

The Impact of Prosthetic Limbs on Children with Bilateral Lower Limb Amputations Using the Lived Experiences of Two Adult Prosthetic Users and Healthcare Practitioners

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Declaration

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Abstract

Background

Major lower limb amputations can have a life-changing impact on an individual's functional mobility. The literature supports the view that children with lower limb amputations, even bilateral amputations, have the potential to be highly functional with a prosthesis. However, there is insufficient research to demonstrate the impact of prostheses on children with bilateral lower limb amputations. This challenges the screening and prescription requirements currently in use which tends to hinder the equitable distribution of prosthetics among people with bilateral lower limb amputations.

Aim

The aim of this study was to explore and describe the constructs that determine the impact of prosthetic interventions on children with bilateral lower limb amputations.

Method

A multiple-methods approach was adopted for this study which consisted of a secondary scoping review and a primary qualitative study. The scoping review used Arksey & O'Malley's (2005) five steps to explore and described the constructs used to evaluate the prosthetic impact in children with lower limb amputations in current literature. The information obtained from this review was then used to design the qualitative study.

A qualitative approach and descriptive design were also taken for this study. Semi-structured interviews were conducted with two groups of key informants. Group A (five participants) consists of physiotherapists and prosthetists who have experience rehabilitating children with bilateral lower limb amputations. Group B (two participants) include adult prosthetic users who have undergone bilateral lower limb amputations in childhood. In total, seven individuals participated in the study. The interviews were conducted virtually and were recorded, transcribed and analysed using deductive analysis.

Results

The findings from the scoping review showed that the constructs and outcome measures used to evaluate the prosthetic impact in children with lower limb amputations

had a high focus on physical function as an outcome and were limited in evaluating other constructs of impact in prosthetic intervention, with little focus on the qualitative experiences of prosthetic users, specifically relating to satisfaction, quality of life, and other socio-relational constructs. There was also a low number of children with bilateral amputations included in the studies.

The qualitative study exploring the experiences of children who are prosthetic users identified the constructs that impact children with bilateral prosthetic limbs; these include mobility, activities of daily living, physical participation, education, body image, quality of life and socio-economic participation. Challenges that impact prosthetic use are also explored and include personal and environmental challenges such as finances, prosthetic equipment, availability of resources and supportive relationships, as well as pain.

Conclusion

While physical function has been a consistently evaluated theme in prosthetic rehabilitation, this study provides other areas of impact that healthcare providers might not assess or consider in their decision-making on prosthetic prescription.

The emerging themes are holistic and encourage the use of the International Classification of Functioning, Disability and Health (ICF) model which could be helpful in developing a holistic outcome measure that is appropriate for children with bilateral lower limb amputations. It is hoped that this can provide evidence to improve the distribution of necessary resources to optimise equality among the vulnerable children with bilateral amputations.

Keywords: Lower limb amputation; bilateral lower limb amputation; prosthetic limbs; impact; constructs; children.

Abstrak

Agtergrond

Belangrike onderste ledemaat-amputasies kan 'n lewensveranderende impak op 'n individu se funksionele mobiliteit hê. Literatuur staaf die siening dat kinders met onderste ledemaat-amputasies, selfs bilaterale amputasies, die potensiaal het om hoogs funksioneel te wees met 'n protese. Daar is egter onvoldoende navorsing beskikbaar oor die impak van kinders met protese met bilaterale onderste ledemaat-amputasies. Dit skep 'n uitdaging vir die siftings- en voorskrifvereistes wat tans gebruik word, wat geneig is om die billike verspreiding van prostetika onder mense met bilaterale onderste ledemaat-amputasies te verhinder.

Doel

Die doel van hierdie studie is om ondersoek in te stel na die konstrakte wat die impak bepaal van protetiese ingrepe op kinders met bilaterale onderste ledemaat-amputasies.

Metode

Hierdie studie het gebruik gemaak van 'n gemengde metode benadering wat bestaan uit 'n omvangsoorsig en 'n kwalitatiewe studie. In die omvangsoorsig is gebruik gemaak van Arksey en O'Malley (2005) se vyf stappe om die konstrakte te verken en beskryf wat gebruik word om die protetiese impak by kinders met onderste ledemaat-amputasies te evalueer in hedendaagse literatuur. Die inligting wat uit hierdie oorsig verkry is, is gebruik om die kwalitatiewe studie te skep. 'n Kwalitatiewe benadering en beskrywende ontwerp is ook vir hierdie studie onderneem. Semi-gestruktureerde onderhoude is met twee groepe sleutelinformante gevoer: Groep A (vyf deelnemers) bestaan uit fisioterapeute en prostetikusse wat ondervinding het met die rehabilitasie van kinders met bilaterale onderste ledemaat-amputasies. Groep B (twee deelnemers) sluit in volwasse gebruikers van protese wat bilaterale onderste ledemaat-amputasies in hulle kinderjare ondergaan het. In totaal het sewe individue aan die studie deelgeneem. Die onderhoude is virtueel gevoer en is opgeneem, getranskribeer en ontleed met behulp van tematiese deduktiewe analise.

Resultate

Die bevindinge van die omvangoorsig het getoon dat die konstrukte en uitkomsmaatstawwe wat gebruik is om die prostetiese impak by kinders met onderste ledemaatamputasies te evalueer, 'n groter fokus op die fisiese funksie as 'n uitkoms gehad het en beperk was in die evaluering van ander impakkonstrukte in prostetiese ingrepe. Daar is min fokus geplaas op die kwalitatiewe ervarings van gebruikers met protese. Die studie het ook min kinders met bilaterale amputasies ingesluit.

Die kwalitatiewe studie wat die ervarings van kinders met protese ondersoek het, het die konstrukte geïdentifiseer wat kinders met bilaterale prostetiese ledemate beïnvloed. Dit sluit in mobiliteit, daaglikse aktiwiteite, fisiese deelname, opvoeding, liggaamsbeeld, lewenskwaliteit en sosio-ekonomiese deelname. Die uitdagings wat 'n impak op prostetiese gebruik het, word ook ondersoek. Dit sluit uitdagings in soos finansies, prostetiese toerusting, die beskikbaarheid van hulpbronne, ondersteunende verhoudings, asook pyn.

Gevolgtrekking

Alhoewel fisiese funksie 'n konsekwente geëvalueerde tema in prostetiese rehabilitasie is, bied hierdie studie ander areas van impak wat verskaffers van gesondheidsorg dalk nie assessee of oorweeg in hul besluitneming oor die voorskrif van protese nie. Die temas wat ter voorskyn kom is holisties en moedig die gebruik van die internasionale klassifikasie van funksionering, gestremdheid en gesondheid (FGG) aan wat bruikbaar kan wees in die ontwikkeling van 'n holistiese uitkomsmaatstaf wat geskik is vir kinders met bilaterale onderste ledemaat-amputasies. Dit skep hoop dat dit bewyse kan lewer om die verspreiding van die nodige hulpbronne te verbeter.

Sleutelwoorde: Onderste ledemaat-amputasie; bilaterale onderste ledemaat-amputasie; prostetiese ledemate; impak; konstrukte; kinders.

Dedication

This work is dedicated to The Bionic Club, a group of extraordinary kids who are so incredibly heroic and who have made this study more personal than it ever was when I initially started working on it. Your resilience has not gone unnoticed, and I feel honoured to have met and worked with you. I hope you continue to showcase your talents and that your prosthetics take you further than you would have ever imagined. You are limitless.

To my grandparents: Thank you, Tamkhulu, for constantly reminding us to reach further than the stars. This work is dedicated to you as a reminder of the impactful and laborious work you have done throughout your life. This is only the beginning and I am so overjoyed that I can share just one more monumental moment in my life with you.

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Definition of Terms

Constructs. An abstract idea that has been explicitly chosen (or made) to explain particular phenomena is known as a 'construct'. A construct can also be a straightforward idea, or it can combine a number of closely related ideas which are made up of multiple underlying ideas (Bhattacharjee, 2012). When used in research, constructs must have clear and specific definitions so that others can understand what is meant and not meant by them (Bhattacharjee, 2012).

Developing Settings. For analytical purposes, the World Bank divides a country's economy into four income groups: low, lower-middle, upper-middle, and high-income (World Bank, n.d). Countries are classified according to their Gross National Income (GNI). As of 2021, low-income countries were classified as those with a GNI per capita of \$1 085 or less, lower-middle-income countries have a GNI per capita of \$1 086 and \$4 255 and upper-middle-income countries have a GNI per capita of \$4 256 and \$13 205 (World Bank, n.d). Countries classified as low-income or middle-income are known as developing countries (Gbadamosi, 2016).

Impact. Positive and negative, primary and secondary, long-term effects produced directly or indirectly, intentionally and unintentionally, by a development intervention (Alavi et al, 2010).

Lower Limb Amputation. The removal of a part of, or multiple parts of the lower limb (Esquenazi & Yoo, 2016).

Outcome Measure. A tool for evaluating a patient's present condition is an outcome measure (Fetters & Tilson, 2018). An outcome measure can also be used to assess the results of any interventions over time (Copeland, 2009).

Abbreviations

ADL	Activities of Daily Living
BLLA	Bilateral lower limb amputation
HPCSA	Health Professions Council of South Africa
ICF	International Classification of Functioning, Disability and Health
LLA	Lower limb amputation
LLD	Lower limb discrepancy
LCI-5	Locomotor Capabilities Index-5
OM	Outcome measure
PI	Primary investigator
PODCI	Paediatric Outcomes Data Collection Instrument
RMI	Rivermead Mobility Index
SIGAM	Special Interest Group in Amputee Medicine
TAPES-R	Trinity Amputation and Prosthesis-Satisfaction Scales-Revised
TWT	Timed Walking Test
WHO	World Health Organisation

Chapter 1: Introduction and Overview

1.1 Introduction

This Chapter will provide the background, rationale and purpose of the study. In this Chapter, the research question will be outlined and the aims and objectives will be discussed.

1.2 Background

Major lower limb amputations can have a life-changing impact on an individual's functional mobility (Marzen-Groller et al., 2008; Mduzana, 2017). People with lower-limb amputations have to adapt physically, socially and physiologically to changes in structure, function and body image (Novotny, 1986; Holzer et al., 2014). Persons who suffer limb loss are not only physically affected, but also experience challenges with their body image. The reconstruction of a limb and prosthetics play a vital role in increasing functional performance, creating favourable participation and improving quality of life and body image (Sakkers & van Wijk, 2016).

The literature supports the view that children with lower limb amputations, even with bilateral amputations, have the potential to be highly functional with a prosthesis (Şener et al., 1999). Children are more motivated to be functional compared to adults, which results in improved functional outcomes for young prosthetic users (Pruitt et al., 1999; Yilgilter et al., 2005). They are also able to adapt much faster and easier than adults (Smith & Campbell, 2009).

While there is some evidence to support the fact that children with lower-limb amputations can be high functioning with a prosthesis, there is insufficient literature to demonstrate the impact of a prosthesis on children with lower limb amputations. This is with particular reference to bilateral lower limb amputations, making prosthetic prescription hard to justify in low resourced settings.

The prevalence of amputations ranges from 1.2 to 1.4 per 10 000 occupants in various countries (Unwin, 2000; Ephraim et al. 2003; Holzer et al. 2014). Up to 90% of all amputations are performed on lower limbs (Ephraim et al. 2003; Holzer et al. 2014).

There is a lack of statistics on the prevalence of amputations in children, even though traumatic limb amputations are more common and severe in children in comparison to adults (Letton & Chwals, 1994; Khan et al. 2016). Data from the emergency departments of the United States recorded 111 600 amputations (an average of 775 amputations per month) performed on children between the years 1990 to 2002 (Hostetler et al. 2005; Khan et al. 2016).

In children, the rate of congenital limb loss versus acquired limb loss is 2:1 (Masada et al. 1986; Vannah et al. 1999; Yilgilter et al. 2005). The overall incidence of congenital limb deficiencies is 0.3 to 1 per 1 000 live births in the United States and affects about 1 500 to 4 500 children annually in this country (Trautwein et al. 1996; Smith, 2006).

It is not yet known what the exact cause of congenital limb deficiencies at birth is. However, in acquired amputations in children, tumours are known to be the main leading cause of disease. Vascular malformations, neurogenic problems and rare diseases can also result in a child having an amputation (Carnegie 1999; Pandian et al. 2001; Yilgilter et al. 2005). A study done in Turkey by Yilgilter et al. (2005) showed the prevalence of congenital limb loss to acquired limb loss was 1:2, which was the exact opposite finding in international literature. This study suggested that the increase in acquired limb loss could be due to socioeconomic and educational challenges, which result in children being exposed to more work accidents (Yilgilter et al. 2005).

Psychological adjustment disorders are more prevalent in younger persons with lower limb amputations as compared to older persons with lower limb amputations (Frank et al. 1984; Tatar, 2010). Anxiety can arise from feelings of insecurity and inadequacy should there be no proper support and preparation for amputation.

Social receptiveness and care also play a role in how a person with a lower limb amputation accepts their new body image (Maguire & Parkes, 1998; Racy, 1989; Svoboda, 1992; Waites & Zigmond, 1999; Tatar, 2010). A well-fitting prosthesis could mitigate these feelings of anxiety. When combined with acceptance, affection, and a supportive home environment, children can return to healthy competition at work and play, which in turn improves their self-image (Breiner et al. 2016; Masten & Cicchetti, 2010; Brooks et al. 1962).

Clinical expertise plays a vital role in prescribing prosthetics that are adequate. However, there is no clear evidence-based motivation for the choices made by clinical practitioners (Van der Linde et al. 2003). Individual service providers use their discretion to decide whether or not to refer or issue a person with a prosthesis. This ad hoc practice could exclude and discriminate against some patients (Mduzana, 2017).

Children with bilateral lower limb amputations often fall under this discriminatory category as there is a lack of appropriate outcome measures or screening criteria. These children could potentially have good functional outcomes, but are overlooked due to the “floor effects” seen on outcome measures used in those with unilateral limb loss.

Some international studies have shown inconsistencies with regard to prosthetic prescription in developed countries, as well as a lack of consensus amongst prosthetists on the potential outcome of persons with lower limb amputations (Van der Linde et al. 2003; Schaffalitzky, 2010; Mduzana, 2017). Prosthetics has, therefore, been noted as a field that has fallen behind other fields in using evidence-based practice (Ramstrand & Brodtkorb, 2008; Schaffalitzky, 2011).

The goal for people with limb loss is usually to restore function and quality of life to the fullest extent possible with prostheses, wheeled mobility and other assistive devices.

Being able to identify vital outcomes, predictors, and facilitators when prescribing lower limb prostheses, and the use thereof, is important in meeting the needs of prosthetic users (Schaffalitzky et al. 2012). Whilst no consensus exists on which outcomes are most important in the prescription of lower limb prostheses (Schaffalitzky et al. 2012), age and mobility prior to the amputation were noted to have strong influences on prosthesis use (Mundell et al. 2016).

A study by Akarsu et al. (2013) compared people with unilateral and bilateral lower limb amputations on the use of their prosthesis, quality of life, independent ambulation, capacity and gait parameters for the first time in literature (to this author's knowledge). Amongst the parameters assessed in this study, prosthetic use was similar between people with unilateral and bilateral lower limb amputations. Prostheses were noted to improve quality of life as they provided a normal body image and increased the capabilities of people with lower limb amputations.

In addition, the satisfaction with one's prosthesis and body image did not alter with the level of the amputation. However, the quality of life and satisfaction with one's prosthesis did increase in parallel with the use of the prosthesis. According to this author, it is important to note that the study included participants who were war veterans. This could not be relevant to people with lower-limb amputations where finances could be a limiting factor for the type of prosthesis that can be acquired (Akarsu et al. 2013).

There is a lack of evidence supporting the impact of prosthetic prescriptions in children with bilateral lower limb amputations. Clinicians make use of outcome measures for the screening of people with lower limb amputations in order to refer them for prosthetic fitting. As a result of people with bilateral limb loss being fewer in number and more limited in function, they often do not meet the functional criteria for prosthetic referral.

Children wear their prostheses for longer periods of time and are more active when compared to adults, potentially making them excellent candidates for prosthetics (Vannah et al. 1999). The lack of evidence of the impact of prosthetic intervention among children with bilateral amputations means that they are often not considered prosthetic candidates, especially in resource-constrained environments.

