HEEL COMPLIANCE AND
WALKING MECHANICS USING
THE NIAGARA FOOT PROSTHESIS

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Abstract

The Niagara Foot (NF) is a relatively new prosthetic design, primarily intended for use in developing countries. It combines low cost and durability with high performance energy return features. The design has been successfully tested mechanically and in field trials, but to date there has been little quantitative gait data describing the performance of the foot. Biomechanical gait analysis techniques will be used to extract quantitative gait measures.

The current study is designed to characterize the effect of heel section stiffness parameter differences between a NF normal heel and a NF with a reduced material heel section., on gait characteristics in persons with unilateral trans-tibial amputations (TTA). Standardized biomechanical gait analysis techniques, adapted for this population, were used to extract quantitative gait measures. Five persons with TTA performed walking tasks while 3D ground reaction forces were recorded via an embedded force platform. A motion capture system also recorded the 3D segmental motion of the lower limbs and torso of each subject. These were combined to calculate net joint moments and mechanical power at the hip and knee of both limbs. These data were compared between a normal NF and a NF with a modified heel. Each participant had a period of two-week adaptation prior to any testing. An EMG system and a prosthesis evaluation questionnaire were used to help analyze the condition. The overall hypothesis of this study was that modification of the heel section stiffness would change several aspects of gait.

Although the gait pattern differences between participants and the low participant number produced no significant differences between the conditions for all variables, trends were observed in multiple outcomes. These results report preliminary evidence that for some participants the heel material reduction does impact their gait by showing a different loading phase during the transition between the heel strike and the full contact with the ground. The NF2 may move the gait toward a more flexed knee position. Furthermore, despite a reduction in the material of the heel section results showed that the overall foot stiffness increased. This may be the result of the one-piece design and mechanics of the NF.

Further investigations with a bigger cohort of people with TTA are required to look at the importance of the impact of the prosthetic foot heel stiffness.

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List of Acronyms

Acronyms	Description
Abd/add	Abduction / Adduction
AL	Anatomical Locations
AKA	Above-knee Amputation
A/P	Antero-posterior
BKA	Below-knee amputation
COG	Centre Of Gravity
DER	Dynamic Energy Return
EMG	Electromyography
ERG	Ergonomics Research Group, Queen's University, Kingston, Canada
F/E	Flexion / Extension
HMRC	Human Mobility Research Centre, Queen's University and Kingston General Hospital, Kingston, Canada
ISO	International Organization for Standardization
ISPO	International Society for Prosthetics and Orthotics
LC	Lateral Epicondyle
LM	Lateral Malleoli
MBL	Musculoskeletal Biomechanics Lab
MC	Medial Epicondyle
M/L	Medio-Lateral
MM	Medial Maleoli
NF	Niagara Foot
NF1	Niagara Foot™, original version 19
NF2	Niagara Foot™, modified heel version 19

NPO	Niagara Prosthetics and Orthotics, St Catharines, Canada
PAC	Physical Activity Complex
PEQ	Prosthesis Evaluation Questionnaire
ROM	Range Of Motion
SACH	Solid Ankle Cushioned Heel
SPSS	Statistical Package for the Social Sciences
SSWV	Self-selected walking velocity
TTA	Transtibial amputation
USD	United States Dollars

Chapter 1

Introduction

1.1 Niagara foot general description

The Niagara Foot (NF) is a relatively new type of prosthetic foot, constructed from injection-molded thermoplastic, and was developed in Canada to fulfil the need for an improved foot prosthesis in developing and post-conflict countries. The availability to more functional prostheses, in location such as El Salvador and Thailand, is often compromise due to prostheses high cost or non-compatibility with the environment. The NF has the benefit of a simple, low cost design while providing some of the enhanced performance characteristics of more expensive dynamic energy return foot (DER) prosthesis. The NF has the ability to store and liberate energy due to its material properties and its design. The NF is design to fit common prosthetic pylons and to accommodate an active population.

1.1.1 Niagara Foot characteristics

The important element of the design is its one-piece S-shaped that acts as a spring to provide energy storage and return during gait (Ziolo, Zdero, & Bryant, 2001). Furthermore, the injection-moulded acetal resin Delrin (DuPont™) material shows good properties as this material exhibits a combination of strength, stiffness, and hardness essential for good stability. This material is fatigue, solvent, fuel and abrasion resistant. Also the material has low wear and low friction properties, which are important for durability in environments of developing countries. Furthermore, because of its ease of manufacturing the NF costs only a fraction of any low-end prosthetic foot. The NF costs $7 US to $10 US, which represents approximately 10% of the cost of a low end prosthesis such as the Solid Ankle Cushioned Heel (SACH). The latest model of the NF is designed with layers at the heel and at the keel. Theses layers can be shaved by a prosthetist to adjust the degree of rigidity needed specifically for each individual.

1.1.2 Biomechanics of the Niagara Foot design

Compared to other single-axis DER feet, the NF has a C-section that creates the ankle articulation and contributes to the propulsion of the limb during the gait. During the loading phase, the C-section rotates posteriorly reducing the space between the top plate and the heel and increasing the space between the horn and the top plate. Alternatively, during mid-stance, the C-section rotates anteriorly gradually reducing the space between the horn and the top plate and increasing the space between the heel and the top plate (Figure 1.1).

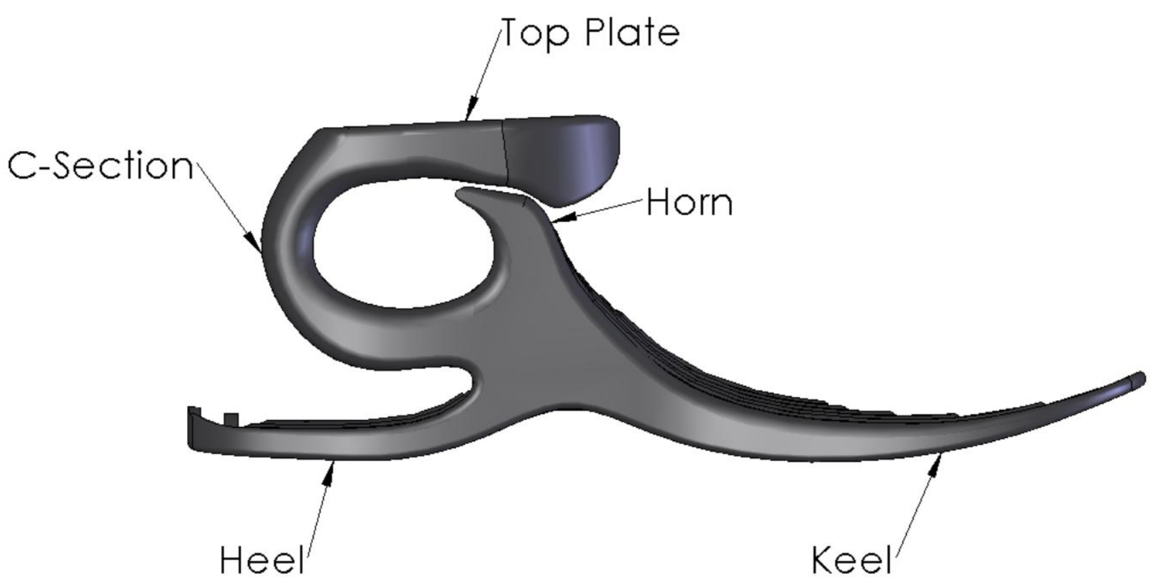


Figure 1.1. Niagara Foot key sections

1.1.3 Previous Niagara Foot Testing

The Niagara prosthetic and orthotics (NPO) team developed a fatigue-testing instrument to assess the NF service life. This fatigue tester was made with respect to the International standards developed by the International Organization for Standardization (ISO) and the International Society for Prosthetics and Orthotics (ISPO) and was able to test different types of prosthetic feet. During the testing the NF was compared to another commercially available foot, the SACH, that is still the most widely used foot in developing countries. The NF showed a better durability than the SACH foot. The foot is held in place during testing and metal plates apply loading to the bottom surface, the testing allows a heel strike and toe off of 15 and 20 degrees, as demanded by the ISO standards. Under a 1 Hz cycling frequency, the latest NF version still performs after more than 2 million cycles with a range of force from 50N to 970N (Gabourie, 2010).

The NF is constantly undergoing multiple field trials in El Salvador and in Thailand where initially all of the participants are using a SACH foot. These trials allowed the designed team to modify the foot to better adapt to the conditions of use as well as address general concerns regarding the overall design. During the field trial the participants were able to give feedback on their satisfaction of the foot; the majority of them were able to detect the performance improvement. The participant feedback consensus was that they felt they needed less muscular effort during walking, which can be related to the energy return characteristic. The field trials indicated no failure of the keel after six months, which was consistent with the fatigue testing results (Bryant & Bryant, 2002).

1.1.4 Future and ongoing work

To date, the NF has been mechanically tested to evaluate its fatigue resistance and has undergone several successful field trials, which have provided qualitative information about the performance of the foot (Potter, 2000; Potter, Costigan, Bryant, & Gabourie, 1999; Ziolo et al., 2001). However, there is a lack of quantitative information regarding the effects of some of the adjustment parameters of the NF on the gait of the wearer.

1.2 Study purpose

The current study was designed to characterize the effect of heel section stiffness modifications on gait patterns in men with unilateral transtibial amputation (TTA). Furthermore, the mechanical deformation and energy return characteristics of the NF were analyzed for the two different heel conditions. The data from this study is important for both designers and prosthetists to better understand the relationship between heel stiffness and gait patterns with the NF.

The term heel stiffness in this document defined the actual stiffness of the heel section only. The heel section is defined as the cantilever piece which extends from the back of the C-section and contacts the ground first in heel-first gait (Figure 1.1). Because the NF is a one-piece design changing the stiffness of the heel section may or may not change the entire mechanical foot stiffness. The heel stiffness of the NF can be adjusted by the prosthetist by manually shaving the layers of material on the heel section. The present study looked specifically at the effect of two heel section stiffness values for the NF. Only the reduction in material at the heel section was examined for this study. The ability to adjust heel stiffness is not a common design feature in prosthetic feet and so far relatively little research has been done in this area. The overall hypothesis of this study is that modification of the heel section stiffness would change several kinematics and kinetics aspects of gait (ie. Spatio-temporal, forces, joint moments, joint powers). It was expected that a compliant heel section would reduce the duration of the loading phase and decrease the range of motion at the hip of the affected limb (Klute, Berge, & Segal, 2004). A compliant heel section would also be expected to reduce the net joint torques at the hip and knee in the affected limb and cause an increase in hip and knee torques magnitudes in the non-affected limb (Underwood, Tokuno, & Eng, 2004). It was expected that a more compliant heel section would show greater deformations resulting in a higher potential of energy storage and return compared to a stiffer heel section.

1.3 Hypotheses details

1.3.1 Loading response phase duration

The loading response phase starts with the heel strike event and ends with the foot flat position. This phase lasts generally from 7% to 10% (Perry, 1992) of the total gait cycle phase. It was thought that a stiffer heel section would show a longer heel-toe loading period. One may explain the longer loading period for a stiffer heel section by the increase in the need of the stabilisation muscles during this period and because the material offer more resistance to the deformation. Klute et al. (2004) have suggested that compliant heel generally shows a larger deformation in the material and a more rapid anterior progression of the centre of pressure. When different prosthetic feet are compared in a ballistic fashion with a pendulum impact apparatus, a foot with a stiffer heel showed two well-defined force peaks, one larger peak during the impact phase and one smaller peak during the deceleration phase (Klute & Berge, 2004). Oppositely, the more compliant foot showed the absence of the impact peak but showed a large deceleration peak. Using a different model, Nigg & Liu (1999) observed the effect of shoe soles on ground reaction forces using a mass-spring-damper system. They obtained the same conclusions that stiffer heels show greater impact peaks than compliant ones. Perry et al. (1997) tested gait using stiffer foot models (Seattle Lite and Flex foot) and indicated a longer heel loading compared to a more compliant foot (Single axis). Increasing the stiffness of the heel might increase the need for additional stabilizing forces in the upper leg producing an increase in the time between the heel contact and the flat foot (Klute et al., 2004). During heel strike to foot flat, people with TTA normally ensure their stability with their knee and hip extensors (Perry et al., 1997). When the heel-only support is longer, an increase in knee extensor muscular group (quadriceps femoris) activity is observed. This is why it is hypothesised that a more compliant heel would decrease the duration of the loading time.

The flat foot marks the position between the heel loading and the mid-stance. The duration of this loading phase will then be measured at the initial foot contact on the ground until the toes contact the ground. To verify the hypothesis, the loading time of the two NF conditions will be compared within each participant.

1.3.2 Range of motion and net joint torques

It is hypothesized that a more compliant heel would increase the range of motion at the hip of the affected limb and would also reduce the net joint moment at the hip and knee in the affected limb (Klute et al., 2004). The unaffected limb would show an increase in the moment magnitude of the hip flexion and the knee extension with a more compliant heel.

The full angular excursion of a joint is known as the range of motion (ROM). Increase in the ROM, especially in the ankle-joint component dorsiflexion, was observed when comparing DER to conventional feet (Hafner, Sanders, Czerniecki, & Fergason, 2002a). The construction of the DER was suggested (Postema et al., 1997) to influence the increase in the ankle-component ROM. Cortes, Viosca, Hoyos, Prat, & Sanchez-Lacuesta, (1997) proposed that one of the most important factors concerning the ROM in prosthetic feet is the fact that there is a lack of a component that acts as an ankle joint. The ROM of the ankle would then depend on the torque generated at the ankle joint. Following Postema et al. (1997), the dorsiflexion mobility influences the balance-control mechanism, which affects the entire limb kinetics. In the present study, the ROM of the limb joints depends on the overall foot mechanical deformation of the NF. For example a more compliant heel on a NF might change the ankle-joint component of the foot in comparison to an unmodified NF. This would then affect the dorsiflexion mobility and subsequently the ROM of the hip and the knee joints.

1.3.3 Energy storage and return & mechanical deformations

In regards to energy use, it is hypothesised that a stiff heel section would show a smaller deformation resulting in a lower potential energy storage and return in comparison to a compliant heel section.

In the human body multiple types of energy can be observed. Metabolic energy is the type of energy extracted by food through a metabolic process. Another main type of energy is the mechanical energy, which is the capacity to do mechanical work. Only the mechanical energy is the focus of this study. Muscles are the primary source of energy generation. In synergy with the bones and tendons they generate and absorb the mechanical energy during movements. During walking two types of mechanical work (i.e. energy generation or loss) are observed: internal work that is applied on a body segment and external work which is applied on a load (Winter, 2005.). In the literature the calculation of mechanical work has been based on different approaches: the energy increase in segments, centre of mass, sum of segment energies, joint power and work, muscle power and work, and isometric work against gravity (Cavagna & Margaria, 1966; Fenn, 1929; Ralston & Lukin, 1969). Since the force applied on the body's segments is not constant, the use of power, defined by the rate of energy change, will be used to define the mechanical energy changes that occur during gait following Winter's assumption (D. A. Winter, 1983). The electromyography (EMG) data collected during the activity will be considered in the analysis and comprehension by using the average muscle activity of the loading phase and the swing phase of the gait cycle. Results from the EMG may explain which individual muscles may be accountable for the joint moment's results.

The present study also looks at the deformation of the heel that may explain the mechanical energy change. It is assumed that the NF is part of the body but does not have the same characteristics found in a human foot. The NF utilizes a specific shape and a material that allows the foot to deform in compression and have a rotation in the A/P direction (Ziolo et al., 2001) and is also considered as a DER foot. Stress occurs in the NF and creates an additional mechanical energy generation and absorption system to the body observed. The energy absorbed during the heel strike of the prosthetic foot depends on the stiffness of the rear part of the foot (Rietman, Postema, & Geertzen, 2002). Generally the energy absorbed during the heel loading is not transmitted to the forefoot which may bring a loss of energy in case of great energy absorption. The specific NF design may allow a different material deformation and change the energy distribution. Hence, the deformation occurring at the heel strike will be measured to help understand what energy change might be taking place.

Chapter 2

Prosthesis overview

2.1 Amputation condition

2.1.1 Cause & implications

Amputation defines a condition in which there is a loss of a limb. In 2005, an estimated 1.6 million people were living with an upper or lower amputation in the United States (Ziegler-Graham, MacKenzie, Ephraim, Travison, & Brookmeyer, 2008). In 2002, Dillingham (Dillingham, Pezzin, & MacKenzie, 2002) reported there were more than one million lower limb amputations between the years 1988 and 1996. Upper and lower limb amputations are classified under four main categories: dysvascular, cancer, trauma, and congenital abnormalities.

2.1.2 Dysvascular amputation

In North America, neuropathy and vascular conditions lead to the majority (81.9%) of amputations (Lusardi & Nielsen, 2007). Dysvascular amputation seems highly linked to diabetes as in 2002, an epidemiological study (Dillingham et al., 2002) reported a 27% correlation increase from 1988-1996 between amputations and diabetes patients. Diagnosed-diabetes affects a low percentage (6%) of the United States population; however, it represented more than 50% of lower limb amputations (Legro, Reiber, Smith, del Aguila, Larsen, & Boone, 1998b).

2.1.3 Traumatic amputations

Traumatic amputation (16.4%) is the second leading cause of amputation (Dillingham et al., 2002). Vehicular or work accidents are often the causes of traumatic amputation, but situations of violence such as gunshot or warfare may also be the reason (Lusardi & Nielsen, 2007). Although this type of amputation touches mainly the young male population, it can affect any gender or age group. Even with technology allowing the re-attachment of the limb in traumatic cases, it is still difficult to achieve good functional limb rehabilitation.

2.1.4 Cancer related amputations

Usually cancer related amputation occurs during childhood or in young adults. This type of cancer (osteosarcoma) affects the epiphyses of long bones, primarily the femur, during rapid growth bouts. Even though the etiology of this rare cancer is unknown (Picci, 2007), it now shows a better cure rate than years ago. Presently limb salvage is preferred over amputation; however, in some cases amputation is the only solution.

2.1.5 Congenital amputations

Rare (0.8%) but present (Dillingham et al., 2002), congenital abnormalities may be the cause for the amputation. This condition typically affects the upper limbs; however, it still can affect the lower limbs. The failure in formation, differentiation, duplication of parts, overgrowth, and compromised blood circulation are principal reasons for congenital amputation (Lusardi & Nielsen, 2007). Situations such as foetal position constriction, endocrine disorders, or chromosomal disorders can cause these congenital abnormalities.

2.2 Amputation procedure

Regardless of the reason for the amputation, surgeons apply two general principles to ensure a successful surgery and rehabilitation. First, they make sure that there is enough circulation to insure a successful healing. Second, they try to keep as much of the anatomical joint as possible. The preservation of the anatomical knee often shows (Munin et al., 2001) enhanced successful outcomes in terms of healing and rehabilitation.

2.2.1 Lower limb amputation

Different levels of amputations are performed on the lower limb. The two major operations are the transfemoral and the transtibial, which is above the knee amputation (AKA) or below the knee (BKA), respectively. The term BKA describes the situation where the knee joint is intact, as opposed to AKA where the prosthetic knee replaces the anatomical joint. TTA is a condition that is included in the BKA amputation category. Generally, surgeons try to preserve the knee joint because the energy cost of walking is considerably higher without the knee joint than with it (Waters, Perry, Antonelli, & Hislop, 1976).

2.3 Prosthetic Components

Four important devices describe the TTA lower limb prosthesis: the socket and its interface, the suspension mechanism, the pylon (shank), and the prosthetic foot (Figure 2.1).

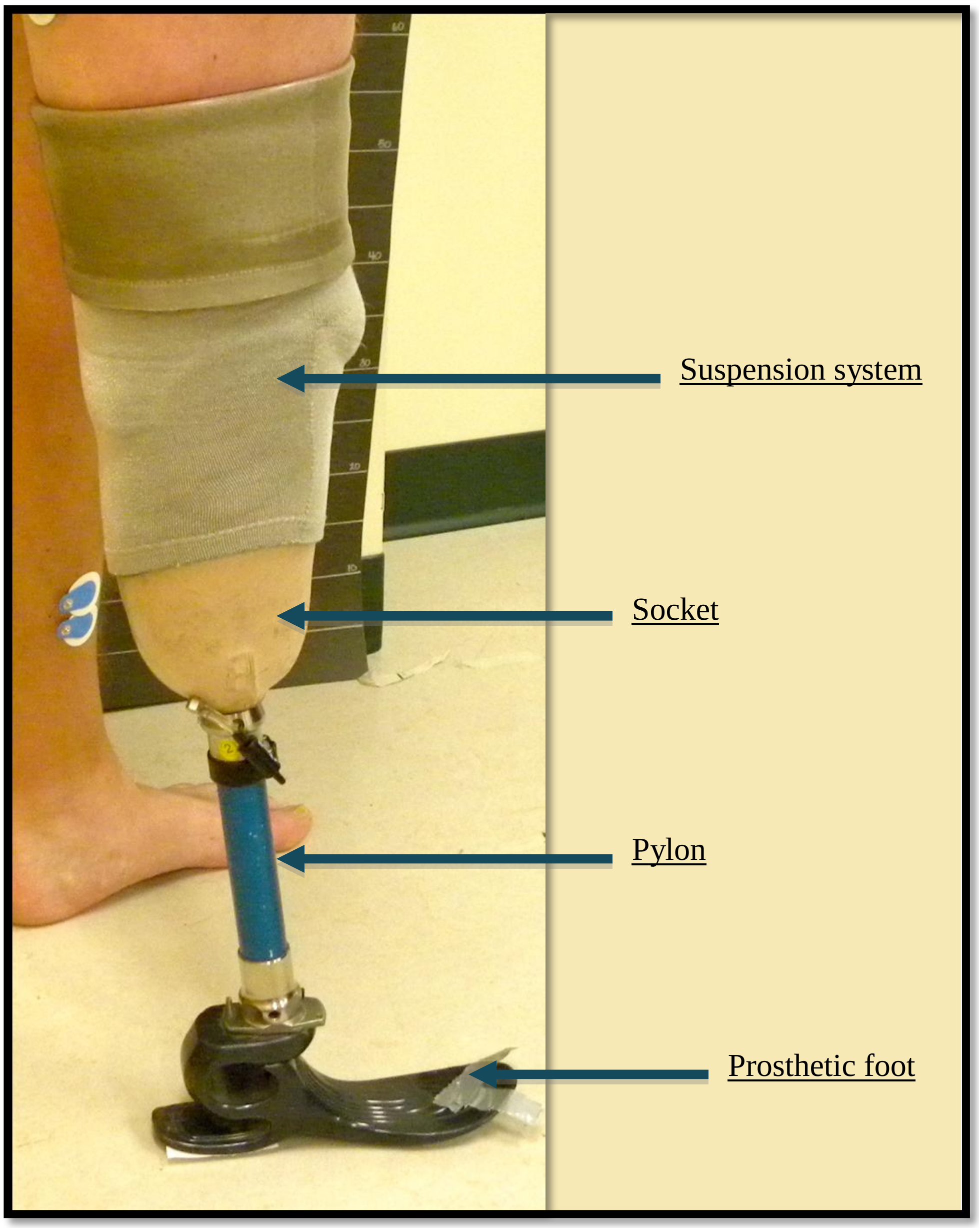


Figure 2.1. Typical prosthetic components with someone with a TTA

The *socket* encompasses the residual limb and is the connection between the user and the prosthesis. It distributes of the pressure from the limb. Therefore, when more area of the limb contacts the socket the comfort is typically increased. The evolution of the socket design introduced the socket liner, which minimizes the local pressure. Currently, many users utilize a 'suction socket' that creates a vacuum and offers the user a close fit between the limb and the socket.

The *suspension system* holds the prosthesis during movement and allows for a comfortable sitting position. In a sitting position, where the knee is at 90 degrees, the suspension system needs to adapt to more tension on the anterior side and less in the posterior side. One of the secondary purposes of the suspension system is to prevent skin irritation (Lusardi & Nielsen, 2007). The suspension system must minimize the piston-like movement between the limb and the socket. The suspension system prescribed will differ with the patient's activity level. The suspension systems can be described by 4 categories: atmospheric pressure, anatomical contour, straps and hinges (Table 2.1) (Amputee Coalition of America & U.S. Army Amputee Patient Care Program [ACA], 2009).

Table 2.1. Example of suspension systems used for people with TTA**.**

<table>
<tr><th colspan="2">Suspension systems</th><th>Description of the concept</th></tr>
<tr><td rowspan="3">Atmospheric pressure</td><td>Knee sleeve</td><td>Tight sleeve that covers the prosthesis and rolls up to the mid thigh. (Neoprene or latex)</td></tr>
<tr><td>Roll-on locking liners</td><td>Roll-on sleeve with a locking pin mechanism in the socket.</td></tr>
<tr><td>Hypobaric seals with suction</td><td>Hypobaric seal incorporated into a sleeve that has an expulsing valve, where the bottom part of the sock creates the vacuum chamber.</td></tr>
<tr><td rowspan="2">Anatomic</td><td>Supracondylar wedge</td><td>Lateral and medial walls capture the two femoral epicondyles and secure the prosthesis on the residual limb.</td></tr>
<tr><td>Supracondylar suprapatellar</td><td>Lateral and medial walls capture the two femoral epicondyles and secure the prosthesis on the residual limb with an anterior wall capturing the patella.</td></tr>
<tr><td rowspan="2">Straps</td><td>Cuff</td><td>X-shape leather links the lateral and medial walls above the patella.</td></tr>
<tr><td>Waist belt</td><td>Anterior elastic strap hooked to a cuff or to the prosthesis and to a waist belt.</td></tr>
<tr><td>Hinges</td><td>Thigh cuff</td><td>Corset style that is around the thigh with a side joint.</td></tr>
</table>

The *pylon* acts as the link between the socket and the foot component. The design of the pylon is fundamentally simple and inexpensive. The pylon is usually built with lightweight material such as aluminium or carbon fibre, but with an adequate stiffness to accept the normal loading. More expensive shock-absorbing pylons are also available to reduce the load during the foot loading phase.

Finally, the *prosthetic foot* fits at the end of the pylon and provide the roles of both the natural foot and ankle during locomotion. The prosthetic foot has two main functions: distributing the force during the loading and transmitting the force during the mid-stance and push off phases. Over the past decade the prosthetic foot has evolved and has became more and more specialized for different tasks such as: walking, swimming, running, dancing, cycling and golfing. (ACA, 2009). The new foot designs show a wide range of features: energy-return property, toe and heel spring, waterproof material, adjustable heel level, shock absorption and multi-axial rotation.

2.3.1 Fitting process

The prosthetist experience has a lot of influence on the fitting process, because many adjustment procedures are not standardized (Isakov, Mizrahi, Susak, Ona, & Hakim, 1994). Therefore, prosthetists use visual evaluations and manual tests to determine the optimal fitting of the prosthesis to the residual limb. Very few technological devices exist to help these technicians in their task (Fang, Jia, & Wang, 2007). One of the main observations done during the fitting is to examine the limb for the presence of erythematous skin after the removal of the prosthesis. The discoloration indicates a location of increased pressure. Modification of the fitting occurs to ensure better distribution of the pressure around the side of the socket. Adding or removing liners (sometimes called socks) within the socket might also help with the adjustment. A 3mm to 6mm space between the residual limb and the bottom of the socket indicates a well-fitted prosthesis.

In addition, a good therapeutic relationship between the patient and the prosthetist is essential to better localize the pain linked to fitting problems. For example, if the patient feels pain at his inferior patella or at his anterior distal tibia the limb might be too deep in the socket. Pain felt in the posterior calf can indicate distal socket tightness. The fitting of the permanent prosthesis takes place when the residual limb has obtained its mature size. Either endoskeletal finish or exoskeletal finish can cover the permanent prosthesis. The exoskeletal finish will cover all the prosthetic components with an outer plastic laminated skin in opposition to the endoskeletal prosthetic finishes which will leave the prosthetic components visible. The endoskeletal finish has the advantage of being adjustable at any time, compared to the exoskeletal that includes all the components in one rubberized skin element.

Because the residual limb will change size in time, the prosthetist does not fit the patient with a permanent prosthesis (Lusardi & Nielsen, 2007) until maturation of the limb. When the residual limb size is stable for an 8- to 12-week period, the fitting of the definitive prosthesis takes place. In this time, the patient follows an individualized schedule to wear the prosthesis in order to prevent any pressure wounds from the new socket. Furthermore, when a new prosthesis is fit, frequent fitting and alignment sessions are necessary to find the best adjustment possible to obtain comfort and functionality for the client.

2.3.2 Prosthetic alignment

The fitting and the alignment of the prosthesis are essential to provide a natural gait pattern and ensure the optimal functional characteristics of each component. The alignment refers to the spatial relationship between the prosthetic components and the residual limb (Lannon, 2004) (Lannon, 2003). The main purpose of the alignment is to position the prosthesis in a manner so it excludes unwanted forces applied on the residual limb. The centre of rotation of the limb-prosthesis system is localized on the socket.

A good posture resulting from a proper alignment could reduce the joint friction and the tension on the soft tissues. Small adjustments in the alignment are often preferred over socket adaptation and/or redesigns to overcome pressure-induced injuries. The latter choice can be time consuming and expensive. The alignment plays an important role in the patient prosthetic comfort (Klute, Kallfelz, & Czerniecki, 2001). To evaluate important configuration aspects of the prosthesis the prosthetist first performs a static alignment. The weight bearing must be equally distributed between the prosthetic limb and the intact limb. The anterior-posterior superior iliac spine and iliac crest must be level (Lusardi & Nielsen, 2007). The foot must be flat and parallel to the floor in the frontal and transverse planes. The knee must not be forced into either a flexion or extension position.

Assuming a successful static evaluation, a dynamic evaluation follows. During the dynamic alignment, the patient walks while the prosthetist observes the impact on the kinematics of the gait (Lusardi & Nielsen, 2007). The amplitude of the force absorbed by the residual limb depends on multiple factors such as: the loading characteristics of the liner and socket material, the quality of the socket fit, health and characteristics of the skin and soft tissue, and the quality of the alignment between the feet and the socket (Winter & Sienko, 1988). Depending on the position of the foot with respect to the socket, the torque around the residual limb will fluctuate. During weight bearing, if the foot is offset from the socket centre the socket will tend to rotate around the limb, increasing the reaction force on the residual limb (Lusardi & Nielsen, 2007). To modify the alignment, the prosthetist adjusts the setscrews located on the lower and upper part of the pylon.

The alignment of the prosthesis depends on the prosthetist experience but it also depends on the patient. The prosthetist tries to bring the patient's gait toward the norms seen in able-bodied individuals. More experienced patients do their own adjustments. They do their adjustment based on the comfort fit; the alignment is then a qualitative variable that provides the patient with the most comfortable adjustment.

2.4 Prosthetic feet

Prosthetic feet are designed differently but all have the same overall goal: to substitute anatomical functions of the human body that were lost due to the amputation. Common sections of prosthetic feet are the heel, the keel and the top plate. The heel describes the rear part of the foot, the keel refers to the forefoot observed in an able-bodied foot and the top plate is the section where the pylon will connect to the foot (Figure 2.2).

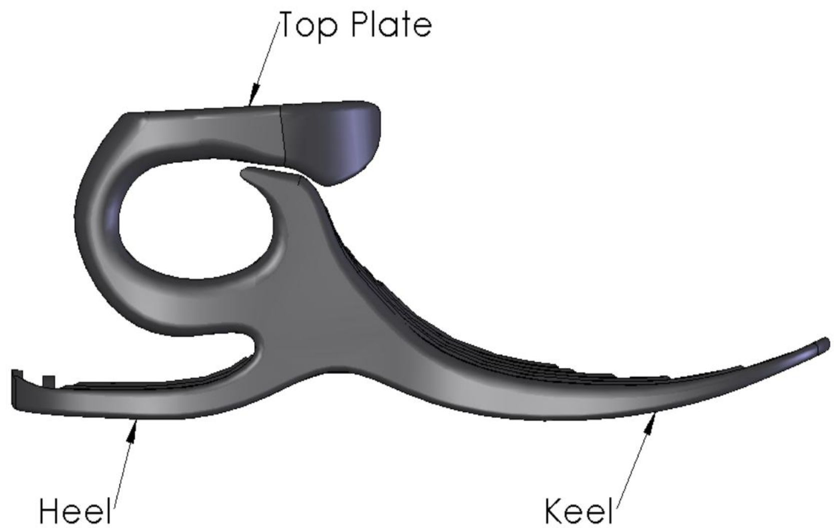


Figure 2.2. Prosthetic feet: common section

2.4.1 Function of the prosthetic foot

The prosthetic foot needs to recreate as much as possible the biomechanics of the human foot and ankle to allow for a smooth contact with the ground. The Able-bodied foot-ankle complex needs to perform multiple functions during the phases of the stride. Essentially, the human foot-ankle absorbs shocks, adapts to uneven terrain, stabilizes the knee, transfers the weight, adjusts the limb length, and offers a stable base (Lusardi & Nielsen, 2007). Even though prosthesis designers aim to mimic the human function, a permanent challenge remains to offer all the properties in the same design.

2.4.2 Prosthetic foot: the functional design

The prosthetic design quality will depend on the response during the gait phases. First, during the initial contact, an intact foot/ankle absorbs the shock of the heel strike reducing the force on the residual limb and contributing to the knee flexion moment preparing for the loading event. Thus, it transfers softly the weight bearing to achieve the foot-flat position of the loading response. In able-bodied gait, the posterior location of the ground reaction force vector with respect to the ankle creates a plantar flexion motion controlled with an eccentric dorsiflexor muscle action controlling the lowering of the foot (Lusardi & Nielsen, 2007; Perry, 1992). However, in the TTA situation, the absence of ankle muscles must be compensated by a foot design that regulates the rate of the plantar flexion of the foot especially during the stance phase after the initial loading; the heel material will contribute to absorption of the load (Klute & Berge, 2004). The dorsiflexion is also closely related to the foot design and material. This criterion is essential to provide a gentle contact with the ground. During the early stance, the ability to mimic an inversion and eversion is desired for the adaptation to uneven surfaces. Once passed the loading point, the ankle muscles are working towards a plantar-flexor moment for the rest of the stance. Second, to achieve a forward progression during the midstance, the gastrocnemius and the soleus must contract eccentrically to control the dorsiflexion moment.

The gastrocnemius and the soleus are important muscles in terms of the limb propulsion since they control the raising of the heel during the second half of the stance. To ensure such stability and function during the stance phase, the prosthetic foot keel is adjusted to an appropriate stiffness varying from rigid to flexible. The stiffness will allow a proper smooth forward progression of the foot. To keep the rolling effect in the push-off phase, the prosthetic foot must provide a terminal stance support to ensure stability. The rolling effect is also paired with a compression of the keel section, which is a good source of energy for the preparation of the swing. The spring action combined with the knee flexion will provide an adequate clearance for the swing of the limb (Lusardi & Nielsen, 2007).

