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Designing an accessible body-powered hand prosthesis for soldiers with partial hand amputations

Colophon

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In collaboration with
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Preface

I am proud to share this graduation report with you. Creating this report marks the end of my student journey. After six years, I am happy to finalize my studies and graduate as a Master of Science in Industrial Design Engineering. This also marks the end of my time at TU Delft. When I started in September 2018, a master's degree seemed very far away. Yet, the time has flown by, and looking back, I feel incredibly fortunate to have had the opportunity to complete such an amazing study experience. While I am sad to leave this faculty, I am also proud of what I've learned and achieved over the past few years.

Since I was young, my goal has always been to help people and improve their lives. This is also something I have always tried to achieve in my designs, which is why I chose to specialise in Medisign. Over the years, I've developed a deep passion for design, and I'm grateful for the invaluable lessons I've learned.
For the past three years, I've also had the opportunity to work for the army, which provided an unique and enriching learning environment. I quickly realized the value of Industrial Design Engineers in this context, and that's why I wanted to combine my passion for design with my experience in the army for my graduation project.

I had the privilege of doing my graduation project at the Militair Revlidatie Centrum (MRC) in Doorn.
Working on this project for the MRC was an incredible opportunity for me. I want to thank the MRC for giving me the chance to complete my graduation project there. I'm deeply grateful to everyone in the team for their support and for welcoming me as part of their team. Thank you for sharing your knowledge, skills, and passion with me, and for supporting me throughout the project. The humour and your expertise kept me motivated and helped me finish this project.

This accomplishment would not have been possible without the support of many people. I am especially grateful to my supervisors. Thank you to my mentor, Richard Goossens, for guiding me with your encouragement throughout the process. Our small talks during coaching meetings were invaluable, and I always left those sessions feeling more confident and less stressed about the project.

Thank you to my chair, Kaspar Jansen, for your honest feedback, enthusiasm and for steering me in the right direction. Your ability to help me limit the scope of the project was crucial to its success.

In addition to my academic supervisors, this project wouldn't have been possible without Niels Jonkergouw, who immediately saw the potential for this project. Thank you for your support, enthusiasm, and can-do mentality. Your efforts made my graduation project an amazing experience and helped me stay motivated throughout. Your guidance and effort was invaluable and an unique experience for me.

I also want to thank everyone who contributed to my research, your input was invaluable.

A special thanks to my family for always believing in me when no one else did and for supporting me in every way possible. To my parents, thank you for the pep talks over the years and for showing me what I am capable of. Your encouragement kept me believing in myself, and without your unwavering support, I wouldn't be where I am today. Your safety net allowed me to chase my dreams and push myself, knowing that I could count on you. The 16-year-old me could never have imagined I'd be graduating with a Master of Science degree, and it's partly thanks to you. As my father repeatedly told me when I was younger: "Even if everyone's nagging at you, never give up."
I'm so glad I didn't.

Marit, thank you for reviewing my report, listening to my presentation, and giving me the pep talks when needed. Jeroen and Thijs, thank you for taking the time and patience to help me out when I was facing difficulties. Not only during this project but throughout my studies, you've always been there for me. Sometimes helping me with your expertise and sometimes just a small reminder to stop doubting myself. I'm incredibly grateful and proud to have you all as my family.

To my friends, thank you for your support and encouragement along the way. The distractions, coffee breaks (thanks for the endless coffee breaks, Odine!) and your understanding were truly valuable to me. I'm so lucky to have such wonderful friends.

I hope you enjoy reading this graduation report as much as I enjoyed working on it!

Executive Summary

The goal of this project was to design an affordable, body-powered hand prosthesis that restores functionality after a partial hand amputation, enabling users to perform activities of daily life. The design particularly focuses on supporting soldiers and enhance their rehabilitation. Currently, options for individuals who lose their hand up to the MCP joint are limited. Well functioning prostheses are often too expensive, and insurance coverage is most of the times unavailable. Even when insurance is available, long waiting times and dependency on prosthesis companies for repairs increases the burden.

With the increasing number of partial hand amputations, particularly due to global conflicts, the need for affordable prostheses is urgent for soldiers. However, effective solutions remain limited. This project addresses this gap by creating a prosthesis that meets these needs.

The result of this project is a modularly designed prosthesis that is simple to repair instead of replacing the entire prosthesis. This feature ensures that repairs can be done anywhere and by anyone, thanks to the 3D printing production technique used. Unlike traditional prostheses that require specialist manufacturing, this prosthesis can be produced locally, making it more affordable and accessible. This prosthesis is the first step towards a hand that supports tripod and power grips. The newly designed finger mechanism enhances freedom of movement by representing an innovative approach to body-powered prosthetics.

The development of this concept involved multiple design phases. Throughout the project, an iterative process was followed, continuously integrating expert feedback to create a prosthesis that offers a new approach to prosthetic design.

The frame phase included a literature review, expert consultations, interviews with an occupational therapist, and patient observations, which provided valuable insights. These insights were integrated in the ideation phase, where nine design directions were explored based on the desired product's sub functions. Two concepts were chosen, tested and refined and one concept was selected for further development. In the embodiment phase, each component of the prosthesis was detailed, integrated, and tested, resulting in a final design and prototype. The prototype was evaluated compared to the design requirements which led to positive results. Nevertheless, the amount pinch force could be improved.

The conclusion after this project is that the design is promising, but improvements are needed. Recommendations for next steps include testing the prosthesis with people who have a partial hand amputation to gain more insight and refine the design. The future implementation of this prosthesis depends on the outcomes of these tests.

Glossary

ADL
Activities of daily life

DOF
Degrees of Freedom

DIP
Distal interphalangeal

IOF
Index of functionality

MCP
Metacarpal phalangeal

MRC
Militair Revalidatie Centrum

OTA
Orthopedie Techniek Aardenburg

PP
Prehensile Patterns

PIP
Proximal Interphalangeal

VO
Voluntary Opening

VC
Voluntary Closing

Table of content

4 EMBODIMENT

5 FINAL CONCEPT

6 EVALUATING

7 REFERENCES

8 APPENDIX

1 Introduction

1.1 Context introduction

Hand amputations are a significant and recurring issue worldwide. Exact numbers in the Netherlands are not publicly available, however in the United States, approximately 7.5 per 100,000 individuals are having a hand amputation every year (Essien et al., 2022). Approximately 3,000 people undergo limb amputations annually. And of all the upper extremity amputations, partial hand and finger amputations are the most common (BSLredactie, 2023). From these data, it can be concluded that this is a common injury.
They occur in a wide range of environments, including the military (Reitsma, 2023). Hand amputations in military settings are relatively common due to the physically demanding and hazardous work conditions during military operations. Hand amputations can lead to diminished hand functionality and loss of work ability, particularly among active-duty military personnel. (Jordan et al., 2022).

As conflicts in the world are increasing, so does the number of soldiers that is injured during combat and thus suffering from this trauma. Ideally, this injury should be treated with immediate medical care, followed by rehabilitation with a suitable prosthesis. However, access to well-functioning prosthetic remains limited due to the high cost. Some prosthetics are covered by insurances, but these are not always the most functional models. Some require manual adjustments to function, which can be particularly challenging for individuals with bilateral hand injuries or they are not very intuitive to use. There are good options available but the cost of these prostheses are very high since they are not covered by insurances and therefore it is most of the time not possible for patients to afford them on their own.

This lack of well-functioning and affordable hand prostheses presents opportunities to improve the recovery of people who suffer from partial hand amputations.

The problem is defined as:

Soldiers who lose their hand do not have access to a prosthetic solution that is affordable and meet their functional needs. This can result in soldiers not being able to perform activities of daily life

During the first phase of the design process, the problem definition and project goal will be defined which will result in an adjusted and strengthened problem definition and project goal.

1.2 Project assignment

This project aims to design a functional hand prosthesis for soldiers to use after a hand amputation that is affordable and can be created in a short amount of time.

To ensure that this project achieves the desired results, the design goal was defined.
The aim is to enable users to perform activities of daily living (ADL) as they did before the amputation. The prosthesis should not feel difficult to control, but it should feel like an automatic operation. Therefore the focus will be to restore the functionality of the hand instead of mimicking the finger.

Currently, there are no affordable options on the market that meet these criteria and therefore the aim is to create a prosthesis that is affordable and by that, available for the patient.

1.3 Militair Revalidatie centrum

The Militair Revalidatie Centrum (MRC) is a treatment and expertise centre within the Dutch army focused on rehabilitation care. The MRC has its own instrument workshop: Orthopedie Techniek Aardenburg (OTA). At OTA, prostheses and orthoses are designed and produced. Their goal is to restore the quality of life for rehabilitants as much as possible. Rehabilitation care for military personnel primarily focuses on enabling them to return to their job and meeting the job requirements that come with it.
The treatment of patients with a partial hand amputation is also a current challenge where they, among other things, are focused on. OTA is visibly progressive with use of technologies and how they can be deployed in different ways.
The MRC indicated the problem and need for a new prosthesis and this project is carried out in collaboration with the MRC.

Project goal

The goal is to help soldiers after a partial hand amputation by designing a prosthesis that is cost-effective, quick to develop and will restore the functionality of the hand

Figure 1: Logo MRC

1.4 Project Approach

This report explains the different design phases that led to the final concept of this project; Framing, Concepting, Embodiment and Evaluating. These phases correspond to Figure 2 and are referenced throughout the chapters to guide the reader through the design steps.

The design approach follows the double diamond principle (Figure 3). This principle provides a clear and understandable way to illustrate the design steps, especially for non-designers. Since neither the users nor the company are Industrial Design Engineers, it is even more important to present the approach in a logical way.

The first phase is the exploration phase where the problem is explored in a broad way. Before determining which problem to solve or how it impacts the user, it is necessary to understand the current situation and define the problem. This is a divergent step to gain knowledge about this topic.

In the next phase, the gathered information is converged to define the focus of the project. This is called the framing phase. All the relevant information is selected to scope the challenge. This helps to select what background information will be used and defines the area that will be designed for.

During the third phase is the development phase, there will be diverged again by generating a wide range of design ideas. After exploring multiple design options, decisions must be made to narrow it down to one concept. This concept will be refined and improved until the final result is achieved. This phase is called the deliver phase.

This is not a step-by-step guide, but rather an iterative process. Sometimes, it requires narrowing down the information or ideas and sometimes it is needed to take a broader perspective.
In short, this explains the project approach and how the report should be read.

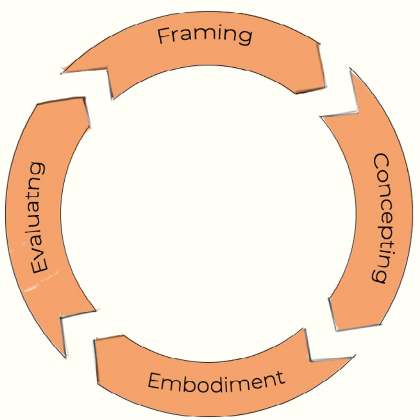


Figure 2: Report structure

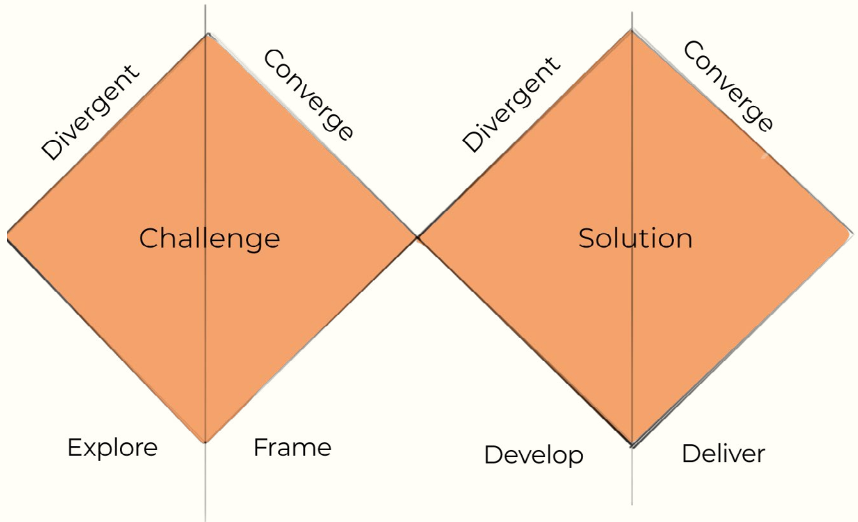


Figure 3: Double diamond approach

2 Framing

2.1 Anatomy of the hand

The hand is a very complex part of the body. To understand how the prosthesis should work, it is important to first understand the anatomy of the hand. By understanding the anatomy, it becomes clear what factors must be considered and which movements the prosthesis should be able to perform.

2.1.1 Research question

Main Question:
- How does the anatomy of the hand work?

Sub Questions:
- What enables movement in the hand?
- What are the mechanisms of the hand?
- Do the fingers differ from each other?
- Understanding of clinical terms

2.1.2 Anatomy and movement

The hand can perform all kinds of movement, such as waving, grasping or pointing at something. These movements are made possible by two primary types of movement: flexion/ extension and adduction/abduction of the fingers, see Figure 4. Flexion of the fingers refers to the bending of the fingers, while extension occurs when the fingers are straightened. Flexion of the fingers occurs in the sagittal plane, see Figure 5. Adduction involves moving the fingers toward each other, while abduction refers to spreading the fingers apart. These movements occur in the frontal plane.

To make these kinds of movements possible, muscles, tendons and joints are needed. Without these body parts, moving your finger would not be possible (Kidshealth, n.d.).
With the exception of the thumb, this finger exists out of two joints, there are three joints within the fingers; the Metacarpo phalangeal (MCP), the Proximal Interphalangeal (PIP) and the Distal Interphalangeal (DIP) joint (Jersey Finger, n.d.). The MCP joint is the joint between the hand and base phalanx. The PIP joint is the joint between the basis and middle phalanx. The DIP-joint is the joint between the middle and outermost phalanx , see Figure 6 for an overview.

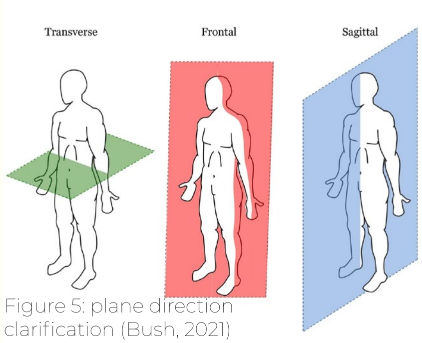


Figure 5: plane direction clarification (Bush, 2021)

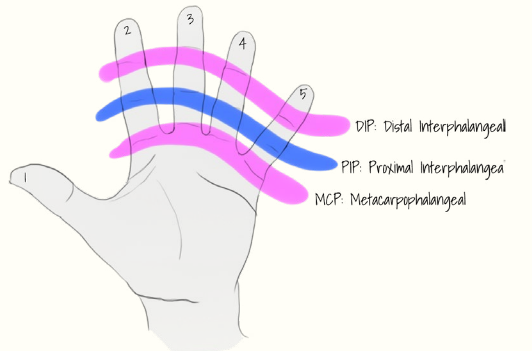


Figure 6: Clarification of the joints and numbers describing the fingers

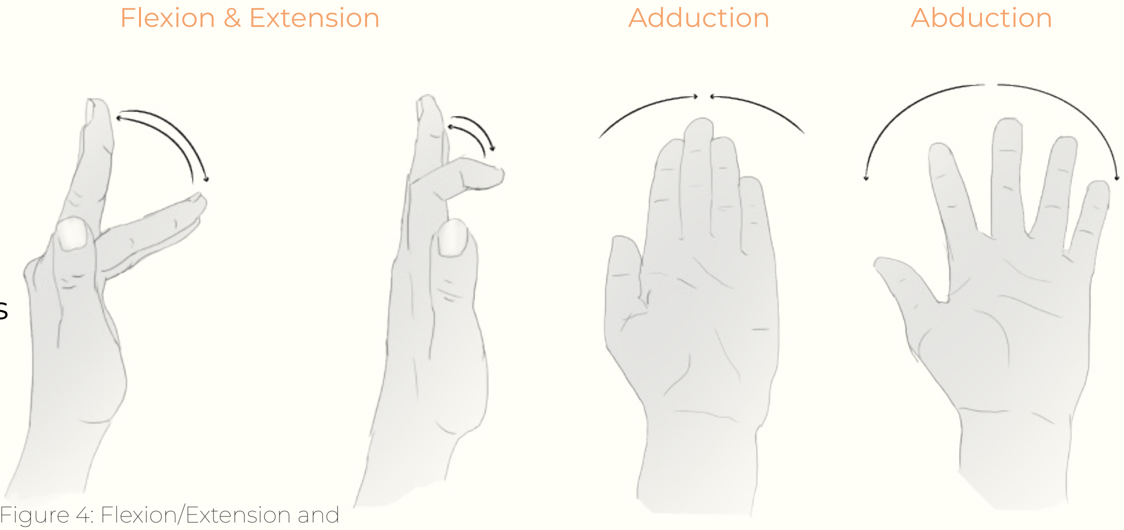


Figure 4: Flexion/Extension and Adduction/Abduction movement

Finger movement is preformed by two main tendons to facilitate flexion/extension and abduction/adduction movements. These tendons are connected between the muscles and bones of the hand (Figure 7).

When a muscle contracts, the tendon attached to the bone pulls on it, causing movement in the finger. The thumb has one of these tendons, the other fingers all have two.
The first one is the flexor digitorum superficialis which is a superficial flexor tendon. This tendon is connected to the metacarpal and able to move the PIP joint.
The second tendon is the flexor digitorum profundus which is a deep flexor tendon. This tendon is connected to the distal phalanx. This tendon bends the DIP joint, enabling flexion. Because of this mechanism, it is possible to extend and flex the fingers or to make adduction and abduction movements with the fingers (Difonzo et al. 2020).

The MCP-joint has two degrees of freedom and is able to make flexion/extension and abduction/adduction movements. The PIP-and DIP-joints both have one degree of freedom and are only able to make the flexion/extension movement. (Stanley & Tribuzi, 1992).
This explained mechanism is for finger 2-5, since the anatomy of the thumb is different. Instead of two tendons to flex the fingers, the thumb has only one long bending tendon. Only two types of tendons are needed for the thumb, as it has only two bones in its digit, rather than three. Besides that, the thumb is able to move in more directions and is the only finger that is able to oppose the other fingers. Therefore, it can be said that the thumb is anatomically as well as functional, different then the other fingers (Difonzo et al. 2020). This is the reason that for this project there is chosen to keep the thumb out of the scope, and to only focus on fingers 2-5.

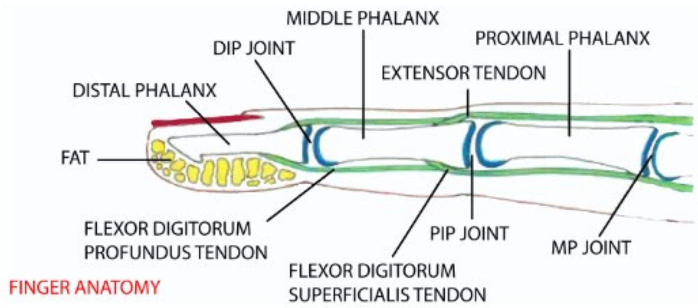


Figure 1. Finger anatomy [8].

Figure 7 Difonzo et al. (2020)

Direction of movement joints

Metacarpophalangeal (MCP):
Flexion and extension
Abduction and adduction

Proximal interphalangeal (PIP) :
Flexion and extension

Distal interphalangeal (DIP):
Flexion and extension

Function tendon

Flexor digitorum superficialis
· Bending PIP-joint

Flexor digitorum profundus
· Bending DIP joint

2.1.3 Dimensions

An important aspect is the dimension of the hand since the design and functionality of a prosthesis must align with the anatomy and measurements of the hand.

Therefore the anatomical dimensions of the human hand were collected using the anthropometric data from DINED ((TU Delft [DINED], n.d.)). This data includes measurements such as palm length, hand width, and the length of each finger, Figure 8.

The data is based on Dutch adults between 31-60 years old, both men and woman. To represent the variations within the population, the dataset includes the median, as well as the P25 and P75 percentiles.
Furthermore, the data from the Decathlon hand was also used since the first data set did not have all the measurements available, like the length of the fingers. This data can be seen in figure 9.

These measurements were chosen because they are relevant sizes to consider when designing a prosthesis that will cover the hand. In addition, the finger sizes are relevant because not everyone needs the same finger sizes. To know which sizes to produce, the measurements are needed. These measurements show that there is a large variation which needs to be considered when designing a prosthesis. However, a one-size-fits-all prosthesis is probably not realistic. The spread between P25 and P75 explains that there is a need for customization or a flexible concept.

	P25	P50	P75
Hand thickness (mm)	22	26	30
Hand thickness without thumb (mm)	81	86	91
Hand length (mm)	178	186	194
Forefinger breadth (mm)	17	18	19

Figure 8; anthtropometric data DINED, hand measures Dutch adults (31-60), mixed (TU Delft [DINED], n.d.)

	P25	P50	P75
Ring length (mm)	71	74	77
Middle length (mm)	75	79	83
Index length (mm)	69	72	75

Figure 9; anthtropometric data DINED Decathlon hand, hand measures (EU/China) 30-49, mixed. (TU Delft [DINED], n.d.)

Key insights
Only the MCP is able to create an abduction and adduction movement.

MCP, PIP and DIP are all able to flex and extend the finger. Because of the orientation of these joints, the finger is able to bend.

There are two important tendons that enable the flexion and extension of the finger.

The anatomical differences between the thumb and other fingers are big as well as the direction of movement. Due to this, the thumb will be out of scope and will not be included in the design.

There are strong variations in hand measurements. Flexible or customizable design is needed

2.2 Function of the hand

A hand may perform multiple grips which enables different ADL activities. By understanding what these functions are, how this works and which movement is the most important to focus on, this can be integrated in the prosthesis to make the prosthesis function in the best way.

2.2.1 Research question

Main Question:
- Which functionalities are most important to consider

Sub questions:
- What functionalities does the hand have?
- Which grips are the most difficult for people with a finger prosthesis?
- Which functionality is the most important to restore?

2.2.2 Prehensile Patterns

To test hand functionalities, the Southampton Hand Assessment Procedure was created. This procedure tests the hand function by different assessments for the hand. There are 12 assessments that focus on the weight of an object and 14 assessments that evaluate the functionality of the hand during activities of daily life (ADL's). These tasks are scored and categorized within 6 groups which are called the prehensile patterns (PP). The six PP are: Tip, lateral, tripod, spherical, power and extension grip (figure 10). These PP are linked to different ADL's in table 1 which results in an overall Index of Functionality score (IOF) (Resnik et al., 2021).

Tip	Lateral	Tripod	Spherical	Power	Extension
Pick up coins	Pour water from jug	Food cutting	Remove jar lid	Food cutting	Page turning
Undo buttons	Move a tray	Undo buttons	Pour water from carton	Move a full jar	Move a tray
Rotate a key 90 degrees	Rotate a key 90 degrees			Move an empty tin	
Open/close a zip	Open/close a zip			Rotate a screw 90 degrees	
				Rotate a door handle	

Table 1: Overview ADL in relation to SHAP (Kyberd et al., 2009)

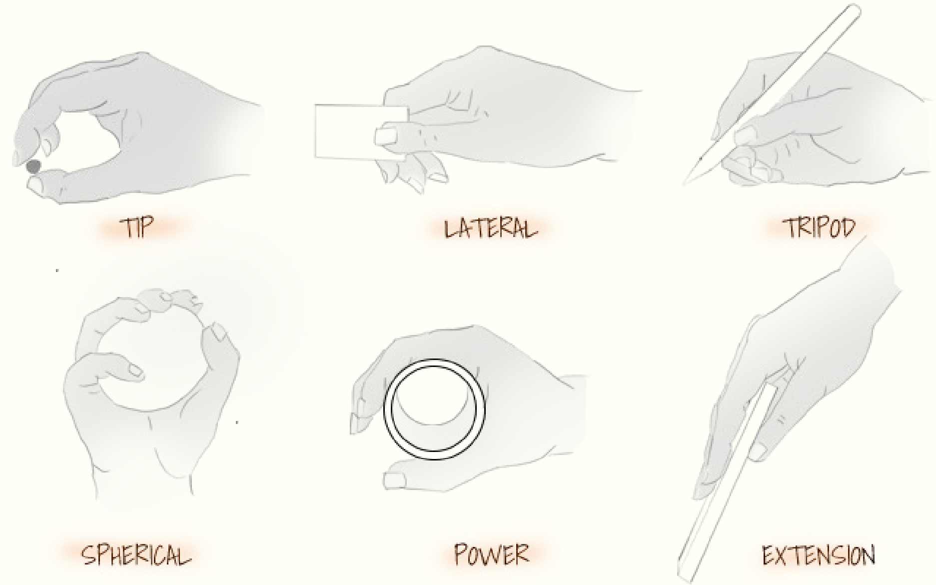


Figure 10: Six grip classifications: (Kyberd et al., 2009)

2.2.3 Functions of the finger

Naturally, each finger has an influence on the functionalities of the hand.
The thumb is a finger that makes it possible to grasp, stabilize objects and has sensory functions. Without this finger, an essential part of hand functionality is missing.
The four fingers are used for different grasps. The Index and middle fingers are mainly used for prehensile patterns, like writing. While, the ring and small finger are more effective for grasping. Big, small cylindrical or multiple objects will be hard to grasp when the ring and small finger are affected.
To perform all of those grasps, the fingers are required to be able to push, pull and manipulate objects. For this, a lot of finger force is needed (Difonzo et al. 2020). According to the fingers can deliver a force between 30 to 110 N. The relative contribution of each finger was described by Difonzo et al. (2020) and can be seen in figure 11.

However, looking at the partial hand amputation, the amount of functionality depends not only on which finger is amputated but also on the level of the amputation. Amputation at the PIP-joint will still make it possible to perform most activities but amputation below the PIP-joint, will limit the hand to be able to only stabilize and grasp objects and limited abduction and adduction function due to a reduced tendon length.
(Stanley & Tribuzi, 1992b)

Every finger has its own functionality which is hard to restore one on one. Therefore it is good to look at the grip patterns to decide which functionality is most important to restore with a prosthetic.
An important function within most gripping patterns is to be able to have a tip and tripod grip, it is that the thumb should be able to be opposed against the fingers. This makes it is possible for humans to grasp objects like a coin or undo a button. This movement is very important for a patient to do but is often limited by a partial hand amputation.
Restoring this hand function by making it possible for the patient to be able to oppose the thumb against the fingers with enough force and opening width, will give the hand important functionalities back (Imbinto et al., 2016).

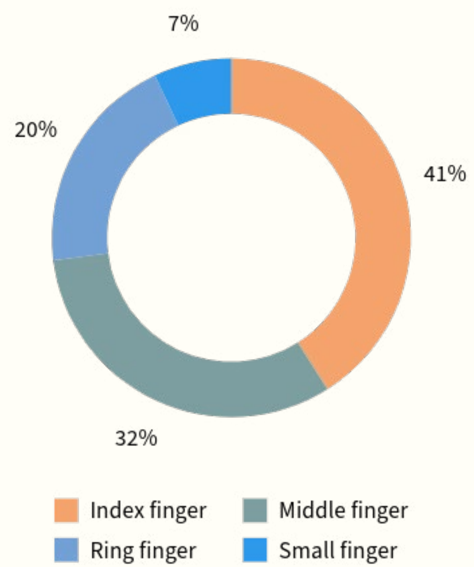


Figure 11: Contribution of each finger according to Difonzo et al. (2020)

2.2.4 Focus area SHAP

Since the goal is to restore the function of the hand rather than mimicking the finger, it is important to analyse which functionalities are important to restore. Research about this explained the following.

A SHAP assessment was done by 42 patients with an amputated hand with a (silicone) prosthesis, see Figure 12 (Montagnani et al., 2015). This data suggests that the tripod, power and tip grips are the most difficult with such a prosthesis. Kyberd et al. (2009) also indicated the relation between different types of prosthesis and their IOF. In Figure 13, it can be seen that within the electrical driven prosthesis, the tip, power and tripod grips are also the most difficult prehensile patterns to perform.
Nevertheless, there should be taken into account that this is a different type of prosthesis than a body powered prosthesis. Therefore an interview was done with an occupational therapist, to understand what the experiences are during rehabilitation.
This gave additional insights about the importance of each grasping-grasp. Instead of what literature states, the spherical grasp is the most important grasp movement. But, when the dominant hand is affected, the patient misses the tip and tripod grasp. From the therapeutic point of view, it would not be the goal to restore those prehensile patterns.

However, the patient, who was testing a prosthetic, was seeking for the tripod and tip grasp since the patient wanted to be able to pick up objects with it. For this patient, this added value to daily life, enhancing the patient's independence.
The options of the prehensile patterns were also discussed with hand orthopaedic G. Kraan (Personal communication). He noted that it also depends on the work field/hobbies someone has and therefore which functionalities they need. Therefore it is hard to say that one PP is better than the other.

After a conversation about these insights with Orthopaedic technologist N. Jonkergouw, the conclusion was that the tripod and power grip are the most grasp patterns that patients ask for to be restored. The coarse motor skills are not limiting the patient as much as the tripod grip is. Patients are seeking that kind of grasping combined with enough power. Combining and considering all the input resulted in a decision to focus on the tripod and power grip.

SHAP index score	Injured hand without prosthesis		Injured hand with prosthesis	
	Mean (SD)	Median (min., max.)	Mean (SD)	Median (range)
Overall	87.3 (9.7)	90 (58, 97)	88.4 (8.9)	91 (60–98)
Spherical	91.1 (4.4)	91 (71, 97)	92.5 (3.9)	93 (85–99)
Tripod	85.2 (10.8)	89 (50, 97)	86.0 (10.7)	89 (44–97)
Power	84.4 (7.8)	86 (53, 95)	85.8 (7.5)	88 (55–93)
Lateral	91.8 (7.1)	93 (63, 98)	91.1 (7.8)	94 (65–98)
Tip	87.9 (10.7)	92 (40, 98)	88.6 (10.9)	93 (53–98)
Extension	93.3 (6.0)	95 (74, 99)	95.1 (4.3)	96 (80–99)

SHAP: Southampton Hand Assessment Procedure; SD: standard deviation.

Figure 12: Descriptive statistics and summary of statistical tests for the SHAP test (Montagnani et al., 2015)

Category	Otto Bock (7.25")				Otto Bock (6.25")			Centri
Participant	P1	P2+	P3+	P4	P5+	P6	P7	P8
Gender	M	M	M	M	F	M	F	F
Side	L	R	R	R	L	L	L	R
Overall	**80**	**66**	**76**	**48**	**44**	**17**	**23**	**43**
Spherical	84	75	85	79	37	23	32	55
Tripod	76	72	68	43	26	13	26	37
Power	78	47	71	55	30	15	24	27
Lateral	75	69	83	53	60	17	17	38
Tip	69	32	72	19	48	16	18	34
Extension	87	63	75	61	54	22	25	56

A cross [+] indicates if the prosthesis used a powered wrist.

Figure 13: Results of using the SHAP with anthropomorphic prostheses (Kyberd et al. 2009)

Key insights

SHAP explains different prehensile patterns that is used in ADL.

The focus for this project will be on the **Tripod** and **Power** grips.

For this grip, the most important fingers that contribute to this movement are the index (2) and middle finger (3).

Since the chosen grips are all based on a flexion/extension movement, there will be focused on this movement ass well. The abduction/adduction movement is not taken into account.

The focus for this project will mainly lay on restoring the function instead of the looks of the finger.
Function before design

2.3 Partial hand amputation

A partial hand amputation is a broad term since not every amputation is located at the same place. This chapter will explain about the levels of the partial hand amputation and defines the amputation level to consider for this project. Furthermore the impact on the patient after an amputation will be explained to understand the relevance of this project.

2.3.1 Research question

Main Question:

- What is a partial hand amputation

Sub questions:

- What are the differences between the amputations
- What is causing a partial hand amputation
- What are the effects of this amputation on the patient

2.3.2 Levels of amputation

In 2020, the United States Bureau of Labor Statistics stated that hand and wrist injuries were the most common work-related injuries. This did not always result in a hand or finger amputation but the estimation is that 1 in 18.000 people live with a partial hand amputation. By that, a partial hand amputation is the most common upper extremity amputation. (Graham et al., 2023). This amount is probably even higher in developing countries and areas where the work conditions are less safe, like war regions.
A partial hand amputation can be caused due to a trauma, malignancy, disease or birth anomaly (Imbinto et al., 2016). Trauma's can happen due to accidents during sports, hobby's or work. Think of working with machines or getting your finger stuck when moving. Besides that it can also be caused by an infection, malignant cancer or congenital malformations. In this last situation the deformity may be caused by a genetic defect. In those situations, amputation might be necessary to maintain the patient's long-term health (Leven met een Vingeramputatie, n.d.).
In some cases it is possible to replace the severed fingers, this is called re-plantation. This surgery is very complex, not always possible and depends on the status of the remaining finger as well. In these cases, the only alternative will be a partial hand prosthesis.

Not every hand amputation is the same since not every finger is amputated at the same location. This is because most of the time the amputation is caused by a trauma and is dependent on the remaining functioning parts of the hand. It is possible to amputate the finger around the DIP-joint but also at the MCP-joint for example.
The partial hand amputation includes any amputation distal to or through the carpal bones without affecting wrist movements. Four amputation levels may be defined:

1) transphalangeal where the thumb is spared;
2) thenar, partial or complete and involves the thumb;
3) transmetacarpal distal, thumb is spared or involved;
4) transmetacarpal proximal, amputation is near the wrist, the thumb is spared or involved. (Imbinto et al., 2016).

These four amputation levels are visualized in Figure 14.

The MCP-joint has two degrees of freedom and is able to make flexion/extension and abduction/adduction movements. When the hand is amputated around this level, this will affect the DOF of the hand by not being able to make the flexion/extension and abduction/adduction movements. When the

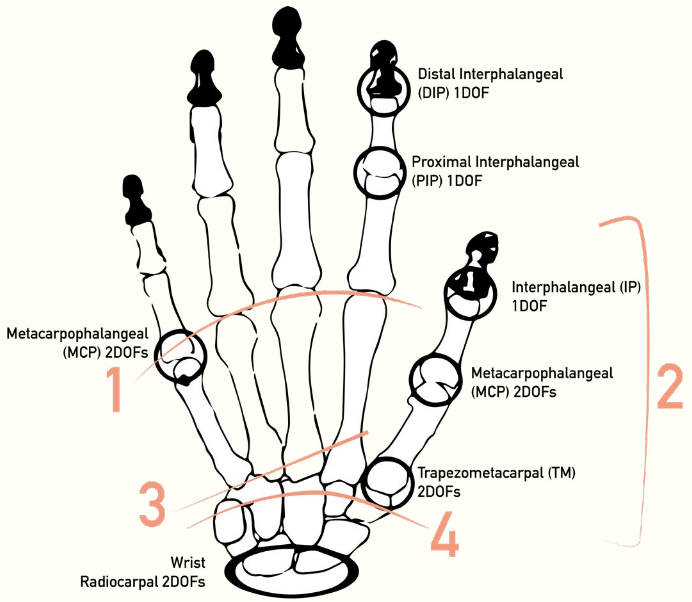


Figure 14: levels of hand amputation

amputation would be around the PIP-or DIP-joint, the flexion/extension is limited but this movement can still be made with the residual part of the finger.
When the hand is amputated around the MCP-joint, this means that neither a flexion/extension or abduction/adduction movement can be done. The different amputation levels result in different possibilities and options.
Naturally, a partial hand amputation results in significant limitations. For some of these limitations, a prosthesis can offer a solution and restore much of the hand's functionality. However, a prosthesis cannot fully replace the function of a human hand, which may prevent an individual from performing certain tasks required in their job. 35.3% of the patients who had a partial hand amputation had to change their jobs because of this and 23.5% had to retire (Burger et al., 2007). Taking into account that more heavy manual workers had to change their job or retire after the amputation than non-manual workers, see Figure 15.
The usage of the prosthesis and its type also play a significant role in this. Heavy manual workers wore their prostheses fewer hours per day compared to non-manual workers. According to Burger et al. (2007), of all the individuals fitted with their first prosthesis, 35.4% discontinued wearing it, 29.2% wore it occasionally, and the remaining 35.4% wore it daily.

Interestingly, none of the individuals who had three or more fingers amputated were able to return to their previous job, see Figure 26 (Burger et al., 2007).

Creating a well fitting prosthesis is challenging since not every amputation is the same. An example illustrating only the possible variations in the number and combination of amputated fingers is shown in Figure 19 to provide an idea of the variations.
The prosthesis has to be custom made and fitted with the patient. Therefore, an experience based trial and error approach is often used. As a result, this typically leads to a prosthesis that is costly, inefficiently made, and whose quality and functionality depend on the individual making the prosthesis (Imbinto et al., 2016).

Table VI. Patients' opinions on the usefulness of their silicone prostheses for work.

Usefulness for work	Same job as before amputation		Changed their job due to amputation		Total	
	n	%	*n*	%	*n*	%
Not useful at all	3	21.4	7	58.3	10	38.5
Not useful	1	7.1	2	16.7	3	11.5
Fairly useful	4	28.6	2	16.7	6	23.1
Useful	4	28.6	1	8.3	5	19.2
Very useful	2	14.3	0	0.0	2	7.7
Total	14	53.8	12	46.2	26	100.0

Figure 15: levels of hand amputation (Burger et al., 2007)

Table V. Influence of number of amputated fingers on employment.

Employment	No. of amputated fingers 1	2	3	4	5	7	Total *n*	%
Same job as before amputation	10	4	0	0	0	0	14	29.1
Changed their job due to amputation	3	2	3	2	1	1	12	25.0
Retired due to amputation	0	1	5	0	1	1	8	16.7
Did not work even before amputation	6	1	2	3	0	0	12	25.0
Still on sick leave	1	0	1	0	0	0	2	4.2
Total	20	8	11	5	2	2	48	100.0

Table III. Relationship between type of work before amputation and employment status after the amputation.

	Same job as before amputation		Changed their job due to amputation		Retired due to amputation		Total	
	n	%	*n*	%	*n*	%	*n*	%
Heavy manual	6	27.3	11	50.0	6	75.0	23	67.6
Non-manual	8	72.7	1	9.1	2	25.0	11	32.4
Total	14	41.2	12	35.3	8	23.5	34	100.0

Figure 16: levels of hand amputation in relation to work (Burger et al., 2007)

Figure 18: Röntgenphoto of partial hand amputation after trauma, not corresponding with Figure 17.

Figure 17: Example of partial hand amputation after trauma

Key insights
When amputated around the MCP level, the impact is enormous for the patient, since none of the SHAP is possible. Therefore the focus for the project will be on the amputation from the MCP joint.

The goal is that more people can participate in ADL and are more willing to use the prosthesis by having the option to adjust the prosthesis to the patient's preferences.

Every amputation is different since it is caused by a trauma.
Therefore a prosthesis needs to be custom made and can therefore be costly to create.

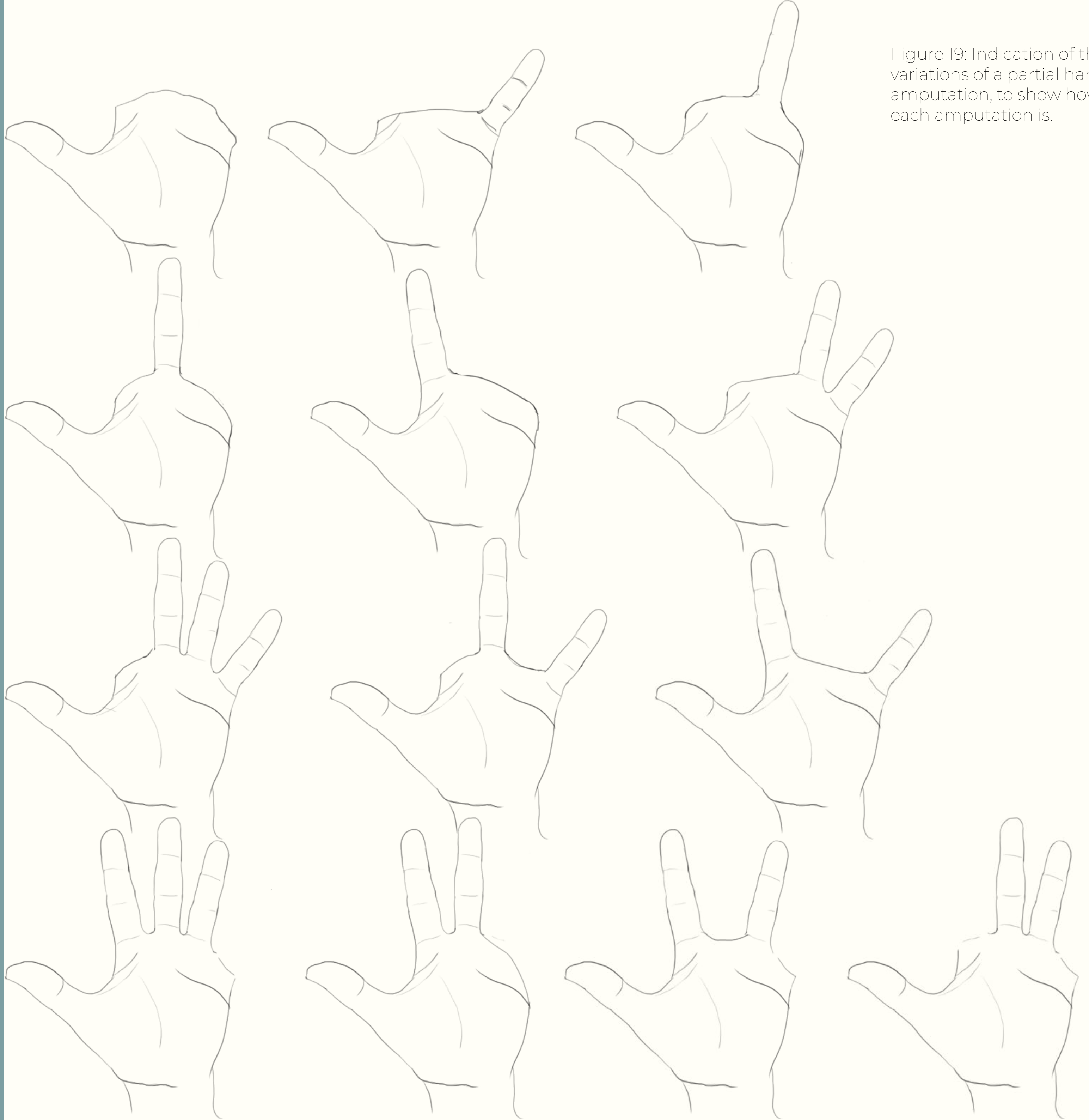


Figure 19: Indication of the possible variations of a partial hand amputation, to show how specific each amputation is.

2.4 Hand prosthesis

A partial-hand amputee may be fitted by a variety of different prosthetic components. It is of importance to seek the existing solution in order to determine which aspects are of importance for users.

2.4.1 Research question

Main Question:
- What kind of prostheses are available after a partial hand amputation?

Sub questions:
- What is the function of each prosthesis?
- What are the advantages and limitations of the different prostheses?
- Why is there a need for a new design?
- What is the main functionality of the prostheses?
- Which type of prostheses is the best to choose from when having a partial hand amputation at the MCP joint?

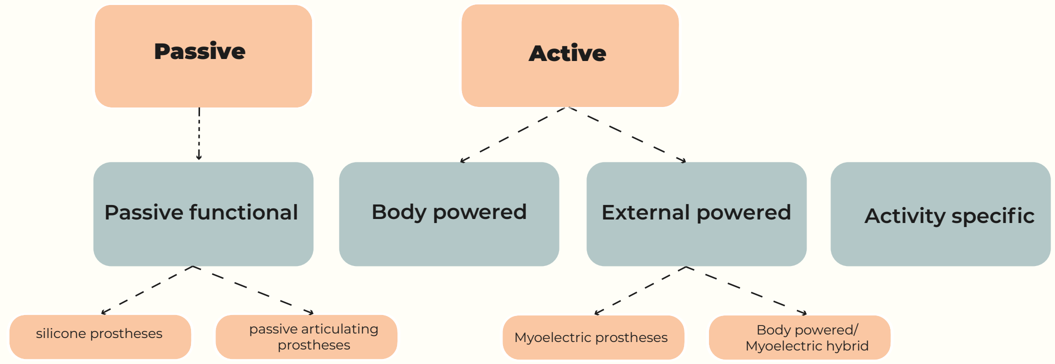


Figure 20: Overview type of prosthesis

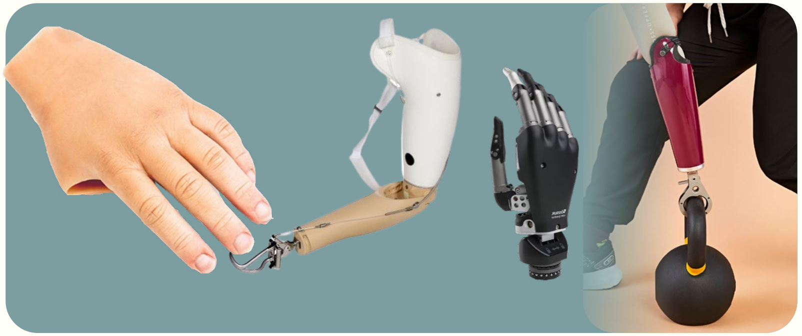


Figure 21: From left to right, Passive functional, Body powered, external powered, activity specific[1].

2.4.2 Types

Currently, there are multiple options available to restore the hand form or function. In that case, different prostheses options are available which can be broken down into four main categories. Passive functional, body-powered, externally powered and activity specific prostheses. (Figure 20-21).

The first category is the passive functional prosthesis which can again be divided into two subclasses; silicon prostheses and passive articulating prostheses. These types of prostheses are called functional but the user will not be able to have an active grasp and release. However, it will be possible for the user to push against and stabilize objects (Imbinto et al., 2016).

The silicon prostheses are mainly used to restore the length of the amputated hand and restore some functionality like pushing, pulling and position motions. In the case of high definition silicone it is even possible to mirror the other hand to mimic the fingers. Therefore the accuracy of the prosthesis is really high (Figure 22). According to Burger et al. (2007), this type of prosthesis is helpful for prosthetic users whose work involves personal contacts and whose aesthetics is important. It is more likely that because of this, the user tends to avoid hiding the hand with the silicone prosthesis and therefore will use the hand more then before the amputation (Imbinto et al., 2016).

[1] (Passive - Limbs 4 Life, n.d.), (Hands — الطوف للمستلزمات الطبية و الأطراف الصناعية, n.d., (Young, 2023), (I-Limb Quantum | Prosthetic.com.sg, n.d.)

The passive articulating prostheses are passive articulating devices that have the main goal to sustain high loads to be able to resume manual work where carrying high loads is needed and restore the length of the amputated hand. This type of prostheses is considerably different from the silicone prostheses, since the appearance is more mechanical (Figure 23) (Graham et al., 2023).


Figure 22: silicone prosthesis((Mobilis, n.d.)


Figure 23: passive articulating prosthesis (Graham et al., 2023)

The second category is the body powered prostheses, see Figure 24. This type of prostheses restores the active hand motion by using the flexion and extension of the remaining joints. Using the strength of the user's body part, kinaesthetic and proprioceptive feedback is provided, giving the user coordination feedback. (Imbinto et al., 2016). This prosthesis is not powered by any external source, which offers several advantages over other prostheses, such as improved water resistance. The relatively low cost and lightweight nature of the prosthesis further contribute to its many benefits

However, the appearance of the body powered prostheses is more mechanical. But these prostheses can restore most functions since the movements are already familiar to the user. According to Graham et al. (2023), the bulk is a disadvantage of using these prostheses. Furthermore, the limited grip force and range of motion and discomfort from the harness is another drawback to using a body-powered prosthesis (Graham et al., 2023).

There are currently three options for placement of the harness of the body powered prostheses to generate movement. It is possible to have a shoulder-, wrist-, or finger driven device. Which place on the limb will be chosen depends on the amputation level (Imbinto et al., 2016).

The third category is the externally powered prostheses which restores the hand motion with use of external power.
The first subcategory is the myoelectric prostheses which uses the electromyography signals from the muscle contraction to make movements. This way, the nervous system controls the muscle activity and by that the contraction or extraction of the muscle (Reaz et al., 2006) (Graham et al., 2023). The motion of the hand is better then the other prostheses since the fingers can move independently and synchronously. However, this type needs an external power source to work, can not get wet, is expensive and it is not suitable for every high impact activity.

There is also a combined prosthesis available;


Figure 24: Body powered prosthesis (The London Prosthetic Centre, n.d.)


Figure 25: Activity specific prosthesis (The London Prosthetic Centre, n.d.-a)

the body-powered/myoelectric hybrid. This prosthesis combines both mechanisms by using the reactivity and specificity of a myoelectric prostheses and the robustness of the body-powered prostheses(Graham et al., 2023).

The last prostheses are the activity specific prostheses. This type is made for specific activities to help the user perform those activities, like sports. This prosthesis is for short term use, see Figure 25. (Graham et al., 2023).

An overview of the opportunities and limitations of each prosthesis is showed in Table 2.

	Passive functional	Body powered	External powered	Activity specific
Opportunities	• Push against objects and stabilize objects • Restore length • Accuracy of the prosthesis is really high	• Active hand motion • Not driven by any power source • Low cost • Light weight • Movements already familiar to user, intuitive	• Improved phantom limb pain is high • Fingers can move independently and synchronously	• For specific activities, not everyday use
Limitations	• Not able to have an active grasp and release	• Appearance is more mechanical • Limited grip force • Range of motion • Discomfort from the harness	• Use of external power • Can not get wet • Expensive • Not suitable for every high impact activity	• Short term use

Table 2: Overview opportunities and limitations of the different prosthetic types

2.4.3 Market References

Multiple hand and finger prostheses already exist on the market. For amputations around the MCP joint the options are limited. Some types of prostheses are widely available through rehabilitation centres, while other types are hardly possible to obtain. This results in the patient having limited options. Which is not something which should be limited since the rejection among prosthesis users is already high, between 16-58% for body powered prosthetics. This is due to the appearance, discomfort, pain, dissatisfaction about the receiver preparation and training (Huinink et al., 2016). Therefore, it is important to learn from other existing designs and identify the opportunities and limitations to make sure the new design will not be rejected by the user.
In this paragraph, a short research is done for the different available prostheses.

Main Question:

- What are the currently existing prostheses on the market and what are their opportunities and limitations?

Sub questions:

- What types of prosthetics already exist?
- What kind of movements do these prosthetics facilitate?
- What is the amount of force the prosthetic can give
- Which materials are used for hand prostheses?
- What is the price of the current used prosthetics
- What is the amount of weight of a prosthetic?
- What mechanisms are currently used to simulate movements?
- What are the pros and cons?
- What are the differences between the prosthetics on the market?

Brand: Pointdesigns
Name/type: Point digit prosthetic
Movement: Flexion, 11 finger positions
Control movement: Ratcheting mechanism
Material: Titanium and stainless steel
Socket needed: Yes
Weight: 30-36 g, depending on length
Force: 68 kg load capacity
Grip:
Price: €4600
Production: 3D printing, SLS (laser sintering)
Amputation level: MCP-joint
++: 6 standard lengths, 11 levels of flexion, fingertip pads that are touch screen compatible. Only prosthetic finger with anatomical rotation about the MCP-joint.
– : Not intuitive, the user has to position the finger into one of the 11 locking levels, only possible if the other hand is intact.

(Point Digit: Heavy-Duty Titanium Full Prosthetic Finger, n.d.)

Figure 26: Point Digit prosthetic (Point Digit, n.d.)

Figure 27: HeroGauntlet, (Hero Gauntlet - Open Bionics, 2024)

Brand: Open Bionics
Name/type: Hero Gauntlet
Movement: Flexion/extension
Control movement: Body driven by the wrist, Flex wrist the fingers close. Extends wrist, fingers open.
Material: High- tensile strength nylon 12 for the fingers, flexible thermoplastic polyurethane for the body. BOA dial to tighten the prosthetic
Socket needed: No
Weight: 300 gram
Force: 20 kg hook grip, 5 kg fingertip load
Grip:
Price: €15000
Production: Multi Jet Fusion (MJF) 3D printing
Amputation level: MCP-joint
++: Waterproof, not the whole hand palm is covered, colour of cover can be personalized.
– : Robot-like appearance

(Tisshaw, 2024)(Hero Gauntlet - Open Bionics, 2024)

Brand: Naked Prosthetics
Name/type: MCP driver
Movement: Flexion/extension and adduction/abduction
Control movement: Body-driven by an intact MCP joint with enough residuum distal to the joint.
Material: Silicone backplate, silicone tip, stainless steel linkages
Socket needed: No
Weight:
Force: 7-9 lb force each finger tip
Grip: Pinch, lateral, cylindrical and power grasp
Price: €12000
Production:
Amputation level: Proximal Phalanx (MCP-PIP joint)
++: Suspension rings can be changed to find the ideal fit
– : MCP joint needs to be intact with enough residuum to attach the prosthetic.

