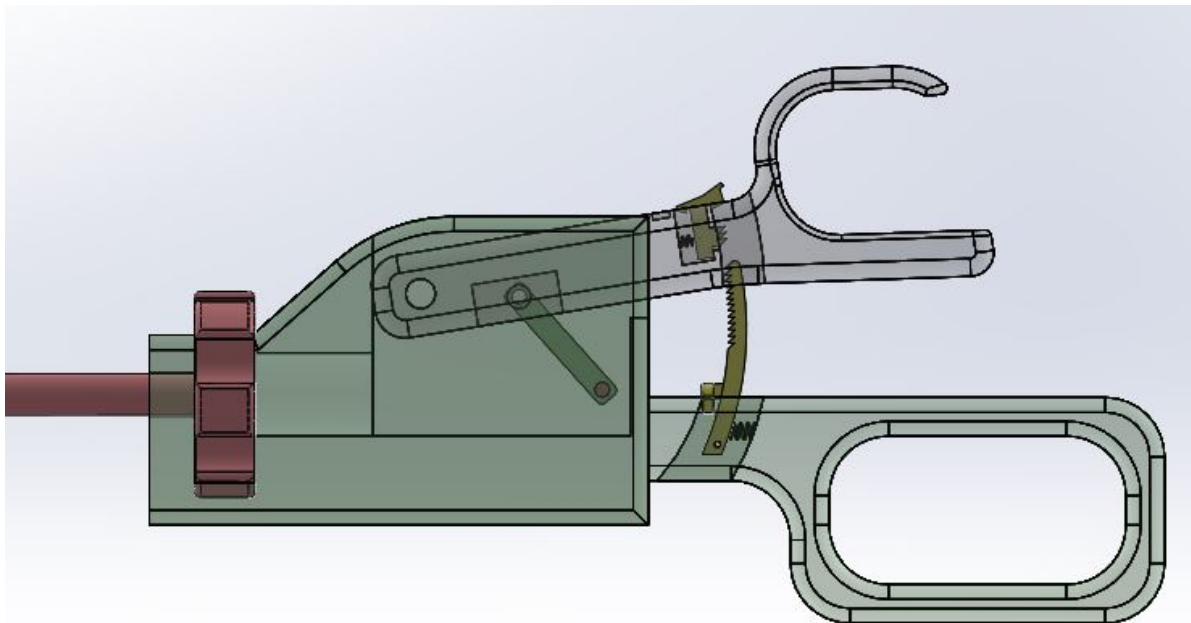
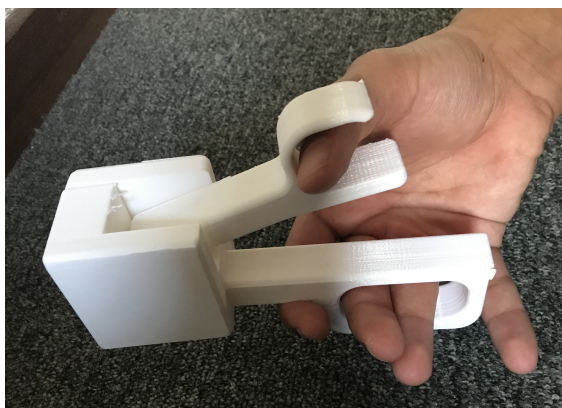
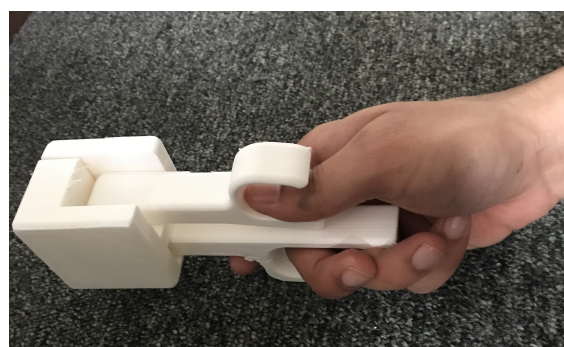


Figure 5.10: Side view of handle assembly

signed in accordance with the ergonomic guidelines which indicate that finger rings should be a minimum of 30mm in length and 24mm in width [Van Veelen et al., 2001]. The interaction of the user with the handle is via the force exerted by the thumb in the vertically downward direction on the loop. The thumb loop is open from one side in order for the user to rest the thumb by performing a suture, in order to replicate a cylindrical grip. The cylindrical grip offers more stability than the pistol grip [Büchel et al., 2010]. Therefore the handle is designed in a way that it gives the user control via the finger rings when being used as a grasper and stability while being operated as a needle holder.



(a) Pistol grip for grasper function



(b) Cylindrical grip for needle holder function

Figure 5.11: 3D printed design of the handle

Since the handle is designed to be used for both a grasper and a needle holder, it will be gripped differently while performing both functions. For a grasper, the user would use the finger loops for control, whereas for the needle holder, they would need a more stable

grip. To validate this, a 3D model of the handle design was printed to confirm the grip for both functions and to validate the size of the design with respect to the anatomical lengths and dimensions. It was confirmed that the handle offers control via the loops when it is intended to be used as a grasper. When it is locked in a fixed position, it can be gripped by the cylindrical model grip with the thumb resting on the loop. The gripping of the handle with a pistol model and cylindrical model can be seen in Figure 5.11. The rectangular housing which holds the handles has dimensions in such a way that the end of the housing is at the same length from the thumb as the rotation knob. Therefore, that distance was also validated and observed that it can be reached comfortably by the thumb. The other knob or button to be used by the thumb is the release of the locking mechanism which will be detailed later in the chapter. The release lever can also be reached by the thumb from either side due to its location as can be seen in the exploded view in Figure 5.9

5.1.3. Safety feedback mechanism

The safety mechanism in this instrument is responsible for giving feedback to the user about the exertion of force. Since this instrument is intended to be used as a grasper and a needle holder, it is important to make sure that the instrument can exert sufficiently high forces but it is more important to ensure that the instrument does not exert higher forces than intended. In the instrument, the form of feedback is in the form of auditory information. The safety mechanism is incorporated in the shaft of the mechanism and can be seen in Figure 5.12. The mechanism is going to be placed in the handle assembly to make use of the space available.