2.4.3 Feet categories

Prosthetic foot categorization depends on the motion the foot allows or simulates. Prosthetic feet can be classified into four broad categories: Non-articulating feet (conventional), articulating designs, prosthetic feet with an elastic keel, and DER prosthesis (Lusardi & Nielsen, 2007). Figure 2.3 presents a variety of prosthetic feet used by TTA patients.

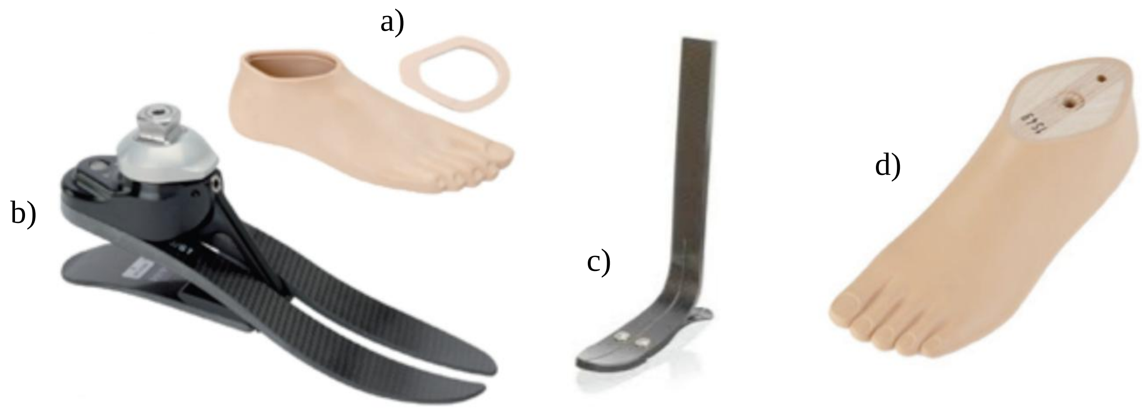


Figure 2.3. Prosthetic feet variations, a) Hollow foot cover versatile for a variety of articulated feet (Endolite, 2011), b) Endolite Epirus offers multi-axial and low profile energy return properties (Endolite, 2011), c) Ossur Modular III offers energy return features (Össur, 2011) d) SACH foot is a non-articulating foot (Otto Bock, 2011)

Compared to other designs, conventional prostheses provide stability and have a lower cost; but they may have a reduced performance. One of the most common conventional designs is the SACH foot, popular for its simplicity and low cost. Primarily used in Canada as a starting foot for new patients or for less active people, the SACH foot is the most commonly used foot in developing countries. Unfortunately, the SACH foot routinely under-performs in rugged rural environments (Hafner et al., 2002a). The articulating designs allow A/P and M/L rotations of the foot.

Elastic keel feet designs recreate the human foot capacities and properties without true joints or moving parts. To allow such movements, the foot emphasis is put on the keel of the foot as well as the foot shell material. At the other end of the design spectrum, DER feet tend to provide increased dynamic performance due to mechanical energy storage and return during the gait cycle, but can have more complex designs and higher costs.

There is a need for a foot design that can provide improved performance while still maintaining simplicity and low cost. It has been shown that people with amputation tend to be more comfortable with a DER foot design because it allows them to maintain a higher walking velocity and can give enhanced stability on uneven ground (Nielsen, Shurr, Golden, & Meier, 1989).

2.5 Rehabilitation issues

Following the amputation procedure, an intensive rehabilitation journey starts for new patients with amputation. The rehabilitation period includes exercises and programs focusing on gait training. Exercises focus on the ROM of the hip and knee, the functional strength of the muscles at the hip and at the knee, motor control and balance, aerobic and anaerobic capacities, and control of the residual limb. The ROM is important for effective ambulation, mobility, and to prevent further complications. For example, with a reduce knee extensor ROM the patient may show a functionally shorter limb, which creates a gait deviation. This limitation can cause poor stability in the midstance, and requires the need for prosthetic lengthening adjustment. Reduction of functional strength may occur because the muscles are partially or totally removed during the amputation surgery.

Emphasis in strengthening the hip abductors, adductors, flexors, extensors, quadriceps, and hamstrings are a priority to reach optimal mobility. The muscle strengthening works in synergy with the stability training. New patients with an amputation have a tendency to avoid putting weight on the prosthetic leg for fear of falling. Rehabilitation works such that the patient is gradually encouraged to put more weight on their prosthetic leg, which increases their confidence. Although the fear of applying weight on their new prosthesis is a psychological barrier, increasing the stability with muscle strengthening helps the patient achieve a functional ambulation. To achieve a good balance, the patients have to reorient themselves with the environment and with the new prosthetic device. The loss of the distal limb causes concomitant somatosensory and proprioception loss limiting sensory feedback about the relationship between the limb and other surfaces. With practice, the patient can learn to maintain their centre of mass over their base of support, thereby improving ambulation. The rehabilitation process can start as soon as two weeks after amputation or as long as 12 weeks post-amputation after the operation, depending on the situation and the condition of the limb.

2.6 Prostheses in developing countries

2.6.1 Differences between western and developing countries

At first glance, there might not be any difference between western and developing countries in terms of prostheses. However, the differences in cultures and environment require attention, to give developing populations such devices that will be useful for their way of living. Developing countries (ex. El Salvador, Thailand) differ from western countries as their population mostly lives and works in rural locations. Many of them are farmers, herdsman, nomads, or refugees that rely on physical labour to survive. Furthermore, many of the aforementioned countries are located in humid and warm climates. The weather difference is an important factor in the design of the foot in order to provide prosthetic materials that are resistant to hard outdoor work conditions and different climates. Another difference in developing countries is the cause of the amputation. In America, disease is the leading cause of amputation, in contrast to war related amputation in developing countries. Remaining landmines throughout the world cause numerous war-related amputations. OneWorld (2007) estimates that there are 70 million landmines still active in the ground across the continents.

2.6.2 Prosthetic technology

Constantly improving over the years, prosthetic related technology allows people with amputation to consistently improve performance (Camporesi, 2008). The world record for the 100-meter sprint in an individual with an amputation is 10.91 sec (International Paralympic committee [IPC], 2009). However, the current availability of prosthetic devices depends on the location where people live in the world. Across the world, the access to prostheses is considered essential. For numerous people with amputation, an adapted prosthesis allows them to return to their previous level of functioning. However, advanced prosthetic technology is not accessible in many developing countries. The cost of better quality prostheses is a main concern in those areas. In America, the average cost of a prosthesis, socket, and maintenance is $7,312 USD (Hermodsson & Persson, 1998), which is not affordable to low income populations. Moreover, the lack of knowledgeable and skilled personnel to build, fit, align, and adjust prostheses is an ongoing issue. To aspire to a higher level of functioning less fortunate people with amputations often create homemade prostheses. They use material found in their surroundings like wood, bamboo, leather, PVC, metal bars, tires, and bicycle seats (Vivian, 2004). Some patients have the opportunity to access a medical relief program that gives medical services including prostheses such as the NF.

2.7 Summary

A wide range of prosthetic feet are available presently, but very few are useful for developing countries because most of them are not adapted to the environment conditions and/or the populations occupational needs. Already used in some locations, the NF is a good alternative for developing countries because of its simple design and weather resistance characteristics. The NF is constantly undergoing development to enhance properties and functions to provide a foot that will better serve this population. Several studies have examined overall foot stiffness and have shown relationships between foot compliance and gait characteristics (Goujon et al., 2006; Hafner et al., 2002a; Hafner, Sanders, Czerniecki, & Fergason, 2002b; Vickers, Palk, McIntosh, & Beatty, 2008; van Jaarsveld, Grootenboer, de Vries, & Koopman, 1990). There has also been one study that looked specifically at heel stiffness (Klute et al., 2004) but no investigations have examined the effects of changes in heel section stiffness within the same prosthetic foot design. The NF design allows this type of test. The relationship between heel section stiffness and gait performance are not well understood; this might be because heel stiffness is not normally a variable property for prosthetic feet.

Chapter 3

Gait analysis literature

To insure a better understanding of the present document, a brief description of universal anatomic terms and basic gait components are introduced in Appendix A.

3.1 Able-bodied gait

3.1.1 Typical pattern

The kinetics and kinematics of able-bodied gait follows very specific patterns (Winter, 2005). The defined patterns of gait are similar across the population but can still differ for each individual. Variations are generally observed in the amplitude of kinetic variables due to differences in velocity and body mass. Typical gait is described by Perry (1992) in four elements. First, stability of the weight-bearing foot throughout the stance period is essential; second the importance of the clearance of the non-weight-bearing foot during the swing period. Third, an appropriate prepositioning during terminal swing of the foot for the next gait cycle is necessary. Finally, an adequate step length is required. Muscle activity, and joint kinematics and kinetics are important sources of information describing the gait patterns required to achieve these objectives.

3.1.2 Muscle activity

The muscle activation patterns of gait evolve until 7 years of age (Sutherland, Cooper, & Daniel, 1980) when the adult gait pattern is reached. Multiple groups have studied muscle activity during locomotion (Winter & Sienko, 1988; Perry, 1992; Isakov, Keren, & Benjuya, 2000) since it is directly related to the kinematics and kinetics of the gait cycle.

During loading response and midstance, the hip extensors contract concentrically. They are active until the terminal stance where they fall silent and the hip flexors start their concentric contraction in the pre-swing and initial swing. The terminal swing is marked by a hip concentric extensor activity. The knee extensors are eccentrically mostly active during the loading response and the terminal swing. At late swing the knee flexor muscles are controlling the concurrent rate at which the knee will extend. Two-dimensional kinetic analysis shows that 85% of the energy in able-bodied gait comes from the plantar flexors, and the hip flexors procure the other 15% percent (Winter, 2005).

3.1.3 Joint Kinematics

Joint angles are important when describing the kinematics of locomotion. The relative joint angles describe the motion of a segment distal to a joint with respect to the segment proximal to the joint (Winter, 2005). During lower limb gait analysis, joint angles are observed at the pelvis, hip, knee, and ankle. The hip reaches the adduction peak during the stance loading response, extension peak in the terminal stance and flexion peak during the loading response. Two knee flexion peaks are observed in the typical gait at the early stance and in the swing phase for the foot clearance (Kadaba, Ramakrishnan, & Wootten, 1990). The small amount of knee flexion observed in the loading response allows for weight absorption. Finally, the ankle shows peak plantar flexion in terminal stance and plantar flexion at heel strike and in the initial swing. The total ROM of the ankle, is generally ranging from 10 degrees of dorsiflexion to 30 degrees plantarflexion.

3.1.4 Joint kinetics

The kinematics of the human system is possible because of the numerous muscles applying linear forces in different directions on the bones. Even though the muscle's forces are linear, motions observed at the joints are rotary. The net joint moment of force is then defined as the resultant rotation moment occurring around the joint due to the muscles-tendon unit and other soft tissues (ie. ligaments, articulation cartilage). The net joint force represents the forces from the segment attached through the joint and the muscle and soft tissues; it is the combination of the joint reaction force and the muscle and soft tissues force. Often in biomechanical analyses the joint forces and the joint moments of force are calculated using the inverse dynamic process.

The calculation of joint moment (M_p) is derived from Newton's laws (Equation 3-1). These equations are applied on a segment-by-segment basis starting from the most distal segment (i.e. the foot). The force and moments acting on each segment are shown in Figure 3.1. For the most distal segment, the distal joint reaction force is known (i.e. either it is the ground reaction force in the stance phase or zero in the swing phase) and the distal joint moment is known. The equations are used to calculate the proximal joint reaction force and then the proximal joint moment can be calculated. Applying Newton's law of action and reaction, the proximal force and moment from that segment then become the distal force and moment of the next segment and the calculations are repeated.

$$\sum F = ma$$

$$F_p + F_d + F_g = ma$$

$$M_{FD} = r_d \times F_d \;\&\; M_{FP} = r_P \times F_P$$

$$\sum M_{cg} = I\,\alpha$$

$$M_p + M_d + M_{FP} + M_{FD} = I\,\alpha$$

Equations 3.1: Joint moment calculation

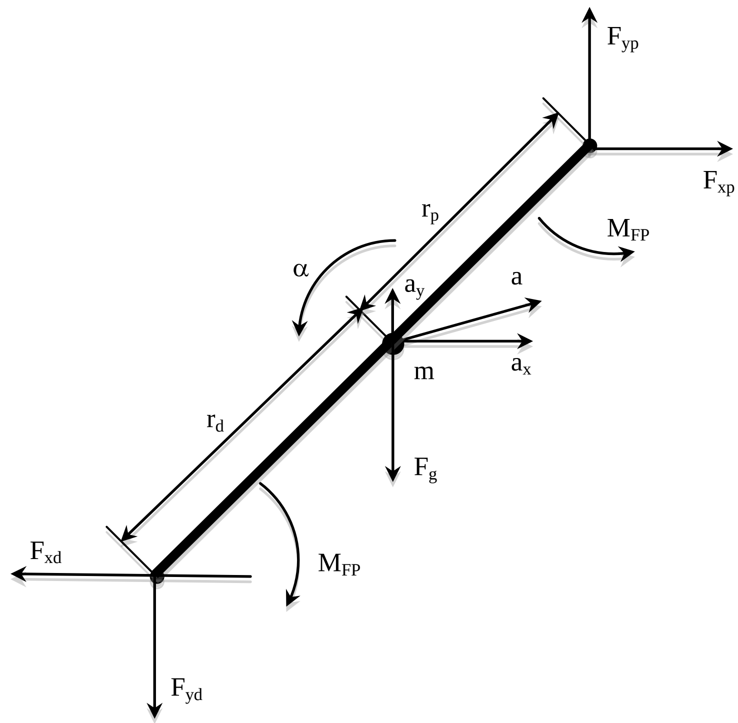


Figure 3.1. Free-body diagram

Inertial parameters are required for the equations. The segment mass (m) is estimated from anthropometric tables (de Leva, 1996) using the total body mass. The acceleration (a) of the centre of mass (CM) of the segment is obtained from the motion capture data. The location of the CM for each segment is obtained as a percentage of the segment length, described in anthropometric tables (de Leva, 1996). The distal joint reaction force (F_d) is obtained by the ground reaction force data for the foot segment. With this information, calculation of the proximal force (F_p) is possible. The proximal and distal moments (M_{FP} & M_{FD}) use the distance (r_d & r_P) from the joint reaction forces to the CM. The principle moments of inertia (I) are obtained from the same table using the segment parameters. Finally the angular acceleration (α) is calculated by taking the derivative of the segmental angular velocity obtained from the motion capture data. The mass and CM of each of the sockets were calculated experimentally (see section 4.2.6).

Combined with the kinematics, kinetics analysis gives information on forces of the gait. Several researchers (Davis, Õunpuu, Tyburski, & Gage, 1991; Kadaba et al., 1990; Winter & Sienko, 1988) have analyzed forces in each event of the stride. Vertical ground reaction, anterior-posterior and medial-lateral forces are measured at the foot using a force platform. The vertical ground reaction force shows the weight transfer during locomotion. During typical gait, a rapid initial spike is observed at heel strike. Following this initial peak, the reaction force shows a rapid force rising higher than the body weight. The weight is partially unloaded at the midstance during the knee flexion creating a lower force than the body weight line. The second force peak is observed in the push-off due to the plantar flexor activity. The ground reaction force goes back to zero when the contralateral limb starts the initial contact.

Joint power is the rate of work represented by the scalar product of the net joint moment and the joint angular velocity. In terms of power, Winter (2005) concluded that the knee is primarily an energy absorber. The extensors of the knee are negatively active in the loading response (K1), preswing (K3), and at the end of the swing (K4). Midstance is the only period where the knee serves as an energy generator with a positive work contributed by the knee extensors (K2). The ankle is an important energy generator in the toe-off period due to the intense activity of the plantar flexors. Minor energy absorption is observed at the midstance in the ankle. In the typical gait pattern, negative work is observed at the hip in the mid-stance phase (H2) in opposition to the positive work in the swing phase (H3). A small positive power is also sometimes observed during the loading response (H1).

3.2 TTA gait

3.2.1 Introduction of gait deviation in TTA

Typical gait analysis (DeVita & Hortobagyi, 2000; Kadaba et al., 1990; Winter & Sienko, 1988) gives a reference to better understand the differences observed in TTA gait. People with TTA have modified gait patterns when compared to able-bodied persons primarily because of the loss of ankle plantar-flexor muscles in the affected limb. Although TTA gait patterns differ from the typical gait pattern, TTA gait still shows similar tendencies. The specific patterns adopted by TTA patients are similar across the population, but individuals may vary their peak amplitude due to a velocity or body mass change (Winter & Sienko, 1988). Gait pattern differences in TTA patients are observed in the muscle activity and in the kinematics and kinetics. Within the TTA population, gait analysis methods can also vary depending on the type of prosthesis used.

3.2.2 Muscle activity, kinematic and kinetics in TTA

Differences in the muscle activity between TTA and able-bodied gait were reported in previous studies (Isakov et al., 2000; Pinzur et al., 1995; Powers, Rao, & Perry, 1998). Increases in the magnitude and duration in muscle activity of the knee extensors, hamstring and gluteus maximus were previously reported (Winter & Sienko, 1988; Torburn et al., 1994; Powers et al., 1998; Isakov et al., 2000). An increase in the EMG was observed in both quadriceps and hamstrings during the stance phase, which was greater than the activity observed in able-bodied. Furthermore, ground reactions force analysis (Sanderson & Martin, 1997; Snyder, Powers, Fountaine, & Perry, 1995) has shown a relatively higher ground reaction force in the intact limb at moderate speed for TTA compared to able-bodied subjects.

Bateni & Olney (2002) suggested that because of a feeling of insecurity, persons with TTA tend to bring their COG forward over their unaffected foot during the heel strike of the affected limb creating a large ankle power generation. Also related to insecurity, persons with TTA tend to spend more time on their unaffected limb compared to their affected limb. This asymmetry seems to also be related to the loss of the plantar flexors (Silverman et al., 2008). It has also been shown in multiple studies (Liu, Anderson, Pandy, & Delp, 2006; Neptune, Kautz, & Zajac, 2001; Zajac, Neptune, & Kautz, 2003) that the plantar flexors are important muscles contributing to the support of the body. They are also key muscles for the forward propulsion and the leg swing (Winter & Sienko, 1988).

Chapter 4

Methodology

This chapter describes the methods used to collect and analyze the data and is composed of three main sections. The first section describes the methods used for patient recruitment and the participating subjects' characteristics as well as the instrumentation used to collect and analyze the data. The second section explains the experimental protocol used. The final section shows the data processing procedure and the analysis of the data.

4.1 Methods

4.1.1 Experimental protocol overview

The experiment was a within-subjects design examining two levels of heel stiffness using the NF. Baseline data was also obtained with subjects using their usual prosthetic foot. Each participant who agreed to participate in the study via a consent form (Appendix J) underwent three data collection sessions, each separated by a two-week adaptation period. The data collection took place at the Musculoskeletal Biomechanics Lab (MBL, Figure 4.2) located in the Physical Activity Complex (PAC) on the University of Saskatchewan campus. The outline of the experimental procedure for each subject is given in Figure 4.1.

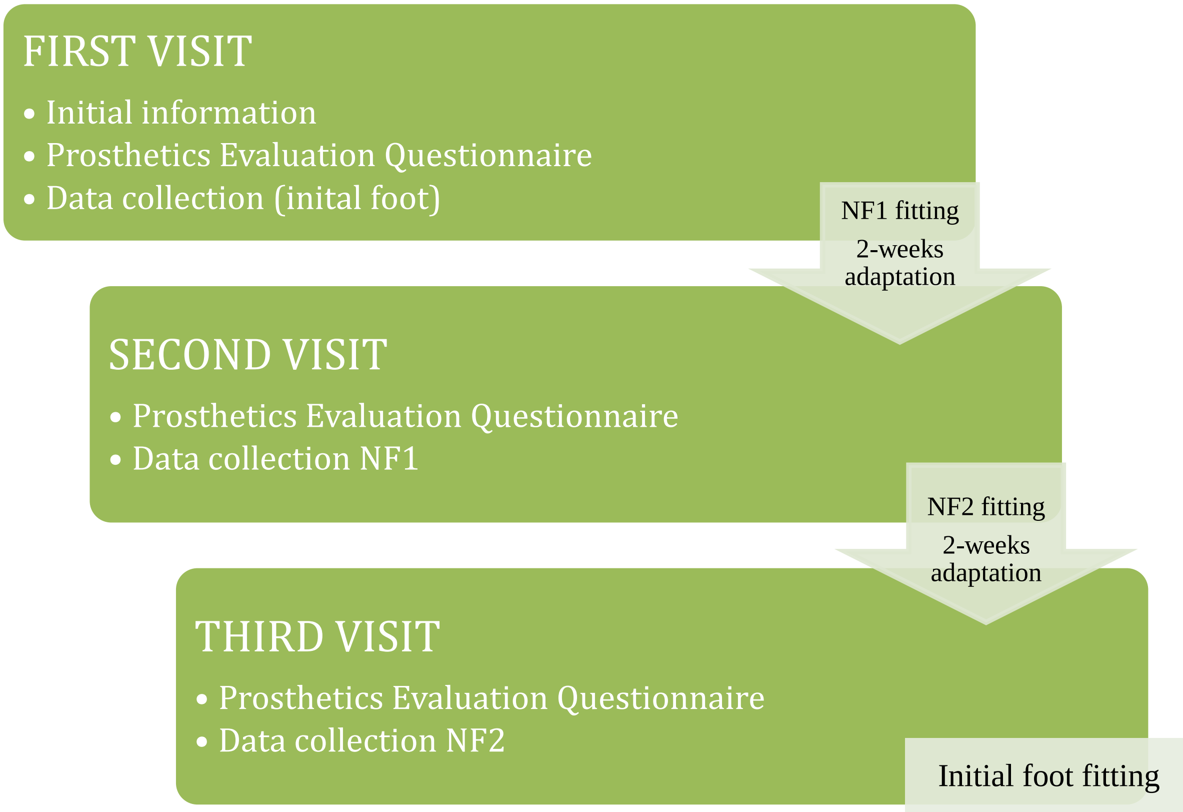


Figure 4.1. Protocol flow chart

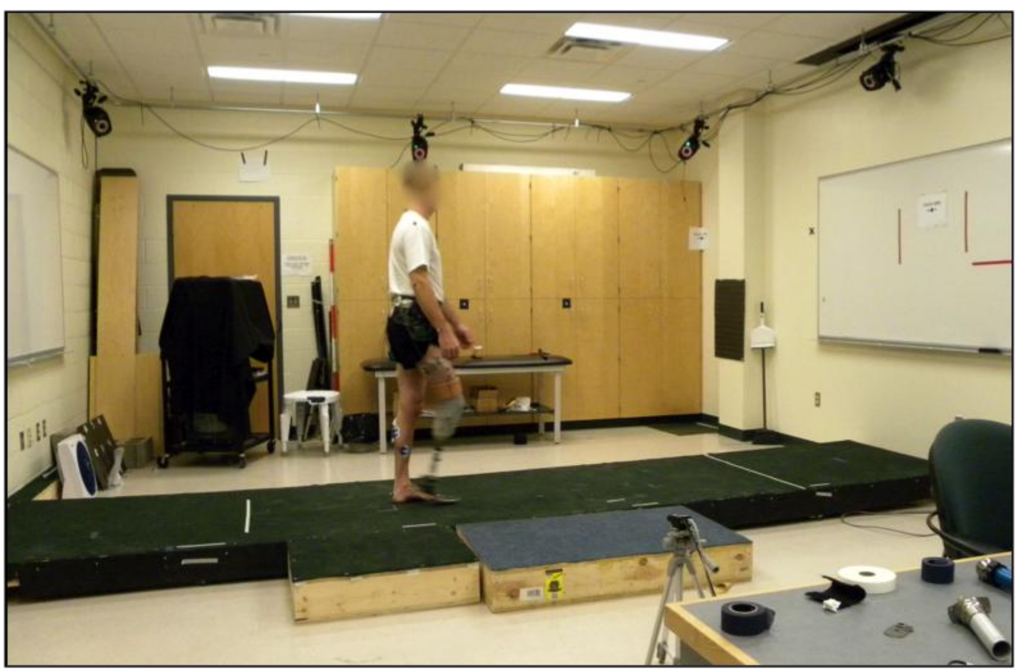


Figure 4.2. Musculoskeletal Biomechanics Laboratory

Prosthetic feet were fitted by a skilled senior prosthetist at the Saskatchewan Abilities Council in Saskatoon. The NF foot used for all conditions and subjects in the study was the Model2, version 19. The first NF condition corresponded to the standard, unmodified model (NF1). The second NF condition was a standard NF (NF2) that was modified by the researchers. The modification was done on the heel section where the two top layers of the heel section were shaved with a vertical belt sander. The heel material was shaved from a thickness of 10.41mm to 8.38mm. The material reduction represented a 20% decrease of the NF1 heel section thickness (Figure 4.3). This heel thickness was within the NF normal operating levels suggested by the manufacturer. The heel section thickness condition was blinded to the participants but not to the researchers. Each subject started with the NF1 and followed with the NF2. All feet were previously unused for all conditions in all subjects (a total of 10 different feet used in the study).

Figure 4.3. Niagara Foot heel modifications, Left picture shows the normal NF1 and the right show the modified NF2.

4.1.2 Participant overview

The subjects were 5 healthy male volunteers aged 39-67 yrs (mean 39yrs ±12.66). Individual descriptive data are presented in Table 4.1. Subject selection was limited to active males with unilateral TTA, between the ages of 18 to 70 years. The gender limitation was set to exclude any gender gait pattern effect. The participants were not eligible if they needed a cane or other external assisting devices to walk. Subjects with a body mass of less than 100 kg were preferred as per the specification of the NF, but one subject was accepted just over this limit with a mass of 107.27kg (subject 3). This subject was included in the study before the weight limitation was known. Since there were no noticeable problems, this participant was still kept in the study even after the weight limitations were set. This participant was closely monitored to ensure that the foot functioned properly for the conditions of this study. After this participant, the NF designers informed the researchers of the 100kg weight restriction. At this point one subject was excluded from the study because his body mass was 8kg over the inclusion criteria (subject 4). No restriction on the post-operation time was set.

Each fitting of the NF was performed by a certified prosthetist. The prosthetist also made sure the patient was in healthy condition and that no pressure wounds were observed on the residual limb. Participants were recruited via the Saskatchewan Abilities Council and by Dr. Gary Linassi of the Department of Physical Medicine and Rehabilitation in the College of Medicine at the University of Saskatchewan.

Table 4.1. Individual characteristic data

Subjects ID	Age (yrs)	Affected side	Mass (kg)	Height (cm)	Post-amputation (yrs)	Amputation reason
1	67	L	75.22	167	5	Cancer
2	57	R	92.27	179	20	Trauma
3	40	L	107.27	182	17	Trauma
5	39	R	74.5	182	10 months	Trauma
6	61	R	57.27	170	6	Trauma
Mean	52.8		81.31	176	12	
SD	12.66		19.08	7.04	7.62	

Prior to participating in the study, the participants were given a verbal and written explanation of the study’s protocol by the researcher. They were also introduced to the instrumentation used in the study. After the description, participants had the option to continue in the study or drop out at any time. Those that decided to continue signed the University of Saskatchewan Research and Ethics Board approved consent form (Appendix J).

4.1.3 Instrumentation

4.1.3.1 Questionnaires

At the first visit, basic subject information (Appendix K) was collected (age, height, mass, medical reason for the amputation and physical activity level). In each of the three visits to the MBL, the participants filled out a Prosthesis Evaluation Questionnaire (PEQ). The present study is using a modified version of the PEQ as reported by Legro et al. (1998a). This qualitative questionnaire evaluates the prosthetic foot function and the quality of life related to the prosthesis. This tool was employed in this study to obtain standardized appreciation feedback from the prosthetic user. The original version of the PEQ was found to be a valid and reliable measure for TTA (Legro et al., 1998a). The original version of the PEQ was too general for the purpose of this study, so sections and question groups were removed from the original PEQ by the researchers. The original PEQ includes sections about body sensation, pain, phantom limb and questions regarding the general amputation process, which was not pertinent in our study. Since score scales are not dependent on each other (Prosthetics Research Study [PRS], 1998) it was possible for us to use only the appropriate sections of questions.

The standard PEQ consists of 41 questions distributed into 9 scales: ambulation, appearance, frustration, perceived response, residual limb health, social burden, sounds, utility, and well being. In addition to the scales questions, 41 individual items are found and listed as satisfaction, pain, transfer, prosthetic care, self-efficacy, and importance questions. The modified PEQ (Appendix L) consists of 25 questions separated in 4 different main group or questions: the prosthetic aspect, the social and emotional aspect of using the prosthesis, the ability to move around, and the satisfaction with particular situations. The utility, frustration and ambulation scales as well as the individual questions from the transfer questions were taken integrally from the standard PEQ. In addition 2/3 questions from the individual satisfaction questions were included in the modified PEQ.

4.1.3.2 Force plate

A force plate (OR6, Advanced Mechanical Technology, inc. [AMTI], MA) recorded the forces exerted by the participants against the ground (Figure 4.4) with a sampling rate of 2000 Hz. The force plate is a rectangular metal platform that houses force transducers that measure the three-dimensional forces applied to the plate's top surface. The data is collected using computer software synchronized with the other equipment in the MBL. The force plate is rigidly embedded into the 6-meter MBL walkway and its top surface is level and equal height with the floor, making it a part of the floor surface.

Figure 4.4. OR6, AMTI force plate (AMTI, 2011)

4.1.3.3 Motion capture system

The 3D kinematics of both lower limbs as well as the torso of each participant was recorded using a commercial motion capture system (Vicon Nexus, Vicon Motion Systems, CO). The motion capture system consists of eight specialized high speed video cameras (Model F20, Figure 4.5) that can track and resolve the 3D coordinates of small reflective spheres attached to the body. The spheres are adhered to the body with hypoallergenic double-sided tape. The spheres attached to the subjects' limbs were 14mm in diameter and those attached to the prosthetic foot were 10mm in diameter. The system is completely passive and requires no cables to be attached to the subject. Motion data were collected at a sampling rate of 100 Hz. The motion capture system used in the lab had a typical resolution of approximately 0.1 mm.

Figure 4.5. Vicon motion capture camera

4.1.3.4 Surface electromyography

A surface EMG system (2400GT2, Noraxon Inc., AZ, Figure 4.6) was used to collect information regarding muscle activation patterns. The EMG system has a small battery powered amplifier / transmitter attached to a belt worn by the participant. The system has a maximum of 8 channels. Nine Ambu® Blue Sensors M-00-S with a skin contact of 34mm of diameter and 154mm^2 of gel area were used. The electrodes were placed on the muscle belly in pairs and were directly wired to a channel in the amplifier / transmitter belt. The first channel has an extra electrode attachment for grounding purpose. The EMG data was collected and transmitted wirelessly to the main data collection system and synchronized with the other instruments. There were no “tether” cords attached to the subject, which allowed free movement and eliminated any risk of tripping. Muscle activation was collected at a sampling rate of 2000 Hz.

Figure 4.6: Noraxon 2400GT2, EMG system (Noraxon, 2011)

4.1.3.5 High-speed video

A high-speed digital video camera (A602fc, Basler Vision Tech., Germany, Figure 4.7), synchronized with the rest of the data collection system, visually recorded the prosthetic foot as it stepped on the force plate. This video was used in the analysis of the prosthetic foot deformation throughout the gait phases. Video from this camera was recorded at 100Hz.

Figure 4.7. Basler Vision Tech high-speed digital video camera (Basler Vision Technologies, 2011)

4.1.3.6 Mechanical testing

Material testing on the unmodified and modified Niagara feet was conducted using an InstronTM 5500 series materials testing machine located at the Human Mobility Research Centre (HMRC) at Queen’s University, Kingston, ON. The testing was done at the HMRC because they possess a special rig to hold the foot. The purpose of this testing was to examine the overall foot stiffness (i.e. load verses deflection) characteristics while loading the heel region in a manner similar to heel contact during gait. The foot was put under a cyclic load going from 0N to 1200N at a rate of 2mm/sec. Video-based analysis was also conducted to qualitatively identify the point of contact on the heel section. Because of the one-piece design the mechanical testing performed gives a measure of the overall stiffness of the foot as a system and not the isolated stiffness of the heel section. Because components of the foot other than the heel section interact with each other during the loading, the overall foot stiffness is not simply a function of the heel section stiffness.

The testing machine was equipped with a 5kN load cell and Merlin Version 4.3 Software. Data was collected at a sampling rate of 10Hz. The testing was run on two NF1 and on two NF2 previously used by the study participants and one unmodified NF v19 that was unused. Each foot was secured on a special rig and inclined at 15 degrees to simulate the foot position at heel contact during walking (Figure 4.8). The testing protocol and instrumentation used for this testing followed the description used in Haberman (2008).

Figure 4.8. Instron heel testing set-up

4.2 Experimentation protocol

4.2.1 Subject preparation

For the testing, each subject wore athletic shorts, a short sleeve shirt and removed their shoes and socks. Anthropometric data was recorded (age, mass, and height). After being introduced to all the apparatus, EMG and motion capture markers were placed on the participant.

4.2.2 Surface EMG

The EMG data was recorded on both limbs. Surface EMG electrodes were placed over the rectus femoris, biceps femoris and gluteus maximus of both limbs and the gastrocnemius and soleus of the unaffected limb of the participant (Winter & Sienko, 1988; Isakov et al., 2000; Blumentritt, Schmalz, Jarasch, & Schneider, 1999).

The skin surface at each EMG electrode site was shaved and cleaned with an alcohol swab to enhance the quality of the signal, and to prevent discomfort when removing the adhesive tape after measurement. The electrodes were placed in parallel to the muscle fibre orientation along the line of action of the muscle with an inter-electrode distance of 20mm (Figure 4.9).

Figure 4.9. EMG sensor locations (Missing: left and right gluteus maximus)

To insure repeatability and accuracy of the EMG data, the sensor locations of each muscle were determined following the guidelines published by the Surface Electromyography for the Non-Invasive Assessment of Muscles (SENIAM) project (Surface Electromyography for the Non-Invasive Assessment of Muscles [SENIAM], 2011). To increase the inter-session repeatability of the EMG sensor placements, clear plastic sheets were used to create templates for each participant recording the locations of the EMG sensors relative to anatomical landmarks and permanent skin features such as prominent freckles or moles.

