Prosthetic Use by Persons with Unilateral Above Knee Amputation in the Western Cape

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Declaration

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Abstract

Background: Walking with an above knee prosthesis places high physical demands on a person. People with an above knee amputation tend to use their prosthesis less frequently compared to people with a below knee amputation. Within the Western Cape's Public Health Sector, guidelines for pre-prosthetic rehabilitation services and prosthetic prescription are well developed and practised. However, once a prosthesis has been obtained, access to, and use of, prosthetic rehabilitation services seem limited. Furthermore, little is known about prosthetic use and mobility once the person has received an above knee prosthesis.

Aim: To determine prosthetic mobility and prosthetic use of people with unilateral above knee amputation who have received their prosthesis from the Western Cape Government.

Methods: The study used a quantitative, descriptive study design. The study population included all adults who had received a first prosthesis from the Orthotic and Prosthetic Centre in the Western Cape between 1 June 2011 and 31 December 2014. 43 people participated in the study. Data was collected through telephone interviews. An adapted version of the Prosthetic Profile of the Amputee (PPA) was completed. The original tool was tested for validity and reliability, but in a different context, with a different population. Data was captured on an Excel spreadsheet. Descriptive and some inferential analysis, with the Ci square- test, were done.

Results: The majority of the 43 study participants were older than 50 years (77%), and men (79%). Vascular conditions (47%), followed by diabetes (23%), caused the highest number of amputations. More than half of participants waited longer than a year before receiving their prosthesis, however, it had no clinical or statistically significant impact on prosthetic use. Thirty five participants (81%) used their prostheses at least once a week and eighteen (42%) used it daily. A statistically significant effect (p=0.000) was found between prosthetic rehabilitation and prosthetic walking distance. Seventeen, less than half of participants, that received prosthetic rehabilitation, reported that they could walk for longer distances. Two (5%) participants could walk 1 000 or more steps without having to rest, however, more than half (56%) were limited to less than 200 steps. Of the prosthetic users, twenty six (74%) could walk indoors without assistive devices. On outdoor, uneven terrain, twenty six (74%) needed one or two elbow crutches, where nine (26%) did not rely on any hand held assisted devices across all terrains. Less than half (44%) of the participants felt the prosthesis completely met their expectations.

Conclusion: The majority of the study participants used their prosthetic leg; although limitations were experienced in frequency of wear and mobility, such as walking distances and the need for additional hand held assisted devices. Initial expectations of what the prosthesis will offer were not often met. The results highlight the lack of prosthetic rehabilitation and also the benefit of prosthetic

rehabilitation on mobility. It is recommended that access to rehabilitation is improved, from pre-prosthetic which could shorten waiting time to prosthesis, through to prosthetic rehabilitation, to improve mobility outcomes. It is also recommended that emphasis is placed on education at the pre-prosthetic phase, to determine realistic goals for the prosthetic phase.

Key terms: above knee amputation, prosthetic use, prosthetic mobility, prosthetic rehabilitation.

Abstrak

Agtergrond: Dit verg meer fisiese inspanning van ‘n persoon om met ‘n bo-knie prostese te loop. Mense met ‘n bo-knie amputasie is geneig om hul prosteses minder te dra in vergelyking met die wat ‘n onder-knie amputasie gehad het. Riglyne vir pre-prostetiese rehabilitasie en die voorskryf van prosteses is goed ontwikkel en word prakties toegepas in die Wes Kaap se Publieke Gesondheidsektor. Dit wil egter voorkom asof daar minder toegang tot en of gebruik van prostetiese rehabilitasie dienste is. Daar is ook min inligting beskikbaar oor die gebruik van en mobilitiet met bo-knie prosteses in die Wes Kaap.

Doel: Om die mobiliteit en prostetiese gebruik van mense met ‘n bo-knie amputasie wat hul prostese ontvang het deur die Wes Kaap Publieke Gesondheids Sektor te evalueer.

Metode: ’n Kwantitatiewe, beskrywende studie is gedoen. Die studie populasie het bestaan uit individue met ‘n bo-knie amputasie wat tussen 1 Junie 2011 en 31 Desember 2014 hul eerste prostese ontvang het vanaf die Wes Kaapse ‘Orthotic and Prosthetic Centre’. Drie en veertig mense het aan die navorsing deelgeneem. Die data is versamel deur middel van telefoon onderhoude waar ‘n aangepaste bestaande vraelys ‘*Prosthetic Profile of the Amputee (PPA)’* beantwoord is. Die oorspronklike vraelys was getoets vir betroubaarheid en geldigheid, maar in ‘n ander konteks ten opsigte van kultuur en populasie. Versamelde data was in Excel opgesom en beskrywende analise is gedoen. Die Chi`square toets is gebruik om vas te stel of veranderlikes `n statisties beduidende verhouding met mekaar het.

Resultate: Meeste van die deelnemers was manlik (79%) en ouer as 50 (77%). Meeste amputasies was gedoen as gevolg van vaskulêre probleme (47%) en diabetes (23%). Meer as die helfde van deelnemers het langer as ‘n jaar gewag voor prostese ontvang is, die wag periode, het egter nie ‘n statistiese of klinisie impak op prostetises gebruik gemaak nie. Vyf en dertig (81%) deelnemers het hul prostese ten minste een keer per week gebruik en agtien (42%) het dit daagliks gebruik. `n Statisties beduidende verhouding (p=0.000) was gevind tussen prostetiese rehabilitasie en stap afstand met die prostese. Deelnemers wat prostetiese rehabilitasie ontvang het, kon langer afstande loop met die prostese. Sewentien deelnemers, minder as die helfde, het egter prostetiese rehabilitasie ontvang. Slegs twee deelnemers kon 1 000 tree of meer loop sonder om te rus en meer as helfde deelnemers (56%) kon nie meer as 200 treë op ‘n slag loop nie. Van die deelnemers wat die prostese gebruik het, kon ses en twintig (74%) binnehuis loop sonder die hulp van krukke. Ses en twintig (74%) deelnemers het een of twee krukke nodig gehad om op ongelyke grond te loop, waar nege (26%), kon loop sonder krukke oor alle terreine. Minder as die helfde (44%) van die deelnemers het gevoel dat die prostese volkome aan hul verwagtinge voldoen het.

Slotsom: Meeste van die deelnemers het hul prosteses gebruik, alhoewel baie beperkinge ondervind het soos beperkte loop afstande en die afhanklikheid van krukke. Verwagtinge van prostese was dikwels nie gevul nie. Die resultate dui daarop dat prostetiese rehabilitasie ‘n positiewe impak het op mobiliteit, asook dat daar beperkte toegang tot prostetiese rehabilitasie is. Beter toegang tot rehabilitasie word dus voorgestel; vanaf pre-prostetiese rehabilitasie, om die wag tydperk tussen amputasie en prostese te verkort, tot prostetiese rehabilitasie, om mobilitiet te verbeter. Dit word ook voorgestel dat meer inligting gegee word gedurende pre-prostetiese rehabilitasie om realistiese doelwitte te skep vir prostese fase.

Sleutelterme: bo-knie amputasie, gebruik van prostese, prostetiese mobilitiet, prostetiese rehabilitasie.

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Definition of terms

Prosthetic Use: Frequency of prosthetic wear expressed in terms of hours per day or days per week (Glemne, Ramstrand, Crafoord & Nygren 2012).

Prosthetic Mobility: Ambulatory status whilst wearing prosthesis, expressed in terms of dependency on hand-held assisted devices.

Major lower limb amputation: Any amputation above the ankle (e.g. below knee amputation, through knee amputation, above knee amputation)

Table of contents

List of Figures

List of Tables

Appendices 66

List of acronyms

AK:	Above Knee
BK:	Below Knee
GSH:	Groote Schuur Hospital
OPC:	Orthotic and Prosthetic Centre
PPA:	Prosthetic Profile of the Amputee
SACH:	Solid ankle-cushion heel
WCRC:	Western Cape Rehabilitation Centre
WC:	Western Cape
WCDoH:	Western Cape Department of Health
WHO:	World Health Organisation

Chapter One: Introduction and overview

1.1 Background to the study

The loss of a lower limb through amputation negatively impacts on mobility, function and an overall quality of life. More often than not, the person's wish is to regain mobility by means of a prosthesis (Godlwana 2009). Walking with an above knee prosthesis is challenging, compared to able bodied gait or gait with a below knee prosthesis (Davies & Datta 2003). It requires high energy expenditure, adequate dynamic balance and strength (Geertzen, Van der Linde, Rosenbrand, Conradi, Deckers, Koning *et al.* 2014). Therefore, not all people who have undergone above knee amputation will be able to mobilise with a prosthesis.

In the late nineties, Bakkes (1999) reported that waiting lists for prosthetic casting in the Western Cape government service took several months to address, much longer compared to the same service in the private sector. She recommended that one way to shorten the waiting list was to only refer appropriate prosthetic candidates. Over the years, an official prosthetic screening tool, based on her research findings and clinical expertise, *Guidelines for Screening of Prosthetic Candidates: Lower Limb* (WCDoH 2010) (Appendix 1), was drafted and refined. This tool is currently used by the Western Cape Department of Health to guide rehabilitation pathways of persons with lower limb amputations and to ensure that appropriate candidates are referred for prosthetic fitting and rehabilitation. The waiting list for prosthetic casting in the Western Cape (WC) has essentially been eradicated and it is believed that the use of the screening tool has played a pivotal role in this improvement. However, this assumption has not been substantiated through research.

The Western Cape Department of Health has one 'Orthotic and Prosthetic Centre' (OPC) that serves the entire Western Cape population, that, accesses government orthotic and prosthetic services (with the exception of Eden/Karoo which is outsourced to the private sector). Two lower limb pre-prosthetic screening clinics service the WC Metro District: one at Groote Schuur Hospital (GSH), a tertiary training hospital, serves the south-western area. A second pre-prosthetic screening clinic that covers the north-eastern area of the Metro Health District is situated at the Western Cape Rehabilitation Centre (WCRC), a specialised rehabilitation centre. Clients are referred to either of these two clinics where a prosthetist and physiotherapist use the screening tool: *Guidelines for Screening of Prosthetic Candidates: Lower Limb* to determine whether or not the client is a prosthetic candidate and ready for casting. The OPC also runs an outreach service that travels to towns outside the metro health district which are managed by an orthotist and most often an orthopaedic sister.

People with above knee amputation who are referred for prosthetic casting directly from the OPC outreach clinics, might therefore not have undergone the in-depth pre-prosthetic screening by physiotherapists.

Prescription of type of socket, suspension and prosthetic components is usually based on the diagnosis, condition of the residual limb and activity level of the person. However, choice of components in the government sector in the Western Cape Province, is extremely limited, due to financial restrictions.

While the pre-prosthetic pathway is, thus, rather clear in the Western Cape Metro, prosthetic rehabilitation is not routinely provided at all specialised rehabilitation services, and where services are available, clients' attendance are not optimal. Thus, contact with people using prostheses is mostly lost as is the knowledge of how they are coping with prosthetic mobility.

1.2 Problem Statement

The Western Cape Department of Health has come a long way in establishing a pre-prosthetic management pathway for persons with lower limb amputations through specialised clinics and a screening tool (WCDoH 2010). Since the implementation of these initiatives, no studies have been conducted to determine prosthetic use and/or mobility of those who have qualified for a prosthesis.

The problem statement: *The Western Cape Department of Health has no evidence as to whether persons, who have received above knee prostheses from their services, are using the prostheses or how successful prosthetic mobility is.*

1.3 Study question

What is the prosthetic use and mobility in persons with above knee amputation since the implementation of the prosthetic screening tool in the Western Cape Department of Health?

1.4 Study Aim

To determine current prosthetic use, prosthetic mobility and level of satisfaction of people with unilateral above knee amputation who received their prosthesis from the Western Cape Government between 1 June 2011 and 31 December 2014.

1.5 Study Objectives

- To describe the demographic profile of the study population
- To describe prosthetic use
- To determine prosthetic mobility in terms of;
  - indoor and outdoor mobility
  - mobility with and without crutches
  - distances walked
- To determine barriers to prosthetic mobility
- To determine employment status
- To determine if users' expectations of prostheses have been met

1.6 Significance of the research

It has been well established that above knee prosthetic mobility is challenging (Davies & Datta 2003). Improved knowledge of prosthetic mobility outcomes and an understanding of the factors that directly, or indirectly, impact mobility amongst people with unilateral above knee amputation, should help to guide future prosthetic rehabilitation in the Western Cape. There is also not enough available literature on lower limb amputation and amputation rehabilitation in South Africa and this study will add to the body of local knowledge.

1.7 Motivation for undertaking the research

The researcher, a physiotherapist, has been intensely involved in the pre-prosthetic and prosthetic rehabilitation of people with lower limb amputations at Western Cape Rehabilitation Centre (WCRC) from 2011 to 2016. The researcher found that on initial interview, the goal of most people with a lower limb amputation, was to obtain a prosthesis for prosthetic mobility and that their expectation of what the prosthesis would offer was quite high. Examples: to free both hands from their crutches in order to do functional tasks (such as hanging the washing, doing gardening, carrying a cup of coffee or groceries), to walk outdoors without any hand held assistive devices, to walk the same distances they walked before, or to return to open labour market. The researcher also found that the aim of obtaining a prosthesis was their top priority, and most people who accessed the service, would attend all their appointments till the day of prosthetic prescription.

In the researcher's experience, most people with an above knee amputation who did return for prosthetic rehabilitation, did not achieve their expectations, as more often than not, they still relied on additional hand held assistive devices for mobility. Some might even stop wearing their prosthesis. No recent local studies have been conducted to reflect on

prosthetic mobility or use. With this study, the researcher will investigate and describe prosthetic mobility and prosthetic use amongst people with unilateral above knee amputation who have accessed local government services.

1.8 Summary of chapter

The aim of this study was to determine prosthetic use and prosthetic mobility of people with unilateral above knee amputation who received their prosthesis from the Western Cape Government. There is a clear pre-prosthetic rehabilitation pathway in the Western Cape Metro. However, prosthetic rehabilitation services are less well defined. The extent to which clients are mobile with their prosthesis and the barriers that they experience, have not been studied. This study will contribute much needed knowledge on these aspects to provide some guidance to above knee prosthetic rehabilitation service delivery in the government's health service setting.

1.9 Outline of the study

Chapter 1 presents the study background information, the study's problem, aim and objectives. This is followed by the literature review in Chapter 2; an overview of lower limb amputations nationally, within Africa, and internationally. In Chapter 3 the methodology is described, and in Chapter 4 the study results are presented, followed by an in-depth discussion in Chapter 5. The manuscript concludes in Chapter 6 with study limitations, conclusions and recommendations.

2 Chapter Two: Literature Review

2.1 Introduction

Major lower limb amputation, to save a life, has been a surgical procedure performed since the days of Hippocrates. Since then, healthcare has come a long way from saving a life, progressing to restoring the quality of life and mobility after amputation (Asano, Rushton, Miller & Deathe 2008). The current study explores the restoration of mobility and aims to describe prosthetic use and prosthetic mobility after above knee amputation. Thus, this review of the literature covers an overview of the epidemiology of lower limb amputation and rehabilitation post amputation. It also explores components used in above knee prostheses, the use of, and functioning with above knee prostheses that provide background information against which to interpret current study findings.

A number of the studies referred to in this review are older than five years and may, thus, be deemed outdated, if not considering the study setting. The Western Cape OPC uses only basic above knee prosthetic components, which, in developed countries, was used more commonly several years ago (> 5years). Thus, older studies from developed countries were included in the literature of this study, to enable comparable discussions. The results from Bakkes (1999) and Hendry (1993) were included too, since they provided the only local comparable findings, from the same setting as the current study. Most recent studies on prosthetic mobility and use are international studies, where participants have access to more advanced prosthetic components, and regular prosthetic rehabilitation, which was taken into consideration in the discussion.

Literature was sourced from Pubmed, Science Direct, ISPO, AJOL, AOSIS, Google scholar and Stellenbosch University library. Search terms included lower limb, above knee and trans femoral amputa*, prosthe*, use, mobility, outcomes.

2.2 Epidemiology of amputation

2.2.1 Incidence and prevalence of amputation

The number of people who have amputations worldwide is not currently tracked by any organization (Cumming, Barr & Howe 2015), but the World Health Organization estimates that there are more than 1 million annual limb amputations globally (WHO 2011). The Global Lower Extremity Amputation Study Group describes the Navajo population of America as the group with the highest incidence of lower limb amputations in the world with 43.9 per 100,000 people and the population of Madrid, Spain has the lowest incidence rate, at 2.8 amputations per 100,000 of the population per year (Global Lower Extremity Amputation

Study Group 2000). The Global Lower Extremity Amputation Study Group, however, only included Japan, Taiwan, Spain, Italy, North America and England in their studies. Dillon, Kohler and Peeva (2014) reports a lower limb amputation rate of 32.4 per 100, 000 of the population in Australia and that the incidence rates varied across the country. Furthermore, a recent large-scale study conducted in America (Pasquina, Carvalho & Sheehan 2015) predicts that the incidence of amputations is likely to increase significantly and double by the year 2050.

Literature on lower limb amputation incidence and prevalence numbers in Africa is scant. A descriptive study in a tertiary teaching hospital in Nigeria, studied epidemiology of lower limb amputations over a five-year period and reported 94 amputations (Kidmas, Nwadiaro & Igun 2004). A study conducted in a Rwandan teaching hospital reported 107 amputations over a 2-year-and- three- month period, with 38 being above knee amputations (Murwanashyaka, Ssebuufu & Kyamanywa 2013).

South African literature is mostly based on studies conducted in the Western Cape where the current study is to take place. In the late eighties, Hendry (1993) conducted an epidemiology study at one of the tertiary hospitals in Cape Town and found that 597 major lower limb amputations had been performed over a three-year period. Further studies conducted on lower limb amputation, in this province, had other objectives and no new data on amputation incidence or prevalence could be found.

Most studies conducted on major lower limb amputations, reported lower numbers of above knee amputations, compared to below knee amputations; this was also observed in America (Stepien, Cavenett, Taylor & Crotty 2007), across the UK (Cumming *et al*. 2015), in a study in Turkey (Seker, Kara, Camur, Malkoc, Sonmez & Mahirogullari 2016) and in Africa (Dunbar, Hellenberg & Levitt 2015; Chalya, Mabula, Dass, Ngayomela, Chandika, Mbelenge *et al.* 2012).

2.2.2 Cause of Amputation

Some studies differentiate between vascular disease and diabetes, while other studies include diabetes as part of vascular causes. The amputation, however are ultimately caused by ischemia, with vascular disease and diabetes being comorbidities. The majority of people with an amputation has existing co-morbidities; such as, diabetes, cardiovascular disease, obesity, hypertension and renal disease (Cumming *et al*. 2015; Pasquina *et al*. 2015).

In developed countries, vascular disease is the main cause of amputation (Cumming *et al.* 2015; Pasquina *et al.* 2015). In a study, set in a major Australian teaching hospital, 58% of lower limb amputations were due to diabetes (Lazzarini, O'Rourke, Russell, Clarkand & Kuys

2012) and in a study conducted in England, the researchers found that 16,693 people out of a total of 34,109 who had undergone lower limb amputation, had been diagnosed with diabetes, making it a total of 48.9% persons with diabetes (Holman, Young & Jeffcoate 2012). In a large scale, Canadian study of 396 people with lower limb amputations, vascular disease was found to be the main cause of amputation (47.5%) followed by diabetes mellitus (30.8%) and trauma (Gauthier-Gagnon, Grisb & Potvin 1999).

Literature from Africa shows that amputation patterns vary between hospitals in, and between, countries. In a Tanzanian Medical Centre, a descriptive study of 162 patients with major limb amputations, found that the main cause of amputations had been diabetic foot complications, followed by trauma and vascular disease (Chalya *et al*. 2012). Similar findings came from studies conducted by Jawaid, Ali and Kaimkhani (2008), in Pakistan, where diabetes was the major cause of amputations. In parts of Africa where violence is common and/or where there are wars, the findings differ, and trauma becomes the leading cause of major lower limb amputations (Godlwana, Nadasan & Puckree 2008; Kidmas *et al*. 2004). A retrospective study in Nigeria over an 11-year period, found trauma (49.9%), followed by diabetic foot sepsis (31.4%), and peripheral vascular disease (13%) as the primary causes of amputation. Similar results were reported by Sie Essoh, Koko and Dje Bi Dje Lambin (2009), reflecting high rates of trauma and diabetic causes. Although trauma may be the leading cause for amputation in some parts of Africa, it does not erase the alarming figures of vascular complications due to diabetes in the same countries. Bertram, Jaswal, Van Wyk, Levitt and Hofman (2013) reported that in South Africa, 2000 new amputations were caused by diabetes annually.

Studies conducted in the Western Cape Province, South Africa, reflect the 'pattern' of a developed country. Data for the primary cause of lower limb amputations in one of the largest tertiary hospitals, shows that the main cause was vascular (83%), followed by trauma (12%), malignancy (3%), infection (2%) and congenital limb defects (0.2%). Further reported comorbidities were hypertension, chronic obstructive airway diseases, ischemic heart disease and myocardial infarction (Hendry 1993). Bakkes (1999) also found vascular diseases to be the most common causes of above knee amputation amongst people who have accessed rehabilitation. Dunbar *et al.* (2015), in a more recent study, examined the proportion of lower limb amputations, due to diabetes, in four public hospitals, in Cape Town, over a two-year time span. Data from theatre records showed 72.3% of the lower limb amputations had been performed on people with diabetes (this included multiple amputations on the same person). Within the non-diabetic group, ischaemia was the dominant cause with smoking being the dominant risk factor.

2.2.3 Age and gender

Men have a higher amputation incidence rates than women. This was found in developed countries (Seker *et al*. 2016; Lazzarini *et al.* 2012), in Africa (Ogundele, Ifesanya, Oyewole & Adegbehingbe 2015; Chalya *et al.* 2012; Sie Essoh *et al.* 2009; Kidmas *et al.* 2004) and in South Africa (Dunbar *et al.* 2015; Hendry 1993; Bakkes 1999).

