university of groningen / faculty of science and engineering

Development of an interim prosthesis for use in rural South Africa: A problem analysis

Bachelor thesis BME –
University of Groningen

Author:
R.J.C. de Koster
S2968746

Date:
22 March 2018

First supervisor:
G.J. Verkerke

Second supervisor:
L. Ennion

Thesis index

Background: global disability 2

Problem definition: South Africa's disability 2

Cause-effect diagram 4

Stakeholder overview 5

Goals: South Africa's disability 6

Cause-effect diagram 6

Problem definition: Interim prosthesis 7

Cause-effect diagram 8

Goals: interim prosthesis 8

Cause-effect diagram 8

Design assignment: Interim prosthesis socket 9

Demarcation 9

Requirements and wishes of the interim prosthesis socket 10

Analytic hierarchy process 11

Function analysis: interim prosthesis socket 13

Conclusion 14

References 15

The images on the front page were taken from the report "Establishing the feasibility of a low-cost, interim, trans-tibial prosthesis prototype: A case-series"[11] and the University of Groningen website.

Background: global disability

The term "disability" has been defined by The International Classification of Functioning, Disability and Health (ICF) to be an umbrella term for activity limitations, participation restrictions and impairments which limit the interaction between individuals with a health condition and their environmental and personal factors.[1] About 10 percent of the world's population lives with a disability of some kind per estimate of the World Health Organisation (WHO), which is about 650 million people.[2] Eighty percent of these people live in low-income countries, of which only three percent have access to the required rehabilitation services.[2]

An important indicator used to determine the availability of rehabilitation for people with disabilities, is the amount of health professionals that can provide rehabilitation services. These professionals can range from rehabilitation specialists, to any health professional able to deliver some kind of rehabilitation service. In the last decade, an increase in the prevalence of health conditions causing disabilities where rehabilitation is useful has been recorded by the WHO[3] to be nearly 183 million (23 percent) worldwide. As a result the amount of years lived with disability (YLDs, a measurement for disease burden developed by the World Health Organisation) caused by these conditions has risen by more than 17 million over the same period of time.[3] Another cause of this rise was the aging of the population. Because of this rapid rise in YLDs the world is currently experiencing an enormous shortage of rehabilitation practitioners, which especially comes to expression in low- and lower-middle-income countries. The shortage in these countries is quantifiable as less than 10 skilled rehabilitation practitioners per one million population, or more specifically, 890 general health professionals per million population (African region).[3] For reference, the amount of health professionals needed to achieve an adequate coverage for general healthcare intervention, determined by the WHO[3], is 2,300 per million population. To make matters worse, the world is currently experiencing a surge in diabetes prevalence, which is set to double from 285 million in 2010 to 592 million in 2035 and which brings an increased global amputation rate with it.[4] When the amputation rates gets higher, the shortage of rehabilitation professionals worsens. The WHO estimates that 0.5 percent of the total population of developing countries needs a prosthesis and that 180,000 rehabilitation professionals are required to help 30 million people acquire one.[5]

Being disabled in a low- or lower-middle-income country usually presents more barriers than just rehabilitation availability alone. Not being able to afford healthcare often is a bigger hurdle for people with disabilities than for the general population. It prevents around 51-53 percent of disabled people from receiving rehabilitation, compared to about 33 percent of people without disabilities being unable to receive general healthcare.[6] Other barriers may be physical barriers such as hospital entrances not being accessible for people with disabilities, and inadequate skill of the health workers available. The costs of rehabilitation and availability of rehabilitation professionals are seen as the main huddles to overcome the disability problem.[6]

Problem definition: South Africa's disability

Manyema[4] states that the sub-Saharan African region is currently experiencing a surge in type 2 diabetes prevalence, with South Africa at the forefront. Caused mainly by the increase in obesity as a result of the enormous supply of cheap sugar-sweetened beverages, the diabetes rates in adults went up from about 5.5 percent in 2000 to nine percent in 2009.[4] These kind of drinks are popular because of their sweetness, huge availability and relatively low price. In 2009 more than 73,000 YLDs and close to 2,000 amputations could be attributed to diabetes.[4] Diabetes is tenably putting a strain on South Africa's healthcare. Statistics South Africa[7] determined South Africa's national disability prevalence rate to be 7.5 percent, with a higher prevalence among females (8.3 percent) compared to males (6.5

percent). Disability also becomes more frequent at higher ages, with over 50 percent of the 85+ population having a disability.[7]

Though South Africa officially qualifies as an upper-middle-income country, it has an enormous inequality problem.[8] The poorest 20 percent of its population controls three percent of South Africa's total income, while the richest 20 percent controls 65 percent.[9] This often means that even if a person with a low income is physically able to receive healthcare, they aren't able to afford it. An even bigger problem that comes forward from this is a vicious 'circle of poverty' caused by disability, preventing a person, and thus social communities as a whole, from experiencing economic growth.

This circle starts by having a community with very little average expendable income (meaning a poor macroeconomy on community scale) containing a fairly large number of people with functional disabilities. They won't be able to receive a prosthetic, nonetheless rehabilitation therapy, so any development in recovering function of their missing limb(s) will not be possible. Therefore, they can't take an active part in the community, i.e. have a job or do volunteer work, which makes it impossible for them to receive a prosthetic and escape poverty. As a result, this prevents the entire community from undergoing economic growth and so the poor will remain poor, thus closing the circle.[2]

Receiving a prosthetic has proven to be crucial for the quality of life of people with disabilities, not only because it is a means to take a more active part in their community, but also a way to give a boost to psychological function and to how they are perceived socio-culturally. Cultural stigmatisation of people with a disability is very common in South Africa. The cause of a disability is often believed to be of divine in origin. The South African Department of Health conducted a survey called the 'Disability Survey' which showed that three percent of its population believed 'bewitchment' to be the cause of their disability.[10] This cultural attitude towards disability often leads to stereotyping and discrimination in daily life. The stigma resting on disability is of such prominence in some rural communities that it can even actively prevent people with disabilities form accessing or adhering to rehabilitation.[10] They often are refused public transport, like taxis, since the driver believes the person to be cursed or otherwise punished for a sin they are believed to have committed. Therefore, if a patient living in a rural area with no nearby health facilities doesn't own a car or is unable to drive due to their disability, reaching the hospital, and thus receiving rehabilitation therapy becomes impossible.

