The Effect of Prosthetic Foot Component Stiffness on Initiation and Termination of Transtibial Amputee Gait

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Abstract

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Lower limb loss is an increasingly common clinical problem in our society. Along with the loss of limb, amputees must also learn to use their new prosthetic device for their daily activities. The ideal stiffness characteristics of prosthetic feet for different functional activities may vary depending on each activity. Therefore the prescribed foot must be a compromise of multiple ideals out of functional necessity. Quantification of gait and stability characteristics is necessary to provide vital information into the design and prescription of future prosthetics to align with prosthetic users' needs and activity profiles.

The purpose of this study was to determine the effects of varying component stiffness of the prosthetic foot on locomotion and stability measures during gait initiation and termination. It was hypothesized that the leading sound condition would display greater excursions than the leading prosthetic condition for both mediolateral and anteroposterior excursions of the center of mass and center of pressure. It was also hypothesized that there would be differences between compliant and stiff heel components in each excursion measure.

Six male unilateral transtibial amputees participated in this study (41 ± 13.7 years, 1.82 ± 0.06 m, and 85.8 ± 15.5 kg). Subjects completed gait initiation and termination trials while force plates recorded ground reaction forces and motion capture was used to measure body kinematics. Center of mass (COM) and center of pressure (COP) measures were derived from the data gathered. The originally captured data were filtered to obtain a clear signal to noise ratio. Specific gait events from the analysis provided consistent intervals to measure center of mass and center of pressure excursions in the two gait activities studied.

Results indicated that leading with the sound limb during initiation and termination increased the COM excursion in the anteroposterior direction. A lack of significant results in the COP and all M/L directions between leading foot conditions indicates there are multiple strategies to achieve initiation and termination. A reliance on the sound limb agrees with previous studies, and appears to be functionally necessary to transtibial amputee gait. However, prosthetic foot stiffness levels have varied effects and should be taken into account for the design and prescription of future prosthetic feet.

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Chapter 1. INTRODUCTION

1.1 DEVELOPMENT OF PROBLEM

Lower limb loss is an increasingly common clinical problem in our society. Along with the loss of limb, amputees must also face the challenge of learning to ambulate with their new prosthetic device. A return to normalcy in their everyday lives is often desirable and the ability of a prosthetic limb to facilitate normal activities is a major point of concern for the amputee. It is accepted that the physician or therapist matches patients with the most suitable foot for their particular functional abilities and goals. There is a multitude of commercially available prosthetic feet that provide a wide range of stiffnesses, energy rates of return, and general shock absorption. However, the suitability of a foot to adequately provide the performance that the patient desires remains a topic for debate. The ideal stiffness characteristics of different functional activities may vary on an activity-by-activity basis. Walking ability is important to most, but many who are very active and perform a multitude of starting and stopping activities may benefit from a stiffer prosthetic foot. There are other amputees who may spend a substantial amount of time standing who could benefit from a more compliant foot to cushion the limb and provide shock absorption. Therefore the prescribed foot must be a compromise of multiple ideals out of functional necessity. Quantification of gait and stability characteristics is necessary to provide vital information into the design and prescription of future prosthetics to align with prosthetic users' needs and activity profiles. Clinically, this could greatly improve the development of lower limb prosthetics, but more importantly, could enhance the functionality of lower limb prosthetics users.

1.2 BACKGROUND

Lower limb amputations are most commonly linked to complications from dysvascular diseases, such as type II diabetes mellitus (Dillingham et al. 2002). When losing a limb, the musculature, skeletal structure, and neuronal feedback are also lost. This affects the ability of the amputee not only to ambulate, but sense changes in the environment and adapt gait to different situations involved in activities of daily living. In addition, the architecture of the body must also adapt to using a prosthetic limb to carry out daily locomotion tasks. An example of this is how the residual limb must bear weight and attempt to modulate forces when it was once the job of the foot-ankle complex to carry out this task.

There are different ways to readjust gait to ease the residual limb's impact shock absorption, and it has been shown that by altering the leg segment orientation during the gait cycle, impact shock absorption can be modulated (Nigg 1985; Zatsiorsky and Prilutsky 1987; Collins and Whittle 1989; Dufek and Bates 1990; DeVita and Skelly 1992; Cook et al. 1997; Ferris et al. 1998; Kovacs et al. 1999; Zhang et al. 2000; Self and Paine 2001). At heel strike, the transient force occurring at the beginning of gait cycle is affected by impact shock absorption of footwear (Light et al. 1980; Nigg et al. 1981; Simon et al. 1981; Nigg 1985; Dufek and Bates 1991; Verdini et al. 2006), the ground surface (Nigg 1985; Dufek and Bates 1991; Verdini et al. 2006) and velocity of the heel striking the ground (Nigg et al. 1981; Nigg 1985; Dufek and Bates 1990; Cook et al. 1997; Zhang et al. 2000). Historically the prosthetics community has altered the impact of heel strike using a solid ankle cushioned (SACH) foot, or improving push-off with dynamic elastic response (DER) feet (Gordon and Mueller 1959; Hittenberger 1986; Wagner et al. 1987; Edelstein 1988; Nielsen et al. 1988; Gitter et al. 1991).

Stiffness level is a key factor in how the user can utilize the foot and has an effect on overall body dynamics (Lebiedowska et al. 2009). Although important in terms of impact shock absorption and amputee pain, the effect of varying prosthetic foot stiffness levels has not been highly studied in regards to energy loss during gait (Goldstein and Sanders 1998). Furthermore, there has been no study that varied hindfoot and forefoot stiffness while holding all other prosthetic variables constant to optimize prosthetic feet for amputee users' functional abilities and goals.

Although sometimes overlooked, gait initiation and termination are integral parts of daily function for lower limb amputees. These tasks are performed with predictable patterns of center of mass (COM) and center of pressure (COP), where the COP moves beyond the COM to retain balance control. With a lack of musculature, innervation and joints, these tasks pose a great challenge to lower limb amputees (Vrieling et al. 2008a, 2008b). As a result, amputees' COP profiles vary from the able bodied population, and compensation strategies necessary to fulfill these tasks are factors that cause deficiencies in mobility and standing stability in this population (van Keeken et al. 2008).

Studies have also shown that amputees are capable of achieving center of mass velocities that are similar to able-bodied subjects (Michel and Do 2002; van Keeken et al. 2008), however they must compensate with the intact limb to do so (Michel and Chong 2004; van Keeken et al. 2008). This compensation has downstream effects such as increased risk of osteoarthritis in the intact limb. Overall, there is a lack of information regarding the effect of prosthetic foot component stiffness on gait initiation and termination. By studying the effects of different stiffness profiles for specific gait activities, it may be possible to minimize the compensation strategies of amputees, reduce asymmetric tendencies, and facilitate more balanced initiation and termination of gait.

1.3 STATEMENT OF PURPOSE

Some groups have studied the effects of lower limb stiffness in regards to their ability to reproduce "normal" lower limb mechanics during gait (van Jaarsveld et al. 1990; Miller and Childress 1997; Quesada et al. 2000; Blaya and Herr 2004; Hansen et al. 2004a), while others have focused on gait stability and performance measures for lower limb amputees (Jian et al. 1993; Vrieling et al. 2008a, 2008b). However none have combined these efforts to examine the effects on prosthetic foot stiffness on gait stability and performance metrics. With the development of a novel multi-component foot, it was possible to parametrically alter the prosthetic foot stiffness characteristics while holding other prosthetic variables constant. Therefore, the overall objective of this line of study was to determine ideal stiffness characteristics of prosthetic feet for lower limb amputees' individual abilities and goals. In support of this long-term goal, the purpose of the present study was to assess the relationship between prosthetic foot component stiffness and locomotion and stability measures during gait initiation and termination of lower limb amputees.

1.4 HYPOTHESES

1.4.1 *Primary Hypothesis*

It was hypothesized that the COM and COP excursions in both the mediolateral (M/L) and anteroposterior (A/P) directions would be greater while initiating (IN) and terminating (TR) gait with the sound (S) limb versus the prosthetic (P) limb.

$$H_{01}: \mu_S = \mu_P$$

$$H_{a1}: \mu_S > \mu_P$$

The notations μ_S and μ_P represent the excursion value of the COM and COP in the M/L and A/P directions while leading with the sound or prosthetic limb, respectively.

1.4.2 *Secondary Hypothesis*

It was also hypothesized that within the groups of initiating prosthetic, initiating sound, terminating prosthetic, and terminating sound, the COM and COP excursions of compliant, nominal, and stiff heel or toe components would be significantly different from each other.

$$H_{02}: \mu_C = \mu_N = \mu_S$$

$$H_{a2}: \mu_C \neq \mu_N \neq \mu_S$$

The notations μ_C, μ_N, μ_S represent the excursion value of the COM and COP in the M/L and A/P directions while using compliant, nominal, and stiff components, respectively.

Chapter 2. LITERATURE REVIEW

2.1 INTRODUCTION

Prosthetic feet currently available to lower limb amputees are able to meet the basic demands of the average user in terms of daily uses and activities. However, the commonly used passive prosthetic foot systems limit mobility and fully adaptive functioning in this population. In order to create better matches between prosthetic feet and prosthetic users, performance of prosthetics must be determined within a variety of activities. To test every prosthetic foot on the market is not feasible, nor practical. Therefore, a test foot has been designed wherein the forefoot and hindfoot components can be exchanged for more compliant or stiffer parts. This allows the simulation of a range of foot compositions and stiffness values to be tested in a systematic way. The study of the interaction of user and prosthetic in terms of the physical response is critical in understanding the usefulness of different stiffnesses in certain activities. This study examined the gait characteristics of unilateral transtibial amputees while using a range of prosthetic foot stiffnesses.

To fully understand the nature of prosthetic use in the transtibial amputee population, this chapter will review previous literature that covers a wide variety of topics related to this research. The manner in which amputees walk, the effects amputation has on different gait activities, the measurements used to quantify these effects, and prosthetic design will all be reviewed. These topics address the full spectrum of relevant research and ideas related to the current study.

2.2 LOWER LIMB AMPUTEES

As of 2005, it was estimated that 623,000 Americans were living with a major lower limb amputation; and this number is projected to increase with an aging population and more people living with dysvascular diseases (Ziegler-Graham et al. 2008). Dillingham et al. conducted a study of limb amputation statistics between 1988-1996; they reported that dysvascular disease was the major cause for lower limb amputation (82.0%), while trauma (16.4%), cancer (0.9%) and congenital defects (0.8%) were also contributing factors (Dillingham et al. 2002). This study also observed that lower limb amputations accounted for 97% of all dysvascular amputations. Of these dysvascular amputations, 25.8% were above-knee (transfemoral) and 27.6% percent were below-knee (transtibial) (Dillingham et al. 2002).

Dysvascular amputations can be caused by a variety of different reasons – ranging from cellulitis to foot ulcers to sepsis (Dillingham et al. 2002). Although sometimes categorized separately, most often dysvascular amputations occur due to having comorbidity with diabetes mellitus. In fact, more than 65,700 non-traumatic lower limb amputations were performed on diabetic patients in 2006 alone (CDC 2011). Diabetes can lead to amputation in multiple forms. Diabetic neuropathy often occurs due to vasoconstriction of the blood vessels that feed the nerves throughout the body. As a result, loss of proprioception occurs. In the lower limb, this can lead to the diabetic patient being unable to feel when they have stepped on a foreign object (e.g. a splinter), or if their shoes are causing blisters. With the dysvascular nature of the diabetic patient's foot tissue, wound healing is greatly diminished due to the lack of proper blood flow to the affected tissue. If the wound was left untreated in the diabetic population, this could cause a relatively minor initial injury to develop into a more serious injury, such as an ulcer. These ulcers are at risk of progressive infection which ultimately can lead to amputation as a form of proximal limb salvage.

2.3 PROSTHETIC DESIGN

2.3.1 *Impact Forces*

In typical gait, the gait cycle begins with the initial contact of the ground with the foot. For the majority of people, this occurs when the heel strikes the ground. The reaction force experienced from this collision is commonly referred to as a "transient" force (i.e. the force is not directly under the person's control). The first 50ms of a gait cycle normally encompasses the transient impact peak force. This short amount of time is not long enough for the neural reflex system to initiate any type of controlled response, thus making the force occur without any real control by the individual. The rate of loading and transient impact force magnitude are both dependent on the impact velocity of the heel (Nigg et al. 1981; Nigg 1985; Cook et al. 1997; Zhang et al. 2000), the material properties of the ground surface (Nigg 1985; Dufek and Bates 1991; Verdini et al. 2006), and the amount of impact shock absorption due to footwear (Light et al. 1980; Nigg et al. 1981; Simon et al. 1981; Nigg 1985; Dufek and Bates 1991; Verdini et al. 2006). By altering the orientation of limb segments prior to heel-strike, rate of loading and impact force magnitude can be controlled somewhat. For example, increasing knee flexion angle can facilitate impact shock absorption by reducing total leg stiffness (Nigg 1985; Zatsiorsky and Prilutsky 1987; Collins and Whittle 1989; Dufek and Bates 1990; DeVita and Skelly 1992; Cook et al. 1997; Kovacs et al. 1999; Zhang et al. 2000; Self and Paine 2001).

Clinically, lower limb amputees find impact shock absorption to be a significant issue in their daily lives. The ability to naturally mitigate impact using the natural foot and ankle structures has been removed and the remaining structure and tissues of the residual limb are not well designed to absorb impact energy. Up to 60% of lower limb amputees report pain to be moderately to severely bothersome due to impact shock on the residual limb (Ehde et al. 2000), and this pain can coincide with mechanical injury (Goldstein and Sanders 1998). Shock absorbing pylons (SAPs) have been developed to help address this problem and a few studies have attempted to determine the usefulness of such pylons, with mixed effect (Buckley et al. 2002; Gard and Konz 2003; Berge et al. 2005). Buckley et al. reported no significant effects of SAPs on energy expenditure as compared to standard pylons when walking at a self-selected pace (Buckley et al. 2002). At much faster speed (160% of self-selected) energy expenditure was 10% lower using the SAP (Buckley et al. 2002). Gard and Konz discovered a reduction in isolated-force transient magnitude during loading response phase of gait using an Endolite Telescope Torsion Pylon, with the reduction of magnitude becoming more pronounced when gait speed increased (Gard and Konz 2003). Berge et al. found no significant differences when using the Mercury Telescopic Torsion Pylon except for prosthetic limb knee angle at initial contact. It was found that when using this pylon, users decreased knee angle by an average of 2.6°, to 1.4° of knee flexion ($p = 0.004$). This led the authors to believe that users can modulate effective stiffness in the residual limb in response to changes in the stiffness of the prosthetic components used (Berge et al. 2005). This agrees with the ability of non-amputees, who also modulate leg stiffness as a response to changes in ground compliance (Ferris et al. 1998).

2.3.2 *Stiffness and Gait*

Human gait depends on many variables including muscle activity, joint kinematics and kinetics and properties of the foot to ground interface. Lower limb stiffness plays a key role in determining the interaction between the body and the ground surface. Many studies have been undertaken to understand stiffness and damping properties in high impact activities which include hopping and landing (Cavagna 1970; Bach et al. 1983; Farley and Gonzalez 1996; Ferris and Farley 1997; Ferris et al. 1998; Farley and Morgenroth 1999; Ferris et al. 1999; Moritz and Farley 2003; Moritz et al. 2004; Moritz and Farley 2005, 2006) and running (Farley and Gonzalez 1996; Ferris et al. 1998, 1999).

In a specific example of vertical compliance and damping testing, Cavagna had subjects perform a vertical jump onto a force plate, landing with the knees locked and toes extended (Cavagna 1970). With the results of the landing activity, stiffness and damping ratios were calculated. The approximate stiffness calculated for jumping onto one leg was 24 kN/m and for jumping onto 2 legs was 37 kN/m. With a similar approach protocol, Bach et al. found a vertical stiffness of 31 .9 kN/m for jumping onto one leg (Bach et al. 1983).

Other studies have focused on the effects of lower limb stiffness during walking. Hortobagyi and DeVita concentrated on the effects of muscular pre- and coactivity associated with leg stiffness and aging (Hortobagyi and DeVita 2000). This study reported that increasing leg stiffness may be preemptive compensation for impaired neuromotor function (Hortobagyi and DeVita 2000). Lebiedowska et al. focused on the effects of foot position on body dynamics during the stance phase of gait (Lebiedowska et al. 2009). In this study, it was found that increased leg stiffness and foot landing position affects overall body dynamics (e.g. stiffness and damping) as shown by changes in GRFs at the foot (Lebiedowska et al. 2009).

The flexed knee during walking decreases total leg stiffness because the total leg stiffness is equal to the summation of the in-series stiffnesses of all joint elements, the heel pad and foot arch; therefore, total leg stiffness is smaller than the smallest stiffness of the elements. Other possible reasons for decreased stiffness during walking are that the single-leg angle varies with respect to the vertical during walking, the single-leg interactions are only present during the single support phase of walking, and the dynamics is changed by muscle activation. Further studies should clarify the role of each of these components in body dynamics (Lebiedowska et al. 2009). The higher frequency of the leg during heel contact implies that the leg may be inherently less sensitive to small disturbance during heel contact than during toe contact (due to a higher stiffness), it is comparatively more responsive to disturbances (due to a faster response). These properties help the leg to automatically adjust to changes ground surface while walking (Lebiedowska et al. 2009).

2.3.3 *Prosthetics and Stiffness*

The task of optimizing prosthetic stiffness has historically been handled in the prosthetic engineering community by reducing heel-strike impact with the solid ankle cushioned heel (SACH) foot (Gordon and Mueller 1959; Wagner et al. 1987) and improving push-off with dynamic elastic response (DER) prosthetic feet (Hittenberger 1986; Wagner et al. 1987; Edelstein 1988; Nielsen et al. 1988; Gitter et al. 1991). The effect of limb stiffness on body dynamics has been studied by comparing the ability of commercially available prosthetic feet to replicate “normal” ankle mechanics and leg motions during gait (van Jaarsveld et al. 1990; Miller and Childress 1997; Quesada et al. 2000; Blaya and Herr 2004; Hansen et al. 2004b).

To properly compare prosthetic feet to “normal” lower limb mechanics, it is necessary to understand the stiffness properties of the multitude of prosthetic foot choices now available to know more about the particular advantages of the different feet (van Jaarsveld et al. 1990). The stiffness properties of the SACH foot were reported by using a 3-D stiffness testing device (Daher 1975), which warranted more reproducible results as compared to clinical tests (Winter and Sienko 1988). Another study compared the SACH foot with the Carbon Copy II (Ohio Willow Wood Co., Mount Sterling, OH) and Flex-Foot (Flex-Foot Inc., Aliso Viejo, CA) by finding the maximum jump height after 10 hops with the designated prosthetic foot as the bottom component of a “pogo stick apparatus” (Michael 1987). Since these trials were conducted with only one person jumping and in only one foot position on a “pogo stick apparatus,” reproducibility and accuracy of results are highly questionable. One study directly compared weight acceptance in three prosthetic foot designs (Perry et al. 1997). They reported that a single axis foot delivered the most biomimetic timing from heel strike to foot flat, but displayed instability due to the lack of plantar flexion constraint. They also showed that the Seattle Lightfoot (Model+ Instrument Development, Inc., Seattle, WA) and Flex Foot designs have more stability in controlling dorsiflexion (improving push-off potential). Although an improvement, these two feet also were reported to be “stiff” and had limited ability to absorb shock by allowing knee flexion during weight acceptance (Perry et al. 1997). However, no direct impact shock measures were analyzed in this study.

Another study by van Jaarsveld et al. used a mechanical testing device to determine stiffness and hysteresis properties of nine different prosthetic feet (van Jaarsveld et al. 1990). They observed that the various feet have a wide range of stiffness levels (~50-225 N/mm), but that the effect of footwear was quite substantial (up to 50 N/mm maximum stiffness increase with introduction of footwear) (van Jaarsveld et al. 1990). By wearing different shoes, the point of maximum stiffness could change by 13° and could increase the actual stiffness by up to 180 N/mm (van Jaarsveld et al. 1990). They also reported that the uni- and multi- axial feet absorb more energy than feet with rigid ankle devices (van Jaarsveld et al. 1990).

Miller and Childress analyzed a prosthetic foot designed to provide vertical compliance (Miller and Childress 1997). They discovered that greater vertical compliance showed little change in gait parameters during normal walking, however larger differences were observed during high impact events such as fast walking and jogging in place (Miller and Childress 1997). With the addition of vertical compliance, it has been postulated that lower limb amputees can reduce shock during vertical impulse events (e.g. stepping off curbs or walking down stairs) (Miller and Childress 1997). This notion presents obvious advantages owing to the fact that lower limb amputees cannot plantar flex at the ankle (Miller and Childress 1997). Normal ankle plantar flexion provides a mechanism for the body to absorb shock during vertical impulse events. With a prosthetic foot, plantar flexion cannot occur and compliance of this type of prosthetic foot compensates by providing a substitute mechanism to reduce shock.

Choosing a prosthetic foot that best represents the missing limb depends on the stiffness properties of the foot. To go along with this, van Jaarsveld et al. found that the stiffness grade of the prosthetic foot depends on the body weight and activity level of the amputee and that the main differences were restricted to the heel stiffness characteristics of only one prosthetic foot type (van Jaarsveld et al. 1990). None of the prosthetic feet on the market today have multi-component stiffness characteristics and must be chosen mainly based on the measures of the entire foot stiffness. There clearly is a need for research of multi-component foot stiffness characteristics and their effects on amputee gait. Research in this area of concern will be critical in the development and improvement of prosthetic feet and the prescription of these feet for the amputee population.

