Experimental Validation of the Lower Leg Trajectory Error, an Optimization Metric for Prosthetic Feet

by

Victor Prost

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Abstract

In India alone, there are about one million people with lower limb amputation who require significantly more effort to walk than able-bodied individuals. They are subject to social stigmas preventing them from employment and independent living. There is a gap between the high-performance prosthetic feet in the United States that come at a cost of thousands of dollars and affordable prostheses in the developing world, which lack quality, durability and performance.

The aim of this project was to design a high-performance, mass-manufacturable passive prosthetic foot for Indian amputees that complies with international standards at an affordable cost. This work was conducted in collaboration with Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS, the Jaipur Foot organization), in Jaipur, India. Through a novel, quantitative method called Lower Leg Trajectory Error (LLTE) which maps the mechanical design of a prosthetic foot to its biomechanical performance, we can optimize the compliance and geometry of a passive prosthesis to replicate able-bodied gait and loading on the foot using affordable materials.

This thesis is focused on evaluating the accuracy and validity of the LLTE as a novel design tool. To validate feet designed using the LLTE, field trials and clinical testing were performed on prosthetic feet prototypes with varying stiffnesses and geometries. The novel merits of these prototypes are that they can replicate a similar quasi-stiffness and range of motion of a physiological ankle using interchangeable custom U-shaped constant stiffness springs ranging from 1.5 to 24 Nm/deg and having up to 30° of range of motion. Initial testing conducted using these feet validated the consitutive model of the LLTE and suggested that prosthetic feet designed with lower LLTE values could offer benefits to the user. In future work, the validated design tool will be used to create high-performance, low-cost and mass-manufacturable prosthetic feet for amputees, throughout the developing world and in the developed world.

Thesis Supervisor: Amos G. Winter, V
Title: Associate Professor of Mechanical Engineering

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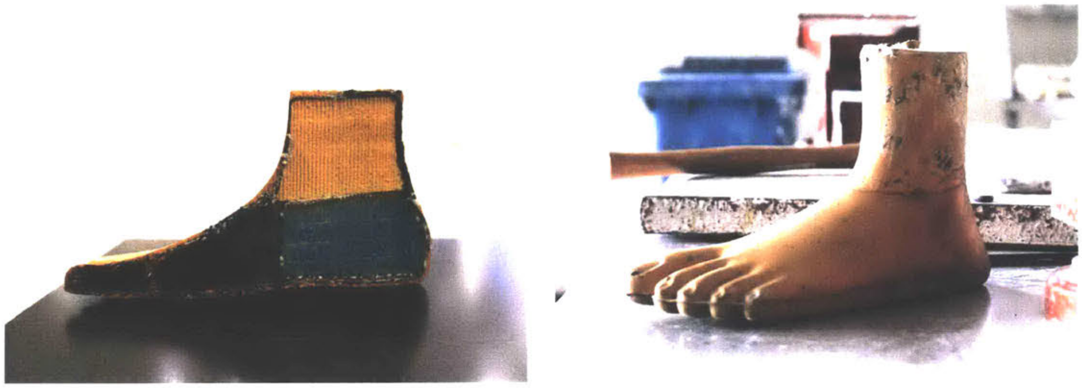
Chapter 1

Introduction

1.1 Background and Motivation

According to the government of India, there is an estimated 960,000 lower limb amputees in the country [8, 9]. Another 600,000 people in the U.S. are reported with lower limb loss, and this number is expected to grow by over 1.4 million by 2050 from cancer, circulatory diseases, diabetes, and population increase [10]. Globally there is around 25 million amputees in the world. The global prosthetics market as a whole is expected to reach US $23.5 billion by 2017 [11]. Despite the wide choice of lower limb prosthesis currently available, amputees still need improved prosthetic limbs, enabling them to circumvent the barriers to social engagement, employment, and independent living at an affordable cost. This is even more significant in India, where people suffer from social stigmas and have neither access nor the means to obtain a high-performance prosthetic foot.

Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS, 'Jaipur Foot organization'), is an NGO located in Jaipur, India. It is the largest organization serving persons with disabilities in the world [12, 13], has distributed over 1.3 million prosthetic limbs since it was started in 1975, and currently provides 29,400 limbs every year. The organization is entirely funded by private donations and government subsidies. Since its inception, all of the limbs and assistive devices are supplied free of charge to people coming to BMVSS.



(a) (b)

Figure 1-1: Photographs of the Jaipur Foot. (a) Cross-section view, with the wooden block at the ankle and the two rubber blocs covered by an aesthetic vulcanized rubber layer (b) Full view of the foot.

BMVSS is widely known for its prosthetic foot called that Jaipur Foot. The foot was developed in 1968 by Professor P. K. Sethi to suit the specific needs of Indian amputees. The SACH foot, or Solid Ankle, Cushioned Heel foot, that was widely used previously was inappropriate for Indian people [13, 14]. The SACH foot has a rigid internal structure unlike the more flexible Jaipur foot, which enabled users to squat, sit cross-legged, walk barefoot through mud and negotiate uneven terrain.

The Jaipur Foot is currently handmade from a block of wood and two blocks of micro-cellar rubber (MCR): a compressible and elastic block at the heel and a less compliant one at the forefoot (Fig.1-1). Technicians carve the three blocks which are then coated with rubber cement and bounded with fiber-reinforced nylon-rubber bands. The assembled blocks are then covered with a skin-colored, light and soft rubber (shore A45), before being tightly enclosed in a mold and vulcanized in an autoclave [14, 15]. Once removed, the Jaipur Foot mimics the appearance of a biological foot (Fig.1-1) and is ready to be fitted on the amputee. The foot costs around $8 to fabricate and the entire fitting process costs $30 [9]. In addition to having an inexpensive, simple and fast process of fabrication, the Jaipur Foot supports developing country lifestyles and is widely regarded as robust and relatively high performance prosthetic foot [16].

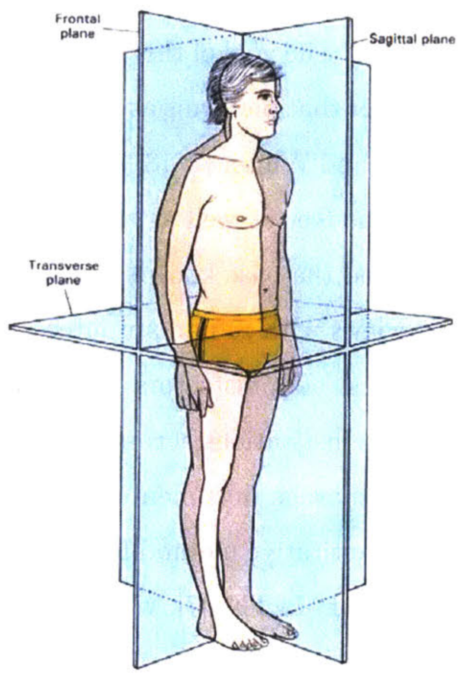
In 2010, after several attempts to make an improved polyurethane version of the

Jaipur Foot [9, 17], BMVSS started a collaboration with Prof. Winter at the Global Engineering and Research (GEAR) Laboratory at MIT. The goal of this work is to design an affordable, mass-manufacturable prosthetic foot that performs as well as, if not better than, the Jaipur Foot. The work of Olesnavage and Winter [7, 18, 19, 20, 21, 22] on understanding the governing behavior of prosthetic feet as well as the social factors that determine their design requirements provided the base knowledge on which this thesis is built. After conducting personal interviews with Indian amputees, prosthetists, technicians, engineers, physicians, professors, administrators at prosthesis fitment centers, rehabilitation hospitals, and academic institutions across India, along with on field testing prosthetic foot prototypes, Olesnavage documented many specific design requirements. She also created a novel quantitative method for evaluating foot performance called the Lower Leg Trajectory Error (LLTE) [7], which maps the mechanical design of a prosthetic foot to its biomechanical performance. Using the LLTE as a design tool, the shape and compliance of the prosthetic foot can be optimized to replicate able-bodied gait and loading on the foot using affordable materials such as injection molded plastic while meeting the needs of amputees in India.

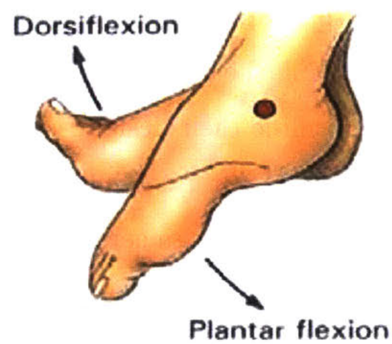
Thus far, work regarding the LLTE has been mainly theoretical. In order to use this framework to design commercial prosthetic limbs, it is necessary to evaluate the validity of the LLTE as a design objective for prosthetic feet through clinical and field testing.

1.2 Typical Human Gait and Biomechanics

Anatomical motions are usually described regarding three planes: the sagittal plane that splits the body left and right, the frontal plane that splits the person front and back and the transverse plane, as shown in Fig.1-2a. The ankle joint does 93% of its work in the sagittal plane during flat ground walking [23]. The motions of the ankle in this plane are called plantarflexion, which is when the toes point downward and dorsiflexion, which is when the toes point upward (Fig.1-2b). Reference axes and the anatomical terms of location for a foot-ankle system that will be used further in



(a) Anatomical Reference Planes



(b) Ankle Plantar and Dorsiflexion

Figure 1-2: Anatomical Vocabulary [1]

this thesis are shown in Fig.1-2a. The human ankle has the ability to move in the transverse and frontal planes through inversion/eversion, or abduction/adduction as a way to comply with uneven ground and enable a vast diversity of walking and standing strategies. However, since the vast majority of ankle work for flat ground walking is done in the sagittal plane, this study focused, as a start, on kinematics and kinetics of the ankle-foot system in this plane of progression.

Gait refers to a periodic motion that people exhibit to support and propel themselves. It is a broad term that includes many motions such as walking, running, or hopping. This thesis mainly addresses flat ground walking but the findings can be extended to other gait patterns. Hence, in this thesis, the word gait will only refer to walking. A gait cycle covers one complete sequence (or stride) which starts with one heel making contact (heel strike) to the next time the same heel makes contact with the ground. A simple way to break this process down is to divide this cycle into two phases, stance and swing, as shown in Fig.1-3. During stance phase, the foot is in contact with the ground while the rest of the cycle is swing phase. Stance phase starts when the heel strikes the ground and ends when the toe of the foot leaves the ground (toe-off), which makes up about 60% of the cycle; swing phase makes up the remaining 40% [24]. As shown in Fig.1-3, during the gait cycle, while one foot is in stance phase the other foot is always in swing phase. Thus, twice during each gait cycle, both feet are in contact with the ground, which is referred to double limb support.

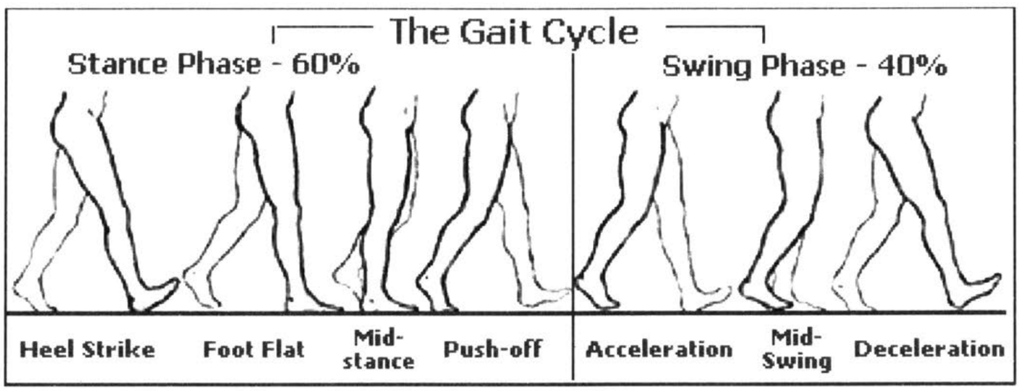


Figure 1-3: Typical gait cycle and nomenclature of each phase [1]

For passive prostheses design, it is useful to describe the stance phase in more details since it is during this phase that the behavior of the prosthesis will matter the most. The stance phase can be broken down into the controlled plantarflexion, controlled dorsiflexion and powered plantarflexion phases [25]. These phases are defined from the ankle angle versus ankle torque curve (Fig.1-4). The controlled plantarflexion happens between heel strike and foot flat, the controlled dorsiflexion spans from foot flat to push off (pre-swing), and the powered plantarflexion from pre-swing to toe-off. Over a gait cycle, the ankle produces net positive work to propel the person forward. This positive work mostly happens during the plantarflexion phase. Since passive prostheses cannot output any additional energy, most prostheses focus on the controlled plantarflexion and controlled dorsiflexion during which the prosthesis can store and return energy (Fig.1-4).

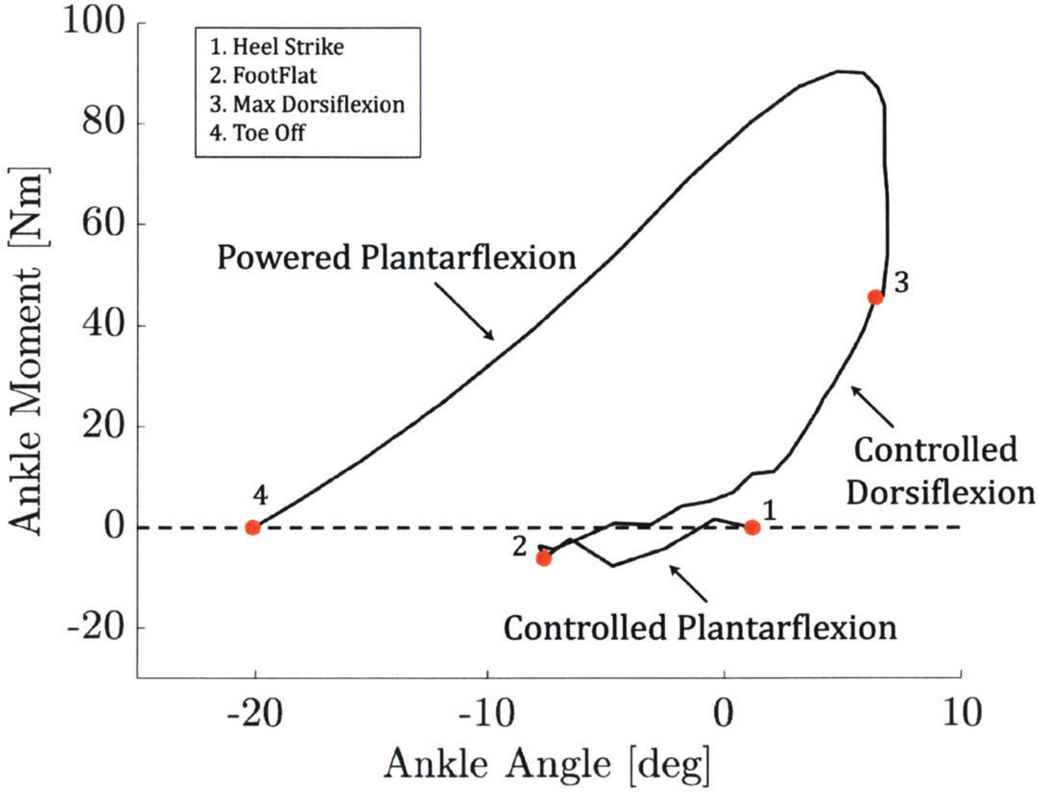
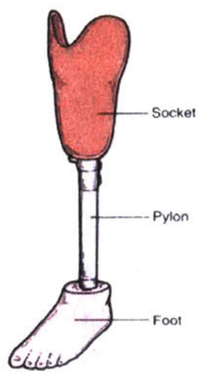


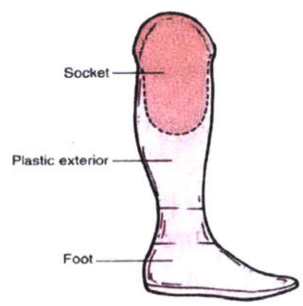
Figure 1-4: Ankle Moment and Angle from Winter's data set [2].