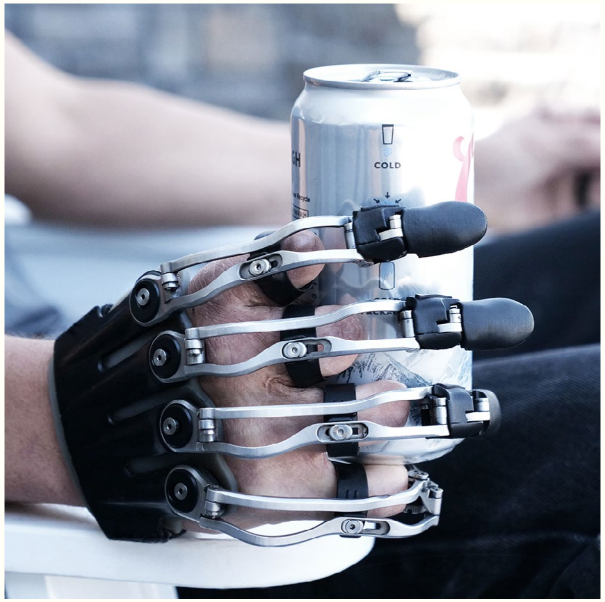


Figure 28: MCP driver (Naked Prosthetics, 2024)

Figure 29: PIP driver (Naked Prosthetics, 2024)

Brand: Naked Prosthetics
Name/type: PIPdriver
Movement: Flexion/extension
Control movement: Body driven by flexing the PIP joint
Material: Durable high-quality nylon, rubber tip pads, titanium fasteners
Socket needed: No
Weight:
Force:
Grip:
Price: €8500 per finger
Production: 3D printing
Amputation level: PIP-joint
++: Custom design, easy to do on/off and clean, cage-like structure protects residuum
– : Only for amputation at the middle of the Distal phalanx

(Naked Prosthetics, 2024)

Brand: Ottobock
Name/type: Silicone prosthetic
Movement: No movement
Control movement: No movement
Material: Silicone
Socked needed:
Weight:
Force:
Grip:
Price:
Production:
Amputation level: All amputations
++: Reproduce appearance to the smallest detail, unlimited possibilities for details, resistant to fresh water, salt water and UV radiation, simple maintenance, firm support,
– : No movement possible, not always possible for MCP-joint amputations.

(Ottobock, n.d.)

Figure 30: Silicone prosthetics (Ottobock, n.d.)

Currently, the point digits prostheses is the only option available for patients with a partial hand amputation near the MCP joint. Silicone prostheses are not always feasible to attach, and the HeroGauntlet by Openbionics is too expensive. Additionally, due to limited knowledge among insurers about the usability of such prostheses, these costs are often not covered. As a result, not every functional and intuitive prosthesis is possible to receive, as noted by T. Singer (personal communication, October 18, 2024).

Insurance coverage for these more intuitive prostheses is generally limited to cases resulting from personal injury. Consequently, some patients may be considered “functional” with only a silicone or point digits prosthesis, which might not align with their preferences. In some cases, patients are left without any viable solution.

Key insights

There is a need for an affordable and more functional prosthesis that is intuitive to use.

From the MCP joint there are not a lot of prostheses on the market.

Body powered prosthesis offers many advantages for the user.
This type of prosthesis are promising since it contains:
- Active hand motion
- Not driven by any power source
- Low cost
- Light weight
- Movements already familiar to user, intuitive

Therefore this type could be of added value.

Therefore, the focus will be on designing a Body powered prosthesis

2.4.4 Voluntary Opening and Voluntary Closing

Current prostheses have two primary mechanisms for operating: voluntary opening (VO) and voluntary closing (VC). In the VO system, the neutral position of the hand is closed. Activating the prosthesis opens the hand, and when no force is applied, the hand automatically returns to its neutral position and closes.

The VC system works in the opposite way. The neutral position of the hand is open, and the user applies force to close it (Berning et al., 2014).

Advantages of the VO system are that it is easy to operate, picking up small objects is the easiest with this system and it is very user friendly. However, VO systems have several limitations: the grip force is predefined and cannot be controlled by the user, there is no feedback of the movement and the gripping force is limited and dependent on the system's configuration (TRS Prosthetics, 2021).

Advantages of the VC system include the ability to have a controlled grip where the force can be dosed. Because of this, there is an existing feedback of the anatomical movement. Furthermore, the movement mimics the normal hand movement and therefore the reaction time is faster. However, maintaining the necessary force to hold an object can be tiring and ergonomically challenging for the user. Choosing this system would not be ideal without adding a clamping mechanism to maintain the hand's position without sustained effort (TRS Prosthetics, 2021).

The VC system is initially more difficult to design, but offers long-term benefits. The possibility for better feedback and control better suits the user's needs when functionality is considered. By adding a clamping system, the VC system can contribute to a more functional prosthesis that is better to use than a VO system. Moreover, to make a tripod and power grip, sufficient force must be applied and there is a chance that this cannot be done because the pre-generated force is too low

Therefore, the decision was made to integrate a VC system into the hand prosthetic.

Figure 31: Neutral positions of the VO and VC system

2.4.5 Measurable data

In order to know if the prosthesis is functional, it is important to understand what the requirements are. Especially the measurable data, as it will be tested later and will indicate whether performance is adequate.
Therefore it is defined how much force the finger should be able to transmit, what the activation force should be, how many degrees the finger should bend, how far the wrist should bend to control the finger and what the maximum weight should be of the prosthesis.

The amount of pinch force that the finger should be able to transmit is not a strict requirement. This is because the prostheses often do not need to achieve the same level of performance as the human hand to enable an amputee to complete most of their ADLs, according to Damerla et al. (2021). Furthermore, Damerala et al. (2021) explains that in several cases, lower capabilities are recommended, by clinicians and prosthesis designers, as acceptable performance for prostheses. A grasp strength that is as high as the biological hand may be unnecessary for completing ADLs and challenging to control without sensory feedback.
Therefore, comparing the maximum force with results from the human body is not always the ideal situation.

For this project there is chosen to focus on the power and tripod grip. For both grips, the amount of force that it will transmit is important to know.
For the tripod grip it is the best way to define the pinch force.
For the power grip, there should be defined what the grasping force is.

According to Smaby et al, (2004), the ADL tasks based on the SHAP did indicate a range of pinch force requirements, as can be seen in Figure 32. The pinch force requirements for the tasks span from 1.4 N (push remote button) to 31.4 N (insert plug-under the most slippery condition).
Smaby et al, (2004) is concluding this with stating that all the tasks except inserting and removing the plug and closing the large horizontal zipper require a maximum pinch force of 10.4 N or less. Therefore, the requirement that the finger should be able to generate at least a pinch force of **10.4 N**.

For the power grip, the overall force is distributed over several places of the finger. Thus, this requirement is different than the pinch force when the force is located at a specific area of the finger.
Kargov et al. (2004) describes a test that was done where they measured the average forces at the finger tips during sub-maximal static grasping, the results can be seen in Figure 33.
An outcome from this test shows that index finger needs an average force between 1-3 N during grasping. The index finger contributes the most with the highest force. The conclusion is therefore that a minimum force of **1 N** should be generated.

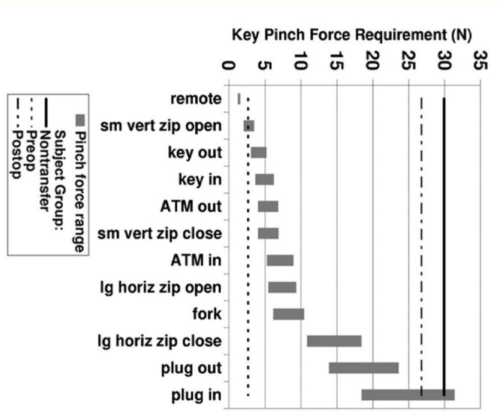


Figure 32: Pinch force requirements (Smaby et al, 2004)

Finger	*This study* d = 57 mm m = 522 g	*de Castro 00* d = 50 mm, m = 400 – 600 g
Thumb	1.3 N	2.8 – 4.5 N
Index	1.0 N	1.8 – 3 N
Middle	0.9 N	1.8 – 3 N
Ring	0.8 N	nn
Small	0.4 N	nn

d = grip diameter, m = weight of object.

Figure 33: Grasping force (Kargov et al. 2004)

The activation force defines how much force is needed to have a maximum pinch force. According to Trejo-Letechipia et al. (2021), to avoid fatigue, the activation force should be below 38 N for the average female and 66 N for the average male. Concluded from this should the activation force not be higher than **38 N**.

When using the hand, it also required to be able to use the finger in extended position to push a button for example. According to Force Guidelines, (2013), the maximum push button force is 3lbs, which is around 13 N. According to Rahman et al. (1998) the guidelines for push-buttons switches are between **3-6N**. Therefore, the minimum push force that the finger should withstand is 6N.

The transmission ratio is the relation between the activation force, how much force is needed to bend the finger and the output force, the pinch force. Tousi (2011) stated that the calculated force transmission ratio of approximately 0.5 is nearly equal to the best performing VC prosthesis. Therefore the transmission ratio should not be higher than **0.5**.

According to Smit (2013) the prosthetic hand should not weight more than 273 g, to be comfortable to wear it. He stated that ''Mechanism and glove should weigh less than a human hand (426 ± 63 g [23]), as the hand is not directly attached to the musculoskeletal system of the user and is therefore perceived as an external load. The requirement for the maximum weight of the prosthesis is **273 g.**

Data that was collected from Stanley, B. G., & Tribuzi, S. M. (1992) which explained that the normal flexion range of the wrist is 0°-60°. This means that the flexion when activating the prosthesis from the wrist is not allowed to be higher than **60°**.

The fingers also have a total active motion (TAM), where the standard maximum flexion of the MCP is 85°, PIP is 110° and DIP is 65°. The TAM is 260°.
This means that the finger should not exceed a TAM of **260°** when the goal is to have the same anatomical range off motions. However, this is also task dependent and for a power and tripod grip is not the full TAM needed .
Arauz et al. (2016) stated that the PIP joint at 40-50° flexion facilitates grip strength and leads to more natural precision pinch postures. Their research aimed to determine the optimal arthrodesis angles for fixing the PIP joint during surgery. Fixing the PIP joint at 40-50° resulted in the most natural precision pinch. Therefore, it can be concluded that the minimum flexion angle the finger should achieve is between **40-50°**.

Key insights

VO system: the neutral position of the hand is closed.

VC system: The neutral position of the hand is open

For the design will be focused on the VC system

Measurable data:
Min. Pinch force of **10.4 N**
Min. Power force of **1 N**
Max. Activation force of **38 N**
Min. Push force is 6N
Angle finger range of **40-50°**
Angle wrist rang of **0°-60°**
Transmission ratio **<0.5**

Weight of maximum **273 g**

2.5 Field research

Due to the medically sensitive subject matter, there is limited ability to test and communicate with the user. However, it is very important to understand the challenges of the user. An interview with an occupational therapist was executed since they are guiding the patients through the rehabilitation process and are able to guide the prosthetic user throughout different obstacles of prosthetic use. Additionally, I've joined a prostheses fitting appointment of a patient who has a partial hand amputation. By observing and taking notes, some relevant insights were obtained. This paragraph explains the key outcomes from this qualitative research. In Appendix C, the whole interview and insights of the observation can be found.

2.5.1 Insights interview occupational therapist

Methodology

An interview was done with one occupational therapist from the MRC in Doorn. The questions were beforehand prepared and discussed.

Results

Use

- Users go through a mental acceptance process before they can use a prosthesis effectively.
- First discover how much they can do without a prosthesis before determining whether they need one.
- Using a prosthesis too early often leads to disappointment and non-use.
- Over time, some users stop wearing their prosthesis. Benefits do not outweigh the limitations (if the hand is completely wrapped up, for example). User is more agile without a prosthesis than with.

Functionality

- Many prostheses are not perceived as functional enough due to limited fitting, lack of sensitivity feedback and complexity.
- Not a lot of MCP prostheses that are functional, causing some users not wear them.
- The more intuitive a prosthesis is, the faster it will be accepted and used.
- Body-powered prostheses are often more intuitive and less fragile than myo-electric options.
- A functional prosthesis should have a firm grip and a good balance between strength and smoothness.
- A functional power grip is essential. When the dominant hand is amputated, the need for a tripod grip is higher.
- Users are not looking for a replacement hand, but an aid to better grasp or fixate something.
- The length of the fingers should be compatible with the thumb and the other hand. Sizing system for that.

Current limitations

- MCP prostheses often require complete encasing of the hand, which reduces sensation.
- Existing prosthesis options are often too expensive or incompatible and is therefore always declined by insurances.
- Health insurance does not always reimburse test phases or complex solutions which makes it hard to know which prosthesis is the best for the user.
- The dominant hand is always missed with amputation, and the impact is greater than with the non-dominant hand.
- Bilateral amputation patients often have frustrations when using prostheses, especially with passive and point-digit solutions since it is not intuitive.

Specifications

- Users often have to choose between an attractive or functional prosthesis.
- Younger users sometimes like an eye-catching prosthesis, while older people are more likely to opt for a realistic look.
- Military users prefer functionality.
- Metal is more robust but heavier, plastic is lighter but more fragile.
- Cleanability, colour, water and dust resistance play a role in the choice and is of value for the user
- Cost and efficiency are crucial to the success of a new product.

User

- Many users have unrealistic expectations due to media and high-tech examples.
- A prosthesis will never provide the same function and intuitive control as a real hand.
- The pre-prosthetic process is crucial to properly prepare users and emphasise independence without a prosthesis.
- The more intuitive the prosthesis is, the higher the chance that the user will choose that prosthesis.

2.5.2 Observation patient

Methodology

An observation was done with a patient at the MRC in Doorn, who was fitted with a prosthesis. Due to the sensitive subject, it was only possible to take notes and observe. Below the results are listed.

Results

Patient observation

- The liner is easy to put on, but the tube is perceived as less comfortable.
- Patient X actively seeks a tripod grip and possibly sees this as the most important feature.

Conclusions

- The more intensively a prosthesis is used, the more fragile it is.
- Depending on whether the prosthesis is supportive or used for full functionality.
- In case of damage, the prosthesis is sent and the user is given a loaner hand.
- Depending on where the patient is living, how easy it is to repair. In a country abroad this means that it would be possible to replace an axle but not all parts.
- Faster and simpler adjustments, such as finger position, would be desirable.
- What the user wants to do with it determines which prosthesis is suitable.
- An intuitive and functional grip is essential.

Figure 34:
Context of work environment

2.6 User

The Militair Revalidatiecentrum is a rehabilitation centre in first place for people from the military. Therefore, before this project started the target group was already set. The target group will be soldiers who had a partial hand amputation around the MCP joint.
These soldiers incurs this trauma most of the times due to blasts when they are on a mission. The aim of this project is not to send them back into another mission since it is not realistic that they can perform the same tasks again. But making it possible to have an office job within the army, which requires ADL tasks, would be a realistic goal.

This user group is estimated between the age of 18, the age when you can start with the training, until 62, the retirement age within the Dutch army. The intended users all work at the army, in the Netherlands or other foreign armed forces linked to the Dutch armed forces. It often happens that the user is from a different country and is being treated at the MRC in Doorn. After this treatment, some of the patients eventually return back to their home country. Most of the time the prosthesis can be fitted and distributed in The Netherlands before they return. In that case, repairs do currently have to be done in the Netherlands. Still, it would be more ideal if they could repair it themselves by producing spare parts locally. Within this criteria, the user is not specified by a particular gender.

This user has values that are congenital or acquired by the army. They are described as having courage, sense of duty, respect, comradeship, loyalty, integrity, selfless commitment and excellence. (Vandenberghe & Peggy Bogaert, n.d.). On the orange part of this page, the competences expected of a soldier are listed (Militair | Carrièretijger, n.d.). These are the competences that can be expected of a soldier and is something that every person in the army is trained to develop.

These users with these values and mindset, are used to handling difficult situations and are always seeking for solutions. Most of these cases will be seeking for a functional solution with less focus on the aesthetic appearance of the product(Conversation T. Singer).

Competences

- Collaborate
- Flexibility
- Stress resistance
- Discipline
- Perseverance
- Decisiveness
- Integrity
- Planning and organising
- Handling conflicts
- Self-knowledge
- Good physical condition

Value

- Courage
- Sense of duty
- Respect
- Comradeship
- Loyalty
- Integrity
- Selfless commitment
- Excellence

Figure 35: Persona

2.7 Rehabilitation

The rehabilitation of the patient is an important part of the recovering process where the patient among other things learns how to use a prosthesis. This chapter explains where in the process the prosthesis will be used and also what is important for a patient during rehabilitation.

2.7.1 Research question

Main Question:
- What is the rehabilitation process for the patient after partial hand amputation?

Sub questions:
- What is important for the patient during rehabilitation?
- When will there be trained with the prosthesis?
- How will the functionality of the prosthesis be tested?
- What are the current obstacles?

Naturally, getting a prosthesis is not happening directly after the amputation. A whole process is done and it is important to be aware of the steps prior to the production of a prosthesis. This way, it becomes clear who is involved and if there are certain circumstances to take into account.
Most of the time, no amputation plan could be discussed with the patient before the amputation. This is because, in most cases, the amputation is caused by a trauma and is therefore not planned.
When the trauma occurs, an amputation is performed immediately to stabilize the patient and prevent further complications.

After the amputation, almost right away the pre-prosthesis phase starts which will approximately take 8 weeks.
The first step is mostly about wound care and is focused on the mobility.
The goal is to enhance the patient's mobility, help them adapt to the new situation, and encourage them to use the amputated hand as much as possible. This enables them to identify obstacles faced without a prosthesis and finding suitable solutions. Aiming to ensure that the independence without a prosthesis is already high.
During this phase, a psychologist, hand therapist, occupational therapist, rehabilitation physician and sometimes social worker will be involved.
After this phase a prosthetic consultation will take place. Here the expectations of the patient will be discussed and a plan of action will be defined. In the Netherlands this means that the patient will start with the stepped care; the patient starts with the most general prosthesis to try. If this step is skipped, the chances are high that the more expensive and advanced prosthesis will be rejected by patient and insurance. A D-quest questionnaire will be filled in for every prosthesis to reflect on

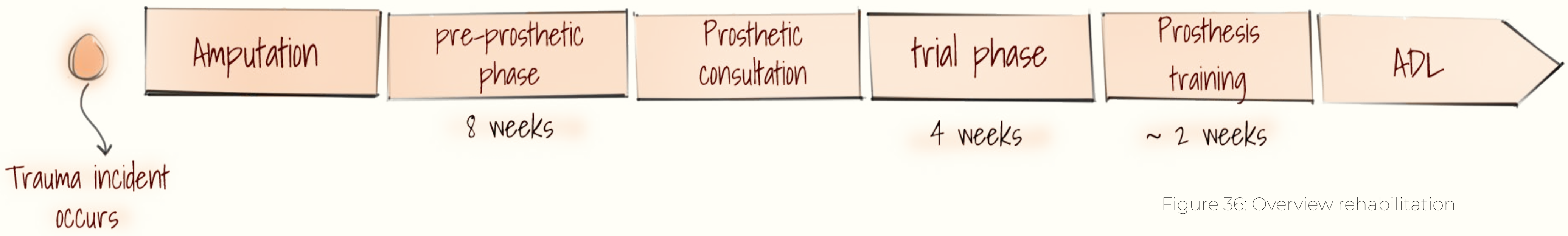


Figure 36: Overview rehabilitation

the comfort and functionality and compare them with each other, see Appendix B for this questionnaire.

Then the trial phase starts which will take approximately 4 weeks. For the amputation around the MCP-joint, this trial phase is not always possible. Creating a prosthesis to test is not always insured and therefore costly since the prosthetic fingers in combination with the socket can be quite expensive.

After the trial fitting of possible solutions on the patient the prosthesis which was deemed most suitable will be submitted to the insurance company for approval. While doing so information from the rehabilitation physician, occupational therapist, prosthetic consultant, will be provided to support the prescribed prosthesis.

While waiting, the training phase will be planned. Not every prostheses requires training, like cosmetic finger prosthesis. This type of prostheses is very intuitive and no training is needed. The same applies for body powered prostheses, which requires limited training. A point digit prosthetic will probably need some training since this type of prosthetic is less intuitive. (T. Singer, personal communication, October 18 2024)

Key insights

The partial hand amputation is in almost every case caused by a trauma and not planned.

The intuitiveness of the prosthesis has a lot of influence on the amount of training that is needed. More intuitive means less training.

The trial phase for a prosthesis is not always possible due to the cost.

2.8 Stakeholders

This chapter shows a compact overview of the stakeholders that are connected to the patient. This overview shows which parties are important to take into account and understand the relation of people/organizations and the patient.

2.8.1 Research question

Main Question:
- Which stakeholders play a role for the patient and are therefore connected to it

Within the stakeholder overview, four different categories of stakeholder relationships were defined. At the centre is the user. The stakeholder categories are colour-coded: green represents social relationships, yellow indicates distributors, blue corresponds to supportive foundations, and pink represents the healthcare network surrounding the user. These categories are placed within the circles that represents different types of stakeholders. The inner circle represents the core stakeholders, the second circle includes the direct stakeholders and the outer circle consists the indirect stakeholders.

Patient:
Central in this overview is naturally the patient, the end user of the prosthetic.

Social
People who are in a social context close to the patient are important stakeholders for the user to take into account. This can be family, friends but also colleagues. Since these people are close or within the social environment of the user, this influences the comfort of the user. Loved ones may feel the need to assist the person with an amputation, while the user may also feel motivated to return to their previous work within their home and work environment.

Supportive foundations
Some foundations bring people in similar situations together. The KorterMaarkrachtig Foundation focuses on connecting individuals with amputations and providing them with information (KorterMaarKrachtig, n.d.). Furthermore, the ProtheseAcademie collaborates with various parties to develop solutions for prosthetic-related challenges. By doing this, they improve their knowledge about the use of arm- and leg prosthesis and help users with these prostheses. (De ProtheseAcademie, n.d.)

Healthcare
The patient has a lot of contact with different stakeholders within the healthcare. Which kind of specialist is important, depends on the patient but also the phase of the rehabilitation. This can shift during the rehabilitation process and changes over time.

Distributor
For the development of prostheses, some distributors need to be taken into account. This can be an organization or company that distributes prostheses, with a focus on supporting the rehabilitation of the patient. They have an huge contribution when producing a prosthesis.

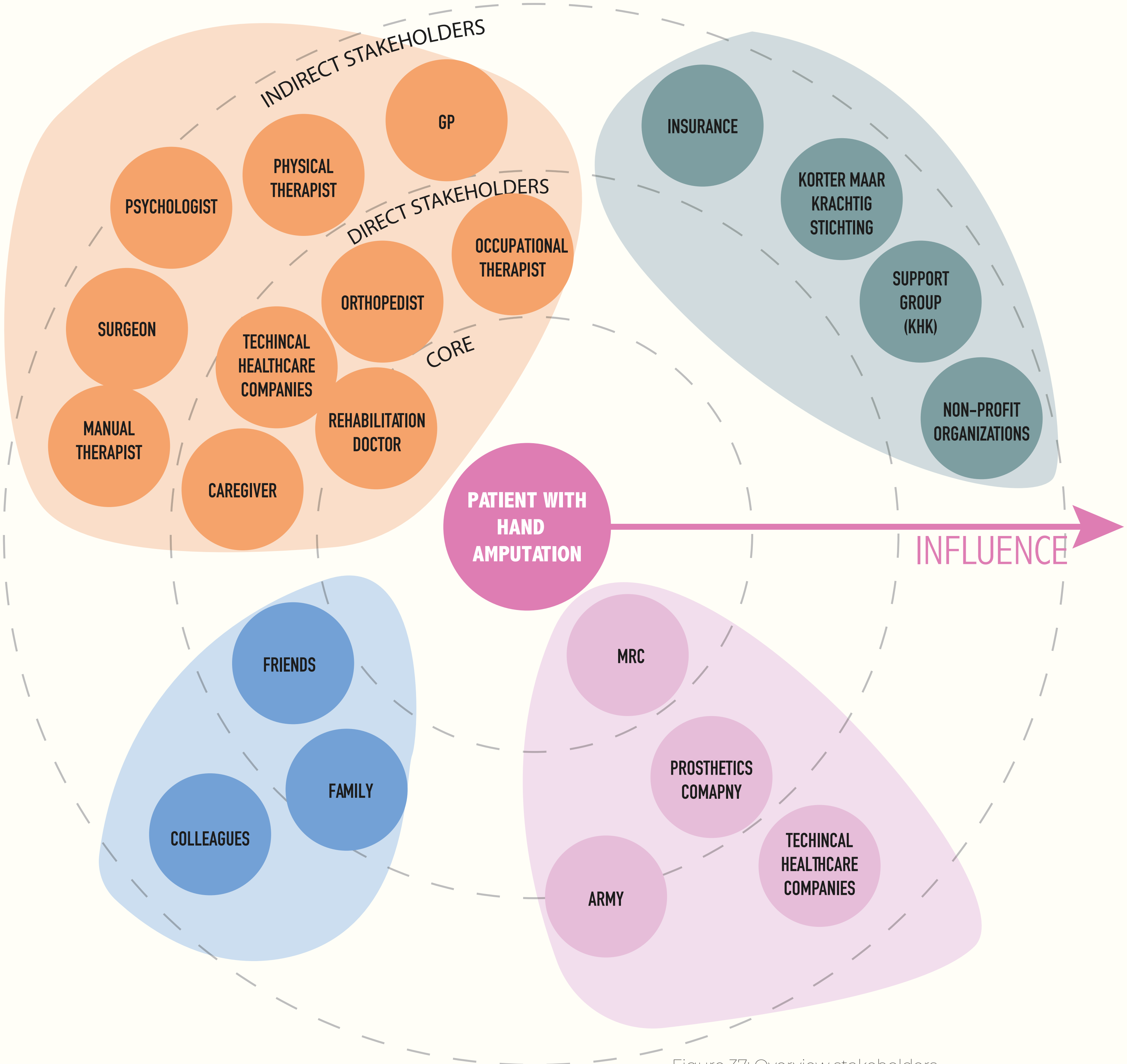


Figure 37: Overview stakeholders

2.9 Research conclusions

The research that is done, created the preconditions for the product to be designed.
Therefore, all these insights are combined here in an overview, so that this can be applied in the next phase.

The intuitiveness of the prosthesis has a lot of influence on the use and the ease with which the user can learn to use it.
This is important to have a high acceptance level of the prosthesis and stimulates the user to continue wearing the prosthesis. Therefore the prosthesis should be **intuitive** for the user. This is the case for the body powered prosthesis. Besides that, the cost is low and the weight is in general light. Since this is of added value, the focus will be on designing a **body powered prosthesis.**

There are different amputation levels, but there is chosen to focus on the amputation level from the **MCP joint.** The impact is high since none of the SHAP grasps are possible and there are not a lot of functional options for prosthesis for this level of amputation that are affordable. This increases the need for a prosthesis from this level.

The aim is that soldiers can **participate in ADL**. These activities are related to an office job and does not aim to allow them to return to missions.
To reach this goal, the focus will be on the **Tripod and Power** grips since these grips have a high contribution to the ADL activities. To be able to perform these grips, restoring the function for the **index and middle finger** by enabling them to **flex and extend** is the most important.
The thumb is not included in the design, due to the anatomical and functional differences.

Every amputation is different and every size of the limbs are different. There is a strong variation in sizes and due to the trauma, the amputation depends on the trauma damage and therefore varies greatly. No amputation is the same.
Therefore it is needed that the prosthesis is either **custom made, is flexible or is a customizable design** without increasing the price.

A few times, the user is from a different country and returns back with their obtained prosthesis. In case it breaks, they have to send back their prosthesis, resulting in waiting without their well fitting prosthesis until it is send back.
To avoid this situation, spare parts should be able to be **produced on site** to avoid long waiting times for repairs.

Lastly, for soldiers it is most important to restore the function instead of the appearance. Therefore the **function comes before the design.**

This research helped specifying the design goal and problem definition, which can be read on the next page.

Problem definition

Soldiers with a partial hand amputation from the **MCP joint** experience a shortage of **functional, affordable** prostheses that can mimic the grips essential for ADL. Available body-powered prostheses are often **expensive,** have long **production times,** are difficult to **fit** with the user and are hard to **repair**. There is a need for a prosthesis that is both **cost-effective** and **functional**, without causing the user being less functional than having no prosthesis at all

Leading to

Design goal

My goal is to **design** an **affordable body-powered** hand prosthesis for soldiers to restore the **functionality** of the hand after a partial hand amputation and which will enable the user to perform **ADL** tasks.

2.10 Design Scope

The scope outlines the focus areas of this design and is visualised in Figure 38. The conclusions from the research that was done, led to the design scope.
Starting with the user, this project is centred on soldiers who have been affected by a hand trauma. While the design could eventually be extended to non-soldiers, the initial focus is on soldiers, as they represent a primary driver of demand for this product.

This project is focused on designing an affordable prosthesis that is powered by the body itself, to contribute to the intuitiveness and therefore ease of use of the user.
The aim is to focus on restoring the functionality of the hand of the soldier, instead of restoring the finger. By doing so, the approach becomes slightly different, ensuring that the prosthesis serves as a functional supplement rather than a non-functional addition.

The prosthesis concept is only focused on the flexion and extension movement of the fingers and the abduction and adduction of the fingers is out of scope. Assumed for this concept will be that the thumb is still present on the hand. Additionally, the prosthesis is determined to have a VC system and will therefore have a open position when the prosthesis is not under tension.

The aim is to end up with a prosthesis that contributes to the autonomy of the user. By doing that, the soldier will have the idea that they can participate and continue with their life, with limited limitations. This will stimulate the soldier to contribute in ADL which will have a positive effect on their well being.

The scope explains the intended direction for the concepts. However, this does not exclude other directions.

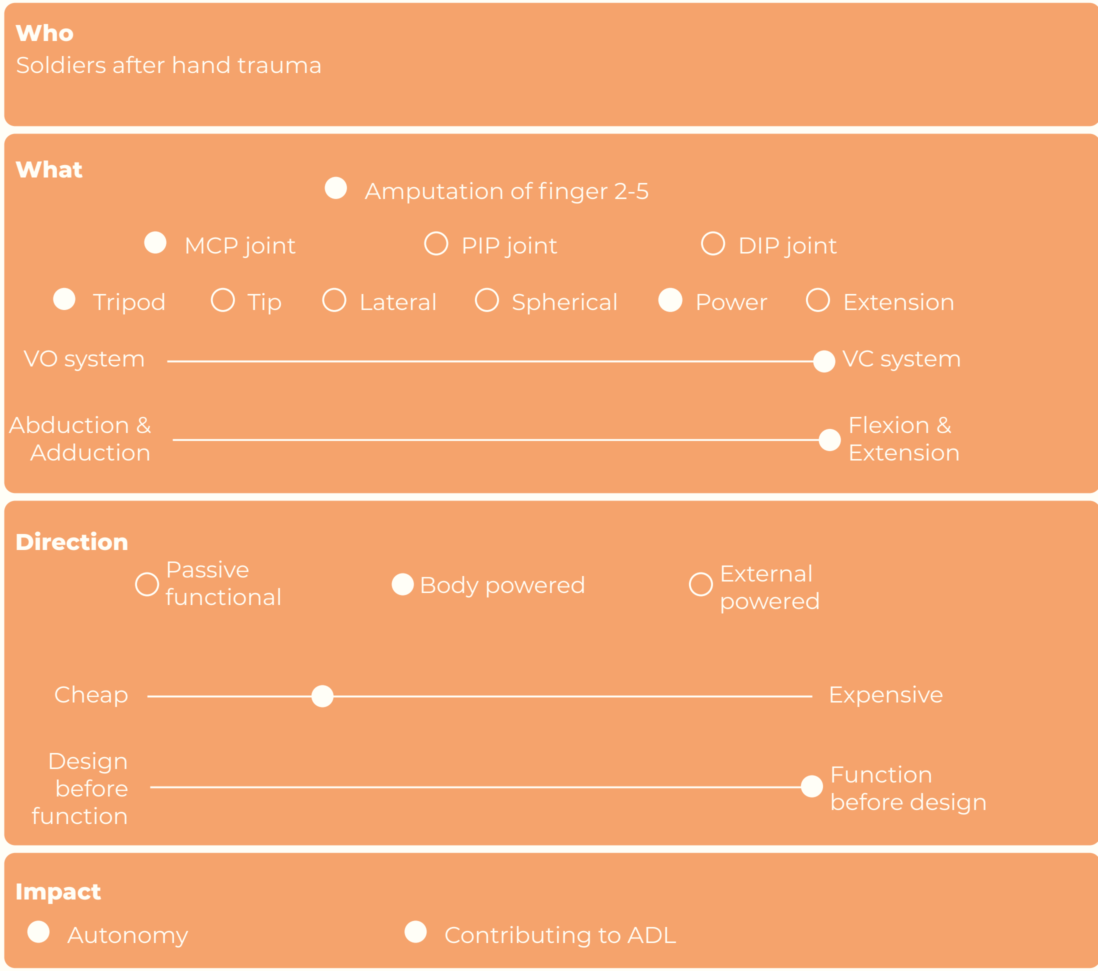


Figure 38: Overview Scope

2.11 Prerequisites from insights

From the research that had been done, a number of preconditions emerged, which the design has to meet. This should be taken to the next phase in which this condition will have to be met. These prerequisites are listed below.

- Ambition from OTA is to utilize 3D printing.
- The prosthesis must support both a tripod and power grip.
- The user should be able to bend the finger without applying excessive force.
- The prosthesis must not be fragile.
- The palm must remain uncovered for sensory feedback.
- Th prosthesis should be ergonomic and not cause skin damage.
- The prosthesis should appear as a single unit, not as separate parts.
- The prosthesis has to be produced quickly and efficiently.
- There should be no long wait times for production.
- The production process has to be cost-effective.
- The prosthesis should be easy to tailor to individual needs.
- The prosthesis must not be too bulky or robust.
- The prosthesis should be attachable with one hand.
- A one-size-fits-all solution is not acceptable, as every amputation is different.
- The costs should remain as low as possible.
- The prosthesis should be shareable across different locations.
- Design freedom should allow for customization in both appearance and functionality.
- The prosthesis should be useful in various situations.
- The prosthesis should feel comfortable and natural during use.
- The prosthesis has to be quickly and efficiently manufactured.
- The production process has to remain inexpensive.
- The product will be a medical product.

2.12 Opportunities & Limitations

This project offers an opportunity to explore a new direction in prosthetic design, focusing on affordability, personalisation and integration with orthopaedic specialisation. Such an approach could improve the rehabilitation process for soldiers after trauma, making it easier for them to perform ADLs again. While there is already extensive research on body-powered prostheses and existing products, this project offers a chance to bring a fresh perspective and integrate identified improvements to create a functional prosthesis that fits to this specific target group.

The need for this prosthesis is even more relevant due to ongoing global conflicts, which result in increased hand trauma. As a result, the demand for affordable prostheses that can be produced quickly is significantly higher, providing an opportunity for innovative impact in the medical field.

However, there are certain limitations that should be considered. The target group is difficult to test with due to the medical circumstances, which limits the research and testing opportunities to improve the user experience.

Moreover, the expertise at MRC is a specialist subject and not an expertise taught to Industrial Designer Engineers. It will be a challenge to integrate both expertises in such a way that MRC can move forward with the final product.

Given the short time frame of this project, it is to a certain degree possible to evaluate the user experience when wearing the prosthesis. However, determining the long-term effects, such as whether the user experiences an improved quality of life and wears the prosthesis more consistently than in previous studies, is challenging.

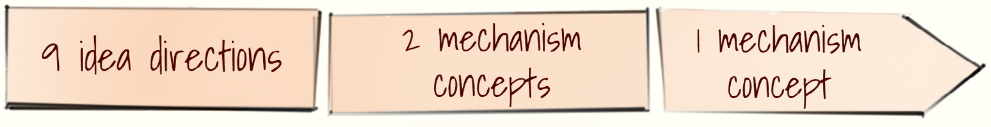
Lastly, each amputation is unique. Not everyone has the same number of fingers amputated or the same amputation level, making it difficult to design a one-size-fits-all prosthesis. Since this product has to be produced without the ongoing involvement of an Industrial Design Engineer, this will create a challenge when designing the hand component.

3 Concepting

3.1 Approach

Several steps preceded the development of the concept. Since the prosthesis consists of multiple parts, each with its own function, a function analysis was made. The outcomes of this analysis were used to break down the different aspects of the product, which then led to “How To's” and mind map brainstorming session.

The results from this phase were included into the morphological chart, where multiple potential solutions were identified. This process led to two possible mechanism directions, which were prototyped and evaluated. After selecting one mechanism direction, the first prototype was created to evaluate the idea and improve it during the embodiment phase.



3.2 Requirements

The research that was done defined requirements that needs to be integrated in the design. These requirements are measurable data what can be referred to during the next phase when testing and evaluating the concept.
The most important requirements for this phase are listed below. The complete list can be found in appendix H.

General requirements

- The minimum pinch force is 10.4 N
- The maximum activation force is 38 N
- The minimum push force is 6N
- The angle wrist range is between 0° and 60°
- The prosthesis is able to make a tripod and power grip
- The weight of the prosthesis is lower than 273g
- The prosthesis should work with a VC system
- The prosthesis should contain as little parts as possible to avoid damage

Material requirements

- The material should not cause reactions with the skin
- The material has to be able to withstand wear and forces applied to it
- A prosthesis should be as light as possible to improve comfort and minimise stress on surrounding tissues.
- The material should be easily shaped or adjusted to fit the user's specific anatomy and needs.
- The material should be easy to clean and not attract
- The material must be humidity and temperature resistant bacteria
- The cost of the material has to be low

3.3 Production technique

Before the concept phase begins, the production method is already determined. Due to various considerations, 3D printing is a preferred technique to use.
Because this will have an influence on the ideas that are possible and because of preferences from the OTA this was already clear and therefore best to determine before the concepting phase started.

3D printing is chosen in advance when determining the production technique because of the following advantages:

- 3D printing allows parts to be produced quickly and at low cost. This reduces both development time and production costs which are one of the main requirements and goals for this product.

- Print files can be easily shared with other foreign armed forces that is collaborated with, allowing prosthesis or parts to be printed locally. This eliminates the need to ship from the Netherlands and reduces waiting times here at location.

- When a part fails, it can be printed and replaced directly on site. This avoids delays due to production or delivery.

- 3D printing makes it easy to customise prosthesis and parts to individual needs, without additional production costs or time.

- Different materials can be used depending on specific requirements such as flexibility, strength or weight. This offers additional design freedom and optimisation which is at this phase preferred but may also offer opportunities for the future.

- OTA wants to expand its production capacity with 3D printing technology and has expressed a preference for this. Through this choice, the production method is in line the future development of products at OTA.

With all these advantages of using 3D printing, this ensures that this is a considered and the proper decision.

3.4 Design direction

3.4.1 Function analysis

Before starting with the generation of ideas, a function analysis was done. Since the initial product has a lot of different aspects, this will help to create an overview. By doing this, coming up with ideas can be divided into phases which eventually makes it easier to zoom in on each feature. The function analysis is visible in Figure 39 and was defined by analysing every part of the prosthesis and clustering those elements. The main function is defined as;
Replacing grip function and basic functionality of a human hand.
This will eventually be the final goal to achieve with this project. The three main sub functions are:

- Transferring force from body to prosthesis
- Moving fingers
- Attaching the prosthesis

3.4.2 Idea generation

After creating the function analysis, an idea generation phase was started. This phase began with using the HOW TO" method regarding the sub-functions, which were brainstormed in a mind map to provide an overview of the possibilities. This was followed by a brain dump, collage, and creative exploration. By doing this, multiple mechanism solutions were defined for each sub function. These solutions were used for the next step in the morphological chart.
The details of this process can be found in Appendix E-F).

During the brainstorming phase, two options emerged for transferring force from the body to the prosthesis. The two potential sources of movement to transfer force were the thumb and wrist. A decision was made based on several input directions (see figure 40). It was chosen to focus on using the wrist to transfer force to the prosthesis.

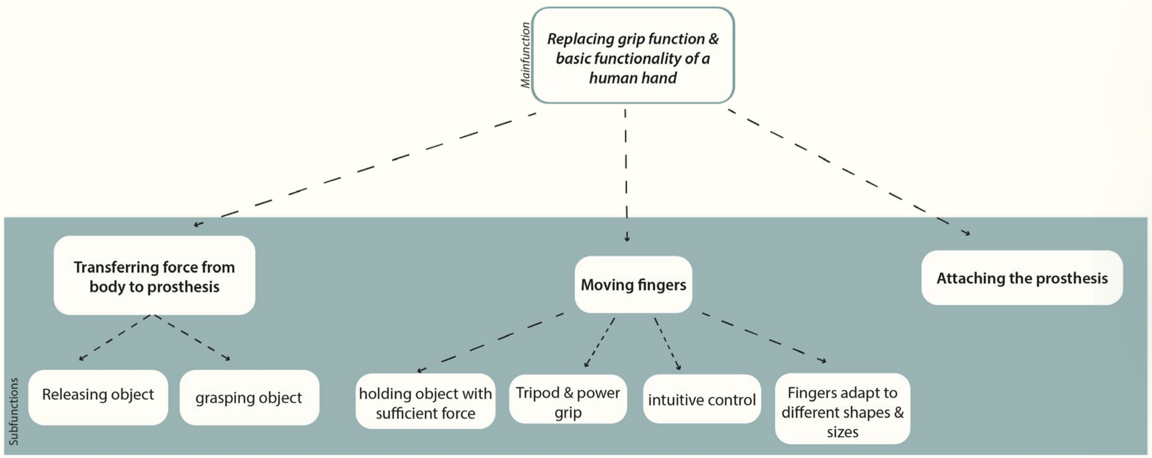


Figure 39: Function analysis

Figure 40: Overview decision location of control movement

3.4.1 Morphological chart

To enable the mechanism of a body-powered prosthesis, two sub-functions are crucial:

- Transferring force from body
- Moving fingers

The mechanism of a body-powered hand prosthesis is based on the actuator of the force, the translation to the finger and bending the finger. That is why the two mentioned sub-functions were used in the morphological chart, instead of using many columns and rows.
Solutions for each sub-functions were generated during the brainstorming phase which is presented in the morphological chart. Every solution supports a mechanism that could be integrated. In the morphological chart, these mechanism ideas were combined, resulting in nine possible combinations. These served as the initial design directions for further development and can be seen in Figure 41.

The identified combinations were:

- **String + Structures**
- **String + Soft materials**
- **Pneumatic pressure + Soft materials**
- **String + Hinges**
- **String + Spring**
- **Spring + Fixed shape**
- **Hinges + Structures**
- **Hinges + Fixed shape**
- **Hinges + Hinges**

Creating this morphological chart encourages thinking about combinations that may not have been considered initially.
All these options were evaluated, and a decision was made based on logical reasoning. Since the result is not a concept, it is challenging to apply a specific method for evaluation and decision-making.

- **Pneumatic pressure + Soft materials**

The pneumatic pressure is a promising mechanism that could be of relevance in the future. However, currently the technique is not developed enough yet. It would not be possible to generate enough air displacement without an external air pressure machine. Therefore, this will not be an option.

- **String + Spring**

Adding a spring with a string mechanism could work, but spring fatigue is something that needs to be taken into account. Using the spring as a finger is not stable and could deform over time. This is not preferred and therefore not a good idea direction to choose.

- **Hinges + Fixed shape & Spring + Fixed shape**

Using a fixed shape could be something to include in the design since it is not always necessary to mimic every finger joint to rotate the finger part. However, since the tripod grip is one the requirement of the prosthetic hand, bending the finger is necessary. Therefore, this finger principle will not be chosen.

- **Hinges + Hinges**

The hinges + hinges combination is not an odd idea. Using hinges from the wrist to power the hinges in the finger. The downside of adding too many hinges, it that the product becomes more fragile. As explained by the occupational therapist, that is something that needs to be avoided. Therefore, this design direction is not the best option.

- **String + Structures & Hinges + Structures**

After a conversation with R. Raedlli, it became clear the integrating structures as a concept is not the best way to design. The best approach is to start with a functioning mechanism and then work on redesigning it into a compliant mechanism structure. This is therefore not a good direction to choose but it is something to keep in mind which could be integrated later on.

Using a string to pull on hinges could provide a stable and efficient way to transfer force. Since not all parts of the mechanism rely on hinges, this design would have fewer hinge connections, making it less fragile. This could be a promising direction for further exploration.

- **String + Soft materials**

Using soft materials, as seen in soft robotics, but applying them in a different way could be an interesting approach. In soft robotics, the actuators are electronic, but this could be replaced with a string mechanism. The compliant mechanism structure could also be integrated into this design. The softness of the material allows it to form better around objects, which could add significant value to the prosthesis, improving its functionality and user experience.

The only promising mechanism directions are the **String + hinges** and the **String + Soft material**. Other directions might be promising in the future or are too limited. Therefore there is chosen to continue and explore the possibilities of the last two combinations.

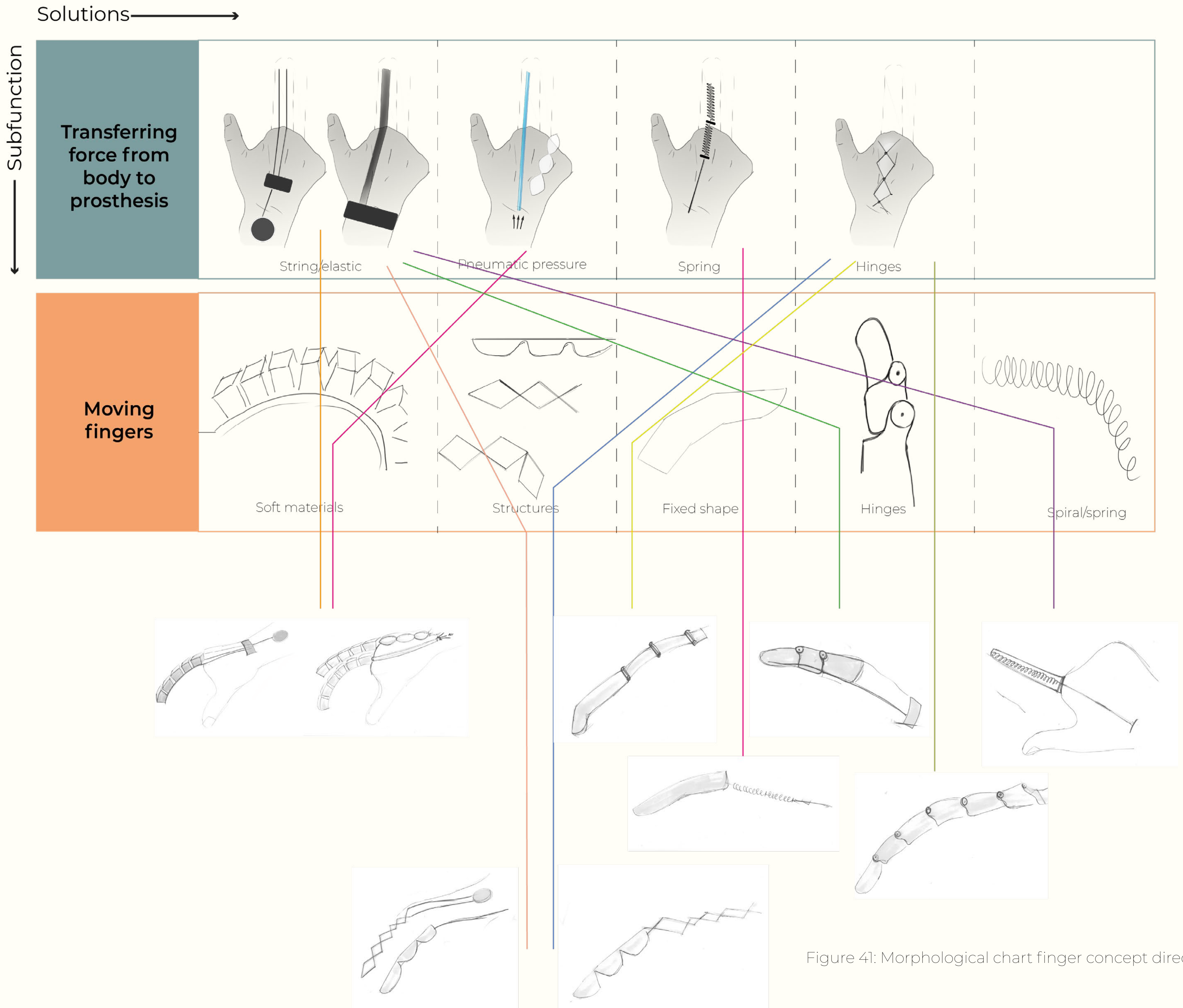


Figure 41: Morphological chart finger concept directions

3.5 Mechanism concepts

3.5.1 Mechanism direction one

The first concept direction is based on a result from the morphological chart. It focuses on a string to transfer force from the wrist to the finger, which can bend due to the use of soft materials such as TPU or silicone.

The strength of this mechanism lies in the absence of hinges and screws to connect the 'finger.' Additionally, it is flexible and can be easily adjusted. The soft material would allow the finger to bend and, when the body exerts force, it becomes a compact, rigid structure that gains strength. This results in a finger with significant freedom of movement.

However, a potential downside of this design is that the finger's flexibility may cause it to lack the necessary rigidity to pick up objects, as this requires a certain amount of strength. Therefore, such a design could limit its ability to handle heavier tasks.

3.5.2 Mechanism direction two

This idea direction utilizes a string to transfer force through a finger, which exists out of two parts connected by a hinge. The middle of the finger is connected by a flexible hinge, allowing it to bend, while the finger itself is constructed from a strong material like PLA. The hinge is made from TPU material, which is adding flexibility to the hinges.

This idea direction mimics the appearance of a natural finger and is very strong. There are not a lot of parts of this mechanism, although assembly is still required. However, the increase in components may make the product more prone to damage, as the overall fragility of the mechanism increases with more parts.

