A Biomechanical evaluation of three Prosthetic feet.

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Declaration

This thesis is the result of the author's original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.

Signed:

Date:

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Abstract

Countless new prosthetic products are released for sale in the UK every year. Manufacturers attend prosthetic centres and inform the clinicians of the benefits of each product but provide little or no evidence to support their claims. Budget constraints on the NHS mean that use of any product should be supported with good clinical evidence to justify the prescription cost.

A primary aim of this study was to show the importance of evidence based practice within prosthetics.

This goal was achieved by using 3D gait analysis to compare gait patterns with 3 moderate activity Prosthetic Feet (Ossur Assure, Blatchfords Epirus and College Park Tribute) walking down an incline. The gait patterns were compared to a normal subject walking down a slope.

It was hypothesised that;

1. All of the feet would perform in a similar manner in relation to joint angle, moments and GRF.
2. The joint angle, moments and GRF will significantly differ from the control subject.
3. Subjectively due to the similarities in the design the amputees will feel equally confident wearing the Blatchford's Epirus foot and College Park's Tribute foot but differently wearing the Ossur Assure foot.

Six individuals with unilateral trans tibial amputations participated in walking down a seven-degree slope using 3DGA; each trying all three prosthetic feet. Each participant was also asked to complete a short questionnaire relating to the confidence they felt while walking down the slope with each prosthetic foot.

All feet performed equally well throughout all tests. Compared to the control subject the closest matching joint movement was the knee joint, which in the normal subject remained flexed throughout the gait cycle but in some amputee subjects is extended at IC. The most dissimilar joint behaviour for the amputees was the ankle; this remained predominantly in plantar flexion throughout the gait cycle except for a brief spell which showed a reduced amount of dorsiflexion at 50% of the gait cycle

compared to the control subject. The moment at the hip, knee and ankle joint followed a similar pattern as the control data with the ankle joint being the closest. The GRF data indicated which foot the subjects may have preferred.

The questionnaire showed no foot was significantly preferred by the subjects.

No one foot walked significantly better down the slope than another. Each subject demonstrated a gait that was stable. However, their gait didn't match the control subject exactly. Objective testing did not give a definitive answer of what foot should be prescribed and neither did the subjective data. The small sample size means definitive answers were difficult to achieve. However, the research does highlight the need for the use of evidence based practice in clinic's as the results could potentially be worth £500 per amputee patient to the NHS.

As a result of the findings of this study it could be suggested that further research is recommended in the locating the prosthetic ankle joint position, further investigating the link between the GRF and the subject's opinion and defining the optimal gait for an amputee.

ABBREVIATIONS

Flex foot;	FF
Early Stance	ES
3D gait analysis	3DGA
conventional foot;	CF
initial contact;	IC
initial contact opposite limb	ICOL
mid stance;	MS
toe off;	TO
late stance;	LS
range of motion;	ROM
self-selected walking speed;	SSWS
energy store and release;	ESAR
activities-specific balance confidence;	ABC
solid ankle cushion heel;	SACH
rate of perceived exertion;	RPE
patient;	pt
prosthetic;	pros
Below Knee	BK
Trans tibial	TT

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CHAPTER 1. INTRODUCTION

Currently there are approximately 5000 lower limb amputees in Scotland and each year there is an addition of approximately 730, Scott et al (2013). Following amputation, it is assumed that each patient will be considered for a prosthetic limb to allow them to achieve as high a standard of living as possible. However, in reality only 40% of amputees are actually fitted with an artificial limb Scott et al (2013).

Every component within the prosthesis is chosen specifically by the prosthetist to match the patient's perceived activity level and weight. Subsequently, there are a large amount of new prosthetic products entering the market each year promising to give the amputee a better quality of life and make the prosthetists job a little easier. Therefore, it needs to be asked; how does a prosthetist reliably choose which is the best product to prescribe?

Various studies have agreed that currently, 'prescription is driven by the market place and advertising (Czerniecki and Gitter, 1996) but also by clinicians' experience (Neuman E.S., 2006; Uellendahl J.E., 2006). It has been noted that prosthetists do not use scientific evidence for prescription due to 'lack of objective and quantitative methods Goujon et al (2006) and that they prefer not to read research papers as they are too abundant in 'statistics and jargon'. As a result, prescriptions are often made without any substantial evidence to say a new component is better than an existing product. Indeed, is there proof to say a new component is much different from those produced by its competitors? This lack of evidence based prescription raises questions on how ethical this practice is. Furthermore, as the average cost of a below knee prosthesis within the NHS is £500 then it has an ever increasing financial impact.

One of the aims of this study is to show the effect evidence based practice can have on a prescription choice. Prosthetic feet have been chosen to be examined, as they are required for all lower limb prostheses, and in particular moderate activity feet as there is little evidence supporting their use even though they are widely prescribed. The feet chosen are, the Ossur Assure, Blatchfords Epirus and College Park Tribute. They have been used across Britain for more than 10 years however, no research paper found included these particular prosthetic feet. The literature provided with these feet makes five common claims regarding them:

1. Stable on uneven terrain.
2. Smooth gait.
3. Dynamic Response at toe off.
4. Good gait symmetry.
5. Good for moderate walkers.
6. Protects the sound foot (Assure only)

As with many prosthetic components these statements are made with no numerical results, explanation or frame of reference to help put them into context. Each statement could be interpreted in numerous ways for example, dynamic response could mean many things and is very un-specific.

For this investigation the focus will be on the claim that the feet are stable on uneven terrain, as it is one of the primary reasons the former three selected feet would be prescribed. Again this claim could be interpreted in various ways, one being walking on slopes. A particular area of interest to the author is the effect of walking down an incline. This area is important to amputees as they often comment that they try to avoid slopes and inclines because they find them difficult and unsafe.

The study will investigate the biomechanics of Prosthetic Feet walking down an incline? Uni-lateral trans-tibial amputees will be asked to wear each of the three feet and walk down a slope. Kinematic/Kinetic sagittal plane data will be captured at the ankle, knee and hip and will be compared and contrasted to each other and against a control subject.

Furthermore, a questionnaire will be given to the participants asking for their subjective opinion on the stability of the feet after testing each one.

It is hypothesized that objectively all of the feet will perform in a similar manner, with regards to joint angles, moments and GRF. This will differ significantly from the control subject. Due to the similarity in design between two of the feet, it is thought that subjectively the amputees will feel equally confident wearing the

Blatchford's Epirus and College Park's Tribute foot but differently wearing the Ossur Assure foot. The Epirus and Tribute feet both include devices that facilitate movement on uneven terrain, a spherical joint proximal within the Epirus and anterior and posterior bumpers in the Tribute. These feet also include a full length carbon fibre sole plate. The Assure foot's major difference from the former two feet is that it has a higher build height as a result of a long carbon fibre spring extending from the proximal joint to the toes. This higher build results in a longer lever arm and potentially greater energy return.

It is hoped that a combined objective and subjective study, will be of some practical use to practicing clinicians rather than a purely objective study. Objective studies have been poorly received in the past. There is also an aim to discover what impact evidence based practice could actually have on prescription choice.

CHAPTER 2. LITERATURE REVIEW

The Prosthetic foot is continually being improved upon and developed. It has progressed through the centuries from being a simple wooden block, with the main function of resembling a foot, to a device comprised of materials such as carbon fibre and kevlar. The foot is now produced not only to imitate the aesthetics of a human foot but also to mimic its actions of shock absorbing, energy return and is becoming lighter in weight than ever before.

