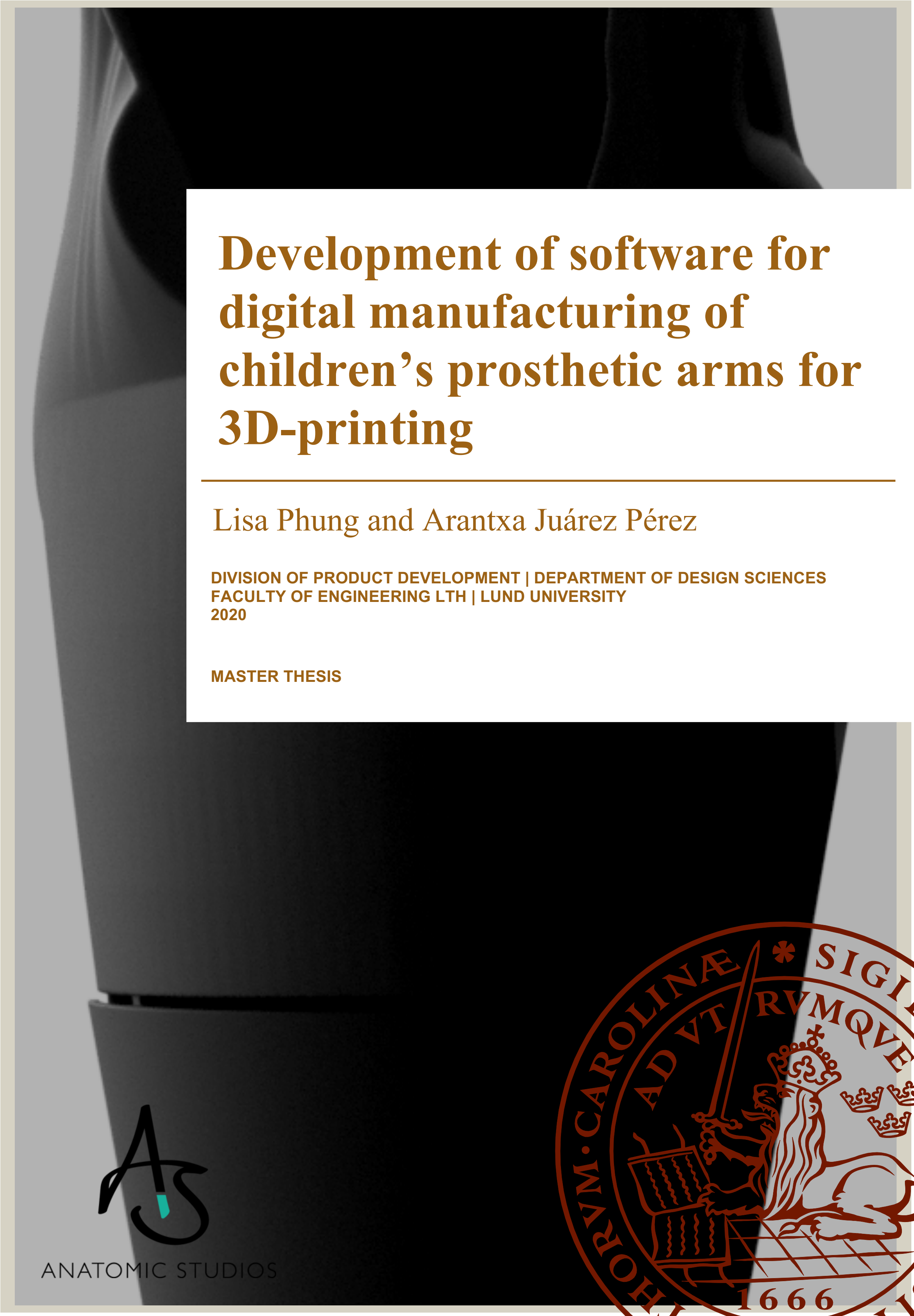


Development of software for digital manufacturing of children’s prosthetic arms for 3D-printing

Lisa Phung and Arantxa Juárez Pérez

DIVISION OF PRODUCT DEVELOPMENT | DEPARTMENT OF DESIGN SCIENCES
FACULTY OF ENGINEERING LTH | LUND UNIVERSITY
2020

MASTER THESIS

Development of software for digital manufacturing of children’s prosthetic arms for 3D-printing

Lisa Phung and Arantxa Juárez Pérez

LUND
UNIVERSITY

Development of software for digital manufacturing of children's prosthetic arms for 3D-printing

Published by
Department of Design Sciences
Faculty of Engineering LTH, Lund University
P.O. Box 118, SE-221 00 Lund, Sweden

Subject: Technical Design (MMKM10)
Division: Product Development
Supervisor: Axel Nordin
Co-supervisor: Christian Veraeus
Examiner: Giorgos Nikoleris

Abstract

The conventional method to manufacture prosthetic arms is a time-consuming and complicated process. It is a process that has many manual steps that allow much room for human errors. With today's technology advancement it is possible to offer a more efficient technology that can replace the conventional manufacturing method of prostheses. This master thesis aims to develop a new way of manufacturing prosthetic arms.

This report describes the development process of a software to digitally and automatically manufacture children's prosthetic arms for 3D-printing. The project aims to offer prosthetists a faster, cheaper and more intuitive way to manufacture prostheses without requiring extensive knowledge in CAD or programming. 3D-printing is considered to be a more advantageous technique than the traditional laminating method since it is possible to customize the design and tailor the model to a specific individual.

The development process began with basic research on the human anatomy, special focus is on amputations and different types of prosthetics. In addition to medical research, research was also conducted on 3D printing and 3D printing materials to gain knowledge about the technical aspects of this project.

Interviews and user studies were conducted to investigate the customer needs and to rank them accordingly. Based on the discovered needs, product specifications were established and concepts were developed. The development process was an iterative process where prototyping and testing had a central role.

The final product is a Rhino & Grasshopper script that auto-generates a prosthesis based on the scan of a limb and length and width of the non-amputated arm. The user is given a set of options to adjust the digital model for a customized design.

Keywords: *3D-printing, prosthetics, Grasshopper, process development, amputation*

Sammanfattning

Den konventionella metoden för tillverkning av armproteser är en tidskrävande och komplicerad process. Det är en process som har många manuella steg och ger stort utrymme för mänskliga fel. Med dagens tekniska framsteg är det möjligt att erbjuda ett effektivare tillverkningssätt som kan ersätta den konventionella tillverkningsmetoden av proteser. Syftet med detta examensarbete är att utveckla ett nytt sätt att tillverka armproteser.

Denna rapport beskriver utvecklingsprocessen av ett program för att digitalt och autonomisikt tillverka barnarmproteser för 3D printning. Projektet strävar mot att erbjuda protestillverkare ett snabbare, billigare och mer intuitivt sätt att tillverka proteser utan att kräva omfattande kunskaper inom CAD eller programmering. 3D-printning anses vara en mer fördelaktig teknik än den traditionella lamineringsmetoden eftersom det är möjligt att anpassa designen och skräddarsy modellen till en specifik individ.

Utvecklingsprocessen började med en förstudie om människans anatomi, speciellt fokus på amputationer och olika typer av proteser. Förutom den medicinska studien undersöktes även 3D printing och material för 3D printing för att få mer kunskap om den tekniska aspekten av detta projekt.

Intervjuer och användarstudier genomfördes för att undersöka kundernas behov och för rangordning av vikt. Baserat på behoven som identifierades så fastställdes produktspecifikationer och koncept utvecklades. Utvecklingsprocessen var en iterativ process där prototypande och testning hade en central roll.

Den slutliga produkten är ett Rhino- och Grasshopper-program som autogenererar en protes baserad på en scan av en stump och längd och bredd på den icke-amputerade armen. Användaren ges olika alternativ för att anpassa den digitala modellen för att kunna anpassa designen till den specifika individen.

Nyckelord: *3D-printning, proteser, Grasshopper, processutveckling, amputation*

Acknowledgements

We would like to express our great gratitude to our mentor at Anatomic Studios, Christian Veraeus, who has supported us throughout this master thesis with his professional expertise and kindly provided us with physical material to make this project possible. We would like to thank Christian for always being a helping hand in this project and for pushing us to explore freely.

We would also like to extend our gratitude to our supervisor at the institution of Design Sciences, Axel Nordin, who has provided us with guidance through the highs and lows of this project and also been the best of help when it comes to programming in Grasshopper.

We would like to thank the prosthetists who answered our survey, that resulted in the identification of the user needs which were a foundation for this project.

Finally, we would also like to thank the prosthesis user which we had the opportunity to interview in order to validate the result of this project.

Lund, June 2020

Lisa Phung and Arantxa Juárez Pérez

In this report, parts of prosthetic arms are mentioned frequently. Presented below in Figure 1 is a picture of the basic components of a prosthetic arm:

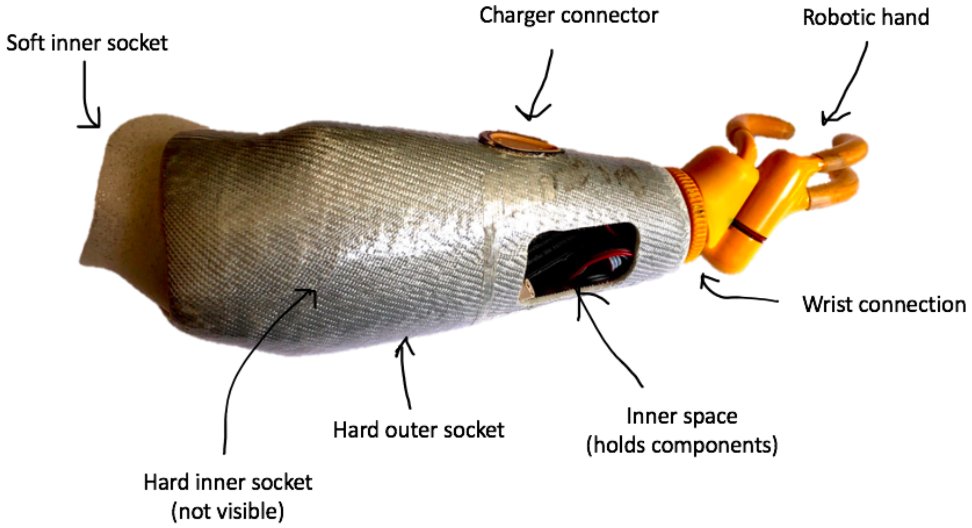


Figure 1: Parts of a prosthesis.

Contents

1 Introduction

1.1 Introduction to company

Anatomic Studios is a Swedish startup company that was established in 2015 by the three co-founders Christian Veraeus, Emelie Strömshed and Staffan Dahlberg. Anatomic Studios is a company that is designing tailor-made prosthetic covers for lower limb prostheses with the help of 3D-printing technology and an example is shown in Figure 2. They aim to give amputees the possibility to express their individuality and style through the look of their prostheses. By 3D-printing personalized prosthetic covers, Anatomic Studios wants to encourage prosthetic users to wear their prostheses with pride.

The company has close co-operations with orthopedic clinics to get in touch with prosthetic users. Anatomic Studios assists with the scan of the limb and then proceeds with the creative process of choosing the color and pattern together with the customer. The cover is digitally modeled and then 3D-printed [1].

Today Anatomic Studios has 2 employees and is based in Malmö, Sweden. Christian Veraeus has a background as a prosthetist and is in charge of the company business while Emelie Strömshed is the prosthetic cover designer. In June 2019 the company was awarded 'Springboard company of the year' which is an award for new companies with big growth potential [2].

n 

Figure 2: Prosthetic cover by Anatomic Studios.

1.2 Scope of the project - aims and purpose

The manufacturing process of arm prosthesis is very time-consuming and requires the experience of orthopedic technicians and orthopedic engineers to achieve good results. Traditional manufacturing methods also entail limitations in the choice of design and expression, which is today a strong customer need among prosthetic users. Because of the increasing demand for customization there is a need for a more efficient way to manufacture prosthetic arms that can customize the design and still assure both high quality and endurance. 3D-printing is considered to be an extremely well-suited method and more advantageous than today's laminating technology. The 3D-printing method gives significantly bigger opportunities for customized design and individual shaping of the prosthesis exterior. Today Anatomic Studios makes 3D-printed prosthesis covers and with this master thesis they want to take the next step into doing the actual prosthesis [3].

1.3 Objective

The goal of this master thesis is to design a concept (software / methodology) to digitally design a model of prosthetic arm with pre-designed shape. The objective is to develop a way to auto-generate the digital design of the prosthesis. In the future the goal is to make the software able to fit every individual's needs, but in this master thesis, the main focus will be on the software to fit one specific individual. A wrist connection for the robotic hand will be taken into consideration when developing the design. The model should be designed to fit all the interior components such as batteries, sensors and connectors. A charger hole and inspection hatch should be in the design. At the end of the project, the goal is to have at least one prosthetic arm 3D-printed.

1.4 Approach

The process will start with basic research on the human body, prostheses, today's prosthetic trends and 3D-printing. A programmable CAD software will be used to develop a program to design the digital model. Traditional prostheses and scans will be used as references for the designing of the digital model. Solutions for the hatch and placement of the inner components will be developed. Once potential concepts are found they are modelled in CAD and 3D-printed for test and evaluation. This will be an iterative design process where testing is a big focus point. At the end the model generated from the program will be 3D-printed.

1.5 Delimitation

In order to have a result to deliver and to finish the project in time, it is decided to limit the scope of the project.

Delimitations to the model:

- The model will be designed to fit one specific individual.
- The model will be designed for a child.
- The development of the soft inner socket will not be considered.
- The model to be compatible with one specific wrist connection.
- At the end of the project the goal is to have at least one prototype 3D-printed.

Delimitations due to financial resources:

- The use of the software is limited to free software and to the software the university can provide.
- Materials such as metals, ceramics or other materials that are non-plastic will not be considered for prototyping.

1.6 Assumptions

In this master thesis, it is assumed that the amputee has one amputated arm and that the other arm is not amputated. The arm that is not amputated is referred to as the non-amputated arm in this report. This assumption is made because the provided scans of the person that is used as the reference amputee has one amputated arm.

In those cases where the amputee has both the arms amputated it is assumed that measurements for making prostheses for that amputee already exist.

1.7 Prioritization

Important to emphasize is that this master thesis's goal is to develop the foundation of digital modeling software and for the next person to continue working on this so that someday in the future it is possible to make custom made prostheses with the use of this software. In order to keep the focus on what is important a list of focus points has been established. The prioritization is ranked as seen below.

What will be prioritized:

1. Finding a software that is compatible with the objective of this master thesis.
2. Finding a way to auto-generate the model.
3. Auto-generating the model, starting with an existing prosthesis/scan.
4. Designing the model so the interior components will fit.
5. Designing the model in consideration of the wrist connection.
6. Designing for 3D-printing.
7. Develop the software to auto-generate models for different individuals.

Important to note is also that the focus of this master thesis is to develop an alternative manufacturing process to the conventional process and not to design a new prosthesis. The software that is developed in this master thesis will generate a prosthesis with a design inspired by the conventional prosthesis.

2 Method

The methods used in this project is based on the Product Design and Development process by Ulrich and Eppinger and the Double Diamond method [4, 5, 6].

It is chosen to implement these two design methods because they complement each other very well. While the Double Diamond is a very broad and general method, the Ulrich and Eppinger method goes deeper and gives big insights into each stage of the process. The Double Diamond method is used throughout this project and is used to structure this report. The Ulrich and Eppinger product development process is used in the concept development of this project. The Ulrich and Eppinger method is specifically chosen because it gives good tools for decision making when selecting concepts. Since this project is limited by time only the relevant steps of Ulrich and Eppinger's concept development process will be considered.

2.1 The Ulrich and Eppinger Product Development Process

The Product Design and Development method by Ulrich and Eppinger is divided into six phases, as illustrated in Figure 3. Each step of the sequence transforms a set of inputs into outputs. The method is an approach to help develop an idea to a finished product [4, pp. 13–15].

The six phases of the product development process:

0. **Planning**
1. **Concept development**
2. **System level design**
3. **Detail design**
4. **Testing and refinement**

5. **Production ramp-up**

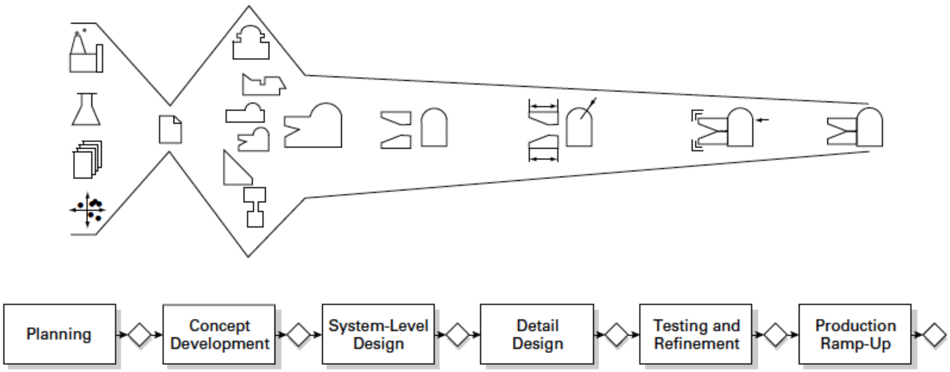


Figure 3: Ulrich and Eppinger product development process

Since only the Ulrich and Eppinger's Concept Development phase is considered in this project the focus will therefore be on phase 1 and the other five phases will not be raised further in this report.

2.2 Concept Development

The Concept Development phase is the most relevant phase in this master thesis and that is why the focus will be mostly on this phase. The Concept Development phase consists of seven inter-relative activities, as listed below and shown in Figure 4 [4, pp. 16–17, pp. 56].

1. Identify Customer Needs.
2. Establish Target Specifications.
3. Generate Product Concepts.
4. Select Product Concept.
5. Test Product Concept.
6. Set Final Specifications.
7. Plan Downstream Development.

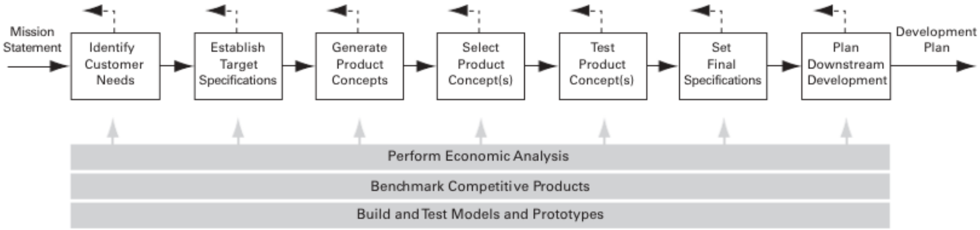


Figure 4: The Concept Development Process.

2.2.1 Identify Customer Needs

In this activity the goal is to identify the needs of the customers to fully understand what they want and to ensure that the product is focused on the customer needs. According to Ulrich and Eppinger (2016) the philosophy is to "create a high-quality information channel that runs directly between customers on the target market an the developer of the product" (Ulrich & Eppinger, 2016. p.74). The customer needs are crucial for the establishing of the product specifications in the next step of the process [4, pp. 74–75].

The five steps of identifying customer needs:

1. Gather raw data from customers.
2. Interpret the raw data in terms of customer needs.
3. Organize the needs into a hierarchy of primary, secondary and (if necessary) tertiary needs.
4. Establish the relative importance of needs.
5. Reflect on the results and the process.

2.2.2 Establish Target Specifications

After the customer needs are identified, they are translated into target specifications. Here it is crucial to interpret the costumer needs so that it can reflect into the product. The target specifications are seen as goals for the project and is expressed in the "language of the customer". In order to not leave room for any misinterpretations, these specifications are defined by metric values and are measurable. The target specifications represent the unambiguous agreement on what is expected from the product to satisfy the customer needs [4, pp. 92].

The four steps of establishing target specifications:

1. Prepare the list of metrics.
2. Collect competitive benchmarking information.
3. Set ideal and marginally acceptable target values.
4. Reflect on the result and the process.

2.2.3 Generate Product Concepts

With the target specification as foundation, product concepts are generated. The result of this step will be a number of concepts from which at least one will be selected. Even though the concept generation can be seen as linear, the reality is most often the contrary. Product concept generation is usually an iterative process as there is a lot of problem solving in developing new concepts [4, pp. 118–119].

The five steps of generating product concepts:

1. Clarify the problem.
2. Search externally.
3. Search internally.
4. Explore systematically.
5. Reflect on the solutions and the process.

2.2.4 Select Product Concept

In this step of the concept development process the generated concepts are evaluated and compared. Each concepts' strengths and weaknesses are assessed with respect to the customer needs. At the end of the concept selection one or more concepts are selected for further development. Ulrich and Eppinger propose two different concept selection methods; Concept Screening and Concept Scoring. Both methods use a matrix a basis and follow the same six-step process [4, pp. 144, pp. 149].

The six steps of selecting product concepts:

1. Prepare the selection matrix.
2. Rate the concepts.
3. Rank the concepts.
4. Combine and improve the concepts.
5. Select one or more concepts.
6. Reflect on the results and the process.

2.2.5 Test Product Concept

The purpose of the concept testing is to verify that the selected concept is the appropriate choice and if there is a choice between two or more concepts to help the selection process. The concept testing is closely related to the concept selection because both of the activities aim to further narrow the set of concepts under consideration. The concepts usually develop into rapid prototypes with the purpose of communicating the concept [4, pp. 168].

The seven steps of testing product concepts:

1. Define the purpose of the concept testing.
2. Choose a survey population.
3. Choose a survey format.
4. Communicating the concept.
5. Measure customer response.

6. Interpret the results.
7. Reflect on the result and the process.

2.2.6 Set Final Specifications

The product specifications are revisited and refined to the selected concept. The final specifications are one of the key elements of the development plan, it is the agreement on what the development team agrees to achieve (Ulrich and Eppinger, 2016, p.94). When the specifications were first established, they had a relatively broad perspective but at this stage the specifications are set to be more precise. A known difficulty in setting final specifications are the trade-offs. Decisions have to be made regarding the product and how it will be manufactured and sometimes hard choices have to be made that will ultimately influence the product [4, pp. 103].

The five steps of setting the final specification:

1. Develop technical models of the product.
2. Develop a cost model of the product.
3. Refine the specifications, making trade-offs where necessary.
4. Flow down the specifications as appropriate.
5. Reflect on the result and the process.

2.2.7 Plan Downstream Development

This is the last stage of the concept development process. A detailed product development plan is created and a strategy is devised. The required resources to complete the project are identified (Ulrich and Eppinger, 2016, p.17). The plan is a road map for the development process and is important for coordinating the activities and the development time. The plan is usually called a "baseline project plan" and includes details such as a task list, project schedule, budget and risk plan [4, pp. 403–407].

2.3 Double Diamond

Double Diamond is a process model created by the Design Council, a British organization, in 2005. The model provides a graphic representation of a design process, Figure 5. Its development was based on case studies gathered from the design departments at eleven global firms. Four generic stages are identified and described in this process model.

The model presents four main stages across two adjacent diamonds. As illustrated in the Double Diamond model's first diamond, the problem identification and understanding of a problem are equally important [5].

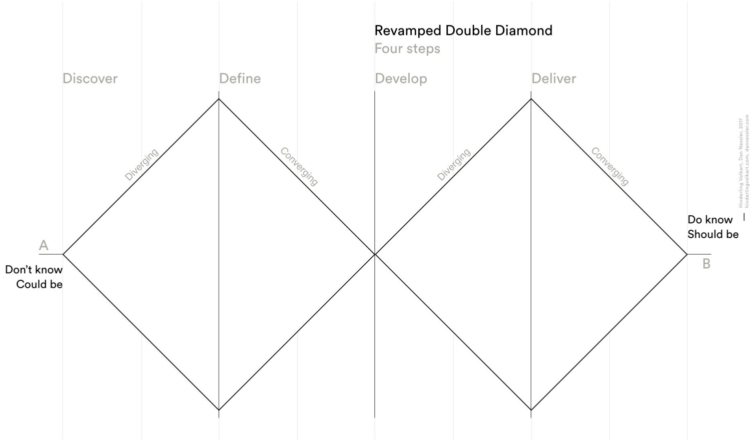


Figure 5: Double Diamond design process.

Each of the four stages is characterised by either convergent or divergent thinking. These stages are [5]:

- **Discover:** Identify, research and understand the initial problem.
- **Define:** Limit and define a clear problem to be solved.
- **Develop:** Focus on and develop a solution.
- **Deliver:** Test and evaluate, ready the concept for production and launch.

Diversion vs conversion. Each phase of this process either makes you diverge or converge.

- **Diverging phases (Discover & Develop):** Diverging phases requires you to open up and take anything possible into account or develop as many ideas and potential solutions as possible.

- **Converging phases (Define & Deliver):** Converging phases require you to narrow down, get your ideas and approaches straight to make sense and decisions.

2.3.1 Discover - Research phase

This phase is the starting point for this project, as well as for most of them. Here, a broad range of ideas and opportunities are investigated, questions are asked, hypotheses researched and problem statements formulated. This requires a 'divergent thinking' approach, which means to maintain a broad perspective during the Discover phase.

Understand the initial situation or challenge. Define what additional knowledge you need. Figure out how to obtain it. Talk to people and do your homework and research [6].

2.3.2 Define - Prestudy/Research areas

The second phase involves the evaluation and selection of ideas. To achieve this, the results from the previous stage are analyzed, developed and detailed and some ideas for these results are prototyped. For this, it is needed a 'convergent thinking' where the ideas identified in the Discover phase are analyzed and synthesized including all new product development.

Understand and make sense of your research to define whether you are solving the right problem and phrase your vision accordingly [6].

2.3.3 Develop - Ideation phase

The third phase, called 'Develop', aims to materialize the idea into a product. One or two concepts are developed further that will solve the problem presented in the first stage. Main activities, including brainstorming, visualization, prototyping, etc. are important in this phase.

It is all about getting into solution mode by evaluating ways and means to solve the core issues deduced from the research synthesis [6].

2.3.4 Deliver - Implementation phase

The Deliver state, the last one, is where the final concept is achieved. Final testing, production and evaluation are needed to see whether the product can solve the specific problem presented in the beginning.

Design, craft, develop or do whatever it takes to turn your ideas and potential solutions into something tangible. Build, test and fail to learn and to do it again [6].

3 Discover

In this section, basic research for this master thesis is given. This research is conducted to get a deeper understanding of the project and to gain knowledge in the areas related to building prosthetic arms.

3.1 Arm amputation

Upper limb amputations are much less common than lower limb ones. One of the main causes of upper limb loss in adults is trauma and cancer. Other reasons might be infections, congenital deformities and burns.

Even though dysvascular diseases rarely affect the upper limbs, it could be another cause of amputation. This is related to diabetes and peripheral arterial diseases.

The traumatic amputations are decreasing over the last decades due to changes in work patterns and safety concerns.

Self-inflicted injuries and assaults are other common reasons for traumatic upper limb amputations [7].

3.1.1 Amputation level

The amputation level describes the location at which the arm is amputated. This is defined by the doctor with the help of a prosthetist. The different levels can be appreciated in Figure 6 [7].

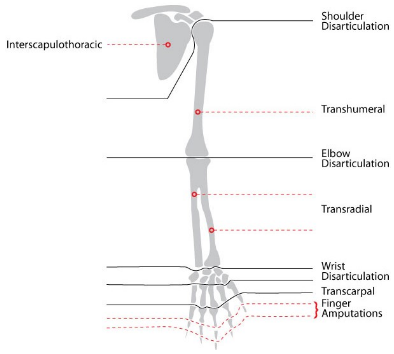


Figure 6: Levels of upper extremity amputation.

- **Metacarpal amputation.** The hand is amputated, but it can vary. The amputation can be of the digit, finger or even the metacarpal, including all the bones of the hand. The different options are shown in Figure 7. A classification of the metacarpal amputation is shown below [8]:

  1. Transphalangeal. This amputation involves the four fingers, but the degree of amputation can vary. The thumb remains.

  2. Thenar. Usually this amputation involves the metacarpal as well as the phalanges, so it could be partial or complete amputation.

  3. Distal transmetacarpal. Thumb may remain, partially amputated or completely amputated.

  4. Proximal transmetacarpal. Thumb may remain, partially amputated or completely amputated.

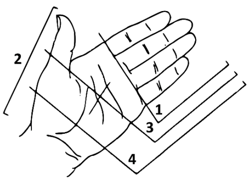


Figure 7: Levels of partial hand amputation.

- **Wrist disarticulation.** Through the wrist joint occurs the amputation, thus through the radius and the metacarpal bones. It offers the benefit of maintaining the distal radioulnar joint and length and no bones are cut during this surgery [9].

- **Transradial amputation.** This amputation is also known as below-elbow and it occurs through the radius and ulna of the lower arm [9].

- **Elbow disarticulation.** The upper arm is kept and, through the elbow joint, the lower arm and hand are removed from the body and no bones are cut during this surgery [10].

- **Transhumeral amputation.** This amputation is also known as above-elbow and it occurs through the humerus (the upper arm bone). In this case, the elbow is removed [10].

- **Shoulder disarticulation.** This amputation occurs through the shoulder joint, maintaining the clavicle and scapula [8].

- **Intrascapular thoracic.** This consists of the removal of the entire shoulder, including the humerus, scapula and clavicle [8].

3.2 Prostheses

There are different kinds of prostheses depending on the user's needs [11]:

- **Body powered or conventional upper extremity prosthetic device.** This kind of device is used together with a harness system, which is controlled by body movements. Theses prostheses have a longer durability due to their heavy-duty construction and are less expensive, both in cost and in maintenance.

- **Myoelectric upper extremity prosthetic device.** The myoelectric prostheses are powered by batteries and controlled by EMG signals. These signals are generated by the contractions of the muscles.

- **Passive functional or cosmetic upper extremity prosthetic device.** The main function of these prostheses is to provide a similar appearance of the non-amputated arm and to replace what was lost. They are lightweight, simple to use and cosmetically appealing.