The impact of a health condition is often assessed in terms of functioning and collateral disability. It ultimately seeks opportunities for improvement in terms of a performance gap. The characteristics of impact refer to the condition(s), outcome(s) and associated interventions that a measure would address (Institute of Medicine, 2013).

The World Health Organisation's ICF is a framework for describing functioning and disability in relation to a health condition (Konstanjsek, 2011). This framework uses the lived experiences of an individual as perspective, i.e., insider perspective. The classification utilises a common language and framework for identifying and classifying a person's level of function within their unique environment.

The health of each individual lies in their ability to carry out the full range of activities needed to engage in all aspects of life. Knowing the functional status of individuals and populations is beneficial for record keeping and it enables us to evaluate outcomes, compare treatments, predict and manage costs associated with health care delivery and establish eligibility for government programmes. It also helps to inform key stakeholders (Sykes, 2008).

With the high costs of manufacturing prosthetic limbs, costs could run even higher for children who are constantly growing and changing. Rehabilitation with a prosthesis that is well-fitted is vital in maintaining an active lifestyle, which is the primary requirement of children. They are, then, also able to be successful in their daily activities and the functional outcome gained plays a major role in schooling and social adaptations (Şener et al. 1999).

This study aims to explore how prosthetic limbs impact children with bilateral lower limb amputations on a wide range of functioning behaviours. This includes, but is not limited to their level of functional independence, social integration and relationships, participation, belongingness and body image. The information gained from this study might demonstrate the impact of prosthetic fitting on this group of children.

1.3 Problem Statement

The provision of prosthetic lower limbs in persons (especially children) with bilateral lower limb amputations is problematic. Children with bilateral lower limb amputations are not prioritised and often discriminated against in the provision of prosthetic limbs. As a result of this, criteria often used to recommend the provision of prosthetics rely upon outcome measures that were developed for adults. These criteria are not always sensitive or calibrated to differentiate between unilateral and bilateral amputations, leaving children with bilateral lower limb amputations at a disadvantage.

While the development of outcome measures for children with bilateral amputations is slow, there is a need to demonstrate the impact of prosthetics on the lives of children who have managed to receive them privately or via a non-governmental organisation (NGO). This could be used as evidence to support the consideration and provision of prosthetics in the public sector. This information could provide relevant stakeholders and policymakers with much needed information on the benefits of prosthetic provision in those more severely affected.

1.4 Research Aim

The aim of this study is to explore and describe the constructs that determine the impact of prosthetic interventions in children with bilateral lower limb amputations.

1.5 Research Questions

1. Which constructs (e.g., physical, psychological, emotional, social reintegration, participation) are currently being evaluated in order to assess the impact of prosthetic intervention in children with a lower limb amputation?
2. What are the perceived benefits of receiving prosthetic limbs for children with bilateral lower limb amputations in the local setting?
3. What are the additional constructs that should be considered for children with bilateral lower limb amputations?

1.6 Research Objectives

The study objectives were:

1. To explore and describe the constructs used to evaluate prosthetic impact in children with lower limb amputation.
2. To explore and describe which additional constructs should be considered specifically for children with bilateral lower limb amputations, as opposed to adults and unilateral amputations.
3. To explore and describe the experiences and impact of prosthetic intervention on children with bilateral lower limb amputations who are current prosthetic users. This information will be obtained from key stakeholders, including prosthetists and physiotherapists who rehabilitate children with bilateral lower limb amputations and adult prosthetic users who underwent bilateral lower amputations as children.

Chapter 2: The Evaluation of Prosthetic Impact in Children with Lower Limb Amputations – A Scoping Review of Constructs and Outcome Measures

2.1 Introduction

There is general consensus that children with lower limb amputations fare significantly better with prosthetics when compared to adults (Smith & Campbell, 2009; Vannah et al. 1999). Children with unilateral lower limb amputations have better functional outcomes when compared to their peers with bilateral lower limb amputations and they are more likely to receive a prosthesis. Clinically, children with bilateral lower limb amputations also achieve higher levels of function and do well when issued with the correct prosthetics. Children with bilateral lower limb amputations are rarely issued with prosthetics (especially in developing and resource-constrained settings) and there is even less evidence supporting the issuing of prosthetics for these children.

The impact of issuing prosthetic devices to these children is not well documented. The lack of scientific evidence supporting the provision of prosthetics to children with lower limb amputations negatively affects how many children are receiving prosthetics, especially in developing countries. A possible explanation for the lack of impact studies could be that there are very few (if any) standardised outcome measures that can be used to measure the impact of prosthetics on the paediatric population (Pruitt et al. 1996).

Furthermore, the psychometric testing of outcome measures in child populations further impedes the development process. In the past, prosthetics practitioners have also not used standardised outcome measures. The lack of familiarity with using standardised outcome measures could be a reason for practitioners not using them frequently in practice. This would provide supporting evidence to guide future practice which, in turn, would contribute to fairness and the equitable distribution of scarce resources (Gaunard et al. 2015; Duncan & Murray, 2012; Hatfield & Ogles, 2004; Jette et al. 2009).

Outcome measures are tools used for evaluating a patient's present condition (Fetters & Tilson, 2018). These measures are used for a variety of reasons within clinical settings. They provide baseline information that can be used before any treatment is given and this also helps to guide therapy intervention and treatment planning to set therapy goals. The same instrument may be used in subsequent assessments after therapy has begun to identify whether the patient has shown a change in the outcome of choice and relevance (Copeland, 2009). There is currently a lack of adequate outcome measures designed specifically for measuring the impact of prosthetic limbs in children with lower limb amputations. This is especially true for children with bilateral lower limb amputations, which puts the children at a disadvantage when it comes to the issuing of prosthetics.

There are few tools for determining whether healthcare initiatives provide actual health benefits. This is particularly relevant in the field of prosthetics for children (Pruitt et al., 1996). The lack of relevant outcome measures for children with bilateral lower limb amputations means that the issuing of prosthetic technology can be very subjective. This, in turn, could affect how the impact of these prosthetic limbs is measured when only certain constructs are considered when evaluating these children.

Physical function can be defined as the ability to carry out simple and complex activities of daily living, mobility and performing activities of leisure (Garber et al. 2010; Young & Wright, 1995; Coster & Ludlow, 1991; Meenan, 1987). While physical function may be the most direct and widely used outcome for prosthetic prescription to evaluate impact, other constructs such as psychological aspects, community integration and quality of life must be further emphasised in this field to effectively meet user's requirements (Schaffalitzky et al. 2011). This could be true for other constructs as well, including (but not limited to) body image, self-esteem, participation and social inclusion.

It is also important to note that “children are not just small adults” (Gills & Loughlan, 2007). Children with lower limb prosthetics have lower non-use levels when compared to adults. This includes children with bilateral lower limb amputations, who are reported to have higher functional levels when compared to adults with the same amputation level and laterality (Vannah et al. 1999).

The majority of children, including those with high-level bilateral lower limb amputations, engage in high levels of physical activity. They are noted to place high physical demands on their prosthesis and often needing major services and repairs on their prosthetic limbs (Smith et al. 2022).

The number of studies reporting functional outcomes in children who use prosthetic limbs to ambulate is low. However, constructs beyond physical functioning are even more underreported. These constructs could be important to evaluate the impact of prosthetic limbs in children with lower limb amputations and even more so, in children with bilateral lower limb amputations.

While there is a lack of agreement in the research regarding the result that represents successful lower limb amputee rehabilitation and the most suitable outcome instrument to measure that chosen outcome (Deathe et al. 2009; Condie et al. 2006; Deathe et al. 2002; Turner-Stokes & Turner-Stokes, 1997), there is also no classification that is accepted worldwide. In order for healthcare practitioners to exchange and compare the functional results of patients with lower limb amputations, only a few outcome measures can be used across cultural boundaries (Xu et al. 2011).

The ICF is a flexible classification that can be used for a variety of purposes across many sectors (World Health Organisation, 2002). It serves as a conceptual framework that is anticipated to be accepted universally and by academic and professional fields, funders, service providers, policy-makers, governmental institutions and advocacy groups (Stucki et al. 2007; Stucki, 2005). The ICF also uses standard language to describe and code functional status information. In this framework, the term ‘disability’ refers to impairments, activity limitations and participation restrictions (Konstanjsek, 2011). (i) Impairments refer to problems people experience with bodily functions and structures; (ii) Activity limitations are difficulties people have in executing a task or

action; and (iii) participation restrictions are obstacles one can encounter “in engaging in life circumstances” (Rhoda, 2012; World Health Organisation, 2001).

A preliminary search on the impact of prosthetic limbs on children specifically with bilateral lower limb amputations yielded minimal results. Subsequently, the scope was broadened to include all outcome measures used in the paediatric population, regardless of laterality. This review aims to explore and describe the constructs used to evaluate the prosthetic impact on children with lower limb amputations from existing literature. The findings from this scoping review will be used to inform the interviews to explore the lived experiences regarding the impact on constructs reported in the literature. Additional constructs of relevance from user and service provider perspectives within the local South African setting will also be explored.

2.2 Aim

This study aimed to explore and describe the outcome measures and constructs used to evaluate prosthetic impact in children with lower limb amputations.

2.3 Methodology

This scoping review was conducted using Arksey & O'Malley's (2005) five steps that make up the framework for this study design. The scoping review of the literature allowed for the collection and examination of existing studies on the topic. Scoping reviews are often done to (i) examine the extent, range and nature of research activity, (ii) to summarise and share research findings for the relevant research area, and (iii) to identify gaps in the literature. (iv) Scoping reviews also provide an overview of current existing literature and do not critically appraise individual studies. (v) Scoping reviews therefore focus on mapping key concepts in certain research areas and the main sources and types of evidence available for the research area (Arksey & O'Malley, 2005).

This scoping review aimed to provide a descriptive overview of evidence from various sources of literature on the impact of a prosthesis on children with lower limb

amputations and did not aim to critically appraise individual studies. It also aimed to identify any gaps in the literature and a scoping review was, therefore, an appropriate design. Arksey & O'Malley's (2005) framework for conducting a scoping review includes five stages; namely, i) Identifying the research question; ii) Identifying relevant studies (eligibility and search strategy); iii) study selection; iv) charting the data; and v) collating and summarising the results.

2.3.1 Identifying the research question

A preliminary search of the impact of prosthetic prescription on children with bilateral lower limb amputations in the literature found a lack of focus on bilateral lower limb amputations. The scope was, therefore, broadened to include children with unilateral and bilateral lower limb amputations. This scoping review, therefore, aims to explore the outcome measures and constructs currently being evaluated to assess the impact of prosthetic intervention in children with all types of lower limb amputations.

The two questions guiding the scoping review are: "Which constructs (physical, psychological, emotional, social reintegration, participation) and associated outcome measures are currently being evaluated to assess the impact of prosthetic intervention in children with lower limb amputation?"

The research questions informed how the search strategies were constructed and it was, therefore, important to carefully consider aspects of the question such as the study population, interventions and/or outcomes.

2.3.2 Identifying relevant studies (eligibility and search strategy)

The second stage of the scoping review involved searching for available research on the relevant topic using various sources (Arksey & O'Malley, 2005). Prior to commencing the search, numerous factors had to be considered and these include the type of database to use for research, key concepts and related terms that are appropriate to search for, piloting the search strategy to make room for refinement and the potential costs for accessing electronic databases. (Arksey & O'Malley, 2005).

An extensive search was conducted using multiple electronic databases. These databases included Ebscohost, PubMed, Cochrane, and Scopus. However, only a few results were yielded from the search. Only full-text articles published from inception to June 2020 were included to inform the type of questions asked in the qualitative study. The time frame in the inclusion criteria was set to June 2020 as a result of the semi-structured interviews in the qualitative study being conducted soon after the scoping review data was collected and articles published after June 2020 were not included to inform the type of questions asked in the qualitative study.

The articles had to address any construct used to evaluate the impact of prosthetic limbs for children with lower limb amputations. The keywords used to identify relevant literature included “impact”, “prosthetic limbs”, “lower limb amputation (LLA)”, “evaluate” and “children”. The search strategy is indicated in Table 1 below.

Table 1: Search strategy

Concept	Keywords	MeSH terms
1. Participant	Children	Child OR Paediatrics
2. Intervention	Prosthetic limbs	Prosthetics OR prosthetic legs OR Prosthetic limb OR Prosthetic
3. Outcome	Impact	Impact OR Effect OR Influence

2.3.3 Study selection

The eligibility criteria included all study designs, except for systematic reviews. The study population included children with any level of lower limb amputation and both unilateral and bilateral amputations were included. Outcomes also formed a part of the eligibility criteria and included the constructs categorised under broad categories of function, psychological status, body image, activities and participation. Inclusion and exclusion criteria were used to aid in identifying the studies that will be included in the scoping review. A Study Eligibility Form was used to document each study's eligibility to be included in this research project.

Inclusion Criteria

- **Type of publication:** All types of electronic articles, except for systematic reviews
- **Language:** English
- **Time frame:** From inception to June 2020
- **Study population:** Children with lower-limb amputations who are prosthetic users
- **Types of intervention:** Prosthetic prescription (including no intervention)
- **Outcomes:** Impact on any of the broad outcomes of function, psychological status and body image, activities and participation. Qualitative experiential data that was contributed by children who are lower limb prosthetic users was also included.

2.3.4 Charting the data

Once the final full-text articles were included, a data extraction form was created to align with the research question. The data extracted from this form included key elements such as the author and the year of publication, the title, study design, sample size, the laterality (unilateral vs bilateral) of the amputation and the evaluated constructs, including outcome measures used to evaluate these constructs. Additional information that was extracted from the articles included the constructs and outcome measures used for evaluation as well as any other qualitative elements that were contributed by children who are lower limb prosthetic users.

2.3.5 Collating, summarising, and reporting the data

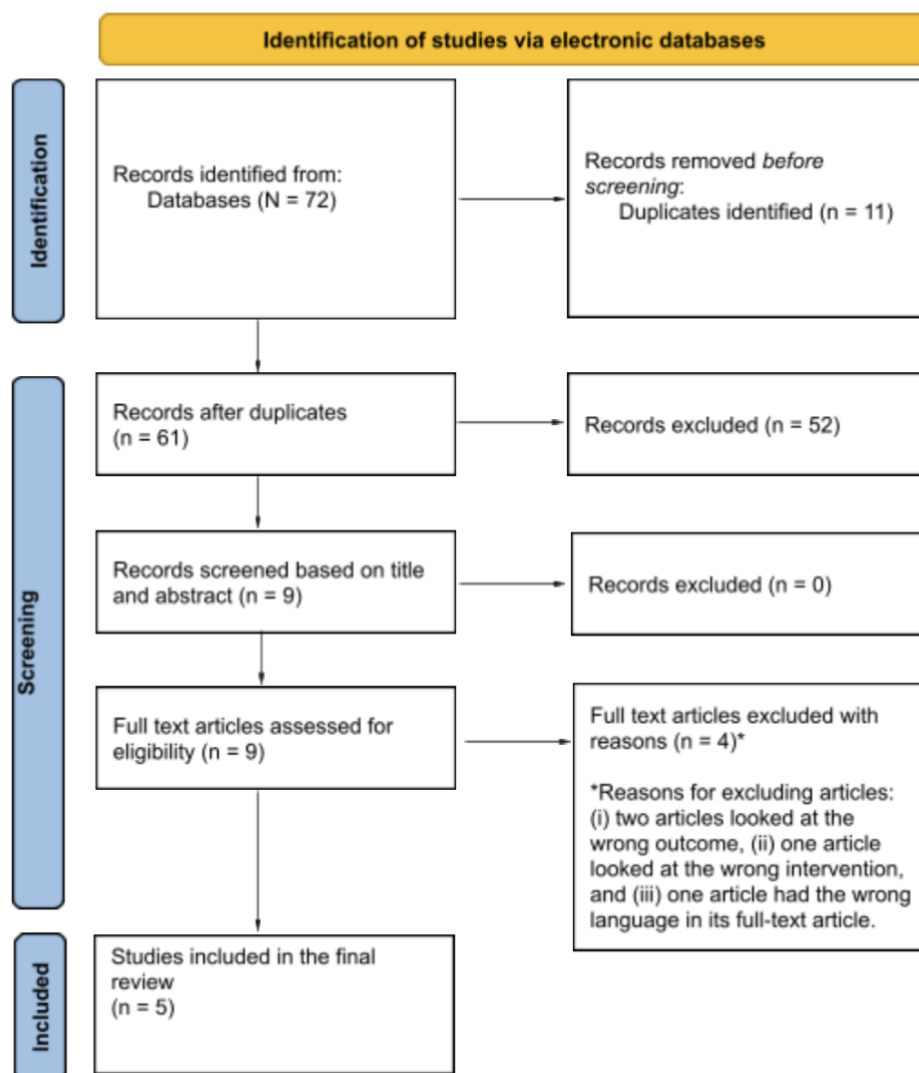
The information extracted from the data forms were collated and reported in a narrative table. The key findings were collated based on the relevance to the study aim and the research question, which included the level of amputation, the constructs evaluated and the outcomes measure used to evaluate the construct.

