Developing a cosmetic cover for transtibial amputees

Alicia Nordberg

DIVISION OF PRODUCT DEVELOPMENT | DEPARTMENT OF DESIGN SCIENCES
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MASTER THESIS

LINDHE XTEND
xtend your life

Developing a cosmetic cover for transtibial amputees

Alicia Nordberg

LUND
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Abstract

For someone who has undergone an amputation, it is important to be able to decide what the prosthesis should look like. Since many people today choose to have some sort of cover on their prosthesis, either to fill the void or to regain the feeling of a leg, it is very important that it is something that the user feels comfortable with. To go through an amputation is often a very shocking event and to not make this situation more challenging, the process of making the prosthesis look like a real leg should not be complicated and should not result in any complications. Throughout this master thesis, which is executed in collaboration with the prosthetic foot manufacturer Lindhe Xtend AB, a concept for a new cosmetic cover for lower leg amputees is developed.

In this process, the users have been the main focus and it is their thoughts and opinions together with the orthopaedic engineers' thoughts and opinions that laid the foundation for the project. With the information that was gathered in the user study, the requirements for the product could be specified and prioritized. With these requirements in mind, several concepts were developed through an iterative design process where brainstorming, sketching and prototype building were alternated. The two best concepts were selected for further development and full-scale prototypes were made. The users and the orthopaedic engineers got to say what they thought about the two concepts, and with their opinions, the final concept could be chosen.

The master thesis resulted in a design concept for a new cosmetic cover for lower leg prostheses. The cover is easy to mount and to take off, and it does not cause any of the complications that can occur with today's foam cosmesis. The cover consists of two parts, the main cover, and the foot insert. Together they give the shape and the feeling of a lower leg. This solution can help lower leg amputees feel more comfortable with their prosthesis, and to accept this new stage in life more easily.

Keywords: Amputation, Prosthesis, Cosmetic, Cover, Product development, Design concept, User centered.

Sammanfattning

För någon som gått igenom en amputation är det viktigt att själv få kunna bestämma hur protesen ska se ut. Då många idag väljer att ha någon form av skal på sin protes, för att antingen fylla tomrummet eller för att få tillbaka känslan av ett ben, är det väldigt viktigt att det är något som användaren känner sig bekväm med. Att genomgå en amputation är ofta en väldigt omtumlande händelse och för att inte göra situationen jobbigare så ska processen med att få protesen att likna ett ben inte vara krånglig och inte resultera i några komplikationer. I detta examensarbete, som sker i samarbete med protesfotstillverkaren Lindhe Xtend AB, tas ett koncept fram för ett nytt kosmetiskt skal för underbensproteser.

I denna process har användarna legat i fokus och det är deras tankar och åsikter sammantaget med ortopedingenjörernas tankar och åsikter som har legat till störst grund för arbetet. Med informationen som samlades ihop genom användarstudien så kunde kraven för produkten specificeras och prioriteras. Med dessa krav i åtanke togs ett flertal koncept fram genom en iterativ designprocess där brainstorming, skissning och prototypbygge alterneras. De två bästa koncepten valdes ut för att utvecklas vidare och fullskaliga prototyper gjordes. Användarna och ortopedingenjörerna fick sedan säga vad de tyckte kring de två koncepten och med deras åsikter kunde det slutgiltiga konceptet utses.

Examensarbetet resulterade i ett designkoncept för ett nytt kosmetiskt skal till underbensproteser. Skalet är både lätt att sätta på och ta av och det medför inga av de komplikationer som kan ske med dagens skumkosmetik. Skalet består av två delar, huvudskalet och fotinsatsen. Tillsammans ger de både formen och känslan av ett underben. Denna lösning bidrar till att underbensamputerade kan känna sig mer bekväma med sin protes och att lättare acceptera detta nya skede i deras liv.

Nyckelord: Amputation, Protes, Kosmetik, Skal, Produktutveckling, Designkoncept, Användarcentrerat.

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Table of contents

Introduction 10
1.1 Background 10
1.2 Lindhe Xtend AB 10
1.3 Problem description 11
1.4 Project description 12
1.5 Structure of thesis 13
1.6 Delimitation 13
2 Methodology 14
2.1 Double diamond design process 14
2.2 Human-centered design 15
3 Discover 16
3.1 Prosthesis terminology 16
3.1.1 Prosthesis 16
3.1.2 Socket 17
3.1.3 Pylon 18
3.1.4 Adapter 18
3.1.5 Foot 18
3.1.6 Cosmetic cover 18
3.2 Literature study 19
3.2.1 Who uses prostheses 19
3.2.2 The importance of being able to choose 20
3.3 Benchmarking 21
3.3.1 Lindhe Xtend AB product portfolio 21
3.3.2 Similar products on the market for a functional prosthesis 23
3.3.3 Patents 28
3.4 User study 28
3.4.1 Questionnaire 28
3.4.2 Interviews with potential users 29
3.5 Expert interview 30
3.5.1 Interview with Shahrokh Arami 31
3.5.2 Interview with Christoffer Lindhe 32
3.5.3 Interviews with unbiased experts 33
3.6 Key findings 33

3.6.1 Literature study 33
3.6.2 Benchmarking 34
3.6.3 User study 34
3.6.4 Expert interview 35
4 Define 37
4.1 User needs 37
4.2 Function analysis matrix 38
4.3 Mood board 40
4.4 Personas 40
4.5 Design brief 41
5 Develop 42
5.1 Brainstorming 42
5.1.1 Mind mapping 43
5.1.2 Braindrawing and brainwriting 43
5.2 Mock-ups 43
5.2.1 Sketches 44
5.2.2 Paper models 44
5.3 Concepts 45
5.3.1 Concept A – Foam with attachment 45
5.3.2 Concept B – Mouldable plastic 46
5.3.3 Concept C – EVA foam 49
5.3.4 Concept D – Stretchy fabric 50
5.3.5 Concept E – Stripes 50
5.3.6 Concept F – Puzzle 52
6 Deliver 53
6.1 Evaluation 53
6.1.1 Lo-fi prototypes 53
6.1.2 Meeting with Mälarplast 54
6.1.3 Strength and weakness 55
6.1.4 Concept scoring 58
6.2 Concepts to proceed with 60
6.2.1 Concept A 60
6.2.2 Concept C 65
6.3 Development of concepts 66
6.3.1 Concept A 66
6.3.2 Concept C 73
6.4 Evaluation of concept A and C 79
6.4.1 Users' thoughts 80
6.4.2 Experts' thoughts 80
6.4.3 Choosing the final concept 81

7 Final concept 82
7.1 Xtend TT Cover 82
7.1.1 Main cover 83
7.1.2 Foot insert 85
7.1.3 The completed cover 85
8 Discussion and conclusion 88
8.1 Evaluation of the design process and methodology 88
8.2 Evaluation of the final concept 89
8.3 Future development 90
8.4 Planning and time management 91
8.5 Conclusion 92
References 94
Appendix A – Expected and actual time plan 98
Appendix B – Patents 100
Appendix C – Questionnaire questions and summary of responses 104
Appendix D – Interview questions to amputees 113
Appendix E – Interview summary amputees 114
E.1 Cecilia 114
E.2 Lena 114
E.3 Katalin 115
E.4 Maria 115
E.5 Carina 116
E.6 Sonia 116
E.7 Gert 117
Appendix F – Interview questions to unbiased experts 118
Appendix G – Interview summary unbiased experts 119
G.1 Lina 119
G.2 Marianne 119
G.3 Adrian 120
Appendix H – User needs 121
H.1 Statements from questionnaire and user interviews 121
H.2 User needs from amputees and experts 124
H.3 Function analysis matrix – desired 126
Appendix I – Personas 127
I.1 David 127
I.2 Megan 127
I.3 Becky 128
I.4 Mark 129

Introduction

This section presents the background to the project, the project's purpose, and its delimitation.

1.1 Background

Each year around 2250 leg amputations are done in Sweden and the most common amputation level is a transtibial amputation (lower leg amputation) with around 60 percent of all leg amputations being transtibial amputations [1]. According to Saint Luke's [2], a healthcare provider in Kansas City, a leg amputation is normally performed due to underlying problems that cannot be solved in any other way. The most common causes are tissue damage that develops from diabetes and vascular diseases. The decision to amputate a leg or not is not easy to make and the situation can be very overwhelming even for the people around the soon to be amputee [1].

Today, a prosthesis, an artificial replacement for an amputated part of the body, can look however the patient wants it to look, since it can vary from just being functional and sterile to having a cosmetic cover that mimics a natural limb [3]. William Root [4], an industrial designer that has developed an exoskeleton for transtibial prostheses, mentions that a more recent development is the ability to accessorize your prosthesis with a decorative cover or structure that can express the user's personality. All these options are developed to increase the user's satisfaction and to make them feel more comfortable and satisfied with their prosthesis.

1.2 Lindhe Xtend AB

Lindhe Xtend AB [5] is a company founded by Christoffer Lindhe in 2013. The idea behind the company came together after Christoffer Lindhe became a triple amputee where he lost both his legs and his right arm in a train accident. After trying many different foot prostheses, he never found one that worked with his active everyday life and that was when he realised that it was the restricted mobility in the foot that was the main problem. Therefore, Lindhe started to develop his own foot prosthesis called Xtend Foot.

According to Lindhe Xtend's business strategy [6], their ambition is that all leg or foot amputees should feel that they can have a high quality of life and to not be hindered by their prostheses. At Lindhe Xtend all products are developed in close collaboration with users and with the phrase "make it possible" in mind to ensure that the users can live a life without limitations. To work towards their goal to give every amputee a high quality of life, Lindhe Xtend has now expanded with distributors in 14 different countries worldwide, and they want to continue expanding. An important factor to Lindhe Xtend is that their production must be in Sweden and preferably close to Halmstad since that allows for a full control in the quality of the products.

Today, Lindhe Xtend has been contacted by Shahrokh Arami, the head of unit by orthopaedic technology at the Sahlgrenska University Hospital in Gothenburg (enhetschef inom ortopedteknik på Sahlgrenska Universitetssjukhuset i Göteborg), to ask if they could develop a new and better solution for a cosmetic cover that makes the prosthesis look more like a real leg. This, because today's cosmetic cover is not the best solution to the problem. Lindhe Xtend has taken on this problem and one solution is going to be presented in this report.

1.3 Problem description

The problem description consists of information that was gathered through interviews [7; 8] with both Christoffer Lindhe at Lindhe Xtend and Shahrokh Arami at Sahlgrenska University Hospital. Most of the information comes from Arami since he works with prostheses and cosmesis every day and therefore sees the problems with the existing solution.

Today, if a transtibial amputee wants a realistic cover they usually get a foam cosmesis, according to Shahrokh Arami. He describes that the first step is to cover the empty space between the socket, the part that joins the amputee's residual limb to the prosthesis, and the foot with a block of foam that is then glued to the socket. He points out that this glue needs to dry before any other work can be done. When the glue has dried, the foam can be shaped after the person's other leg or to a generic lower leg shape. Arami says that this procedure usually takes about 4 hours or more and because of this the patient needs to leave the prosthesis overnight and then come back to pick it up when it is done.

This solution has its problems that the orthopaedists now want to avoid with a new cosmetic cover. Shahrokh Arami says that the main problem is that not all amputees can be away from their prostheses that long, both mentally and physically. Being without a prosthesis can lead to a swollen stump, which in turn means that the prosthesis does not fit the amputee correctly anymore. He also talked about how, if

an amputee must leave their prosthesis at the hospital overnight, he or she needs another form of assistance to get around, and being separated from their prosthesis could have a negative effect on the amputee and be an overall unpleasant experience. The material costs for this procedure are close to zero since the foam cosmesis is not very expensive. Although, the staff costs are a lot higher since it takes around one day to meet the amputee, to glue and shape the foam piece, and to have a second appointment with the amputee to try the prosthesis with the cosmesis on. Another problem that Arami brought up was that if some modification needs to be done to the prosthesis, the foam piece cannot be removed since it is glued to the prosthesis, and therefore might be destroyed. This means that the amputee must go through the whole procedure once again if it cannot be put back together. One last but still very important aspect that Arami would like to address is the environmental aspect; the more visits to the hospital the amputee must make, the worse it is for the environment. Therefore, a new solution that still has the same amount of details and can be fitted at one visit is preferable according to Arami.

1.4 Project description

The aim of this project is to develop a new and improved cosmetic cover for transtibial amputees that can be installed in one sitting to ease the process. This cover should meet the requirements and needs of both the amputees and orthopaedists, which can be seen in Table 4.1 on page 39. Therefore, a human-centered design process is adopted in this project. When developing a new solution, the function and appearance should not be overlooked since they are crucial to the users. However, a balance between production, costs, appearance, and functionality needs to be found so that the new product is both usable, manufacturable, and not too expensive. The final product could be used both in private and public hospitals, and to be used by the public hospitals the price on this product must be competitive enough for them to purchase it.

The main target audience is adults that have gone through a transtibial amputation and that uses prostheses that have a cosmetic cover. However, since this audience is rather small, a secondary target is transtibial amputees that have prostheses without cosmetic covers. Another secondary target is the orthopaedists who are working with the product.

The intention of this project is to come up with a concept and to build a working prototype that could lay as a foundation for further development. The expected time plan and the actual time plan can be found in Appendix A.

1.5 Structure of thesis

This master thesis is divided into eight main chapters: introduction, methodology, discover, define, develop, deliver, final concept, and discussion and conclusion.

Chapter one and two describe the background, the company behind the thesis, the problems with today´s solution, the goal of the project, the delimitations, and the methodologies used. Chapter three thru six cover the development phase. Chapter three, discover, is where new information for the project is researched through a literature study, benchmarking existing solutions, a user study, and expert interviews. In chapter four, define, the research is compiled and interpreted to generate needs from the users as well as the experts. Chapter five, develop, is where ideas and concepts are developed. In chapter six, deliver, these concepts are evaluated, and the two most promising concepts are developed further. Chapter seven, final concept, is where the final concept is presented. Chapter eight, discussion and conclusion, is where the entire thesis is summarized, discussed, and concluded.

1.6 Delimitation

Some delimitations must be set to limit the scope of the project.

Design limitations:

- Designed for transtibial prostheses only
- Designed for prostheses that have a pylon, a tubular piece, between the socket and the foot
- Designed after the measurements of the prosthesis that is used in this project
- Designed for adults and the elderly

Production limitations:

- Production in Sweden
- Production costs should be kept low

Other limitations:

- The Coronavirus

2 Methodology

This section presents the methods that are used in this project.

2.1 Double diamond design process

The design process applied to this project is the Double Diamond Design Process, DDDP. It was developed by the Design Council [9] in 2004 to be a graphical framework for innovation. The method behind the DDDP is to see everything with a larger perspective, narrowing it down and then repeating this process. It was because of this broader and narrowed perspective that this method was chosen for this master thesis. The DDDP allows for an open mindset but at the same time offers a structure which was important for this project as it was quite open.

The Design Council [9] states that there are two phases to go through within the DDDP, and within each phase there are two different stages as can be seen in Figure 1.1. The first phase is finding the right problem and the second phase is finding the right solution. The four different stages are discover, define, develop and deliver. The first stage, discover, aims to understand the problem and to collect information through various channels. The second stage, define, uses the information that was collected in the first stage to define what is important. The third stage, develop, encourages creativity to generate various solutions to a clearly defined problem. The fourth and last stage, deliver, is where the solutions from stage three are evaluated and the best concepts are chosen and developed further.

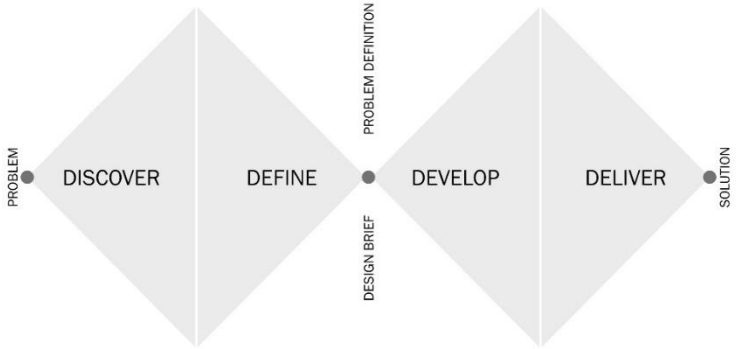

Figure 1.1: An illustration of the Double Diamond Design Process.

2.2 Human-centered design

Don Norman writes in his book *The Design of Everyday Things* [10, pp. 219-222] that Human-centered design, HCD, is an approach that puts the human needs and its capabilities first. HCD takes place within the DDDP to help find the right problem and to fulfil the human needs, while finding the right solution. This is done through finding potential users and listening to what they have to say [11, p. 39]. The final product should meet the needs of the users and it should also be understandable and usable.

According to Don Norman [10, pp. 221-229] the HCD process contains four different activities that are iterated, and they are observation, idea generation (also called ideation), prototyping and testing. Observation is the part where the initial research about the potential user is done to understand the problems that exist and to determine the design requirements. Idea generation is where the designer generates numerous ideas, and no ideas should be criticized or prematurely dismissed. All ideas are welcomed, and a creative mindset is critical for succeeding. Prototyping is where quick mock-ups are built to see if the ideas are reasonable and worth proceeding with or not. Testing the prototypes with potential users is important, since they can provide valuable input on the prototype and give new insights on how the product can be improved. These four activities are then iterated until the problems are well understood, and later iterated again to ensure that the final product meets the needs of the users.

3 Discover

This section covers prosthesis terminology and a literature study about prosthesis users and the importance of cosmesis. In addition, products that already exist are brought up and discussed, and knowledge from both amputees and orthopaedic engineers are presented.

3.1 Prosthesis terminology

3.1.1 **Prosthesis**

According to the national encyclopaedia [12] a prosthesis is an artificial replacement for an amputated part of the body. A prosthesis can be needed after losing for example a tooth, an eye, a leg, or an arm. In this report, when the word prosthesis is used, it refers to a prosthesis of a lower leg, also known as a transtibial prosthesis.

Alberta Association of Orthotists and Prosthetists [13] describes a transtibial prosthesis, see Figure 3.1, as a prosthesis used for patients that have had an amputation below the knee and want the function and/or look of a leg. A prosthesis is always custom made for the patient since no residual limbs are alike. When developing this new cosmetic cover, each prosthesis will be different which is a factor that must be considered. The prosthesis consists of many different parts to ensure a good fit. Since it is only the outer parts of the prosthesis that will interfere with the cosmetic cover, only these parts will be explained further.

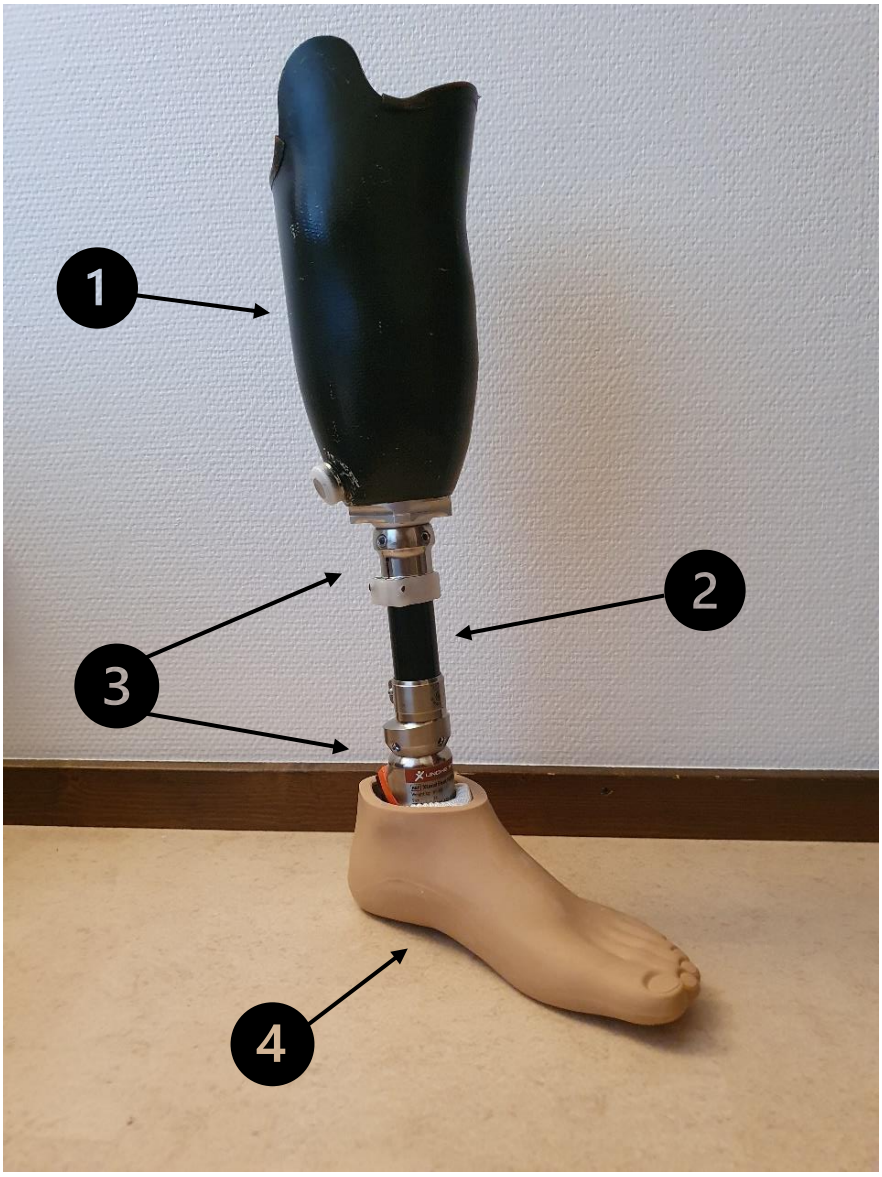

Figure 3.1: A transtibial prosthesis. 1: socket, 2: pylon, 3: adapter and 4: foot.

3.1.2 **Socket**

The socket, see number 1 in Figure 3.1, is the part that joins the amputee's residual limb to the prosthesis, and it being tailored to the amputee's residual limb ensures a proper fit and comfort [14]. The socket is an important component since it protects the residual limb and supports and distributes the weight of the amputee [15, pp. 2-3].

3.1.3 **Pylon**

The pylon, see number 2 in Figure 3.1, is the tubular piece that connects the foot to the socket, and it also compensates for the length of the limb that was amputated [15, p. 7]. The pylon is usually made of aluminium, stainless steel, or titanium and around 80 to 90 percent of these tubes have a diameter of 30 mm [7; 15, p. 7].

3.1.4 **Adapter**

Ottobock [14], a company that produce prostheses, describes an adapter as a connection between different components to keep the prosthesis together, as well as positioning the components correctly. For example, an adapter can be placed between the pylon and the foot. There are also adapters that have additional functions, for example enabling the amputee to change between different feet if the amputee has more than one pair. The adapters are shown by number 3 in Figure 3.1.

3.1.5 **Foot**

According to Ottobock [14] there are two components to a foot: the prosthetic foot and the foot shell. The prosthetic foot is there to replace the function of the amputated foot and its main functions allow for balance, comfortable standing, and ease of walking. There are many different prosthetic feet on the market to ensure that the amputee's needs are met. The prosthetic foot is shaped to resemble a normal foot, although, to make the prosthesis look like a real foot and for shoes to fit well, a foot shell is always added. The prosthetic foot and the foot shell are shown by number 4 in Figure 3.1.

3.1.6 **Cosmetic cover**

When 'cosmetic cover' is mentioned in this report, it refers to a cover that mimics the real leg and not a cover that has design patterns as for example Anatomic Studios' prosthesis covers [16]. As stated in the care guide from the rehabilitation clinic in Halmstad [17, p. 27], a cosmetic cover should not be mistaken for a cosmetic prosthesis since they are worn only for its appearance and not for its function. A cosmetic cover however is placed on the outside of a functional prostheses and that allows the amputee to walk and move around while still having the appearance of a real leg. The main goal for a cosmetic cover is for the prosthesis to look like a real leg and to not draw attention to it while still being able to walk and move around.

3.2 Literature study

A literature study was completed to gain more knowledge about amputees, prosthetics, and cosmesis. The knowledge that was gained from this study will also serve as a foundation for the development phase. A literature study can contribute with facts that have not been conducted through the user study and expert interviews, however, it can also support or contradict the conclusions that are drawn. The literature study can be a great compliment to the user study since the audience is rather small and especially the target group who uses cosmesis. It can also provide an understanding of what solutions have already been developed and which fields have already been researched by others.

3.2.1 **Who uses prostheses**

According to Swedeamp [18, pp. 9, 11-12], a amputation and prosthesis register for the lower extremity, around one third of all patients that have gone through a transtibial amputation in 2019 in Sweden were provided with prosthetics. This group was dominated by elderly. This can be supported by Figure 3.2 where the predominant age category for amputations of a lower extremity, including feet amputations, is from 60 years and above. In their annual report it can also be seen that out of all lower extremity amputations 39 percent are women and 61 percent are men. The average age for a lower extremity amputation is quite high and that can be explained by the cause of the amputations: 84 percent of all lower extremity amputations are done due to diabetes with or without vascular diseases. Diabetesförbundet (the Swedish diabetes association) [19] states that around 500 000 people in Sweden were registered with diabetes in 2019 and of these around 85 to 90 percent has diabetes type 2, also known as age-related diabetes. To understand the extent of age-related diabetes, around ten to twenty percent of the population that is 65 years or older get diabetes type 2. The second most common underlying cause behind an amputation is arteriosclerosis, also known as vascular calcification, without diabetes, and this disease is also most common in the older generation [18, p. 11; 20].

