Manual for building a prosthetic socket in developing countries

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Abstract

This thesis is about the creation of a process manual for building a lower limb prosthesis socket. The target group is children between the age of 8-14 in developing countries. It is designed with local materials and tools so it can be used in rural areas without proper access to Prosthetic and Orthotic (P&O) facilities.

This manual will contain the general guidelines for building prosthetic parts. The project is done in collaboration with fellow student Martijn Hortensius whose thesis focusses on the foot and shaft of the prosthesis. It also supplies a list of requirements for manual design.

To better describe the working of a prosthetic socket it was split up in three parts: the socket exterior, the socket interior and the suspension. For all of these parts requirements are created. This is done by researching literature and looking at examples of successful prostheses used in developing countries. Important criteria are mechanical performance, durability and adaptability to a growing body.

In the design process each requirement is approached with the question: which materials do I have to use to fulfil the demands set by the requirements and what is the effect on the design.

Several designs and ideas where evaluated if, and to which extent, they are fitting the requirements. Eventually several designs are made, 5 exterior sockets, 3 interior sockets and 2 suspensions. These are made into simple construction manuals. The manuals contain instructions about materials, tools, and some basic construction steps. These instructions are referred to as guidelines. The manual is evaluated in two ways. The content of the manual is evaluated by how successful the conversion from requirement to the guidelines is.

The design of the manual is evaluated by a list of requirements made by fellow student Martijn Hortensius. The manuals themselves will not yet be sufficient to build an actual prosthesis but will provide a good starting point. The guidelines in the manual are to be tested and experimented with on location in rural areas.

Samenvatting

Deze scriptie beschrijft het ontwerp proces van een handleiding voor het vervaardigen van de socket van een onderbeen prothese. De doelgroep is kinderen in de leeftijdscategorie 8-14, levend in de rurale gebieden in ontwikkelingslanden waar geen toegang is tot prothese en orthese (P&O) faciliteiten.

Deze handleiding zal de algemene richtlijnen voor het bouwen van een prothese socket bevatten. Het project is gedaan in samenwerking met medestudent Martijn Hortensius wiens scriptie over de voet en pylon van de prothese gaat. Ook leverde hij een lijst van eisen voor de vormgeving van de handleiding.

Om een beter beeld te krijgen van de werking van een prothese socket is deze opgesplitst in drie onderdelen. De buiten socket, de binnen socket en de ophanging. Voor de prothese onderdelen is een set van eisen opgesteld. Dit is gedaan doormiddel van een literatuur onderzoek en een marktonderzoek naar, in ontwikkelingslanden, succesvolle protheses. Belangrijke criteria zijn mechanische prestaties, comfort, duurzaamheid en de mogelijkheid om de socket aan te passen op een groeiend lichaam.

In het ontwerp proces werd elke eis benaderd met de vraag: welke materialen moet ik gebruiken om aan de gestelde eisen te voldoen en welk effect heeft dit op het ontwerp.

De ontwerpen en ideeën worden geëvalueerd om ze aan de eisen te toetsen. Hieruit komen enkele ontwerpen, vijf buiten sockets drie binnen sockets en twee ophangingen zijn tot handleiding verwerkt. Deze handleidingen bevatten instructies over materiaal, gereedschap en enkele basis bouw instructies. De handleiding wordt inhoudelijk geëvalueerd op hoe de manier waarin de eisen zijn omgezet naar richtlijnen. De vorm en presentatie van de handleiding worden geëvalueerd aan de hand van de eisen voor het maken van handeidlingen, gemaakt door mede student Martijn Hortensius.

De handleidingen zelf zijn nog niet voldoende om een uiteindelijke prothese te bouwen maar bieden een goed startpunt. De handleidingen kunnen verbeterd worden doormiddel van experimenteren en praktische ervaring op te doen op locatie.
1.1. Introduction

In developing countries many people do not have access to proper Prosthetic and Orthotic (P&O) facilities. Modern prosthesis are scarcely available and when available, people living in the rural areas. Do not have acces to them. This limits the possibility of people with amputations to actively participate in society. In the case of people with leg amputations it limits their mobility.

Modern leg prosthesis break down in the more demanding (tropical) environments of developing countries as found in studies done by Strait, E. (2006) and Andreysek, J. (2010). In the most favourable conditions a prosthesis lasts only 18 months. Common problems include excessive wear of the foot, corrosion and failing of the mechanical parts because of dirt and moisture.

Regular replacement is difficult because of the travel times to medical facilities and the cost of replacement. Moreover, there are a multitude of organizations working on different approaches and concepts for prosthetics to solve this problem. But between these organisations there is not much cooperation or sharing of ideas because of patent rights.

The patch project (Patch Project ,2015) is an open-source website dedicated to the spread of information about building a prosthesis, for arm or leg, in developing countries. Which would make the inhabitants more self-sufficient in their need for a prosthesis. The information on the website is extensive but for a potential user it is unclear what information is useful for a given situation, area or problem. The target group of the organisation is disabled children aged between 8-14 living in rural areas, an often overlooked group.

If we look at leg amputations, the majority are of the below the knee lower-limb type, also called a Trans-tibial amputation. The greater availability of lower leg prostheses would affect the most people. Because these prostheses have no need for a, often complicated, knee joint a simpler prosthesis can be used.

Despite being the 4th country by population Indonesia only possesses 34 P&O facilities, almost 7milion people per shop (Giesberts, B. 2012). This made Indonesia an interesting choice for the project. Another reason was the amount of information already available about the region. During conversations with Patch Project creator, Bram Sterke, Indonesia was chosen as the target area of this assignment.

1.2. Goal

The goal of this project is to create a process manual which will describe the necessary steps for designing a Lower Leg prosthetic socket by showing the possible design choices using the materials and tools available in rural areas. The main question in this process is: What materials do I have to use to meet the requirements for a prosthetic socket and what influence does this have on the design.

The process manual does not serve as a definitive manual but as an intermediate step that will highlight the possible design choices and materials suitable for building a prosthetic socket. This will give a person a better overview of the information available. An actual manual will have to be made on location where all the details can be figured out.

The process manual consists of two parts. A selection diagram showing the design possibilities for each part of the prosthesis and a design specific manual showing what is required to build a specific part. This is illustrated in figure 1.1.

The process manual will describe the consequences of different materials, for example strength requirements and durability, for each design choice. The process manual will be the basis from where design specific manuals can be created in the future.
2. Analysis

A prosthesis is an artificial device intended to replace a body part that is missing as a result of an amputation or birth defects. It (partly) replicates the function of a normal human leg. A prosthesis generally consists of three or four main parts, the socket, the pylon (or shaft) the foot and optionally a suspension. Each part has their own unique function. A more detailed description can be found in Appendix D. This thesis will focus on the socket and suspension.

As mentioned in the introduction, the goal of manual is to illustrate the steps necessary for building a prosthetic socket with the locally available materials, tools and skills. This will most likely pose limitations on the design of a prosthetic socket. This creates the need to create a set of requirements with the most vital requirements for a prosthetic socket and suspension.

To establish the requirements for each part, a combination of literature study and interviews with professionals from the industry was performed. by reviewing the researching literature about prosthetics (Geertzen, J.H.B. Rietman, J.S. 2008), (Seymour, R. 2002), (May, B.J. Lockard, M.A. 2011) and interviews with prosthetic specialists Cornelis Visser at Livit Den Bosch (Visser, C. 2015), and Anthony Rombach, prosthetic specialist at Endorso and (Rombach, A. 2015). Chapter 2.1. Users of the manual will discuss the skills and limitations of the population in rural areas. Chapter 2.2. is a market research about successful prosthesis for developing countries.

Chapter 2.3 will discuss the mechanical properties and the necessary performance of all prosthesis parts. Further it will cover donning and doffing (fitting the prosthesis on the individual wearer), and its ability to adapt to different sizes will be discussed.
2.1. Users of the manual.

For the creation of the manual it had to be clear what the local craftsman and family of the child is capable of. This is necessary to determine the form and complexity of the information that has to be transferred. With this knowledge it is possible to decide how much information is necessary per category. The International Society for Prosthetics and Orthotics (ISPO, 2001) has created a set of guidelines for the training of P&O professionals that is used world wide. In short, three categories can be identified. Category 1 are the Prosthesist and Orthotist, usually working at the academic level and preforming research. The category 2 group refers to Orthopaedic technologist, who directly treat patients with limb deficiencies. Category 3 consists of Prosthetic Technicians, the people who build and maintain prostheses.

Categories 1 trough 3 consist of trained professionals who work from the city. Children and their families in rural areas often don’t have the opportunity to reach these professionals. As stated in a report by the world bank about health financing in Indonesia (Rokx Et Al, 2009). Travel cost to P&O workshops is estimated to cost at least €6,22. This equals about 1 week of pay for people living on the poverty line. These costs, in combination with being away from home, makes it difficult for a lot of people in rural areas to reach a P&O facility. For this reason we looked at people in the direct surroundings of the child.

By interviewing people with hands on experience working in developing countries (Visser, C. 2015), (Steijger, P. 2015) two new categories, 4&5, below the existing categories 1-3 were created. Figure 2.2. gives a schematic representation of the five groups.

Local Craftsmen. (Category 4)
This group has vital knowledge about the local materials and how to work them. This group can contain furniture builders, bike repair shop personal, tailors and shoemakers. They lack the knowledge required to build a well fitted prosthesis. (Availability of materials and skill with these is further discussed in chapter 2.3.6).

Non skilled person. (Category 5)
The family of the disabled child have to provide more care than usual would fall in this category. This group is not expected to have any knowledge about prosthetics or any relevant skills with available materials. This group would require a highly detailed step by step instruction for building a prosthesis.

This information will be further used for setting up a list of requirements for the form of the manual. This list can be found in chapter 3.2.
2.2. Prosthetic solutions in developing countries.

Many attempts to introduce western prosthesis in developing countries often fail. One of the main problems is because the people and the environment place different demands on the prosthesis. The climate is often more humid which causes corrosion on metal parts and deterioration of wooden parts. Since the infrastructure often consists of uneven dirt roads the wear and tear on the foot is much greater.

The look of a prosthesis can play a different role in developing society than in developed countries. According to (Rombach, A. 2015) people with a physical handicap have trouble being accepted in their society in some cultures. The causes of this can be superstitions, religion and lack of knowledge about people with a physical handicap. For instance, people with a congenital limb deficiency can be rejected in Hindu culture because of the believe in reincarnation, A congenital limb deficiency will then be seen as punishment. People therefore prefer a prosthesis that looks similar to the missing limb. A solution to this can be to make the prosthesis as life like to a real leg as possible.

Studies like the ISPO studies performed by Jan Andreysek, Lower-limb prosthetic technologies in the developing world: A review of literature (Andreysek, J. 2010) and P.K.Sethi’s ‘Technological choices in prosthetics and orthotics for developing countries’ (Sethi, P.K.1989), give a detailed description of prosthetics in developing countries. A few successful designs are listed below.

ICRC Prostheses.

Socket that have booked relatively good results are sockets designs made of polypropylene. The International Committee of the Red Cross (ICRC) prostheses, where prosthetic fit is attained in 43–78% of cases. The Centre for international Rehabilitation (CIR) uses a sand casting method for polypropylene sockets with 68% of individuals achieving comfortable fit. The fit is reported to be more intimate than with conventional plaster cast methods. This socket is designed for adults.

Mukti Socket

The Mutki Limb (Mukti, India 2015) uses HDPE by heating HDPE 75mm drainage pipes and pulling them over a plaster mould of the patients limb. This creates a long socket which doubles as the shaft. The limb is than fitted with a Jaipur foot.


David Werner wrote two books, 'Disabled village children and 'nothing about us without us' about low tech medical solutions for developing countries. It has an extensive list of simple makeshift prostheses build with local materials which that will function as inspiration for this thesis.

In conclusion.

There have been several successful designs in the past like the Mukti Limb and the ICRC prosthesis. D.Werner’s work contains a treasure of ideas, though no information can be found about the performance of these designs general, simple designs have more success than more advanced designs which contain more complicated parts fail more often in rugged train. These designs have are successful because they all take in account the higher demands in durability the infrastructure of developing countries places on them. They also take in account the differences in physical demands placed upon the prostheses. Lessons can be learned from this, performance requirements of the prostheses for people living in developing countries can differ from those in the west. Environmental factors have also to be taken in to account. These will be covered in more detail in chapter 2.3.
2.3.1. Performance and mechanical requirements.

When in use the socket must be able to withstand the forces causes by standing, walking, running and jumping, as well as a certain Range of Movement (RoM).

As said children are more active than adults. It requires the prosthesis to have sufficient structural strength to be usable. In a research by John Paul 'Strength requirements for internal and external prostheses' (Paul, J. P. 1999) it was found that regular loads in adults while walking are 261% of body weight (BW) and peak loads in adults while running and descending stairs are up to 350% of bodyweight. When taking data from the world health organisation we find a bodyweight of 78kg for 14 year old in the 3th percentile (WHO 2007), the prosthesis must carry a peak load of (3,5*78)=2730 Newton in vertical forces. And a regular load of (2,61*78) =2036 Newton. Full tables about bodyweight en height can be found in appendix B.

An active child also requires good mobility from the prosthesis. The design of the socket and suspension can hinder mobility of the knee joint ('Suspensions' in appendix D describes the various implications of different suspensions). In certain regions and cultures squatting is desirable. When squatting people need their full Range of motion in the knee joint. This means the prosthesis must allow for a knee flexion of 150° (±5) (About health, 2014). When a LLP is undergoing static alignment, the tibia plateau of both legs must be at equal hight (Seymour, R. 2002). In conversations with Cornelis Visser from Livit the conclusion was made that the weight of a LLP for children should be as light as possible. A maximum threshold could be set at the weight of a healthy leg. The leg weight is calculated as 5,05% of total body mass (78kg= 3,94kg) (Plagenhoef, S, et al, 1983). Research by (Bateni, H. et al 2004) has show that increasing the weight of the prosthesis does not have a significant influence on the cadence, being slightly slower than a lighter prosthesis. Therefore the aim is to keep the weight of the prosthesis similar to that of a healthy leg.

-Requirement: The prosthesis is capable of withstanding a peak 2730 N vertical force.
-Requirement: The prosthesis allows natural knee movement of 150° knee flexion.
-Requirement: The prosthesis allows for a knee extension of 4°.
-Requirement: The prosthesis must be of equal length as the healthy leg.
-Requirement: The prosthesis weight is no more than the natural weight of (5% of bodyweight).
-Requirement: Prosthesis can be adjusted by the user or by family

2.3.2. Suspension

Suspension is a vital part of a prosthesis. The suspension, either vacuum assisted or with straps, prevents the prosthesis from coming off involuntarily. Different types of suspension are described in appendix D. Suspension will always be a critical part of a prosthesis if a patient wants to do more than just stand on it. The more active the person is the more important suspension becomes.

As mentioned before, four kg is set as a maximum for the weight of prosthesis. Meaning the suspension materials must be strong enough to suspend a minimum of 4kg on. For safety this weight is doubled to 8 kg giving us a tensile strength of 80N. Several suspension types are suspended above the knee. To accommodate the child's growth an estimation of its knee growth is made. Knee width in Dutch children changes by 0-8,1% per two years (Appendix B). The data is not directly comparable with children in developing countries but a maximum percentage of 8,1% in knee width growth per year can be calculated.

-Requirement: The suspension may not cause pain.
-Requirement: The suspension allows natural knee movement of 150° knee flexion
-Requirement: The suspension must hold a weight of 80N
-Requirement: The suspension is adjustable in size by >8,1% per year from its original dimension.
2.3.3. Adaptability and alignment

A child between the age of 8-14 has an average total increase in leg length of 10cm (Sterke,B.T. 2013). This translates to roughly 1.67cm per year. Depending on the durability of the prosthesis its shaft must have a certain adaptability in leg length.

Alignment can be divided in static and dynamic alignment. Static alignment, the placement of the weight on the forefoot is a requirement for comfortable standing. Dynamic alignment, the fine-tuning of the prosthesis for walking requires careful examination of the gait pattern by a skilled Prosthetic advisor.

Dynamic Alignment in the developed world is done with a pyramid connection, as described earlier in chapter 1.5, between the shaft and the socket. These systems are complex to fabricate without the right knowledge and tools. Also several source (Vannah,W. 1999), (Krebs,D.E. 1991) and interviews confirm the general opinion that children are quick to adapt their gait pattern.