1.3 Prosthesis Terminologies

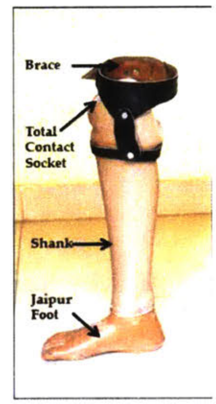
Prosthesis users are often distinguished by their level of amputation. An above knee amputation is referred to as transfemoral while a below knee amputation is referred to as transtibial. Transfemoral prostheses are more complex than transtibial ones since they require an additional mechanism to replace the knee. However, most of the terminologies for a transtibial prosthesis also applies to a transfemoral prosthesis, as they both include a prosthetic foot. About 80% of lower limb amputees are transtibial amputees [26].Therefore this thesis focused on prosthetic feet intended for this population. Lower limb transtibial prostheses are integrated systems of custom-made parts and off-the-shelf components. The three main components are: the socket which interfaces with the residual limb, the foot, and the shank connecting the foot to the socket (pylon for an endoskeletal shank or plastic enclosure for an exoskeletal shank such as the Jaipur Foot) (Fig.1-5). In addition to the fitting of the custom-made socket, the alignment between the foot and the socket must be tuned to ensure optimal performance of the entire system. The comfort of the prosthesis is mainly influenced by the socket fit while the biomechanical functions are ensured by the foot design [27].



(a) Endoskeletal system



(b) Exoskeletal system



(c) Jaipur Leg

Figure 1-5: Drawing of typical trans-tibial prostheses [3] and photograph of a Jaipur Leg distributed in BMVSS

Lower limb amputees have reduced muscle function, neural response and bone structure, resulting in altered gait patterns and requiring more effort to walk [28]. The ideal prosthetic foot would compensate for the musculature and bone structure loss and enable the person to engage in all activities with little effort and no long term injuries.

1.4 Thesis Outline

This thesis, as described at the beginning of this chapter, builds upon the earlier work done by Olesnavage K. and Winter A., [7, 18, 19, 20, 21, 22] and is primarily focused on the mechanism design and testing of a fully passive prosthetic foot that can be used to evaluate and validate the LLTE as a metric for optimizing passive prosthetic feet designs. The outline of the thesis is the following:

Chapter 2: Overview of prosthetic feet design and performance metrics

Current types of prosthetic feet, methods of quantifying the differences between prostheses and metrics used for designing and evaluating prosthetic feet are reviewed and discussed in this chapter.

Chapter 3: Analysis of prototype concept using the LLTE metric

The Lower Leg Trajectory Error is introduced in this section and applied to a simple prosthetic foot model. The results of the prosthetic foot design optimization using the LLTE framework are presented and discussed.

Chapter 4: Mechanical design and testing of the prosthetic prototypes

The physical embodiement and mechanical design of the prosthetic foot model are presented in this chapter along with the custom ankle spring design enabling high stiffness and high range of motion. The mechanical testing of the prosthetic feet prototypes is descibed and the results of this testing are discussed.

Chapter 5: Clinical testing results and LLTE framework validation

This chapter presents the results obtained from testing the prototype with amputees in India and in the gait lab. The insights from these tests on the LLTE framework as a tool to design prosthetic feet are discussed. In conclusion, validation of our design framework and its use in future work are examined.

Chapter 2

Litterature Review

2.1 Prosthetic Feet Overview

Most commercially available prostheses are passive devices. Powered prostheses such as the BiOM are not commonly used and come at a cost of tens of thousands of dollars [29]. These devices use motors (pneumatic or electric) to generate the torque required for propulsion and ankle motion. Studies have shown that these prosthesis improve gait performance and enable users to walk at a lower metabolic cost compared to passive feet [30]. However these prostheses, need daily battery charging, are much heavier, less robust, fragile, not waterproof, very expensive and extremely complex to fabricate and maintain compared to passive devices. These drawbacks prohibit their use in developing world settings in favor of passive prosthetic feet.

Passive devices are more affordable and can be purchased for several thousand dollars in the developed world and tens of dollars in the developing world [9]. They are usually composed of passive components such as springs, dampers, or compliant structures of various forms. Passive prosthetic feet can generally be placed into one of the three following categories: conventional feet, single and multi-axis feet, and energy storage and return (ESAR) feet [31].

Conventional feet, widely used in the developing world, are basic designs that have no moving parts. These feet are designed to primarily support body weight and have minimal functionality. The most common example is the solid ankle cushioned heel

(SACH) foot (Fig.2-1). It consists of a rigid wooden of plastic ankle, a foam heel and a plastic covering. Because of the simplicity of the design, the SACH foot is generally regarded as a light-weight, stable, durable and inexpensive foot with low maintenance for basic uses. They usually cost ten to a hundred dollars [9]. However most of these rigid designs prevent deformations of the foot under normal loading and do not store and return energy during gait, thereby increasing the effort required by the user to walk and resulting in poor gait patterns.

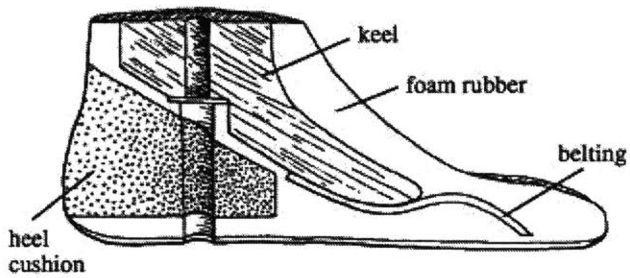


Figure 2-1: Schematic of a SACH foot internal structure, with a rigid keel, foam heel and plastic covering [4].

Single and multi-axis feet (Fig.2-2) have hinges or other mechanism that allow the foot to flex in many directions. These feet provide ankle articulation and great range of motion, leading to improved stability and enabling walking on uneven terrain and enhanced walking patterns. They are generally heavy, not very durable, more complex and come at a high cost for the amputees - around several thousand dollars [5]. Like conventional feet, they do not store and return energy during gait, thus requiring some additional effort by the user to walk. Some examples are the Willowood, 1A30, Greissinger, TruStep, Odyssey or Genesis II [5].

Energy storage and return (ESAR) feet have flexible keels allowing greater degree of ankle range of motion compared to conventional feet and are able to store and return energy during the gait cycle (Fig.2-3). These prostheses are designed to store energy like a spring during the early phase of a step and return it to the amputee to propel the body towards the end of a step. People doing athletic activities or having an active

Figure 2-2: Single and Multi-Axis feet schematics, along with a photograph of the Single axis foot from College Park [4, 5]

lifestyle prefer these lightweight feet since they provide a more dynamic response. They generally consist of carbon fiber leaf springs, requiring less maintenance but lack stability and cost several thousand dollars. Examples are the Flex Foot, Niagara Foot, Freedom Innovation Foot, or Rush Foot [6, 32]. The use of elastic properties in this way can also be seen currently in single and multiple axis feet such as the College Park TruStep foot [5], since it helps with the propulsion of the amputee at each step in the gait cycle.

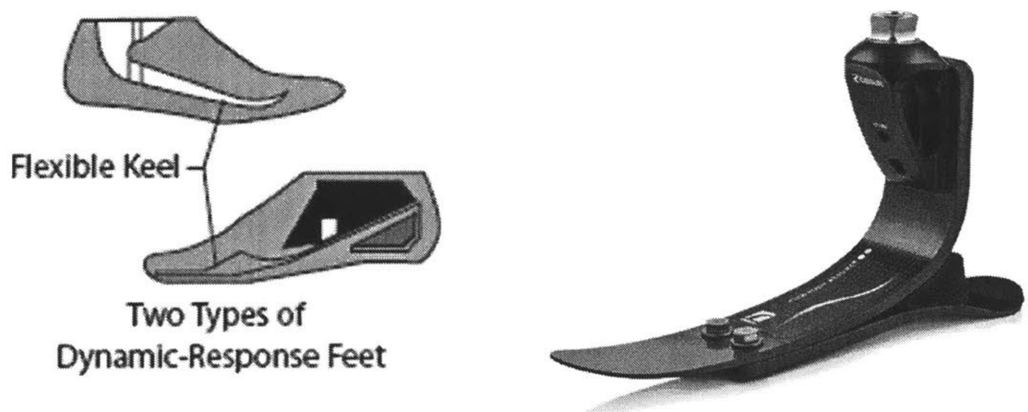


Figure 2-3: Two ESAR feet schematics examples along with Ossur's Flex-Foot sold at $1099 [6, 4].

2.2 Evaluating and Measuring Prosthetic Feet Performances

In an effort by foot manufacturers, international standards associations, and academics to compare different prosthetic feet and evaluate their effects on the patient's walking performance, gait analysis and perception studies are conducted. During these studies three types testing are conducted:

- Mechanical testing of prosthetic feet
- Gait analysis which consist in collecting kinematics, kinetics, stride and temporal characteristics [31] over a gait cycle (Fig.1-3)
- Subjective and metabolic assessment including muscle activation, metabolic expenditure, comfort, and performance perception.

These measures are then used to provide insight into the performance of the prosthetic foot. Mechanical metrics are the most useful in designing a foot, as they map directly to design requirements and can often be understood in terms of fundamental principles of engineering. However, they are further removed from human use scenarios which ultimately determine the success of a prosthetic foot. On the other end of the spectrum, subjective and metabolic comparisons are directly related to the satisfaction of the prosthesis user and the perceived performance of the foot. Yet, these metrics are difficult to relate to the prosthetic foot design as they are dependent on many factors that are not necessarily known and cannot be tested until a foot is built.

Mechanical Testing

Mechanical testing of a prosthetic foot has been standardized as an attempt by prosthetic feet manufacturers to categorize their products by mechanical behavior and functionality, and to ensure the safety and durability of the manufactured foot. The American Orthotic and Prosthetic Association (AOPA) established a coding standard to classify prosthetic feet based on eight different mechanical tests using the foot and universal testing machines such as Instrons or MTS [33]. These tests include measurements such as the foot deformation under static loading, and energy storage and return (ESR). The ISO 22675 and ISO 10328 standards [34, 35] were developed to prove safety and durability of a prosthetic foot through static and fatigue testing. These standards describe tests that replicate the loading of a prosthetic foot during a step. In order to pass the ISO 22675, a prosthetic component must undergo three million cycles of this loading without any sign of failure, representing approximately three years of use [34]. These standards, while being widely used in the industry, have failed to find consistent behaviors within categories of feet. As an example, two feet having the same value of energy storage and return can exhibit different behaviors, as the manner in which the foot stores and returns energy during the gait cycle can vary and have significant effects on the performance of the foot.

Researchers have introduced alternative mechanical metrics as means to consistently compare prosthetic feet. These mechanical metrics are often compared to biological feet mechanical response in order to assess the performance of the foot. The most studied metrics are listed below:

- Stiffness and viscoelasticity of a prosthetic foot are measured to evaluate the behavior of the foot under loading and assess the propulsive force provided by the prosthesis during push-off (Fig.1-3). A prosthetic foot exhibiting larger push-offs results in improved walking efficiency [36, 37, 38, 39].

- Roll-over shape (Fig.2-4) introduced by Hansen [40], describes the path of the center of pressure on the foot from the heel strike to the opposite heel strike in the ankle-knee reference frame. A roll-over shape closest to the biological foot roll-over shape has been experimentally shown to improve walking patterns [41].

- Effective foot length ratio (EFLR) investigated by Hansen corresponds to the ratio between the effective length of the roll over shape and the overall length of the foot [42]. An EFLR closest to the physiological value of 0.83 seems to result in more symmetric walking.

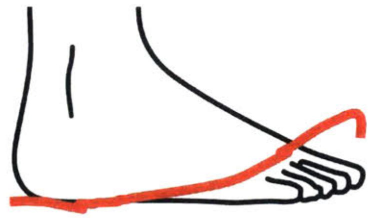


Figure 2-4: Roll-over shape of an able-bodied foot from Winter's data set [2]

- Shock absorption and impact loading are also measured to evaluate both the impact load that the user will experience at the socket interface and also the behavior of the foot under high impact daily living activities [43].

Gait Analysis

Gait analysis refers to studies of legged locomotion and collecting kinematics, kinetics, stride and temporal characteristics over gait cycles by using a set of sensors such as force plates or motion capture systems. These studies are used to test commercially available prosthetic feet to evaluate their performance by comparing the collected data to physiological data, or test prosthetic prototypes with varying design parameters such as shape, geometry, stiffness, or number of joints to determine how each parameter affects the gait of the patient.

The goal of a given prosthetic foot is to restore the functionality of the loss limb. Studies have focused on each of the measurable characteristics listed in Table 2.1 over a gait cycle to evaluate the performance of a prosthetic foot. Evaluating a prosthetic foot through gait analysis is crucial, since it can also prevent further injuries. A prosthetic foot resulting in asymmetrical kinematics and loading on each foot can lead to long term injuries on the patient [41, 33, 44]. By considering all of these gait analysis studies, it is noticeable that we can relate gait kinematics parameters to mechanical characteristics. For example, the ground reaction forces (GRF), the center of pressure (CoP) and kinematics are related to the stiffness and geometry of the foot. The combined measurement of the center of mass (CoM) and the CoP can give insights on the gait stability and the balance of the person using the prosthesis [45]. Likewise, the CoP is directly linked to the roll-over shape and the energy storage and return is correlated to the viscoelasticity and stiffness of the foot.

Category	Measurables
Kinematics	Joint Angles (ankle, toes, knee, hip) and accelerations, Joint moments, Limb-markers positions, Center of Mass (CoM)
Kinetics	Ground reaction forces (GRF), Center of Pressure (CoP), Mechanical work, Energy storage and return (ESR), Push-Off power
Stride Characteristics	Symmetry between sound and prosthetic side motion, Step Length, Stability, Double support, Cadence, Muscle activation

Table 2.1: List of measurable characteristics over a gait cycle

Subjective and Metabolic Comparisons

Subjective questionnaires and metabolic measurements to compare prosthetic feet are usually determinant factors of the superiority of a prosthetic foot over another prosthetic foot [46, 47]. For example extensive experiments of metabolic expenditure have shown that amputees demonstrate elevated heart rate and as far as 55% to 83% higher oxygen consumption when walking at similar speeds as non-amputees [48]. Thus a prosthetic foot that allows a user to expend less energy while walking is preferred over other prosthetic feet. Determining what mechanical and gait analysis parameters cause feet to be superior lacks a definitive answer. Hence, subjective and metabolic metrics both provide useful evaluation tools for existing prosthetic feet.