Due to cultural stigmatisation, people with disabilities are seen as less valuable for their communities or household if they cannot contribute to it. This became even more apparent when the disabled person received no disability grant.[10] With a maximum of 1,600 South African Rand (135 USD), the disability grant inadequately covers the cost of a prosthesis and rehabilitation. For example, the cost of a below-knee prosthesis ranges from R6,000 to R22,000 (500 USD to 1900 USD) with refit costs of R800 to R5,000 (70 USD to 430 USD) and prosthetic accessories costing R80 to R400 (7 USD to 35 USD).[11] Rehabilitation therapists reported that the disability grant in some cases even became a barrier to rehabilitation, as patients would lose their grant if they improved functionally or received a prosthesis. Due to the poverty and lack of employment opportunities in rural settings, entire households rely on a single disability grant as their only source of income.[12]

Even if someone would be able to cover the cost of a prosthetic and rehabilitation, receiving either one would still be extremely challenging in most cases. As mentioned in the background, low- and lower-middle-income countries have a skilled rehabilitation practitioner density of less than 10 per million population. South Africa, whilst being an upper-middle-income country, is no exception as a result of its inequality problem and culture. This shortage of skilled rehabilitation practitioners becomes even more alarming when their spread over South Africa is taken into account. Most practitioners concentrate in the richer urban areas, leaving the poorer rural areas largely uncovered.[5]

The practitioner shortage, the earlier mentioned rise in diabetes prevalence and the aging of the general population has caused the average waiting period for a prosthesis and rehabilitation to become three to six years.[13] This is problematic given the fact that the first period after amputation is crucial for rehabilitation purposes, since muscle degeneration won't have happened yet. The benefits of early mobilisation after amputation are well documented.[14] Ideally, rehabilitation with a well-fitting prosthetic should be started as soon as possible after the amputation has taken place. Unfortunately, this is currently not possible for most patients in South Africa, due to the earlier mentioned waiting list and high costs.

Cause-effect diagram: South Africa's disability

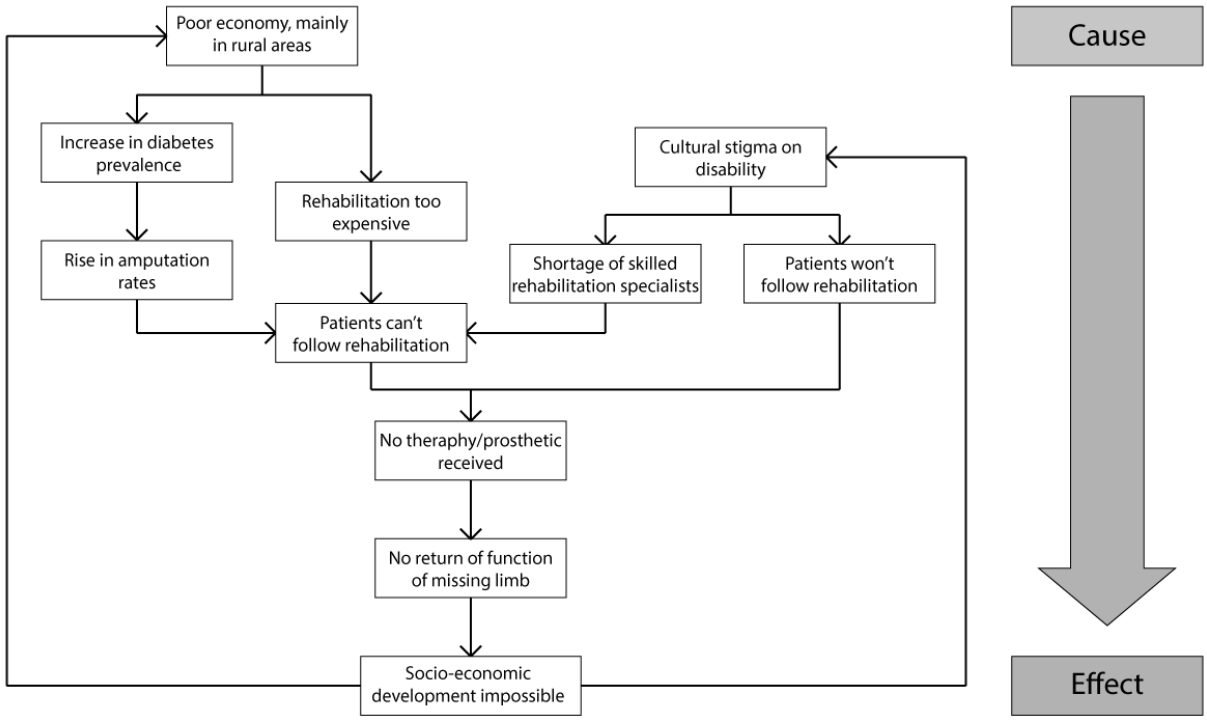

Figure 1. Cause-effect diagram displaying a fast overview of the disability problem in South Africa.

Figure 1 presents a clear overview of the problem at hand, focusing on the resulting 'circle of poverty' as mentioned in the problem definition. This focus has been chosen since the 'circle of poverty' presents the biggest impact on (rural) South Africa (both on communal and national levels), as a result of the disability prevalence problem. It should be noted that 'Cultural stigma on disability' encompasses both religion and the perception of people with disabilities as less valuable, as the origin of the stigma on disability. 'Patients can't follow rehabilitation' represents both the inability to afford rehabilitation and the long waiting list of three to six years caused by both the rise in amputation rates and the shortage of skilled rehabilitation specialists.