2.3.4 *Energy Storage and Return*

It has been stated that walking with a prosthesis should demand the least amount of energy as possible (van Jaarsveld et al. 1990). Prosthetic foot stiffness is important for assessing energy storage and return during weight bearing conditions. Energy absorption, storage and return in prosthetic feet have been addressed in prosthetic foot design in several different ways. Typically this is arranged by a foam covered heel portion that dissipates heel strike energy (e.g. SACH foot) and a forefoot keel which functions as a stable surface for stance and stores energy to be returned in propelling the individual into the next step (e.g. Seattle Foot) (Geil 2001; Hafner et al. 2002). These two sections are intended to replace the energy features of the intact limb. There have been advancements on this classic scheme such as the Flex-Foot, which uses a carbon composite leaf spring in the heel section to release energy to the foot during mid-stance. However, this increase in energy release comes at the cost of increased impact absorption by the musculoskeletal system (Hafner et al. 2002). The effects of prosthetic foot stiffness have been acknowledged as being important, but there have only been a few reports that study the effects of prosthetic foot stiffness on energy loss during gait (Michael 1987; Geil 2001; Hafner et al. 2002; Hsu et al. 2006).

There are a wide variety of methods used to measure energy storage and return data (Hafner et al. 2002). This is compounded by the fact that there are no standardized methodology, terminology and metrics reported by prosthetics manufacturers (Geil 2001; Hafner et al. 2002). There is a need for a standardization of reporting that will allow clinicians to make more informed decisions when prescribing prosthetic feet to their patients (Geil 2001). Hysteresis defines the viscoelastic behavior by showing the difference of path in the force-deformation curve during loading and unloading (Hafner et al. 2002). This is the single most important parameter in designing a foot that stores and returns energy, since it is desirable to know how much energy is returned to the amputee during late stance to aid in propulsion (Geil 2001). Hysteresis is rarely reported directly, but more often coined as “efficiency” which is the amount of energy returned divided by the amount stored (usually given as a percentage) (Geil 2001). In a study of dynamic elastic response (DER) feet using a servohydraulic material testing system, Geil found the College Park feet to have the largest unloading energy (5.77 J). However, these feet were less efficient in achieving unloading energy, having the largest amount of hysteresis (31.27%) (Geil 2001). This led Geil to believe that there may be some cost attached to high unloading energy (Geil 2001).

Historically, multiple approaches have been reported for analyzing the energy storage and return capabilities of prosthetic feet. In their review paper, Hafner et al. described a few of these methods as functional, mechanical, and kinetic analysis (Hafner et al. 2002). An example of functional analysis can be seen in the previously discussed “pogo stick apparatus” experiments by Michael (Michael 1987). In these experiments, the prosthetic feet were ranked (least-greatest vertical displacement during hop): SACH, SAFE, STEN, Carbon Copy II, Seattle, Flex-Foot (Michael 1987). Although this measure is related to energy return, it does not take into account energy efficiency (Hafner et al. 2002). van Jaarsveld and colleagues showed that the Quantum foot dissipated less energy than the SACH foot, and the Dynamic foot dissipated more energy than the SACH foot in an example of mechanical analysis (van Jaarsveld et al. 1990). Even though the Dynamic foot is an energy-storage, energy-return foot (ESER), it rated worse than the SACH foot (non-ESER) (Hafner et al. 2002). Kinetic analysis was used in the experiments of Ehara and colleagues (Ehara et al. 1990, 1993). In these studies, the prosthetic feet were grouped as follows: STEN, SACH, Quantum, and Seattle LiteFoot as “low energy”; Dynamic, Carbon Copy II, Seattle and SAFE as “intermediate” energy; SAFE II and Flex-Walk as “high-energy” (Ehara et al. 1990, 1993). In this brief overview, it seems clear there needs to be a standardized method to measure and report prosthetic foot stiffness by manufacturers. Understanding how these prosthetic devices differ is a key requirement for properly fitting prosthetic feet (Hafner et al. 2002).

Metabolic energy expenditure is another common area where prosthetic design efforts have sought to improve efficiency. In a treadmill walking study by Hsu et al., it was found that transtibial amputees exhibited a 10% increase in energy expenditure when walking between 0.894 – 1.788 m/s (Hsu et al. 2006). The extra expenditure necessary to ambulate demonstrates the importance of prosthetic limbs to store and return energy. In the same study, it was reported that the Flex Foot reduced energy cost, increased gait efficiency and decreased exercise intensity as compared to the SACH and C-Walk (Hsu et al. 2006).

2.3.5 *Foot Design*

Although prosthetic feet differ in the details of their design, there are several functions that are common to all prosthetic foot-ankle assemblies. They provide a base of support while standing or in the stance phase of gait, absorb shock at heel strike as the device plantar flexes, and simulate metatarsophalangeal joint hyperextension during the late stages of stance (Edelstein 1988). One of the earliest examples of modern prosthetic feet was the SACH foot (Gordon and Mueller 1959). The SACH foot utilized a laminated rubber heel attached to a wooden keel with a neoprene toe. The premise of this design was that the cushioned heel provided shock absorption at heel strike (HS) while the keel provided a rocker-like action and carries most of the load (Gordon and Mueller 1959). During stance, the weight balances between the heel and the keel, and as body weight transfers to the forward end of the keel at the end of stance/beginning of swing phase, the neoprene toe assists in push off (Gordon and Mueller 1959). Although the SACH foot provided advancement in prosthetics technology of the day, there are some drawbacks to its effectiveness. Edelstein reported that the rigidity of the SACH foot keel prevents dorsiflexion, ease of plantar flexion is difficult to adjust and the lack of a definite ankle axis requires a substantial load on the prosthesis to achieve foot-flat (Edelstein 1988).

In contrast to the SACH foot, other prosthetic feet have been designed with articulating ankle components. The simplest of these is the single-axis foot, which has been manufactured longer than any other contemporary prosthetic foot (Edelstein 1988). Although the single-axis foot allows both dorsiflexion and plantar flexion in the sagittal plane, the range of motion allowed is less than that achieved naturally. This limited range of motion is sufficient for walking on level surfaces, but may cause issues when forcing the foot to conform to steep inclines (Edelstein 1988). As an extension to this design, multiple axis feet (e.g. Greissinger multi-axis assembly, Mauch ankle) allow for passive motion in the transverse, frontal and sagittal planes. This also means that the multiple axis components can absorb energy in all three planes, reducing the likelihood of shear in the proximal residual limb-socket interface and subsequent skin irritation (Edelstein 1988).

Prosthetic foot design efforts before the 1980s were focused on the goal of basic walking and occupational tasks (Hafner et al. 2002). However, more active amputees demanded increased functionality and the ability to participate in higher level activities. This led to the beginning of the “energy storing” foot era (Hafner et al. 2002). The Seattle Foot (Seattle Limb Systems, Poulsbo, WA) was one of the first feet that were classified as an energy storing prosthetic foot. It incorporated a Delrin® semi-rigid keel, cushioned heel, and Kevlar® fabric toe pad (Hittenberger 1986). The foot was designed to control and store energy available at HS and foot flat (via the flexible keel) and later releasing a portion of that energy during push-off to increase forward momentum and eliminate “drop-off” (early knee flexion between mid-stance and toe-off) (Hittenberger 1986; Hafner et al. 2002).

Further designs of prosthetic feet incorporated some of the same features as the SACH foot and Seattle Foot. Those incorporating some form of flexible keel(s) surrounded by a foam foot or a cosmesis included: the Dynamic (Otto Bock Industries, Minneapolis, MN) which had an automatically adjusting short keel for flat soled and low-heeled shoes (Edelstein 1988), the STEN foot (Kingsley Manufacturing Co., Costa Mesa, CA), the SAFE foot (Campbell-Childs, Inc., White City, OR) built of a keel composed of a rigid polyurethane bolt block attached to a flexible endoskeleton which was designed to emulate the anatomic subtalar joint (Edelstein 1988), the Carbon Copy II (Ohio Willow Wood Co., Mount Sterling, OH) which included a double carbon fiber composite keel and resilient heel (Edelstein 1988)), the TruStep® (College Park Industries, Inc., Fraser, MI), and the Quantum (Hanger Orthopedic Group, Bethesda, MD), amongst many others (Hafner et al. 2002). In 1987, the Flex-Foot (Flex-Foot Inc., Aliso Viejo, CA) became available. The foot incorporates a flexible carbon fiber shank and leaf spring which allows the entire length of prosthesis to flex, absorb, and return energy. This design allowed the Flex-Foot to store energy through a longer keel than any other foot-ankle component, providing a maximum assistance to the wearer (Michael 1987). The design and component combination also made the Flex-Foot the lightest foot-ankle assembly available (Edelstein 1988). Nielsen et al. reported that walking with the Flex-Foot tended to facilitate faster walking and tended to conserve energy at higher velocities (≥ 2.5 mph) (Nielsen et al. 1988). At this point, the Flex-Foot was considered the most “advanced” energy-storing prosthetic available (Hafner et al. 2002).

Other prosthetic feet such as the Reflex VSP (Flex-Foot, Inc.) have improved on the original Flex-Foot (Miller and Childress 1997; Hafner et al. 2002; Hsu et al. 2006). The Springlite (Salt Lake City, UT) was also similar to the Flex-Foot, but had a one piece design (heel spring fused to pylon spring with compressible urethane elastomer heel web) (Hafner et al. 2002). The Ohio Willow Wood Pathfinder (introduced in 2000) is similar to the Flex-Foot Reflex VSP, but added an adjustable heel shock absorber to the composite keep spring system. This allowed for customizability to the activity level and the chosen tasks of the individual patient (Hafner et al. 2002). The 1C40 Otto Bock C-Walk foot (C-Walk) is one of the newest energy-storing prostheses available. This foot features carbon fiber reinforced plastic spring elements (C-spring and base spring) and a control spring. With its unique design, the C-Walk is claimed to allow people with transtibial amputation to walk smoothly and comfortably at slow as well as higher walking speeds and also appears well suited for use in recreational activities (Hafner et al. 2002).

In the previously reviewed literature, prosthetics design had been mainly focused on passive devices. There has been some recent work on a motorized ankle-foot prosthesis attempting to attain better energetics (Au et al. 2007b, 2007a; Au and Herr 2008). This Powered Ankle-Foot Prosthesis (PAFP) uses a physical spring in parallel with a high powered output force-controllable actuator that serve as a spring and torque source, respectively (Au et al. 2007b, 2007a; Au and Herr 2008). Au et al. reported that use of this device decreased the metabolic cost of transport an average of 14% when compared to passive prostheses, despite the fact that the PAFP is twice as heavy (Au et al. 2007a). During early stance of stair descent, it was found that when activated, the PAFP absorbed -14 J of mechanical energy as compared to -0.1 J when the PAFP was inactive (Au and Herr 2008).

The high cost of powered feet is a barrier to their widespread acceptance, and for the time being, passive prosthetic feet dominate the market. Research into transferring energy stored in the heel to terminal energy release in the forefoot keel segment will be critical to the advancement of passive prosthetic feet. If new prosthetic feet designs can be modified to utilize input energy in a more efficient manner rather than dissipating that energy, amputee performance will likely be enhanced (Hafner et al. 2002).

2.4 AMPUTEE GAIT

There are definite differences between the gait of lower limb amputees and those of their unimpaired healthy counterparts. The amputated limb lacks musculature, skeletal structure and neural response. This results in altered gait strategies and increased metabolic energy expense (Waters et al. 1976; Skinner and Effeney 1985). The lack of plantar flexor activity causes major shortcomings in the ability of TT amputees to push off from the toe into the swing phase of gait (Gitter et al. 1991). It has been previously demonstrated that the amputated limb of TT amputees is less active during walking and standing. Isakov et al. found that step time, swing time and step length were longer and single limb support time was shorter in the TT amputated limb versus the sound limb (Isakov et al. 2000). This study exclusively used the SACH foot, which most likely was the cause of the short step length in the sound limb due to the fact the SACH foot did not allow for normal dorsiflexion moment and therefore the sound limb was put in contact with the ground earlier (Lemaire et al. 1993; Isakov et al. 2000). Winter and Sienko conducted a study of below-knee amputees and found that this population partially compensated for lack of plantar flexors with hyperactive hip extensors during early and mid-stance. This hyperactivity of the hamstring muscles was counteracted by the quadriceps muscles and the net knee moment was found to be close to zero in the same section of the gait cycle (Winter and Sienko 1988). These compensations were thought to be due to the fact that the dorsiflexion moment was observed to continue further through stance and the plantar flexor moment reached about 2/3 the magnitude seen in the normal population (Winter and Sienko 1988).

2.5 GAIT STABILITY MEASURES

2.5.1 *COM and COP*

Quantifying measures of stability and performance have historically been done by computing both the COP and COM. The COM is defined as the point of equivalent total body mass in the global reference system; it is the weighted average of the COM of each body segment in 3D space. The balance control system manages the COM progression throughout gait, making this a passive, rather than an active variable. The vertical projection of the COM onto the ground is often called the center of gravity (COG) (Winter 1995b). From here on, COM will be used in regards to only its horizontal trajectories (synonymous to COG) unless otherwise specified. The COP is a weighted average of all pressures of surface in contact with the ground and is considered to represent the single point of application of the ground reaction force (GRF) vector (Winter 1995b). The COP is completely independent of the COM. The COP is considered to be the physical concept behind the balance control system’s mechanism to adjust the COM position during normal gait and quiet stance.

2.5.2 *COP Controls COM*

The COP moves with changes in the net moments about the ankle and can therefore be reflected in levels of relative muscular activity. For example, increasing plantar flexor activity moves the COP anteriorly, while invertor activity moves the COP laterally (Winter 1995b). The action of the COP can therefore be observed to correct for movements in the COM, leading to a range of motion of the COP that is greater than the COM (Winter 1995b). Over time however, the average COP position should equal the average COM position during quiet standing (Winter

1995b). Different researchers have discussed the possibility of achieving this by way of an inverted pendulum model (Jian et al. 1993; Winter 1995b), where the body is considered an inverted pendulum (point mass at the COM, with zero-mass attachment to the ground, at the COP) during quiet standing and the action of the plantar flexors/dorsiflexors and invertors/evertors provide the moments necessary to move the COP and affect the position of the COM, keeping it within the base of support (BOS) (Winter 1995b). Winter observed that the difference between the COP and COM position is proportional to the horizontal acceleration of the COM, and may represent an "error" signal within the balance control system (Winter 1995b). In inverted pendulum theory, sufficient moments must be applied to balance and maintain stability, however, if the COM reaches the extent of its limit, the neuromuscular system may not be able to move the COP to correct for the change, and a fall is likely to occur without some outside action (Winter 1995b).

2.5.3 *Role of COM and COP in Gait*

Whereas the goal in quiet standing is to keep the COM within the BOS, while walking the goal changes to move the COM outside the BOS without falling (Winter 1995b). During walking, the COM is repeatedly outside the BOS and it is the next step that determines balance, and can be referred to as a state of dynamic balance (Winter 1995b). This can be seen by Jian et al.'s findings that the net COP initially moved behind and then ahead of the COM, and also that the COM remained clearly within the medial borders of the feet and always medial to the COP (Jian et al. 1993). The COM passes forward through the COP four times in the gait cycle in the plane of progression during steady-state gait (once in each double-support period, and once in each single-support period) (Jian et al. 1993). Jian et al. described the motion of the body's COM as rotating around the COP in space, where the destabilizing forces created by the COM moment around the COP must be controlled. This further supports the idea of whole body dynamic balance (Jian et al. 1993).

2.5.4 *COM/COP Relation to IN/TR*

The interaction between the COM and COP provides insights into how the transient periods of initiation and termination take place. Jian et al. postulated that since the COP is a direct reflection of the motor control profiles, comparing the COP with the horizontal COM trajectory showed how the COM was accelerated or decelerated to attain smooth initiation and termination of walking (Jian et al. 1993). Using this approach it is evident that during the early stages of initiation, an increasingly large distance between the COM and COP indicates that the COM is being accelerated forward quite rapidly (Jian et al. 1993). During initiation and termination, the COM moves forward and through the COP three times. The remainder of these periods the COM was ahead of the COP (being accelerated) or behind the COP (being decelerated) (Jian et al. 1993). These observations suggest that the COP-COM vector can be considered the primary variable predicting the horizontal accelerations of the COM (Jian et al. 1993).

2.5.5 *Summary*

Clearly, the interactive relationship between the COM and COP is an important factor in understanding balance control and motion in human standing and gait. This brief review justifies the need to analyze both the COM and COP separately to understand the controlled variable (COM) and the controlling mechanism (COP) (Jian et al. 1993). Not only does the vector joining the COM and COP help determine the horizontal accelerations of the COM, but the horizontal ground reaction forces as well. The body can modulate this vector in one of two ways: a change in macro-control of foot placement and micro-control of the COM-COP vector after the foot reaches the ground. The dominant strategy is macro-control of foot placement that depends on previous step length and width, thereby creating a dynamic boundary within which lies the state of dynamic balance. The secondary strategy of controlling the COM-COP vector is that of micro-control of the COP by plantar/dorsiflexors and invertors/evertors, achieving the final trajectory of the body COM (Jian et al. 1993). Thus, the connection between the COM and COP is a key variable in predicting motion of the COM and vital to understanding balance and stability control not only in quiet standing and steady-state gait, but also in the transition periods of initiation and termination of gait.

2.6 DIFFERENT GAIT ACTIVITIES

2.6.1 *Initiation*

The initiation of gait is often overlooked as a simple task, but it is indeed a much more complex task that is the result of integration of neural mechanisms, muscular activity and biomechanical forces (Mann et al. 1979). This combination of actions occurs with a predictable, and well-documented, pattern revealing the relationship between the COM and COP within the base of support (BOS). Gait initiation begins with a posterior shift in COP position as the triceps surae muscles are inhibited, while tibialis anterior is activated to produce plantar flexion (Carlsöö 1966; Winter 1995b; Elble et al. 1994; Herman et al. 1973). Approximately 20% through the gait initiation cycle, the triceps surae activate to produce dorsiflexion in preparation for toe-off near the 35% point of the gait initiation cycle (Mann et al. 1979). In the period of 35-60% of gait initiation (single limb stance), the stance limb performs hip flexion and progressive ankle plantar flexion (Mann et al. 1979; Breniere et al. 1981; Michel and Do 2002). This muscle action produces a posterior shift in COP while the COM accelerates forward towards the stance limb (Cook and Cozzens 1976; Mann et al. 1979; Breniere and Do 1986; Michel and Chong 2004). While this occurs, the swing limb initially flexes and then extends the knee, flexes the hip, and plantar flexes the ankle. After this period, the gait cycle enters a period of double-limb stance (60-72% of gait initiation), and allows for the stance limb to now behave in a way previously described for the initial swing limb. Between 72-100% (100% = heel strike of second limb) the COM velocity increases, and this second step occurs in much the same manner as the first (Mann et al. 1979). The gait pattern progresses through the first three steps until steady state walking is reached (Mann et al. 1979; Miller and Verstraete 1996).

Jian et al. stated that gait initiation cannot begin unless the COM and COP separate and this separation has major implications on balance control of the body (Jian et al. 1993). During quiet standing, the COM and COP are coincident, or have minimal differences that the GRF ankle moments correct for. However, to initiate gait, a counter movement is necessary to progress the COM forward. By separating the COP posterior to the COM, a driving force is developed to thrust the body anteriorly wherein the COM travels forward. To prevent falling, the leading limb must then step forward to maintain the COM within the BOS and create a situation of dynamic balance.

Studies have shown that mobility-impaired subjects deviate from the norm in terms of their gait characteristics. Halliday et al. conducted a study with young healthy adults, elderly adults and those with Parkinson’s disease, in which they measured both spatial and temporal parameters of gait initiation. They reported that the gait patterns were preserved in those with Parkinson’s disease, but the parameters tended to be smaller, slower and less forceful, compared to their age-matched counterparts (Halliday et al. 1998). Specifically, the patients with Parkinson’s disease exhibited decreased posterior and lateral shifts of the COP during release, decreased forward impulse under both limbs and increased unloading time compared with the elderly and young adults (Halliday et al. 1998). Similar problems may be faced by lower limb amputees, in that the amputee population is also lacking neural feedback and muscular control.

Although lacking the musculature in the amputated limb, it has been reported that horizontal velocity of the COM (at heel contact of leading limb) is not significantly different in the prosthetic versus sound leg (Michel and Chong 2004; van Keeken et al. 2008). This led van Keeken et al to postulate that lower limb amputees have an initiation strategy that treats the two legs as a functional unit (van Keeken et al. 2008). In contrast to this, Michel and Chong showed that the COM progression velocity asymmetry between the sound and prosthetic limbs suggested a different strategy in each lead limb condition used to generate similar propulsive force (Michel and Chong 2004). This alternate strategy could be explained in part by observations made by Tokuno et al.; that the downward vertical COM velocity at the end of gait initiation was increased when subjects lead with their prosthetic limb (Tokuno et al. 2003). Although similar COM velocities are found between lead limb conditions of amputee subjects, there appears to be a difference between the average COM horizontal velocities of amputees versus their able-bodied counterparts. Specifically, two studies reported that this horizontal velocity was lower in amputees (Michel and Do 2002; van Keeken et al. 2008).