In recent years, countless new Prosthetic foot designs have become available with each manufacturer stating that it can perform and function better than the one before. The information provided by the manufacturers is often vague with statements such as 'superb gait symmetry on any terrain' (Chas A Blatchford & Sons Ltd Basingstoke RG24 8PZ), 'stable gait' (Ossur UK Stockport SK1 2AE) or 'controlled dynamic response' (Collage Park Inc Warren, MI 48088 USA) with no numerical results or frame of reference to support them. The industry is not obliged to perform clinical studies before marketing the product, Water et al (1998). Therefore, it is often up to clinicians to perform any real clinical research to determine the effectiveness of the feet.

Clinicians however, are limited in the amount of research they can perform due to time, finance and organisational restraints. This is shown in the limited amount of literature that is actually available on Prosthetic feet from such practising groups.

In order to assess the research that has already been done and in particular comparisons of the functions of various feet, Recal, Medline, pubmed and the Cochrane Library were searched under the key words: 'Prosthetic Feet', 'Comparisons', 'Prosthetic feet comparisons trans tibial', Prosthetic feet comparisons trans tibial unilateral', Prosthetic feet comparisons slopes', Prosthetics feet comparisons inclines' 'Gait Analysis' and 'walking on inclines'.

Articles were included if the amputee subjects were all unilateral trans tibial; the content was a comparison of prosthetics feet; the content discussed prosthetic feet design; the content discussed trans tibial gait; the content included walking down an incline; results included objective or subjective data. Due to the limited amount of data there was no restriction on date of articles and paediatrics were included. Articles were excluded if they; included other levels of lower limb amputation other than trans tibial; included microprocessor or hydraulic ankle joints; were not written in English; were case studies. No articles found included the Tribute, Assure or Epirus foot and very few assessed walking on inclines or slopes.

The literature search produced 126 articles; 27 from Medline, 77 from pubmed, 22 from Cochrane Library and 14 from reference lists. The articles were assessed using the Critical appraisal skills programme (CASP). The titles of 131 articles were screened which removed 73 articles. The full articles text was then screened which removed a further 34, resulting in 24 articles being reviewed. (appendix 13)

For the purposes of this section of the study**,** the papers that compare prosthetic feet objectively will be analysed and in a later section those making subjective comparisons will also be investigated**.** Firstly**,** the practical use and validity of the studies will be discussed**.** Secondly, it will be ascertained which feet have been studied and what aspects of the feet have been researched. There were only four papers found that specifically investigated BK amputees walking on inclines. These four research papers have been included separately in this literature review.

2.1 VALIDITY AND PRACTICAL USE OF PROSTHETIC RESEARCH

While reviewing the research on foot comparisons, it was found that the majority of the articles held no statistical significance largely due to small sample sizes, and this concurs with findings of Czerniecki and Gitter (1996). The most common problems with the papers are: type of study used, this is, were they blind or not blind, number of subjects included in the study, dissimilar groups of subjects and testing environment.

2.1.1 Type of Study Used

When comparing the feet**,** the most common method of examination is bringing patients into a gait lab and putting a number of feet onto their current limb and asking them to perform various tasks. Only one paper by discussed a double blind study being performed McMulkin et al (2004). The double blind (subject and researcher are blind to product being tested) study is said to be the gold standard in clinical trials as it eliminates any biased that may occur. However, is this really practical in prosthetics? Being able to test these feet without the subject knowing the manufacturer may be possible, but blinding the practitioner is virtually impossible Neuman et al (2006). The practitioner needs the test to be accurate, therefore a foot needs to be aligned to the manufactures instructions and in addition a foot can often be identified by simply looking at it.

2.1.2 Number of Subjects

Another reason many of these studies do not reach statistical significance is small sample sizes. The numbers of subjects used are often small. The largest number of subjects used was 16 but they consisted of children and adolescents McMulkin et al (2004). Moreover, of the adult studies carried out 10 was the greatest number of subjects used (Goujon et al, 2006; Perry et al, 1997; Royer et al, 2006; Thomas et al, 2000; Underwood et al, 2004). Therefore, as it would take a sample sizes much larger than this to provide statistically significant results the research would have to be considered with a level of uncertainty. Neuman (2006).

The difficulties that occur, when a topic such as prosthetic feet is investigated is that; firstly, the feet need to be acquired- preferably free of charge; secondly patients need to be available to take part in the trials that are often tiring and time consuming and thirdly the tests need to be done within a reasonable time frame, as due to the rate of prosthetic foot development and testing, the feet can become obsolete very quickly. Czerniecki (2005). These issues make it fundamentally difficult to gather a large enough subject group per study that would be considered significant.

2.1.3 Dissimilar Groups of Subjects

Another issue, with regards to the subjects within these studies, is that they are often dissimilar in their reason for amputation and subsequent general health. Feet are also being tested on subjects that do not fall within the manufacturers recommended activity categories.

Royer and Wasilewski (2006) considered frontal plane moments in 8 transtibial amputees wearing the flex foot**.** The cause of amputation varied between trauma, diabetes and congenital. Barth et al (1992) examined gait and energy cost of below knee amputees wearing six different prosthetic feet, which included conventional and energy storing**.** Within the 6 subjects that were used**,** 3 were traumatic amputees and 3 were peripheral vascular disease amputees. Macfarlane et al (1991) tested gait comparisons for below knee amputees using flex feet versus conventional prosthetic feet and one of the patients did not wear a shoe, which would give questionable results.

Due to their higher fitness level**,** it is often assumed**,** that traumatic and congenital amputees**,** are more likely to have an activity level compatible with an energy storing foot rather than vascular amputees**.** Royer and Wasilewski (2006) did use a day activity score to test (Appendix 6) the fitness of each patient**,** however this is the exception rather than the rule**.** All other papers found did not perform formal activity level testing and compared all patients equally on the same foot regardless of capability.

Barth et al (1992) found that vascular patients walk at a slower self-selected velocity than traumatic patients**;** 45.0 meters/minute compared to 64.4 meters / minute respectively. Studies have shown that the energy storing and return (ESAR) capabilities of feet are related to the velocity. When walking at slower speeds**,** the ESAR foot was found to be stiff and showed no significant capabilities compared to a conventional foot MacFarlane et al (1991). However, at faster velocities it showed improvements in range of movement (ROM) in late stance and push off power (Barr et al 1992; Hsu 2006; Murray et al, 1988) **It** can be assumed therefore, from these studies, that patients who cannot reach higher velocities are not likely to feel the benefits of an energy storing foot.

The reverse would also be true for putting active patients on conventional feet**.** Hsu et al (2006) found that at slower walking speeds**,** the difference in energy expenditure between energy storing feet and conventional feet was small but at higher velocities the conventional foot had a higher energy expenditure rate than the energy storing foot. Therefore, with these results, it does not seem reasonable to give active people conventional feet for test purposes, as they are likely to use up more energy.

These differences between the feet have been widely studied throughout the years. However, many papers still continue to test lower activity patients on higher activity feet and vice versa. Is it useful testing patients on products that are not designed to suit their particular ability?

2.1.4 Environment

Most instrumented gait studies are done in a gait laboratory, and often incorporate a treadmill Rietman et al (2002). Within these environment researchers are able to gain vast amounts of kinetic and kinematic data. Prosthetic foot study patients are commonly asked to walk on a 10m walk way or walk on a treadmill at various speeds and inclines. The results of these tests are then compared to the sound limb or control subjects. However, this may not be comparable with the patient’s home or work environment. Rietman et al (2002). Most patients will not spend the majority of their time walking on smooth level floors such as those in a gait lab and will not have the shock absorption such as that built into a treadmill. When assessing the capabilities of an energy storing foot, for example, clinicians would most probably want to see some data related to its ability to run outside on pavements and grass. Also, when the conventional foot is being studied, it would be beneficial to gain information about its ability to adapt to uneven terrain, as the wearers will be walking outside on cambers in the road.