2.4 Results

After the initial search, 72 results were retrieved. These titles were exported to Rayyan Systems Inc, which is a free software package used for research studies in the process of screening and selecting literature (Elmagarmid et al. 2014). Once the duplicate titles were identified and deleted, 61 articles were eligible for inclusion. Of these articles, only nine were deemed relevant to the research question.

These articles were screened at an abstract level by an independent scorer for relevance and thereafter, four articles were further excluded. These four articles were excluded as two of the articles only included an adult population and the other two articles evaluated upper limb amputations. Five studies met the inclusion criteria and were included in this scoping review. This data was then filtered and a PRISMA Diagram (Figure 1) was used to document the search strategy (Stovold et al. 2014). The results of the data extracted from these articles are found in Table 2 below.

Figure 1: Prisma Diagram



2.4.1 Study demographics

A total of 354 participants were included in the final five articles. However, three of the studies included both adults and children (Alan et al. 2007; Morrison et al. 2020; Ryall et al. 2003), and the number of child participants was not disclosed. Two of the included studies focused specifically on child participants as per the inclusion criteria (McQuerry et al. 2019; Engsberg et al. 1991), and three of the articles included both children and adults in their studies (Alan et al. 2007; Morrison et al. 2020; Ryall et al. 2003).

All the participants included in the studies had some form of lower limb deficiency, except for the ten child participants in the study by Engsberg et al. (1991). These ten participants were able-bodied children and were used as a comparison in the article.

2.4.2 Amputation laterality

The number of participants with unilateral lower limb amputations was 317, while the number of participants with bilateral lower limb amputations was 37. Two of the five studies included participants with bilateral lower limb amputations (McQuerry et al. 2019; Ryall et al., 2003).

2.4.3 Outcome measures and constructs evaluated

The articles included in this scoping review assessed various constructs using different outcome measures to evaluate the impact of prosthetic limbs on children with lower limb amputations. Physical function was the most consistent construct to appear in the articles (n=4), with activities of daily living being the most evaluated outcome. McQuerry et al. (2019) was the only study that compared the results according to amputation level, laterality and cause of amputation (congenital versus acquired). The outcome measures used to evaluate the constructs included both standardised outcome measures (McQuerry et al. 2019; Engsberg et al. 1991; Ryall et al. 2003; Morrison et al. 2020) and a non-standardised outcome questionnaire (Alan et al. 2007).

The constructs described below are: body structure and function; activities of daily living (physical function); participation; psychological function; qualitative experiences.

Body structure and function. Engsberg et al. (1991) measured the impact of intersegmental forces (joint structure and function) in children with unilateral transtibial amputations who are prosthetic users when they are standing and compared the results to able-bodied children. This study used an EMED ® pressure system and Locam cameras to collect ground reaction pressure data and spatial data, respectively. This was the only comparison study that included able-bodied participants.

The findings of this study demonstrated that there were significant disparities in the intersegmental forces between the dominant and non-dominant joints of able-bodied children and the prosthetic and non-prosthetic knees and hips of children with lower limb amputations. However, these forces were substantially lower in children when they are standing as compared to when they are walking and running. These results imply that the intersegmental pressures endured when children with a transtibial amputation are standing would not be harmful to their health.

Pain and discomfort as body functions were evaluated in two studies (McQuerry et al. 2019; Alan et al. 2007). By using the Paediatric Outcomes Data Collection Instrument (PODCI), the study by McQuerry et al. (2019) shows there were no significant differences in pain/comfort between the participants with unilateral or bilateral amputations. The following issues were mentioned as occurring at least once: sores or pressure sores, poor fit, stump pain, foot breakage and unscheduled visits to the prosthetist in the past 12 months.

Activities of daily living (physical function). Activities of daily living were assessed across the articles in a number of ways, including transfers (n=2), basic and global mobility (n=4) and the performance of activities of daily living (ADLs) (n=1) and functional activities with and without a prosthesis (n=1). While three of the studies included only children with unilateral lower limb amputations, two studies did include children with bilateral lower limb amputations as participants. According to laterality in the study by McQuerry et al. (2019), participants with unilateral and bilateral ankle amputations had no significant difference in their functioning.

In the study by Alan et al. (2007), functional outcomes were assessed using a non-standardised questionnaire. This questionnaire assessed how frequently participants used their prosthetic limbs to perform functional activities such as walking, transfers, climbing of stairs and performing ADLs. The results showed good functional outcomes in those fitted with a prosthesis. The average time spent walking with a prosthesis was ten hours. In addition, those participants who walked using a prosthesis reported being able to walk better with a prosthesis than without one.

Morrison et al. (2020) used a non-standardised survey to assess the functional abilities of participants with a Boyd/Syme amputation with a prosthesis. Two standardised outcome measures were also used: the Trinity Amputation and Prosthesis Experience Scales-Revised (TAPES-R) and the Locomotor Capabilities Index-5 (LCI-5). The findings showed that children with a small leg length amongst this type of amputation could perhaps be limited in functionality and prosthetic componentry. This was evident in the results which demonstrated that those with a more distal amputation had a lower LCI-5 score. The TAPES-R activity restriction also showed the least restriction in participants with a more proximal amputation.

Participation. While participation was not explicitly evaluated in any of the articles, sports function was assessed by McQuerry et al. (2019) using the PODCI. The results from this study reported that there was a significant difference in sports/physical functioning scores between prosthetic users with an ankle versus a knee amputation.

Sports functioning and participation were numerous times repeated as a limitation with prostheses in the study by Morrison et al. (2020). The responses shared included swimming, running, “being a wicketkeeper” (cricket), pointing toes, walking along the side of the pool, rugby, motocross and scuba diving. Participant comments further touched on the subject as they reported “(wishing for) different kinds of prostheses for various activities,” and “funding for sports prostheses” (Morrison et al. 2020).

Alan et al. (2007) asked the children who participated in the study to compare their functional abilities with and without their prosthetic limbs. The children who made use

of prostheses were found to perform their functional activities better than those who did not use a prosthesis. There were also more children making use of prosthetics than not in the included studies.

Psychological function. McQuerry et al. (2019) was the only study that evaluated psychological function by assessing happiness. The results showed that even though children with bilateral knee amputations who used prosthetic limbs performed worse than those with unilateral lower limb amputations across ADL performance parameters, there was no difference in happiness between the two groups.

Concerns regarding cosmetic appearances were raised and participants specifically noted having reservations about wearing shorts in public and experiencing shyness when swimming in public spaces. Some also commented that “in America, there are more skin tones available (Morrison et al. 2020).”

Qualitative experiences. While the data collected from the included articles does support prosthetic limbs improving physical function and ADL performance, additional qualitative data was also obtained that addressed some of the children’s lived experiences with prostheses and prosthesis satisfaction. Morrison et al. (2020) gave their participants the opportunity to provide comments regarding some of their functional limitations. The limitations reported included both physical and psychological functions.

The results of the data extracted from these articles are found in Table 2 below.

Table 2: Results of extracted data

FIRST AUTHOR AND YEAR OF PUBLICATION	COUNTRY	AIM	DESIGN	NUMBER OF PARTICIPANTS (n)	LATERALITY [n (%)]	OUTCOME MEASURE USED FOR EVALUATION (Standardised and non-standardised)	CONSTRUCT EVALUATED
McQuerry et al. 2019	United States of America	To determine if children with amputations have different subjective functions and quality of life depending on the level, laterality and cause of amputation.	Retrospective observational study	96	Unilateral: 84 (88) Bilateral: 12 (12)	Paediatric Outcomes Data Collection Instrument (PODCI).	<u>Physical functioning:</u> Transfer, basic mobility, global functioning, and sports/physical functioning <u>Pain/Comfort</u> <u>Psychological well-being:</u> Happiness
Alan et al. 2007	United States of America	To determine the functional prosthetic use in children who had undergone a lower limb amputation due to myelomeningocele.	Retrospective observational study	8 (n= the number of children at the time of the study included both children and adult participants)	Unilateral: 8 (100) Bilateral: 0 (0)	Non-standardised questionnaire	<u>Physical function</u> Mobility (walking, transfers, stair climbing), ADL performance and explored which environment the prostheses were used in and frequency (school, home, around friends, special occasions).

							<u>Pain/comfort</u> The presence of ulcers
Engsberg et al. 1991	Canada	To compare intersegmental forces in the knees and hips between children with below-knee amputations and able-bodied children during standing.	Retrospective observational study	13 (n= 10 able-bodied children used as a comparison)	Unilateral: 3 (23) Bilateral: 0 (0)	Ground pressure data were collected from the EMED pressure system. Spatial data was taken from Locam cameras.	<u>Physical function:</u> Standing
Morrison et al. 2020	Australia and the United Kingdom	The study aims included (1) investigating the relationship between leg length discrepancy, function, restriction in SA; (2) weight-bearing on a stump with no prosthesis; and (3) the limitations experienced by those who make use of a prosthetic limb	Retrospective observational study	47 (n= the number child participants at follow-up included both children and adult participants)	Unilateral: 47 (100) Bilateral: 0 (0)	Non-standardised survey. Data were also collected to calculate the subscales of the Trinity Amputation and Prosthesis-Satisfaction Scales-Revised (TAPES-R) and the Locomotor Capabilities Index-5 (LCI-5)	<u>Physical function:</u> Ambulation with and without a prosthesis and in various environments <u>Prosthesis satisfaction</u> Limitations experienced with the prosthesis
Ryall et al., 2003	United Kingdom	To create a valid outcome measure	Retrospective	200	Unilateral: 175 (87.5)	The Special Interest Group	<u>Physical function:</u>

		for the mobility of those with lower-limb amputations that would be appropriate to use in the typical clinical setting and be able to monitor change.	experimental design	(n= unknown as the number of child participants was not recorded)	Bilateral: 25 (12.5)	in Amputee Medicine (SIGAM). The Rivermead Mobility Index (RMI) was used to examine ambulation as a co-calibration method. The Timed Walking Test (TWT) was used as a means of testing concurrent validity and sensitivity to change for the SIGAM.	Mobilising (environment specific, distance, and level of independence).
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2.5 Discussion

This scoping review provides an overview of the constructs and outcome measures used to evaluate the impact of prosthetic limbs in children with lower limb amputations. Due to a lack of existing literature regarding children with lower limb loss, articles from inception were included to yield a greater pool of studies and the researcher anticipated a lack of studies that included children with bilateral lower limb amputations. Only five articles met the inclusion criteria and were included in this review.

The main constructs used to evaluate the impact of prosthetic provision for children with lower limb amputations in this scoping review were body structure and function, ADLs (physical function), participation, psychological function (happiness) and qualitative experiences. The constructs were evaluated using standardised and non-standardised outcome measures and only two of the five articles included participants with unilateral and bilateral lower limb amputations.

Body structure and function were evaluated using an EMED® pressure system and Locam cameras to obtain pressure data. The PODCI was used to measure pain and comfort and a non-standardised questionnaire was used by Alan et al. (2007) to measure pain. There is, therefore, a need to develop standardised measures for children that are able to track impairment outcomes and help with the development of interventions to address “pain”, for example.

The most accurate measurement of pain in children is said to be multidimensional, using self-reported, behavioural observation and physiological measures (Brand & Thorpe, 2016). Since self-report is the only method that directly measures pain, it is occasionally referred to as the gold standard of assessment (Schiavento & Craig, 2010; Brand & Thorpe, 2016). Self-report pain assessment scales and tools used for children need to be appropriate in terms of age and developmental level and they need to be sufficiently practical to be used in a clinical setting.

The tools also need to be reproducible, reliable, valid and transferable between the assessor and they must be selected with both the child's and the caregiver's input (Brand & Thorpe, 2016). Some self-reported pain scales include the Wong-Baker FACES and the Visual Analogue Scale (VAS). The Wong-Baker FACES pain scale uses facial expression drawings to illustrate pain severity (Chambers & Craig, 1998; Chambers et al. 1999). Although there is disagreement on the best way to develop facial expressions, research reveals that children prefer to convey their pain by using drawings of facial expressions (Keck et al. 1996; Garra et al. 2010).

The VAS is a commonly used tool that measures the intensity of pain on a scale of 0 to 100, from low to high and indicating no pain to the worst pain (Garra et al. 2010). This outcome measure has been validated in both adults and older children and is easy to administer. These pain scales could be incorporated into evaluating pain in children who are prosthetic users to assess the impact of their prosthetic limbs on their pain. They are also specific to the paediatric population and are applicable to younger and older children (Brand & Thorpe, 2016).

Activities of daily living (physical function) were assessed using standardised and non-standardised outcome measures. The use of standardised outcome measures is generally recognised to have benefits in clinical practice, which include improving the reproducibility of assessments. Standardised outcome measures also serve as a reliable foundation for the planning and evaluation of therapies (Hanna et al. 2007).

Using standardised outcome measures is emphasised for effective service delivery and for the well-being of children and their families. However, when these outcome measures are not properly utilised or are misinterpreted, the results could be affected and have a negative impact on service delivery (Hanna et al. 2007).

This is particularly important as healthcare practitioners have come under growing pressure to adopt standardised outcome measures to establish a solid foundation for characterising a child's state, evaluating services and assessing clinical improvement (Cole et al. 1994; Van Deusen & Brandt, 1997; Hanna et al. 2007).

All of the relevant studies that were included evaluated physical function to measure the impact of prosthetic limbs on the participants. This large focus on physical function is to be expected as successful mobilisation with a prosthesis and social reintegration at a high level is seen as the ultimate goal of rehabilitation with a prosthesis (Lusardi & Owens, 2013). However, the outcomes of healthcare are attributed to more than just physical function and include the status of one's health, behaviour and satisfaction which are associated with the treatment received (Aggarwal, et al. 2019).

Although physical function was a prevalent measure in the outcome measures reported, some of the outcome measures evaluated more than just physical function. The PODCI, for instance, was able to measure body impairments by looking at pain/comfort as well as psychological function (happiness). Although restoring physical function is a crucial part of prosthetic intervention, this points to how prosthetic limbs also play other vital roles and impact children in various ways. It is important to know how prosthetic limbs impact children with limb loss to re-evaluate how prosthetic prescription is facilitated. This knowledge could also be helpful in the development of targeted outcome measures.

Although participation is a recurring theme in the qualitative responses from the participants in the study by Morrison et al., (2020), it was not well evaluated in the studies. This shows that there is still a major gap in what people view as important when evaluating how prostheses impact children even with physical function. Children also go through various stages of development and their functional demands change accordingly, whether they have an amputation or not (Eccles, 1999).

The functional development of children could perhaps be evaluated according to age and appropriate development and the ever-growing interests of children, who might have new physical demands, for example, sports participation (Eccles, 1999; Haywood, 2020). The environment in which children perform their functional activities should also be taken into consideration as the prostheses should be able to help them navigate accordingly. Prosthetic satisfaction could be important and potentially influence effective use (Andrysek, 2010; Haywood, 2020).

Outcome measures play a vital role in the decision-making on how to best care for patients and predict how certain interventions could benefit a specific population. Outcomes result from care for a patient over a period of time and should cover the condition, the intervention as well as the follow-up process (Ellis, 2017; Pantaleon, 2019). These outcomes must be continuously advanced as patient care goes beyond the patient himself/ herself. Healthcare workers and stakeholders often require objective feedback for the continuation of care, or to account for funds and services provided for the patients. Outcome measures, therefore, become a beneficial methodology to streamline clinicians' efforts in meeting regulatory requirements and the demand for high-value care (Ellis, 2017).