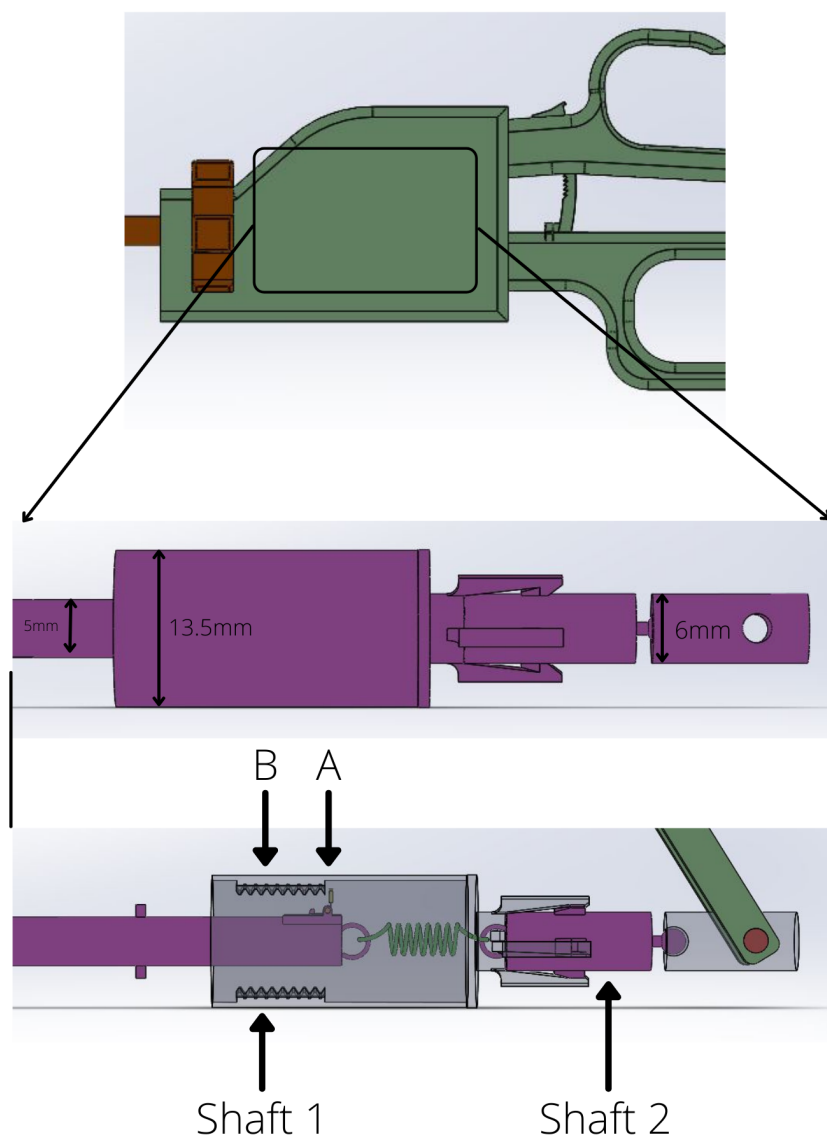


Figure 5.12: Safety mechanism in the handle assembly

When forces are going to be exerted on the shaft from the handle and the tip of the instrument has a tissue or an organ between the jaws, the spring is going to get elongated and

therefore generate the clicks with a sound. Figure 5.12 shows the entire assembly. There are two parts of the bigger shaft, 1 & 2. Shaft 1 contains the ribbed pattern and is detachable as it will be attached to the assembly after the spring is attached properly. The spring is attached between the smaller shaft and shaft 2.

The clicker is going to be attached to the smaller shaft and with the help of a torsion spring, it will be ensured that it maintains a vertically straight position. When there is a linear displacement between the smaller shaft and the bigger shaft, the clicker would collide with the ribbed pattern, and again with the help of the torsion spring, the clicker comes back to its rest position before the next rib in the pattern. The torsion spring in a close up can be seen in Figure 5.13

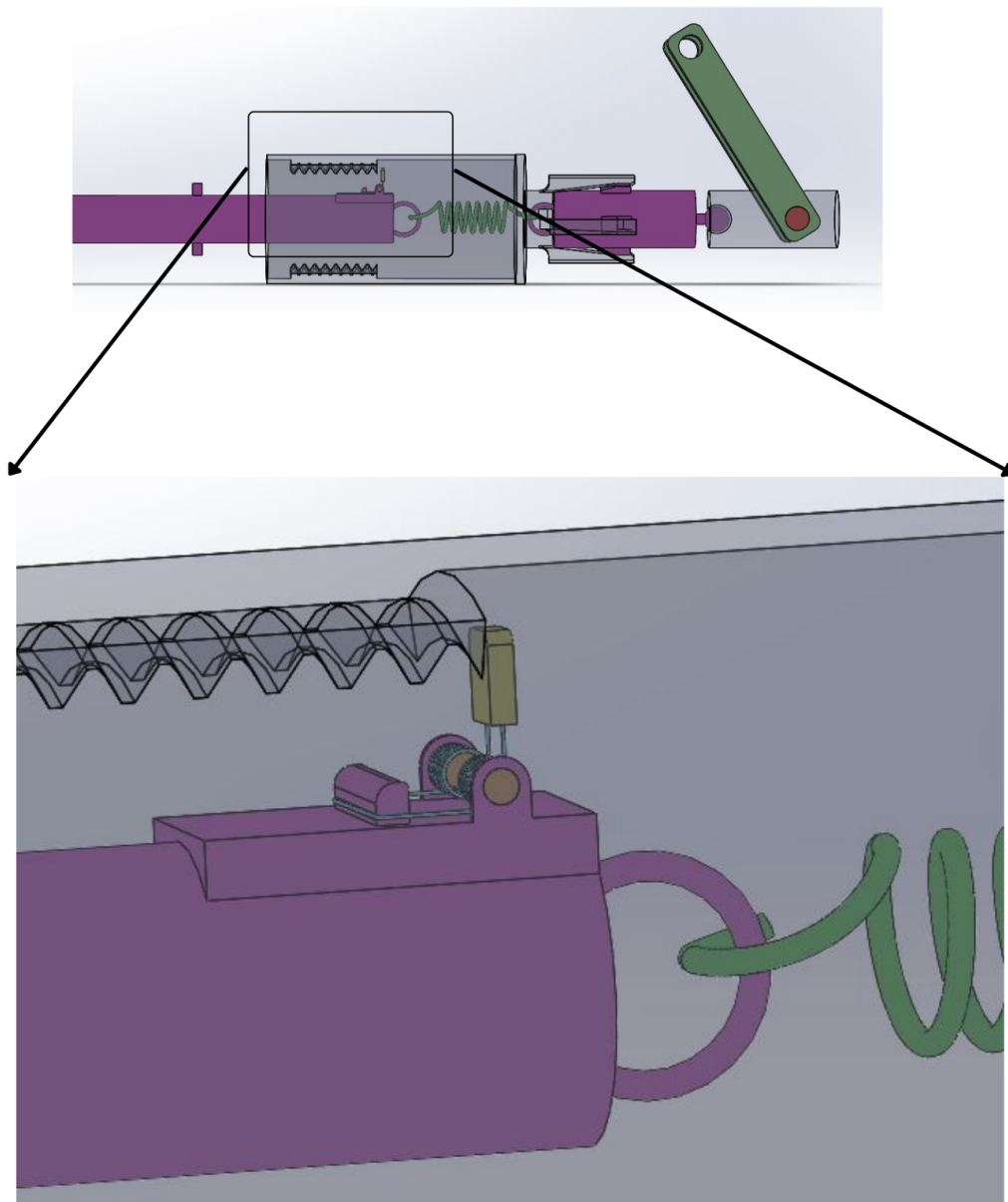


Figure 5.13: Close up view of the clicker

In a spring, the displacement is directly proportional to the force exerted as

$$F = kx$$

where F is the force exerted in the shaft, k is spring constant and x is the displacement. Because of this relation between the force and the displacement, as the user exerts more force on the handle and thereafter more shaft force is generated, the spring would elongate more and enable further linear displacement between the shafts and more collisions of the components with each other. These successive collisions are an indication to the user that they are exerting more force. In case this force exertion is unintentional, the user becomes cautious and in case the force exertion is intentional, the user simply has more information.

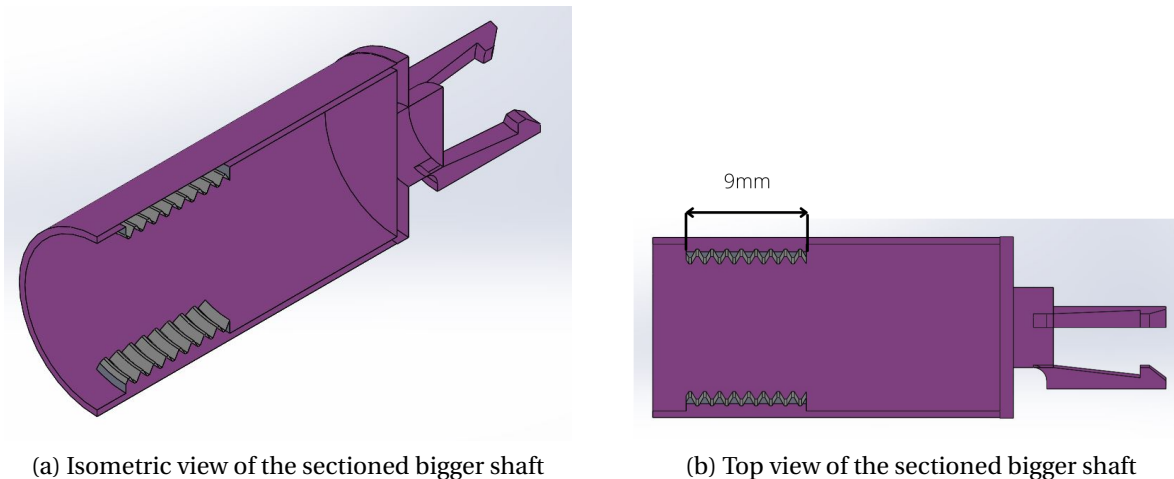


Figure 5.14: Ribs in the sectioned bigger shaft

The ribbed pattern in the outer shaft can be seen in Figure 5.14. Figure a) shows the isometric view of the bigger shaft when it is sectioned by the vertical plane along the length of the shaft. Figure b) shows the top view of the bigger shaft when it is sectioned by the horizontal plane along the length of the shaft. The successive ribs in the pattern make sure that even a small linear displacement of the smaller shaft is going to make successive collisions.