For the placement of the electrode on the gastrocnemius, the gluteus maximus and the hamstring muscle, the participant was asked to lie in a prone position. With the knees flexed, the biceps femoris electrode was localized at half the distance between the ischial tuberosity and the lateral epicondyle of the tibia. The bicep femoris electrodes were placed at midpoint between the lateral epicondyle of the tibia and the ischial tuberosity. The electrodes on the gluteus maximus were located at the midpoint of a straight line from the sacral vertebrae to the greater trochanter.

For the soleus and the quadriceps muscle, the participant was seated in an upright position on a physiotherapy table. To locate the soleus muscle, the participant flexed his knee with his foot flat on the table. The electrodes were place at 2/3 of the distance between the medial epicondyle of the femur and the medial malleolus. Finally, the rectus femoris electrodes were placed with the participant sitting with his upper body slightly extended backwards. The sensors were located midway between the anterior superior iliacspine and the superior part of the patella iliaca.

4.2.3 Motion capture

After the EMG electrodes were attached, the motion capture markers were placed on the subject. A total of 50 markers were used on the body during calibration. During the data collection only 43 markers remained on the body. A uniform marker set was used for every participant; Figure 4.10 shows the location of markers for a left affected limb set-up. The marker protocol used for this study is an adapted version of the marker protocol used by the MBL. The MBL model was validated with able-bodies subjects and uses dynamic functional calibration to locate the hip and knee joint centres.

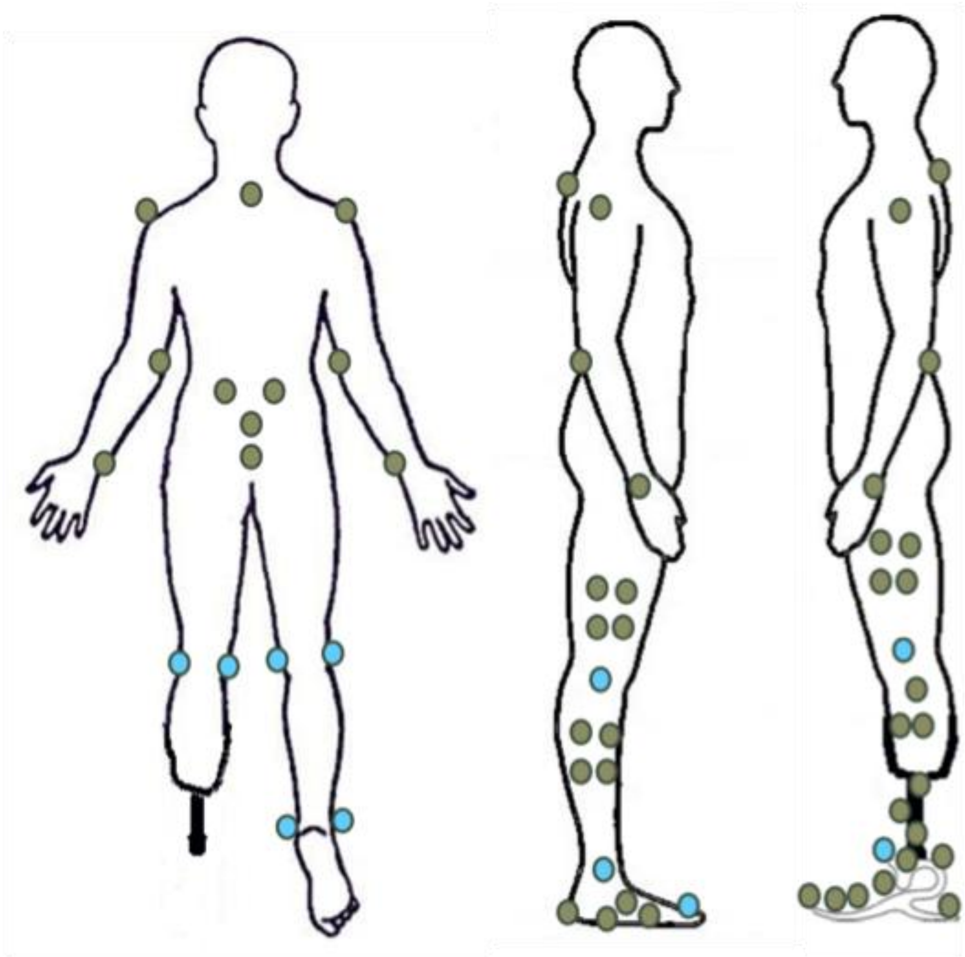


Figure 4.10. Left Limb-affected motion capture marker set template, data collection markers (green), calibration only markers (blue)

Markers that were placed on the second metatarsal and malleoli of the unaffected limb, the femoral epicondyles of both limbs and the front top plate of the prosthetic foot were used only for calibration purposes. The other 43 markers were composed of 7 upper body markers and 36 lower body markers. The upper body markers were used for visualization only and were comprised of the wrist, elbow, and shoulder of both arms and a marker on the C7 vertebrae. A rigid cluster was used to track the pelvis; four markers were installed on a plastic T-shaped base plate and attached to a belt placed snugly over the hips (Figure 4.11). The unaffected limb was tracked by 12 markers: femur (4), tibia (4) and foot (4). The remaining 15 markers were tracked the affected limb: femur (4), socket (3), pylon (3) and foot (7).

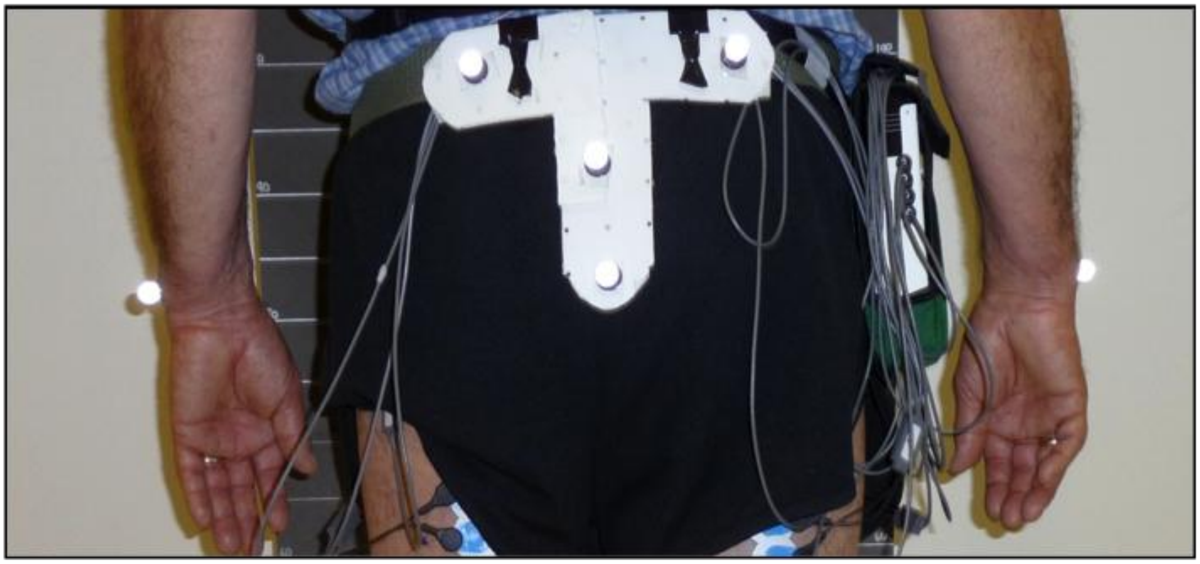


Figure 4.11. Pelvis marker cluster

The markers on the femurs and on the tibia were directly adhered to the skin in a rectangular shape with hypoallergenic double-sided tape (Figure 4.12). The markers on the femur were positioned as distally as possible to avoid being covered by the hands while walking, but just above the prosthetic sleeve line on the affected side. The majority of the participants were asked to roll their prosthetic sleeve as low as possible without losing the suction properties, to allow the femur markers to be applied. The markers on the pylon were positioned in a triangular fashion, two vertically aligned on the front and one in the middle of the two on the side.

Figure 4.12. Lower body markers

The foot markers of the unaffected limb were arranged in a triangular shape on the side of the foot and one marker was placed on the heel at the base of the Achilles tendon. The affected foot markers (Figure 4.13) were placed on the top plate (3), along the keel (4) and on the heel (1).

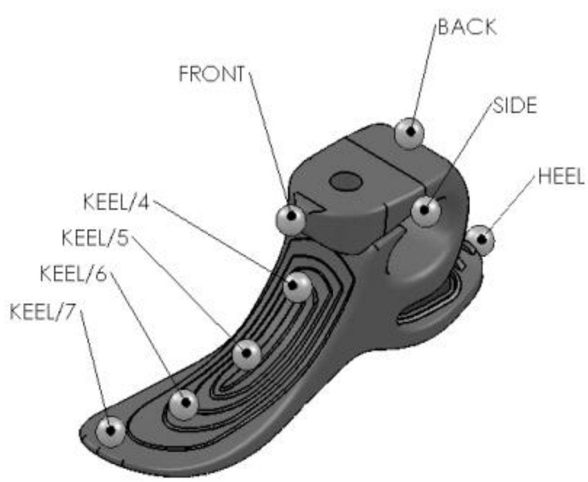


Figure 4.13. NF markers

The markers on the NF were located at the same positions for the NF1 and NF2 conditions. All markers but the side marker were installed on the centre line of the foot. Specific locations of the markers were standardized by using the layers on the keel and the marks left by the injection-molding process. The markers on the NF1 and NF2 were placed directly on the prosthetic foot (Figure 4.14). For the collection of data with the subject's own prosthetic foot the markers were placed directly on the foot cover.

To allow the markers to be directly attached to the NF, the cover of the foot was removed and a custom bottom foot cover was adhered to the NF. This procedure allowed visualization of the foot's deformation during gait.

Figure 4.14. NF markers

The custom bottom foot cover was essential to provide a secure environment for the participant by reproducing the same friction that would be present with a full foot cover; as using the NF directly on the runway surface was too slippery. The custom foot covers were constructed from standard full foot covers and were attached to the NF with double-sided carpet tape.

The high-speed digital video camera was automatically synchronized with the rest of the data collection equipment. The digital camera was zoomed in on the foot for 2/3 of the trials to better observe the foot deformation. For the other third, the camera was focused on the body to examine the entire gait.

4.2.4 Equipment verification

The participant was asked to walk around the room to make sure none of the equipment was interfering with their normal gait pattern. During this period the participant was also asked to contract the muscles with EMG electrodes to verify that the electrode placement was correct and that cross talk between the channels was minimized. Adjustments were done when needed to insure a good quality EMG and motion capture data. Before starting the experimental trials, several practice walking trials were performed by the participant to allow the participant to feel comfortable with the set-up.

4.2.5 Calibration session

Once the participant was feeling comfortable, the participant started the calibration session. During this time, the participant was asked to stand motionless for a few seconds in the centre of the data collection area for a neutral position recording. This position required that the participant stand with 20cm between the feet, the arms slightly apart from the body, the weight distributed evenly on their feet as much as possible and the eyes looking forward. This position was used to calibrate the marker-tracking algorithm in the motion capture system and to obtain reference data from the subject in a neutral static position. During the static position each subject stood on a wood jig equipped with a heel ridge that allowed the feet to be on the same line. Markers on the wooden jig were used to identify the heel alignment line.

Following the capture of the static position, the participant proceeded to the dynamic functional calibration to estimate the hip and knee joint centres (Cappozzo, Catani, Croce, & Leardini, 1995). The hip calibration consisted of a combination of a flexion/extension (F/E) hip movements and abduction/adduction (abd/add) leg swing movement while the knee calibration was a F/E movement of the knee. Both movements were demonstrated to the participant prior to starting. Custom computational geometrical fitting routines in were applied to the functional calibration data. For the hip, the centres of rotation between the femurs and pelvis were found assuming a 3 degree of freedom joint (Cappozzo et al., 1995; Ehrig, Taylor, Duda, & Heller, 2007; O'Brien, Bodenheimer, Brostow, & Hodgins, 2000). For the knee, the F/E axis of rotation was determined (O'Brien, Bodenheimer, Brostow, & Hodgins, 2000) and the knee joint centre was estimated by projecting the midpoint between the femoral condyle markers on to the estimated F/E axis (Hagemeister et al., 2005). The functional calibration method is explained in more detail in section 4.3.1.

4.2.6 Walking trials

Following the calibration period the calibration markers were taken off and the walking trials started. The participant was asked to walk on the walkway from one end to the other. A walk was considered successful only if the entire foot of the test leg struck the force plate embedded in the walkway. Because the participant was changing his direction at each trial, the test leg was designated as the leg on the side of the high-speed video camera. To help the participant achieve successful and consistent trials, the departure location was marked with a piece of tape. A minimum of 10 successful trials for each limb was collected. For each trial the participant was asked to wait for the verbal start trigger given by a research member. Each trial was monitored to ensure that the EMG signal was clear of noise.

After the walking trials were complete, the mass and CM of the participant’s socket was calculated experimentally. The socket was removed from the participant and was placed in 5 different poses on the force plate. The CM was calculated as the intersection of the ground reaction force vectors from those trials. The CM location was expressed in the local socket coordinate system using tracking markers located on the socket. The moments of inertia for the sockets were estimated using geometrical methods assuming a constant density (Figure 4.15).

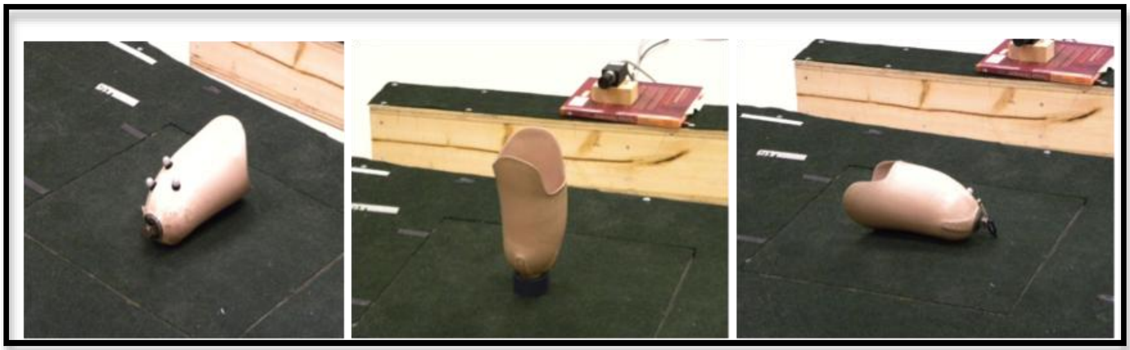


Figure 4.15. Partial socket positions during the socket calibration

4.3 Data processing and analysis

The data processing was accomplished with custom Matlab (R2008bSV for Mac & R2006b for PC, The Mathworks, MA) routines to generate graphs and extract values.

4.3.1 Kinematics

The kinematic data obtained with the motion capture during the calibration was used to find the location for the ankle, knee and hip joints. First, the estimation of the functional joint centres was approximated following the method described by O'Brien (2000) and Ehrig et al. (2007). Second, the anatomical orthogonal coordinate systems for the pelvis, the femur, the tibia and the foot were defined. Finally, joint rotations were described by the Cardan sequences (Grood & Suntay, 1983) where z is the positive longitudinal axis and y is the positive anterior direction.

4.3.1.1 Step 1 – Functional joint centers

As described earlier in the experimentation protocol, lateral and medial malleoli (LM, MM), lateral and medial epicondyles (LC, MC) were palpated and were identified as anatomical locations (AL). Motion capture skin markers were then placed on those ALs for the definition of the anatomical functional calibration (Cappozzo et al., 1995). The halfway point between the malleoli was identified as the ankle joint centre.

For the knee joint centre, the midpoint between the epicondyles was first identified as a temporary knee joint centre. From the flexion/extension movement performed in the dynamic calibration session an F/E axis was determined following the method described by O’Brien (O'Brien et al., 2000). The temporary knee joint centre was then perpendicularly projected on this F/E axis (Hagemeister et al., 2005). The hip centre was identified following the method described by O’Brien (O'Brien et al., 2000) using dynamic hip calibration. Movements performed by the participant for the hip calibration were F/E of the hip reaching ~60 degrees of flexion and ~40 degrees of extension followed by abd/add of the hip reaching ~30 degrees of abduction and ~50 degrees of adduction. The aforementioned ranges of motion were approximations only. The ranges of motion reached during the exercises were dependent of the flexibility of the participant.

4.3.1.2 Step 2 – Anatomical coordinates

The pelvis coordinate system was created with the standing calibration using the standing jig and the global coordinate system. The origin of the pelvis was located halfway between the hip joint centres. The vertical axis (z) was created from the global vertical axis. The lateral axis (y) of the pelvis went from the right side to the left side of the body based on the markers on the standing calibration jig. The AP axis (x) was the y-z cross product result.

For the femur coordinate systems the vertical axis (z) went from the knee centre to the hip centre. For the right femur the y-axis went from lateral to medial and for the left femur it went from medial to lateral. The AP axis was the result of the cross product of the x and z-axis. The tibia coordinate systems were defined by the vertical (z) axis going from the ankle joint centre to the knee joint centre. For a right tibia the y-axis went from lateral to medial and for a left tibia the z-axis went from medial to lateral. The AP axis was the result of the cross product of the x and z-axis. For the affected limb, the socket coordinate system was defined the same way the tibia was.

The foot coordinate system was described as follows: the vertical axis (z) was a translation of the global vertical axis. The AP axis (x) went from the heel to the toes. The y-axis was the result of the cross product of z and x. For the NF coordinate system the AP axis was created from the top plate back centre marker towards the front centre top plate marker. The vertical (z) axis was a translation of the global vertical axis. The y-axis was the result of the x and z product and was approximately directed lateral to medial.

4.3.1.3 Step 3 – Data analysis

Once the locations of the functional joint centres were localized, further analysis was possible to procure information about each joint and their ROM. Using the Cardan sequence method (Grood & Suntay, 1983; Davis et al., 1991) a series of 3D joint angles were calculated for each subject. The F/E and abd/add ROM of the knee and the hip were analyzed during the stance and the swing for the affected and unaffected side. The F/E ROM is a factor that can describe the adaptation strategy used by prosthetic users (Hafner et al., 2002a; Hafner et al., 2002b).

To observe the stride characteristics, the self-selected walking velocity (SSWV), and the stride length and cadence for the affected and unaffected limb were analyzed. Walking velocity considerably affects the kinetics and kinematics of the sound and affected limbs (Bateni & Olney, 2002). Studies on the influence of walking speed on EMG activity have demonstrated that the affected and unaffected limb EMG signals are influenced by an increase in walking velocity (Fey, Silverman, & Neptune, 2010). Silverman et al. (2008) also suggest that ground reaction forces and joint power increase significantly in the sound and affected limb with a SSWV increase.

4.3.2 Kinetics

The gait kinetics analysis was defined based on the GRF, the joint moments and the joint powers.

4.3.2.1 Ground Reaction force

With the walkway imbedded force platform, the ground reaction forces were collected. Using the force platform outputs, the forces in the A/P (y-axis) and vertical (z-axis) directions were calculated for the hip and the knee. The following variables were calculated in each direction: peak amplitude, time of peak amplitude, rate of loading, impulse and average stance force.

4.3.2.2 Joint moments

By combining ground reaction forces outcomes and kinematics data, the F/E moments of the affected and unaffected limb of the knee and hip were computed. Only the F/E moments were analyzed for the knee and the F/E and abd/add moments were examined for the hip. Peak values were identified at standard locations during the gait cycle as defined by Winter (Winter, 2005). The minimum and maximum moment observed during the swing were also obtained.

4.3.2.3 Joint power

Derived from the moments and the joint angular velocities, the power at each joint was calculated to examine the absorption and generation of mechanical energy. Joint power peaks (Figure 4.16) typically associated with walking defined by Winter (Winter, 2005) were identified. The terminology *peak* defines the maximum point reached during a certain period. Again specific periods were selected (weight acceptance, flat-foot, mid-stance, toe off and push off) to verify significant difference between NF conditions. The term *burst* will often be used to qualify the joint power peaks.

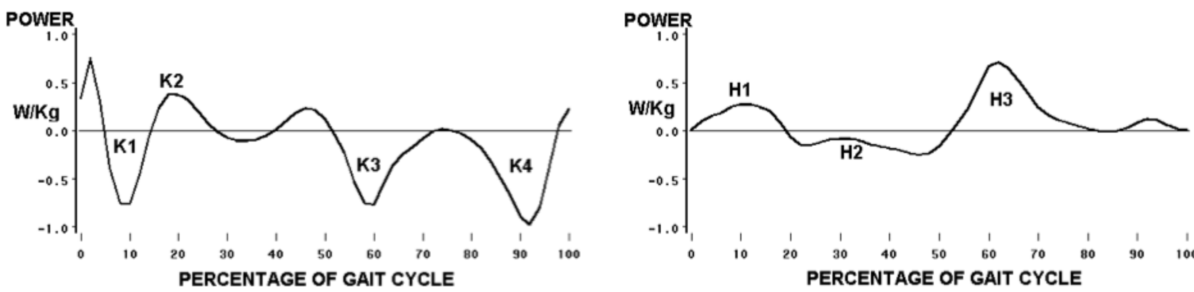


Figure 4.16. Typical able-bodied joint power profiles of the knee (left) and the hip (right) with the typical knee and hip peaks. (Winter, 2005).

4.3.3 Mechanical foot deformation testing

The mechanical foot deformation outcome was defined by the results obtained during the Instron testing done at the HMRC. Two main outcomes were analyzed, the displacement of the heel section towards the central C-Section of the foot and the overall foot stiffness. The displacement was measured while an increasing force was applied to the rear part of the foot. The stiffness values were calculated from the first derivative of the force-displacement values and are described in terms of displacement of the heel section.

4.3.4 Gait-based foot deformation

The foot deformation is an important outcome of this study because it is directly related to the heel modification and creates the relationship between the heel modification and possible changes in the kinetics and kinematics. To explain the foot deformation, 6 major variables were measured: the heel compression and extension (heel deformation), the keel shape-compression, the roll-over shape, flat foot time, the foot angle at heel strike, and the loading time. The overall foot deformation was also examined qualitatively through the high-speed video camera footage.

4.3.4.1 Heel compression

The mechanical compression of the heel section was analyzed. The distance between two predetermined locations of the NF were used to describe the compression of this section: the back of the top plate (Figure 4.17, Back) and the end part of the heel section (Figure 4.17, Heel). The 3D locations of those markers were tracked throughout each trial. The distance between the two markers at rest was used as a reference point and represented an uncompressed or un-extended heel. Heel compression was compared within each participant between both NF conditions.

4.3.4.2 Keel shape compression

Similar to the heel compression, the keel shape-compression outcomes were tracked with the 4 motion capture markers on the keel. The distances between each of the markers were tracked to reconstruct the movement of the keel during the gait. Since the foot is one piece, each point of the keel was also referenced to the heel marker and the front top plate marker (Figure 4.17) to observe the global deformation produced by the C-section.

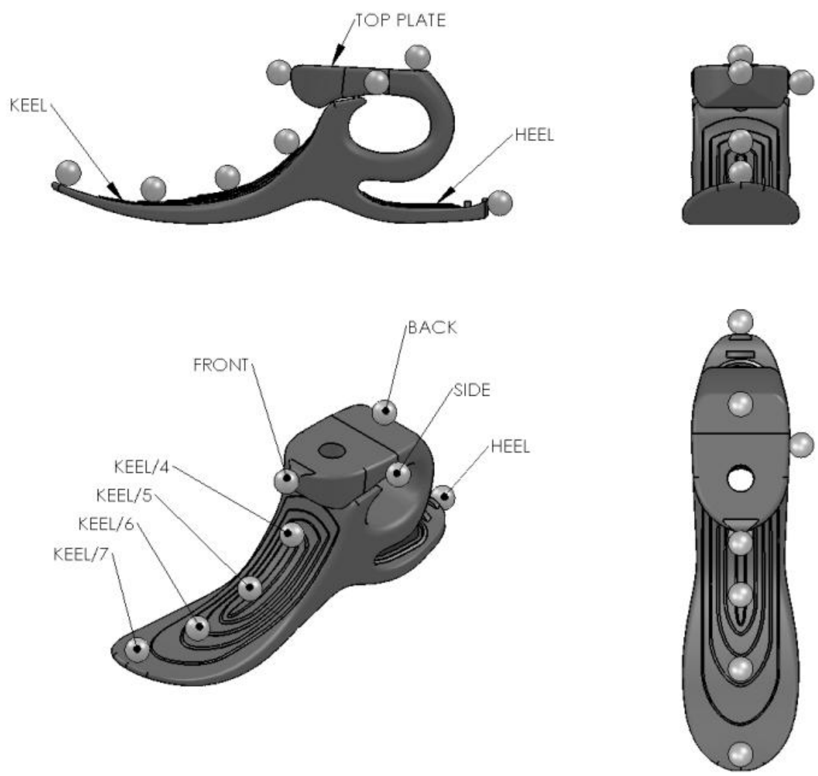


Figure 4.17. Niagara foot marker positions. Top left: side view, top right: front view, bottom left: isometric view and bottom right: top view

4.3.4.3 Roll-over shape

The roll-over (also called rocker) shape has been used to analyze the alignment, the mechanical deformation and the overall gait pattern in foot prostheses (Hansen, Childress, & Knox, 2004). The roll-over shape is defined in the literature (Hansen, Childress, & Knox, 2000) as the observed geometry that the foot/ankle unit follows during the single limb stance during the gait. Basically, the roll-over can be compared to a rocker model and can be thought of as the shape the foot would take if it was a wheel. In the literature the roll-over model was studied in different prostheses and able-bodied analyses (Curtze et al., 2009; Hansen et al., 2004; Perry, 1992). It is believed that the roll-over shape is an important factor in the general understanding of foot function and alignment. The roll-over shape allows the comparison between two different feet by locating the centre of pressure of the foot with respect to a fixed point on the ankle-knee axis in the sagittal plane (Curtze et al., 2009). The roll-over shape was computed by transforming the forward ground reaction force from the lab coordinate system into the foot coordinate system. The roll-over shape represents the effective rocker starting from the heel contact to the toe-off with respect to the foot. The roll-over shape was characterized in this study only by using the shape arc length. It was calculated by measuring the length along the path of the roll-over profile. The roll-over shape arc length and shape is dependent on the foot stiffness (Figure 4.18).

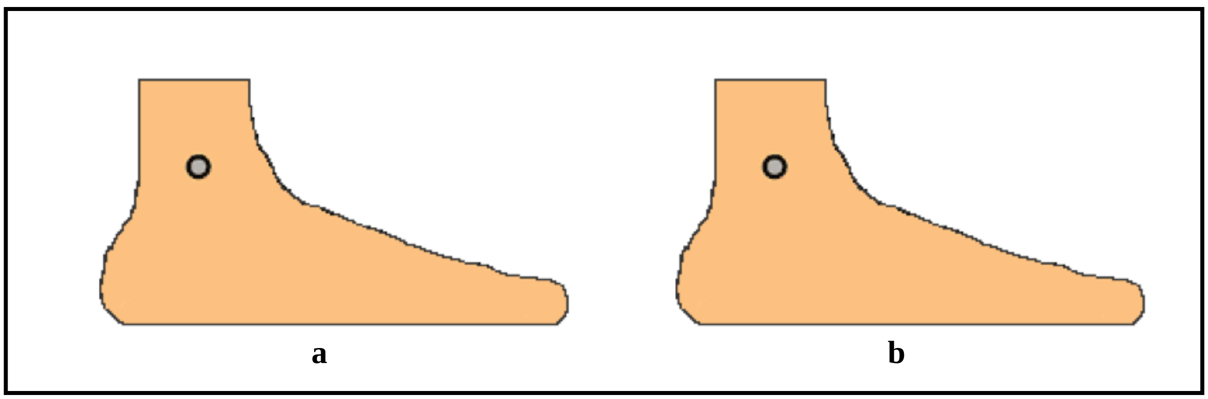


Figure 4.18. Roll-over representation with respect to the foot coordinate system (Adaptation from Hansen, 2000); (a) soft heel with stiff toe (b) Stiff heel and soft toe

Hansen, Meier, Sessoms, & Childress (2006) showed that when reducing the roll-over arc length, the maximum external dorsiflexion moment on the affected side was also reduced. This is due to the reduction of the forefoot moment arm at the ankle. The arc length is a good variable to describe the external dorsiflexion moment and loading force.

4.3.4.4 Loading time

The loading time is calculated as the time between the initial contact of the foot with the ground and the moment where the entire foot touches the ground (i.e. foot-flat). The time of initial contact was defined as the instant the vertical ground reaction force rose above a threshold of 10N, when a force was first applied to the force plate.

Because no access to a footswitch was possible (Perry et al., 1997) the flat foot event was defined with the F/E angular acceleration of the foot segment. To determine when the foot was in a flat position a threshold of 1 rad/sec^2 was set. When the angular acceleration of the foot dropped below the threshold, this indicated the frame (time) when the foot was flat with the ground. The approach was verified by observing trials that were captured with the high-speed video.

4.3.5 EMG

Muscle activation is important to better understand the kinematics and kinetics observed. The EMG signal was first extracted as a raw signal directly from the data collection. It was then processed in a Matlab routine with a high-pass filter set at 20Hz and low-pass filter at 500 Hz. The filtered data was then full-wave rectified, making the entire signal positive. Finally a linear envelope was created at a frequency of 6Hz using a 4th order Butterworth filter. The analysis of the EMG signal concentrated on the maximal and minimal amplitude reached by each muscle (Winter & Sienko, 1988; Isakov et al., 2000). Since the EMG system was synchronized with the motion capture system, important muscle activity was associated with specific kinematic phases (ie. early stance and swing phase).

4.3.6 Prosthesis Evaluation Questionnaire

The scales of the PEQ were independently analyzed and sorted into 4 variables: utility, frustration, ambulation, and satisfaction. The PEQ uses an analogue visual scale (Figure 4.19). For each question the participant needed to draw a vertical line across the 100 mm ruler.

Over the past two weeks, rate your ability to walk when using your prosthesis.

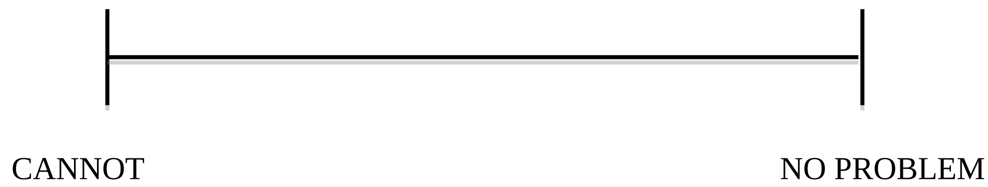


Figure 4.19. PEQ question sample

The score was measured from the left to the right in millimetres with a ruler. For each question the score was rated with a maximum score of a 100. For each scale, the average score of all questions in this scale determines a single score. Because of their individual aspect, the transfer and the satisfaction items were reported separately without group average according to the PEQ evaluation guide (PRS, 1998).

4.4 Statistical Analysis

In preparation for this study, statistical analysis was considered to better organize, treat, present and interpret data. But this was not feasible because of the low sample size. To start a statistical analysis a normality test is required; with a low sample size (n=5) a normality test is invalid. Since the sample is then considered as a non-normal distribution, evaluation of data with parametric tests would not be valid. It was then decided to analyse trends in the kinematics, kinetics, EMG and PEQ outcomes (Table 4.2).

The means for each of the kinematics, kinetics and EMG outcomes were calculated for session 1 (C1), session 2 (NF1) and session 3 (NF2). Only results for NF1 and NF2 will be presented in the results section. All the results are available in the appendices B to H. One mean trial was created from 5 trials for each subject’s leg per condition. When considering trends, it is implied that at least 4 or 5 participants showed a similar change between the conditions. Between subjects mean was created from the subject means for each variable.

Table 4.2. List of variables

Outcome category	Variable	A-side	U-side	Units
Spatio-temporal	Walking speed	x	x	m/s
	Cadence	x	x	step/min
	Stride length	x	x	m
	Stance phase	x	x	% gait cycle
Foot deformation	Rollover shape arc length	x		mm
	Foot flat	x		% stride
	Foot flat	x		second
	Heel strike angle	x		degrees
	Heel compression	x		% normal state
	Heel extension	x		% normal state
EMG	**Average strike phase**			
	Rectus femoris	x	x	mv
	Biceps femoris	x	x	mv
	Gluteus maximus	x	x	mv
	Gastrocnemius medial		x	mv
	Soleus		x	mv
	Average swing phase			
	Rectus femoris	x	x	mv
	Biceps femoris	x	x	mv
	Gluteus maximus	x	x	mv
	Gastrocnemius medial		x	mv
	Soleus		x	mv
PEQ	Utility	N/A	N/A	%
	Frustration	N/A	N/A	%
	Ambulation	N/A	N/A	%
	Transfer	N/A	N/A	
	sitting in a car	N/A	N/A	%
	sitting on a high chair	N/A	N/A	%
	Sitting on a soft chair	N/A	N/A	%
	Sitting on toilet	N/A	N/A	%
	Showering	N/A	N/A	%
	Satisfaction	N/A	N/A	
	Prosthetics satisfaction	N/A	N/A	%
	Gait satisfaction	N/A	N/A	%
Range of motion	**Knee F/E**			
	Minimum F/E	x	x	degrees
	Maximum F/E	x	x	degrees
	Total F/E	x	x	degrees
	Hip F/E			
	Minimum F/E	x	x	degrees
	Maximum F/E	x	x	degrees
	Total F/E	x	x	degrees
	Knee Abd/Add			
	Minimum Abd/Add	x	x	degrees
	Maximum Abd/Add	x	x	degrees
	Total Abd/Add	x	x	degrees
	Hip Abd/Add			
	Minimum Abd/Add	x	x	degrees
	Maximum Abd/Add	x	x	degrees
	Total Abd/Add	x	x	degrees

Table 4.2. List of variables (continued)

Outcome category	Variable	A-side	U-side	Units
Forces	**A/P GRF**			
	1st peak			
	Amplitude	x	x	N
	Amplitude normalised	x	x	N/kg
	Time	x	x	s
	Rate of loading	x	x	N/s
	Rate of loading normalised	x	x	N/kg•s
	2nd peak			
	Amplitude	x	x	N
	Amplitude normalised	x	x	N/kg
	Time	x	x	s
	Rate of loading	x	x	N/s
	Rate of loading normalised	x	x	N/kg
	Force impulse			
	Impulse negative	x	x	kg·m/s
	Impulse positive	x	x	kg·m/s
	Impulse total	x	x	kg·m/s
	Vertical GRF			
	Amplitude	x	x	N
	Amplitude normalised	x	x	N/kg
	Time	x	x	s
	Rate of loading	x	x	N/s
	Rate of loading normalised	x	x	N/kg·s
	Impulse total	x	x	kg·m/s
	Stance average force	x	x	N
	Stance average force normalised	x	x	N/kg·s
Moments	**Knee F/E peaks**			
	Early stance	x	x	Nm/kg
	Middle stance	x	x	Nm/kg
	Late stance	x	x	Nm/kg
	Swing minimum	x	x	Nm/kg
	Swing maximum	x	x	Nm/kg
	Hip F/E peaks			
	Early stance	x	x	Nm/kg
	Middle stance	x	x	% stance
	Late stance	x	x	Nm/kg
	Swing minimum	x	x	Nm/kg
	Swing maximum	x	x	Nm/kg
	Hip abd/add peaks			
	Maximum 1st peak	x	x	Nm/kg
	Maximum 2nd peak	x	x	Nm/kg
	Minimum	x	x	Nm/kg
Power	**Knee peaks**			
	K1	x	x	Watts/kg
	K2	x	x	Watts/kg
	K3	x	x	Watts/kg
	K4	x	x	Watts/kg
	Hip peaks			
	H1	x	x	Watts/kg
	H2	x	x	Watts/kg
	H3	x	x	Watts/kg

Chapter 5

Results

This chapter focuses on the differences between the two NF conditions for the kinematics, kinetics, mechanical deformations, electromyography, and PEQ variables. Multiple trends were observed in the kinematics and kinetics variables between the NF1 and NF2 conditions. The results section will then concentrate on the description of those trends.