As outcome measures in the field of amputations and prosthetics are frequently adapted to local demands, there is no agreement regarding standards or the best suitable outcome measures (Xu et al. 2011; Rommers et al. 2001; Deathe et al. 2009). It is important to note that the qualitative and descriptive contributions made by the participants in these studies may be relevant in assessing what is of impact and importance to children who are prosthetic users. These participants' reported experiences might also be of assistance in the development of outcome measures that are able to measure impact across a variety of constructs that directly affect children in prosthetic fitting and rehabilitation.

While physical function across various scales, including happiness and pain, was evaluated using a variety of outcome measures, there is still a gap in evaluating the impact of prosthetic limbs in children with limb loss across other constructs and using paediatric-specific outcome measures. There was only one outcome measure, the PODCI, that was specifically tailored for a paediatric population. The remaining outcome measures were not specifically developed for children, but were utilised in the studies. There is very little research that specifically looks at how healthcare practitioners working with children with disabilities conduct and evaluate outcome measures (Hanna et al. 2007).

Healthcare practitioners reported a lack of time and knowledge of outcome measures as a barrier to effectively using these measures (Law et al. 1999; Hannah et al. 2007). Variations in measurement techniques may, to some extent, be the result of a discrepancy between the objectives of clinical researchers who develop the measures and the objectives of practicing therapists who use them (Hanna et al. 2007). Alternatively, patient-reported outcomes allow the patients to give direct feedback on their intervention as they are viewed as the 'experts' and add value in defining which outcomes are important (Makrinioti, Bush & Griffiths, 2020).

2.6 Limitations

While this scoping review attempts to reveal the literature regarding the constructs used to evaluate the impact of prostheses in children with lower limb amputations, certain limitations are acknowledged.

Firstly, there was a lack of larger-scale studies which could impact the level of evidence generation in support of prosthesis prescription. Secondly, the inclusion of studies with both children and adults could be considered a limitation, as the findings may not exclusively be related to children with amputations. Thirdly, constructs such as body image, participation and social inclusion are not included in the studies, with the physical function being the most consistently recorded construct. Fourthly, the keywords that were included in the search strategy could also have limited the study results. Additional

keywords such as paediatrics, adolescents or young children might have yielded more sources of evidence. Fifthly, as the aim of the scoping review was to inform the type of questions asked in the qualitative study, the time frame in the inclusion criteria could be a limiting factor as the semi-structured interviews in the qualitative study were made soon after the scoping review data was collected and articles published after June 2020 were not included. This study recognises that this could have led to some articles being omitted.

2.7 Chapter Conclusion

Prosthetic interventions are beneficial for children with lower limb amputations, including children with bilateral lower limb amputations. The literature, however, has limited evidence due to the lack of research specifically focused on children with limb loss. The evidence sources presented did measure prosthetic impact in children with lower limb deficiencies. However, the major focus was on constructs related to physical function.

The impact of prostheses on other important constructs such as impairments (pain and discomfort) and psychological functions have been reported, but should be evaluated using age-appropriate and standardised measures. Qualitative data regarding the lived experiences of children who are lower limb prosthetic users could be instrumental in the development of appropriate and culturally relevant measures.

2.8 Funding

There was no funding received for this scoping review.

Chapter 3: The Experiences of Adults Prosthetic Users and Healthcare Practitioners Working with Children with Lower Limb Amputations – An Explorative Qualitative Study

3.1 Introduction and Background

Lower limb amputations can have a significant effect on an individual's functioning and social inclusion (Darter et al. 2018). Owing to the mobility challenges that result from an amputation, amputees can have trouble performing activities of daily living and recreational activities (Gallagher et al. 2011; Godlwana & Stewart, 2013). The role of prosthetic intervention in people with lower limb amputations is to restore ambulation and overall functionality (Haywood, 2020). While the effect of prosthetic limbs on lower limb loss is widely recognised to improve functional abilities, there is currently insufficient literature available regarding the impact of prosthetic limbs in children with lower limb amputations. In addition, prosthetic intervention can be a highly subjective process (Gailey, 2006; Schaffalitzky et al. 2011; Van der Linde, 2003).

Previous studies evaluate the impact based predominantly on physical function. However, there is a lack of data for the outcome measures, with very few being specifically tailored to assess the paediatric population. Another knowledge gap is the lack of inclusion of children with bilateral lower limb amputations for how prosthetic limbs impact this specific population. There is, therefore, a need to qualitatively explore the impact through the experiences of this population to inform outcomes - and therefore, to influence the distribution and equitability of prostheses.

This chapter provides information on the methodology used to obtain the objectives outlined in the study. The method chosen to collect the data is discussed in detail under the relevant headings and the rationale for the chosen method is presented. The measures taken to assure the data's reliability are discussed in-depth and the process of data analysis is highlighted.

3.2 Study Approach and Design

A qualitative approach and descriptive design were chosen for the study. Qualitative research is a methodical investigation of social phenomena in real-world contexts (Teherani et al., 2015). A qualitative approach is a strategy for the main investigator to identify any novel information that the participants might supply (Padgett, 2011). Such an approach allowed this researcher to develop an in-depth description of the participant's perceptions and experiences and to stay as close to the data as possible (Neergaard et al., 2009). In this study, semi-structured interviews were conducted to identify and obtain new information regarding the impact of prosthetic limbs in children with bilateral lower amputations. An additional objective is to establish which constructs are important in evaluating the impact on this population (Padgett, 2011).

In qualitative data collection, interviews continue up until the point of 'data saturation,' or when no fresh information or subjects emerge (Guest et al. 2006). However, the concept of saturation offers little in the way of actual assistance for predicting sample sizes prior to data collection, which is essential for doing high-quality research (Guest et al. 2006). While previous research has shown that saturation is reached after 12 interviews, fundamental components of meta-themes are already present in the first six interviews (Guest et al. 2006).

Focus groups, semi-structured interviews, document studies and observations are the qualitative data collection techniques most frequently employed in health research (Busetto et al. 2020). As this study was conducted during the Covid-19 pandemic, focus groups were not chosen as social distancing rules were still in place. Instead, virtual individual interviews were conducted to avoid compromising the safety of the participants and the quality of the interviews.

3.3 Study Setting

The semi-structured interviews were conducted through virtual platforms and were recorded. The participants were all based in South Africa from the following provinces: the Eastern Cape (n=3); the Western Cape (n=1); and Gauteng (n=3). Participants

working as physiotherapists and prosthetists (N=5) in the following healthcare sectors: private (n=2); public (n=2); and non-government organisations (n=1). The two adult prosthetic users were based in Gauteng.

3.4 Study Population, Sampling Methods and Participants

The study population included key informants who are considered professionals in their field - from both the insider (service user) and outsider (service provider) perspectives. They included prosthetists and physiotherapists registered with the HPCSA and specifically involved in, or have experience in, the rehabilitation of children with bilateral lower limb amputations within the South African context. Adults who suffered bilateral lower-limb amputations when they were children and who are prosthetic users were also included in this phase of the study to explore their experiences.

The participants who formed part of this study can be divided into two groups:

- healthcare professionals; and
- adult prosthetic users.

The healthcare professionals who participated had experience working in the private, public and non-government organisation sectors.

3.4.1 Sampling criteria

Inclusion criteria:

- Physiotherapists and prosthetists who are registered with the Health Professions Council of South Africa (HPCSA) and who have experience in the rehabilitation of children with bilateral lower limb amputations;
- Only physiotherapists and prosthetists on the HPCSA registry who have experience within the South African context were included, but need not be South African citizens; and
- Adults who suffered bilateral lower limb amputations as children and are prosthetics users. They must reside in South Africa currently, but need not be South African citizens.

The adult prosthetic users were required to have undergone their bilateral lower limb amputations as children and to have been fitted with prosthetic limbs. The objective of this criteria was to enable the research process to draw on their lived experiences. Because these adults would be reporting on their lived experiences from childhood, recall bias was anticipated. Recall bias is when participants provide incorrect responses because they are not able to recall past events (Althubaiti, 2016). This has the potential to overestimate or undermine the true effect or association if proper consideration is not given (Althubaiti, 2016). To try and overcome recall bias as far as possible, the questions asked to the adult participants were well-worded to prevent any misunderstanding. The participants were also given an opportunity for further clarification prior to answering a question if they did not understand it. While attempts were made to avoid recall bias, it is important to note that because the recall periods were long, there might have been recall bias that was unavoidable.

3.4.2 Sampling strategy and size

The initial participants in this study were recruited using a purposive sampling strategy. Purposive sampling involves selecting participants specifically for their personal attributes. This type of sampling also entails choosing people who are knowledgeable about the topic of interest (Etikan et al., 2016). The criteria used to select the groups of participants were based on the participant's experience either in working with children with lower limb amputations, or having had bilateral lower limb amputations themselves as children.

The primary investigator (PI) invited one adult prosthetic user and two therapists (one physiotherapist and one prosthetist) to participate in the study. All the invited participants were willing to be involved in the study. The remainder of the participants (n=4) were recruited after the three initial interviews were completed. The selection of the participants also ensured there was adequate representation of therapists.

The PI then focused on selecting therapists who had experience working in various sectors including the private, public and non-governmental sectors. In total, seven

participants were interviewed for this study. According to Saunders and Townsend (2016), semi-structured or in-depth interviews require a minimum sample size of between 5 to 25, while Cresswell and Cheryl (2016) suggest that a heterogeneous population would require between 25 and 30 interviews.

No 'a priori' sample size was set to include key stakeholders/experts and data were collected from at least two physiotherapists, two prosthetists and two adults with bilateral lower limb amputations.

The PI contacted various organisations and bodies to recruit physiotherapists and prosthetists on the registry who are also registered with the HPCSA. An additional set criterion was for the registered physiotherapists to have experience in rehabilitating children with bilateral lower limb amputations in the South African context. Adults who are prosthetic users after sustaining bilateral lower limb amputations were also recruited from a non-governmental organisation, named 'Jumping Kids'.

3.5 Instrument of Data Collection

Data was collected by means of a semi-structured interview (see Appendix D and E). The interview questions aimed to obtain information regarding how prosthetic limbs impacted children with bilateral lower limb amputations. The questions between the two groups (Group A: the prosthetists and physiotherapists and group B: the adult bilateral prosthetic users) varied slightly.

The questions for the prosthetists and physiotherapists were to gain a therapist's perspective on dealing with and treating children with bilateral lower limb amputations. The questions for the adult prosthetic users aimed to draw on their experiences as a child with bilateral lower limb amputations and to explore and understand what role prosthetic limbs played in their lives.

3.5.1 Questions for the health care providers

The following questions were included:

- How long have you been working as a prosthetist/physiotherapist?
- How would you describe your experience of working with children with bilateral lower limb amputations?
- Do you think children with bilateral lower amputations benefit from prosthetic intervention? What would you say those benefits are?
- Are there any additional constructs that you think need to be taken into consideration when it comes to children with bilateral lower limb amputations as opposed to adults **and** as opposed to children with unilateral lower limb amputations? Why do you think these constructs are important?

3.5.2 Questions asked to the adult prosthetic users

These included the following:

- How did you end up with bilateral lower limb amputations?
- What difficulties did you experience as a child with bilateral lower limb amputations?
- Can you describe your experiences as a child having had no prosthetic limbs to then being fitted with prosthetic limbs?
- Which parts of your life and experiences were positively impacted as a result of you having prosthetic limbs?
- What constructs/ lived experiences do you think need to be considered for children with bilateral limb amputations as opposed to adults?

3.6 Data collection

3.6.1 Procedure for data collection

Ethics Clearance was obtained from the Health Ethics Research Committee of Stellenbosch University (HREC Reference number: S20/10/268). Upon receipt of the Ethics Clearance and with permission to conduct the study, the primary researcher contacted the recruited participants to determine their willingness to participate in the study.

A Participation Information Leaflet and Consent Form (see Appendix B) was sent to the participants to explain the details of the study, including the aims of the study and the voluntary participation process.

The participants indicated their willingness to participate in the study on the Participation Information Leaflet and Consent Form after the questions regarding the study had been answered satisfactorily and the primary researcher was content that the participant understood what the research study is about. A suitable date was arranged for the data collection using a semi-structured virtual interview where participants discussed additional constructs they thought should be considered for children with bilateral lower limb amputations. The interviews were recorded and the primary researcher used a field diary to take notes. The participants were advised of this recording process prior to the interview and all participants consented to continue with the interviews.

Data was collected by means of semi-structured virtual interviews with two groups of key informants: adults who had undergone amputations when they were younger and received prosthetic limbs, as well as physiotherapists and prosthetists who are registered with HPCSA. This method of data collection allowed for a more open discussion between the primary researcher and the participants. The interviews were also conducted on an individual basis, as opposed to focus groups. This allowed the participants to share their experiences without feeling uncomfortable or pressured to answer the questions based on group responses.

This study anticipated that interviewing both groups of key stakeholders would shed light on constructs of impact not necessarily reported on in research due to the possibility of unique socio-environmental challenges as well as categories of functioning not readily explored in children with bilateral lower-limb amputations.

3.6.2 Procedure for interviews

The interviews were set and conducted on virtual platforms at the most convenient times for the key informants. Owing to the current Covid-19 pandemic and the possibility of participants being scattered across South Africa, no physical interviews were

conducted. Prior to the interview, the primary researcher sent each participant (i) the study proposal, (ii) the Ethics Approval Form, (iii) the relevant Consent Form, as well as (iv) the questions to be asked during the interview. A suitable date was arranged with the participant to conduct the interview. The interviews were scheduled for a time of approximately 45 to 60 minutes each.

The primary researcher initially welcomed the participants at first contact to thank them for making themselves available for the interview. A full explanation regarding the study, the background, as well as the purpose of the study was provided to the participants. Formal informed consent was obtained electronically and the participants were given the opportunity to ask questions before the interview began. Consent Forms were provided in English as all participants were fluent in reading, writing and speaking English. The interviews were recorded and the participants were made aware of this prior to the start of the interview. All participants gave their consent to having their interviews recorded and transcribed verbatim.

3.7 Data Management

Once the data was collected and the interviews transcribed, the information was stored in a password-protected laptop to which only the researcher has access. It was also uploaded onto a Drive document, which is also password protected and only the primary researcher has access to this Drive. The data will be stored safely for five years after the completion of the study in the Division of Physiotherapy at Stellenbosch University.

3.8 Data Analysis

The interviews were recorded and transcribed verbatim by the PI. This was done as the researcher had personally conducted the interviews and was familiar with the interview content and process. Once all the interviews were transcribed, the researcher then listened to the interviews again while reading the transcript to highlight the themes that emerged. The qualitative data was then analysed using thematic analysis.

Thematic analysis is a technique used not only for describing data, but for choosing codes and creating themes. It also involves a level of interpretation (Kiger & Varpio, 2020). Thematic analysis is a technique for studying qualitative data that involves reviewing data collection to find, examine and document recurring patterns (Kiger & Varpio, 2020; Braun & Clarke, 2006).

The transcripts were coded manually and analysed by the primary researcher. All statements relating to prosthetic impact were highlighted and similar words were placed together to formulate a category. Some of the phrases such as 'they can walk', 'they can mobilise independently', and 'I can walk confidently' were identified and coded descriptively, initially using open coding. These phrases were then grouped into a more meaningful category relating to 'mobility'.

Sub-categories were then identified and codes relating to any form of mobility were grouped according to how mobility was translated for children. This included 'independence', 'reaching things at height' and 'navigating terrain'. While these are all different actions, they were all a result of the theme 'mobility' and strongly influenced by each other. Sub-categories that were relevant were then compared for resemblance and organised into larger categories or themes.

The main theme was then identified as 'activities and participation.' Three main themes from the data collection emerged and were explored in depth once the data analysis process was completed. Each phase of the data analysis process was checked and verified by the primary researcher's supervisors. Where differing opinions arose, discussions took place until a consensus was reached.

3.9 Ethical Implications

The researcher obtained Ethics Clearance and registered the study with the Human Research Ethics Committee of Stellenbosch University (see Appendix A). Ethics is the umbrella term for the study of the origins of morality and the particular moral decisions that must be made also falls under ethics (Varkey, 2021).