Generally, research in developed countries shows that the incidence of lower limb amputations increases with age and mean ages of study participants are often above 60 years of age (Davie-Smith, Kennon, Wyke & Paul 2015; Asano *et al.* 2008). In the UK, a Cochrane review reported that the majority of people with lower limb amputations, were older than 60 years (Cumming *et al.* 2015). Similarly, the Western Cape study by Hendry (1993) reported a mean age of 60 years.

In some African studies, the average ages of persons with amputations are much lower, compared to persons in developed countries (Ogundele *et al.* 2015; Murwanashyaka *et al.* 2013; Sie Essoh *et al.* 2009; Kidmas *et al.* 2004), as trauma is a major cause of amputation and diabetes is, also often, found among younger ages. In Nigeria, Kidmas *et al.* (2004) and Sie Essoh *et al.* (2009) reported mean ages of 44.5 years and of 42 years, respectively.

2.2.4 Mortality

Lower limb amputation is associated with significant morbidity and mortality. The survival rate varies across countries, but the mortality rate is generally high. In America, more than half of those who have an amputation due to vascular causes will require an amputation of the contra-lateral limb within two to three years, and the five-year mortality rate is over 50 percent (Pasquina *et al*. 2015). The Netherlands showed mortality figures of up to 44% within the 1st year (Fortington, Geertzen, van Netten, Postema, Rommers & Dijkstra 2013). A recent systematic review (Van Netten, Fortington, Hinchliffe & Hijmans 2016) stated that the mortality rate amongst people with lower limb amputation at 30 days varied between 7% and 22 %, with people undergoing an above knee amputation, being proportionally at higher risk, compared to people with below knee amputation. A Turkish study found mortality rates of 65.5% by the 5th year post-amputation (Seker *et al.* 2016).

In a Nigerian hospital, they recorded a total of 25 deaths within one month after lower limb amputation surgery, resulting in a mortality rate of 16%. Most deaths were due to diabetic foot septicaemia and peripheral vascular disease (Sie Essoh *et al.* 2009). Kidmas *et al.* (2004) also a Nigerian study, reported a 15.2 % mortality rate. However, the authors did not specify the time period post-amputation during which mortality had been recorded.

A South African study conducted in Johannesburg, Gauteng, reported that twenty four out of the 73 participants had died by the time of the follow up, 3 months post-surgery. This represents a 33% death rate and of those who had died, the majority (67%) had diabetes and 46% had suffered from hypertension (Godlwana 2009).

2.3 Employment

Financial concerns and high unemployment rates are a reality that people with amputations face in South Africa. In the study of Godlwana, Steward and Musenga (2012), 52.5% of participants had no income and expressed concern about the implications of the amputation for their finding jobs. Fredericks and Visagie (2013) also found that people with lower limb amputations found it difficult to secure employment. In another local study, 24 people were employed prior to amputation, with only 7 returning to employment (Bakkes 1999), and this was after they had received intensive prosthetic rehabilitation.

Re-employment, seems to be associated with more sedentary work and workplace modifications (Schoppen, Boonstra, Groothoff, van Sonderen, Go¨eken & Eisma 2001a; Schoppen, Boonstra, Groothoff, de Vries, Go¨eken & Eisma 2001b). Factors that were found to negatively impact a person's return to work were the presence of co-morbidity, being older than 40 years at amputation date, having a vascular cause for amputation, poor prosthetic comfort and low education levels (Geertzen *et al*. 2014).

2.4 Rehabilitation

Rehabilitation management after above knee amputation, for people who will receive a prosthesis, generally consists of a pre-prosthetic and a prosthetic phase. Early, and comprehensive, rehabilitation intervention, by a multidisciplinary team, improves the person's overall outcome in the long-term (Sansam, Neumann, O'Connor & Bhakta 2009). Generally, in South Africa, rehabilitation and team work post amputation have been found lacking (Ennion & Rhoda 2016; Fredericks & Visagie 2013; Godlwana 2009). Rhoda, Mpofu and De Weerdt (2009), found that only 20 of the 39 Community Health Clinics, in the WC Metro Health District, offered therapy services. Thus, a large percentage of people did not have access to therapy services.

Limited access to rehabilitation services, post amputation, is also a reality in the rest of Africa. According to Kidmas *et al.* (2004) rehabilitation services for people with lower limb amputation are scarce in Africa, often centralised in large cities where people have to travel far to prosthetic centres. This option is not possible for the majority due to lack of transport, time or finances. Kam, Kent, Khodaverdian, Daiter, Njelesani, Cameron *et al*. (2015)

interviewed prosthetists working in low income countries and they found that a lack of physiotherapy post amputation and the discontinuity of care in the prosthetic rehabilitation process, served as barriers to prosthetic use.

2.4.1 Pre-prosthetic Rehabilitation

According to evidence based guidelines developed by Geertzen *et al.* (2014) and other reliable sources, the following is important in preparing for functioning with a prosthesis:

- The above knee **residual limb** should be **bandaged** completely into the groin area, to reduce oedema, improve venous return and form a conical shape for future prosthetic fit.
- **Joint mobility,** especially, full extension and adduction range of the hip joint is crucial for prosthetic walking. The residual limb range of motion is maintained through an active range of motion exercises and the correct positioning.
- **Muscle strength:** The most important muscle groups that need to be strengthened are the hip extensor and abductor muscles, as well as, the abdominal muscles for core stability. These muscles are important in controlling the prosthesis.
- **Cardiovascular** fitness: Above knee prosthetic gait is a strenuous activity, and conditioning of the cardiovascular system for prosthetic walking is essential.
- **Balance:** the ability to balance on the contra-lateral leg is associated with the ability to walk with an above knee prosthesis (Tezuka, Chin, Takase, Azuma, Nakatsuka, Fujie *et al.* 2015; Schoppen, Boonstra, Groothoff, de Vries, Go¨eken & Eisma, 2003; Gailey, Roach, Applegate, Cho, Cunniffe, Licht *et al.* 2002; Bakkes 1999).
- **Mobility with crutches**: Frequent wheelchair use or use of mobility assistive devices before the amputation, is associated with poor prosthetic ability and poor outcomes (Mundell, Kremers, Visscher, Hoppe & Kaufman 2015; Roffman, Buchanan & Allison 2014). Mobility with crutches post amputation is a positive indicator for functional prosthetic mobility (Bakkes 1999).

2.4.2 Prosthetic Rehabilitation

The goal of prosthetic rehabilitation is to assist the person to function as well as possible with the prosthesis. This requires the learning of new skills related to walking with a prosthesis and caring for the residual limb. A well fitted prosthesis (Roth, Pezzin, McGinley & Dillingham 2014) and early rehabilitation (Sansam *et al.* 2009) are important to optimise prosthetic use.

According to the guidelines developed by Geertzen and colleagues (2014) prosthetic rehabilitation should include:

- **Home exercises**: continuation of home exercises focusing on joint mobility, muscle strength, balance and endurance as started during pre-prosthetic phase.
- **Functional activities and ADL**: instruction in prosthesis care and fitting; transfers, prosthetic mobility and ADL activities with prosthesis.
- **Integration in community situation**: Initiate prosthetic use in work situation and recreational activities; training skills such as climbing stairs, steps and walking on uneven ground; improving walking distance; training in use of public transport or driving with prosthesis when appropriate; information for partner and informal carers.
- **Advice relating to general movement and sport.**

Literature has shown positive results from prosthetic rehabilitation interventions. A 12-week exercise programme (minimum of 3 sessions per week) incorporating strength, flexibility, balance and aerobic exercises, demonstrated improved prosthetic mobility. Gait endurance, gait speed, turning ability and hence falls prevention improved (Schafer, Tinley, Hancock, White, Perry & Vanicek 2017). The program also improved gait symmetry (Vanicek, Schafer, Hancock, Tinley & Perry 2017). In contrast, a UK study has found that a significant number of people who underwent amputation due to vascular reasons were prescribed a prosthesis for walking, but that many did not achieve a high level of function following prosthetic rehabilitation (Cumming *et al.* 2015). The participants, however, were all older than 60 year and pre-morbid mobility were not fully known.

2.5 Prosthetic Use

Prosthetic Use is defined as frequency of use and expressed in terms of hours per day or days per week (Glemne, Ramstrand, Crafoord & Nygren 2012). In developed countries, most studies reported daily prosthetic use amongst people with an above knee amputation. In studies where the majority of amputations had been done for vascular reasons, 85% (Puhalski, Taylor & Poulin 2008), 77% (Tezuka *et al.* 2015), 75% (Whitehead & Scott 2017), and 75% (Gauthier-Gagnon *et al.* 1999), daily prosthetic use was reported. All of the above studies were conducted after discharge from prosthetic rehabilitation, ranging from 3 months to 5 years post discharge. A study where the cause of amputation was non- vascular, reported a slightly higher figure of daily prosthetic use, namely, 87% (Hagberg & Branemark, 2001).

A retrospective review of 56 Nigerian participants who had major, lower limb amputations, found that 93% of the participants did not use their prosthesis (Onyemaechi, Oche, Popoola,

Ahaotu & Elachi 2012). The authors did not explore possible reasons for this finding. Participants who had received prosthetic rehabilitation from a centre in Cape Town, South Africa, in contrast, showed that 85% used their prosthesis at the time of discharge (Bakkes 1999). It must be noted that this study was conducted with participants (n=46) who had all received pre-prosthetic and prosthetic rehabilitation and that observations were made at the time of discharge, and might not necessarily reflect longer term prosthetic use.

Frequency of prosthetic wear, in terms of hours per week, was significantly associated with prosthetic mobility capabilities. Capabilities were expressed in further walking distances (Gudmundson & Englund 2017; Puhalski *et al.* 2008; Gauthier-Gagnon *et al.* 1999) and less need for crutches during walking (Puhalski *et al.* 2008, Gauthier-Gagnon *et al.* 1999).

2.6 Prosthetic Mobility

The energy cost of prosthetic gait is higher, compared to able-bodied gait (Vllasolli, Orovcanec, Zafirova, Krasniqi, Murtezani, Krasniqi *et al.* 2015). A Swedish study compared the walking performance of people with a non-vascular above knee amputation to the performance of able-bodied peers and found that prosthetic walking needed 77% more energy. The participants walking with an above knee prosthesis also walked slower and walked limited distances outdoors; only 32% walked 500m more than once per week, compared with 82% of their able-bodied peers (Hagberg, Häggström & Brånemark 2007).

Asono *et al.* (2008) and Andrysek (2010) found that prosthetic mobility improved the quality of life in a person with a lower limb amputation; the more independent the mobility, the higher the quality of life.

2.6.1 Factors influencing Prosthetic Mobility

Prosthetic mobility is affected by various factors, including cause of amputation, amputation level, and age (Mundell *et al.* 2016; Kidmas *et al.* 2004), physical abilities, such as, balance, pre-morbid mobility, cardiovascular fitness, stump strength and joint mobility (Geertzen *et al.* 2014). Prosthetic mobility is also affected by the prosthetic components used and prosthetic fit.

Amputation level: Above knee (AK) prosthetic mobility is more challenging than below knee (BK) prosthetic mobility (Stepien *et al.* 2007; Davies & Datta 2003; Pohjolainen, Alaranta & Karkkainen 1990) due to the loss of the normal knee joint and energy demands that increase as the level of amputation increases (Norvell, Turner, Williams, Hakimi & Czerniecki 2011). Vllasolli *et al.* (2015) recently investigated prosthetic walking performances amongst people with non-vascular AK and BK amputations. All the study participants walked with a SACH-foot, and quadrilateral sockets. The study's outcomes are in agreement with that of

Karmarkar, Collins, Wichman, Franklin, Fitzgerald, Dicianno *et al.* (2009), indicating that AK prosthetic mobility demands more energy and walking speed is slower, in comparison with BK prosthetic mobility. Difficulty with mobility activities, such as navigating a ramp, getting in and out of cars and buses, carrying groceries and participating in sports and leisure activities, were reported more frequently by people using AK prostheses (Karmarkar *et al.* 2009).

Cause of amputation: Wezenberg, de Haan, Faber, Slootman, van der Woude and Houdijk (2012) conducted a cross-sectional study, comparing aerobic loads between persons with above knee amputation due to vascular causes and non-vascular causes. They found that persons with amputations due to vascular causes had lower aerobic capacity and walked slower. Similar results were reported by Norvell *et al.* (2011).

Age: Normal aging impacts mobility, with slower walking speeds, reduced distances, and an increased need for assistive devices combined with general weakening of musculature and poorer balance. Age also negatively impacts on prosthetic mobility (Mundell *et al.* 2016; Puhalski *et al*. 2008; Davies & Datta 2003). In a study by Davies and Datta (2003) (n = 281), of those above 50 years of age, only 25% achieved community mobility in comparison with those under the age of 50 years where almost all persons in the latter age group achieved community mobility. The possible impact of age is also shown in findings by Hagberg and Branemark (2001). They found that younger participants (mean age 48 years), with non-vascular amputations, showed less dependence on crutches; 9% needed 1 crutch and 7% 2 crutches. A recent study by Vllasolli *et al.* (2015) also reported on the favourable effects of younger age groups on prosthetic walking speed and the energy required for walking. Bakkes (1999) showed that at least 80% of each group, those older than 60 years, and those younger than 60 years, managed to walk with prostheses. They had all received prosthetic rehabilitation and thus may not be representative of others who had not received the necessary rehabilitation. However, these findings show it is not age, per se, but the associated physical and medical conditions that influence prosthetic gait ability (Bakkes 1999).

Physical abilities: Literature has shown positive results from prosthetic rehabilitation interventions addressing physical abilities such as, balance, stump strength, joint mobility and cardiovascular fitness (Geertzen *et al.* 2014), as discussed in section 2.4.

Prosthetic components and fit: Will be discussed in section 2.7.

2.6.2 Indoor and outdoor mobility

Both Hagberg and Branemark (2001) and Gauthier-Gagnon *et al.* (1999) found that indoor mobility was mostly not achieved through wearing an above knee prosthesis. Participants mobilised in other ways, e.g. using a wheelchair, or crutches or holding onto furniture. These options may be quicker and less complicated than having to don a prosthesis. The same two studies showed that the prosthesis was used more often outdoors than compared to indoors.

Bakkes (1999) found that 34 of 46 participants (74%) who had received a prosthesis and rehabilitation were able to walk 500m and more, at a time. Unlimited community ambulation was defined as walking a distance of 500m. Those who walked the furthest also required the fewest walking aids (Bakkes 1999). Hagberg and Branemark (2001) showed that 85% of prosthetic users (n = 90) could walk 50 metres without stopping; while 35% could walk 500 metres and 14% walked two kilometres at least twice a week. An American study that investigated long term prosthetic activity in 17 participants with an above knee amputation, found that almost all of them lead a sedentary lifestyle (defined as below 2500 steps per day). Most of the amputations had been performed for non-vascular reasons (Halsne, Waddingham & Hafner 2013) and participants had a mean age of 49.1 years. Stepien *et al.* (2007), similarly, reported a sedentary lifestyle amongst persons with above knee amputations.

Persons with lower limb amputations living in areas with rough, stony and/or sandy, uneven outside surfaces, as do many of the people in the Western Cape, have significantly more challenges in their prosthetic walking abilities than those functioning on smooth, paved surfaces (Magnusson, Ramstrand & Fransson 2013).

2.6.3 Additional mobility assisted devices

Walking without a hand-held assistive device, such as, a stick or crutch/es allows the person to perform functional tasks while walking, e.g. carrying objects, pushing a vacuum cleaner or opening a door. However, the majority of above knee prosthetic users, are reliant on hand-held walking devices. Magnusson *et al.* (2013) found in their study, in Malawi, that 60% of persons with above knee amputations (n=27) needed crutches to assist them with prosthetic mobility.

From the 111 participants in the Canadian study by Gauthier-Gagnon *et al.* (1999) 15% used no hand-held mobility devices, and 47% used one crutch. Those who could walk without aids, or with one elbow crutch, showed a higher frequency of prosthetic use and had the ability to walk further (Gauthier-Gagnon *et al.* 1999). Bakkes (1999) found that 33% of participants used no hand-held devices and 28% used one crutch. In both studies,

participants had received prosthetic rehabilitation; however, participants in the latter study were younger.

Amongst 35 Finnish AK prosthetic users only 28% could walk indoors with their prosthesis alone and only 14%, could walk outdoors with only their prosthesis, the rest of the prosthetic users needed either one or two elbow crutches (Pohjolainen *et al*. 1990). Hagberg and Branemark (2001) showed less dependence on crutches with 84% of participants walking indoors without hand-held assistive devices; however, for outdoor mobility, participants needed more assistance from crutches. The above studies did not indicate if outdoor mobility was over even or uneven terrain. Uneven terrain proves more challenging (Magnusson *et al.* 2013) and may potentially impact findings.

The ability to climb stairs facilitates integration into the home and community environments. Many homes have a few steps at their entrance, streets have sidewalks to step over and many public buildings have steps. Those reliant on public transport need to take a big step into a taxi or a few steps to get into a bus or a flight of steps to catch a train. Accessibility of stairs can be enhanced if a hand-rail is also provided as reported by Gauthier-Gagnon *et al*. (1999) who found a significant difference in stair climbing ability when a handrail is used; 73% could climb steps with a handrail where only 37% could climb steps without a rail. De Laat, Rommers, Dijkstra, Geertzen and Roorda (2013) reported similar findings, with 60% of participants being able to climb stairs with a handrail and only 16% of participants being able to climb stairs with no handrail.

2.7 Prosthetic components

This section provides the reader with a broad overview of prosthetic components, with a focus on components that are used in the public sector, in the Western Cape.

2.7.1 Socket design and suspension

The socket forms the interface between the residual limb and the prosthesis and is the most individually customised component of the prosthesis. Socket manufacturing requires specialised skill of the prosthetist. The quality of the socket fit influences the overall function of the prosthesis (Andrysek 2010). Proprioceptive feedback, weight bearing and reaction forces are relayed through the socket (Andrysek 2010). There are two main types of above knee socket designs, the quadrilateral socket (picture A), introduced in the 1950s and the ischial containment socket (picture B), introduced in the 1980s (Gholizadeh, Abu Osman, Eshraghi & Ali 2014). These two designs are both used by prosthetists at the Prosthetic Centre in the Western Cape where this study was performed.

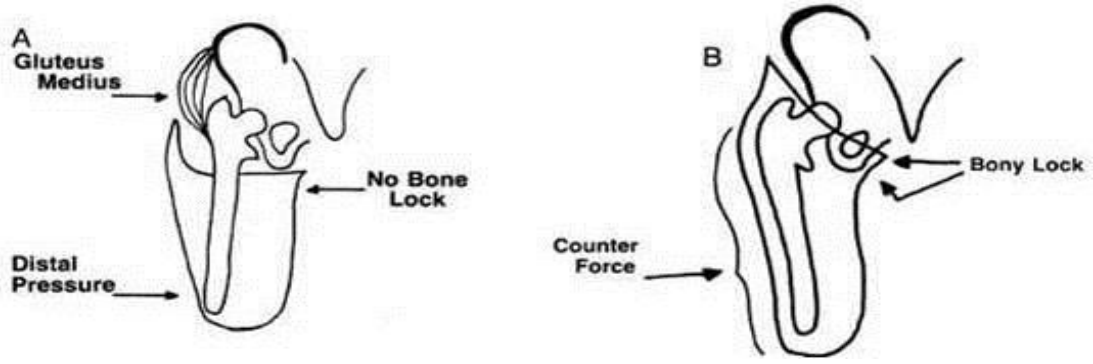

Figure 2.1: Main types of socket design

In the quadrilateral design, the socket is divided into four walls; the ischium is positioned on top of the posterior wall and forms an ischial 'weight bearing seat'. The medial wall contains the soft tissue and the lateral wall controls side displacement of the femur (Gholizadeh *et al*. 2014). Even though there is a dedicated ischial weigh bearing seat, the design offers poor stability during stance phase:

- At heel strike the ischial tuberosity is not on the 'weight bearing seat'
- The gluteus maximus contraction lifts the ischium off the seat during mid stance and the pelvis slides medially on the seat
- At terminal stance the brim of the socket gets trapped between the ischium and extended femur, and the residual limb has to be 'pulled out' causing gapping (Bakkes 1999)

With the ischial containment design, the ischium and the ischial ramus are inside the socket. This increases weight bearing stability and stabilises the femur in normal alignment i.e. relative adduction. The ischial seat is slanted and the ischium is provided with three-dimensional support within the socket, preventing lateral movement of the socket during stance phase, like in the quadrilateral design, thus providing better mediolateral stability and a counter force against femur abduction (Gholizadeh *et al*. 2014). The improved fit and stability during ambulation results in less compensatory patterns, reduced energy consumption, and increased walking ability. Gailey, Lawrence, Burdilt, Spyropoulos, Newell and Nash (1993) compared prosthetic mobility between the two socket designs and found the ten study participants using the quadrilateral socket design used more energy walking at normal walking speed (67m/min), compared to the ten participants fitted with the ischial containment socket design.

2.7.2 Suspension systems

The suspension system secures the prosthesis to the residual limb. Various suspension systems have been developed over the years, including, the use of body contour (shape of socket with socks and belts), using pressure differentiation (suction), and, most recently, through Osseo-integration (direct structural connection between bone and prosthesis).

The silesian pelvic belt with residual limb socks to complete the final comfort and fit of the socket is easy to don and allows for some accommodation in stump volume fluctuation. Disadvantages of this suspension method are that of pistoning and instability. This type of suspension system is usually used with elderly clients who have complaints of vascular insufficiency, and those clients with a short residual limb (Gholizadeh *et al.* 2014). With suction suspension, suction inside the socket is sealed by a valve and the residual limb and the socket maintain close contact. The suction allows for better control and stability of the residual limb which leads to improved mobility and comfort. However, this type of prosthetic design is difficult to don and it does not accommodate volume changes (Gholizadeh *et al.* 2014). There is no need to replace liners or socks. Osseo-integration is mainly the choice if people have problems with conventional sockets, e.g., challenges of fitting a short stump, soft tissue scarring, recurrent skin infection, or a socket creating volume fluctuations, while the client is using the conventional sockets (Gholizadeh *et al.* 2014).

Selection criteria for the prosthetic suspension system and socket design usually follow amputation etiology, the evaluation of the person's functional abilities and the prosthetist's experience. At the Western Cape Orthotic and Prosthetic Centre, it is common practice to fit people who have been given a vascular diagnosis with a quadrilateral socket, and as suspension, the silesian belt with stump socks. Up to three socks will be provided prior to recasting, to ensure optimal fit. Ischial containment sockets with suction suspension are mostly used for clients who have had an amputation for non-vascular reasons.

