

# The Perfect Fit

Development process for the use of 3D technology in the manufacturing of custom-made prosthetic arm sockets

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





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UNIVERSITY

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## Preface

This master thesis is the result of the final stage of my studies in Mechanical Engineering with Industrial Design. The thesis has been conducted at the Division of Product Development, the Faculty of Engineering at Lund University and in collaboration with Aktiv Ortopedteknik.

There are several people who in different ways have been part of this project and to whom I would like to direct my gratitude;

Christian Veraeus, prosthetist and my supervisor at Aktiv Ortopedteknik, who has provided his assistance throughout all stages of the work process. Thank you for your inspiring enthusiasm and commitment to this project.

Professor Olaf Diegel, my supervisor at Lund University, for giving me the opportunity to work on this project and for his valuable input on both practical and theoretical aspects of the process.

I would also like to thank the two patients who were willing to volunteer in the case studies performed during the validation phase, Sven-Olof Frank, manager at Aktiv Ortopedteknik who has shared his knowledge and experience from the prosthetics industry and my assisting supervisor Christian Antfolk, Postdoc at the Department of Biomedical Engineering, Lund University, for offering his guidance whenever it was needed in the project.

Last but not least, I would like to thank Jonny Nyman, research engineer at the ID-A workshop at Lund University, for all his help involving the 3D printing of the prototypes in this project.

Lund, March 2016

Emelie Strömshed



## **Abstract**

This report describes the development of a manufacturing process for creating custom-made prosthetic arm sockets using 3D scanning and 3D printing. The process is intended to function as a guide for a prosthetist without requiring an extensive experience in CAD. The project aims to offer a viable alternative to the often time consuming and manual labour-intensive conventional manufacturing method, as well as to provide amputee patients with perfectly fitted prosthetic sockets.

Prior to initiating the process development, a thorough pre-study was performed in order to gain an understanding of both the medical and technical aspects concerning the project.

The first development phase involved performing a user study to determine what was required from the new process both from a user and a patient perspective. Findings from the user study were then converted into process requirements to be used as guidelines in the further development.

A main structure for the process was then established based on the generic approach to create products using 3D scanning and 3D printing. To adapt the process to creating a prosthetic socket, the key focus was to evaluate and select an appropriate software and modelling method that also would align with the process requirements.

By creating socket prototypes, both quality and design could be assessed together with the user. After minor adjustments, case studies involving two patients were conducted, which resulted in a successful validation of the process.

The final process offers the possibility to produce both passive and myoelectric sockets. It consists of seven main steps, each with their own set of substeps. The majority of these substeps are core activities performed regardless of the type of socket to be created, whereas a handful of substeps are added to the process when creating a myoelectric socket or applying a pattern.

In the final phase, learning material was elaborated in order to facilitate a possible implementation of the process. A time and cost comparison was also performed and showed time savings of 400 h/year and cost reductions of up to 60 %, corresponding to 261 000 SEK/year by using the new process.

**Keywords:** *Process development, amputation, prosthetic socket, 3D printing, 3D scanning*



## **Sammanfattning**

Denna rapport beskriver utvecklingen av en tillverkningsprocess ämnad för framtagning av skräddarsydda armproteshylsor. De huvudsakliga verktygen för processen är 3D-scanning och 3D-printing och utan att kräva omfattande kunskaper i CAD ska processen kunna fungera som vägledning för en ortopedingenjör.

Övergripande målen med projektet har varit att erbjuda ett användbart alternativ till dagens tillverkningsmetod, vilken involverar ett flertal manuella arbetsmoment som ofta både är tidskrävande och har brister i precision, samt att kunna förse amputerade patienter med individuellt anpassade hylsor.

Innan starten av själva processutvecklingen genomfördes en förstudie med syftet att få en grundläggande förståelse för både de medicinska och tekniska aspekterna aktuella för projektet. Detta följdes sedan av den första utvecklingsfasen där en användarstudie utfördes med avsikt att identifiera behov hos användaren. Dessa omsattes sedan till processspecifikationer att använda som riktlinjer under utvecklingsarbetet.

En övergripande processtruktur upprättades sedan, vilken grundades på en allmän metod för produktframtagning med 3D-scanning och 3D-printing. För anpassning av processen till framtagningen av en proteshylsa lades fokus på utvärdering och val av lämplig mjukvara och modelleringsmetod. Dessa användes sedan för att tillverka prototyper som tillät en tidig bedömning av design och kvalitet tillsammans med användaren och resulterade i mindre justeringar av processen. Efter detta utfördes två patientfallstudier, vilka resulterade i en framgångsrik validering av processen.

Den slutliga processen utgörs av sju huvudsakliga steg och möjliggör tillverkning av både passiva och myoelektriska hylsor. Varje huvudsteg har en egen uppsättning delsteg där majoriteten utförs oavsett hylstyp, medan ett fåtal delsteg inkluderas då en myoelektrisk eller mönstrad hylsa skall tillverkas.

I projektets avslutande fas togs utbildningsmaterial fram för att underlätta en eventuell implementering av processen. En jämförelse med avseende på tid och kostnad utfördes även och visade på möjliga tidsbesparningar av nära 400 timmar/år samt en kostnadsreduktion på upp till 60 %, motsvarande 261 000 SEK/år genom att använda den framtagna processen.

**Nyckelord:** *Processutveckling, amputation, proteshylsa, 3D-printing, 3D-scanning*



# Table of Contents

<b>1 Introduction .....</b>	<b>1</b>
1.1 Company presentation .....	1
1.2 Background .....	1
1.3 Aims and purpose .....	2
1.3.1 Objectives .....	2
1.4 Scope .....	2
1.5 Delimitations .....	3
<b>2 Method.....</b>	<b>5</b>
2.1 Project Plan .....	5
2.2 Pre-Study .....	5
2.3 Development Methodology .....	5
2.3.1 The Ulrich & Eppinger Product Development Process.....	5
2.3.2 The Double Diamond Model .....	7
2.3.3 Thesis Methodology .....	8
<b>3 Pre-study.....</b>	<b>13</b>
3.1 Amputation .....	13
3.1.1 Amputation Level .....	13
3.2 The Prosthesis .....	15
3.2.1 The Passive Prosthesis.....	16
3.2.2 The Body-Powered Prosthesis.....	16
3.2.3 The Myoelectric Prosthesis .....	17
3.3 The Prosthetic Socket .....	17
3.3.1 Suspension Systems .....	20
3.3.2 Conventional Manufacturing Method .....	21
3.4 3D Technology .....	25
3.4.1 3D Scanning .....	25
3.4.2 3D Printing .....	26

3.4.3 Applications in the Field of Medicine & the Prosthetics Industry .....	28
<b>4 Define .....</b>	<b>31</b>
4.1 Process Start and End Point.....	31
4.2 User Study.....	31
4.2.1 The User .....	31
4.2.2 User Needs .....	32
4.3 Process Requirements.....	33
<b>5 Identify.....</b>	<b>35</b>
5.1 From Scan to Print - Generic Approach.....	35
5.2 From Generic to Adapted Approach .....	36
5.3 Software .....	37
<b>6 Explore &amp; Evaluate .....</b>	<b>39</b>
6.1 Options for Collecting Patient Data.....	39
6.2 Software Use.....	40
6.3 Socket Modelling Methods .....	40
6.3.1 Main Shape.....	40
6.3.2 Electrodes .....	43
6.3.3 Evaluation and Selection of Modelling Method .....	44
6.4 Software Evaluation & Selection .....	45
<b>7 Create .....</b>	<b>47</b>
7.1 Hardware.....	47
7.1.1 iSense 3D Scanner .....	47
7.1.2 EOS Formiga p110 3D Printer .....	47
7.2 Socket Prototypes .....	48
7.2.1 First Prototype.....	49
7.2.2 Second Prototype .....	50
7.2.3 Third Prototype .....	50
7.3 Assessment.....	51
7.4 Iteration .....	51
<b>8 Integrate .....</b>	<b>53</b>
8.1 Compilation of Final Process .....	53
8.1.1 Collect Patient Data .....	53
8.1.2 Repair Scan .....	54
8.1.3 Design Socket.....	54

8.1.4 Prepare for Printing.....	56
8.1.5 Print Socket.....	56
8.1.6 Post-Processing.....	57
8.1.7 Ready-To-Use Socket.....	57
<b>9 Validate.....</b>	<b>59</b>
9.1 Case Studies .....	59
9.1.1 Case Study 1 .....	59
9.1.2 Case Study 2 .....	61
9.2 Validation Assessment.....	62
9.3 Extension of Case Study 1 .....	63
<b>10 Deliver .....</b>	<b>65</b>
10.1 Process Instructions .....	65
10.1.1 Booklet User Guide.....	65
10.1.2 Video Tutorial.....	66
10.1.3 User Evaluation.....	66
10.2 Process Comparison.....	66
10.2.1 Lead Time .....	67
10.2.2 Cost .....	70
<b>11 Conclusions .....</b>	<b>73</b>
11.1 Process Conclusions.....	73
<b>12 Discussion .....</b>	<b>75</b>
12.1 Methodology.....	75
12.2 Work Process & Results .....	75
12.3 Recommendations for Further Development.....	77
<b>13 References .....</b>	<b>79</b>
<b>Appendix A: Project Plan.....</b>	<b>85</b>
A.1 Initial Project Plan .....	85
A.2 Actual Project Plan .....	86
A.3 Comments to Time Deviations .....	87
<b>Appendix B: Ranking of Process Requirements.....</b>	<b>89</b>
<b>Appendix C: Evaluation Matrices .....</b>	<b>91</b>
<b>Appendix D: Material Data Sheet PA2200 .....</b>	<b>93</b>
<b>Appendix E: Booklet User Guide.....</b>	<b>95</b>



# **1 Introduction**

## **1.1 Company presentation**

Aktiv Ortopedteknik is a Swedish company that offers orthopedic services and products such as prostheses, orthoses and sitting aids to the Swedish market.

The company has over 300 employees and is established in nearly 25 Swedish cities whereof 18 have orthopedic centres. At a centre, patients can see specialists within fields such as orthopedic engineering, physiotherapy and occupational therapy. The specialist team cooperates to provide the best possible solution with regard to individual needs and wishes of each patient.

Aktiv Ortopedteknik is for the past 20 years owned by the German prosthetics company Ottobock Healthcare, one of the world's leading suppliers of orthopedic services and products. Through Ottobock, Aktiv Ortopedteknik is part of a global PatientCare-network comprising more than 70 orthopedic centres worldwide, guided by the motto "Quality for life" in the mission to improve and restore mobility and independence among their patients [1].

## **1.2 Background**

A prosthesis is a tool to enable an amputee patient to more independently perform their daily life activities. The purpose is to restore as much as possible of the functionality and many times also the appearance of the missing body part [2, p.177].

The comfort and effectiveness of the prosthesis, however, is determined by how well it fits on the residual limb of the patient. A crucial role for the fit is therefore played by the prosthetic socket. The socket serves as the interface between the prosthesis and the patient's body by enclosing the residual limb.

Due to its importance, the socket is made according to the anatomy, requirements and preferences of each individual patient [3, p.178].

At Aktiv Ortopedteknik, prosthetic arm sockets are currently manufactured using the most commonly practised method within the prosthetics industry where a plaster model is made from a cast created directly from the patient's residual limb. This is followed by a number of steps involving manual processing of the plaster model, creating a test socket, patient fittings, adjustments and the fabrication of the final socket, resulting in a rather time consuming process.

In spite of the socket being moulded directly from the patient's residual limb, a good fit can still be difficult to obtain. The many manual steps open up for human error and going back in the process to make detailed adjustments is not always possible [4].

With today's 3D technology, such as scanners, printers and various software, precise re-creation, design and production of complex geometries have become reality [5]. How could Aktiv Ortopedteknik use 3D technology when creating an arm socket, in order to facilitate the manufacturing process and offer their patients a perfectly fitted product?

### **1.3 Aims and purpose**

The purpose of this project is to develop a complete step-by-step process describing the approach to create a custom-made, 3D printed socket for upper limb prosthetics. The process is to function as a guide for a prosthodontist or other person involved in the manufacturing of a prosthetic socket, without requiring an extensive experience in CAD. The aim is to offer the prosthodontist a viable alternative to the conventional manufacturing process as well as to provide amputee patients with perfectly fitted prosthetic sockets.

#### *1.3.1 Objectives*

The main objectives of the project are to:

- Define process requirements based on user needs.
- Establish an overall process structure.
- Test and select a suitable software and modelling method to be used in the process.
- Create prototypes and validate the process with amputee patients.
- Present learning material to the user in order to facilitate an implementation of the developed process.
- Provide a comparison between the conventional and the developed process in terms of lead time and cost.

### **1.4 Scope**

The process to be developed will extend from the 3D-scanning of a patient's residual limb to the modelling of the socket in relevant software preparing it for 3D-printing, ultimately resulting in a ready-to-use prosthetic socket.

The project will revolve around Aktiv Ortopedteknik's centre in Lund and the focus will be on the creation of upper limb prosthetic sockets, specifically for patients with transradial amputation. This is due to transradial amputation being the most common amputation level among upper limb patients treated at Aktiv Ortopedteknik [4].

### **1.5 Delimitations**

The step-by-step process will be developed by using a low-cost 3D scanner and a mid-range to high-end 3D printer available at Lund University. No 3D printer is available at Aktiv Ortopedteknik.

It is assumed that all necessary hardware and software will be in place when the finished process is being carried out. Instructions on how to assemble hardware and install software will therefore not be included in this project.

Due to limited financial resources available for the project, only free software and software licenses provided by Lund University are considered.

Important is also to emphasise that when the term ready-to-use or finished socket is mentioned, further work of completing the entire prosthesis for the patient still remains, such as aligning the finished socket to the artificial limb or connecting required electronics. These manufacturing steps are left outside of the scope when developing the process and therefore not further discussed in this report.



## **2 Method**

*This chapter describes the development methodology used throughout this project. It is inspired by several aspects of the Ulrich & Eppinger Development Process and the Double Diamond Model, both familiar to the writer. Phases and activities were modified and added to better suit the purpose of the project.*

### **2.1 Project Plan**

As a tool to assist in structuring the thesis work, a tentative time plan was created and updated as the project proceeded. Both the initial and the actual project plan together with comments on time deviations can be found in Appendix A.

### **2.2 Pre-Study**

Before initiating the work of creating the process, a pre-study is performed consisting of literature studies on medical and technical aspects relevant to the project.

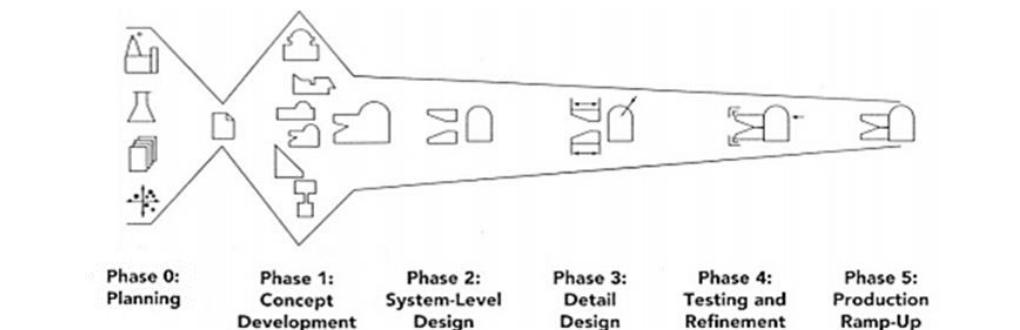
The purpose of the pre-study was to gain a deeper knowledge of the current manufacturing process, the anatomy of an upper-limb amputee and the function as well as significance of a prosthetic socket. The pre-study also contains an overview of the 3D technology used in the course of this project and its scope of use within the field of medicine in general and the prosthetics industry in particular.

### **2.3 Development Methodology**

#### **2.3.1 The Ulrich & Eppinger Product Development Process**

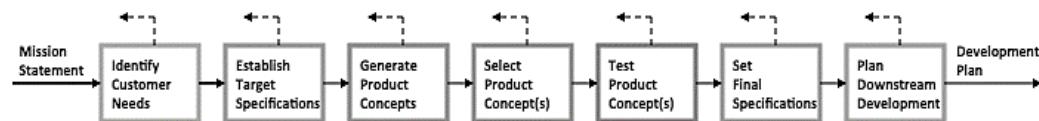
The development process elaborated by Karl T. Ulrich and Steven D. Eppinger extensively describes an approach to taking a product from idea to market [6]. The process consists of six phases, starting with an initial planning phase followed by five phases from concept development to production ramp-up, as seen in Figure 2.1.

Many of the phases use an iterative approach and involve several important functions at a company, such as marketing, design and manufacturing.



**Figure 2.1** The six phases of the Ulrich & Eppinger Product Development Process.

The phase most relevant for this project is the concept development phase, which comprises seven steps shown in Figure 2.2.



**Figure 2.2** The seven steps of the Ulrich & Eppinger concept development phase.

Starting with a mission statement created during the planning phase, the concept development involves identifying customer needs and transforming these needs into target specifications. The specifications are exact descriptions of what a product should do, expressed in technical terms. This is followed by concept generation where various possible solutions or parts of solutions are explored. The activity often involves a blend of external search, creative problem solving and systematic exploration of generated ideas [6, pp.13-17].

One or several concepts are selected for further development by using a concept screening or concept scoring matrix. Generated concepts are evaluated and ranked in relation to each other according to criteria derived from identified customer needs. Concept screening is a rather quick and approximate method where the concepts are rated as better, equal or worse than a chosen reference. Concept scoring is performed in a similar manner, but with the difference of providing a more detailed evaluation since the criteria are weighted according to their relative importance [6, pp.149-157].

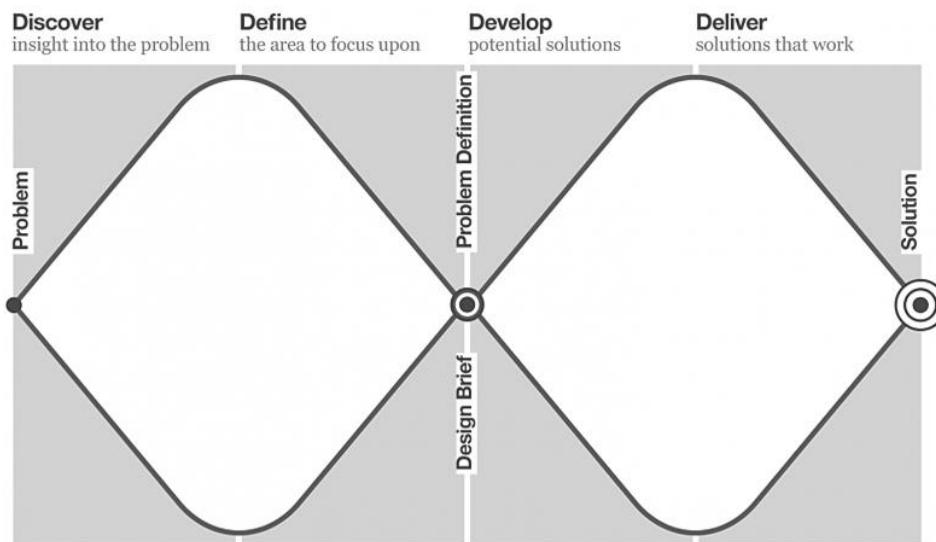
The most promising concept(s) is tested to verify that customer needs are fulfilled. If necessary, some earlier performed activities may be repeated.

After a concept has been selected and tested with customers, the previously established specifications are revised. Final specifications are set by taking limitations that have been identified during the process, into consideration. This can, for example, be constraints regarding available technology or trade-offs between cost and performance.

Finally, a detailed development plan is created, containing customer needs, final specifications, detailed descriptions of the selected concept and the resources required to materialize the product [6, p.17].

### 2.3.2 The Double Diamond Model

The Double Diamond Model is a design methodology developed by the UK Design council [7]. The model divides the design process into four distinct phases – Discover, Define, Develop and Deliver – and is characterised by alternating a divergent and convergent way of thinking while moving through the phases to the final solution (see Figure 2.1).



**Figure 2.3** The Double Diamond Model and its four phases.

The Discover phase initiates the project. Market and user research is performed to gain new insights to the problem and generate an initial idea or an inspiration.

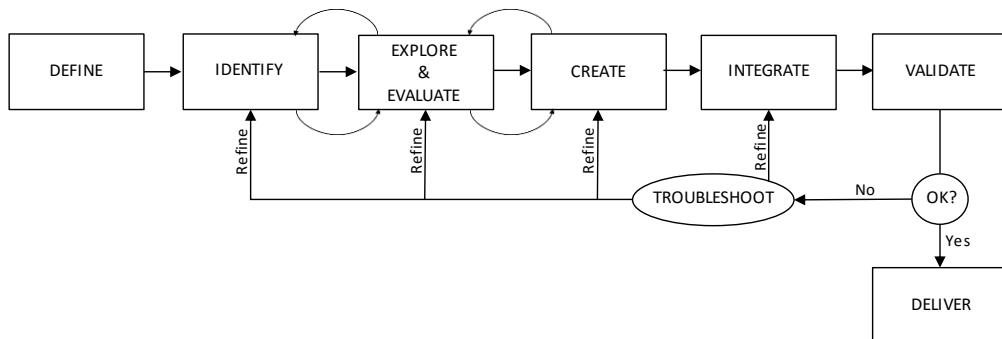
In the Define phase, the information gathered in the previous phase is analysed and interpreted. A clear image of the problem should be established and user needs converted into project objectives.

During the Develop phase, potential solutions and concepts are generated, prototyped, tested and iterated in order to improve and refine good ideas and discard weak ones.

In the fourth and final Delivery phase, the project is finalized, produced and launched in the relevant market.

### 2.3.3 Thesis Methodology

Important to mention is that both of the previously described methodologies first and foremost were created as processes for developing a physical product and not the development of a process itself. However, just as in the case of a physical product, a process has a user and several of the activities performed can also be directly applied to the design of a process. Relevant activities and structures were therefore adopted from the described methodologies to the thesis methodology. Some phases were modified or removed, while others were added to better suit the purpose of this project. This resulted in a 7-phase process development model, shown in Figure 2.4.



**Figure 2.4** The 7-phase process development model applied to the thesis work.

Key characteristics of the 7-phase model, similar to the Double Diamond model and the Ulrich & Eppinger methodology, are the sequences of broadening and narrowing down the perspective while working through the phases and the use of an iterative trial-and-error approach to finding a suitable and viable solution.

The seven phases of the created model are more closely described in the following subchapters.

#### 2.3.3.1 Define

In the Define phase, similar to its namesake in the Double Diamond (DD) model, a clear image of the problem is established [7]. The primary input and desired output are determined, setting the start and end point of the process.