- **Hybrid.** A combination of both body-powered and electrical component. Theses prostheses are usually used for amputations above the elbow.

3.3 Conventional manufacturing method of prosthetic arm

The conventional manufacturing process has a central role in this master thesis hence following is a detailed description of all the steps of the process.

The most frequently used manufacturing methods for prostheses are creating a plaster mold of the residual limb, a silicone socket and then a hard inner socket to fit into the outer hard socket of the prosthesis. It is a time-consuming and expensive process with a lot of fittings and adjustments. This process requires a lot of expertise and experience and because of the many manual steps there is a high risk for human errors.

The manufacturing process starts with taking precise measurements of the residual limb and the non-amputated arm. After the measurements are taken, the bony prominences are located as well as areas that are sensitive to pressure. The residual limb gets covered by a casting sock and the areas that were located get marked on the sock. In some cases a skin-friendly protecting care cream will be applied directly to the skin before the casting sock is put on. This because it will protect the skin, but also works as a lubricant so it will be easier to remove the cast. The prosthetist lays the cast and mark out the trim line, Figure 8, and once the cast is dried, Figure 9, the prosthetist will cut the cast so it can be removed from the amputee, Figure 10.

Figure 8: Trim line.

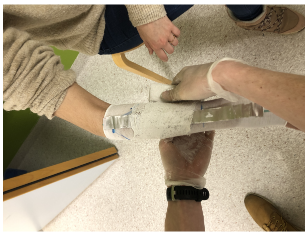


Figure 9: Casting.

Figure 10: Cast removal.

The cast is usually stitched and patched together until it is watertight. The next step is to fill the cast with plaster, Figure 11. It takes the plaster approximately 10 minutes to dry and once it is dry the cast will be removed and the result is a plaster mold of the residual limb. The plaster mold needs some post-processing for a refined the surface and some adjustments to the shape, Figure 12. Some areas need a bit more pressure relief than others, therefore more plaster can be added to those areas while other areas need more pressure and then, material is removed from those areas. When the finish is smooth and the shape is good, the mold is placed in a heating chamber for complete drying, Figure 13.

Figure 11: Pouring plaster.

Figure 12: Grinding surface.

Figure 13: Drying the mold.

The next step is the silicone soft inner socket. The silicone is a two-component silicone mass that is blended and then rolled into a thin layer with the help of the rolling machine shown in Figure 14. The silicone, Figure 15, is placed on the plaster model. In order to make out cavities for the inner components dummies will be placed between the silicone and the mold, Figure 16. The silicone socket is shaped by vacuum forming [3].

Figure 14: Rolling machine.

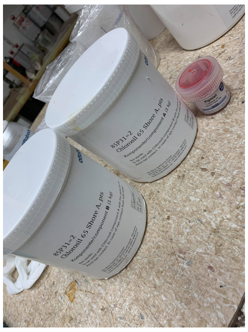


Figure 15: Silicone.

Figure 16: Dummy placement.

The hard inner socket is made by a similar process like the silicone socket except that the material in not silicone but hard plastic. A plastic sheet is heated and vacuum-formed on top of the silicone socket and its plaster model, see Figures 16 and 17 [3, 12].

Figure 17: Lamination of inner hard socket - Start.

Figure 18: Lamination of inner hard socket - Finish.

The outer hard socket is made through a lamination process, shown in Figure 19. But first a wax model is made to support the lamination of the hard outer socket. The wax model is created on top of the hard inner socket and once it is dry the lamination can begin. The wax model gets covered by a fabric sock, strengthening fibers, another fabric sock and a thin plastic sock. There can be a different number of layers depending on the aimed thickness and strength. There is a vacuum suction attached to the bottom of the plastic sock so the layers are pressed against the model and follow the shape. Resin will pour trough the plastic sock and with the help of the suction the resin will cover the whole model. The resin has to be worked so that the surface is nice, smooth and most importantly even, see Figure 18. The resin solidifies the fibers and the socks and makes it one piece. There should only be enough resin to impregnate the fiber. An overflow of resin means that the socket will be weak and sensitive to cracking. When the lamination is fully hardened the whole model gets placed in a heating chamber and the wax melts away and as a result is the hollow space inside the prosthesis. The final step is to cut off the excess material around the trim line and grind the edges until it is nice and smooth [3, 13].

Together the three components; the silicone soft inner socket, the hard inner socket and the hard outer socket make one prosthesis.

Figure 19: Smoothing of the surface.

3.4 Competitors

Over time, more and more companies emerge to dedicate themselves to 3D-printing, and more specifically 3D-printing of prostheses. Some of these companies are discussed below.

Aesthetic Prosthetics inc. Aesthetic Prosthetics is a company whose priority is the well fit of the prosthesis, which has to be comfortable. They aim for a genuinely realistic look, trying to match with the user's skin color as can be seen in Figure 20. The prostheses they produce are durable enough to endure everyday use. The relationship between the company and the client is very personal, so the prosthetists can find out how they can make a piece that meets the user expectations [14] .

Figure 20: Prosthesis with a realistic look by Aesthetic Prosthetics inc.

ProtUnix. ProtUnix is specialized in prosthetic equipment for both temporary or permanent needs and provide advanced technical expertise in orthopedic. High definition aesthetic prostheses, upper limb prostheses and lower limb prostheses can be purchased at ProtUnix, as can be seen in Figure 21 [15].

Figure 21: High definition aesthetic prosthetics by ProtUnix.

Naked Prosthetics. They define themselves as visionaries of elegance, providing devices for finger amputees for partial hand amputation, Figure 22, which aim to restore the client's ability to perform daily tasks, supporting job retention and encouraging an active lifestyle. These devices mimic the natural motion of the finder, using the amputee's finder to power it, thus each user will have a customized device [16].

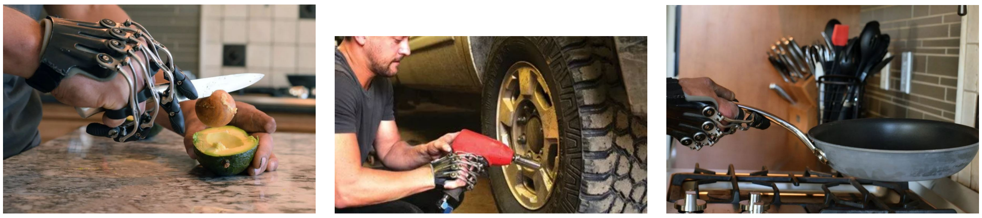


Figure 22: Finger prostheses by Naked Prosthetics.

Ossur. Creating the most effective, non-invasive mobility solutions on the market is their goal. They are focused on devices for elite athletes, paralympians, record holders and role models, but also on children's prostheses. Some of these devices are shown in Figure 23 [17].

Figure 23: Sport-focused prostheses by Ossur.

Brain Robotics. An Artificially Intelligent EMG Prosthetic Hand, Figure 24, was developed thanks to advanced machine learning that allows controlling the prosthesis hand intuitively [18].

Figure 24: Artificially Intelligent EMG Prosthetic Hand by Brain Robotics.

Ottobock. Ottobock is one of the largest providers of both lower and upper limb prostheses and aim for continuous improvement and development through clinical studies and real-world feedback. Ottobock also sells materials and equipment. Some of their products are shown in Figure 25 [19].

Figure 25: Prosthetics by Ottobock.

Fillauer. Fillauer is committed to working to create only the best solutions, including upper and lower limb prostheses and natural-looking silicone gloves. Fillauer works in partnership with Sweden's hospitals to develop innovative and high-tech machinery. Two of their prosthetic arms are shown in Figure 26 [20].

Figure 26: Prosthetics by Fillauer.

Steeper. Steeper's mission is to empower patients and enhance people's lives by creating turning points and never losing sight of the purpose behind their products and services. Some of their devices are shown in Figure 27 [21].

Figure 27: Prosthetics by Steeper.

College Park. College Park designs customized lower and upper limb prostheses as well as endoskeletal components and MetroLiner gel products, as can be seen in Figure 28. Technology, innovation and the creation of new benchmarks are their passion and College Park's products are custom-built for each user with its unique specifications and needs [22].

Figure 28: Prosthetics by College Park.

e-NABLE. It is an online global community of volunteers who use their on 3D-printers to produce low-cost upper limb prostheses for people in need, including children and adults, Figure 29 [23].

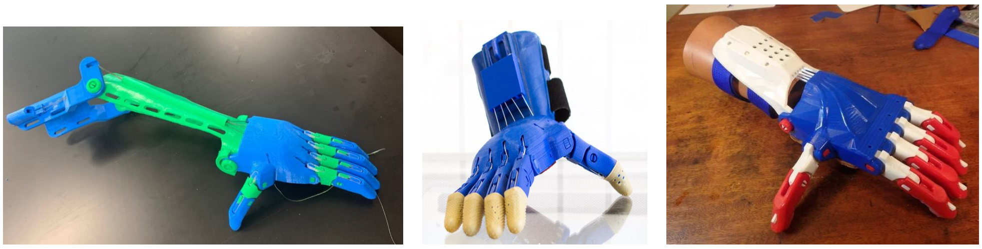


Figure 29: 3D-printed prosthetics by volunteers by e-NABLE.

Open Bionics. Their last development was the Hero Arm, Figure 30, the first 3D-printed bionic arm clinically approved. It has multi-grip functionality and empowering aesthetics and is a lightweight and affordable myoelectric prosthesis [24].

Figure 30: Hero Arm by Open Bionics.

3.4.1 The most innovative prosthesis

After 15 years of research and tests, the University of Utah has developed the most sophisticated articulated prosthetic arm so far, shown in Figure 31. To tribute to the character Luke Skywalker, who loses his arm in one of the scenes of the Star Wars saga, they decided to call the prosthesis Luke. This device not only moves according to the orders of the patient's brain, but it is even able to "feel" what the hand is touching or when pressure is exerted on the bionic limb.

This new prototype even provides manual dexterity to people who have shoulder amputations since it has some sensors that are fed by electrical impulses to the muscles of the user's arm and the brain. This allows users to feel when touching an object and is possible to make several movements at the same time both with the wrist and the hand. Thanks to the configuration of the fingers, up to six different positions, the user can hold all kinds of objects, no matter how small they are [25].

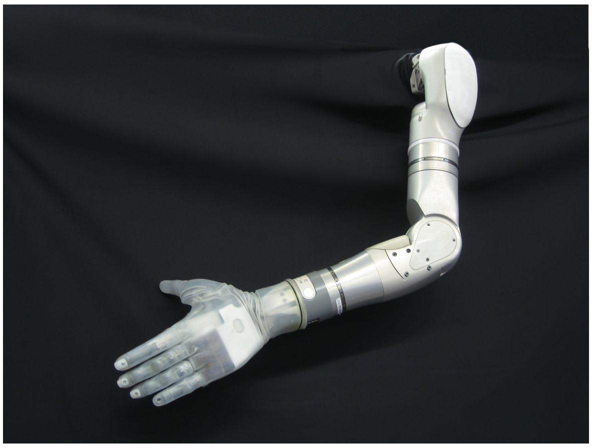


Figure 31: Luke, Bionic prosthetic arm by Utah.

3.5 Software

There are many software available that are suitable for this project, however, in this project the 3D software Rhino and the plug-in Grasshopper will be used to develop the program. Rhino and Grasshopper are very relevant for this project since Anatomic Studios already has implemented them in previous projects.

For the rapid prototyping of concepts, SolidWorks will be used. SolidWorks is chosen because it is a good tool for 3D modeling in solids which is personally preferable when designing for 3D-printing.

3.5.1 Rhino

Rhinoceros, also known as Rhino or Rhino 3D, is a 3D CAD modeling software. Rhino enables the user to model their designs ready for rendering, animation, drafting, engineering, analysis, and manufacturing. The software is a free-form NURBS, Non-Uniform Rational B-Splines, surface modeler, which means that Rhino uses mathematical representations of 3D geometry for describing curves and surfaces. NURBS can represent any geometry from a simple 2D line to the most complex 3-D organic free-form surface or solid [26].

3.5.2 Grasshopper

Grasshopper is known as a development platform and is featured as a plug-in software for Rhino. It is a parametric design tool developed specifically for Rhino. Inside the Grasshopper environment it is possible to reference to Rhino geometry such as curves, surfaces, points, etc. Grasshopper also allows the creation of its own geometry which can be implemented in Rhino. As mentioned, Grasshopper is a visual programming language which means that programs are created by dragging the objects onto canvas. An example is shown in Figure 32 [27].

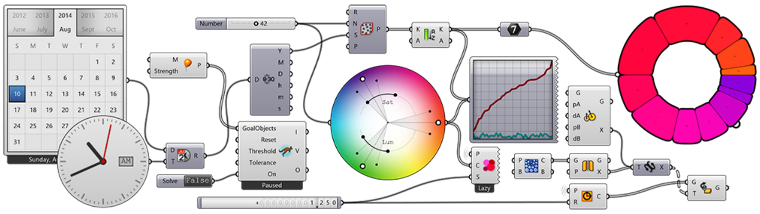


Figure 32: Example of Grasshopper.

3.5.3 SolidWorks

SolidWorks is a 3D CAD modeling and CAE software. It uses a solid modeling technology, which means that the program is a parametric feature-based. The software is used worldwide and is one of the most used CAD software on the market today. Solidworks was originally aimed for mechanical engineers, but later branched out to a variety of engineering disciplines and design industries [28].

3.6 3D-Printing

3D-printing is a relatively new manufacturing process. It is also known as additive manufacturing since the 3D-printed objects are created using an additive process. A 3D-printed object is created by laying down successive layers of material until the object is formed. This is an opposite process to the traditional subtractive methods where the material is cut out of a block. Compared to subtractive manufacturing, 3D-printing allows complex geometry without a higher cost [29, pp.1-2, pp.9]. The most common materials for 3D-printing are plastics, but metals are also quite commonly used. Depending on the material, the properties will be different. Plastic is most common because it is relatively fast and cheap, however metal is more durable, but at the same time more expensive. 3D-printed objects rarely are ready to use after being printed, usually they require some post-processing [30].

The most popular 3D-printing methods [30]:

- Material Extrusion (FDM).
- Vat Polymerization (SLA & DLP).
- Powder Bed Fusion (SLS, DMLS & SLM).
- Material Jetting (MJ).
- Binder Jetting (BJ).
- Direct Energy Deposition (LENS, LBMD).
- Sheet Lamination (LOM, UAM).

The focus will be on the Powder Bed Fusion method since the prototyping in this project will be built by using the University SLS 3D-printer.

3.6.1 Powder Bed Fusion (SLS)

The Power Bed Fusion method is generally known as Selective Laser Sintering. This is a process where thermal energy, usually a CO_2 laser, selectively induces fusion between polymer particles in a powder bed. The induced fusion binds the particles together. The laser scans the entire cross-section and when the scanning is done the building platform moves down one layer and then the recoating blade deposits a new layer of thin powder on top of the recently scanned layer. The printer will repeat this process until the object is manufactured. The process is shown in Figure 33. The powder which has not been sintered works as support material. The finished parts are dug out from the powder bed and which is usually easy since the parts are surrounded by loose powder. Usually some post-processing is required to enhance the visual appearance, such as polishing or dying [31].

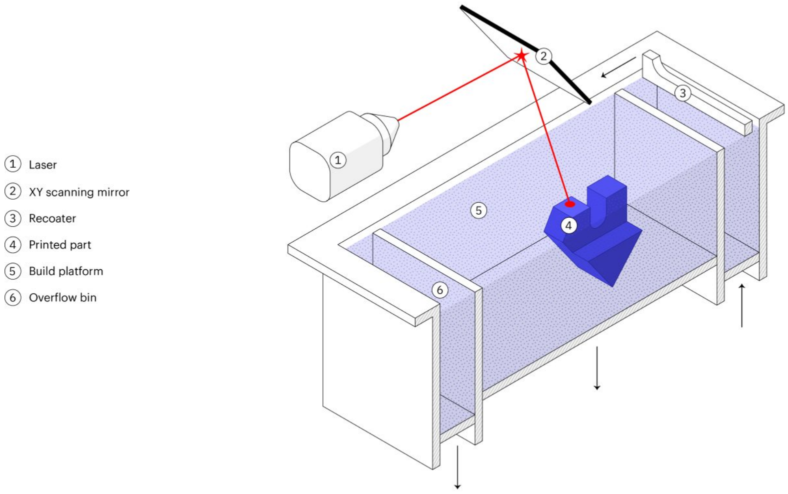


Figure 33: Selective Laser Sintering.

3.6.2 3D-printing prostheses

Today 3D-printing in the health and medical industry is getting significantly bigger and bigger. The customization, complexity and flexibility of 3D-printing makes it possible for medical professionals to provide patients with solutions that are specially designed for their patient's anatomy. 3D-printing is used in areas such as dental implants, hearing aids, surgical cutting and drill guides, replicas of bones, organs, and blood vessels as well as prostheses. The advantages of 3D-printing have resulted in lighter, stronger and safer products and also reduced lead times and lowered costs [32].

The complexity and demand for tailor-made solutions in prostheses make 3D-printing a perfect way to manufacture prostheses. That is why it is getting more common with 3D-printed prostheses. It is not just the fact that prostheses can be custom designed but also that a personal element can be added. The prosthetic user can implement their design into the prosthesis to personalize it and show their unique style [33].

3D-printing prostheses for children is seen as greatly beneficial. As the child grows the need for a new prosthesis will too. Compared to traditional ways to manufacture prostheses, 3D-printed prostheses can be made in a matter of a day. It is also beneficial for children because they can pick out color and styles which help them adapt better to the prosthesis [34].

3.7 Materials and properties

This research aims to analyze various materials that are currently implemented in different technological advances within the development of limb prostheses.

The main intention is to seek out the most appropriate materials for the advantage of the user in terms of ergonomics, weight, resistance. And yet, it is also important to think about the global economic and monetary accessibility of the end-user, as well as their ideal characteristics for the daily life of the prospect.

3.7.1 Materials currently used in the production of bionic arms and legs

Different materials that make up limb prostheses are mentioned below. Three different classes are distinguished: metals, polymers and carbon fiber.

Metals. A diversity of metals is used for limb prostheses; aluminum, titanium, magnesium, copper, steel, among others. The use of one or another depends on the final application [36].

- **Stainless steel** is a robust and heavy material, it is used only in parts that are subjected to high weights, like load pieces and it is presented in bars of different diameters.

- **Aluminium** is a material in which its physical properties lend themselves to the development of huge volume parts and load distribution. A number of its properties are its lightweights, medium mechanical resistance, great elasticity coefficient, minimum oxidation and, good presentation. Besides, it is one of the most used materials to produce prostheses and has a low cost in the market.

Polymers. Polymers are more often used for phalanges, joints, and other smaller components or specialized features than in the main load-bearing structure of limbs. Common polymers utilized are:

- **Polyoxymethylene (POM)** can be used instead of metals thanks to its stiffness, dimensional stability and corrosion resistance [37].

- **Polyurethane (PU)** has a high load capacity in both tension and compression. Some of its properties are its high load-bearing capacity, flexibility, abrasion and impact resistance [38].

- **Polyvinyl chloride (PVC)** is used as a coating. PVC first developed in the early part of the twentieth century and it has been one among the foremost important plastics because it is very durable but has a limited color range. It is unstable when exposed to heat and light so it requires the addition of stabilizers [39].

- **Ionic polymer-metal composites (IPMC)** are sort of electroactive polymer actuation materials due to their characteristics of large electrically induced bending, mechanical flexibility, low excitation voltage, denseness, and simple fabrication [40].

- **Parylene** is polymer coatings without holes and offers properties that help the treatment of surfaces, such as humidity, thermal stability, resistance to environmental influences and UV radiation. This coating adapts perfectly to any surface, providing consistent protection and with a thickness of a couple of microns. It offers protection to take care of performance in harsh environments and facilitates cleaning and purification [41].

- **Silicone** is a polymer non-receptive to extreme temperatures, excellent electrical properties as an insulating material, is easy to mold and has a long service life. It does not absorb water but is less durable. Silicone is now used as a filling material for sockets and is the preferred material for high-quality foot reconstructions [42].

- **Teflon**. The atomic structure of Teflon is composed of carbon and fluorine atoms and the union of these atoms offers high chemical resistance, low and high-temperature capability, resistance to weathering, low friction and electrical and thermal insulation. It is inert and insoluble [43].

- **Thermoplastics** are organic materials and the most common categories are polypropylene and polyethylene. Polypropylene is a high rigidity plastic, and polyethylene has low density and flexibility and is one of the cheapest and most common materials that are used as a coating for prostheses. It is used in larger quantities when the prosthesis needs to be waterproof. The advantage of these plastics is that it is easy to remodel using heat or even remelted back into the liquid [44].

Carbon fibre. The use of carbon fibers happened within the twentieth century, when medics and engineers were in search of a lighter load-bearing material. The properties of carbon fibers are high stiffness, high tensile strength, low weight, high chemical resistance, high-temperature tolerance and low thermal expansion and specific modulus. It had been determined that it might be strong enough for even an important weight amputee. Carbon fiber reinforced composites have very high specific tensile and compressing strengths, as well as high responsive elastic deformation. Carbon fiber is used to develop foot prostheses [45].

3.7.2 Materials used in 3D-printing

There is a wide range of materials to choose from when it comes to 3D-printing. These materials have their own unique features, strengths and weaknesses. Some of their distinct characteristics and drawbacks are presented below [35].

Nylon.

- **Advantages:** it is durable, it has excellent strength to flexibility ratio and little warpage. This sort of material is often easily dyed or colored.

- **Disadvantages:** it should be kept dry since it is hygroscopic. It has a shelf life of 12 months. This material can shrink during cooling, thus, prints could also be less precise.

ABS.

- **Advantages:** it is one of the cheapest materials for 3D-printing. ABS is highly available and has a wide variety of colors and a longer shelf life compared to Nylon. It is mechanically strong and provides a high-quality prototype production.

- **Disadvantages:** it requires a heated bed when printing and since ABS materials have a high melting point, it has a tendency to experience warping if cooled while printing. This type of filament is a non-biodegradable toxic material that releases toxic fumes with awful smell at high temperature.

Resin.

- **Advantages:** it has low shrinkage, high chemical resistance and is rigid and delicate.

- **Disadvantages:** it is expensive. This type of filament also expires so it must be stored securely due to its high photo-reactivity. When exposed to heat, it can cause premature polymerization.

PLA (Polylactic Acid).

- **Advantages:** it is easy to print since it has low warping and it also can be printed on a cold surface, unlike ABS. It can be printed with sharper corners and features compared to ABS material and is available in several colors.

- **Disadvantages:** PLA materials are not very powerful and can be damaged when exposed to extreme heat.

Stainless steel.

- **Advantages:** it can be heat treated to get higher strength and hardness. It performs well in high strength applications, provides strong resistance against corrosion and has high ductility.

- **Disadvantages:** it takes longer building time and printing with stainless steel is expensive.

Titanium.

- **Advantages:** it provides great complexity, precision and resolution in design. It is biocompatible and resists corrosion.

- **Disadvantages:** titanium 3D-printing is expensive.

Ceramics.

- **Advantages:** it has high-precision components with a flat and bright surface and has resistance to acid, heat and lye. It has a wide range of colors.

- **Disadvantages:** it requires high temperature to melt. It has limitations in printing objects with enclosed and interlocking parts since it is fragile, thus it is not recommended for piece assembly process.

PET/PETG.

- **Advantages:** it is durable, impact-resistant, recyclable, temperature resistant, easy to print and can be sterilised. It has an excellent layer adhesion.

- **Disadvantages:** The material can be weakened by UV light and can be easily scratched.

4 Define

In the define phase the primary user is defined and the user needs are identified. Once the needs are identified product specifications are established. This is a key point for understanding the product and to steer the development in the right direction.

4.1 Definition of the user

The primary user of the project is the prosthetist. The prosthetist is the primary user due to the fact that the focus on this project is to find a new way to manufacture prostheses and this will enable prosthetists to use our method to manufacture prostheses instead of the conventional way. It will be the prosthetist that will use and interact with the developed software in this master thesis. The main focus on the concept development will be on the primary user.

The secondary user is the amputee. The amputee will have an indirect connection to the software and since the amputee is the reason why the software is used, the amputee is seen as the secondary user. The amputee can also be seen as the secondary user because there is a possibility in the future that the amputee will use the software to make their own prosthesis.

4.2 Customer Needs

To identify the customer needs a user study is conducted on the primary user. This user study was made through an in-depth interview with the prosthetist Christian Veraeus. The result of this interview were 18 customer statements that were interpreted into customer needs. The customer needs were grouped into areas of manufacturing, inner space and aesthetics. In order to validate the importance of the customer needs they were sent through a survey to 9 other prosthetists in Sweden and Denmark for investigating how well they agree to the customer statements. The 10 prosthetists make out about 50% of all prosthetists is Sweden and Denmark. The customer needs were ranked on a scale of 1-5 and based on the average number of what the 10 prosthetists answered.

The details and answers of the survey can be found in Appendix B. The customer needs are seen in Table 1 below.

Need no.	**Area**	**Statement**	**Need**	**Imp.**
1	Manuf.	There are too many manual steps in manufacturing prostheses	The manufacturing process have few manual steps	4
2	Manuf.	It takes too long time to manufacture prostheses	The manufacturing process does not take long time	4
3	Manuf.	There are too much room for human errors in the manufacturing process	There are not a lot of room for human error in the manuf. process	3
4	Manuf.	It should not be required to need a lot of training to manufacture prostheses	It is not required to have a lot of training to manufacture prostheses	2
5	Manuf.	It costs too much to manufacture prostheses	It does not cost a lot to manufacture prostheses	3
6	Manuf.	Everyone should be able to manufacture prostheses	Everyone can manufacture prostheses	1
7	Manuf.	It is too to hard to go back and make changes once a step is done in the manufacturing process	It is easy to make changes to the finished prosthesis	3
8	Manuf.	It is too uncertain to know what step comes next in the manufacturing process	It is easy to know what step comes next in the manufacturing process	2
9	Manuf.	The prostheses are not durable enough	The prostheses are more durable than the traditional prostheses	2

Need no.	Area	Statement	Need	Imp.
10	Aesthetics	The prosthesis is not aesthetically pleasing	The prosthesis is aesthetically pleasing	3
11	Aesthetics	There is a too much extra material needed to smooth the area where the sensors are sticking out	Little to none material is needed to smooth the area around the sensors	3
12	Aesthetics	I want the prosthesis to look more like a real arm	The prosthesis looks like a real arm	3
13	Inner space	Too often I need to make the prosthesis bigger to fit all the inner components (batteries, etc.)	The prosthesis does not need extra inner space to fit the components	4
14	Inner space	It is important that the center of gravity of the prosthesis is centered	The center of gravity of the prosthesis is centered	3
15	Inner space	Too often the desired size of batteries can't be used	The desired size of batteries can be used	3
16	Inner space	The inner space of the prosthesis is not optimally used	The inner space of the prosthesis is optimally used	3
17	Inner space	I want to be able to get to the inside of the prosthesis in an easy way	The inside of the prosthesis is easily accessed	4
18	Inner space	I don't want to fill the prosthesis with more material in order to hold the inner components (batteries, etc.) in place	The inner components (batteries, etc.) are placed inside and prevented from movement	3

Table 1: User needs.

4.3 Establish Product Specifications

From the identified customer needs in the previous sub-chapter product specifications were established. In Table 2, the Target Product Specification can be found. The product specifications are established for the specific model of the reference amputee thus not general for all the amputees. The list of metrics represents the specification of what the product would do. Not all needs could be translated into quantifiable metrics and in those cases the metric would be subjective and measured by personal intuition. For those needs that were quantifiable ideal values as well as marginally accepted values were set. The values were based on specifications from prosthetic arms that were provided by Anatomic Studios, 3D-printing attributes or wishes from Christian Veraeus.

Metric no.	**Need**	**Metric**	**Imp.**	**Unit**	**Marginal value**	**Ideal value**
1	1, 2, 3, 4, 6	Number of steps in manufacturing process	5	Steps	5 - 20	5 - 10
2	2	Program processing time (excluding 3D-printing)	5	hr	1 - 8	< 5
3	5	Unit manufacturing cost	3	kr/cm3	1 - 4	1
4	9	Durability (Tensile Strength)	4	MPa	20-60	40
5	11	Wall thickness around the sensors	3	mm	2 - 4	2
6	13, 15, 16, 17	Volume inner for components	4	cm3	500 - 600	500
7	14	Center of gravity	2	x cm from mid-point of prosthesis	± 6	±3
8	18	Weight without inner components	2	g	100 - 200	120
9	3, 4, 6	No CAD/ programming experience needed for using the program	2	Yes / No	Yes	Yes
10	7, 8	Possible to make changes to the finished model	5	Yes / No	Yes	Yes
11	10, 12	Aesthetically pleasing prosthesis	3	subjective	N/A	N/A
12	17	The inside of the prosthesis is easily accessed	4	Yes / No	Yes	Yes

Table 2: Target product specifications.

As an addition to the list of metrics, there is a list of general product specifications that would serve as a guideline for the development process. This was to give a complete sense of grip of the overall product.

The product should be:

- **Easy to learn.** Someone that has not been introduced to the software should be able to operate it after a short amount of time after the introduction.
- **Intuitive.** The interface should be easy to understand and simplified.
- **Effective.** There should be few steps to create a basic prosthesis.
- **Adaptable.** It should be easy to make changes and adjustments to the prosthesis.
- **Economical.** The process should cost less than the traditional manufacturing process.
- **Time-saving.** The process should take less time than the traditional manufacturing process.

5 Develop

The development phase of this project is divided into three sections; one for the development of the software - Rhino and Grasshopper -, one for the design of the interior of the prosthesis and another one for the hatch. At the end of this phase the three development processes are combined and integrated into one solution.

The method in Section 5.1 follows a feature-oriented process since the basic features were known from the start of this project. The method is to build the base and then to successively add improvements and details.

Like the define phase, Section 5.2 follows the development process by Ulrich and Eppinger.

