PRINTING PROSTHETICS

Designing an additive manufactured arm for developing countries

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Luleå University of Technology
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PRINTING PROSTHETICS
DESIGNING AN ADDITIVE MANUFACTURED ARM
FOR DEVELOPING COUNTRIES

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ABSTRACT

The traditional prosthetic arms that are being fitted in developing countries are facing major issues in supplying patients with proper assistive aids. Not only is the process time consuming with every single unit having to be customized for the user but some parts can’t be locally produced which drives up price even further. The objective of this master thesis was to develop a prosthetic arm for developing countries with the help of additive manufacturing (3D printing) for the client 3D Life Prints which are based in Nairobi, Kenya. A prosthesis is used to aid an amputee in daily living activities. With additive manufacturing the intention is that a local manufacturing process could be developed and improved which would reduce the time of fitting and distributing a prosthesis. The initial prosthesis, that was the origin of the design, was a below elbow prosthetic arm that was being developed by the client. The prosthesis was fabricated with the additive manufacturing process fused deposition modelling (FDM) which has the advantage of providing the cheapest printers. To summarize the aim of the project the research questions that was established was as followed

How are conventional prosthetic arms generally being manufactured, distributed and used compared to additive manufactured prostheses in Nairobi, Kenya?

Who is the primary user of prosthetic arms in developing countries, what problems are they facing with current solutions and what factors are considered as the most important? And why?

How should additive manufactured prostheses be designed for optimal usage in developing countries?

In addition to answer the research questions the aim was that the development of the system would lead to enhanced functionality for the user and to facilitate manufacturing for the organization.

KEYWORDS: 3D printing, Additive manufacturing, Prostheses, Prosthetic arm, Developing countries, Nairobi, Kenya, Industrial design engineering

To get a general overview of additive manufacturing prostheses the fields theories that was studied included context of developing countries, user centred design (since the aim was to approve on a product which needed to suit a specific user), upper limb prostheses and additive manufacturing. As a result, from different stages of the design process a final design was reached called the “3D Life Arm”. The final system was comprised of four main components, the Harness system, the Insert, the Cover and the Socket. These components used additive manufacturing in both rigid material (Harness parts, Socket and Insert) and flexible material (the Cover). Locally available components were used for parts not feasible to additive manufacture e.g. fishing wire and screws. The two factors that were concluded to be the most important for the user were the aesthetic appeal and cost. With social stigmas playing a major part according to users and experts in Nairobi, the prosthesis needs to resemble the missing limb as much as possible. It was concluded that cost was the major factor when designing prostheses for developing countries since user just wasn’t able to afford the prostheses that was being manufactured in Nairobi. In the end a cost and time analysis was conducted to verify what price the complete system would need to be manufactured. With three printers all parts could be printed for the price of 282 SEK and would take approximately 15 hours and 15 minutes to print which is considerably lower than that of the functional prosthesis being distributed in Nairobi. Further evaluations need to be done to establish that the prosthesis will manage the strains and stresses of daily living activities of the user and a complete fitting strategy needs to be evaluated further. It’s the authors belief however, that with the help of fully educated prosthetist there is a future for additive manufacturing of upper limb amputees.
SAMMANFATTNING

De traditionella armprotser som tillverkas i utvecklingsländer står inför stora problem i att leverera patienter med lämpliga hjälpmedel. Processen är inte bara tidskrävande eftersom varje enhet måste anpassas för varje enskild användare men vissa komponenter kan inte produceras lokalt vilket driver upp priset ytterligare. Syftet med detta examensarbete var att utveckla en armprote för utvecklingsländerna med hjälp av additiv tillverkning (3D Printing) för klienten 3D Life Prints som baseras i Nairobi, Kenya. En prote är ett hjälpmedel som används för att underlätta en amputerad människa i dagliga aktiviteter och med hjälp av additiv tillverkning kan även en lokal tillverkningsprocess utvecklas och förbättras vilket skulle kunna minska tiden för tillverkning och distribution av proteser. Den initiala protesen, som låg till grund för designarbetet, var en underarmsprote som förbättrades och var i utvecklingsstadiet hos klienten. Protesen tillverkades med hjälp av tillverkningsmetoden Fused Deposit Modelling (FDM), som har den fördelen att den använder sig av relativt billiga 3D skrivare. För att sammanfatta syftet med projektet utvecklades följande frågeställningar

1. Hur tillverkas, distribueras och används konventionella proteser i jämförelse med additiv tillverkade proteser i Nairobi, Kenya?

2. Vem är den primära användaren av proteser i utvecklingsländer, vilka problem upplevs hos dagens lösningar och vilka faktorer anses vara den viktigaste hos användaren? Och varför?

3. Hur ska additivt tillverkade proteser utformas för optimal användning i utvecklingsländer?


NYCKELORD: 3D Printing, Additiv Tillverkning, Proteser, Armprotes, Utvecklingsländer, Nairobi, Kenya, Teknisk design
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01 INTRODUCTION

the birth of the project
1 INTRODUCTION

A large part of the population in developing countries depends on a fully functional body to be able to coop with often physical work and lifestyle. When an individual is missing a limb means to give that person more equal prerequisites is needed, providing him or her with a prosthetic limb is often a big step towards it. Unfortunately, many circumstances are restraining many of these people to get what they need. With advancing technology, additive manufacturing is breaking ground in the field of medical devices with its beneficial qualities. The question is if this is the future of prosthetics? Many attempts are currently being made but the field is new and needs more research. This master thesis project is meant to contribute to this research and is the final part of the MSc’s in Industrial design engineering, Product design at Luleå University of Technology (LTU). The overall project objective was that of exploring the possibilities to improve the “3D Life Arm” for the company 3D Life Prints (3DLP). The 3D Life Arm is an additive manufactured prosthetic arm in development targeting developing countries. The thesis was carried out in the spring of 2016 at LTU and covered 20 weeks of fulltime work which equals 30 Swedish university credits. As part of the thesis a so called Minor Field Study (MFS) was conducted in Nairobi, Kenya, for 8 weeks in cooperation with the client, 3DLP and with support from The Swedish International Development Cooperation Agency (SIDA).

1.1 BACKGROUND

Today the quality of life for amputees is considered to be lower than for the general population hence the development of prostheses should be a priority (Eiser, Darlington, Stride, & Grimer, 2001; Sinha, Heuvel, & Arokiasamy, 2011). Part of the reason may lie in how disabilities affect labour and education in developing countries. The World health organization (WHO) refers to the majority of studies done in this field which shows that individuals with disabilities don’t achieve the same level of education and a lower proportion receive employment than people without disabilities (World Health Organization [WHO], 2011). By providing more amputees in this group with prostheses we hope that they can pursue academics and provide better opportunities for employment. The authors conclude that in the end, this will benefit society as a whole and is a step forward in the development of these countries. The record over amputees in different regions vary a lot in different parts of the world but is generally inadequate. To give a sense of the general prevalence, data from United States can be found were one in 190 is living with the loss of a limb (Ziegler-Graham, MacKenzie, Ephraim, Travison, & Brookmeyer, 2008).

The body’s biomechanics is very complex to emulate and every prosthesis must be adapted to the user which makes manufacturing even more complicated and resource demanding. This is a problem according to International Committee of the Red Cross (ICRC), (2006) particularly in low-

![Figure 1. The streets of Nairobi](image-url)
income countries where many don’t have the financial means to acquire or maintain their prostheses, which makes development even more sought after. Kenya (Figure 1) clearly falls into the group of developing countries with a large economic inequality which gives them a Human Development Index (HDI) of 145 out of 188 countries (United Nations Development Programme [UNDP], 2015). HDI is a measure of the prosperity of countries and is based on a combination of GDP, educational attainment and life expectancy. In Kenya 45.9% of the population lives below the poverty line and almost exactly one-third live on less than a 1.9 US dollars per day (The World Bank, 2005). Agriculture (Figure 2) is often referred to as the backbone of Kenya’s economy and employs nearly 80% of the population in rural areas (Kenya Institute for Public Policy Research and Analysis, 2013). Agriculture is a physical (Bowler et al., 2011) demanding labour that requires a fully functioning body and to provide individuals who lack limbs with greater job opportunities, hence it’s important to give more people access to functional prostheses that can handle the harsh conditions.

Initially 3D printing or Additive Manufacturing (AM) was merely used to create prototypes or models because of the limited material alternatives, low durability offered by the technology and the high cost. Today AM is breaking into the market as an industrial manufacturing method that can match or even surpass conventional processes (Gibson, Rosen, & Stucker, 2009; Li et al., 2014; Rayna & Striukova, 2016). Some of the reasons for this success is the ability to create a very complex designs and efficiently customize products. These are the most important elements that makes the technology well suited for medical devices where the importance of being able to design for the individual is central (Hochstein, 2015). According to WHO (2005) more than 75% of developing countries doesn’t have prostheses and orthotic (P&O) programs which leads to very few people having the expertise that’s needed in the maintenance of these devices. This is another issue where part of the solution may be new technology that could make it easier for relatively untrained personnel to assist in manufacturing according to the authors. A report from Sierra Leon indicates the increased wear on different prostheses in developing countries and the need for repairs. The study found that 86% of the prostheses were in use but almost half required repairs (Magnusson, Ramstrand, Fransson, & Ahlström, 2014). From this aspect additive manufacturing has an additional advantage in its ability to create customized components, such as spare parts, which could help these people and thereby reduce the demand.

1.2 STAKEHOLDERS

The stakeholders can be described as users and according to Bowler et al. (2011) be divided in to three types the primary-, secondary- and tertiary user.

The primary users are upper extremities amputees in Africa, more specific the inhabitants of Nairobi, Kenya, since the field study took place there. The product that’s being developed is a trans-radial prosthesis, meaning that the amputee of the user needs to be below the elbow and above the wrist to be able to use the product.

With an ever expanding online 3D printing community where ordinary people and companies can share their design as open source, hopefully our work could reach other amputees in developing countries. These users are classified as primary users as well.

The secondary user who will be affected by the project is the client 3D Life Prints, it’s future employees and manufacturers since the goal ultimately is for our work to be applied to their product. They will not directly use the artifact like the primary user but work as an intermediary providing the user with the prostheses. Family and friends to the user could also be classified as secondary user as they might sometimes help the user with putting the prosthesis on or with reparation.

The tertiary user is the person affected by the user’s use of the product (Bowler et al., 2011). These include organizations like the ICRC and the United Nations (UN) which on a regular basis try to improve the situation of people in the developing world. In turn they grants funding for companies like 3D Life Prints so the products can be developed and distributed to primary users. Currently the company has a collaboration with Alder Hey Children’s Hospital in Liverpool, England, where they work in an innovation hub to develop and produce AM anatomical models. Similar collaborations could potentially include more tertiary users like hospitals and governments that are in need of technical development to be able to provide better solutions for their inhabitants or patients.
1.3 PROJECT OBJECTIVES AND AIM

The aim of the project was to develop and improve the current version of The 3D Life Arm (Figure 3). The development was focused on enhancing **functionality** for the user and to facilitate manufacturing for the organization. These aims would in a longer perspective result in providing individuals with amputated limbs and low income a better quality of living through improving the prostheses and making them accessible. To achieve the aims objectives were established through continues discussions with the client.

These objectives were final but differentiate quite dramatically from the initial objectives which progressed through the project. Instead of just focusing on intended finger design the whole system was included and more incremental changes was applied to end up with a launch able product.

The initial objective was to deliver CAD-files that the client could print and test but with the focus shifting AM was conducted continuously to test prototypes to verify if the design was working on different components. The final deliverable was then shifted to a **functional prototype**. In addition, documentation of the work through the master thesis itself, workbooks and instructions to enable future iterations was included as part of the deliverables for the client.

The following research questions was established to be answered during the field study and the course of our master thesis project.

1. How are conventional prosthetic arms generally being manufactured, distributed and used compared to additive manufactured prostheses in Nairobi, Kenya?
2. Who is the primary user of prosthetic arms in developing countries, what problems are they facing with current solutions and what factors are considered as the most important? And why?
3. How should additive manufactured prostheses be designed for optimal usage in developing countries?

1.4 PROJECT SCOPE

The thesis was conducted over 20 weeks, starting with 8 weeks in Sweden followed by 8 weeks in Kenya and ending with 4 weeks back in Sweden. The primary users for the study was located in Kenya but since the project was initiated in Sweden a direct contact with the users wasn’t possible until week 8. The design process differed from a conventional processes and the need finding was initially based on interviews with experts from 3D Life Prints, prosthetist and prosthesi users in Sweden. The target was to have a consulting group of 5-20 patients during the field study and comparing the results from the interviews in Sweden with the ones in Kenya.

The scanning, fitting and to align the socket of the prosthesis wasn’t treated. In addition, with the company only having a below elbow prosthesis this is the type of prosthesis that was studied and improved.

The objectives were briefed as following:

- Make the system more **comfortable** to supply the user with a device that would be used more and for a longer period of time.
- Provide better **retention** to make a prosthesis that will stay on in more situations with less effort.
- Increase the **usability** through facilitate actuation of the terminal device and increased reliability.
- Facilitate **assembly and repairs** through revising and redesigning current assembly solutions to provide a more sustainable and functional prosthesis.
- Increase the **production efficiency** in the sense of time and money through new solutions and material selection.
1.5 PROJECT TEAM
A partnership was created during the course of the project with Luleå University of Technology and 3D Life Prints. The project team consisted of

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3D printing advisor, 3DLP
Adam Arabian,
Technical advisor and P&O expert, 3DLP
Paul Fotheringham,
CEO & founder of 3DLP

1.6 THESIS OUTLINE
The Context for the thesis covers information gathered to form an impression of the field of prostheses, additive manufacturing and the global context. The following chapter, Theoretical framework, covers the connection to industrial design engineering, developing prostheses and the field of AM technology. To gather more information and generate ideas and concepts different methods was used which are presented in the chapter Method, including how we used the methods, their reliability and validity discussed. For each phase of the project different results and conclusions could be made which is covered in the chapter Results. With the company wanting a finished product at the end of the project the Final design chapter includes a description of each of the components in the new 3D Life Arm 3.0. The final two chapters Discussion and Conclusion is a compilation of thoughts and reflection gathered during the 20 weeks of work on the project with conclusions finally answering the research questions we set out to answer.
02 CONTEXT
understanding the setting
2 CONTEXT

This chapter contains basic insight in implementing prosthetic care in developing countries for the purpose of understanding some main factors that have been considered during the project. General information of the partners SIDA and 3D Life Prints are presented mainly to understand their mission. With AM of prosthetics gaining traction globally some similar work and studies are presented for context gathered from reports and company’s official webpages. Lastly the reader is reminded that getting a prosthetic arm may only be part of a complete rehabilitation.

2.1 PROSTHESES IN DEVELOPING COUNTRIES

According to Cummings (1996) there are a number of factors that needs to be considered when implementing appropriate prosthetic or orthotic care in developing countries (Figure 4)

1. Low cost
2. Locally available
3. Capable of manual fabrication
4. Considerate of local climate and working conditions
5. Durable
6. Simple to repair
7. Simple to process using local production capability
8. Reproducible by local personnel
9. Technically functional (not gratuitously “high-tech”)
10. Biomechanically appropriate
11. As lightweight as possible
12. Adequately cosmetic
13. Psychosocially acceptable

These factors was first established to be suited for India but concluded by Cummings (1996) is that they could be applied to most developing countries.
2.2 SIDA & MINOR FIELD STUDY (MFS)
Swedish International Development Cooperation Agency (SIDA) is a Swedish government agency with the mission to reduce poverty around the world. In cooperation with other companies the agency seeks out to implement Sweden’s policy for global development on behalf of the Swedish parliament (Sida, 2015).

To finance student projects in developing countries SIDA grants different institutions and universities all over Sweden with scholarships (MFS). The scholarship enables students to gather material for essays and different these and at the same time offer students a practical experience from a developing country (Swedish Council for Higher Education, 2012). Given the grant students get the opportunity to work in a global context in association with UN’s Sustainable Development Goals (SDGs). The SDGs (Figure 5) is a plan of action for people, planet and prosperity (UNDP, 2016). The SDGs consists of 17 goals and 169 targets that balance the three dimensions of sustainable development: the economic, social and environmental. The agenda seeks to eradicate extreme poverty, strengthen universal peace in larger freedom and transforming our world before 2030.

One way, suggested by IDEO.org (2016) to improve lives and transforming the world is through design. This means designing for impact, building partnerships with organizations that know how to bring innovative solutions to life. The three ways of creating an impact is through: Design (create new products, services, and experiences), Fuel (empower others to become creative problem solvers), Inspire (tell stories of human-centered design in action).

2.3 THE CLIENT 3D LIFE PRINTS
When examine the market and possible organizations working in the field, 3D Life Prints was found. The company was founded by social entrepreneurs, technologists, manufacturers, medical experts and experts in logistics with members from several nations which denotes the range of competence the organization holds. According to 3D Life Prints website, they aim

“To seek out those in need of medical prosthetics, focusing on developing nations, and to provide them with options for a range of affordable, functional, durable, mechanically simple, aesthetically pleasing and highly customized products, utilizing 3D printing and mobile 3D scanning technologies wherever possible.” (3D LifePrints, 2015)

The major part of their humanitarian work and development is based in Kenya, but the organization spans over several developing countries such as Malawi, Zimbabwe, Uganda, South Sudan and Myanmar and 3D Life Prints are constantly expanding and reaching more countries’. Their work is carried out in Kenya and will benefit the local population, but we believe that the work can extend to more developing countries in time.

2.4 RELATED WORK
By browsing the internet, a couple of companies and projects were discovered that focused on aiding people with additive manufactured prostheses around the world. The range of products that were analysed includes simple body powered prosthesis to highly sophisticated myoelectric prostheses.

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1 P. Fotheringham, personal communication, January 20, 2016
2.4.1 e-NABLE

The open-source community e-NABLE consists of anyone who wants to design and create an additive manufactured upper-limb prosthesis and help to “Give the world a helping hand” (e-NABLE, 2015). The community have a vast range of different prostheses ranging from wrist powered to bionic arms. The people who benefit most current and recommended devices are people missing fingers or arms below the elbow. Some of the most popular designs are the Raptor Reloaded (Figure 6), the Cyborg Beast (Figure 7) and the Flexy-Hand 2 (Figure 8).

All three prostheses are wrist actuated, meaning that the amputee needs to have a movable wrist to actuate the prosthesis and a cavity in the palm of the terminal device to fit the residual limb. The Cyborg Beast and Raptor Reloaded are printed in rigid material while the Flexy hand 2 is printed in mostly flexible material.

2.4.2 Victoria Hand Project

The Victoria Hand Project (VHP) designs and develops low-cost, highly functional, upper-limb AM prostheses for developing countries according to their website (Victoria Hand Project, 2016). With the help of AM and 3D scanning they fabricate devices directly within countries such as Haiti, Guatemala, Nepal, Ecuador and Cambodia as well as promote a technology transfer where they train full-time technicians from the local community. According to VHP (2016) the Victoria Hand prosthesis (Figure 9) is a body powered, upper-limb, prosthesis that can be constructed and fitted for approximately 2700 SEK.

In connection with VHP launching a ground operation in Haiti a cooperation with the e-NABLE Community has
stated to train Haitian prosthetists in AM and provision of AM prosthetics.

2.4.3 Open Bionics
A British company specializing in creating low-cost bionic hands for a fraction of the price using AM (Open Bionics, 2016). The company came out of the Open Hand Project while developing their robotic prosthetic and is currently creating affordable bionic hands (Figure 10). The company is looking to charge customers 33 000 SEK for a bionic arm (including cost of fitting) and markets the arm as customizable, low lost and high functionality (Kelion, 2015).

2.4.4 Limbitless Solutions
Limbitless is according to their webpage a non-profit organization that uses AM to create bionics and solutions for children with disabilities in association with e-NABLE (Limbitless solutions, 2016). Their drive force is that no family should have to pay for their child to receive an arm. The organization consisting of engineers, tinkers, and developers and have currently created a bionic arm (Figure 11) which takes around 8-12 weeks to produce. In addition, they are currently developing a bionic arm with an elbow. The Limbitless arm is a great example of how open-source can work with them using a version of the Flexy hand 2 as the terminal device.

In addition, Limbitless solutions are working on bringing Bionic arms with a personalized theme like superheroes or other fictional characters.

2.4.5 Nia technologies Inc.
Nia technologies Inc. 3D prints lower limb prosthetic sockets (Figure 12) for children in Uganda and is a Canadian non-profit organization supported by Christian Blind Mission (CBM) Canada, The University of Toronto, Autodesk Research and Stronger Together. In addition, they partnered with Comprehensive Rehabilitation Services Uganda (CoRSU) Rehabilitation Hospital in Uganda. Using 3D scanning and printing they believe that human labour and time is reduced when producing prosthetic sockets and increase the accuracy of the fit at the same time (Nia Technologies Inc., 2016). By training current and new prosthetic technicians on the use of AM technology they anticipate that more children will have access to assistive devices with the simplified production method.
2.4.6 International Committee of the Red Cross (ICRC) prostheses

ICRC is a humanitarian institution based in Geneva, Switzerland. Created in 1863 the ICRC’s webpage describes themselves as

"an impartial, neutral and independent organization whose exclusively humanitarian mission is to protect the lives and dignity of victims of war and internal violence and to provide them with assistance." (ICRC, 2010)

Their mission has brought more than 179 206 fitted prostheses to developing countries all over the world since the unit started 1979. Polypropylene (PP) was introduced 1988 and is the main material used when creating a prosthesis with Ethylene-vinyl Acetate (EVA) used as a liner and other standardized components such as the hook and harness straps imported to the specific country. ICRC offers two types of upper-limb prostheses; the body-powered trans-radial prosthesis (Figure 13) and body-powered trans-humeral Prosthesis (Figure 14). The trans-radial devices offer the user functionality and an interchangeable terminal device which can be changed into a cosmetic hand or activity specific devices. ICRC refers to the devices as high-quality assistive devices. According to an interview held in Nairobi, Kenya, where the ICRC’s PP technology is practiced, a functional trans-radial prosthesis cost 150 000 KES and a functional trans-humeral prosthesis costs more than 300 000 KES (material and fitting costs).

The ICRC provides anyone with the access to internet with manuals for manufacturing the prostheses on their webpage (ICRC, 2006a, 2006b).

2.4.7 Related studies

Both in Sweden and across the world studies and projects with the aim to test the limits of AM of prostheses and prosthetic components are being conducted. The following are some examples.

Strömshed (2016) published a master thesis at Lund University of Technology (LTH). Strömshed developed a manufacturing process for prosthetist to create custom-made prosthetic arm sockets using 3D scanning and AM. The work showed viable results in both reducing lead time and cost for creating a prosthetic socket for prosthetists. Zuniga et al. (2015) published a research paper with the aim to investigate the feasibility of an additive manufactured prosthetic arm for children in developing countries and a fitting methodology that’s performed at a distance. The conclusion is that the product and method is a possible low-cost alternative with the Cyborg Beast from e-NABLE which can have a positive impact in the quality of life and daily usage for children.

Norgren (2015) wrote and published a bachelor thesis at Royal Institute of Technology (KTH), Stockholm stating that additive manufacturing can be suited for producing a simple body-powered prosthesis. In addition, she concludes that Fused Deposition Modelling (FDM) is a suitable technique of 3D printing in developing countries.

2015 Umeå University published Arturo & Tovar (2014) master thesis where a creative prosthetic system for children was developed using both 3D printing and LEGO Mindstorm. The idea was to explore and empower children with hand-disabilities by letting them be creative in a playful, social and friendly way. Arturo gives a new perspective of living with a disability for children.

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2 D. K’ochumba, personal communication, June 28, 2016
2.5 REHABILITATION

Providing Prosthetics and orthotics (P&O) services in developing countries is extremely challenging according to The Swiss Agency for Development & Cooperation and Landmine Survivors Network (2006). When planning the following principles should be ensured so that the maximum number of people can access P&O services, devices of acceptable quality and enable people with disabilities to participate and be included in society:

- Services are long-term
- Services are financially possible to sustain at a satisfactory level
- Services are integrated in the national health care structure
- Services are known, and physically and financially accessible to potential users
- Non-discrimination principles are applied
- Comprehensive planning is done, both at the program and the national level
- Appropriate technologies and working methods are used
- Staff are well trained technically and managerially
- The quality of the services is monitored

This means that for some people an affordable and durable prosthesis may be the only requirement to resume activities of daily living (ADL) but for many it may be a complex procedure with several actions and steps to be taken. When providing good quality P&O services three areas need specialized actions:

- Manufacturing and fitting of P&O devices
- Physiotherapy/ Occupational Therapy
- Medical work

P&O rehabilitation benefits the individual, their family and the local communities as well by contributing to the economic development of the community and not being regarded as a burden to society. According to Gilad (1986) both medical rehabilitation personnel and prosthetic designers need a simple, quickly applied process of evaluation that at the same time demonstrates the amputees skills and training progress objectively.
03 THEORICAL FRAMEWORK

understanding the field
3 THEORETICAL FRAMEWORK

This chapter contains the theories that was needed to understand a develop a prosthetic arm for developing countries from an industrial design engineers point of view. Most of the theories was a result from a literature study conducted in the beginning of the thesis. The framework is based scientific reports as much as possible.

