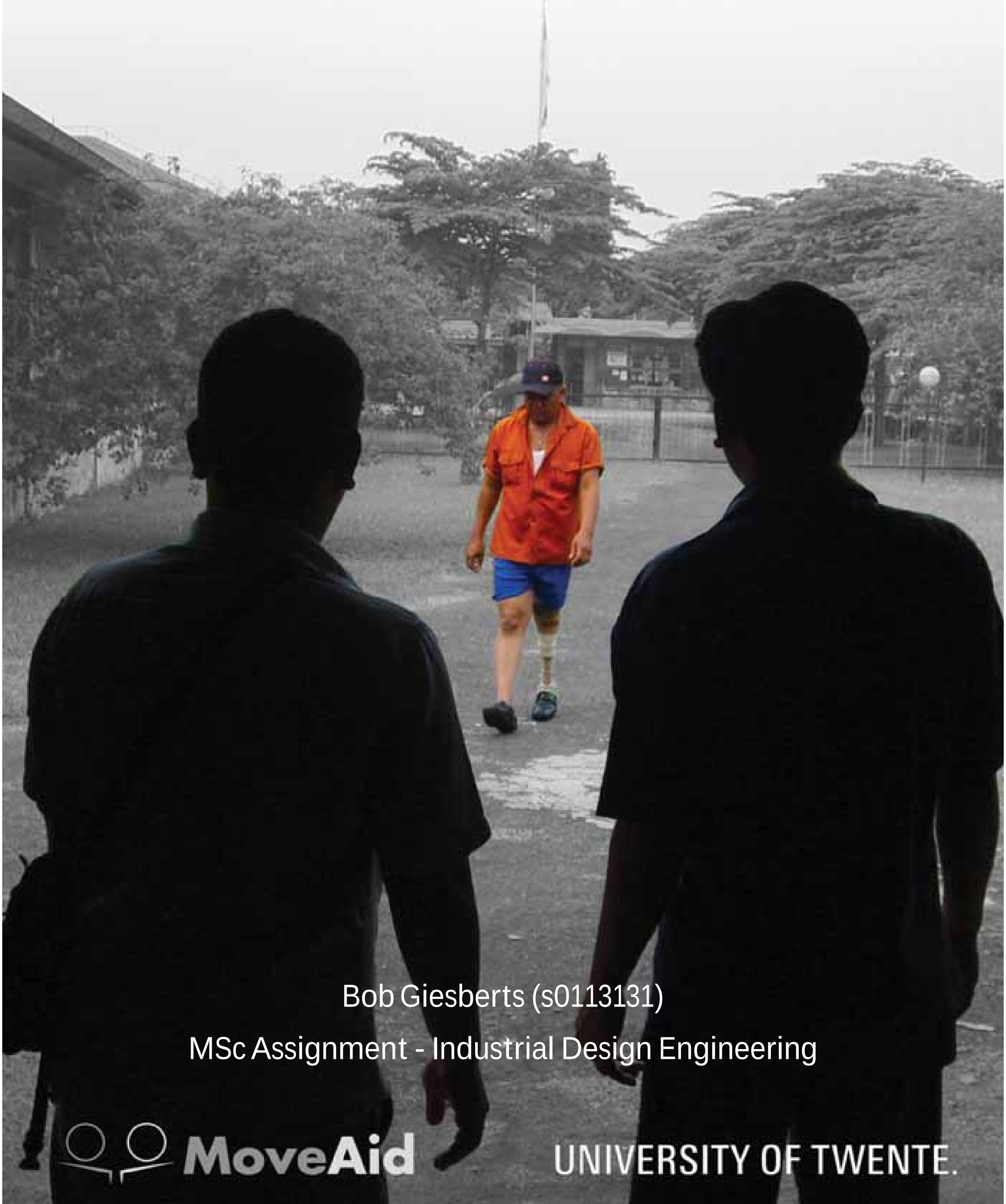
P O N T A S

A New Lower Leg Prosthesis for a Mobile Workshop in Indonesia



Bob Giesberts (s0113131)

MSc Assignment - Industrial Design Engineering

MoveAid

UNIVERSITY OF TWENTE.

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Examination committee:

Assignment:	Ir. Arjen Bergsma
	Ir. Wilco Kleine
Supervisor:	Ir. Edsko Hekman
Chairman:	Prof. Dr. Ir. Bart Verkerke
External Examinator:	Ir. Wieteke de Kogel-Polak

SAMENVATTING

Indonesië heeft slechts een zeer beperkt aantal orthopedische werkplaatsen, waardoor het voor patiënten erg lastig is om orthopedische hulpmiddelen te krijgen. Het huidige productie proces van onderbeenprothese kost ongeveer twee weken en veel mensen kunnen het zich niet veroorloven zo lang van huis te zijn. Een goede strategie om arme mensen in afgelegen gebieden te bereiken is de orthopedische werkplaats te mobiliseren en het product naar de mensen zelf te brengen.

Bestaande technologie voor het maken van onderbeenprotheses in onderzocht en oplossingen zijn bedacht voor problemen in het productie proces. Er is een aantal concepten ontworpen en hiervan is er een uiteindelijk verder ontwikkeld. Dit ontwerp heeft de naam Pontas gekregen. Het kan binnen twee uur worden geproduceerd en daarvoor zijn geen zware machines nodig. Het is daarom erg geschikt voor het gebruik in een mobiele werkplaats. Voor het maken van de Pontas wordt synthetisch gipsverband om de stomp gewikkeld waarna druk wordt aangebracht om de stompkoker de juiste vorm te geven. Lokaal beschikbare standaard onderdelen worden gebruikt om de prothese af te maken met een been en een kunstvoet.

Het concept is ontwikkeld en getest in revalidatie centrum Harapan Jaya in Indonesië. De locale prothese makers begrepen het productie proces goed en het product leek direct toepasbaar te zijn. Verscheidene onderbeenprotheses zijn gemaakt met een goede pasvorm, een goede uitlijning en een goede ophanging. In de toekomst zal de duurzaamheid van het product moeten worden onderzocht.

ABSTRACT

With a very limited number of Prosthetic and Orthotic (P&O) workshops in Indonesia, the accessibility of assistive devices is a problem. The current production process of lower leg prostheses (LLP) takes about two weeks and many people cannot afford to be away from home for such a long period. A good strategy to reach people in poor, rural areas is to mobilize the prosthetic workshop and bring the product to the people.

Existing technology to produce LLPs has been investigated and solutions were sought for problems in the production process. Various concepts are developed and finally, one of the concepts is further developed. This design is named Pontas. It can be produced in less than two hours and does not require any heavy machinery for its production, therefore being suitable for use in a mobile P&O workshop. In this method synthetic cast tape is wrapped around the stump and pressure is applied to create an appropriate socket. Available standard components are used to finish the prosthesis with a shank and a foot.

The concept is developed and tested at rehabilitation center Harapan Jaya in Indonesia and the production process was well understood and readily applicable. Several LLPs were made with a good fitting, good alignment and good suspension. Future research has to be done to investigate the durability of the product.

PREFACE

This is my thesis for the master Industrial Design Engineering (IDE), track Emerging Technology Design (ETD), specialization Design of Biomedical Products (DBP). In my products and in my personal life I am dedicated to make a meaningful contribution to the world and I am happy that with this assignment I got the opportunity to do so. In this preface I want to explain how this project came to existence, how I tried to contribute to it and what this project means to me.

This project was initiated by Arjen Bergsma. With the help of the Waag Society in Amsterdam, the House of Natural Fibers' Fablab was set up in Yogyakarta, Indonesia. Arjen got involved in their project called the *$50 prosthesis* (SCHAUB, 2009; KOOIJMAN, 2011) and created a large network in both the Netherlands and Indonesia. He got inspired by the Zwolle Isala Prosthesis (ZIP) method (EMMELOT, JORNING, OVERBEEK, BRINKMANN, & HOL, 2005), which uses synthetic cast tape to produce the socket for an LLP, and visited Yogyakarta to investigate the requirements for LLPs in Indonesia. He concluded that Indonesia could benefit from a mobile workshop and that using an adapted form of the ZIP method could make this possible (BERGSMA, 2011). He created the current assignment to design an LLP for a mobile workshop in Indonesia.

To continue the good work of Arjen, I started developing the existing network and had interesting conversations with numerous inspiring experts. Several old projects were found that had targeted the same problem in other countries. INNE TEN HAVE (1992) made the design for the Do-It-Yourself Prosthesis for landmine victims in Cambodia, which was used as the start for multiple projects of BOUDEWIJN WISSE (2002, 2005) in Sri Lanka. His final result is the Universal Prosthesis. Dubbele de Boer, who helped me understand the difficulties of working on such a subject for a developing country, previously helped FRANK NAUS (2008) to create the D-I-Y knitted prosthesis. Many international organizations working on the development of assistive devices in developing countries were contacted. I have taken effort to use as much as possible of the enormous amount of knowledge that resides in all these projects to create the best suitable prosthesis for people in Indonesia. Without the patient support of all experts I consulted, this project would have been of considerably inferior quality.

I entered the wonderful world of writing (research) proposals for funds and presented my project to various organizations. I succeeded in raising enough money to execute my plan and visited rehabilitation center Harapan Jaya, Indonesia were I was able to form a great design team to develop and test my concept. Together we created a product we are proud of. With Stichting MoveAid I hope to be able to develop the product even further and implement it in a fully functional mobile workshop.

On my last day at Harapan Jaya I was offered an *Ulos*, a traditional Batak scarf, which is offered to connect to family. Indeed the people at Harapan Jaya gave me the warmest welcome imaginable. This feeling stimulates my commitment to make a meaningful contribution to the world.

TABLE OF CONTENTS

1 INTRODUCTION

As an introduction to this report here a short description is given of the approach of the project.

The accessibility of prosthetic and orthotic (P&O) facilities in Indonesia is a problem. Every year about 33.000 people in Indonesia need a lower leg prosthesis (LLP), from which only a small percentage can be helped. The main question of this project is:

> *How can people in poor rural areas be provided with good prosthetic services?*

How to approach the assignment of answering this question is described with the following design philosophy.

1.1 BoP DESIGN

Efforts to innovate products are mostly targeted on the richer markets of this world. Together about 800 million highly affluent consumers make up the Top-of-the-Pyramid (ToP). The efforts of current project are targeted at the markets on the other end of the scale, in the Base-of-the-Pyramid (BoP). The average income of the four billion people in these markets is estimated to be less than € 1,60 a day (VELING, 2012B).

In contrast to ToP consumers, BoP consumers cannot afford to buy products they do not necessarily need. Designers aiming at the BoP have the challenging task to develop a low-cost product that is both high-quality and absolutely worth it. Attempts by multinationals to reach BoP markets often fail and VELING (2012B) strongly suggests to learn from BoP innovators. They are inherently immersed in the BoP, do not suffer from existing inappropriate business models and have proven their success. Similar to the approach of bio-mimicry it is expected that much can be learned from processes that have evolved over centuries.

Current project is yet another attempt to design a product for the BoP. Striving to a successful result, careful attention is paid to both successful and failed projects concerning LLPs designed for developing countries. Intense cooperation has been established with rehabilitation center Harapan Jaya on Sumatra, Indonesia to understand what approach would be appropriate and to discuss ideas.

1.2 SUSTAINABILITY

A well known statement about developing aid is the following:

> *"Give a man a fish and you feed him for a day. Teach him to fish and you feed him for a lifetime." (RITCHIE, 1885)*

This statement is about providing a sustainable solution. Note that there is a difference between teaching a man to fish and giving him a fishing rod. Although a fishing rod is used to catch many fish, once the fishing rod breaks the solution has vanished. A truly sustainable solution makes the man independent of any external influences, whatever happens. Teaching the man how to create a fishing rod or a fishing net is the best solution in this example. Also in the prosthetic world the importance of transferring technology rather than transporting products is now internationally recognized and it was point of focus at the conference of the Center for International Rehabilitation of 2006 (CIR, 2006).

It is possible to take it one step further. If the man who just learned how to fish will create a fishing school the knowledge is actively shared and likely to evolve. Independence and a feeling of responsibility are key in this process (SUSEBEEK, 2012). Improvement of education is therefore a good strategy and also in the prosthetic field researchers are working on this topic (KHENG, 2008). This year the first students graduate from the new school for prosthetics and orthotics in Jakarta (JSPO). Awaiting this school to start doing research and developing new solutions, current project focuses on sharing knowledge to find appropriate solutions to problems with the accessibility of lower leg prosthesis for people in poor rural areas.

1.3 READER'S GUIDE

This report describes the development of a new LLP in three different sections:

- Problem describes the context of the problem (CHAPTER 2), existing LLPs and production methods (CHAPTER 3) and gives an analysis of the problem (CHAPTER 4). The conclusion of this section is the list of requirements.
- Solution gives a view on the creative process of idea generation (CHAPTER 5) resulting in concepts (CHAPTER 6) and the detailed description of the product (CHAPTER 7).
- Evaluation shows how the design is evaluated with tests on manikin stumps in the Netherlands (CHAPTER 8) and with real people in Indonesia (CHAPTER 9). The results are discussed with recommendations for future research (CHAPTER 10) and final conclusions are made (CHAPTER 11).

An LLP consists of an artificial foot, a shank and a socket. The International Committee of the Red Cross (ICRC) has developed an excellent method of creating the shank and a good artificial foot is made at Harapan Jaya. Therefore the socket has the highest priority and the shank and the foot will not be discussed in the main part of this report. Relevant information can be found in APPENDIX F [THE FOOT] and APPENDIX G [THE SHANK]. The focus of this assignment is the design of a socket of an LLP and its production method.

Statistical data about amputations or LLPs in Indonesia is unavailable and although research is done on the development of assistive devices for developing countries, relatively little can be found in literature. Therefore much information is gathered from conversations with numerous experts (see APPENDIX E [EXPERTS]). With years of experience their knowledge is considered as valuable as a published source and therefore in this report references to these conversations are presented in the same way.

1.4 GLOSSARY

Technical language and abbreviations are explained within the context and here a short list is added to make it very easy to understand the text.

Harapan Jaya	Rehabilitation center in Indonesia (see Appendix H [Harapan Jaya])
Icecast®	Device to put an even pressure on the surface of the stump, developed by Össur
ICRC	International Committee of the Red Cross, inventor of the ICRC prosthesis
LLP	Lower Leg Prosthesis
OIM	Dutch Prosthetic / Orthotic company, co-developer of the ZIP
P&O	Prosthetic and Orthotic
PCAST	Device to put an even pressure on the surface of the stump (see PCAST, p.44)
Pontas	Name of the new LLP developed for this assignment, named after Malapontas Tamba
PP	Polypropylene, a form of plastic
PS (areas)	Pressure Sensitive areas of the stump, e.g. the fibula head and the distal tip of the stump
PT (areas)	Pressure Tolerant areas of the stump, e.g. the patella tendon
ZIP	Zwolle Isala Prosthesis, prosthesis developed at a.o. OIM (see Direct Casting, p.16)

PROBLEM

This section starts with describing the context and discussing relevant background information, followed by a detailed analysis of the problem concluded with a list of requirements.

2 PROSTHETIC WORKSHOP

This chapter describes the context of lower leg prostheses in Indonesia.

Value of any object is determined by its relation with its context. Therefore proper understanding of the context is key in designing a successful product. This is not only necessary to find preconditions for the new design, but mostly to understand underlying problems and their causes. For LLPs in Indonesia the main problems are not found in the product itself but in its context: most prostheses function well but are poorly accessible (KAMER, 2012).

2.1 INDONESIA

There is a strong connection between Indonesia and the Netherlands. The Dutch resistance of Indonesian independence severely damaged the relationship between the countries, but over time this relationship has grown strong again. The existence of rehabilitation center Harapan Jaya can be seen as one of many examples of this connection.

> *"Indonesia is the world's fourth most populous country, with a population of 248 million. It ranks 108th of 169 countries in the 2010 Human Development Index. Following remarkable socio-economic and political progress since the return to democracy in 1998, Indonesia is now a lower-middle-income country, a G20 member, the largest economy of the Association of Southeast Asian Nations (ASEAN) and one of Asia's most decentralized democracies.*
>
> *Despite notable progress, development has not been inclusive or even. (...) Regional disparities in terms of human development and resources are exacerbated by low technical and administrative capacity at the provincial and local level."* (WFP, 2011)

This citation reveals how Indonesia is increasingly more adequate in its political organization, but lacks the experience and financial means to properly cover important aspects like health and education. Both topics are discussed below.

DAILY LIFE

In Indonesia many (poor) people have physically demanding jobs in agriculture like working in paddy fields (CENTRAL INTELLIGENCE AGENCY, 2010). Compared to a desk job in the developed world, daily life can be quite a challenge for disabled people in Indonesia. Heavy-duty 'farmer-legs' have been developed in Thailand (SKILBECK, 2011) and Vietnam (NLR, 2009) but were not found in Indonesia yet. Even with these LLPs the combination of moisture and dirt can cause irritating places or even infected skin under the socket. Especially for diabetic people or Leprosy patients this is a problem because wounds do not heal easily.

Indonesia is the largest Muslim community in the world, and many people in Indonesia kneel several times a day to pray. For praying in a mosque, it is disrespectful to wear shoes and also in most homes it is common to walk barefoot. In fact, one can often recognize somebody who uses an LLP because he will be the only one wearing shoes and long trousers (WIJNANS, 2012). In history, introduction of Western LLPs has often failed because it did not fit their activities of daily living (SETHI, 1989).

2.2 HEALTH

From all countries in the East-Asia and Pacific region, Indonesia has the lowest relative health expenditure, almost the lowest doctor-to-population ratio and one of the lowest number of beds per 1.000 p0pulation (ROKX, SCHIEBER, HARIMURTI, TANDON, & SOMANATHAN, 2009). The development of the Indonesian public health system is lacking behind the overall development of the country (GEIGER, 2011). For P&O services the low development is most apparent in low number of facilities, almost all lacking capacity in every aspect: material, machinery, knowledge and experience. As PETER CAREY (2012) says *"How can we expect something as sophisticated as P&O to be a priority? The Indonesians haven't even got the basic health issues worked out."*

The newly ratified convention UNCRPD (UN Convention of the Rights of Persons with Disability) is expected to have a positive effect on this part of the health system, but the magnitude of this effect is questioned (CAREY, 2012; WIDAGDO, 2012). The convention, which Indonesia ratified on 30 November 2011, states that States Parties shall take "*effective measures to ensure personal mobility with the greatest possible independence for persons with disabilities, including by (...) encouraging entities that produce mobility aids"* (article 20). Health services should be provided "*as close as possible to people's own communities, including in rural areas"* (article 25) (UN, 2007).

AMPUTATION

In Indonesia disability is caused by diseases (50 %), congenital malformations (35 %) or accidents (15 %) (IRWANTO, KASIM, ASMIN, LUSLI, & SIRADJ, 2010). At rehabilitation center Yakkum-Yogyakarta the causes for amputation of the lower leg are said to be accident (55%), diabetes (25%), congenital (15%) and fall from a tree (5%) (RATUM, 2012). At Harapan Jaya mostly children are treated and there the causes for lower leg amputation are accident (65%), congenital (35%) and occasionally diabetes (~1 %) (HALOHO, 2012). Amputation of lower legs is done by orthopedic, oncologic or vascular surgeons (DEWO, 2012).

Because in Indonesia most amputations are caused by accidents (instead of diabetes like in the Netherlands), relatively young patients can be expected with overall healthy conditions (OVERBEEK, 2012), but with varying stump quality (KAMER, 2012). People with an amputation due to landmine injury are more likely to be satisfied with their prosthesis than people who suffered a non-violent trauma or other causes (VAN BRAKEL, POETSMA, TAM, & VERHOEFF, 2010). This might mean that overall people in Indonesia will be more motivated to learn to use their LLP than in the Netherlands.

After amputation, further rehabilitative care is not naturally following and many patients in need of an LLP still do not have one (SAPTYONO, 2012). It is expected that only 5 % (CAREY, 2012) or 10 % (WIDAGDO, 2012) of patients who have lost their leg have ever visited a P&O facility. More information on the number of amputations can be found in APPENDIX B [AMPUTATIONS].

HEALTH FACILITIES

Indonesia has a rather decentralized system of health facilities. Basically there are three increasingly smaller different types of health facilities: the hospital, puskesmas and puskesmas pembantu. TABLE 1 gives information about the number of these facilities in Indonesia plus the amount of people they serve in theory (ROKX, ET AL., 2009). In Indonesia 94% of households has access to a health facility located within five km (FIGURE 1). The costs for traveling to these health facilities are low (see TABLE 1), but are significantly greater for people living in rural areas than for people in urban areas (SANJAYA, 2007). Almost 64% of the people living below the national poverty line (€ 1,20 per day) live in rural areas (FIGURE 2) (WFP, 2009). In general, physical access to health services is considered less of a problem than quality of services (ROKX, ET AL., 2009).

Table 1: Four different types of Indonesian health facilities and their data from ROKX, ET AL. (2009) and SANJAYA (2007).

Facility type	Number	People per facility	Travel costs
Hospital	1.250	190.000	IDR 2.083 (€ 0,17)
Public Health Center (puskesmas)	8.000	30.000	IDR 1.008 (€ 0,08)
Public Health Sub-Center (puskesmas pembantu)	22.200	10.500	IDR 1.008 (€ 0,08)
P&O workshop	34	7.000.000	No data

There are only about 34 P&O workshops in Indonesia, in theory each serving seven million people (see APPENDIX C [P&O WORKSHOPS]). Following the available data of travel costs to hospitals, traveling to a P&O workshop is expected to cost at least IDR 76.581 (€ 6,22 for people living on the poverty line about 1 week of loan) and since most P&O workshops are situated on Java, greater costs are expected for people in rural areas. No data about these numbers can be found in literature. Many people cannot afford these travel costs in combination with the costs of being away from home for a long period.

Figure 1: Map of Indonesia with the percentage of households with access to health facilities within 5 km (WFP, 2009).

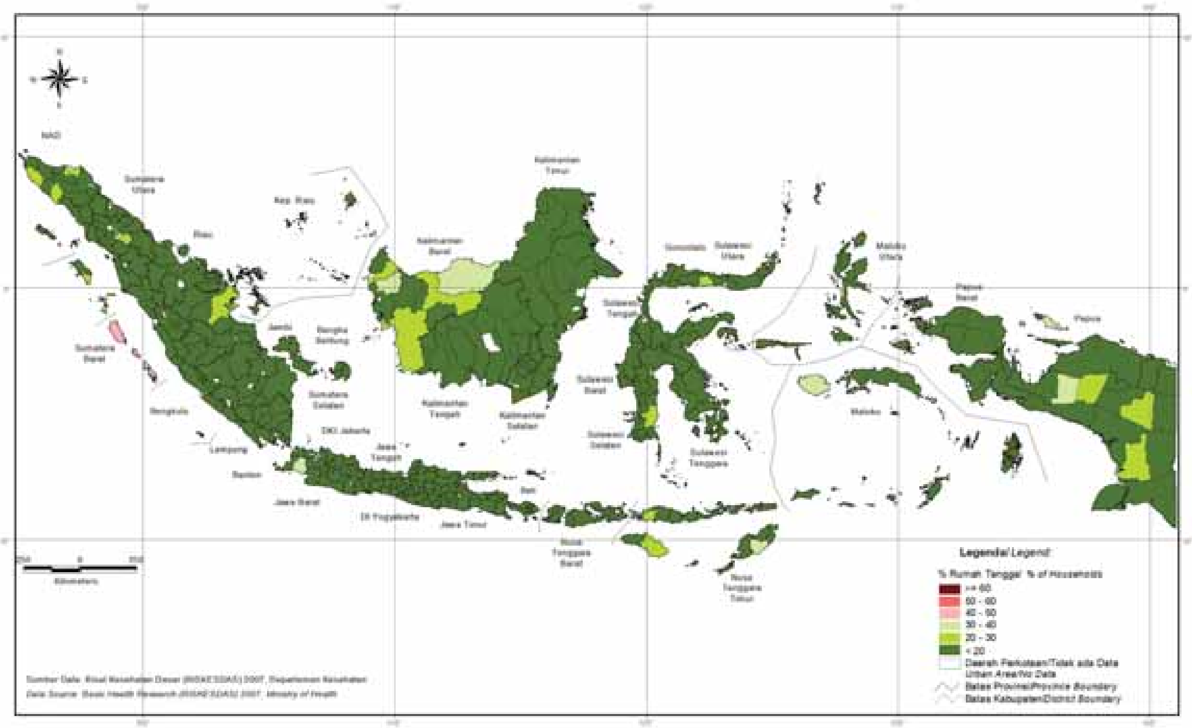
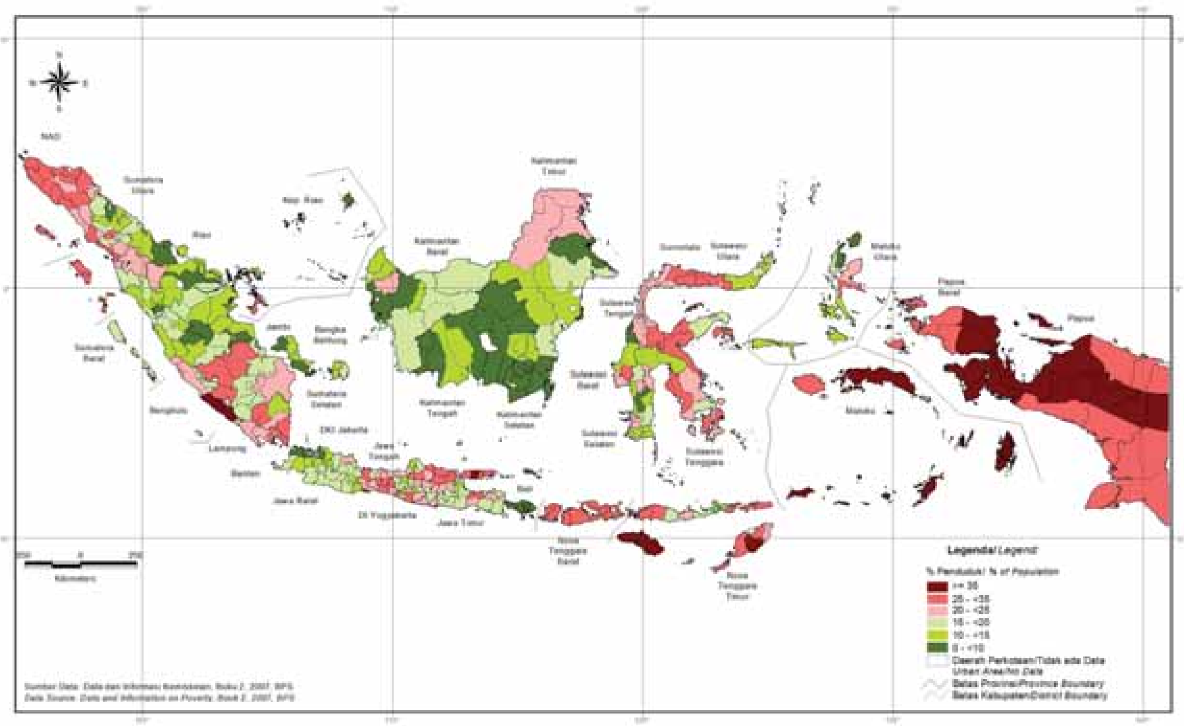


Figure 2: Map of Indonesia with the percentage of population living below the poverty line (WFP, 2009).



HEALTH INSURANCE

Two Indonesian sayings give a sad but accurate description of the public health system in Indonesia. First there is "*Orang miskin dilarang sakit*", or the poor are not allowed to get sick. Second there is Sadikin, an acronym for "*Sakit sedikit miskin*", or if you get sick, you will become poor (GALE, 2011). Indeed many sources (E.G. FILMER, 2008) show a strong relation between poverty and disability.

Indonesia has a public health insurance for different groups of people. *Jamsostek* is for workers in large factories, *Askes* is for government employees and *Asabri* for the military (ROKX, ET AL., 2009). Since 2008 there is one more state health insurance, being most relevant to this project, called *Jamkesmas*.

JAMKESMAS

Jamkesmas is an acronym for *Jaminan Kesehatan Masyarakat* (Community Health Insurance) and is an extension of the earlier *Askeskin* (Health Insurance for Poor Population). This insurance is for poor and near-poor people. The definition of near-poor is living below 1,2 times the poverty line (meaning € 1,44 per day), which relates to approximately 26,9% of the population (CARDENAS & PRYDZ, 2011).

Jamkesmas holders have cards that are given away for free at certain locations in Indonesia and expire in six months. 76,4 million people (32 %) are covered by this insurance and get free access to public health care (ROKX, ET AL., 2009). However, currently Jamkesmas only covers assistive devices for Leprosy patients (BEISE, 2012). This means that leprosy hospitals can give their patients an LLP for free and afterwards claim to Jamkesmas. Note that currently only cheap prostheses made from bamboo or aluminum are covered and polypropylene prostheses are not. The Department of Social Affairs also has a program to provide assistive devices for persons with disabilities, but the number of assistive devices is low compared to the needs (WIDAGDO, 2012).

Anyone involved in a car accident who is permanently disabled (e.g. lower leg amputation) receives a maximum of IDR 25.000.000,- (€ 2.100,-) plus an additional maximum of IDR 10.000.000,- (€ 850,-) for treatment costs (SAPTYONO, 2012). For people involved in a motor accident only the driver is insured and receives a maximum of IDR 2.000.000,- (€ 170,-) plus an additional IDR 200.000,- (€ 17,-) if the person is hospitalized. For accidents in public transport on land and see, the disbursed amount is the same as for car accidents (JASA RAHARJA, 2008). The money is given directly to the person and not to the health facility. This means the person can decide what to do with the money. Often this means the money is not spend on health care or an assistive device (SAPTYONO, 2012).

2.3 EDUCATION

The WHO AND ISPO (2005) have made guidelines for training personnel in developing countries for P&O services, which are now internationally recognized standards. In these standards the educational level is categorized in three levels, being *ISPO Cat III (Technician / Bench worker)*, *ISPO Cat II (Orthopedic Technologist)* and *ISPO Cat I (Prosthetist / Orthotist)*. Accreditation of P&O schools is done by ISPO which decides which degree the graduates will become. Note that ISPO definitions are not strictly followed in this report and anyone making a prosthesis is called a Prosthetist.

