## Thesis - BSc Life Science Technology

The improvement of the ankle of an accessible, adaptive, trans-tibial, temporary prosthesis for patients in rural areas in South Africa



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University of Groningen CoPP

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## Disclaimer

This thesis was written in collaboration with R.J.C. de Koster, student of the University of Groningen. The literature and contents of the problem definition, goal and design assignment were researched cooperatively, but were written separately. Therefore, these parts of the thesis could show similarities. Since both theses have the same problem owner and part of the literature was provided, the references also could show similarities.

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## Background

Worldwide, over 1 billion people have a disability. This is approximately 1 in 7 people in the world¹. Of these people, approximately 1 in 10 has access to assistive products². On top of this, 50% of the world population is unable to afford the health care that they require. In short, this means a large amount of people who need health care are not able to acquire it.

Therefore, the last couple of years worldwide more attention is paid to make health care more available. Multiple organisations were founded to improve orthoses and prostheses accessibility worldwide. Since 2008, there is an international law stating everyone is entitled to the right of access to orthotic and prosthetic services<sup>3</sup>. Also, the United Nations has obligated countries to promote research in assistive technology<sup>4</sup>. However, the improvement in accessibility in the last couple of years has shown to be minimal in developing countries<sup>5</sup>.

Currently, the majority of people with a disability, 80%, lives in developing countries, such as South Africa. The number of people in developing countries in need of prosthetic devices is estimated to exceed 29 million<sup>5,6</sup>. In these countries access to required assistance is insufficient. Less than 3% of people with a disability in developing countries have access to adequate care<sup>5</sup>. This is mainly because rehabilitation is not prioritised there, since primary health care takes precedence. This actually enlarges the problem because more people survive infancy, thus more people with a disability grow old<sup>5</sup>. Besides the ageing population, chronic diseases leading to amputations, such as diabetes, also occur more often<sup>7</sup>. Disability is a growing problem and developing countries need to focus more on rehabilitation. In South Africa a lot of policy changes improving health care were implemented in 2010, which include more attention to rehabilitation services<sup>8</sup>.

A disability has large consequences on the quality of life and wealth, especially for people living in rural areas. Mainly in these areas this leads to a vicious cycle of poverty (see figure 1): poor people suffer from poor health, living and working conditions, which causes vulnerability to disability. Once these people become disabled, the poor conditions and insufficient care make it harder to work, which results in them becoming even poorer. This leads to a lot of people with disabilities unable to afford necessary assistive products<sup>5</sup>.



*Figure 1 – Vicious cycle of poverty*<sup>6</sup>

Especially lower limb amputations cause a sense of loss and stress and can lead to a deteriorated functioning, resulting in a decrease in the quality of life<sup>9</sup>. The most prominent cause for lower limb amputations in developing countries is dysvascularity (have a defective blood supply)<sup>10</sup>. For lower limb amputations it has been proven that early mobilisation is highly beneficial for recovery<sup>10</sup>. Unfortunately, there is a shortage of prosthetic resources and trained personnel in developing countries, which makes early mobilisation unfeasible<sup>11</sup>. In some areas of South Africa, people have to wait three to six years for a prosthesis<sup>9</sup>.

Recently, organisations have been trying to come up with a solution for this shortage of prosthetic services in developing countries. One of these organisations is the Community of Prosthetic Practice (CoPP). This organisation designed a temporary prosthesis to make early mobilisation possible for everyone. However, there are two aspects of the interim prosthesis prototype in need for improvement. First, the socket has to be improved, so adequate comfort can be provided. Next, the ankle has to be stronger, so that it does not break, and the prosthesis can last longer. If these two aspects are improved, this prosthesis is very promising to improve life of people with a disability in rural areas of developing countries <sup>12</sup>.

### Problem definition

### 1.1 The complete problem

With disability as a rising problem, more attention is paid to prosthetic rehabilitation worldwide. There are multiple problems concerning prosthetic services in developing countries. In this thesis the problems around prostheses in South Africa are reviewed. The main problems include policy, lack of rehabilitation, awareness, cultural beliefs, untrained personnel, shortage of personnel, accessibility, costs and availability.