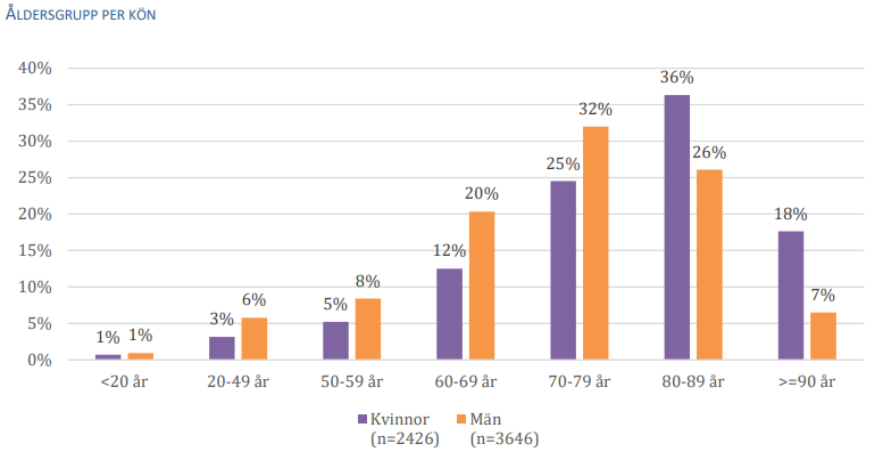

Figure 3.2: A diagram of age distribution for amputations of lower extremity [18, p. 11].

3.2.2 The importance of being able to choose

According to a study by Murray [21, p. 4] all prosthetic users have different visions of what they want their prosthesis to look like. To be able to accept, to feel proud, and comfortable with the prosthesis, it is important that it has a pleasing appearance to the amputee. Some amputees choose to hide their prosthesis after an amputation with a cosmetic cover or with clothes since they do not want the attention and they feel more comfortable blending into the crowd, while some feel that the prosthesis is worth showing [21, p. 15; 22]. Murray's study showed that the freedom to choose a cosmetic cover was very valuable to the participants and the most important part of this cosmetic cover was that it could conceal the working parts and that it had the appearance of a leg [21, p. 12]. If the amputee wears his or her prosthesis, Murray says that it increases the independence of the amputee since he or she then can be more active, continue to work, live a normal life, and proudly take part in social activities [21, pp. 4, 9, 18].

While searching for information regarding amputees and prostheses one common area that was brought up in most of the studies, articles and books was the psychological effect that the amputation has on the amputee. According to a study on the psychological distress and well-being in prosthetic users by Stefania Sansoni and Andrew Wodehouse [23, pp. 553, 554, 558], an amputation generates both profound effects on the amputee's body image as well as different psychological consequences. Some of the psychological consequences that were brought up in this study were stress, depression, insecurity, and denial. In this study they conclude that cosmesis in the early stage after an amputation might help the amputee to find self-confidence again and therefore is of great importance for the amputee to have alternatives to choose from.

In the July 2018 issue of the magazine The O&P EDGE [22] Betta Ferrendelli stated that mostly the older generation prefer prostheses with skin tone covers to mimic a real leg, and that mostly older women use cosmetic covers today. The fact that it is mostly elderly that use cosmetic covers today can be justified by the mid-90's focus on cosmesis before function within prostheses, and around 95 percent of all prostheses were covered with a foam cover that mimicked a real leg. Back then, that was the norm, but today a prosthesis can look however the patient wants it to look [3]. It was also stated in The O&P EDGE issue [22] that the natural skin toned covers are becoming less popular by prosthesis users today but that there is still a demand for them and that they therefore should not be forgotten. In the end all people are different and therefore have different factors behind their decision to cover or not, and it comes down to how the amputees feel about his or her prosthesis.

3.3 Benchmarking

3.3.1 **Lindhe Xtend AB product portfolio**

Lindhe Xtend sells and distributes four different products today. These are called Xtend Foot, Xtend Connect, Xtend Cover and Xtend Testrig.

3.3.1.1 Xtend Foot

Xtend Foot [24, pp. 2-3] is a foot prosthesis that is intended to work as close to a real foot as possible. It can be seen in Figure 3.3. Xtend Foot has a unique ability since it has a greater lateral mobility than its competitors which allows the amputee to walk comfortably on uneven surfaces. This mobility lets the foot do the work when walking on uneven surfaces and not the residual limb, hips, or knees. It also gives the amputee a superior balance and stability.

Figure 3.3: Three photos of the Xtend Foot [24, pp. 2-3].

3.3.1.2 Xtend Connect

Xtend Connect [25, p. 2] is a connector that allows the amputee to easily change feet, change pants and change knee joints. The Xtend Connect can be seen in Figure 3.4. This connector can be used by both above and below the knee amputees to make changes of prosthetic parts quick and easy.

Figure 3.4: Xtend Connect in locked and opened position [25, pp. 3-4].

3.3.1.3 Xtend Cover

Xtend Cover [26, p. 1] is a cover primarily designed for knee prostheses. The two different models can be seen in Figure 3.5 and Figure 3.6. This cover is for amputees who want to show off their prosthesis while protecting it, and the cover also gives the prosthesis a personal touch. Xtend Cover consists of a front and back piece with a 3D printed core. Additionally, the front piece is covered in leather.

Figure 3.5: Xtend Cover with honeycomb design [26, p. 2].

Figure 3.6: Xtend Cover with the flower design [26, p. 3].

3.3.1.4 Xtend Testrig

Xtend Testrig [27] is a ramp that lets the amputee practice standing on different angles with their prosthetic feet. This rig has an inclination between 10 to 20 degrees.

3.3.2 **Similar products on the market for a functional prosthesis**

A benchmarking session was performed to gather information about existing products, understanding how they work, and to find inspiration. This information could help with the idea generation further on in the design process [28, p. 17]. The market research was performed online since cosmetic covers are a small business in Sweden and are mostly fitted by the hospitals or orthopaedic clinics. As a result of the online research, products and methods that are not often used in Sweden could be discovered. The research was narrowed down to only looking at similar products that are being used on a functional prosthesis, since a functional prosthesis is what the new cosmetic cover will be mounted on.

In the online research, it was discovered that the market for cosmetic covers was rather small, not only in Sweden but also in other regions. Only three different solutions were found: foam covers, realistic covers and expressive covers.

In addition to the foam cover, Shahrokh Arami talked about two more that they use at the hospital. These two solutions are simpler than the foam cover, however they are not as realistic looking and do not have the same quality as the foam cover. Arami said that these two other solutions can be mounted on the prosthesis in one sitting, and therefore do not have the same problem as the foam cover. He also said that some amputees settle for these simpler options, but most amputees only use

these as a temporary solution until they can get the foam cover. Because of this, these two solutions will only be mentioned and not focused on in this benchmarking session.

3.3.2.1 Foam covers

Foam covers are the most common cosmeses that are applied to a prosthesis today, and it begins with a foam block that has a hollow centre [29]. These blocks can have different original shapes depending on the manufacturer. For transtibial prostheses these foam blocks can have a round shape, a square shape or already have a generic calf shape which can be seen in Figure 3.7. The hollow centre usually has a diameter of 30 mm or 34 mm since these are the standard dimensions of the pylon. However, the inside of the foam blocks must be hollowed out even further to be able to fit the amputee's socket inside, since all sockets are individually made.

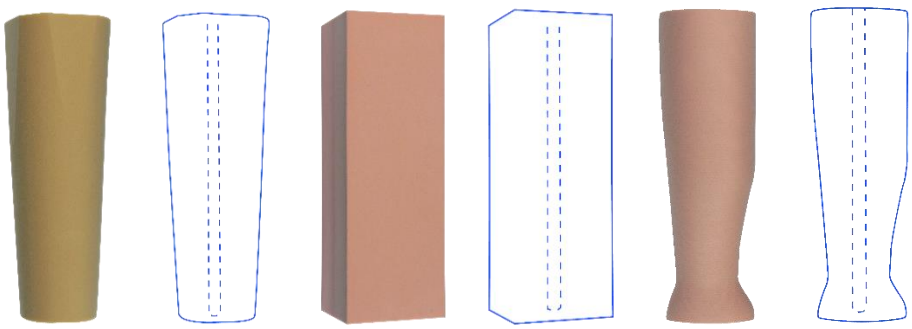

Figure 3.7: Ottobock foam covers for transtibial prosthesis [30].

The foam blocks can be used on the right as well as on the left leg without any additional changes being made [31, p. 273]. If the foam block is not already shaped, this needs to be done and it can be shaped after a general calf or after the amputee's other leg [29]. The foam blocks usually come in different stiffnesses to accommodate the amputee's needs [29; 31, p. 273]. When the foam block has been glued on to the socket and has gotten the right shape, they are usually covered with a stocking that matches the skin tone of the amputee [29]. Faez Abdulsattar is an orthopaedic engineer at Sahlgrenska University Hospital in Gothenburg, and he sent pictures of three different foam cosmeses that have been shaped into a lower leg, and these can be seen below in Figure 3.8.

Figure 3.8: Three different foam cosmeses that has been shaped as a lower leg.

To get an understanding of what a foam cosmesis costs, Shahrokh Arami was contacted through email. He wrote that a foam cosmesis cost around 500 SEK for them to buy, but when the cost for the tools and the time spent is added it comes up to around 4000 SEK per cover.

3.3.2.2 Realistic covers

If the amputee feels that the foam cover, that was described in heading 3.3.2.1, is not enough and that they want a more realistic look on their prosthesis, realistic covers are the next step, see Figure 3.9 and Figure 3.10. Realistic covers are most similar to a regular leg in both appearance, shape, details, and material.

Realistic covers [32, p. 5] are flexible enough to be stretched over the prosthesis, but at the same time keep their shape and elasticity. Details such as body hair, blood vessels, pigment spots, tattoos and different nails are offered by some companies to fully match the look of the healthy leg and the leg that was lost. A realistic cover with details can be seen in Figure 3.9. However, the most common realistic cover is the dream skin from Fillauer [33], as it is a cheaper alternative. Unfortunately, the exact costs for these realistic covers could not be obtained. A dream skin has no details and only mimics the shape and colour of a leg, and it can be seen in Figure 3.10. Before the realistic cover can be placed on the outside of the prosthesis, the void between the foot and the socket needs to be filled with a foam cover [32, p.5].

Figure 3.9: A custom silicone cover from Ottobock with details [32].

Figure 3.10: A dream skin cover from Fillauer without details [33].

3.3.2.3 Expressive covers

Expressive covers, see Figure 3.11, are a fairly new branch of cosmeses that in recent years have grown more popular [22]. Anatomic Studios [34], a Swedish company that produces expressive covers for both transtibial and transfemoral prosthesis, uses 3D scans of the prosthesis and the healthy leg of the amputee and then imports them to a 3D modelling software to create the covers. The amputee can

then describe how they want their cover to look, and it will be designed according to their wishes both in design and colour. To design the cover yourself allows the amputee to express his or her own personality and to be able to proudly show off the prosthesis. When the amputee is happy with the design, the cover is then 3D printed and mounted on the prosthesis. Another way of producing expressive covers is through injection moulding. Two different styles of injection moulding covers are the Confetti TT covers from ID Ethnos [35] and the leg covers from Limb-art [36]. To get an idea of what these expressive covers cost, their respective prices were tried to be found. However, only the price of a cover from Limb-art was found as they are sold on their own webpage, and there the price starts from £229.00 [36]. The biggest difference between the injection moulded covers and the 3D printed ones is that the injection moulded covers have a generic size and are not tailored to the amputee like the 3D printed covers.

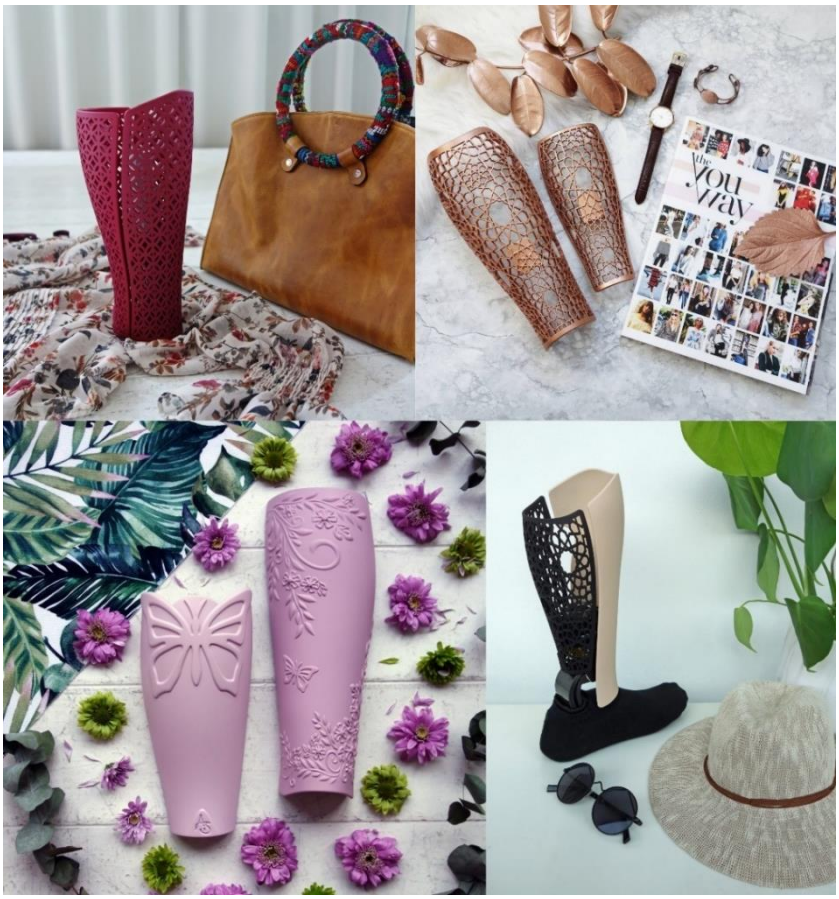

Figure 3.11: Four different expressive covers from Anatomic Studios in Sweden [16].

3.3.3 **Patents**

A patent search was performed to see if any ideas were already patented, to ensure that if a patent already exists, that the solution is not used in future development. In addition, expired and abandoned patents can be used as inspiration for future development since the patents no longer apply.

The patent search showed that there were generally very few patents on cosmeses for leg prostheses or other prostheses. There were many patents regarding how prostheses are constructed and on specific parts that add something to the function, but less regarding the looks and cosmesis. Only five patents for similar products were found and they were all expired or abandoned. These five patents can be found in Appendix B.

3.4 User study

To be able to develop a product that the user will feel satisfied with, it is important to understand what the user wants and needs. Sharp, Rogers and Preece states in their book *Interaction design: beyond human-computer interaction* [37, p. 264] that method triangulation is when at least two different data gathering techniques are being used to gather information. Different techniques allow for a broader perspective when collecting data and the limitations of one technique can be accommodated by another. Collecting information from different techniques gives a deeper and more nuanced understanding of the users' needs and the results can be compared and thereby become more reliable.

A questionnaire was conducted, and interviews were performed to find these user needs. Everything had to be done electronically because of the restrictions with Covid-19 and this meant that observations were not an option since the orthopaedic clinics did not allow any visitors other than patients inside.

3.4.1 **Questionnaire**

A questionnaire was conducted to get both qualitative and quantitative data about the users' needs [37, p. 278]. Since the target group is rather small the questionnaire was done electronically to reach out to potential users more easily.

Google Forms was used to compile the questionnaire since it has a simple interface, and the answers can easily be analysed later on. The questionnaire included questions about how transtibial amputees use their prosthesis today, how they feel about their prostheses, their view on cosmeses, what they want in a new cosmetic

cover and some questions regarding the design. The entire questionnaire can be found in Appendix C.

A pilot study was performed before the main study to ensure that the questions were understandable [37, p. 265]. The questionnaire was sent to four design students, one medical student, one music student, an occupational therapist and to the supervisor. All these five different occupations were chosen to get different views on the content of the questionnaire. They all gave valuable input and tips that were incorporated into the questionnaire.

The final questionnaire consisted of 26 to 29 questions depending on how the questions were answered. The questionnaire was available in English and in Swedish. Both open-ended, closed, and Likert scale questions were used to get both specific answers and qualitative data [37, p. 311]. Likert scales are used to measure the respondent's opinions, attitudes, and beliefs and in the questionnaire a five-point scale was used [37, pp. 280-281].

The questionnaire was primarily for the main target audience, but since the main target audience is rather small, the questionnaire was open for all leg amputees to collect more data. The potential users were mainly reached through posting the questionnaire in a Facebook group for amputees and through direct messages to amputees on both Facebook and Instagram. In addition, the questionnaire was sent to various orthopaedic clinics, rehab clinics, and walking-schools in Sweden. In the effort to try to reach as many lower leg amputees as possible, the questionnaire was also sent to various Red Cross associations in Sweden and Swedish retirement associations (SPF - svenska pensionärsförbundet).

After sending out the electronic questionnaire, some of the people that were contacted asked for a paper copy of the questionnaire so that elderly and individuals with less computer skills also would have the possibility to answer. Therefore, a paper copy of the questionnaire was sent to them via mail. However, no paper copy of the questionnaire was returned.

The final questionnaire had 32 responses from lower extremity amputees. The answers gave an understanding of what the users considered important in cosmeses in both quantitative and qualitative data. A summary of the responses can be found in Appendix C.

3.4.2 **Interviews with potential users**

According to the book Universal Methods of Design [38, p.102] are interviews a great complement to questionnaires since they allow for open discussions and more detailed answers. In an ideal situation the interviews would have taken place in

person and not over the phone as it would have allowed for recognising personal expressions and body language. All interviews had to be done over the phone due to Covid-19, though it would have been hard to do the interviews in person even without Covid-19 since the participants all live across Sweden.

In the questionnaire, the participants were asked if they would like to participate in an interview and therefrom five of the participants were selected. One person who was contacted through Instagram was also interviewed. To get a better understanding of cosmesis, a selection was done so that only amputees who currently use cosmesis were contacted. Thus, five transtibial amputees and one knee amputee that use cosmesis were interviewed. An interview was also conducted with a person who recently had to amputate and has therefore not had his prosthesis for so long. His contact details were given by a close family member.

The interviews had six predetermined questions that kept the discussion going. Some interviews had more personal questions related to what the participant had answered previously in the questionnaire, or if no information previously had been given. In order to let the participants develop their answers, follow-up questions were asked. The follow-up questions allowed for more detailed answers and information that otherwise would not have been discussed. The predetermined questions can be found in Appendix D and a summary of the interviews can be found in Appendix E.

3.5 Expert interview

In addition to contacting amputees and collecting valuable information from them, people who will work with the product were also contacted. They might have a different view of what is important when designing a new cosmetic cover and they are more familiar with previous products and what they are lacking in. Therefore, five expert interviews were conducted to gather other aspects of requirements and information that the amputees might not have thought about.

The expert interviews were divided into two parts. The first part consisted of interviews with Shahrokh Arami and Christopher Lindhe who have knowledge about the project. Arami is the person that wants a new solution to the foam cover and Lindhe is the founder of the company that the product will be designed for. The second part of the expert interviews consist of interviews with unbiased experts.

3.5.1 Interview with Shahrokh Arami

During an interview with Shahrokh Arami [8], he shared his view on how a new cover could look like, the requirements that must be achieved for it to be used by him and his colleagues, as well as other small things that could be good to know before starting the design process. Since he is an expert in the field, he has a great knowledge about the problem as well as the solution and was therefore able to give valuable inputs.

The 3D-printed covers that are more popular among the younger generation are mainly designed and used for knee or femur amputations according to Shahrokh Arami. Although 3D-covers for transtibial amputees exist, they do not have a good transition to the socket and therefore do not look as close to a regular leg as Arami wants the new solution to look. According to him, the cover for transtibial amputees must lay against the socket and form a nice transition. If the material is too stiff and does not have a proper fit towards the socket, it will move around when walking and release sounds when the cover and the socket come into contact. To avoid these sounds, Arami suggests that a softer and more flexible material should be used at the part of the cover that will be placed over the socket.

Another important thing that Shahrokh Arami mentioned was that the part of the cover that will be closest to the foot has to be flexible or consist of loose parts since today's feet are very mobile in all directions. He said that the foot must not be restricted in any way. Arami did not have any specifications on the material that will be between the foot and the socket since it has no major role in the function of the prosthesis. However, he pointed out that the cover needs to be adjustable in length since all amputees have different amputation levels. He recommended that the cover should be attached to the prosthesis at the pylon but that was not a requirement.

Shahrokh Arami said that a nice to have specification is that the cover can easily be removed by the orthopaedic engineers without destroying it when adjustments to the prosthesis must be made. This allows the cover to last longer, and the amputee does not have to go through the process of adding a new cover again. He could not see a significance for the amputee to be able to take off the cover by him or herself since most of the people who wear foam covers today are older people that usually do not change feet. Although if it could be taken off by the amputee it would be a bonus.

Shahrokh Arami pointed out that the cover does not have to look exactly like the amputee's other calf, but that it could have a generic shape that resembles a calf. Since all human calves have different sizes, Arami said that if the cover comes in three different generic sizes it would cover all amputees' needs. The last thing that Arami pointed out was that for them, as a public hospital, to be able to purchase the new cosmetic cover, it must not cost more than 1500 to 2000 SEK per cover.

3.5.2 **Interview with Christoffer Lindhe**

Christoffer Lindhe who is the founder and vice president of Lindhe Xtend AB was interviewed [39], because Lindhe Xtend is the company that the final product will be designed for. During the interview he shared his view on what Lindhe Xtend feels is important and more production related requirements.

One thing that was important to Christoffer Lindhe was that the cover needs to be adjustable in such a way that it can fit every amputee's personal socket. Lindhe said that a one-size-fits-all cover that has a customizable material straight through would be ideal, but he also pointed out that this was not a requirement. Lindhe said that if the prototype works for both the small and the large socket that fits on the prosthesis that are used in this project, it would be good enough and cover most sizes.

Another thing that was important to Christoffer Lindhe was that the cover needs to be adaptable in length to fit all transtibial amputee levels, and that the mounting of the cover can be done during one session at the orthopaedic clinic.

According to Christoffer Lindhe, the final product should be designed for pylons that are 30 mm in diameter since this is the size that is used in over 80 percent of all transtibial prostheses. He mentioned that in the United States they sometimes use a carbon fibre plate instead of a pylon but that is very unusual in Sweden and should not be taken into consideration when developing the cover. He also said that if the prototype works with the foot shell that is on the prosthesis used in this project, it would be good enough since there are no big differences in the opening between different sizes of foot shells.

Another thing that Christoffer Lindhe mentioned, was that the product does not have to be completely assembled when it is delivered to the orthopaedic clinics. The orthopaedic technicians and engineers have the knowledge that it takes to do the last adjustments on site to make the cover fit every individual prosthesis. Another thing that he mentioned was that amputees more often choose to have a suspension sleeve over the socket to get a better vacuum. This sleeve is placed over the socket and goes up on the remaining leg and it might be good to keep its existence in mind when designing the new cosmetic cover.

When it came to the design of the cover, Christoffer Lindhe had no specific requirements other than that the transitions between the cover and the socket and between the cover and the foot shell needs to be as smooth as possible to make the prosthesis look as natural as possible when the amputee wears tight pants or similar. A nice to have specification that Lindhe had was that the cover should be able to fit over their Xtend Connect product. At the same time, he pointed out that the focus needs to be to solve today's problem before thinking about how the cover could fit over their Xtend Connect.

An important factor that needs to be taken into consideration is the production cost. Christoffer Lindhe mentioned that if the cosmetic cover is expensive to produce it will not be profitable for the company. Since today's foam covers are fairly cheap, this new cosmetic cover will need to be sold to the orthopaedic clinics for a maximum of 2000 SEK for them to be interested, but if the cover could be sold for 1500 SEK with the same profit that would be great, he said. For this to happen, the production cost cannot be over 500 SEK per cover. Therefore, it is important that the cover can be mass produced to keep the production cost at a minimum, he said. Lindhe mentioned that the profit might seem large at first glance, but since the ambition is to distribute this cosmetic cover globally the profit decreases because there always are a lot of intermediaries who all take out a profit for their service. Because of this, the profit margin must be large enough to make a profit in the future. The last requirement that Lindhe mentioned is a deal breaker for Lindhe Xtend: the production must be possible in Sweden and the production must be efficient.

3.5.3 **Interviews with unbiased experts**

Three orthopaedic engineers were interviewed since they have not previously been involved in the project and therefore do not have any preconceptions about what the cover should look like, the materials, its requirements etc. This gives unbiased information that is also important to include in the project. The orthopaedic engineers were found through email conversations with Aktiv Ortopedteknik [16] (an orthopaedic technical centre) in Malmö, Lund, and Helsingborg. The seven predetermined questions that were asked can be found in Appendix F and a summary of their answers can be found in Appendix G.

3.6 Key findings

3.6.1 **Literature study**

The majority of all transtibial amputations are carried out on older people due to diabetes with or without vascular diseases. It is also mostly the older generation that wants cosmesis to make their prosthesis look like a normal leg. To ease the process for the amputee to accept the loss of a part of a leg, it is important to be able to choose whether he or she wants cosmesis or not.

3.6.2 **Benchmarking**

There are not many variants of cosmetic covers out on the market today, which could be due to a lack of development within this area. There are also not many patents on cosmeses for prostheses and it shows that the focus lies on the prostheses and not on the cosmesis. The orthopaedic clinics have become familiarized to using the same products year after year when it comes to cosmesis. This may mean that they have become comfortable with the products that always have been available and could therefore oppose a new innovative solution that they are not familiarized with. However, the 3D printed solution that has gained in popularity over the years has shown that new solutions can be accepted and find their place on the market. One thing that became clear among today's few solutions was that most of them must be destroyed if an adjustment to the prosthesis must be made. Always having to destroy and replace the cosmesis is a big disadvantage with today's solutions.

3.6.3 **User study**

The questionnaire and the interviews revealed that many amputees use some form of cosmesis today, but at the same time there are those who proudly want to show their prosthesis to the world. The majority of all participants said that the cosmetic cover only had to look similar to their other healthy leg and that it did not need to have exactly the same dimensions. Some use cosmesis only to fill the void so that it looks more natural when wearing pants. This gives an indication that the solution may not have to be exactly the same size as the healthy leg, just similar to it.

Those who had to live without their prosthesis for a short period of time felt limited by not having their prosthesis, and one felt that she lost her femininity. They wrote that they became dependent on others and on walking aids and that they have a hard time to live a normal life in the meantime. This affects them both mentally and physically and when they get their prosthesis back, they regain their freedom. Therefore, it is important that this period away from their prosthesis is not extended unnecessarily because they must add a new cosmetic cover. This information was especially brought up during the interviews. Here several participants pointed out that they would like to avoid going through the process of mounting a cosmetic cover again as soon as an adjustment to their prosthesis must be done.