5.1 Concept development of the software

5.1.1 Generate product ideas - first stage, possible software and coding methods

This section aims to explain the design process, from the first idea to the last, explaining all the challenges and problems that appeared along the way. Until the final result was achieved, several ideas were developed and optimized, getting better results in each iteration.

The scans of the non-amputated arm and the soft inner socket were used to develop the first design, Concept A. The scans were provided by Anatomic Studios. The scans in STL (an abbreviation of "stereolithography") of the non-amputated arm and of the soft inner socket can be seen in Figures 34 and 36, respectively. These STL files were imported in Rhino and converted into meshes, Figure 35 and 37. The concept of non-amputated arm is linked to the arm that has not undergone any amputation.

Figure 34: Scan of the non-amputated arm - STL.

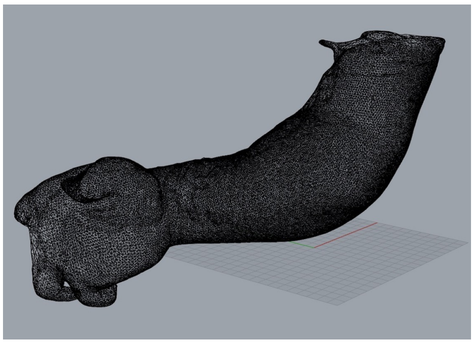


Figure 35: Scan of the non-amputated arm - Mesh.

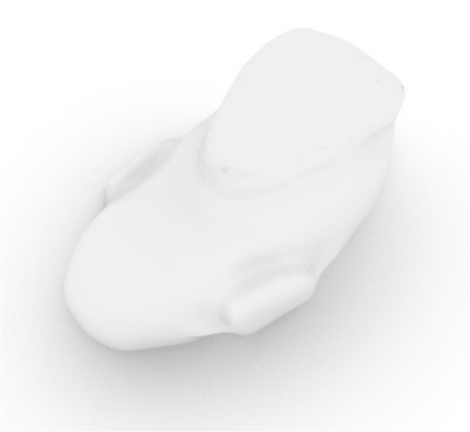


Figure 36: Scan of the soft inner socket - STL.

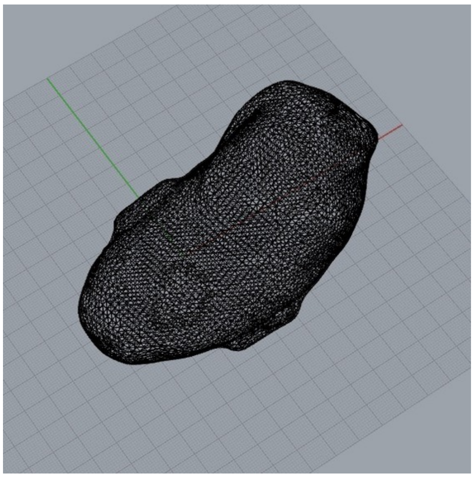


Figure 37: Scan of the soft inner socket - Mesh.

The first idea, Concept A, consisted of using both scans to develop the model. Thanks to the mesh of the soft inner socket, it was possible to model the hard inner socket. The hard outer socket of the prosthesis was the result of following the shape of the mesh of the non-amputated arm. In this way, a result more similar to the human arm was achieved, Figure 38.

Figure 38: Concept A.

An optimal result was not achieved in terms of volume since much more material than necessary was being used. This was because, since the prosthesis was irregular, there were some areas thicker than others. Besides, an irregular shape always presents problems when it comes to 3D-printing and in the integration of the components.

Lastly, it was not possible to improve the area where the non-amputated arm and the soft inner socket meet, thus giving a thicker prosthesis in the elbow area. The wrist connection was not improved since this design was discarded. If this design had been followed, it would have had to be improved. However, it would have been difficult to get a good result since the human wrist has an irregular shape and the wrist connection had a specific diameter (34 mm), so the transition from one shape to the other would have been hard to achieve.

After introducing Concept A to Christian Veraeus, it was discussed and decided that the concept did not meet the expectations. Another idea was discussed and it was agreed to move on this idea that were turned into a new concept, Concept B. The prosthesis in Concept B, instead of following the shape of the healthy arm, will be defined by three curves. Concept B is presented in Figure 39. Each step that was carried out until the Concept was achieved is explained in the following sections.

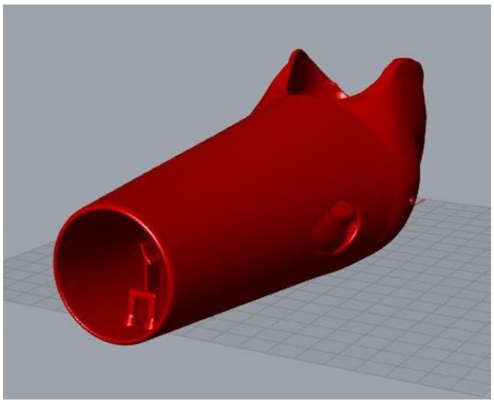


Figure 39: Concept B.

In the following subsections, all the steps followed to achieve this solution are presented.

5.1.1.1 Hard inner socket

The hard inner socket is the socket placed right after the hard inner socket. Thereby, the hard inner socket had to have the same shape as the soft inner socket but scaled. In almost all operations in Grasshopper for this Master Thesis, volumes were used with the help of the plugin Dendro [46]. A plugin is a software add-on that is installed on a program, enhancing its capabilities and Dendro is a volumetric modeling plugin for Grasshopper and provides multiple ways to wrap points, curves, and meshes as a volumetric data type, allowing to perform various operations on those volumes. Dendro includes components for boolean, smoothing, offsets, and morphing operations.

In order to get the hard inner socket, the first thing to do was to transform its mesh, Figure 40, into a volume, Figure 41.

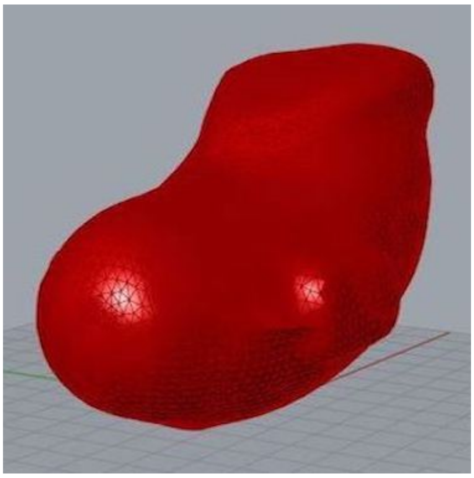


Figure 40: Soft Inner Socket - Mesh.

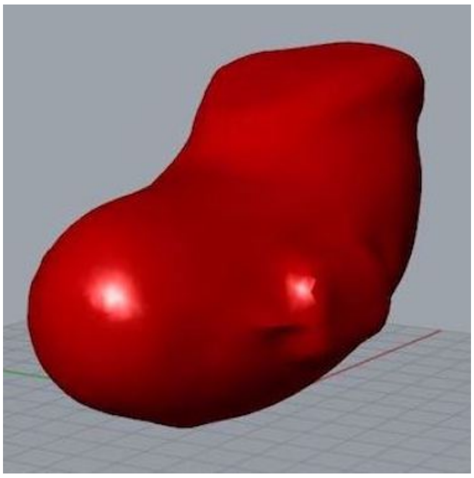


Figure 41: Soft Inner Socket - Volume.

An offset of 2 mm was applied to the previous volume. The resulting volume can be seen in Figure 42. The next operation was a Volume Difference between the hard inner socket and the soft inner socket, obtaining a hard inner socket 2 mm wide and hollow inside. Since the shape of the hard inner socket and the soft inner socket is almost the same, it is quite difficult to see the difference between these two.

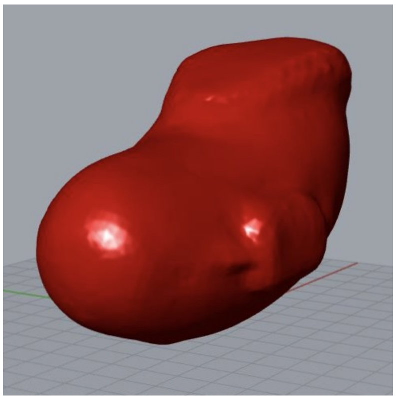


Figure 42: Hard inner socket.

5.1.1.2 Generating Surfaces

In the attempt of simplifying the design as much as possible, the prosthesis was the result of lofting three curves, instead of following the shape of the non-amputated arm as before. The Loft command fits a surface through selected profile curves that define the surface shape. The green curve, Figure 43, is the result of rebuilding and offsetting the intersection between the hard inner socket and a YZ-plane. The Rebuild command reconstructs selected curves or surfaces to a specified degree and control point number. For this specific curve, the degree and the control point number were 10 in both cases. The first curve starting from the left is determined by the size of the wrist connection, given by the prosthetist. The curve on the middle is an ellipse defined by two radii and can be modified as the user likes.

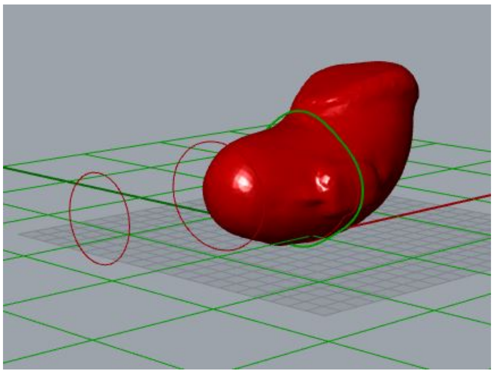


Figure 43: Intersection, rebuild and offset a curve.

Once these curves were defined, the next step was to loft them, giving the result presented in Figure 44.

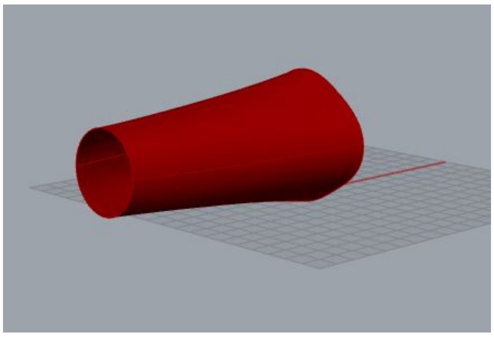


Figure 44: Result of lofting the three curve.

Right after lofting the curves and after a few operations - get its volume, offset it, and adding this volume to the hard inner socket one - the result can be seen in Figure 45.

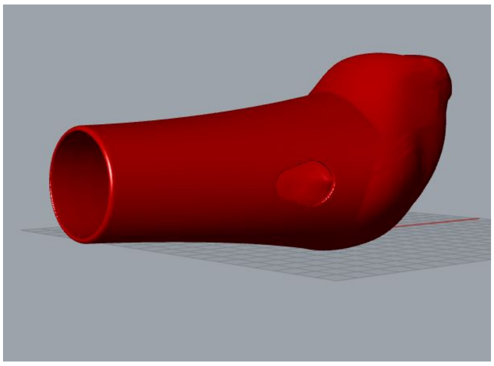


Figure 45: Loft - Final result.

5.1.1.3 Trim line

The trim line defines the boundary between the hard inner socket and the amputated arm, which is different in each patient. Therefore, the trim line was defined with a few points that the prosthetist can modify as wished to adapt it to the user. These points define a polyline, Figure 46 and this polyline is then projected on a surface, as can be seen in Figure 47.

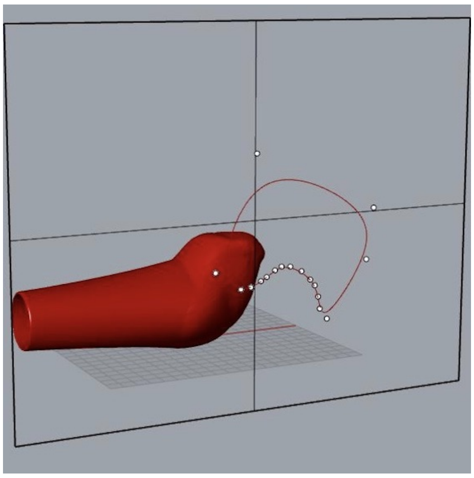


Figure 46: Trim line - Definition.

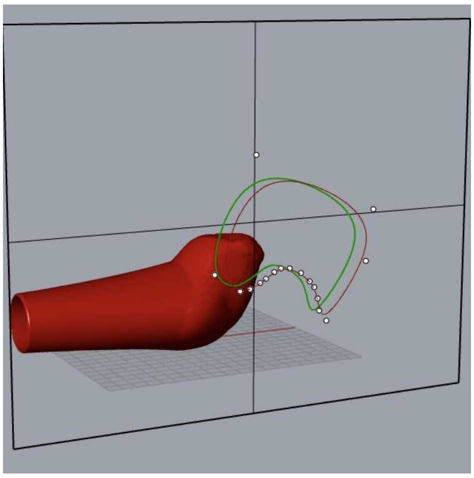


Figure 47: Trim line - Projection.

Using this projected polyline, a volume is created by extruding the polyline, Figure 48. Then a Volume Difference is applied to get the result presented in Figure 49. By changing the position of the points, Grasshopper will redefine a new polyline and therefore a new volume, generating another different prosthesis.

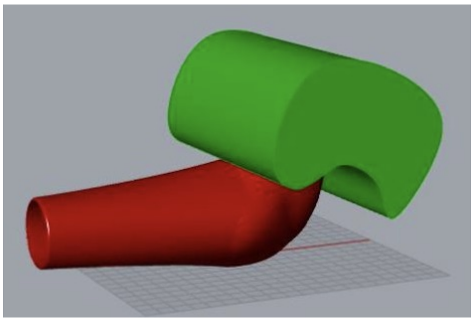


Figure 48: Trim line - Volume.

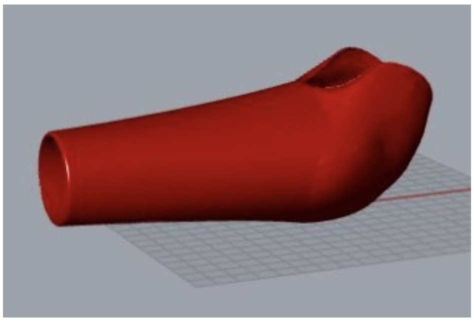


Figure 49: Trim line - Subtraction.

5.1.1.4 Charger hole

The next implementation was the hole for the battery charger. To do so, the shape of the charger hole was drawn in Rhino, as can be seen in Figure 50, and imported in Grasshopper.

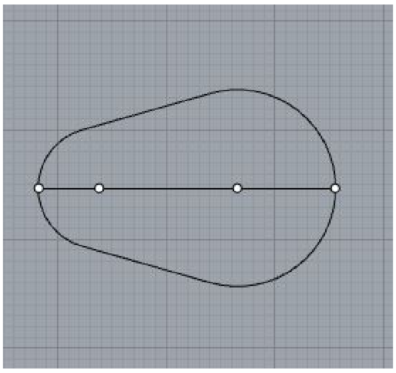


Figure 50: Charger hole - Drawn in Rhino.

In the prostheses used as example, the charger hole was placed in their side, Figure 52. Even so, an alternative in which the charger hole would be positioned at the bottom of the prosthesis was implemented, Figure 51. In this way, the prosthetist is free to choose the position of the charger hole as he deems most convenient. The operations followed were the same as for the trim line: draw the curve, project it into a surface, extrude the curve and generate a volume and a volume difference between the prosthesis and the volume previously generated.

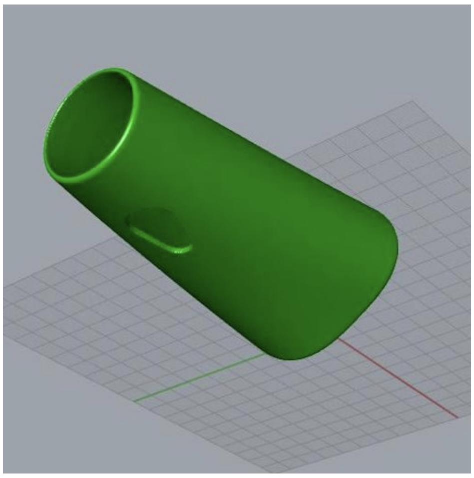


Figure 51: Charger hole - Bottom.

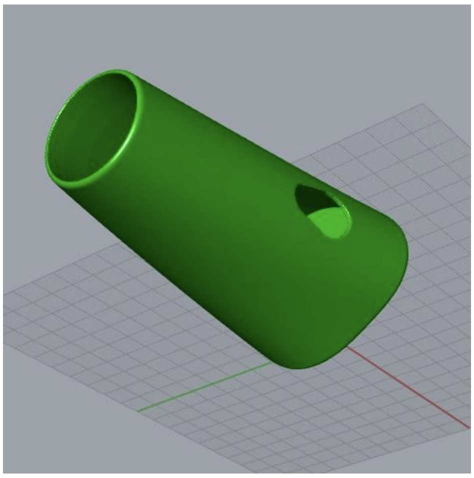


Figure 52: Charger hole - Side.

When the user wants to make use of the small and medium batteries, it is recommended to place the charger hole on the side because otherwise the batteries and the charger interfere. When it comes to big batteries there is no problem with choosing any of the two options for the position of the charger hole because there is no interference between components.

5.1.1.5 Supports for the components.

One of the most challenging parts was the design of the supports for the components, which is explained in great detail in Subsection 5.2. There are three different battery sizes, thereby three different supports were designed, as can be seen in Figures 53, 54 and 55.

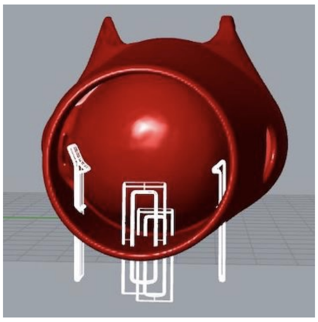


Figure 53: Supports - Big ones.

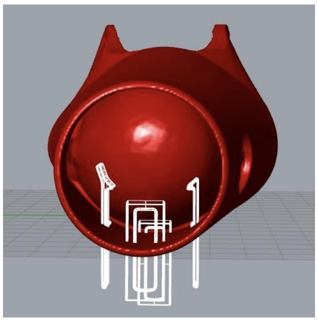


Figure 54: Supports - Medium ones.

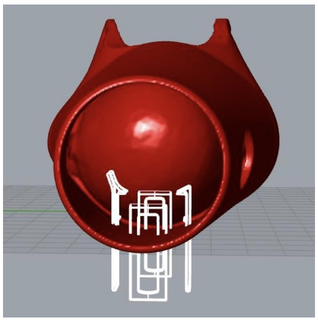


Figure 55: Supports - Small ones.

The prosthetist can choose between these three options as he/she wishes. For example, if he/she decides the large size, he/she has to indicate it in a filter in Grasshopper and with this information Grasshopper generates the volume of the supports and does the Volume Difference between the supports and the prosthesis. This way, just the upper part of the supports are modeled, as can be seen in Figure 56.

In order to obtain a more robust support design, four fillets with pyramidal shapes were included. These fillets distribute the stress over a broader area and effectively make the parts more durable and capable of bearing larger loads.

Later, a Volume Union is performed between the upper part of the supports and the prosthesis to get a single volume instead of two independent ones, giving the result presented in Figure 56.

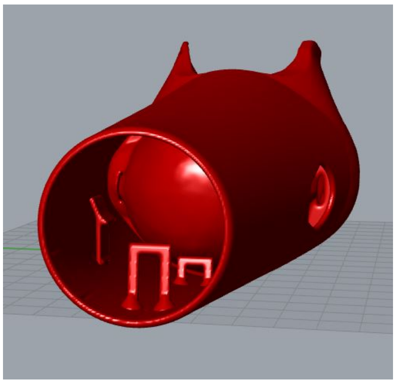


Figure 56: Supports - Final result.

5.1.1.6 Smoothing the sensors

After the implementation of Concept B, it was arranged for a meeting with Christian Veraeus to show him the progress. He suggested a few ideas for improvement that will be explained in the following subsections.

The first thing he suggested was to smooth the area where the sensors were placed. The way it was before can be seen in Figures 57 and 58, where it can be seen the position of the sensors.

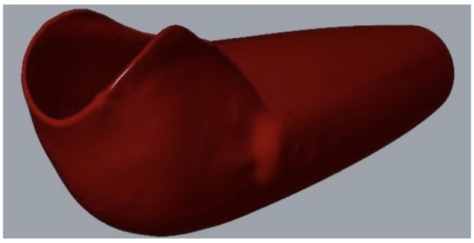


Figure 57: Sensors before smooth - 1.

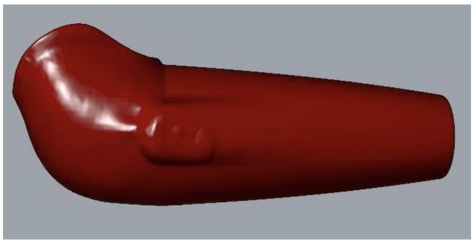


Figure 58: Sensors before smooth - 2.

The idea was to create and add a volume that would allow the sensors be more discrete. To do so, five different curves were required.

The two curves shown in Figure 59 were the intersection between two YZ-planes and the loft explain previously. On the other hand, the three curves presented in Figure 60 were the intersection between three YZ-planes and the hard inner socket.

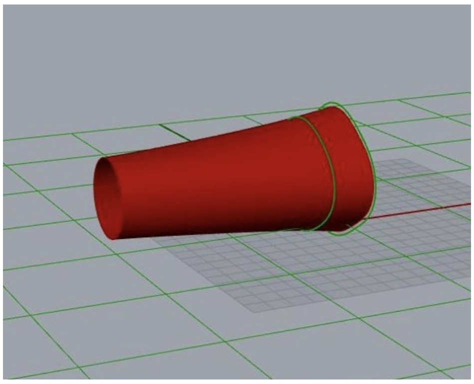


Figure 59: Smooth the sensors - Intersections 1.

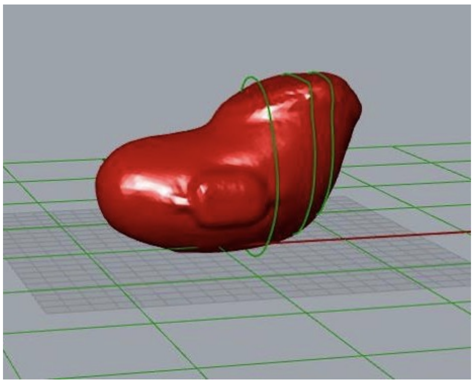


Figure 60: Smooth the sensors - Intersections 2.

These curves, presented in Figure 61, are then lofted, from which its volume was created, Figure 62.

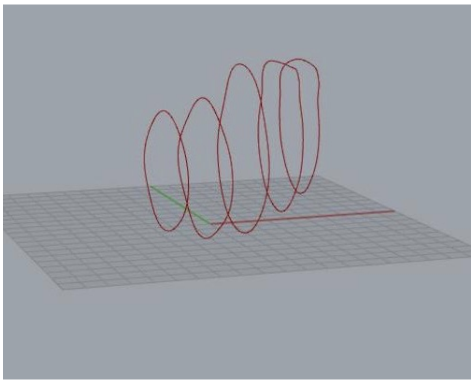


Figure 61: Smooth the sensors - Curves.

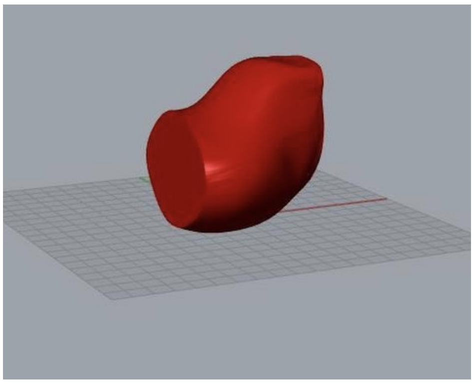


Figure 62: Smooth the sensors - Lofting the curves.

The last operation in this improvement was to add the generated volume to the hard inner socket, as can be seen in Figure 63.

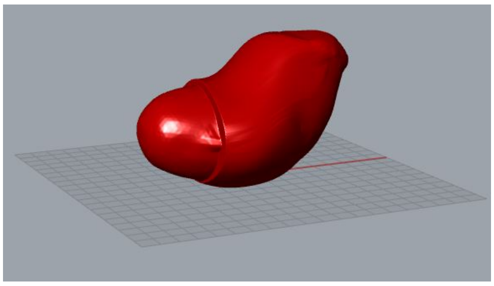


Figure 63: Smooth the sensors - Total volume.

Before this implementation, the position of the sensors could be noticed, as can be seen in Figures 57 and 58. In spite of this, it was achieved a way to smooth them so the objective was achieved, as can be seen in Figures 64 and 65.

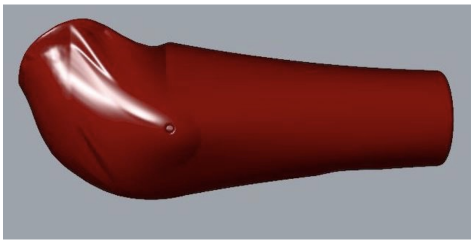


Figure 64: Sensors after smooth - 1.

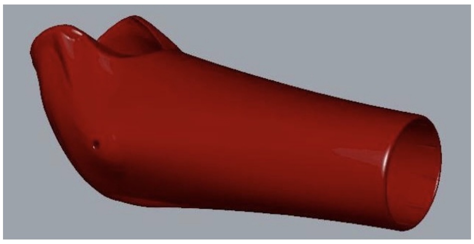


Figure 65: Sensors after smooth - 2.

5.1.1.7 Pattern in the wrist connection

The way to connect the wrist connection to the prosthesis is through pressure and gluing both parts. In this case, an attempt was made to find a solution that would allow the glue to be distributed more evenly, while generating a rough surface that would prevent the pieces from separating, thus providing a better grip.

The idea that was carried out was to create a pattern along the inner surface of the wrist connection. The steps are explained below.

The first thing to do was to get the wrist connection curve, Figure 66, and divide it into ten equal segments, as can be seen in Figure 67.

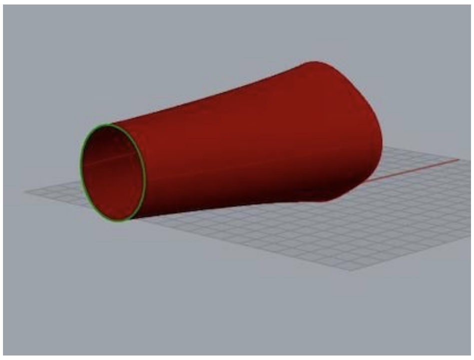


Figure 66: Pattern in the wrist connection - Curve.

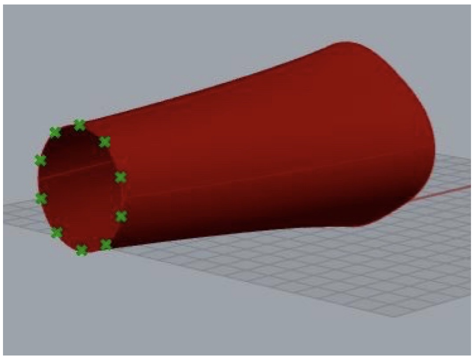


Figure 67: Pattern in the wrist connection - Divide the curve.

In each vertex of the segments, it was drawn a circumference of radius 4 mm, Figure 68 and then extruded 10 mm, as can be seen in Figure 69.

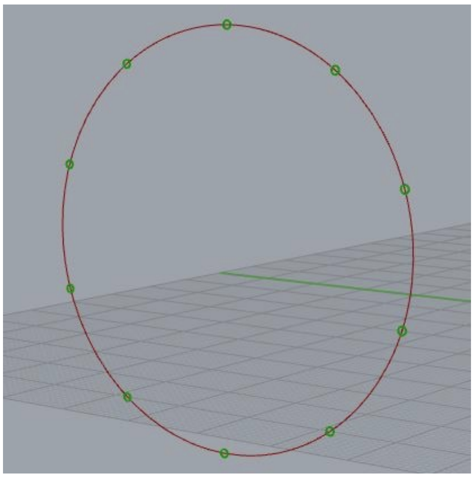


Figure 68: Pattern in the wrist connection - Circumferences.

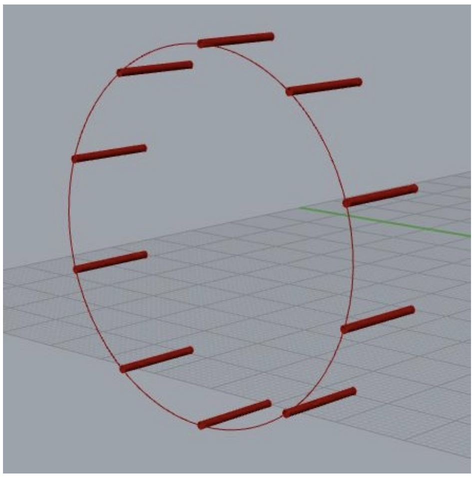


Figure 69: Pattern in the wrist connection - Extrusion.

In Figures 70 and 71 it can be seen the before and the after of the implementation. In the figure on the left, it can be seen the previous design, where no patter was included. On the right, it can be seen how ten cylinders were created and placed along the wrist.

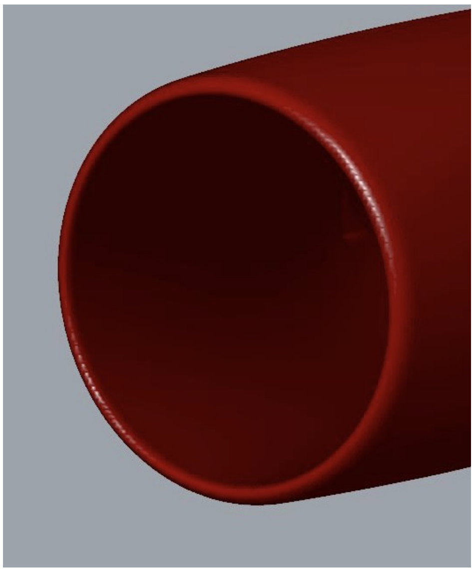


Figure 70: Pattern - Before.