2.7.3 Prosthetic knees

The dynamic control provided by the human knee, during gait, is lost in most prosthetic knees. The prosthetic knee's aim is knee flexion during swing phase, and knee extension during weight bearing, to prevent 'buckling' of the knee (Andrysek 2010). During initial stance phase the human knee is flexed to 20 degrees and acts as a shock absorber; it gradually extends during mid stance and starts to flex again at terminal stance. During walking, friction in the prosthetic knee is used to control the knee joint. Friction controls the speed and range of knee flexion and extension. Types of friction systems used in prosthetic

knees include: 1) Mechanical (provide constant friction) 2) Hydraulic or Pneumatic (able to alter friction) and 3) Microprocessor / computerized knees (alter friction).

The simplest knee component is a single-axis hinge joint (Andrysek 2010) and is classified as a basic, prosthetic knee component (WHO 2017). A version of the single-axis hinge joint, is used in the public sector in the Western Cape. It is a mechanical single speed, single-axis, stainless steel knee joint. It has a load dependent brake system that locks in stance phase and an “extension assist” in the swing phase. This type of knee is suitable for indoor and limited outdoor mobility. Its main limitation is that it only allows one speed of walking which makes it more suitable for elderly clients who mostly walk at one, set speed. If a person wants to walk faster, compensatory methods are typically displayed, such as vaulting, medial whip, excessive terminal impact and excessive knee flexion (Bakkes 1999). Advantages of the knee are its reliability, ease of adjustment and low maintenance.

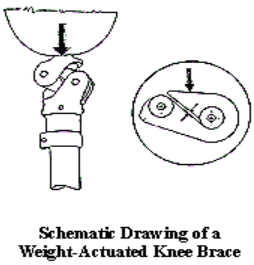

Figure 2.2 Weight activated stance control knee

An intermediate level prosthetic knee is controlled by more sophisticated designs that can be either hydraulic or pneumatic in nature (WHO 2017), e.g. a polycentric knee joint. Polycentric knees are designed so that the centre of rotation of the knee varies, reflecting more closely true, anatomical knee movement. It shortens the prosthesis during the swing phase, providing better ground clearance, and supports different walking speeds through variable-friction swing phase control, resulting in reduced energy expenditure.

Advanced prosthetic knee components have added “smart parts” that capture signals and detect the movements of the user to control the prosthetic knee automatically (WHO 2017). The microprocessor knee senses the position of the knee during walking and adjusts the settings accordingly. Hafner, Willingham, Buell, Allyn and Smith (2007) compared mechanical knee joints with microprocessor knee joints in 21 participants. They found greater client satisfaction, reduced stair- and hill descent time, a decrease in stumbles and falls, and improved multi-tasking abilities of users. Kaufman, Levine, Brey, Iverson, McCrady, Padgett *et al*. (2007) found that the microprocessor knee provided a better gait pattern with less knee extension during stance phase and also improved balance during

walking. It should be noted that users who are less active, will not, necessarily, benefit from all the advantages of a microprocessor knee and, thus, prescription of the most optimal prosthetic knee should be based on the activity level and the particular needs of each individual.

Most developed countries make use of intermediate to advanced knee components, however, in developing countries, the use is limited. This might be due to several reasons: sophisticated components are more likely to break down compared to simpler ones, thus requiring more frequent appointments at a prosthetic centre. Attendance might be challenging due to longer distances to travel, lack of financial resources or transport. The devices may, consequently, be continually used in a broken or poorly aligned state, thus, taking away from the functional benefits that the more sophisticated prosthetic knee had initially offered. The balance between biomechanical function and durability, requires careful consideration in the further development of prosthetic knees (Andrysek 2010). The WHO further encourages local industries to develop alternative, affordable products of good quality and that are context appropriate.

2.7.4 Prosthetic feet

There are over 200 different prosthetic feet on the market and the number is increasing (Burger, Vidmar, Zdovc, Erzar & Zalar 2017). Types of prosthetic feet that are available are: traditional, multi-axial and energy storing. The traditional solid ankle-cushion heel (SACH) foot is the simplest type of non-articulated prosthetic foot and it is the prosthetic foot used in government services in the Western cape Province. It has no definite ankle joint, where the ankle action is provided by the soft rubber heel which compresses under load during heel strike. This action lacks energy storing properties and most ground reaction forces are translated back through the shaft, to the socket and the stump, thus using the foot requires more energy in gait. The benefit is that SACH foot is long lasting and needs minimal repair. It provides stability, but limited lateral movement in mid stance. The SACH foot is classified as a basic level component in the WHO standards for prosthetics and orthotics manual (WHO 2017) and is made for low level activity on level, indoor surfaces (Andrysek 2010).

Energy storing prosthetic feet are designed with the purpose of following the physiological patterns of the ankle and foot. Energy stored at heel strike, is used to assist in the push off phase, increasing forward propulsion and reducing the energy cost of walking (Low, Tsimiklis, Zhao, Davies & Bryant 2017). It allows for good shock absorption and pro- and supination over uneven terrain. It is, thus, more suitable for use on outdoor, uneven terrain. It is expensive, but needs little maintenance (Bakkes 1999), which is of benefit as less visits

need to be made to a prosthetic clinic. A study comparing SACH feet with energy storing feet found that there was more symmetry in gait, using the energy storing foot (Houdijk, Wezenberg, Hak & Cutti 2017). The Western Cape's OPC provides only SACH feet. Thus, as with the other components, clients are limited to a foot that was designed for low level activity on level, indoor surfaces and with limited outdoor mobility. An energy storing foot that also needs little maintenance could potentially improve mobility over uneven terrain; a reality in accessing communities.

In summary, intermediate to advanced prosthetic components, as classified by the World Health Organisation document on standards for prosthetics and orthotics (WHO 2017), are not available in the public sector of the Western Cape. Basic prosthetic components made for low level activity, indoor and limited outdoor mobility, with the aim to assist the masses, as opposed to individual needs, are the only option. Most clients, reliant on public health care services in the Western Cape, are, however, from lower income groups. They often work as labourers or need to walk long distances to access services or transport. The surfaces they need to traverse are often uneven, sandy or rocky. Thus, they require a higher level of responsiveness from their prostheses (Magnusson *et al.* 2013; Hagberg *et al*. 2007).

2.8 Satisfaction with the prosthesis

Satisfaction with the prosthesis may dependent on variable factors, such as socket fit, user activity, prosthetic components or prosthetic alignment. In a retrospective study, Dillingham, Pezzin, MacKenzie and Burgess (2001) examined the prosthetic satisfaction of persons with lower limb, traumatic amputation. The people with above knee amputation used either a silesian belt or suction suspension. Half of the participants (57%) were not satisfied with their prosthesis. However, the correlation between the suspension system and patients' satisfaction was not investigated. Karmarkar *et al.* (2009) reported that high levels of satisfaction with the prosthesis did not necessarily translate as an increased use of prostheses, or necessarily improvement in terms of prosthetic mobility (Gholizadeh, Abu Osman, Eshraghi, Ali & Yahyavi 2013).

2.9 Summary

Epidemiological information shows that amputations are mainly performed due to vascular insufficiency. People who undergo amputations are often in the second half of their life. Both pre-prosthetic and prosthetic rehabilitation plays an important role in prosthetic function. Figures on above knee prosthetic use vary, but most studies appear to indicate a

use percentage of 75% to 85% daily use. However, while this percentage may seem high, mobility is often severely restricted and only a few above knee prosthetic users can walk with unlimited ease in the community. They, also, often need hand-held assistive devices in conjunction with the prosthesis. Very little research is available on prosthetic use and mobility in South Africa. What has been done dates back to the 90's. It is therefore difficult to describe or compare current prosthetic use in the Western Cape with current international research findings, as summarised above. There is a clear pre-prosthetic rehabilitation pathway in the Western Cape, however, since being implemented prosthetic rehabilitation services has not been studied.

Prosthetic components should be functional, yet, at the same time, affordable and durable. Components used in the public sector, in the Western Cape, are limited to basic level only, as classified by the WHO. These components have the advantage of durability and affordability, but offer an activity level of indoor, to limited outdoor use, only. Prosthetic components and fit also plays a role in prosthetic use and prosthetic mobility, which should be taken into consideration when looking at outcomes.

3 Chapter Three: Methodology

3.1 Introduction

Chapter 3 describes why a quantitative descriptive methodology was used. It introduces the reader to the study setting and explains how the study population was demarcated and the study participants identified. The reasons for adapting an existing tool with which to collect data and the changes made are explained. The methodology then describes the recruitment, role and training of research assistants. The pilot study, data collection and analyses processes are, subsequently, explained. The chapter ends with an overview of the ethical considerations relevant to the study.

3.2 Study Design

A quantitative cross sectional, descriptive design was used in this observational study (Carter, Lubinsky & Dumholdt 2011). Descriptive studies aim to identify, quantify and describe characteristics in a specific population (Joubert & Ehrlich 2007). In this study, the data collected was aimed at describing prosthetic use and prosthetic mobility, as well as exploring factors associated (positively or negatively) with prosthetic use and mobility, without intervening in any way.

3.3 Study Setting

The study was conducted by means of telephonic interviews with participants residing in the Western Cape Province. The Western Cape Province has a total population of 6 362 000 people. The average household in the province lives in a formal dwelling (80%), has adequate sanitation (94.3%), has access to tap water in their dwelling (98.7%), has electricity (80.9%), and weekly removal of refuse (90.7%). Most households (95.8%) have a land line or cellphone, or both, while 68.5% have access to the internet (Statistics South Africa 2016). The major languages spoken in the Western Cape Province are Afrikaans (34.9%), followed by isiXhosa (29.2%) and English (27.8%) (Statistics South Africa 2012).

The population is racially diverse and is comprised of 42.4% Coloured, 38.6% Black African, 15.7% White, 1.4% Indian / Asian and 1.9% Other. The male to female ratio is fairly equal with 51.1% females compared to 48.9% males. The education levels of the province reflect that 50.2% of the population has an education level below grade 12, 29% have successfully completed grade 12 and 18,8% has some tertiary education (StatsSA 2012). The unemployment rate of the province is 25.5%, the lowest in South Africa (StatsSA 2016).

Participants were identified through the two pre-prosthetic screening clinics, held at WCRC and GSH (as described in Chapter 1). The rehabilitation of persons with amputations at

WCRC consists of pre-prosthetic and prosthetic rehabilitation, managed dominantly by the physiotherapy department. Pre-prosthetic rehabilitation and uncomplicated below, and through knee prosthetic rehabilitation are conducted on an out-patient basis, whilst above knee prosthetic training is done on an in, or outpatient basis, depending on the needs of the client (WCDoH 2010). At GSH, the pre-prosthetic clinic is managed by the physiotherapy department, as an outpatient service, with referrals from within the hospital and from relevant CHC services. It was not routine practice (at the time of the study) for GSH clients to receive follow up appointments at the clinic, after receiving prostheses.

3.4 Study Population, sampling and participants

The study population consisted of all persons with a unilateral above knee amputation who had received prostheses after screening, at either the Western Cape Rehab Centre (WCRC), or Groote Schuur Hospital (GSH) prosthetic screening clinics, between 1 June 2011 and 31 December 2014. The reason for only including clients from the WCRC and GSH screening clinics was three-fold:

1. The majority of persons with an above knee amputation who received prostheses from Western Cape Government services, are referred from one of these two clinics. Alternative to these clinics, are the OPC outreach clinics that take place a few times per year outside of the city's metropolitan borders, at towns upcountry. Referrals for AK prosthesis from the outreach clinics however are few as potential candidates are referred to either GSH or WCRC's clinic.
2. The services at the GSH and WCRC clinics are guided by a pathway set out by '*Guidelines for Screening of Prosthetic Candidates: Lower Limb'* (WDOH, 2010) (Appendix 1). Both clinics are managed by physiotherapy services and following the same treatment protocol guided by the screening tool (Appendix 1). The outreach clinics referrals are not necessarily managed by physiotherapy services, it can be managed by an orthopaedic sister, or an orthotist. This means that persons with AKA might not undergo the in-depth pre-prosthetic rehabilitation as at the clinics at GSH and WCRC which might bring in bias at recruitment.
3. This study is interested to observe prosthetic use post implementation of the screening tool; hence including only clinics that implement the tool to a high standard was of utmost importance.

Eighty-eight names were identified from the records of the Provincial Orthotic and Prosthetic Centre (OPC), located in Pinelands, Cape Town.

Inclusion Criteria

- Persons 18 years and older with unilateral above knee amputation
- Persons who received their prosthesis from the OPC after referral from the prosthetic screening clinics at WCRC or GSH
- Persons fluent in Afrikaans, isiXhosa or English, the three languages most commonly spoken in the Western Cape. For purposes of data collection, persons who were not fluent in at least one of these languages had to be excluded
- Persons with access to a phone as data was collected by phone

Exclusion Criteria

- Persons with unilateral lower limb amputation at a level other than above the knee.
- Persons with bilateral lower limb amputations
- Persons with unilateral above knee amputation who did not meet the government criteria to receive a prosthesis from the OPC
- Persons who had received a prosthesis through the OPC outreach clinics, either at rural hospitals, or community health centres
- Persons who obtained their prosthesis privately
- Persons with additional major upper limb amputation (e.g. hand or arm) or upper limb impairment (e.g. brachial plexus injury) that interfered with hand function and crutch walking ability
- Persons with above knee amputation who suffered from additional co-morbidities such as cerebro-vascular accidents, extensive peripheral neural damage, spinal cord injury, or head injury that could negatively impact their function
- Persons who had passed away by time of data collection

From the initial 88 persons identified, 13 had to be excluded, based on the exclusion criteria. This was due to people who had passed away (7), people who had, subsequently, undergone a further amputation (5) and one person who did not have access to a phone. This left 75 people for potential recruitment; no sampling was done and attempts were made to contact all 75. Thirty persons could not be located due to either a change in phone number, or unanswered phone call (three attempts were made on separate days and times), or no response to a text message. Two people initially gave consent, however, on follow up contact, did not answer the phone or were not available. In total, 43 people participated in the study, which calculated as 57% from a potential 75 participants.

3.5 Data Collection Instruments

Data was collected through a questionnaire (Appendix 4), based on the *Prosthetic Profile of the Amputee (PPA),* which had been developed by Grise, Gauthier-Gagnon and Martineau (1993), to collect data on prosthetic use and mobility in elderly Canadian populations. Validity and reliability had been demonstrated for elderly Canadian populations (Gauthier-Gagnon & Grise 1994). The PPA evaluates prosthetic use amongst persons with lower limb amputations and the factors related to use or disuse of such prosthetics. The questionnaire consists of five sections: 1) co-morbidities, 2) demographic characteristics, 3) prosthetic use and mobility, 4) physical environment, 5) satisfaction with prosthesis.

To determine the profile of the person with lower limb amputation and the factors related to prosthetic use, associations between the outcome variable and various independent variables can be explained (Zidarov, Swaine & Gauthier-Gagnon 2009).

Approval to use and adapt the PPA was obtained from the developer, via e-mail (Appendix 5), on condition that credit be given to the original authors and that this researcher be aware of the limitations when applying the PPA in populations other than those for whom it had been developed. Validity and reliability had been demonstrated for elderly Canadian populations (Gauthier-Gagnon & Grise 1994) who lives in a developed country, thus culturally very different from a South African setting. The questionnaire was hence adapted for use with a different population, in a different setting, i.e. the Western Cape Province of South African. Changes were made, referring to a study by Groenewald (1999), where an altered PPA questionnaire had also been used for data collection amongst persons with below knee amputation, in the Western Cape. The changes made to the original questionnaire are presented, in detail, in Appendix 11a and 11b.

In broad terms, the following issues were addressed in the alteration of the original PPA questionnaire:

- The language was changed to reflect South African English, rather than Canadian English, to facilitate understanding.
- Original questions, not applicable to the current study population, or study aims, were removed.
- Questions applicable to the current study setting and study aims that were not in the original PPA, were added.

Following Ethics approval of the English language questionnaire, it was translated into Afrikaans and Xhosa by translators from the Language Services of the Western Cape Department of Health. The translated copies were assessed by first language isiXhosa, and Afrikaans speaking professionals who worked in the field of prosthetic rehabilitation as either

prosthetist or a physiotherapist, by comparing the translations to the original English version. The adapted, translated questionnaires were used in the pilot study after which further minor changes were made.

3.6 Research Assistants

Three research assistants collected the data by means of telephonic interviews. The research assistants were WCRC colleagues who had volunteered to act as research assistants. The volunteers were not directly involved in the provision of prosthetic rehabilitation services at WCRC. Approval from WCRC management was given with recognition of data collection time commitments. The research assistants could between them speak Afrikaans, English, and isiXhosa fluently. All were comfortable with being audio recorded. The researcher introduced them to the study and their roles. The process of data collection was explained, step by step, as follows:

1. Introduction and confirming the participant's identity by name
2. Information as set out in the Information Leaflet and Consent Form to be shared. In addition, consent for recording the interview was asked and formed part of the consent given.
3. Informed consent obtained verbally over the phone, recorded as evidence
4. Verification of demographic data
5. Completion of the adapted PPA questionnaire. The questions had to be read as it was written, without rephrasing or additional explanations to the participant. The questions could be repeated.
6. Questions or comments from the participants in addition to the data collected were recorded in writing and referred to the researcher.
7. All telephone interviews were audio recorded (dictaphone).
8. All telephone calls were documented and telephone costs were paid by the researcher.

The importance of confidentiality was explained to the research assistants. Research assistants signed a confidentiality form (Appendix 7), prior to data collection. The data collection interview was practised amongst research assistants through role play, while the researcher provided feedback.

3.7 Pilot Study

The pilot study was conducted with 3 volunteers; one English speaking person with a unilateral above knee amputation using a private prosthesis and two people with unilateral below knee amputations using government issued prostheses and who were Afrikaans and

isiXhosa speaking respectively. The three participants were interviewed via telephone by the three research assistants, using the adapted PPA questionnaire. These volunteers did not participate in the main study as they did not fit the inclusion criteria.

The pilot study provided research assistants with the opportunity to practise and familiarise themselves with the questionnaire and recording process. Each pilot study participant was interviewed twice, but by different research assistants. This provided an opportunity to assess if answers to the same questions, but asked by two different research assistants, were consistent and, if not, to explore possible reasons for the variations. Is it due to ambiguity of questions, or, could the answer be misinterpreted by the research assistants? The process helped to determine if 1) the questions in the questionnaire were understood by participants, 2) whether answers were recorded correctly by the research assistant, 3) if the questions followed a logical sequence and 4) how long it took to complete the questionnaire. 5) It also reflected that the questionnaire collected information that could address the study aims and objectives.

3.8 Data Collection

Demographic data was collected from the Government's patient database, Clinicom software, and recorded on the data sheet by the researcher (Appendix 2). Clients who met the inclusion criteria were phoned by the researcher to ask whether they were interested in participating in the study. They were informed that the interview will be telephonic, and that the interview will be recorded via a Dictaphone as evidence of consent and to verify data given. The researcher asked if the client will be comfortable to be recorded prior to putting their name forward to be contacted for the research interview. In instances where an eligible participant could not be reached, after attempts to contact them, telephonically, on at least 3 occasions, on 3 separate days, a text message was sent to their phone, explaining the reason for the missed call. If they were interested in participating in the study, they could reply with a text saying 'yes 'and the researcher would phone again. The process was captured on a data sheet (Appendix 2). The telephone conversation was initiated in English, however, in instances where English was not understood, either Afrikaans was used by the researcher, or the call was terminated and the isiXhosa speaking research assistant phoned the person back. A date and time for data collection was set with those who were interested in participating in the study. The participants were asked to indicate in which language they would prefer to be interviewed.

Data collection was conducted in May and June 2015 by means of recorded telephonic interviews. The three research assistants conducted the interviews in the languages of the participants` choice. First, after verification of person, the purpose of the study was

explained to the participant as set out in the information leaflet (Appendix 6), after which consent to record the interview and consent for taking part in study was obtained. Demographic data was verified with the individual, followed by completion of the adapted PPA questionnaire. All interviews were audio recorded, by dictaphone, as proof of informed consent and data collection. There was an opportunity at the end of the interview for questions or comments from the study participants. Interviews lasted between 15 and 25 minutes.

3.9 Data Analysis

Demographic data and answers from the questionnaire was coded and captured on an Excel spread sheet by the researcher. The PPA questionnaire collects mostly nominal, categorical data, that was described in percentages, and presented in tables and graphs.

- Prosthetic mobility: in terms of hand-held devices used were described through comparative figures and clinical trends between variables.

Further analysis of data was performed between certain variables using the Chi-Square test, to determine whether there were any statistically significant relationships between groups. Variables tested:

- To determine the relationship between the demographic, medical and rehabilitation variables (age, time since amputation, cause for amputation, prosthetic rehabilitation) and prosthetic use.
- To determine the relationship between prosthetic use and prosthetic mobility: in terms of reported distances walked
- To determine the relationship between prosthetic rehabilitation and prosthetic mobility: distances

A significance level of alpha ($p < 0.05$) was determined.

3.10 Ethical Implications

There are four, basic, ethical considerations in health care research (Joubert & Ehrlich, 2007). This section describes how these principles were applied in the current study.

Principle of Beneficence

The principle of *Beneficence* in health research focuses on bringing benefit to patients in the future. Immediate benefits are put aside for the promise of new knowledge in research (Carter *et al.* 2011). The outcome of the study may assist in guiding professional staff involved in prosthetic rehabilitation with the addition of necessary information. This information may offer more effective prosthetic rehabilitation programs and pathways to

future patients with an above knee amputation. The study participants will only benefit from the satisfaction of helping in the current research.

Principle of Non-maleficence

This principle focuses on not exposing participants to unnecessary risks (Carter *et al.* 2011). Data collection was conducted by means of participants' answering a questionnaire about their mobility and prosthetic use and was not collected by means of any intervention or physical measure. Other than emotional feelings of pride or disappointment regarding their own mobility status, the participants were not exposed to risks and no problems in this regard were reported during data collection. The research assistants collected data with sensitivity to not cause harm of any kind to participants.