The following major ethical considerations were taken into account:

3.9.1 Principle of beneficence

The principle of beneficence is the moral responsibility of healthcare practitioners to act in their patient's best interest (Jahn, 2011). This includes the moral obligation to uphold patient rights, avoid injury, eliminate hazards that could cause harm, assist people with disabilities and save those in danger (Varkey, 2021). While this principle calls on not doing harm, it also emphasises benefitting patients and promoting their welfare (Varkey, 2021).

To advance and promote the welfare of patients, effective research needs to be conducted to know which healthcare interventions are most beneficial to patients (Gillon, 1994). This study might help healthcare practitioners who work with children with bilateral amputees to know more about the role that prosthetic limbs play in this population's lives. It could also help to influence the manner in which rehabilitation and prosthetic service delivery are managed in the future. The participants of the study also stand to gain knowledge through the research results and feedback process once the study is completed.

3.9.2 Principle of non-maleficence

The duty of healthcare practitioners to act in the patient's best interest is known as non-maleficence (Varkey, 2021). It is strongly associated with doing no harm. The following regulations are in line with the principle of nonmaleficence: i) do not kill; ii) do not inflict pain or misery; iii) do not incapacitate; and iv) do not offend (Jahn, 2011).

In practical settings, the above regulations involve weighing up the advantages and the disadvantages of healthcare interventions. This is done to avoid using more disadvantageous interventions that could be non-beneficial or damaging to patients (Varkey, 2021). This study, therefore, did not cause harm to any of the participants involved. While the interviews were conducted during the Covid-19 pandemic, all interviews were conducted virtually and were recorded.

3.9.3 Respect for autonomy

We are required under the principle of respecting autonomy to uphold the self-determination of individuals who are capable of making decisions (Jahn, 2011). In healthcare and research, respecting autonomy entails i) telling the truth; ii) respecting others' privacy; iii) protecting confidential information; and iv) obtaining informed consent (Jahn, 2011).

For this study, informed consent was required to be obtained for the interviews to take place. The participants' involvement in the study was also completely voluntary. This researcher explained to the participants that they could choose to no longer be involved in the study and that they would not be negatively impacted (even if they had initially agreed to be involved in the study). Truth-telling was upheld as the participants were provided with full disclosure. None of the information relating to the participants has been disclosed to anyone other than those individuals directly involved in the study.

3.9.4 Principle of justice

Justice is typically understood as the fair, equitable and suitable treatment of individuals (Varkey, 2021). During the undertaking of this study, this principle was applied in various processes, including the recruitment of participants and during the interview process. The participants were recruited fairly according to the inclusion criteria and no individuals were discriminated against based on gender, sex or religious beliefs. The interviews were also conducted fairly. Each participant was provided with a fair opportunity to share their experiences.

3.9.5 Trustworthiness

The primary researcher strived to ensure trustworthiness in the study through credibility, dependability, transferability, and confirmability. Credibility was pursued through the use of purposive sampling and collaborating with the researcher's supervisors during the coding and data analysis process. This collaboration resulted in competing perspectives being offered during the process. By having more than one researcher involved, meaningful discussions were had prior to coming to conclusions. This helped to avoid bias, as not all researchers had the same thoughts, beliefs, and cultural experiences. Discussions were then undertaken with the support of literature. Only all researchers

agreed after the discussion, was a conclusion drawn. The abstract findings were also supported by associated verbatim quotations.

By describing the data collection process, including the participants' membership, experience, and setting in detail, transferability was enhanced. In order to allow for repetition, the methods were described progressively in an effort to increase dependability and confirmability. The primary researcher made the data collection and interpretation clear and transparent, as well as provided examples of how the open coding process led to sub-theme and theme development. Verbatim quotes were included in the study to explain the findings.

Chapter 4: Results and Discussion

4.1 Demographics of Participants

In total, seven participants were included in this study. In Group A, five participants were included and all of these participants were females. They had a mean age of 29. The average number of years they had worked as physiotherapists and prosthetists rehabilitating children with bilateral lower amputations was 3.8 years.

For group B, two adult participants were included and both were males. The mean age for the two males was 36 and both participants were from Gauteng. While they both had bilateral lower limb amputations as children, the causes and levels differed between them. One participant had his amputations due to a congenital birth defect and this resulted in bilateral trans-tibial amputations. The second participant's amputations were acquired due to electrical burns at the age of 12 which resulted in one trans-tibial and one transfemoral amputation. Both participants received their first prosthetics at the age of 15.

4.2 Themes and Constructs

Three themes with sub-themes emerged from the data and were analysed using a deductive approach. The themes that emerged were; i) activities and participation; ii) psychosocial function; and iii) challenges (personal and environmental). These themes that emerged in the exploration of the constructs were deemed most important. Their impact is within the context of prosthetic availability as they allow children with bilateral lower limb amputations to function optimally on a more holistic basis.

The themes and subthemes are shown in Table 3 below.

Table 3: Themes and sub-themes identified in the data

Themes	Subthemes
1. Activities and participation	• Mobility • Activities of daily living • Physical participation • Education (school/university) • Socio-economic participation
2. Psychological function	• Body image • Quality of life • Adaptability
3. Challenges	Personal: • Pain • Socio-economic standing
	Environmental • Prosthetic equipment • Resource constraints in healthcare settings • Relationships

4.3 Activities and Participation

The participants reported how prosthetic limbs allowed them, as children with bilateral prosthetic limbs, to perform a wide range of activities, to partake in various aspects of life (such as mobility) and gain more independence. Participants also stated that they are able to perform activities of daily living, participate physically in sports and recreational activities. They were also able to access education to enable them to participate socio-economically.

4.3.1 Mobility

The participants reported that the prosthetic limbs restored their mobility and allowed them to perform various tasks. In particular, their prosthetic limbs further enable them to gain independence to develop their locomotor skills. Locomotor skills are important for playing, engaging with peers physically and navigating difficult terrain. Some of the concepts that were reported included independence, walking, running and jumping,

reaching things at a higher level, navigating difficult terrain and being able to drive a car when they were older.

- **Independence**

Independence in children is important as it promotes confidence and self-esteem. Feelings of independence also provide children with a sense of importance and belonging. This allows them to form supportive relationships and contribute positively to the world (Williams, 2003; Cerino, 2021). The comments below reveal aspects of independence observed by some caregivers:

P2 (prosthetist): *“...they can mobilise independently...”*

P6 (physiotherapist): *“...independence. I think that's the first thing that I always try to reach with kids and anyone with a prosthesis.”*

- **Walking, running, and jumping**

Physical activity helps young children build their fundamental motor abilities in early childhood. The improvement of these motor skills comes with age and through the practice of specific abilities and activities (Collins & Staples, 2017; Haywood, 2020). Walking, running and jumping are, therefore, essential parts of physical activity. They translate into play and promote normal gross motor skills that are important in the development of children. Active, goal-oriented play that involves using the body's muscles enhances the muscles' natural activities (Sutapa et al. 2021). The comments on physical activity below were made by several amputee participants and caregivers:

P1 (adult): *“From ‘95 onwards I found a private prosthetist within South Africa who upgraded me to a level where I can walk, and I can use crutches. And then once I got good enough, I could use one crutch. And once I got good enough, I could use no crutches in situations. I was able to be without crutches and walking around. And that then is probably from 95, 96 to 1999. Um, where my progression is quite..., um, it's very good. I go from,... um, basic walking to, by the time I was 18, 1998,... um, I could do all those things.”*

P3 (adult): *“I think I can do everything with, you know. So, this doesn't exclude me from even running, ...um, jumping around, walking long distance,... um, standing in the queue.”*

P4 (physiotherapist): *“They can walk, they can run, they can play with other learners or other kids in the community.”*

a) Reaching things at a higher level

Bilateral amputations result in height reduction. Depending on the level of the amputation, the child's height can be significantly affected. Prosthetic limbs were reported to restore height for functional purposes, such as reaching things at a higher level.

P3 (adult): *“I mean, um, when I was young, uh, the physical challenges would be, uh, reaching for things in our, like having to grab something in the fridge.”*

P3 (adult): *“Um, obviously I'm not tall enough to get there and I don't have feet where I could extend with my toes and reach something [without prosthetics].”*

b) Navigating difficult terrain

In 2018, some 43 percent of children in South Africa resided in rural households (Hall, 2022). Rural dwellings are often made up of terrain that can be difficult to navigate. The participants reported that prosthetic limbs helped children more effectively navigate these terrains as a result of their prosthetic fitment.

P4 (physiotherapist): *“And since he lives in a ..., I think in a rural area, he's even able to move around because he got the blades and he got other prosthetics as well that he uses daily. So at home, he is able to move around on the terrain because his balance has improved as well.”*

c) Driving a car

Although children cannot drive, prosthetic limbs could potentially enable them to drive later in life.

P1 (adult): *“So, you know, you can drive a car.”*

4.3.2 Activities of daily living

The phrase "activities of daily living" (ADLs) refers to a group of basic abilities, including eating, bathing and moving around independently (Katz, 1983; Edemekong et al., 2021). Prosthetic intervention assisted children with bilateral lower limb amputations to gain independence with their ADLs. It also provided them with the freedom to perform ADLs when they needed to, for example, when going to the toilet.

a) Independence with ADLs

When children are infants, they will need assistance with most ADLs, but they should gradually become more independent as they grow older. When children are unable to perform ADLs independently, they become dependent on other people and their quality of life can be affected (Edemekong et al. 2021).

P6 (physiotherapist): *“They achieve their ADLs physically very well...”*

P4 (physiotherapist): *“The children get to maintain their mobility and their independence in activities of daily living.”*

b) Toilet use

Prior to prosthetic fitment, one participant reported that a child needed assistance to make use of the toilet. After the prosthetic intervention, the child was able to use the toilet as he or she needed to. This is important, not only to uphold the dignity of the child, but for social acceptance and a better and improved quality of life for the child.

P4 (physiotherapist): *“And yeah, he can walk to the toilet as he pleases.”*

4.3.3 Physical participation

All children, including those with physical disabilities, benefit from physical activity (Murphy et al. 2008). The gap between children with disabilities and their classmates in terms of participation restrictions increases as they grow older (Brown & Gordon, 1987; Murphy et al. 2008). By encouraging involvement in sports, recreation and physical activities in the least restricted setting, healthcare practitioners can assist children with disabilities to participate fully in the lives of their families and communities (Murphy et al. 2008).

a) Sports/recreational activities

Once the children were fitted with prosthetics, they were able to partake in sports and recreational activities. The opportunities within sports were also recognised as having the potential to create better opportunities for these children. These points are illustrated by the following comments:

P1 (adult): *"I had done more than most of my friends. I'd gone to school with [those] who had all of their body attached and none of the issues that I had, you know, I had driven, I had travelled. I had seen places in the world that most people never get to see."*

P3 (adult): *"And I wouldn't do a lot of things. Some of the stuff where, you know, I can just interact with other kids. I mean, I would exclude myself from that because sometimes you could see people using their legs to play around. I don't have legs, so how am I going to do whatever game they're playing?"*

P4 (physiotherapist): *"... Yes, he is the learner with the bilateral lower limb amputation, but he is partaking in sports. He was also invited to partake in athletics. ...He now has more options for sport. And because he doesn't come from a high-income home, the opportunities that he might get with the athletics could benefit him in the long run."*

P6 (physiotherapist): *“They can participate in games in a way that makes them look the same as their peers – even if before they might have said that they can participate in sports like soccer and all of that, they would have been doing it on their hands and they are ‘lower’.”*

P7 (physiotherapist): *“...but with a prosthesis, they can maybe participate in sports...”*

b) Access

A lack of prosthetics was reported as a limitation when it came to having access to homes, buildings and other types of properties. Not all spaces in society are accessible for people with disabilities. Prosthetic limbs allowed children to be able to access various spaces. This observation is illustrated by the following comments:

P1(adult): *“So that became the part of the, how do you figure out, uh, how to do things now because society is not designed to assist you in a wheelchair. The only places wheelchairs work, a hundred percent are shopping malls and airports. Everywhere else, you're going to find a challenge that you won't necessarily be able to get somewhere.”*

P1 (adult): *“...so your freedoms, then you start to understand that I was no longer trapped by my situation. I had prosthetics that allowed me to navigate the world and not worry about the fact that there were stairwells and things that weren't necessarily in the way”*

P4 (physiotherapist): *“They can use public transport because that also becomes very difficult to travel with the wheelchair because they have to pay for the wheelchair.”*

4.3.4 Education (school/university)

One of the most crucial settings for a child to engage in worthwhile activities is at school. Schooling is a common childhood experience that fosters academic and social development (Rehm & Rohr, 2002; Sussman & Hoy, 2015). In South Africa, there is a 70 percent non-attendance rate due to system failures (which include exclusions and quality problems), as well as financial barriers and also illness or disability (Hall & De Lannoy, 2019).

a) Access

Having access to school is highlighted as one of the positive impacts of prosthetic intervention by the participants. Prosthetic limbs have provided opportunities for children to attend school. One of the participants (who integrated into a mainstream school) discussed reaching the same milestones as his (able-bodied) peers and doing well academically.

P1 (adult): “...the milestones, my friends were chasing and meeting, I was meeting as well. So, I was finishing up school. My goal was to get a university exemption.”

P3 (adult): “And again going to school was one of the other challenges. Cause I had to walk on my stumps for like, um, a kilometre and five. And it was really, um, a challenging thing for me physically...”

P7 (physiotherapist): “To be able to be a part of a community, being able to attend school out of a community.”

b) Participation

When reflecting on their school-going journey, one of the adult participants, who ended up attending a school for physically disabled children, reported that he would have opted to be in a mainstream school after being issued with prosthetic limbs. He stated that this was because he did not feel as physically challenged as he had been prior to his prosthetic fitting.

P3 (adult): “I think now, I mean, now I can actually go to a mainstream school. I mean, I can attend with able-bodied people. Um ..., I wouldn't feel as physically

challenged as before you know, where you need to brush it off my face like - you're disabled, you can't do this, you can't do that. And so now for me, it's something like I can go and study and finish. I think it stands because I've got prosthetics."

c) Social inclusion

The idea of social inclusion is complicated and sometimes misinterpreted. According to some previous research, children with disabilities frequently experience bullying, isolation and exclusion in their social life (Koller et al. 2018). With prosthetics, the participants reported that they were able to engage and become included in social activities with their peers. Social inclusion occurred in school, during play and in their communities at large.

P1 (adult): *"When I go to university, I can go into the lecture hall and I'm not going in the door and sitting at the front, uh ..., because it's the only place I can be. I can go three rows up and sit next to my friend. I can go 10 rows up and sit next to my friend. I can go trek 20 rows up and sit next to no one because I don't want to be there."*

P3 (adult): *"Like, one of the difficulties would be going to school. And at school, they will always tease me about me not having legs..."*

P4 (physiotherapist): *"In terms of around the school is [the issue of being] able to not only help himself, but he's able to help the others who are now wheelchair bound and might not be able to push their own wheelchair. And if they are somewhere, he's able to do that as well. So he's able to help his peers."*

P7 (physiotherapist): *"And if we're talking about children, we're talking about school and integration into society. In the case of bilateral amputees, they are often kept at home and there's no integration into the community." ... "It's kind of a vicious cycle. In the end, they don't end up getting their chance at schooling and staying home which also has quite an emotional aspect or impact to it."*

4.3.5 Socio-economic participation

In South Africa, 70% of children live in poverty and poverty is usually correlated with children dropping out of school (Dieltiens, & Meny-Gibert, 2008). Disability and poverty are often synonymous in low-income countries (Loeb et al. 2008). However, the study by Loeb et al. (2008) found that people living in the Eastern Cape and Western Cape live under harsh conditions of poverty regardless of the presence of someone with a disability in the household. There is a high number of people with disabilities who are disadvantaged in terms of education and employment. People with disabilities were found to be dependent on a disability grant supplied by the government. While this grant can be helpful as it is an immediate answer to urgent situations, the lack of access to employment and education exacerbates the problem and it tends to prolong the dependence on grants (Whyte & Ingstad, 1995; Loeb et al. 2008).

a) Acquisition of necessities

Children usually rely on adults to provide necessities for them. However, as they grow older they are able to do this themselves or with their family and friends. This includes going to the shops and, as they grow older, being able to go to the bank. One participant identified these activities as a way their prosthetic limbs positively impacted his life.