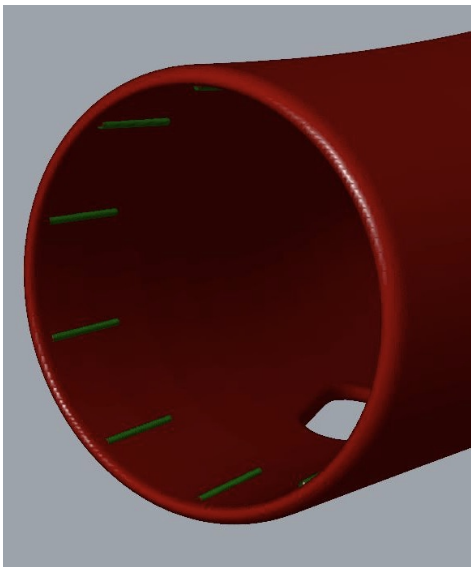


Figure 71: Pattern - After.

Nevertheless, the first attempt was to add these volumes to the model, Figure 72. Once it was 3D-printed and tested, it was clear that it would have been better to subtract these volumes instead of adding them since it would let the glue be better distributed. The final design is presented in 73.

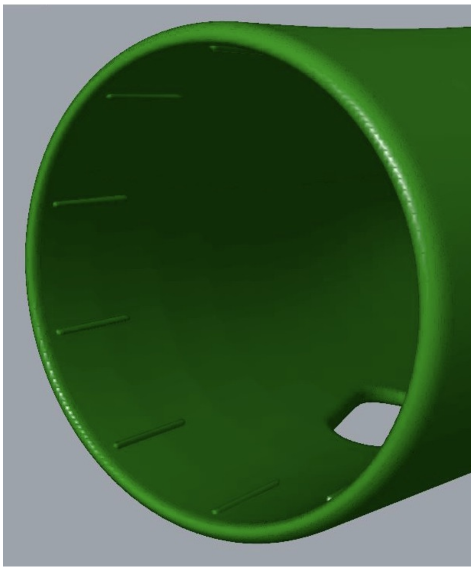


Figure 72: Pattern - Union.

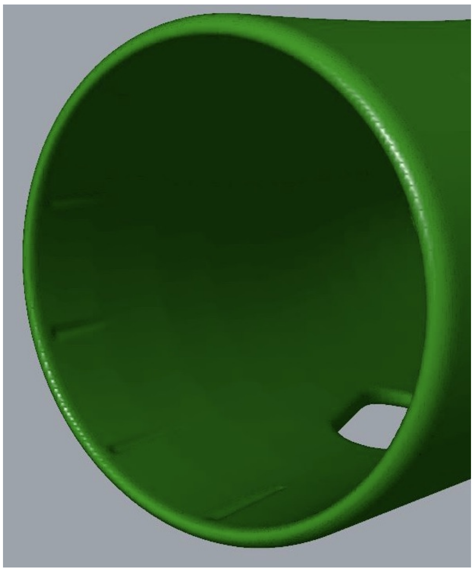


Figure 73: Pattern - Difference.

The wrist connection was tested with the final diameter of 34.00 mm. It was also tested 34.2 mm, but this small difference greatly influenced the grip of the connection. The final result can be seen in Figure 74.

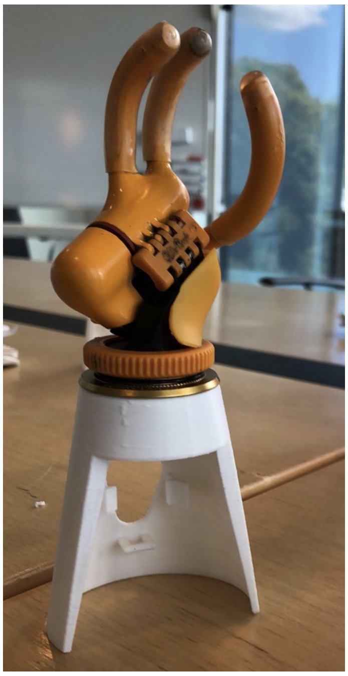


Figure 74: Wrist connection - Testing.

5.1.1.8 Holes for the cables of the sensors

The sensors are placed right in the amputee, inside of the soft inner socket. These sensors have cables that need to go all the way through the prosthesis to the wrist connection. For this reason, it was needed two holes for the cables in the hard inner socket. The way how the holes were created is explained in the following lines.

As in previous cases, two polylines with four points each were defined, Figure 75, and then these polylines were projected into a surface and extruded until they reached the hard inner socket.

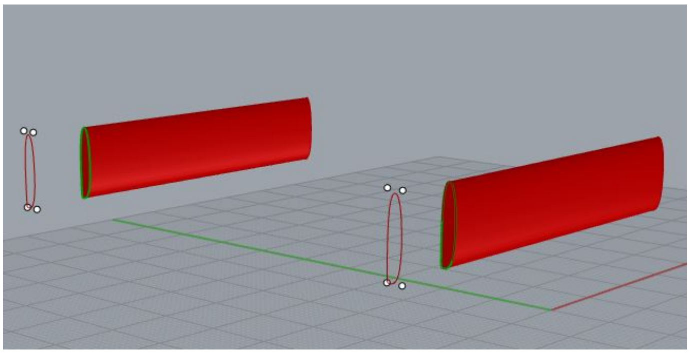


Figure 75: Holes for the cables of the sensors - Creation.

The last operation was a Volume Difference between the hard inner socket and these two volumes and the final result is presented in Figure 76.

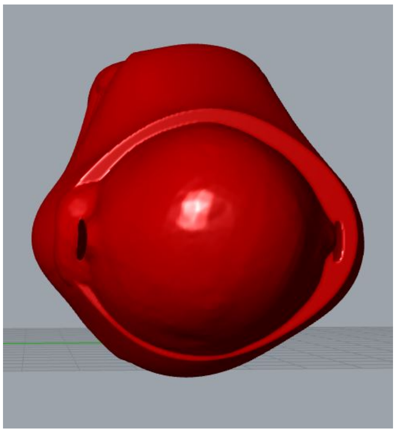


Figure 76: Holes for the cables of the sensors - Result.

Although the result presented in the previous figure is the final one, the holes were placed differently before. The Figures 77 and 78 show that the holes were placed more in the middle of the hard inner socket. However, Christian Veraeus suggested that it would be better if the holes were placed right after the sensors, as can be seen in Figures 79 and 80. In this way, the cables are less in contact with the amputee.

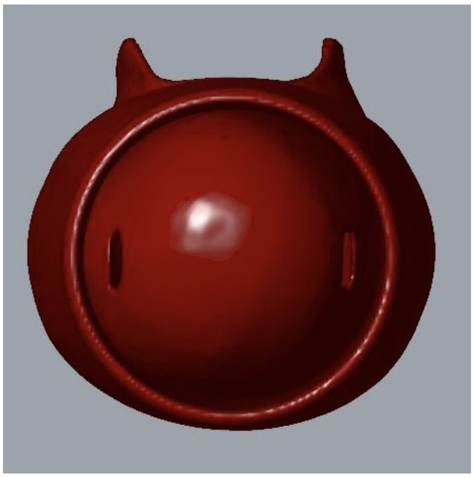


Figure 77: Holes for the cables - Before (1).

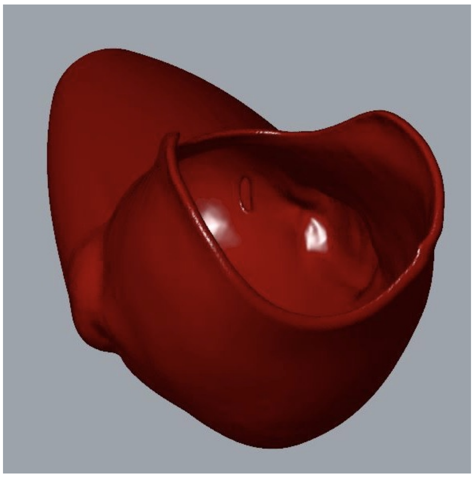


Figure 78: Holes for the cables - Before (2).

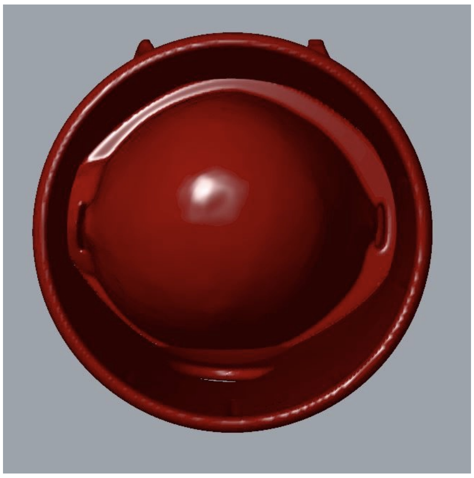


Figure 79: Holes for the cables - After (1).

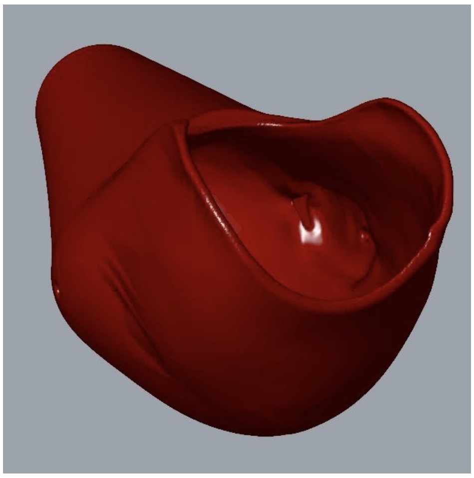


Figure 80: Holes for the cables - After (2).

5.1.1.9 Holes to control the electrodes

The last improvement was to include a hole of 3 mm on each side of the model to control the electrodes.

The holes were created independently since their position is not always fixed. This way, the prosthetist could modify their position as he/she wishes. Once the curve is projected on a surface, then it is extruded, as can be seen in Figure 81.

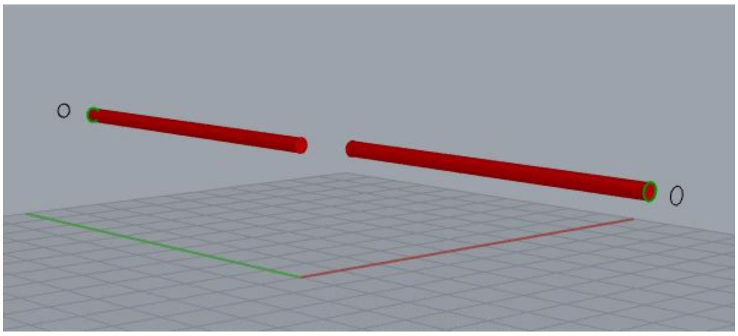


Figure 81: Sensor holes - Creation.

The last operation was a Volume Difference between the prosthesis and the two extrusions. The result is presented in Figure 82.

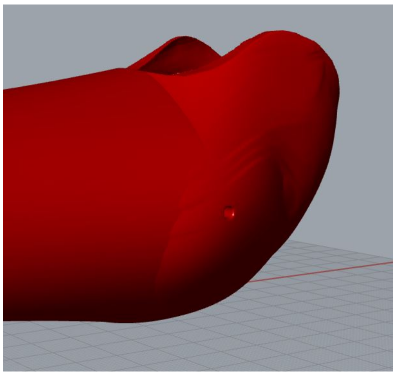


Figure 82: Sensor holes - Result.

5.1.1.10 Hole for the hatch

For implementing the hatch, a hole was performed in the model. Once the hole was made, the three different support sizes were added to this hatch.

It was added supports for the batteries in the three different sizes, as can be seen in Figures 83, 84 and 85.

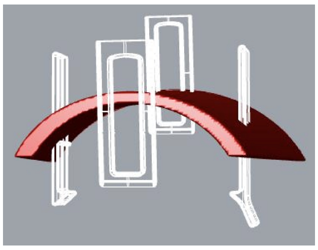


Figure 83: Supports - Big ones.

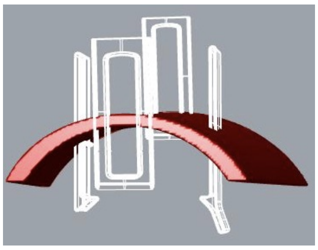


Figure 84: Supports - Medium ones.

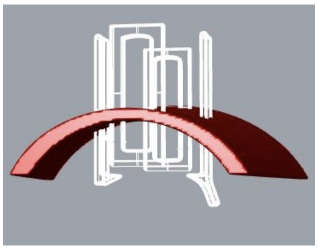


Figure 85: Supports - Small ones.

Once the supports were added to the hatch, this was split from the model so two independent parts were created, as can be seen in Figures 86 and Figure 87.

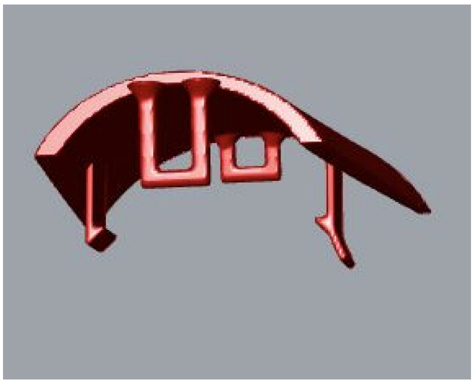


Figure 86: Hatch - Separated from the prosthesis.

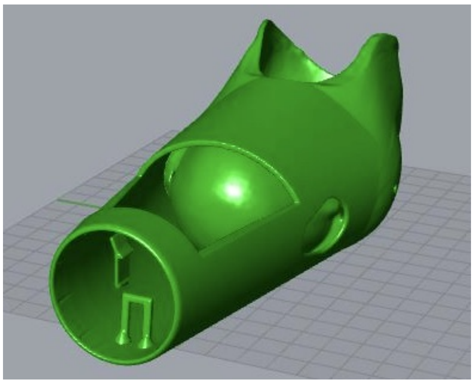


Figure 87: Hatch - Hole in the prosthesis.

The result of the hatch in Rhino can be seen in Figure 88, where the two independent parts are presented together.

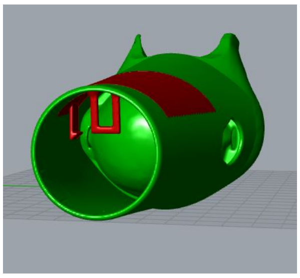


Figure 88: Prosthesis with the hatch.

5.2 Concept development of the prosthesis interior and hatch

The prosthesis interior is defined as the inner space between the outer hard socket and the inner hard socket. Components that are connected to the robotic hand will be placed inside this space. These components are two batteries, one control unit and one charge connector. Due to the limited space it is important that all components will fit and the weight is distributed evenly. To control where the components are placed inside the prosthesis solutions are developed to hold the components in place. These solutions will be referred to as supports. The biggest issue was the batteries as they take up most of the space inside. For this reason one of the two main focuses would be on finding supports for the batteries.

The other main focus is to develop a hatch to be able to open the prosthesis and get to the inner components in an easy and effective way. This way both the prosthetist and the prosthetic user can access the components without having to use any tools or send the prosthesis to a specialist.

The process of the concept development of the prosthesis interior and hatch is shown in Figure 89. Once a concept is 3D-printed and evaluated the model usually goes through adjustments and then 3D-printed again, in some cases the concept is discarded and the development process starts over.

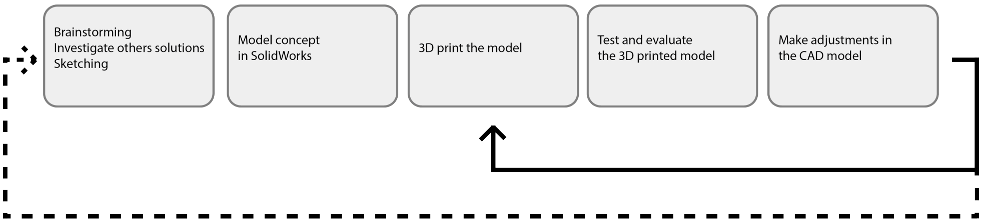


Figure 89: The process of concept development.

5.2.1 Product requirements

Components that are required inside the inner space:

- Two interconnected batteries.
- One control unit.
- One robotic hand connector.
- One charge connector.

Components sizes:

- Batteries, Figure 90:
  - Big batteries: 51.6 mm x 36 mm x 9.4 mm.
  - Medium batteries: 51.3 mm x 24.5 mm x 10 mm.
  - Small batteries: 35 mm x 19.5 mm x 7 mm.
- Control unit, Figure 91: 28.0 mm x 26.5 x 5.3 mm.
- Robotic hand connector, Figure 92: 25.0 mm Diameter x 5 mm.
- Charge connector, Figure 93: 27.0 mm long x 17.8 mm widest part x 7.2 mm.

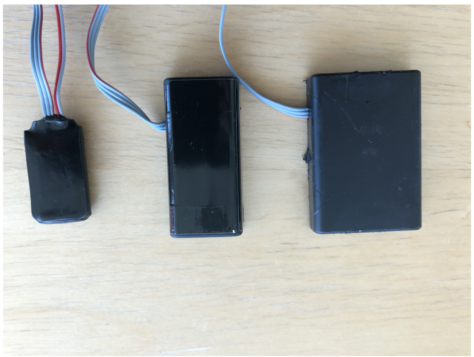


Figure 90: Three sizes of batteries.

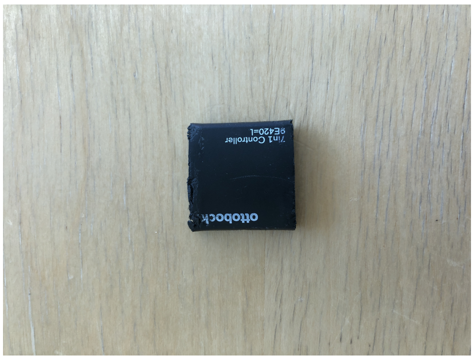


Figure 91: Control unit.

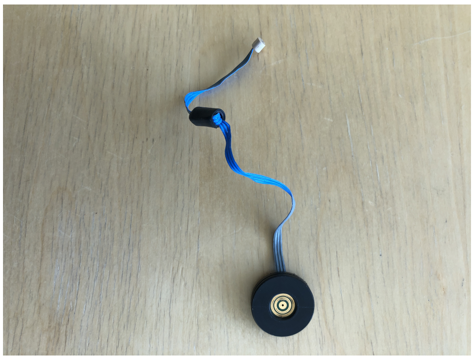


Figure 92: Robotic hand connector.

Figure 93: Charge connector.

Two of the most important customer needs were to enable prosthetists to use the desired size of the battery and to optimize the use of the inner space. For this reason it was decided to have the biggest attention on designing supports for the biggest batteries. Supports for the biggest batteries would be the ideal outcome, however, once a good solution was found in the big batteries similar but scaled supports would be developed for the smaller batteries as well. This was to give the user the option of choosing and to be able to adapt to what size of batteries the user sees fit.

As mentioned earlier, the batteries are the components that make up the biggest volume. As can be seen in Figure 94, the other components are significantly smaller than the batteries and therefore it was decided that the other components other than the batteries would be given less attention to.

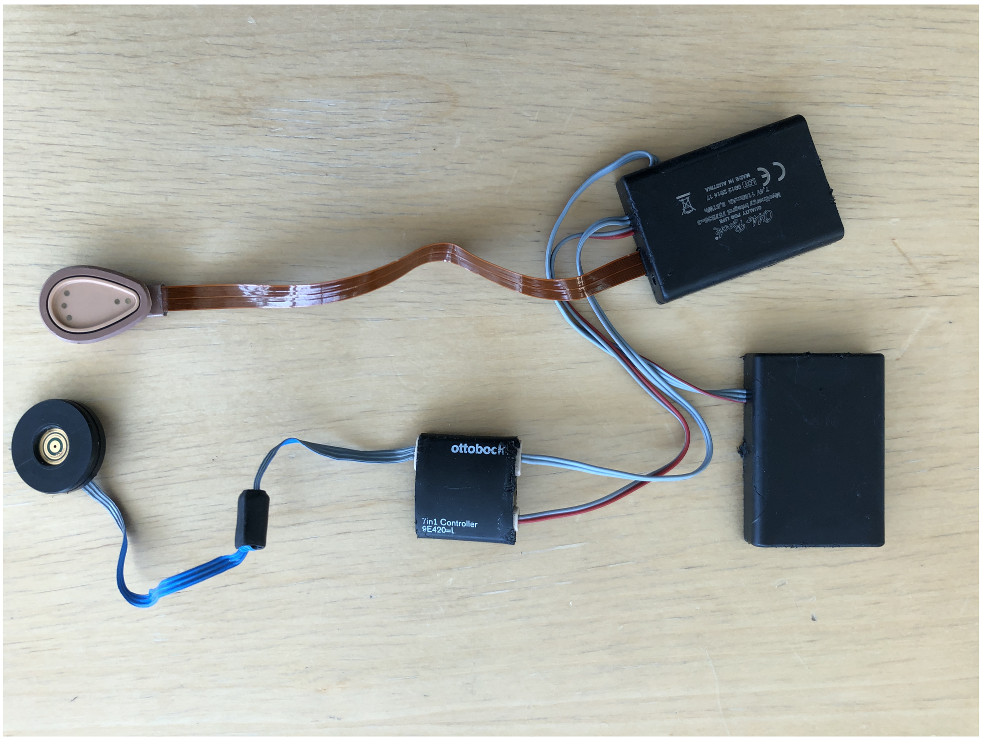


Figure 94: The inner components interconnected.

The solution for the charger connector would be a hole in the outer hard socket that the charger connector would be placed in. The hole was an already existing solution that was implemented in the traditional manufactured prostheses and was an optimal solution for the charger connection and for that reason there would be no further development of this. The only thing that was being looked into was the placement of the hole.

The robotic hand connector would be placed in the already fixed place on the wrist connection and for that reason there would be no further development of the supports for the robotic hand connector.

The control unit is connected to the batteries and to the robotic hand connector. Because of its lightweight and the fact that it is connected to other components makes it static and secure without any supports. Nevertheless, even though it was not necessary to create supports for the control unit it would be looked into if there was time to spare for it.

5.2.2 Concept Development of interior

5.2.2.1 Specific product specifications - Interior

Specific product specifications were established to help the development process of the interior and these are presented in Table 3. The importance of the specifications were based on the importance of the customer needs. Some metrics were not quantifiable and are therefore subjective and is evaluated by personal intuition.

Metric no.	Metric	Imp.	Unit	Marginal Value	Ideal Value
1	Minimum distance between the inner hard socket and the outer hard socket (vertical)	2	mm	>52	>52
2	Scaleable	5	Yes/No	Yes	Yes
3	Adaptable to different shapes of the outer hard socket	5	Yes/No	Yes	Yes
4	Adaptable to different shapes of the inner hard socket	5	Yes/No	Yes	Yes
5	Easy to access inner components	4	Yes/No	Yes	Yes
6	Wall thickness	4	mm	1 - 2	2
7	Support parts	3	piece	1 - 4	2
8	Added weight	5	g	1-10	5
9	Stop movement of components in every direction	4	Yes/No	Yes	Yes

Table 3: Interior specifications.

5.2.2.2 Product Concept Generation - Interior

With the product specifications as a foundation, ideas were generated through brainstorming and comparative analysis of solutions to similar problems.

In the beginning paper models and metal wire models were created to visualize the volume and explore what kind of shape on the outer hard socket that was needed for the batteries, Figures 95, 96 and 97. This was a good step to get a feeling of the inner space and to get a grip of the interior volume.

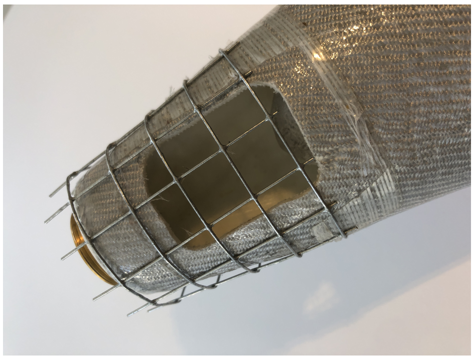


Figure 95: Size of the metal wire model.

Figure 96: Metal wire model with batteries.

Figure 97: Paper model.

It was found that if the shape was elliptical rather than circular the batteries take up less space because they could be placed closer to the surface, as can be seen in Figure 98. An elliptical shape was the best choice given that the batteries will be placed on the long sides of the ellipse.

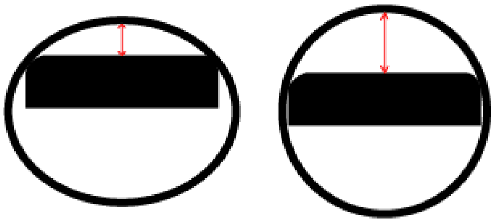


Figure 98: Elliptical vs circular shape.

As a result of the paper models it was decided not to work with the narrow space between the inner hard socket and outer hard socket, as a contrast to what prosthetists do today. Usually the prosthetist places the battery as far down as possible, often in the narrow space between the hard inner socket and the hard outer socket. Instead, it was decided to use a space where the hard inner socket does not intersect. In order to fit the big batteries this space was decided to have the minimum height of the battery plus 4 mm, 2mm from the top and the bottom of the battery. This is shown in Figure 99.

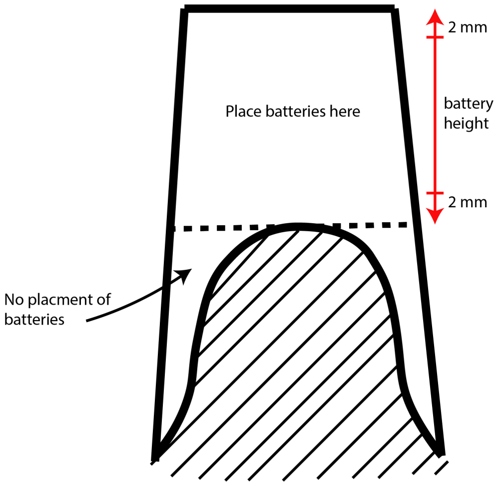


Figure 99: Illustration of the space for placement of batteries.

One major challenge was to figure out how both the batteries can fit inside and how to easily access them. It was discovered that placing both the batteries through a hole that is smaller than the size of the batteries was very difficult. Placing the second battery inside was especially difficult since there is not much room to move the battery around. Therefore, it was decided to have an opening that has the same dimensions as the batteries height and width. Later it was also discovered that the big issue of placing the second battery inside would be solved if the second battery was to be placed on the hatch instead of together with the first battery, as can be seen in Figure 100. This solution makes it possible to place the second battery on the hatch when it is opened and then when it is closed the battery gets inside without any additional effort.

Figure 100: Battery placement on the hatch and inside.

5.2.2.3 Product Concepts - Interior

From brainstorming sessions three different concepts for the battery supports was chosen to be developed further. They are presented in Figure 101.

- Concept 1: Hug. A support with a two hooks to hold the battery in place.
- Concept 2: Slot. A support with tailored slot for the battery.
- Concept 3: Wave. A support with a wave shaped clip.

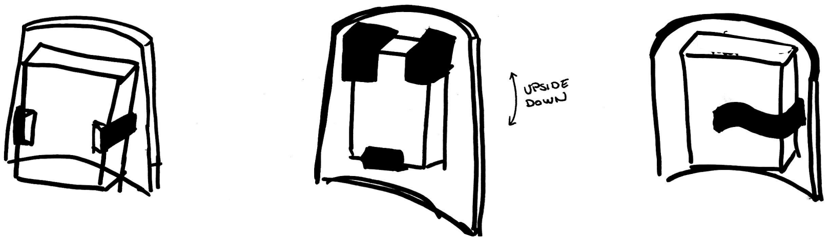


Figure 101: The three selected concepts for development.

Concept 1: Hug

This concept, Figure 102, was based on the idea of two arms holding an object. The support has two hooks that will hold the battery in place. The hooks have a drafted surface that makes it easy to place the battery inside while they have a 90 degree surface on the other side which makes it harder for the battery to get out. The principle is that the arms are flexible enough to bend when the battery is removed and stiff enough to hold the battery in place. The battery is pushed down until the hooks bend outward and the battery is in its position.

Figure 102: Concept 1: Hug.

Concept 2: Slot

This concept, Figure 103, has a tailored slot for the battery and a hook. The slot is positioned on the short side of the battery and the other side has a hook that will hold the battery in place. The drafted surface of the hook makes it easy to place the battery inside while it is needed more force to take the battery out. The hook will be flexible enough to bend to take the battery out. The battery's short side is placed in the slot and then on the other side pushed down until the hook is bent and the battery reach its position.

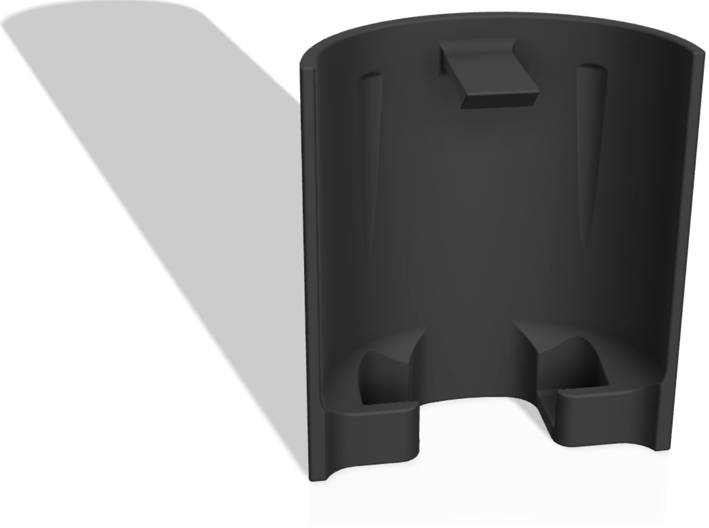


Figure 103: Concept 2: Slot.

Concept 3: Wave

The third concept, Figure 104, is using the principle of a press fit. The battery is held in place by a wave shaped clip. The slot for the battery is slightly smaller than the thickness of the battery and by taking advantage of the flexibility of the material the clip holds the battery with enough force when the battery is inserted under the clip.