5.1 Kinematics & kinetics

5.1.1 Spatio-temporal parameters

The walking speed was similar between conditions for all subjects (Table 5.1). Since the average velocity was stable from one condition to another it was possible to compare the kinetic variables (Winter, 1983). All subjects showed an increase in stride length of the affected limb with the NF2 (1.29m ±0.02) compared to the NF1 (1.25m ±0.02). The stride length of the unaffected limb with the NF2 also increased in 4/5 participants (NF1: 1.24m (±0.02) NF2: 1.19m (±0.02)). The stance phase duration was smaller in the affected side than the unaffected side in 3/5 participants. This situation was observed for both the NF conditions.

Participants showed a variety of cadence. (NF1: 107.56 steps/min (±4.52), NF2: 106.75 steps/min (±4.95)). All results are reported in Appendix B.

Table 5.1. Walking speed

Subjects	NF1	NF2
S1	1.26 (±0.02)	1.26 (±0.02)
S2	1.11 (±0.03)	1.19 (±0.03)
S3	1.22 (±0.02)	1.23 (±0.02)
S5	1.06 (±0.01)	1.07 (±0.01)
S6	0.91 (±0.03)	0.98 (±0.03)

Values are presented in (m/s) with standard deviation

5.1.2 Joint ranges of motion

When compared to the unmodified NF1, the NF2 did not show any difference in the F/E ROM of the knee and the hip joint angles of both limbs. Table 5.2 shows an overview of the affected relative F/E ROM average seen in the 5 subjects. When looking at the knee abd/add ROM a small reduction was seen in the affected knee in 4/5 participants but none in the unaffected side. The abd/add hip ROM did not show any difference in the affected or unaffected side between the two conditions. More details on the peaks of the F/E and abd/add ROM are presented in Appendix C.

Table 5.2. Relative F/E knee and hip ROM during the affected side gait cycle

		S1	**S2**	**S3**	**S5**	**S6**	**Avg**	**SD**
Knee	NF1	68.37	57.00	63.32	60.38	65.42	62.90	4.41
	NF2	65.07	58.77	67.29	64.41	63.38	63.79	3.15
Hip	NF1	40.70	35.74	36.31	45.09	43.91	40.35	4.27
	NF2	37.97	38.88	31.98	38.22	44.57	38.33	4.47

The ranges of motion are represented in degrees

5.1.3 Forces

Although, ground reaction forces were collected in the three directions, only the A/P and vertical direction were analyzed (Table 5.3). ML forces are important forces, but were left out in order to focus on the forces where greater effects were hypothesised. The highest peak on the force curve was defined as the maximal force amplitude. The time is measured in seconds and represents the time between the start of the stride, to the moment the force reaches the maximal amplitude indicated by the peak. The rate of loading is relevant only for the first peak in the A/P direction and the first vertical peak because it represents the speed the body weight is being loaded onto the foot. Prior to a complete foot flat, the rate of loading describes the moment where the individual will slow down to accept the load during early stance (Riskowski, Mikesky, Bahamonde, Alvey, & Burr, 2005). The rate of loading is the amplitude divided by the time and its units are in N/kg·s. All the force data were normalized to body mass.

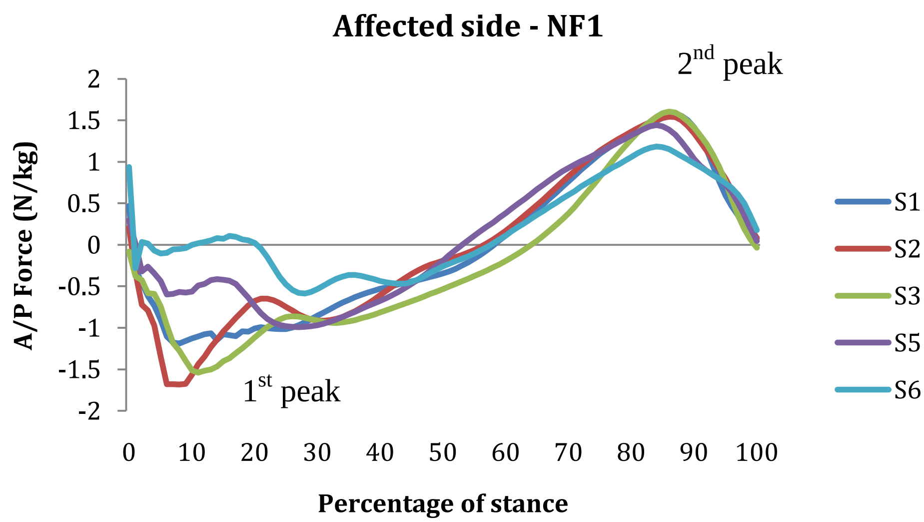
Table 5.3. Mean ground reaction peaks in A/P and vertical direction

			Amplitude (N/kg)		Time (seconds)		Rate of loading (N/kg·s)	
			A	**U**	**A**	**U**	**A**	**U**
A/P	**1st peak**	**NF1**	1.22 (0.39)	1.85 (0.31)	0.13 (0.06)	0.10 (0.01)	12.71 (8.28)	19.72 (3.92)
		NF2	1.38 (0.47)	1.90 (0.38)	0.13 (0.02)	0.09 (0.02)	14.19 (9.60)	20.72 (5.46)
	2nd peak	**NF1**	1.48 (0.17)	1.80 (0.48)	0.59 (0.04)	0.61 (0.03)	-	-
		NF2	1.47 (0.08)	1.96 (0.41)	0.59 (0.03)	0.60 (0.04)	-	-
Vertical		**NF1**	7.55 (1.67)	8.02 (2.08)	0.07 (0.03)	0.07 (0.02)	108.75 (33.21)	121.86 (42.99)
		NF2	7.84 (1.89)	8.82 (1.75)	0.07 (0.02)	0.06 (0.02)	126.02 (44.91)	149.62 (58.91)

Note: Each peak is described in terms of the maximal amplitude in N/kg and the time in seconds to reach the maximal amplitude from the start of the stride and the rate of loading in N/kg·s. The first peak of the A/P direction is the maximum breaking force, where as the second represents the maximum posteriorly directed push-off force. Standard deviations are presented in the parentheses.

Anterior/Posterior ground reaction forces - In the anterior-posterior direction, two distinct peaks were observed in each subject (Figure 5.1). The first peak represents the maximum braking force during the first half of stance and the second peak represents the maximum posteriorly directed push-off force during the second half of stance. During the first peak an increase in the force amplitude was seen in 4/5 participants from NF1 to NF2 for both limbs (Un*affected limb – NF1:* 1.85N/kg (±0.31) NF2: 1.90N/kg (±0.38) *affected limb* - NF1: 1.22N/kg (±0.39) NF2: 1.38N/kg (±0.47)). The time where this first peak happened did not change between the two conditions, which made the rate of loading of the first peak increase in 4/5 participants for both limbs as well (*affected limb* - NF1: 12.71 N/kg·s (±8.28) NF2: 14.19 N/kg·s (±9.60); *unaffected limb – NF1:* 19.72N/kg·s (±3.92) NF2: 20.72N/kg·s (±5.46)).

With respect to the second peak, only the amplitude in the unaffected limb showed an increase in all participants (NF1: 1.80N/kg (±0.48) NF2: 1.96N/kg (±0.41)). The time where the second peak occurred did not change. The total A/P impulse (Appendix D) was not significantly different between conditions in both limbs; but an increase in negative (braking) impulse was observed in both limbs for all participants between conditions (*affected limb* – NF1: -18.22kg·m/s (±8.43) NF2: -18.9kg·m/s (±8.77); *unaffected limb* - NF1: -21.4kg·m/s (±8.02) NF2: -24kg·m/s (±8)). All the results are presented in Appendix D.



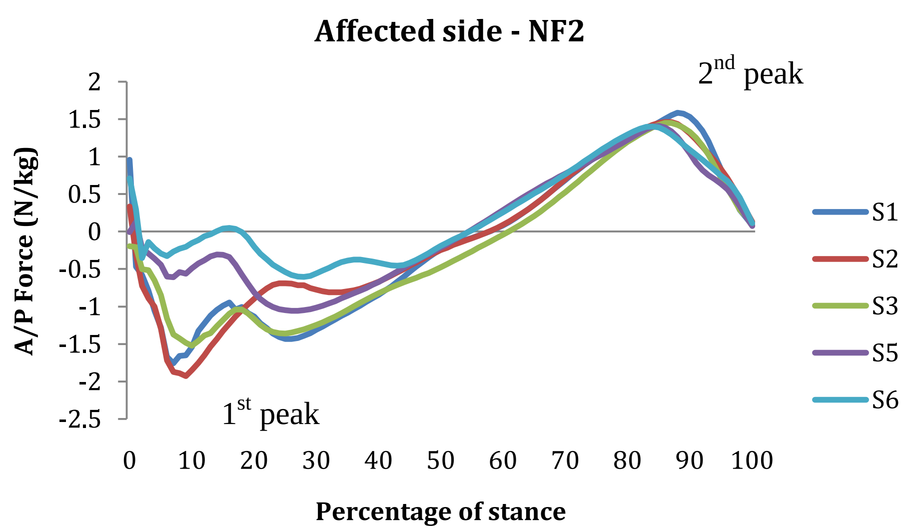


Figure 5.1. Affected side ground reaction forces in the antero-posterior direction. Individual lines represent mean values from a given subject. The NF1 condition is shown in the top graph and the NF2 condition is given on the bottom graph. Data are time normalized to percent of stance

Vertical ground reaction force – The vertical forces were fairly similar in terms of amplitude and time of occurrence (Figure 5.2), but the rate of loading to the initial peak force seemed to increase in both limbs between conditions. In the unaffected limb the increase is observed in 3 subjects while on the affected limb the increase is seen in all participants (*affected limb* NF1: 108.75N/kg (±33.21) NF2: 126.02N/kg (±44.91); *unaffected limb* – NF1: 121.86N/kg (±42.99) NF2: 149.62N/kg (±58.25)).

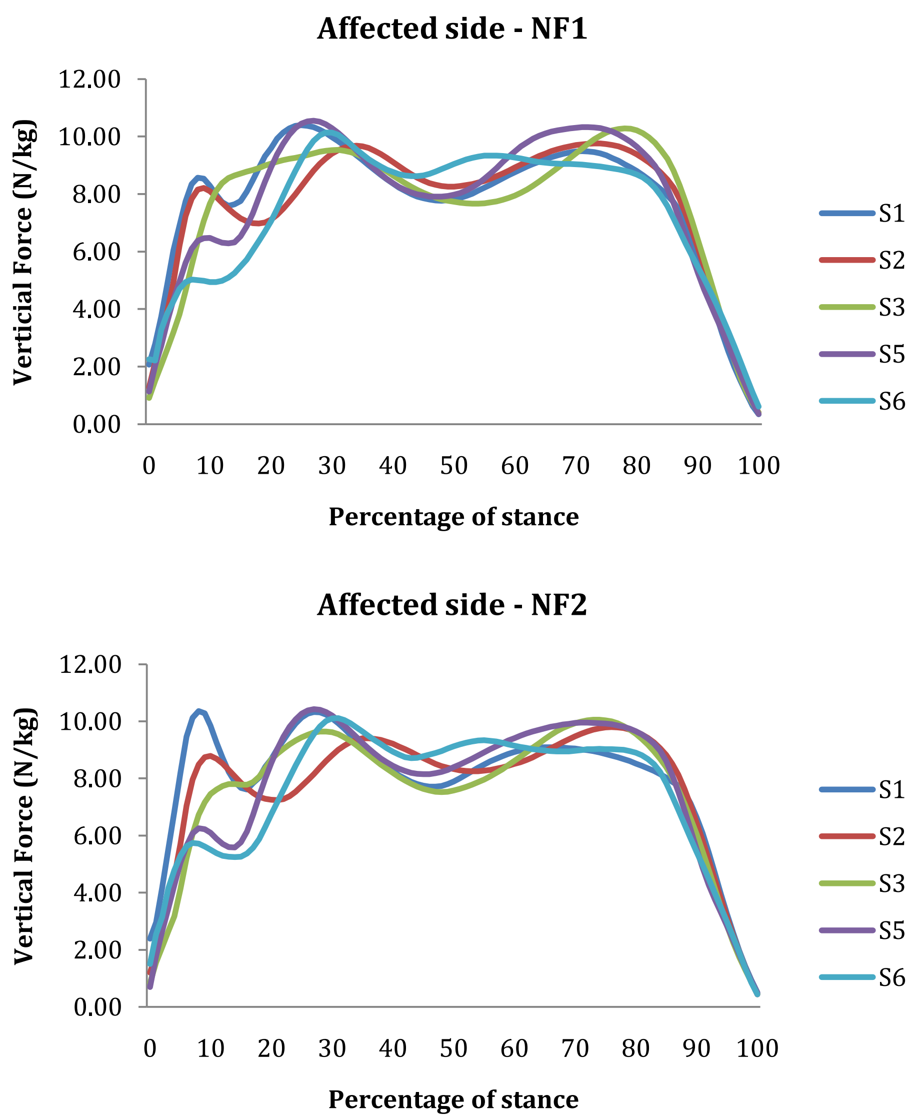


Figure 5.2. Affected side average ground reaction force in the vertical direction. Individual lines represent mean values from a given subject. The NF1 condition is shown in the top graph and the NF2 condition is given on the bottom graph. Data are time normalized to percent of stance.

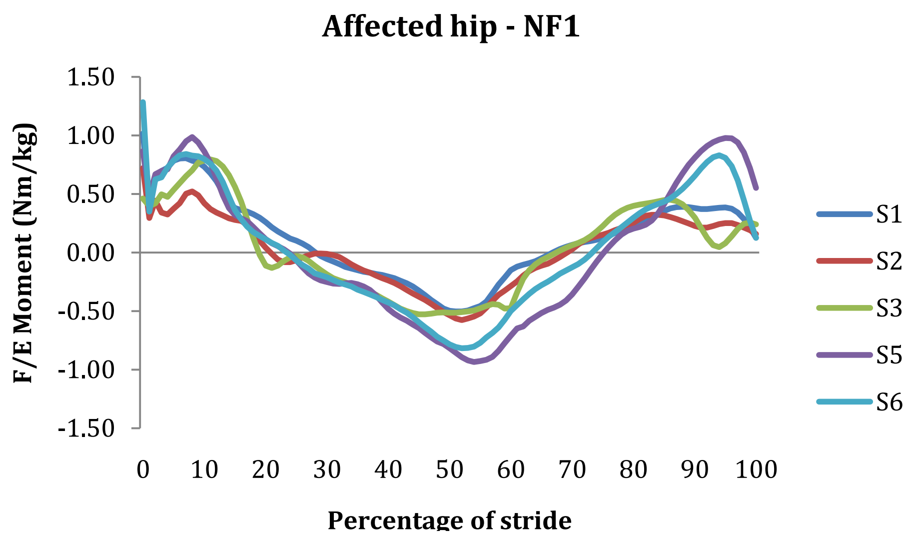
The average vertical force throughout the stance was not significantly different between conditions; some subjects showed an increase and some others showed a decrease. The increase was seen in 2 subjects for the unaffected and affected limb support. The decrease was seen in 3 subjects in the unaffected limb, and only 2 people showed a decrease in the affected limb because one subject did not show any difference in average ground reaction force on the affected limb. On average the affected limb showed a very small decrease, where the unaffected limb showed a slightly bigger difference (affected limb NF1: 7.29N/kg (±1.04) NF2: 7.30N/kg (±1.07); unaffected limb – NF1: 7.72N/kg (±1.08) NF2: 7.85N/kg (±1.19)). All results are presented in Appendix D.

5.1.4 Net joint moments

Affected side - At the hip, F/E trends were observed during the last part of the stride (Figure 5.3). An increase in hip flexor moment in the late stance phase was found in 4/5 subjects (NF1: -0.69N/kg·m (±0.19) NF2: -0.71N/kg·m (±0.20)). During the swing phase the maximum hip flexion moment was reduced in all subjects (NF1: -0.32N/kg·m (±0.16) NF2: -0.41N/kg·m (±0.18)) and the maximum hip extension moment increased in 4/5 subjects (NF1: 0.44N/kg·m (±0.04) NF2: 0.61N/kg·m (±0.29). At the hip, the abd/add moment did not show any trend. All the affected hip F/E results are presented in

Table E.2 and affected abd/add results in Table E.5.

In the affected limb, F/E trends were observed during the early and late stance at the knee in 4/5 subjects (Figure 5.4). The peak knee extensor moment in early stance increased between conditions (NF1: -0.33N/kg·m (±0.29) NF2: -0.29N/kg·m (±0.23)) while the late stance knee extensor moment decreased (NF1: -0.29N/kg·m (±0.10) NF2: -0.32N/kg·m (±0.07)). All the affected knee F/E results are presented in Table E.1.



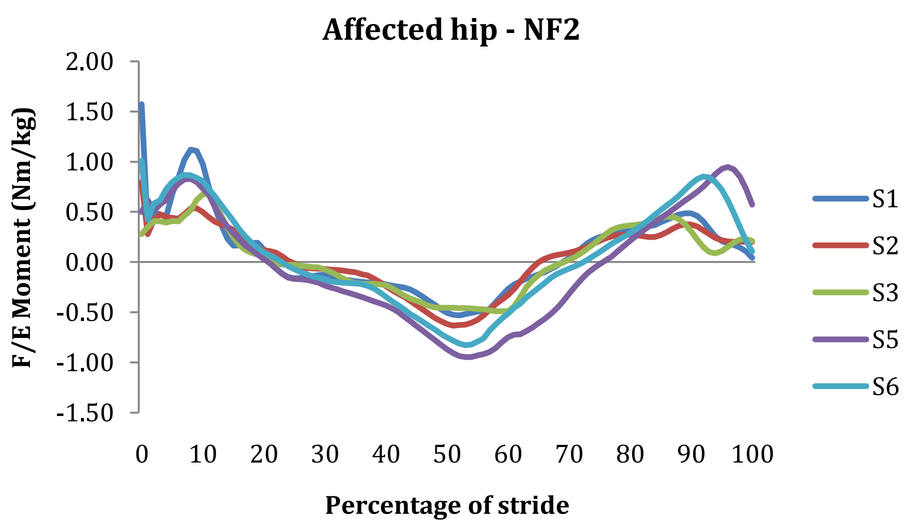


Figure 5.3. Affected flexion/extension hip moment. Individual lines represent mean values for a given subject. Positive values represent extension moments and negative represent flexion moments. The NF1 condition is shown in the top graph and the NF2 condition is given on the bottom graph. Data are time normalized to percent of stride.

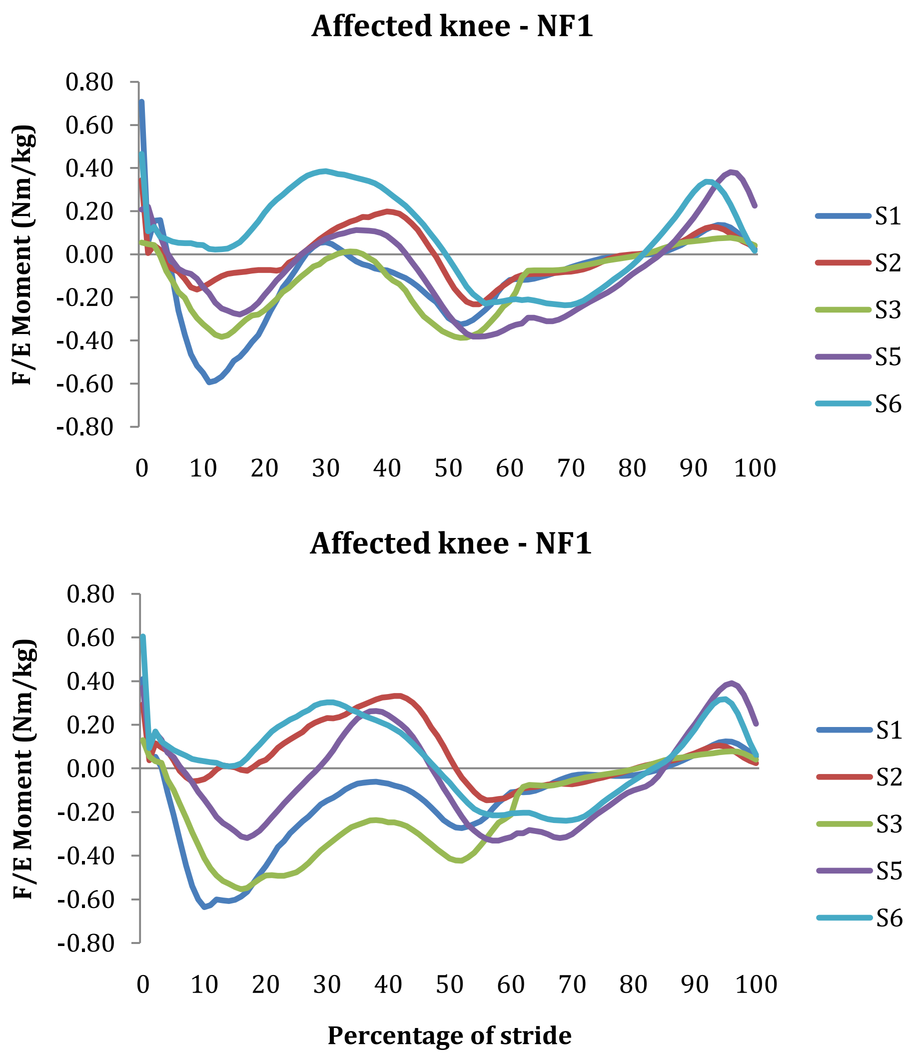
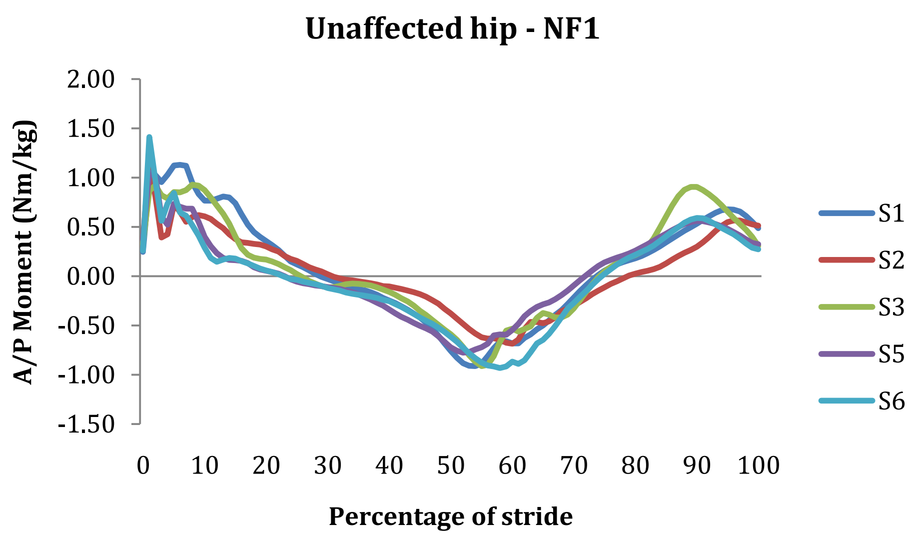


Figure 5.4. Affected flexion/extension knee moment. Individual lines represent mean values for a given subject. Positive values represent flexion moments and negative represent extension moments. The NF1 condition is shown in the top graph and the NF2 condition is given on the bottom graph. Data are time normalized to percent of stride.

Unaffected side – Although no significant differences were found between the NF1 and NF2 conditions in the knee and hip moments of the unaffected side, strong trends were seen especially in the hip. The peak hip extension moment (Figure 5.5) at early stance increased between conditions in 4/5 subjects (NF1: 0.83N/kg·m (±0.23) NF2: 0.91N/kg·m (±0.21)). During the swing phase the minimum and maximum hip F/E peak moments decreased (NF1: -

0.44N/kg·m (±0.05) NF2: -0.51N/kg·m (±0.08)) and increased (NF1: 0.70N/kg·m (±0.13) NF2: 0.80N/kg·m (±0.10)) respectively. The maximum knee moment (Figure 5.6) during the swing increased in 4/5 subjects (NF1: 0.34N/kg·m (±0.02) NF2: 0.36N/kg·m (±0.03)). All the unaffected knee F/E results are presented in Table E.3 and unaffected hip F/E results in Table E.4. At the hip, the abd/add moments did not show any trend throughout the stance. All results are presented in Table E.6.



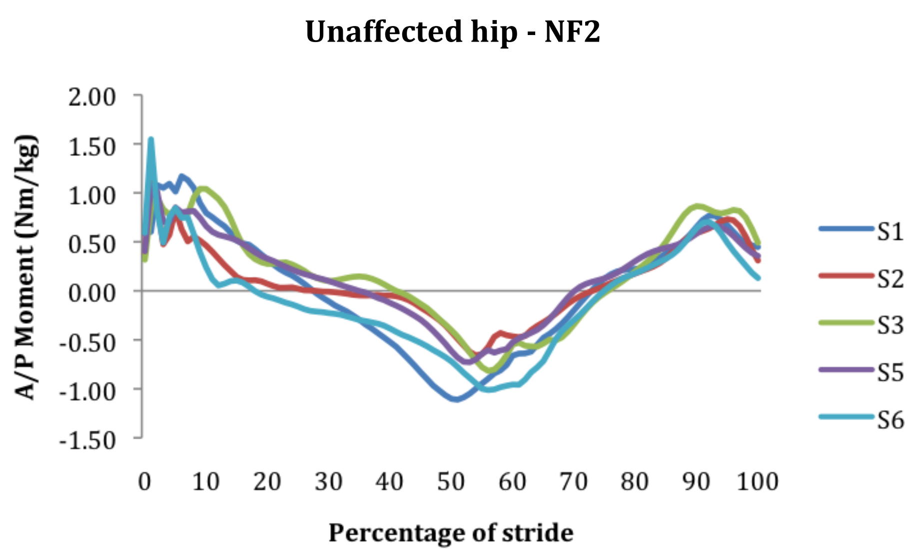


Figure 5.5. Unaffected flexion/extension hip moment. Individual lines represent mean values from a given subject. Positive values represent extension moments and negative represent flexion moments. The NF1 condition is shown in the top graph and the NF2 condition is given on the bottom graph. Data are time normalized to percent of stride.

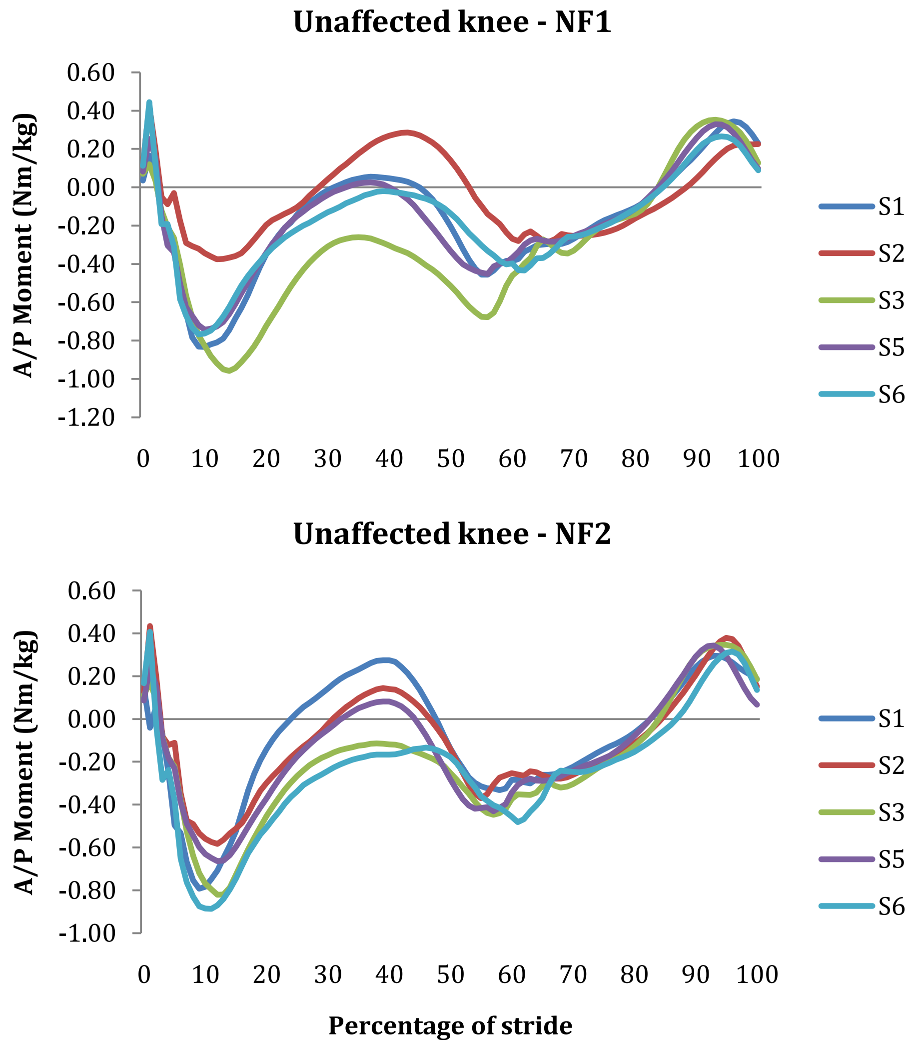


Figure 5.6. Unaffected flexion/extension knee moment. Individual lines represent mean values from a given subject. Positive values represent flexion moments and negative represent extension moments. The NF1 condition is shown in the top graphs and the NF2 condition is given on the bottom graphs. Data are time normalized to percent of stride.

5.1.5 Net joint power

Affected side – For the affected limb, trends were observed in the joint power at the hip and at the knee level. During the affected leg stance, the hip energy generation of the affected limb decreased with NF2 (Figure 5.7). This decrease was observed at the H1 burst between conditions (NF1: 1.42W/kg (±0.37) NF2: 1.14W/kg (±0.40)). For some subjects (2,3,5), a reduction of over 25% in magnitude was seen from NF1 to NF2; subject 2 showed a decrease of over 50%. The knee (Figure 5.8) of the affected side showed an increase in energy absorption (K1) with the NF2 at early stance (NF1: -0.43W/kg (±0.54) NF2: -0.47W/kg (±0.60)). All knee power results are shown in the Table F.1 and hip power results in Table F.2.

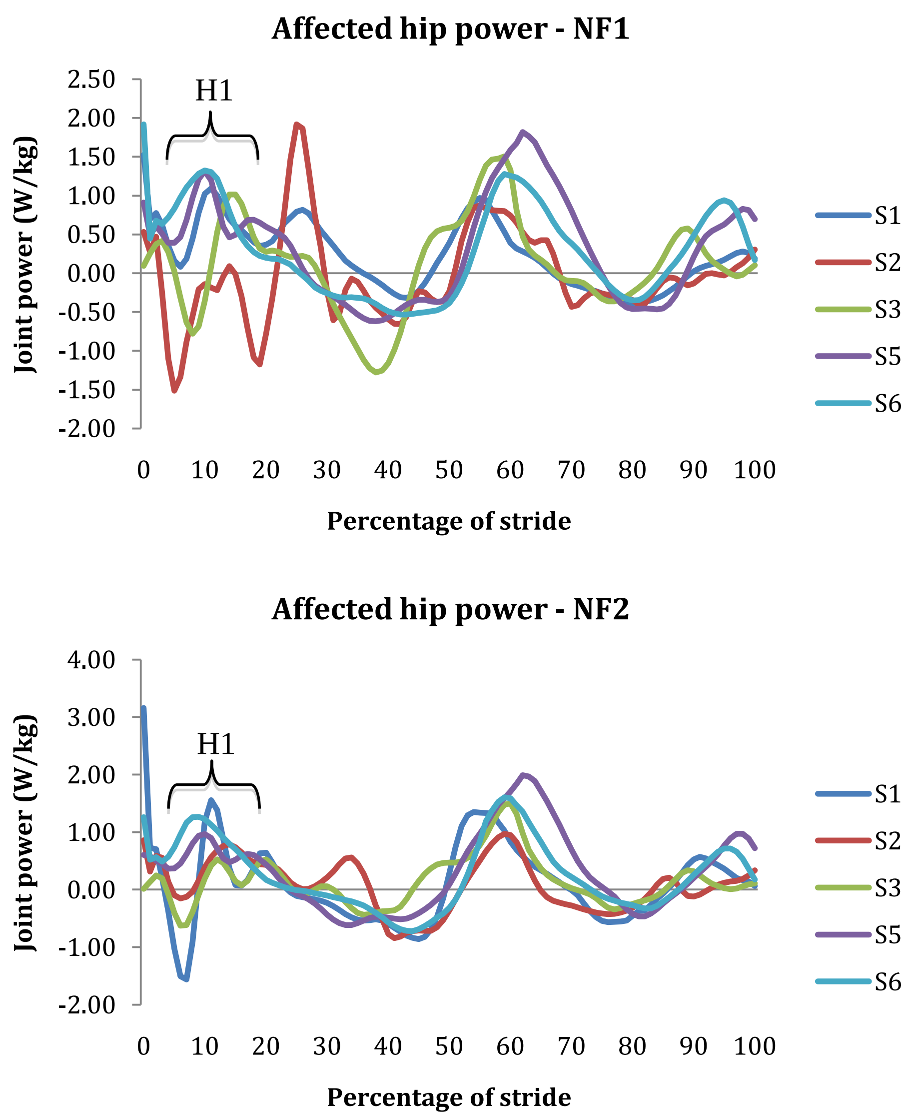


Figure 5.7. Mechanical power generation and absorption at the affected hip. Individual lines represent mean values from a given subject. The NF1 condition is shown in the top graph and the NF2 condition is given on the bottom graph. Energy generation is +ve and energy absorption power is –ve. Data are time normalized to percent of stride.