P3 (adult): *“...standing in the queue, is the one thing, especially at the banks. When you are at the shops, you've got like... uh, you're pushing a trolley in the supermarket, walking a long distance. Um, um,... I don't know what else, but there's just a lot, you know, that I feel that's positive to take with when I have,... uh, prosthetics.”*

b) Civic duties

Performing civic duties, such as obtaining a driver's license, is a task for older children and adults. When children turn 16, they are able to obtain a learner's licence, which is necessary before obtaining a driving licence. One participant reported that getting his driver's licence allowed him to meet certain milestones, similar to those of his peers.

P1 (adult): *“...I was in matric, I got my driver's license, ... um, before everybody else, uh,... I, um,... expanded and everything that's, uh,... the, the milestones, my friends were chasing and meeting, I was meeting as well.”*

c) Social integration

Children with bilateral amputations were able to integrate well into society socially through play and peer interactions with family and friends. The following comments attest to this notion:

P2 (prosthetist): *“...this [independence] is very important for integration so they're able to interact with their families and friends and it increases the chances for peer involvement and their overall well-being. And they can mobilize independently, and if they couldn't before, can integrate society.”*

P7 (physiotherapist): *“...it's not so much an aesthetic thing but also a psychological impact for them, and interaction with their peers is very limited. [without prosthetics]”*

d) Work and employment

The child participants recognised the increased potential for work and employment when they got older because prosthetics allowed them to access education and other opportunities.

P1 (adult): *“...I've achieved all this stuff at this stage. I'm 29, I was running a big business, driving fancy cars. I was a well ahead of some of my peers.”*

P7 (physiotherapist): *“...or have more opportunities as they get older when it comes to jobs and things like that.”*

4.4 Psychosocial function

Psychological functioning is defined as the ability to accomplish one's goals within oneself and in the outside world. A person's conduct, emotions, social skills and general mental health are all important elements of psychological functioning (Preedy, 2010). The sub-themes relating to psychological function in the interviews included body image, height aesthetic, stigma and self-esteem. Prosthetic limbs were found to positively influence the psychosocial function of children, allowing them to feel more equal to their peers, and reducing stigmas related to their disability.

4.4.1 Body image

Body image is the subjective perception that people have of their own bodies, regardless of how those bodies actually seem (Alleva et al. 2015; Hosseini & Padhy, 2019; Shoraka et al. 2019).

Body image is a multidimensional construct made up of one's thoughts, feelings, judgments and behaviours around one's physical appearance (Hosseini & Padhy, 2019; Spreckelsen et al. 2018). The adult participants reported a number of factors relating to their body image that made them feel equal to their peers as a result of prosthetic intervention, for example: height and aesthetic appearance.

a) Height

The prosthetic limbs added height to the children's residual limbs and this allowed them to appear to be at the same height as their friends. This positively resulted in them not feeling inferior to their peers.

P6 (physiotherapist): *"...they're at the same height as their peers which is important, and they don't feel lesser from that perspective."*

P6 (physiotherapist): *"I remember one of the children telling me once that he feels like he's just one of the dogs in the family because he's the same height as them being quite, like, being of an impactful statement. So, yes, I fully believe that children benefit from prosthetic intervention because it makes them look the same as their peers which makes them feel equal and not 'other'."*

b) Aesthetics

While functional abilities had a significant impact, cosmetics and appearance was also viewed as an important factor for children with bilateral lower limb amputations. Not only did their prosthetic limbs allow them to look like their peers, but the participants stated they were also able to wear their desired items of clothing. Another participant mentioned being able to wear certain clothing and that made him feel happy. The healthcare practitioners who participated in this study also stated that prostheses are more than just about physical function. In older children, aesthetics played a role in and assisted with challenges with low self-esteem. Without prosthetic limbs, one participant

reported that he attracted (unwanted) attention while one therapist reported that children without prosthetic limbs were shunned by their peers.

P3 (adult): *"I can wear shorts."*

P6 (physiotherapist): *"...kids might score highly on a physical ranking, but it is clear that they do need prostheses based on, you know, their physical aesthetic and once again their emotional wellbeing."*

"...it makes them look the same as their peers which makes them feel equal and not 'other...'"

c) Stigmatisation

Stereotypes, prejudice and stigmatisation play a role in the discrimination and exclusion that disabled persons and their families are often faced with wherever they go (Rohwerder, 2018). Without prosthetic limbs, participants felt that children with bilateral lower limb amputations received unwanted attention and were shunned by their peers, as well as society as a whole.

P3 (adult): *"...when you don't have prosthetics, people tend to look at you in a way you feel like you shouldn't be around them. Um, some, they were just surprised that this guy can walk without, uh, you know, feet and all."*

P3 (adult): *"...I feel like if you don't have prosthetics, you catch a lot of attention from the public."*

P7 (physiotherapist): *"I think just, for me it's largely a psychological thing. Not being shunned by other children when children don't understand disabilities. It's especially emotional for the one with the disability to be shunned by their peers. So, for me, it's more emotional than mobility."*

d) Self-esteem/self-confidence

As reported by some child participants with bilateral lower limb amputations, prosthetic limbs positively impacted their self-confidence and self-esteem. Prior to prosthetic fitment, one participant mentioned that it affected him (negatively).

P3 (adult): *“Yeah. I mean, mentally, it affected me a lot to be honest, because I kept questioning myself. What kind of a person am I? And why don’t I have legs? You know, other kids that have legs. Other people have legs and I don’t have legs. So, from which planet do I come from, you know? It kept coming in my mind for long, and I really never had an answer for that.”*

P4 (physiotherapist): *“...he has so much more self-confidence.”*

P6 (physiotherapist): *“...prosthetic intervention is appropriate to also support that discrepancy in that emotional and self-esteem space.”*

P7 (physiotherapist): *“I think the biggest thing from my side is the emotional and psychologically more than a mobility thing because they find their own way to mobilise.”*

4.4.2 Quality of life

The WHO defines quality of life as “an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns” (WHOQOL Group, 1995; Lam et al. 2011).

a) Improved overall well-being

The participants reported that the overall well-being of children improved with prosthetic intervention. From physical to mental well-being, participants reported that ‘there was a lot of’ positive impact from prosthetic intervention.

P2 (prosthetist): *“...[it] improves their quality of life as well as their physical and mental well-being.”*

“...So, at the end of the day, what we want to achieve is the improvement of the quality of life. Early signs of ways that they've been impacted are basically one of those, yeah.”

“...it increases the chances for peer involvement and their overall well-being.”

P3 (adult): *“...there's just a lot, you know, that I feel that's positive to take with when I have, uh ..., prosthetics.”*

P5 (prosthetist): *“And then physically, the development of their bodies as well, socially, psychosocially and emotionally – I think they benefit on all fronts and all aspects.”*

4.4.3 Adaptability

Adaptability refers to an individual's ability, skill, disposition and willingness to change or adjust to different tasks, social, or environmental features (Ployhart & Bliese, 2006; Zhou & Lin, 2016). Higher levels of adaptability allow people to hold onto their psychological resources longer than lower levels of adaptability do (Ployhart & Bliese, 2006).

a) Higher adaptability

Children were reported to adapt easier and more quickly after a prosthetic fitment, due to having higher outcomes of success with a prosthesis.

P2 (prosthetist): *“...children, in general, have a higher chance for adaptability when it comes to ambulating with a prosthesis and, therefore higher outcomes of success with a prosthesis whether that be unilateral or bilateral [lower limb amputation].”*

P5 (prosthetist): *“I work with a lot of adults and children with prosthetics and the kids are just amazing. They adapt so easily and so quickly.”*

P6 (physiotherapist): *“...it's incredible to see how well they adapt to life...”*

4.5 Challenges

While prosthetic intervention for children with bilateral amputations was recognised as having had a positive impact on their lives, there were certain challenges identified that impacted prosthetic use. These were both personal and environmental challenges. The personal challenges included pain and a lack of finances as prosthetic technology can be costly, particularly for children who outgrow their equipment more frequently than adults. The environmental challenges result from the prosthetic technology itself, as prosthetic equipment varies and quality prosthetic equipment can be more highly effective. Environmental challenges also include resource constraints in the healthcare sector and the capacity to build positive relationships.

4.5.1 Personal challenges

Some of the personal challenges were reported to affect prosthetic use. These included pain and socioeconomic background (finances). Some participants reported experiencing pain prior to prosthetic intervention due to limb length discrepancy. For other participants prosthetic intervention helped to alleviate this pain, while for one participant the prolonged wear of his prostheses caused pressure and pain in his residual limbs.

a) Pain

Several participants described how prosthetic limb wear resulted in pain and pressure on their skin due to prolonged wear of the prosthesis. This in turn negatively impacted their use of their prosthetic limbs. However, one participant noted that the prosthetic limbs played a key role in rectifying leg length discrepancy due to his limb loss and they helped to reduce the back pain that he had experienced prior to having prosthetic limbs.

P3 (adult): *“No, I didn't use anything, you know. And remember my legs are not like, uh..., equal, so the one leg is longer than the other, which every time I walk, it's more like I'm limping a bit and, and so, so that somehow it kind of affected my back.”*

P1 (adult): *“I had been walking on injuries as in a hole in my leg with a plaster on it from 15 to 29. And that, and at that point, I reached a [stage to say; What am I doing this for? Why am I putting myself under all this pressure? Um, when I've achieved all this stuff at this stage, I'm 29. I was running a big business, driving fancy cars. I was [for] a while ahead of some of my peers. And, um, that headspace then made me start to look at the balance of life as a person with the disability. How do I manage this better? So that I live the life I want without doing jobs and putting so much pressure on my legs that I break myself and I kill myself by 35.”*

a) Socio-economic background

Prosthetic limbs can be quite costly, particularly for children with bilateral lower limb amputations who require two prostheses because as they are constantly growing and developing, they require new prosthetic limbs their existing ones are outgrown. At this time, the financial status of children and their families can play a significant role in determining whether children have further access to prosthetic equipment. Finances imply the ability to purchase prosthetic limbs, and also cover the financial costs of travel to healthcare sectors to access services.

P1 (adult): *“Um,... it is still around, it's one of the biggest international prosthetic manufacturers and essentially got a quote and an idea of what they do and what it would cost me. Um, that was a complete shock. The actual financial side of that was, ... you know,... very intimidating for a 19-year-old kid.”*

P5 (prosthetist): *“There's very rarely funding for children to have everyday legs with a knee, ankle, and foot for them to go to school, to play with their friends, and then [have] a separate leg for sport and running and doing extramural activities.”*

P7 (physiotherapist): *“They're constantly growing and from a state financial aspect, they can't afford to adjust and replace the prosthetic as regularly as what we needed, and the demographic themselves as I mentioned before: socioeconomic status plays a huge role. [Also] a lot of the carers can't afford to*

go to these regular check-ups as frequently as what is needed for a growing child.”

4.5.2 Environmental challenges

a) Prosthetic technology

Prosthetic equipment was recognised to differ according to quality and whether it was activity-specific, for example, sports prostheses. The participants shared their experiences of using different prostheses and how effective quality prosthetic equipment was.

P1 (adult): *“Uh,... my lesson was that not all prosthetic equipment is equal, that not all providers of prosthetic equipment are equal, and that you're... it's, it's a shopping and learning process. So, it probably took me six years to find the right kind of stuff.”...*

“I mean, just to say that effective prosthetics change all access elements to all amputees, especially bilaterals.”

“So, when I came back to South Africa, I had great equipment. I was still learning to walk again, because each time you change equipment, you re-learn everything.”

P3 (adult): *“‘Cause what I was using before, it was like ..., it's a government thing. And they just do it so that you can walk, you know. They don't perfect it as it should be like in a private clinic or hospital. So they would just make a wooden leg and put on a shoe. I can't remember very well what they did, but I can remember it was a wooden leg. And it was sore when you walked and you had to wear a lot of socks inside also just to be comfortable like to get that comfort.”*

b) Resource constraints in healthcare settings

The healthcare practitioners highlighted how resource constraints and a lack of funding can lead to the lack of the provision of prostheses. They also mentioned the long waiting periods for the issuing of prosthetic limbs to children.

P4 (physiotherapist): *“I think when you work within a government setting, you are trained to use the government resources, and getting resources from the government is always difficult because there's a long waiting list. And if you need something replaced such as like a prosthetic or an AFO or something, it takes very long because of procurement processes and whatever else happens there.”*

P7 (physiotherapist): *“Resources are hard to change from the public [sector's] perspective...”*

c) Relationships

One of the challenges of not having prosthetic limbs for children is the increased burden of care placed on caregivers. Once children were fitted with prostheses, the participants reported being able to attend school independently and a decreased reliance on care and caregivers.

P3 (adult): *“...back to when I didn't have prosthetics at school. The only other difficulty that I had was that I had my uncle who had to carry me on his back for that kilometer and five, you know. So, for me it also felt like I'm actually being- [a burden]”*

P7 (physiotherapist): *“So, I think for the carer's side, there is a lesser burden of care in a way. Like I said, they can still be mobile, but if the child is now going to school and leaving the house and not having a 24-hour carer, that is a lesser burden for the carer.”*

4.6 Conclusion

In this chapter, the experiences of children who are bilateral lower limb prosthetic users are shared by the participants. The participants included physiotherapists and prosthetists who have experience working with children with bilateral lower limb amputation and adult prosthetic users who had undergone bilateral lower limb amputations in their childhood. From the information shared by the participants, it was evident that there are both positive constructs and challenges that impact children with bilateral lower limb prosthetics.

The constructs that were reported to be of impact in children who are bilateral prosthetic users included mobility, activities of daily living, physical participation, education, socio-economic participation, body image, quality of life and adaptability. There were also some challenges that were explored and reported to impact prosthetic use. These challenges included personal challenges such as pain and socio-economic standing, as well as environmental challenges such as prosthetic equipment, resource constraints in healthcare settings and relationships.

The findings in this chapter show that prosthetic limbs impact children with bilateral lower limbs in more holistic ways than previously reported in literature. These constructs could be helpful for healthcare providers to assess or consider other areas of impact in their decision-making on prosthetic prescription. The constructs could also be helpful in encouraging the use of more holistic models such as the ICF in developing a more comprehensive outcome measure that is also appropriate for children with bilateral lower limb amputations.

Chapter 5: Integrated Discussion of the Project Results

5.1 Introduction

Prosthetic limbs are frequently provided to compensate for lost function and to increase independence (Strafella, 2021; de Witte et al. 2018). It has been acknowledged that individuals who undergo an amputation face both physical and mental challenges during the complex and multidimensional process of prosthetic rehabilitation (Schaffalitzky et al., 2011). However, it is crucial to identify prosthetic prescription's most significant outcomes and benefits for both prosthetic users and service providers. This helps to establish a foundation to evaluate when and why prosthetic limbs should be issued and to identify outcome measures that are sensitive to the users' life goals (Schaffalitzky et al. 2011).

Owing to the lack of research regarding children with lower limb amputations and, more specifically, children with bilateral lower limbs amputations, this study explores and describes the experiences of children with bilateral lower limb amputations who are prosthetic users. The study's objectives also include identifying the additional constructs reported by the participants that should be considered for this younger population group, as opposed to adults and unilateral amputations.

From the scoping review, the following constructs were highlighted: activities of daily living (physical function), psychological function, participation and limitations were expressed through qualitative experiences. In addition, specific categories or items within each theme emerged from the interviews in the second phase of the study. This included physical participation, access to schooling, socio-economic participation, body image, quality of life and adaptability.

Certain challenges were also included; pain, socio-economic standing (finances), prosthetic equipment, resource constraints in healthcare settings and relationships. The main findings from the scoping review and the interviews conducted in the qualitative study are discussed, and the results are explored in an integrated discussion in this chapter.

5.2 Participant Demographics

The prosthetists and physiotherapists who were part of this study were all registered with the HCPSA, a statutory body that is guided by a formal regulatory framework. There were five participants in this group with experience working in various sectors and provinces in South Africa. This enabled them to provide impactful insight into what they observed in the workplace when rehabilitating children with bilateral lower limb amputations.