One of the problems concerning prostheses in South Africa is the **policy**. In 2010 South Africa had a lot of policy changes around medical guidelines. At first, only primary health care was financed properly. Lately, the problem of a rising number of people with a disability has caused more attention to rehabilitation services, especially in rural areas. The policy has changed, but in practice it has not yet been fully implemented. The coming years, South Africa stands before the challenge of actually making a difference in rural areas<sup>8,13</sup>.

As stated before, early mobilisation and **rehabilitation** are crucial for recovery after a lower limb amputation. In South Africa, a lot of people get no rehabilitation after the amputation. After the amputation, people are sent to the prosthetic clinic. At the prosthetic clinic a fitting is done, and it is checked if the patient is able to walk with it. After this the patient is sent home, without any therapy or training. Without the necessary therapy, the stump can change in shape, because of deteriorating tissue. Ultimately, the lack of rehabilitation results in misfit prostheses and people unable to use their prosthesis properly<sup>9,11,14</sup>.

One of the main problems resulting in the lack of rehabilitation is the **awareness** of the options the people with a disability have to obtain a prosthesis. This is partially caused by the **cultural beliefs** of people living in the rural areas. They believe that they are bewitched and only their local traditional healer can cure them. It is also encouraged by their **environment** to seek help at traditional healers rather than going to the hospital. Besides, the cosmetics of prosthesis are very important for them, since they are afraid to be rejected by the community with a prosthesis. People living in rural areas also are not aware of their options because they are badly informed. More emphasis should be placed on increasing awareness of the problems caused by disability in rural areas and de-stigmatising the prosthesis in communities<sup>11,14,15</sup>.

The lack of rehabilitation is partially caused by **untrained personnel and a shortage in personnel**. To offer an adequate rehabilitation a multidisciplinary team is required, with different healthcare professionals. A multidisciplinary team is of great importance in the rehabilitation process for reintegration in the community and psychological support. Unfortunately, there are not enough well-trained healthcare professionals to provide adequate rehabilitation all over South Africa. Often, physiotherapists are in charge of physical rehabilitation. However, there is a large shortage in staff in South Africa. In certain areas there are only two physiotherapists to serve a whole hospital and community. Therefore, they are unable to provide adequate rehabilitation services, due to the extremely high workload<sup>9,11</sup>.

Furthermore, the lack of rehabilitation is increased by the problem of **accessibility**. To get therapy or a prosthesis, patients would have to go back to the hospital. But, in rural areas options of transportation to the hospital are poor. Especially when their mobility is low, the public transport can be too far away from their homes. Because of this, a lot of people from rural areas do not get to the hospital when they experience problems<sup>9,11</sup>.

One of the larger problems people with a disability encounter is the **financial issue**. As stated before, people often end up in a vicious cycle of poverty, becoming poorer because of their disability<sup>5</sup>. People in these communities in rural areas often have to survive on less than

R800 per month<sup>13</sup>. The South African Social Security Agency (SASSA) tries to support them with a monthly allowance of maximum R1600<sup>16</sup>. However, people with a lower limb amputation only qualify for a temporary disability grant, which is rendered for only 6 to 12 months, after which they have to file again<sup>16</sup>. A lot of people living in rural areas have no knowledge about this allowance or do not know how to get it.

The largest problem concerning prostheses in South Africa is the **availability**. When people get to the prosthetic clinic, overcoming the barriers stated above, the prosthesis is fitted. After this, they often have to wait three to six years until they get the prosthesis. This is a lot longer than the 6 months they receive the disability grant. The waiting time is caused by shortage of staff, shortage of materials and a growing demand. Because of this time without prosthesis, adequate rehabilitation is extremely important. Without the rehabilitation, the patients encounter complications with the fitting of the prosthesis<sup>9,11</sup>.

The last years the number of people with a disability has increased, especially in developing countries like South Africa. There are a lot of people with lower limb amputations, who require rehabilitation services and a prosthesis. In South Africa, multiple factors lead to the health system being unable to provide adequate rehabilitation services and to an extremely long waiting period for prostheses of three to six years. Because of this, the people of South Africa living in rural areas become even poorer, unable to fulfil their working tasks. Next to this, the waiting period causes tissue to deteriorate, which results in misfit prostheses. These problems combined makes it very hard for people with a disability to continue their everyday lives in rural areas of South Africa.