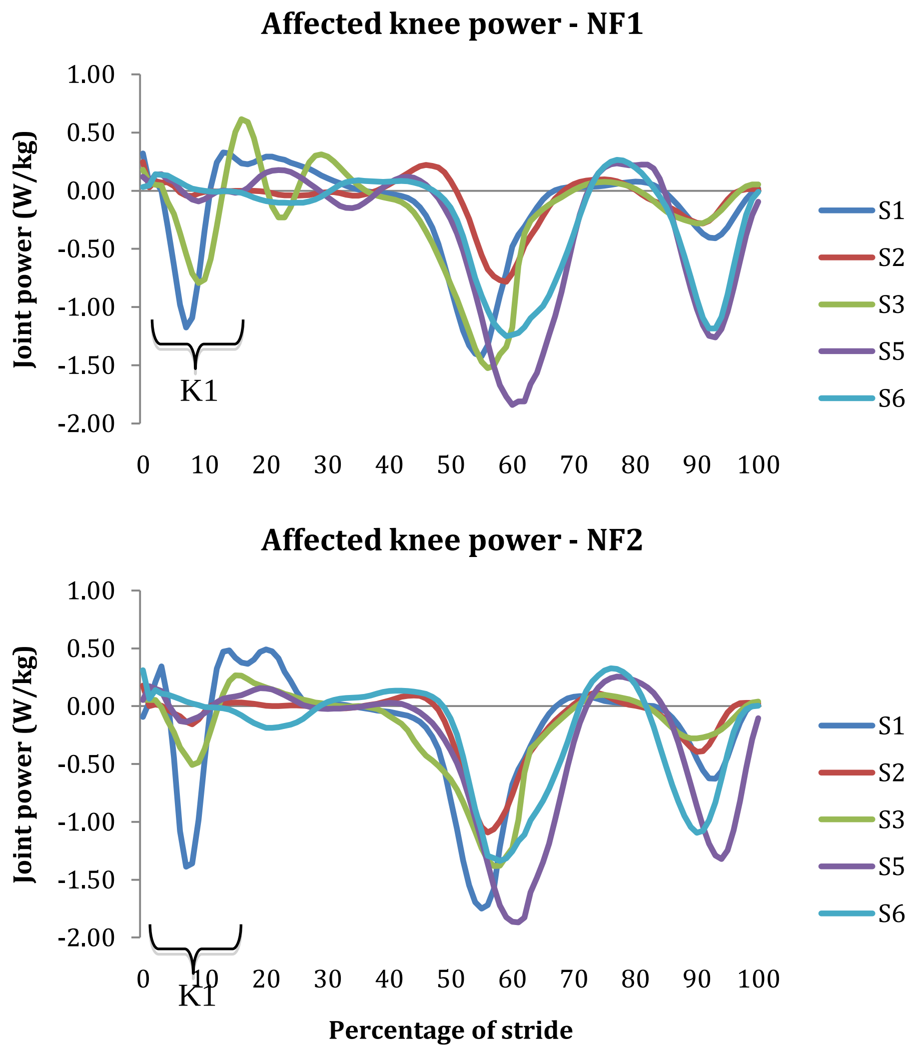
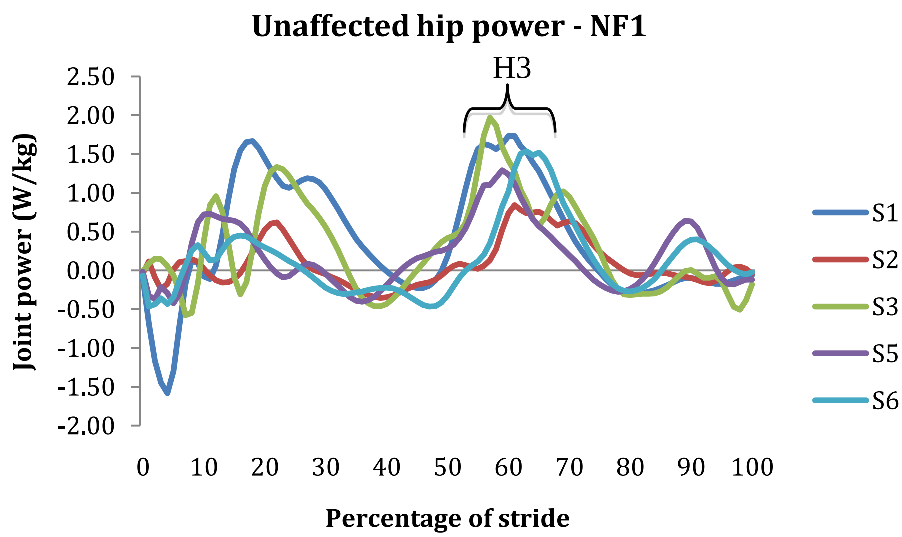


Figure 5.8. Mechanical power generation and absorption at the affected knee. Individual lines represent mean values from a given subject. The NF1 condition is shown in the top graph and the NF2 condition is given on the bottom graph. Energy generation is +ve and energy absorption is –ve. Data are time normalized to percent of stride.

Unaffected side - When looking at the stance phase of the unaffected leg stance, a decrease in energy generation was observed during late stance in the hip (H3) (Figure 5.9), (NF1: 1.67W (±0.45) NF2: 1.54W (±0.30)). This point in time corresponds to the initial foot contact of the affected leg. The unaffected knee did not show any trends (Figure 5.10). All knee power results are showed in Table F.1 and hip power results in Table F.2.



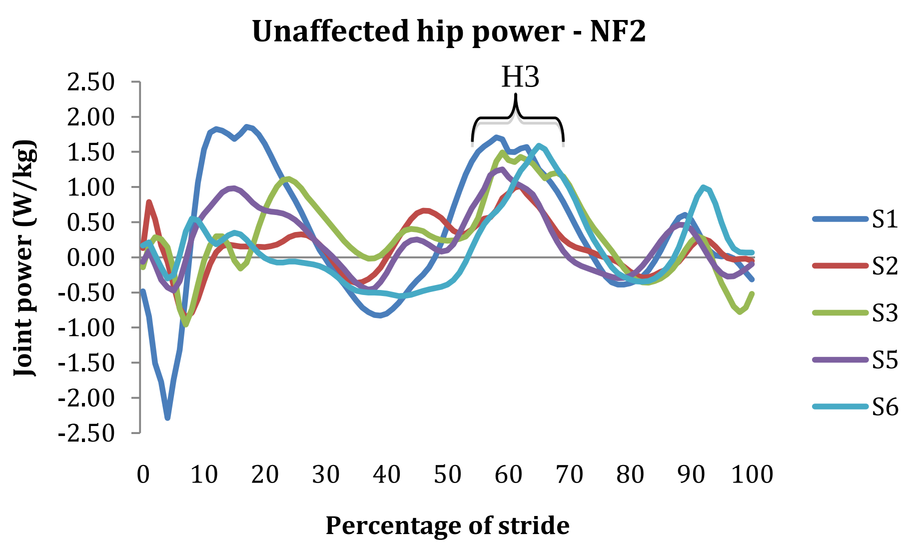


Figure 5.9. Mechanical power generation and absorption at the unaffected hip. Individual lines represent mean values from a given subject. The NF1 condition is shown in the top graph and the NF2 condition is given on the bottom graph. Energy generation is +ve and energy absorption is –ve. Data are time normalized to percent of stride.

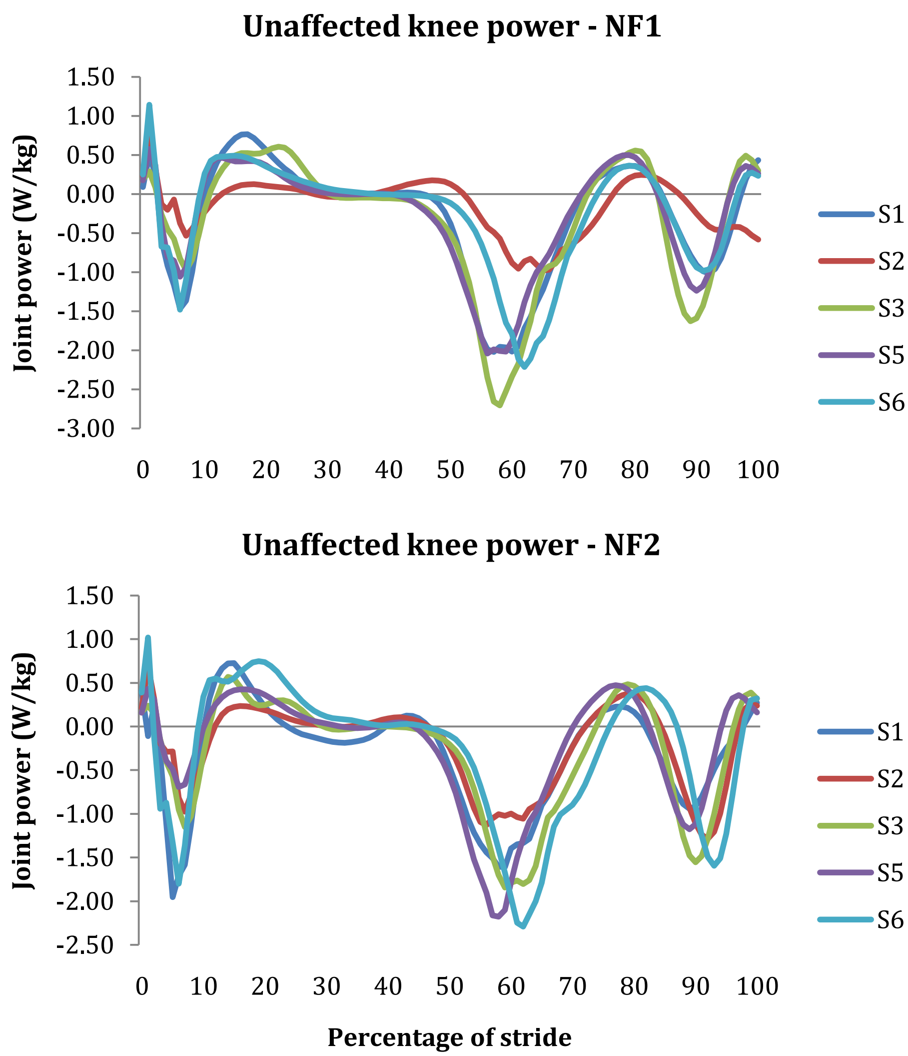


Figure 5.10. Mechanical power generation and absorption at the unaffected knee. Individual lines represent mean values from a given subject. The NF1 condition is shown in the top graph and the NF2 condition is given on the bottom graph. Energy generation is +ve and energy absorption is –ve. Data are time normalized to percent of stride.

5.1.6 Foot deformation

5.1.6.1 Mechanical deformation

In order to characterize the stiffness of the foot material, one previously used NF1 foot (used by S2) and one previously used NF2 foot (used by S5) were mechanically tested. These were compared to one unused NF1 and one unused NF2 foot model.

Testing on the heel section was at an angle of 15 degrees in order to reproduce loading during weight acceptance in the gait phase. This test showed that the NF2 condition had less overall deflection at 1200 N of load when compared to the NF1 (Figure 5.11). The NF2 feet displacement under a load of 1200N, reached a total of 6.5mm where the NF1 unused and control reached a total of 7.5mm. The used NF1 showed a tendency toward the NF2 displacement. The feet started showing a difference in displacement at around 100N of load (Figure 5.11, zone 2). The different trend started to be more obvious when the load reached 400N (Figure 5.11, zone 3), where the NF2 group showed a displacement of 4.5mm and the NF1 group of 5.5mm.

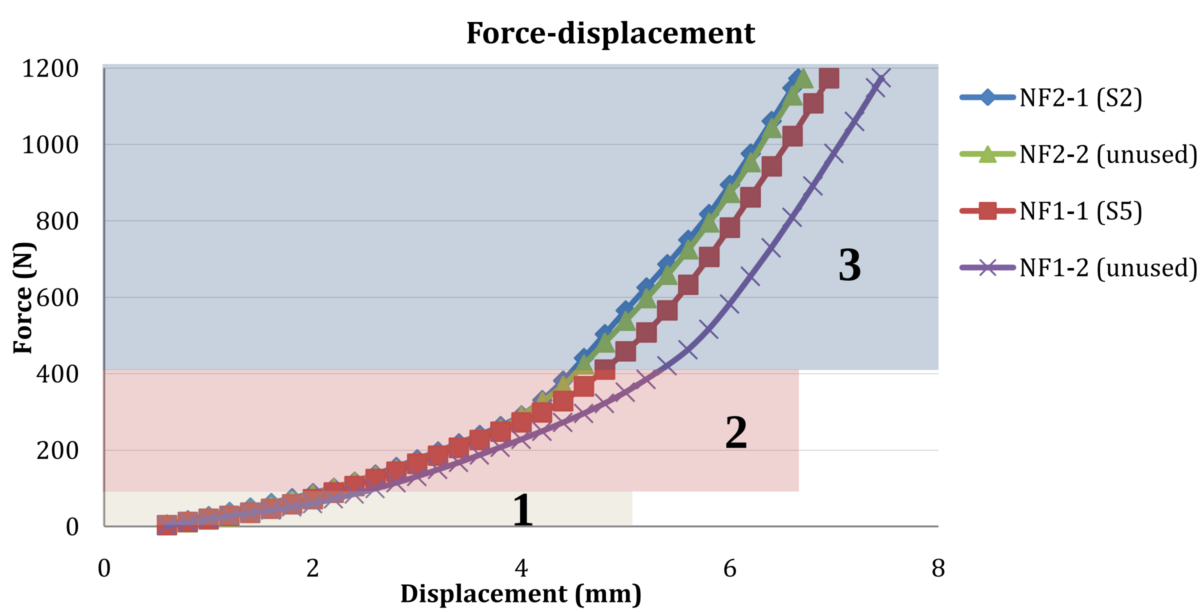


Figure 5.11. Force-displacement for the loading on the heel at 15 degrees. Individual lines represent one foot. The three zones highlight changing force-displacement relationships over the range of loading.

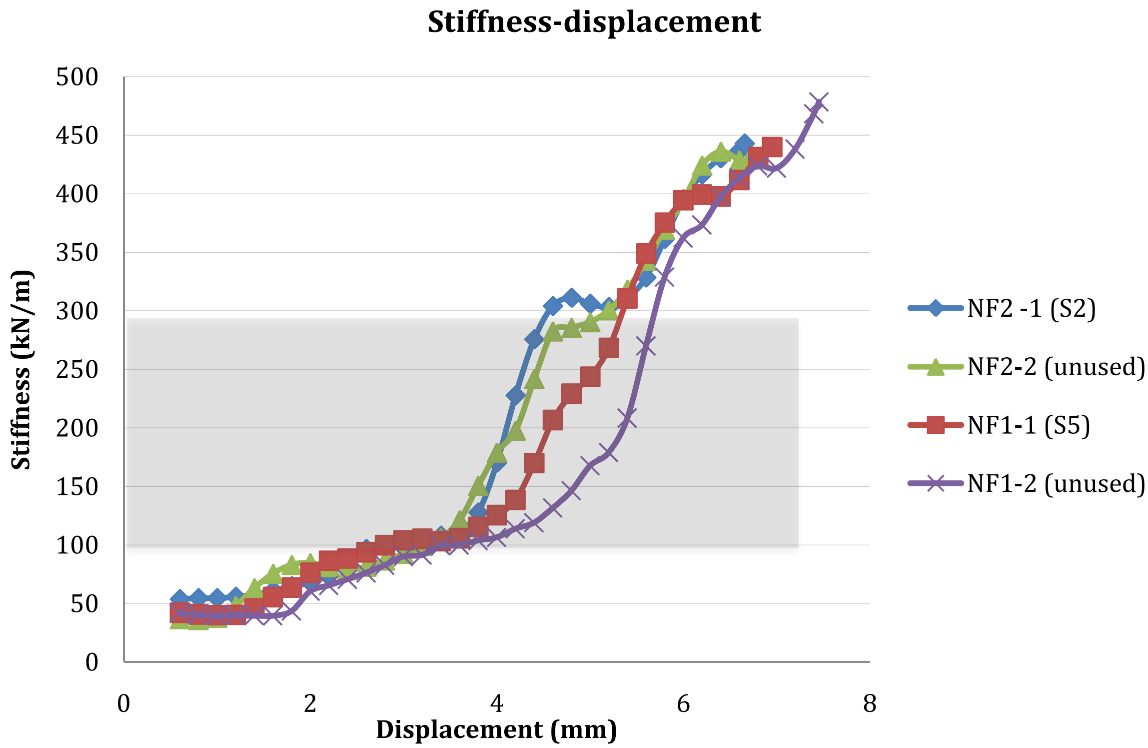


Figure 5.12. Stiffness-displacement curve for the loading on the heel at 15 degrees. Individual lines represent each foot tested. The shaded region highlights where the main difference between the heel conditions occurs.

When observing the stiffness-displacement trends of the NF1 and NF2 feet during the heel compression tests (Figure 5.12), the NF1 and NF2 showed comparable overall foot stiffness up to 3.5 mm of displacement and more than 6 mm of displacement. The main difference between the two heel conditions was observed during the middle phase (3.5 to 5 mm of displacement), where the overall foot stiffness changes more rapidly in the NF2 compared to the NF1.

5.1.6.2 Gait-based deformation

Distances between markers attached to the prosthetic foot were compared between conditions to observe the foot deformation during gait. The mechanical deformations observed between the NF1 and NF2 conditions were not significantly different but showed trends in 4 to 5 participants. The heel extension was defined as an increase in the distance between the heel marker and the top marker on the foot. Conversely, the heel compression was defined as a reduction of the distance. During the weight acceptance phase, an increase in the deformation of the NF2 heel section was observed (Figure 5.13). This increase was observed in 4/5 participants (NF1: 9.7mm (±4.29) NF2: 11.66mm (±4.85)). During the push off phase at the end of stance, a decrease in the heel extension was observed in all participants (NF1: 4mm (±0.94) NF2: 3.47mm (±0.86)). Some subjects showed an increase in the heel compression up to 5% but only a decrease of 1% in the heel extension (Figure 5.14).

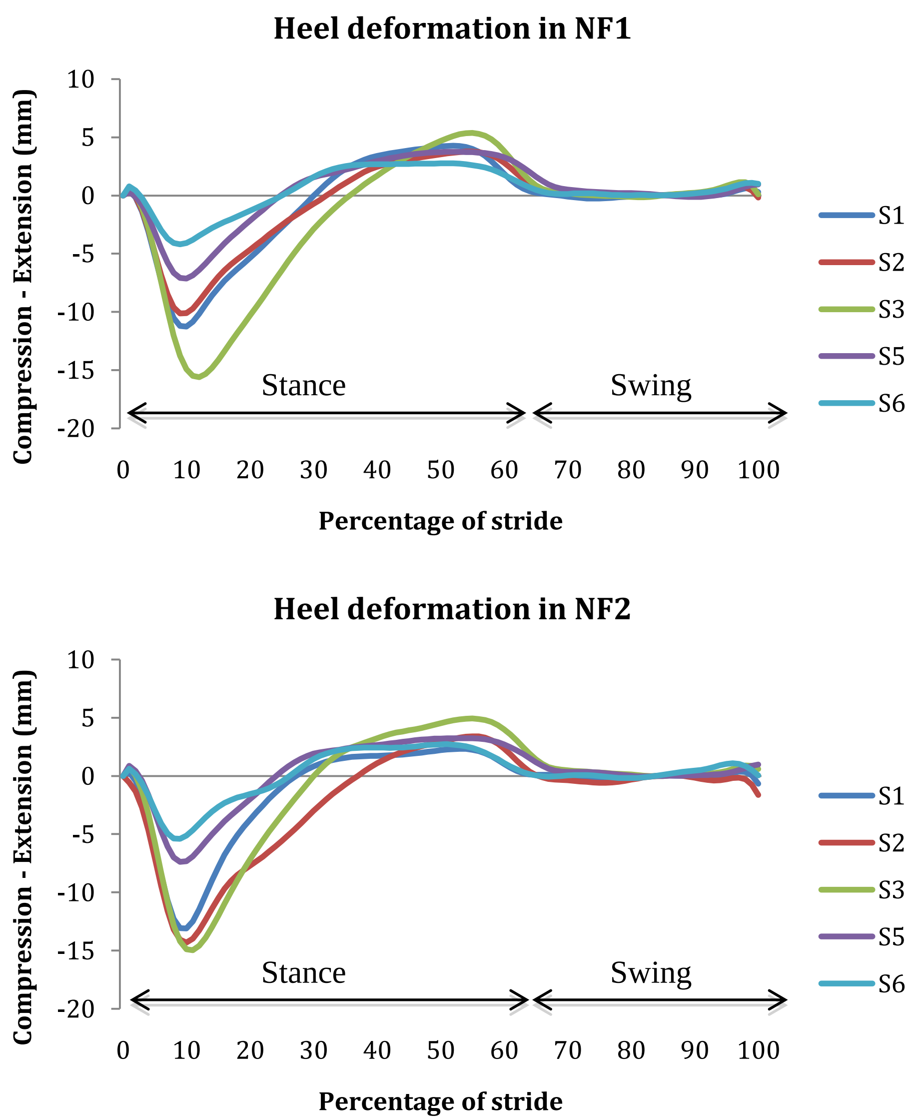


Figure 5.13. Mechanical heel compression and extension deformations. The NF1 condition is shown in the top graph and the NF2 condition is given on the bottom graph. Individual lines represent mean values from a given subject. Data are time normalized to percent of stride.

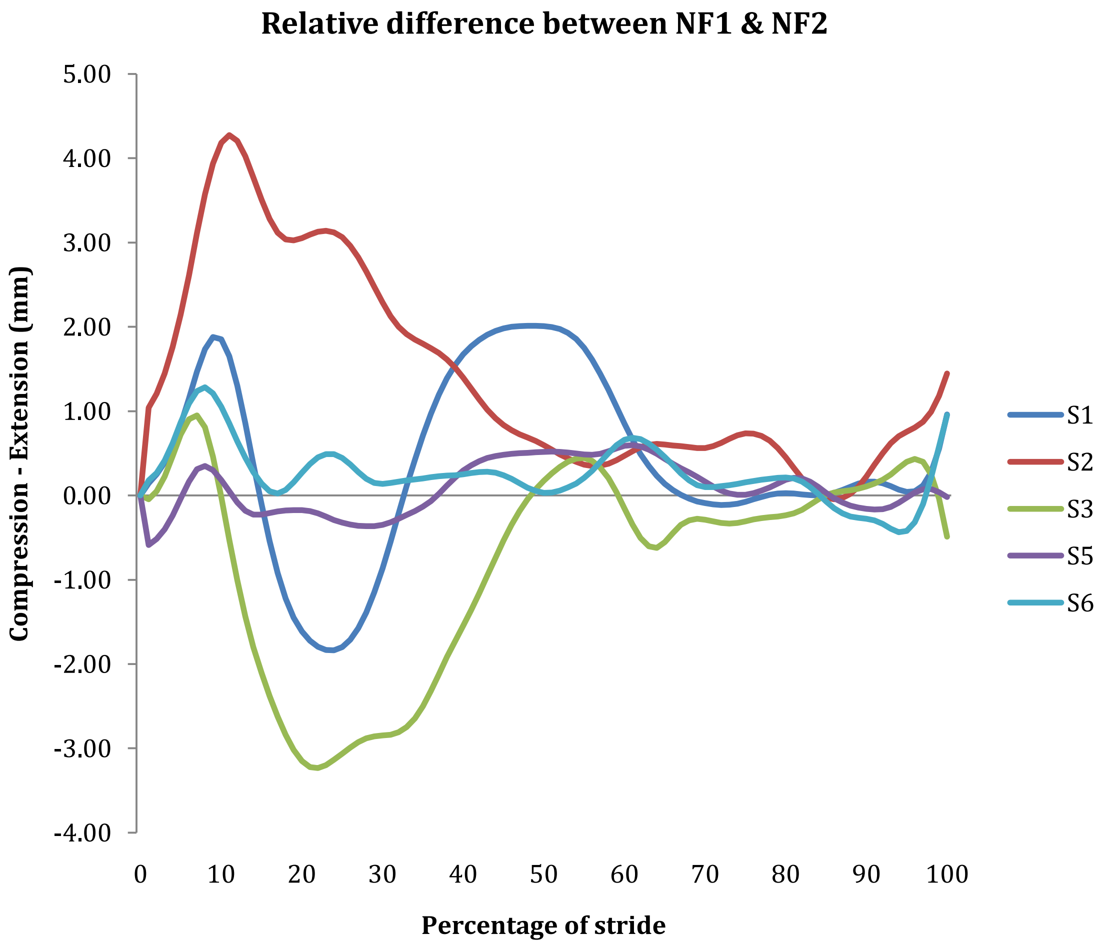


Figure 5.14. Relative heel deformation difference between NF1 and NF2. Individual lines represent mean values from a given subject. Individual lines represent the result of (NF1 – NF2) of the same subject. Relative heel extension deformation is +ve and heel compression deformation is –ve. Data are time normalized to percent of stride.

At the time of heel strike the angle of the foot did not change from one condition to another and no trends were observed (Table G.1). To pass from heel strike to foot flat, 3 subjects showed a faster transition in the NF2 condition (time after beginning of the stride of all five participants NF1: 0.144s (±0.028) NF2: 0.142s (±0.015)). This observation may be related to the shorter stance phase mentioned for the NF2 condition of the affected limb. The foot flat occurred at 12.74% of the stride (±2.26) for the NF1 and at 12.57% of the stride (±1.28) for the NF2.

5.1.6.3 Roll-over shape

When describing the mechanical deformation with the roll-over shape no trends were found comparing the NF1 and NF2 by the arc length variable. A decrease of 7mm in the arc length was seen in 2/5 participants, where two others showed an increase of ~1mm and ~3mm and the last participant did not show any change (Table 5.4).

Table 5.4. Arc length of the roll-over shape

	C1 (mm)	NF1 (mm)	NF2 (mm)
S1	202.56	185.70	178.26
S2	229.63	187.15	180.21
S3	231.02	183.10	186.21
S5	214.03	190.28	191.92
S6	225.32	197.66	197.20
Average	220.51	188.78	186.76
SD	12.05	5.60	7.92

C1: Participant's own foot data, NF1: NF1 data, and NF2: NF2 data

The overall shape of the roll-over was comparable from NF1 to NF2. Visual inspection reveals some differences in the inclination of the arc especially in the late phase of the gait (Figure 5.15).

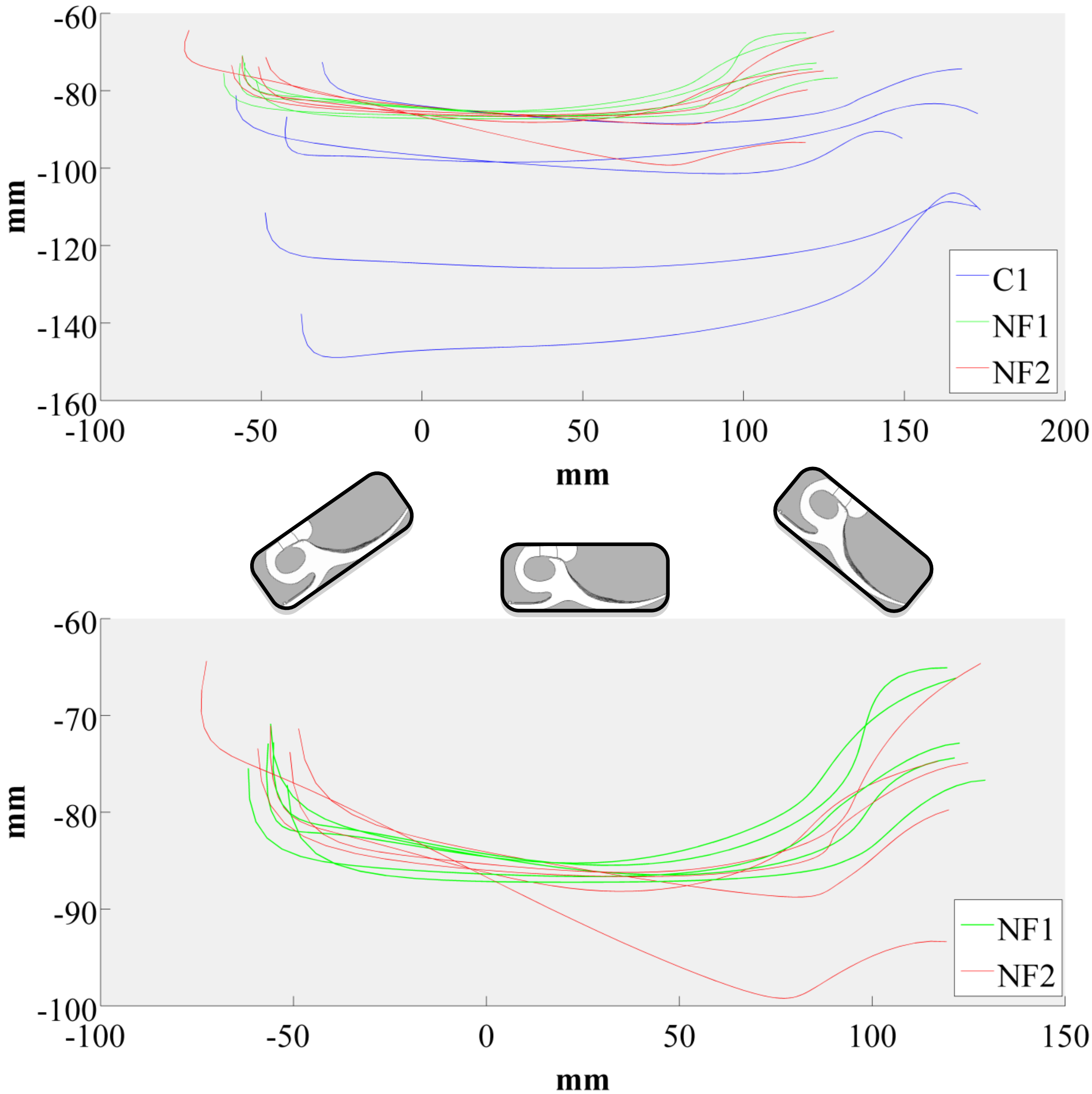


Figure 5.15. Roll-over shape, the top graph represent the three conditions and the bottom graph shows the same data but only for the NF conditions. Individual lines represent mean condition values from a given subject. The participant's original foot condition is shown in blue (C1) where the NF1 is in green and the NF2 is in red. The heel strike occurs on the left side around the -50mm mark and the toe off at the right at the 120mm mark. Data are normalized and expressed in absolute displacement.

5.2 EMG

Muscle activity was recorded throughout the gait cycle. The EMG signals during the heel strike phase and the swing phase were averaged for each muscle. Emphasis was placed on the period around heel strike of the affected limb and the swing phase of the unaffected limb where the effect of the heel modification on the EMG signal was suspected. During the heel strike phase of the affected leg, the rectus femoris of the affected limb (Figure 5.16) decreased its activity in 4/5 participants (NF1: 8.41mv (±6.06) NF2: 7.66mv (±5.66)) and the biceps femoris of the affected limb (Figure 5.17) increased its activity in 4/5 participants (NF1: 11.34mv (±4.12) NF2: 19.42mv (±11.58)).

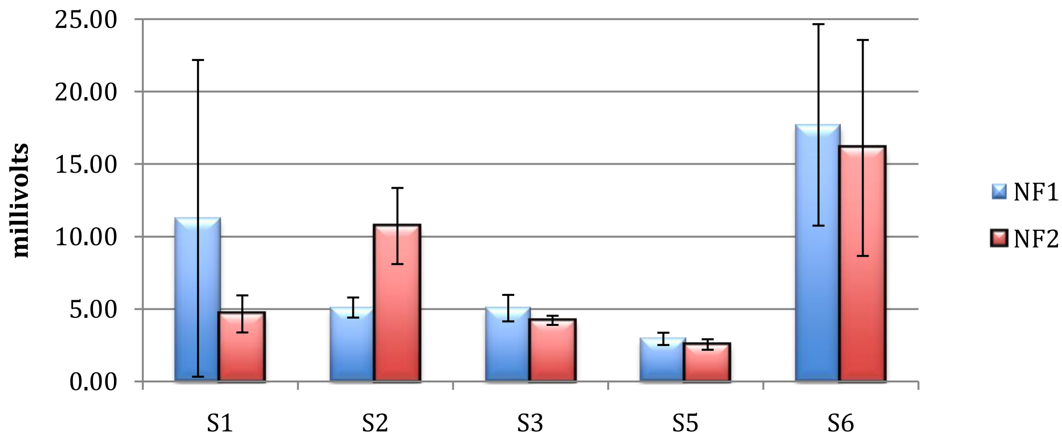


Figure 5.16. Average affected rectus femoris EMG activity during the heel strike phase. Individual bars represent mean values from a given subject with standard deviations.

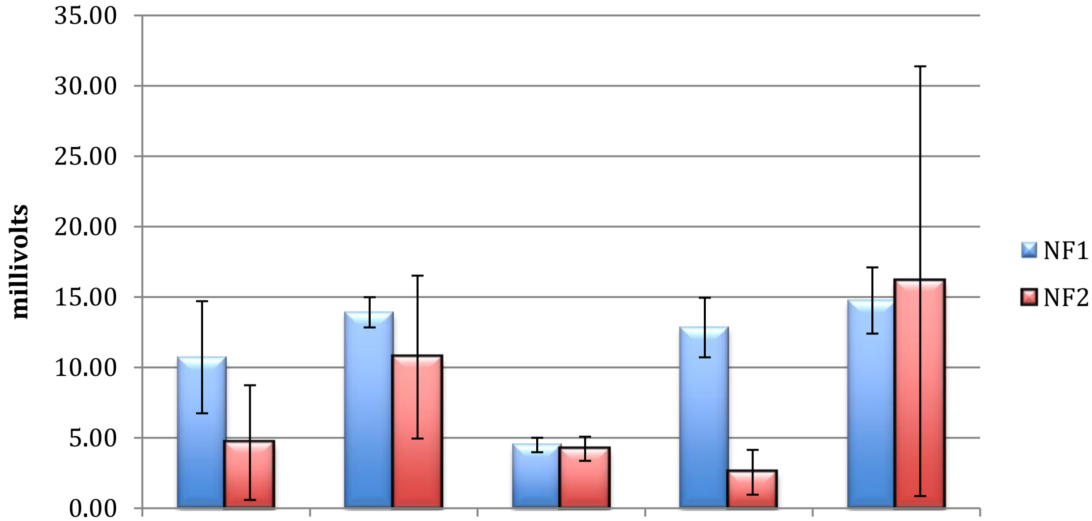


Figure 5.17. Average affected biceps femoris EMG activity during heel strike phase. Individual bar represents mean values from a given subject with standard deviation.