When analysing the quantitative data, it became clear that the most important properties of a new cosmetic cover was that the cover should resemble a leg in shape, that it should be easy to remove by the amputee itself without help, that it is easy to clean, that it has a low weight, that it does not make sounds when moving around, and that it is durable. There was also one participant that pointed out that he would like to be able to take off the cosmetic cover by himself so that he can change feet.

Both in the questionnaire and the interviews, it was pointed out that those who used silicone covers often have problems with them getting dirty and discoloured. In addition, it was mentioned during an interview that if you have a silicone cover and use slightly tighter pants, they easily travel up which makes a part of the prosthesis visible, which is the opposite of what you would want with your pants. Also, something that was mentioned several times was that the foam gradually changes shape and that it becomes permanently deformed when leaned against an edge of a living room table for example. These deformations make the cosmesis look strange and unnatural. Not many of those answering the questionnaire use nylon stockings and over 70 percent said that they would not want to use them, but those who do pointed out that they break easily.

A problem that was brought up during one of the interviews was that during the year your skin tone changes but the colour of your prosthesis always stays the same. When the colour mismatches it is very easy to see that the prosthesis is not a real leg, and the interviewee would like to be able to change the colour of the cosmesis so that it matches her skin tone all year around. When it came to the hardness of the cover, 29% of the participants did not have a preference, and 22,6% would like the cover to be in a silicone material.

3.6.4 **Expert interview**

3.6.4.1 Interview with Shahrokh Arami and Christoffer Lindhe

Shahrokh Arami and Christoffer Lindhe agreed on most things when it came to the design and to production costs. They both agreed that the cover needs to have smooth transitions from the cover to the socket and from the cover to the foot, since a smooth transition and a proper fit are needed to avoid unwanted noises when walking. Also, since today's feet are very mobile in all directions, they both said that the feet cannot be restricted in any way. The cover needs to be adjustable both in length and around the socket so that every amputee's personal socket will fit properly.

Some requirements that only Shahrokh Arami had was that the cover does not have to have the exact dimensions of the amputee's healthy leg but more of a generic shape. He also mentioned that a good to have requirement is that the cover could easily be removed by the orthopaedic engineer without destroying it and a bonus would be if the amputee is also able to remove the cover on their own.

Primarily they both want a product that can fit all sizes of calves but at the same time they said that this is an ideal solution. Three different generic sizes of calves would accommodate all amputees' wishes according to Shahrokh Arami. If the

prototype works with the prosthesis used in this project, it will work for most of the prosthesis that are used today. Two things that only Christoffer Lindhe mentioned was that the product does not have to be completely assembled when it is delivered to the orthopaedic clinics, and one nice to have specification is that the cover should fit over their Xtend Connect product.

3.6.4.2 Interview with unbiased experts

All three orthopaedic engineers said that most of their patients want some kind of cosmesis. They all mentioned that they would love to see a cosmetic cover that could be taken off without destroying it and that it could be personalised to fit every amputee's prosthesis. One of the experts also wanted a cover that can be reshaped after it is mounted to the prosthesis so that if the amputee needs a new socket the cosmesis can be reshaped. They would love to see a solution that could be mounted in one sitting, that the cover is easy to work with, that it has a low price, and that it is easy to clean, since many of their patients have complaints on that point.

General information that they shared that could be good to know was that moving parts often make noises, a good-looking transition at the foot is important if the patient wants to wear sandals or lower shoes, and that materials used in 3D-printed covers cannot be placed against the socket because they will be too noisy.

4 Define

To be able to use the knowledge and insights that were gathered during the discovery phase, the information must be sorted out and structured. This is performed in this section by defining user needs and prioritizing them. To more easily understand what the product should do and how it should be presented, a mood board, personas, and a design brief was developed.

4.1 User needs

To specify the user needs from the information gathered in the questionnaires and the user interviews, the statement method from Ulrich & Eppinger [28, pp. 81-82] is used. Here the thoughts from the user interviews and questionnaires are expressed in statements that then are translated into user needs. According to Ulrich & Eppinger [28, p. 82] there are five guidelines on how to write these user needs:

- Express the user's need in what the product must do and not how it might do it
- Express the user's needs as specifically as the raw data
- Use positive phrasings
- Express the user needs as an attribute of the product
- Avoid the words must and should

A table that includes the statements and needs from the questionnaire and the user interviews can be found in Table H.1 in Appendix H. Since all information that provided the statements was in Swedish and in order to not lose any information in an early translation, the table was kept in Swedish. The user needs that came from this table were later translated into English.

All the quantitative information that came from the questionnaire was directly interpreted into user needs. These together with the user needs that came from Table H.1 in Appendix H can be found in a summarized list in Table H.2.1 in Appendix H. The user needs that emerged from the expert interviews were directly interpreted since they had a clear vision of what they wanted. They can be found in Table H.2.2 in Appendix H. Table H.2.1 and Table H.2.2 both contain certain needs that overlap, but most needs are unequal as the amputees and the experts have different points of

view on what is important. The users only expressed needs related to the design, its usability, and its function, while the experts also expressed needs related to their work situation.

4.2 Function analysis matrix

The function analysis matrix is a summarized list of all the unique user needs. All user needs are marked with either an “N” for need or with a “D” for desired. This is a ranking system that later can be used when developing the product to know what is needed and what is not. In addition, one of the user needs is selected as a head function “HF” as it is the most important need. The end solution must strive to meet as many of the needed requirements as possible and if it meets any of the desired requirements, that is a bonus. The head function and the needs can be found in Table 4.1 below. The wished user needs can be found in Table H.3 in Appendix H.

Table 4.1 Function Analysis Matrix – head function and need.

HF – Head function N – Need

The product is quick to mount	**HF**
The product is easy to shape	N
The product can be worn with any type of clothing	N
The product looks good under any type of clothing	N
The product does not make any sounds	N
The product does not move around	N
The product is cheap	N
The product cost is at its minimum	N
The product is manufactured in Sweden	N
The product has a smart and efficient production	N
The product can be cleaned	N
The product makes the user feel more comfortable with their prosthesis	N
The product gives a feeling of having two legs again	N
The product looks well made	N
The product looks good	N
The product had the shape of a calf	N
The product can be taken off by orthopaedic engineers and technicians	N
The product is easy to handle	N
The product allows the foot to move	N
The product is attached to the prosthesis	N
The product fits 30 mm pylons	N
The product can be used with a suspension sleeve	N
The product fits all sizes	N
The product can withstand smaller impacts and pressure without damage	N
The product keeps it shape	N
The edges of the product are smooth	N
The product has smooth transitions to the socket and the foot	N
The product can be adjusted to fit all lengths	N
The product is adjustable at the socket	N
The product fits all sockets	N

4.3 Mood board

According to Wikberg Nilsson et al. in their book *Design: process och metod* [40, p. 101], a mood board is a way to visualize the feeling of what the final product should mediate. The pictures show both information about the final design of the product and about the emotional experience that hopefully is created when the product is used in the future. A mood board for this project can be seen in Figure 4.1.

Figure 4.1: Mood board [41].

4.4 Personas

Sharp and Preece [37, p. 404] describe personas as a detailed description of potential users of the product who are created to assist the designer during the development phase. The description of the personas include what they are like as a person and their goals relating to the product. They also have a photograph or an illustration of a person and a full name, making it easier to see these personas as real potential users. When making design decisions the persona is used to see if the design will help or hinder the users. According to Sharp & Preece the two main goals for a persona is to help the designer make design decisions and to remind them that real people will be using the product.

Four personas were created using the information that was gathered through the user study and expert interviews. These are later used in the brainstorming sessions. The personas can be found in Appendix I.

4.5 Design brief

To eliminate the complications that can occur when today's foam cosmesis is put on, a new product that does not cause these complications will be developed. This product should make the users feel comfortable wearing and using their prosthesis. Regarding the user, the main purpose for this product is for it to resemble a normal calf in both shape and colour, in order to satisfy both those who want the prosthesis to look like a real leg and for those who only want it to look good wearing pants and other clothing.

In addition to eliminating the complications that can occur, the solution also focuses on the fact that the product is able to be removed without being destroyed when adjustments to the prosthesis must be made. This problem exists on most of the cosmetic covers that are used today, and this forces the amputee to go through the process of putting cosmesis on their prosthesis multiple times. Therefore, the main focus of what the product should do is that it should be quick and easy to mount, easy to shape and fit onto the amputee's prosthesis, easy to remove without damage, and be aesthetically pleasing.

Since the product is supposed to be used daily, it is important that it is durable, that it can withstand minor impacts, and that it cannot easily be damaged or broken. The product should also be able to be used in normal weather conditions and withstand temperature variations. For this product to be used by public hospitals and orthopaedic clinics the production cost must be kept to a minimum and therefore ideally have an efficient production that produces a one-size fits all product. Also, the production must be located in Sweden as per specifications set by Lindhe Xtend.

5 Develop

This section describes the methods used to develop different concepts and then how these concepts are further developed through sketches and quick prototypes. At the end of this section, the most promising concepts are presented.

5.1 Brainstorming

Brainstorming is a widely used technique for generating all kinds of ideas [37, p. 402]. Brainstorming can be done in many different ways, but for it to be as effective as possible, the four ground principles, that are stated below, have to be followed [40, p. 125].

1. Never criticize yourself or others
2. Aim for crazy and wild ideas
3. Combine different ideas to improve them
4. Aim for quantity before quality

To gather as many ideas and thoughts as possible, two brainstorming sessions were performed. The first one was with a former student that has some knowledge about product development and the second one was with Christoffer Lindhe and Patrik Svensson at Lindhe Xtend. Svensson is the product development engineer at the company and Lindhe was the one who came up with the Xtend Foot that started the company. Therefore, both have knowledge about product development, but they also have a great knowledge about the industry. The brainstorming session with Lindhe and Svensson was done over a video conference due to the Covid-19 restrictions. During the brainstorming sessions, the personas that were previously created was used to remind the participants of who the users are and what their needs were.

The brainstorming sessions consisted of two different ways of creating and gathering thoughts and ideas: mind mapping and brainwriting/brainwriting.

5.1.1 **Mind mapping**

Hannington [38, p. 118] describes mind mapping as a visual thinking tool that allows the participants to write or sketch down all thoughts and ideas on the topic without restrictions.

In this project, six different topics were used, and these were flexible and mouldable materials, existing products that are flexible and mouldable, width at the socket, left and right, nice transitions, and length. The first two topics are there mostly to start the thinking process, but also to see what materials that could be used and if any existing products that solve similar problems could be helpful in generating ideas. The rest of the topics are problem areas that must be solved in the product.

All participants got around five minutes to write down or draw down as many thoughts and ideas that came to mind, and then, when the session was over, all ideas and thoughts were added to a mind map to get an overview of everything more easily. Since the sessions were held through a video conference, an online platform where all participants could enter their ideas and thoughts in a so-called word cloud was used.

5.1.2 **Braindrawing and brainwriting**

According to Wikberg Nilsson et al. [40, pp. 127-129], braindrawing and brainwriting are two similar brainstorming methods. It states that each participant is given a topic that they will focus on and then for three minutes, everyone draws or writes down all ideas they can come up with. When the three minutes have passed, the participants exchange topics with each other and then have three minutes for the new topic. This is performed until all topics have been passed around. The ideas that are either drawn or written down can both be built on previous participants' ideas or be completely new ones. Here, ideas and thoughts that were brought up during the mind mapping session were free to use. When all topics had been passed around, all ideas were discussed, explained, and analysed.

5.2 Mock-ups

Don Norman [10, p. 227] describes mock-ups as quick and simple prototypes that can, for example, consist of pencil sketches and paper or cardboard models. He says that they can be done to understand if an idea is reasonable and whether it works in practice.

5.2.1 **Sketches**

To gather all the thoughts and ideas that came up during the brainstorming sessions, quick and easy sketches were done. Ideas and thoughts that popped up earlier in the project were also put down on paper so that they were not forgotten. These sketches could then be further developed and be turned into fully working concepts.

Sketches is a way of communicating a concept visually and to easier analyse the idea [28, p. 170]. During the sketching process, new thoughts and ideas can often emerge and these can then contribute to the final product [40, pp. 156-157]. Therefore, sketches are a very valuable tool for the development phase.

5.2.2 **Paper models**

To more easily understand how the ideas that came up during the brainstorming sessions work in practice, full-scale paper models were made. Paper models enable an understanding of the ideas proportions as well as its functionality [40, p. 157]. Questions such as: “Will it work?” and “How well does it meet the customer needs?” can be asked and analysed to later evaluate which concepts are to be further developed [28, p. 294]. Some of the paper models can be seen in Figure 5.1.

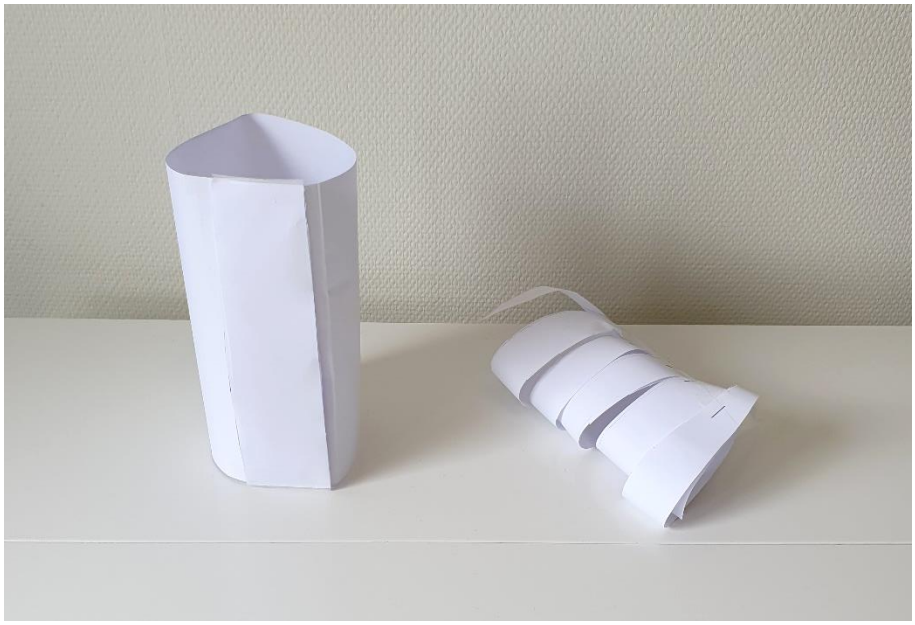

Figure 5.1: Simple paper models.

5.3 Concepts

A video meeting with Christoffer Lindhe and Patrik Svensson at Lindhe Xtend was held to discuss and reflect on all ideas that have come up during the brainstorming and mock-up sessions. Some ideas were less feasible than others and could be ruled out immediately. For example, all ideas that were of a cone-shape were excluded since they do not express the shape of a calf, and ideas that did not work well in practice were also excluded. The six ideas that remained were discussed more thoroughly and these concepts are described in more detail below.

5.3.1 **Concept A – Foam with attachment**

The foam with attachment solution is a similar solution to the one that is used by orthopaedic clinics today, although with all complications avoided. This solution consists of two foam halves with a groove in the middle for the pylon to fit. In addition, the middle part of the groove is covered with a hard plastic that is there to stabilize the cover and to attach the cover to the pylon with a closing mechanism. This allows the foam to stay in place without having to glue it on, which is one of the problematic features with today's solution. An advantage of this new solution is that it can be removed without being destroyed when adjustments on the prosthesis must be made.

This idea may be suitable because some orthopaedic clinics, after being contacted about the project, replied that they were satisfied with the cosmetic covers they use today. Since today’s foam solution has been around for a very long time, it may be that the orthopaedic clinics feel comfortable with the solution they always worked with, thus not being willing to start over using an entirely new solution. This new foam cover is not very different compared to what exists today, thus not meeting all the improvements that the amputees requested from the user study. Figure 5.2 shows a sketch of the concept.

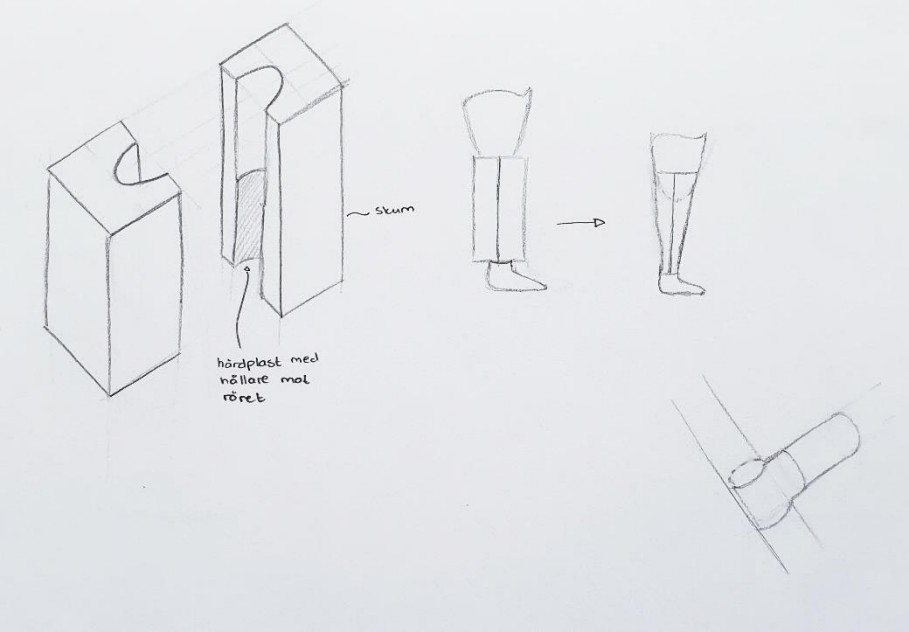

Figure 5.2: A sketch of concept A.

5.3.2 **Concept B – Mouldable plastic**

The overall thought with this idea is that the cover should have a basic shape of a generic lower leg that then can be adapted and personalized with some heat and sculpting. The mouldable material, preferably a thermoplastic material, allows specific parts of the cover to change shape when heated, and when the plastic then solidifies it retains its new shape. The upper half of the cover that is placed around the socket can be heated, broadened, and then pressed up on the socket to get a perfect fit. The main idea is that this mouldable cover should be produced in either one part or in two halves, depending on what works best. The lower part of the cover does not need to be heated and reshaped as it already has the right dimensions to fit the foot.

To be able to adapt the cover to different lengths, the idea is that the cover should be longer than necessary on both ends and this means that the cover can be cut to the right length. Being able to personalize the length of the lower part of the cover means that the calf can begin at the same height as the amputee's other leg. By heating the cover where the calf is to be placed and then pushing on the material from the inside to form a calf, the cover can take on a shape that is very similar to the amputee’s other leg.

To avoid any unnecessary noise from the socket and the cover while walking, a

textile tape or similar can be placed on the outside of the socket or on the inside of the cover. For the foot to be able to move, no hard material must be placed near the foot, but at the same time there must not be any gaps between the cover and the foot. Therefore, an insert made from a softer material such as EVA foam (ethylene-vinyl acetate foam) or similar could be placed between the foot and the cover. Figure 5.3 to 5.5 show some sketches of the concept.

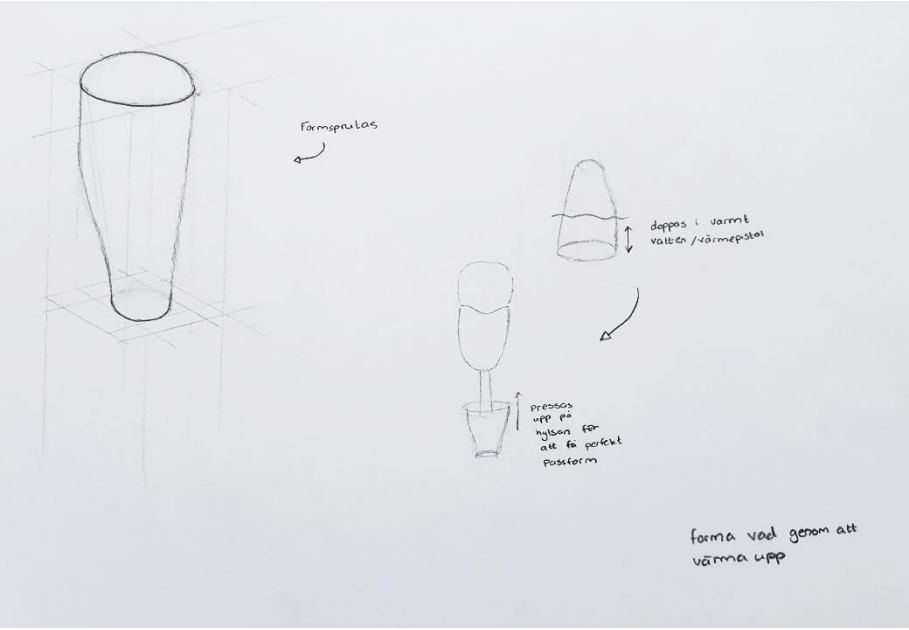

Figure 5.3: A sketch of concept B where the cover is dipped in hot water.

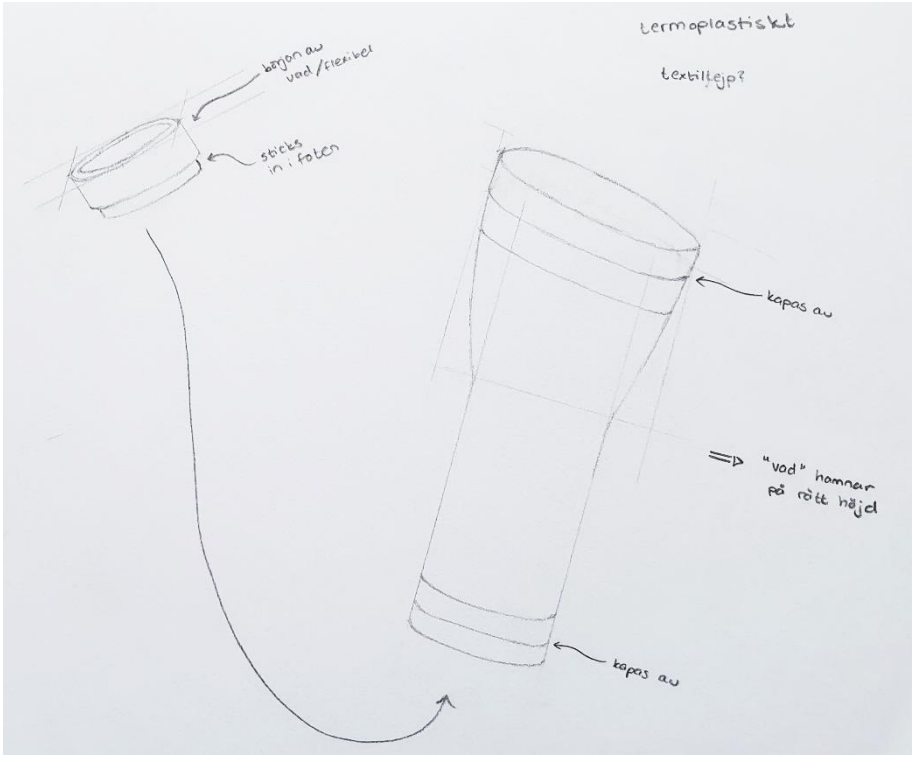

Figure 5.4: A sketch of concept B with the EVA foam insert.

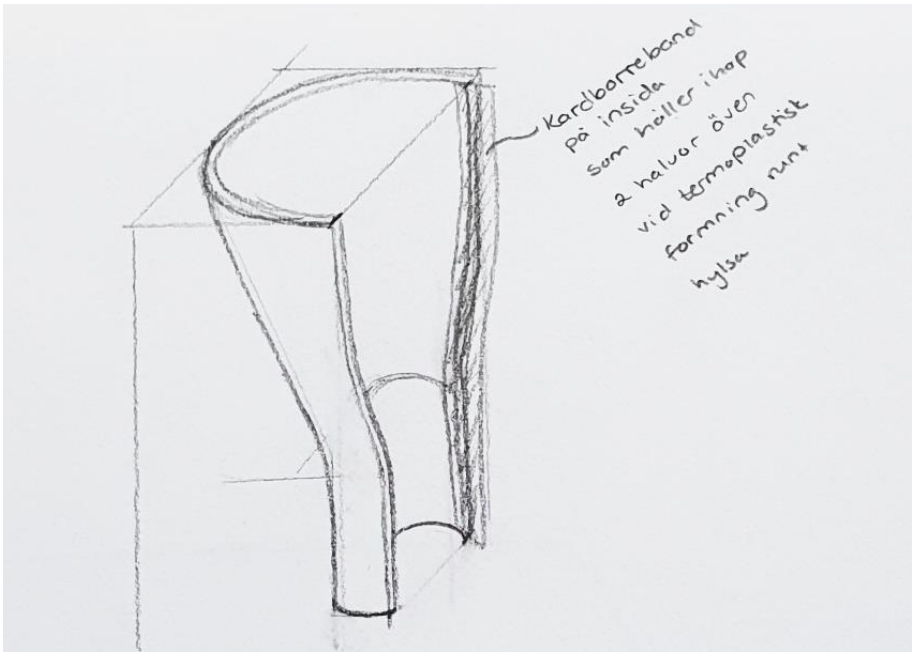

Figure 5.5: A sketch of concept B in halves.

5.3.3 **Concept C – EVA foam**

The idea of using EVA foam for the cover is a quite simple idea where the product only consists of one material and not many extra manufacturing steps have to be taken to finish the product. The disadvantage with EVA foam is that the cover cannot be reshaped and personalized to the same extent as, for example, the mouldable plastic cover. This means that this cover will only have a generic shape.

The idea is that this cover will be manufactured so that the upper part of the cover has a large circumference which later can be adapted, while the lower part of the cover has a fixed shape that matches the foot. For the cover to get a good fit around the socket, V-shaped pieces can be cut out and the edges can be glued together so that the circumference is reduced. The cover will also be adjustable in length since the cover will be produced so that it is longer than necessary and can be cut down to the right length. This also allows the generic calf to be placed at the same height as the healthy leg. Figure 5.6 shows a sketch of the concept.