In terms of the range of motion, the handle can provide an axial displacement of the shaft of 9mm, whereas the tip mechanism needs an axial displacement of 3.44mm to go from one extreme position to the other. That implies that a minimum full spring extension of 5.56mm is possible. The maximum full spring extension that is possible is the entire axial displacement, which is 9mm. The maximum spring extension would happen when an object is grabbed at the open extreme of the tip and the handle is closed. The minimum spring extension would happen when the tip is closed all the way and a very thin object is grabbed. The minimum spring extension would help us in modelling the spring constant k . The required pinch force is a maximum of 9N and the maximum required shaft force for this pinch force 64.2N. Since the spring would start extending the moment forces are applied, the maximum required shaft force needs to be considered for the spring constant of the spring. Therefore, the spring constant would be

$$k = \frac{\Delta F}{\Delta x}$$

$$k = \frac{64.2}{5.56}$$

$$\Rightarrow k = 11.54 \text{ N/mm}$$

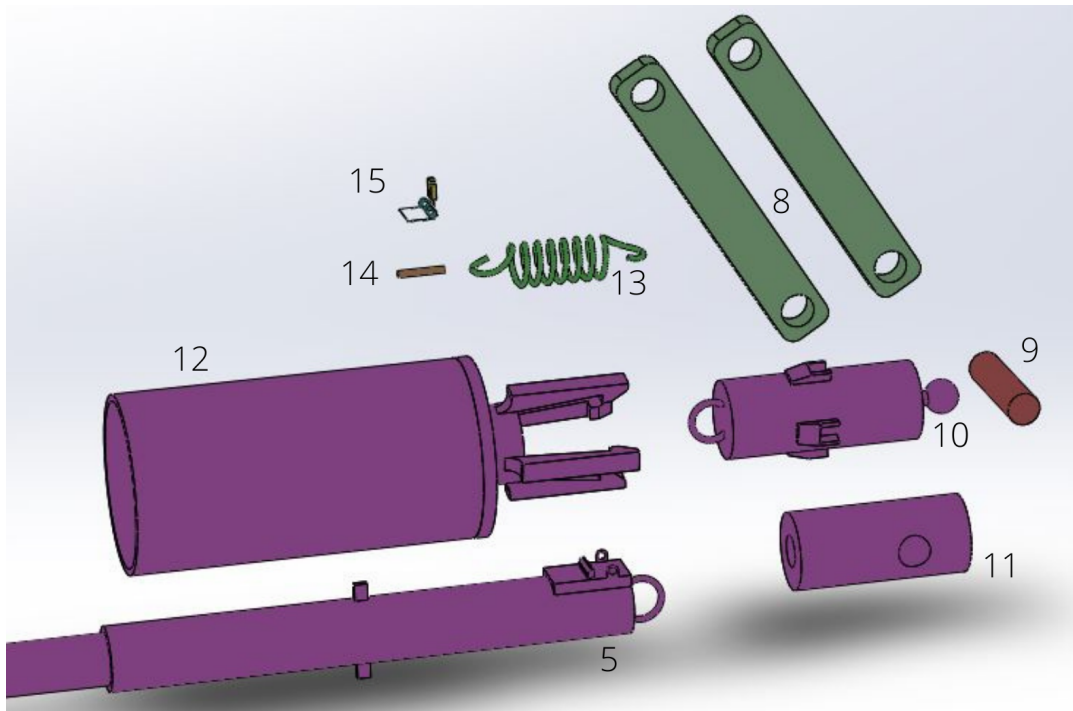


Figure 5.15: Exploded view of safety mechanism assembly

This value of the spring constant, therefore, indicates that every millimetre of spring indication indicates an increase of 11.54N of shaft force. Since the maximum spring extension of 9mm is possible, the ribbed pattern in the bigger shaft is also of the same length. In the ribbed pattern of 9mm, there are 9 clicks possible, therefore every click indicates an increase of 11.54N of shaft force, giving the user information that they are increasing the applied force.

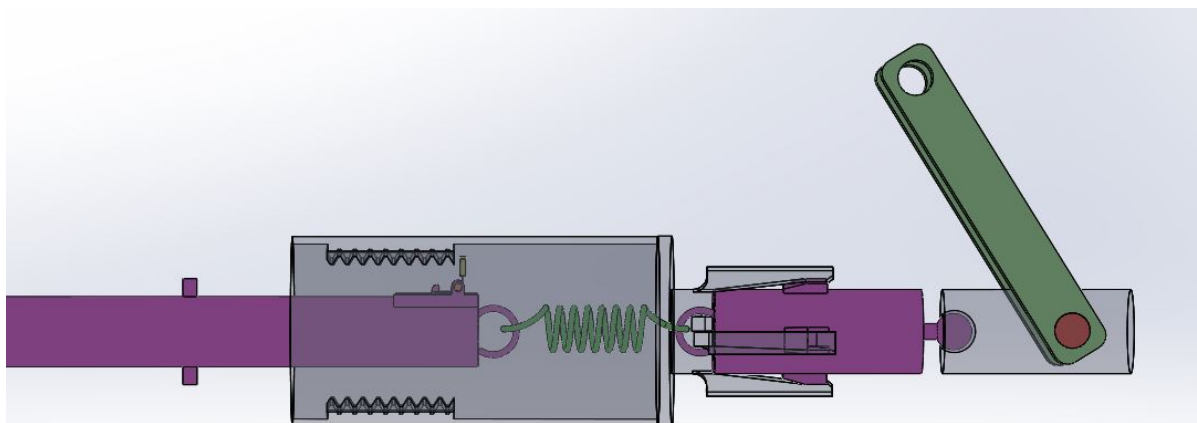


Figure 5.16: Side view of handle assembly

Just like the assemblies presented earlier, the safety mechanism also consists of various parts that come together to ensure that the mechanism functions as intended. The exploded view can be seen in Figure 5.15. 11 is the shaft with the socket hole. 10 is the shaft with the ball, 13 is the extension spring, 12 is the bigger shaft with the ribbed pattern on the inside, 15 is the clicker of the safety mechanism, 14 is the pivot pin and 5 is the inner push-pull rod. The assembling of the safety mechanism will be shown in detail as well.

This assembly comes together with the handle assembly via parts 8 and 9. The articulating levers 8 interact with 11 via the pivot pin 9. 11 is attached to 10 via a ball and socket joint. This joint is created to ensure that the rest of the assembly can rotate along with the tip mechanism. The spring 13 is attached to 10 via the hook in 10 on the left-hand side in the shaft. The other end of 13 is attached to 5 via a similar hook. Shaft 12 with the ribbed pattern is mounted onto 10 with the help of snap-fit. 12 has four finger-like extrusions which snap-fit onto the slots created in 10. The zoomed view of this can be seen in Figure 5.18. 5 is concentric to 12 and moves linearly with respect to it and therefore is not attached directly to 12. It can be seen in Figure 5.17 that clicker 15 is attached to 5 through the pivot pin 14 on platform 5a. The clicker is fit onto 5a via the pivot pin on one side and an extrusion to fit the other end of the clicker spring. The clicker 15 in itself consists of the double torsion spring 15a and an extrusion 15b fit onto the top of the spring.