During the swing phase the unaffected limb showed a decrease in muscle activity in the rectus femoris in 4/5 participants (NF1: 5.38mv (±2.17) NF2: 3.25mv (±1.95)) and an increase in muscle activity in the biceps femoris (Figure 5.18) in 4/5 participants (NF1: 3.67mv (±2.21) NF2: 4.56mv (0.61)) and the gluteus maximus in 4/5 participants (Figure 5.19, NF1: 2.67mv (±2.25) NF2: 5.47mv (±6.02)).

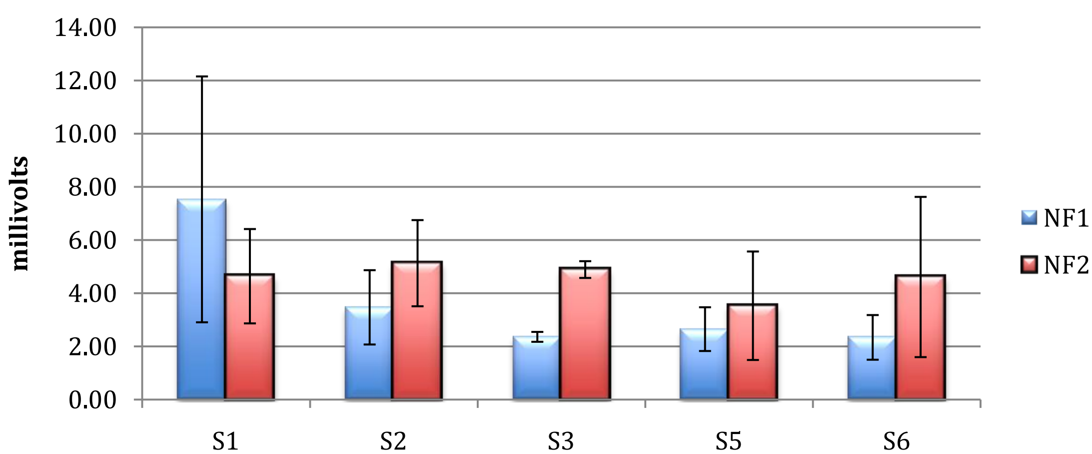


Figure 5.18. Average unaffected biceps femoris EMG activity during swing phase. Individual bar represents mean values from a given subject with standard deviations.

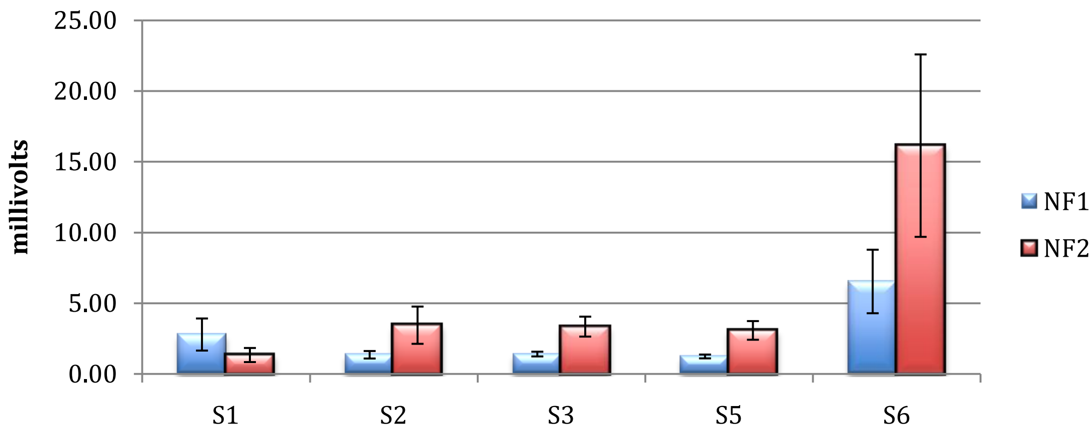


Figure 5.19. Average unaffected gluteus maximus EMG activity during swing phase. Individual bar represents mean values from a given subject with standard deviations.

The complete results of the EMG signals are presented in Table H.1.

5.3 Prosthesis Evaluation Questionnaire

On average, the changes in the PEQ scores were relatively small between the NF1 and NF2 conditions. However, a high standard deviation was found when looking at the total scale scores (Figure 5.20). This may indicate that the perception of the NF was different between participants (Table 5.5).

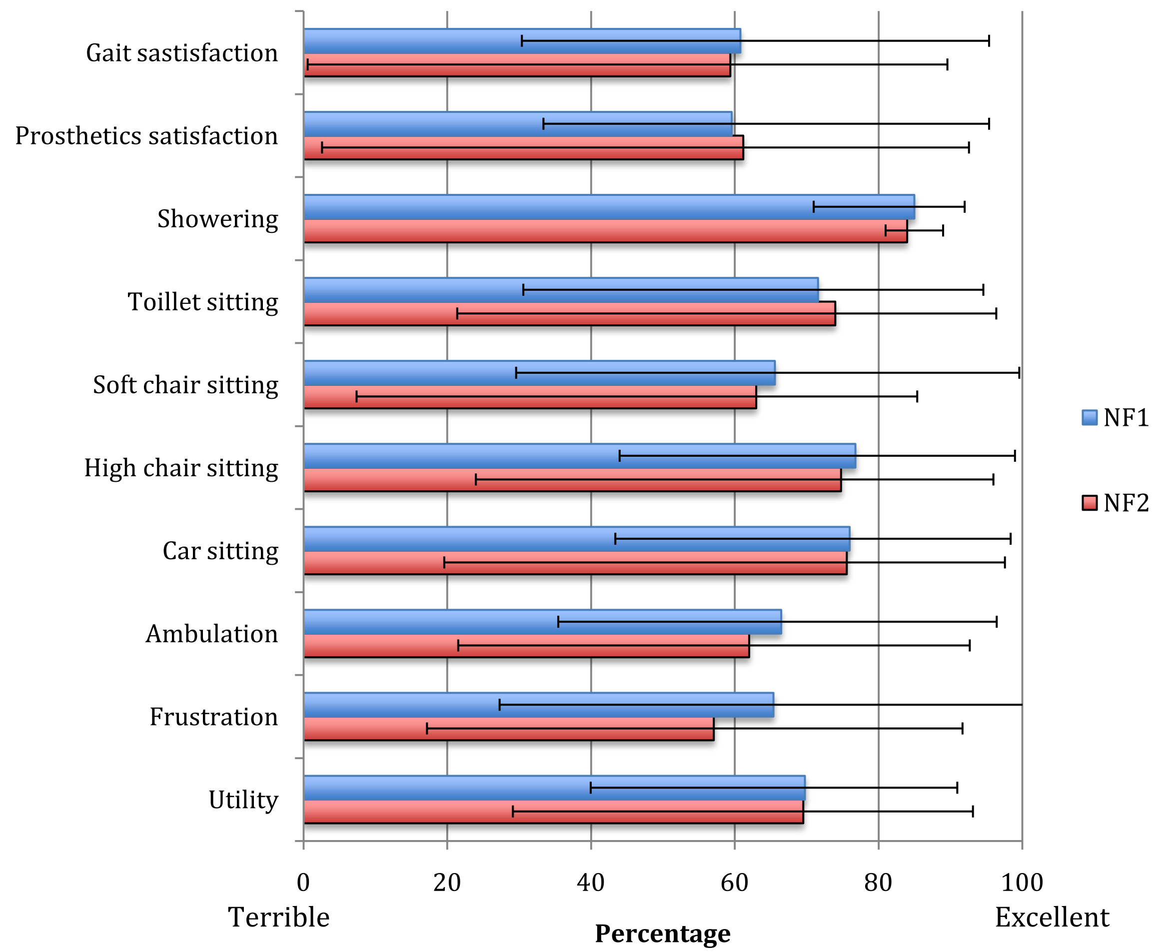


Figure 5.20. PEQ scale results. Individual bars represent mean values from all subjects with the bar error indicating the minimal and maximal values for the scale. Greater values indicate a more positive response.

Greater differences were found between participants in the frustration, gait and prosthetic satisfaction area. A strong majority (4/5) (Figure 5.21), of the participants had greater scores (more positive response) with the NF2 in the utility scale that describes, in general, the direct interaction with the prosthesis (fit, weight, standing, sitting, balance, energy, feeling, and donning). Smaller standard deviation for the NF2 was observed in the two satisfaction scales.

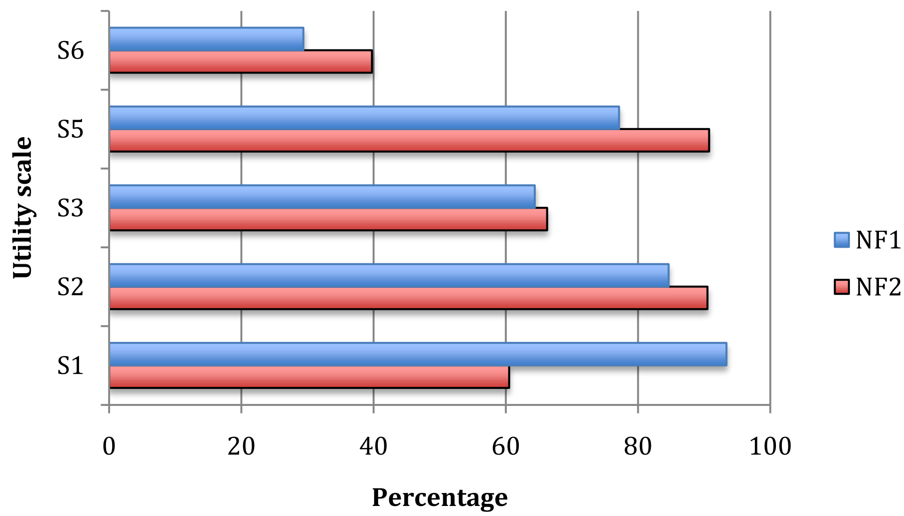


Figure 5.21. PEQ utility scale results. Individual bars represent values for a given subject.

Table 5.5. PEQ subject average results of the scales categories

Scale		NF1		NF2	
		Subject mean (SD)		Subject mean (SD)	
Utility	Total (max 800)	558.20	(200)	556.40	(171)
	Average	69.78	(25)	69.55	(21)
Frustration	Total (max 200)	130.80	(70)	114.20	(59)
	Average	65.40	(35)	57.10	(30)
Ambulation	Total (max 600)	471.60	(217)	514.60	(208)
	Average	66.48	(29)	62.02	(24)
Sitting in a car	Average	76.00	(32)	75.60	(22)
Sitting on a high chair	Average	76.80	(30)	74.80	(22)
Sitting on a soft chair	Average	65.60	(32)	63.00	(28)
Sitting on toilet	Average	71.60	(30)	74.00	(26)
Showering	Average	85.00	(4)	84.00	(12)
Prosthetic satisfaction	Average	59.60	(40)	61.20	(28)
Gait satisfaction	Average	60.80	(39)	59.40	(31)

Only NF1 and NF2 are presented here. The C1 session is presented in the Appendix I. Categories including more than one question show the total of all the questions and the average.

The complete results of the PEQ are presented in Table I.1.

Chapter 6

Discussion

Keel stiffness has been studied fairly extensively (Geil, 2002; Klodd, Hansen, Fatone, & Edwards, 2010; van Jaarsveld et al., 1990); however, less is known about the effect of the heel compliance in a prosthetic foot (Klute et al., 2004), especially in vivo. Changing the heel stiffness in prosthetic feet was identified as an important factor affecting gait patterns (Perry, 1992); however, this was done while comparing different feet to each other. Hence, the purpose of the present study was to describe the effect of changing the heel compliance within the same foot design (NF) on the gait characteristics of a person with a TTA. To characterize the effects, the kinematics, the joint forces and kinetics, the mechanical deformations, the EMG and the PEQ outcomes were analyzed. Although in all outcome measures, no statistical differences were found between the NF1 and NF2 conditions, the results provided important quantitative data to better understand the impact of heel stiffness for the NF designers, as well improving the gap in the literature on prosthesis heel stiffness characteristics in people with TTA. This study also showed a counter-intuitive relationship between the compliance of the heel section and the apparent overall foot stiffness in the NF design.

6.1 Kinematics & Kinetics

Spatio-temporal parameters – Gait patterns, in people with amputations, are more dependent on the stride cadence rather than the prosthetic foot type (Cortes et al., 1997). In this study, participants used the same prosthetic foot but did not walk with the same cadence (a variation from 103 to 115 step/min). This variation may have played a role in the high inter-individual variability between the participants. The high cadence difference between the participants may be affected by the socket comfort and vacuum performance (Astrom & Stenstrom, 2004). The difference in the spatio-temporal parameters observed across participants in this study explains the necessity to compare within participants.

The average stride lengths found in this study were 1.25m for NF1 and 1.29m for NF2, which appear low when compared to Murray, Kory, & Clarkson (1969) or Winter (1991) who observed healthy older men's gaits where the average stride length was 1.56m. The average found in the current study is still slightly shorter when compared to other gait studies in populations with amputation such as Waters et al. (1976) and Bateni & Olney (2002) who reported an average of 1.32m and 1.33m respectively. This average is comparable to Winter & Seiko's (1988) results with 1.27m. The small difference seen with previous studies (Bateni & Olney, 2002; Waters et al., 1976) that report higher stride lengths may be explained by the participant's weights and barefoot walking condition used in this present study. Also, only men were included in this study to account for sex differences in gait patterns.

When observing the stance phase of the unaffected limb compared to the affected limb (Table B.1, SPU-SPA), some participants (3/5) in the current study also showed asymmetrical gait confirming previous findings in multiple amputation gait studies (Bateni & Olney, 2002; Culham, Peat, & Newell, 1986; Prince, Allard, Therrien, & McFadyen, 1992). The asymmetrical gait in people with amputations is often explained by the psychological insecurity of the person to bring the weight of their body forward on their unaffected foot during the heel strike of the affected limb (Bateni & Olney, 2002). Furthermore, this asymmetry is also normally explained by the lack of the plantar flexor muscle (Silverman et al., 2008). In this study, 2/5 participants did not show this asymmetry which may be explained by the combination of the energy return effect of the NF and their gait pattern.

Joint ROM – Very few differences were found between the conditions in the ROM in the knee and hip for the F/E and abd/add directions and observed values were comparable to the range described by Bateni & Olney (2002). During the early stance phase the present results agree with previous literature on TTA gait (Bateni & Olney, 2002; Buckley, 1999) when compared to able-bodied gait. Bateni & Olney (2002) have suggested that the smaller knee flexion observed in TTA at early stance lies in the lack of a plantar flexion control in TTA gait. Hence, the similarity in NF1 and NF2 knee flexion ROM may suggest that there is no difference in outcomes between the 2 conditions in order to compensate for plantar flexion action. The only different trend in the ROM that was observed was the decrease from NF1 to NF2 in abd/add of the knee total ROM for 4/5 participants. The small decrease in the knee abd/add ROM in the NF2 may be associated with a possible different alignment between the NF1 and the NF2 systems.

Forces – Ground reaction forces in TTA gait have been previously reported to be lower in the affected side when compared to the unaffected side (Silverman et al., 2008). This was confirmed in this study. When grouping NF1 and NF2 results, 7/10 occasions showed a GRF smaller for the affected side when compared to the unaffected side. When comparisons were made between NF1 and NF2, 2/5 participants showed a greater A/P GRF on the affected side with the NF1 and 1/5 with the NF2. This indicates that GRF changes may not be a function of the heel modification and does not conclusively indicate being a function of the NF either, because 3/5 participants showed the same observation with their own prosthetic foot.

The rate of loading of the GRF during weight acceptance seemed to be slightly faster with the NF2 compared to the NF1. This may indicate that the compression of the foot and absorption of the load might occur faster when the heel component of a prosthetic foot is compliant. One might think that a rapid weight acceptance may provide less comfort to the user by reducing the absorption factor. Although the present study participants did not report any major comfort issues with respect to the NF2, they did mention that the NF2 felt stiffer when compared to the

NF1. This comment was interesting because the NF2 heel section material was thinner and deformed more during the loading phase when walking. The feel of an increase in foot stiffness reported by the subjects may be the result of the faster forward transition of the centre of pressure during the early stance phase. The increase in absorption is also seen in the increase in the extensor knee moment observed in the NF2 limb.

Net joint moments – The NF2 condition seemed to change the late stance pattern of the affected limb. The hip extensor moment of the affected side appears to decrease in the late stance with the use of the NF2. During the same time the knee extensor moment also decreases. The decrease in the hip extensor moment in late stance may consequently reduce the forward motion of the upper body.

Power - The present study also found an important trend between NF1 and NF2 in the net joint power during the early stance of the affected limb that corresponded to the late stance of the unaffected limb, in 4/5 subjects. It is important to note that these time periods occur simultaneously as the early stance of the affected limb corresponds to the late stance of the intact limb.

Although, K1 (Winter, 2005) (the first energy absorption peak in the knee at the start of stance) is a standard peak observed in able-bodied gait, it is not a commonly observed peak in most of the previous studies on TTA gait. Gitter, Czerniecki, & DeGroot (1991) did observe a K1 peak in the affected limb in TTA walking in 2/5 of their subjects using a SACH foot and a Seattle foot. The K1 burst found in the current study does not seem to be a function of the NF design because the peak was also observed while the participants were using their own prosthetic foot. This K1 peak is normally observed in able-body walking as shock absorption during the loading response (Winter, 2005). The increase in energy absorption at the knee may show that the NF2 condition may move the affected limb gait toward the same pattern as the intact limb.

At the hip level the high H1 burst of the affected hip (the first energy generation peak in the hip at the start of stance) is often seen in TTA gait, this burst normally helps propel the affected limb forward. This energy is normally described as compensation for the lack of energy due to the absence of the plantar-flexor muscles in the affected limb (Winter & Sienko, 1988). The NF2 tends to show a better adjustment to the lack of plantar flexor activity in the early stance; therefore, this may result in the reduction in the H1 power burst and in less effort required to propel the body forward during the stance.

The data in this study did not reveal a trend towards a more rapid flat foot position with a more compliant heel section (NF2); this refutes this study's hypothesis of a decrease in the duration of the loading time with a more compliant heel section. The faster flat foot position transition expected was only observed in 3/5 participants. The NF foot has a curved keel that increases the difficulty of the capture of the exact time where the toes touched the ground. Flat foot event outcomes obtained from the angular acceleration method use in this study were visually verified with the video camera recording. The use of the video camera for all the trials was not possible because some trials did not have a close-up view of the foot. The hypothesis of the more rapid flat foot is based on results found by Perry et al. (1997). They studied people with TTA and found that heel stiffness had a strong influence on the duration of the heel-only support prior to foot flat position. They concluded that to improve prosthetic gait, the feet must show an early flat foot to preserve stability.

Foot deformation – During the walking trials, the heel section generally showed larger deformation during early stance in the NF2 condition. This was expected as the heel section was 20% thinner and, by definition, more structurally compliant. However, despite the removal of the material in the heel section of the NF2, the mechanical testing showed an apparent increase in overall foot stiffness after about 4mm of deformation while loading the foot on the heel section. The rapid change in stiffness at that time point can be explained by the observation that, for the NF2 condition, the point of contact on the heel section moved rapidly toward the centre of the foot during the mechanical testing. This change in the point of load application had the effect of reducing the effective lever arm of the heel section which would, in turn, increase the overall stiffness. The change in the point of contact also appeared to bring other portions of the C-section design into play, also likely increasing the overall foot stiffness. These observations from the mechanical tests may explain why some of the participants felt that the NF2 was stiffer despite it having a more compliant heel section.

6.2 EMG

The trends in the EMG activity were observed in both legs in the rectus femoris and biceps femoris muscles and the gluteus maximus in the unaffected leg. These trends were during the heel-strike for the affected limb and during the swing phase of the unaffected limb. The EMG results indicated the knee extensor muscles (rectus femoris) seemed to be not as active with the NF2 during the heel strike in comparison with the NF1. In contrast, the knee flexor muscle (biceps femoris) EMG activity showed an increase in the same time frame. This shows the same trend as seen in the moments with a knee in a more flexed position. The rectus femoris seems to decrease its activity during the heel strike creating a smaller extension of the knee; counter balanced by an increase of the biceps femoris that increased flexion of the knee abilities. During this time, the unaffected limb in swing phase with the NF2 has a smaller hip flexion activity in the rectus femoris but an increase in the biceps femoris and gluteus maximus.

6.3 PEQ

The PEQ result did not show any significant differences between the two conditions. The gait satisfaction and the overall prosthetic satisfaction were comparable from one condition to another but a greater range of values with higher standard deviations were seen for the NF2 condition. One participant reported a really poor satisfaction for the NF2, which skewed the results. This shows that most of the participants really enjoyed the prosthetic foot. It was unclear what was the exact cause for the one poor satisfaction report.

6.4 Data analysis and interpretation

The low sample in this study restrained us from statistical analysis. A post-hoc power analysis was performed to determine the minimum sample size needed to run parametric analyses and find possible significant changes between NF1 and NF2 (GPower, Version 3.1.2.). The post-hoc test was run using the effect size calculated using the joint power data (H1: NF1:

1.42W/kg (±0.37) NF2: 1.14W/kg (±0.40)). The post-hoc test revealed that with a power (1-ß) equal to 0.8, a probability of error (α) equal to 0.05 and an effect size of 0.7 the sample size must be higher than 20. Further analysis should include a minimum of 20 participants to have to possibility to run parametric analysis. Data could then be evaluated with paired t-test. To protect from a type II error possible due to the large number of paired t-test a Bonferoni adjustment test should also be applied.

Chapter 7

Conclusion

7.1 Limitations of the study

A high inter-individual gait variability, low sample size and low statistical power precluded statistical analysis in this small study. However, consistent differences were seen during the weight acceptance phase of the affected limb which is the most logical time point when considering the change to heel section stiffness. The small sample size was primarily a result of difficulties in the recruitment of participants.

The relatively small reduction in heel material was based on recommendations provided by the manufacturer in order to guard against permanent deformation and failure of the heel section. If the heel material was reduced more, a larger difference between the two conditions might have been found.

During the present study, analysis of the alignment of the foot with the prosthetic component was attempted; however, throughout the 2-week adaptation period it was found that the participants were changing the alignment and the fitting of their own foot by themselves. Due to this self-adjustment, which was not anticipated by the researchers, it was impossible to draw any correlations between our results and the alignment of individual prostheses.

The NF conditions were not randomized between the subjects. This approach was chosen so that the original alignment could be performed on the NF1 with the intention of maintaining the same alignment for the NF2. It is possible that the subjects had a learned adaptation with the unmodified NF that was transferred to the modified foot. To control for footwear and to better understand the mechanics of the NF, the participants walked bare foot during the study. The barefoot walking may have changed the gait pattern of the participants because the NF required a cover to ensure adequate surface friction. A previous study observing indoor walking with barefoot and shoe conditions with a prosthetic foot observed gait abnormalities while walking barefoot (Han, Chung, & Shin, 2003). Further investigations could include a foot cover and shoes.

The mechanical testing could have included the bottom foot cover using with the walking task. The point of contact on the foot was difficult to track with the foot cover bottom, which is why it was not used in the mechanical testing.

Some of the prosthetic feet available on the market have a stiffness model options defined by the user's mass and cadence. In this study, the stiffness of the NF1 and NF2 were the same for all participants, who were a variety of weights. Although, 4/5 participants were in the prescribed weight range, a wide range was observed. Having a foot stiffness design for each participant may have brought different results in terms of kinematics and kinetics.

Normally designed as a four-week recall, the PEQ was modified to a two-week recall to match the two-week adaptation period given to the participant after the fitting of each NF. This time frame modification may have limited the PEQ's validity. Because the PEQ recall period was reduced from 4-weeks to 2-weeks to match the prosthetic foot adaptation period this study results should not be compared to other study results using a 4-week recall.

7.2 Conclusion

This study attempted to determine whether or not the heel stiffness modification had an impact on the gait in TTA people while using the NF. The effect of change in heel conditions was assessed with common variables previously used in gait analysis and prosthetic studies. Gait kinematics (ROM), and kinetics variables (forces, moments of forces, power, joint angles) helped to characterize the gait of each participant while using the NF. The EMG and PEQ results were also used to confirm observation in the gait pattern and feeling described by the participants.

Important trends were highlighted and indicated possible behaviours a modified NF heel. The following changes in the conditions may be observed with the use of a foot with a more compliant heel section:

- A NF2 may show a more rapid anterior progression of the contact point at the early stance creating a feeling of a stiffer foot for the patients;
- An increase in biceps femoris activities in both legs and a decrease in activities in the rectus femoris for both legs with the use of the NF2;
- A possible decrease in the hip abductor moment during the middle stance followed by a decrease in the hip extensor moment during late stance and reduced hip flexor moment peak during the swing phase for the affected limb;
- An increase in the net amplitude of the F/E moments at the knee and hip during the swing for the unaffected limb;

- A hip energy generation decrease at early stance combined with a knee energy absorption increase for the affected leg, while the unaffected side may show a hip energy generation decrease at late swing;

- A similar overall patient satisfaction with either NF conditions.

Based on this study, the 20% reduction of the heel section material of the current v19 NF version may not have been enough of a reduction to show a large change in the gait of the patients using the foot. The present results did show that the 20% reduction might be enough to change some gait parameters depending on individual gait patterns, patient's weight, daily use and personal feeling. Further investigations should look at a more substantial heel material reduction to better observe the possibilities of different heel characteristics. The participants' verbal description of the NF2 did reveal a feeling of a stiffer foot. The data collected in this study brought new information on the gait characteristics while using the NF. This information is important to further research as it may be used for further design decisions for the NF or any other prosthetic foot when considering the heel section stiffness.

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Appendix A.

Anatomical terminology

A.1. Anatomical planes and directions

Anatomical planes are imaginary planes that separate either the entire body or any organ. The medial plane is the vertical plane that splits the body in half vertically, dividing the body into left and right. The sagittal plane is parallel to the medial but is not necessary in the middle of the body. The coronal (frontal) plane also splits the body in half vertically but is perpendicular to the medial plane; it separates the front (anterior) from the back (posterior). Finally, the transverse (horizontal) plane separates the body horizontally and also the body parts creating the upper and the lower parts.

Orientation terms are also introduced to describe precisely the anatomical structures. Each body part can be localized within the body. The Table A.1 explains the term use in the present report.

Table A.1. Anatomical planes

Terms	Description
Superior	Describe a limb or an organ that is over or above and closer to the head.
Inferior	Describe a limb or an organ that is below or under and closer to the feet.
Medial	Describe a limb or an organ that is located towards the midline away from the side.
Lateral	Describe a limb or an organ that is located towards the side away from the midline.
Proximal	Describe a limb or an organ that is located near to the body centre or closer to its origin.
Distal	Describe a limb or an organ that is located away from the body centre or farther from its origin.

A.2. Movement

Human movement is possible in part because of the coordinated muscles. The movement of the body structures are also described with specific terms to better explain how limbs move relatively to each other and to exclude any confusion. The present document uses commonly used terms: flexion, extension, abduction and adduction. The flexion movement is generally described by a reduction of the joint angle while the extension is normally described by the increase of the joint angle in the sagittal plane. In the foot, the flexion is described by the dorsiflexion and the extension is described by the plantar flexion. Abduction describes the motion of a limb that moves away from the body midline in the frontal plane and adduction towards the midline.

A.3. General information on the gait

Gait is the medical term that describes human locomotion involving the synchronization of the cardiovascular and the neuromuscular systems. It describes the action of propulsion with the use of the lower limbs (Dutton, 2008). Therefore, gait analysis defines the assessment of movement, in this case walking. Gait assessment describes an individual's gait function, advices on further treatments in pathological cases, and is a helpful evaluation method during a treatment. The examination is done in all three planes of motion and is described with relevant terms. Gait stride, can be describe in terms of step length, stride length, velocity, and cadence. Gait analysis may be done using various technologies: high-speed video cameras, clinical examination, stride parameters, three-dimensional kinematics, joint kinetics, muscles activation, oxygen consumption, and foot pressure.

A.4. Gait cycle phases

During the analysis, the walking pattern is divided into gait cycles. The interval of time between repetitive events describes this cycle. The interval generally defining the gait cycle is the initial contact between the foot and the ground, to the following event by the same foot. Also called the stride, the gait cycle is divided into two phases (Perry, 1992): the stance and the swing phase (Figure A.1). Occasionally, the term step is also used; it refers to the interval between the contacts of the two different limbs with the ground.

STRIDE						
STANCE				SWING		
Heel Strike	Midstance	Push off		Initial swing	Midswing	Terminal swing
Loading response		Terminal stance	Preswing	Acceleration		Deceleration
Foot Flat 7%		Heel off		Toe off		

0% 10% 30% 40% 50% 60% 70% 85% 100%

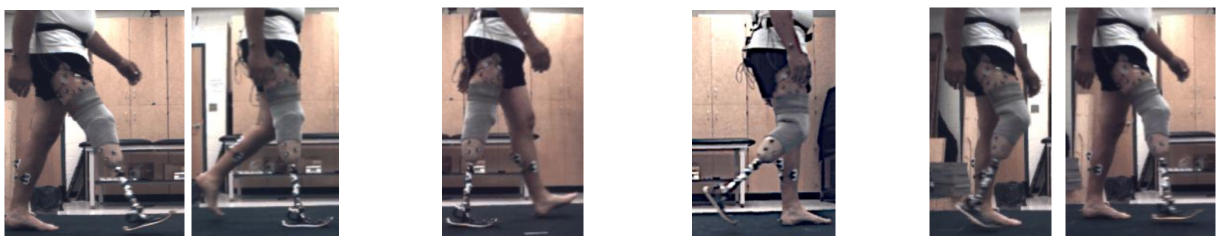

Figure A.1. Gait events

A.4.1 Stance phase

When analysing the walk, the stance phase represents around 60% of the stride and defines the time interval when the foot touches the ground. Three main intervals define the stance: the heel strike, the midstance, and the push off. The heel strike is the first contact with the foot on the ground. During this interval, the loading response occurs accepting the weight (weight accepting phase) into a double support. The midstance interval starts when the foot is flat on the ground (7%). During midstance, 10% of the total gait cycle represents the moment when the weight is directly over the support limb in a single support. The lift of the heel of the weight-bearing foot triggers the final interval of the stance: the push off. The terminal stance period describe the time when the heel of the weight-bearing foot lifts until the contact with the ground with the opposite foot. Triggered by the contralateral limb ground contact and ended with the ipsilateral toe-off, the preswing refers to the last 10% of the stance. During the push off, both feet are in contact with the ground, which creates a second double support in the stance phase in preparation for the swing.

A.4.2 Swing phase

The swing phase is the last 40% of the stride during the walk. The movement observed in this phase is the result of gravity and momentum action. The swing phase explains the motion of the non-weight-bearing limb. Three intervals represent the motion of the swing: initial swing, midswing, and terminal swing. The initial swing is the first event to occur; during this phase the angular velocity increases creating an acceleration situation. The midswing follows when the swinging limb is beneath the body until deceleration. The terminal swings starts when the tibia of the swinging limb is vertical to the ground and end with the stance phase trigger: the heel.

Appendix B.

Spatio-temporal Data

The spatio-temporal data described in Table B.1 were taken for 5 trials for both conditions. Each subject column is divided into two columns for the NF1 and NF2 condition. The values are the average of the five trials with the standard deviation. The walking speed is presented in m/s. The cadence represented in step/min. The stride length was measured for the affected and unaffected limb. It is represented in meters and was tracked by measuring the distance between the positions of the same heel between two steps. The stance phase is reported for both limbs and is represented as a percentage of a total stride.

Table B.1. Spatio-temporal parameters

		WS		CDC		SLU		SLA		SPU		SPA	
		mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD
S1	C1	1.17	0.05	112.05	0.62	1.25	0.05	1.26	0.06	0.64	0.02	0.60	0.02
	NF1	1.26	0.02	114.97	0.71	1.32	0.02	1.33	0.04	0.63	0.02	0.58	0.02
	NF2	1.26	0.02	115.52	0.63	1.31	0.04	1.36	0.02	0.61	0.03	0.58	0.01
S2	C1	1.15	0.01	97.59	0.32	1.41	0.02	1.38	0.02	0.61	0.01	0.60	0.01
	NF1	1.11	0.03	104.31	0.12	1.27	0.07	1.31	0.02	0.65	0.03	0.61	0.01
	NF2	1.19	0.03	104.49	0.18	1.36	0.02	1.35	0.02	0.60	0.02	0.60	0.01
S3	C1	1.23	0.02	107.66	0.22	1.37	0.05	1.39	0.01	0.64	0.03	0.62	0.00
	NF1	1.22	0.02	106.98	0.42	1.37	0.03	1.35	0.01	0.64	0.01	0.61	0.01
	NF2	1.23	0.02	104.88	0.56	1.40	0.02	1.37	0.01	0.64	0.02	0.61	0.00
S5	C1	1.08	0.01	101.96	0.67	1.27	0.05	1.24	0.03	0.60	0.02	0.64	0.01
	NF1	1.06	0.01	107.95	0.54	1.18	0.04	1.19	0.01	0.61	0.02	0.63	0.01
	NF2	1.07	0.01	105.30	0.86	1.22	0.03	1.22	0.03	0.61	0.01	0.63	0.01
S6	C1	0.99	0.04	103.12	0.67	1.15	0.05	1.16	0.04	0.67	0.03	0.61	0.03
	NF1	0.91	0.03	103.58	0.56	1.05	0.03	1.06	0.04	0.66	0.02	0.60	0.02
	NF2	0.98	0.03	103.55	0.72	1.14	0.02	1.14	0.01	0.66	0.01	0.59	0.02
mean	C1	1.12	0.03	104.48	0.50	1.29	0.04	1.29	0.03	0.63	0.02	0.61	0.01
	NF1	1.11	0.02	107.56	0.47	1.24	0.04	1.25	0.02	0.64	0.02	0.61	0.01
	NF2	1.15	0.02	106.75	0.59	1.29	0.03	1.29	0.02	0.62	0.02	0.60	0.01

WS: Walking Speed (m/s), CDC: cadence (step/min), SLU: Stride length (m) U side, SLA: Stride length (m) A side, SPU: Stance phase (%GC) U side, SPA: Stance phase (%GC) A side.