Equipment to measure the above information may be difficult to acquire. However, even within the gait lab, tests such as those done by McMulkin et al (2004) can be advantageous. McMulkin et al (2004) examined three paediatric feet during functional activities: cutting drill, (run around 8 cones as fast as possible) measuring inversion/eversion angle characteristics; vertical jump test (take off from floor with feet leaving ground at same time) where height and distance jumped are measured. These tests were well intentioned but the cutting drill test measured the speed at which the subjects ran around the cones with timing lights. This test relied on a theory that a foot that allows increased frontal plane motion will be more functional. Hence a faster speed in the test. This theory has not been proven. Therefore, the results of this test may provide little more than subjective information and not the inversion/eversion angles, which would be more insightful.

As the design of prosthetic feet becomes more complicated, the need for more accurate outcome measures is becoming more apparent. In particular, these measures should be able to assess the function and performance in domains beyond flat level walking. Additionally, these measures should be sensitive to changes in prosthetic devices and be validated for use by targeted amputee populations. Hafner (2005).

In conclusion**,** the amount of research available regarding prosthetic feet does not provide compelling evidence to guide a prescription. It is limited and generally lacks clinical significance. Problems such as small sample sizes, mixed populations and limited test environments plague the application of scientific results, as well a**s** clinical prescription of components Hafner (2005). In today's evidence based culture**,** it is becoming increasingly important that the prosthetic profession learns to resolve these issues and adapts its own methodologies, which would allow scientific research to play a primary role in prescription of prosthetic feet.

2.2 FEET EXAMINED

Prosthetic foot ankle units are often differentiated by their physical design, mechanical behaviour and functionality Hafner (2005). There are 3 main categories of feet, conventional, multi axial and energy storing and return (ESAR).

2.2.1 Conventional Feet

Conventional feet are the most basic design**.** They generally incorporate a solid ankle and have limited movement within all planes due to the deformation of the foam foot shell of which some can be detached. These feet are generally given to less active patients who are mostly indoor walkers or walk with an aid. Table 2.1 shows a list of some conventional feet that are currently available.

Conventional Feet	**Manufacturers**
SACH (Solid ankle cushion heel)	Otto Bock Healthcare
Pedalin Foot	Otto Bock Healthcare
Senior Foot	Blatchfords
Uniaxial Foot	Otto bock Healthcare

Table 2.1: Examples of Conventional Prosthetic Feet

Figure 2.1 Blatchford Senior Foot

Figure 2.2 Otto Bock SACH Foot

2.2.2 Multi Axial Feet

Multi axial is a term that incorporates feet that move within one plane (uni axial), two planes or all planes. The feet used within this study would fall under this category. Another term that is becoming increasingly popular is moderate activity feet. Single plane movement would be considered the sagittal plane allowing plantar flexion and dorsiflexion. Movement within all planes would allow sagittal plane motion but it would also allow coronal plane motion**;** inversion/eversion and transverse plane motion showing axial rotation. Multi axial feet will make use of hinges and bumpers to allow this varying degree of movement and will be used by moderately active people who partake in outdoor walking and some light sports. Table 2.2 shows some multi axial feet that are available.

Multi axial Feet	**Manufacturers**
Multiflex	Blatchford
Tribute	College Park
Sure flex (Former version of Assure)	Ossur
Epirus	Blatchford

Table 2.2: Examples of Multi axial Prosthetic Feet

Figure 2.3 Blatchford Multiflex Foot

Figure 2.4 Ossur Sure Flex Foot

2.2.3 Energy Storing and Return Feet

Energy storing and release (ESAR) is a term that incorporates feet that store energy during early to mid-stance**.** The energy stored is later used during push off to increase forward acceleration of the leg and body Wing et al (1989). This energy storage is commonly achieved with the use of carbon fibre leaf sole plates. Some of these have flexible internal keels and some have keels that extend into the ankle or shank. Most commonly tested is the Ossur Vari Flex Foot Figure 2.5. These feet are aimed at very active patients who partake in activities that involve running and high impact sports. Table 3 lists some ESAR feet.

Energy Storing Feet	Manufacturers
Vari Flex Foot (Flex foot range)	Ossur
Elite Foot	Blatchford
Renegade	Freedom
Seattle Foot	Seattle
C walk	Otto bock healthcare
Carbon Copy II	Ohio Willowood
Flex foot with pylon	Ossur

Table 2.3: Energy Storing Prosthetic Feet

Figure 2.5 Ossur Vari Flex Foot

Figure 2.6 Blatchford Elite2 Foot

2.2.4 Multiple Category Feet

There are also feet that incorporate multiple categories, for example, College Park Trustep could be said to be multi axial and ESAR. There are also feet that involve additional features such as adjustable heel heights, for example, the Ossur Elation foot and more recently, feet that incorporate computerised technology for movement at the ankle joint namely, Ossur Proprio Foot and Blatchfords Elan foot and those that include hydraulics namely, Blatchfords Echelon and RSL Steepers Kinterra foot. There is also a foot design that is used primarily for running, which is commonly known as a Blade. The Blade is a carbon fibre spring that bends and provides large amounts of energy return for short bursts of speed, such as those needed in sprinting. Figure 2.7

Figure 2.7 Ossur Flex Run

Figure 2.8 Ossur Flex foot with pylon

Throughout this literature review the most common foot type studied was the ESAR foot and the most common comparison was between energy storing and conventional feet. The majority of studies that have been completed are out dated and do not include feet that have been produced within the past 5 years, such as Tribute, Epirus or Assure. Table 2.4 shows the feet that were used in 23-foot examination papers to date

Feet	**Number of a specific foot used totalled within 24 examination papers used for the literature review of this thesis.**
Seattle light foot	10
Single axis	4
SACH	10
C-Walk	1
Flex foot	13
Carbon Copy II	3
Trustep	1
Truper	1
SAFE	4
Quantum	2
Greissinger	3
Dynamic	2
Sure flex	1
Genesis	1
Re flex VSP	2

Camp	1
Proprio Foot	10

Table 2.4: Feet used in research papers 1988 to date.

It can be seen from these results Table 2.4, that the SACH, Seattle Light and Flex Feet have been extensively examined but the findings on the other feet cannot be treated as significantly important, as there is too little information regarding them. The area of interest for most researchers is obviously the biomechanical effects that ESAR and conventional feet have on gait and subsequently the differences there are between them.

2.3 GAIT ANALYSIS COMMON FINDINGS

Over the past 30 years the methods of analysing amputee gait have greatly improved. 'Today, a myriad of tools, techniques, methods and analyses exist to aid the researcher and Prosthetist in the study of amputee gait' Hafner et al (2002).

From the papers reviewed the biomechanical analysis of amputee gait is primarily aimed at 4 main areas; stride characteristics, kinematics, kinetics and metabolic energy expenditure. There is very little focus on amputees walking down inclines.

2.3.1 Stride Characteristics

Stride analysis concentrates on measuring a number of gait parameters. The majority of papers focus on walking velocity, cadence, stride length and support time.

2.3.2 Speed

Self-selected walking speed (SSWS) is a common measure for gait analysis. It represents the comfortable speed that an individual naturally chooses to walk and is believed by many to represent the speed at which the energy expended per unit distance travelled is minimized Gard (2006). SSWS can be obtained in various ways including motion analysis systems, treadmills and a simple 10-meter walkway using speed = distance/time calculation.