Stakeholder overview

Stakeholder	**Characteristics**	**Expectations for solution**	**Difficulties contributing to problem**	**Influence on project**
Patient	Experienced amputation, misses limb and its function. Usually unable to contribute to society and gets discriminated because of it.	Better availability of rehabilitation therapy and prosthetics, both at lower costs than currently normal.	Unwilling to follow therapy due to cultural stigma on disability. Often living in hard to reach rural areas.	Presents problems with multiple hard to change causes. Best aspects for project are the costs and the availability.
Patient's household (family)	Caretakers of the patient. Have to support a person that usually won't be able to contribute to the household.	Decreased disability burdening for both patient and household.	Often located in hard to reach rural areas with no access to transportation for the patient.	Household must be willing to offer even more help to patient during rehabilitation. Project must be regarded as a good solution.
Rehabilitation therapist	Is able to give amputation patient rehabilitation therapy and prosthetic.	Helping a willing patient in retrieving function of missing limb. Being able to help more patients than currently possible.	Far too few to support entire South African population. Often concentrated in urban areas while needed in rural areas.	Project must create better availability by reducing workload per patient. (reducing amount of patient visits while keeping same quality)
South African culture	Stigmatizes disability from a religious and participation standpoint.	When taking into account only the participation aspect, contribution to society by people with disabilities is expected.	Unforgiving towards disability. (religion) Sees people with disabilities as less valuable to society. (participation)	Project must lift away stigma by hiding disability/ making disability acceptable for SA culture.
Academic institutions (mainly UWC & UG)	Want to find a solution to the cost and availability problem by using the skills of professors and students.	A well executable solution to the cost and availability aspects of South Africa's disability problem.	far away from the problem. No experience with being disabled while trying to better disability situation.	Have to put in effort to better understand the problem and its causes.

Table 1. A stakeholder overview of the problem.

Most stakeholders have already been identified in the problem definition. However, a new one has been introduced in the stakeholder overview.

Academic institutions: These institutions are universities actively seeking a solution for the disability problem in South Africa. Because most causes are out of scope for a university to handle, like the inadequate disability grant determined by the government, their main focus lies on solving the cost and availability (waiting list) aspects of the disability problem. The solution targets South Africa specifically, since the University of the Western Cape (UWC) originally presented and initially handled the problem. The University of Groningen (UG) also puts focus on South Africa since it collaborates with the UWC for the project. This focus should not present a problem, as a well thought-out and well-handled solution should be applicable worldwide to most secluded areas.

Goals: South Africa's disability

Multiple inherently different causes can be seen as the root of South Africa's disability problem, which makes finding an all-embracing solution difficult. Many of these problems can't be solved by an academic institution on its own and would need intervention of the South African government. Since the project is unable to involve the government, these kind of solutions were determined to be out of scope. For example, the problem of rehabilitation costs being too high could be easily solved by raising the disability grant, but this is impossible for an academic institution or organisation.

Similarly, solutions that involved changing the cultural perception of people with disabilities were also deemed impossible. Instead, the focus is on solutions that were considered more acceptable to South African Culture. The cultural stigma could be diminished by making prosthetics more cosmetically and socially appropriate. Examples of this would be the usage of apt materials (e.g. not using cow leather, if this problem had laid focus on India) and the prosthetics making cultural activities possible (e.g. kneeling during prayer). This would also mean patients will be more willing to follow rehabilitation, which in turn could attract people to be educated as a rehabilitation specialist.

Decreasing diabetes prevalence and making rehabilitation more affordable are two hard to solve problems with the same root. If it were possible to work out these problems, it may prove to be an escape for the 'circle of poverty' which in turn may provide a better economy. However, this also means the solution would be an upwards spiral. This means a starting point needs to be decided. In line with the problem definition, the best solution would be one which solves both the cost and availability aspect of the problem. Luckily, The Community of Prosthetic Practice (CoPP) has started a project in order to address the challenge of prosthetic staff shortages, poverty and challenges with accessing rehabilitation services. The CoPP is an international consortium of healthcare professionals trying to address the shortage of prosthetic services in rural areas. They built a low/cost, interim trans/tibial prosthetic prototype from locally available materials that will be affordable and available to all, while the patient receives a prosthetic and retrieves the functionality of the lower leg.