3.1 INDUSTRIAL DESIGN ENGINEERING

Design is a very broad concept and hard to define because everybody designs in some way or another (Dubberly, 2008; Wikberg-Nilsson, Ericson, & Törlind, 2015). To further imply the vastness of the term, design can be described

"as the human capacity to shape and make our environment in ways without precedent in nature, to serve our needs and give meaning to our lives." (Heskett, 2005, p. 5)

Design as discipline is also very wide and has many meanings and sub-fields. Though, a common aspect usually concerns how a creation is conceived by a user or an observer. Industrial design is one of these fields where the creation typically is a product. When defining industrial design, it is usually considered to concern the interface between the user and the product, i.e. the meeting between the designer’s intention and the user’s perception and needs (Heskett, 2005). This is through affordance and aesthetics, how a product is perceived by the user (Heskett, 2005; Smets & Overbeeke, 1994).

Industrial design focuses on the human perspective and developing for the user is central.

Engineering design, on the other hand, is perceived as having a more functional approach. In engineering, technical aspects are central to achieve a scientific knowledge and thereby fulfill design and manufacturing requirements (De Vere, Melles, & Kapoor, 2010; Hurst, 1999; Pahl, Beitz, Feldhusen, & Grote, 2007).

This divergence can cause problems as the two fields usually needs to be combined to create modern products. Kleinsmann and Valkenburg (2008) concludes the importance of a shared understanding in an interdisciplinary design project to increase effectiveness and quality of the process. Cross (2000) claims that often occurring conflicts between engineers and industrial designers can be bridged by knowledge in both fields, the combination of the fields is known as industrial design engineering. According to Smets and Overbeeke (1994) industrial design engineering is the understanding of both technical details and expressiveness of the whole products. As a discipline it evolved in Glasgow, Scotland in the late 1980’s according to De Vere et al. (2010).

Inspired by change in the manufacturing industry that asked for knowledge in both engineering and design for a better understanding of the whole product design process. In a field like prosthetics, where interdisciplinary knowledge is key, applying methodology and knowledge of industrial design engineering ought to be beneficial. When developing a prostheses knowledge included in both fields are needed. The many aspects of the users, e.g. anatomy and culture and the engineering aspects like, basic mechanics and material science are central in design a sustainable prosthesis (Cummings, 1996).

How a product, like a prosthesis in this case, is designed can vary a lot and so do the approach. The design process can be categorized in two types of design: incremental or radical design.

3.1.1 Incremental and radical design

Incremental design work is the process of changing or developing something gradually. According to Wikberg-Nilsson et al. (2015) companies who manufacture a specific product to a specific market and want to keep developing product for the same market but with some change can describe their developing process as incremental design work. The process usually starts with an analysis of the product and translate that information into an improved product. This project was formed out of this mind-set as the existing product was considered very innovative but had flaws that partly kept it from being launched. An incremental design approach would thereby be appropriate to tweak the product and get rid of the flaws instead of making radical changes.

This leads to the opposite of incremental design which is radical design and it is, as the name suggest, developing something entirely new to the market (Wikberg-Nilsson...
et al., 2015). In this methodology the designers proceed from issues that doesn’t concern an exciting product which makes the form of the end product indefinite.

3.1.2 User centered design

The User centered design (UCD) approach originates from The User-Values Approach discussed and reviewed by Dervin & Nilan (1986). The concept called for focusing on making the user’s problem central when designing information systems and was later adapted to suit different areas of design where intended user’s needs can take centre stage. According to Bowler et al. (2011) UCD reflects over how the user function, it can be typically from a cognitive, affective, behavioural point of view, social, organizational and cultural context in which user’s function. From a product design point of view Yalman & Yavuzcan (2015) and Sanders (2002) states that putting the user in centre means that the outcome of the design can be used by the people whom it was created for with ease. This means that the creation should not just work, it must be usable for the intended user. According to Bowler et al. (2011) and Preece, Rogers, and Sharp (2002) it’s important that users are involved but at which degree may vary from time to time, usability test after the product is built to other cases where designers and user work alongside each other. In addition, the best practice of UCD is concluded in the begin with identifying the user, the user can be primary, secondary and tertiary.

3.1.3 Humanity-centered design

Humanity-centered design is taking human or user centered design to a wider perspective and considering a whole community (Madsen & Sklar, 2010). This can be very valuable when designing for the developing world as rural communities in these countries usually are tightly integrated, hence change brought to an individual can affect many people around them. According to Madsen and Sklar (2010) when practicing design in developing countries there are some principles that designers need to keep in mind for communities that have cultures and infrastructures that differs from our own. The principles are the following: start with empathy, design for communities, take a system view, make appropriate trade-offs, prepare your team. These five principles are presented as a way of guidance, but also as a form of reassurance and encouragement since the idea of Western designers focusing on the developing world is something met with scepticism according to Madsen and Sklar (2010). To apply the knowledge to the project IDEO.org’s (2015) theory of looking at the design process through peoples’ perspective was kept in mind to keep this humanity-centered and user centered approach from an early stage.

3.1.4 Reverse Engineering

According to Raja & Fernandes (2008) engineering is the process of designing, manufacturing, assembling and maintaining products and systems. Traditionally the engineering process is forward engineering where you move from the abstract world with logical design and move into the physical world with the implementation of a system. The inverse of this process is reverse engineering, meaning that you duplicate something that already exists to obtain a geometric CAD model (Figure 15) without any technical details (e.g. drawings, bills-of-material or engineering data). This process of engineering can be applied to existing parts, sub-assemblies and products without drawings, documentation or a computer model. When designing a product with an organic shape (e.g. a prosthetic hand) CAD modelling becomes more challenging, but by using reverse engineering a modeller can scan a hand and get a sculpted CAD representation that’s a replicate of the human hand.

In addition, reverse engineering can be used when manufacturing a socket by taking a scan and creating a digital model of the residual limb. The advantages of reverse engineering are compressed product development cycle time, shorter lead times. According to Colombo, Filippi, Rizzi and Rotini (2010) the quality of the final product is better as well and well-suited for specific customized products.

3.2 ERGONOMICS

Ergonomics (or human factors) are an important part of engineering since almost every system there are humans whom interact with products, machines or other people in different environments with different cultures (Bohgard et al., 2010). As an engineer designing a part of a system it’s important to know the physical, mental and social limitations of people since you may design something that impacts people’s daily living, as in the case of prosthetics. The central factors in this project, and concerning prosthetic design, are mainly briefed in three areas. Comfort as the prostheses needs be worn by the user an excessive amount of time. Psychosocial theory, an understanding of the individual in a social context is important as prostheses often are linked to stigma. Anthropometry is a important to consider as prostheses mimics and should follow the human body that differs in size and form on all individuals.
3.2.1 Comfort

The term *comfort* is used in a broad aspect without a real concrete definition. According to Hägg, Ericson, & Odenrick (2010) a variety of factors make up comfort including experiences, relaxation and general well-being. Measuring comfort is something that’s based on subject opinion and physical conditions. Given that comfort is very complex and hard to measure, Hägg et al. (2010) states that the first step in improving comfort is taking a look at discomfort. Discomfort is not the inverse of comfort and ridding the body of discomfort doesn’t necessarily mean that comfort is achieve and vice versa. Though, discomfort should be managed first since it’s the first noticeable sign that may lead to pain and ache followed by inquiry (Hägg et al., 2010).

3.2.2 Psychosocial theory

Psychosocial theory is based on the presumption that peoples’ actions are driven by their desires to satisfy certain needs. For instant people in the western countries where the need for shelter, food and water are satisfied other needs are pursued. These popular theory of needs reasoning was theorized by Abraham Maslow’s (1908-1970). According to Thylefors (2010) Maslow visualized his psychosocial theory with a hierarchy of needs (Figure 16) where human needs are culture dependent in the sense that different needs are more prominent in different cultures.

![Figure 16. Maslow's hierarchy of needs](image)

The five stages of Maslow’s hierarchy are physiological, safety, love and belonging, esteem and self-actualization. Reservations should be taken when considering Maslow’s theory whether the needs are specifically culture based or a consequence of the well-being and welfare of the state can be discussed.

3.2.3 Anthropometry

For different tools and aids being used by people it’s imperative that they are designed for human’s physical capabilities and dimensions according to Hägg et al. (2010) if not, this leads to difficulties for the user to adjust which in turn might affect health, well-being and safety in a negative way. Anthropometry considers areas like measurements, proportions, posture, range and operating space for humans. The theory of anthropometry is that the dimensions of the human body are statistically normally distributed for a population, this means that with the help of a mean value and standard deviation a dimension of a population can be described.

When designing with the help of anthropometric data the usual practice is to relate to percentiles. For example, when a space is designed the 95 percentile is used, meaning that 95 % of the standard population can fit inside the designed space. The most optimal case would be to design for all, so men and women can use it, but this is more complex because or practical and economical limitations, in many case it’s impossible. For example, tools should consider to be produced in different sizes.

3.3 THE BIOMIMETIC DESIGN APPROACH

According to (Kakoty & Hazarika, 2011) a definitive step towards designing an ideal upper body prosthesis is by taking a biomimetic approach. This approach involves investigation of the human hands physiology and biomechanics carefully, enlisting the expected properties of a future prototype, selecting suitable material and develop the prototype. Taking the approach in both mimicking the human hand in function and geometry shows promise in developing a prosthesis that can perform daily living activates with a high accuracy. In addition, Bundhoo and Park (2005) propose that improved performance can be achieved by designing a biomechanically accurate hand with the help of the biomimetic design approach as well. In product design as well as other domains ranging from medicine and rehabilitation, psychology understanding the way humans grasp objects and common use patterns is important according to Feix, Romero, Ek, Schmiedmayer and Kragic (2013).

Zheng, Rosa, Dollar and De La Rosa (2011) discusses the disadvantages of taking a biomimetic design approach, with the hands 21 degrees of freedom (DoF), muscles and thousands of sensory organs and the current engineered systems that level of complexity and performance cannot be fitted in the same size package. Caution should be taken when taken the approach since added complexity traditionally comes with added cost and lower durability.

3.3.1 Physiology of the human hand

The Manus, or the human hand as it is usually called, is mainly built for “prehensile” functions (grasping and manipulating), but the complex structure and the human
imagination gives it endless other functions e.g. pulling, pushing, striking to name a few. The skeleton of the human hand is divided in three regions: the carpus (carpals), the metacarpus (metacarpals) and the phalanges (fingers) (Figure 17). The wrist bones (carpus) consists of eight carpal bones running in two rows between the forearm (radius) and at the base of the metacarpals. From the distal head of the metacarpals (knuckle) fourteen phalanx (finger bones) make up each finger with three in each finger (proximal, middle and distal or first, second and third).

3.3.2 Functionality
According to Colin M Light, Chappell and Kyberd (2002) the general definition of functionality in relation to the human hand is the ability to perform tasks encountered during everyday living. This means that not only does the design of the hand have to be suitable for a specific task, it has to be adaptable to different tasks. Functionality includes dexterity and gross manipulative ability as well.

3.3.3 Grasping
Grasping is one of the five basic motion elements involved in the manipulative processes. According to Kumar (2008) hand grasp and finger pinch forces (compressive, thrust, or rotational) may be required for e.g. holding or stabilizing an object, squeezing parts together or helping to create torque on handles when preforming different tasks. Several factors may vary the type of hand grasp or pinch a person uses and the amount of force needed, among the most important factors are the intended activity, size, weight and shape of the object. Other factors are frictional properties (hand to object contact), stability of the object and the influential factors (e.g. generating torque for a screwdriver and a jar lid is the same activity but the gripping may be different).

In order to understand the theory of grasping types of the human hand a definition of the practice is given as stated by Feix et al. (2013)

“A grasp is every static hand posture with which an object can be held securely with one hand, irrespective of the hand orientation.” (p.2)

The first attempt of categorize how the human hand grasps different objects was presented by Schlesinger (1919) according to Cutkosky (1989), Iris (2015) and C. M. Light, Chappell, Kyberd and Ellis (1999). The six grasp types presented was Cylindrical, Tip, Hook or Snap, Palmer, Spherical and Lateral (Figure 18).

According to Kumar (2008) from a functional standpoint the first carpometacarpal (CMC) joint is the most important. That is the first joint of the thumb. It is a modified saddle joint between the base of the first metacarpal and the trapezium. The design of this joints makes for a wide range of movements, it is this difference in the thumb to the other fingers that yields the ability to grasp, grip, pinch, hold and manipulate objects. The remaining fingers range of motion in the CMC joints increases from the second (index) finger to the fifth, these motion makes it possible for the hand to preform cupping of the palm and making a fist. This gives the fingers a total of 19 DoF since the thumb is missing one joint. With an additional three DoF from the wrist, including supination (the rotation of the radius over the ulna), the human hand has a total of 22 DoF (Kakoty & Hazarika, 2011; Kargov, Pylatiuk, Martin, Schulz, & Doderlein, 2004; Kumar, 2008).

Later Cutkosky (1989) proposed to further develop the classification by constructing a taxonomy of grasps

![](Image)

*Figure 17. Skeleton of the human hand*

![](Image)

*Figure 18. The different types of grasps.*
where grasps is divided in two categories (power and precision). The taxonomy is expected to streamline hand design, construction and control.

3.4 MEDICAL BACKGROUND

Before a person is fitted with a prosthesis there are some directions that need to be considered, according to Winterberger (2015) the first consideration accounts for the medical reason why a person needs a prosthesis. The distinction is usually depending on if a person has an amputation cause by e.g. an accident, or sickness or if a person has a congenital difference (dysmelia).

3.4.1 Amputation

Amputation stems from the Latin word *Amputatio*, meaning to cut off or cut away and mans the complete loss of all limb elements below a certain point. According to Kirkup (2007) one of the first time the word amputation was used as early as 1612 to describe a limb excision, before that the word was used as a reference of cutting off the hands of criminals. The need for amputation difference depending on circumstances such as diseases or acute trauma (Norgren, 2015). In developing countries, the lack of healthcare leads to complications like infections and gangrene making amputations more common as well as the injuries caused by landmines in warzones. In western countries we can see a majority of new amputations being caused by complications of the vascular system caused by diabetes.

Typical amputations according to Stolov and Clowers (1981) for different segments of the arm can be performed on the fingers (metacarpal amputation), forearm (transradial amputation), above the elbow (transhumeral amputation). In special cases the amputation can be performed right between the different bones (disarticulation).

3.4.2 Congenital hand & arm differences

A congenital difference of the hand or arm can consist of a partial or complete absence of the limb and is divided into two categories: transverse and longitudinal dysmelia (Figure 19).

According to Stolov & Clowers (1981) individuals with a congenital difference have problems quite different from those of an amputee since the individual didn’t experience a sudden loss of a limb. Even if a person is born with the difference the person may be hospitalized because of different surgeries. Congenital deficiencies like hand or arm differences are included in the term amputation.
3.5 PROSTHESES

The main components for a prosthetic arm is the terminal device, the socket and, if the prosthesis is body powered, a harness system is included in the figuration (Figure 20).

![terminal device, socket, harness](image)

*Figure 20. The three main components of an upper-limb prosthesis.*

*The terminal* device replaces the hand (e.g. a hand or hook). Depending on the amputee the function and mechanics of the prosthesis differ e.g. the prosthesis can be purely cosmetic with little to no function (passive) except to resemble the missing limb and a highly functional prosthesis with little to no cosmetic appeal but with functions matching that of the human hand (active) according to (Norgren, 2015). *The socket* (where the prosthesis meets the residual limb) is an extension which matches the length of the lost limb (with the elbow reconstructed for amputees with an above-elbow amputation) and in some cases retain the prosthesis. Some prostheses are utilizing a *harness* system. This is used to retain the device (when the socket isn’t enough) or harness the users body power to activate a functional terminal device to grasp objects, or it could be both.

### 3.5.1 Cosmetic prostheses

The cosmetic prosthesis is a passive device, meaning its function is mainly to hide or mask an amputation or congenital difference. According to Strait (2006) these devices are desired in cultures where amputees are perceived as second-class citizens and is a cheaper alternative then a functional prosthesis. Even if the cosmetic prostheses is used for its aesthetic appeal some of the prosthesis has some functionality which can be useful. According to Caine-Winterberger (2015) a cosmetic prosthesis can be used as support in activities that require two hands e.g. holding books, trays and tricks when for example taking on clothes as well.

### 3.5.2 Body powered prostheses

As the name might suggest this type of prosthesis uses a part of the body’s movement to create a force that in turn operates the prosthesis or the terminal device (e.g. an active prosthesis). The most commonly used body-powered prosthesis uses a functional hook as the terminal device because of its reliability, functionality and still low cost according to Cupo and Sheredos (1998). In addition Carey, S. L., Lura, D. J. and Highsmith (2013) states that advantages have been shown in durability, training time, frequency of adjustment, maintenance. The higher up an amputation is preformed the more difficult create the force needed to open or close the prosthesis (Cupo & Sheredos, 1998). Disadvantages with body powered prostheses include the limitation in the control (Carey, S. L., Lura, D. J., & Highsmith, 2013). Depending on the level of amputation the prosthesis carrier can power the prosthesis using the different motions created by the movements of the residual limb (e.g. the flexion of the wrist, elbow or the shoulder). For prosthesis below the elbow the function can be achieved with single control, meaning you need only one cable to achieve the grasping mechanism attached between the terminal device and harness.

The above-elbow prosthesis demands not only the need for prehension to be provided but it needs various degrees of forearm flexion as well. By using arm flexion, arm extension and scapular abduction the body can change the degree of the forearm by accessing an elbow lock and still being able to change back to control prehension. To achieve both a rotation of the forearm and opening and closing of the terminal device a two control system is used, meaning you need two cables, one attached to the terminal device and harness and one cable from the harness to a mechanism locking and unlocking the elbow lock (Pursley, 1955).

#### 3.5.2.1 Harness for body-powered prostheses

The harness for standard upper-limb prostheses that’s used to today was created in the 1950’s spurred by World War II and since then not much has happened (Cupo & Sheredos, 1998; Zealand, 2007). The harness has three main requirements; first and foremost the ability to create a *source of power* to the terminal device creating a gripping or releasing function, holding the prosthesis securely (*retention*) and being *comfortable* with maximum comfort being most important of the latter two according to Pursley (1955). Without comfort the user will stop wearing the prosthesis. Additionally, Pursley (1955) concludes that complications arises when designing the whole system since satisfying one of the requirements is usually done on expense of the other two. The dependence can be thought of as a circle where the three requirements are in placed evenly around it (Figure 21).

![comfort, source of power, retention](image)

*Figure 21. The three factors to consider when designing a harness system*
This solution is still being used today where the abduction (Protration) and adduction (Retraction) of the scapula is utilized to create a grasp or release function for the terminal device (Figure 22). In addition, flexion of the shoulder joint can be used to achieve the mechanism as well.

The mechanism can be used for both voluntary closing (VC) and voluntary opening (VO) depending on the terminal device. Of all the types of prosthetic arm the unilateral below-elbow prosthesis is the simplest to harness according to Pursley (1955). Since the amputee still has an elbow, the ability to replace prehension is exclusively the mechanism required to be replaced. The higher up an amputation is performed the more difficult the prosthesis is to harness and operate (Taylor, 1955).

The figure-nine pattern is a simple loop that’s put over the sound shoulder which can provide the user with the tensioning of the cable system when using the motions to create power for the prosthesis. However the pattern doesn’t suspend the prosthesis in anyway its simplicity does on the other hand makes it very easy to produce and is used for the ICRC’s trans-radial prosthesis (Hess, n.d.).

The figure-eight pattern adds an inverted Y-suspension to the figure-nine which is used to give better retention than the figure-nine. The Y-suspension is the attached to a cuff (or triceps pad) which in turn is retaining the socket for the prosthesis. In addition, the cuff adds a protective guiding of the cable that activates the motion of the prosthesis, the configuration is still pretty simple and according to Pursley (1955) its simplicity usually only leads to minor deviations that are not serious, it still needs some points for adjustments and it’s not as simple as the figure-nine.

3.5.3 Electric prostheses

An Electric/ Robotic prosthesis is an active device which uses electronic elements to offer a wider range of functionalities. The motions are externally powered and there are two control methods available according to Iris (2015) which are the switch control and the myoelectric control.

The switch control has buttons that controls the movement of different parts of the prosthesis. depending on the number of buttons and programmed movements in the microprogram the user can switch between commands and use a similar movement of the residual limb as in the case of a body powered prosthesis to make the prosthesis perform the desired movement. According to both Iris (2015) and Phillips, Zingalis, Ritter and Mehta (2015) there are switch control prosthesis like the Nevedac Arm which are made from locally-available material, costs $300 and with 3D printed parts that can be adjusted e.g. when children grow. The cost however is only for the terminal device and is based upon a wrist connection already existing.

The myoelectric prosthesis uses two sets of muscles located on the front and back of the forearm (flexor digitorum and extensor digitorum groups) myopotentials associated with contraction is used to control the movement of an artificial hand. The electric signals from the muscles are picked up with surface electromyogram (sEMG) electrodes placed on the residual limb which enables it to operate with less movement and energy need from the user (Iris, 2015).

Disadvantaged with the technique are the high price, heavy weight, higher maintenance, the response time from the muscles to the desired movement and training up muscles and mental power to make the muscle behave the right way (Carey, S. L., Lura, D. J., & Highsmith, 2013; Iris, 2015; Kakoty & Hazarika, 2011)

Some other more experimental methods of controlling a robotic hand are still being studied e.g. using Quick Response (QR) Codes to change between the different grasp types (Iris, 2015), Using brain signals (Nicolelis, 2001) or Myo gesture control armbands which pick up the muscles signals (Steele, 2016).
### 3.5.4 Food & Drugs Administration approval

The Food and Drug Administration (FDA) is a federal agency of the United States Department of Health and Human Services and was founded in 1906 to protect and promote public health (U.S. Food & Drug Administration [FDA], 2016). The FDA regulates all products in the U.S including veterinary drugs, biological products, medical devices, the nation’s food supply, cosmetics, and products that emit radiation and tobacco products (regulating the manufacture, marketing and distribution). According to (FDA, 2011) the economic and technological changes during the last decades leading to a truly global marketplace and the U.S being one of the leading superpowers the standards set by the FDA are a great approval to have. In addition, FDA cooperates with regulators and industries of medical devices all over the world to achieve global harmonization of regulating medical devices.

To market any medical devices in the United States a premarket approval is needed by the FDA where the device is classified as either a I, II or III device or found Substantial Equivalence (SE) to a predicate. SE means that the new device is at least as safe and effective as the predicate. The classification of the devices is made according to the degree of difficulty in assuring safety and effectiveness with class I being devices which is the one with the lowest risk and class III being the highest. Simple body powered prosthetic arms can be classed as class I devices since they follow the following FDA (2016) guidelines:

1. For use in supporting or sustaining life
2. Of importance in preventing impairment to human life; and may not
3. Present a potential unreasonable risk of illness or injury

This means that the device only need to satisfy the FDA’s General Controls which include:

1. Adulteration
2. Misbranding
3. Device registration and listing
4. Premarket notification
5. Banned devices
6. Notification and repair, replacement, and refund
7. Records and reports
8. Restricted devices
9. Good Manufacturing Practices

According to Resnik (2011) prosthetics are generally considered Physical Medicine Devices, which are Class I or low-risk devices. This means that manufacturers are rarely required to conduct research on their new products, hence the lack of usability research may be explained by this factor (FDA, 2016).

### 3.6 ADDITIVE MANUFACTURING

Additive manufacturing (AM) differs from traditional manufacturing techniques in its ability to build up three-dimensional solid object by adding material for each layer instead of subtracting material. Basically the AM process breaks down a computer model into a series of 2D cross-sections of a finite thickness and feeds it into a AM machine which adds them together layer by layer (Figure 23).

