Design optimisation and development of a pneumatic prosthetic foot

by

Zanodumo Thandazani Godlimpi

Student number: 12018082

A Master's research thesis submitted in fulfilment of the requirements for a degree of

Master of Engineering

in

Mechanical Engineering

in the

School of Engineering and the Built Environment

at the

UNIVERSITY OF SOUTH AFRICA

Supervisor: Prof. T. Pandelani

External Supervisor: Dr D. Modungwa

Co-Supervisor: Prof. H. Ngwangwa

May 2026

Plagiarism

- I, Zanodumo Thandazani Godlimpi, hereby declare that this masters research proposal is wholly my own work and has not been submitted anywhere else for academic credit either by myself or another person.
- I understand what plagiarism implies and declare that this dissertation is my own ideas, words, phrases, arguments, graphics, figures, results, and organization, except where reference is explicitly made to another's work.
- I understand further that any unethical academic behaviour, which includes plagiarism, is seen in a serious light by the University of South Africa and is punishable by disciplinary action.

Signed.............................. Date: 27/05/2026

Abstract

Lower-limb amputation is a life-saving and life-changing surgery that significantly impacts mobility and quality of life, particularly in South Africa, where access to advanced prosthetic technology is hindered by socio-economic factors and infrastructure challenges. Prosthetic feet are classified into three distinguishable categories: conventional feet, which include solid ankle cushion heel and articulated prosthetic feet, energy storage and release feet and bionic feet. Conventional passive prosthetics, such as the SACH foot, often fall short in replicating the normal walking dynamics, leading to asymmetries when walking and increased energy cost of walking. This study piloted a pneumatic prosthetic foot to investigate the biomechanical benefits of using this innovation while walking at self-selected walking speed over flat surfaces.

The study utilized a quantitative (experimental) research method, commencing with the Finite Element Analysis (FEA), using the ANSYS software to simulate axial structural loads during standing positions on titanium and aluminum alloy shank segments. A prototype was developed featuring a crank-slider mechanism and a pneumatic cylinder to modulate ankle stiffness. Clinical evaluation involved a case study of two transtibial participants. Walking gait was analysed using the Templo markerless motion capture system (Theia3D) across three conditions: the prescribed passive prosthetic foot, an unpressurized version of the pneumatic prosthetic foot, and a pressurized version of the pneumatic prosthetic foot (4 bars). Spatiotemporal parameters, kinetics, and kinematics, including stride length, cadence, and vertical ground reaction forces (vGRF), were systematically recorded and analyzed across varying conditions.

A stark contrast between participants was revealed by the study findings, participant 1 demonstrating improvements in walking symmetry (spatiotemporal parameters and kinetics), while participant 2 demonstrated minimal benefit when using the pneumatic prosthetic foot. The study findings suggest that device performance, one way or another, was influenced by the user adaptation and biomechanical conditions of the participant. The preliminary findings align with the broader body of literature, suggesting that semi-active prosthetic devices can bridge the gap between expensive powered devices and passive prosthetics. On the contrary, the pneumatic prosthetic foot was not practically lighter than other powered prosthetic devices.

This research developed a functional pneumatic prosthetic prototype that can withstand the axial loading of the human body, and can be used for mobility. Though the pneumatic prosthetic prototype has demonstrated potential, the findings need to be interpreted with caution due to the small sample size (n=2), which limits the generalizability of the findings. The current pneumatic prosthetic foot prototype requires further refinements to reduce both the mass and the height of this prosthetic foot. Also, improvements in the control system are required to modulate the ankle stiffness during walking. Additionally, the system faced challenges in replicating passive shock absorption during the load acceptance phase in the early stance. Future research should include large and diverse participant cohorts, and longitudinal studies to monitor neuromuscular adaptation and changes in the walking dynamics.

Contents

Table of figures

1. Introduction

1.1. Introduction

Lower-limb amputation is a significant and growing global health concern, with recent statistics reporting that it affects over 57.7 million people globally as of 2017 (McDonald *et al*., 2020). In developed countries such as the United States of America, approximately 2 million people live with limb amputation, and new amputations carried out annually are estimated to be around 185,000 (Manickum *et al*., 2019). These numbers emphasise the serious need for effective prosthetic solutions that restore mobility, promote independence, and facilitate the social and economic reintegration of patients post-amputation (Ziegler-Graham *et al.*, 2008). Despite advances in prosthetic technology, most conventional prosthetic devices fail to mimic the normal biomechanics of the human ankle-foot complex. Therefore, amputees ambulating at walking speeds that are comparable to non-amputees demonstrate a metabolic energy expenditure of between 10-30% (Herr & Grabowski, 2012), experience an asymmetrical gait pattern, and are at a higher risk of developing secondary musculoskeletal disorders such as osteoarthritis and low back pain (Wade *et al*., 2022; Norvell *et al*., 2005).

In Africa, the main drivers of lower limb amputation statistics are trauma, Peripheral vascular diseases, and infections, including those related to tuberculosis and HIV/AIDS (Okunlola *et al*., 2024; Boateng *et al*., 2022; Ennion & Manig, 2019). The estimated figure of people living with amputation in the context of Africa is 2.1 million, with the majority of these people residing in low- and middle-income countries (World Health Organisation, 2017). However, inequalities persist, as evidenced by the significant discrepancy in the availability and affordability of recent prosthetic innovations across the continent (Ennion & Johannesson, 2018). These discrepancies are significantly affecting access to these devices, as a result, many amputees in the sub-Saharan region of Africa rely on basic passive prosthetic devices, such as the Solid Ankle Cushion Heel (SACH) foot, which, while affordable and durable, it fails to replicate the dynamic behaviour of the biological ankle and does not meet the biomechanical requirements of performing activities of daily living (William *et al*., 2022). This contributes to poor gait performance, increased energy expenditure, and diminished quality of life for amputees (Ismawan *et al*., 2021).

In South Africa, the challenges faced by lower-limb amputees are particularly acute due to significant disparities in healthcare access and socioeconomic inequalities(Mduzana *et al*., 2020). In KwaZulu-Natal, it was estimated that 2,400 lower limb amputations are conducted per year, while in Cape Town, 69,6% of lower limb amputations were due to diabetes, and 26,8% were vascular causes (Naidoo & Ennion, 2019; Pienaar & Visagie, 2019). These statistical figures in lower limb amputation have been on an upward trajectory, largely influenced by diabetes and atherosclerotic peripheral vascular disease (Khan *et al.,* 2020; Limakatso *et al*., 2024; Mgibantaka *et al*., 2024; Naidoo & Ennion, 2019). Access to prosthetic care is heavily centralised in urban areas, with rural populations facing long travel distances, extended waiting times, sometimes up to five years, and limited prosthetic device options (Ennion & Manig, 2019a). These challenges are compounded by reliance on basic SACH feet, which are the most commonly prescribed prosthetic feet due to their affordability and minimal maintenance requirements (William *et al*., 2022). However, this basic design lacks the functional capabilities needed to adapt to uneven terrains and does not support the active lifestyles or diverse mobility requirements of users, particularly in rural areas (Naidoo & Ennion, 2019).

The significance of these issues extends beyond individual well-being. Limited mobility and high energy expenditure restrict amputees' ability to participate in social, educational, and vocational activities, ultimately affecting economic participation and perpetuating cycles of poverty and social exclusion (Yu & Ennion, 2019; Adamczyk & Kuo, 2015). Addressing these challenges requires prosthetic solutions that not only replicate the mechanical actions of the biological ankle but also meet the practical, economic, and environmental needs of users in low-resource settings (Cherelle *et al.*, 2014; Sup *et al.*, 2008).

Recent research has shown that active prosthetic feet incorporating powered ankle joints, particularly those using pneumatic actuation, can better replicate the mechanical work of biological plantarflexors, improving gait symmetry and reducing energy expenditure (Zheng & Shen, 2015; Caputo & Collins, 2014). Pneumatic actuators, due to their high force-to-weight ratios and inherent compliance, offer significant potential for creating prosthetic devices that adapt to the dynamic requirements of walking in diverse terrains (De Volder & Reynaerts, 2010; Jiménez *et al.*, 2020). Yet, despite their promise, there is a lack of affordable, locally manufactured pneumatic prosthetic solutions tailored to the unique biomechanical and socio-economic needs of the South African population (Ennion & Manig, 2019). This dissertation aims to address these critical challenges by developing and evaluating a pneumatic actuated prosthetic foot designed to enhance gait performance, reduce metabolic energy expenditure, and improve the quality of life for South African amputees. By prioritising local design, affordability, and adaptability to various terrains, this research seeks to bridge the gap between advanced prosthetic technology and the practical realities faced by amputees in both urban and rural South African settings. Ultimately, this work aims to contribute to the broader global effort to create inclusive, biomechanically effective, and socially responsive prosthetic solutions.

1.2. History and background of pneumatic transtibial prosthetics

The field of actuators has recently been rapidly evolving, with new advancements in terms of capability, power, and force output being consistently reported in the literature (Fernández *et al.*, 2020; Dong *et al.*, 2020; Zheng & Shen, 2015). These advancements are of benefit to the field of active prosthetics and orthotics as they could deliver the required force output without increasing the overall mass and size of the device. In other applications, such as robotics, the use of pneumatics and hydraulics is relatively rare compared to electrostatic, thermal, and piezoelectric actuators (Ali *et al.*, 2009; Debta & Kumar, 2018; Versluys *et al.*, 2009). The scarcity of use of pneumatics and hydraulic actuators in recent active prosthetic devices is quite significant, with very few studies that report on the outcomes of using these actuators, even after researchers have demonstrated the feasibility of replicating ankle movements using fluid power actuators (Zheng *et al.*, 2016; Zheng & Shen, 2013, 2015; Versluys *et al.*, 2009). Further evidence demonstrates that pneumatic and hydraulic actuators offer the highest force and power densities at a small scale, are back-drivable, have low friction, and boast a high force-to-weight ratio (Suzumori, 2020; Kedzierski & Holihan, 2018; De Volder & Reynaerts, 2010). However, researchers who implemented fluid power actuators have not been able to overcome the limitations of providing a mobile pressurised air source that delivers sufficient pressurised air for normal walking. As a result, studies by Zheng & Shen (2015) and Versluys *et al.* (2009) utilised lab-based prototypes that had an external pressurised air source, but further recommended that a high-pressure carbon fibre tank or a liquid propellant be considered as potential air sources; for future developments.

The ultimate goal of powered prosthetic feet is to replicate the anatomical ankle-foot during normal locomotion (see Figure 1), and this can be achieved by accurately meeting the biomechanical requirements of normal walking, which include torque, mechanical power, and work. Biological plantar flexors generate up to 80% of the mechanical work necessary to finish each stride when walking on level ground, and normally, they produce more positive work than negative work (Winter, 1990; Kuo & Donelan, 2010). In the absence of an actuator, a regular body-powered dynamic prosthetic foot, which is usually spring-loaded and uses carbon leaf springs made of carbon fibre, can only absorb and discharge mechanical energy while it interacts with the ground (Chiriac & Bucur, 2020). The device's capacity to produce mechanical energy is significantly restricted, and it can only produce as much as half of the mechanical energy required for ambulation (Herr & Grabowski, 2012). These prosthetic designs cannot generate net positive work and can only release less than 12,5% of the mechanical power needed for propulsion from the biological plantar flexors (Grabowski, 2011).

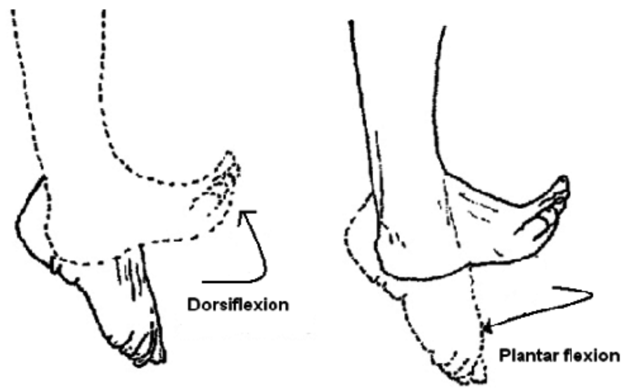


Figure 1: Ankle plantarflexion and dorsiflexion movements in a non-weight-bearing position (Hegde 2013).

The concept of dynamic prosthetic feet that absorb and release energy during gait is derived from the features of muscle tendons. An early study by Maganaris and Paul (2002) categorised the Achille's tendon feature into two components: tensile force transfer and absorption and discharge of elastic energy during gait. The elasticity of the Achilles tendon enables it to store and release mechanical energy, therefore decreasing the energy requirements for elevating and launching the centre of gravity during push-off (Versluys *et al.*, 2009).

1.2.1. Categories of prosthetic feet

The Selection of prosthetic devices largely depends on the user's functional ability requirements and affordability. An amputee mobility predictor tool developed by Gailey *et al.*, (2002) remains reliable for evaluating amputee patients' functional abilities without a prosthesis and predicting their potential for ambulating with one. Prosthetic feet can be classified into three distinguishable categories (see Figure 2): conventional feet, which include solid ankle cushion heel and articulated prosthetic feet, energy storage and release feet and bionic feet (Versluys *et al.*, 2009). These classifications are based on the physical capabilities of the prosthetic foot and the ability to replicate some of the basic functions of the biological ankle-foot. The introduction of these prosthetic feet follows a sequence that maps out the evolution of prosthetic feet from the oldest peg leg to the recent bionic prosthetic designs, as shown below.

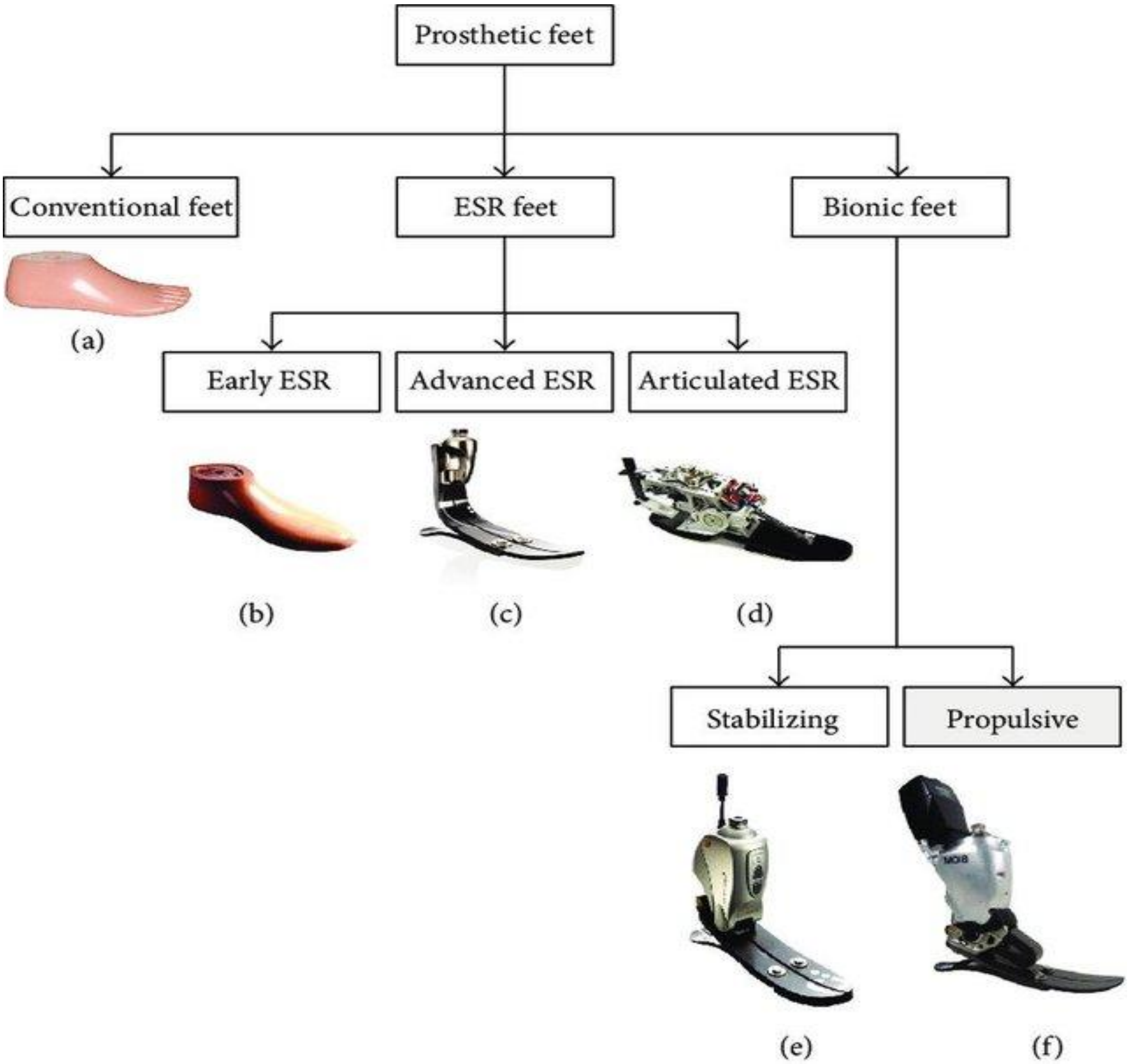


Figure 2: Categories of prosthetic feet with (a) the SACH foot, (b) the SAFE foot, (c) Ossur's Flex-Foot, (d) the CESR foot, (e) Ossur's Proprio Foot, and (f) iWalk's Powerfoot BiOM (Chiriac & Bucur 2020).

1.2.2. Conventional prosthetic feet

The conventional prosthetic foot designs consist of the Solid ankle cushion heel, also known as the SACH foot (see Figure 3); this prosthetic foot design consists of a rubber heel and keel that are compressible during impact, resulting in a pseudo-ankle range of motion (Versluys *et al.*, 2009). This prosthetic foot design offers an option of a fitted passive ankle joint attachment that uses rubber bumpers as dampers during locomotion.

Figure 3: Solid ankle cushion heel.

SACH foot designs are usually prescribed for limited and unlimited household ambulators, whereas articulated prosthetic foot designs are more suitable for limited community ambulators (Agrawal *et al.,* 2015). However, this prosthetic foot design is energetically passive during locomotion. The SACH foot is widely regarded as the most suitable choice for individuals with limited mobility in the transtibial amputation (TTA) community. It is highly prescribed due to its affordability, user-friendly design, and perceived stability and safety among less mobile amputees (Paradisi *et al.,* 2015).

1.2.3. Energy storage and return (ESAR) feet

Energy storage and return feet are typically made of carbon fibre, as shown in Figure 4, and their development has been influenced by the desire of people with lower-limb amputations to participate in sports. These prosthetic feet function like a leaf spring, absorbing energy during gait, storing that energy and utilising this energy during the terminal phase of gait. Transtibial amputees tend to prefer energy storage and return feet due to their ability to restore symmetry in step length, improve balance and contribute to the forward propulsion of the centre of mass (Houdijk *et al.*, 2018). Usually, these prosthetic feet are prescribed to patients who have the potential or ability to ambulate at variable cadence; however, limited community ambulators have also been shown to benefit from these prosthetic designs (Wezenberg *et al.*, 2014).

Figure 4: Energy storing and release prosthetic foot by the Steeper Group (n.d).

1.2.4. Bionic prosthetic feet

Bionic prosthetic feet are considered prosthetic devices with an active component that is also referred to as an actuator that can replicate the normal movements of a biological ankle foot.

These prosthetic foot designs can also be categorised based on their power output into two groups, namely, propulsive and stabilising (Cherelle *et al.*, 2014). Various actuation methods may be used to power these prosthetic devices, with the most commonly used being the electric motor (see Figure 5), followed by pneumatic and hydraulic actuators. To match the biomechanical requirements of normal human locomotion, actuators are paired with springs (either connected in series or parallel with the actuator) to improve compliance (Cherelle *et al.,* 2014), and protect the actuator during dynamic impacts (Herr & Grabowski, 2012). There is a strong shared belief that powered prostheses can significantly improve amputee gait (Azocar *et al.,* 2020; Chiriac & Bucur, 2020; Xie *et al.*, 2020; Cherelle *et al.*, 2016). However, most research prototypes are not yet ready to transition from laboratory settings to everyday use.

Figure 5: A powered prosthetic foot prototype by Li et al. (2024).

1.2.5. State of the art of lower limb prosthetics in South Africa

There are significant disparities in access to prosthetic devices in South Africa, with rural populations being more deprived compared to urban residents (Ennion & Manig, 2019). This lack of access is primarily due to the centralisation of services in urban areas and the uneven distribution of prosthetists, who are predominantly located in metropolitan regions. In the past, the centralisation of Orthotics and prosthetic services was driven by the scarcity of Medical Orthotist prosthetists, with only one institution producing Prosthetists for South Africa. Consequently, individuals in rural areas often remain underserved and must travel long distances to receive care (Mduzana *et al.,* 2020; Ennion & Johannesson, 2018). The influx of patients to understaffed centres results in extended waiting periods, sometimes between three to five years, indicating a pressing need for transformation (Ennion & Manig, 2019). This situation limits access to prosthetic devices and hampers pre-prosthetic rehabilitation.

According to the World Health Organisation (WHO) definition, environmental factors can act as facilitators and barriers to access to rehabilitation services. Additionally, impairments in bodily function were recognised as another barrier, whereas personal factors were seen as facilitators in accessing rehabilitation (Naidoo & Ennion, 2019). Those who access rehabilitation services, including prosthetic devices, are issued a solid ankle cushion heel, which is the most basic prosthetic foot on the market, intended for low-activity prosthetic users. This is the most prescribed prosthetic foot in low to middle-income countries due to its affordability, because of the low number of parts needed for the production of this prosthetic foot (William *et al.*, 2022). However, the SACH foot fails to replicate the movements and functions of a biological ankle-foot in a laboratory setup; this escalates the problem when the user has to ambulate in uneven terrains, like people living in rural areas, more specifically in provinces like Eastern Cape and Limpopo.

This highlights the need for active prosthetic devices that will be able to address the needs of people who have suffered amputation. These needs include both biomechanical and socio-economic(Naidoo & Ennion, 2019; Renjewski & Seyfarth, 2012). The distance travelled by amputees who live in rural areas makes it difficult to visit a health care centre frequently, which calls for a prosthetic device that will be able to adapt to different surfaces, be durable and have a reduced reliance on electricity. Given these challenges, there is a critical need for prosthetic designs that better mimic the natural movement of the human foot and can handle diverse terrains. The optimisation of a pneumatic prosthetic foot offers a promising solution. Pneumatic cylinders, widely used in industrial devices, provide several advantages, including low cost, easy maintenance, significant force exertion, and ease of assembly (Jiménez *et al.*, 2020). These benefits can be leveraged to enhance prosthetic foot designs, providing improved functionality and adaptability. Pneumatic technology, with its potential for enhanced flexibility and adaptability, can address many of the shortcomings of the SACH foot. By improving the functionality and accessibility of prosthetic devices, particularly for underserved rural populations, we can significantly enhance the quality of life for individuals requiring prosthetics.

1.3. Problem statement

Individuals with lower-limb amputations expend 10–30% more metabolic energy than non-amputees to walk at similar speeds when using passive-elastic prosthetic feet, which lack an active ankle joint and cannot replicate the biomechanical behaviour of the human ankle (Herr & Grabowski, 2012). This inefficiency often results in reduced walking speeds, lower daily step counts, and diminished health, with most amputees not meeting the recommended 4,000–10,000 steps per day, which is vital for maintaining physical and psychological well-being (Polak *et al.*, 2023; Hofstad *et al.*, 2020; Reynard & Terrier 2017; Kuo, 2007). The asymmetrical gait and elevated metabolic cost stem from altered joint kinematics and greater muscular demands, particularly increased dorsiflexion, knee flexion, and hip extension on the sound limb, along with abnormal mechanics on the prosthetic side due to the lack of dorsiflexor control and ankle push-off (Orekhov *et al.* 2019; Rábago & Wilken, 2016; Adamczyk & Kuo, 2015; Ferreira *et al.*, 2014; Bateni & Olney, 2002). Though powered prostheses have attempted to restore ankle push-off, studies show that even excessive push-off power fails to reduce energy cost below normative levels, largely due to the difficulty in replicating the biarticular function of the gastrocnemius muscle that acts across both the ankle and knee joints (Davidson *et al.*, 2021; Pickle *et al.,* 2019; Adamczyk & Kuo, 2015). Notably, researchers like Zheng and Shen (2015) and Versluys *et al.* (2009) explored pneumatic actuation with double-acting cylinders in prosthetic feet, but high air consumption limited the integration of onboard air sources. Building on their insights, this study proposes a quasi-active prosthetic foot design using a single-acting pneumatic cylinder that enables active plantarflexion and passive dorsiflexion to significantly reduce air demand and facilitate the integration of a compact air supply. The study sought to develop and manufacture this advanced foot locally in South Africa, enhancing affordability, mobility, gait symmetry, and social inclusion for amputees while expanding their vocational and economic opportunities.

1.4. Aim

The study aim was to determine the biomechanical behaviour, specifically the joint kinetics and kinematics, of a semi-active pneumatic prosthetic foot during ambulation at a self-selected walking speed in a controlled environment. This research evaluated how the new prosthetic design impacts gait symmetry and overall mobility for lower-limb amputees, ultimately contributing to the development of a cost-effective and functional prosthetic solution in South Africa.

1.5. Objectives

i) Analyse the kinematic data captured by the motion capture system to compare the joint angles and gait characteristics between the pneumatic and passive prosthetic feet.

ii) Evaluate the ground reaction forces and pressure distribution patterns during gait using the pressure mat for both prosthetic foot types.

iii) Assess the symmetry of gait in terms of step length, timing, and joint movements between the two prosthetic foot conditions.

1.6. Research questions

i. How do the kinematic parameters (joint angles and gait patterns) of participants using the pneumatic prosthetic foot compare to those using a prescribed passive prosthetic foot during ambulation?
ii. What are the differences in ground reaction forces and pressure distribution patterns between the pneumatic prosthetic foot and the prescribed passive prosthetic foot as measured by the pressure mat?
iii. How does the pneumatic prosthetic foot affect gait symmetry compared to the prescribed passive prosthetic foot?

1.7. Significance

Amputation is a worldwide problem that affects every country on a different scale. It has proven to be an ongoing problem that can potentially worsen in the future. Statistics reveal that in 2017, approximately 57.7 million people were living with at least one limb amputated due to trauma (McDonald *et al.*, 2020). In the United States alone, about 2 million people live with limb amputation, with around 185,000 new amputations performed each year (Manickum *et al.*, 2019). These figures underscore the ongoing need for fully functional prosthetic limbs that assist patients in performing activities of daily living and facilitate reintegration into the community.

Current prosthetic solutions often fall short in replicating the complex dynamics of a biological ankle, leading to increased metabolic energy expenditure, gait asymmetry, and reduced mobility for amputees. This research addresses these limitations by exploring the potential benefits of using pneumatic circuits in prosthetics to create functional, cost-effective, and customisable prosthetic limbs. Previous studies have demonstrated the promise of pneumatic-actuated prosthetic limbs in mimicking the angle and force trajectories of biological limbs (Zheng & Shen, 2013; 2015; Sup et al., 2007; 2008). Building on these findings, this study aims to document new data on the biomechanical behaviour of pneumatically actuated prostheses during ambulation at self-selected walking speeds collected in a laboratory environment with human participants. This research is poised to contribute valuable knowledge to the development of more adaptive and efficient pneumatic prosthetic solutions for amputees worldwide.

1.8. Hypotheses

Hypothesis 1 (Kinematics parameters):

- The kinematic parameters in terms of joint range of motion of the ankle, knee, and hip for participants using the pneumatic actuated prosthetic foot will differ from those of the same participants using the prescribed below-knee prosthetic foot.

Hypothesis 2 (Vertical ground reaction forces):

- There will be a noticeable variation in the vertical ground reaction forces of participants using the pneumatic actuated prosthetic foot and the prescribed prosthetic foot below the knee, and the pneumatic actuated prosthetic foot will exhibit improved vertical ground reaction forces.

Hypothesis 3 (Gait symmetry)

- Participants using the pneumatic actuated prosthetic foot when acclimated to the device will demonstrate an improved gait symmetry in terms of step length, timing and joint movements compared to when using the prescribed below-knee prosthetic devices.

2. Literature Review

2.1. Introduction

Pneumatic actuation plays a crucial role in enhancing the functionality and performance of prosthetic devices, offering significant biomechanical advantages. Pneumatic actuators, particularly pneumatic cylinders and pneumatic artificial muscles (PAMs), provide motion through the use of compressed air, making them a preferred choice for prosthetic applications due to their high power-to-weight ratio, inherent compliance, safety and simplicity, biomimetic capabilities (Andrikopoulos & Nikolakopoulos, 2018). These actuators are capable of mimicking the contractile properties of human muscles, as their operation involves changes in volume rather than length, which is similar to the basic contractile unit of a human muscle, the sarcomere (Trinkel, 2006; Piazzesi *et al.*, 2002). For instance, pneumatic cylinders have demonstrated the ability to closely replicate normal ankle angle and torque trajectories in transtibial prostheses, contributing to more natural and efficient gait patterns (Zheng & Shen, 2015). Additionally, pneumatic artificial muscles exhibit impressive performance metrics, such as peak velocity and peak power per unit volume, although their response times differ from biological muscles (Hannaford, 1996)

Integrating pneumatic components within prostheses can significantly improve their functionality and user experience. For instance, a double-acting pneumatic cylinder used in transtibial prostheses demonstrated the potential for enhanced ankle control and reduced energy consumption by mimicking the push-off phase of natural gait (Caputo & Collins, 2014). Furthermore, single-acting cylinders can optimise air consumption, making the system more efficient without compromising performance (Bimba, 2012). Innovations such as combining pneumatic cylinders with tension springs to create series elastic actuators can further enhance shock tolerance and energy absorption, improving gait dynamics and reducing musculoskeletal stress (Fernández *et al.*, 2020). These advancements underscore the importance of pneumatic actuation in developing prosthetic devices that replicate natural limb functions and enhance the overall quality of life for amputees through improved mobility and reduced physical strain.

This literature review thoroughly examines the evolution, biomechanical considerations, control strategies, advantages, and disadvantages of pneumatic actuators in prosthetics, and the impact of prosthetic foot design on gait parameters. Tracing the historical development of prosthetic feet highlights how advancements in medical techniques and material sciences have progressively improved prosthetic technology from basic devices to complex modern designs. Significant milestones, such as early prosthetic innovations by ancient civilisations and the Introduction of modern amputation techniques and materials, are discussed to illustrate the continuous efforts to enhance the quality of life for individuals with lower limb amputations.

A key focus of the review is the biomechanical analysis of human gait and the specific behaviours of the biological ankle joint, which are crucial for developing practical prosthetic feet. The review investigates the gait cycle, muscle actions, and forces involved, providing foundational knowledge for optimising prosthetic designs. Understanding these biomechanical principles helps create prosthetic feet that mimic natural limb functions, enhancing amputees' mobility and comfort. Detailed discussions on the roles of the gastrocnemius and Achilles tendon during locomotion and the mechanics of the ankle joint are included to identify essential biomechanical requirements for prosthetic design.

The review evaluates the impact of various prosthetic foot designs on gait parameters and user experience, analysing how different design aspects influence gait dynamics and comfort. By examining the benefits and limitations of designs such as energy storage and return (ESR) and dynamic elastic response (DER) feet, the review provides insights into how modern prosthetic technologies aim to reduce musculoskeletal stress and improve walking efficiency. The review also identifies gaps in current research and suggests directions for future studies, aiming to stimulate innovations in prosthetic foot design that enhance functionality, comfort, and the overall quality of life for users. This comprehensive approach ensures that the review is a valuable resource for researchers, clinicians, and engineers, offering an integrative understanding of past advancements, current challenges, and future possibilities in prosthetic foot design.

2.2. Historical Progression of Prosthetic Foot Design

The development of lower limb prostheses has historically been interconnected with advancements in medical techniques and the availability of prosthetic materials and components. People's beliefs and perceptions in the 16th century were the main drivers for low prosthetic demands, such that people would rather succumb to death than face the mutilation of limb amputation. The Introduction of modern amputation techniques and the construction of lower limb prostheses in 1536 marked a major milestone in limb amputation, but experienced a low acceptance rate due to people's beliefs (Daniele, 2019). The decreased demand for prosthetic devices, coupled with the increased mortality rate of injured soldiers succumbing to their wounds, led to the prioritisation of improving surgical techniques, which at the time were reserved for patients with gangrene (see Figure 6).

Figure 6: venous gangrene on the right foot (Rosenbaum, Yu, Rooke & Heit 2014).

It was only in the 18th century that major breakthroughs through the invention of anaesthesia were made, which improved amputation surgeries by allowing more time to close the distal wound. This was followed by the invention of a tourniquet that minimized blood loss during surgeries, increasing the safety of surgeries and enabling the creation of healthy stumps (Kinch & Clasper, 2011). This led to an improved acceptance rate amongst the broader population and contributed to an increase in prosthetic demand. However, the major drawbacks of prosthetic devices of that era were the inability to replicate natural biomechanical functions and improve the quality of life for individuals with lower limb amputations (Daniele, 2019). Formerly, limited access to biocompatible materials also played a significant role in the development of prosthetic devices (Chiriac & Bucur, 2020). This limitation remained for quite some time up until the mid-19th century, and it is unclear what developments in terms of prosthetic designs were made in this period.