-requirement: The shaft must have a length adaptability of 1.67cm per year.
-requirement: The alignment of the shaft and socket must result in the body weight being placed on the forefoot.

2.3.4. Socket fit and Donning/Doffing

A comfortable socket fit is a logical requirement. In conversations with Antony Rombach and Cornelis Visser the conclusion was made that the comfort and optimisation of the socket fitting to the residual limb is the key to a successful prosthesis. Sockets used for standard trans-tibial amputations, where 20-50% of the limb below the knee is still present, covers about 8-16cm of the leg.

A person can be mobile with a less than optimal alignment or foot by adjusting his gait. But if the socket causes discomfort the patient will often stop wearing the prosthesis altogether. In chapter 2.1 it is explained how the socket interface takes in account the pressure sensitive and the pressure bearing parts of the residual limb.

Research by (Mak.A. 2001) on advanced prosthetic designs concluded that the interior materials have a friction coefficient between 0.48 and 0.89.

In a study by David E Krebs about prosthetic management for children (Krebs,D.E. 1991), the conclusion was made that children tend to experience less discomfort and pain than adults during activities as walking. Meeting this requirements will not be too difficult.

In a study by Robert Jensen about the growth of segments of body mass it was concluded that, Between the eight and fourteen year the mass of the leg and foot roughly doubles (Jensen,R.K. 1987). If calculated as a linear growth this means a 17% increase in volume every year. In a cylindrical mass volume change depends on the increase of cylinder hight and the radius of the ground circle ($\pi \times $ radius² x height). If we assume an equal increase from both dimensions we can calculate an 5.7% increase in radius and height.

$(17/3=5.7\%$ divided by three because increase in radius has an exponential).

A well fitting sockets relies on being well shaped for the limb. Since the limb does not increase in volume like a cylinder the calculation above is a rough estimation of its dimensional growth. In the long run this will be insufficient and the socket has to be replaced.

-Requirement: The socket fit may not cause pain.
-Requirement: Socket fit covers about 8-16cm of the leg.
-Requirement: The socket interface takes account of the sensitive and pressure bearing parts of the body.
-Requirement: The socket radius and height is adjustable by 5.7% per year.
-Requirement: The socket dimensions have an adaptability that accommodates 17% volume increase per year.
-Requirement: Material have a coefficient of friction between 0.48 and 0.89.
2.3.5. Environmental

The environment in developing countries is a bigger factor than in western countries. People spend more time outside. In some cultures it is unusual to wear shoes. This in combination with walking outside on dirt roads places a heavy demand on the durability of the prosthetic feet. Any mechanism in the foot/ankle is vulnerable to dirt and moisture. As mentioned in the introduction, Western prosthesis often have trouble with the higher humidity (tropical humidity is 70-98%) and dirt in which shortens their lifespan. The earlier mentioned studies of (Andreysek, J. 2010), (Strait, E. 2006) and P.K. Sethi describe this extensively.

-Requirement: The prosthesis materials are fit for a humidity range of 70-90%.
-Requirement: The prosthesis foot is made of material resistant to water.
-Requirement: The prosthesis foot is wear proof for uneven grounds.
-Requirement: The prosthetic foot is easy to clean.

2.3.6. Materials and techniques

In interviews with Paul Steijger and Cornelis Visser an estimation of the capabilities of the craftsmanship in Indonesia has been made. The population of the rural areas had proven to be skilled in the following techniques. The region he visited is Bali, Indonesia.

Metal is a material which is often discouraged for several reasons. It is fairly heavy and in tropical environments it is more prone to corrosion. However, if the expertise to work metal exist locally there is no reason to not consider it for the manual. What must be considered if the extra weight of the metal part is less of a negative aspect than the mechanical strength it provides.

<table>
<thead>
<tr>
<th>Material</th>
<th>Prevalence</th>
<th>Local craftsman skill</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wood</td>
<td>abundant</td>
<td>furniture shops have skilled craftsmen who can work every local available wood.</td>
</tr>
<tr>
<td>Metals</td>
<td>Steel and cast iron is available. Aluminium is rare.</td>
<td>Metal working is done mostly for fences (with detailed decorations). These are made from cast iron.</td>
</tr>
<tr>
<td>Rubbers</td>
<td>Available as old tires and spare parts</td>
<td>motorbike shops use small ovens, they can vulcanise rubber using fire ovens.</td>
</tr>
<tr>
<td>Leather &amp; textiles</td>
<td>abundant</td>
<td>There are plenty of skilled tailors and shoemakers. Leather can be worked by skilled people just as most textile fabrics.</td>
</tr>
<tr>
<td>Plastics/thermoplastics</td>
<td>PVC pipes available. Plastics can be found as waste materials.</td>
<td>Food shops often have ovens with controllable temperatures up to 200-230 c°.</td>
</tr>
<tr>
<td>Plasters</td>
<td>limited</td>
<td>casting is done by doctors.</td>
</tr>
</tbody>
</table>

Figure 2.4. availability of materials and the people with the skill to process the materials.

-Requirement: The prosthesis can build from the following materials: Wood, bamboo, rubber, PVC, HDPE, aluminium, leather.
-Requirement: The working of these materials must be achievable with non electric tools.
-Requirement: The used materials must be workable within a maximum temperature of 200-230 c°
-Requirement: The working of these materials must be in the capabilities of the craftsman as described above.
The translation of prosthesis guidelines to their materials and craftsmanship knowledge is vital. As P.K. Sethi testifies in this quote:

'I was forced to turn to our traditional craftsmen. They are often illiterate but they are the real possessors of manual skills in our countries. They have tremendous capacity to innovate and they know all about locally available materials. One, of course, has to learn to treat them with respect and communicate with them in a different manner. They feel ill at ease with drawings or illustrations but show them a 3-dimensional model and they would amaze you with the ease with which they can reproduce it using their own technology, tools and materials. Quoted from (P.K.Sethi, 1989 Technological choices in prosthetics and orthotics for developing countries, page 120)

2.3.7. Service requirements and maintenance

Prostheses in developing countries last a maximum of 18-24 months as found in the earlier mentioned study of (Andreysek, J. 2010) and as noted in chapter 1.6. With the growing child in mind we aim for the same time period.

In a research by John Paul 'Strength requirements for internal and external prostheses' (Paul, J.P. 1999). It is noted that leg prosthetics are replaced every 3-4 years in the developed world. In this period the leg has to make at least 3million cycles (defined as heel contact to heel contact).

The 3million cycles for 36-48 months can be 750,000 cycles per year for children prosthetics. This will be a minimum as children are expected to be more active than adults. If one expects the prosthesis to last for two years this means 1,500,000 cycles.

-Requirement: The prosthesis lasts for a minimum of 1,500,000 cycles per year
3. Requirements

3.1 Prosthesis requirements

The requirements for the socket design are split up in 3 main components: the socket exterior, the socket interface, the socket Suspension. The requirements are divided over the corresponding prosthesis parts.

Socket exterior
1.1 requirement: The prosthesis is capable of withstanding a peak 2730 N vertical force.
1.2 requirement: The prosthesis allows natural knee movement of 150° knee flexion
1.3 requirement: The prosthesis allows for a knee extension of 4°

Socket Interface
2.1 requirement: The socket fit may not cause pain.
2.2 requirement: Socket fit covers about 8-16cm of the leg.
2.3 requirement: The socket interface takes account of the sensitive and pressure bearing parts of the body. Hard materials for pressure bearing and soft materials for sensitive parts.
2.4 requirement: Material with skin contact have a coefficient of friction between 0.48 and 0.89.
2.5 requirement: The socket radius and height is adjustable by 5,7% per year.
2.6 requirement: The socket dimensions have an adaptability that accommodates 17% volume increase per year.

Suspension
3.1 requirement: The suspension may not cause pain.
3.2 requirement: The suspension must hold a weight of 80N
3.3 requirement: The suspension allows natural knee movement of 150° knee flexion.
3.4 requirement: The suspension is adjustable in size by >8,1% per year from its original dimension.
3.5 requirement: The suspension allows for a knee extension of 4°

General
4.1 requirement: The prosthesis foot is made of material resistant to water.
4.2 requirement: The prosthesis weight is no more than the natural weight of (5% of bodyweight)
4.3 requirement: The prosthesis must be of equal length as the healthy leg.
4.4 requirement: The prosthesis must can build from the following materials: Wood, bamboo, rubber, PVC, HDPE, aluminium, leather.
4.5 requirement: The working of these materials must be achievable with non electric tools.
4.6 requirement: The used materials must be workable within a maximum temperature of 200-230 c°
4.7 requirement: The prosthesis foot is wear proof for uneven grounds.
4.8 requirement: The prosthetic foot is easy to clean
4.9 requirement: The alignment of the shaft and socket must result in the body weight being placed on the mid foot.
4.10 requirement: The prosthesis materials are fit for a humidity range of 70-90%
4.11 requirement: The prosthesis lasts for a minimum of 1,500,000 cycles per year
3.2. Manual requirements

Because the task of transferring information can be complicated. A brief study about manual design has been done. This resulted in a list of requirements for the manual. Most of this is done by fellow student Martijn Hortensius. Below is the list of requirements. More in depth information can be found in his thesis. (Wiens,K. Bluff,J. 2015), (Hodgson,P. 2012).

Manual specific requirements
5.1-The manual is downloadable in PDF format.
5.2-The manual is written in English.
5.3-The manual contains page numbers
5.4-The manual follows a logical step by step structure.
5.5-All images in the manual are open source images.
5.6-The manual is published under the ‘Creative Commons’ licence (Free publishing and editing with mention of the author).
5.7-The manual contains a reference list written accordingly to the APA-style.
5.8-The manual can be edited. (by adding parts through the patch project forum)
5.9-The manual contains a disclaimer where the legal accountability is described.

Content specific requirements

Manual Front-page:
6.1-The front page only contains an image or illustration, a title and reference to the patch project
6.2-the front-page must inform the user of its content at a glance.

Manual Introduction
7.1-The introduction describes who the content was written for.
7.2-Each manual has an introduction which list the necessary tools and materials.
7.3-The manual has to show a way how additions/feedback can be made via the patch project website.
7.4-The introduction describes the content of the manual and how it should be used.
7.5-The manual refers to local craftsman who can assist with building the part from the manual when necessary.

Manual Content
8.1-The manual refers to the other manual that is required to make a complete prosthesis.
8.2-When necessary illustrations or photos are used to.
8.3-The manual covers the most essential guidelines necessary to construct a LLP socket.
8.4-The manual shows the possibilities and solutions to for the guidelines.
8.5-Text is divided over paragraphs of ±five sentence for easy scanning.
8.6-Avoid long sentences, divide information over several short ones.
8.7-Avoid technical terms unknown to target audience (reading level=writing level).
8.8-Language used should be a simple as possible. (to make translation easier).
8.9-Language style can be informal.
4. synthesis

This chapter will discuss the possibilities of constructing the socket and the suspension with local materials that meet the requirements of chapter 3. The decision was made to discuss each of the three parts separately. The socket or exterior socket, the inner socket or liner and the suspension.

As mentioned in chapter 1.2 the process manual will consist of two parts. One: the selection manual (see figure 4.1) in the shape of a diagram that guides the user/prosthetic builder from the available materials to the corresponding prosthesis. An online version of the selection manual will eventually be placed on the patch project website.

Two: A part specific manual that lists the materials and steps necessary for constructing each specific part. The manual lists all the necessary materials, tools, any pre-existing instructions for the prosthetic parts. Each manual will be evaluated in chapter 5 by checking if it contains all necessary information and indicate what is missing from the construction process.

The selection of suitable prosthesis is covered in chapter 4.1, 4.2 and 4.3. In total there are five concepts for the socket exterior, three concepts for the socket interior and two suspension concepts that meet the requirements. This chapter will describe how the chosen parts and concepts meet the requirements listed in chapter 3.1. All parts will be rated with a cardinal utility scale on criteria reflecting the guidelines.

The selection diagram.

In chapter 2 the prostheses was examined in separate parts. This was useful for writing the requirements for each part. For the user of the manual this would actually be more confusing. To give the user an overview of which construction options the different materials provide, a selection diagram was created. This diagram also gives an overview about the most vital tools and other resources, like the craftsmen covered in chapter 2.3.6, who are essential for the production of the prosthetic parts. Finally, it shows which socket, interface, suspension and foot combination are compatible with each other.

Because all part are described individually a user might do double work. As example, if a user had to make an interface and suspension out of leather the easiest way to go about this is to gather the material and cut all the leather in one go. If the reader starts at the first manual, finishes it, and then continues to the next manual the user might find out it has to go to whatever place the leather originated from for a second time. With the selection diagram the construction process becomes more streamlined.

To reduce the amount of variables, we base the prostheses sockets around the five exterior sockets. A user chooses a material, for example PVC. This allows him or her to create a PVC exterior socket and a variety of options for the interface and suspension depending on what other materials are available to the user. This provides a basis to start from, and at the same time allows for different options in materials.

The use of the selection diagram works in the following manner. There are 3 large coloured rectangle. The blue rectangle on the left lists available materials and tools necessary for a prosthesis type. The yellow rectangle lists the possible prosthetic parts possible with these materials and tools. The horizontal green bars overlap both rectangles and shows the connection between the materials and tools and the possible prosthetic parts.

The starting point is the row of blue boxes which list materials for the exterior of the socket, interface and suspension. Moving to the right it lists the materials for the corresponding parts: the interior socket and the suspension. Further to the right it lists the possible choices for parts that go with the exterior socket. In the final column the connector possibilities are listed. The details of the last column, “possible connector”, can be found in Martijn Hortensius thesis. A larger version can be found in appendix G.
Figure 4.1: The selection diagram.
4.1. Socket exterior.

In this chapter five exterior socket designs are discussed. The designs are loosely based on existing concepts, among others the work of David Werner (Werner, D 1987) and thesis work done for the Patch project (Brouwer, I. 2013). The designs in this chapter are rated on the basis of the requirements set in chapter 3.1. The ratings can be seen in figure 4.4.

As stated in chapter 2 the function of the exterior part of the socket is to carry the weight of the user and counter the ground reaction forces. The mechanical strength of the designs are rated in two ways. Its ability to withstand compressive forces and bending forces. Compressive forces are calculated as the vertical forces working on the prosthesis. Bending forces occur when running, or jumping and work at an angle or with a moment arm on the prostheses. This is further explained in figure 4.3. A table of materials has been made with their compressive and bending strength. The used strength calculations are shown in figure 4.2.

Strength calculation:
Calculations are made to determine if the design can withstand the peak force of 2730N set by the Requirements in chapter 3. The socket is simplified as a cylinder tube. From here we can calculate the minimal dimensions the material must have to resist the peak forces. $\sigma_{c\text{-max}}$ represents the compressive strength of the material while, $\sigma_{c\text{-stress}}$ represents the stress in the material as a result of those forces. All values are in N/mm². The $\sigma_{s\text{max}}$ represents the bending yield strength of the material in N/mm². This is the point before the materials begin to deform. The peak forces calculated in chapter 2.3.1 represent the 3rd percentile, the very heaviest of children. Because these are high estimations a safety margin of 0.7 of the bending yield strength was seen as sufficient.

Compressive stress as a result of compressive force, $'\sigma_{c\text{-stress}}'$ is calculated by simplifying the prostheses as a cylinder tube which has a certain the surface area $A = \pi \left( R^2 - r^2 \right)$ $\sigma_c = \frac{F}{A}$

Bending stress $'\sigma_t'$ as a result of bending forces (calculated in figure 4.3) is calculated by determining the resistance against tension $w = \pi \left( D^4 - d^4 \right)$ $32 * D$ $\sigma_t = \frac{M}{W}$

Complete calculations of all sockets can be found in appendix E.

Figure 4.2. calculations made for the prosthetic socket.

Figure 4.3a. Free body diagram of a prosthetic leg.

Figure 4.3b. Calculations used for the free body diagram.
Socket designs.
Following below is a detailed description of the five sockets exteriors
Figures 4.4a till 4.4e give an overview of the five designs and their compatibility with other parts.