In Indonesia two P&O schools exists, one in Surakarta (founded in 2003) and one in Jakarta (JSPO, founded in 2009). JSPO has the ISPO Cat II status and one of its first graduates (Coki Tobing) takes part in this project in Indonesia. The P&O School of Surakarta is working on their ISPO Cat II approval (WIDAGDO, 2012) but currently the graduates only have the Cat III level. The level of these Cat III technicians is found to be too low to produce prostheses of sufficient quality (KAMER, 2012). Yakkum Yogyakarta is said to provide better but only practical education and the Prosthetist of Harapan Jaya was also trained here.

The WHO AND ISPO (2005) provide a calculation for the required amount of P&O facilities and P&O employees. They assume that 0,5 % of the population needs an assistive device and a product needs to be replaced every third year. For Indonesia, with a population of 248 million people, this means every year 413 thousand assistive devices should be produced. Following their calculation (TABLE 2) Indonesia should have about 1.500 Cat I / Cat II professionals. Currently the JSPO has a capacity of 18 students per year (CAMODIA TRUST, 2010) so this need will never be met.

Table 2: Calculation for the required amount of ISPO Cat II professionals.

	District level	Provincial level	National level	Total
Facilities	10	2	1	
Referrals	80%	70% x 20%	30% x 20%	
Ratio (Cat II / Cat III)	1:5	1:3	1:1	
Devices	330.667	57.866	24.800	413.333
Production rate (Devices / Cat II)	300	250	125	
Cat II professionals	1.102	231	198	1.531
Cat III professionals	5.510	693	198	6.401

Many developing countries experience problems with braindrain (talented people leaving the country to earn more money). Indonesia is said to have less of these problems than very sophisticated countries like Germany and Austria (SCHWAB, 2010). At the JSPO braindrain is prevented by providing a grant to the students. People attending the JSPO get a grant from the Ministry of Health, for which they have to work two years in Indonesia for each year of college they received (CAREY, 2012). In practice this means that all P&O graduates are obliged to stay in Indonesia for at least six years. After this period it is not expected that these graduates would be leaving the country since even all Indonesian ISPO Cat II graduates who trained in schools abroad (TatCot, VietCot, PSPO, CSPO) are now working in Indonesia (CAREY, 2012).

2.4 CONCLUSION

The public health system of Indonesia in general and P&O services in particular are not very well developed, while the need for these services is rather high. There are few P&O workshops, not enough Prosthetists and only limited education. For many patients living in poor rural areas, accessibility of P&O workshops is a problem and it is very difficult to get an LLP.

3 PROSTHESIS

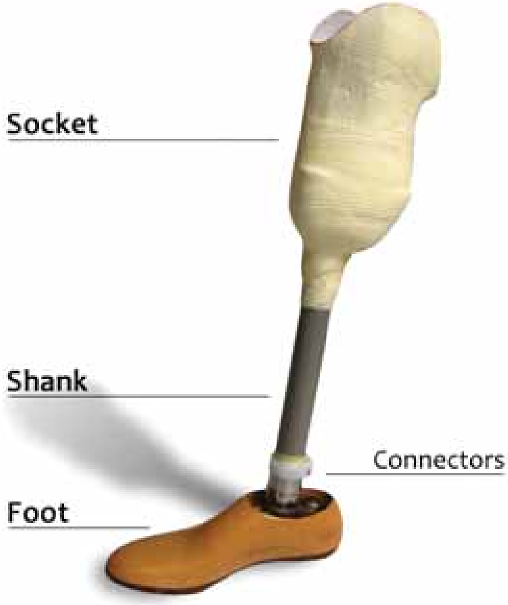
Now the focus will be on existing solutions and the opinion of involved stakeholders.

Without the ability to walk, many people are unable to continue their normal job and take care of their family. Often people are discriminated for their disability and social isolation occurs frequently. An LLP will serve as a new leg and give people who have lost their leg a new chance of a better future.

3.1 COMPONENTS

Every LLP consists of three basic components: the artificial foot, the shank and the socket (FIGURE 3). How these elements are combined can be different for each type of product but their basic functions are the same. Often certain connectors are used to combine the components and additionally provide adjustability.

Figure 3: A lower leg prosthesis consists of three basic components: the socket, the shank and the foot. Connectors and adapters are used to combine these parts correctly. The presented prosthesis is one of the first prototypes made for this project.



THE FOOT

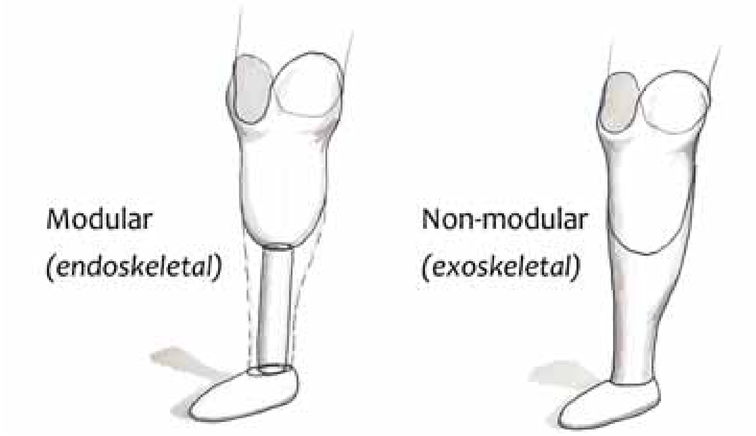
The artificial foot is the contact with the ground. It enables a natural gait, often has cosmetic features and is wear resistant. From interviews with experts it was learned that in Indonesia relatively good feet are available. These feet (Otto Bock imitations) are better adapted to the tropical climate than the ICRC foot and less labor intensive to produce than the Jaipur foot (KAMER, 2012; WIJNANS, 2012). APPENDIX F [THE FOOT] gives more information on the foot.

THE SHANK

The shank is the artificial alternative for the tibia. In most cases this is a simple metal pipe and many different connectors and adaptors exist for the connection with the socket and the foot. The International Committee of the Red Cross (ICRC) has developed a lower leg prosthesis with a system of plastic components to create the shank (ICRC, 2006). This system is used in P&O workshops all over the developing world, including Harapan Jaya. APPENDIX G [THE SHANK] gives more information about the shank.

The connection of the shank to the socket and to the foot defines whether the design of the prosthesis is called modular or non-modular (FIGURE 4). Generally developed countries only use modular prostheses because they provide fine adjustability which may add quality. Removing the function of (fine) adjustability dramatically reduces the costs, which is the reason non-modular prostheses are almost only used in developing countries.

Figure 4: How the shank is connected to the socket defines if a lower leg prosthesis is called modular or non-modular.



THE SOCKET

The prosthesis is connected to the stump with the socket. The socket is the most important part of the prosthesis, because a patient may not use it if it is uncomfortable (HERBERT, SIMPSON, SPENCE, & ION, 2005). The functions of this component are to transmit the load of the body on the artificial leg, provide stability and provide control for mobility (MAK, ZHANG, & BOONE, 2001).

3.2 THE SOCKET

Three aspects of a socket determine the quality and comfort of a socket: fitting, alignment and suspension.

FITTING

Primarily there are two types of sockets used for transtibial amputations. The Patellar Tendon Bearing (PTB) socket offers areas of pressure and relief, while the Total Surface Bearing (TSB) socket distributes the weight over the total contact surface of the residual limb (SEYMOUR, 2002).

The basis for PTB sockets is that certain areas can tolerate pressure (like the patellar tendon) and some areas cannot (like the fibula head, see APPENDIX A [THE STUMP]). These limited weight bearing areas create pressure peaks which can produce a painful stretch effect over the soft tissues (YIĞITER, ŞENER, & BAYAR, 2002). Additionally, the assumptions for the biomechanics for a PTB socket have been widely refuted (LAING, LEE, & GOH, 2011) and some even state that the Patellar Tendon Bar is an unnecessary feature and may be eliminated (ABU OSMAN, SPENCE, SOLOMONIDIS, PAUL, & WEIR, 2010). TSB socket are relatively easier-fabricated and offer comparable quality of comfort (MOO ET AL., 2009), but the comfort level of TSB sockets decreases over time (MANUCHARIAN, 2011).

Prosthetists at OIM and Harapan Jaya agree with this last statement. They say that when the stump shrinks, it can sink deeper into the socket creating a very different pressure distribution with a peak on the sensitive distal tip of the stump. Pressure tolerant areas like the patellar tendon should bear the weight and should therefore be included, also in TSB sockets even though theory disagrees on this. The debate on which one is best is ongoing.

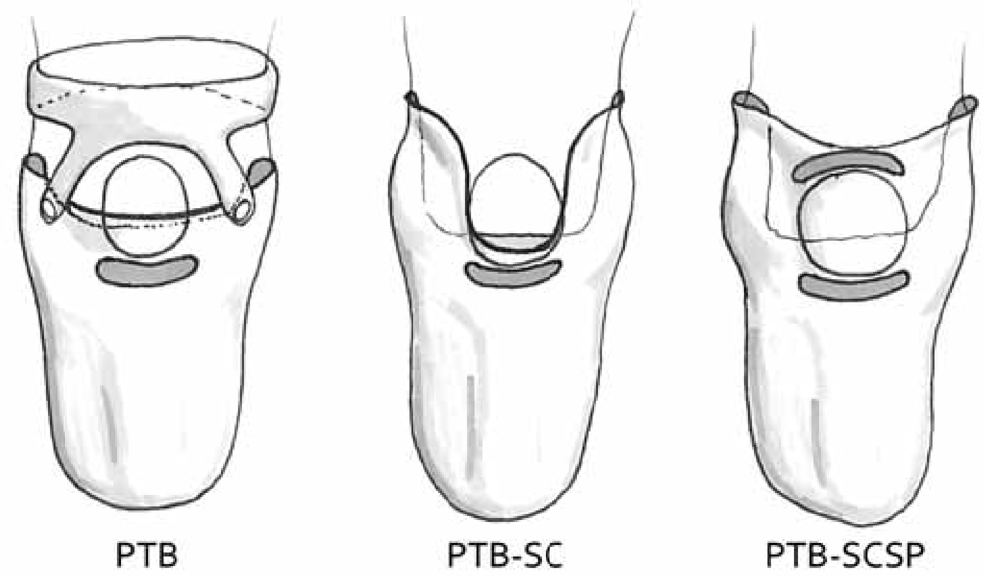
ALIGNMENT

Although most alignment is done by adjusting the shank, alignment starts in the socket. Most sockets have a flat base with a connector for shank. Normally this connector has four holes or a square which has to be oriented in the right direction user. For a plaster stump there are several methods to find the right alignment. For direct casting this alignment is done on sight and quality depends on the experience and dexterity of the Prosthetist.

SUSPENSION

In history corsets and belts above the femoral condyles (PTB, FIGURE 5), around the thigh or around waist have always been used as a suspension, to secure an LLP on the stump (SEYMOUR, 2002). Nowadays sockets are often higher to create a suspension above the condyles (Supracondylar, PTB-SC) and above the patella (Supracondylar / Suprapatellar, PTB-SCSP). A sleeve can be added for extra support and for improved cosmetics. Other options are a pin/shuttle system and a suction system but these systems require the use of a liner. A malfunctioning suspension will allow a piston-like movement of the stump inside the socket, leading to skin abrasion.

Figure 5: Three different suspension types based on the weight bearing principle of the PTB. In the drawings the circle represents the location of the patella (PTB = Patella Tendon Bearing, PTB-SC = Patella Tendon Bearing Supracondyllar, PTB-SCSP = Patella Tendon Bearing Supracondylar / Suprapatellar).



3.3 EXISTING PRODUCTS

Because every patient is different, every LLP is custom made and a finished product will only suit its user. The design of a prosthesis is determined by the chosen components and the used methods to produce the socket. With very different production methods very similar products are created. For current project this means it is more relevant to analyze the differences between existing production methods (see PAGE 12). Nonetheless, good overviews of existing prostheses for developing countries exist (ANDRYSEK, 2010; LAING, ET AL., 2011; STRAIT, 2006; WISSE, 2005). Interesting strategies are the Do-It-Yourself prosthesis (E.G. NAUS, 2008; TEN HAVE, 1992) and attempts to standardize the shape of the stump (WISSE, 2005).

TRANSFER TECHNOLOGY

In developed countries, much research is being done on systems for energy storing and releasing (ESAR) to enhance gait and decrease the excessive energy consumption of users of LLPs. Treadmills, video registration and lasers are used to make the gait of the patient perfect and the costs are usually very high. Research on the production process focuses on how FEA can be used to create a comfortable socket with CADCAM that is also well aligned. The Monolimb project is an example of such a system (LEE & ZHANG, 2005).

Trends

Years ago in the Netherlands, much attention was paid to the cosmetic aspects of the artificial leg, to have it resemble the real leg up to perfection. Instrument maker were painting the artificial leg to give it the exact same skin color, add veins and even add hairs. Currently interest for these aspects decreases and focus has shifted from cosmetics to performance (Overbeek, 2012). Others tend to use their prosthesis as a form of art (NOS, 2012b). This trend can also be seen in other assistive devices like glasses and hearing aids. At Harapan Jaya cosmetics is said to be important and the prosthesis is covered with a thick layer of skin colored foam and given an anatomically correct shape.

Other recognized trends are the use of microprocessors to enhance gait, and osseo-integration which connects a prosthetic device directly to residual bone (Overbeek, 2012). One decade ago, Marks & Michael (2001) already expected these exact same trends. They concluded that in their future, developments would be driven by financial constraints more and more, meaning an increased use of "modern industrial fabrication, particularly with injection molded plastics".

3.4 CONVENTIONAL PRODUCTION

In the Netherlands P&O workshops need about 24 hours of work to create a fully customized prosthesis. Two weeks after taking measurements the patient will receive his prosthesis (Kamer, 2012). At Harapan Jaya these numbers are 44 hours of production and also two weeks waiting time. Some standardization (like using exoskeletal prostheses) enables the Prostheses Foundation to produce LLPs within six hours in Vietnam (Robijn, 2012).

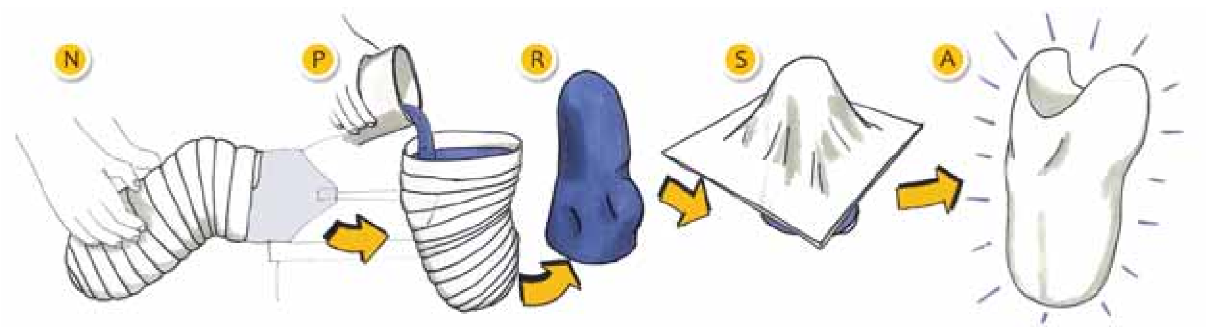
In P&O workshops patients are then sent home with instruction how to learn to walk properly. Rehabilitation centers provide more care by giving physiotherapy and teaching the patient internally to walk properly. In these centers the rehabilitation process can be as long as two months (Wijnans, 2012). During this period the patient can stay at the rehabilitation center. Many hospitals and rehabilitation centers do not have an own P&O workshop and patients are brought to external workshops.

The most difficult part of producing a proper LLP is the socket. Because every stump is unique, no standard sockets exist and each socket needs to be custom-made. A good overview of the various existing methods to produce sockets (and the other components for LLPs) together with an evaluation is given Andrysek (2010). Below these and other methods are discussed.

PRODUCTION PROCESS

The most common method of producing a socket in both developed and developing countries, is to use a manikin stump: a cast copy of the stump (Figure 6). To do this, first the stump is wrapped with plaster cast tape to create a **negative impression** (N). When dry, it is removed from the stump and filled with plaster to get the **positive mould** (P).

Figure 6: Conventional method to produce the socket for a lower leg prosthesis (adapted from Seymour, 2002, p. 179).



On the real stump the Prosthetist already marks important places, e.g. pressing his thumbs on the location of the patellar tendon to create an indentation in the cast copy. The Prosthetist understands the biomechanics of the stump and knows the pressure-tolerant (PT) and pressure-sensitive (PS) areas (see APPENDIX A [THE STUMP]). He removes material to increase pressure on PT areas, and removes material to relieve PS areas (SEYMOUR, 2002). During this process, called **rectification** (R), the original information is lost. This part of the production process requires the most knowledge and experience (LAING, ET AL., 2011).

In the next step the **socket** (S) is created over the rectified positive mould. Depending on the local availability of materials a polypropylene sheet is thermoformed or the mould is laminated with fiber-reinforced resin. The positive mould is removed and **final adjustments** (A) (like trimming) are made to the socket to allow for freedom of movement (e.g. for sitting, walking, squatting).

Problems

When looking at the conventional production process the following obstacles are observed:

- Positive mould: requires **time** for curing of plaster
- Rectification: requires **experience** for recognition of PS and PT areas
- Socket forming: requires **machines** for thermoforming of polypropylene

3.5 OTHER METHODS

Around the world many different research groups and companies are working on new ways of producing the socket for an LLP (see APPENDIX J [INTERNATIONAL PROJECTS]). Many interesting methods were found and are described below.

HYDROSTATIC CASTING

The soft tissue in the stump can be seen as a fluid and is expected to behave according to Pascal's law of fluids. It states that a confined fluid will transmit external pressure uniformly in all directions perpendicular to the container's surface. If the socket behaves like a hydrostatic system when loaded, areas of high pressure are eliminated (LAING, ET AL., 2011). This forms the basis for Total Surface Bearing (TSB) sockets.

PCAST

Different media can be used to realize a uniform pressure while making the negative impression. Air (or vacuum) is used in pressurized bags like the commercially available Icecast® Anatomy (Össur), while water is used in a slightly different technique called PCAST (Pressure CAST), first created by MURDOCH (1965). PCAST uses a vertical cylinder filled with water in which a plastic bag is placed (FIGURE 24). After wrapping the stump with plaster cast tape, the patient is asked to insert his stump in this plastic bag and put increasingly more weight on this leg. Initially this will cause the water level to rise, but at a certain point this is hindered by a diaphragm. If the patient now puts even more weight on his stump he is actually compressing the contained water, causing the overall pressure to rise. With this system the patient can alter the applied pressure with his own weight.

Casting the patient in standing position uses objective parameters like stump anatomy and body weight, to generate a uniform pressure on the stump and create a unique socket shape. This technique does not require rectifications to the positive mould and is said to produce sockets that are more comfortable than PTB sockets (LAING, ET AL., 2011). Multiple researchers have investigated the resulting pressure profile of the stump in the socket and compared with traditional PTB sockets (A.O. J.C.H. GOH, LEE, & CHONG, 2004; MANUCHARIAN, 2011). Their overall conclusion is that the pressure distribution of PCAST sockets is better than traditional PTB sockets. Patients do not perceive much difference in comfort.

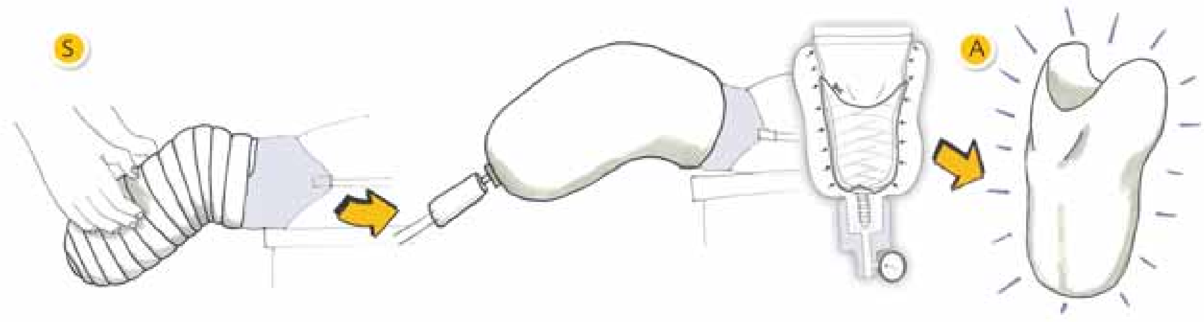
DIRECT CASTING

With direct casting the requirement of a manikin stump is eliminated, the socket is created directly over the stump. Four examples of direct casting are described below.

ZIP

As a team effort of a Dutch Prosthetist, cast specialist and rehabilitation specialist the Zwolle Isala Prosthesis (ZIP) developed (EMMELOT, BRINKMAN, HOL, JORNING, & OVERBEEK, 2007; EMMELOT, ET AL., 2005). For the ZIP method first pelottes are placed on the PS areas of the stump (see FIGURE 23). A silicon liner is put over the stump and wrapped with plastic foil. Now the cast specialist wets a few rolls of synthetic cast tape (typically Delta Cast® Conformable, BSN Medical), wraps them around the stump and applies another layer of plastic foil (S in FIGURE 7). Next the Icecast® is connected to the distal end of the liner and put over the stump to create a tight socket (A). In combination with the applied pelottes the pressure eliminates the rectification step and creates the right shape for the socket. The ZIP method allows the patient to start walking within one hour (OVERBEEK, 2012).

Figure 7: Direct casting with pressurized bag. Note that certain steps are eliminated with this production method.



MSS

The Modular Socket System (MSS) is developed by Össur. In this method multiple sheets of fiberglass are sandwiched between two watertight layers of elastic plastic and wrapped tightly over the stump. Resin is injected and creates a strong connection with the fiberglass. When the resin is evenly spread, the Icecast® is placed over the stump and pressure is applied for ten minutes. The resin needs to cure for an additional two hours before the socket can be loaded.

Comparing MSS to the conventional production process, MSS is more expensive (€ 783,- vs. € 534,-), more than twice as fast (88 min vs. 211 min) and can be delivered a lot faster (1 day vs. 17 days) (NORMANN, OLSSON, & BRODTKORB, 2011).

STS

For the method of STS a special sock is developed that is made from polyester / Lycra yarn impregnated with a water curable resin (STS COMPANY, N.D.). The material is shaped and rolled like a donut and when wet it can be unrolled over the prepared stump as if it were a large condom. The Icecast® is used to apply pressure and create a good fitting socket. Advantage of this sock over the use of synthetic cast tape is that it is much easier to create an even thickness. In 2001 the concept of the 'STS Rolon Socket' was tested on a small scale at VIETCOT in Vietnam, but unfortunately the market did not embrace it (STESS, 2012).

SocketCone

Multiple plastics exist that can be formed at relatively low temperatures. Polycaprolactone (PCL) is such a plastic and has a melting point of about 60°C. A USA company has developed a method of using this material to form a socket for an LLP (CHESAPEAKE MEDICAL PRODUCTS, 2007). After the stump is prepared with stockinet and pelottes, the preshaped SocketCone is heated in a bucket of warm water and applied on the stump of the patient. While the material cools down, the Prosthetist manually applies pressure to create a good fitting socket. Later a shank and foot are attached and the LLP is ready for use.

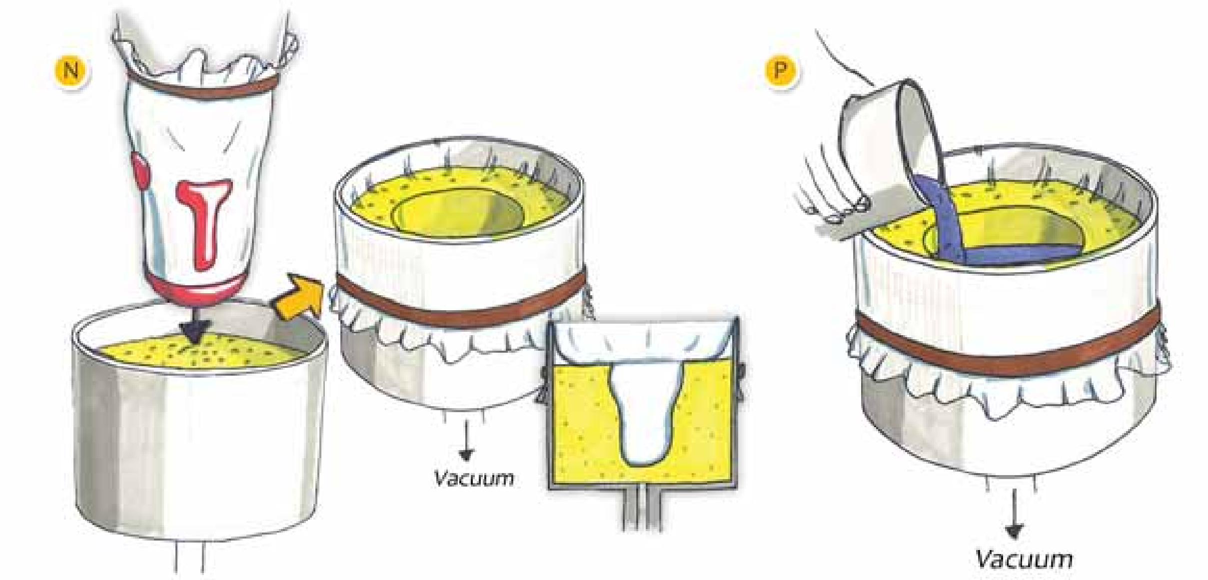
Although this method is very fast and simple, PCL is not available everywhere in the world and can therefore be rather expensive. Additionally durability of a material with such a low melting point in a tropical climate can be questioned.

CIR-WU CASTING

A very fast method of creating a positive mould for the stump is developed by the Center of International Rehabilitation (WU, CASANOVA, REISINGER, SMITH, & CHILDRESS, 2009). This method uses the 'dilatancy' principle, which is best known for the packaging process of coffee beans. Loose granules are enclosed in a flexible container and become a solid mass when a vacuum is applied.

A casting bag containing polystyrene beads is placed around the stump and a vacuum is applied. The stump is removed and as long as the vacuum is applied, a negative impression remains in the casting bag (N in FIGURE 8). This impression is filled with a plastic bag containing silica sand or glass beads and again vacuum is applied to create the manikin stump (P). The shape can easily be rectified and a sheet of polypropylene (PP) can be thermoformed over this shape to create the socket. It is said to increase portability for service in remote areas (WU, ET AL., 2009) and indeed, the method has been successfully applied in some mobile workshops in Thailand and a clinic in Indonesia (JIVACATE, DEVAKULA, TIPAYA, & YESUWARN, 2011). On average they were able to make about 100 prostheses within four operating days.

Figure 8: Schematic representation of a lesser developed form of the CIR-Wu Casting technique, previously called sand casting. In recent developments the silica sand (yellow) is replaced by lighter polystyrene beads and the negative impression is not filled with Plaster of Paris (blue) but with silica sand.



CADCAM

CADCAM techniques are also used to produce a transtibial socket. The stump is scanned (e.g. with laser scanning) and imported into a CAD program (e.g. Tracer CAD). The software allows the Prosthetist to rectify the CAD model, and a positive mould is created with CNC milling. The socket is thermo folded over this mould and tested by the user. In some cases the socket is created directly using Rapid Prototyping technology like Fused Deposition Modeling (HSU, HUANG, LU, HONG, & LIU, 2010) or 3D printing (HERBERT, ET AL., 2005).

Despite the high initial costs and complex technology, using CADCAM for the production of sockets has multiple advantages. Production costs are relatively low because the costs are related to the volume of the part, not the complexity (ROGERS ET AL., 2007). It gives a lower demand for highly skilled personnel at the P&O workshop because fabrication would typically be performed externally (ANDRYSEK, 2010). Especially for long distance fittings using CADCAM seems to be advantageous.

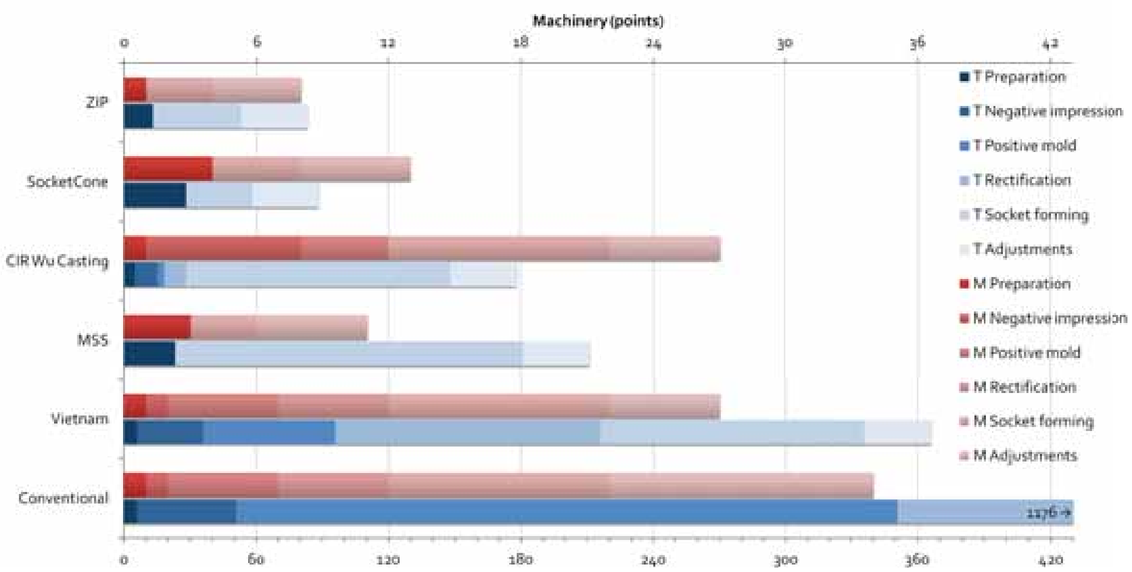
Currently much research is aimed at improving this method. Examples are the development of a portable indentor to enable the ability to add stiffness distribution to the CAD model (COLOMBO, FILIPPI, RIZZI, & ROTINI, 2010), the integration of the lower leg with the socket in a Monolimb (LEE & ZHANG, 2005) and realizing control of flexibility in the produced socket to fit the biomechanics of the stump (ROGERS, ET AL., 2007).