By following the first two steps of the Ulrich & Eppinger (U&E) methodology, a user study is conducted in order to identify user needs that can be transformed into process requirements in terms of functionality and usability<sup>1</sup>.

The user study is performed by means of an in-depth interview with two prosthetists at Aktiv Ortopedteknik. During the interview, the conventional way of manufacturing

<sup>1</sup> The ease of use and learnability of an object created by a human. The object can be a physical product, a process or anything a human interacts with.

the sockets is discussed including its advantages and disadvantages. Moreover, the role of the prosthetist, patient diversity and interaction and finally the importance of the socket are also topics for the interview.

Due to the process being developed for the prosthetist as a user, no interviews are performed with amputee patients at this stage. The patient is nevertheless the user of the product derived from the future process. It is therefore of great importance to have an understanding for the diversity among patients in terms of preferences and requirements regarding the fit of a prosthetic socket. Such information can however, according to the writer and in agreement with the prosthetists, be obtained from statements by the interviewees, supported by their extensive experience from the profession and contact with patients.

Identified needs are rated by the user according to importance, followed by being categorised and converted into process requirements [6, p.86].

In the U&E methodology, user needs are converted into target specifications for the product. These are presented as detailed metrics with ideal and marginally acceptable target values to be achieved [6, pp.16-17]. However, since this project aims to develop a process consisting of several different steps and not one specific product, using overall requirements are considered by the author to be more suitable. These requirements can instead of being detailed values, function as general guidelines throughout the development of the process ensuring that user needs are fulfilled for each step.

### 2.3.3.2 Identify

This phase was created by the writer to complement the two described methodologies and to better suit the development of this type of process. The phase involves identifying the main steps of creating a 3D printed object from a scan. Essential tasks of the process are analysed and literature on 3D scanning used in combination with 3D printing is consulted in order to establish a clear image of the necessary overall structure of the process being developed.

Finally, options regarding potential software to use in the process are identified for further testing.

### 2.3.3.3 Explore & Evaluate

As the name indicates, the first part of this phase is of exploratory nature and involves becoming familiarised with the potential software to be used in the process. The work is characterised by a combination of comprehensive studies of existing software tutorials and a more practical learning-by-doing approach where different methods of creating a prosthetic socket are distinguished and explored, corresponding to the concept generation-step of U&E and the first part of the DD Develop phase.

The knowledge gained while exploring is in the second part of this phase used to evaluate the modelling methods and software according to criteria based on previously established requirements. The evaluation is performed with the assistance of U&E's concept screening and concept scoring and will result in the selection of the software and modelling method best suited for the process [6, pp.149-157].

#### 2.3.3.4 Create

In this phase, the selected software and modelling method are used together with all necessary hardware to create 3D printed socket prototypes. By prototyping, both process and socket quality and design can be better assessed.

This phase can be considered an initial test or a pre-validation of the process since no patients are yet involved. However, to imitate the shape of a residual limb, a plaster model from Aktiv Ortopedteknik is used.

The prototypes are 3D printed in the product lab at Ingvar Kamprad Design Centre (IKDC) at Lund University and assessed together with a prosthetist at Aktiv Ortopedteknik.

The iteration of exploring, evaluating and creating will continue until a satisfying result is obtained, similar to the DD Develop phase and the concept testing of the U&E methodology.

#### 2.3.3.5 Integrate

The Integrate phase was created by the writer to compile and combine the knowledge and data collected thus far into a clear and concise overview of the complete process. Main steps are broken down into substeps and necessary line of action is further described.

#### 2.3.3.6 Validate

This phase can be considered an extension of the previous Create phase and the concept testing of U&E. The testing now involves actual patients and is partly performed in the natural environment of the user. As proof-of-concept, a set of case studies with amputee patients at Aktiv Ortopedteknik is therefore performed. Custom-fitted sockets are produced in each separate case in order to determine the viability of the elaborated process.

The participating patients are persons willing to volunteer in the project after being selected and informed by the prosthetist. The selection aims to reflect the diversity among patients in terms of socket requirements, shape and size of the residual limb.

Due to the necessary software and 3D printer currently not being available at Aktiv Ortopedteknik, only scanning and socket fitting are performed at the company.

Activities involving software and printing are conducted at IKDC, Lund University without the presence of the patients or the prosthetist. The printed sockets are later

taken back to the company for fitting and evaluation. The results, based on statements from the patients and the prosthodontist, determine whether or not the process is validated.

An unsuccessful validation will initiate a troubleshooting activity where the phases in need of refinement are identified and revised, followed by a new validation - an iterative approach adopted from the two previously described methodologies.

#### 2.3.3.7 Deliver

This phase corresponds to the last phase of the DD model, where the product is finalised and launched in the relevant market [7]. For this project this means fully adapting the validated process to the user, i.e. the prosthodontist, in terms of how the process instructions are presented. By what means these instructions are delivered is determined by consulting the previous user study and through further discussions with the user. The result is to function as a manual allowing the user to quickly learn and independently follow the process step-by-step, producing a custom-fit socket for the patient and if time allows, an evaluation of the full process will be conducted together with the user.

Finally, a comparison between the new and the conventional process in terms of approximate lead times and costs is performed. Statistics and other information provided by Aktiv Ortopedteknik regarding the conventional process will be used as well as calculations concerning time and costs for the new process.



## **3 Pre-study**

*This chapter gives a medical and technical background to the project. A description of amputation, the prosthesis and the role of a prosthetic socket is given and the conventional manufacturing process of the socket is further explained. The technical aspects are covered by an overview of the 3D technology used in the course of the project and its use within the field of medicine in general and the prosthetics industry in particular.*

### **3.1 Amputation**

Amputation is the removal of all or part of a limb such as an arm, hand, finger, leg, foot or toe, due to disease, injury or a congenital deficiency.

The most common reason for amputation overall, is circulation issues. This is often a consequence of diabetes or atherosclerosis<sup>2</sup>, impeding the blood flow from reaching the extremities and subsequently causing dying tissue and infections.

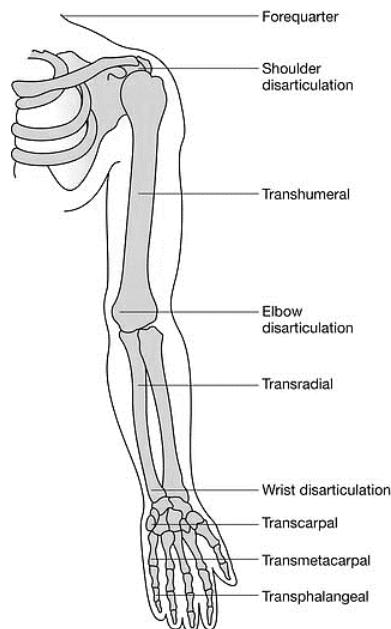
Amputation is normally a planned procedure while some cases require an unexpected amputation, for example after a traumatic injury from an accident where the injured limb cannot be restored. During the procedure, dead tissue and bone are removed. The bone is smoothed to facilitate future use of an artificial limb and as much healthy skin as possible is saved to cover the residual limb [2, pp.169-171].

#### *3.1.1 Amputation Level*

An amputation is either upper or lower-limb related but to describe the location of the amputation more specifically, the term amputation level is used. The amputation level is determined by a doctor before the surgery and the decision is based on the reason for the amputation [8]. Figure 3.1 illustrates the various levels of upper-limb amputees.

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<sup>2</sup> Accumulation of plaque on the inner walls of arteries.



**Figure 3.1** The various upper-limb amputation levels.

### 3.1.1.1 Transradial amputation

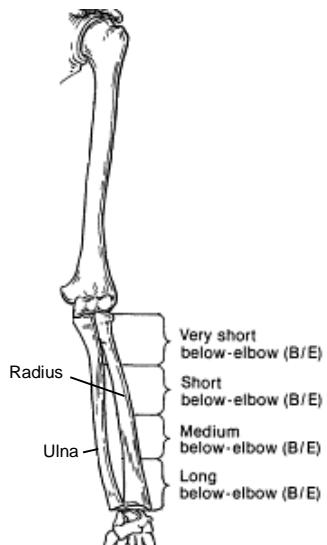
Transradial amputation, the focus of this project and also known as below-elbow amputation (see Figure 3.2), is an amputation level where the hand and part of the forearm is removed through the ulna and radius bone [8]. The most common reason for this particular amputation is traumatic injury [9].



**Figure 3.2** An example of a transradial amputation.

The transradial amputation level can be further classified according to the length of the remaining forearm. These sub-levels can affect the appearance of the resulting

residual limb; a more proximal amputation leaves a greater amount of muscle to cover the bones of the forearm, whereas a distal amputation exposes more of the radius and ulna, resulting in a more irregular shape of the residual limb [2, p.170]. Figure 3.3 shows the sub-levels of a transradial amputation.



**Figure 3.3** Sub-levels of transradial amputations.

### 3.2 The Prosthesis

An entire or part of a limb that has been lost through amputation or as a result of a congenital deficiency can be replaced by an artificial limb - a prosthesis.

The prosthesis is a tool to enable the patient to more independently perform their daily life activities, restoring as much as possible of the functionality and many times also the appearance of the missing part of the body. How well the prosthesis enables the user is determined by several factors; fit, type and the user's goals, age, health and general mindset [2], [4].

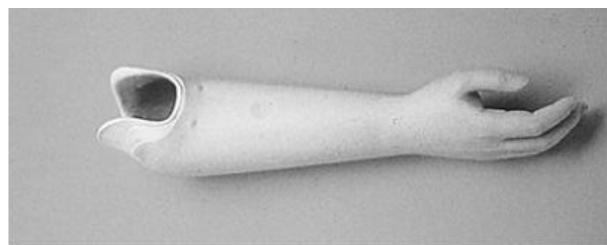
The prosthesis is designed, build and fit by a prosthetist who generally is part of a larger clinical team. The design is determined by the patient's amputation level, physical ability and needs.

The creation of a prosthesis can however be a complicated process where skill and often sophisticated technology are necessary to take the many differences in human anatomy into consideration. Advancements in material science and technology have, nonetheless, made it possible to create even more lifelike prostheses in terms of both form and function. Materials such as carbon fibre, titanium and lightweight thermoplastics are commonly used in contemporary higher-end prostheses [10].

A prosthesis replacing a missing limb consists primarily of three parts; the socket (thoroughly explained in subchapter 3.3), the components and the cover. The features of these parts depend on the type of prosthesis chosen, based on the needs and preferences of the patient. The three main types of prostheses are passive, body-powered and myoelectric prostheses [4]. These are, in the case of a transradial prosthesis, further described in the three following sub-chapters.

### ***3.2.1 The Passive Prosthesis***

A passive prosthesis, such as the one shown in Figure 3.4, is primarily used for cosmetic purposes and has little functionality on its own. The realistic appearance is created by using a custom or non-custom cosmetic glove, often made from silicone. The prosthesis does not contain any mechanical or electrical components but can, however, support the healthy arm in tasks such as holding and placing an object [3, p.181].

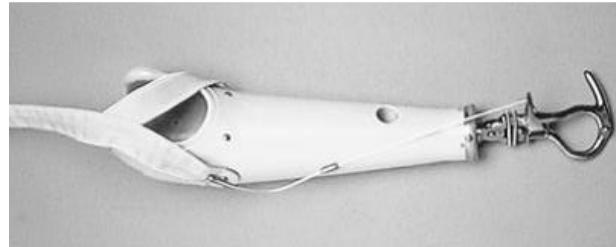


**Figure 3.4** Passive transradial prosthesis.

### ***3.2.2 The Body-Powered Prosthesis***

A body-powered prosthesis (see Figure 3.5) is a functional prosthesis that also could fulfil cosmetic purposes. By using cables and a shoulder harness system the prosthesis allows the amputee to perform more tasks than with a passive prosthesis. Movements of the shoulder or the arm are used to pull the cables, in order to open or close a so called terminal device. The terminal device can for example be a hand, hook or a prehensor.

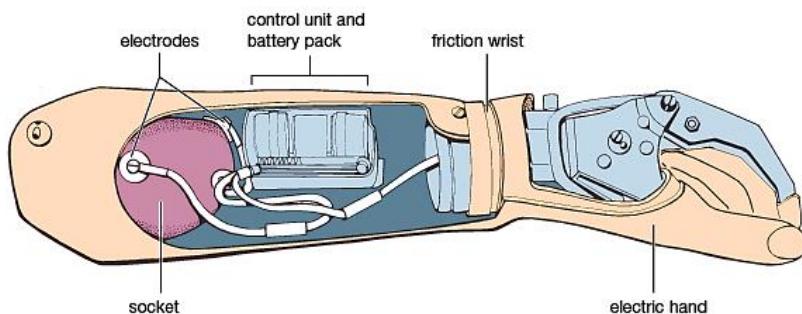
The prosthesis can be either voluntary-opening or voluntary-closing; the former requires applied force to open the terminal device but is automatically closed with the help of rubber bands, while the latter requires body force to close the terminal device giving the user more control over the strength of the grip. The mode of operating the voluntary-closing prosthesis can be compared to the way a handbrake system of a bicycle works [11].



**Figur 3.5** Body-powered transradial prosthesis with hook as terminal device.

### 3.2.3 The Myoelectric Prosthesis

The myoelectric prosthesis, just like the body-powered, is a functional prosthesis that can fulfil cosmetic purposes. The myoelectric prosthesis, however, is battery-powered and operates the terminal device by using electrical signals generated by the muscles of the residual limb. The signals are registered by electrodes built in to the prosthetic socket passing them on to a controller where the information is translated to commands for a motor that ultimately creates the movement. Figure 3.6 shows the main components of a myoelectric prosthesis.



**Figure 3.6** Main components of a transradial myoelectric prosthesis.

The myoelectric prosthesis generally offers a wider range of motion and function than the two previously described types of prostheses. It is however heavier and more expensive, due to its additional complexity and amount of components [12].

### 3.3 The Prosthetic Socket

A prosthetic socket encloses the residual limb, creating the interface between the patient's body and the prosthesis. An appropriate design and fit of the socket is crucial for the success of the prosthesis since it determines comfort, aids suspension and provides the user with both sensory and pressure feedback. An ill-fitting socket can cause pain or discomfort such as skin irritation and breakdown or pressure on bony prominences. It is therefore of great importance to achieve a total-contact fit for

an even distribution of pressure while at the same time providing relief to mentioned sensitive areas. By doing this, the residual limb is stabilised in the socket, minimising energy and motion loss and increasing control of and response from the prosthesis.

Factors also necessary to take into consideration when designing the socket are

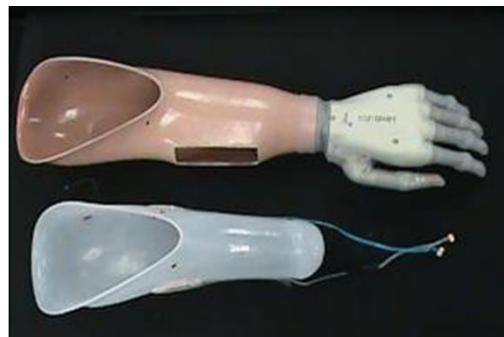
- **Amputation level** – length of the residual limb.
- **Type of prosthesis** – a myoelectric prosthesis, for example, require a socket with space for placement of electrodes.
- **Intended use of the prosthesis** – everyday use or specific purpose.
- **Type of suspension** – how the socket attaches to the body.

The socket consequently needs to be custom-fabricated according to the anatomy, requirements and preferences of each individual amputee. In addition, since the shape and size of the residual limb tend to change over time, due to weight gain or loss, swollenness or, as in the case of a child, growth, a new socket needs to be created from time to time.

Several materials can be used when creating the socket; common is to laminate the socket with plastic resin and carbon fibre or fibreglass as reinforcements, resulting in a lightweight, durable but expensive socket, or using a thermoplastic – easy to modify, less expensive but also less durable and slightly heavier. Different options are also available for the inner surface of the socket that is in direct contact with the residual limb; the hard, laminated socket or its thermoplastic counterpart can be used as they are or a gel liner interface can be added [3, pp.178-187, 281]. Common is also to create an inner socket made from silicone stabilised with a laminated outer support socket [4]. Examples of these four options are given in Figure 3.7-3.10 and their respective advantages and disadvantages are further described in Table 3.1.



**Figure 3.7** Laminated hard socket.



**Figure 3.8** Thermoplastic socket.

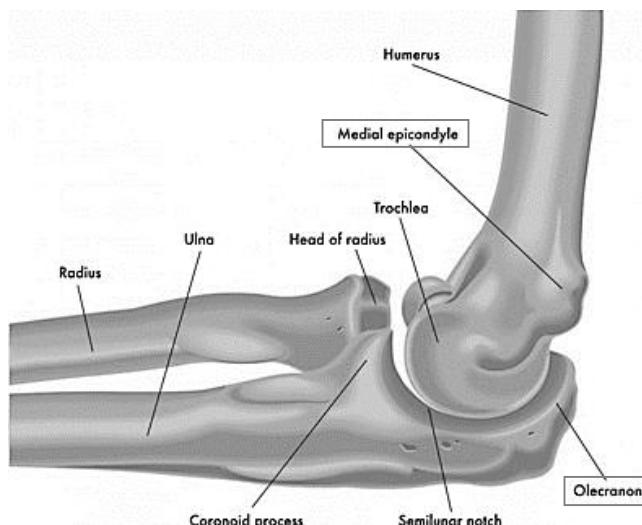
**Figure 3.9** Socket with liner.**Figure 3.10** Silicone socket with support socket hidden in the outer frame.**Table 3.1** Overview of socket interface types for upper-limb prostheses.

Type	Description	Advantages	Disadvantages
Hard socket	Rigid interface with the residual limb	<ul style="list-style-type: none"> <li>1. Hygienic because laminate does not absorb perspiration</li> <li>2. Increased cosmesis because it is not as bulky as other designs</li> <li>3. Increased durability</li> </ul>	<ul style="list-style-type: none"> <li>1. Not advised for patients who have prominent bony landmarks, thin tissue coverage, adherent scar tissue or tendency for skin breakdown</li> </ul>
Soft plastic	Flexible inner socket with a rigid outer frame	<ul style="list-style-type: none"> <li>1. Shape can be modified by the prosthetist with heat application</li> <li>2. Windows can be cut out from the rigid outer frame to decrease weight</li> <li>3. Can be replaced or modified based on residual limb volume changes</li> </ul>	<ul style="list-style-type: none"> <li>1. Less cosmetic when compared to the hard socket</li> <li>2. Increased time for fabrication</li> </ul>
Gel liner	Urethane, silicone or thermoplastic elastomer	<ul style="list-style-type: none"> <li>1. Decreased friction and shear forces are experienced by the skin; especially useful over skin graft or adherent scar tissue areas</li> <li>2. Liners are provided in different thicknesses</li> <li>3. Greater cushioning can be provided by using thicker gel</li> </ul>	<ul style="list-style-type: none"> <li>1. Meticulous daily cleaning of the liner is required</li> <li>2. Hygiene is more difficult since these materials absorb perspiration and unpleasant odors can develop</li> <li>3. These materials are somewhat fragile and are not very durable</li> <li>4. Expensive</li> </ul>
Silicone socket	Very flexible inner socket with a laminated outer support socket	<ul style="list-style-type: none"> <li>1. Material is forgiving in terms of volume and shape changes of the residual limb. Thus, the need of frequently creating new sockets for growing child patients decreases.</li> <li>2. Correctly designed socket gives a very good suspension suitable for both cosmetic and myoelectric prostheses</li> <li>3. Increased comfort, especially for patients with prominent bony landmarks and high skin sensitivity</li> </ul>	<ul style="list-style-type: none"> <li>1. The material does not allow any reshaping after being vulcanised</li> <li>2. The material is not breathable, which can cause perspiration or skin discomfort for the patient</li> <li>3. The material can be fragile; wear and cracks can appear, especially in areas where the silicone meets the edge of the outer support socket</li> </ul>

### 3.3.1 Suspension Systems

The suspension system determines how the prosthetic socket attaches to the user's body and can be either self-suspending or non-self-suspending. Self-suspension is achieved by using the anatomy of the residual limb, either by indirect skeletal attachment, soft tissue constriction/friction or suction/skin friction.

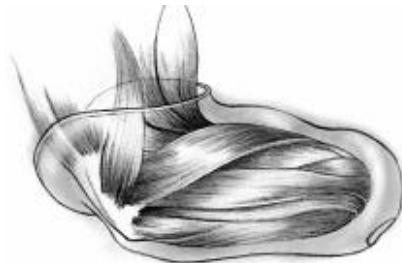
Self-suspension is the most common type for transradial sockets and the indirect skeletal attachment is the method most frequently used to achieve that suspension. Indirect skeletal attachment involves contouring of the bone prominences of the elbow, such as the olecranon and epicondyles (see Figure 3.11). These sockets can roughly be divided into three groups; supracondylar, supraolecranon and a combination of both.



**Figure 3.11** Side view of the elbow joint with the location of the olecranon and one of the epicondyles marked out.

The supracondylar socket is equipped with elongated wings fitted above the humeral epicondyles. Trim lines are cut below the cubital fold and olecranon which facilitates flexion and extension of the elbow. However, this type of socket does not provide a bony lock during movement and can therefore be pulled off in any position if the force is large enough. It can also create discomfort since the pressure is only concentrated around the epicondyles.

The supraolecranon socket extends over the olecranon and provides the bony lock in extension that the supracondylar socket is lacking. However, for increased comfort and stability with good suspension and a more even pressure distribution, a combination of the two is often preferred [13, pp.51-52]. An example of a socket combining supracondylar and supraolecranon suspension is illustrated in Figure 3.12.



**Figure 3.12** Line drawing of an example of a transradial socket using a combination of supracondylar and supraolecranon suspension.

Self-suspension for a transradial socket can also be achieved by using a liner or sleeve, often made from silicone. This method is more common in cases where the socket does not suspend over the elbow. The liner or sleeve is pulled over the residual limb and used in combination with suction, friction or by adding a pin at the bottom to lock it to the prosthesis.

The non-self-suspending sockets are dependent on external devices to stay in place over the residual limb. Most commonly used is a harness across the torso and shoulders. A harness can be used for self-suspending sockets as well, but in such case with the purpose of controlling the terminal device of a body-powered prosthesis [3, pp.178-187, 281].

### 3.3.2 Conventional Manufacturing Method

Within the prosthetics industry, including Aktiv Ortopedteknik, the most widely used method of fabricating a prosthetic socket is by first creating a plaster model of the patient's residual limb. This is followed by the creation of a test socket, one or several fittings and adjustments before the final socket can be created and incorporated with the prosthesis.