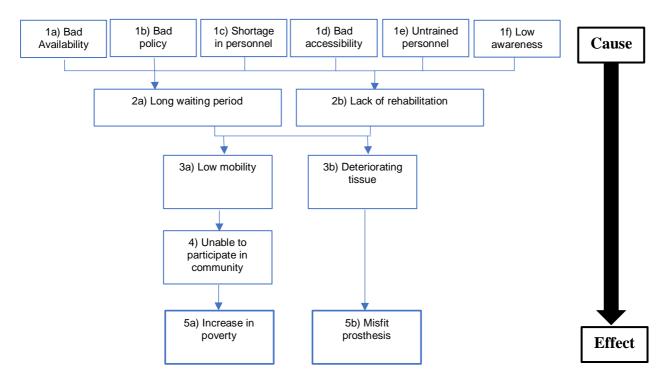


Figure 2 – Cause-effect scheme of the problem

#### 1.2 The temporary prosthesis prototype

A possible solution to this problem could be a temporary prosthesis. Because of the long waiting period, in which people do not receive rehabilitation, people have a low mobility and tissue deteriorates. With a temporary prosthesis, directly available for everybody, people can be mobile during this waiting time and tissue is deteriorating less.

A temporary prosthesis prototype has been developed by the COPP and the initial feasibility study was done by students from the University of Western Cape<sup>12</sup>. The prosthesis prototype is built from a PVC SABS pipe, a PVC waste adaptor, a PVC plain junction, masking tape, alcolin fillafoam, blu plum PVC cement, gutter bolt and nuts, tile sponge, duct tape and a Stanley hacksaw. It also has a casting of delta-lite, only available at a hospital pharmacy. The delta-lite is essential for the moulding of the cast<sup>12</sup>.

The feasibility of this prosthesis has been researched<sup>12</sup>. To be feasible it has to meet certain requirements. Often, people in rural areas cannot afford expensive care, so the temporary prosthesis has to be low-priced. Furthermore, the prosthesis has to be available for everyone in rural areas in South Africa. To accomplish these two aspects, all materials were obtained from a local hardware store 'Buco Hardware and Buildware'. The materials of this prosthesis cost around R350 and the store has 21 branches in the Western Cape, which makes it affordable and available<sup>12</sup>. If the prosthesis would be used in another area or country another hardware store has to be searched for the materials. Furthermore, the prosthesis is built easily, so it can be done by someone with little training or experience, which makes it more available<sup>12</sup>.

Next to the cost and availability requirements, the strength of the prosthesis also has to be ensured. The prosthesis has to be able to withstand different forces from different angles without breaking or failing. The average force the prototype of the prosthesis could withstand is 130 Nm. The main weakness lies in the ankle joint of the prosthesis, which causes the prosthesis only to be able to withstand a person under 100 kg<sup>12</sup>.

An important aspect to consider is also the function and comfort of the prosthesis. The functional level of the prosthesis is feasible. However, the functioning decreased because of an insufficient level of comfort offered by the prosthesis, resulting in pain. This pain obstructs the functioning when high intensity activities are performed. The comfort of this prosthesis received less than half the score of an average prosthesis. The comfort of this prosthesis is therefore not feasible. Nevertheless, patients state that they would use this prosthesis prototype if they had no other assistive device<sup>12</sup>.

Altogether, the prosthesis prototype shows promising results. The prototype is already low-priced, available and functioning. There are two main aspects in need for improvement: the strength and the comfort. The strength can be improved by designing a stronger ankle joint.

The comfort can be increased by improving the socket.