Subjective questionnaires include several parameters used to rank different prosthetic feet such as comfort, perceived performance, confidence while walking, aesthetics, fatigue, agility, stability, weight, shock absorption, ease of use, walking speed, and functionality [49]. Metabolic studies consist of longer walking scenarios on treadmills where oxygen consumption, carbon dioxide production, and heart rate data are collected [50, 51]. These studies have also come to the conclusion that feet requiring less energy expenditure are superior to feet that require more. However there is little understanding on which features of a prosthetic foot affect the metabolic cost of walking with it [52]. For example, the effect on metabolic cost of varying the forefoot or keel stiffness in different prosthetic feet have failed to reach similar conclusions [44].

2.3 Prosthetic Foot Design Methods

The design of passive foot structures built of carbon fiber, plastic, foam, wood and metal has largely been done through an iterative process driven by intuition formed by observations and experience of prosthetists [14]. Alternatively, prosthetic feet have been designed by matching mechanical characteristics of physiological feet such as the geometry, ankle, or metatarsal stiffnesses [53]. The major drawback of this approach is that, passive prosthetic feet are not able to generate any power, nor can be actively controlled as physiological feet. The mechanical characteristics of a physiological foot cannot be considered seperately from its muscle and nervous system as they work in pair. Thus, by only matching the geometry and stiffness of physiological feet this method disregards some crucial information.

Prosthesis engineers are often tasked to design prosthetic feet by tuning the prosthesis stiffness in order to maximize the energy storage and return (ESR) for a given user's weight [6]. It is well accepted that walking with a prosthesis should demand the least amount of energy possible; hence the goal of maximizing ESR. However, it has been shown that more compliant feet allow for increased ESR, flexibility, and impact absorption, but require a greater amount of muscle activity in both the amputated and intact limb to balance during flat ground walking [54]. The effects of prosthetic foot stiffness remains unclear [31].

Fey et al. used simulated metabolic cost through an amputee muscoskeletal model along with intact knee loading during below-knee amputee walking to tune the stiffness and geometry of a prosthetic foot model [55, 56]. However, the effect of muscle activation and metabolic cost of walking on an amputee remains an inconsistent variable. Furthermore, the scope of these studies were purely theoretical and no experimental validation has been performed thus far.

One simplified metric, the roll-over geometry, has been used to design passive prosthetic feet. As a reminder, the roll-over geometry is defined as the path of the center of pressure along the foot from heel strike to toe off in the ankle-knee reference frame [41]. The roll-over geometry of a prosthetic foot is a spatial measure of stiffness. When the center of pressure is at a certain position along the foot, the roll-over geometry shows what the vertical deflection of that point will be. The rollover geometry also serves to simplify the many variables that can be measured during a biological step into a single curve that can be used as a design objective. Roll-over shapes vary little for people of similar leg lengths. The roll-over shape has been found to be invariant to walking speed, added weight, and shoe heel height. Studies suggest that prosthetic feet that replicate roll-over geometry result in increased metabolic efficiency, more symmetric gait, and higher subjective preference [44, 47].

Recently, it has been shown that this metric does not provide enough information to accurately describe the biomechanical performance of a prosthetic foot. Feet with similar roll-over shapes can result in very different kinematics, kinetics and biomechanical performance, thus affecting its ability to be used as a reliable design metric for prosthetic feet [7]. A novel design objective for passive prosthetic feet, building upon the roll-over geometry, the Lower Leg Trajectory Error (LLTE), was developed [57]. It provides a quantitative connection between the stiffness and geometry of a prosthetic foot and its biomechanical performance. This metric enables the optimization of prosthetic feet by modeling the trajectory of the lower leg segment (ankle-knee segment) throughout a step for a given prosthetic foot and selecting values of design variables to minimize the error between this trajectory and target physiological lower leg kinematics. This metric was used in this thesis to optimize the geometry and stiffness of a prosthetic foot in order to validate the LLTE-based design method.

2.4 Discussion

While there are a wide variety of passive prosthetic feet commercially available, they are far from providing the full functionality of an able-bodied foot, and there is a lack of information available to quantify and understand differences in their performance. Most foot design work relies on empirical knowledge, numerous iterations and personal experience of prosthetists. Currently, a foot's performance and behavior cannot be reliably assessed without building and testing it. Many studies have attempted to characterize types of prosthetic feet based on mechanical testing, gait analysis, energy expenditure, and user perception. They have shown substantial evidence suggesting that the mechanical function of passive below-knee prostheses affects walking mechanics and efficiency of users. However, how the mechanical features of a passive prosthesis affects its functionality is not fully understood [52].

Without this knowledge, passive prosthetic feet cannot be optimized for cost, manufacturability, specific activities or peak performance. Prosthetic foot designs for both passive and active mechanisms have focused on replicating the functionality of the physiological foot-ankle complex to maximize functional mobility for the user [58]. However, the physiological foot-ankle complex is a complicated system capable of feedback, active control, and power generation. A passive prosthesis cannot reproduce all of these functions. The recently developed LLTE-based design tool [7] for prosthetic feet enabling the design of prosthetic feet optimized for performance seems the most promising. Work thus far regarding this method has been purely theoretical. It has yet to be validated and needs to be evaluated before being used to create high performance, low-cost, and mass-manufacturable prosthetic feet for amputees in India and throughout the developing world.

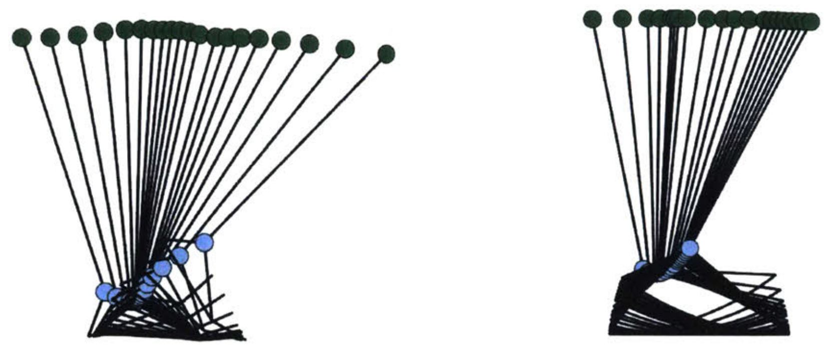
Chapter 3

Prototype Concept

3.1 Lower Leg Trajectory Error

The purpose of a passive prosthetic foot is to fulfill the missing limb functionality through a mechanical device. This device will deform or move under a specific loading scenario. Knowing the loading scenario and the mechanical characteristics (geometry, stiffness, pin joints...) of the passive foot, the behavior of the prosthesis can be calculated and give critical insights on the induced gait pattern. As explained in the previous section, the roll over shape compiles the loading scenario and the mechanical characteristics of the foot into a single curve. This curves contains information on the behavior of the foot under this specific loading and it is usually compared to the physiological roll-over shape. However, it omits any information regarding the lower leg segment (shank) orientation in the lab reference frame, hence the position, orientation, and loading of the socket and the knee (or residual limb) are unknown for a given roll over shape. Therefore, any changes in the lower leg segment orientation for a given roll over shape will affect both the gait kinematics and loading of the user's residual limb. As shown by Olesnavage K. [57], a rigid foot shaped so that it exactly exhibits the roll-over shape of a physiological foot will not induce physiological lower leg kinematics (Fig.3-1). In consequence, the amputee will experience different kinematics from able-bodied gait patterns while using this rigid foot.

By including the physical structure of the prosthetic foot in the model, the design



(a) Physiological Foot (b) Rigid Foot

Figure 3-1: Comparison of physiological lower leg trajectory from able-bodied gait data with a rigid foot with physiological roll-over geometry (b) [7].

of this prosthesis can be optimized not only for roll over geometry but also for the orientation of the lower leg and thus providing an improved link between the mechanical behavior of the prosthesis and it's biomechanical performance. The combination of the roll over geometry and the orientation of the lower leg, is equivalent to the trajectory of the lower leg segment, leading to the lower leg trajectory error (LLTE) metric described here after.

The LLTE is a measure of the normalized root mean square (RMS) error between the lower leg trajectory of a prosthetic foot model under able-bodied loading versus the trajectory of the corresponding physiological step during stance phase [57]. Thus, a lower LLTE value corresponds to a prosthetic foot that better replicates able-bodied ankle-knee kinematics under able-bodied kinetics, and the ideal prosthetic foot would result in a LLTE value of zero.In other words, it would exactly exhibit able-bodied ankle-knee trajectory under physiological loading.

The lower leg trajectory in the sagittal plane can be described by three variables: x_{knee}, y_{knee} and θ (Fig.3-2). To compute the LLTE, these variables are compared to target physiological values taken from published gait data [2], $\hat{x}_{knee}$, $\hat{y}_{knee}$ and $\hat{\theta}$. These variables are a set of discrete points taken at different time intervals. The normalization of the RMS error was chosen to reduce the bias towards any of the kinematic variables and was done by using the average values of each of the physi-

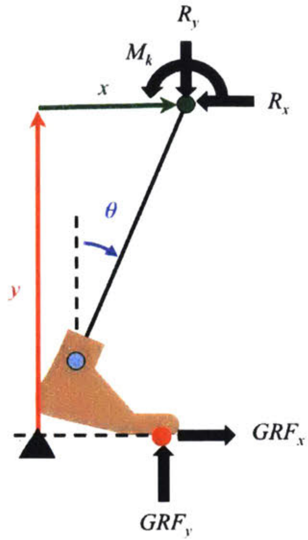


Figure 3-2: Free-body diagram of foot-ankle-knee system in the saggital plane. The system is acted on by the ground reaction forces (GRF_x and GRF_y) and the reaction loads (R_x and R_y) and moment (M_k) at the knee. The position and orientation of the lower leg segment is fully defined by three variables: the horizontal and vertical position of the ankle (x_{knee} and y_{knee} respectively) and the angle of the lower leg with respect to vertical (θ_{LL}). The orientation of the lower limb affects not only the gait kinematics of the user, but also the reaction moments on his or her residual limb and at her knee.

ological parameters over the portion of the step included in the optimization, $\bar{x}_{knee}$, $\bar{y}_{knee}$ and $\bar{\theta}_{LL}$. The equation for computing the LLTE can thus be written as

$$LLTE = \sqrt{\frac{1}{N}\sum_{n=1}^{N}\left[\left(\frac{x_n^{knee} - \hat{x}_n^{knee}}{\bar{x}_{knee}}\right)^2 + \left(\frac{y_n^{knee} - \hat{y}_n^{knee}}{\bar{y}_{knee}}\right)^2 + \left(\frac{\theta_n^{LL} - \hat{\theta}_n^{LL}}{\bar{\theta}_{LL}}\right)^2\right]} \quad (3.1)$$

where n refers to the n^{th} time interval and N is the total number of time interval considered in a step. Currently, the LLTE framework includes the lower leg trajectory from midstance, where the foot is flat on the ground and the lower leg angle is zero, to toe off.

The underlying idea behind this metric is that the amputee does not 'feel' the prosthesis; he only feels the socket through his residual limb. Having that in mind, the prosthesis could be a device completely different from a physiological foot as long as the residual limb experiences able-body kinematics and loading. If this is accomplished, the amputee may have a natural gait, reduced long term injuries, and reduced discomfort. Focusing on the residual limb kinematics and kinetics through the LLTE metric enables us to consider and evaluate an entirely new range of prosthetic foot designs.

The assumptions made by the LLTE metric are the following:

- The socket and residual limb are rigidly attached and there is no relative motion between the socket and the residual limb of the amputee.
- No slipping is occurring during the entire step between the prosthesis and the ground.
- The prosthetic foot is fully mechanically characterized; the resulting deformation of the prosthesis can be computed when subjected to a loading case.
- During the entire stance phase the loading response of the foot can be described using the quasistatic assumption, which is common in prosthetic feet studies since the natural frequency of most prosthetic feet are one or two magnitudes larger than the loading rate during straight flat ground walking [59, 60, 61].
- Prosthetic feet users aim to have able-body kinematics and kinetics during normal walking. The prosthetic foot should restore the functionality of the lost limb. Targeting able-body kinematics and kinetics during normal walking also targets symmetric gait and symmetric loading on each foot, which reduces long term injuries. It has been shown that asymmetric gait patterns usually lead to increased loading on the sound limb, the development of chronic back pain, or degenerative changes such as osteoarthritis of the knee or hip joints [62].
- Using physiological GRFs along with CoP data as inputs in our optimization framework leads to close to physiological GRFs and CoP when amputees walk with these optimized feet (low LLTE value). Therefore, the predicted kinematics

will be close to the measured kinematics for the optimal feet. However, we expect that prosthetic feet designs that are far from optimal (high LLTE value) will not exhibit close to physiological GRFs, CoP and the predicted kinematics will not be the measured kinematics. For a very compliant prosthetic foot design, applying the able-body GRFs and CoP data on the prosthesis would result in a lower leg trajectory where the user falls on the ground. In reality, the user will maintain balance and stability on the compliant foot to avoid falling and thus load the foot differently during a step. This high-LLTE prosthetic foot design will nonetheless remain a worse design than the optimal case since both the exhibited kinematics and kinetics are far from able body data.

Lower Leg Trajectory Error (LLTE) maps the mechanical design of a prosthetic foot to its biomechanical performance. It provides a quantitative connection between the stiffness and geometry of a prosthetic foot and its biomechanical performance. Using the LLTE as a design tool (Fig.3-3), the shape and compliance or other design variables of a prosthetic foot can be optimized to replicate able-bodied gait and loading on the foot.

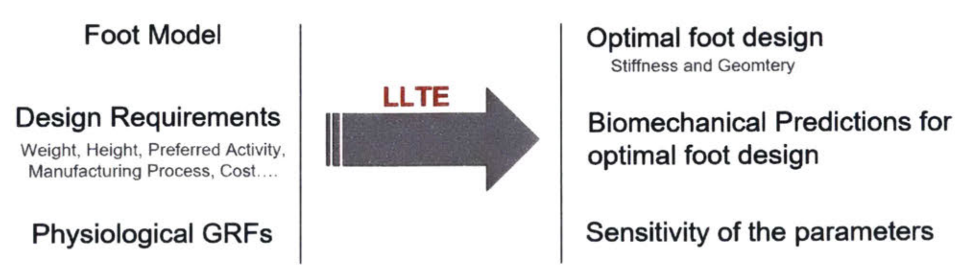


Figure 3-3: Schematic of the LLTE framework for designing prosthetic feet.

3.2 Prosthetic Foot Concept and LLTE Optimization

To evaluate the accuracy and validity of the LLTE as a design tool we applied it to a simple conceptual architecture consisting of a rotational ankle joint with constant stiffness k_{ank}, and a cantilever beam forefoot with a bending stiffness k_{met} (Fig.3-4), [7, 20]. The geometry of the rotational ankle, beam forefoot foot were selected to replicate the articulation of the physiological foot-ankle complex from a set of published gait data, with h = 8 cm and d_{rigid} = 9.3 cm [2]. The rigid structure's length, d_{rigid}, was chosen such that during late stance, the effective rotational joint of the pseudo-rigid-body model of the cantilever beam forefoot would be approximately at the center of rotation of the metatarsal joint for physiological data. The pseudo-rigid-body model approximates a cantilever beam with a vertical end load as a rigid link and a rotational joint with stiffness related to the beam bending stiffness [63].