The 20th century was a period of major advancements in terms of prosthetics functional output and designs, following the order demonstrated in Figure 7, and some of the inventions remain relevant even in the present day. A considerable number of amputees who were victims of the American Civil War spurred innovations such as the Hanger limb by James Hanger. By the late 1970s, advancements in aeronautics and military technology catalyzed the development of carbon-fibre feet and a continuous reduction in component weight with aluminium alloys and titanium, ushering in a new era of prosthetic limbs that were lighter, more durable, and capable of energy release (Daniele, 2019). Unlike conventional feet, these early Energy Storage and Return (ESR) featured energy early in the gait cycle and released it during push-off (Chiriac & Bucur, 2020). The desire of amputees to engage in sporting activities also influenced this development (Versluys *et al.*, 2008).

Following World War II, the Introduction of the solid ankle cushion heel (SACH) foot marked a significant advancement in prosthetic technology (Daniele, 2019). However, it was not until the 1980s that prosthetic foot designs began to facilitate basic walking and enable amputees to perform fundamental tasks (Chiriac & Bucur, 2020). In 1981, the first dynamic elastic response (DER) prosthetic foot, made from Delrin (polyamide PA6), was introduced following the Vietnam War (Daniele, 2019). With its sturdy functionality, the SACH foot remains in use due to its benefits for individuals with lower activity levels (Narayanan *et al.,* 2016). These innovations paved the way for the development of bionic feet, incorporating hydraulic or electric mechanisms to mimic natural ankle movements and adapt to varying terrains intelligently (Versluys *et al.*, 2008; Cherelle *et al.*, 2014; Ismawan *et al.*, 2021; Xie *et al.*, 2020).

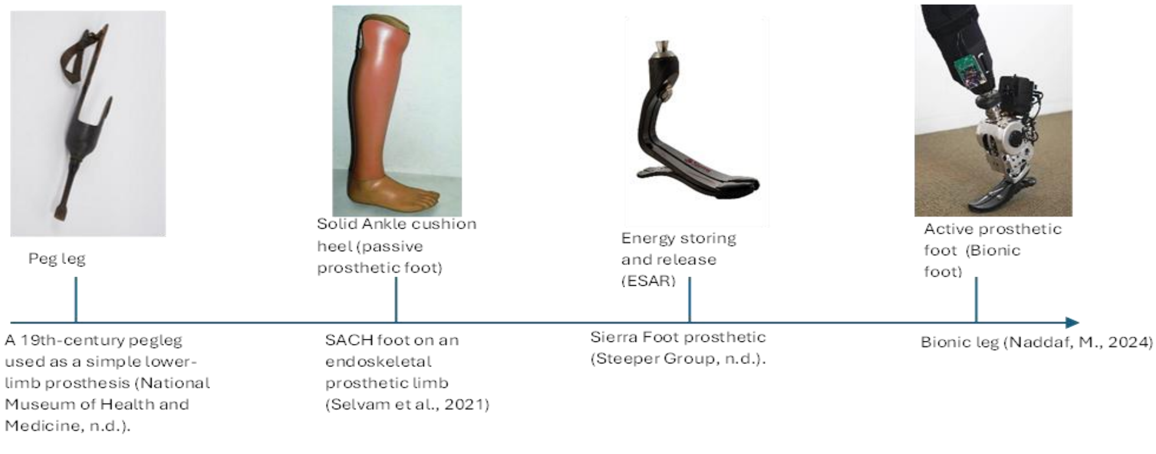


Figure 7: Evolution of prosthetic feet from Pegleg to the most advanced prosthetic foot available.

The prosthetics market has relied heavily on developments in surgical techniques, which may have contributed to the minimal development of prosthetic designs during the early years. The 20th century has emerged as a very progressive period in terms of prosthetic design developments, with the introduction of SACH feet and dynamic elastic response (DER). These prosthetic foot designs have recently been categorized as conventional prosthetic feet, and the DER has continued to play a significant role in the recently developed active and semi-active prosthetic feet. At the same time, the solid ankle cushion heel has continued to be a widely prescribed prosthetic foot option for patients who exhibit limited mobility. The continued use of the solid ankle cushion heel, especially in developing countries, may highlight the gap between the problem facing amputees and the proposed solution of recently developed prosthetic feet that mimic normal joint motion.

2.3. Biomechanics of Human Gait and Ankle Function

The normal human gait consists of two phases defined by the foot contact with the ground during forward progression. The first phase is the stance phase, which is also considered as the longest phase of gait and takes up about 60% of the gait cycle; it begins when the foot makes contact with the ground and terminates when the foot is lifted off the ground. During the stance phase of gait, there are activities that are considered similar amongst all humans who exhibit a normal walking pattern, such as heel strike, foot flat, mid stance, push-off, and toe-off. This has been a conventional way of defining activities that take place during gait; however, Palmer (2002), characterized the sagittal plane movement of the ankle joint during ambulation as controlled plantarflexion, controlled dorsiflexion and powered plantarflexion. Ankle dynamics during controlled plantarflexion is characterized as a linear torsional spring that modulates joint stiffness when walking at a constant speed. The ankle stiffness requirements increase with an increase in walking speed. The controlled dorsiflexion is characterized as a nonlinear torsional spring, with spring stiffness that increases with joint rotation. Meanwhile, during powered plantarflexion, the ankle joint behaves like a spring that requires an actuator for energy injection to improve gait speed. This characterization has found refuge in recent prosthetic foot developments.

A relationship exists between particular gait parameters like walking speed, cadence and step length, and these parameters have been widely used to assess the quality of a walking pattern or the effectiveness of an intervention (Roberts *et al.*, 2017). Interestingly, these spatiotemporal parameters were found to be the most relevant single parameters in studies exploring human gait biomechanics of both normal and transtibial amputees. However, when looking at the broader grouping of parameters that share a similar nature, power, work, and energy are the most measured parameters, followed by the spatiotemporal parameters. On the spatial and temporal parameters, the normal cadence for ages between 21 and 40 has been reported to be between 109 and 129 steps per minute (Tudor-Locke *et al.,* 2019), a walking speed of 1.31 metres per second (Murtagh *et al.*, 2021), and a step length that varies based on the walking speed and leg length of the participants. Evidence supports the significant role played by age and gender in the observed walking speed, favouring relatively younger males (Andrews *et al.*, 2023).

Throughout the gait cycle, a variable ankle joint stiffness has to be maintained to facilitate a smoother step-to-step transition and in normal gait, the joint stiffness results from muscle co-contraction of the plantar flexors and dorsiflexors. Recent studies have investigated the contributions of muscles and tendons to impedance and ankle stiffness. While passive joint stiffness is associated with various tissues (muscles, ligaments and tendons), individual muscle or tendon elasticity variations are not directly correlated with passive ankle joint stiffness (Chino & Takahashi, 2015). However, activation levels of the biological ankle joint significantly influence ankle joint stiffness during both standing and walking (Joshi *et al.*, 2022). Interestingly, above very low loads, ankle joint stiffness is determined predominantly by Achilles tendon stiffness rather than muscle stiffness (Jakubowski *et al.*, 2023). This is evident during gait, where the time of peak ankle stiffness is seen in the passive dorsiflexion sub-phase, whereas the point of peak muscle activity is in the active plantarflexion sub-phase. This suggests that the nervous system utilizes the nonlinear properties of the Achilles tendon to control ankle stiffness during postural control in gait. To better understand these complex interactions, researchers have developed techniques to simultaneously quantify muscle, ankle, and tendon impedance using ultrasound imaging combined with joint-level perturbations (Jakubowski *et al.*, 2022). These advancements provide valuable insights into the mechanical properties governing ankle control during posture and movement.

2.4. Prosthetic Foot Design and Gait Parameters

Research on the effects of ankle joint stiffness on human gait biomechanics highlighted the impact of joint stiffness on ankle joint range of motion, push-off dynamics and overall human gait. Halsne *et al.* (2020) discovered that elevated ankle stiffness is associated with reduced ankle push-off power, which may increase reliance on the intact limb for propulsion and stability and can ultimately reduce gait efficiency. These findings suggest that increasing prosthetic ankle stiffness typically reduces push-off power and energy return during late stance, particularly impacting transtibial amputees. The highlighted demand shift can potentially affect gait symmetry, as well as stability and comfort, especially when performing tasks with high energy requirements, like incline walking (Halsne *et al.*, 2020).

On the contrary, lower-stiffness prosthetic feet allow greater dorsiflexion, which improves the capacity of the prosthetic ankle to adapt to various terrains by increasing dynamic joint stiffness during controlled dorsiflexion. A smoother transition is supported by this adaptability, contributing to a more natural ambulatory pattern that can improve energy storage and return. However, individual preferences and perceptions vary widely; while some users prefer softer settings that offer an increased range of motion and smoother movement, others prefer a prosthetic device that offers a sense of stability and controlled push-off. Moreover, a feeling of security during ambulation associated with stiffer settings was reported by some users, as the additional resistance improves forward progression, while these settings may produce lower push-off power (Ármannsdóttir *et al.*, 2024; Proebsting *et al.*, 2020). The users' perceptions in this study are consistent with the trend observed by William *et al.* (2022) on the use of the SACH feet to promote midstance stability in developing countries.

Despite these biomechanical responses, stiffness changes within clinically available ranges do not consistently improve step length symmetry or overall community mobility. While reduced ankle stiffness settings may replicate natural limb movements more closely, they do not promote a symmetrical gait pattern, suggesting that Ankle stiffness requirements during gait may be specific to certain gait phases. A noticeable discrepancy in user preferences and human gait biomechanics may be influenced by the minor differences in user gait pattern, prosthetic experience and leg length. As such, individualized ankle stiffness settings are significant in order to meet the required comfort and stability of prosthetic users ambulating in various walking terrains (Halsne *et al.*, 2020; Proebsting *et al.*, 2020).

2.5. Pathological Gait in Transtibial Amputees

An asymmetrical walking pattern resulting from the altered neuromuscular skeletal system of the human body is consistently observed in unilateral transtibial amputees (Adamczyk & Kuo, 2015; Norvell *et al.*, 2005). These walking pattern asymmetries often include increased joint loading of the sound limb, increased stance time of the sound limb, decreased walking speed, increased energy expenditure, wider step width, and shorter step length on the intact side(Wolf & Pruziner, 2014; Norvell *et al.*, 2005). Some of these gait asymmetries (joint load and gait timing) may have a cause-and-effect relationship, and this relationship can be better understood by focusing on the motions of the center of mass (COM) and the stance phase of the affected side. The pendulum movement of the stance leg is responsible for the acceleration and deceleration of the center of mass, and a decrease in the stance time of the leg may affect the deceleration of the COM, subsequently increasing the collision of the contralateral heel with the ground. Therefore, an increase in the collision of the heel with the ground increases vertical ground reaction forces, thus increasing the loading of the joints, and over time, this results in secondary diseases (Adamczyk & Kuo, 2015).

Joint degeneration, osteoarthritis, and low back pain are some examples of secondary injuries caused by gait asymmetries, such as increased joint loading and stance time(Wade *et al.*, 2022; Wolf & Pruziner, 2014). Evidence shows that people who suffered unilateral lower-limb amputation are at greater risk of developing osteoarthritis on the sound limb's weight-bearing joints (Kim *et al.*, 2021) compared to non-amputees (Wade *et al.*, 2022; Struyf *et al.*, 2009; Norvell *et al.*, 2005). This may be due to the compensatory mechanisms utilized by amputees in attempting to limit the load on the amputated side and redirect this load to the contralateral limb. Similar behaviour is also noticeable in patients with unilateral traumatic lower-limb injuries, and this places them at greater risk of developing secondary injuries on the contralateral side due to increased loading of the limb (Wolf & Pruziner, 2014).

This review is an overview of a holistic gait analysis of people with lower-limb amputations and also covers some of the compensatory techniques used during levelled ground walking. People living with lower-limb amputation have to relearn how to walk, and also make sense of the new reality of using an artificial leg and an assistive device. Winter and Sienko (1988) emphasized studying the motor patterns of amputees because these motor patterns are the cause of the new amputee's gait, and variables like mechanical power, moment of force, and electromyographic patterns correlate with the change in amputee's motor patterns. Any human system that has been altered structurally in the neuromuscular skeletal system cannot be optimal even when gait symmetry has been achieved (Winter & Sienko, 1988). Amputees ought to achieve a new asymmetrical optimal within the limitations of the mechanical advantages of the prostheses and the residual limb (Winter & Sienko, 1988). However, the long-term effects of these asymmetries are irreversible and somehow introduce secondary disabilities.

2.6. Advantages and Challenges of Pneumatic Actuation in Prosthetic Feet

Various types of pneumatic actuators are used in rehabilitation; however, there are two most commonly used pneumatic actuators, namely pneumatic cylinders and pneumatic artificial muscles (see Figure 8). Both of these pneumatic actuators are operated using pressurised air, with two major differences between them highlighted in Figure 8 below. This study focuses more on pneumatic cylinders, as variables are being studied using this type of actuator. Zheng and Shen (2015) utilised a double-acting cylinder with a 32mm stroke length and a 38mm bore size to test the concept of a pneumatically actuated transtibial prosthesis. The cylinder actuator was electrically controlled, and the prosthesis performed quite well, showing ankle angle and torque trajectories that were close to normal. The air supply system was installed externally in an attempt to minimise the mass of the prostheses, and is still working on incorporating it within the prosthesis (Zheng & Shen, 2015). Integration of pneumatic components within the prostheses can be improved by decreasing the air consumption of the cylinder, and it can be done in two ways: (1) by decreasing the internal surface area or (2) by using a single-acting cylinder(Jiménez *et al.*, 2020).

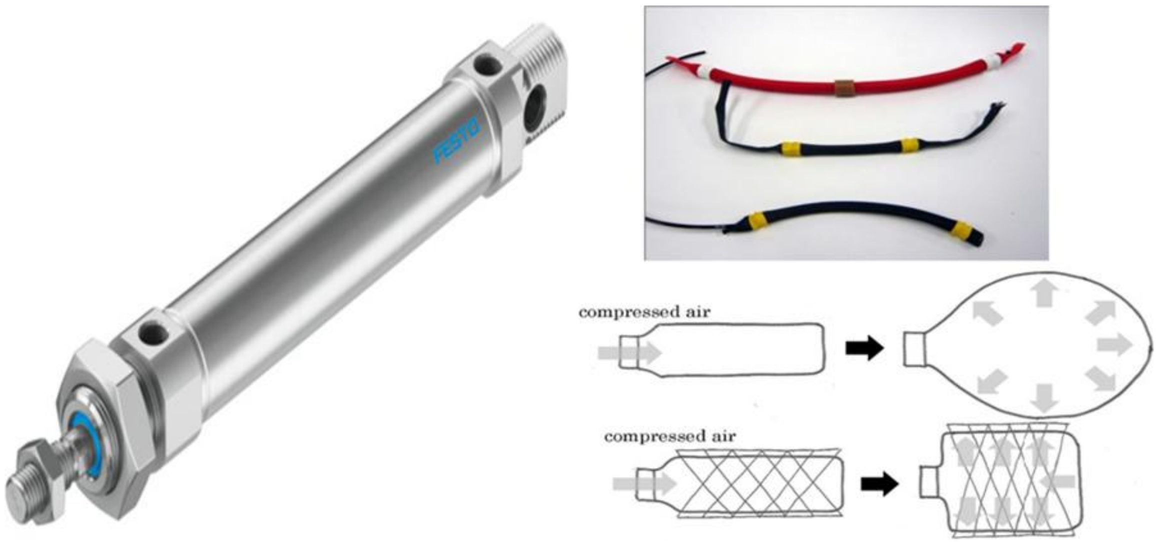


Figure 8: Pneumatic actuators used for comparison (1) Left: Pneumatic cylinder, a rigid actuator with linear motion; (2) Right: Pneumatic artificial muscle, a compliant actuator that contracts and dilates upon pressurization.

In this case, decreasing the internal surface area would require more pressure to maintain the required magnitude of the force, which might impact the durability of the cylinder (Waycaster, 2010). Using a single-acting cylinder would be a better option to improve air consumption, as single-acting cylinders consume close to half the amount of air consumed by a double-acting cylinder in one stroke (Bimba, 2012). This is because the two compartments of a double-acting cylinder are pressurized air-driven, whereas on the contrary, only one compartment is driven by pressurized air in a single-acting cylinder the second compartment is passively controlled by a spring (Lee *et al.*, 2017; Xie *et al.*, 2020). This is advantageous, especially in cases where contraction and extraction speed and force are not the same. However, the force produced by air has to overcome the force of spring as they are acting in opposite directions, and this might affect the acting speed (Bimba, 2012).

Cylinder speed can be improved by installing a quick exhaust valve, which would allow the cylinder to accelerate more rapidly, increasing the cylinder's natural speed by up to 50%, depending on the cylinder type and loading (Norgren, 2017). The magnitude of force generated can be improved without changing the cylinder dimension; a combination of a pneumatic cylinder with a tension spring connected in series to mimic the function of a series elastic element has proven to be a viable option for this task (Zhu, 2010). A series elastic actuator has the potential to decrease the force requirements and improve shock tolerance during a dynamic encounter with the ground surface because of the spring's ability to absorb and release energy(Fernández *et al.*, 2020).

A pneumatic cylinder is somehow comparable in function (mechanically) with a human muscle's basic contractile unit (a sarcomere). The basic contractile unit of a human muscle consists of two main protein filaments (myosin and actin), which do not exhibit any changes in length during muscle shortening (Piazzesi *et al.*, 2002) but can slide past one another to reduce the overall length of the skeletal muscle. The cylinder pneumatic actuator is just like a striated muscle sarcomere; the components of the cylinder itself do not shorten or lengthen; it's only the volume inside the cylinder that changes (Trinkel, 2006).

Pneumatic actuators store energy in the form of compressed air and are mostly preferred over other actuators because they are relatively easy to install, have low maintenance requirements, and can be operated without electrical signals of any kind (Tassa *et al.*,2011). The initial costs of pneumatic actuators are very low; however, the operational cost can climb up to 10 times more (Tassa *et al.*, 2011). Therefore, when developing pneumatic actuated prosthetic devices, the cost of ownership needs to be evaluated and prioritised more than the initial cost of purchase. This ensures that the prototype is developed not only to improve functional output, but to also to accommodate the socio-economic factors faced by the target population.

Pneumatic muscle actuators (PMAs), better known as pneumatic artificial muscles, have been reported to offer numerous advantages, such as a high power-to-weight ratio, smooth speed adjustment, and longer operating life (Donskoj *et al.*, 2019). This makes pneumatic artificial muscle an ideal alternative to other prosthetic actuators due to the design requirements of low mass, step-to-step adaptability, and ability to control prosthetic joints for prolonged periods. However, they have several disadvantages, like a limited contraction, nonlinear and time-variable behaviour, hysteresis, and step-jump pressure (Sárosi *et al.*, 2015). The highly nonlinear dynamic behaviour of pneumatic artificial muscles makes them difficult to model and control (Tóthová & Hošovský, 2013), which limits the practicality of utilizing this actuator type. Due to the inability of pneumatic muscle actuators to lengthen after shortening, they require an antagonistic setup to generate bi-directional motion, which further complicates the implementation of these actuators (Sárosi *et al.*, 2015). Moreover, they face general issues related to pneumatic systems like leaks and portable compressed air source (Tóthová & Hrehová, 2015). Despite these drawbacks, researchers have developed models to enhance the performance of pneumatic artificial muscles, including static force models for stiffness (Sárosi *et al.*, 2015) and comprehensive mathematical models for describing the process of lifting and lowering loads (Donskoj *et al.*, 2019). Understanding the properties of pneumatic muscle actuators and developing accurate models are critical for overcoming their limitations and enhancing their pertinency in other fields, including biomechanical applications (Tóthová & Hrehová, 2015).

2.7. Prosthetic Control Strategies

The most widely used control strategies for controlling active prosthetic devices of the lower limb are the impedance control, finite state control and the proportional myoelectric control. These control strategies are essential for regulating the interaction of a prosthetic device with the user and the environment while maintaining an acceptable level of safety. Proportional myoelectric control relies on signals from muscle contractions in the residual limb; finite state control segments human gait activities into discrete states, adjusting prosthetic behaviour to match each phase, and impedance control modulates joint stiffness in response to interaction forces between the external environment and the user.

The proportional myoelectric method involves using electromyography (EMG) signals from the residual muscles to control the prosthetic device directly. In proportional control, the intensity of the EMG signals modulates the output force or movement of the prosthetic foot proportionally. This type of control can be challenging because of signal variability and environmental influences, but it allows the user a high degree of intuitive control over movement. Studies show that incorporating myoelectric signals alongside mechanical sensors can improve device responsiveness and adaptability to complex activities like navigating uneven terrain (Sun *et al.*, 2023; Mohebbian *et al.,* 2021). However, this control technique, when it is being used independently, does not give sensory signals back to the user for an improved proprioceptive sense, making the wearer rely more on visual checks (Windrich *et al.*,Beckerle, 2016). This indicates that both primary and secondary patients (patients with experience in prosthetic ambulation) equally require gait and ankle activation training (both seated and standing) to attain their maximum level of function.

The impedance control strategy is widely used to manage joint dynamics in powered prostheses by modulating stiffness and damping. The objective is to adjust the joint's resistance to movement, simulating natural muscle behaviour. The prosthesis can maintain stability and adapt to different gait cycle phases by adjusting the impedance. Impedance control assists in providing a smoother transition between phases by dynamically altering the resistance of the foot based on the user's activity (Tucker *et al.*, 2015). Adjusting stiffness and damping parameters for different activities and users can be challenging. Each user may require individual tuning for optimal performance, increasing setup time and complexity. Impedance control relies on precise force and motion data to adjust joint resistance. Inaccurate or delayed sensor feedback can disrupt control, particularly during rapid changes in gait (Mohebbian *et al.*, 2021; Tucker *et al.*, 2015).

The finite state control is similar to impedance in terms of sensor requirements, and accurate state transitions require consistent and reliable sensor input. Any sensor error can lead to improper state transitions, such as remaining in the stance phase when the user is attempting to initiate a swing, compromising safety and usability (Mohebbian *et al.*, 2021; Tucker *et al.*, 2015). This control strategy has been used in pneumatic prosthetics and has enabled amputees to achieve a gait cycle that closely resembles the normal gait (Zheng & Shen, 2015). However, Finite-state controllers operate based on predefined states and transitions, which may not cover all real-world scenarios or adapt well to irregular movements. This rigidity can make transitions between activities feel less fluid and responsive.

2.8. Evaluation of Active Prosthetic Feet Performance

2.8.1. Spatiotemporal parameters

The normal human gait is a rhythmic and automated activity, according to Beauchet *et al.* (2009), which implies that the activities of the left leg must be similar to the activities of the right leg during level-ground walking at a constant self-selected speed. Also, since the human walking pattern is a rhythmic function, minimizing variability in step length, stance time, and gait timing becomes crucial (Beauchet *et al.*, 2009). It is worth noting that most of the studies evaluating prosthetic foot performance in this literature review predominantly featured male participants, with the exception of only four studies that had female participants (D'Andrea *et al.*, 2014; Gabert *et al.*, 2020; Kim *et al.*, 2021; Wolf & Pruziner, 2014). This discrepancy in terms of gender representation may potentially influence the spatiotemporal data, such as stride time, step length, and overall gait timing.

There is evidence suggesting that females aged 20 to 59 tend to have a slightly lower normative self-selected walking speed compared to males of the same age (Beauchet *et al.*, 2009). While the differences in self-selected speeds between males and females may not always be statistically significant, when combined with other parametric variations, they can lead to noticeable differences in the frontal and sagittal plane gait patterns (Rowe *et al.*, 2021). Additionally, females typically exhibit slightly shorter stride lengths during normal walking in comparison to their male counterparts. This variance in stride length, when considered alongside the minor differences in self-selected speed,
In practical terms, this means that females may need to take more steps to cover the same distance as their male counterparts when maintaining a similar self-selected walking speed.

2.8.2. Amputee Gait Kinematics

Studies show that when using powered prosthetic devices, people with limb amputation tend to have a walking pattern that closely resembles that of non-amputees (De Pauw *et al.*, 2020; Zheng & Shen, 2015; Wolf & Pruziner, 2014). The ability of active prosthetic feet to closely mimic the physiological movements of the ankle joint enables them to produce improved ankle angle trajectories and spatiotemporal data. Furthermore, an improved ankle range of motion in below-the-knee amputees has been reported during the late stance and swing phase of gate (Gabert *et al.*, 2020). This is of significance because, during late stance, the ankle joint is tasked to actively plantarflex to push off the ground in an attempt to progress forward. Moreover, the improved ankle range of motion is powered externally using a battery and an actuator. This implies that the user does not directly incur the energy cost of actively moving the ankle joint during locomotion(Herr & Grabowski, 2012). Therefore, the additional mechanical energy introduced by the active prosthetic foot should be evident in kinematic data.

On the contrary, a study by Kim and Wensman (2021) found no significant increases in walking speed and physical activities of participants using powered prosthetic feet. What is more interesting about these findings is that, even though the powered prosthetic foot did not increase the walking ability and physical activity of the participants, some participants still preferred the powered prosthetic foot, stating that the foot enables them to walk faster (Gabert *et al.*, 2020).

What is more common in these studies is that, when a prosthetic device is able to generate an external force of whatever magnitude, it will contribute positively to the gait of the prosthetic user, and it is mostly observed in the gait kinematic data. However, some of the benefits of an actuated prosthetic limb come at a cost. The findings of a study conducted by De Pauw *et al.* (2020) revealed that transtibial participants using the AMP-foot 4.0 exhibited compensatory trunk movements during the swing phase of gait. The observed compensatory trunk movements may be due to several reasons; however, since this movement was observed during the swing phase of gait, it may suggest that the user was attempting to compensate for the increased rotational inertia of the prosthetic side during the swinging movement (Kim *et al.*, 2021). Furthermore, one of the muscles responsible for maintaining trunk stability during locomotion is the gluteus Medius (Anderson & Pandy, 2003), and this muscle is active throughout almost all phases of gait (Kim et al., 2021).

2.8.3. Amputee gait Kinetics

The changes in the biomechanical characteristics of transtibial amputee gait is characterized by asymmetries which also have an impact on the knee joint loading of the sound limb. Studies support that transtibial amputees tend to compensate for the biomechanical abnormalities using the sound limb or the non-amputated side when using unpowered prosthetic feet (Kim *et al.*, 2021; Esposito & Wilken, 2014). The benefits of using powered prosthetic feet have not been consistently reported. Esposito and Wilken (2014) reported that a powered prosthetic foot decreases the external knee flexion moment, peak ground reaction force, and loading rate as the walking speed increases. However, the powered prosthetic foot did not decrease the external knee adduction moment and the knee adduction impulse, which are considered to be the risk factors for the development of osteoarthritis in the amputee population(Esposito & Wilken, 2014).

The decrease in the sound knee loading is somehow linked to the ability of powered prosthetic feet to produce mechanical push-off force during a late stance of gait. The Introduction of an external force during push-off may also decrease the workload in terms of the metabolic cost of walking (Hafner *et al.*, 2022; Wolf & Pruziner, 2014; Au *et al.*, 2009). Some evidence points out that an increase in the prosthetic ankle push-off does not improve the user's metabolic cost of walking(Quesada *et al.*, 2016) and collisional work of the leading limb (Davidson *et al.*, 2021), while some studies show that the benefits of a powered prosthetic foot may be user-specific, and activity-based (Ingraham *et al.*,, 2018; Montgomery & Grabowski, 2018). What is evident from these findings is that powered prosthetic feet improve the metabolic energy expenditure of users ambulating in a controlled environment. However, the controlled environment in a laboratory setup does not resemble the terrain that the user will be exposed to after leaving the rehabilitation center.

The changes in the energy cost of walking for people with transtibial amputation moderately correlate with the activities of several muscles of the residuum (Kim, Gardinier, *et al.*, 2021). Low energy cost of walking correlates with high activity of the gluteus Medius and low activity of the vastus medialis, while an increased activity of the Biceps femoris when initiating the swing phase and during the initial stance phase indicates a high energy cost of walking (Kim *et al.*, 2021; Quesada *et al.*, 2016; Huang & Ferris, 2012). The noticeable increase in the activity of the Biceps femoris is a compensatory mechanism due to the loss of the Gastrocnemius muscle through amputation. The role of the biceps femoris in transtibial amputees is to stabilize the knee joint during the initial swing, ensuring that the work done at the prosthetic ankle joint correlates with the work done at the hip joint and the center of mass.

In conclusion, although research on amputee gait kinetics and kinematics highlights the potential benefits of powered prosthetic devices, limitations and gaps remain. The predominantly male participant cohorts, along with the controlled laboratory environments, may not fully capture the dynamics of real-world gait. Further research is necessary to explain the effects of powered prosthetic feet on gait biomechanics, metabolic expenditure, and nuanced muscle activity in diverse real-world settings. Understanding these complexities will facilitate the development of tailored interventions to optimize functional outcomes and enhance the quality of life of individuals with transtibial amputation. Limitations of the current body of research include small sample sizes, limited representation of female participants, and controlled laboratory environments, which may not fully reflect real-world conditions. Additionally, the heterogeneity of prosthetic interventions and outcome measures across studies complicates direct comparison and generalizability. Future research should strive for larger, more diverse cohorts, longitudinal designs, and assessments in real-world settings to address these limitations and effectively inform clinical practice.

2.9. Acclimation Period for Lower-Limb Amputee Participants

2.9.1. Acclimation Period for Lower-Limb Amputee Participants

The acclimation phase for individuals utilizing lower-limb prosthetics is an essential part of the rehabilitation continuum, facilitating the adaptation necessary for functional gait restoration and the execution of activities of daily living (ADLs). This period involves a progressive process of neuromuscular adaptation, during which amputees reacquaint themselves with their altered biomechanics, gradually approaching the pre-amputation gait dynamics. The eventual functional outcome is significantly influenced not only by the design and functional characteristics of the prosthesis itself but also by the user's adaptability and comfort with the device. Despite the importance of acclimation, there remains no consensus within the current literature on the optimal timeframe for below-knee amputee participants to acclimate before undertaking biomechanical testing. This lack of standardization creates challenges in comparing outcomes across studies and limits the establishment of best practices for assessing both prosthetic functionality and patient adaptation.

2.9.2. The Complexity of Establishing Acclimation Durations

The individual variability observed during the acclimation phase is a crucial challenge when attempting to standardize these periods across studies. Factors such as the patient's age, activity level, cardiovascular fitness, residual limb conditions, and psychological readiness contribute to the complexity of determining an "adequate" acclimation duration. Setting a standardized acclimation period risks oversimplifying this inherently individualized process, potentially failing to capture the unique dynamics of each participant's adaptation journey. As such, the comparison of results from different studies becomes problematic, especially where the acclimation timelines differ, raising critical questions about the validity of the resultant gait assessments as representations of long-term prosthetic use. This concern underscores the need for a more personalized approach to evaluating functional outcomes and adaptation rates.

The existing literature highlights that biomechanical testing performed immediately after a new prosthetic fitting may yield non-representative data due to the presence of compensatory gait patterns (Zhang *et al.*, 2019; Wanamaker *et al.*, 2017). During the early stages of acclimation, amputees exhibit irregular gait cycles as they attempt to adapt to novel weight-bearing dynamics and altered proprioception, which significantly deviates from the stable gait characteristics observed post-acclimation. Therefore, assessing gait kinetics and kinematics during these preliminary stages may reflect merely transient, compensatory adaptations rather than the establishment of efficient, steady-state gait patterns. For studies focusing on the long-term functional impact of prosthetic devices, sufficient acclimation is essential to mitigate such transient effects and allow for the proper integration of the device into neuromuscular control strategies (Zhang *et al.*, 2019).

2.9.3. Approaches to Acclimation Periods Across Studies

There is considerable variation in the duration of acclimation periods reported in literature, with typical protocols ranging from one to four weeks, often involving structured rehabilitation interventions to expedite the adaptation process (Ernst *et al.*, 2022; Altenburg *et al.*, 2021; Kim *et al.*, 2021). This variability reflects the lack of a universally accepted acclimation guideline, with most studies basing their decisions on anecdotal evidence or individual researcher judgment. Structured acclimation involving supervised physical therapy has been shown to improve confidence and adaptation outcomes; however, for some experimental prosthetic devices, especially those focusing on tethered or externally assisted gait interventions, shorter acclimation periods are often employed. These shorter periods are justified by the need to assess immediate biomechanical alterations rather than long-term functional changes (Caputo *et al.*, 2021).

Despite the potential advantages of a standardized acclimation timeframe, such a rigid approach risks negating the individuality of each participant's adaptation process. Notably, prosthetic adaptation does not proceed uniformly across individuals; it varies based on intrinsic factors such as physiological reserve, psychological disposition, and experience with prosthetic devices. Thus, enforcing a standardized acclimation period could lead to a mismatch between the participant's readiness and the timing of assessments, ultimately affecting the study's validity and reliability (Zhang *et al.*, 2019). To address this, it has been suggested that more personalized metrics, such as tracking the total number of steps taken with the prosthesis or evaluating functional milestones, should replace fixed acclimation timelines. As a surrogate marker of adaptation, step count provides a practical measure of prosthetic utilization frequency and intensity, which are pivotal in determining adaptation success and, therefore, may serve as a more reliable indicator of readiness for biomechanical evaluation.