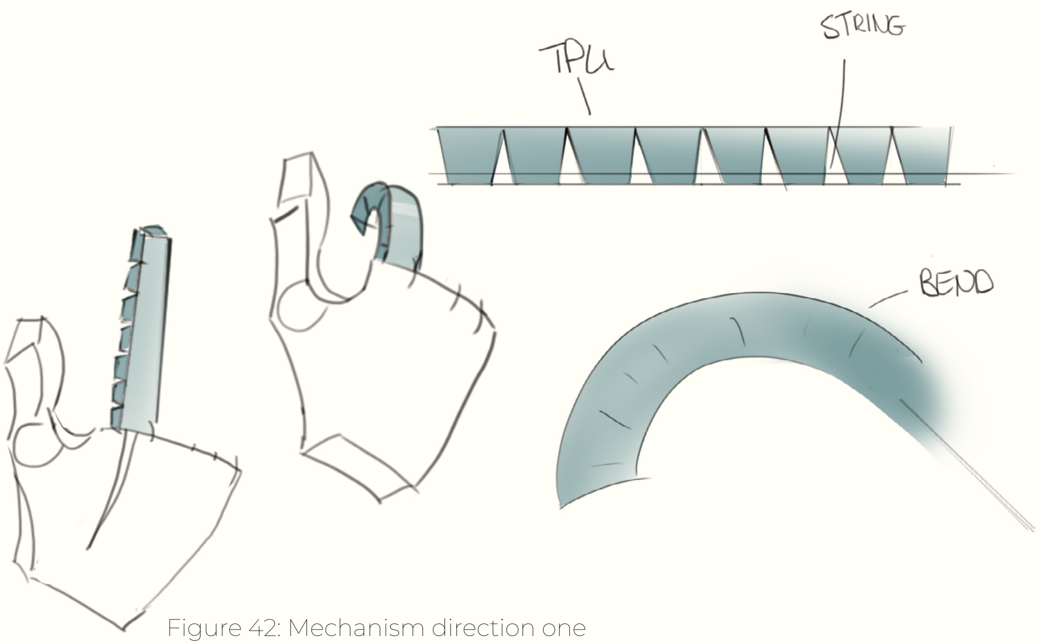


Figure 42: Mechanism direction one

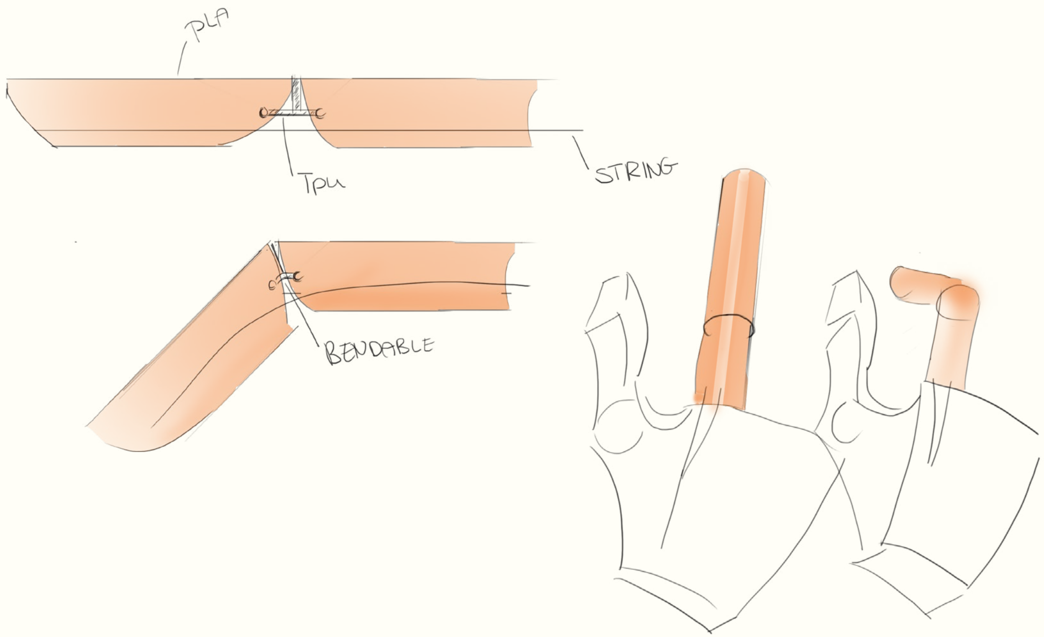


Figure 43: Mechanism direction two

3.5.3 Finger Mechanism design exploration

To be able to choose the most promising direction, a rapid prototyping was done. This way it was possible to test the possibilities of the mechanism and materials as this is hard to predict. Therefore a few 3D prints were made.

The combination of the shape, material and use of a string was examined first by making small prototypes.
The result of these tests can be seen in Figure 44-47).

The first concept idea was working exactly like the intention was. The force that can be generated is quite large and the finger is easily to bend. This shows that it will not take a large force to bend the finger. A lot of elements of this finger could be adjusted and improved, like the amount of flexibility. According to Mutlu et al. (2015), this mechanism has some advantages that are interesting, related to the design requirements.

"Fully compliant mechanisms and structures can be built using soft materials. Having a fully compliant system –a monolithic body- will reduce the manufacturing and assembly costs and show a whole-body bending performance similar to its natural counter-parts." (Mutlu et al., 2015).

This is interesting to take into account when making a concept decision, since this has some promising advantages.

The second concept idea was printed with PLA and did contain the flexible TPU hinge. There was a lot of force needed to pull the string to flex the finger. This can be caused by the material of the hinge and the location of the holes where the string is passed through. It should be possible to improve this in the next steps.

Both concepts have promising elements and function well. They both meet the requirements for the prosthesis and could be integrated into the concept design.

The first concept offers more design freedom and has additional benefits compared to the second concept. As it better aligns with the requirements, the decision was made to proceed with and further develop the first concept.

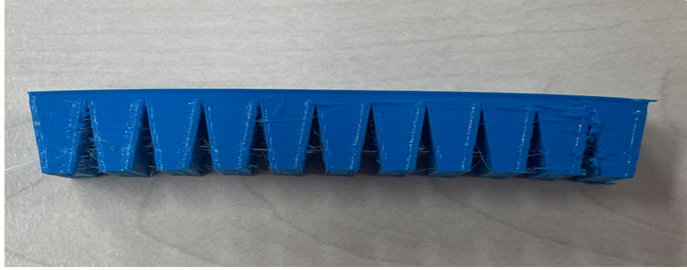


Figure 44: Test finger concept 1 in extension

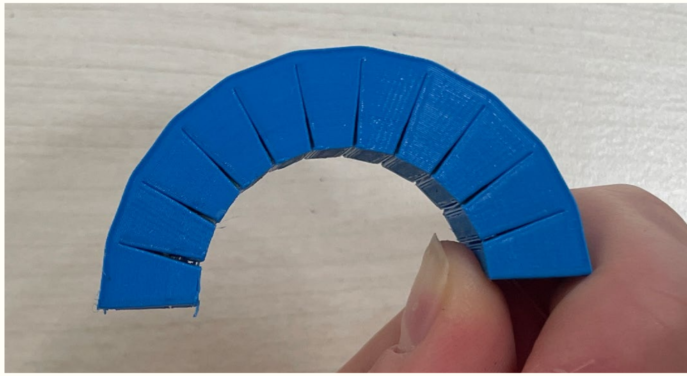


Figure 45: Test finger concept 1 in flexion


Figure 46: Test finger concept 2 in extension

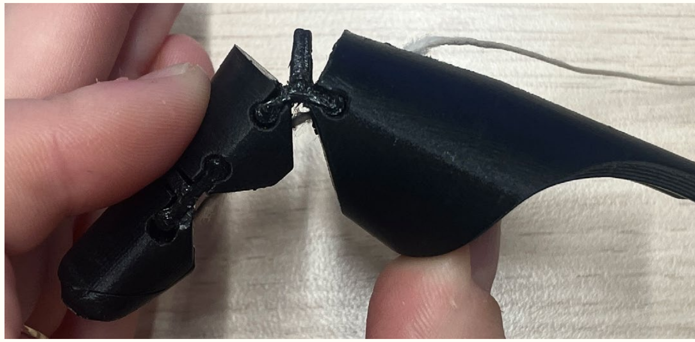


Figure 47: test finger concept 2 in flexion

3.6 Mechanism integration

3.6.1 Prototype as a whole

The working mechanism of the prosthesis is explained in Figure 55.

The finger is connected to the wrist with a wire. When the wrist is not applying a force on the wire, the finger will be in the neutral straight position. When the wrist bends, there will be pulled on the wire which will pull on the tip of the finger, forcing the finger to bend. The hand component makes sure that the wires are guided from the finger to the wrist and that the fingers can be attached. The hand component is connected to the amputated residue of the hand.

The wrist component secures all the wires and is able to apply a force on the wires. This component is attached to the wrist of the user.

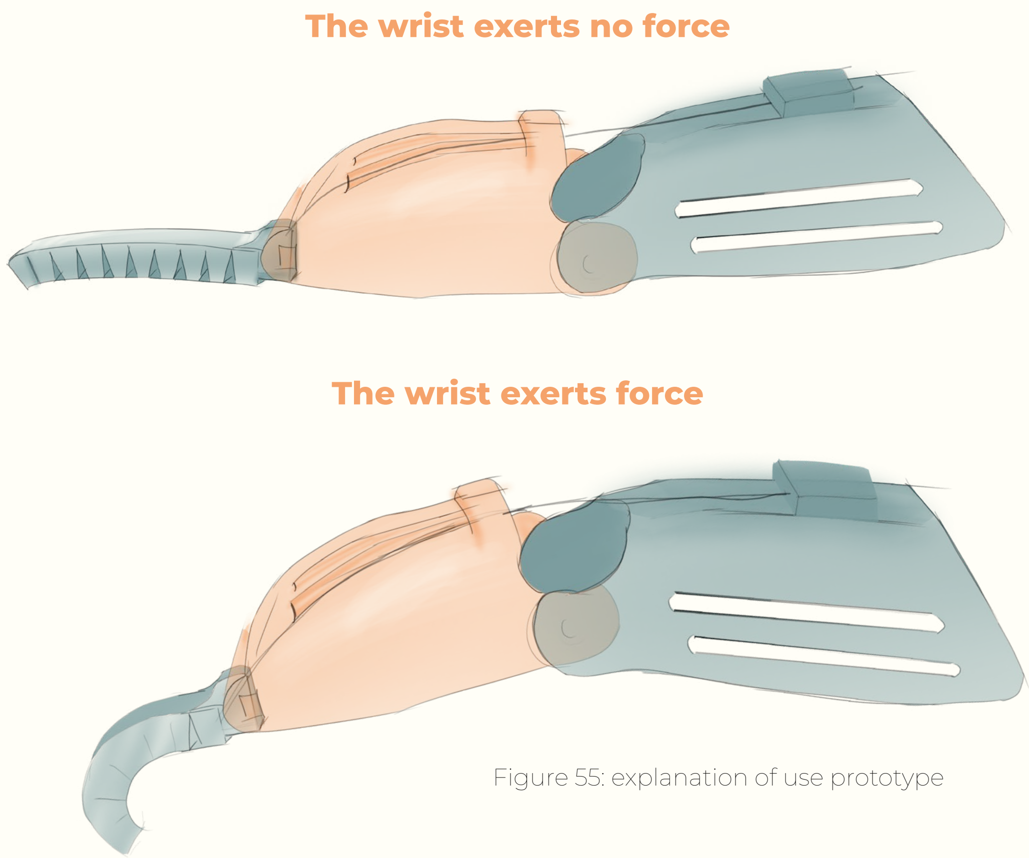


Figure 55: explanation of use prototype

3.6.2 Integration prototype

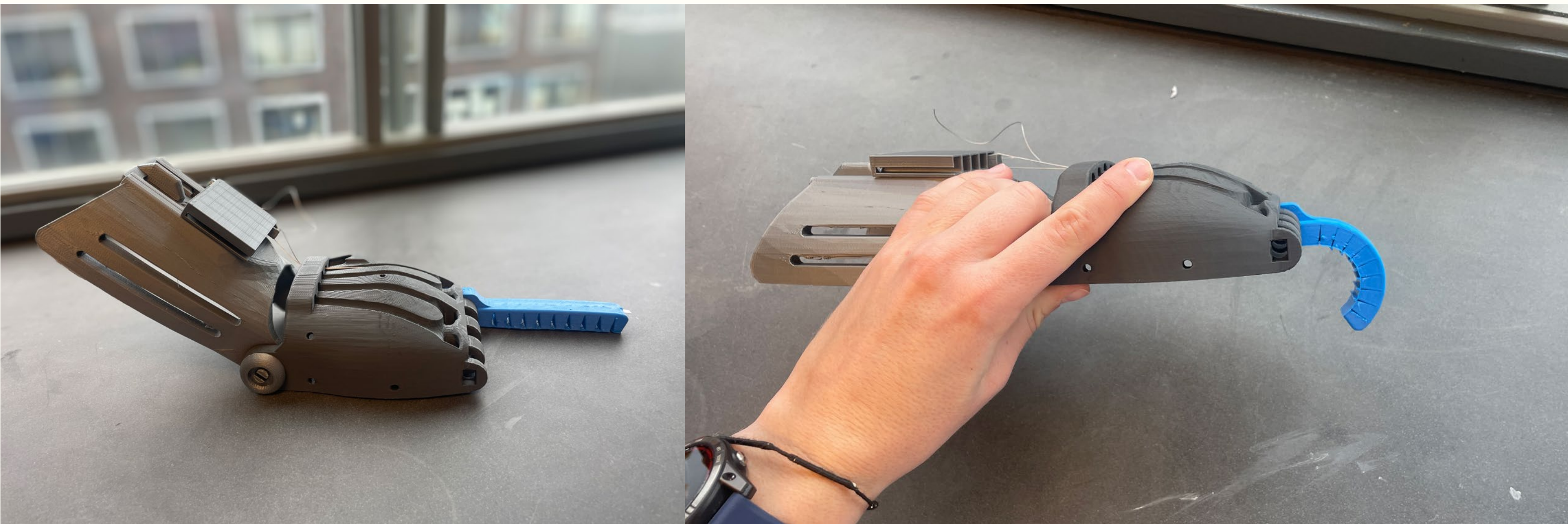
A first prototype was created to test whether the overall concept works (see Figure 48). The hand and wrist components were sourced from Thingiverse.com, n.d. and redesigned in SolidWorks, while the finger part was modified to connect with the hand.

The initial concept was deemed using nylon wire to transfer force. While testing the device, the nylon wire was too elastic, deforming and losing strength, which resulted in insufficient force being applied. A design change was implemented to address this issue, the nylon wire was replaced with a steel wire, allowing for greater force application and ensuring the wire maintained its strength without deforming.

Despite this improvement, the finger does not extend when the wrist releases the tension on the wire. This is a challenge that will need further investigation and improvement in the next iteration. Additionally, the current prototype is too bulky and robust. Made from PLA for a quick test, this material might not be ideal for the final design, as it requires additional cushioning to ensure the prosthetic is ergonomic and safe to use.

During the testing of the mechanism, some improvements for the hand, finger as well as the wrist component were identified which will be explained during the next steps.

Figure 48: First prototype to test the functionality



Key insights

- The used nylon wire is too elastic to withstand the force needed. Steel wire works much better and is able to withstand more force.

- It it important to take into account that the steel wire is much stronger and is more likely to tear the TPU plastic over longer term like the way the wire is attached in the prototype.

- The finger is not in every direction strong enough to apply force on an object.

- The material used for the part of the hand and arm of the prosthesis is not ergonomic. Different material then PLA might be preferred

- The prosthesis should be less robust and the material can be thinner.

- When opening the wrist, the finger is not extending.

3.6.3 Improvements of the finger

Since the finger part flexed but did not return to the extended position, the prosthesis was not yet functional. After analysing the prototype, two potential causes for this issue were identified:

1. The cable did not move smoothly enough due to the angle it made at the end of the finger where it connected to the hand component (Figure 49). This could have been resisting the motion and preventing the finger from extending properly.
2. The TPU material used was flexible but not elastic. While it bent easily, it did not return to its original position after bending, which was essential for the finger's functionality. This lack of elasticity might have contributed to the finger's inability to extend back into its stretched position.

To address this issue, for both identified issues the solutions were explored.
The holes through the finger were initially aligned in a straight line. This resulted in the wire having to move from the lower part of the finger all the way up towards the top of the hand. The sharp angle that was forced because of this generated resistance and restricted the smooth movement of the wire. To solve this, the holes were relocated. The holes at the base of the finger were moved upwards, while the hole at the tip of the finger remained in the same location. This meant that the hole through the finger was no longer a straight line but curved. By doing this, the wire followed a smoother path, reducing the sharp angle and thus lowering the resistance when the finger extended. Figure 51-52 shows the relocation of the holes.

For the second issue, the finger had to extend when no force was applied. This could have been done by pulling the finger back with another wire or spring or looking for a different material that was more elastic. Research for other filaments did not result in new material options that had the same functional properties as TPU. Putting a spring on top of the finger would have added a new construction, making it more susceptible to damage. Nevertheless, a spring would have helped bring the material back to its natural shape. Since the finger was small, there was not enough space to integrate the spring, but there were possibilities for integrating spring steel. A small test was conducted by adding the spring steel on top of the finger (Figure 50). It was immediately noticeable that

Figure 49: wire blocked due to the angle

Figure 50: Added spring steel on top of the finger part

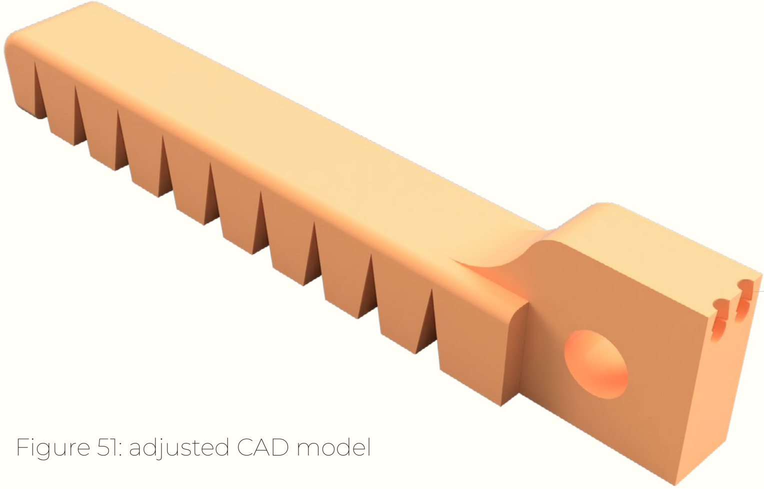


Figure 51: adjusted CAD model

The holes now end higher. As a result, the wire curves upward and is guided outward. This ensures that the wire does not get stuck and can move freely back and forth. To make this a bit easier, a small notch has also been added from the top.

A slot has been added to allow the spring steel to be placed inside the finger. This ensures that the finger bends back when the wrist opens.

The holes start low to make sure the finger bends when a force is applied.

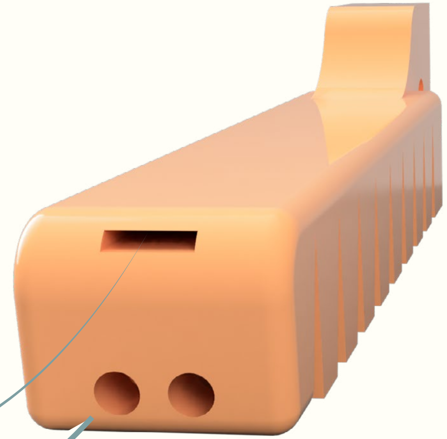


Figure 52: adjusted CAD model

the finger was brought back into its straight position, adding some strength when extending while also bending easily. As a result, a new CAD model was created to evaluate the improvements discussed above.

All these improvements were integrated into a new prototype version of the finger. When attaching the improved finger to the prototype, the result was immediately noticeable. The wire smoothly moved back and forth, and the wire did not get stuck anymore. Integrating the spring steel into the prototype resulted in a finger that bent easily but also stretched back into the preferred position. Therefore, it can be concluded that these suggested improvements had an impact on the finger and resulted in a working prototype.

To know if the prototype was really working and met the requirements, a small measurement was done. The forces within the prototype were tested, including how much force it took to bend the finger. This was influenced by the resistance and the location from which the wire was pulled. Therefore, measurements were taken to determine the force required to bend the finger when it was not connected to the prosthesis, as well as when it was connected to the hand and wrist components. Additionally, measurements were taken with one and two fingers attached to the system. This thereby examined at what component of the hand it became difficult to bend the finger. This highlighted areas for improvement in the next phase of development. The outcomes can be seen in Figure 53. The outcomes were all below the maximum amount of force needed from the hand to bend the finger.

When the force was measured from the hand, the outcomes were a lot higher than expected. It was possible that this was due to the friction from the wire and the material of the hand. In the next chapter, this will be elaborated on.

	Force needed from wrist		1 Finger only	2 Finger only	From hand component 1 finger	From hand component 2 fingers	From wrist component 1 finger	From wrist component 2 fingers
N	19	Kg	0,6	0,8	2,4	3	1	1,2

Figure 53: Results of test

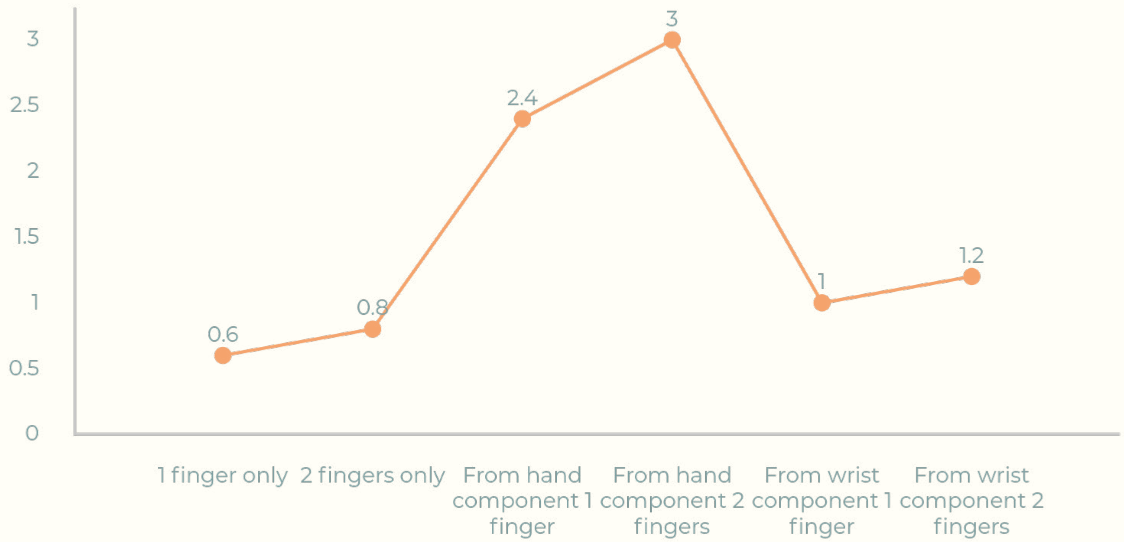


Figure 54: Graph of results

3.6.4 Improvements of the hand

The prototype has a number of elements that need improvement, when looking at the hand component. One of them is that it still takes quite a lot of force to bend the finger, especially when there are two fingers attached. This needs to be solved since it is not very comfortable for the user. As explained earlier, the result is acceptable but it would improve the concept if the force needed to bend the fingers would be lower.

One explanation is that there is a lot of friction when the wires are guided over the hand (Personal communication, J. van Frankenhuyzen). Solving this by reducing the wires from two to one would not solve the problem since it needs to be compensated with the amount of force needed to bend the finger. The only thing that could solve this problem is to ensure that the wires run as easily as possible from the finger to the wrist by taking out all forced angles and removing the bridge on top of the hand. This should allow the wires to move more smoothly with less resistance.

Furthermore, the hand is very large and not fitting with an amputated hand of the user. There has to be thought about a solution to fit every hand component with every amputation. Besides that, the material is very hard and therefore not comfortable on the hand to wear.

Figure 56: Hand component

3.6.5 Improvements of the wrist

The wrist component works fine and the fitting is good. However, the wrist component is quiet large and bulky which does not feel comfortable on the wrist. Besides that, the used material, PLA, is a very hard material which is not comfortable to wear, especially when a force has to be delivered from the wrist. The used FDM production method for 3D printing requires a lot of support for this print that will create a robust finish that is difficult to avoid.

Furthermore, the block where all cables are secured is quite large and present on top of the wrist component. This can cause the user to snag on something more often, or be irritated by the size of the prosthesis On the other hand it is beneficial that the wires can be tightened according to the users preference. This part should be improved but also taking into account the benefits.

Using this prototype also gave insights on the ease of use. It is a hard task for the user to bend the wrist to hold an object, since the wrist needs to deliver a constant force in a not very comfortable angle. A solution for this issue is preferred to improve the user's comfort.

Figure 57: Wrist component

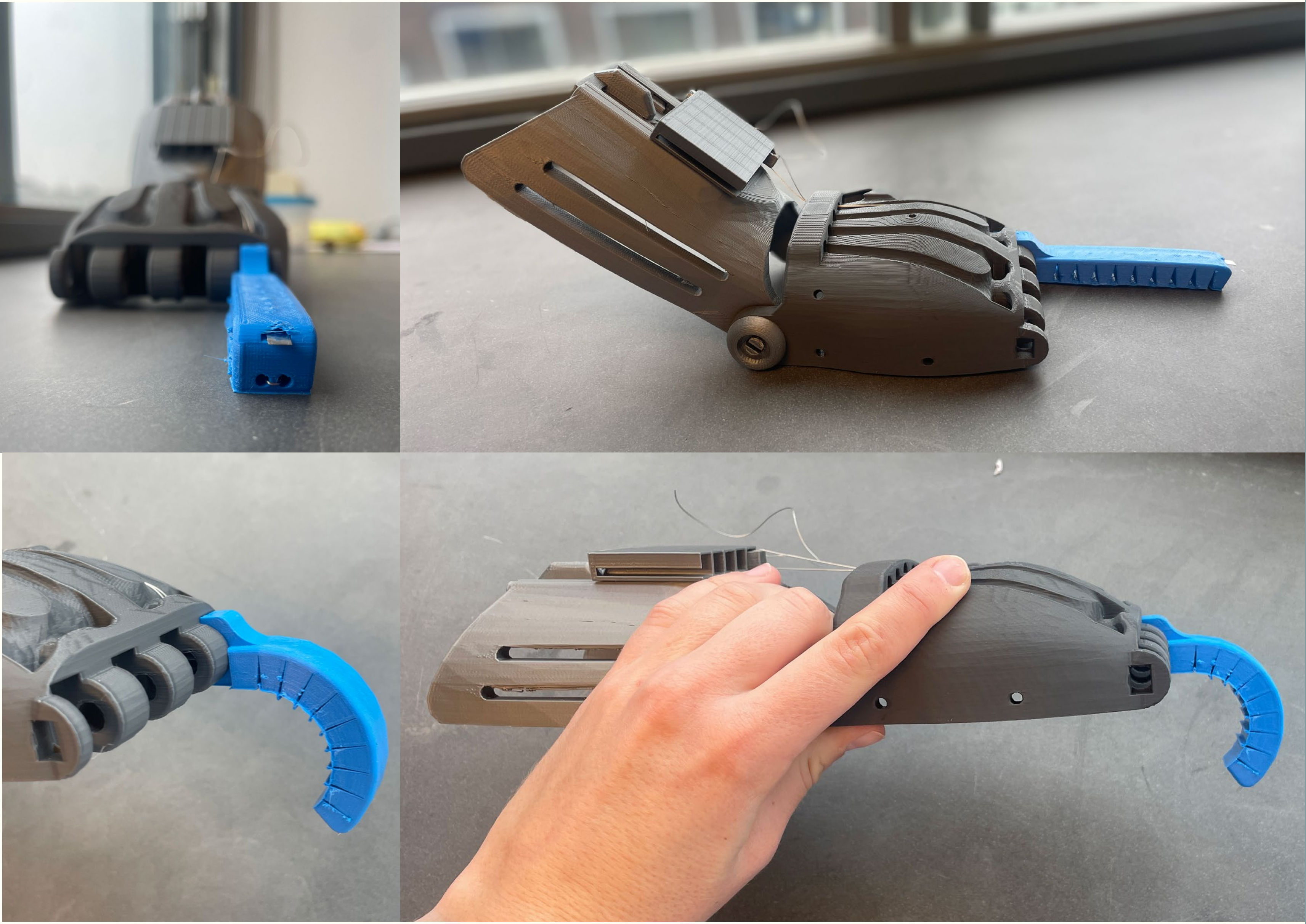


Figure 58: Integration improvements in new print

Key insights

Adding spring steel on top of the finger seems to make it easier to extend.

Making the holes start below at the finger and ending at the top, creates less friction and ensures that the wire is not blocked because of the angle. Therefore, the wire can move freely and the flexion and extension movement is not restricted anymore.

Implementing both adjustments, results in a finger that is easy to bend but is also able to extend back to it’s neutral position. This is an huge improvement, looking at the first prototype.

The hand component needs adjustments in case of comfort and decreasing the friction with the wires

The wrist component should be made less bulky and softer. There has to be thought about a way to secure the cables and improve the comfort of the user when having to bend the wrist for a longer time

4 Embodiment

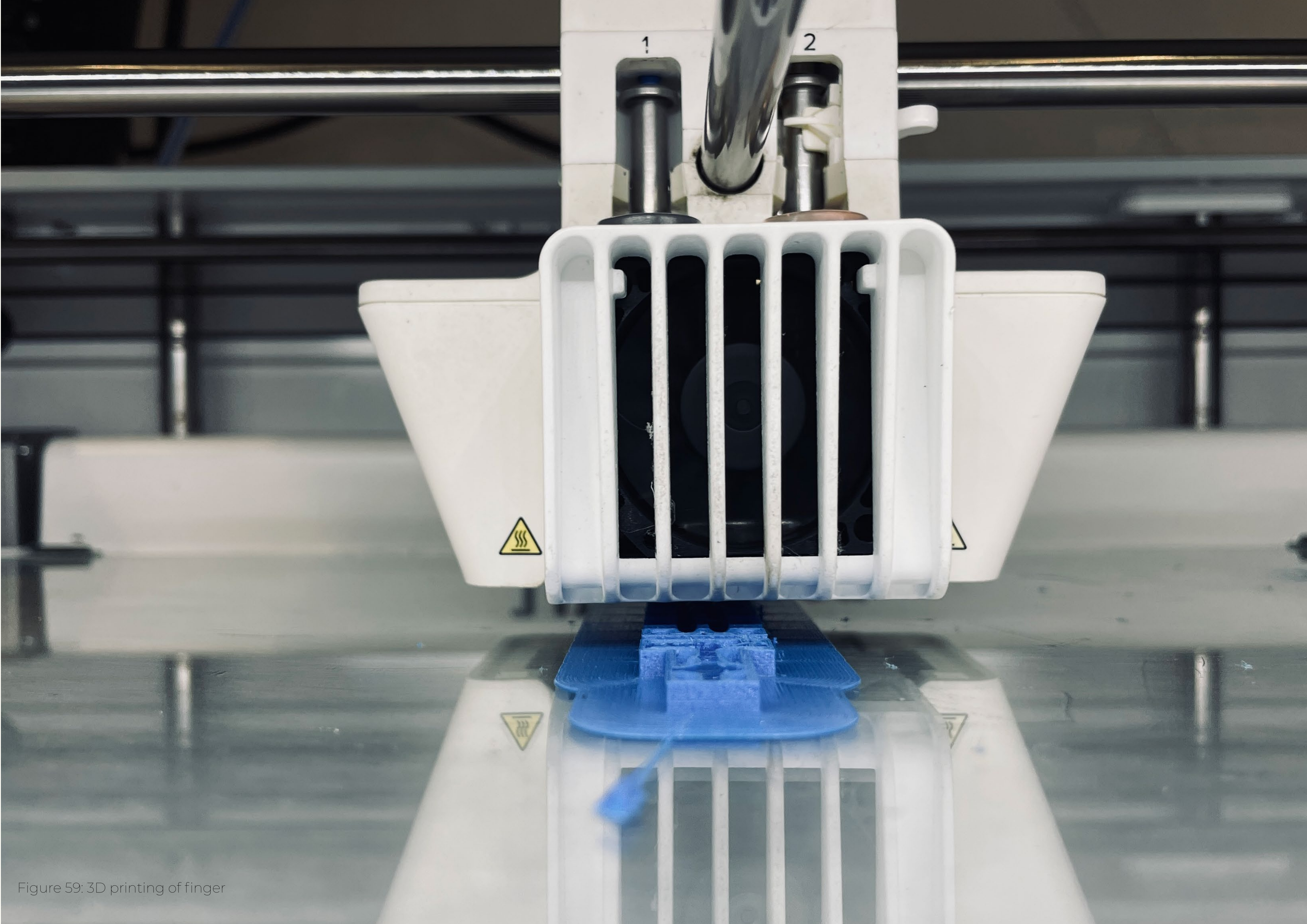


Figure 59: 3D printing of finger

4.1 Prerequisite from concept

During the concepting phase, a number of preconditions emerged, which the design has to meet. Before starting the embodiment phase, these preconditions that were defined have to be taken into account. These conditions are listed below.

- The finger should be able to bend easily by using soft material.
- The finger should be stiff enough to press a button.
- The finger should expand automatically when the force decreases.
- Preference for standardised production methods.
- Should be able to be printed using a precise printing technique.
- The resistance of the wire should be minimal.
- Not too difficult material to 3D print.
- Fast and cheap to print
- There should be as few loose parts as possible as this makes the model more fragile
- Bulky constructions should be minimised as much as possible

4.2 Main components

The concept is split in main components which will be detailed in the next steps. Figure 60 shows the main components which will be elaborated on.

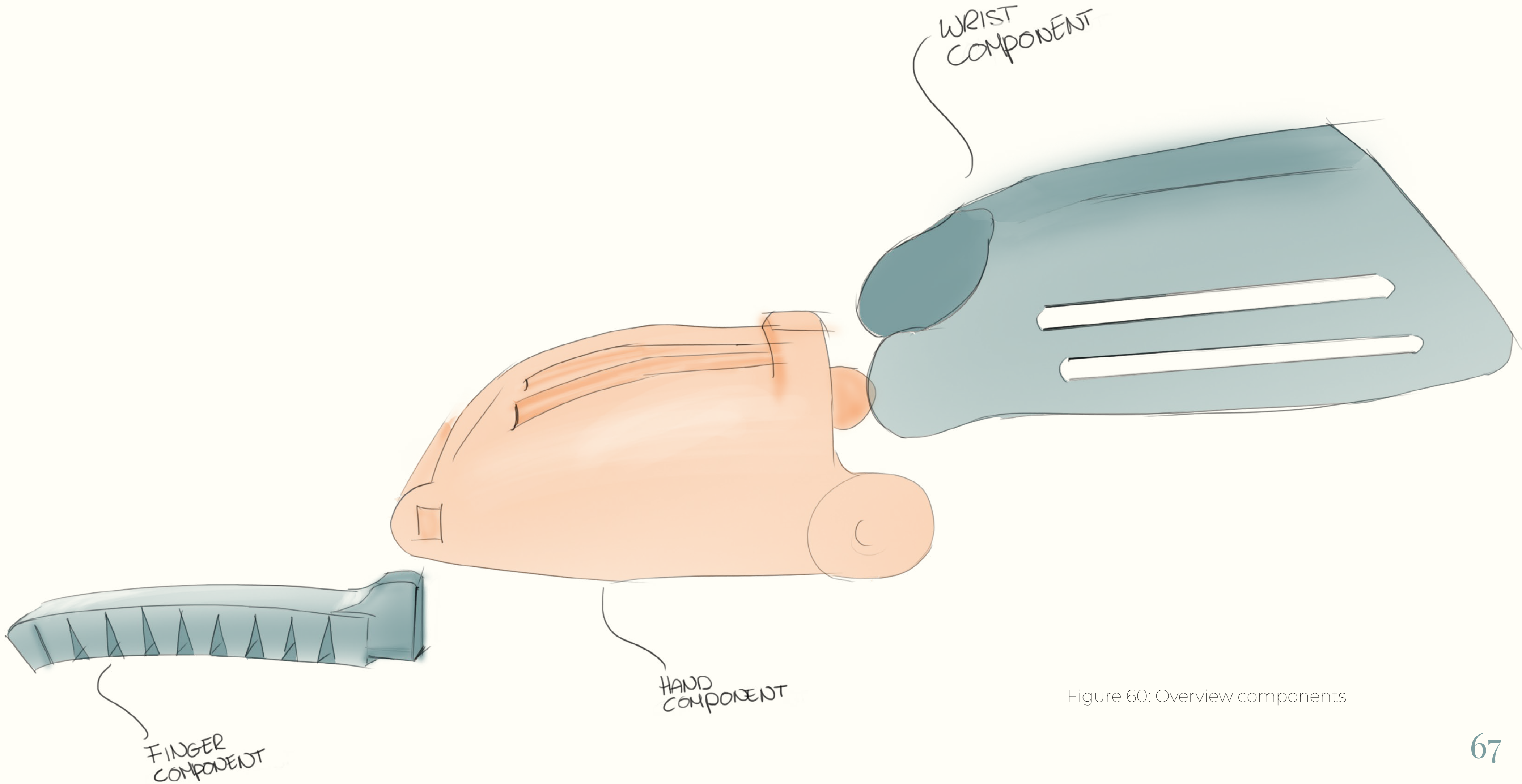


Figure 60: Overview components

4.3 Finger component

4.3.1 functional improvements

From the first prototype, a lot of improvements could be made. The finger component has several considerations to take into account:

- The finger should be able to bend easily by using soft material.
- The finger should be stiff enough to press a button.
- The finger should expand automatically when the force decreases.

Two different iterations of the finger design were created: one where the bottom side of the finger is attached by a small layer, and the other that remains unattached, similar to the original design. The purpose of this iteration was to improve the finger's strength and to make sure the finger extends enough.

The new iteration, which included a layer on the bottom (Figure 61) that connects the finger segments, resulted in a finger that was better able to return to its original form. In contrast, the design without the layer did not stretch sufficiently to fully extend the finger. Based on these observations and measurements, it was concluded that the new iteration with the extra layer performed better, see Figure 62.

Figure 61: Comparison fingers with and without bottom layer

Figure 62: Layer at the bottom of the finger

	Applied force on finger extended	Applied force on finger flexed
Concept with layer bottom part	11 N	7 N
Concept without layer bottom part	3 N	5 N

Table 3: Comparison fingers with and without bottom layer with respect to the force in Newton

It was assumed that the force that the tip of the finger could withstand would also improve. To validate this assumption, the forces were measured using a force gauge and evaluated. The results, which can be seen in Table 3, show that both the extended and flexed finger can apply more force when the bottom layer is attached. Only this finger is in line with the requirements that had been set beforehand for the finger. In conclusion, adding a bottom layer significantly enhances the performance of the finger.

It is also possible that different variations in thickness, width, segments and infill will improve the design. Optimizing the finger is an extensive process in which the precise simulation of the finger in bend position, is not possible to do within the given time-frame. This is due to software capabilities that make it complex to perform optimisation with this combination of material and movement direction. Therefore, an other approach was chosen.

The finger needs to be stiff enough, to push a button for example, to be able to use the finger in extended position. In the current situation, this is 11 N with the bottom layer attached to the finger (Table 3) .
Three different variations were simulated by applying a force of 11 N on the finger.
The variations were:

- Widening the finger with 3 mm
- Thickening the finger with 3 mm
- Changing the degrees between the segments from 20° to 30°. This had an influence on the amount of segments which is increased with 1.

These simulations were compared with each other.
The simulations of the finger without the bottom layer can be

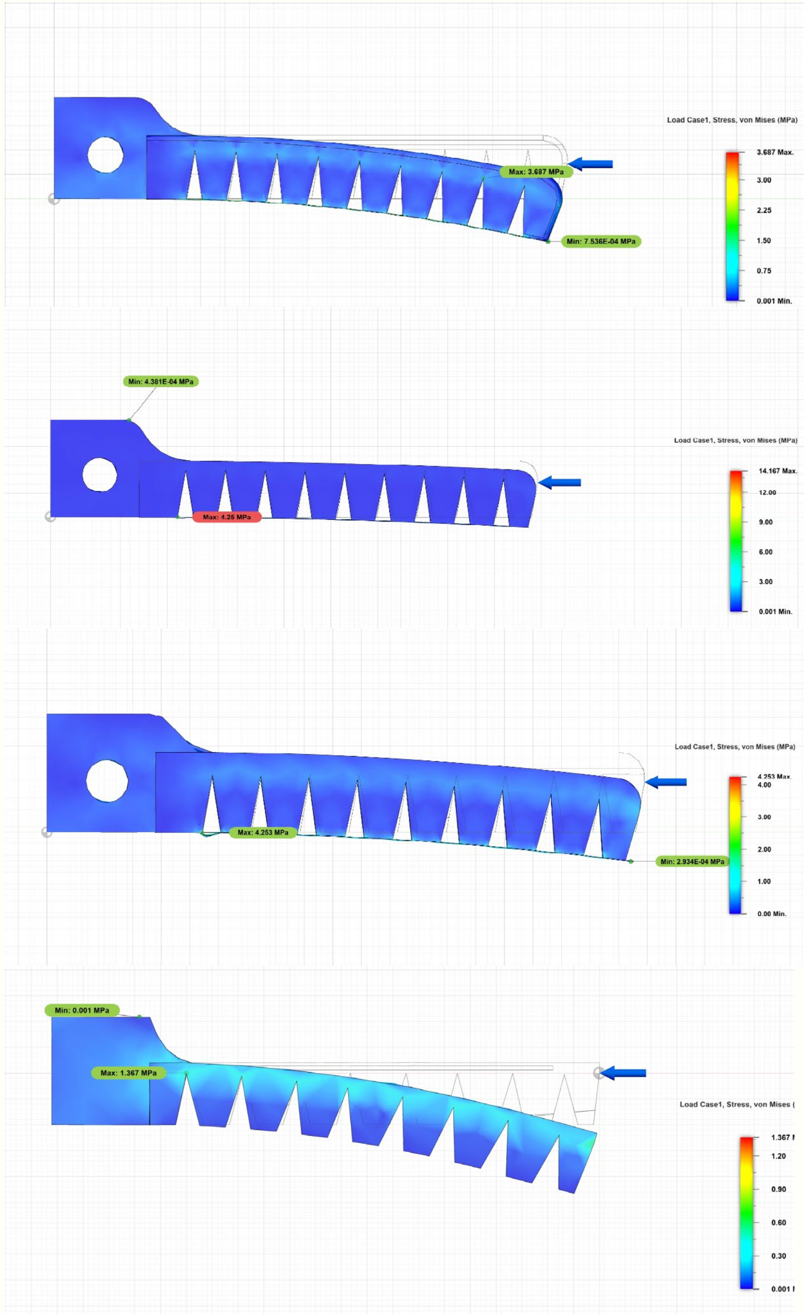


Figure 63: FEM stress analysis

found in Appendix J. In Figure 63, the results of the simulation is visible.

Every tested finger has acceptable results when looking at the stress. The finger with 30° angle, shows a bit more stress than the others. However, this does not mean that the finger will break or tear. What also can be seen on the FEM analysis, is how much the finger will bend when there is a force of 11 N applied. The finger with +3mm in width barely bends when the force is applied, where the finger with 30° angle shows a lot of bending. Preferred is to avoid a lot of bending when there is a force applied. However, it is also not desired that because of its stiffness, the finger is hard to flex when there is pulled on the wire.

Therefore it is important to know how much force it takes to flex the finger, which was done with physical tests.
The above finger variations were 3D printed and measured with an ulster, see Appendix K for the test setup. There are limitedness variations possible which could improve the design of the finger, like density of the print, type of infill and there are also a lot of TPU material variations.
To understand the impact of the infill on the performance of the finger, two fingers with 10% and 30% infill were printed.
To understand the impact from the different TPU materials, three different brands were used to print, so that it would be possible to compare them with each other. The basic TPU 95A

	Ultimaker 95A		Ninjaflex 85A		Bambu 95A HF	
	Measured applied force extended (N)	Force needed to bend the finger (N)	Measured applied force extended (N)	Force needed to bend the finger (N)	Measured applied force extended (N)	Force needed to bend the finger (N)
Width +3mm	37	15,7	10	9,81	70	41,20
Thickness +3mm	38	28,45			74	52,97
Degrees + 10°	30	13,73				
Infill 10°	40	21,58			68	33,35
Infill 30°	50	23,54				

Table 4: Outcomes measurement finger variations

from Ultimaker, the Ninjaflex TPU 85A, and the Bambu 95A HF filament were used. An overview of the specifications of each of the materials can be found in Appendix L.

Not all five variations of the finger design were printed with all of the mentioned materials, since this is not needed to compare the materials with each other.

The maximum amount of force that can be applied on the finger when extended is measured with a force gauge.
After that, the amount of force that is needed to bend the finger was measured with an unster. Every measurement was done three times and the average is included (see Table 4).

The Bambu 95 HF material is very strong, the measured force is almost the maximum force that was possible to apply with the human force. However, the force that is needed to bend the finger is in almost every case more than 38N, which is very high.
This TPU material is not ideal to use for the finger concept.

The amount of force that could be applied on the Ninjaflex 85A material is 10N, which is above 6 N minimum force, but is not very high when it is compared to the other fingers. The force that is needed to bend the finger is therefore very low, it will not take a lot of force from the user to bend the finger.

When comparing the design variations from the Ultimaker 95A TPU, the push force is the highest with an infill of 30% which seems logical. Because the infill percentage is higher, the density increases. All the push measurements are quite high and meet the requirements.
The force that is needed to bend the finger is also lower than the maximum activation force. However, the finger would perform optimally if it could generate a high force when extended while requiring only a minimal force to flex.

The least force that is needed to bend the finger is, except from the Ninjaflex material, the least when the degrees between the segments is increased. The force that can be applied is 30 N. When the width is increased with +3mm, the force that is needed to bend the finger is only 15N. The force that can be applied when extended is 37N.
Both of these variations show good performance of the finger, related to the requirements.
However, for this project is chosen to continue with the finger that can deliver a high force but bends the easiest. Therefore, optimizing the finger with an increased degree between the segments is chosen to continue with.

Only a few variations were tested since the amount of possible variations which could influence the performance of the finger are unlimited. Variations within the design but also variations with printer settings, like infill and infill textures. A recommended next step after this project would be to determine the optimal dimensions through a FEM optimization of the finger.

4.3.2 Material

For the prototype is a TPU filament used. This material was chosen, because this is strong but also easy to bend, this is one of the mentioned requirements. The options of flexible 3D printing material is not broad and therefore TPU was chosen. During testing, the performance of this material was as intended.

By changing the design and infill, it is possible to variate with the flexibility of the finger. The mechanism relies on the use of soft materials, allowing the finger to adapt to the shape of an object.

Besides TPU, there are not a lot of other options to use which can be used the same way.

TPU is not too difficult to print, can be printed with a FDM printer and is also fast and cheap to print.

Therefore, the decision was made to keep using this material for further development.

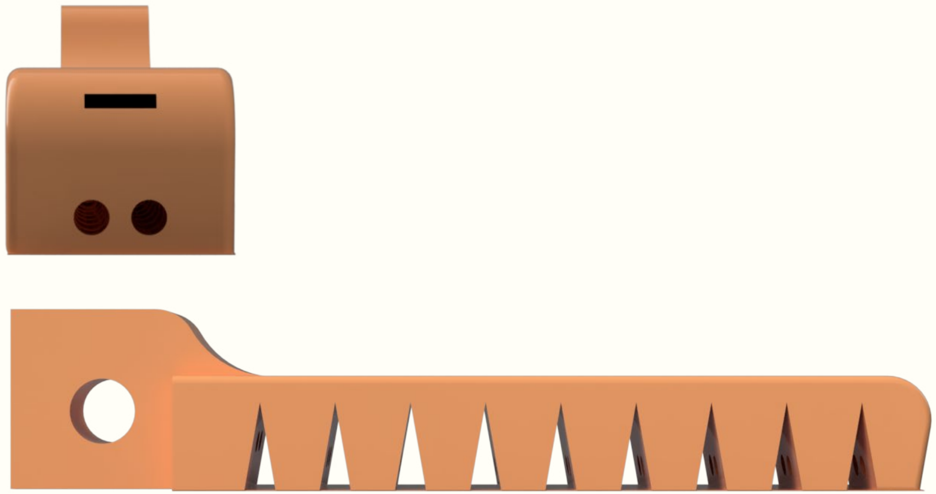


Figure 64: Finger component

4.3.3 Design

The design of the visualised finger is still the design that was used for the first concept. As explained earlier, it is more important for the user to have a well functioning prosthesis instead of a realistic prosthesis that mimics the hand. However, this does not mean that it is unimportant. The finger is now very rectangle shaped. Nature shapes are based on rounded shapes, just like the humans finger. This could also be integrated in the finger design, see Figure 65.

To conclude if this shape is preferred by people from the military, a small test was done where the two design options were compared to each other, see Figure 66.

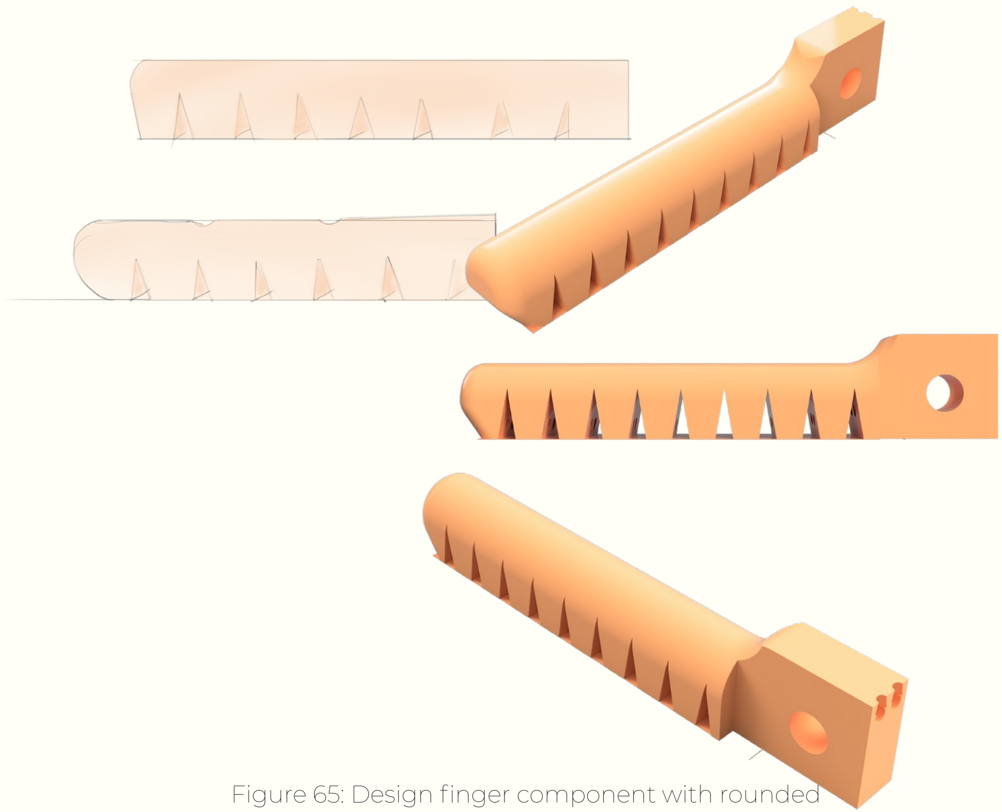


Figure 65: Design finger component with rounded edges

Results showed that 60,5% thinks that the finger should look as natural as possible. 9,1% thinks it does not matter as long as it is functional and 30,4% thinks it is better to have a prosthesis that stands out from the standard. Since the amount of people who participated is not that high, there is a great division in preference. It is safe to say this is a personal preference. Standing out or having a prosthesis as natural as possible can be achieved with the design and colour of the finger.

The visuals of the two finger designs were shown as explained in Figure 66. The second option with the fillets was preferred by 83,3%. The remaining participants had no preference. No one chose the firsts design without the fillets. Quoted from the explanation from the participants for their selected finger

''This one looks more like a real finger. It also seems that it would be less likely to get caught or cause pain, such as cutting the skin when you brush against it.''

''I think the rounded shape fits better with a hand, arm, and the rest of the body, and it doesn’t come across as a sort of Lego block''

These results led to the decision to continue with the finger that has rounded edges and thus looks more like a real finger. Since the human body also lacks sharp angles, this design will integrate better as a whole and appeal to a larger audience. By adjusting the design, the performance of the finger, as tested earlier in this chapter, will most likely change as well. While this is certainly interesting, it is not desired. However, the previous tests have made it clear how and in what way the performance of the finger can be improved. This is a matter of an extensive optimization step in the future and therefore adjusting the design does not make it infeasible.