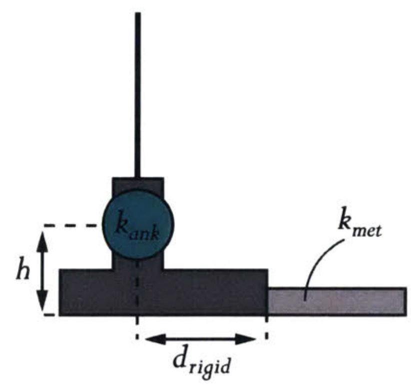


Figure 3-4: Foot concept architecture, comprising of an ankle joint and a forefoot cantilevered beam. The position of the ankle joint and the forefoot beam have been chosen to replicate the articulation of the physiological foot-ankle complex.

The LLTE design method works by imposing physiological ground reaction forces through a step on a model prosthetic foot with given stiffness and geometry. The resulting deflection, and thus the trajectory of the lower leg (shank) can then be calculated (Fig.3-2). The design variables, k_{ank}, and k_{met}, were optimized using our LLTE-based design method [57]; for each k_{ank}, and k_{met} values, the position and orientation of the lower leg were computed by imposing able-body GRFs and CoP from midstance to toe-off on the prosthetic foot model. From this lower leg trajectory, the LLTE was calculated using a RMS error with able-body lower leg kinematics. The stiffness of the ankle and forefoot can then be tuned/chosen to reduce the LLTE value [7]. For this study, Winter's gait data [2] for a subject of body mass 56.7 kg was used as inputs into the LLTE model. The set of design variables giving the lowest value for the LLTE was taken to be the optimal design. The minimum LLTE value, 0.222, was calculated for k_{ank}= 3.7 Nm/deg and k_{met} = 16.0 Nm^2 (Fig.3-5).

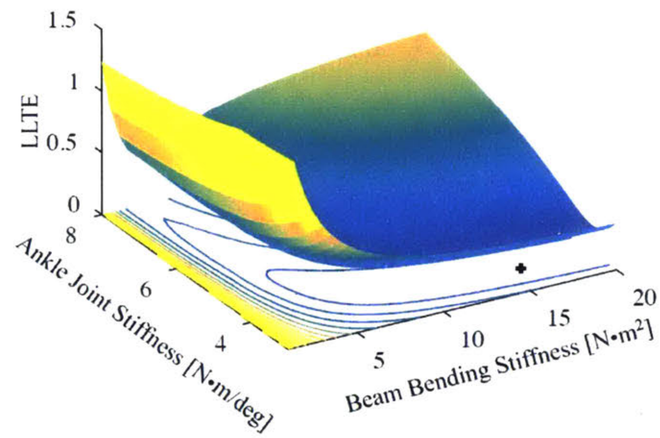


Figure 3-5: LLTE values calculated for each conceptual model foot over ranges of design variables. The optimal designs are those which produce the minimum LLTE, indicated here by the cross.

3.3 Requirements for Validating LLTE

Thus far, all work regarding the LLTE had been purely theoretical. The next step in moving towards using the LLTE to design commercial prosthetic limbs was to clinically test the validity of the LLTE as a design objective for prosthetic feet. These tests will have to ensure that the model accurately predicts the lower leg kinematics of a subject using a fully characterized prosthetic foot. In order to validate the LLTE as a design metric, it is necessary to design, build, and test a set of prosthetic feet based on the optimal design presented in the previous section and determine that the LLTE-optimal foot does indeed allow a user to walk with close to able-bodied kinematics. It is also important to understand the sensitivity of the design parameters on a foot's performance.

Looking at the dependence of the LLTE value on each of the design variables around the optimal design, Fig.3-6 show that the LLTE value is much more sensitive to the ankle stiffness than the forefoot beam stiffness. As a first study, testing was thus focused on varying the ankle stiffness on the prosthetic foot design. For the clinical testing, ankle stiffnesses that vary from 1.5 to 24 Nm/deg were chosen for prototyping (Fig.3-7). The predicted LLTE values for an ankle rotational stiffness of 1.5 Nm/deg and 24 Nm/deg are 1.96 and 1.14, respectively (Fig.3-7). These LLTE values are nearly an order of magnitude different from the optimal design (0.222), therefore it was expected that they would greatly affect gait kinematics. Also, this range of rotational stiffness spans a similar range as ankle quasi-stiffness data from normal walking, which have been estimated as roughly 1.5 – 6.3 Nm/deg [53], 3.5 – 17.3 Nm/deg [64] or 3.5 – 24.4 Nm/deg [65] during different phases of gait.

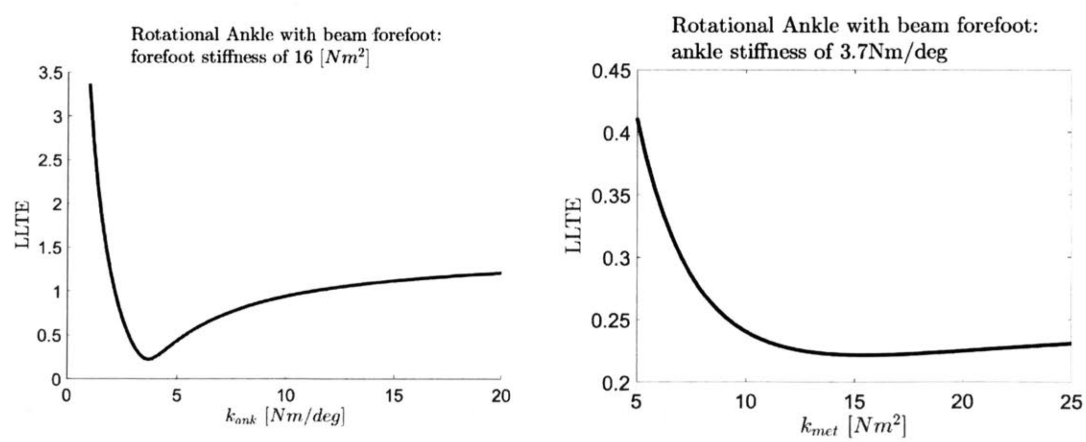


Figure 3-6: (a) Dependence of the LLTE value on the ankle rotational stiffness for $k_{met} = 16.0$ Nm^2. (b) Dependence of the LLTE value on the forefoot beam stiffness for $k_{ank} = 3.7$ Nm/deg. The minimum LLTE value is achieved for $k_{ank} = 3.7$ Nm/deg and $k_{met} = 16.0$ Nm^2.

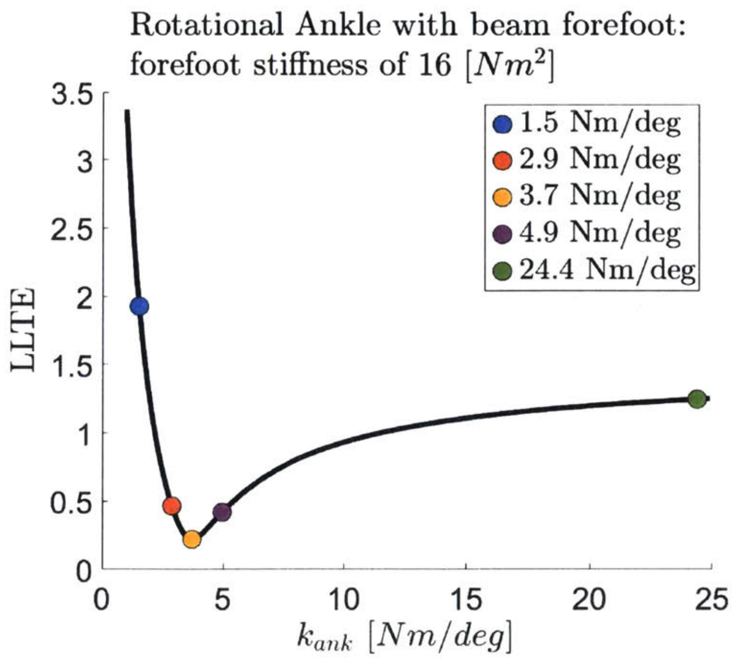


Figure 3-7: Plot of the foot model sensitivity on the ankle stiffness with the chosen ankle stiffness values that will be built and used in the subject testing.

Chapter 4

Mechanical Design

4.1 Overall Requirements and Design

The goal of the present study was to create a prototype prosthetic foot that can be used for a gait study to test the clinical viability of LLTE. A prototype prosthetic foot had to be built so that it was:

- Light enough that the weight of the foot does not affect the gait kinematics over the duration of the test.

- Fully mechanically characterized, such that the deformation of the foot under a given load can be calculated, thereby allowing evaluation of the LLTE value for the foot.

- Modular so that at least one design variable can be altered during testing in order to compare gait kinematics across a range of values of that design variable eg. ankle stiffness or forefoot bending stiffness. In our case the ankle stiffness was chosen since the prosthetic foot design is highly sensitive to this variable.

The objective in this work was to design a proof-of-concept foot prototype that can accommodate our specified wide range of ankle stiffnesses with interchangeable springs (Fig.3-7). A solid model of this prototype is shown in Fig.4-1. The rigid structural components were machined from acetal resin. The ankle joint rotates about a steel pin. Custom machined nylon 6/6 springs fitted in aluminum mounts provide the ankle joint rotational stiffness. The compliant beam forefoot was made from nylon and was fixed to the rigid acetal resin structure with machine screws fastened directly into tapped holes in the acetal resin (Fig.4-1). As built, the prototype has an average mass of 1.12 kg, which is approximately 45% less than the mass of the previous prototypes used to evaluate the LLTE [21]. This reduction in mass was achieved by replacing the metal coil springs with custom nylon flexural springs in the new architecture.

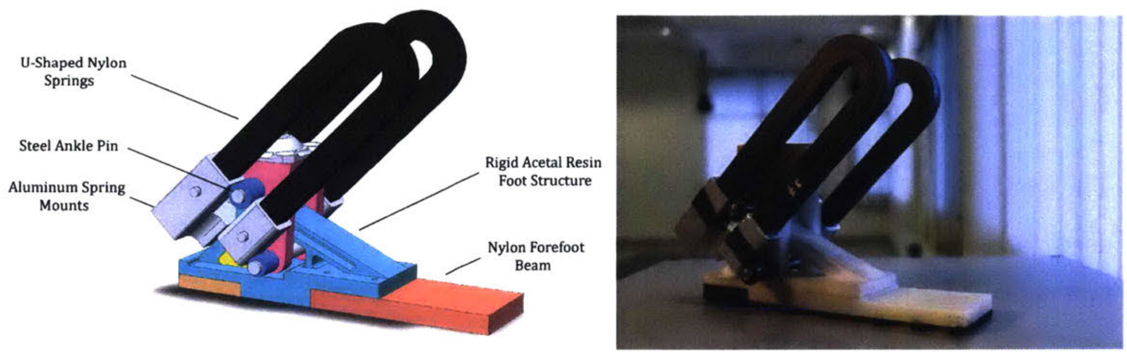


Figure 4-1: Solid model (a) and photograph (b) of the prosthetic foot prototype with a constant rotational stiffness at the ankle of $k_{ank} = 3.7Nm^2$ and a forefoot beam stiffness of $k_{met} = 16.0Nm^2$.

4.2 Spring Design

For this study, a range of ankle joint rotational stiffnesses from 1.5 Nm/deg to 24 Nm/deg were selected. The springs for these range of stiffnesses had to undergo a moment of 105 Nm before yield, corresponding to the case in which a 56.7 kg user applies their body weight on the tip of the prosthesis toe. Additionally, the entire mechanism needed to be compact and lightweight so that it did not interfere with the gait, as well as modular to enable fast interchangeable springs to alter ankle joint rotational stiffness values during testing.

These requirements immediately precluded the use of commercially available coil springs, as existing coil springs of sufficient stiffness do not provide enough range of motion and spings providing the correct range of motion were not stiff enough. They also appeared to be too heavy and bulky to allow interchangeability. To meet these requirements, the material showing a high yield strain ($\epsilon_{yield} = \sigma_y/E$), where σ_y and E are the yield strength and elastic modulus of the material, respectively) combined with a high strain energy density ($u = \sigma_y^2/E$) was selected. Nylon 6/6 exhibited the best characteristics for a readily available, easy to machine material, with a high strain energy density of 1.77 kJ/kg and a large yield strain of 0.034 [66]. A novel nylon 6/6 spring was designed to enable high stiffness, high range of motion and interchangeability while being light and compact.

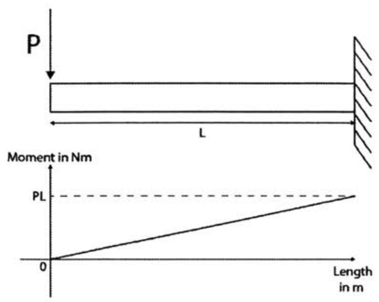
4.2.1 Bending Analysis

The stiffness and range of motion requirements; 1.5 to 24 Nm/deg with a range of motion up to 30° for the ankle spring exceeded the possible values for most common springs, even flexural springs, which would commonly be used for a device of this size. Therefore, it was necessary to consider how to best maximize the strain energy stored in a bending beam. The U-shape ankle spring design was thus inspired by the idea of maximizing the strain energy stored in a bending beam.

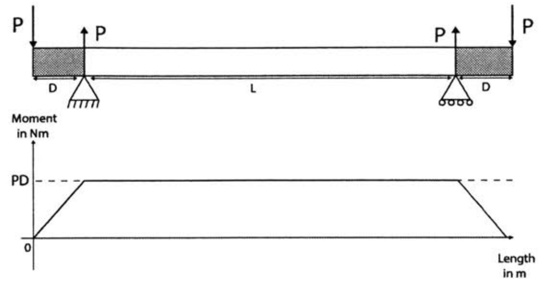
The material will yield under a stress σ_y, corresponding to a maximum bending moment M_y under which the beam can be loaded. In a typical cantilevered beam bending scenario (Fig.4-2a) the moment varies linearly from the tip to the base of the beam. The maximum moment occurs only at a single location, where the beam is constrained. Strain energy density in the beam is proportional to the elastic modulus times the square of moment in the beam:

$$u \sim \frac{\sigma^2}{E} \sim \frac{(My)^2}{EI^2}, \tag{4.1}$$

where y is the distance from the neutral axis.



(a) Cantilevered Beam Bending



(b) Four Point Beam Bending

Figure 4-2: Schematic of a beam of length L under a load P, and the corresponding moment in the beam. For the four point beam bending scenario (b), the moment arm length D corresponds to the beam length outside of the vertical supports.

In the case of the cantilevered beam, most of the strain energy is stored at the base of the beam. No strain energy is stored at the tip. To maximize the strain energy stored in a bending beam, it has to experience a constant maximum moment M_y across the entire length. To achieve that, a four-point beam bending scenario with rigid extremities was considered (Fig.4-2b). A beam loaded in this manner is able to store four times more elastic energy than a cantilevered beam of the same size. In other words, by changing the constraints of the spring the same elastic energy can be stored in a smaller, lighter beam.

4.2.2 Packaging and Fabrication

To package this spring in the prosthetic foot design while keeping the same characteristic, a constant moment loading scenario, the four-point beam was packaged into a U-shape. The springs are held by aluminum mounts that act as the rigid extremities and impose a rotation on the ends of the beam. These mounts also enable interchangeability of springs (Fig.4-1,4-3).

To design these U-springs, first order calculations were performed using Euler-Bernoulli beam bending theory, with b the thickness of the beam, w the width of the beam and L its length. A relation between the rotational stiffness of the ankle k_{ankle}, the beam's length L, thickness b, width w, Young's Modulus E, and yield stress σ_y was derived using Eqs.4.2-4.4.