In a study of transfemoral amputees, van Keeken and associates found that the active ankle function in the sound leg compensates for lack of ankle function in the prosthetic limb. The intact limb moves the COP in the anterior-posterior direction, manipulates forces, and produces end velocities. van Keeken and colleagues concluded that the lack of ankle function did not allow for posterior COP motion, causing the sound limb to produce this compensation (van Keeken et al. 2008).

Compensation strategies are often difficult to understand, where multiple strategies can achieve the same goal of initiating gait. For example, van Keeken et al. observed deviations in both the amputee and able-bodied groups that differed from the majority of subjects. These included a toe-standing strategy when initiating gait where the COP moves anteriorly from the toe (van Keeken et al. 2008). In a similar study with transtibial amputees, smaller COP displacements were reported for the prosthetic limb of transtibial amputees compared to control subjects (Tokuno et al. 2003). As the COP shift posteriorly causes forward motion, less posterior shift results in smaller forward displacement of the COM. A possible explanation for this could be that by limiting forward COM displacement, TT amputees experienced less disequilibrium and lessened the chance of falling or stumbling during initiation. However it is more probable that the rigid prosthetic foot didn't allow for rocking back without raising the toes, and the amputee subjects only rocked posteriorly on the intact limb. Visible differences in the path of the COP have also been noted (Tokuno et al. 2003). This is in disagreement with Rossi et al., who found that there was no difference in the COP path between a subject with a TT amputation and those of the able-bodied (Rossi et al. 1995). The lack of musculature of the lower limb in TT amputees almost certainly dictates that ankle motion, and consequently, the COP shift, must be inherently different than able-bodied COP shift.

Since COP is dependent upon ground reaction force (GRF) for its calculation, it is pertinent to discuss the forces involved in gait initiation. Rossi et al. observed that initiation forces were consistently higher for the prosthetic limb. They also reported that amputees bear more weight on the intact limb whether it is the swing or stance limb (Rossi et al. 1995). Other conclusions of their study were that amputee initiation was seemingly designed to minimize time on prosthetic limb (Rossi et al. 1995). Similarly, Nissan et al. observed that loading and unloading time of the amputee's stance leg was shorter than normal in below-knee amputees (Nissan 1991). In addition, it was reported that below-knee amputees took more time to complete initiation. The major cause for this was the time spent in double-limb support. The longer time for the force to be applied in the posterior direction occurred because the limb could not generate as much of a peak force. Intact limb compensation occurred by applying a smaller force over a longer amount of time which Tokuno et al. referred to as the "horizontal impulse strategy" (Tokuno et al. 2003).

It has been reported that lower limb amputees tend to prefer initiating gait with the prosthetic limb (van Keeken et al. 2008; Vrieling et al. 2008a). There are many reasons for this. By leading with the prosthetic limb, it is not necessary to shift weight towards the sound limb since the weight is already over the sound limb. Bearing weight on the sound limb allows the COM to move vertically, straight up above the sound limb. The COM velocity at foot off is also small, so amputees may feel a smaller risk of falling (van Keeken et al. 2008; Vrieling et al. 2008a).

In summary, it has been observed that gait initiation is a complex task due to its requirements of the neural system, muscular activity, and biomechanical forces. It has also been proven that the COM and COP must separate to develop the propulsive force necessary for gait initiation. However, this action must occur within the limits of stability, forcing the body to extend one leg forward to arrest the fall, which creates the basis for the initiation of walking. The challenge of initiating gait to amputee subjects is their lack of musculature, neural feedback and force production capabilities, precisely the same mechanisms that make initiating gait so complex. These characteristics put this population at a disadvantage while initiating gait. As a result of their limb loss, amputees display smaller COP displacements during gait initiation in the amputated limb. Patients with Parkinson's disease suffer from similar maladies (lack of neural feedback and muscular control), and it has been reported these patients also have decreased values of COP displacement. Both of these populations must find a way to initiate gait using non-traditional methods due to their lack of gait producing mechanisms. In the amputee community, the way the body adjusts to achieve gait initiation is highly dependent on the prosthetic foot used. This makes the study of the response to varying stiffness prosthetic feet important to the prescription and design of prosthetic feet for the lower limb amputee community.

2.6.2 *Termination*

Gait termination is the period of time that occurs between normal, cyclic gait and coming to complete stop. It has been described as being the opposite of gait initiation – where the COP and COM trajectories are mirror images of gait initiation (Jian et al. 1993; Winter 1995b). For safe gait termination, forward movement of the body has to be slowed down to achieve a stable upright position (Hase et al. 1998; Vrieling et al. 2008b; Meier et al. 2001). This occurs by activating the vasti and gluteus medius muscles to extend the knee and prevent the trunk from bending forward. In the trailing limb the tibialis anterior, biceps femoris and gluteus medius muscles increase activity to bring the body down and backwards with the foot flat to the ground, resulting in a further decrease in forward movement (Stein and Hase 1999). A large burst of soleus muscle activity and reduced activation in the tibialis anterior muscle of the leading limb bring the foot flat to the ground (Hase et al. 1998; Stein and Hase 1999; Bishop et al. 2002).

It has been reported that a stimulus during the first 20% of gait cycle may be sufficient for subjects to arrest forward momentum within that step (Bishop et al. 2002). After this point in the gait cycle, time to gait termination increases, as a second step is required to terminate gait (Jaeger and Vanitchatchavan 1992). However, gait termination patterns vary from individual to individual, where the time and number of steps needed to terminate gait depends on the gait excursion velocity, termination command and when termination is required (Jaeger and Vanitchatchavan 1992; Jian et al. 1993; Hase et al. 1998; Bishop et al. 2002; Vrieling et al. 2008b). For example, multiple sources have reported that there was a decreased push-off, and therefore acceleration, from at least the step just prior to stopping during planned stopping at a self-selected pace (Jaeger and Vanitchatchavan 1992; Jian et al. 1993; Winter 1995b; Wearing et al. 1999). Jian et al. also observed that as much as 90% of deceleration occurred in the final step of termination (Jian et al. 1993). While Jaeger and Vanitchatchavan reported GRF data which suggests that an increase of braking force in final stance phase was necessary to terminate gait (Jaeger and Vanitchatchavan 1992). In studies on the effects of cadence and velocity during gait termination, it was observed that: peak decelerations increased for the leading limb during planned stopping (Bishop et al. 2002), subjects relied less on the trailing limb and more on the leading limb as cadence and velocity increased, the lead limb had the greatest contribution to slowing the COM, the sequence of muscle activation was no different, but the duration of muscle activity was longer than normal walking (Bishop et al. 2002, 2004), and the braking GRF was increased in the final stance phase as compared to normal walking (Jaeger and Vanitchatchavan 1992; Bishop et al. 2002, 2004).

As a person comes to terminate gait, the interrelationship between the COP and COM becomes critical. During toe off of the last swing limb, COP tends to be forward and lateral of COM. This causes the COM to decelerate in the anterior-posterior direction and accelerate medially (Jian et al. 1993; Crenna et al. 2001). The COM slows and moves towards the center-line, while the last stance foot bears weight and moves the COP anteriorly and towards the second stance foot. Here, the COP is anterior of the COM, at which point the anterior and medial velocities are near zero and the COP quickly travels posteriorly to a position almost coincident with the COM (within minor fluctuations of 1 cm or less while standing) while final braking is achieved (Jian et al. 1993). The pattern of the COP trajectory shows the effect the musculoskeletal system has on managing the trajectory of the COM by varying torque application to the ground through the musculature of the lower limb (e.g. pronators and supinators in the frontal plane, dorsiflexors and plantar flexors in the sagittal plane) (Jian et al. 1993; Hase et al. 1998; Stein and Hase 1999).

Similar to gait initiation, gait termination places certain demands on postural control, where successful termination requires exact integration and management of sensory information, visual inputs and muscle activity (Meier et al. 2001). The loss of nerves, muscles and joints and the subsequent detriment to gait has long been established in the literature (Fernie and Holliday 1978; Hermodsson et al. 1994). Subjects with mobility impairments (i.e. decreased neuronal response due to aging, diabetes, etc.) have reduced capabilities during gait and often deviate from gait characteristics of their unimpaired counterparts. Due to their lack of neuronal input, diabetic neuropathic subjects have been reported to have weaker maximal braking forces an increased amount of time to achieve these forces than healthy elderly subjects. The diabetic subjects approached stopping at a slower speed, but also showed a reduced ability to terminate gait as shown by increased anterior-posterior and medial-lateral COM and COP overshoots (Meier et al. 2001). Patients with Parkinson’s disease have also been studied while terminating gait and have been found to use stopping strategies similar to healthy adults, however with diminished response. Patients with Parkinson’s disease were also unable to modulate stance limb forces in time-critical conditions, such as stopping unexpectedly at a cross-walk (Bishop et al. 2003).

Gait termination in the amputee population has received little attention in the scientific literature. Vrieling et al. studied lower limb amputees of different levels (TF and TT, versus able-bodied subjects) and the effect of amputation level on COM, COP, and GRF patterns during gait termination and gait cycle durations (Vrieling et al. 2008b). In their study, it was reported that there was a decreased peak braking GRF for the prosthetic limb, and an extended period of braking force in the intact limb. These phenomena likely played a role in the COP shift as well. Due to the lack of force production in the prosthetic limb, the COP did not move anteriorly while leading into termination with the prosthetic limb, and also exhibited an increased medial-lateral COP shift (Vrieling et al. 2008b). It is thought that the stiffness of the prosthetic foot does not allow for a smooth shift of COP anteriorly, however no underlying effects in GRF have been found in normal walking (Hillery et al. 1997; Vrieling et al. 2008b). The larger medial-lateral COP shift in the leading prosthetic condition could possibly stem from a decrease in balance control.

Amputees tended to prefer leading into termination with their sound limb. This may represent an adjustment strategy, wherein amputees benefit from leading with the sound limb due to increased anteroposterior force, anterior motion of the COP with respect to the COM and a smaller medial-lateral shift of the COP. Amputees may also decide to adjust their step length prior to stopping to begin their termination pattern with the sound limb (Vrieling et al. 2008b).

The transient period between cyclic gait and coming to a complete stop merits a review as it pertains to the amputee population. Planned stopping often occurs with the assistance of a decreased push-off prior to stopping, where the lead limb plays the greatest role in slowing the COM and ultimately, stopping forward motion. Much like gait initiation, the interplay between the COM and COP is a key characteristic of gait termination. The COM-COP interaction creates the forces necessary to terminate gait. As the COP becomes anterior to the COM, a deceleration occurs that arrests forward motion and brings the body to quiet stance. However, in populations that are lacking musculature and neural control, gait termination becomes a more difficult task. Amputees have a more challenging time terminating gait as has been displayed by their varied COP shifts. This leads to compensation strategies such as amputees adjusting step length and leading limb condition when approaching a stop. Understanding amputee gait termination is a necessary step in the process of the advancement of prosthetic foot use and design.

2.6.3 *Quiet Stance*

Standing balance control is an important functional task that is challenging to lower extremity amputees. Balance control is defined as the ability to maintain the body’s center of mass over its base of support with minimal postural sway (Shumway-Cook et al. 1988). During active control of balance, there is a natural fluctuation of COP position in the anteroposterior and mediolateral directions. An argument has been presented that explains fluctuations of the COP in the anteroposterior direction as being controlled by the ankle dorsiflexors and plantar flexors causing the body to behave like an inverted pendulum with its pivot point at the ankle (Winter 1995b, 1995a). Mediolateral sway is said to be controlled by using a load-unload strategy powered by the hip abductors (Winter 1995a). Balance performance is most often expressed using some quantification of the COP fluctuations (Doyle et al. 2007). It is known that horizontal force measures and COP measures are significantly correlated. This comes as no surprise, due to the fact that the COP represents the single point location of the GRF vector (Winter 1995b, 1995a; Karlsson and Frykberg 2000). Thus, it can be extrapolated that COP displacements reflect the acceleration of the COM and can directly affect COM movements (Karlsson and Frykberg

2000; Winter 1995a). Because displacements in the COP reflect lateral movements (sway) of the center of mass, it is inferred that individuals who demonstrate the greatest excursion in COP are the least stable and therefore have poorer balance (Buckley et al. 2002). It is clear that a robust control system must be put in place to maintain balance during quiet stance. The degeneration of this balance control system in the elderly and in many pathologies with balance challenges (e.g. Parkinson's disease, diabetes mellitus, amputation, etc.), has motivated researchers and clinicians to understand more about how the system works and how to quantify its status at any point in time (Winter 1995b).

It has often been reported that a restoration of symmetry is important to those with amputations. Some research groups have charged that it is important to regain symmetry as portrayed by the correlation between increased loading on the sound limb and the development of degenerative changes (early onset osteoarthritis) in the limb after five years of prosthesis use (Hungerford and Cockin 1975; Burke et al. 1978; Hurley et al. 1990; Isakov et al. 1996; Nadollek et al. 2002). Others have argued that energy efficiency during gait is a more optimal goal (Andres and Stimmel 1990; Hubbard and McElroy 1994). Although there is some controversy regarding the topic of returning to a symmetrical gait pattern, it has been confirmed that energy cost to amputees during gait is higher than normal subjects (Dingwell et al. 1996).

Some of the same reasons responsible for asymmetrical gait could be responsible for asymmetrical quiet stance. Stump pain (Summers and Morrison 1987), lack of proprioception (Rossi et al. 1995; Nadollek et al. 2002; Isakov et al. 1992), weight, shape, components and alignment of the prosthesis (Summers and Morrison 1987; Pinzur et al. 1995; Snyder et al. 1995) are all contributing factors to asymmetrical gait. It is widely accepted that amputees tend to place more weight on the sound limb than the prosthetic limb (Summers and Morrison 1987; Isakov et al. 1992; Jones et al. 1997; Nadollek et al. 2002). This could be used to indicate weight bearing tolerance of the prosthetic (Jones et al. 1997) and lead to an objective measure of clinical improvement (Summers and Morrison 1987). This preference to bear weight on the sound limb could be due to a lack of confidence in the amputated limb, increased comfort by standing with more weight on the sound limb or increased reliance on proprioceptive input from the sound limb (Nadollek et al. 2002).

Lacking the ankle and foot, lower limb amputees are unable to utilize the ankle strategy of postural adjustments during quiet stance. This is likely the cause of the increased postural sway observed for this population during quiet standing (Fernie and Holliday 1978; Isakov et al. 1992; Aruin et al. 1997). Buckley et al. reported this increase in postural sway to be almost twice as much (Buckley et al. 2002) as indicated by the excursions of the COP (Isakov et al. 2000). Greater postural sway indicates that amputees had poorer static balance than able-bodied controls, highlighting the importance of ankle function when maintaining balance during motions involving movements in the sagittal plane (Buckley et al. 2002). In amputees it was observed that younger age, longer time since amputation and prosthetic provision, and longer time wearing the prosthesis each day were associated with smaller excursions in COP (Nadollek et al. 2002). As previously discussed, the COP excursions give a measure of stability and balance control, with smaller excursions equating to a more capably balanced subject. Nadollek et al.'s observations take into account the subject dependent measures of stability, but do not account for the characteristics of the prosthetic foot used.

This literature review has ranged from quiet stance in general and how the COP and COM interact to achieve balance, to the idea of a return of symmetry to the gait and balance patterns of amputees to the strategies used by amputees to achieve standing balance (e.g. applying more weight on the sound limb and an increase in postural sway). All of these topics are valuable to the discussion of amputee balance. While some of these studies compare and contrast the prosthetic feet and the changes in the balance measures, there are none that systematically give characteristics of the prosthetic feet to use as a comparative metric.

Chapter 3. METHODS

3.1 RESEARCH SUBJECTS

Research subjects were recruited from the population of lower limb amputees at the VA Puget Sound Health Care System (VAPSHCS) and surrounding communities. The inclusion/exclusion criteria for this study were as follows:

Inclusionary criteria for amputee group:

- Unilateral transtibial amputee
- Over 18 years of age and less than 65 years of age
- Duration since amputation of greater than one year
- Currently ambulating with a prosthetic limb

Exclusionary criteria for amputee group:

- History of rheumatic diseases such as gout, rheumatoid arthritis, pseudogout, or ankylosing spondylitis that would affect gait
- History of neurologic deficits or other musculoskeletal disorders that would affect gait
- Required use of an upper extremity gait aid

The research protocol was approved by the Institutional Review Board (IRB) of the VAPSHCS and the University of Washington. All subjects signed the IRB approved informed consent document prior to their involvement in the study (Appendix A).

3.2 PROTOCOL

3.2.1 *Subject Preparation*

Upon arriving at the Motion Analysis Laboratory (MAL) at the VAPSHCS, subjects were made aware of the scope of the research protocol and were provided with both verbal and written descriptions of the procedures they would be involved in. After obtaining the subject’s written informed consent, the subject’s height and weight were measured using a physician’s beam scale. Following this, the subject’s self-selected walking speed (SSWS) was determined using a timed hallway walking test. The subject then was asked to change into form-fitting athletic clothes provided by the MAL to lessen the chance for marker occlusion. Anthropometric measurements for link-segment model definitions were taken including: upper arm width (L/R), hand width (L/R), hand thickness (L/R), thigh width (L/R), knee width (L/R), ankle width (L/R) and foot width (L/R). Next, 55 retroreflective markers, 14 mm in diameter, were placed on the front of the head (L/R), temple (L/R), back of the head (L/R), 7th cervical spinous process, 10th thoracic spinous process, right scapula, jugular notch of sternum, xyphoid process of sternum, acromion process (L/R), lateral arm (L/R), medial elbow (L/R), lateral elbow (L/R), lateral forearm (L/R), radial styloid process (L/R), ulnar styloid process (L/R), dorsal surface of hand (L/R), anterior superior iliac spine (L/R), posterior superior iliac spine (L/R), patella (L/R), lateral malleolus (L/R), heel (L/R), and the second metatarsal head (L/R) (Figure 3-1). In addition to these markers, clusters of 4 markers each were attached to the lateral thigh (L/R) and lateral shank (L/R) with a self-adhesive medical wrap. The purpose of these clusters will be described later (see section 3.2.2).

As part of this study, the prosthetic foot component stiffness was parametrically varied to determine the effects of hindfoot (heel) and forefoot (toe) stiffness. This foot was comprised of a heel and a toe component attached to an aluminum pylon mount that acted to mimic both the heel strike and push-off capabilities of the normal human foot (Figure 3-3). Based on the subject's height and weight, they were placed in a category of stiffness. For example, a subject weighing 80kg and standing 1.80m would fall into category 4B (Table 3-1) (see Appendix B for foot component stiffness matrix). These categories determined stiffness and length of the prosthetic foot components where the aim was to maintain similar ankle-foot length (0.34) and foot length-height (0.13) ratios between all subjects by changing the position on which the heel and toe components were attached to the pylon mount. These initial ratios were loosely based upon subject feedback from the initial pilot study. Along with length ratios, the components were matched so that nominal stiffness components had similar stiffness values compared to other commercially available prosthetic feet (Geil 2001; Klute et al. 2004). The differences in stiffness level between compliant, nominal, and stiff components resulted from an attempt to keep a standardized change between levels (~15 N/mm), but was limited by the set of components available. Each subject first went through a training session where the subject completed all tasks with their prescribed (PRES) limb. After the subject became familiar with the protocol, the first novel multi-component foot condition tested was the nominal stiffness (NS) condition. Each subsequent testing condition changed only one of the two components (e.g. using a toe component one level of stiffness higher than nominal, but using the nominal stiffness heel component) (see Figure 3-2). This led to four additional conditions (5 total, including NS): compliant heel (CH), compliant toe (CT), stiff heel (SH), and stiff toe (ST). The average stiffness values of the components used in this study can be found in Table 3-2, and all component stiffnesses can be found in Appendix B.

Table 3-1: Height and weight categories used to determine foot stiffness components.

		Height (cm)					
		< 160	160 - 168	168 - 175	175 - 183	183 - 190	> 190
Weight (kg)	< 77.3	1A	2A	3A	4A	5A	6A
	77.3 - 90.9	1B	2B	3B	4B	5B	6B
	> 90.9	1C	2C	3C	4C	5C	6C

Table 3-2: Subject component stiffness values [N/mm].

Subject	**Category**	**CH Stiffness**	**NS Heel Stiffness**	**SH Stiffness**	**CT Stiffness**	**NS Toe Stiffness**	**ST Stiffness**
A01	4A	21.2	31.1	49.4	27.1	37.2	45.8
A02	4A	21.2	31.1	49.4	27.1	37.2	45.8
A04	5B	31.1	49.4	60.7	37.2	45.8	62.3
A05	5A	21.2	31.1	49.4	27.1	37.2	45.8
A06	6C	49.4	60.7	66.4	45.8	62.3	88.8
A07	3B	31.1	49.4	60.7	37.2	45.8	62.3
Mean		29.2	42.1	56.0	33.6	44.3	58.5

3.2.2 *Subject Testing*

The activities for testing included steady state walking, gait initiation and termination, and quiet standing. Subjects used their PRES limb to train and familiarize themselves with the tasks involved with the study. The protocol was then completed first with the NS foot, and then a randomized order of the remaining conditions (CH, CT, SH, ST). After subjects had been fitted and aligned by a certified prosthetist, the subject was allowed some time (~1-5 min) with each foot condition to walk around and become comfortable enough to begin the gait activity protocol. Prior to collection of walking trials, functional joint center (FJC) trials were taken for the hip (L/R) and knee (L/R) utilizing the four pelvis markers, and clusters of markers on the thigh and shank (Schwartz and Rozumalski 2005).