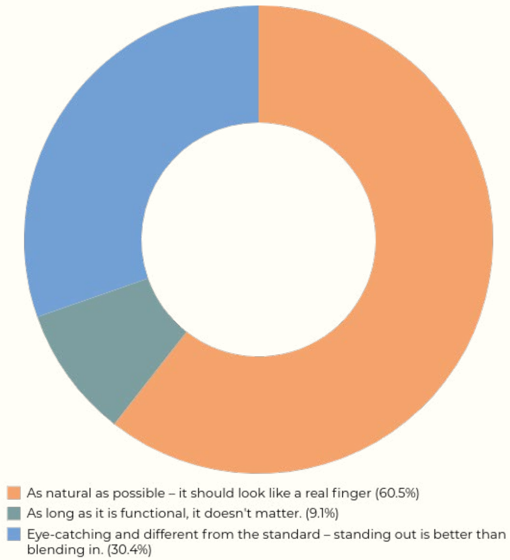


Figure 67: Results of appearance

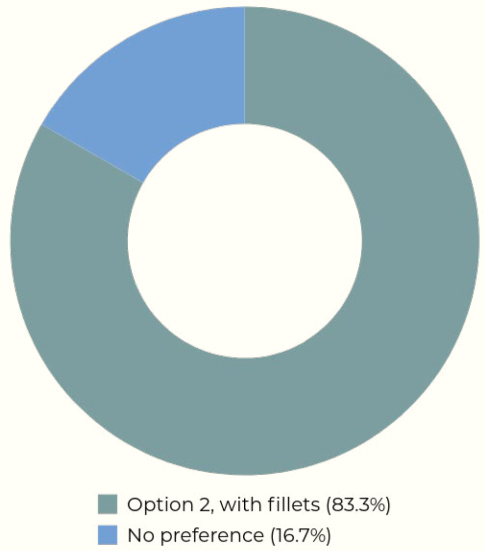


Figure 68: Results of finger shape

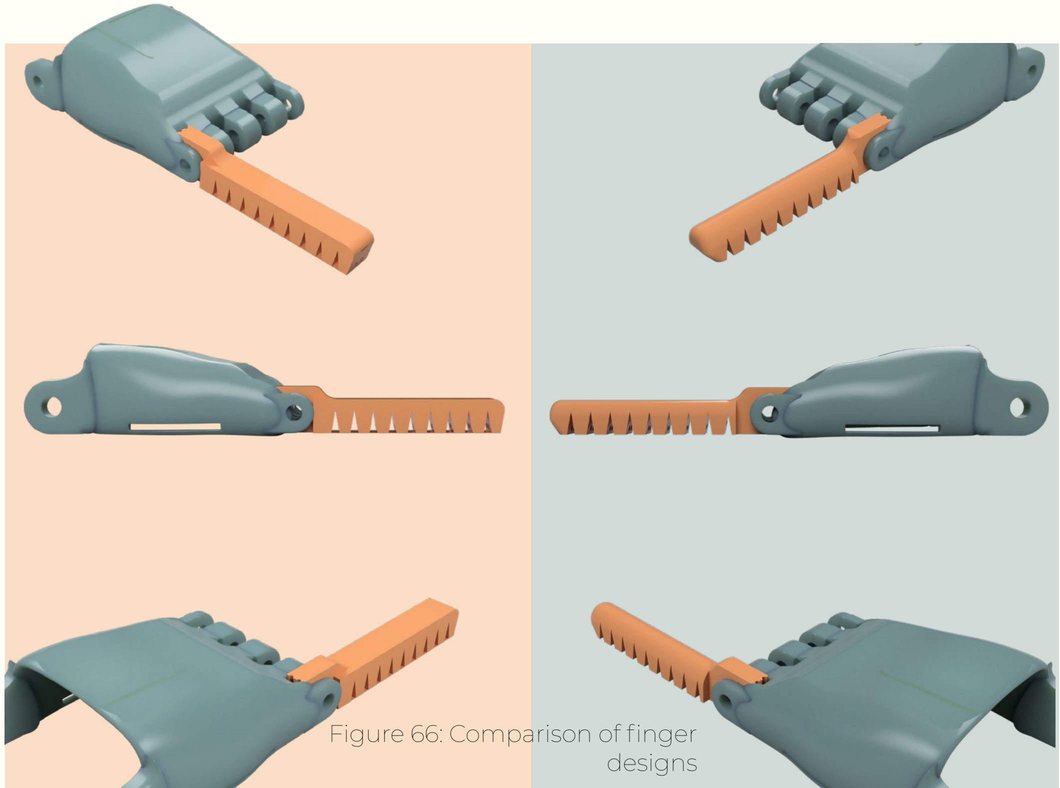


Figure 66: Comparison of finger designs

The colour is the second adjustment that can improve the design of the finger. Therefore, this was also evaluated in a questionnaire. Different colours of de finger were shown next to each other, see Figure 69. Each participant explained one or multiple preferences for a colour. The outcomes are shown in Figure 70.

Most of the times, the skin tone was chosen. However, the results differ between natural colours, skin tones and bright colours. Two quotes from the participants are as follows:

''This is about the same colour as my fingers now. It fits best and looks most natural with the rest of my limbs.''

''Blue, despite its striking colour, is still fairly neutral.''

As it is hard to pick one colour after evaluating the results, it would be ideal if the user can choose the colour they prefer. That is also something what the occupational therapist pointed out, since this is a very personal preference. The preference depends on the age, gender and the way they cope with their amputation. At OTA, the specialists explained that it is most of the times the best decision to choose a neutral colour but not a skin tone since this stands even more out. Therefore, black is a commonly chosen colour. For this project, the colour is also chosen for the prototype. However, since the 3D printing techniques offers a lot of colours, the user can choose their colour by themselves. This will contribute to a prosthesis that will be even more personal and customizable.

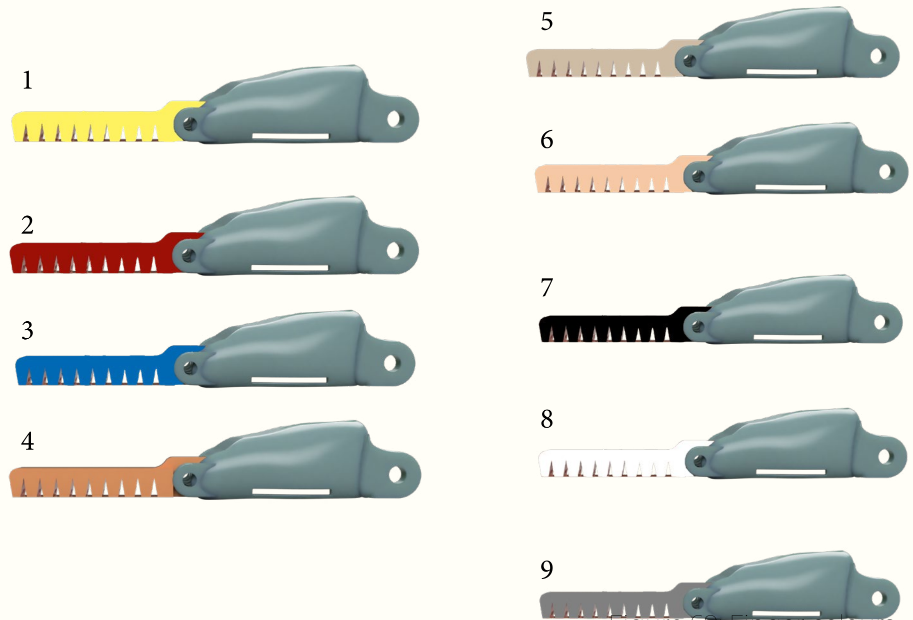


Figure 69: Finger colours

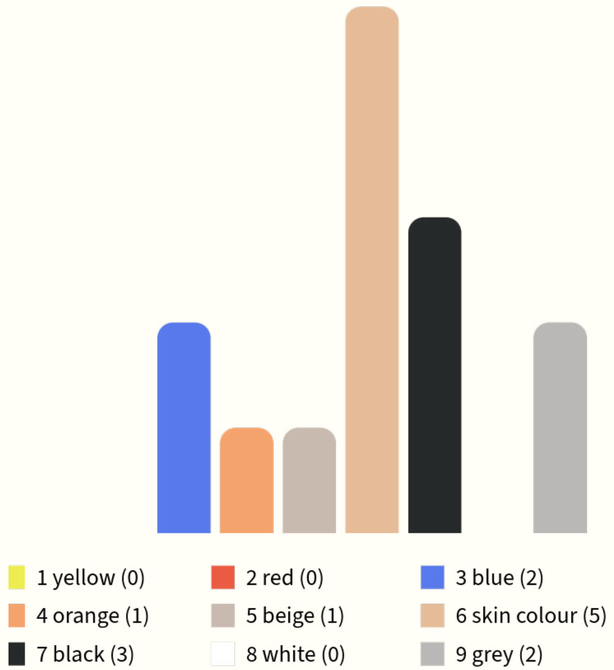


Figure 70: Finger colours results

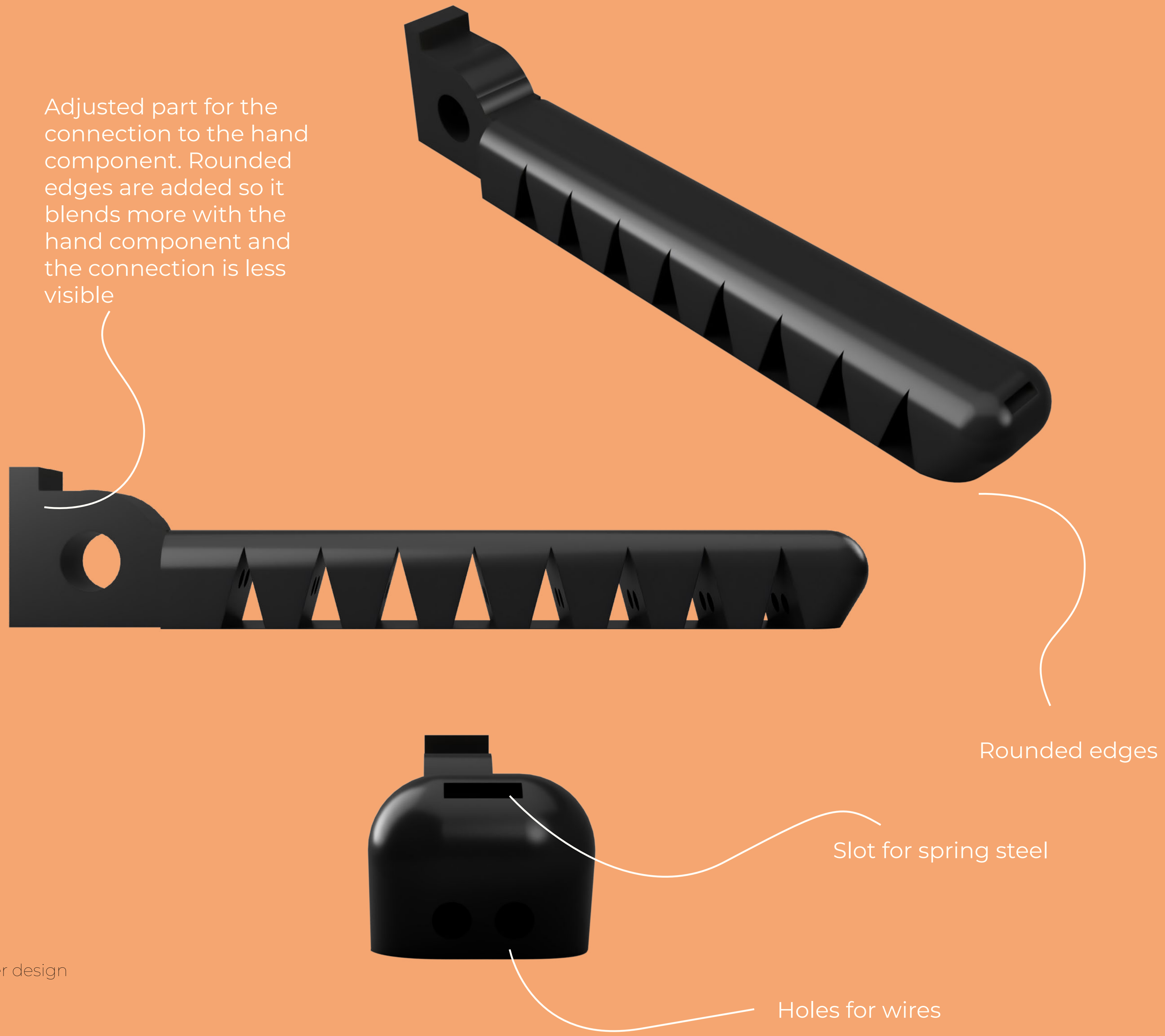


Figure 71: CAD of final finger design

Figure 72: Prototype of final finger design

4.4 Hand component

4.4.1 Design

The design of the hand is a critical component of the product since there are a lot of requirements to take into account. It is also the component that needs to be attached to the hand that is sensitive due to the amputation and trauma. Besides that, every amputation and the amount of fingers that is amputated differs per situation. Consequently, a one-size-fits-all approach is not feasible.

One key requirement to take into account is the feedback sensitivity of the palm. Users emphasized the importance of leaving the palm area uncovered when wearing a prosthesis, since this defines the user experience and improves the usability and comfort of the prosthesis. Therefore multiple design options were explored, see Figure 73.

The prosthetic hand component consists of a topside and a bottom side. The first design ideas focused on the bottom side as this is were the prosthesis attaches to the hand. Furthermore, ensuring the palm’s feedback sensitivity was a decisive factor in shaping the design.

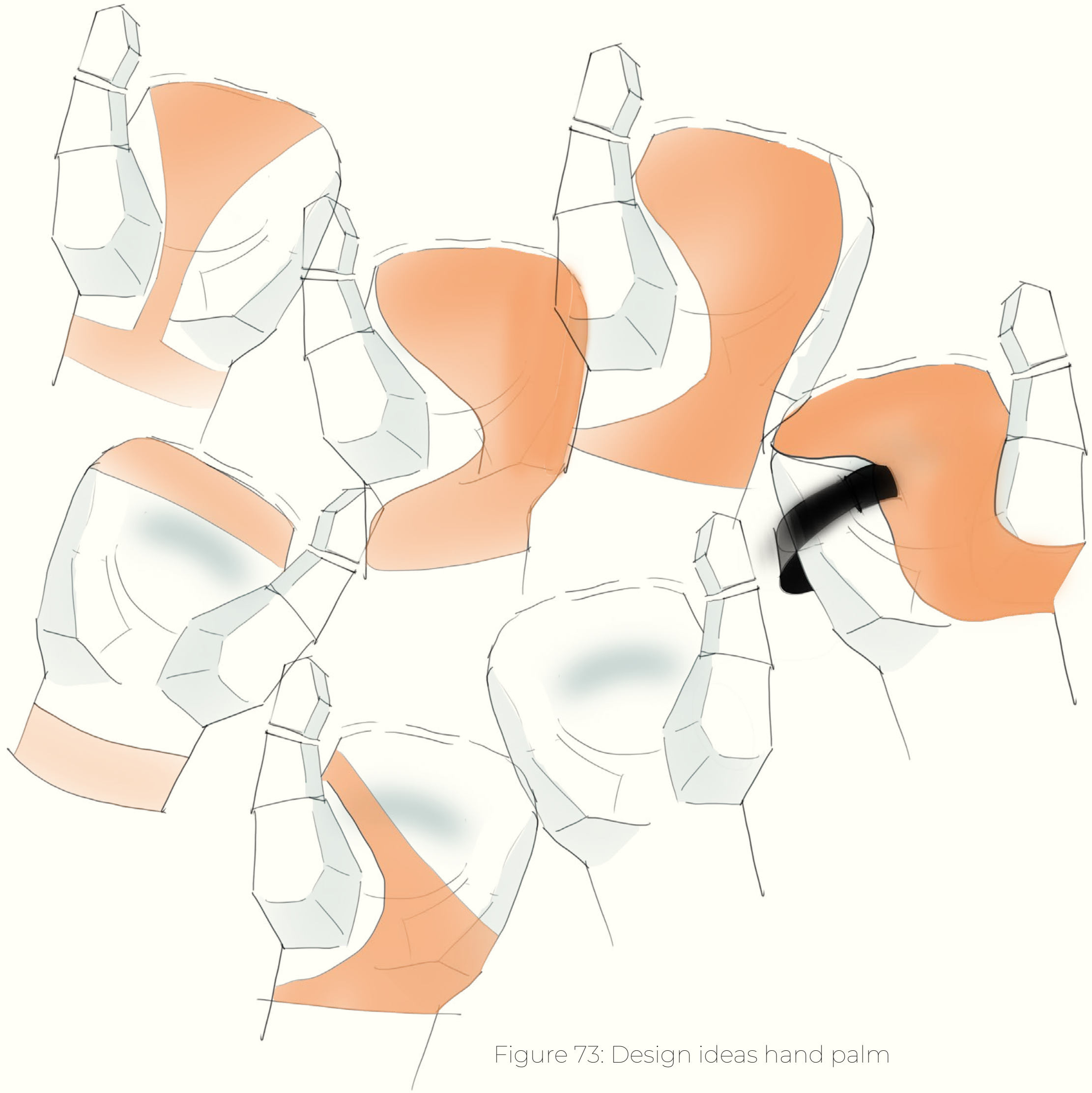


Figure 73: Design ideas hand palm

Insights

The design directions were discussed with OT specialist, N. Jonkergouw (personal communication, 10 January 2025), which led to the following insights. The design directions are appealing, but considering the implementation phase, there are some obstacles. When thinking about the production of the hand, it becomes clear that this will require specialized work. Each hand is different, and no amputation is the same. This demands skilled knowledge in 3D CAD software to customize each prosthesis. However, an orthopaedic technologist does not possess the expertise to personalize the hand component for each patient. They have their own production process, which ensures that the hand component, critical for comfort and proper fit, is custom-made.

Therefore, it is better to leave the hand component with the orthopaedic technologist and focus on applying the wrist and finger designs, along with the mechanism, to complement their work.

A sizing system and handing over the CAD files is in this case not sufficient enough. The final concept will be an integration of both expertises.

4.4.2 Production process

At the orthopaedic centre, prostheses are made to fit the body precisely. Getting a well fitting prostheses involves a whole process. This will be briefly explained to get an understanding of this process which can be integrated in the production process of the whole prosthesis.

1. The patient is on site to take a plaster cast of the hand.

2. This plaster cast will be used as a mould. It will be filled with plaster which will result in a positive model of the hand. It is then possible to also make some adjustments and corrections to the model to make sure that the prosthesis will be the right fit. See Figure 74 for an example.

3. A liner is applied consisting of foam so that there will soon be a soft layer between the prosthesis and the skin

4. Then it is possible to create the prosthetic socket. This will be done by building different layers on the positive model. Starting with a layer of foil, possible carbon reinforcement. Then another layer of foil is added, which is pulled tight with vacuum to the model. By doing this, all the layers all layers are tight to the model.

5. Liquid resin is poured into the plastic foil and it hardens by itself. This makes all the layers stick together.

6. The prosthesis is assembled and ready to be fitted by the patient. An example of a result is visible in image

Figure 74: Example positive model

Figure 75: Result prosthesis after described process

4.4.3 Prototype improvements

Since there was chosen to let the hand compartment be produced by orthopaedic technologist, the development of the design of the hand compartment of the prosthesis will not be focused on. Nevertheless, the hand component will be created for the functioning of the prototype, to explain and test the mechanism and show the final result. However, some adjustments needed to be made in order to improve the mechanism. This is also of added value for further development of the prosthesis when it will be created at OTA.

As explained in chapter 3, there are a number of elements that need improvement but one improvement is very essential for the performance of the prosthesis.:

- There is a lot of force needed to bend the fingers due to friction. This has to be solved by taking out all forced angles and removing the bridge on top of the hand. This should allow the wires to move more smoothly with less resistance.

This can be improved by removing the bridges and lowering the holes for the wires. This way, the wires do not have to make inconvenient angles from the finger to the hand resulting in the a lower friction and easier movement of the wire.

This will be improved in the design of the prototype, besides that the hand component will not be redesigned.

4.4.4 Material

The material of the final hand compartment will be determined by the orthopaedic technologist and will correspond to the process described earlier.

4.4.5 Final result
To improve the mechanism, an design iteration of the hand component was needed. In Figure 76, the CAD design of the hand component is shown.

The first hand component prototype had a lot of bridges on the hand design, that was enabling resistance on the wire. This is extracted.
Holes through the hand component are created to make it easier for the wire to move without making inconvenient angles when it crosses from the finger to the hand. This way, the wire will not be guided over the hand but through the hand.
The holes of the finger design end at the same hight as the holes of the hand component start. This will improve the design and reduce the friction that was mentioned at the first prototype. The design if improved by adding more rounded edges so it fits better with the design of the finger. Lastly, there are grooves added in the design, which will make it possible to attach Velcro. By doing this, the hand component can be attached to the users hand which will make it possible to test, see Figure 78.

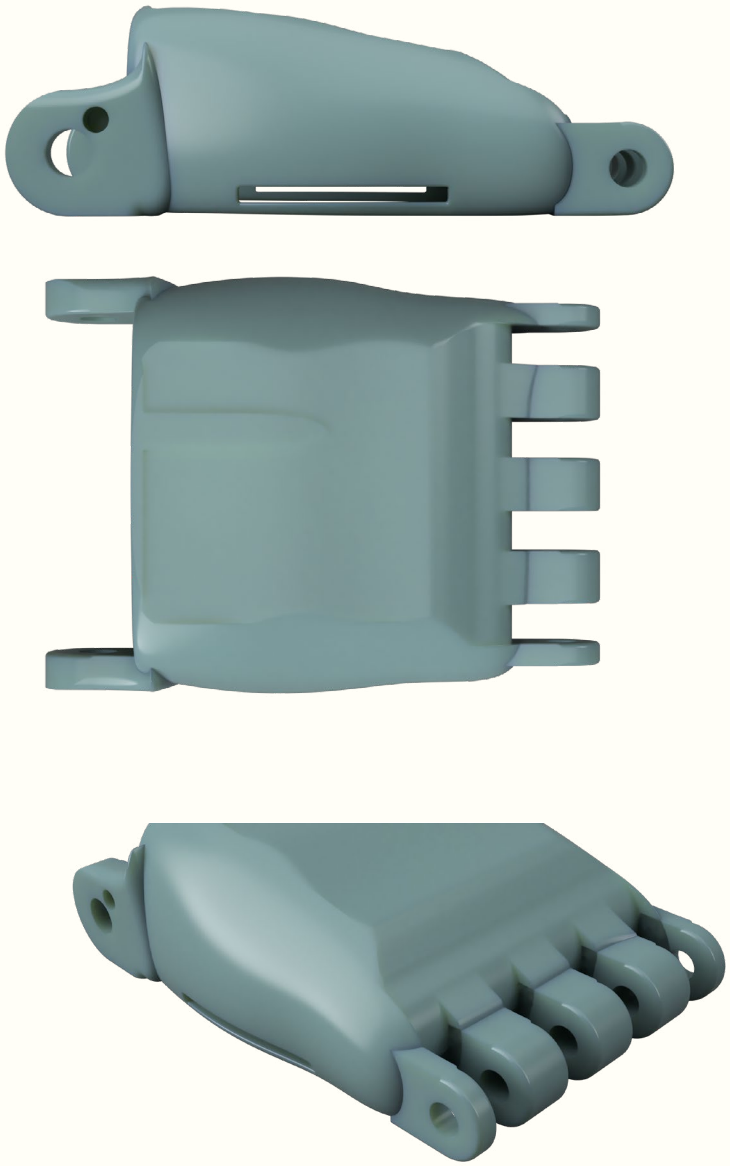


Figure 76: New CAD design of hand component

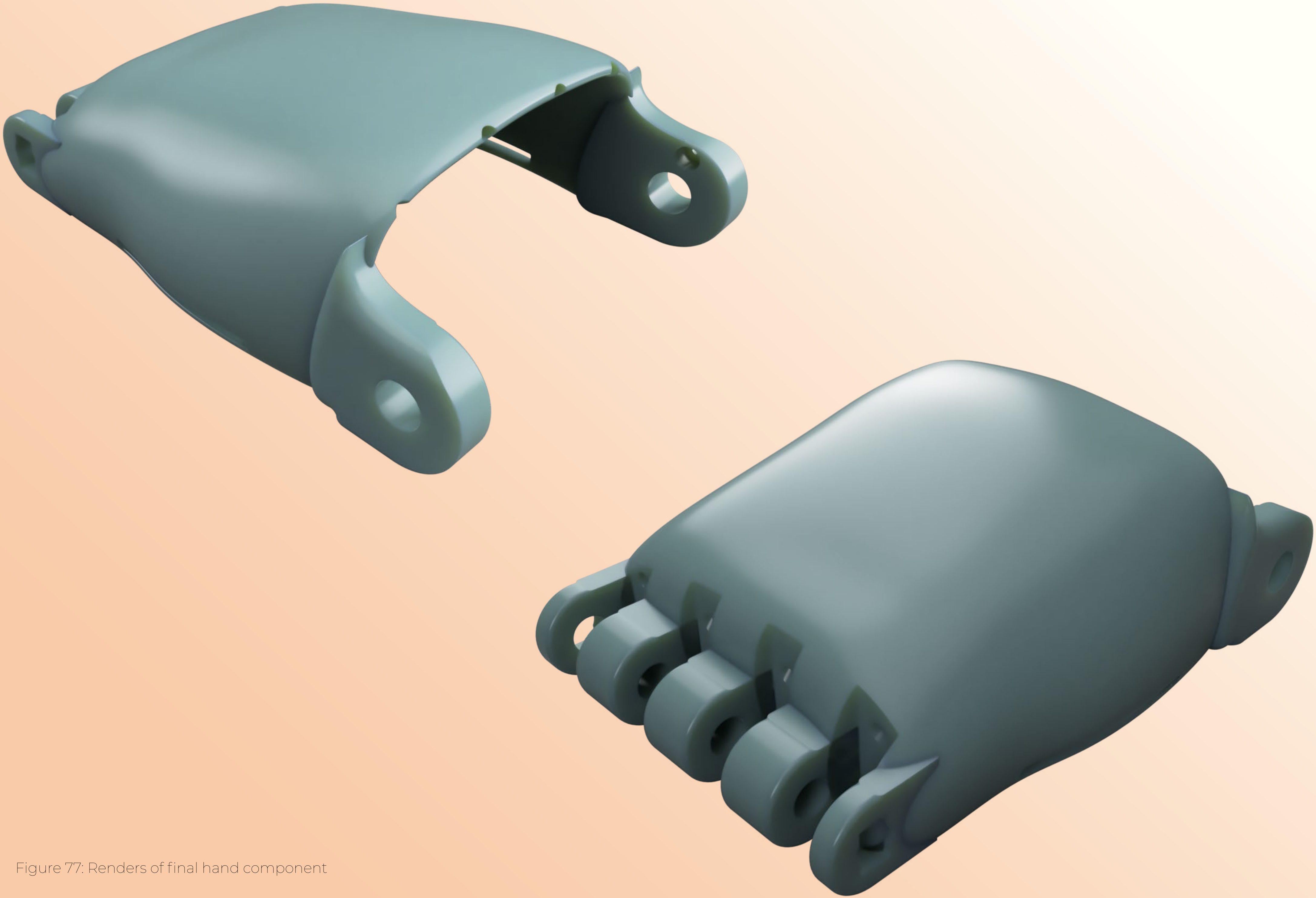


Figure 77: Renders of final hand component

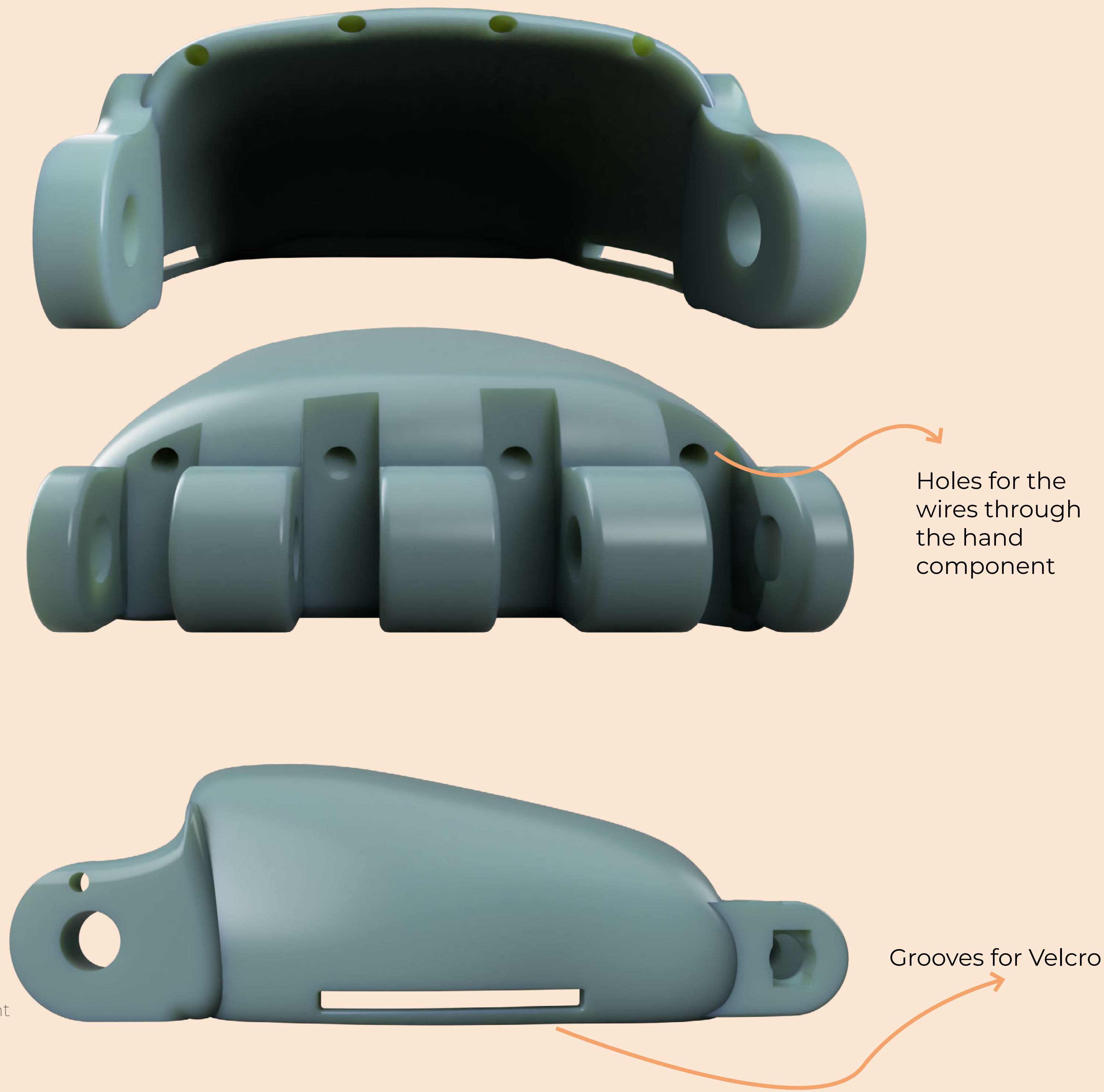


Figure 78: Renders of final hand component

4.5 Wrist component

4. 5. 1 First design step

The wrist component has several considerations to take into account:

- This component has to fit securely around the wrist to generate sufficient force when moving the wrist.
- It has to be producible in multiple sizes to allow for standardized production. This way, it does not need to be custom-made for each individual but should still fit snugly.
- The wiring needs to converge here and be secured.
- There need to be a mechanical connection to the hand.

To start with the first considerations, four design options for the wrist component were visualised, see Figure 79.

To understand what the benefits and limitations are from these design directions, a rapid prototyped with the use of clay was done, see Appendix M.

Before defining the design options it was best to first start thinking about the material possibilities, since this has a large contribution to the ergonomics.

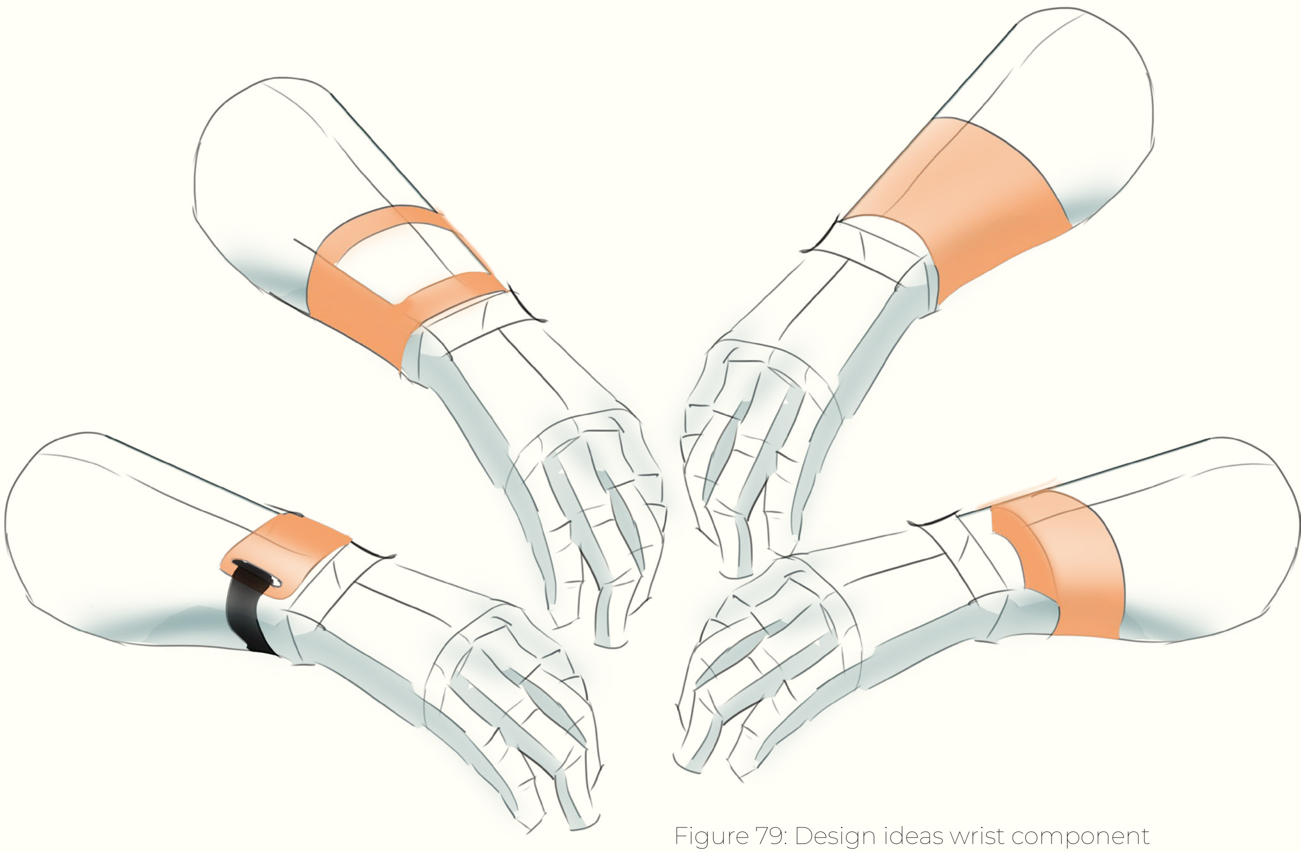


Figure 79: Design ideas wrist component

4.5.2 Material

Since the product should be 3D printed, the amount of material options were not unlimited.
As described in the requirements, these are some key properties the material must fulfil.

- The material should not cause reactions with the skin
- The material has to be able to withstand wear and forces applied to it
- A prosthesis should be as light as possible to improve comfort and minimise stress on surrounding tissues.
- The product should be easily shaped or adjusted to fit the user's specific anatomy and needs.
- The material should be easy to clean and not attract bacteria
- The material must be humidity and temperature resistant
- The material must be a low cost material

Discussing this with the Faculty Workshop at Mechanical and considering the print options. Some first design iterations were created, See Appendix M.

Since the materials should feel ergonomic on the wrist, a different material then PLA, that was used in the prototype, is preferred. It should be a material that is lightweight, easy to clean and comfortable on the wrist. After comparing different materials, there was advised to use Biomed flex 80A. For this material is SLA printing method required.

However, the connection and upper part of the hand should be more stiff and able to withstand the forces applied to it. Discussed was that it would be the best to create a kind of shell that can be glued on the elastic wrist part. The first prototype that was made, used the FDM technique. The result was fine, but a lot of support is needed and the resolution is not that good. The SLA printing technique is printing a lot better and the result is more precise. Since this is a medical product, this is a detail that is very important. Therefore the decision was made to use the SLA printer as well for the upper part and Formlabs Standard Resin will be used. The properties are very similar to PLA but the finish and strength are a bit better.

Advances of this way of assembling the wrist component, is that the flexible part will form to the wrist when attached and no difficult sizing system needs to be taking into account. As a result, the wrist part will fit better and is more ergonomic than when using a sizing system.

By selecting the material first, it is possible to modify the current design, taking into account the material properties and capabilities on which the design will then be based

4.5.3 Attachment

By using a Velcro band, the prosthesis can be attached to the hand. Besides that, it is an easy task to do with just one hand and therefore user friendly.

The Velcro band has an important contribution besides only attaching the wrist part. Since the material is flexible, it can be shaped to the users wrist. To be able to do that, it is needed to hold this shape and make sure that the wrist component fits well.
To attach this Velcro, a groove has to be made in the inner part of the wrist component.

Next, the wires need to be collected and tightened. The current solution in the first prototype will be replaced by a BOA system. This will integrate better within the design and is very easy for the user to adjust the strength and natural position of the fingers. This can be adjusted any time using the BOA and it is a modular system which will make repair easy.

4.5.4 Final design

The final design of the wrist component is created in two parts; the inner-and outer part. The inner part is flexible and the outer part is from a strong and hard material. The inner part is meant to feel ergonomic around the wrist of the user and will not cause irritation. The outer part has to cover the wrist as less as possible but enough to attach the wrist component to the hand component and transfer the force from the wrist. The design idea in Appendix M is used for the first prototype of this concept. This is visible in Figure 80. By testing this design, existing obstacles were possible to identify and improved before the final design was produced. Concluding from this was:

- There are too much sharp edges in the product. Since this is a medical product, this is not allowed in the product since it could harm the user.
- The design should be improved to have a better fit and the appearance is better
- The sizing is not correct
- The BOA system should be recessed deeper into the wrist area
- The thickness is reduced to 3mm. This is halved from the first prototype. However, the material is now a bit flexible and not very sturdy. Thickening the component with 1 or 2 mm would improve the product.

The flexible inner part of the wrist component is first tested with TPU to explore if this fits on the outer part and if the idea works as intended (Figure 81).
This combined design of the wrist component can be seen in Figure 82. This design is printed with the intended materials using the SLA printer (Figure 84).

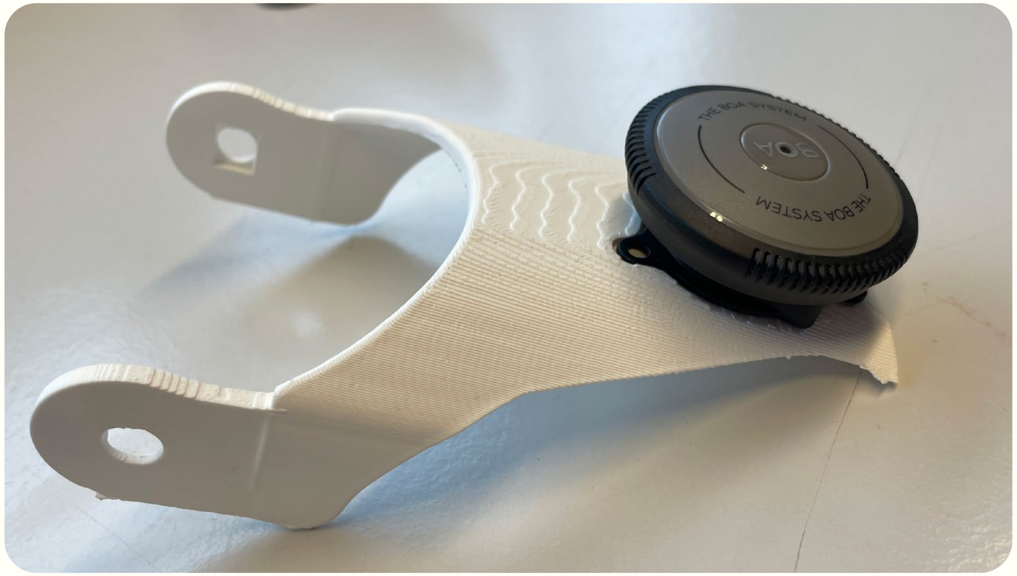


Figure 80: First test with new design idea

Figure 81: Improved design and printed with SLA printer

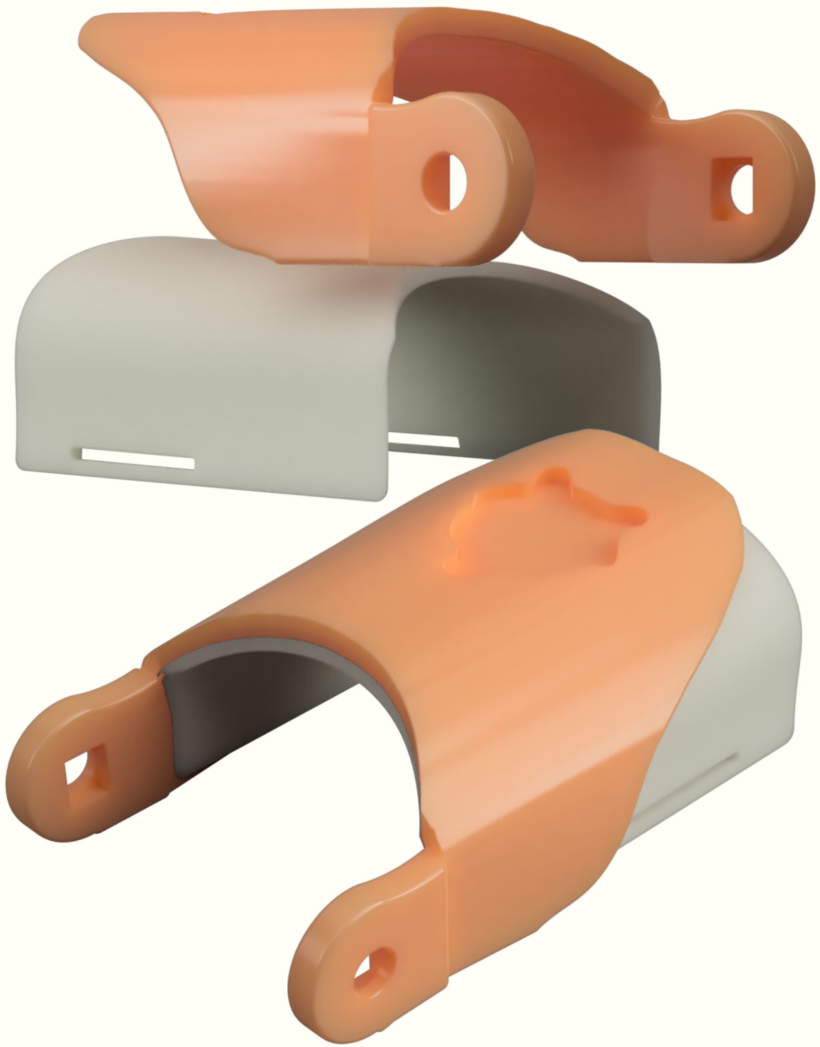


Figure 82: CAD model of final design

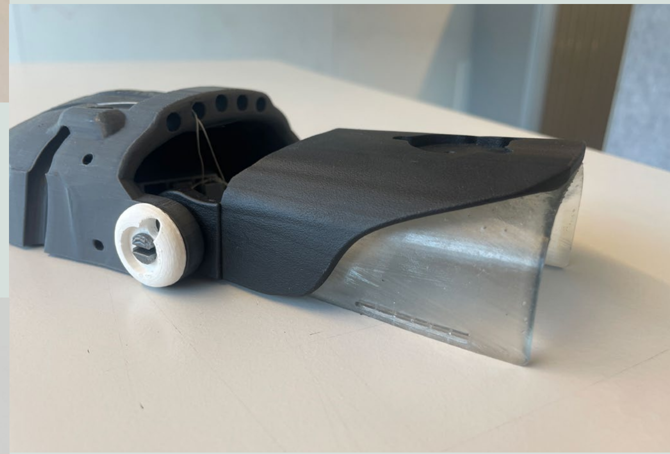


Figure 84: Prototyping design wrist component

Concluded from this prototype was that:
- The inner part of the wrist component should be longer to fit better around the wrist
- The cut-out for the BOA should be bigger.

The inner part is widened with 3 cm, taking into account the measurement of the wrist in Appendix N.
The BOA is remeasured and scaled on top of the outer part to make it fit better.

These improvements were made within the CAD as well in the physical prototype.
This resulted in the final prototype which can be seen in Figure 85.

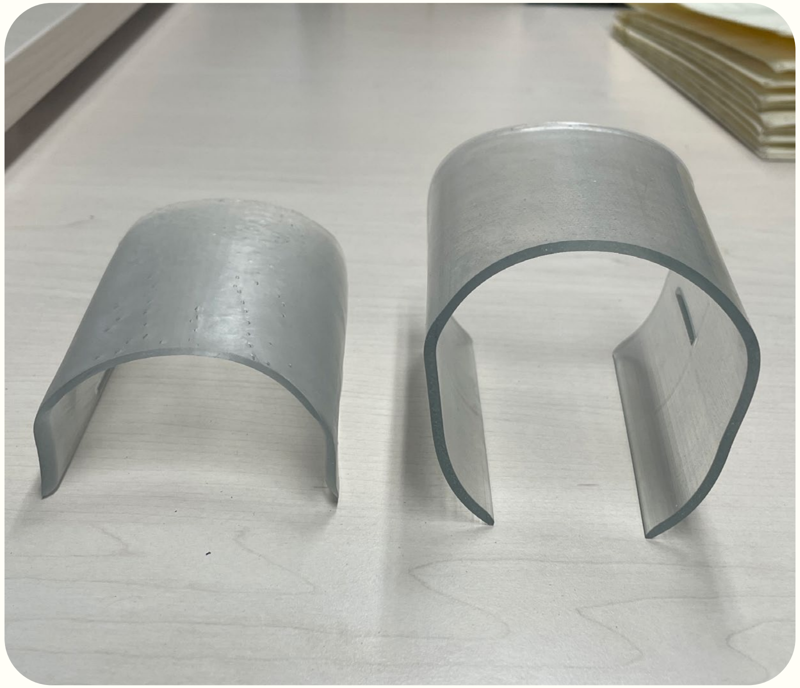


Figure 85: Longer inner part on the right, on the left is the first prototype

Besides the shape of the components, the colour of the hand and wrist component is also important to consider. Because this will contribute to the appearance of the prosthesis and will influence if the user is willing to wear the prosthesis.

A small consumer research was done to gain insights in the form and colour preferences (Appendix O). The outcomes showed that most of the people preferred to have a prosthesis that does not stand out too much. 66,7% said they wanted to have a skin toned prosthesis to blend as much with the arm as possible. 33,3% said they preferred to have a prosthesis in a neutral colour, like black, grey and white.

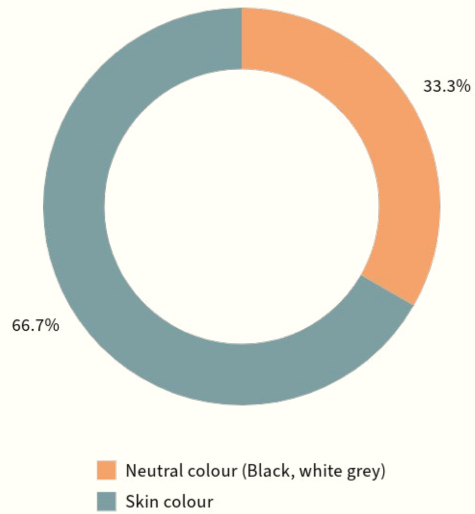
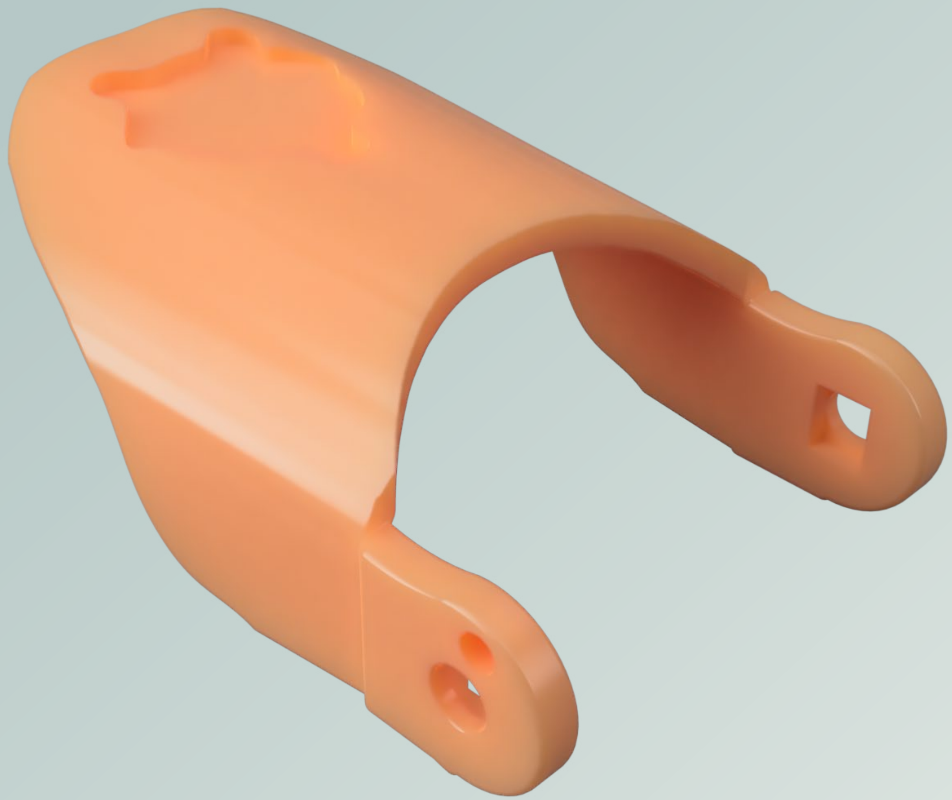


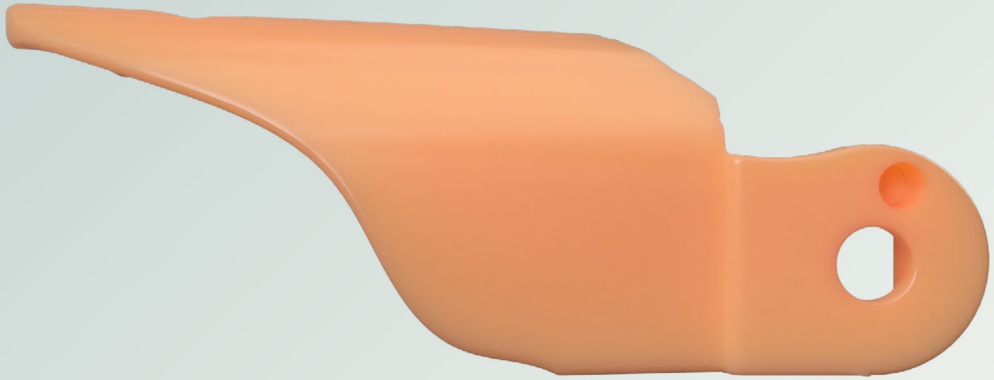
Figure 86: Preference for skin coloured prosthesis and not preference for a bright colour

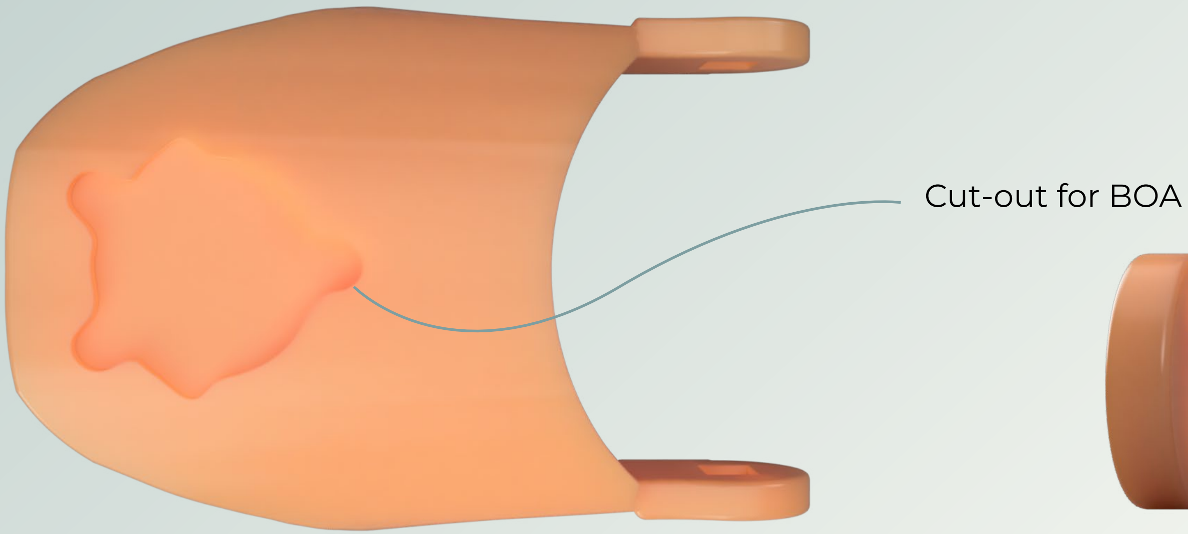
Discussing this result with employees from the orthopaedic centre made it clear that most of the prosthesis are made in a neutral colour, since the difference between a skin coloured prosthesis and the skin of the arm is very big. Choosing a skin coloured prosthesis will therefore stand even more out than a neutral colour.
As the occupational therapist already explained in the framing phase, it often happens that the patient even prefers to have a prosthesis that stands out since they think it looks cool.
This is a decision that is specific for every person. Therefore, like the finger component, the colour that the prosthesis should have can be decided by the user. For this project, there is chosen to design a prosthesis that is completely black. This gives the prosthesis a tough look which will fit this project's user. It is a neutral colour that is not bright so it does not stand out too much. The hand component that in the future will be made by OTA, will also have a black colour, like the example showed.