COMPARISON

Above the relevant methods to produce the socket for an LLP are described. To make a comparison more data is provided about the time and machinery that is required to use these methods. The data and the method to produce the graph presented below (FIGURE 9) can be found in APPENDIX D [PRODUCTION METHODS]. Data for the STS method and CADCAM was not found and these methods are not included in this comparison.

The graph shows how dramatic improvements have been made when comparing the newer methods with the conventional production method of LLPs. It also shows that from these production methods, only the ones available in the developed countries (ZIP, SocketCone and MSS) have succeeded to decrease the required machinery.

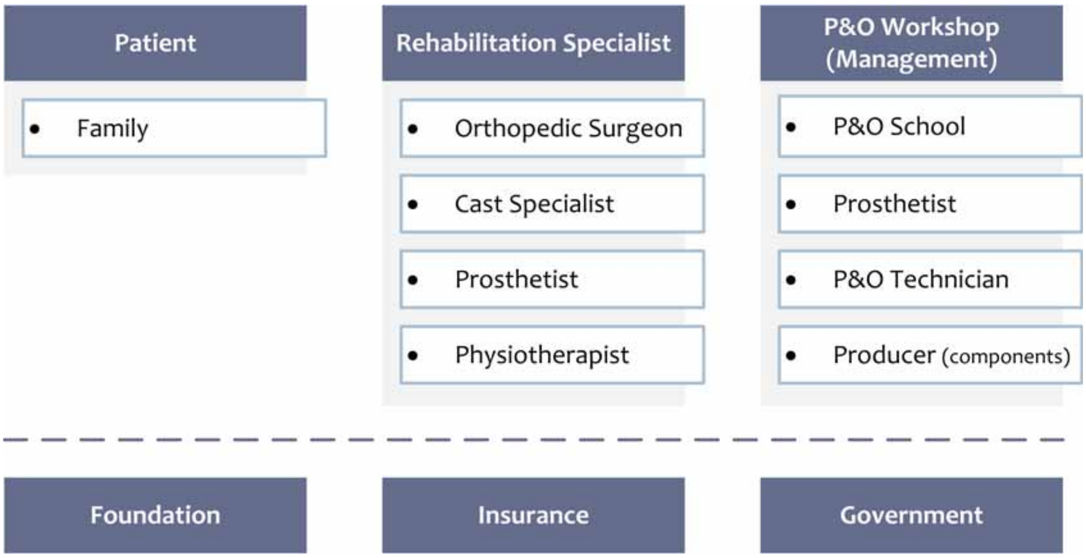
Figure 9: Comparison of the production time and required machinery of different methods to produce a prosthesis.



3.6 STAKEHOLDER ANALYSIS

Making an LLP involves many people (FIGURE 10). They all have influence on the production process and have their own interest in it. The paragraphs below describe which stakeholders are involved and how they are related to the different steps in the rehabilitation process. A few stakeholders (e.g. Designer, Distributor) have not been included in this analysis because their involvement is very brief or minimal.

Figure 10: Schematic presentation of selected stakeholders



Patient

Without a normal leg, many activities of daily living become very hard or even impossible. An artificial lower leg creates new opportunities and can bring patients back into society. For the patient it is important that he regains as many functions as possible, meaning the ability to get up and walk but also e.g. to work in paddy fields, play football and visit a place of worship. The patient wants to be able to get the right amount of service and care to get his prosthesis, without having to travel through difficult terrain and being away from home and work for weeks (BEISE, 2012; CAREY, 2012).

The patient needs the product to be perfectly adjusted to his body and his way of moving. He will not use a product that is painful or difficult to work with. For the patient the reliability of his prosthesis is of the utmost importance because he wants it to solve the problem, not create new ones. A failing prosthesis creates dangerous situations for the patient and can result in an unusable stump which disables the patient ever more. In using the prosthesis a patient wishes it to be as comfortable as possible, have an acceptable appearance and have a low price.

Family

After amputation, the patient is heavily dependent on his family which can be rather stressful. The family is expected to care for the patient and help him to get to a P&O workshop. Especially with younger patients one or more family members will also be away from home to get a prosthesis, so it is important that this process is short. It is important that the prosthesis provides (a feeling of) independence for the patient to relieve the family.

The family of the patient is also expected to help in later stages of the rehabilitation process. Since family members will most probably get information second hand, it is important that information about maintenance and adjustments is easily understood and shared.

Rehabilitation Specialist

In the developed world a lower leg amputation is approached with a multi disciplinary team, commonly headed by the rehabilitation specialist. The rehabilitation specialist (or doctor) will setup the rehabilitation program and select the right specialists. After amputation he makes sure the wound and stump are treated correctly and decides what assistive device would fit the needs of the patient best. The goal of the rehabilitation specialist is to make the rehabilitation process as fast and comfortable and to remobilize the patient as soon as possible.

Orthopedic Surgeon

Amputation of limbs has saved many lives and procedure almost never fails. Conversely, treatment of an open bone fracture can be very difficult and in Indonesia this is often treated with amputation (WELMERS, 2012). The orthopedic surgeon is responsible for creating a suitable shape of the stump and for him it is unnatural to amputate (too) much healthy tissue. Often the stump lacks quality creating challenging situations for the Prosthetist (CIR, 2006). A stump can be too short because the surgeon wanted to keep the knee intact, but it can also be too long to construct a shank and foot under it. In some cases a re-amputation is necessary to allow a comfortable and functional prosthesis to be made.

Communication about the requirements of the Prosthetist and the possibilities of the orthopedic surgeon can therefore be very important. In the developed world communication often goes via the rehabilitation specialist or the cast specialist. In the developing world this communication can be completely absent (WELMERS, 2012).

Cast Specialist

Immediately after amputation, the cast specialist will treat the wound and cast the stump in the correct way to enhance the recovery of the wound and create a usable shape of the stump. In history this was done with elastic bandaging, but this has been replaced by a more rigid cover, called Rigid Removable Dressing (RRD). The cast specialist is able to reduce or even remove contractures. The cast specialist is often the first to indicate that the stump is ready for a prosthesis (OVERBEEK, 2012).

Prosthetist

The Prosthetist is the actual producer of the prosthesis. He collects all relevant information (stump measurements, activity level, etc.) and uses this to fit the prosthesis to the needs of the patient. Much knowledge and experience is needed to be able to understand what the needs of the patient really are.

> *"When I see the patient, in my mind I already start constructing the prosthesis. When I see how the patient uses the prosthesis, I immediately understand how the prosthesis can be improved and what should be adjusted" (KAMER, 2012)*

For P&O facilities the LLP is just one product in a large variety of possible services. It is one of the easiest services that can be provided although it takes much effort to get it right (KAMER, 2012; WELMERS, 2012). The interest of the Prosthetist is that the production process is fast and easy so he can focus on the more difficult problems. It is important that his customers are satisfied and that the rehabilitation process is fast and trouble-free.

Physiotherapist

The physiotherapist trains the patient to use the prosthesis and therefore enhances the mobility of the patient. Additionally the physiotherapist helps to prevent contractures by giving physical exercises. The physiotherapist gives advice about the required adjustments to the used product to improve the walking pattern and other activities of daily living. To speed up the rehabilitation process, the physiotherapist would like to make these adjustments himself. To enable this, the physiotherapist could be interested in an interface that would make this process intuitive.

Management P&O Workshop

The management of the P&O workshop is interested in increasing the production rate, improving the product quality and increasing profit. For the P&O workshop it is desirable that the production time of the new LLP is low, low-cost materials can be used, no expensive specialist are needed but instead low-cost workers are able to produce it, and no expensive machinery is required. It is important that the quality is high so customers will recommend the product to other potential customers and donors will keep donating money.

For P&O workshops in developing countries it is very difficult to import components or materials that are unavailable in their own country. It is therefore very important to use local materials to be independent of foreign producers. Producing a product locally instead of buying it abroad can also create new job opportunities (HALOHO, 2012).

P&O School

In almost all developing countries there is a great lack of Prosthetists and P&O Schools are working hard to improve this problem. One of the difficulties they face is the quality of education, which means graduates lack capability of producing high quality assistive devices (KAMER, 2012). Following the definition of ISPO, these graduates will not be called Prosthetists but P&O Technicians (see 2.3 EDUCATION). The P&O School in Surakarta has a rather bad reputation because of this and apparently the knowledge of producing LLPs is difficult to transfer to new students. Changing the curriculum to improve this is a sluggish process, so for the P&O School it is desirable to have simpler prostheses and methods that are easily applied and learned.

P&O Technicians

A P&O technician differs from the Prosthetist in that he is less well educated and will not be making the important decisions. He is an excellent production worker but is unable to adjust the product to the needs of the patient unless the Prosthetist tells him how (KAMER, 2012). A simpler and more intuitive production process is more suitable for P&O technicians. This could relieve the pressure on the Prosthetist and more patients could get high quality prostheses

Producer (Components)

Many of the available components for LLPs are produced by big European countries like Össur and Otto Bock. Most of these high quality components are too expensive to be used in developing countries and currently only few companies exist that target the BoP. Current producers could be interested in the development of a new LLP to reach the BoP market and increase their market.

Foundation

One of the main objectives of foundations like ISPO and the Liliane Foundation is to provide equal opportunities for disabled people. An LLP is a means to target this objective. For a foundation it is important to know the effectiveness of a project they support so it is easily communicated to donators. Effectiveness can be measured in the number of disabled people that are given a high quality solution. Additionally a project is only considered effective if it provides a sustainable solution. For the design of a new LLP this means it should be easy to measure how many people are effectively helped and it should be easy to teach local Prosthetists how to produce it from locally available materials.

Insurance

As explained in 2.2 HEALTH, health insurance for the poor (Jamkesmas) does not cover expenses for assistive devices, except for Leprosy patients. If a prosthesis is covered by insurance, the insurance company actually determines the maximum price for it, since more expensive prostheses will not be paid for (BEISE, 2012). Assuming insurance companies will get more involved in the near future (WIDAGDO, 2012), their interest will be that the total costs for the prosthesis is low, and that the product is exceptionally durable, requiring only limited maintenance.

Government

Indonesian Health Minister Endang Sedyaningsih said the government is committed to improving P&O services nation-wide (JAKARTA POST, 2011). The ratification of UNCRPD seems to prove this statement. As stated by the Health Minister, many of the existing problems are caused by lack of facilities, infrastructure and skills. It will cost decades to improve education and infrastructure nationwide, so the government would be interested in a solution that is immediately applicable with limited costs.

CONCLUSION

Many people influence the process of making an LLP and many different interests exist. One interest that seems to be shared by everybody is a fast production process. The other influences and interests are briefly summarized in the table below (TABLE 3).

Table 3: Interests and influence of all involved stakeholders on the product

Stakeholder	Influence	Interest
Patient	Available money	Reliability, appearance
Family	Available money	Independence
Rehabilitation Specialist	Stump condition	Fast mobilization
Orthopedic Surgeon	Shape of stump	Fast recovery
Cast Specialist	Stump quality	Fast rehabilitation
Prosthetist	Quality, comfort, durability	Quality
Physiotherapist	Rehabilitation speed	
Management P&O Facility	Production rate	Increased income
P&O School	Skills of personnel	
P&O Technician	Quality, durability	Easy process
Producer (components)	Needed money	Increased market
Foundation	Available money	Increased production
Insurance	Available money	Decreased costs
Government	Infrastructure, education	Fast implementation

3.7 CONCLUSION

The socket is the most important component of an LLP but is also the most difficult to produce. The conventional production method requires much time, experience and machinery but multiple other methods exist to produce a good socket.

4 PROBLEM ANALYSIS

This chapter describes the analysis of the problem. Without a well defined problem, a good solution can never be found.

4.1 PROBLEM DEFINITION

Every year approximately 33.000 people in Indonesia need a (new) LLP (see APPENDIX B [AMPUTATIONS] for a calculation). But with only about 34 P&O workshops in a huge country of 17.000+ islands with poor infrastructure, assistive devices are badly accessible in Indonesia. Every year only about 1.600 prostheses are provided (see APPENDIX C [P&O WORKSHOPS]). The percentage of people having an appropriate LLP is therefore expected to be below 10%. Others expect that from all people who have lost their lower leg only 5 % (CAREY, 2012) or 10 % (WIDAGDO, 2012) have ever visited a P&O workshop.

ACCESSIBILITY

Patients who have lost their lower leg are impeded from accessing P&O workshops, not only physically, but also in distance, financially, and in terms of education / information. Not everybody is insured (SANJAYA, 2007), the capacity of the limited number of P&O workshops is insufficient (BERGSMA, 2011) and the need for a prosthesis can be misunderstood (SAPTYONO, 2012). Many patients and their families cannot afford to be away from home for the long period of the rehabilitation process (BEISE, 2012; CAREY, 2012; HALOHO, 2012).

CAPACITY

Since disability is strongly related to poverty (CAREY, 2012; FILMER, 2008; KAMER, 2012; WIDAGDO, 2012), patients cannot pay for their product and rehabilitation centers have limited budgets based almost solely on donations. Many rehabilitation centers have long waiting lists and with their limited budget it is difficult to improve capacity (SCHAUB, 2009). In an attempt to be less dependent on donations, Yakkum Yogyakarta recently realized a shift from 70-80% of the assistive devices covered by donors to a current 50% (WIDAGDO, 2012). This means halve of the patients is paying the costs for the prosthesis themselves. This has also caused some funds to stop their financial support, so the effectiveness of this approach can be questioned (WIJNANS, 2012).

KNOWLEDGE

Production of good fitting LLPs remains a challenge, partially because it requires well trained people (ANDRYSEK, 2010). In Indonesia, there are only two P&O Schools, both at Java, so the needed knowledge can be hard to acquire (see 2.3 EDUCATION). This means that at some P&O facilities there is a lack of P&O knowledge and quality of the provided prostheses is low. Performance to walk with these prostheses is low with a high risk of further injuries (CAREY, 2012; KAMER, 2012). Some patients create LLPs themselves, often severely damaging their stump (FIGURE 11). VELING (2012B) concludes that patients are incapable of producing appropriate prostheses and should be encouraged to buy a high quality prosthesis at a P&O workshop.

Figure 11: Two examples of self created lower leg prostheses. Both patients said to be in constant pain when wearing the device but needed it to be able to work.

CORRUPTION

All personally interviewed people who have worked in developing countries for many years encounter the same problems, but give it a different name. Whether the underlying reason is working ethics, hierarchic structures, communication or a combination of factors, it causes much frustration (BEISE, 2012; CAREY, 2012; DE BOER, 2011; HONDEBRINK, 2012; KAMER, 2012; WIJNANS, 2012). None of this, or rather the opposite, was observed at rehabilitation center Harapan Jaya where high quality products are provided for a good price. However, all employees knew examples of fraud or corruption at other P&O workshops.

The long periods of suppression, natural disasters and corruption have hindered the developments of Indonesia. As the Dalai Lama says:

> *"A human society without laws aimed at establishing justice will find itself enmeshed in suffering. The strong will impose their will upon the weak, the wealthy upon the poor, the governing upon the governed. So justice is something very important within society"* (INAMDAR, 2005, P. 336).

Indeed Indonesia still suffers from much corruption at customs (GEIGER, 2011) making it very difficult for P&O workshops to get good machinery and materials (BEISE, 2012; KAMER, 2012; WIJNANS, 2012). Also in the prosthetic field corruption can be observed, for example with under the counter selling of assistive devices. In some P&O workshops focus is said to be more on earning money than delivering high quality products. Inappropriate products are provided because of these standards and lack of knowledge (CAREY, 2012; HALOHO, 2012; KAMER, 2012).

In various P&O workshops in Indonesia, employees are prosthesis users themselves. According to TED speaker ALBERTO CAIRO (2011), these are the most motivated employees and take great pride in their work. After a visit to Dr. Jivacate's Prostheses Foundation in Thailand, VELING (2012A) was able to observe seven benefits of having former patients as technicians:

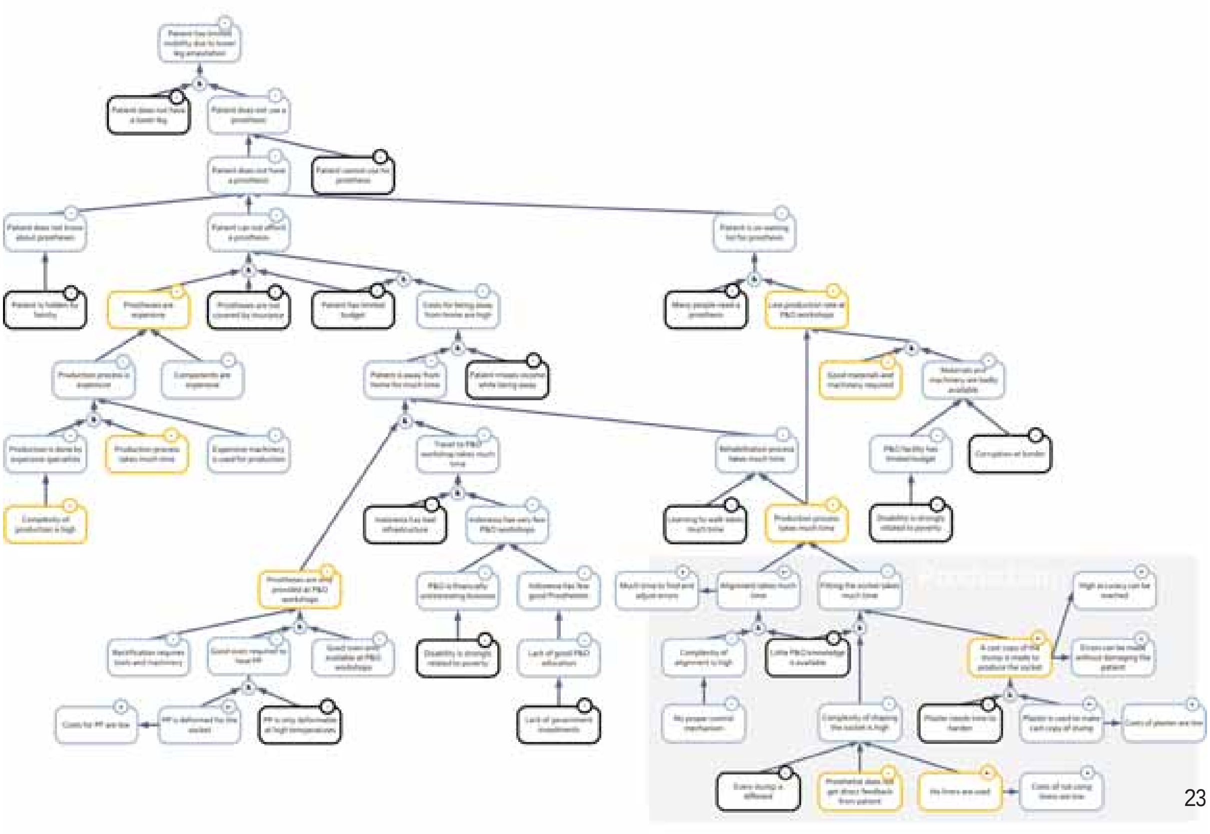
- Dramatically reduced costs
- Passionate approach
- Stimulates demand since they can credibly convince patients that the product works
- Improved quality with the most customer-centric approach
- They understand customer feedback which leads to continuous process improvement
- Instant empathy and high degree of trust
- Creates job opportunities for the poor

RCA+

In the design philosophy of TRIZ a conflicting cause is often regarded as an interesting possibility for innovation. The Root Conflict Analysis (RCA+) is a tool that is developed to find the conflicting causes for a problem (SOUCHKOV, 2005). For current project it is used to summarize above findings and to get a detailed overview of the identified problems and their relation. APPENDIX I [RCA+] gives the result of this analysis. A miniature version of the scheme is presented below (FIGURE 12).

In this tool the investigated negative effect is "Patient has limited mobility due to lower leg amputation", and for each effect the question is asked "what causes this effect to occur?". In theory all causes eventually lead either to an unsolvable cause (black), a conflicting cause (yellow with +- mark) or an interesting solvable cause (yellow with - mark). Small round entities with an ampersand (&) are used to show how negative effects only exist in combination with other negative effects: if only one of these causes is solved, the negative effect is also solved.

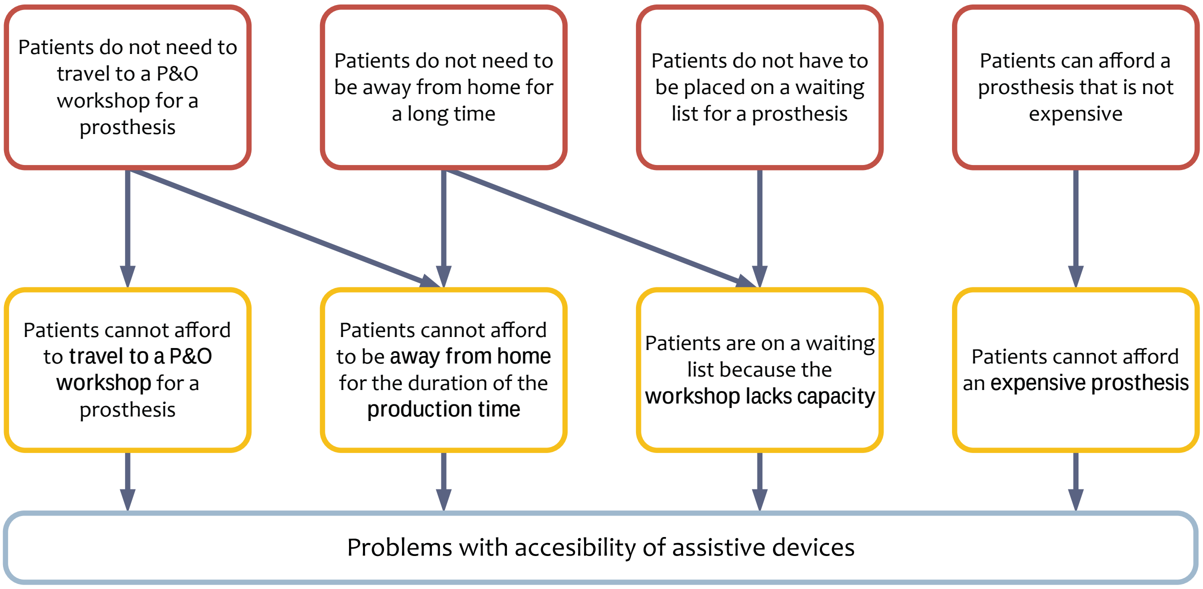
Figure 12: This diagram is the result of an analysis of a negative effect (Patient has limited mobility due to lower leg amputation) and its causes.



4.2 DESIGN GOAL

The fundamental problem of prosthetics in Indonesia seems to be its accessibility. The resulting fundamental goal is therefore to improve the accessibility of prosthetics in Indonesia. Using the RCA+ diagram, some interesting causes for problems with accessibility have been identified. These causes are combined to find a total of four causes, or sub-problems. FIGURE 13 presents these sub-problems with their subsequent goals.

Figure 13: Goals (red) for sub-problems (yellow) of problems with accessibility of assistive devices (blue).



4.3 STRATEGIES

Below, five different strategies are described to target one or more sub-problems.

Mobile Prosthetics

Provide assistive devices from a mobile workshop. Patients in need of assistive devices have been identified by field workers surveying P&O needs in local villages, or the home address has been noted by the hospital performing the amputation. In P&O workshops a list is created of patients who can be helped and visits are scheduled. A Prosthetist and a physiotherapist travel to the patient and fit him a proper LLP. While the Prosthetist is adjusting the alignment of the prosthesis, the physiotherapist is teaching the family how to support the patient in his daily physiotherapy exercises. Within two hours the patient is helped and able to walk his first few meters.

Do-It-Yourself Prosthesis

A few weeks after amputation a large package is send by post to the patient. Because the hospital shared the information about the length and condition of the patient's stump, the producer knows the exact type of prosthesis he should send to the patient. Together with his family the patient soon discovers how he can construct his own prosthesis. The package consists of a pair of pre-shaped plastic parts which the patient can trim to form a good fitting socket. A metal frame then encloses the plastic parts to create a kind of peg leg. Now the patient needs to do a short measurement to find out how much of the metal part needs to be trimmed. Finally an artificial foot is attached to the prosthesis and the prosthesis is properly aligned using the provided manual.

Mass Produced Prosthesis

Every patient is different, but much of their stumps are the same. The new LLP comes in 10 different sizes and minor adjustments can always be done to create the best possible fit for the patient. The product is mass-produced (meaning a much lower price and fast fitting process) and therefore enhances the capacity of the workshop giving the specialist more time to focus on more complex problems.

Simple Prosthesis

Indonesia has many thousands more puskesmas (Community Health Centers) than P&O workshops (Rokx, et al., 2009). After amputation a complete prosthesis is send to the closest puskesmas to the patient's home address. The patient knows the people working at the puskesmas because he goes there twice a week to monitor the wounds of his stump. After several visits the nurses will help the patient fit the new prosthesis, which is as easy as a ski boot. The artificial leg is attached and roughly aligned. Clear instructions on the prosthesis (together with the manual) explain how to align the prosthesis more accurately. During the first weeks the patient should still visit his local puskesmas to check the state of his stump and further adjustments to the prosthesis can be easily made.

3D Printed Prosthesis

A field worker carrying a portable 3D scanner is his pocket scans the stump and residual limb of a patient who has lost his lower leg. He uploads the file and adds some data about the needs and wishes of the patient. The 3D file is received on an online platform to which two different types of partners are connected. Certified prosthetic companies examine the 3D file and propose a price for which they are willing to construct the prosthesis, charity organizations raise the required amount of money. As soon as enough money is raised for the prosthesis, a prosthetic company accepts the 3D file and constructs the new prosthesis on one of their computers. This new 3D file can be printed to any 3D printer in Indonesia. Once the print job is finished, the prosthesis is ready to use and send to the patient.

STRATEGY SELECTION

Involved experts (see Appendix E [Experts]) were asked to give feedback on these strategies and select a favorite. Additionally, for every strategy the effect on the four different goals (Figure 13) was assessed and given a score between 0 (no effect) and 5 (perfect solution). The table below (Table 4) shows that the strategy of **Mobile Prosthetics** has the most potential and is selected for the creation phase of this assignment. Combined with the strategy of involving puskesmas this strategy seems to be most promising.

Table 4: Strategy selection

	Experts	Travel	Time	Capacity	Money	Total
Mobile	3	4	4	2	1	14
D-I-Y	0	4	2	4	1	11
Mass production	0	0	2	3	3	8
Simple	2	3	2	3	2	12
3D Print	0	0	4	4	2	10

The **D-I-Y strategy** is rejected because many people in rural parts of Indonesia are low educated and partly illiterate, so a D-I-Y prosthesis is very likely too difficult. Additionally, it is expected that mail to the more rural parts of Indonesia will not function well, a.o. due to corruption. A very different argument is that every patient and every stump is different and it will be very difficult to create a prosthesis that fits everybody. Fast implementation of this strategy is not likely. This argument is even more applicable on the **Mass Production** strategy. This strategy is also rejected because it will only reduce existing problems (time, money), and not solve them. It is not expected to lower the costs significantly.

The **3D Print** strategy is also rejected for its feasibility in the near future. Especially in rural areas of Indonesia internet and even electricity is not always available. Most people in Indonesia are not used to high-tech machinery and it is expected that as soon as the 3D printer / scanner does not work it will immediately be abandoned.

The **Simple** strategy is well appreciated by experts but rejected because it would require additional education for each nurse in every puskesmas. Additionally it will be difficult to control the selling of prostheses to third parties under the counter. In other words, this strategy is expected to be susceptible to corruption. Still the idea of involving local puskesmas in the system seems to be good. Combined with the Mobile Prosthetics strategy this is expected to be a very suitable, simple and feasible strategy. Challenges are the limited number of Prosthetists in Indonesia and the required training of nurses at the puskesmas.

4.4 DESIGN ASSIGNMENT

The design assignment that results from the selected strategy is the following:

Design a lower leg prosthesis and its production process for a mobile prosthetic workshop.

Demarcation

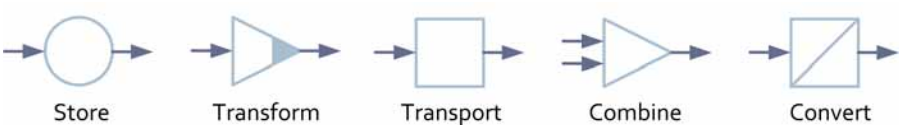
The focus of the assignment will be on the socket (design and its production) and the connection between this part and the rest of the artificial leg (the adapter and its alignment). Current available artificial feet and shank are considered as sufficient and will not be included in this project. Improving the socket and alignment is expected to be more effective. All lower leg amputees are targeted with this assignment and no discrimination is made on the cause of amputation, time since amputation or shape of the stump.

Above-knee prostheses will not be included in this project.