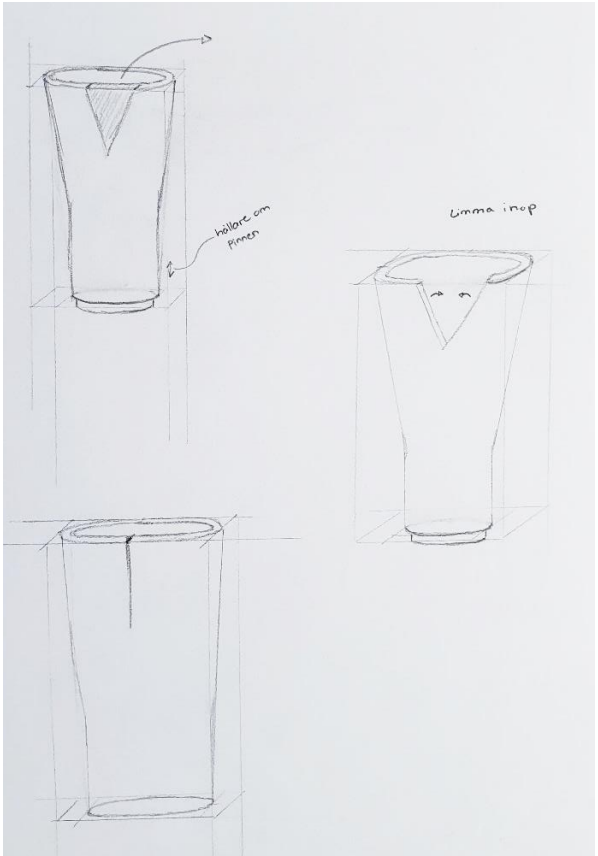

Figure 5.6: A sketch of concept C.

5.3.4 **Concept D – Stretchy fabric**

The stretchy fabric solution is quite similar to concept B that uses mouldable plastic. In this idea, fabric with enough stretch is coated with a mouldable plastic layer and then shaped into a generic lower leg. This generally shaped cover can later be altered by heating the plastic layer and stretching the fabric. When the cover cools down it keeps its new shape and can therefore be personalized to look like the amputee's healthy leg. One problem with this solution is that the stretchy fabric wants to retract to its original position. To avoid this, the plastic must be able to withstand the forces from the fabric and hold the given shape.

As with concept B, this cover also needs an insert made of a softer material between the foot and the cover, as well as some fabric tape or similar at the socket, to allow the foot to move and for the cover to not make any noise when the amputee is walking around. This idea is therefore very similar to the idea in concept B except that less plastic material could possibly be used by having a stretchy fabric as a base. Figure 5.7 shows a sketch of the concept.

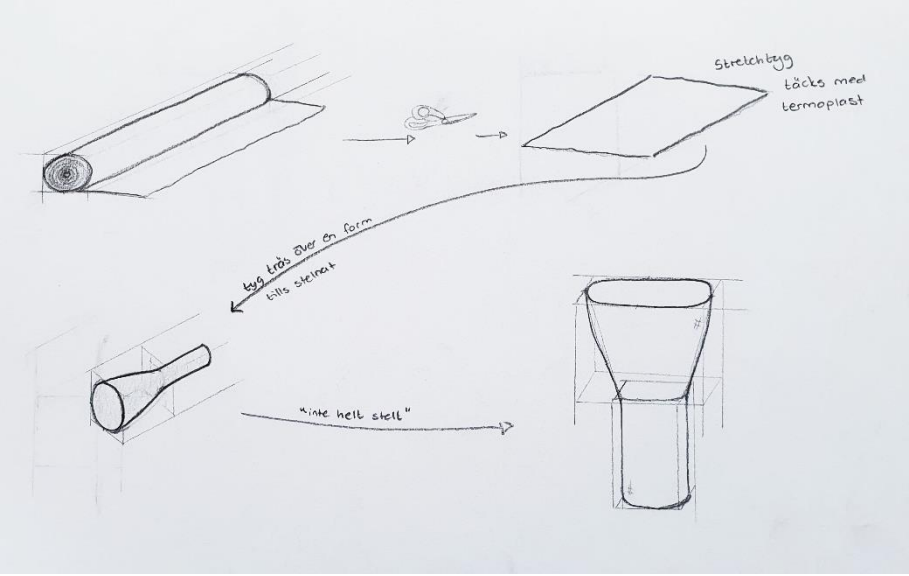

Figure 5.7: A sketch of concept D.

5.3.5 **Concept E – Stripes**

The stripe solution is a cover that consists of smaller vertical sections that are made of hard or flexible material. This cover can be stretched out to fit all different sizes of sockets, which implies that the original shape must be small in circumference to be able to fit a smaller socket as well. The flexible material must therefore be

stretchy enough to fit all sizes, or the cover must be produced in a few different sizes.

The sections made from a harder material could be thermoplastic. If a thermoplastic material is used it could be shaped and personalized as in previous concepts, but since the cover for natural reasons always wants to retract to its original position, it will be difficult to change the shape. Therefore, the sections that are made from a harder material will probably not be mouldable and the cover will have a generic shape instead. Like the previous concepts, the cover must be produced longer and then be cut to the desired length. Figure 5.8 shows a sketch of the concept.

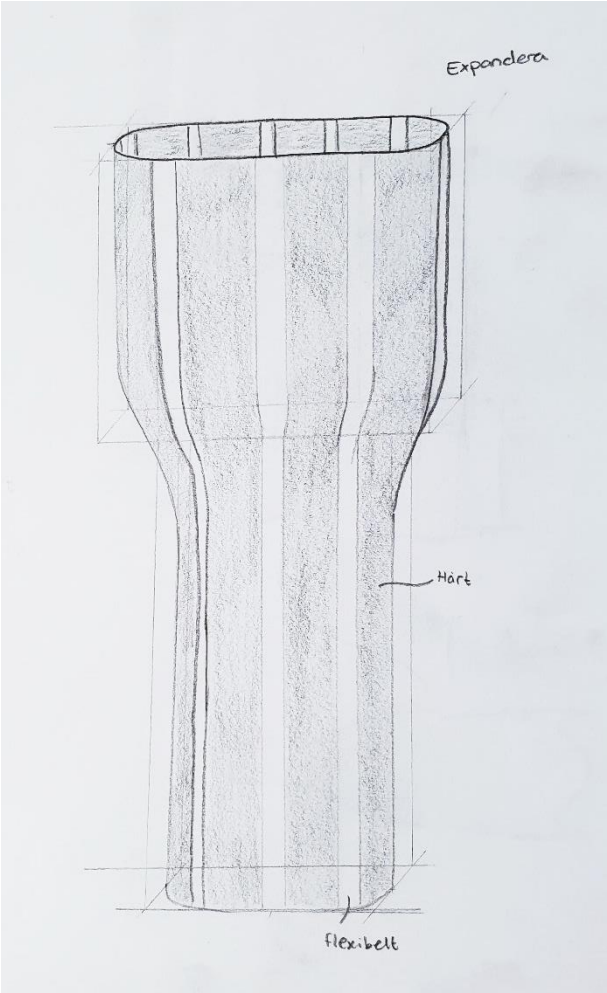

Figure 5.8: A sketch of concept E.

5.3.6 **Concept F – Puzzle**

The puzzle concept is where different sized and angled tubular parts are stacked on top of each other to build a customizable lower leg. These tubular parts are placed inside a “sock” made from a softer material that will expand when the tubular parts are inserted into the sock. The sock is shaped like a tube where there is an inside and an outside wall and between these walls the tubular parts can be placed. With this solution, an external calf part can be positioned anywhere in the sock. The tubular parts must be made of a harder material to be able to withstand the pressure that comes from expanding the sock.

For this solution to work for all amputees, there must be many different tubular parts to choose from to be able to build a cover that suits everyone. Many different parts easily make the production very costly which is something that should be avoided. Figure 5.9 shows a sketch of the concept.

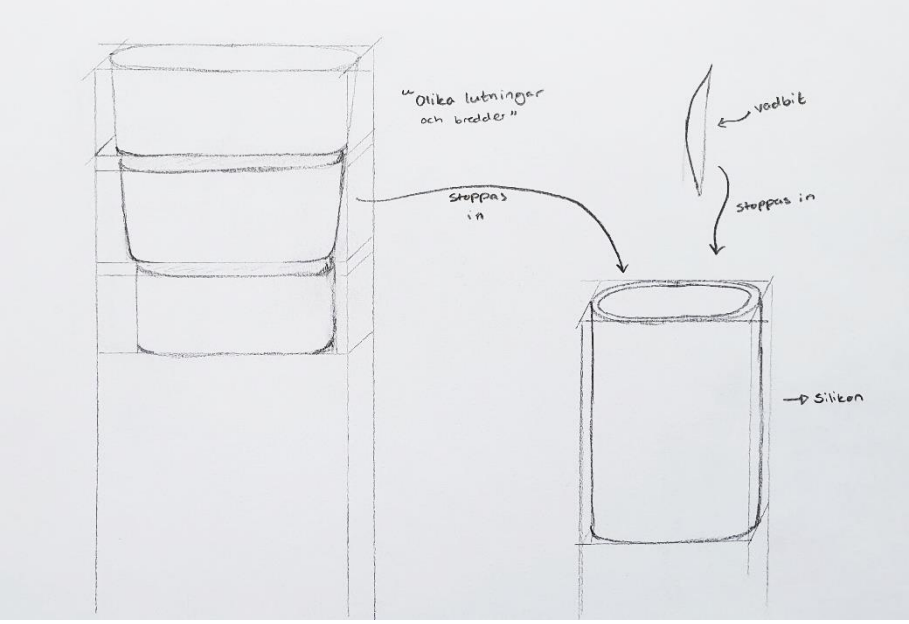

Figure 5.9: A sketch of concept F.

6 Deliver

In this section, all concepts are evaluated, and the two most promising ones are further developed. Full scale prototypes are done and a final evaluation with users and experts are concluded. At the end, the final concept is chosen.

6.1 Evaluation

All concepts under heading 5.3 are evaluated to see the concepts' potentials and problems. This is done through building more detailed prototypes, having a meeting with Mälarplast, looking at the concepts' strengths and weaknesses, and through a selection matrix called concept scoring. After this evaluation process, the two top concepts will be chosen for further development.

6.1.1 **Lo-fi prototypes**

To get a better understanding of how the concepts under heading 5.3 work, simple but more detailed prototypes were made. The lo-fi prototypes were made from cardboard, paper, and sponges to try to imitate the intended material and to capture its functionality. These prototypes raised new questions and provided a deeper understanding of how they work in practice and what a possible production would look like. Examples of the lo-fi prototypes that were made can be seen in Figure 6.1.

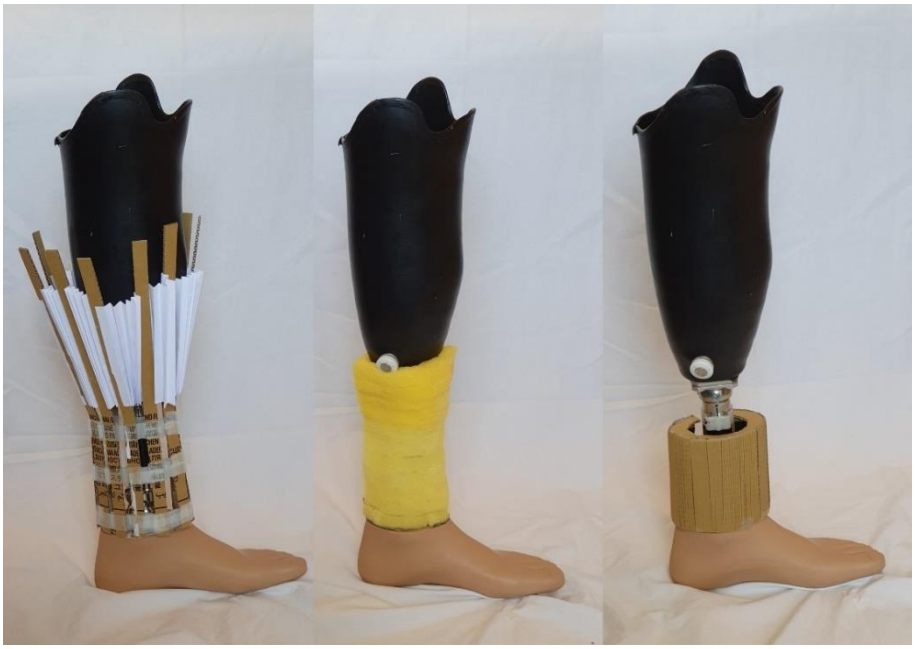

Figure 6.1: Lo-fi prototypes of some of the concepts in section 5.3.

6.1.2 **Meeting with Mälarplast**

After some research, it was discovered that thermoplastics that can be formed at lower temperatures are not common in industrial uses. When reading about different thermoplastics and their properties, it was discovered that the glass transition temperature, where the material becomes softer and mouldable, was over 100 degrees Celsius for almost all plastic materials and sometimes much higher. To be able to shape the thermoplastic cover over the amputee's prosthesis without any major problems, it is required that the thermoplastic is mouldable below or near 100 degrees Celsius. This glass transition temperature seems to only be found in hobby materials such as Thermoworx mouldable plastic pellets. These thermoplastic pellets [42] become mouldable if they are placed in water that is above 62 degrees Celsius and then they can be formed into any desired shape. When the material has cooled down and solidified it can be reheated and reshaped endless amounts of times.

To get an understanding if the thermoplastic ideas is feasible and if any existing materials have the right properties, Mälarplast [43] was contacted. Mälarplast is a supplier of environmentally friendly and customer-adapted plastic solutions. During a meeting with Alberto Bonnet and Conny Tapper at Mälarplast [44], some valuable information was gathered regarding the concept and the material.

Alberto Bonnet and Conny Tapper were curious about the concept, but at the same time it is something completely new to them and therefore an unknown area. They said that the cover could maybe be made in polypropylene (PP), but it would be a challenge. Injection moulding the cover itself would not be a problem, but it is the post-forming that will be a challenge. Tapper said that plastic materials like to return to their original shape after forming and that is something that must be further investigated to ensure that it does not happen. In addition, it will be a challenge to stretch the plastic up to 10 to 15 centimetres since the thickness of the cover will be thinned out, according to Tapper. Maintaining the strength and stiffness in the cover will be difficult if the plastic must be stretched out so much and a solution for this would be to have a thicker wall or to produce the cover in several sizes. If the plastic were to be stretched only a few millimetres, it would not be a problem, but stretching the plastic several centimetres will possibly generate issues according to Tapper.

Creating a product with thicker goods or producing several sizes makes the product more expensive. In addition, Mälarplast must conduct a study and do preparatory work to see if there is any material that has the right properties and how it behaves in different environments and situations. The study and the preparatory work must be conducted since this is a completely new area to them. Alberto Bonnet estimated the time for this to be around a week, and the labour cost will be added to the production costs.

After this meeting, it was quite clear that the concept of using an adaptive material that can be post-formed to this extent would be quite difficult to implement, and that it will easily become very expensive. However, it does not seem impossible to produce such a solution and the idea in itself is not bad, but there are far too many unclear questions around how well the product works in reality and at what cost.

6.1.3 **Strength and weakness**

The strengths and weaknesses of all six concepts are written down to get an overview of which concepts are better than the others. These strengths and weaknesses are good to have written down and can be used as a guide in a later evaluation. All concepts both have strengths that are marked with an "+" and weaknesses that are marked with an "-", but some also have a middle category that are marked with a "●" for more uncertain statements.

6.1.3.1 Concept A – Foam with attachment

+ A well-known product
+ Easy to shape
+ Quick to mount
+ Can be customized
+ Could be used under a dream skin or similar

+ Can easily be mass-produced
+ Could use the same technique to hold the cover and the prosthesis together as Xtend Cover does
+ Allows the foot to move
+ If nylon stockings are used it can have different skin tone colours

- The foam can tare
- Without glue, the foam must be attached to the socket in another way and that is an unknown area
- The foam and the hard plastic piece that holds the cover onto the prosthesis may detach from each other
- Requires a nylon stocking

6.1.3.2 Concept B – Mouldable plastic

+ Easy to shape
+ Quick to mount
+ Can be customized
+ Could probably be used under a dream skin or similar
+ Can easily be reshaped

- Might be expensive to produce since tool costs is expensive
- Might be difficult to disassemble when adjustments on the prosthesis has to be done
- Could maybe be coloured to match the amputees skin tone

- Difficult to find a suitable material with the right properties
- Could be deformed if used in high temperatures
- It is a hard cover that may not feel like a real leg

6.1.3.3 Concept C – EVA foam

+ Quick to mount
+ Can easily be removed from the prosthesis
+ Can be produced in Sweden if thermoformed
+ If thermoformed, then a right and left calf could be produced
+ If thermoformed, it is cheap to produce since the moulds are cheap

- Might be hard to get skin-type colours
- Could maybe be casted or injection moulded in Sweden

- It will be a generic shape of a lower leg
- Might not work with a dream skin since it is not stiff enough

6.1.3.4 Concept D – Stretchy fabric

+ Easy to shape
+ Quick to mount
+ Can be customized
+ Can easily be reshaped
+ The fabric could be available in several colours and patterns

- Might be difficult to disassemble when adjustments on the prosthesis has to be done
- Might be a bit flexible and therefore feel more like a leg than the mouldable plastic solution
- The thermoplastic might not withstand the forces from the stretched fabric

− Difficult to find a suitable material with the right properties
− Difficult to coat the fabric in thermoplastic material
− Could be deformed if used in high temperatures
− Must be shaped after coated in thermoplastic (another production step)
− Expensive production since difficult and lots of steps

6.1.3.5 Concept E – Stripes

+ Quick to mount
+ Can easily be taken off

− Difficult to find a suitable stretchy material with the right properties
− Expensive due to difficult production and many pieces
− Gets a generic shape without a calf or two products have to be made with a left and a right calf

6.1.3.6 Concept F – Puzzle

+ Quick to mount
+ Can easily be taken off
+ Can be customized
+ If a silicone “sock” is being used it will look and feel somewhat like a real leg

- The different pieces might move around inside the “sock”

− Many individual parts must be produced to fit all sizes
− Expensive since a lot of parts
− Hard to mass-produce due to many parts

6.1.4 **Concept scoring**

According to Ulrich and Eppinger [28, p. 154], concept scoring is a method where the concepts are ranked from the best to the worst concept. The main goal with this matrix is to see which concepts perform best based on the selected criteria. The selected criteria consist of the most important criteria from the function analysis matrix, that can be found in Table 4.1 on page 39. All criteria get a weighted value corresponding to their importance and each concept is given a score of 1-5 on each criterion. The higher the score the better the concept meets the criterion.

Not all criteria that were classified as necessary in the function analysis matrix were included in the concept scoring matrix as some criteria were similar and some were more personal. The concept scoring matrix can be seen in Table 6.1.

Table 6.1. Concept scoring matrix for concept A to F.

		Concept A		Concept B		Concept C		Concept D		Concept E		Concept F	
Selected criteria:	**Weight (%):**	Rating	Score	Rating	Score	Rating	Score	Rating	Score	Rating	Score	Rating	Score
The product is quick to mount	10	3	0.30	3	0.30	4	0.40	3	0.30	4	0.40	3	0.30
The product is easy to shape	3	4	0.12	3	0.09	4	0.12	3	0.09	1	0.03	3	0.09
The product does not make any sounds	9	5	0.45	3	0.27	5	0.45	3	0.27	2	0.18	3	0.27
The product does not move around	5	4	0.20	5	0.25	3	0.15	4	0.20	2	0.10	2	0.10
The product cost is at its minimum	5	4	0.20	2	0.10	4	0.20	1	0.05	1	0.05	2	0.10
The product has a smart and efficient production	2	3	0.06	2	0.04	3	0.06	1	0.02	2	0.04	1	0.02
The product can be cleaned	4	2	0.08	4	0.16	4	0.16	3	0.12	4	0.16	4	0.16
The product looks good	5	5	0.25	4	0.20	3	0.15	3	0.15	1	0.05	3	0.15
The product has the shape of a calf	6	5	0.30	4	0.24	1	0.06	4	0.24	1	0.06	4	0.24
The product can be taken off by orthopaedic engineers and technicians	1	4	0.04	4	0.04	4	0.04	4	0.04	5	0.05	4	0.04
The product is easy to handle	2	4	0.08	4	0.08	4	0.08	3	0.06	4	0.08	2	0.04
The product allows the foot to move	9	5	0.45	2	0.18	5	0.45	2	0.18	2	0.18	3	0.27
The product fits 30 mm pylons	6	5	0.30	5	0.30	5	0.30	5	0.30	5	0.30	5	0.30
The product can withstand smaller impacts and pressure without damage	6	3	0.18	4	0.24	5	0.30	3	0.18	4	0.24	4	0.24
The product keeps its shape	6	3	0.18	4	0.24	4	0.24	4	0.24	2	0.12	4	0.24
The product has smooth transitions to the socket and the foot	3	4	0.12	2	0.06	3	0.09	2	0.06	2	0.06	3	0.09
The product can be adjusted to fit all lengths	7	5	0.35	4	0.28	4	0.28	4	0.28	3	0.21	4	0.28
The product is adjustable at the socket	7	5	0.35	4	0.28	4	0.28	4	0.28	3	0.21	4	0.28
	Total score:	4.01		3.35		3.81		3.06		2.52		3.21	
	Rank:	1		3		2		5		6		4	
	Continue:	YES		NO		YES		NO		NO		NO	

6.2 Concepts to proceed with

The goal was to move forward with two or three concepts with the help of the information that was gathered during the evaluation process. After the evaluation process it was clear that the three best concepts were concept A, B and C. With the information from the meeting with Mälarplast it could be determined that concept B would be too expensive to produce. In addition, there was no guarantee that the product would be functional or have a pleasant appearance in the end. The concept is not a bad idea, it is just too expensive to produce at the moment. Therefore, concept B was not chosen to proceed with. Concept B also came in third place in the concept scoring matrix, see Table 6.1, which indicates that concept A and C are slightly better in their performance.

The two concepts that are taken further for development are:

- Concept A – Foam with attachment
- Concept C – EVA foam

6.2.1 **Concept A**

The concept using soft and hard foam and an attachment piece can be separated into two different ideas:

1. A separate attachment
2. Foam and attachment as one part

6.2.1.1 A separate attachment

Producing the attachment piece separately from the foam means that the foam cosmesis that is already produced could still be used. However, some small modifications to the foam cosmesis may be required so that the attachment piece stays in place. These separate attachment pieces need to be glued together with the foam cosmesis in advance so that the amputee does not have to wait for the glue to dry when the cosmesis is put on. Since the orthopaedic engineer has assembled the prosthesis beforehand, he or she should know approximately where the attachment piece must be placed. As the foam cosmesis is produced longer than what is often needed, it can be cut afterwards so that it fits the prosthesis. This means that the attachment piece does not have to be glued on in an exact spot from the beginning.

In a conversation with Christoffer Lindhe at Lindhe Xtend, he said that they would rather see a complete solution where they can sell both the attachment piece and the foam cosmesis. With this information, there are two solutions that can be further developed:

- Make the attachment piece separately and also produce a foam cosmesis that has the same profile as the attachment piece on the inside
- Make the attachment piece and the foam cosmesis as one part

Before any thought was given to how the attachment piece might look, it was considered whether the attachment mechanism that Lindhe Xtend already uses on their Xtend Cover could be used here as well. The Xtend Cover has a snapping mechanism further up on the cover and a holder around the pylon that is fixed using force and friction. With the foam cover it is difficult to place attachments further up on the cover since the material is quite thin around the socket. This means that the attachment piece that sits around the pylon must be strong enough to secure the cover, and using only tape or similar, to secure the edges of the foam. Since the attachment mechanism that Lindhe Xtend uses today seems to work on their Xtend Cover, this concept was taken into consideration later on in the development.

When thinking about how the attachment piece can be strong enough to secure the entire cover, an idea came up where the attachment piece could be fastened with screws. However, this means that holes must be made in the foam so that the screws can be accessed from the outside when the cover is put on or taken off. Since many of the users stated previously in the questionnaire, see Appendix C, that they would not like any joints or holes in the cover, the idea with screws was let go.

A brainstorming session was held where all kinds of ideas were sketched down on paper, these sketches can be seen in Figure 6.2 to Figure 6.5. Afterwards, a Google search was performed to see if similar products could be found and if there were any good ideas already developed that could be used in the product. To see how the ideas that came up during the brainstorming session work, simple prototypes were made in cardboard. These can be seen in Figure 6.6.

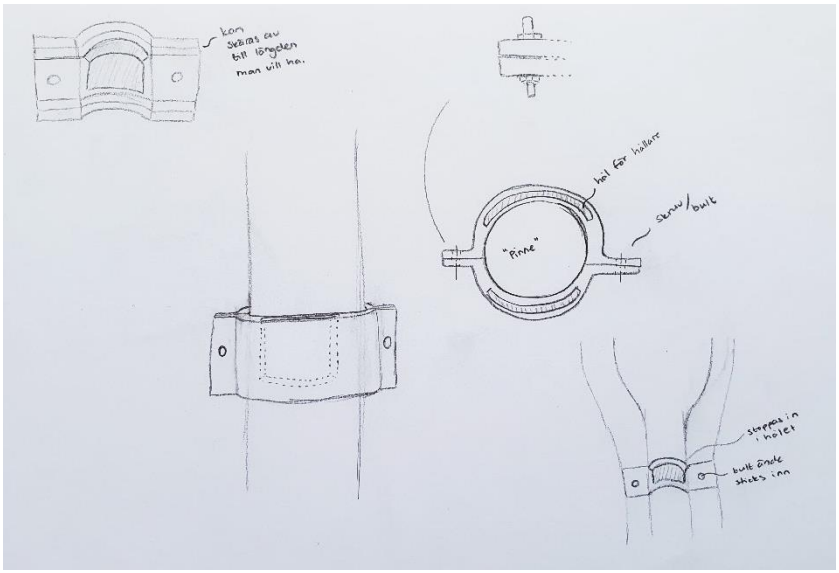

Figure 6.2: Sketches on some ideas for the attachment piece.