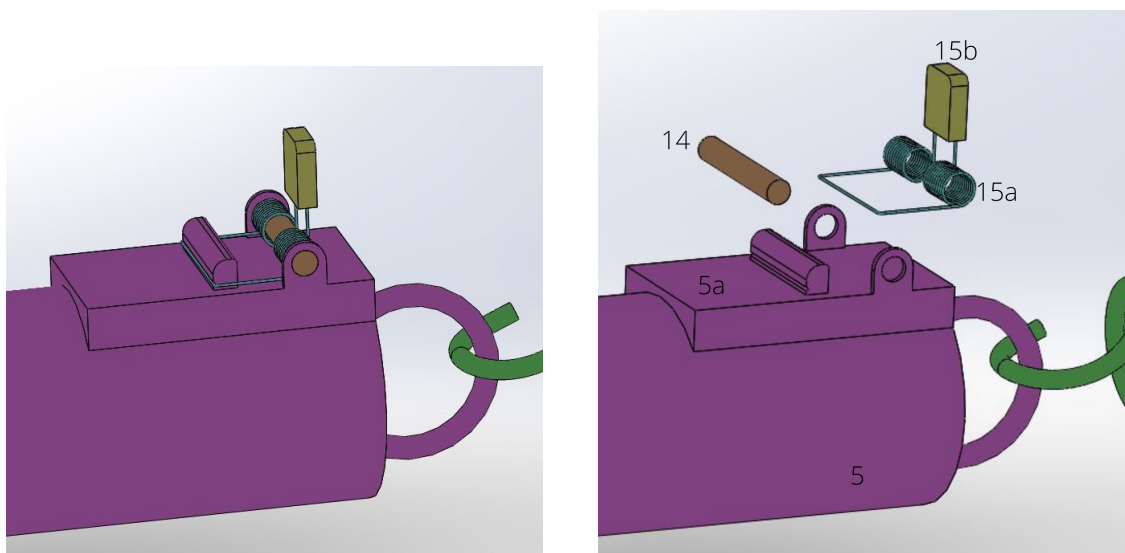


Figure 5.17: Exploded view of the clicker mechanism

The shaft from pivot pin 9 to the tip assembly is 33 cm long, like in most laparoscopic instruments [Manasnayakorn et al., 2008]. Shafts 10 and 11 are 6mm in diameter, shaft 12 is 13.5mm in diameter as it has the ribbed pattern inside and needs to be bigger for the clicker to interact and the push-pull rod 5 is 5mm in diameter for a length of 4cm and then 4mm for the rest of the length until the tip assembly.

The validation of the working principle of the safety mechanism was done using some 3D prints and a torsion spring. 2 shafts of different diameters were made along with a small torsion spring, as shown in 5.19. The torsion spring was fit onto the smaller shaft to form the clicker of the mechanism. The bigger shaft had a ribbed pattern on the inside. The pattern however was not produced exactly as designed because of the shaft being produced

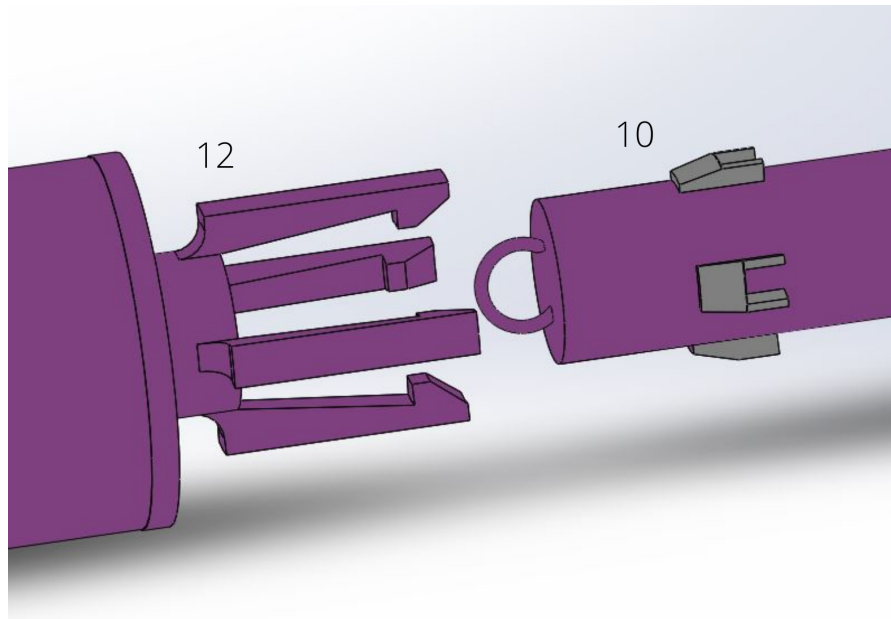
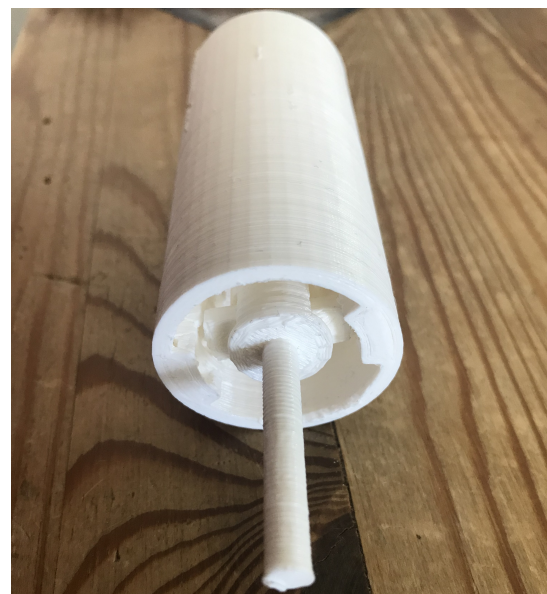


Figure 5.18: Attachment of shaft 12 onto shaft 10

as a single object because the printer performed additive manufacturing where layers are added on top of each other. The shafts were set concentric to each other and moved relatively and it was confirmed that with a torsion spring attached to the smaller shaft, it was clicking against the ribbed pattern and generating sound. Although the clicking was not performed exactly as intended in the design, it confirmed the principle in terms of generating clicks because of the relative movement of the two shafts and the torsion spring.