4.5 FUNCTION ANALYSIS

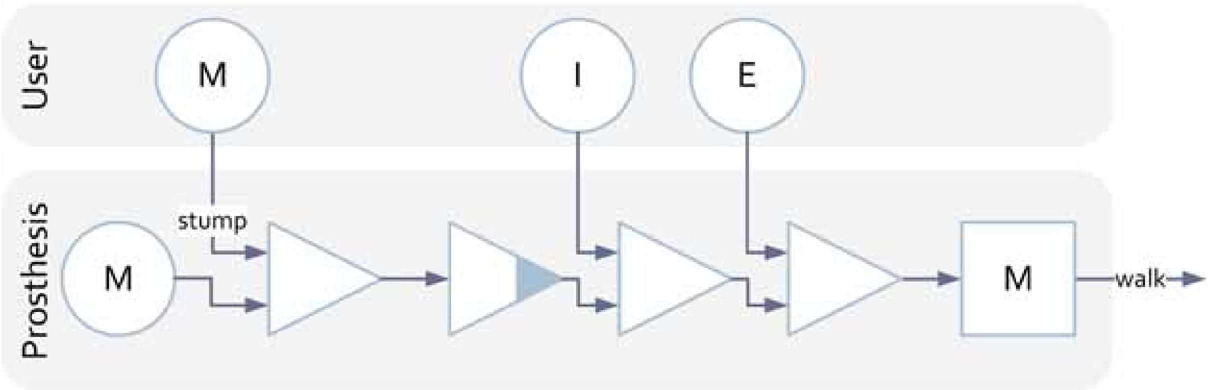
A function analysis is a systematic tool to transform the product into a model that is as abstract as possible. Being forced to think in an abstract way about the product stimulates creativity (ROOZENBURG & EEKELS, 2004). Many different methods for a function analysis exist and for this analysis the MEI method (Material, Energy, Information) is used with 5 different building blocks (FIGURE 14).

Figure 14: The function schemes are constructed from 5 different building blocks



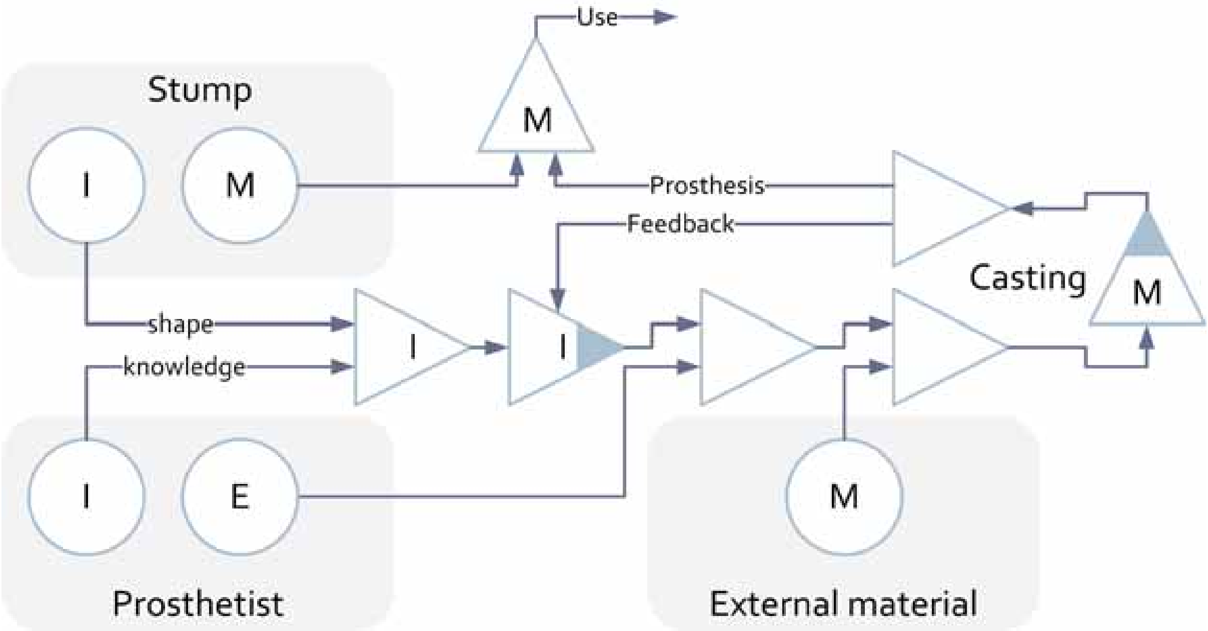
The LLP has to connect itself firmly to the stump of the user and has to provide information about this connection and the alignment: the user should notice when to adjust, or even replace the product. The energy of the user is used to enable walking (FIGURE 15).

Figure 15: Function scheme of the lower leg prosthesis and its user



The identified functions of the production of the prosthesis are presented in FIGURE 16. The Prosthetist uses an external material to create a prosthesis.

Figure 16: Functions of the production of the lower leg prosthesis.



4.6 LIST OF REQUIREMENTS

For the design of an LLP for a developing country many researchers (E.G. VAN BRAKEL, ET AL., 2010) refer to a list in the WHO Technical Report Series No. 100:

> "*The qualities of a prosthetic device that should be accepted as important for a developing country are:*
>
> - simplicity, *ease of construction and possibility of local repair;*
> - durability*;*
> - adaptability *to local conditions of living and occupation*
> - inexpensiveness *of primary cost and repair."* (SANKARAN, 1984)

Current design has to meet all these requirements and a more detailed list of requirements is given below.

Production

1. The components for the prosthesis are commercially available or can be produced from locally available materials, and with locally available machinery, tools and knowledge
2. The prosthesis can be adjusted to the user,
   a. with a good fitting that fits comfortably and does not cause any pain
   b. with a good suspension that fits comfortably and does not cause any pain
   c. with a good alignment that fits the walking pattern of the user
3. Fitting the prosthesis can be done with locally available machinery, tools and knowledge
4. Fitting the prosthesis can be done outside a P&O workshop
5. Fitting the prosthesis can be done within 2 hours
6. Fitting the prosthesis requires a maximum of 1 skilled but inexperienced person

Maintenance

7. Adjustments to the fitting of the prosthesis can be made in a later stage
8. Adjustments to the alignment of the prosthesis can be made in a later stage
9. The prosthesis is robust with a minimum life span of 3 years or 10.000.000 cycles with a person of 80 kg (STESS, 2012)
10. The prosthesis requires only little maintenance with a maximum of 10 minutes per week
11. The prosthesis can be cleaned within 5 minutes and does not attract dirt

Use

12. The prosthesis can handle the full weight of users below 100 kg without being damaged
13. The prosthesis is lightweight with a maximum weight of 1 kg
14. The prosthesis allows the user to stand, stand-up, walk and sit down comfortably and without pain
15. The prosthesis allows the user to jump, squat, sit cross-legged and to kneel
16. The prosthesis can be put on and off without pain

Other

17. The costs for the prosthesis are below 1.000.000 IDR (~ € 80,-)
18. The prosthesis can be implemented in existing systems within 1 year
19. The prosthesis enhances the mobility of the patient, giving the patient a feeling of independence.

WISHES

6. ...inexperienced user	+ including the user
7. ...a later stage	+ by the user
8. ...a later stage	+ by the user
11. ...not attract dirt	+ but repels it
15. ...and to kneel	+ comfortably and without pain

SOLUTION

This section describes the creation of ideas, concepts and prototypes. It uses the conclusions of previous section to form great ideas.

5 IDEA GENERATION

This chapter attempts to describe how the idea for current design was created. Several tools and many conversations with inspiring experts were used for inspiration.

The chosen strategy is to mobilize the production of LLPs and bring the product to the people. To do so, multiple concepts are generated and this chapter is a small intermezzo discussing the generation of these concepts.

5.1 SPARK

SPARK is an open multidisciplinary brainstorm session held by employees of the University of Twente (WENDRICH & JAUREGUI BECKER, 2012). The current design problem was posed and multiple new insights were created. One of the interesting ideas was to look at process innovation tools like Lean and Six Sigma to reduce the production time without changing the production steps. Although this idea was never executed, it did inspire to analyze the current production process and create FIGURE 9. A very practical other result of this session was a large amount of new interesting experts to contact.

5.2 BRAINWRITING

Together with a few fellow master students of Industrial Design Engineering the design problem was analyzed with a brainwriting session. Three design problems were stated on three different papers and every student was asked to sketch a solution in three minutes time. After this period the papers were passed on to the right and the student was again asked to sketch a solution using the previous answer as inspiration. After two rounds the session was ended to have a total of six solutions for each design problem. One of the results of this session was the idea to use of water instead of air to put pressure on a stump. Later this exact same idea was recognized in literature with the name PCAST (see FIGURE 24).

5.3 MORPHOLOGICAL CHART

A morphological chart is often used to generate ideas in an analytical and systematic manner, using the results of a function analysis as a starting point. For every identified function a set of means is created and the combination of these means create a concept. For this project the morphological chart is only created to have a usable set of available means for relevant functions (TABLE 5).

Table 5: The morphological chart is used to have a usable set of available solutions for relevant sub-problems.

Function				
Create negative impression	Laminate - Cast tape - Fiber / Epoxy	Coating - Candle Grease - Clay	Casting - PUR Foam - Putty	Thermoform - PP - PCL
	Dilatancy - Sand Casting - PS Casting			
Apply pressure	Pressure bladder - Icecast® - Car tube	Vacuum	Elastic	PCAST
	Creep	Manual	Expanding foam	Shrink Sleeve
Rectification	Pelottes	Grinding plaster stump	Clay stump	Digital
Connection with lower leg	Splitted tube	Connector - ZIP Connector - ICRC Cup	Internally	Monolimb

6 CONCEPTS

In this chapter all concepts are presented with one scenario. The best suitable concept is further developed.

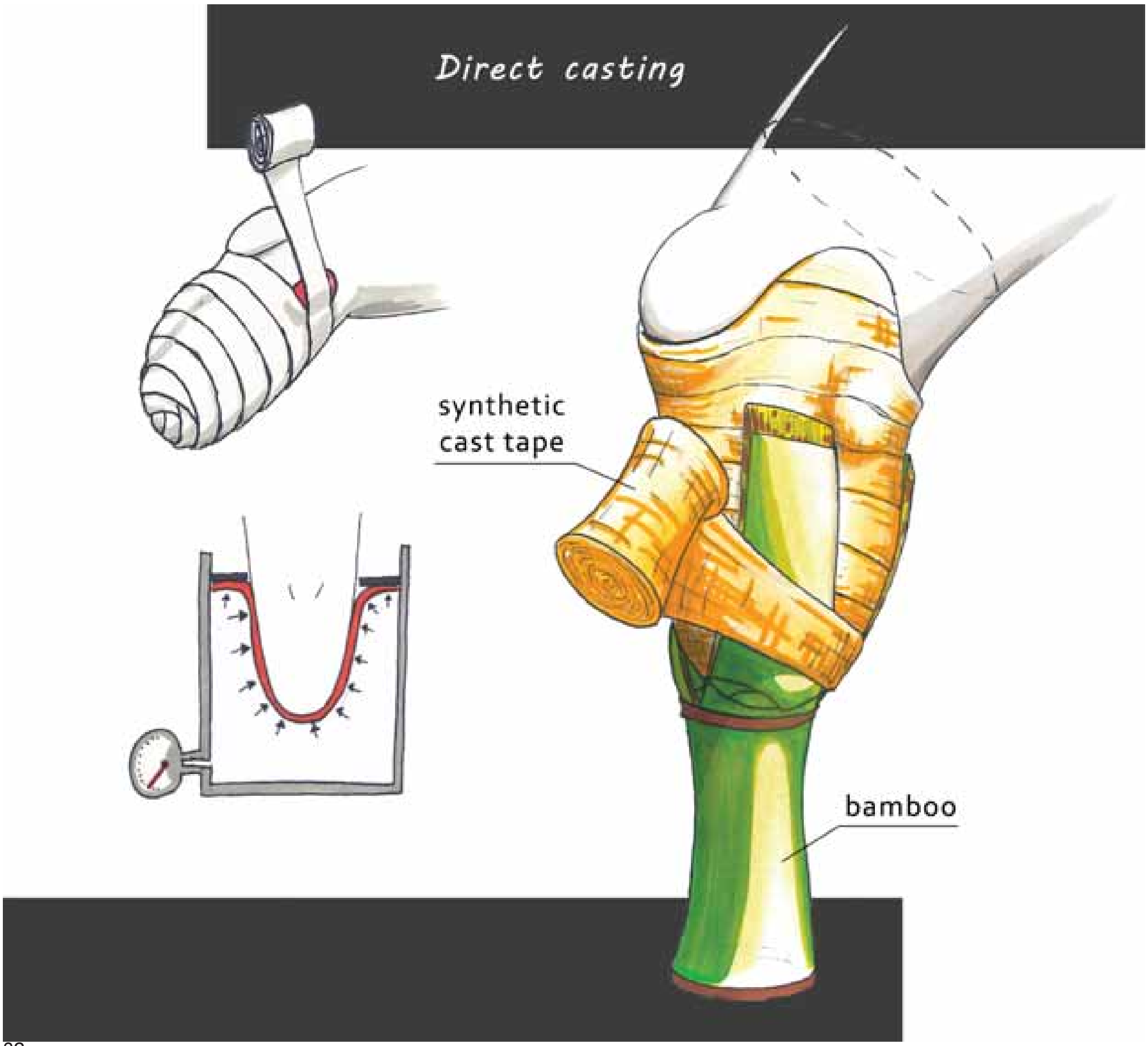
"After amputation the patient is told to visit a local puskesmas to monitor the healing of the wound and to get an LLP when the stump is ready for it. The patient and his family know and trust the people at this small community health center and visit it right after the amputation. A few weeks later the mobile workshop gets a notice from a puskesmas in a rural area that they have found a group of patients that will come together in their puskesmas next week.

The mobile workshop team consists of a Prosthetist, a Physiotherapist and an assistant. While the Prosthetist makes an LLP in less than two hours, the Physiotherapist investigates the quality of the stump of the next patient and teaches others to learn to walk again. In between helping the Prosthetist producing LLPs the assistant provides information to the nurses of the puskesmas how to give after care to the patients."

6.1 CONCEPT: DIRECT CASTING

Synthetic cast tape with water activated resin is wrapped around the stump. While the material is curing, uniform pressure is applied to create a socket with a tight fit. The shank is made from a bamboo stalk that is split in three, folded around the socket and covered with another wrapping of synthetic cast tape. While the material is curing the shank is properly aligned and later a food is attached to the shank (FIGURE 17).

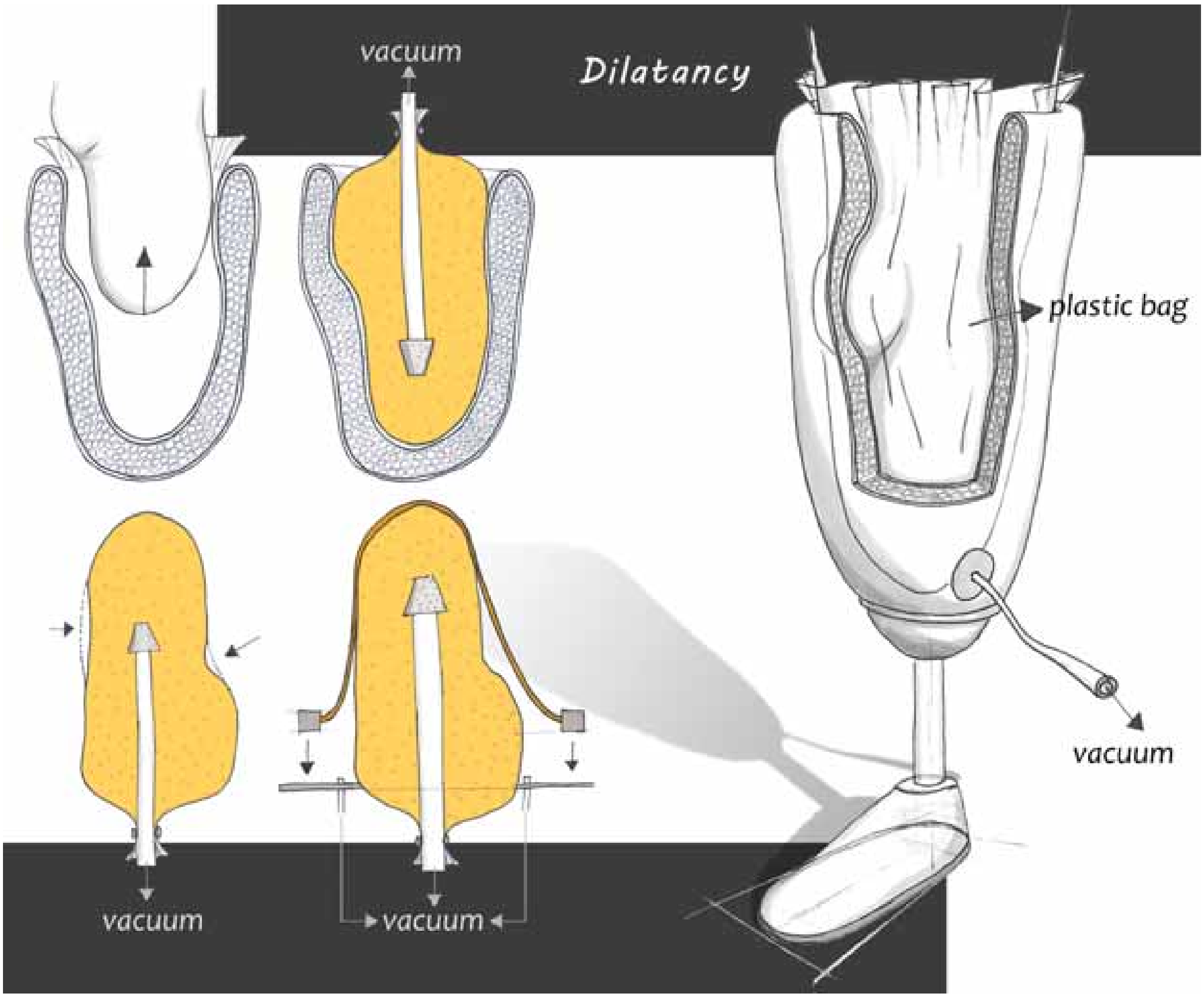
Figure 17: Concept Direct Casting. Synthetic cast tape is wrapped around the stump and pressure is applied to create a socket with a good fitting. A stalk of bamboo is used as shank and connecter with another layer of synthetic cast tape.



6.2 CONCEPT: DILATANCY

The device with a foot, a shank and a silicon bag containing polystyrene beads is pressed around the stump. Vacuum is applied to create a solid negative impression with a tight fit around the stump. While the patient is walking around with the device, the Prosthetist makes adjustments to the alignment. The device is removed from the stump and a plastic bag inside the negative impression is filled with silica sand. With a metal tube again a vacuum is applied to get the positive mold. While keeping the vacuum the shape is easily rectified by modeling the shape as if it was made of clay. A sheet of heated PP is formed over the shape to create a good fitting socket and a shank and foot are attached and correctly aligned (FIGURE 18).

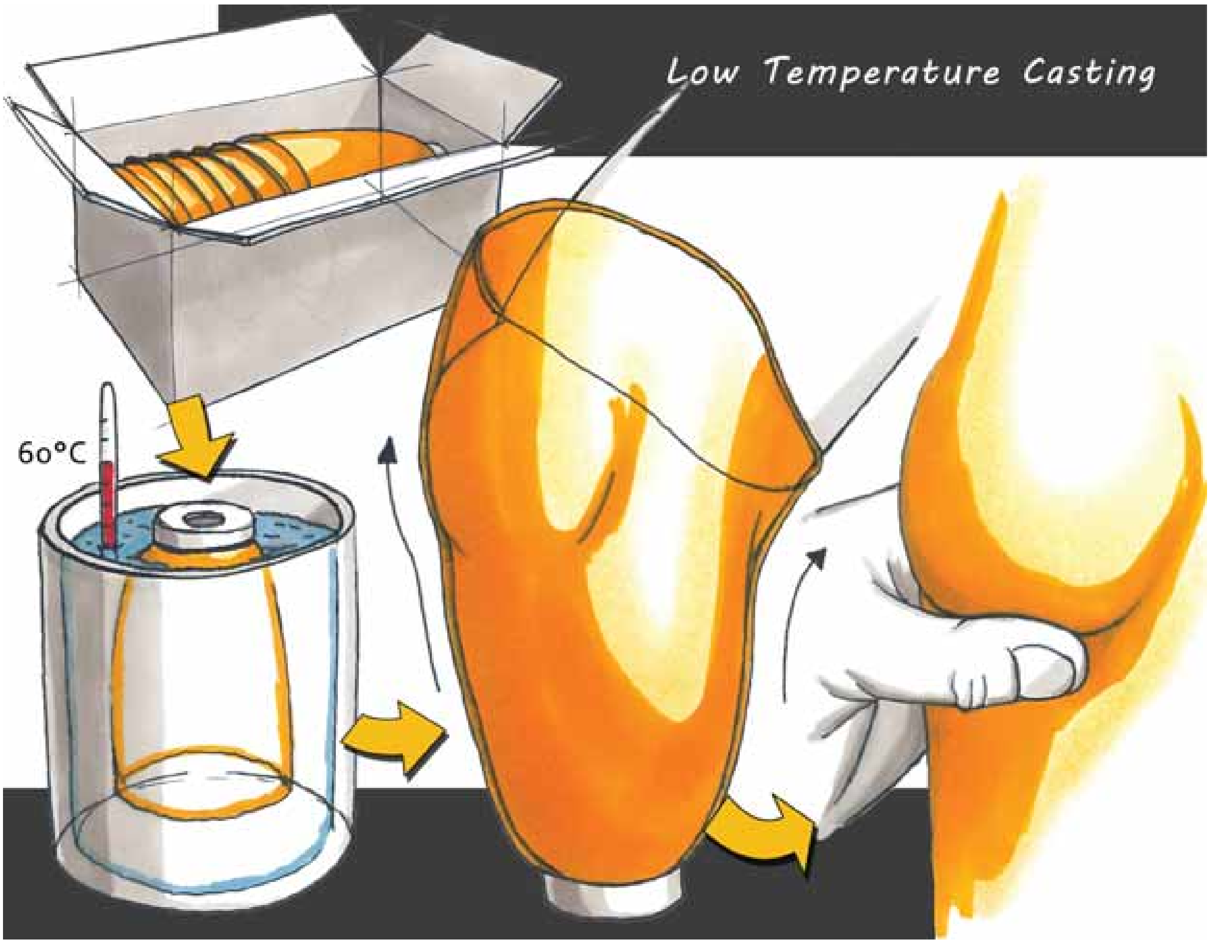
Figure 18: The concept Dilatancy uses a special bag with polystyrene beads to make a negative impression of the stump. The plastic bag is filled with sand and vacuum is applied to get a copy of the stump.



6.3 CONCEPT: LOW-TEMP CASTING

A cone made from a plastic with a relatively low melting point is heated in a bucket of warm water to make it very compliant. It is pressed around the stump and manual pressure is applied on strategic locations like the patella tendon. The material cools down and due to creep a tight fit is created with good weight bearing areas. A connector from a different material is already included and the prosthesis is quickly finished. If necessary the socket is easily adjusted with applied heat. When all adjustments are made the socket is coated with a material to improve its mechanical strength and its appearance (FIGURE 19).

Figure 19: Concept Low-Temp Casting.



6.4 CONCEPTCHOICE

To a certain degree all three concepts have been tested in other projects. It is therefore likely that all these concepts are feasible, but their suitability for current project is questioned.

For a developing country with significant difficulties of importing goods the concept of Low-Temp Casting does not appear to be very suitable. A brief inquiry of the available materials at some P&O workshops in Indonesia did not suggest the presence of any suitable material for this concept. Additionally the tropical climate of Indonesia might be fatal for the material. This concept is not the best suitable concept.

A similar form of the Dilatancy concept is successfully used in Thailand and Vietnam, also in mobile workshops (JIVACATE, ET AL., 2011). Their method is fast but still requires the use of heavy machinery. These smaller countries have a better infrastructure (SCHWAB, 2010) and a denser population of people who have lost their lower leg. In Indonesia patients are living more remotely and are harder to reach making it important to have a very flexible mobile workshop. A large truck packed with heavy machinery might not be able to reach a large proportion of the patients. Because it will be very difficult to make the dilatancy concept independent from heavy machinery, it is not the best suitable concept.

Discussions with many experts pointed to Direct Casting as the best concept for a mobile P&O workshop. The method does not require any heavy machinery and the required material (synthetic cast tape) is commercially available in Indonesia. The simplicity of the concept will allow great adaptability. To put a uniform pressure on the stump the PCAST system will be used. Direct casting in combination with PCAST is considered to be the best suitable concept.

7 THE PONTAS

This chapter describes the specifications of the concept.

As described above, a method for the production of LLPs for a mobile P&O workshop is developed. It was chosen to do this with direct casting in combination with the PCAST technique. With the help of Prosthetist Malapontas Tamba the concept was further developed and several prototypes were made. Because of his dedication and great contribution to this project, the product has gotten the same nickname as Mr Tamba: **Pontas**. This name also reflects the bridge (Spanish: *pontas*) that this project creates between theoretical research in the developed world and practical application in the developing world.

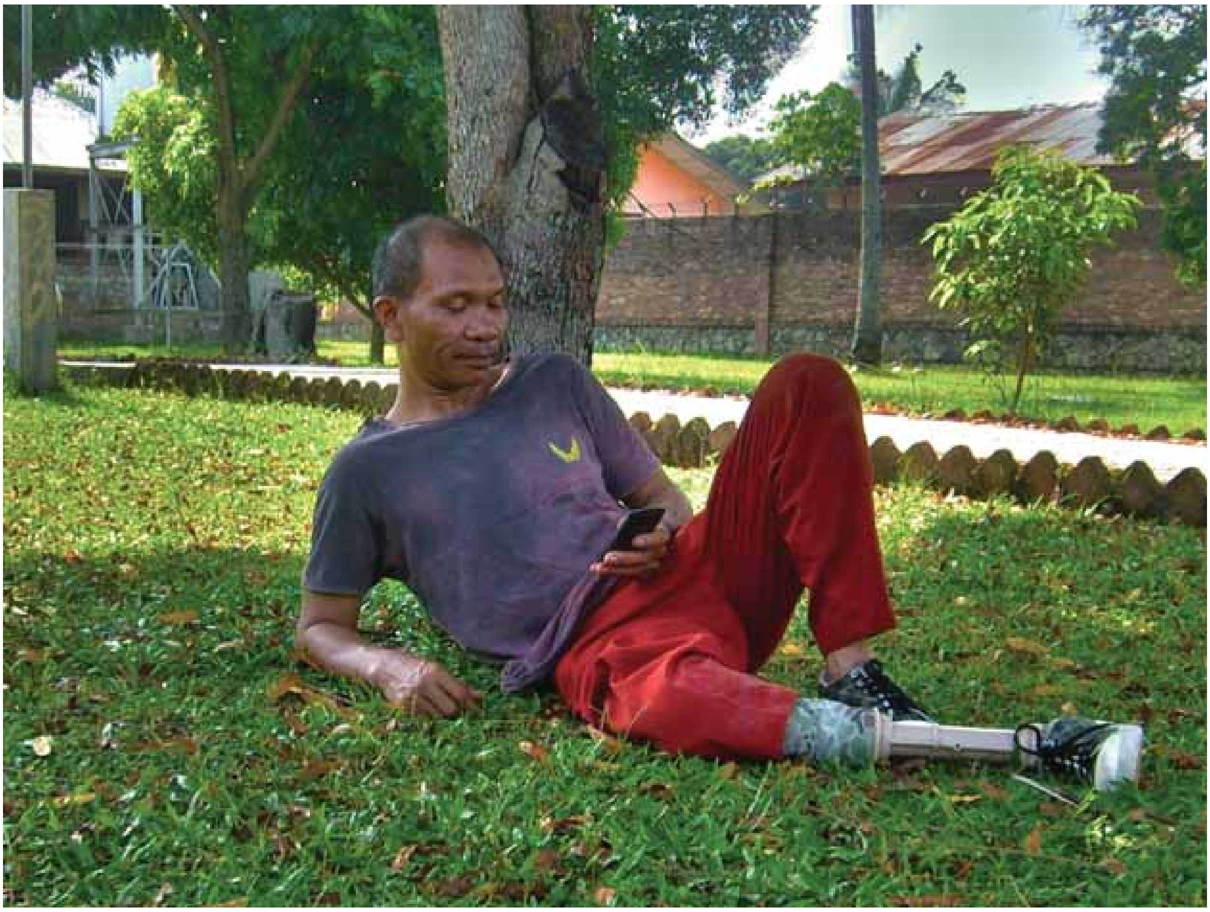
Below the specification for the product, its production process and its business model are described in detail.

7.1 PRODUCT

For the user the Pontas is not expected to be very different from other LLPs. That has never been the focus of this assignment. The goal is to enable patients in poor rural areas of Indonesia to get a good quality LLP. The product itself does not have to be any better to reach this goal.

Because both shank and socket are made from lightweight materials, the prosthesis is relatively light, which is generally appreciated by users (FIGURE 20). The socket is a bit more flexible than a standard PP socket. Because the socket uses a supracondylar suspension (PTB-SC) it is easier to use than the more commonly used waist belt or supracondylar cuff (see SUSPENSION, P.11).