Figure 104: Concept 3: Wave.

5.2.2.4 Test and Evaluation - Interior

This part of the process includes many iterations of modeling the concepts in SolidWorks, 3D-printing the models and making adjustments to the models. Once the model is 3D-printed a battery is placed to test and evaluate the solution. Depending on what is discovered in the testing, changes to the model is made accordingly. Figures 105, 106 and 107 show the different versions of the concepts.

Figure 105: Generations of Concept 1 - Hug.

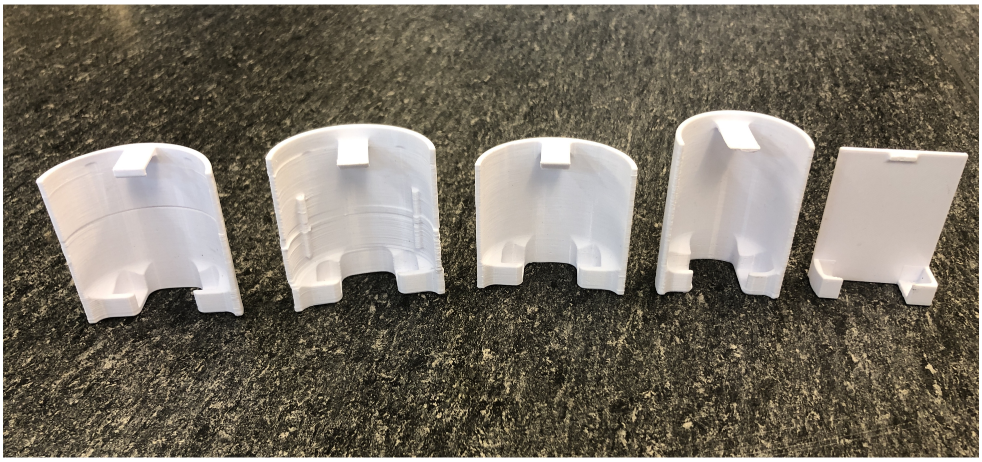


Figure 106: Generations of Concept 2 - Slot.

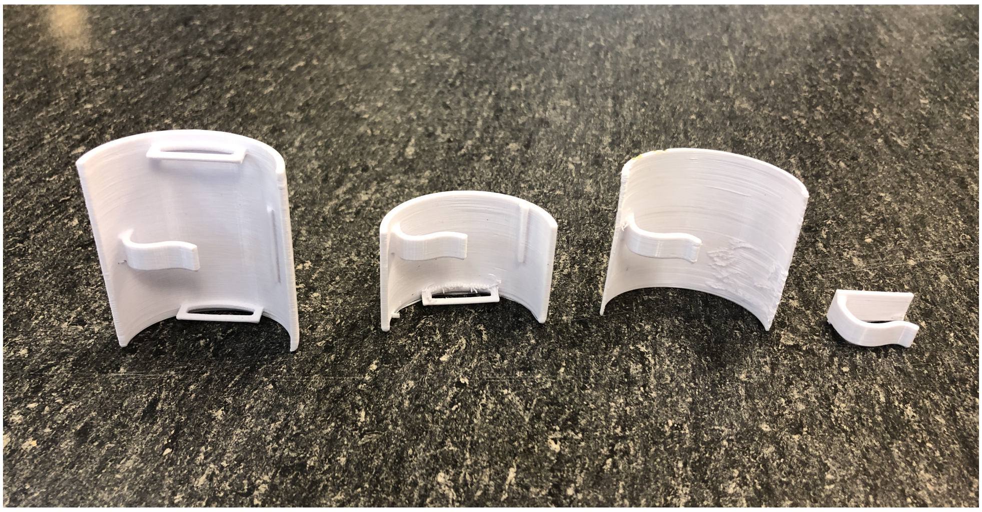


Figure 107: Generations of Concept 3 - Wave.

In the testing phase it was discovered that Concept 1 and 3 do not stop the movement of the battery in every direction like it was set to do by the product specifications. Concept 1 allowed the battery to move in the horizontal direction and as for Concept 3 allowed the battery to move in the horizontal direction but also in the right vertical direction. As a result of the testing it was created stops on the sides of the battery to block all movements in all directions as can be seen in Figure 108.

Figure 108: Concept 1 and 3 with stops.

Another thing that was investigated was the ideal shape of the outer hard socket. It started with a simple circular cylinder and then evolved to a diverging elliptical cylinder. The initial thought was that a consistent circular shape would be the easiest one to adapt to all types of prostheses. It was discovered that there was no need for the shape to be consistent for the whole volume, but as long as it is symmetrical, it is easier to make the supports adaptable to different shapes of the outer hard socket. This means that the outer hard socket could have one ellipse on the top and another on the bottom, which makes it easier to control the aesthetics of the prosthesis. It was decided that the shape of the volume will be a smaller ellipse on the top and then the shape will diverge into a bigger ellipse at the bottom. This decision was made to give the prosthesis continuity in its shape. The comparison between the two shapes can be seen in Figure 109.

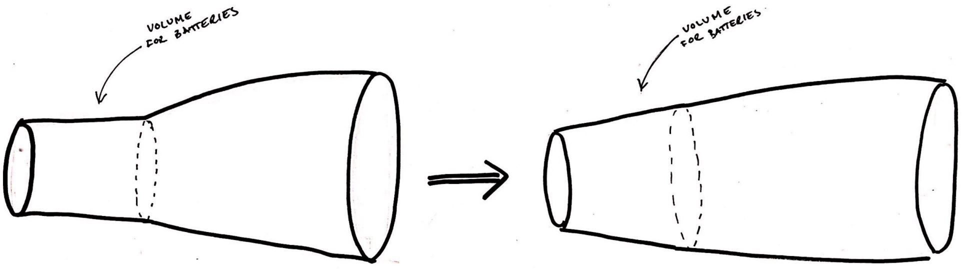


Figure 109: Consistent shape compared to diverging shape.

5.2.2.5 Concept Selection - Interior

The concept selection is based on a concept screening matrix. The concept screening matrix is a selection method that evaluates and ranks the concepts. In order to make the scoring easier Concept 2 will serve as the reference concept. For each selection criteria the concept will be given a +, - or a 0.

As can be seen in Table 4, Concept 1 is ranked the highest.

	Concepts		
Selection Criteria	Concept 1 Hug	Concept 2 Slot (Reference)	Concept 3 Wave
Easy to remove battery	0	0	-
Easy to place battery	+	0	-
Easy to adapt to different shapes	+	0	+
Few parts	-	0	-
Stops movement of battery	0	0	0
Flexible parts	+	0	+
Takes up little space	+	0	0
Sum +'s	4	0	2
Sum -'s	1	0	3
Sum 0's	2	7	2
Net Score	3	0	-1
Rank	**1**	**2**	**3**

Table 4: Concept screening matrix.

In order to validate the result of the concept screening the concepts were also presented to the user Christian Veraeus for an external decision. Christian's experience and expertise enabled him to make a well-founded selection of the concepts based on his intuition. The concept that was chosen was Concept 1.

From the result of the concept screening matrix and Christian Veraeus it is clear that Concept 1 is the best option. Therefore Concept 1 is the concept that will be taken into further development.

5.2.2.6 Final Development of Concept 1 - Interior

The final development of Concept 1 includes finding an easier way to remove the battery, refining of the measurements and adjusting the model so it can be implemented in Grasshopper. The final prototype of Concept 1 can be seen in Figure 110.

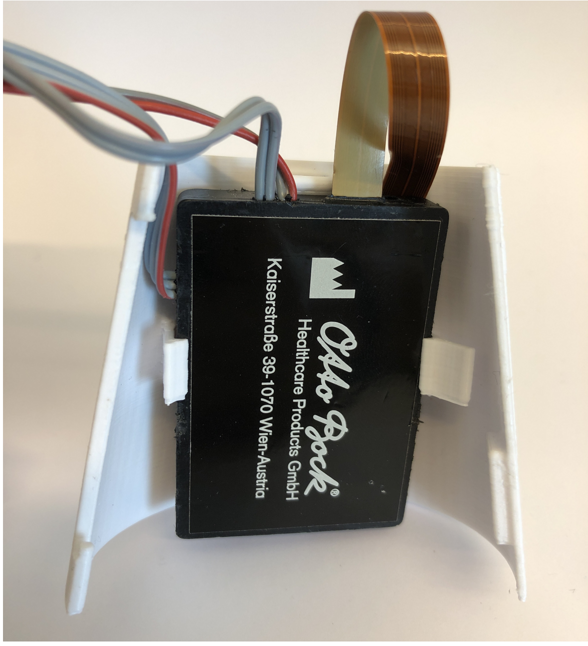


Figure 110: Final prototype of Concept 1

One of the main concerns about the concept was how to easily remove the battery especially when it is located in a confined space. This was solved by adding a 5 mm lever on top of the hook to give it a higher momentum, shown in Figure 111. By adding the lever the higher torque makes the hook bend much easier than without the lever. An additional advantage of the lever is also that it gives the user a cognitive indication of how to remove the batteries.

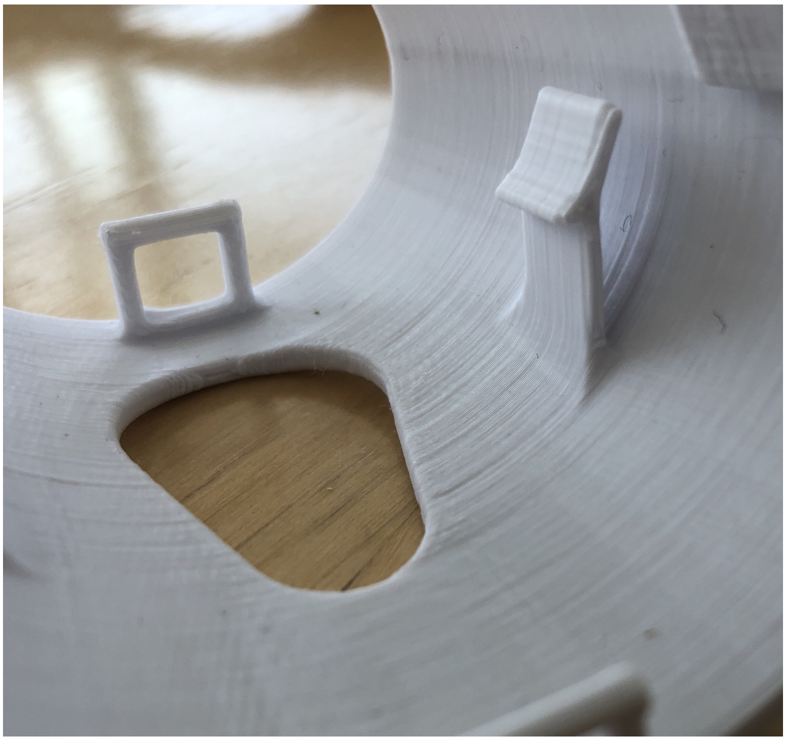


Figure 111: Support hook with lever.

After testing and refining the finishing step is to implement the solution into the program in Grasshopper. Only the supports are going into the program and everything else is scaled away. This is particularly hard since it is hard to control the exact tolerances, especially with the goal of auto-generation of different prostheses in mind. Therefore the exact space that the battery is inserted in must be kept the same. To make the supports adaptable to all kinds of prostheses the length of the supports was lengthened, but the distance where the battery will be placed is marked on the supports. The excess material will be trimmed away in the program, this is discussed earlier in sub-chapter 5.1.1.5.

5.2.3 Concept Development of the hatch

5.2.3.1 Specific Product Specifications - Hatch

A few specific product specifications were established to help guide the development process of the hatch. The importance is ranked in descending order.

- Easy to close.
- Easy to open.
- Adaptable to different shapes of the outer hard socket.
- One hand operation to open and close the hatch.
- Intuitive.
- As small as possible.
- No added material on the outside of the hard outer socket.

5.2.3.2 Product Concept Generation - Hatch

The concept generation of the hatch included comparative analysis to solutions with similar problems and brainstorming. Areas that were looked into for inspiration were buttons, watches, zip lock bags, latches, ball pens, belts, luggage straps, TV remote controls, hinges and other closing mechanisms. The flexible 2-component solutions were the ones that inspired many of the concepts that were generated in the brainstorming. Even though there were no restrictions or directions for the brainstorming a similarity between all the concepts that were generated can clearly be seen. All the concepts are based on a closing mechanism with some kind of a press fit. The concepts include some kind of hole with an opening that is slightly smaller than the inserted object. It was decided to develop solutions with simplicity in mind and that is why press-fit became the natural option.

Many of the concepts were discarded right away due to the fact that they are too complex to create in small sizes. Out of ten concepts, three were selected for further development. The three selected concepts were chosen because of their different shapes. It was clear to select concepts that were different from each other in order to cover as much ground as possible when investigating what the ideal solution is for this type of hatch.

The idea is to make the hatch as small as possible and not add anything that is not necessary. For this reason it is decided to have the closing mechanisms on one side of the hatch and a hinge on the other side as a primary solution. This solution will result in that the hatch will be connected to the prosthesis and not a removable part. The backup solution is to have locks on at least both sides of the hatch and make it a removable part of the prosthesis.

5.2.3.3 Product Concepts - Hatch

From brainstorming sessions three different concepts for the battery supports was chosen to be developed further and they are shown in Figure 112.

- Concept 1: Block. A hatch with a block press fit closing.
- Concept 2: Sphere. A hatch with a sphere through a hole closing.
- Concept 3: Ziplock. A hatch with a zip lock closing.

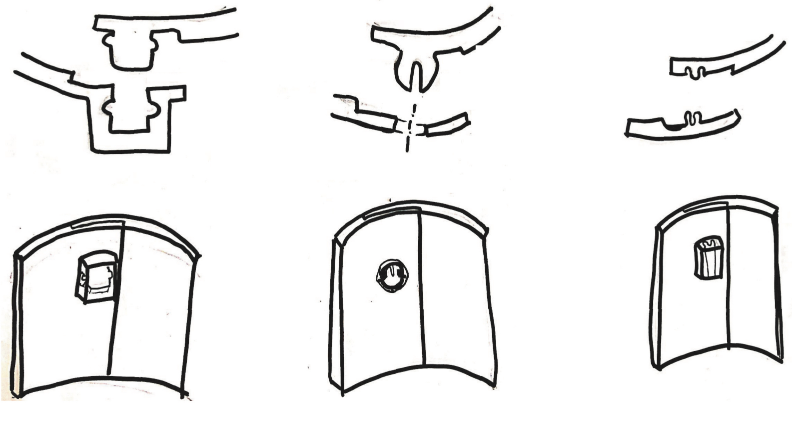


Figure 112: The three selected concepts for development of the hatch.

Concept 1: Block

This concept is based on the principle of a solid block pushed through a hole. The thing that is holding the block in place is the circles on the side of the block and the circular cavities with a slightly smaller diameter. When the block is inserted in the hole, the circular cavities will apply pressure to the circles on the side of the block which have the effect of requiring a bit of force to pull the block out. This is illustrated in Figure 113 and 114.

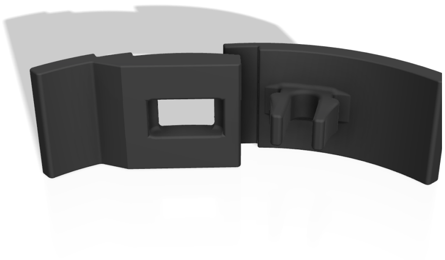


Figure 113: Block - Open.

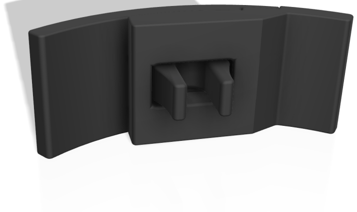


Figure 114: Block - Closed.

Concept 2: Sphere

This concept is inspired by a jeans button. The closing mechanism for this concept has e spherical solid that is inserted in a round hole. The hole has a slightly smaller diameter than the sphere. To enable the sphere to go through the hole sections of the sphere is cut out to make it flexible. This is illustrated in Figure 115 and 116.

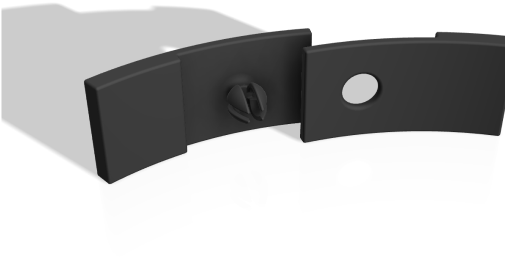


Figure 115: Sphere - Open.

Figure 116: Sphere - Closed.

Concept 3: Ziplock

This concept is inspired by the closing mechanism on the plastic zip-lock bag. The principle is two rows of clasps that hooks into a stem. This is illustrated in Figure 117 and 118.

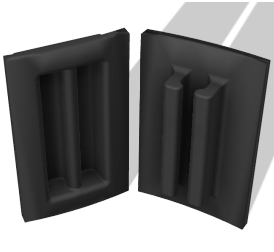


Figure 117: Ziplock - Open.

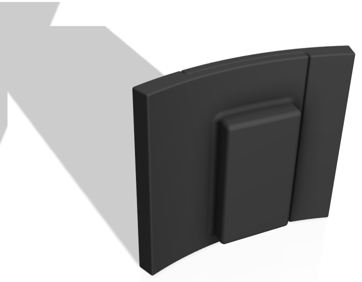


Figure 118: Ziplock - Closed.

5.2.3.4 Test and Evaluation - Hatch

In this part of the project the concepts are modeled in SolidWorks and then 3D-printed for testing and evaluation. The first step is to only 3D-print the closing mechanism and once the solutions are satisfactory the closing mechanisms are integrated into the hatch.

During the testing it was found that Concept 2 was too complex to make in such a small size. The cut-outs that were designed to make the sphere flexible made the sphere fragile instead. The parts were broken off directly when removing the 3D-printed support material because the parts of the sphere were too weak. Even the attempts that were made to make the solution more durable failed. Due to the several failed models and lack of time the confidence in this concept was lost and it was decided to stop any further development of Concept 2.

In this stage it stood between Concept 1 and Concept 3.

5.2.3.5 Concept Selection - Hatch

The concept selection of Concept 1 and Concept 3 was based on a list of pros and cons. The list of pros and cons for both concepts can be found in Tables 5 and 6, respectively.

From the list of pros and cons it was decided to continue with concept 3 for further development. It was felt that Concept 3 had the strongest strengths. The pro; "*Satisfying to open and close*" was particularly weighing in this decision. The pleasing feel of closing the lock made the decision very easy to choose Concept 3.

Pros - Block	**Cons - Block**
- Durable - Intuitive - Adaptable to different surfaces - Satisfactory closing sound - Needs only one hand to open - No added material on the outside of the hard outer socket	- Takes up much volume - Need much force to open - Need much force to close - Must be opened directly from above

Table 5: Concept 1: Block - Pros and Cons.

Pros - Ziplock	**Cons - Ziplock**
- Easy to open - Easy to close - Durable - Intuitive - Satisfying closing sound - Needs only one hand to open - No added material on the outside of the hard outer socket - Satisfying to open and close	- Takes up much volume inside - Curvature dependent - Complex geometry - Harder to adapt to different surfaces

Table 6: Concept 3: Ziplock - Pros and Cons.

5.2.3.6 Final Development of Concept 3 - Hatch

The final development of Concept 3 is implementing the lock into the hatch and to create the hinge.

The closing mechanism was in the beginning implemented in two places on the left side on the hatch. One lock in the bottom and one on the top. After 3D-printing the hatch it was discovered that the top lock made it impossible for the big battery to be placed inside because the lock and battery collided with each other. Therefore, it was decided to only have one lock on the side of the hatch if the big battery was used. If the smaller sizes of the battery will be used, then two locks can be implemented. However as learned from testing the solution with one lock it is not necessary with two since one lock is strong enough to hold the hatch closed.

In the first iteration of the hatch it was found that the hinge was too weak and the axis broke off when rotating the hatch. The problem was the small diameter of the axis and in an attempt to thicken it and solve the durability problem by printing it on the SLS 3D-printer another problem appeared instead. This time the excess powder from 3D-printing could not be removed from the hinge since the gap was too small.

The hinge was increased in size to make the axis thicker, which led to the consequence that the hinge is sticking from the surface. This compromise had to be made to make a viable hinge for the purpose of prototyping. The final prototype is presented in Figures 119, 120 and 121.

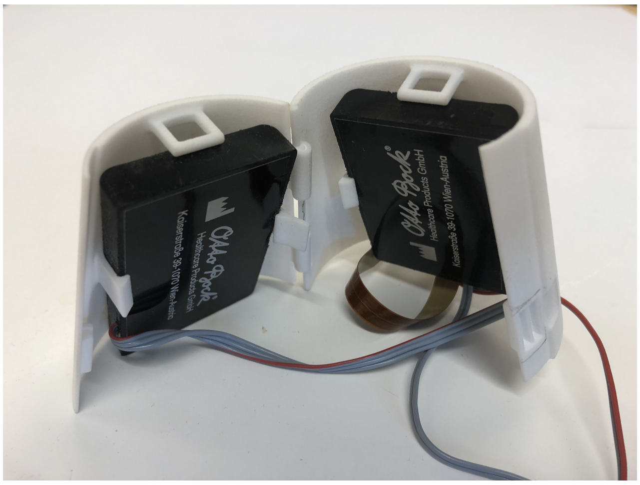


Figure 119: Final prototype with the hatch - Open.

Figure 120: Final prototype - Closed. Hinge.

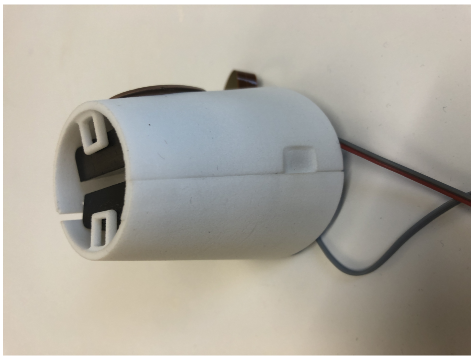


Figure 121: Final prototype - Closed. Zip lock.

6 Validation - User Study

In order to validate the proof-of-concept of this project an in-depth interview was conducted on a prosthetic user. The first step was to ask the subject general questions about the current use of prosthesis to get an overall picture of the subject their relation to prosthetic arms. At the end of the interview the subject was informed about the project and asked their first impression of the project and if they could see potential with it. The goal of the user study was to find out the users' prosthesis habits, if the result of the project will be beneficial to the prosthesis user and if there is any additional information that could be useful. The protocol of the interview can be found in Appendix C.

The subject is a 38-year-old man who had used prostheses since he was 3-month-old. He currently has four different prostheses, two myoelectric prostheses and two cosmetic ones.

From the interview it was clear that an adult, in general, does not change that much in size, which makes the need for a new prosthesis among adults low. The subject informed that he has not changed prosthesis in the last 10-15 years due to the fact that his weight and appearance have been very static. However, it is more actual to change prosthesis frequently as a child since a child grows much faster. The subject changed his prosthesis up to 2-3 times a year when he was a teenager. Even though it was already known that children grow faster than adults, the user study made it clearer that the objective of this master thesis should be aimed for children.

Another thing that was validated in the user study was the need to be able to open the prosthesis at any time. If the subject needs anything to be fixed inside, he will send the prosthesis so a specialist. This will take a few days. The subject expressed a need to be able to open the prosthesis by himself. However, it was not because of the need to change the inner components, but to be able to open it for other practical reasons like when going through the security in an airport. It was discovered that the inner components such as batteries and sensor usually do not need to be changed because the components rarely has any malfunction.

The first impression of the project from the subject was excitement. He is very open to new technology and sees a big potential with a program to auto-generate prostheses for 3D-printing.

6.1 Evaluation of the solution

In order to validate the software and since only one scan of the soft inner socket was provided, this scan was mirrored so the program could be tested with what could be seen as another mesh, Figure 122. The effectiveness of the software was validated since Grasshopper was able to recalculate automatically everything and generated a new prosthesis as can be seen in Figure 123.

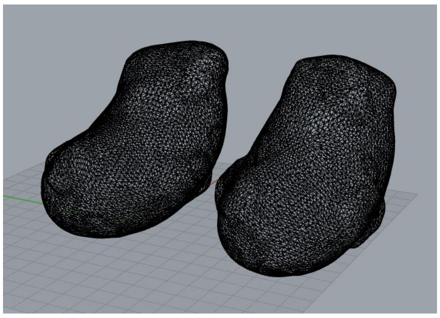


Figure 122: Soft inner socket scan and its mirror.

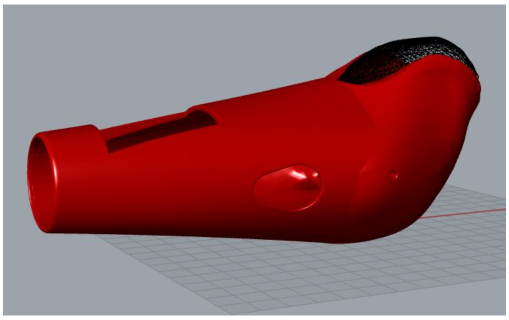


Figure 123: Prosthesis generated with the mirrored scan.

Nevertheless, it would have been better to try out a completely different scan - i.e, a bigger or smaller one, a larger or shorter one - to get a more different result.

7 Deliver

7.1 Result - Final Solution

The result is a Grasshopper script that takes the scan of the residual limb and measurements of the non-amputated arm and generates a customized prosthesis. The prosthesis has supports for the batteries and a hatch that can be open and closed. As the finishing step, a model of the prosthesis generated from the program is 3D-printed.

The development process of the software and the development process of the interior and hatch were united into one. The solutions for the supports were implemented into Grasshopper. However, due to lack of time the hatch could not be implemented to Grasshopper. Renderings of the final model and the details can be seen in Figures 124, 125, 126, 127 and 128.

The program is developed so that the user can make a basic model with just one scan and a few measurements but also to give the user a number of additional options to adjust the model. The basics are that the user can import the scan of the residual limb and set the length and the width of the arm and then the software will generate a prosthesis. Additional options such as changing the trim line, choosing battery size, placement of the charger hole, outer hard socket thickness and surface smoothing is given to the user.

Figure 124: Rendering of the final model.

Figure 125: Details - Hinge.

Figure 126: Details - Hatch.

Figure 127: Details - Charger connector.

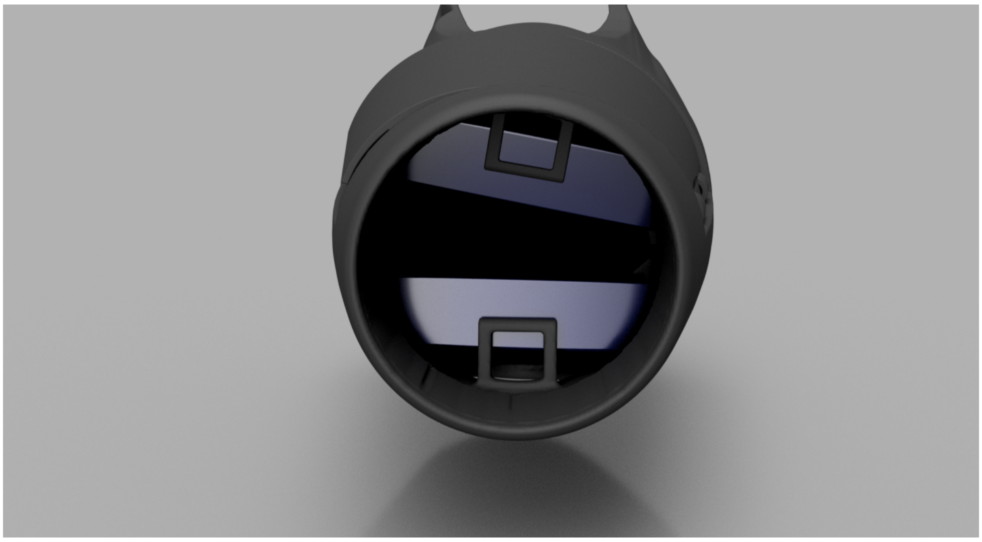


Figure 128: Details - Supports for the batteries.

Figures 129 130, 131 shows pictures of the 3D printed prosthesis that was generated from the software. In Figure 130 the placement of the inner components can be seen. The 3D printed prosthesis confirmed that the developed design was possible and achieved what it was designed to do. The components for the robotic hand was placed inside the prosthesis and the supports obtained the intended function.

Figure 129: 3D printed model.

Figure 130: 3D printed model - Inner space.

Figure 131: 3D printed model - Closed hatch.

7.2 Product Implementation

The developed method has 7 steps and can be found in the list below. The total amount of steps are depending on the amount of adjustments needed for the model. See the user guide in Appendix A for a detailed description of the steps.

Steps of the process:

1. Scan the soft inner socket.
2. Insert the scan of the soft inner socket into the program.
3. Place the imported scan correctly.
4. Set the length and width of the prosthesis
5. Make optional adjustments:
    - Adjust the trim line.
    - Select the battery size.
    - Select the position of charger hole.
    - Adjust The thickness of the prosthesis.
    - Adjust the wrist diameter.
6. Export the model to an STL file.
7. 3D-print the model.

7.3 Final Product Specifications

Below is Table 7 with the final product specifications. The specifications were established from the testing in the concept development phase and from 3D-printing the model generated with the program. Metric 4 and 7 could not be established since there was no time to test the durability or time to establish the center of gravity of the 3D-printed model. Metric 9 and 11 could not be established with reliability because no extensive user testing was conducted. All of the values are within the range of the marginally accepted values that were set in subsection 4.3.