According to Bogue and Bogue (2013) and Gibson et al. (2009) 3D printing was developed and commercialized as early as the 1980’s by introducing the Stereolithographic (SLA) technique, since then AM has gained traction with new techniques such as Selective laser sintering (SLS) and Fused Deposit Modelling (FDM) and the evolution of stronger and versatile materials to print with (Upcraft & Fletcher, 2003). In the beginning the technology was limited to manufacturing prototypes, so called Rapid prototyping (RP) which according to (Gibson et al., 2009) in product development terms means developing a prototype directly from digital data. With the development of AM the process is now capable of distributed manufacturing, with applications in architecture, construction, industrial design, automotive, aerospace, military, engineering, civil engineering, dental and medical industries, biotech (human tissue replacement), fashion, footwear, jewellery, eyewear, education, geographic information systems, food, and many other fields (Rayna & Striukova, 2016; Dantong et al., 2014; Gibson, Rosen & Strucker, 2010). In addition, advances in material properties has led to 3D printers being able to print with different materials e.g. Flexible, rigid, semi-flexible, biodegradable materials with different advantages and areas of usage.
3.6.1 Slicing software
Before the 3D model can be additive manufactured it's exported as a STL-file (most common) which is a representation of the models surfaces as a finite element of polygons, and exported to a suitable slicing software. A slicing software converts the file to code in x-y and z-based coordinates (slicing) that the 3D printer can read. Depending on the slicing software the user can control different settings (e.g. Printing temperature, Infill percentage, Shell thickness).

Cura is Ultimaker’s own slicing software which can be downloaded free of charge for Mac OS X, Windows and Linux. This is one of the biggest advantages with the software. Cura is fairly limited in available settings but on the other hand it makes it very user friendly. (Ultimaker, 2016).

Simplify3D however isn’t an open source software but offers a solution with more features such as: repairing models, generate support structures, setup dual-extrusion prints and changing the infill percentage on different layers. In addition, Simplify3D markets that they are compatible with more printers than any other software available. The software is available for Mac OS X, Windows and Linux as well (Simplify3D, 2016).

3.6.2 Technologies
AM is the process of building physical model out of computer model, layer by layer. That is the basic principle, how this is done though varies a lot depending on the technique, as mentioned earlier. The following section briefs the most relevant of those techniques.

3.6.2.1 Fused Deposit Modeling (FDM)
This method, developed by Scott Crump of Statesys 1989, is the most common manufacturing technology for rapid prototyping (Gross, Erkal, Lockwood, Chen, & Spence, 2014). By extruding thermoplastic materials and depositing the semi-melted material in thin layers on top of each other building up the object bottom to top. The material which comes in spools is feed into the extruder by rollers and then heated up by a preheated nozzle, since the material is heated as it’s extruded the layers will stick to each other and harden when it’s cooled down. With this relative simple solution, it’s significantly cheaper than other methods such as SLS (Ventola, 2014), the materials are cheap and no chemical post-processing is required making it an overall cost effective process. The disadvantage of FDM printing is the need for support structures, the resolution is lower compared to other methods and it’s a slow process (Wong & Hernandez, 2012).

3.6.2.2 Selective laser sintering (SLS)
This method uses a CO₂-laser which fuses a layer of powdered material. When one layer is finished a new layer of powder is deposited on top of the old and the laser fuses (sinters) the new profile with the old layer. The method makes it possible to use a wide range of materials from polymers to metals with a very good finish with the unsintered material acting as a support material according to Upcraft and Fletcher (2003). The big disadvantage with the method is its high price for the printer (William, 2005).

3.6.2.3 Stereolithography (SLA)
Using an adjustable build plate with photopolymer (typically a liquid resin) a laser traces the cross-section of the part, where the laser hits the polymer solidifies and the build plate rise or falls and the next slice begins building up the part layer by layer like FDM. When finished the part is cured in an ultraviolet oven. According to (Upcraft & Fletcher, 2003) using SLA gives good surface finish with easy obtainable complex geometry that generally has good accuracy. Continuing, the models does still need support structures that need to be removed, some acrylate resins can warp, the resins are hazardous and need careful handling and overall both machines and materials are more expensive than with the FDM technique.
3.6.3 Materials

The material possibilities of AM are expanding very quickly, which is one of the seeds to this project. The following section presents the most relevant materials used for FMD-printers in the project and their properties.

3.6.3.1 Thermoplastic elastomers (TPE) & Thermoplastic polyurethane (TPU)

Thermoplastic elastomers (TPE) is typically a mix of a thermoplastic and an elastomeric giving the filament these properties like being able to stretch twice its size repeatedly without being deformed (Figure 24). Benefits with thermoplastic elastomers flexibility, hardness and tensile strength. But its flexibility makes it hard to print with traditional FDM 3D printers.

Recreus Filaflex is a flexible TPE filament with a polyurethane base and some additive to make it printable. Adding a polyurethane base makes it a Thermoplastic polyurethane (TPU) material. Some key features (Table 1) according to Recreus technical data sheet (APPENDIX A) include

![Figure 24. Flexible test piece made out of Filaflex filament](image)

Comparing the technical sheets of Ninjaflex and Filaflex and according to Yarwindran, Sa, Ibrahim, & Periyasamy (2016) found that overall Filaflex showed higher value in hardness, tensile strength and flexure when using FDM printing technology. With Ninjaflex being a bit less flexible however it should be easier to print with.

<table>
<thead>
<tr>
<th>NINJAFLEX</th>
<th>STANDARD</th>
<th>VALUE</th>
<th>UNIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shore hardness, method A</td>
<td>ASTM D2240</td>
<td>85</td>
<td>SHORE A</td>
</tr>
<tr>
<td>Ultimate tensile strength</td>
<td>ASTM D638</td>
<td>26</td>
<td>MPa</td>
</tr>
<tr>
<td>Yield Tensile Strength</td>
<td>ASTM D638</td>
<td>4</td>
<td>MPa</td>
</tr>
<tr>
<td>Elongation to break</td>
<td>ASTM D638</td>
<td>660</td>
<td>%</td>
</tr>
<tr>
<td>Toughness (integrated stress–strain curve; calculated stress x strain)</td>
<td>ASTM D638</td>
<td>82.7 m*N/m² x 10⁶</td>
<td>%</td>
</tr>
<tr>
<td>Impact strength (notched izod, 23C)</td>
<td>ASTM D256</td>
<td>4.2 kJ/m²</td>
<td>%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FILAFLEX</th>
<th>STANDARD</th>
<th>VALUE</th>
<th>UNIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shore hardness, method A</td>
<td>ISO 868</td>
<td>82</td>
<td>SHORE A</td>
</tr>
<tr>
<td>Ultimate tensile strength</td>
<td>DIN 53504</td>
<td>54</td>
<td>MPa</td>
</tr>
<tr>
<td>Elongation to break</td>
<td>DIN 53504</td>
<td>700</td>
<td>%</td>
</tr>
<tr>
<td>Impact resilience</td>
<td>ISO 4662</td>
<td>42</td>
<td>%</td>
</tr>
<tr>
<td>Tear propagation resistance</td>
<td>ISO 34-1</td>
<td>70</td>
<td>kN/m</td>
</tr>
</tbody>
</table>
3.6.3.2 Polylactic acid (PLA)

PLA is a biopolymer filament meaning it’s produced by living organisms (making it a polymeric biomolecules). PLA is one of the most popular filaments being used today because of its toughness, being thermoformable and not petroleum based (biodegradable) since it being produced from renewable resources such as corn starch, potato starch, sugarcane or tapioca roots. During printing PLA doesn’t emit any fumes which means you don’t need any ventilation systems during printing. Recently there has been some flexible PLA filament on the market (MattterHackers, 2016).

However, being a biopolymer there’s some downsides, PLA is very prone to water absorption meaning it will become more brittle and difficult to print with if it’s exposed to moisture during an extensive period. Being easily thermoformable can be a disadvantage since the temperature needed for the material to reform can be as low as 50°C, usually around 60°C, making it hard to preserve its shape in warm climates. In addition, PLA may be a biopolymer but the colour pigments used may not (3D Printing from scratch, 2016; Lu et al., 2016).

According to Colorfabbs webpage (Colorfabb, 2016) and technical data sheet (APPENDIX C) and PLA has the following key features (Table 3)

<table>
<thead>
<tr>
<th>PROPERTIES</th>
<th>STANDARD</th>
<th>VALUE</th>
<th>UNIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modulus of elasticity</td>
<td>ISO 527</td>
<td>2,960</td>
<td>MPa</td>
</tr>
<tr>
<td>Tensile strength</td>
<td>ISO 527</td>
<td>61.5</td>
<td>MPa</td>
</tr>
<tr>
<td>Tensile strain at break</td>
<td>ISO 178</td>
<td>10.5</td>
<td>%</td>
</tr>
<tr>
<td>Flexural modulus</td>
<td>ISO 178</td>
<td>3,295</td>
<td>MPa</td>
</tr>
<tr>
<td>Flexural stress at 3.5 % strain</td>
<td>ISO 178</td>
<td>88.8</td>
<td>MPa</td>
</tr>
<tr>
<td>Impact strength (Charpy), RT</td>
<td>ISO 179-1/1 eU</td>
<td>30.8</td>
<td>kJ/m²</td>
</tr>
<tr>
<td>Shore D hardness</td>
<td>DIN 53505</td>
<td>n/a</td>
<td>MPa</td>
</tr>
<tr>
<td>Glass Transition Temperature</td>
<td>n/a</td>
<td>55</td>
<td>°C</td>
</tr>
</tbody>
</table>

3.6.3.3 Nylon & Plasticized Copolyamide TPE (PCTPE)

First developed by Dr. Carothers, Nylon was the first polymer to engineered with specific properties in mind, this later led to a family of nylon materials being developed with a broad range of properties (Mastro, 2016).

According to (Mastro, 2016) Nylon is flexible, tough, strong with a low coefficient of friction. In addition, its biocompatible making it well suited for example the prosthetic socket where skin contact is a factor and you can dye the filament before printing easily in colour baths. Disadvantages include being prone to water absorption which can affect properties and dimensions negatively. Adhesion to the print bed and lamination is a big issue as well (3D Verkstan, 2016).

Taulman3D is an American 3D printing filament company specializing in high strength materials such as Nylon. Taulman’s Plasticized Copolyamide TPE (PCTPE) is a Highly flexible nylon and TPE for FDM printers. Even if it’s classed as a TPE it’s not as flexible as Filaflex or Ninjaflex which means it’s suited for applications where a small degree of flexibility is needed (Taulman3D, 2016).

3.6.3.4 Polyethylene terephthalate glycol (PETG)

Polyethylene terephthalate glycol (PETG) is a clear amorphous thermoplastic. The plastics is lightweight and has good impact strength (much higher the PLA). PETG is an easy material and even if it’s not biodegradable like PLA its 100% reclaimable (MatterHackers, 2016). Just like PET bottles for example. Furthermore, you can polish the material with flame for a better finish. The filament is prone to water absorption and need to be stored in a dry environment (3D Printing from scratch, 2016).

The brand Colorfabb was officially launched 2013 and is a Dutch producer of filament for 3D printers. Colorfabb_XTs PETG is a co-polyester based material for FDM 3D printing (Colorfabb, 2016).
3.6.4 AM and sustainability

Sustainability is becoming increasingly important across the world and a term that many companies and organization are striving to fulfil. The term varies depending on its context. As described by Merriam-Webster’s dictionary sustainable is defined as

"Able to be used without being completely used up or destroyed; involving methods that do not completely use up or destroy natural resources; able to last or continue for a long time." (Merriam-Webster, 2016)

Sustainability can be broadly categorized in sustainable biological resource use, sustainable agriculture, sustainable carrying capacity, sustainable energy, sustainable society & economy, sustainable development and alternative perspective of sustainability according to Brown, Hanson, Liverman and Merideth (1987).

Discussed by Campbell, Williams, Ivanova and Garret (2012) 3D printing leads to significantly less amounts of waste product compared to subtractive manufacturing, making it possible to enhance global resource productivity. The carbon footprint is reduced by providing locally based manufacturing and less transportation of products since designs will be digitally transferred around the world instead with complex supply chains of parts being produced around the world. The number of unsold products can be reduced or eliminated which in turn will eliminate the cost of storage of inventory and spare parts. Future usage of every family having a 3D printer. Might be less sustainable with failed prints etc. but with when producing is working better people will be able to create a vast variety of products with just a few raw materials stored at home. For lower end products AM could enhance the ability to recycle materials such as plastics and metals.

Given this, 3D printing can be categorized as sustainable development or even more specific eco-development which promotes the symbiotic relationship between mankind and nature.
04 METHOD

from idea to design
4 METHOD

This chapter is divided into 4 stages: Context immersion, Ideation, Development and Implementation. For each stage the theory and execution of each method is described. As part of the project the process was planned and design in the initial phase. With the team jumping back and forth between the last two phases they are presented as one.

4.1 DESIGN PROCESS

The process used in this project was similar to the process illustrated by Wikberg-Nilsson et al. (2015), which spanned from Planning, Exploring, Creating and Prototyping and using different methods for each step to archive a goal (Figure 25).

An iterative process is described by Wikberg-Nilsson et al. (2015) as a non-linear process where stages are presented but not followed in that order, for example the process can span from planning, explore, create, prototype and then start all over again. This was particularly the same for us as well, the first stage of our project followed a very linear process up to the point of exploring, with the help of AM we could prototype and evaluate different segments so fast that we needed to move backwards and try to ideate new possibilities and explore them further and repeating this over and over again.

4.2 PROJECT PLANNING

The design process was planned using a Gantt-chart with the different stages taken into consideration (APPENDIX D). Something that was special with the project was that it performed in three geographical phases with the start in Luleå followed by the field study and development in Nairobi and ending with the finalization back in Luleå. According to Wikberg-Nilsson et al. (2015) mistakes during the process can have huge negative economic consequences as well as hurt the company brand, that’s why a good initial planning phase is very important. The planning will eventually affect the end result as well.

The project was planned to cover four Stages (excluding the Planning phase), which were Context immersion (leading to a List of Requirement), Ideation (leading to three concepts), Development (leading to one concept) and Implementation (refining the Final prototype). Some data couldn’t be collected in Sweden in the initial phase which extended the Context immersion phase. Having just 8 weeks of work in Nairobi the final 3 phases were planned to coincide with the Field study. This segmentation of the design process (Figure 26) organizes it and creates a more rational form of cooperation between different professions according to Lundequist (1995) In addition, it creates space for the elements of a design process that needs to be considered.
Being too detailed with the project planning can according to Lundequist (1995) inhibit creativity so a balance should be sought after or not to be too strict. In our case, we researched methods to use during the project so not to be totally clueless but we agreed that it wouldn’t mean that the project would fail if certain methods wasn’t used.

4.3 CONTEXT IMMERSION

This stage consists of the data collection through literature reviews, analysing the existing product, interviews and questioners done in Sweden as well as in Kenya. The data that was collected was later applied to a List of Requirements.

4.3.1 Literature review
To gain relevant information on the field of prosthesis, developing countries and 3D printing a literature review was conducted. The total field, which we call 3D printing prosthesis for developing countries included: Additive manufacturing, Additive manufacturing of prostheses, Biomechanics, Prostheses, Design & Inspiration and Kenya & Developing countries. The material was gathered from books and articles found online on the Schools database for scientific articles. The reliability of every source that was collected and checked to see if it was peer-reviewed or for multiple sources saying the same thing.

4.3.2 Analysis in CAD
Better understanding of the existing product was created when a stitched CAD model (Figure 27) was presented to the design team by the company. The model could be rotated, zoomed at specific points and a transparent shader could be applied to understand how the product was constructed internally.

*Figure 27. Render of initial CAD-model that was sent in the initial phase of the project.

Before the design team had access to the model the only basis was pictures of the product which made this a great step forward. In addition, with the model opportunities of A was created as well.

4.3.3 Cost & time analysis
According to Boothroyd (1994) there is overwhelming evidence that product design for manufacturing and assembly can be the key to high productivity in all manufacturing industries. The traditional process the designer makes sketches and drawings that are handed over to the manufacturer whom find flaws in the design from a manufacturing and assembly perspective which leads to delays in the product release. Furthermore, if the changes occur later in the development cycle the more expensive changes will be. Boothroyd (1994) therefore suggest that manufacturing and assembly is important to consider early in the design cycle.

With AM the manufacturing step is significantly easier than traditional manufacturing methods since what is needed is simply a 3D model, a printer and stock material with no real regard to the complexity of the shape of the part. We can utilize the slicing software’s calculation capacity to get a realistic time estimate to print, and the amount of material needed for each print. In addition, we access the cost for each individual roll of filament. This gives us a realistic estimation of what the end product will cost to manufacture and the time it will take to print each part. This was all created and compiled in an excel spreadsheet which made it easy to change parameters and see what the outcome would be from the original product and the new. These calculations were updated through the project as more knowledge of the end result was gained progressively.

4.3.4 Questionnaire
The advantages according to Jordan (2000) of designing a questionnaire is that it can be copied and issued to as many people as the investigator feels appropriate without spending too much time or money. In addition, it’s a versatile method which can be used early or late in the design process and the responses will be free of the investigator effects with the option of anonymity, for example when evaluating concepts or prototypes. The biggest disadvantage of questionnaires are the low response rates with the absence of the investigator with a large population of the responses often being from people with extreme or strong points of views about the subject which in turn doesn’t represent the target group that was of interest. This can be avoided by being present but this will cost some of the advantages such as time and total anonymity.

The questionnaire was developed using Google Forms which is an online questionnaire application within Google Drive. Google Forms enabled online editing, collaboration and an easier access to prosthesis users in Sweden by e-mailing out the questionnaire. In addition, the application compiled all the data automatically. The questionnaire was of a qualitative nature with open-ended and fixed response question meaning that the participants could write down their answers to certain questions, mark alternatives and rate how they felt on a scale. This type of questionnaire was used due to the primary need finding in this early stage was the demand.
to get general understanding of the prosthetic use in Sweden and finding hints of unexplored needs. The first part of the questionnaire was constructed to identify the experience and relationship the user had to prostheses. The second part was constructed to identify if the user thought there was any flaws or room for improvements in any areas of prosthetics and if we should have changed anything on the questionnaire (APPENDIX E).

When the questionnaire was finished it was sent to experts in the field of prostheses in Sweden and they gave their feedback on the questions and layout. With some minor changes different amputee, P&O associations were contacted to aid with getting the questionnaire out using their connections to patients and users of prostheses. The three associations that gave the biggest support was Svensk Dysmeli Förening, DHR- Förbundet för ett samhälle utan rörelsehinder and Bräcke Diakoni that also helped us get in contact with users for later interviews. The questionnaire was estimated to take approximately 15 minutes to do but could varied a lot depending on the participant since there was a lot of questions which required the user to answer by writing.

4.3.5 Interviews

According to Jarratt (1996) you develop a deeper understanding of the participant and problems when you get to experience feelings associated with the answers that are given while conducting an interview. Furthermore, the investigator can gather information from experts in the field and gain useful understanding about consumer’s perception, opinions, motivation and behaviour according to van Boeijen, Daalhuizen, Zijlstra, and van der Schoor (2014). When comparing interviews with other methods like questionnaires misinterpretation can be avoided and with a semi-structured interview the ability to add follow-up questions to further the depth of a response given is possible when the investigator wants to raise issues that are of particular importance to them. In the case of an unstructured interview a more open discussion is carried out. Limitations in interviews include being very time consuming, the result varies depending on the investigators ability to carry out an interview and the participants can only respond to what they know consciously. In addition, the data might be distorted with the investigator being present and a strong opinion might not be raised when not given the chance to be anonymous Jordan (2000). Expert interviews (Figure 28) according to IDEO.org (2015) can be helpful to quickly get access to information on a topic and giving insight in relevant history, context and innovation, this can be a valuable method when you want to gain perceptive of the user.

Initial interviews were conducted in Sweden to gain insights from users of upper limb prostheses and P&O experts. Before any users could be reached an interview request had to be forwarded by amputee and P&O associations (APPENDIX F). The questions were of semi-structured nature which concentrated on gaining knowledge in the field, filling up gaps in the literature review and inspiration on what could be improved and added to a design specification. The interviews were recorded so to be able to review the gained data afterwards and giving the interview a more fluent nature since less time was needed taking notes. Being two whom conducted the interview made it possible for one to take notes in the background as a back-up measurement if something would go wrong with the recording. The interviews took around 30 minutes too complete.

Figure 28. Interview with prosthetist F. Mkilla
Landing in Nairobi, Kenya unstructured interviews were carried out with stakeholders regarding the project, the product and the vision of 3DLP’s work in the country. Other experts and users were then contacted and semi-structured interviews were conducted to get a broader perspective and compare the data. Discussion followed after each interview about what could be relevant data.

In conjunction with a field trip to a medical school unstructured interviews with teachers were carried out while the facility and working students were observed. These interviews were conducted to gain knowledge about the traditional manufacturing steps and the education of new prosthetic fitters in Kenya.

4.3.6 Field observation
A filed observation is carried out to experience the people and product in the environment in which it’s intended to be used, this gives the method a more ecological validity then studying the context in a sterile environment (e.g. From Sweden or in a laboratory). Stated by Wikberg-Nilsson et al. (2015) observation is a method used to discover new developing opportunities and identify users’ needs in specific areas. According to Jordan (2000) it’s important that the investigator minimizes the effect of his or her presence during the field observation since if participants know that they are being watch, they might consciously or subconsciously change their reaction regarding a subject or product.

Two types of field observations were conducted in Nairobi, Kenya. The first was visiting and working in Nairobi to gain insight in the contextual environment and meeting the people of a developing country in their natural environment. This was a valuable experience that lasted for 8 weeks. In combination with the contextual observation two field trips to Kenya Medical Training College (KMTC) was carried out (Figure 29). The KMTC offers students training in orthopaedic plaster and technology. The faculty and facility was visited first when no students were present to scope out the premises and to interview the teachers whom at the same time described the process of manufacturing prostheses. On a separate occasion during student’s practical exams observations were carried out to observe different steps in manufacturing and to find developing opportunities when the students were working. During the observations different prostheses were presented by teachers and pros and cons was discussed. Each field trip was conducted over a period of two days, not successively.

4.3.7 A-E-I-O-U
From observations, the experience obtained by 3D Life Prints and prosthetists the team used a framework to categorizes the observations from five different perspectives: activities, environments, interactions, objects and users.

- **Activities** are the paths and actions people chose to reach their goals.
- **Environments** are the settings in which the user perform the tasks.
- **Interactions** are the interactions between people but also between people and objects.
- **Objects** the objects in peoples’ environment and how they are related to their activities.
- **Users** are the peoples that are observed or studied that performs the activities.

The method is known by its initials AEIOU and was developed in 1991 as complimentary tool to conventional
ethnographic methods like photos and interviews (Martin & Hanington, 2012; Wasson, 2000). As many other ethnographic methods it’s carried over and used in the field of design due to the importance of understanding the user. The method was used to organize and cluster the information and in that way be able to grasp the big spectrum of scenarios the prosthetics would be used in. This would help describing the most important aspects of the user-product interactions and in that way ease a comparison between them. The method helped the team circle the most important areas of use especially for Kenyan users but efforts were made to generalize the usage for all developing countries (Figure 30).

By examine the Life Arm 2.0 and the function analysis and comparing it to the areas of use the team could point out the most important areas of development for the current version of the prosthesis. The areas were prioritized and the top four were chosen to start ideating on.

4.3.8 List of Requirements, Needs analysis

A needs analysis is a method used to qualitative information about the user is extracted. According to Wikberg-Nilsson et al. (2015) the best solution can be developed through deeper understanding about people’s needs. By documenting needs new design solutions can be created which can outlive solutions that are developed. Through the literature review, initial interviews, the questionnaire, 3D printing and basic functionality test of a prototype certain needs could be extracted. These needs were mainly developed to be evaluated by 3D Life Prints and with more interviews, observations and context immersion new needs would arise. The needs were then compiled in a List of Requirements that could be used throughout the next phases.

A List of Requirements according to van Boeijen et al. (2014) can be used to gather all the information on a product, compile it in a structured list and used during the whole design process to ensure that the team is moving in the right direction. The list can be useful to ensure that designers and client is on the same page. Spending too much time on the list of requirements can lead to hinder the creative process and too many requirements can limit the possibilities of your design.

The List of Requirements was a result of all information gathered in the Context immersion stage before leaving for Kenya. This list was mainly developed as a tool that later would be revised by users, experts, and the client 3D Life Print in Africa. The first List of Requirement was divided into users and manufacturers and categorized into different needs which could be either a Demand or a Wish. The Demands was needs that would have to be met by the user and manufacturer to have a plausible product and the wishes were sub-needs that would lead to a more appealing product. When arriving in Nairobi a List of Requirements had been developed simultaneously.
4.4 IDEATION

In this stage the findings from immersion stage was processed and transformed into concepts. The initiating face focused on lateral thinking to get a big quantity of ideas to explore and ended with a more convergent face. 3D printing and testing the existing product was done in Sweden before leaving for Kenya where the initial Brainstorming and Braindrawing were used to generate ideas, this led to two areas being chosen to develop into the new product “The Life Arm 3.0”.

4.4.1 AM the existing product

With access to the stitched CAD model and a Ultimaker 2+ at Luleå University of Technology a 3D printed prototype of the product could be created. Using Meshmixer a test pieces was created which consisted of the middle and distal phalange for the index finger, a smaller sphere with different form elements and the thumb (Figure 31).