Figure 87: Prototype of wrist component as a whole

Outer part wrist component







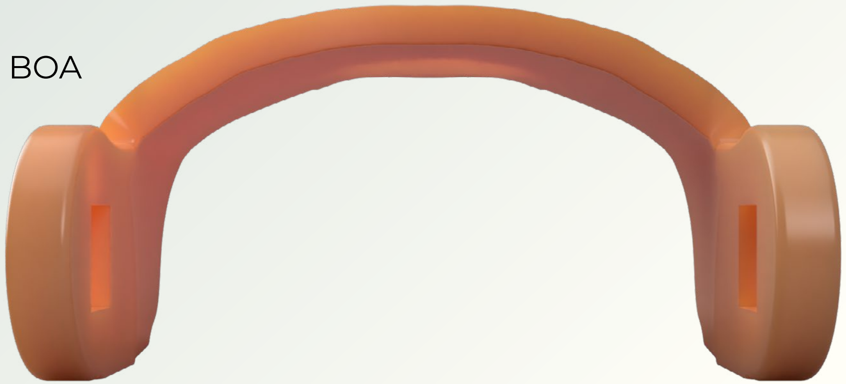


Figure 88: Renders of final wrist component, outer part

Inner part wrist component

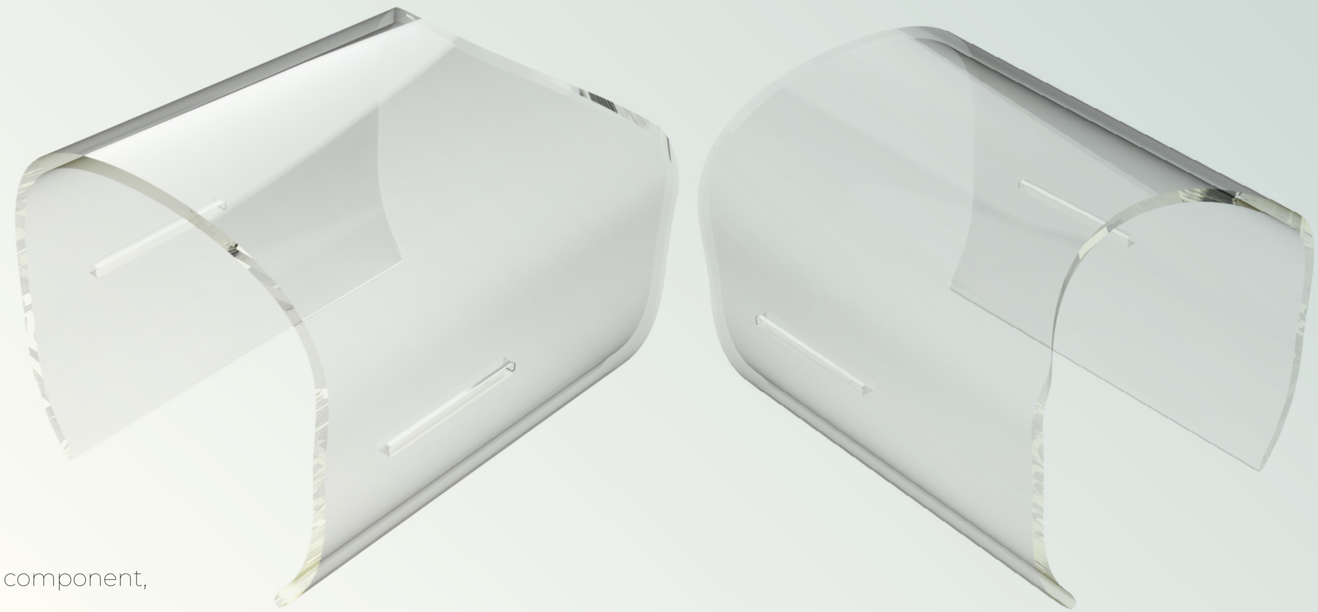
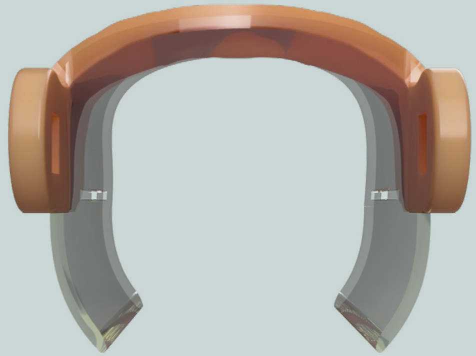
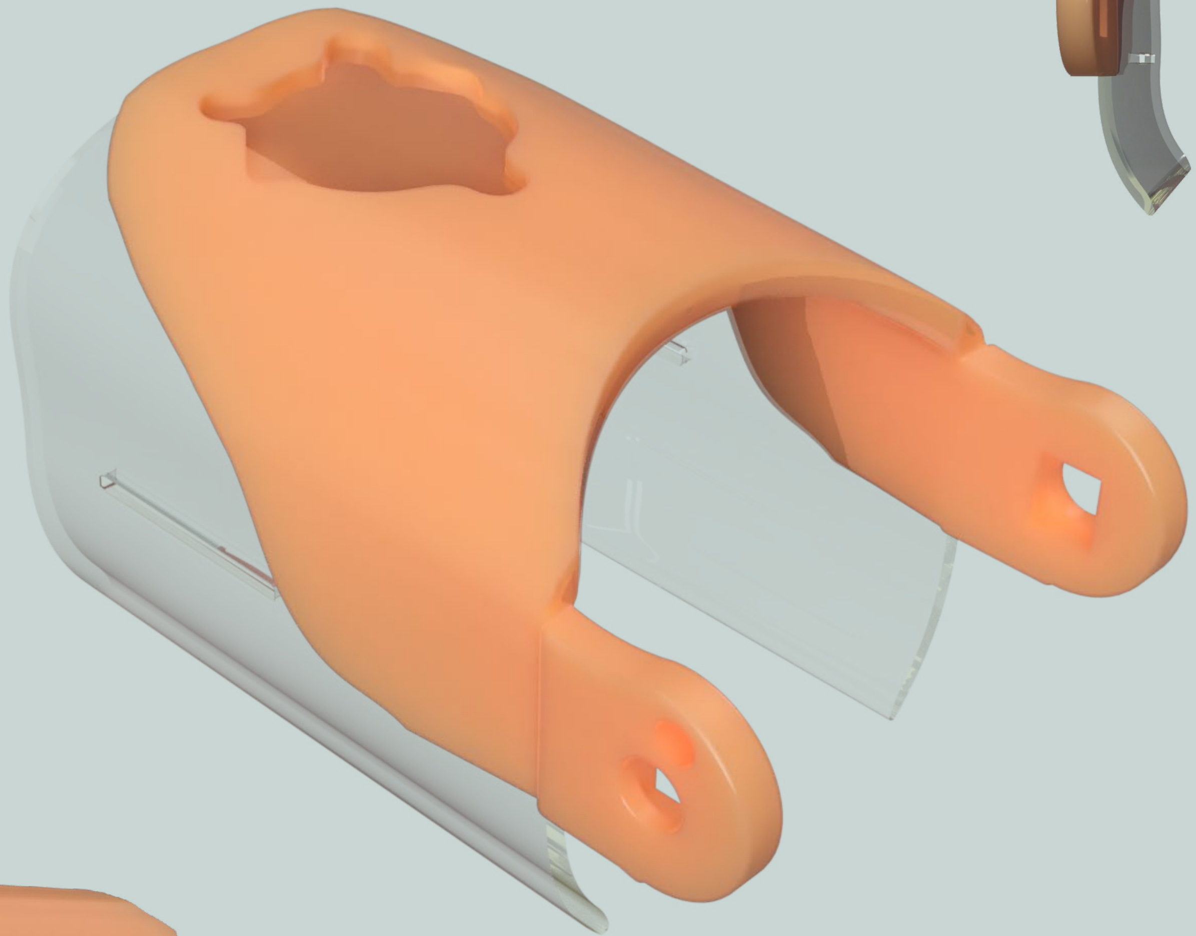


Figure 89: Renders of final wrist component, inner part

Wrist component





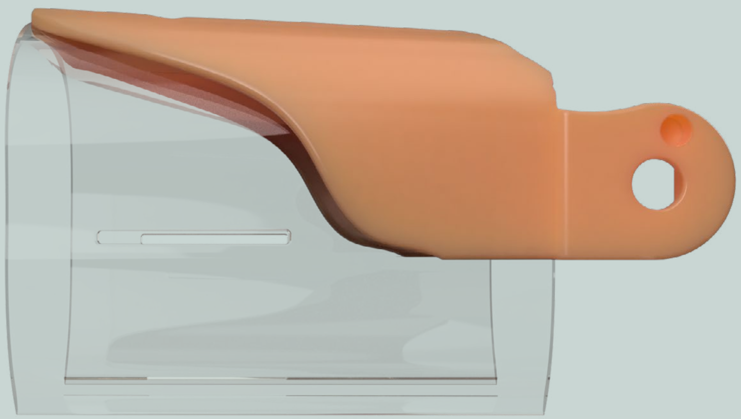


Figure 90: Renders of final wrist component, combined

4.6 Clamping mechanism

To ensure that the user is as little restricted as possible during ADL, a clamping system will have to be integrated. This will make sure that when the hand is flexed and therefore the finger is bending, that this position can be locked to release the wrist.

Since it is preferred that the prosthetic does not look very bulky, the options were limited. In Appendix P, is the first idea explained for further developments to integrate an automatic operating clamping mechanism. However, due to the time limit, there is chosen to focus on a clamping mechanism that needs to be released manually.

The reason why a clamping mechanism is preferred, is because it will make sure the user does not have to hold the tension in it's wrist when grabbing an object. This allows the wrist to relax and no force needs to be applied continuously.

The concept is based on the adjustable mechanism commonly found on rods, think for example of a walking stick. This idea uses the existing components from the hand and wrist.
The hand component has a small hole where a pin with a spring is attached. The wrist component also has a hole that holds a pin and spring on the outside of the part.
When the hand is turned, the pin falls into the hole, blocking the turning mechanism. Only when the pin is pushed from the wrist component to the hand component can the hand move freely. This mechanism is explained in Figure 91-92. As the hand component rotates when the fingers need to flex, this pin rotates with the hand component. As a result, it is pushed through the wrist hole, clamping the position.
A first idea for this was tested by using the hand component and the ring part, which can be seen in Appendix P. After prototyping several iteration steps, this mechanism resulted in the best result. The prototype steps and the integration in the final prototype is visualised in Figure 92. The location of the holes are shown in a CAD render in Figure 93.
The angle between the component holes (the number of degrees the hand has to turn) is 30° because this was the measured angle needed to bend the fingers in the first prototype.

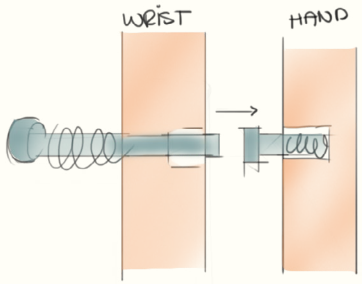


Figure 91: Explanation of clamping mechanism

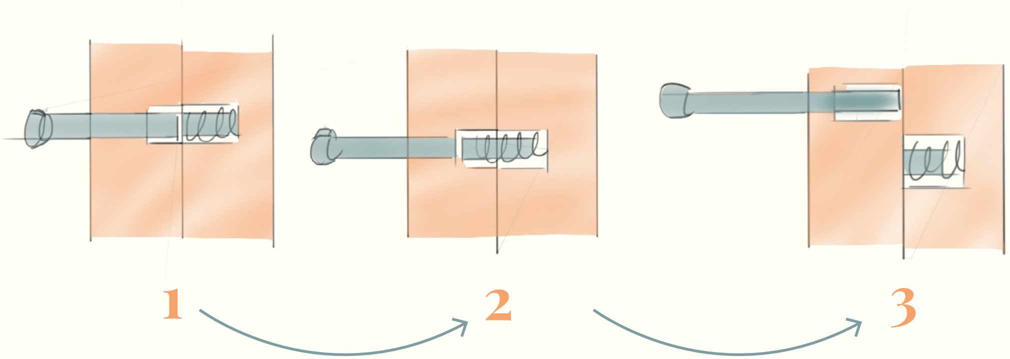


Figure 92: Steps to clamp the hand

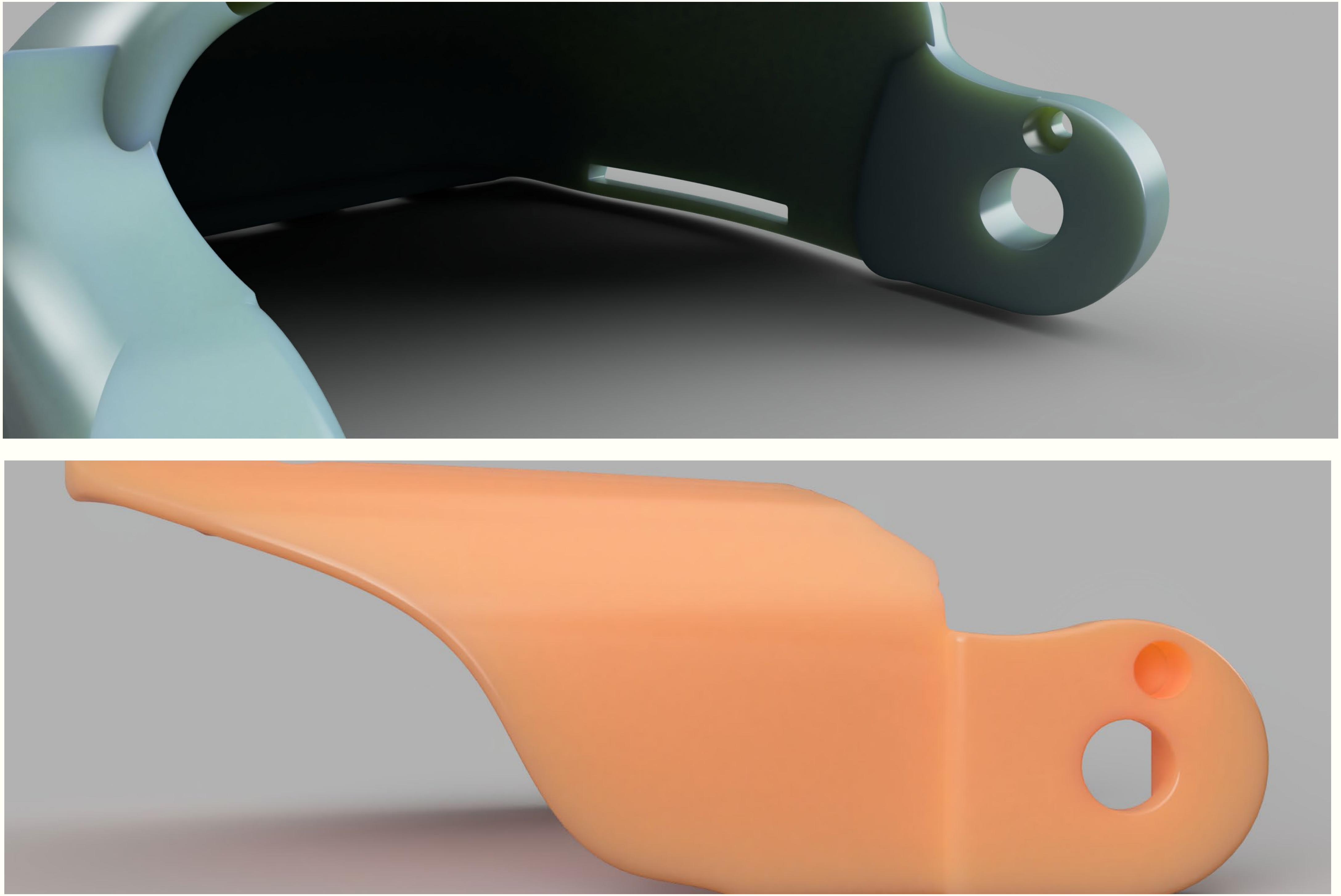


Figure 93: Renders of the hole in both components, 30° distance from each other.

Figure 94: Prototype and integration step of the wrist component

Figure 95: Prototype and integration step of the hand component

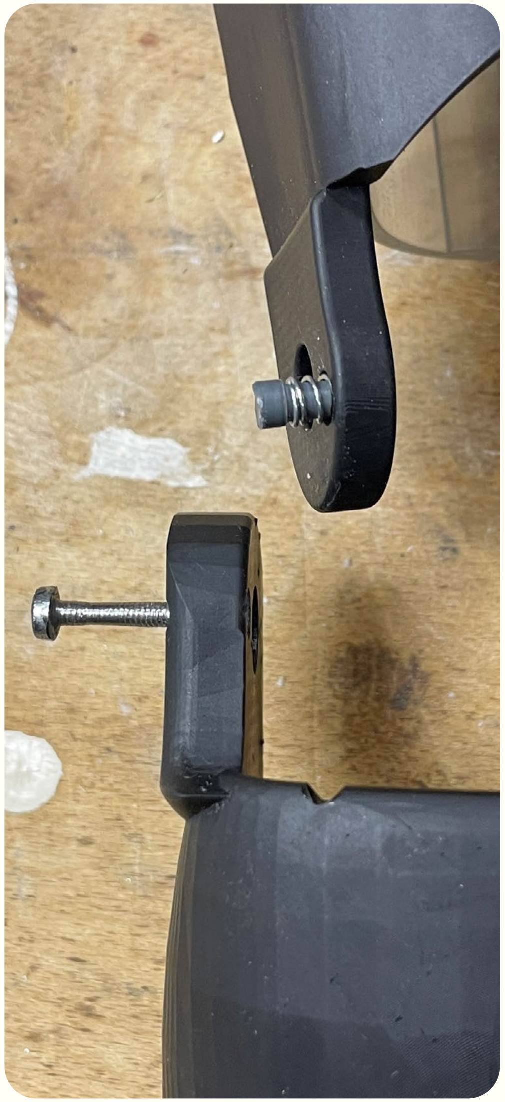


Figure 96: hand and wrist component with integrated clamping system

4.7 Connection

The created concept contains different components which are all connected with each other. This created the whole mechanism system that is able to deliver force from the wrist to flex the fingers.

Hand - Finger

To connect the hand component to the fingers, the principle from the online found CAD model is used. It is integrated in the new designed hand component where a pin is connecting the finger to the hand component.
The finger itself is shaped in a way that it perfectly fits the model of the hand. Therefore it is already tight connected but to be sure the finger is stable, the pin is added.

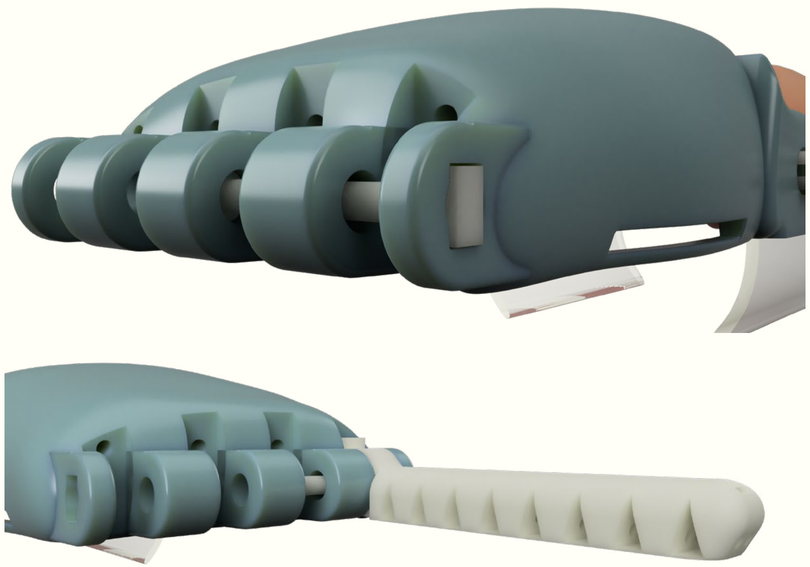


Figure 97: Connection between hand and finger

Hand - Wrist

The connection between the hand and the wrist works the same way. By pushing a pin through the wrist component all the way through the hand component, this connection is made. This pin is round and therefore the hand component can easily turn around this pin (Figure 98).
To make sure this connection is sturdy enough, a ring is placed at the ends of the pin. This way, the user will not scrape past the pin every time. On the other side where the clamping mechanism is placed, this ring has a hole in it, to ensure that the push mechanism can pass through it (Figure 99).

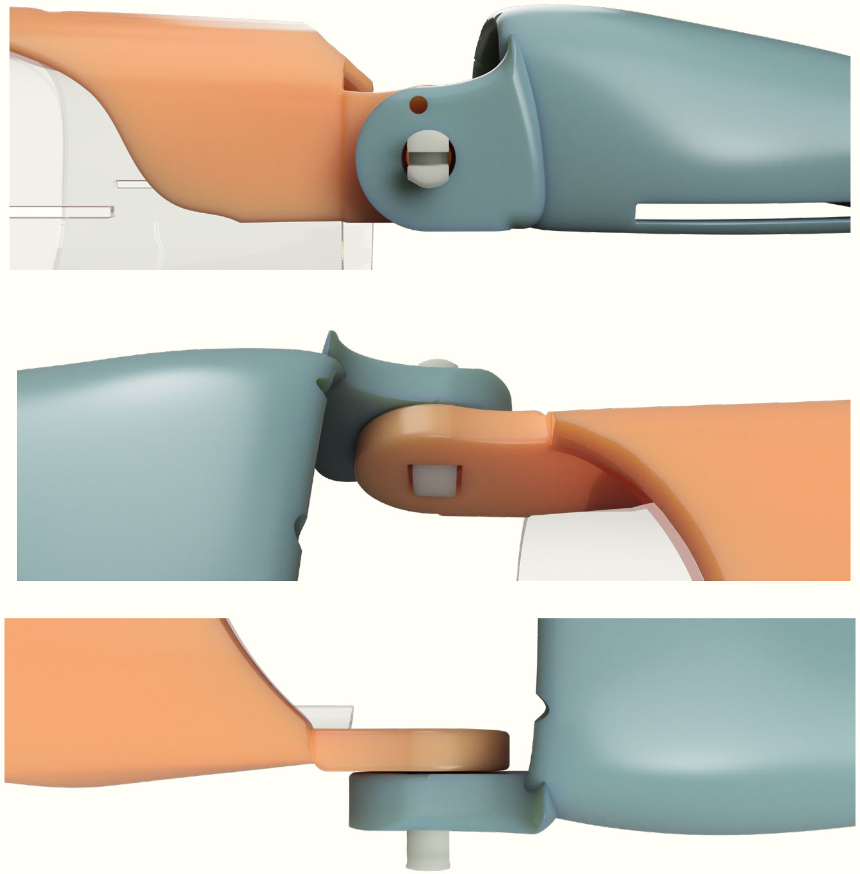


Figure 98: Connection between hand and wrist

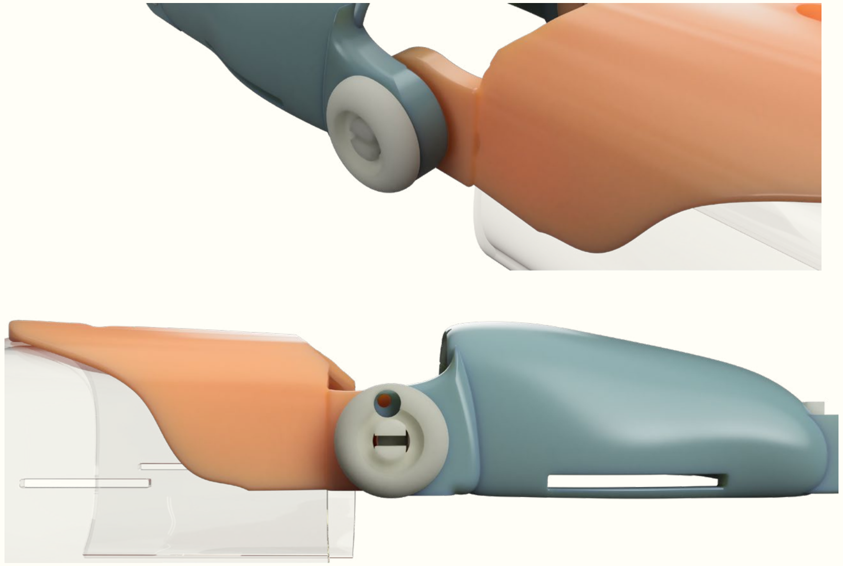


Figure 99: Connection between hand and wrist, with ring

Wrist outer part - Wrist inner part

The wrist component consists of two parts; the inner and outer part (Figure 100). The outer part operates as a shell and the inner part created the connection with the users wrist. These parts need to be connected as well, and due to the ergonomics, no screws or pins could be used. Therefore, these parts will be glued together.

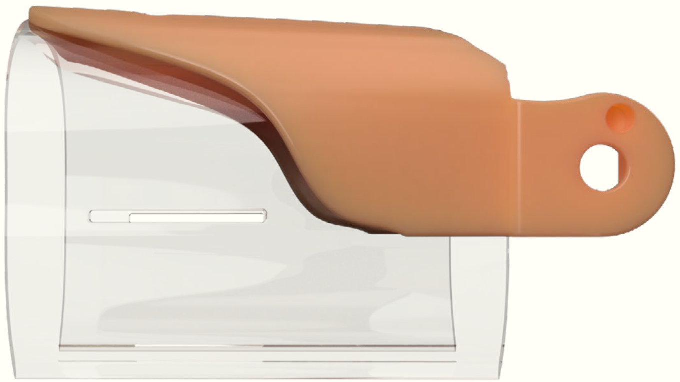


Figure 100: Connection between inner and outer part wrist

Wire control

The wires that is used to control the fingers, need to be attached to the wrist component. If this is not properly done, it is not possible to transfer the force from the wrist to the fingers. In the first prototype, a bulky block was used on top of the wrist. This was a bit wobbly and contained a lot of different parts, which is not preferred. To make the design less fragile, more elegant and feeling a bit stronger for the user, the BOA system is integrated.
The BOA system is a strong dial system that is used in a lot of products, like helmets and ski shoes.
By attaching the BOA, the strength of the wire through the finger can be adjusted and released easily. Therefore, the force and the natural position of the finger can be adjusted according to the users preference. It is a modular system that makes it possible to replace all the wires if one of them breaks.

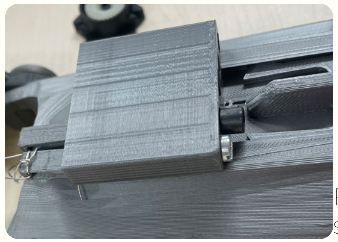


Figure 101: Wire system first prototype

Figure 102: Placing of BOA

Figure 103: Wire system using BOA

Wires

From each finger, two wires will go from the finger to the wrist. Two wires are needed instead of one to generate enough force and to attach the wires.
From the finger, the wires go through the hand component, see figure 104. The BOA contains one wire which can be tightened. This wire needs to be connected to the wires from the finger. When coming out of the hand component, all of the finger wires will come together at the wire from the BOA system. This way, 8 wires will split into two wires.
This is done by using a 3D printed split bar where the BOA wire goes through horizontally, and the finger wires go through in the opposite direction.
The wires from the finger can be adjusted in the length as preferred and attached to each other using a crimp bead, see figure 106.
The BOA system can be turned to tighten the BOA wire, putting all wires in tension.

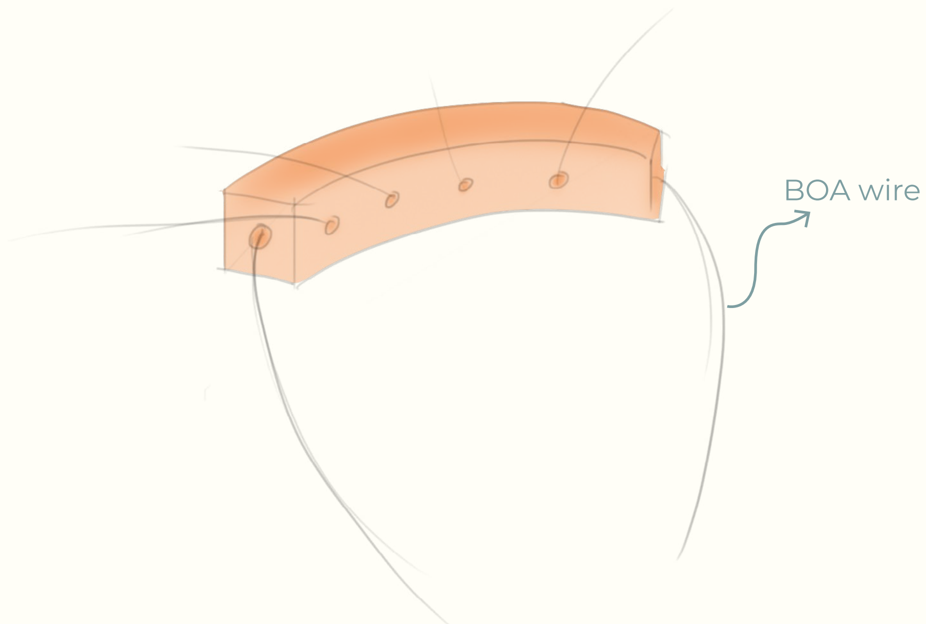


Figure 105: Explanation of split bar

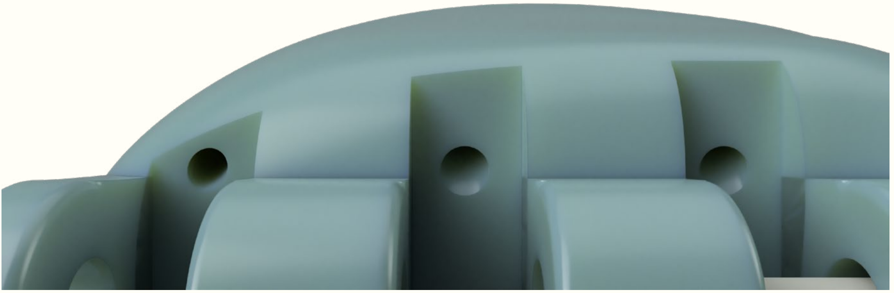


Figure 104: Holes within the hand which is connected to the holes of the finger

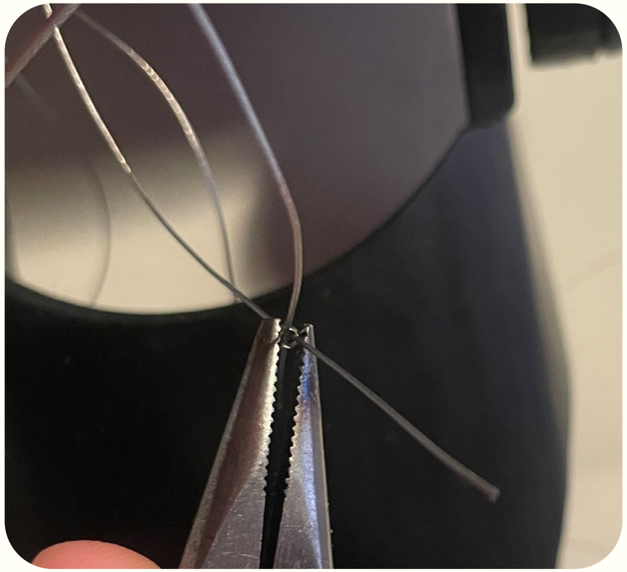


Figure 106: Crimp bead attaching two wires

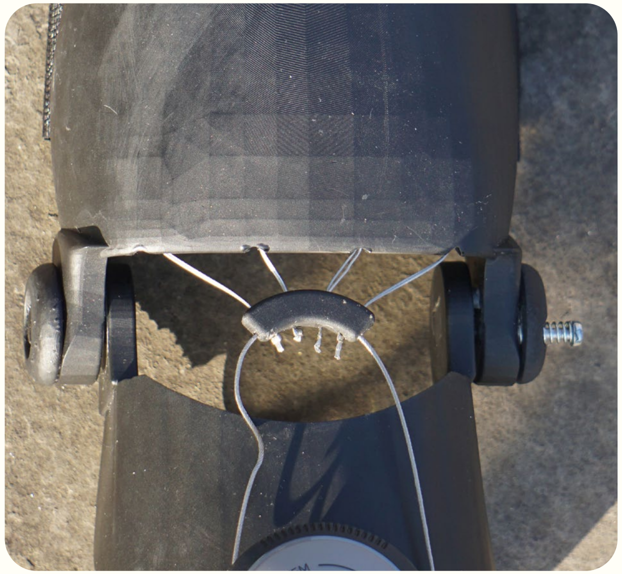
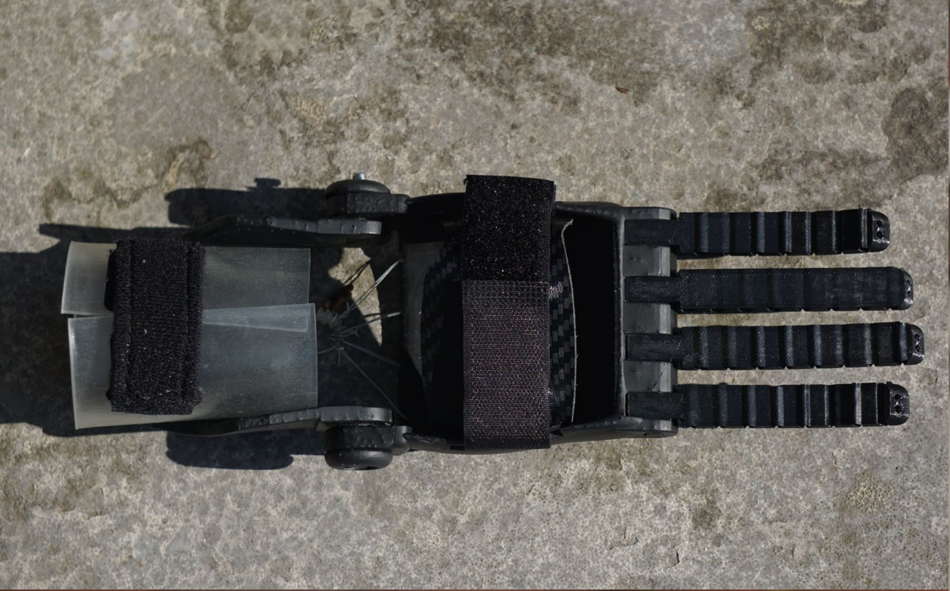
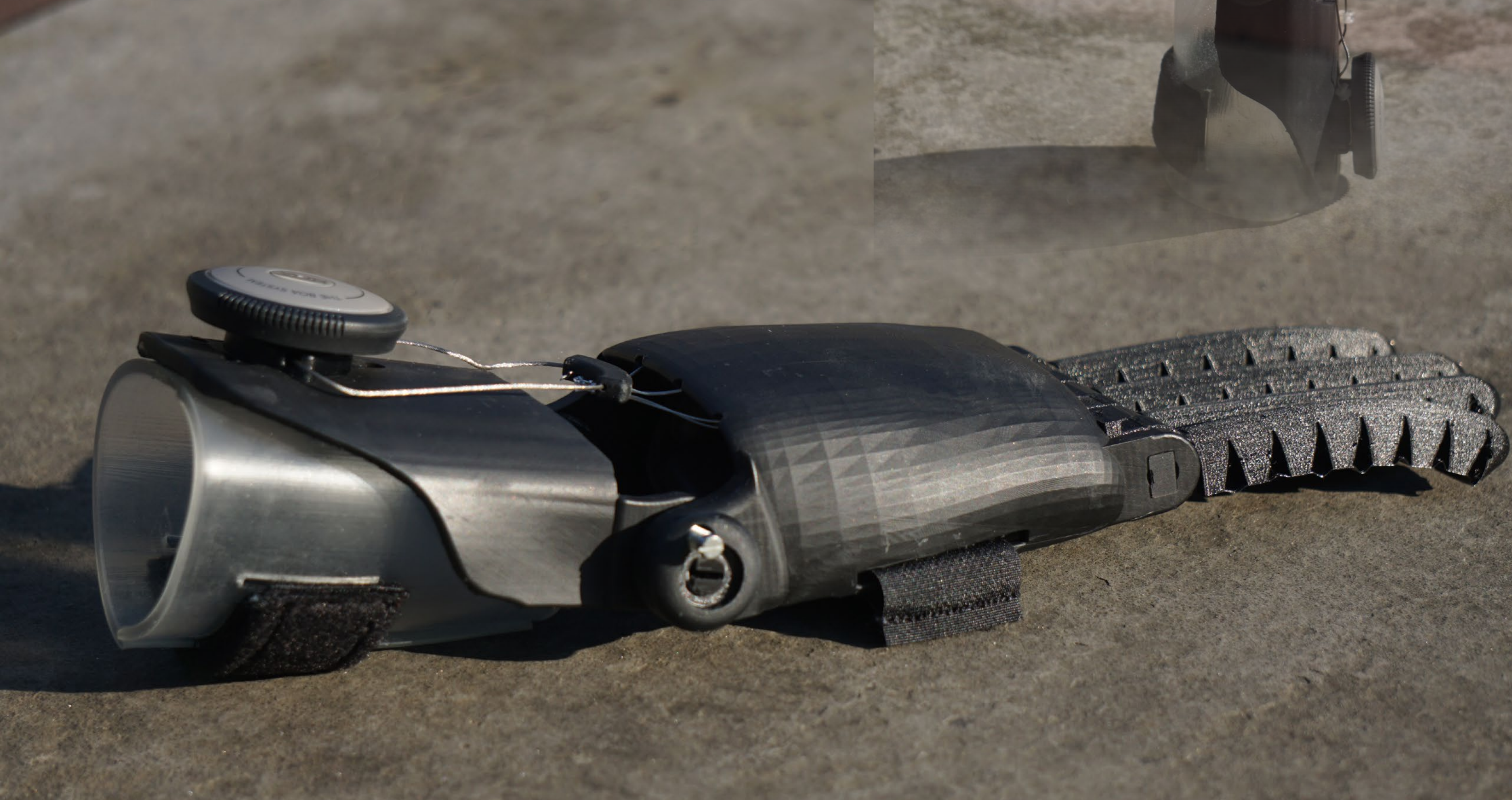


Figure 107: Split bar on prototype

Figure 108: Photo's o



All the components parts were printed and assembled to each other. The result of the prototype as a whole are visualised here.



5

Final Concept

5.1 Presentation of product

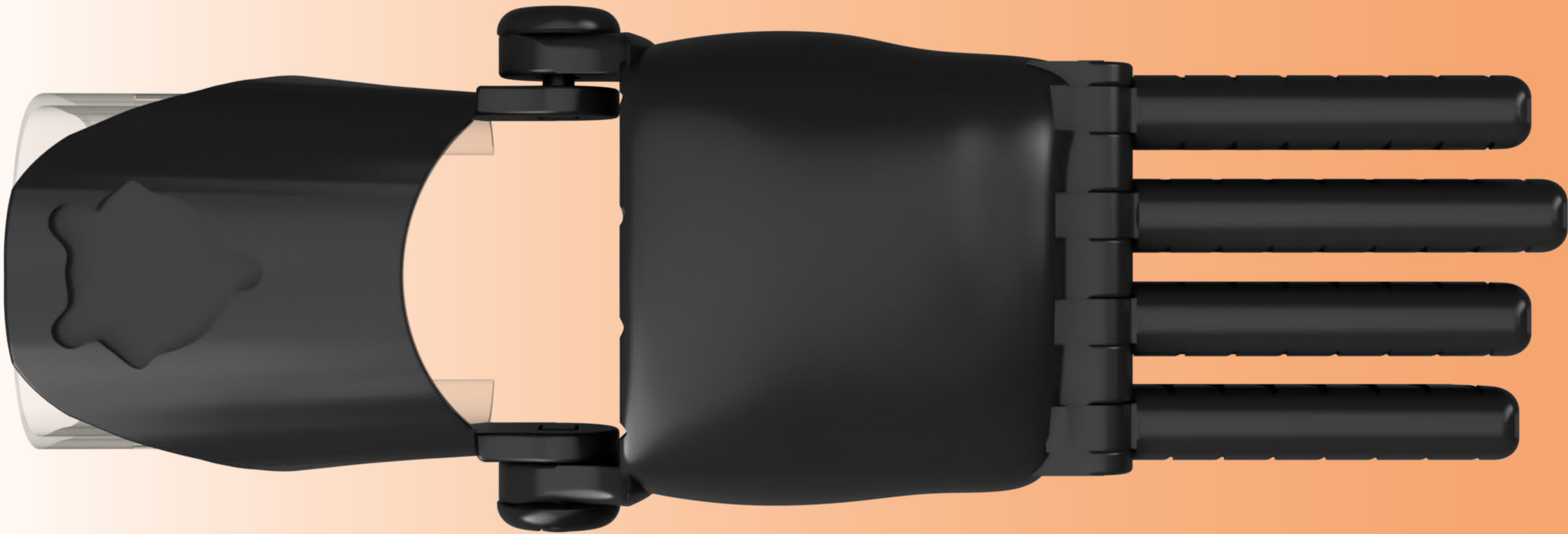


Figure 109: Top view prosthesis

Figure 110: Side view and positions prosthesis

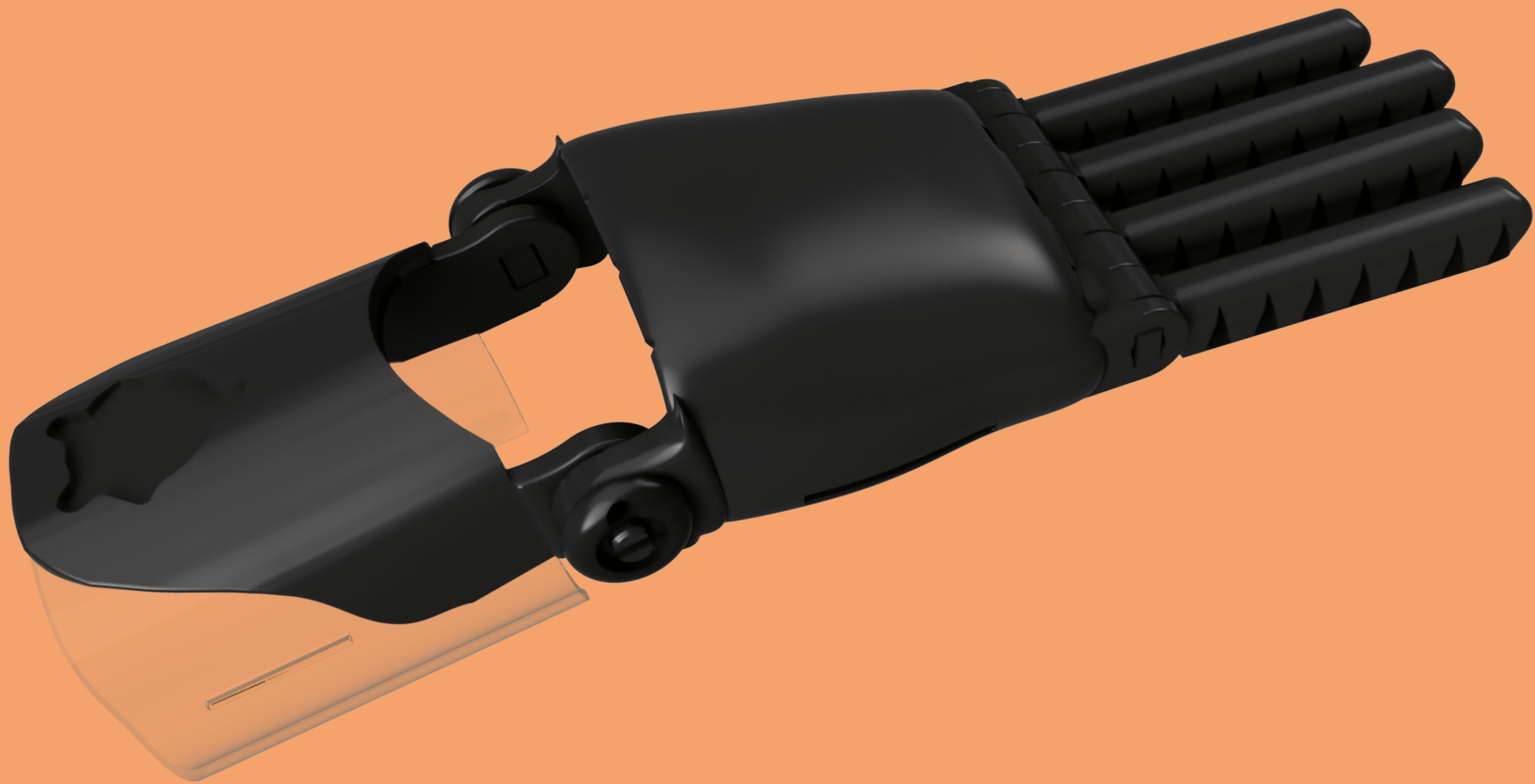
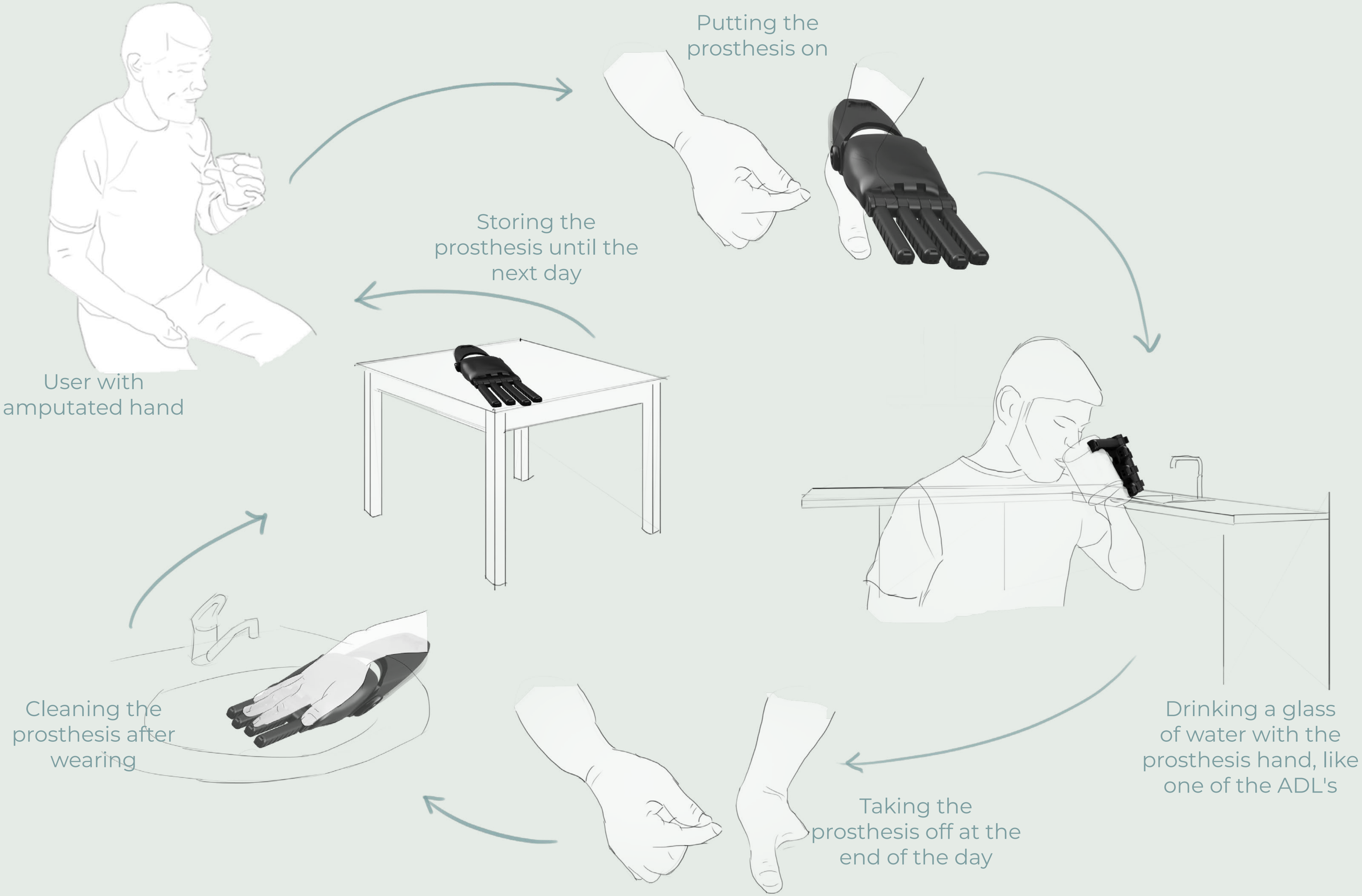
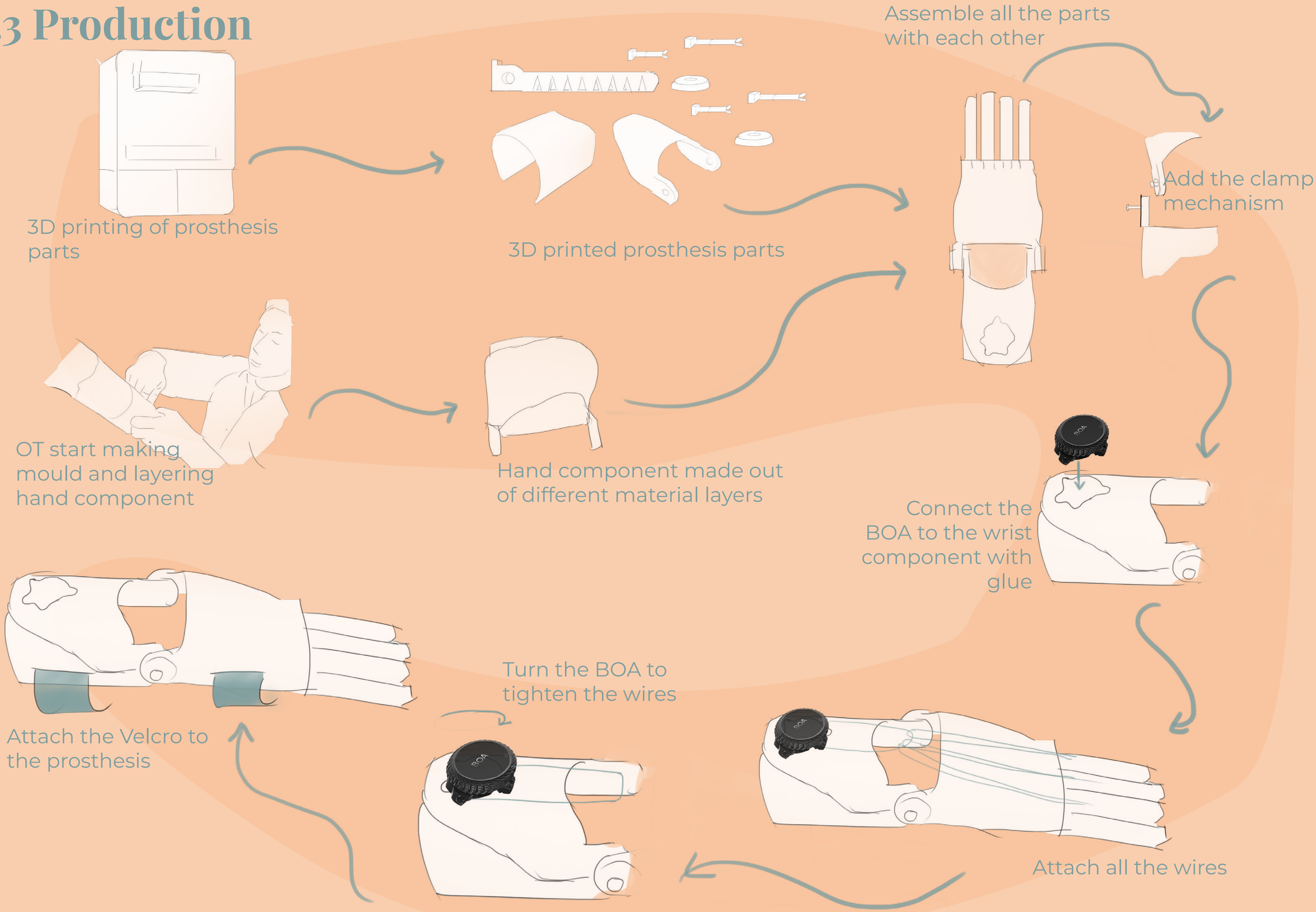


Figure 111: 3D view prosthesis

5.2 Product in use



5.3 Production



5.4 Repairment

When using a product for daily activities, it can happen that it breaks. The wrist component can tear or the wires can break. It is therefore important to think about the repairment. For the soldiers here in The Netherlands but also in other countries who received their prosthesis from OTA. The 3D technology provides opportunities to repair the prosthesis locally. A roadmap is shown on this page.