2.9.4. Assessing Prosthetic Acclimation through Biomechanical Parameters

Evaluating whether an individual has sufficiently acclimated to a new prosthesis typically involves examining several biomechanical parameters, including cadence, stride length, step variability, double limb support time, and asymmetry in stance phase (Zhang *et al.*, 2019; Wanamaker *et al.*, 2017). Cadence, or the number of steps taken per minute, is a critical parameter for assessing gait efficiency, with any significant deviation suggesting incomplete acclimation. When comparing a new prosthesis to a previously used one, gait metrics such as cadence, walking speed, and stance time symmetry should ideally not differ by more than 10%, as this degree of difference is considered indicative of successful functional integration (Wanamaker *et al.*, 2017).

The double limb support phase, characterized by both feet being in contact with the ground, is also indicative of adaptation status. Extended double limb support time often signifies instability or a lack of confidence in the prosthetic limb. Conversely, a reduction in this time over repeated trials suggests that the participant is becoming more accustomed to the device, demonstrating improved postural stability and enhanced motor control. Thus, these spatiotemporal parameters offer insight into the adaptation timeline and overall effectiveness of prosthetic integration. However, further exploration is needed, particularly to validate these metrics for studies employing short acclimation durations.

2.9.5. Proposing a Personalized Acclimation Protocol

A standardized acclimation protocol, although beneficial for ensuring consistency in research, may potentially disregard the individualized adaptation process inherent to each prosthetic user. The variance in physiological and psychological adaptation among individuals demands an approach that acknowledges these differences to enhance the ecological validity of research findings. As such, it is crucial to shift towards a personalized acclimation strategy that utilizes individualized markers, such as cumulative step counts or the achievement of predefined functional milestones, instead of strictly adhering to temporal constraints. This strategy would allow for a more precise assessment of prosthetic adaptation, thereby ensuring that biomechanical evaluations are conducted when participants have genuinely achieved a stable, adaptive gait.

In summary, the acclimation period is fundamental to the reliability of prosthetic outcome measures. However, the current approach to standardization may overlook the intrinsic variability present in individual adaptation trajectories. To accommodate this complexity, a move towards more personalized measures, such as step counts or the attainment of functional milestones, should be considered. This approach acknowledges the nonlinear nature of adaptation, ensuring that acclimation genuinely reflects readiness for biomechanical testing rather than a predetermined timeline. By refining acclimation protocols in this manner, research into prosthetic interventions will be better positioned to produce reliable, meaningful results that account for the individual variability inherent in rehabilitation, ultimately leading to improved patient outcomes and more effective prosthetic designs.

2.10. Extraction of motion characteristics

When extracting gait characteristics for slow walking, integrating Theia3D markerless motion capture with pressure-sensitive gait mats presents a promising alternative to traditional marker-based systems in gait analysis. Theia3D is a non-invasive option with a short setup time and allows for a more natural gait pattern by eliminating the physical markers. Evidence reveals that Theia3D produces kinematic and spatiotemporal data that is comparable to the widely used marker-based systems (Ripic *et al.*, 2022; Kanko *et al.*, 2021). In particular, Theia3D demonstrated root mean square errors <5° in major joint angles and excellent agreement in gait phases and cadence, making it viable for both clinical and field assessments (Lander *et al.*, 2025). When used together with pressure mats, the system enhances the understanding of force distribution on the plantar surface and foot placement without compromising the accuracy of motion tracking (McGuirk *et al.*, 2022). However, there are some notable variabilities in the transverse plane motions and foot strike detection, where marker-based systems still show superior fidelity (Wren *et al.*, 2023). For paediatric, neurological, and mobile populations, the portability and scalability of Theia3D are significant advantages. Overall, integrating Theia3D with pressure mats delivers a practical and accurate solution for gait analysis across both laboratory and community settings. The ease of use, absence of markers and quick setup time make it a desirable option for active prosthetic users, as this will minimize interference with the moving components of the leg.

2.11. Concluding Remarks

The review of relevant literature notes the significant strides and milestones achieved in the development of prosthetics in general; however, these strides were not enough to change people's perspectives on amputation. The primary contributors to amputation have changed over time from military action to neurovascular diseases, but the demand for prosthetics still remains significant. The large biomechanical requirements that arise after an amputation can not be met by the passive prosthetic designs, but these prosthetic designs still remain relevant in the present day, which may suggest that there are underlying needs like affordability, accessibility and practicality that are still not met. Recent innovations in active prosthetics have not made significant contributions at scale, especially in developing countries, primarily because of their limitations, which suggest that alternative technologies are needed. Alternative actuators and control mechanisms have been under development, and significant progress has been made, but despite the reported progress, these prosthetic innovations have not managed to produce results that exceed the biomechanical contribution of biological structures in gait. Some of these reported findings lack statistical power due to low sample size, most studies were conducted in controlled environments which do not resemble the outside terrain, and others did not allow for proper acclimation to the new prostheses. These findings suggest that future studies may need to focus on developing advanced portable data collection tools that will enable the availability of gait data in real time to facilitate gait optimization. Furthermore, the development of alternative prosthetic actuation methods that can be tested outside of the lab environment with simplified control strategies are needed. Lastly, longitudinal studies that seek to establish the correct acclimation period to enhance the quality of the data collected and the generalizability of results and explore the biomechanical behaviour of pneumatic prosthetic feet in various terrains while participating in day-to-day activities.

3. Design and Development of a Pneumatic Actuated Prosthetic Foot

Prosthetic devices have long been developed to emulate the natural functions of amputated body segments. However, the development of active prosthetic limbs in South Africa still lags compared to the first-world countries, and as a result, people with lower limb amputation are often prescribed a conventional prosthetic limb (Ennion & Johannesson, 2018). The current ankle prostheses, predominantly rigid and utilising traditional hinge joints or bearings for motion, usually fall short in replicating the intricate mechanics of a healthy human gait. While effective in shock absorption and supporting body weight during movement, conventional prosthetic designs lack the nuanced functionality of biological feet, particularly in achieving propulsion during the terminal stance phase (Jin *et al.,* 2023; Ismawan *et al.,* 2021). These prosthetic designs offer fewer degrees of freedom when compared to the anatomical joint and are missing the most crucial aspect of the biological foot, which is propulsion at the terminal stance.

Research indicates that these simplified prosthetic designs inadequately improve natural gait mechanics compared to non-disabled individuals. The limitations stem from the limited degrees of freedom in prosthetic joints, thus hindering optimal biomechanical performance (Jin *et al.,* 2023). To address this deficiency, prosthetic designs that closely mimic the movements of biological feet have emerged, demonstrating notable enhancements in walking capabilities among individuals with lower limb amputations (Windrich *et al.*, 2016). Specifically, robotic prostheses have shown promise in augmenting walking speed, reducing energy expenditure, mitigating fall risks, and preventing secondary complications(Azocar *et al.,* 2020). Prosthetic devices are an integral part of people with lower limb amputations, and designing these devices to support the body weight during locomotion does not holistically address the needs of people who have suffered lower limb amputation.

The significance of improving mobility and physical function in amputees cannot be overstated, as these advancements substantially contribute to their overall quality of life (Bonanni *et al.*, 2020). However, the current focus on designing prosthetic devices primarily for weight support during locomotion overlooks the holistic needs of individuals with lower limb amputations. Setting precise design objectives that align with the target population is paramount in addressing these concerns. Prioritising user-centred design principles and fostering collaboration with healthcare professionals ensures that prosthetic designs adhere to clinical standards while integrating advanced technologies, enhancing accessibility and affordability, and facilitating long-term follow-up for iterative improvements (Anderson *et al.*, 2023).

This chapter seeks to introduce a novel approach to prosthetic design—specifically, the pneumatic actuated prosthetic foot. The aim is not only to replicate normative ankle mechanics and provide net positive ankle work during walking (Tran *et al.*, 2022; Herr & Grabowski, 2012) but also to address the unique challenges faced by South African amputees, such as rural access, socio-economic constraints, and environmental factors. By prioritising affordability, accessibility, customisation, and durability, this prosthetic solution endeavours to enhance mobility, optimise biomechanical function, and improve the overall quality of life for individuals across the South African population.

3.1. Problem identification and analysis

The current prosthetic designs prescribed to people with lower limb amputation are not adequately adapted to perform the function of a biological foot. This is evident through the gait kinematics, kinetics and energy expenditure. Individuals with lower extremity amputations using conventional passive prostheses often experience asymmetrical gait patterns and lameness, leading to discomfort, pain, and more significant strain on the unaffected leg (Ismawan *et al.*, 2021). This overcompensation can cause secondary musculoskeletal injuries, such as chronic joint disorders. Additionally, these individuals expend 20-30% more metabolic energy to walk at the same pace as non-disabled individuals, resulting in increased fatigue and reduced mobility (Ismawan *et al.*, 2021). Improving prosthetic design and functionality is crucial to addressing these challenges and enhancing the quality of life for prosthesis users.

Lower extremity amputees experience increased metabolic costs of ambulation compared to non-amputees, with dysvascular amputees demonstrating higher costs. Their gait patterns are less economical, particularly among dysvascular amputees, influencing overall mobility and rehabilitation strategies (Czerniecki & Morgenroth, 2017). The cost of walking for transtibial amputees currently using conventional prosthetic feet can be attributed to the prosthetic foot biomechanical capabilities. Evidence suggests that high plantarflexion and low dorsiflexion stiffness slightly reduce net metabolic cost, suggesting modest energy-saving benefits (Shell et al., 2017). The ankle dorsiflexion movement plays a crucial role in energy absorption during the stance phase, particularly mid-stance. On the contrary, high dorsiflexion stiffness reduces the contralateral side knee flexion, which can potentially increase joint stress (Shell *et al.,* 2017).

Abnormal knee kinematics in the general population have been associated with the onset of knee osteoarthritis (OA). Specifically, knee flexion angle and timing deviations are notably correlated with knee OA in the general population (Orekhov *et al.*,2019). This is supported by evidence indicating that reduced midstance flexion angle and altered temporal characteristics can lead to abnormal knee kinetics (Farrokhi *et al.*,2015). Knee flexion movement during the stance phase occurs concurrently with the same side's ankle dorsiflexion and hip flexion. The inability of conventional prosthetic foot designs (just like the widely used solid ankle cushion heel) to dorsiflex during the stance phase of gait results in less than the average values of knee flexion.

3.2. Design Objectives and Requirements

3.2.1. Biomechanical Requirements

Replicating natural ankle mechanics: ensuring that the mechanical ankle foot replicates the natural movements of the anatomical ankle-foot complex while also performing the essential functions of the ankle-foot to reduce asymmetries in gait. The plantarflexion and dorsiflexion movements of the ankle joint are mandatory to ensure a smooth step-to-step transition and the completion of the three rockers of the foot.

Providing sufficient propulsion: the pneumatic prosthetic must be able to produce energy that will be injected into the gait of the prosthetic user to facilitate forward progression. This will be achieved by enabling the pneumatic prosthetic foot to plantarflex and produce a range of motion that closely resembles that of a biological foot. This action is significant for maintaining stability and walking speed.

Table 1: Biomechanical requirements for an active prosthetic foot.

Biomechanical requirements			
Parameters	**Target Specification**	**Purpose**	**Reference**
Ankle Range of Motion (ROM)	~20° plantarflexion, ~15° dorsiflexion	Enables the three rockers of the foot.	(Rodgers, 1995)
Peak Ankle Torque	~1.5 Nm/kg (≈120 Nm for an 80 kg person)	Enables propulsion and joint stability during the second foot rocker and the first rocker	(Au *et al.*, 2008)
Peak Ankle Power	~3.0–3.5 W/kg (≈240–280 Watts for an 80 kg person)	Assist in ankle plantarflexion during forward propulsion	(Herr & Grabowski, 2012)
Control Timing Precision	Within ~50 ms during gait cycle transitions	Synchronises actuation with gait events (e.g., push-off)	(Rajt'úková *et al.*,2014)
Weight of Prosthesis	Less than 2.5 kilograms.	Reduces swing-phase effort and preserves the gait symmetry	(Rajt'úková *et al.*, 2014)
Prosthesis Users (Transtibial)	~2,000–3,500	Minimum number of steps for daily mobility & independence	(Esposito, *et al.*,2016)
User-Specific Adjustment	Torque, stiffness, and timing per user gait profile	Personalization for optimal performance	(Herr & Grabowski, 2012)

Reducing energy expenditure: Minimising the metabolic energy cost of walking significantly reduces fatigue, improves user comfort, and enhances overall mobility. This objective can be achieved by optimising the design to reduce resistance and improve energy return during gait.

3.2.2. User-Centred Design Considerations

The design goals of the pneumatic prosthetic foot must consider the biomechanical and basic needs and desires of the end user, preferences, and experiences in mind. However, the functionality of the pneumatic prosthetic foot in terms of assisting the user in carrying out daily living activities must supersede aesthetics. The involvement of the user and feedback throughout the design process is significant for ensuring that the final product meets the practical and functional requirements of the target population.

3.2.3. Accessibility, Affordability, and Customisation

Ensuring that a wide range of users can gain access to the pneumatic prosthetic foot, including those from underserved and disadvantaged communities, is needed to promote inclusivity and equity in healthcare access. Another crucial aspect is affordability, which ensures that the prosthetic foot is financially accessible to users across different socio-economic backgrounds and considerable for subsidies for the Department of Health. Furthermore, options for customisation allow for adapting the prosthetic foot to meet individual users' specific anatomical, biomechanical, and lifestyle needs, enhancing comfort, performance, and overall satisfaction.

3.2.4. Specific Needs of the South African Amputee Population:

Recognising and addressing the unique challenges and requirements of the South African amputee population is essential for ensuring that the pneumatic actuated prosthetic foot meets the diverse needs of users in this context. Considerations such as socio-economic constraints, rural access, cultural preferences and environmental factors should be integrated into the design process to maximise the prosthetic foot's relevance, effectiveness, and impact within this specific demographic.

3.3. Description of the Pneumatic Cylinder and Helical Spring Mechanism

3.3.1. Pneumatic Cylinder

The pneumatic cylinder functions similarly to a biological muscle, producing linear force to power propulsion and control ankle joint stiffness during ambulation. Sharing a point of origin and insertion with the biological soleus muscle, the pneumatic cylinder is classified as a uni-articular actuator. While controlling the mechanical ankle joint, the pneumatic cylinder may induce knee extension when the foot is in contact with the ground. During the terminal phase of gait, the pneumatic cylinder activates to produce joint rotation at the ankle.

A study by Zheng and Shen (2015) utilised a 38mm bore cylinder with a 32mm stroke length, demonstrating the feasibility of using a linear pneumatic actuator to replicate the movements of the biological ankle joint. However, the air consumption of the double-acting cylinder made it impractical for amputees outside a laboratory setting. This design employs the same cylinder size and stroke length from Festo (ESNU-32-35-P ISO), along with a solenoid valve and an 8mm diameter pipe. The pneumatic cylinder serves as the core component for adaptive movement, adjusting to different walking conditions by modulating pressure and providing a dynamic response to varying terrains. Its specifications include a lightweight aluminium body, a 0-150 psi pressure range, and a compact design to fit within the prosthetic foot. Due to height limitations, the cylinder is tilted backwards to fit within the confined space.

3.3.2. Helical spring

The helical spring functions with the pneumatic cylinder to absorb shock during dynamic impact and store energy during the mid-stance phase, which is then returned during push-off.

This feature intends to lower the energy requirements of the pneumatic actuator during gait and preserve the actuator for long-term use. The spring is made of high-tensile steel, with a length of 10 cm and a variable stiffness that can be customised to user needs.

3.3.3. Design concepts

Two design concepts were developed based on the biomechanical requirements and the manufacturing capabilities. In both designs, the pneumatic cylinder was tilted in order to fit within the confined space of the prosthetic design. The predetermined volumetric profile and mass of the prosthetic leg were based on a 75kg individual with a height of 1,75m. In comparison, the height of the prototype was determined by prototypes in published peer-reviewed papers, which is 180mm from the ground to the prosthetic adapter (Chiriac & Bucur, 2020). However, due to the length of the components used, the height of the pneumatic prosthetic device exceeded the predetermined upper limits and was capped at 270mm, as shown in Figure 9. Based on a 1.75m tall individual versus mass, the overall mass of the prosthetic foot must be less than 2.5% of the total mass of the body (Zheng & Shen 2015), which is approximately 1,87kg and serves as the maximum mass of the prosthetic foot.

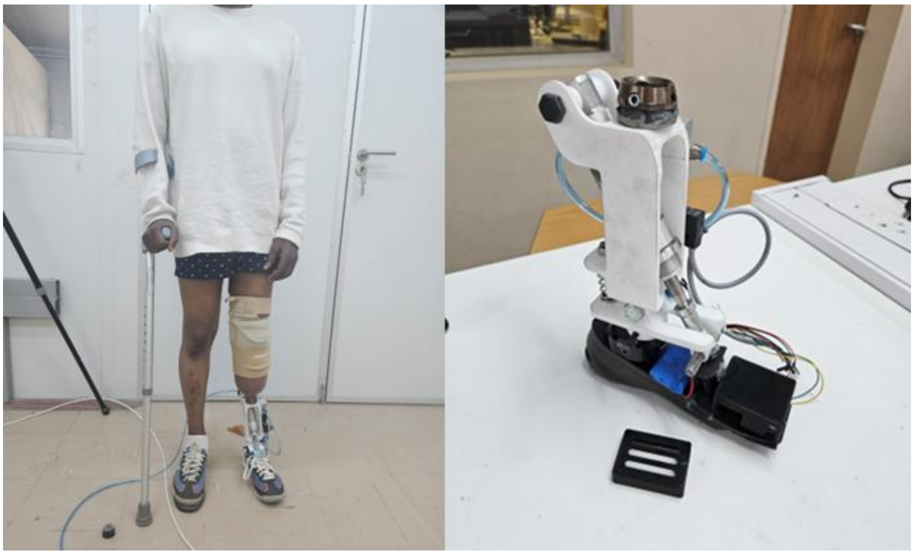


Figure 9: A picture showing the design of the pneumatic prosthetic foot concept number 1 and the final product fitted on the participant.

The first concept shown in Figure 9 was picked based on the practicality of this design, which managed to slightly lower the height of the pneumatic prosthetic foot. Slight alterations to the prosthetic height are welcomed because this improves access for individuals with amputation sites closer to the ankle joint. Also, the foot component of this prosthetic design can be changed; however, pressure sensors are incorporated into the prosthetic foot for the control mechanism. The second design concept was rejected because of the limitations in the orientation of the pneumatic cylinder. The orientation of the pneumatic cylinder does affect the maximum torque that the prosthetic foot can produce. However, in this case, the priority was access over mechanical capabilities.

3.4. Structural analysis

The shank is the structure that will be responsible for weight-bearing when the patient dons the prosthetic device. This segment has to meet strict specifications in order to perform its function throughout the lifespan of the prosthetic device. The pylon is traditionally known to be a cylindrical structure that connects the prosthetic socket to the prosthetic ankle joint or prosthetic foot. However, the pneumatic prosthetic design does not have a cylindrical pylon, and this is to accommodate for the pneumatic components responsible for moving the prosthetic foot at the ankle joint. Moreover, this segment is also responsible for the proximal attachment of the pneumatic cylinder actuator.

Traditional prosthetic pylons are made of two materials: aluminium alloy, which caters to patients up to the mass of 100kg, and stainless steel, which accommodates patients up to 120 kilograms (Rebin *et al.*, 2023). Apart from carrying the weight of an amputee, the pylon has to withstand corrosion to improve the chances of the pylon lasting for the duration of the prosthetic limb's lifespan. This section focuses on the structural analysis of the shank segment of the pneumatic prosthetic foot, which is expected to hold a mass of 75 kilograms patient; however, the load capacity of the shank segment goes up to 100kg. The expected load is in line with the industry standards and is consistent with previous research on prosthetic pylon (Rebin *et al.*, 2023; Tahir & Kadhim, 2021).

3.5. Method

This chapter presents a segment of the pneumatic prosthetic foot that will receive the mass of the patient and transmit this force to the Otto Bock 1C10 Terion prosthetic foot. The shank segment is designed to carry the mass of the patient, bridge the gap between a prosthetic socket and foot/ ankle, and also provide attachment points to the pneumatic cylinder and other pneumatic components. Figure 10 below demonstrates the exact copomponent referred to as the shank segment in this chapter.

Figure 10: The model of the pneumatic prosthetic foot with the shank labelled.

The model of the pneumatic prosthetic foot was created in SolidWorks and, upon completion, was then imported into the Ansys Workbench for structural analysis. The existing pylon structural analysis data, which was collected through reverse engineering, is readily available and is used as a reference to compare the results of the pneumatic prosthetic foot shank design analysis (Amal Rebin *et al.*, 2023). Figure 11 represents the methodological workflow followed during FEA analysis using axial loading and how simulation findings were verified.

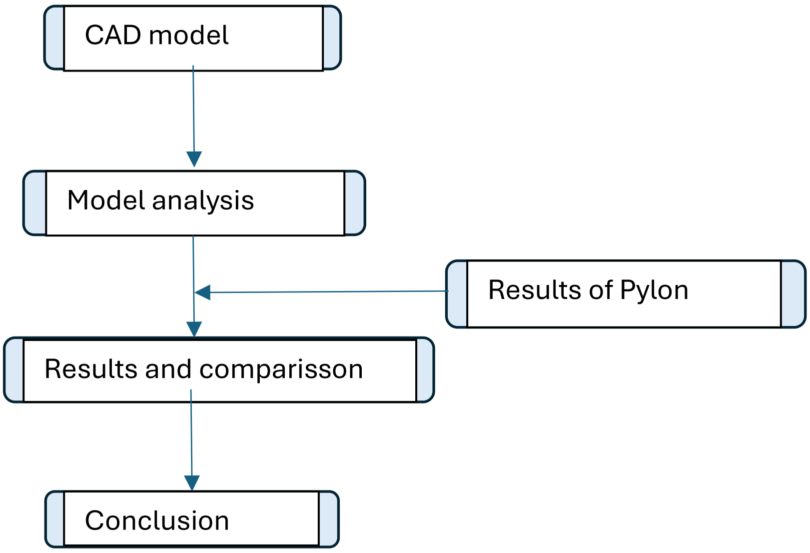


Figure 11: Shows a diagram of the methodology workflow, showing all the steps followed for structural analysis.

There are two widely used prosthetic pylon variants: one is made of aluminium, and the other is made of steel. For the sake of comparison, the pneumatic prosthetic shank segment is assigned two materials, namely steel and aluminium. The material properties of the two materials are presented in the table below.

Table 2: Considered parameters when choosing material. The values for the existing pylon model were extracted from a study by Rebin et al. (2023)

Model	Material	Yield strength	Corrosion resistance
Pneumatic prosthetic foot shank	Aluminium Alloy 6061	241MPa	High
	Titanium Alloy grade 5 Ti-6Al-4v	845,70 MPa	High

3.5.1. Meshing

In the Geometry Preparation stage, the CAD model of the shank segment was imported into the ANSYS Student 2024 R1 software. The geometry was checked for cleanliness and error-freeness. Small features, such as fillets and holes, were removed since they were not expected to influence the structural performance of the model. The shank segment had its distal and proximal ends clearly defined with boundaries. Material properties were then assigned to the shank segment, selecting Aluminium Alloy 6061 and Titanium Alloy Grade 5. Important material properties, such as Young's Modulus, Poisson's Ratio, and Yield Strength, were accurately defined to describe the material's behaviour under load.

The first process was initial meshing, which was done based on a general mesh size using tetrahedral elements due to the complexity of the geometries. Afterwards, a mesh quality check was undertaken to ensure good quality aspects of the mesh: the aspect ratio, skewness, and element size distribution. Finally, boundary conditions were applied in the form of a fixed support at the distal end of the shank to be modelled onto the prosthetic foot to create a mechanical ankle joint. The applied loads were incremental on the proximal surface, with 700 N, 800 N, and 1000 N corresponding to patient masses of 70 kg, 80 kg, and 100 kg, respectively.

The general mesh refinement analysis was performed using the general mesh to obtain preliminary values for equivalent stress, strain, deformation, and factor of safety. High areas of stress concentration were recognised, and mesh refinement was conducted within these high-stress areas using smaller-sized elements to maintain higher mesh quality and accuracy. The overall mesh sizing was refined to 8mm to achieve a balanced distribution of elements, thus enhancing accuracy, as shown in Figure 12. The 8mm mesh sizing represented the minimum mesh size that converged under the limitations of the student version of ANSYS.

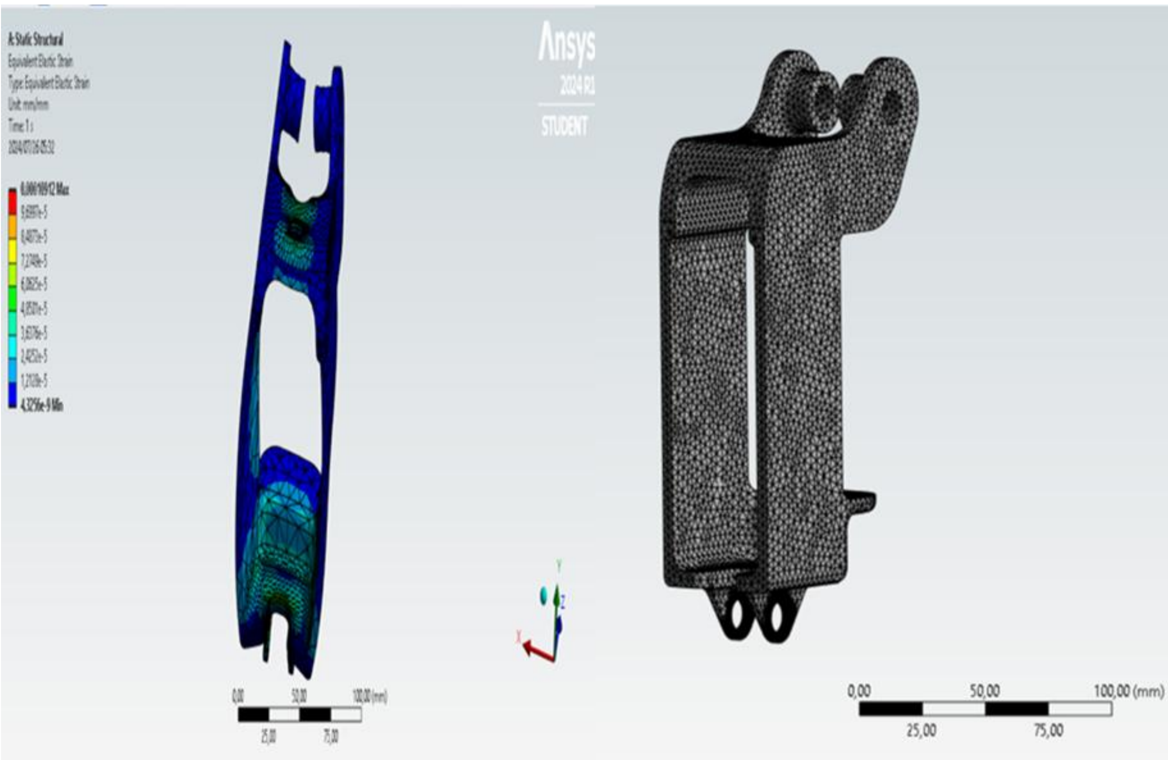


Figure 12: A picture showing the shank segment with a refined mesh.

3.5.2. Mesh quality

The quality of the mesh is one of the most influential parameters that affect the convergence, stability, and accuracy of results in finite element analysis. The mesh is, therefore, a framework for making physical geometry discretisation approximations such that complex physical geometry may be approximated numerically. It is important to have the mesh meet some predefined quality, like aspect ratio, skewness, element size distribution, and overall element quality, so that the results obtained are reliable. These criteria put together have a direct bearing on the ability of the mesh to represent the geometry and boundary conditions of a model with minimal numerical errors. The simulation model of the shank segment of the pneumatic prosthetic foot has been meshed with 49,258 elements and 76,913 nodes, respectively, using tetrahedron elements. The mesh quality was determined through the mesh convergence study, which looked at creating the finest mesh within the limitations of the student version of ANSYS. The selection of tetrahedral elements was based on the fitting nature for complex geometrical features and the expected stress distribution in the model.

Some of the key parameters taken into consideration in ensuring simulation robustness were evaluated, and they included determining mesh quality:

1. **Skewness** - As described above, skewness is a measure of how much an element deviates from the ideal shape. For 2D triangular elements, this basically refers to an equilateral triangle, while for 2D quadrilateral elements, an ideal geometry could be a square or rectangle with angles measuring 90°. High skewness may cause inaccuracy in the numerical solution by poor interpolation over the elements and integration. The average skewness in this study was 0.28925, with 78.8% of the elements being below 0.35 of skewness.

2. **Aspect ratio** - defined as a measure of how much an element is stretched or compressed. This can be presented as the ratio between the length of the longest side of the element and that of the shortest one. A high aspect ratio will bring numerical instability and very slow convergence in areas with a large gradient. The best case scenario is when the elements have an aspect ratio close to 1, meaning it is as near square or equilateral triangle as possible. The average aspect ratio of the mesh for the shank segment was 2.0668. This means that the shortest element edge was half the length of the longest element edge. The average value is also not far from ideal.

3. **Element quality** - This is a much more general parameter, which often merges the effects of skewness, aspect ratio, and orthogonality. It provides a general rating on how well an element fits ideal geometry and numeric properties. Poor quality elements will impact the simulation to some extent, raising problems of convergence loss. This overall quality measure provides a general indicator of how well a mesh can perform a simulation. In the study, the average mesh quality was 79.05%, with a standard deviation of 13.719, suggesting a relatively good mesh.

3.5.3. Mesh convergence

A mesh convergence study was conducted by systematically refining the mesh and observing the changes in the maximum von Mises stress results, to ensure that the results are mesh independent (see figure 13). The overall mesh used the tetrahedral elements, with a mesh refinement focusing on high stress concentration points and global mesh sizing was maintained at 8mm. The 8mm mesh size represents the finest mesh that was able to converge without exceeding the limitations of the ANSYS student version. A summary of the results is presented in Table 13, which summarises the stress values, proportion of difference (change), number of nodes and elements.

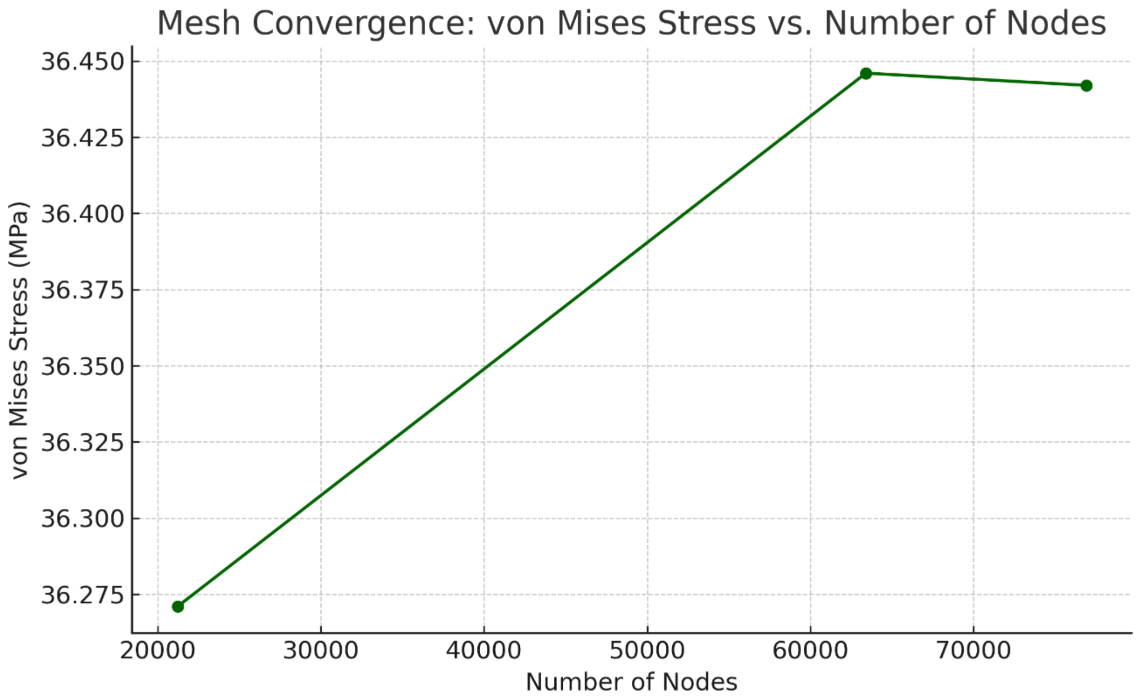


Figure 13: Mesh convergence plot showing von Mises stress versus number of nodes. Stress stabilizes as the mesh is refined beyond 63,000 nodes, confirming mesh independence.