Participant's personal details were kept confidential to eliminate any social harm to their reputation or person name (Carter *et al.* 2011). Confidentiality was assured by giving each participant a randomly assigned number, namely, their participant number. Only this number was used as identification. The list where client names and their respective, assigned research identification number were recorded, was stored in electronic format, on the researcher`s computer, with password protected software. The captured data, was stored electronically on the researcher`s computer and backed up on an external hard drive, which was secured by means of a password and was only shared for purposes of data analysis. The data will be kept until dissemination has been completed.

Principle of Autonomy

Autonomy at research level, revolves around informed consent (Carter *et al*. 2011). **Informed consent** is an ongoing process throughout the research event and is not just an isolated action of giving consent at the beginning of the study.

- *Disclosure* – The study was explained, in detail, to the participants, in their language of choice, i.e. Afrikaans, English or isiXhosa. The explanation was given telephonically and there was opportunity for questions.
- *Comprehension* – Lay terms were used much as possible in the study explanation of the study, prior to consent, and during the questionnaire. The research assistants allowed sufficient time for the answering of questions and repeated questions where necessary.
- *Voluntariness* – The researcher and research assistants emphasized to participants that their participation in the study was on a voluntary basis and that refusing to continue, at any point, would not negatively impact future health care needs. Giving consent, initially, did not mean participants were bound to completing the questionnaire.

- *Competence* – Participants recruited, according to the inclusion criteria, were all legally empowered to make decisions for themselves, as they were 18 years and older. Severe cognitive fallout or psychological instability is a contra-indication for receiving prostheses in government services, in the Western Cape. Thus, these issues should not have been present and could not have impacted the consent process.

Informed consent was obtained telephonically (Appendix 6), and recorded by a Dictaphone and signed for by a witness.

Justice

Participants were treated equally during recruitment and data collection. Recruitment of participants occurred according to the inclusion criteria, set out in the methodology, without any discrimination on the basis of gender, age, ethnicity or preference of language. In the data collection phase, the researcher and research assistants treated everyone fairly.

Approval from Authorities

The proposed study was ethically approved by the Human Research Ethics Committee of the University of Stellenbosch, with ethics reference number: S14/10/215. Informed consent letter does accommodate for informed consent given over the phone (Appendix 6). Permission from Western Cape Department of Health was obtained, as well as permission from the CEO of WCRC and OPC, along with approval to access GSH prosthetic clinic patient names (Appendix 8).

The researcher signed the plagiarism declaration and adhered to it at all times. The researcher will ensure to the best of her ability, and with the guidance of her supervisor, that the results are reported honestly and correctly.

3.11 Summary

The study aimed at describing prosthetic mobility and prosthetic use amongst people with an above knee amputation. A descriptive study design was used and, after implementing the exclusion criteria, 75 participants were eligible of which 43 completed the data collection process by answering a questionnaire adapted for this particular population. Descriptive and inferential analysis of data was performed. A pilot study was conducted prior to data collection. The researcher and research assistants adhered to ethical considerations, such as, beneficence and non-maleficence, autonomy, and confidentiality, throughout the study. Approval from the Health Research Ethics Committee of the University of Stellenbosch was obtained for the execution of this study.

4 Chapter Four: Results

4.1 Introduction

This chapter presents the findings of the interviews of the 43 participants, according to the study objectives. It describes prosthetic use, in terms of the period of time the prosthesis was worn and prosthetic mobility, in terms of distances walked and dependence on the additional use of elbow crutches with indoor and outdoor mobility, across different walking terrains.

4.2 Demographic and medical profile of study participants

4.2.1 Age and gender

The mean age of the study participants was 55.2 years. Ages ranged from minimum, 19 to maximum, 80 years. Figure 4.1 illustrates that ages are relatively evenly distributed between the age groups with the age category 50 to 59 years occurring the most commonly. The majority of study participants were men (34; 79%) with a male-to-female ratio of just below 3:1.

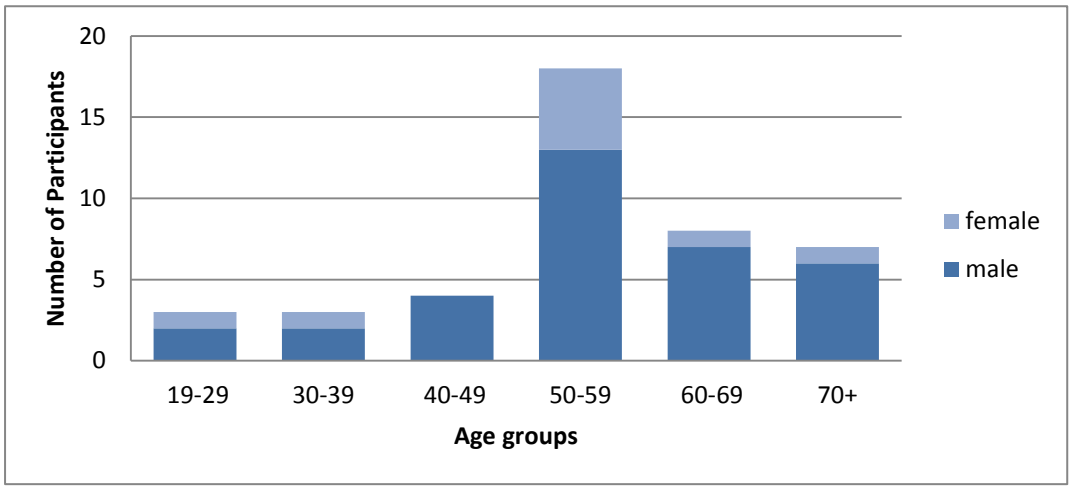

Figure 4.1: Age and gender distribution of the study participants (n=43)

4.2.2 Cause of amputation

Vascular conditions (20; 47%) followed by diabetes (10; 23%), were the reasons for the highest number of amputations, illustrated in Figure 4.2. These figures were followed by trauma (7; 16%), cancer and infection.

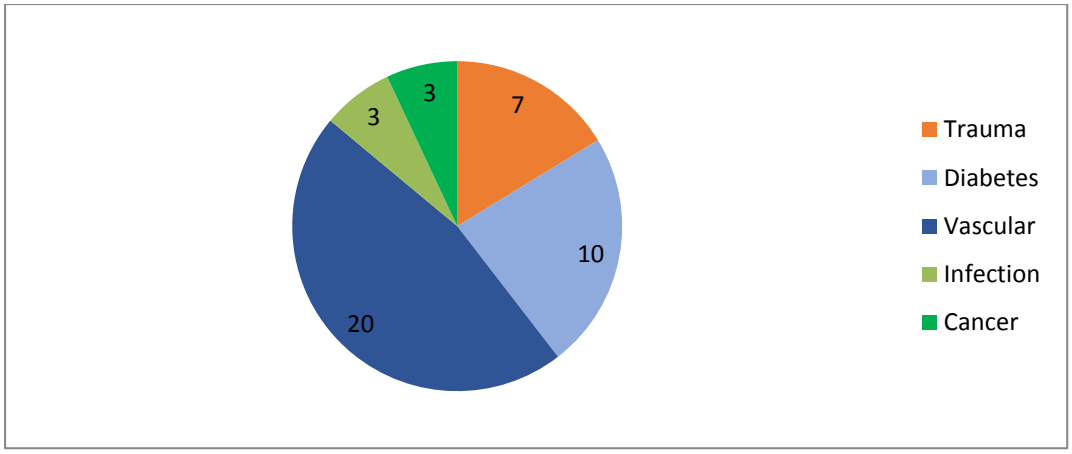

Figure 4.2: Cause of amputation (n=43)

Figure 4.3 shows the cause of amputation across the age groups. Non vascular causes were mostly found in the age group below 50 years and the majority of vascular causes was found in the age group above 50 years.

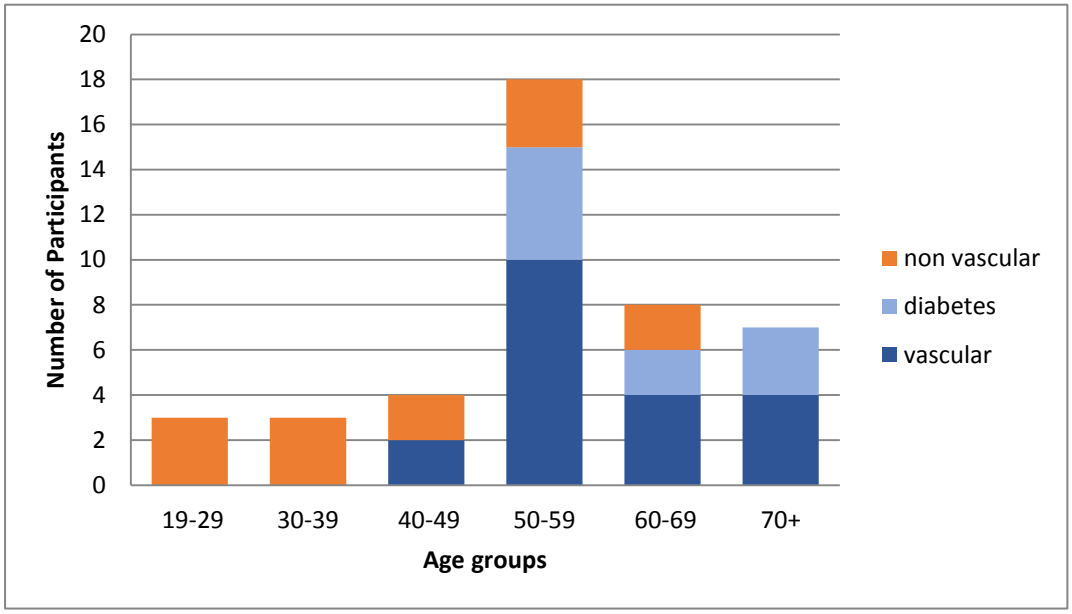

Figure 4.3: Cause of amputation across age groups (n=43)

4.2.3 Residual limb problems

Just over half of the study population (24; 56%) reported residual limb problems (Figure 4.4). The three most common problems were:

- Phantom pain (14, 33%)
- Residual limb swelling (11, 26%)
- Residual limb pain (7, 16%)

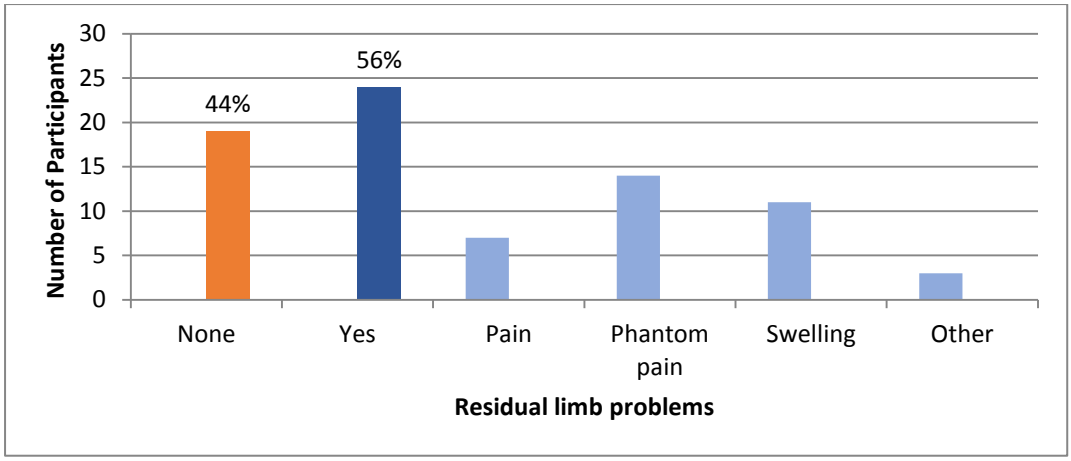

Figure 4.4: Residual limb problems experienced by study participants (n=43)

4.2.4 Contra-lateral leg

The majority of participants (27, 64%) reported having a healthy, intact contra-lateral leg**.** Figure 4.5 shows that amongst the sixteen participants (36%) who reported problems, circulation (7; 16%), pain (6; 14%) and swelling (6; 14%) were the main concerns.

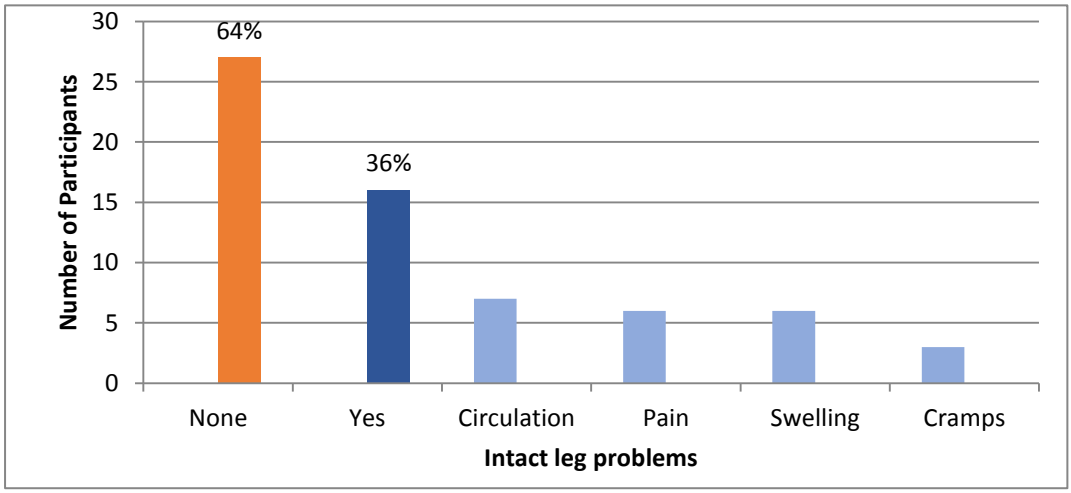

Figure 4.5: Problems experienced with the contra-lateral intact leg (n=43)

4.2.5 Return to employment

The statutory retirement age, in South Africa, starts at 60 years. Of the twenty eight participants younger than 60 years, 79% (22) were dependent on a disability grant, meaning 21% (6) were either gainfully employed, or a full time student at the time of the study.

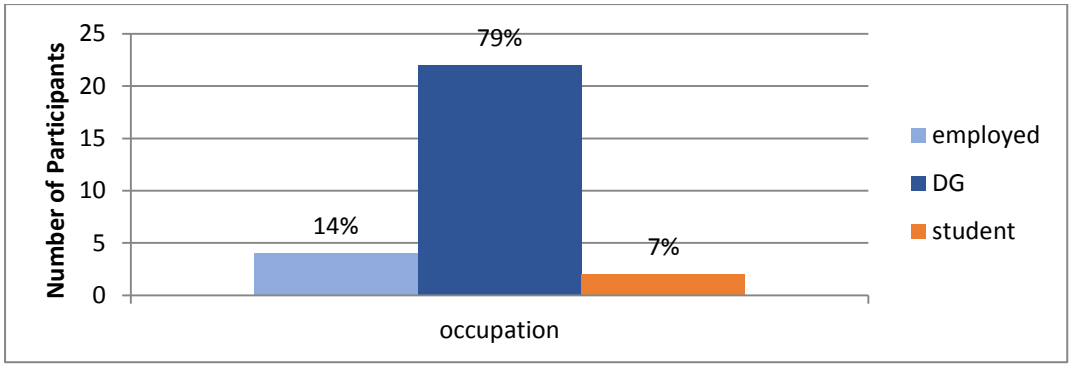

Figure 4.6: Employment status of participants 60 years and younger (n=28)

4.2.6 Waiting time for first prosthesis

Forty two percent (18) of participants had received their prosthesis within a year of the amputation, while 12% (5) had waited more than three years for their prosthesis. Figure 4.7 shows that 73 % (11) of participants referred by the tertiary hospital's (GSH) pre-prosthetic screening clinic had received their prosthesis within the first year compared to 25% (7) of those referred by the rehabilitation hospital (WCRC).

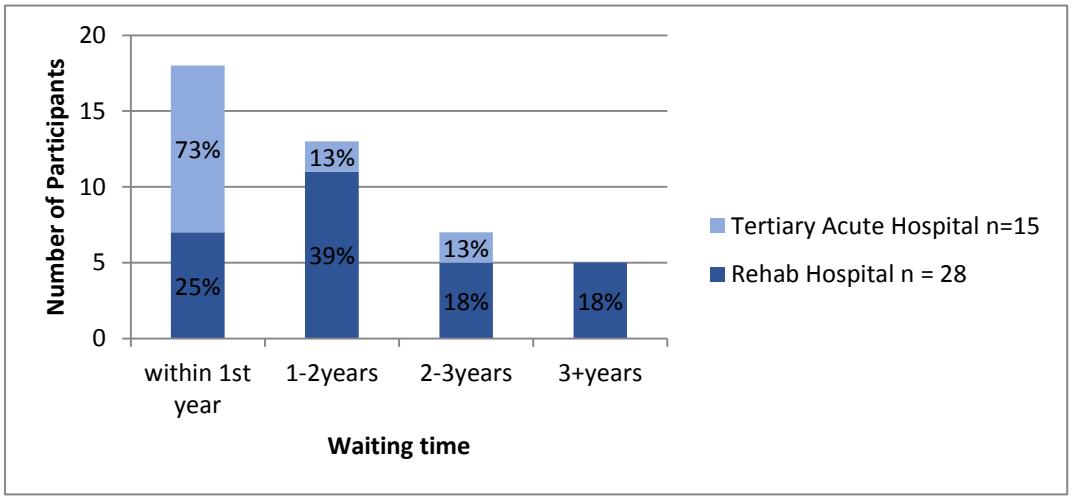

Figure 4.7: Waiting time from amputation till first prosthesis (n=43)

Whether participants had waited less than a year, between 1 and 2 years or more than 2 years for their prosthesis, had no clinical or statistically significant (p=0.649) impact on prosthetic use.

4.3 Prosthetic Use

Four of the 43 participants needed assistance to don their prosthesis, the rest could do so independently. Eighty one percent (35) of participants wore their prosthesis at least once a week, or more as shown in Figure 4.8. Of this total, 20 (mean age of 53 years) uses the prosthesis 5 days and more per week, and fifteen (mean age of 57.5 years) uses their prosthesis 3 days or less per week. A total of 42% (18) of participants reported daily prosthetic use.

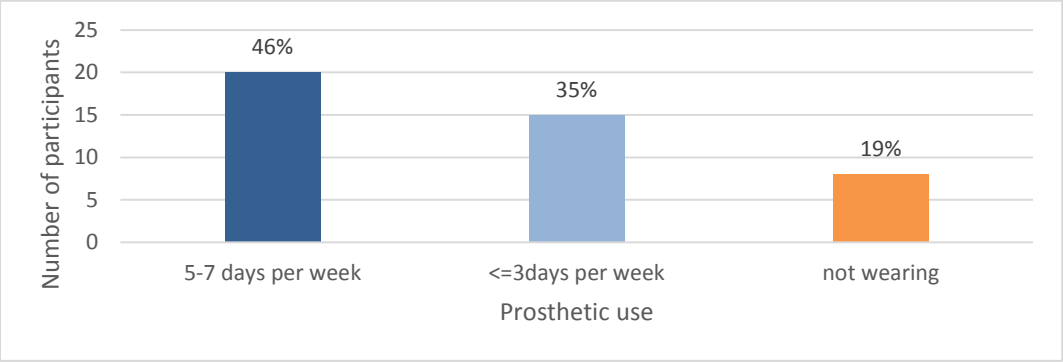

Figure 4.8: Prosthetic use of participants (n=43)

4.3.1 Reasons for non-use

Prosthetic fitting problems (5; 63%) were the main reasons given for non-use. Participants who used their prosthesis the most, experienced the least fitting problems. Those wearing their prosthesis 5-7days per week reported residual limb sweating inside the socket, as their main concern (5; 25%) and those not wearing their prosthesis, reported skin irritation and pain (5; 63%) as the main concerns. Other reasons for non-use included:

- Tiring to walk with prosthesis (4)
- Prosthesis is heavy (3)
- Fear of falling (2)
- Pain (2)
- Do not know how to walk with the prosthesis (1)
- Slow (1)

4.3.2 Prosthetic use and age

More frequent prosthetic use was found among age groups below 60 years compared to those participants above 60 years. Non-use occurred in all age groups and could not be

related to a greater, or lesser, extent, to age, as Figure 4.9 shows**.** Age did not have a statistically significant impact on prosthetic use (p = 0.121).

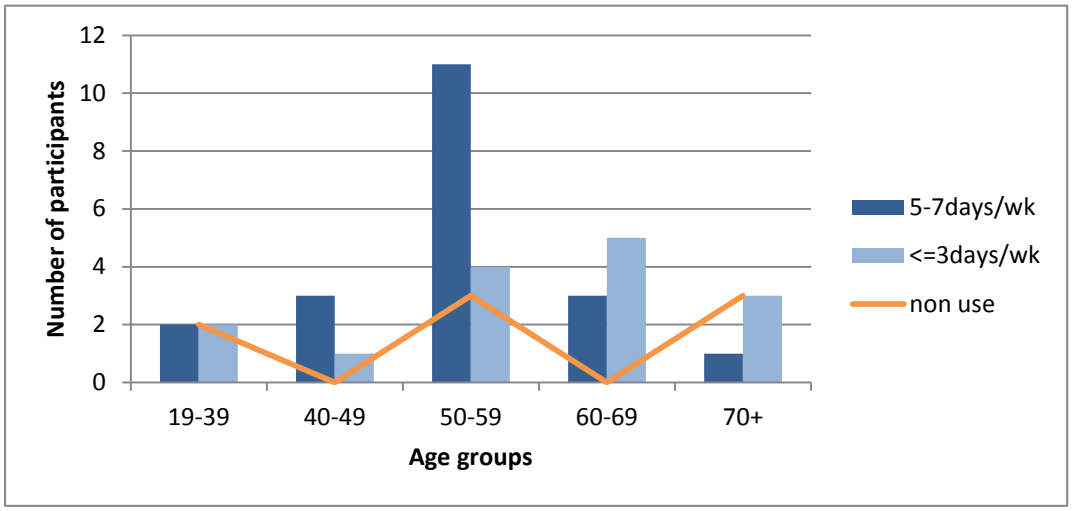

Figure 4.9: Age and prosthetic use

4.3.3 Prosthetic use and cause of amputation

According to Table 4.1, participants who had had an amputation for non vascular reasons, used their prostheses more often (5 – 7 days per week) than those who had had an amputation for vascular reasons. The groups showed similar percentages of non-use. No statistically significant relationship could be found between cause of amputation and prosthetic use (p=0.627).