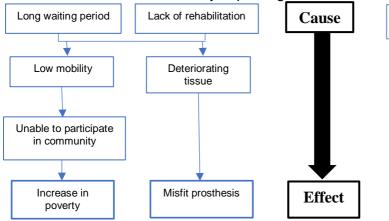


Figure 3 – Cause-effect scheme of the problem to be solved by the prosthesis

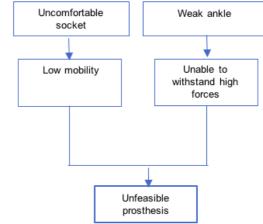


Figure 4 – Cause-effect scheme of the problem of the prosthesis itself

## Stakeholders

	What they want (ideal image)	Characteristics	Where they are involved <sup>i</sup>	What they do
User	A fitting prosthesis (and know where to get it) being able to do everything of their everyday life	Poverty  Lack of mobility  Mainly living in rural areas	1 t/m 5	Walk around without or with a misfit prosthesis Unable to properly work
Caregivers/ Families	A mobile patient with a fitting prosthesis able to work	Poverty  Can help the user	5	Help the user in every way they can
Prosthetist	Guarantee a good prosthesis without waiting time	Lack of materials and time	1a, 1c, 1e, 2a, 2b	Provide a prosthesis as fast as possible, but too slow provide little rehabilitation service
Academic institutions	Train enough prosthetists and surgeons  Educate people in rural areas	Lack of capacity and adequate educators	1c, 1e, 1f	Train health workers, not enough and not trained well  Provide little education in rural areas
Health service providers	Offer good rehabilitation services Offer good prostheses	Lack of personnel and materials	1a, 1d, 1e	Try to provide care when and where they can as good as possible, but not enough
Government	Prosthesis for everyone without derogating anyone	Provides a disability grant	1b	Changed policy but not yet implemented in society
Organizations (WHO and smaller, like CoPP)	Searching for a solution to realise a shorter waiting period and better rehabilitation	Research takes time and money	1 & 2 & 4	Different types of organizations trying to solve a part of the problem (at its core)

Table 1 – Stakeholders and their involvement in the problem

 $<sup>^{\</sup>mathrm{i}}$  See figure 2 for corresponding problem

#### Goal

## 1.1 The complete goal

The goal is to solve the problem concerning disability in rural areas of South Africa. Because of bad availability, bad policy, bad accessibility, low awareness, shortage in personnel and lack of training two large problems occur. The first main problem is the long waiting period of three to six years for people to receive a prosthesis. Because of this long waiting period they are not mobile for a long time, which eventually results in them being pushed further into poverty. The second main problem is the lack of rehabilitation, which results in deteriorating tissue and eventually a misfit prosthesis. Altogether, disability makes life in rural areas in South Africa extremely hard in the current circumstances. The goal is to solve these problems, so the waiting period is shortened, or a temporary solution can be given for those three to six years, and everyone can receive adequate rehabilitation services.

All stakeholders are involved in part of the problem. They each have a goal for (partially) solving this problem. The government has shown that it wants improvement by changing the policy for hospitals and institutions. However, these policy changes have not yet been implemented in society. The goal of the government is to properly implement these policy changes, so more attention is paid to prosthetic rehabilitation. Academic institutions are delivering too little well-trained personnel for the hospitals to provide adequate rehabilitation services. The goal of the academic institutions is to train more people. Furthermore, they want to provide education about the options of obtaining a prosthesis all over the country, also in rural areas. Health service providers want to attract more well-trained personnel, so they can provide good rehabilitation services and prostheses for everyone. They also want to improve their accessibility for people from rural areas.

Recently, diverse organisations are more involved in this problem. More and more organisations were founded to solve a part of the problem. The largest organisation involved is the WHO, trying to improve health care worldwide and protect the right of health care for everyone 17. They want health care to be available for everyone by removing the physical barriers to health facilities, information & equipment. Also, health care must be affordable for everyone. Additionally, they want to train all health care workers in disability issues and invest in specific services, such as rehabilitation services. Besides WHO, there are more small organisations interested in this disability problem. Their goals are to shorten the waiting period and provide the opportunity for good rehabilitation services for everyone.

If all these problems would be solved, people with a disability living in rural areas in South Africa would not be pushed further into poverty and would be able to do everything they did before they became disabled (*see figure 5*). Good availability, good policy, good accessibility, high awareness, enough personnel and well-trained personnel will lead to a shorter waiting period and good rehabilitation services. This will lead to everyone being able to move around and participate in the community and overcoming the problem of tissue degeneration. Eventually, people will not become poorer and will have a fitting prosthesis, which makes them mobile. The ultimate goal is to make it possible for everyone to do the activities of their everyday life.