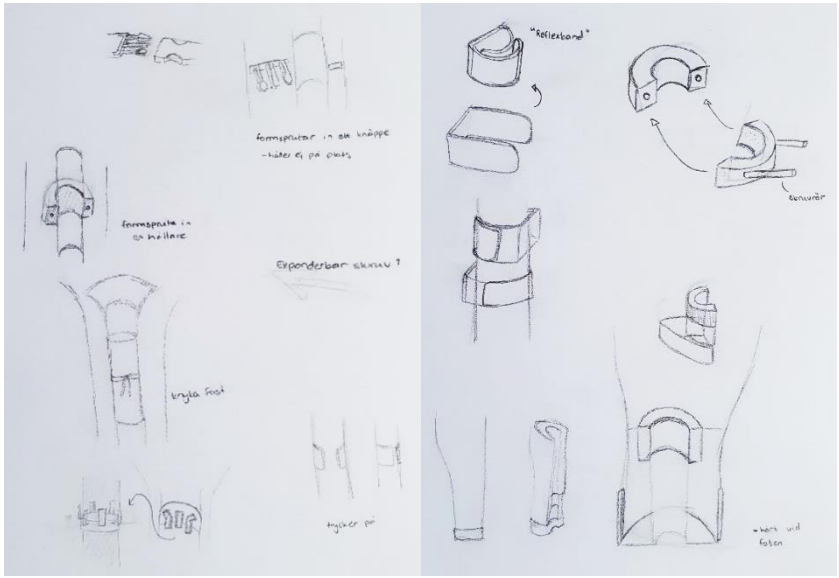

Figure 6.3: Sketches on some ideas for the attachment piece.

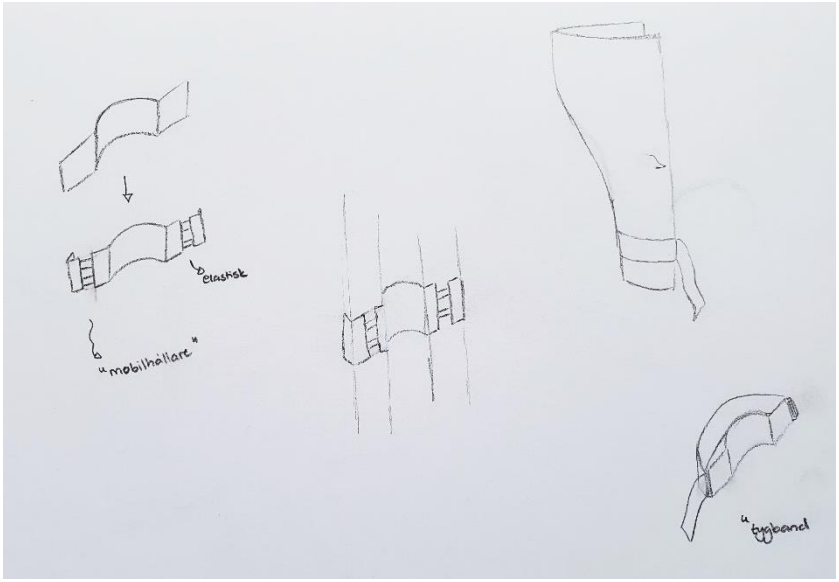

Figure 6.4: Sketches on some ideas for the attachment piece.

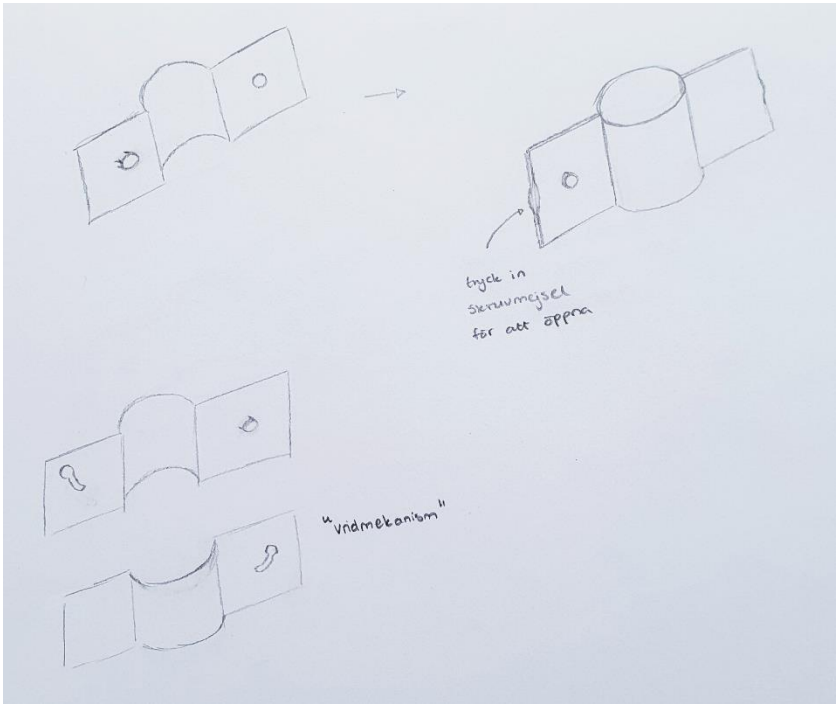

Figure 6.5: Sketches on some ideas for the attachment piece.

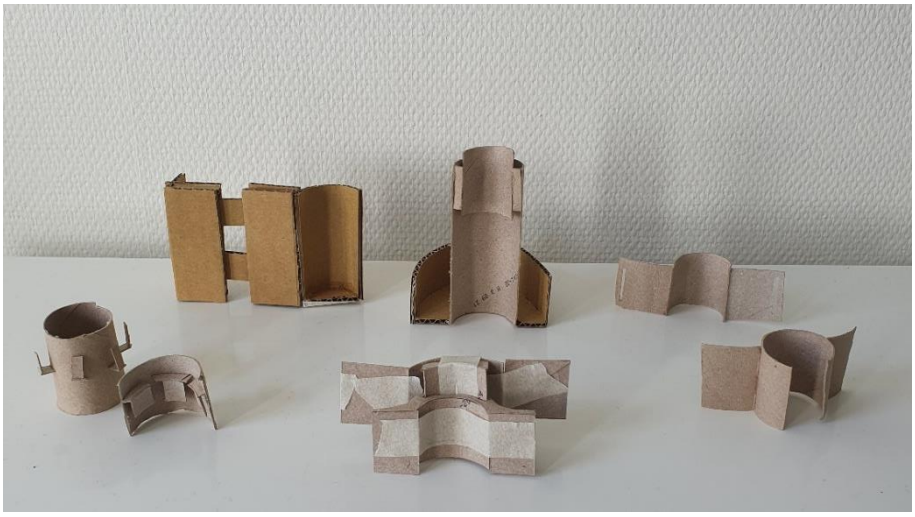

Figure 6.6: Simple prototypes in cardboard of the attachment piece.

6.2.1.2 Foam and attachment as one part

Producing the foam and the attachment piece as one part is only going to be considered if a separate attachment piece does not perform well. This could be done by, for example, injection moulding. If the foam and the attachment piece are produced as one part, they will have a stronger bond and therefore become more durable. For the attachment piece to get a great bond with the foam, it may be required that the attachment piece looks a little different than it would have if it were produced as a separate piece, however, the main function will still be the same.

A negative thing that comes with producing the attachment piece and the foam as one part, is that the attachment piece is placed in a permanent spot. This could result in that more foam must be cut off at the foot for the holder to end up at the same place as the pylon. Furthermore, this means that the foam tube must be produced even longer than today to fit all lengths of lower leg prostheses. A longer foam tube means that more material must be cut and thrown away, which is not material efficient.

After some thought where the pros and cons of all attachment ideas were examined and after a meeting with Christoffer Lindhe at Lindhe Xtend, two attachment pieces were chosen to develop further. The first idea that was chosen can be seen in Figure 6.2 on page 62, and a more detailed figure of the second idea that was chosen can be seen below in Figure 6.7.

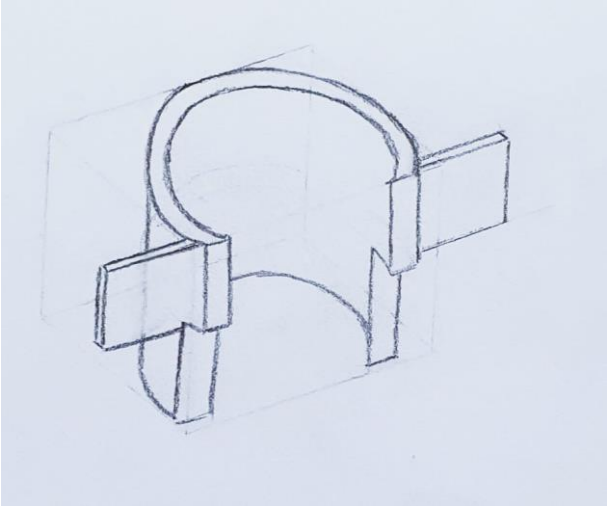

Figure 6.7: Simple sketch of the second idea that was chosen to continue with.

6.2.2 **Concept C**

The concept using EVA foam can be separated into three different ideas:

1. Thermoforming - two halves
2. Injection moulding - one continuous part
3. Foot insert

6.2.2.1 Thermoforming – two halves

This idea is based on the cover being produced in two halves where each half gets its shape through thermoforming. Through thermoforming, the cover gets a generic shape with a large circumference at the socket so that it can fit all socket sizes. The circumference can then be narrowed by removing a V-shaped part at the top half of the cover, and then gluing the sides together. This idea is a cheap solution since thermoforming is more affordable than injection moulding, as the tool costs is much lower, and the production can take place in Sweden. In addition, the thermoformed cover could be produced in two or three different sizes so that the circumference does not have to be reduced so much if the amputee has a smaller socket.

6.2.2.2 Injection moulding – one continuous part

The injection moulding idea is only to be performed if the thermoforming idea does not perform well. This cover has the same principles as the thermoforming idea when it comes to narrowing the circumference, the only difference being that it is produced in one continuous part instead of two halves. Because the cover is produced in one continuous part, it gets fewer seams that must be glued together and might therefore look neater. However, the production cost immediately

becomes more expensive as injection moulding is an expensive production method when the product is not produced in large quantities [45].

After some research, no companies were found in Sweden that produce EVA foam products through injection moulding. If EVA foam is to be the final material, production will have to be transferred to a company abroad where this type of production already exists.

6.2.2.3 Foot insert

As the main cover is only held in place by being tight around the socket and by tape or similar, there must be a part at the foot that prevents the cover from rotating during use. Therefore, an extra part that can be tucked into the foot to reduce rotation was designed. This part is called the foot insert and it is required in both the thermoforming idea and the injection moulding idea above.

For the thermoforming idea, the foot insert must be produced as a separate part and then glued onto the cover. For the injection moulding idea, the foot insert could be added directly to the cover during the production, or it could be produced separately and glued on afterwards. Here it depends on whether the cover must be able to be cut to any length or not. If the bottom part of the cover must be okay to cut to any length, the foot insert must be produced separately as for the thermoforming idea. However, if the length does not need to be changed, the foot insert could be incorporated into the mould when the cover is injection moulded.

6.3 Development of concepts

To get a general understanding of how the concept should work, full-scale prototypes of both concept A and concept C were made.

6.3.1 **Concept A**

In order to understand what material the foam cosmesis is made out of today and whether it is suitable for gluing on the attachment piece, the two most used foam cosmeses were procured. These two foam blocks can be seen in Figure 6.8 and Figure 6.9. When seeing the foam in reality, thoughts began to wander about whether gluing the foam and the attachment piece together would really work.

Figure 6.8: The beige and the white foam cosmesis that are used today.

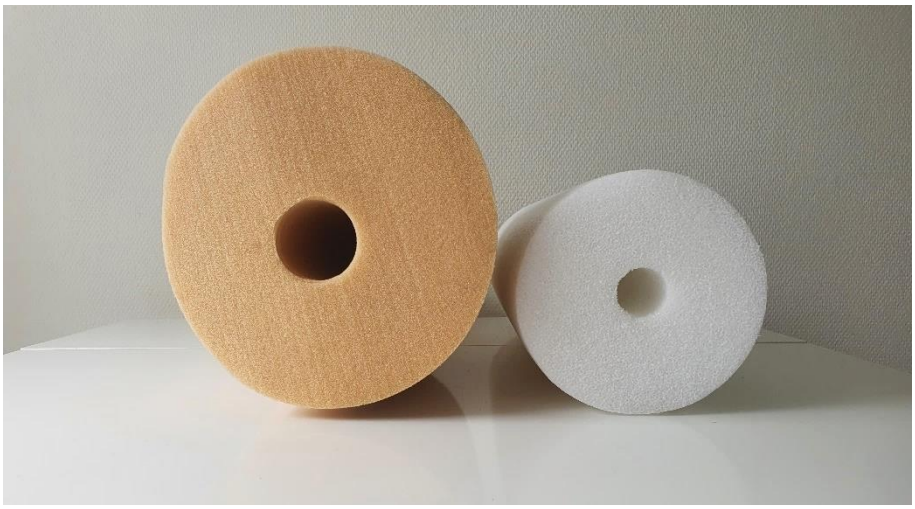

Figure 6.9: The hollow centre in the beige and the white foam cosmesis.

The foam cosmesis must be hollowed out at the top so that the socket can fit well. This is done by sanding down the inside of the foam which covers the inside with foam dust. If the foam cosmesis that is used today will be glued together with this attachment piece, the inside of the foam must be sanded down so that the attachment piece fits well with the foam. If the inside is covered with foam dust, the attachment piece may not adhere properly to the foam and ideas on attachments that do not require glue were therefore considered. However, today's foam cosmesis are sanded

down at the top to fit around the socket and then glued to the prosthesis, which indicates that it would work. To get more information about how it works with gluing the foam cosmesis and the prosthesis together, Shahrokh Arami was contacted once more through email.

According to Shahrokh Arami, the beige and soft foam cosmesis is glued to the socket while the white and hard foam cosmesis is not. The beige foam is more flexible and does not stay in place, which is why it must be glued together with the socket. The white foam is stiff and therefore stays in place better. In addition, Arami said that the white foam does not tolerate adhesives that contain acetone which is good to know for further development. After the beige cosmesis has been hollowed out, the dust is blown away with compressed air and gluing that together with the socket works today according to Arami. Therefore, it should not be a major problem to glue the attachment piece together with the beige foam cosmesis, but with the white foam cosmesis it could be a problem. If the attachment piece is to be used with the white foam, it must be investigated whether an adhesive without acetone works in terms of durability, or if the attachment piece and the foam must be produced as one single part, through for example, injection moulding.

As the foam will be cut into two parts, seams will occur on the sides that must be held together with something, for example tape, to keep the seams together and to make the cosmesis look nicer. As previously mentioned, nylon stockings or silicone covers are often used over the foam to protect it, and if any of these are to be used over the new foam cosmesis, the taped edges would probably not be so pronounced.

To make the cover fit and stay in place better, it was considered whether the entire foam cover must be cut into two parts or whether only the lower part could be cut. Being able to keep the top of the foam in one piece means that the foam fits tighter around the socket and thereby fits better. However, this only works on the softer foam as it is more flexible and can therefore be bent without breaking.

To produce the cover and the attachment piece as one part would probably be the best alternative for the white and hard foam, since it cannot be used with adhesives that contain acetone. However, the white foam does not need to be glued to the prosthesis today, which means that the process to put on and shape the cosmesis does not take as long as the beige one that must be glued on to the prosthesis. The only major problem that exists with the white foam is that the cosmesis might be destroyed when adjustments must be done to the prosthesis. Since the white and hard foam cosmesis does not have as many complications as the beige and soft one, the focus will be on solving the complications with the beige foam. It will be a bonus if the final concept works for both the white and the beige foam.

3D models of the two attachment ideas that were selected earlier were made in PTC CREO, a 3D modelling software. These were later 3D printed so that a more

accurate form and function could be tested. The 3D printer used in this project uses PLA filament which is not the same material that will be used in the final product, however, at this stage, it is the function of the product that is most important to test and not the material. The fact that the prototype is made of a different type of plastic means that the durability cannot be tested at this stage, but a feeling of what the product will look and feel like is obtained.

A 3D printed prototype of the first attachment piece can be seen in Figure 6.10 and Figure 6.11. This attachment piece consists of four parts in total, one that is placed on the inside of each foam half and two that is placed around the pylon. Since it took a long time to 3D print everything, only one copy of each part was printed, but it was enough to get a feel for the function. The two parts that are placed around the pylon should be riveted together so that it is stuck to the pylon and does not move around. The part that is to be placed on the inside of the foam, has a curved protruding piece that fits perfectly into the slot that is to be found in the part that is riveted around the pylon, see Figure 6.12. When the protruding piece is placed inside the slot, it restricts the cosmesis from rotating and it is also fixed in one horizontal direction depending on which way the part on the foam is mounted. It is considered most appropriate that the attachment piece restricts movements upwards since that facilitates the process of putting on tight clothes. In addition, the foot prevents the foam from moving downwards, which means that the cosmesis is kept in place when clothes are taken off.

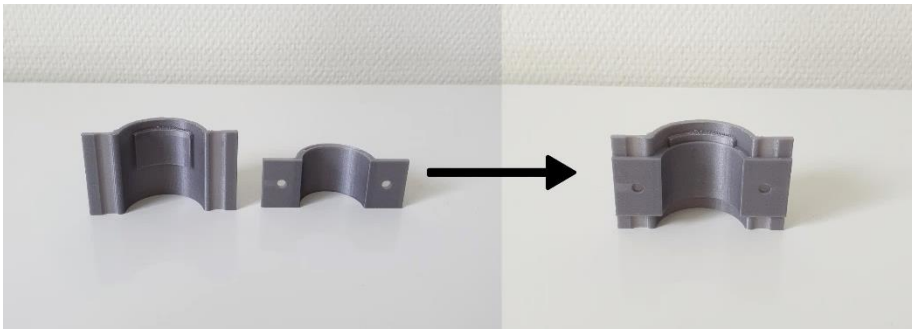

Figure 6.10: Prototype of the first attachment piece.

Figure 6.11: Prototype of the first attachment piece on the pylon.

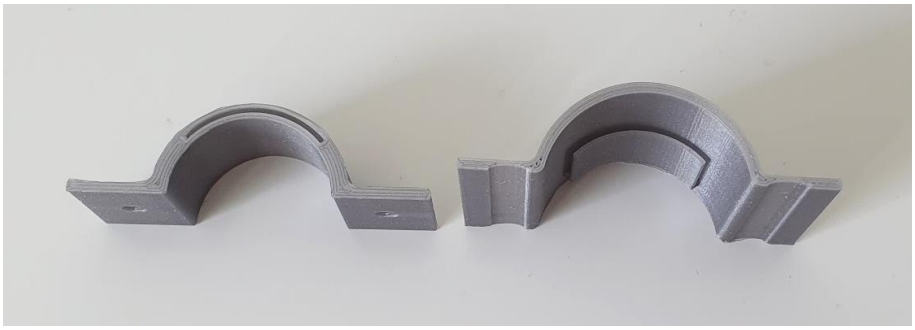

Figure 6.12: Prototype of the first attachment piece where the slit and the protruding piece is visible.

A 3D printed prototype of the second attachment piece can be seen in Figure 6.13 and Figure 6.14. This attachment piece is similar to the one that Lindhe Xtend uses on their Xtend Covers, but with a slight modification. The attachment piece consists of two identical parts that are placed around the pylon. One half of the attachment piece is more than 180 degrees and that allows it to snap around the pylon. This allows the attachment piece to be mounted to the pylon by friction and force. When the attachment piece was tested on the pylon, it turned out that it was a little too big

and was therefore looser than what was desired. This was solved by placing red textile tape on the inside, see Figure 6.13, and with the tape on it got a tighter fit. Once the attachment piece was correctly fitted to the pylon, it was realised that it could be rotated quite easily. This might be because the textile tape and the metal pylon do not have a high friction against each other, so a tape that gives more friction would be advantageous here. If more friction does not help, the cover could still be rotated, and that is something that must not happen.

Figure 6.13: Prototype of the second attachment piece with textile tape.

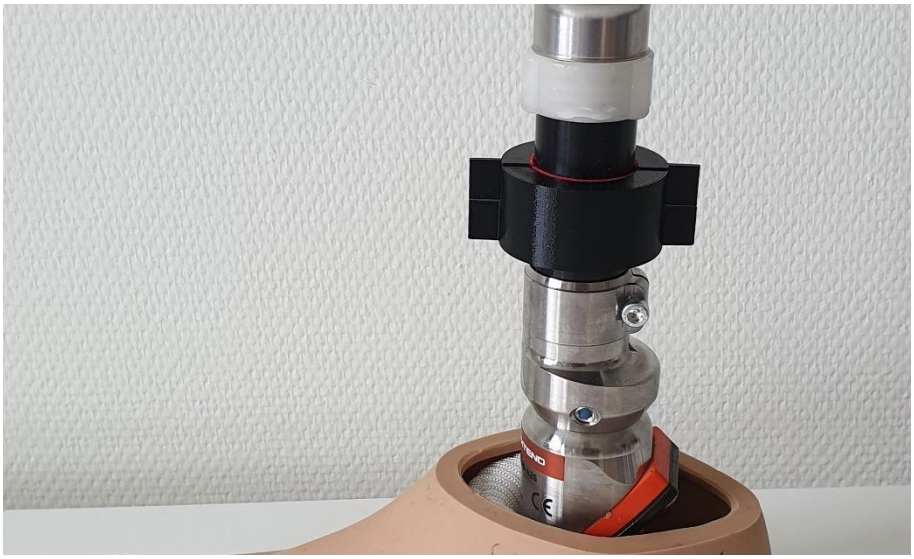

Figure 6.14: The second attachment piece on the pylon.

While holding the prototypes in hand, a better feeling of their size in relation to the foam cosmesis was obtained. Even though the dimensions of the attachment pieces have always been known, they felt much smaller in reality than what they looked like when designing them in PTC CREO. Redesigning the attachment pieces to be longer is not an option since the pylon is short for lower leg amputees. As the

attachment pieces are small in comparison to the foam cosmesis, it was realised that it will be difficult to attach them to the foam by using glue and to have a good mechanical strength at the same time. The small area of the attachment piece will have to take all the forces that the cover is subjected to, and the smaller the attachment piece is, the less force it can take before the foam breaks off. In addition, the second attachment piece is only slightly smaller than what the foam is at the lower part of the leg, which means that the foam must be sanded down quite much. This leaves the foam very thin and brittle, and further contributes to an impaired durability.

To mitigate these potential issues, the attachment piece and the foam cosmesis could be produced in one piece to make the cover more robust. By producing it in one piece, the attachment piece's adhesion to the foam is strengthened. When the cover is produced in one piece, the design of the attachment piece could be changed so that it strengthens and stabilizes the cover. This could be done by adding a larger plastic panel to the attachment piece which is then permanently placed on the inside of the foam at the lower part of the cover. The panel strengthens the cover around the pylon, but at the same time it must not be too long so that it comes in contact with the socket. However, this panel can only support the region around the pylon, and there is nothing more than tape that can support the foam around the socket since the foam becomes very thin and brittle after shaping. Therefore, it is necessary to find a tape that is strong enough to hold the foam together, but at the same time it must be loose enough so that it does not tear the foam when removed. If the tape were to tear the foam, the whole idea of the cover being able to be removed without being destroyed would be lost.

If this idea is chosen to be the final one, the alternative where the foam and the attachment piece are produced as one part will be chosen as it is a more durable solution.

6.3.1.1 Material and production research

Since the attachment piece and the foam is to be produced in one piece, the production cost will increase drastically if it is done by injection moulding. This is because split moulds are very expensive, especially if the product is produced in smaller batches [45]. If the attachment piece were to be produced separately, today´s foam cosmesis could have been used and the attachment piece could have been produced by, for example, 3D printing or by casting until a bigger market is secured.

Because the cover will be produced in one piece, the most efficient production method is injection moulding since it could be done in the same factory. However, this is probably not the most cost-effective way of producing the cover. If the cover is to be produced in smaller batches, a cheaper production method could be used to

reduce the costs. Here it could be investigated whether the attachment piece could be cast instead of injection moulded, since it usually is a cheaper alternative.

The attachment piece could be made of, for example, polyurethane as it is a flexible material with properties that works both for injection moulding and casting [46]. In addition, polyurethane is used in other cosmetic covers for prostheses and could therefore be seen as a material that works within this area. However, the material for the attachment piece must still be tested with the foam to see if they will adhere to each other in a good way.

Since the material that is currently available for lower leg foam cosmeses still performs well, the same material could be used in this new cosmetic cover as well. The usage of an already known material could lead to a smoother acceptance curve with the orthopaedic clinics with a higher sales volume as a result. Other materials could be investigated to see if there exists any other foam with similar properties like today's foam cosmeses, but with an improved durability and at a lower cost.

The material for the foam and for the attachment piece will not be investigated further in this report as the concept development is the main focus. If Lindhe Xtend choses to take this idea to production, they could look further into the materials.

6.3.2 **Concept C**

Full-scale prototypes of concept C were made in EVA foam. Since the injection moulding idea will be produced only if thermoforming does not work, the prototype method is therefore similar to thermoforming. A generic shape of a half lower leg was carved out in XPS, an insulation material, and it was used as a mould to form the cover over. The EVA foam was cut down to a reasonable size and heated with a heat gun and then formed around the mould. XPS was a good material to use for the mould as it could withstand both the heat from the heat gun and the pressure from holding the EVA foam in place when cooling. However, a mould in XPS is only good for prototypes and not for real production. When the EVA foam has cooled it acquires the shape of the mould, and the edges can then be cut so that two halves can be glued together with contact adhesive or with hot-melt adhesive to form a complete lower leg. The mould and a prototype of the cover can be seen in Figure 6.15.

Figure 6.15: The first XPS mould and a prototype in 6 mm EVA foam.