Table 4.1: Cause of amputation and prosthetic use

Cause of amputation and prosthetic use		
	Vascular n = 30	**Non Vascular n = 13**
5 – 7 days/week	12 (40%)	8 (62%)
<= 3 days/week	12 (40%)	3 (23%)
Non use	6 (20%)	2 (15%)

4.4 Prosthetic Mobility

4.4.1 Indoor and outdoor mobility

Figure 4.10 shows that more participants used their prosthesis for outdoor mobility 86% (30), compared to indoor mobility 63% (22).

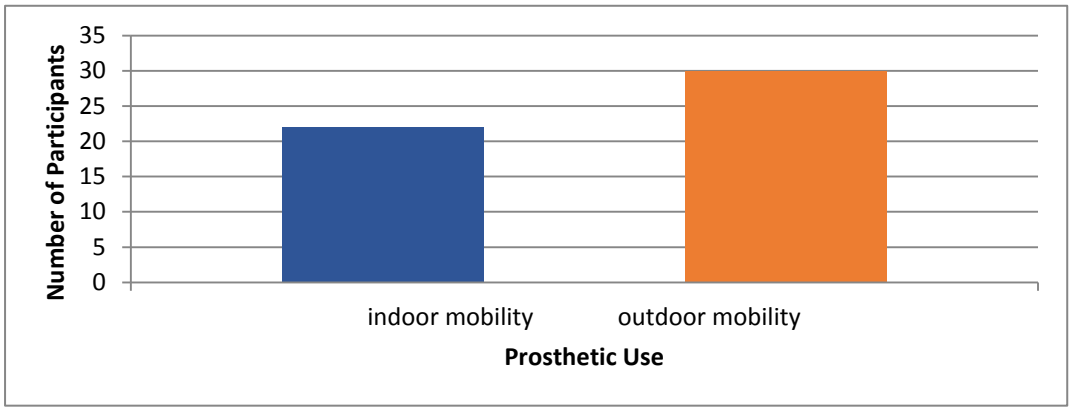

Figure 4.10: Indoor and outdoor mobility (n=35)

Of the 13 participants with the ability to walk with the prosthesis indoors, but chose not to do so, most of the time, just over half of the participants (7; 54%) cited the main reason for not opting for prosthetic walking being that their moving ability was too slow.

Other reasons given included:

- Tiring to walk with prosthesis (2), walking feels unsteady (1), easier to move without it (1) and more functional without prosthesis (1)
- Need to use crutches and, thus, have no hands free for tasks (1)
- Challenges related to prosthesis (2), such as fitting discomfort and sweating inside socket.

4.4.2 Prosthetic Mobility with and without crutch(es)

Over different terrain: Figure 4.11 shows that as the demands of the terrain increased, more participants used one or two crutches. In total, 26% (9) participants did not rely on any hand held assisted devices during prosthetic mobility across all terrains.

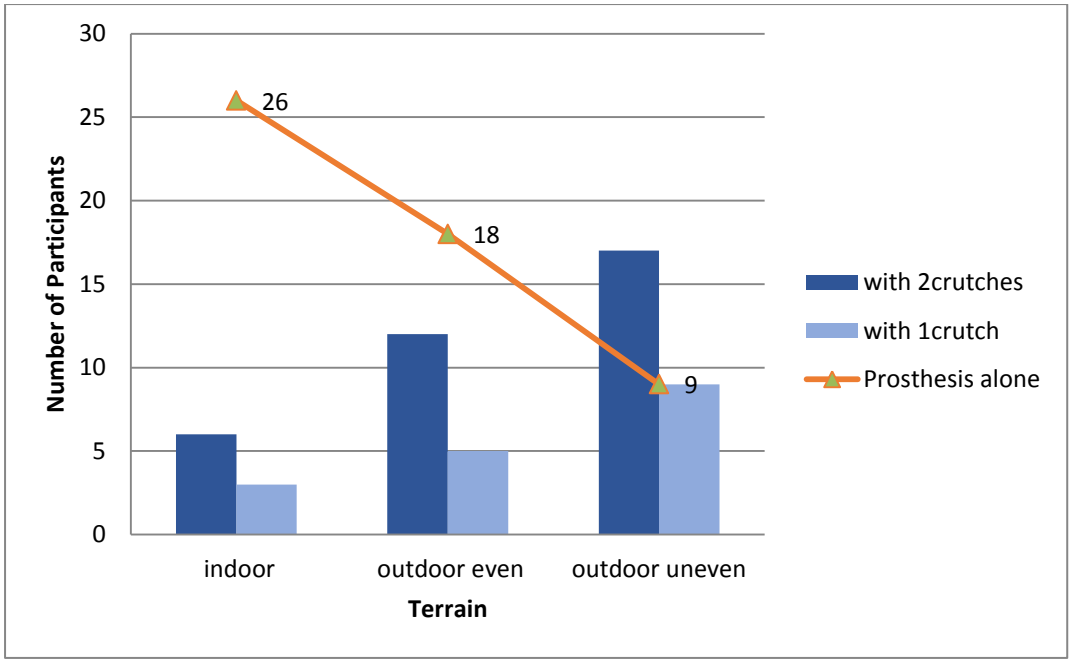

Figure 4.11: Prosthetic mobility and crutch use over different terrains (n=35)

Prosthetic use: As shown in Table 4.2, participants who used their prosthesis more frequently, showed less dependency on elbow crutches during prosthetic mobility across terrains.

Table 4.2: Prosthetic mobility across different terrain and prosthetic use

	Different Terrain		
Prosthetic use	**Indoor**	**Outdoor even**	**Outdoor uneven**
5-7days/ week **(n=20)**	**85% prosth alone** 5% +1 crutch 10% +2 crutches	**60% prosth alone** 10% +1 crutch 30% +2 crutches	25% prosth alone 35% +1 crutch **40% +2 crutches**
<= 3days/ week **(n=15)**	**60% prosth alone** 13% +1 crutch 27% +2 crutches	40% prosth alone 20% +1 crutch 40% +2 crutches	26% prosth alone 14% +1 crutch **60% +2 crutches**

Climbing stairs with hand-rail:

All participants could perform the task with 51% (18) doing it using the prosthesis only.

Climbing stairs, no rail:

- 14% (5) were unable to do the task
- 66% (23) needed additional assistive devices: either one (10), or two (13) elbow crutches

Carrying objects whilst walking with prosthesis:

- 70% (30) were able to carry an object using one hand
- 28% (12) were able to carry an object with both hands

4.4.3 Prosthetic Mobility with or without crutches across age groups

Most participants (70%) younger than 60 years, could walk with their prosthesis alone, over even terrain. However, the majority of participants older than 60 years, (83%) relied on elbow crutches for prosthetic mobility over even terrain (indoor and outdoor). None of the 4 participants aged 70+ years could walk with the prosthesis alone. Outdoor, uneven terrain proved most challenging across all ages, however, those aged over 60 years relied the most (83%) on 2 elbow crutches.

Table 4.3: Prosthetic mobility across age groups

Prosthetic Mobility across terrain			
Age	**Indoor**	**Outdoor even**	**Outdoor uneven**
< 40 (n=4)	100% prosth alone	75% prosth alone	**50% prosth alone** 50% +1 crutch
40 – 49 (n=4)	100% prosth alone	**100% prosth alone**	25% prosth alone 75% +1 crutch
50 – 59 (n=15)	93% prosth alone	60% prosth alone 20% +1 crutch	40% prosth alone 46% +2 crutches
60 -69 (n=8)	50% prosth alone	25% prosth alone 63% +2 crutches	**75% +2 crutches** 25% +1 crutch
70+ (n=4)	**75% +2 crutches**	75% +2 crutches	100% +2 crutches

4.4.4 Prosthetic mobility with or without crutches and cause of amputation

Table 4.4 shows that the cause of the amputation showed little difference in whether participants needed crutches to walk in the different settings.

Table 4.4: Prosthetic mobility without crutch(es) over different terrain

	Participants walking without crutches		
Prosthetic Users n = 35	**Indoor terrain**	**outdoor even terrain**	**outdoor uneven terrain**
Non vascular n = 11	8 (73%)	6 (55%)	2 (18%)
Vascular (including diabetes) n = 24	18 (75%)	12 (50%)	7 (30%)

4.4.5 Walking distance

According to Figure 4.12, most participants (24; 70%) were limited to a walking distance of less than 500 steps without resting. Approximately half of the participants (19; 56%) were limited to fewer than 200 steps and only 5 % (2) of the participants reported being able to walk 1000 steps or more at a time. Further analysis showed no significant relationship between walking distance and age (p = 0.498) or walking distance and prosthetic use (p = 0.221). A statistically significant relationship (p=0.000) was found between walking distance and prosthetic rehabilitation, this will be discussed further in section 4.5 following.

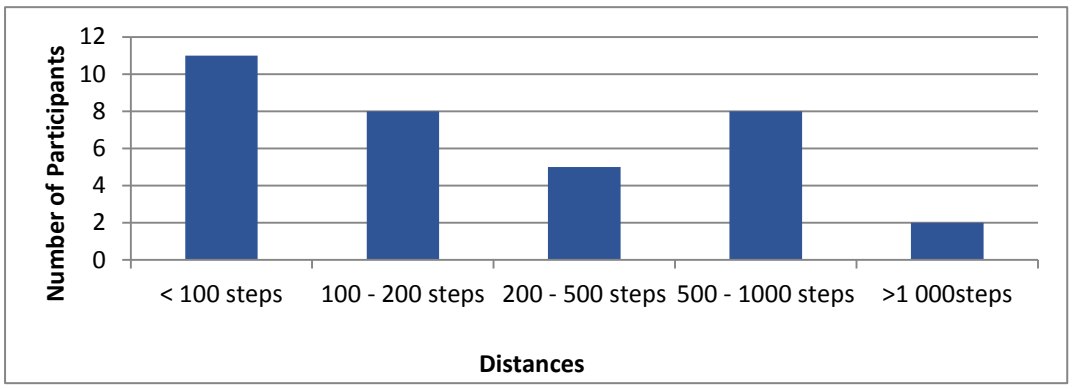

Figure 4.12: Walking distances with the prosthesis without stopping

4.5 Prosthetic Rehabilitation

Less than half (16; 37%) of the study participants had received at least one session of prosthetic rehabilitation and one participant had received inpatient rehabilitation. Figure 4.13 shows that within the group who had received prosthetic rehabilitation, a higher percentage of participants (59%) wore their prosthesis 5-7 days per week than those who had not received rehabilitation (38%). This might have a positive clinical impact, however further analysis shown no significant relationship between prosthetic rehabilitation and prosthetic use (p = 0.349).

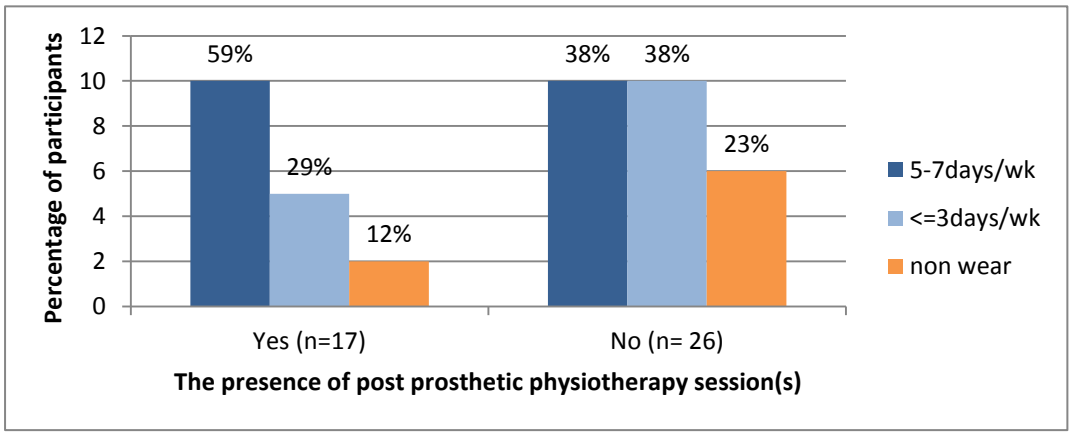

Figure 4.11: Prosthetic rehabilitation and prosthetic use (n=43)

The majority (32; 74%) of the participants felt that prosthetic rehabilitation was or would have been beneficial to their prosthetic mobility performance. This was reflected in walking distance, where a statistically significant relationship (p=0.000) was found between walking distance and prosthetic rehabilitation, indicating that those that received prosthetic rehabilitation walked longer distances than those who did not. Descriptive data shown that those who received prosthetic rehabilitation, in general, reported less dependency on elbow crutches mobilising over outdoor terrain; 26% relied on 2 elbow crutches compared to 65% from the group who did not receive prosthetic rehabilitation.

4.6 Experience of prosthesis

4.6.1 Meeting of participants' initial expectations

Less than half (19; 44%) of the participants felt their prosthesis completely met their expectations (Figure 4.14).

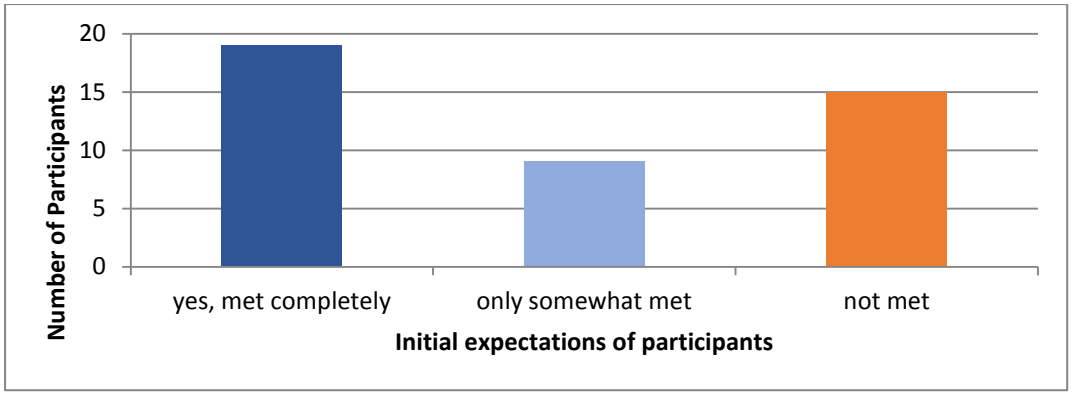

Figure 4.12: Extent to which prosthesis met participant's initial expectations (n = 43)

A higher number of participants who used their prosthesis more often indicated that their expectations of the prostheses were met, as shown in Table 4.5. Those that received prosthetic rehabilitation also indicated a higher number of expectations being met.

Table 4.5 Days per week used compared to expectations being met (n = 35)

Expectations	not met	somewhat met	completely met
5-7days/wk n=20	2 (10%)	6 (30%)	12 (60%)
<=3days/wk n=15	6 (40%)	3 (20%)	6 (40%)

4.6.2 Satisfaction with the prosthesis

Figure 4.15 shows higher levels of satisfaction (71% and more) with prosthetic comfort, look and weight amongst participants who used prostheses, than those who did not use prostheses.

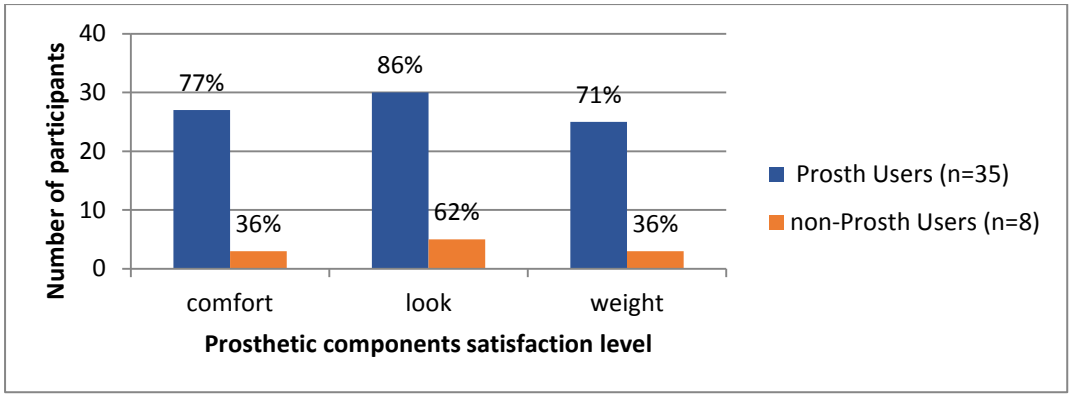

Figure 4.13: Satisfaction with prosthesis amongst participants (n=43)

Figure 4.16 shows that of the participants who used the prosthesis 5-7days per week, 85% (17) were completely, to moderately, satisfied with the way they walked. A similar result was found amongst those using the prosthesis 3 days or less per week, with 80% (12) of the participants being completely, to moderately, satisfied with the way they walked. In total, however only 43% (15) was completely satisfied with the way they walked.

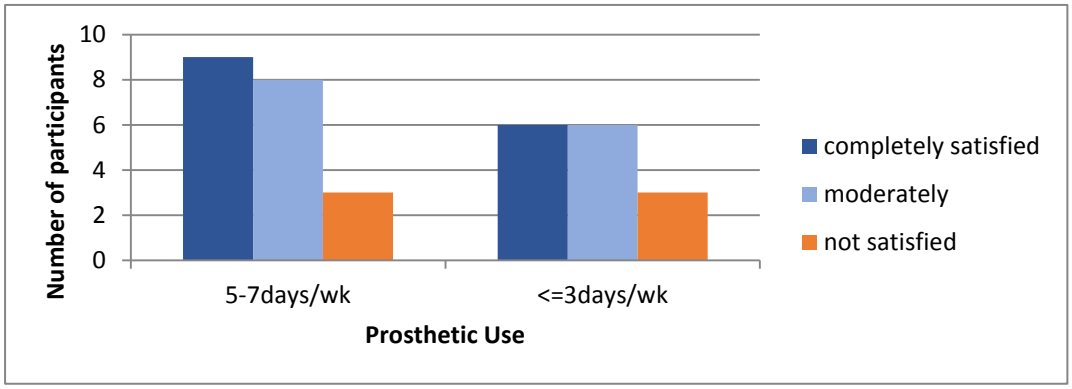

Figure 4.14: Satisfaction with the way participants walked with their prosthesis

4.7 Summary

This study included 43 participants who had a unilateral, above knee amputation and had received a prosthesis. More than half waited more than a year before being issued with a prosthesis. The mean age was 55.2 years with ages ranging from 19 to 80 years, the majority being male and with 70 % reason for amputations being vascular problems, which included diabetes. The majority (81%) of participants used their prosthesis, however, only 41% used their prosthesis daily. Forty four percent of participants felt the prostheses completely met their initial expectations.

Participants that used prosthesis more often, had a younger mean age of 53 years, reported fewer prosthetic fitting problems and fewer residual limb problems. No statistically significant

relationships were reported between prosthetic use and variables: age, cause of amputation, waiting time for prosthesis or prosthetic walking distance. Less than half of participants received any form of prosthetic rehabilitation, those that did, reported being able to walk longer distances, further analysis shown a significant level (p= 0.000) between prosthetic rehabilitation and walking distance with the prosthesis.

As the terrain became more challenging, the need for assistive devices increased across all age groups. Forty three percent of the reported prosthetic users were completely satisfied with the way they walked.

- Summary of descriptive and inferential results (Appendix 10)

5 Chapter 5: Discussion

5.1 Introduction

The aim of this study was to determine prosthetic mobility and prosthetic use of people with an above knee amputation (AKA), in the Western Cape. In this chapter, the findings from the 43 participants are discussed and compared to findings from similar studies in South Africa, Africa and internationally. The discussion follows the study objectives, namely, 1) describing the demographic profile, 2) describing prosthetic use, 3) determining prosthetic mobility that includes mobility with, or without, assistive devices, 4) discussing perceived barriers to prosthetic mobility 5) user's expectations of their prosthesis and 6) employment status of participants.

5.2 Demographic profile of the study population

In this study, the main cause of above knee amputations was vascular complications (including vascular disease and diabetes). Similar results were found in earlier studies conducted in the Western Cape, amongst people with lower limb amputation who had received rehabilitation (Fredericks & Visagie 2013; Bakkes 1999) and also, an epidemiological study (Hendry 1993). Thus, it seems as if during the last 30 years, the main cause of amputation in the Western Cape has remained vascular, which mirrors results reported in developed countries (Cumming *et al.* 2015; Asano *et al.* 2008) and some African countries (Murwanashyaka *et al.* 2013; Chalya *et al.* 2012).

The findings that study participants were for the most part younger than 60 years and predominantly male are similar to the results from other studies conducted in the Western Cape (Fredericks & Visagie 2013; Bakkes 1999), while the results reflect a slightly younger population than recorded by Hendry (1993). Younger aged people have been associated with increased referral for prosthesis and prosthetic use (Davie-Smith *et al.* 2015; Mundell *et al.* 2015). Current study participants included only those who had been referred for prostheses. This could possibly be the reason for the younger mean age of 55.2 years than the age group of 60.3 years, identified by Hendry (1993).

The current findings reflect a comparable picture regarding age, also from African studies, where the most common age category was between 50 and 69 years. However, the mean age of participants in the current study is lower than mean ages reported in studies from developed countries (Cumming *et al.* 2015; Asano *et al.* 2008). A possible reason for South Africa's and Africa's population undergoing vascular amputations at a younger age when compared to developed countries, could be due to diabetes presenting at a younger age (Bertram *et al.* 2013). According to the International Diabetes Federation (IDF 2017); middle,

and low-income countries have a younger population of people with diabetes, being more prevalent among people under the age of 60 years.