The physiotherapists (n=2) in the public sector expressed concern over a lack of resources for prosthetic intervention. The prosthetists (n=2), on the other hand, were both based in the private sector and shared positive responses regarding the children they had fitted with prosthetic limbs. One physiotherapist who had experience working for a non-government organisation, shared useful information on how prosthetic limbs impacted children who had suffered bilateral lower limb loss. She reported that the children had better outcomes functionally, and that prosthetic limbs improved the children's self-esteem.

The adult prosthetic users were both males, with a mean age of 36 at the time that the interviews were conducted. The cause of the amputations between the two differed. One of the participants had suffered electrical burns which resulted in lower limb amputations. Another participant's amputations were congenital due to a birth defect. While the highest level of education is only known for one of the participants, both attended school with one participant being integrated into a mainstream school and the other attending a school for children with physical disabilities.

5.3 Activities and Participation

A wide range of outcomes related to physical function were reported as positive consequences of prosthetic intervention. These were reported by both healthcare practitioners and adult prosthetic users. While this was expected, the relationship between physical activities and participation should be noted as an important outcome of prosthetic intervention (Haywood, 2020).

The articles explored in the scoping review evaluated physical function and prosthetic impact according to various categories. These included i) mobility (McQuerry et al. 2019; Alan et al. 2007; Morrison et al. 2020; Ryall et al. 2003); ii) activities of daily living (McQuerry et al. 2019; Alan et al. 2007; Engsberg et al. 1991); iii) navigating through various environments (Alan et al. 2007; Morrison et al. 2020; Ryall et al. 2003); and iv) sports participation (McQuerry et al. 2019).

These parameters were similar to those reported by the participants in the qualitative study. However, the participants reported a greater impact on independence and participation in recreational activities and schooling. This impact later created opportunities for socio-economic participation for adult prosthetic users. This new information provided insight into how mobility can be used to reach patient-specific goals, particularly for growing children with varying interests.

Setting goals is crucial for rehabilitation as it can motivate the patient. This is especially true if the patient is practical and has a direct connection to real-life activities (i.e. by participation). A meaningful goal can increase patient involvement and encourage a patient to take part in rehabilitation in order to reach their goals (Wade, 2009). It is crucial to ensure the strategy is successful by involving the user in the process, that the goals are appropriate for the individual and that the user's comprehension of the procedure and its significance is considered (Siegert & Taylor, 2004; Schaffalitzky et al. 2011).

The literature supports the claims that children can accurately reflect on their well-being, psychological health and health-promoting behaviours by the age of eight (Bevans, et al. 2010; Oakley, et al. 1995; Piko & Bak, 2006; Chhina, et al. 2021). In paediatric populations, goal setting may vary according to age as well as the child's development and interests.

Family-centred intervention is a generally established practice in pediatric rehabilitation (Law et al. 2005; Dunst & Dempsey, 2007; Øien et al. 2010). Mobility and activities related to physical activity were unsurprising, but the translation of these activities into real-life circumstances was frequently reported by all participants. They also allowed children to gain independence in order to perform activities of daily living, toileting and reaching objects due to the additional height the prosthetics allowed them to gain.

More importantly, children are also able to partake in walking, running and jumping activities, which are essential physical activities that help to build their fundamental abilities in early childhood (Collins & Staples, 2017; Haywood, 2020). These motor skills translate into play and promote the development of children as they engage their body's muscles to enhance their natural activities (Sutapa et al., 2021). The improvement of these motor skills develops with age and the practice of these specific skills.

In South Africa, Section 29(1) of the Constitution of the Republic of South Africa guarantees all children the right to fundamental education (McConnachie et al. 2017). The Department of Education (DBE) developed the White Paper 6 (WP6), a policy that envisions a system of inclusive education built on the values of non-discrimination and the human dignity of all students (Khumalo & Hodgson, 2017). Despite these advancements, the most recent DBE progress report on WP6 implementation notes that there are still over 600 000 disabled children who are not enrolled in school (Khumalo & Hodgson, 2017).

The participants in this study reported that prosthetic intervention allowed children with bilateral lower limb amputations to access school, sports and recreational activities. One participant was able to integrate into a mainstream school and eventually access higher education. Being able to attend school resulted in this participant's positive socio-economic participation. This is important as it allows people with disabilities to contribute to the country's economy instead of depending on disability grants. It develops financial independence and an improved quality of life (WHO, 2001).

5.4 Psychological Function

Data is limited on the psychological outcomes after an amputation for children and adolescents. The psychological adjustment pattern that has been outlined for adults may not be applicable to children's age groups (Griffet, 2016). The study by Chhina et al. (2021) reported that variations in the look and functionality of a child's lower limbs can make the child less likely to engage in social, recreational and leisure activities. This can lead to challenges with the child's behaviour, mood, psychological health and social adjustment.

In this study, the participants reported how prosthetic intervention improved various aspects of psychological function. Peer equality was the overarching theme as each subtheme was measured against how each child 'felt more equal to their peers'. An amputee can be given a new sense of normalcy with the use of a prosthesis, according to Wittkower (1947). A person's psychological perception of their body is greatly improved by wearing a prosthetic (Wittkower, 1947; Haywood, 2020).

The height of children increases with their prosthetic limbs which enables them to be the same height as their peers. As the children's height improves, they are more able to partake in activities 'like their peers.' According to recent research, social interaction and early peer acceptability serve as a trigger for the growth of social competence (Küçüker et al. 2014).

By contrast, when early peer rejection persists throughout the school years, it has been identified as a psychological risk factor for subsequent behavioural and emotional issues in adulthood (Parker & Asher, 1987; Roberts & Zubrick, 1992; Küçüker et al. 2014).

Lower limb amputations can also have a negative impact on patients both psychologically and socially (Atherton and Robertson, 2006; Holzer et al., 2014). Psychosocially, it is normal for patients to experience anxiety and despair as they get used to a new body (Horgan & MacLachlan, 2004; Ibrahim et al., 2019).

In underdeveloped nations, there is frequently an additional social stigma because amputees are seen as incomplete people (Odatuwa-Omagbemi & Vadiki, 2012; Ibrahim et al. 2019). Having a physical disability also affects children's perceptions of their body image and their levels of self-esteem (Wallander & Varni 1998; Quarry, 2016). Owing to the great value society places on physical appearance, children with an apparent physical difference may feel stigmatised and lack higher levels of self-esteem, which in childhood are frequently obtained from peer approval (Varni & Setoguchi, 1992; Quarry, 2016).

The adult prosthetic users and therapists reported that prosthetic limbs improved the self-confidence and self-esteem of the children with bilateral lower limb amputations. Participation in activities with and like their peers was reported to provide children with a sense of achievement and belonging and to improve their overall well-being. Children were also noted to be highly adaptable to prosthetic equipment.

5.5 Challenges

Prosthetic intervention can positively impact children with bilateral lower limb amputations. However, it is also important to note the various challenges that make accessibility to prosthetic equipment difficult or that negatively impact the use thereof for these amputee children; One factor is the leg length discrepancy of the amputations; for example, one of the adult participants reported experiencing back pain from walking on his residual limbs that were unequal. The prosthetic limbs played a crucial role in rectifying this as he was able to walk on equal footing, which helped to alleviate the back pain.

In addition, prosthetic users are prone to experiencing an abuse or injury to the skin of their stump. Most leg prostheses have a tight-fitting socket where perspiration is trapped and air cannot readily circulate (Barnes, 1956; Bhandari & Jain, 1996). Additionally, skin is often reported to be susceptible to potential allergic or irritating effects of materials used in prosthesis manufacturing (Bhandari & Jain, 1996). For example, one participant reported increased pressure on his stumps caused by prolonged wear of the prosthetic limbs, resulting in the injury of the skin and pain. The majority of people who use

prosthetic limbs experience problematic pain symptoms, including residual limb, phantom limb, and back pain. These symptoms have the potential to significantly limit involvement in daily activities (Bhandari & Jain, 1996).

Themes relating to pain were only raised and discussed by adult prosthetic users and not by the therapists who work with children with child prosthetic users. This is valuable to note as adult prosthetic users have the experience of using prosthetic limbs. Therefore, pain could be a valuable construct to consider in evaluating prosthetic impact. Some of the challenges outlined by the participants are described below.

5.5.1 Personal challenges

Assistance devices such as prosthetic limbs can vary in that some can be simple and require low-tech devices, while others can be expensive and complex (de Witte et al. 2018). In developing countries, the availability, accessibility and expense of prosthetics can cause serious challenges for people with limb loss not only for physical function, but also to succeed and be accepted by society (Strait, 2006).

South Africa faces the challenge of manufacturing a high number of prosthetic limbs, which are costly due to the demand (Naude et al. 2015). An additional challenge exists of a child outgrowing his or her prosthetic limb, which then increases the expenses and costs involved in treatment (Naude et al. 2015). The challenges of inequalities in poverty, socio-economic status (SES) and access to basic social services among population groups, provinces, and socio-economic categories are common and pervasive in South Africa (Ataguba, 2010; Coovadia et al. 2009; Ataguba et al. 2011) and contribute to the amplification of health disparities.

Participants reported that financial constraints often lead to children not obtaining new prosthetics when they outgrow their existing ones. Also they did not always receive the appropriate prosthetic for the relevant activity, for example, sports prostheses. The cost of travelling to regular appointments to have their prosthetic equipment checked, repaired, or replaced is also viewed as a challenge. This could negatively impact a child who is using a prosthetic effectively and requires a new one.

5.5.2 Environmental challenges

Having acknowledged that prosthetic limbs differ according to complexity and cost, they also vary according to the level of limb loss. The prescription of prostheses is based on the work experience of the prosthetist and tends to be subjective according to the prosthetist's knowledge (Van Der Linde et al. 2004). While prescriptions can be subjective, funders and other key stakeholders may need a justification for the purchase of costly prosthetic equipment (Menard et al. 1992; Van Der Linde et al. 2004).

The adult prosthetic users who participated in this study both had the experience of using basic prosthetic limbs, as well as more advanced prosthetic limbs. They noted there was a difference in prosthetic equipment and stated that while the quality of the prosthetic and its components improved, the cost increased as well. However, they commented on the effectiveness of the quality prosthetic equipment. The quality equipment is not obtained from the government sector.

This could be important to consider when evaluating the impact of prosthetic limbs on children with bilateral lower limb amputations. A typical prosthetic limb manufactured in a developing country costs roughly \$125 to \$1 875 USD, depending on the region and healthcare setting in which it is made. While prosthetic limb prices may vary widely from country to country, however, the average cost of a prosthesis in the United States (a developed country) is between \$5 000 and \$15 000 USD, making the cost of a prosthetic limb in a developing country as little as \$41 USD. However, replacement and maintenance expenditures can reach thousands of dollars over the course of a lifetime. Given that the usual yearly family income in rural areas in developing countries is roughly \$300 USD, this is a significant concern (Strait, 2006).

Another issue is the high cost of importing parts from industrialised nations to construct prosthetic limbs in developing nations. In addition, these parts are typically not durable enough to withstand the challenges in such rural settings and are typically designed for quite different lifestyles. Developing nations usually have agricultural economies and tropical climates, consequently conventional limbs of wood and resin only last approximately 18 months in such severe settings (Strait, 2006).

Participants also reported on the lack of resources within the government sector and some limitations within the private sector as well due to limited funding and resources. This results in the types of prosthetics manufactured being of a lower quality. This aspect is often experienced alongside a prolonged waiting period for prosthetic limbs which could also be due to these limited resources.

Significantly, therefore, a lack of prosthetic limbs can possibly impact the family if a child is not able to gain independence. The younger a child, the higher the burden of care that is placed on the caregiver. Participant 3, an adult prosthetic user, reported the following prior to prosthetic intervention; “...back to when I didn't have prosthetics at school. The only other difficulty that I had was that I had my uncle who had to carry me on his back for that kilometre and five, you know. So, for me, it also felt like I'm actually being [a burden].” After being issued with prosthetic limbs, this participant reported being able to walk to school with his peers which freed up his family members to continue with their daily tasks and everyday lives.

5.6 Summary

This study included two groups of key stakeholders: i) prosthetists and physiotherapists who have experience working with children with lower limb amputations; and ii) adult prosthetic users who underwent bilateral lower limb amputations as children.

Owing to a lack of research, the evaluation of the impact of prosthetic limbs on children with bilateral lower limb amputations was limited or poorly documented. This study highlighted how prosthetic intervention has impacted those children with bilateral lower limb amputation. This information was obtained from the perspective of therapists who rehabilitate such a population of children and adult prosthetic users.

The additional constructs highlighted in this study over and above those identified in the scoping review included: activities of daily living, physical participation, education, body image, quality of life and adaptability. Challenges that could play a role in prosthetic impact include pain, finances, the type of prosthetic equipment and the effect of prosthetic limbs on the child's prosthetic intervention. These challenges should also be

earnestly considered to evaluate the impact of prosthetic limbs on children with bilateral lower limb amputations. The emerging themes are holistic and encourage the use of the ICF, which is multidimensional.

Chapter 6: Conclusion

6.1 Introduction

This chapter focuses on providing recommendations from the study findings for future research and application in a clinical setting. To assist future researchers to enhance the calibre of their research the limitations of this study are also discussed.

6.2 Summary of Main Findings

The findings of the scoping review has shown a gap in the literature regarding research and information on prosthetic impact in children with lower limb amputations. Furthermore, the outcomes and constructs used to evaluate such an impact are limited in that they focus predominantly on physical function, which is not necessarily the only construct when it comes to the prosthetic interventions in children. The outcome measures were also not designed specifically for a paediatric population and might not be appropriate in clinical practice.

After conducting interviews with healthcare practitioners and adult prosthetic users who had undergone bilateral lower limb amputations as children, this study finds that prosthetic limbs have a far greater impact than just physical function in the paediatric population. Constructs that play a role in the use of bilateral prosthetic limbs of children include activities and participation in numerous categories such as, mobility, activities of daily living, physical participation, participation in education via school attendance and socio-economic aspects.

The psychological impact that is also reported. This includes body image, quality of life and adaptability. While there were positive outcomes due to prosthetic intervention, certain challenges remained due to personal and environmental factors. Personal challenges included pain and socio-economic standing (finances). Environmental challenges were reported in prosthetic equipment, resource constraints in healthcare settings and the lack of supportive relationships.

6.3 Study Recommendations for Future Research

The gaps evident in research in the prosthetics and rehabilitation field, particularly for children with bilateral lower limb amputations appears neglected. Previous research that includes children with bilateral lower limb amputations seems overlooked as this population has been excluded from data collection in many source articles. It is recommended, therefore, that children should be participants in future data collections when researchers to collect data first-hand. The inclusion of more adult participants is also recommended. While more data is necessary for future studies, representative sampling should be prioritised in the recruitment process to add more diverse data and to be draw to conclusions from the research. When creating the questions for future interviews, a more neutral stance could help to highlight more balanced benefits versus risks or challenges.

There is also a need to obtain a broader range of experiences and data from a wider number of participants in a variety of settings to ensure diversity and transferability to all relevant sites.

In addition, outcome measures to evaluate a variety of constructs need to be developed. These outcome measures should address children with bilateral amputations and be applicable and sensitive enough to specifically take a child's development into consideration. Furthermore, appropriate cut-off points should be developed to ensure that prosthetic provision is linked to utility and safety.

6.4 Study Recommendations for Service Providers

This study emphasises the total wellness of patients and how prosthetic limbs impact a variety of aspects. Healthcare practitioners should, therefore, remain patient-centred and adopt a holistic approach to prosthetics rehabilitation and prescriptions. Patient goals are also paramount and should be revisited either with the child or the family (if the child is too young). As the prosthesis will affect both the child and the family, all family members ought to feel part of the process for improved cooperation and the correct use of the limb.

Children constant development is multifaceted. The issue of prosthetics, therefore, should focus on whether the prosthetic meets the demands of the child's development. These demands include a child's body structure and function, activities and participation, psychological function and challenges. Although other various challenges might arise, educating the family on prosthetic fitments, repairs and the need for replacement should take place during rehabilitation.

Within the South African context, prosthetic provision might be a challenge for healthcare providers working in the government sector who have limited resources available. It is, therefore, recommended that healthcare workers collaborate and communicate with healthcare providers in other sectors, such as the private sector and non-government organisations.