(a) 3 components of the prototype



(b) the 2 shafts moving relative to each other

Figure 5.19: Prototype of safety mechanism

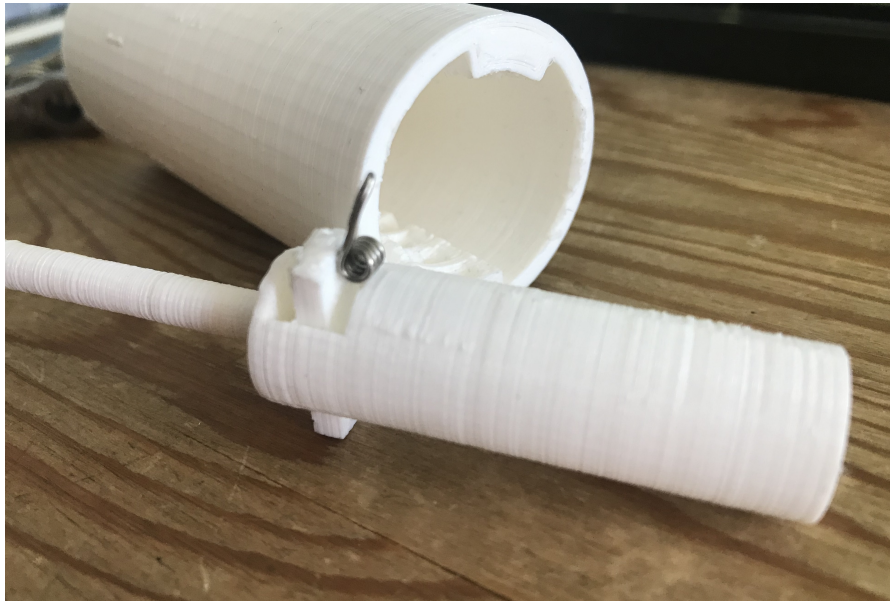


Figure 5.20: The spring mounted on top of the smaller shaft

5.1.4. Rotation collar

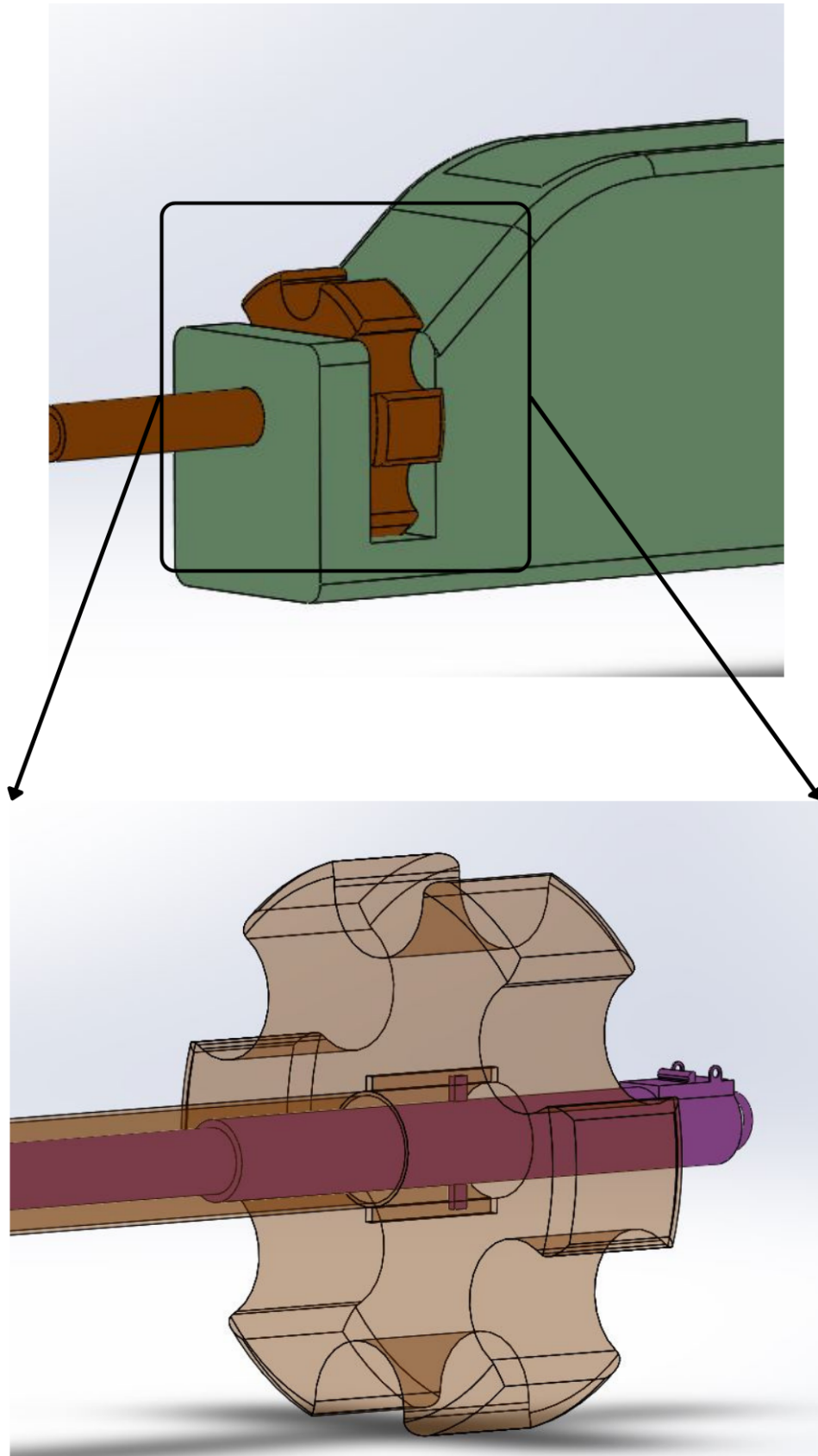


Figure 5.21: Rotation collar attached to outer shaft

One of the requirements of a laparoscopic grasper is steerability i.e. the instrument should have 4 degrees of freedom to avoid uncomfortable movements of the user's hand in order to perform the desired action. One of the required degrees of freedom is an axial rotation of the instrument along the axis of the shaft. To make the instrument rotate about its shaft, a rotation collar is used. The rotation collar is placed in the base of the handle assembly, as seen in Figure 5.21. The rotation collar also has the outer shaft extending from one side. The user would engage with the rotation collar with the index finger.

The working principle of the rotation collar involves the rotation of 2 components - the rotation collar and the inner shaft. The rotation collar is fixed on one end of the outer shaft. The push-pull rod is placed inside this outer shaft and has an axial translation. For that purpose, there is a slit cut out in the rotation wheel. The push-pull rod has vertical pins which are extrusions on the top and bottom, as seen in Figure 5.21. The slit ensures that the push-pull rod can freely translate axially in the outer shaft. Therefore, when the rotation wheel rotates, the push-pull rod will rotate as well. The rotation is also performed at the tip assembly as the outer shaft is connected to the tip via a pivot pin, as shown in Figure 5.5. The width of this rotation wheel is 10mm and the maximum translation of the push-pull rod is 9mm, therefore the vertical pins always translate within the rotation wheel,

5.1.5. Locking mechanism

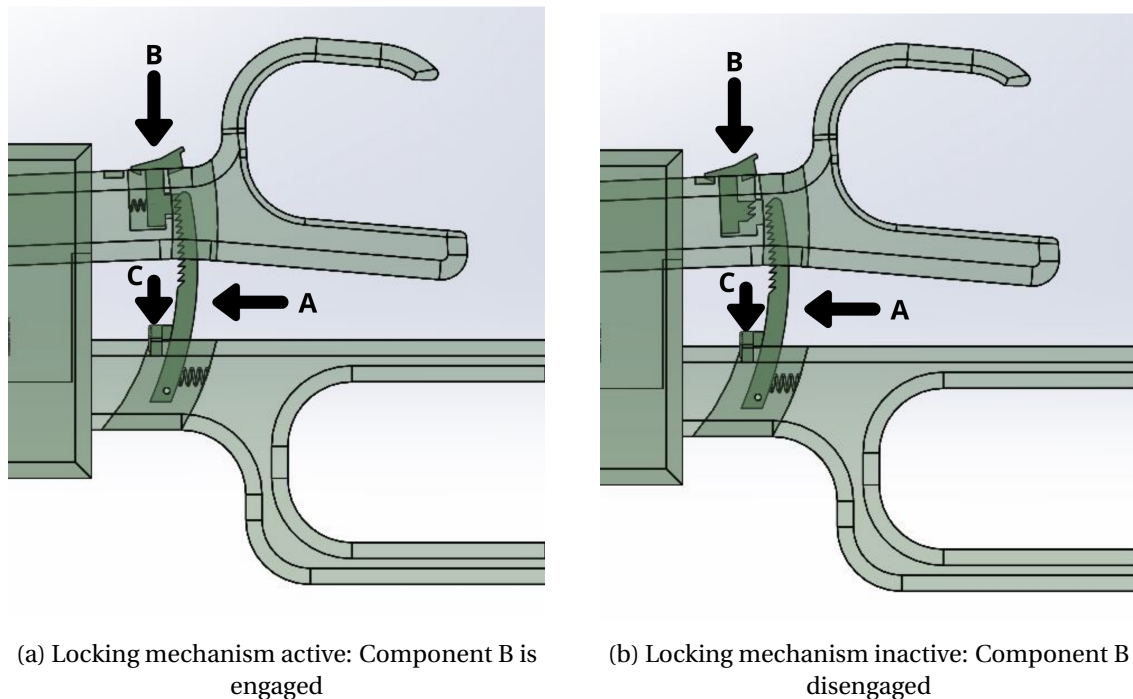


Figure 5.22: Locking mechanism in the handle

One of the most essential functionalities required in a needle holder is the ability of the instrument to lock with constant handle force. Similarly, in this instrument, there is a locking mechanism in place to lock the handle when a constant force is required at the handle. For this purpose, a ratchet locking mechanism is used.