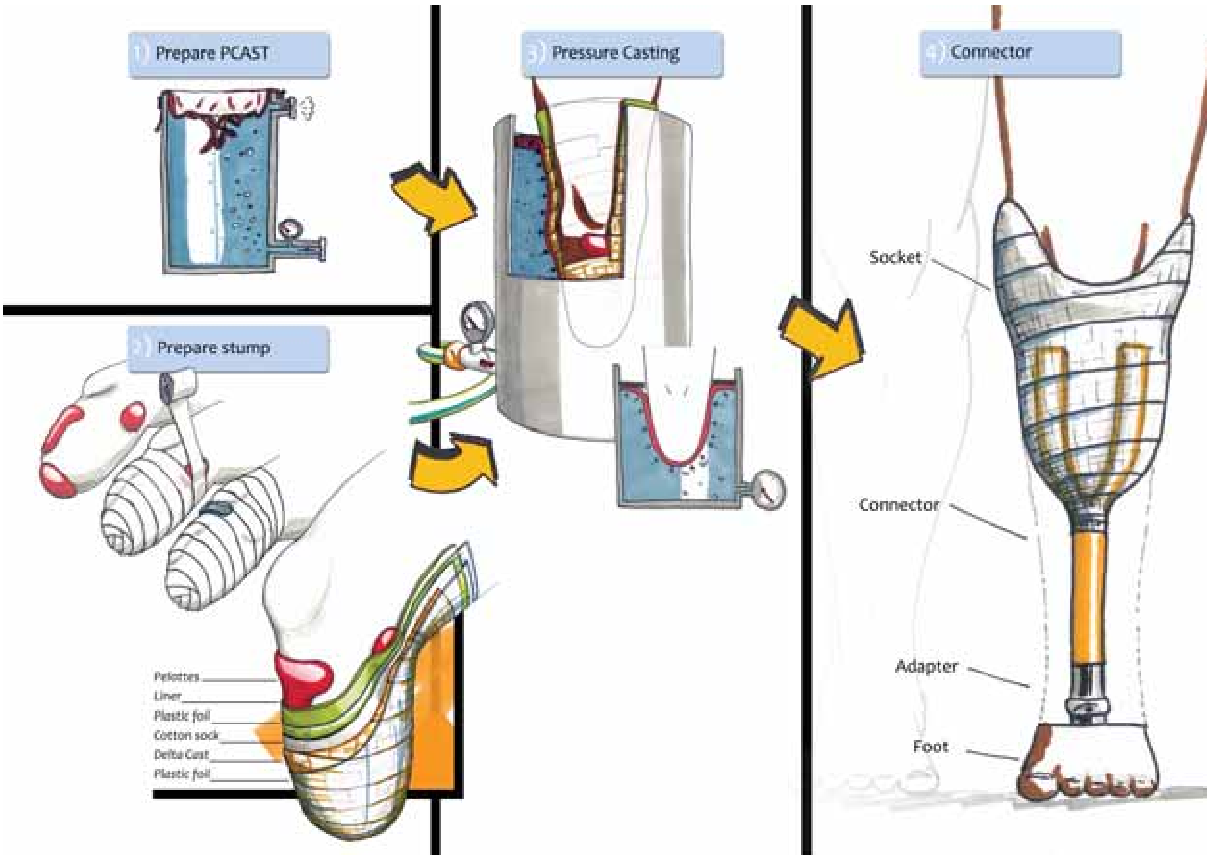
Figure 20: Subject S and his new Pontas with a camouflage print.



7.2 PRODUCTION PROCESS

A graphical representation and a brief description of the protocol are presented below (FIGURE 21). In APPENDIX M [THE MANUAL] a larger version of the image and a very detailed description of the protocol can be found.

Figure 21: A larger version of the production process can be found in APPENDIX M [THE MANUAL].



PROTOCOL

Unlike the conventional production method (see PAGE 12), the developed production method should not be described in five, but rather in three phases. These phases are Preparation, Socket production and Alignment. No consensus exists on which pressure device is best to use so both the use of the PCAST and vacuum pump are included in the protocol. All phases have a strict order of activities and are described below.

Preparation

1. The stump of the patient is investigated, pressure sensitive areas are covered with pelottes
2. A stockinet is put over the stump and covered with plastic foil
3. The pressure device is prepared, a bucket of water is prepared and gloves are worn
   PCAST: the PCAST is filled with water
   Vacuum: the vacuum pump is plugged in and a tube is connected

Socket Production

4. A roll of Delta Cast® is wetted and wrapped over the stump and covered with plastic foil
   a. Distally to proximally, 3 to 4 layers
   b. Upper-pelottes are placed on pressure tolerant areas, e.g. to create a patellar bar
5. Pressure is applied for about 5 – 10 minutes
   PCAST: the patient is asked to stand with half his weight into the PCAST
   Vacuum: a plastic bag connected to the vacuum pump is pulled over the stump
6. The plastic foil is removed, the socket is removed from the stump and the socket is trimmed
7. The outer surface of the socket is roughened with sandpaper and the socket is put on again

8. The ICRC connector is held against the distal end steps 4 to 6 are repeated to fix the connector
   a. While the Delta Cast® is still flexible the ICRC connector is aligned on sight
   b. Manual pressure is applied to the socket for 5 – 10 minutes

Alignment

9. The other ICRC components and the artificial foot are connected to the socket and aligned (see APPENDIX G [THE SHANK])
10. The LLP is aligned to the walking pattern of the user

CASTING

Casting a stump is a delicate process which is difficult to exactly define with parameters like tension and speed. Much experience is needed to understand the subtle differences of changing these parameters.

Material

The socket of the LLP is created with synthetic cast tape and should be strong and durable. The same principle has been developed in history but at that time cast tape based on fiberglass was used (WU, 1981). That material was brittle and deteriorated over time. For the current project a different cast tape is used which is based on PP fibers. At OIM this material (Delta Cast® Conformable, produced by BSN Medical) was recognized as being feasible for an LLP because it adheres to the metal of scissors. This meant a metal connector could be included in the socket to create a strong LLP (see ZIP, P.14). More information about materials can be found in APPENDIX L [MATERIALS].

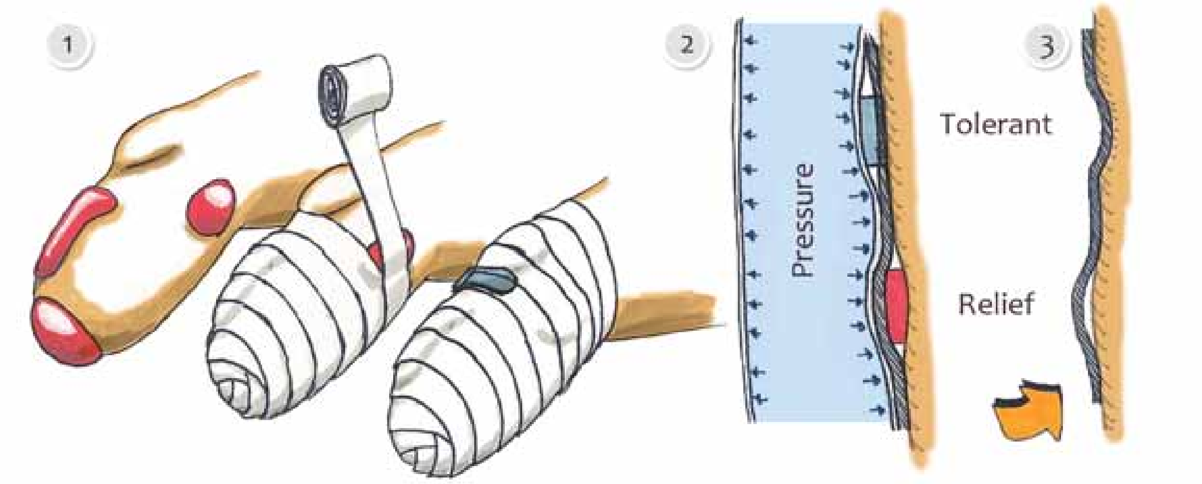
Because Delta Cast® Conformable (DCC) is not (yet) available in Indonesia, Delta Cast® Prints (DCP) is used for the production of the socket. This material is slightly less elastic and creates a rougher surface. The water activated resin of the DCP is visibly pressed out when wrapping the stump more tightly. Spreading out this fluid creates a smoother surface, but the higher tension on the cast tape also changes the shape of the socket in a negative way (FIGURE 22).

Figure 22: Close-up photo of a socket made with Delta Cast® Prints. First the socket was wrapped with low to moderate tension which resulted in a rather rough surface (left). Then this socket was wrapped with an extra layer, this time wrapped with high tension (right). Notice the stretched football print on the right and the smoother surface.

Technique

Pelottes are placed on PS areas like the fibula head (also see APPENDIX A [THE STUMP]). Then, when the stump is wrapped with plastic foil, DCP and again plastic foil these pelottes create bumps for relief. Additionally, pelottes on the outside of these layers produce indentations and are used at PT areas like the patellar tendon (FIGURE 23).

Figure 23: (1) Pelottes under the synthetic cast tape (red) will create bumps and are used at sensitive locations (e.g. fibula head). Pelottes on the outside (blue) will create indentations at pressure tolerant locations (e.g. patella tendon). (2) During the curing process of the synthetic cast tape uniform pressure is applied on the surface of the stump. (3) The socket is finished.



Casting is done in two phases to enclose the ICRC Cup as a connector. In the first phase the pelottes are applied and the stump is wrapped from distally to proximally with moderate tension on the cast tape. After this layer is cured, trimmed and grinded, in the second phase the stump is wrapped with high tension around the ICRC Cup and around the condyles. The rest of the stump is wrapped with low to moderate tension. It was learned that strong tension on the synthetic cast tape around the rest of the stump would create a relatively round shape, while low tension creates a triangular shape. A triangular shape is preferred because it is more anatomically correct and it provides support for rotation.

PRESSURE

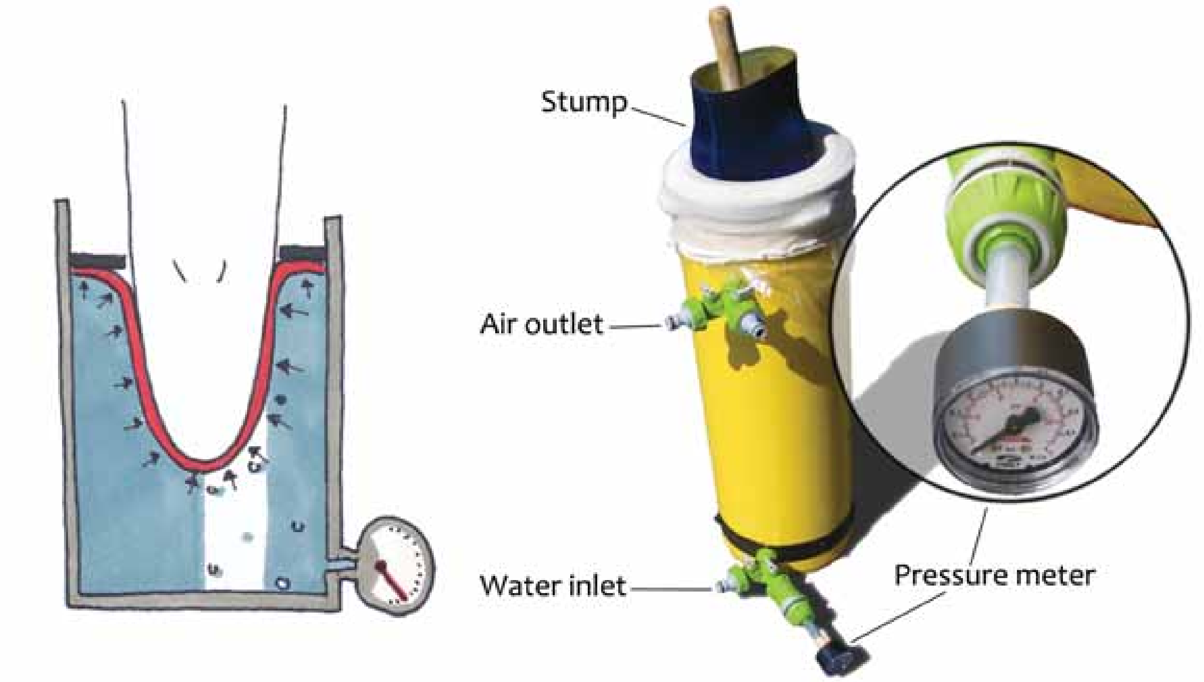
While the synthetic casting tape is curing it is important to put uniform pressure on the complete surface of the stump. This will ensure a tight fit of the socket and smooth the surface of socket. In combination with the pelottes on both sides of the synthetic cast tape it also helps to shape the socket in an anatomically correct way.

PCAST

Different researchers describe their creation of a PCAST tank (J. C. H. GOH, LEE, & CHONG, 2003; LAING, ET AL., 2011; MANUCHARIAN, 2011; SHARIFAH SOFIAH SYED SHIKH, ABU OSMAN, & ABDUL LATIF, 2008). For this project three increasingly larger prototype PCAST tanks were created and here a description is given of the final PCAST.

The PCAST consists of a 2 mm thick, ø 24 x 70 cm aluminum cylinder with a closed bottom. On the side of the cylinder, a water inlet with pressure meter (1,0 bar) is placed at the lowest location and an air outlet at the highest location. Both inlet and outlet are created with standard metal components for a tap and can be opened and closed. A heavy-duty plastic bag is placed inside the cylinder, folded around the top and sealed with strips of rubber bicycle tire and a hose clamp. A plastic and a foam ring are added as diaphragm and cotton stockinet is added to reduce friction with the plastic bag (FIGURE 24).

Figure 24: (left) A schematic representation and (right) the second prototype of the PCAST system. Note that when the stump is pressed into the tank, the water cannot get higher than a certain point due to a diaphragm, created a uniform pressure on the whole surface of the stump.



The PCAST is filled with water up to a certain level. Effort is made to release remaining air before both water inlet and air outlet are closed. When the patient lowers his stump into the PCAST the water level naturally raises. However, from a certain point the plastic diaphragm at the top of the cylinder stops this from happening. If the patient tries to lower his stump even more by applying some pressure on his leg, the water in the PCAST is compressed and uniform pressure on the entire surface of the stump is achieved.

Assuming a 70 kg patient applying half his weight on his stump with a diameter of 15 cm, a uniform pressure of 19 kPa is realized. This pressure is similar to the 2 psi (14 kPa) described by GOH ET AL. (2004), and can easily be adjusted by shifting the weight. The final prototype had some minor defects and PCAST ON PAGE 47 shows how much practice differed from theory.

Vacuum

A vacuum pump, a tube and a plastic bag around the stump also creates a uniform pressure on the surface of the stump (FIGURE 29). The negative of the produced vacuum (e.g. -0,2 bar) is applied on the stump by the atmospheric pressure. Effort should be made to create an airtight connection between the opening of the plastic bag and the stump. The plastic bag should be thin to reduce the influence of folds and inelastic to eliminate shear forces. There are evidences that using this method can give even better results than the PCAST. In VACUUM ON PAGE 48 more can be read about this.

7.3 BUSINESS STRATEGY

The development of current prosthesis strives to a simple yet effective new product. Despite the simple design of both product and production process, great care should be given to the design of the distribution of the product and the used business model to enable effectiveness.

MOBILE WORKSHOPS

Three examples in three different countries of mobilizing the provision of prosthetic services:

1. In **Vietnam** the Netherlands Leprosy Relief (NLR) has an extended outreach program to provide prosthetic services to remote leprosaria (NLR, 2009). Their teams make about 25 trips per year and visit multiple leprosaria per trip, striving to visit each leprosarium at least every third month.
2. In **Thailand** the Prostheses Foundation (PF) has successfully adapted the production technique to the requirements for their current mobile workshop truck (JIVACATE, ET AL., 2011). By using an adapted form of the CIR-Wu casting technique (see PAGE 15), these workshops serve over 100 patients in just a few days. In fact, with 664 prostheses, the Prostheses Foundation holds the Guinness Book world record for manufacturing the highest number of prosthetic limbs in a ten-day period (SKILBECK, 2011).
3. In the **Netherlands** OIM Zwolle provides ZIP prostheses to patients in the Zwolse Isala Kliniek. An OIM Prosthetist takes his Icecast®, metal components and some simple tools to the hospital where he constructs the prostheses together with the cast master. Liners, Feet and rolls of Delta Cast® are stored at the hospital.

The NLR teams (Vietnam) use existing shoe workshops in the leprosaria as their temporary orthopedic workshops, while the people of PF (Thailand) bring all their equipment in their mobile workshop truck. All approaches are adapted to the local requirements, as should be done for current project. With its large amount of puskesmas, Indonesia has a relatively dense network of health facilities. This valuable network is used for the provision of current product.

A rehabilitation center (e.g. Harapan Jaya) will set up a mobile unit. This unit ultimately consists of the equipment and resources for the production of a minimum number of prostheses. The mobile unit will visit a puskesmas or hospital in a strategic location where many amputees can easily be reached. In this location the mobile workshop will be deployed for a few days to serve as many patients as needed.

In practice the mobile unit can be a normal car with the equipment and components for 50 LLPs, including 100+ rolls of Delta Cast®. The driver and passengers of the car must be able to work with this equipment to produce appropriate and comfortable prostheses. Additionally, they should instruct employees of the hospital / puskesmas how to do small repairs and replacements to the prostheses.

Cost Effective

Only a fraction of the patients, the customers, is able to pay for his prosthesis, the product. Remaining costs are covered by NGOs or by other donations and cost-effectiveness is therefore considered not relevant. Here a short analysis is given for the realistic situation of a patient living in Jambi in need of an LLP with Harapan Jaya as the closest P&O workshop, a two day drive. Two scenarios are presented and the costs for the P&O workshop and for the patient are discussed.

1. The patient gets his LLP at Harapan Jaya in Pematang Siantar.
2. The patient gets his LLP at the mobile workshop, located at a local puskesmas in Jambi.

In the first scenario the patient has travel costs, costs for food and accommodation for two weeks and costs for the prosthesis. Additionally he misses more than two weeks of salary. In the second scenario the patient only has costs for the prosthesis and possibly misses salary for one day.

The second scenario allows the P&O workshop to reach a market it will never reach without a mobile workshop. Compared to the first scenario, the mobile workshop has additional costs with the purchase of a car, new equipment and training, and trip costs. Insufficient data is available to make a thorough analysis of the benefits of the new market versus the new costs. Providing as many LLPs as possible with each trip will be more beneficial than only providing a few and therefore it is important that the Pontas can be made in just two hours so about four or five patients can be helped each day.

AMPUTEE TECHNICIANS

As observed by many (CAIRO, 2011; VELING, 2012B), the benefits of having former patients as technicians are numerous (see CORRUPTION, P.22). Interested patients should be offered a training to get involved in the mobile prosthetic workshop team. As seen by VELING (2012B) this will enable a rapid development process and will spur innovation.

FIXED WORKSHOP

Harapan Jaya is interested in the new production process and is eager to use it as a supplement to their current assortment. For Harapan Jaya the new product is cheaper and much faster to produce but quality is not yet guaranteed. Because the size of the stump dramatically reduces in the first years after amputation it is thought best to be used for this first period. It allows the patient to start working much faster and earn money for a ‘real’ prosthesis. Rapid mobilization is also in Indonesia recognized as being valuable. Additionally, if the socket does not fit anymore, a replacement is quickly made (less than two hours) and easily assembled to the modular design. The costs for a replacement would not be much more than the costs of two rolls of Delta Cast® Prints (~ € 30,-).

7.4 CONCLUSION

A new method is developed to create an appropriate socket for an LLP and prototypes are made for the pressure device. A protocol is developed for the production of the new LLP and a description is given for a suitable business strategy for the concept.

EVALUATION

This section gives an evaluation of the developed concept. First the usability of the production method is investigated; second the quality of the new lower leg prosthesis.

8 IN VITRO TESTING

First the usability of the developed production method is evaluated with some manikin stumps.

The developed concept is an LLP with a production method for a mobile workshop. Initially this will make the Prosthetist, and not the patient, the test subject. The first question is therefore if the Prosthetist is able to produce an LLP with the new production method. As a first proof-of-principle, the developed method is performed with several in vitro tests, meaning sockets are made on manikin stumps.

8.1 METHODOLOGY

The goal of the test is to get information about the usability of the developed production method. In two separate sessions the new method is presented to two Prosthetists:

1. Ard Kuiper, working at OIM (the Netherlands). Expert in the ZIP method (see ZIP, P.14).
2. Malapontas Tamba, working at Harapan Jaya (Indonesia). Expert in the conventional method.

Both have more than 20 years of experience with prosthetics in general and producing LLPs in particular. After presentation the method is performed by the Prosthetist on a plaster or silicon stump. During and after the process the expert is asked for his opinion about the steps.

8.2 RESULTS

Although liner, Icecast® and ZIP-adapter are discarded, the technique and production steps of the new method are still found to be very similar to the ZIP method. Therefore the new method is well understood by the ZIP expert and adjustments are easily made. The new socket is almost identical to a ZIP socket, but because no silicon liner will be used great attention should be paid to the fitting of the socket. The idea of using upper-pelottes originates from this discussion. It was tested on stump made from silicon and gave promising results (FIGURE 25).

Mr Tamba also quickly understood the new production process and on a plaster stump he introduced an easy and effective method to include the ICRC Cup as connector for the shank and foot. After this introductory test Mr Tamba explained he understood the process well enough to start patient testing. For ethical reasons not patients but employees of Harapan Jaya were asked to join the experiments.

Figure 25: Upper-pelottes (blue) placed on the sides of the tibia of a stump made of silicon. Note that the pelottes are placed on top of the synthetic cast tape instead of underneath it.

9 PATIENT TESTING

Second the quality of the developed lower leg prosthesis is investigated with the help of three patients.

In a 30 days visit to rehabilitation center Harapan Jaya in Indonesia (see APPENDIX H [HARAPAN JAYA]) the created concept was tested and adapted to the local settings. Together with Mr Tamba experiments were done to tweak the production method. In a later stadium the first graduate of the JSPO Coki Tobing joined the team.

9.1 METHODOLOGY

In previous test the question was if it was possible to produce an LLP with the developed production method. The next step is to investigate if it is possible to produce a good LLP and inherently the goal is proof-of-principle. The question therefore is whether the quality of the produced LLP is sufficient, meaning a good fitting, good alignment and a good suspension. This is investigated with patient tests.

Three unilateral lower leg amputees (see TABLE 6) working at Harapan Jaya were fitted with the Pontas by Mr Tamba. The subject did walk around for a moment and if necessary Mr Tamba adjusted the alignment. If the socket functioned satisfactory, the subject was asked to test the prosthesis for a longer period (commonly until the next working day). At the following meeting the walking pattern and the skin of the stump were investigated and the user was interviewed. For an experienced Prosthetist this evaluation gives enough information to understand what could be adjusted to the LLP. Together with an evaluation of the production process, this information was used to create a production plan for the next socket.

Using this approach, new sockets were made until the LLP and its productions process were considered appropriate by user, Prosthetist and designer. In total 15 sockets were made and all three subjects were fitted with a Pontas. APPENDIX K [TEST SOCKETS] gives an overview of all produced sockets and their evaluation reports. Next paragraph discusses the results of this process and the produced sockets.

Table 6: Particular subject details.

Subject	Age	Sex	Cause	Affected leg	Time since amputation	Age of current prosthesis
E	14	F	Trauma (car)	R	6 yrs	2 yrs
M	43	M	Trauma (car)	L	27 yrs	27 yrs
S	49	M	Trauma (tree)	R	28 yrs	26 yrs

9.2 RESULTS

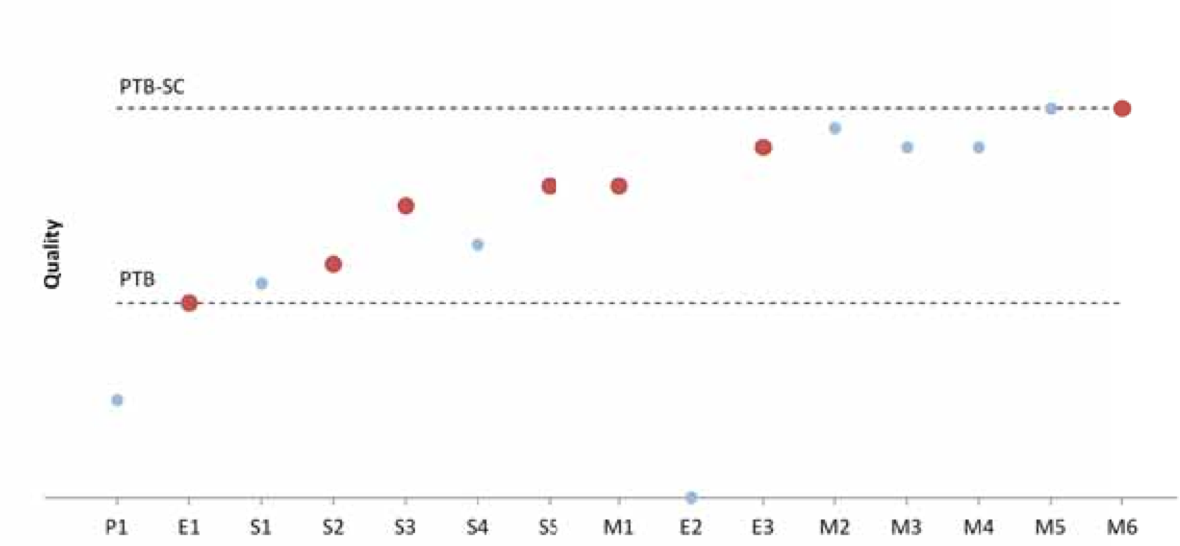
In response to user feedback slight changes were made to the production process to improve the final result. Additionally all subjects were fitted multiple times. This means for every test in fact n = 1 and the results cannot really be used for scientifically significant conclusions. However it does yield credible information for the practical application of the concept.

QUALITY

Every produced socket was graded for fitting and suspension (FIGURE 26) (also see APPENDIX K [TEST SOCKETS]). Due to a limited stock of ICRC components, only a few sockets were developed to a finished prosthesis (red marker in FIGURE 26).

As expected for any new method that requires some learning, the quality of the produced sockets increased with every attempt and each successive socket was deemed better by both the Prosthetist and the subject. Socket E2 is an outlier to the increasing quality. For this socket a fatal step in the production process was forgotten (a sock to reduce friction between plastic foil and skin), most probably due to nerves for the presence of a film crew.

Figure 26: Upper-pelottes (blue) placed on the sides of the tibia of a stump made of silicon. Note that the pelottes are placed on top of the synthetic cast tape instead of underneath it.



More important than increasing relative quality over time, is absolute quality. Mr Tamba and Mr Tobing evaluated every socket and concluded from the first few sockets that with some adjustments these sockets could be used as PTB (excellent fitting, bad suspension), but that PTB-SC (excellent fitting and suspension) would also be possible with this method (see SUSPENSION, P.11). Although a PTB socket is of sufficient quality for an LLP, a PTB-SC socket has a better suspension and is therefore considered of a superior quality. For the last few sockets a very good supracondylar suspension was realized and two good LLPs are currently still in use to investigate the durability of the product.

CASTING

In the conventional production method the stump is wrapped with plaster cast tape (e.g. Gypsona® by BSN Medical) to get a negative impression. This means the Prosthetist is already used to wrap a stump with cast tape but there are several differences in the casting technique.

Working with gloves was not at all appreciated by the Prosthetist. Plaster cast tape is processed without gloves which gives better feedback. Opening a new package can be difficult with wet and dirty hands, so as a preparation the packages of plaster cast tape are normally opened before starting the procedure. Synthetic cast tape starts curing immediately after opening the package and several rolls were wasted due to this misunderstanding.

Wrapping the stump with plaster cast tape is a rather simple procedure and as long as the complete surface is covered not much can go wrong. With the synthetic cast tape the number of layers should be equal throughout the entire socket so a careful strategy should be used to achieve this. The tension on the synthetic cast tape has much influence on the final shape of the socket. When the complete stump is covered with cast tape the Prosthetist is used to spread out the plaster with his hands and to give manual pressure to several areas of the stump. When using the PCAST there is no time or space to do so and it is impossible to manually give uniform pressure to the entire surface of the stump. This caused some frustrations. Conversely, when using the vacuum pump, manual pressure can still be applied and the Prosthetist can still influence the shape of the socket (see FIGURE 29). For this reason the vacuum method was preferred over the PCAST.

TORSION TEST

To get an idea about the strength of the connection between the synthetic cast tape and the (roughened) ICRC Cup, a torsion test was performed (FIGURE 27). With a metal bar (0,60 m) and bucket of water (10 L) a maximum moment of 60Nm was applied. Only slight deformation of the socket was observed which disappeared when the moment was relieved. No movement between synthetic cast tape and ICRC Cup was observed. Whether 60 Nm is sufficient could not be verified with scientific data from literature, but it was thought to be high above the pain threshold.

Figure 27: The torsion strength of the connection between the synthetic cast tape and the ICRC Cup is at least 60 Nm.

PRESSURE

After wrapping the stump with synthetic cast tape, pressure is applied and three different devices were constructed for this purpose.

PCAST

The PCAST prototype (see PCAST, P.39) was extensively tested in Indonesia but unfortunately slightly leaking. It was learned that the used water level is highly important to create proper pressure distribution on the complete surface of the stump. As a preparation the tank is completely filled with water, the patient is asked to step into it and water is released until the stump has sunk deep enough to cover the knee. This is necessary to create a proper shape around the condyles. While filling the tank effort should be made to remove air, because this causes overall decrease of applied pressure and local pressure peaks.

To investigate the influence of leaking water and other minor defects in the prototype, the relationship between applied pressure and measured pressure was investigated. The PCAST was filled with water, placed on a weighing scale and a socket (diameter 13 cm) was pressed into it to realize a pressure of 0,15 bar. The

Figure 28: (left) Subject M standing in the PCAST. (right) With an added weight of 41,5 kg on a stump with a diameter of 13 cm, a pressure of 0,15 bar was measured, 105 % lower than expected.

weighing scale measured an added mass of 41,5 kg, 21 kg (105 %) more than expected. This means some pressure is 'leaking'. In fact the PCAST is indeed leaking a tiny amount of water at a few locations but this will only have a minor effect on the resulting pressure. The remaining air bubbles inside the plastic bag, as well as the rising of the slightly elastic plastic bag will have a greater contribution. A pressure leak causes a bad pressure distribution with typically a pressure peak on the tip of the stump and lower pressure at the condyles.

To investigate the influence of the pressure of the stump, two extra sockets were made with an applied pressure of 0,05 bar and 0,20 bar respectively (FIGURE 28). The expected result was a socket with a slightly smaller diameter and more pronounced indentations at the locations of the upper-pelottes. However, the resulted sockets were almost identical and both user and Prosthetist could not identify any difference but the used prints (footballs versus camouflage). The conclusion was made that a low pressure also gives good results, making the process more comfortable for the patient.

Vacuum

Despite its weight (~ 6 kg), a small vacuum pump is more portable than the rather large PCAST. At first the vacuum pump was discarded because it didn't provide any information about the applied pressure and when tested, the user noticed only a slight pressure on his stump. Later, when a lower pressure with the PCAST proved to give good result too, the vacuum pump was accepted for a new experiment.

After the stump is wrapped with synthetic cast tape a conical plastic bag is pulled over the stump and vacuum is applied. With this method the Prosthetist is still able to put manual pressure on the condyles and even make some slight adjustments to the alignment of the socket (FIGURE 29). The result is a well fitting socket with a very good suspension, better than all sockets made with the PCAST.