Table 3: A table showing the results of a mesh convergence study.

Von mises stress MPa	Changes (%)	Nodes	Elements
36,271		21220	12007
36,446	0,47964	63411	39911
36,442	-1,0071e-002	76913	49258

A mesh convergence study was performed by evaluating the von Mises stress at three mesh densities. As shown in the table, the stress increased slightly from 36.271 MPa at 21,220 nodes to 36.446 MPa at 63,411 nodes, representing a 0.48% change. Further refinement to 76,913 nodes resulted in a negligible decrease to 36.442 MPa, with a change of just 0.01%. These minimal differences between successive refinements indicate that the solution has reached mesh independence. Therefore, the mesh with approximately 63,000 nodes and 40,000 elements was deemed sufficiently refined for accurate and efficient simulation.

3.6. Results

The CAD model of the pneumatic prosthetic foot was used for the full FEA through Ansys software. The simulations were carried out for loading conditions of 700N, 800N, and 1000N, representing the maximum allowable weight (1000N) ofr the user. These loading conditions simulate static forces exerted on the pneumatic prosthetic foot when bearing the weight of an individual weighing up to 100 kg during a standing position. This study was to evaluate the distribution of stress, maximum deformation, and safety in the shank segment, one of the most essential components of the prosthetic foot for weight bearing.

The following table (see Table 4) represents the finite element analysis results of the shank segment of the pneumatic prosthetic foot when static axial loads (700N, 800N and 1000N) are exerted on to the segment, The maximum value of the von Mises stress experienced by the shank segment during loading was 36,476 MPa. Thus, since the shank segment was made of Aluminium Alloy 6061, which has a yield strength equal to 241 MPa, the observed stress is much less in magnitude (15%) compared to it. This confirms that the design of the shank segment works within well-permissible limits and tolerances; the applied load can be accommodated by the material without any yielding or failure taking place. This large margin between the yield strength of Aluminium 6061 and the maximum von Mises stress, as expressed in Table 4, showing further potential for topology optimisation to reduce the mass of the shank segment and ultimately make the pneumatic prosthetic foot lighter. The following Figures 14 and 15, summarizes the stress and strain values, respectively.

Table 4: Results of the FEA for titanium alloy and Aluminium alloy for 700N, 800N and 1000N loads

Shank segment									
Model	**Results load**	**VON mises**		**Deformation**		**Strain**		**FOS**	
		Min	**Max**	**Min**	**Max**	**Min**	**Max**	**Min**	**Max**
Titanium Alloy Grade 5 (Ti-6Al-4V)	700N	7,3032e-005 MPa	25,533 MPa	0, mm	1,2604e-002 mm	4,3919e-009 mm/mm	2,4709e-004 mm/mm	> 10	15
	800N	8,3465e-005 MPa	29,181 MPa	0, mm	1,4405e-002 mm	5,0193e-009 mm/mm	2,8239e-004 mm/mm	> 10	15
	1000N	1,0433e-004 MPa	36,476 MPa	0, mm	1,8006e-002 mm	6,2741e-009 mm/mm	3,5299e-004 mm/mm	> 10	15
Aluminium alloy 6061	700N	7,0224e-005 MPa	25,509 MPa	0, mm	2,0307e-002 mm	6,994e-009 mm/mm	3,979e-004 mm/mm	9,6056	15
	800N	8,0257e-005 MPa	29,154 MPa	0, mm	2,3208e-002 mm	7,9932e-009 mm/mm	4,5474e-004 mm/mm	8,4049	15
	1000N	1,0032e-004 MPa	36,442 MPa	0, mm	2,901e-002 mm	9,9915e-009 mm/mm	5,6843e-004 mm/mm	6,7239	15

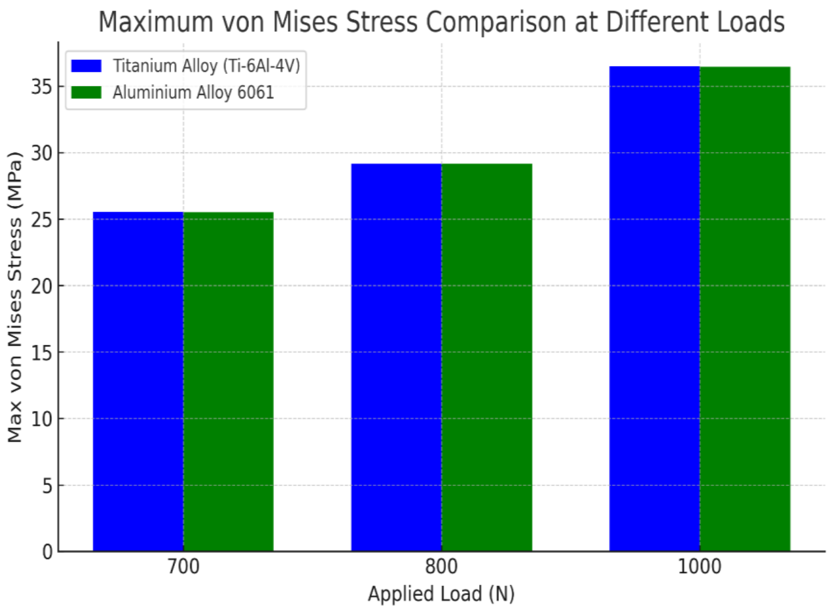


Figure 14: Maximum von Mises stress versus applied load for Titanium Alloy (Ti-6Al-4V) and Aluminium Alloy 6061.

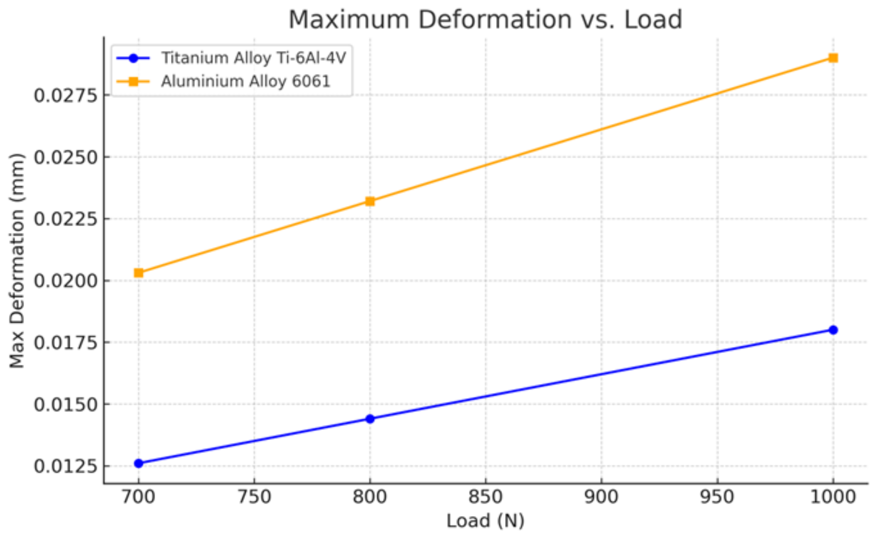


Figure 15: Maximum deformation versus applied load for Titanium Alloy (Ti-6Al-4V) and Aluminium Alloy 6061.

The shank segment of the pneumatic prosthetic foot, made of aluminium had a total mass of 356.54 g,, highlighting the need for mass reduction to minimise the energy consumed by the user during ambulation and may result in functionality and user comfort . Attainment of such a mass reduction can be achieved through alternative materials characterised by a better strength-to-weight ratio. Titanium alloy: This has excellent mechanical properties and is highly used for high-performance prostheses (Daniele, 2019). To study this further, the FEA was again done with the shank segment modelled with Titanium alloy.

The finite element analysis results of the shank segment are presented in Table 2 for the titanium alloy. The corresponding stresses at applied loads of 700N, 800N, and 1000N were calculated to be 25,533 MPa, 29,181 MPa, and 36,476 MPa, respectively. Even though the calculated Von Mises stress values for Titanium alloy material were more or less similar in magnitude to those found for Aluminium 6061, the remarkable finding has been the deformation results. In the static load, the maximum deformation attained in the shank segment was 2.901e-002 mm for Aluminium 6061, while for Titanium alloy, it was 1.8006e-002 mm, the highest, as indicated in Table 2. The reduced deformation of the titanium alloy represents superior stiffness and high resistance to deformation during axial loading, which could be favourable for the alignment and functionality of the prosthetic foot over time.

In addition to the calculations and results obtained for the stresses and deformation, the factor of safety for the two materials considered was also obtained and are presented in Table 2 above. The safety factor is an essential parameter that represents the margin by which the component strength exceeds the applied load. For the Aluminium 6061 shank segment under a 1000 N load case, a minimum safety factor of 7.7239 was computed, while for the Titanium alloy shank segment, a higher value of 10 was attained as the minimum safety factor. Both materials provide a dsuperior safety margin; however, for titanium, a much higher safety factor was provided, confirms the behavioural superiority towards the assurance of structural reliability, primarily when high loads were exerted.

3.7. Conclusion

The international standard for testing prosthetic feet remains the gold standard for determining the safety and practicality of use; however, the FEA results are intended as a precursor to internationally acceptable standards. The result specifies that both the Aluminium 6061 and the Titanium alloy are potential materials of the pneumatic prosthetic foot for the shank segment, with each material showing special advantages. Aluminium 6061 material was able to give a modest level of strength at a minimum cost, and it is a pragmatic option for the first design. Hence, for the same dimensional performance, Titanium alloy offers a superior strength-to-weight ratio, lower deformation under load, and a higher safety factor, making it a suitable alternative for improved performance and extended prosthetic foot life. Further optimisation, either in the topology or in the selection of materials, needs to be applied to these results to obtain a final design balanced across these three parameters: weight, strength, and user comfort. In line with these results, aluminium 6061 was chosen as a preferable material for manufacturing the pneumatic prosthetic foot.

4. Methodology

The methodology section of this research study is structured according to the framework of the research onion, which provides a systematic approach to designing and conducting research. This section outlines the research philosophy, approach, strategy, choices, time horizon, and techniques and procedures employed in this study. The aim was to determine the biomechanical behaviour, specifically the joint kinematics, overall kinetics, and spatiotemporal parameters of an optimized semi-active pneumatic prosthetic foot during ambulation at a self-selected walking speed in a controlled environment.

4.1. Research Philosophy

The research established measurable and observable data through quantitative methods in order to answer the research questions accurately. The philosophical stance of this study, which assisted in answering the research questions, was primarily positivist. Positivism is a research paradigm aligned with the hypothetico-deductive science model, emphasizing the importance of data and statistical analysis, allowing for objective conclusions regarding the effectiveness of the pneumatic prosthetic foot (Park *et al*., 2020). The hypothetico-deductive method is described as a circular process that commences with a theory from the literature to build testable hypotheses, design an experiment through operationalizing variables, and conduct an empirical study based on experimentation. This approach aligns with the research goals of analyzing kinematic parameters, ground reaction forces, and gait symmetry since the hypotheses are stated quantitatively.

Alternative research philosophies, such as interpretivism and pragmatism, were considered but ultimately set aside to keep a clear and objective approach for this study. Interpretivism focus on understanding complex human experiences and believes that human actions and meanings vary across cultures, situations, and times (Allemang *et al*., 2022). This approach assumes that human behaviour can not be studied in the same way as physical phenomena, as people create unique and layered meanings within their social realities. However, interpretivism was unsuitable since this study aimed to collect measurable, consistent data on prosthetic performance.

Conversely, pragmatism is an approach that focuses on using the best tools and methods to solve real-world problems, often combining different types of data to answer research questions (Allemang *et al*., 2022). This flexibility allows researchers to explore problems from multiple angles, including qualitative and quantitative data. While pragmatism can be useful for practical problem-solving, the goal of this study was to follow a structured, quantitative approach to test a specific hypothesis under controlled conditions. For this reason, pragmatism was also not a suitable choice, as this study focused directly on analyzing the mechanical effects of a prosthetic foot on human gait rather than exploring patient experiences or perspectives.

Several recently published studies that evaluated the influence of prosthetic foot on human gait biomechanics employed the positivist research philosophy, which further highlights the relevance of this research theory in addressing similar research questions. These studies evaluated prosthetic feet performance on various terrains, using gait parameters such as walking symmetry and plantar pressure, location of the functional joint centre, and leg trajectory error as measured outcomes(Chiriac & Nițu 2022; Lecomte *et al*., 2020; Prost et al., 2017). All the outcomes mentioned above can be observed and measured quantitatively.

4.2. Research Approach

The research utilized a deductive approach, commencing from existing theories of biomechanics and knowledge about prosthetic designs. This approach was of significance in this study as the study builds on the published research work on pneumatic actuated prosthetic feet in particular and active prosthetic feet in general (Zheng & Shen, 2015). This approach allowed for hypothesis testing and examining specific variables, such as the relationship between the vertical ground reaction forces, joint kinematics and other human gait parameters like walking speed, cadence and step length variation. The deductive method was appropriate for this study, and it facilitated the evaluation of predefined study objectives through systematic experimentation within a controlled environment.

4.3. Research Strategy

An experimental design was employed as a research strategy in this study, which allowed for the controlled evaluation of the performance of the pneumatic prosthetic foot. This strategy included:

- Controlled Experiments: Conducting experiments in a controlled laboratory setup at a self-selected walking speed to ensure reliability and validity.
- Comparative Analysis: Comparing the performance of a pneumatic prosthetic foot against a prescribed passive prosthetic foot to evaluate differences in gait and vertical ground reaction force production.

4.4. Research Choices

The study utilised a mono-method quantitative approach, focusing solely on quantitative data collection and analysis. This method is consistent with recent literature, such as Chiriac & Nițu (2022) and Rasheed *et al*. (2023) which also focused exclusively on quantitative data. The objectives of the study aligned with this research choice, allowing for statistical analysis of the collected data on kinematic parameters, vertical ground reaction forces, and gait symmetry. The quantitative approach enabled the objective measurement and comparison between the prescribed prosthetic limb and the pneumatic actuated prosthetic foot.

4.5. Time Horizon

The study adopted a cross-sectional time horizon, as data was collected at a single point in time during the experiments. Participants only visited the Orthotics and prosthetics laboratory once; data was collected for both gait with prescribed prostheses and the pneumatic prosthetic foot with an acclimation period in between. This approach was suitable for evaluating the immediate effects of the pneumatic prosthetic foot on participants' gait without the need for longitudinal tracking. The cross-sectional design allowed for efficient data collection while providing relevant insights into the prosthetic performance.

4.6. Techniques and Procedures

This section details the specific techniques and procedures employed in the research:

4.6.1. Ethics

An ethical clearance was applied for and received from the University of South Africa with a registration number REC-170616-051. Following an approval from the University of South

Africa, another application was submitted to the Eastern Cape Department of Health, which was also granted with a reference number EC_202311_005. Subsequent to the clearance of the Department of health, a gate keeper's permission application was filed fro in The Nelson Mandela Academic Hospital, which gave access to patient infprmation.

4.6.2. Settings

The study was conducted at the Orthotics and Prosthetics Laboratory at Walter Sisulu University in Mthatha (see Figure 16). Experiments were performed in a ten-by-five-meter laboratory with eight high-speed cameras from Baumer International GmbH and a 2-metre pressure mat from Zebris Medical GmbH. The cameras were recording at 100 frames per second, which is the recommended frame rate by the supplier, while the pressure mat was recording data at 50 Hertz. Intrinsic frame calibration was conducted by the supplier upon installation of the cameras, while extrinsic object calibration was performed before and after every data collection session to ensure that the global equilibrium remained constant. The recommended calibration template by Theia 3D was followed when performing object calibration, and a calibration file was assigned to the captured videos for a particular session.

Figure 16: A picture of the gait lab situated in the Walter Sisulu University orthotics and prosthetics laboratory.

4.7. Participants

- Sampling Method:

  The study employed a stratified sampling method to recruit participants from the Orthopaedic unit (Bedford) of the Nelson Mandela Academic Hospital. Initial identification was done through the Bedford Hospital prosthetic patient database, which listed individuals who were previously fitted with prosthetic devices. Patients with unilateral transtibial (below-knee) amputations and active contact details were shortlisted, and they were contacted telephonically to provide preliminary information about the study. Patients who expressed interest were invited to the Orthotics and Prosthetics Laboratory at Walter Sisulu University for a screening session.

During the laboratory visit, extensive assessments were performed to verify eligibility for involvement in the study. These assessments involved obtaining measurements of body mass, stump length, standing height, and shoulder height, and the researcher performed an evaluation of functional mobility status. Participants were included if they met the following criteria: unilateral transtibial amputation, body mass below 100 kg, short to medium residual limb length, foot size between 6 and 10, and a standing height of at least 170 cm. The design limitations of the pneumatic prosthetic foot prototype informed this criterion, which features a fixed build height of 27 cm, including the female pyramid adapter, and accommodates foot sizes 8 to 10 via interchangeable foot shells, in line with the manufacturer's specifications (see Figure 17).

Participants eligible for involvement were fully briefed about the study objectives, procedures, and ethical considerations. Written informed consent was obtained before the commencement of any experimental procedures. Participation in this study was of a voluntary nature, and individuals were assured they could withdraw from the study at any time without penalty.

Figure 17:Participants 1 and 2 walking on a pressure mat in the Walter Sisulu University orthotics and prosthetics laboratory.

Two male participants were recruited, and informed consent was obtained by means of written consent. They were profiled as non-restricted community ambulators exhibiting walking abilities that are beyond basic walking. Participant 1 was recruited with a socket that no longer fit comfortably, and the researcher manufactured a new socket similar to the previously prescribed socket. The original prosthetic alignment of the prescribed prosthetic limb was slightly changed, ensuring that the new socket fits comfortably and that the patient can ambulate with minimal disturbances to the original gait. Both participants used similar prosthetic limbs with similar components, such as the Solid Ankle Cushion Heel, Patella tendon bearing socket and a below-knee socket strap for suspension. There were differences in amputation dates; Participant 1 was amputated in 2018 due to trauma, while Participant 2 was amputated in 1996 (see Table 5) due to infection.

Table 5: A brief profile of the study participants

Participant profile		
	Participant 1	Participant 2
Age	45	50
Shoulder height	141	144
Mass	65	81
Foot size	7	10
Leg length	97	91
	97	91
Date of amputation	2018	1996
K-level	K3	K3

4.8. Experimental Setup

A series of experiments were conducted to evaluate the pneumatic prosthetic foot's performance. Participants went through training to familiarise themselves with the pneumatic prosthetic foot before the commencement of the data collection. The training was also intended to familiarise the participants with the setup and the data collection tools. A variety of outcome measures were carefully checked, such as a visual inspection checklist, gait speed, and patient feedback, which were utilised to gauge the acclimatisation to the new prosthetic foot. The participants were required to walk on a straight path of approximately 10 metres with a 2-metre pressure mat embedded on this path, giving them enough time to adjust their gait before collecting pressure data.

4.9. Experiments

A 90-minute acclimation period was adopted for the pneumatic prosthetic foot to allow participants to familiarise themselves with the device before data collection. During this time, participants engaged in repeated walking trials along the laboratory walkway under supervision, ensuring they were comfortable and able to maintain a consistent gait. For each participant, the order of testing between the passive and pneumatic prosthetic foot conditions was randomised to minimise the influence of fatigue or adaptation bias. Data for the first condition, whether passive or pneumatic, were collected once the participant demonstrated consistent gait performance. After a brief rest period, the same procedures were repeated for the second condition. In both cases, participants walked at a self-selected speed over a 10-meter walkway with 2 meters embedded with a Zebris pressure mat, while kinematic data were simultaneously captured using the Theia3D markerless motion capture system. A minimum of nine successful gait cycles over the 2-meter pressure mat were recorded per condition to ensure that the datasets are reliable, robust and comparable.

4.9.1. Data Collection Tools

The following instrumentation was used during data collection:

A 1,5 kilowatt, 50-litre, 2-horsepower, direct-drive pneumatic compressor with an onboard pressure gauge was used to power the pneumatic cylinder (see Figure 18). The compressor provided pressurised air to the pneumatic prosthetic foot, while the pressure gauge measures relative air pressure.

Figure 18: Pneumatic compressor with an onboard pressure regulator.

The kinematic data collection involved four pairs of Baumer VLXT-31C.IJP, 10 Gigabit Ethernet (10GigE) industrial cameras with a picture resolution of 2048 x 1536 pixels (3.2 megapixels), able to provide a frame rate of up to 216 frames per second. These high-speed cameras, shown in Figure 19, were set up in a rectangular configuration and are used to capture videos of whole-body movement. These videos were transmitted to the THEIA3D software that tracks joint movement and produces instantaneous joint angles during gait.

Figure 19: Baumer high-speed camera.

To measure the vertical force generated by the foot when coming into contact with the ground, a Zebris Medical GmbH FDM-2 pressure mat was used (see Figure 20). This pressure mat is 212 cm long, 60,5 cm wide and has a height of 2,1 cm, and has a total of 15,360 sensors distributed across the platform, with a sampling rate of 100Hz.

Figure 20: Zebris Medical GmbH FDM-2 pressure mat.

4.9.2. Data Analysis

The data collected during the course of this study were stored electronically in the laboratory computer, using the Temlpo software. This software is integrated with the THEIA-3D software that analyses and quantifies joint motion.

When conducting the statistical analysis, descriptive statistics were employed to summarise and describe the data and examine similarities to the normative data. This includes the analysis of kinematic data captured through motion capture and pressure distribution patterns from the pressure mat. A similarity index and root mean square error were utilised to determine how close the data is to the normative data and quantify how much the data deviates from the normative data, respectively.

The outcome measures of the study included joint angles, ground reaction forces, pressure distribution, and gait symmetry to draw conclusions about the performance of the pneumatic prosthetic foot.

4.9.3. Testing conducted

To ensure that all biomechanical measurements were accurately associated with the individual participant and their respective prosthetic foot condition, each data collection session was recorded under a unique participant identifier. Before the commencement of the walking trials, the height of the participant, body mass, and residual limb characteristics were documented to calibrate the Theia3D motion capture system and normalize kinetic and kinematic outputs. The Theia3D system uses full-body video tracking to extract joint angles and segmental motion without requiring reflective markers; it identifies anatomical landmarks and tracks joint trajectories relative to the body dimensions of each individual. In parallel, the Zebris pressure mat recorded plantar pressure and vertical ground reaction forces specific to the limb in contact with the surface, allowing force curves to be independently analysed for the prosthetic and sound limbs. Each walking condition (passive and pneumatic foot) was labelled separately within the software environment, and trial metadata included the participant number, prosthetic type, and trial sequence. This ensured that each measurement, whether spatiotemporal, kinetic, or kinematic, could be directly linked to the correct individual, limb, and prosthetic condition, enabling precise within-subject comparisons.

4.10. Participant profiling

The travelling cost made it impractical for this participant to continue participating. The other two patients were excluded due to amputation sites that are closer to the ankle joint, limiting space for accommodating the pneumatic prosthetic foot. Consequently, only two participants were able to participate in the data collection for this study to evaluate the feasibility of a pneumatic prosthetic foot. Both participants were unilateral left transtibial amputees with a K3 functional level, indicating the ability to walk at various cadences and navigate environmental obstacles. The key demographic and anthropometric details are summarised in Table 1.

Table 6: Participant profiles

Characteristic	Participant 1	Participant 2
Age (years)	45	50
Shoulder Height (cm)	141	144
Mass (kg)	65	81
Foot Size (UK)	7	10
Leg Length (cm)	97	91
Date of Amputation	2018	1996
K-Level	K3	K3

Participant 1 was a 45-year-old male weighing 65 kg with a left transtibial amputation performed in 2018. His shoulder height was 141 cm, leg length was 97 cm, and he wore a UK size seven prosthetic foot. The patient was using his second below-knee prosthetic foot that was issued in March 2024, with a solid ankle cushion heel and a patella tendon bearing socket with a supracondylar suspension. A secondary sleeve suspension made of neoprene was used to fixate the prosthetic socket to the stump of the participant. All of these components were prescribed by the orthotist-prosthetist who was assisting the participant, and no alterations were made before testing.

Participant 2, a 50-year-old male weighing 81 kg, had a transtibial amputation in 1996. His shoulder height was 144 cm, leg length was 91 cm, and he wore a UK size ten prosthetic foot. This participant was amputated as a result of trauma that involved a motor vehicle accident. Apart from the amputation surgery done on the left leg, internal fixators were used on the right ankle, which impacted the range of motion of the right ankle joint. Upon assessment, the right foot was in slight pronation during the full weight-bearing position, and there was also a visible arch collapse. Both participants represented active amputees capable of variable cadence walking, making them suitable for assessing the performance differences between the pneumatic prosthetic foot and their prescribed prosthetic foot.

Both participants were observed under 3 conditions, namely walking with a prescribed prosthetic foot, walking with a pneumatic actuated prosthetic foot without air pressure and lastly, walking with a pneumatic actuated prosthetic foot with pressure. When using the prescribed prosthetic feet, the participants were allowed 10 free trial runs to familiarise themselves with the laboratory setup and the verbal commands. Upon completion of the trial run, a ten-minute break was allowed, and participants were instructed to walk at a self-selected speed in a straight line, ensuring that they walked over the pressure mat that was placed on the floor. The walkway had a total length of 6 mitres of level ground, with a protruding pressure mat that accounts for a 2 cm height difference from the ground surface. The participants were required to walk on the walkway three times, which equates to 9 steps in total on the pressure mat, and these were used for spatiotemporal and kinetics parameter data collection.

On conditions two and three, an acclimation period of 90 minutes was allowed to familiarise the participants with the new prosthetic device. The mass differences, ankle joint range of motion and the powered plantarflexion movement were all new to the participants, as they were both using the solid ankle cushion heel. The acclimation period allowed the patient to walk inside the lab while taking beaks when tired, and minimal gait training was offered to facilitate acclimation. During the acclimation period, both patients started walking with two elbow crutches, with patient one progressing to using a single crutch and ultimately walking without any assistive devices. Patient two struggled with balance while walking without a crutch and when using a single crutch, which dictated that patient two must walk with two crutches during data collection. The first trial of patient two could not be analysed and had to be discarded due to the interference of crutches with the pressure mat.

5. Preliminary Data

5.1. Introduction

This results section contains a detailed biomechanical analysis comparing the pneumatic prosthetic foot prototype with the prescribed passive prosthetic feet of both patients. The data was collected during controlled walking trials conducted in a laboratory environment, focusing on critical gait variables that provide insight into the performance, adaptability, and potential clinical value of the developed pneumatic system. The results were structured to cover three fundamental parameters of biomechanical analysis, which are spatiotemporal parameters, gait kinetic measures, and ankle joint kinematics. The first part of the results focuses on spatiotemporal parameters such as cadence, walking speed, step length, stride length, stance and duration of swing phase. These parameters offer a basic understanding of the gait pattern of individual participants and symmetry under both prosthetic foot conditions.

The comparison of the two conditions sought to evaluate the abilities of both prosthetic feet to promote more normalised and efficient walking dynamics. The results section that follows informs about the vertical ground reaction forces by quantifying the magnitude of these forces using a pressure mat from Zebris. These results demonstrate the loading patterns of each foot and also show how pressure was distributed across the plantar surface of the foot during the stance phase. The discrepancies observed between the left and the right foot under each condition reflected the effectiveness of each prosthetic design in replicating the fundamental characteristics of the foot during locomotion.

Finally, kinematic data obtained through markerless motion capture with Theia3D were analysed to evaluate joint angle trajectories at the hip, knee, and ankle. These findings are critical in determining whether the pneumatic prosthetic foot enables more physiological joint movements, particularly during critical gait events such as heel strike, midstance, and push-off. Joint angle graphs are presented to illustrate the timing and magnitude of motion for each joint in both limbs under each prosthetic condition. The entire results aimed to answer the research questions mentioned in the previous section of the dissertation, the format in which they are presented allow for a dircect comparison between the two feet, and the pneumatic and passive conditions. Each subsection concludes with a brief summary of key findings to facilitate interpretation, while these results were further contextualised and discussed in relation to existing literature in the subsequent discussion chapter.

5.2. Spatiotemporal Parameters

This section presents the results of the spatiotemporal parameters recorded during the walking trials for both participants using the prescribed prosthetic foot and the pneumatic prosthetic foot (both with and without pressure). The peak force, foot rotation, step length, stride length, step width, stride time, double stance, step time, cadence, velocity, stance percentage, swing percentage, and double stance percentage are all parameters that were analysed.

Table 7: A table showing a summary of the spatiotemporal parameters.

Spatiotemporal parameters							
		Participant 1			**Participant 2**		
	Side	**Prescribed prosthetic foot**	**Pneumatic prosthetic foot without pressure**	**Pneumatic prosthetic foot with pressure**	**Prescribed prosthetic foot**	**Pneumatic prosthetic foot without pressure**	**Pneumatic prosthetic foot with pressure**
Peak force	L	693,6	462,9	685,9	855,9	213	442,4
	R	665,2	685,7	664,2	865,3	436,1	686
Foot rotation (degrees)	L	1,3±0,00	5,2±0,7	-5,9±1,2	14,3±0,00	15,5±1,2	19,4±1,4
	R	16,8±1,6	14,2±0,5	5,0±0,8	22,3±1,2	5,7±11,8	21,6±2,0
Step length (cm)	L	54±0,00	62±5	58±3	48±0,00	41±0,00	42±3
	R	53±0,00	51±0,00	56±4	53±0,00	66±6	64±0,00
Stride length (cm)	Both	104±1	114±4	112±5	104±3	111±14	106±3
Step width (cm)	Both	13±3	9±2	7±1	17±4	13±2	13±2
Stride time (s)	Both	1,22±0,01	1,55±0,02	1,16±0,07	1,61±0,01	1,82±0,03	2,09±0,02
Double stance (s)	Both	0,41±0,01	0,51±0,01	0,37±0,03	0,59±0,01	0,32±0,20	0,58±0,02
Step time (s)	L	0,61±0,00	0,78±0,00	0,59±0,03	0,81±0,00	0,98±0,00	1,02±0,01
	R	0,62±0,00	0,76±0,00	0,58±0,06	0,8±0,00	0,86±0,01	1,06
Cadence (steps/min)	Both	99±1	77±1	104±6	75±0	66±1	57±1
Velocity (km/h)	Both	3,1±0,0	2,6±0,1	3,5±0,3	2,3±0,1	2,2±0,3	1,8±0,1
Stance %	L	67,4±0,00	60,9±0,3	66,0±6,7	67,7±0,00	50,8±1,4	58,5±0,7
	R	66,6±1,6	71,2±0,3	67,4±3,9	68,9±0,6	62,9±12,9	69,5±1,7
Swing %	L	32,1±0,00	39,6±2,3	35,3±3,2	32,9±0,00	48,4±0,5	41,3±0,7
	R	33,7±0,8	28,3±0,0	31,3±0,8	30,7±0,3	37,9±12,1	30,6±1,9
Double stance %	Both	33,7±0,8	33,1±0,8	31,7±2,6	36,3±0,9	17,6±11,0	27,7±1,0

5.2.1. Step and Stride Length

Step and stride lengths varied for both participants. For Participant 1, the stride length was the longest when using the pneumatic foot without pressure (114 ± 4 cm), while for Participant 2, the stride length was slightly reduced when using the pneumatic foot with pressure (106 ± 3 cm). Interestingly, Participant 1 demonstrated a slightly increased step length with the pneumatic foot without pressure (62 ± 5 cm) compared to the prescribed foot (54 cm). For Participant 2, step lengths were similar across conditions, with the prescribed foot and pneumatic foot without pressure showing close values (48 cm and 41 cm, respectively) (Table 2).

5.2.2. Step Width

Step width was influenced by the type of foot used, with more significant variations seen in Participant 1 compared to Participant 2. Participant 1 demonstrated a decrease in step width when using the pneumatic foot with pressure (7 ± 1 cm) compared to the prescribed foot (13 ± 3 cm). The pneumatic prosthetic foot without pressure achieved an intermediate step width but was still lower than the prescribed prosthetic foot. In contrast, Participant 2 exhibited more consistent step widths when using the pneumatic prosthetic foot (13 ± 2 cm), but it was still lower than the prescribed prosthetic foot (17 ± 4 cm).

The pressurised pneumatic foot appears to encourage forward progression (narrower step width) but may compromise lateral stability in Participant 1. Adjusting the ankle stiffness or compliance of the pneumatic prosthetic foot could help balance forward progression and lateral stability better. The influence of ankle stiffness in controlling lateral stability may need to be further evaluated. For Participant 2, the consistent step widths imply that the pneumatic foot does not disrupt the natural balance, making it a viable option without substantial design adjustments. However, significant design adjustments may be needed to enhance the level of function of the prosthetic device and improve independence for people with a restricted range of motion on the contralateral ankle joint. The discrepancy in step width between the two participants suggests that there may be a need for user-specific fine-tuning of the prosthetic foot properties to accommodate varying biomechanical needs.

The variation in step width across conditions may represent the level of influence these two prosthetic designs have in modulating lateral stability during ambulation. In both participants one and two, the prescribed prosthetic feet exhibited the most expansive step, indicating the need for stability. The need for stability in participants one and two may be a result of perceived balance. The observed narrower step width in Participant 1 with the pressurised pneumatic foot affirms the need for further testing in dynamic or uneven environments to assess real-world stability.