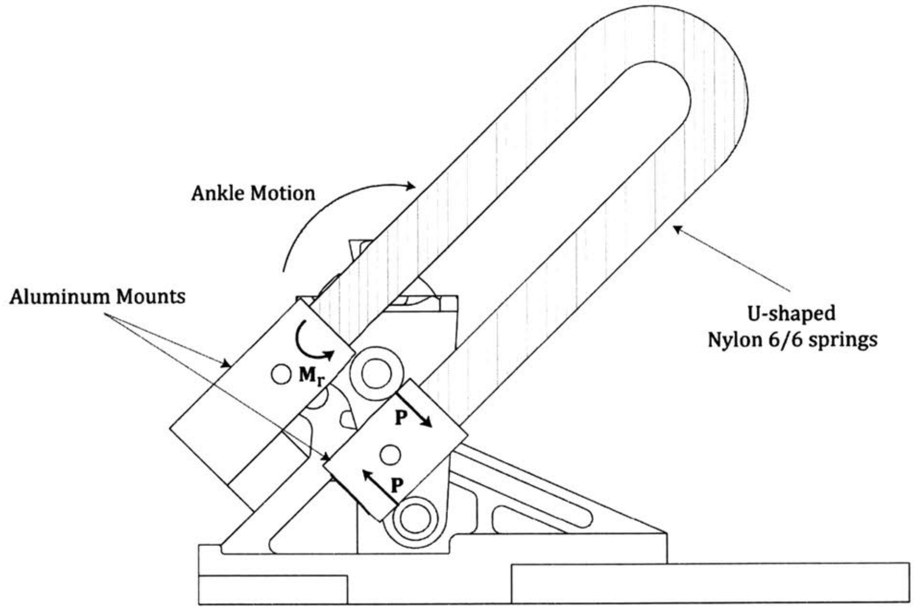


Figure 4-3: Schematic of the U-shaped ankle spring under typical loading. With P being the load applied to the beam similar to the four point beam bending scenario in Fig.4-2b and M_r the reaction moment at the base.

The maximum moment M_y under which the beam was loaded was derived from the yield stress of Nylon 6/6 with a safety factor of 1.2 (Eq.4.2). Then, the maximum end slope of the beam was calculated from the moment under which the beam was loaded, the Young's Modulus of Nylon 6/6 and the beam geometry (Eq.4.3). The end slope corresponded to half of the ankle angle θ_{ankle} , since in the ankle reference, one of the ends of the beam remains still. The rotational stiffness was then calculated as the moment divided by the ankle angle (Eq.4.4).

$$M_y = \frac{2I\sigma_y}{b} \tag{4.2}$$

$$\theta_{max} = \frac{M_y L}{2EI} = \frac{\theta_{anklemax}}{2} \tag{4.3}$$

$$k_{ankle} = \frac{M}{\theta_{ankle}} = \frac{Ewb^3}{12L} \tag{4.4}$$

Using these relations, a first estimate of the beam geometries was calculated to achieve the desired rotational stiffness with an applied moment of 105 Nm before yield, corresponding to the case in which a 56.7 kg user applies their entire body weight on the tip of the prosthesis toe. Because the radius of curvature of the beam at the curve is on the same order of magnitude of the thickness of the beam, the U-shaped beam is stiffer than a straight beam of similar length, width and thickness. Therefore, FEA was performed using the Solidwork FEA tool (Dassault Systemes, Inc) mimicking typical loading scenario as shown in Fig.4-3 to adjust the length of the U spring from the Euler-Bernoulli solution to achieve the desired rotational stiffness and range of motion with a minimum safety factor of 1.2 (Fig.4-4).

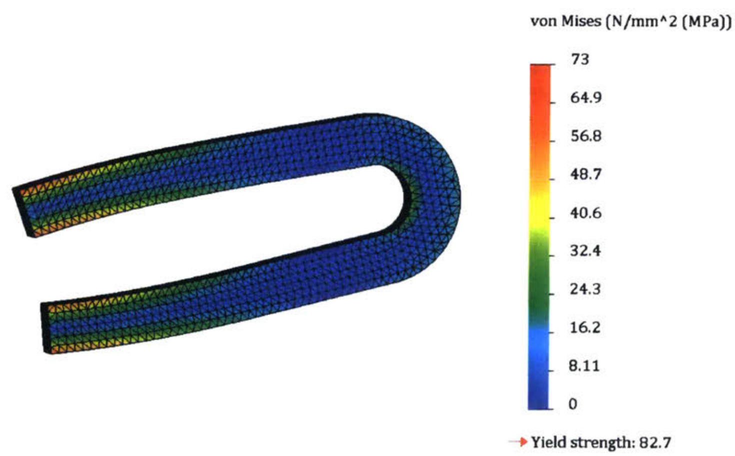


Figure 4-4: FEA analysis of the U shaped spring undergoing a moment of $52.5Nm$.

For the U-shaped springs that yield the optimal ankle stiffness of 3.7 Nm/deg, the beams have a width of 14 mm, a thickness of 18.24 mm and a length of 160 mm. The length or thickness of the beams was varied to achieve the desired range of ankle stiffnesses (Fig.4-5). The total mass of a pair of nylon U-shaped springs was 80 g to 400 g, with the optimal 3.7 Nm/deg springs weighing 225 g. The springs were mounted at an angle rather than vertically to reduce the total foot volume and mass of the structure required to support them (Fig.3-4).

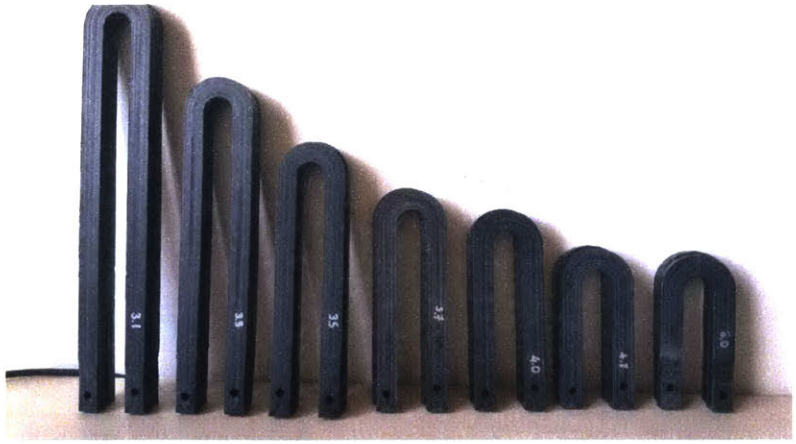


Figure 4-5: Set of springs with different rotational stiffness values. The longer the spring, the more compliant it is.

4.3 Cantilever Forefoot Design

The geometry of the beam forefoot foot was selected to replicate the articulation of the physiological foot. Thus the width and length were respectively w_b = 0.058 m and l_b = 0.07 m, such that the total length of the foot was 21 cm. To achieve the beam bending stiffness of k_{met} = 16.0 Nm^2, several materials were considered such as acetal resin, nylon, polycarbonate, aluminum and steel. The beam thickness h_b and maximum force F_{max} that can be applied to the tip of the beam were derived from their Young Modulus E and yield stress σ_y using Eqs.4.5-4.6.

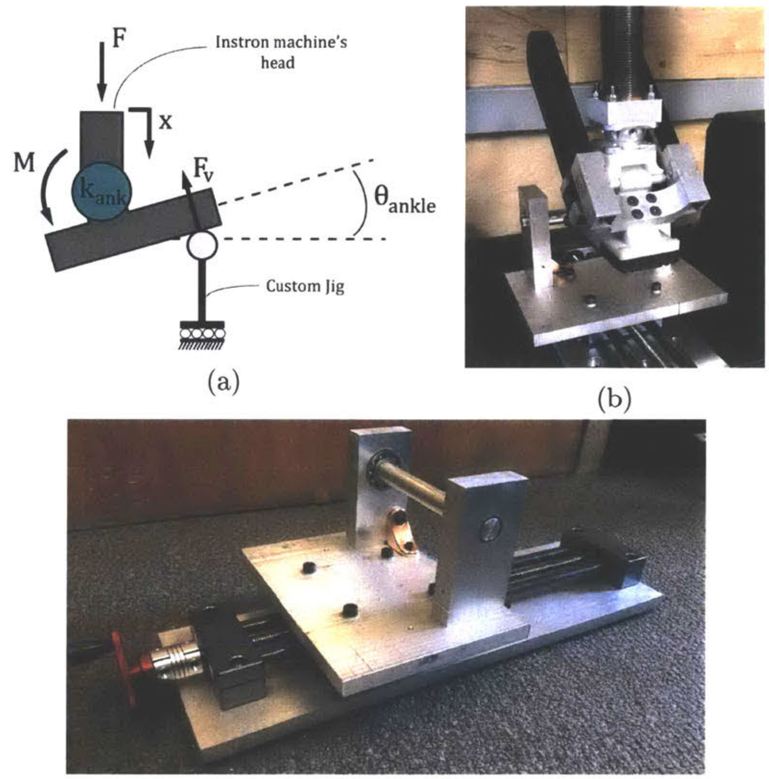
$$k_{met} = \frac{E w_b h_b^3}{12} \tag{4.5}$$

$$F_{max} = \frac{\sigma_y h_b^2 w_b}{6 l_b} \tag{4.6}$$

From the desired stiffness values, nylon could withstand the highest load before yielding. Thus the beam forefoot was machined out of nylon with a thickness of h_b = 11.1 mm achieving a bending stiffness of k_{met} = 16.0 Nm^2 and undergoing the maximum experienced vertical GRF during flat ground walking of 612 N (Winter's gait data [2]) with a safety factor of 2.3.

4.4 Experimental Validation

4.4.1 Experimental Setup



(a) (b)

(c)

Figure 4-6: Experimental setup schematic (a) and photograph (b) measuring the ankle rotational stiffness k_{ank} of the prototype. The foot is fixed on the Instron through the pyramid adapter mounted on the foot's ankle. The Instron loads the ankle springs by lowering the foot on the custom jig (c), F is the measured load on the Instron, F_v is the vertical load applied on the forefoot, M is the resulting moment on the ankle and θ_{ankle} the measured ankle angle.

The ankle rotational stiffnesses were then measured using an Instron load testing machine. The experimental setup consisted of a jig constraining the prototype while the Instron (universal testing system (Instron, Norwood, MA, USA)) loaded the rigid part of the forefoot, thus applying a moment on the ankle joint. The foot was loaded at a constant rate of 150 mm/min until a moment of approximately 90 Nm on the ankle (corresponding to the maximum ankle moment experienced during flat ground walking from the Winter's data [2]) or the maximum ankle angle computed during the LLTE calculation of the specific ankle spring was achieved. The vertical load and displacement were recorded at a rate of 10 Hz.

The custom jig fixtured on the Instron machine is composed of a linear stage on which an aluminum rod is mounted on a set of bearings. The foot is then loaded on the rigid part of the forefoot through the aluminum rod so that the load remains perpendicular to the foot at the contact point and the linear stage enables us to choose the exact position at which the vertical loads are applied (Fig.4-6).

4.4.2 Results and Discussion

The acetal foot structure on which the loads where applied was considered rigid in respect to the ankle springs since under a moment of 90 Nm the resulting deformation lead to an ankle angle error of 0.45° which is up to two orders of magnitude smaller than the ankle spring range of motions tested here (5° to 25°). The load and displacement data were then converted using geometric relations (Fig.4-7) into ankle moment and angle data. Equation 4.8 was first solved to get θ the ankle angle and then equation 4.9 was used to compute M the ankle moment.

$$F_v \cos(\theta) = F_i \tag{4.7}$$

$$\sin\theta\,(d - r\sin\theta - (e - x + r(1-\cos\theta)\tan\theta)) = e - \frac{e - x + r(1-\cos\theta)}{\cos\theta} \tag{4.8}$$

$$M = F_v d_m = F_i(d - r\sin\theta - (e - x + r(1-\cos\theta)\tan\theta) \tag{4.9}$$

The U-shaped springs all exhibited constant linear stiffnesses ranging from 1.5 to 24 Nm/deg, as desired. The U-spring experimental data are plotted in Fig.4-8 showing rotational stiffnesses of 1.5, 3.7, 5, and 24 Nm/deg. The linear fits of the experimental data agree with the finite element analysis for the rotational stiffness values with a 3% error and an average R^2 correlation value of 0.994. The energy storage and return efficiency of these springs was on average of 88% (Table.4.1).

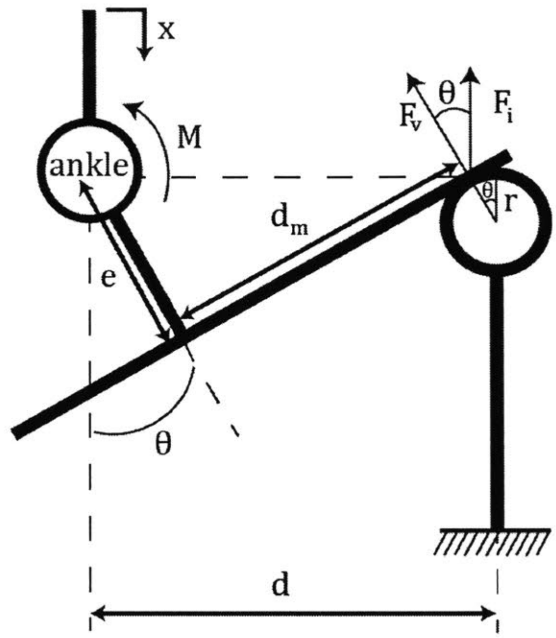


Figure 4-7: Schematic of the geometric relations used to convert the collected load and displacement Instron data (x, F_i) into the ankle angle and moment data (M, θ)

The experimental testing of the foot presented above ensures the validity of our mechanical model used in the calculation of the LLTE for this set of prosthetic foot prototypes. With this fully characterized set of prosthetic feet, clinical studies and field trials were conducted to assess the performance of each prosthetic foot prototype and evaluate the validity of the LLTE design framework.

Spring stiffness [Nm/deg]	1.5	2.88	3.64	5.0	24.4
Efficiency [%]	89.0	89.4	88.1	83.7	89.4

Table 4.1: Ankle U-spring efficiencies, ratio between the stored and returned energy

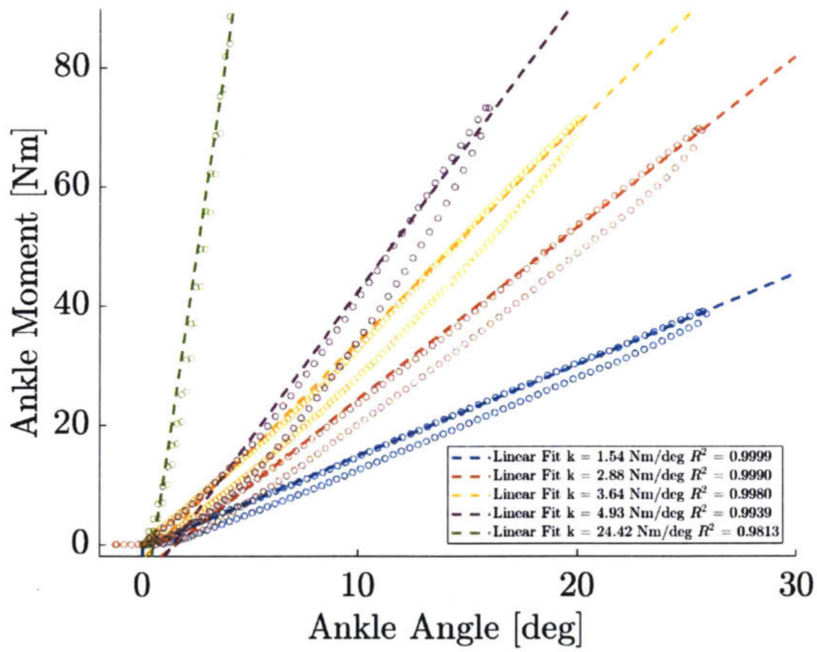


Figure 4-8: Experimental data from testing the set of springs with corresponding rotational stiffness of 1.5, 3.7, 5, and 24 Nm/deg. Linear fits verifying the rotational stiffness value of the springs, which agree with the FEA predicted values, are also shown. The springs showed some hysteresis due to viscous flow in the material.