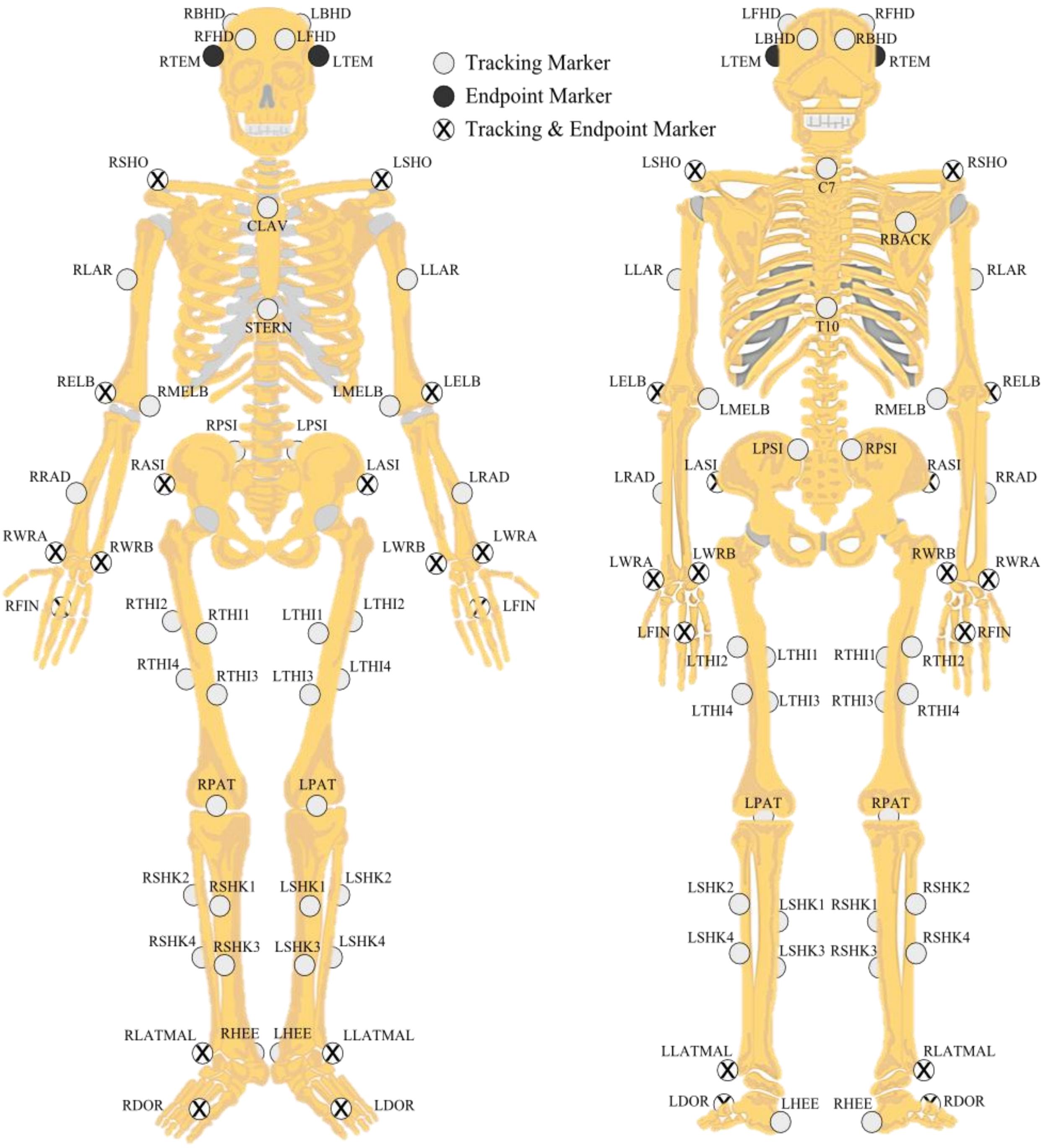

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Figure 3-1: Anterior (left) and posterior (right) view of marker setup used for collection.

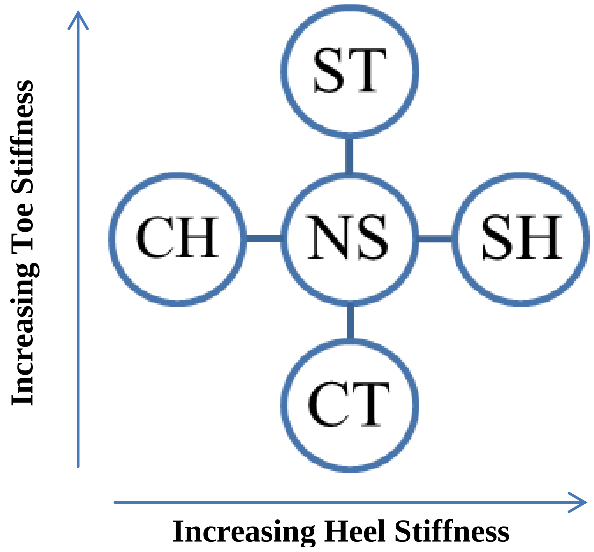

Figure 3-2: Schematic representing the variation of stiffness between testing conditions. NS = nominal stiffness foot, CH = compliant heel foot, SH = stiff heel foot, CT = compliant toe foot, and ST = stiff toe foot.

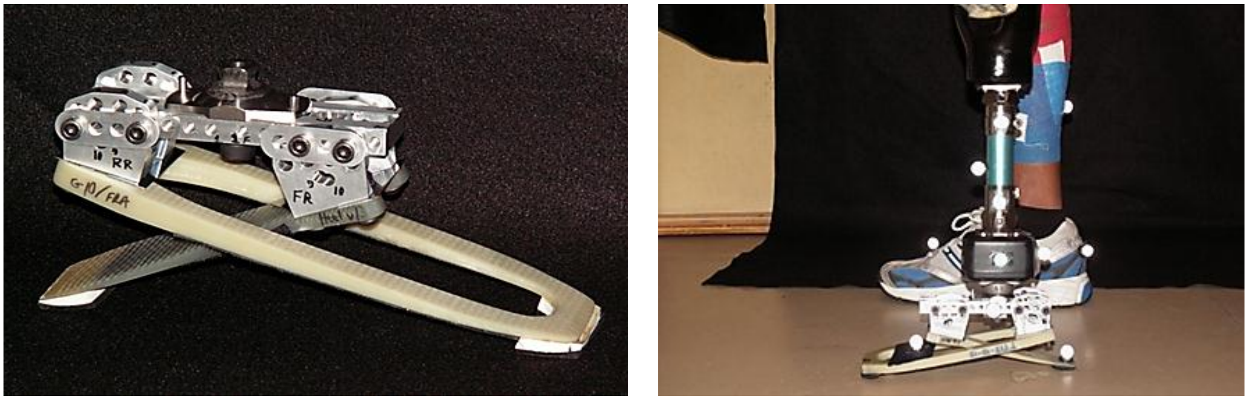

Figure 3-3: Multi-component foot (left) and marker setup (right).

For the hip FJC trials, the subject was asked to keep the body still and stand on the contralateral leg while circumducting the ipsilateral hip in five small circles (~30 cm diameter) with a straight leg. For the knee FJC trials, the subject again was asked to stand still on the contralateral limb, while performing 5 ipsilateral knee flexion-extension (zero to ~45° flexion) activities in the sagittal plane. A static trial was then taken with the subject in anatomical position to determine link segment model coordinates.

The subject then performed steady state walking across a walkway until three successful trials were collected. A trial was deemed successful if three consecutive clean force plate strikes were achieved. After this, the subject was asked to perform three successful initiation trials leading with the prosthetic limb (INP), starting with both feet side-by-side on a single force plate and walking across the walkway. A trial was deemed successful if the subject cleanly struck the two subsequent force plates. Similarly, the subject repeated the initiation trials leading with the sound limb (INS). The subject then performed three successful termination trials leading prosthetic (TRP), meaning that the prosthetic limb was the first foot to strike the final force plate and the trailing sound limb came to rest alongside the prosthetic limb. A termination trial was deemed successful if the subject had cleanly struck the final two force plates. Next, the subject completed a set of three trials of termination while leading with the sound limb (TRS). In all walking gait trials, subjects were instructed to walk at a self-selected pace, and to not target force plates. The subjects' feet were aligned by the research team so that their feet struck the force plates in their natural stride in all trials.

After each subject had completed the protocol, they were given a questionnaire asking them to rate the feet they had been walking on. The questionnaire asked the subject to rate each of the feet on a scale of 1-10 (1 being poor and 10 being excellent) in each of the following categories: comfort, stability, ability to stand, ability to accelerate, and ability to stop.

3.3 DATA COLLECTION

Marker coordinate data were collected at 120 Hz using a 12 camera Vicon MX motion collection system (Vicon, Oxford, UK) and synchronized with ground reaction force (GRF) data collected at 1200 Hz from embedded force platforms (1 Kistler, Winterthur, Switzerland; 2 Bertec, Columbus, OH; 4 AMTI, Watertown, MA). Marker position and force plate data were extracted for further kinematic and kinetic processing in Visual3D (C-Motion Inc., Germantown, MD).

3.4 DATA PROCESSING

The analog signals recorded from all trials were processed with digital filters using custom Visual3D processing pipelines. Marker position data were filtered with a 4th order, zero-lag, low-pass (6 Hz) Butterworth filter (Robertson and Dowling 2003; Jian et al. 1993; Winter and Sienko 1988). Force plate data were filtered with a 4th order, zero-lag, low-pass (50 Hz) Butterworth filter (Robertson and Dowling 2003). This cut-off frequency was sufficient to dampen high frequency noise levels while maintaining sufficient true signal response, and is within the range of cut-off frequencies used by other similar studies (20-80 Hz) (Robertson and Dowling 2003; Zhang et al. 2006; Jian et al. 1993; MacKinnon and Winter 1993; Crenna et al. 2001).

In each trial, COP and COM position were calculated, where the COM was a weighted sum of a 15-segment link segment model based on subject anthropometrics, and the COP was the resolution of the ground reaction forces and moments measured from the force plates. Excursion measures in the anteroposterior (A/P) and mediolateral (M/L) directions of IN conditions were max-min values between initial quiet stance to heel strike of the leading limb. Similar measures were made during TR conditions; max-min values between trailing limb toe-off until anterior motion stopped. Further measurements of the COP were taken to gain a more detailed view of the mechanisms used by the balance control system during initiation and termination. These four data points were denoted as COPx1, COPx2, COPy1 and COPy2. Similar measures have been used elsewhere in the literature to further understand these motions (Vrieling et al. 2008a, 2008b). Definitions of various metrics are listed below, and are further depicted in Figure 3-4 and 3-5.

Definitions:

- Initiation
  - IN A/P Excursion (COM and COP) – max-min A/P value between initial quiet stance and heel strike of leading limb
  - IN M/L Excursion (COM and COP) – max-min M/L value between initial quiet stance and heel strike of leading limb
  - IN COPx1,y1 – the distance between the quiet standing position and the position on the leading limb side where the subject has started to transfer load to the trailing limb
  - IN COPx2,y2 – the distance between the quiet standing position and the position on the trailing limb side where the subject starts to propel forward
- Termination
  - TR A/P Excursion (COM and COP) – max-min A/P value between trailing limb TO and stoppage of anterior motion

- TR M/L Excursion (COM and COP) – max-min M/L value between trailing limb TO and stoppage of anterior motion
- TR COPx1,y1 – the distance between the final bipedal stance position and the most anterolateral position on the leading limb side
- TR COPx2,y2 – the distance between the final bipedal stance and the most anterolateral position on the trailing side before coming back toward the final bipedal stance

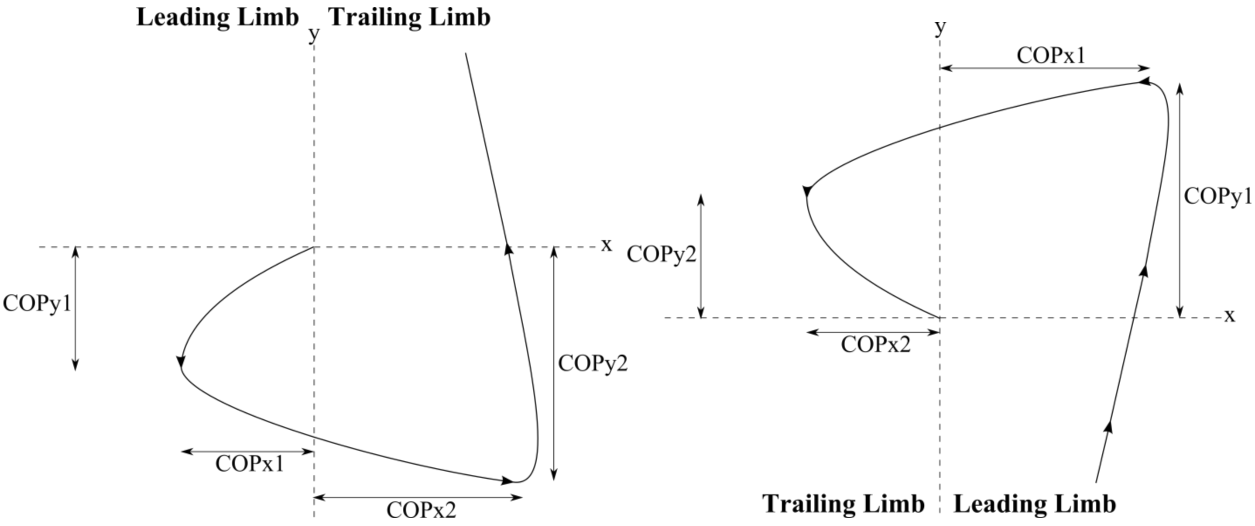

Figure 3-4: Schematic representation of gait initiation (left) and gait termination (right) COP path with values of COPx1,y1 and COPx2,y2 denoted in each.

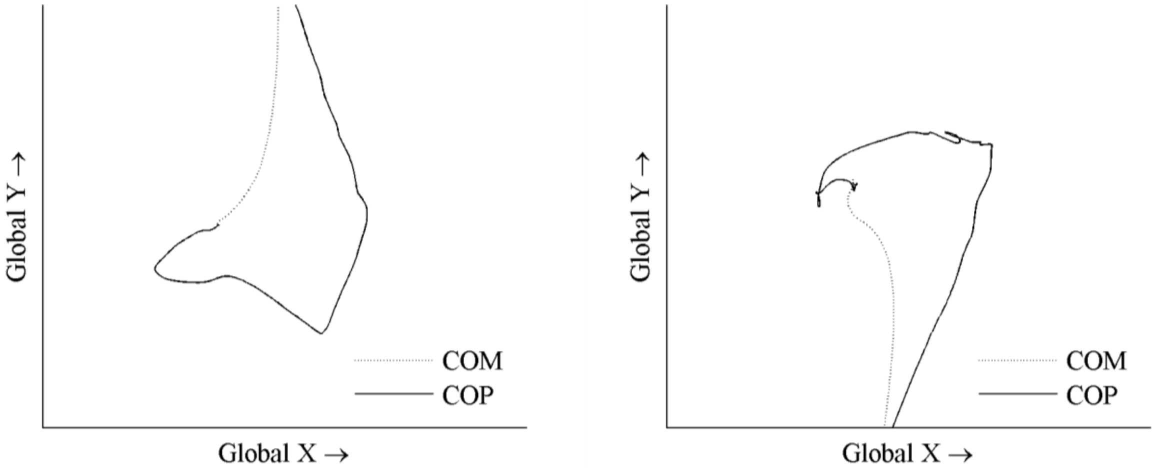

Figure 3-5: Example subject gait initiation (left) and gait termination (right) COM and COP paths using the prescribed foot.

3.5 STATISTICAL ANALYSIS

To test the primary and secondary hypotheses, two statistical analyses were completed. A two-factor analysis of variance (ANOVA) was used to test main effects of limb and foot stiffness ($\alpha = 0.05$). If the effect of foot stiffness tested significant, post-hoc analysis was conducted using Bonferroni adjustment for multiple comparisons (adjusted $\alpha = 0.0083$). All statistical tests were conducted using Systat (v.13, Systat Software, Inc., Chicago, IL).

Chapter 4. RESULTS

Six male transtibial amputees participated in this study. Their average age, height, and weight were 41 ± 13.7 years, 1.82 ± 0.06 m, and 85.8 ± 15.5 kg, respectively. More descriptive details of the subjects' prosthetic use are presented in Table 4-1. For all subjects, gait initiation and termination measures were collected for all five conditions (NS, CH, CT, SH, ST). Due to time constraints, subject A06 did not complete the compliant toe condition and this subject's CT condition has been left unreported.

The primary hypothesis of this study was that the COM and COP excursions would be greater in both the A/P and M/L directions while initiating and terminating gait with the sound limb versus initiating and terminating gait with the prosthetic limb. The second hypothesis of this study was that within the groups of INP, INS, TRP and TRP, the COM and COP excursions of compliant, nominal and stiff heel or toe components would be different from each other. The quantitative analysis of these hypotheses is presented in the ensuing sections.

Table 4-1: Subject descriptive data.

Subject[a]	**Affected Limb**	**Time Since Amputation (months)**	**Etiology**	**Socket**	**Liner**	**Suspension**	**Pylon**	**Prosthetic Foot**
A01	L	96	Trauma	*TSB	Gel	Pin Lock	Rigid	Flex Foot®
A02	L	72	Infection	Carbon Fiber	Gel	Pin Lock	**N/A	Highlander®
A04	L	468	Trauma	*TSB	Silicone	Pin Lock	Endoskeletal	Vari Flex®
A05	L	12	Trauma	**N/A	**N/A	Pin Lock	**N/A	Elite Blade
A06	R	24	Infection	*TSB	Gel	Pin Lock	Rigid	Multi-axial
A07	R	24	Infection	**N/A	**N/A	Pin Lock	**N/A	Renegade®

[a]Subject 03 was excluded due to change in stiffness choice matrix. *TSB: Total Surface Bearing. **N/A: Not Available.

4.1 GAIT INITIATION

4.1.1 *Initiation COM Analysis*

The COM excursion values were calculated during the initiation phase of gait. Figure 4-1 and Figure 4-2 display the excursion values in both the anterior-posterior (A/P) and mediolateral (M/L) directions. The COM excursion exhibited a significant limb effect between initiation prosthetic (INP) and initiation sound (INS) in the A/P direction (*p* = 0.029). A foot stiffness effect was also observed (*p* = 0.031) with significant post-hoc differences being detected between the CH and CT feet (*p* = 0.003). In the M/L direction, COM excursion was determined to have a significant trend (*p* = 0.05). However, a foot stiffness effect was detected (*p* = 0.047) with a near-significant difference (post-hoc adjusted significance level $\alpha = 0.0083$) between CH and CT feet (*p* = 0.017). Descriptive statistics for these measures are presented in Table 4-2.

4.1.2 *Initiation COP Analysis*

The A/P and M/L excursions of the COP during gait initiation are presented in Figure 4-3 and Figure 4-4. The INS condition was determined to have a significant trend of greater excursion than the INP condition in the A/P direction (*p* = 0.204) and the M/L direction (*p* = 0.193). There was no foot stiffness effect in the A/P direction (*p* = 0.221) or M/L direction (*p* = 0.194). Descriptive statistics for the gait initiation COP analysis can be found in Table 4-2.

4.1 GAIT TERMINATION

4.1.1 *Termination COM Analysis*

The COM excursion values were also calculated during the termination phase of gait. Figure 4-5 and Figure 4-6 display the excursions in the A/P and M/L directions, respectively. The COM A/P direction showed a significant difference between TRP and TRS (*p* < 0.001), with the TRP conditions being less than the TRS condition. A significant foot stiffness effect was also observed in the COM A/P direction (*p* = 0.007), with significant post-hoc differences detected between the CT and SH feet (*p* < 0.001). No significant effects were observed in the termination COM M/L excursion measure which displayed highly variable differences between TRP and TRS across all feet. Descriptive statistics for these measures is presented in Table 4-3.

4.1.2 *Termination COP Analysis*

No significant effects of leading limb or foot stiffness were observed in either the termination COP A/P or M/L excursions. The TRS condition trended towards a greater excursion than the TRP condition (*p* = 0.337), though with a non-significant result where the CT foot showed an opposite trend compared to the other feet. In the termination COP M/L condition, the lead foot seemed to have a random effect on the excursion value (*p* = 0.492), where the ST foot displayed TRP excursion greater than the TRS excursion, whereas all other feet showed the opposite trend. Descriptive statistics of these measures are presented in Table 4-3.