5.2.3. Stride Time and Step Time

For Participant 1, the stride time was the longest for the pneumatic foot without pressure (1.55 ± 0.02 s), while the shortest stride time was recorded with the prescribed prosthetic foot (1.22 ± 0.01 s). Participant 2 displayed a similar trend, with the pneumatic foot with pressure showing the longest stride time (2.09 ± 0.02 s) and the prescribed foot showing the shortest (1.61 ± 0.01 s). Step time analysis indicated longer step times for both participants using the pneumatic foot, particularly Participant 2, whose step time increased significantly with the pneumatic foot with pressure.

For participant 1, ambulation with a pneumatic prosthetic foot without pressure resulted in the longest stride time, indicating a slower walking speed. This condition produced the most extended step length and stride length, which may have increased the force required to lift and progress the centre of mass, which may have resulted in the patient taking longer to cover the distance. This may be due to reduced propulsion or instability without the added support of active actuation when there is pressure. When ambulating using the pneumatic actuated prosthetic foot, participant 2 exhibited an increased stride and step times, suggesting that the pneumatic prosthetic foot with pressure may have introduced mechanical resistance or stiffness, slowing down the gait. This could also indicate that the participant adapts to unfamiliar dynamics, requiring more deliberate movement. The shortest stride and step times for both participants were observed when walking with the prescribed prosthetic feet, highlighting their effectiveness in facilitating quicker, more efficient gait cycles.

5.2.4. Cadence and Velocity

For Participant 1, cadence was highest with the pneumatic prosthetic foot with pressure (104 ± 6 steps/min) and lowest with the pneumatic foot without pressure (77 ± 1 steps/min), indicating that the absence of pressure reduces walking speed. Participant 2 exhibited a different trend, with the prescribed prosthetic foot producing the highest cadence (75 ± 0 steps/min) and the pneumatic foot with pressure resulting in the lowest (57 ± 1 steps/min). Walking velocity followed a similar pattern to cadence. For Participant 1, velocity was highest with the pneumatic prosthetic foot (3.5 ± 0.3 km/h) and lowest with the pneumatic foot without pressure (2.6 ± 0.1 km/h). In contrast, for Participant 2, walking speed was highest with the prescribed prosthetic foot (2.3 ± 0.1 km/h) and lowest with the pneumatic foot with pressure (1.8 ± 0.1 km/h).

When pressure is applied to Participant 1, the pneumatic foot improves cadence and velocity, suggesting improved stability and propulsion. The absence of pressure reduces gait efficiency, probably due to insufficient generated force or reduced energy return during the push-off phase of gait. However, in Participant 2, the prescribed prosthetic foot remained superior, which may indicate that the participant had not fully adapted to the pneumatic design. Even with pressure, cadence, and velocity decreased, suggesting that the participant was experiencing some level of discomfort, instability, or a need for further tuning of the pneumatic system.

5.2.5. Stance and Swing Percentage

The stance phase was reduced for Participant 1 when using the pneumatic foot without pressure (60.9% left, 71.2% right) compared to the prescribed foot (67.4% left, 66.6% right), further increasing the variability between the left and right leg. For Participant 2, a similar trend was observed, with stance phase percentages slightly decreasing when using the pneumatic foot with pressure (58.5% left, 69.5% right) compared to the prescribed foot (67.7% left, 68.9% right). The swing phase increased with the pneumatic foot without pressure for Participant 1 and with the pneumatic foot with pressure for Participant 2.

A shorter stance phase may indicate reduced stability or confidence in weight acceptance, potentially due to differences in foot mechanics or perceived comfort. A more extended swing phase may suggest quicker foot clearance but could also indicate compensatory mechanisms, such as increased hip/knee flexion or asymmetry in gait patterns. The different trends between participants suggest that individual gait patterns and adaptation strategies differ based on factors like residual limb strength, proprioception, and prosthesis control. Prosthetic interventions should be patient-specific, and further analysis (e.g., muscle activation and energy cost of walking) may be necessary to determine the best configuration.

5.2.6. Double Stance Percentage

Both participants demonstrated a decrease in double stance time when using the pneumatic foot. Participant 1 showed a reduction from 33.7% with the prescribed foot to 31.7% with the pneumatic foot with pressure, while Participant 2 showed the most significant variation, with double stance time decreasing dramatically from 36.3% to 27.7%.

Double stance time reflects stability and confidence in weight transfer. A reduction in double stance suggests increased confidence in transitioning between steps, as participants spend less time in both-foot support. The more significant reduction in Participant 2 (from 36.3% to 27.7%) indicates a substantial shift in gait dynamics, possibly due to a greater reliance on the intact limb or increased propulsion efficiency with the pneumatic foot. While reduced double stance time may indicate better dynamic balance and smoother walking, it could also mean less stability, especially if compensatory strategies (e.g., excessive reliance on the intact limb or altered upper body posture) are used. Further kinematic and kinetic analysis is needed to assess joint loading and energy efficiency during weight transfer.

5.3. Kinetics

The peak force data for both participants revealed some variability across conditions 1, 2, and 3. For Participant 1, the peak force values were lowest when using the pneumatic foot without pressure (462.9 N on the left, 685.7 N on the right) and highest with the prescribed prosthetic foot (693.6 N on the left, 665.2 N on the right). For Participant 2, the peak force was lower for the pneumatic foot without pressure (213 N left, 436.1 N right) and higher for the prescribed foot (855.9 N left, 865.3 N right). The pneumatic foot with pressure showed intermediate values for both participants (605.9 N left, 587 N right for Participant 1; 442.4 N left, 686 N right for Participant 2), as seen in Table 2.

The pneumatic foot without pressure demonstrated the lowest peak force for both participants one and two when compared to the pressurised pneumatic foot and the prescribed prosthetic foot. The absence of pressure in the system reduced the ability of the unpressurised prosthetic foot to provide sufficient energy return during gait, consequently reducing the stability during the stance phase. The low peak force observed during the stance phase on the prosthetic side for participants one and two may also highlight a less efficient weight transfer. The prescribed prosthetic foot demonstrated the highest peak force for both participants, which may indicate an improved function in meeting the prosthetic user demands when compared to pneumatic prosthetic foot with pressure. These results may be a reflection of better alignment, energy return or improved stability compared to pneumatic prosthetic foot. Meanwhile, the left and right consistency for Participant 2 may suggest that the prescribed foot supports a more balanced weight distribution during walking.

5.3.1. Participant 1 Vertical Ground Reaction Force

The vertical ground reaction force of Participant 1 in all three conditions was compared to the vertical ground reaction force of normal individuals (Senden *et al.*, 2024) To eliminate the effects of differences in mass, a data normalisation strategy was used where the vertical ground reaction force values were divided by the body weight of participant 1. The values presented in the graph below are a percentage of the actual body weight of Participant 1, while the normative values were already normalised using the average body weight of all participants. Instead of using time values in seconds as an independent variable, the percentage of a gait cycle was used to normalise this data further.

The overall shape of the vertical ground reaction forces curve of Participant 1 in all three conditions resembles the double peak curve observed in normal gait, with minor differences in peak values and timing (see Figures 21 and 22). The most obvious observation was that in all three conditions, the first peak occurred earlier than in normal walking. This highlights an increased loading rate that may negatively affect the joints of the lower limb by increasing joint stress and the risk of injury. This study did not evaluate the knee and ankle joint loading; however, the increased loading rate observed in all three conditions gives rise to the need to evaluate the knee and ankle joint loading pattern to determine the likelihood of secondary injuries. The limitations of the prosthetic devices in absorbing shock in all three conditions during early stance may have been one of the contributing factors. The controlled passive plantarflexion during heel strike in normal walking allows for the gradual loading of the leading limb, which ultimately lowers the loading rate, as seen in the vertical ground reaction force curve for normal walking.

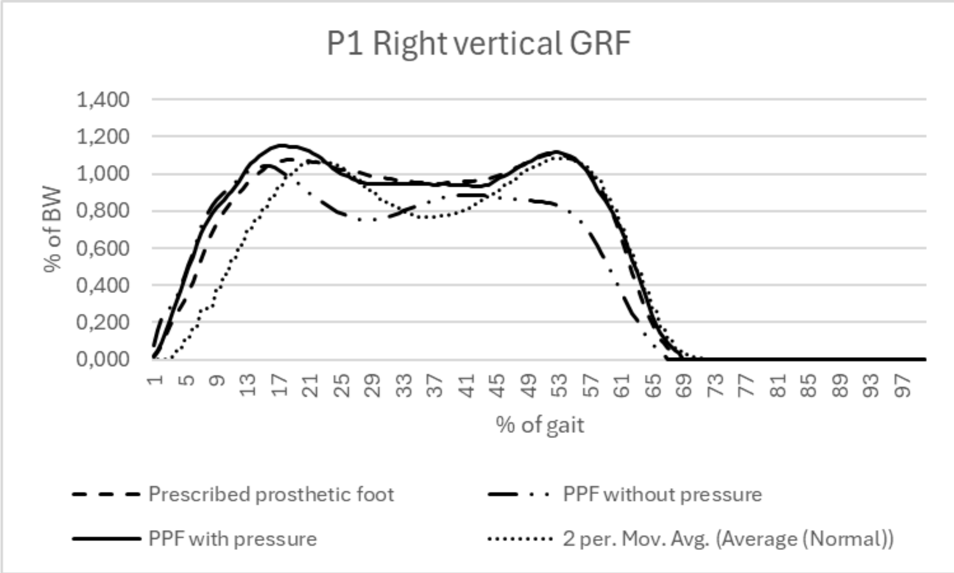


Figure 21: Participant 1's right vertical ground reaction force curve under three conditions vs the normal curve.

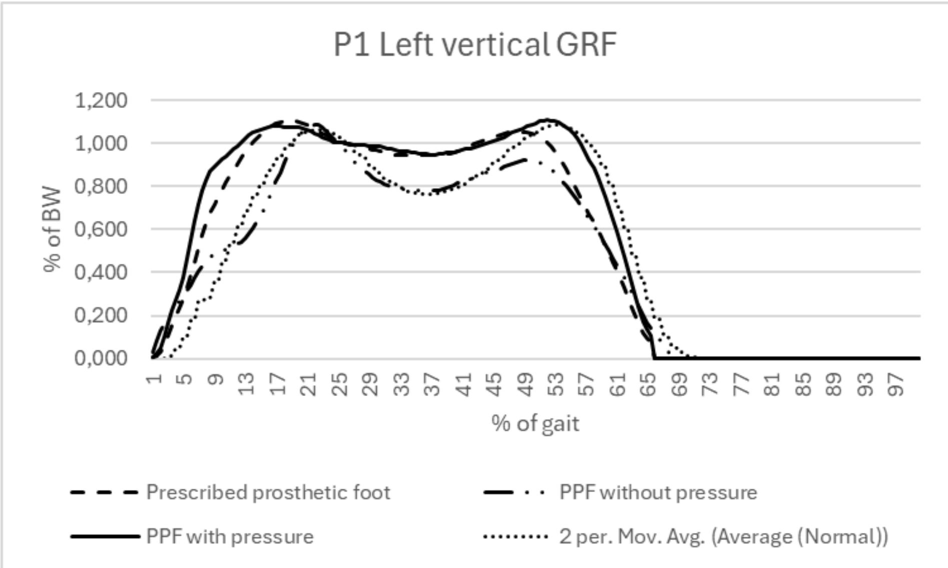


Figure 22: Participant 1's left vertical ground reaction force curve under three conditions vs the normal curve.

On the amputated side, the vertical ground reaction force curve resembled the normal double-peak M-curve seen in normal walking. However, observable differences between the first and the second peak were present for the prescribed prosthetic foot and the pneumatic prosthetic foot without pressure. The second peak was slightly lower than the first peak, with the pneumatic prosthetic foot without pressure displaying a more pronounced discrepancy. This highlights the inherent limitations of the two prosthetic feet in producing the push-off force during the terminal stance phase of gait. The differences in freedom of movement between the two prosthetic feet may have been the cause of the observable discrepancy in the second peak. Without pressure, the pneumatic prosthetic foot could not restrict further passive dorsiflexion during the stance phase by rapidly plantarflexing the ankle joint. This enabled a prolonged ankle rocker, eliminating the ankle resistance that may have resulted in the elevation of the ankle joint before the leading limb came in contact with the ground. The ankle joint elevation ensures that there is an increased concentration of pressure in the forefoot.

5.3.2. Participant 2 vertical ground reaction force

Participant 2 on the sound limb demonstrated a slightly different curve when using the prescribed prosthetic foot from the normal double-peak M-curve. The vertical ground reaction force curve had a flat top that eliminated the double peak shape of the curve that represents the loading response (first peak) and push-off (second peak). The flat top is in the region of the double peak, signalling that the problem might not be the loading response or push-off; however, the problem was in the midstance. The mid-dip between the two peaks occurs because the centre of mass is progressing smoothly over the stance foot, facilitated by the tibial progression about the ankle joint. Participant 2 had a limited range of motion on the sound limb ankle joint caused by internal fixators, which limits ankle movements in both dorsi and plantar direction. This limited range of motion may have affected the tibial progression during mid-stance and ultimately prevented the smooth progression of the centre of mass over the stance foot.

The introduction of the pneumatic prosthetic foot did not benefit the sound limb in terms of vertical ground reaction force. As a result, Participant 2 utilised two elbow crutches to aid in forward ambulation and balance, which affected weight bearing on the right side. The vertical ground reaction force curve shows that Participant 2 demonstrated partial weight-bearing on the sound side with peak values ranging from 54% and 85% of the body weight when using the pneumatic prosthetic foot without pressure and with pressure, respectively (see Figure 23). The partial weight bearing on the sound side indicates the level of dependency on the mobility aid during gait, which increased in the absence of pressure. When looking at the overall shape of the curve, both conditions demonstrated similar curves that are parabolic in shape with a single peak, indicating a loss of typical gait phases. This undermines the dynamic modulation of load during gait and reflects a support strategy rather than active propulsion and push-off.

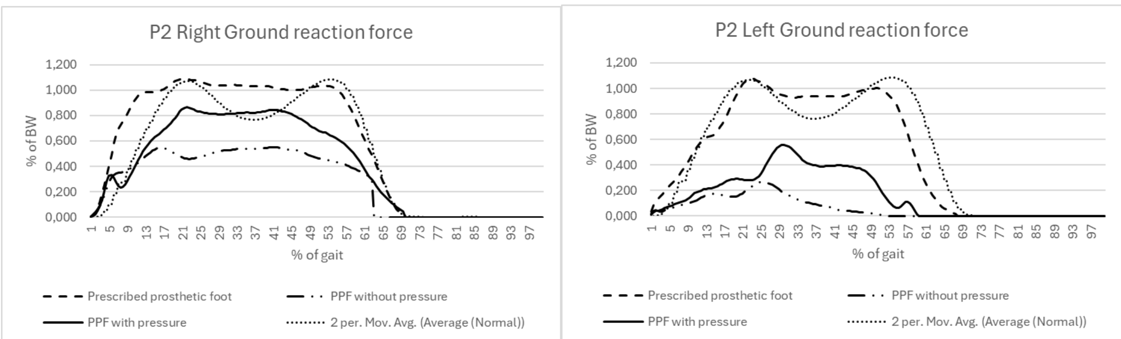


Figure 23: Participant 2's right and left vertical ground reaction force curve under three conditions vs the normal curve.

On the amputated side, the vertical ground reaction force curve of the prescribed prosthetic foot closely followed the normal curve with two peaks and a valley. However, the two peaks were not on the same level; the push-off peak was slightly lower than the weight acceptance peak, highlighting a low push-off force. Low push-off force in solid ankle cushion heel prosthetic feet is common because these prosthetic feet rely on the flexible keel during push-off and can not actively plantarflex. As a result, the prosthetic side can not produce enough forward propulsion, leading to reduced forward momentum. The early push-off peak observed on the prosthetic side suggests that the user may be shortening the stance time due to comfort or reduced stability or possibly off-leading the prosthetic side early, shifting weight to the sound side.

The pneumatic prosthetic foot with and without pressure performed poorly, showing peak values of 54% and 31%, respectively. These values suggest that the pneumatic prosthetic foot did not bear the full body weight at any gait phase, showing signs of significant offloading through elbow crutches. This suggests that there was poor energy return from the prosthetic foot or limited confidence and instability. The absence of a physiological curve shape, even under pressurised conditions, indicates that the foot may not be providing sufficient support, stability, or energy return to facilitate a typical gait pattern. This points to a need for further optimisation of the pneumatic mechanism and tuning parameters.

5.4. Kinematics

5.4.1. Foot Rotation (Degrees)

Foot rotation was most varied across conditions. Participant 1 showed substantial differences, with foot rotation on the left foot shifting from 1.3° for the prescribed foot to 5.2° ± 0.7° for the pneumatic foot without pressure and -5.9° ± 1.2° with pressure. The pneumatic foot without pressure on the contralateral side demonstrated a reduced rotation compared to the prescribed prosthetic foot, but with pressure, their foot rotation was significantly reduced to 5.0°. For Participant 2, foot rotation was more consistent, with the prescribed foot showing 14.3° and the pneumatic foot with pressure showing a higher 19.4° ± 1.4°. The pneumatic foot without pressure demonstrated rotation closer to the prescribed foot for both participants (Participant 1: 5.2° ± 0.7°, Participant 2: 15.5° ± 1.2°). The pneumatic foot without pressure on the contralateral side drastically reduced rotation (5.7°), but with pressure, rotation is closer to the performance of the prescribed foot (21.6° vs. 22.3°).

Minimal rotation of the prescribed prosthetic foot in participant 1 may suggest good alignment and stability, reflecting a well-tuned prosthetic foot, while an increased rotation in the unpressurised pneumatic prosthetic foot may indicate reduced control or alignment, potentially due to reduced stiffness or lack of stability. The introduction of a free-moving ankle joint may have negatively impacted the stability of the patient during gait, forcing Participant 1 to adopt compensation strategies to minimise the effects of reduced stability. The noticeable shift to negative rotation observed in the pneumatic prosthetic foot with pressure may suggest possible overcompensation from the prosthetic user or uncontrolled ankle stiffness, which may have been excessive in the pressurised condition, resulting in unnatural gait patterns.

There was an interesting observation in Participant 2, when using a prescribed prosthetic foot, of a higher foot rotation compared to that of Participant 1 under a similar condition. However, this foot rotation was still less than that of the contralateral limb. Even though it is common practice for a prosthetist to align the prosthetic side similar to the sound limb for aesthetic reasons, an increased foot rotation, in this case, may reflect individual gait pattern differences or alignment preferences. Using the prescribed prosthetic foot as the baseline, the unpressurised pneumatic foot displayed its ability to maintain the natural alignment of Participant 2, while the pressurised prosthetic foot increased the foot rotation of the prosthetic side. The increase in foot rotation may indicate that the pressurised prosthetic foot may have amplified the deviation in alignment, leading to overcompensation during gait.

5.4.2. Participant 1: Ankle range of motion

The following graph represents the ankle angle trajectory of the right and left side throughout gait for Participant 1 in all three conditions. The ankle angle trajectory data captured during all three conditions are compared to the normative datasets of 244 healthy adults. The zero line on the graph represents the reference angle of the ankle joint, which is 90 degrees, while the space above and below the line represents dorsiflexion and plantarflexion, respectively. The ankle range of motion during gait is determined by adding the peak dorsiflexion angle and the peak plantarflexion angle, while gait phases are represented as a percentage of gait (single stride).

The left ankle joint, which is the amputated side, demonstrated a significant range of motion in the dorsiflexion direction in all three conditions compared to normative data (see Figure 24). This may be due to the inherently higher range of motion offered by the pneumatic prosthetic foot with or without pressure, whereas the SACH foot benefits from the pseudo-range of motion supported by the soft heel and flexible keel. When compared to the normative joint data, the ankle angle trajectory of the pneumatic prosthetic foot has a curve that is similar to the normative data during the stance phase. The similarity in the two curves demonstrates that the pneumatic prosthetic foot, when pressurised, can replicate the normal kinematics during the stance phase. However, four major differences can also be seen from this curve, namely the increased range of motion, the delayed plantarflexion during push-off, the delayed dorsiflexion during the swing phase and the absence of plantarflexion during heel strike. The increased range of motion in the dorsiflexion direction may be due to several factors, such as the inherently large range of motion of the pneumatic prosthetic foot, low and uncontrolled ankle stiffness, and delayed activation of the front sensor, which is responsible for plantar flexion. Controlling the ankle stiffness during the stance phase may assist in both improving the ankle range of motion and plantarflexion timing to closely follow the normative values. Controlling the ankle stiffness means that the ankle stiffness values must change at every instance of gait, with maximum ankle stiffness values located near the push-off initiation time. This facilitates a quicker transition of the centre of mass on the plantar surface of the foot towards the forefoot, where the pressure sensor is located. Meanwhile, during the swing phase, the delayed dorsiflexion demonstrates that there was a slow ejection of air from the cylinder, which slowed down the dorsiflexion. To mitigate this, a larger exhaust valve or an integrated spring with a larger stiffness value is needed to improve the dorsiflexion time. This is supported by the improved ankle kinematics of the pneumatic prosthetic foot in the absence of pressure, which indicates that pressure may have played a role in delaying the dorsiflexion during the swing phase.

In the absence of pressure, the pneumatic prosthetic foot managed to produce a moderate range of motion, with dorsiflexion being more pronounced, while limitations in plantarflexion range of motion were evident. The limitations in plantarflexion range of motion were largely due to the absence of pressure in the pneumatic cylinder, which was limiting the ability of the pneumatic cylinder to produce sufficient force to plantarflex beyond the neutral position. However, the presence of the helical spring managed to bring the foot back to the neutral position, which further contributed to replicating the passive plantarflexion during the heel strike. In terms of replicating the normal ankle trajectory, the pneumatic prosthetic foot without pressure exhibited a prolonged passive plantarflexion, which subsequently delayed the passive dorsiflexion and push-off. The prescribed prosthetic foot had the lowest range of motion out of the three prosthetic feet, which does not go beyond the neutral position in the plantarflexion direction. The dorsiflexion movement was allowed by the flexible keel, which allowed movement in the dorsiflexion direction and back to the neutral position. When compared to the normal ankle angle trajectory, the prescribed prosthetic foot did not replicate the normal movement of the ankle joint, and as a result, there is no distinction between the different activities during the stance phase.

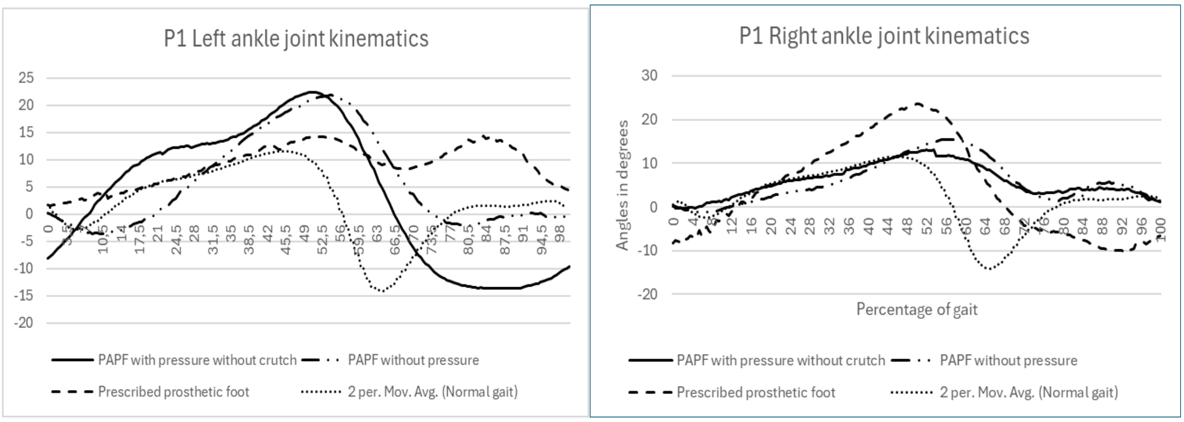


Figure 24: Ankle joint kinematics of Participant 1 under three conditions.

On the contralateral side, the prescribed prosthetic foot demonstrated an increased ankle range of motion, exceeding the normative values. This behaviour may be due to the limited range of motion demonstrated by the prescribed prosthetic foot on the amputated side, which forced the contralateral side to increase the range of motion as a compensation mechanism. On the amputated side, the dorsiflexion was not significantly affected as compared to the plantarflexion range of motion during gait; however, on the sound limb, the dorsiflexion contributed more in terms of the range of motion. The plantarflexion range of motion beyond the neutral position was well within the normative values with a significant delay. The significance of the increased range of motion of the passive dorsiflexion coupled with the longer step length of the sound limb was to advance the centre of mass, which is critical for forward ambulation. Moreover, the increased powered plantarflexion was significant for a smooth centre of mass transition towards the leading limb.

The pneumatic prosthetic foot with and without pressure managed to significantly decrease the overall range of motion of the sound limb during gait. The decrease in range of motion affected both the passive dorsiflexion and powered plantarflexion, which also eliminated the powered plantarflexion that goes beyond the neutral position. This observation indicates that even though the anatomical limb has been lost, the introduction of a mechanical ankle joint that enable sufficient range of motion may eliminate the need for compensation and lower the range of motion of the sound limb. However, minor adjustments need to be effected on the pneumatic prosthetic foot to closely mimic the normative ankle angle trajectories by introducing a different control mechanism that can monitor the plantar pressure while controlling the ankle stiffness.

5.4.3. Participant 2 Ankle range of motion

The ankle joint motion results of this participant reveal significant discrepancies between the walking pattern of the prescribed prosthetic foot and the pneumatic prosthetic foot (see Figures 25 and 26). The introduction of the elbow crutches when using the pneumatic prosthetic foot may have contributed to these discrepancies. On the amputated side (left), the pneumatic prosthetic foot increased the range of motion of the ankle joint beyond the required range, especially in the dorsiflexion direction. When using the prescribed prosthetic foot, the participant exhibited ankle motion closer to normal gait, largely due to the pseudo ankle motion of the Solid Ankle cushion heel, particularly during the push-off phase (57–67% of the gait cycle), where dorsiflexion reached +5° to +10°, similar to able-bodied reference data. In contrast, when walking with the pneumatic actuated prosthetic foot and crutches, the ankle remained more dorsiflexed (positive values) during mid-stance and displayed delayed and reduced plantarflexion, suggesting an over-reliance on the two elbow crutches.

The increased range of motion of the pneumatic prosthetic foot seems to have benefited the sound limb by reducing the range of motion of the sound side during gait. The reduction in the dorsiflexion range of motion indicates the reduced demand for aggressively progressing the stance limb because of the pivoting movement at the ankle level. The decrease in the range of motion during push-off may also indicate the reduced need to propel the body forward due to the added propulsion force present on the prosthetic side.

During the initial contact phase of gait (0–10% gait cycle), the pneumatic prosthetic foot condition demonstrated significant plantarflexion (−9.19° at 10%) compared to the prescribed foot (−5.96° at 0%). This was likely due to altered loading mechanics during the stance phase when using crutches. In mid-stance of gait (10–30%), the prescribed prosthetic foot maintained close to neutral ankle angles, while the pneumatic prosthetic foot remained more plantarflexed, indicating reduced energy return or increased stiffness. The push-off phase (60–80%) was particularly notable, while the prescribed foot achieved smooth dorsiflexion, mimicking natural gait, the pneumatic prosthetic foot with crutches delayed, possibly due to reduced propulsion demand when relying on crutch support.

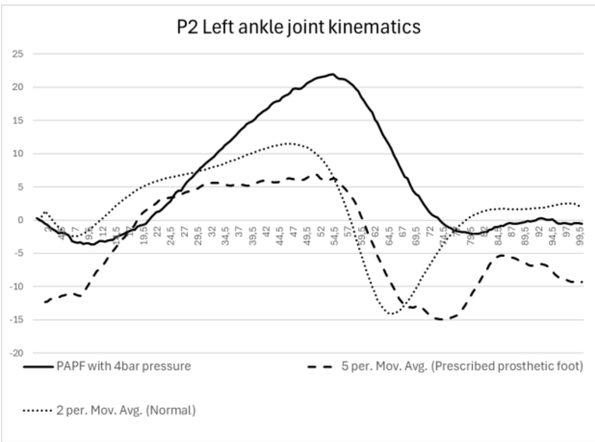


Figure 25: Participant 2 left ankle joint kinematics.

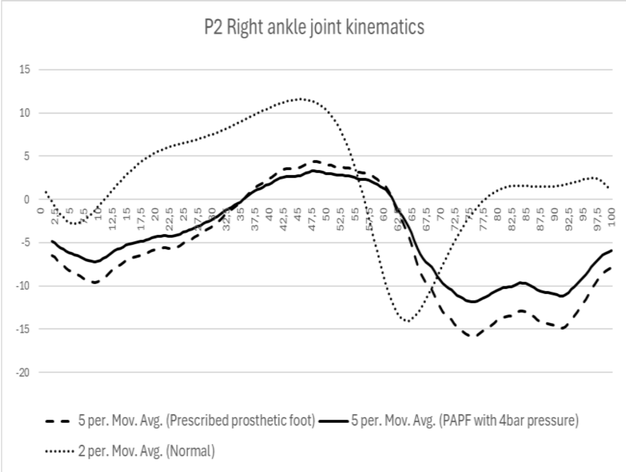


Figure 26: Right ankle joint kinematics for Participant 2.

Overall, the findings suggest that for this participant, the prescribed prosthetic foot allowed for a more natural, independent walking pattern by better replicating normal ankle biomechanics, particularly in energy return during push-off. However, when used with crutches, the pneumatic actuated prosthetic foot alters gait mechanics, leading to excessive plantarflexion and delayed dorsiflexion, potentially due to compensatory unloading of the prosthetic limb. This highlights the importance of prosthetic design optimisation (e.g., adjusting pneumatic pressure or ankle joint stiffness) and gait retraining to reduce crutch dependence when using the pneumatic actuated prosthetic foot.

5.5. Analysis

5.5.1. Vertical ground reaction force

This study compared vertical ground reaction force (vGRF) curves under three prosthetic conditions, namely Prescribed Prosthetic Foot, Pneumatic Prosthetic Foot without pneumatic pressure, and Pneumatic Prosthetic Foot with pneumatic pressure against the standard vGRF curve for normal gait (Senden *et al*., 2024) Key metrics included peak forces (Fz1, Fz2), loading rate, root mean square error (RMSE), and Pearson correlation (r) to assess how closely each condition replicated the natural gait kinetics.

5.5.2. Interpretation Framework

The analysis utilised a biomechanical time-series comparison to evaluate how closely three prosthetic conditions replicated natural gait kinetics in terms of the vertical ground reaction force. The key aspects of the methodology included:

5.5.2.1. Data Normalisation

- All four vertical ground reaction force curves were normalised to 100% of the stance phase (x-axis) and body weight (BW) (y-axis) to facilitate direct comparison of the curves.
- Time was aligned such that peaks (Fz1, Fz2) were identified at consistent % stance phases (Fz1: 20–30%; Fz2: 70–80%).

5.5.2.2. Key Metrics

The peak Forces (Fz1, Fz2) was determined as the magnitude of the body weight (BW) and timing (% stance) of the impact of the first peak (Fz1) and propulsion during the second peak (Fz2). The loading Rate was determined by analysing the slope (BW/s) of the initial 5–15% stance, reflecting the shock absorption phase, also known as the weight acceptance. The root Mean Square Error (RMSE) was used to quantify the deviation from the normal vGRF curve with lower values viewed as a better match. Lastly, the Pearson's *r*atio was used to determine the Correlation coefficient (0–1) measuring curve shape similarity. This was used to determine which condition produced vGRF values that closely matched that of the normal curve.

5.5.2.3. Statistical Validation

- Paired comparisons were conducted, where each prosthetic condition was tested against the normal curve for each participant.
- Thresholds for significance:
  - RMSE < 0.15 and $r > 0.90$ indicated a close match.
  - RMSE > 0.20 or $r < 0.80$ indicated significant deviation.

5.5.3. Participant 1

On the right limb, the pressurised pneumatic prosthetic foot enabled this side to produce a vGRF curve that closely matches the normative vGRF curve (RMSE = 0.09, r = 0.95), demonstrating peaks (Fz1: 1.08 BW, Fz2: 1.01 BW) that are well-balanced. This is an indication that the pneumatic prosthetic foot managed to produce sufficient propulsive force during push-off, which in turn lowered the force burden from the contralateral side. The sound side performance when using the prescribed prosthetic foot was slightly worse (RMSE = 0.11, r = 0.94) but still replicated natural loading patterns seen in the normative vGRF curve. Without pressure, the pneumatic prosthetic foot deviated significantly, showing elevated early loading (Fz1: 1.12 BW) and reduced late-stance propulsion (Fz2: 0.98 BW) on the sound side.