Metric no.	**Need**	**Metric**	**Imp.**	**Unit**	**Value**
1	1, 2, 3, 4, 6	Number of steps in manufacturing process	5	Steps	7
2	2	Program processing time (excluding 3D-printing)	5	hr	3.3
3	5	Unit manufacturing cost	3	kr/cm3	1.3
4	9	Durability (Tensile Strength)	4	MPa	N/A
5	11	Wall thickness around the sensors	3	mm	2
6	13, 15, 16, 17	Volume for inner components	4	cm3	525
7	14	Center of gravity	2	x cm from mid-point of prosthesis	N/A
8	18	Weight without inner components	2	g	115
9	3, 4, 6	No CAD/programming experience needed for using the program	2	Yes / No	N/A
10	7, 8	Possible to make changes to the finished model	5	Yes / No	Yes
11	10, 12	Aesthetically pleasing prosthesis	3	subjective	N/A
12	17	The inside of the prosthesis is easily accessed	4	Yes / No	Yes

Table 7: Final product specifications.

7.4 Final Product Specifications - Interior

In Table 8 the final product specifications for the interior is shown. Almost all the values are within the range of the marginally accepted values that were set in subsection 5.2.2.1. The value of metric 8 is below the marginal value which is positively lower than expected.

Metric no.	Metric	Imp.	Unit	Value
1	Minimum distance between the inner hard socket and the outer hard socket (vertical)	2	mm	>52
2	Scaleable	5	Yes/No	Yes
3	Adaptable to different shapes of the outer hard socket	5	Yes/No	Yes
4	Adaptable to different shapes of the inner hard socket	5	Yes/No	Yes
5	Easy to access inner components	4	Yes/No	Yes
6	Wall thickness	4	mm	2
7	Support parts	3	piece	4
8	Added weight	5	g	0.5
9	Stop movement of components in every direction	4	Yes/No	Yes

Table 8: Final Interior specifications.

7.5 Costs

The cost of the manufacturing process will entirely lay on the 3D-printing. The cost will depend on the size of the model, the type of 3D-printer used for 3D-printing the prosthesis, what kind of material and if the job is outsourced or not. In this project the prosthesis is designed to be printed in Nylon 12 (PA12).

The cost calculation in this specific case is based on the cost of 3D-printing the final model of the prosthesis that was generated by the program. Because the 3D-printed prosthesis was required for the presentation of this master thesis, an additional fee was paid to get a faster delivery date. The estimated time for 3D-printing the model was 24 hours and the cost was 2.500 SEK.

8 Discussion

8.1 The decision to aim for children's prosthetic arms

Due to the rapid growth of children, children needs to renew their prosthesis frequently. In addition to growth, there is also the possibility of prosthetic breakage when they are playing. Swedish healthcare has the advantage that it bears all the costs of the prosthesis. However, not all countries offer this possibility. For this reason, the so recurrent change of prostheses in children can greatly affect the family economy. That is why this software is more beneficial for children, getting a much cheaper solution compared to those currently available. Nevertheless, it may also be useful for adults that frequently needs to change their prostheses.

8.2 Usability of the program

The program has a user guide where there is explained step by step what to do to generate a prosthesis in addition to some comments in the script itself. All the necessary operations for the design of the prosthesis, but that the user does not have to know, have been grouped into clusters, which is an effective technique to reduce the visual complexity of the file. On the right side of the script, all those parameters that the user can change have been grouped, so the user does not have to read throughout the entire program, making it more intuitive.

To check the effectiveness of the program to automatically generate arm prostheses, what was done was to mirror the soft inner socket mesh to verify how automatic the program is. It was found that once Grasshopper was done with all the calculations, a new prosthesis was obtained without the need to readjust anything. This proved that the program is somewhat automatic.

8.3 Choice of method

This project followed the two methods double diamond and Ulrich and Eppinger product development process. The double diamond method was used for the whole project while the U&E method was used primarily in the concept development phase. The U&E method was implemented in the concept development phase because it made more sense to follow a strict method when developing concepts to control the process from diverging too much. The concept development phase is a phase where a lot of decisions are being taken and the U&E method provides good tools to help the decision making. However the development of the software did not follow the U&E structure since that part of the project did not involve a lot of concept generation and decision making. The development of the program followed a more feature-oriented process since it was determined from the beginning what features were to be developed. The method was to build the base and then to add details and future which made it feel natural to deviate from the U&E method [47].

8.4 User studies and user needs

The user studies conducted in this project were a key factor in the development process. By conducting the interview and the survey before the development process it was possible to identify the customer needs and rank them by importance. It was discovered needs that were not known about until the interview was conducted, needs that had a big impact on the direction of this project. One of those needs was need no. 17: The inside of the prosthesis is easily accessed, which guided the development towards a hatch. If the user study had been conducted all over again, it would be beneficial to conduct additional interviews with prosthetists to uncover more user needs.

Out of the 18 user needs 10 needs were proven to be fulfilled, see Table 9 below.Need 1, 2, 5, 7, 11, 13, 15, 16, 17 and 18 are fulfilled and proven though the evaluation and testing in the concept generation phase. The reason why Need 3, 4, 6 and 8 could not be evaluated is because extensive user testing is needed to get a credible validation and due to lack of time it was impossible to conduct. As for need 9 and 14 could not be assessed because the 3D printed model did not go through any testing. Need 10 and 12 are two needs that cannot be assessed since the view of the aesthetic of prosthetic arms is highly subjective.

Need no.	Need	Imp.	Validation
1	The manufacturing process have few manual steps	4	Testing
2	The manufacturing process does not take long time	4	Testing
3	There are not a lot of room for human error in the manufacturing process	3	Not validated
4	It is not required to have a lot of training to manufacture prosthetics	2	Not validated
5	It does not cost a lot to manufacture prosthetics	3	3D-printing the prosthesis
6	Everyone can manufacture prosthetics	1	Not validated
7	It is easy to make changes to the finished prosthesis	3	Testing
8	The manufacturing process is intuitive	2	Not validated
9	The prostheses are more durable than the traditional prostheses	2	Not validated
10	The prosthesis is aesthetically pleasing	3	Subjective
11	Little to none material is needed to smooth the area around the sensors	3	Testing
12	The prosthesis looks like a real arm	3	Subjective
13	The prosthesis does not need extra inner space to fit all the components	4	Testing
14	The center of gravity of the prosthesis is centered	3	Not validated
15	The desired size of batteries can be used	3	Testing
16	The inner space of the prosthesis is optimally used	3	Testing
17	The inside of the prosthesis is easily accessed	4	Testing
18	The components (batteries etc.) are placed inside and are prevented from movements	3	Testing

Table 9: Validation of the customer needs.

The interview conducted on a prosthesis user after the development phase resulted in a successful validation of the project. The interview was conducted on one user and would ideally be performed on several users to get a broader perspective. Other subjects agreed to do the interview, however when contacted them again none of them responded back. Although only one interview was performed it was enough to validate the value of this project and it was discovered needs that did not surface when investigating the need from the prosthetists' perspective.

To evaluate how easy to learn the program is, Christian Veraeus volunteered to make some adjustments in Rhino & Grasshopper to auto-generate a new prosthesis. After ten minutes of explanation he felt he could be able to use the program on his own, so he spent twenty minutes modifying some parameters and he concluded that the software is something he would like to learn. According to him, the software offers a simple interface that he could learn in no more that one day.

8.5 Reaching the objective

At the start of this master thesis the objective of the project was determined. The finished program can generate a prosthetic arm based on a scan of a residual limb and the length and width of the non-amputated arm. The final model has all the details that were determined in the objective but also additional details such as optional placements for the charger hole, three different choices of supports for the batteries, holes for cables and sensors and a pattern for the wrist connection to attach better. All the elements of the objective were developed into the program and therefore it is argued that the objective has been reached.

8.6 Reduction of the steps in the manufacturing process

One of the biggest goals for this project was to reduce the number of steps in the manufacturing process of prosthetic arms and thereby also reducing the time of the process. The conventional manufacturing process has at least 25 steps where 13 of these steps cover the manufacturing of the hard inner and outer socket. The resulted program does not replace the whole manufacturing process of prosthetic arms, but a substantial part of the process. The program can replace the manufacturing process of the hard inner and outer socket which was the goal of this master thesis. A comparison between the two processes for the hard inner and outer socket shows that the new method has reduced the process by 6 steps. A comparison of the processes are shown below in Table 10. There is a 46% reduction of the steps in the manufacturing process which is seen as a big improvement to the effectiveness of the process. The most significant advantage is that the steps of the new process does not require any manual labor since everything is done in the computer. Compared to the conventional manufacturing process where every step of the process requires manual labor the new process reduces the required effort remarkably.

The conventional process of the hard inner and outer socket has a lead time of approximately 15 hours while the new process has a lead time of approximately 26,65 hours. Although it might not be seen as a reduction of the lead-time with the new process, the labor steps in the new process are significantly smaller and take less time than the steps of the conventional method. It is important to note that the majority of the time is dedicated to 3D-printing the prosthesis which does not require any effort from the user. If only the active time where effort is required from the user is considered, the process time is approximately 2,65 hours. Which a significant reduction of 82% of the process time.

Conventional Process	**Time (h)**	**New Process**	**Time (h)**
1. Heat the the plastic sheet and place on the mold	1	1. Scan the soft inner socket	1
2. Vacuum form the plastic sheet to be the hard inner socket	1	2. Insert the scan of the soft inner socket into the program	0,1
3. Create vax model of arm	1	3. Place the imported scan correctly	0,25
4. Wait for wax model to dry	1	4. Set the length and width of the prosthesis	0,1
5. Cover the vax model with fibers and fabric socks	0,3	5. Make optional adjustments	0 - 1
6. Cover the hard inner socket with a plastic sock	0,1	6. Export the model to an STL file	0,1
7. Make vacuum in the plastic sock	0.1	7. 3D-print the model	24
8. Cover the layers with resin	0,1		
9. Work the resin so the surface is nice and smooth	0,4		
10. Wait for the resin to harden	3		
11. Place the prosthesis in the heating chamber and wait for the wax to melt away	5		
12. Trim the excess material by the trim line	1		
13. Grind the edges	1		
Total time	**15**	**Total time**	**26,65**

Table 10: Comparison between the conventional process and the developed process.

8.7 Cost comparison

Cost calculations are based on the direct costs of manufacturing the prosthesis, labor cost and material cost. Anatomic Studios provided the labor cost per hour (650 SEK/h) and the total labor cost is calculated with the active time spent on the prosthesis. In these calculations, the manufacture of the soft inner socket is not taken into account since its design is not included in the developed software. Tables 11 and 12 show the total time, the passive time and the active time for each step of the new process and of the conventional process, respectively.

New Process - Step:	**Total time (h)**	**Passive time (h)**	**Active time (h)**
1. Scan the soft inner socket	1	0	1
2. Insert the scan of the soft inner socket into the program	0,1	0	0,1
3. Place the imported scan correctly	0,25	0	0,25
4. Set the length and width of the prosthesis	0,1	0	0,11
5. Make optional adjustments	0 - 1	0	0 - 1
6. Export the model to an STL file	0,1	0	0,1
7. 3D-print the mode	24	24	0
Total time	**26,65**	**24**	**2,65**

Table 11: Total time, passive time and active time of the new process.

Conventional Process - Step:	**Total time (h)**	**Passive time (h)**	**Active time (h)**
1. Heat the the plastic sheet and place on the mold	1	0,75	0,25
2. Vacuum form the plastic sheet to be the hard inner socket	1	0,75	0,25
3. Create vax model of arm	1	0	1
4. Wait for wax model to dry	1	1	0
5. Cover the vax model with fibers and fabric socks	0,3	0	0,3
6. Cover the hard inner socket with a plastic sock	0,1	0	1
7. Make vacuum in the plastic sock	0,1		0,1
8. Cover the layers with resin	0,1	0	0,1
9. Work the resin so the surface is nice and smooth	0,4	0	0,4
10. Wait for the resin to harden	3	3	0
11. Place the prosthesis in the heating chamber and wait for the wax to melt away	5	4,75	0,25
12. Trim the excess material by the trim line	1	0	1
13. Grind the edges	1	0	1
Total time	**15**	**10,25**	**5,65**

Table 12: Total time, passive time and active time of the conventional process.

The data is summarize in Table 13.

Process	**Total time (h)**	**Passive time (h)**	**Active time (h)**
Conventional	15	10,25	5,65
New	26,65	24	2,65

Table 13: Comparison of total time, passive time and active time between the conventional process and the new process.

Average material cost per prosthesis in the conventional process is 350 SEK, according to Anatomic Studios. More details are presented below:

- Plastic sheet (step 1): 200 SEK.
- Vax (step 3): 50 SEK.
- Fibers and fabric socks (step 5): 50 SEK.
- Plastic sock (step 6): 10 SEK.
- Resin (step 8): 40 SEK.

Total labor cost is the result of Labour cost times Active time. The prices of the machine costs - i.e, the vacuum, the rolling machine and the scanner - are not taken into consideration. The cost of the 3D-printing is highly dependant on the size of the model. In this case, 3D-printing the prosthesis was 2.500 SEK and it was more expensive than usual since an additional fee was paid. In other circumstances, it might be cheaper. A comparison between the cost of the prosthesis following the conventional and the new process can be seen in Table 14.

Cost comparison	**Conventional**	**New Process**
Labour cost (SEK/h)	650	650
Active time (h/prosthesis)	5,65	2,65
Total labour cost (SEK/prosthesis)	3.672,5	1.722,5
Material cost (SEK)	350	-
3D-printing cost (SEK)	-	2500
TOTAL (SEK)	**4.022,5**	**4.222,5**

Table 14: Comparison between the cost of the conventional process and the developed process.

9 Future Improvements

Future improvements for the project are first to implement the hatch in Grasshopper and to further develop the hinge of the hatch. The hinge has been increased in size for the axis to be more durable, however, this has resulted in the hinge sticking out from the outer hard socket. The ideal solution would be if the hinge could follow the surface or to find another solution that can replace the hinge. Also, implementing the hatch is a complicated process and require some time, but nonetheless feasible. The closing mechanism and hinge are 3D modeled and ready to be implemented in the program.

A durability test of the 3D-printed model should be conducted to see how well the model resists to outer force. A suggestion is to conduct impact testing and finite element analyses.

One improvement that will automatize the program more is to simplify the placement of the scan. The user has to correctly insert and place manually the scan of the soft inner socket because otherwise, the program would not work.

Further improvements regarding the program is automating the trim line. The trim line should be improved since the solution covered in the software is an approximation of the real trim line. The final trim line should be independent on each side of the prosthesis. Currently, the curve that generates the volume that cuts and defines the trim line crosses the entire prosthesis.

A suggestion from Christian Veraeus was to be able to place the charger hole on the other side as well, so the user could choose between: on the bottom, on the right side or on the left side. Due to lack of time, the last alternative position of the charger hole could not be implemented. In the current program, the user can place the charger hole either on the bottom or on the side The prosthetist might want the charger hole in the inner part of the prosthesis and this depends on whether the amputated arm is the left one or the right one.

Another thing that should be performed is user testing on both the software and the printed prosthesis. It would be beneficial to have the primary users test the software to evaluate how intuitive the program is and if the user can operate the program as intended. It would also be helpful if a 3D-printed prosthesis is tested on the corresponding amputee. This to see how well the prosthesis fits and how the amputee adjusts to it.

In the long perspective the big focus for the continuous development should be to make the program adaptable to all kinds of lower child arm amputations. While in the short perspective the first step should be to have to program read another scan of a residual limb without any changes to the script just to see how well the program handles other parameters.

10 Conclusion

The objective of this master thesis was to develop a working software to auto-generate a digital model of a prosthesis for one amputee. This was achieved with regards to that the program successfully generated a prosthesis for the imported mesh. The long term goal of this project is to make the software auto-generate prostheses for all imported scans of residual limbs. Even though the complete auto-generation was not reached in this project a foundation for further development was laid. It is proven that the software has great potential and it is believed that someday in the future the software could be fully automated.

As for the Customer Needs, 10 out of 18 were fulfilled. The needs were validated through testing and validation from Christian. Some of the needs that could not be verified are subjective, like for example the aesthetics of the prosthesis.

The followed method throughout the development of the project has helped to be more efficient, being able to delve into each of the phases of the project. For instance, the user study was necessary to identify the user needs which was a key point of this project.

One of the great advantages of this project is that it offers an alternative to the conventional manufacturing process, allowing the user to generate a prosthesis in fewer steps for almost the same price. Furthermore, these steps are less labor-intensive, thus leaving fewer chances for human errors. The program offers a simplified interface, grouping functions into clusters to reduce the visual complexity of the file. Each step necessary to generate a prosthesis by the program is explained in the script, as an addition to the explanation in the script a User Guide is provided for a detailed explanation of the program.

Not only has the objective been achieved, but additional details have also been included that make the program more complete, such as the supports for the three different sizes of batteries and holes to control the electrodes, among others.

Furthermore, it was set really big goals, to find a faster, cheaper and more intuitive process that could replace the conventional manufacturing process. The new process has a big potential in replacing the conventional manufacturing process by reducing the number of steps as well as reducing the time and costs for manufacturing children's prosthetic arms.

References

[1] Anatomic Studios, Retrieved February 11, 2020, from `https://www.anatomic-studios.com`

[2] Jangenfeldt,Hanna. (2019, June 25). Anatomic Studios prisas med Årets Språngbräda – väntas ha en stabil tillväxt. 3DP.se. Retrieved February 11, 2020, from `https://3dp.se/2019/06/25/anatomic-studio-prisas-som-arets-sprangbrada/?fbclid=IwAR0NkjbofK8sbhB0FuIaNXytVZTmrHd6kcPcZ3Ejpyhw0FdVFJYvzQgmQnU`

[3] Veraeus, Christian. Prosthetist at Aktiv Ortopedteknink and Co-founder of Anatomic Studios. Interview 2020-03-10.

[4] Ulrich, Karl.T., Eppinger, Steven.D. (2012). `Product Design and Development` (5th ed.). New York: McGraw-Hill.

[5] UK Design Council. What is the framework for innovation? Design Council's evolved Double Diamond. Retrieved February 11, 2020, from `https://www.designcouncil.org.uk/news-opinion/what-framework-innovation-design-councils-evolved-double-diamond`

[6] Nessler, Dan. (2016, May 19), How to apply a design thinking, HCD, UX or any creative process from scratch. Retrieved February 11, 2020, from `https://medium.com/digital-experience-design/how-to-apply-a-design-thinking-hcd-ux-or-any-creative-process-from-scratch-b8786efbf812`

[7] Ottobock. (n.d.). Information for upper limb amputees and their families. Retrieved February 14, 2020, from `https://www.ottobockus.com/prosthetics/info-for-new-amputees/information-for-upper-limb-amputees-and-their-families/`

[8] Leonard F. Bender and Richard D. Koch (1976, March), *Meeting the challenge of partial hand amputation*, from `http://www.oandplibrary.org/op/pdf/1976_01_003.pdf`

[9] Aspire, Prosthetics & Orthotics. Information for wrist disarticulation. Retrieved February 17, 2020, from `https://aspirepo.com/services/prosthetics/transradial -amputation-wrist- disarticulate/`

[10] Aspire, Prosthetics & Orthotics. Information for transhumeral amputation. Retrieved February 17, 2020, from `https://aspirepo.com/services/prosthetics/transhumeral -amputation- elbow-disarticulate/`

[11] Amputee Coalition (2019, October). Information for prosthetic arm options, from `https://www.amputee-coalition.org/arm-amputation-guide/`

[12] `ThermoLyn - fabrication of definitive sockets`. Instructions for technicians. Ottobock. [online video] Retrieved March 13, 2020, from `https://pe.ottobock.com/en/pem/materials/instructions -for-technicians/`

[13] #1 Master prosthetic technician Darren Hattingh shows how to laminate a below knee socket. (2018, June 2). [online video] Retrieved March 13, 2020, from `https://www.youtube.com/watch?v=NnHj4erqsgs`

[14] Aesthetic Prosthetics inc. - About us. Retrieved February 12, 2020, from `http://www.aestheticprosthetics.com/about-us/`

[15] ProUnix - High definition aesthetic prosthetics. Retrieved February 12, 2020, from `http://protunix.com/en/prosthetics/`

[16] Naked Prosthetics - About us. Retrieved February 12, 2020, from `https://www.npdevices.com/`

[17] Össur - About us. Retrieved February 12, 2020, from `https://www.ossur.com/en-us`

[18] Brain Robotics - World's leading Artificial Intelligent EMG prosthetics Hand. Retrieved February 12, 2020, from `https://www.brainrobotics.com/blank-3`

[19] Ottobock - About us. Retrieved February 12, 2020, from `https://www.ottobock.com/en/company/about-ottobock/`

[20] Fillaeur. Information for upper extremity prosthetics. Retrieved February 13, 2020, from `http://fillauer.com/Upper-Extremity-Prosthetics/index.php`

[21] Steeper. Information for prosthetics and orthotics. Retrieved February 13, 2020, from `https://www.steepergroup.com/`

[22] College Park - Technology for the human race. Information for Espire Elbow. Retrieved February 13, 2020, from `https://www.college-park.com/upper-limb/cpi-espire-products/espire-elbow`

[23] e-NABLE - About us. Retrieved February 13, 2020, from `http://enablingthefuture.org/`

[24] Open Bionics. Information for Hero Arm. Retrieved February 13, 2020, from `https://openbionics.com/`

[25] Mobius Bionics. Information for LUKE Arm details. Retrieved February 13, 2020, from `https://www.mobiusbionics.com/luke-arm/`

[26] Rhinoceros. Information for NURBS. Retrieved February 9, 2020, from `https://www.rhino3d.com/nurbs`

[27] Rhinoceros. Information for Grasshopper. Retrieved February 9, 2020, from `https://www.rhino3d.com/6/new/grasshopper`

[28] SolidWorks. SOLIDWORKS 3D CAD. Retrieved May 15, 2020, from `https://www.solidworks.com/product/solidworks-3d-cad`

[29] Diegel, Olaf. Nordin, Axel. Motte, Damien. (May 21, 2019). Springer Series in Advanced Manufacturing. `A Practical Guide to Design for Additive Manufacturing`

[30] 3D HUBS. The basics - What is 3D printing? Retrieved February 17, 2020, from
`https://www.3dhubs.com/guides/3d-printing/#basics`

[31] ALL 3DP. (Feb 7, 2020) 2020 Types of 3D Printing Technology. Retrieved February 17, 2020, from
`https://all3dp.com/1/types-of-3d-printers-3d-printing-technology/`

[32] Tractus 3D. 3D Printing in Healthcare. Retrieved February 18, 2020, from
`https://tractus3d.com/used-by/healthcare`

[33] 3Dprinting.com. What is 3D Printing? Retrieved February 18, 2020, from
`https://3dprinting.com/what-is-3d-printing/`

[34] Reidel, Heidi. (July 2017) The Successes and Failures of 3D Printed Prosthetics. Retrieved February 18, 2020, from
`https://www.prescouter.com/2017/07/3d-printed-prosthetics/`

[35] C-mac (2020, February). Information fot top 10 materials used for industrial 3D-printing. Retrieved February 10, 2020, from
`https://www.cmac.com.au/blog/top-10-materials-used-industrial-3d-printing`

[36] GE Additive. Information for metals in additive manufacturing. Retrieved February 18, 2020, from
`https://www.ge.com/additive/additive-manufacturing/information/metal-additive-manufacturing-materials`

[37] George Wypych (2017), *Odor in relation to different polymers.* Information for Polyoxymethylene. Retrieved February 10, 2020, from
`https://www.sciencedirect.com/topics/engineering/polyoxymethylene`

[38] Precision Urethane. Information for Polyurethane (PU) advantages & properties. Retrieved February 10, 2020, from
`https://www.precisionurethane.com/urethane-advantage.html`

[39] Omnexus. Information for Polyvinyl Chloride (PVC). Retrieved February 10, 2020, from `https://omnexus.specialchem.com/selection-guide/polyvinyl-chloride-pvc-plastic`

[40] C. Bonomo, C. D. Negro, L. Fortuna and S. Graziani (2003), *Characterization of IPMC strip sensorial properties: preliminary results.* Information for Ionic Polymer Metal Composites (IPMC). Retrieved February 10, 2020, from `https://ieeexplore.ieee.org/document/1206338`

[41] Parylene Engineering. Information for Parylene. Retrieved February 10, 2020, from `http://www.paryleneengineering.com/why_use_parylene.htm`

[42] Silicone (2020, January). Information for Silicone. Retrieved February 10, 2020, from `https://www.mindbodygreen.com/articles/is-silicone-toxic`

[43] WS Hampshire Inc. Information for PolyTetraFluoroEthylene (teflon). Retrieved February 10, 2020, from `http://catalog.wshampshire.com/Asset/psg_teflon_ptfe.pdf`

[44] Heba Soffar (2017, Mach), *Thermoplastics properties, types, uses, advantages and disadvantages.* Retrieved February 10, 2020, from `https://www.online-sciences.com/industries/thermoplastics-properties-types-uses-advantages-and-disadvantages/`

[45] Innovative Composite Engineering (ICE). Information for carbon fiber. Retrieved February 10, 2020, from `http://www.innovativecomposite.com/what-is-carbon-fiber/`

[46] Food4Rhino. Information for Dendro plug-in for Grasshopper. Retrieved March 15, 2020, from `https://www.food4rhino.com/app/dendro`

[47] Education. State University. Information for stages of growth child development. Retrieved March 17, 2020, from `https://education.stateuniversity.com/pages/1826/Child-Development-Stages-Growth.html`

Figure references

Figure 2 Prosthetic cover by Anatomic Studios. Adopted from [1].

Figure 3 Ulrich and Eppinger method. Adopted from [4, pp. 14].

Figure 4 The Concept Development process. Adopted from [4, pp. 16].

Figure 5 Double Diamond design process. Adopted from [6].

Figure 6 Levels of upper extremity amputation. Adopted from [7].

Figure 7 Levels of partial hand amputation. Adopted from [8].

Figure 7 Prosthesis with a realistic look by Aesthetic Prosthetics inc. Adopted from [14].

Figure 17 Lamination of inner hard socket - Start. Adopted from [12].

Figure 17 Lamination of inner hard socket - Finish. Adopted from [12].

Figure 19 Smoothing of the surface. Adopted from [13].

Figure 20 Prosthesis with a realistic look by Aesthetic Prosthetics inc. Adopted from [14].

Figure 21 High definition aesthetic prosthetics by ProtUnix. Adopted from [15].

Figure 22 Finger prostheses by Naked Prosthetics. Adopted from [16].

Figure 23 Sport-focused prostheses by Ossur. Adopted from [17].

Figure 24 Artificially Intelligent EMG Prosthetic Hand by Brain Robotics. Adopted from [18].

Figure 25 Prosthetics by Ottobock. Adopted from [19].

Figure 26 Prosthetics by Fillauer. Adopted from [20].

Figure 27 Prosthetics by Steeper. Adopted from [21].

Figure 28 Prosthetics by College Park. Adopted from [22].

Figure 29 3D-printed prosthetics by volunteers by e-NABLE. Adopted from [23].

Figure 30 Hero Arm by Open Bionics. Adopted from [24].

Figure 31 Luke, Bionic prosthetic arm by Utah. Adopted from [25].

Figure 32 Example of Grasshopper. Adopted from [27].

Figure 33 Selective Laser Sintering. Adopted from [30].

Table 2 Target Product Specifications. Created based on information from [3, 29].

Table 3 Interior Specifications. Created based on information from [3, 29].

Appendix A: User Guide

The following pages of this appendix contains a version of the user guide both for Rhino and Grasshopper.

User guide

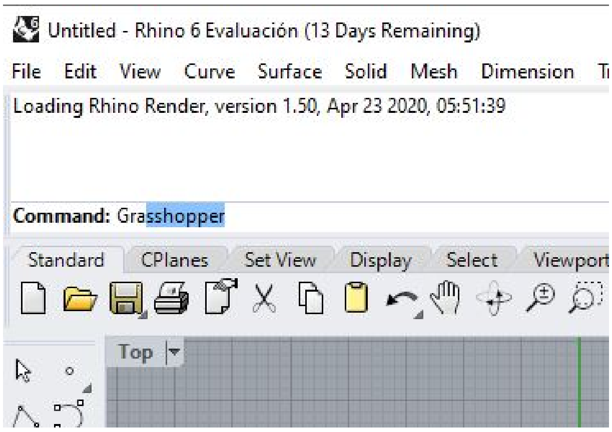
Lisa Phung, Arantxa Juárez Pérez

These pages aim to explain everything the user must know in order to use the developed program. The goal is that the user does not have to have a deep knowledge of Rhino and Grasshopper to be able to generate a prosthesis. The user guide is divided into four different sections:

- Start running Rhino and Grasshopper.
- Grasshopper - Interface and Clusters.
- Rhino - Layers.
- Steps of the process.

Start running Rhino and Grasshopper

To develop the software, it was used Rhino 6 and this program can be downloaded from their webpage, (https://www.rhino3d.com). Once Rhino is installed, to start running Grasshopper, what the user has to do is to write in the command window "Grasshopper" and press intro, Figure 1.



Untitled - Rhino 6 Evaluación (13 Days Remaining)

Loading Rhino Render, version 1.50, Apr 23 2020, 05:51:39

Command: Grasshopper

Figure 1: Running Grasshopper.

There are two different files:

- For Rhino: Extension **.3dm**
- For Grasshopper: Extension **.gh**

The user has to open both in each program and it does not matter the order, any of them can be opened first. It might take a little bit to open the files since both programs are working together to generate a prosthesis.

Once both files are opened, what the user would see would be:

- In Rhino: The prosthesis.
- In Grasshopper: Blocks and inputs, Figure 2.