It is a rather tedious process involving several manual steps [4]. Figure 3.13 shows an overview of the conventional manufacturing process. These steps are also further described in the following sub-chapters according to a publication on upper-extremity limb fitting by the Amputee Coalition of America [14].



**Figure 3.13** Workflow displaying the steps and approximate timeframe of the conventional manufacturing method for a prosthetic socket.

### 3.3.2.1 Measurement & Casting

Before initiating the casting procedure, the prosthetist covers the patient's residual limb with a thin casting sock or a liner, whereupon instructions are given to the patient on how to position the limb. Measurements are then taken of the length of the residual limb as well as of the opposite arm, in order to have a corresponding prosthesis. To document the volume of the residual limb, the circumference of several areas are also measured.

When the measurements are taken, the location of bony prominences, e.g. olecranon and condyles, and sensitive areas in need of pressure relief are marked by the prosthetist on the casting sock (see Figure 3.14). If the socket is intended for a myoelectric prosthesis, placement of the electrodes are also marked out.



**Figure 3.14** Bony prominences, electrode placement and trim lines marked out on the casting sock.

Wet plaster bandage is then wrapped around the residual limb to create a negative mould. The plaster is shaped by the prosthetist to closely fit over the limb while also relieving sensitive and bony areas. After the cast has set it is removed from the patient's body (see Figure 3.15). This needs to be done carefully to avoid discomfort for the patient and distortion of the cast. Liquid plaster is then poured into the cast to create a positive mould of the residual limb and is left to dry and harden.



**Figure 3.15** Removal of the cast from the patient's residual limb.

### 3.3.2.2 Modification of Mould

When the liquid plaster has dried and hardened, it is removed from the bandage cast. The marks previously made on the casting socket have now been transferred via the cast to the filled mould and can be used as guidelines for modifications. Plaster is added to bony areas (see Figure 3.16) while plaster in areas with more soft tissue is removed with a file. This is a crucial stage for the fit of the resulting socket and the skill and experience of the prosthodontist plays an important role. Extra time is taken to create a smooth finish since the outer surface of the mould will form the inner surface of the socket.



**Figure 3.16** Manual modifications of the positive plaster mould.

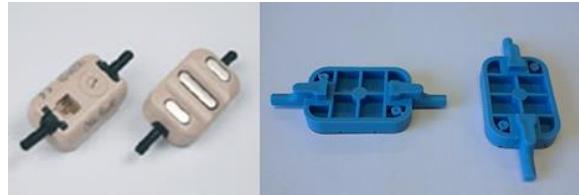
### 3.3.2.3 Create Test Socket

After modifications are made of the positive plaster mould it is used to create a test socket. It is commonly made from transparent thermoplastic that is vacuum formed around the mould, see Figure 3.17.



**Figure 3.17** Vacuum forming of the test socket.

Consideration to space for myo-electrodes is also taken when creating the test socket. The electrodes are represented by so-called dummies, which have the same shape and size as the electrodes but without the electrical function, see Figure 3.18.



**Figure 3.18** Actual electrodes to the left, electrode dummies to the right.

The dummies are attached to the mould before the vacuum forming, according to the previously made placement markings.

In cases where the socket interface is intended to be made from silicone, no test socket is created before the final socket. This is due to the difficulty of imitating the properties of silicone with another material. The created silicone socket is therefore used for the finished prosthesis and if it ends up not fitting, a new one has to be made from scratch [4]. The silicone is shaped over the plaster mould and later cured in an oven through vulcanisation [15].

### 3.3.2.4 Fitting & Adjustments

The test socket, such as the one shown in Figure 3.19, is used to assess the fit of the socket on the patient. Volume, trimlines, motion range of the joint and the ease of donning and doffing the socket are evaluated. If necessary, adjustments are made by softening the plastic with a heat gun, allowing the socket to be reshaped. To increase motion range and comfort, the trimlines can be cut, lowered or flared out.



**Figure 3.19** Example of a transparent test socket with windows created for placement of electrodes.

Alignment marks for the prosthesis are also made. In case of a myoelectric prosthesis, the arm can be roughly assembled to investigate the impact of the weight on the socket fit as well as the positioning of the electrodes.

When the prosthetist and the patient have agreed on the shape and fit of the socket, the construction of the final socket can commence.

### 3.3.2.5 Create Final Socket

The initially created plaster mould often breaks during the removal of the test socket. Therefore, when fabricating the final socket, the test socket is filled with liquid plaster in order to create a new mould. After the plaster has dried the test socket is cut off the mould. The final socket is then constructed by either laminating plastic resin (see Figure 3.20) with reinforcing materials such as fibreglass or carbon fibre or by vacuum forming a thermoplastic over the mould, just as in the procedure of the test socket [4].



**Figure 3.20** Lamination of the socket with plastic resin.

In the case where the socket interface is made from silicone, a support socket is laminated on top of the silicone to add stability and an attachment surface for prosthetic components. The silicone socket is later glued to the inside of the support socket [15].

When the socket is finished and again fitted to the patient, further work of completing the prosthesis and aligning its components can begin.

## 3.4 3D Technology

### 3.4.1 3D Scanning

3D scanning is the process of creating a 3D digital copy of an already existing object. A variety of scanning technologies are available and based on the use of lasers, lights or x-rays to capture the size, shape and colour of an object.

3D scanning has evolved from exclusively being an expensive technology in professional and industrial devices to offering a wider scope including more affordable options of hand held scanners and even smaller scanners that can be integrated with a regular iPad or smartphone. Companies such as Google and Microsoft have even developed hardware that allow their users to create 3D scanners in their own homes. An example of this is Microsoft's XBOX game controller Kinect [5].

### 3.4.2 3D Printing

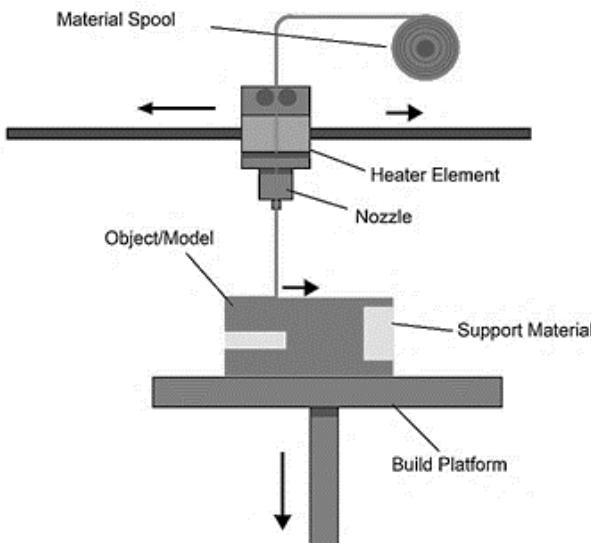
3D printing, also known as additive manufacturing, is a process of creating three dimensional objects from a digital file. The file can be created from a CAD-drawn model or from a 3D scan of an existing object. A software slices the model into thin layers given as instructions to the printer that builds the physical object layer by layer. The technology allows the creation of more complex geometries than what is offered by many conventional manufacturing methods and also contributes to a more efficient use of materials, reducing the amount of waste material in the manufacturing process [5].

Three of the most common 3D printing processes relevant and available for this project are further described in the following three subchapters.

#### 3.4.2.1 Fused Deposition Modelling (FDM)

Fused deposition modelling is a material extrusion process where a plastic filament or a metal wire from a spool is heated, melted and distributed through a nozzle, see Figure 3.21.

The most commonly used plastic materials for the FDM process is ABS (Acrylonitrile Butadiene Styrene) and PLA (Polylactic acid). The material is deposited on a building platform, one layer at a time and hardens and bonds to the previous layer immediately after being extruded. This continues until the complete object has been built. If the object has overhanging geometry, support material needs to be added. This extra material can however be removed after the print is finished [5].



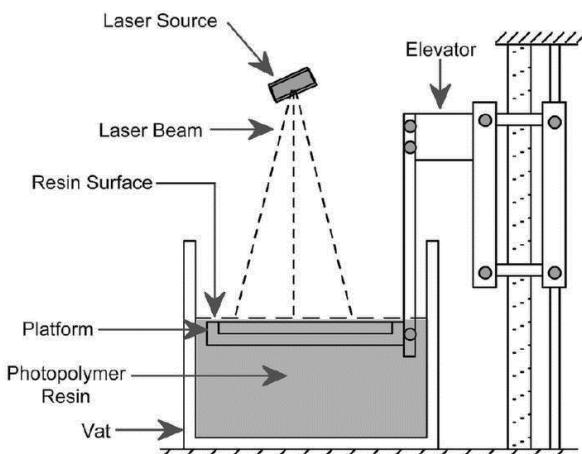
**Figure 3.21** The principle of the FDM process.

### 3.4.2.2 Stereolithography (SLA)

Stereolithography, or SLA, is a process where an ultraviolet laser is used to cure a liquid photopolymer resin held in a container, see Figure 3.22. The object is built layer by layer as a result of the laser tracing a cross-section of the object on the surface of the resin. The resin cures, hardens and bonds to the previous layer when exposed to the laser. In between creating the layers, the elevator platform descends a distance equal to the thickness of a layer, allowing a new coat of liquid resin to cover the part. This process is repeated until the object is complete. The object is then cleaned with a liquid solvent in order to remove excess resin and then further cured in an ultraviolet oven.

As with the FDM technology, support material is necessary in this process for overhanging geometries, to attach the object to the platform and keep it from floating in the liquid resin. The support material can be removed after printing is finished.

SLA is considered to be one of the most precise 3D printing technologies due to the excellent surface finish of the printed objects. Disadvantages, however, are the post-processing steps and the tendency of the materials to become more brittle over time [16].

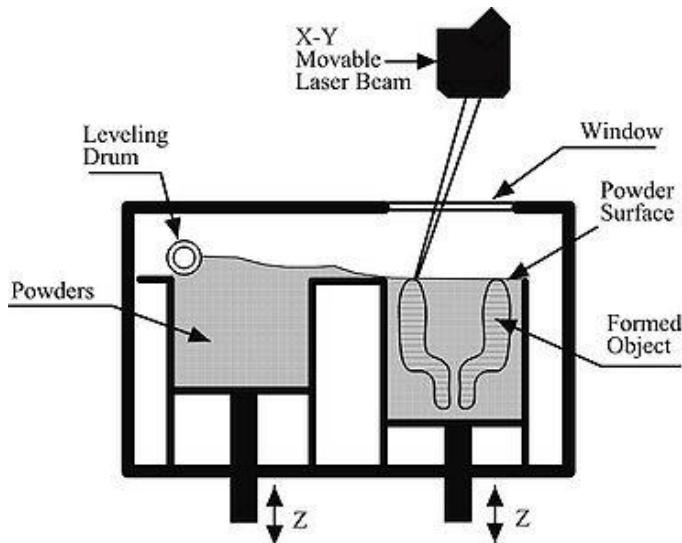


**Figure 3.22** The principle of the SLA process.

### 3.4.2.3 Selective Laser Sintering (SLS)

The SLS technology, as seen in Figure 3.23, is in many ways similar to the one of SLA, but instead of liquid resin, SLS uses a powder of plastic, metal, ceramic or glass. A high power laser fuses the powder particles together by tracing layers of the 3D object one by one on a powder bed. In between each layer the powder bed descends by the thickness of one layer followed by a levelling drum or roller distributing a new layer of powder on top. This procedure continues until the whole object is finished.

As opposed to the FDM and SLA process, SLS does not need any separate support material since all unused powder remains around the object providing a natural support structure. Much of the remaining powder can also be reused for the next print session [5].



**Figure 3.23** The principle of the SLS process.

### 3.4.3 Applications in the Field of Medicine & the Prosthetics Industry

As the 3D technology has evolved, so has its application in various fields. When it comes to medicine, 3D printing is for example used to fabricate anatomical models for surgeons to simulate complex operations, in pharmaceutical research to personalize dosages and creating multi-dosages and in the new, evolving application bio-printing where living cells are used for 3D printing of human tissue for organs and body parts. Bio-printing is however still at an early development stage.

Furthermore, 3D scanning and printing have enabled the customisation of prostheses, orthoses and implants [17]. However, in the prosthetics industry, the largest manufacturers have not yet adopted 3D printing on a larger scale. Most prostheses are created according to a range of standardised sizes and appearances of the components, often by using more traditional machining processes based on subtractive manufacturing, while other prosthetic parts that are more customised, such as the socket, often involve a great deal of manual work to produce [18], [4]. Nevertheless, some collaborations between large prosthetic manufacturers and smaller companies focusing on 3D technology and the personalisation of prostheses are starting to appear [19], [20].

Several projects involving the creation and implementation of custom-made prostheses using 3D technology have received public attention. One of these is “A Leg That Fits”, see Figure 3.24 - a prosthetic leg where not only function but also aesthetics was given a central role, demonstrating much of the potential of using 3D technology in the manufacturing and personalisation of prostheses [21].



**Figure 3.24** A Leg That Fits - a customized 3D printed prosthetic leg.

Over the last few years, a number of non-profit organisations using 3D printing to create custom-made and affordable prostheses have emerged. One of the most established is e-Nable, an open source community where 3D printed prosthetic hands (see Figure 3.25) and arms are provided for free to those in need [22].



**Figure 3.25** The Raptor Reloaded, one of the hand designs from e-Nable.

Other organisations such as Project Daniel, Nia Technologies and 3D LifePrints focus on using 3D technology to provide amputees in developing countries with prosthetic devices [23], [24] & [25].



## 4 Define

*In this chapter the start and end points of the process are defined and results of a user study is presented. The user study clarifies who the main user is and the identified needs of the user with regards to the process. The needs are interpreted and converted into process requirements that are ranked in relation to each other and used as guidelines in the future work of developing the new process.*

### 4.1 Process Start and End Point

As previously stated, the desired output of the process to be developed is a perfectly fitted prosthetic arm socket. Hence, when the patient has been provided with a ready-to-use socket, the end point of the process has been reached. However, in order to give the socket its customised features, patient data regarding shape and size of the residual limb is necessary. This data will be the primary input to the process and the activity of collecting the data, the start point. Together with start and end points, all intermediate steps are to be determined, adapted and described to ultimately form the new process.

A simple visualisation of the input-output relation is shown in Figure 4.1.



**Figur 4.1** Primary input and output of the process.

### 4.2 User Study

#### 4.2.1 The User

The primary user of the new process is the maker of the socket, generally a prosthetist. The prosthetist takes part in all stages from measuring, designing, producing, and fitting of the socket with a patient in the current process.

#### 4.2.2 User Needs

An in-depth interview was conducted with two employees at Aktiv Ortopedteknik in Lund; Christian Veraeus, prosthodontist and Sven-Olof Frank, prosthodontist and orthopaedic manager.

Table 4.1 shows statements from the interviewees interpreted into user needs. The importance of these needs were later rated by the user on a scale of 1-5, where 5 is *Critical process feature* and 1 is *Unnecessary process feature*.

**Table 4.1** User statements interpreted into user needs and their rated importance.

Topic	Statement	User Need	Imp.
Issues with the current way of manufacturing.	<i>There are many steps to create the mould of the residual limb.</i>	Fewer steps to create the socket.	4
	<i>A socket can take up to 2 weeks, +- a few days, from start to finish.</i>	Shorter lead time of the socket.	4
	<i>There are many human errors and manual processing involved, hence a constant error margin.</i>	The process is accurate.	5
	<i>It is difficult to go back in the process to make changes with precision.</i>	Ability to make detailed changes.	4
	<i>Making the initial cast mould is a rather messy and smudgy procedure, which is not very appreciated.</i>	The process is tidy.	3
	<i>The cast has to remain on the patient's residual limb until it has dried and hardened. The process of later removing the cast can sometimes create discomfort for the patient.</i>	Methods are gentle to the patients.	4
Advantages of the current way of manufacturing.	<i>The current manufacturing method gives you a type of muscle memory knowing where the soft and bony parts are located.</i>	Ability to identify and visualise the patient's anatomy.	4
	<i>Material-wise, making the cast mould is cheap.</i>	Material is inexpensive.	3
Important aspects of a new process.	<i>I want to feel that I am in control of the process.</i>	The process is easy to manage.	4
	<i>I want the result to be what I envision beforehand.</i>	The process can create a product aligned with the initial idea.	4
	<i>When learning a new method, I prefer a combination of theoretical and practical instructions.</i>	Process instructions are presented both in writing and practise.	3

Previous experience.	<i>CAD/CAM and scanners do exist in the company but are used for orthoses and lower-limb sockets preparing them for milling. It is not exactly a part of the work tasks to use CAD, but we have a software for creating insoles, however, it is very simple and customised for the purpose of just making insoles.</i> <i>We don't have any 3D printers so the experience is very low.</i>	3D technology and software are easy to learn.	3
The patient.	<i>Every patient is unique which also applies to the sockets.</i>	Possibility to create different types of sockets.	4
	<i>Most patients start with a cosmetic prosthesis, some decide to have both a cosmetic and a myoelectric. When making the socket for a myoelectric prosthesis, dummies need to be used to create space for electrodes.</i>		
	<i>If the amputation is due to e.g. an accident, the look of the residual limb can differ a lot and have more areas that are sensitive or sore.</i>	The process is adaptable.	4
	<i>Some amputations leave a lot of soft tissue while others have mostly bony parts. This affects how the feel of different materials are experienced and also the look of the socket.</i>		

### 4.3 Process Requirements

User needs identified in the previous subchapter were categorised and converted into process requirements. By using the importance rating of the needs, the requirements were given a relative ranking, see Appendix B. These requirements are to function as guidelines throughout the development of the process to ensure that user needs are fulfilled.

In descending order of importance, the process requirements are:

- **Effective**
- **Flexible**
- **Efficient**
- **Patient-friendly**
- **Easy to learn and manage**
- **Economical**

The process should be effective in the sense of successfully producing the desired result, allowing the user to go from idea to finished product and doing so in an efficient way reducing the lead time of the socket.

Process flexibility is essential in order to meet each patient's individual needs and preferences in terms of comfort and fit of the socket and also since the socket design differs depending on which type of prosthesis the patient chooses.

The process should also be patient-friendly, not inflicting any pain or discomfort on neither adult nor child patients.

Owing to the user's limited experience in 3D technology the process should be easy to learn and manage, giving the user a feeling of being in control of every step along the way.

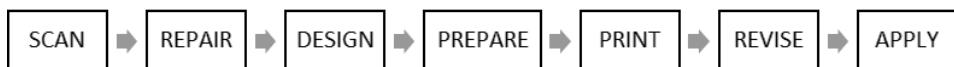
Furthermore, the process should be economical, financially competitive when compared to the conventional way of manufacturing.

## 5 Identify

*In this chapter essential steps to create an object with 3D technology are first identified. This is followed by the steps being adapted to the case of producing a prosthetic socket. Moreover, potential software to be used in the process is considered for further testing.*

### 5.1 From Scan to Print - Generic Approach

As known from the very beginning of this project, the main tools to be used are 3D scanning and 3D printing. When these tools are used in combination with each other the scanner is essential in the initial step of capturing and digitalising the desired object, whereas the printer is part of the production stage, creating the physical object [26 pp.4-6], [27]. To get from start to finish, however, a series of intermediate as well as additional finalising steps need to be completed in order to have an object ready to be put to use. Figure 5.1 roughly illustrates this workflow and each step is briefly explained below.



**Figure 5.1** Overview of how to create a 3D printed object from a scan.

**Scan** – by scanning, a digital model of the object is created.

**Repair** – a digital clean-up of the scan is made since it might contain unwanted gaps, holes and other imperfections, depending on the quality of the scanner.

**Design** – if wanted, the scanned object can be modified with the help of a CAD or other 3D modelling software to obtain a desired design. It is also possible to skip this step and use the scan as it is.

**Prepare** – if the model is not already in the appropriate file format, it needs to be converted. Most commonly used is the STL format. For the object to print properly the model needs to be inspected to ensure it is manifold, all surfaces are closed, minimum wall-thickness is fulfilled and that normal vectors are not inverted.

**Print** – the software connected to the printer is used to digitally size, orient and slice the model into layers. This information is provided as instructions to the 3D printer, which then builds the physical object layer by layer.

**Revise** – the printed object is inspected and post-processing such as removal of excess material, painting etc. is performed if necessary.

**Apply** – the printed object is put to use.

## 5.2 From Generic to Adapted Approach

In chapter 4, the process start and end points were defined as “Collect patient data” and “Provide patient with ready-to-use socket”. With this in mind and by using the generic approach from the previous subchapter, an approach adapted to the case of producing a prosthetic socket, see Figure 5.2, could be created and used as a main structure for the further work of developing the process.



**Figure 5.2** Adapted approach to creating a prosthetic socket with 3D technology.

**Collect Patient Data** – by 3D scanning the patient’s residual limb, data in terms of shape and size is collected, resulting in a digital model of the limb.

**Repair Scan** – the digital scan might contain incomplete sections such as gaps and holes. By using appropriate software these sections can be filled in and surface touch-ups can be made to obtain a scan as corresponding to the actual limb as possible.

**Create 3D Model of Socket** – with the scan of the patient’s residual limb as reference, a 3D model of the socket is designed. A CAD or 3D sculpting program is required in this stage. Furthermore, adjustments of pressure points as well as space for possible electrodes need to be taken into consideration when designing.

**Prepare Socket for Printing** – convert the socket model to the appropriate file format and ensure that the file is printable.

**Print Socket** – the physical socket is 3D printed according to instructions generated by the printer software.

**Post-Processing** – the printed socket is inspected and depending on the type of 3D printer used, sanding or other surface processing methods might be necessary to smoothen surfaces or remove sharp edges and excess material.

**Ready-To-Use Socket** – the patient can be provided with the custom fitted socket. If electrodes are required, they are added in this stage.

As from now, further work of aligning the finished socket with the artificial limb can begin.

### 5.3 Software

In order to edit the scan and create the socket before printing, 3D software is necessary. A number of relevant software was therefore identified to eventually be tested further along in the project. Due to time limitations, the number of software to test was confined to three different options.

The list below comprises software already familiar to the writer of the thesis, as well as software described in studied material [28], [29].

- Blender – free software for 3D modelling, animation and rendering.
- Meshmixer – free 3D modelling software from Autodesk.
- Creo Parametrics 2.0 – sophisticated CAD software. License provided by Lund University.

These software programs were selected to achieve a broad range in terms of interface style, offered functions and sophistication.