On the Left Limb, which is also the amputated side, similar trends were observed, with the pressurised pneumatic prosthetic foot again demonstrating a curve that closely matched the normative curve (RMSE = 0.08, r = 0.96). However, the unpressurised version of the same Pneumatic Prosthetic Foot exhibited erratic kinetics, including a higher Fz1 (1.10 BW) and lower Fz2 (0.96 BW) than the normal curve. The inability to actively plantarflex during terminal stance greatly affected the unpressurised pneumatic prosthetic foot, making it an undesirable prosthetic device for replicating normal vGRF. While the pressurised pneumatic prosthetic foot demonstrated its ability to improve gait kinetics, normalising peak forces and reducing asymmetry compared to the prescribed and unpressurised pneumatic prosthetic foot, as shown in the table below.

Table 8: Vertical ground reaction forces analysis for Participant 1

Participant 1 vGRF Analysis				
Right Limb				
Metric	**Normal**	**Prescribed Foot**	**PPF w/o Pressure**	**PPF w/ Pressure**
First Peak (BW)	1.07	1.05	1.12	1.08
Second Peak (BW)	1.05	1.03	0.98	1.01
Loading Rate	8.5	8.2	9.3	8.4
RMSE	-	0.11	0.19	0.09
Correlation (r)	-	0.94	0.87	0.95
Left Limb				
Metric	**Normal**	**Prescribed Foot**	**PPF w/o Pressure**	**PPF w/ Pressure**
First Peak (BW)	1.06	1.04	1.10	1.07
Second Peak (BW)	1.04	1.02	0.96	1.00
Loading Rate	8.3	8.0	9.1	8.2
RMSE	-	0.10	0.18	0.08
Correlation (r)	-	0.95	0.88	0.96

5.5.4. Participant 2

On the Right Limb, also referred to as the sound limb, the prescribed prosthetic foot closely matched the normal kinetics better than the pneumatic prosthetic foot (RMSE = 0.15, r = 0.91), though with slight overloading (Fz2: 1.09 BW) during the push-off phase. The pneumatic prosthetic foot with pressure demonstrated underloaded peaks (Fz1: 0.66 BW, Fz2: 0.86 BW) with better correlation (r = 0.85) than the unpressurised pneumatic prosthetic foot. In the absence of pressure, the pneumatic prosthetic foot exhibited a catastrophic failure, with peaks <60% of normal (Fz1: 0.55 BW, Fz2: 0.54 BW) and poor correlation (r = 0.45). Even though the right side was the sound limb, the inability of the pneumatic prosthetic foot to closely mimic the anatomical ankle movements and reduced balance greatly influenced the vertical ground reaction force data.

On the left amputated limb, results mirrored the right limb, with the prescribed foot demonstrating superiority, while the pneumatic prosthetic foot without pressure was severely underloaded (Fz1: 0.53 BW, Fz2: 0.52 BW). In the case of Participant 2, The pneumatic prosthetic foot did not improve gait kinetics in terms of the vertical ground reaction force data. The prescribed foot remained the better option out of the three conditions, when compared to the normative vGRF curve, while the unpressurised pneumatic prosthetic foot condition was non-functional.

Table 9: A vertical ground reaction force analysis for participant 2

Participant 2 vGRF Analysis				
Right Limb				
Metric	**Normal**	**Prescribed Foot**	**PPF w/o Pressure**	**PPF w/ Pressure**
First Peak (BW)	1.07	1.08	0.55	0.66
Second Peak (BW)	1.05	1.09	0.54	0.86
Loading Rate	0.09	0.10	0.03	0.06
RMSE	-	0.15	0.35	0.18
Correlation (r)	-	0.91	0.45	0.85
Left Limb				
Metric	**Normal**	**Prescribed Foot**	**PPF w/o Pressure**	**PPF w/ Pressure**
First Peak (BW)	1.06	1.09	0.53	0.65
Second Peak (BW)	1.04	1.06	0.52	0.84
Loading Rate	0.08	0.09	0.03	0.06
RMSE	-	0.14	0.34	0.17
Correlation (r)	-	0.92	0.46	0.86

5.5.5. summary

The pneumatic prosthetic foot improved gait kinetics for Participant 1, demonstrating its potential to replicate natural loading patterns when properly tuned. However, for Participant 2, the prescribed non-pneumatic foot performed better, highlighting individual variability in prosthetic response. The non-pneumatic condition was unsuitable for both participants, causing either overloading (Participant 1) or severe underloading (Participant 2). The results clearly indicate that the pneumatic prosthetic foot may benefit some prosthetic users but require individualised refinement. On the other hand, the solid ankle cushion heel feet remain a reliable option when pneumatic prosthetic feet are ineffective; the unpressurised pneumatic prosthetic foot in its current state should be avoided due to the inability to replicate the normal gait kinetics.

5.5.6. Symmetry index

The symmetry index (SI) was calculated using the Robinson SI (Robinson, Herzog & Nigg 1987), comparing the left and the right sides during gait to assess the symmetry between the sound limb and the prosthetic side during gait. The following formula was used to calculate the symmetry index:

$$Symmetry\ Index = \frac{2 \times (X_{Sound\ limb} - X_{Prosthetic\ side})}{X_{Sound\ limb} + X_{Prosthetic\ side}} \times 100$$

A number that is closer to zero indicates a more symmetrical gait pattern, which is key for forward ambulation, while a number that is further away from zero indicates a more asymmetrical gait pattern. The number represents how asymmetrical the parameter was, while a positive or a negative sign represents the side that contributed more to the specific parameter during the gait cycle. A positive sign indicates that the sound limb contributed more, whereas a negative sign indicates that the prosthetic side contributed more. The sign, however, does not give a clear indication of the side that contributed to the resultant asymmetry. The table below contains the values of the symmetry index

Table 10: The results of the symmetry index

Symmetry index %			
	condition 1	**Condition 2**	**Condition 3**
Peak force	-4,18	38,795	-3,21
	1,09	68,74	43,18
Step length	-1,869	-19,469	-3,51
	9,9	46,7	41,51
Stance time	-1,19	15,59	2,099
	1,76	18,9	17,19
Swing time	4,86	-33,28	-12,01
	-6,92	-24,94	-29,76

A symmetry index that was between 0%-5% represented a highly symmetrical gait pattern, and a number that wass greater than five percent but less than ten percent indicated a moderate symmetrical gait pattern, while 10-20% represented a moderate asymmetrical gait pattern, and lastly, a severe asymmetrical gait pattern was identified by values greater than 20% . The comparison was between the amputated side and the sound side in each condition. Condition 1 was when the participant was ambulating using the prescribed prosthetic foot, condition 2 was ambulation with a pneumatic prosthetic foot without pressure, and lastly, condition3 which was ambulation with a pneumatic prosthetic foot with pressure.

Participant 1 demonstrated a highly symmetrical gait under all parameters when using the prescribed prosthetic foot. However, even though the gait was highly symmetrical when analysing the four parameters, there was no perfect symmetry between the left and the right side. It is also worth noting that the variations between the left and the right limb were quite minimal, representing normal variations for normal gait. When the same participant used the pneumatic prosthetic foot without pressure, the level of asymmetry was hovering between moderate and severe. The asymmetries observed in peak force and swing % are characterised as severe, which indicates that further gait training or prosthetic adjustment is needed as these asymmetries may result in major compensation during gait and lower gait efficiency. The step length and stance% were moderately asymmetrical, which may lead to minor gait deviations and compensation. When the pressure of 4bars was introduced to the same pneumatic prosthetic foot, the gait symmetry of participant 1 improved significantly, with parameters like peak force, step length and stance time demonstrating a high level of symmetry, while swing time % showed moderate asymmetry. This data indicates that the use of the pressurised version of the pneumatic prosthetic foot, may increase contribution to the gait cycle, leading to a more symmetrical gait pattern. Given the positive results that the pneumatic prosthetic foot demonstrated, it is also significant to report that the level of symmetry attained when using the pneumatic prosthetic foot does not outperform the prescribed prosthetic foot.

Participant 2 demonstrated mild asymmetries in swing% and step length and a high level of symmetry in peak force and stance time. It is quite unclear why the prosthetic side of this participant would have more contribution in swing%, while the sound side contributed more in step length. The swing phase allows the leg that is in the swing to progress; it is quite expected that the leg that spends more time in the swing phase would have a longer step length because the leg had more time to cover the angular and linear distances. However, if the angular speed of the leg in the swing phase is less than that of the contralateral swing, the discrepancy would be understandable. When this participant used the pneumatic prosthetic foot without pressure, it was largely severe, with the exception of the stance %, which was moderately asymmetric. The gait pattern of this participant presented significant compensation and deviation, and as a result, the participant used elbow crutches to locomote. When the same pneumatic prosthetic foot was pressurised, the walking pattern of this participant did not improve in terms of symmetry, resulting in a walking pattern that is severely asymmetrical. Significant gait contribution in terms of peak force, step length and stance % was largely noticeable, indicating that this participant relied heavily on the sound side. This significant reliance on the sound limb may emanate from a number of reasons, some of which may be patient-related or prosthetic-related. One of the reasons could be the differences in ankle stiffness between the two prostheses, insufficient energy return from the prostheses, the differences in prostheses mass, fear of falling, perceived instability, reduced proprioception, anatomical joint stiffness or habitual gait asymmetry.

In summary, participant 1 showed improved gait symmetry when using the pressurised pneumatic prosthetic foot, indicating an improved balance, but the same prosthetic foot had a negative effect on Participant 2. The severe levels of asymmetries demonstrated by both participants 1 and 2 when using the unpressurised pneumatic prosthetic foot indicate that pressure is a key factor in improving the level of function. Moreover, the differences in response between participants 1 and 2 highlight the effects of both prosthetic-related and patient-related factors, as well as the significance of refining pneumatic prosthetic foot to meet individual prosthetic needs.

5.6. *Summary of results*

5.6.1. Spatiotemporal Parameters

The comparison of spatiotemporal parameters between the prescribed prosthetic foot and the pneumatic prosthetic foot revealed significant variations in gait biomechanics. Participant 1 demonstrated a longer stride length when using the pneumatic prosthetic foot without pressure, reaching 114 ± 4 cm, compared to the prescribed foot. This increase in stride length may indicate more significant forward progression; however, it also raises concerns about mediolateral stability and control. In contrast, Participant 2 exhibited a slight reduction in stride length with the pneumatic foot when pressurised (106 ± 3 cm), possibly suggesting limited propulsion or energy return. The observed differences between participants emphasise the individualised nature of prosthetic adaptation, where increased stride length does not necessarily equate to improved function. However, the observed results of Participant 2 must be looked at with caution, as this participant was ambulating with the assistance of a walking aid, and this interfered with the outcomes of the intervention (powered prosthetic ankle). Step width was another important parameter affected by the prosthetic conditions. The effects of the observed increase in stride length must be compared with step width in order to determine the impact of these changes in maintaining mediolateral stability. Participant 1 decreased step width with the pneumatic prosthetic foot when pressurised (7 ± 1 cm) compared to the prescribed prosthetic foot (13 ± 3 cm). This reduction suggests an enhancement in forward propulsion at the potential expense of lateral stability. Participant 2, however, maintained a relatively stable step width across conditions, implying that the use of elbow crutches negated the influence of the prosthetic foot in maintaining mediolateral stability. The variation in step width between the two participants is of concern; however, the current results do not provide sufficient information to establish any correlation between forward propulsion and mediolateral stability.

Further gait efficiency differences were highlighted by stride time and cadence, and these two parameters may influence the resultant velocity. An increase in stride time may indicate a slower gait as this means the participant spends more time completing a stride, while the cadence reflects the step frequency, however, without looking at the stride length, this relationship is incomplete. For Participant 1, the longest stride time was observed with the pneumatic foot without pressure (1.55 ± 0.02 s), likely due to a slower walking speed caused by insufficient propulsive force. However, when pressure was introduced, cadence increased to 104 ± 6 steps/min, while the stride time decreased, leading to an improvement in velocity (3.5 ± 0.3 km/h). Conversely, the second participant displayed the highest cadence and velocity with the prescribed prosthetic foot, while the pneumatic foot with pressure resulted in lower values (57 ± 1 steps/min cadence, 1.8 ± 0.1 km/h velocity). These findings suggest that while the pneumatic prosthetic foot can enhance walking efficiency, the benefits of the pneumatic prosthetic foot are individualised. In order to achieve similar benefits, some users may require an extended adaptation period or additional mechanical optimisation to suit individual needs.

5.6.2. Kinetics

A variation was observed on the second peak of the vertical ground reaction force curve, which provided insights into the propulsive force efficiency of the pneumatic prosthetic foot. Both participants exhibited lower peak forces when using the pneumatic foot without pressure, likely due to the significant reduction in energy return, which may disturb weight transfer. For Participant 1, peak force values increased when the pneumatic foot was pressurised, approaching levels observed with the prescribed prosthetic foot (605.9 N vs. 693.6 N on the prosthetic side). This highlights the benefits of injecting an external force to facilitate propulsion; even though these results are not impressive and do not show any dominance of the pneumatic prosthetic foot over the passive prescribed foot, improving adaptation to the pneumatic prosthetic foot may yield different results. These results were not replicated or improved by Participant 2, as peak forces during push-off remained lower than those recorded with the prescribed prosthetic foot. The observed discrepancy may indicate an ongoing adaptation challenge or an inherent limitation in the pneumatic system's ability to match the energy return characteristics of the prescribed foot. Moreover, the biomechanical limitations and inherent comorbidities of Participant 2 may have played a significant role in delaying adaptation to the pneumatic prosthetic foot. The inability to match the

The asymmetry in load distribution further supports the need for individualised prosthetic tuning. The pneumatic foot without pressure exhibited the lowest peak forces, which could contribute to reduced stability during stance. While the pressurised pneumatic foot improved force generation for Participant 1, it did not fully match the effectiveness of the prescribed prosthetic foot. This reinforces the importance of adjusting the pressure settings to optimise energy return and ensure proper weight distribution for each user.

5.6.3. Kinematics

The analysis of kinematic parameters, particularly foot rotation and joint range of motion, revealed notable differences between conditions. Participant 1 demonstrated increased foot rotation when using the pneumatic prosthetic foot without pressure (5.2° ± 0.7°), suggesting a potential reduction in stability due to the introduction of a free-moving ankle joint. When pressure was applied, foot rotation shifted to -5.9° ± 1.2°, which may indicate overcompensation or excessive ankle stiffness, leading to an unnatural gait pattern. Participant 2 exhibited more consistent foot rotation, but the pneumatic foot with pressure resulted in a higher angle (19.4° ± 1.4°), suggesting that alignment deviations may have contributed to altered walking mechanics.

These findings highlight the importance of proper alignment and tuning when introducing pneumatic actuation into prosthetic designs. While the flexibility of the pneumatic foot offers potential advantages in mimicking natural ankle motion, it also introduces variability that may require extensive adjustment. The increased foot rotation observed in some conditions could negatively impact joint stability and gait efficiency, reinforcing the need for further optimisation of the pneumatic prosthetic foot's stiffness and compliance.

Overall, the pneumatic prosthetic foot demonstrated the ability to influence gait biomechanics, particularly in terms of stride length, cadence, and propulsion efficiency. However, the effects varied between participants, highlighting the importance of personalised prosthetic adjustments. While Participant 1 benefited from increased stride length and improved force generation when pressure was applied, Participant 2 struggled with adaptation, experiencing reduced cadence and velocity. Ground reaction forces were lower with the unpressurised pneumatic foot, but applying pressure partially mitigated this issue, particularly for Participant 1.

The kinematic analysis suggests that while the pneumatic foot enhances flexibility and mobility, it may also introduce alignment challenges that could impact gait stability. Fine-tuning of the prosthetic foot's mechanical properties, such as pressure levels, ankle stiffness, and rotational control, is essential to optimising its performance. Future research should focus on increasing the sample size, refining pressure modulation strategies, and conducting long-term adaptation studies to determine the full potential of pneumatic actuation in lower-limb prosthetics.

6. Discussion

6.1. Spatiotemporal parameters: Asymmetry and gait efficiency

The pneumatic prosthetic foot in both the pressurised and unpressurised state managed to increase the stride length of participants 1 and 2 while decreasing the step width of both participants. The increased stride length does not universally improve the efficiency of gait, especially when it reduces step width. Walking with an increased step width is a common occurrence in transtibial amputees and has been reported to increase the gluteus medius activation during gait (Kubinski *et al*., 2015; Varrecchia *et al*., 2019). This phenomenon may seem to favour mediolateral stability, but it is not ideal for energy conservation during gait. The average step width for slow walking is reported to be 10cm (Lee *et al*., 2011); however, another study reported that the preferred step width is 0,135 of the leg length (Donelan *et al*., 2001). When calculating the preferred step width for participants 1 and 2, the values are 12,6cm and 12,3cm, respectively, which are slightly lower than their average step width of 13cm and 17cm when using the prescribed prosthetic foot. The limited range of motion on the sound side in Participant 2 may have introduced a level of instability during gait, leading to the exaggerated step width that is close to that observed in bilateral transtibial amputees in slow walking (Mohanty *et al*., 2020; Su *et al*.,2007) The reduced step width displayed by both participants may be driven by different factors, which were also evident in the quality of gait. Participant 2 benefited from the use of elbow crutches that assisted in improving mediolateral stability, decreasing the need for wider steps, while Participant 1 drastically increased the stride length, especially when using the unpressurised pneumatic prosthetic foot, which may be a reflection of compensatory overstriding to maximise forward progression. This is a common strategy that has been previously observed in amputees with low push-off capacity and has been proven to compromise gait energetics as this is seen as a trade-off between energy economy and task goal variability in above-the-knee amputees (Lee *et al*., 2022; Winter & Sienko, 1988).

The introduction of a pneumatic prosthetic foot on both participants proved to influence cadence and velocity, even though the results differed for each participant. For participant 1, there was an improvement in velocity and cadence when using the pressurised pneumatic prosthetic foot. However, there was a decline in velocity and cadence when using the unpressurised pneumatic prosthetic foot. This observation indicates that the energy return mechanism had a direct influence on velocity and cadence, aligning with previous studies on active prosthetic feet (Colas-Ribas *et al*., 2022) . In contrast with this observation, participant 2 demonstrated a decline in velocity and cadence when using the pneumatic prosthetic foot. This comes as no surprise, as this participant was relying heavily on elbow crutches, with the ankle joint on the sound side demonstrating a limited range of motion, negating the benefits of energy return. These observations emphasise that energy return alone can not overcome the intrinsic neuromuscular, anatomical, and physiological constraints of the human body, aligning with broader literature (Tran et al., 2022; Prost *et al*., 2021) . The influence of the pneumatic prosthetic foot on velocity and cadence during gait seems to be patient-specific, depending on the ability to harness the external energy injected into human gait.

Individual adaptation capacity is another factor that needs to be considered, as this may dictate the success of a prosthetic device. Participant 1 presented more favourable biomechanical conditions, including more recent amputation, which likely facilitated adaptation to the new prosthetic device. This is supported by studies showing that adaptation periods can enhance energy return and gait symmetry when transitioning to new prosthetic devices (Zhang *et al.*, 2018). In contrast, participant 2 demonstrated biomechanical limitations facilitated by the joint pathomechanics and compromised foot structure integrity. Also, participant 2 has been using a prosthetic leg for more than two decades, and judging from the biomechanical data attained during trials, this participant has developed compensatory techniques and entrenched gait habits that are deeply ingrained. This is consistent with literature showing long-term musculoskeletal adaptations such as reduced muscle mass and joint stiffness (Fleischer *et al.*, 2022). As a result, participant 2 felt more comfortable and performed better when using the prescribed prosthetic device as opposed to the pneumatic prosthetic foot, because the prescribed prosthetic foot was familiar. The comfort and performance observed with the prescribed device may reflect both biomechanical familiarity and reduced neuromuscular plasticity, aligning with findings that long-term prosthetic users may exhibit resistance to postural and gait adjustments (Sadeghi *et al.*, 2001). These made it difficult for Participant 2 to imitate normal gait mechanics when using the pneumatic prosthetic foot, leading to compensatory gait patterns. While some studies suggest that the time since amputation alone may not directly correlate with functional control (e.g., postural stability), the combined effects of duration, joint pathology, and habitual motor patterns appear to have influenced this participant's adaptation capacity.

6.2. Kinetics: Energy Return and Asymmetry

Kinetic responses of the two individuals to the pneumatic prosthetic foot revealed that load symmetry and energy return are highly dependent on the biomechanical condition of the contralateral limb and user adaptability. Participant 1, who had a more recent amputation relative to the second participant and no apparent comorbidities, demonstrated a favourable kinetic profile when using the pressurised pneumatic foot. The vertical ground reaction force (vGRF) data revealed a strong similarity to normative data, with a root mean square error of 0.08 and a correlation coefficient (r) of 0.96 when comparing the vertical Ground Reaction Force curve of the pneumatic prosthetic foot to that of a normal biological foot. Moreover, a near-equal loading between the two limbs was observed when looking at the peak force symmetry index (SI) of −3.21%, highlighting the ability of the pneumatic prosthetic system to promote balanced gait in users with sufficient neuromuscular adaptability. These findings are consistent with the findings of previous studies, which reported that powered prostheses improve limb load symmetry and load sharing, reducing the tendency of overloading the sound limb (Hill & Herr 2015) The sound limb overloading has been shown to increase the likelihood of developing knee osteoarthritis (Russell Esposito & Wilken 2014). Therefore, the kinetic data of Participant 1 highlights the significant role played by the pneumatic prosthetic foot in attempting to preserve the anatomical structure of the knee on the sound side.

In contrast, when the pneumatic prosthetic foot was not pressurised, Participant 1 exhibited a less stable kinetic response. The second peak of the vGRF (Fz2) dropped to 0.96 times body weight, indicating poor push-off and erratic energy transfer. This kinetic profile is consistent with the limitations of passive feet, which have limited capacity for energy storage and return during the late stance phase, as discussed by Herr and Grabowski (2012). These observations suggest that pressurisation of the pneumatic prosthetic foot can significantly normalise gait kinetics in users with the biomechanical capacity for adaptation, while an unpressurised pneumatic prosthetic foot negates these benefits and reproduces the energy deficits typically observed in passive devices.

The kinetic performance of Participant 2 further emphasised the significance of the role played by the contralateral limb health in determining prosthetic success. This participant presented with significant biomechanical constraints, including ankle fixators on the sound limb that limit the range of motion, which resulted in abnormal load distribution patterns. The first vGRF peak (Fz1) was markedly reduced to 0.53 times body weight, suggesting significant underloading of the prosthetic limb and compensatory overuse of the contralateral side. This deviates from the characteristic double-hump pattern observed in normal vGRF curves and instead exhibits a more parabolic curve, indicating a "support-dominant" gait strategy. Such a strategy reflects an attempt to avoid discomfort and preserve stability on the structurally compromised sound side, consistent with the findings of Morgenroth *et al*. (2011), who noted that users with joint pain or instability tend to adopt compensatory loading strategies that reduce effective prosthetic function.

Additionally, Participant 2 used crutches during trials, which further altered load-bearing dynamics and masked the contribution of the pneumatic prostheses to gait. Crutch use shifts body weight away from the lower limbs and can disrupt natural force transmission, thereby complicating the interpretation of the kinetic efficacy of the prosthesis. In such complex cases, external assistive devices may obscure whether reduced performance is a function of the prosthetic design or a result of altered whole-body mechanics. Therefore, while the pneumatic foot as a powered prosthetic device has the potential to normalise loading, its effectiveness is highly contingent upon the user's biomechanical context and the absence of secondary supports.

Interestingly, higher peak force values were observed when Participant 2 used the prescribed prosthetic foot, custom-made and accustomed to over many years, achieving 855.9 N compared to the pneumatic foot's 442.4 N. This significant difference suggests that a prescribed prosthetic foot may offer more reliable load-bearing performance in individuals with comorbidities and entrenched compensatory strategies, though this device may be biomechanically passive. For users with greater prosthetic experience, exhibiting compromised contralateral joints, or using additional assistive devices, the familiarity and mechanical predictability of a prescribed foot might allow for more confident weight transfer and greater limb engagement. This supports a pragmatic approach in prosthetic prescription, where optimal device selection may not hinge solely on innovation but also on contextual fit with the user's motor behaviour, joint integrity, and assistive requirements.

In summary, these findings demonstrate that prosthetic success from a kinetic perspective is not universally dictated by technological advancement but rather mediated by user-specific variables. Adaptable users with healthy contralateral limbs can benefit from the enhanced energy return and loading symmetry of pneumatic systems. However, in users with biomechanical limitations, the advantages of such systems may be constrained, and familiar prescribed feet may offer more practical support for everyday function. These insights highlight the need for individualised prosthetic evaluation frameworks that account for adaptation potential, contralateral limb health, and habitual gait strategies.

6.3. Kinematic changes and joint behaviour

Ankle Motion and Range of Motion

The use of a pneumatic prosthetic foot improved the ankle range of motion in both pressurised and unpressurised states due to the articulation at the ankle level. The ankle articulation, together with active control of the ankle joint, demonstrated significant improvement in the ankle angle trajectory of the prosthetic side, resulting in an ankle angle trajectory curve that resembles the normative curve. These improvements were present in both participants, demonstrating the influence of a powered prosthetic ankle joint in replicating the normative curve. This is a continuation of a pattern observed in previous studies that evaluated the kinematic beneficence of using powered prosthetic feet (Gabert *et al*., 2020) Moreover, this study did not evaluate if the observed improvements in the kinematic characteristics of the ankle joint translate to improved energy efficiency. However, evidence suggests that transtibial amputees that demonstrate significant improvement in joint kinematics when using powered prosthetic devices, improving energy efficiency during gait (Kim *et al.*, 2021).

There were some concerns regarding the ankle kinematic curve of both participants when using the powered pneumatic prosthetic foot. The notable absence of passive plantarflexion during the early stages of gait is most likely caused by the delay of the exhaust valve in releasing air from the cylinder. This observation is of concern because the role of passive plantarflexion is to absorb the shock of initial impact with the ground, minimising the mechanical stress on anatomical structures. This observation was also supported by the steep vertical ground reaction force curve from the initial contact to the first peak of Participant 1, comparable to that of the prescribed passive prosthetic foot. Some of the implications of the absence of a shock absorption phase in gait are increased joint stress that results in degenerative joint disorders and lower back pain (Buckwalter *et al*.,2013)

During the swing phase of gait, there was a significant delay in the passive dorsiflexion of the pneumatic prosthetic foot. The delay in passively dorsiflexing the ankle joint during the swing phase may interfere with the ability of the amputated limb to shorten and clear off the ground, facilitating limb progression. A similar observation may be seen in patients with weak dorsiflexors and drop foot, which results in the body exaggerating knee flexion to compensate for the delayed ankle dorsi flexion(Wiszomirska *et al.*, 2017). Without any compensation for the limb length, patients are more likely to trip and fall, resulting in injuries. This observation is of primary concern and needs to be addressed by either substituting the spring responsible for elongating the single-acting cylinder or by changing the exhaust valve to improve airflow. In a previous study that evaluated a double-acting pneumatic prosthetic foot these challenges were not present likely due to improved control offered by the powered dorsiflexion(Zheng & Shen, 2015) However, air consumption of a double-acting cylinder limits the feasibility of being used outside the laboratory environment. Overall, the pneumatic prosthetic foot did not closely follow the normal ankle joint trajectory due to the increased range of motion, the inability to replicate the biological ankle stiffness values, and the limited capabilities of the implemented control system.

6.3.1. Foot Rotation and Alignment Stability

The observed foot rotation increase in Participant 2 when using the pneumatic prosthetic foot (19.4° ± 1.4°) was due to the efforts made to match the contralateral side foot rotation of 21,6±2,0. It is common practice that the prosthetic foot is rotated to replicate the sound side to make the prosthetic foot look aesthetically appealing. However, general literature recommends external foot rotation values of five to fifteen degrees to enhance walking biomechanics and also acknowledging that transtibial amputees are able to control foot rotation at the hip level (Fridman, Ona & Isakov 2003)(Fridman, Ona & Isakov 2003) Concerns have been raised regarding the effective lever arm of the foot, suggesting that five degrees of external rotation yield the maximum effective lever arm(Major *et al.*, 2012) There seems to be no consensus on the optimal foot rotation alignment in the coronal plane, while some studies suggest the inclusion of kinetics when performing dynamic alignment (Jonkergouw *et al.*, 2016) In clinics and public hospitals, the inclusion of kinetics when performing dynamic alignment is not feasible due to the unavailability of measuring tools and the high cost of purchasing pressure mats. In light of this, the results highlight that the participant who demonstrated the highest benefit from using an active pneumatic prosthetic foot had external rotation values that fell between zero and seven. However, it is not yet clear whether these external rotation values were largely because of misalignment or overcompensation, but in future, adjustments in alignment or stiffness modulation may be required to restore normal biomechanics.

6.3.2. Contralateral Compensatory Kinematics

On the contralateral side, the pneumatic prosthetic foot showed to have an influence by reducing the range of motion in both dorsiflexion and plantarflexion directions. This reduction was observed in both the pressurised and unpressurised states of the pneumatic prosthetic foot, signalling that this change was likely due to the articulation at the mechanical ankle level. The mechanical ankle articulation facilitated forward progression during midstance, reducing reliance on the sound limb biological ankle joint. There was a minor reduction in the range of motion of the sound side when the pneumatic prosthetic foot was pressurised, highlighting the minor role played by pressurisation when likened to ankle articulation. The pressurised pneumatic prosthetic foot appeared to minimise compensatory movements on the sound limb, however. minimising such compensations is essential for preventing secondary musculoskeletal issues and enhancing overall mobility (Li *et al.*, 2024).

6.4. Individual Adaptation and User Response

There was a variation in the time it took for the 2 participants to adapt to the pneumatic prosthetic foot. This time was influenced by factors that are participant-specific, such as time since amputation and pre-existing comorbidities. The participant with a longer prosthetic history and internal joint fixators on the contralateral limb exhibited different gait adaptations compared to the other participant. The internal fixators on the sound limb limited the range of motion of the ankle joint, and this participant has been living with this biomechanical limitation for more than a decade. Also, considering that the two prosthetic feet used in this study exhibited vastly different mechanical capabilities, which may have led to different operational requirements due to their gait contribution. This participant needed more time to unlearn the entrenched biomechanical behaviours of ambulating with a prosthetic foot in order to learn and adapt to the new prosthetic device. This process can, in future, be facilitated by targeted rehabilitation methods for unlearning maladaptive behaviours (Levin & Demers, 2021). The differences in biomechanical behaviours exhibited during locomotion highlight the necessity for personalised prosthetic solutions and the consideration of individual user characteristics in prosthetic design and rehabilitation. The prosthetic solution must also be dynamic enough to adapt to varying mechanical needs during gait, which is also a recommendation for an improved control system that can cater for varying ambulatory needs. This is because normal human locomotion occurs as a result of an enhanced interaction between the biological structures and the environment, which can not be pre-planned but requires consistent adaptation to changes.

6.5. Implications for Pneumatic Foot Design

The findings have demonstrated the potential strengths and current weaknesses of the interim pneumatic prosthetic foot prototype. The major weakness of the current design was adjustability and adaptability, which are partly inherent to the control system used to control the ankle movement. Suggesting that further optimisation is required for the pneumatic prosthetic feet and developing new features like adjustable stiffness capacity and pressure settings that can enhance gait biomechanics. Adjustable ankle stiffness can be achieved in various ways, one of which is by adopting the double-acting pneumatic cylinder to facilitate ankle movements. This strategy was once adopted by Zheng and Shen (2015); however, practical limitations hindered the development and adoption of this innovation outside of the laboratory environment. The major obstacle with the use of pneumatic systems in mobility aids and mobile medical devices is a component like air storage tanks, which, due to the air requirements of these systems, cannot be fitted within the confinement of the biological leg volume. A solution that can potentially work for the current pneumatic prosthetic foot design is to increase the spring stiffness and make it slightly more than the preferred plantarflexion stiffness (Clites *et al*., 2021), to enhance reliance on a pneumatic cylinder for ankle stiffness modulation. Features such as real-time stiffness modulation and adaptive control systems may improve user outcomes and enhance individuality. Future designs must explore sensor-based feedback mechanisms that should be integrated not only for data collection purposes but also to enhance prosthetic control and tailor prosthetic responses to individual gait patterns (Li *et al*., 2024).

7. Conclusion

This study comprehensively explored the biomechanical performance during walking trials and the practicality of employing a pneumatic prosthetic foot compared to the passive prosthetic feet (Solid Ankle cushion Heel) that were prescribed to the two amputee participants. The findings of the study highlight the relationship between user-specific factors, prosthetic design outcomes and biomechanical outcomes. For Participant 1, the pneumatic prosthetic foot, particularly when pressurised, demonstrated a clear capacity to enhance gait dynamics. Improvements were noted in stride length, cadence, and velocity, approaching levels comparable to that of able-bodied gait. The pressurised pneumatic foot also promoted more symmetrical loading, as evidenced by a near-normal vertical ground reaction force (vGRF) curve and an increased symmetry index, suggesting the potential for partial restoration of natural gait mechanics. These improvements can be attributed to the active push-off provided by the pneumatic prosthetic foot, which facilitated more dynamic propulsion during late stance. Furthermore, the kinematic analysis showed that the pneumatic prosthetic foot more closely replicated the shape of normative ankle joint trajectory, supporting the potential for restoring natural ankle mechanics.