The general consensus from the papers is that below knee amputees SSWS is slower than that of able-bodied subjects, approx.; 45.0-64.4m/min and 79-90m/min respectively. Barth et al (1992). When viewed as a group, subjects SSWS with ESAR feet is faster than with conventional feet (Hsu, et al 2000, Barth et al 1992, Underwood et al 2004). Hsu et al (2000) found patients SSWS with ESAR feet was 9% faster than with conventional feet. It is important to note that vascular and traumatic patients SSWS will vary regardless of the foot. Therefore, patient's pathology should be taken into account when considering SSWS.

2.3.3 Cadence

Cadence is the number of steps taken per unit time. Cadence is naturally linked with velocity as an increase in velocity causes an increase in cadence. Able-bodied subjects have a higher cadence level than amputees, approx.; 120steps/min, Whittle (1996) compared to 82.4-94.7 steps/min, Barth et al (1992). Studies found that the difference in cadence between ESAR and conventional feet was not statistically significant (Hafner et al 2002; Thomas et al 2000). However, MacFarlane et al (1991) found the conventional foot had a higher cadence than ESAR. It was also found that the subject tended to stay on the ESAR foot longer as was found by Gailey (2005) and Goujon et al (2006). They suggested the reason could be due to the mechanical properties of the foot, such as the shape of the keel or the materials of the foot.

2.3.4 Step and Stride Characteristics

The stride length is the distance between two successive placements of the same foot. The average stride length of a normal subject is 1.45m. Whittle (1996). When comparing the stride length to the normal limb, Barr et al (1992) found step length was 26% longer for the prosthetic limb than for the residual limb when wearing SACH and Carbon Copy II foot. However, the majority of studies found the prosthetic limb had a shorter stride length than the sound limb (Barth et al 1992; Hafner et al 2002; Perry et al 1997). When comparing stride lengths, for ESAR and conventional feet, the ESAR foot consistently had a longer stride (Barth et al 1992; Gailey 2005; Goujon et al 2006; Hafner et al 2002; MacFarlane et al 1991). The longer stride of the ESAR foot was attributed to the flexibility of the keel in late stance. This allows the centre of mass to progress over the supporting limb to delay heel rise, allowing a larger sound limb step. The softer toe in conventional feet causes an early heel rise and hence shorter step.

2.3.5 Support Time

Support time could be split into double and single. Double support is the period throughout gait when both feet are in contact with the ground. This occurs between initial contact of one foot and toe off of the other. Single support occurs when only one foot is on the ground during swing phase.

It was seen that, prosthetic patients spend longer in heel only contact than able-bodied patients, especially while wearing ESAR feet (MacFarlane et al 1991; Perry et al 1997) due to the stiffness of the material and lack of mobility at the ankle joint. Perry et al (1997) noted that this was seen in the delay to reach foot flat of the Seattle Light foot till 21% of the gait cycle.

When comparing ESAR and conventional feet, the results showed more time spent on the ESAR foot due to its longer keel delaying heel rise. Goujon et al (2006) found that there was an increase in double support time with conventional feet, as patients feel less stable in single stance and because they walk at a slower velocity.

2.3.6 Joint Moments

Moments of force refer to the external or internal moments applied to a joint. Throughout most studies, the moment of force was displayed by separating the joints into hip, knee and ankle of the sound and prosthetic limb. As has been seen with parameters earlier in the thesis the conventional and energy storing feet are the most popular to be investigated for moments of force. Two papers will be primarily discussed as examples, Underwood et al (2004) and Barr et al (1992).

Underwood et al (2004) aimed to determine the effects of two prosthetic feet on the three-dimensional kinetic patterns of the prosthetic and sound limbs during unilateral trans-tibial gait. Eleven unilateral trans-tibial amputees took part in two walking sessions on a level surface: one using the conventional SAFE foot figure 2.9, the other using the dynamic flex foot. Peak joint moments were examined in the sagittal plane as subjects walked at a SSWS. It was concluded that the dynamic foot allowed subjects to rely more heavily on the prosthetic foot for propulsion and stability during walking with minimal compensations at the remaining joints. Underwood et al (2004) results at the hip, knee and ankle are discussed further.

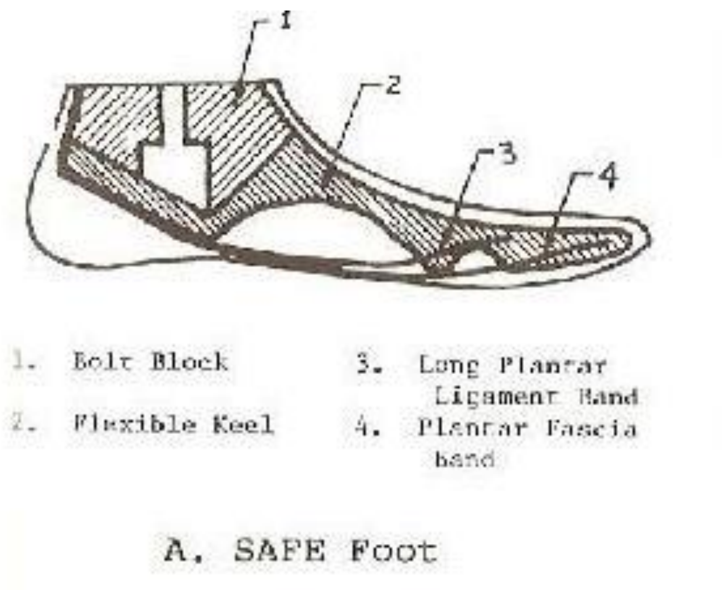


Figure 2.9 SAFE Foot (prosthetics.umwblogs.org)

Barr et al (1992) compared the kinetic and kinematic capabilities of the solid ankle cushion heel (SACH) and carbon copy II prosthetic feet during the stance phase of gait figure 2.10. This paper is limited in its significance as only one subject was used however it is a good example of early research into the differences between conventional and dynamic feet. A single uni lateral below knee amputee tested the feet under dynamic loads. Ten trials per foot of bilateral stride at SSWS were collected. The ground reaction vector was progressed along the foot more slowly through stance while using the stiffer more dynamic carbon copy II foot compared to the SACH foot. The carbon copy II foot showed slower unloading in later stance and later peak propulsive force than did the SACH foot. Barr et al (1992) results at the hip, knee and ankle will also be discussed further in this section.

Figure 2.10 Carbon Copy II Foot (www.willowwoodco.com)

Hip Joint: The difference between ESAR and conventional feet was found to be very small and the results varied depending on the study. Underwood et al (2004) found none of the hip moments on the sound and prosthetic side were significant between Flex and SAFE feet but did not provide an explanation for this Table 2.5.

Internal Hip Moments (Nm/kg)	**Prosthetic Limb**		**Sound Limb**	
	SAFE foot (P value)	Flex Foot (P value)	SAFE foot (P value)	Flex foot (P value)
Hip extensor	0.75 (0.31)	0.67 (0.28)	0.95 (0.40)	0.89 (0.44)
Hip Flexor	1.40 (0.50)	1.68 (0.64)	1.60 (0.58)	1.79 (0.71)

Table 2.5 Internal Hip moments extracted from Underwood et al (2004) average of 11 subjects on a level walk way. $P<0.05$

Subjects characteristics (n=11)	
Mass (mean) kg	80.33
Mass (SD) kg	14.32
Mass (Range) kg	56.8-104.5

Table 2.6 Subject Characteristics (n=11) Underwood et al (2004)

Barr et al (1992) compared SACH and Carbon copy II at the hip joint and found they both create a large extensor moment on the prosthetic side Figure 2.11. This was approximately twice that of the sound side, and peaked at 15% of stance and at 50% of stance the net muscle moment for the remainder of stance was close to zero. During late stance a greater flexor moment would have been expected to prepare for swing phase of both limbs. It was noted, that due to the deformation of the SACH and Carbon copy II foot shells, the rate of change of vertical ground reaction force was higher and progressed along the foot faster than the sound foot. This resulted in a large extensor moment in ES for the prosthetic feet compared to the sound and would cause the subject to walk with flexion at the hip for a larger portion of stance. Barr et al (1992) noted a slight flexor moment on the sound side in ES which may have been expected to be larger for normal gait, however this was only one subject walking and may vary if a number of subjects were tested in the same manner. This changed quickly into an extensor moment and peaked at 10% of stance which dropped to nearly zero at 15% until late stance when the flexors began to work.