## 6 Explore & Evaluate

*This chapter describes the work of exploring different options when collecting patient data and methods of modelling the socket. It involves becoming familiarised with potential software followed by the evaluation and ultimately the selection of the best suited modelling method and software to be used in the process.*

### 6.1 Options for Collecting Patient Data

The first step of the new as well as the conventional process involves collecting patient data. Since this, together with providing the finished socket, is the only step of the new process where the patient is physically involved, the requirement “Patient-friendly” needs to be taken into consideration.

Using a 3D scanner as the main tool for the initial step of the new process was known from before. The scan of the residual limb will provide the foundation for shaping a customised socket for each individual patient. Nevertheless, the scan itself does not provide specific information of sensitive or less sensitive areas. This information has to be obtained in dialogue with the patient.

As found during the pre-study, information regarding bony prominences, skin sensitivity and soft tissue areas of the patient is crucial for the prosthodontist to collect in order to create a comfortable, well-fitting socket. In the conventional manufacturing process this information is marked out with a water-soluble pen on the patient’s residual limb when making the initial cast and transferred to the following plaster model.

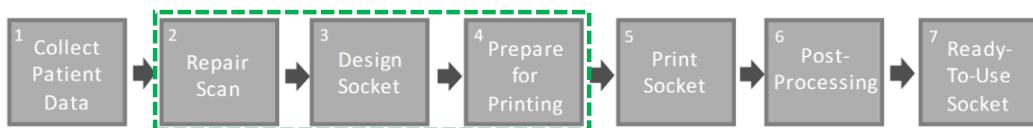
The only thinkable option to the method already in use would be to avoid the markings. In this case, it would be necessary to rely solely on the prosthodontist’s memory from examining and speaking to the patient as well as making many assumptions when modelling the socket. Naturally, the risk of creating an ill-fitting socket would in this case be considered far greater than if the information was visually available from the beginning and throughout the modelling procedure.

Since the 3D scanner to be used is able to capture colour, markings made on the residual limb prior to scanning will subsequently be visible also on the digital model, facilitating more precise adjustments when designing the socket. The activity of making the markings is from the conventional process known to be rather swift and also not a cause of discomfort or pain for the patient. The latter consequently verifies the fulfilment of the established requirement “Patient-friendly”.

With this background, the current method of marking out important areas on the residual limb was decided by the writer of the thesis, after discussions with Christian Veraeus at Aktiv Ortopedteknik, to be the best option also for the new process. Performing further testing and evaluation of the two mentioned options was therefore considered unnecessary.

## 6.2 Software Use

As shown in Figure 6.1 below, the steps 2-4 from the adapted approach described in chapter 5, require the use of software.



**Figure 6.1** The steps where software is needed, marked out with dashes.

By using practical learning, tutorial studies and previous experience in CAD, the functions of the three potential software were explored in order to determine what they offer in terms of methods of designing the socket. Which of the three steps – Repair, Design and Prepare – they can perform, was also investigated.

## 6.3 Socket Modelling Methods

The two most common types of transradial prostheses created at Aktiv Ortopedteknik are the passive and myoelectric [4]. On this basis, only modelling methods for sockets intended for these prostheses were explored.

If the same type of interface and suspension system are used, the overall design of a passive and myoelectric socket is identical except for one feature – the cavities required to provide space for electrodes on the myoelectric socket [4]. When exploring different modelling methods, the procedure of creating the main shape of the socket was therefore considered to be the same for both socket types. In the case of a myoelectric socket, methods for creating and including the electrodes were handled separately, but with the intention of further ahead being incorporated, much like an add-on, to the main modelling procedure.

### 6.3.1 Main Shape

By experimenting with the software, four methods of designing the main shape of the socket were identified. Common for all four is that they involve performing a so called boolean operation where parts imported or created in the software can either be united, an intersection of the parts can be generated or, as in the case of creating the hollow socket, parts can be subtracted from each other [30].

The way each method is performed can differ between the tested software. As a result of this, general descriptions of the four identified methods are given:

- A1.** Create a generic solid socket by using sketch planes at adjustable distances in a CAD software. Each plane contains an ellipse, also with adjustable dimensions. By using a blend or loft tool between the ellipses, a solid socket is created. An adjusted scan of the residual limb is then imported and used to subtract material from the solid shape created between the planes. This leaves a hollow socket with the interface formed according to the residual limb.
- A2.** Import the scanned residual limb to the software and add or remove material as necessary, according to previously made markings. Create a copy and scale it slightly larger followed by shaping the trimlines. The original adjusted scan is then used to subtract material, leaving a hollow socket with an interface shaped according to the residual limb.
- A3.** Import the scanned residual limb to the software and add or remove material as necessary. Create and keep a copy of the adjusted scan while using the original to create an offset of selected areas. The offset value is set according to the desired thickness of the socket. The created copy is now used to subtract material from the offset scan, leaving a hollow socket.
- A4.** Scan a finished socket. Scale, thicken and manually adjust the shape in the software followed by importing a scan of the residual limb that is modified according to markings. Subtract the scan of the residual limb to create the hollow socket.

In Table 6.1, advantages and disadvantages, as experienced by the writer, are described for the respective modelling method and an overview showing which of the software that can perform each method is given. Included is also which of the steps Repair, Design and Prepare the software can manage.

**Table 6.1** Advantages and disadvantages of the respective modelling method as well as which method and process step are offered by each software.

Modelling Method	Main shape	Advantages	Disadvantages			Software
			Blender	Meshmixer	Creo Parametrics	
A1 (Adjustable planes)		1. Exact geometry values can be used when modelling. 2. The main structure of the socket only has to be created once. After establishing the main structure it can be adapted to each new patient by adjusting the measurements of the ellipses and the distances between the sketch planes.	1. The scan of the residual limb has to be repaired and adjusted in another software and converted to a file format compatible with the CAD program (Creo) before it can be imported and used to hollow out the socket model. 2. Requires taking measurements of several parts of the patient's residual limb, which means an additional activity in the process. 3. Difficult to obtain an even wall-thickness. 4. Time consuming and difficult to create and modify trimlines.	NO	NO	YES
A2 (Scale)		1. A rather quick method since the overall socket shape does not need to be modelled from scratch. It reuses the existing shape of the scanned residual limb.	1. Difficult to control the exact wall-thickness. 2. Shaping the trimlines involves some freehand sculpting, which can require extra time before proficiency increases.	YES	YES	YES
A3 (Offset)		1. Thickness of the socket is easily controlled by simply typing in desired value. 2. A rather quick method since the overall socket shape does not need to be modelled from scratch. It reuses the existing shape of the scanned residual limb.	1. Shaping the trimlines sometimes involves some freehand sculpting or smaller modifications, which can require extra time before proficiency increases.	YES	YES	YES
A4 (Scanned socket)		1. Trimlines are already shaped. 2. The finished socket used as a base requires a great deal of modification to adapt it in shape and size to every new residual limb. Difficult to obtain a good match between them both. 2. Difficult to control the exact wall-thickness.	1. The finished socket used as a base requires a great deal of modification to adapt it in shape and size to every new residual limb. Difficult to obtain a good match between them both. 2. Difficult to control the exact wall-thickness.	YES	YES	YES
Step						
Repair					YES	YES
Design					YES	YES
Prepare					YES*	YES*
						YES&NO**

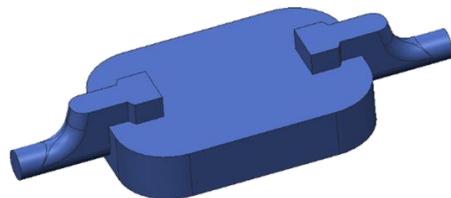
\* Both Meshmixer and Blender can modify, export and completely prepare STL files. Meshmixer can be directly connected to a 3D printer. However, the number of printers compatible with the software are few. Currently compatible are desktop printers from MakerBot and Type A Machines and also a variety of printers from Stratasys. In other cases, an additional 3D printer software needs to be used to generate the necessary instructions for the printer.

\*\* Creo can export to but not modify an STL file. A secondary software is needed to further inspect and prepare the file for printing.

### 6.3.2 Electrodes

Regarding the digital reproduction of the electrodes for a myoelectric socket, following three methods were considered for inclusion in the process:

- B1.** Scanning the electrode dummy separately, repairing the scan if needed before using it when modelling the socket.
- B2.** Temporarily attaching the two electrode dummies to the desired location of the patient before scanning the complete residual limb.
- B3.** Measuring the physical electrode dummy and recreate it in a CAD software (see Figure 6.1), followed by importing and using it when modelling the socket.



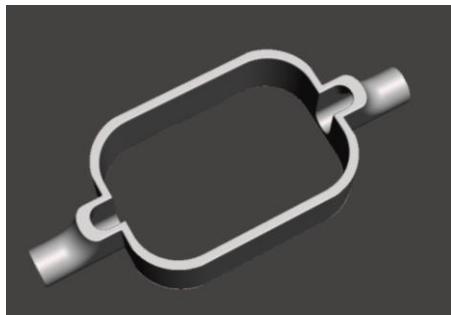
**Figure 6.1** CAD model of the electrode dummy used in the conventional process of creating sockets for myoelectric prostheses.

When exploring the three different options it was quickly discovered that the scanner to be used throughout this project does not properly capture the electrodes due to their small size. This left B3 as the only feasible option.

The two options B1 and B2 which were discarded, could however still be possible alternatives if a scanner of higher precision were to be used [31].

Recreating the electrode dummy in CAD from the actual measurements is considered by the thesis writer to be a highly suitable option. In this case it provides more control over the dimensions with less risk of deviations created by the current scanner. Also, since the electrodes used at Aktiv Ortopedteknik are standardised in shape and size, the CAD model of the electrode only needs to be created once.

The CAD model was then used to create attachments to be added to the main socket shape. Two attachment designs were made, shown in Figure 6.2 and 6.3. Both have two notches to facilitate the insertion of the electrode pins from the outside of the socket.

**Figure 6.2** Attachment design 1.**Figure 6.3** Attachment design 2.

After discussions with Christian Veraeus at Aktiv Ortopedteknik, attachment design 2 was chosen since it has a smoother transition to the socket, which would facilitate the following work of completing the entire prosthesis.

The file containing the attachment and the dummy was saved and can easily be imported every time it is needed during modelling.

### *6.3.3 Evaluation and Selection of Modelling Method*

The identified modelling methods for the main socket shape were evaluated by using a concept screening matrix, see Appendix C. Evaluation criteria were:

- Ease of learning
- Accuracy
- Adaptability
- Efficiency
- Adjustability

Ease of learning refers to the possibility of quickly mastering the method of modelling the socket.

The accuracy of the method is important in order to create the complete socket with an overall precision and according to the initial idea.

Adaptability relates to being able to form the socket according to the shape and size of the scanned residual limb.

In order to shorten the lead time, the efficiency of the method is highly relevant.

Adjustability is important to allow both minor and major design modifications while modelling.

The concept screening resulted in the selection of modelling method A3 (Offset) as the best suited option.

## 6.4 Software Evaluation & Selection

Since a central part of the process and determining factor for the process output is the user's interaction with the software, the requirements established for the complete process in chapter 4 were used as criteria to evaluate the tested software. The requirement "Patient-friendly", however, was not included since the patient does not interact with the software.

The evaluation was conducted by using a concept scoring matrix with the following criteria:

- Effective
- Flexible
- Efficient
- Easy to learn and manage
- Economical

For further descriptions of these criteria, refer to chapter 4.

The concept scoring, found in Appendix C, resulted in the selection of Meshmixer to be used as software for the process.

According to the thesis writer, the chosen software is the most suitable for the purpose of this project since the simple, uncluttered user interface enables an intuitive navigation where key functions are easily accessed in the software - important aspects when the user has little to no previous experience in 3D modelling.

The software is free and allows the user to easily adapt the design of the socket to each individual patient. It is easy to undo operations and make detailed changes, giving the user control over the process. The software can also perform all three of the process steps – repair, design and prepare, which adds to process efficiency compared to having to use several different software.



## 7 Create

*This chapter describes the first round of process testing. Socket prototypes are created by using the selected software and modelling method together with all necessary hardware in order to better assess both process and socket quality and design before involving actual patients.*

### 7.1 Hardware

The hardware used for prototyping, as well as for the validation further ahead, is the hand-held iSense 3D scanner and the EOS Formiga p110 3D printer. Both are provided by the Department of Design Sciences at Lund University and further described in the following two subchapters.

#### 7.1.1 iSense 3D Scanner

The iSense scanner, see Figure 7.1, is a low-cost scanning device mounted on a regular iPad. It uses laser technology where an invisible infrared laser pattern is projected onto the surroundings and picked up by an infrared sensor to determine distance. The iSense also has two cameras, where one captures geometry and the other captures colour. All the collected data is then, by the scanner using a complex algorithm, turned into a 3D model of the scanned object [32], [33].



**Figure 7.1** The iSense 3D scanner used throughout this project.

#### 7.1.2 EOS Formiga p110 3D Printer

The EOS Formiga p110, seen in Figure 7.2, uses the SLS technology described in chapter 3.

After consulting Professor Olaf Diegel at the Division of Product Development at Lund University, it was decided that the SLS technology is the most suitable for

printing the sockets since it creates objects with high accuracy, close to equal quality in all xyz-directions and with a good surface finish, requiring little post processing.



**Figure 7.2** The EOS Formiga p110 3D printer available at the IKDC product lab at Lund University.

#### 7.1.2.1 Printing Material

The EOS Formiga p110 can print objects in a variety of materials, but the one used at the product lab and thus for the sockets is PA2200, also known as polyamide 12 or nylon 12. It is a thermoplastic that gives the printed parts a white colour. It can however be dyed or painted to achieve a variety of other colours as well [34].

PA2200 has material properties such as flexibility, high strength, excellent long-term constant behavior and biocompatibility – properties that make it suitable to use e.g. for prosthetic parts [35]. For more detailed information regarding material properties, refer to the Material Data Sheet in Appendix D.

### 7.2 Socket Prototypes

To create the first prototype, a plaster model from Aktiv Ortopedteknik was used to imitate the residual limb, see Figure 7.3. Due to the lack of flexibility in the plaster model, as opposed to an actual limb, the fit of the prototype could not be tested at this stage.

For the second prototype, a scan of an actual limb was used, see Figure 7.4. Since no amputee patients were yet involved, a healthy arm was scanned and adjusted in the scanner software. This was decided by the writer of the thesis in order to practice modelling sockets for different shapes of residual limbs. As in the case of the first prototype, the socket fit could not be tested. However, markings to indicate trimlines, condyles, electrode placement and areas to remove or add material were still made on the plaster model and healthy arm to simulate the initial step of the actual future process.



**Figure 7.3** Plaster model used for the first prototype.



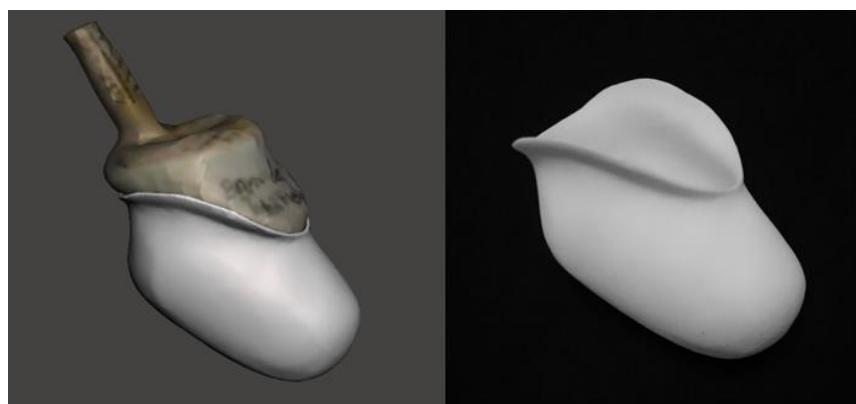
**Figure 7.4** Scan of healthy arm adjusted in the scanner software and used for the second prototype.

After discussions with the prosthetist Christian Veraeus and Jonny Nyman, research engineer at the ID-A workshop at Lund University, the general wall-thickness of the sockets was set to two millimeters. Due to the fact that it is the average wall-thickness of the current sockets made at Aktiv Ortopedteknik and also after inspecting previously printed objects at the product lab, two millimeters was decided to be a suitable first choice.

After being modelled and printed, post-processing of the sockets was made in terms of removing excess powder and smoothening of surfaces by sanding with 800-1000-grit sandpaper.

### 7.2.1 First Prototype

A socket intended for a passive prosthesis was first prototyped, see Figure 7.5 for both the digital and printed version.



**Figure 7.5** Digital and printed version of the first socket prototype.

### 7.2.2 Second Prototype

Secondly, a myoelectric socket was prototyped where the previously created electrode attachment was twice added to the model, one on each side. After being printed, an electrode was fitted to each attachment. Figure 7.6 shows both the digital and physical version of the prototype.



**Figure 7.6** The digital and printed version of the second socket prototype, intended for a myoelectric prosthesis.

### 7.2.3 Third Prototype

The two previously created prototypes are firm and robust, much alike the hard laminated sockets made in the conventional way of manufacturing. Similar to a laminated socket, they lack the flexibility provided by a thermoplastic or silicone socket.

In order to provide a more flexible option when it comes to the 3D printed sockets, a third prototype was later designed and printed, see Figure 7.7. Just as the first two prototypes, the third was modelled using the previously selected software Meshmixer.



**Figure 7.7** The digital and printed version of the third, more flexible socket prototype.

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The prototype design has an added lattice pattern and an overall wall-thickness of two millimeters, where the pattern constitutes one millimeter and the smooth solid part of the socket was reduced to one millimeter. This provides the socket with increased flexibility while maintaining stability.

Obtaining a socket with equal flexibility and softness as a silicone socket is however not possible due to the difference in properties of the available printing material.

### 7.3 Assessment

The prototypes were assessed by consulting the prosthetist Christian Veraeus. Socket design was discussed and a summary of expressed opinions are listed below.

- Two millimeter wall-thickness works well for the sockets. Reducing the thickness to one and a half millimeter for the standard smooth socket could also be an alternative if a slightly more flexible socket is needed.
- The trimline shape of the second prototype should be more similar to the ones of the first and the third prototype – a deeper opening in the front near the bend of the arm and reach slightly higher above olecranon.
- The third prototype with the lattice pattern is a very good complement to the standard smooth socket, both in terms of aesthetics and function. The pattern provides a structure that facilitates the attachment of fairings in the further work of assembling the entire prosthesis.
- The overall shape of the electrode attachments would also work very well in the further work of completing the prosthesis. The cavity created for the electrode itself could however be slightly narrowed and the notches added to facilitate the insertion of the electrode pins, rotated 180 degrees to the inside of the socket. This is to avoid the risk of the electrodes being pushed out of the attachments when exposed to pressure from the residual limb. These adjustments would mean that the electrodes need to be inserted from the inside of the socket instead of the outside, which, according to Christian Veraeus, will not be an issue in the assembly.

Based on the discussion, a mutual decision was made that after minor adjustments of the electrode attachment and by keeping the assessment result in mind, the process was ready to be tested with actual patients.

### 7.4 Iteration

To ensure that the desired adjustments of the electrode attachments are correctly made before proceeding, one attachment was 3D printed and fitted with an electrode, see Figure 7.8.



**Figure 7.8** The digital and printed version of the revised electrode attachment.

The width and inner edge radius of the attachment cavity were reduced by one millimeter each and the notches were rotated 180 degrees from the top of the attachment to the bottom.

As desired, the adjustments secured the positioning of the electrode, preventing it from being pushed out of its attachment when exposed to pressure from the residual limb.

## 8 Integrate

The knowledge and information acquired thus far is in this chapter used to compile the complete process. In order to have a clear overview of the procedure, each of the seven previously defined steps is divided into several substeps.

### 8.1 Compilation of Final Process

By integrating the findings from preceding phases with the structure of the adapted approach established in chapter 5, see Figure 8.1, the main steps of the elaborated process were broken down into substeps.

Following subchapters describe these steps and related substeps further.



**Figure 8.1** The seven steps of the adapted approach described in chapter 5.

#### 8.1.1 Collect Patient Data

As described in Figure 8.2, the process starts with the prosthetist, in dialogue with the patient, marking out important areas of the residual limb that need to be taken into consideration when modelling the socket. These involve areas in need of pressure relief or additional pressure. Shape and location of trimlines are also marked out as well as placement of electrodes if the socket is intended for a myoelectric prosthesis. This is followed by the prosthetist instructing the patient on how to position the residual limb. Thus far the procedure follows the conventional way.

Finally, the residual limb is scanned by the prosthetist and the file is saved to the iPad connected to the scanner.



**Figure 8.2** Substeps of collecting patient data.

### 8.1.2 Repair Scan

The saved file containing the scanned residual limb is transferred from the iPad to the computer, where it is imported into the software Meshmixer.

The scan is inspected to determine if it contains any incomplete sections such as holes or other unwanted features. These sections can be filled in either by using the automatic repair function of the software or by manually performing necessary surface touch-ups, in order to obtain a scan as corresponding to the actual residual limb as possible.

Figure 8.3 below summarises the subtasks of this process step.



**Figure 8.3** Substeps of repairing the scan of the residual limb.

### 8.1.3 Design Socket

By digitally adding or removing material according to the markings made before scanning, necessary pressure points as well as trimlines are adjusted in the software.

Copies are made of the scan to keep as reference and for hollowing out the socket further ahead in the modelling procedure.

The areas needed for the socket are selected on the adjusted scan and used to create an offset with the same value as the desired thickness of the finished socket. One of the previously created copies of the adjusted scan is now used in a boolean operation to subtract material, leaving a hollow socket.

After this, complementary shaping of the trimlines and surface smoothening of the socket is performed. For a plain socket intended for a passive prosthesis, this is the last substep of designing the socket.

In the case of a myoelectric prosthesis, two additional substeps are included, marked as blue in Figure 8.4 below. These involve importing the file containing the electrode module and placing one on each side of the socket, followed by subtracting the accompanied electrodes. This is also performed through a boolean operation, in order to create the necessary cavity all the way through the socket wall.

To apply a pattern to the passive or the myoelectric socket, similar to the third prototype created in chapter 7, another substep, marked as orange in Figure 8.4, is added to the process.

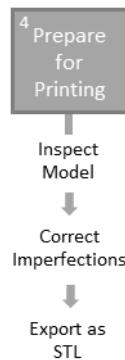


**Figure 8.4** Subtsteps of designing the socket.

### 8.1.4 Prepare for Printing

To ensure that the modelled socket is printable, it needs to be inspected. Just as in the *Repair Scan* step, this can be done by using the Inspector function in the software. The function will indicate if the model contains imperfections such as holes, non-manifold edges or disconnected parts. These imperfections are corrected either by using the automatic repair function or by manual correction, one by one.

When no imperfections remain, the model is finally exported as an STL-file. The whole sequence of substeps can be seen in Figure 8.5 below.