This instrument design consists of 2 handles, as explained before. Therefore, the ratchet lever is fixed in the stationary handle for more stability. The moving handle has a cavity or hollow extrusion that the ratchet lever is inserted inside as the handle closes, and the ratchet clicks while locking the instrument. Figure 5.22 show the interaction of the ratchet in the 2 handles. The curvature of the ratchet lever is designed to match the motion of the moving handle so that it can easily slide into the cavity in the moving handle. In the locking mechanism, component A engages with component B in the form of a clicking mechanism and the moving handle moves close to the stationary handle, successive clicks take place to lock the position of the handles. There is a spring placed behind component B to push it towards component A when the two components are locked together. The clicking can only take place in one direction i.e. when the handles are coming closer and the tip of the instrument is closing. Component A also has a spring though which it receives it elastic force and pushes against component B to lock. To unlock, an extrusion component C is used. Component C is placed across the length of the handle and is attached to component A. It can be pulled using the index finger so that the spring compresses and component A and component B stop to engage together. Since the index finger can be used to disengage these two components, the thumb can be used to easily move the moving handle up or down. An angular view of component C can be seen in Figure 5.23

Since this instrument has 2 functions and in the case of a grasper, there are times when a repetitive opening and closing action is performed, a locking mechanism is not needed at all times. Therefore, this locking mechanism can also be deactivated using component B. Component B is snap-fit into the moving handle and disengaging this fit is going to move the part of component B which engages with the ribs of component A. Therefore, even when the moving handle moves down, component A would have no part to engage with and there would be no successive clicking. The disengaged component B can be seen in Figure 5.22 (b)

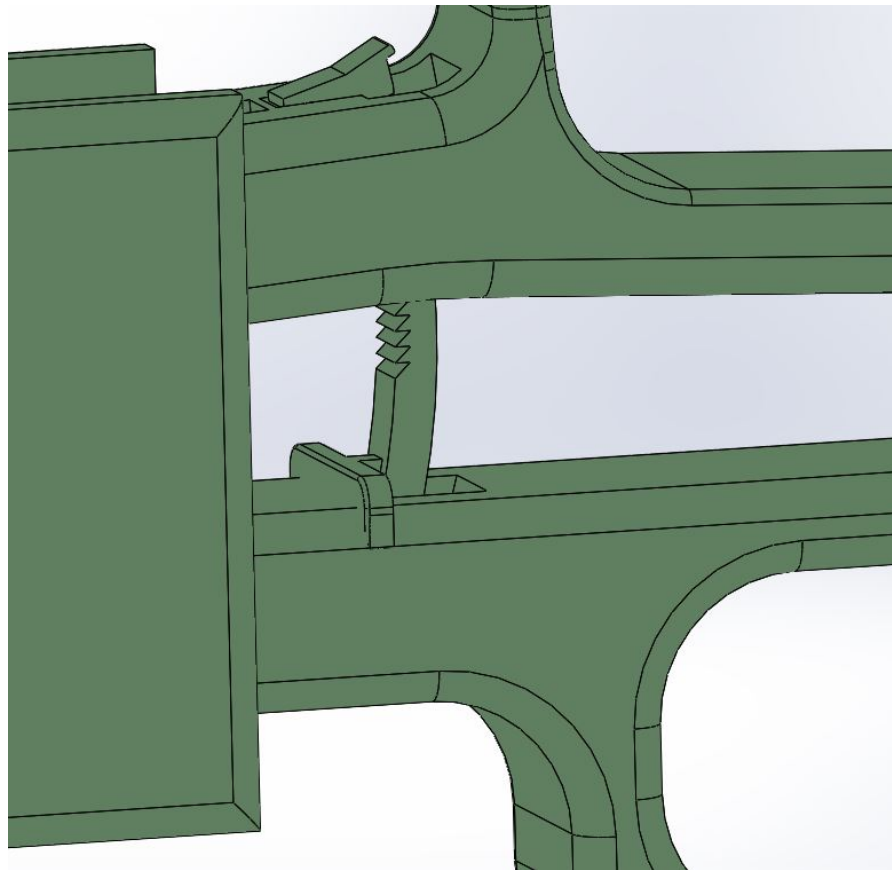


Figure 5.23: Angular view of disengaging element

5.1.6. Type of tip

The user is going to interact with the instrument at the handle and an end effect is going to be seen at the end effector i.e. at the tip of the instrument. Since the instrument being designed is going to be used to interact with tissues as well as securely hold the needle, the point of interaction at the tip is of prime importance in the design. The way the tip interacts with tissues is different from how it needs to interact with a suturing needle. In the case of the needle, it needs to be ensured that a secure hold is established whereas, in case of the interaction with tissue, care needs to be taken with respect to holding and pinching tissue while avoiding damage.

A study performed by Heijnsdijk et al. [2004b] analyzed the damage caused by various jaw patterns and find out the best damage-slip ratio. The damage slip ratio was defined as

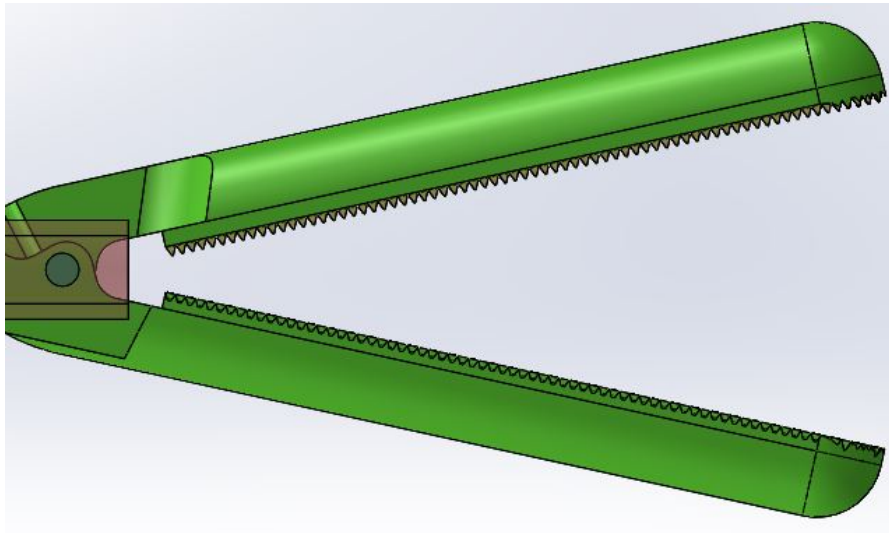
'the ratio of maximally allowable pinch force divided by the minimally required pinch force at 5N pull force.' Therefore, the higher the damage slip ratio, the better the jaw pattern. In the use of laparoscopic graspers, pinch and pull forces are exerted. The successful grasping of the tissue depends on the relative amount of pinch and pull forces together as indicated in Section 3.1.1. For laparoscopic instruments, no specific guidelines exist for the jaws of the instruments to fulfil. Therefore this study examined and compared the various patterns for safety and usefulness on the basis of the type of profile, depth of profile and the contact area. The types of patterns analyzed were: flat rectangular surface, flat rectangular surface with a hemispherical pattern, flat rectangular surface with diamond-shaped profile and flat rectangular surface with a ribbed pattern. In conventional laparoscopic needle holders, a flat surface is used, and as expected the study revealed a low damage slip ratio of 0.9 for this pattern, indicating that it is impossible to pull the tissue with 5N without damaging the tissue. The pattern that emerged as the best one was the diamond profile pattern with a 3mm diameter with a damage slip ratio of 9. This means that the maximum allowable pinch force is 9 times the required pinch force for a 5N pull force. Additionally, the advantage with a diamond profile pattern is also that it is suitable in case the forces are exerted in a direction apart from the length of the jaws of the tip.

For needle holders, a study was performed by Thacker et al. [1986] to analyze design specifications of conventional needle holders for ensuring needle security. The study was conducted to analyze needle security with jaws with straight surfaces and toothed surface. It was concluded that having toothed jaws for needle holders increased the security of the needle holder in comparison to a flat surface. In another study by Bond et al. [1990], it was confirmed that a toothed jaw also results in damage to the needle, therefore affecting the performance of the suturing process. As a compromise, metallurgically bonded tungsten particles on the jaws were observed to damage the suturing needles less but the needle security offered by the same was less than toothed jaws.