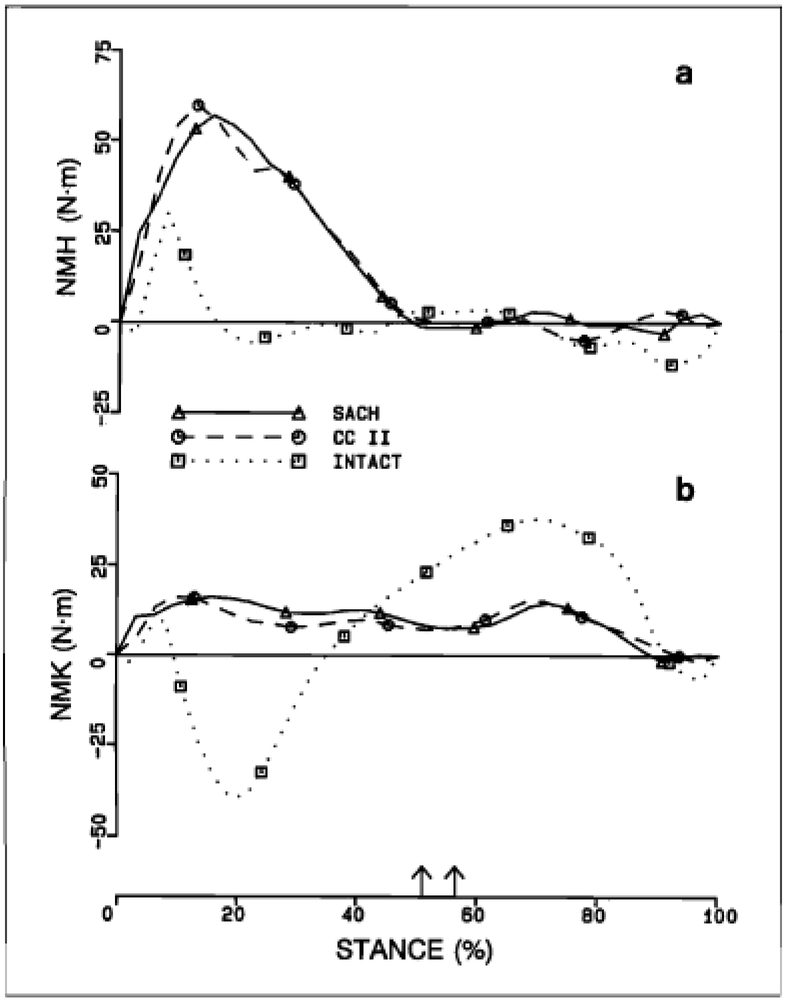


Figure 2.11 Barr et al (1992**)** Muscular moments about (a) the hip (NMH) positive extensor, negative flexor and (b) the knee (NMK) positive flexor, negative extensor for BK subjects.

<u>Knee Joint</u>: The results of moments at the knee for BK amputees has resulted in scattered disagreement amongst authors. Some report that the use of conventional feet creates a larger knee flexor moment during early stance on the prosthetic side (Barr et al 1992; Winter, Sienko 1988). Underwood et al (2004) compared the flex and SAFE feet, they noted with the use of the flex foot resulted in a larger flexor moment on the prosthetic limb but slightly smaller knee flexor moment on the sound limb, in comparison to the SAFE foot condition, Table 2.7. Underwood et al (2004) also noted that as push-off began to occur, the second peak knee extensor moment was greater in both the prosthetic (34% increase) and sound (14% increase) limbs

when walking with the flex foot compared to the SAFE foot. It was reasoned that the deformation properties of the more dynamic foot allowed for a greater plantar flexor moment which resulted in an increase of late stance knee extensor moment to control knee collapse, which it is felt is a reasonable assumption.

Barr et al (1992) noted the two prosthetic feet, SACH and carbon copy II showed similar results for moment at the knee through stance figure 2.11 Both prosthetic feet demonstrated a purely flexor moment throughout stance. This result was unusual as the subject would be required to walk with an extended knee throughout gait which would be difficult. The knee of the intact limb showed a normal gait pattern of initial flexor moment, followed by a larger extensor moment that peaked at 20% of stance and continued until 35%. During the remainder of stance, the intact limb demonstrated a flexor moment which was greater than the prosthetic side and peaked at approximately 70%. Barr et al (1992) concluded that due to the deformation properties of the SACH and carbon copy II feet the centre of pressure was more anterior than on the sound side resulting in greater knee flexor net muscular moment through mid-stance. However, the prosthetic side knee remained fully extended. Therefore, Barr et al (1992) reasoned the net muscular flexor moments throughout stance may not have muscular origin, but rather may be derived from the resistance of the joint itself. This conclusion could be plausible however, the question of why this subject was then used could be asked. It could also be considered that the subject's limb alignment may have been extended giving skewed results or the fit of the socket could have been encouraging extension at the knee.

Internal Moments (Nm/kg)	Prosthetic		Sound	
	SAFE foot (P-value)	Flex foot (P-value)	SAFE Foot (P-value)	Flex foot (P-value)
Knee extensor	0.31 (0.24)	0.47 (0.19)	0.92 (0.58)	0.85 (0.34)
Knee flexor	0.11 (0.24)	0.18 (0.14)	0.08 (0.27)	0.03 (0.12)

Table 2.7 Internal Peak Knee moments. Average of 11 subjects on a level walk way Underwood et al (2004)

Ankle Joint: The findings of ankle moments resulted in some disagreement among authors but primarily compared the effect on the prosthetic side between ESAR and conventional feet. Some reported that ESAR gave an increase in plantar flexion moment in late stance compared too conventional (Barr et al 1992; Underwood et al 2004). Underwood et al (2004) found significant results at the ankle. The subjects were able to apply a 15% greater ankle plantar flexor moment on their prosthetic limb using the dynamic flex foot compared to the SAFE foot Table 2.8. This again was attributed to the deformation properties of the dynamic foot allowing for greater power absorption during weight acceptance and consequently, a trend toward a greater plantar flexor moment. It can also be seen that the plantar flexor peak on the sound side was higher using the SAFE foot as the subject has to work harder to over-come the lack of dynamic action in the more conventional foot.

Internal Moments (Nm/kg)	Prosthetic		Sound	
	SAFE Foot P-(value)	Flex Foot P-(value)	SAFE Foot P-(value)	Flex Foot P-(Value)
Ankle Plantarflexor	1.21 (0.16)	1.39 (0.21)	1.51 (0.30)	1.48 (0.27)
Ankle Dorsiflexor	0.33 (0.14)	0.43 (0.15)	0.30 (0.15)	0.30 (0.10)

Table 2.8 Internal Peak Ankle moments. Average of 11 subjects on a level walk way Underwood et al (2004)

Barr et al (1992) found the net prosthetic moment about the ankle were similar for the two prosthetic feet; SACH and carbon copy II figure 2.12. Both feet showed a dorsiflexor moment until approximately 25% of stance which then changed to a plantar flexor moment which peaked at 80% then dropped to zero. The SACH foot plantar flexor moment rose more sharply than the carbon copy II however the more dynamic carbon copy II's peak was marginally higher. Unfortunately, Barr et al (1992) did not show the intact limb ankle moment graph for comparison. The faster moving centre of pressure on the SACH foot due to its deformation properties explained the rapid climb in moment of the plantar flexors. It is felt that the carbon copy II foot peaked higher than the conventional foot because its stiffer materials prevented it from collapsing the late stance as the conventional foot would have.