Chapter 5

Clinical Studies and Results

5.1 Preliminary Testing

After the initial set of mechanical testing described in the previous section, the prototype with different sets of ankle springs was tested using pseudo-prosthesis boots (Fig.5-1) to ensure that both the compliant elements and the foot could withstand the typical loads experienced during extended flat ground walking. No signs of failure, change in mechanical properties or early wear were observed.

Figure 5-1: Pseudo-prosthesis boots mounted with the prosthetic foot prototype for preliminary testing.

The prototype with the different U-shaped springs was then brought for a round of testing with below-knee amputees at BMVSS, India (Fig.5-2). Following the MIT Committee on the Use of Humans as Experimental Subjects (COUHES) approved protocols, initial qualitative user testing in India to analyze comfort, functionality, spring interchangeability, reliability, and structural integrity was performed to determine the suitability of this prototype for use in a gait analysis study. Our goal is that the technology resulting from this work will manifest in a high-performance, low-cost prosthetic foot appropriate for India and other developing countries. The prototype was fitted on three male subjects with unilateral transtibial amputations who have been long time users of the Jaipur Foot. The subjects had body masses ranging from 55 kg to 65 kg. Apart from the amputations, the subjects had no further pathologies. The subject selection, prosthesis fitting and alignment process with the exoskeletal socket was handled by the organization's prosthetists. The subjects were asked to walk on flat ground using the prototype until they felt comfortable with it, at which point they were asked to walk at different self-selected speeds, walk up and down stairs, and on ramps.

Figure 5-2: Subject with below knee amputation testing the prototype.

The prototype withstood 30 min to an hour of testing with no mechanical issues, on multiple subjects with multiple ankle springs. The springs could be interchanged in a matter of minutes without removing the foot from the socket. The weight of the prosthesis was not a concern for the users and no additional issues were raised during testing. The subjects were then surveyed and asked to describe qualitatively what they liked and disliked about the prototype. Subjects liked the energy storage and return of the prototype and the increased walking speed. Dislikes were mainly focused on the aesthetics of the foot and one of the participant mentioned an increased heel strike impact load. This positive feedback from preliminary testing was compelling enough to warrant its use for clinical studies.

5.2 Testing Protocol

After thorough mechanical testing and preliminary testing on amputees in India to establish the reliability, comfort, and physical behavior of the prototype, an extensive gait analysis was conducted with Dr. Matthew J. Major and Rebecca Stine at the Motion Analysis Research Laboratory at Northwestern University (NU). The foot with the five different conditions for rotational ankle stiffnesses (1.5, 3.0, 3.7, 5.0 and 24.4 Nm/deg) respectively labeled condition A to E (with A the most compliant, C the LLTE-optimal and E the stiffest foot) (Fig.5-3) was fitted to a female subject of 54.2 kg and measuring 169 cm.

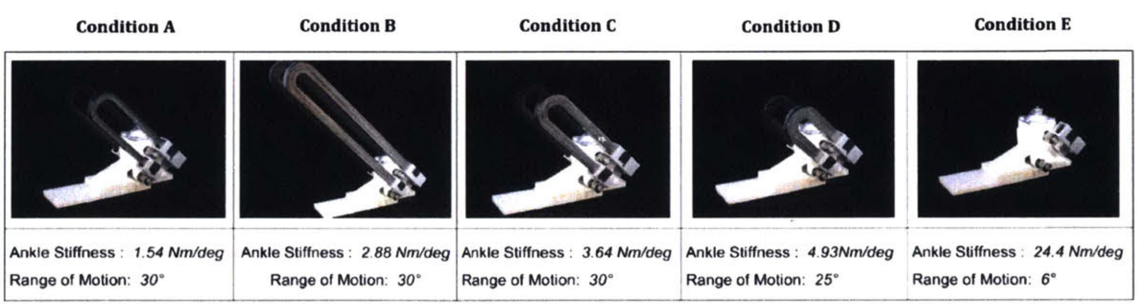


Figure 5-3: Photographs of tested prosthetic foot prototypes with ankle stiffness and range of motion values.

Similarly, the testing at NU was performed according to the MIT Committee on the Use of Humans as Experimental Subjects (COUHES) approved protocol to carry overground gait analyses for this prosthetic foot prototype. An experienced prosthetic user between 18-65 years old was recruited by our collaborators at NU. After the informed consent of the selected subject, retro-reflective markers were attached bilaterally by the study team to the participant's anatomical landmarks (Fig.5-4).

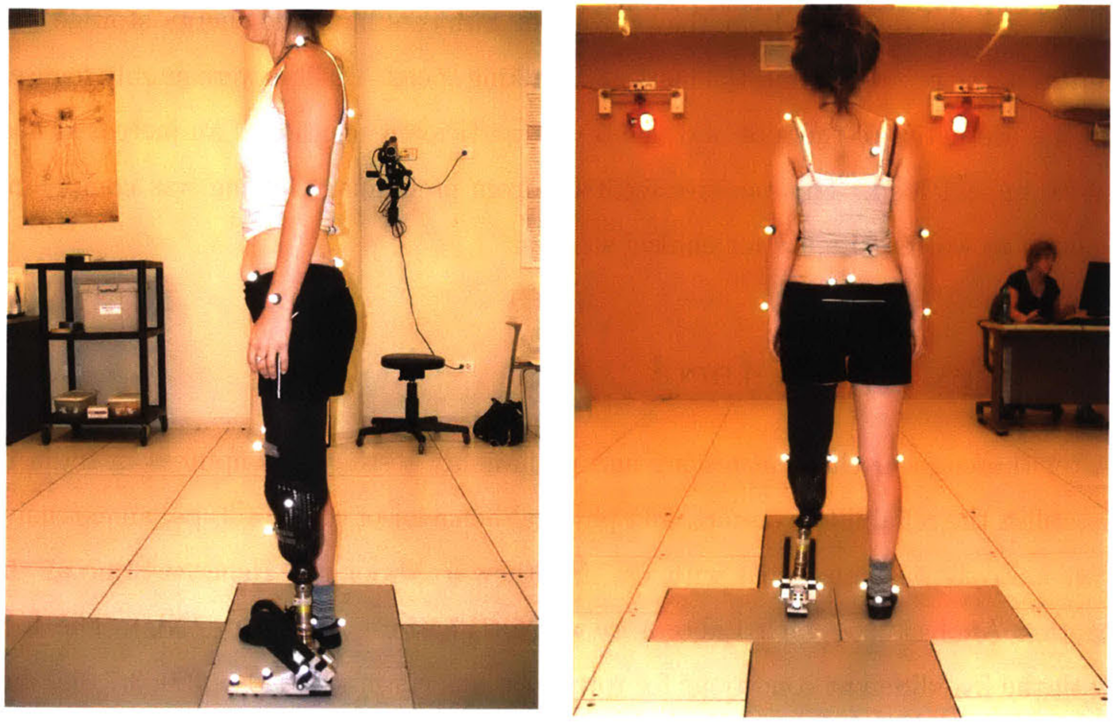


Figure 5-4: Gait lab setup and marker positions on the transtibial subject standing on the force plates and testing the prosthetic foot prototype with $k_{ank} = 3.7$ Nm/deg.

The subject was then asked to walk on flat ground using the prototype until she felt comfortable. After 10 min using the prototype, the subject walked at a comfortable speed on the walkway, during which gait kinematic and kinetic data for at least five steps for each set of ankle springs were collected. The ankle springs were changed on the prosthesis in a random order to avoid any biases from the subject. There was no need of any realignment between the socket and the foot since the foot remained firmly attached to the pylon during the entire process. Participants could rest as needed between each condition. Kinematic data was recorded through a motion capture system, kinetic data was measured by force plates embedded within the walkway and several videos along with pictures were taken for each trial. The entire set of data was then processed and analyzed through custom scripts implemented in Matlab (The MathWorks, Inc, Natick, MA). After each condition, (test of one of the prosthetic foot prototype), the subject was then surveyed and asked to describe qualitatively what they liked and disliked about the prototype.

5.3 Gait Lab Results

The following results are shown for one experienced unilateral transtibial amputee (female, traumatic, 54.2kg, 169cm). The subject walked at a self-selected speed on flat ground for each one of the five conditions (Fig.5-3) according to the protocol described above.

This gait lab study was conducted to test the following hypothesis:

- The mechanical characterization of the prosthetic feet prototypes is valid: the designed prosthetic feet exhibit the predicted mechanical behavior in terms of ankle stiffness for all of the conditions.
- Using physiological GRFs along with CoP data as inputs in our LLTE-optimization framework leads to close to physiological GRFs and CoP when amputees walk with LLTE-optimized feet (low LLTE value).
- The kinematic modelling in the LLTE-optimization framework is accurate: the predicted kinematics of the lower leg trajectory over the stance phase for each of the prototype prosthetic feet match the measured kinematics.
- The LLTE-optimal foot does indeed allow a user to walk with close to able-bodied kinematics

From the collected data, ankle moment and ankle angle in the sagittal plane during stance were computed from the GRFs, CoP, and reflective marker's position for each step and each condition. For each condition, the ankle moment and ankle angle were averaged over all the steps and plotted against the mechanical testing data (Fig.5-5). The measured ankle stiffnesses of the prosthetic prototypes in the gait lab align with the mechanical testing and designed ankle stiffness values.

Using the measured GRFs, and CoP data, the $x_{knee}^{predicted}$, $y_{knee}^{predicted}$, $\theta_{LL}^{predicted}$ values were predicted for each individual prosthetic side step, for a minimum of 5 steps for each condition and compared to measured values of x_{knee}, y_{knee}, θ_{LL} (Fig.5-6). Across

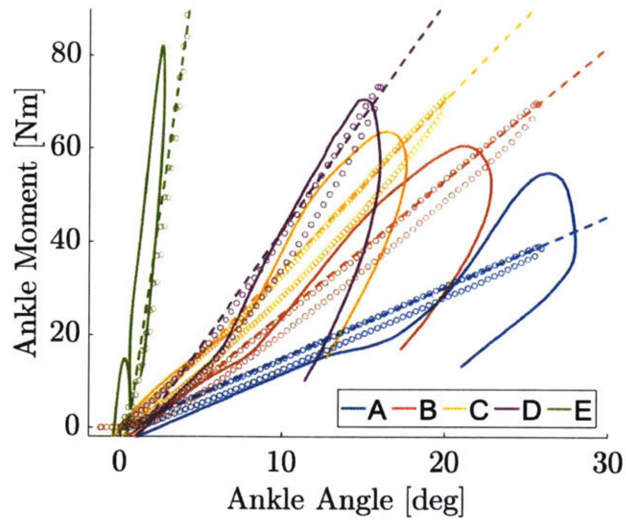


Figure 5-5: Experimental Data from testing the set of springs labeled condition A to E corresponding to rotational stiffnesses of 1.5, 3.7, 5, and 24 Nm/deg are plotted in solid lines. Circle markers representing the Instron measured data and the dotted lines representing the expected ankle stiffness.

all the data collected in these steps, the average absolute value of the difference between the predicted and measured values for each of the lower leg coordinates were 0.9 cm for x_{knee}, 0.3 cm for y_{knee} and 1.4° for θ_{LL}. The ankle angle and moment curves along with the the predicted kinematic data in Fig.5-5 and Fig.5-6 thus demonstrate the validity of our prosthetic foot model along with the LLTE constitutive model.

The measured kinematic and kinetic data that directly contributes to calculating the lower leg trajectory; x_{knee}, y_{knee}, θ_{LL}, GRF_x, GRF_y, and CoP for both the sound and prosthetic sides are shown along with the physiological data used initially in designing and optimizing the experimental feet (Fig.5-7). For each condition, these parameters were averaged across all measured steps and plotted in the above mentionned figure. The kinetic and kinematic data was also normalized to account for small differences in body weight, and limb length between our subject and Winter's data subject [2]. The GRF measured data was thus multiplied by the ratio between the body mass of Winter's subject and our subject. Similarly, the CoP, x_{knee} and y_{knee} data was also multiplied by the ratio between the lower leg segment length of Winter's subject and our subject.

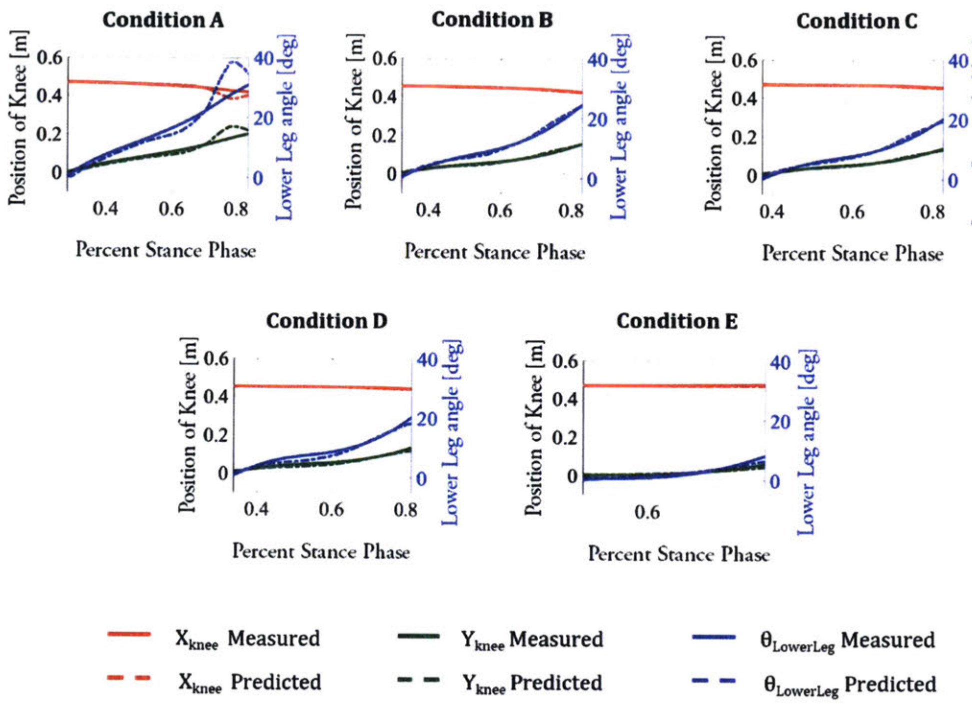


Figure 5-6: Predicted kinematics using measured GRFs and CoP data compared to measured kinematic data for an example step for each of the stifffness conditions, with condition A being the most compliant ankle and condition E the stiffest ankle.