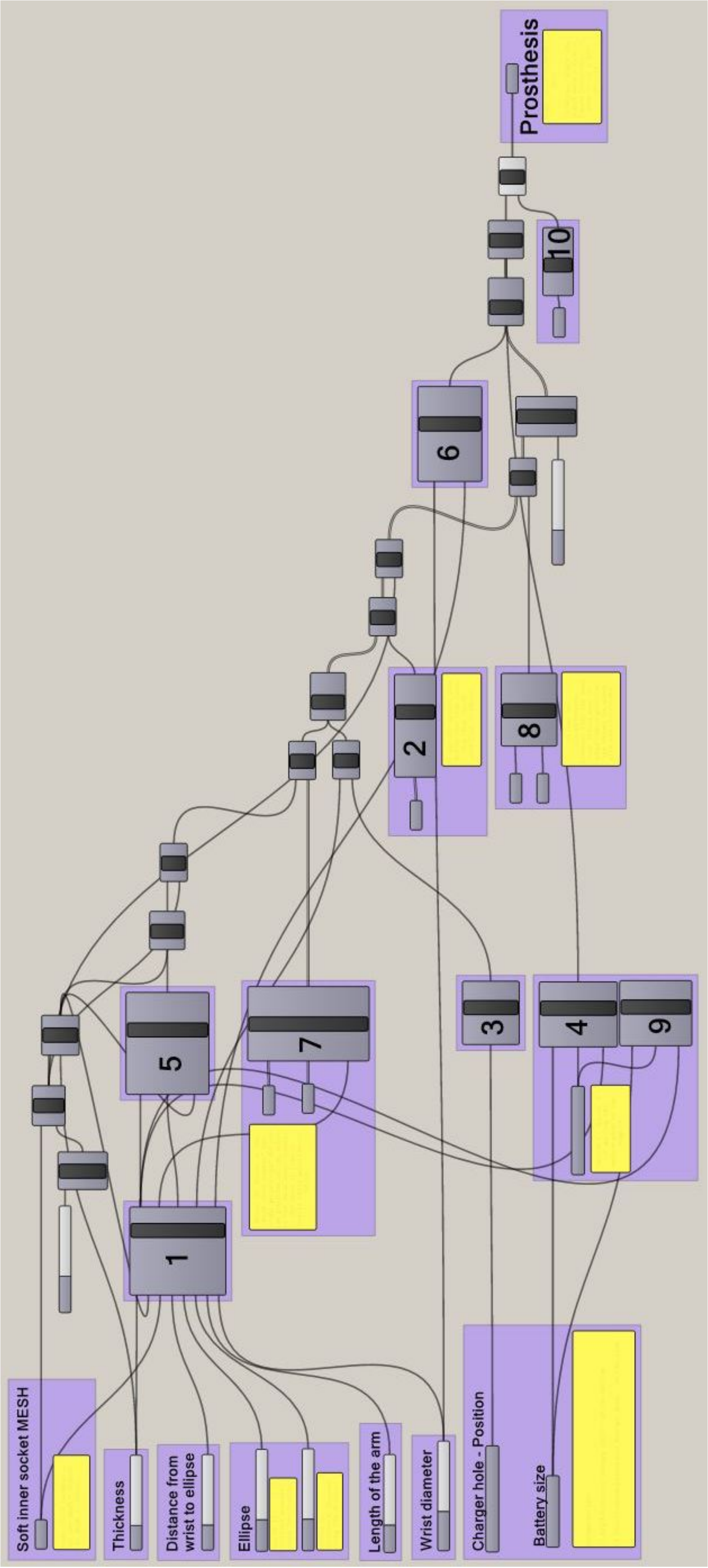


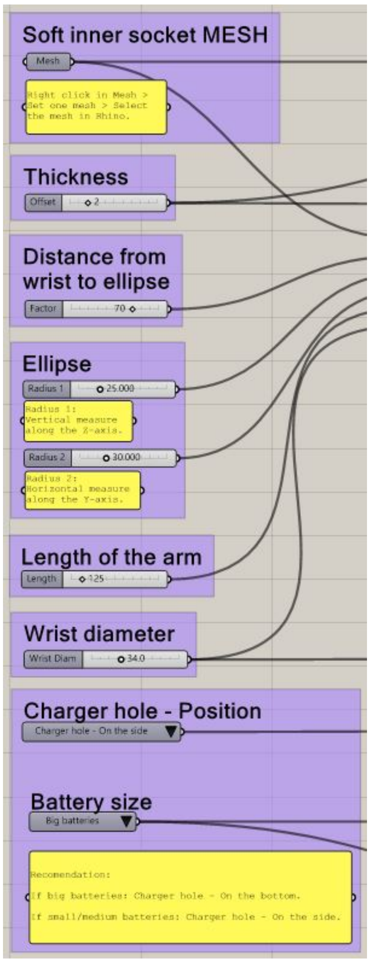
Figure 2: Grasshopper Interface.

Grasshopper - Interface and Clusters

The goal was to present a user friendly interface in Grasshopper. To achieve this, clusters have been used, in which all the necessary programming is inside of them to generate certain results (volumes, surfaces, etc.). Grouping functions in Grasshopper into Clusters is an effective technique to reduce the visual complexity of the file. There are nine different clusters:

- Cluster 1: Generating surface.
- Cluster 2: Trim line.
- Cluster 3: Charger hole.
- Cluster 4: Batteries supports.
- Cluster 5: Smoothing the sensors.
- Cluster 6: Wrist pattern.
- Cluster 7: Holes in the hard inner socket.
- Cluster 8: Sensor holes.
- Cluster 9: Batteries supports - hatch.
- Cluster 10: Hatch.

Each of the clusters has different inputs and outputs. In the following lines the inputs that the user can modify will be introduced and these are presented in Figure 3.



Soft inner socket MESH

Mesh

Right click in Mesh >
Set one mesh > Select
the mesh in Rhino.

Thickness

Offset 2

Distance from wrist to ellipse

Factor 70

Ellipse

Radius 1 25.000

Radius 1:
Vertical measure
along the Z-axis.

Radius 2 30.000

Radius 2:
Horizontal measure
along the Y-axis.

Length of the arm

Length 125

Wrist diameter

Wrist Diam 34.0

Charger hole - Position

Charger hole - On the side

Battery size

Big batteries

Recomendation:

If big batteries: Charger hole - On the bottom.

If small/medium batteries: Charger hole - On the side.

Figure 3: Grasshopper - Inputs.

1. **Soft inner socket MESH.** The user should insert the scan of the soft inner socket in Rhino and set it as a mesh in Grasshopper. To do so:
   - In Rhino: File > Insert > Scan.
   - In Grasshopper: Right click in Mesh > Set one Mesh > Select the previously inserted mesh in Rhino.
2. **Thickness.** The offset or thickness can be modified with a number slider. Double-click on the number slider for more options: to set the number domain or the slider accuracy among others.
3. **Distance from wrist to ellipse.** This will define the position of the ellipse. It is important to play around with different values to see which one presents better results.
4. **Ellipse.** The last two parameters that are needed to define this ellipse are its two radii. There are two number sliders:
   - Radius 1: Vertical measure along the Z-axis.
   - Radius 2: Horizontal measure along the Y-axis.
5. **Length of the arm.** This measurement can be modified with a number slider.

6. **Wrist diameter.** This number represents the diameter of the wrist connection.

7. **Charger hole - Position.** The user can choose the position of the charger hole thanks to a dropdown list. By pressing the arrow on the right side, two options will appear:

   - Charger hole - On the bottom.
   - Charger hole- On the side.

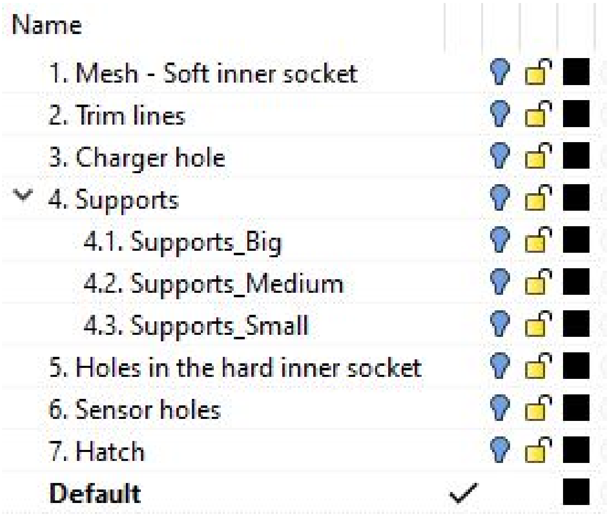
8. **Battery size.** There are three different sizes of batteries and the user is free to choose the one that fits better. By pressing the arrow on the right side, two options will appear:

   - Big batteries.
   - Medium batteries.
   - Small batteries.

Every time the user changes a parameter, Grasshopper recalculates all the operations offering a new prosthesis design in Rhino. This process can take a few minutes.

Rhino - Layers

In the following lines, everything that the user can change in Rhino will be explained. These things are grouped in different layers so the user can activate or deactivate those layers that he/she is going to use or modify.



Name
1. Mesh - Soft inner socket
2. Trim lines
3. Charger hole
4. Supports
    4.1. Supports_Big
    4.2. Supports_Medium
    4.3. Supports_Small
5. Holes in the hard inner socket
6. Sensor holes
7. Hatch
Default ✓

Figure 4: Rhino - Layers.

The layers, presented in Figure 5, are:

1. **Mesh - Soft inner socket.** This layer has the mesh of the soft inner socket.

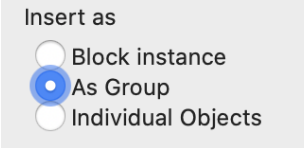
2. **Trim lines.** This layer has the points that define the trim line and the surface where those points are projected. The user should change just the points.

3. **Charger hole.** This layer has the two polylines needed to define both positions of the charger hole: on the bottom and on the side. It also has two surfaces where these polylines are projected. The user should not change the position of the surfaces, but he/she can modify the position of the polylines.
4. **Supports.** This layer has three sublayers, one for each size of supports (big, medium and small).
5. **Holes in the hard inner socket.** This layer has eight points that define the position of the holes in the hard inner socket. The user is free to modify their position to change the holes.
6. **Sensor holes.** This layer has two circumferences that the user can freely move to adapt their position to match with the electrodes.
7. **Hatch.** This layer has the curve and the surface needed to define the hatch. The user can change the position and the size of the hatch.

Steps of the process

The developed method has 7 steps and they are explained in the list below.

1. **Scan the soft inner socket.** The user should scan the amputated arm in order to implement it in Rhino. It is recommended the STL format for the scan of the soft inner socket.
2. **Insert the scan of the soft inner socket into the program.** In Rhino go to *File*, click on *Insert*, select the STL file and insert it as *As Group*.



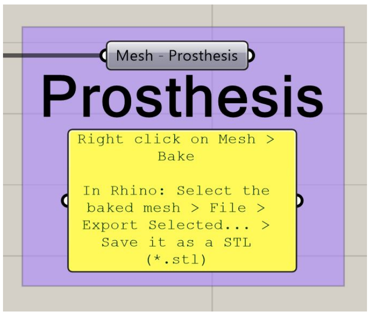
Insert as
○ Block instance
● As Group
○ Individual Objects

Figure 5: Insert scan - *As Group.*

3. **Place the imported scan correctly.** It is highly recommended to place it where the scan as example is. To know where the example scan is, activate the layer *Mesh - Soft inner socket* in Rhino. Then go to Grasshopper and in the input space, right click on *Mesh*, *Set one mesh* and select the previously inserted mesh in Rhino.
4. **Set the length and width of the prosthesis.** These parameters will define the new prosthesis and they can be found in the input space in Grasshopper.
5. **Make optional adjustments:**
    - Adjust the trim line.

- Select the battery size.
- Select the position of charger hole.
- Adjust The thickness of the prosthesis.
- Adjust the wrist diameter.

6. **Export the model to an STL file.** Once the user is done modelling, the last step is to export the mesh in STL. To do this, the user should right click on **Mesh - Prosthesis** in Grasshopper and *Bake* the mesh, Figure 6. Then, in Rhino, select the baked mesh and in *File*, click on *Export Selected...* and save it as a STL file (*.stl).



Right click on Mesh >
Bake

In Rhino: Select the
baked mesh > File >
Export Selected... >
Save it as a STL
(*.stl)

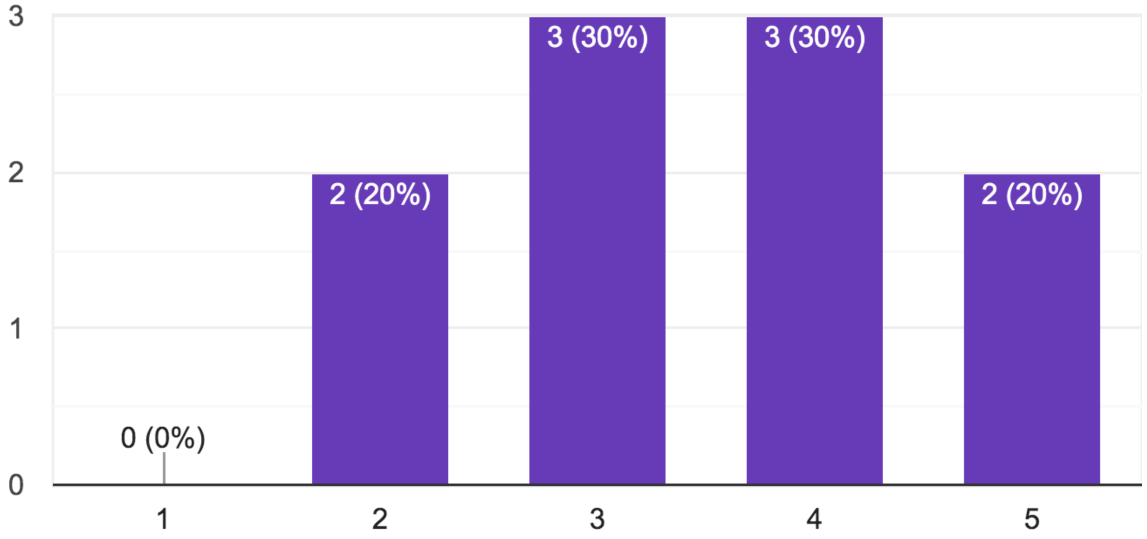
Figure 6: Mesh - Prosthesis.

Appendix B: User Study - Survey of Customer Needs

The following pages of this appendix contains the survey conducted on 10 prosthetists for ranking of the customer needs.

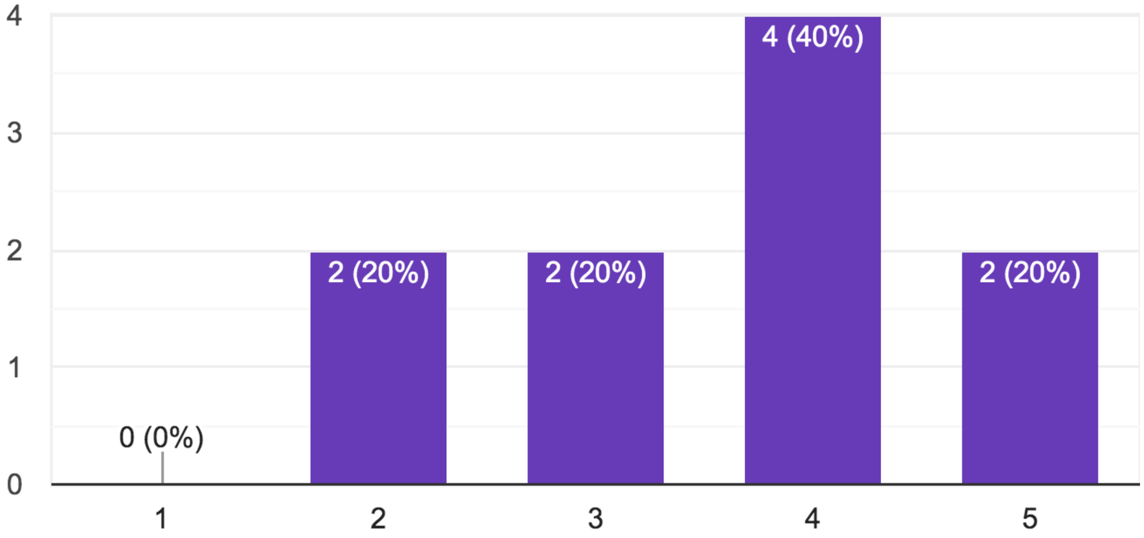
There are too many manual steps in manufacturing prosthetics

10 responses



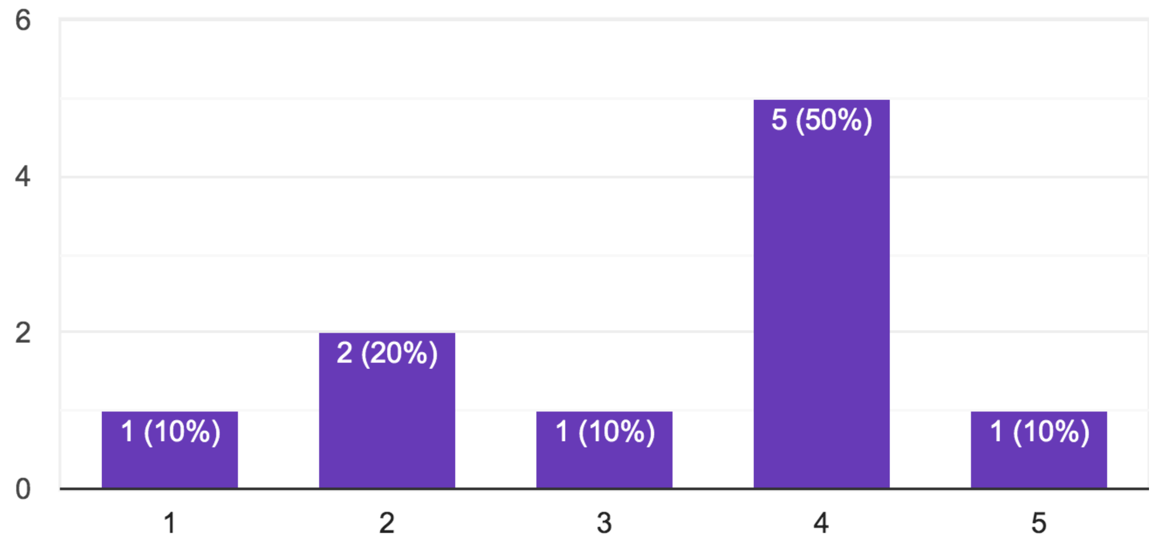
It takes too long time to manufacture prosthetics

10 responses



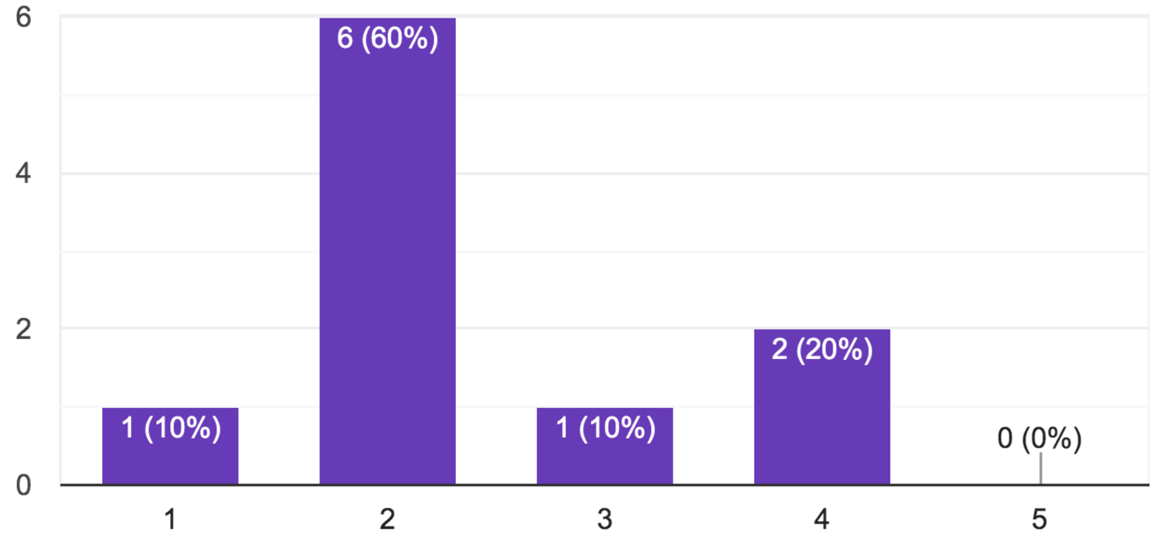
There are too much room for human errors in the manufacturing process

10 responses



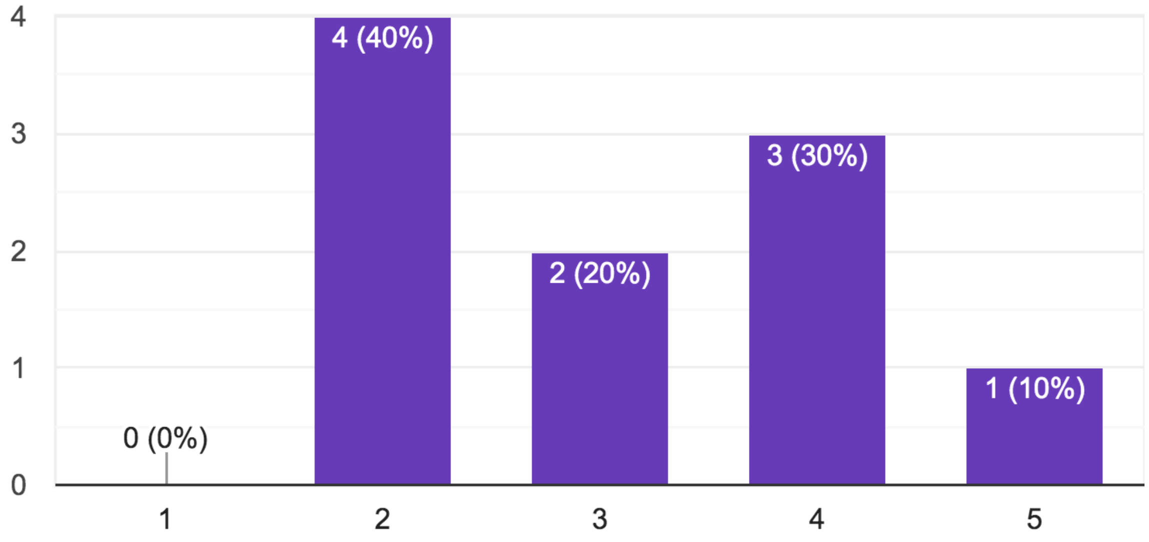
It should not be required to need a lot of training to manufacture prosthetics

10 responses



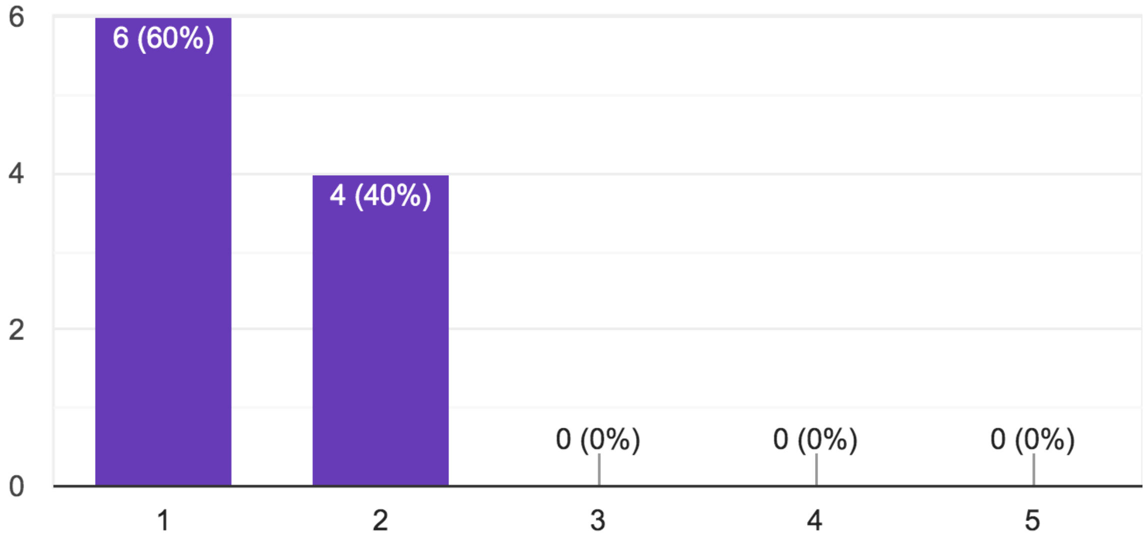
It costs too much to manufacture prosthetics

10 responses



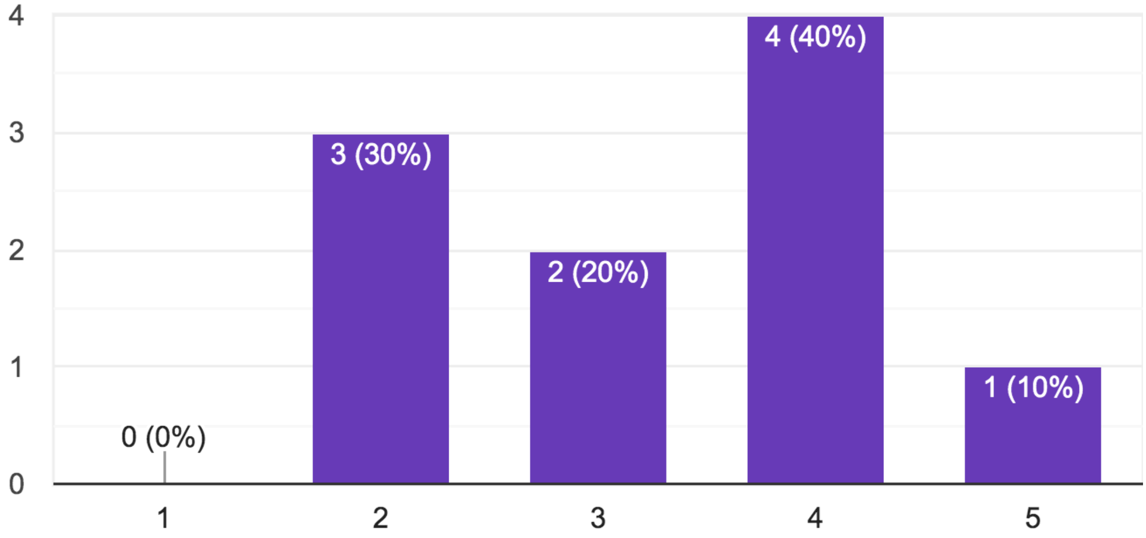
Everyone should be able to manufacture prosthetics

10 responses



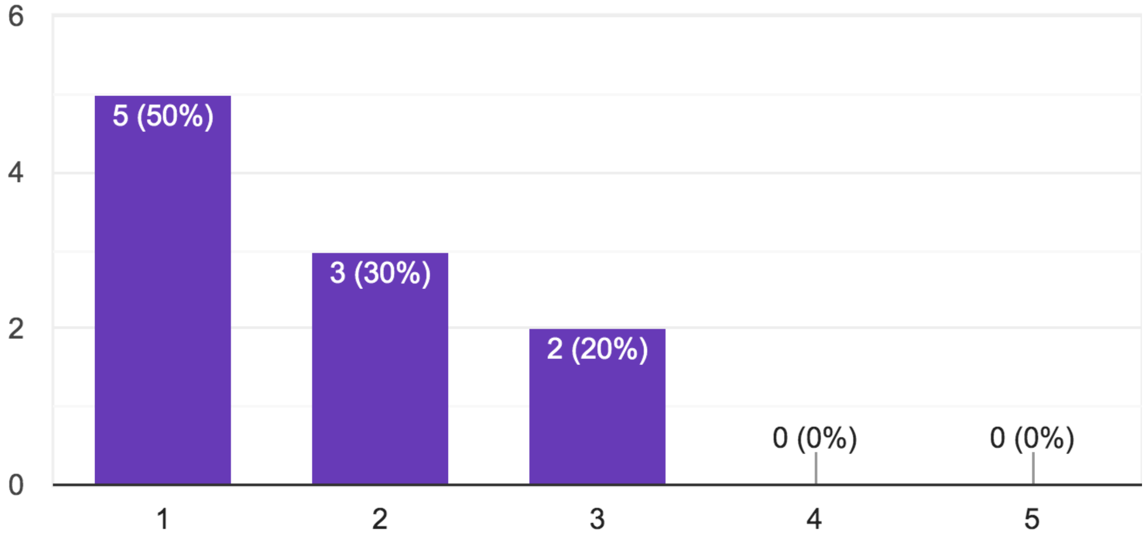
It is too to hard to go back and make changes once a step is done in the manufacturing process

10 responses



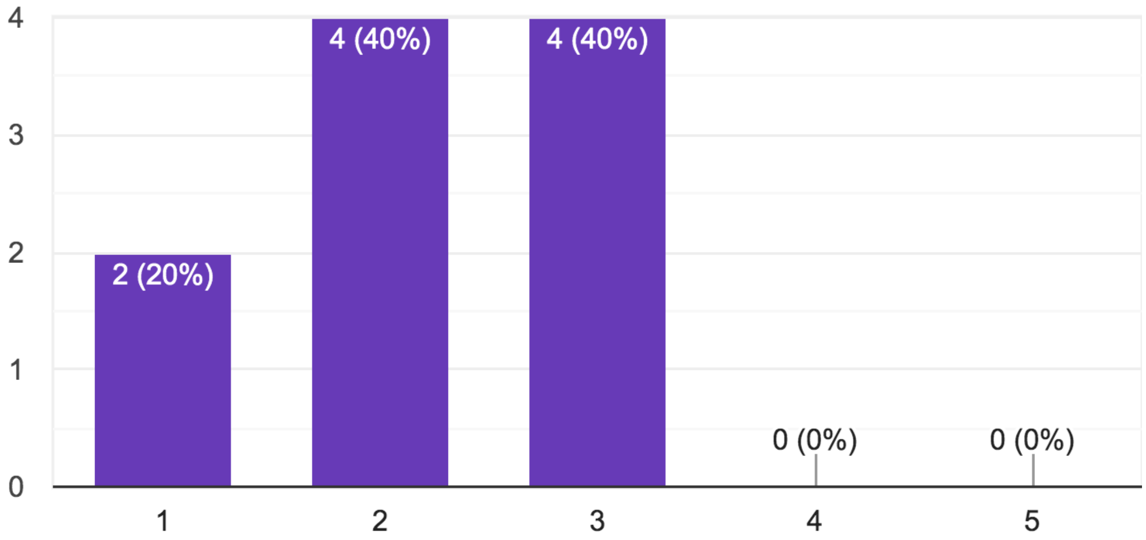
It is too uncertain to know what step comes next in the manufacturing process