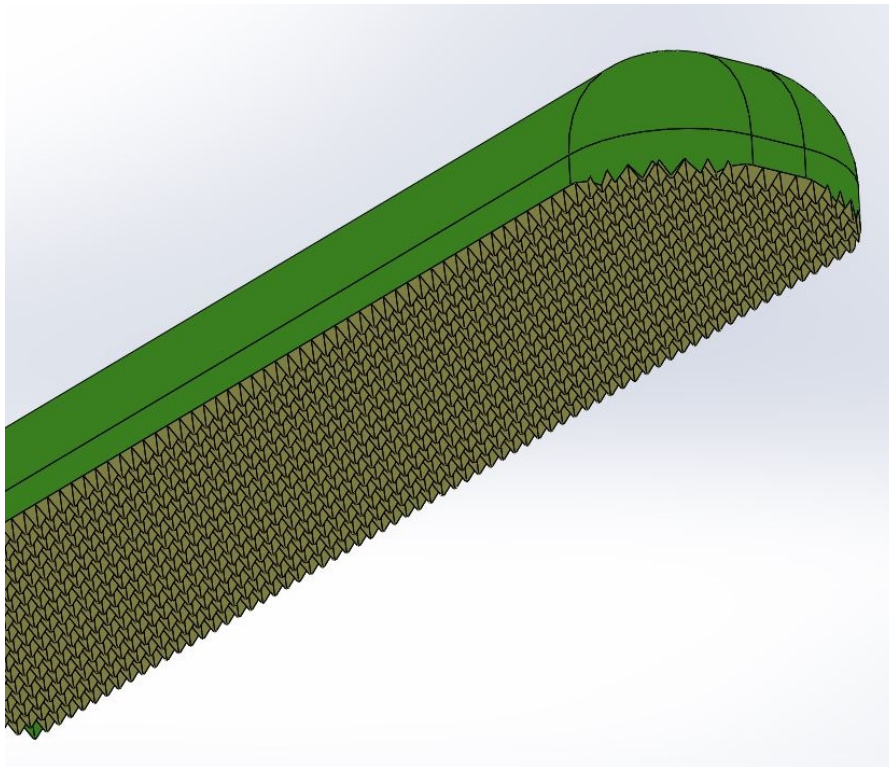
In a flat-surfaced jaw in graspers, due to stress concentration, there is the presence of high pressures at the edges which can result in damage to tissue. Rounding the edges of the jaw has shown to moderate these high pressures [Shakeshaft et al., 2001]. Additionally, rounding of the edges is also beneficial in case of a needle holder function as the synthetic monofilament suture is prone to damage if it is clamped by flat jaws with sharp edges [Abidin et al., 1989].

Therefore, for this instrument, a diamond-shaped pattern is used. The detailed tip design and the diamond-shaped pattern can be seen in Figure 5.24. (a) shows the side view of the tip and (b) shows the angular view of the tip's surface. For a needle holder, the general surface of the needle holder tip is flat with a pattern.

Graspers and needle holders come in different shapes and forms. For this instrument, a straight universal non-fenestrated grasper tip is chosen. For special use graspers or needle holders, such a combination of two instruments would need tip modifications. As specified in the section which details the tip assembly the beak of the assembly opens up to an angle of 65° as per the requirements of the instrument. Universal needle holders available in the market have a cross-section of length around 22mm and therefore the cross-section of the tip that would interact with tissue is 22mm in length and 5mm in width.



(a) Side view of the tip



(b) Angular view of the tip surface

Figure 5.24: Diamond profile pattern of the tip

5.2. Design Overview

The different assemblies have been designed separately along with their various components, they come together to form the complete instrument. The complete instrument, as seen in Figure 5.25 has 3 major assemblies that come together to complete the instrument: the handle assembly, the safety mechanism assembly and the tip assembly. The user interacts with the handle, the tip performs the intended function and the safety mechanism is

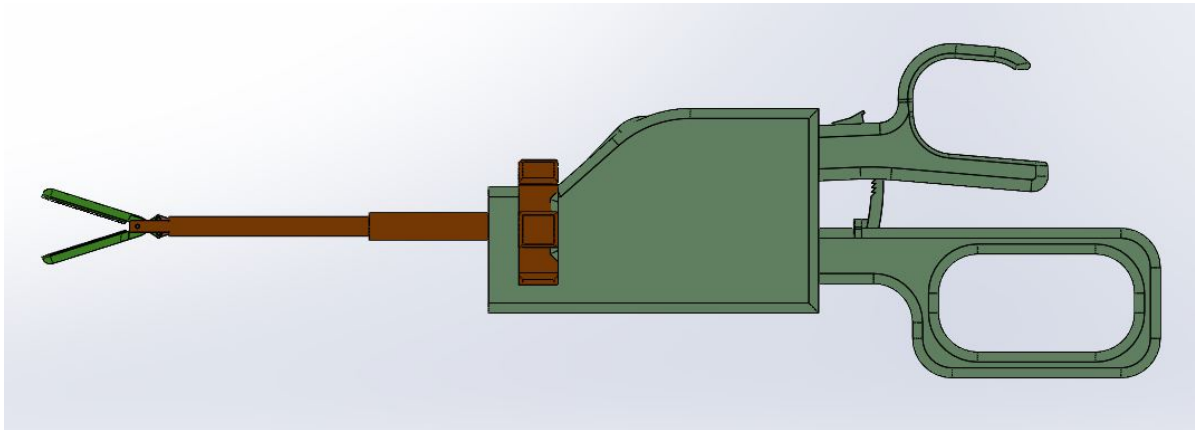


Figure 5.25: Design assembly of the instrument

present to provide feedback about the application of forces.

The effective working of the instrument is by exerting vertically downward force at the handle, which in turn results in a horizontal push-pull motion of the inner rod. The push-pull motion of the inner rod then results in the opening and closing of the beaks via the 4 bar linkage mechanism. The output parameter of the instrument is the pinch force that is obtained at the tip, acting perpendicular from the length of the tip and equal on both sides due to the symmetrical geometry. Therefore the force input and output motions happen in a way that vertically downward force is given to the finger loop in the handle which gives a pinch force perpendicular to the length of the tip. The safety mechanism is transmitting the force from one mechanism to the other and performing its intended function of providing the user with information about the use of force.

6

Conclusion

The motivation behind this project was to solve the problem regarding multiple instrument exchanges in laparoscopic surgery, therefore, establishing the design goal of this project to develop a novel laparoscopic instrument with the combined mechanical functions of a grasper and a mechanical needle holder. The design problem was solved by analyzing both instruments and understanding their important functional requirements and focus areas. Using these requirements, design criteria were defined for this novel instrument as it needed to perform the functions of both instruments. Apart from the individual requirements, an additional requirement of a safety mechanism was established. This was done because even though the mechanical action of the instruments is similar, the purpose and use are different in terms of safety factors. Using these design criteria, conceptual solutions were generated with the help of a morphological overview. These concepts were detailed in order to be compared with each other according to a set of comparison criteria. Once the conceptual solutions were compared, the most suitable concept was chosen and then detailed further for the various components. Therefore, with the completion of the final design, the design goal of this project was completed. The outcome led to the design of an instrument that contains the functional requirements of both individual instruments along with certain other features like the safety feedback mechanism that would make the combination of the functionality into a practical solution. The development of such an instrument, therefore, would mean that the number of instrument exchanges would be reduced as the user would now not need to remove a grasper and introduce an additional needle holder or vice versa. The working principles of the focus areas were first validated theoretically using the respective force models. Calculations were done to ensure that the required force at the tip of the instrument can be obtained with the range of handle force already used with a state of the art grasper. Physical validation of the working principles of the handle design and the safety mechanism was also done using 3D prints. Individually, these assemblies worked as intended. Therefore the next step would be to develop a full prototype of the instrument to confirm and validate the functionality of the entire instrument with all its various components together.