5.3 Prosthetic Use

Although most of the current study participants used their prosthesis, less than half used their prosthesis, on a daily basis. Higher rates of daily use were found in studies from developed countries where most participants had, also, undergone an above knee amputation for vascular reasons and had an older mean age, than participants in the current study. Pohjolainen *et al.* (1990) found that 50% of their Finnish participants wore their above knee prosthesis daily (mean age 62 years). Pulhalski *et al.* (2008) observed 27 community dwelling Canadians (mean age of 66 years) and found that 85% used their prosthesis daily after having received prosthetic rehabilitation. Tezuka *et al.* (2015) observed 61 Japanese participants, at least one year post discharge from prosthetic rehabilitation and reported that 77% used their prosthesis daily. Tezuka *et al.* (2015) found that the younger people used their prosthesis for more days per week. This is also reflected in the current study where more frequent prosthetic use, in days per week, was found in age groups below 60 years compared to those above 60 years of age. This observation however carried no statistically significant value. Comparisons to African studies regarding frequency of prosthetic wear are not really possible, as insufficient information exists. The information that could be found is highly contrasting, as illustrated in Chapter 2, section 2.5.

According to the above mentioned studies and those discussed in literature review, possible predictors for higher prosthetic use frequency are 1) younger age, 2) receiving prosthetic rehabilitation and the 3) reason for the amputation being non-vascular. Descriptive results from this study reflected that the participants who used their prosthesis more frequently (5-7 days per week), as a group, had a younger mean age compared to the group that wore prosthesis less often. This observation however did not proof to hold any statistically significant value concluding that age did not have a significant effect on prosthetic use. Most participants with non vascular diagnosis did wear their prosthesis 5-7days per week, however, a statistically significant relationship could not be found between prosthetic use and diagnosis. Prosthetic rehabilitation too, did not have a significant relationship with prosthetic use, however, the prosthetic rehabilitation participants received in this study was not as intensive as in studies that proofed rehabilitation to be beneficial (refer to chapter 2 section 2.4.2). Prosthetic rehabilitation, in this study, was defined as a person having had at least one therapy session. The importance of rehabilitation is seemingly further underscored in the reasons that participants gave for not using their prosthesis. Issues such as how to

walk with their prosthesis, fear of falling and lack of endurance, are all addressed during rehabilitation.

In the Western Cape there is a well-established pathway for pre-prosthetic rehabilitation, as described in Chapter 1. All participants of this study had attended pre-prosthetic rehabilitation; however, the number of participants receiving prosthetic rehabilitation was low and is of concern to the researcher. In the researcher's experience this might be due to various reasons: some of the participants might not have received follow up appointments which might have been related to a shortage of service providers, a lack of co-ordinated teamwork (Ennion & Rhoda 2016), or a lack of service providers' understanding of the importance of prosthetic rehabilitation. On the other hand, some users had been given appointments, but had not attended. This might also be due to a lack of knowledge on how rehabilitation could assist to improve function with the prosthesis, or could have been due to various environmental barriers such as a lack of transport, funding and time.

A further concern, is that despite a clear pre-prosthetic pathway and no waiting list at the OPC, many participants only received prostheses after a year or more. Waiting times were especially long for participants who had been referred via WCRC. This may be due to the referral processes, as WCRC relies completely on referrals from outside, while amputations are performed at GSH. Previous studies and reviews have demonstrated that the less time is lost, from surgery to prosthesis fitting, the more positive the impact on prosthetic use and mobility (Sansam *et al.* 2009). In the current study, waiting time for prostheses had no statistically significant impact on prosthetic use, however, other variables could have impacted this finding, such as poor access to prosthetic rehabilitation, complications to residual leg or uncomfortable prosthetic fit.

The majority of participants in the current study reported having a healthy, intact contra-lateral leg. That is an important consideration, as the literature has shown the important role being able to balance on the contra-lateral leg and mobilise with crutches, play in the person's ultimate ability to walk with an above knee prosthesis (Tezuka *et al.* 2015; Mundell *et al.* 2015; Roffman *et al.* 2014; Schoppen *et al.* 2003; Gailey *et al.* 2002; Bakkes 1999)

Phantom pain was the most common complication experienced with the residual limb. However, phantom pain is not a deterrent to walking with a prosthesis, as previous research has shown that wearing a prosthesis actually has a positive impact on phantom limb pain and decreases the experience of this phenomenon (Pasquina *et al.* 2015).

Prosthesis:

Participants who used their prosthesis most frequently, reported less prosthetic fitting problems compared to those who had abandoned their prostheses. A systematic review (Gholizadeh *et al.* 2013) reported that discomfort, skin problems and high energy expenditure were causing people to stop using their prosthesis. Amongst non-use in this study, similar reasons were given; skin irritation, pain and tiring to walk with prosthesis. Prosthetic fitting problems leading to discomfort may also influence overall function with the prostheses (Roth *et al.* 2014). The socket design and suspension used by current participants has limitations, as described in 2.7 and could have negatively affected user comfort, use, mobility and satisfaction (Gholizadeh *et al*. 2013).

The problem most commonly reported by current participants who wore their prosthesis, was perspiration inside the socket**.** Studies by Trieb, Lang, Stulnig and Kickinger (1999), and Gholizadeh *et al.* (2013) reported less perspiration inside the socket when using a liner as suspension, compared to skin suction. It also showed a reduction in skin trauma, less stump oedema and subsequent longer duration of wear. A liner is not a product option in Western Cape government, however it could be an option to explore for certain prosthetic users, e.g. the active user. The foot and knee components used, could also have negatively impacted prosthetic use. All participants received a SACH foot and a single-axis knee. These two components might have been especially trying for younger active participants, since the components are designed for indoor and limited outdoor use only. A cross-sectional survey of 135 persons from Turkey (Yilmaz, Gulabi, Kaya, Bayram & Cecen 2016) found that being younger than 35 years was associated with higher levels of function. Current findings showed that, of the five participants younger than 35 years, two were not using their prosthesis and two used their prosthesis 3 days or less per week. The limitations that the prosthetic components might have imposed on their mobility needs might have resulted in their opting to use crutches rather than the prostheses.

5.4 Prosthetic Mobility

5.4.1 In, and outdoor mobility with the prosthesis

Interestingly, higher levels of prosthetic use were found in outdoor mobility (86%) compared to indoor mobility (63%) even though outdoor mobility places more demands on the person and the prosthesis. This pattern is reflected in other studies (Puhalski *et al.* 2008; Hagberg & Branemark 2001; Gauthier-Gagnon et al.1999) where the above knee prosthesis was used more often outdoors than compared to indoors. Outdoor prosthetic use encompasses more than just the physical demands of prosthetic mobility. During interview, participants in a

South African study reported that they were self-conscious about their image in public and that attempts to preserve normal, physical appearances were important, e.g. wearing long pants over the prosthesis when going out (Godlwana & Steward, 2013). Other possible reasons for lower levels of indoor prosthetic mobility might be that indoor space was limited and one could perform many tasks while seated. Some participants reported that the prosthesis was too slow and that it was uncomfortable to sit with the prosthesis.

As can be expected, due to greater challenges with regard to balance and endurance, the need for crutches increased when participants were walking outdoors and even further increased when they were walking outdoors, on uneven terrain. Gauthier-Gagnon et al. (1999) reported that frequency of prosthetic wear, in hours per week, were positively associated with fewer assistive devices. Other researchers concurred (Tezuka *et al.* 2015; Puhalski *et al.* 2008). Similar results are reflected in this study (Table 4.2), were people who used their prosthesis more often tend to be less reliant on hand-held assisted devices across terrains. Increased age impacts negatively on prosthetic mobility (Puhalski *et al.* 2008; Hagberg & Branemark 2001). Davies and Datta (2003) found that participants under the age of 50 years, who had undergone above knee amputation, almost all achieved household and community mobility, while of those above 50 years of age, only 25% achieved community mobility. Similar observations were made in current study, increase in age also showed an increase in the need for additional assistive devices, across all terrains

The ability to climb steps is important as it impacts on overall mobility within the context of a person's indoor and outdoor living environment. The findings of the current study on stair climbing ability with a prosthesis was similar to findings from research conducted by De Laat *et al.* (2013) where most participants could do so, but when stairs did not have a handrail, approximately 15% of the persons were unable to climb stairs. This inability may limit household or community mobility, as many public and private buildings have a few steps at the entrance, often with no handrail.

5.4.2 Prosthetic walking distance

Prosthetic rehabilitation had a statistically significant impact on walking distances. Overall walking distances, however, were limited, with only 30% of the study population being able to walk 500 steps or more. Bakkes' (1999) findings, in comparison, reported that 74% could walk 500m and more at a time, the intensity of rehabilitation could have impacted these differences. In the current study, prosthetic rehabilitation where mostly limited to 3 outpatient sessions, compared to Bakkes' (1999) study where more intensive rehabilitation was provided. Both studies, however, highlight the importance of prosthetic rehabilitation.

It is further, important to note that reported walking distances in this study, was subjective estimates and not objectively verified measures.

The limitations of the prosthetic components have been discussed and could have played a role in limited walking distances. The interface between skin and prosthesis becomes increasingly important, the further one walks and if chaffing or undue friction occurs it will limit walking distance. Residual limb pain and swelling, as well as the impairments of the contra-lateral leg which were reported as complications, will also increase as the walking distance increases and would, thus, limit walking distances even more. These findings seem to concur with the opinion of Stepien *et al.* (2007) that participants with above knee amputations mostly lived a sedentary lifestyle, depending on the number of steps that they took over a period of a week. The question that remains unanswered in both this study and the one by Stepien *et al.* (2007) is whether this sedentary lifestyle had been the person's pre-morbid lifestyle or whether it was as a result of the post-amputation disability.

5.5 Experience of prosthesis

Study participants' initial expectations of what their prosthetic leg would offer, was higher than what reality confirmed, over time. As could be expected, for the most part, those who used their prosthesis more often expressed a greater degree of satisfaction that expectations had been met. Results also showed higher levels of satisfaction with prosthetic comfort, aesthetics and weight amongst those participants who wore their prostheses more frequently. Dissatisfaction with the prosthesis however, does not always suggest poor prosthetic use and, vice versa, according to studies by Pezzin, Dillingham and MacKenzie (2000). This inverse relationship between satisfaction with the prosthesis and prosthetic use and mobility was also observed amongst 6 participants in the current study.

Younger participants where less satisfied with their prostheses, compared to the other age groups. The possible impact that prosthetic components (designed for indoor and limited outdoor use only) may have had on activity levels of, especially, younger people, who live active lives, has already been discussed and may also be the reason for this finding. The problems the participants experienced with the fitting of the prostheses may also have negatively impacted on their satisfaction with the prostheses, as had been the case in the study by Roth *et al.* (2014).

5.6 Employment

No data was collected on participants' employment status, prior to the study, thus, the researcher cannot comment on their return to work rate. However, unemployment rates in South Africa are 25.5% amongst the general population (StatsSA 2016), thus, 53.5% lower

than amongst the participants in this study. In the Netherlands, Schoppen *et al.* (2001a) and Schoppen *et al.* (2001b) found employment rates of people who had undergone lower limb amputation (majority BKA) comparable to that of the general Dutch population. Contextual differences between the Netherlands and South Africa, and the current study population's lower socio-economic status, as shown by their dependence on government services, may create a less favourable scenario for their future prospects. This is, especially, significant as employment of persons with disabilities, in South Africa, remains a big challenge, due to so many other barriers. These barriers include (amongst others), poor physical access to environments and access to transportation, negative attitudes, low levels of education (Maya, Mann, Sing, Steyn & Naidoo 2011). In addition, not being able to walk more than 500 steps at a time, or needing crutches to walk on uneven terrain, will certainly severely curtail a person's ability to do manual work.

Tezuka *et al.* (2015) and Hagberg & Branemark (2001) found that employment status was significantly related to more frequent prosthetic use. In addition, the age of the person, at the time of amputation (Schoppen *et al.* 2001b), was significantly related to employment. In the current study, the employed participants (with an average age of 48.6 years) reported that 50% used their prostheses daily- this may be an indication that the barriers to return to work may be factors beyond merely the daily wearing of prostheses.

6 Chapter Six: Conclusion

6.1 Limitations of study

The following study limitations have been identified:

- Selection/recruitment bias. The questionnaire was administered telephonically, thus, only people who were responsive to telephone calls were included. This recruitment process excluded one person without a cell phone or land line phone number. It also excluded people who had changed contact numbers, since having been discharge from pre-prosthetic services.
- Validity. Although the PPA is a reliable and valid measurement tool (Gauthier-Gagnon & Grise, 1994), this study cannot take full credit for its strengths as:
    - The population for which the PPA had originally been developed and tested has been an elderly Canadian population group, while this study was performed in a South African population of all ages.
    - The PPA questionnaire was adapted for this study population.
    - Validity and reliability had only been established for the English version (Gauthier-Gagnon & Grise, 1994), and not for the Afrikaans or isiXhosa translations that were used in this study.
    - However, some of the changes to the original questionnaire were made with face and content validity in mind, e.g. using South African English to simplify certain terms, seeking the input from experts and doing a pilot study which looked, amongst other things, at the clarity of the questions.
    - The Afrikaans and isiXhosa questionnaires were translated and back translated in attempt to minimise instrumentation / measurement error.
- The questionnaire collects data on self reported physical capabilities. Certain questions may enquire about an activity not yet done by the participant and then the answer may be based on 'imaginary capabilities'. This may result in over scoring, underscoring, influencing the study's internal validity. It may also influence the reliability of results as the participant may score higher on a day where confidence is high, but lower on a day when mood is low.
- Interrater bias: Interrater bias could have occurred between the three research assistants. Thorough training was completed with the research assistants to minimise interrater bias. Training focused on the consistent application of the data collection instrument, e.g. questions were read as they had been written, no rephrasing of wording was allowed and no further explanation was provided. This limited any bias that may have been introduced by the research assistants` interpretation of

questions. The researcher also listened to the recordings of the English and Afrikaans interviews to confirm that data collection had, indeed, been recorded and to assess if any individual trends occurred that might have led to interrater bias. No such challenges were identified. This procedure was not performed with the isiXhosa interviews as researcher was not fluent in isiXhosa.

- By electing not to collect data herself, the researcher, who provided rehabilitation to some of the participants, ensured that potential bias, which might have been introduced through her expectations and opinion, and/or from participants inflating their abilities in order to please her, was limited.
- To limit recruitment bias of eligible participants not wanting to consent to the study due to fear of judgement on his/her performance, research assistants were not known to the participant.
- Concerning external validity, it needs to be considered that the study participants did not provide a true representation of all Western Cape persons who have received an above knee prosthesis, as they only represented a population at a certain time period and those persons who had received government subsidised prostheses. Therefore, caution needs to be exercised in generalizing any of the results.
- The small number of participants prevented inferential analysis.

6.2 Conclusions

The study participants were relatively young, especially, in a group where vascular reasons were the main cause of amputation. While it was heartening to find that the majority of participants used their prosthesis, a higher rate of daily use would have been even more encouraging. Participants were also quite limited in the distances they were able to walk without having to rest. The significant impact the prosthetic rehabilitation had on walking distances provides strong motivation for prosthetic rehabilitation. Across terrains, participants who used their prosthesis more regularly, also enjoyed better quality of mobility with less need for elbow crutches. As to be expected, an increase in age and increasingly demanding terrain, presented an increase in the need for hand-held, assistive devices. The finding that participants often chose not to use a prosthesis indoors, should be taken into consideration during prosthetic prescription. Disappointment in the realisation of initial expectations of what the prostheses would deliver, was experienced by most participants. This may reflect unrealistically high hopes on the side of users or may be an indication of the limitations of the prosthetic components used, or may be due to a lack of rehabilitation. Employment figures of participants were low in a setting where unemployment is already at high levels.

6.3 Recommendations for further research

- An epidemiological study on amputations in South Africa will add significantly to health information, nationally.
- Qualitative research will obtain richer data from the person's perspective on the use of the prosthesis.
- Research on the effect of prosthetic rehabilitation on prosthetic use and prosthetic mobility, may provide guidance in the development of a prosthetic rehabilitation pathway for the province.
- A study that compares the impact of different prosthetic components on prosthetic mobility and use in the Western Cape will provide valuable evidence on which criteria to base the prescription of prosthetic components.
- A study to explore the reasons for the time delay between amputation date and prosthetic prescription.
- A Study to validate the adapted PPA questionnaire in the South African context.

6.4 Recommendations for service providers

- Improve access to prosthetic rehabilitation

Less than half of the study participants received prosthetic rehabilitation, which is concerning especially in the light of rehabilitation showing a positive correlation with walking distances. The WC Department of Health, in collaboration with service providers, should develop a pathway for better access to prosthetic rehabilitation in the province.

In line with their role, according to Healthcare 2030 (WCDoH, 2014) therapists from WCRC can do capacity building and provide training on prosthetic rehabilitation to colleagues in other settings where applicable.

- Shorten prosthetic waiting times

More than half of study participants waited longer than a year for their prosthesis. WCRC is to establish an improved referral pathway through collaboration with rehabilitation professionals from all levels of service provision so that clients are referred to their services sooner.

In addition, OPC clinics can be expanded to other settings in the metro, other than just GSH and WCRC, for example, expand to Khayelitsha Hospital (Metro East) and Karl Bremer Hospital (Metro West). More clinics will have positive impact on local access for clients.

- Improve education/information sharing regarding prosthetic pathway and realistic expectations of prosthesis. Develop written format to share information across the Western Cape

Less than half of study participants' initial expectations of prosthesis have been met. This can be due to various reasons, and not all people's expectations will always be met, however, through education and information sharing we can improve our clients' experience.

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DEPARTMENT of HEALTH
Provincial Government of the Western Cape

Appendix 1
GUIDELINE FOR SCREENING OF PROSTHETIC CANDIDATES: LOWER LIMB

Patient:

Sticker Name

Age_____

Date of assessment: _____**Seen bv**

Dr	Nursing	OPC	PT	OT	SW

Signed: _____

Date and level of amputation(s)_____

Rehab to date (period and intensity) _____

_____

Aspect/standard	Contraindication * /poor prognosis	Negative predictor/borderline candidate	Positive predictor
Aetiology	Any acutely terminal condition	Vascular or other progressive condition	Traumatic, congenital, orthopaedic or non-progressive condition
Number and level of amputations	Bilateral above knee amputations in adults	Above and below knee or bilateral below knee	Unilateral above or below knee
Substance abuse including smoking	Continues with habits post amputation	Has recently stopped (<2yrs) or has cut down but still continues to use substances	No substance (ab)use in the past two years
Ischaemic heart disease. ECG recommended in diabetics	*BKAs: Uncontrolled IHD AKAs or bilateral amputees: even if good compliance and controlled.	Good compliance and controlled (unilateral BKAs only)	No IHD
Cardiac failure	*Uncontrolled	Good compliance and controlled	No CCF
Diabetes	Uncontrolled	Good compliance and controlled	No DM
Hypertension	Uncontrolled	Good compliance and controlled	No HTN
Respiratory conditions (e.g. PTB, COPD, Asthma)	Uncontrolled	Good compliance and controlled	No past or current history
BMI	Underweight	Overweight	Within normal range
Continence	Incontinent bladder and bowel due to neurogenic causes	Other causes of incontinence	No bladder or bowel problems
Cognition (examine for stroke, head injury, multi infarct dementia)	*Poor insight, judgement and reasoning requiring supervision in daily activities	Limitations present but do not impact on activities of daily living	No cognitive fallout
Expectations	Unrealistic expectations of prosthesis, request for cosmetic prosthesis	Intermediate. Patient has not considered or is unaware of functional aspects of rehabilitation	Realistic expectations of prosthesis and role it has to play in complete rehab plan

Co-ordination and mobility with crutches (observation and history indicates ability to walk 200m with crutches)	*Cannot mobilise with elbow crutches	Achieves basic standard only. Reasons for poor function are to be addressed	Unlimited mobility with crutches and can negotiate all terrains including steps
Wheelchair use	*Only uses wheelchair	Uses wheelchair for community access or when bilateral hand function is required	None
Stand independently and throw and catch a ball 5 times, hop and perform functional activities standing on one leg	Cannot	Achieves basic standard only. Reasons for poor function are to be addressed	Achieves standard with ease
Stand on remaining limb for 40 min	Cannot	Achieves basic standard only. Reasons for poor function are to be addressed	Achieves standard with ease
Stand up from sitting without using hands	*Cannot	Achieves basic standard only. Reasons for poor function are to be addressed	Achieves standard with ease
Self care	*Dependent	Any degree of dependence	Totally independent
Domestic activities	Dependent	Any degree of dependence	Totally independent
Community activity: pre morbid and current	*None. Bed bound	Active in house	Scholar, employed or highly active in community
Remaining limb	Threatened remaining limb	Questionable viability or deterioration in viability in last 6 months	No problems. Good pulses and circulation
Amputation stump: range	*Fixed flexion deformity of hip and/or knee	Any reduction in full range of hip and/or knee still to be addressed	Full range of movement with hip extension beyond neutral
Amputation stump: power	*<4/5 hip extensors and abductors (BKA and AKA) and knee extensors (BKA). Patient generally weak	Good general strength but <4/5 hip extensors and abductors (BKA and AKA) and knee extensors (BKA).	5/5 all movements of hip and/or knee
Amputation stump: length AKA: 1/3 of opposite femur BKA: >12-15 cm from knee joint line	Markedly shorter with minimal fulcrum	Shorter than standard	Meets standard or is longer
Amputation stump shape and soft tissue	Poor compliance or response with coning and mobilisation of soft tissues. Persistent dog ears and hard spots	Improvement in shape evident or anticipated. Surgical intervention considered	Conical form
Amputation stump: bony prominence causing soft tissue tension	Un-correctable	Amenable to coning or surgery correction	No bony protuberances
Amputation stump: Wound healing	*Open wound, draining sinus	Healed but immobile scar	Healed and mobile scar
Amputation stump: skin condition	Thin skin or easily abrades with compression bandage Skin graft on weight bearing area	Healed skin grafts	Healthy, supple and flexible skin with no skin grafts on stump
Amputation stump pain/sensation	*Ischaemia	Neuroma, hypersensitive stump. Phantom pain impacting on function	No pain. Phantom pain not impairing function
Total score both pages			
Block in which highest score is obtained	**Patient is not a prosthetic candidate. Put care plans to place**	**Remediate correctable factors through medical and therapeutic interventions**	**Potentially good candidate**

Appendix 2
Participant contact and calling sheet

No	Participants name	Telephone number(s)	Contact register			Informed consent	Questionnaire Language	Date of interview	Participant no
1	*Mr Example*	*0768 737 584* *021 87 32867*	1may	3may		yes	Afrikaans		88
2	*Mrs X*	*0605041847*	*2May*	*5May*	*7May*	*No answer*	Xhosa		04
3	Mr Y	021370 2458	5May			no	English		11

Appendix 3

DATA SHEET
clinic notes and client database

COMPLETE THIS INFORMATION SHEET BY WRITING THE CORRESPONDANCE NUMBER INTO THE BLANKS PROVIDED FOR EACH QUESTION. INFORMATION OBTAINED FROM CLINICAL NOTES AND CLIENT ELECTRONIC DATABASE.