When all the settings were adjusted on the Ultimaker a hand (Figure 32) could be printed and then used for some basic gripping tests to get a better understanding of some of the flaws in the design. A part of the socket was also printed to test the screw used to attach the terminal device to socket.

4.4.2 Function analysis

Suited for the beginning of idea generation according to van Boeijen et al. (2014) a function analysis is carried out help find and explore new possibilities to embody certain functions in a product. The method analyses what the product should do (functions) and what yet to be developed should do (sub-functions) which can lead to unconventional solutions. Essentially it forces the team to ask the questions what is the new product intended to do and how could it do that?

To figure out what functions and sub-functions the prosthesis has the existing product was reverse engineered and tested. According to Wikberg-Nilsson et al. (2015) a physical model of full scale can be utilized to test function, ergonomics and operating space and can be used early in the process. Furthermore, it can explain the interaction between the user and the product.

To test the functionality and limits of the Mock-up a testing contraption with a handle was built for a person with a functional hand to enable testing of the prosthesis (Figure 33). The contraption was design after a demonstration prosthesis presented by (Doshi, Yeh, & LeBlanc, 1998), but simplified. In addition, a harness was built and was connected to the actuation cables of the terminal device for creating movement of the prototype. Different items were scavenged for testing the gripping functionality.
Figure 33. Trying out the prototype of the 3D Life Arm on items with different shapes, sizes and weights.

The test used 5 different objects in various size and shapes. If the test subject was able to grip an object he proceeded to move it around freely. This method was relevant since it gives a basic understanding of the initial products functions, a deeper understanding of how it feels for the user to use the prosthesis and areas of development.

4.4.3 Brain drawing

When arriving in Kenya, it was important to get started quickly with generating ideas as the time there was restricted. The team chose to start with brain drawing as the group had good experiences of the method (Figure 34). Since the group of three had studied product sketching they were all comfortable with drawing and the method gave all an opportunity to express their early individual ideas without getting disturbed or affected by the others. The method was thereby considered as a good way to quickly produce quantities of ideas (van Boeijen, Daalhuizen, Zijlstra, & van der Schoor, 2014b). The method was started by choosing one development area to ideate around then the rules were decided. Each participant was given one paper where the goal was to sketch three ideas each in a time period limited to 5 minutes. The ideas were then presented and explained to the others to spur new ideas. It was repeated until all four development areas were covered.
4.4.4 Brainstorming

To further build on the initial ideas from the Brain drawing a brainstorming session was held. The session was opened with a brief presentation of all the sketches to include and engage our supervisor, A. Arabian, and the founder of 3DLP, P. Fotheringham (Figure 35). During the presentation the management were allowed to ask questions and add ideas that arise from the presentation. Following the presentation the session was started with the intention to avoid criticism to create a creative atmosphere that would give a good spread and quantity of ideas (Jones, 1992; Tovey, 1984; van Boeijen et al., 2014b). The group had different experiences and backgrounds which both created divergences, which complicated the process but on the other hand the diverseness added more depth to the ideas and evolved them quicker.

This method can come in hand during any of the different stages of the design process, but especially when starting up the idea generation phase according to van Boeijen et al. (2014) The method power lies in participants being stimulated creatively from hearing and seeing each other’s ideas according to Wikberg-Nilsson et al. (2015). Limits to the methods include being more suited for simple problems instead of complex problems which in turn can lead to the group losing sight of the problem as a whole. For problems which require a highly specialized knowledge the method isn’t recommended.

4.4.5 Product Concept Evaluation

Typically, some sort of evaluation process should be used throughout the design process according to van Boeijen et al. (2014). The Product Concept Evaluation method is used when a number of concepts or ideas needs to be judged and often, through a screening where experts, such as managers, engineers and marketers are used instead of representatives from the user group.

The evaluation was constructed so each of the members presented their ideas from the previously mentioned idea generation methods by presenting pictographic ideas and a quick elevator pitch. First the concepts were presented to A. Arabian, whom gave feedback on each idea and then with that feedback the ideas were again pitched to P. Fotheringham whom then made a go/no-go decision on every idea, reducing the spans of ideas to the point where the team had one area to work on for the next step.
4.5 DEVELOPMENT & IMPLEMENTATION

This chapter consists of the originally planned two phases Development and Implementation and is presented as one because the Development phase didn’t result in the one concept that it was supposed to. This concept was in turn going to be refined into one final prototype. The new phase consists of two areas of improvements being developed and refined over and over again with new solutions being tested over the remaining time of the project. This change was done with the client wanting to have a launch ready product at the end of the field study. Presented in the chapter is the Computer modelling steps, the Prototyping step with 3D printing and the analysis of the final prototype.

4.5.1 Computer modelling

With ideas ready to be tested computer aided modelling using different software was the next step since this enabled us to then take the 3D models, slice them up and 3D print them to test the design, manufacturing and assembly of each parts. Adding specific parameters made it easy to change the size, width length and different features without having to start all over with the modelling. Previously taught solid modelling software’s were not used during this project because of licensing issues, instead Autodesk Fusion 360 was used for all solid modelling and for some basic shape changes and sculpting Autodesk Meshmixer were used. Fusion 360 enabled all saved files to be stored in a web based cloud making it possible for everyone in the team to access the files. When a model was ready to be tested the file was exported as a STL-file.

4.5.2 Prototyping

With the access to 3D printers and filament, prototypes were build every time a new shape, size or function needed to be tested, this was possible since everything was solid modelled and easy to export to a 3D printer who printed the part relatively quick. Usually the printer was printing over night or for smaller parts it was running during the day while the modeller was working on something new to test, basically when a printer was working it was running 24 hours a day.

*Figure 36. Sewing a shoulder pad for a harness prototype

Some parts of the product weren’t printed and needed to be obtained from different parts of Nairobi. This gave the team a new challenge, to take in to consideration local availability to make a plausible product in the end. By asking around from people who had a better knowledge of the city and asking around in different shops parts were found in different locations. This was truly a unique experience which wouldn’t have been possible to execute without being located in Nairobi. Most these components were needed for the harness system that team sew and fabricated with the simplest tools that was available (Figure 36).

During the prototype building problems with printing flexible material was a factor which meant that everything that was going to be printed in flexible material had to be modelled and sent to Liverpool where the parts could be test printed and tested and with feedback improved and tested again. This was a problem since the designer had to rely on the feedback, but at the same time it was a chance to experience how it was to develop a product with someone who was roughly 7100 km away, testing a “distant prototyping” procedure.

4.5.3 Evaluation and feedback of concepts

With prints being carried out at least ones a week in Liverpool a feedback and evaluation meeting was carried out where our technical advisor was included to give feedback on the concepts that were being developed. The feedback and evaluation was used as an insurance that we were on the right track and issues could be disused and solved in a bigger group, along the lines of a focus group.

4.5.4 Final cost & time analysis

With the whole system being developed to the point where it could be implemented different materials were tested and analysed with the help of data from the slicing software and the excel spreadsheet. The data was then compared with the original 3D Life Arm 2.0 to get some sort of estimation if any positive changes were made. This was done by adding up all the printed parts for each of the segments (terminal device, harness and socket) with options to add parts that weren’t printed (mostly harness parts). In addition, a new material was introduced at this point called PCTPE which was a semi-flexible nylon. This material had to be added into the spreadsheet since the socket were printed in nylon because of it being approved to be used on medical devices that required skin contact.
4.5.5 Process and method discussion

Initially in the design process it seemed like a good idea to develop the functionality of the fingers, adding more features and focusing on Radical design for a more complete user experience. It would both test our creative side and be a good connection to user centered design. It was later decided to shift the focus towards developing a product that was more launch-able from a business point of view since it was deemed that the product needed to be producible before radical improvements could be made on functionality, this led the team to focus more on Incremental design, making small changes and analysing the system so the end result would be a prosthesis that could be additive manufactured and fitted for people in the developing countries. In addition, with the opportunity to experience the environment it was deemed important to focus on determine if the technology is suited for the context since no reliable studies were found where people had actually implemented the technology successfully in developing countries.

The field of P&O was an unknown field that had to be studied extensively and on top of that AM on FDM printers was relatively new. These fields were then going to be applied in a completely new environment for the team members. The field of P&O could be studied using previously conducted research in the field, e.g. Cummings (1996) covered over 130 publications between 1961 and 1994 which gave a good indication on key factors to consider even if a lot may have changed since 1996. These factors could be compared with interviews and responses from the questionnaire conducted in Sweden giving a general picture of the situation that was later on going to be experienced in Nairobi. Though, more contact with the actual users in an early stage would have been preferred if it was possible. With AM the availability of a Ultimaker 2+ could be used to gain practical knowledge in AM which could be complimented with theory. AM a prototype proved to be harder than planned which costed a lot of time just to get comfortable with the machines and different materials. While printing got progressively easier during the design process it was also becoming gradually a bigger part of the project with prototypes having to be printed more and more with different concept having to be tried. The time spent how to operate printers should have been taken into consideration in a larger scale in the initial part of the project.

When functionality was researched in the initial phase the idea was to try and mimic the functionality of the human hand as much as possible by adding functions which was studied by taking a biomimetic design approach as described by Kakoty & Hazarika (2011). The approach was concluded not to being suited for a body powered prosthesis in developing countries, the need for a such high level of complexity would come at a price which didn’t correspond with the needs of the user since the prosthesis needed to be low cost, which wasn’t only concluded by Cummings (1996), but also from user and expert interviews. The functionality of being able to grasp seemed to be achieved already by the existing product but it was still analysed to see how well. The focus of increasing functionality was instead shifted to working on the harness system to see if tensioning could be improved and to see if the insert would decrease the force needed to actuate the device. The study into the anthropometry of the hand was still deemed necessary since this was necessary to understand the user and what the prosthes was replacing for amputees.

Discussing what should have been done different a lot came down to the initial planning. It’s very hard to predict exactly what’s going to happen in a project of this magnitude but most importantly a more detailed plan should have been done which should have been revised often. Since revision wasn’t done it was hard to follow the plan and keep track of where we should have been and what the set-backs meant to the results of the different stages. The way of having a detailed presentation prepared each week with company stakeholders should have been implemented from the start since weekly goals could have been better formulated and concrete results could have been presented and summarized. The belief is that this is of utmost important since it forces you converge, summarize, conclude and document each phase, this in turn makes it easier to iterate since you will have a quick reminder of what you have done and what direction you are heading so you don’t lose track of your goal(s).

Since the many changes during the project, as discussed earlier, the finale shape of it progressed into something that can be illustrated with an oscillating motion (Figure 37). The magnitude of the oscillations symbolizes the volume of material accumulate in each stage and the length the time that was used over the 20 weeks’ period. Where ideation face was shortened to get a quicker start on the detailed development. The implementation was merged into the development face due the complications in getting a working prototype and that the current product wasn’t at the level we first predicted.
05 RESULTS
outcome of the project
5 RESULTS

The results from the different stages Context immersion, Ideation, Immersion & Development are presented in this chapter leading up to the Final design. For each of the chapters, different conclusions are drawn as well from the findings.

5.1 CONTEXT IMMERSION

With the help of the methods used from the context immersion phase findings on the usage of prostheses are presented leading up to one List of Requirements made by the team and one made by the client. The chapter includes the findings done in Sweden as well as Kenya.

5.1.1 Product analysis

With the product being analysed in three stages: the CAD analysis, AM and function analysis some issues with the design was brought up and discussed (Figure 38).

The following 5 issues where discovered and were as followed:

1. **Printability**: there was some issues with printing the terminal device mostly due to the usage of flexible filament.

2. **Retaining the prosthesis**: the retention system of the socket didn’t feel trustworthy in holding the prosthesis in place.

3. **Wrist connection**: the connection between the socket and terminal device felt unstable and made it hard to wire the prosthesis since you had to connect the terminal device before wiring.

4. **Unnecessary bending**: using the flexible filament meant that the fingers would bend in a desired way but that the palm would also bend as well when carrying heavy loads.

5. **Force needed**: to make the fingers bend a lot of force was needed to create and sustain the wanted grasp.

*Figure 38. The main issues the team discovered with the initial product.*
5.1.2 Market analysis
The market analysis resulted in better comprehension of the current possibilities of AM. What was available and the qualities of both conventional and AM-prostheses up to date. It also contributed with inspiration of what was possible and what should be avoided. A conclusion of the analysis was that most of the designs for additive manufactured prosthetics had a poor cosmetic appearance, looked plastic and robotic. Vice versa the other alternatives on the market which offered a better cosmetic appearance however did so by giving up the functionality of the device. This resulted in the team visualizing this on a position chart (Figure 39) which graded devices on function versus cosmetic appeal.

From the position chart we could conclude that there was an area of improvement that devices in developing countries should strive for, offering the user a prosthesis that was both adequately functional as well as cosmetic. This was then studied during interviews and questioners.

5.1.3 User interviews (Sweden)
The feedback from users in Sweden was compared and statements that the team concluded to be valuable was written down (APPENDIX G). The most powerful statements according to the team was presented in this chapter. Reoccurring answers are also presented and analysed.

When it came to how users perceive themselves and the prosthesis a central conclusion that was drawn by the team was that its highly individual but a trend was that people whom had a congenital difference tended not care that much about blending in for example

“I don’t view myself as missing on hand, rather that I have one normal looking hand and one that’s a bit different, this since I was born this way”

When discussing blending in even if someone expressed that it wasn’t that important further discussion revealed that everyone had at least at one point in their life been concerned with blending in. This could regard having something that looked natural or just being able to carry out everyday tasks like functioning in a queue as expressed by a participant who only used activity based prosthesis

“I tried a cosmetic prosthesis when I was younger but I just found them warm, clumsy and ugly so I thought I would be better off without one”
From the literature review this attitude seemed to match the attitude from developing countries where blending in seemed to be more important than in the western countries. The way users perceived their prosthesis was also interesting. For some of the participants their prosthesis wasn’t just a tool, it was like part of them making it possible to do more and even blending in more since they could do tasks while still looking natural as expressed by one participant

“If there was a balance between functionality and appearance that would be amazing, I think that if you only have a purely cosmetic prosthesis you will still draw more attention to yourself when you do different tasks because your body movements will be unnatural”.

One of the most noticeable results from the interviews was the usage of myoelectric prostheses was more represented then the others. This could be a result of the Swedish healthcare system which makes it possible for people in need of prostheses to get a consultation and acquire the suited prosthesis that’s needed and get it funded. According to a participant you get your voice heard during consultations and by being persistent you can get more advanced prosthetics. Even if price isn’t a big issue in Sweden some participants voiced their concern and showed a great compassion for people in developing countries as expressed by one participant

“It’s an expensive aid, so if you can cut down on the price that would be great so people in developing countries can fit in and join society again”.

The issue of price was something that recurred in literature done in the initial literature review. The team concluded that making a cheap product was defiantly something that need to be a focus point. The prosthesis didn’t only have to be cheap to manufacture and easy to distribute, as a contradiction it has to be durable which was also an issue raised by all the interviewed users

“A lot of my parts take a beating, I have had my mechanical parts repaired and the sensors on my myoelectric prosthesis needs to be changed soon”.

As a result, the team thought about how complex the system really had to be, is there a point in adding complexity when this might just be ending up breaking and render the whole prosthesis useless? Voiced by another participant having a durable prosthesis could be the difference between being a part of society and shying away, according to him

“The most important part for me is the relationship with my technician, to know that if something breaks I can get it fixed. Now that I have gotten used to have my prosthesis if it was to break and I was without it for a longer period I would shy away from different social interactions”.

This statement is important on many levels; it raises the issue on not only making it easy to have a durable product with easy replicable parts but that an established operation might be a vital part of implementing a successful product. Another occurring comment as a result of the interview was also the weight of the prosthesis, for those using a myoelectric prosthesis it was expressed that these were too heavy.

5.1.4 Questionnaires (Sweden)

The biggest part of the group heard in the questionnaires was using a prosthesis daily (14) or occasionally (6) out of the 32 answering. The result corresponds to 5 out of 8 that was in the habit of using a prosthesis. The high rate of usage was shown in the satisfaction grading of their current prosthesis where the biggest the amount answered that they were satisfied as seen in following (Figure 40).

The type of prosthesis used in the group was divided relatively even between cosmetic, body powered and electric prostheses. If the users had experienced malfunctions it was mostly related to electric prostheses where the engine or the battery had problems. Most of the respondents that didn’t use a prosthesis didn’t think a prosthesis contributed with any assistance for them. Other reasons to not use one was that they were usually heavy, clumsy which adds up to that the prosthesis is being the opposite of its purpose, obstructive. The flaws and improvements the users would want to see coincide much with the none users reason to not use it. The most common wishes among users were that the socket would handle heat transport better, that it was more comfortable, lower weight and more agile. The reasons why they used their prosthesis in contrast to the non-users was that they thought it helped them, it was the only option they had and that it made them blend in easier. Respondents requirements on prostheses were first and foremost that it has a function but it must also be comfortable, low weight and have a good cosmetic appearance. The users that use a prosthesis occasionally mostly use it specific

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5 Participant D., personal communication, 10 June 2016
6 Participant B., personal communication, 27 May 2016
activities like training, sports or driving but also when they feel the need to avoid attention. If the respondents would avoid to use a prosthesis it was usually at home. Lastly the respondents weighed aesthetics against function where a slight traction towards having a functional prosthesis was observed and for the aesthetics a majority want it to look life like compared to an extravagant attention drawing design (Figure 41).

5.1.5 Expert interviews (Kenya)
The interviews that was conducted in Kenya with experts (Figure 42) in the field resulted in the following perceptive on different areas concerning the situation in Kenya.

5.1.5.1 Education
The education for orthopaedic technology 2 years to get certificate and plaster technology takes 5 years to complete and to afford the education students and their family will have to pay for the education in a so called cost-of-sharing (sharing the cost with sponsors). The sponsorships are for example funds and grants from the governments or different organizations and trusts. Even if the education is expensive there are over 1800 applicants/year with each class taking in around 25-30 students/year. The students are trained in all types of technologies including locally available material, PP, wood, metal and methods used by ICRC and Ottobock for example. Ottobock is one of the world leading producers of prosthetics and components to them, which is widely used in Kenya. When the students finish school the majority of the students work in the government and the armed forces but a large portion leaves Kenya to work in America, Australia and Saudi Arabia to name a few which is a big concern since there is a shortage of trained prosthetist in Kenya.

Figure 41: Comparison of life-like design contra attention drawing artistic design. Where 1 is attention drawing and 4 is life-like.

During the practical exams each student is assigned a patient and get a first-hand experience of fitting a patient with a prosthesis. The type of prosthesis that’s fitted is up to the student but mostly it’s lower limb prostheses since the school doesn’t have the recourses to fit upper limb prostheses anymore. The patients are applicants from all over Kenya and the departments get a lot more patients then there are students since the prosthesis is given for free and the cost for transportation and accommodation is paid for as well. The practical exam takes approximately on to one and a half weeks to complete but depending on the prosthesis or technology used some students are done faster.
5.1.5.2 Working as a prosthetist in Kenya

Emerging into the field of P&O around one patient is fitted per week, to manufacture doesn’t take that long but there is a lot of other factors to consider. The beginning of the process as described by a working prosthetist in Nairobi begins with a house visit to access the environment, this means a lot of traveling. The patient is also assessed and some measurements are taken, the casting isn’t done right away since some of the parts needs to be ordered from other countries like Germany (Ottobock components) and during the waiting time the cast might not fit as well anymore. One’s part are at place the process of manufacturing the prosthesis doesn’t take that long, actually just a few days but with the demand being so high a prosthetist usually works with several at one time. The whole process was summarized in a visualization (Figure 43) which describes the time it takes from the first meeting with the patient to when the prosthesis is finished.

In addition to getting the prosthesis there’s an extended period of rehabilitation and training with the prosthesis, if a person is hard to fit and the training takes a long time the prosthesis will eventually be more expensive.

in Kenya there’s a problem with the level of amputation not being favourable to prosthetist, a lot of times it’s hard to fit just because the doctor and prosthetist hasn’t had a discussion of how the patient might be fitted with a prosthesis afterwards. When asked about this an American prosthetics engineer revealed that this was something that was still pretty new in the states to, the discussion is something that has occurred for the last 20 years or so which, according to him, was still a pretty recently and a global problem.

The functional trans-radial prosthesis from the ICRC is usually manufactured and fitted for 250 000 KES, for the above-elbow its upwards to 300 000 KES or more. Depending on complexity more have to be charged, training time has to be considered when charging a patient. For a fitter if something is wrong with the prosthesis we will have to fix it free of charge, usually we give a period of 6 months for a person if they have any complaints. But for example a child who outgrows the socket we will charge the family for a new prosthesis.

In the middle of one the interviews the prosthetist F. Mkilla (2016) got a call, when he had hung up he explained what the call was about:

“You see all the patients that are calling me asking for sponsorship, once they call they ask me if they can get any sponsor for a prosthesis. I have a friend of mine who is usually sponsored by a company but they have a fixed number of patients/year. This year they were sponsoring 90 patients and that number is filled up already. So next year I will have to convince him to sponsor someone who is calling me, if I don’t I have nothing”

He then continuous to explain his passion for helping people in his community and his ingenuity for using locally available resources

“Sometime out of my own will I have to improvise, I use water pipes, plastic water pipes (PVC) to make a prosthesis. It’s very low cost so for around 5000 KES (approximately 420 SEK) I can fit a patient with a leg. I am very passionate about children so I try to improvise a prosthesis here and there, when I go to the village there are so many people asking me for help”

F. Mkilla, personal communication, 17 June 2016
5.1.5.3 The typical user

Concluded from the interviews the typical patient is a male age 18-40 who suffered an acute amputee with farming, traffic and industry being one of the more usual environments but many patients come from domestic violence, assaults and war as well. When farming was brought up, a chaff cutter (Figure 44) was mentioned on numerous occasions as one of the biggest causes. The chaff cutting machine is used to shred or chop up sugarcane when producing sugar. Since this accident is very common a big share of the arm amputee are men in working age and has a below elbow amputation (around the wrist) This pointed us towards a user-group.

The number one reason, when asked why a patient wanted a prosthesis, it was purely cosmetic, they want to blend in. When asked what type of activities people wanted to do the response was typically to help them to carry a handbag or work in the garden or farming. The most important activities however were concluded to be related to independence such as being able to put on cloth, feeding and writing. Writing however was something that was becoming less and less important with computers becoming more and more usual.

Usually people get a cosmetic prosthesis but this was largely because of the price, patients “settle” for a cosmetic prosthesis. The typical user was unsatisfied with the ICRC hook. Even if the process of manufacturing and fitting the prosthesis was easy and patients being able to control the device fast they were still perceived as unhappy. The conclusion from cost contra functionality, functionality was considered a bonus since not that many people could even afford a cosmetic prosthesis. Estimated by F. Mkilla if the cost could be reduced by half, 90% of the people needing a prosthesis could afford it in Kenya.

![Figure 44. Hand powered Chaff cutter by Panhard, 2009, https://upload.wikimedia.org/wikipedia/commons/d/da/Hand_powered_Chaff_cutter_R_Hunt_and_Co_3.jpg. Used under CC BY-SA 3.0, https://creativecommons.org/licenses/by-sa/3.0/deed.en](image-url)
The typical user will compare their prosthesis to their lost hand, this creates a problem since that level of functionality is impossible achieve. Similarities was drawn between America and Kenya where both prosthetists described how the level of expectations need to be lowered from the start. For example, the Kenyan prosthetist could tell a patient that a prosthetic leg that would be fitted was so bad that the patient wouldn’t be able to climb a stair, then after training when the patient could climb a stair their expectations was exceed what leaving them more satisfied.

During the first consultation with patients the different alternatives of prostheses are shown and explained, everyone wants the functional but when price is presented they want the cosmetic and when that price is revealed a majority of the patient leave since they can’t afford it.

A trend in Kenya is that people perceive themselves like they are less regarded than other people, they will feel like a person is more superior to them because they have two hands so a lot of people suffer low self-esteem, the general opinion is starting to change, for example you would never see an amputee on Kenyan national television but now it’s getting more common like the Para-Olympic teams and people who display they artificial limbs on television. They are no longer hiding.

A lot of people go back to work after they are fitted, sometimes the same job or they have to adjust. Kenyan people are very sympathetic so sometimes the employer are reluctant to give them the same responsibility so they shift their responsibilities even if they can manage their old duties.

5.1.5.4 Components of the upper limb prosthesis

With a lot of components having to be shipped the quality of some parts are reduced significantly. The staff at the KMTC had noticed that some parts that were shipped by shipping containers would tend to disintegrate faster leaving the patient with a prosthesis that would break very fast, there was some cases where the prosthesis would break after a week after fitting and in some extreme cases the patient didn’t even leave the building before the prosthesis was broken.

Cosmetic components like covers for terminal devices usually come in the wrong colour which draws a lot of attention to the prosthesis (Figure 45).