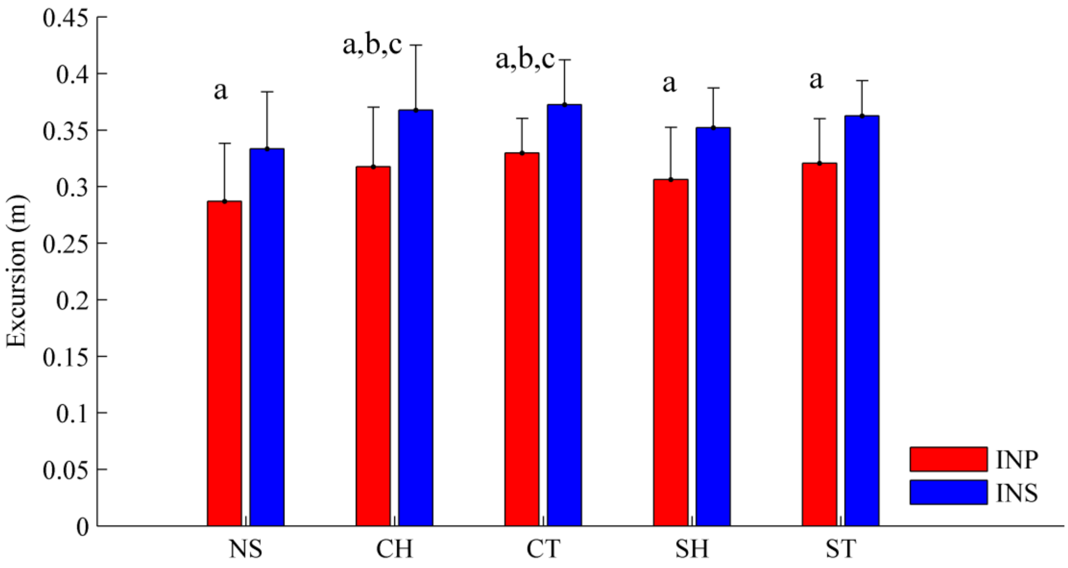

Figure 4-1: Initiation COM A/P excursion results. ^{a}limb effect ($p < 0.05$), ^{b}foot stiffness effect ($p < 0.05$), ^{c}post-hoc ($p < 0.0083$). Error bars represent one standard deviation.

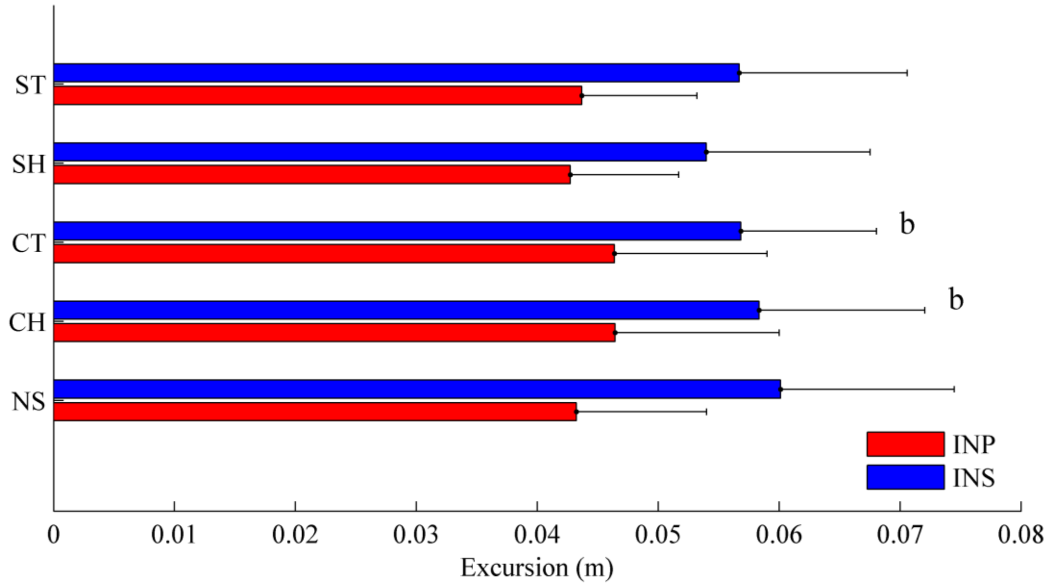

Figure 4-2: Initiation COM M/L excursion results. ^{b}foot stiffness effect ($p < 0.05$).

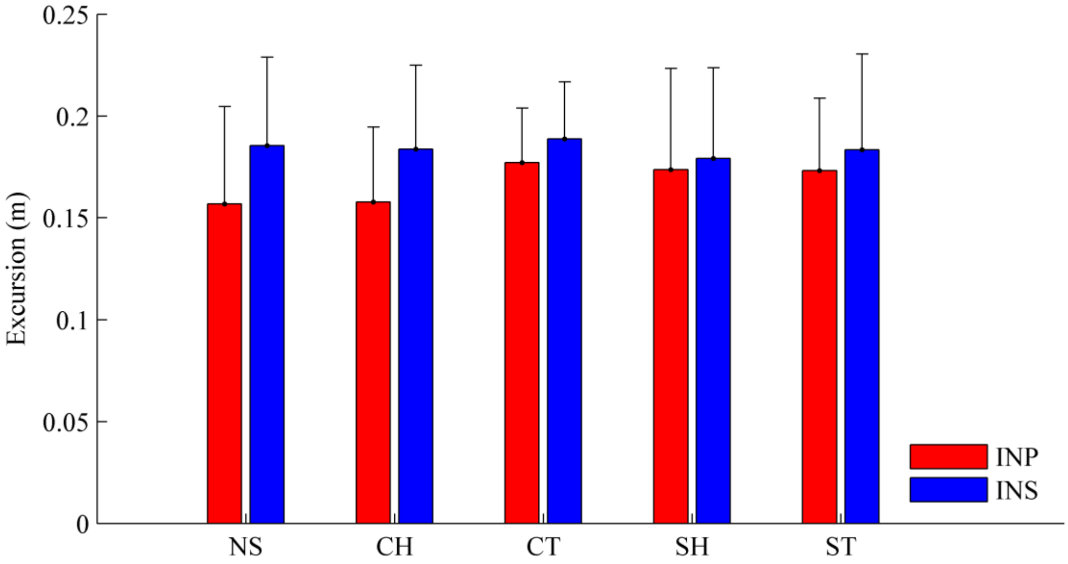

Figure 4-3: Initiation COP A/P excursion results

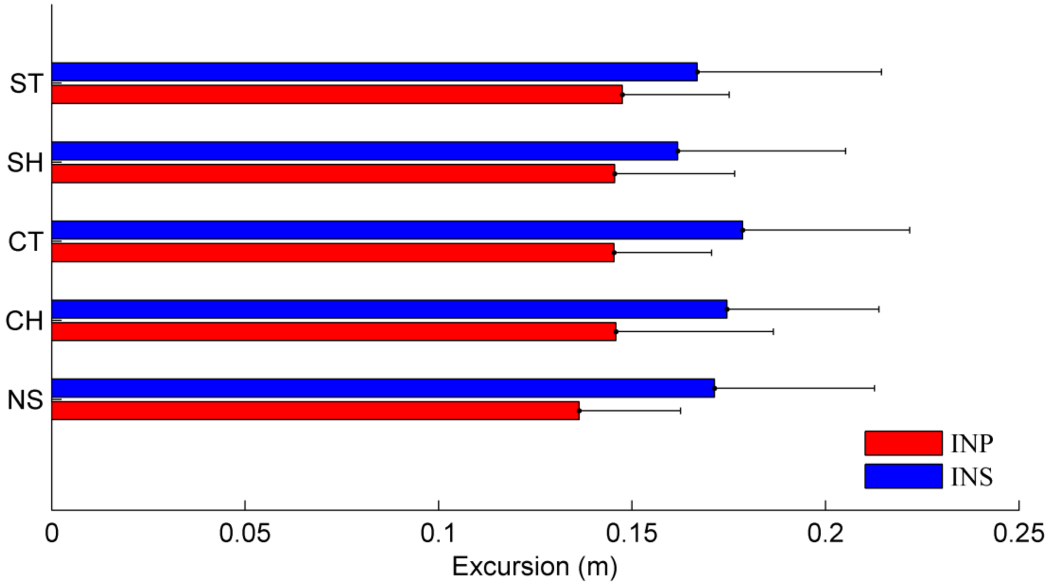

Figure 4-4: Initiation COP M/L excursion results.

Table 4-2: Limb and foot stiffness effects (p-value) and sample mean (SD) for COM and COP excursions (m) during gait initiation.

	IN COM A/P	**IN COM M/L**	**IN COP A/P**	**IN COP M/L**
NS	0.287	0.043	0.157	0.136
P	(0.051)	(0.011)	(0.048)	(0.026)
NS	0.333	0.060	0.186	0.171
S	(0.050)	(0.014)	(0.043)	(0.041)
CH	0.318^c	0.046	0.158	0.146
P	(0.053)	(0.014)	(0.037)	(0.041)
CH	0.368^c	0.058	0.184	0.175
S	(0.057)	(0.014)	(0.041)	(0.039)
CT	0.330^c	0.046	0.177	0.145
P	(0.030)	(0.013)	(0.027)	(0.025)
CT	0.373^c	0.057	0.189	0.179
S	(0.040)	(0.011)	(0.028)	(0.043)
SH	0.306	0.043	0.174	0.146
P	(0.046)	(0.009)	(0.050)	(0.031)
SH	0.352	0.054	0.179	0.162
S	(0.035)	(0.014)	(0.044)	(0.043)
ST	0.321	0.044	0.173	0.148
P	(0.039)	(0.010)	(0.036)	(0.028)
ST	0.363	0.057	0.173	0.148
S	(0.031)	(0.014)	(0.036)	(0.028)
Limb Effect	$p = 0.029^a$	$p = 0.05$	$p = 0.204$	$p = 0.193$
Foot Stiffness Effect	$p = 0.031^b$	$p = 0.047^b$	$p = 0.221$	$p = 0.194$

^{a}limb effect ($p < 0.05$), ^{b}foot stiffness effect ($p < 0.05$), ^{c}post-hoc ($p < 0.0083$)

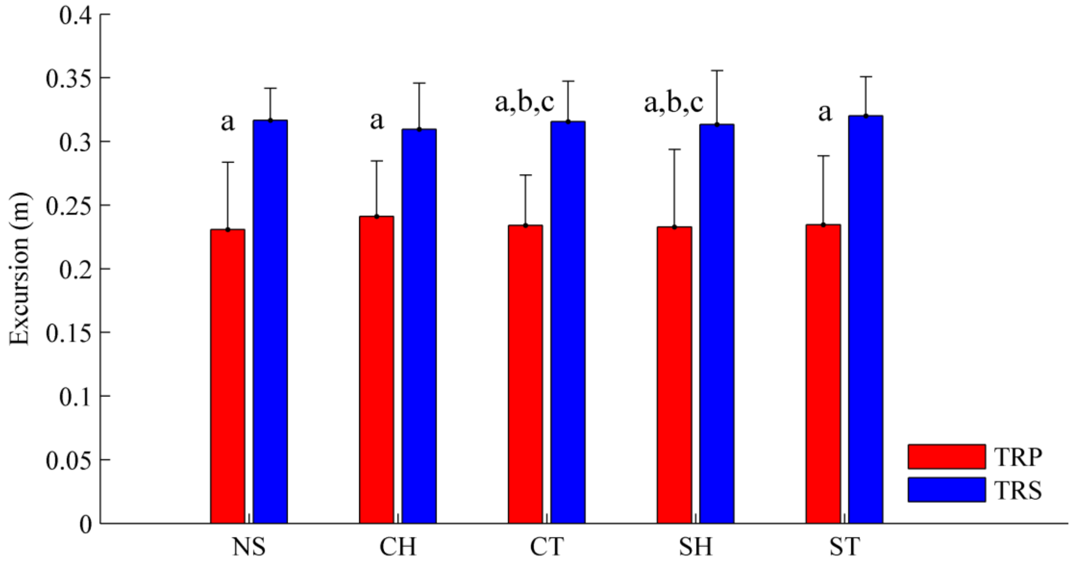

Figure 4-5: Termination COM A/P excursion results. [a]limb effect ($p < 0.05$), [b]foot stiffness effect ($p < 0.05$), [c]post-hoc ($p < 0.0083$). Error bars represent one standard deviation.

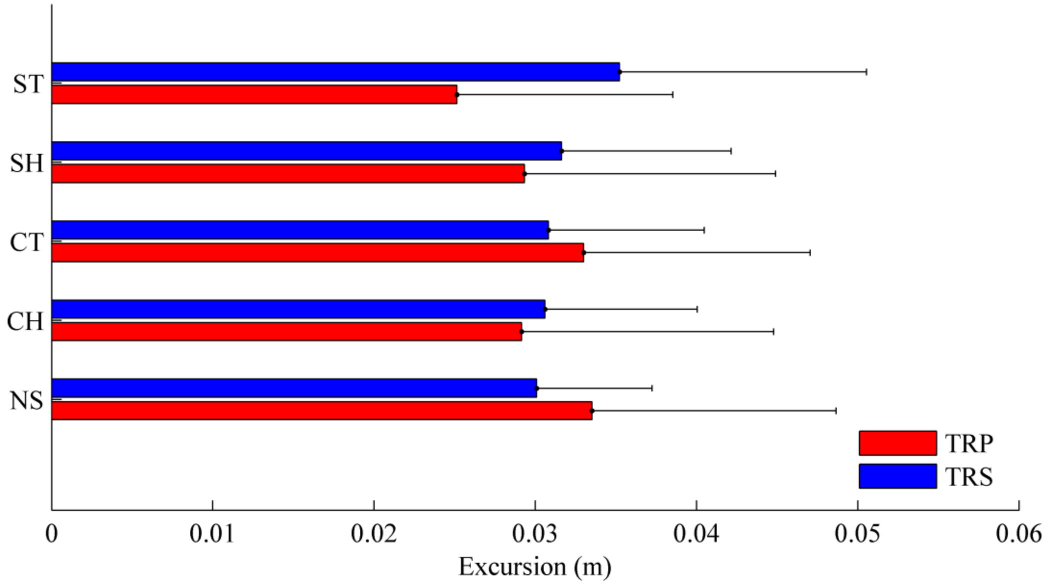

Figure 4-6: Termination COM M/L excursion results.

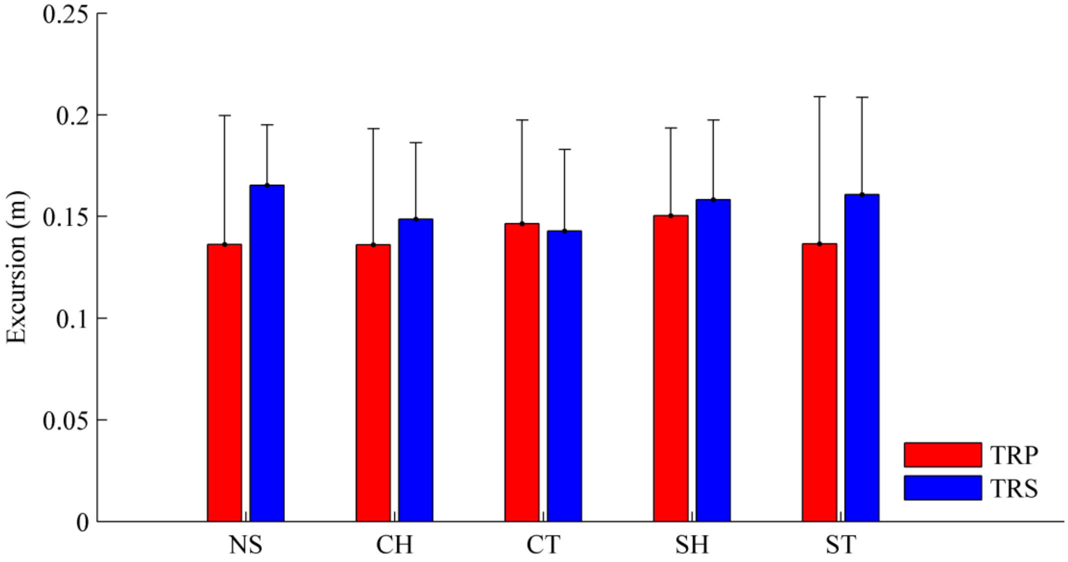

Figure 4-7: Termination COP A/P excursion results.

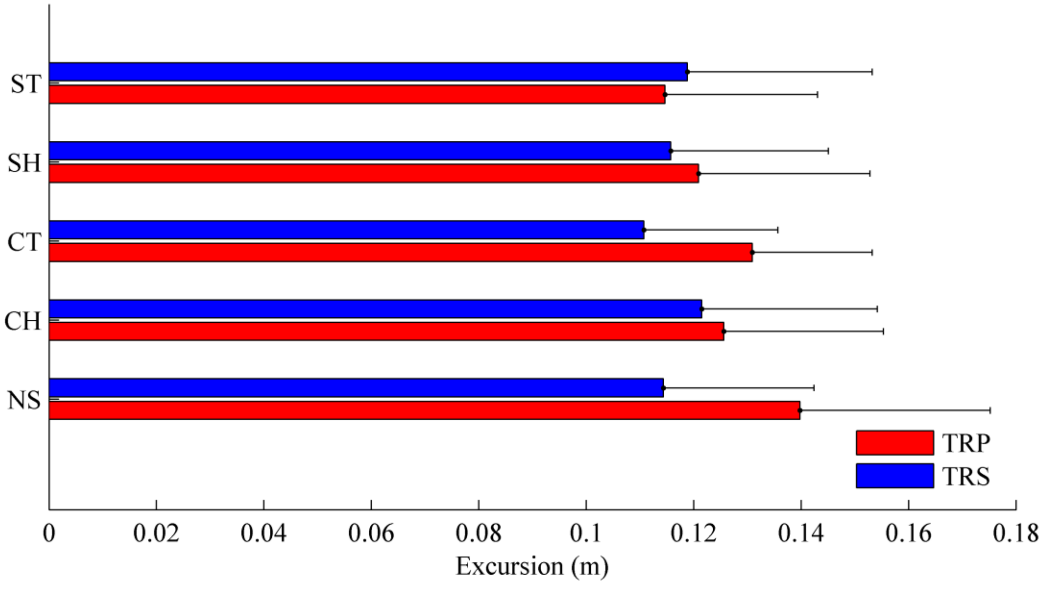

Figure 4-8: Termination COP M/L excursion results.

Table 4-3: Limb and foot stiffness effects (*p*-value) and sample mean (SD) for COM and COP excursions (m) during gait termination.

	TR COM A/P	**TR COM M/L**	**TR COP A/P**	**TR COP M/L**
NS P	0.231 (0.053)	0.034 (0.015)	0.136 (0.063)	0.140 (0.035)
NS S	0.317 (0.025)	0.030 (0.007)	0.165 (0.030)	0.114 (0.028)
CH P	0.241 (0.044)	0.029 (0.016)	0.136 (0.057)	0.126 (0.030)
CH S	0.310 (0.036)	0.031 (0.009)	0.149 (0.038)	0.122 (0.033)
CT P	0.234^c (0.039)	0.033 (0.014)	0.146 (0.051)	0.131 (0.022)
CT S	0.316^c (0.032)	0.031 (0.010)	0.143 (0.040)	0.111 (0.025)
SH P	0.233^c (0.061)	0.029 (0.016)	0.150 (0.043)	0.121 (0.032)
SH S	0.313^c (0.042)	0.032 (0.011)	0.158 (0.039)	0.116 (0.029)
ST P	0.235 (0.054)	0.025 (0.013)	0.137 (0.072)	0.115 (0.028)
ST S	0.320 (0.031)	0.035 (0.015)	0.161 (0.048)	0.119 (0.034)
Limb Effect	$p < 0.001^a$	$p = 0.818$	$p = 0.337$	$p = 0.492$
Foot Stiffness Effect	$p = 0.007^b$	$p = 0.959$	$p = 0.630$	$p = 0.709$

[a]limb effect ($p < 0.05$), [b]foot stiffness effect ($p < 0.05$), [c]post-hoc ($p < 0.0083$)

4.2 SUMMARY OF STATISTICAL ANALYSIS

Initiation COM excursion in the A/P direction was determined to be significantly greater in the INS condition compared to the INP condition. Initiation COM excursion in the M/L direction did not show significant difference between leading limb conditions. Termination COM excursion in the A/P direction was also significantly greater in the TRS condition compared to the TRP condition. Post-hoc analysis displayed significant differences between CH and CT feet in IN COM A/P as well as between CT and SH feet in the TR COM A/P excursion.

4.3 SUBJECT QUESTIONNAIRE RESULTS

Table 4-4: Subject ratings of the capabilities of the prosthetic feet, rated on a scale of 1-10 (1 being poor and 10 being excellent). Values shown: mean (SD).

	PRES	**NS**	**ST**	**SH**	**CT**	**CH**
Comfort	8.3 (0.5)	5.3 (1.1)	5.8 (2.5)	5.2 (2.6)	7.8 (1.6)	6.7 (2.9)
Stability	8.5 (1.4)	5.0 (2.8)	6.8 (2.5)	4.8 (2.6)	7.8 (1.8)	6.3 (3.0)
Ability to stand	8.7 (1.5)	7.5 (2.1)	8.0 (1.8)	7.8 (2.0)	8.4 (1.5)	7.7 (2.6)
Ability to accelerate	8.7 (1.2)	5.5 (0.8)	6.5 (1.6)	5.0 (1.8)	7.2 (1.9)	6.2 (3.4)
Ability to stop	8.2 (1.8)	6.3 (2.6)	7.0 (1.7)	5.8 (2.3)	7.4 (2.1)	7.2 (1.9)

Chapter 5. DISCUSSION

To determine ideal stiffness characteristics of prosthetic feet for transtibial amputees to meet the amputees' individual abilities and goals, it is first necessary to analyze the relationship between prosthetic foot component stiffness and locomotion and stability measures of gait initiation and termination of transtibial amputees. Previous studies have examined the effects of lower limb stiffness in regards to their ability to reproduce "normal" lower limb mechanics during gait (van Jaarsveld et al. 1990; Miller and Childress 1997; Quesada et al. 2000; Blaya and Herr 2004; Hansen et al. 2004a), while others have focused on gait stability and performance measures for lower limb amputees (Jian et al. 1993; Vrieling et al. 2008a, 2008b). However none have combined these efforts to examine the effects of prosthetic foot stiffness on gait stability and performance metrics.