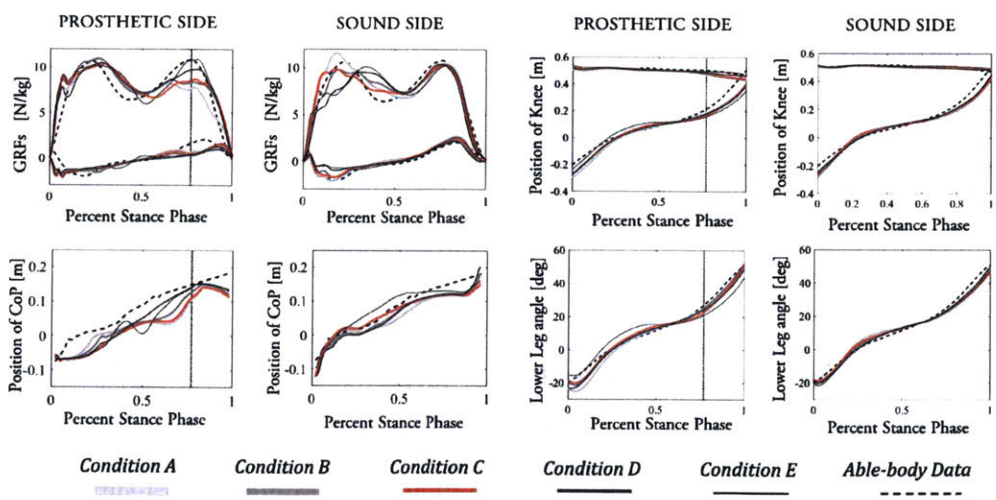


Figure 5-7: Measured kinematic and kinetic data averaged across the five collected steps are plotted against physiological data for both prosthetic and sound side. The vertical dotted line in the prosthetic data corresponds to the time during stance phase after which a biological ankle would produce net positive work (84% of stance phase). Condition A being the most compliant ankle and condition E the stiffest ankle.

5.4 Discussion

5.4.1 Constitutive Model

The ankle angle and moment curves (Fig.5-5) as measured during *in vivo* testing aligns with the mechanical behavior of the foot as measured on the Instron material testing machine. During the controlled dorsiflexion phase of stance, the ankle angle-moment curves fit the Instron measurements with R^2 values of 0.84, 0.96, 0.92, 0.96 and 0.82 for conditions A through E, demonstrating that the analytical model of a purely rotational pin joint with the specified constant rotational stiffness used in the LLTE framework adequately represented the ankle of the prosthetic foot prototype.

However, during *in vivo* testing, the ankle springs exhibited a larger hysteresis during the 'powered' plantarflexion phase of stance (unloading of the ankle springs) compared to the mechanical behavior of the foot as measured on the Instron machine. This reduced energy storage and return efficiency of the ankle springs during *in vivo* testing could be explained by increased rotational friction in the pin joint from out of plane moments applied on the ankle.

As evidenced by both the ankle angle versus moment curves in Fig.5-5 and the lower leg trajectories (x_{knee}, y_{knee}, θ_{LL}) in Fig.5-6, the stiffness of the ankle affected the subject's gait mechanics. Across these ankle stiffness conditions, the model accurately predicted the lower leg kinematics. However for condition A (most compliant ankle spring), the model failed to precisely predict lower leg kinematics towards the end of stance phase. For all five of the prosthetic side steps, for the condition A, the model predicted a much larger ankle angle and consequently a larger lower leg angle (θ_{LL}) and horizontal knee postion (x_{knee}) as well as a decreased knee vertical position (y_{knee}) than the measured values. Based on the ankle moment computed from the measured GRFs and CoP values, and the mechanical behavior of the ankle as measured on the Instron, the model predicted that the ankle would reach 38.3° of dorsiflexion, which would place the lower leg segment at 38.6°. This is a much larger angle than what is observed during typical walking at this point in stance, when the biological ankle reaches maximum dorsiflexion the lower leg segment angle is at approximately 18.4°.

When the model predictions diverge significantly from typical gait kinematics, it is expected that the subject will exhibit compensatory behaviors not captured in the model to maintain close to able bodied motion. In the most compliant case, condition A, the subject likely avoided this extreme lower leg segment angle that would have made her fall through dynamic effects and compensatory joint or out of plane motions neglected by our model. These compensatory motions are evidenced by the fact that the subject spent 7.3% of stance phase more in single support on the sound side than the prosthetic side compared to all other conditions which averaged around 3.4%. The subject put her sound side foot down much earlier for condition A, likely to prevent the excessive prosthetic side lower leg progression. This effect is also exhibited on the ankle angle-moment plot for ankle stiffness A where the ankle joint appears to stiffen in late stance relative to the Instron measurements.

This difference between the predicted and measured values is only expected for feet with large LLTE values, which induce extreme gait kinematics such as condition A and E. For low LLTE value ankle stiffnesses, conditions B,C and D the model prediction aligned with measured kinematics with average errors of 0.7 cm, 0.2 cm and 1.0° for x_{knee}, y_{knee}, and θ_{LL} respectively.

5.4.2 Physiological Data as Inputs

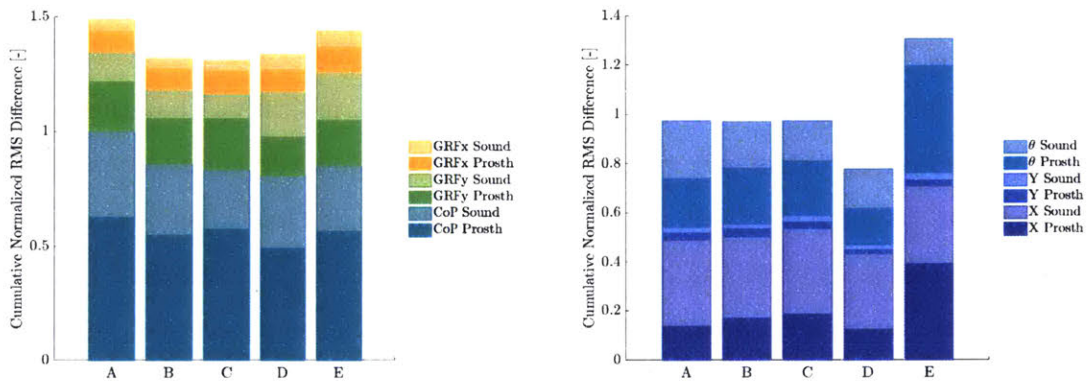
Across all the tested feet conditions, the data measured during the gait analysis were similar in trends and magnitudes to the physiological data used as inputs in the foot design optimization. Since the passive prosthetic foot prototypes in this study cannot generate any power, the data is likely to depart from physiological data during late stance when the net ankle work from the biological ankle over the course of the step becomes positive, indicated by the vertical dotted line in Fig.5-7. Prior to this point in stance, the negative ankle work exactly balances the positive ankle work, so it is possible for a perfectly efficient energy storage and return foot to exactly replicate physiological kinetic and kinematic data up until this time during stance phase. As we can see in Fig.5-7, in the early stance phase of the sound limb, when the prosthetic side is not able to replicated physiological values, the corresponding sound side measured data diverges to compensate.

The different ankle stiffness conditions also affected the foot flat portion of stance. The time during which the foot is flat on the ground decreased with increasing ankle stiffness ranging from 56% of stance phase for condition A to 37% of stance phase for condition E due to the differences in the lower leg angle possible under the applied ankle moments before the heel must be lifted off the ground to allow the lower leg to further progress forward. Despite these differences, the kinematic variables x_{knee}, y_{knee}, and θ_{LL} closely matched physiological target data during stance. In order to do this, while using feet with higher LLTE values, the kinetic data deviated from typical physiological values as evidenced by differences in GRFs and CoP data (Fig.5-7).

If this tendency seen in this subject to maintain typical kinematics and similar trends and magnitudes for kinetic data, the method of optimization employed here in which typical kinetic data were assumed as inputs and used to calculate output kinematics, remains valid. This is not to say that for high LLTE value cases, where physical limitations of the foot and extreme motions are exhibited, the measured kinematic and kinetic data will further diverge. However the high LLTE value, for feet with stiffnesses far above optimal is still meaningful, in that it indicates that it is not possible for someone to walk on the foot with close to typical loading and close to typical motion simultaneously.

5.4.3 Effects of the LLTE value on Gait Mechanics

The aim of the LLTE optimization is to determine which prosthetic foot design offers more benefits to the user. For this specific foot model, the optimal ankle stiffness was found to be 3.7 Nm/deg corresponding to condition C in our study. Any deviation from that ankle stiffness was predicted to induce far from typical gait mechanics on the user (Fig.4.4). As with all gait analysis studies, there is an excessive amount of data that can be considered in evaluating the performance of the five ankle stiffness conditions as described in Chapter 2. Since LLTE as defined here aims for able-bodied kinematics and kinetics, the effectiveness of each of the tested feet can be measured by computing the cumulative normalized RMS errors between measured and physiolgical kinematic and kinetic data for each condition, for all five steps and for both the prosthetic and sound side (Fig.5-8 and 5-9) since compensatory motions and loading where exhibited on the sound side as described above. Normalization using the average values of each of the physiological parameters over the stance phase was necesarry in order to reduce any biases towards any of the parameters.



(a) Kinetic Data

(b) Kinematic Data

Figure 5-8: Cumulative normalized RMS error between physiological data and measured kinetic data (a) and kinematic data (b) across all five ankle stiffness conditions, for both the prosthetic and sound side, and for all collected steps. The error bars for each condition indicates the variance between each step for a given condition. Condition A being the most compliant ankle and condition E the stiffest ankle.

Little variation is seen regarding gait kinematics for both the prosthetic and sound side in Fig.5-7, showing that the comparative kinematic error between each condition in Fig.5-8b is less significant. It also suggests that this particular subject walked in such a way as to maintain close to able-body motions regarless of the foot she was given. In order to do this while using feet with higher LLTE values, the loading patterns on the feet subsequently deviated from typical physiological values as evidenced by the differences in GRFs and CoP in Fig.5-7. This divergence in the loading patterns for each condition from able-bodied values was computed using a cumulative normalized RMS Error. This cumulative RMS error for the kinetic data across the tested foot conditions in Fig.5-8a seems to indicate that feet with lower LLTE values induce a closer to typical physiological kinetic data. The conditions B, C and D are very close to each other both in the cumulative error shown below and in terms of LLTE value (respectively 0.382, 0.222 and 0.452), as seen on Fig.3-7, compared to condition A and E (LLTE value of 1.96 and 1.14). This also matches the subject's feedback regarding each of the tested feet, where condition C and D were stated as the preferred feet over condition A, B and E. The subject could easily state her discomfort and dislikes towards condition A and E but could not tell which one of condition C or D she liked the most.

Looking at the cumulative error for both kinematic and kinetic data in Fig.5-9, the above mentionned trend, seen in the kinetic data, indicating that the LLTE optimal foot induced better gait mechanics is less clear. However, condition A and E still appear to produce the farthest from physiological kinetic and kinematic data as described by the user during testing. This single subject study is insufficient to draw any definitive conclusions about how unilateral transtibial amputees will generally respond to the five feet with varying LLTE values used in this work. Nevertheless the presented data offers some initial insight on the possible effects of the LLTE value on gait mechanics and how prosthetic feet designed with lower LLTE values could offer benefits to the user.

5.4.4 Study Limitations

This study was conducted on a single participant who tested the set of feet in two seperate visits to the NU gait lab. The weight of the participant changed by 5% between the two visits but was accounted for in the data normalization. The subject was only asked to walk at a self selected speed on flat ground, thus the behavior of the foot in different environments such as on uneven terrain, on slopes or at different walking speeds was not investigated. This study should be repeated on a larger set of subjects and in different walking scenarios before any generalization can be made about the validity of the LLTE framework.

Metabolic testing was not performed during this study and any information regarding metabolic expenditure during level ground walking with each of these prosthetic foot prototypes was based on the subject's perception and feedback. Additionally, the feet were only tested for a limited amount of time in each configuration

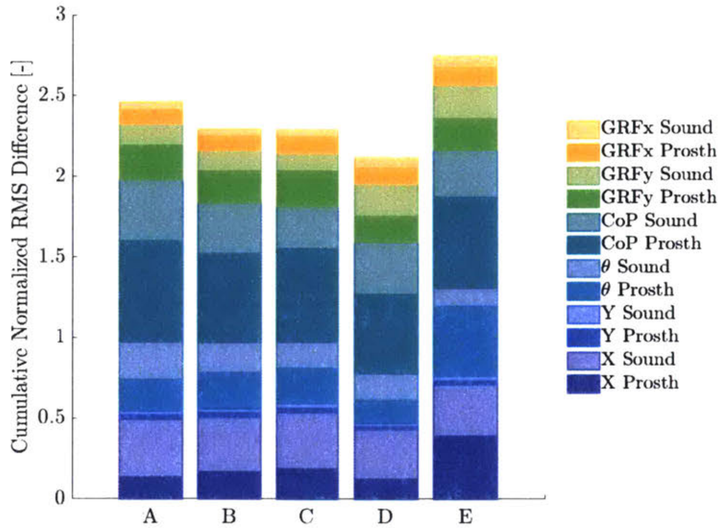


Figure 5-9: Cumulative normalized RMS error between physiological data and measured data across all five ankle stiffness conditions, for both the prosthetic and sound side, and for all collected steps. Condition A being the most compliant ankle and condition E the stiffest ankle.

because of the subject's availability making it difficult for the subject to evaluate the cost of walking with each prosthetic foot prototype.

Another limitation lies in the prosthetic foot prototypes used for this study. The aesthetics changed from one condition to another with the ankle U-springs being thinner or longer for the more compliant conditions and shorter or thicker for the stiffer conditions. This change in appearance might have influenced the subject and changed her gait mechanics.

Chapter 6

Conclusion

This study presented the physical design, mechanical characterization, and initial gait testing of a prototype prosthetic foot to evaluate the effectiveness of the Lower Leg Trajectory Error (LLTE) as a design objective.

The LLTE framework was applied to a conceptual foot architecture, a prosthetic foot with a rotational ankle with constant stiffness and a cantilever beam forefoot, from which an LLTE-optimal foot design enabling a user to walk with close to able-bodied kinematics was determined. The LLTE value, and thus the performance of the foot architecture, was most sensitive to the ankle rotational stiffness.

A physical prototype design reducing the overall weight of the prosthesis while achieving a forefoot bending stiffness of 16 Nm^2 and set of interchangeable custom U-shaped springs allowing us to vary the rotational ankle stiffness from 1.5 Nm/deg to 24 Nm/deg was presented. This prototype enabled testing of an LLTE-optimal foot with an optimal rotational ankle stiffness of 3.7 Nm/deg along with similar feet with higher LLTE values in order to investigate the sensitivity of ankle stiffness on gait mechanics. The unique merits of this foot is that it enables a wide range of ankle stiffnesses to be tested over a large range of motion, similar to the quasi-stiffness and range of motion of physiological ankles.