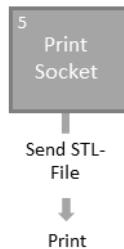


**Figure 8.5** Substeps of preparing the socket for printing.

### 8.1.5 Print Socket

Since no 3D printer is currently available at Aktiv Ortopedteknik, the STL-file containing the modelled socket can be sent to a prototype workshop, such as the product lab at Lund University. An alternative is online 3D printing services such as Shapeways and Sculpteo, where an uploaded file can be printed and shipped to the customer. For additional fees, the printed object can also be post-processed and coloured. The use of online printing services will however not be further investigated in this report.

The only action necessary from the prosthetist, is providing the STL-file to the chosen printing service. All tasks involving the actual printing procedure and the removal of the model from the machine are handled by the printer operator. These tasks, such as generating printer instructions, operating the printer in general as well as rinsing or blasting the model after cooling, were therefore consolidated under the name Print, without being further specified or described, see Figure 8.6.



**Figure 8.6** Substeps of printing the socket.

### 8.1.6 Post-Processing

The printed socket is inspected by the prosthetist to identify areas particularly in need of refinement. Excess powder left from printing is removed and the inside of the socket that will be in direct contact with the patient's skin may require extra surface smoothening. This can be performed by polishing the surface with a fine-grit sandpaper.

Figure 8.7 below shows the three substeps of post-processing the socket.



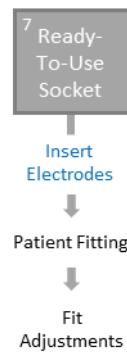
**Figure 8.7** Substeps of post-processing.

### 8.1.7 Ready-To-Use Socket

For a myoelectric socket, the electrodes are mounted to the attachments in this stage. This additional substep is marked as blue in Figure 8.8 below.

The socket can now be fitted with the patient and a myo-test of the electrodes are performed when needed. If necessary, minor adjustments are made and could involve using sandpaper to further smoothen the socket surface or a heat gun for reshaping smaller areas of the socket.

Hereafter, the finished socket can be used in the further work of completing the entire prosthesis for the patient.



**Figure 8.8** Substeps of the last step in the process.

# 9 Validate

*This chapter describes the validation of the elaborated process, where case studies involving two patients are performed as proof-of-concept. By following the previously established steps, a custom fitted socket is produced for each patient in order to determine process viability.*

## 9.1 Case Studies

The case studies were performed partly at Aktiv Ortopedteknik and partly at Lund University. The first and the last step of the in total seven step process, described in chapter 8, were performed at Aktiv Ortopedteknik. These are *Collect Patient Data* and *Ready-To-Use Socket*. Step two to six; *Repair Scan, Design Socket, Prepare for Printing, Print Socket* and *Post-Processing* were performed at Lund University.

The task handled by the prosthetist in the first step was marking out important areas of the residual limb. For the last step, the patient fitting was handled by the prosthetist. Remaining tasks were performed by the thesis writer.

After consulting Professor Olaf Diegel, performing two case studies were considered to be sufficient as proof-of-concept for the process. Moreover, after discussions with the prosthetist, it was decided that both case studies should involve a myoelectric socket. This is due to the process of creating the socket for a myoelectric prosthesis is identical to the one for a passive, except for the added electrode attachments. Hence, by using myoelectric sockets the validation applies to both processes.

### 9.1.1 Case Study 1

#### 9.1.1.1 Patient Information

The patient is a two-and-a-half-year-old girl with a congenital, transradial amputation on her left arm.

The residual limb, see Figure 9.1, is of medium length and with normal amount of soft tissue for her age and reason for amputation. There is no scarring or additional bone prominences to take into consideration, except for olecranon.

The patient has had a passive prosthesis since the age of five months and will soon receive her first myoelectric prosthesis.



**Figure 9.1** The residual limb of the first patient.

#### 9.1.1.2 Result

The 3D printed socket was donned on the patient with the help of some vaseline, which is common during patient fittings. Figure 9.2 shows the patient wearing the socket.



**Figure 9.2** The patient wearing the socket.

According to the prosthetist, the socket had a perfect volume and the myo-test indicated a good contact between the electrodes and the skin surface.

Due to the young age of the patient, evaluating statements from the patient herself was difficult to obtain. However, the fact that the patient was wearing the socket for a long time and with no complaints is according to the prosthetist a very good sign.

In addition, statements from the parent of the patient was very positive with regards to aesthetics - slimlined design and the added pattern.

### 9.1.2 Case Study 2

#### 9.1.2.1 Patient Information

The patient is a 34-year-old man with a congenital, transradial amputation on his left arm.

The residual limb, seen in Figure 9.2, is of medium length and has a normal distribution of soft tissue and bone prominences. There is no scarring.

The patient has been using a prosthesis since the age of three months. He currently has both a passive and a myoelectric prosthesis, however the myoelectric is more frequently used.



**Figure 9.3** The residual limb of the second patient.

#### 9.1.2.2 Result

The socket was donned and doffed independently by the patient, who can be seen wearing the socket in Figure 9.4.

The fit and the material was considered by the patient to be comfortable, light and with a perfect amount of space in the front of the socket.



**Figure 9.4** The patient wearing the socket.

The shape of the trimlines were considered to be very good, not causing any chafing against the skin.

The myo-test indicated a good contact between the electrodes and the skin surface. The personal preference of the patient was however for the socket to be slightly tighter over the electrode attachments, approximately one millimeter.

## 9.2 Validation Assessment

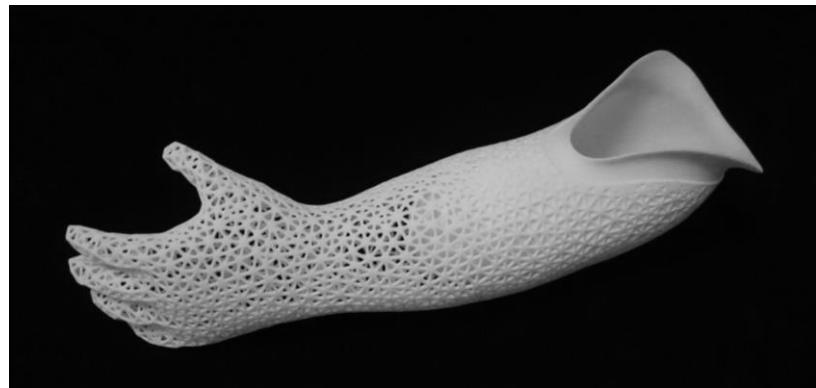
A follow-up discussion was held with the prosthetist after finishing the case studies. By looking at opinions and statements from both the patients and the prosthetist regarding fit, feel and appearance as well as the outcome of the myo-tests, both case results were considered successful.

The one millimeter fit adjustment that would be necessary in the second case study in order to achieve the perfect fit, is considered to be more a result of the thesis writer lacking orthopedic and patient experience rather than a process flaw. Such a small adjustment can be performed simply by using a heat gun. However, an important learning from this, when keeping a dialogue with the patient during the *Collect Patient Data* step, is to actively seek this type of information in order to detect specific preferences of the patient regarding the fit. This can then be used when later designing the socket.

Moreover, what could be done is to add slightly more flexibility in the movement of the electrodes. This can easily be adjusted by, for example, increasing the diameter of parts of the holes created for insertion of the rubber pins of the electrode, which would allow for a freer perpendicular movement of the electrode in relation to the residual limb. This, together with the one millimeter fit adjustment in the second case study were however not considered to affect the process itself in terms of structure or line of action. On this basis, the process was considered to be validated and thus no iterative troubleshooting activity was carried out.

### 9.3 Extension of Case Study 1

After the validation sessions had been performed it was decided together with Professor Diegel to extend the first case study. The extension involved the creation of a complete cosmetic arm prosthesis integrated with a passive socket, see Figure 9.5. This was however kept outside of the original process validation, but included in the thesis as a way of displaying the role of the socket as well as to further demonstrate some of the possibilities offered by 3D technology in the manufacturing of prosthetics.



**Figure 9.5** The 3D printed cosmetic arm prosthesis integrated with a passive socket.

Just as the previously made sockets, the arm was created using Meshmixer. The intention was to 3D scan the healthy arm of the patient, mirror it and integrate it with the socket. However, due to lack of time, an existing file of an arm was used instead. It was then redesigned and resized according to patient measurements previously obtained by the prosthetist.

The patient wearing the 3D printed arm can be seen in Figure 9.6.



**Figure 9.6** The patient wearing the 3D printed arm.



# 10 Deliver

*This chapter describes how the validated process is presented to the user in terms of theoretical and practical instructions. The instructions are also evaluated together with the user and lastly, a comparison between the new and the conventional process with regard to lead times and costs is performed.*

## 10.1 Process Instructions

By consulting the previous user study and in further discussions with the prosthodontist, the need of having access to a combination of theoretical and practical process instructions was identified.

In order to facilitate the learning and implementation of the process, it was therefore decided that a booklet and a video tutorial were to be created as learning material.

### 10.1.1 Booklet User Guide

The booklet, see Figure 10.1, was created as a complete step-by-step manual to the elaborated process. It uses both images and text to describe each step, guiding the user from start to finish.



**Figure 10.1** The printed booklet user guide.

The finished booklet was printed in an A5-format and provided to the user both in digital and printed versions. A version of the booklet, formatted to suit this report, can be found in Appendix E.

### 10.1.2 Video Tutorial

As a more hands-on complement to the written instructions, a video tutorial was created to guide the user in the interaction with the software. This involves process steps 2-4, *Repair Scan*, *Design Socket* and *Prepare for Printing*. When designing the socket, the tutorial demonstrates the creation of the two traditional sockets types – the plain passive and the plain myoelectric. To apply a pattern to the socket, the user is referred to the written instructions.

Interacting with the software is, according to the thesis writer, the part of the process requiring the most practice. A video tutorial was therefore considered to be a good option to assist the user in quickly gaining proficiency. It can also be used alone or in combination with the written instructions.

The video tutorial was provided to the user as a media file and an online link to the video sharing platform Vimeo [36].

### 10.1.3 User Evaluation

Due to time limitations of this project, no extensive user evaluation was conducted where the prosthetist independently could carry out the full process. Nevertheless, the created learning material was presented to the user, who was asked to evaluate it in terms of structure, content and comprehensibility.

Although not being able to perform the various tasks while going through the material, the user expressed an overall positive review on all three evaluation points and was of the opinion that the material would be of valuable assistance in gaining proficiency in the process. However, by request of the user, a minor modification of the video tutorial was made, where the part of demonstrating the adjustments of pressure points and trimlines was slightly extended.

## 10.2 Process Comparison

The comparison between the conventional and the new process is made with regard to lead-time and cost and allows to further determine the fulfilment of the two process requirements *Efficient* and *Economical* that were defined together with four additional requirements in chapter 3.

The comparison is done with regard to a plain, myoelectric socket made from plastic. To be comparable, only sockets from the conventional process that have similar properties as the ones that can be achieved with the current 3D printing material, nylon 12, will be considered. Sockets made from silicone are therefore not taken into account when comparing the processes.

During one year, an average of 150 transradial sockets are produced at Aktiv Ortopedteknik in Lund. Out of these, 90 are plastic sockets that are distributed in three different categories; *Thermoplastic*, *Laminated* and *Thermoplastic with laminated support socket*. Due to the flexibility and softness of half of the sockets in

the third category, these 50% will not be part of the comparison. This results in a total of 67.5 sockets per year with properties comparable to the current 3D printing material. This corresponds to 75% of the plastic sockets and 45% of all 150 transradial sockets produced during one year.

The relative distribution between the three categories of plastic sockets from the conventional process as well as the number of sockets applicable for the process comparison can be found in Table 10.1.

**Table 10.1** Relative distribution between the three categories of plastic sockets as well as the number of sockets created with the conventional process that are applicable for the comparison.

	PLASTIC SOCKETS		
	THERMOPLASTIC	LAMINATED	THERMOPLASTIC WITH LAMINATED SUPPORT SOCKET
Transradial plastic sockets produced by the prosthodontist (sockets/year)	90		
Distribution (%)	15%	35%	50%
Distribution (sockets/year)	13.5	31.5	45
Applicable for comparison with Nylon 12 (%)	100	100	50
Applicable for comparison with Nylon 12 (sockets/year)	13.5	31.5	22.5
	67.5		

### 10.2.1 Lead Time

The total lead time for each process includes both time actively spent by the prosthodontist on the socket as well as time needed for drying of the plaster, cooling or curing of the plastic, 3D printing time etc, i.e. time when the prosthodontist is not bound to the process.

Time approximations are based on a high level of proficiency for the conventional process and an intermediate to high level of proficiency for the new process and with the assumption that no step needs to be redone. Furthermore, for the new process, time for printing of the socket is based on the use of Lund University as printing service. Due to its proximity to Aktiv Ortopedteknik, no consideration is taken to shipping time.

#### 10.2.1.1 Conventional Process

An overview of the main steps of the conventional process is shown in Figure 10.2.



**Figure 10.2** Main steps of the conventional manufacturing process.

Based on time approximations from the prosthodontist, lead time and active time for each of the three categories of plastic sockets are specified for these five steps. Time distribution and total time can be found in Table 10.2.

**Table 10.2** Total lead time and active time per socket for the three categories of plastic sockets using the conventional manufacturing process.

STEP	THERMOPLASTIC		LAMINATED		THERMOPLASTIC WITH LAMINATED SUPPORT SOCKET	
	Total lead time (h)	Active time (h)	Total lead time (h)	Active time (h)	Total lead time (h)	Active time (h)
1. Measurements & Casting	2.5	1.5	2.5	1.5	2.5	1.5
2. Modification of Mould	1.5	1.5	1.5	1.5	1.5	1.5
3. Create Test Socket	2.5	1.25	2.5	1.25	2.5	1.25
4. Fitting & Adjustment	1.5	1.5	1.5	1.5	1.5	1.5
5. Create Final Socket	2.75	2	15	2.75	6	3.75
<b>TOTAL</b>	<b>10.75</b>	<b>7.75</b>	<b>23</b>	<b>8.5</b>	<b>14</b>	<b>9.5</b>

#### 10.2.1.2 New Process

The time distribution of the new process, shown in Table 10.3, results in a total lead time of 14.85 hours from start to finish, based on approximations made by the thesis writer when carrying out the process.

Important to note is that the twelve hours required for the step *Print Socket* are six hours for the printing itself and six hours for cooling of the plastic in the printer. These twelve hours are time that can be spent doing other things. In other words, only 2.85 hours of the entire process requires the prosthodontist to actively work on the socket.

**Table 10.3** Total lead time and active time per socket, using the new process.

STEP	3D PRINTED SOCKET	
	Total lead time (h)	Active time (h)
1. Collect Patient Data	0.5	0.5
2. Repair Scan	0.2	0.2
3. Design Socket	0.75	0.75
4. Prepare for Printing	0.1	0.1
5. Print Socket	12	0
6. Post-Processing	0.3	0.3
7. Ready-To-Use Socket	1	1
<b>TOTAL</b>	<b>14.85</b>	<b>2.85</b>

### 10.2.1.3 Time Comparison

Due to the difference in lead time and active time between the three categories of plastic sockets in the conventional process, the comparison with the new process is first made for each category separately, see Table 10.4.

**Table 10.4** Comparison between the conventional and the new process with regard to total lead time and time actively spent working on a transradial socket.

	THERMOPLASTIC		LAMINATED		THERMOPLASTIC WITH LAMINATED SUPPORT SOCKET	
	Total lead time (h)	Active time (h)	Total lead time (h)	Active time (h)	Total lead time (h)	Active time (h)
	10.75	7.75	23	8.5	14	9.5
<b>3D PRINTED SOCKET</b>	14.85	2.85	14.85	2.85	14.85	2.85
Difference with regard to the new process (h/socket)	+ 4.1	- 4.9	- 8.15	- 5.65	+ 0.85	- 6.65
Sockets produced by the prosthetist (sockets/year)	13.5		31.5		22.5	
Difference (h/year)	<b>+ 55.35</b>	<b>- 66.15</b>	<b>- 256.73</b>	<b>- 177.98</b>	<b>+ 19.13</b>	<b>- 149.63</b>
Difference (%)	<b>+ 38</b>	<b>- 63.2</b>	<b>- 35</b>	<b>- 66.5</b>	<b>+ 6</b>	<b>- 70</b>

By using the new process, the total lead time is increased in comparison to a thermoplastic and a thermoplastic with laminated support socket, while it is reduced for the laminated type.

What is more interesting to look at, however, is how the time actively spent on the socket is affected; by using the new process the active time is significantly reduced (63.2-70%) for all three categories of plastic sockets, resulting in an overall reduction of 67%.

Over a year, with the current amount of transradial sockets that are comparable with the 3D printed ones, the total liberated time would be 394 hours by using the new process, see Table 10.5. Based on an 8-hour workday, this corresponds to 50 complete workdays.

**Table 10.5** Total amount of hours liberated per year by using the new process and the relative percentage distribution of these hours.

	ACTIVE TIME REDUCED WITH NEW PROCESS (h/year)	RELATIVE DISTRIBUTION OF REDUCED TIME (%)
THERMOPLASTIC	66.15	16.8
LAMINATED	177.98	45.2
THERMOPLASTIC WITH LAMINATED SUPPORT SOCKET	149.63	38
<b>TOTAL</b>	<b>393.76</b>	100

### 10.2.2 Cost

Cost calculations are based on the direct costs of creating the socket, i.e. labour cost and material cost. Hourly labour cost is data provided by Aktiv Ortopedteknik (650 SEK/h) and total labour costs are with regard to time actively spent on the socket. Tooling and machine costs are not taken into consideration. However, the one-time-cost of purchasing the iSense scanner and an iPad for the new process will be taken into account in the final result of the comparison.

#### 10.2.2.1 Conventional Process

Average material cost per socket in the conventional process is, according to Aktiv Ortopedteknik, 1000 SEK. Total cost per socket for the three categories of plastic sockets is shown in Table 10.6 below.

**Table 10.6** Cost per socket for each category of plastic socket in the conventional process.

COST	THERMOPLASTIC	LAMINATED	THERMOPLASTIC WITH LAMINATED SUPPORT SOCKET
Labour cost (SEK/h)	650	650	650
Active time (h/socket)	7.75	8.5	9.5
Total labour cost (SEK/socket)	5037.5	5525	6175
Material cost (SEK/socket)	1000	1000	1000
<b>TOTAL</b>	<b>6037.5</b>	<b>6525</b>	<b>7175</b>

#### 10.2.2.2 New Process

The labour cost for sockets manufactured with the new process is based on the hourly labour cost provided by Aktiv Ortopedteknik. Material cost is based on printing prices at Lund University.

Printing price is determined by the volume the object occupies in the printer and is currently 1 SEK/cm<sup>3</sup>. For a standard myoelectric child socket, the total average price is 450 SEK and for the corresponding adult socket 1400 SEK.

Important to note is that if several sockets are printed in the same session, smaller sized sockets can be placed inside larger sockets, resulting in a significantly reduced price. As an example, if a child socket completely fits inside an adult socket, the final price is only calculated based on the space occupied by the adult socket.

In this comparison, however, the price for printing one socket is considered. Since the sockets created per year by the prosthetist are approximately 50 % child and 50% adult, the mean price of 925 SEK is used.

Table 10.7 below shows the total cost of creating a socket using the new process.

**Table 10.7** Cost of creating a socket with the new process.

COST	3D PRINTED SOCKET
Labour cost (SEK/h)	650
Active time (h/socket)	2.85
Total labour cost (SEK/socket)	1852.5
Material cost (SEK/socket)	925
<b>TOTAL</b>	<b>2777.5</b>

### 10.2.2.3 Cost Comparison

As in the previous time comparison, also the cost comparison is first made for each socket category of the conventional process separately, see Table 10.8.

**Table 10.8** Comparison between the conventional and the new process with regard to cost.

	THERMOPLASTIC	LAMINATED	THERMOPLASTIC WITH LAMINATED SUPPORT SOCKET
			SEK/socket
	6037.5	6525	7175
<b>3D PRINTED SOCKET</b>	<b>2777.5</b>	<b>2777.5</b>	<b>2777.5</b>
Difference in cost with regard to the new process (SEK/socket)	- 3260	- 3747.5	- 4397.5
Sockets produced by the prosthetist (sockets/year)	13.5	31.5	22.5
Difference (SEK/year)	<b>- 44 010</b>	<b>- 118 046</b>	<b>- 98 944</b>
Difference (%)	- 54	- 57.4	- 61.3

By using the new process, costs are reduced by 54-61.3% over the three categories of plastic sockets, resulting in an overall cost reduction of 58%. This amounts to a total of 261 000 SEK per year, see Table 10.9.

Taking the one-time-cost of purchasing an iSense scanner and iPad Air for the new process into account, the cost reduction for the first year would be 253 000 SEK and the previously mentioned amount of 261 000 SEK the following years if the current number of sockets produced per year would remain unchanged.

**Table 10.9** Total cost reduction per year by using the new process and the relative percentage distribution of the reduced cost.

	COST REDUCED WITH NEW PROCESS (SEK/year)	RELATIVE DISTRIBUTION OF COST REDUCTION (%)
THERMOPLASTIC	44 010	17
LAMINATED	118 046	45
THERMOPLASTIC WITH LAMINATED SUPPORT SOCKET	98 944	38
<b>TOTAL</b>	<b>261 000</b>	100
iSense 3D scanner	- 4500	
iPad Air	- 3500	
<b>TOTAL (first year)</b>	<b>253 000</b>	

# 11 Conclusions

*This chapter presents conclusions regarding the development of the process as well as the results derived from using it.*

## 11.1 Process Conclusions

This project was set out to develop a complete step-by-step process to creating custom-fitted, prosthetic arm sockets by using 3D scanning and 3D printing and without requiring an extensive experience in CAD. The aim was to, through the developed process, offer the user – the prosthetist – a viable alternative to the often time-consuming conventional manufacturing process, while at the same time providing amputee patients with perfectly fitted sockets.

The generic approach to creating products using a combination of 3D scanning and 3D printing served well as a main structure for developing and adapting the process to prosthetic arm sockets.

The final process comprises seven main steps, each with their respective substeps, see Figure 11.1. Which substeps are performed is determined by the type of socket to be created; the process offers the possibility to produce both passive and myoelectric sockets as well as adding a pattern to the socket.

The developed process proved to produce ready-to-use, custom-fitted sockets when tested with actual amputee patients. This applies to both passive as well as myoelectric sockets. The process enables the adaption of each socket to the individual needs and preferences of the patient and provides the user with full control over socket thickness while reducing the number of manual processing steps that could open up for human error. If larger modifications of the socket would be necessary, the patient data is saved and available in the form of a digital scan as opposed to the conventional method where a completely new cast mould of the residual limb would have to be made.