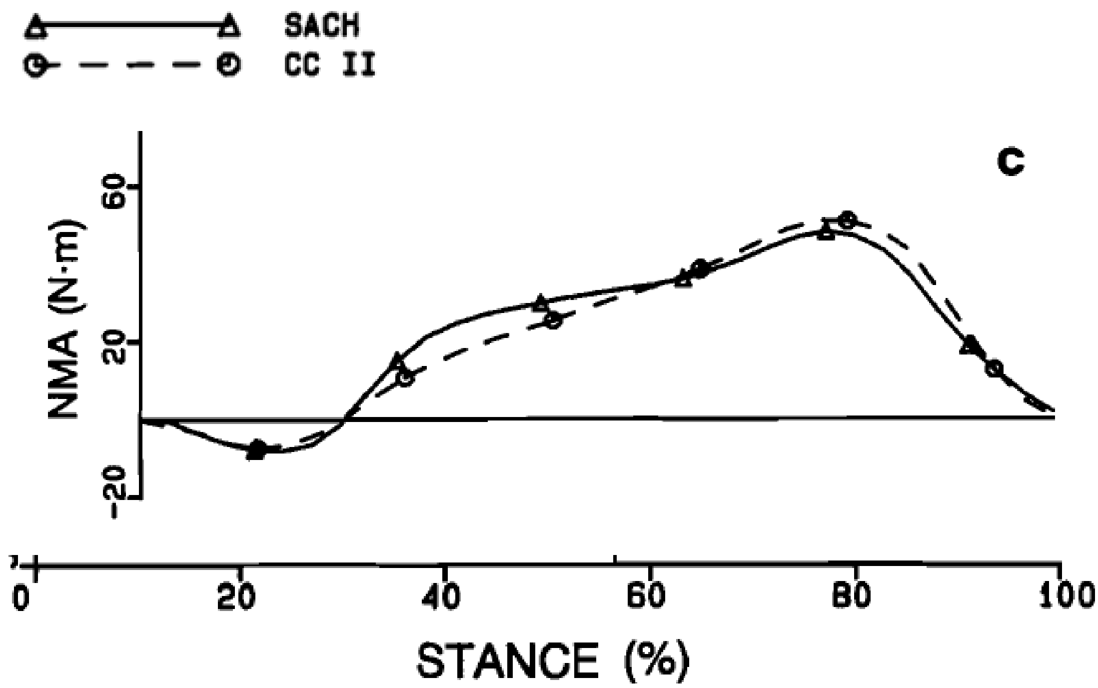


Figure 2.12 Ensemble averages of prosthetic moment about the ankle using the SACH and Carbon Copy II prosthetic feet. Positive plantar flexors, negative dorsiflexors. Barr et al (1992)

In conclusion it can be seen the type of prosthetic foot has a large influence on the moment at all joints of the lower limb. When testing the conventional and more dynamic energy storing feet the deformation properties of the feet directly impact the rate of progression of the centre of pressure. The stiffer properties of the energy storing feet delayed the centre of pressure allowing subjects to rely on this foot for forward progression and stability with minimal compensations required at the remaining joints.

2.3.7 Kinematics

Kinematics is the study of human limb movements and is commonly used when analysing gait. When comparing ESAR and Conventional feet, the ESAR commonly shows an increased ROM at the ankle (Hafner, et al 2002; Menard, Murray 1989; Snyder, Powers 1995; Thomas et al 2000; Toburn et al 1990). A large dorsiflexion angle was found, which has been attributed to the flexibility of the keel in ESAR feet. Gailey (2005) noted that the increased dorsiflexion in ESAR flex feet is due to the larger moment arm created by the pylon and foot being a single section Figure 2.8. This permits the body's weight to progress over the foot allowing the pylon to mimic the tibia's forward progression.

Hip Joint

Few papers on the analysis of feet compared the effect at the hip and knee ROM. Barr et al (1992) compared SACH and Carbon Copy II feet to each other which showed virtually identical results but differed from the normal subject figure 2.13. At HS the hip flexion angle of the effected side was greater than the sound. It was shown that from 20% - 40% of the gait cycle the hip joint angles for both sides and feet were nearly identical. After 40% of gait the hip angle was more flexed in the amputated side than the sound. The reduced motion of the hip on the amputated side compared to the sound could be attributed to the reduced motion at the ankle causing the proximal joints to have to compensate. However, there was a difference in plantar flexion and dorsiflexion of the prosthetic feet so more of a difference at the hip may have been expected.

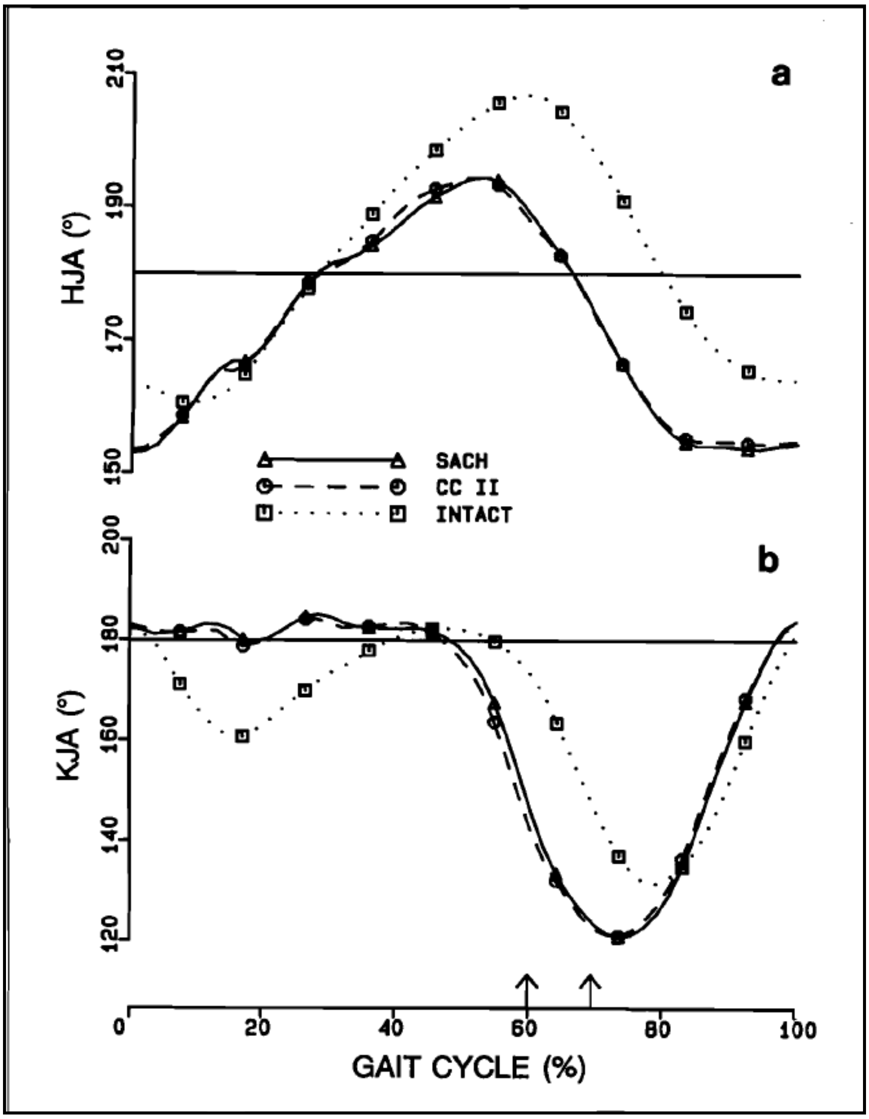


Figure 2.13 Barr et al (1992) (a) Hip joint angle (HJA) positive extension, negative flexion and (b) knee joint angle (KJA) positive extension, negative flexion.