The usual harness for trans-radial prosthesis is that of the ICRC but for trans-humeral the figure-eight is used since it retains the socket. Creating retention by the sockets the length of the socket goes above the elbow hanging of “the bony parts” around the elbow, this is usually a good socket to fit but for shorter stumps a harness retention system is preferred. The harness system needs to be adjustable and usually the adjustment point is located on the back of the figure-eight configuration. If the harness needs to be loosen or tighten some kind of marking can be used so the patient knows where it was originally fitted and can adjust it without the need of the prosthetist. The patient need to be taught how to adjust the harness, usually a three-day testing period is done when fitting the harness. Parts for the harness are being purchased from Ottobock including the adjustable figure-eight straps (webbing size 25mm), pads for comfort (2-3 pads/patient, washable) and wires with a crimping systems.

The size of fishing wire (or Palon with is the equivalent used by Ottobock) is around 2mm and is very strong. A metal crimp is used to tighten the Palon between the Harness and Terminal device and without Lock-tight it will slide out when patient applies a strong pull. A cuff is something that has been fitted with success to retain a prosthesis in Kenya. For patients with short stumps an anchor on the cuff can guides the wire so it doesn’t cut in to the arm.

An adjustable wrist would be desirable to help with matching posture of different people when fitting. Something like an adapter that would allow rotation of the terminal device could be a solution.

When discussing durability, it takes around three months for a harness to break, usually because the patient isn’t properly trained. Covers for the hand last for a long time, proper care and not putting it in hot water it will last for 10 years, but a lot of people doesn’t clean it since they only see it as an artificial thing.
5.1.5.5 How 3D printing is perceived

When discussing 3D printing and the opportunity of having parts locally made the response was very positive. To locally produce components was the direction that the department at the KMTC wanted to head but the expertise was lacking. From an interview a case where a boy who was attending university had lost two fingers was brought up, in this case the prosthetist thought that 3D printing would be well suited since he used PP and making bendable finger with that was very difficult, he believed that if something functional and cosmetic could be created using 3D printing that would solve a lot of problems but he didn’t know if that was even possible.

5.1.6 User interview (Kenya)

With the help of the staff at the KMTC a patient was located and interviewed. The patient was a boy at the age of 7 who had lost his arm after getting it cut off by a Chaff cutter at the age of 5. This left him with a small stump right below his elbow on his right hand. The boy was very shy and most of the responses from him was usually a quiet yes or no. most of the in-depth responses was expressed by his mother who participated in the interview.

The result of the interview was mainly portraying the life of the boy as told by his mother including the process she had to go through.

Today he has a non-functional cosmetic prosthesis which was fitted at the KMTC, this because it was a lot cheaper then acquiring on from e.g. the hospital. For an expressed long period of time the mother had looked for a sponsor, calling and talking to people who she thought could help but was repeatedly told to wait and not now, not now. She then got in contact with the KMTC and after paying around 5000 KES (420 SEK) the boy was fitted with the prosthesis.

There was no problem with the fitting of the prosthesis and it was perceived as a good fit and comfortable, but with the boy being of such young age and not used to carrying the prosthesis it was very heavy to start with. The mother described how the boy use to be unbalanced in the beginning with one shoulder below the other, but with time he got used to it and the shoulders started to balance out. In addition, during this period the boy had to relearn to do different tasks with his left hand that he used to do with his right, this according to his mother was very difficult.

With the prosthesis being used every day when the boy went to school or left the house after 4 months of usage it had broken and the process of trying to find a sponsor had to start all over again. The mother felt that with the cosmetic prosthesis limited function a functional prosthesis would be a great upgrade since it enabled her son to help out with chores around the house. With the stump being so small she felt that he was very limited with what he could do, with some function at least he could help out some. Drawing to the end of the interview the mother also expressed her concern regarding the future,

“He is growing very fast. Soon this will be too small and he will need a new”.

5.1.7 A-E-I-O-U

The result of this method was gathered in a table (Table 4) due to it being done early a lot of the activities were based on experiences that the team had and likely to be found globally like Clothing, Writing and Bathing to name a few. From interviews some new activities were added like the vast sugar production and objects like the Chaff cutting machine that was discussed with the P&O manufacturer Francis in chapter 5.1.5 Activities like Driving and Farming were based on observations and facts gathered on Kenya during the literature review.

The A-E-I-O-U resulted in an open discussion as well where the team talked about the situation of the people in Kenya and developing countries. Questions like the need for more versatile grips and dexterous prostheses were discussed as well as what types of activities were the most important. The activities most important was agreed to be the activates that gave the user the most independence and usually meant being able to tackle everyday tasked for a general population. These types of users were named the Daily users. With farming being such a large occupation for the local population these activity was deemed important to consider as well.

The method was done fast and was only used to inspire the team for the next ideation step, so not to limit the creativity.

---

8 Participant E., personal communication, 8 July 2016
<table>
<thead>
<tr>
<th>Activities</th>
<th>Environment</th>
<th>Interaction</th>
<th>Objects</th>
<th>Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gardening</td>
<td>Dusty, dirty, wet</td>
<td>Plucking, watering, trimming hedges, digging, rake leaves</td>
<td>Hedge trimmer, flowers, shovels, rake</td>
<td>Gardeners</td>
</tr>
<tr>
<td>Household</td>
<td>At home</td>
<td>Vacuuming, washing, sweeping</td>
<td>Vacuum, utensils, washing machine, broom</td>
<td>Women, maids</td>
</tr>
<tr>
<td>Driving</td>
<td>In car, traffic, stressful, A/C</td>
<td>Opening the hood and doors of cars, steering, shifting</td>
<td>Wheel, switches, hood, knob</td>
<td>Drivers</td>
</tr>
<tr>
<td>Sugar mill</td>
<td>Factory, busy, stressful</td>
<td>Heavy duty machines, bag packing machines, picking up sugar canes, carrying sugar cane</td>
<td>Tractors, sugar canes, bags of sugar.</td>
<td>Factory workers</td>
</tr>
<tr>
<td>Eating*</td>
<td>At home, restaurants, streets (getting food from street vendors)</td>
<td>Cutting, picking up, holding knife, holding fork, picking up plates</td>
<td>Fork, knife, plates</td>
<td>Daily users</td>
</tr>
<tr>
<td>Shopping</td>
<td>Supermarket, marketplace</td>
<td>Lifting bags, push shopping cart</td>
<td>Bags, basket, shopping carts</td>
<td>Daily users</td>
</tr>
<tr>
<td>Construction</td>
<td>Dusty, dirty, heavy, repetitive</td>
<td>Hammering, carrying crates and toolbox, screwing, digging</td>
<td>Hammer, crates, toolbox, screwdriver, shovels</td>
<td>Construction workers</td>
</tr>
<tr>
<td>Family</td>
<td>At home</td>
<td>Clothing, feeding and playing with children, driving children, sewing</td>
<td>Children, sewing machine, needle and thread</td>
<td>Daily users</td>
</tr>
<tr>
<td>Cooking*</td>
<td>Kitchen, moisture</td>
<td>Opening fridge, cutting vegetables, Filling/emptying saucepan with water</td>
<td>Vegetables, knives, ladle, frying pans, saucepan</td>
<td>Daily users</td>
</tr>
<tr>
<td>Mining</td>
<td>Heat, Sweating, Repetitive</td>
<td>Pushing carts, carrying bags and crates, shovelling, cut stone, swinging mining pick, operating heavy machinery</td>
<td>Carts, shovels, mining pick, bags, mining machines</td>
<td>Miners</td>
</tr>
<tr>
<td>Bathing*</td>
<td>Wet</td>
<td>Removing cloth, removing prosthesis, putting on a towel, pouring water</td>
<td>Cloth, towels, water bowl, showers</td>
<td>Daily users</td>
</tr>
<tr>
<td>Clothing*</td>
<td>At Home</td>
<td>Putting on Prosthesis, pulling on socks, underpants, pants and shirts, butting shirt, buckling belt, tying shoes</td>
<td>Socks, underpants, pants, shorts, skirt, shirt, buttons, T-shirt, Belt, Shoes, Shoelaces.</td>
<td>Daily users</td>
</tr>
<tr>
<td>Farming*</td>
<td>Dusty, dirty, wet, repetitive</td>
<td>Repetitive, driving tractors, handling and feeding animals, shovelling/digging</td>
<td>Tractors, bags with animal feed, animals, shovel, sticks, chaff cutter machine</td>
<td>Farmers (80% of the population of Kenya)</td>
</tr>
<tr>
<td>Writing</td>
<td>School, at home</td>
<td>Picking up pen, writing with pen, holding paper in place, Writing on computer</td>
<td>Pen, paper, computer, keyboard, mouse</td>
<td>Students, daily users</td>
</tr>
</tbody>
</table>

Table 4. The result of the A-E-I-O-U comprised in a table

5.1.8 List of Requirements

Given the List of Requirements from 3DLP we could at least compare it to the one developed in Sweden (APPENDIX I, APPENDIX J) before coming to Kenya. The one given by 3DLP was a lot more comprehensive and covered subject like 3D printers and distribution which was outside the scope of the project. The biggest difference was that the requirements developed left more room for ideating new possibilities and ideas that could eventually lead to improvements in the product which were classed as wishes. Similarities included the demands that were developed in Sweden which gave a feeling that the literature review, questionnaire and the initial interviews had resulted in valid data that could be used.

Given the strict nature of the already developed list of requirements by 3DLP the list wasn’t regarded during the idea generation phase. Since the requirements were handed to the team the validity wasn’t further developed and backed by scientific evidence to make sure the needs of the user are truly met by the team.
5.2 IDEATION

This chapter includes the results from the idea generative stage. Preliminary the stage was supposed to result in a large amount of ideas that would then be scaled down in to three concepts, with the wishes from the company and a new team member working on an own part of the design the ideation phase was divided into, four then later, three main areas of development where the thesis membered kept working on two of the three areas.

5.2.1 Brainstorming

The brainstorming resulted in two sessions where different developing areas was created and what would be desired for each of the categorize. The brainstorming was carried out by the team consisting of the authors and the intern, N. Rao. To get inspiration the A-E-I-O-U was used and a whiteboard to write down the keywords which was then summarized in Table 5.

<table>
<thead>
<tr>
<th>Retention (Socket)</th>
<th>Relieving force (Locking mechanism)</th>
<th>Usability (Dynamic Grip)</th>
<th>Actuation (Harness)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Socket creates retention</td>
<td>- Less friction</td>
<td>- Variations of objects</td>
<td>- Harness creates retention</td>
</tr>
<tr>
<td>Perfect fit/Snug</td>
<td>- Less noise</td>
<td>- Better mechanism</td>
<td>- Comfortable straps</td>
</tr>
<tr>
<td>Ventilation</td>
<td>- Less muscle tension</td>
<td>- Fit into hand</td>
<td>- Strap mounting points</td>
</tr>
<tr>
<td>Light</td>
<td>- Longer holding time</td>
<td>- Less force gives more actuation</td>
<td>- Easy to put/take off (95% has a functional hand)</td>
</tr>
<tr>
<td>Soft &amp; comfortable</td>
<td>- Relaxing</td>
<td>- Friction reducing</td>
<td>- Different/easier activation mechanism (using body)</td>
</tr>
<tr>
<td>Suited for different climates</td>
<td>- Less moving parts</td>
<td>- Better grip at fingertips</td>
<td>- Doesn’t restrict other motions</td>
</tr>
<tr>
<td>Easily replicable</td>
<td>- Replicable by person/relative</td>
<td>- Hold heavy &amp; Light stuff</td>
<td>- Gripping only activated</td>
</tr>
<tr>
<td>Easy to clean</td>
<td>- Not too complex</td>
<td>- Life of mechanism &amp; cables</td>
<td>- Adjustable for body types</td>
</tr>
<tr>
<td>Reparable</td>
<td>- Variable force &amp; position</td>
<td>- Replaceable cables</td>
<td>- Adjust grip types (strong-medium-light)</td>
</tr>
<tr>
<td>Formable to relieve pressure points</td>
<td>- Local parts</td>
<td>- Cable end ties design</td>
<td></td>
</tr>
</tbody>
</table>

Some keywords that the team agreed was necessary to keep in mind for all the developing areas was summarized in the following 5 bullets:

- **Use less material** to avoid excessive material cost, keep the production time down Use locally available parts
- **Less complexity** to focus on making a durable product, not complicate functionality and more natural looking
- **Less operation during manufacturing** to avoid failed prints
- **Easy Assembly** so too much time isn’t spent on putting together and disassemble the product

The team was then expanded to include A. Arabian and P. Fotheringham after the brain drawing session and as a result a new developing area was added called simply The Block. This item was a developing area of the terminal device where the team wanted to try if it was possible to add a rigid element to the flexible hand.

5.2.2 Brain drawing

The brain drawing resulted in four sessions, one for each development area created earlier in the ideation phase. The result was quick sketches of ideas with complimentary comments and advantage and disadvantages was also something that was added (Figure 46).
The method proved useful with ideas being further developed and inspiring each of the team members to form new ideas from the inspiration of each other’s creativity. Getting to sketch and explain the ideas with text resulted in ideas being generated faster. To speed along the process a quick verbal explanation between the passing along of each sketch led to the next person having less down time in figuring out what to sketch. Misunderstanding wasn’t regarded as a failure instead it was a way to expand the space of generated ideas.

5.2.3 Evaluation process
For the first evaluation one thing was made clear by the company. The following statement summarize the intentions during the next coming 8 weeks

“we need a working product in the end of this project”

With the cooperation of A. Arabian and P. Fotheringham concepts to further developed were chosen. The decisions were mainly based on the plausibility of having a working product as a result of the project. This meant that placing bets on concept with an uncertain outcome wasn’t possible. Since the categories Dynamic grip and Utility/usability was of a more experimental nature and mostly added complexity to the prosthesis most of these concepts were crossed out. New ideas of more practical nature concerning utility and streamlining the production emerged from a combination of these categories. The new concept was aimed at minimizing the use of flexible material which is more time consuming and harder to print than rigid material. This modification would also reduce material costs and hopefully decrease friction in the terminal device when tensioning the fish wires for closing the hand this would be achieved by replacing the flexible material in the core of terminal device with a rigid insert (Figure 47).
The result from the evaluation was thereby to aim the development around the three components of the prosthesis, the terminal device or more specific the **insert**, **the harness** and **the socket**. The first two became the concern for this project. Further discussions around the two components, resulted in four main areas each of development and exploration. The areas for the insert were as followed:

- **Size**: the bigger the size the more flexible material would be removed which in turn would lead to less complications while printing since flexible material was concluded to be harder to print with and shorter printing time since flexible material was slower to print with.

- **Shape**: using the flexible materials flexion the insert could be pushed inside and then kept in place do to the nature of the material that capsulated the insert. However, the insert couldn’t be too big making it impossible to fit inside the hand and making the thickness of the hand too weak at different points.

- **Canal system**: needed be routed to coincide with the hand and the socket so the wires were tensioned correctly. In addition, the canals needed to fit inside of the insert with space for the wire and a tolerance that enabled the wires to be threaded through the whole system easy.

- **Mounting system**: the mounting system needed to fit onto the insert and at the same time make it possible to fit the hand on top of the insert with the mount and then lock into place with the socket.

For the harness system the four main areas to consider and develop was:

- **Comfort**: a system that could provide acceptable comfort to let users wear the harness under a long period of time without fatigue, pain or chafing

- **Retention**: it should give the socket the required extra retention to keep it from falling off and in place on the residual limb.

- **Tension**: to transfer the maximum potential force from preferred control motion (three available, commonly used, **arm flexion**, **shoulder depression** and **scapular abduction**) to the terminal device.

- **Local availability**: as the harness system required parts that not could be 3D printed and some parts that would needed to be deliberated if it still would be the most effective and profitable way of manufacturing/getting it. When the part would not be 3D printed the need for it to be locally available in most countries like Kenya and also more remote isolated regions is essential to keep the prosthesis value for its targeted market/user group.

These areas were developed and evaluated constantly with focus to have a complete system for each of the weekly meetings, the evaluation kept going through the prototype phase with different parts being develop until the Final design was achieved.

In addition to the terminal device being modified the mounting connection was redesign from the current threaded solution to a bayonet type. This solution could make it easier to assemble the parts and with a rigid mounting connection a more stable wrist could be tested. Before agreeing on further develop the bayonet mount different ideas of design was discussed (Figure 48) to assure that the bayonet was a good choice.

The second area of development was the harness system and the third was the socket. During the planning phase of the project the scope was limited to not include the socket. This meant that the decisions and designing of the socket that didn’t include changes made in correlation with changes done in the development of the first and second developing area.
5.2.4 Harness sketching

The harness design was further iterated and new sketching sessions were implemented to explore and develop the concept. It resulted in more detailed ideas and a broader concept base. The ideas were finally clustered into three main categories because of their different. They were named west, 3DP and fig-8 (Figure 49). During this iteration initial ideas about materials and manufacturing were further explored.
5.3 DEVELOPMENT & IMPLEMENTATION
This chapter includes the development of the insert, the harness and parts of the Socket regarding the previously mentioned components. This lead up to the final design of the components. The developing process includes computer modelling, prototyping, evaluation and then redoing the steps over and over until a satisfactory component was achieved and could be implemented.

5.3.1 Computer modelling
The team decided early on in the project that the final components needed to be parameterized so that the final design would be able to be scaled and fitted to as many people as possible. As a result, all models were created with changeable parameters like thickness, height, width etcetera by adding different expressions in the Change Parameters window in Fusion 360.

With three people cooperating in designing the whole system with different components depending on each other Fusion 360’s cloud service proved very useful. It enabled the team to save parts online which in turn could be accessed and imported by other team members into their model. For instance the male and female parts of the mounting system was modelled by one member and then added to the Insert and the Socket by the two team members working on those parts (Figure 50). The parts could then be printed and evaluated, the result of the collaboration led to more features being modelled and 3D printed simultaneously which saved a lot of time when prototyping. If other team members in other countries wanted access to models they could grab the CAD-files in the cloud as well.

With Slicing software’s doing most of the preparations for 3D printing like infill percentage and support structures the files only needed to be solid modelled and exported as STL-files. This resulted in the whole process of creating many models and then translating that to physical prototypes very easy.

5.3.2 Prototyping
Through additional evaluation the conclusion was that the west concept would require extensive sewing and customization which could add production time and material inconveniences. Through making a quick replica of the figure-nine (Figure 51), for example used in the ICRC prosthesis (3.5.2.1), it was found that the most critical part for comfort and tension of the harness system was where it wrapped around the shoulder of the user and especially the armpit. This lead to that four shoulder loop variations for a figure-eight configuration were fabricated, tested and evaluated by the team members (Figure 52).

The insight that the arm pit was the most crucial point when treating comfort and without possibility to produce flexible parts first hand made the team consider the additive manufactured shoulder pad not to be a beneficial concept. Since retention can be given both through socket and harness they have to be designed parallel so that the sum of retention will be sufficient. The socket design didn’t provide enough retention to be combined with a harness that wouldn’t add retention, like the figure-nine. This is further elaborated in the chapter 6.2. What it resulted in was a decision to exclude any concept of this type.

Discussions about fabrics and other materials that could be used as a solution for the shoulder loop, would be locally available and provide sufficient properties. Untreated mosquito nets is a product of low cost, would be easy to get hold of in many of the developing countries in the southern hemisphere, it could work as a breathing material to avoid moist for the user.
In addition, as 3DLP was in dialog with UN that’s a big provider of mosquito nets around the world they could possibly be a provider of material. If this idea was going to be realized a discussion had to be done its feasibility. This is due to the problems that occur when using mosquito nets in different ways than what they were intended to, e.g. fishing nets, because like in that case it could lead to less people get access to mosquito nets (Gettemen, 2015).

Variation A was fabricated with mosquito net that wrapped around the shoulder to be able to give a wider pressure area. In addition, the mesh structure would increase breathing and thereby decrease perspiration. Flexible filament (Filaflex) was sawn into the edges of the loop to provide extra strength durability. By testing this prototype, it was found that the wider strap would still be compressed and dug into the armpit where most of the unpleasant pressure would be. By trying move this strap down the shoulder, almost over to the upper arm, a more pleasant feeling was achieved but it also made it bound to slide down if no tension was applied to it. The discovery evolved into the Variations B and Variations C, the first was made by sewing two pads of mosquito net together that would enfold a bigger part of the shoulder which would both hold it up and move the pressure point away from the armpit when straining it. The other concept did instead add another strap so that the shoulder loop would be split in two which would give the same features in a different way. The disadvantages with these were that they could restrain movements in the sound arm since they wrapped around parts of it and also the user did consider it more complicated to supply force to the terminal device. Lastly the Variation D was made out of a wide webbing strap that would make a larger pressure area and also wouldn’t need cutting the strap at this section which could make it less durable, add elasticity and more sewing. It was found to be the most comfortable and easiest to apply force with. The testing combined with considerations around fabrication resulted in that Variation D was chosen as the final design.

Since the socket design demanded more retention a prototype of a cuff that was ideated on in harness sketching phase was printed in a rigid filament of PETG (colorFabb_XT). This was thermoformed in a half cylindrical form to be able to embrace the arm. This allowed a faster print due to it being printed flat and still being an easy way of customizing it to the user. The specific material was formed easily after being heated in an oven for 10 minutes in 100 °C. Tests were also performed with boiling water but it often resulted in that outer layers became uneven and that the piece absorbed water. In the current version of the prosthesis a part of the actuation consisted of a bike brake cable, a principal which was taken from ICRC’s prosthesis. Though, after testing the brake cable it leads to it being eliminated due to added production steps, expenses and that the previous suspect elongation of the fishing wire when putting tension on it wasn’t an issue.
This resulted in that different designs of a buckle that would connect the wires to the harness was finally tested and selected.

To evaluate how the bayonet mount would behave in print and find a suitable spring it was prototyped repeated times. It resulted in compromise between minimizing clearance and at the same time provide sufficient ability to lock the terminal device to the socket. Rubber bands, pieces of flexible filament and a printed flexible pad was compared to act as a spring (Figure 53). To get the best control over the compromise a printed pad was chosen as the relation then wouldn’t be dependent on the actual assembly.

(Figure 54). The circumference was compared for different segments of the insert with the base of the insert (144.54 mm in final design).

With some basic mathematics the stretch was calculated and tested by 3D printing prototypes as well of the covers and inserts

\[
1 - \frac{144.54}{166.384} \approx 0.1313
\]

A good size of stretch was concluded to be 13% which made it possible to fit the insert inside the cover with ease but still with a snug fit that would keep the insert in place. The canal system had to be evaluated as well so when wiring the prosthesis, the wire wouldn’t get stuck at the transition between the cover and insert as well as between the insert and the socket. During all the prototypes testing the fingers were removed from the cover (Figure 55) to save material and printing time but in the later stages of prototyping they were added to test the whole terminal device.
06 FINAL DESIGN

the result of the design work
6 FINAL DESIGN

The final design of the protheses system is presented in this chapter with each of the individual components described. The components are the Insert, Harness and Socket. The presented material on the Socket is only regarding the work done by the thesis team. The modelling of the Socket is credited to N. Rao, part of the 3DLP team.

The new system consists of the Cover (which is a flexible hand with a hollowed palm) the Insert (that’s inserted inside the cover), the Socket (connected to the wrist-lock of the Insert) and the Harness system (which is connected to the socket).

6.1 INSERT

The Insert (Figure 56) was printed in either PLA or PETG which reduced the flexible material needed. Since flexible material was harder to print with the reduction meant that the terminal device was now less prone to failed prints. By altering infill, the insert can become very strong or less strong but faster to print. The Insert is printed standing up on the Wrist-lock meaning that some support material is needed.

To fit different sizes, the model was parameterized so it could be scaled but the focus mainly was to get a working product of the original size. By changing the infill of the insert can be made stronger and more durable. The shape and size of the Insert meant that the Cover would still have a thickness so it wouldn’t be worn out and by utilizing the stretch of the cover the insert would slip in without much force but then keep in place, making it very hard to move it from it position.

The whole process of creating the insert was briefed in a workbook for further development (APPENDIX K).
6.1.1 Wrist lock

The Wrist-lock (Figure 57) is using a bayonet mechanism to connect and disconnect from the socket.

![Figure 57. The male part of the wrist-lock](image)

The female and male part of the wrist-lock (Figure 58) was parameterized so it could be easily modified to fit the Insert and Socket. Spring pad is added between the male and female lock so the insert would lock in place and kept in place by sliding into a slot. Pressing down and twisting in a counter-clockwise rotation will unlock the Insert. The springs where printed with 30% infill making them flexible enough to keep the terminal device at place and making it possible to unlock the mechanism.

![Figure 58. The wrist-lock, the object that’s blue marked is the male part that was added to the Insert.](image)

This enabled the person assembling the prosthesis to wire the prosthesis by first wiring the hand first and then the socket.