Cause-effect diagram goals: South Africa's disability

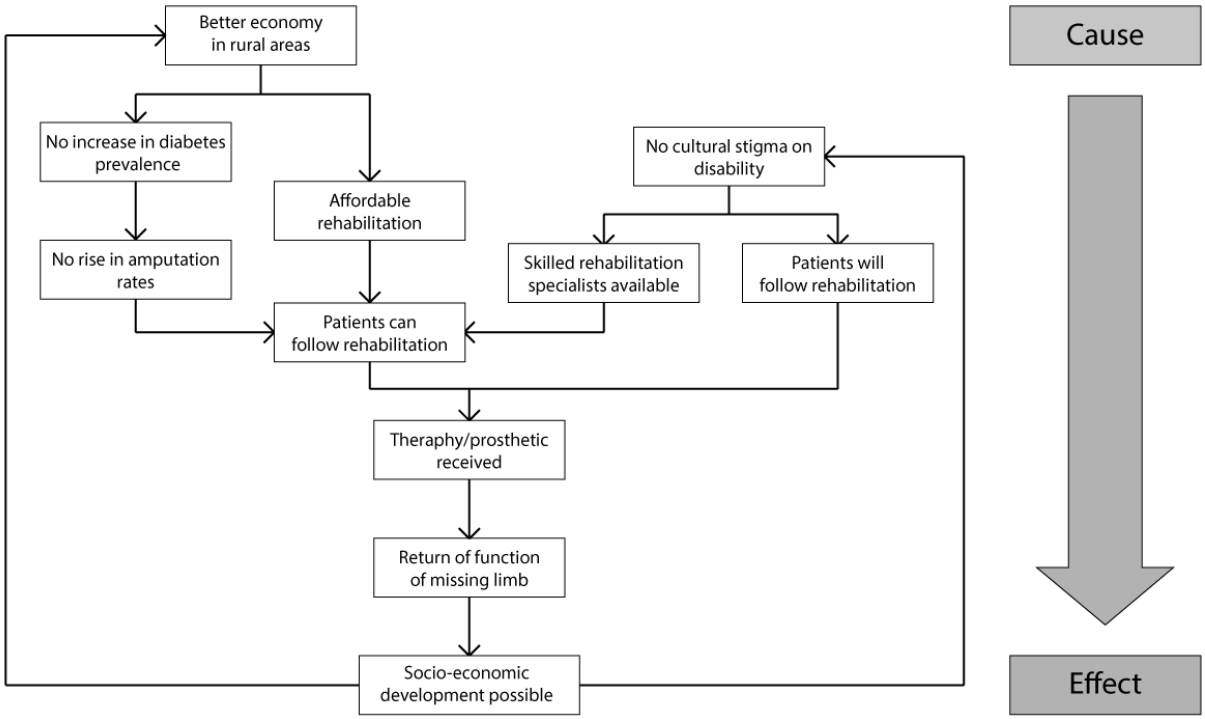

Figure 2. Cause-effect diagram displaying a fast overview of with goals regarding the disability problem in South Africa.

Figure 2 presents an overview of the desired effects possible solutions can have. Many of the points will seem unrealistic, such as “No increase in diabetes prevalence”. Thus this binary approach does not display the expected outcome, but a perfect outcome if a perfect solution was somehow implemented.

Problem definition: Interim prosthesis

To counter South Africa’s disability problem, Dr. Liezel Ennion and the Community of Prosthetic Practice developed a lower leg interim prosthetic prototype build almost entirely from hardware store components (project approved by the UWC Ethics committee, registration number BM17/2/4). The idea of this lower limb prosthetic satisfied both the cost and availability aspects of the problem, since people would be able to build it themselves after a visit to the hardware store and hospital pharmacy. Although far from perfect this prototype would enable the patient a K1-level of domestic ambulation (K0 = no ambulation, K4= near perfect ambulation), meaning he/she is able to use the prosthetic to ambulate on levelled surfaces at a fixed cadence.[15] Not needing a rehabilitation practitioner for the interim prosthetic, patients no longer need to wait three to six years to recover mobility. This also means that they will remain mobile while waiting for a genuine prosthetic. The costs of the prototype were significantly lower than for a genuine prosthetic, with R344.72 (29.63 USD) for the prototype compared to a range of R2,000 to R6,000.

Figure 3. The latest interim prosthesis prototype.[11]

The prototype uses Delta-Lite Plus casting tape from a hospital pharmacy as the prosthetic’s socket. This product is widely used to put a cast around broken bones. Its quick and easy way of application makes it very suitable for the interim prosthetic’s socket. A cut-up belt together with the cast functions as the entire socket. The interim prosthetic’s pylon exists out of PVC plumbing tube cut at the right length for the patient and uses a sponge to make interaction with the stump more comfortable. For the ankle, the same PVC tube is used together with a PVC T-junction. This ‘foot’ then gets placed inside a shoe, while the shoe is stuffed with newspaper to create a tight fit. To strengthen the ankle, expanding polyurethane foam is sprayed into the pipe. After connecting all pieces with PVC cement, the prosthetic is ready for use. A more detailed build guide is available as appendix F in the report: “Establishing the feasibility of a low-cost, interim, trans-tibial prosthesis prototype: A case-series”.[11]

For the same report, three lower limb amputees (all K4 level of domestic ambulation) volunteered as participants for a Timed-Up-and-Go test (TUG)[16], the Orthotics and Prosthetics Users Survey (OPUS)[17], a socket comfort scoring (SCS)[18] and multiple functional activity observations while wearing the interim prosthetic prototype. Individual changes were made to the prototypes following participant feedback. The tests revealed that the prototype’s socket is regarded as uncomfortable. However, the last participant stated that he would fully use the interim prosthetic, would his own prosthetic be unavailable. While this participant underwent the tests, the prototype’s ankle broke after nine meters of ambulation since the expanding polyurethane foam was missing. It had gone old between participants and was removed. The tests revealed three main problems: the uncomfortable socket limiting ambulation, the socket losing its good fit and the weak ankle bringing down the durability of the entire interim prosthetic.

Cause-effect diagram: interim prosthesis

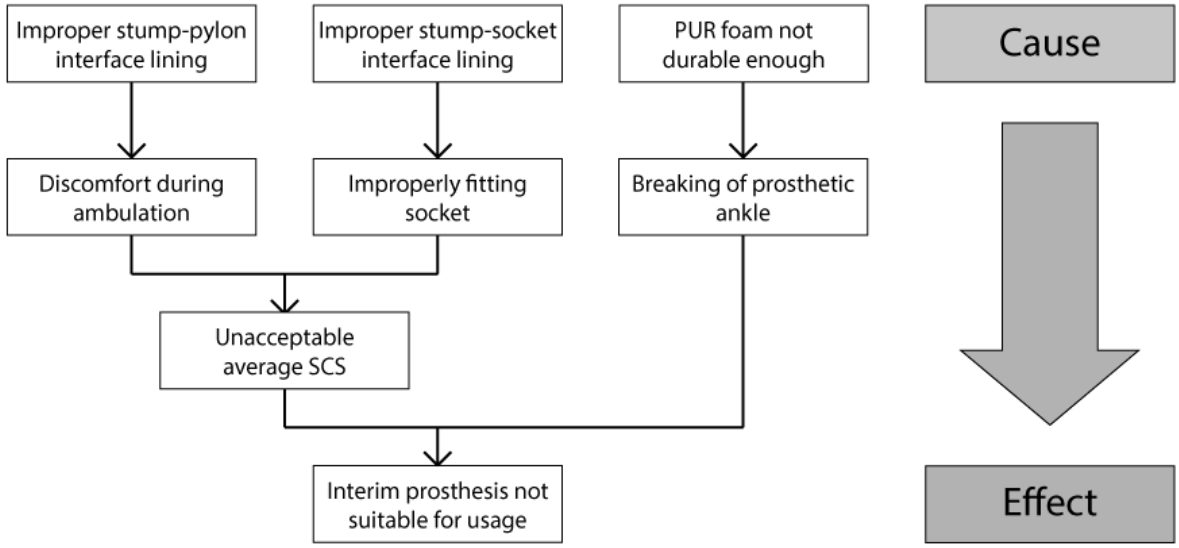

Figure 4. Cause-effect diagram displaying an overview of the problems regarding the prototype interim prosthesis.