Car Tube

As an alternative to the PCAST, a pressure container was made from an old inner tube of a car tire. At an Indonesian *Tempelban* (car tire repair shops) people know how to process this material and a simple prototype can be made for only IDR 50.000,- (€ 4,30). For this pressure container it proved to be best to 'glue' it inside out (actually vulcanizing the material with applied pressure and heat) to have the seam on the inside. Additionally this seam should have a semi-circular shape for more comfort with the stump.

When testing the device a pressure peak on the distal end of the stump was noticed by the patient, as well as shear stress caused by the stretched elastic car tire. When inflated, the diameter of the car tire was rather small making it unsuitable for the production of an LLP. Although this concept is closest to the professional Icecast® by Össur, it misses the fine details and was never used to create sockets.

Figure 29: When using a plastic bag and a vacuum pump, the Prosthetist (left in blue) is able to give manual pressure to the stump of the patient (right in orange) to create a good suspension around the condyles.

9.3 CONCLUSION

In total 15 sockets were made for three users of LLPs. After thirty days of development the result is two prostheses with a good fitting, good suspension and good alignment. The prosthesis seems to be of sufficient quality but long term evaluation is necessary to make any statements about the durability. The production process is highly suitable for a mobile workshop.

10 DISCUSSION

This chapter discusses the results of the design assignment and gives recommendations about future research.

The results of this project are evaluated with the design assignments formulated on PAGE 26.

Design a lower leg prosthesis and its production process for a mobile prosthetic workshop.

Following the four elements of this statement, the design and the test results are discussed below. Recommendations to improvements of the design and to future research are given as a conclusion in the last part of this chapter.

10.1 DESIGN

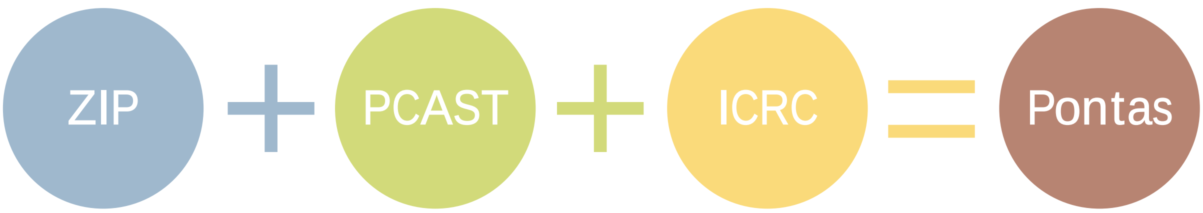
Design...

DESIGN PROCESS

BERGSMA (2011) proposed the ZIP method, developed by OIM, as a candidate for an LLP in Indonesia. Although the ZIP method is very simple and cheap in the Netherlands, it depends on many aspects that are difficult or expensive in a developing country like Indonesia. In particular: the ZIP method uses a silicon liner, the Icecast® and a special ZIP connector to connect standard Otto Bock parts to. All these components are unavailable or very expensive in Indonesia. Still, the concept of direct casting is very smart.

Piece by piece all unsuitable aspects of the ZIP method were discarded, transformed or replaced. To make it possible to discard the liner, the socket is transformed with the use of upper-pelottes. For the Pontas two good alternatives are found for the Icecast®: the PCAST and using a vacuum pump. The components of the ICRC system replace the ZIP adapter and standard Otto Bock components. The same smart concept of direct casting is used, but the final result is very different from the ZIP (FIGURE 30).

Figure 30: Schematic representation of the building blocks of the production method for the Pontas.



As an alternative to elastic bandaging, Removable Rigid Dressing (RRD) was introduced in 1977. Advantages of RRD are complete elimination of skin breakdown, good wound healing and rapid stump shrinkage (WU & KRICK, 1987). Soon the idea came up to incorporate a shank and a foot to create an LLP, first only as a temporary solution, later also as definitive LLP (WU, 1981). Clearly direct casting with synthetic cast tape and using pelottes are no new techniques. They have been used for decades and not solely for lower leg amputations. The idea of using pressure to create an appropriate shape seems to be even older (MURDOCH, 1965), but the combination of direct casting and pressure is relatively new, maybe not even 10 years old. Currently a few methods exist that use direct casting with the Icecast® to apply pressure. What is new about current project is the combination of PCAST with direct casting and the use of upper-pelottes to create indentations at pressure tolerant areas.

PRACTICAL CREATIVITY

One of the concepts of applying pressure on the stump was a pressure bladder made from a car tube, similar to the Icecast®. In the Netherlands attempts were made to create a prototype for this concept but even with help from the rubber experts of the University of Twente it seemed impossible to glue a car tube to itself. Four different kinds of glue were tried but all failed. Eventually it was proposed to try and vulcanize it, but it was said that this would require high temperature and high pressure and such an advanced machine was not available. The technology of gluing a car tube seemed too advanced.

Months later the same concept was proposed in Indonesia. A quick stop at a *Tempelban* was made and the idea was presented. The local tire repairman took an old car tube, and created a very strong prototype in less than an hour. When he was asked what advanced machine he had used to produce this prototype he showed a small metal box with a burner at the bottom and a simple press at the top (FIGURE 31). For him this technology was one of the easiest to understand.

Many similar examples were encountered in Indonesia which created a sad feeling about the developed world. In the developed world people are used to products that are made by machines and if something breaks, buying a new one is cheaper than repairing it. This has severely damaged practical creativity of many people in the spoiled developed world. This observation is probably the basis of frugal innovation. It is expected that if new 'western' ideas are introduced in a less developed world, many practical improvements will be made to the design, simply because advanced options are unavailable. The Pontas already is an example of this process but is very likely to evolve even further in the near feature.

Figure 31: With the advanced technology of high temperature (left) and high pressure (right) a car tube can be 'glued' together.

TESTING VS. DEVELOPING

When testing a product it is important to keep all parameters the same but one. This means every aspect of the design is set and nothing should be changed during the tests. When developing a concept the opposite might be true. Most, if not all, aspects are open to change and should be varied to come to a final design. In current project each socket is different and compared with earlier sockets to find the best settings in the production method. In these comparisons two methods are compared with n = 1 and therefore no scientifically significant value can be given to this evaluation. Additionally most of the time improvement is very difficult to quantify and simply noted as *"yeah, this is better!"*.

Initially the goal of the trip to Indonesia was to test the concept with the local Prosthetists, but this would imply that their input could not be used to improve the concept. Instead their valuable experience with prosthetics in a developing country is used to develop the concept and give a substantial added value.

10.2 PRODUCT

... a lower leg prosthesis...

NEW PATIENTS

The fitting, alignment and suspension of the produced LLPs were well appreciated by Prosthetists and users. Some effort was needed to find the right method of creating an appropriate suspension, but the final result is good. Although this proves the principle of the design (it is possible to make a good LLP with this method), there is no evidence that it will be possible for all patients. For current project two very experienced users of prostheses were fitted with the new prosthesis and no problems were found. In the setting of a mobile workshop the provided prosthesis will be the first one for most patients. It is not unlikely that these patients will respond very differently.

The socket of the Pontas is very similar to the ZIP. The ZIP is developed specifically as a first prosthesis and provided almost solely to new patients, on average 3,5 weeks after surgery (EMMELOT, ET AL., 2007). Their satisfactory results suggest that the Pontas might be very suitable for new patients. However, for the ZIP a silicon liner is used, for the Pontas only a (thick) sock. More research with a larger patient group and a longer testing period will have to show the quality of the new design.

DURABILITY: FITTING

The socket is the most important part of the prosthesis, because a patient may not use it if it is uncomfortable (HERBERT, ET AL., 2005). The durability of a prosthesis therefore largely depends on the fitting of the socket. Conventional sockets use a soft foam socket or a liner between the stump and the hard socket. This gel interface allows for a larger margin of error, can bear slight changes of the stump and thus increases the durability of the prosthesis (MANUCHARIAN, 2011). The Pontas only has a (thick) sock and is therefore expected to have a lower product life time.

In theory TSB sockets have a better fitting than PTB sockets (see 3.2 THE SOCKET, P.10). In practice durability of TSB sockets is worse because the slightest change in stump geometry changes the pressure distribution. Since the geometry of the patella tendon is very unlikely to change, a patella bar can bear these changes. In contrast to the ZIP, the Pontas has a patella bar, possibly contributing to the durability of the prosthesis. If so, using upper-pelottes to create a patella bar might increase the durability of the ZIP too. The mean life time of the ZIP is reported to be three months (EMMELOT, ET AL., 2007), but many have been used for more than two years (OVERBEEK, 2012).

Compared to a PP socket, the surface of the Pontas can be rather rough. Over time this could damage the sock and the trousers of the patient. It would be interesting to search for a coating (possibly a resin) to give the socket a smoother surface.

DURABILITY: MECHANICAL

The durability of the prosthesis also depends on its mechanical strength, largely determined by the used synthetic cast tape. When a socket felt too weak or flexible, simply more synthetic cast tape was used to increase the wall thickness and the strength of the socket. For this project no tests were performed to find quantitative information about the strength of the material and BSN Medical does not have mechanical data either. Some points of attention are discussed below.

LAYER ADHERENCE

For the production process it is necessary to work in two separate phases to be able to include the ICRC Cup as connector. This means one wet, uncured layer of synthetic cast tape is wrapped around a dry cured one. With DCC the two layers fuse but with DCP the two layers sometimes split (FIGURE 32). The used amount and temperature of the water, the tension on the cast tape and the diligence of grinding the first layer all influence the adherence of the two layers. Bad adherence between the two layers does not necessarily decrease mechanical strength significantly. Due to the shape of the stump the inner socket is fully enclosed by the

Figure 32: The lateral condyle of one socket split in half. Clearly the two different layers did not adhere properly to each other.

outer socket and the rough surface cause high friction between the layers. Thus, despite bad adherence the layers are effectively bond together keeping much of their mechanical strength. Gluing the rim together with a strip of vinyl improves this bond and cosmetics.

Torsion

In one of the first sockets rotation was visible and a mechanical test was performed in an attempt to find the torsion strength of the connection between synthetic cast tape and ICRC Cup. Long before the maximum torque of 60 Nm was applied some movement was seen between a convex and a concave ICRC component. This happened at a torque of about 30 Nm. Although these components are connected with a bolt, two extra screws were added to improve strength (FIGURE 33). Mr Tamba explained that he normally also adds screws, but only for his heavier patients. No data was found in literature about a minimum torsion strength for sockets, but from the explanation of Mr Tamba can be concluded that 60 Nm is sufficient.

Climate

BSN Medical is a German company with most customers situated in developed countries. Not much information is available about the suitability and durability of Delta Cast® in a tropical climate like in Indonesia. The technical manual of the product depicts a maximum storing temperature of 25°C, but it was learned that a higher temperature is not fatal to the product. Extended high temperature will make the resin sink down, but monthly turning the product upside down will prevent any problems with storage in a tropical climate.

In 2006 one socket made from Delta Cast® was placed in the garden of one of the developers of the ZIP. After passing all seasons as a flower box the socket was investigated and found to be still strong enough to be used as a socket for an LLP (OVERBEEK, 2012). No data is available from this test.

Figure 33: A screw through the convex and concave ICRC components is added for extra strength.

10.3 PRODUCTION

... and its production process...

FAST AND SIMPLE

The Pontas is produced in less than two hours, requires minimum equipment but at least two people. For several steps in the process two hands are not enough and an assistant is needed. In the conventional process the Prosthetist can do everything on his own so the need for an assistant is considered a significant drawback. It was learned that this assistant literally only needs to give an extra hand and does not require any knowledge of biomechanics or prosthetics. For a mobile workshop an assistant is thought not to be a big problem because any present nurse or family member can help. For an existing P&O workshop it is thought to be inconvenient for the Prosthetist to depend on the availability of his colleagues.

Fabricating a standard LLP is not often considered a very difficult process. The reduced production time will therefore allow Prosthetists to spend their valuable time and attention to other orthopedic problems in the P&O workshop. The fast and simple production method of the Pontas can lead to better overall healthcare in current P&O workshops. This is acknowledged by a.o. BERGSMA (2011) and WISSE (2005).

It is a misunderstanding that a fast process will naturally reduce costs. This is generally true in high-income countries like the Netherlands were time is expensive, but if a Prosthetist only costs € 1,10 per hour the chosen materials and production process have more influence on the total costs. In the developed world automation is a common solution to a variety of problems. In the developing world a machine might never repay itself and will even eliminate job opportunities. For a designer familiar with expensive workers this is a paradigm shift.

FLEXIBLE

The first few samples of the 15 produced sockets initially did not match the set requirements and could not be used for an LLP. However, almost all of these ‘failed’ sockets were easily transformed into good functioning prostheses by adding some foam, deforming the shape with a heat gun or with the addition of Velcro strips. In a country where material is more expensive than labor, it is important to have these options available to save material. It makes the design rather flexible and more suitable for a mobile workshop. Being able to make mistakes during the process (because later they are easily solved) could make it more difficult to transfer the process to others who are new to the process. For teaching purposes a very strict protocol would be better. APPENDIX M [THE MANUAL] provides such a strict protocol both in pictures and in words.

PRESSURE

After wrapping the stump with synthetic cast tape, pressure is applied to create the right shape. For the PCAST a pressure of 13 - 80 kPa is used (S.S. SYED SHIKH, ABU OSMAN, & LATIF, 2008), and the technical manual of the Icecast® advises a pressure of 7,8 kPa or 13 kPa for people with a low or high activity level respectively. Current research could not find any difference between a socket made with 5 kPa or 20 kPa (n = 1), therefore approving the use of a rather weak vacuum pump (~5 – 10 kPa). If no pressure would be applied, the socket is expected to become too large but the results suggest only a very limited pressure could already be sufficient. A very limited pressure is already applied by wrapping the stump with plastic foil and it should be investigated if this pressure could already be sufficient. If so, this could dramatically improve the portability of the production method. Alternatively, improvements to the PCAST and the vacuum pump are discussed below.

PCAST

A prototype PCAST pressure tank similar to the ones described in literature was made and tested in Indonesia. It took some time to learn to use the method properly, but the results were satisfactory when the right amount of water was used and if all air was carefully removed. After filling, the system is rather heavy and not very portable. Approximately 20L of water is wasted during the process making it rather unethical to be used in dry areas.

For the PCAST prototypes first a fully opaque PVC sewer pipe was used and later an aluminum tube. For both the patient and the Prosthetist a transparent pipe would be an improvement. The functionality would be better to understand for the patient, making it less scary, while for the Prosthetist it would give insight and better control over the process. PCAST systems in literature all use a transparent part but do not describe any advantage or disadvantage of it (E.G. MANUCHARIAN, 2011).

Vacuum

Improved suspension was realized by using a vacuum pump instead of the PCAST, while fitting and alignment were the same. Only a few sockets were made with the vacuum method (n = 2) but the results suggest the vacuum method to be superior. More sockets should be made with this method for a quantitative evaluation. Disadvantages of using a vacuum pump are the higher initial costs and the need for electricity. Both vacuum pump and a small aggregate can be bought for about € 100,-. This makes the vacuum method four times more expensive than the PCAST which had a total cost of € 50,-. Using a simple hand pump would be much cheaper, but requires one extra man giving a uniform vacuum for five to ten minutes which can be very exhausting and difficult.

10.4 PROJECT

... for a mobile workshop.

The last element of the design assignment is to make the product suitable for a mobile workshop. Since no actual mobile workshop was used in this project, this discussion interprets this element as the continuation of the project. It discusses the challenges and opportunities for further development and implementation of the project.

MOBILE WORKSHOP

During tests at Harapan Jaya, the situation of a mobile workshop was often simulated. The Prosthetists were asked to grab all the tools and materials they needed and were not allowed to use anything else during the process. For safety reasons the process was always performed inside the workshop were escapes are available, but the Prosthetist never had to use more tools than initially planned. If the mobile workshop has water and electricity, or it will stop at a location where this is available, the LLP can be produced in a mobile workshop.

Days before the finish of this report, three stories were told about existing mobile P&O workshops. These three examples show the feasibility of a mobile workshop and the need for a high quality, low cost product with a fast and simple production process.

Dr Dewi

In Indonesia a Christian organization exists that provides free LLPs to poor people (HALOHO, 2012). In their program a patient is visited and a negative impression of his stump is made. In a P&O workshop in Jakarta this is used to make an LLP and later this is brought back to the patient. In total now about 110 LLPs are produced but one of the patients visiting Harapan Jaya explained that only about 10% can actually be used. Also his prosthesis did not fit properly and was about 5 cm too long. Still patients gratefully accept the free prosthesis so the problem is not likely to be solved soon.

Mobile Dentist

At RS Harapan (the hospital connected to rehabilitation center Harapan Jaya) in 1983 the plan was made to equip a large available van with tools for a mobile dentist. Because at that time many dentists already exists and the van was much too large for the small rural roads, the plan was never executed and the van was left unused. Later at Harapan Jaya the idea was made to use this van for a mobile P&O workshop, but, as the manager of that time explains, the production process took about two weeks and it always required an extra driver (VAN PAASSEN, 2012). In the end the plan was cancelled because the van needed new tires that were unavailable in Indonesia and too expensive to import.

Paralympics

At the Paralympics in London 'King of Prostheses' Frank Jol had a mobile P&O workshop in which he makes and repairs all prostheses for the Dutch Paralympic team (NOS, 2012A). In his small truck he has everything to make the most advanced running blades, starting at almost € 6000,- a piece (RADIO 538, 2012)

WORLD IMPLEMENTATION

The first question all experts ask when introducing the concept to them is "*Why Indonesia?*", and although the answer is just a practical decision, the question is valid. Why design a product for Indonesia and not for Vietnam? Why not design a product for the whole world? Decades ago Prosthetist Sethi had the same idea and tried to bring LLPs from the 'advanced countries' to the developing world. Later he designed the Jaipur foot which was very well adapted to Indian culture.

> *"When we first started providing lower limb prostheses to our amputees, the majority of whom belonged to the lower income groups, we used designs which we had learnt from the west. I thought we were making a decent attempt, even though our limbs looked like "blurred Xerox copies" of those available in the advanced countries. It came as a surprise, however, when I started encountering many of these amputees reverting to their crutches. I started closely questioning them about the reasons for this rejection. It soon became obvious that a design which was appropriate in the shoe-wearing, chair-sitting culture of the colder countries of Europe or North America was quite inappropriate for the barefoot walking, floor-sitting culture of the warmer countries."* (SETHI, 1989, P. 119)

Clearly differences in culture exist and examples like Sethi are numerous. It seems difficult, even unlikely to successfully introduce an advanced product from the developed to the developing world. It is thought that the opposite direction (from developing to developed world) is easier because with frugal innovation the need for advanced existing systems is eliminated (VELING, 2012B). OIM using the Pontas as their newest version of the ZIP to eliminate the need for expensive Otto Bock components would be a very good example, but for now only subject of imagination.

Developing World

The connection between socket and ICRC components is very strong and easy to make. In fact, it fits so well that in time, the Pontas could become ICRC Lower Leg Prosthesis 2.0. ICRC already has the network and distribution channels to reach the entire developing world and their first version is widely accepted as a good product. If the problems with the material for the ICRC Foot are solved and BSN Medical will team up with ICRC, the Pontas would be a feasible second version of the ICRC Lower Leg Prosthesis.

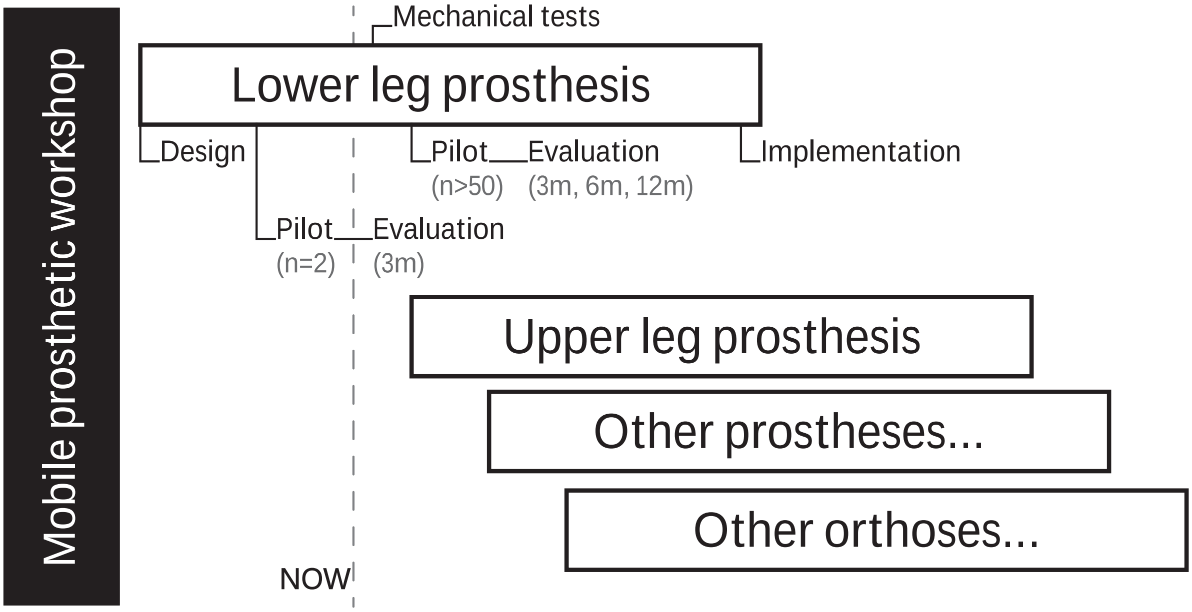
10.5 RECOMMENDATIONS

As a conclusion to the discussion a set of recommendations is given, divided into three topics.

Validation

More research on the Pontas is needed to validate its design and to quantify its quality and durability (FIGURE 34). Timed walking tests and timed up and go tests for both the Pontas and a standard LLP can be used to investigate quality (CONDIE, SCOTT, & TREWEEK, 2006). Durability can be investigated by prolonged use of the Pontas by the two current users at Harapan Jaya. Before these tests have given positive results it would be unethical to test the product with external patients. Mechanical testing is possible anywhere in the world but is advised to be done at the JSPO or a technical university in Indonesia to involve them in the project. It is important to get information about the (long term) influence of a tropical climate on the used materials.

Figure 34: Proposal for the next research steps for the mobile workshop. The next step for the lower leg prosthesis would be to do mechanical tests (to find more information about the strength and durability) and a larger pilot with a longer evaluation period.



Production Design

Only a few sockets have been made with the vacuum method and although results were promising it is likely that the process can be further improved. More sockets should be made with this method to understand the subtle differences of available settings and to be sure the method is better than the PCAST. The vacuum method could be improved by measuring the applied vacuum and testing the influence of the amount of it. At the same time the PCAST should be improved with a better connection system of the plastic bag inside the cylinder to completely eliminate any problems with leaking. A very different improvement could be the use of a transparent PCAST.

Effort should be made to eliminate the required assistant to make the complete production process realistic for just one Prosthetist. It is thought that more practice would already be enough to realize this.

Future

A mobile P&O workshop with just one product will not be very effective so its product range should be increased. Current technique with some slight adaptations could be suitable for many other orthopedic products like upper leg prostheses, ankle foot orthoses and lower arm prostheses. Students who like travelling can work on these new assignments and bring current project to a higher level. Eventually a very complete mobile P&O workshop will be created that is suitable for all countries in the world.

11 CONCLUSION

The main question of this project was:

How can people in poor rural areas be provided with good prosthetic services?

It was found that the conventional production method of a lower leg prosthesis (LLP) does not allow it to be made in a mobile setting because it requires much time, knowledge and machinery. The new LLP that is developed for this project can be made in less than two hours without using any heavy machinery. This makes it suitable for use in a mobile prosthetic workshop, enabling poor patients in remote areas to be reached.

In the production of an LLP, the socket is considered the most difficult to make because it has to fit perfectly on the stump of the patient. The synthetic cast tape that is used to produce the socket for current LLP is commercially available in Indonesia and the required pressure tank (PCAST) was constructed by a local craftsman. This means all required material, tools and knowledge are locally available and the new production process is independent from foreign companies. If something breaks, it can be solved locally.

The new production method was well understood and accepted by the local Prosthetists of rehabilitation center Harapan Jaya in Indonesia. That the management of this rehabilitation center is eager to include the new LLP in their product range suggests that the product is well appreciated and the advantages of the product are clear. Also for a non-mobile prosthetic workshop a fast and simple production process is highly desirable. The potential of extending the new technique to the production of other prosthetic and orthotic products was immediately recognized. It was envisaged that in the near future the mobile workshop could have the complete product range available in just a few hours time.

With this project an acceptable prosthetic device is found for physically disabled people in poor rural areas in Indonesia. Further research into the durability of the product and the realization of a mobile workshop is highly recommended.

ACKNOWLEDGEMENTS

I have taken efforts in this project. However, it would not have been possible without the kind support and help of many individuals and organizations. I would like to extend my sincere thanks to all of them. To prevent a word of thanks of multiple pages I have put everybody who has been important to me in this process in one big figure.

Special thanks go to Malapontas Tamba (aka Pontas), Brutu and Ard Kuiper who helped me realize my idea. Also I really have to give special gratitude to Ezra, Manurung and Simbolon who are the most patient people I will ever meet. You made me understand the word difabled. Finally I want to thank Sister Xaveria for giving me such a warm welcome at Harapan Jaya and giving me so much freedom. Thank you all for transforming this design into something that has the potential to help people around the world!

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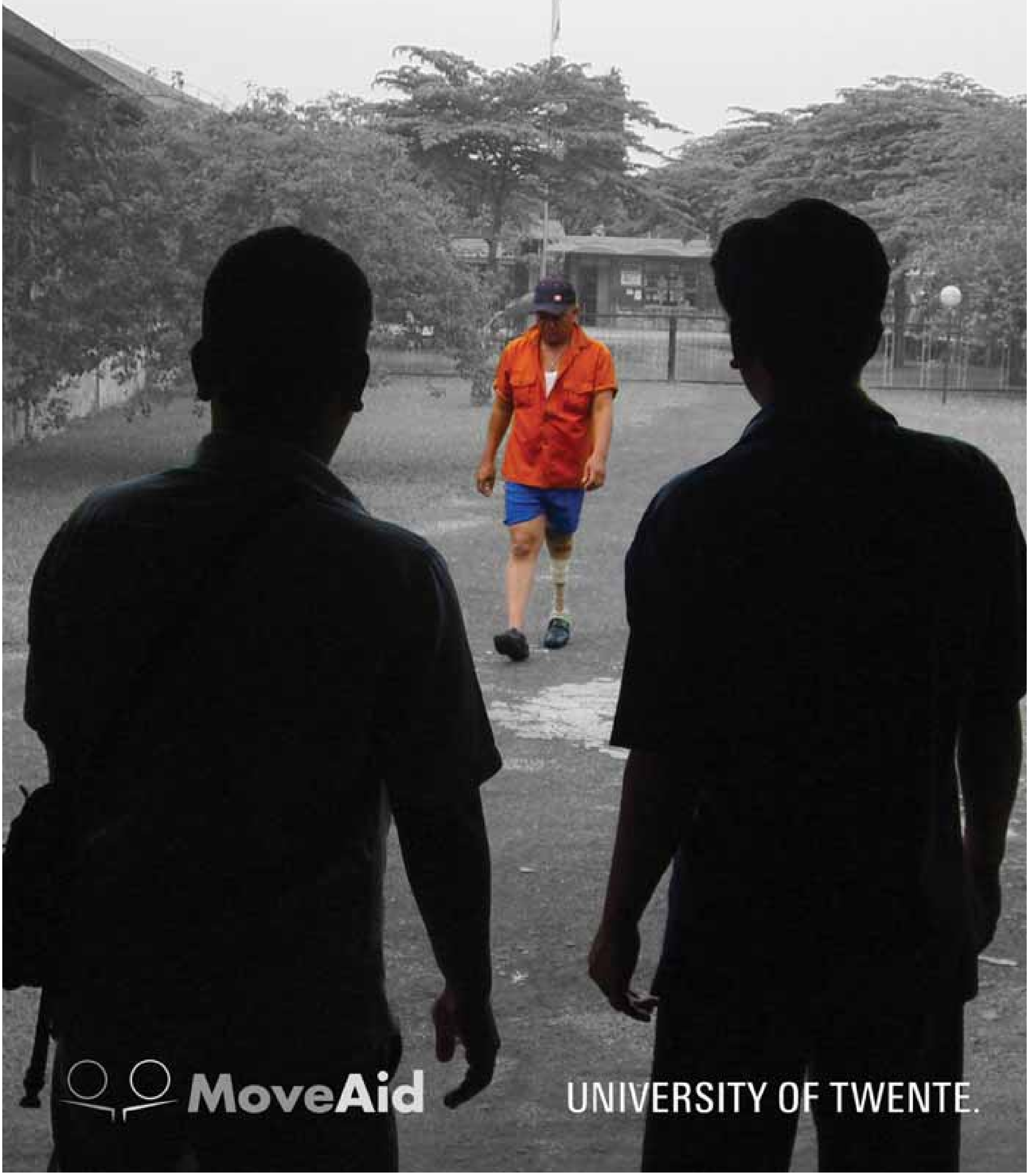
PONTAS

A New Lower Leg Prosthesis for a Mobile Workshop in Indonesia

- APPENDICES -



P O N T A S

A New Lower Leg Prosthesis for a Mobile Workshop in Indonesia

- APPENDICES -

Bob Giesberts (s0113131)

MSc Assignment - Industrial Design Engineering

October 2012

Faculty of Engineering Technology - Laboratory of Biomechanical Engineering

Universtity of Twente

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TABLE OF CONTENTS

A THE STUMP

Amputation of lower legs has saved many lives, but is also a source of significant disability (VAN BRAKEL, POETSMA, TAM, & VERHOEFF, 2010). One technique for lower leg amputation is called Burgess. In this technique, the calf muscle is used as a long posterior flap to cover the distal end of the tibia and fibula and provides excellent weight-bearing surface. To avoid distal pain, the fibula is cut about 2 cm shorter than the tibia and the anterior surface of the tibia is beveled (SEYMOUR, 2002). The scar will run transversely on the anterior side of the stump.