6.1.2 The cover

The Cover is the flexible hand that covers the Insert with bendable fingers and a sleeve to make the transition between the Socket and Cover smoother. The Cover is printed in Filaflex and is the only part that needs to be flexible now. With users wanting to have a lifelike prosthesis no changes were made on the exterior which would compromise the appearance. The sleeve (Figure 61) that was removed from the socket and added to the cover coincides with the traditional covers used, in addition this offers the opportunities to experiment with the materials used for the socket.

The printability of the cover had to be prototyped and evaluated with the sleeve which resulted in a thinnest wall-thickness being 1.5 mm and height of 9.5 mm. This meant that the cover still could be printed standing up as it did originally and connected to the socket using the new Wrist-lock.

![Figure 60 The “Half-moon” that was cut out on the socket from the entering hole for the wires.](image)

To “fool proof” the mounting a dimple was added to the female and cut off on one of the pins making it impossible to mount the insert to the socket the wrong way. When testing the Wrist-lock a gap (Figure 59) was created due to the male part having to be pushed up to lock in place. By cutting of a “half-moon” (Figure 60) in connection with the wiring hole the gap worked as a space for the wires to be kept intact when locking and unlocking the terminal device.

![Figure 59 Space making it possible to twist of the insert without cutting the wires.](image)

![Figure 61 The sleeve with the hollowing for the Insert viewed in Fusion 360.](image)
By constructing the Insert with the same origin as the original terminal device the hand could be hollowed out using Autodesk Meshmixer (Figure 62), in addition the sleeve could be constructed using Meshmixer as well after the hollowing was done.

![Figure 62 Hollowing the cover by using the size of the insert, the sleeve could then be added in Meshmixer as well.]

6.1.3 Canal system

The result of the canal system (Figure 63) featured a smoother transition then the previously since their no longer was a screw hole in the way. To keep a smooth transition between the different components tangents were created so the direction of the canal system didn’t change between the cover and insert and inset and socket.

From the interviews it was concluded that the size of the canals for each finger should be wide enough so fishing wire of roughly Ø2 mm could be fitted, this since Ottobock uses a Palon of that size. Before the wires was guided into the socket an exit holes were created and sized to fit all five of the wires without squeezing them together.

![Figure 63 The canal routing inside the insert.]

An idea that was going to be tried was routing the exit hole for all the wires in the middle of the wrist-lock but as a result of the interview which showed that many of the amputees had a long residual limb the wiring for the socket would have to take a tight turn once the wires had passed into the socket, therefore the exit holes was located below the thumb to leave some space for the residual limb and a smoother transition of the canals system from the insert to the socket but this problem was solved with the new Wrist-lock.

The canal system was parameterized so it could be scaled accordingly in the Change Parameter window in Fusion 360 (Figure 64). The only thing that isn’t scaled proportionally is the diameters of the canals.

<table>
<thead>
<tr>
<th>Favorites</th>
<th>scale</th>
<th>mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>User P... canal_hole_small</td>
<td>mm</td>
<td>4 mm * (1 / scale) + 1 mm</td>
</tr>
<tr>
<td>User P... canal_hole_big</td>
<td>mm</td>
<td>6 * (1 / scale) + 1 mm</td>
</tr>
</tbody>
</table>

With the rigid material the theory was that the wires wouldn’t ship away at the material and less friction between the wires and the surface would reduce the force needed to create the motion of grasping. Further test is needed to give a reliable result.
6.2 HARNESS

The harness (Figure 65) was constructed in so called figure-eight it means that the loops around the sound shoulder and then the straps crosses in a printed buckle centred over the vertebrae as recommended by Pursley (1955) to give maximum excursion of the control cable. The strap width was selected to a 40-millimetre nylon webbing for best comfort and durability. The strap is looped so that one end goes in a downwards diagonal direction and is connected to the cable system that controls the terminal device. The other end goes over the shoulder on the amputee side is connected to a printed triceps cuff. This gives the socket additional retention which is of great help if the printed socket isn’t sufficient (Figure 66). Under the prevailing circumstances this could be the case as scanning and constructing the ideal fit without any anatomical knowledge is problematic. Sometimes a loser fit of the socket could even be needed for users in warmer countries like Kenya.

The whole harness system is assembled out of four AM parts printed in a rigid filament, two 40 millimetre straps, two 26 millimetre straps, one plastic tube and 5 screws. The straps and screws that are not printable are standard parts that should be locally available at any hardware store or similar. No sewing is needed which is which streamlining the fabrication further through eliminating a step in the process.

The only tools needed for assembly is a screwdriver, a pair of scissors and a lighter or equivalent that could provide heat to burn the edges of the straps. All the AM parts are constructed with slots for the straps which provides many adjustment points which makes the system very adaptable to the user. The attachment is made out of three slots which makes the straps fix very well, when threaded through all the slots. If, however an easier adjustment is required the straps are threaded through two of the slots, unfortunately often on the account of clasping it. The strap pulled in Figure 66 would be recommended to be threaded through two slots because losing the strap when doing this eases putting it on and taking off.
The triceps cuff (Figure 67) is printed flat and is then thermoformed by any source of heat that’s prevalent, e.g. boiled or preferably heated in an oven. PLA only needs to reach its glass transition temperature of 60°C to be soft enough to form and can then be formed over the user’s arm with a towel to protect the skin or over something cylindrical like a glass bottle (3.6.3.2 Polylactic acid (PLA)). The cuff is perforated in a hexagonal pattern to minimize problem with perspiration for the user and still provide strength to the cuff. Additionally, the cuff is provided with retainer loops where the plastic tube is inserted to lead the control wires over it to keep them from cutting in to the user’s arm. At the other end the of the wires the buckle that connects them to the strap is and adjusted so that the wires won’t cut in to the back of the user. The buckle has slots for 5 screws to which the wires for each finger is threaded. The wires are crimped by a screw between the buckle and a printed washer to avoid tearing of the wires. In the end of the buckle the wires are gathered through a combined opening to avoid tangling in use. When assembling the Harness, the fishing wires are firstly threaded through the terminal device and the knotted in the end to grip the tips then thorough the socket and lastly crimped and adjusted to get the right tension at the buckle. To make the system ready for production the harness was finalized with an assembly guide for the manufacturer that will hand the system to the user (APPENDIX L).

6.3 SOCKET
The areas that were revised in connection with the project were mirroring the sleeve and the connection to the terminal device which meant that the female part was modelled in the new socket (Figure 68). The result meant that the sockets total height was reduced which was desired since for larger versions it could be a problem to fit inside a FDM-printer, it also gives a better base to start the print off. The other sought after result was to leave more space in the terminal device for future design iterations on functionality of the hand. For example, one concept of using an old mechanism called a whippletree to better distribute the force over the fingers was discussed as a possibility early on of the project.

With more rigid material being tested to reduce the need of flexible material, resulting in reduced cost and time to print. With more rigid material however the old retention strap on the socket needed to be redesigned but after a discussion with the company it was concluded that the solution was in need of redesigning in any case since it offered little to no retention to start with.

In addition, ways of letting the socket provide more retention was explored based on existing socket solutions like indirect skeletal attachment called supracondylar and supraolecranon attachment where the socket is formed to lock onto bones in the elbow. The other way is indirect skeletal attachment called soft tissue suction and skin friction where the socket has openings where the soft tissue can flow out or hypotension is created. These designs would demand more professional knowledge and special customization. Consequently, it would counteract the objective of the prostheses fitting being streamlined and done without an extensive education.
6.4 COST & TIME ESTIMATION

The following result shows a comparison in cost and time of the previous design, the so-called Life Arm 2.0 and the new design, Life Arm 3.0 (Figure 69). As shown in Table 6 the total saved cost with the new design comes down to 131,77 SEK. The terminal device resulted in a marginal higher price which is mostly due to the mirroring of the connection between the terminal device and the socket. This means added volume to the terminal device and the opposite goes for the socket. In the socket a bit snugger fit and new profile also reduced volume. The big difference in cost is due to the harness system where formerly expensive bike wire could be removed and only fishing line was used instead. All the expenses are presented in APPENDIX M.

Table 6. Material cost difference (cost of Life Arm 3.0 subtracted with cost of Life Arm 2.0)

<table>
<thead>
<tr>
<th>Material cost difference</th>
<th>Cost (SEK)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terminal device</td>
<td>-4,94</td>
</tr>
<tr>
<td>Socket</td>
<td>31,61</td>
</tr>
<tr>
<td>Harness</td>
<td>105,10</td>
</tr>
<tr>
<td>Total</td>
<td>131,77</td>
</tr>
</tbody>
</table>

When the printing time for the terminal device before and after was compared only the cover that had a printing time of 15 hours 15 minutes was inserted in Table 7. Since the insert only has a printing time of 4 hours 23 minutes the cover demands the longest time to complete and are printed on separate printers which means that the cover is the only relevant. The printing time of the socket was saved due to replace the flexible material with the semi flexible nylon which can be printed faster.

Table 7. Comparison of printing time

<table>
<thead>
<tr>
<th>Printing time (h)</th>
<th>Terminal device</th>
<th>Socket</th>
<th>Harness</th>
</tr>
</thead>
<tbody>
<tr>
<td>LifeArm 2.0</td>
<td>16,29</td>
<td>22,43</td>
<td>0,0</td>
</tr>
<tr>
<td>LifeArm 3.0</td>
<td>15,25</td>
<td>13,08</td>
<td>6,05</td>
</tr>
<tr>
<td>Difference</td>
<td>1,04</td>
<td>9,35</td>
<td>-6,05</td>
</tr>
</tbody>
</table>

Figure 69. All the components of the 3D Life Arm 3.0. From the Left: Harness system, Cover, Socket and Insert.
07 DISCUSSION

evaluating the project
7 DISCUSSION

Reflection and discussion is brought up in this chapter relating to the result and theory. Thoughts regarding the process and the context of applying an industrial design engineers touch in the field Prosthetics & Orthotics in a completely new environment is discussed as well. With the product never getting to be fully printed and tested most of the discussion and conclusions consist of reflections surrounding the process of producing a additive manufactured prosthesis for Nairobi and developing countries.

As industrial design engineers we have tried to bring innovative solutions to life which correspond with the work IDEO.org (2015) are carrying out. Our focus was to, through Design, improve and create a product that would help amputees in developing countries so they could acquire a prosthesis that would improve their lives. Furthermore, the project hopefully worked as fuel for people in developing countries such as Sweden and people working in the field of Industrial design engineering to try and solve problems in the field of prostheses, to work in an unknown field and come in with a different set of eyes might just be what is needed to solve some of the big issues facing the field. A red line through the work have been to try as much as possible to Inspire by trying to tell a human-centered design story, even if users haven’t been involved as much as we hoped it was always our intention to create something that would benefit their lives. Hopefully the user will play a bigger part in evolving the product in the future. Stated by Bowler et al. (2011) to conduct UCD its important to put the user in centre and we can argue that that’s what we are doing by using 3D scanning to make a better fit of the socket, by reducing costs the intended user will be able to access the product since does it really matter that the product is perfect for the user if they can’t afford it? and providing the user with a more comfortable product since according to (Pursley, 1955) without the user feeling comfortable they won’t use it.

Many of the world's largest companies such as General Electric, Google, and IBM Services, etc. have regional headquarters in Nairobi which may indicate that Kenya is one of the most influential countries in Africa. We believe that this at least should increase the chances of technology and knowledge reaching to other developing countries.

7.1 THE FINAL DESIGN

The work presented in this thesis shows a design one step closer to a finished product and at the same time a mapping of a much clearer picture of the technology of 3D printing in developing countries. With the company having a lot of competence in Business & Entrepreneurship and Mechanical engineering our work as Industrial design engineers contributed to a new way of looking at the field of prostheses, finding the “real problems” with the product while trying to keep the user in mind when trying to develop the product further. This meant exploring the context of the product (the technology, the environment and the user) became a large part of the project to find the problems with the product and determine if the approach of 3D printing prostheses really was plausible. Hopefully the user will be more involved when testing the product. According to Bowler et al. (2011) the most defining part of UCD is that the user is involved in some way, even if it’s after the product has been built. When the project was presented in the initial phase the focus was improving parts and adding value to a product, it was later revealed that having a launch able product was the real problem since a patient hadn’t been fitted with the prosthesis yet. It was up to us as Industrial design engineers to identify problems with production and designing, solving problems which later would be tested with the user to evaluate the product.

7.1.1 Printability

With 3D printing there was a lot of problems just getting the printers to work and print. Since 3D printing with desktop FDM printers being such a new technology you have to spend countless hours testing and trying different settings and theories about how to 3D print, with this said ones you get a hang off it you can reap the benefits of your hard work with successful prints.

Using a rigid material, we can conclude that the Insert and parts for the Harness system is definitely printable. In addition, all the parts can be placed on one build plate meaning that you can set of one print to get all the rigid parts which will save time in set up and effort. Downsides are that the infill will have to be the same unless you are
using Simplify3D but that feature should slicing-software’s like Cura be working on. If parts are separated this might work as a buffer for failed prints since if the print fails all parts might be affected since the printer builds parts layer by layer and not part by part. However, with both PLA being easy to print with and the Ultimaker 2+ and access to Simplify3D its concluded that using one build plate is optimal.

With the Cuff being printed flat and then thermoformed it’s concluded that the success rate of printing is much higher than if it would have been printing in the thermoformed shape.

When setting up the print it was discussed how the direction of the infill pattern was placed. With the help of a cylindrical test piece it was concluded that this factor needs to be considered since layer orientation can affect both durability and the desired function (e.g. flexion in flexible material). It was discussed if the orientation can be used as an advantage so placing the grid so the fingers won’t flex in one direction and not restricting the direction of the flexion. This might pose a problem with the digits not aligning the same since the thumb is flexing in another direction.

With Nylon being tried for the socket since it was classed as a biocompatible material there was now three different materials being used. Further evaluations should be done on what combinations should be used, the different combinations are presented in Table 8.

<table>
<thead>
<tr>
<th>Table 8. Different material combinations of the prosthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>COVER</td>
</tr>
<tr>
<td>SOCKET</td>
</tr>
<tr>
<td>INSERT</td>
</tr>
<tr>
<td>HARNESS PARTS</td>
</tr>
<tr>
<td>NUMBER OF PRINTERS</td>
</tr>
</tbody>
</table>

PLA in the cases described can also be exchanged with any other rigid material such as PETG. The only thing we can say for certain is that the cover needs to be printed in a flexible material and that the socket should be printed in a material classed as biocompatible. There’s also the opportunity of printing, unloading material, load new material and print all on one printer but a more viable production process would be to print different materials on separate printers. Still we can argue that with the prices of traditional machines you could by a couple of FDM printers.

7.1.2 Cost and durability
The fact that cost should be highly considered when developing the product isn’t only concluded from interviews and observations but is concluded by authors for example Cummings (1996); Phillips et al. (2015); Zuniga et al. (2015). With this said cost isn’t only achieved by lowering the manufacturing cost but the product itself needs to be easy to serve and durable so the user can use the prosthesis for an extended period of time. The company had concluded that the product needs to last for 2 years and cost less than 50 USD. The benefit of 3D printing means that we can control the infill percentage of the components which by making a more solid part means a more durable product but in turns cost more material, printing time and being less lightweight. Further test should be done both computer based and physical tests to secure that the product is adequately durable.

As the new design requires an extra printer to give the desired effect of streamlining the manufacturing to make it profitable. It’s debatable if investing in an extra printer for every established workshop would be profitable as the time saved with the new design for the terminal device only is around one hour as showed in the result. To add to the contrary, as pointed out in the result about the cost difference of the terminal device, is the mirrored connection. As mentioned, the volume is just moved over to the terminal device. This means that a comparison of the separate parts doesn’t provide a reliable result. The time saved on the terminal device with that in account would be a bit more and a bit less for the socket.

7.1.3 Stigma & Social factors
Regarding rejection rates, a quick look at the traditionally made prosthesis for example the ICRC shows that the prosthesis should be reasonably cosmetic if a standard set of filament can be utilized which the company is working on right now. To keep the cover as natural looking as possible was a reasonable design call if we look at other similar products which offer more functionality but with less cosmetic appeal, for example Zuniga et al. (2015) concluded that prosthetic arms that uses a hook had a high rejection rate in part due to an unacceptable cosmetic appearance.

7.1.4 Comparing to theory
With the previously mentioned factors by Cummings (1996) we can compare the product with these factors to conclude how well it’s suited for the developing world

1. Low cost, being printed for less than 430 SEK which is a lot cheaper than ICRCs functional prosthesis. With that price it’s in the price range of a cosmetic prosthesis but with the added bonus of extra function. More detailed calculations should be done which considers e.g. failed prints and electricity.
2. Locally available, the manufacturing process can be moved to developing countries instead of having to order parts that are being manufactured in e.g. Germany.

3. Capable of manual fabrication, might not be as relevant anymore with the opportunities of 3D printing and digitally prepared components.

4. Considerate of local climate and working conditions, the climate was discussed but tests were never conducted.

5. Durable, further test should be carried out on the durability but we can see that parts can be 3D printed in a good quality in rigid material. According to the technical data sheets (APPENDIX A; APPENDIX B) flexible material is very durable but the cover should be tested further.

6. Simple to repair, easy to re-print parts and only locally available parts were used that people should be able to find across the developing world. Fishing wire was already acquired before arriving in Nairobi so further investigations should be done on its availability but it’s concluded that it should be reasonably available.

7. Reproducible by local personnel, we see that for example Victoria Hand Project (2016) educating local personnel which means that there is a possibility, with the harness system not needing any sewing it should be easy enough for personnel to construct and fit a harness.

8. Technically functional (not gratuitously “high-tech”), uses no “high-tech” solutions to fit or operate the prosthesis. The auction of the hand is still body-powered which is very “low-tech” and something that has been proven to work in traditional prostheses.

9. Biomechanically appropriate, test on how much power is needed after rehabilitation to actuate the prosthesis should be considered. The preliminary tests show that the power needed now might be too much.

10. As lightweight as possible, using no metal and as much 3D printing material as possible means that the weight shouldn’t be a problem. To change infill percentage is very easy with slicing software meaning parts can be less dense, but this will off course in turn mean a less durable part.

11. Adequately cosmetic, scanning can be used to replicate a human hand but preliminary prints show that the flexible material is still not printing in a high—resolution leaving “scars” on hard-to-print areas. But with flexible material and reverse engineering a hand as a terminal device shows great promise.

12. Psychosocially acceptable, with a simple grasping function and relatively life-like appearance the product should be acceptable but further tests with users should be done with users. We can conclude that the prosthesis offers more function than the purely cosmetic prosthesis and a more aesthetic appeal than the terminal hook which seems like a logical balance.

7.2 SUSTAINABILITY

Working with the SDG’s we can discuss and conclude that some goals are directly correlating with the project regarding 3D printing and medical assistive devices. It’s important to reflect on how the project address some of the goals since it’s a global initiative addressing a range of social needs while tackling climate change and environmental protection. The following goals may be affected by the project

7.2.1 Goal 3: Good health & well-being

The goal is to ensure healthy lives and promote well-being for all at all ages (United Nations, 2015). This mainly focus on ridding the earth of disease with this in mind we still see some targets that are relevant in the category such as promoting mental health and well-being and substantially increase health training and retention of the health work force in developing countries. We know from our interviews that there are professionals being trained in Kenya but at a slow pace with facilities not being able to contain more than estimated 30 students per semester with over 1800 applicants. It’s concluded that with the product a prosthetist still needs to be involved but evidence showed in the report the manufacturing method will provide them with a tool that will reach more amputees in the developing world since the time to fit will be reduced. This is possible since the prosthesis will be both cheaper so more people will afford the prosthesis and the production of parts will be locally available meaning that the waiting period for components being shipped will be reduced. The project and other evidence
such as Zuniga et al. (2015) suggests that a 3D printed low-cost prosthesis can improve the quality of life for amputees which would promote well-being for amputees across the developing world.

7.2.2 Goal 8: Decent work & economic growth

This goal was created to promote inclusive and sustainable economic growth, employment and decent work for all (UN, 2015). The fact still remains that machines and material will be shipped for now but this is believed to be less of a problem then having to order custom-made parts from Europe and other parts of the world, at least the material can be bought in bunk and customization can be locally created or digitally manufactured elsewhere and sent to a local printer. The fact that parts can be digitally prepared on different locations might solve the problem of there not being enough fitters in developing countries, what could be created is a cooperation with experts working in different locations and 3D printing hubs being set up throughout the developing world where technicians are trained to work and serve 3D printers, this would mean a whole new field of work in countries like Kenya, leading to economic growth and more patients being fitted at the same time. With Kenya having a large corn production and the plastic filament like PLA being produced from corn starch the possibility to set up a filament production isn’t impossible, this would generate new jobs, solve the need for expensive shipping of some material and overall lead to economic growth.

7.2.3 Goal 9: Industry, innovation & infrastructure

The goal is to build resilient infrastructure, promote sustainable industrialization and foster innovation (UN, 2015). A perspective given by Campbell et al. (2012) suggest that indeed 3D printing is emerging to be a truly transformative technology, it’s even suggested in numerous articles that 3D printing is starting to compete with traditional manufacturing methods which could lead to the next industrial revolution. With 3D printing offering a more locally based industry this might lead to developing countries being less depending on countries who depend on export-led growth. According to the UN manufacturing is an important employer worldwide, accounting for more than half a billion jobs in 2013, with 3D printing the share of employees can be shifted to a more domestic production in developing countries which coincides with the targets of the goal.

7.2.4 Goal 10: Reduced inequalities

This goal is established to reduce inequalities within and among countries (UN, 2015). With the conclusions drawn from the previous chapters we can conclude that the economy and industry might blossom from 3D printing prostheses, with this being said the developing countries might not be as depending on exporting countries which would even out the economic inequality between developed and developing countries. As discovered from the interviews the ability to blend into society was something that was deemed important for the user. Fitted with a prosthesis users felt more included to society. We heard on different occasions that amputees would shy away from social activities or felt like second class citizens, with for people having the opportunity to acquire a prosthesis with some function blending in and functioning to be able to carry out some daily living activities a social inequality might be reduced.

7.2.5 Goal 12: Responsible consumption & production

To achieve this goal, countries need to ensure sustainable consumption and production patterns, this means to break unmindful production and unmindful consumption (United Nations, 2015). We can hopefully create a product that will be locally producible and with further testing a durable product that will hold for usage. Furthermore, if parts break they will be locally available and by using 3D printers the parts that are 3D printed will be locally replaceable meaning that the product will not be regarded as consumed if one part breaks like the traditional products. One example for instance is an old prosthesis we stumbled upon while conducting the field trip to the KMTC (Figure 70). A socket was presented that was in need of repair and stitching was tested but failed. Repairing might not be possible with 3D printing either but with a STL-file of the socket already existing a new socket can be easily printed giving the user a fully functional prosthesis again. In production shipping parts will also decrease in a much larger scale.

*Figure 70. Broken socket that was stitched together but without success
sustainable way of conducting responsible design work. A thought into the value of every single prototype should be considered before 3D printing. One way the design team tried to keep down the consumption of prototypes was to always consult all members before making a prototype so more ideas and solutions could be tested in a 3D printed part. Trying to avoid failed prints as much as possible was a factor to consider in every print as well.

7.3 FUTURE WORK
The following areas need to be studied deeper and evaluated with the user in mind to complete the work that was started. To involve the user more in any future work is something that the authors feels should be a priority, keeping in mind that as part of the project the authors went to Nairobi to establish a cooperation with primary user which proved to be much harder than anticipated. Involving more users will with most certainty reveal flaws that was overlooked during the project. These flaws can be considered future developing areas that lead to vital improvements and even radical design innovations.

7.3.1 Durability tests
All components of the system could go through strain and stress tests to evaluate if the product can handle the forces that it might be exposed to since one of the requirements being that the prosthesis should at least withstand 2 years of daily usage (APPENDIX J). The test should evaluate how much the prosthesis can carry (without breaking), on the Inserts durability and the Wrist-locks locking capability. Some basic test with infill shows that the part can become quite strong by just increasing infill but this will add both material cost and printing time. Wear and tear tests should be studied on the cover, for example how it handles water, dirt, heat and general daily activities. If the thickness of the walls for the Cover is too thin for example at the hollowing for the insert (Figure 71) the cover should be reinforced at these places. For the cavities caution should be taken since thicker walls will mean more force needed to actuate the gripping which isn’t desirable.

Concerns about the reliability of lifting objects were raised due to the lack of any skeletal structure in the fully flexible fingers. This would mostly effect the lifting of heavier objects but since this is found likely to occur regularly for many users it would demand reviewing.

The parts printed for the harness system should be evaluated as well but these parts should be evaluated to handle the force needed to actuate the terminal device. The force needed to grasp different object can be calculated using a baggage or fishing scale. According to one interview with F. Mkilla (2016) the part where the cables are tied of will be exposed to attrition, this was kept in mind during designing but tests on how much attrition it would handle was never done.