10 responses



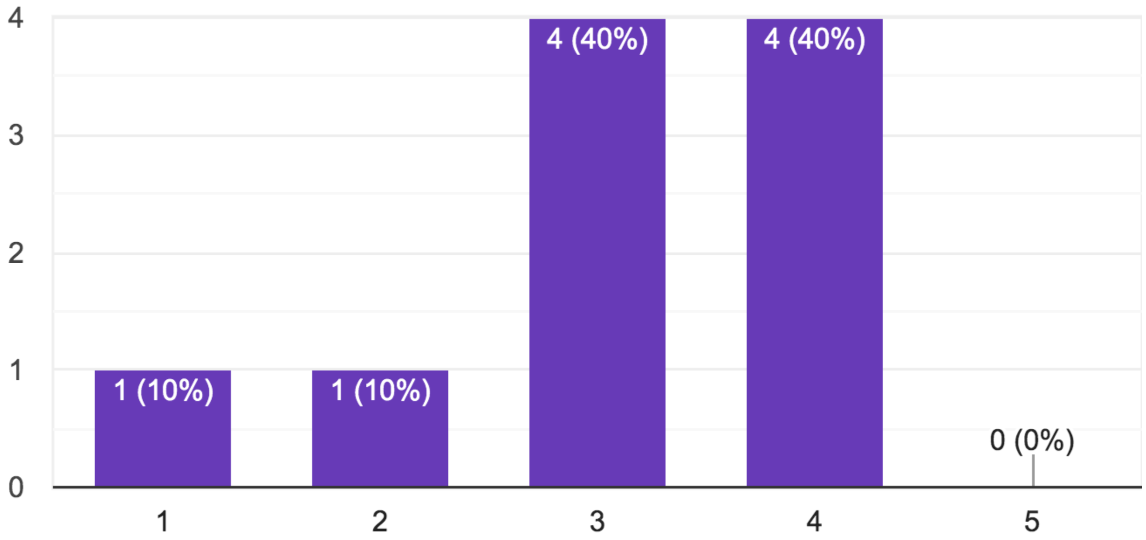
The prosthetics are not durable enough

10 responses



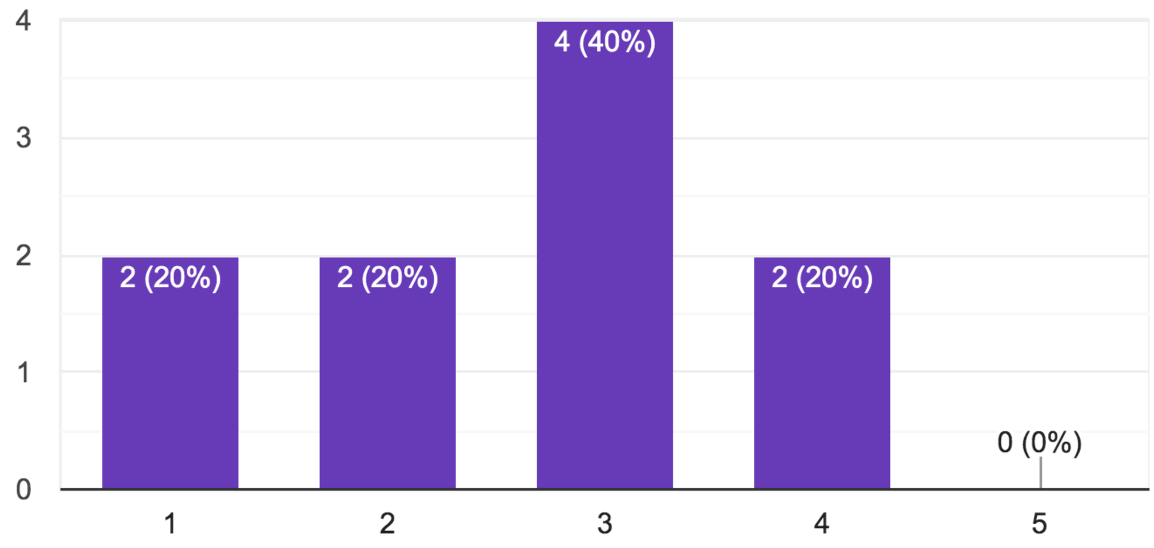
The prosthesis is not aesthetically pleasing

10 responses



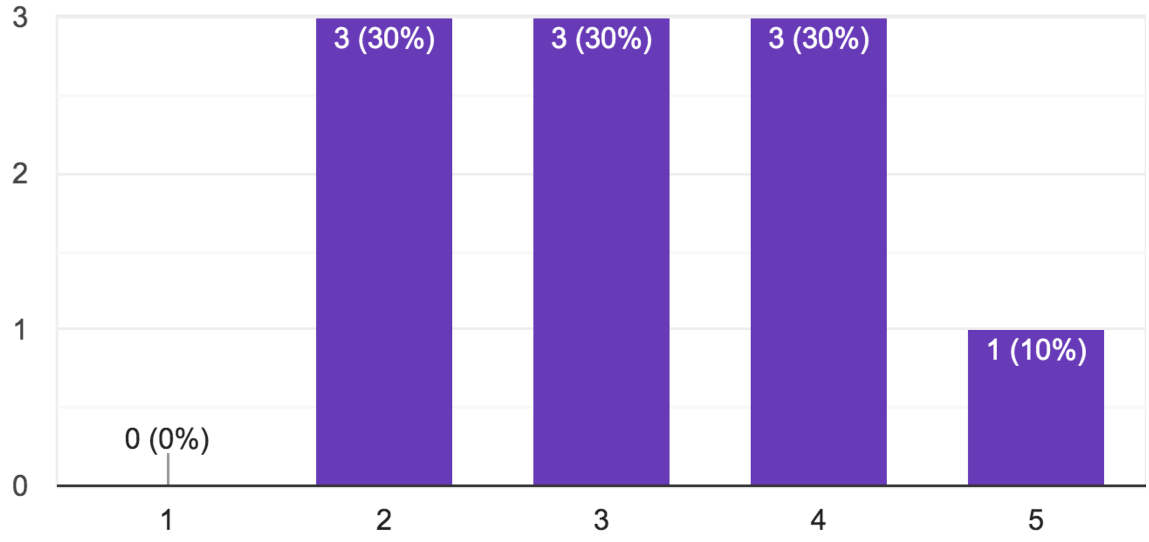
There is a too much extra material needed to to smooth the area where the sensors are sticking out

10 responses



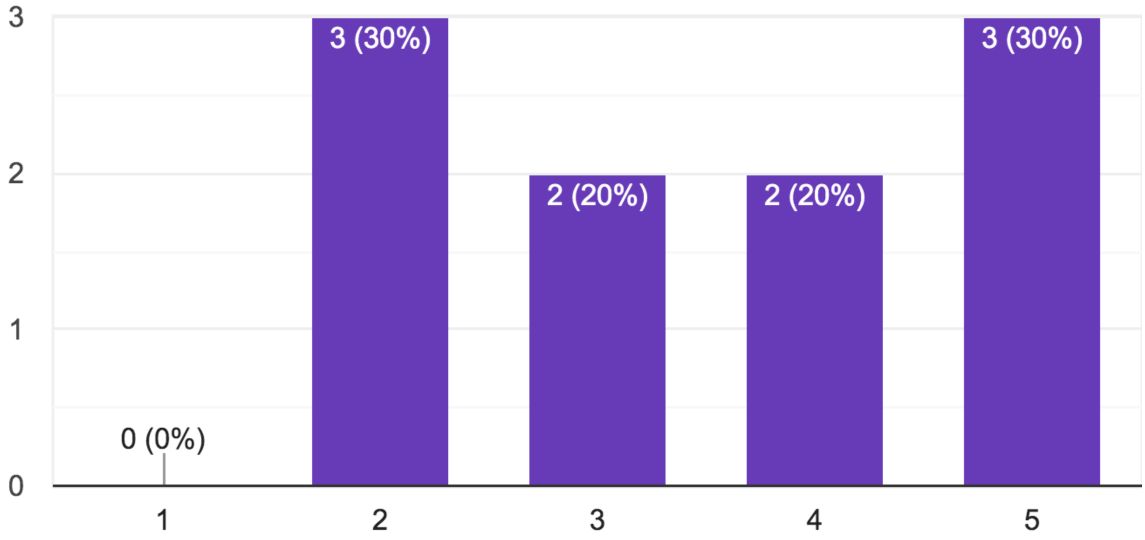
I want the prosthesis to look more like a real arm

10 responses



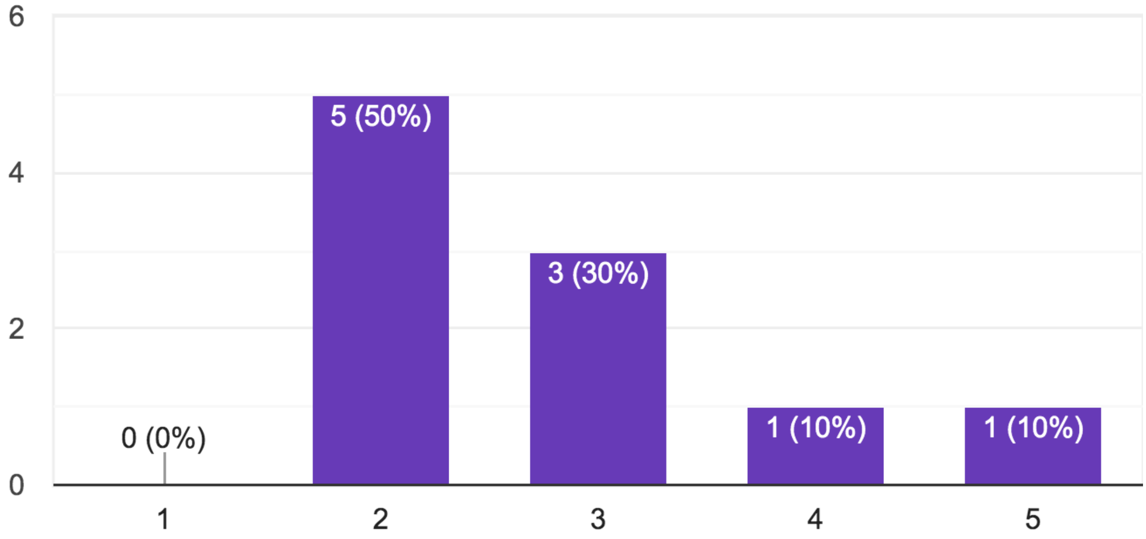
Too often I need to make the prosthesis bigger to fit the inner components (batteries etc.)

10 responses



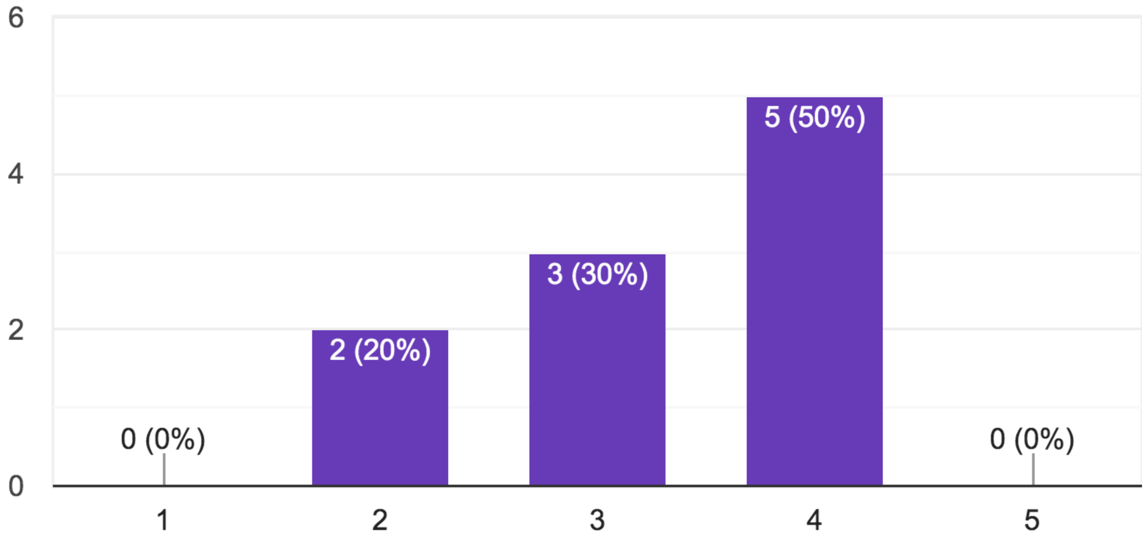
It is important that the center of gravity of the prosthesis is centered

10 responses



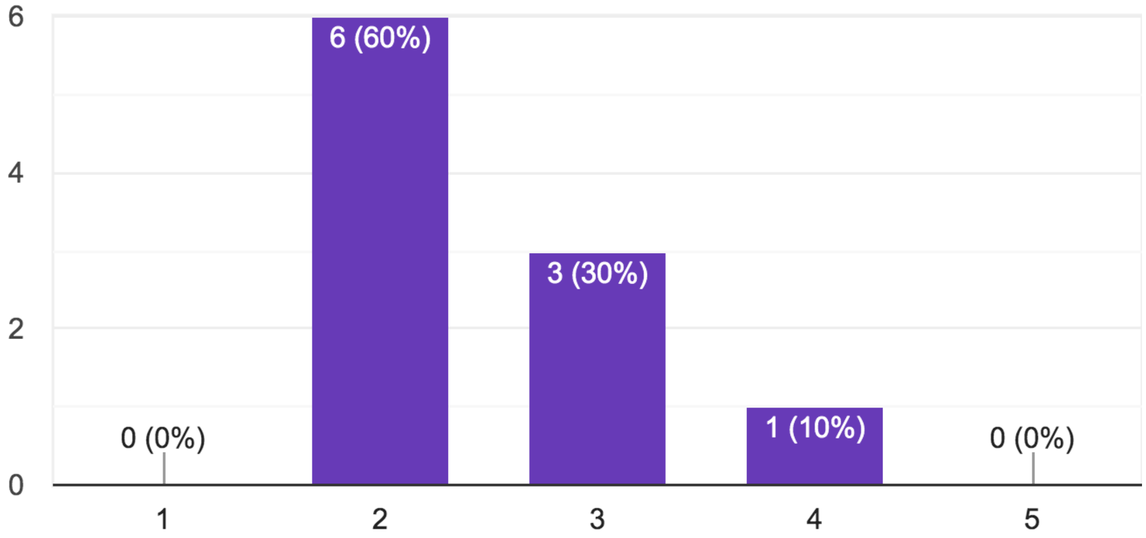
Too often the desired size of batteries can’t be used

10 responses



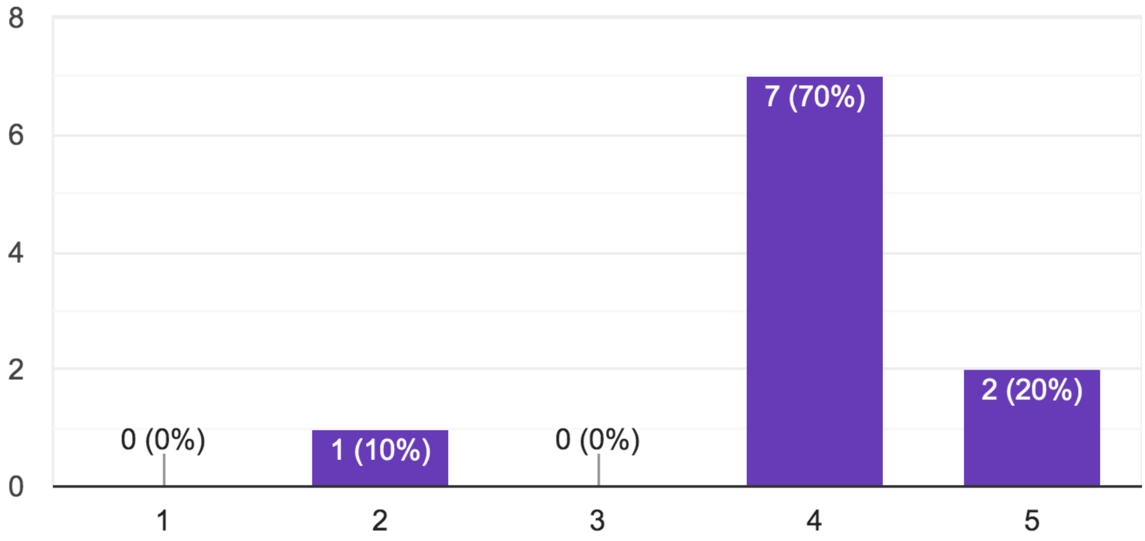
The inner space of the prosthesis is not optimally used

10 responses



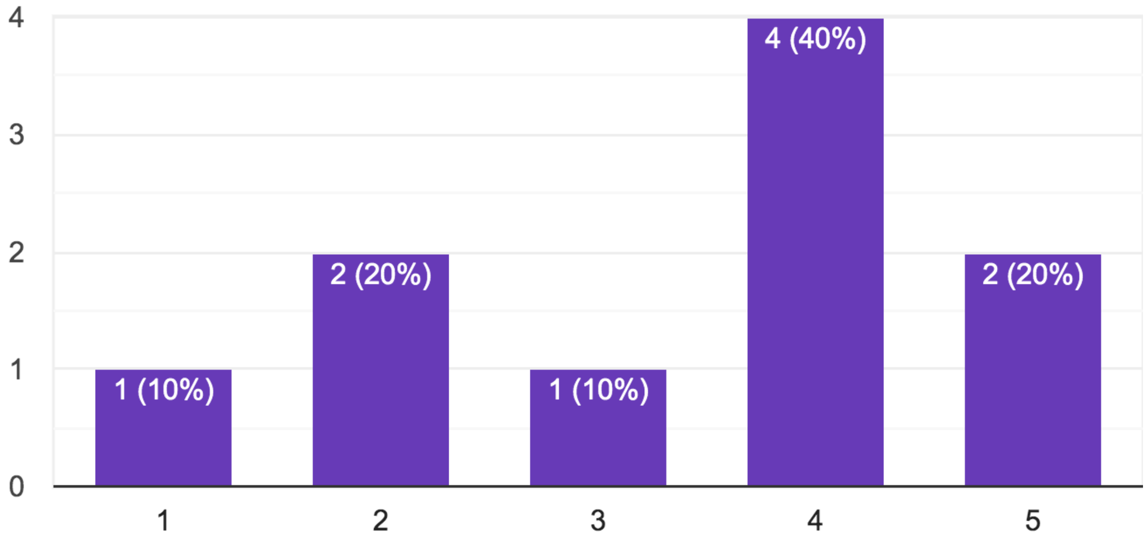
I want to be able to get to the inside of the prosthesis in an easy way

10 responses



I don't want to fill the prosthesis with more material in order to hold the inner components (batteries etc.) in place

10 responses



Appendix C: User Study - Interview questions

The following pages of this appendix contains the survey conducted on a prosthesis user for validation of the project.

Master Thesis - Lisa and Arantxa
Prosthetics User's Survey

---

1. About you

1.1. Name and surname

Anders Persson

1.2. Sex

○ Female
○ Male
○ Prefer not to say

1.3. Age

38

1.4. How long has the user been using prosthesis? And what kind?

He has been using prostheses since he was 3 months old. He has right now 4 prostheses. Two of them are electric with mechanical grip function and the other two are fixed. One of the two mechanical ones is a design prosthesis that was created by a designer to look like the healthy arm. It has veins and the user likes that it look like a real arm. Nevertheless, this prosthesis is sensitive, it gets dirty fast. He only uses it on special occasions, when he really look his best.
He uses one of the fixed ones in the gym or whenever there is a risk for it to get dirty and also when he works, it is about 12 hours a day in front of computer.

---

2. Change of prosthesis

2.1. How often does the user change the prosthesis?

Never, it is very static. For the last 10-15 years nothing has happened. His weight and appareance does not change that much and that is why he does not need to change the prosthesis. When he was younger (13-15 years old), he used to change the prosthesis up to 2-3 times a year. When you grow fast, you change it accordingly.

However, he changes the skin every sis months. Ink is bad fot the skin because it is impossible to remove.

2.2. Is it a complicated process to change it? If so, why?

The healthcare system takes care of everything. He just need to make an appointment.

In order to change the sking, he email Christian and order a new skin and they send it to him to his house. Nevertheless, it is tricky to change it. He needs someone to help him to change it. But he changes the skin when he cannot get the dirt off.

2.3. How much is the cost for a new prosthesis? Are there any additional costs?

Nothing at all, everything is free. He just makes Christian a call and he fixes everything. Everything is paid. The swedish healthcare only allows to have one of each prosthesis. He has four prosthesis and all of them are worth around 300.000 kr.

2.4. How long before the prosthesis is done?

It is quite fast. When you are a kid, you usually have to schedule appointments to change the prosthesis. Your measurements are taken and later some day you try out a prototype. Then it takes approximately 2-3 days to have it.

2.5. What is the reason why the user usually changes the prosthesis?

The two reasons why he would change a prosthesis are if he loses/gained weight or needed reparation or new technology.

2.6. Are there any post-adjustments made with a new prosthesis?

---

3. Components

3.1. How does the user experience the change of components? What is the process?

He had never changed the components since he cannot open it by himself. Prestanda worked very well. He charges the batteries once a week. He does not care about opening the prosthesis.

3.2. Can you do it by yourself?

No.

3.3. Does the user have any problems with the hatch?

He cannot open it by himself. He has to send it to a speciallist if anything is wrong. Sometimes he has problems in the airtports, so they have to extra scan him. The components inside cannot be taken out so the security does not know what it is inside. Need to send through a scanner. The hand still has issues due to the mechanics inside. He saw the positive aspects about being able to look inside.

3.4. Are there any problems with moving components? Or the filling to stop components moving?

4. About the model of the project

4.1. What is your first impression of this?

He was excited.

4.2. Do you have any thoughts or improvements?

He suggested to make the inner socket flexible so people can grow.

4.3. Is this something you want to use to make your own prosthesis?

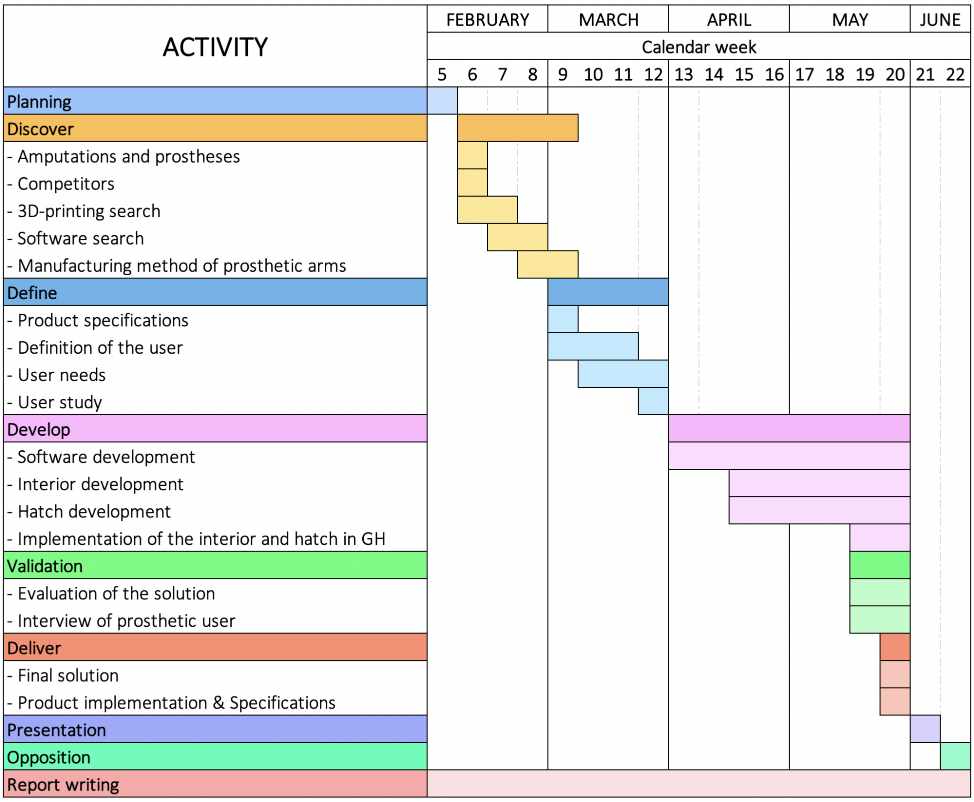
Yes, but there is no point beause he is not changing it much. However, he thought that the idea is really good. For children it is better. 3D printer makes sense.

5. Overall

He is happy as it is but open to technology and about the swedish healthcare. The prosteses are psychologically good for him. He said that he is now on Tinder and that he is good on dates. It is hard to use a knife, a fork or a spoon and that doing it in a proper way in fancy restaurants is important.

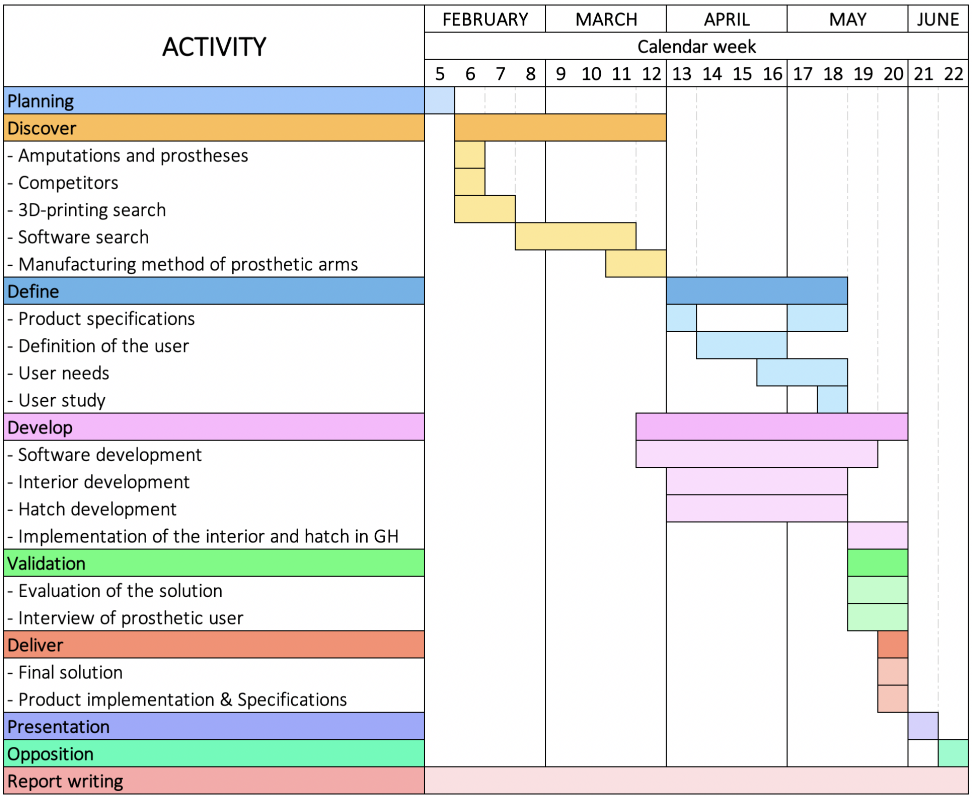
Appendix D: Project Plan

Appendix D.1: Initial Project Plan



ACTIVITY	FEBRUARY				MARCH				APRIL				MAY				JUNE	
	Calendar week																	
	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Planning	■																	
Discover		■	■	■	■													
- Amputations and prostheses		■																
- Competitors		■																
- 3D-printing search		■	■															
- Software search			■	■														
- Manufacturing method of prosthetic arms				■	■													
Define					■	■	■	■										
- Product specifications					■													
- Definition of the user					■	■	■											
- User needs						■	■	■										
- User study								■										
Develop									■	■	■	■	■	■	■	■		
- Software development									■	■	■	■	■	■	■	■		
- Interior development											■	■	■	■	■	■		
- Hatch development											■	■	■	■	■	■		
- Implementation of the interior and hatch in GH															■	■		
Validation															■	■		
- Evaluation of the solution															■	■		
- Interview of prosthetic user															■	■		
Deliver																■		
- Final solution																■		
- Product implementation & Specifications																■		
Presentation																	■	
Opposition																		■
Report writing	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■

Appendix D.2: Final Project Plan



ACTIVITY	FEBRUARY				MARCH				APRIL				MAY				JUNE	
	Calendar week																	
	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Planning	■																	
Discover		■	■	■	■	■	■	■										
- Amputations and prostheses		■																
- Competitors		■																
- 3D-printing search		■	■															
- Software search				■	■	■	■											
- Manufacturing method of prosthetic arms							■	■										
Define									■	■	■	■	■	■				
- Product specifications									■				■	■				
- Definition of the user										■	■	■						
- User needs												■	■	■				
- User study														■				
Develop								■	■	■	■	■	■	■	■	■		
- Software development								■	■	■	■	■	■	■	■			
- Interior development									■	■	■	■	■	■				
- Hatch development									■	■	■	■	■	■				
- Implementation of the interior and hatch in GH															■	■		
Validation															■	■		
- Evaluation of the solution															■	■		
- Interview of prosthetic user															■	■		
Deliver																■		
- Final solution																■		
- Product implementation & Specifications																■		
Presentation																	■	
Opposition																		■
Report writing	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■

Appendix E: Work Distribution

This master thesis has been developed in collaboration of both team members. Nevertheless, each team member had different main responsibilities in some parts of the project.

Lisa Phung had the main responsibility for the development of the interior and hatch.

Arantxa Juarez Perez had the main responsibility for the development of the software.

The research and writing the report were conducted together, including the validation, results, discussion and conclusions.