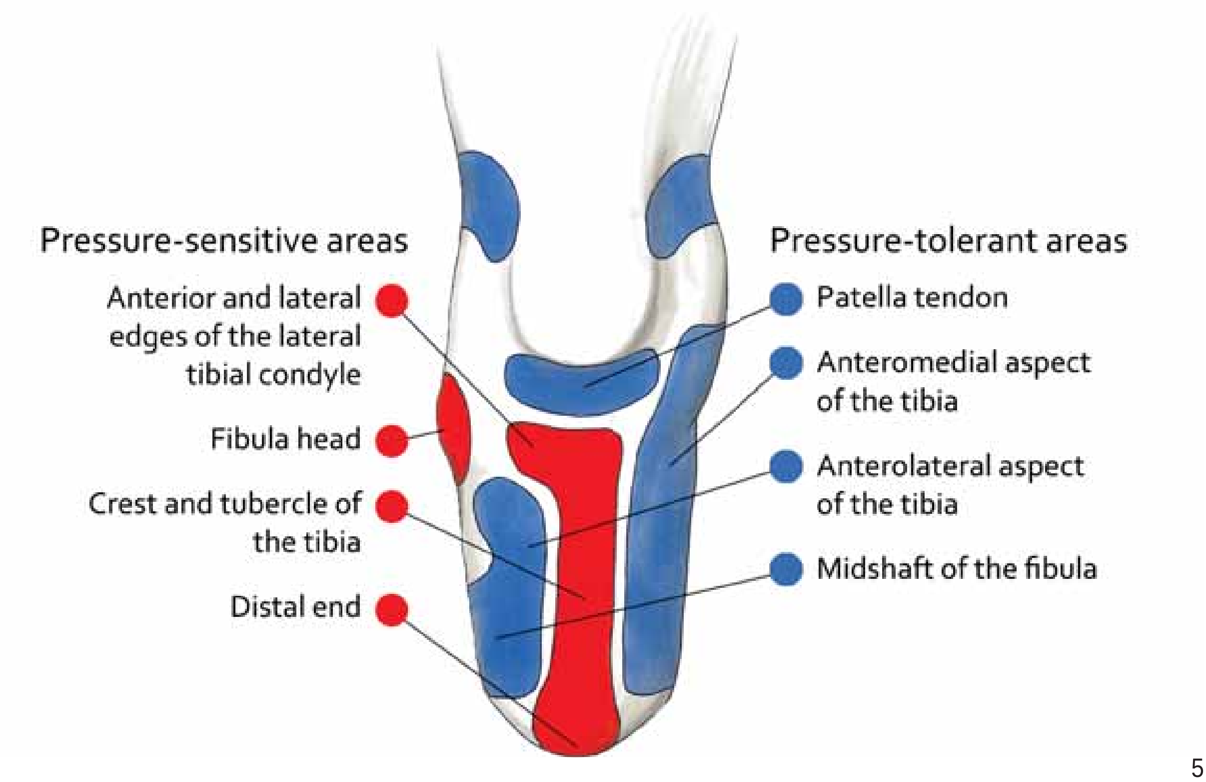
The resulting stump can be conical, cylindrical or bulbous. It is more difficult to create a good socket for a bulbous stump and a conical or cylindrical shape is preferred by the Prosthetist. Additionally it is important that the stump is not too short so a good socket can be made to give the patient good control over his lower leg prosthesis. On the other hand, a stump can also be too long, making it impossible for the Prosthetist to construct a shank and a foot under the socket. Good communication between orthopedic surgeon and Prosthetist is important.

A.1 WEIGHT BEARING LOCATIONS

The anatomy of the residual bone structures in the stump largely determines which areas of the stump can bear weight and which cannot. Because these bone structure are very similar for every patient, attempts have been made to create an adjustable socket that will fit everybody (E.G. WISSE, 2005). These studies inherently require large datasets of stump measurements. Custom made PTB (Patella Tendon Bearing) sockets are created by experienced Prosthetists who know the exact locations of these areas and how to create the right pressure on the right area.

Some of the fleshy parts of the stump have a good blood supply and are capable of dissipating pressure. These areas can be used to bear weight and are called pressure-tolerant (PT) areas. Examples of PT areas are the patella tendon, the anteromedial and anterolateral aspect of the tibia and the calf muscle (SEYMOUR, 2002). Perpendicular forces are better tolerated than shear forces and pressure should be dissipated over a large area to prevent pain and skin problems.

Figure 1: Pressure-sensitive areas (red) and pressure-tolerant areas (blue) of the stump.



Some areas of the stump can be very sensitive to contact and should not be used to bear any weight: pressure-sensitive (PS) areas. Examples of PS areas are the anterior and lateral edge of the tibia, the head and distal end of the fibula, the crest and tubercle of the tibia and the distal end of the tibia (SEYMOUR, 2002). FIGURE 1 gives an overview of PT and PS locations of the stump.

With the technique of direct casting, pelottes (bumps of foam) are placed on PS areas before applying any (synthetic) cast tape to create areas of relief. Following this principle, pelottes can be placed on PT areas to create indentations on areas of weight bearing.

B AMPUTATIONS

To get a good view on the magnitude of the problem, it is important to know how many people need to have a (new) lower leg prosthesis each year. Each year new amputations with various causes are added to the group of existing amputations. At the same time a portion of the group of existing amputations passes away. It is assumed that these two groups are equal and the total number of amputees is in balance. Figures from Vietnam even show a decreasing number of amputees due to these flows (NLR, 2009).

B.1 AVAILABLE DATA

Limited reliable data is available on the number of disabled people in Indonesia. This is partly caused by the fact that very different definitions exists for disability, but also by the fact that in Indonesia there is no clear advantage of showing a disability (like insurance, special aid, etc.). This might explain why disability rates are said to be as high as 20,0 % in Australia and only 1,38% (3.425.383 people) in Indonesia (UNESCAP, 2009).

In Indonesia a large survey called SUSENAS is performed which includes the question *“are you disabled”*. The most recent results of this survey show 0,86% (2.126.785 people) answering *“yes”*. Of these people 33,75 % (717.790 people) said to have a physical disability (IRWANTO, KASIM, ASMIN, LUSLI, & SIRADJ, 2010).

ASSISTIVE DEVICES

Peter Carey is doing research on the need for assistive devices and his preliminary results show that 4,2 % of all disabled people in Indonesia might benefit from an assistive device. Using the data from SUSENAS, this equals 89.325 people. He thinks the percentage is on the low side and will proof to be higher when he moves to surveys with a higher number of households (CAREY, 2012).

Generally the assumption is made that 0,5% of a population might need an assistive device (WHO & ISPO, 2005). This is quite in contrast with the estimation of Carey, because for Indonesia this percentage would represent 1.241.081 people.

LOWER LEG AMPUTATIONS

Lower leg prostheses form only a small portion of the assistive devices. A survey covering 14 (of the 33) provinces concludes that Indonesia has 1.167.111 disabled people of which 20,4% (238.091 people) have a “disabled use of the foot” (MARJUKI, 2010). This includes lower leg amputations but also very different disabilities (e.g. dropfoot). What percentage of this number represents lower leg amputation is not described, but estimated to be at least 20 %. This would equal 47.618 people (20 per 100.000) who lost their lower leg.

Ossür has data on the existing amputees in France (12 per 100.000), the Benelux (43 per 100.000) and Germany (53 per 100.000) (OSSÜR, 2012) (FIGURE 2). Much higher numbers can be found for Vietnam (98 per 100.000) (VAN BRAKEL, ET AL., 2010) and Thailand (106 per 100.000) (VELING, 2012). The average of this mix of countries (62 per 100.000) would equal 148.225 people for Indonesia.

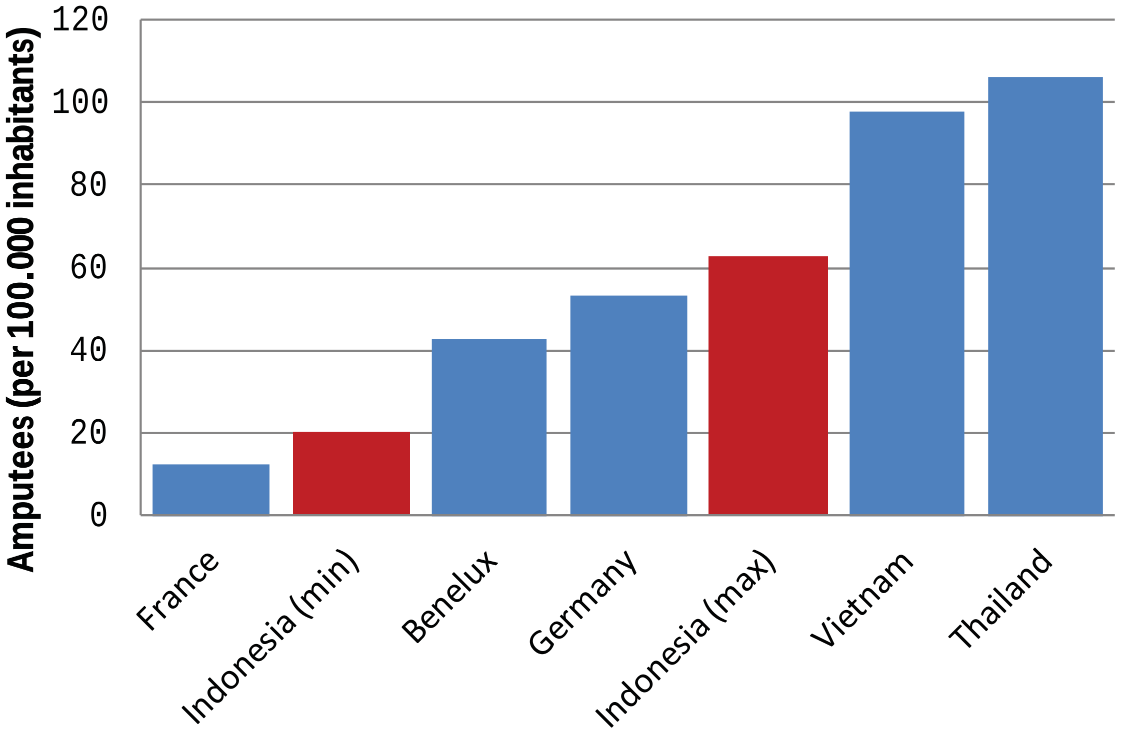
B.2 CONCLUSION

From the available data it can be concluded that the number of lower leg amputees is somewhere between 47.618 and 148.225 people.

There are multiple reasons to think that the number of 47.618 amputees is on the low side: the number of disabled people might be higher because disabled people are sometimes hidden by the family (SAPTYONO, 2012) and people are reluctant to show their disability because there is no clear advantage of doing so (CAREY, 2012). Additionally, the research by MARJUKI (2010) excludes the 3 poorest provinces of Indonesia, Papua, West Papua and Maluku (BPS, 2011), while it is known that poverty is strongly related to disability (E.G. FILMER, 2008).

However, the number of 148.225 amputees might also be too high, because Indonesia has a very different demographic and financial situation than the mentioned European countries. In Europe people tend to get much older (typically 79,76 years in the European Union versus 71,62 in Indonesia) (CENTRAL INTELLIGENCE

Figure 2: Amputees (per 100.000) for selected countries.



AGENCY, 2010) and are more likely to suffer from vascular diseases and diabetes. The incidence of lower leg amputation is eight times higher in diabetic than in nondiabetic individuals (JOHANNESSON ET AL., 2009). Not only is this factor expected to be lower for the shorter Indonesians (TSENG, 2006), but the cause for amputation is also different in Indonesia. More amputees have lost their leg due to trauma, they are less likely to survive this trauma and in Indonesia many people in need for amputation will never see an orthopedic surgeon. At the same time Indonesia does not have as many unexploded mines as Vietnam and Thailand which casualties in these countries.

To level out the different arguments, the actual number is assumed to be of the average of the two numbers: 98.000 people (41 per 100.000). Due to changing stump geometry a lower leg prosthesis should be replaced at least each third year. So, one third of this population will need a new lower leg prosthesis this year:

In Indonesia, every year 33.000 people need a (new) lower leg prosthesis.

C P&O WORKSHOPS

Using the list of BERGSMA (2011) as a start, a list of P&O workshop in Indonesia was created. One publication (SANKARAN, 1984), multiple conversations (BEISE, 2012; KAMER, 2012; SAPTYONO, 2012; WIJNANS, 2012) and online sources (UNESCAP, 1997) were used to make the list complete and to confirm the entries. The figure below (FIGURE 3) gives an overview of the location of the 34 P&O workshops. More information can be found in the table (TABLE 1).

Figure 3: Location of all P&O workshops in Indonesia. (Orange = confirmed, contacted |Yellow = confirmed, not contacted | Red = Not confirmed, not contacted. The size of the orange circles indicate the production rate of lower leg prostheses in 2011)

Every contacted P&O workshop was asked about their production rate of lower leg prostheses in 2011. Additionally the workshop was asked to provide information about other P&O workshops in Indonesia. Because most respondents were eager to help, it is expected that this list is complete for about 90%. As shown in the picture with red circles, some workshops were mentioned by only one source but could not be contacted and are therefore not included in the list. These workshops were sometimes found to be closed for various reasons. 17 P&O workshops did not respond and could not be contacted but were mentioned by many sources. These workshops are included in the list and for the calculation it is assumed that they have the same average production. Together, in 2011 the 34 P&O workshops of Indonesia have produced a total amount of about 1.600 lower leg prostheses.

$$LLP_{Total} = 726 \cdot \frac{1}{0{,}90} \cdot \frac{34}{34-17} = 1.613$$

Table 1: Identified P&O workshops in Indonesia. (LLPs = Lower Leg Prostheses produced in 2011, RC = Rehabilitation Center)

	Name	Location	Type	LLPs
Java				
1	RSK Sitanala	Tangerang (Banten)	Hospital (Leprosy)	20
2	RSPAD Gatot Soebroto	Jakarta (DKI Jakarta)	Hospital (Army)	
3	RS Dr. Cipto Mangunkusumo	Jakarta (DKI Jakarta)	Hospital (Private)	
4	RSUP Fatmawati	Jakarta (DKI Jakarta)	Hospital	
5	JSPO	Jakarta (DKI Jakarta)	P&O School	
6	Sunter	Jakarta (DKI Jakarta)	Clinic	
7	Kementerian Pertahanan Ri	Jakarta (DKI Jakarta)	RC	
8	Harapanku / Stichting Revalidatie Cirebon	Cirebon (West-Java)	P&O workshop	9
9	RS Hasan Sadikin	Bandung (West-Java)	Hospital	
10	RS Dr. Kariadi	Semarang (Central-Java)	Hospital	
11	RS Ortopedi Purwokerto	Purwokerto (Central-Java)	Hospital	52
12	Kuspito	Surakarta (Central-Java)	RC	300
13	Prof. Dr. Soeharso Rehabilitation Centre	Surakarta (Central-Java)	RC	
14	BBRSBD Prof. Dr. Soeharso	Surakarta (Central-Java)	RC	
15	RSK Kelet Donorojo	Jepara (Central-Java)	Hospital (Leprosy)	14
16	Yakkum Yogyakarta	Yogyakarta (DI Yogyakarta)	RC	100
17	RS Dr. Soetomo	Surabaya (East-Java)	Hospital	6
18	RSAL Dr. Ramelan	Surabaya (East-Java)	Hospital (Navy)	
19	RSUD Saiful Anwar	Malang (East-Java)	Hospital	
20	RSK Sumberglagah	Mojokerto (East-Java)	Hospital (Leprosy)	77
21	RSUD Dr. Wahidin Sudirohusodo	Mojokerto (East-Java)	Hospital	
22	RSK Kediri	Kediri (East-Java)	Hospital (Leprosy)	12
Nusa Tenggara				
23	Yakkum Bali	Ubud (Bali)	RC	
Sumatra				
24	RS Zainoel Abidin	Banda Aceh (Aceh)	Hospital	
25	Harapan Jaya	Pematang Siantar (North-Sumatra)	RC	23
26	RSK Pulau Sicanang	Belawan Medan (North-Sumatra)	Hospital (Leprosy)	24
27	RSK Dr. Rivai Abdullah	Palembang (South-Sumatra)	Hospital (Leprosy)	19
Kalimantan				
28	Subatu	Pontianak (West-Kalimantan)	RC	20
29	RSK Alverno	Singkawang (West-Kalimantan)	Hospital (Leprosy)	8
Sulawesi				
30	RSUP Dr. Kandou	Manado (North-Sulawesi)	Hospital	
31	RSAD Pelamonia	Makassar (South-Sulawesi)	Hospital (Army)	1
32	RS Dr. Wahidin Sudirohusodo	Makassar (South Sulawesi)	Hospital	
33	RSK Dr. Tadjuddin Chalid	Makassar (South Sulawesi)	Hospital (Leprosy)	32
Papua				
34	RSK Sele Be Solu	Sorong (West Papua)	Hospital (Leprosy)	9
			Total:	726

C.1 QUESTIONS

All contacted P&O workshops received the following email, both in English as in the Indonesian language.

"Subject: Kaki Palsu

Dear [P&O Workshop],

As a student Industrial Design Engineering at the University of Twente (the Netherlands) I'm currently working on the design of a new lower leg prosthesis. To get a better view on what problems this new product should solve I'm searching for data about the number of lower leg prostheses in Indonesia. I hope you are willing to help me answer some of the following questions.

1. *Are you a rehabilitation center? Do you have your own P&O workshop?*
2. *Do you produce lower leg prosthesis?*
3. *Can you tell me how many patients come to your rehabilitation center for a lower leg prosthesis every year? How many lower leg prostheses have you provided last year (2011)?*
4. *Are there any other P&O workshops in Indonesia where lower leg prostheses are produced?*

I hope you can help with these questions. Thank you very much!

Best regards,

Bob Giesberts"

D PRODUCTION METHODS

Presented below are six selected production methods and their data about the required time and used machinery (TABLE 2). Arbitrary units between 1 (negligible, e.g. scissors) and 5 (non-portable machine, e.g. large oven) are chosen for machinery. Note that for certain simple steps a bench vise (4 points) is necessary and that the points for multiple machines can be added to get a score higher than 5 points.

Some of this data is found in literature (NORMANN, OLSSON, & BRODTKORB, 2011; WU, CASANOVA, REISINGER, SMITH, & CHILDRESS, 2009), some extracted from instructional videos (CHESAPEAKE MEDICAL PRODUCTS, 2007; CIR, 2009; ÖSSUR, 2011) and some from personal communication (OVERBEEK, 2012; ROBIJN, 2012). Data for the STS method and CADCAM was not found.

Table 2: Details for 5 different production methods for lower leg prostheses. (T = Time [min], M = Machinery)

	Conventional		Vietman		MSS		CIR Wu Casting		SocketCone		ZIP	
	T	*M*	*T*	*M*	*T*	*M*	*T*	*M*	*T*	*M*	*T*	*M*
(Preparation)	6	1	6	1	23	3	5	1	28	4	13	4
Check stump condition	2	-	2	-	2	-	2	-	2	-	2	-
Measurement	4	1	4	1	1	1	1	1	1	1	1	1
Pelottes	-	-	-	-	-	-	-	-	5	-	5	-
Socks / liners	-	-	-	-	20	2	2	-	20	3	5	3
Negative impression	45	1	30	1	0	0	10	7	0	0	0	0
Wrapping	15	1	15	1	-	-	10	7	-	-	-	-
Curing	30	-	15	-	-	-	-	-	-	-	-	-
Positive mold	300	5	60	5	0	0	3	4	0	0	0	0
Casting	5	2	5	2	-	-	3	4	-	-	-	-
Curing	295	3	55	3	-	-	-	-	-	-	-	-
Rectification	240	5	120	5	0	0	10	0	0	0	0	0
Pressure tolerant areas	120	4	60	4	-	-	10	-	-	-	-	-
Pressure relief areas	120	1	60	1	-	-	-	-	-	-	-	-
Socket forming	120	10	120	10	158	3	120	10	30	4	40	3
Forming	60	10	60	10	28	3	60	10	20	4	20	-
Curing	60	-	60	-	130	-	60	-	20	-	20	3
Adjustments	465	12	30	5	30	5	30	5	30	5	30	4
Trimming / Felt	15	3	15	3	15	3	15	3	15	3	15	3
Assembly	120	3	5	1	5	1	5	1	5	1	5	-
Cosmetics	300	5	-	-	-		-	-	-	-	-	-
Alignment	30	1	5	1	10	1	10	1	10	1	10	1
Total:	1176	34	366	27	211	11	178	27	88	13	83	8

E EXPERTS

The table below (TABLE 3) shows on what selected topics the interviewees are considered expert, and what type of contact was established.

Table 3: Interviewed persons being experts on selected topics.

	Indonesia	Development Aid	P&O education	Orthopedics	P&O services	Lower Leg Prostheses	
Kerstin Beise (Netherlands Leprosy Relief, Indonesia)	X	X	X		X		Email
Dubbele de Boer (Founder RC Sajocah, Cameroon)		X		X	X	X	Interview (14-12-2011)
Peter Carey (Research on P&O Needs, JSPO, Indonesia)	X	X	X		X		Skype (14-02-2012)
Punto Dewo (Orthopedic surgeon, Indonesia)	X			X			Email
Swetika Eko Saptyono (Handicap International Indonesia)	X				X	X	Email
Xaveria Haloho (Manager RC Harapan Jaya, Indonesia)	X	X					Interviews
Peter Hondebrink (Physiotherapist RC Sajocah, Cameroon)		X		X	X		Interview (15-01-2012)
Willie Houben (Program manager Asia, Liliane Fonds)	X	X					Interview (27-03-2012)
Ger Kamer (Founder P&O workshop Harapanku, Indonesia)	X	X		X	X	X	Interview (16-01-2012) Interview (30-01-2012)
Ard Kuiper (Prosthetist OIM)		X		X	X	X	Interviews
Ben Overbeek (Prosthetist OIM, designer ZIP prosthesis)				X	X	X	Interview (13-01-2012) Interview (12-04-2012)
Miyanto Ratum (Prosthetist RC Yakkum Yogyakarta, Indonesia)	X			X	X	X	Email
Jan Robijn (Netherlands Leprosy Relief, Vietnam)		X			X	X	Email
Malapontas Tamba (Prosthetist RC Harapan Jaya, Indonesia)	X			X	X	X	Interviews
Jan Welmers (Technical adviser Liliane Fonds)	X	X		X	X	X	Interview (27-03-2012)
Maria Widagdo (Manager RC Yakkum Yogyakarta, Indonesia)	X				X		Email
Jan Wijnans (Co-founder multiple RCs, Indonesia)	X	X			X		Interview (05-03-2012)
Boudewijn Wisse (MSc on new Lower Leg Prosthesis)		X			X	X	Interview (30-01-2012)

F THE FOOT

Before moving to Indonesia, it was learned that artificial feet were not a problem of much concern in Indonesia. However, when arriving at Harapan Jaya, the first thing mentioned by the workshop employees was the extensive production time of their artificial feet.

F.1 PRODUCTION

The Prosthetist of Harapan Jaya, Malapontas Tamba, is very skillful in making feet from a piece of wood from the *Waru* tree (sea hibiscus), foam and a strip of car tire. Using a standard paper model he draws the outline of the sole of the foot on the piece of wood and roughly shapes it with a large knife (FIGURE 4). Extensive work on the sanding machine creates the final shape of the foot. The heel and toe-joint are cut out and replaced by foam to create a comfortable walking foot. A hole is drilled through the foot to provide connection to ICRC components for the shank and vinyl is used as cosmetic finishing. In total it takes Mr Tamba about 12 hours to make one good foot and the costs are IDR 250.000,- (€ 21,-).

Figure 4: Production steps of the artificial foot constructed by Mr Tamba.

With a minimum life of about 10 years the feet is very durable and the product is really cheap. However, for a mobile workshop it would be highly inconvenient to produce feet with this method. It would take 2 days to finish one lower leg prosthesis, making the production rate very low. Instead the mobile workshop should have a large stock of artificial feet with all sizes for left and right.

F.2 OTHER FEET

Previously Harapan Jaya has been using the ICRC foot, but after only a few years these feet turned into something Mr Tamba calls chocolate (FIGURE 5). Indeed the pieces of the feet still present at Harapan Jaya do not only look like chocolate, they also feel like it: melting away in the sun and breaking apart when touched. This material is absolutely not suitable for artificial feet. This problem is also recognized by others (ANDRYSEK, 2010).

Multiple sources mentioned the existence of cheap, high quality imitation Otto Bock feet, provided by a Java based company. Inquiry at several P&O workshops on Java could not confirm the existence of this company, nor the feet. Coki Tobing (DARE Foundation) knows about a company (Samudera Medika) producing similar feet for IDR 500.000 (€ 42,-) but this foot does not provide connection to the ICRC components. Jan Wijnans (rehabilitation center Sabatu) has found a company that produces excellent feet but with a very limited capacity of about one foot per two days.

Other available feet are the Jaipur foot and a similar foot produced at Yakkum Yogyakarta. For both feet a wooden base is placed in a mould and included by molten rubber. At Harapan Jaya it is difficult to get this high quality material and is therefore not used.

Figure 5: Two decaying ICRC feet.

F.3 CONCLUSION

The artificial foot produced by Mr Tamba is of high quality and adequate alternatives cannot be found in Indonesia. For a mobile workshop a fast solution is necessary so a large stock is needed. As a solution Harapan Jaya could hire a part-time worker who will produce feet all day long, or it could search for a foreign donator willing to import a large number of artificial feet.

G THE SHANK

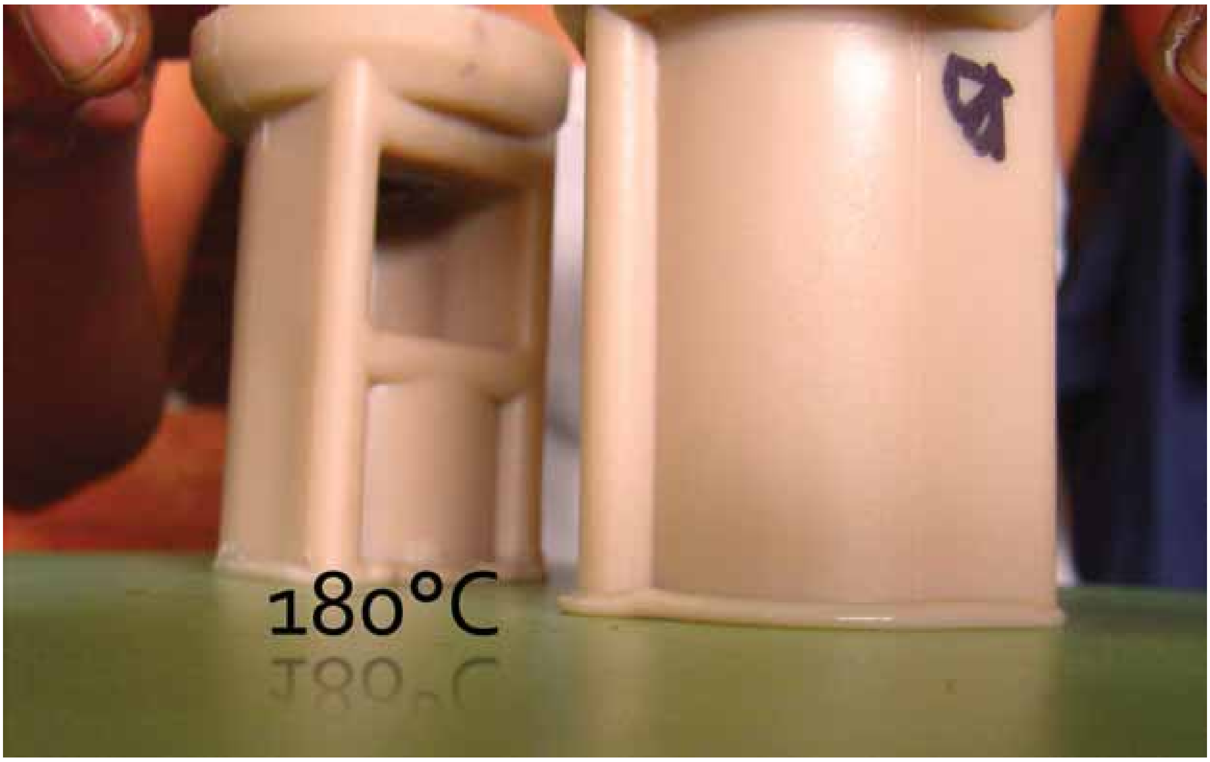
The International Committee of the Red Cross (ICRC) has developed a modular system to create a lower leg prosthesis (LLP) (ICRC, 2006). Part of this system is a set of five polypropylene components to form the shank with (FIGURE 6). Two pipes with one concave end are sawn off to give the shank the right length. Two plates (one for the foot, one for the socket) with a convex part fit on this and are used to adjust the alignment of the socket and the ankle. The last part, here called the ICRC Cup is the connector between the socket and the shank. The pipes both have an internal T-nut. Two bolts and a metal washer are used to combine all parts. The concave and convex surfaces have a pattern of small ridges for increased friction.

Figure 6: The shank is constructed using the five polypropylene components of the ICRC system. It consists of a convex foot piece, two pipes with a convex part, a convex upper piece and the ICRC Cup. Two bolts and a metal washer are used for the assembly.

G.1 ASSEMBLY

First measurements are taken to find the correct length for the shank. The two pipes are cut off at the right length and placed on a horizontal plate of 180°C until they slightly melt (FIGURE 7). The two pieced are pressed together and the molted plastic acts as a glue. Great care is taken to create a straight connection because any kink will severely decrease the strength. The foot plate is glued to the foot and grinded down to fit the right shape. A bolt is passed through the foot and foot plate and screwed into the T-nut of the pipe to create a foot and shank combination.

Figure 7: The two pipes of the ICRC system are cut at the right length and placed on a plate of 180°C. The polypropylene slightly melts and acts as glue when the pieces are pressed together.



The ICRC Cup is included in the production of the socket so it can be used as a connector for the rest of the shank (see FIGURE 6). This means the socket has a hole in the bottom and a large metal washer placed in the ICRC Cup. A piece of foam is glued to this connector for increased friction between ICRC Cup and the upper plate. A bolt is passed through the socket and the upper plate with its convex part downward. The bolt is screwed into the upper pipe of the shank. Both bolts are still rather loose and the Prosthetist first aligns the LLP before fully tightening them. When completely satisfied about the alignment, four small screws are used to create a very strong connection between the concave and convex surfaces (FIGURE 8).