At this stage, prototypes were made with EVA foam in three different thickness, 2, 4 and 6 mm, to understand what works and what does not. The covers that were made with a thickness of 2 mm and 4 mm were far too thin and wobbly. EVA foam with a thickness of 6 mm gave a good result and it kept its shape quite well, however, the cover was still a little wobbly and soft at the ankle. If a thicker material were to be used, it would probably be more difficult for the cover to keep its shape and the transition at the socket looks worse with a thicker material since the EVA foam lies on the outside of the socket. Thus, a test to see if the edges of the EVA foam could be sanded down to get a smoother transition between the cover and the socket was performed. Here a smaller grinding machine was used to sand down the edges and the result was that EVA foam could be sanded down and thus get smoother

transitions at the socket. The result can be seen in Figure 6.16. Therefore, sheets of EVA foam with a thickness of 6 mm were used from now on.

Figure 6.16: A piece of EVA foam where the edge has been sanded down to see if a smoother transition could be obtained.

When the first complete cover was made, it was clear that the cover did not fit the prosthesis very well due to the mould having wrongful measurements. It was also realized that the pylon is not positioned in the centre of the hole in the upper part of the foot, resulting in the socket not being placed in the centre of the hole either. The original mould was designed after the belief that everything was placed in a straight line in the centre of the hole in the upper part of the foot. In addition, the upper part of the foot is not level and instead it has a slight angle. Also, the outline of the upper edge of the foot is not a symmetrical shape because of the way the ankle is formed. This means that there is a difference between the right and the left foot and because of this there must be a left and a right cover for the transitions at the foot to look good. If the covers are produced by thermoforming, different parts for the right and left leg do not cause any major change in production cost, however, if it is to be produced through injection moulding, the production cost will increase drastically as the split mould that forms the product is very expensive. With all the new information, a new mould in XPS was made so that a more accurate prototype could be made. This can be seen in Figure 6.17.

Figure 6.17: The second XPS mould and a prototype in 6 mm EVA foam.

After some attempts to get the two halves together in a nice way, it was quickly realized that it was quite difficult to get nice and flat seams. This is mainly due to the fact that the edges of the EVA foam are difficult to cut straight and smooth after shaping. If the cover is instead produced by injection moulding, the seams on the sides disappear. However, the seam that is obtained when reducing the circumference at the socket will always exist, see Figure 6.18. If the seams cannot be glued together smoothly, it will not look nice when the amputee is wearing tights or similar clothing.

Figure 6.18: A prototype with a V-shaped cut out and the seam that it creates when glued together.

The foot insert, which can be seen in Figure 6.19, had the same problem: it was rather difficult to get its edges smooth after cutting. The foot insert consists of two parts: one that lays on top of the foot and one that is tucked inside the foot. It is important that the lower end of the cover and the foot insert have the same dimensions so that they get a nice transition when glued together.

Figure 6.19: The foot insert that hold the cover in place at the foot.

To see what the cover looked like under clothing and how it performed, a test was made where a pair of tight pants were put on the prosthesis. The upper part of the cover was attached to the prosthesis with tape and since it was the only part that was stuck to the prosthesis, the cover moved in a vertical direction when the pants were put on. This could be avoided if the fit of the cover is perfect at the socket and that the cover sits just below the widest part of the socket so that it will not go past that point. An additional safety could be that a hole for the air valve is cut out, which

helps the cover to keep its place since the air valve is sticking out of the cover. However, the area around the hole will probably be exposed to some stress when clothes are put on and taken off, which then could lead to the hole being deformed and later destroyed. Otherwise, the cover keeps its shape quite well with tight clothes on, even though the cover is made from a softer material.

To see how the cover behaved during use, two tests were performed. Unfortunately, the tests could not be performed by an amputee because of the Corona restrictions. Instead, the weight of a body was represented by pushing down on the upper part of the prosthesis during the tests. In the first test a walking-pattern was mimicked, and the second test showed how the cover behaved in a standing position. Both tests showed no problems with the cover moving or restricting any foot movements. However, real-life tests must still be performed to ensure that the cover does not move around during long-time use, and that foot movements are not restricted.

6.3.2.1 Material and production (research)

EVA foam proved to be an adequate material to use for the cosmetic cover. However, the material is not entirely ideal as it is quite soft and could therefore be compressed at the ankle during use. This problem could be solved by placing another layer of EVA foam on the inside of the cover at the lower part where a void exists. This increases the thickness of the lower part of the cover to 12 mm instead of 6 mm, which makes the cover firmer and more structurally stable. EVA foam is otherwise a material well suited for thermoforming as it easily takes on the shape of the mould and the production and material cost is not too high. Some advantages with EVA foam is that it is water-resistant, UV-resistant, and it can withstand stress without cracking or breaking [47].

EVA foam has been the only material used in the development of concept C as it was an easily accessible material. If this concept becomes the final one, other materials such as cross-linked polyethylene foam could be further investigated to see if they are better suited for the cover than the EVA foam. As EVA foam with a thickness of 6 mm might be too soft for the lower part of the cover, a denser material could be used, but at the same time it must be flexible enough so that the circumference can be reduced in size. In order for the edges on the cover to be straight and smooth, the thermoformed sheets could be laser-cut or punched out since that gives a clean cut. The same goes for the foot insert.

The cover can easily and quickly be glued together with contact adhesive or with hot-melt adhesive since it works well on EVA foam. To ensure that the seams are durable enough for daily use, a test was performed where the seams were pulled at with human strength. The seams were eventually pulled apart, but it was considered that the cover would not be exposed to that kind of force in everyday use. Therefore, contact adhesive is considered to work well for this type of use. If the seams that are glued together are not good enough for the users, the seams could possibly be

welded together with heat or laser during the production. This is something that needs to be tested before production.

Another potential problem with the thermoformed cover is that if EVA foam is exposed to high heat, it wants to return to its original shape. Since a heat gun that blows air at 375 degrees Celsius was used to shape the prototypes, it indicates that a higher temperature is required to form and deform the cover. This entails that there will be no problems with the cover losing its shape due to heat in Scandinavia or similar climate countries. However, if the amputee goes on a holiday in a warmer country and uses the cover directly in the sun, it could possibly start to lose its shape. If this concept becomes the final one, it must be investigated further to see exactly at which temperature the EVA foam starts to lose its shape.

If the cover is to be injection moulded instead, the production cost will be much higher due to the high cost of split moulds. However, most of the problems that occur with the thermoformed cover disappear because there are fewer seams that must be glued together, the cover can have thicker walls at the bottom so that it becomes firmer, the cover gets a more even shape, and it cannot lose its shape due to heat. In addition, there are several different foam materials that can be used in injection moulding. This means that different materials can be evaluated and the material that is best suited for the product can be chosen.

If the cover is to be produced in EVA foam, the advantage between the EVA foam cover and the original foam cover is that the EVA foam cover already has a generic shape of a lower leg and therefore does not need to be shaped afterwards. This means that less time is needed for shaping the cover and therefore the orthopaedic technician gets more time to help other patients.

6.4 Evaluation of concept A and C

As there is still an ongoing pandemic, the cover cannot be tested on potential users. To collect opinions and thoughts from potential users, an email was sent to those who earlier in the questionnaire said that they could be contacted and to those who participated in the interviews. The email consisted of a detailed description of each idea and pictures of the prototypes. Below is a summary of what the users and the experts thought about the two covers, as well as an evaluation that leads to a final concept.

6.4.1 **Users' thoughts**

Six users responded to the email. It was generally a very positive feedback and the majority of the users would like to try the covers in the future. They expressed that it was quite difficult to evaluate the ideas fairly when only pictures and a description of the product was given. If they could have tested both covers, a more accurate feedback could have been provided.

Something that was mentioned by one of the users was that if the cover has any cracks or creases, tights or similar clothing will not look good when worn over the cosmesis. This person indicated that if the cosmesis is only there for filling the void between the socket and the foot, both solutions could work well, but if tights shall be used, the EVA foam cover was considered the best solution. Three other users also conveyed that they would prefer to use the EVA foam cover based on the information and the pictures that they received. One of them pointed out that the EVA foam cover was chosen as she has an unusually low amputation level, which means that the pylon is almost non-existent. Therefore, she believed that the attachment piece concept would not work for her prosthesis. However, she liked that it could be shaped after the healthy leg and after a generic shape. Another user had a hard time choosing between the two products without being able to try them out and to see them in reality. The last user who answered the email could see a combined solution where the EVA foam was attached to the pylon using an attachment piece instead of being tucked into the prosthetic foot shell.

One feature that was much appreciated was that the covers easily can be mounted on the prosthesis and that the amputees do not have to leave their prosthesis at the orthopaedic clinic overnight. In addition, it was appreciated that the cover is not destroyed when adjustments to the prosthesis must be done.

6.4.2 **Experts' thoughts**

Two of the three orthopaedic engineers that were interviewed earlier in the design process answered this email and they both thought that the EVA foam cover looked good. The first orthopaedic engineer wrote that if the foot insert works and the transition to the cover looks good, she could definitely see a market for this cover. One thing that she mentioned was that this EVA foam cover looked similar to Erimed's IDIA cover [48] that is a so called fast cosmesis. However, the IDIA cover is a very thin and see-through cover that is only taped to the foot and to the socket for stability, which the EVA foam cover is not. One problem that she could see with the EVA foam cover was that the foot shells do not always have the same shape since different companies produce their own foot shells that fit with their prosthetic feet. She seemed more concerned about the other foam cover that has an attachment piece since she asked about how much force it can take before the cosmesis breaks

and how durable it is. The second orthopaedic engineer wrote that she liked the EVA foam cover the most, and that she could see this as a cosmesis that the amputee receives before getting a dream skin. She also wrote that in the clinic that she works for, they use Erimed's IDIA cover as a fast cosmesis, but she explained that this cover is cumbersome, and it is hard to make it look nice and to be durable. Therefore, she sees this EVA foam cover as a potential replacement for Erimed's IDIA cover.

Shahrokh Arami was also contacted, and he got in touch over the phone where he gave his thoughts and ideas regarding the two solutions. Arami also saw a similarity between the EVA foam cover and Erimed's IDIA cover as the orthopaedic engineer above, and he also wondered how it is going to fit all different foot shells. He said that in addition to the feet shells having different shapes, some also have a smaller space between the prosthetic foot and the foot shell which means that the foot insert might not fit with all prosthetic feet. Arami also said that he could potentially see a problem with the foot insert falling out of the prosthetic foot during use if it is not long enough. Otherwise, he thought that EVA was a good material as it is soft, and he pointed out that a soft material is required at the socket so that it does not emit any sounds. However, Arami expressed a concern that the cover might restrict movements at the foot when the foot insert is tucked into the foot shell. Instead, he could see that a gap between the foot and the cover might be needed so that the foot can move freely. Arami therefore said that a solution where the EVA foam could be attached around the pylon could be preferred instead of the foot insert.

When it came to the other foam cosmesis with an attachment piece, Shahrokh Arami was not as positive as with the EVA foam cover. He was, like the orthopaedic engineer, worried about the durability of the cover and he also mentioned that they do not have any tape that sticks well to the foam today. Even if a tape that sticks to the foam were to be found, Arami was afraid that the tape would tear the foam when the cover is taken off. Therefore, he said that possibly something other than tape would be needed to hold the edges of the foam together so that the problem with the tape tearing the foam could be avoided.

6.4.3 **Choosing the final concept**

With all information that emerged during the development of both concepts and with the statements from users and experts, it was quite clear that the EVA foam cover was the best product. It was the most durable solution, the most affordable solution, and the best-looking solution. The EVA foam cover is easier to mount on the prosthesis and it requires less work to be done for it to look good. This means that less time is required and that makes it more attractive for the orthopaedic clinics since they can then spend that time on helping more clients. In addition, Lindhe Xtend also thought that this solution seemed promising, and they liked the concept and the look of the EVA foam cover.

7 Final concept

In this section the final concept is presented, and all different parts are described in detail along with pictures. In addition, production, and how to mount the cover to the prosthesis is brought up.

7.1 Xtend TT Cover

Figure 7.1: The final cosmetic cover.

The final concept, Xtend TT Cover, can be seen in Figure 7.1. It is a cosmetic cover for transtibial amputees who either want the prosthesis to look and feel like a normal leg or for those who just want to fill the void between the socket and the foot. Xtend TT Cover makes it easier for both the amputee and the orthopaedic engineer when it is being mounted to the prosthesis and when adjustments to the prosthesis must be made. This because the cover does not need to be glued to the prosthesis and therefore the prosthesis does not need to be left at the orthopaedic clinic for a longer period of time. In addition, the cover can be removed without being destroyed and the material of the cover is soft to the touch.

As the cover can be mounted in one sitting, the orthopaedic engineer gets more time for other patients and complications such as a swollen stump are avoided since the prosthesis does not need to be left at the orthopaedic clinic. The concept behind this cover does probably not work on knee or femoral prostheses as they require a moving joint at the knee. EVA foam is a material that is not optimal for moving joints and therefore is the Xtend TT Cover designed for transtibial prostheses only. The Xtend TT Cover consists of two parts: the main cover, and the foot insert.

7.1.1 **Main cover**

The main cover is made up of four parts: the front part of the cover (the shin), the rear part of the cover (the calf), and two inserts that support the cover and make it more robust at the pylon. These four parts can be seen in Figure 7.2.

Figure 7.2: The final main cover and its four parts.

The cover is to be produced in either a white coloured EVA foam or in different skin tone colours. It gets its shape through thermoforming, and this production method makes the cover cost efficient as it is a cheaper option. By choosing a cheaper production method it provides the opportunity to produce a left and a right calf, and different sizes of the cover to be made because the cost of a thermoforming mould is relatively small in comparison with injection moulding. As EVA foam is a fairly cheap material, it is considered that the production costs for the entire cover will be below the 500 SEK that Christoffer Lindhe previously set as a limit. The idea is to produce three different sizes that cover the range of all socket circumferences. To produce the cover in three different sizes means that the circumference at the socket does not have to be reduced as much as if only one size were to be provided. This allows the cover to retain a good shape since only a smaller V-shaped piece must be removed to fit the cover to the socket.

First, the EVA foam is purchased on a roll, and then cut into sheets of a suitable size. These sheets are then heated and thermoformed around a mould. When all parts have been thermoformed they are punched out of the sheet. This makes the edges of the cover smooth and that allows the cover to be put together nicely. After all parts have been punched out, the inserts are glued together with its respective half. This can be seen in Figure 7.3. After that, the cover is then glued or welded together, depending on the quality needed.

Figure 7.3: The final main cover with a thicker end.

7.1.2 **Foot insert**

The foot insert is made up of two parts: one part that lies on top of the foot shell and one part that is inserted between the prosthetic foot and the foot shell. These parts are punched out from a flat sheet of EVA foam and then glued or welded together, depending on the quality needed. This foot insert is only compatible with Lindhe Xtend's Xtend Foot, and it can be seen in Figure 7.4.

Figure 7.4: The final foot insert that is compatible with Lindhe Xtend's Xtend Foot.

7.1.3 **The completed cover**

When the Xtend TT Cover arrives at the orthopaedic clinic it consists of two parts: the main cover, and the foot insert. The orthopaedic clinic chooses a size that best suits their patient, but before the cover can be mounted, some adjustments must be made. In order to situate the calf at the same level as the patient's healthy leg, the cover is produced longer than what might seem necessary so that the orthopaedic engineers can cut the cover to the right length. As EVA foam is a soft material, it can be cut with a sharp knife or similar. The cover needs to be cut so that it sits just below the widest part of the socket. This will prevent the cover from moving in a vertical direction. Then, if the circumference of the cover is too big, it is simply reduced by cutting away a V-shaped piece and then gluing the edges together with contact adhesive. Contact adhesive dries quickly and holds the edges together firmly. Finally, a hole for the air vent is cut out.

When the main cover has been cut to its proper length and circumference, the foot insert is glued to the lower part of the cover with contact adhesive. The entire cover can be seen in Figure 7.5.

Figure 7.5: The final cover when its glued together.

The last thing that must be done before the cover can be mounted to the prosthesis is to sand down the edge at the top of the cover. This allows for a smooth and good-looking transition between the cover and the socket. The transition can be seen in Figure 7.6.

Figure 7.6: The final cover with a sanded edge.

Finally, the cover can be mounted on the prosthesis and the edge around the end of the cover is taped to the socket to provide more support. The final product can be seen in Figure 7.7.

Figure 7.7: The final Xtend TT Cover on the prosthesis.
Xtend Foot.

8 Discussion and conclusion

This section presents a discussion about the design process and methodology, the final concept, future development, and time management. At last, a conclusion is made.

8.1 Evaluation of the design process and methodology

The Double Diamond Design Process worked excellently in this project and it provided guidance on how to structure the design process. The thesis idea given by Lindhe Xtend was a very open project which had both its advantages and disadvantages. It was difficult to know where the project would end up and where to start. This open project gave greater freedom regarding how to tackle the problem, and the product could be steered into any direction of choice. However, it was the needs that emerged during the user study with both potential users and experts that led the development towards the final product. These needs really helped the development of the product since they gave guidance of what the cover should offer and for it to become a product that the users would prefer.

Something that worked better than expected was the brainstorming session over a video meeting. Before the meeting, it felt difficult to come up with a good strategy that kept the ideas flowing, but the meeting went very smooth, and many good ideas came from this meeting. However, it was still a bit difficult for everyone to explain their ideas and thoughts through the screen, which may have meant that some information was lost in the discussion. It would have been better to perform this brainstorming session in person, but due to the corona pandemic this could not happen and performing the brainstorming session over a video conference proved to be better than expected.

Something that was of less importance during the development were the quick and easy prototypes. They did not help the development as much as anticipated since it was hard to produce simple prototypes that worked in a similar way as the idea that was drawn on paper. However, they still gave a visual feeling of the idea and therefore were in no way a waste of time.

Had it not been for the corona pandemic, physical meetings with transtibial amputees as well as observations in orthopaedic clinics would have been carried out to get more well-developed and honest answers during the user study. A more open and relaxed conversation could have been held, and thoughts and ideas that did not emerge through the questionnaire and the telephone interviews could have been gathered.

The interviews and the questionnaire otherwise provided valuable information that was used to develop the final product. The only negative aspect with these choices of information gathering was that the older generation did not participate. An attempt to reach out to the older generation was made through contacting orthopaedic clinics, diabetes associations and pensioners' associations directly, but no one got back. As it is generally the older generation that uses cosmetic covers today, they have a greater knowledge about the cosmesis and thoughts about what they like and do not like. As this generation could not be reached, the answers from the other age categories laid as a basis for the project. However, this could mean that the information gathered from the amputees is not the same as if more people from the main target group would have responded. This could possibly have been avoided if observations and physical meetings could have been carried out. Otherwise, more answers than expected were received in the questionnaire, and it was easier than expected to reach out to orthopaedic engineers to get their point of view on the problems. In addition, there was a good mixture between female and male participants in the questionnaire and in the interviews. This was appreciated as it gave different insights and thoughts of how they wanted the new cosmetic cover to look and what characteristics the cover should have.

The development of the two final concepts took longer than expected because the time to obtain the material for the prototypes took longer than expected, and further to make and iterate the prototypes. In addition, it took time to get access to a 3D printer and workshop tools since the school was closed due to the corona pandemic.

8.2 Evaluation of the final concept

At the end, a final concept was delivered, which also was the goal for this thesis. The Xtend TT Cover facilitates the mounting process as well as simplifying the use of a cosmetic cover. All complications that exist with today's foam cover can be avoided with this product, and to avoid these complications was the main purpose of this thesis. Xtend TT Cover is a simple but good-looking solution that is designed after the users' and experts' requests. It can be considered that the user experience would be improved with this cover compared with those foam covers that exist today, as the majority of the needed functions in Table 4.1 on page 39 now are fulfilled. Some of the functions are difficult to know if they are fulfilled or not as

they are about how the user feels about the cosmetic cover, although all physical functions are fulfilled.

A weakness of the cover is that it has not been tested on a prosthesis during use as physical encounters had to be avoided due to the corona pandemic. The cover could perhaps have been sent via mail for a user to try, but unfortunately there was no time for that. This meant that a typical use of the prosthesis with the cover on only could be recreated as best as possible without an amputee. It is important to test the product in its intended environment with the right conditions to be able to see how the cover reacts to, for example, foot movements. Since it was difficult to recreate real movements, the cover may behave differently once in a real situation.

The production cost was investigated as it was an important factor for Lindhe Xtend, but it was very difficult to obtain even an approximate number. Therefore, the production cost has mostly been discussed in comparison to injection moulding since that is a good and easy way of producing the cover, but a very expensive production method because of tooling costs. In addition, it was very difficult to estimate the size of the production. As the cover only will be sold in Sweden in the beginning, and that the number of transtibial amputees in Sweden are quite small, it was assumed that the cover will be produced in smaller batches. This was taken into consideration when the production method was chosen. Since the production cost was an important factor for Lindhe Xtend, it could have been prioritized better so that more time could have been devoted to this area.

EVA foam turned out to be an adequate material, and after the lower part of the cover became twice as thick with the inserts, the cover became very stable but still had a good amount of flexibility to it. This flexibility was important to maintain since the cover then mimics the feeling of a normal lower leg.

8.3 Future development

Because this master thesis only lasts for a total of 20 weeks, some things could not be included in the project. If Lindhe Xtend chooses to take the Xtend TT Cover to production, there are some things that first must be developed further:

- When the cover should be able to be compatible with other prosthetic feet and foot shells than Lindhe Xtend's Xtend Foot, it must be investigated how they are designed. It could be solved by having different foot inserts for every type of feet and that the cover is produced a little larger than all feet and then sanded down so that a smooth transition is obtained.

- It must be investigated whether the cover works on other prostheses that are not from the same manufacturers as the one used in this project. The cover is only tested on two different socket sizes, but otherwise the same prosthesis.

- Real-life tests must be performed to see how the cover reacts to, for example, foot movements and whether the cover stays in place during long-term use. If the cover is found not to stay in place during use, a holder around the pylon might be a solution.

- It must be investigated whether EVA foam is the material to be used for the cover or if a more suitable material is available and within the right price range. In addition, the material chosen must be inspected so that it complies with the requirements that exist for healthcare products.

- The costs for the materials used and the production must be investigated more thoroughly to see if it is within the framework of profitability. The cost depends on what material is used, the materials' classification towards healthcare regulations, where and how the material is procured, and where the production takes place.

- A few different moulds for the thermoforming must be made and details such as the cover's length and width must be determined. It must also be decided how many different sizes the cover should be produced in.

- It must be decided whether the cover is to be glued together by the orthopaedic engineers or if it is to be welded together during production. This depends on how large the welding costs in comparison to gluing the cover together are, and whether the welding improves the durability and the appearance of the cover.

- The cover must be tested in different climates to see how the cover reacts to heat, moisture and cold, so that the cover does not lose its shape or is damaged during normal use.

8.4 Planning and time management

Before the thesis was started, a detailed time plan was made according to how much time each area was believed to take, to ensure that the time plan is somewhat followed and so that no critical area would be forgotten. In retrospect, it felt good that the time plan was so detailed as it was easy to follow, and it gave a guideline for how long each area would take. It turned out that some smaller details had not

been taken into consideration when the time plan was made and that caused some areas, for example the prototyping stage, to take longer than planned.

The thesis was started two weeks in advance, and the presentation and opposition took place the week after the thesis was planned to end. Thus, the actual time plan is three weeks longer than the twenty weeks originally planned. Slowly starting the thesis two weeks early was a good decision as the project could be eased into. The initial time plan and the actual time plan can be seen in Appendix A. When comparing the time plans, they look fairly similar to one another, but the prototyping stage took much longer time than planned. This was largely due to shipping times and the fact that time for material procurement was not taken into consideration, and the prototyping took longer in general than anticipated. In addition, it was originally intended that most areas would be done separately and in chronological order, but for the project to be run smoothly, many areas had to be done simultaneously and therefore be spread over longer time periods than planned.

If there had been more time for this project, the next step would have been to investigate the cost of the material and production to get a more detailed knowledge of what the product would cost for Lindhe Xtend and for how much it could be sold to the orthopaedic clinics. In addition, a detailed description of the mould for the thermoforming would have been made so that the step to take the product to production would be smaller.

8.5 Conclusion

Having to undergo an amputation is a very big change in a person's life, and to facilitate this step it is imperative that the amputee feels comfortable with his or her prosthesis. Being able to look like everybody else is important for many amputees and it should not be a complicated process for this to become a reality. Therefore, it is important that the process of making the prosthesis look like a normal leg is fast, however, the cosmesis should still look good and above all feel good to the user. The most commonly used cosmesis for transtibial prostheses today is the foam cosmesis. However, this type of cosmesis must be glued to the prosthesis and the prosthesis must be left at the orthopaedic clinic overnight for the glue to set. Leaving the prosthesis overnight sometimes causes complications such as a swollen stump since the amputee must be away from its prosthesis. Another problem with the existing foam cosmesis is that the foam often breaks when adjustments must be made.

The purpose of this project was achieved as a new cosmetic cover that does not cause any of these complications mentioned above, and meets the users' and the orthopaedic engineers' requirements, has been developed. It is important that the

cover looks and feels like a real lower leg and that all transitions are smooth so that it looks realistic. In addition, it is important that the cover sits in place during use and does not move around. For some amputees, a cosmetic cover means that they get a strengthened self-confidence, and they can live a normal life again without feeling different. Accordingly, it is extra important that the cover is something that the users like, because if the user does not like the new cosmetic cover, they will not use it and the product will not find its place on the market. Therefore, the users have been in focus when the cover was developed. However, the cost was a very important aspect for the product to be profitable, and the final product has therefore been developed with the cost as a main focus together with the user requirements.

The final concept, Xtend TT Cover, consists of two parts: the main cover and the foot insert. The main cover has the shape and the feel of a real leg while the foot insert is there to secure the cover in place during use. The cover can easily be mounted on the prosthesis and the amputee can take it home without having to leave the prosthesis at the orthopaedic clinic overnight. In addition, it can easily be removed as it is not glued to the prosthesis anywhere, and that means that it can be removed without being destroyed.

Xtend TT Cover is a simple solution that gives the amputees a realistic looking lower leg. It fills the void between the foot and the socket, which means that trousers and dresses flow normally during use. This simple but functional solution is believed to fit well within Lindhe Xtend's product portfolio and it will hopefully be developed further so that it can be produced and give confidence back to many generations of prosthetic users.