7

Discussion

7.1. General Discussion

7.1.1. Prototype of working principles

The instrument was designed by breaking it down into 3 different assemblies. The tip mechanism uses the state of the art 4 bar linkage, although with a modified geometry. The handle mechanism is a mix between a cylindrical grip and a pistol grip mechanism. The 3D print of the mechanism showed that it offered the benefits of both grips and thus making it possible to be used for an instrument that intends to perform the functions of a grasper and needle holder. It offers control needed for a grasper via its finger rings and it offers the stability needed for a needle holder. Some discussion also led to another modification of the handle to offer more grip under the palm while being held in the cylindrical grip. The extension can be seen in Figure 7.1

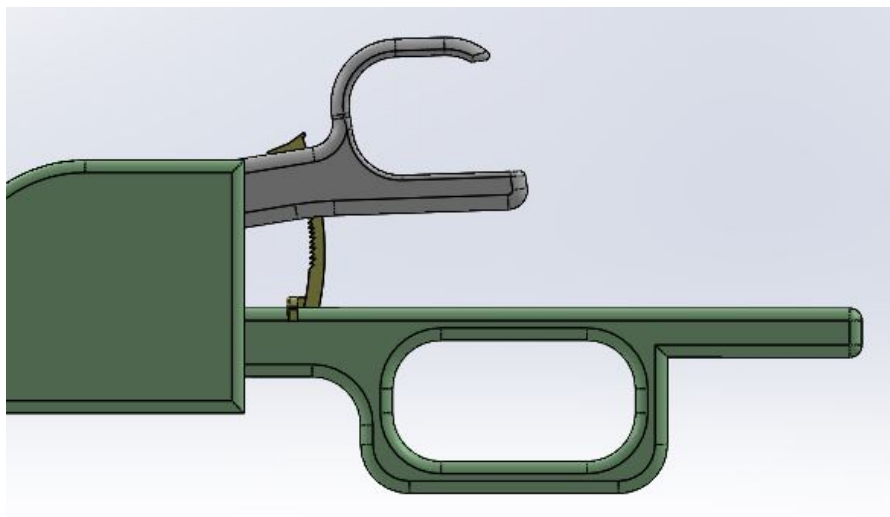


Figure 7.1: Extension in the handle for palm support

The safety mechanism used the idea of 2 concentric shafts sliding relative to each other and therefore generating a clicking sound with the relative movement. The clicking sound relied on the concept of torsion spring movement and how it resists rotation, thus making the clicker come back to its straight position after every click. The proof of concept of this assembly involved the 3D print of 2 shafts a clicker made out of a torsion spring obtained

from a cloth pin or wasknijper. The spring used in a cloth pin is shaped differently than the one that would be used in this instrument, however, it works the same. The different shape of the spring made it difficult to exactly replicate the working principle of the safety mechanism. However, it was possible to observe that the relative movement of the shaft along with a torsion spring which is less stiff than the one used would generate a clicking mechanism as intended for this instrument. Obtaining the most appropriate spring was difficult with constraints regarding time and material availability. Therefore, although the working principle was validated, there was still some scope to exactly replicate the working principle in a better way.

7.1.2. Efficiency gap for tip mechanism

The tip mechanism of the instrument converts the force in the shaft to the pinch force at the tip. As discussed in Section 5.1.1 the force applied at the tip of the instrument depends on the shaft force and the opening angle of tip via the relation

$$F_{pinch} = \frac{1}{2} \lambda F_{shaft}$$

where λ is the force transmission coefficient which depends on the opening angle. Therefore, even with a constant shaft force, the force exerted at the tip would decrease as the tip closes. This dependency of the pinch force on the opening angle results in varying force transmission. The relationship between the force transmission and the opening angle can be seen in Figure 7.2. Force transmission is defined as the ratio of the pinch force to the shaft force.

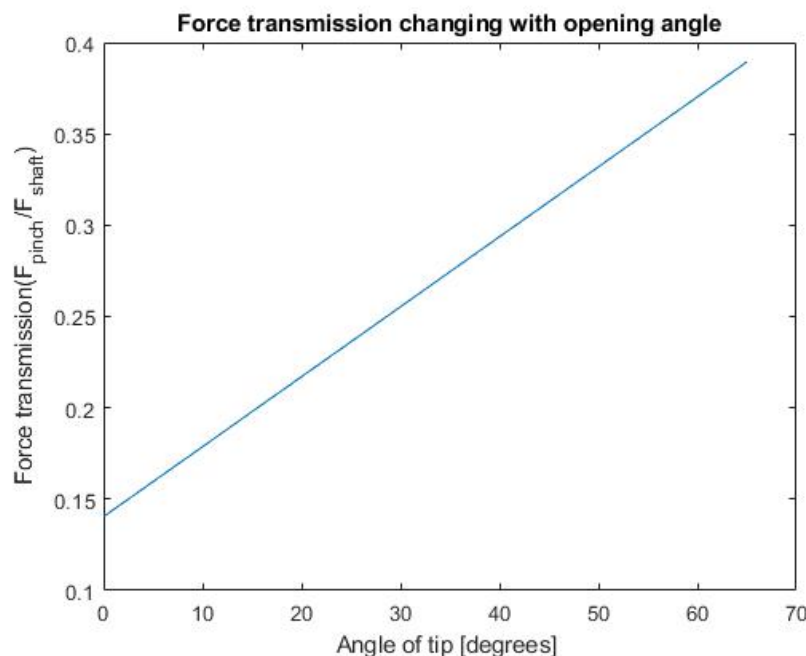


Figure 7.2: Varying force transmission with opening angle of the tip

The consequence of this varying force transmission is seen in the safety mechanism. The safety mechanism is an indicator of increasing or decreasing shaft forces, by the means

of auditory information. This change in shaft force however cannot be translated to the pinch force as the pinch force can still change with constant shaft force. Therefore, if the user gets information that they are increasing the forces in the shaft, that would only mean that the pinch forces are also increasing in case of a constant angle of the tip. But in case a soft object is grabbed and the user increases the force applied and the angle of the tip also reduces, it cannot be deduced by certainty that the pinch forces are also going to increase. Therefore it must be noted that the safety mechanism is only an indication of increased applied forces, and increased pinch forces only in case of a fixed position of the tip.

7.1.3. Feedback mechanism

The feedback mechanism in this instrument uses auditory information in the form of clicks. Although auditory feedback has not been extensively used in laparoscopic surgery, auditory information been used previously in clinical medicine for image-guided needle placement. In a study performed by Black et al. [2017], it was concluded that combining audio feedback with visual feedback in navigated interventions led to increased accuracy and lesser workload. Audiovisual feedback has been used in image-guided therapy and has shown significant benefits.

In another study where the performance of surgical knot tying of novice medical students was examined by providing different types of feedback at different timings, it was concluded that providing immediate audio feedback led to superior results[Al Fayyadh et al., 2017]. The results were supported by a theory by Baddeley [2012] which states that visual stimuli are processed by a visuo-spatial sketchpad subsystem but when auditory feedback is used, the cognitive resources are spread over 2 subsystems as another subsystem called the phonological loop subsystem is engaged, enhancing the feedback provided. Auditory force feedback has also shown to improve performance in the case of a peeling task during simulated ophthalmic surgery[Cutler et al., 2013]. These examples of auditory feedback being used in clinical medicine show the scope and possibilities regarding auditory feedback. It also opens room for more research into different types of auditory feedback and their effectiveness in the operation room. Additionally, the feedback mechanism uses a helical spring in between two parts of the shaft. Even though the force is effectively transformed from the handle to the tip, there is a limitation regarding the use of a spring - the closing action of the handle does not result in a 1:1 position transformation at the tip.

7.1.4. Design process analysis

During the course of the project, there were certain assumptions made with respect to the instruments. Looking back at the design process and analyzing how these assumptions affected the outcome, certain changes could have been for a better outcome. An early analysis of the type of tip mechanisms available might have helped to overcome the efficiency gap that was discussed in the previous subsection. The scope of the project itself could have been limited to the feedback mechanism and its detailing and prototyping. Designing a whole instrument meant that a lot of different components had to come together and had to be detailed individually to complete the instrument, therefore taking away the focus which could've been given to more important sub-parts of the instrument which were designed new in this project.

7.2. Future Work & Recommendations

7.2.1. Development of prototype

One of the recommendations for any future work of this project would be the development of a full prototype with its various components combined together to see how they would function together as an instrument. This would also include the validation of the force models that have been theoretically defined. With force sensors, the performance of the instrument and its various components should be analyzed with respect to the force models.

7.2.2. Auditory feedback improvement

Auditory feedback has been used in surgery and outside in various combinations. Future work could also be on improving this form of audio feedback and discovering the possibility of combining it with other forms of feedback like visual feedback.

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