Knee Joint

The majority of researchers were in agreement about the findings of the knee, however it has to be noted that few papers actually included this analysis. Many reported a larger extension angle on the affected side in ES compared to the sound no matter what foot type they were wearing (Barr et al 1992; Bateni, 2002)

Barr et al (1992) found the knee joint for the intact side demonstrated a flexion-extension-flexion pattern which is typical of normal gait figure 2.13. However, the prosthetic limb for each foot showed a predominantly extended position and during swing flexed approximately 10 degrees more than the intact side. The plantar flexed position of the prosthetic ankle joint is likely to be the cause of this extended gait in early stance but as noted previously Barr et al (1992) should also consider the subjects, alignment, socket fit and position of underlying anatomy. Bateni (2002) suggested the cause of this reduced knee flexion angle, might be due to the prosthetic foot not being able to produce controlled plantar flexion, which in turn can cause the amputee to actively extend their knee providing extra stability.

<u>Ankle Joint</u>

The greatest difference seen when comparing prosthetic feet kinematic ally appears to be at the ankle joint. Barr et al (1992) found the angles at the hip and knee when the SACH and Carbon copy II feet were compared were very similar. However, when the ankle joint angle was compared larger differences could be seen figure 2.14. At HS the carbon copy II foot showed a greater plantar flexion angle than the SACH. From 20% of stance both prosthetic feet began to dorsiflex with the carbon copy II-foot peaking at a higher angle at 80% of stance. Both feet follow a normal pattern of ankle motion. The increased motion from the carbon copy II foot can be attributed to the deformation properties of the carbon fibre heel spring and sole plate but may also have been the limbs alignment.

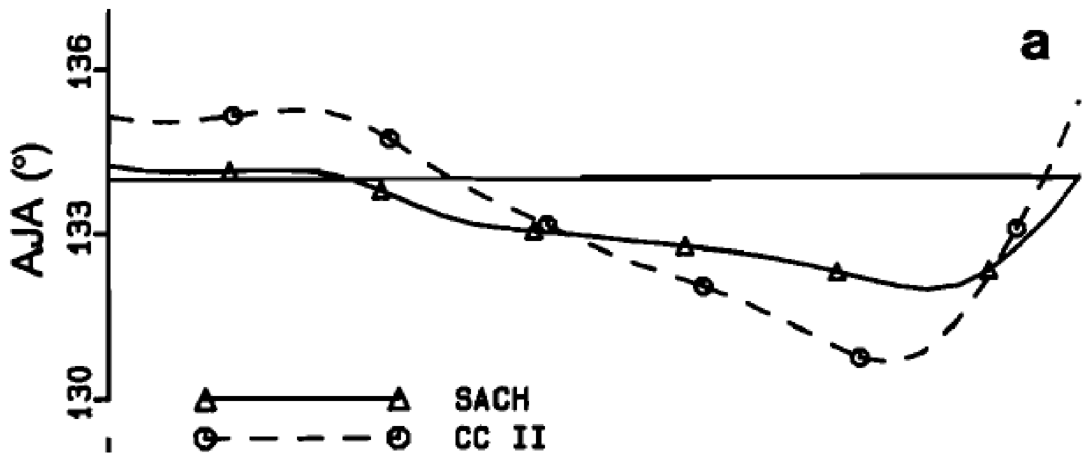


Figure 2.14 Averages of Prosthetic ankle joint angle (AJA) (in degrees). Positive plantar flexion, negative dorsiflexion Barr et al (1992).

Murray et al (1988) took part in a study comparing the conventional SACH foot and dynamic Seattle foot. The research primarily looked at subjective data however a small amount of objective data was included. A single amputee with experience wearing the SACH and Seattle foot was asked to walk in a gait laboratory. The prosthetic feet were compared and also compared to the non- prosthetic side. The greatest differences between the prosthetic feet were seen at the ankle joint. The pattern of plantar flexion-dorsiflexion for the Seattle foot more closely resembled that of the non-prosthetic side. This study was very brief and was limited in significance as there was only one subject but it does agree that the effect of differing prosthetic feet influences the ankle joint more than the more proximal joints.

2.3.8 Energy Expenditure

Metabolic energy expenditure is another common measure when analysing amputee gait. It has been well documented that the energy expenditure of amputees exceeds that of able bodied persons. Perry et al (1997) noted, trans tibial amputees can use up to 25% more energy, which may be due to an increased demand on hip and knee extensors.

Since energy cost of walking is directly linked to the velocity, the higher the velocity the greater the energy cost (Hafner et al 2002; Hsu et al 2006; Nielsen et al 1989; Thomas et al 2000). It can also be seen that at SSWS the difference in energy cost between ESAR and conventional feet is negligible. However at higher velocities the ESAR foot has been found to be marginally more energy efficient than the conventional foot (Hafner et al 2002; Hsu et al 2006; Nielsen et al 1989; Thomas et al 2000). The aetiology of a subject's amputation has also been found to be an important factor when analysing energy expenditure. Vascular patients often show a reduced energy efficiency compared to trauma patients (Barth et al 1992; Neilsen et al 1989). The test environment could also contribute to energy expenditure as McMulkin (2004) noted when testing 4 types of feet on a treadmill. The patients found that walking on the treadmill was very unstable and may have used additional energy when trying to balance themselves.

2.3.9 Subjective Opinion

In the past prosthetic prescription was relatively simple due to the lack of choice in componentry. However, in recent years, this choice has grown making prescription for the clinician more difficult. Ideally the selection of componentry would be a result of examining published scientific outcomes and would be supported by the prosthetists successful clinical experience. Yet it should be noted it is more often a result of personal and peer opinion as well as trial and error.

Traditionally the choice of componentry has been made between the prosthetist and consultant but it is becoming increasingly obvious that the patient should also be involved. With the increase in commercial advertising and use of the internet amputees are now more informed than ever about what is available to them and as such, have more of an opinion on function, comfort and cosmesis of their limb.

The objective amputee gait studies often fail to show significant differences between feet, therefore the incorporation of a subjective insight could provide practical and valuable information.

Subjective information in studies is given little attention; it varies between simply asking the wearer's opinion to using specially developed questionnaires. It could be argued that the user's thoughts and opinions are more useful and important than the data gathered within a gait lab. However, there are limitations in this approach. These include; difficulty in performing quantitative analysis, the potential for bias, possible placebo effects plus the ability of a subject to describe a situation effectively Hafner et al (2002).

Questionnaires can help overcome some of these limitations because the results can be quantified using different outcome measures. Also more subjects can be incorporated than in objective studies, thus the results can have more statistical significance.

When using a questionnaire within a study, it is essential that a validated and well-developed design of questionnaire is chosen, as this would give the results more credibility. Hafner et al (2002) noted that there are two types of questionnaire commonly used within subjective studies: the functional assessment questionnaire and the numerical rating scales.