Study Participant number

1. Gender

1. Male
2. Female

2. Date of birth

3. Age

4. Ethnic Group

5. Residence

1. South-East Cape Metropole
2. North- West Cape Metropole
3. Outside of Cape Metropole

6. Referral source

1. GSH
2. WCRC

7. Date prosthesis issued

Appendix 4

Questionnaire for Prosthetic Use

CONSENT

A. YOUR PHYSICAL CONDITION

1. Why was your leg amputated?

- ☐ a. Traumatic
- ☐ b. Diabetic complications (gangrene)
- ☐ c. Vascular problems (gangrene)
- d. Infection
- ☐ e. Malignancies
- ☐ f. Other _____ 'specify'

2. What was the date of your amputation?

D	D	M	M	Y	Y	Y	Y

3. When did you receive your prosthesis

D	D	M	M	Y	Y	Y	Y

4. Do you have any health problems at the moment?

- ☐ a. Cardiac (heart) problems
- ☐ b. Blood pressure
- ☐ c. Respiratory (breathing) problems
- d. Visual problems
- ☐ e. Diabetes/ Sugar
- ☐ f. Other problem _____ 'specify'
- ☐ g. No

5. Do you smoke?

- ☐ a. No
- ☐ b. Yes

6. At the moment, do you have any problems with your <u>STUMP?</u>

- ☐ a. Stump pain (muscle, joint or bone)
- ☐ b. Phantom pain
- ☐ c. Wounds or sores
- ☐ d. Swelling
- ☐ e. Other problems _____"Specify"
- ☐ f. NO

7. At the moment, do you have any problems with your other leg?

☐ a. Poor circulation (e.g. foot always cold and discoloured)
☐ b. Pain in the joints when I walk
☐ c. Muscle cramps when I walk
☐ d. Pain in leg when I walk or rest
☐ e. Wounds or sores
☐ f. Leg swelling
☐ g. Reduced feeling in foot (neuropathy) / drop foot
☐ h. Other problems _____"Specify"
☐ i. NO

B. YOUR PROSTHESIS / ARTIFICIAL LEG

8. How satisfied are you with the…….of your prosthesis

	a. Not at All	b. Moderately	c. Completely
8.1 Comfort	☐	☐	☐
8.2 The look/appearance of your prosthesis	☐	☐	☐
8.3 Weight	☐	☐	☐
8.4 Way you walking with your prosthesis	☐	☐	☐

9. When you wear your prosthesis, does it cause you any problems?

☐ a. Skin irritations?
☐ b. Wound (eg:in the stump, groin,etc)?
☐ c. An increase of pain (eg: in the stump, groin,etc)?
☐ d. An increase of phanton pain?
☐ e. Excessive stump perspiration?
☐ f. Problems because it makes noise?
☐ g. Others _____"Specify"
☐ h. I do not wear my prosthesis
☐ i. NO

C. YOUR PROSTHETIC USE

10. When putting on your prosthesis, do you need another person's help?

☐ a. No
☐ b. Yes

11. 11.1. Do you wear your prosthesis at least once a week?

☐ Yes

☐ *No – go to Q 12 and 13 and thereafter* ***skip*** **** ****

11.2. How many days___ per week do you wear your prosthesis?

11.3. Approximately how many hours____ a day do you wear your prosthesis?

THE FOLLOWING 2 QUESTIONS CONCERN ONLY PERSONS WHO DO NOT WEAR THEIR PROSTHESIS.

12. When did you stop wearing your prosthesis?

☐ *a. Less than one (1) month ago*
☐ *b. Less than six (6) months ago*
☐ *c. Less than one (1) year ago*
☐ *d. Less than two (2) years ago*
☐ *e. I never wore it*

13. Why did you stop wearing your prosthesis?

☐ *a. The socket of the prosthesis was too large (loose) for my stump*
☐ *b. The socket of the prosthesis was too small (tight) for my stump*
☐ *c. It was too tiring*
☐ *d. I had surgery on my stump (eg: re-amputated, other surgery)*
☐ *e. Do not know how to correctly walk with my prosthesis*
☐ *f. Other reasons_____"Specify"*

***14.* * *** **WITH YOUR PROSTHESIS ON, *ARE* YOU ABLE TO……**

a. Get up from a chair

1. No
2. Yes with 1 elbow crutch
3. Yes with 2 elbow crutches
4. Yes alone

b. Pick up an object from the floor when you are standing up with your prosthesis

1. No
2. Yes with 1 elbow crutch
3. Yes with 2 elbow crutches
4. Yes alone

c. Get up from the floor (e.g. : if you fell)

1. No
2. Yes with 1 elbow crutch
3. Yes with 2 elbow crutches
4. Yes alone

d. Walk in the house

1. No
2. Yes with 1 elbow crutch
3. Yes with 2 elbow crutches
4. Yes alone

e. Walk outside on even ground

1. No
2. Yes with 1 elbow crutch
3. Yes with 2 elbow crutches
4. Yes alone

f. Walk outside on uneven ground (e.g. : grass, gravel, slope)

1. No
2. Yes with 1 elbow crutch
3. Yes with 2 elbow crutches
4. Yes alone

g. Walk outside in unpleasant weather (e.g. : rain, wind)

1. No
2. Yes with 1 elbow crutch
3. Yes with 2 elbow crutches
4. Yes alone

h. Go up and down the stairs with a handrail

1. No
2. Yes with 1 elbow crutch
3. Yes with 2 elbow crutches
4. Yes alone

i. Step up and down a pavement

1. No
2. Yes with 1 elbow crutch
3. Yes with 2 elbow crutches
4. Yes alone

j. Go up and down a few steps (stairs without a handrail)

1. No
2. Yes with 1 elbow crutch
3. Yes with 2 elbow crutches
4. Yes alone

k. Walk while carrying an object in one hand

1. No
2. Yes with 1 elbow crutch
3. Yes with 2 elbow crutches
4. Yes alone

l. Walk while carrying an object with two hands

1. No
2. Yes alone

15. When you move about INSIDE your HOUSE , it is mostly done with….

☐ A wheelchair?
☐ OR Walking with your elbow crutches?
☐ OR Walking with your prosthesis ?

(If the person does not mostly use their prosthesis for moving inside the house, go to question 16)

16. Can you give reasons why you do not walk with your prosthesis inside the house?

☐ a. Because it is not fast enough
☐ b. Because it is too tiring
☐ c. Because my hands are not free
☐ d. Because of problems with my non-amputated leg (e.g.: fatigue, pain, etc.)
☐ e. Because of problems caused by the prosthesis (discomfort, sweating, too tight, or loose)
☐ f. Because of stump problems (e.g.: skin irritations, pain, wounds, etc.)
☐ g. Because I feel unstable with the prosthesis
☐ h. Other reasons_____"Specify"

17. When you move about OUTSIDE your HOUSE , it is mostly done with…

☐ A wheelchair?
☐ OR Walking with your elbow crutches?
☐ OR Walking with your prosthesis ?

18. If you do not mostly use your prosthesis for moving outside, can you give reasons why not?

☐ a. Because it is not fast enough
☐ b. Because it is too tiring
☐ c. When distances to cover are too long
☐ d. Because of problems with my non-amputated leg(eg: fatigue, pain, etc.)
☐ e. Because of problems caused by the prosthesis (eg: discomfort, perspiration, etc.)
☐ f. Because of stump problems (eg: skin irritations,pain, wounds, etc.)
☐ g. Because I am afraid of falling
☐ h. Other reasons_____"Specify"

19. **** WHEN WALKING WITH YOUR PROSTHESIS, APPROXIMATELY WHAT DISTANCE CAN YOU COVER WITHOUT STOPPING?**

☐ a. less than a 100 steps (e.g. steps within the house from one room to another)
☐ b. more than 100 steps (one block) at a time nonstop
☐ c. 200 to 500 steps nonstop
☐ d. 500 to 1000 steps nonstop (approximately 1km)
☐ e. I am not limited to walking distances outside of the house or in wide open spaces such as a shopping mall

20. *** * WHEN WALKING WITH YOUR PROSTHESIS, DO YOU HAVE TO THINK ABOUT EACH STEP YOU TAKE?**

☐ a. No, walking has become automatic for me
☐ b. Yes, I have to concentrate on every step I take
☐ c. Sometimes only (e.g. over uneven terrain)

21. When you received your prosthesis, did you receive physiotherapy treatment to learn how to walk with your prosthesis?

☐ a. No
☐ b. Yes, less than 3 sessions
☐ c. Yes, more than 3 sessions

Where?_____

22. Do you think it helped / could of helped?

☐ a.No

☐ b. Yes

D. YOUR ENVIROMENT

23. What type of housing do you live in?

☐ a. in a house?

☐ b. In an apartment?

☐ c. informal housing (shack or wendy house)?

☐ d. other_____"specify"

24. Do you have to use steps to get into your house, or steps inside your house?

☐ a. No

☐ b. Yes, with a handrail

c. Yes, without a handrail

25. Do these steps interfere with your daily activities?

☐ a. No

b. Yes_____"Specify"

26. How is the area outside around your house

☐ a. Level ground

b. Sandy

☐ c. Uneven grounds

E. OTHER

27. Are you employed?

☐ No→ GO TO QUESTION 27
☐ Yes

28. Are you…

a. on disability grant?
b. pension (disability pension, government pension)?
c. a student?
d. at home?
e. other_____"specify"

29. Was your initial expectation of what the prosthesis will give you met?

a. Yes completely
b. Yes, somewhat
c. No

We have come to the end. If you don't mind, I'd like to take a moment just to see that we have covered all the relevant questions.

Thank you

Is there any further comments or questions?

_____
_____
_____
_____

Thank you for your participation, it is greatly valued!

Appendix 5

Permission from author to adapt original PPA questionnaire

RE: TR: Questionnaire Prosthetic Profile of the Amputee - Demande Inbox x

Christiane Gauthier <christiane.gagnon@sympatico.ca> 17/09/2014
to me

Dear Mrs Pienaar

You will find enclosed the necessary material for your research. However the PPA was developed for an elderly disvascular population.

Please acknowledge the source of the PPA in any future présentations or publications.

Christiane Gauthier-Gagnon

De : elzbeth pienaar <elzzbissie@googlemail.com>
Date : jeudi 4 septembre 2014 16:01
À : Geneviève Tanguay <genevieve.tanguay@umontreal.ca>, Serge Brochu <serge.brochu@umontreal.ca>
Objet : PPA

To Research team at Montreal University
Apology for my English as I unfortunately cannot write French.
I am a physiotherapist from South Africa busy with my Masters degree in Rehabilitation and am writing for your department's guidance.
I would like to use the questionnaire : Prosthetic Profile of the Amputee developed from a research study done at Montreal University by Christiane Gauthier-Gagnon.
- Gauthier-Gagnon C, &Grise MC. Prosthetic profile of the amputee questionnaire:validity and reliability. Arch Phys Med Rehabil, vol 75, Dec. 1994
- Grise MC, Gauthier-Ganon C, Martineau GG. Prosthetic profile of people with lower extremity amputation: conception and design of a follow up 1993
My proposed study will look at prosthetic use of Above Knee Amputees in Western Cape, South Africa.

Appendix 6

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH STUDY:

Prosthetic use by persons with unilateral above knee amputation in the Western Cape

REFERENCE NUMBER:

PRINCIPAL INVESTIGATOR: Elzbeth Pienaar

ADDRESS:
Western Cape Rehabilitation Centre
103 Highlands Drive
Mitchell's Plain
7789

CONTACT NUMBER: (021) 370 2366 / 0768 737584

You are being invited to take part in this research study; as titled above. Please take time to listen to/*to read* the information presented, which will explain the details of this study. Please ask the research staff any questions about any part of this study that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do at first agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

- ✓ The Western Cape Government provides a Prosthetic service, and an amputee care pathway, where clients receive prosthesis. Little is known regarding mobility and prosthetic use of people with lower limb amputation after prosthetic issue.
- ✓ The researcher wants to determine what are the mobility and prosthetic use of people with an above knee amputation in the Western Cape.
- ✓ Determining the mobility and prosthetic use and learning what the possible contributing factors are to poor or better use can help staff to improve rehabilitation programs for people with an above knee amputation
- ✓ All people with unilateral above knee amputations who received pre-prosthetic services from Western Cape Rehab Centre (WCRC) and received their first prosthesis from the Orthotic and Prosthetic (OPC) in the time period between 1 June 2011 to 31December 2014 are being asked to take part in the study
- ✓ A sample of people with unilateral above knee amputations who received pre-prosthetic services from Grootte Schuur Hospital (GSH) and received their first prosthesis from the Orthotic and Prosthetic (OPC) in the time period between 1 June 2011 to 31December 2014 are being asked to take part in the study
- ✓ The researcher aim to involve an estimate of 80 people with above knee amputations who received services from GSH and 80 who received services from WCRC

✓ If you agree to participate in this project the following procedure will be followed:

1. An appointment will be made with you in order to complete a telephonic questionnaire / An *appointment will be made with you to complete the questionnaire in person* in your chosen language; English, Afrikaans or Xhosa.
2. The researcher will gather information from your clinical file at OPC such as your age, gender, date of prosthetic issue.
3. The research staff will phone you on the set date and time / *visit you at the set place, date and time* to complete the questionnaire via interview.
4. The telephonic conversation/ *visit to complete questionnaire* will take up to 25 minutes of your time.

The questionnaire titled; *Adapted Prosthetic Profile of the Amputee* consists of 42 questions regarding your physical condition, your prosthesis, your prosthetic use, prosthetic mobility and environment.

Why have you been invited to participate?

You are being asked to participate in this study as you received your prosthesis from the Western Cape Government and attended pre-prosthetic services either at Western Cape Rehab Centre or Grootte Schuur Hospital.

What will your responsibilities be?

It will be expected that you answer the questions as best as you can.

Will you benefit from taking part in this research?

You will not directly benefit from participating in this study. Only future people with unilateral above knee amputations with a prosthesis may benefit. Knowledge and insight gained can help guide professional staff to offer better prosthetic rehabilitation programs which in turn may improve prosthetic mobility of future clients.

Are there any risks involved in your taking part in this research?

No risks have been identified.

Who will have access to your clinical records?

Only the researcher will have access to your records in order to gather clinical data. Information will be saved on a computer file which will be password protected. Only a number, randomly assigned, will reflect on your questionnaire sheet, no personal data will be displayed on it. If used in publication or thesis, the individual will remain anonymous.

Will you be paid to take part in this study and are there any costs involved?

- No, you will not be paid to take part in the study. There will be no costs involved for you, if you do take part.

You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been addressed clearly enough by the researcher.

You will receive a copy of this information and consent for your own records.

Postal address:

_____

_____

_____

Declaration by participant

By signing below, Mr / Mrs / Ms _____agree to take part in a research study entitled: *Prosthetic use by persons with unilateral above knee amputation in the Western Cape.*

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished if the researcher feels it is in my best interests, or if I do not follow the study plan as agreed to.

Yes: ☐

Telephone conversation held on (*date*) _____and (*time*) _____

_____
Signature of witness

OR (if in person)

Signed at (*place*) _____ on (*date*)_____

_____ _____
Signature of participant **Signature of witness**

Declaration by investigator

I *(name)* _____ declare that:

- I explained the information in this document to _____.
- I encouraged him / her to ask questions and took adequate time to answer them.
- I am satisfied that he / she adequately understands all aspects of the research, as discussed above
- I did / did not use an interpreter.

Signed at (*place*) _____ on (*date*) _____

Signature of investigator **Signature of witness**

Declaration by interpreter

I *(name)* _____ declare that:

- I assisted the investigator (*name*) _____to explain the information in this document to (*name of participant*) _____ using the language medium of Xhosa.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (*place*) _____ on (*date*) _____

_____ _____ .....

Signature of interpreter **Signature of witness**

Appendix 7

RESEARCH ASSISTANT CONFIDENTIALITY FORM

TITLE OF THE RESEARCH Study:

Prosthetic use by persons with a unilateral above knee amputation in the Western Cape

REFERENCE NUMBER:

PRINCIPAL INVESTIGATOR: Elzbeth Pienaar

ADDRESS:

Western Cape Rehabilitation Centre

103 Highlands Drive	Private Bag X19
Mitchell's Plain	Mitchell's Plain
7789	7789

CONTACT NUMBER: (021) 370 2366 / 0768 737 584

I (*name)* _____ herewith declare that I will treat all participant information and data related to and collected during the study as confidential and protected. I will not disclose any information or data that I obtain from study participants or the researcher as part of the above mentioned research study. I will uphold each participant's right to confidentiality and to be treated in a fair and just manner at all times.

Signed at (*place*) _____ on (*date*) _____2013.

_____	_____
Signature of research assistant	**Signature of witness**
_____	_____
Signature of investigator	**Signature of witness**

Appendix 8

Letters of approval, Department of Health: WCRC and GSH

Western Cape Government
Health

STRATEGY & HEALTH SUPPORT
Health.Research@westerncape.gov.za
tel: +27 21 483 6857: fax: +27 21 483 9895
5th Floor, Norton Rose House,, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za)

REFERENCE: 2014RP138
ENQUIRIES: Ms Charlene Roderick

P O Box 113
Wellington
7655

For attention: **Elzbeth Pienaar**

Re: PROSTHETIC USE BY PERSONS WITH UNILATERAL ABOVE KNEE AMPUTATION IN THE WESTERN CAPE

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Please contact the following people to assist you with any further enquiries in accessing the following sites:

Western Cape Rehabilitation Centre **J Hendry** **Contact No. 021 370 2316**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final report within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. The reference number above should be quoted in all future correspondence.

Yours sincerely

DR J EVANS
ACTING DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE: 14/01/15

Western Cape Government
Health

GROOTE SCHUUR HOSPITAL
Enquiries: Dr Bernadette Eick
E-mail : Bernadette.Schmitz@westerncape.gov.za

Ms E. Pienaar
University of Stellenbosch
P O Box 113
WELLINGTON
7655

E-mail: Elzbeth.Pienaar@westerncape.gov.za

Dear Ms. Pienaar

RESEARCH PROJECT: Prosthetic Use By Persons with Unilateral Above Knee Amputation in the Western Cape

Your recent letter to the hospital refers.

You are hereby granted permission to proceed with your research.

Please note the following:

a) Your research may not interfere with normal patient care.
b) Hospital staff may not be asked to assist with the research.
c) No hospital consumables and stationary may be used.
d) **No patient folders may be removed from the premises or be inaccessible.**
e) Please introduce yourself to the person in charge of an area before commencing.
f) Please discuss the study with HOD before commencing.
g) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
h) Confidentiality must be maintained at all times.

I would like to wish you every success with the project.

Yours sincerely

DR BERNADETTE EICK
CHIEF OPERATIONAL OFFICER
Date: 25th February 2015

C.C. Mr. L. Naidoo
Ms. C. Davids
Ms. J. Hendry

G46 Management Suite, Old Main Building,
Observatory 7925

Private Bag X,
Observatory, 7935

Tel: +27 21 404 6288 fax: +27 21 404 6125

www.capegateway.go.v.za

Appendix 9

Ethical Approval

UNIVERSITEIT·STELLENBOSCH·UNIVERSITY
jou kennisvennoot • your knowledge partner

Approved with Stipulations
New Application

06-Nov-2014
Pienaar, Elzbeth E

Ethics Reference #: S14/10/215
Title: Prosthetic use by persons with unilateral above knee amputation in the Western Cape.

Dear Ms Elzbeth Pienaar,

The **New Application** received on **15-Oct-2014**, was reviewed by members of **Health Research Ethics Committee 2** via Expedited review procedures on **06-Nov-2014**.

Please note the following information about your approved research protocol:

Protocol Approval Period: **06-Nov-2014 -06-Nov-2015**

The Stipulations of your ethics approval are as follows:
1. After the pilot study, the revised questionnaire (if applicable) has to be sent to the HREC prior to commencement of the main study.

2. Copies of approval from the relevant authorities (WC DoH, OPC and WCRC) to undertake the study at their facilities should be sent to the HREC prior to commencement of the study.

3. Incorrect spelling of Grootte Schuur Hospital in the consent form (it should be Groote Schuur), also, "The researcher aim to involve an estimate of 80 people with above knee amputations who received services from GSH and 80 who received services from WCRC" (it should be the "The researcher aims to involve....); these minor spelling/grammar corrections to the consent form need not be sent back to the HREC for re-checking.

Please remember to use your **protocol number** (**S14/10/215**) on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:
Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.
Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.
For standard HREC forms and documents please visit: www.sun.ac.za/rds

If you have any questions or need further assistance, please contact the HREC office at 219389207.