Figure 4 gives an overview of problems experienced from the latest prototype interim prosthesis. The average Socket Comfort Score the participants gave to the prototype prosthesis was less than half of the acceptable score of 7.23/10. This is a good indicator of how comfortable the prosthesis is, as 7.23/10 is the average SCS of a person with a genuine lower leg prosthesis.[19] Discomfort of the socket is caused by the stump-pylon lining and stump-socket lining being inadequate. Currently, the stump-pylon lining does not ease the pressure of the stump on the sharp PVC pylon and the stump-socket lining does not account for the variable form of the stump. Also, the PUR foam used for the ankle is not durable enough to provide strength for a long amount of time, which means the PUR foam no longer has any function for the prosthesis. This causes the ankle to break after a while.

Goals: Interim prosthesis

Now that the problems are clear, the solutions that have to be found for the stump-pylon lining, stump-socket lining and ankle problems should be easily determinable. A solution for the stump-pylon lining has to be found that provides the prosthesis with a proper structural integrity, which simultaneously eases the pressure on the stump caused by the patient's bodyweight. The stump-socket lining needs to be redesigned to account for deformation of the stump during ambulation, to assure a proper fit. These redesigns are considered acceptable if they reach at least an acceptable average SCS of 7.23/10.

As for the ankle, a way to improve the durability of PUR foam has to be found, or another more durable material must be found to strengthen it. With a new type of ankle the prosthesis as a whole should be a lot more durable, to the point of it being suitable for daily usage.

Cause-effect diagram goals: interim prosthesis

Figure 5 on the next page gives an overview with binary approach that does not display the expected outcome, but a perfect outcome if a perfect solution was somehow implemented.

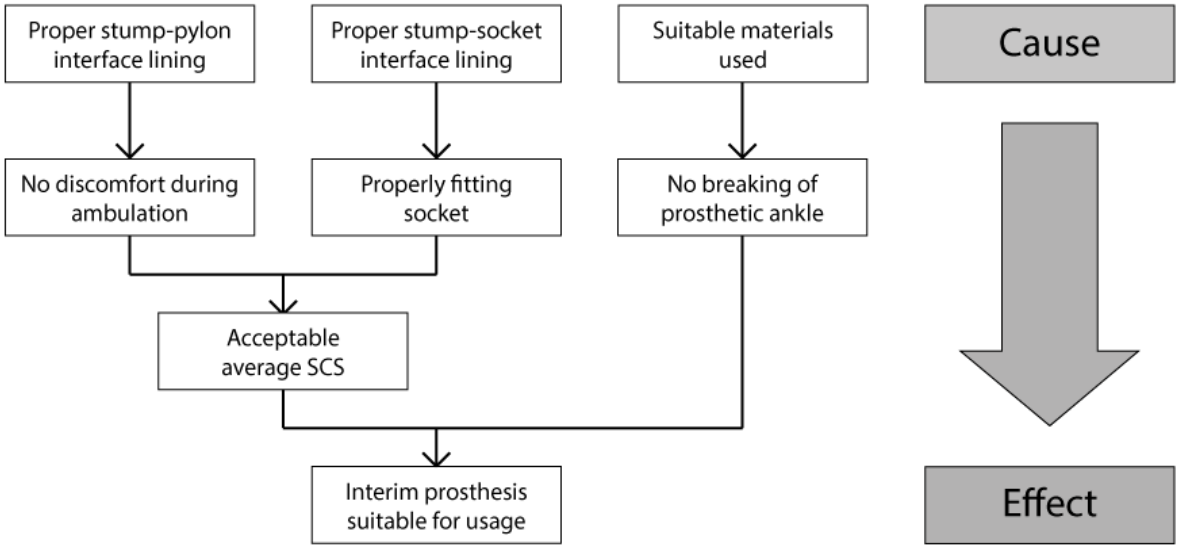

Figure 5. Cause-effect diagram displaying an overview of the goals regarding the interim prosthesis prototype.

Design assignment: Interim prosthesis socket

Thus far, this thesis provided an insight into South Africa's disability problem, why Dr. Ennion and the CoPP are designing an interim prosthesis and the current problems concerning the interim prosthesis. From now on, the thesis will focus specifically on designing solutions for the problems the current socket design has.

To improve the current socket, multiple approaches could be taken:

1. One possibility is to remove to sponge as a part of the socket and find a new material to use as lining in the Delta-Lite cast. This new material would then be used to cushion the stump from the pylon, while also guaranteeing a tight fit.
2. Another possibility is to remove the sponge and use multiple different materials to solve the discomfort and fitting problem. This could also be implemented as a new material for a more comfortable lining in combination with a fixation system. The Delta-Lite cast would still be used to structure the socket.
3. A more rigorous approach is to redesign the socket entirely, removing the Delta-Lite cast from the prosthetics components. This approach is less desirable since the Delta-Lite cast has proven to be a very sturdy and easily applicable component.

All of these approaches will be considered during the design process, so the broad strategy could be stated as "replacing the sponge for a more suitable material". To guide the project to a good outcome, special attention will be paid to the costs of the designs, the feasibility of the designs, chances of success of the designs and how easily available the components for the designs are.

Demarcation

Of course, the interim prosthesis would ideally be usable in every environment. However, for this project a line has to be drawn to guarantee its feasibility. The prosthesis' socket should keep a good firm grip on the patient's stump while walking on a regular street or hard dirt path. This means the socket won't slip of the patient's stump on these kinds of roads, rendering the prosthesis useless. Usability on sand paths would be ideal, but not strictly necessary for the project to be deemed a success. Muddy roads and wet stone paths were decided to be out of scope for the project. These kind of roads will be problematic because suction created by mud presents an even harder barrier to good

socket grip and wet stone paths may become slippery. If a patient slips while walking the prosthesis might be propelled away from them, leaving them largely immovable. The amount of grip the socket must have to prevent this propulsion is considered to be too large for this initial design.