Appendix C.

Range of motion

The ROM presented in this appendix is divided for each subject and for each NF condition and includes the session 1 data (C1) collected with their baseline prosthetic foot. The maximum and the minimum joint angle reached during the stance and the swing are reported. Furthermore the total ROM is presented for each condition for each subject. The ROM is measure in degrees.

Table C.1. Flexion extension ROM of the unaffected knee .(degrees)

		S1		S2		S3		S5		S6			
		Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Avg	SD
Stance	C1	8.02	40.01	4.83	37.83	16.96	40.43	12.31	46.87	5.67	24.07		
	NF1	12.75	40.89	3.66	26.20	18.52	45.36	11.42	44.11	8.87	28.53		
	NF2	3.67	34.88	6.98	39.74	15.92	38.72	12.81	46.97	10.40	28.61		
Swing	C1	6.90	62.96	1.40	61.74	12.76	66.75	8.05	63.74	4.98	62.47		
	NF1	9.19	62.91	3.80	52.50	10.99	69.01	5.48	63.91	5.72	61.29		
	NF2	4.32	54.59	3.78	59.20	9.61	66.87	7.15	64.77	3.37	66.20		
Total ROM	C1	69.85		63.14		79.50		71.78		67.45		70.34	6.05
	NF1	72.10		56.16		80.01		69.39		67.00		68.93	8.66
	NF2	58.26		62.99		76.47		71.92		69.57		67.84	7.24

Table C.2. Flexion extension ROM of the affected knee (degrees)

		S1		S2		S3		S5		S6			
		Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Avg	SD
Stance	C1	7.45	48.62	4.39	44.67	6.15	47.02	5.53	31.89	-1.10	43.70		
	NF1	9.96	52.41	-3.34	32.75	4.08	44.57	0.70	29.86	0.46	35.73		
	NF2	4.03	52.83	1.49	38.47	5.45	41.11	5.18	31.30	-0.93	39.03		
Swing	C1	8.21	60.02	5.08	69.28	2.35	64.60	9.18	65.76	2.11	75.16		
	NF1	8.89	59.48	-4.73	52.27	3.50	59.82	10.51	59.69	3.84	64.96		
	NF2	2.14	62.94	-1.62	57.15	3.85	63.44	5.36	59.23	4.37	62.45		
Total ROM	C1	67.46		73.67		66.95		71.29		76.26		71.15	3.99
	NF1	68.37		57.00		63.32		60.38		65.42		62.90	4.40
	NF2	65.07		58.77		67.29		64.41		63.38		63.78	3.15

Table C.3. Flexion extension ROM of the unaffected (degrees)

		S1		S2		S3		S5		S6			
		Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Avg	SD
Stance	C1	-28.19	12.05	-19.90	16.43	-28.58	13.17	-24.88	9.29	-15.29	20.19		
	NF1	-32.71	10.85	-17.98	13.42	-30.53	9.41	-22.10	7.75	-19.25	13.03		
	NF2	-27.06	18.79	-23.22	10.09	-28.88	15.11	-24.05	6.13	-22.77	13.54		
Swing	C1	-23.14	5.92	-21.02	8.54	-23.88	8.03	-24.61	-0.31	-15.72	17.53		
	NF1	-27.07	3.48	-18.04	11.68	-28.20	2.99	-24.41	-1.65	-20.36	10.14		
	NF2	-20.76	9.26	-24.27	3.71	-26.34	9.13	-26.68	-4.28	-23.81	10.99		
Total ROM	C1	40.24		37.44		41.75		34.17		35.92		37.90	3.10
	NF1	43.56		31.45		39.93		32.16		33.39		36.10	5.36
	NF2	45.84		34.35		43.99		32.81		37.35		38.87	5.79

Table C.4. Flexion extension ROM of the affected hip (degrees)

		S1		S2		S3		S5		S6			
		Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Avg	SD
Stance	C1	-20.63	13.87	-24.65	13.87	-26.98	8.48	-22.36	13.72	-14.19	28.91		
	NF1	-27.99	10.15	-20.42	14.86	-25.28	6.49	-22.76	16.40	-16.24	20.79		
	NF2	-25.72	10.72	-25.70	11.24	-21.79	7.12	-21.63	11.34	-18.04	20.77		
Swing	C1	-25.38	2.03	-27.73	5.85	-28.89	-0.72	-25.07	10.26	-21.77	14.22		
	NF1	-30.55	-2.95	-20.88	10.32	-29.82	-2.00	-28.69	8.94	-23.12	12.78		
	NF2	-27.24	-3.12	-27.64	3.19	-24.86	2.53	-26.88	6.36	-23.80	9.25		
Total ROM	C1	39.25		41.60		37.37		38.78		50.68		41.54	5.33
	NF1	40.70		35.74		36.31		45.09		43.91		40.35	4.27
	Nf2	37.97		38.88		31.98		38.22		44.57		38.32	4.46

Table C.5. Abduction adduction ROM of the unaffected knee (degrees)

		S1		S2		S3		S5		S6			
		Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Avg	SD
Stance	C1	-1.64	6.68	-1.92	4.80	-1.33	5.21	-4.39	2.19	-3.38	-0.58		
	NF1	-1.21	5.83	-3.67	0.23	-1.13	5.75	-3.17	2.97	-3.61	0.24		
	NF2	-3.08	2.80	-4.42	1.73	0.58	7.40	-4.76	2.47	-2.03	0.92		
Swing	C1	-1.54	9.06	-1.44	10.08	-1.26	2.39	-3.38	3.63	-3.41	-1.37		
	NF1	-4.43	6.90	-2.97	2.13	-3.25	3.38	-2.10	3.97	-3.78	-0.10		
	NF2	-5.42	4.10	-4.42	3.47	-0.80	3.67	-5.24	1.68	-2.85	1.97		
Total ROM	C1	10.69		12.00		6.53		8.01		2.83		8.01	3.61
	NF1	11.34		5.80		9.00		7.14		4.02		7.46	2.83
	NF2	9.52		7.89		8.21		7.71		4.82		7.63	1.72

Table C.6. Abduction adduction ROM of the affected knee (degrees)

		S1		S2		S3		S5		S6			
		Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Avg	SD
Stance	C1	-3.29	1.80	1.16	8.03	-5.19	1.54	-2.46	4.10	-2.54	7.67		
	NF1	-5.43	1.69	-4.63	8.56	-4.20	0.57	0.03	5.57	1.59	8.20		
	NF2	-9.05	0.99	0.42	8.38	-5.37	0.90	-0.44	2.90	1.62	6.73		
Swing	C1	-1.01	5.53	-2.09	9.05	-7.56	5.95	-4.19	6.11	-6.99	1.85		
	NF1	-4.58	3.55	-1.54	8.34	-2.48	5.06	-2.80	2.82	-2.17	1.99		
	NF2	-10.13	8.00	-0.09	7.14	-6.19	2.82	-3.63	2.94	-2.52	3.63		
Total ROM	C1	8.82		11.14		13.50		10.30		14.66		11.68	2.38
	NF1	8.98		13.19		9.26		8.37		10.37		10.03	1.91
	NF2	18.13		8.47		9.01		6.57		9.25		10.29	4.51

Table C.7. Abduction adduction ROM of the unaffected hip (degrees)

		S1		S2		S3		S5		S6			
		Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Avg	SD
Stance	C1	0.92	11.44	-6.06	7.12	-7.18	4.69	-8.10	1.37	-2.99	2.79		
	NF1	-0.36	7.82	-5.20	3.51	-10.21	1.20	-7.29	1.58	-4.41	-0.41		
	NF2	2.47	10.54	-9.35	7.38	-7.54	5.52	-8.96	2.42	-5.32	6.30		
Swing	C1	-2.20	5.72	0.02	7.96	-12.15	-2.95	-3.81	2.27	-2.25	4.71		
	NF1	-3.45	1.74	-1.17	5.18	-17.69	-8.85	-5.55	3.58	-3.00	1.87		
	NF2	1.65	6.89	-1.48	7.85	-12.35	-3.23	-3.75	3.00	-4.99	6.22		
Total ROM	C1	13.65		14.03		16.84		10.37		7.70		12.52	3.54
	NF1	11.27		10.38		18.89		10.88		6.27		11.54	4.57
	NF2	12.19		17.20		17.87		11.97		11.62		14.17	3.09

Table C.8. Abduction adduction ROM of the affected hip (degrees)

		S1		S2		S3		S5		S6			
		Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Avg	SD
Stance	C1	-1.96	6.00	-11.45	-4.32	-8.23	-0.14	-7.38	-0.13	-5.66	2.89		
	NF1	-2.09	10.26	-26.08	-7.02	-8.06	2.16	-8.05	-1.21	-7.23	-1.00		
	NF2	-1.87	7.09	-13.66	-6.82	-6.81	8.58	-7.35	0.33	-9.23	-2.90		
Swing	C1	-1.39	7.67	-13.90	-8.48	-6.25	5.47	-11.16	-3.58	-7.85	-3.20		
	NF1	-0.18	10.14	-27.45	-13.75	-4.99	6.20	-10.51	-4.64	-8.63	-1.57		
	NF2	-3.32	9.00	-14.50	-7.40	-4.42	11.00	-10.14	-5.48	-9.23	-0.34		
Total ROM	C1	9.63		9.58			13.70			11.03	10.73	10.93	1.68
	NF1	12.35		20.43			14.26			9.30	7.63	12.79	4.99
	NF2	12.32		7.67			17.81			10.47	8.89	11.43	3.97

Appendix D.

Forces

The force data is separate in 2 mains sections: A/P and vertical forces. The ground reaction force in the A/P direction is divided in 2 peaks (Figure D.1).

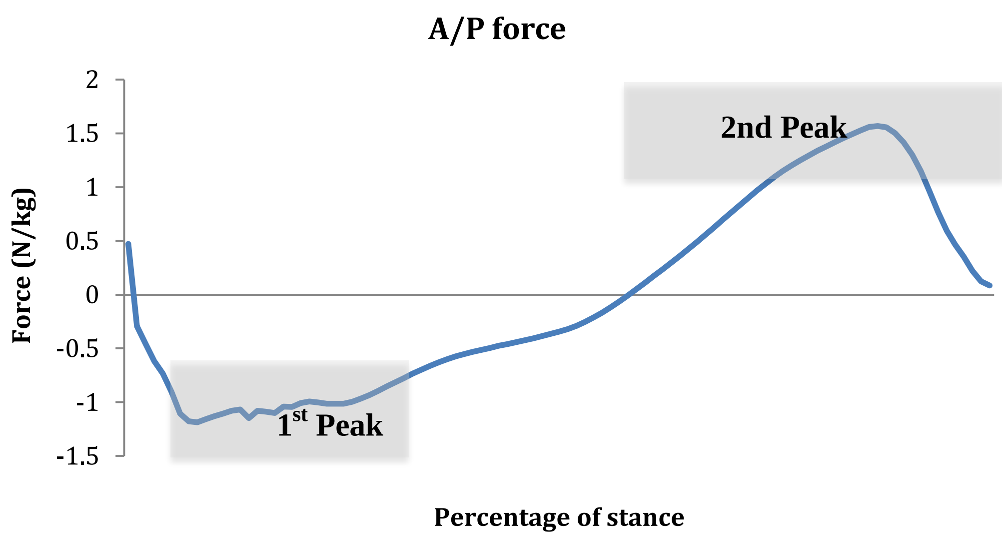

Figure D.1. Typical TTA ground reaction forces in the antero-posterior direction. Data are time normalized to percent of stance.

Each table (Table D.1, Table D.2) includes the maximum force amplitude in absolute units (N) and mass normalized unit (N/kg). The peak time in noted in seconds, the baseline is the start of the stride. The rate at which this peak is reach is described in N/s and standardized units: N/kg·s.

Table D.1. Ground reaction forces in A/P direction at the 1st peak

		Amplitude (N)		Amplitude (N/kg)		Time (s)		Rate of loading (N/s)		Rate of loading (N/kg·s)	
		A	U	A	U	A	U	A	U	A	U
S1	C1	74.19	141.05	0.99	1.88	0.12	0.09	630.21	1554.12	8.42	20.77
	NF1	94.75	156.8	1.27	2.1	0.1	0.09	973.38	1780.61	13.01	23.79
	NF2	126.47	158.5	1.69	2.12	0.08	0.08	1569.15	2027.36	20.97	27.09
S2	C1	125.89	169.97	1.36	1.84	0.09	0.08	1357.79	2199.91	14.72	23.84
	NF1	147.28	150.27	1.60	1.63	0.07	0.08	1971.66	1846.58	21.37	20.01
	NF2	172.21	177.2	1.87	1.92	0.07	0.08	2414.56	2250.4	26.17	24.39
S3	C1	175.15	144.6	1.63	1.35	0.08	0.11	2130.23	1324.2	19.86	12.34
	NF1	166.14	160.78	1.55	1.5	0.08	0.11	2187.21	1417.6	20.39	13.22
	NF2	166.06	186.68	1.55	1.74	0.11	0.11	1534.14	1676.92	14.30	15.63
S5	C1	108.15	121.44	1.45	1.63	0.2	0.10	538.06	1169.5	7.23	15.72
	NF1	74.56	132.07	1.00	1.78	0.19	0.09	393.16	1510.73	5.29	20.31
	NF2	80.93	100.83	1.09	1.36	0.19	0.09	420.92	1082.82	5.66	14.56
S6	C1	29.35	93.76	0.51	1.64	0.09	0.10	315.85	943.6	5.52	16.48
	NF1	37.83	128.21	0.66	2.24	0.19	0.11	199.33	1217.81	3.48	21.26
	NF2	41.02	134.75	0.72	2.35	0.19	0.11	221.01	1254.87	3.86	21.91
Mean NF1		**104.11**	**145.63**	**1.22**	**1.85**	**0.13**	**0.10**	**1144.95**	**1554.67**	**12.71**	**19.72**
SD NF1		**52.60**	**14.63**	**0.39**	**0.31**	**0.06**	**0.01**	**902.58**	**260.03**	**8.28**	**3.92**
Mean NF2		**117.34**	**151.59**	**1.38**	**1.90**	**0.13**	**0.09**	**1231.96**	**1658.47**	**14.19**	**20.72**
SD NF2		**56.17**	**34.62**	**0.47**	**0.38**	**0.06**	**0.02**	**906.00**	**495.24**	**9.60**	**5.46**

Table D.2. Ground reaction force in A/P direction at the 2nd peak

		Amplitude (N)		Amplitude (N/kg)		Time (s)		Rate of loading (N/s)		Rate of loading (N/kg·s)	
		A	U	A	U	A	U	A	U	A	U
S1	C1	99.76	143.33	1.33	1.92	0.55	0.59	180.58	243.99	2.41	3.26
	NF1	118.76	156.47	1.59	2.09	0.54	0.56	221.57	277.51	2.96	3.71
	NF2	119.79	160.55	1.6	2.15	0.55	0.54	216.55	297.73	2.89	3.98
S2	C1	144.33	189.4	1.56	2.05	0.65	0.63	220.71	300.57	2.39	3.26
	NF1	142.68	175.9	1.55	1.91	0.64	0.62	224.46	284.66	2.43	3.09
	NF2	135.54	199.1	1.47	2.16	0.61	0.59	223.91	336.15	2.43	3.64
S3	C1	154.71	251.17	1.44	2.34	0.62	0.61	248.53	410.39	2.32	3.83
	NF1	172.72	251.07	1.61	2.34	0.58	0.62	297.14	407.19	2.77	3.8
	NF2	156.02	259.26	1.45	2.42	0.6	0.62	260.26	419.46	2.43	3.91
S5	C1	124.1	123.86	1.67	1.66	0.65	0.61	191.45	202.3	2.57	2.72
	NF1	107.75	111.32	1.45	1.5	0.59	0.59	181.35	188.71	2.44	2.54
	NF2	105.25	124.36	1.41	1.67	0.61	0.6	173.41	205.91	2.33	2.77
S6	C1	65.78	74.07	1.15	1.29	0.59	0.65	110.92	114.68	1.94	2
	NF1	68.55	65.55	1.2	1.14	0.59	0.64	116.04	102.37	2.03	1.79
	NF2	80.67	80.38	1.41	1.4	0.58	0.64	139.07	125.88	2.43	2.2
Mean NF1		**122.09**	**152.06**	**1.48**	**1.80**	**0.59**	**0.61**	**208.11**	**252.09**	**2.53**	**2.99**
SD NF1		**38.96**	**69.88**	**0.17**	**0.48**	**0.04**	**0.03**	**66.27**	**114.23**	**0.36**	**0.84**
Mean NF2		**119.45**	**164.73**	**1.47**	**1.96**	**0.59**	**0.60**	**202.64**	**277.03**	**2.50**	**3.30**
SD NF2		**28.73**	**68.70**	**0.08**	**0.41**	**0.03**	**0.04**	**47.07**	**114.14**	**0.22**	**0.78**

The impulse force in the A/P direction (Table D.3) is separated between the negative and positive impulse for the affected (A) and unaffected (U) limb. The impulse is the result of the force integral and represents the change in the momentum of the body. The total impulse is the sum of the negative and the positive impulse. All impulses are represented in kg·m/s.

Table D.3. Impulse force in the A/P direction

		Impulse negative		Impulse positive		Impulse Total	
		A	U	A	U	A	U
S1	C1	-16.83	-21.1	17.69	21.83	0.86	0.73
	NF1	-17.08	-21.32	19.26	24.21	2.18	2.89
	NF2	-17.39	-21.9	25.14	25.31	7.75	3.41
S2	C1	-27.62	-34.08	23.14	35.58	-4.48	1.50
	NF1	-28.74	-30.71	26.3	27.40	-2.44	-3.31
	NF2	-30.09	-33.83	23.15	29.00	-6.94	-4.83
S3	C1	-21.25	-24.84	38.42	40.66	17.17	15.82
	NF1	-22.63	-27.56	36.96	40.69	14.33	13.13
	NF2	-23.57	-30.24	39.86	45.23	16.29	14.99
S5	C1	-18.49	-19.59	21.18	25.82	2.69	6.23
	NF1	-16.69	-16.36	20.71	25.37	4.02	9.01
	NF2	-16.95	-19.92	18.88	17.93	1.93	-1.99
S6	C1	-5.2	-11.91	12.61	19.43	7.41	7.52
	NF1	-5.96	-11.04	12.91	23.05	6.95	12.01
	NF2	-6.47	-14.04	14.88	22.82	8.41	8.78
Mean NF1		**-18.22**	**-21.398**	**23.228**	**28.15**	**5.01**	**6.75**
SD NF1		**8.43**	**8.02**	**9.04**	**7.20**	**17.46**	**15.22**
Mean NF2		**-18.894**	**-23.986**	**24.382**	**28.06**	**5.49**	**4.07**
SD NF2		**8.77**	**8.00**	**9.52**	**10.41**	**18.29**	**18.40**

The ground reaction force of the vertical force (Table D.4, Figure D.2) is described the same way the A/P ground reaction force was. The same description applies for the impulse data (Table D.5).

Table D.4. Ground reaction force in the vertical direction

		Amplitude (N)		Amplitude (N/kg)		Time (s)		Rate of loading (N/s)		Rate of loading (N/kg·s)	
		A	U	A	U	A	U	A	U	A	U
S1	C1	624.82	591.31	8.35	7.90	0.05	0.06	11819.71	9446.63	157.93	126.22
	NF1	648.57	571.59	8.67	7.64	0.05	0.06	11933.75	9707.35	159.46	129.71
	NF2	780.08	836.30	10.42	11.17	0.05	0.05	15056.94	17974.47	201.19	240.17
S2	C1	834.48	787.10	9.04	8.53	0.11	0.11	7741.11	7502.62	83.90	81.31
	NF1	760.81	787.15	8.25	8.53	0.07	0.07	11197.00	10875.99	121.35	117.87
	NF2	817.52	744.60	8.86	8.07	0.07	0.07	11545.14	10011.99	125.12	108.51
S3	C1	1070.74	720.30	9.98	6.71	0.13	0.18	8398.21	3996.34	78.29	37.25
	NF1	978.82	591.19	9.12	5.51	0.13	0.10	7775.71	5807.37	72.49	54.14
	NF2	838.57	933.84	7.82	8.71	0.09	0.09	8958.14	10443.16	83.51	97.35
S5	C1	441.69	628.39	5.94	8.45	0.08	0.08	5884.30	8072.43	79.10	108.51
	NF1	490.80	831.02	6.60	11.17	0.07	0.08	7084.15	10056.54	95.23	135.19
	NF2	469.87	718.35	6.32	9.66	0.06	0.06	7652.55	12853.42	102.87	172.78
S6	C1	337.10	366.67	5.89	6.40	0.07	0.04	4897.57	8747.83	85.52	152.75
	NF1	292.25	413.81	5.10	7.23	0.05	0.04	5453.53	9872.46	95.22	172.38
	NF2	330.46	371.79	5.77	6.49	0.05	0.05	6724.70	7403.27	117.42	129.27
Mean NF1		**634.25**	**638.95**	**7.55**	**8.02**	**0.07**	**0.07**	**8688.83**	**9263.94**	**108.75**	**121.86**
SD NF1		**261.01**	**170.56**	**1.67**	**2.08**	**0.03**	**0.02**	**2770.22**	**1983.70**	**33.21**	**42.99**
Mean NF2		**647.30**	**720.98**	**7.84**	**8.82**	**0.07**	**0.06**	**9987.49**	**11737.26**	**126.02**	**149.62**
SD NF2		**231.87**	**212.78**	**1.89**	**1.75**	**0.02**	**0.02**	**3364.63**	**3986.96**	**44.91**	**58.25**

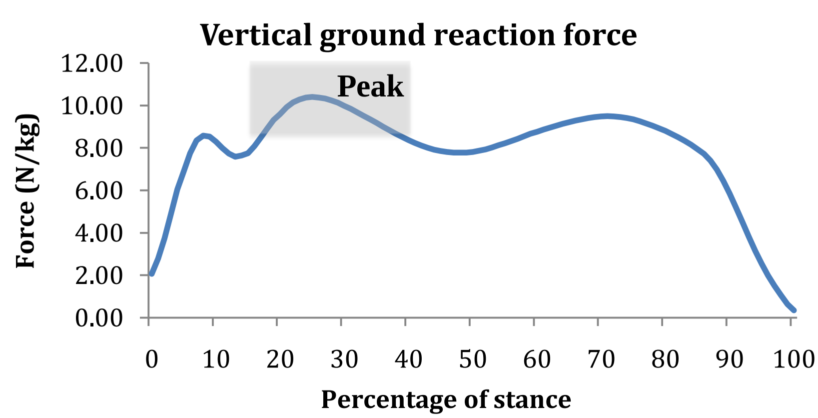

Figure D.2. Typical TTA ground reaction force. Data is time normalized to percent of stride

Table D.5. Total impulse and stance average in the vertical direction

		Impulse Total (kg·m/s)		Stance average force (N)		Stance average force (N/kg·s)	
		A	U	A	U	A	U
S1	C1	382.68	416.73	594.09	605.67	7.94	8.09
	NF1	364.95	413.54	594.40	626.67	7.94	8.37
	NF2	376.65	408.87	603.53	644.89	8.06	8.62
S2	C1	530.34	573.80	730.47	773.34	7.92	8.38
	NF1	529.11	554.14	720.89	761.14	7.81	8.25
	NF2	503.06	529.99	720.77	779.61	7.81	8.45
S3	C1	591.39	589.09	849.70	820.48	7.92	7.65
	NF1	558.45	602.86	833.60	844.39	7.77	7.87
	NF2	567.66	628.30	822.67	860.67	7.67	8.02
						0.00	
S5	C1	423.55	430.23	578.58	605.96	5.39	5.65
	NF1	412.25	427.10	585.53	624.46	5.46	5.82
	NF2	413.54	429.81	580.95	617.87	5.42	5.76
S6	C1	307.60	344.53	423.78	449.71	7.40	7.85
	NF1	299.14	365.65	428.62	473.62	7.48	8.27
	NF2	296.23	366.50	430.51	480.95	7.52	8.40
Mean NF1		**432.78**	**472.66**	**632.61**	**666.06**	**7.29**	**7.72**
SD NF1		**109.50**	**100.76**	**152.87**	**142.44**	**10.04**	**1.08**
Mean NF2		**431.43**	**472.69**	**631.69**	**676.80**	**7.30**	**7.85**
SD NF2		**106.41**	**44.91**	**148.53**	**147.67**	**1.07**	**1.19**

Appendix E.

Moments

The F/E moments of the knee and the hip were measured during the early, middle, and late stance and the maximum and minimum value was recorded for the swing. All the moment results are presented in Nm/kg. The hip middle stance value is a percentage of the stance where the moment hip curve crosses the *x*-axis. The abd/add moment of the hip was measured for the affected and unaffected limbs.

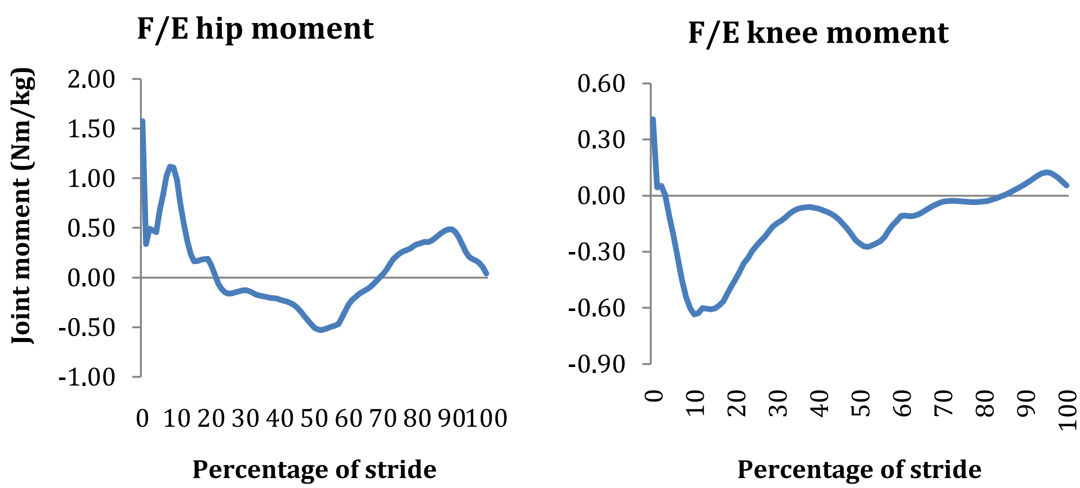

Figure E.1. Typical flexion/extension hip and knee moment. Positive values represent flexion moments and negative represent extension moments. Data is time normalized to percent of stride

Table E.1. Knee F/E peak moment of the affected side (N/kg·m)

		S1	S2	S3	S5	S6	Average	SD
Knee Early Stance	C1	-0.5258	-0.2937	-0.4362	-0.2521	-0.1383	-0.3292	0.1531
	NF1	-0.6710	-0.0765	-0.5654	-0.3254	-0.0165	-0.3310	0.2891
	NF2	-0.6152	-0.1703	-0.3923	-0.2825	0.0029	-0.2915	0.2326
Knee Middle Stance	C1	0.0905	0.3083	-0.0939	0.2865	0.4604	0.2104	0.2150
	NF1	-0.0519	0.3387	-0.2320	0.2723	0.3186	0.1291	0.2567
	NF2	0.0668	0.2024	0.0146	0.1218	0.3990	0.1609	0.1502
Knee Late Stance	C1	-0.2626	-0.2803	-0.4688	-0.3311	-0.1822	-0.3050	0.1061
	NF1	-0.2815	-0.1618	-0.4277	-0.3449	-0.2455	-0.2923	0.1005
	NF2	-0.3338	-0.2424	-0.3912	-0.3842	-0.2462	-0.3196	0.0722
Knee Swing Minimum	C1	-0.1170	-0.0876	-0.0787	-0.1008	-0.1326	-0.1033	0.0218
	NF1	-0.1166	-0.0912	-0.0802	-0.3263	-0.2733	-0.1775	0.1140
	NF2	-0.1227	-0.0941	-0.0766	-0.3145	-0.2475	-0.1711	0.1044
Knee Swing Maximum	C1	0.1169	0.1112	0.0903	0.1330	0.1732	0.1249	0.0310
	NF1	0.1315	0.1101	0.0797	0.4007	0.3295	0.2103	0.1447
	NF2	0.1415	0.1330	0.0783	0.3933	0.4106	0.2313	0.1577

Table E.2. Hip F/E peak moment of the affected (N/kg·m)

		S1	S2	S3	S5	S6	Average	SD
Hip Early Stance	C1	0.6971	0.6541	0.6025	0.7192	0.7754	0.6897	0.0655
	NF1	0.8235	0.5388	0.8041	0.9875	0.8544	0.8017	0.1635
	NF2	1.1471	0.5481	0.7192	0.8350	0.8931	0.8285	0.2215
Hip Middle Stance (% Stance)	C1	32.0559	40.4391	35.2894	33.6128	38.3633	35.9521	3.4292
	NF1	48.1437	45.2695	36.1677	37.7645	39.7605	41.4212	5.0924
	NF2	36.7265	41.1976	35.7285	33.0938	39.9202	37.3333	3.2612
Hip Late Stance	C1	-0.6178	-0.6535	-0.5662	-0.7292	-0.8915	-0.6916	0.1265
	NF1	-0.5250	-0.5834	-0.5448	-0.9430	-0.8462	-0.6885	0.1924
	NF2	-0.5406	-0.6446	-0.5095	-0.9602	-0.8787	-0.7067	0.2026
Hip Swing Minimum	C1	-0.1672	-0.2245	-0.1730	-0.2709	-0.2278	-0.2127	0.0430
	NF1	-0.1654	-0.2104	-0.2403	-0.5348	-0.4518	-0.3205	0.1626
	NF2	-0.2925	-0.2674	-0.2947	-0.6657	-0.5351	-0.4111	0.1792
Hip Swing Maximum	C1	0.4089	0.3829	0.4679	0.4582	0.4906	0.4417	0.0444
	NF1	0.4229	0.3423	0.4525	0.9877	0.8467	0.6104	0.2873
	NF2	0.5134	0.3889	0.4567	0.9646	0.9761	0.6599	0.2868

Table E.3. Knee F/E peak moments of the unaffected side (N/kg·m)

		S1	S2	S3	S5	S6	Average	SD
Knee Early Stance	C1	-0.5501	-0.5633	-0.6405	-0.8043	-0.4737	-0.6064	0.1255
	NF1	-0.8549	-0.3855	-0.9647	-0.7536	-0.7873	-0.7492	0.2187
	NF2	-0.7994	-0.5921	-0.828	-0.6766	-0.8994	-0.7591	0.1232
Knee Middle Stance	C1	0.1152	0.1605	-0.1275	0.0514	0.0178	0.0435	0.1104
	NF1	0.0612	0.2937	-0.2554	0.0327	-0.015	0.0234	0.1961
	NF2	0.2856	0.15	-0.1082	0.0889	-0.1246	0.0583	0.1748
Knee Late Stance	C1	-0.4693	-0.4362	-0.5874	-0.4621	-0.4418	-0.4794	0.0619
	NF1	-0.4776	-0.3089	-0.6866	-0.4817	-0.4862	-0.4882	0.1339
	NF2	-0.373	-0.3812	-0.4671	-0.4697	-0.4982	-0.4378	0.0568
Knee Swing Minimum	C1	-0.2984	-0.2923	-0.344	-0.2912	-0.2642	-0.2980	0.0289
	NF1	-0.3064	-0.2769	-0.3513	-0.2917	-0.2671	-0.2987	0.0330
	NF2	-0.2832	-0.2856	-0.3287	-0.2935	-0.2499	-0.2882	0.0281
Knee Swing Maximum	C1	0.3286	0.3567	0.327	0.3663	0.3318	0.3421	0.0181
	NF1	0.3586	0.3224	0.3572	0.3601	0.3156	0.3428	0.0219
	NF2	0.3686	0.3967	0.362	0.3734	0.3187	0.3639	0.0284

Table E.4. Hip F/E peak moments of the unaffected side (N/kg·m)

		S1	S2	S3	S5	S6	Average	SD
Hip Early Stance	C1	1.0879	0.3403	1.0534	0.7734	0.8529	0.8216	0.2998
	NF1	1.1919	0.6599	0.9387	0.7281	0.643	0.8323	0.2329
	NF2	1.186	0.6774	1.0568	0.8391	0.7717	0.9062	0.2097
Hip Middle Stance (% Stance)	C1	52.6547	17.525	36.487	52.4152	33.4132	38.4990	14.6958
	NF1	45.8683	48.7026	40.479	37.4451	34.9301	41.4850	5.7360
	NF2	45.5489	50.2994	64.4711	57.8443	27.4651	49.1258	14.0965
Hip Late Stance	C1	-0.7763	-0.9714	-1.1504	-0.7898	-1.1168	-0.9609	0.1758
	NF1	-0.94	-0.7783	-0.9366	-0.8185	-0.9801	-0.8907	0.0871
	NF2	-1.211	-0.6944	-0.8625	-0.7494	-1.0304	-0.9095	0.2119
Hip Swing Minimum	C1	-0.4558	-0.333	-0.5391	-0.4523	-0.4769	-0.4514	0.0748
	NF1	-0.4847	-0.4646	-0.4311	-0.3551	-0.4522	-0.4375	0.0500
	NF2	-0.6156	-0.4256	-0.5559	-0.4523	-0.4798	-0.5058	0.0783
Hip Swing Maximum	C1	0.7383	0.6611	0.9625	0.7031	0.6666	0.7463	0.1248
	NF1	0.7054	0.6721	0.9191	0.5686	0.629	0.6988	0.1333
	NF2	0.8767	0.7629	0.9196	0.7168	0.7125	0.7977	0.0950

Table E.5. Hip abd/add moment of the affected side (N/kg·m)

		S1	S2	S3	S5	S6	Average	SD
Hip abd max (Pk1)	C1	0.7216	0.9262	1.2741	0.974	0.5398	0.8871	0.2770
	NF1	0.7811	1.5963	1.0392	0.8867	0.4574	0.9521	0.4186
	NF2	0.8488	0.8277	1.2073	1.1165	0.404	0.8809	0.3136
Hip abd max (Pk2)	C1	0.7436	0.8038	1.0413	1.0664	0.2698	0.7850	0.3211
	NF1	0.6585	1.1941	1.1039	0.8921	0.2845	0.8266	0.3669
	NF2	0.9245	0.7196	1.0621	1.076	0.3211	0.8207	0.3139
Hip abd min	C1	0.5424	0.7676	0.8527	0.8385	0.2388	0.6480	0.2603
	NF1	0.4483	0.6935	0.6986	0.5667	0.2498	0.5314	0.1882
	NF2	0.5540	0.5266	0.7818	0.8229	0.2402	0.5851	0.2338

Table E.6. Hip abd/add hip moment of the unaffected side (N/kg·m)

		S1	S2	S3	S5	S6	Average	SD
Hip abd max (Pk1)	C1	1.1292	1.1151	1.1788	1.2854	0.8403	1.1098	0.1648
	NF1	1.4948	0.9829	1.3607	1.1915	0.8454	1.1750	0.2658
	NF2	1.2614	1.3565	1.1867	1.4873	0.8337	1.2251	0.2460
Hip abd max (Pk2)	C1	0.7261	1.0047	0.8908	0.9734	0.7576	0.8705	0.1251
	NF1	0.9998	1.0860	1.0276	0.9483	0.8061	0.9736	0.2770
	NF2	0.7016	1.0160	0.8519	1.2641	0.8956	0.9458	0.2770
Hip abd min	C1	0.6508	0.6691	0.6167	0.6858	0.4950	0.6235	0.0763
	NF1	0.7406	0.5898	0.6622	0.7129	0.4961	0.6403	0.0989
	NF2	0.4901	0.6639	0.5765	0.9307	0.5382	0.6399	0.1746

Appendix F.