**HDPE Socket**

4.4a HDPE socket and its corresponding parts.
HDPE is available in the form of drainage pipes or waste materials. The material has process temperatures of 137°C, and are shape-able in almost any form. Local food shops and workshops for motorbikes are known to have ovens who can work in those temperature ranges. The Mutki Limb (Mukti, India 2015) uses the same approach with HDPE by heating HDPE 75mm drainage pipes with a 3mm wall and pulling them over a plaster mould of the patients limb. It is extensively described in David Werner’s ‘Nothing about us without us’ (Werner, D. 1998). All forces are well within the limitations of the material when using a 75mm*3mm pipe as seen in figure 4.5. The disadvantage of these materials is that it has to be reheated to adjust to the growing child. For this, a new cast has to be made or the person adjusting has to rely on his skill to make accurate adjustments off the existing socket. Because suitable plaster to make a mold is not always available and the handling of HDPE at high temperatures takes some skill, this is one of the more difficult socket types to construct. Still it will be included in the manual because the design and production method have been proven. It can be used with all types of interfaces depending on the fit. For a close fitting HDPE socket a textile interface would be sufficient. Both types of suspension could be attached to the HDPE. Both a Stubby foot or a Sachs foot can be attached to the end of the tube.

**PVC pipe socket,**
4.4b PVC socket and its corresponding parts.
Examples of PVC made prosthetics are shown in ‘Disabled village children, (Werner, D. 1987). It uses a PVC pipe that is split in four by cutting it lengthwise. The framework of PVC can be used to suspended an inner socket. PVC pipes are available as noted in chapter 2.3.6. as drainage pipes and waste materials. These pipes are very durable (Gecker, D 2009) so they are expected to last in the tropical climate. Because the split PVC doesn't cover the entire leg it needs a relatively sturdy interface. Therefore a rubber or leather socket is advised in the diagram. For walking a stubby foot or Sach foot can be attached on the bottom of the socket. PVC can be processed starting from temperatures as low as 75 degrees (Appendix A). This can also be a drawback as even body temperature can have an influence on its mechanical strength. The influence of this is yet unknown. To keep the socket from falling of, a supracondylar or thigh suspension is advised.
**PET Bottle socket**

4.4c PET socket and its corresponding parts.

Pet Bottles are widely available and come in standard sizes for 1, 1.5 and 2 litre bottles. Respectively 79.5mm, 88mm and 101.5mm in diameter. These materials are relatively strong and light. They are moldable around temperatures of 68°. Because thickness of carbonated drink bottles is required to be 0.45~0.55mm these are preferred over thinner un-carbonated drink bottles. Single bottles are not strong enough so a minimum of two have to be molded together to create a thicker wall.

Temperature can have an influence on the mechanical strength of the material, it is unknown how big this influence is. The bottle opening provides opportunities for a connection with a shaft, making it suitable to attach a stubby foot or Sachs foot. (Brouwer, I. 2013) has an example of this type of prosthetic socket. Though it has not seen any practical testing.

**Wood frame socket**

4.4e: Wood socket and its corresponding parts.

Tropical wood has very good mechanical properties. It is suitable to build a frame like prosthesis which. It is available everywhere and there are lots of workers who are skilled with it. Wood is also more susceptible to environmental factors such as high humidity when not treated with a finish. This type would need an inner socket (liner) to work. Though it is a cheap material and easy to work with the durability of wood is known to suffer in tropical environments. Because the design is a frame it needs a sturdy interface like rubber or leather that can be suspended in the frame. Depending on how the base of the frame is built all types of foot and shaft parts could be attached.

**Aluminium frame socket**

4.4d: Aluminium socket and its corresponding parts.

Aluminium has a very good strength to weight ratio. It could be used to build frame similar to the wooden frame. The downside of aluminium is that it is difficult to weld which makes it harder to customise parts in the desired shape. Without welding, attaching different parts should be done by bolts or screws.

Aluminium has been used for sockets, though in a different design. As shown in disabled village children (Werner, D 1987) as a aluminium frame with a leather interface suspended between the rods. Depending on how the base of the frame is build all types of foot and shaft could be attached.
Sockets

<table>
<thead>
<tr>
<th>Sockets</th>
<th>HDPE socket</th>
<th>PVC pipe socket</th>
<th>Pet bottle socket</th>
<th>Wood frame socket</th>
<th>Aluminium frame socket</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials</td>
<td>HDPE</td>
<td>PVC</td>
<td>PET</td>
<td>wood</td>
<td>aluminium</td>
</tr>
<tr>
<td>-diameter</td>
<td>75mm</td>
<td>60mm</td>
<td>79.5-101.5mm</td>
<td>20mm each</td>
<td>34mm</td>
</tr>
<tr>
<td>-wall thickness</td>
<td>3mm</td>
<td>3mm</td>
<td>0.5mm per bottle</td>
<td>N/A</td>
<td>2mm</td>
</tr>
<tr>
<td>Strength $\sigma_{\text{c max}}$</td>
<td>43N/mm²</td>
<td>55N/mm²</td>
<td>61.5N/mm²</td>
<td>10.5N/mm²</td>
<td>327N/mm²</td>
</tr>
<tr>
<td>$\sigma_{\text{c stress}}$</td>
<td>4N/mm²</td>
<td>5N/mm²</td>
<td>11N/mm²</td>
<td>8.7N/mm²</td>
<td>3.4N/mm²</td>
</tr>
<tr>
<td>Material $\sigma_{\text{t max}}$</td>
<td>48N/mm²</td>
<td>53N/mm²</td>
<td>55N/mm²</td>
<td>60N/mm²</td>
<td>240N/mm²</td>
</tr>
<tr>
<td>$\sigma_{\text{t stress}}$</td>
<td>23.2N/mm²</td>
<td>37.4N/mm²</td>
<td>29.7N/mm²</td>
<td>34.8N/mm²</td>
<td>180N/mm²</td>
</tr>
<tr>
<td>Weight estimation</td>
<td>105gram</td>
<td>120gram</td>
<td>140gram</td>
<td>285gram</td>
<td>205gram</td>
</tr>
</tbody>
</table>

Ratings 1-5

| Strength     | 4 | 3 | 3 | 5 | 5 |
| Simplicity   | 2 | 4 | 3 | 4 | 1 |
| Durability   | 4 | 5 | 5 | 3 | 4 |
| Adaptability | 2 | 4 | 3 | 3 | 2 |
| Average (X out of 5) | 3/5 | 4/5 | 3.5/5 | 3.2/5 | 3/5 |

Figure 4.5. Materials, dimensions and material stress of all 5 designs. All calculations can be found in appendix G. A rating table is made to judge each design on several aspects. Material strength, simplicity of fabrication, material durability and possibility to adapt in size are rated on a scale of 1-5. In this scale 1 is the least optimal and 5 being is the most optimal. Chapter 5 will give a more thorough evaluation of the designs.

4.2. Socket interface

The Socket interface is one of the most critical parts of the prosthesis. As noted in chapter 2 Its function is to distribute force to the suitable body parts. The ideal situation is to create the socket around a proper cast of the residual limb. When this is not available the best alternative is to take accurate measurements of the limb for a Leather and rubber are both available and within the working skills of local craftsman. Because it comes in different hardness/softness it is suitable to use as an alternative to the poly-form and silicon used in modern sockets. The parts are rated for comfort simplicity durability and adaptability. The ratings for durability in figure 4.5 are estimates based on the analysis in chapter 2. Comfort and adaptability are again estimations as these also are depended on the exact design the builder will make.

An estimation of the interfaces weight has been made (appendix E). By simplifying the design as an 8 to 16cm long cylinder with a diameter of 7.2cm (WHO, 2007) and a wall thickness of 4mm. In table 4.6 a low and high weight estimation is given. To leave room for the limb to grow it is advised to leave add an extra 5cm for the biggest circumference of the leg and 3cm to the length. (WHO, 2007).

The socket also has the requirement of allowing flexion and extension around the knee joint. To allow this the socket has to be a certain shape which does not hinder the movement of the knee joint. However this can not be
tested in theory so this requirement can not be tested. It will be mentioned in the manual by writing an advice to leave enough room at the posterior of the socket to allow for the desired flexion of 150°.

**Leather interface:**
Leather provides good friction on skin contact and can absorb perspiration. Leather has good mechanical properties and is also durable enough (Appendix A). It can be processed to various levels of hardness which makes it suitable as a socket interface (Brouwer, I. 2013). This makes it possible to use various levels of hardness in the interface to better distribute the forces in the socket. The materials can be sewn or laced together. This makes the socket adjustable which is necessary for the demanded volume adaptation which will occur.

**Rubber Tire interface:**
Examples of this design are shown in ‘disabled village children’ (Werner, D. 1987). Rubber tires are available as waste material or in bike shops. As shown in chapter 2.3.6 local craftsmen are able to cut and even put separate bike parts together by vulcanisation, though no numbers about the used temperature could be found. Bike tires may be used for the pressure supporting limb parts while inner tires for pressure distribution. Rubber may dry out and start to deteriorate in time but this happens after several years. Older tires can be used but may deteriorated if the rubber has already dried out.

**Textile interface:**
Being very soft compared to leather and rubber wool and cotton can be used to supplement the designs by using it to relieve pressure from the sensitive parts of the limb. Similar to the leather interface extra patches of material can be sewed on to relieve sensitive areas. Wool may be too warm for the Indonesia climate so cotton has preference over wool. Deterioration of the material may be a problem but materials like textile are easy replaceable or repairable so this is not considered a huge disadvantage. This part works best with a already well fitting socket exterior like a HDPE tube (Seymour, R. 2002).

<table>
<thead>
<tr>
<th>Interface</th>
<th>Leather socket</th>
<th>Rubber tire socket</th>
<th>Textile socket</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Materials</strong></td>
<td>Leather, sewing wire</td>
<td>Tires, rubber</td>
<td>Textile, sewing wire</td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
<td>Diameter: leg circumference+5cm length: leg length +3cm</td>
<td>Diameter: leg circumference+5cm length: leg length +3cm</td>
<td>Diameter: leg circumference+5cm length: leg length +3cm</td>
</tr>
<tr>
<td><strong>Weight estimation</strong></td>
<td>60-120gram</td>
<td>90-180gram</td>
<td>80-160gram</td>
</tr>
<tr>
<td><strong>Ratings 1-5</strong></td>
<td><strong>Comfort</strong> 4</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td><strong>Simplicity</strong> 4</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td><strong>Durability</strong> 4</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td><strong>Adaptability</strong> 4</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td><strong>Average (X out of 5)</strong></td>
<td><strong>4/5</strong></td>
<td><strong>3/5</strong></td>
<td><strong>4/5</strong></td>
</tr>
</tbody>
</table>

Figure 4.6. Table for socket interfaces. A score table was made to judge each design on several aspects. Simplicity of fabrication, material durability and possibility to adapt in size are rated on a scale of 1-5. In this scale 1 is the least optimal and 5 being is the most optimal.
4.3. Suspension

For the suspension there are two viable pre-existing options are available. The most important demands for the suspension is the allowance of good mobility. When designing a suspension there is always a trade-off between these two aspects. The goal is to find balance between the two. A brief list of different suspensions can be seen in appendix D.

**Supracondylar suspension (Supracondylar Cuff)**
Supracondylar suspensions where regularly used before vacuum-assisted suspension became the norm in developed countries. A supracondylar cuff system is a simple suspension design that suspends the prosthesis from the femoral condyles and the proximal end of the patella. It has one disadvantage: it loosens at knee flexion and tightens at knee extension (Seymour, R. 2002). A design like this could be made with simple leather belts already available. Leather belts are adjustable in size and the material is relatively strong. A simple leather version of this is described in 'Disabled Village children' (Werner, D. 1987).

**Thigh suspension**
A rigid suspension similar to the Supracondylar cuff with the main difference being it suspends the prosthesis from the tight. This design requires more material to manufacture and is heavier than the other designs which can make it less suitable for smaller children (Seymour, R. 2002). It does provide a very firm suspension from the leg. It can be made with simple items already available like leather belts.

<table>
<thead>
<tr>
<th>Suspension</th>
<th>Supracondylar</th>
<th>Thigh suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Materials</strong></td>
<td>Leather/nails</td>
<td>Leather/textile/rope</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>Leather strap suspended above knee</td>
<td>Leather corset suspension from thigh</td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
<td>Length of belt: Circumference of the leg just above the knee+5cm. -leather thickness: 2mm -Belt height 10mm</td>
<td>Length of belt: Circumference of the leg just above the knee+5cm. -leather thickness: 2mm -Belt height 10mm</td>
</tr>
<tr>
<td><strong>Ratings 1-5</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strength</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Mobility</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Simplicity</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Durability</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>adaptability</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td><strong>Average (X out of 5)</strong></td>
<td>4/5</td>
<td>3.4/5</td>
</tr>
</tbody>
</table>

Figure 4.7. Table for suspension designs, their materials, dimensions and their ratings.

The ratings table was made to judge each design on several aspects. Mechanical strength of the suspension, the potential for knee mobility, simplicity of fabrication, material durability and possibility to adapt in size are rated on a scale of 1-5. In this scale 1 is the least optimal and 5 is the most optimal.
4.4. The Manual

The goal for the manual is to translate as many requirements for the prosthetic parts to practical guidelines. In this chapter the requirements will sometimes be referred to by their number inside brackets (#, #). For the socket exterior some of these have already been done in the form of material dimensions to fulfill the strength requirements from Chapter 3.1. Requirements like adaptability for growth (2.5, 2.6) and comfortable fit are harder to convert to a guideline without going into detailed building instructions, which are hard to do without being actually on location with the wearer. With help of illustrations and simple instructions the attempt is made to convert as many requirements as possible to guidelines. A spread overview of the manual is created in figure 4.8. PVC socket, leather interface and supracondylar suspension manuals have been joint together for this example. The requirements that form the basis of the guidelines can be found in the appendix of the manual. By making this background information accessible to the user it becomes easier to modify and adapt he manual.

![Figure 4.8. A set-up of the process manual. Requirements from chapter 3.1 and 3.2 are referred to by their number in brackets (#,#).](image-url)
Figure 4.9. gives an example of a PVC socket with all the requirements translated to guidelines. As example, the strength and durability requirements have already been converted to simple material and dimensional instructions. The manual starts with a short summary and the ratings given to the part earlier in this chapter. Below that is a table with two columns: the first column lists the type of construction guideline, the second column is the instruction about how the guideline can be fulfilled. In the table below the required materials and their dimensions are listed. An estimation of the weight of the socket is listed for the user to take into consideration. Comfort tries to translate requirements like, the socket causes no pain (2,1). Mobility translates the requirements for range of movement from degrees to instructions (1,2,1,3). Adaptability governs the requirements that are about leg growth (2,5, 2,6).

In the case of any pre-existing instructions the source of these will be listed and a link to a website is provided if available. Finally the basic construction steps are listed and a list of unsolved issue’s. The unsolved issue’s are known requirements for who no satisfying guideline has yet been made.

Tables for every part can be found in appendix G.

**PVC socket**

Examples of PVC made prosthetics are shown in ‘Disabled village children, Page 632.’ from the David Werner collection (Werner, D. 1987). It uses a PVC pipe that is split by cutting it lengthwise. The framework of PVC can be used to suspend an inner socket. PVC pipes. Because the split PVC doesn’t cover the entire leg it needs a relatively sturdy interface. Therefore a rubber of leather socket are advised in the diagram. To keep the socket from falling of, a supracondylar or thigh suspension is also advised.

For walking a stubby foot or flat foot can be attached on the bottom of the socket.