After the new socket has been implemented, the interim prosthesis should still be usable for normal ambulation, standing up from a sitting position and walking up and down stairs. Comfortability of the socket should at least be scored as is required (in "requirements and wishes") for all of these activities. The new socket should also still be buildable for everyone in need of the interim prosthesis.

Requirements and wishes of the interim prosthesis socket

To be able to say if the interim prosthesis has reached its goal, a set of requirements and wishes has to be determined. If the new socket refrains the interim prosthesis from one of these requirements, it will be deemed unsuitable. Focus has been put on requirements of the socket and total prosthesis, while also including the most important ankle requirements. The requirements of the prosthesis are general requirements, needing to be fulfilled by both the socket and the ankle.

Requirements that were deemed necessary for the project (like all components must be available from a hardware store) were taken over from the report[11] on the first interim prosthesis prototype. If no source is mentioned, the requirement originates from the report[11] or from Dr. Ennion herself. New requirements specific to the problems that are yet to be solved were also added.

Requirements prosthesis (general):

Build requirements:

- The components for the prosthesis must be easily available, e.g. at a hardware store.
- The costs should be completely coverable by the South African disability grant of R1,600 (135 USD).
- Building of the prosthesis shouldn't involve electric or specialized tools.

Visual requirements:

- The prosthesis should resemble a "normal" leg as close as possible, i.e. invisible under trousers.

Strength requirements:

- The prosthesis should be able to handle up to 130 Nm of torque from knee to heel in the sagittal plane.
- The prosthesis should weigh no more than 4 Kg. (Average African body weight: 60.7 Kg,[20] average body weight percentage of the lower leg and foot: 6.43 percent.[21])
- The lifetime of the prosthesis should be at least 2 years.

Use requirements:

- Should return the patient to at least a K1-level of domestic ambulation.

Safety requirements:

- Wearing and using the prosthesis may bring the patient absolutely no harm whatsoever.

Requirements socket:

Strength requirements:

- Should assure a good fit for at least 2 years.

Use requirements:

- Should receive an average Socket Comfort Score of at least 7.23/10.[19]
- Should fit a knee circumference range of 35.0 cm to 47.8 cm. Average knee circumference of 24 patients determined to be 41.4 (±3.2) cm.[22]

Requirements ankle:

Strength requirements:

- The ankle should be able to withstand at least 24.95 Nm of torque.[23] This is comparable to the average tensile force of a human ankle during a normal gait cycle.
- The lifetime of the ankle has to be at least 2 years.

Wishes:

Build wishes:

- Keep prosthesis costs as low as possible.

Use wishes:

- Provide the patient with a K4-level of ambulation.
- Socket should be very comfortable to wear.

Strength wishes:

- The prosthesis should be as strong as a real human leg.

Analytic hierarchy process

To decide which requirements are most important, the analytic hierarchy process[24] (AHP) is used. This process calculates a weight factor for each requirement group per relevant stakeholder, taking into account what they deem most important. For example, what the prosthetic looks like will be more important to the patient than to the rehabilitation specialist. The AHP has been executed for the combination of socket and general requirements, ignoring the ankle requirements as they are mostly irrelevant to the socket design.

Patient

It is important that the patients are able to build the prosthesis themselves. A nearly unnoticeable prosthesis would have their preference. Obviously the usability and comfort will be very important to them too. The strength of the prosthesis would be less important to them, as they will find it good enough when it works. Not wanting to wait for three to six years, patients will be eager to try the interim prosthesis. While doing so, they place the usability over the safety of the prosthesis.

	Building ease	Visual	Strength	Use	Safety
Building ease	1	5.00	6.00	0.50	7.00
Visual	0.20	1	3.00	0.33	3.00
Strength	0.17	0.33	1	0.20	2.00
Use	2.00	3.00	5.00	1	8.00
Safety	0.14	0.33	0.50	0.12	1
Priority	**0.357**	**0.125**	**0.063**	**0.413**	**0.042**

Table 2. Results of the analytic hierarchy process from the patient's point of view.

Patient's household

The household of a patient will find building ease less important, as they can help in building the prosthesis. The visual aspect of the prosthesis will be a bit less important to them as they won't directly experience any form of stigmatisation. Strength prioritisation will be comparable to the patient's. The usability will be prioritised as a better usability would mean the patient can contribute to the household more. A household will find the safety of the prosthesis more important than the patients themselves, because the household will want to prevent the patient from experiencing harm.

	Building ease	Visual	Strength	Use	Safety
Building ease	1	4.00	6.00	0.14	0.50
Visual	0.25	1	3.00	0.17	0.25
Strength	0.17	0.33	1	0.11	0.25
Use	7.00	6.00	9.00	1	3.00
Safety	2.00	4.00	4.00	0.33	1
Priority	**0.151**	**0.066**	**0.036**	**0.544**	**0.203**

Table 3. Results of the analytic hierarchy process from the patient's household's point of view.

Rehabilitation specialists

The interim prosthesis is a means to lighten the workload of the rehabilitation specialists, having the important aspect of being buildable by patients themselves. Because they see it as a purely interim prosthesis, they will prioritise the usability of the prosthesis a bit less than the patients will. Visibility will also be of lesser importance. Rehabilitation specialists are more knowledgeable on the minimal strengths required for the prosthesis, meaning they will probably give it a higher priority. Safety is of the highest concern for them, as their job encompasses keeping the patient from harm.

	Building ease	Visual	Strength	Use	Safety
Building ease	1	6.00	4.00	2.00	0.50
Visual	0.17	1	0.12	0.25	0.11
Strength	0.25	8.00	1	2.00	0.50
Use	0.50	4.00	0.50	1	0.25
Safety	2.00	9.00	2.00	4.00	1
Priority	**0.300**	**0.033**	**0.173**	**0.108**	**0.387**

Table 4. Results of the analytic hierarchy process from the rehabilitation specialist's point of view.