The primary hypothesis of this study was that the COM and COP excursions would be greater in both the A/P and M/L directions while initiating and terminating gait with the sound limb versus initiating and terminating gait with the prosthetic limb. The secondary hypothesis of this study was that within the groups of INP, INS, TRP and TRP, the COM and COP excursions of compliant, nominal and stiff heel or toe components would be different from each other. The first hypothesis was only partially supported, wherein certain conditions (IN COM A/P & M/L, IN COP A/P & M/L, and TR COM A/P) showed this pattern, whereas others did not (TR COM M/L, TR COP A/P & M/L). The secondary hypothesis was not supported by the results of this study, which leads us to believe that the role of prosthetic foot stiffness is only one part of the individuals' complex and diverse strategies of gait initiation and termination.

As part of the collection protocol the NS foot was tested first for all subjects. During initial analysis, an apparent order effect was observed in regards to the NS foot and the novelty of the new foot design. To remove these order effects, the NS foot condition has been disregarded in the analysis and the following material will only discuss findings related to the remaining four foot conditions.

5.1 GAIT INITIATION

The COP patterns during gait initiation with the prosthetic limb generally agreed with those previously reported in the literature, similar to Figure 3-6 (Mann et al. 1979; Breniere et al. 1981; Jian et al. 1993; Elble et al. 1994; Rossi et al. 1995; Halliday et al. 1998; Vrieling et al. 2008a). The COP followed the classic pattern of a posterolateral shift towards the leading limb as a counter movement to begin the gait process, then a more posterior and lateral shift (opposite direction) to the trailing foot, and finally an anterior progression through the trail foot as the lead foot swings and the trailing limb provides propulsive force through toe-off. However, the COP path during gait initiation leading with the sound limb displayed a different pattern. In this case, the COP begins similarly with a posterolateral shift towards the lead limb. At this point in the INS COP progression, the path differentiates from the INP condition. The COP path instead takes an anterior and lateral shift (opposite direction) to the trail foot, where it progresses almost immediately to a point near the toe. This suggests that the prosthetic limb is considered unstable and the user would rather quickly get off the prosthetic limb. Similar patterns have also been reported in the literature (Tokuno et al. 2003; Vrieling et al. 2008a). COM paths for both INP and INS conditions follow similar progressions, with an initial path directed anterolaterally towards the trail limb and then anterolaterally towards the lead limb as it comes into contact with the ground. These findings suggest that although the strategy is different, the end result of initiating the gait cycle is similar in either case.

5.1.1 *Initiation COM*

The values observed for INP COM A/P and INS COM A/P are similar to those reported for normal subjects by Jian and colleagues (~0.32 m), while INP COM M/L and INS COM M/L values are larger than those previously noted (~0.038) (Jian et al. 1993). These comparisons are made with respect to only one subject's data described by Jian and associates (Jian et al. 1993). Other studies have also measured similar values, however due to differences in collection and experimental protocol, direct comparisons could not be made with the present study's findings (Halliday et al. 1998; Tokuno et al. 2003).

Within groups of initiating gait with the prosthetic or sound limbs, it is seen that the INS condition allows a significantly larger COM excursion value (p = 0.029) in the A/P direction than the INP condition (regardless of foot stiffness), supporting the primary hypothesis. The same was not observed for the M/L direction. The COM A/P progression exhibited greater movement when pushing off with the prosthetic limb. With a larger posterior COP A/P shift, it would be expected that the COM would have more propulsive force in the A/P direction, given its larger COP-COM mismatch (Jian et al. 1993). This pattern was not observed in the present study. A more posterior (more negative) IN COPy2 (COP excursions beneath trailing/propulsive limb) value should lead to a larger IN COM A/P excursion. In the present study, the INP COPy2 values were all negative (see Appendix C), whereas the INS COPy2 values were positive. This should correlate to larger INP COM excursion values larger than INS COM excursion values; however this was not the case. It is possible that this could be a compensation strategy where the COM is in a progressive state of imbalance and the body is falling further forward due to the imbalance felt (Winter 1995b; Pai and Patton 1997). The INP condition had less COM excursion anteriorly, where the COM is located further back over the sound limb and is not accelerated anteriorly as much due to the overall stability and control of the sound limb.

Post-hoc analysis revealed a significant difference between the CH and CT feet ($p = 0.003$) in the COM A/P excursion (see Figure 4-1). It is interesting to note that no other significant differences were found between foot stiffness conditions, most likely due to large variation in the other conditions. This finding, however interesting, does not show a relationship within changes of stiffness in the heel or the toe. Having a CH or a CT gives an effectively stiff toe or stiff heel (in relation to the opposite component), and it would be assumed the same effect should also be seen in the SH and ST conditions. That is unless the foot itself is much stiffer than normal, wherein any normal reactions may be overshadowed by the extreme overall stiffness. Many subjects complained of extreme stiffness, or board-like action of the experimental prosthetic in the stiffer conditions. A previous study reported that many of the effects of foot stiffness are lessened by the use of footwear (van Jaarsveld et al. 1990). It is possible that the range of stiffnesses used in the present study were too high for subtle differences to be teased out by the current protocol.

5.1.2 *Initiation COP*

Although on average, the INS condition tended to have a greater initiation COP A/P and M/L excursion than the INP condition, the differences were determined to be insignificant and therefore do not support the primary hypothesis. The COP A/P excursion in the INP condition was similar to previously reported values, however excursions for the INS conditions were much greater than that reported by Jian and colleagues for able bodied subjects (~0.152 m) (Jian et al. 1993). Further, the COP M/L excursion for INP and INS conditions were greater than the same measure reported by Jian et al (~0.104 m) (Jian et al. 1993). When compared to those suffering from Parkinson's disease, the present study's INS and INP COP A/P measures were similar to those reported by Hass and company (~0.175 m), as were the COP M/L measures (~0.134 m) (Hass et al. 2008). It must be noted that the comparable excursion values of Hass and colleagues were recorded through toe-off of the trailing limb (Hass et al. 2008), whereas the excursion value in the current study were recorded through heel strike of the leading limb. This tends to inflate the values of COP A/P excursion, while the effect on COP M/L excursion is most likely unaffected. In any case, the values found in the current study are overall greater than the previous literature with both able bodied subjects (Jian et al. 1993), and subjects with balance issues similar to the amputees in the current study (Hass et al. 2008).

There were no significant differences of the excursion values between foot stiffness levels in the current study. Therefore the secondary hypothesis was not supported. It is possible that the subjects in this study used an alternate strategy where the two legs were perceived as one functional unit (van Keeken et al. 2008). This seems likely when looking at the similar values within both the IN COP A/P and the IN COP M/L conditions across feet stiffness levels, given the relatively large standard deviation values. In this strategy, it is proposed that the sound leg provides the majority of propulsive action, while compensating when necessary. Reliance on the sound limb agrees with previously reported findings (Tokuno et al. 2003; van Keeken et al. 2008). Due to the novelty of the experimental prosthetic foot used in the current study, it is possible that the subjects were uncomfortable using the foot, which made stiffness level relatively unimportant in the overall functionality of the prosthetic foot. In this way, subjects could have placed even more importance on the sound limb to provide the action necessary to initiate gait. Future protocols may choose to have the subject initiate gait with each foot on a separate force plate to study the separate effects of the two limbs. Shoes were not worn on the prosthetic limb, and the difference of walking on a non-cushioned foot (whether cosmesis or shoe, or both) could have also played a role in the reliance on the sound limb and lack of differences in foot stiffness conditions (van Jaarsveld et al. 1990)

5.2 GAIT TERMINATION

In general, subjects completed gait termination while leading with the sound limb with similar COP patterns as exhibited in previous studies (Figure 3-6) (Jian et al. 1993; Vrieling et al. 2008b). The COP traveled anterolaterally towards the lead limb, and then made a posterolateral movement towards the trail limb as it came into contact with the force plate, and finally a posterolateral movement occurred back towards the lead limb to settle into the final stopped position. As in the initiation case, a different COP pattern occurred for the termination prosthetic condition as compared to the termination sound condition. Instead of a posterolateral movement towards the trailing sound limb, there was generally an anterolateral COP shift towards the trailing sound limb. This was followed by a similar posterolateral movement back towards the leading prosthetic limb to settle into the final stopped position. Similar patterns have been reported before (Vrieling et al. 2008b). The difference in termination patterns while leading with the prosthetic or sound limb suggests differences in the importance of each limb and the stability felt while terminating gait in either case. Similar COM paths occurred for both TRP and TRS conditions. The COM traveled anterolaterally towards the lead limb, then anterolaterally towards the trail limb with a slight overshoot laterally, and then settled back towards the lead limb into the final resting position. Although the strategies differ in COP path trajectory during TRP and TRS, the resulting stoppage of motion of the COM is similar.

5.2.1 *Termination COM*

The values recorded of TRP COM A/P for all feet conditions were smaller than the values previously reported, however the values for TRS COM A/P for all feet conditions were similar to previous results for able bodied subjects (~0.30 m) (Jian et al. 1993). In the M/L direction, all feet regardless of lead foot condition showed smaller COM excursion than those previously reported (~0.058 m) (Jian et al. 1993). Similar measures were made by Oates and colleagues, but the difference in data collection procedures does not allow for direct comparisons (Oates et al. 2005).

Between groups of TRP COM A/P and TRS COM A/P conditions, it was observed that the TRP COM A/P had a significantly smaller excursion ($p < 0.001$), in support of the primary hypothesis. No difference was found between TRP or TRS COM M/L conditions. Overall, TRS COM M/L measures were greater than TRP COM M/L measures, but average values of the CH foot displayed greater COM M/L excursion in the TRP condition than the TRS condition (see Figure 4-6). The similarity between TRS COM A/P values and able bodied subjects agrees with what is expected, in that the ankle musculature and anatomy is present to contribute greatly to decelerating the COM (Bishop et al. 2002, 2004). The smaller excursion for TRP COM A/P values presents an interesting case. It is possible that the subjects adjusted their cadence to shorten the last step length when leading with the prosthetic limb to provide for easier stopping COM motion in the direction of progression. While leading with the sound limb, it is likely that the subjects felt comfortable in their ability to stop anterior motion and therefore did not need to make any adjustments in step length to terminate gait. In the M/L direction, it is possible that adjustment strategies used in TRP and TRS, coupled with the small excursion values and relatively large standard deviations reduced the ability to detect differences between leading limb condition using this measure.

A significant difference between CT and SH feet was found in the TR COM A/P excursion measure ($p < 0.001$). This finding may be artificially high however, as the two-factor analysis used in this study effectively doubled the sample size, adding numerical strength to the probability calculations. Combining this effect with the paired t-test post-hoc analysis that assumes the sample has the same natural variance between tests produces a statistically significant result that may not necessarily coincide with practical significance.

5.2.2 *Termination COP*

The TRP COP A/P and TRS COP A/P excursion values with all feet showed values comparable to those reported previously for able bodied subjects (~0.144 m) (Jian et al. 1993). However, TRP COP M/L and TRS COP M/L measures in the current study were found to have similar and smaller excursions than previous findings (~0.154 m), respectively (Jian et al. 1993). With the exception of the CT foot, the TRP A/P condition was observed to have a smaller excursion than the TRS A/P condition within each foot tested. In the M/L measures, the ST foot exhibited greater COP excursion in the TRS condition while the other feet allowed greater COP M/L excursion in the TRP condition. These findings do not support the primary hypothesis. Finally, there were no significant differences found between foot stiffness levels, thereby providing no support for the secondary hypothesis.

One possible explanation for large variation in the TR COP A/P excursion metric could be that final foot placement was not controlled. A cursory review of toe marker positions revealed a large range of differences between sound and prosthetic foot placement during the termination process, which could have led to skewing of the COP position in the A/P direction. A more controlled foot placement position or an experimental protocol that takes foot placement into account may lead to more consistent results. As mentioned previously, the differences in M/L COP shift may be due to the geometry of the novel prosthetic foot used and potentially subject uneasiness in its M/L stability.

5.3 PROSTHETIC FOOT RANKINGS

As a general view on subject rankings, subjects ranked their prescribed limbs highest across all capabilities. There were some cases where the nominal prosthetic foot compared favorably (e.g. ability to stand), but this was more the exception than the rule. Individually, subjects had varying opinions of the foot stiffness levels for different capabilities, signifying a preference towards using different foot conditions for different foot capabilities. Although obtaining subject feedback was not the primary purpose of the study, this analysis supports some of the results discussed previously, and has informed the research team of the preferences of the prosthetic users. In the future, these findings could help shape new iterations of this study in terms of the stiffness ranges of prosthetic feet tested, overall design, and usability of the novel multi-component foot.

5.4 SUMMARY

There were significant differences between the leading limb conditions in the COM excursions in some of the cases of gait initiation and termination (IN COM A/P, TR COM A/P). Additionally, significant differences between foot stiffnesses were observed in the A/P and M/L excursions of the COM during gait initiation, as well as the COM A/P measure during gait termination. It appears that A/P excursion of the COM is the most important variable to control for while initiating and terminating gait. The lack of definitive differences between leading limb conditions in the COP excursions suggests that control of the COP is achievable in numerous ways. Subjects appeared to use multiple strategies to control motion of the COM in both gait initiation and termination, as can be seen in the large variations of the COP excursions. In gait initiation, posterior shifts in the COP provide propulsive force to move the COM anteriorly. Less importance was placed on the prosthetic limb to contribute to this effect as was displayed by the separated IN COPy1 and IN COPy2 measures. During gait termination an opposite effect was expected, but not displayed due to alternate strategies such as changes in step length and foot placement. Overall, COP and COM excursions are a functional measure of gait stability and locomotion ability which are performance characteristics that should be accounted for in the design of prosthetic feet.

5.5 LIMITATIONS

Transtibial amputees are an extremely diverse population in terms of their physical characteristics, surgery type, time since amputation, activity level and type of prosthetic foot typically used. This study did not control for any of these variables. All of these measures may play a role in the ability of the subject to ambulate on a novel prosthetic foot. The sample pool in this study captures a wide diversity of possible subjects, yet may only represent a smaller subset of the larger transtibial amputee population.

Another limitation lies in the novel prosthetic foot used and the footwear of the subjects during testing. The type of footwear worn on the sound limb was not controlled for in this study and could have played a role in the excursion values reported (van Jaarsveld et al. 1990). The prosthetic foot tested in this study was not designed as a commercial foot to be worn, but rather an experimental device to determine influence of foot component stiffness. Although functional, the foot was not specifically designed for M/L stability, which may have led to M/L excursions not typically seen while using commercial prosthetic feet.

5.6 FUTURE EFFORTS AND APPLICATIONS

Future efforts would ideally control for some, if not all of the limitations discussed previously. Increasing the sample size and diversity may better allow subtle details to be ascertained. An improved design of the multi-component prosthetic foot may also facilitate better understanding of the mediolateral effects of gait stability and locomotion measures. Also, since our excursion measures were defined as finite values taken between scalar endpoints, some of the essence of the COM and COP paths was lost. In the future, an analysis that captured the movement of these paths could increase the knowledge gained from these experiments.

Examples of this analysis could include vector plots of the motion or acceleration plots of the path movement as it progresses through time.

These results can be applied toward future commercial prosthetic feet to customize and tailor prosthetic feet to the users’ individual needs and goals. The same metrics may be re-tested before and after exposure to novel prosthetic feet to determine adaptations of the prosthetic users’ performance with a more individualized system.

Chapter 6. CONCLUSION

The purpose of this study was to determine the effects of varying component stiffness of the prosthetic foot. To study this effect, two hypotheses were considered. The primary hypothesis was that the leading sound condition would display greater excursions than the leading prosthetic condition for both mediolateral and anteroposterior excursions of the center of mass and center of pressure. The secondary hypothesis was to assess differences in compliant and stiff heel components in each excursion measure. Subjects completed gait initiation and termination trials while force plates recorded ground reaction forces and motion capture was used to measure body kinematics. Center of mass and center of pressure measures were derived from the data gathered. Specific gait events from the analysis provided consistent intervals to measure center of mass and center of pressure excursions in the two gait activities studied.

Six male transtibial amputee subjects completed this protocol. Center of mass and center of pressure patterns were consistent with those reported in previous studies. Center of mass excursion in the anteroposterior direction of both gait initiation and termination displayed significantly greater excursions in the leading sound condition versus the leading prosthetic condition. A strong trend towards this same effect was seen in the mediolateral direction of center of mass gait initiation excursion as well. No significant differences were observed in any of the other excursion measures. There were also no cases in which stiffness played a role within heel or toe components. However, differences between compliant heel and compliant toe conditions were observed in gait initiation center of mass anteroposterior excursion and between compliant toe and stiff heel conditions during gait termination center of mass anteroposterior excursion.

Gait initiation is only possible when the center of mass and center of pressure separate to create a propulsive force forward. A greater anteroposterior center of mass excursion while leading with the prosthetic limb may seem intuitive given the natural anatomy of the sound limb to produce force; however this was not the case. This may be due to a compensation strategy during the initiation prosthetic condition, where weight is held on the sound limb and not directed as far anteriorly during the first step. In the initiation sound condition it is also possible that the subjects felt more imbalanced pushing off the prosthetic limb and directing the center of mass further due to this imbalance, as was seen with further separated center of pressure analysis. This reliance on the sound limb agrees with strategies reported in previous studies. In gait termination, it is vital to stop motion in the path of progression. Anteroposterior center of mass excursions were significantly larger in the leading sound condition across all feet. The similarities between terminating with the sound limb as compared to able bodied subjects in previous literature makes sense with respect to the natural musculature and skeletal architecture available to provide stopping ability in both cases. An individual strategy used by some subjects to terminate gait was altered foot placement to produce stopping ability. This was not controlled for and variations in the anteroposterior center of pressure excursions (especially in the termination prosthetic condition) may have contributed to the lack of significant differences seen in this study.

Further investigation beyond the current study should include controlling for time since amputation, activity level, and footwear, providing a multicomponent prosthetic foot better suited for mediolateral balance, and increasing the sample size. The results of this study could be used by future prosthesis designers to create prosthetic feet with more complete stiffness profiles, allowing performance tailored to specific activities and lifestyles. This study has demonstrated that there are multiple ways in which prosthetic feet are used to control the motion of the center of pressure and center of mass during gait initiation and termination. Prosthetic foot stiffness levels have been shown to have varied effects and should be accounted for in the design and prescription of prosthetic feet in the future.

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APPENDIX A: SUBJECT CONSENT AND PRIVACY FORMS

Department of Veterans Affairs

VA PUGET SOUND HEALTH CARE SYSTEM (663)
RESEARCH CONSENT FORM

SUBJECT NAME		**SSN:**
TITLE OF STUDY	**Optimizing Stiffness in a Multi-Component Prosthetic Foot**	
PRINCIPAL INVESTIGATOR	**Michael E. Hahn, PhD**	

LAY TITLE: Optimizing Stiffness in a Multi-Component Prosthetic Foot

Researchers:

Michael Hahn, PhD	Research Health Scientist, Rehabilitation R & D	(206) 277-6310
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Natalie Doerr, PhD	Program Coordinator, Rehabilitation R & D	(206) 764-2593

24-hour emergency contact: Please call 911 or page Jan Pecoraro at (206) 416-4143. To page Jan, dial the pager number, enter the telephone number including the area code at which you wish to be called back, and press the # key.

You are being invited to participate in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide whether you want to be in the study. You are free to discuss this with friends or family. This process is called "informed consent." We will give you a copy of this form once it is signed for your records.

1. **Purpose of research study and how long it will last:** You are being asked to participate in a research study because we wish to understand whether lower limb amputees walk and stand better on prosthetic limbs that are rigid or on prosthetic limbs that are flexible. We would also like to know whether your activity levels influence your preference for rigid or flexible limbs.

IRB APPROVED
JUN 23 2011
VA Puget Sound
Health Care System

The information we gather will be used to help us design devices and experiments that will help amputees walk farther with less effort. This study is sponsored by the Department of Veterans Affairs. We will recruit 40 subjects (25 lower limb amputee subjects and 15 able-bodied subjects) from the Veterans Affairs Puget Sound Health Care System (VAPSHCS) in Seattle to participate in this study.

2. **Description of the study including procedures to be used:** All procedures will be performed at the Motion Analysis Laboratory at the VAPSHCS. You will need to visit the lab two times for this study. Each visit will last 2 to 2.5 hours. The times of these lab visits are flexible depending on your schedule, but we will try to complete the experiment within one month of enrolling in the study.

All procedures in this study are research related and provide no clinical treatment. The procedures in which you are asked to participate are marked below with an "X."