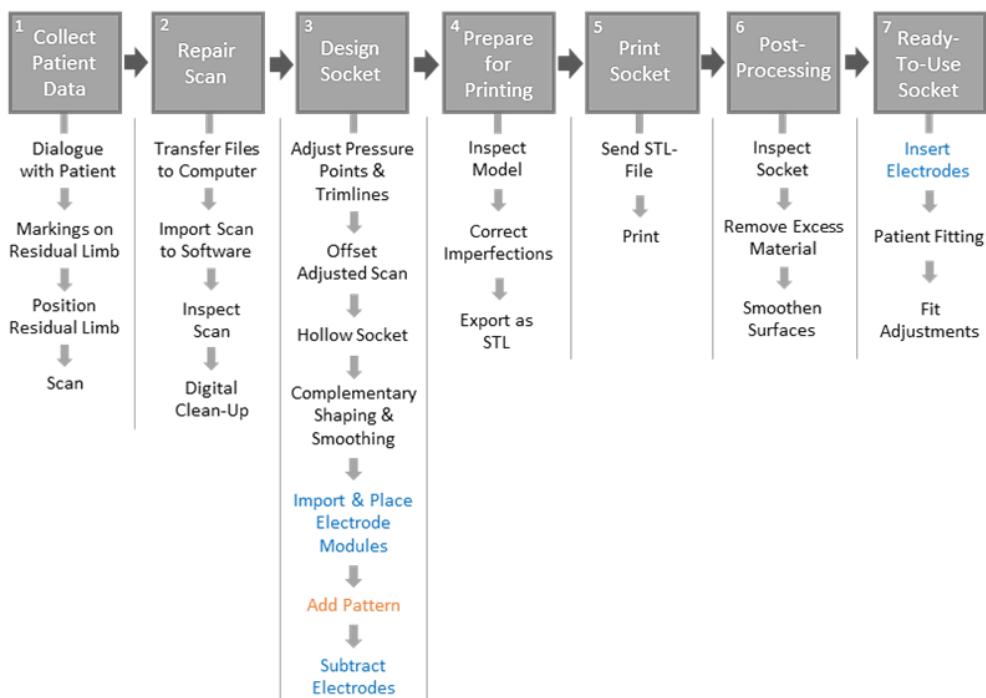
It is clear that the socket fit plays an important role for the overall performance of the prosthesis. The results obtained during process validation indicate that the use of the new process would provide good conditions for achieving a successful prosthetic treatment of the patient.

Based on data from Aktiv Ortopedteknik in Lund, the developed process using nylon 12 as printing material is considered to be a viable substitute to the conventional

manufacturing method for 45% of all transradial sockets currently produced at the company. Although not yet completely replacing all types of sockets, the developed process could be used as a time and cost saving complement to the conventional way of manufacturing.

By implementing the new process, manufacturing efficiency with regard to active time spent by the prosthetist on the socket would improve significantly; calculations based on the current amount of sockets produced, show that close to 400 hours or 50 workdays per year would be liberated for the prosthetist. This liberated time could for instance be used for spending more time with patients, producing more sockets or completing entire prostheses and other orthopedic products.

In terms of cost, the new process is highly competitive; calculations show that implementing the new process would result in a total cost reduction of nearly 60 %, corresponding to 253 000 SEK the first year and 261 000 SEK the following years if the number of sockets produced would remain unchanged. Implementation costs are low if an external printing service is used; the modelling software is free and a one-time cost would be purchasing the scanner, which in the case of the iSense scanner together with an iPad would amount to approximately 8000 SEK – a rather insignificant sum in relation to the cost reductions achieved by using the new process.



**Figure 11.1** The seven main steps of the developed process with their respective substeps. Substeps marked in black are performed for all socket types, whereas blue substeps are added when creating a myoelectric socket and the orange substep is added when applying a pattern to the socket.

## 12 Discussion

*In this chapter the applied methodology, the work process and the result of it are discussed and reflected upon. Recommendations for further development are also presented.*

### 12.1 Methodology

The generic product development process by Ulrich & Eppinger and the Double Diamond model by the UK Design Council provided an important base on which to build the thesis methodology. However, due to the nature of this project, where a complete process was to be developed and not a physical product alone, it was at times necessary to diverge from the two generic processes and add, remove or modify phases and activities. This was mainly done before initiating the work process and based on the author's idea of what was needed in order to create a line of action with a clear and logical structure. In hindsight, the resulting 7-phase process development model applied as methodology has suited the purpose of the thesis well, allowing an exploratory and iterative approach to the project.

### 12.2 Work Process & Results

The user study conducted during the initial Define phase played an important role in the subsequent work of developing the new process. The study provided an understanding of what was required from the process both from a user and patient point of view as well as under which conditions and in what environment it would be carried out. Two prosthetists participated and the process requirements that were later established are derived from the output of the study – the user needs. By interviewing several users from this category of profession, the study would naturally have been more representative and perhaps additional needs would have been identified. However, the needs that actually were identified were considered by the thesis writer to provide a solid foundation to establish an extensive set of process requirements.

Out of these requirements, five out of six could be fully confirmed as fulfilled by the thesis writer during the project; Effective and Flexible were fulfilled by successfully producing customised sockets and by allowing the creation of different types of sockets - both passive, myoelectric and sockets with an added pattern as well as adapting the design according to different shapes and sizes of residual limb. Patient-friendly was considered fulfilled when no signs of the process inflicting any pain or discomfort to the patient were discovered or expressed during the validation phase.

Efficient and Economical were confirmed in chapter 10 where the process comparison showed a significant reduction of both cost and time spent on the socket. However, Easy to learn and manage is a qualitative requirement whose fulfilment thus far only is based on the opinion of the author. It is not possible to fully confirm the fulfilment of this particular requirement until the complete process has been carried out and evaluated by the prosthetist.

The choice of modelling method and software are considered the key determining factors of how easy to learn and manage the process is since they are so far the parts most unfamiliar to the user. Out of the three evaluated software, Meshmixer was without a question considered the most suitable for the purpose. Nevertheless, due to the numerous software available, it cannot be excluded that equally or even better suited alternatives may have been selected if more time were available for the project.

The prototyping phase has been of great value for the work of developing the process. Both process and socket quality and design could be better assessed and important feedback could be acquired from the prosthetist, which allowed for necessary fine-tuning of the process before involving actual patients.

The two case studies conducted as validation proved the process to be viable. The case studies were performed directly after each other, and although resulting in an overall successful validation, an alternative approach could have been to perform them at separate occasions. In this way, allowing to more thoroughly reflect upon the results and procedure together with the prosthetist.

The lack of orthopedic experience of the author has at times been a challenge during the project, especially when collecting patient data and modelling the sockets. In order to obtain a correctly shaped socket in regard to appropriate angles and shape of trimlines, the prosthetist Christian Veraeus needed to be consulted at several occasions. Although requiring additional time of the project, this also lead to valuable insights that could be integrated into the process.

The 3D scanner that has been used during the project is very straightforward and has been sufficient to capture the residual limbs. However, smaller sized or detailed objects, such as the electrodes were not possible to scan correctly. The scanner also had minor difficulties capturing details of the small residual limb of the child patient in the first case study. Nevertheless, after a few attempts a sufficient scanning result was obtained.

Achieving a proper digitalisation of the residual limb is an essential factor in reaching a perfect fit since it is the primary input to the process and the base from which the socket is modelled. With this background, a scanner of higher precision would be recommended in order to avoid unsuccessful collection of patient data if the residual limb were to be smaller than the one of the first case study. High precision scanners are currently very expensive, but as the technology advances it is likely that higher precision will be introduced in low-cost scanners as well.

The chosen modelling procedure of creating a passive socket or the main socket shape of a myoelectric socket is exactly the same regardless of the shape and size of the residual limb. However, for the add-on electrode module it was discovered during modelling of the sockets for the validation, that the individual curvature of the residual limb in some cases, and particularly for smaller sizes, can cause incomplete contact with the flat bottom surface of the electrode attachment. As a result, gaps between the socket and attachment surface can appear and/or parts of the attachment can protrude on the inside of the socket. To solve this, an attempt to create a universal one-fits-all attachment was made, but discarded since no satisfying result was accomplished and an alternative solution was found where the original attachment with the flat bottom surface could be kept as a standard. The solution was included in the learning material and can be applied to the process if the issue would appear.

Moreover, it is important to clarify that the results of the process comparison in terms of lead time and cost provide an approximation of the potential savings of implementing the new process if the same resources and conditions as in this project are used. If important factors such as choice of printing service or material would change, the results would most certainly differ.

### **12.3 Recommendations for Further Development**

Although the work performed during this project has shown results of a viable process in producing custom-made transradial sockets as well as reductions in both lead time and cost, there are still certain areas in which improvements and further development would be recommended in order to refine the process or to adopt it on a larger scale.

A main area to focus on is material; currently 45% of the produced transradial sockets would be possible to substitute with sockets printed in the material nylon 12. To also cover the remaining 55% of transradial sockets, printing materials with other properties need to be used, which means both the conventionally made silicone sockets as well as the thermoplastic sockets with a laminated support socket that were too soft to replace with the current printing material. A suggestion would be to look into the possibilities for silicone printing and multi-material printing, both from a technological as well as financial perspective.

Recommended is also to perform finite element analysis on the sockets to determine, for example, load resistance. This would also be important if the process were to be applied to lower limb sockets as well. Naturally, lower-limb sockets are subject to additional load in comparison to the upper-limb socket.

Adjusting pressure points and trimlines of the residual limb in the new process is, although performed digitally, still much of a free-hand sculpting activity just as in the conventional process. To further increase precision and speed of the new process, a suggestion is to develop a script adapted to the socket-making-process that would allow for a more control over the exact removal or adding of material. It could also

include parameters to quicker generate the socket as well as to adapt and place the electrode attachments.

Since time limitations of the project did not allow for the prosthodontist to independently perform the full process, a follow-up testing and evaluation by the user is recommended for any further development of the process. The elaborated learning material may then be subject to change as a direct effect of this evaluation.

Important to note is that the process has been developed in collaboration with a prosthodontist who, although not having an extensive experience in 3D modelling, is not a complete novice to such software. However, that is not the case for all people active in this category of profession. It is therefore suggested to test the developed process also with prosthodontists without any previous modelling experience to see if the process would be suitable under those conditions as well.

Furthermore, a more extensive financial investigation would be relevant to perform, comparing the new and conventional process using different scenarios and alternatives in terms of hardware, materials, use of other printing services as well as looking into possibly investing in an in-house 3D printer if the process were to be implemented on a larger scale

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## Figures & tables

**Figure 2.1** The six phases of the Ulrich & Eppinger Product Development Process. Adopted from [6].

**Figure 2.2** The seven steps of the Ulrich & Eppinger concept development phase. Adopted from [6].

**Figure 2.3** The Double Diamond Model and its four phases. Adopted from [7].

**Figure 3.1** The various upper-limb amputation levels.

<http://clinicalgate.com/rehabilitation-and-prosthetic-restoration-in-upper-limb-amputation/>

**Figure 3.2** An example of a transradial amputation. Adopted from [13].

**Figure 13.3** Sub-levels of transradial amputations. Adopted from [2, p.170]

**Figure 3.4** Passive transradial prosthesis.

<https://www.pinterest.com/pin/412149803377977692/>

**Figure 13.5** Body-powered transradial prosthesis with hook as terminal device.

<https://www.pinterest.com/pin/412149803377977692/>

**Figure 3.6** Main components of a transradial myoelectric prosthesis.

<http://kids.britannica.com/comptons/art-167510/The-myoelectric-prosthesis-such-as-the-below-elbow-model-fits>

**Figure 3.7** Laminated hard socket.

[http://www.oandp.com/articles/2012-05\\_08.asp](http://www.oandp.com/articles/2012-05_08.asp)

**Figure 13.8** Thermoplastic socket.

Murphy, D. (2013). *Fundamentals of Amputation Care and Prosthetics*. (p.134). New York: Demos Medical Publishing.

**Figure 13.9** Socket with liner.

Murphy, D. (2013). *Fundamentals of Amputation Care and Prosthetics*. (p.134). New York: Demos Medical Publishing.

**Table 3.1** Overview of socket interface types for upper-limb prostheses. Created based on information from [3], [4] & [15].

**Figure 3.11** Side view of the elbow joint with the location of the olecranon and one of the epicondyles marked out.

<http://www.noonanlawma.com/broken-bones-fractures/forearm-fracture-ulna-and-radius-bone.html>

**Figure 3.12** Line drawing of an example of a transradial socket using a combination of supracondylar and supraolecranon suspension.

<http://www.lakeprosthetics.com/published/JPOOctober2003.pdf>

**Figure 3.14** Bony prominences, electrode placement and trim lines marked out on the casting sock Adopted from [13].

**Figure 3.15** Removal of the cast from the patient's residual limb. Adopted from [13].

**Figure 3.16** Manual modifications of the positive plaster mould.

<http://assets.osur.com/library/13935/Upper-X-Transradial-HandCasting.pdf>

**Figure 3.17** Vacuum forming of the test socket.

[http://www.stokosaclinic.com/html/the\\_process.html](http://www.stokosaclinic.com/html/the_process.html)

**Figure 3.19** Example of a transparent test socket with windows created for placement of electrodes Adopted from [13].

**Figure 3.20** Lamination the socket with plastic resin.

Adopted from [13].

**Figure 3.21** The principle of the FDM process.

<http://www.lboro.ac.uk/research/amrg/about/the7categoriesofadditivemanufacturing/materialextrusion/>

**Figure 3.22** The principle of the SLA process.

<https://www.whiteclouds.com/3dpedia-index/stereolithography>

**Figure 3.23** The principle of the SLS process.

<http://www.sd3d.com/fff-vs-sla-vs-sls/>

**Figure 3.24** A Leg That Fits - a customized 3D printed prosthetic leg.

<http://www.fabbaloo.com/blog/2014/5/7/theres-a-lot-more-to-natashas-3d-printed-leg>

**Figure 3.25** The Raptor Reloaded, one of the hand designs from e-Nable.

<http://enablingthefuture.org/2014/12/18/raptor-reloaded-design-and-intent/>

**Figure 5.1** Overview of how to create a 3D printed object from a scan.

Created by Emelie Strömshed based on information from [26] & [27].

**Figure 7.1** The iSense 3D scanner used throughout this project.

<http://cubify.com/compare/scanners>

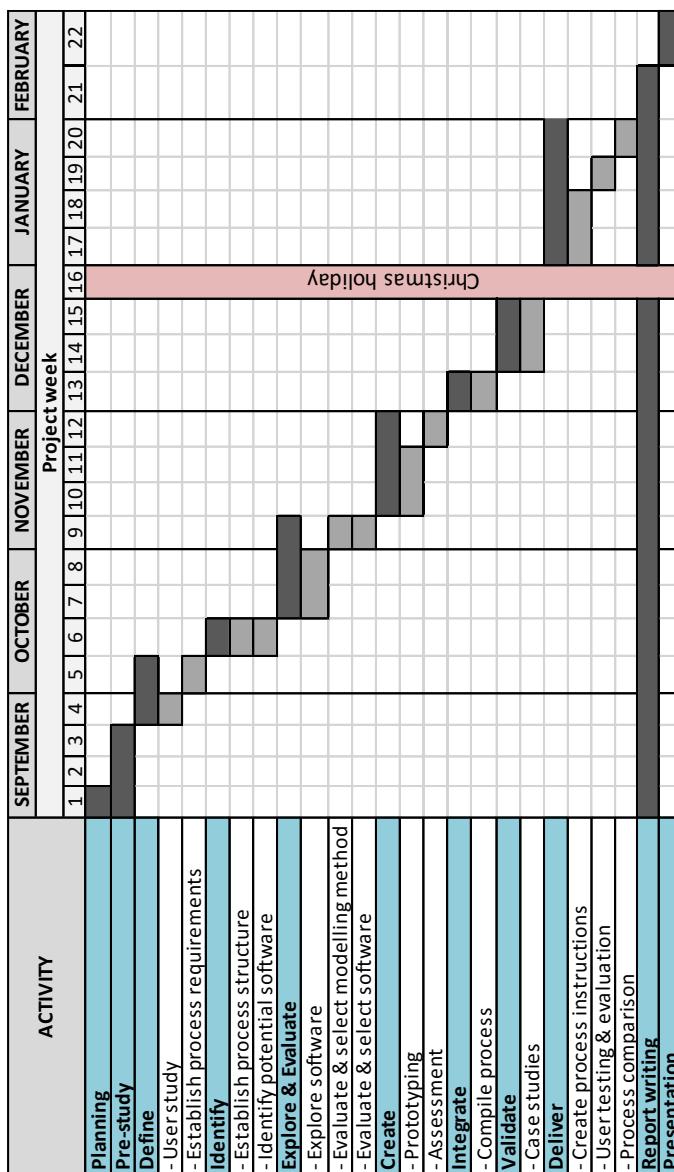
**Figure 13.1** The EOS Formiga p110 3D printer available at the IKDC product lab at Lund University.

[http://www.eos.info/systems\\_solutions/plastic/systems\\_equipment/formiga\\_p\\_110](http://www.eos.info/systems_solutions/plastic/systems_equipment/formiga_p_110)



# Appendix A: Project Plan

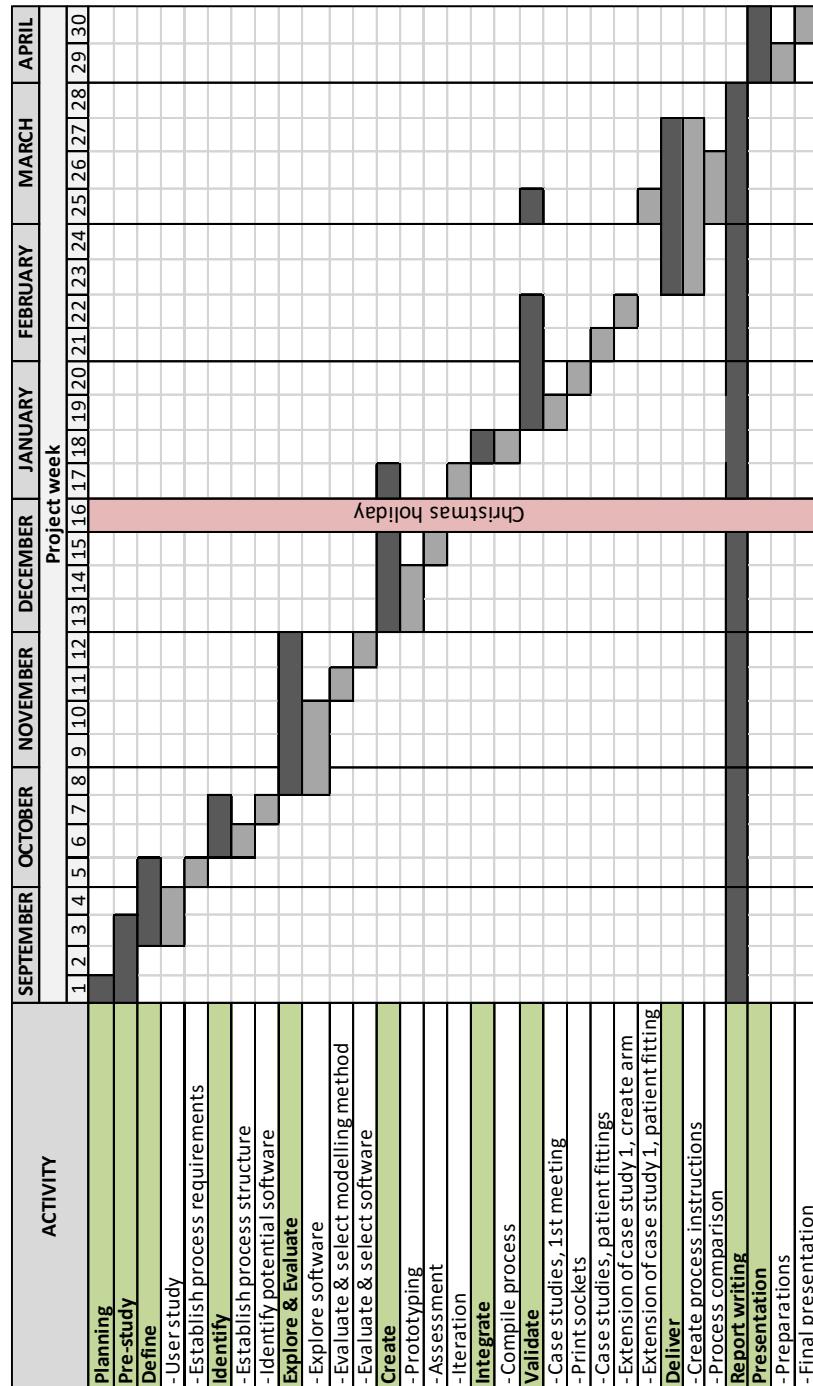
## A.1 Initial Project Plan



## Appendix A: Project Plan

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### A.2 Actual Project Plan



### A.3 Comments to Time Deviations

The project ended up being eight weeks longer than initially anticipated. This was mainly an effect of the extension of the first case study in the Validation phase, where a complete cosmetic arm prosthesis integrated with a socket was designed and 3D printed for the patient. This activity was not previously planned for but included further on since it was considered relevant for the project as a whole. Moreover, the Validation phase was further delayed due to difficulties to synchronise meeting time and date between all parties involved.

The development phase Explore & Evaluate also required additional time in order to get familiarised with the three software, distinguish alternative ways of modelling the socket and integrating the electrodes and finally evaluate these to be able to select the most suitable options. To be able to thoroughly learn all three identified software, additional weeks would have been necessary. The knowledge gained during the weeks already spent exploring the software was however considered sufficient to perform a proper evaluation.

As a result of necessary iterations of the electrode attachment design, the Create phase had to be extended. Furthermore, deciding to create both a booklet and video tutorial as learning material, the Delivery phase required more time than accounted for initially. The total amount of delays unfortunately lead to having to exclude the activity of letting the user test and evaluate the complete process.



## Appendix B: Ranking of Process Requirements

User needs categorised and converted into requirements that were ranked according to average relative importance.