South African Culture

As a stakeholder, the South African culture is rather unsuitable for the AHP. Using the participation argument (see stakeholder overview) one could say that culture would prioritise usability. However, the other aspects aren't important to it, making it hard to rank them for the culture.

Academic institution

The academic institutions involved are trying to make an interim prosthesis for daily usage. This means the usage and strength of the prosthesis are the main priorities of these institutions. When trying to make the perfect interim prosthesis, they will have to balance out the priority of all the aspects.

	Building ease	Visual	Strength	Use	Safety
Building ease	1	3.00	1.00	1.00	0.33
Visual	0.33	1	0.50	0.33	0.33
Strength	1.00	2.00	1	0.50	0.50
Use	1.00	3.00	2.00	1	0.50
Safety	3.00	3.00	2.00	2.00	1
Priority	**0.178**	**0.080**	**0.153**	**0.220**	**0.368**

Table 5. Results of the analytic hierarchy process from the academic institutions' point of view.

General weight factor

By calculating the average of all stakeholder priorities, the general weight factor for each requirement aspect is retrieved. These weight factors will be used during (pre-) concept selection.

	Building ease	Visual	Strength	Use	Safety
Patient	0.357	0.125	0.063	0.413	0.042
Patient's household	0.151	0.066	0.036	0.544	0.203
Rehabilitation specialists	0.300	0.033	0.173	0.108	0.387
Academic institutions	0.178	0.080	0.153	0.220	0.368
Weight factor	**0.247**	**0.076**	**0.106**	**0.321**	**0.250**

Table 6. Average results of the analytic hierarchy process.

Function analysis: interim prosthesis socket

The socket of the interim prosthesis has three main functions: connecting the stump to the pylon, cushioning the stump from pylon and guaranteeing a good hold on the stump. These are dividable into the following sub-functions:

1. Introducing the stump into the socket, the socket forms to the stump for a good grip.
2. The socket now holds onto the stump tightly.
3. By moving the stump, the movement of the socket (and the entire prosthesis with it) can be controlled.
4. To perform an activity like walking, the prosthesis is moved while the socket holds on to the stump.
5. When the prosthesis makes contact with the ground again, after the swing-phase of ambulation, the socket (lining) dampens the impact force of the pylon directly on the stump.
6. The impact energy is conducted over a larger part of the stump, ensuring that pressure point won't develop upon impact. This part is mainly responsible for the comfortability of the socket. All the while, the socket must keep a good grip on the stump.
7. The stump is closely held by the socket, ensuring a good connection to the pylon.

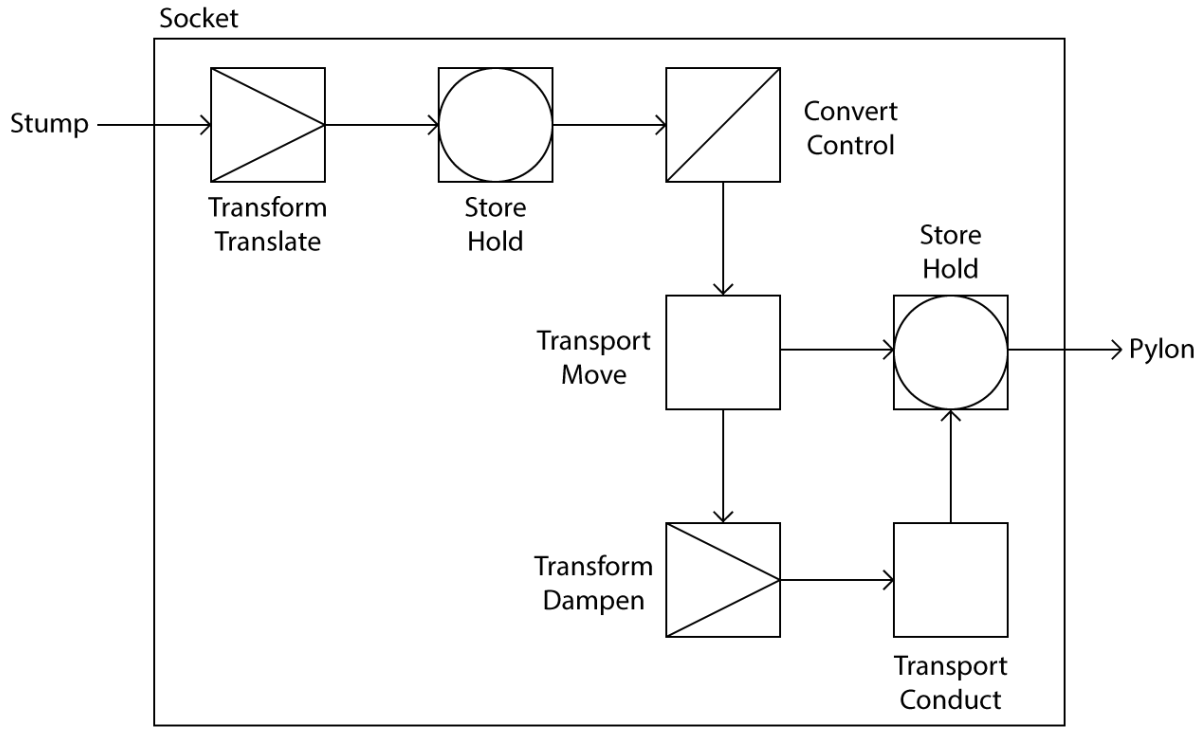

Figure 6. Function analysis of the socket of the interim prosthesis.

Conclusion

Enough insight into South Africa's disability problem and the current problems concerning the interim prosthesis has now been gained to properly start the first synthesis phase. During the analysis of the interim prosthesis the situations in which the prosthesis has to be usable was determined in the design assignment. Furthermore, a list of requirements and wishes has been drafted for the socket design. This list was then converted into weight factors using the AHP and the stakeholders identified in the problem definition. For the concept selection, the weight factors can now be used to determine if a concept fulfils the requirements. The usability of the prosthesis is considered to be most important, with safety in a second place. Lastly, a function analyses was done to determine the sub-functions of the interim prosthesis's socket.