6.5 Study Limitations

It is acknowledged that there are a number of limitations in this study. The first limitation is the number of participants. Initially, the study included prosthetists and physiotherapists registered with the South African Orthotic and Prosthetic Association (SAOPA) or with the International Society for Prosthetics and Orthotics (ISPO). At first, the primary research reached out to these organisations, but due to a lack of response, using different strategies to aid recruitment, the recruitment strategy changed. This change resulted in a smaller number of participants being involved in the study.

The participants included in this study were interviewed virtually. As these interviews were semi-structured, some questions were varied in their phrasing. However, the primary researcher did obtain the necessary information that was required. Since adults with bilateral prostheses were included, recall bias cannot be dismissed as participants were asked to share past experiences.

This study was conducted during the Covid-19 pandemic and only virtual interviews were feasible. While the virtual interviews were recorded, transcribed and meticulously checked, there was room for human error due to a lack of clarity in the recordings. The researcher attempted to mitigate this risk by writing field notes during the interviews.

Once the interviews were transcribed, the transcriptions were also emailed back to the participants to read and approve the content.

Initially, the study intention was to include children with bilateral lower limb amputations as participants but, due to the Covid-19 pandemic, no in-person interviews were feasible.

6.6 Conclusion of this Study

This multiple-methods study attempted to make an important contribution to highlight the lack of literature evaluating the impact of prosthetic limbs on children with lower limb amputations. The first objective was to explore and describe the current constructs used to evaluate prosthetic impact in children with bilateral lower limb amputations. The research finding is that there has been a high focus on physical function with only one outcome measure designed specifically for the paediatric population. As only limited constructs were found in evaluating prosthetic impact in children, particularly children with bilateral lower limb amputation, this qualitative study is conducted to find out which constructs impact participants most (healthcare providers who rehabilitate children with bilateral lower limb amputations, and adult prosthetic users who had undergone a bilateral lower limb amputation as a child).

The qualitative data revealed constructs that participants found important beyond function, are: the activities of daily living, physical participation in recreation and sports, access to education, the potential for socio-economic participation, body image, quality of life and adaptability were all reported to be valuable outcomes of prosthetic intervention.

These are therefore considered the specifics to keep re-evaluating for constantly growing children as their prosthetic limbs support them with their goals. Also revealed in the data is that personal and environmental challenges such as pain, finances, prosthetic equipment, resources and relationships should also be factored in during prosthetic impact evaluation.

In conclusion, it is evident that prosthetic intervention can positively impact children across a wide range of aspects beyond physical function, which should serve as further motivation to improve access to prostheses.

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Appendix A



Approval Notice

New Application

19/02/2021

Project ID :18648

HREC Reference No: S20/10/268

Project Title: The Impact of Prosthetic Limbs on Children with Bilateral Lower Limb Amputations

Dear Miss Siphosethu Zantsi

The **Response to Modifications** received on 21/01/2021 was reviewed by members of **Health Research Ethics Committee** via **expedited** review procedures on 19/02/2021 and was approved.

Please note the following information about your approved research protocol:

Protocol Approval Date: 19 February 2021

Protocol Expiry Date: 18 February 2022

Please remember to use your Project ID 18648 and Ethics Reference Number S20/10/268 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

Translation of the informed consent document(s) to the language(s) applicable to your study participants should now be submitted to the HREC.

Please note you can submit your progress report through the online ethics application process, available at: [Links Application Form Direct Link](#) and the application should be submitted to the HREC before the year has expired. Please see [Forms and Instructions](#) on our HREC website (www.sun.ac.za/healthresearchethics) for guidance on how to submit a progress report.

The HREC 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.

Please note that for studies involving the use of questionnaires, the final copy should be uploaded on Infonetica.

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. Please consult the Western Cape Government website for access to the online Health Research Approval Process, see: <https://www.westerncape.gov.za/general-publication/health-research-approval-process>. 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 instructions, please visit: [Forms and Instructions](#) on our HREC website <https://applyethics.sun.ac.za/ProjectView/Index/18648>

If you have any questions or need further assistance, please contact the HREC office at 021 938 9677.

Yours sincerely,

Mrs. Ashleen Fortuin
Health Research Ethics Committee 1 (HREC1)

National Health Research Ethics Council (NHREC) Registration Number:

REC-130408-012 (HREC1)•REC-230208-010 (HREC2)

Appendix B

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	✓
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	✓
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	✓
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	✓
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	✓
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	✓
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	✓
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	✓
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	✓
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	✓
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	✓
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	✓
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	✓



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SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	✓
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	✓
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	✓
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	✓
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	✓
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	✓
Limitations	20	Discuss the limitations of the scoping review process.	✓
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	✓
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	✓

JB1 = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med*. 2018;169:467–473. doi: [10.7326/M18-0850](https://doi.org/10.7326/M18-0850).



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Appendix C

LETTER TO AUTHORITIES

To Whom It May Concern

RE: REQUEST TO ASSIST WITH RECRUITING PARTICIPANTS FOR RESEARCH STUDY

I am writing this letter to request assistance with conducting my master's thesis by recruiting participants who are either physiotherapists or prosthetists currently on the International Society of Prosthetics and Orthotics (ISPO) or South African Orthotics and Prosthetics Association (SAOPA) registry. My name is Siphosethu Zantsi and I am currently a master's student at Stellenbosch University. The aim of my research is to investigate the impact of prosthetic limbs on children with bilateral lower limb amputations and to explore and describe the constructs that determine the impact of prosthetic interventions in children with bilateral lower limb amputations. Professor Conran Joseph and Dr. Ennion will supervise the conducted research.

The purpose of this study is to interview children who have bilateral lower limb amputations and have received prosthetic limbs. The study aims to explore how prosthetics have impacted children with bilateral lower limb amputations on a wide functioning scale such as physical function, social integration, participation, belongingness, and body image. Key stakeholders will also be interviewed in this study and will include physiotherapists and prosthetists on the International Society of Prosthetics and Orthotics (ISPO) or South African Orthotics and Prosthetics Association (SAOPA) who rehabilitate children with bilateral lower limb amputations and have at least five years of experience working within the South African context, as well as older persons who are prosthetic users and suffered bilateral lower limb amputations during their childhood. The aim of including these key stakeholders in the study is to explore which additional constructs should be considered specifically for children with bilateral lower limb amputations.

A copy of my thesis protocol discussing all aspects related to the proposed research study along with all relevant addenda has been attached to this letter. A copy of the Ethics Approval from the University of Stellenbosch Research Ethics Committee has been provided. It is the intention of the primary researcher to publish the study results.

I would therefore like to request your assistance in recruiting any physiotherapists and prosthetists who are on the International Society of Prosthetics and Orthotics (ISPO) or South African Orthotics and Prosthetics Association (SAOPA) registry and have at least five years of experience working within the South African context. South African nationals and non-nationals will be included in the study so long as they have the specified five years of working experience in South Africa.

Thank you for your time and cooperation.

Kind regards,

Siphosethu Zantsi

BSc Physiotherapy (Stellenbosch University)

Appendix D

PARTICIPATION INFORMATION LEAFLET AND CONSENT FORM: KEY STAKEHOLDERS

TITLE OF THE RESEARCH PROJECT

“The Impact of Prosthetic Limbs on Children with Bilateral Lower Limb Amputations: A Qualitative Study”

ETHICS REFERENCE NUMBER: S20/10/268

PRINCIPLE RESEARCHER: Miss Siphosethu Zantsi

ADDRESS: Stellenbosch University

Faculty of Medicine and Health Sciences

Division of Physiotherapy

Francie van Zijl Drive

Tygerberg

7505

Cape Town

South Africa

CONTACT NUMBER: 073 956 3478

You are cordially invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the researchers any questions about any part of this project that you do not fully understand. It is very important that you are completely 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. In other words, you may choose to take part, or you may choose not to take part. Nothing bad will come of it if you say no: it will not affect you negatively in any way whatsoever. Refusal to participate will involve no penalty. You are also free to withdraw from the study at any point, even if you do agree to take part initially.

This study has been approved by the Health Research Ethics Committee at Stellenbosch University. The study will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, the South African Guidelines for Good Clinical Practice (2006), the Medical Research Council (MRC) Ethical Guidelines for Research (2002), and the Department of Health Ethics in Health Research: Principles, Processes and Studies (2015).

What is the research about?

The purpose of this study is to interview children who have bilateral lower limb amputations and have received prosthetics. The study aims to explore how prosthetics have impacted

children with bilateral lower limb amputations on a wide functioning scale such as physical function, social integration, participation, belongingness, and body image. Key stakeholders will also be interviewed in this study and will include physiotherapists and prosthetists on the International Society of Prosthetics and Orthotics (ISPO) or South African Orthotics and Prosthetics Association (SAOPA) who rehabilitate children with bilateral lower limb amputations as well as older persons who are prosthetic users and suffered bilateral lower limb amputations during their childhood. The aim of including these key stakeholders in the study is to explore which additional constructs should be considered specifically for children with bilateral lower limb amputations.

The study will involve being interviewed telephonically by the primary researcher. The interview will be recorded, and the researcher will take notes in a research diary. Should a follow-up interview be required, you may be contacted for a time and date suitable for you. We may contact you after the interviews to check that we have all the correct information.

The information obtained during the study process will be kept strictly confidential should the research paper be published.

Why have you been invited?

You have been invited to participate in the study as you have had a bilateral lower limb amputation since childhood and are a prosthetic user. Alternatively, you may be a physiotherapist or prosthetist who is registered with the International Society of Prosthetics and Orthotics (ISPO) or the South African Orthotics and Prosthetics Association (SAOPA) and is involved in the rehabilitation of children with lower limb amputations.

What is the role of the interview?

The role of the interview is to discuss which constructs you find need to be considered for children with bilateral lower limb amputations as opposed to adults and persons with unilateral lower limb amputations. The interviewer will remain independent and will keep her perspectives out of the interviewing process.

What will your responsibilities be?

Should you agree to be a part of the study, you will be required to sign a consent form as well as a data collection sheet to confirm your demographic information. The interview will be approximately 45 minutes to 60 minutes long and will be conducted telephonically. The interviewer will record the interview with a digital recorder in order for the interview to be transcribed later.

Will you benefit from taking part in this study?

By taking part in this study, you will not receive any personal benefits. The information gained from this study might demonstrate the additional constructs that need to be considered for children with bilateral lower limb amputations as opposed to adults and persons with unilateral lower limb amputations. This study could benefit the field and assist with policy recommendations.

Are there any risks involved in taking part in this study?

This is a low-risk study, however, recalling your experiences may cause psychological distress. Should you show any signs of psychological distress, you will be referred to a relevant healthcare worker.

Who will have access to your information and data?

Any information that could be used to identify you will be removed from the study. Only the primary researcher and the supervisors of the research study, Liezel Ennion and Conran Joseph, will have access to your information obtained from this study. The transcriber will be required to sign a confidentiality form to keep all information confidential.

What will happen in the unlikely event of some form of injury occurring as a direct result of your taking part in this research study?

It is highly unlikely that you will suffer injury by taking part in the interviews for this study. The primary researcher will provide her contact details should you feel the need to discuss your experiences from the interview process.

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

A R200 voucher will be provided to you for your time to partake in the study. This is merely to reimburse you for your time loss.

Is there anything that you should know and do?

The primary researcher can be contacted on 073 956 3478 should you require more information regarding the study.

You can also contact the Health Research Ethics Committee on 021 938 9207 should you have any concerns.

A consent form and copy of the above information will be provided for your own records. Communication will be provided should the study process be altered during the study.

Declaration by participant

By signing below, I agree to take part in a research study entitled "The Impact of Prosthetic Limbs on Children with Bilateral Lower Limb Amputations." I declare that:

- I have read this information and consent form, or it was read to me, and it is written in a language in which I am fluent and with which I am comfortable.
- I have had a chance to ask questions and I am satisfied that all my questions have been answered.
- I understand that taking part in this study is voluntary, and I have not been pressured to take part.
- I may choose to leave the study at any time and nothing bad will come of it – I will not be penalised or prejudiced in any way.

- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan that we have agreed on.

Signed at (place) on (date) 20__.

.....

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

Signed at (place) on (date) 20__.

.....

.....

Signature of investigator

Signature of witness

Appendix E

SEMI-STRUCTURED INTERVIEW GUIDE: PHYSIOTHERAPISTS AND PROSTHETISTS

BRIEF INTRODUCTION

The primary researcher will introduce herself and allow time for any questions regarding the study. Once the questions have been answered satisfactorily, the primary researcher will commence with the interview. During the interview, the primary researcher will ask the participant about their experience with regards to rehabilitating children with bilateral prosthetics and which additional constructs they find need to be considered for children with bilateral lower limb amputations as opposed to adults and unilateral lower limb amputations. The primary researcher will emphasise that there are no right or wrong answers.

OBJECTIVES OF THE STUDY

To explore and describe which additional constructs for impact should be considered specifically for children with bilateral lower limb amputations as opposed to adults and unilateral lower limb amputations.

QUESTIONS

1. How long have you been working with children with bilateral lower limb amputations?
2. How would you describe your experience of working with and rehabilitating children with bilateral lower limb amputations?

Benefits

3. Do you think children with bilateral amputations benefit from prosthetic intervention? Why?
4. In which way do they benefit?

Need for criteria to prescribe prosthesis prescription

5. Are there universal or local criteria for rehabilitation goals for children with bilateral lower limb amputations?
6. Are there universal or local criteria for the prescription of prostheses in children with bilateral lower limb amputations?
7. Is there a need for local criteria to be applied for the prescription of prostheses?
8. What constructs or rehabilitation goals do you consider when rehabilitating a child with bilateral lower limb amputations for prosthetic intervention?
9. How do you assess a child with bilateral lower limb amputations for prosthetic qualification? Are there certain outcome measures that you use?
10. What outcome measures do you use to assess prosthetic qualification for children with unilateral amputations?

Gaps in the prescription of prostheses for children with bilateral lower limb amputations

11. In your opinion, what gaps would you say exist currently in clinical practice when it comes to children with lower limb amputations, especially children with bilateral lower limb amputations?
12. Which constructs are being considered for the impact of prosthetic intervention in children with bilateral lower limb amputations? Are there post fitment assessments that get done to observe how prosthetic technology impacts these children?
13. Are there any additional constructs that you think need to be taken into consideration when it comes to children with bilateral lower limb amputations as opposed to adults and unilateral lower limb amputations? Why do you think these constructs are important?

Appendix F

SEMI-STRUCTURED INTERVIEW GUIDE: ADULT PROSTHETIC USERS WITH A BILATERAL LOWER LIMB AMPUTATION

BRIEF INTRODUCTION

The primary researcher will introduce herself and allow time for any questions regarding the study. Once the questions have been answered satisfactorily, the primary researcher will commence with the interview. During the interview, the primary researcher will ask the participant about their experience of living with a bilateral lower limb amputation since childhood and how prosthetics and which additional constructs they find need to be considered for children with bilateral lower limb amputations as opposed to adults and unilateral lower limb amputations. The primary researcher will emphasise that there are no right or wrong answers.

OBJECTIVES OF THE STUDY

To explore and describe which additional constructs of impact should be considered specifically for children with bilateral lower limb amputations as opposed to adults and unilateral lower limb amputations.

QUESTIONS

1. Can you tell me a little bit about how you ended up with a bilateral lower limb amputation?
2. What difficulties did you experience as a child with bilateral lower limb amputations functionally, psychologically, with social integration and participation?
 - Functionally: in a manner that relates to the purpose or use of something.
 - Psychologically: how it affects the mind or how it affects you emotionally
 - Social Integration: attachments you're sustaining with the larger society and are measured in terms of occupational, organisational, and community roles.
 - Participation: taking part in an event or activity
3. Can you describe the process of having a bilateral lower limb amputation and having no prosthetic technology, to being fitted with prosthetic limbs? What were some of your experiences?
4. Which parts of your life and experience were positively impacted because of the prostheses?
5. What was the process of acquiring prosthetic limbs like?
 - Was it clear?
 - Did you have enough information?
 - Was there support if questions arose?
6. Having lived with a bilateral lower amputation as a child, what constructs* do you think need to be considered for children with bilateral lower limb amputations as opposed to adults and unilateral lower limb amputations? Why do you think these constructs are necessary additions?

- *Constructs: Complex ideas created by making several simple ideas. In this case, things that you consider are important that affect prosthetic fitting and impact.