However, even in Participant 1, the pressurised pneumatic foot did not outperform the prescribed passive foot across most parameters, indicating that while pneumatic actuation offers advantages, it does not fully replace the functional stability and familiarity of well-fitted passive designs. In contrast, additional challenges faced by Participant 2 due to the sound-side joint limitations and reliance on mobility aid negated the benefits of a pneumatic prosthetic foot. The reliance of this participant on elbow crutches heavily affected the load distribution across both feet, likely shifting the load away from the feet and towards the upper limbs, which diminished the kinematics and kinetics advantages of using the pneumatic prosthetic foot. This highlights user-specific factors such as residual limb health, contralateral limb function, and long-standing gait adaptations in shaping prosthetic performance outcomes. While the pneumatic foot theoretically offers improved push-off and dynamic stability, these benefits are constrained if the user cannot effectively utilise them due to underlying musculoskeletal or neuromuscular limitations. In fact, Participant 2 achieved superior performance with their familiar prescribed foot, illustrating how entrenched motor patterns and biomechanical compensations may override the theoretical benefits of new prosthetic technologies.

The kinetic data also revealed that the absence of pressure in the pneumatic foot significantly diminished its capacity for energy return and effective weight transfer, highlighting the necessity of active pressurisation for optimal performance. The pneumatic prosthetic foot, in its unpressurised state, demonstrated a reduction in peak force and pronounced gait asymmetries in both participants, reinforcing the need to maintain pressurisation of the prosthetic foot during use. Additionally, observed delays in dorsiflexion during swing and increased foot rotation during stance in some conditions suggest that further prosthetic control improvements, such as modulation of ankle stiffness and improved ankle torque approximation, are needed to mimic the biomechanical ankle function closely. Most importantly, while the pneumatic foot improved specific gait parameters for Participant 1, these improvements did not universally translate to a more energy-efficient or symmetrical gait for Participant 2. These findings highlight the need for a patient-specific approach in prosthetic prescription, one that carefully considers not only the technical capabilities of the device but also the user's biomechanical and functional capacity to adapt to new technologies. The observations align with existing literature that emphasises the interplay between prosthetic design and individual neuromuscular adaptation in achieving optimal outcomes.

The study also revealed limitations in the current pneumatic foot design, particularly in replicating the passive shock absorption during heel strike and ensuring a timely dorsiflexion response during swing. These are critical aspects of normal gait that, if not addressed, may compromise long-term joint health and increase the risk of falls. Future development of pneumatic prosthetic feet should focus on refining control algorithms to better mimic natural ankle stiffness modulation and improve responsiveness during rapid phase transitions. Moreover, the small sample size in this study, while providing comprehensive case-specific insights, limits the generalisability of the findings to the broader population of below-knee amputees. Future research should include a larger and more diverse cohort to assess the broader applicability of pneumatic actuation in lower-limb prosthetics. Longitudinal studies evaluating the effects of extended acclimation periods would also be valuable, as they may reveal whether initial adaptation challenges can be overcome with time and training.

7.1. Evaluation of research questions

The study results show that enough data was collected to answer the research questions posed in the previous chapter. Three questions were posed, each seeking to address specific parameters of gait. The first question considered the kinematic parameters to determine the discrepancies in joint angle trajectories when participants walked with the pneumatic prosthetic foot compared to their prescribed passive device. The results show that the pneumatic prosthetic foot allowed for a more physiological pattern of ankle motion. Even though the pneumatic prosthetic foot did not replicate the ankle joint kinematics of a biological ankle close enough, participants demonstrated improved dorsiflexion during midstance and more controlled plantarflexion during push-off. The presence of joint motion during gait suggests that the pneumatic actuator was able to replicate the function of the ankle plantarflexors and dorsiflexors. While these results are welcome, more improvements are still required, and data from more proximal joints are needed to study how the pneumatic prosthetic foot influences the knee and the hip. This outcome affirms the hypothesis that targeted actuation can positively influence ankle kinematics, supporting the premise that even limited active control has measurable functional benefits.

The second research question focused on the differences in vertical ground reaction forces (vGRFs) and plantar pressure distribution between the two prosthetic foot conditions. The vertical force results revealed that the pneumatic foot reduced peak impact forces for both participants at heel strike and continued to produce a smoother force progression for participant 1 throughout the stance phase. However, these benefits were only observed in participant 1, while participant 2 showed minimal benefits and over-reliance on elbow crutches. These differences in the gait kinetic improvements are clinically relevant, as rapid impact loading and unnatural force transitions have been linked to discomfort, instability, and long-term joint degeneration in amputee populations. By promoting a more even force distribution, the pneumatic design may reduce compensatory loading on the contralateral limb, lowering the risk of overuse injuries. The results provide a strong case for including single-acting pneumatic actuation mechanisms in future prosthetic developments, especially for users exposed to variable walking terrains.

The last question assessed the contribution of the pneumatic prosthetic foot to a more symmetrical gait pattern, as evidenced by spatiotemporal parameters. Although the pneumatic prosthetic foot did not perform exceptionally well, one participant demonstrated an increased cadence and good symmetry in terms of step length when using the pneumatic foot. While the pneumatic prosthetic foot in its current form did not outperform the prescribed prosthetic foot, these results represent meaningful steps toward the use of a single-acting cylinder for achieving functional gait restoration. Most importantly, these benefits were achieved after only a short acclimation period, suggesting that greater improvements may be observed with prolonged use, muscle strengthening and improved control mechanisms. The partial restoration of gait symmetry highlights the potential of single-acting pneumatic actuation solutions to reduce reliance on compensatory strategies, which expend more metabolic energy and are biomechanically inefficient.

Taken together, the evidence suggests that the collected data was sufficient to answer each of the research questions in a clinically relevant manner and biomechanically substantiated manner. While limited by sample size and testing duration, the findings provide evidence of the immediate benefits of using the pneumatic prosthetic foot for ambulation. Moreover, these results contribute to the broader discussion of finding alternative actuation methods that are capable of generating force values comparable to the biological plantarflexors during energy-intensive activities, while remaining within the volumetric profile of a human leg. In lower-limb prosthetics, advocating for approaches that prioritise biomechanical fidelity without compromising affordability or local manufacturability is key for normal gait restoration and equality. Further research, involving larger cohorts, refined control mechanisms and extended acclimation protocols, is required to fully assess the long-term viability of such devices in real-world contexts.

7.2. Limitations and Recommendations for Future Work

This study explored the potential of utilizing pneumatic systems to improve the biomechanical contribution of transtibial prosthetic devices in ambulation, yielding insights into stride length, kinetics, kinematics, and symmetry. However, various limitations impacted the generalizability of these findings and suggested significant avenues for future research and prototype development.

7.3. Small Sample Size

The one noticeable limitation of this study is the relatively small sample size (n=2), limiting statistical power and generalizability. What also magnified this limitation was the recruitment of participants with varying biomechanical requirements and limitations. Each of the two participants represented a specific group of prosthetic users within the general targeted population. This limitation dictated an analysis that is case-based and offered valuable insights; however, a larger, more diverse sample is necessary to validate the observed behaviour across a broader population. The challenge of small sample size is not unique to this study, as this has been a trend in numerous studies in prosthetic research. A secondary analysis paper of prosthetic research authored by Hafner and Sawers (2016) found that more than half of the included papers had a sample size of fewer than 10 participants. This limitation is inherent to the highly personalized nature of the intervention and the costs associated with the production of each prosthetic limb (Fagioli *et al*. 2024). New strategies need to be developed to overcome this challenge in order to cater for factors like residual limb characteristics, comorbidities and long-term use that have been highlighted as influencers for prosthetic gait adaptation (McCorkle & McCullough 2022).

7.4. Need for Longer Acclimation Periods

The relatively short acclimation period adopted in this study may have arguably not been efficient, specifically for those with comorbidities and limited biomechanical capabilities to fully adapt to the pneumatic prosthetic foot. Although there is currently no set period for acclimation, as individuality has to be acknowledged, studies have suggested that acclimation to new prosthetic components can take weeks or even months(McCorkle & McCullough, 2022; Zhang *et al*., 2019), specifically for devices that introduce new movements and actuation dynamics. However, the acclimation period adopted in this study was sufficient to determine the immediate effects of the intervention and has been used before in other studies evaluating active prosthetic devices (De Pauw *et al.*, 2018). Future studies must prolong the acclimation period to further gain insight into the long-term effects of the pneumatic prosthetic foot and to allow for a more representative assessment of steady-state gait behaviour and prosthetic performance. This suggestion is not unique to this study, but researchers who conducted similar studies share the same sentiments(Fagioli *et al.*, 2024; Rogers-Bradley et al., 2024).

7.5. Controlled walking conditions

This study focused on levelled walking at a self-selected walking speed, ambulating in a straight line fashion. The advantage of this testing method is that it isolates particular walking dynamics to enable the researcher to study the cause-and-effect relationship among variables. However, does not simulate the dynamics of the unpredictable environment where this prosthetic device is intended to be used. When performing daily activities or navigating through congested spaces like shopping malls and offices, the biomechanical requirements are completely different and require a lot of sudden movements, like quick stops and starts, that test the capabilities of swiftly adjusting to volatile force requirements. Zelik & Honert (2018), and Seethapathi, Jain2 and Srinivasan (2024) thoroughly explained the requirements for performing activities of daily living, such as turning, responding to sudden changes in direction or pace and navigating slopes and uneven terrain. The straight-line fashion of walking adopted in laboratory tests underestimates the true demands of ambulating in the real world.

Recent literature recommends conducting dynamic and multi-directional laboratory tests in an attempt to closely simulate the real-world conditions of ambulating on a levelled surface. For example, Simon *et al*. (2014) and Hughes *et al*. (2023) demonstrated that turning and changes in surface elevation during walking impose unique biomechanical demands on lower-limb prostheses that are different from straight-line walking.

8. References

1. *2008 2nd IEEE RAS and EMBS International Conference on Biomedical Robotics and Biomechatronics*. 2008. I E E E.
2. “50504711-MIT”. n.d.
3. Adamczyk, PG & Kuo, AD. 2015a. Mechanisms of gait asymmetry due to push-off deficiency in unilateral amputees. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*. 23(5):776–785. doi.org/10.1109/TNSRE.2014.2356722.
4. Agrawal, V, Gailey, RS, Gaunaurd, IA, O’Toole, C, Finnieston, A & Tolchin, R. 2015. Comparison of four different categories of prosthetic feet during ramp ambulation in unilateral transtibial amputees. *Prosthetics and Orthotics International*. 39(5):380–389. doi.org/10.1177/0309364614536762.
5. Allemang, B, Sitter, K & Dimitropoulos, G. 2022. doi.org/10.1111/hex.13384.
6. Amal Rebin, AX, Amal Krishna, A, Sharavana Kumar, A & Christu Paul, R. 2023. Design development and analysis of pylon prosthesis through reverse engineering. In: *Materials Today: Proceedings*. V. 90. Elsevier Ltd. 150–155. doi.org/10.1016/j.matpr.2023.05.249.
7. “An Evolution of Novel Developments in Lower -Limb Prosthetics”. n.d.
8. Anderson, FC & Pandy, MG. n.d. *Individual muscle contributions to support in normal walking*. Available from: www.elsevier.com/locate/gaitpost.
9. Anderson, CB, Kittelson, AJ, Wurdeman, SR, Miller, MJ, Stoneback, JW, Christiansen, CL & Magnusson, DM. 2023. Understanding decision-making in prosthetic rehabilitation by prosthetists and people with lower limb amputation: a qualitative study. *Disability and Rehabilitation*. 45(4):723–732. doi.org/10.1080/09638288.2022.2037745.
10. Andrews, AW, Vallabhajosula, S, Boise, S & Bohannon, RW. 2023. Normal gait speed varies by age and sex but not by geographical region: a systematic review. *Journal of Physiotherapy*. 69(1):47–52. doi.org/10.1016/j.jphys.2022.11.005.
11. Andrikopoulos, G & Nikolakopoulos, G. 2018. HUmanoid Robotic Leg via pneumatic muscle actuators: implementation and control. *Meccanica*. 53(1–2):465–480. doi.org/10.1007/s11012-017-0738-6.
12. Ármannsdóttir, AL, Lecomte, C, Lemaire, E, Brynjólfsson, S & Briem, K. 2024. Perceptions and biomechanical effects of varying prosthetic ankle stiffness during uphill walking: A case series. *Gait and Posture*. 108:354–360. doi.org/10.1016/j.gaitpost.2024.01.001.
13. Au, S, Berniker, M & Herr, H. 2008. Powered ankle-foot prosthesis to assist level-ground and stair-descent gaits. *Neural Networks*. 21(4):654–666. doi.org/10.1016/j.neunet.2008.03.006.
14. Au, SK, Weber, J & Herr, H. 2009. Powered ankle-foot prosthesis improves walking metabolic economy. *IEEE Transactions on Robotics*. 25(1):51–66. doi.org/10.1109/TRO.2008.2008747.
15. Azocar, AF, Mooney, LM, Duval, JF, Simon, AM, Hargrove, LJ & Rouse, EJ. 2020. Design and clinical implementation of an open-source bionic leg. *Nature Biomedical Engineering*. 4(10):941–953. doi.org/10.1038/s41551-020-00619-3.
16. Bateni, H & Olney, SJ. 2002. *Kinematic and Kinetic Variations of Below-Knee Amputee Gait*.
17. Beauchet, O, Annweiler, C, Lecordroch, Y, Allali, G, Dubost, V, Herrmann, FR & Kressig, RW. 2009. Walking speed-related changes in stride time variability: Effects of decreased speed. *Journal of NeuroEngineering and Rehabilitation*. 6(1). doi.org/10.1186/1743-0003-6-32.
18. Bimba Manufacturing Company. (2021). *Bimba Technical Data Catalog*. BIMBA BIM-NP-0621 Catalog. Available at: https://www.bimba.com [Accessed 9 Jul. 2025].
19.
20. Boateng, D., Ayellah, B. B., Adjei, D. N., & Agyemang, C. (2022). Contribution of diabetes to amputations in sub-Sahara Africa: A systematic review and meta-

analysis. *Primary Care Diabetes*, *16*(3), 341–349. https://doi.org/10.1016/j.pcd.2022.01.011

21.

22. Bonanni, C, Foti, C, Traballesi, M & Brunelli, S. 2020. doi.org/10.33137/cpoj.v3i1.33640.
23. Buckwalter, JA, Anderson, DD, Brown, TD, Tochigi, Y & Martin, JA. 2013. The Roles of Mechanical Stresses in the Pathogenesis of Osteoarthritis: Implications for Treatment of Joint Injuries. *Cartilage*. 4(4):286–294. doi.org/10.1177/1947603513495889.
24. Cherelle, P, Mathijssen, G, Wang, Q, Vanderborght, B & Lefeber, D. 2014. doi.org/10.1155/2014/984046.
25. Cherelle, P, Grosu, V, Cestari, M, Vanderborght, B & Lefeber, D. 2016. The AMP-Foot 3, new generation propulsive prosthetic feet with explosive motion characteristics: Design and validation. *BioMedical Engineering Online*. 15. doi.org/10.1186/s12938-016-0285-8.
26. Chino, K & Takahashi, H. 2015. The association of muscle and tendon elasticity with passive joint stiffness: In vivo measurements using ultrasound shear wave elastography. *Clinical Biomechanics*. 30(10):1230–1235. doi.org/10.1016/j.clinbiomech.2015.07.014.
27. Chiriac, OA & Bucur, D. 2020a. From conventional prosthetic feet to bionic feet. a review. In: *Lecture Notes in Networks and Systems*. V. 143. Springer. 130–138. doi.org/10.1007/978-3-030-53973-3_14.
28. Chiriac, OA & Bucur, D. 2020b. From conventional prosthetic feet to bionic feet. a review. In: *Lecture Notes in Networks and Systems*. V. 143. Springer. 130–138. doi.org/10.1007/978-3-030-53973-3_14.
29. Chiriac, OA & Nițu, C. 2022. Research on the Analysis and Evaluation of the Performance of the Prosthetic Foot. In: *2022 10th E-Health and Bioengineering Conference, EHB 2022*. Institute of Electrical and Electronics Engineers Inc. doi.org/10.1109/EHB55594.2022.9991395.
30. Chou Blake Hannaford, C-P. n.d. Measurement and Modeling of McKibben Pneumatic Artificial Muscles "lÄBTKS?ö Apfrnw-u ,5 &« f;i(£.
31. Clites, TR, Shepherd, MK, Ingraham, KA, Wontorcik, L & Rouse, EJ. 2021. Understanding patient preference in prosthetic ankle stiffness. *Journal of NeuroEngineering and Rehabilitation*. 18(1). doi.org/10.1186/s12984-021-00916-1.
32. Colas-Ribas, C, Martinet, N, Audat, G, Bruneau, A, Paysant, J & Abraham, P. 2022. Effects of a microprocessor-controlled ankle-foot unit on energy expenditure, quality of life, and postural stability in persons with transtibial amputation: An unblinded, randomized, controlled, cross-over study. *Prosthetics and Orthotics International*. 46(6):541–548. doi.org/10.1097/PXR.0000000000000187.
33. Czerniecki, JM & Morgenroth, DC. 2017. Metabolic energy expenditure of ambulation in lower extremity amputees: what have we learned and what are the next steps? *Disability and Rehabilitation*. 39(2):143–151. doi.org/10.3109/09638288.2015.1095948.
34. D'Andrea, S, Wilhelm, N, Silverman, AK & Grabowski, AM. 2014. Does Use of a Powered Ankle-foot Prosthesis Restore Whole-body Angular Momentum During Walking at Different Speeds? *Clinical Orthopaedics and Related Research*. 472(10):3044–3054. doi.org/10.1007/s11999-014-3647-1.
35. Daniele, B. 2019. Evolution of prosthetic feet and design based on gait analysis data. In: *Clinical Engineering Handbook, Second Edition*. Elsevier. 458–468. doi.org/10.1016/B978-0-12-813467-2.00070-5.
36. Davidson, AM, Childers, WL & Chang, YH. 2021. Altering the tuning parameter settings of a commercial powered prosthetic foot to increase power during push-off may not reduce

collisional work in the intact limb during gait. *Prosthetics and Orthotics International*. 45(5):410–416. doi.org/10.1097/PXR.0000000000000036.
37. Donelan, JM, Kram, R & Kuo, AD. 2001. Mechanical and metabolic determinants of the preferred step width in human walking. *Proceedings of the Royal Society B: Biological Sciences*. 268(1480):1985–1992. doi.org/10.1098/rspb.2001.1761.
38. Ennion, L & Johannesson, A. 2018a. A qualitative study of the challenges of providing pre-prosthetic rehabilitation in rural South Africa. *Prosthetics and Orthotics International*. 42(2):179–186. doi.org/10.1177/0309364617698520.
39. Ennion, L & Manig, S. 2019. Experiences of lower limb prosthetic users in a rural setting in the Mpumalanga Province, South Africa. *Prosthetics and Orthotics International*. 43(2):170–179. doi.org/10.1177/0309364618792730.
40. Esposito, ER, Whitehead, JMA & Wilken, JM. 2016. Step-to-step transition work during level and inclined walking using passive and powered ankle-foot prostheses. *Prosthetics and Orthotics International*. 40(3):311–319. doi.org/10.1177/0309364614564021.
41. Fagioli, I, Mazzarini, A, Livolsi, C, Gruppioni, E, Vitiello, N, Crea, S & Trigili, E. 2024. Advancements and Challenges in the Development of Robotic Lower Limb Prostheses: A Systematic Review. *IEEE Transactions on Medical Robotics and Bionics*. 6(4):1409–1422. doi.org/10.1109/TMRB.2024.3464126.
42. Farrokhi, S, O'Connell, M & Fitzgerald, GK. 2015. Altered gait biomechanics and increased knee-specific impairments in patients with coexisting tibiofemoral and patellofemoral osteoarthritis. *Gait and Posture*. 41(1):81–85. doi.org/10.1016/j.gaitpost.2014.08.014.
43. **Festo. (n.d.).** *Round cylinder, double-acting – DSNU series*. [online] Available at: https://www.festo.com/za/en/p/round-cylinder-double-acting-id_DSNU_PUB/ [Accessed 24 June 2025].
44.
45. Ferreira, AEK, Neves, EB, Melanda, AG, Pauleto, AC, Iucksch, DD, Knaut, LAM, da Silva, RM & da Cunha, RFM. 2014. Transtibial amputee gait: Kinematics and temporal-spatial analysis. In: *IFMBE Proceedings*. V. 41. Springer Verlag. 61–64. doi.org/10.1007/978-3-319-00846-2_15.
46. Fridman, A, Ona, I & Isakov, E. 2003. *The influence of prosthetic foot alignment on trans-tibia1 amputee gait*.
47. Gabert, L, Hood, S, Tran, M, Cempini, M & Lenzi, T. 2020. A compact, lightweight robotic ankle-foot prosthesis: Featuring a powered polycentric design. *IEEE Robotics and Automation Magazine*. 27(1):87–102. doi.org/10.1109/MRA.2019.2955740.
48. Gailey, RS, Roach, KE, Applegate, EB, Cho, B, Cunniffe, B, Licht, S, Maguire, M & Nash, MS. 2002. The Amputee Mobility Predictor: An instrument to assess determinants of the lower-limb amputee's ability to ambulate. *Archives of Physical Medicine and Rehabilitation*. 83(5):613–627. doi.org/10.1053/apmr.2002.32309.
49. de Gea Fernández, J, Yu, B, Bargsten, V, Zipper, M & Sprengel, H. 2020. Design, modelling and control of novel series-elastic actuators for industrial robots. *Actuators*. 9(1). doi.org/10.3390/act9010006.
50. Hafner, BJ & Sawers, AB. 2016. Issues affecting the level of prosthetics research evidence. *Prosthetics & Orthotics International*. 40(1):31–43. doi.org/10.1177/0309364614550264.
51. Hafner, BJ, Halsne, EG, Morgan, SJ, Morgenroth, DC & Humbert, AT. 2022. doi.org/10.1002/pmrj.12693.
52. Halsne, EG, Czerniecki, JM, Shofer, JB & Morgenroth, DC. 2020. The effect of prosthetic foot stiffness on foot-ankle biomechanics and relative foot stiffness perception in people with transtibial amputation. *Clinical Biomechanics*. 80. doi.org/10.1016/j.clinbiomech.2020.105141.

53. Hegde, K. 2013. *Fuzzy logic Control For Active Ankle Foot Orthosis*. Available from: https://www.researchgate.net/publication/261995964.
54. Herr, HM & Grabowski, AM. 2012. Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation. *Proceedings of the Royal Society B: Biological Sciences*. 279(1728):457–464. doi.org/10.1098/rspb.2011.1194.
55. Hill, D & Herr, H. 2015. *Effects of a powered ankle-foot prosthesis on kinetic loading of the contralateral limb: A case series*. Available from: www.ossur.com.
56. Hofstad, CJ, Bongers, KTJ, Didden, M, van Ee, RF & Keijsers, NLW. 2020. doi.org/10.3390/s20236770.
57. Houdijk, H, Wezenberg, D, Hak, L & Cutti, AG. 2018. Energy storing and return prosthetic feet improve step length symmetry while preserving margins of stability in persons with transtibial amputation. *Journal of NeuroEngineering and Rehabilitation*. 15. doi.org/10.1186/s12984-018-0404-9.
58. Huang, S & Ferris, DP. 2012. Muscle activation patterns during walking from transtibial amputees recorded within the residual limb-prosthetic interface. *Journal of NeuroEngineering and Rehabilitation*. 9(1). doi.org/10.1186/1743-0003-9-55.
59. Hughes, LD, Bencsik, M, Bisele, M & Barnett, CT. 2023. Using Lower Limb Wearable Sensors to Identify Gait Modalities: A Machine-Learning-Based Approach. *Sensors*. 23(22). doi.org/10.3390/s23229241.
60. Ingraham, KA, Choi, H, Gardinier, ES, Remy, CD & Gates, DH. 2018. Choosing appropriate prosthetic ankle work to reduce the metabolic cost of individuals with transtibial amputation. *Scientific Reports*. 8(1). doi.org/10.1038/s41598-018-33569-7.
61. Ismawan, AR, Ismail, R, Novriansyah, R, Setiyana, B, Ariyanto, M & Prahasto, T. 2021. Conceptual Design of Bionic Foot for Transtibial Prosthesis. In: *2021 IEEE International Biomedical Instrumentation and Technology Conference: The Improvement of Healthcare Technology to Achieve Universal Health Coverage, IBITeC 2021*. Institute of Electrical and Electronics Engineers Inc. 124–129. doi.org/10.1109/IBITeC53045.2021.9649405.
62. Jakubowski, KL, Ludvig, D, Bujnowski, D, Lee, SSM & Perreault, EJ. 2022. Simultaneous Quantification of Ankle, Muscle, and Tendon Impedance in Humans. *IEEE Transactions on Biomedical Engineering*. 69(12):3657–3666. doi.org/10.1109/TBME.2022.3175646.
63. Jakubowski, KL, Ludvig, D, Perreault, EJ & Lee, SSM. 2023. Non-linear properties of the Achilles tendon determine ankle impedance over a broad range of activations in humans. *Journal of Experimental Biology*. 226(14). doi.org/10.1242/jeb.244863.
64. Jiménez, M, Kurmyshev, E & Castañeda, CE. 2020. Experimental Study of Double-Acting Pneumatic Cylinder. *Experimental Techniques*. 44(3):355–367. doi.org/10.1007/s40799-020-00359-8.
65. Jin, J, Wang, K, Ren, L, Qian, Z, Liang, W, Xu, X, Zhao, S, Lu, X, et al. 2023. Design of a Flexible Bionic Ankle Prosthesis Based on Subject-specific Modeling of the Human Musculoskeletal System. *Journal of Bionic Engineering*. 20(3):1008–1020. doi.org/10.1007/s42235-022-00325-7.
66. Jonkergouw, N, Prins, MR, Buis, AWP & Van Der Wurff, P. 2016. doi.org/10.1371/journal.pone.0167466.
67. Joshi, V, Rouse, EJ, Claflin, ES & Krishnan, C. 2022. How Does Ankle Mechanical Stiffness Change as a Function of Muscle Activation in Standing and during the Late Stance of Walking? *IEEE Transactions on Biomedical Engineering*. 69(3):1186–1193. doi.org/10.1109/TBME.2021.3117516.

68. Kanko, R, Strutzenberger, G, Brown, M, Selbie, S & Deluzio, K. 2021. *Assessment of spatiotemporal gait parameters using a deep learning algorithm-based markerless motion capture system*.
69. Kedzierski, J & Holihan, E. 2018. *Linear and rotational microhydraulic actuators driven by electrowetting*. Available from: http://robotics.sciencemag.org/.
70. Kim, J, Wensman, J, Colabianchi, N & Gates, DH. 2021a. The influence of powered prostheses on user perspectives, metabolics, and activity: a randomized crossover trial. *Journal of NeuroEngineering and Rehabilitation*. 18(1). doi.org/10.1186/s12984-021-00842-2.
71. Kim, J, Gardinier, ES, Vempala, V & Gates, DH. 2021. The effect of powered ankle prostheses on muscle activity during walking. *Journal of Biomechanics*. 124. doi.org/10.1016/j.jbiomech.2021.110573.
72. Kim, J, Wensman, J, Colabianchi, N & Gates, DH. 2021b. The influence of powered prostheses on user perspectives, metabolics, and activity: a randomized crossover trial. *Journal of NeuroEngineering and Rehabilitation*. 18(1). doi.org/10.1186/s12984-021-00842-2.
73. *KJ Kinch, JC Clasper. A Brief History of War Amputation*. n.d.
74. Kubinski, SN, McQueen, CA, Sittloh, KA & Dean, JC. 2015. Walking with wider steps increases stance phase gluteus medius activity. *Gait and Posture*. 41(1):130–135. doi.org/10.1016/j.gaitpost.2014.09.013.
75. Kuo, AD. 2007. The six determinants of gait and the inverted pendulum analogy: A dynamic walking perspective. *Human Movement Science*. 26(4):617–656. doi.org/10.1016/j.humov.2007.04.003.
76. Kuo, AD & Donelan, JM. 2010. *Dynamic Principles of Gait and Their Clinical Implications*. Available from: www.ptjournal.org.
77. Lecomte, C, Starker, F, Guðnadóttir, E, Rafnsdóttir, S, Guðmundsson, K, Briem, K & Brynjolfsson, S. 2020. Functional joint center of prosthetic feet during level ground and incline walking. *Medical Engineering and Physics*. 81:13–21. doi.org/10.1016/j.medengphy.2020.04.011.
78. Lee, IC, Fylstra, BL, Liu, M, Lenzi, T & Huang, H. 2022. Is there a trade-off between economy and task goal variability in transfemoral amputee gait? *Journal of NeuroEngineering and Rehabilitation*. 19(1). doi.org/10.1186/s12984-022-01004-8.
79. Lee, JD, Mooney, LM & Rouse, EJ. 2017. Design and characterization of a quasi-passive pneumatic foot-ankle prosthesis. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*. 25(7):823–831. doi.org/10.1109/TNSRE.2017.2699867.
80. Lee, SY, Chou, CY, Hou, YY, Wang, YL, Yang, CH & Guo, LY. 2011. The effects of changes in step width on plantar foot pressure patterns of young female subjects during walking. In: *Journal of Mechanics in Medicine and Biology*. V. 11. 1071–1083. doi.org/10.1142/S0219519411004319.
81. Levin, MF & Demers, M. 2021. doi.org/10.1080/09638288.2020.1752317.
82. Li, B, Xu, G, Teng, Z, Luo, D, Pei, J, Chen, R & Zhang, S. 2024a. Intelligent ankle–foot prosthesis based on human structure and motion bionics. *Journal of NeuroEngineering and Rehabilitation*. 21(1). doi.org/10.1186/s12984-024-01414-w.
83. Limakatso, K., Tucker, J., Banda, L., Robertson, C., & Parker, R. (2024). The profile of people undergoing lower limb amputations at Groote Schuur Hospital. *African Journal of Disability*, *13*. https://doi.org/10.4102/ajod.v13i0.1152.
84. Major, MJ, Howard, D, Jones, R & Twiste, M. 2012. The effects of transverse rotation angle on compression and effective lever arm of prosthetic feet during simulated stance. *Prosthetics and Orthotics International*. 36(2):231–235. doi.org/10.1177/0309364611435996.

85. Manickum, P, Ramklass, S & Madiba, T. 2019. A five-year audit of lower limb amputations below the knee and rehabilitation outcomes: the Durban experience. *Journal of Endocrinology, Metabolism and Diabetes of South Africa*. 24(2):41–45. doi.org/10.1080/16089677.2018.1553378.
86. McCorkle, JO & McCullough, MBA. 2022. Development of a finite element–based model for the thermal assessment of transtibial prosthetic liners. *Prosthetics & Orthotics International*. 46(5):432–436. doi.org/10.1097/PXR.0000000000000126.
87. McDonald, CL, Westcott-McCoy, S, Weaver, MR, Haagsma, J & Kartin, D. 2020. Global prevalence of traumatic non-fatal limb amputation. *Prosthetics and Orthotics International*. (December, 4):0309364620972258. doi.org/10.1177/0309364620972258.
88. Mduzana, L, Tiwari, R, Lieketseng, N & Chikte, U. 2020. Exploring national human resource profile and trends of Prosthetists/Orthotists in South Africa from 2002 to 2018. *Global Health Action*. 13(1). doi.org/10.1080/16549716.2020.1792192.
89. Mgibantaka, A. S., Musekiwa, A., & Zunza, M. (2024). Survival rate of diabetic-related lower extremity amputees in hospitals in the Eastern Cape. In *AFRICAN JOURNAL OF DISABILITY* (Vol. 13). https://ajod.org/index.php/ajod/rt/printerFriendly/1503/0.
90. Mohanty, RK, Kumar, JP, Rout, S & Das, SP. 2020. Successful prosthetic rehabilitation and gait analysis of individual with bilateral transtibial amputation: A case study with comparison to able-bodied gait. *Journal of Orthopaedics, Trauma and Rehabilitation*. 27(1):93–100. doi.org/10.1177/2210491719893071.
91. Mohebbian, MR, Nosouhi, M, Fazilati, F, Esfahani, ZN, Amiri, G, Malekifar, N, Yusefi, F, Rastegari, M, et al. 2021. *A Comprehensive Review of Myoelectric Prosthesis Control*. Barcelona.
92. Montgomery, JR & Grabowski, AM. 2018. Use of a powered ankle–foot prosthesis reduces the metabolic cost of uphill walking and improves leg work symmetry in people with transtibial amputations. *Journal of the Royal Society Interface*. 15(145). doi.org/10.1098/rsif.2018.0442.
93. Murtagh, EM, Mair, JL, Aguiar, E, Tudor-Locke, C & Murphy, MH. 2021. doi.org/10.1007/s40279-020-01351-3.
94. Naddaf, M., 2024. *Bionic leg moves like a natural limb — without conscious thought*. MIT Technology Review, 1 July. [online] Available at: https://www.technologyreview.com/2024/07/01/1094459/bionic-leg-neural-prosthetic/ [Accessed 23 June 2025].Naidoo, U & Ennion, L. 2019. Barriers and facilitators to utilisation of rehabilitation services amongst persons with lower-limb amputations in a rural community in South Africa. *Prosthetics and Orthotics International*. 43(1):95–103. doi.org/10.1177/0309364618789457.
95. Narayanan, G, Gnanasundaram, S, Ranganathan, M, Ranganathan, R, Gopalakrishna, G, Das, BN & Mandal, AB. 2016. Improved design and development of a functional moulded prosthetic foot. *Disability and Rehabilitation: Assistive Technology*. 11(5):407–412. doi.org/10.3109/17483107.2014.979331.
96. Norvell, DC, Czerniecki, JM, Reiber, GE, Maynard, C, Pecoraro, JA & Weiss, NS. 2005a. The prevalence of knee pain and symptomatic knee osteoarthritis among veteran traumatic amputees and nonamputees. *Archives of Physical Medicine and Rehabilitation*. 86(3):487–493. doi.org/10.1016/j.apmr.2004.04.034.
97. Norvell, DC, Czerniecki, JM, Reiber, GE, Maynard, C, Pecoraro, JA & Weiss, NS. 2005b. The prevalence of knee pain and symptomatic knee osteoarthritis among veteran traumatic amputees and nonamputees. *Archives of Physical Medicine and Rehabilitation*. 86(3):487–493. doi.org/10.1016/j.apmr.2004.04.034.