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required materials</td>
<td>PVC pipe, Belt (leather) or rope</td>
</tr>
<tr>
<td>Dimensions</td>
<td>60mm diameter</td>
</tr>
<tr>
<td></td>
<td>3mm wall thickness</td>
</tr>
<tr>
<td></td>
<td>Length: Depends on stump length see figure 1</td>
</tr>
<tr>
<td></td>
<td>Rope: 1,3 meters</td>
</tr>
<tr>
<td>Weight estimation</td>
<td>Ca 120grams</td>
</tr>
<tr>
<td>Tools required</td>
<td>1: oven or heating equipment capable of reaching 75 degrees C°</td>
</tr>
<tr>
<td></td>
<td>2: Saw or cutting tools</td>
</tr>
<tr>
<td>Comfort</td>
<td>The socket may not cause discomfort, beware of any sharp edges</td>
</tr>
<tr>
<td>Mobility</td>
<td>When designing the socket make sure it allows for the natural range of movement of the knee. This means the socket material should not cover the entire knee and leave sufficient room at the knee cavity for flexion. How much room is unknown.</td>
</tr>
<tr>
<td>Adaptability</td>
<td>Circumference of the leg is expected to increase from 1-2,5cm per year. PVC has some flexibility. By reheating the shape can be altered.</td>
</tr>
<tr>
<td>Person or place of assistance</td>
<td>Food shops often have ovens who can control heat.</td>
</tr>
<tr>
<td>Existing instructions</td>
<td>David Werner collection, Disabled Village Children, Page 632</td>
</tr>
<tr>
<td>Construction steps (summary)</td>
<td>1. Use a rope or measuring tape to measurements as shown in step 1</td>
</tr>
<tr>
<td></td>
<td>2 make 4 cuts in the PVC tube length wise</td>
</tr>
<tr>
<td></td>
<td>3. Heat the PVC tube to 75 degrees C°</td>
</tr>
<tr>
<td></td>
<td>4. Shape PVC pipe according to measurements taken in step 1</td>
</tr>
<tr>
<td>Unsolved issues</td>
<td>- Even though the child may grow, the soft tissue may shrink over time making the socket fit loose.</td>
</tr>
<tr>
<td></td>
<td>- Method of keeping the split PVC part together unclear a rope or a belt could work.</td>
</tr>
<tr>
<td></td>
<td>- Attaching the inner socket still unclear</td>
</tr>
<tr>
<td></td>
<td>- Preferably needs a cast of limb stump to make shape materials in correct dimensions</td>
</tr>
<tr>
<td></td>
<td>- Attachment to shaft foot still unclear</td>
</tr>
<tr>
<td></td>
<td>- It is not known how big the influence of body heat is on the material strength.</td>
</tr>
</tbody>
</table>

Short discrition and example picture of the corresponding part. (Requirement 5.5, 6.2, 7.2)

Describes the required materials. (requirement 4.4, 4.10, 4.11)

Weight of part (requirement 4.2)

Comfort. (requirements 2.1, 3.1)

Adaptability. (requirement 2.5,2.6)

Existing instructions In case any pre-existing instructions exist.

List of unsolved issues and construction steps that are still uncertain where improvements can be made.
Figure 4.10 shows how requirements as: '2.1 the socket may not cause pain' and '2.3 The socket interface takes account of the sensitive and pressure bearing parts of the body'. Can be converted to guidelines by simple instructions and illustrations for the builder.

The builder is to use a leather cutout with a width a little bigger than the legs circumference. The green color represent pressure bearing areas and red represents pressure sensitive areas. By adding extra material on the leather cutout the distribution of force can be concentrated on the green areas.

---

**Step 1 Inspection of the stump.**

1. Always be aware of the pressure sensitive parts of the stump. The red parts in illustration are more sensitive. The green parts are ok to put pressure on. By adding extra material on the material of the interface on the location of the pressure sensitive areas you can distribute the forces more better. And relief the pressure sensitive areas as shown in figure 2.

![Figure 1](image1.png)

**Figure 1. Sensitive and pressure bearing parts of the stump.**

![Figure 2](image2.png)

**Figure 2. Pressure bearing areas of the stump on the inside of the material.**
The guidelines for the suspension are made in a similar way, it starts with a table similar to the socket part (appendix G). As seen in figure 4.11 it illustrates how to take measurements for the suspension and where above the knee the suspension is placed. To meet the requirements for knee mobility instructions are given to the builder to be aware of the material at the rear of the socket. These materials could hinder free movement of the knee joint. By removing material here the lower leg can go into flexion without being obstructed by material at the back of the socket.

**Step 1 Taking measurements**

1. Measure the circumference just above the knee cap (figure 1).
2. Measure the height between the socket edge and the top of the knee cap (figure 3). Cut out a piece of strong leather like shown in the drawing with the length of X' plus an extra 5cm. A belt can also be used. Make sure the piece is at least 2mm thick and 1,5cm broad.

Make 2 holes in the leather at a quarter length of the edges as shown in figure 3.

The first step is to take measurements for the suspension. The circumference just above the knee and the distance between the former and the socket edge have to be measured.

The user is made aware of the restriction of movement the suspension can cause. (requirement 3.3, 3.5)

By using a simple illustrations of the limb the area where the suspension hangs from can be indicated to the user. (requirement 3.1, 3.2)

Fig. 4.11. Instructions for the building a supracondylar cuff suspension out of leather.

The builder has to take notice of the material at the rear of the socket. By removing material here the lower leg can go into flexion without being obstructed by material at the back of the socket. (Requirement 3.3, 3.5)
5. Evaluation

In this chapter the manual will be evaluated on the basis of the requirements from chapter 3. Because there are two separate lists of requirements, 3.1 the requirement for prostheses and 3.2 requirements for the manual. The evaluation is done in two parts, the first part evaluates the manual made in chapter 4.4 on the basis of the requirements of 3.1. The main question is, 'are the requirements of 3.1 converted to guidelines in the manual. The answers can be yes, the requirement is converted to a guideline. 'partly', the manual appoints or treated the requirement but there is no clear solution. Or 'no' the requirement has not been converted to a guideline. Figure 5.1 gives the list of requirements from chapter 3.2.

In the second part of the evaluation the manual is on the basis of the requirements of chapter 3.2. The question here is 'does the design of the manual satisfy the requirements of chapter 3.2. Figure 5.1 gives the list of requirements from chapter 3.2.

Translation from requirement to guidelines

The final result is that out of the 26 requirements, 11 requirements are successfully converted. 10 are partly converted and 5 still need an addition in the manual.

Socket exterior.

Strength, durability requirements are converted to guidelines (1,1). The requirement for a natural range of movement (1.2, 1.3), is converted to a guideline that mentions the requirement but does not yet give a proper solution to the problem. This requirement is therefore evaluated as partly meeting the requirement as a guideline.

Socket interface.

Attention has been given to the way a prosthesis interacts with the human anatomy (2.1, 2.3). This is done in the form of illustrations and instructions how to use the correct material for correct part of the limb. Requirement 2.2 is translated by instructing the user to make the socket length the same as the residual limb length. Since no data could be found about friction coefficient on human skin for the interface materials, requirement (2.4) could not be fulfilled.

The requirements that 'demands' volume increase for the socket (2.5, 2.6) are translated to instructions to have some extra materials or use belts or straps so the interface can be tightened or loosened but detailed instructions have yet to be made. These are therefore evaluated as partially satisfying the requirement.

Suspension.

3.1 is partially met, some instruction is given so the builder is aware of problems that might cause discomfort. 3.2. Requirements 3.3, 3.4 and 3.5 can only be translated properly by being on location with the patient. The requirements are therefore partially satisfied.

General.

For requirement 4.2 an estimation of the weight of parts has been given The requirements for the use of local materials and simple tools (4.4, 4.5, 4.6) have been met and are evaluated positively in the way they are converted to guidelines. The requirement for durability (4.11) and the materials being fit for tropical humidity (4.10) are partly met by selecting materials that fit these criteria in chapter 4.

Requirements about the foot and shaft (4.1, 4.3, 4.7, 4.8, 4.9) are not treated in this thesis and are therefore evaluated as not satisfying the translation to guidelines.

Conclusion.

42% of the requirements from chapter 3.1 have been translated to guidelines. 38% are partly in the manual and for 20% of the requirements a satisfying translation to guidelines could not be found. The inability to translate a requirement to a guideline is mostly contributed to the fact that theoretical knowledge alone is not sufficient to do this. Actual building of the prosthetic parts have to be done on location to make the translation to guidelines. This will be further discussed in chapter 6.
<table>
<thead>
<tr>
<th>General requirements</th>
<th>conversion to guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exterior specific requirements</strong></td>
<td>Yes</td>
</tr>
<tr>
<td>1.1-The prosthesis is capable of withstanding a peak 2730 N vertical force.</td>
<td>X</td>
</tr>
<tr>
<td>1.2-The prosthesis allows natural knee movement of 130° knee flexion</td>
<td>X</td>
</tr>
<tr>
<td>1.3-The prosthesis allows for a knee extension of 4°</td>
<td>X</td>
</tr>
<tr>
<td><strong>Socket Interface specific requirements</strong></td>
<td></td>
</tr>
<tr>
<td>2.1-The socket fit may not cause pain.</td>
<td>X</td>
</tr>
<tr>
<td>2.2-Socket fit covers about 8-16cm of the leg.</td>
<td>X</td>
</tr>
<tr>
<td>2.3-The socket interface takes account of the sensitive and pressure bearing parts of the body.-Hard materials for pressure bearing and soft materials for sensitive parts.</td>
<td>X</td>
</tr>
<tr>
<td>2.4-Material with skin contact have a coefficient of friction between 0.48 and 0.89.</td>
<td>X</td>
</tr>
<tr>
<td>2.5-The socket radius and height is adjustable by 5,7% per year.</td>
<td>X</td>
</tr>
<tr>
<td>2.6-The socket dimensions have an adaptability that accommodates 17% volume increase per year.</td>
<td>X</td>
</tr>
<tr>
<td><strong>Suspension specific requirements</strong></td>
<td></td>
</tr>
<tr>
<td>3.1-The suspension may not cause pain.</td>
<td>X</td>
</tr>
<tr>
<td>3.2-The suspension must hold a weight of 80N</td>
<td>X</td>
</tr>
<tr>
<td>3.3-The prosthesis allows natural knee movement of 150°</td>
<td>X</td>
</tr>
<tr>
<td>3.4-The suspension is adjustable in size by &gt;8,1% per year from its original dimension.</td>
<td>X</td>
</tr>
<tr>
<td>3.5-The suspension allows for a knee extension of 4°.</td>
<td>X</td>
</tr>
<tr>
<td><strong>General prosthetic requirements</strong></td>
<td></td>
</tr>
<tr>
<td>4.1-The prosthesis foot is made of material resistant to water.</td>
<td>X</td>
</tr>
<tr>
<td>4.2-The prosthesis weight is no more than the natural weight of (5% of bodyweight)</td>
<td>X</td>
</tr>
<tr>
<td>4.3-Requirement: the prosthesis must be of equal length as the healthy leg.</td>
<td>X</td>
</tr>
<tr>
<td>4.4-The prosthesis must can build from the following materials: Wood, bamboo, rubber, PVC, HDPE, aluminium, leather.</td>
<td>X</td>
</tr>
<tr>
<td>4.5-The working of these materials must be achievable with non electric tools.</td>
<td>X</td>
</tr>
<tr>
<td>4.6-The used materials must be workable within a maximum temperature of 200-230 c°</td>
<td>X</td>
</tr>
<tr>
<td>4.7-The prosthesis foot is wear proof for uneven grounds.</td>
<td>X</td>
</tr>
<tr>
<td>4.8-The prosthetic foot is easy to clean</td>
<td>X</td>
</tr>
<tr>
<td>4.9-The alignment of the shaft and socket must result in the body weight being placed on the mid foot.</td>
<td>X</td>
</tr>
<tr>
<td>4.10-The prosthesis materials are fit for a humidity range of 70-90%</td>
<td>X</td>
</tr>
<tr>
<td>4.11-The prosthesis lasts for a minimum of 1,500,000 cycles per year</td>
<td>X</td>
</tr>
</tbody>
</table>

The manual evaluated to the requirements of 3.2.
Out of the total of 25 requirements the current manual is able to fulfil 14 of these positively. 7 of the requirements are partially met and 3 requirements are yet to be fulfilled.

**Manual specific requirements.** The basic requirements for the manual are mostly met. At the time of writing the manual has not yet been uploaded to the Patch Project website so this requirement (5.1) is partly met. The manual also does not contain a reference list or a legal disclaimer yet.
Manual front-page
The manual has a front-page which gives the user information at a glance.

Manual Introduction
The introduction explains who the manual is written for (7.1) The necessary tools and materials are listed in the beginning (7.2) and local craftsmen are referred to when necessary (7.5). The patch project website is in the manual but no explanation is yet given how to best make additions (7.3).

Manual content
By using the selection diagram a user has an overview of the other manuals available (8.1) Illustrations are used to clarify instructions but are far from completed (8.2). The manual shows several essential guidelines and their possible solutions, but it is unknown if these are enough for a proper functioning socket. Requirement 8.3 and 8.4 are therefore seen as partially satisfied.
Sentence use is short and long paragraphs are avoided (8.5, 8.6). The language could be made more simple (8.8, 8.9) though technical terms are mostly avoided (8.7).

<table>
<thead>
<tr>
<th>Manual specific requirements</th>
<th>Satisfies requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1-The manual is downloadable in PDF format.</td>
<td>X</td>
</tr>
<tr>
<td>5.2-The manual is written in English.</td>
<td></td>
</tr>
<tr>
<td>5.3-The manual contains page numbers</td>
<td>X</td>
</tr>
<tr>
<td>5.4-The manual follows a logical step by step structure.</td>
<td></td>
</tr>
<tr>
<td>5.5-All images in the manual are open source images.</td>
<td>X</td>
</tr>
<tr>
<td>5.6-The manual is published under the ‘Creative Commons’ licence</td>
<td>X</td>
</tr>
<tr>
<td>5.7-The manual contains a reference list written accordingly to the APA-style.</td>
<td>X</td>
</tr>
<tr>
<td>5.8-The manual can be edited. (by adding parts through the patch project forum)</td>
<td>X</td>
</tr>
<tr>
<td>5.9-The manual contains a disclaimer where the legal accountability is described.</td>
<td>X</td>
</tr>
</tbody>
</table>

Manual Front-page:
6.1-The front page only contains an image or illustration, a title and reference to the patch project X
6.2-the front-page must inform the user of its content at a glance. X

Manual Introduction
7.1-The introduction describes who the content was written for. X
7.2-Each manual has an introduction which list the necessary tools and materials. X
7.3-The manual has to show a way how additions can be made via the patch project website. X
7.4-The introduction describes the content of the manual and how it should be used. X
7.5-The manual refers to local craftsman who can assist with building the part from the manual X

Manual Content
8.1-The manual refers to the other manual that is required to make a complete prosthesis. X
8.2-When necessary illustrations or photos are used to. X
8.3-The manual covers the most essential guidelines necessary to construct a LLP socket. X
8.4-The manual shows the possibilities and solutions to for the guidelines. X
8.5-Text is divided over paragraphs of ±five sentence for easy scanning. X
8.6-Avoid long sentences, divide information over several short ones. X
8.7-Avoid technical terms unknown to target audience (reading level=writing level). X
8.8-Language used should be as simple as possible. (to make translation easier). X
8.9-Language style can be informal. X

Figure 5.2 evaluation accordingly to the requirements from chapter 3.2.
6. Discussion

The goal of this thesis is to create a process manual, for the Patch project, which will describe the necessary steps for designing a Lower Leg prosthetic socket. The results, the process that led to the results and future recommendations are discussed in this chapter.

The process
To create an actual manual for building a prosthetic socket one has to actually build the socket first. Since it is not possible to build an actual prosthetic without going to Indonesia, the focus of the manual would be on the process in the form of guidelines. By a combination of literature study and market research, information for the most critical requirements of a prosthesis where gathered. However building methods and availability of materials may vary from what has been researched trough literature and interviews.

The process manual is in a small grey area between theoretical knowledge and actually building the prosthesis. This made the design process more abstract, something a human kinetic technology student is less accustomed to. During the design phase (synthesis) it was tempting to go deeper into the design process, but this would only lead to speculation. The fact that both the student and the client did not have a very clear idea what a process manual should look like in the beginning, made the process more difficult. Fortunately, the form of the manual gradually became clear during the design process.

The result
In the evaluation 42% of the requirements from chapter 3.1 have been translated to guidelines. 38% are partly translated and for 20% of the requirements a satisfying translation to guidelines has yet to be made. The ratings from the cardinal method in chapter 4 are, with an exception of the strength calculations, estimations based on the preformed analysis from chapter 2. Which means the designs are still theoretical and need proper building and testing. Some of the guidelines form chapter 3.1. could not be evaluated at all. A requirement like 'the prosthesis allows for a knee extension of 4°' is dependent on the actual shape of the prosthesis and the limb of the wearer. Guidelines like these are difficult to translate to instructions without actually being on location with the person the prosthesis is being build for.

The breakdown of the prosthesis into separate parts might make individual parts easier to build and understand but it is not clear if this is the best approach of making a complete prosthesis. It might make things more confusing for a potential user. On the positive side, the dissection of the design process makes it easier to make adaptations to the manual. It is easier to trace and pinpoint flaws in either the requirements or the guidelines.