References

1. The World Health Organisation (WHO). International Classification of Functioning, Disability and Health (ICF) [Internet]. Geneva: WHO; 2017 [cited 5 March 2018]. Available from: http://www.who.int/classifications/icf/en/.

2. Harkins CS, McGarry A, Buis A. Provision of prosthetic and orthotic services in low-income countries: A review of the literature. Prosthet Orthot Int. 2012 June; 37(5): 353–361. DOI: 10.1177/0309364612470963.

3. The World Health Organisation (WHO). The need to scale up rehabilitation [Internet]. Geneva: WHO; 2017 [cited 18 February 2018]. Available from: http://www.who.int/disabilities/care/NeedToScaleUpRehab.pdf.

4. Manyema M, Veerman JL, Chola L, Tugendhaft A, Labadarios D, Hofman K. Decreasing the Burden of Type 2 Diabetes in South Africa: The Impact of Taxing Sugar-Sweetened Beverages. PLoS ONE. 2015 Jan; 10(11):e0143050. DOI:10.1371/journal.pone.0143050. [Epub ahead of print]

5. The World Health Organisation (WHO). The World Health Report 2006 – working together for health [Internet]. Geneva: WHO; 2006 [cited 18 February 2018]. Available from: http://www.who.int/whr/2006/en/.

6. The World Health Organisation (WHO). Disability and health: fact sheet [Internet]. WHO; 2018 [cited 18 February 2018]. Available from: http://www.who.int/mediacentre/factsheets/fs352/en/.

7. Statistics South Africa. Stats SA profiles persons with disabilities [Internet]. Statistics South Africa: 2014 [cited 19 February 2018]. Available from : http://www.statssa.gov.za/?p=3180.

8. The World Bank. World Bank Country and Lending Groups [Internet]. The World Bank: Washington D.C.; 2018 [cited 18 February 2018]. Available from: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519.

9. The World Bank. The World Bank in South Africa [Internet]. The World Bank: Washington D.C.; 2017 [cited 18 February 2018]. Available from: http://www.worldbank.org/en/country/southafrica/overview.

10. Wegner L, Rhoda A. The influence of cultural beliefs on the utilisation of rehabilitation services in a rural South African context: Therapists' perspective. African Journal of Disability. 2015 Apr; 4(1): art. #128, 8 pages. DOI:http://dx.doi.org/10.4102/ajod.v4i1.128.

11. Ennion L, Burger NB, de Lange S, Louw LS, Robison CL, Singleton CC. Establishing the feasibility of a low-cost, interim, trans-tibial prosthesis prototype: A case-series. University of the Western Cape. 2017 Nov.

12. Ennion L, Johannesson AJ. A qualitative study of the challenges of providing pre-prosthetic rehabilitation in rural South Africa. Prosthet Orthot Int. 2017 feb; 1–8. DOI: 10.1177/0309364617698520.

13. Ennion L, Johannesson AJ, Rhoda A. The use of a direct manufacturing prosthetic socket system in a rural community in South Africa: A pilot study and lessons for future research. Prosthet Orthot Int. 2017 Oct; 41(5):455-462. doi: 10.1177/0309364616683982. [Epub ahead of print]

14. VanRoss ER, Johnson S, Abbot CA. Effects of Early Mobilization on Unhealed Dysvascular Transtibial Amputation Stumps: A Clinical Trial. Arch Phys Med Rehab. 2004 Oct; 90(4): 610-617. DOI: https://doi.org/10.1016/j.apmr.2008.10.026.

15. Bliss Mishler R. What are K Levels? [Internet]. Ottobock. 2017 [cited 27 February 2018]. Available from: https://www.ottobockus.com/therapy/resources-for-prosthetics/what-are-k-levels.html.

16. Schoppen T, Boonstra A, Groothoff JW, de Vries J, Göeken LN, Eisma WH. The Timed "up and go" test: reliability and validity in persons with unilateral lower limb amputation. Arch Phys Med Rehab. 1999 Jul; 80(7): 825-828. DOI: https://doi.org/10.1016/S0003-9993(99)90234-4.

17. Resnik L, Borgia M. Reliability of outcome measures for people with lower-limb amputations: distinguishing true change from statistical error. Phys Ther. 2011 Apr; 91(4):555-565. DOI: 10.2522/ptj.20100287.

18. Hanspal RS, Fisher K, Nieveen R. Prosthetic socket fit comfort score. Disabil Rehabil. 2003 Nov; 25(22):1278-1280. DOI:10.1080/09638280310001603983.

19. Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. J Am Geriatr Soc. 2004 Nov; 52(11): 1817-1825. DOI:10.1111/j.1532-5415.2004.52504.x.

20. Walpole SC, Prieto-Merino D, Edwards P, Cleland J, Stevens G, Roberts I. The weight of nations: an estimation of adult human biomass. BMC Public Health. 2012 Jun; 12(1), 439. DOI: https://doi.org/10.1186/1471-2458-12-439.

21. Plagenhoef S, Evans G, Abdelnour T. Anatomical Data for Analyzing Human Motion. Res Q Exercise Sport. 1983; 54(2), 169-178, DOI: 10.1080/02701367.1983.10605290

22. Holm B, Kristensen MT, Husted H, Kehlet H, Bandholm T. Thigh and knee circumference, knee-extension strength, and functional performance after fast-track total hip arthroplasty. PM R. 2011 Feb; 3(2):117-24. DOI: 10.1016/j.pmrj.2010.10.019.

23. Landin D, Thompson M, Reid M. Knee and Ankle Joint Angles Influence the Plantarflexion Torque of the Gastrocnemius. J Clin Med Res. 2015 Aug; 7(8): 602–606. DOI:10.14740/jocmr2107w

24. Saaty RW. The analytic hierarchy process—what it is and how it is used. Maths Modelling. 1987; 9(3-5): 161-176. DOI: https://doi.org/10.1016/0270-0255(87)90473-8.