Included Documents:

Checklist
Declaration S Visagie
CV S Visagie
Declaration E Pienaar
Protocol
CV E Pienaar
Application form
Synopsis

Sincerely,

Mertrude Davids
HREC Coordinator
Health Research Ethics Committee 2

Appendix 10

Summary of study's descriptive results

Participants		n=43	
Gender			
Male	34		
Female	9		
Age (19yrs – 80yrs)			
Mean		55.2yrs	
Reason for Amputation			
Vascular		30 (70%)	
Non-Vascular		13 (30%)	
Time from amp to prosth			
< 1year		18 (42%)	
1+ years		25 (58%)	
Prosthetic Use			
Yes		35 (81%)	
Daily		18 (42%)	
None		8 (19%)	
Prosthetic Rehabilitation			
Received		17 (40%)	
P. Walking distances (n=35)			
< 200 steps		19 (56%)	
P. Mobility without crutches (n=43)			*(n= 35)*
Not walking		8 (19%)	
Indoor		26 (60%)	*(74%)*
Outdoor even		18 (42%)	*(51%)*
Outdoor uneven		9 (21%)	*(26%)*
Completely satisfy with the way you walk (n= 35)		15 (43%)	
Expectation completely met? (n=43)		19 (44%)	

Summary of study's inferential results

Variables	**P value** Chi square test
Prosthetic use vs Age	0.121
Prosthetic use vs Cause of amputation	0.627
Prosthetic use vs waiting time for prosthesis	0.649
Prosthetic use vs rehabilitation	0.394
Prosthetic use vs distances walked	0.221
Prosthetic rehabilitation vs prosthetic use	0.221
Prosthetic rehabilitation vs distances walked	**0.000**

Appendix 11a

Adaptations made to PPA Questionnaire for this study population:

1. Question 1 removed neurological problems as an option since persons with neurological problems were excluded from the study
2. Question 2 removed as study population is persons with AKA, thus no need to indicate amputation level
3. *Two questions added 1) reason for amputation 2) date of amputation 3) date prosthesis received*
4. *Added question: do you smoke?*
5. In Section B, question 5 and 6 removed two of the options of satisfaction scores to simplify answers
6. Question 8 removed as could be confusing: not all received prosthetic rehabilitation and at OPC same type of prosthetic components are used for all
7. Question 9 removed: there is only one Prosthetic centre for all participants, max appointment waiting time: approx. 2 weeks
8. Section C, question 11 are questions on doing activities with prosthesis on: changed answer options from *'Yes if someone helps me'* to *'Yes with 2 elbow crutches'* and '*Yes if someone is near me'* to *Yes with 1 elbow crutch'* to suit study population as all participants can walk with two elbow crutches and aim of study is to describe prosthetic mobility in terms of hand-held devices used
9. Question 21 has been removed, as this question has been incorporated into adapted question 11 answering questions on hand-held devices used/needed for activities
10. Question 13 deleted with question 14 and 16 collapsing options to simplify answer options for study participants
11. Question 18 changed distance options as a 'block' in a Canada neighbourhood is different to a block in a suburb or informal settlement in RSA
12. Question 19 removed, question about falling: *could have been useful data describing prosthetic mobility*
13. Question 23 asks why the participant stopped using the prosthesis, added reason 'do not know how to walk with prosthesis' as many participants in this study has not received post prosthetic rehabilitation
14. Question added asking 'if client received any prosthetic rehabilitation from a physiotherapist', as relevant to study setting

15. Environment: Question 25 of where participant live, added 'informal housing' as option as many government patients live in shacks or wendy houses
16. Question 26 – 30: collapsed to 2 questions regarding steps. Average housing in RSA does not have as many steps as Canadian housing thus extra detail not necessary
17. Added question regarding outdoor environment
18. Question 31 has been removed as it does not reflect activities whilst wearing prosthesis, but rather focus if extra help is needed- study objective is to determine prosthetic use
19. Question 32 on transportation: changed options to fit SA context.
20. Question 33 on the degree of acceptance of others of your prosthesis, removed, not part of this study's objectives
21. Added question on client's expectations of his or her prosthesis
22. Section D on Leisure Activities was not included as this is not a focus of the study
23. Section E: simplified employment questions 40 and 41 to 'yes' and 'no' only
24. Question 42 on non-employment status: added option of 'disability grant' to replace 'sick leave' as researcher found disability grants more applicable in current study than sick leave
25. Question 43 removed re: schooling
26. Question 44 on income removed as classification on income will be obtained from the medical records
27. Question 45 removed: if answered through a 3rd party it will be stated/documented on informed consent form

Appendix 11b

Adaptations made to Original PPA Questionnaire document

Université de Montréal

FACULTÉ DE MÉDECINE
ÉCOLE DE RÉADAPTATION

Questionnaire

THE PROSTHETIC PROFILE OF THE AMPUTEE (PPA)

Research supported by the
Fonds de la recherche en santé du Québec (FRSQ)

and

the National Health Research and Development Program (NHRDP)

CONFIDENTIAL

THANK YOU FOR PARTICIPATING IN OUR RESEARCH PROJECT. TO FILL OUT THIS QUESTIONNAIRE, YOU MUST CHECK [√] THE BOX THAT CORRESPONDS TO YOUR ANSWER.

A. YOUR PHYSICAL CONDITION

- *NOTE: Written language, where necessary, was changed to reflect South African English, rather than Canadian English, to simplify understanding of questions.*

1. Presently, do you have any particular health problems?

«Check* [√] the appropriate *boxes»

a) Cardiac (heart) problems…….....……..……..……... O

b) Respiratory (breathing) problems ……..……..……..……... O

c) Visual problems which interfere with your moving about ……..……..……O

~~d) Neurological problems (e.g.: paralysed on one side of your body)~~……O*Removed neurological problems as an option since persons with neurological problems were excluded from the study*

e) Diabetes ……..……..……... O

f) Other problems _____ ……..……..……..O
«specify»

~~**2. The following question pertains to your leg amputation(s). Please indicate the level(s) of your amputation(s).**~~

Question 2 removed as study population is persons with AKA, thus no need to indicate amputation level

	RIGHT	LEFT
a) Toe(s) ……	O	O
b) Partial foot ……	O	O
c) Below the knee ……	O	O
d) Above the knee ……	O	O
e) Other level _____ «specify» ……	O	O

***PLEASE NOTE :**
~~IF YOU HAVE «BOTH (2) LEGS» AMPUTATED HIGHER THAN~~ THE «ANKLES», PLEASE PROCEED TO QUESTION 24, PAGE 13. IF NOT PROCEED TO QUESTION 3.

3. At the present time, do you have any of the following problems with your non-amputated leg (or the leg which is not amputated above the ankle)?

«Check* [√] the appropriate *boxes»

a) Poor circulation (e.g. : foot always cold and discoloured) ……. O

b) Pain in the joints when you walk …… O

c) Muscle cramps when you walk …… O

d) Pain all the time, even at rest …… O

e) Wounds or sores …… O

f) Leg swelling …… O

g) Other problems _____ …… O
«specify»

4. At the present time, do you have any of the following problems with your STUMP?

«Check* [√] the appropriate *boxes»

a) Occasional stump pain …… O

b) Constant stump pain …… O

c) Phantom pain (the missing part of your leg is painful) …… O

d) Wounds or sores …… O

e) Other problems _____ …… O
«specify»

B. YOUR PROSTHESIS

5. Four characteristics concerning your prosthesis are listed below. Please indicate your degree of satisfaction for each one of these characteristics.

Removed two of options of satisfaction scores to simplify

	NOT AT ALL SATISFIED	~~SLIGHTLY SATISFIED~~	MODERATELY SATISFIED	~~QUITE WELL SATISFIED~~	COMPLETELY SATISFIED
a) Comfort	O	O	O	O	O
b) Appearance (the look of your prosthesis)	O	O	O	O	O
c) Weight	O	O	O	O	O
d) The way you walk with the prosthesis (appearance of your gait)	O	O	O	O	O

6. The adaptation (in the sense of GETTING used to…) to the amputation and to the prosthesis may be more difficult for some people than for others, and this adaptation is not always easy to evaluate. After examining the given choices of possible answers, please indicate the answer that best describes your actual adaptation to your…

Removed two of options of satisfaction scores to simplify

	NOT AT ALL ADAPTED	~~SLIGHTLY ADAPTED~~	MODERATELY ADAPTED	~~QUITE WELL ADAPTED~~	COMPLETELY ADAPTED
a) … amputation	O	O	O	O	O
b) … prosthesis	O	O	O	O	O

7. At the present time, when you wear your prosthesis, does it cause you …

«Check* [√] the appropriate *boxes»

a) … skins irritations? ……..……..……... O

b) … wounds (e.g. : on the stump, groin, etc.)? ……..……..O

c) … an increase of pain (e.g. : in the stump, groin, etc.)? ……O

d) … an increase of phantom pain? ……..……... O

e) … a decrease of phantom pain? …… O

f) … excessive stump perspiration? …….. O

g) … problems because your prosthetic foot allows you to wear only one heel height? ……. O

h) … problems because it makes noise? …….. O

i) … others _____ ……..……O
«specify»

j) … I don't know because I do not wear my prosthesis ……..… O

8. ~~**Since the time you completed your rehabilitation program, has your prosthesis been …**~~

Question 8 removed as could be confusing: not all received prosthetic rehabilitation and at OPC same type of prosthetic components are used for all

a) … changed for the same type of prosthesis? …..……... O

b) … changed for a different type of prosthesis?

_____ ……..……..…… O
«specify»

c) … my prosthesis has never been changed ……. O

9. ~~In your opinion, your prosthesis laboratory …~~

	NO	YES	I don't know
a) … is able to quickly give you an appointment?	O	O	O
b) … is located sufficiently close to your home?	O	O	O

Question removed: all participants access the same Prosthetic Centre, app waiting time: approx. 2weeks

C. YOUR PROSTHETIC USE

After learning how to walk with a prosthesis, some people continue to use their prosthesis, while others are unable to use it. Personal reasons motivate these choices.

WHETHER YOU WEAR YOUR PROSTHESIS OR NOT, PLEASE ANSWER THE NEXT TWO QUESTIONS (10 and 11)

10. Would you say that you are able to don (put on) your prosthesis …

«Check [√] one box only»

O … alone without difficulty?

O … alone but with difficulty?

O … alone, but with the supervision of another person?

O … only if you have the help of another person?

11. Whether or not you wear your prosthesis, at the present time, would you say that you are «able» to do the following activities «WITH YOUR PROSTHESIS ON»?

*Changed answer options '**Yes if someone helps me'** to **Yes with 2 elbow crutches** and '**Yes if someone is near me'** to **Yes with 1 elbow crutch'** as all study participants can walk using two elbow crutches and aim of study is to describe prosthetic mobility in terms of hand-held devices used.*

	NO	~~YES, IF SOMEONE HELPS ME~~	~~YES, IF SOMEONE IS NEAR ME~~	YES ALONE
a) Get up from a chair	O	O	O	O
b) Pick up an object from the floor when you are standing up with your prosthesis	O	O	O	O
c) Get up from the floor (eg. : if you fell)	O	O	O	O
d) Walk in the house	O	O	O	O
e) Walk outside on even ground	O	O	O	O
f) Walk outside on uneven ground (eg. : grass, gravel, slope)	O	O	O	O
g) Walk outside in inclement weather (eg. : snow, rain, ice)	O	O	O	O
h) Go up the stairs with a handrail	O	O	O	O
i) Go down the stairs with a hand-rail)	O	O	O	O
j) Step up a sidewalk curb	O	O	O	O
k) Step down a sidewalk curb	O	O	O	O
l) Go up a few steps (stairs without a handrail	O	O	O	O

***PLEASE NOTE :**

Questions 12 to 21 concern the people who wear their prosthesis at least once a week. If you do not ever wear your prosthesis please go to question 22.

12. For the following question, write the appropriate number in the designated space.

I wear my prosthesis _____ day(s) a week
I wear my prosthesis approximately _____ hour(s) a day

~~**13. In general, you spend *approximately* what percentage of your day …**~~ *Section C question 13 deleted with question 14 and 16 collapsing options to simplify answer options for study participants*

	almost 0%	25%	50%	75%	almost 100% (all day)
a) … sitting?	O	O	O	O	O
b) … standing and/or walking around?	O	O	O	O	O

14. During the day, when you have to move about IN THE HOUSE, *approximately* what percentage is done …

	almost 0%	25%	50%	75%	almost 100% (of all your moving around)
a) … in a wheelchair?	O	O	O	O	O
b) … walking with your prosthesis (*technical aids can be used)?*	O	O	O	O	O
c) … walking without your prosthesis (*technical aids can be used)?*	O	O	O	O	

15. If you do not use your prosthesis 100% of the time for your activities IN THE HOUSE, could you tell us why? ***Those who use their prosthesis 100% of the time to move about in the house, please proceed to question 16.***

«Check* [√] the appropriate *boxes»

a) Because it is not fast enough …… O

b) Because it is too tiring …….. O

c) Because my hands are not free …… O

d) Because of problems with my non-amputated leg

(e.g. : fatigue, pain, etc.) ……. O

e) Because of problems caused by the prosthesis

(e.g. : discomfort, perspiration, etc.) ……. O

f) Because of stump problems

(e.g. : skin irritations, pain, wounds, etc.) ……. O

g) Because I feel unstable with the prosthesis …… O

h) Because the prosthesis needs adjustments

(e.g. : the socket is too tight, too large (loose), etc.) ……O

i) Other reasons _____ …….. O

«specify»

16. During the day, when you have to move about OUTSIDE, ***approximately*** **what percentage is done …**

«Check* [√] *for each statement»

	almost 0%	25%	50%	75%	almost 100%
			(of all your moving around)		
a) … in a wheelchair?	O	O	O	O	O
b) … walking with your prosthesis (technical aids can be used)?	O	O	O	O	O
c) … walking without your prosthesis (technical aids can be used)?	O	O	O	O	O

17. If you do not use your prosthesis 100% of the time for your activities OUTSIDE of the house, could you tell us why? ***Those who use their prosthesis 100% of the time for moving about outside, please proceed to question 18.***

_____

«Check* [√] the appropriate *boxes»

a) Because it is not fast enough …….…… O

b) Because it is too tiring ……..……..……...O

c) When distances to cover are too long ……..O

d) Because of problems with my non-amputated leg

(e.g. : fatigue, pain, etc.) …….. O

e) Because of problems caused by the prosthesis

(e.g. : discomfort, perspiration, etc.) …….…… O

f) Because of stump problems

(e.g. : skin irritations, pain, wounds, etc.) ……... O

g) Because I am afraid of falling …….…….. O

h) Other reasons _____ …… O

«specify»

18. When walking with your prosthesis, approximately what DISTANCE can you cover WITHOUT STOPPING?

«Check* [√] the *most appropriate box»

O … I am not limited in my walking distances outside of the house or in wide open spaces (e.g. : shopping mall)

O … I walk one block (approximately 5-6 houses) or its equivalent non stop

O … I walk more than 30 steps at a time, but less than one block non stop

O … I walk between 10 to 30 steps non stop (e.g. : approximately the length of a hallway in the house)

O … I walk less than 10 steps (e.g. : a few steps within one room in the house)

O … I do not walk with my prosthesis

Question 18 changed distance options as a 'block' in a Canada neighbourhood is different to a block in a suburb or informal settlement in RSA

~~19. Since you have returned home, have you fallen with your prosthesis?~~ *Removed, could have been useful data describing prosthetic mobility*

O NO

O YES _____

«number of falls in the last month»

20. When you walk with your prosthesis, do you have to think about each step you take?

O … NO, walking has become automatic for me

O … YES, I have to concentrate on every step I take

O … I don't know

21. ~~What technical aid(s) do you mainly use to perform activities with the prosthesis (standing up, walking, climbing stairs, etc.)…~~

Question 21 has been removed, as this question has been incorporated into adapted question 11 answering questions on hand-held devices used/needed for activities

	…. In the house ?	.... Outside of the house ?
a) None	O	O
b) One (1) cane	O	O
c) Two (2) canes	O	O
d) Crutches	O	O
e) Walker	O	O

«PLEASE PROCEED TO QUESTION 24.»

***PLEASE NOTE :**
THE FOLLOWING 2 QUESTIONS CONCERN ONLY PERSONS WHO DO NOT WEAR THEIR PROSTHESIS.

22. When did you stop wearing your prosthesis?

«Check* [√] *one box only»

O … Less than one (1) month ago

O … Less than six (6) months ago

O … Less than one (1) year ago

O … Less than two (2) years ago

O … Less than three (3) years ago

O … Less than four (4) years ago

O … Four (4) years ago or more

O … I never wore it

23. Why did you stop wearing your prosthesis?

«Check* [√] the appropriate *boxes»

a) The socket of the prosthesis was too large (loose) for my stump …... O

b) The socket of the prosthesis was too small (tight) for my stump …….O

c) It was too tiring ……. O

d) I had surgery on my stump (eg. : re-amputated, other surgery) …….. O

e) Other _____ ……... O
«specify»

Question 23 asks why the participant stopped using the prosthesis, added reason 'do not know how to walk with prosthesis' as many participants in this study has not received post prosthetic rehabilitation

«PLEASE PROCEED TO QUESTION 24.»

YOUR ENVIRONMENT

~~**24. Do you live …**~~ *Removed*

O … alone?

O … with another person (family member(s), friend(s) or someone else)?

25. Do you live …

«Check [√] one box only»

O … in a residential house or apartment?

O … in a senior citizen's home?

O … in a chronic care hospital or nursing home?

O … Other _____

where participant live, added 'informal housing' as option (Groenewald,1999) as many government patients live in shacks or wendy houses

«specify»

26. Do you have to use stairs inside your house?

Question 26 – 30: collapsed to 2 questions regarding steps. Average housing in RSA does not have as many steps as Canadian housing

O … NO **«GO TO THE QUESTION 29»**

O … YES, with a handrail

O … YES, without a handrail

27. How many steps are in the house?

29. Must you use stairs to enter and leave your house?

O … NO [redacted] **GO TO QUESTION 31»**

O … YES, with a handrail

O … YES, without a handrail

30. How many steps are there to enter and to leave your house?

O … 1 to 9

O … 10 to 19

O … 20 and more

31. ~~**Do you need help to do the following activities, if yes, do you have the required assistance?**~~ *Removed question*

«Check one box [√] for each statement»

	Yes I need help but I do not have the required help	Yes I need help and I have the required help	No I do not need help	I do not have to do the activity
a) Donning (putting on) the prosthesis ..	O	O	O	O
b) Dressing with your prosthesis	O	O	O	O
c) Walking in the house with your prosthesis	O	O	O	O
d) Getting out of your house	O	O	O	O
e) Walking outdoors	O	O	O	O
f) Housekeeping	O	O	O	O
g) Preparing your meals	O	O	O	O
h) Errands/shopping	O	O	O	O

32. What type(s) of transportation do you use when you go out? *Question 32 on transportation: changed options to fit SA context.*

«Check one box [√] for each statement»

	NO	YES accompanied	YES alone
a) Public transport (e.g. : train, bus, metro/subway)	O	O	O
b) Adapted transport	O	O	O
c) Car	O	O	O
d) Taxi	O	O	O
e) Other _____ «specify»	O	O	O

33. ~~Thinking about the people who are close to you, can you indicate the~~ **answer** ~~which best describes their acceptance of your~~ …*Question 33 on the degree of acceptance of others of your prosthesis, removed, not part of this study's objectives*

«Check [√] only one box for each statement»

	DO NOT ACCEPT IT AT ALL	ACCEPT IT SLIGHTLY	ACCEPT IT MODERATELY	ACCEPT IT QUITE WELL	ACCEPT IT COMPLETELY
a) … amputation ?	O	O	O	O	O
b) … prosthesis ?..	O	O	O	O	O

D. YOUR LEISURE ACTIVITIES

34. Do you partake in any sports?

O … NO «GO TO QUESTION 37»

O … YES

35. Which sports do you practice?

«Check one box [√] for each statement»

	Mainly with the prosthesis	Mainly without the prosthesis
a) Golf	O	O
b) Swimming	O	O
c) Cycling	O	O
d) Walking, Hiking	O	O
e) Downhill skiing	O	O
f) Cross-country skiing	O	O
g) Racket sports (eg. : tennis, badminton, etc.)	O	O
h) Fishing	O	O
i) Hunting	O	O
j) Ice skating	O	O
k) Other sports _____ «specify»	O	O

***Section D** on Leisure Activities was not included as 1)this is not a focus of the study 2) to shorten questionnaire and 3) study participants culturally will have other leisure activities*

36. Approximately, how many hours per week do you spend practising these sports?

O … 1 to 4 hours / week

O … 5 to 9 hours / week

O … 10 hours / week and more

37. Do you partake in any recreational activities or hobbies other than sports?

O … NO [redacted] **«GO TO QUESTION 40»**

O … YES

38. Indicate your recreational activities?

«Check* [√] the appropriate *boxes»

a) Reading/television/music ……..……..……..O

b) Cards/bingo/parlour games …...……..……..O

c) Arts and crafts/odd jobs ……..……O

d) Gardening …… O

e) Social clubs/outings …….. O

f) Travelling ……..……. O

g) Other activities _____…….. O
«specify»

39. Approximately, how many hours per week do you spend practising these recreational activities?

O … 1 to 4 hours / week

O … 5 to 9 hours / week

O … 10 hours / week and more

E. GENERAL INFORMATION

The information obtained from the following questions will be used to group the persons answering this questionnaire.

40. Are you currently employed?

O … NO **GO TO QUESTION 42»**

O … YES

~~**41. If you are currently employed, do you have …**~~

Removed Q41: simplified employment questions 40 and 41 to 'yes' and 'no' only

O … the same job as before your amputation?

O … a new job because of your amputation?

O … a new job but not because of your amputation?

«PLEASE PROCEED TO QUESTION 43»

42. If you are not currently employed, are you presently?

Question 42 on non employment status: added option of 'disability grant' to replace 'sick leave' as researcher found disability grants more applicable in current study than sick leave

O … on sick leave because of your amputation?

O … on sick leave because of other health problems?

O … on pension (disability pension, government pension)?

O … a student?

O … at home?

O … other _____

~~**43. How many years of schooling have you completed? _____ years**~~

44. ~~In which category is your FAMILY'S GROSS ANNUAL INCOME situated~~ (meaning ~~the total amount of revenue prior to taxes from all the people who contribute~~ to the family expenses)? *Question 44 on income removed as classification on income will be obtained from the medical records*

O … less than 29,999$

O … 30,000$ to 59,999$

O … 60,000$and more

45. ~~Please indicate who filled in the questionnaire, if the person to whom the questionnaire was addressed to could not answer it personally~~. *Question 45 removed: if answered by 3rd party will be indicated on informed consent document*

O … spouse or other family member

O … person who takes care of him/her (other than a family member)

O … other _____

« specify»

WE INVITE YOU TO MAKE ANY COMMENTS WHICH MAY HELP US TO BETTER UNDERSTAND THE DIFFICULTIES FACED BY AMPUTEES WITH RESPECT TO THEIR ADAPTATION TO THEIR PROSTHESIS.

COMMENTS :

_____

_____

_____

_____

We greatly appreciate your participation and we thank you for your valued collaboration !

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