☐ **Baseline Data.** On your first visit to the lab, we will record your age, weight, and height. If you have a lower limb amputation, we will ask why and when your limb was amputated, what type of prosthesis you have, and how many hours per day you wear your prosthesis. We will also record the length of your residual limb.

☐ **Health and Activity Questionnaires.** On your first visit to the lab, we will ask you to complete two questionnaires. The first is a survey that will help us assess your overall health. The survey asks whether you have had certain conditions, such as diabetes or a heart attack. The survey also asks whether you have, or used to have, certain diseases, such as hepatitis. The second questionnaire asks about your activity levels. It describes 14 activities which you will need to rate how comfortable you feel performing those activities (such as when you walk up a flight of stairs). You have the right to refuse to answer any question in the questionnaires.

☐ **Step Monitoring Device.** We will ask you to wear a small plastic device around your ankle that will record the number of steps you take each day. You will need to wear the step device for 7 days whenever you are awake. We will give you the step device on your first visit to the lab, and we will ask you to return it on your second visit. You can also mail the device back to us in the envelope provided. Please do not get the step device wet. You must take it off before bathing or showering.

☐ **Prosthesis Simulator.** You will wear a boot that is supposed to mimic what it is like to have a prosthetic limb. The boot will hold your ankle in place, so you will not be able to move your ankle while wearing the boot. The boot will have a prosthetic foot attached to the bottom, which will allow you to experience what it is like to walk on a prosthetic limb. We will flip a coin to determine on which foot you should wear the boot. Because the boot and attached prosthetic foot will increase your height by several inches, you will also wear another boot on the opposite foot. This boot is similar to a platform shoe, and it will be the same height as the boot and prosthetic foot combination you will be wearing on your other foot. While wearing the boots, you will participate in the walking experiments described below.

☐ **Walking Experiments.** These experiments examine how well you walk on prosthetic feet that are rigid compared to prosthetic feet that are flexible. You will be testing a total of six prosthetic feet. If you are an amputee, we will examine how well you walk on your own prosthetic foot compared to five new prosthetic feet. If you are not an amputee, you will wear the prosthesis simulator described above, and we will examine how well you walk on five new prosthetic feet compared to a commonly prescribed prosthetic foot. The order in which you wear the feet will be randomly determined, much like drawing a number from a hat.

Our prosthetist will check the fit and suspension of each of the feet. Once a satisfactory fit is achieved, you will be given time to walk around the lab in order to get comfortable with each foot. If you are not able to feel confident and stable on one or more of the feet, we will stop the session. We will also give you time to rest before wearing a new foot.

You will complete one set of walking experiments on your first visit to the lab and one set on your second visit. The order in which you perform the sets will be randomly determined.

Walking Experiments (Set 1)

While wearing one of the feet, we will ask you to stand on top of two metal plates that are embedded in the floor of the lab. You will need to stand quietly in place for 1 minute with one foot on each plate while staring straight ahead at a target on the wall. The metal plates will measure characteristics of your standing ability, such as whether you tend to stand with more of your weight on one foot than the other. You will need to do this three times for each prosthetic foot.

While wearing one of the feet, we will ask you to stand in place for 5 seconds. Then we will ask you to walk at your normal walking speed for several steps before stopping. You will need to walk over metal plates that are embedded in the floor of the lab. The plates will collect data about how you walk, such as the length of your steps. You will need to do this ten times for each prosthetic foot. You will need to begin walking by taking the first step with your right foot for a total of five times. Then we will have you begin walking by taking the first step with your left foot for a total of five times.

While wearing one of the feet, we will ask you to walk in a straight line for several steps. Then we will ask you to come to a complete stop with your feet on top of a metal plate embedded in the floor of the lab. Once you have stopped on the plate, we will ask you to stand there for about 5 seconds. You will need to do this ten times for each prosthetic foot. You will need to stop walking by taking the final step with your right foot for a total of five times. Then we will have you stop walking by taking your final step with your left foot for a total of five times.

Walking Experiments (Set 2)

We will ask you to walk straight to the end of a 90-foot hallway at your normal walking speed. You will need to do this three times or so while we time how long it takes for you to walk this distance. If you are an amputee, you will need to do this while wearing your prescribed prosthesis. If you are not an amputee, you will need to do this while wearing the commonly prescribed prosthesis.

You will then complete a series of walking trials in our lab. If you are an amputee, we will ask you to walk on a treadmill for about 10 minutes while wearing your prescribed prosthetic foot. If you are not an amputee, we will ask you to walk on the treadmill for about 10 minutes while wearing the commonly prescribed prosthetic foot. You will then be asked to walk for up to 15 minutes at six different speeds (all within a comfortable range) while wearing one of the five prosthetic feet. You will need to repeat this 15-minute treadmill walk for each of the five feet. We will give you 10 minutes to rest between each walking session. You can also stop and rest at any time if you get tired. The treadmill is built flush with the floor of our lab, so you do not have to step up to get onto the treadmill. You will also be asked to wear a safety harness attached to the ceiling in the event of a loss of balance.

To record your movements during both sets of walking experiments, we will ask you to change into a tight-fitting shirt and shorts that we provide. Then we will take a standard set of body measurements, such as the length of your foot and leg. Next, we will attach small reflective markers to your body using double-sided tape. These markers work together with an infrared camera system to record your movements while you walk. We may also take photographs or standard video recordings of you while you walk. The photos and recordings will be a visual record to help us analyze and interpret the data.

At the end of each study day, we will ask you to fill out a short questionnaire asking you to rate the comfort level of each of the feet during the day's activities. The questionnaire will also ask which foot you thought was best for different types of activities, such as steady walking and standing in place. We will ask whether you have any other comments about the comfort and functionality of the test feet. You have the right to refuse to answer any question in the questionnaire.

3. Description of any procedures that may result in discomfort or inconvenience: If you are an amputee, you may feel some discomfort on your residual limb while wearing the new prostheses. It may feel different walking on these limbs than your current prescription.

If you are not an amputee, you may find it tiring to wear the prosthesis simulator because it is taller and slightly heavier than normal walking shoes. It may feel different walking on the prosthesis simulator than your normal walking shoes.

The experimental procedures that take place in our laboratory may be an inconvenience to you because we will ask you to travel to and from our location to participate in these experiments.

The double-sided tape and straps used to secure markers to your body may cause discomfort to your skin while worn and when they are removed.

You may feel emotional discomfort from wearing the provided tight-fitting clothing. Visitors or other observers are not allowed in the lab unless you agree that they can be there, and you can change your mind at any time.

You may find it inconvenient to wear the step device for 7 days and to take it off every time you bathe or shower.

4. **Potential risks of the study:** These procedures increase your risk of falling or becoming injured as the result of a fall. We will make every effort to monitor your gait to reduce these risks, including the use of a safety harness during the walking experiments on the treadmill. You should notify the investigators immediately if you feel uncomfortable during any portion of the protocol. There is a risk that you may feel emotional and/or physical stress during this study. Adapting to the study prostheses and having to visit the VAPSHCS for data collection may cause stress.

If we use any photographs or recordings during a scientific presentation or publication, we will obscure your identity. You may view the photographs and recordings and delete any that you wish. Although we will make every effort to keep your information secret, no system for protecting information can be completely safe. It is still possible that someone could find out you were in this study and find out information about you. Section 7 describes how we will protect your privacy to the best of our ability.

The particular treatments or procedures in this study may involve risks that are currently unforeseeable. We will contact you as soon as possible if new findings occur during this research that may pose a risk to you.

5. **Potential benefits of study:** There will be no direct benefit to you by participating in the study. However, people who have undergone a lower limb amputation may benefit as a result of the work we are doing to develop new prosthetic limbs.

6. **Other treatment available:** This is not a treatment study. Your alternative to participating in this study is to not participate.

7. **Use of research results / Confidentiality:** The information obtained about you will be held confidential. However, for purposes of this study, the following list of people or groups may know that you are in this study. They will have access to your records, which may include your medical records:

- Research team members
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with the VA to conduct research)

- Federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), and the VA Office of the Inspector General (OIG), Government Accountability Office (GAO)
- The VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies
- The VAPSHCS Fiscal Department will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study

The purpose of this access is to review the study and make sure that it meets all legal, compliance, and administrative requirements. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy.

Your identity will be strictly confidential. Only the investigators will have access to the information that we collect from you. The data will be stored on computers in locked offices or in the lab.

To make sure no one other than study personnel can match you to your test results, we will use a secret code instead of identifying information such as your name or social security number. The key to the code will be stored in a locked cabinet in a locked office. If data are to be transmitted to our offsite collaborators, Drs. Art Kuo and Peter Adamczyk (University of Michigan, Ann Arbor, Michigan), the data will not include any information that could be used to identify you except for the secret code known only to study team members at the VAPSHCS in Seattle.

Once this study is completed, we will not use your data (or the code linking it to you) for any additional research. Your data and code will be held in a secure database until VA receives authorization to destroy them in accordance with federal records regulations. It may be several years before the data and code are actually destroyed, but they will not be used for research after this study is completed.

Study data that does not have identifying information may be accessed by any member of our research team for analysis, interpretation, and publication purposes. This data without identifiers will be kept indefinitely to be used for comparison in future research studies.

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to appropriate authorities.

There may be publications about this study in the future. If so, your identity will be held confidential. No personal information will be given in a publication without your approval in writing.

Your study information will be used only for research purposes and will not be sold. Information gained from this research may be used commercially for the development of new ways to diagnose or treat diseases. However, neither you nor your family will gain financially from discoveries made using the information and/or specimens that you provide.\

8. **Special circumstances:** The VA requires some Veterans to pay co-payments for medical care and services. You will still have to pay these co-payments as long as they are not related to this research study.

You will be paid $20 an hour for each visit to the VAPSHCS. You may receive payment in cash or by check. Checks will be mailed about 6-8 weeks after your last visit. In order for these payments to be processed, you will be asked to give your full name, social security number, telephone number, and address. This information will only be used to process these payments. The VAPSHCS reports to the Internal Revenue Service (IRS) as income all payments for study participation. You may receive a 1099 form from the IRS at the end of the year that indicates how much we have paid you.

If you are a VA patient, you already have a VA medical record. If you are not a VA patient, we will create a VA medical record for you. We will put information about you from this study into your medical record. All authorized users of the national VA medical records system can have access to your medical record. This may include health insurance companies who are being billed for medical costs. This record will be kept forever.

9. **Withdrawal from the study:** You do not have to take part in this study. If you are in this study, you can withdraw at any time. You will not be penalized for your decision to not participate or withdraw nor will you lose your VA or other benefits if you decide to do so.

Your doctor has the right to terminate your participation in this study if he or she feels that it is not in your best interest. This termination will not require your consent.

If you decide to withdraw, or if you are terminated from the study, the study physician will then need to meet with you to discuss the necessary steps that you may need to take to end your participation in the study.

10. **Questions or concerns related to the study:** The study researchers (listed below) *must* be contacted immediately if:

- You think you may have harmed or injured yourself as a direct result of this research; and/or
- You have any questions regarding your medical care issues.

During business hours: **(8:00 a.m. — 4:30 p.m.)**	Call Dr. Michael Hahn at (206) 277-6310
After business hours: **(nights and weekends)**	Call Janice Pecoraro, R.N., at her pager number (206) 416-4143

You may contact the Institutional Review Board (IRB) – VA Office at (206) 277-1715 if you:

- Would like to speak with a neutral party who is not involved with this study;
- Have questions, concerns, or complaints about the research;
- Would like to verify the validity of the study; or
- Have questions about your rights as a research subject.

An IRB is an independent body made up of medical, scientific, and non-scientific members, whose job it is to ensure the protection of the rights, safety, and well-being of human subjects involved in research.

11. Research-related injury: Medical treatment will be provided, if necessary, by the VA if you are injured by being in this study. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

You do not waive any legal rights by signing this consent form.

12. Research subject's rights: I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts, possible benefits of the study, and other choices of treatment available to me. My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

I agree to participate in this research study as you have explained it in this document.

____________________________ ____________
Subject Signature **Date**

____
Print Name of Subject

____________________________ ____________
Signature of Person Obtaining Consent **Date**

____
Print Name of Person Obtaining Consent

Department of Veterans Affairs

DEPARTMENT OF VETERANS AFFAIRS

CONSENT FOR USE OF PICTURE AND/OR VOICE

CONSENT OF *(Name)*

NOTE: The information requested on this form is solicited under the authority of title 38, United States Code. The execution of this form does not authorize disclosure of the materials specified below except for the purpose(s) stated. The specified material may be used within the VA for authorized purposes, such as for education of VA personnel or for VA research activities. It may also be disclosed out the VA as permitted by law. If the material is part of a VA system of records, it may be disclosed outside the VA as stated in the 'Routine Uses' in the "VA Privacy Act Systems of Records" published in the Federal Register. A copy of the 'Routine Uses' is available upon request to the administration office of the VA facility involved.

You do not have to consent to have your picture or voice taken, recorded, or used. Your refusal to grant your consent will have no effect on any VA Benefits to which you may be entitled.

I hereby voluntarily and without compensation authorize pictures and/or voice recording(s) to be made of me (*or of the above-name Individual, if the individual is legally unable to give consent*) by (*specify the name of the VA facility, newspaper, magazine, television, etc.)*
Puget Sound Health Care System, Seattle Division

While I am (*describe the activity, if any to be photographed or recorded*)
Standing and walking

I authorize disclosure of the picture and/or voice recording to (*specify name and address of the organization, agency, or individual(s) to Whom the release is to be made*)

Name of agency: Puget Sound Health Care System, Seattle Division

Address of Agency: 1660 S. Columbian Way, Seattle Wa 98108

I understand that the said picture(s) and/or voice recording(s) is intended for the following purposes(s)
Education and written publications

I have read and understand the foregoing and I consent to the use of my picture and/or voice as specified for the above-described purpose(s). I further understand that no royalty, fee or other compensation of any character shall become payable to me by the United States Government.

Signature of individual or other legally authorized person
Date of Signature

Interview and Permission obtained by:
Name: Janice A. Pecoraro
Title: Research Coordinator
Address: 1660 S. Columbian Way, Seattle Wa 98108

Signature of Interviewer
Date of Signature

Production Title	Production Number	IMPORTANT: This form must always be completed prior to making or using pictures and/or voice recording(s) of any individual. If that individual has any history of drug abuse, alcoholism or sickle cell anemia or infection with human immunodeficiency virus, an additional VA Form 10-5345 is required to release any data to any source.

IMPRINT PATIENT PLATE OR WRITE IN INDIVIDUAL'S NAME & ADDRESS

VA FORM 10-3203 (663 Automated 09/04)

DEPARTMENT OF VETERANS AFFAIRS

Puget Sound Health Care System
1660 South Columbian Way, Seattle, WA 98108-1597

Authorization for the Release of Protected Health Information for Research Purposes

Study Title	**Optimizing Stiffness in a Multi-Component Prosthetic Foot**
Principal Investigator (PI)	**Michael E. Hahn**

Purpose *(Instructions for the PI- describe the study in a few meaningful sentences)*

You have been asked to be part of the above research study under the direction of the Principal Investigator and the research team. The purpose of this study is to:

Many lower limb amputees have difficulty walking and doing the things they like to do. We are trying to determine whether lower limb amputees walk and stand better on prosthetic limbs that are rigid or prosthetic limbs that are flexible. We would also like to know whether the activity levels of amputees influence their preference for rigid or flexible limbs.

Use and Disclosure *(Instructions for the PI- Check all that apply)*

This authorization is necessary to be in this research. However your VHA treatment, payment, enrollment, or eligibility for benefits does not depend on your signing this form. By signing this form, you give permission to the Veterans Health Administration (VHA) to disclose the following information about you to the research study team identified above:

Subject Initials	Check if relevant	Description
	☐	Drug Abuse or Use
	☐	Alcoholism or Alcohol Use
	☐	Testing for or Infection with the Human Immunodeficiency Virus (HIV)
	☐	Sickle Cell Anemia
	☒	Past and Present Medical Information
	☐	Laboratory Reports
	☐	Imaging Reports
	☐	Diagnostic Reports
	☒	All Personal Identifiable Information (PII) contained in the VHA Computerized Patient Record System (CPRS)
	☒	Other medical records maintained by the VA Puget Sound Health Care System including information created and collected during this study

RECEIVED
IRB Office
JUL 06 2010
VA Puget Sound
Health Care System

The research team may also need to disclose your information to others as part of the study process. This may include:

Subject Initials	Check if relevant	Description
	☒	Study Sponsor: **Department of Veterans Affairs R&D**
	☒	The Institutional Review Board (IRB) that reviews the study
	☐	The Food and Drug Administration
	☒	Compliance and Safety Monitors *(Specify):* **Eileen Gormly (Information Security Officer) and Sweden De Matas (Privacy Officer)**
	☒	**Puget Sound VA Fiscal Department will be provided with your full name, address, phone number, and Social Security Number in order to authorize payment for your participation in the study.**
	☐	
	☐	

☒ Yes ☐ No	Are monitors/sponsors authorized to receive your Individually Identifiable Information (III) such as name, social security number or date of birth?

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations, and with all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. The VHA Notice of Privacy Practices includes information on how we protect you. We can give you a copy, and you can also find it on the Internet at this link: http://vaww.vhaco.va.gov/privacy/Notice.htm.

Expiration *(Instructions for the PI: Check only one box)*

☐	This authorization to use your information will expire at the end of the research study.
☐	This authorization has no expiration date. This is because the information will become part of a database or repository.
☒	This authorization will expire on **October 1, 2020.**

The following statement is applicable ☐ not applicable ☒ to this research study: While this study is being conducted, you will not be allowed to see research-related medical records that are created or obtained by the research team. You will be able to see them again when the study is completed. This will not affect your doctor's ability to see your records as part of your normal health care.

Authorization Revocation

If you sign this form, you can change your mind later and take back this authorization, by sending a written request to **Janice Pecoraro, Seattle VAMC MS 151, 1660 South Columbian Way, Seattle WA 98108.** The research team is allowed to keep and use any information collected before the date you sign your letter that stop this authorization. If you do change your mind, you may not be able to continue to participate in this study. Changing your mind about this authorization will not affect your rights as a VHA patient to treatment or benefits outside this study.

Authorization

☐ I have been given the opportunity to ask questions. If I have any questions in the future, I can ask **Janice Pecoraro** at **(206) 764-2962.**

☐ I have read this document, and I authorize the use and disclosure of my information as described.

☐ I understand I will be given a signed copy of this authorization form for my records.

Signature of Subject or Authorized Individual Subject's Printed Name

☐ Copy of legal authorizing document attached if this form is not signed by the subject

Subject's Full Social Security Number Date

The execution of this form does not authorize the release of information other than that specifically described. The information requested on this form is solicited under Title 38, U.S.C. This form authorizes release of information that you specify in accordance with the Health Insurance Portability and Accountability Act, 45 CFR Parts 160 and 164, 5 U.S.C.552a, and 38 U.S.C. 5701 and 7332. Your disclosure of information requested on this form is voluntary. If the information on this form includes your Social Security Number (SSN), the SSN will be used to locate your records for release.