User Need	Imp.	Requirement	Average imp. (Requirement)	Rank
The process is adaptable.	4	Flexible	4	2
Possibility to create different types of sockets.	4			
Ability to make detailed changes.	4			
Fewer steps to create the socket.	4	Efficient	4	2
Shorter lead time of the socket.	4			
The process is easy to manage.	4			
Process instructions are presented both in writing and practise.	3	Easy to learn and manage	3.3	3
3D technology and software are easy to learn.	3			
Material is inexpensive.	3			
Methods are gentle to the patients.	4	Patient-friendly	4	2
The process can create a product aligned with the initial idea.	4	Effective	4.3	1
Ability to identify and visualise the patient's anatomy.	4			
The process is accurate.	5			
The process is tidy.	3	Other	3	4



## Appendix C: Evaluation Matrices

Concept screening matrix for evaluation and selection of modelling methods.

Criteria	Modelling Method			
	A1 (ref) Adjustable Planes	A2 Scale	A3 Offset	A4 Scanned Socket
Ease of learning	0	+	+	+
Accuracy	0	0	+	-
Adaptability	0	+	+	-
Efficiency	0	+	+	+
Adjustability	0	0	+	-
Sum +'s	0	3	5	2
Sum 0's	5	2	0	0
Sum -'s	0	0	0	3
Net score	0	3	5	-1
Rank	3	2	1	4
Continue?	NO	NO	YES	NO

+ = Better than reference, 0 = Same as reference, - = Worse than reference

Concept scoring matrix for evaluation and selection of software. The weight percentage was determined from the user's previous rating of needs.

Criteria	Weight	Software					
		Blender (reference)		Meshmixer		Creo Parametrics	
		Rating	Weighted Score	Rating	Weighted Score	Rating	Weighted Score
Effective	23.2%	<b>3</b>	0.696	4	0.928	2	0.464
Flexible	21.4%	<b>3</b>	0.642	3	0.642	3	0.642
Efficient	21.4%	<b>3</b>	0.642	4	0.856	2	0.428
Easy to learn and manage	17.9%	<b>3</b>	0.537	5	0.895	2	0.358
Economical	16.1%	<b>3</b>	0.483	3	0.483	1	0.161
	Total score	3		3.804		2.053	
	Rank	2		1		3	
	Continue?	NO		YES		NO	

1=Much worse than reference, 2=Worse than reference, 3=Same as reference, 4=Better than reference, 5=Much better than reference  
Blender is selected as overall reference. Reference point for each criterion has the rated value marked in bold.



## Appendix D: Material Data Sheet PA2200



### PA 2200 Performance 1.0 PA12

EOS GmbH - Electro Optical Systems

#### Product Texts

#### Product Texts

This whitish fine powder PA 2200 on the basis of polyamide 12 serves with its very well-balanced property profile a wide variety of applications. Laser-sintered parts made from PA 2200 possess excellent material properties:

- high strength and stiffness
- good chemical resistance
- excellent long-term constant behaviour
- high selectivity and detail resolution
- various finishing possibilities (e.g. metallisation, stove enamelling, vibratory grinding, tub colouring, bonding, powder coating, flocking)
- bio compatible according to EN ISO 10993-1 and USP/level VI/121 °C
- approved for food contact in compliance with the EU Plastics Directive 2002/72/EC (exception: high alcoholic foodstuff)

Typical applications of the material are fully functional plastic parts of highest quality. Due to the excellent mechanical properties the material is often used to substitute typical injection moulding plastics. The biocompatibility allows its use e.g. for prostheses, the high abrasion resistance allows e.g. the realisation of movable part connections.

100 µm layer thickness

Performance is the parameter set of choice for parts with high demands on mechanical properties and fracture behaviour, especially when the part is going to be subjected to multiaxial loading in all three directions. Performance parts are characterized by the highest degree of isotropic strength and rigidity. The choice of 100 µm layer thickness results in fine resolution and also very high surface quality and detail resolution.

Mechanical properties	Value	Unit	Test Standard
Izod Impact notched (23°C)	2.09	ftlb/in <sup>2</sup>	ISO 180/1A
Shore D hardness (15s)	75	-	ISO 868

#### 3D Data

The properties of parts manufactured using additive manufacturing technology (e.g. laser sintering, stereolithography, Fused Deposition Modelling, 3D printing) are, due to their layer-by-layer production, to some extent direction dependent. This has to be considered when designing the part and defining the build orientation.

Tensile Modulus	Value	Unit	Test Standard
X Direction	247000	psi	
Y Direction	247000	psi	
Z Direction	247000	psi	
Tensile Strength			ISO 527-1/-2
X Direction	7250	psi	
Y Direction	7250	psi	
Z Direction	7250	psi	
Strain at break			ISO 527-1/-2
X Direction	20	%	
Y Direction	20	%	
Z Direction	10	%	
Charpy impact strength (+23°C, X Direction)	25.2	ftlb/in <sup>2</sup>	ISO 179/1eU
Charpy notched impact strength (+23°C, X Direction)	2.28	ftlb/in <sup>2</sup>	ISO 179/1eA
Flexural Modulus (23°C, X Direction)	218000	psi	ISO 178

#### Thermal properties

Property	Value	Unit	Test Standard
Melting temperature (20°C/min)	349	°F	ISO 11357-1/-3
Vicat softening temperature (50°C/h 50N)	325	°F	ISO 306

#### Other properties

Property	Value	Unit	Test Standard
Density (lasersintered)	930	kg/m <sup>3</sup>	EOS Method
Powder colour (ac. to safety data sheet)	White	-	-

Last change: 2010-03-21 Source: [www.materialdatacenter.com](http://www.materialdatacenter.com)

Page: 1/2

The data correspond to our knowledge and experience at the time of publication. They do not on their own represent a sufficient basis for any part design, neither do they provide any agreement about or guarantee the specific properties of a product or part or the suitability of a product or part for a specific application. It is the responsibility of the producer or customer of a part to check its properties as well as its suitability for a particular purpose. This also applies regarding the consideration of possible intellectual property rights as well as laws and regulations. The data are subject to change without notice as part of EOS' continuous development and

## Appendix D: Material Data Sheet PA2200

<b>PA 2200 Performance 1.0</b>		EOS GmbH - Electro Optical Systems
PA12		
<b>Characteristics</b>		
<b>Processing</b> Laser Sintering, Rapid Prototyping	<b>Ecological valuation</b> FDA approval acc. to USP Biological test (classification VI/121°C)	
<b>Chemical Resistance</b> General Chemical Resistance		

Last change: 2010-03-21 Source: [www.materialdatacenter.com](http://www.materialdatacenter.com) Page: 2/2  
The data correspond to our knowledge and experience at the time of publication. They do not on their own represent a sufficient basis for any part design, neither do they provide any agreement about or guarantee the specific properties of a product or part or the suitability of a product or part for a specific application. It is the responsibility of the producer or customer of a part to check its properties as well as its suitability for a particular purpose. This also applies regarding the consideration of possible intellectual property rights as well as laws and regulations. The data are subject to change without notice as part of EOS' continuous development and improvement processes.

## **Appendix E: Booklet User Guide**

The following pages of this appendix contains a version of the booklet user guide, reformatted from the original booklet to suit this report.





# The Perfect Fit

---

## User Guide

to creating custom-made  
transradial prosthetic  
sockets by using  
3D technology

Created by

Emelie Strömshed

as part of the final project in my master's studies in  
mechanical engineering with industrial design at Lund University

2015/2016

# Table of Contents

STEP 1: Collect Patient Data 1-2

STEP 2: Repair Scan 3-4

STEP 3: Design Socket 5-12

STEP 4: Prepare for Printing 13

STEP 5: Print Socket 14

STEP 6: Post-Processing 15

STEP 7: Ready-To-Use Socket 16

# STEP 1: Collect Patient Data

## DIALOGUE WITH PATIENT

1

- ▶ Explain the procedure.
- ▶ Are there certain areas of the residual limb that need to be taken into consideration?

## MARKINGS ON RESIDUAL LIMB

2

Mark out with a water-soluble pen:

- ▶ Condyles and olecranon.
- ▶ Areas in need of additional pressure or pressure relief.
- ▶ Shape of trimlines.
- ▶ Electrode placement for a myoelectric socket.

## POSITION RESIDUAL LIMB

3

- ▶ Position the residual limb in preferred angle.
- ▶ Instruct the patient to hold the position while being scanned.

## SCAN

4

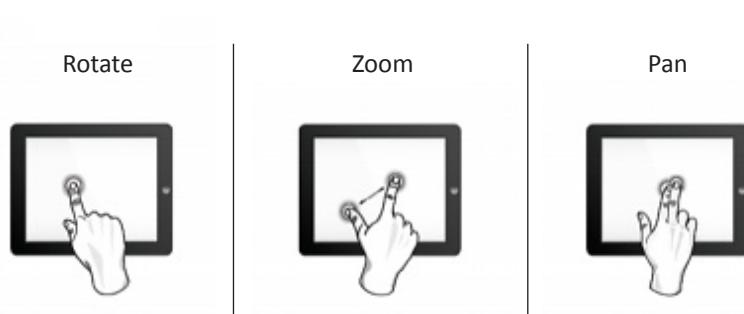
### SCANNING BEST PRACTICE

- Light should be distributed as equal as possible over the residual limb to enhance colours and reduce shadows.
- Position the patient and residual limb so that there is 360°-clearance, allowing you to scan from all angles.
- For the most accurate result, the residual limb should be as still as possible during the scanning session.
- Optimal distance range when scanning is 40-150 cm from the residual limb.

- ▶ Start the iSense application in the iPad.
- ▶ Hold the scanner ≈40 cm from the residual limb and keep the limb centered on the screen.
- ▶ Zoom in/out to size the outlined box. Make sure it encloses the complete residual limb.

- Start scan .
  - Move the scanner slowly and steadily around the residual limb while watching the screen.
  - Fill unwanted gaps in the scan by passing multiple times or holding the scanner still over the gap.
  - When needed, tap  to pause scan. Tap  to resume.
  - When satisfied with the scan, tap the right arrow to finish and move on to editing.
  - Use the **Crop tool** to drag a box around  Crop the part of the scan you want to keep. Tap Crop again to turn off the tool.
  - If necessary, use the **Erase tool** to remove any unwanted, smaller portions of the scan by dragging your finger over them. Make sure not to erase parts that are important for the final fit of the socket. Tap Erase again to turn off the tool.
  - Tap **Solidify** to fill in holes and make the scan solid.
  - In the next stage of editing, use **Auto Enhance** if the  Auto Enhance scan needs increased brightness, clarity or contrast. It is important that the previously made markings are visible.
  - If unwanted areas around the scanned residual limb still remain, use the **Trim tool** to slice these areas away by drawing a line with your finger. The smaller area will be removed. Tap Trim again to turn off the tool.
  - When satisfied with editing, tap the right arrow to move on to saving. Tap  to ensure the file format is set to **OBJ**. This format will allow saving the colour of the scan as well.
  - Tap  to **save** the scan to the iPad. Name the scan “*patient's name\_scan number*”.
- 

## NAVIGATION



- A** Undo last change.
- B** Reset view to initial position & orientation.
- C** Return to start screen.
- D** Settings for the current work flow.
- E** Help menu.

# Meshmixer

## Navigation & Handy Hotkeys

### NAVIGATION

Tumble	<code>Alt</code> +	or	
Pan	<code>Alt</code> +	or	<code>Shift</code> +
Zoom	<code>Alt</code> +	or	<code>Alt</code> + <code>Ctrl</code> +

### ACTION

Undo	<code>Ctrl</code> + <code>Z</code>	Redo	<code>Ctrl</code> + <code>Y</code>
Show Object Browser	<code>Ctrl</code> + <code>Shift</code> + <code>O</code>		
Show Wireframe	<code>W</code>		

### TOOL

Select	<code>S</code>	Cancel	<code>Esc</code>
Transform	<code>T</code> (object or selection) (move/scale/rotate)	Accept	<code>Enter</code>

### SELECTION

Select All	<code>Ctrl</code> + <code>A</code>	Expand Selection	<code>E</code>
Deselect	<code>Ctrl</code> +	Invert Selection	<code>I</code>

### BRUSH

Brush Size		(Selection & Sculpt mode)
Strength		(Sculpt mode)
Invert Brush Property	<code>Ctrl</code> +	(Sculpt mode)

# STEP 2: Repair Scan

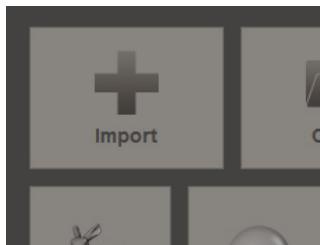
## TRANSFER FILES TO COMPUTER

1

- ▶ Connect the iPad to a computer.
- ▶ Open iTunes and click the Apps tab → iSense.
- ▶ Select the file(s) under iSense Documents and click **Save to**.
- ▶ Select which folder on the computer you want to transfer the file(s) to.

## IMPORT SCAN TO SOFTWARE

2



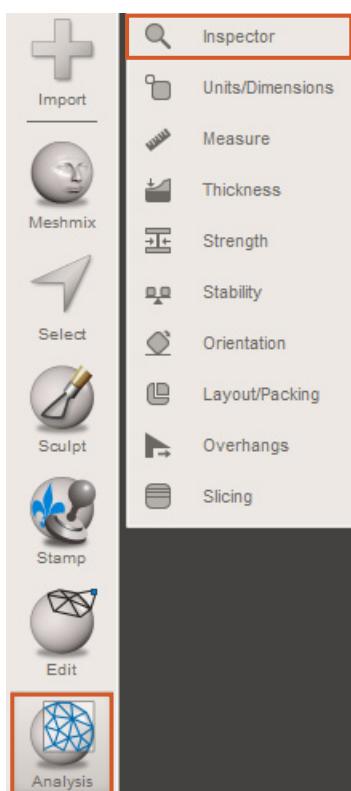
- ▶ Start Meshmixer.
- ▶ Click **Import** to find and import the scan of the residual limb to the software.

## INSPECT SCAN

3

- ▶ Click **Analysis** → **Inspector** to check the scan for any incomplete sections.

**pink sphere** = disconnected  
**blue sphere** = hole  
**red sphere** = non-manifold edges



## DIGITAL CLEAN-UP

4

- ▶ If incomplete sections appear, first try running the **Auto Repair All** function.
- ▶ If the auto repair leaves an unsatisfying result, then manually fix the sections by right-clicking the spheres one by one.
- ▶ Run the **Inspector** again until no incomplete sections remain.
- ▶ Click **Done** to leave the tool.

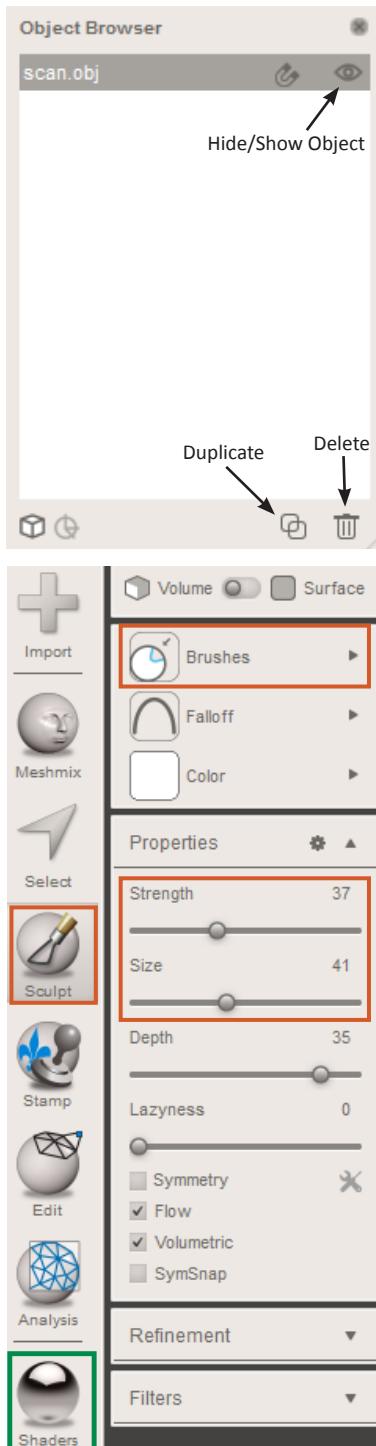
# STEP 3: Design Socket

## TIPS WHILE MODELLING

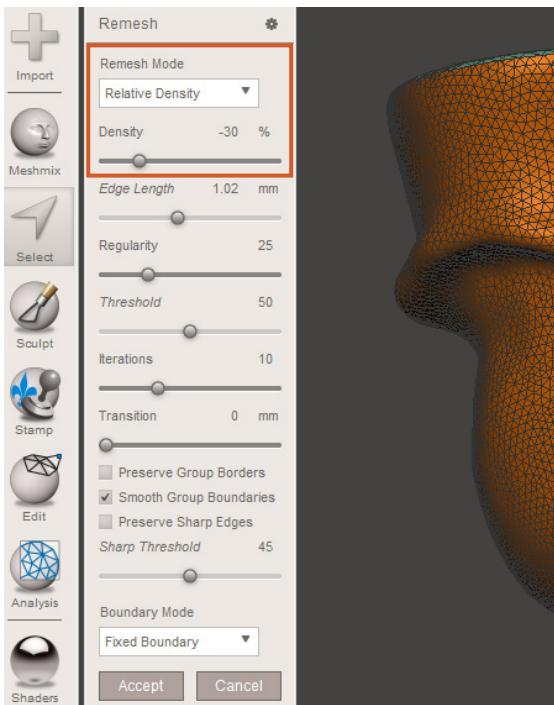
- Make sure there is always a copy of the original scan and, further ahead, the adjusted scan in the Object Browser. It is very helpful to keep them as reference while modelling.
- In order to have a good overview of all the parts in the Object Browser, rename them by double clicking the name.
- Save often, especially after finishing each substep.
- For a plain socket intended for a passive prosthesis, follow substeps 1-4. For a myoelectric socket, add substeps 5 & 6 and for a patterned socket, add substep 7.

## ADJUST PRESSURE POINTS AND TRIMLINES

1



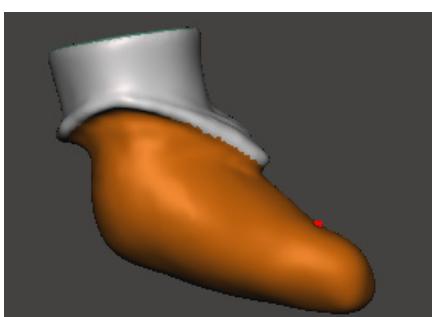
- ▶ **Duplicate** the scan of the residual limb, using the Object Browser window.  
If the window is not visible → press **Ctrl + Shift + O**.
- ▶ **Hide** the created copy and keep it for reference if needed when making the adjustments.
- ▶ Click **Sculpt**.
- ▶ Expand the **Brushes** menu and choose a suitable brush to add/remove material on the scan according to the markings.  
If no original colours are showing on the scan, click **Shaders** → Drag & drop the **globe** onto the scan.  
Recommended brushes are the **BubbleSmooth** brush and the **Inflate** brush.
- ▶ Alternate between the brush types and experiment with **Size** and **Strength** of the brush depending on the amount of material that needs to be added/removed.  
Use to add material and **Ctrl + mouse cursor icon** to remove.
- ▶ If necessary, alternate between the grey and the globe shader in order to better see how the surface changes as you are making the adjustments.
- ▶ Finish sculpting by refining the surface using the **Bubble Smooth** brush with a low strength ( $\approx 6-9$ ). Smoothen the surface without distorting the adjustments you have just made.
- ▶ Press **S** to activate the **Select tool**.
- ▶ Click the scan and press **Ctrl + A** to select the whole part. It should now be completely orange.



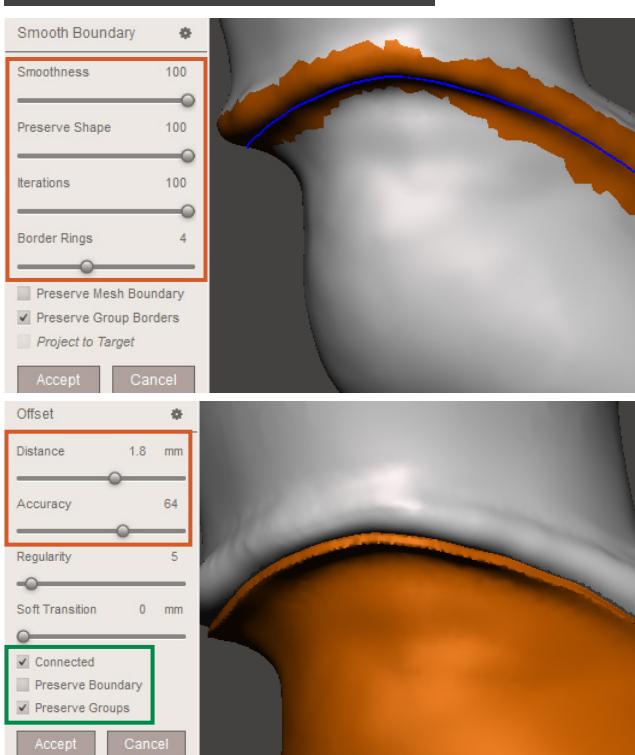
- ▶ Press **W** to show the wireframe.
- ▶ Press **R** to start the Remesh tool.
- ▶ Set the **Remesh Mode** to **Relative Density**.
- ▶ Reduce the mesh density to in between -10 and -30 %. Make sure there is no noticeable change in the shape of the adjusted scan, but that the mesh density is evenly distributed over the socket surface.
- ▶ When satisfied with the result, click **Accept** followed by **Esc** to leave the Select tool.
- ▶ Press **W** to hide the wireframe.

## OFFSET ADJUSTED SCAN

2



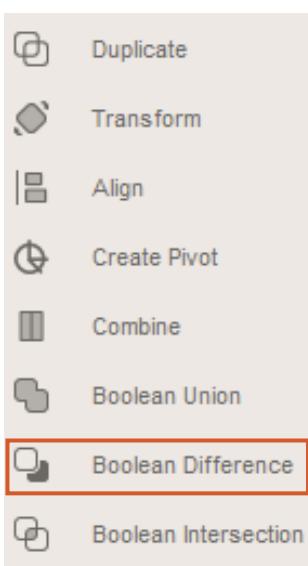
- ▶ Duplicate the adjusted scan twice and **Hide** the created copies.
- ▶ Use the brush to select the areas to be used for the socket.
- ▶ Click **Modify** → **Smooth Boundary** or press **B** to improve the shape of the selected trimline.