Figure 8: Four small screws are used to fix the settings for the alignment (left). The resulting lower leg prosthesis (right).

H HARAPAN JAYA

Rehabilitation center Harapan Jaya was founded in 1981 by Sr. Jeanette van Paassen and a few others. It is situated in Pematang Siantar, North Sumatra, Indonesia, and is currently home to seven catholic nuns. Sister Xaveria Haloho is the manager of the approximately 45 employees who take daily care of the rehabilitation of 80 to 100 patients, mostly children. Only a small amount of patients is visiting Harapan Jaya for the provision or reparation of a lower leg prosthesis (LLP). This is done by Prosthetist Mr Tamba and three fellow technicians.

At the P&O workshop of Harapan Jaya, prostheses are made using the ICRC method. This means a socket is made from polypropylene with the conventional method and a foot is connected using standard plastic ICRC components. These components are imported from the Netherlands and cost about IDR 420.000 (€ 38,-). The price of one LLP is IDR 4.500.000 (€ 380,-) and a patient commonly has to wait for 2 weeks for his product. Administration shows that on average it takes 32 hours of labor (excluding the foot) to produce this product which with IDR 416.000 (€ 35,-) does not add significantly to the total costs. Children do not pay for the prosthesis and costs are covered by donations. Adults do have to pay and often have to search for a sponsor to help them. Whenever possible, Harapan Jaya assists in the search for a sponsor.

Because of the poor distribution of the three P&O workshops on Sumatra, Harapan Jaya covers a rather large area. Examples are patients coming from Jambi, a province on a two-days driving distance. Looking solely at prostheses, the capacity of the P&O workshop is mostly determined by the production time of the products. According to the sister Xaveria the capacity is currently not sufficient and a waiting list exists. Increasing the capacity of the P&O workshop is difficult because good Prosthetists are scarce in Indonesia.

A different strategy to increase the capacity would be to increase the production rate by reducing the required time to produce assistive devices. As an example Mr Tamba explained that he needs about 12 hours only to produce a proper artificial foot. If a standard commercially available foot would be used, this time could be completely eliminated, increasing the capacity with a fourth patient for every three patients. However, commercially available feet are either too expensive or of insufficient quality.

Because Harapan Jaya only has one Prosthetist, setting up a mobile workshop is currently not a feasible project. The rehabilitation center cannot miss its valuable employee, nor will the Prosthetist be able to set up the project alone. However, plans for a mobile workshop have existed for years and if the situation allows it, Harapan Jaya is eager to implement it.

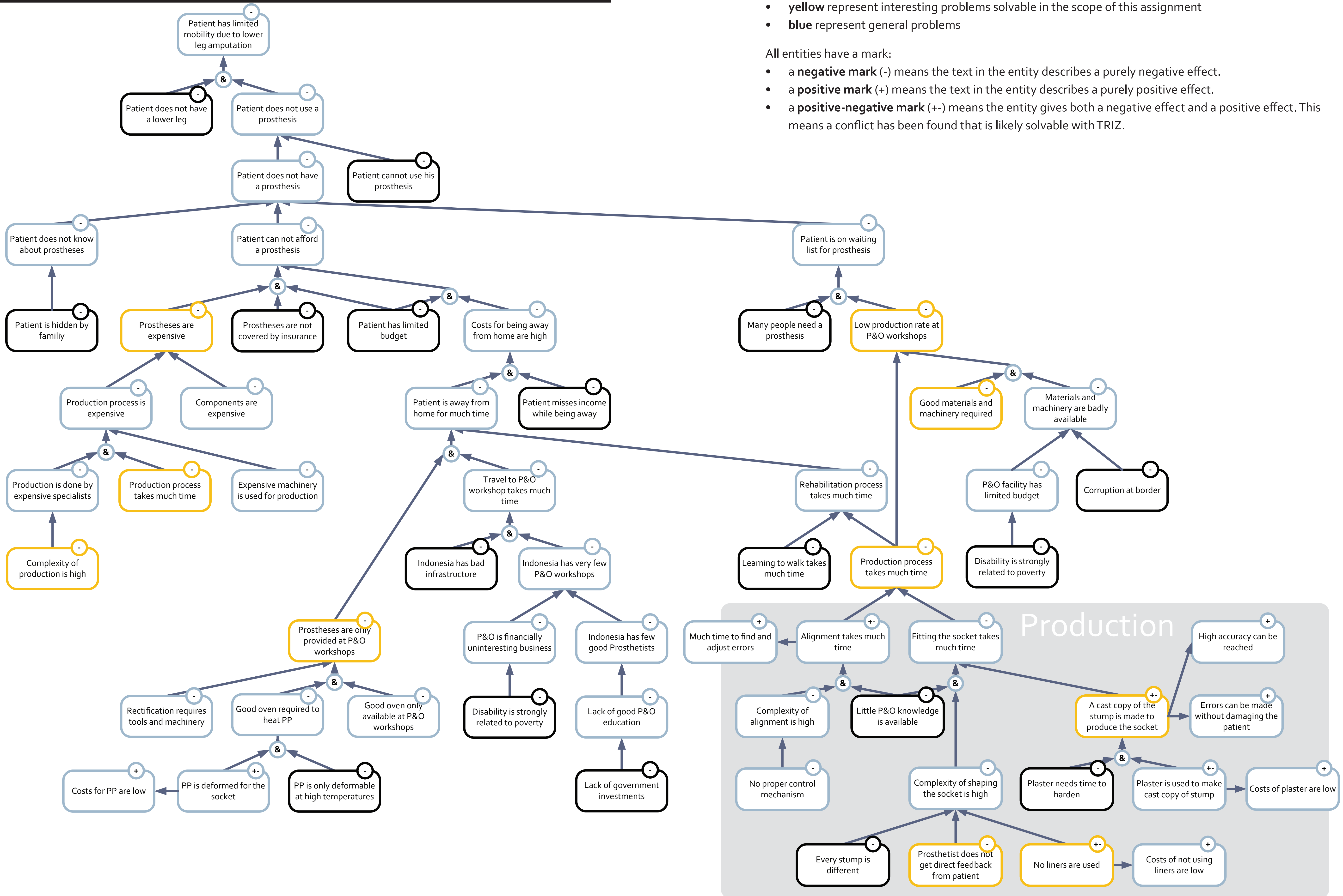
I RCA+

In the figure entities in:

- **black** represent problems unsolvable in the scope of this assignment
- **yellow** represent interesting problems solvable in the scope of this assignment
- **blue** represent general problems

All entities have a mark:

- a **negative mark** (-) means the text in the entity describes a purely negative effect.
- a **positive mark** (+) means the text in the entity describes a purely positive effect.
- a **positive-negative mark** (+-) means the entity gives both a negative effect and a positive effect. This means a conflict has been found that is likely solvable with TRIZ.



J INTERNATIONAL PROJECTS

Multiple organizations exist that are working on the development of orthopedic products for developing countries. Here a list is given of relevant centers that have been contacted or that have produced patents or publications are that were used for current project.

	Institute	Country	Results / Products
CT	Cambodia Trust	Cambodia	Set up JSPO in 2009
CIR	Chicago Institute for Rehabilitation	USA	ScotchCast (WU, 1981) CIR Casting + patent (WU, 2004) CIR Wu Casting (WU, ET AL., 2009) CIR Wu Casting Patent (CASANOVA & WU, 2009)
GBI	Gereja Bethel Indonesia	Indonesia	Outreach program in Indonesia 140 lower leg prosthesis (~10% effective)
ICRC	International Committee of the Red Cross	Switzerland	Enormous global network The ICRC prosthesis (ICRC, 2006)
ISPO	International Society for Prosthetics and Orthotics	Denmark	Standards in education Set up JSPO in 2009 Quality benchmark (STEEN JENSEN, NILSEN, & ZEFFER, 2005) Sand casting (STEEN JENSEN, POETSMA, & THANH, 2005) PUR Feet (STEEN JENSEN, NILSEN, THANH, SALDANA, & HARTZ, 2006) CIR Casting (THANH, POETSMA, & STEEN JENSEN, 2009)
NLR	Netherlands Leprosy Relief	Netherlands	Outreach program in Vietnam Farmer's leg (NLR, 2009)
Össur	Össur	Sweden	Iceross® (liners) Icecast®(pressure bladder) MSS (Modular Socket System)
PF	Prostheses Foundation	Thailand	Farmer's leg Socket from Yakult bottles (VELING, 2012) CIR Casting in mobile clinics (JIVACATE, DEVAKULA, TIPAYA, & YESUWARN, 2011)
POF	Prosthetic Outreach Foundation	USA / Vietnam	Mobile outreach programs in Vietnam, Bangladesh, Sierra Leone and Haiti
VietCOT	Vietnamese College of Orthopedic Technology	Vietnam	PCAST STS Rolon Socket
ZIP	Zwolse Isala Klinieken + OIM Orthopedie	Netherlands	ZIP, Zwolle Isala Prothese (EMMELOT, BRINKMAN, HOL, JORNING, & OVERBEEK, 2007)

K TEST SOCKETS

This chapter gives detailed information about what was learned from the produced sockets at Harapan Jaya (FIGURE 9). Every socket has its own code of a letter and a number. The letter gives information about the user (Subject E, M and S. P = Plaster stump), the number gives information about the version. For every socket a short description is given about what is new in the production method for this socket, the result is analyzed and recommendations for the next socket are given. Grades are given for fitting and suspension.

Figure 9: All sockets made for this project except P1, M2 and M6. Note that not every socket reached the same level of development.

K.1 SOCKET 1 – P1

New: With a plaster model of a stump it was tested to attach an ICRC Cup with Delta Cast Conformable.

Result (+): Mr Tamba understands how to wrap the stump and the ICRC Cup seems to be very feasible as a connector. (Fitting: 0,5. Suspension: 0)

K.2 SOCKET 2 – E1

New: For the first time an actual patient will be using the plastic PCAST prototype, Delta Cast Prints (DCP) will be used instead of Delta Cast Conformable (DCC).

Result (+): DCP is indeed available in Medan, Indonesia. The patient experienced the PCAST as comfortable and DCP seems to be very similar as DCC. With some added foam to the condyles good suspension was achieved.

Result (-): The water level of the PCAST was rather high which made it impossible for Subject E to sink deep enough into the PCAST. Therefore the DCP around the condyles did not get any pressure and were too large to give suspension.

Result: Subject E could walk some meters with the new concept and experienced a slight piston like movement of the stump in the socket. (Fitting: 0,7. Suspension: 0,3)

Next: The water level of the PCAST will be lowered to get better pressure around the condyles.

K.3 SOCKET 3 – S1

New: The water level of the PCAST is lowered to give better pressure around the condyles.

Result (+): Adjusting the water level of the PCAST gives good pressure around the condyles. Even with residual air a pressure of 0,10 bar was easily obtained.

Result (-): The socket is slightly too large and there is no good pressure on the patellar bar. Therefore subject S sinks deeply into the socket causing pain to the distal tip. The surface of the DCP is rather rough.

Result: The socket will not be used. (Fitting: 0,8. Suspension: 0,3)

Next: An upper-pelotte will be used to create a patella bar.

K.4 SOCKET 4 – S2

New: An upper-pelotte (pink foam, soft) was used to create a patella bar.

Result (+): A good patella bar can be created with the upper-pelotte (pink).

Result (-): The socket is not long enough causing a ripple of the stockinet to cause some pain to the distal end of the stump. The condyles are slightly too loose / flexible to provide sufficient suspension.

Result: The socket is used for 4 hours by Subject S. It is experienced to be much lighter than his previous one. Additionally it is simpler because his previous prosthesis is attached with belts. (Fitting: 0,7. Suspension: 0,5)

Next: A thicker distal pelotte will be used to create a larger space for the distal tip of the stump. More layers of DCP will be wrapped around the condyles and wrapped tighter to get a better suspension.

K.5 SOCKET 5 – S3

New: A very thick upper-pelotte (black foam, hard) was used to create a good patella bar. Because the ICRC Cup seemed to be loose it was enhanced with 3 extra screws and some extra DCP. The condyles were corrected with foam.

Result (+): A very good patella bar can be created with the very thick (black) upper-pelotte.

Result (-): The DCP does not adhere very well to the plastic of the ICRC Cup, slight torsion with be fatal. Once opened, DCP prints cannot be stored. The condyles are slightly too wide and had to be corrected with foam.

Result: Subject S played a good match of volleyball. The socket was slightly too loose allowing the stump to move which causes pain to the medial condyle. Later some foam was added to the inside of the condyles to create a better suspension and Subject S was able to use it for several days. Then the ICRC components were needed for socket 10 (E3) and the prosthesis disassembled. Later the LLP was assembled again and subject S will try to test the socket for 3 months. (Fitting: 1,0. Suspension: 0,5)

Next: The ICRC Cup will be roughened and more layers of DCP will be applied on the ICRC Cup to create a stronger connection. A test will be done to investigate the maximum torsion strength of this connection.

K.6 SOCKET 6 – S4

New: Upper-pelottes (pink) on condyles, extra pressure with bicycle tube. Extra pelottes (black) are placed in the back of the knee to create a good popliteal area. Later this area was heated and slightly deformed.

Result (+): The condyles are tighter. DCP can be deformed when heat is applied.

Result (-): The popliteal correction was aimed too high and later cut off. It does not really work because for every patient you would have to create the perfect pelotte. The bicycle tube creates an incorrect shape.

Result: The socket could not be used. (Fitting: 1,0. Suspension: 0,3)

Next: No bicycle tube, no popliteal pelotte.

K.7 SOCKET 7 – S5

New: Upper-pelottes (pink) on condyles. A combination of DCP and DCC was used. The stump was wrapped more tightly. The plastic PCAST was leaking a lot and can be considered broken. It was difficult to reach a pressure of 0,10 bar.

Result (+): The condyles are tighter. DCC has good adhesion on DCP. The surface of DCC is really smooth.

Result (-): The shape of the socket is rounder and less like a triangle. This is most probably caused by wrapping the stump too tight.

Result: The socket is used by Subject S for 1 day and has caused him some pain on the tibia because of the more circular shape of the socket. (Fitting: 0,8. Suspension: 0,8)

Next: Looser wrapping of the DCP. In the second phase the ICRC Cup and the condyles will be wrapped very tightly, but not the rest of the stump.

K.8 SOCKET 8 – M1

New: This was the first socket for Subject M and the first time the aluminum PCAST was used. Only DCC was used. Pelottes (pink) were used on fibula head, tibia and distal end. Upper-pelottes (black) were used on the patella tendon and on the condyles. A pressure of 0,10 bar was achieved and held for about 6 minutes. In the first wrapping 1 roll of DCC was used, in the second 2 rolls. The ICRC Cup and the condyles were wrapped very tightly and in the second wrapping manual pressure was added to the condyles.

Result (+): The fitting is very good, Mr Tamba is getting more experienced and the process is going increasingly faster

Result (-): The suspension is not so good. It could be used as a PTB socket meaning an extra belt should be added above the patella. Other options are to heat the condyles and reshape them, or to add foam on the inside of the condyles. It was chosen to use some Velcro to make the condyles tighter and this created a fairly good suspension.

Result: The socket seems to be rather flexible around the condyles allowing some piston-like movement. Additionally it was mentioned that the socket seemed to be bigger in warmer temperatures. (Fitting: 1,0. Suspension: 0,6)

Next: The socket will not be cut over the patella but in the poplitea area. Mr Tamba and Mr Tobing have an idea about creating better condylar suspension by leaving the knee covered.

K.9 SOCKET 9 – E2

New: We forgot the sock! Instead we wrapped the stump directly with plastic and Delta Cast.

Result (-): It was a rather painful process for Subject E to get the socket off. (Fitting: 0,0. Suspension: 0,0)

Next: We will never forget the sock again.

K.10 SOCKET 10 – E3

New: Instead of using a thin silicon hose, a thicker strip of foam was used to create a path for the scissors over the patella. Much attention was paid to the alignment.

Result (+): Although at first it seemed like the socket was not made well enough, with some adjustments to the alignment the socket did not cause any pain anymore.

Result (-): After a few days the socket started to cause some pain due to some alignment mistakes.

Result: Subject E used the socket for approximately 4 days, then the ICRC components were needed for a new prosthesis for Subject S. (Fitting: 1,0. Suspension: 0,8)

Next: Since Subject E's other leg is not very strong (yet) it was thought to better not to give her a test prosthesis with potential harmful effects. If something goes wrong, her other leg cannot compensate.

K.11 SOCKET 11 – M2

New: The socket was created in two steps: in the first step the bottom part of the socket was created with an additional upper-pelotte (black) in the popliteal area. The patellar bar was already created in this step. In the second step the upper part around the condyles was 'draped' with six layers of DCP, leaving the backside of the socket open. In the second step the ICRC Cup was also included. Additionally the socket was cut out higher at the patella-area to give a more rigid structure. This type of socket is called PTB-SCSP.

Result (+): Because no manual pressure can be given while the stump is inside the PCAST it is good to not create the suspension yet. In the second step a very good suspension was created with manual pressure. Because the part around the patella was higher, the condyles were a lot less flexible giving a good suspension.

Result (-): The 'draping' was not long enough causing the condyles to be too thin on the backside. Subject M has a hyper extended stump and was casted in this position which causes a wrong socket. The PTB-SCSP has some ridges on the lateral and medial side of the knee which make the knee aesthetically incorrect.

Result: A new principle of creating a good suspension (with 'draping') has been proven but the socket was not complete and will therefore not be used by Subject M. (Fitting: 0,9. Suspension: 1,0)

Next: When the 'draping' method will be used again, a longer strip will be used so the condyles are covered well. Additionally the top part of the stump will first be wrapped with one layer of DCP to eliminate the forming of a ridge.

K.12 SOCKET 12/13 – M3 / M4

New: To investigate the influence of the used pressure two subsequent sockets were made with the PCAST. For one the pressure was kept constant at 0,20 bar while for the other the pressure was 0,05 bar.

Result: There was no noticeable difference between the resulting sockets. Both subject M and Mr Tamba could not find any difference. The conclusion was drawn that high pressure may not be so important and the rather weak vacuum pump might be strong enough to give some result. (Fitting: 1,0. Suspension: 0,8)

Next: Instead of the PCAST, the vacuum pump will be used to put pressure on the stump.

K.13 SOCKET 14/15 – M5 / M6

New: A conical plastic bag was created from a sheet of PVA to fit around the stump. Instead of the PCAST a vacuum pump was used to put pressure on the surface of the socket. The hose of the vacuum pump is placed on top of the DCP, not underneath because the DCP seems to block the hose. Advantage of this approach is that manual pressure can still be applied to create a proper suspension around the condyles.

Result (+): There was no noticeable difference between the fitting of these sockets (M5 / M6) and the ones made with the PCAST (M3 / M4). However, the suspension of these sockets was a lot better because Mr Tamba could give manual pressure around the condyles. Additionally, the hyperextended stump of subject M could actively be corrected during the curing of the DCP.

Result (-): A good vacuum pump and electricity is needed for this process.

Result: Subject M will try to test the socket for 3 months. (Fitting: 1,0. Suspension: 1,0)

Next: This was the last socket.

L MATERIALS

Synthetic cast tape is mostly used for immobilization of injured limbs and joints. The material consists of woven fibers impregnated with a water activated resin. As an alternative to Delta Cast® Conformable, multiple other materials have been investigated. Many products use polyester as fabric with water activated polyurethane (PUR) resin, but much difference exist between the final result. Flexibility can be different (conformability), curing time, thickness, adherence, etc. This appendix gives an overview of the investigated materials.

L.1 BSN MEDICAL

BSN Medical produces a large variety of synthetic cast tape. Only their Delta Cast® series uses polyester fibers and is therefore expected to be strong enough for the use in a socket.

- BSN Medical Delta-Cast® Conformable (polyester fabric + PUR resin)
- BSN Medical Delta Cast® Prints (polyester fabric + PUR resin)
- BSN Medical Delta-Lite® Plus (fiberglass fiber)
- BSN Medical Gypsona® (Plaster of Paris)

L.2 3M

3M also produces synthetic cast tape, most with a fiberglass fabric as basis.

- 3M™ Scotchcast™ One-Step Splint (fiberglass fabric + PUR resin)
- 3M™ Scotchcast™ Plus Casting Tape (fiberglass fabric + PUR resin)
- 3M™ Scotchcast™ Soft Cast Casting Tape (fiberglass fabric + PUR resin)
- 3M™ Scotchcast™ Poly Casting Tape (polyester fabric + PUR resin)

L.3 LOHMANN & RAUSCHER / ACTIVA

Lohmann & Rauscher / Activa also produces synthetic cast tape, one of them with a polyester fiber as basis.

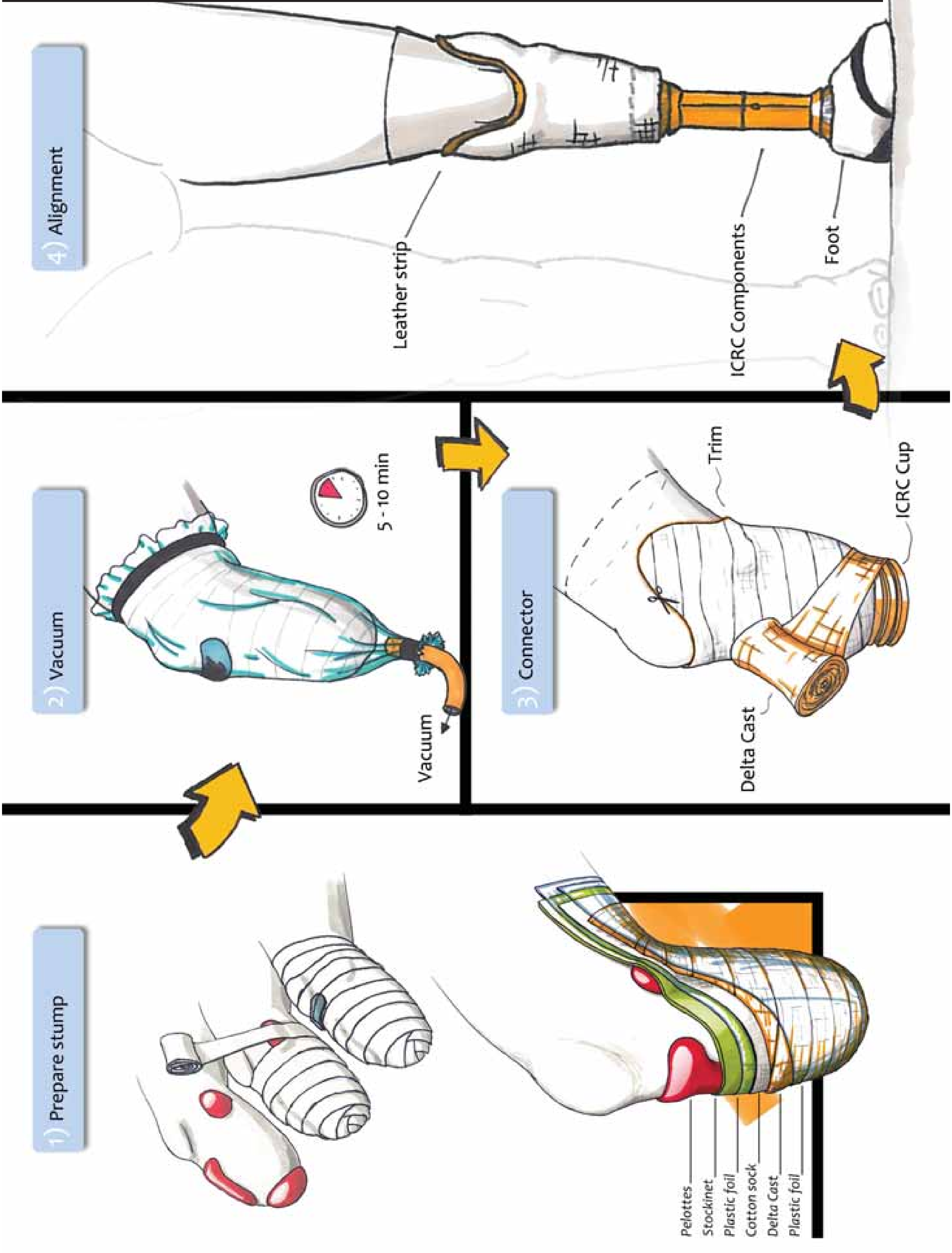
- Cellacast® Active (polyester + PUR resin)
- Cellacast® Soft (fiberglass fabric + PUR resin)
- Cellacast® Xtra Casting Tape (fiberglass fabric + PUR resin)

L.4 STS

This USA-based company produces pre-shaped socks that are made of synthetic cast tape. The complete sock is immersed in water and can be rolled over the stump like a condom.

- Tubular Casting Socks (Lycra® + PUR resin)
- Fitted Polyester Casting Socks (Lycra® + PUR resin)
- Veterinary Casting Socks (Lycra® + PUR resin)

M THE MANUAL


1) Prepare stump
Pelottes
Stockinet
Plastic foil
Cotton sock
Delta Cast
Plastic foil
2) Vacuum
5 - 10 min
Vacuum
3) Connector
Trim
ICRC Cup
Delta Cast
4) Alignment
Leather strip
ICRC Components
Foot

M.1 INGREDIENTS

No consensus exists on which pressure device is best to use, so both the use of the PCAST and vacuum pump are included in the protocol.

RESOURCES

- 3 rolls of Delta Cast® Prints (for smaller stumps 2 rolls are sufficient)
- 1 Thin plastic tube
- 1 ICRC set (1 cup, 1 convex top piece, 2 pipes, 1 convex foot piece)
- 1 Washer (flat metal ring)
- 2 Bolts
- 1 Artificial foot
- 2 Small screws
- 1 Suspension sleeve
- Soft (pink) foam (pelottes)
- Hard (black) foam (upper-pelottes)
- Leather
- Water
- Plastic foil
- Stockinet
- Sandpaper
- Sticky tape

EQUIPMENT

- Pressure device
  PCAST: PCAST tank
  Vacuum: Vacuum pump + tube + conical plastic bag
- Bucket
- Gloves
- Pen
- Scissors
- Saw
- Heat plate
- Wrench (hex)
- Screwdriver

M.2 PROCEDURE

All phases have a strict order of activities and are described below.

PREPARATION

1. Create or buy a suitable foot and glue the ICRC convex foot piece to it
2. Prepare pressure device

   PCAST:

   a. Fill PCAST to high water level (remove air), make room until the bottom of the bag is visible
   b. Let patient stand into PCAST and lower water level until knee is also covered
   c. Get patient out of PCAST and make the bottom of the bag visible again

   Vacuum:

   a. Test if the conical plastic bag is air tight
   b. Wrap a piece of foam around the end of the tube to prevent obstruction of the tube
3. Prepare a bucket of water and make the Delta Cast® Prints, plastic foil and gloves ready for use
4. Prepare the pelottes

SOCKET PART 1

5. Place pelottes (tibia, fibula-head, distal end) and fix with plastic foil
6. Apply stockinet and plastic tube on knee, wrap stump with plastic foil
7. Put the gloves on and wet one roll of Delta Cast® Prints
8. Wrap the stump with Delta Cast® Prints (moderately tight, distal to proximal)
9. Give a short massage to spread out the resin and then remove the gloves
10. Wrap the stump with plastic and include upper-pelottes (patella tendon, popliteal area)
11. Apply (thick) stockinet to reduce friction and reduce effect of ridges in the plastic
12. Apply pressure

    PCAST:

    a. Apply stockinet to reduce friction and reduce effect of ridges in the plastic
    b. Place patient in PCAST, wait 5 – 10 minutes and make sure the pressure is above 0,10 bar
    c. Get patient out of PCAST, remove stockinet

    Vacuum:

    a. Apply stockinet to reduce friction and reduce effect of ridges in the plastic
    b. Pull plastic bag over the stump, insert the tube and turn on the vacuum pump. Wait 5 – 10 min
    c. Apply manual pressure around condyles to form a good suspension
    d. Turn off vacuum pump, remove the plastic bag and stockinet
13. Remove plastic foil, upper- pelottes and plastic tube
14. Cut the socket over the knee (over indentation from plastic tube) and remove socket
15. Remove plastic from the inside of the socket (leave pelottes and stockinet on the stump)
16. Mark anatomical locations and cut socket in appropriate shape, also cut a hole in the bottom
17. Test the socket on the patient (do not bear weight yet) and adjust the shape if necessary
18. Roughen the socket with sandpaper so the next layer will adhere well

SOCKET PART 2

19. Roughen the ICRC Cup and tape the metal washer inside
20. Wrap the stump with plastic (over the pelottes and stockinet)
21. Put the socket on the stump
22. Put the gloves back on and wet one roll of Delta Cast® Prints
23. Wrap the stump and include ICRC Cup on distal end (strongly around condyles and ICRC Cup only)
24. Make sure the socket is 6-8 layers thick everywhere. If not, use one extra roll of Delta Cast® Prints
25. Give a short massage to spread out the resin and then remove the gloves
26. Wrap the stump with plastic (no upper pelottes)
27. Apply manual pressure around ICRC Cup and condyles for 5 – 10 minutes
28. Remove plastic, socket, plastic, stockinet and pelottes
29. Put stockinet / stump sock around stump
30. Mark anatomical locations and cut socket with scissors in appropriate shape
31. Test the socket on the patient (bear weight now)

SHANK

32. Prepare heat plate
33. Paste layer of foam on the bottom of ICRC Cup (for extra friction)
34. Measure the length of the other leg
35. Saw the ICRC components on the correct length
36. Place both ICRC components on the heat plate, wait 5 – 15 minutes and 'paste' them together
37. Loosely connect the foot to the shank with a bolt
38. Loosely connect the socket with the convex ICRC component and a bolt
39. Correctly align components and tighten bolts
40. Test the prosthesis on the patient and adjust fitting or alignment if necessary

COSMETICS

41. Paste layer of leather around the proximal edge of the socket
42. Use a suspension sleeve for extra suspension

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