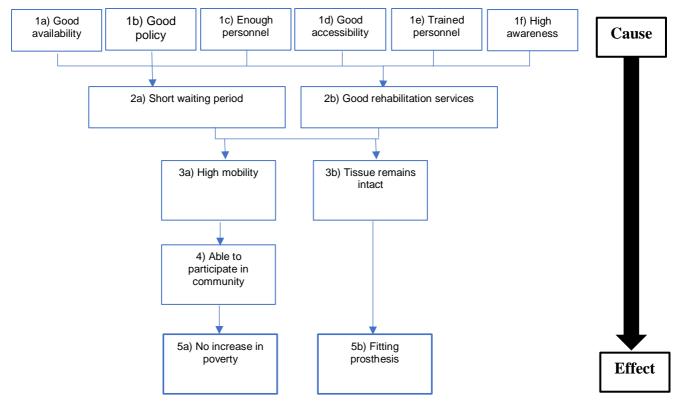


Figure 5 – Cause-effect scheme of the goal

## 1.2 The goal of the temporary prosthesis prototype

The different aspects of the problem could be solved by a temporary prosthesis designed by CoPP. This prosthesis shows very promising results. The goal of this prosthesis is for people with a disability to be able to continue with their everyday lives without an increase in poverty and with a fitting prosthesis (see *figure 6*). This goal can be achieved by improving the prosthesis (see *figure 7*). The two parts in need of improvement are the ankle joint and socket. With these two qualities added, the prosthesis could make it possible for people with a disability in rural areas to immediately be mobile and do their everyday jobs.

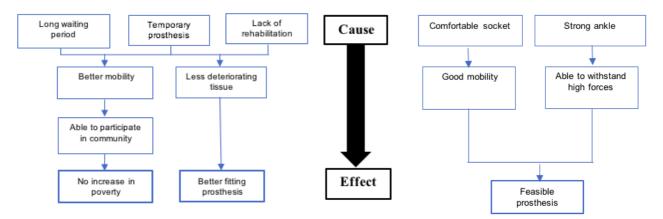


Figure 6 – Cause-result scheme of the goal with prosthesis

Figure 7 – Cause-result scheme of the goal for the prosthesis

## Design assignment

The design assignment of this project is to improve the low-cost, temporary, lower limb prosthesis prototype. This temporary prosthesis is designed to minimalize the problems caused by the waiting period and provide mobility until the patients can receive a prosthesis from the hospital (see *figure 6*). It will be feasible once the costs are low enough to make the prosthesis available for everyone, when the tensile strength is good enough and function and comfort are sufficient for people to do their everyday tasks (see *figure 7*).

This project is owned by the organisation CoPP<sup>18</sup>. This organisation was founded in 2015. It is one of the new founded organisations, trying to solve a part of the problem. The organisation focuses on increasing the accessibility of assistive technology for mobility in rural areas, such as Malaysia and South Africa.

The focus of this assignment lies in improving the prosthesis prototype. Previous research has shown that the socket and ankle are not yet good enough to realise this prosthesis <sup>13</sup>. This project focuses on rural areas in South Africa. The target audience is thus the people with a lower limb amputation in need of a prosthesis in rural areas in South Africa. The design project will follow the steps of the programme of the university of Groningen. The design will be made in 9 weeks, so the strategy will be to plan and time. The focus of this thesis will lie on improving the ankle of the prosthesis prototype.

The ankle joint is of great importance, especially in developing countries. This is because the durability and aesthetics of the whole prosthesis are determined by it. The ankle and foot also provide an increase in functioning, especially on muddy uneven terrains, because it establishes knee stabilisation during a forward transfer<sup>12</sup>. In the prosthesis prototype the ankle joint and foot is currently built from<sup>12</sup> a 50 mm PVC plumbing plain junction, a small piece of a 1 m PVC 50 mm plumbing pipe, a mini hacksaw, expanding polyurethane foam, PVC cement, a closed shoe and a newspaper. This construction gave stability to the prosthesis, but it cracked with too much weight (more than a 100 kg), because of a low gait cycle, and was not durable enough. The focus of the project will be to improve the gait cycle of the prosthesis, while delivering adequate stability.

The ankle will be the core of this project. However, the requirements of the total prosthesis prototype also have to be taken in consideration. With the improvement of the ankle the prototype still needs to be affordable, available and functional.

## Requirements & Wishes

A list of requirements and wishes is made to determine the aspects necessary to reach the goal. The requirements are divided in different categories. These categories are: build, durability, use, safety and price. Within each category the requirements for the prosthesis prototype and requirements for the ankle are stated. There is also a list of wishes, which ideally also could be met.