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[48] Erimed. (n.d.). NEW IDIA SNABBKOSMETIK, LÄTT. Retrieved May 10, 2021, from https://www.erimed.se/product/new-idia-snabbkosmetik-latt/

Appendix A – Expected and actual time plan

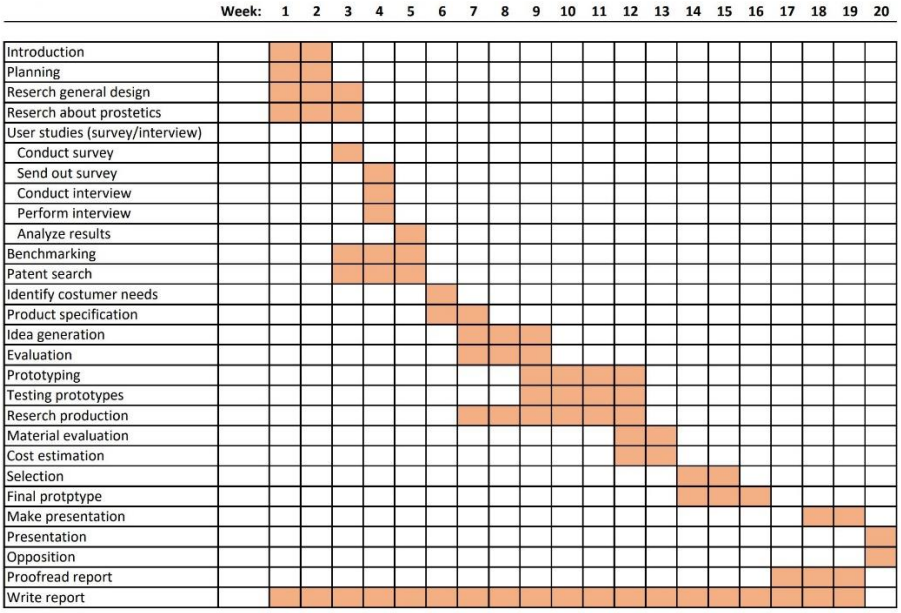


Figure A.1 Expected time plan.

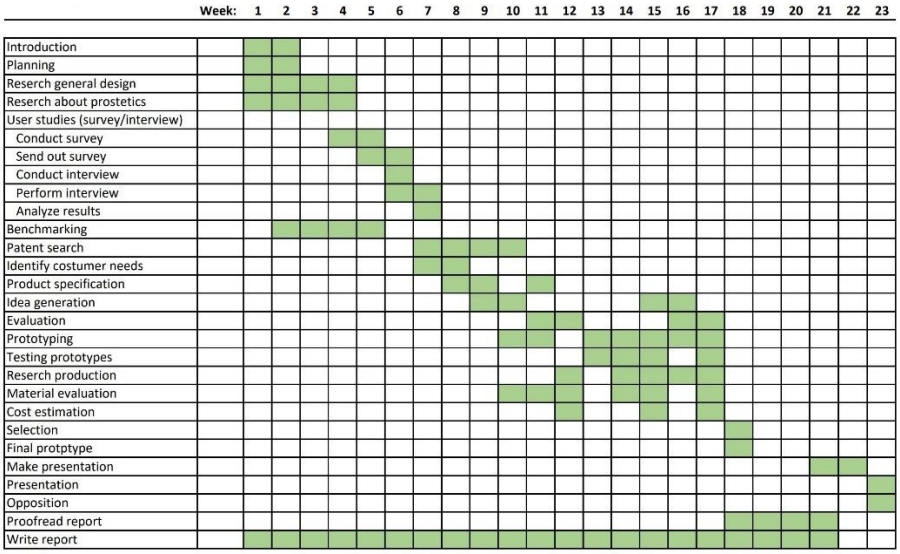


Figure A.2 Actual time plan.

Appendix B – Patents

Above the knee and below the knee prosthetic covers
US20160095723A1
Status: Abandoned

Abstract:
"A cover for a prosthetic leg having an **outer layer**, an **inner layer** and a **foam insert**. The outer layer has at least two side edges and an inner surface. The inner layer is permanently attached to the outer layer at the two side edges so as to form a pocket between the inner surface of the outer layer and the inner layer. The foam insert is shaped as a partial human leg, and has an inner cavity and an outer surface. The foam insert is positioned inside the formed pocket such that its inner cavity is located adjacent to the inner layer, its outer surface faces the inner surface of the outer layer, and the entire foam insert is located below the top edge of the inner layer. Further, the cover includes a **closing mechanism** attached to the two side edges to selectively and securely attach the two side edges to each other."

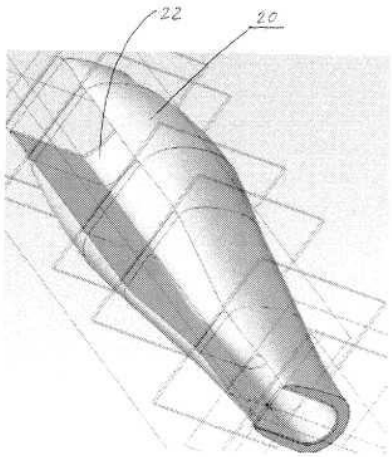


Figure B1: The foam insert.

Below the knee prosthesis and method of making the same
US5152800A
Status: Expired - Lifetime

Abstract:
"A prosthesis for fitting a below-the-knee amputee is disclosed and includes a **socket** for receiving the stump of the below-the-knee amputee, a keel having a peripheral groove formed about the periphery of a bottom portion of the keel, a **tubular shin member** extending from the socket and surrounding lateral and medial portions of the keel and filling the peripheral grooves formed about the bottom portion of the keel leaving a substantial portion of the bottom of the keel exposed. A **resilient foot member** is then secured to the exposed portion of the keel with the material of the tubular shin member being formed into the grooves of the keel and maintaining such keel within the shin member. Also the method of manufacturing such prosthesis."

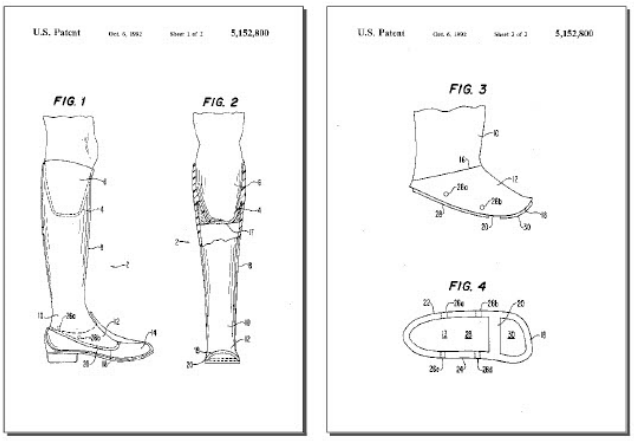


Figure B2: The foam tubular shin membrane.

Artificial limb with three-part cosmetic covering
US3953900A
Status: Expired - Lifetime

Abstract:
"An artificial limb of the endoskeletal type has an **outer cosmesis** or covering in **two or more parts**, whereby a worn or damaged part can be removed and replaced without the expense of replacing the complete outer cosmesis."

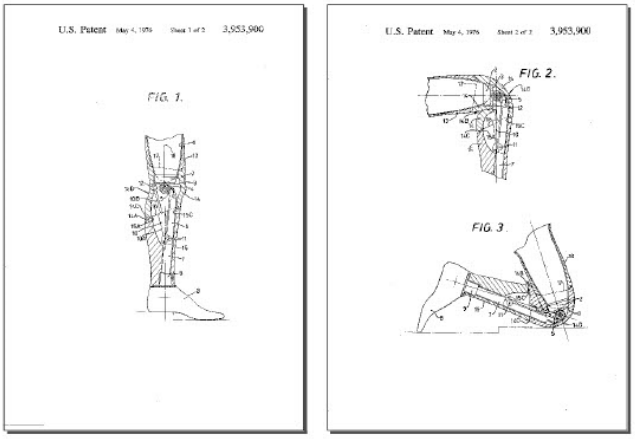


Figure B3: Cosmesis of two or more parts.

Method for fabricating a cosmetic cover for a prosthetic limb
US5880964A
Status: Expired - Lifetime

Abstract:
"A **system and method** for fabricating a cosmetic cover for a prosthetic limb comprises the steps of: fitting and aligning a prosthetic limb to a wearer's residual limb; collecting orientational and positional data from adjustment points between the various endoskeletal and/or socket components of the residual limb; transmitting the orientational data to a **CAD system** that has access to the socket and endoskeletal component dimensions; using the CAD system to calculate inner surface dimensions for a cosmetic cover to be worn over the prosthetic limb according to the socket and endoskeletal component dimensions and according to the orientational and positional data; and downloading the inner surface dimensions from the CAD system to a **CNC milling machine**, which is adapted to carve the inner surface of a cosmetic cover from a carving blank using the calculated inner surface dimensions. Preferably, the system and method also includes the steps of gathering sound-side dimensions of the opposing sound limb and transmitting the sound side dimensions to the CAD system; using the CAD system to calculate outer surface dimensions for the cosmetic cover that is a **"mirror image"** of the sound limb; and downloading the outer surface dimensions from the CAD system to the milling machine, which is adapted to carve the outer surface of the cosmetic cover from the carving blank using the outer surface dimensions. The data gathering and calculating steps are 4512 performed using the digitizing tool integrated into the CAD tool."

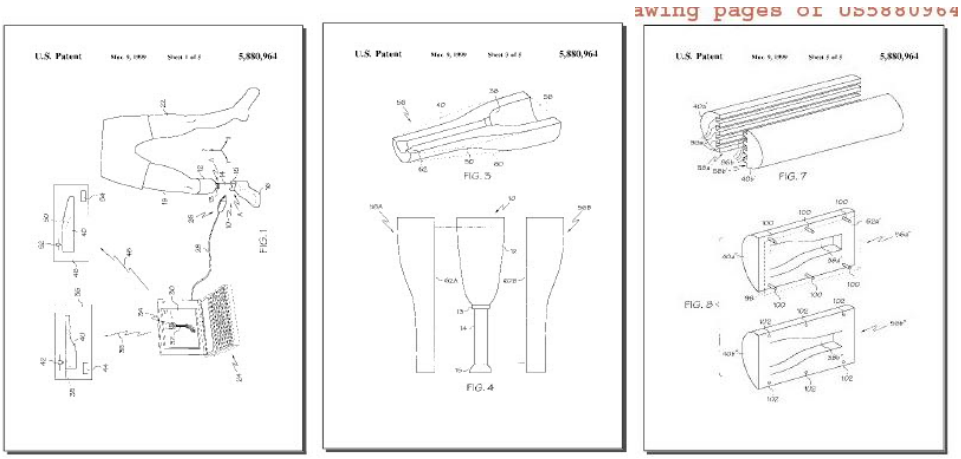


Figure B4: CAD and CNC milled cover.

Prosthesis cover and method of producing
US5376127A
Status: Expired - Lifetime

Abstract:
"A light-weight cover or shield, having the appearance of, and contour of, a human limb, adapted/designed to surround the endoskeletal component of a prosthesis, is provided by **heating and deforming** a preform composed of a closed cell **polyethylene sheet material** of specified thickness, to yield said contoured cover/shield of extremely light weight and being toolable for tailor finishing to individual requirements."

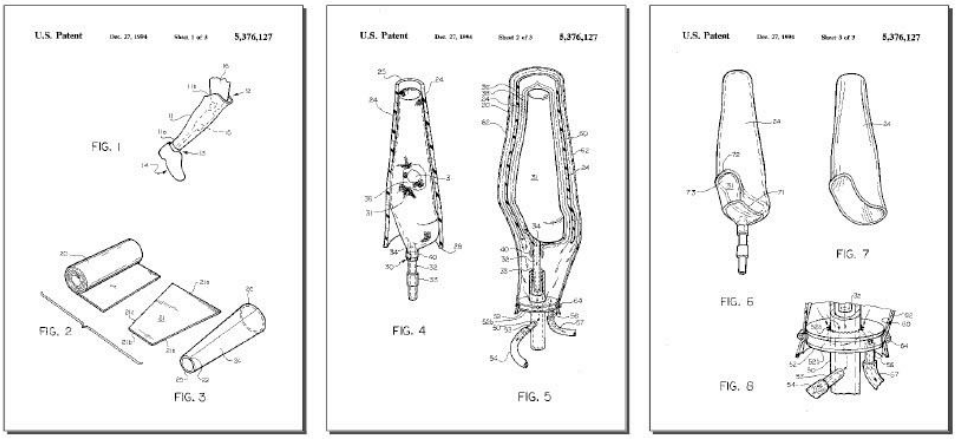
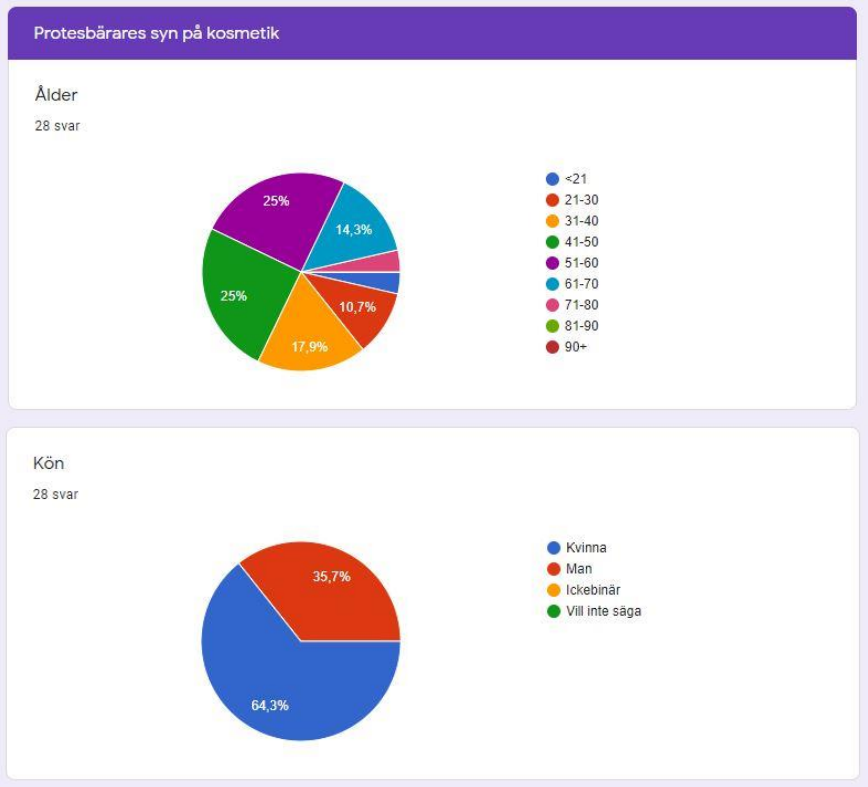


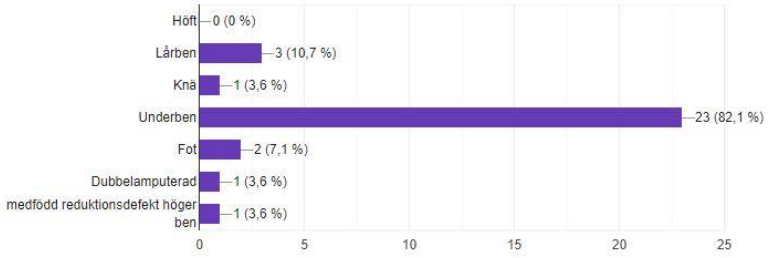
Figure B5: Sheet material that are formed as a calf.

Appendix C – Questionnaire questions and summary of responses



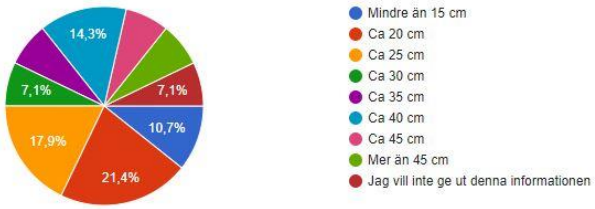
Vilken amputationsnivå av nedre extremitet har du? Är du amputerad på båda benen så markera flera svarsalternativ.

28 svar



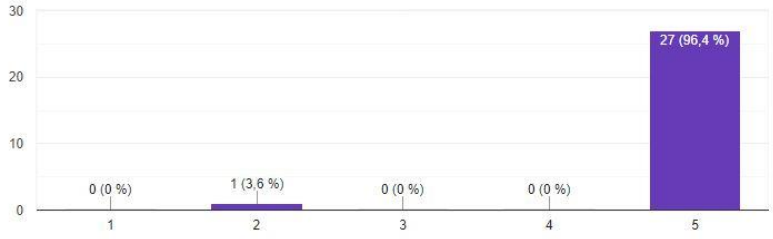
Ungefär hur högt upp på underbenet är du amputerad? (från golv till stump i cm)

28 svar



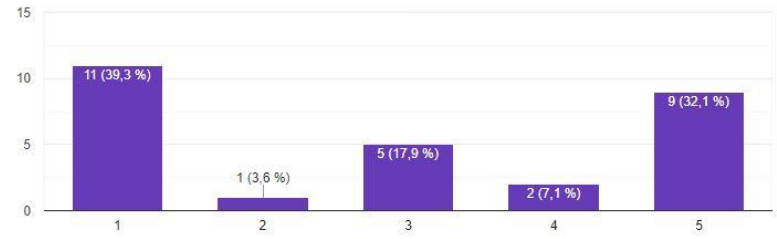
Protesens funktion betyder mycket för mig (dvs att man kan gå och stödja sig utan problem)

28 svar



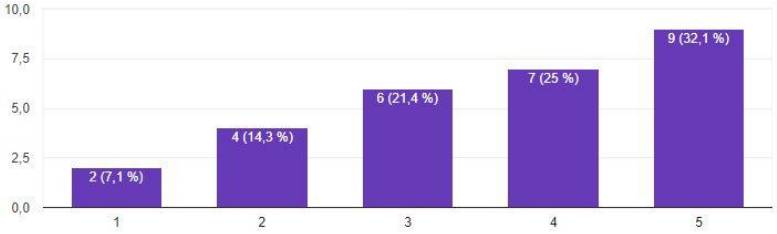
Att protesen liknar ett vanligt ben är viktigt för mig

28 svar



Jag känner mig bekväm med min nuvarande protes (dvs är nöjd med utseendet, funktionen etc)

28 svar



Utveckla ditt svar på föregående fråga (valfri)

16 svar

Jag är nöjd med min protes. Den funkar bra för mig & jag har minimalt med problem med den. Den sitter bekvämt & jag får inte ont av att ha den på eller att gå med den. Det är väll det som är det viktigaste för mig så jag tänker inte särskilt mycket på utseendet. Men den är ju klart att den hade kunnat se roligare ut. Jag trivs med att man ser att det är en protes & är inte särkilt intresserad över att den ska se ut mer som ett riktigt ben, även om jag kan förstå varför andra vill det och tycker att det borde finnas större möjligheter till det. Jag skulle dock önska att man kunde få den mer symmetrisk med det andra benet i själva formen, men den måste inte tvunget se realistisk ut för min del.

Önskar snyggare och mer realistisk kosmetik som finns utomlands.

Med Kosmetik så hade byxor suttit snyggare

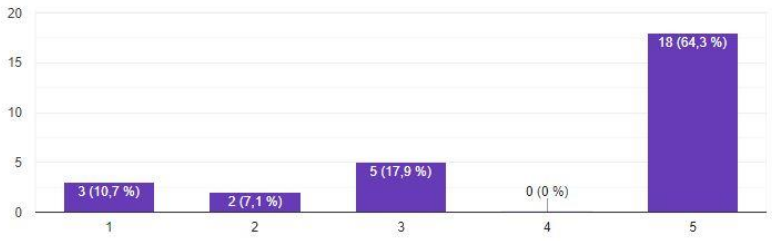
Ser tråkig ut och fungerar bara hyfsat

Funktion före utseende

Just nu får jag kramp i vaden när jag går ca 500. Testar lite olika former på protesen så jag kan slippa krampen. Misstänker att proteserna är lite thigha över vadmuskeln.

Jag känner mig mer motiverad att använda min protes om jag är bekväm med dess utseende

28 svar

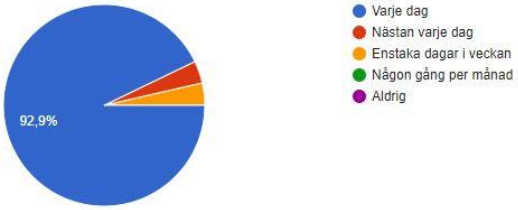


Hur ser min protes ut idag?

28 svar

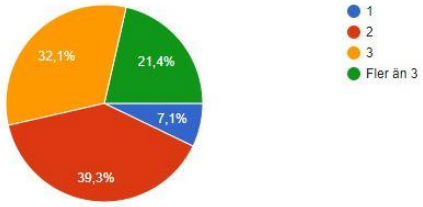
Hur ofta använder du din protes?

28 svar



Hur många proteser har du?

28 svar



Vad har du för olika proteser? (för funktion, sport, utseende etc)

26 svar

Jag har en ”normal” protes som jag använder till vardags. Jag har även en såkallad ”runningblade” som jag använder när jag tränar.
Nej
hygien (ej kosmetik) spor och vardagsprotes.
Ställbar fot, hygienprotes, extraprotes
Vanlig protes och badproteser (hygienprotes)

Under vilka aktiviteter använder du din protes/dina proteser?

27 svar

Alla
Min vardagsprotes använder jag oftast från stunden jag kliver upp på morgonen till stunden jag går och lägger mig. Ibland händer det att jag tar av den om jag sitter i soffan & kollar på film eller sitter ner en längre stund. Använder den till alla vardagssysslor. Min runningblade använder jag när jag tränar gruppträningspass som ofta består av både styrka & kondition.
Allt från gång till mc åkning
Gym, bad utomhus
Promenad, träning och i mitt dagliga liv.
Sport vid träning, gym, golf.
Strongman/styrkelyft/innebandy/vandring
Se ovan, samt kosmetiska protesen som back-up om olycka är framme med vardagsprotes och om jag vill

Använder du din protes i sociala sammanhang? Varför / varför inte? (valfri)

26 svar

Ja

Alltid

Jag använder alltid min protes i sociala sammanhang. Att ha protesen på är hur jag enklast & bekvämast tar mig fram. Om jag inte haft min protes hade jag behövt använda mig av olika hjälpmedel som kryckor eller rullstol. Nu bryr jag mig inte särkilt mycket om att visa att jag är funktionshindrad men för min del hade det varit mer uppenbart om jag inte haft min protes. Många brukar inte ens märka att jag är amputerad när jag har långbyxor och protes på mig. Som sagt hade det också gjort det mer komplicerat att ta sig fram. Så ser ingen anledning till varför jag inte skulle använda den.

Visar du din protes för andra eller döljer du den? Varför? (valfri)

27 svar

Jag är aldrig rädd för att visa min protes för andra. Jag skulle inte ha på mig långbyxor i sommarvärme eller undvika ställen med mycket folk för att jag inte vill att man ska se. Jag har aldrig känt mig obekväm med att visa min protes. Snarare tvärt om, jag vill gärna visa upp den. Jag är också född med mitt funktionshinder och alltid använt någon form av hjälpmedel för att kunna gå. Jag tror det kan vara svårare för någon som haft 2 normala friska ben & sen tvingats amputera.

Visar den naturligtvis

visar

Mest döljer

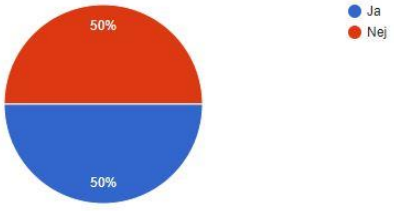
Inga problem att visa den.

Visar ibland

Tränar alltid i shorts på gym, padel mm

Har du någon gång behövt vara ifrån din protes ofrivilligt? (t.ex. för reparationer etc)

28 svar



Hur påverkade det dig fysiskt och psykiskt att vara utan din protes? Upplevde du några problem? Vad var mest jobbigt under tiden du var utan din protes?

14 svar

- Jag har inte varit utan min protes under en längre period. Oftast när jag behövt reparera eller fixa till någonting har det varit lättfixat & jag fått tillbaka den samma dag eller 1-2 dagar efter. Eftersom jag har god fysik & lätt för att använda kryckor har det inte varit några större problem även om det är bekvämare & jag föredrar att använda mig av min protes.
- Jag har alltid en reserv men självklart så blir man hämad när något går sönder.
- Nej
- det är fruktansvärt att vara utan protes. jag känner mig riktigt handikappad och förlorar min kvinnlighet
- Att vara begränsad
- Ja det är klart att det är jobbigt när man inte kan göra de aktiviteterna man vill och måste vänta.
- När jag har haft skavsår har jag använt min stödprotes : lema, den är helbensprotes stel och går upp i ljumsken. Kan inte vara lika aktiv med den. Får ont i rygg mm. Men jag slipper rullstolen och kryckorna.

Fick du några komplikationer (exempelvis svullen stump, depression, ångest etc.)?

12 svar

- Nej
- Nej.
- svullen stump, kronisk inflammation i stumpen eller tekniska problem med protesen
- Nedstämdhet
- Ja, skavsår
- Haft problem med stump men inte nu.

Hur kändes det när du fick tillbaka din protes?

14 svar

- Det kändes bra att kunna gå som vanligt igen.
- Bra
- svårt att börja igen
- jättebra
- Skönt att kunna återgå till vanlig aktivitet

Vad är din åsikt om att proteser kan efterlikna ett vanligt ben till utseende? (valfri)

26 svar

Som jag skrev tidigare är jag personligen inte intresserad av att ha en protes som ser ut som en kopia av mitt andra ben. Jag är stolt över att vara amputerad & tycker att det är kul att kunna sticka ut bland mängden. Men jag förstår helt att alla inte tänker så & jag vet att det finns många amputerade som väldigt gärna hade velat ha möjligheten att kunna få ett mer realistiskt ben. Så jag tycker absolut att det är något man kan jobba mer på. Däremot hade jag gärna haft själva formen på benet mer realistisk & symmetriskt med mitt andra ben. Men jag hade hellre haft ett skal ungefär som dem 3D-printade mönstrade protesskalen man kan se på sociala medier eller med någon häftig målning på än att den ska vara hudfärgad.