Preliminary user testing in India showed that the presented foot design reduced weight compared to previous prototypes, maintained structural integrity, allowed fast interchangeability of the ankle U-springs and was well received by the users. The initial *in vivo* testing of the prosthetic foot with the five ankle stiffness conditions verified the mechanical behavior of the designed prosthetic foot prototypes, and demonstrated the accuracy of the LLTE framework in predicting lower leg segment kinematics using kinetic data for prosthetic foot designs close to the LLTE-optimal design. The similarity in trend and magnitude between the measured data during gait analysis and physiological data further justified the use of physiological GRFs and CoP progression data as inputs in the LLTE framework especially for prosthetic foot conditions close to the LLTE-optimal condition. This initial study did not provide a definitive conclusion regarding the effect of the LLTE value on gait mechanics but the presented data suggests that prosthetic feet designed with lower LLTE values could offer benefits to the user.

Future work should focus on further clinical testing to provide a general answer regarding the validity of the LLTE as an objective metric to optimize prosthetic foot designs. Confirming the LLTE framework as a valid design tool for prosthetic feet would enable its use in optimizing single part compliant architectures leading to the design of mass-manufacturable and affordable prosthetic feet for Indian amputees meeting the Jaipur Foot organization's requirements. Additional work should also be done in order to include other gait activities in the framework such as walking at different speeds, on slopes or uneven terrains. Thus the LLTE framework would not only be used to design a prosthesis for a patient's specific body weight and size under predefined manufacturing and cost constraints but also for preferred level of activities.

Bibliography

[1] F. H. Martini, J. L. Nath, and E. F. Bartholomew, "Fundamentals of Anatomy and Physiology. 2001," *Pentice Hall New Jersey*, pp. 538–557, 2015.

[2] D. A. Winter, *Biomechanics and Motor Control of Human Movement.* John Wiley & Sons, 4th editio ed., 2009.

[3] R. Seymour, *Prosthetics and orthotics: lower limb and spinal.* Lippincott Williams & Wilkins, 2002.

[4] R. Versluys, P. Beyl, M. Van Damme, A. Desomer, R. Van Ham, and D. Lefeber, "Disability and Rehabilitation: Assistive Technology Prosthetic feet: State-of-the-art review and the importance of mimicking human ankleâĂŞfoot biomechanics Prosthetic feet: State-of-the-art review and the importance of mimicking human ankleâĂŞfoot biomechani," 2017.

[5] "College Park, Inc,"

[6] "Ossur, Inc."

[7] K. M. Olesnavage and A. G. Winter, "Lower Leg Trajectory Error: A novel optimization parameter for designing passive prosthetic feet," in *IEEE Int. Conf. Rehabil. Robot.*, vol. 2015-Septe, pp. 271–276, 2015.

[8] I. National Sample Survey Organisation and G. o. I. National Sample Survey Organization, Ministry of Statistics and Programme implementation, "Disabled persons in India National Sample Survey, 58th round, July - December 2002," *A. N. D. India*, vol. 485, no. 485, pp. 43 – 46, 2003.

[9] S. Macke, R. Misra, A. Sharma, and C. Prahalad, "Jaipur Foot: Challenging Convention," *UofM Bus. Sch. Case Study Ser.*, pp. 1–21, 2003.

[10] K. Ziegler-Graham, E. E. J. MacKenzie, P. L. P. Ephraim, T. T. G. T. Travison, and R. Brookmeyer, "Estimating the prevalence of limb loss in the United States: 2005 to 2050.," *Arch. Phys. Med. Rehabil.*, vol. 89, no. 3, pp. 422–9, 2008.

[11] Global Industry Analysts Inc., "Orthopedic prosthetics - a global strategic business report. Technical report, Research and Markets," tech. rep., 2012.

[12] "Bhagwan Mahaveer Viklang Sahayata Samiti."

[13] A. Neukermans, E. Neukermans, and T. McGirk, "BMVSS: Changing Lives , One Jaipur Limb at a Time," no. November 2012, pp. 1–21, 2013.

[14] P. K. Sethi, M. P. Udawat, S. C. Kasliwal, and R. Chandra, "Vulcanized rubber foot for lower limb amputees," *Prosthet. Orthot. Int.*, vol. 7, pp. 195–225, 1978.

[15] M. Sharp, "The Jaipur limb and foot," *Med. War*, vol. 10, no. December 2012, pp. 207–211, 1994.

[16] A. P. Arya, A. Lees, H. C. Nirula, and L. Klenerman, "A biomechanical comparison of the SACH, Seattle and Jaipur feet using ground reaction forces," *Prosthet. Orthot. Int.*, vol. 7, pp. 37–45, 1995.

[17] A. H. Hansen, S. G. Moulic, S. S. Oinam, and S. Steer, "SHAPE & ROLL / JAIPUR HYBRID PROSTHETIC FOOT (I)," vol. 16, no. 2, p. 30030, 2004.

[18] K. M. Olesnavage and A. G. Winter, "Mimicking Physiological Rollover Shape in a Prosthetic Foot with a Single Degree of Freedom Ankle Joint," p. 15.

[19] K. M. Olesnavage and A. G. Winter, "The Effect of stiffness on roll-over geometry and energy storage and return capacity of cantilever beam-type prosthetic feet: a theoretical analysis," no. September, pp. 1–11, 2014.

[20] K. M. Olesnavage and A. G. Winter, "Design and Preliminary Testing of a Prototype for Evaluating Lower Leg Trajectory Error as an Optimization Metric for Prosthetic Feet," *Proc. ASME 2016 Int. Des. Eng. Tech. Conf. Comput. Inf. Eng. Conf.*, pp. 1–8, 2016.

[21] K. M. Olesnavage and A. G. Winter, "Design and Qualitative Testing of a Prosthetic Foot with Rotational Ankle and Metatarsals Joints to Mimic Physiological Roll-Over Shape.," *Proc. ASME 2015 Int. Des. Eng. Tech. Conf. Comput. Inf. Eng. Conf.*, 2015.

[22] K. M. Olesnavage, *Design and evaluation of a Cantilever Beam-Type Prosthetic Foot for Indian Persons with Amputations.* PhD thesis, 2014.

[23] J. J. Eng and D. A. Winter, "KINETIC ANALYSIS OF THE LOWER LIMBS DURING WALKING: WHAT INFORMATION CAN BE GAINED FROM A THREE-DIMENSIONAL MODEL?," *Pergamon .I Rmwchanrcs*, vol. 28, no. 733.

[24] D. A. Winter, "Biomechanical motor patterns in normal walking.," *J. Mot. Behav.*, vol. 15, no. 4, pp. 302–330, 1983.

[25] M. L. Palmer, "Sagittal Plane Charactrization of Normal Human Ankle Function Across a Range of Walking Gait Speeds," *Rehabilitation*, pp. 1–74, 1999.

[26] D. G. Shurr, J. W. Michael, and T. M. Cook, *Prosthetics and orthotics.* Prentice Hall, 2002.

[27] M. M. Lusardi, M. Jorge, and C. C. Nielsen, *Orthotics and prosthetics in rehabilitation.* Elsevier Health Sciences, 2013.

[28] R. L. Waters, J. Perry, D. Antonelli, and H. Hislop, "Energy cost of walking of amputees: the influence of level of amputation.," *J. Bone Joint Surg. Am.*, vol. 58, no. 1, pp. 42–46, 1976.

[29] S. K. Au, J. Weber, and H. Herr, "Biomechanical design of a powered ankle-foot prosthesis," *2007 IEEE 10th Int. Conf. Rehabil. Robot. ICORR'07*, vol. 00, no. c, pp. 298–303, 2007.

[30] S. K. Au, H. Herr, J. Weber, and E. C. Martinez-Villalpando, "Powered ankle-foot prosthesis for the improvement of amputee ambulation," *Annu. Int. Conf. IEEE Eng. Med. Biol. - Proc.*, pp. 3020–3026, 2007.

[31] B. J. Hafner, "Clinical Prescription and Use of Prosthetic Foot and Ankle Mechanisms: A Review of the Literature," *JPO J. Prosthetics Orthot.*, vol. 17, no. Supplement, pp. S5–S11, 2005.

[32] "Rush Foot,"

[33] AOPA, "L Code Testing AOPA," *Patient Care*, 2007.

[34] I. Standard, "International Standard 22675," 2006.

[35] I. Standard, "International Standard 10328," 2006.

[36] P. G. Adamczyk and A. D. Kuo, "Mechanisms of gait asymmetry due to push-off deficiency in unilateral amputees," *IEEE Trans. Neural Syst. Rehabil. Eng.*, vol. 23, no. 5, pp. 776–785, 2015.

[37] J. M. Caputo and S. H. Collins, "Prosthetic ankle push-off work reduces metabolic rate but not collision work in non-amputee walking.," *Sci. Rep.*, vol. 4, p. 7213, 2014.

[38] M. Geil, "Energy storage and return in dynamic elastic response prosthetic\nfeet," *Pediatr. Gait A New Millenn. Clin. Care Motion Anal. Technol.*, pp. 134–142, 2000.

[39] M. D. Geil, "An iterative method for viscoelastic modeling of prosthetic feet," *J. Biomech.*, vol. 35, no. 10, pp. 1405–1410, 2002.

[40] A. H. Hansen and D. S. Childress, "Roll-over characteristics of human walking with applications for artificial limbs," vol. 3050531, no. June, pp. 332–332 p., 2002.

[41] A. H. Hansen and D. S. Childress, "Roll-over shape as a tool for design, alignment, and evaluation of ankle-foot prostheses and orthoses," in *Assist. technol. Res. Ser.*, vol. 26, pp. 99–101, 2010.

[42] A. H. Hansen, M. Sam, and D. S. Childress, "The Effective Foot Length Ratio: A Potential Tool for Characterization and Evaluation of Prosthetic Feet," *JPO J. Prosthetics Orthot.*, vol. 16, no. 2, pp. 41–45, 2004.

[43] D. M. Ehde, J. M. Czerniecki, D. G. Smith, K. M. Campbell, W. Edwards, M. P. Jensen, and L. R. Robinson, "Chronic phantom sensations, phantom pain, residual limb pain, and other regional pain after lower limb amputation," *Arch. Phys. Med. Rehabil.*, vol. 81, pp. 1039–1044, aug 2000.

[44] E. Klodd, A. Hansen, S. Fatone, and M. Edwards, "Effects of prosthetic foot forefoot flexibility on gait of unilateral transtibial prosthesis users.," *J. Rehabil. Res. Dev.*, vol. 47, no. 9, pp. 899–910, 2010.

[45] Y. Jian, D. A. Winter, M. Ishac, and L. Gilchrist, "Trajectory of the body COG and COP during initiation and termination of gait," *Gait Posture*, vol. 1, pp. 9–22, 1993.

[46] K.-F. Huang, Y.-L. Chou, F.-C. Su, and P.-H. Chou, "Kinematic properties and energy cost of below-knee amputees," *Biomed. Eng. (NY).*, vol. 13, no. 2, pp. 99–107, 2001.

[47] E. Klodd, A. Hansen, S. Fatone, and M. Edwards, "Effects of prosthetic foot forefoot flexibility on oxygen cost and subjective preference rankings of unilateral transtibial prosthesis users Elizabeth," *J. Rehabil. Res. Dev.*, vol. 47, no. 9, pp. 899–910, 2010.

[48] R. L. Waters, "The Energy Expenditure of Amputee Gait," pp. 1–9.

[49] R. S. Gailey, I. Gaunaurd, V. Agrawal, M. S. Bioe, C. O. Toole, M. S. Bioe, and R. Tolchin, "Determine functional differences between four categories of prosthetic feet," vol. 49, no. 4, pp. 597–612, 2012.

[50] P. G. Adamczyk, S. H. Collins, and A. D. Kuo, "The advantages of a rolling foot in human walking.," *J. Exp. Biol.*, vol. 209, no. Pt 20, pp. 3953–3963, 2006.

[51] P. G. Adamczyk and A. D. Kuo, "Mechanical and energetic consequences of rolling foot shape in human walking.," *J. Exp. Biol.*, vol. 216, no. Pt 14, pp. 2722–31, 2013.

[52] H. V. D. Linde, C. J. Hofstad, and A. C. H. Geurts, "A systematic literature review of the effect of different prosthetic components on human functioning with a lower Âŋ limb prosthesis," *J. Rehabil. Res. Dev.*, vol. 41, no. 4, pp. 555–570, 2004.

[53] E. J. Rouse, L. J. Hargrove, E. J. Perreault, and T. A. Kuiken, "Estimation of human ankle impedance during the stance phase of walking," *IEEE Trans. Neural Syst. Rehabil. Eng.*, vol. 22, no. 4, pp. 870–878, 2014.

[54] N. P. Fey, G. K. Klute, and R. R. Neptune, "The influence of energy storage and return foot stiffness on walking mechanics and muscle activity in below-knee amputees," *Clin. Biomech.*, vol. 26, pp. 1025–1032, 2011.

[55] N. P. Fey, G. K. Klute, and R. R. Neptune, "Optimization of prosthetic foot stiffness to reduce metabolic cost and intact knee loading during below-knee amputee walking: a theoretical study.," *J. Biomech. Eng.*, vol. 134, no. 11, p. 111005, 2012.

[56] T. S. Jang, J. J. Lee, D. H. Lee, and Y. S. Yoon, "Systematic methodology for the design of a flexible keel for energy-storing prosthetic feet.," *Med. Biol. Eng. Comput.*, vol. 39, pp. 56–64, 2001.

[57] K. M. Olesnavage and A. G. Winter, "Correlating mechanical design of passive prosthetic feet to gait kinematics using a novel optimization parameter: lower leg trajectory error," *Rev.*

[58] A. H. Hansen, D. S. Childress, S. C. Miff, S. A. Gard, and K. P. Mesplay, "The human ankle during walking: Implications for design of biomimetic ankle prostheses," *J. Biomech.*, vol. 37, no. 10, pp. 1467–1474, 2004.

[59] J. F. Lehmann, R. Price, S. Boswell-Bessette, A. Dralle, K. Questad, and B. J. DeLateur, "Comprehensive Analysis of Energy Storing Prosthetic Feet: Flex Foot and Seattle Foot Versus Standard SACH Foot.," *Arch. Phys. Med. Rehabil.*, vol. 74, no. 11, pp. 1225–1231, 1993.

[60] J. F. Lehmann, R. Price, S. Boswell-Bessette, A. Dralle, K. Questad, and K. Quest, "Comprehensive Analysis of Dynamic Elastic Response Feet: Seattle Ankle/Lite Foot Versus SACH Foot,"

[61] M. Sam, A. H. Hansen, D. S. Childress, and A. Hansen, "Characterisation of prosthetic feet used in low-income countries," *Prosthet. Orthot. Int.*, vol. 28, pp. 132–140, 2004.

[62] R. Gailey, K. Allen, J. Castles, J. Kucharik, and M. Roeder, "Review of secondary physical conditions associated with lower-limb amputation and long-term prosthesis use.," *J. Rehabil. Res. Dev.*, vol. 45, no. 1, pp. 15–29, 2008.

[63] L. L. Howell, *Compliant mechanisms.* John Wiley & Sons, 2001.

[64] K. Shamaei, G. S. Sawicki, and A. M. Dollar, "Estimation of quasi-stiffness of the human hip in the stance phase of walking," *PLoS One*, vol. 8, no. 12, 2013.

[65] E. Singer, G. Ishai, and E. Kimmel, "Parameter estimation for a prosthetic ankle," *Ann. Biomed. Eng.*, vol. 23, no. 5, pp. 691–696, 1995.

[66] M. P. D. Matweb, "Material Data Sheet."