Future recommendations.
By dissecting the process of building a prosthetic socket the process has been opened up. The manual at the moment is just a framework. The best method for expanding the manual would be to go to rural areas and experimenting with local materials. Do the recommend materials work? What problems are overlooked in the manual? If a prosthesis fails, does this have to do with flawed building instructions (the guidelines) or was the underlying requirement flawed to begin with? These are questions that should be asked. By keeping the design process open and visible problems in the design process can be located more accurately. The information and experience gained by this should be added to the manual. This should be done by people already working in the field of Prosthetics and Orthotics. The ideal is that by people engaging in discussion with each other on The Patch Project website, the manuals become constantly evolving pieces of information.

Field testing is necessary for complete evaluation of the designs. During this feedback should be given to all parts of the manual.

Guidelines for future development of the manual.
-Use professionals or students in the field of Prosthetics and Orthotics to come up with new ideas for simple prostheses.
-Bring the guidelines into practice on location, start experimenting with tools and materials.
-Any new information found, for the requirements and the guidelines, should be added to the manual.
-differentiate between requirements and guidelines. If a prosthesis fails is this because the building process was insufficient or was the requirement where the guideline was based on flawed as a whole?
7. Conclusion

The main question in this project was: What materials do I have to use to meet the requirements for a prosthetic socket and what influence does this have on the design.

By researching the requirements for a prosthetic socket and looking at the steps that are necessary to build a prosthetic socket, a process manual was created. This process manual lists: several materials for socket construction, the construction steps and the describes consequences for the used materials.

At this point the manuals does not contain enough information to build actual prostheses parts. However, the information is now more organised and better visible. Therefore the manual provides a basis which can be expanded upon.

The next step is proper testing in the field and by experimenting, gaining practical experience. This way the guidelines can be properly evaluated and expanded. The underlying basis, the requirements for the parts, are also to be evaluated and changed where necessary. The knowledge gained can be added to the manual through the Patch project website and forum.
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A: Material properties

<table>
<thead>
<tr>
<th>Material</th>
<th>Mold temp C°</th>
<th>Density [g/cm³]</th>
<th>Bending strength [N/mm²]</th>
<th>Tensile strength [N/mm²]</th>
<th>Compressive Strength [N/mm²]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plastics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HDPE</td>
<td>137</td>
<td>0.97</td>
<td>48</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>PET (bottle grade)</td>
<td>68</td>
<td>1.37</td>
<td>55</td>
<td>61,5</td>
<td></td>
</tr>
<tr>
<td>PVC</td>
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<td>1.38</td>
<td>53</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td>PP</td>
<td>100</td>
<td>0.92</td>
<td>29</td>
<td>38</td>
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</tr>
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<td>Rubber</td>
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<td>1,3</td>
<td>28</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Textile</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leather</td>
<td></td>
<td>0,86</td>
<td></td>
<td>9</td>
<td></td>
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<tr>
<td>Cotton</td>
<td></td>
<td>N.A.</td>
<td></td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Nylon</td>
<td></td>
<td>1,15</td>
<td></td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>Wool</td>
<td></td>
<td>1,3</td>
<td></td>
<td>1,35</td>
<td></td>
</tr>
<tr>
<td>Woods</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bamboo</td>
<td></td>
<td>0,35</td>
<td>148</td>
<td>39</td>
<td></td>
</tr>
<tr>
<td>Bangkirai Tropisch</td>
<td>0,65</td>
<td>50</td>
<td></td>
<td>9,7</td>
<td></td>
</tr>
<tr>
<td>Teak</td>
<td></td>
<td>0,59</td>
<td>40</td>
<td>8,8</td>
<td></td>
</tr>
<tr>
<td>Kempas</td>
<td></td>
<td>0,7</td>
<td>60</td>
<td>10,5</td>
<td></td>
</tr>
<tr>
<td>Merbau</td>
<td></td>
<td>0,7</td>
<td>60</td>
<td>10,5</td>
<td></td>
</tr>
<tr>
<td>Meranti, rode</td>
<td></td>
<td>0,33</td>
<td>20</td>
<td>0,5</td>
<td></td>
</tr>
<tr>
<td>Metals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aluminum</td>
<td>400-800</td>
<td>3,1</td>
<td>240</td>
<td>327</td>
<td></td>
</tr>
</tbody>
</table>

*Similar to bottle grade pet
**Highly variable,

Retrieved 05-02-2015
B: Anthropometric data

World Health Organisation (WHO) tables

Anthropometric data body length and weight children 8-14.

<table>
<thead>
<tr>
<th>Ages</th>
<th></th>
<th>8</th>
<th>14</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weight</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Source: WHO</td>
<td>Boys (average): (3% low–97% high)</td>
<td>26kg</td>
<td>51kg</td>
</tr>
<tr>
<td></td>
<td>Girls (average): (3% low–97% high)</td>
<td>21kg</td>
<td>73kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25kg</td>
<td>50kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>19kg</td>
<td>78kg</td>
</tr>
<tr>
<td><strong>Height</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Source: CDC</td>
<td>Boys (average): (3% low–97% high)</td>
<td>117cm-127cm</td>
<td>163cm-177cm</td>
</tr>
<tr>
<td></td>
<td>Girls (average): (3% low–97% high)</td>
<td>117cm-138cm</td>
<td>148cm-178cm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>116cm-137cm</td>
<td>146cm-173cm(WHO)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>115cm-126cm</td>
<td>160cm-173cm(CDC)</td>
</tr>
<tr>
<td><strong>Length knee-top to foot-bottom</strong></td>
<td>Average length</td>
<td>39cm</td>
<td>50.5cm</td>
</tr>
<tr>
<td></td>
<td>Average yearly growth</td>
<td>2.2cm</td>
<td>2cm</td>
</tr>
</tbody>
</table>
| Tu Delft gives lengths for ground to knee cavity
| Tu Delft (1993) DINED anthropometric data database

<table>
<thead>
<tr>
<th>Ground to knee cavity</th>
<th>Lower leg length</th>
<th>Growth (percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8-9 jaar (3%low-97%high)</td>
<td>330-403mm</td>
<td>-</td>
</tr>
<tr>
<td>10-11 jaar (3%low-97%high)</td>
<td>361-453mm</td>
<td>31-50mm (9,3-12,4%)</td>
</tr>
<tr>
<td>12-13 jaar (3%low-97%high)</td>
<td>385-490mm</td>
<td>24-37mm (6,7-8,2%)</td>
</tr>
</tbody>
</table>

Growth of the leg circumference is hard to find. Data has been taken about lower limb growth in Dutch children and there growth percentage every 2 years. This gives a growth percentage of 6,7-12,4%.

http://dined.io.tudelft.nl/dined/nl/

<table>
<thead>
<tr>
<th>Knee width</th>
<th>8-9 jaar (3%low-97%high)</th>
<th>10-11 jaar (3%low-97%high)</th>
<th>12-13 jaar (3%low-97%high)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>68-86mm</td>
<td>73-93mm</td>
<td>73-98mm</td>
</tr>
</tbody>
</table>

Knee width in Dutch children changes by 0-8,1% per two years. The data is not directly comparable with children in developing countries but a figure of 8,1% in knee width growth is a requirement for a prosthesis.
C: Interviews

Interview Paul Steijger
26-03-2015

Subject: Interview about capabilities and availability of materials in developing countries. Bali Indonesia. P. Steijger stayed in a urban area but has some knowledge about the rural areas surrounding the city.

What are the local capabilities working with wood and metal:
There are very skilled wood workers. Most of them work in furniture shops. Metal working is done mostly for fences (with detailed decorations). These are made from iron. Aluminium is less prevalent. Electronic equipment is available as are turning lathe’s.

Leather and cotton, wool et.
There are plenty of skilled tailors and shoemakers. Leather can be worked by skilled people just as most textile fabrics.

Prevalence of plastics.
PVC is available in the cities. Probably also in the rural areas as garbage. HDPE might be more difficult to obtain outside the cities.

How about the use of plaster of paris or similar casting methods.
Plaster of paris is available in hospitals and the casting is done by doctors. Its hard to say if its available in the rural areas.

Methods of heating plastic parts like HDPE and PVC
Motorbike shops use small ovens, they can vulcanise rubber using fire ovens. Food shops often have ovens with controllable temperatures up to 200-230 c°

How is the availability of equipment in the rural areas.
There are motor bike repair shops. They have the basic tool to make repairs on bikes. Don't expect much electrical equipment.

 Anything you would like to add.
The people are very skilled with the materials they work with. They don't know how to apply it to the human body in form of a prosthesis, they underestimate their own capabilities. If you can show them how a certain method they use building furniture or repairing a bike can be used to build a prosthesis they should be able to do it with relative ease.
Interview/Internday Cornelis Visser.
prosthetic specialist working at Livit Den Bosch
13-03-2015

To update my knowledge of prostheses and fitting I contacted Livit to organize an intern day.

Cornelis Visser was happy to oblige.

His experience as a prosthetic caregiver in developing countries has given him the conclusion that training is the most important part of providing good prosthetic care to patients.

**What is the most critical part of a prostheses**

For a prostheses the socket is in his view the most important part. The fitting of the socket is relies even more on the training of the orthotic worker than the chosen materials. People are able to handle a not 100% efficient working foot but if the interface with the stump does not work properly the prostheses will fail because of insufficient fit, pain etc.

**Is the design of lower leg and upper leg prostheses similar enough to be included in the same manual?**

No, there are significant differences between the two. The production of upper leg prostheses without modern cad/cam methods is very time consuming.

**What is the most successful approach to achieving good prosthetic care in rural areas according too you?**

Self enablement is a very noble cause but it only works on the micro level. Using premade parts and training people to use these to build a prostheses is the way to go if you want to achieve results on a macro level. The material costs are higher but this is compensated by the lower man-hour costs. There are several companies active in this sector. Alimco in India (http://alimco.in/index.aspx) Saathi, Vic and the Icrc

**Materials**

The materials that are being applied successfully at the moment are High Density Polyethylene (HDPE) and PVC. HDPE is mold-able in the 300-400°C temperature range. PVC is widely available and workable at temperatures of 180-200 °C.
D. Western Prosthetic designs

A prosthesis is a artificial device intended to replace a body part that is missing as a result of an amputation or a birth defects. It (partly) replicates the function of a normal human leg. For the thesis the focus of this chapter will be on an endoskeletal trans-tibial prosthesis or, Lower Leg Prosthesis (LLP). This type of prosthesis generally consists of three main parts. The socket, the pylon (or shaft) and the foot.

As explained in chapter 2, a lower leg prostheses has three to four parts. Each part has their own unique function. Suspension, which prevents the prosthesis from coming off, can be considered a fourth part of the prostheses but is often integrated in the socket. A more detailed description of the foot, pylon and suspension can be found in the appendix. Below a more detailed description of the socket is given.

The socket.
The socket is one of the most vital parts of the prosthesis. It form the connection between the foot and the residual limb. These sockets are best used for standard trans-tibial amputations where 20-50%, or 8-16cm of the lower leg is left.

The main functions of the socket are:
- the transportation of force from the foot to the residual limb.
- distribution of this force to the pressure tolerant parts of the limb.
- provide pressure to reduce oedema (optional).
- depending on socket type the proximal part can provide a suspension from the leg.

Depending on the type of socket it can also fulfil the function of providing suspension of the limb. Modern sockets such as the Total Surface Bearing (TBS) socket and the Patellar tendon Bearing (PTB) socket provide this function. Sockets have a hard exterior shell and a softer interior shell.

The exterior shell is made from carbon fibres or kevlar. The inside of the sockets, the liners, are made of softer materials like polyform, PVC gel/co-polymer or Silicon.

The standard for developed countries in LLP production is to make a plaster wrap cast of the residuum limb from which a modified plaster model is made. The plastic socket is then formed around this model. More and more often CAD/CAM technology and 3D scanning is being integrated in this process. (Visser, C. 2015).

The 'Patellar Tendon Bearing' Socket (PTB) is one of the most common used sockets (Seymour, R. 2002). The inside of the socket had weight bearing and pressure relieving parts as shown in figure 3.

The weight bearing areas are.
- the patellar tendon
- flare of the medial tibial condyle and the anteromedial aspect of the tibia shaft.
- the mid-shaft of the fibula.
- distal end of the limb if tolerated.

Areas of relief
- lateral and anterior aspect of the tibia.
- head and distal end of the fibula
- crest and tubercle of the tibia
- anterior distal end of the tibia

Fig.1 A Transtibial endoskeletal prosthesis. (Seymour, R. 2002)

Fig.2 Red: pressure bearing areas. Pink: pressure sensitive areas. (Seymour, R. 2002)
Total Surface Bearing (TSB) Socket
Another commonly used socket type is the 'Total Surface Bearing' (TSB) Socket. This socket type distributes the forces equally over the entire stump surface. This is done with assistance of a so called 'liner' which is rolled over the residual limb. The distal end of the liner contains a connection pin to lock the socket onto. Both sockets are suspended by pushing out the air through a valve in the bottom of the socket. This is a simple method of vacuum-assisted suspension. The advantage of this type of socket is that by giving equal pressure distribution it reduces the build up of oedema in the residual limb.

Liners
A liner a sock like piece of cloth, made of polyethylene foam or viscoelastic material which is worn over the residual limb. Liners are formed over the positive mould to fit inside the socket. Liners are made from Polyform, PVC gel/co-polymer or Silicon. Polyform is worn with a prosthetic sock, the silicon is worn directly on the skin. It's function are:
- Provide extra protection of the sensitive parts of the residual limb.
- Provide suspension from the limb (as with silicon liners).

Sockets can be worn with or without liners. This depends on the patient preference. A individual wearing a socket without a liner is often a sign of a healthy residual limb.

The advantages and disadvantages of liners:

**Advantage**
- Total contact with the limb reduces build-up of oedema.
- Liners are easy to modify.

**Disadvantages**
- Deterioration over time.
- Sanitation due to perspiration absorption.
- Difficult to apply for patient with reduced hand function.
- Increased bulk and weight.

Liner choice is influenced by the skin condition, allergies and the activity level of the patient.
suspensions
The suspension of a prosthesis has the function of securing the prosthesis onto the residual limb. Besides its main function a suspension, depending on the design, can create stability around the knee.

The Supracondylar Cuff.
Often used system for trans tibial amputations. It suspends from the femoral condyles and the proximal end of the patella (Figure 5). This kind of suspension tightens with knee flexion and loosens with extension

Supracondylar systeem (PTB SC)
Commonly used in PTB sockets. Has a higher medial an lateral end with a wedge on the medial side for suspension on the femoral condyle. Commonly used when less than 5cm of residue limb is present.

Supracondylar/suprapatellar systeem (PTB SC/SP)
Version of the PTB where the lateral, medial and anterior ends completely cover the femoral condyles and the patella. This provides good support around the knee. Is used when there is less than 5cm of residue limb present. Kneeling is difficult and therefore less suitable for children

Thigh Corset

Sleeve/sock
Very light. No pistoning. Not very durable and has the same sanitation problems as liners.

Vacuum-assisted suspension.
Used in combination with Silicon liners. Vacuum suspension is available in a active and passive version. Active vacuum suspensions are used for the most active patient types and athletes.

Figure 4. Left Bottom of a socket with a black valve on the bottom left for vacuum-assisted suspension. Right: A Supracondylar cuff suspension.
The shaft
The shaft connects the socket to the foot. In exoskeletal prosthesis the socket and foot are made of one single component. The material of the socket runs down the entire length of the leg until the connection with the foot is made. In endoskeletal prosthesis the connection is made with a metal shaft. Mostly made of aluminium.

The alignment of the prosthesis is mostly done in the connection between the socket and the shaft. At first static alignment is done to make sure the weight is equally divided over the foot. The guideline for this is that most weight is on the fore foot.

After that the prosthetic advisor will perform dynamic alignment. The goal of dynamic alignment is to have an energy efficient walking pattern (gait). This is done by looking at the gait of the patient and making small adjustments accordingly (R. Seymour, 2002). The adjustments can be made through systems like a pyramid connection as shown in figure X.

Dynamic alignment begins in the trans-tibial socket, the socket is usually placed under an angle that simulates ±5° of knee flexion.
Dynamic alignment relies on the skill of the P&O advisor to notice subtle changes.