98. Okunlola, AO, Ajao, TO, Karim, A, Sabi, M, Kolawole, O, Ugwoke, K & Mahadevaswamysusheela, MK. 2024. A Review of Peripheral Artery Disease in Diabetic Patients in Sub-Saharan Africa. *Cureus*. (September, 20). doi.org/10.7759/cureus.69808.
99. Orekhov, G, Matt Robinson, A, Hazelwood, SJ & Klisch, SM. 2019. Knee joint biomechanics in transtibial amputees in gait, cycling, and elliptical training. *PLoS ONE*. 14(12). doi.org/10.1371/journal.pone.0226060.
100. Paradisi, F, Delussu, AS, Brunelli, S, Iosa, M, Pellegrini, R, Zenardi, D & Traballesi, M. 2015. The conventional non-articulated SACH or a multiaxial prosthetic foot for hypomobile transtibial amputees? A clinical comparison on mobility, balance, and quality of life. *Scientific World Journal*. 2015. doi.org/10.1155/2015/261801.
101. Park, YS, Konge, L & Artino, AR. 2020. doi.org/10.1097/ACM.0000000000003093.
102. De Pauw, K, Cherelle, P, Roelands, B, Lefeber, D & Meeusen, R. 2018. The efficacy of the Ankle Mimicking Prosthetic Foot prototype 4.0 during walking: Physiological determinants. *Prosthetics and Orthotics International*. 42(5):504–510. doi.org/10.1177/0309364618767141.
103. De Pauw, K, Serrien, B, Baeyens, JP, Cherelle, P, De Bock, S, Ghillebert, J, Bailey, SP, Lefeber, D, et al. 2020. Prosthetic gait of unilateral lower-limb amputees with current and novel prostheses: A pilot study: Kinetics and kinematics of prosthetic gait. *Clinical Biomechanics*. 71:59–67. doi.org/10.1016/j.clinbiomech.2019.10.028.
104. Piazzesi, G, Reconditi, M, Linari, M, Lucii, L, Sun, YB, Narayanan, T, Boesecke, P, Lombardi, V, et al. 2002. Mechanism of force generation by myosin heads in skeletal muscle. *Nature*. 415(6872):659–662. doi.org/10.1038/415659a.
105. Pickle, NT, Silverman, AK, Wilken, JM & Fey, NP. 2019. Statistical analysis of timeseries data reveals changes in 3D segmental coordination of balance in response to prosthetic ankle power on ramps. *Scientific Reports*. 9(1). doi.org/10.1038/s41598-018-37581-9.
106. Polak, P, Polaszek, M, Stencel, K, Berner, A, Pękała, M, Olszewska, A, Stelmaszak, K, Bogowska, M, et al. 2023. One step closer – the impact of daily step count on health and how many steps should be taken per day. *Journal of Education, Health and Sport*. 21(1):170–184. doi.org/10.12775/jehs.2023.21.01.016.
107. Proebsting, E, Altenburg, B, Bellmann, M, Schmalz, T & Krug, K. 2020. Effects on prosthetic foot ankle power on transfemoral amputee gait. *Gait & Posture*. 81:285–286. doi.org/10.1016/j.gaitpost.2020.08.038.
108. Prost, V, Olesnavage, KM & Winter, AG. 2017. *DESIGN AND TESTING OF A PROSTHETIC FOOT PROTOTYPE WITH INTERCHANGEABLE CUSTOM ROTATIONAL SPRINGS TO ADJUST ANKLE STIFFNESS FOR EVALUATING LOWER LEG TRAJECTORY ERROR, AN OPTIMIZATION METRIC FOR PROSTHETIC FEET*. Available from: http://www.asme.org/about-asme/terms-of-use.
109. Prost, V, Johnson, WB, Kent, JA, Major, MJ & Winter, AG. 2021. doi.org/10.21203/rs.3.rs-944164/v1.
110. Quesada, RE, Caputo, JM & Collins, SH. 2016. Increasing ankle push-off work with a powered prosthesis does not necessarily reduce metabolic rate for transtibial amputees. *Journal of Biomechanics*. 49(14):3452–3459. doi.org/10.1016/j.jbiomech.2016.09.015.
111. Rábago, CA & Wilken, JM. 2016. The prevalence of gait deviations in individuals with transtibial amputation. *Military Medicine*. 181:30–37. doi.org/10.7205/MILMED-D-15-00505.
112. Rajt'úková, V, Michalíková, M, Bednarcíková, L, Balogová, A & Živčák, J. 2014. Biomechanics of lower limb prostheses. In: *Procedia Engineering*. V. 96. Elsevier Ltd. 382–391. doi.org/10.1016/j.proeng.2014.12.107.
113. Rasheed, F, Martin, S & Tse, KM. 2023. doi.org/10.3390/bioengineering10070773.

114. Renjewski, D & Seyfarth, A. 2012. Robots in human biomechanics- A study on ankle push-off in walking. *Bioinspiration and Biomimetics*. 7(3). doi.org/10.1088/1748-3182/7/3/036005.
115. Reynard, F & Terrier, P. 2017. Determinants of gait stability while walking on a treadmill: A machine learning approach. *Journal of Biomechanics*. 65:212–215. doi.org/10.1016/j.jbiomech.2017.10.020.
116. Ripic, Z, Signorile, JF, Kuenze, C & Eltoukhy, M. 2022. Concurrent validity of artificial intelligence-based markerless motion capture for over-ground gait analysis: A study of spatiotemporal parameters. *Journal of Biomechanics*. 143. doi.org/10.1016/j.jbiomech.2022.111278.
117. Roberts, M, Mongeon, D & Prince, F. 2017. Biomechanical parameters for gait analysis: a systematic review of healthy human gait. *Physical Therapy and Rehabilitation*. 4(1):6. doi.org/10.7243/2055-2386-4-6.
118. Robinson, RO, Herzog, W & Nigg, BM. 1987. Use of force platform variables to quantify the effects of chiropractic manipulation on gait symmetry. *Journal of manipulative and physiological therapeutics*. 10(4):172–6.
119. Rodgers, MM. 1995. *Dynamic Foot Biomechanics*. doi.org/10.2519.
120. Rogers-Bradley, E, Yeon, SH, Landis, C, Lee, DRC & Herr, HM. 2024. Variable-stiffness prosthesis improves biomechanics of walking across speeds compared to a passive device. *Scientific Reports*. 14(1). doi.org/10.1038/s41598-024-67230-3.
121. Rosenbaum, AN, Yu, RC, Rooke, TW & Heit, JA. 2014. Venous gangrene and intravascular coagulation and fibrinolysis in a patient treated with rivaroxaban. *American Journal of Medicine*. 127(6). doi.org/10.1016/j.amjmed.2014.02.014.
122. Russell Esposito, E & Wilken, JM. 2014. Biomechanical risk factors for knee osteoarthritis when using passive and powered ankle-foot prostheses. *Clinical Biomechanics*. 29(10):1186–1192. doi.org/10.1016/j.clinbiomech.2014.09.005.
123. Science Museum Group. Aritificial peg leg, Europe, 1850-1900. A205286/2 Science Museum Group Collection Online. Accessed 23 June 2025. https://collection.sciencemuseumgroup.org.uk/objects/co8247466/aritificial-peg-leg-europe-1850-1900.Seethapathi, N, Jain2, AK & Srinivasan, M. 2024. Walking speeds are lower for short distance and turning locomotion: Experiments and modeling in low-cost prosthesis users. *PLoS ONE*. 19(1 January). doi.org/10.1371/journal.pone.0295993.
124. Senden, R, Marcellis, R, Willems, P, Witlox, M & Meijer, K. 2024. Normative 3D gait data of healthy adults walking at three different speeds on an instrumented treadmill in virtual reality. *Data in Brief*. 53. doi.org/10.1016/j.dib.2024.110230.
125. Shell, CE, Segal, AD, Klute, GK & Neptune, RR. 2017. The effects of prosthetic foot stiffness on transtibial amputee walking mechanics and balance control during turning. *Clinical Biomechanics*. 49:56–63. doi.org/10.1016/j.clinbiomech.2017.08.003.
126. Simon, AM, Ingraham, KA, Fey, NP, Finucane, SB, Lipschutz, RD, Young, AJ & Hargrove, LJ. 2014. Configuring a powered knee and ankle prosthesis for transfemoral amputees within five specific ambulation modes. *PLoS ONE*. 9(6). doi.org/10.1371/journal.pone.0099387.
127. Struyf, PA, van Heugten, CM, Hitters, MW & Smeets, RJ. 2009. The Prevalence of Osteoarthritis of the Intact Hip and Knee Among Traumatic Leg Amputees. *Archives of Physical Medicine and Rehabilitation*. 90(3):440–446. doi.org/10.1016/J.APMR.2008.08.220.
128. Steeper Group, n.d. *Sierra Foot product image*. [image online] Available at: https://www.steepergroup.com/prosthetics/lower-limb-prosthetics/feet/sierra/ [Accessed 23 June 2025].Su, PF, Gard, SA, Lipschutz, RD & Kuiken, TA. 2007. Gait characteristics of persons with bilateral transtibial amputations. *Journal of Rehabilitation Research and Development*. 44(4):491–501. doi.org/10.1682/JRRD.2006.10.0135.

129. Sun, H, He, C & Vujaklija, I. 2023. Design trends in actuated lower-limb prosthetic systems: a narrative review. *Expert Review of Medical Devices*. 20(12):1157–1172. doi.org/10.1080/17434440.2023.2279999.
130. Sup, F, Bohara, A & Goldfarb, M. 2007. *Design and Control of a Powered Knee and Ankle Prosthesis*.
131. Sup, F, Bohara, A & Goldfarb, M. 2008. Design and control of a powered transfemoral prosthesis. In: *International Journal of Robotics Research*. V. 27. 263–273. doi.org/10.1177/0278364907084588.
132. Suzumori, K. 2020. doi.org/10.20965/jrm.2020.p0854.
133. Tahir, MSA-D & Kadhim, FM. 2021. Design and Manufacturing of New Low (Weight and Cost) 3D Printed Pylon Prosthesis for Amputee. *IOP Conference Series: Materials Science and Engineering*. 1094(1):012144. doi.org/10.1088/1757-899x/1094/1/012144.
134. Tassa, Y, Wu, T, Movellan, J & Todorov, E. 2011. *Modeling and Identification of Pneumatic Actuators*.
135. Tran, M, Gabert, L, Hood, S & Lenzi, T. 2022a. *A lightweight robotic leg prosthesis replicating the biomechanics of the knee, ankle, and toe joint*. Available from: https://www.science.org.
136. Tran, M, Gabert, L, Hood, S & Lenzi, T. 2022b. A lightweight robotic leg prosthesis replicating the biomechanics of the knee, ankle, and toe joint. *Science Robotics*. 7(72). doi.org/10.1126/scirobotics.abo3996.
137. Tucker, MR, Olivier, J, Pagel, A, Bleuler, H, Bouri, M, Lambercy, O, Millán, JDR, Riener, R, et al. 2015. *Control strategies for active lower extremity prosthetics and orthotics: a review*. Available from: http://www.jneuroengrehab.com/content/12/1/1.
138. Tudor-Locke, C, Aguiar, EJ, Han, H, Ducharme, SW, Schuna, JM, Barreira, T V., Moore, CC, Busa, MA, et al. 2019. Walking cadence (steps/min) and intensity in 21-40 year olds: CADENCE-adults. *International Journal of Behavioral Nutrition and Physical Activity*. 16(1). doi.org/10.1186/s12966-019-0769-6.
139. Varrecchia, T, Serrao, M, Rinaldi, M, Ranavolo, A, Conforto, S, De Marchis, C, Simonetti, A, Poni, I, et al. 2019. Common and specific gait patterns in people with varying anatomical levels of lower limb amputation and different prosthetic components. *Human Movement Science*. 66:9–21. doi.org/10.1016/j.humov.2019.03.008.
140. Versluys, R, Lenaerts, G, Van Damme, M, Jonkers, I, Desomer, A, Vanderborght, B, Peeraer, L, Van Der Perre, G, et al. 2009. Successful preliminary walking experiments on a transtibial amputee fitted with a powered prosthesis. *Prosthetics and Orthotics International*. 33(4):368–377. doi.org/10.3109/03093640902984587.
141. Versluys, R, Beyl, P, Van Damme, M, Desomer, A, Van Ham, R & Lefeber, D. 2009. doi.org/10.1080/17483100802715092.
142. De Volder, M & Reynaerts, D. 2010. doi.org/10.1088/0960-1317/20/4/043001.
143. Wade, L, McGuigan, MP, McKay, C, Bilzon, J & Seminati, E. 2022. Biomechanical risk factors for knee osteoarthritis and lower back pain in lower limb amputees: protocol for a systematic review. *BMJ Open*. 12(11). doi.org/10.1136/bmjopen-2022-066959.
144. Wanamaker, AB, Andridge, RR & Chaudhari, AMW. 2017. doi.org/10.1177/0309364616682385.
145. Waycaster, GC. 2010. *DESIGN OF A POWERED ABOVE KNEE PROSTHESIS USING PNEUMATIC ARTIFICIAL MUSCLES*.
146. Wezenberg, D, Cutti, AG, Bruno, A & Houdijk, H. 2014. Differentiation between solid-ankle cushioned heel and energy storage and return prosthetic foot based on step-to-step

transition cost. *Journal of Rehabilitation Research and Development*. 51(10):1579–1590. doi.org/10.1682/JRRD.2014.03.0081.
147. William, O, Godwin, A, Promise, M & Promise, U. 2022. Comparative Analysis of a Locally Fabricated SACH Foot and a Foreign SACH Foot. *OALib*. 09(10):1–12. doi.org/10.4236/oalib.1109167.
148. Windrich, M, Grimmer, M, Christ, O, Rinderknecht, S & Beckerle, P. 2016a. doi.org/10.1186/s12938-016-0284-9.
149. Windrich, M, Grimmer, M, Christ, O, Rinderknecht, S & Beckerle, P. 2016b. doi.org/10.1186/s12938-016-0284-9.
150. Winter, DA & Sienko, SE. 1988a. *BIOMECHANICS OF BELOW-KNEE AMPUTEE GAIT*.
151. Winter, DA & Sienko, SE. 1988b. *BIOMECHANICS OF BELOW-KNEE AMPUTEE GAIT*.
152. Wiszomirska, I, Błazkiewicz, M, Kaczmarczyk, K, Brzuszkiewicz-Kuźmicka, G & Wit, A. 2017. Effect of drop foot on spatiotemporal, kinematic, and kinetic parameters during gait. *Applied Bionics and Biomechanics*. 2017. doi.org/10.1155/2017/3595461.
153. Wolf, EJ & Pruziner, AL. 2014a. *Use of a Powered Versus a Passive Prosthetic System for a Person with Bilateral Amputations during Level-Ground Walking*. Available from: http://journals.lww.com/jpojournal.
154. Xie, H, Li, Z & Li, F. 2020. Bionics Design of Artificial Leg and Experimental Modeling Research of Pneumatic Artificial Muscles. *Journal of Robotics*. 2020. doi.org/10.1155/2020/3481056.
155. Zelik, KE & Honert, EC. 2018. doi.org/10.1016/j.jbiomech.2018.04.017.
156. Zhang, X, Fiedler, G & Liu, Z. 2019. Evaluation of gait variable change over time as transtibial amputees adapt to a new prosthesis foot. *BioMed Research International*. 2019. doi.org/10.1155/2019/9252368.
157. Zheng, H & Shen, X. 2013. Sleeve muscle actuator and its application in transtibial prostheses. In: *IEEE International Conference on Rehabilitation Robotics*. doi.org/10.1109/ICORR.2013.6650444.
158. Zheng, H & Shen, X. 2015a. Design and control of a pneumatically actuated transtibial prosthesis. *Journal of Bionic Engineering*. 12(2):217–226. doi.org/10.1016/S1672-6529(14)60114-1.
159. Zheng, H & Shen, X. 2015b. Design and control of a pneumatically actuated transtibial prosthesis. *Journal of Bionic Engineering*. 12(2):217–226. doi.org/10.1016/S1672-6529(14)60114-1.
160. Zheng, H, Wu, M & Shen, X. 2016. Pneumatic Variable Series Elastic Actuator. *Journal of Dynamic Systems, Measurement and Control, Transactions of the ASME*. 138(8). doi.org/10.1115/1.4033620.
161. Ziegler-Graham, K, MacKenzie, EJ, Ephraim, PL, Travison, TG & Brookmeyer, R. 2008. Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050. *Archives of Physical Medicine and Rehabilitation*. 89(3):422–429. doi.org/10.1016/j.apmr.2007.11.005.

Appendices

APPENDIX A: **Human participant information sheet and consent template**

PARTICIPANT INFORMATION SHEET

Ethics clearance reference number: 2023/CAES_HRC/1151
Research permission reference number (if applicable):

19 September 2023

Title: Design optimization and development of the pneumatic prosthetic foot.

Dear Prospective Participant

My Name is Zanodumo Thandazani Godlimpi, and I am doing research with Professor Thanyani Pandelani, an Associate Professor in the School of Engineering, Science and Technology, towards a Master of Engineering, at the University of South Africa. We have funding from the Technology and Innovation Agency for developing the pneumatic prosthetic foot. We are inviting you to participate in a study entitled Design Optimization and Development of the Pneumatic Prosthetic Foot.

WHAT IS THE PURPOSE OF THE STUDY?

This study is expected to collect important information that could investigate the potential benefits of using pressurized air in prosthetics to provide functional prosthetic limbs. Similar studies conducted by (Sup, Bohara, and Goldfarb, 2007, 2008; Zheng and Shen, 2013, 2015a) with restrained prosthetic limbs show that there is a potential for pressurized air-powered prosthetic limbs, with angle and force values that match those of the biological limb. This study is expected to document new data about pressurized air-powered prosthesis that is meant to be collected in the lab environment on living human beings. The data to be obtained throughout the course of the study has the potential to assist in classifying pressurized air-powered prosthetic foot according to the patient's potential level of function (K-level).

WHY AM I BEING INVITED TO PARTICIPATE?

You are chosen to participate in this study because you are a below-knee prosthetic user, and you have been using a prosthesis for the past 6 months. Your contact information was obtained from Nelson Mandela Academic Hospital (Bedford Hospital) in Mthatha, and you were randomly chosen, particularly from the list of patients that were serviced in the last 2 years. You will be one of two participants who will be participating in the research study.

WHAT IS THE NATURE OF MY PARTICIPATION IN THIS STUDY?

Your participation in this study is of a voluntary nature; you will be asked to walk within a lab environment using a below-knee pneumatic prosthetic leg. This exercise will take approximately 60 minutes, and this includes a 30-minute walk to familiarise yourself with using a pneumatic prosthetic foot to walk. Thereafter, you will be asked to walk a distance of approximately 10 meters at a self-selected walking speed.

CAN I WITHDRAW FROM THIS STUDY EVEN AFTER HAVING AGREED TO PARTICIPATE?

Participating in this study is voluntary, and you are under no obligation to consent to participation. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a written consent form. You are free to withdraw at any time and without giving a reason.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THIS STUDY?

The purpose of this study is to investigate the potential benefits of using pneumatic components in below-knee prosthetics. This will assist below-knee amputees living in rural areas or places where electricity is scarce to be able to walk more efficiently.

ARE THERE ANY NEGATIVE CONSEQUENCES FOR ME IF I PARTICIPATE IN THE RESEARCH PROJECT?

The risks of participating in this study have been reduced to minor discomfort and the institution will not be liable for any loss, damages, or injuries sustained during experiments. This discomfort may stem from not being familiar with using a pneumatic prosthetic foot and the alignment of the foot may not be identical to the alignment of the prosthetic leg you are used to. This is done to preserve some key functional features of the prosthetic foot.

WILL THE INFORMATION THAT I CONVEY TO THE RESEARCHER AND MY IDENTITY BE KEPT CONFIDENTIAL?

You have the right to insist that your name will not be recorded anywhere and that no one, apart from the researcher and identified members of the research team, will know about your involvement in this research or your Name will not be recorded anywhere, and no one will be able to connect you to the answers you give. Your answers will be given a code number or a pseudonym and you will be referred to in this way in the data, any publications, or other research reporting methods such as conference proceedings.

Your answers may be reviewed by people responsible for making sure that research is done properly, including the transcriber, external coder, and members of the Research Ethics Review Committee. Otherwise, records that identify you will be available only to people working on the study, unless you permit other people to see the records.

Your permission will be requested to de-identify data for research-related purposes, such as research reports, journal articles, and/or conference proceedings. Your confidentiality will be protected in any publication of the information.

While every effort will be made by the researcher to ensure that you will not be connected to the information that you share during the focus group, there is no guarantee that other participants in the focus group will treat the information confidentially. However, all participants are encouraged to do so. For this reason, you are advised not to disclose personally sensitive information in the focus group.

HOW WILL THE RESEARCHER(S) PROTECT THE SECURITY OF DATA?

Hard copies of your answers will be stored by the researcher for a minimum period of five years in a locked cupboard/filing cabinet for future research or academic purposes; electronic information will be stored on a password-protected computer. Future use of the stored data will be subject to further Research Ethics Review and approval if applicable (such as using the data for a purpose unrelated to the initial aim and objectives of the study). When necessary, *hard copies will be shredded, and/or electronic copies will be permanently deleted from the hard drive of the computer using a relevant software program.*

WILL I RECEIVE PAYMENT OR ANY INCENTIVES FOR PARTICIPATING IN THIS STUDY?

Your involvement in this research is entirely charitable; there will be no compensation for your involvement. You will not be expected to pay for anything during the course of the study. The travel costs to the laboratory and back home will be paid for by the researcher.

HAS THE STUDY RECEIVED ETHICS APPROVAL?

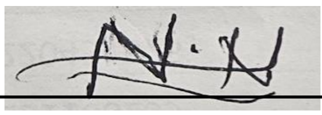
This study has received written approval from the Research Ethics Review Committee of the College of Agricultural and Environmental Sciences (HREC), Unisa. A copy of the approval letter can be obtained from the researcher if you so wish.

HOW WILL I BE INFORMED OF THE FINDINGS/RESULTS OF THE RESEARCH?

If you would like to be informed of the final research findings, please contact Zanodumo.T. Godlimpi on 0715452507. The findings are accessible for 5 years. Should you require any further information or want to contact the researcher about any aspect of this study, please contact Zanodumo. T Godlimpi on 12018082@mylife.unisa.ac.za.

Should you have concerns about how the research has been conducted, you may contact Prof Thanyani Pandelani or tell: 0110712137. Contact the research ethics chairperson of the UNISA-CAES health research ethics committee, Prof M.A Antwi email: antwima@unisa.ac.za or tell: 0116709391 if you have any ethical concerns.

Thank you for taking the time to read this information sheet and for participating in this study. Thank you.

Signature: 

Name & surname: Participant 1

CONSENT TO PARTICIPATE IN THIS STUDY

I, Nkululeko Nqumelwano (participant name), confirm that the person asking my consent to take part in this research has told me about the nature, procedure, potential benefits, and anticipated inconvenience of participation.

I have read (or had explained to me) and understood the study as explained in the information sheet.

I have had sufficient opportunity to ask questions and am prepared to participate in the study.

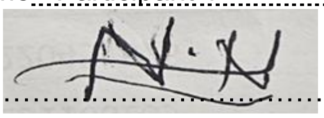
I understand that my participation is voluntary and that I am free to withdraw at any time without penalty (if applicable).

I am aware that the findings of this study will be processed into a research report, journal publications and/or conference proceedings, but that my participation will be kept confidential unless otherwise specified.

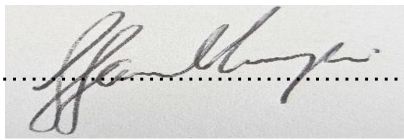
I agree to the recording of my walking pattern using motion capture.

I have received a signed copy of the informed consent agreement.

Participant Name & Surname. Participant 1 (please print)

Participant Signature  .. Date. 10 October 2025

Researcher's Name & Surname. Zanodumo Godlimpi (please print)

Researcher's signature  .. Date. 10 October 2025

APPENDIX B: Human participant information sheet and consent template

university of south africa
UNISA

PARTICIPANT INFORMATION SHEET

Ethics clearance reference number: 2023/CAES_HRC/1151
Research permission reference number (if applicable):

19 September 2023

Title: Design optimization and development of the pneumatic prosthetic foot.

Dear Prospective Participant

My Name is Zanodumo Thandazani Godlimpi and I am doing research with Professor Thanyani Pandelani, an Associate Professor in the School of Engineering, Science and Technology towards a Master of Engineering, at the University of South Africa. We have funding from the Technology and Innovation Agency for developing the pneumatic prosthetic foot. We are inviting you to participate in a study entitled Design Optimization and Development of the pneumatic prosthetic foot.

WHAT IS THE PURPOSE OF THE STUDY?

This study is expected to collect important information that could investigate the potential benefits of using pressurized air in prosthetics to provide functional prosthetic limbs. Similar studies conducted by (Sup, Bohara, and Goldfarb, 2007, 2008; Zheng and Shen, 2013, 2015a) with restrained prosthetic limbs show that there is a potential for pressurized air-powered prosthetic limbs, with angle and force values that match that of the biological limb. This study is expected to document new data about pressurized air-powered prosthesis that is meant to be collected in the lab environment on living human beings. The data to be obtained throughout the course of the study has the potential to assist in classifying pressurized air-powered prosthetic foot according to the patient's potential level of function (K-level).

WHY AM I BEING INVITED TO PARTICIPATE?

You are chosen to participate in this study because you are a below-knee prosthetic user, and you have been using a prosthesis for the past 6 months. Your contact information was obtained from Nelson Mandela Academic Hospital (Bedford Hospital) in Mthatha, and you were randomly chosen particularly from the list of patients that were serviced in the last 2 years. You will be one of two participants who will be participating in the research study.

WHAT IS THE NATURE OF MY PARTICIPATION IN THIS STUDY?

Your participation in this study is of a voluntary nature, you will be asked to walk within a lab environment using a below-knee pneumatic prosthetic leg. This exercise will take approximately 60 minutes, and this includes a 30-minute walk to familiarize yourself with using a pneumatic prosthetic foot to walk. Thereafter you will be asked to walk a distance of approximately 10 meters at a self-selected walking speed.

CAN I WITHDRAW FROM THIS STUDY EVEN AFTER HAVING AGREED TO PARTICIPATE?

Participating in this study is voluntary and you are under no obligation to consent to participation. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a written consent form. You are free to withdraw at any time and without giving a reason.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THIS STUDY?

The purpose of this study is to investigate the potential benefits of using pneumatic components in below-knee prosthetics. This will assist below-knee amputees living in rural areas or places where electricity is scarce to be able to walk more efficiently.

ARE THERE ANY NEGATIVE CONSEQUENCES FOR ME IF I PARTICIPATE IN THE RESEARCH PROJECT?

The risks of participating in this study have been reduced to minor discomfort and the institution will not be liable for any loss, damages, or injuries sustained during experiments. This discomfort may stem from not being familiar with using a pneumatic prosthetic foot and the alignment of the foot may not be identical to the alignment of the prosthetic leg you are used to. This is done to preserve some key functional features of the prosthetic foot.

WILL THE INFORMATION THAT I CONVEY TO THE RESEARCHER AND MY IDENTITY BE KEPT CONFIDENTIAL?

You have the right to insist that your name will not be recorded anywhere and that no one, apart from the researcher and identified members of the research team, will know about your involvement in this research or your Name will not be recorded anywhere, and no one will be able to connect you to the answers you give. Your answers will be given a code number or a pseudonym and you will be referred to in this way in the data, any publications, or other research reporting methods such as conference proceedings.

Your answers may be reviewed by people responsible for making sure that research is done properly, including the transcriber, external coder, and members of the Research Ethics Review Committee. Otherwise, records that identify you will be available only to people working on the study, unless you permit other people to see the records.

Your permission will be requested to de-identify data for research-related purposes, such as research reports, journal articles, and/or conference proceedings. Your confidentiality will be protected in any publication of the information.

While every effort will be made by the researcher to ensure that you will not be connected to the information that you share during the focus group, there is no guarantee that other participants in the focus group will treat the information confidentially. However, all participants are encouraged to do so. For this reason, you are advised not to disclose personally sensitive information in the focus group.

HOW WILL THE RESEARCHER(S) PROTECT THE SECURITY OF DATA?

Hard copies of your answers will be stored by the researcher for a minimum period of five years in a locked cupboard/filing cabinet for future research or academic purposes; electronic information will be stored on a password-protected computer. Future use of the stored data will be subject to further Research Ethics Review and approval if applicable (such as using the data for a purpose unrelated to the initial aim and objectives of the study). When necessary, *hard copies will be shredded, and/or electronic copies will be permanently deleted from the hard drive of the computer using a relevant software program.*

WILL I RECEIVE PAYMENT OR ANY INCENTIVES FOR PARTICIPATING IN THIS STUDY?

Your involvement in this research is entirely charitable; there will be no compensation for your involvement. You will not be expected to pay for anything during the course of the study. The travel costs to the laboratory and back home will be paid for by the researcher.

HAS THE STUDY RECEIVED ETHICS APPROVAL?

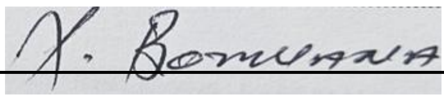
This study has received written approval from the Research Ethics Review Committee of the College of Agricultural and Environmental Sciences (HREC), Unisa. A copy of the approval letter can be obtained from the researcher if you so wish.

HOW WILL I BE INFORMED OF THE FINDINGS/RESULTS OF THE RESEARCH?

If you would like to be informed of the final research findings, please contact Zanodumo.T. Godlimpi on 0715452507. The findings are accessible for 5 years. Should you require any further information or want to contact the researcher about any aspect of this study, please contact Zanodumo. T Godlimpi on 12018082@mylife.unisa.ac.za.

Should you have concerns about how the research has been conducted, you may contact Prof Thanyani Pandelani or tell: 0110712137. Contact the research ethics chairperson of the UNISA-CAES health research ethics committee, Prof M.A Antwi email: antwima@unisa.ac.za or tell: 0116709391 if you have any ethical concerns.

Thank you for taking the time to read this information sheet and for participating in this study. Thank you.

Signature: 

Name & surname: Participant 2

CONSENT TO PARTICIPATE IN THIS STUDY

I, Nkululeko Nqumelwano (participant name), confirm that the person asking my consent to take part in this research has told me about the nature, procedure, potential benefits, and anticipated inconvenience of participation.

I have read (or had explained to me) and understood the study as explained in the information sheet.

I have had sufficient opportunity to ask questions and am prepared to participate in the study.

I understand that my participation is voluntary and that I am free to withdraw at any time without penalty (if applicable).

I am aware that the findings of this study will be processed into a research report, journal publications and/or conference proceedings, but that my participation will be kept confidential unless otherwise specified.

I agree to the recording of my walking pattern using motion capture.

I have received a signed copy of the informed consent agreement.

Participant Name & Surname. Participant 2 (please print)

Participant Signature……………………………………………..Date. 16 October 2025

Researcher's Name & Surname. Zanodumo Godlimpi (please print)

Researcher's signature……………………………………………..Date. 16 October 2025

Table 11: List of appendices

List of Appendices		
Appendix	**Description**	**Attachments**
Appendix C	Ethical clearance from UNISA	UNISA ethical clearance
Appendix D	Ethical clearance from the Eastern Cape Department of Health	DOH ethical clearance
Appendix E	A schematic drawing of the printed circuit board	PCB schematic diagram
Appendix F	An AMPnoPRO assessment results for Participant 1	Participant1 AMPnoPRO assessme
Appendix G	An AMPnoPRO assessment results for Participant 2	Participant2 AMPnoPRO
Appendix H	Pneumatic prosthetic shank drawings	Shank drawings
Appendix I	Prosthetic foot drawings	Foot drawings
Appendix J	Pneumatic cylinder bracket drawings	pneumatic cylinder bracket