1 Part of the prosthesis breaks

2 Contact Orthopaedic centre from MRC

3 Defect parts will be printed again

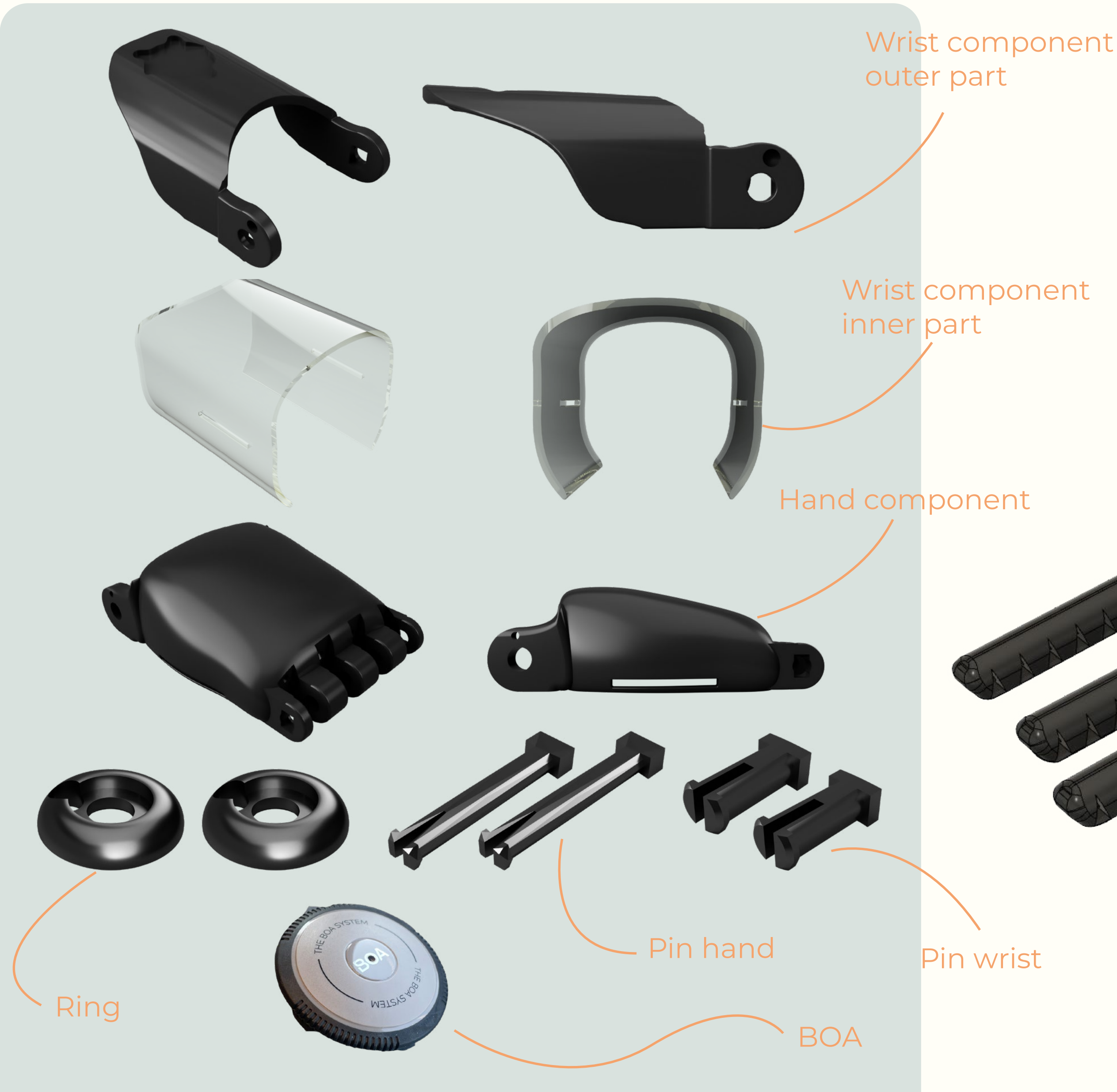
4 **In The Netherlands**
Bring prosthesis to MRC to let them repair

4 **Abroad**
Print prosthesis parts on an available 3D printer nearby.

5 Repair the prosthesis yourself by following the detailed instructions

5.5 Components & Dimensions

All the needed components of the prosthesis are listed below.
The dimensions of each component is visible in Appendix Q.



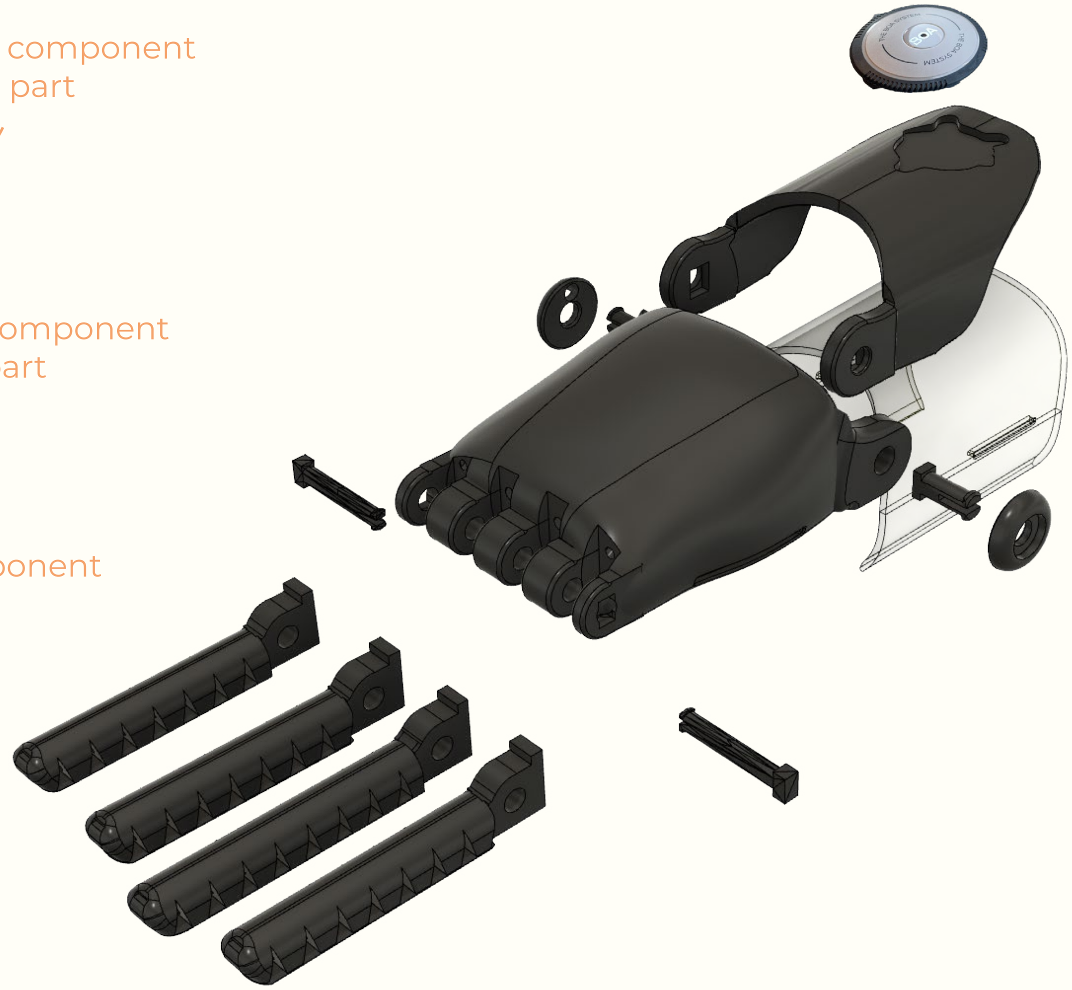


Figure 112: Exploded view prosthesis

5.6 Colour

Throughout the process, from different perspectives there was looked at the preference for the colour for the prosthesis. Concluded was that this is difficult to decide for the user, since not everyone want to stand out too much or prefers to wear a skin toned prosthesis. That is why there was decided to let the user choose which colour they prefer for their prosthesis. This makes it more customizable and the chances are higher that they are more willing to wear their prosthesis.
The used production technique offers this possibility so it would not cost extra and is not more difficult to produce.

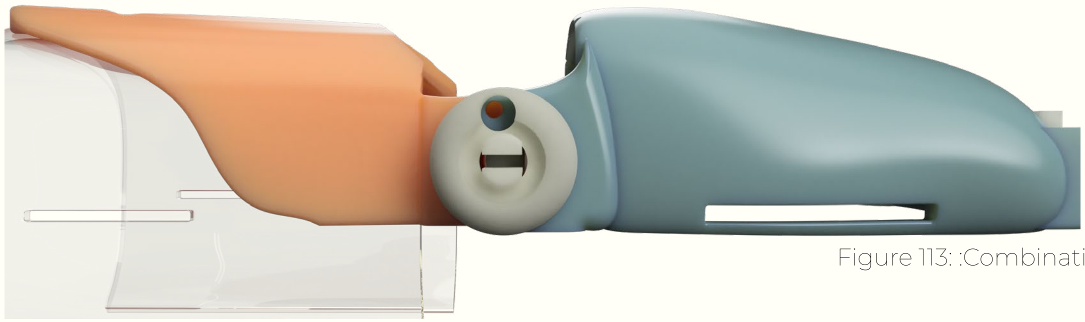


Figure 113: :Combination of colours

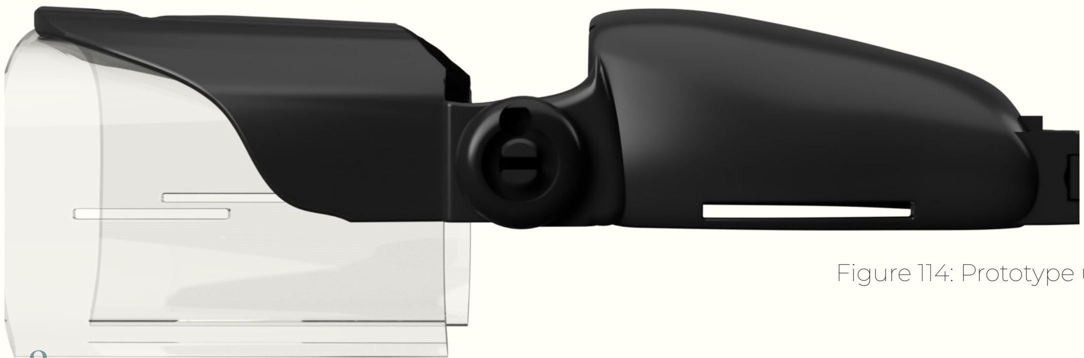


Figure 114: Prototype used black colour

5.7 Name

Presenting the name of the designed prosthesis: **ExoScorp.**

Exo, symbolizing its essence as an exoskeleton, an external framework that seamlessly is connected with the user. **Scorp**, inspired by the scorpion, a creature of resilience and power. Like the scorpion's segmented tail that elegantly curls, the design mirrors the fluidity and strength of the integrated finger design. The scorpion embodies firmness with its unyielding shell, a fitting analogy for the military soldiers.

This name it medical but it also resonates with the mindset of its user; toughness, resilience, and powerful.

And finally, the Scorpio holds a personal connection to me, the designer, as my zodiac sign.

ExoScorp is not just a name. It is a story, a symbol to strength both within and without, bridging the medical and the meaningful.

This is ExoScorp.

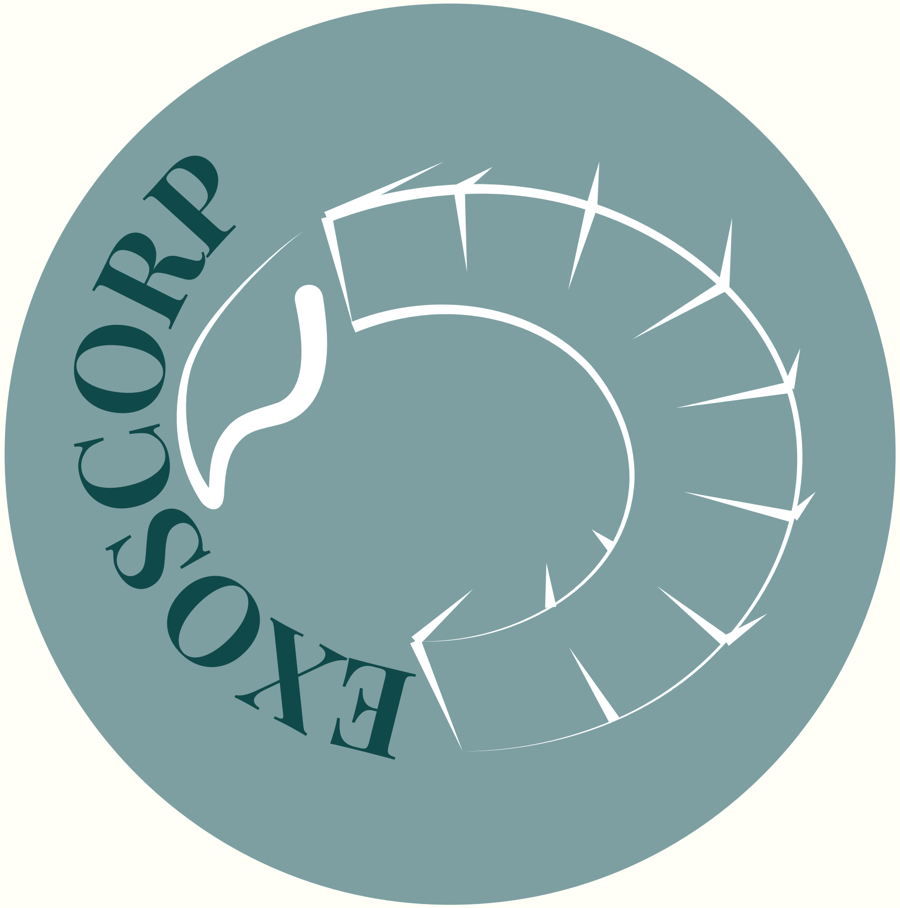


Figure 115: Logo ExoScorp

5.8 Estimated costs

A cost estimation was done, to roughly estimate what the price of the prosthetics will be. To do this, the construction template from the TU Delft was used.
An estimate has been made because it is difficult to know all values with certainty. The used values will be close to the realistic prices and percentages. The cost estimation can be seen in Appendix R.

Production cost

The production cost from the ExoScorp is based on several data.
The material cost was estimated first. The price of all the used material and its units is calculated . The total material cost is around **€40,26**

Next the processing costs of the printers are estimated by defining the capacity and the machine hourly fee. Calculating this results in a total machine cost of **€38,00.**

Following this with the total labour costs, which is a rough estimation since there is not a lot of human/machine occupation needed to use the 3D printers. Estimated is that this should be around **€38,00** per print.

The installation costs of the printers is defined by the installation time and the labour cost to do this. For the Ultimaker this will be around **€26,50** and for the Formlabs SLA printer this will be around **€26,30**.

The equipment costs were defined, using the online available data and comparing this with other companies. Estimated is that this will be a total of **€1,86** when resale value is included.

This results in a subtotal cost of **€132,92.**
Including the general charges, like the failure-factor, the production cost is estimated to be around **€154,18.**

Bill of materials

1	Inner part wrist	1	BioMed Flex 80A
1.1	Outer part wrist	1	Formlabs Photopolymer
1.2	Hand	1	Formlabs Photopolymer
1.3	Finger middle	1	TPU 95A
1.4	Finger index and ring	2	TPU 95A
1.5	Finger pinky	1	TPU 95A
1.8	Pin hand	2	Formlabs Photopolymer
1.9	Pin wrist	2	Formlabs Photopolymer
1.10	ring	1	Formlabs Photopolymer
1.11	ring with hole	1	Formlabs Photopolymer
1.12	BOA	1	
1.13	Wires	4	Coated steel
1.14	Velcro	2	Velcro

Table 5: Bill of materials

Frabricage cost
The cost of the ExoScorp is estimated to be around **158,39.** To define the cost of the fabrication of this product, the procurement and assemble costs need to be considered.

Each material that is needed for the prosthetic, including the wires and BOA system, has to be included in the price. Defining every material will result in a total procurement of **€117,77**.

The assemble costs needed to be calculated next. However, this is difficult to define since this is not concrete. Taking into account the total time needed for the Formlabs washer and curer and sewing and connecting all parts, a total machinery cost was estimated to be around **€23,75.**

In the last step, the total labour cost was estimated to be around **€101,00.**
The sum of all these total costs, will define fabrication cost of **€400,91.**

Retail price
The retail price is hard to define since it is a medical product and the product will not be sold in a shop. However, this cost is calculated to have a rough overview of the cost when taking into account the VAT and profit margin. The VAT on medical products is 9% in The Netherlands. The profit margin is estimated to be very low, since the rehabilitation centre will be the 'seller' and the profit that is needed for a medical environment will be lower than for a competitive seller. Combining all the percentages and production cost of the product will result in a retail cost of **€802,85.**
This is lower than the requirement that stated that the cost of the prosthesis should be lower than **€1000,-.** From this, it can be concluded that the prosthesis is cheap enough, which was one of its main goals.

One side note is that the hand component is now 3D printed but this will not be the case in the future. This will lower the printing costs but other materials are needed to make this hand component. Furthermore, it is custom-made which is more expensive than a standardized production. Therefore the prices can change but this is not possible to estimate already.

5.9 Benefits

The designed prosthesis offers the user as well as the Militair Revalidatie Centrum a lot of benefits. The design creates possibilities, looking at different aspects of the product. The most important benefits are explained in this chapter.

Functional benefits

- The prosthesis is intuitive and easy to operate, so users quickly get used to using it.
- Due to the finger's use of flexible material, it easily bends and forms around an object. The construction of the segments provides strength in the directions required but flexibility when the finger needs to bend. This contributes to a great freedom of movement.
- No loose parts are integrated in the finger, making the finger sturdy and less prone to damage.
- The prosthesis fits any arm by using a flexible material which is adjustable through the use of Velcro. The fingers can be printed in different sizes to match the user's desired ergonomic preferences.
- The use of lightweight materials makes the prosthesis comfortable to use.
- The prosthesis is easy to clean which increases its lifespan. The material is water and dust resistant.
- In the future, the prosthesis will integrate with the specialized work of an Orthopaedic Technologist. The components are designed to be fully compatible with each other, a feature that does not exist yet. The hand component will be custom-made for a perfect fit using specialist techniques. This will be combined with a fast, modular, and 3D-printable system, making the prosthesis fit for any type of amputation.
- When the fingers are bent, the prosthesis can be locked in this position. This prevents the user from having to hold the prosthesis in an unnatural posture, making it easier to hold objects. By pressing the button, the prosthesis returns to its natural position. This improves the ergonomics and offers comfort in daily activities. This feature is not yet available in current body-powered prostheses, users in these cases need to keep tension on the wrist to hold something.
- With a wide range of sizes and customization options, the prosthesis is available to a larger user group.

Technical benefits

- The used materials are strong and easy and affordable to produce. If a part breaks, it can be quickly repaired, eliminating long waiting times.
- If a component needs repair, the necessary files can be sent digitally. Even abroad, the prosthesis can be quickly repaired by printing the parts locally. This reduces waiting times and the need for a temporary replacement hand. The user can receive their own prosthesis back in a short time.
- Modular components make it possible to easily adjust the prosthesis to the user's needs.
- The prosthesis is made from standard CAD components that can be printed in advance. The components are ready within a day, eliminating long waiting times.

Medical benefits

- The ergonomic design improves to the user's comfort, which will increase the chances that they will use the prosthesis more often.
- The prosthesis supports a more natural movement, which contribute to their rehabilitation process.

Psychological benefits

- Since the prosthesis can be customized in colour, the user can personalize it, which increases the chances that they will feel more comfortable with the design. This will probably lower the threshold to use the prosthesis.
- The prosthesis stimulates the ability to participate in ADL, which will contribute to the feeling of being able to keep up with everyday tasks in life.

Economic benefits

- By using efficient production processes and materials, the prosthesis is more affordable than many existing alternatives. This makes the prosthesis more accessible to users and makes it possible to be purchased without insurance. This results in a prosthesis that everyone has access which is affordable and functional.
- The durable construction and simple maintenance make the prosthesis cost-effective in the long term.
- Because of the the modular system, the prosthesis is easy to assemble and disassemble. If something breaks, there is no need to create an entirely new prosthesis. The damaged part can be printed and replaced which will save costs and reduces material waste.

6 Evaluating

6.1 Testing final prototype

In order to test if the product meets the expectations and requirements, a prototype test was done. Since this is a medical product and the prototype will not fit the patient due to the specific trauma, a user test is not possible to complete. Therefore, all the measurable requirements were evaluated and tested.

Method

The test is executed according to the following steps.

1. The prototype is fixed in a lathe or is tested attached to the hand.
2. Using a pressure gauge, weighing scale, protractor and an unster, the forces, angle and weigh are measured. Each measurement is done three times and the average is calculated and used as result.
3. De results are compared to the requirements that were defined during this project.
4. If occurring, deviations are documented and analysed.

Analysis

The results of the measurements can be seen in Table 6.

The amount of force that the fingers were able to give, were measured with a pressure gauge.
The minimal pinch force is defined to be above 10.4 N. This measurement is difficult to execute since this is the amount of force that the thumb against the index and middle finger can apply. This requires measuring instruments, like expensive sensors, that can be added to the thumb and the prosthesis which was not available.
Therefore the force that the finger can apply when it is flexed, was measured. This measurement resulted in a force of 10N. It is slightly below the requirements. As explained earlier, the adjusted design of the finger has an influence on the force the finger can apply. By optimising this design, this result can be improved. It has already been proven that this is possible and that there are plenty of opportunities for improvement.

The power force refers to the strength with which all fingers can enclose an object. For the same reasons this is a difficult measurement to execute. Therefore, the enclosing force of the fingers on the inside has been measured. This resulted in 9N per finger, which is far above the minimum. Detailed measurements still have to be done in next steps to validate.

Requirement	Equipment	Result
1. Minimal Pinch force of 10.4 N	Pressure gauge	10N
2, Minimal Power force of 1 N	Pressure gauge	9N
3. Maximum Activation force of 38 N	Pressure gauge	15,3N
4. Minimal push force is 6N	Pressure gauge	19,6N
5. Angle finger range of 40-50°	Protractor	45°
6. Angle wrist rang of 0°-60°	Protractor	31°
7. Weight of maximum 273 g	Weighing scale	244 g

Table 6: Requirements, used equipment for measurements and results

The activation force that is needed from the wrist is much lower than the requirement. The result of 15N was measured with two fingers attached, since this is a realistic situation. To do a tripod and power grip, not all fingers are needed. In the research phase was already explained that when all the fingers are amputated not all the finger will be replaced in the prosthesis. When only the pink and ring finger are amputated, probably a prosthesis is not even needed. Therefore the measurement was done this way. However, the results when more fingers are attached can be seen in Table 7. Concluded from these results can still be said that the requirements will be met when four fingers are attached.

The minimal push force that is needed to achieve this requirement has been met. However, this is lower than the measured results of the finger design variations in chapter 4.3. It is not low and it meets the requirements but it shows that improvements will be possible. The expected cause for this is because the finger design was improved after the test by making a rounder finger, which affects performance.

The weight of the prosthesis including all the elements and fingers is 244 g, which is below the maximum weight to wear a prosthesis that is comfortable for the user.

The wrist angle and the finger angle were measured with a protractor. Both angles are between the requirement values and therefore also achieved.

All requirements have been successfully met with a wide margin, except for the pinch force. This can be improved my optimizing the design of the finger and to vary within the design and printer settings, as was explained in chapter 4.3. Therefore, this is not a problem and will not result in prosthesis that is not sufficient. Concluded can be that the prosthesis still requires improvements but will be able to comply in the future.

Other measurements

Besides these requirements which can be measured with equipment, other requirements were also defined. These requirements are listed in Appendix H and are evaluated whether they have been achieved. Other measurements and prerequisites that were defined during this project were evaluated as well, since this is interesting for the future steps. These can be seen in Table 8 on the next page.

During the embodiment phase, several measurements were done for the finger. These measurements are repeated with the final prototype and are compared in Table 7. However, the initial testing was not as extensive due to a limited number of fingers available for testing, making direct comparisons difficult. The results indicate that bending the finger was easier with the second prototype than with the final version, though the force required from the wrist was lower in the final version. This can be cause by the improvements of the hand component, reducing the friction of the wire.

The finger design in chapter 4.3 with an increased angle between the segments showed the best result. The design had to be improved and therefore the properties of the finger changed. The force that was needed to bend the finger in the best case scenario was 13,7 N. In this case, this 19,3 N. This is slightly higher, but still the third-best result of the 10 design variants. Adjusting the angles between the segments could improve this design.

Measurement	2nd prototype	Final prototype
Force needed to bend 1 finger	1,4 kg	1,97 kg
Force needed to bend 2 fingers	-	2,9 kg
Force needed to bend 3 fingers	-	3,47 kg
Force needed to bend 4 fingers	-	3,9 kg
Force from wrist needed to bend 1 finger	19 N	14 N
Force from wrist needed to bend 2 finger	-	15,3 N
Force from wrist needed to bend 3 fingers	-	23 N
Force from wrist needed to bend 4 fingers	-	26 N

Table 7: Measurements compared to earlier measuremets

Prerequisite	Conclusion
Ambition from OTA is to utilize 3D printing.	Achieved
The prosthesis must support both a tripod and power grip.	Finger position to be improved
The user should be able to bend the finger without applying excessive force.	Achieved
The prosthesis must not be fragile.	Achieved
The palm must remain uncovered for sensory feedback.	Dependent on design MRC
It should be ergonomic and not cause skin damage.	Dependent on user tests
The prosthesis should appear as a single unit, not as separate parts.	Opinion users
It must be produced quickly and efficiently.	Achieved
There should be no long wait times for production.	Possibility is there
The production process must be cost-effective.	Achieved
The prosthesis should be easy to tailor to individual needs.	Achieved
It must not be too bulky or robust.	Opinion users
The prosthesis should be attachable with one hand.	Achieved
A one-size-fits-all solution is not acceptable, as every amputation is different.	Achieved
The costs should remain as low as possible.	Achieved
The prosthesis should be shareable across different locations.	Achieved
Design freedom should allow for customization in both appearance and functionality.	Only appearance
The prosthesis should be useful in various situations.	Dependent on user tests
It should feel comfortable and natural during use.	Dependent on user tests
It must be quickly and efficiently manufactured.	Achieved
The production process must remain inexpensive.	Achieved
The finger should be able to bend easily by using soft material.	Achieved
The finger should be stiff enough to press a button.	Achieved
The finger should expand automatically when the force decreases.	Achieved
Preference for standardised production methods.	Achieved
Should be able to be printed using a precise printing technique.	Achieved
The resistance of the wire should be minimal.	Improved
Not too difficult material to 3D print.	Achieved
Fast and cheap to print	Achieved
There should be as few loose parts as possible as this makes the model more fragile	Achieved
Bulky constructions should be minimised as much as possible	Dependent on user tests

Table 8: Perequiste and conclusion

6.2 Conclusion and discussion

This project has resulted in an affordable, modular prosthesis that offers not only cost benefits but also advantages in ease of use, comfort, and aesthetics. The prosthesis is designed to meet the needs of soldiers in rehabilitation, with a focus on customization, production, repairability, and accessibility.

The design goal for this project was formulated as follows:
"My goal is to design an affordable body-powered hand prosthesis to restore the functionality of the hand after a partial hand amputation and which will enable the user to perform ADL tasks."

This project has demonstrated that, by using a modular design and an efficient production technique, an affordable body-powered prosthesis can be developed.

The key functionalities targeted for the hand were the tripod grip and power grip. The prosthetic fingers are designed to flex and extend, mimicking the natural motion of a human hand. However, the current prototype does not yet position the fingers optimally. In theory, the fingers should be able to touch the thumb when flexing, but this could not be tested with the current design of the prototype. Future iterations should focus on refining finger placement for an improved functionality.

The prosthesis can deliver a power force of 9N when flexing all fingers and a pinch force of 10N. While these forces are already high, further development is required to improve its performance.
All measurable design requirements were evaluated in Chapter 6.1, confirming that the current prosthesis meets almost all the defined specifications. Except for the pinch force. Due to changes in the design of the finger, the amount of pinch force is decreased. This is a downside of the prosthesis but can be improved as described in this report. The finger design has to be optimized with FEM analysis and iterations and variations have to be tested. Therefore, this finger design is not a final design but a stepping stone to a renewed finger.

One important prerequisite that could not be fully met yet concerns the hand component design. There wass explained that the palm should remain uncovered to have sensory feedback. However, in the current example created by OTA, the palm is covered. This aspect will be addressed in the improved version, where OTA will create a customized hand component tailored to each patient. While this design choice limits control over the final component, it ensures a well-fitting and ergonomic solution, which is required for hand amputees.

The prototype shows the mechanism of the body-powered prosthesis and makes testing of the measurable requirements possible. However, it was not designed to be fitted directly onto a patient with an amputation. This would give additional medical product requirements. As a result, an evaluation based on user experience was not possible. Instead, the design was repeatedly assessed through discussions with military personnel and experts. While this provided valuable feedback, it is still not clear whether the prosthesis fully meets the needs of the end users. Direct testing with patients will be necessary in future development.

This project presents a promising solution to a problem that affects many people and opens the door to future innovations in prosthetic design. While the prosthesis demonstrates an high potential, further development and extensive testing are needed to improve the design and its performance.

Nevertheless, there are possibilities for improvement and optimization, particularly in grip strength, finger positioning, and user experience. With some adjustments, this prosthesis could become a widely accessible and solution for soldiers with partial hand amputations.

The research that was done for this project used different methods. Interviews with experts, observation of a patient, small questionnaires and literature study.

Literature
A wide selection of literature was reviewed, paying careful attention to sources and publication dates. However, not all papers provided the exact information needed. In some cases, conclusions from multiple studies had to be combined to extract relevant insights. Additionally, almost no literature contained data specifically related to patients in the Netherlands or soldiers. As a result, some sources covered broader populations or included data from other countries. Nevertheless, these findings still highlight the need for prosthetic solutions and show that this level of amputation is a relevant issue. It is important to note that papers published after December 2024 were not included in this research.

Interviews
Due to limitations, it was not possible to test the prosthesis directly with patients or have in-depth conversations with them. Instead, there was focused on gathering insights from experts who work closely with the patients. The first interview was conducted with an occupational therapist, and regular discussions with employees from OTA, who provided insights from different perspectives. Additionally, experts from the faculties of Biomedical Engineering and Mechanical Engineering were spoken with frequently to validate and improve the concept.

The final prosthesis was evaluated only by experts from OTA. It would have been beneficial to include all previously mentioned experts in the evaluation phase to gather feedback from multiple professional perspectives.

Observation
Observations took place during an appointment from N. Jonkergouw with a patient with a hand amputation. However, due to the nature of the appointment and a language barrier, it was not possible to ask the patient direct questions. As a result, the data collected was limited to notes based on passive observation. Additionally, it was not possible to observe the patient using their current prosthesis in daily activities, which could have provided more valuable insights.

Questionnaire
A small questionnaire was done to assess the design options for the prosthetic finger and prosthesis. This was done with military personnel, but not with individuals who have an hand amputations. To have a more accurate evaluation, future research should include people with hand amputations to ensure the design meets their specific needs.

While this study provided valuable insights for the development of a modular and accessible prosthesis, certain limitations affected the depth of the findings. Future research should focus on direct patient involvement, larger sample sizes, and further validation with experts. Nevertheless, the project presents a promising first step for further innovation in prosthetic design.

6.3 Recommendations

Design

Shape of the finger
Adjutsments of the design of the finger influenced its perfomance. Optimisation using FEA can improve the functionality

Material selection
The use of BioMed 80A material for the finger is recommended. This could improve durability, flexibility, and user comfort. No FDM printer is needed in this case and the finger can be printer together with the wrist inner part. Furthermore, this material has more grip which will improve the performance of the finger.

Optimization
Further optimization is needed to improve the prosthesis' performance and comfort. This includes both design and functional improvements.

Improved finger design
The design of the finger segments should be looked into. A possible option is adding a solid piece between the segments to provide extra stability and improve finger movement.

Hand palm
It is advised not to cover the palm with the prosthesis, as this influences the sensory feedback for the user. This will contribuet to a better user experience and may increase acceptance of a prosthesis.

Integration with OTA hand component
The prosthesis should be integrated with the OTA hand component. This introduces new challenges regarding connectivity and production integration, which should be considered in further design phases.

Clamping system
The clamping system has to be optimized to provide a stronger grip. Research should explore whether this part can directly be 3D-printed, making the production process faster and more efficient.

Wire
Currently, the wire running through the finger is visible at the front, since it is easier to assemble and disassemble. In the final version, the wire should be better covered to have a more aesthetically finish.

Increase finger grip
The grip of the fingers can be improved by using a different material, like BioMed 80A or adding a coating, such as Plasti-Dip.

Wrist component design
The knuckle at the wrist is uncomfortable due to the hard part of the wrist component. This needs to be taken into account and the design should be adjusted accordingly

Protoype Process

Finger positioning
The current finger placement is not right as it is not possible to touch the thumb when wearing the prosthesis. This should be looked into in the next steps.

Connection between hand and wrist components
There is still too much space between the hand and wrist components. This instability affects the clamping system, making it less effective due to possible movement.

Clamping system
The clamping system should be adjusted to ensure a more secure and stable fit between components.

Cable
The way the cables are placed can be improved for a cleaner, lesss mechanical and more efficient design. Further exploration is needed to determine how they can be integrated into the prosthesis.

Type of cables
The current coated, non-stretchable wire has been used for this prototype. However, other wire options might have a better performance. Further research is needed to determine the optimal cable type for the prosthesis.

User evaluation
Evaluation should start with an user analysis, followed by observations of the use of the prosthesis during daily activities. The final step should involve long-term testing to assess its durability and overall performance over time. The D-quest tool has to be used in evaluating the prosthesis.

Test with multiple users
The prototype should be tested by several people to have a more diverse insight from the design and its functionality. This will provide a more justified evaluation and helps to improve the prosthesis for wider use.

Hand component integration
The hand component created by OTA should be developed and integrated. While the development was described, elements like cable placement and the connection holes on the hand may require a different approach from orthopaedic technicians and an adjusted design of the finger and wrist component.

Force distribution
Advanced techniques should be used to measure the force distribution from the fingers. This way, improvements for the amount of force that the finger can deliver can be verified and improved

Implementation
There has to be explored if the right material is everywhere available in case spare parts need to be produced outside The Netherlands.

6.4 Feasibility | Desirability | Viability

6.6.1 Feasibility

3D printers are currently widely available and used in various industries. This accessibility and the availability of printing materials, makes the creation of prosthetic parts anywhere, at any time possible. 3D printing is rapidly improving and will become even more accessible in the future.
Furthermore, no specific sensors or screws are required for this prosthesis, making it less dependent on specific supplies.

A key challenge is integrating the hand component made by the orthopaedic technologist and improving the clamping system for better functionality and fit. At OTA, there is currently no in-house expertise in CAD design. It was therefore decided to have the hand component, which for every prosthesis needs to be custom-made, made by an orthopaedic technologist.

The current 3D-printed parts of the prosthesis are designed as standard parts that do not require adjustments to the CAD model. Different finger sizes allow to simply determine which finger size is desired. In addition, the wrist component is adjustable because of the flexible material used. This makes producing the prosthesis easy and faster, allowing the user to receive the prosthesis quickly.

The material chosen for 3D printing (TPU, Biomed, Photonicpolymer) is affordable, lightweight, and strong. It is also easy and inexpensive to repair. However, the long-term durability of the material should be tested, since this is not yet fully clear for this specific application.

The strength of the individual fingers has already been evaluated through FEM analysis. Based on structural loading, the chances of damage or excessive deformation are low. However, this analysis has not yet been done for the entire prosthesis.

The prosthesis has been tested to meet almost all the required specifications, and its performance aligns with the expectations established during the research phase.

The integration with the orthopaedic specialism for the hand component, makes the prostheses fit better and will contribute to a prosthesis that is more ergonomic to wear. This integration is not existing yet and is an improvement compared to current products.

Improvements for the finger design needs to be done but there is enough possibilities to improve its performance. Therefore, this design is promising to become even better.

Concluded from this, the technical feasibility is high, but improvements are still needed, including design refinements and further validation testing.

6.6.2 Desirability

This prosthesis, is affordable enough that even if it's not covered by insurance, patients can still purchase it independently, making it a highly desirable product.

In the case of damage, patients won't need to replace the entire prosthesis. Instead, they can simply repair the damaged part, which will lower the long-term costs of the prosthesis. This repairability makes the prosthesis not only an affordable option but also a cost-efficient and durable.

Although further improvements are needed to optimise the performance, the ability to support users in their daily activities will only increase. The addition of the clamp system increases user comfort, making the prosthesis better suited for daily use than existing prostheses. This is likely to enable the user to use the prosthesis in more activities throughout the day.

One important feature of this prosthesis is the customization option. Users can adjust the fitting and colour to match their specific preferences, increasing both comfort and emotional satisfaction. The ability to personalize the prosthesis empowers users to feel more in control, which will contribute to their self-esteem. This customisation also encourages more use of the prosthesis, as users are more likely to wear a prosthesis that meets their individual needs.

The prosthesis enhances psychological well-being by allowing users to feel more independent and ara able tp contribute to ADLs. This is vital for the user's mental health and helps them reintegrate into society without feeling limited by their prosthetic.

Moreover, the prosthesis supports social integration by helping users in both personal and professional activities.

The materials used are skin-friendly and are comfortable to wear, so users experience limited discomfort or irritation. This makes the prosthesis even more desirable, as it offers both functional benefits and comfort.

Initial conversations with the rehabilitation centres and specialists showed a strong demand for affordable prosthetic options, especially for soldiers in rehabilitation who have limited access to high-cost alternative.

6.6.3 Viability

The production cost of the prosthesis is €154.18, with a selling price of €802.85. When compared to other prostheses on the market, which are sold for €15,000 or €1200 per finger, this prosthesis is significantly more affordable. Even if insurance does not cover the cost, the price is low enough that users can still afford to buy the prosthesis themselves.

Although some improvements are still needed, this will not cause the overall cost to increase enormously. This means that the final price will remain low compared to existing prostheses on the market, which will maintain the demand for this prosthesis. Since current expensive prostheses are still being produced and sold, this prosthesis is expected to be viable in the market.

The modularity of the prosthesis makes it easy to print spare parts when repairs are needed. This design also ensures that users stay connected to OTA for repairs and maintenance. Since OTA manages the files for the spare parts, users are more likely to come back for additional services, which will create a consistent revenue stream.

The modular design also ensures long-term usability. With regular updates and improvements, the prosthesis can continue to meet users' changing needs.

With its affordability, lightweight design, intuitive use, integrated clamping system and unique finger design, this prosthesis offers advantages compared to the other prosthesis on the market.

Prosthetic parts can be printed in one batch with a SLA printer. Multiple prostheses can be printed simultaneously, allowing for faster production. However, because this is a medical product that requires the right fit for each user, customisation will always be necessary. While using a SLA printer means that production can be scaled up, it is not always desirable to mass-produce this type product due to the need for individual customisation.

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8 Appendix

Appendix A

Project brief

TU Delft

DESIGN FOR our future

IDE Master Graduation Project

Project team, procedural checks and Personal Project Brief

In this document the agreements made between student and supervisory team about the student's IDE Master Graduation Project are set out. This document may also include involvement of an external client, however does not cover any legal matters student and client (might) agree upon. Next to that, this document facilitates the required procedural checks:

- Student defines the team, what the student is going to do/deliver and how that will come about
- Chair of the supervisory team signs, to formally approve the project's setup / Project brief
- SSC E&SA (Shared Service Centre, Education & Student Affairs) report on the student's registration and study progress
- IDE's Board of Examiners confirms the proposed supervisory team on their eligibility, and whether the student is allowed to start the Graduation Project

STUDENT DATA & MASTER PROGRAMME

Complete all fields and indicate which master(s) you are in

Family name		IDE master(s)	IPD ✓ Dfl SPD
Initials		2nd non-IDE master	
Given name		Individual programme *(date of approval)*	
Student number		Medisign	✓
		HPM	

SUPERVISORY TEAM

Fill in he required information of supervisory team members. If applicable, company mentor is added as 2nd mentor

	sen	dept./section	SDE/MF
mentor	Richard Goossens	dept./section	HCD/AED
2nd mentor	Niels Jonkergouw		
client:	Militair Revalidatie Centrum Doorn		
city:	Doorn	country:	The Netherlands
optional comments			

! Ensure a heterogeneous team. In case you wish to include team members from the same section, explain why.

! Chair should request the IDE Board of Examiners for approval when a non-IDE mentor is proposed. Include CV and motivation letter.

! 2nd mentor only applies when a client is involved.

APPROVAL OF CHAIR on PROJECT PROPOSAL / PROJECT BRIEF -> to be filled in **by the Chair** of the supervisory team

Sign for approval (Chair)

Kaspar Jansen — Digitally signed by Kaspar Jansen Date: 2024.09.12 09:45:15 +02'00'

Name Kaspar Jansen | Date 12 Sep 2024 | Signature

CHECK ON STUDY PROGRESS

To be filled in **by SSC E&SA** (Shared Service Centre, Education & Student Affairs), after approval of the project brief by the chair. The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total		EC
Of which, taking conditional requirements into account, can be part of the exam programme		EC

★	YES	all 1st year master courses passed
	NO	missing 1st year courses

Comments:

Sign for approval (SSC E&SA)

Rik Ledoux 2024.09.12 16:16:31 +02'00'

Name Rik Ledoux | Date 12 Sep 2024 | Signature

APPROVAL OF BOARD OF EXAMINERS IDE on SUPERVISORY TEAM -> to be checked and filled in by IDE's Board of Examiners

Does the composition of the Supervisory Team comply with regulations?

YES	★	Supervisory Team approved
NO		Supervisory Team not approved

Comments:

Based on study progress, students is ...

★	**ALLOWED** to start the graduation project
	NOT allowed to start the graduation project

Comments:

Sign for approval (BoEx)

Monique von Morgen — Digitally signed by Monique von Morgen Date: 2024.09.25 10:23:53 +02'00'

Name Monique von Morgen | Date 25 Sep 2024 | Signature

Personal Project Brief – IDE Master Graduation Project

Name student 	**Student number**

PROJECT TITLE, INTRODUCTION, PROBLEM DEFINITION and ASSIGNMENT

Complete all fields, keep information clear, specific and concise

Project title Designing a functional finger prosthetics accessible for rehabilitation of soldiers after trauma

Please state the title of your graduation project (above). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

Introduction

Describe the context of your project here; What is the domain in which your project takes place? Who are the main stakeholders and what interests are at stake? Describe the opportunities (and limitations) in this domain to better serve the stakeholder interests. (max 250 words)

A lot of trauma is caused during military operations which increases the amount of permanent injury. One of the trauma's that is occuring often is losing one or more fingers. This immobalises the soldiers immediatly. This kind of trauma should get treatment first. After this period, rehabilitation with a suitable prothesis would be ideal. These prothesis should be accessibel for everyone who is injured as a result of their deployment to recover and get their hand function back.
Currently there are two types of finger prothesis; cosmetic and functional. The cosmetic prosthetics looks like a normal finger but is not able to make movements. The functional prosthesis focusses on bringing back the functionalities of the hand and its fingers. This second prothesis is ofcourse the ideal situation, especially when you take into account the work field of soldiers.
But at this moment, these prosthesis are very expensive and has to be custom made by a company that is specialised in this type of prosthesis.
That's why not everyone is able to get acces to this type of prothesis from the first moment on.

Opportunities within this domain lies mainly within the design.
The ideal situation is to use the functionalities of the hand that is not damaged, to create a functional prosthesis that can be produced everywhere at any time to improve the rehabilitation of soldiers. Furthermore, it is important that the components of the finger are modular and can easily be replaced.

At the end of this project, the result will show an accessible finger prothesis and it's componants that can be produced and replaced anywhere anytime for anyone and with a low costs.

Livit Ottobock Care. (2024, 29 april). Cosmetische vingerprothese (kunstvinger) | Livit Ottobock Care. https://www.livit.nl/prothesen/cosmetisch

➔ *space available for images / figures on next page*

introduction (continued): space for images

image / figure 1 Hero Gauntlet, current functional finger prosthesis OpenBionics.

image / figure 2 Finger Prosthesis with no function.

DESIGN FOR our future

TU Delft

Personal Project Brief – IDE Master Graduation Project

Problem Definition

What problem do you want to solve in the context described in the introduction, and within the available time frame of 100 working days? (= Master Graduation Project of 30 EC). What opportunities do you see to create added value for the described stakeholders? Substantiate your choice.
(max 200 words)

To design a functional prosthesis that can be created at the place of treatment for a much lower cost than currently available. This way the waiting time for rehabiliation with a fitting prosthesis will be decreased and will be available for more people.

Assignment

This is the most important part of the project brief because it will give a clear direction of what you are heading for. Formulate an assignment to yourself regarding what you expect to deliver as result at the end of your project. (1 sentence)
As you graduate as an industrial design engineer, your assignment will start with a verb (Design/Investigate/Validate/Create), and you may use the green text format:

Design a functional finger prosthesis for soldiers after a finger amputation that is affordable, can be created witin a short amount of time and can move with the still excisting functions of the hand.

Then explain your project approach to carrying out your graduation project and what research and design methods you plan to use to generate your design solution (max 150 words)

Project planning and key moments

To make visible how you plan to spend your time, you must make a planning for the full project. You are advised to use a Gantt chart format to show the different phases of your project, deliverables you have in mind, meetings and in-between deadlines. Keep in mind that all activities should fit within the given run time of 100 working days. Your planning should include a ***kick-off meeting***, ***mid-term evaluation meeting***, ***green light meeting*** *and* ***graduation ceremony***. *Please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any (for instance because of holidays or parallel course activities).*

Make sure to attach the full plan to this project brief.
The four key moment dates must be filled in below

Kick off meeting	9 sept 2024
Mid-term evaluation	20 nov 2024
Green light meeting	6 feb 2024
Graduation ceremony	7 mrt 2024

In exceptional cases (part of) the Graduation Project may need to be scheduled part-time. Indicate here if such applies to your project

Part of project scheduled part-time	✓
For how many project weeks	27
Number of project days per week	4,0

Comments:
Probably I will be on vacation in January. The schedule of the project can be viewed via this link: https://ap.lc/YMsUXv

Motivation and personal ambitions

Explain why you wish to start this project, what competencies you want to prove or develop (e.g. competencies acquired in your MSc programme, electives, extra-curricular activities or other).

Optionally, describe whether you have some personal learning ambitions which you explicitly want to address in this project, on top of the learning objectives of the Graduation Project itself. You might think of e.g. acquiring in depth knowledge on a specific subject, broadening your competencies or experimenting with a specific tool or methodology. Personal learning ambitions are limited to a maximum number of five.
(200 words max)

Appendix B

D-quest form

Wessels et al. (2000)

D-QUEST

iRv, versie februari 2000

Naam cliënt: ....

Hulpmiddel / voorziening: ....

Datum: ....

Tevredenheid over uw hulpmiddel en de bijbehorende dienstverlening

Het doel van deze vragenlijst is na te gaan hoe tevreden u bent over uw hulpmiddel en de bijbehorende dienstverlening.

- Wilt u bij elk van de vragen aangeven hoe tevreden u bent over uw hulpmiddel en de bijbehorende dienstverlening, met behulp van de volgende 5 antwoord-mogelijkheden:

  Totaal niet tevreden
  Niet tevreden
  Min of meer tevreden
  Tevreden
  Zeer tevreden

- Wilt u alstublieft voor elk van de volgende vragen het antwoord aankruisen dat het best bij uw mate van tevredenheid past?
- Wilt u alstublieft alle vragen beantwoorden?
- Indien u niet helemaal tevreden bent, wilt u dan alstublieft de reden daarvan toelichten in de daarvoor bestemde ruimte achter de vraag?

1 Hoe tevreden bent u over de **afmetingen** van uw hulpmiddel? (maat, hoogte, lengte, breedte)	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
2 Hoe tevreden bent u over het **gewicht** van uw hulpmiddel?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
3 Hoe tevreden bent u over de **verstel-mogelijkheden** van uw hulpmiddel?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
4 Hoe tevreden bent u over de **veiligheid** van uw hulpmiddel?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
5 Hoe tevreden bent u over de **duurzaamheid** van uw hulpmiddel? (bestendigheid, slijtvastheid)	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
6 Hoe tevreden bent u over het **gemak** waarmee u uw hulpmiddel kunt **gebruiken**?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
7 Hoe tevreden bent u over het **comfort** van uw hulpmiddel?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
8 Hoe tevreden bent u over de **effectiviteit** van uw hulpmiddel? (De mate waarin het hulpmiddel doet waarvoor het bedoeld is)	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
Hoe tevreden bent u, **alles bij elkaar genomen,** over uw **hulpmiddel**?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	

9 Hoe tevreden bent u over het **verstrekkingsproces** waarmee u uw hulpmiddel heeft verkregen? (procedures, tijdsduur)	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
10 Hoe tevreden bent u over de geboden **reparaties en onderhoud** voor uw hulpmiddel?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
11 Hoe tevreden bent u over de **professionaliteit van de dienstverlening**? (kwaliteit van de informatie en vakkundigheid van de dienstverleners)	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
12 Hoe tevreden bent u over de **service en dienstverlening na aflevering** van uw hulpmiddel? (na-zorg, blijvende ondersteuning, begeleiding)	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
Hoe tevreden bent u, **al deze vier onderwerpen bij elkaar genomen,** over de **totale dienstverlening**?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	

Hieronder is een lijst van dezelfde12 onderwerpen weergegeven.
Wilt u de drie onderwerpen die u het meest belangrijk vindt uitkiezen?

Zet een kruisje voor de **drie onderwerpen** die u het belangrijkste vindt.

Afmetingen	Comfort
Gewicht	Effectiviteit
Verstel-mogelijkheden	Verstrekkingsproces
Veiligheid	Reparaties en onderhoud
Duurzaamheid	Professionaliteit van de dienstverlening
Gebruiksgemak	Service en dienstverlening na aflevering

Appendix C

Notes interview occupational therapist

Alle vinger maar wel nog een stomp dan zou je er myo op kunnen zetten. Andere opties maar alleen als de hulpvraag zo hoog en specifiek is en iemand goed trainbaar is.
Sok=liner
Patient: bilateraal; 2 armen mist hij. Automatisch naar prothese hulpstuk voor 1 hand. Zoveel als mogelijk met zo min mogelijk middelen. Passieve, digits points veel frustratie want mist dominante hand. Enkelvoudig iemand altijd de andere kant als dominante hand.
Vinger amputatie komt veel voor want is trauma gericht.
Partiële hand; weinig opties de mechanische optie die er is wordt heel veel afgewezen door verzekering doordat die te duur is en niet compatible met iedereen.
iemand iets bieden wat beter compatible is en ook in productie goedkoper, veel grotere markt bereiken.
Nu doen mensen het niet (zelf betalen) of er moet letsel schade zijn.
Niet alles is leverbaar in europa. Niet specifiek voor als je wel nog 1 vinger hebt. Doelgroep is heel klein.
Verzekering moeilijk prothese partiële hand; overtuigd dat mensen prima met een vinger kunnen functioneren.
Landelijke richtlijn, landelijke werkgroep (WAP-A). Werkgroep amputatie arm.
Kleine scharnierpunten lastig bij PIP-driver
MCP weinig opties die als functioneel beschouwd kunnen worden. Misschien myo-elektrisch maar dan moet iemand heel trainbaar zijn.
Silicone prothese zit vaak in de weg. Pols is super functioneel; dinger fixeren, tillen.... Zonder vingers niet grijpen maar wel fixeren en duwen.
Fijn motorische functie altijd met andere hand doen.
Nooit 2 myo tegelijk want brein werkt symmetrisch. Dat maakt bodypowered interessant want is intuitief. Iets minder kwetsbaar.
Geen training nodig. Body powered handstuk, iets meer therapie maar vele mate minder van myoelektrisch. Meer postuur, houding, werkhoogte. Binnen 2 weken snappen ze dat.
Meerwaarde myoelektrisch is steeds minder. Hand amputatie bodypowered wordt vergoed (meerwaarrde) maar partiële niet waar je nog meerdere vingers hebt (niet goeie alternatieve en de opties zijn heel duur en vinden ze niet opwegen)
kosten en efficientie = hoofdpijlers voor succes nieuw product.
Bodypowered meest beperkend; digit points, vingers altijd in vorm plaatsen.
Fixatie/grijp functie en je zoekt geen vervangende hand, die onaangedane hand is altijd sneller.
Stevig goeie grip geven. Grip krachtig maar ook gladder.
Metaal op metaal, kunststof op kunststof. Meerdere vingers niet zon probleem, maar wel zo dan ervaar je dit meer.
MCP, alleen ed mogelijkheid tot een cylinder grip want alle vingers bewegen gezamenlijk. Dat kan in de weg zitten. Iets pakken want niet gemaakt is voor een cylindergreep dan zitten die vingers in de weg.
Cylinder greep het belangrijkste zodat je iets kan pakken. Wij leren mensen de andere hand is echt dominant. Dominante hand dan kost dat veel meer moeite en dan missen ze echt die pinch en tripod greep dan wanneer ze aan niet dominante hand zijn aangedaan, dan missen ze dit wat minder.
Specifieke hulpvragen (nu iemand kapper), zon beroep zonder fijn motorische grepen red ik het niet. Voor bepaalde doelgroepen si het gat in de markt.
Vanuit therapeutisch oogpunt; niet ons eind streven, dat iemand fijn motorisch. Het liefst iemand alles beiden.
Vanuit multiarticulaire handen (myo), specifieke grepen, gebruiken ze maar 3 of 4 grepen. Omdat zon hand vaak ook niet als dominante hand wordt ingezet.