The foot
Prosthetic feet provide the following functions
- simulation of the ankle joint
- Shock absorption
- A cosmetically pleasing appearance.

Prosthetic foot come in simple single axis variants for patients with low activity, carbon copy multi-axis foot for the athletic user and everything in between.
A single axis foot only provides plantar and dorsal flexion to the user. A multi-axis foot allows for supination and pronation in the ankle joint.
The more simpler designs try to absorb shock with rubber parts in the heel. More advanced models use springs or composite materials to store and release energy.

![Fig 5. Left the SACH foot, a cheap single axis foot made of polyurethane foam or vulcanized rubber.](image)
E: Calculating bending stress and compression stress of materials.

**HDPE pipe (Muki limb)**

D=75mm d=69mm  
M=273Nm=273000Nm  
W=π(75^4-69^4)/32*75=11746mm³  
σt=273000/11746=23,2N/mm²  
A=π(37.5³-34.5³)=678mm²  
σc=2730/678=4N/mm²

**PVC pipe**

D=60mm d=54mm  
M=273Nm=273000Nm  
W=π(60^4-54^4)/32*60=7292mm³  
σt=273000/7292=37,4N/mm²  
A=π(30³-27³)=678mm²  
σc=2730/678=4N/mm²

**Pet Bottle socket**

D=79,5mm d=75,5mm  
M=273Nm=273000Nm  
W=π(79,5^4-75,5^4)/32*79,5=9203mm³  
σt=273000/9203=29,7N/mm²  
A=π(39,75³-37,75³)=486mm²  
σc=2730/486=5,6N/mm²

**Wood frame (cylinder)**

D=25mm  
M=273Nm=273000Nm  
W=π20¹⁴/64=7853mm³  
σt=273000/7853=34,8/mm²  
A=π*10²=314mm²  
σc=2730/314=8,7N/mm²

**Aluminum frame**

D=34mm d=30  
M=273Nm=273000Nm  
W=π(34¹⁴-30¹⁴)/32*34=1519mm³  
σt=273000/1519=180/mm²  
A=π(34²-30²)=804mm²  
σc=2730/804=3,4/mm²

**Calculations for interface weight.**

R=36mm  
r=32mm  
h₁=8mm  
h₂=16mm  
V₁=π(36²-32²)*h₁=68mm³  
V₂=π(36²-32²)*h₂=137mm³  
leather=D*V₁=60grams->D*V₂= 120grams  
textile=D*V₁=80grams->D*V₂= 160grams  
rubber=D*V₁=90grams->D*V₂= 180grams

Surface area of a tube.  
\[ A = \pi \left( R^2 - r^2 \right) \]

Compressive stress  
\[ \sigma_c = \frac{F}{A} \]

Bending stress  
\[ \sigma_t = \frac{M}{W} \] [N/mm²]

Second moment of inertia  
\[ w = \pi \left( D^4 - d^4 \right) \]

\[ W = \frac{\pi}{32} \cdot D^3 \]

\[ D = \text{outer diameter} \quad [\text{mm}] \]
\[ d = \text{inside diameter} \quad [\text{mm}] \]
\[ R = \text{outer radius} \quad [\text{mm}] \]
\[ r = \text{inner radius} \quad [\text{mm}] \]
\[ A = \text{surface area} \quad [\text{mm}^2] \]
\[ \sigma_t = \text{bending stress} \quad [\text{N/mm}^2] \]
\[ \sigma_c = \text{compressive stress} \quad [\text{N/mm}^2] \]
\[ M = \text{moment} \quad [\text{Nmm}] \]
\[ F = \text{Force} \quad [\text{N}] \]

Density (D)
leather=0.83g/cm³  
textile=1.2 g/cm³  
rubber=1.3g/cm³

Manual for socket construction.

Manual for Children prosthetic by The patch project is licensed under the Creative Commons Attribution 4.0 International License. To view a copy of this license, visit http://creativecommons.org/licenses/by/4.0/.

http://patchproject.net/
Introduction.

This manual can be used to create a lower limb prosthetic socket for children between 8-14 years old in Indonesia.

The materials covered in this manual are:
- HDPE
- PVC
- Wood
- Aluminium
- Pet Bottle

This manual will guide you through the following steps:

**Step 1:** choose material most available to you in figure 1 preferably a material you have experience working with, or know people who have experience with. The material you choose will determine the type of prosthesis socket you will build.

**Step 2:** The diagram point to the manuals for the necessary parts.

**Step 3:** follow the instructions of the manual as best as possible.

**Step 4:** Use The Patch Project forum to give feedback about the manual so we can improve upon it.
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Step 1 Selection diagram.

A prosthesis generally consists of three or four main parts, the socket, the pylon (or shaft) the foot and optionally a suspension. Each part has its own unique function.

Figure 1.1 The selection diagram.

The starting point is the column of blue boxes which list materials for the exterior of the socket. Moving to the right it lists the materials for the corresponding parts, the interior socket and the suspension. Further to the right it lists the possible choices in parts that go with the exterior socket. In the final column the connector possibilities are listed.

How to use the selection diagram on the next page
1: Choose the material available to you, HDPE, PVC, Wood, aluminium, PET bottle,

2: follow the row to the right. For example when choosing PVC, you can build a Split tube frame. Other parts are a rubber or leather socket, and a suspension made of leather or textile. To finish it a Stubby foot or a Saddle foot can be attached on the end.
The materials necessary for this are PVC, leather and rubber.

3: The diagram point to the manuals for the necessary parts. follow the instructions of the manual as best as possible. These can be found in the table of content.

For construction of the interior socket or “liner” look up the Socket interior manual on the patch project website.

For construction of the foot and shaft or “liner” look up the foot_shaft manual on the patch project website.
Step 2 explanation of the manual.

All parts have a table which gives an overview of the following points

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required materials</td>
<td>Describes the required materials</td>
</tr>
<tr>
<td>Dimensions</td>
<td>List of dimensions of the main materials to be used.</td>
</tr>
<tr>
<td>Weight estimation</td>
<td>An estimation of the weight of the part.</td>
</tr>
<tr>
<td>Tools required</td>
<td>List of required tools</td>
</tr>
<tr>
<td>Comfort</td>
<td>Describes the steps for completing the guideline that concern comfort</td>
</tr>
<tr>
<td>Mobility</td>
<td>Describes the steps for completing the guideline that concern mobility</td>
</tr>
<tr>
<td>Adaptability</td>
<td>Describes the steps for completing the guideline that concern adaptability</td>
</tr>
<tr>
<td>Person or place of</td>
<td>Points to craftsman or locations that could be of assistance</td>
</tr>
<tr>
<td>assistance.</td>
<td></td>
</tr>
<tr>
<td>Existing instructions.</td>
<td>If case any pre existing instructions exist.</td>
</tr>
<tr>
<td>Link:</td>
<td>In case any pre existing instructions can be found online.</td>
</tr>
<tr>
<td>Construction steps</td>
<td>Lists the basic steps to be undertaken for construction of the part.</td>
</tr>
<tr>
<td>(Summery)</td>
<td>Detailed instructions have to be written and experimented with on location.</td>
</tr>
<tr>
<td>Unsolved issues</td>
<td>List of unsolved issues and construction steps that are still uncertain</td>
</tr>
<tr>
<td></td>
<td>improvements can be made.</td>
</tr>
</tbody>
</table>
PVC socket

Examples of PVC made prosthetics are shown in ‘Disabled village children, Page 632’ from the David Werner collection (Werner, D. 1987). It uses a PVC pipe that is split by cutting it lengthwise. The framework of PVC can be used to suspended an inner socket. PVC pipes. Because the split PVC doesn’t cover the entire leg it needs a relatively sturdy interface. Therefore a rubber of leather socket are advised in the diagram. To keep the socket from falling of, a supracondylar or thigh suspension is also advised. For walking a stubby foot or Sach foot can be attached on the bottom of the socket.

<table>
<thead>
<tr>
<th>Ratings 1-5</th>
<th>Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength</td>
<td>3</td>
</tr>
<tr>
<td>Simplicity</td>
<td>4</td>
</tr>
<tr>
<td>Durability</td>
<td>5</td>
</tr>
<tr>
<td>Adaptability</td>
<td>4</td>
</tr>
<tr>
<td>Average (X out of 5)</td>
<td>4/5</td>
</tr>
</tbody>
</table>

Guideline

Required materials  PVC pipe, Belt (leather) or rope

Dimensions  60mm diameter  3mm wall thickness  Length: Depends on stump length see figure 1  Rope: 1,5meter

Weight estimation  Ca 120grams

Tools required  1: oven or heating equipment capable of reaching 75 degrees C°  2: Saw or cutting tools.

Comfort  The socket may not cause discomfort, beware of any sharp edges

Mobility  When designing the socket make sure it allows for the natural range of movement of the knee. This means the socket material should not cover the entire knee and leave sufficient room at the knee cavity for flexion. How much room is unknown.

Adaptability  Circumference of the leg is expected to increase from 1-2,5cm per year. PVC has some flexibility. By reheating the shape can be altered.

Person or place of assistance.  Food shops often have ovens who can control heat.

Existing instructions.  David Werner collection, Disabled Village Children. Page 632

Link:  http://www.dinf.ne.jp/doc/english/global/david/dwe002/dwe00269.html#628

Construction steps (Summery)  1. Use a rope or measuring tape to measurements as shown in step 1  2 make 4 cuts in the PVC tube length wise.  3. Heat the PVC tube to circa 75 degrees C°  4. Shape PVC pipe according to measurements taken in step 1

Unsolved issues  -Even though the child may grow, the soft tissue may shrink over time making the socket fit loose.  -Method of keeping the split PVC part together unclear a rope or a belt could work.  -Attaching the inner socket still unclear  -Preferably needs a cast of limb stump to make shape materials in correct dimensions  -Attachment to shaft&foot still unclear.  -It is not known how big the influence of body heat is on the material strength.
**Step 1 Inspection of the stump.**

Use a rope or measuring tape to measure the distance from the knee cap till the end of the stump. As shown in figure 1.

2. Measure the circumference of the stump on the two places as shown in figure 2, just below the kneecap and about 1-2cm above the edge of the stump.

3. Always be aware of the pressure sensitive parts of the stump. The red parts in illustration are more sensitive. The green parts are ok to put pressure on.

![Fig.1. Stump length from kneecap till bottom of the stump](image1)

![Fig.2. circumference measurements just above stump end and below the kneecap](image2)

![Front of leg](image3)

![Back of leg](image4)

**Figure 3. sensitive and pressure bearing parts of the stump.**
Leather socket interface

Leather provides good friction on skin contact and can absorb perspiration. Leather has good mechanical properties and is also durable enough. It can be processed to various levels of hardness which makes it suitable as a socket interface (Brouwer, I. 2013). This makes it possible to use various levels of hardness in the interface to better distribute the forces in the socket. The materials can be sewn or laced together. This makes the socket adjustable which is necessary for the demanded volume adaptation which will occur.

<table>
<thead>
<tr>
<th>Ratings 1-5</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength</td>
<td>4</td>
</tr>
<tr>
<td>Simplicity</td>
<td>4</td>
</tr>
<tr>
<td>Durability</td>
<td>4</td>
</tr>
<tr>
<td>Adaptability</td>
<td>4</td>
</tr>
<tr>
<td>Average (X out of 5)</td>
<td>4/5</td>
</tr>
</tbody>
</table>

**Guideline**

**Instruction**

<table>
<thead>
<tr>
<th>Required materials</th>
<th>Leather, rope, sewing material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>Circumference of stump+5cm length of stump +3cm</td>
</tr>
<tr>
<td>Weight estimation</td>
<td>60-120gram</td>
</tr>
<tr>
<td>Tools required</td>
<td>1. Sewing materials, tread and wire. 2. Cutting tools for leather</td>
</tr>
<tr>
<td>Comfort</td>
<td>The stump has pressure sensitive and pressure bearing parts. For optimal comfort of the wearer the right materials have to be applied to the right place. The illustration in figure 1 gives an explanation of the areas that need attention.</td>
</tr>
<tr>
<td>Mobility</td>
<td>When designing the socket make sure it allows for the natural range of movement of the knee. This means the socket material should not cover the entire knee and leave sufficient room at the knee cavity for flexion (See figure 3) The exact amount of space left open is unknown.</td>
</tr>
<tr>
<td>Adaptability</td>
<td>To accommodate the growing of the limb it is advised to use a belt or a strap of some kind to tighten or loosen the socket. The circumference of the socket should be adjustable by about 5cm Lengthwise a growth of ca 3cm should be possible.</td>
</tr>
<tr>
<td>Person or place of assistance</td>
<td>Shoemaker shops have experience working with leather.</td>
</tr>
<tr>
<td>Existing instructions</td>
<td>none</td>
</tr>
<tr>
<td>Link to instructions:</td>
<td>none</td>
</tr>
<tr>
<td>Construction steps (summery)</td>
<td>1. Use a rope or measuring tape to measure the distance from the knee cap till the end of the stump. As shown in pictures 1&amp;2.</td>
</tr>
<tr>
<td>Unsolved issues</td>
<td>-There is no good solution for solving the length of the leg problem. -</td>
</tr>
</tbody>
</table>
Step 1 Inspection of the stump.

1. Always be aware of the pressure sensitive parts of the stump. The red parts in illustration are more sensitive. The green parts are ok to put pressure on. By adding extra material on the material of the interface on the location of the pressure sensitive areas you can distribute the forces more better. And relief the pressure sensitive areas as shown in figure 2.

Figure 1. Sensitive and pressure bearing parts of the stump.

2. Measure the circumference of the stump on the two places as shown in figure 2, just below the kneecap and about 1-2 cm above the edge of the stump. Also measure the length of the stump from the knee cap till the end of the stump.

Figure 2. Pressure bearing areas of the stump on the inside of the material.
Supradonlar cuff

Because of its simple leather design the supracondylar suspension is good for use in developing countries where there is a lack of proper prostheses. A supracondylar cuff system is a simple suspension design with only one disadvantage which is that it loosens at knee flexion. A second joint will make it a little less stable but more flexible. To adjust it for comfortable wearing a belt buckle or similar is required to change size.

<table>
<thead>
<tr>
<th>Ratings 1-5</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength</td>
<td>4</td>
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<td>4</td>
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<tr>
<td>Adaptability</td>
<td>4</td>
</tr>
<tr>
<td>Average (X out of 5)</td>
<td>4</td>
</tr>
</tbody>
</table>

Guideline | Instruction
--- | ---
Required materials | Leather, preferably an old leather belt. Softer fabric for inside padding.

Dimensions | Length of belt: Circumference of the leg just above the knee+5cm.  
-leather thickness: 2mm  
-Belt height 10mm

Weight estimation | -

Tools required | 1. Measuring tape  
2. Cutting tools for leather.  
3. Sewing materials

Comfort | With the suspension the weight of the socket hangs from the bony part on the side of the knee and as shown in figure 2

Mobility | To make assure the suspension does not restrict mobility follow step 1

Adaptability | Make sure the belt for the cuff above the knee has at least 5cm of extra length so it can grow with the leg.

Person or place of assistance. | Clothing shops ore shoemakers can work with leather

Existing instructions | David Werner collection,  
Disabled Village Children. Page 631

Link to instructions: | http://www.dinf.ne.jp/doc/english/global/david/dwe002/dwe00269.html#628

Construction steps (summery) | 1. Take measurements as shown in figure 1&2  
2. 

 Unsolved issues | -The suspension belt should not move hurt during moving!  
-If the wearer has signs of red skin on the location of the belt, You can try a softer material on the inside. Or use a wider belt to distribute the force more evenly.  
-Making the suspension tighter will make the socket fit better on the limb  
-But! Making it tighter will also make it harder to move the knee.
Step 1 Taking measurements

1a. Measure the circumference just above the knee cap (figure 1).
1b. Measure the height between the socket edge and the top of the knee cap (figure 1). Cut out a piece of strong leather like shown in the drawing with the length of ‘A’ plus an extra 5 cm. A belt can also be used. Make sure the piece is at least 2 mm thick and 1.5 cm broad. Make 2 holes in the leather at a quarter length of the edges as shown in figure 3.

4: Place main belt back on leg, bend knee to look for attachment point on socket. Flex the knee to make sure it allows for the desired range of movement (figure 3 and 4).
Requirements

The manual is based on the following requirements for prosthesis parts. The requirements for the socket design are split up in 3 main components: the socket exterior, the socket interface, the socket suspension. The requirements are divided over the corresponding prosthesis parts.