#### 1. Build requirements

Requirements prosthesis prototype

- The materials must be deemed appropriate for the culture of people living in South Africa<sup>11,15</sup>
- To build the prosthesis no electric materials or specialized tools must be necessary
- The materials must be easily available in South Africa (at a hardware store) Requirements ankle
- The materials must be easily available in South Africa (at a hardware store)

#### 2. Durability requirements

Requirements prosthesis prototype

- The prosthesis must be able to withstand the weather conditions of rural areas, 7 mm/day of rain and 40 degrees Celsius<sup>ii,19</sup>
- The prosthesis must have a durability of minimal 3 years<sup>9</sup>

Requirements ankle

The ankle must have a durability of minimal 3 years<sup>9</sup>

#### 3. Use requirements

Requirements prosthesis prototype

- The prosthesis must be able to withstand an ultimate strength in the sagittal plane of minimal 130 Nm<sup>12</sup>
- The prosthesis must give the patient an ambulation level of minimal K2<sup>iii,12</sup>
- The prosthesis must have a maximum weight of 5 kg<sup>iv,20,21</sup>

Requirements ankle

- The ankle must be able to withstand a torque of 24.95 Nm during a gait cycle<sup>22</sup>
- The ankle must not obstruct the functioning of the prosthesis prototype
- The ankle must be able to withstand 2 times the body weight (during the heel rise of the gait cycle)<sup>v,23</sup>
- The ankle must ensure midstance stability<sup>24</sup>
- The ankle must ensure lateral stability
- The ankle must weigh 2.5% of the total body weight<sup>25</sup>
- The ankle/foot-complex must have a height of maximum 18 cm from the ground<sup>25</sup>
- The ankle must be aligned with the leg/rest of the prosthesis

#### 4. Safety requirements

Requirements prosthesis prototype

- The prosthesis must not bring harm to the person wearing it
- The prosthesis must not have sharp ends

Requirements ankle

- The ankle must be fixated adequately
  - Withstand forces and not break

ii Broad estimation of maximum weather conditions with data from 2009 until 2017

iii K2-level says the prosthesis is functional for uneven surfaces and stairs

iv Leg has an average weight of 6.43 percent of the body weight. The average body weight in Southern Africa is 73.7 kg

<sup>&</sup>lt;sup>v</sup> The gait cycle is further explained in the function analysis, p.16

#### 5. Price requirements

Requirements prosthesis prototype

- The price of the total prosthesis has to be below the disability grant (R1600)<sup>16</sup> Requirements ankle
- The price of the ankle must be maximal R500<sup>vi,12</sup>

#### Wishes

- The prosthesis and ankle as cheap as possible
- The prosthesis and ankle as strong as possible
- The prosthesis and ankle as easy to build as possible (do it yourself)
- The prosthesis and ankle as durable as possible (6 years)9
- The prosthesis and ankle are easy to clean
- The prosthesis is reparable if it fails
- The ankle is able to perform the movements of the gait cycle<sup>v</sup>
  - Dorsiflexion and plantarflexion in the sagittal plane<sup>26</sup>
  - Inversion and eversion in the transverse plane
  - Varus and valgus rotation in the coronal plane
- The ankle is as maintenance free as possible
- The ankle is able to store and return energy during the gait cycle

vi Calculation on the basis of the disability grant minus the price of the prototype so far (R345) minus an amount to improve the socket (R700)

## **AHP** of Requirements

To concretize which requirements are important for each stakeholder the AHP-method is used. Only the most important stakeholders are taken into consideration, which are user, families or caregiver, prosthetists and CoPP. The requirements are put in categories for the AHP. The categories are: build, durability, use, safety and price. These categories are compared from the view of each stakeholder. The results of each stakeholder are compared with each other with help from the AHP-calculator<sup>27</sup>. This calculator gives a percentage of importance to each category for every stakeholder (see *figure 8 up to 11*).

#### User

For the user the safety is the most important. If they purchase the prosthesis, the safety has to be ensured. The people with a disability should not get injured by the prosthesis. Another important aspect is the price. People living in rural areas are often living in poverty. If they are not able to purchase the prosthesis, the prosthesis loses its purpose. Besides the safety and price, the use, durability and build requirements are (in that order) also important. For the user the prosthesis needs to be able to be used. Furthermore, the user will put more effort in building the prosthesis, if it will be more durable, so the durability is slightly more important. Most important is that the difficulty in building the prosthesis and collecting the materials are in balance with the durability of the prosthesis.