Behövs säkert för många

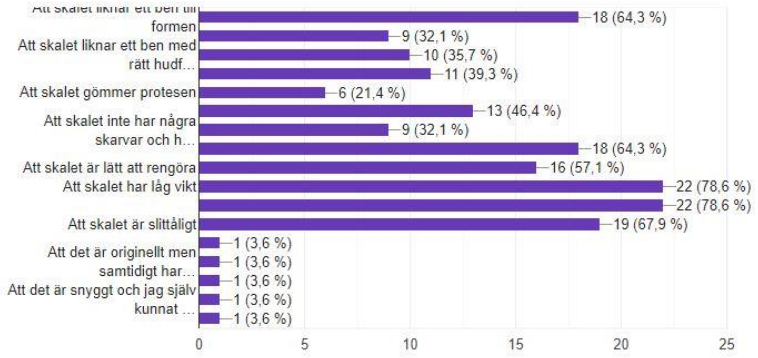
det vore önskvärt. gärna ett lättviktsmaterial med ett verkligt detaljerat skin.

Jätteviktigt

Vore underbart

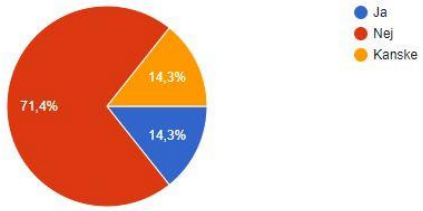
Om du skulle få ett kosmetiskt skal påsatt idag vad skulle vara viktigast för dig? Flera svarsalternativ är möjliga (saknas svar så skriv under annat)

28 svar



Om du har satt på ett kosmetiskt skal, vill du då kunna täcka det med en nylonstrumpa för att ytterligare efterlika ett normalt ben då den är hudfärgad?

28 svar



Är det viktigt att skalet har exakt samma form som ditt andra ben?

28 svar

Varför väljer du att ha eller inte ha kosmetik på din protes? (valfri)

24 svar

För tillfället har jag ingen kosmetik på min protes. Det är väll främst för att jag är en konstnärlig själ & gärna vill experimentera med detta själv. Jag är inte jätte förtjust i den kosmetiken som team olmed har att erbjuda & 3D-printade skal kan vara ganska dyrt att köpa. Jag har planer på att experimentera med att göra egen kosmetik & skal som jag kan sätta på mina proteser & även måla dem med hjälp av airbrush teknik.

Funkar bättre utan för min livsstil

Snyggare till tighta byxor och knälånga klänningar.

Tryggt

Vill inte sticka ut för mycket.

Vilken hårdhet vill du ha på skalet?

28 svar

Är det något du vill tillägga? Kan vara allt från designen på det kosmetiska skalet, utformningen, material eller annan övrig information du skulle vilja ge (valfri)

8 svar

materialet ska vara ömtåligt och ska inte missfärgas. Man borde kunna göra rent det och få bort missfärgningar av skor, strumpor osv.

Min badprotes har en fd kollega paintbrushat så det ser ut som tatueringar, vill gärna ha nåt som inte alla andra har

Kvalitén är ganska viktig så inte färgen slits av direkt till exempel och att det tål stötar till viss del.

Häftig färgsättning och tatueringar vore schysst

Om protesskalet kan hindra damm och skräp att komma ner i fotskalet så vore det bra.

Appendix D – Interview questions to amputees

Vad gjorde att du behövde amputera? / Why did you have to amputate?

Vad för slags kosmetik har du idag? / What kind of cosmesis are you using today?

Varför är kosmetiken viktig för dig? / Why is the cosmesis so important for you?

Finns det något du saknar med din kosmetik idag som du skulle vela att det finns i ett nytt skal? / Is there anything you are missing with your cosmesis today that you would like to add in a new cosmetic cover?

Är det något annat du vill att ett nytt kosmetiskt skal ska erbjuda? / Is there anything else you feel that a new cosmetic cover could need?

Något annat du vill tillägga? Du får prata helt öppet om vad du vill. Alla kommentarer är bra kommentarer. / Is there anything else you would like to add? You can talk about anything you want. All comments are welcome.

Appendix E – Interview summary amputees

E.1 Cecilia

Cecilia is a middle-aged woman that had to amputate her lower leg due to SLE, an autoimmune disease, and vasculitis problems. Her prosthesis has a cosmesis that consists of a foam cover that then is covered with a silicone-like material. She uses cosmesis mostly to make her pants look good when wearing them and therefore the shape is more important than colour and realism. An improvement that Cecilia would like to see in a new cosmetic cover is that it can easily be removed and attached again without it breaking every time an adjustment to the prosthesis must be made. This since she feels that it is a waste of material and that she would like to avoid going through the process of putting on cosmetics several times. One thing that Cecilia talked very strongly about was that this new cosmetic cover should not exclude anyone. She has a smaller foot size and because she has gained some weight, she does not have many options to choose from when it comes to a prosthetic foot. To be able to choose a more complex foot she must get one that is a few sizes larger than her own foot size and this would force her to have different sized feet and that problematizes shoe shopping. That is not something that she wants. So, to not make it harder than it already is she would like to see that nobody is excluded with this new cosmetic cover.

E.2 Lena

Lena is a middle-aged woman that had to amputate her lower leg due to a motorcycle accident that happened fifteen years ago. During these years, she has never felt fully comfortable with her prosthesis even though she uses a cosmesis today that consists of a silicone cover. The cosmesis is important to her because with it she feels comfortable enough to wear dresses and skirts in the summer. It also allows her to be with her grandchildren on the beach without it looking strange. Lena knows that people still can see that she wears a prosthesis but with a cosmesis she feels that it looks a little better and she feels more comfortable. She would love to have a cosmetic cover that looked more natural and one that would be easy to clean since

her cosmesis today easily gets marks that are hard to wash off. One improvement that Lena would love to see in a new cosmetic cover was that it would be great if the cover could be removable as it facilitates the cleaning process.

E.3 Katalin

Katalin is a middle-aged woman that had to amputate her lower leg due to a train accident. At first only the foot was amputated, but after years of pain, she got to amputate her lower leg instead to get a normal life again. One thing that Katalin pointed out was that she did not like that she cannot have a prosthesis for all occasions but must switch between her everyday prosthesis, her party prosthesis that allowed high heels, and her hygiene prosthesis that she uses in the shower. Today Katalin uses a cosmesis that consists of a silicone cover, but she does not like it very much since it easily gets dirty and discoloured by clothes and shoes. Another thing that she points out is that after she has sunbathed in the summer, the colour of the cosmesis does not match her skin tone any more. It is in the summer where she mostly uses clothes that show her prosthetic leg and therefore it is the most important time that the colour matches. Katalin does not like her hygiene prosthesis since it cannot have any cosmetics on it, and she feels so bad when seeing the pylon and all the mechanical parts. She said that when she sees this naked prosthesis, she is reminded of the fact that she once had two beautiful legs. If her everyday prosthesis does not have cosmesis for a while she always tries to fill the void with socks for it to look acceptable with pants. Beneath her silicone cover she has a foam cover that she said very easily gets dented from, for example, having her legs on the living room table. These dents never disappear, and it starts to look very strange after a while, she said. Another thing that she does not like with her silicone cover is that if she uses slightly tight pants they travel up significantly when she walks and that shows her prosthesis when she wants to cover it. So that is something she thinks could be improved in a new cosmetic cover. Another thing that she talked about was that the cover should not be too hard at the top since if you have bigger thighs and sit with your legs in 90 degrees or less the thigh touches the calf. If the top of the cover is harder than a normal leg you can feel that it is not a real leg, and that is not something you would like to be reminded about every time you sit down, she said. The last thing Katalin pointed out was that the cosmetic cover needs to have smooth transitions so that stockings will not rip when using them.

E.4 Maria

Maria is a middle-aged woman that is amputated above her knee and she uses a foam cosmesis that is covered with a nylon stocking. The cosmesis is very important

to her since it makes it look somewhat similar to a real leg. However, Maria never wears tight pants since she does not feel comfortable with that and she always wears long flowy pants and long dresses to hide her prosthesis. Sometimes she wears clothes that show her ankles, but that is the shortest clothing level that she is comfortable to use. Some problems that she has today with her cosmesis is that the stocking that she uses often gets holes in it and that the foam feels dirty and after a while it loses its shape. Maria would love to have a cosmesis that has the same hardness as a normal leg since she does not feel that her cosmesis today has a natural feel to it. She finds it very difficult to be at the beach and swim in the ocean as she must be without her prosthesis and thus show that she is amputated. In the beginning after her amputation Maria had a hygiene prosthesis, but she stopped using it since it was very heavy and cumbersome and now uses crutches instead.

E.5 Carina

Carina is a middle-aged woman that was born amputated on both her legs and her hands. On her left leg she is amputated above her knee and on her right leg she is amputated below the knee. On her right leg she uses cosmesis that is made from styrofoam and then she covers that with a nylon stocking. The cosmesis is very important to her since she wants her legs to look realistic and without cosmesis, she feels that the airflow is different when she walks and that is something she does not like. Since Carina is amputated on both her hands and her legs, she feels more complete when using cosmesis. She is really happy with the prosthesis she has now and its cosmesis but one thing that she thinks could be improved is the ankles since they often are not very realistic. She also pointed out that it is really important for her that the transitions are smooth from the cosmesis to the socket.

E.6 Sonia

Sonia is a middle-aged woman that had to amputate her lower leg due to a motorcycle accident in 2009. She has always wanted to show off her prosthesis and thinks it is cool as it is. Because of this, cosmesis that mimics a normal calf was never an option for her. Instead, Sonia often wears shorts and cuts off the leg of her pants so that anyone can see her prosthesis. One reason for this is that she has noticed that if she shows her prosthesis, others will not be annoyed if she were to walk slowly up a flight of stairs and instead encourage her. Today, Sonia has 3D-printed covers that have been sponsored to her since she is active on social media and can be seen on stage. In addition, Sonia is now training snowboarding to be able to compete in the Paralympics in China in 2022. She really loves her 3D-printed covers and that she can match the covers to her outfit. The covers are easy to take off and

put on again and this is important to Sonia since she only has one prosthesis at the moment and uses that for everything from daily use to her competitions in snowboarding. Her 3D-printed covers are easy to clean, and they stay together with four magnets and two clasps. She would love for these 3D-printed covers to be cheaper and one small problem she sometimes gets is that she puts the covers in the wrong spot from where they were fitted. Placing a cover in the wrong spot can prevent movements in the foot, which means that the cover can crack and break. Although, she usually realises this quickly and then changes the position of the cover.

E.7 Gert

Gert is a middle-aged man that was amputated in 2020. He is a diabetic and he had to amputate due to a small wound on his toe that did not want to heal, and the infection eventually spread to half of his foot. Gert does not have any cosmesis and that is mostly because he never thought about it and he said that if the prosthesis works, he is pretty happy with that. His prosthesis is still not completely finished as his stump is still shrinking and he has recently switched to a better prosthetic foot. This means that he has not yet been asked if he wants cosmesis since the prosthesis constantly needs to be modified. Gert has now gotten a problem with his other foot and because of that he cannot walk normally. Therefore, he has a hard time knowing if it is the prosthesis that makes his back hurt or if it is because of how he walks with his other problematic foot. During the short time he has been amputated he has had a few complications. In the summer he got many blisters on his stump, which made the use of the prosthesis problematic. Gert said that he feels okay using his prosthesis in social events since the prosthesis is his way of getting around. One thing that he mentioned was that in the summer a lot of kids were starring and asking questions when he walked around in shorts and there a cosmesis would have been good.

Appendix F – Interview questions to unbiased experts

Vad jobbar du med? / What do you work with?

Hur många i snitt vill ha kosmetik på sin protes? / How many people on average want cosmesis on their prosthesis?

Vad brukar vara de största anledningarna till att vissa vill ha kosmetik? / What are usually the main reasons for the amputees that want cosmesis?

Vad är den vanligaste kosmetiken ni använder idag? / What is the most common cosmetic covers you use today?

Vad anser du är viktigast med kosmetiken? / What do you think is most important regarding the cosmesis?

Vad behöver ett nytt kosmetiskt skal ha för krav för att kunna användas av dig och dina kollegor? /What requirements does a new cosmetic cover have to have to be used by you and your colleagues?

Är det något som dagens lösningar kan förbättras med? / Is there anything that today's solutions can be improved with?

Appendix G – Interview summary unbiased experts

G.1 Lina

Lina works as an orthopaedic engineer at Aktiv ortopedteknik in Lund. She would love to see a new cosmetic cover that is something in between the foam covers and the 3D printed covers that can be taken off without breaking it but still be similar to a real leg. She mentioned that femoral prostheses with cosmesis over the knee often use hinges or similar to allow movement. The disadvantage of these moving parts is that they often make a lot of noises and that might be good to take into consideration when developing a new cover. Lina said that the ideal product would be a cover that can be modified after it being put on so that if a new socket needs to be done the cosmesis can be reshaped to fit the new socket without having to make a completely new one. The majority of Linas patients want some kind of cosmesis. Some patients use cosmesis to feel more wholesome and confident while others only want it to look good with pants on, she said.

G.2 Marianne

Marianne works as an orthopaedic engineer at Aktiv ortopedteknik in Helsingborg. She said that around 80 to 90 percent of her patients want some type of cosmesis today and that women tend to want it more than men. Most amputees want cosmesis to make the prosthesis look like their other healthy leg, but some use cosmesis only to avoid questions and others staring at them, she said. We use mostly foam covers that are covered with a dream skin that mimics the look of a real leg, but if the patient does not care as much about the look, they get a nylon stocking instead. When it comes to cosmetic covers, they must be easy to work with in order for us to use it. A problem that we have today and that we would like to see a solution to is that when we use a dream skin, we must be sure that the prosthesis is a perfect fit before it is put on. Because if adjustments need to be done, the dream skin has to be cut off and destroyed. One thing that Marianne has often heard is that the cosmesis that they use today cannot be cleaned so easily. So, if the new cosmetic cover could be cleaned more easily that would be great. Another improvement that she would

love to see in a new cosmetic cover is that it could be mounted on the patient's prosthesis during one sitting. Today their patients must leave their prosthesis at their clinic overnight when putting on cosmesis and she said that it would be great if the patient could leave with a completed prosthesis directly instead. One last thing that Marianne commented about was that the cover should have a good-looking transition at the foot so that if the patient wants to wear sandals or lower shoes it would look acceptable.

G.3 Adrian

Adrian works as an orthopaedic engineer at Aktiv ortopedteknik in Malmö. The majority of his patients want cosmesis today but at the same time he sees a downward trend of using cosmesis in recent years. He said that it is mostly older people that want cosmesis on their prosthesis today and the main reason for that is that they have a goal of being able to walk without it being obvious that they are amputated. For him as an orthopaedic engineer the most important part is that the new cosmetic cover is easy to work with and that it has a low price. The majority of all cosmetic covers today have to be taken apart and become unusable when adjustments to the prosthesis needs to be done, and this is something that could be improved, he said. Something similar to the 3D printed covers that easily can be taken off without destroying them but still can be shaped after the patient's healthy leg would be good. However, the 3D printed covers that are done in hard plastic cannot be placed against the socket since that will make sounds when they touch each other, he said. That could be good to know before starting to develop a new cover.

Appendix H – User needs

H.1 Statements from questionnaire and user interviews

Table H.1 User statements and interpreted needs.

Questions:	Statements:	Interpret need:
Varför känner du dig inte bekväm med din protes?	Har du tights eller leggings och ingen kosmetik så ser det konstigt ut då benen fladdrar.	Produkten ska kunna användas under olika typer av kläder utan att det ser konstigt ut.
	När jag solar på sommaren så passar inte hudtonen med kosmetiken längre.	Hudtonen ska kunna ändras under årets gång.
	Har jag ingen kosmetik så försöker jag fylla tomrummet med strumpor för att det ska se okej ut med byxor på.	Kosmetiken ska kunna sättas på snabbt så att den amputerade slipper vara utan.
	Nylonstrumpan har inte exakt samma färg som mitt andra ben vilket gör att det ser konstigt ut.	Kosmetiken ska kunna erbjuda många färgval för att efterlikna den amputerades hudton.
	Jag vill inte ha på mig en damstrumpa.	Produkten ska kunna användas utan en nylonstrumpa.
	Jag tycker skumgummit känns läbbigt då den inte har samma hårdhet som mitt andra ben. Mina lår går emot vaderna när jag sitter med benen i 90 grader och då känner man att det inte är ett riktigt underben jag har.	Hårdheten på kosmetiken ska efterlikna ett vanligt ben.
	Kosmetiken känns ofräsch.	Kosmetiken ska lätt kunna rengöras.
Varför är kosmetiken så viktig för dig?	Jag vill jättegärna kunna gå i kjol och klänning på sommaren.	Kosmetiken ska göra att användaren känner sig bekväm med protesen.
	Jag vill kunna gå med mina barnbarn på stranden och att det ser okej ut.	Kosmetiken ska se naturligt ut.
	Jag vill få känslan av att jag har två ben.	Produkten ska erbjuda en helhetskänsla för användaren.

	Om jag går utan kosmetik så blir luftströmmen blir inte detsamma och den känslan gillar inte jag.	Produkten ska göra att det känns som om man har ett vanligt ben när man går.
Vad saknar du i kosmetiken idag?	Jag vill inte att det ska se ut som något man hafsat ihop.	Produkten ska se välgjort ut.
	Kosmetiken blir ofta missfärgad och får märken som inte går att ta bort.	Produkten ska kunna tvättas av och motstå missfärgningar.
	Det är slöseri med att behöva sätta på en ny kosmetik varje gång en justering behövs göras.	Produkten ska kunna tas av och sättas på igen utan att den går sönder.
	Jag önskar att det lades mer krut på utseendet.	Produkten ska se bra ut.
	Jag vill att fotknölarna ska vara snygga	Produkten ser verklighetstrogen ut.
Övrigt:	Jag har små fötter men är lite större i vikten vilket gör att jag inte kan välja mellan så många fötter och få den funktionen jag har idag. Jag vill inte känna mig begränsad på grund av min vikt.	Produkten ska passa alla och inte exkludera någon.
	Min stump krymper fortfarande och därmed måste jag byta hylsor ofta.	Produkten kan omforma sig efter nya hylsor.
	Små barn frågar och tittar mycket, speciellt när jag har shorts på mig på sommaren.	Produkten gör att det ser mer ut som ett ben. Produkten drar inte till sig blickar och frågor.
	Jag gillar inte min hygienprotes så den inte har kosmetik och då kan alla se att jag är amputerad.	Produkten ska kunna användas på hygienproteser.
	Min festprotes låter och gnisslar vilket är jobbigt, speciellt då folk alltid vet att det är jag som kommer då det låter efter mig.	Produkten ska inte låta när den sitter på.
	Sätter jag mitt 3D-printade skal för högt eller för lågt i förhållande till var det var mätt så kan det skava efter foten.	Produkten fästs alltid på rätt ställe.
	Om jag lägger mina ben på bordet så får kosmetiken ett veck från bordskanten som aldrig försvinner.	Produkten ska kunna motstå tryck och stötar utan att deformeras.

	Skumgummit får en konstig form efter ett tag med störtar och liknande.	
	Skumgummit pressas ihop och håller inte sin form.	Produkten ska hålla sin form under en längre tid.
	Så fort jag sätter på mig strumpbyxor så går det hål vilket är väldigt jobbigt.	Nylonstrumpbyxor ska kunna användas utan att de lätt går sönder.
	Har jag tightare byxor på mig så åker de upp när jag rör på mig och protesen syns påtagligt.	Materialet på produkten ska inte göra så att byxor åker upp vid användning.
	Det är viktigt för mig att det inte är något glapp från foten och en bit upp.	Produkten ska minimera glapp.
Varför har du inte kosmetik idag?	Jag byter fötter ofta vilket inte hade fungerat om jag hade haft kosmetik.	Produkten ska kunna användas med olika fötter.
	Det ser lätt onaturligt ut.	Produkten ska göra att det ser naturligt ut.
	Det är klumpigt och det väger en del extra.	Produkten ska vara lättvikt.

H.2 User needs from amputees and experts

Table H.2.1 User needs from amputees.

The product can be worn with any type of clothing without looking strange
The product can be used without a nylon stocking
The product can be used with nylon stocking without ripping them
The product can be used without pants wandering up the prosthesis
The skin tone on the product can be changed
The product allows many different skin tones
The product is quick to mount
The product is easy to clean
The product can be cleaned
The product cannot be stained
The product makes the user feel more comfortable with their prosthesis
The product gives a feeling of having two legs again
The product does not attract glances
The product does not raise questions from others
The product does not make any sounds
The product keeps its shape
The product has no gaps
The product is lightweight
The product can withstand smaller impacts and pressure without damage
The product allows change of feet
The product is always placed in the right spot
The hardness of the product mimics a real leg
The product looks natural
The product looks well made
The product looks good
The product fits all sizes
The product is inclusive
The product can be taken off and reattached without breaking
The product can be remoulded to fit new sockets
The product can be used on a hygiene prosthesis

Table H.2.2 User needs from experts.

The edges of the product are smooth
The product has smooth transitions to the socket and to the foot
The product looks realistic
The product has the shape of a calf
The product is attached to the prosthesis
The product does not move around
The product does not make any sounds
The product allows the foot to move
The product can be adjusted to fit all lengths
The product is adjustable at the socket
The product fit all sockets
The product is adjustable to fit different sizes of calves
The product fits all sizes
The product can be taken off by orthopaedic engineers and technicians
The product can be taken off by the amputee itself
The product is easy to take off
The product can be taken off without being destroyed
The product allows adjustments to be made on the prosthesis
The product can be modified after it has been mounted on the prosthesis
The product can be used over and over again
The product lasts long
The product is easy to shape
The product is easy to handle
The product is easily cleaned
The product can quickly be mounted
The product fits 30 mm pylons
The product fits 34 mm pylons
The product is ready to use when delivered
The product can be used with a suspension sleeve
The product can be worn with any type of clothing
The product looks good with any type of clothing
The product fits with the extend connect
The product is cheap
The product cost is at its minimum
The product is series produced
The product is manufactured in Sweden
The product has a smart and efficient production
The product can be used worldwide
The product does not attract glances
The product can be worn with different types of shoes

H.3 Function analysis matrix – desired

Table H.3 Function Analysis Matrix - desired

The product can be used without a nylon stocking	D
The product can be used without pants wandering up the prosthesis	D
The skin tone on the product can be changed	D
The product allows many different skin tones	D
The hardness of the product mimics a real leg	D
The product can be used on a hygiene prosthesis	D
The production is series produced	D
The product can be used worldwide	D
The product is easy to clean	D
The product cannot be stained	D
The product looks natural	D
The product does not attract glances	D
The product does not raise questions from others	D
The product looks realistic	D
The product can be taken off by the amputee itself	D
The product is always placed in the right spot	D
The product is easy to take off	D
The product can be taken off and reattached without being destroyed	D
The product lasts long	D
The product can be used over and over again	D
The product can be modified after it has been mounted on the prosthesis	D
The product can be remoulded to fit new sockets	D
The product has no gaps	D
The product allows a change of feet	D
The product can be worn with different types of shoes	D
The product is lightweight	D
The product fits 34 mm pylons	D
The product fits with the Extend Connect	D
The product is inclusive	D
The product can be used with nylon stockings without ripping them	D
The product is adjustable to fit different sizes of calves	D
The product is ready to use when delivered	D

Appendix I – Personas

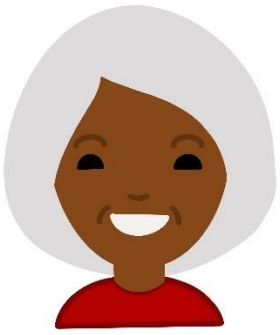
I.1 David

David is 78 years old, and he recently had to amputate his lower leg due to a small wound that did not want to heal because of his diabetes. David is normally a very happy and outgoing person that loves to spend time with his friends and family. His favourite activities are cricket and bridge that he plays with his friends every Tuesday and Thursday. After the amputation, David has become very insecure about his appearance and he does not like the feel and look of his bare prosthetic leg. He wants to feel normal again, like he has two normal legs, because he would feel more comfortable going outside and seeing his friends again.

I.2 Megan

Megan is 83 years old, and she had to amputate her lower leg around 30 years ago when she was involved in a car accident. Today Megan lives at a retirement home where she loves to chat and play cards with the others who live there. When she wants to be alone and not disturbed, she usually listens to one of her favourite audiobooks. Before the accident, Megan always wore knee-length dresses, but now after the amputation she always wears long and flowy pants or skirts to hide the prosthesis from others. Since Megan has had her prosthesis for many years now, she has accepted the fact that she is amputated, and she feels more independent when she uses the prosthesis compared to getting around with a wheelchair. However, she

has never felt comfortable with the look of a prosthesis as she felt like she lost her femininity when she lost a part of her leg. Therefore, cosmesis is very important for Megan so that she can feel herself again. Megan has had her cosmesis for several years now and it has lost its shape and it is very dirty.



I.3 Becky

Becky is 35 years old, and she was born with a rare condition which meant that she was born without a part of her right lower leg. She has always liked her prosthesis and she proudly show it to others. She never hides her prosthesis under clothes, but rather cuts off the leg of her pants to show off the prosthesis. Becky is very active and therefore has different prostheses for different sports. Although she is always open about her amputation and her prosthesis, she sometimes wants to be able to wear longer pants without it looking strange at the prosthesis since the leg of the pants flutters with the wind.

I.4 Mark

Mark is 45 years old, and he works as an orthopaedic engineer and has been for 15 years now. One of the tasks that he does is to put on cosmesis on patients' prostheses. At his clinic they usually use the foam cover and they have done that for as long as they can remember. He would want to see a new solution that does not have the same complications that the foam solution does. Mark sees an increase in interest of 3D-printed covers, but at the same time these are very expensive, and the older generation usually wants the look of a normal leg and not colours and patterns.