Socket exterior
1.1-requirement: The prosthesis is capable of withstanding a peak 2730 N vertical force.
1.2-requirement: The prosthesis allows natural knee movement of 150° knee flexion
1.3-requirement: The prosthesis allows for a knee extension of 4°

Socket Interface
2.1-requirement: The socket fit may not cause pain.
2.2-requirement: Socket fit covers about 8-16cm of the leg.
2.3-requirement: The socket interface takes account of the sensitive and pressure bearing parts of the body. Hard materials for pressure bearing and soft materials for sensitive parts.
2.4-requirement: Material with skin contact have a coefficient of friction between 0.48 and 0.89.
2.5-requirement: The socket radius and height is adjustable by 5.7% per year.
2.6-requirement: The socket dimensions have an adaptability that accommodates 17% volume increase per year.

Suspension
3.1-requirement: The suspension may not cause pain.
3.2-requirement: The suspension must hold a weight of 80N.
3.3-requirement: The suspension allows natural knee movement of 150° knee flexion.
3.4-requirement: The suspension is adjustable in size by >8.1% per year from its original dimension.
3.5-requirement: The suspension allows for a knee extension of 4°

General
4.1-requirement: The prosthesis foot is made of material resistant to water.
4.2-requirement: The prosthesis weight is no more than the natural weight of (5% of bodyweight)
4.3-requirement: The prosthesis must be of equal length as the healthy leg.
4.4-requirement: The prosthesis must can build from the following materials: Wood, bamboo, rubber, PVC, HDPE, aluminium, leather.
4.5-requirement: The working of these materials must be achievable with non electric tools.
4.6-requirement: The used materials must be workable within a maximum temperature of 200-230 °C.
4.7-requirement: The prosthesis foot is wear proof for uneven grounds.
4.8-requirement: The prosthetic foot is easy to clean
4.9-requirement: The alignment of the shaft and socket must result in the body weight being placed on the mid foot.
4.10-requirement: The prosthesis materials are fit for a humidity range of 70-90%
4.11-requirement: The prosthesis lasts for a minimum of 1,500,000 cycles per year
The Patch Project information

The PATCH Project is a non-profit open-source wiki focussed on stimulating the development of prosthetics for children in developing countries. We attempt to collect and spread information about prostheses, organisations, and people, while stimulating development of new prostheses.

This manual was written by P.J. Vervoort as part of a Bachelor thesis for the study human kinetic movement from the Hague University.

The following manuals can be found on The Patch Project website.
- socket interior construction
- Suspension construction
- foot construction
PET socket  These materials are relatively strong and light. Pet Bottles are widely available and come in standard sizes for 1, 1,5 and 2 litre bottles. Respectively 79,5mm, 88mm and 101,5mm in diameter. The bottles are moldable starting at temperatures of 75° and higher. Thickness of carbonated drink bottles is required to be 0.45~ 0.55mm. Single bottles are not strong enough so a minimum of two have to be molded together to create a thicker wall.

<table>
<thead>
<tr>
<th>Ratings 1-5</th>
<th>Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength</td>
<td>3</td>
</tr>
<tr>
<td>Simplicity</td>
<td>3</td>
</tr>
<tr>
<td>Durability</td>
<td>5</td>
</tr>
<tr>
<td>Adaptability</td>
<td>3</td>
</tr>
<tr>
<td>Average (X out of 5)</td>
<td>3.5/5</td>
</tr>
</tbody>
</table>

Guideline

<table>
<thead>
<tr>
<th>Required materials</th>
<th>PET Bottles, preferably for carbonated soda (these are stronger)</th>
</tr>
</thead>
</table>
| Dimensions         | Diameter: 1L: 79,5mm, 1,5L:88mm, 2L:101,5mm  
wall thickness: 0.5mm per bottle  
Length: stump length  
Use 2-3 bottles |
| Weight estimation  | Ca 140grams (at a length of 160mm) |
| Tools required     | 1: cutting tools  
2: heating equipment, capable of reaching 75 degrees C°  
3: |
| Comfort            | The socket may not cause discomfort, beware of any sharp edges |
| Mobility           | When designing the socket make sure it allows for the natural range of movement of the knee. This means the socket material should not cover the entire knee and leave sufficient room at the knee cavity for flexion.  
How much room is unknown. |
| Adaptability       | Circumference of the leg is expected to increase from 1-2,5cm per year. PVC has some flexibility. By reheating the shape can be altered. |
| Person or place of assistance. | Food shops have ovens with controllable temperature. |
| Existing instructions. | none |
| Link:              | none |
| Construction steps (Summery) | 1. Use a rope or measuring tape to measurements as shown in step 1  
2: Heat the PET bottles to circa 75 C°  
3: cover stump in cloth to protect skin from burning.  
4: Shape heated Pet bottle around leg. Beware of different areas as in shown in step 3. |
| Unsolved issues    | -Not strong enough for heavier children. Use until age of 11.  
-original bottle opening can be used to attach shaft. |
HDPE socket

HDPE is available in the form of drainage pipes or waste materials. The materials are form-able at temperatures of 137°, and are shape-able in almost any form. Local food shops and workshops for motorbikes are known to have ovens who can work in those temperature ranges. The Mutki Limb uses the same approach with HDPE by heating HDPE 75mm drainage pipes with a 3mm wall and pulling them over a plaster mould of the patient's limb. This makes it suitable for a PTB like design.

<table>
<thead>
<tr>
<th>Ratings 1-5</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength</td>
<td>4</td>
</tr>
<tr>
<td>Simplicity</td>
<td>2</td>
</tr>
<tr>
<td>Durability</td>
<td>4</td>
</tr>
<tr>
<td>Adaptability</td>
<td>2</td>
</tr>
<tr>
<td>Average (X out of 5)</td>
<td>3/5</td>
</tr>
</tbody>
</table>

Required materials

HDPE Tube

Dimensions

75mm diameter
3mm wall thickness
Length: Depends on stump length

Weight estimation

Ca 110grams (at a length of 160mm)

Tools required

1: oven or heating equipment capable of reaching 137 degrees C
2: Saw or cutting tools.
3: hammer

Comfort

The socket may not cause discomfort, beware of any sharp edges

Mobility

When designing the socket make sure it allows for the natural range of movement of the knee. This means the socket material should not cover the entire knee and leave sufficient room at the knee cavity for flexion. How much room is unknown.

Adaptability

Circumference of the leg is expected to increase from 1-2.5cm per year. PVC has some flexibility. By reheating the shape can be altered.

Person or place of assistance.

Food shops often have ovens who can control heat.

Existing instructions.


Link:

http://www.dinf.ne.jp/doc/english/global/david/dwe001//dwe00126.html#part2chap19

Construction steps (Summery)

1a: make a cast of the limb as shown in the illustrations by David Werner.
1B: Alternative. Use a rope or measuring tape to measurements as shown in step 1
3. Heat the HDPE tube to 137 degrees C
4. Shape the heated HDPE pipe around the plaster cast of the limb. Alternative, shape the pipe according to the measurements taken in step 1.

Unsolved issues

-Forming of the heated HDPE is very difficult without a cast of the limb to form the material around before it cools. -Plaster of Paris or a similar materials is highly recommend. -Finding a pipe in the correct dimensions might not be possible. Smaller children may be light enough to use a 50mm pipe.
Wood socket

Wood has a limitation on design because one has to take the direction of the fibres in account. While its tensile strength is good when looking at tensile strength, its compression strength is much lower. Its elasticity is also lower than thermoplastics. It is available everywhere and there are lots of workers who are skilled with it. Wood is also more susceptible to environmental factors such as high humidity when not treated with a finish. This type would need an inner socket (liner) to work.

<table>
<thead>
<tr>
<th>Ratings 1-5</th>
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</thead>
<tbody>
<tr>
<td>Strength</td>
<td>5</td>
</tr>
<tr>
<td>Simplicity</td>
<td>4</td>
</tr>
<tr>
<td>Durability</td>
<td>3</td>
</tr>
<tr>
<td>Adaptability</td>
<td>3</td>
</tr>
<tr>
<td>Average (X out of 5)</td>
<td>3.2/5</td>
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</tbody>
</table>

Guideline | Instruction
--- | ---
Required materials | Wood, preferably (Kempas or Merbau), leather belts
Dimensions | 20mm diameter.
| Length: stump length +5cm.
Weight estimation | Ca 280grams (at a length of 160mm)
Tools required | 1: saw,
| 2: hammer + nails
| 3: sewing tools
Comfort | The socket may not cause discomfort, beware of any sharp edges
mobility | When designing the socket make sure it allows for the natural range of movement of the knee. This means the socket material should not cover the entire knee and leave sufficient room at the knee cavity for flexion. How much room is unknown.
adaptability | Adaptability has to come
Construction steps (Summery) | 1. Use a rope or measuring tape to measurements as shown in step 1
| 2: attach the two wooden shafts to a base block. Fasten this with screws or nails.
| 3: use leather belt or similar to make a suspension like net. This is where the interface will be suspended from.
Person or place of assistance. | Furniture shops have experience with working wood. Craftsmen here could be of assistance.
Existing instructions. | none
Link: | none
Construction steps (Summery) | 1. Use a rope or measuring tape to measurements as shown in step 1
| 2: attach the two wooden shafts to a base block. Fasten this with screws or nails.
Unsolved issues | -Best method of attaching belts to wood unknown.
| -Needs strong leather interior as interface for the stump.
| -method of attaching interface to frame unknown, sewing might be an option.
| -heaviest design, use for older children.
| -Base of socket needs hole for shaft attachment.
| -can also work with 4 shafts instead of 2.
**Aluminium frame** socket

Aluminium has the best strength to weight ratio. It could be used as a frame similar to the wooden frame. The downside of aluminium is that it is difficult to weld which makes it harder to customise parts in the desired shape. Without welding attaching different parts should be done by bolts or screws.

<table>
<thead>
<tr>
<th>Ratings 1-5</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Strength</td>
<td>5</td>
</tr>
<tr>
<td>Simplicity</td>
<td>1</td>
</tr>
<tr>
<td>Durability</td>
<td>4</td>
</tr>
<tr>
<td>Adaptability</td>
<td>2</td>
</tr>
<tr>
<td>Average (X out of 5)</td>
<td>3/5</td>
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</tbody>
</table>

### Guideline

<table>
<thead>
<tr>
<th>Instruction</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Required materials</td>
<td>Aluminium pipes,</td>
</tr>
</tbody>
</table>
| Dimensions | Diameter: 34mm  
wall thickness: 2mm  
Length: stump length |
| Weight estimation | Ca 210grams (at a length of 160mm) |
| Tools required | 1: iron saw  
2: screw/bolts  
3: sewing drivers  
4: optional, welding equipment |
| Comfort | The socket may not cause discomfort, beware of any sharp edges |
| Mobility | When designing the socket make sure it allows for the natural range of movement of the knee. This means the socket material should not cover the entire knee and leave sufficient room at the knee cavity for flexion. How much room is unknown. |
| Adaptability | Circumference of the leg is expected to increase from 1-2,5cm per year. PVC has some flexibility. By reheating the shape can be altered. |
| Construction steps (Summery) | 1. Use a rope or measuring tape to measurements as shown in step 1 |
| Person or place of assistance. | Bike shops have tools to drill and cut in metal. Might also have leftover metals that can be used for construction. |
| Existing instructions. | none |
| Link: | none |

### Unsolved issues
- You have to find pipes in the right dimensions.
- You need a skilled welder with the right equipment to weld aluminium.
- Best method of fixing aluminium pipes together without welding is not clear.
Textile interface

Being very soft compared to leather and rubber wool and cotton can be used to supplement the designs by using it to relieve pressure from the sensitive parts of the limb. Similar to the leather interface extra patches of material can be sewed on to relieve sensitive areas. Wool may be to warm for the Indonesia climate so cotton has preference over wool. Deterioration of the material may be a problem but materials like textile are easy replaceable or repairable so this is not considered a huge disadvantage. This part works best with a already well fitting socket exterior like a HDPE tube.

<table>
<thead>
<tr>
<th>Ratings 1-5</th>
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<tbody>
<tr>
<td>Strength</td>
<td>4</td>
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<tr>
<td>Simplicity</td>
<td>5</td>
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<tr>
<td>Durability</td>
<td>2</td>
</tr>
<tr>
<td>Adaptability</td>
<td>5</td>
</tr>
<tr>
<td><strong>Average (X out of 5)</strong></td>
<td>4/5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required materials</td>
<td>Linen, cotton.</td>
</tr>
<tr>
<td>Dimensions</td>
<td>Variable, Cover stump from stump bottom up to knee.</td>
</tr>
<tr>
<td>Weight estimation</td>
<td>80-160gram</td>
</tr>
<tr>
<td>Tools required</td>
<td>1. Sewing materials, tread and wire.</td>
</tr>
<tr>
<td></td>
<td>2. Cutting tools for textile.</td>
</tr>
<tr>
<td>Comfort</td>
<td></td>
</tr>
<tr>
<td>Mobility</td>
<td></td>
</tr>
<tr>
<td>Adaptability</td>
<td></td>
</tr>
<tr>
<td>Person or place of assistance</td>
<td>Clothing shops</td>
</tr>
<tr>
<td>Existing instructions</td>
<td>none</td>
</tr>
<tr>
<td>Link</td>
<td>none</td>
</tr>
</tbody>
</table>
| Construction steps (summery) | 1. Use a rope or measuring tape to measure the distance from the knee cap till the end of the stump. As shown in pictures 1 & 2.  
2. use these measurements to make a template with all the pressure sensitive and pressure bearing areas of the stump.  
3. add extra padding or more layers of fabric too pressure sensitive areas |
| Unsolved issues | - Very easy to make.                          |
|                 | - Needs a very solid socket, can not be used in a frame type socket.  |
|                 | - Method of stitching interior socket to exterior not yet known.  |
|                 | - Needs cleaning, filth and sweat can stay in fabric.  |
Leather interface

Leather provides good friction on skin contact and can absorb perspiration. Leather has good mechanical properties and is also durable enough. It can be processed to various levels of hardness which makes it suitable as a socket interface (Brouwer, I. 2013). This makes it possible to use various levels of hardness in the interface to better distribute the forces in the socket. The materials can be sewn or laced together. This makes the socket adjustable which is necessary for the demanded volume adaptation which will occur.

<table>
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<tr>
<th>Ratings 1-5</th>
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<tbody>
<tr>
<td>Strength</td>
<td>4</td>
</tr>
<tr>
<td>Simplicity</td>
<td>4</td>
</tr>
<tr>
<td>Durability</td>
<td>4</td>
</tr>
<tr>
<td>Adaptability</td>
<td>4</td>
</tr>
<tr>
<td>Average (X out of 5)</td>
<td>4/5</td>
</tr>
</tbody>
</table>

Guideline | Instruction
---|---
Required materials | Leather, rope, sewing material
Dimensions | Circumference of stump+5cm length of stump +3cm
Weight estimation | 60-120gram
Tools required | 1. Sewing materials, tread and wire. 2. Cutting tools for leather
Comfort | The stump has pressure sensitive and pressure bearing parts. For optimal comfort of the wearer the right materials have to be applied to the right place. The illustration in figure 1 gives an explanation of the areas that need attention.
Mobility | When designing the socket make sure it allows for the natural range of movement of the knee. This means the socket material should not cover the entire knee and leave sufficient room at the knee cavity for flexion (See figure 3) The exact amount of space left open is unknown.
Adaptability | To accommodate the growing of the limb it is advised to use a belt or a strap of some kind to tighten or loosen the socket. The circumference of the socket should be adjustable by about 5cm Lengthwise a growth of ca 3cm should be possible.
Person or place of assistance. | Shoemaker shops have experience working with leather.
Existing instructions | none
Link to instructions: | none
Construction steps (summery) | 1. Use a rope or measuring tape to measure the distance from the knee cap till the end of the stump. As shown in pictures 1&2.
Unsolved issues | -There is no good solution for solving the length of the leg problem.
-
Rubber interface

Examples of this design are shown in ‘disabled village children’ (Werner, D. 1987). Rubber tires are available as waste material or in bike shops. Local craftsmen are able to cut and even put separate bike parts together by vulcanisation, though no numbers about the used temperature could be found. Bike tires may be used for the pressure supporting limb parts while inner tires for pressure distribution. Rubber may dry out and start to deteriorate in time but this happens after several years. Older tires can be used but may deteriorated if the rubber has already dried out.