Tip/tripod; fijne motoriek. Grotere overgang als het je dominante hand betreft. Je wilt die hand gebruiken om dingen op te pakken.
Iets wat ze herkent.
Of je alleen daar op richt of het dan de hulpvraag van alle beantwoord.
Meeste grepen; grof motorisch cylinder, fijn motorisch lateraal. Want ook daarmee kan je iets oppakken.
Voor iedereen die 2 grepen, wat ook gezien wordt in de praktijk die het meeste gebruik wordt.
Lateraal niet meenemen. Als je een duim hebt, range of motion voor bewegen volledige duim.
Duim gefixeerd. Duim geeft mogelijkheid tot meer grepen.
Cylinder altijd belangrijkste greep. Nu missen met point digit.
Nadeel alleen cylinder is dat ze allemaal tegelijk
bewegen. Ruimte om naast cylinder iets anders te doen is driepuntsgreep. Meer kracht dan tip to tip.
Je kan iets minder met tip.
Heb je alleen 2 vingers dan kan je geen cylinder. Duim wel hebt en wijsvinger buigen dan moet de vinger ook tegendruk aankunnen aan de zijkant. Behoefte van therapeut. Dat die niet alleen top druk maar ook naar beneden druk.
Fitting prothese. MCP is dat ed hand altijd ingepakt moet worden. Gebruiken gevoel van handpalm. Want gevoel is wel je feedback.
Er is geen stomp om op te fixeren. Hand ingepakt omdat er een koker omheen moet. Mini handschoen en daar wordt het op gemonteerd.
Na aantal jaren prothese niet gebruiken omdat ze dan nog functioneler zijn zonder prothese.
Omdat ze niet het gevoel meer hebben. Nadelen MCP, altijd stukje goeie hand moet inpakken om een stevige behuizing te hebben zodat je hem niet verliest.
Point digit, weinig intuïtief. Heel statisch.
Gewicht prothese, is belangrijk maar ook kwetsbaarheid. Hoe goed maak je iets schoon, welke kleur heeft het, zit er een handschoen omheen? Kan ik het met water of stof gebruiken.
Lengte vingers, moet compatible zijn met duim die er nog is en andere hand. Lengte amputatie, zo lang of kort dat het veel afwijkt. Veel producten in verschillende maten te verkrijgen.
Soms maakt het voor mensen uit hoe het eruit zien en sommige niet.
Meeste jongere die vinden anders juist mooi. Oekraïne; ouder moet er mooi uit zien maar ook functioneel.
Altijd kiezen tussen mooi en functioneel. Jonge militairen; voorkeur functioneel. Mensen doen er geen verlenging aan als het niks oplevert. MCP, voorkeur functioneel. Liever functioneel dan cosmetisch en statisch. Aantal vinden het juist mooi om een statement te maken (jongeren vaak).
Schoonmaken; onderhoud bij OTA (in pakket). 3-5 jaar dan mag je weer een nieuwe.
Fanatiek klussen, eerder een haak dan een hand. Body powered sterker dan cosmetisch. Tegen stof en water kunnen, enorme ontwikkelingen. Hoesje, dan loopt het er allemaal in. Of dat stof erin blijft hangen, wil je ook niet.
Water en stof lopen mensen altijd tegenaan.
Hoe complexer de prothese, hoe gelimiteerder. Nadelen. Point digit is stuk robuster dan iets van plastic. Metaal is zwaarder, plastic lichter.
Proeffase van wat mensen uitproberen, en daaruit kiezen (week of 4).
Afhankelijk van leverancier kan je thuis testen. Is wel voorkeur van therapeut. PIPI en MCP driver mag alleen op locatie getest worden. 1-2 weken te leen, nabootsen wat ze thuis zouden doen.
2 mevrouwen, allebei hulpvraag pianospelen. Andere siliconen en andere pip driver. Ene vind cosmetisch belangrijker, ene beter stomp voor driver. Persoonlijke fases.

Hiervoor is er D-quest vragenlijst. Onderdelen waar we een prothese op testen.
meetinstrumentenindezorg.nl
Per product gaat iemand die vragenlijst doornemen en kun je het netjes vergelijken en aan de verzekering laten zien.
Hoe zie je veranderingen bij specifieke activiteiten bij gebruik van prothese, zie je de vooruitgang.
Hele rollercoaster. Het voortraject is belangrijk (verwachtingsmanagement), iemand zelfstandig maken zonder prothese. Temperen de verwachtingen. Iedereen die iets meemaakt hoopt de functie terug te krijgen die hij had. En iedereen denkt dat een prothese dat doet want er zijn veel mooie voorbeelden in de media. Altijd vertellen: het is nooit je eigen hand en nooit meer dezelfde aansturing. Nooit meer zo intuïtief iets voelen of bewegen want dat is er niet.
Prothese toevoeging dat mensen er blij mee zijn. Soms wel fijn om te testen om te ervaren dat ze het niet nodig hebben. Kan ook dat er specifieke hulpvraag kot, bijv fietsen, en dan wordt daar wat voor gemaakt en redden ze zich verder wel.
Hoe hoger amputatie, hoe langer het traject. Middelvinger kan je compenseren met je ringvinger. Missen ze wel want is je krachtigste vinger.
Prothese krijgen en dan niet gebruiken. Doordat ze mentaal in een ander acceptatieproces komen. Verwachten dat ze dat nodig hebben om veel volledig alles te kunnen, je ziet dat ze vaardiger worden. Dan weten ze veel beter wat ze missen en kunnen. Of ze gebruiken hem veel of specifiek of niet. Een prothese is dan niet functioneel genoeg of de fitting niet goed. Hele hand ingepakt. Opties wegen dan niet op, wat je ervoor terug krijgt moet je veel moeite voor doen en je mist gevoel. Ze nemen dan eerder in functie af doordat je het gevoel mist. Gevoel is best wel een ding. HeroGauntlet niet in praktijk geprobeerd maar intuïtief, niet veel voor trainen en met die hand werken. Zou beter ontvangen kunnen worden.
Pols is het eerste gewricht dat dan iets doet. Meerwaarde dan passieve vingers.
Kokers kunnen pijn doen, onprettig aan en uit trekken. MCP niet ervaren, meer soort handschoenen.
Eerst voorprothese fase - 8 weken. Direct na amputatie, liefst zo snel mogelijk. Kunnen ze nog wondzorg doen.
Voor amputatie niet want meestal is het traumatisch. Geen geplande zorg. Iemand spreekuur en dan kijken ze of ze er wat mee kunnen en dan starten ze.
Grote wonden (na explosie, of een ring blijven haken), altijd direct starten. Eerst een stukje handtherapie doen. Wondzorg en mobiliteit. Alles goed is voorwaardenscheppend om met die hand te kunnen functioneren. Psycholoog ingezet voor acceptatie, maatschappelijk werker (arbeidsconflict). Grote wond kan het langer duren maar is afhankelijk van de wond. Wennen aan nieuwe situatie en stimuleren zo veel mogelijk ermee te doen. Waar loopt iemand tegenaan en daarin mee te denken zonder nog protheses. Iemand is daar nog niet om de juiste keuze te maken, het enige wat mensen willen is het stukje functie terug. Verwachtingsmanagement.
Eerst landen en kijken hoeveel je kan zonder prothese, want dan weet je pas waarvoor je hem wilt gaan gebruiken. Gelijk geven dan valt het gelijk tegen en gaan ze het niet gebruiken. Gesprek met OTA: wat gaan we doen en komt soms een prothesevoorlichting uit. Op basis hiervan de verwachtingen horen wat ze echt willen en een plan maken. Binnen NL is dat altijd Stepped care. Met de eenvoudige goedkope prothese proberen. Als je dat niet probeert wordt de meest dure altijd afgewezen. Vingers zijn of cosmetisch of point digit. MCP doen we niet altijd proeffase. We kunnen niet alles vergoeden en uitproberen. Eerst hele koker maken, vingers eraan monteren. Proberen proeffase te doen maar iets complexer. Proeffase, paar silicone vingers regelen want dan zijn ze al gemaakt. Silicone kneden, dan krijgen mensen een gevoel en weten ze

wat materiaal is. Maar mcp kan niet want je kan het nergens aan vast zetten en er moet een hele koker voor gemaakt worden.
Proeffase aanvragen, maar dan al gerichter de proeffase in. Afstemmen wat zij en wij denken wat we moeten gaan testen. Dan PPP rapport opstellen. Iedereen gaat akkoord gaan.
Arm amputatie, hebben ze keuzehulp ontwikkeld. Helpen met wat er allemaal is op het gebied van protheses. Is niet voor een partiële hand, dat doen ze zelf.
Aanvragen en heel lang wachten. Naked Prosthetic wel, altijd afgewezen. Soms makkelijk, duur dan botsen ze het af. Maar eerst afwijzing hebben om het voor een letselschade in te dienen.
Vaak partiële hand geen prothese training. Point digit soms wel, minder intuïtief.
Soms wel mensen naar huis sturen met er is geen conclusie. Niemand met MCP die voor cosmetisch kiest. Point digit HeroGauntlet waarvan ze niet weten hoe mensen erop gaan reageren maar die sowieso wordt afgewezen omdat die te duur is.
Geen letsel schade (vaak het geval, klussen), zelf schuldige. Je mag hiervoor kiezen maar grote kans afgewezen, wil je het dan zelf betalen?
Niet altijd een oplossing voor mensen die ze zelf willen. Iets mechanischer, meer intuïtief en dus functionele. Kunnen ze nu niet voor kiezen als ze geen letselschade hebben.
Iemand komt wel gericht naar MRC dus altijd wel met een oplossing naar huis.
Meneer rechtshandig en ziet dat als dominante hand. Verschil met andere. Patient moet een prothese hebben om functioneel te kunnen zijn.
Functioneel gezien wel ideeën maar niet te bekostigen. Komen uit op minder functionele prothese maar die gebruiken ze dan niet.
Amerikaanse producten; commercieel. Verdienmodel. In NL moet je als therapeut altijd met patiënten hebben over de kosten.
Het hoeft niet zoveel anders als HG. Mooi als je ze individueel kan bewegen, is vernieuwend. Betaalbaarder is ook al een gap. Meer customizable is mooi. Geen amputatie hetzelfde.
MCP, onafhankelijk van elkaar bewegen is uitdaging maar zal ook een winst zijn. Enige beweegbare gewricht is de pols. Pinkmuis, duimmuis. Tenor en hypotenor die kunnen opponeren. Die kan je naar binnen brengen.
Hoe intuïtiever, hoe sneller mensen het kiezen en dus hoe functioneler.
Ze hebben iemand die misschien een leuke ervaringsdeskundige is. Heeft duim en stukje wijsvinger nog. MCP-driver voor wijsvinger en voor die ander point digit. Na jaar toch niet meer gebruiken en terug gegeven. Ook met hem als hij wil als ervaringsdeskundige; als je dit ziet, zou je dit overwegen om te gaan testen.

Appendix D

Observation Patient X

Afweging functioneel inzetbaar vs kwetsbaarheid. Hoe meer je ermee doet hoe kwetsbaarder het product is. Afhankelijk van of een prothese ondersteunend is of dat je er alles mee doet.

Prothese gaat kapot -> wordt deze opgestuurd en krijg je leenhand > dan krijg je hem na een tijdje weer terug. In de gaten houden van locatie van gebruiker, terug in Oekraïne is het makkelijk om een as te vervangen maar niet alle onderdelen. Rekening houden.

Moet elke keer dingen aangepast worden qua vinger positie, zou mooi zijn als dit ter plekke nagenoeg al zou kunnen.

Wat wil je ermee kunnen/doen, de functie bepaalt namelijk de prothese.

Liner is makkelijk om aan te trekken maar de koker werd niet als leuk ervaren.

Wilt graag wel kunnen maar ook intuïtief. Iets kunnen oppakken is belangrijk voor patiënt X. Lijkt alsof hij tripod aangeeft als gewenste functie, hij probeert die greep in ieder geval.

Appendix E

Mindmap of subfunctions

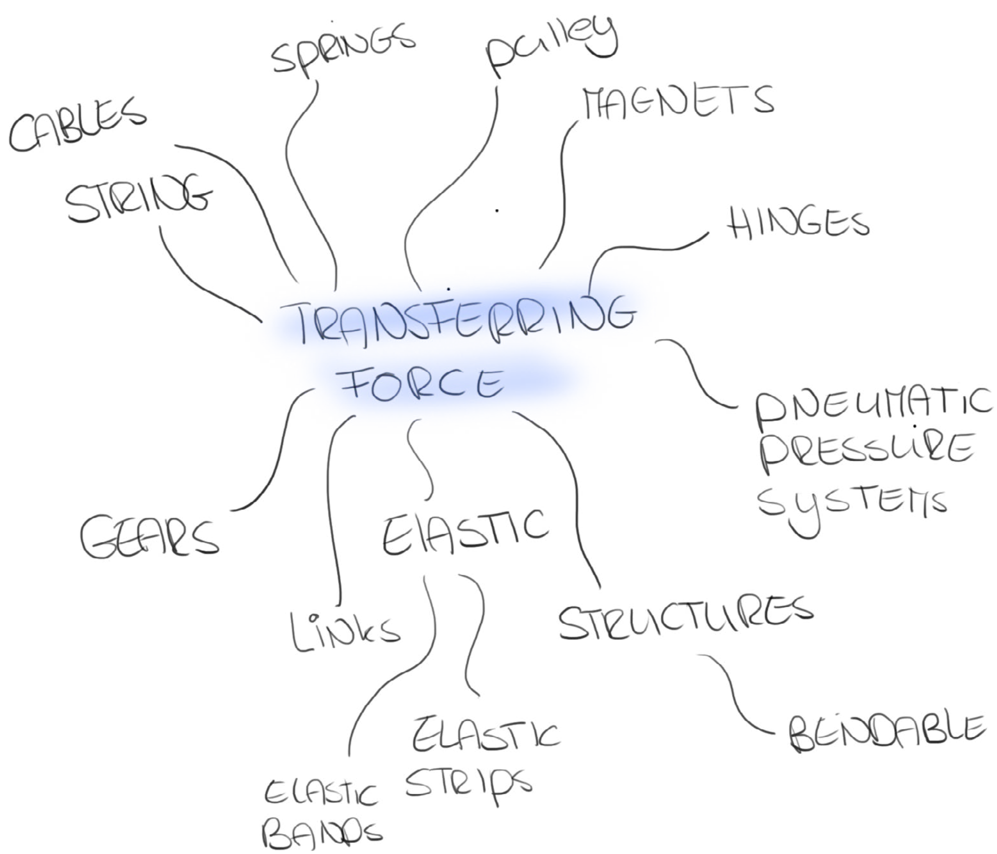


Figure 1: Mindmap transferring force

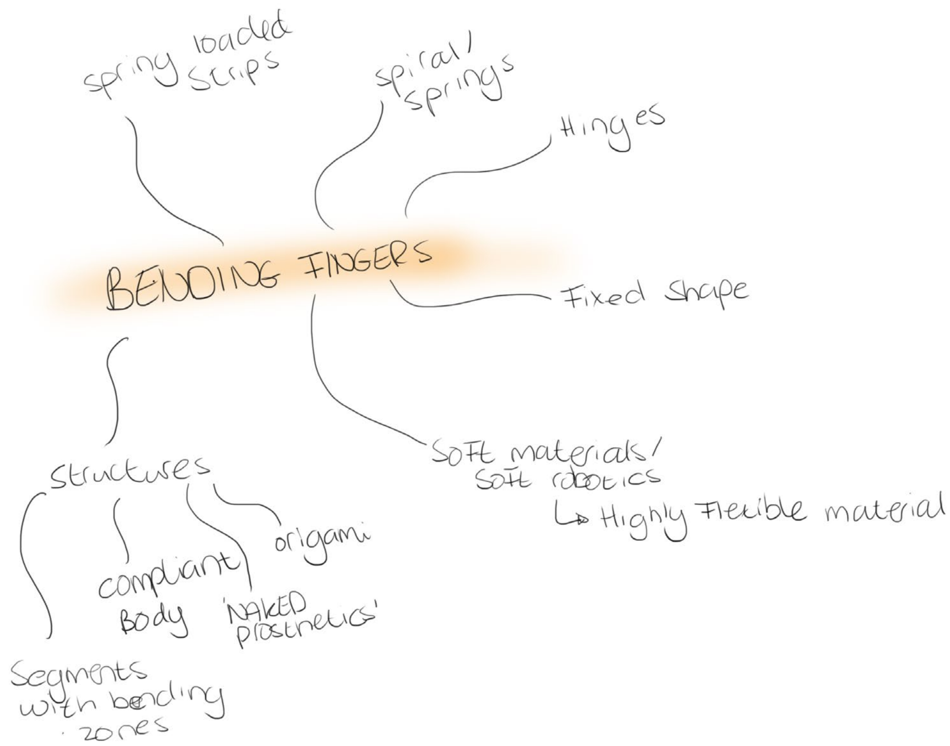
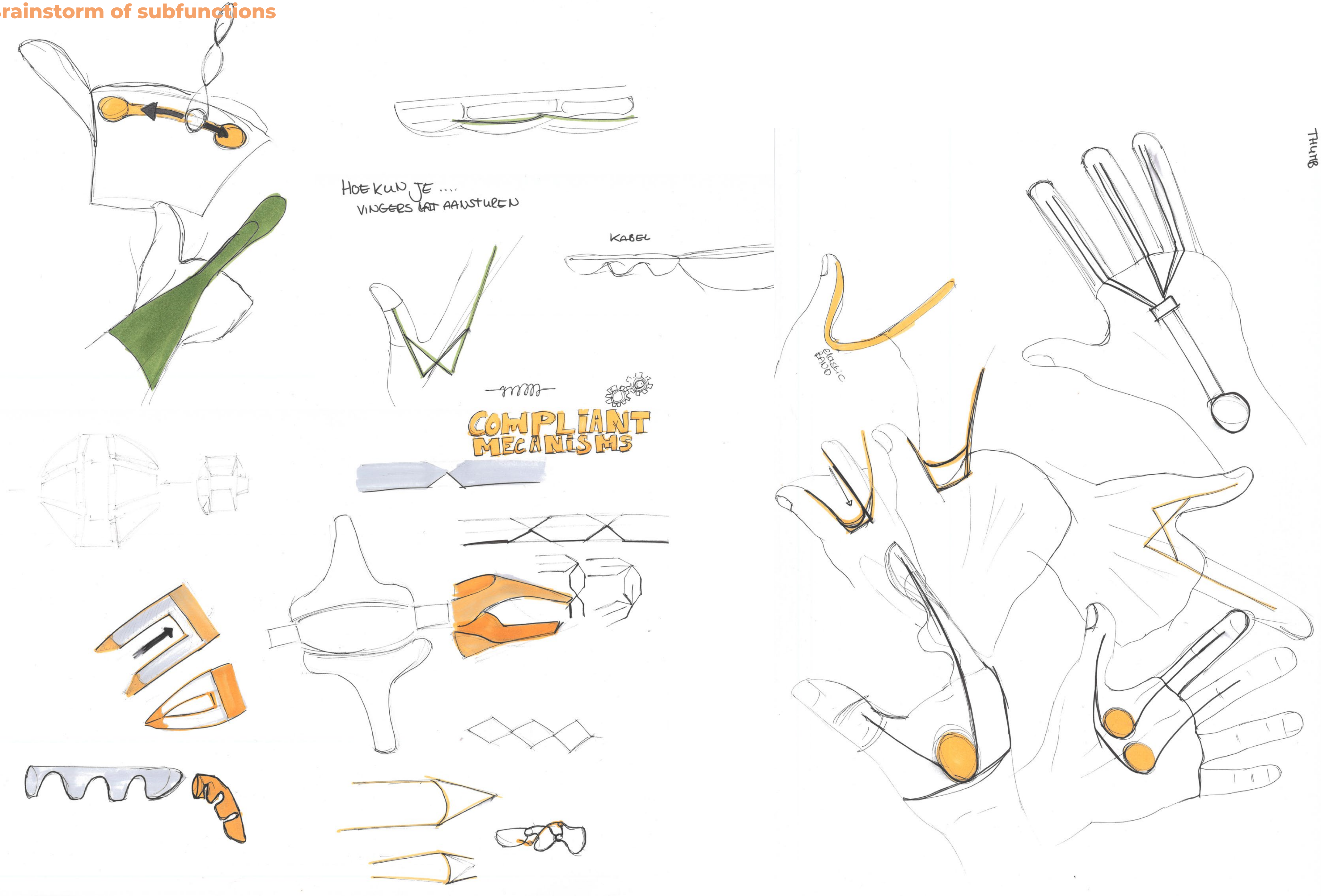
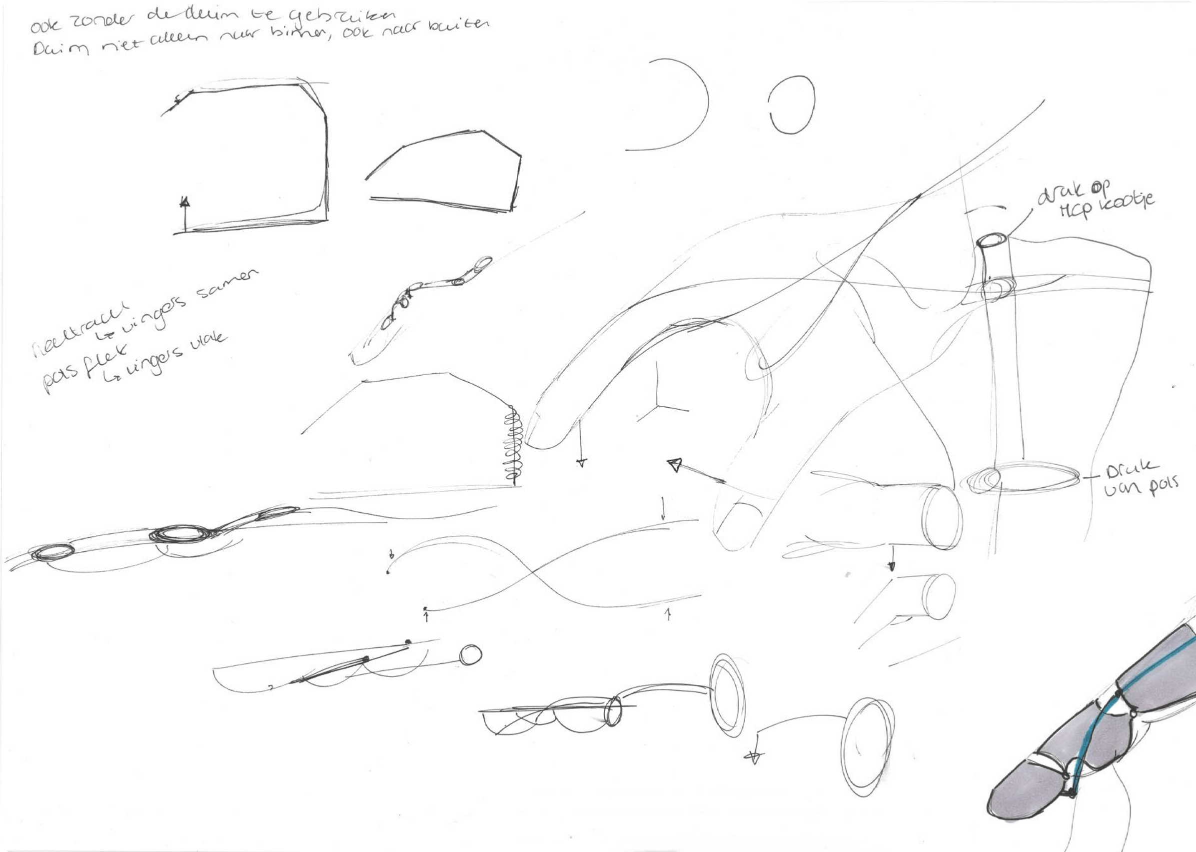


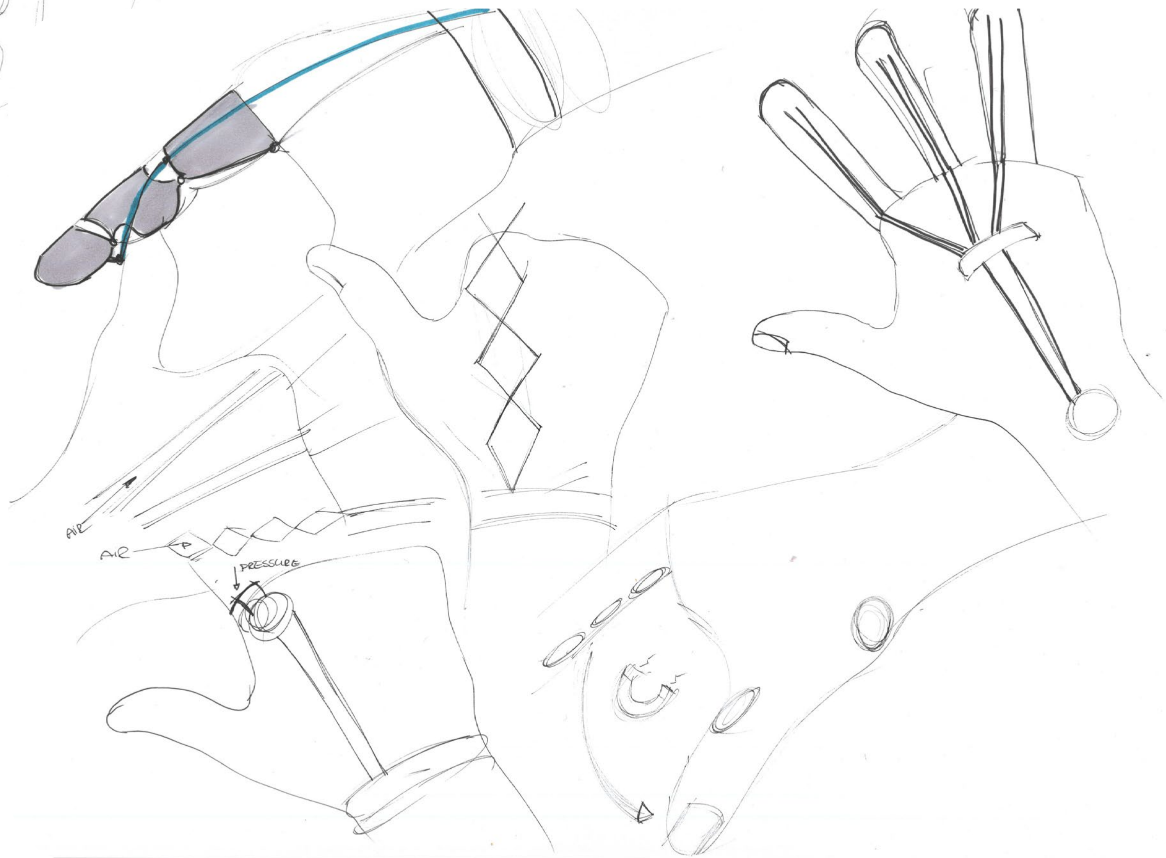
Figure 2: Mindmap bending fingers

Appendix F

Brainstorm of subfunctions




ook zonder de duim te gebruiken
Duim niet alleen naar binnen, ook naar buiten
Veerkracht
↳ vingers samen
pasplek
↳ vingers vlak
druk op
MCP kootje
Druk
van pols


AIR
AIR
PRESSURE

Appendix G

Inspirational collage

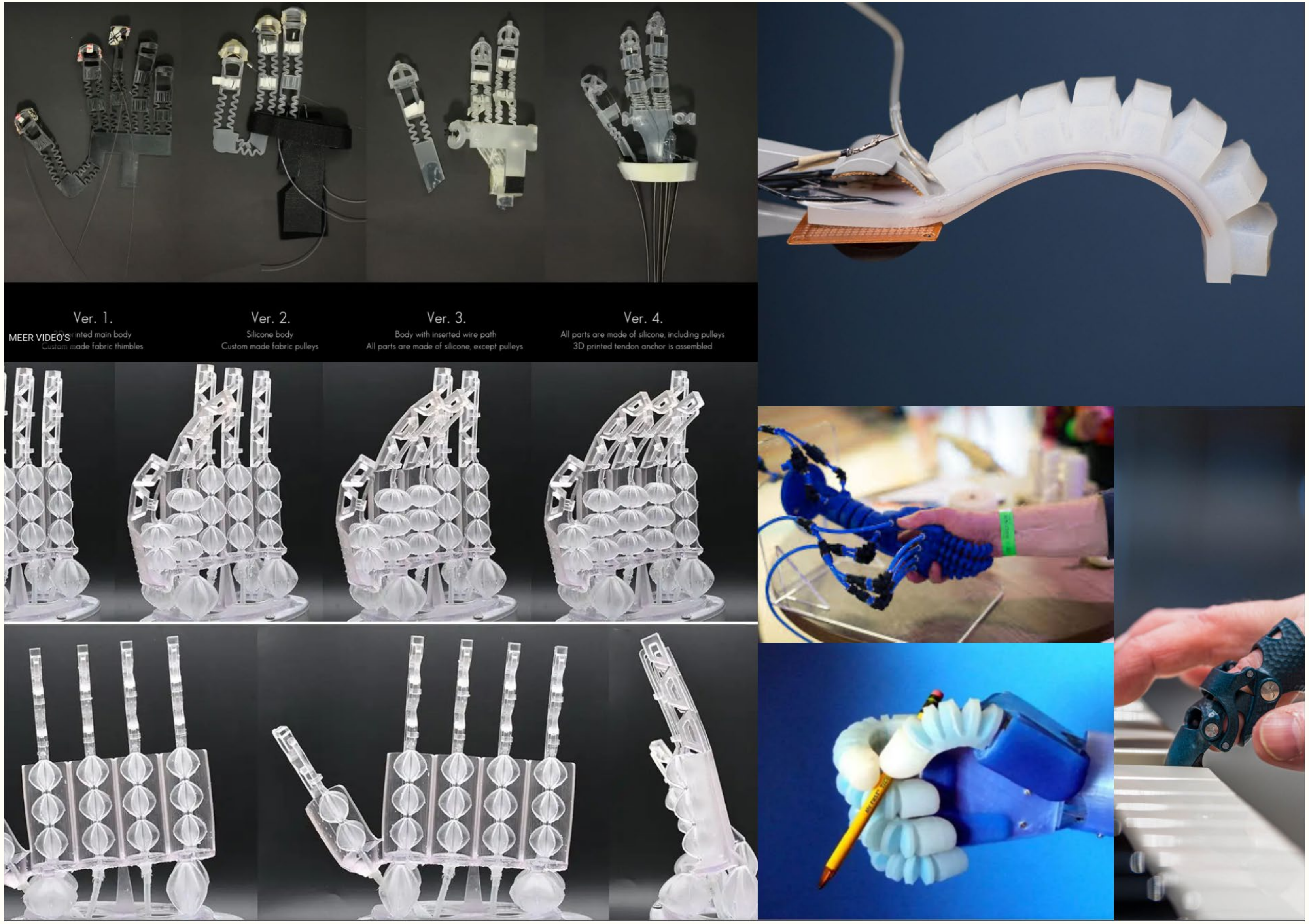


Figure 3: Collage for inspiration

Appendix H
Requirements and wishes

1. Performance

1.1	Pinch force of the finger is not lower than 10.4 N	Almost achieved
1.2	Minimal power force is 1N	Achieved
1.3	Maximum activation force is not higher than 38N	Achieved
1.4	Maximum angle range of the finger is 260°	Achieved
1.5	Maximum angle range of the wrist is 60°	Achieved
1.6	Total weight of prosthesis is below 273 g	Achieved
1.7	The prosthesis should be able to make flexion/extension movement	Achieved
1.8	The prosthesis has to be able to make a tripod grip	Not achieved
1.9	The product must be used by patients with a partial hand amputation at the MCP-joint without a residu finger	Achieved
1.10	The product should show improvement in the rehabilitation process of the patient	Testing required
1.11	The product should fit for every partial handamputation at the MCP-joint with no residu finger	Almost achieved
1.12	The prosthesis should work with a VC system	Achieved
1.13	The minimum push force is 6N	Achieved

Wish

1.14	Fingers can move individually	Not achieved
1.15	Touch screen compatable	Not achieved
1.16	The product will not cover the handpalm	Not achieved

2. Environment

2.1	The product needs to withstand water	Achieved
2.2	The product needs to withstand dust	Achieved

3. Life in service

3.1	Product should last 2 years	Testing required
3.2	the product must be usable on a daily basis	Testing required

4. Maintenance			
4.1	Maintenance has to be possible		Achieved
4.2	the product must be cleanable by the user		Achieved
4.3	It should be possible to produce the spare parts at any location		Achieved
5. Target product cost			Achieved
5.2	Price needs to be below €1000		Achieved
6. Transport		Wish	
6.1	Product should be made inhouse		Achieved
6.2	The product must be able to be sent by parcel service		Achieved
7. Packaging		Wish	
7.1	Packaging should protect the product from transport damage		Out of scope
7.2	Packaging should tell the buyer which product is inside		Out of scope
8. Quantity		Wish	
8.1	Basic parts of the product is produced in batches		Achieved
9. Product facilities		Wish	
9.1	The product is designed for existing production facilities		Achieved
10. Size and weight			
10.1	Weight is lighter than 273g		Achieved
11. Aesthetic, appearance and finish		Wish	
11.1	The product is customizable		Achieved
11.2	The product can not contain sharp edges		Achieved
11.3	The product has to have a reliable appearance		Testing required

12. Materials	
12.1 Material has to have grip	Almost achieved
12.2 Material should be waterproof	Achieved
12.3 Material should be dust proof	Achieved
12.4 The material should not cause irritations with the skin	Achieved
12.5 The material has to be able to withstand wear and forces applied to it	Achieved
12.6 The material should be easily shaped or adjusted to fit the user's specific anatomy and needs.	Achieved
Wish	
12.7 Fewest possible hinges and weak elements resulting in easy disassembly	Achieved
12.8 The material should withstand heath	Testing required
12.9 The material should withstand cold	Testing required
13. Standards, rules and regulations	
13.1 meet CE certification regulations for medical devices	Out of scope
14. Ergonomics	
14.1 The prosthesis must be taken on and off independently	Achieved
14.2 The fitting of the prosthesis has to be comfortable for the user without irritating the wrist or hand	Testing required
14.3 When flexing the wrist, the user should not have to make a painful movement to do so	Achieved
Wish	
14.3 The prosthesis is intuitive to use	Testing required
15. Testing	
15.1 D-QUEST test should be done to evaluate the prosthesis	Testing required
16. Reuse, recycling	
16.1 The product should be modular to make it possible to replace deffect parts	Achieved
Wish	
16.2 Different parts can be reused when the prosthesis is at the end of its life cycle	Not achieved

Appendix I

Force comparison

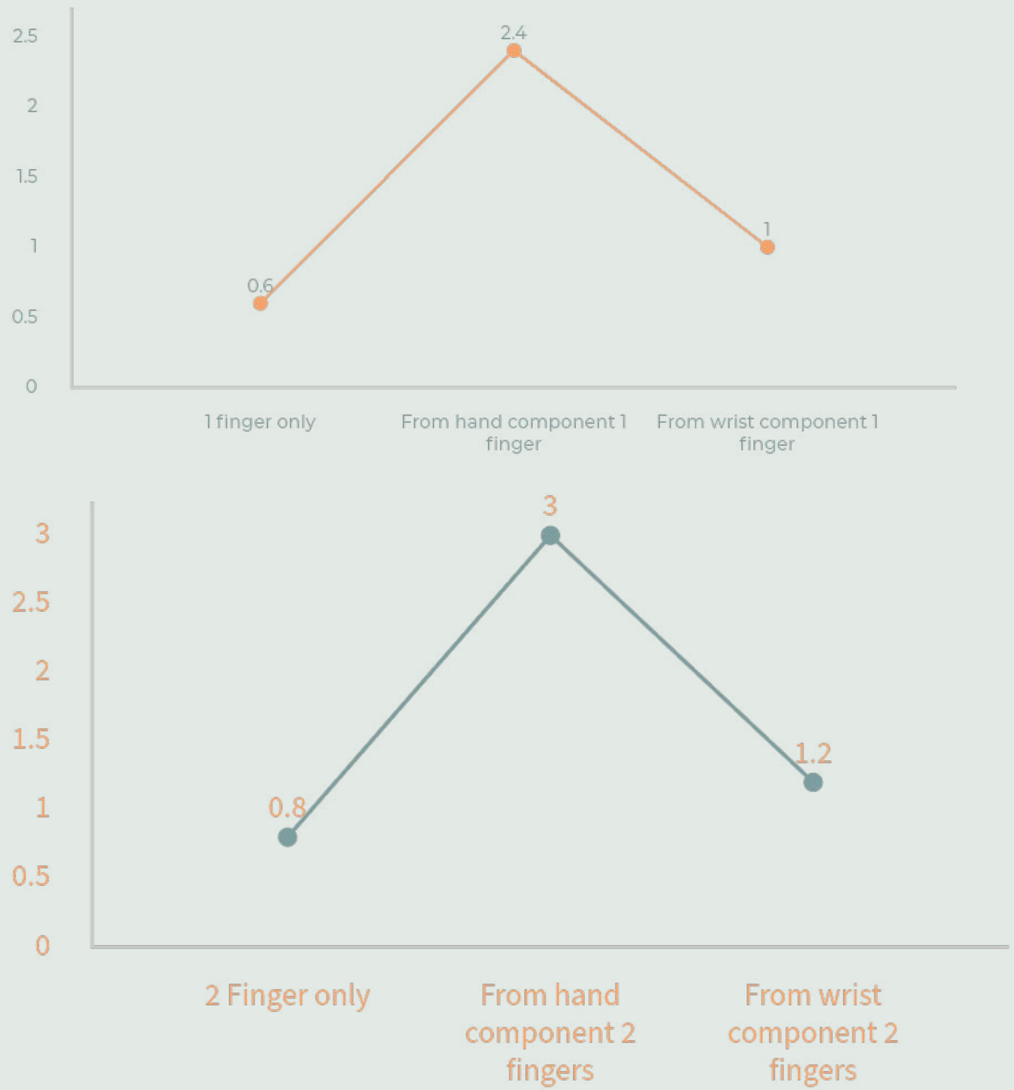


Figure 4: Graph of the force needed to bend finger from different locations

The amount of force that is needed to bend the finger was measured, using an unster.
The results show the amount of force that is needed to bend one and two fingers. Measuring from different locations to identify which component of the prosthesis is limiting the freedom of movement of the wire.
It was measure without the prosthesis, from the hand component and from the wrist component.

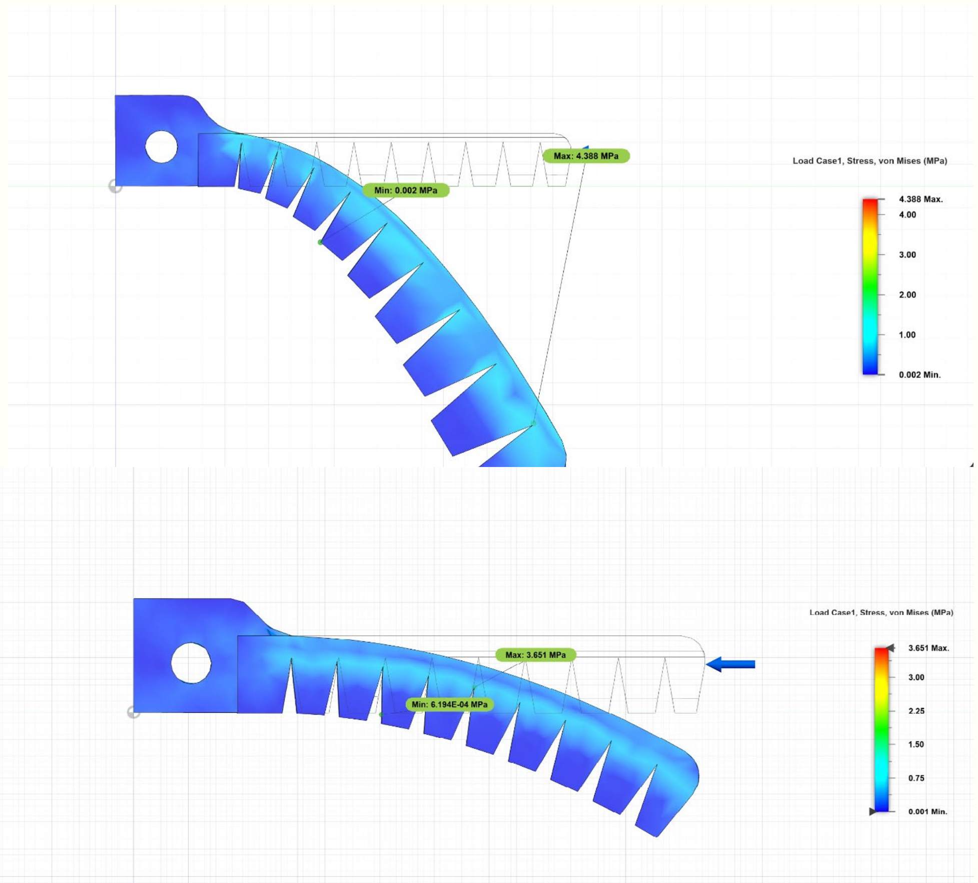
Concluded from this can be that the hand component is limiting the wire and therefore, a higher force is needed. However, it is deviant that the amount of force needed from the wrist is low again.
No cause was identified, unless the way of measuring and the angle of measuring had an influence on this result.

The measurement was done three times and the average was calculated to prevent this problem

Appendix J

FEM analysis, no bottom layer

The FEM analysis was also done to compare the results of the finger without a bottom layer. 11N was also here applied which resulted in a deformation. This is caused by the strength of the force and the material and construction that cannot withstand this.
However, when thickening the finger with 2mm, the deformation is not happing. Concluded from this was that thickining the finger would have a positive influence on the force the finger can withstand.



Width +2mm

Thickness +2mm

Figure 5: FEM analysis

Appendix K
Measurement setup

Unster

Figure 5:Test setup using an unster

pressure gauge

Figure 6: Test setup using a pressure gauge

Appendix L

Specifications different TPU materials

	Test method	Typical value		
		XY (Flat)	YZ (Side)	Z (Up)
Tensile (Young's) modulus	ASTM D3039 (1 mm / min)	67 ± 6 MPa	67 ± 2 MPa	56 ± 3 MPa
Tensile stress at yield	ASTM D3039 (50 mm / min)	No yield	No yield	No yield
Tensile stress at break	ASTM D3039 (50 mm / min)	23.7 ± 2.1 MPa	37.9 ± 1.6 MPa	6.4 ± 0.5 MPa
Elongation at yield	ASTM D3039 (50 mm / min)	No yield	No yield	No yield
Elongation at break	ASTM D3039 (50 mm / min)	>560%	>700%	82.3 ± 18.4%
Flexural modulus	ISO 178 (1 mm / min)	62.6 ± 1.7 MPa	55.1 ± 2.4 MPa	62.6 ± 2.0 MPa
Flexural strength	ISO 178 (5 mm / min)	4.1 ± 0.0 MPa at 9.4% strain	3.8 ± 0.1 MPa at 9.8% strain	4.3 ± 0.1 MPa at 9.7% strain
Flexural strain at break	ISO 178 (5 mm / min)	No break (>10%)	No break (>10%)	No break (>10%)
Charpy impact strength (at 23 °C)	ISO 179-1 / 1eB (notched)	36.0 ± 6.6 kJ/m²	–	–
Hardness	ISO 7619-1 (Durometer, Shore D)	48 Shore D	–	–
	ISO 7619-1 (Durometer, Shore A)	96 Shore A	–	–

Specifications Ultimaker TPU 95A

Figure 7: TPU specications Ultimaker (UltiMaker TPU 95A - Visiativ, 2024)

General Properties	Test Method	Imperial	Metric
Specific Gravity	ASTM D792	1.19 g/cc	1.19 g/cc
Moisture Absorption - 24 hours	ASTM D570	0.22 %	0.22 %
Mechanical Properties			
Tensile Strength, Yield	ASTM D638	580 psi	4 Mpa
Tensile Strength, Ultimate	ASTM D638	3,700 psi	26 Mpa
Tensile Modulus	ASTM D638	1,800 psi	12 Mpa
Elongation at Yield	ASTM D638	65%	65%
Elongation at Break	ASTM D638	660%	660%
Toughness (integrated stress-strain curve; calculated stress x strain)	ASTM D638	12,000 in·lbF/in³	82.7 m*N/m³ x10⁶
Hardness	ASTM D2240	85 Shore A	85 Shore A
Impact Strength (notched Izod, 23C)	ASTM D256	2.0 ft.lbf/in²	4.2 kJ/m²
Abrasion Resistance (mass loss, 10,000 cycles)	ASTM D4060	0.08 g	0.08 g
Thermal Properties			
Melting Point (via Differential Scanning Calorimeter)	DSC	420° F	216° C
Glass Transition (Tg)	DSC	-31° F	-35° C
Heat Deflection Temperature (HDT) @ 10.75psi/ 0.07 MPa	ASTM D648	140° F	60° C
Heat Deflection Temperature (HDT) @ 66psi/ 0.45 MPa	ASTM D648	111° F	44° C

Specifications Ninjaflex TPU 85A

Figure 8: TPU specications Ninjaflex (NinjaTek & Fenner Drives, Inc., 2016)

Recommended Printing Settings		Physical Properties		Mechanical Properties	
Drying Settings (Blast Drying Oven)	70 °C, 8 h	Density	1.22 g/cm³	Tensile Strength	27.3 ± 0.8 MPa
Printing and Keeping Container's Humidity	< 20% RH (Sealed, with Desiccant)	Vicat Softening Temperature	N / A	Breaking Elongation Rate	> 650%
Nozzle Temperature	220 - 240 °C	Heat Deflection Temperature	N / A	Bending Modulus	N / A
Bed Temperature (with Glue)	30 - 35 °C	Melting Temperature	183 °C	Bending Strength	N / A
Printing Speed	< 200 mm/s	Melt Index	36.5 ± 2.6 g/10 min	Impact Strength	N / A

Specifications Bambu 95A HF

Figure 9: TPU specications Bambu (Bambu Lab EU, n.d.)

Appendix M

Design steps wrist component

Design sketch after defining material

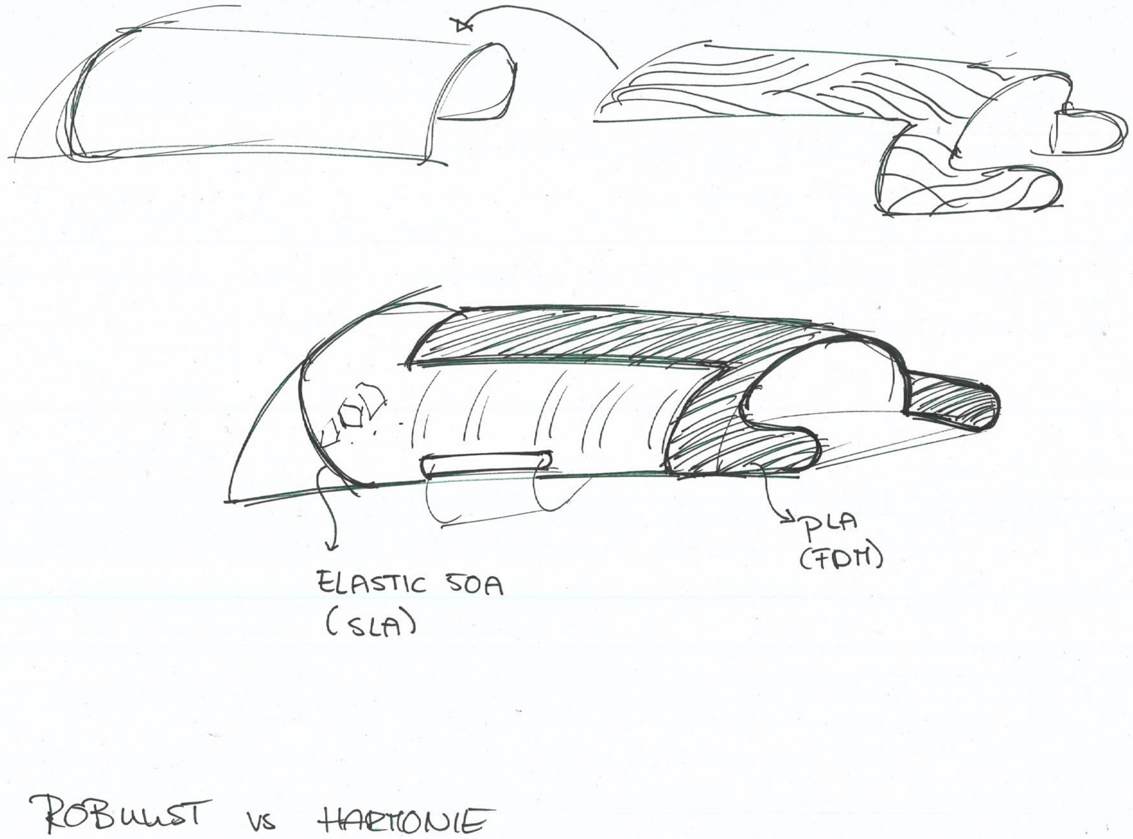
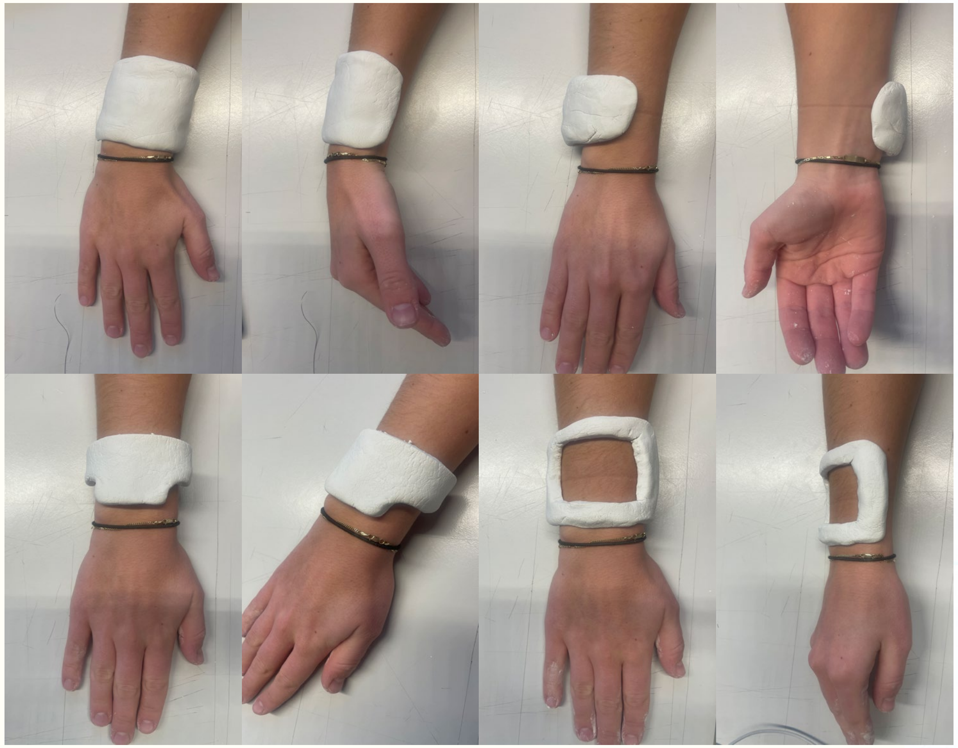


Figure 10: Idea sketch of final prototype design

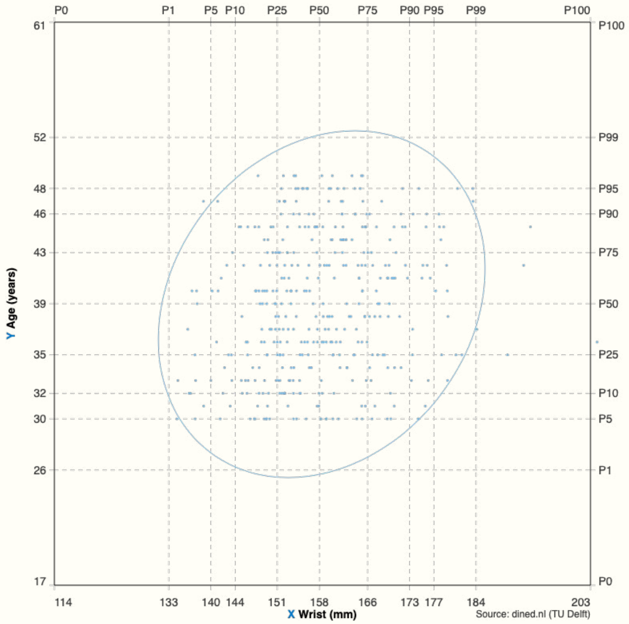


Clay prototypes

Figure 10: Clay prototype for design of the wrist component

Appendix N

Sizes wrist circumferences



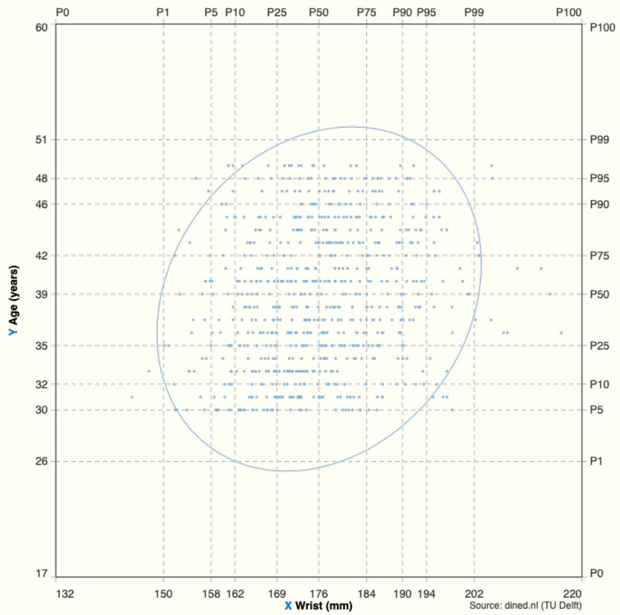


Figure 11: Sized from wrist circumferences from DINED

The design is created in a way that it is possible to adjust the size of the wrist part. To make this possible, different sizes needs to be created to make sure that every men and woman are able to receive a well fitting wrist component.
Therefore the anthropometric data from DINED was used ((TU Delft [DINED], n.d.) (Figure 12). There is looked at the female and male measurements seperately from each other since the differences are quite large.