Priorities			Decision I	Matrix		•							
		e resulting ur pairwise	_		criteria	The resultir		s are	base	d on t	the p	rincip	al eigenvec
	C	ategory	Priority	Rank				1	2	3	4	5	
	1	Build	4.4%	5			1	1	0.25	0.20	0.17	0.20	
	2	Durability	11.0%	4			2	4.00	1	0.50	0.33	0.25	
	3	Use	16.9%	3			3	5.00	2.00	1	0.33	0.50	
	4	Safety	39.5%	1			4	6.00	3.00	3.00	1	2.00	
	5	Price	28.3%	2			5	5.00	4.00	2.00	0.50	1	
		omparison <b>y Ratio CR</b>				Principal Eigenvec	0				delta	a = 2.2	2E-9

*Figure 8 – AHP results for the user* 

#### Families/Caregivers

For the families and caregivers, the safety is the most important. They do not want the person to be harmed by the prosthesis, because it results in having to take more care of them. The next important aspect is the price. They do not have a lot of money and cannot afford expensive health care, because that mean they cannot afford another important need, such as food. The caregiver also finds it important that the prosthesis works. This would mean the patients can take care of themselves more and both, the family and the patient, are able to work more. For the family the durability and build requirements are less important.

Priorities



Figure 9 – AHP results for the families and caregivers

#### Prosthetist

For the prosthetist the safety is also the most important feature. If the prosthesis is safe the prosthetist can recommend it as a temporary option until he can deliver the real prosthesis. Besides safety, the durability is very important. If the temporary prosthesis is durable, the waiting period is not a big problem anymore and it results in less urgent work for the prosthetist. The prosthetist also would like the temporary prosthesis to be easy to build. If his patients can build it themselves or he can do it very quickly, it will also result in less work for him and happier patients. The price is of course also important, because otherwise his patients will not be able to purchase it. The use is less important for the prosthetist, since it is a temporary solution and they will receive a proper prosthesis.

#### **Priorities Decision Matrix** The resulting weights are based on the principal eigenvector of These are the resulting weights for the criteria based on your pairwise comparisons the decision matrix Category Priority Rank Build 15.9% 3 1 1 0.50 3.00 0.25 2.00 2 Durability 25.4% 2 2.00 1 3.00 0.50 3.00 3 7.7% Use 3 0.33 0.33 1 0.33 0.50 Safety 40.2% 4 4.00 2.00 3.00 1 3.00 Price 10.7% 5 0.50 0.33 2.00 0.33 1 Number of comparisons = 10 Principal eigen value = 5.223 Consistency Ratio CR = 5.0% Eigenvector solution: 5 iterations, delta = 7.2E-8

Figure 10 – AHP results for the prosthetist

#### CoPP

The CoPP also has safety as highest requirement. This has to be ensured before the prosthesis can be made available. Their next priority is the use of the prosthesis. The ultimate goal is for people with a disability living in rural areas to be able to fulfil their everyday tasks. This can only be reality if the prosthesis works adequate. The price is also of importance. If the prosthesis is not affordable, there will not be a market for it. Preferably, the prosthesis also meets the durability and build requirements, but they are less important. The prosthesis should however bridge the largest part of the waiting period. Collecting of the materials and building the prosthesis can be done by the prosthetist or another trained person, as long as it does not become too difficult and it can be done in South Africa.

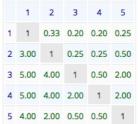
Priorities

Decision Matrix

These are the resulting weights for the criteria based on your pairwise comparisons

Category		Priority	Rank	
1	Build	5.1%	5	
2	Durability	9.9%	4	
3	Use	28.9%	2	
4	Safety	38.3%	1	
5	Price	17.8%	3	

The resulting weights are based on the principal eigenvector of the decision matrix  $% \left\{ \mathbf{r}_{i}^{\mathbf{r}}\right\} =\mathbf{r}_{i}^{\mathbf{r}}$ 



Number of comparisons = 10 **Consistency Ratio CR** = 3.2%

Figure 11 – AHP results for CoPP

Principal eigen value = 5.146 Eigenvector solution: 5 iterations, delta = 2.0E-8

## Function analysis

The ankle and foot are very important parts of the prosthesis. The ankle/foot-complex makes it possible to walk and stand. The core function of the ankle/foot-complex is that it has to attach the foot to the leg and ensure stability, midstance and lateral.