7.3.2 User test
The fitting in relation to comfort should be conducted with users to determine if the fit is nice and snug. In addition, heat and ventilation should be taken into consideration when the prosthesis is tested.

The Harness system is developed to the point where user test should be performed, the test should cover the three previously mentioned areas of tension, retention and comfort (with comfort being the highest priority) and in addition how easy the harness is to put on and remove. How easy it’s to loosen and tighten the straps should be tested by users as well as if the system needs to be adjusted too frequently to the point where the user doesn’t find it convenient.

The use of VC as actuation of the terminal device was chosen mainly because of it being the most elementary mechanical solution. The risk of it causing the user fatigue is pressing due to the need of holding objects for longer periods which requires constant tension on the device. As a big part of the target group would consist of farmers the need of holding objects e.g. farming tools is great.

A basic grasping test should be constructed and preformed with users who are fitted with the prosthesis. If possible a standardized test should be used for example the Southampton Hand Assessment Procedure (SHAP) test described by (Colin M Light et al., 2002) or preferred, a new test developed specific for upper limb

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*F. Mkilla, personal communication, 17 June 2016*
prostheses in developing countries. The test can test the function of the prosthesis, comfort of the whole system and how much a user is able to carry and should be constructed so an observation and interview is conducted simultaneously. Expanding the recommendation, user observations should be conducted to evaluate if the activities described in the chapter 5.1.7 A-E-I-O-U correspond to the reality, the next step should then be to evaluate if the prosthesis can aid the user in any tasks by conducting some sort of task based user test. According to Virzi (1992) 80% of usability problems are detected by the first few participants in a usability test, meaning that most likely the severe problems are detected by four or five participants, which shows that this would not be impossible. Furthermore, the prosthesis should be tested and compared with other prosthesis that are available, to advantages and disadvantages.

7.3.3 Material & Machine tests

Printing with the flexible material Filaflex showed to be a bigger struggled than anticipated, this since the softness of the material made it hard for the printer to feed the material to the extruder. Test of using sewing machine oil on the Ultimaker 2+ showed great improvements in printability in Sweden, this wasn’t the case for the Ultimaker 2 since the improvements on the feeder for the filament was a big factor in printing better with flexible material than the Ultimaker 2.

The 4 FDM printers used during the project was Ultimaker 2, Ultimaker 2+, Witbox and DeltaWASP 20 40. With the Witbox and Deltawasp the feeder was connected directly to the extruder meaning that flexible material was easier to print but during the project both printers stopped printing and the Ultimaker 2 needed to be relied on for all prints in Nairobi which couldn’t print flexible material. Our team member in England could however set up and print with flexible material without fail for the prototyping stage using a Witbox. Recommendation for anybody is to keep material and machines in a clean environment.

Recommendations by the authors to everyone printing is to use materials like PLA since it was perceived as a very reliable material which produces complete prints at a high ratio. In addition, it is considered to be one of the eco-friendliest materials on the market. Stating PLA to be an eco-friendly can further be discussed due to many disadvantages that gives it discredit. Some of many obstacles is that recycling of the material needs to be separated from petroleum based plastics due to avoiding it to contaminate this recycling stream. Furthermore, for disposal of the material although it is biodegradable it takes a long time (Flint, 2013).

7.3.4 Software

To streamline and increase efficiency of the process of fitting the AM prostheses we concluded that the need for compatible software solutions. The existing conventional CAD-software gives total freedom of design but unfortunately demands advanced knowledge in computer modelling. To avoid long education programs for the manufacturers and to additionally speed up the process for each fitting a software with basic box ticking and inputs for measurements would be ideal. This could possibly be done with parametrized models for all parts in a conventional CAD-software that would be simplified with a plugin. This plugin would provide easy access of these parameters for inputs of measurements and facilitated insert of scan data that will hollow the socket.
08 CONCLUSION

answering the research questions
8 CONCLUSION

The views and opinions that are concluded in this chapter where based on the authors thoughts meaning that there’s room for further research to further figure out if the statements are truly accurate. Hopefully the conclusions will provide a clearer picture in the field of AM prosthetics.

(1) How are conventional prosthetic arms generally being manufactured, distributed and used compared to additive manufactured prostheses in Nairobi, Kenya?

Described by technicians in the field and visiting the KMTC where students were in the middle of manufacturing prostheses for patients we can conclude that the practice usually follows a standard set of steps in preparing, producing and fitting an amputee with a prosthesis in Nairobi. The following steps were

- Consultation at patient’s home (assessing the environment)
- Choosing a suitable prosthesis
- Rehabilitation and training to use muscles in a certain way
- Anthropomorphic measurements for ordering components (holding off on casting due to the excessive waiting time for components)
- Ordering parts (i.e. terminal device, harness parts)
- Casting to make positive mould for socket, or modification of cast if the cast was done before ordering parts
- Creating a positive plaster mould from the casting of the patient.
- Using various methods, materials and machines to create the socket
- Assemble with ordered parts, fitting harness system etc.
- Follow up or correction if needed (if the patient hasn’t disappeared).

With the practice being pretty straight forward and following many of the steps being described by the ICRC we can conclude that this practice is common in other developing countries as well. According to Mkilla\(^1\) (2016), K’ochumba\(^2\) (2016) and Strait (2006) material can be as simple as wood or PVC pipes which is both aesthetically unpleasing, hard to work with and will break easily.

Most alarming was the fact stated by the Head of the department at the KMTC that the students were no longer being taught how to fit upper limb prostheses meaning that a more sustainable practice is now more than ever relevant. Acquiring a prosthesis was concluded to be very hard for amputees in Nairobi having to rely on sponsorship in majority of cases, this since the prosthesis is too expensive which is the number one reason of proper practice not reaching the people.

When studying different companies that was undertaking AM of upper limb prostheses, a scepticism from the authors arose if any of the companies or organizations that claimed to have an active fabrication and distribution process had it. The difficulties of finding information about how this works in practice made it hard to map this process. Hence, this process had to be mapped in a speculative way from the information that was gathered.

The following is a summarization of our and 3DLP’s, so far mostly theoretical, manufacturing process (Figure 72) that was studied in Nairobi, however, with the lack of patients we didn’t get the chance to observe the whole process.

\(^1\) F. Mkilla, personal communication, 17 June 2016
\(^2\) D. K’ochumba, personal communication, 28 June 2016
Furthermore, with the lack of patients, it’s difficult to imagine how the distribution of an additive manufactured prosthesis is done but concluded by the authors with fitting and distribution a prosthetist most likely will be needed which is further discussed in research question (3).

Concluded from interviews we see that no user of a prosthesis is the same making it very hard to map exactly who the primary user is since it can be anyone from birth or from an accident and since a user can be anyone the product needs to be truly customizable. If we compare for example Swedish users with the users of Kenya, there’s a huge difference in many cases (e.g. social factors, stigma, anthropometry and economic factors) and with the project not getting to experience any other environments than Sweden and Kenya it’s hard to conclude if there are similarities with other developing countries. The perception of the authors however was that all the factors discussed earlier that were concluded by Cummings (1996) fit into Kenya and with a high probability is similar in most of the developing world even if it was concluded 1996.

We can conclude that some trends of the Kenyan users were too obvious not to discuss when it came to upper limb amputees. With the Chaff cutter being a recurring subject from both user and experts we can conclude that many work related injuries from the sugar industry is caused by this machine. The sugar industry is huge in Kenya, 2015 there was 11 sugar mills producing an average of 500,000 metric tons a year (Ochieng’, 2015). As a result, the typical amputation caused by this machine is preformed around the wrist (wrist disarticulation) or forearm (transradial amputation). In addition, the large portion of the employees at the sugar factories where male between the age of 18-40. Mkilla12 (2016) estimated that 90% of the user that where in need of a prosthesis couldn’t afford them meaning that first and for most cost need to be the main improvement in today’s prostheses. In many cases a sponsor for the user was needed to acquire a prosthesis which was needed for some users to get back to work or education.

Considering the fact that manufacturing a prosthesis is just part of a larger program of rehabilitating amputees back to society as stated by (Landmine Survivors Network, 2006) the fact stands that even if AM prostheses is possible and can reduce the cost, it should be part of a toolset for a fully educated prosthetist concluded by the authors. Looking at some of the principles that are needed

---

**CONTACT WITH USER**

**SCANING AND MEASURING**

- scanning residual limb and taking measurements

**CAD**

- parameterized solid socket hollowed with mesh from scan

**TERMINAL DEVICE**

- select standard model size to fit user

**AM**

- printing all parts

**HARNESS FABRICATION**

- cutting webbing pieces for harness

**ASSEMBLY**

- the parts of the prostheses and harness are assembled

**USER RETURNS**

- in theory this can be the next day

**ADJUSTING HARNESS**

- adjusting harness to fit the user

**DEMONSTRATION**

- demonstrating how get the prostheses on and how to use it

**USE**

- the user can now use the prostheses

---

*Figure 72. Manufacturing process for 3DLP’s prosthetic arm*

---

12 F. Mkilla, personal communication, 17 June 2016
• services are integrated in the national health care structure
• services are known, and physically and financially accessible to potential users
• non-discrimination principles are applied
• comprehensive planning is done, both at the program and the national level
• appropriate technologies and working methods are used
• staff are well trained technically and managerially the quality of the services is monitored

The factors do require an education extending a couple of years to acquire the skill of a prosthetist.

With 3D printing however the conclusion was that a prosthetist will be able to manufacture prostheses faster and cheaper meaning that more people will get access to prostheses. With reasonable training it is believed that a prosthetist can be able to scan and even set of prints and assemble the prosthesis, but the fact is that without a proper way of customizing the cover, insert and socket for each individual these steps needs to be done by someone with training in computer modelling. But for example, a program where the prosthetist feeds in the same measurements they are doing currently on traditional prostheses and a scan of the residual limb the data could be converted into a customized 3D model which in turn could be printed. According to Strömshed (2016) there’s simple ways for prosthetist in Sweden to learn some basic modelling and preparing a socket, but there still hasn’t been enough work done to conclude that this is possible in developing countries (Keep in mind this was for a cosmetic protheses and new problems will occur with a functional prosthesis). If that was the case components like the cover and insert could come in a set of sizes like traditional components do.

With so much of the steps being digitalized a global process could be possible, meaning that the ground work is done by the prosthetist followed by a digital transfer of data to a modeller in another country which in turn sends back the digitally prepared modellers which will be ready to print by the prosthetist at the location of the patient. According to the authors this would reduce the cost and need for shipping parts which is expensive, takes time and is a global environmental issue. In some cases a positive mould is used to scan the residual limb (Anderson Goehrke, 2015), maybe the prosthetist can acquire the positive mould and then leaving the scanning to the modeller if scanning can’t be done on location. Scanning a cast is beneficial since the residual limb won’t be moving making it easier to scan, but if a digital transfer can’t be done the previously mentioned benefits won’t be utilized.

According to Phillips et al. (2015) WHO made a estimation where less than 5% of the population in the developing world has access to rehabilitation services. Rehabilitation has been shown to improve chances of long-term prosthetic use which would mean that if a prosthetist can utilize the benefits of AM prostheses more people would be able to acquire prostheses since the prosthetist would be able to fit more patient with the time to manufacture a prosthesis greatly reduced.
REFRENCES


Norgren, E. (2015). Armproteser i låginkomstländer Adderande tillverkning av armproteser i låginkomstländer av KTH.


http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPrintingofMedicalDevices/default.htm

U.S. FDA. (2016b). General Controls for Medical Devices.


Ziegler-Graham, K., MacKenzie, E. J., Ephraim, P. L.,

APPENDIX A. FILAFLEX, TECHNICAL DATA

<table>
<thead>
<tr>
<th>PROPERTIES</th>
<th>STANDARD</th>
<th>VALUE</th>
<th>UNIT</th>
<th>TEST CONDITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shore hardness, method A</td>
<td>ISO 868</td>
<td>82</td>
<td>SHORE A</td>
<td></td>
</tr>
<tr>
<td>Ultimate tensile strength</td>
<td>DIN 53504</td>
<td>54</td>
<td>Mpa</td>
<td></td>
</tr>
<tr>
<td>Elongation to break</td>
<td>DIN 53504</td>
<td>700</td>
<td>%</td>
<td>200 mm/min</td>
</tr>
<tr>
<td>Compression set</td>
<td>ISO 815</td>
<td>25</td>
<td>%</td>
<td>72 h; 23 °C</td>
</tr>
<tr>
<td>Impact resilience</td>
<td>ISO 4662</td>
<td>42</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>Abrasion resistance</td>
<td>ISO 4649 method A</td>
<td>30</td>
<td>mm^3</td>
<td></td>
</tr>
<tr>
<td>Tear propagation resistance</td>
<td>ISO 34-1</td>
<td>70</td>
<td>kN/m</td>
<td>500mm/min</td>
</tr>
<tr>
<td>Density</td>
<td>ISO 1183-1</td>
<td>1200</td>
<td>kg/m^3</td>
<td></td>
</tr>
<tr>
<td>Tensile storage modulus</td>
<td>ISO 6721-1,-4</td>
<td>48</td>
<td>MPa</td>
<td>20 °C</td>
</tr>
<tr>
<td>Tensile storage modulus</td>
<td>ISO 6721-1,-5</td>
<td>33</td>
<td>MPa</td>
<td>60 °C</td>
</tr>
<tr>
<td>Extrusion-Melt Temperature</td>
<td></td>
<td>200-260</td>
<td>°C</td>
<td></td>
</tr>
</tbody>
</table>

CONSIDERATIONS

Filaflex is not a medical grade material, cannot be used with direct contact with body fluids including direct contact with blood.

Filaflex is not designated to food contact or cosmetics applications.
NinjaFlex® 3D Printing Filament
Flexible Polyurethane Material for FDM Printers

NinjaFlex flexible filament leads the industry with superior flexibility and longevity compared to non-polyurethane materials. Its consistency in diameter and ovality (roundness) outpaces other polyurethane materials. Made from a specially formulated thermoplastic polyurethane (TPU) material, this patented technology contains a low-tack, easy-to-feed texture. The result is uniquely flexible, strong prints ideal for direct-drive extruders.

### General Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Test Method</th>
<th>Imperial</th>
<th>Metric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific Gravity</td>
<td>ASTM D792</td>
<td>1.19 g/cc</td>
<td>1.19 g/cc</td>
</tr>
<tr>
<td>Moisture Absorption - 24 hours</td>
<td>ASTM D570</td>
<td>0.22 %</td>
<td>0.22 %</td>
</tr>
</tbody>
</table>

### Mechanical Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Test Method</th>
<th>Imperial</th>
<th>Metric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensile Strength, Yield</td>
<td>ASTM D638</td>
<td>580 psi</td>
<td>4 Mpa</td>
</tr>
<tr>
<td>Tensile Strength, Ultimate</td>
<td>ASTM D638</td>
<td>3,700 psi</td>
<td>26 Mpa</td>
</tr>
<tr>
<td>Tensile Modulus</td>
<td>ASTM D638</td>
<td>1,800 psi</td>
<td>12 Mpa</td>
</tr>
<tr>
<td>Elongation at Yield</td>
<td>ASTM D638</td>
<td>65%</td>
<td>65%</td>
</tr>
<tr>
<td>Elongation at Break</td>
<td>ASTM D638</td>
<td>660%</td>
<td>660%</td>
</tr>
<tr>
<td>Toughness (integrated stress-strain curve; calculated stress x strain)</td>
<td>ASTM D638</td>
<td>12,000 in-lbf/in³</td>
<td>82.7 m²/N·m² x10⁶</td>
</tr>
<tr>
<td>Hardness</td>
<td>ASTM D2240</td>
<td>85 Shore A</td>
<td>85 Shore A</td>
</tr>
<tr>
<td>Impact Strength (notched izod, 23°C)</td>
<td>ASTM D256</td>
<td>2.0 ft.lbf/in²</td>
<td>4.2 kJ/m²</td>
</tr>
<tr>
<td>Abrasion Resistance (mass loss, 10,000 cycles)</td>
<td>ASTM D4060</td>
<td>0.08 g</td>
<td>0.08 g</td>
</tr>
</tbody>
</table>

### Thermal Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Test Method</th>
<th>Imperial</th>
<th>Metric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting Point (via Differential Scanning Calorimeter)</td>
<td>DSC</td>
<td>420° F</td>
<td>216° C</td>
</tr>
<tr>
<td>Glass Transition (Tg)</td>
<td>DSC</td>
<td>-31° F</td>
<td>-35° C</td>
</tr>
<tr>
<td>Heat Deflection Temperature (HDT) @ 10.75psi/0.07 MPa</td>
<td>ASTM D648</td>
<td>140° F</td>
<td>60° C</td>
</tr>
<tr>
<td>Heat Deflection Temperature (HDT) @ 66psi/0.45 MPa</td>
<td>ASTM D648</td>
<td>111° F</td>
<td>44° C</td>
</tr>
</tbody>
</table>

### Test Specimen Details (by ASTM Test Number)

- **Tensile:** Dogbone Style IV, 100% fill, diagonal line fill. Dimensions: 3.5mm thick. See drawing for other dimensions.
- **Hardness (D2240):** Solid testing block.
- **Impact (D256):** Un-notched test specimen, notch added post print by testing facility.
- **Abrasion (D4060):** Rectangular block fitted to Taber abrader.
- **HDT (D648):** Bar shape.

NinjaFlex filament is capable of being printed by a variety of printers in a variety of configurations. This specification sheet gives results as they pertain to the defined test standard and specimen details. Different slicing and/or printing configurations, test conditions, ambient environments, etc. may result in different results.

Impact Strength and Heat Deflection Temperature results were both provided by an accredited university testing laboratory. Specific Gravity and Hardness are innate characteristics of the material. Moisture Absorption, values associated with the Tensile Strength tests, Melting Point and Glass Transition data were prepared by Fenner Drives, Inc.

NinjaTek makes no warranties of any type, express or implied, including, but not limited to, the warranties of fitness for a particular application.
## Technical data sheet

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Unit</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Modulus of elasticity</strong></td>
<td>2,960</td>
<td>[MPa]</td>
<td>ISO 527</td>
</tr>
<tr>
<td><strong>Tensile strength</strong></td>
<td>61.5</td>
<td>[MPa]</td>
<td>ISO 527</td>
</tr>
<tr>
<td><strong>Tensile strain at tensile strength</strong></td>
<td>5.3</td>
<td>[%]</td>
<td>ISO 527</td>
</tr>
<tr>
<td><strong>Tensile stress at break</strong></td>
<td>38</td>
<td>[MPa]</td>
<td>ISO 527</td>
</tr>
<tr>
<td><strong>Tensile strain at break</strong></td>
<td>10.5</td>
<td>[%]</td>
<td>ISO 527</td>
</tr>
<tr>
<td><strong>Flexural modulus</strong></td>
<td>3,295</td>
<td>[MPa]</td>
<td>ISO 178</td>
</tr>
<tr>
<td><strong>Flexural strain at break</strong></td>
<td>no break</td>
<td>[%]</td>
<td>ISO 178</td>
</tr>
<tr>
<td><strong>Flexural stress at 3.5 % strain</strong></td>
<td>88.8</td>
<td>[MPa]</td>
<td>ISO 178</td>
</tr>
<tr>
<td><strong>Notched impact strength (Charpy), RT</strong></td>
<td>2.8</td>
<td>[kJ/m²]</td>
<td>ISO 179-1/1 eA</td>
</tr>
<tr>
<td><strong>Impact Strength (Charpy), RT</strong></td>
<td>30.8</td>
<td>[kJ/m²]</td>
<td>ISO 179-1/1 eU</td>
</tr>
<tr>
<td><strong>Shore D hardness</strong></td>
<td>n/a</td>
<td></td>
<td>DIN 53505</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td>1.24</td>
<td>[g/cm³]</td>
<td>ISO 1183</td>
</tr>
<tr>
<td><strong>Bulk density</strong></td>
<td>n/a</td>
<td>[kg/m³]</td>
<td>ISO 90</td>
</tr>
</tbody>
</table>

The values listed have been established on standardized test specimens (DIN EN ISO 3167, type A) at standard temperature and humidity conditions.

## Thermal properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Unit</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Melting temperature</strong></td>
<td>&gt; 155</td>
<td>[°C]</td>
<td>ISO 3146-C</td>
</tr>
<tr>
<td><strong>Vicat A softening temperature</strong></td>
<td>n/a</td>
<td>[°C]</td>
<td>ISO 306</td>
</tr>
<tr>
<td><strong>Heat distortion temperature HDT B</strong></td>
<td>n/a</td>
<td>[°C]</td>
<td>ISO 75</td>
</tr>
<tr>
<td><strong>Melt volume rate (190 °C/2.16 kg)</strong></td>
<td>n/a</td>
<td>[cm³/10 min]</td>
<td>ISO 1133</td>
</tr>
<tr>
<td><strong>Melt flow rate (190 °C/2.16 kg)</strong></td>
<td>3.0 - 5.0</td>
<td>[g/10 min]</td>
<td>ISO 1133</td>
</tr>
</tbody>
</table>

## Legal notice

The figures should be regarded as guide values only. Under certain conditions the properties can be influenced to a significant extent by the processing conditions.

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### APPENDIX D. GANTT CHART

#### Month
- May: Week 15-20, 22-24
- June: Week 11-19
- July: Week 20-21
- August: Week 15-19

#### Stage 1
- **Planning**
  - 11 April - 20 May
- **Literature Study**
  - 11 April - 10 June
- **MFS-Course**
  - 11 June - 6 August

#### Stage 2
- **Context Immersion**
  - 20 April - 20 May
- **Ideation**
  - 23 - 17 May
- **Development**
  - 20 June - 8 July
- **Implementation**
  - 11 July - 12 August

#### Stage 3
- **Travel Intensive**
  - 11 June - 6 August
- **Minor Field Study in Nairobi, Kenya**
  - 24 - 27 April
- **Theoretical Framework draft**
  - 11 August - 2 September

#### Stage 4
- **Status report**
  - 29 August - 2 September
- **Midterm**
  - 29 August - 2 September
- **Project Report**
  - 11 August - 10 June
- **Presentation**
  - 29 August - 2 September

#### Week
- 15 - 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28
- 29
- 30
- 31

#### Month
- May
- June
- July
- August
- September
Användning av en Arm-/Handprotes

Vi är två studenter som håller på att utveckla funktionalliteten på en 3D-printad arm-/handprotes för utvecklingsländer och vi hoppas att du skulle vilja hjälpa oss med din kunskap inom området. Alla deltagare är anonyma och kan du inte svara på någon fråga kan du hoppa över den. Enkäten består av 18 frågor och beräknas att ta 15 minuter att utföra.

Detta är till vårt examsarbete i Teknisk design och vi är just nu i informationsinsamlingsfasen så all information du kan bidra med är av värde.

Vill du veta mer eller intresserad av att ställa upp på en intervju maila gärna oss på carlstrom.wargsojd@gmail.com.

*Obligatorisk

1. 1. Kön
   - Markera endast en oval.
   - Man
   - Kvinna
   - Övrigt:

2. 2. Ålder

3. 3. När orsakades din armsgata? *
   - Markera endast en oval.
   - Medfödd (dysmel) Fortsätt till frågan 6.
   - Efter födelse (t.ex. olycka eller sjukdom) Fortsätt till frågan 4.

4. 4. Vilken arm-amputationsnivå har du?
   - Vänster
   - Markera endast en oval.
   - Ingen amputation
   - Finger/thumbamputation
   - Partial handamputation (en del av handen är amputerad)
   - Handdisartikulation (amputation vid handled)
   - Transradial amputation (amputation under armbågen)
   - Ulnar disartikulation (amputation vid armbågen)
   - Trunschmeral amputation (amputation över armbågen)
   - Axeldisartikulation (amputation vid axel)

https://docs.google.com/forms/d/1Gx6C8sqcfJbIA7T1XlG3HEL36fRjveM4wSazFCD4v/edit
5. Höger
   Markera endast en oval.
   ☐ Ingen amputation
   ☐ Fingeramputation
   ☐ Partiell handamputation (en del av handen är amputerad)
   ☐ Handdisartikulation (amputation vid handled)
   ☐ Transradial amputation (amputation under armbågen)
   ☐ Armbågsdisartikulation (amputation vid armbågen)
   ☐ Transhumeral amputation (amputation över armbågen)
   ☐ Axeldisartikulation (amputation vid axel)

Fortsätt till frågan 10.

6. 4. Vilken typ av dysmeti har du?
   Markera endast en oval per rad.

   ☐ Ingen dysmeti
   ☐ Tvångande
   ☐ Längsgående

   Vänster  ☐ ☐ ☐

   Höger  ☐ ☐ ☐

7. Markera endast en oval per rad.

   ☐ Ja
   ☐ Nej

   Kirurgisk behandling

8. På vilken nivå?
   Vid transversell (tvångande) dysmeti den nivån där armen skitar. Vid longitudinal
   (längsgående) dysmeti väcker den nivån (del) av armens påverkan är störst. Vid dysmeti på
   handnivå väljer "saknar grepp" om grepp helt saknas (avser grepp utan hjälpmedel t.ex. protes)
   Markera endast en oval per rad.