Power

Joint power peaks are presented for all subjects for the affected (A) and unaffected (U) side. Knee (Table F.1) and hip (Table F.2) power peak were identified following Winter's (2005) gait power standard peaks. Four peaks are observed for the knee. The K1 peak is a negative power described by an eccentric knee extensor activity during the loading phase. The K2 peak is a positive power described by a concentric knee extensor activity during the midstance. The K3 peak is a negative power described by an eccentric rectus femoris activity during the pre-swing. Finally, K4 peak a negative power described by an eccentric hamstring activity during the final phase of the swing. All power results are presented in Watts/kg.

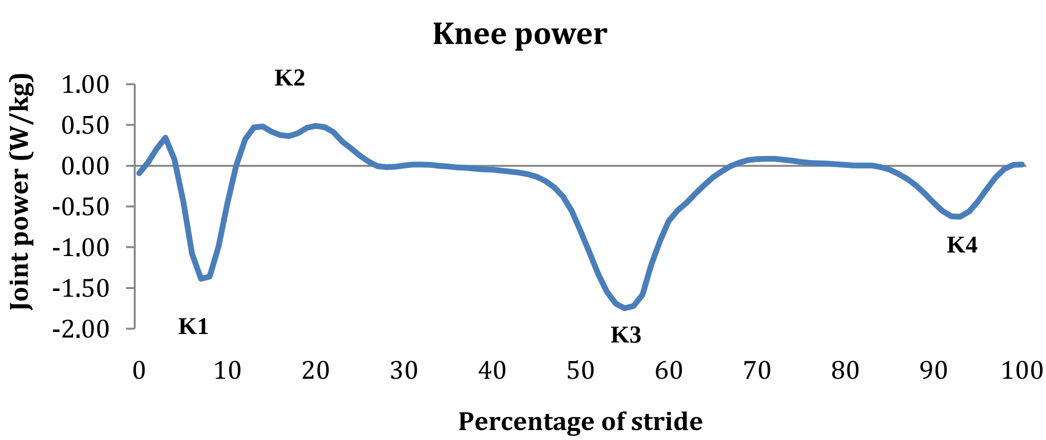

Figure F.1. Typical mechanical power generation and absorption for the knee. Energy generation is +ve and energy absorption is –ve. Four power peaks are identified. Data are time normalized to percent of stride.

The hip power peaks are in count of three: 2 power generation and 1 power absorption. The H1 peak is small and represents a positive power created by the hip extensor activity during the loading phase. The H2 peak is negative and shows an eccentric hip flexor activity during the midstance. The last hip peak is the positive H3 peak corresponding to the hip flexor during the swing.

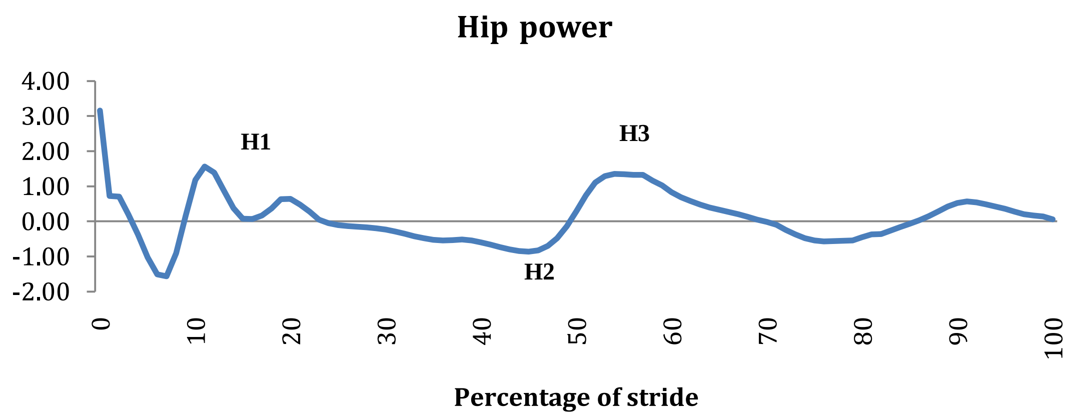

Figure F.2. Typical mechanical power generation and absorption for the hip. Energy generation is +ve and energy absorption is –ve. Three power peaks are identified. Data are time normalized to percent of stride.

Table F.1. Knee power peaks for the affected and unaffected side (Watts/kg)

		S1		S2		S3		S5		S6		Avg		SD	
		A	U	A	U	A	U	A	U	A	U	A	U	A	U
K1	C1	-0.7791	-0.9986	-0.2632	-1.0264	-0.5751	-1.1104	-0.105	-1.0918	0.0068	-0.5937	-0.3431	-0.9642	0.3277	0.2121
	NF1	-1.2013	-1.5496	-0.0559	-0.5997	-0.8078	-0.9854	-0.0972	-1.1141	-0.0021	-1.5461	-0.4329	-1.1590	0.5412	0.4023
	NF2	-1.4815	-2.1266	-0.1676	-1.0492	-0.5404	-1.1704	-0.1417	-0.7376	-0.0047	-1.8321	-0.4672	-1.3832	0.6008	0.5761
K2	C1	0.2465	0.3572	0.1423	0.1411	0.0387	0.839	0.2173	0.5101	0.0225	0.2477	0.1335	0.4190	0.1015	0.2716
	NF1	0.3895	0.7956	0.0098	0.1398	0.6572	0.6363	0.1986	0.4955	0.0231	0.5899	0.2556	0.5314	0.2725	0.2444
	NF2	0.6300	0.7502	0.0394	0.2393	0.3052	0.5793	0.189	0.4375	0.0029	0.8327	0.2333	0.5678	0.2526	0.2390
K3	C1	-1.4122	-2.0589	-1.4039	-1.4248	-1.6087	-2.4724	-1.4418	-2.255	-1.1955	-2.1107	-1.4124	-2.0644	0.1471	0.3918
	NF1	-1.5428	-2.2055	-0.8625	-1.1483	-1.5394	-2.8184	-1.9347	-2.464	-1.4563	-2.4433	-1.4671	-2.2159	0.3858	0.6356
	NF2	-1.7991	-1.7991	-1.1618	-1.2635	-1.3926	-1.9853	-1.9078	-2.473	-1.5547	-2.4255	-1.5632	-1.9893	0.3020	0.4968
K4	C1	-0.4358	-1.0082	-0.3884	-1.3803	-0.2491	-1.7467	-0.4602	-1.2964	-0.6965	-1.5712	-0.4460	-1.4006	0.1621	0.2802
	NF1	-0.4408	-1.0886	-0.307	-1.1173	-0.2852	-1.6733	-1.3086	-1.4111	-1.2373	-1.2825	-0.7158	-1.3146	0.5127	0.2393
	NF2	-0.6673	-1.4303	-0.4187	-1.3292	-0.2878	-1.6806	-1.3531	-1.3187	-1.4495	-1.6017	-0.8353	-1.4721	0.5355	0.1628

Table F.2. Hip power peaks for the affected and unaffected side (Watts/kg)

		S1		S2		S3		S5		S6		Avg		SD	
		A	U	A	U	A	U	A	U	A	U	A	U	A	U
H1	C1	0.753	1.5735	1.1580	0.2767	1.8361	1.1357	1.3418	0.901	0.952	0.6824	-0.6112	-0.5174	0.2455	0.2676
	NF1	1.1686	1.6870	2.0491	0.7087	1.1371	1.3408	1.3564	0.7966	1.4279	0.5117	-0.9236	-0.4561	0.5212	0.0946
	NF2	1.7421	2.0051	0.8926	0.5464	0.7506	1.1831	0.993	1.0631	1.3423	0.6129	-0.7933	-0.5180	0.2358	0.3260
H2	C1	-0.5200	-0.1589	-0.2982	-0.5657	-0.5474	-0.8095	-0.7422	-0.3392	-0.9482	-0.7139	1.3216	1.5905	0.3148	0.3430
	NF1	-0.3786	-0.2932	-1.6259	-0.4591	-1.3087	-0.5305	-0.6732	-0.4938	-0.6314	-0.5041	1.4545	1.6735	0.3705	0.4452
	NF2	-0.9073	-0.9489	-1.1183	-0.4777	-0.5008	-0.0493	-0.659	-0.4706	-0.7811	-0.6436	1.6165	1.5428	0.4230	0.3022
H3	C1	1.0052	1.4903	1.1000	1.3453	1.8141	1.9743	1.3027	1.2162	1.3862	1.9266	-0.6112	-0.5174	0.2455	0.2676
	NF1	1.0796	1.9844	1.0906	0.9588	1.5680	2.0805	1.9513	1.5724	1.5831	1.7715	-0.9236	-0.4561	0.5212	0.0946
	NF2	1.4194	1.9046	1.0527	1.0891	1.5540	1.6491	2.1174	1.4430	1.9391	1.6280	-0.7933	-0.5180	0.2358	0.3260

Appendix G.

Foot deformation

The foot deformation throughout the stance phase (Table G.1) was characterized with the roll-over shape. To describe the roll-over characteristics the length of the shape arc was measured in millimetres. The time when the toes of the prosthetic foot touched the ground was measured for the NF conditions; this time is represented as a percentage of the stride time as well as in seconds from the heel strike starts. The angle of strike of the foot represents the angle between the ground and the foot in degrees. Finally, the heel compression and extension is showed in percentage of the normal heel material state.

Table G.1. Foot deformation properties

		Rollover shape arc length (mm)	Foot Flat (% Stride)	Foot Flat (seconds)	Heel Strike Angle (degrees)	Heel Compression (% normal state)	Heel Extension (% normal state)
S1	C1	202.56	-	-	45.09	-	-
	NF1	185.704	10.28	0.108	54.23	11.29	4.3
	NF2	178.264	12.92	0.138	53.19	16.22	2.96
S2	C1	229.626	-	-	40.33	-	-
	NF1	187.15	13.73	0.166	43.88	10.21	3.78
	NF2	180.196	14.49	0.168	52.52	14.34	3.44
S3	C1	231.016	-	-	42.14	-	-
	NF1	183.098	16.13	0.178	55.12	15.60	5.38
	NF2	186.22	12.65	0.142	46.02	14.85	4.93
S5	C1	214.034	-	-	42.8	-	-
	NF1	190.28	11.63	0.130	36.23	7.17	3.76
	NF2	191.92	11.25	0.128	38.05	7.40	3.26
S6	C1	225.32	-	-	45.55	-	-
	NF1	197.658	11.92	0.140	35.1	4.25	2.8
	NF2	197.196	11.54	0.134	53.05	5.50	2.77
Avg NF1		188.78	12.74	0.14	44.91	9.70	4.00
SD NF1		5.60	2.26	0.03	9.54	4.29	0.94
Avg NF2		186.76	12.57	0.14	48.57	11.66	3.47
SD NF2		7.92	1.28	0.02	6.60	4.85	0.86

Appendix H.

EMG

The EMG results (Table H.1) included all measured muscles during the trials. Three affected muscles were measured during the gait: the rectus femoris, the biceps femoris and the gluteus maximus. For the unaffected limb five muscles were observed: the rectus femoris, the biceps femoris, the gluteus maximus, the gastrocnemius medial and the soleus. The Table H.1 presents the muscles activity for both limbs during the affected and unaffected leg strike. The results are presented in millivolts.

Table H.1. Average EMG during strike and swing phase (millivolts)

		Strike phase						Swing phase					
		C1		NF1		NF2		C1		NF1		NF2	
		U	A	U	A	U	A	U	A	U	A	U	A
S1	A Rectus femoris	6.18	6.53	6.36	11.26	2.96	4.66	3.59	5.33	7.24	10.28	3.32	2.31
	A Biceps femoris	23.52	25.57	7.50	10.72	8.84	17.53	21.96	18.90	9.84	11.20	11.78	9.00
	A Gluteus maximus	2.05	10.44	7.03	5.87	0.80	13.22	3.71	3.14	3.28	7.54	8.38	0.76
	U Rectus femoris	13.91	3.46	5.35	3.32	21.18	4.41	6.02	9.43	7.69	11.20	6.35	13.11
	U Biceps femoris	14.25	5.93	8.81	3.31	18.98	2.90	10.17	11.92	7.53	10.58	4.64	18.06
	U Gluteus maximus	17.99	1.77	10.75	2.61	26.71	1.45	3.19	13.37	2.79	16.11	1.34	21.24
	U Gastrocnemius medial	33.47	13.64	23.88	11.31	24.23	16.78	2.35	41.91	2.01	19.53	7.05	31.48
	U Soleus	16.77	8.18	17.70	7.47	19.43	15.10	4.88	18.42	3.47	17.13	8.58	22.66

Table H.1. Average EMG during strike and swing phase. (millivolts) (Continued)

		Strike phase						Swing phase					
		C1		NF1		NF2		C1		NF1		NF2	
		U	A	U	A	U	A	U	A	U	A	U	A
S2	A Rectus femoris	2.14	2.12	1.79	5.10	7.85	10.73	1.31	1.41	4.21	2.40	11.23	4.72
	A Biceps femoris	12.49	22.42	8.50	13.91	6.05	20.99	17.65	9.35	12.75	6.99	25.10	4.33
	A Gluteus maximus	1.26	10.03	3.70	13.13	1.19	10.89	5.14	1.29	14.77	3.40	6.34	0.98
	U Rectus femoris	5.53	2.25	5.28	6.14	6.72	3.37	1.64	4.60	3.95	6.82	3.63	4.90
	U Biceps femoris	4.68	3.57	7.39	3.77	7.43	5.58	5.86	2.56	3.47	2.40	5.13	4.72
	U Gluteus maximus	8.17	1.09	3.16	1.94	3.43	3.86	1.20	4.90	1.36	3.48	3.45	2.15
	U Gastrocnemius medial	31.75	36.78	9.29	27.00	16.29	28.33	2.88	37.07	4.46	13.54	3.20	24.92
	U Soleus	26.55	17.29	18.58	22.66	18.64	21.15	4.96	31.95	9.11	24.36	4.98	23.88
S3	A Rectus femoris	2.76	4.67	2.14	5.06	4.90	4.22	4.79	3.24	3.48	1.85	6.86	7.25
	A Biceps Femoris	7.18	7.53	3.73	4.49	4.93	7.99	8.04	7.00	3.52	4.86	7.69	7.80
	A Gluteus maximus	2.10	4.93	2.11	4.41	3.60	6.61	4.42	1.75	4.54	2.24	6.67	7.34
	U Rectus Femoris	4.58	1.46	4.02	2.36	4.80	2.28	1.09	3.96	2.46	4.74	2.21	3.64
	U Biceps Femoris	7.81	3.84	4.25	1.98	4.13	4.15	4.58	7.23	2.36	3.37	4.89	3.84
	U Gluteus Maximus	5.91	2.15	8.72	1.65	7.23	3.70	2.21	4.29	1.41	7.86	3.35	5.68
	U Gastrocnemius Medial	6.28	5.13	7.17	5.35	12.19	9.70	3.19	15.08	1.95	16.90	3.10	24.86
	U Soleus	10.89	12.84	9.15	9.43	10.08	11.77	5.07	15.64	4.31	13.38	5.66	15.83
S5	A Rectus femoris	1.22	2.84	1.95	2.94	0.91	2.55	2.07	1.05	2.69	1.68	2.29	0.80
	A Biceps Femoris	15.08	3.45	4.53	12.83	4.81	12.44	3.88	18.57	5.37	4.22	10.75	4.20
	A Gluteus maximus	0.75	5.22	1.26	4.54	15.45	53.42	2.72	0.79	3.16	1.06	100.94	17.87
	U Rectus Femoris	6.89	17.80	12.66	3.54	10.51	1.76	13.60	5.98	5.74	10.36	1.19	9.25
	U Biceps Femoris	38.60	7.83	10.01	2.42	12.03	2.95	8.81	34.39	2.65	11.98	3.53	9.87
	U Gluteus Maximus	7.12	3.37	5.16	1.38	5.13	2.74	3.88	6.22	1.24	5.43	3.08	4.00
	U Gastrocnemius Medial	9.29	13.55	8.58	12.97	7.59	12.97	3.88	7.27	2.39	9.86	3.41	6.73
	U Soleus	7.99	15.78	12.49	19.37	10.45	17.94	2.68	5.70	5.95	12.15	6.92	10.46

Table H.1. Average EMG during strike and swing phase. (millivolts)(Continued)

		Strike phase						Swing phase					
		C1		NF1		NF2		C1		NF1		NF2	
		U	A	U	A	U	A	U	A	U	A	U	A
S6	A Rectus femoris	4.64	10.22	9.21	17.71	6.55	16.12	4.42	4.97	22.24	12.84	12.75	11.57
	A Biceps Femoris	7.82	15.28	11.76	14.75	9.77	38.15	9.21	7.96	12.08	9.94	38.34	18.42
	A Gluteus maximus	1.30	19.71	9.01	14.88	19.76	12.88	15.61	2.45	12.64	8.09	14.93	17.66
	U Rectus Femoris	9.57	4.48	38.57	3.73	20.23	1.47	5.38	12.64	7.07	29.90	2.87	8.80
	U Biceps Femoris	8.74	3.89	11.36	2.69	12.31	2.70	2.25	4.80	2.34	7.38	4.61	8.87
	U Gluteus Maximus	25.16	7.08	16.16	7.33	11.53	12.63	8.64	17.22	6.54	14.13	16.14	11.94
	U Gastrocnemius Medial	4.93	12.05	11.92	8.41	7.55	9.20	4.33	5.88	3.14	4.11	18.14	7.54
	U Soleus	3.61	10.01	10.93	6.66	12.22	14.28	2.59	4.33	3.54	3.91	20.66	8.16

Appendix I.

Prosthesis evaluation questionnaire

The modified prosthesis evaluation questionnaire results are separated in 5 general variable categories (Table I.1). Each subject filled out the questionnaire for the two NF conditions based on the two-week adaptation period that they wore the prosthesis. Participants were asked to leave the question blank if the situation was not applicable. Each variables section was summed up and averaged for each participant for each condition.

Table I.1. PEQ results

		S1			S2			S3			S5			S6		
Variables		C1	NF1	NF2	C1	NF1	NF2	C1	NF1	NF2	C1	NF1	NF2	C1	NF1	NF2
Utility	1A	86	90	61	88	93	93	69	58	56	86	79	93	96	23	61
	1B	92	92	61	89	92	94	84	57	65	82	81	92	93	55	62
	1C	93	92	57	89	90	93	69	69	66	86	73	89	81	8	32
	1D	98	91	63	76	90	92	82	69	84	46	66	82	83	9	29
	1E	71	97	58	92	69	79	96	50	71	71	74	94	93	2	28
	1F	89	95	50	86	76	91	90	67	75	71	79	91	92	46	32
	1G	64	93	65	45	83	91	76	67	43	78	73	91	81	47	35
	1H	98	97	69	80	84	91	76	78	70	80	92	94	87	45	39
	Sum (800)	**691**	**747**	**484**	**645**	**677**	**724**	**642**	**515**	**530**	**600**	**617**	**726**	**706**	**235**	**318**
	Average	**86**	**93**	**61**	**81**	**85**	**91**	**80**	**64**	**66**	**75**	**77**	**91**	**88**	**29**	**40**
Frustration	2A	94	100	54	81	68	83	57	44	27	100	95	95	96	28	32
	2B	80	100	54	-	81	86	34	19	11	-	96	98	91	23	31
	Sum (200)	**174**	**200**	**108**	**81**	**149**	**169**	**91**	**63**	**38**	**100**	**191**	**193**	**187**	**51**	**63**
	Average	**87**	**100**	**54**	**81**	**75**	**85**	**46**	**32**	**19**	**100**	**96**	**97**	**94**	**26**	**32**
Ambulation	3A	96	100	51	97	80	90	76	39	63	98	92	97	90	24	49
	3B	85	100	62	97	81	91	65	45	77	98	74	84	95	26	50
	3C	95	97	51	97	77	82	82	32	74	85	84	93	95	31	35
	3D	94	97	54	75	87	88	79	47	78	68	80	90	92	31	26
	3E	71	-	53	94	74	84	30	-	-	92	88	96	41	29	29
	3F	85	-	47	68	76	91	37	-	-	61	64	91	45	26	24
	3G	93	100	64	84	92	93	74	61	75	94	82	90	93	21	20
	3H	65	89	69	94	88	93	64	67	59	66	77	95	46	-	15
	Sum (800)	**684**	**583**	**451**	**706**	**655**	**712**	**507**	**291**	**426**	**662**	**641**	**736**	**597**	**188**	**248**
	Average	**86**	**97**	**56**	**88**	**82**	**89**	**63**	**46**	**42**	**83**	**80**	**92**	**75**	**27**	**31**

Table I.1. PEQ results (continued)

Variables		S1			S2			S3			S5			S6		
		C1	NF1	NF2	C1	NF1	NF2	C1	NF1	NF2	C1	NF1	NF2	C1	NF1	NF2
Transfer																
Sitting in a car	3I	92	96	65	84	85	90	29	81	82	97	98	98	96	20	43
Sitting on a high chair	3J	88	96	68	85	87	92	77	77	75	96	98	97	88	26	42
Sitting on a soft chair	3K	82	88	50	76	71	85	61	73	56	84	86	97	58	10	27
Sitting on toilet	3L	85	94	67	79	83	91	86	74	82	83	88	97	97	19	33
Showering	3M	79	90	70	79	83	91	86	-	-	66	82	91	91	-	-
Satisfaction																
Prosthetic satisfaction	4A	85	89	54	97	82	83	80	35	35	88	91	97	92	1	37
Gait satisfaction	4B	80	90	57	94	83	87	65	38	30	87	91	94	92	2	29

Appendix J.

Consent form

APPENDIX B

Research Participant Information and Consent Form

Title: Locomotion Biomechanics with The Niagara Foot Prosthesis: Effects of Stiffness and Alignment

Names of Researchers:

Principal Investigator: **Joel Lanovaz**, Ph.D., Assistant Professor, College of Kinesiology, University of Saskatchewan, Phone: 306-966-1073

Additional Investigators: **Dr. Gary Linassi**, Department of Physical Medicine and Rehabilitation, College of Medicine, University of Saskatchewan; **Tim Bryant**, Ph.D., Professor, Dept. of Mechanical and Materials Engineering, Queen's University; **Stanley R. Holcomb**, Prosthetic Coordinator, Saskatchewan Abilities Council; and **Valérie Wellens**, B.Eng., (Masters student supervised by Dr. Lanovaz), Division of Biomedical Engineering, University of Saskatchewan

Introduction: You are being invited to participate in a research study because we want to examine how different heel stiffness in prosthetic feet affect gait characteristics in unilateral below-knee amputees. Specifically, we are studying heel stiffness in the Niagara Foot prosthesis.

Voluntary Participation: You are invited to read this consent form to better understand how you would be involved in this study before you decide to participate. This consent form will explain why the research is being done, what your role will be and the possible benefits, risk and discomforts.

If you decide to participate in the study you will be asked to sign this consent form. Your participation is totally voluntary; it is up to you to decide if you want to participate. If you decide to take part in this study, you are free to withdraw at any time and without giving any reasons for your decision. If you choose not to participate or withdraw at any time, this will not affect in any way the current or future services you receive from the Saskatchewan Abilities Council, the Department of Physical Medicine and Rehabilitation or any relationship you may have with the researchers. We suggest you read this document carefully, ask questions and talk about it with your family, friends, prosthetist and doctor before you decide.

Possible benefits of the study: There are no guaranteed direct benefits from participating in this study. However, at the end of the study you will have the option to keep a Niagara Foot if you so choose.

Procedures: If you agree to be in this study the following will happen:

Over the course of the study, you will be fitted with two versions of the Niagara Foot prosthesis. The fitting and alignment adjustments will be performed by Mr. Stan Holcomb from the Saskatchewan Abilities Council. Only the foot will be changed; you will retain your usual socket and pylon. After each fitting, you will be asked to wear the foot as much as possible in your daily activities for two weeks.

After each two week adaptation period (and at the very start of the study), you will be asked to come to the Musculoskeletal Biomechanics Lab (MBL) located in the Physical Activity Complex on the University of Saskatchewan campus. At the MBL, you will be asked to fill out a short questionnaire to evaluate your experience over the previous two weeks. After this, we will collect information about your walking patterns. This will be done using a motion capture system that tracks the movements of your limbs as you walk. The motion capture system uses specialized video cameras to track small reflective markers that will be attached to your legs using elastic straps. At the same time, we will record the forces that you apply to the ground using an instrumented platform embedded into the floor. Additionally a video camera will be used to record the foot as it touches the ground. This video camera will be set such that only the foot and lower limb are visible. It will be impossible to identify you in the video. Finally, we will also gather information about the activation patterns of your leg muscles using an electromyography (EMG) system. The EMG system uses small sensors taped to your skin to passively record the natural electrical activity produced by your muscles. The areas where the electrodes will be placed may need to be shaved. The total time for each visit to the MBL will be approximately 2 ½ hours.

Figure 1. Experimental Design Flowchart

After the study is completed, you will be fitted with your original foot. If you choose, you may keep one of the Niagara Foot prosthesis that you used. A flowchart showing the timeline for the study is shown above (Figure 1).

Foreseeable risks, side effects or discomfort: It is possible that during the adaptation periods you may feel some muscle soreness due to the use of a new prosthetic foot. During the testing period you may feel some discomfort on your skin from the adhesive tape that temporarily sticks the tracking markers and EMG sensors to your skin, but this is rare. There may be unexpected and unknown risks during the study, or after the study has been completed.

Alternatives to this study: You do not have to participate in this study to use the Niagara Foot prosthetic. You can purchase the Niagara Foot or any other prosthetic foot through your prosthetist.

Research-Related Injury: There will be no cost to you for participation in this study. In the case of a medical emergency related to the study, you should seek immediate care and, as soon as possible, notify the study's principal investigator. Necessary medical treatment will be made available at no cost to you. By signing this document, you do not waive any of your legal rights.

Confidentiality: While complete subject anonymity cannot be guaranteed, every effort will be made to ensure that the information you provide for this study is kept entirely confidential. The data collection will be done in a enclosed space in the MBL. Your name will not be attached to any information, nor mentioned in any study report, nor be made available to anyone except the research team. It is the intention of the research team to publish results of this research in scientific journals and to present the findings at related conferences and workshops. Most research findings will be reported in aggregate form without any reference to specific participants. In the event individual data are used, only participant codes will be referenced and your identity will not be revealed.

Voluntary Withdrawal: Your participation in this research is entirely voluntary. You may withdraw from this study at any time. If you decide to enter the study and to withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled.

If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study will be retained for analysis.

Contact information: If you have questions concerning the study you can contact Dr. Joel Lanovaz at (306) 966-1073. Dr. Lanovaz's number can be called collect if you are phoning long distance. This study has been approved by the University of Saskatchewan Biomedical Research Ethics Board. If you have questions about your rights as a research subject, you should contact the Chair of the Biomedical Research Ethics Board, University of Saskatchewan at (306) 966-4053. Again, this number can be called collect if you are phoning long distance.

CONSENT TO PARTICIPATE

By signing below, I confirm the following

- ❑ I have read (or someone has read to me) the information in this consent form.
- ❑ I understand the purpose and procedures, the possible risks and benefits of the study.
- ❑ I have been informed of the other treatments available for my condition.
- ❑ I was given sufficient time to think about it.
- ❑ I had the opportunity to ask questions and have received satisfactory answers to all of my questions.
- ❑ I am free to withdraw from this study at any time for any reason and the decision to stop taking part will not affect my future medical care.
- ❑ I agree to follow the study researcher team instructions and will tell them at once if I feel I have had any unexpected or unusual symptoms.

By signing this document I do not waive any of my legal rights. I will be given a signed copy of this consent form.

Printed Participant Name: __________________________

Participant's Signature: ____________________________ Date: ____________________

Individual conducting the consent process:_______________________

Date: _____________________

Appendix K.

Participant information questionnaire

UNIVERSITY OF SASKATCHEWAN

The Niagara Foot U of S stiffness
& alignment study

INFORMATION QUESTIONNAIRE

Subject ID: _______________

Date: _______________

Age: _____

Affected limb: ☐ LEFT ☐ RIGHT

Reason of amputation: ____

Time since amputation: _______

Prosthetic feet previously worn:

____

____

Prosthetic feet presently wear: (please list in order of most used – least)

____

____

Qualify your activity level:

Sedentary ☐

Somewhat active ☐

Active ☐

Very active ☐

Athletic ☐

Elite Athlete ☐

Reserved to the study researcher

Weight: __________lbs

Height: ___m ______cm

Length of the limb: ________cm

Appendix L.

Modified PEQ

Study number ______________
Date ______________

Prosthesis Evaluation Questionnaire

Shortened version edited by the University of Saskatchewan

Instructions

As you read each question, remember there is no right or wrong answer. Just think of YOUR OWN OPINION on the topic and make a mark THROUGH the line anywhere along the line from one end to the other to show us your opinion.

If you see different prostheses for different activities, please choose the ONE you use more often and answer all the questions as though you were using that prosthesis.

Example

How important is it to you to have coffee in the morning?

NOT AT ALL — EXTREMELY IMPORTANT

Over the past four weeks, rate your morning coffee.

TERRIBLE — EXCELLENT

OR check __ I haven't drunk coffee in the morning in the past four weeks.

This example shows that the person answered these questions feels that having coffee in the morning is important to him. He also thinks the coffee he has had lately has not been very good.

If he hadn't drunk any coffee in the past four weeks he would have put a check by that statement instead of putting a mark on the line between TERRIBLE and EXCELLENT.

As in this example, make a mark across the line rather than using an X or an O.

Please answer all the questions.

Group 1

These questions are about YOUR PROSTHESIS.

A. Over the past two weeks, rate the fit of your prosthesis.

TERRIBLE — EXCELLENT

B. Over the past two weeks, rate the weight of your prosthesis.

TERRIBLE — EXCELLENT

C. Over the past two weeks, rate your comfort while standing *when using your prosthesis*.

TERRIBLE — EXCELLENT

D. Over the past two weeks, rate your comfort while sitting *when using your prosthesis*.

TERRIBLE — EXCELLENT

E. Over the past two weeks, rate how often you felt off balance while using your prosthesis.

ALL THE TIME — NOT AT ALL

F. Over the past two weeks, rate how much energy it took to use your prosthesis for as long as you needed it.

COMPLETELY EXHAUSTING — NONE AT ALL

G. Over the past two weeks, rate the feel (such as the temperature and texture) of the prosthesis (sock, liner, socket) on your residual limb (stump).

WORST POSSIBLE — BEST POSSIBLE

H. Over the past two weeks, rate the ease of putting on (donning) your prosthesis.

TERRIBLE — EXCELLENT

Group 2

This section is about some of the SOCIAL AND EMOTIONAL ASPECTS OF USING A PROSTHESIS.

A. Over the past two weeks, rate how frequently you were frustrated with your prosthesis.

ALL THE TIME — NEVER

B. If you were frustrated with your prosthesis at any time over the past two weeks, think of the most frustrating event and rate how you felt at that time.

EXTREMELY FRUSTRATED — NOT AT ALL

OR check __ I have not been frustrated with my prosthesis.

Group 3

This section is about YOUR ABILITY TO MOVE AROUND.

A. Over the past two weeks, rate your ability to walk *when using your prosthesis*.

CANNOT — NO PROBLEM

B.* Over the past two weeks, rate your ability to walk in close spaces *when using your prosthesis.

CANNOT — NO PROBLEM

C. Over the past two weeks, rate your ability to walk up stairs *when using your prosthesis*.

CANNOT — NO PROBLEM

D. Over the past two weeks, rate how you have felt about being able to walk down stairs *when using your prosthesis.*

CANNOT — NO PROBLEM

E.* Over the past two weeks, rate your ability to walk up a steep hill *when using your prosthesis.

CANNOT — NO PROBLEM

F. **Over the past two weeks, rate your ability to walk down a steep hill *when using your prosthesis.***

CANNOT NO PROBLEM

G. **Over the past two weeks, rate your ability to walk down on sidewalks and streets *when using your prosthesis.***

CANNOT NO PROBLEM

H. Over the past two weeks, rate your ability to walk on slippery surfaces (e.g. wet tile, snow, a rainy street, or boat deck) *when using your prosthesis.*

CANNOT NO PROBLEM

I. Over the past two weeks, rate your ability to get in and out of a car when using your prosthesis.

CANNOT NO PROBLEM

J. Over the past two weeks, rate your ability to sit down and get up from a chair with a high seat (e.g. a dining chair, a kitchen chair, an office chair).

CANNOT NO PROBLEM

K. Over the past two weeks, rate your ability to sit down and get up from a low or soft chair (e.g. an easy chair or deep sofa).

CANNOT NO PROBLEM

L. Over the past two weeks, rate your ability to sit down and get up from the toilet.

CANNOT NO PROBLEM

M. Over the past two weeks, rate your ability to shower or bathe safely.

CANNOT NO PROBLEM

Group 4

The following section asks about YOUR SATISFACTION WITH PARTICULAT SITUATIONS given that you have an amputation.

A. Over the past two weeks, rate how satisfied you have been with you prosthesis.

EXTREMELY DISSATISFIED EXTREMELY SATISFIED

B. Over the past two weeks, rate how satisfied you have been with how you are walking.

EXTREMELY DISSATISFIED EXTREMELY SATISFIED

THANK YOU VERY MUCH