In a human ankle a gait cycle is performed. Performing an adequate gait cycle is necessary to walk comfortably and to transfer the power of the body on the leg on to the ground adequately. If people are unable to perform any part of the gait cycle, it will result in hip problems. However, performing a perfect gait cycle is hard for a prosthetic ankle. For a prosthetic foot the most important aspect is to ensure stability. To understand the ankle, a function analysis of a perfect prosthetic ankle or human ankle and the function analysis of a basic ankle are performed.

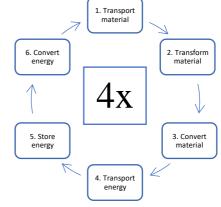
### 1.1 An ideal ankle: the gait cycle

The gait cycle has two main parts: the stance phase and the swing phase. The stance phase is the part where the foot is on the ground. Most of the movement in the ankle is done in this part. The swing phase is the part where the foot is 'swinging' in the air<sup>23</sup>.

The stance phase has different parts where different movements are made. The first part is the 'heel strike', from when the heel touches the ground until the whole foot is on the ground. A mobility in the upper side of the ankle and foot is necessary in this part. The next part is the 'flatfoot', which consists of an early and late stage. During the early flatfoot the body's centre of gravity transfers over the front of the foot and the shock is absorbed. During the late flatfoot the body is in a neutral position and the foot is about to be lift of the ground. In this stage the foot changes from a flexible shock absorber to a rigid lever that can move the body forward. After the flatfoot the 'heel rise' takes place. This is the stage where the heel is lift of the ground. The forces that go through the foot in this stage can be two times a person's body weight. During running even five times the body weight goes through the foot. The last phase is the 'toe off'. This is when the toes leave the ground. This is also the start of the swing phase<sup>23</sup>. The gait cycle has a constant storage and transportation of energy, enabling a person to walk.

Within the gait cycle every phase repeats a certain pattern. To complete the static phase of the gait cycle, this cycle has to be performed four times.

- 1. Transport material
- 2. Transform material
- 3. Convert material
- 4. Transport energy
- 5. Store energy
- 6. Convert energy



*Figure 12 – Scheme of the gait cycle* 

#### 1.2 The prosthetic ankle

A perfect gait cycle cannot be made by a simple prosthetic ankle. The main function of the ankle is to attach the foot to the leg. Furthermore, the ankle has to ensure stability and withstand the forces projected on the ankle. These aspects are taken into consideration to make an adequate functional scheme.

The function analysis consists of two parts. The first part concerns the function of connecting the foot to the leg. The second part represents the function of the ankle in a person standing and the ankle offering stability.

In the first part the ankle provides a transportation of the material of the foot to transform slightly and fit on the material of the leg. This material is stored and transported again towards the leg. This way the leg is attached to the ankle. Then the material is converted to information for the body. This information is needed to be able to stand. The information is transformed (or translated) and converted to energy. This energy is needed to transport the forces projected on the leg, ankle and foot and back. This transport of energy makes it possible to stand and withstand the forces caused by standing. Finally, the energy is converted to a transport of material, which ensures stability in the rest of the body and transfers the power to the rest of the body.

#### Connecting foot to leg:

Transport material material of the foot transported toward the leg
 Transform material material transformed to fit the leg
 Store material material fixated
 Transport material material of the leg transported toward the foot

#### Stability and power transfer

8. Transport material

Convert material material converted to information for the body
 Transport information
 Transform information
 Convert information
 Transport energy material converted to information for the body
 action of the body/ankle
 power transport for stability

6. Transform energy converting energy to stability of material7. Convert energy

power transfer from foot to ankle to leg to the body

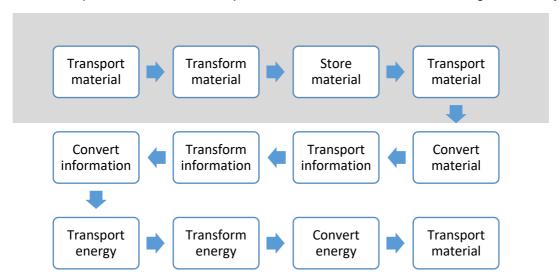


Figure 13 – Scheme of the function of the prosthetic ankle

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