Female	Male
S - 151 mm	S - 169 mm
M - 158 mm	M - 176 mm
L - 165 mm	L - 183 mm

Female

Measures	P25	P50	P75
Wrist (mm)	151	158	165

Male

Measures	P25	P50	P75
Wrist (mm)	169	176	183

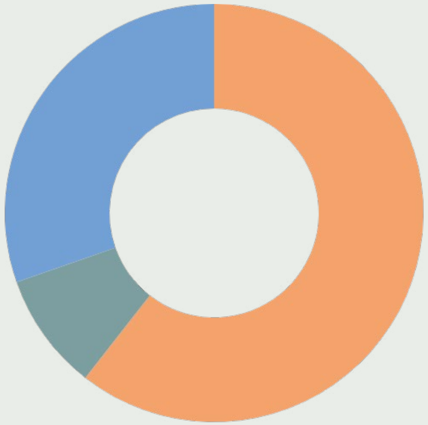
Figure 12: Anthropometric data from DINED female and male (TU Delft [DINED], n.d.)

Appendix O

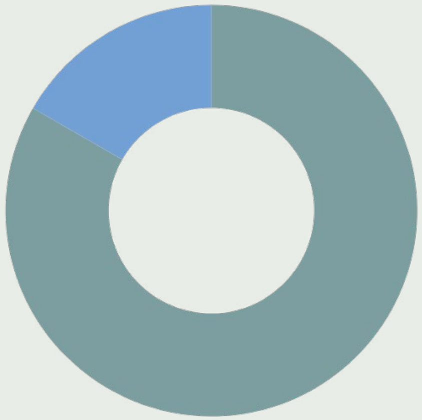
Questionnaire

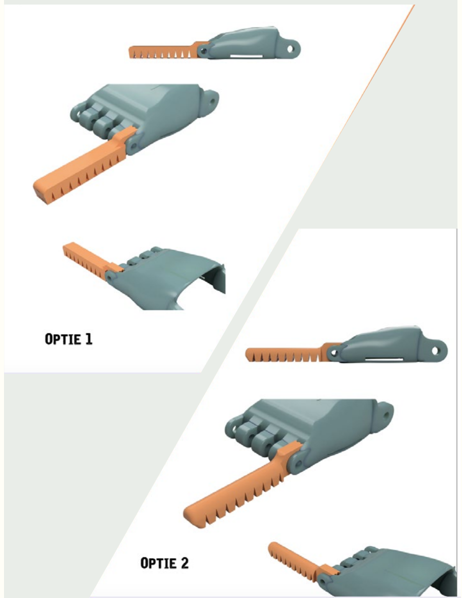
Would the finger design of a hand prosthesis be important to you?

What do you think the appearance of the finger should look like?



See image below Which design of finger would you prefer?





Why did you choose this option?

- It is more important than it functions.
- looks more natural
- I think the round fits better with a hand, arm and the rest of the body and it comes across a bit less like a lego cube.
- This one looks more like a real finger. Also, it seems to me that this one is less likely to snag, or hurt people by, say, cutting a bit as you pass skin.
- Looks nicer
- Looks more natural and hurts less when it bumps into someone

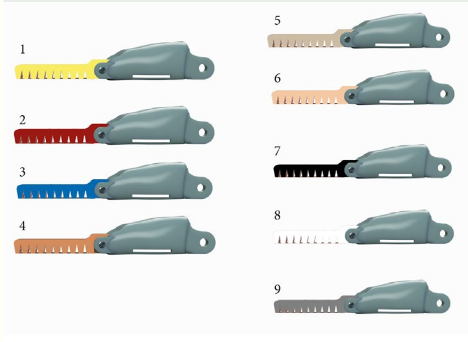
Where could the finger design be improved so that you would wear the prosthesis faster?

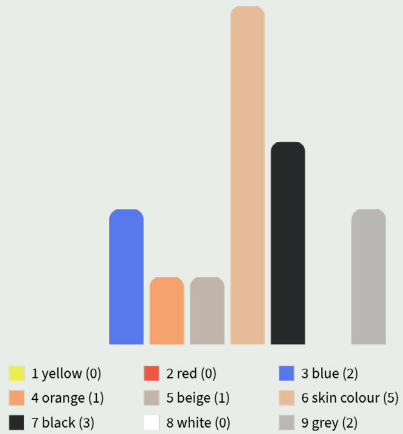
- Skin colour?
- Whole prosthetic skin colour and more like a hand. Or if it's just about the finger, in the ribs think it's still a bit fierce
- I would wear it regardless of the look if it improves your life. I would go for a different (especially change the orange) colour combination myself though.
- Individual control of the fingers.
- Something cheerful to go with it
- Cover/glove for over the prosthesis if it turns out that it snags easily

Would the colour of the finger matter to you?

'See image below, these are examples of colour options.

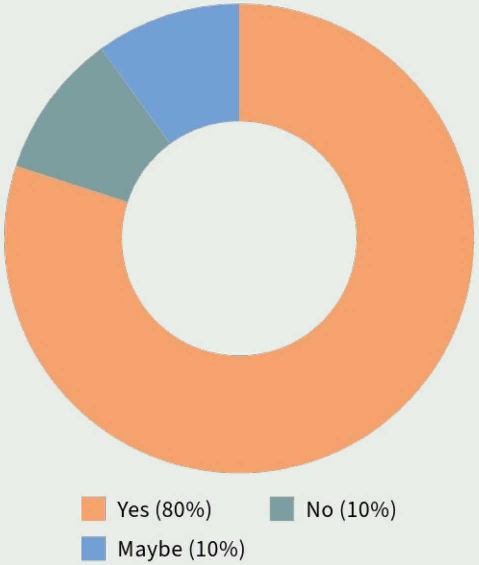
Looking only at the finger, which colour would you prefer? Please explain your choice.'



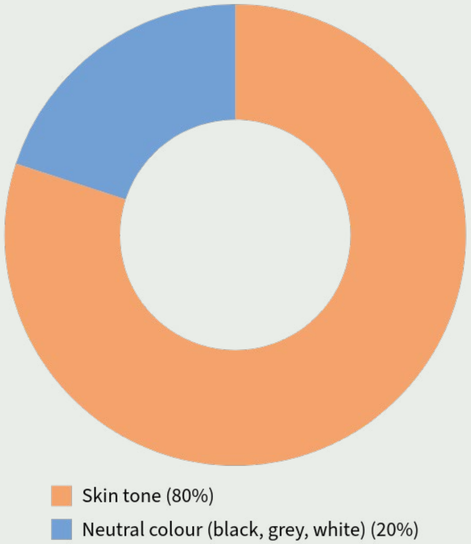


- 3 and 6
- 6, I think is most skin colour
- '3. I think goes nicely with the grey and is fairly neutral despite the striking colour
- 9. Everything in one colour then again I think looks calm and perhaps makes for a little less questioning and attention by being less noticeable'
- 6, This is about the same as the colour of my fingers now. This fits best and most naturally with the rest of my limbs.
- 6, skin tone does look the most normal. You also don't want the finger to stand out super much
- 4, 5, 6, 7 or 9. Would go for a neutral colour

Would the colour of the rest of the prosthesis (hand and wrist part) matter to you?



In that case, would you prefer to wear a neutral colour, skin tone or bright colour?



Could the design of the prosthesis cause you to wear it or not?

- No, it should be functional in this situation
- Yes, rather a beautiful prosthesis than functional
- Maybe
- No, it has to be functional in this situation
- Maybe
- No, it has to be functional in this situation

Appendix P

Clamping system

A first idea that was promising can be seen in Figure 13. However, due to the amount of time, this is not a mechanism that was easy to integrate in time. But it has some promising elements which would be advised to focus on during the next steps.

This mechanism will make a release button redundant. By flexing the fingers, the wire will be pulled under tension and locked. By bending the wrist again, the system will unlock, like a pen mechanism.
However, the quality of the 3D printing is no good enough to produce this small parts. Further development needs to be done, and therefore there is chosen not to continue with this direction. However, this is promising and could change the prosthesis mechanism.

The second idea was created as an inspiration from the tape measure mechanism (Figure 14). This mechanism uses a spiral spring and a release button on top of the mechanism. When there is pulled on the tape, the spring releases and everytime it passes a certain point where the movement is blocked. By pushing the button, this certain point is pressed down which makes sure that the spring can roll back to its origignal shape.
This is an interesting mechanism but this was not chosen since it results in an extra part that needed to be attached to the wrist and it was difficult to find an area for that. To make sure that the hand would not contain too many mechanisms and parts, this was not the right option to choose.

1.

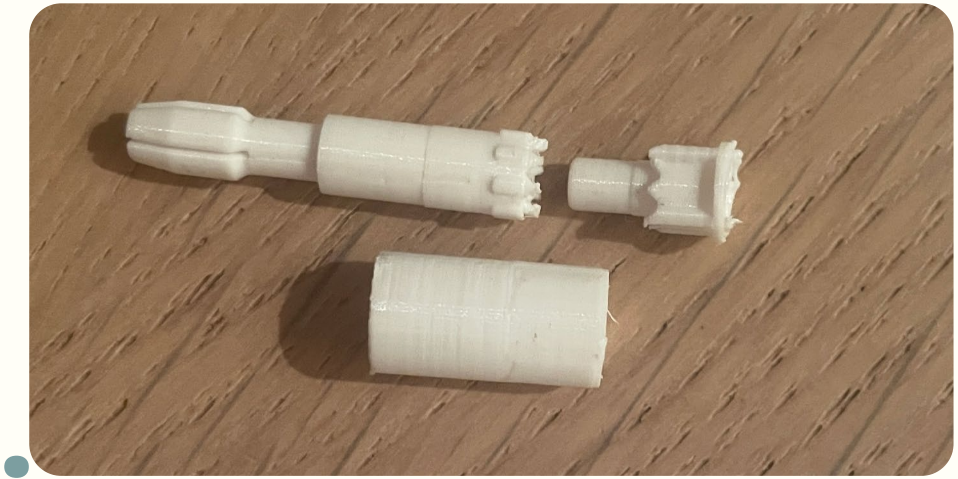


Figure 13: First idea clamping system

2.

Figure 14: Tape measure mechanism

The third idea was to use the mechanism in a rod to adjust the length of the rod (Figure 15-18).
A pin is attached on the hand componentt and a hole is created in the ring that is attached to the pin of the hand-wrist connnection.
When the hand component is turned, the pin falls into the hole of the ring, which will hold the hand, thus the fingers, in position. By clicking on this pin and pushing it backwards into the hand component, the hand component is released and the fingers can stretch. The first idea sketch and CAD model are visualised in Figure 14 and 15. This idea was tested with 3D printing (Figure 16) and visualised when integrated as a whole (Figure 17).
During testing, it was found out that this is not possible to integrate since the ring is not glued to the hand component. Therefore, when the pin will fall through the hole, the ring will turn with it.
Nevertheless, this idea is developed in a different way and integrated in the current design.

3.

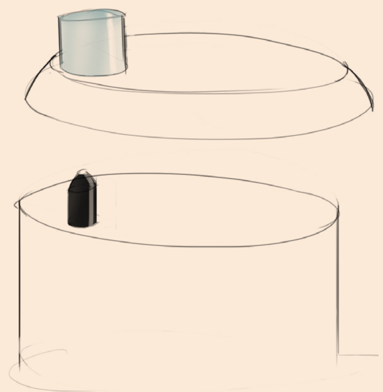


Figure 14: First idea sketch

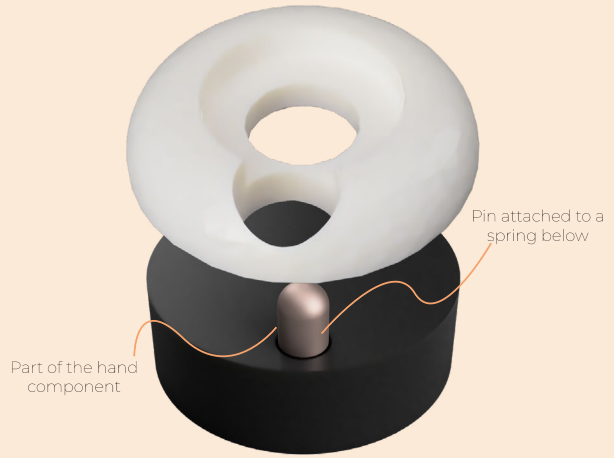


Figure 15: CAD design with explanation

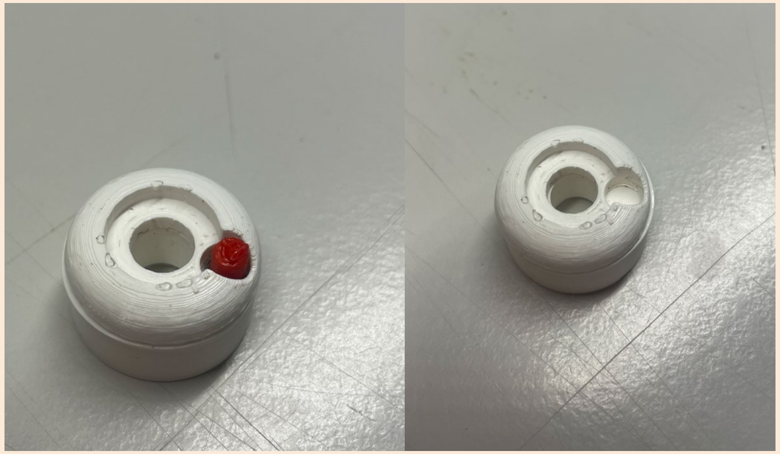


Figure 16: CAD design with explanation

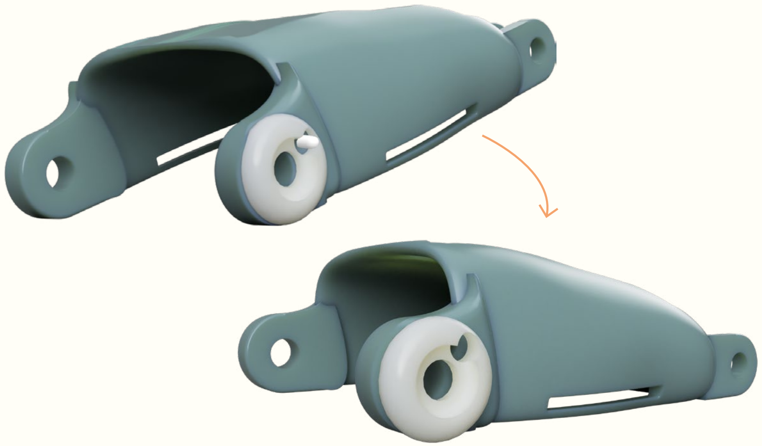
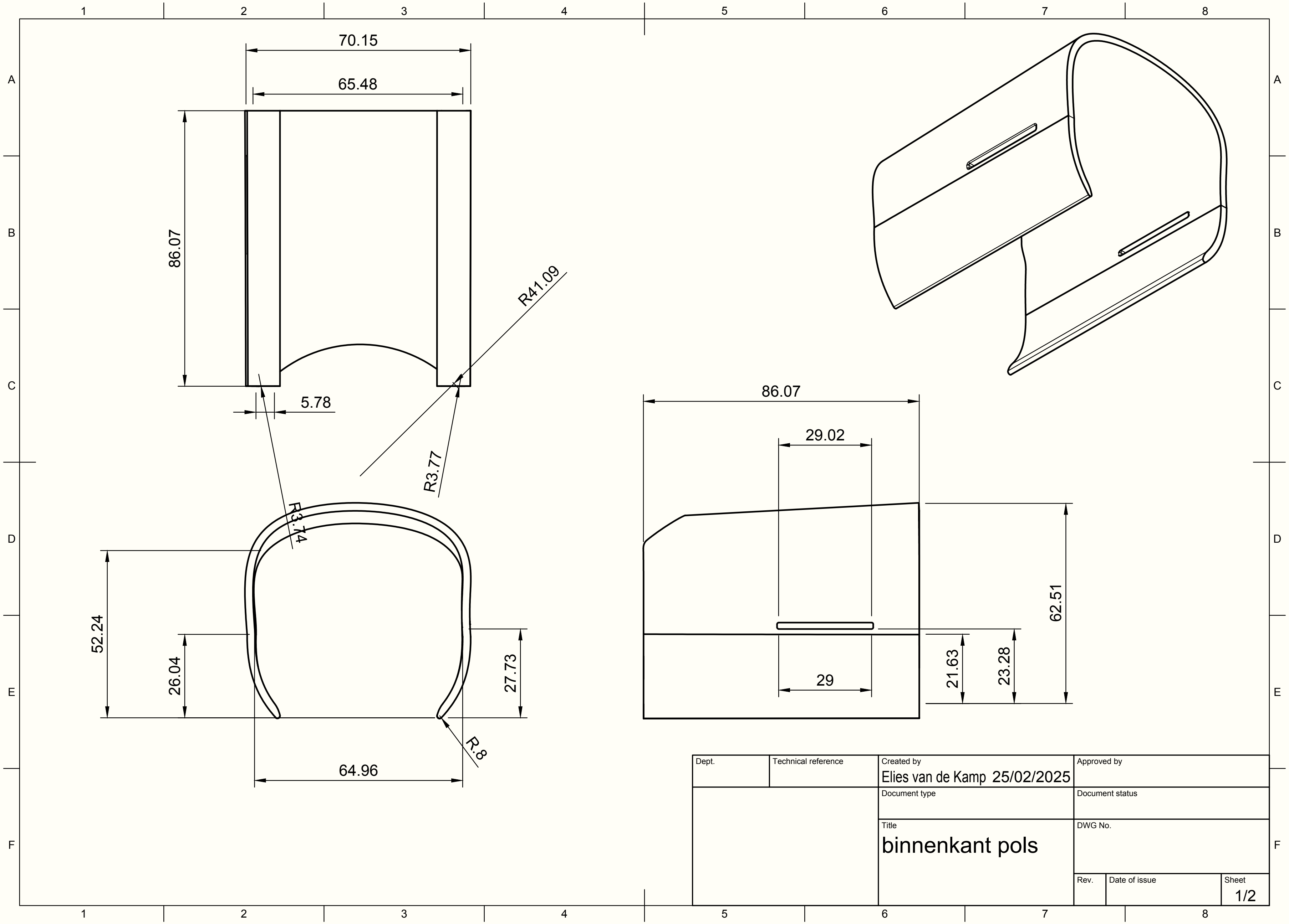
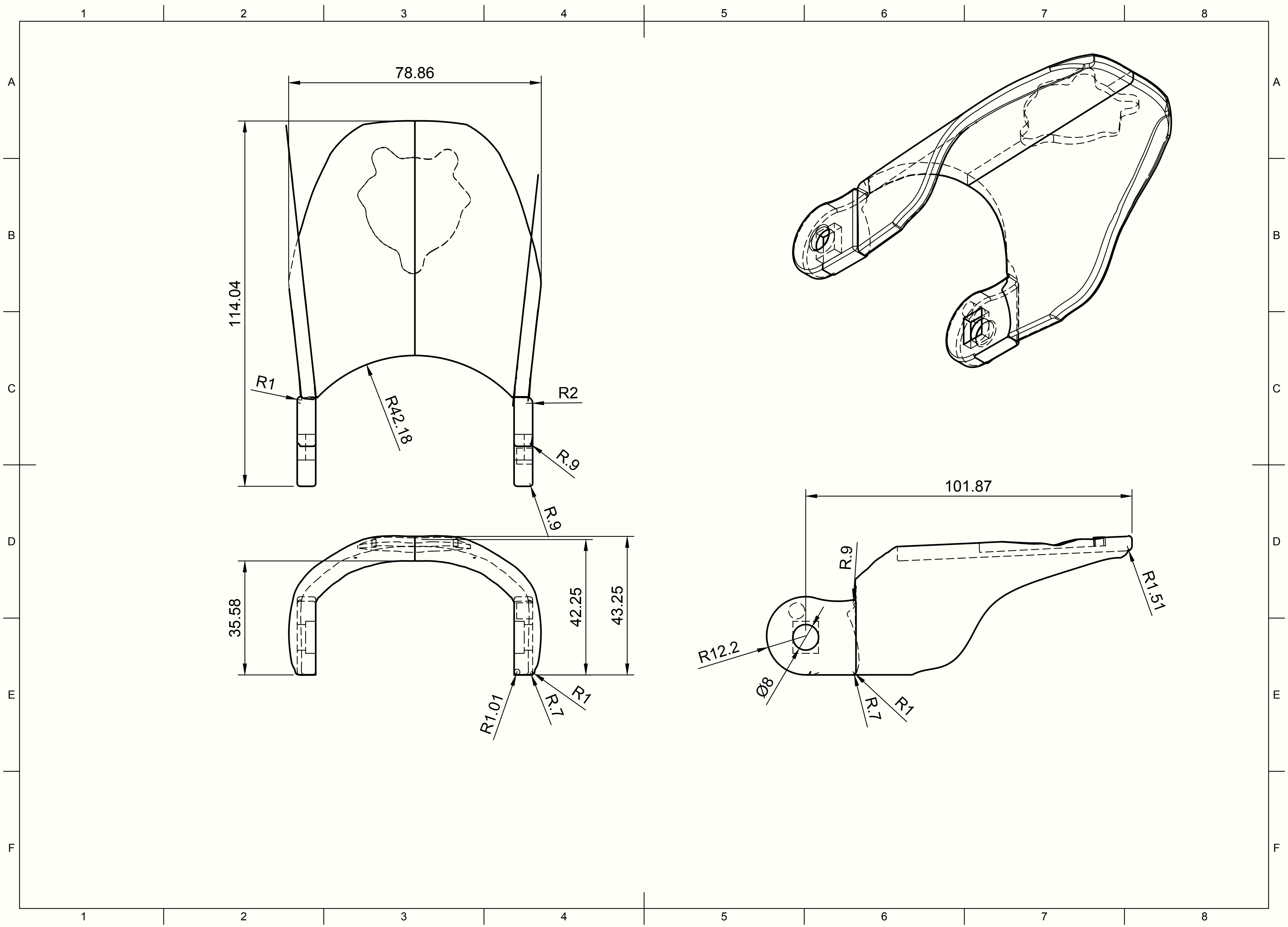


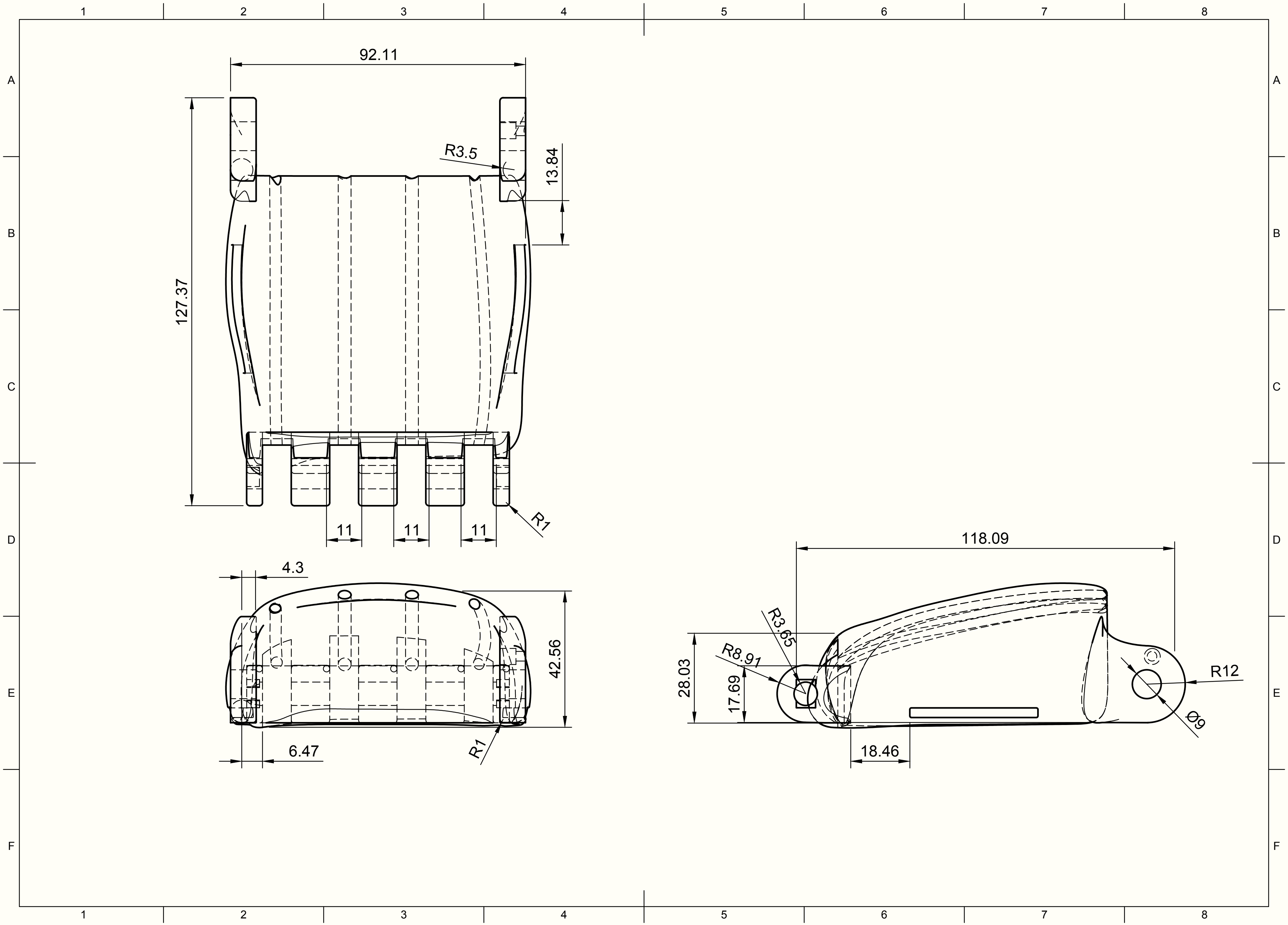
Figure 17: CAD design with explanation

Appendix Q

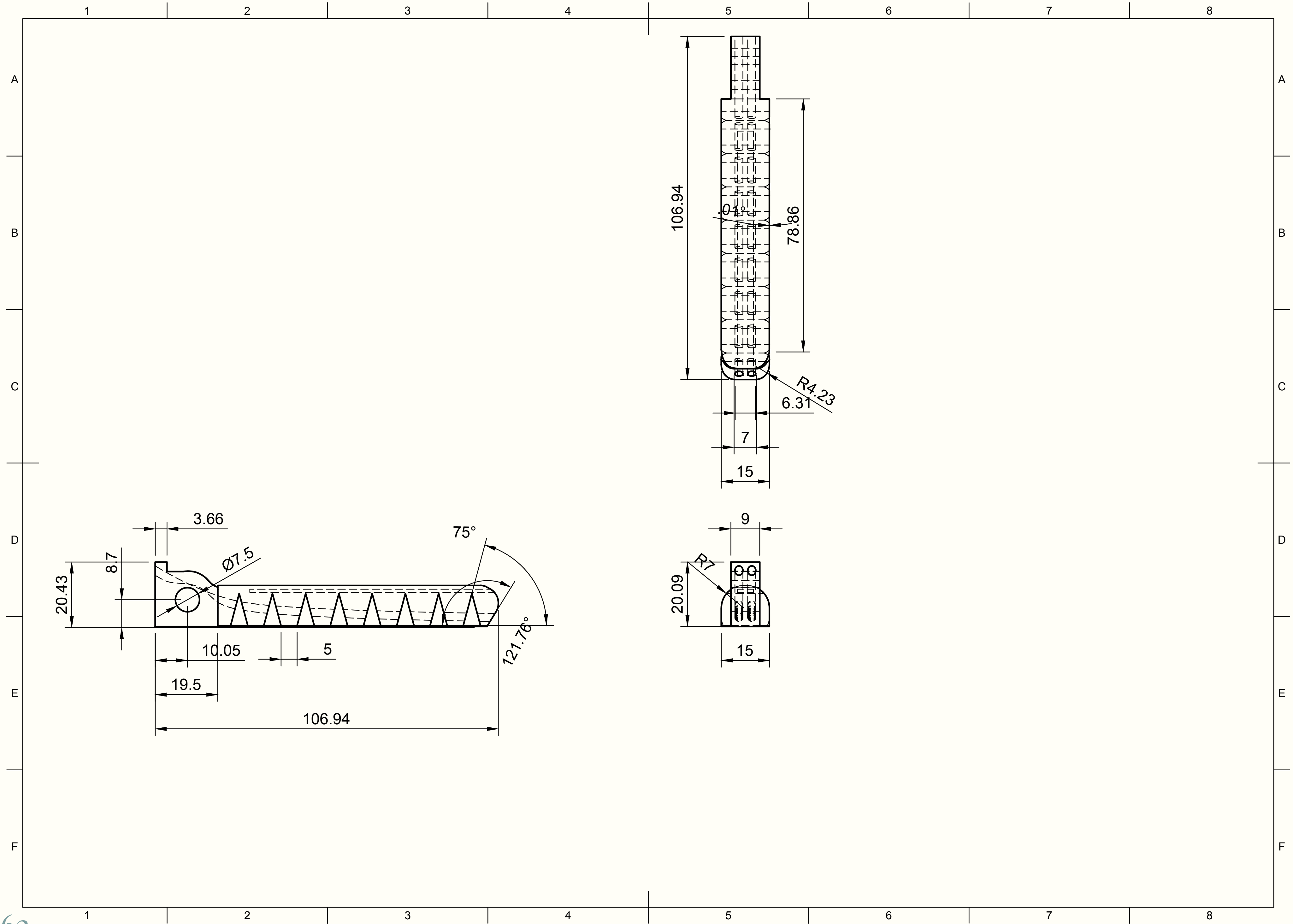
Dimensions components



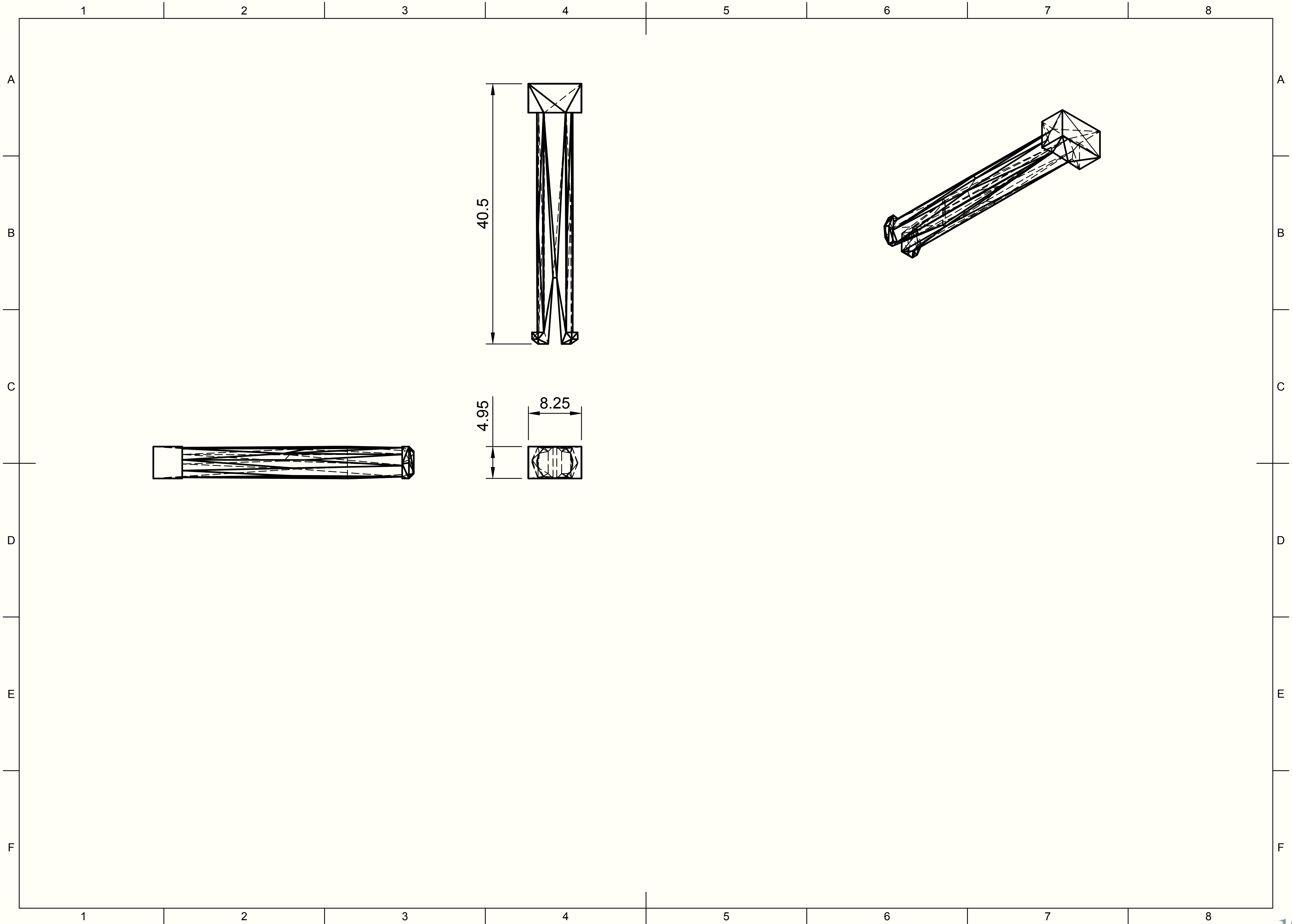

78.86
114.04
R1
R2
R42.18
R.9
R.9
35.58
42.25
43.25
R1.01
R.7
R1
101.87
R.9
R1.51
R12.2
Ø8
R.7
R1

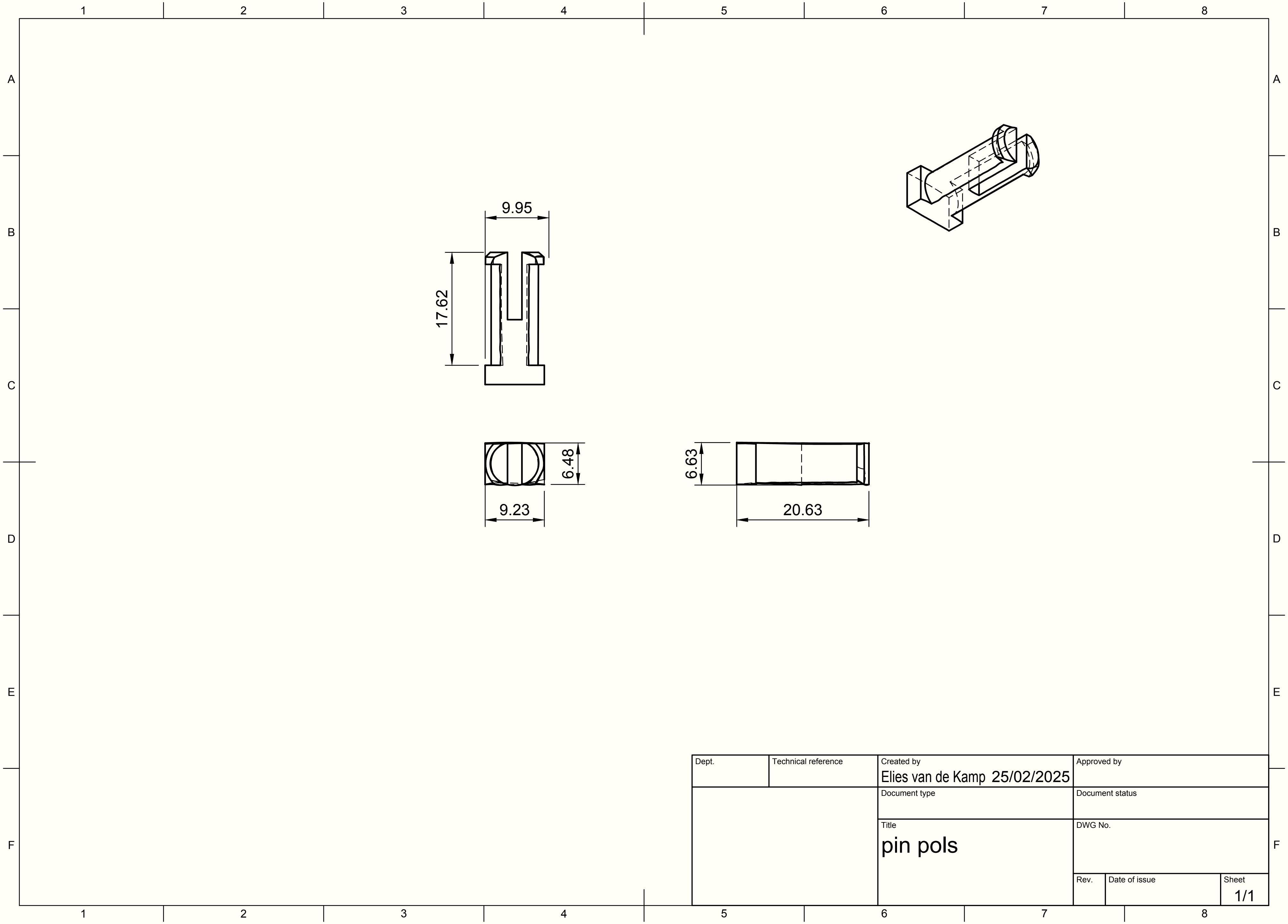


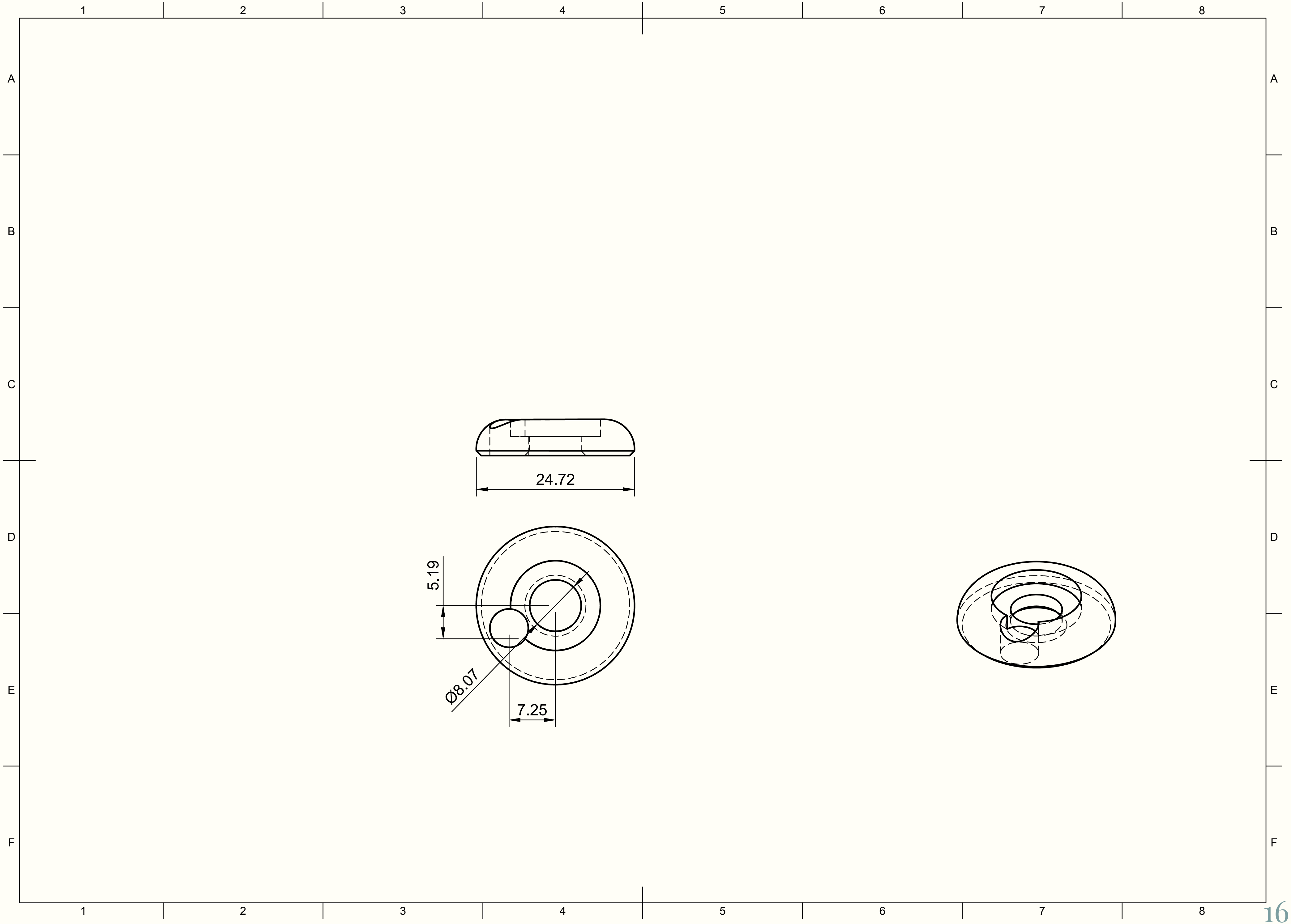
1
2
3
4
5
6
7
8
A
B
C
D
E
F
92.11
127.37
R3.5
13.84
11
11
11
R1
4.3
42.56
6.47
R1
118.09
R3.65
R8.91
28.03
17.69
R12
Ø9
18.46



106.94
78.86
R4.23
6.31
7
15
9
R7
20.09
15
3.66
8.7
20.43
Ø7.5
75°
121.76°
10.05
5
19.5
106.94


40.5
8.25
4.95
1 2 3 4 5 6 7 8
A B C D E F


9.95
17.62
6.48
9.23
6.63
20.63
Dept.
Technical reference
Created by
Elies van de Kamp 25/02/2025
Approved by
Document type
Document status
Title
pin pols
DWG No.
Rev.
Date of issue
Sheet
1/1


24.72
5.19
Ø8.07
7.25

Appendix R

Cost structure

Opbouw van de kosten per onderdeel						
Maak alvorens wijzigingen aan te brengen duplicaten van dit tabblad aan voor elk *in house* te produceren onderdeel van je product. RMK op tabblad K Onderdeel > Move or copy > Create a copy.						
Benaming	**ExoScorp**		**Productieserie**	**1**	**stuks**	**per onderdeel**
Materiaalkosten		**bruto hoeveelheid/product**	**eenheid**	**prijs/eenheid**	**bedrag**	
halffabrikaat	Formlabs Photopolymer	200	ml	€ 0,12	€ 24,00	
halffabrikaat	TPU 95 A	44	g	€ 0,11	€ 4,84	
halffabrikaat	BioMed Flex 80A	50	ml	€ 0,30	€ 15,05	
				totaal materiaalkosten	**€ 43,89**	**€ 43,89**
Bewerkingskosten	**capaciteit [stuks/u]**	**machineuren**	**machine-uurtarief**	**machine-kosten**		
Formlabs SLA printer	0,4	6,00	€ 2,30	€ 13,80		
Ultimaker	0,2	9,68	€ 2,50	€ 24,20		
etc.	1000	0,00	€ 0,00	€ 0,00		
nabewerking	1000	0,00	€ 0,00	€ 0,00		
				totaal machinekosten	**€ 38,00**	
machines als bovenstaand	**mens/machine-bezetting**	**arbeidsuren**	**mensuurtarief**	**arbeidskosten**		
Formlabs SLA printer	1	0,00	€ 18,00	€ 0,00		
Ultimaker	1	0,00	€ 18,00	€ 0,00		
etc.	1	0,00	€ 0,00	€ 0,00		
nabewerking	1	0,00	€ 0,00	€ 0,00		
				totaal arbeidskosten	**€ 0,00**	
				totaal bewerkingskosten	**€ 38,00**	**€ 38,00**
Instelkosten serie	**insteltijd [u]**	**uurtarief insteller**	**mach.uurtarief**	**kosten**	**per product**	
Formlabs SLA printer	1	€ 24,00	€ 2,30	€ 26,30	**€ 26,30**	**€ 26,30**
Ultimaker	1	€ 24,00	€ 2,50	€ 26,50	**€ 26,50**	**€ 26,50**
Gereedschapskosten	**aanschafprijs**	**standtijd [stuks]**	**restwaarde**	**prijs/eenheid**		
Resin tank	€ 91	75.000	€ 40,00	€ 0,00		
Build platform	€ 320	0	€ 50,00			
Form cure	€ 907	500	€ 400,00	€ 1,01		
Form wash	€ 821	500	€ 400,00	€ 0,84		
subtotalen	€ 2.139		€ 890,00			
gemiddelde waarde	€ 1.515					
kapitaalrente	0,0%	rentekosten	€ 0,00	€ 0,00		
				totaal gereedschapskosten	**€ 1,86**	**€ 1,86**
Algemene toeslagen						
uitval-factor*	1,0%	*afgekeurde producten, zie Kals voor percentages			**subtotaal**	**€ 136,55**
overheadfactor**	15,0%	** algemene toeslag voor productiefaciliteiten				
totaal	**16,0%**					**€ 21,85**
		K_{Fi} voor interne calculatie:		**Productiekostprijs ExoScorp**		**€ 158,39**

Opbouw van de fabricagekostprijs van een compleet product (vgl. Kals)						
Product	**ExoScorp**					
						prijs per product
In-huis te vervaardigen	**prijs/stuk**	**stuks/product**	**prijs per product**			
ExoScorp	€ 158,39	1	€ 158,39			
		1	€ 0,00			
		1	€ 0,00			
			€ 158,39			
					totaal vervaardiging	**€ 158,39**
Inkopen	**prijs/eenheid**	**eenheid**	**eenheid/product**	**prijs per product**		
TPU	€ 0,110	g	4	€ 0,44		
Biomed Flex 80A	€ 0,301	ml	50	€ 15,05		
Photopolymer	€ 0,120	ml	200	€ 24,00		
BOA	€ 75,000	stk	1	€ 75,00		
Velcro	€ 6,320	m	0,5	€ 3,16		
Wires	€ 0,059	m	2	€ 0,12		
				€ 117,77	**totaal inkoop**	**€ 117,77**
Assemblagekosten		**assemblageserie**	1			
	capaciteit [stuks/u]	**machineuren**	**uurtarief**			
montagestation	4	0,25	€ 23,00	€ 5,75		
instellen montagestation	nvt	0,00	€ 43,33	€ 0,00		
handmontageplek	2	1,00	€ 18,00	€ 18,00		
verpakken	nvt		€ 0,00	€ 0,00		
					totaal machinekosten	**€ 23,75**
machines als bovenstaand	**mens/machine-**	**arbeidsuren**	**uurtarief**			
montagestation	1	2,00	€ 25,00	**arbeidskosten**		
instellen montagestation	1	0,50	€ 30,00	€ 50,00		
handmontageplek	1	2,00	€ 18,00	€ 15,00		
verpakken	1	0,00	€ 18,00	€ 36,00		
				€ 0,00		
				totaal arbeidskosten	**€ 101,00**	
				totaal assemblagekosten	**€ 101,00**	**€ 101,00**
K_{ft} Productiekostprijs geassembleerd product voor interne calculatie:						
					Productiekostprijs ExoScorp	**€ 400,91**

	Voorbeeldberekening voor de winkelprijs op basis van de fabricagekostprijs (bron: Erik Thomassen).		
K_{Ft}	Productiekostprijs geassembleerd product voor interne calculatie:	**ExoScorp**	**€ 400,91**
F_{OB}	Overheadfactor voor algemene bedrijfskosten*	15%	
F_{OV}	Overheadfactor voor verkoopkosten	2%	
F_{W}	Winstfactor (onvoorziene kosten worden a.h.w. uit de winst betaald)	0%	
	Totaalfactor = product van (elk van deze factoren+1) min 1	17,8%	**€ 71,24**
K_{V}	Verkoopprijs af-fabriek (moet je betalen als je product bij de fabriek zelf ophaalt)		**€ 472,15**
	Marge tussenhandel (bijvoorbeeld: importeur, groothandel, leverancier, distributeur)	20,0%	**€ 94,43**
	Groothandelsverkoopprijs		**€ 566,58**
	Marge detailhandel (winkel) is zeer branche- en aanbiedingsafhankelijk, ligt tussen 25% voor een webshop en 300% voor een servicegerichte detaillist in een mooi pand op een A-locatie. Strategie met oog op o.a. concurrentie en voorraad bepaalt de marge.	30,0%	**€ 169,97**
	Netto verkoopprijs (exclusief BTW)		**€ 736,56**
	BTW (= Belasting op de toegevoegde waarde, = omzetbelasting)**	9,0%	**€ 66,29**
	Verkoopadviesprijs, normale winkelprijs		**€ 802,85**
	*) Voordat iets geproduceerd wordt, moet er doorgaans van alles gedaan zijn: niet alleen het ontwerpproces, maar ook bijvoorbeeld prototyping in meerder stadia, gebruiksonderzoek, marktontwikkeling, certificering, octrooiaanvragen en dergelijke. Als dit allemaal in de productprijs verdisconteerd moet worden, kan deze aardig oplopen.		
	**) hoog tarief = 21%, laag tarief =6% (voeding, boeken), soms ook nog heffingen zoals bijvoorbeeld de wettelijke verwijderingsbijdrage.		