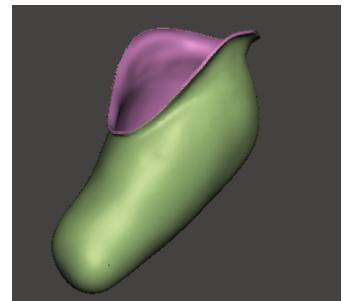
- ▶ In the tool, drag the handles to increase the values until a desired shape is reached → **Accept**.
- ▶ While still in the Select tool, click **Edit** → **Offset** or **Ctrl + D**.
- ▶ In the **Distance box**, type in the desired socket thickness. Press **Tab** to update.  
**Child:** 1-1.5 mm    **Adult:** 1.5-2 mm  
**Patterned socket child/adult:** 0.7-1 mm
- ▶ Increase **Accuracy** slightly.
- ▶ Make sure the boxes **Connected** and **Preserve Groups** are checked.
- ▶ Click **Accept** followed by **Esc** to leave the Select tool.

## HOLLOW SOCKET

3

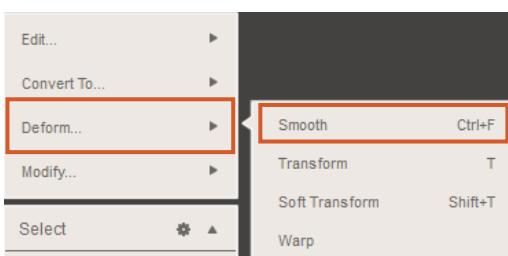
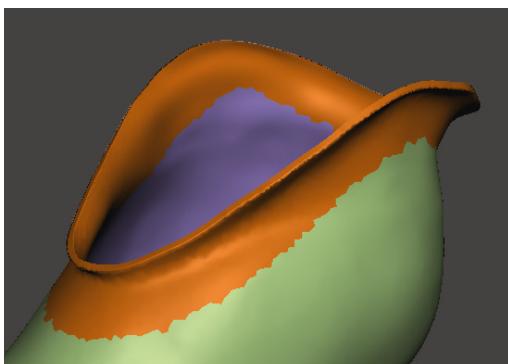
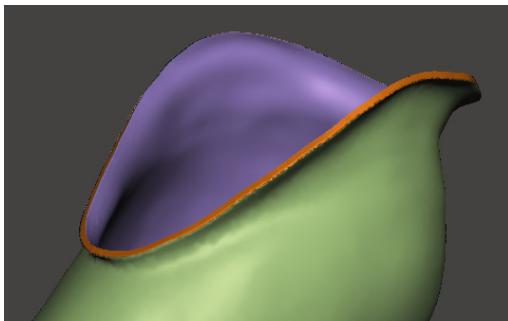


- ▶ Show one of the previously made copies of the adjusted scan.
- ▶ Activate the offsetted scan either by clicking directly on the part or on its name in the Object Browser list.
- ▶ Hold **Ctrl** while also clicking on the now visible copy of the adjusted scan in the Object Browser.
- ▶ A new menu will appear.  
Click **Boolean Difference** to subtract the adjusted scan, creating the hollow socket.
- ▶ Click **Accept**.

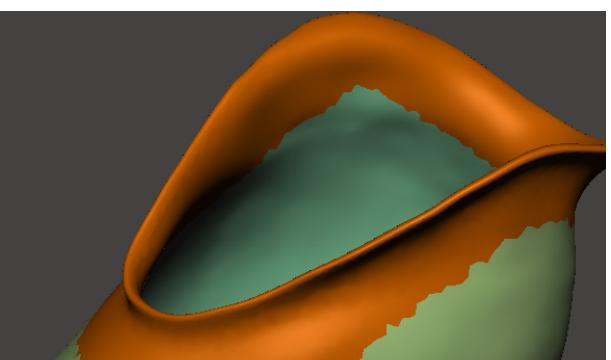
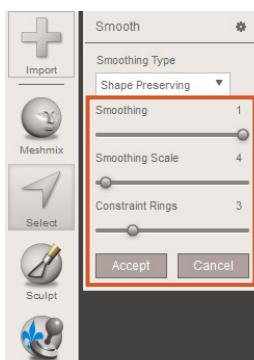


## COMPLEMENTARY SHAPING & SMOOTHING

4



- ▶ Zoom in on the trimline.
- ▶ Press **S** to activate the Select tool.
- ▶ Reduce the brush size and double-click on the trimline edge.
- ▶ Hold & drag to expand the selection further.
- ▶ Click **Deform → Smooth**.
- ▶ Drag the handles in the tool to experiment with the trimline shape. When a desired shape is reached → **Accept**.



- If necessary, continue shaping the trimlines using the **Sculpt tool**.
- Press **S** to activate the Select tool.
- Double-click on the outer and the inner surface of the socket to select them both.
- Click **Deform → Smooth** to smoothen the surfaces.

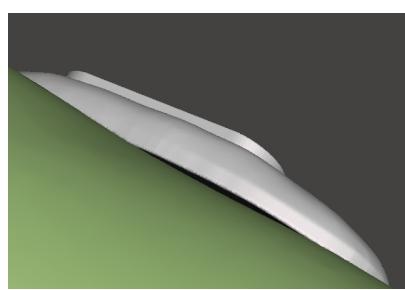
- > For a plain socket intended for a passive prosthesis, the step of designing the socket is now completed. Proceed to Step 4: Prepare for Printing, p. 13.
- > To create a myoelectric socket, continue with substeps 5 & 6, pp. 8-11.
- > To apply a pattern to the socket, add substep 7, pp. 11-12

## IMPORT & PLACE ELECTRODE MODULES

5



- Click **Import** to add the electrode module to the current modelling scene.
- Hold Shift and click on the attachment and the electrode dummy to activate them both.
- Press **T** to start the Transform tool.
- Drag the arrows to move/rotate the complete electrode module as necessary, placing it on the outer surface of the socket. Only the bottom surface of the electrode dummy should be visible from the inside of the socket with a protrusion of  $\approx 1$  mm.
- When satisfied with the placement, click **Accept**.
- With the attachment and dummy still activated, click **Duplicate** in the Object Browser to create a copy of them both.
- Press **T** to start the Transform tool and continue by placing the electrode module on the opposite side of the socket, using the same manner as when placing the first one.



### NOTE!

The curvature of the socket can in some cases result in the flat bottom surface of the attachment not providing full contact with the outside of the socket, leaving a small gap. In this case, perform the following tasks (marked ■) before continuing the regular procedure:

- Place the two modules so that the lower surface of the electrode dummies are visible from the inside of the socket with a protrusion of  $\approx 1$  mm. Some areas of the attachment itself might also protrude slightly on the inside.



- Click one of the attachment to activate it.
- Temporarily **hide** the socket in the Object Browser.

- Press **S** to start the Select tool.

- Double-click the flat bottom surface of the attachment so it turns orange.

- Press **D** to start the Extrude tool.

- **Show** the recently hidden socket.

- Drag the handle, or type in a value large enough to close the gap between the attachment and the outer surface of the socket. Zoom in to make sure the two parts fully intersect.

- Repeat the procedure for the second attachment.

- Click the socket to activate it.

- **Duplicate** the socket to create a copy.

- **Hide** the original socket.

- Press **S** to start the Select tool.

- Double-click the inner surface of the socket copy and press **Ctrl + D** to start the Offset tool.

- Adjust the distance value until the attachments are no longer visible on the inside of the socket.

- Click **Accept** followed by **Esc** to leave the Select tool.

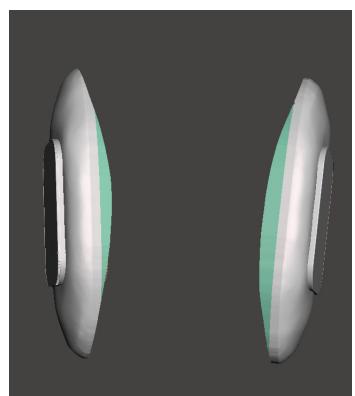
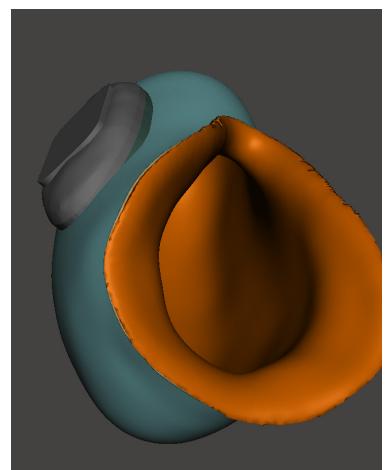
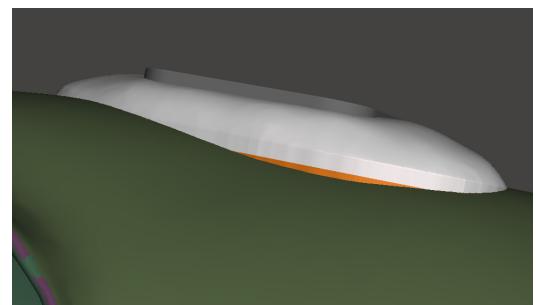
- Duplicate the thickened socket that was just created.

- Activate one of the attachments by clicking on it.

- Hold **Ctrl** while also clicking one of the two thickened sockets in the Object Browser.

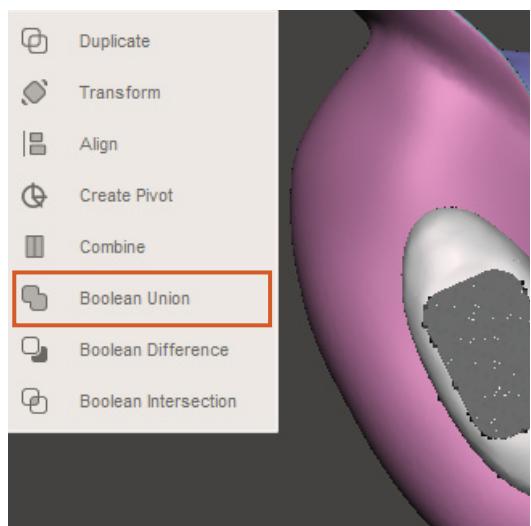
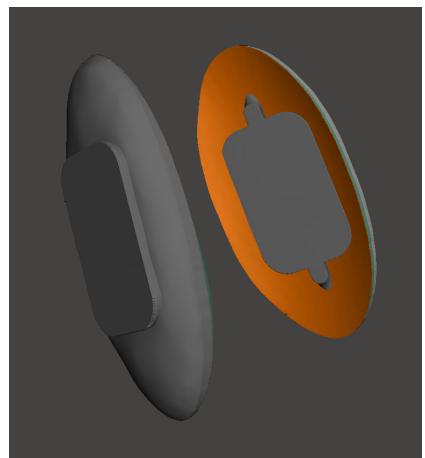
- In the menu that appears, click **Boolean Difference** to remove material from the bottom of the attachment creating a curvature according to the socket shape.

- Repeat the Boolean Difference procedure, using the second attachment and the remaining copy of the thickened socket.



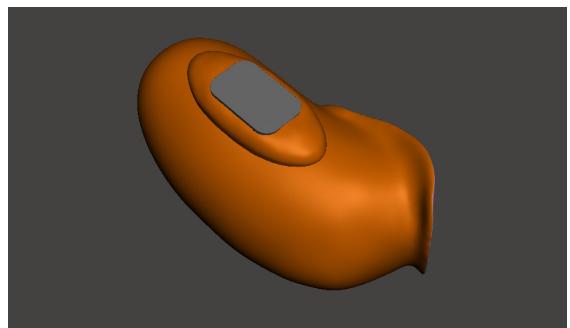
The bottom surfaces of the attachments are now completely aligned with the outer surface of the socket. To be 3D-printable, however, the parts need to be intersected and merged.

- Click one of the attachment to activate it.
- Press **S** to start the Select tool.
- Double-click the curved bottom surface of the attachment so it turns orange.
- Press **D** to start the Extrude tool.
- Set the value to **0.8 mm** and click **Accept**.
- Repeat the procedure for the second attachment.
- Show the original socket, which is now intersected with both attachments.



- ▶ Click to activate one of the attachments.
- ▶ Hold **Ctrl** while also clicking the original socket in the Object Browser or **Shift** while clicking directly on the part in the modelling scene.
- ▶ In the menu that appears, click **Boolean Union** to join the socket and the attachment into one part.
- ▶ Repeat the procedure to join the second attachment to the socket as well.

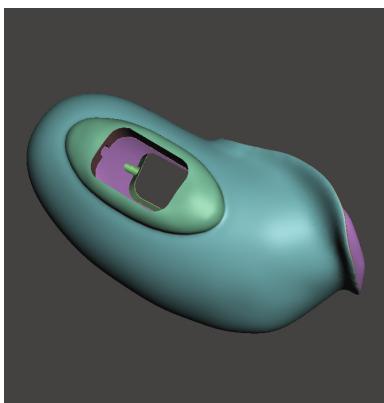
- ▶ Press **S** to activate the Select tool.
- ▶ Double-click the outer surfaces of the socket. Make sure all of it is selected, including the two attachments.
- ▶ Click **Deform → Smooth**.
- ▶ Click **Accept** followed by **Esc** to leave the Select tool.



> To create a myoelectric socket with an added pattern, proceed to substep 7, p. 11.

## SUBTRACT ELECTRODES

6

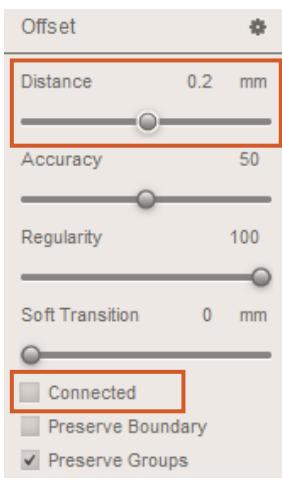


- ▶ Click to activate the socket.
- ▶ Hold **Shift** while clicking one of the two electrode dummies.
- ▶ In the menu that appears, click Boolean Difference to subtract the electrode dummy, creating a cavity all the way through the attachment and the socket wall.
- ▶ Repeat the procedure using the second electrode dummy.

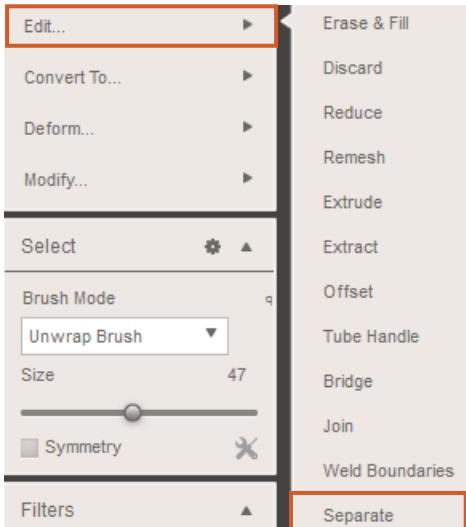
> For a myoelectric socket, the step of designing the socket is now completed. Proceed to Step 4: Prepare for Printing, p. 13.

## ADD PATTERN

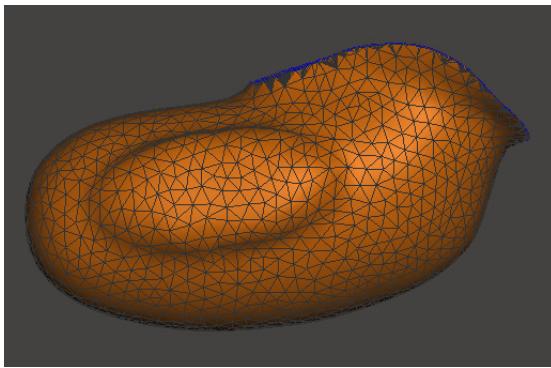
7



- ▶ Press **S** to start the Select tool.
- ▶ Double-click or use the brush to select the entire outer surface of the socket.
- ▶ Press **Ctrl + D** to start the Offset tool.
- ▶ Set the distance value to ≈0.2 mm and make sure the Connected box is unchecked. This creates a surface 0.2 mm from the original socket.
- ▶ Click Accept.



- ▶ With the surface still selected, click **Edit → Separate** or press **Y** to make the created surface and the socket into separate parts in the Object Browser.
- ▶ Press **S** to start the Select tool.
- ▶ Select the entire surface that was just created.
- ▶ Press **W** to show the wireframe.
- ▶ Press **R** to start the Remesh tool.

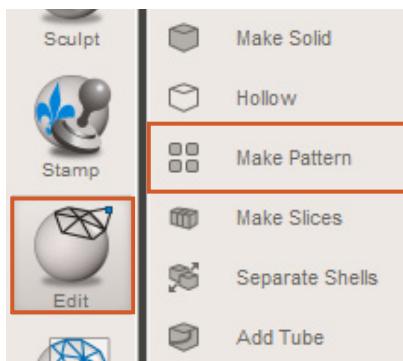


► **Reduce** the mesh density to -50 % → **Accept**.

► With the surface still selected, press **R** to start the Remesh tool again.

► **Reduce** the mesh density to -50 % → **Accept**.

Repeat if necessary until a mesh size similar to the image is achieved. A larger sized mesh will generate a less dense pattern.



► Press **W** to hide the wireframe and **Esc** to leave the Select tool.

► Click **Edit** → **Make Pattern**.

► In the menu that appears, choose desired **Pattern Type** and experiment with the values for **Element Dimension** and **Element Spacing** until a desired result is achieved.

1-1.5 mm as Element Dimension is recommended.

► Click **Accept** to create the pattern.

► Click to activate the pattern.

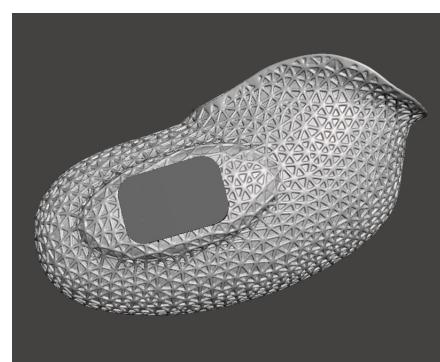
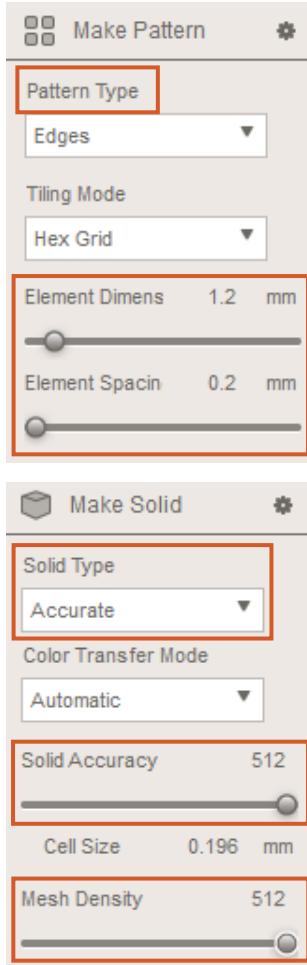
► Hold **Shift** while also clicking the original socket. If it is currently hidden, show it by clicking the eye in the Object Browser.

► In the menu that appears, click **Combine** to make the pattern and the socket into one part.

► Click **Edit** → **Make Solid** to create a water-tight model, suitable for 3D printing.

► For best results, choose **Solid Type** - **Accurate** and maximum value for both **Solid Accuracy** and **Mesh Density**.

► Click **Update** followed by **Accept** to perform the operation.



> For a patterned socket intended for a passive prosthesis, the step of designing the socket is now completed. Proceed to Step 4: Prepare for Printing, p. 13.

> For a myoelectric socket with an added pattern, the electrodes can now be subtracted as described in the previous substep 6, p. 11.

# STEP 4: Prepare for Printing

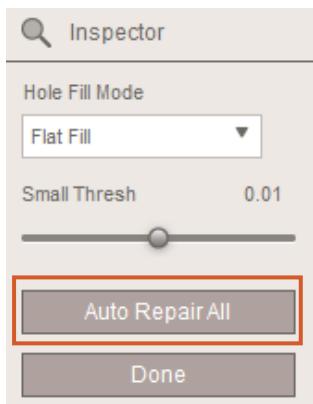
## INSPECT MODEL

1

- ▶ Click **Analysis** → **Inspector** to check the model for any incomplete sections.
  - pink sphere** = disconnected
  - blue sphere** = hole
  - red sphere** = non-manifold edges

## CORRECT IMPERFECTIONS

2



- ▶ If incomplete sections appear, first try running the **Auto Repair All**.
- ▶ If the auto repair leaves an unsatisfying result, then manually fix the sections by right-clicking the spheres one by one.
- ▶ Run the **Inspector** again until no incomplete sections remain.
- ▶ Click **Done** to leave the tool.

## EXPORT AS STL

3



- ▶ Click **File** → **Export** or press **Ctrl + E**.
- ▶ In the Export Mesh dialogue box that appears, set the file format to **STL Binary Format (\*.stl)**
- ▶ Name the file and place it in desired folder.
- ▶ Click **Save**.

# STEP 5: Print Socket

SEND STL-FILE

1

- ▶ E-mail or upload the STL-file to the chosen 3D printing service.

PRINT

2

All activities involving the printing procedure are handled by the 3D printing service.

Depending on the choice of printing service, the finished socket can either be shipped to the customer or collected by the customer at the printing service.

# STEP 6: Post-Processing

## INSPECT SOCKET

1

- ▶ Inspect the printed socket to identify areas in need of refinement.

## REMOVE EXCESS MATERIAL

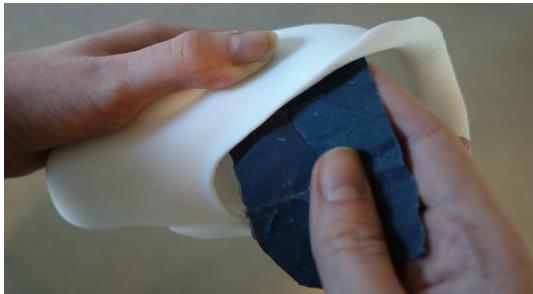
2



- ▶ Depending on the chosen 3D printing method, excess material may need to be removed.  
For the SLS technology that uses powdered material, excess powder is much likely to have accumulated in the holes created for the electrodes in a myoelectric socket. Remove this powder by using a needle, a metal wire or any object small enough to fit in the hole, preferably with a slightly bent shape for better accessibility.

## SMOOTHEN SURFACES

3



- ▶ Where necessary, use a fine-grit sandpaper (800-1000) to smoothen surfaces of the socket. Be particularly thorough with areas that will be in direct contact with the patient's skin.

# STEP 7: Ready-To-Use Socket

## INSERT ELECTRODES

1



- ▶ For a myoelectric socket, insert the two electrodes in the attachments on the socket.

## PATIENT FITTING

2

- ▶ Try the socket fit on the patient.
- ▶ For a myoelectric socket, perform a myo-test to get an indication of the level of contact between the electrodes and the patient's residual limb.

## FIT ADJUSTMENTS

3

- ▶ If necessary, use a heat gun or sandpaper to make smaller fit adjustments to the socket.

---

Hereafter, the finished socket can be used in the further work of completing the entire prosthesis for the patient.