<table>
<thead>
<tr>
<th>Ratings 1-5</th>
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<tbody>
<tr>
<td>Strength</td>
<td>2</td>
</tr>
<tr>
<td>Simplicity</td>
<td>3</td>
</tr>
<tr>
<td>Durability</td>
<td>4</td>
</tr>
<tr>
<td>Adaptability</td>
<td>3</td>
</tr>
<tr>
<td>Average (X out of 5)</td>
<td>3/5</td>
</tr>
</tbody>
</table>

Guideline | Instruction
--- | ---
Required materials | Rubber tire, preferably from a motorbike or similar.
Dimensions | 
Tools required | Oven heating equipment., cutting tools, rope
Comfort | The stump has pressure sensitive and pressure bearing parts. For optimal comfort of the wearer the right materials have to be applied to the right place. The illustration in figure 1 gives an explanation of the areas that need attention.
Mobility | When designing the socket make sure it allows for the natural range of movement of the knee. This means the socket material should not cover the entire knee and leave sufficient room at the knee cavity for flexion (See figure 3) The exact amount of space left open is unknown.
Adaptability | To accommodate the growing of the limb it is advised to use a belt or a strap of some kind to tighten or loosen the socket. The circumference of the socket should be adjustable by about 5cm Lengthwise a growth of ca 3cm should be possible.
Person or place of assistance. | Food shops have ovens that can control temperatures. Bike shops might have the ability to cut and “glue” rubber.
Existing instructions (summery) | David Werner collection, Disabled Village Children. Page 632
Link: | http://www.dinf.ne.jp/doc/english/global/david/dwe002/dwe00269.html#628
Construction steps | 1. Use a rope or measuring tape to measure the distance from the knee cap till the end of the stump.
Unsolved issues | -Needs an external frame to carry weight of user.
-attachment of frame to rubber not solved
-unknown what temperatures
### Thigh suspension

A rigid suspension similar to the Supracondylar cuff with the main difference being it suspends the prosthesis from the thigh. This design requires more material to manufacture and is heavier than the other designs which can make it less suitable for smaller children (Seymour, R. 2002). It does provide a very firm suspension from the leg. It can be made with simple items already available like leather belts.

<table>
<thead>
<tr>
<th>Ratings 1-5</th>
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<tbody>
<tr>
<td>Strength</td>
<td>5</td>
</tr>
<tr>
<td>Simplicity</td>
<td>3</td>
</tr>
<tr>
<td>Durability</td>
<td>2</td>
</tr>
<tr>
<td>Adaptability</td>
<td>4</td>
</tr>
<tr>
<td>Average (X out of 5)</td>
<td>3</td>
</tr>
</tbody>
</table>

#### Required materials

Leather, preferably an old leather belt. Softer fabric for inside padding.

#### Dimensions

- Length of belt: Circumference of the leg just above the knee.
- Leather thickness: 2mm
- Belt height: 10mm

#### Tools required

1. Measuring tape
2. Cutting tools for leather
3. Sewing materials

#### Instruction

- Clothing shops or shoemakers can work with leather
- None

#### Existing instructions

None

#### Construction steps (summary)

1. Take measurements as shown in figure 1 & 2
2. Create a sleeve of leather or a softer fabric for around the tight. Make this adjustable in size so you can adjust the tightness around the leg. Perhaps via a belt.
3. Attach two smaller leather belts of the same size as the length in figure 1B between the prosthesis edge and the sleeve above the knee.

#### Unsolved issues

- These designs can be heavy, use for children aged 11 and older.
- The suspension belt should not move hurt during moving!
- If the wearer has signs of red skin on the location of the belt, you can try a softer material on the inside. Or use a wider belt to distribute the force more evenly.
- Making the suspension tighter will make the socket fit better on the limb but will reduce mobility.
H: Projectplan

Naam: Pieter Joris Vervoort
Studentnummer: 10071830
E-mailadres: pietervervoort87@gmail.com
Behaalde studiepunten in de modules 9 t/m 12: 62
Datum: 18-02-2015

1. Onderwerp: Handleiding voor socket van onderbeen prothese in ontwikkelingslanden.

Werkveld: Revalidatie
Beroepsrol: Onderzoeker/Ontwerper

Extern project
Opdrachtgever bedrijf: the Patch Project
Contactpersoon: Bram Sterke
Emailadres: bram.sterke@gmail.com

2. Probleemstelling

Aanleiding
Er zijn veel verschillende prothesen in de wereld welke ook voor ontwikkelingslanden zijn geschikt. De huidige situatie is dat er protheses bestaan van goede kwaliteit specifiek voor deze landen. Helaas zijn deze momenteel niet duurzaam genoeg en ontbreekt het op lokaal niveau aan de expertise om onderhoud en reparaties uit te voeren. Dit geld vooral voor de rurale gebieden. Ook zijn de meeste protheses gericht op volwassenen en bestaan er voor kinderen minder alternatieven.

Het patch project is een non-profit organisatie die de kennis op dit gebied probeert te verzamelen, samen te vatten en te verspreiden over de wereld in de vorm van een open-source wiki. Hierbij richt de organisatie zich vooral op kinderen in de leeftijd van 8-14 aangezien dit een onderbelichte groep is. Op deze websites moeten bouwplannen komen te staan van simpele doch robuuste protheses die met de in rurale gebieden beschikbare middelen te vervaardigen zijn.

Doelgroep
Hoewel de intentie van het “patch project” is om kinderen in de gehele derde wereld te bereiken is voor de huidige richtlijnen gekozen het gebied te beperken tot Indonesië, en dan vooral Indonesische kinderen in de leeftijd 8 tot 14 jaar die een onderbeen prothese nodig hebben.

Doelstelling
Een ontwerpproces handleiding in de vorm van een schriftelijk document met daarin verschillende vervaardiging methodes om aan de richtlijnen te voldoen. Samen met het deel van Martijn Hortensius die het enkelgewricht ontwerpt, een handleiding voor een complete onderbeen prothese vormen die rekening houd met de lokale materialen en gereedschappen. De handleiding zal in het Engels geschreven worden.

Hierbij is de hoofdvraag:
Constant zal de vraag gesteld worden: Wat voor materialen moet ik gebruiken om aan de richtlijn te voldoen, en wat heeft dit voor invloed op het ontwerproces.
Randvoorwaarden
Om het project succesvol tot voltooiing te brengen moet er aan enkele randvoorwaarden voldaan worden.
- Een grondige studie van de bestaande literatuur over het onderwerp.
- Goede samenwerking met Martijn Hortensius bij het opstellen van de richtlijnen zodat er vanuit dezelfde eisen en wensen gewerkt wordt.
- Vaststellen van de bewegings-eisen die kinderen/cultuur aan de prothese stellen
- Vaststellen van struikelpunten van bestaande protheses
- Advies van professionals op het gebied van de socket
- kennis van de beschikbare middelen (literatuur studie)
- twee wekelijks contact met Bram sterke en Martijn Hortensius

3. Vooronderzoek
Vanuit de geïndustrialiseerde wereld zijn er meerdere protheses ontworpen voor ontwikkelingslanden. In een review van Prosthetics and Orthotics International (J. Andreysek, 2010) Komt naar voren dat de levensduur (6-24 maanden) een struikpunt is en dat reparatie niet mogelijk is. Voor mensen in de rurale gebieden de toegang tot instanties die deze prothese leveren vaak slecht. Ook zijn veel van deze protheses niet op kinderen gericht maar op volwassenen.

In principe bestaan er al sockets voor been protheses die met simpele middelen te vervaardigen zijn (E. Strait 2006). Veel van deze ideeën zijn echter of gepatenteerd (B. Giesberts 2012) en hierdoor niet bruikbaar voor 'the Patch Project', of bestaan uit slechts een theoretisch ontwerp welke nooit vervaardigd is. Ook is hier weer het probleem dat de ontwerpen op volwassenen gericht zijn.

In samenwerking met Martijn Hortensius zal aan de hand van de bestaande literatuur, interviews met ervaringsdeskundige en een krachten onderzoek bij 'Motek Medical', richtlijnen opgezet worden waaraan de Prothese moet voldoen. Elk te ontwerpen onderdeel, de socket, het onderbeen en het voet/enkel gewricht, zal gestoeld zijn op de richtlijnen.

4. Deelvragen
Om de hoofdvraag te beantwoorden zijn enkele deelvragen opgesteld en het beoogde middel om deze te beantwoorden.

<table>
<thead>
<tr>
<th>Deelvraag</th>
<th>Middel</th>
</tr>
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<tbody>
<tr>
<td>Wat zijn de knelpunten van bestaande ontwerpen</td>
<td>Literatuurstudie</td>
</tr>
<tr>
<td>Wat is de Antropometrische data van de doelgroep</td>
<td>Literatuurstudie</td>
</tr>
<tr>
<td>Aan welke kracht-eisen moet de socket voldoen.</td>
<td>Krachtonderzoek bij Motek</td>
</tr>
<tr>
<td>Wat zijn de lokaal beschikbare materialen.</td>
<td>Literatuurstudie/interview</td>
</tr>
<tr>
<td>Welke invloed heeft dit materiaal op het ontwerp.</td>
<td>Literatuurstudie/Werkplaats</td>
</tr>
<tr>
<td>Hoe kunnen deze materialen gebruikt worden voor het gekozen ontwerp.</td>
<td>Werkplaats</td>
</tr>
<tr>
<td>Hoe kan een socket passend gemaakt worden met simpele middelen.</td>
<td>Literatuurstudie/Werkplaats</td>
</tr>
<tr>
<td>Op welke manier moet met lichaams groei rekening gehouden worden</td>
<td>Literatuurstudie/Werkplaats</td>
</tr>
</tbody>
</table>
5. Ontwerpfase

Op basis van de richtlijnen zal gezocht worden naar een oplossing. Dit kan een bestaande oplossing zijn of een nieuwe die proefondervindelijk in de werkplaats wordt gemaakt. Bij elk stukje methode wordt er gekeken wat de invloed is van de gebruikte materialen en gereedschappen is op het Ontwerp. Elke oplossing voor een deelprobleem wordt als een stukje ‘methode’ aan de handleiding toegevoegd. De methode kan meerdere oplossingen bevatten inclusief referentie naar bestaande oplossingen.

Met medestudent Martijn Hortensius zal tijdens dit proces ook nagedacht worden over het koppelstuk tussen de twee helften van de Prothese. Deze zal in beide handleidingen terug te vinden zijn.

6. Vervaardigingsfase

Het te vervaardigen product bestaat uit een ontwerpproces handleiding in de vorm van een document. De handleiding wordt Engelstalig. De verschillende methodes om met lokaal materiaal en gereedschap een socket te produceren die aan de richtlijnen voldoet worden met foto’s, tekeningen en ondersteunende tekst beschreven. In de bijlage staat een illustratie voor verduidelijking.

7. Testfase / Evaluatiefase

Evaluatie kan gedeeltelijk tijdens de ontwerpfase gedaan worden, materialen kunnen getest worden op sterkte en bewerkbaarheid voordat ze aan de handleiding worden toegevoegd. Evaluatie van het totale product is tijdens de afstudeer periode nog niet mogelijk. In opvolging van dit project zou de handleiding mee kunnen met studenten op buitenland stage om Het vervaardigen van een Prothese aan de hand van de handleiding ook echt te testen.

8. Voorlopige literatuurlijst

2) E. Strait (2006) Prosthetics in Developing Countries
3) B. Giesberts (2012) Lower Leg Prosthesis for Indonesia
4) Patchproject.net, grote hoeveelheid literatuur over het onderwerp.

9. Planning

<table>
<thead>
<tr>
<th>Wat</th>
<th>Hoe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1-5 Analyse fase</td>
<td>i.s.m. Martijn Hortensius</td>
</tr>
<tr>
<td>-Week 2 Krachten analyse</td>
<td>Bij Motek Medical.</td>
</tr>
<tr>
<td>-Week 5 Oprichting richtlijnen</td>
<td>i.s.m. Martijn Hortensius</td>
</tr>
<tr>
<td>-Week 6 Afsluiting analyse fase</td>
<td>Evaluatie met – Anthony Rombach van Edorso</td>
</tr>
<tr>
<td>Week 6-12 Ontwerp fase</td>
<td>Werkplaats van HHS</td>
</tr>
<tr>
<td>-Week 7 Ontwerp koppelstuk socket/voet</td>
<td>i.s.m. Martijn Hortensius</td>
</tr>
<tr>
<td>-Week 8-12 Oplossing van deelproblemen</td>
<td>Ontwerpen via feedbackloop.</td>
</tr>
<tr>
<td>-week 9-13 Schrijven van methode</td>
<td>Ontwerp process vastleggen in handleiding</td>
</tr>
<tr>
<td>Week 14 Inleveren Afstudeer scriptie</td>
<td></td>
</tr>
</tbody>
</table>
Bijlage

Persoonlijke leerdoelen afstudeerfase

<table>
<thead>
<tr>
<th>Beroeps specifieke Competenties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Competentie 1: Ontwerpen, vervaardigen en uitvoeren (B2)</strong></td>
</tr>
<tr>
<td>Leerdoelen: <em>Op ontwerpen heb ik eerder goed gescoord. Het doel is nu deze vaardigheid echt specifiek op de menselijke anatomie toe te passen.</em></td>
</tr>
<tr>
<td>Acties: <em>Neem de gebruikers en beweegings-eisen voor de socket mee en integreer die zo goed mogelijk in het ontwerp.</em></td>
</tr>
<tr>
<td>Evaluatie leerdoel aan het eind van de stage: <em>Er is goed gekeken naar welke aspecten een goede socket maken. Deze zijn vertaald naar concrete eisen en omgezet naar bouw instructies in het eind product.</em></td>
</tr>
<tr>
<td><strong>Competentie 2: Testen en onderzoeken (B3)</strong></td>
</tr>
<tr>
<td>Leerdoelen: <em>Dit is bij mijn laatste stage minder aan bod gekomen. Indien mogelijk het te maken prototype testen tijdens het afstuderen.</em></td>
</tr>
<tr>
<td>Acties: Bij het voltooien van het prototype zal getracht worden een loopanalyse te doen bij een Livit/de Hoogstraat.</td>
</tr>
<tr>
<td>Evaluatie leerdoel aan het eind van de stage: <em>Dit is uiteindelijk niet aan bod gekomen, evaluatie is theoretisch gedaan aan de hand van de opgestelde eisen en wensen.</em></td>
</tr>
</tbody>
</table>
### Algemene Beroepsgerichte Competenties

<table>
<thead>
<tr>
<th>Competentie 1: Communicatie (A6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leerdoelen: In het verleden heb ik te weinig assertiviteit getoond als ik vast liep bij een project. Ik bleef onnodig stil staan op een punt waar ik hulp had moeten vragen. Dit gebeurde pas in een laat stadium toen het echt niet meer kon.</td>
</tr>
<tr>
<td>Acties: Sneller hulpbronnen inschakelen als dit nodig is. Bouw een netwerk op van mensen die ondersteuning kunnen bieden tijdens het afstuderen. Bijvoorbeeld, Livit Orthopedie, Werkplaats medewerker Paul Steiger en oud student Kas Peters</td>
</tr>
<tr>
<td>Evaluatie leerdoel aan het eind van de stage: Externen bronnen zijn deze keer beter ingeschakeld. Desondanks was er toch vertraging bij het afstuderen. Dit lag echter aan andere problemen.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Competentie 2: Management (A8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leerdoelen: In mijn laatste stage had ik in het begin slecht overzicht over de vorderingen die wel of niet gemaakt werden om te zien dat ik hierdoor te weinig vorderingen maakte.</td>
</tr>
<tr>
<td>Acties: Wekelijks progressie in de gaten. Ik moet mezelf beter toetsen aan de gemaakte planning en dit ook door de afstudeer begeleider laten toetsen</td>
</tr>
<tr>
<td>Evaluatie leerdoel aan het eind van de stage: Vorderingen werden wel gemaakt, alleen soms niet de goede richting op. Het overzicht zelf was opzich niet kwijt maar de richting waarin gewerkt werd was soms niet goed in lijn met het project. Dit had te maken met een matig gedefinieerd eind doel voor het afstudeer project.</td>
</tr>
</tbody>
</table>