   Överarm  ☐ ☐ ☐ ☐

   Underarm  ☐ ☐ ☐ ☐

   Hand  ☐ ☐ ☐ ☐

   Saknar grepp  ☐ ☐ ☐ ☐

   Vänster  ☐ ☐ ☐ ☐

   Höger  ☐ ☐ ☐ ☐

9. Kompleterande information
   Om dysmeti är svår att beskriva med alternativa ovanför.

   __________________________________________
   __________________________________________
   __________________________________________
   __________________________________________
   __________________________________________
APPENDIX E. QUESTIONNAIRES

2016-06-06

Användning av en Am-Handprotes

15. 7. Vilka krav sätter du på en protes? (t.ex. Min protes måste...)

16. 8. Vilka är de viktigaste egenskaperna hos en protes för dig? (max 3 egenskaper)

Om du aldrig har provat en protes kan du hoppa till Fråga 15

17. 9. Varför väljer du att använda den protes som du använder idag/använda senast?

18. 10. Är du nöjd med den protes som du använder idag/använda senast?

Markera endast en oval.

1 2 3 4 5

Väldigt missnöjd ☐ ☐ ☐ ☐ ☐ Mycket nöjd

19. 11. Kan du ge några exempel på brister du upplevt hos den protesen du använder/använda senast?

https://docs.google.com/forms/d/1GshCfuqJt0biAF7IxJ9fELLih99yM43wSdZFC94/edit
15. 7. Vilka krav sätter du på en protes? (t.ex. Min protes måste...)


16. 8. Vilka är de viktigaste egenskaperna hos en protes för dig? (max 3 egenskaper)


Om du aldrig har provat en protes kan du hoppa till Fråga 15

17. 9. Varför väljer du att använda den protes som du använder idag/använde senast?


18. 10. Är du nöjd med den protes som du använder idag/använda senast?

Markera endast en oval.

1 2 3 4 5

Välj dia missnöjd ☐ ☐ ☐ ☐ ☐ Mycket nöjd

19. 11. Kan du ge några exempel på brister du upplevt hos den protesen du använder/använda senast?


20. Finns det något du tycker kan förbättras hos den protes du använder/använde senast?

21. När du bär protes brukar du undvika att använda den i vissa vardagsliga situationer och är detta väl?

22. Har din protes någon gång gått sönder eller slutat fungera? (Kan du beskriva vad som hände?)

23. Vad är viktigast för dig hos en protes? Funktion eller utseende?

24. Hur vill du att din protes ska se ut?

Funktion (gripa, lyfta, hålla etc.)

Utseende (snygg eller naturtrogen)

Snygg design (sticker ut)

Naturtrogen (smälter in)
APPENDIX E. QUESTIONNAIRES

25. 17. Har du någon övrig kommentar angående proteser och protesanvändning?

---------------------------------------------------------------------

---------------------------------------------------------------------

---------------------------------------------------------------------

26. 18. Tycker du att det är något som bör ändras i den här enkäten? (Frågor som är otydlig, känsliga etc.)

---------------------------------------------------------------------

---------------------------------------------------------------------

Tack så mycket för att du tog dig tiden att svara på vår enkät!

Tillhandahålls av

Google Forms

https://docs.google.com/forms/d/1Gc8CH8qtcO6hiAFTvX1d53E3eH9jeM43wSAYZFCO4/edit
Information om undersökning av protesanvändning


Armprotesen som ska utvecklas görs i samarbete med företaget 3D Lifeprints som är verksamma i Nairobi, Kenya. Protesen kallas för "The 3D Life Arm" och är riktad mot låginkomsttagare och utvecklingsländer för att ge fler tillgång till dessa hjälpmedel. Vårt mål är att förbättra fingerfunktionaliteten hos protesen för att förbättra t.ex. grepp och hållbarhet. Vi gör nu en förstudie för att få en grundförståelse av armproteser, användning av dem och användarens behov. I Juni kommer vi att åka till Nairobi för att stanna där i 8 veckor och få möjlighet att prata med användare och arbeta med teamet för att skapa en design som avslutningsvis kommer detaljutvecklas i Luleå.

Om du är intresserad av att hjälpa oss är vi väldigt tacksamma och det skulle innebära att vi gör en intervju över telefon eller skype på mellan 20-30 minuter. Om du bor i Luleå med omnejd träffar vi dig gärna personligen. Frågorna som ställs kommer involvera ditt användande/icke användande av protes, dina dagliga rutiner och dina önskemål och krav på ett sådant hjälpmedel.

Ditt deltagande i undersökningen är helt frivilligt. Utskriften godkänns av den intervjuade innan den används i rapporten och du kan när som helst avbryta ditt deltagande utan närmare motivering. Alla deltagare i studien kommer att vara anonyma. Resultatet av undersökningen kommer att presenteras i den projekt rapport som kommer skrivas vid Luleå Tekniska Universitet som du sedan kan ta del av om intresse finns. Om du är intresserad av att delta kontaktar du oss via vår gemensamma mail: carlstrom.wargsjo@gmail.com


Luleå, 18 maj 2016

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Participant A. (2016-05-27)
22-year-old female, acute amputee at the age of 3 months due to a blood poisoning. Currently a user of a below-the-elbow myoelectric prosthesis for her left arm. In addition, her right hand was amputated but not to the extent where a prosthesis was needed but still to the point where some function is restricted.

“My shoulder is getting sore because I need to use my whole arm when performing simple tasks like pouring water, an adjustable wrist would be great”.

“I use my prosthesis to do more. Yesterday I forgot my battery at home and at that point I was more disabled then I actually am”.

“I never use my prosthesis to do dexterous activates, for instance if I bake a cake suddenly I could have punched it by mistake”.

“I want a more cosmetic prosthesis to blend in more, if you look quick you don’t see that it’s a prosthesis and I don’t want to draw unnecessary attention to myself”.

“I think more should be happening with prostheses, the design of my prosthetic arm has been the same since I was 15 years old”.

Participant B. (2016-05-27)
50-year-old male who suffered an acute amputee after a workplace accident. Has a below-the-elbow myoelectric prosthesis with an interchangeable hand which can be changed to a body powered hook and different activity based devices. Since the accident 5.5 years ago he has used his myoelectric prosthesis but had to relearn how to use different activities with his left hand.

“From the point where I get up from bed I put on my prosthesis. I use it for about 10 hours a day since I have a desk job as a production engineer, it’s not suited for heavy duty work”.

“Since a lot of the muscles in my arm were kept intact after my operation it was a fast process to get my prosthesis fitted. Almost instantly when I tried the prosthesis I could feel that it felt right”.

“I still have a lot of pain from the operations and taking of the prosthesis and ventilate at the end of the day is a nice relief”.

“For everything dexterous I use my left hand, I had to relearn everything I did with my right hand”.

“With the grip function I’m satisfied, it enables me to fit into and operate in our society. For example, I can go shopping and hold a bag or my wallet and operate in a queue”.

“I’m old enough to want the prosthesis to blend in and not stand out too much, when I’m at home I can use my hook since it’s more functional but when I go out I want to use my myoelectric”.

“It’s an expensive aid, so if you can cut down on the price that would be great so people in developing countries can fit in and join sociality again”.

“A lot of my parts take a beating, I have had my mechanical parts repaired and the sensors on my myoelectric prosthesis needs to be changed soon”.

“The most important part for me is the relationship with my technician, to know that if something breaks I can get it fixed. Now that I have gotten used to have my prosthesis if it was to break and I was without it for a longer period I would shy away from different social interactions”.
Participant C. (2016-05-27)

35-year-old female who was born with a difference on her left hand but still with a functional wrist and a small thumb with some small grasping capabilities. At the moment she chooses only to use activity specific prostheses for kayaking, skiing and eating, all with different sockets and the eating being an orthotic brace with Velcro. In addition, she has a prosthesis with a hook but it’s seldom used.

“I was offered to be fitted with a robotic hand but at that time the battery wouldn’t fit and I don’t see the point in having a cosmetic prosthesis”.

“I tried a cosmetic prosthesis when I was younger but I just found them warm, clumsy and ugly so I thought I would be better off without one”.

“I have some functionality with my hand and with a prosthesis I would lose the sense of touch, I don’t like the idea of touch my child with a plastic hand”.

“I’m so used to not wearing a prosthesis so I think it’s too late for me now, but it seems that the technology is really improving and to be able to grasp is a really great improvement”.

“I wouldn’t mind if a prosthesis would stick out, but I guess that’s very individual I guess”.

“I’m satisfied with my prostheses but the paddle prosthesis where I use vacuum for suspension and its skin contact to plastic it tends to get very hot and sweaty”.

“My left arm is not as strong as my right and having to then add weight to it with a prosthesis makes it harder to do some activities”.

“I would like a more attractive design, the one I have that is skin colored is very ugly. I don’t try to hide my arm so for me it wouldn’t matter if the prosthesis was for example black and silver”.

"For me it’s important that a prosthesis is durable and comfortable”.

“Often the socket has a good fit right away since they make a cast, but somethings you need to get it corrected and when you lose or gain weight you lose the snug fit”.

“For some of my prostheses I wish the cleaning would be easier when I get sweaty, if you could clean it yourself or change a part”.

Participant D. (2016-06-10)

23-year-old female who was born with a partial limb difference on her left hand. When she was around 2.5-3 years old she was fitted with her first cosmetic prosthesis. Since then she has been fitted throughout her life and currently using a myoelectric and cosmetic prosthesis.

“I don’t view myself as missing an hand, rather that I have one normal looking hand and one that is a bit different, this since I was born this way”.

“I use my prosthesis as much as possible since without it I can’t do everything I want to do. But when I shower, sleep and watch a movie by myself I take it off”.

“I get kind of warm when I’m at the gym or during summers but I’m used to it. But know that we’re talking about it yes, it’s a problem and can be bother”.

“I didn’t even know that they made gel liners until I went to Stockholm, I’ve always used a ridged socket and that’s what I’m accustomed to”.

“I’ve used a prosthetic arm for so long, I guess I’m more of an old habits die hard kind of person”.

“Since I studied to become an interior designer I wish my prosthesis had more fine motor skills and I wish that some details like holes and stuff were removed so it looked better”.

“On my cosmetic prosthesis I have very detailed nails, I like that a lot, I wish my myoelectric had that to”.

“I get more handicapped with my cosmetic prosthesis but sometimes I prefer it, like when I go out it’s like a type of safety even if I’m more handicapped”.

“I haven’t really thought about what I demands I put on my prosthesis, first of I want it to be functional then look good. Simply being a complement to my right hand”.

“Since I work a lot in a work shop I need my prosthesis to be durable, I also like to test the limits of stuff, that’s just who I am, even if it hasn’t gone as well at times”.

“If there was a balance between functionality and appearance that would be amazing, I think that if you only have a purely cosmetic prosthesis you will still draw more attention to yourself when you do different tasks because your body movements will be different”.

“Since I use my prosthesis so much it gets dirty very fast, I’ve tried cleaning it with a bunch of stuff like vinegar and nail polish but nothing works so I need to have backup covers”.

“My myoelectric prosthesis is very heavy, but that may change when I’ve gotten more used to using it more. My back is getting sore when I use it, I actually brought a backpack to a concert the other day so I could take it off and move around easier”.

“I tried a device for playing the piano when I was younger. When I was 14-15 it was all about appearance but with time my opinion has changed, I’m more open to it sticking out more now”.

“I love options, if I could have a prosthesis that was natural looking and could be changed to stick out more that would be pretty neat”.

“I think if you get used to wearing and using a prosthesis fast and early your quality of life will improve a lot”.

“Most of the time I forget that I’m wearing a prosthesis, it’s until I see myself in the mirror that I’m reminded”.
APPENDIX H. DESIGN SPECIFICATION

List of development areas from 3DLP

- Field testing
  - Develop stress tests
  - Scanning and fitting at least 3 devices with periodic checkups on performance and outcomes.
  - Same, but for leg covers!
- Socket design
  - Our current socket design is, at best, a wild guess at what would work. There is a LOT of experimentation that can or could or should happen, including
    - thickness
    - Infill Print%
    - stiffness (use of underextrusion to make it spongy or preferred density for print (sanitary issues?))
    - soft inner liner with hard shell?
    - Use of sock - how to fit and adjust around it
- Hand design
  - Continue iteration on cosmetics, function., and durability. Likely we will see a lot of material strength issues through testing.
  - Sizing/Scaling issues
    - Pediatric sizing
  - Buildability / maintainability
  - Inclusion of variable grip / whippletree into palm? (this is clearly more exploratory)
  - Adaptation to ICRC socket
  - Finger Threading, Currently difficult to thread fingers due to open finger pockets.
  - Finger Tips, Grip etc.
  - Threading tie off at tip of finger
  - How fingers meet on contraction
  - Design and implement test apparatus
- Harness design - much like the socket, that was a wild guess (and a poor one at that). I would REALLY like to get the industrial design students thinking about this because there may be some really creative things that can be done.
- Leg covers: Long ignored, but what sorts of improvements can we make on them, and what again, field testing
  - Pediatric designs – scaling and shaping to kid hands
APPENDIX I. DESIGN SPECIFICATION

Design specification by the authors made in Sweden.

Design specification

<table>
<thead>
<tr>
<th>Users</th>
<th>Manufacturers</th>
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<tr>
<td><strong>Functional</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Demands</strong></td>
<td></td>
</tr>
<tr>
<td>- Be able to lift/grip/hold/carry a minimum standard</td>
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</tr>
<tr>
<td>- Will not drop objects unintentionally that has been picked up</td>
<td></td>
</tr>
<tr>
<td>- “Will work”</td>
<td></td>
</tr>
<tr>
<td><strong>Wishes</strong></td>
<td></td>
</tr>
<tr>
<td>- Adjustable grip</td>
<td></td>
</tr>
<tr>
<td>- Adjustable wrist</td>
<td></td>
</tr>
<tr>
<td>- Individual finger movement</td>
<td></td>
</tr>
<tr>
<td>- Will be more practical then not using a prosthesis</td>
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</tr>
<tr>
<td><strong>Ergonomical</strong></td>
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<tr>
<td><strong>Demands</strong></td>
<td></td>
</tr>
<tr>
<td>- Light weight (same weight or lighter than an arm)</td>
<td></td>
</tr>
<tr>
<td><strong>Wishes</strong></td>
<td></td>
</tr>
<tr>
<td>- Low energy expenditure / minimal force input</td>
<td></td>
</tr>
<tr>
<td><strong>Construction</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Demands</strong></td>
<td></td>
</tr>
<tr>
<td>- Durable</td>
<td></td>
</tr>
<tr>
<td>- Body-powered finger movement</td>
<td></td>
</tr>
<tr>
<td><strong>Wishes</strong></td>
<td></td>
</tr>
<tr>
<td>- Easy to repair or replace</td>
<td></td>
</tr>
<tr>
<td><strong>Manufacturing</strong></td>
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<tr>
<td><strong>Wishes</strong></td>
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<tr>
<td>- Easy to customize</td>
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<td><strong>Material</strong></td>
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<td>- Natural looking/nice looking</td>
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<td>- Not cost much more than the current</td>
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<tr>
<td><strong>Wishes</strong></td>
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<tr>
<td>- Not cost more than the current</td>
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<td>- Socially and psychologically acceptable</td>
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<tr>
<td><strong>Wishes</strong></td>
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<tr>
<td>- Appealing or blending in</td>
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</table>
APPENDIX J. LIST OF REQUIREMENTS

GENERAL DESIGN REQUIREMENTS
- Open source, parametric design
- Functionality that meets pre-determined standards
- Aesthetically pleasing as per patients’ needs
- Does not cause patient undue discomfort
- Products that are durable to cater for the patients local environment
- Ability to manufacturer locally
- Standardised and blueprinted design frameworks
- Easily customisable based on the individual patient
- To provide automation facilities wherever possible
- Products are “low cost” to manufacture based on pre-determined levels
- Easy to maintain / repair / clean

HIGH LEVEL DESIGN REQUIREMENTS
FUNCTIONALITY
- Should be able to pick up a [2KG] object
- Should be able to be used by 5%-95% male/female, for all geometric sizes
- Should be open at rest, movement closes
- Should be operated by shoulder harness
- Arm rotation should not be limited by the prosthesis
- AESTHETICS
- Should be tailored to the patients skin tone as much as possible
- Hand should look anthropomorphic
- Should be naturally looking under clothing
- Acceptability should be ascertained by focus groups from patients
- COMFORT
- Should not give skin discomfort
- Should be able to be worn for long periods [10 hours]
- Should be as lightweight as possible [<0.5KG]
- Should not cause excessive heat build-up
- Should be tight fitting (but not excessively) for each patient
- STANDARDISED
- Designs must be repeatable / open source
- Should be manufactured on a defined set of 3D printers
- Should use a defined set of 3D printed materials
- Should use defined set of other materials – fishing wire [20KG]
- Should have small set of “catalogue” offerings to patients

CUSTOMISATION
- Should be based on 3D scans of patient wherever possible using mobile 3D scanners
- Should have customised & accurately built sockets
- Should be able to fit all patients specific requirements

DURABLE
- Should last for [2 years]
- Should be able to operate in challenging environmental conditions
- Dust
- Humidity (>75%)
- Temperature (>40 °C)
- Waterproof

ABLE TO MANUFACTURER LOCALLY
- Should be able to be manufactured at least in the region of the patient’s location
- [% of components manufactured locally]
- Should minimize the need to ship products

LOW COST
- Should be able to manufacturer for less than [550 USD]
- Operational framework should minimize the patient’s cost for expenses to be fitted e.g. travel

MAINTAINABILITY
- Should be easy to assemble /disassemble
- Should be easy to clean /remove dirt by the patient
- Should be easy to replace parts if broken or in need of repair
- Should be able to be maintained by local resources
- Ability to repair with a single hand

ACCESSORIES
- [Use of silicon sock /gel liner?]
- [Other]

QUALITY ASSURANCE
- [HOW DO WE CERTIFY EACH PRODUCT POST PRINT]

TRAINING & POST CARE FOLLOW UP
- Creation of training program for educating new users
- [Use cases, techniques]
- Creation of communication channels for feedback
- [3/6/9 month follow-up in person / on phone / SMS?]

3D PRINT MATERIALS

3D FILAMENT
- Should be [rigid only / flexible / hybrid]
- Look to use e.g. Medically certifiable materials e.g. MED610, or materials that are classified as non-hazardous according to the Global Harmonized system of classification of Labelling of Chemicals (GHS))

COST
- Prosthetic should be printed in less than [x metres]
- Filament should be procured at less than (landed cost) [75 USD]
- LOGISTICS & DISTRIBUTION
- Centralised distribution capabilities must be developed
- [Other]

3D PRINTERS

TECHNICAL SPECIFICATIONS
- Should have a build size of 20cmx20cmx20cm
- Should have ability to print in flexible filament
- Time to print prosthetic of <30 hours for full hand/socket
- Standardized range of [3 printers]
- Should be upgradeable
- Should have standardized 3D print settings [layer height etc.]

COST
- Printer should cost less than (landed) [5K USD]
- Replacement parts should be affordable

LOGISTICS & DISTRIBUTION
- Replacement parts should be easily obtainable
- Centralised distribution capabilities must be developed
How to create the Insert

Step 1: Creating the reference markers

1. Insert the reference markers into the document.
2. Select the reference markers and adjust their position and orientation.
3. Use the "Align" and "Distribute" tools to ensure that the markers are evenly spaced.
4. Add any necessary labels or annotations to the markers.

Keep in mind that the reference markers are only to be used as a reference in relation to the rest of the document.

Tips:
- Use a consistent style for all reference markers.
- Ensure that the markers are clearly visible.
- Consider using different colors or styles for different types of markers.

Additional information:
- For more advanced features, refer to the software's documentation.
- Regularly update the reference markers as needed to maintain accuracy.

Reference:

Appendix K: Insert Workbook
APPENDIX K. INSERT WORKBOOK

Step 5: Adding the Figlock

The Figlock was created as a prototype and is a separate file. During the testing phase, it was decided that the Figlock would not be needed for the final design.

To add the Figlock to the design, follow these steps:

1. Open the design file.
2. Select the Figlock file.
3. Insert the Figlock into the current design.
To make the Male Pin and the Insert, one body use Combine Bodies and Connect. Since you have moved the Weld tool fusion will ask you to capture the new position before you combine the bodies.

After you have imported the Weld tool, select it and make sure the Weld tool is oriented properly. Once you have selected the Weld tool, you can move the Weld tool to the appropriate location.

You can use the Weld tool to weld the Male Pin and the Insert together. Make sure the Weld tool is oriented properly and that you have selected the appropriate edges to weld.

To weld the Male Pin and the Insert together, you can use the Weld tool by selecting the appropriate edges and then selecting the Weld tool. You will be prompted to enter the Weld tool type and the Weld tool orientation.

Once you have entered the Weld tool type and orientation, you can select the appropriate edges and then weld the Male Pin and the Insert together. You can also use the Weld tool to weld the Male Pin and the Insert together by selecting the appropriate edges and then selecting the Weld tool.

You can use the Weld tool to weld the Male Pin and the Insert together. Make sure the Weld tool is oriented properly and that you have selected the appropriate edges to weld. You can use the Weld tool to weld the Male Pin and the Insert together by selecting the appropriate edges and then selecting the Weld tool.
Projections from sketch onto five planes made from the 3D sketches.
Assembled

Pieces

1 strap 2-2.5 m
1 strap 30-40 cm
2 strap 20-25 cm

Pull through
1/2 Length of the strap
The angled slots and top of buckle should point in different directions.

Repeat on opposite side.
APPENDIX L.  HARNESS INSTRUCTIONS

Repeat on opposite side
## APPENDIX M. COST & TIME CALCULATION

### COST & TIME ANALYSIS OF 3D LIFE ARM

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<th>Cost (€)</th>
<th>Cost ($)</th>
<th>Cost/G (g)</th>
<th>Cost/G ($/g)</th>
<th>Time to print (h)</th>
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### 3D LIFE ARM 3.0

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<th>Cost (€)</th>
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### 3D Life Arm 3.0

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<th>Cost/G (g)</th>
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### 3D Life Arm 3.0

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<th>Cost/G (g)</th>
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### Additional Costs

<table>
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<th>Cost (€)</th>
<th>Cost ($)</th>
<th>Cost/G (g)</th>
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<td>Brake wire</td>
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<td>Screws/washers</td>
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### Total

<table>
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### APPENDIX M. COST & TIME CALCULATION

#### 3D LIFEARM 2.0

**Terminal device**

<table>
<thead>
<tr>
<th>Spool size (g)</th>
<th>Diameter (mm)</th>
<th>Device</th>
<th>Cost (€)</th>
<th>Cost ($)</th>
<th>Time to print (h)</th>
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<tbody>
<tr>
<td>Taulman PCTPE</td>
<td>750</td>
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<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
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<td>0.00</td>
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**Socket**

<table>
<thead>
<tr>
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<th>Diameter (mm)</th>
<th>Device</th>
<th>Cost (€)</th>
<th>Cost ($)</th>
<th>Time to print (h)</th>
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<tbody>
<tr>
<td>Colorfabb XT PETG</td>
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**Harness**

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<th>Diameter (mm)</th>
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<th>Cost (€)</th>
<th>Cost ($)</th>
<th>Time to print (h)</th>
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<tbody>
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<td>0.00</td>
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<tr>
<td><strong>Total</strong></td>
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<td></td>
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<td>16.17</td>
<td>18.17 154.33 22.43</td>
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**Total**

<table>
<thead>
<tr>
<th>Size (g)</th>
<th>Cost (€)</th>
<th>Cost ($)</th>
<th>Cost (SEK)</th>
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<td>Terminal device</td>
<td>146.03</td>
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<td>11.64 98.87 16.52</td>
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<tr>
<td>Socket</td>
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#### 3D Lifearm 2.0

**Size (g)**

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<th>Cost (SEK)</th>
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<tr>
<td>Socket</td>
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<td>16.37</td>
</tr>
<tr>
<td><strong>Total</strong></td>
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<td>16.87</td>
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#### Time (h)

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<th>Flexible</th>
<th>Prípe</th>
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<td>0.00 16.92 16.91677</td>
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<td>0.00 22.43 22.43333</td>
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**Spool type**

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APPENDIX M. COST & TIME CALCULATION

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<th>Cost ($)</th>
<th>Cost (SEK)</th>
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<table>
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<th>Harness</th>
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<th>Cost ($)</th>
<th>Cost (SEK)</th>
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<th>Cost (SEK)</th>
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<tbody>
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<td>24.11</td>
<td>204.86</td>
</tr>
<tr>
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<td>32.73</td>
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