APPENDIX B: PROSTHETIC FOOT COMPONENT DECISION MATRIX

Cat 1		Length	T140	T140	T140	T140	T140
Pylon Mount	6	Taper	6_3	8_6	10_2	10_5	13-4
Length	Taper	Keel position	11	11	11	11	11
H130	9_1	1		CH-1A			
H130	10_2	1	CT-1A	NS-1A	ST-1A/ CH-1B		
H130	10_4	1		SH-1A/ CT-1B	NS-1B	ST-1B/ CH-1C	
H130	10_7	1			SH-1B/ CT-1C	NS-1C	ST-1C
H130	10_10	1				SH-1C	

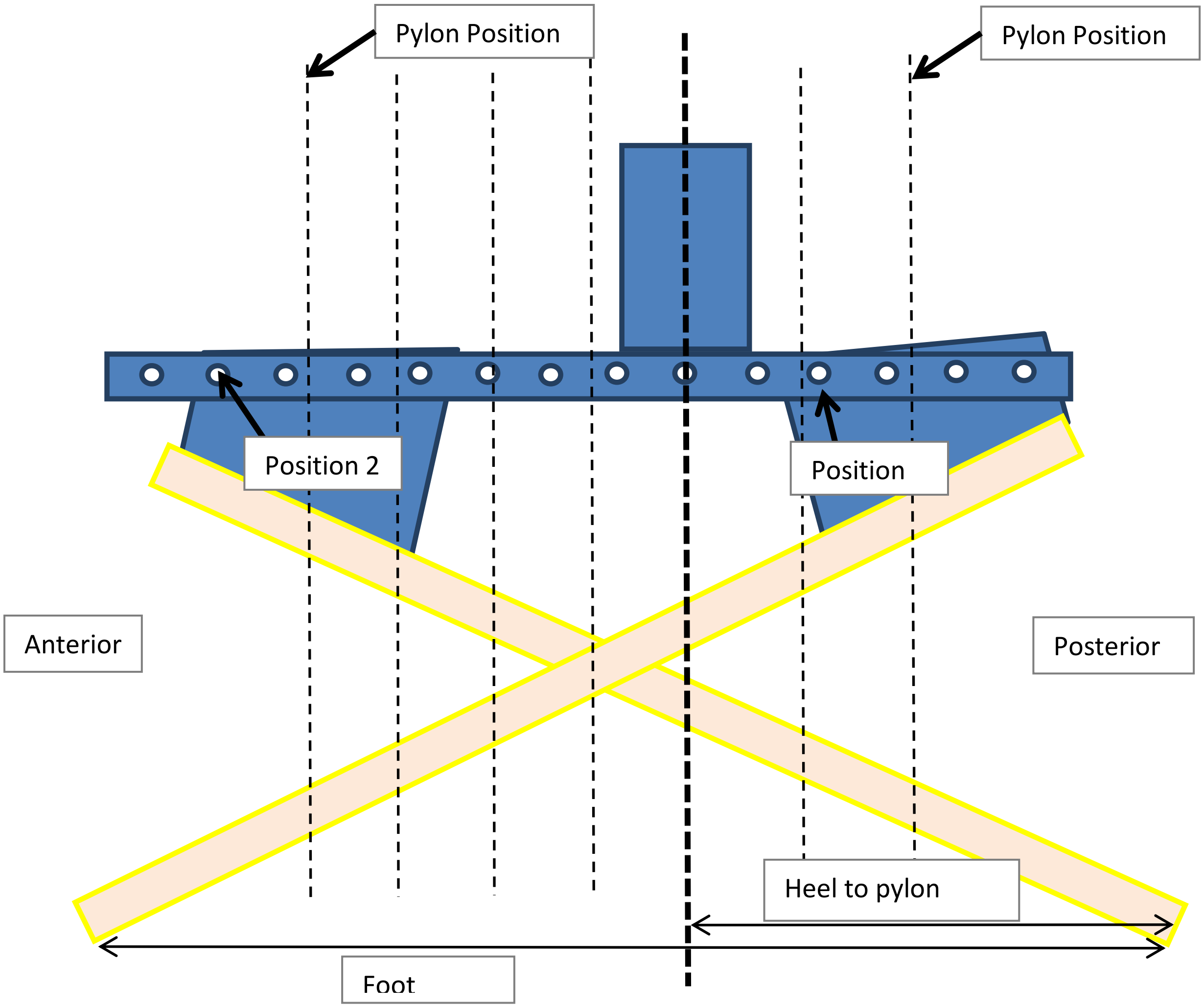
Cat 2		Length	T140	T140	T140	T140	T140
Pylon Mount	6	Taper	6_3	8_6	10_2	10_5	13-4
Length	Taper	Keel position	11	11	11	11	11
H130	9_1	2		CH-2A			
H130	10_2	2	CT-2A	NS-2A	ST-2A/ CH-2B		
H130	10_4	2		SH-2A/ CT-2B	NS-2B	ST-2B/ CH-2C	
H130	10_7	2			SH-2B/ CT-2C	NS-2C	ST-2C
H130	10_10	2				SH-2C	

Cat 3		Length	T175	T175	T175	T175	T175
Pylon Mount	5	Taper	10_5	10_10	13-4	16-2	16-8
Length	Taper	Keel position	11	11	11	11	11
H130	9_1	1		CH-3A			
H130	10_2	1	CT-3A	NS-3A	ST-3A/ CH-3B		
H130	10_4	1		SH-3A/ CT-3B	NS-3B	ST-3B/ CH-3C	
H130	10_7	1			SH-3B/ CT-3C	NS-3C	ST-3C
H130	10_10	1				SH-3C	

Cat 4		Length	T175	T175	T175	T175	T175
Pylon Mount	5	Taper	10_5	10_10	13-4	16-2	16-8
Length	Taper	Keel position	11	11	11	11	11
H130	9_1	2		CH-4A			
H130	10_2	2	CT-4A	NS-4A	ST-4A/ CH-4B		
H130	10_4	2		SH-4A/ CT-4B	NS-4B	ST-4B/ CH-4C	
H130	10_7	2			SH-4B/ CT-4C	NS-4C	ST-4C
H130	10_10	2				SH-4C	

Cat 5		Length	T175	T175	T175	T175	T175
Pylon Mount	5	Taper	10_5	10_10	13-4	16-2	16-8
Length	Taper	Keel position	10	10	10	10	10
H130	9_1	2		CH-5A			
H130	10_2	2	CT-5A	NS-5A	ST-5A/ CH-5B		
H130	10_4	2		SH-5A/ CT-5B	NS-5B	ST-5B/ CH-5C	
H130	10_7	2			SH-5B/ CT-5C	NS-5C	ST-5C
H130	10_10	2				SH-5C	

Cat 6		Length	T175	T175	T175	T175	T175
Pylon Mount	5	Taper	10_5	10_10	13-4	16-2	16-8
Length	Taper	Keel position	9	9	9	9	9
H130	9_1	2		CH-6A			
H130	10_2	2	CT-6A	NS-6A	ST-6A/ CH-6B		
H130	10_4	2		SH-6A/ CT-6B	NS-6B	ST-6B/ CH-6C	
H130	10_7	2			SH-6B/ CT-6C	NS-6C	ST-6C
H130	10_10	2				SH-6C	



Multi-component foot setup. Position of pylon and keels on the pylon mount are illustrated.

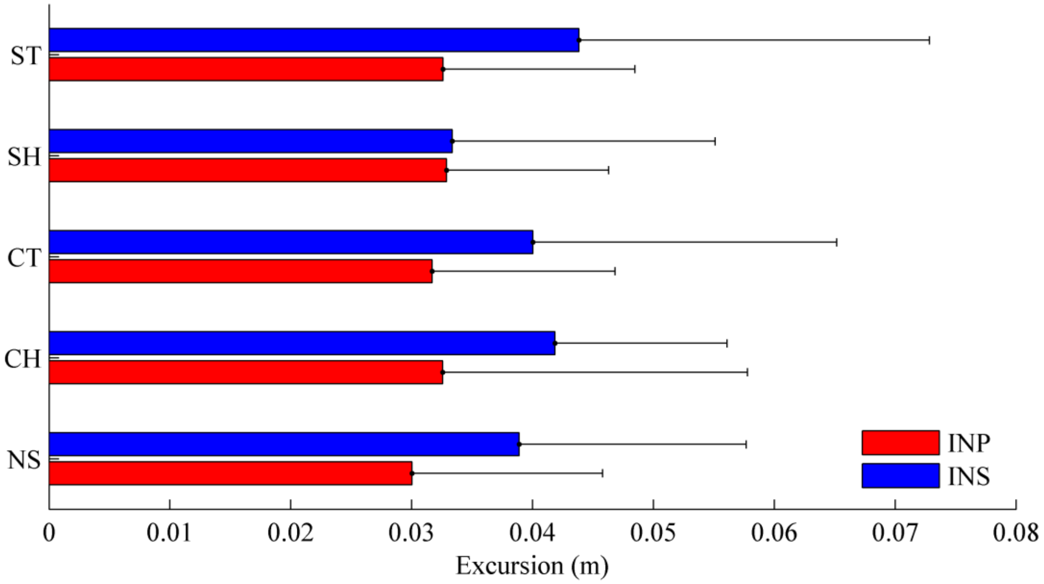
Heel Component Stiffness

Component	Stiffness
H110_6_1	20.6
H110_6_3	35.9
H110_6_6	55.4
H110_8_5	73.6
H110-10-2	76.4
H130_9_1	21.2
H130_10_2	31.1
H130_10_4	49.4
H130_10_7	60.7
H130_10_10	66.4

Toe Component Stiffness

Component	Stiffness
T140_6_3	14.1
T140_8_6	35.9
T140_10_2	51.5
T140_10_5	69.1
T140_13_4	79.3
T175_10_5	27.1
T175_10_10	37.2
T175_13_4	45.8
T175_16_2	62.3
T175_16_8	88.8

APPENDIX C: SEPARATED INITIATION AND TERMINATION COP EXCURSION FIGURES



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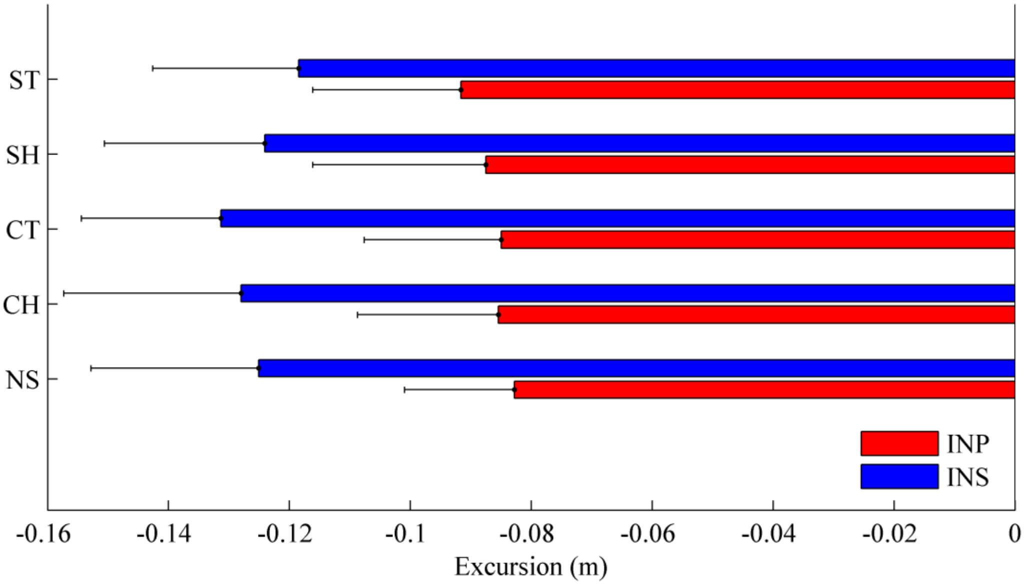

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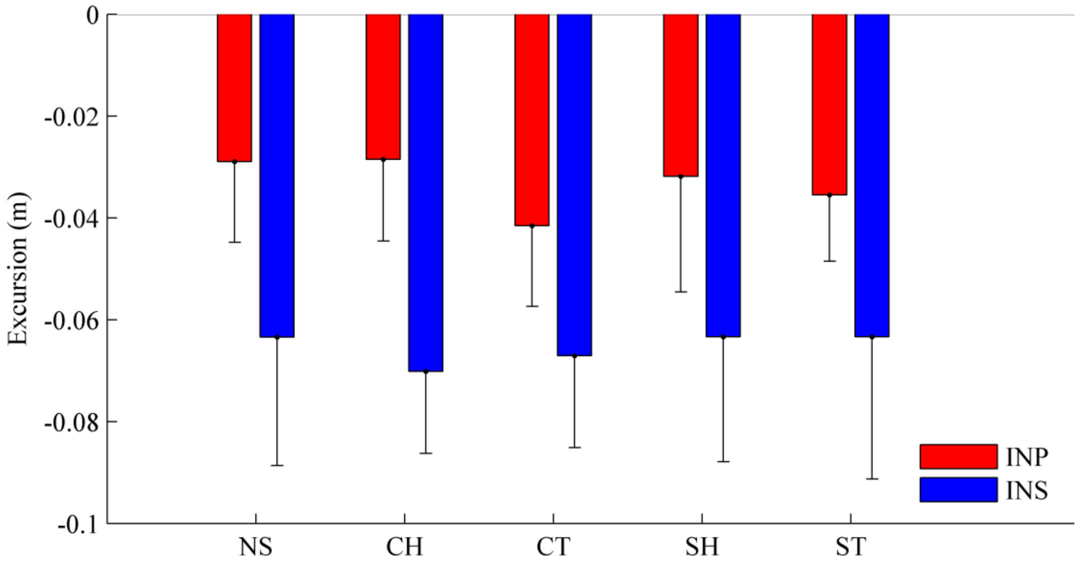

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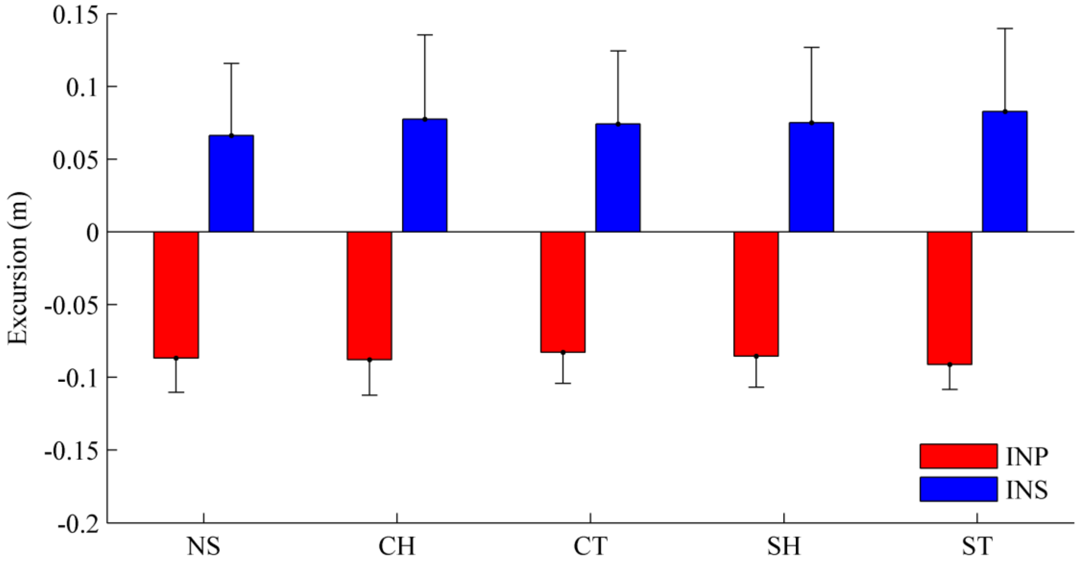

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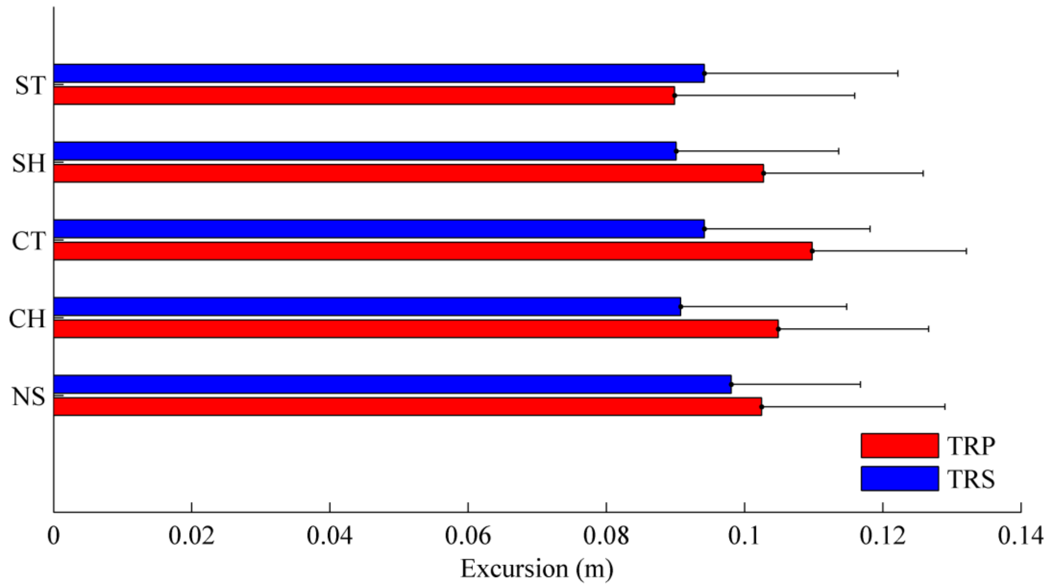

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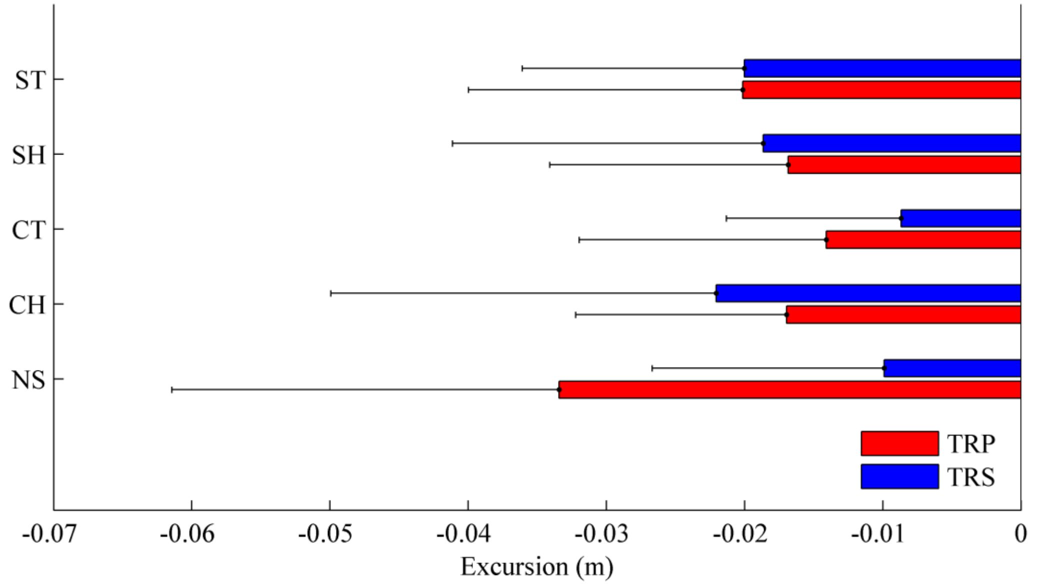

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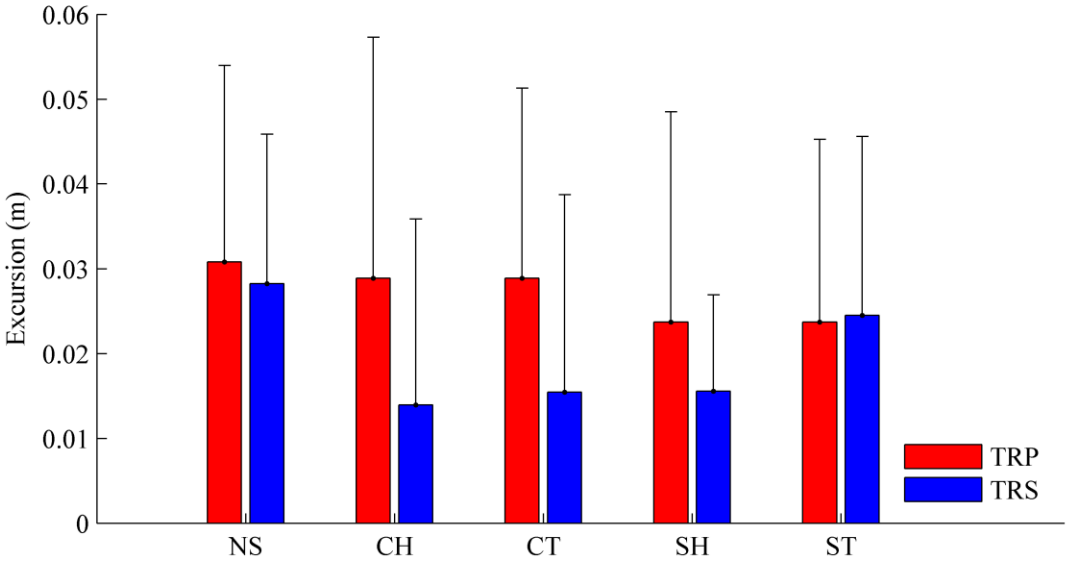

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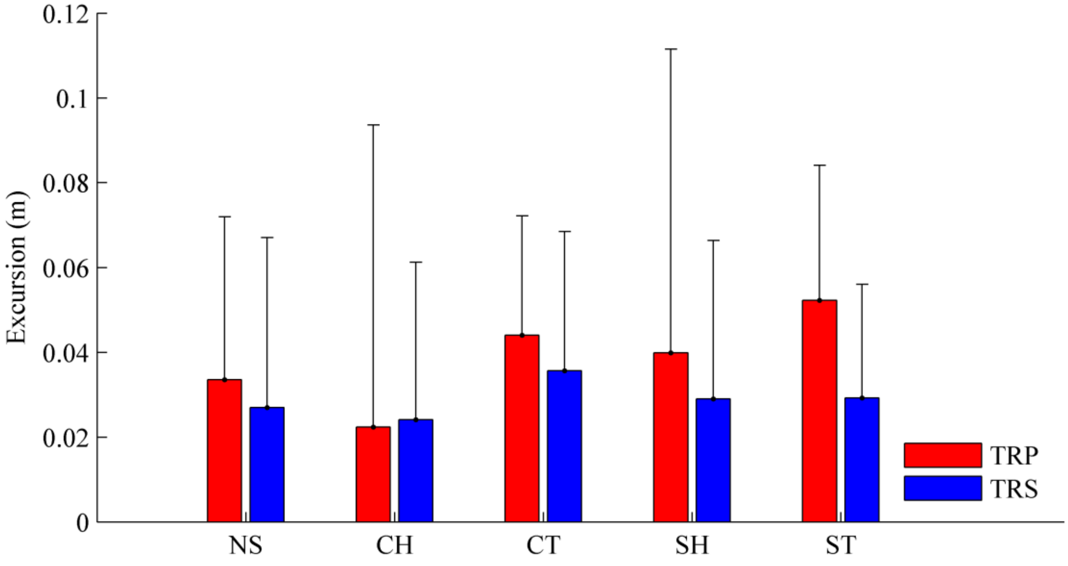

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