<u>Functional Assessment</u>

The functional assessment questionnaire is a standardised series of questions relating to prosthetic function, performance or preference. Menard et al (1989) examined the Flex foot subjectively and objectively. They felt that the merits of the energy storing foot was unclear and wanted to determine the clinical situations in which the energy storing prosthetic foot is superior to a conventional prosthetic foot. The subjective study involved 20 participants who answered a series of questions that were mailed to them comprising of 4 sections:

Section 1

While using the flex foot:

- Do you think your gait is: Less Smooth, Smooth, Same?
- Do you think your balance improved?
- Do you think your endurance improved?
- Were there any mechanical issues? No problems. Breakage

Section 2

Response to Flex foot

- While using the flex foot do you think your gait improved?
- While using the flex foot do you think there was no change in gait?
- While using the flex foot do you think your recreational activity increased?
- While using the flex foot do you think there was no change in recreational activity?
- While using the flex foot did you feel a more dynamic action you're your prosthesis?

Section 3

Dynamic action

- Which best describes the more dynamic action of the flex foot? Appropriate, Prefer More, and Prefer less.

Section 4

While using the flex foot:

- Pain: No change, Decrease, Increase
- Skin Problems: No change, Decrease, Increase
- Normal limb problems: No change, Decrease, Increase

A summary of the main findings was 68% felt their gait had improved with the flex foot and 27% felt no change. Twenty users could feel the dynamic action of the foot. Nine felt a decrease in limb pain, eight no change and three increased pain. Sixteen expressed no difficulties with normal limb, while six stated some problems. Menard et al (1989) give very little discussion relating to their subjective results. However, they do find that most practicing prosthetists would feel sophisticated gait analysis is often unnecessary. Overall the subjects in this study walked very well and were satisfied with their prosthesis while using the flex foot. Menard et al (1989) feel this information would be good enough for most prosthetists which it is felt is a reasonable assumption.

Murray et al (1988) evaluated the performance of the Seattle foot Figure 2.15 compared to SACH and Single axis foot. They used a questionnaire which was responded to by 31 people, 27 males and 4 females. The subjects were asked if the Seattle foot was better or worse compared to the SACH and single axis foot with regards to:

- Heel stiffness
- Ankle motion
- Shock Stress at hip and or knee
- Change in gait
- Toe off action
- Ease of activities
- Balance and Endurance
- Walking on uneven terrain
- Residual limb pain
- Skin problems

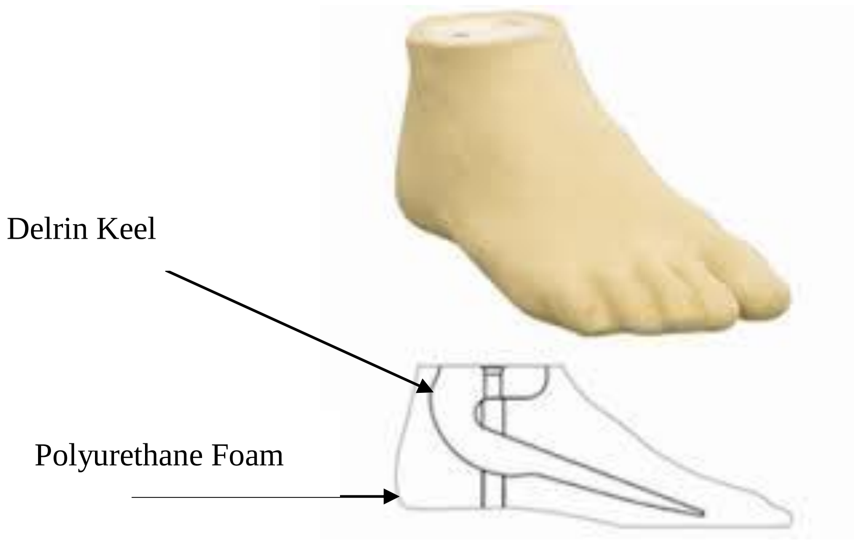


Figure 2.15 Seattle Foot

Results showed 81% of respondents felt they had good ankle motion and 19% felt they did not. Gait was better for 87% and 13% felt it was the same. Uneven terrain was considered easier by 74%, but 3% said it was more difficult. The most noticeable difference was the toe off action with 87% being aware of it and 13% unaware. However, the toe off action became more noticeable at faster speeds or climbing. This noticeable difference in the feet can be attributed to the Seattle foot having a more dynamic design than the SACH. The Seattle foot contains a cushioned heel much like the SACH foot however it also includes a keel spring that is designed to store energy through stance and release it through toe off. The Seattle foot also contains a split composite keel that allows for more medial, lateral movement.

It can be seen the functional assessment questionnaire is an easy to use tool that allows researchers to gain a lot of information about a prosthetic product quickly and effectively. Both the above example's show larger numbers of subjects were able to be included in the study making the results significant. Using descriptive answers to questions makes analysing the data a little more difficult than the use of numbers but no less relevant.

Numerical Rating Scale

A numerical rating scale is a customised metric tool designed to assess the improvements with a prosthetic component change. The advantage to this type of study is that it allows statistical analysis of the results Hafner (2005). The numerical rating scale appears to be the most popular method of subjective analysis (Alaranta et al 1994; MacFarlane et al 1991; Thomas et al 2000; Underwood et al 2004; Water et al 1998).

Thomas et al (2000) compared the Seattle light foot and Genesis II. Ten adolescent unilateral below knee amputees with a mean age of 15 years participated in the study. All participants were given a new prosthesis to use during the testing and each was aligned to the manufacturers recommendations. All subjects were tested after one-month acclimation to each foot. Each subject answered a questionnaire that asked them to rate different aspects of each foot on an increasing scale from 1 to 10 with 10 being the best score. The criteria included:

- Smoothness of gait
- Weight of the foot and device
- Increased activity level
- Ability to run faster for longer periods of time
- Comfort
- Ability to go up and down hills
- Feeling of increased push from the foot.
- Ability to manoeuvre on uneven ground
- Overall performance
- Selection of foot

Subjects found the Genesis foot to excel in the ability to go up hills, in propulsion, and in manoeuvrability on uneven ground in comparison with the Seattle foot, these showed the only significant results table 2.9.

Satisfaction Mean (SD)	Up Hills	Increased Energy	Uneven Ground	Overall
Seattle	6.6 (1.7)	4.4 (2.5)	5.5 (2.7)	6.6 (1.4)
Genesis	8.4 (1.2)	7.8 (3.0)	8.1 (2.1)	7.1 (2.3)
P Value p=.01	.0018	.0089	.0047	.58

Table 2.9 Subject satisfaction results Thomas et al (2000)

Thomas et al's (2000) study proved effective as they had a good number of subjects. They also took into consideration the subjects prosthesis alignment and how long it takes for a person to get used to a change in prescription which is often excluded from prosthetic research. Using a numerical rating scale in the questionnaire also allowed for statistical analysis which paired with the objective data results gave a comprehensive study.

MacFarlane et al (1991) used a modified Borg RPE (Rate of perceived exertion) scale Figure 2.16 to compare conventional SACH feet and flex feet with subjects walking at 3 different walking speeds, over three grades on a treadmill. The Borg RPE scale measures perceived exertion. During MacFarlane et al's (1991) test the subjects were asked to walk for three minutes at various speeds and gradients. They were then asked to evaluate the relative ease or difficulty they experienced at the different speeds/gradients, using a number on the scale.

6
7 very, very easy
8
9 very easy
10
11 fairly easy
12
13 somewhat difficult
14
15 difficult
16
17 very difficult
18
19 very, very difficult
20

Figure 2.16 Borg RPE scale

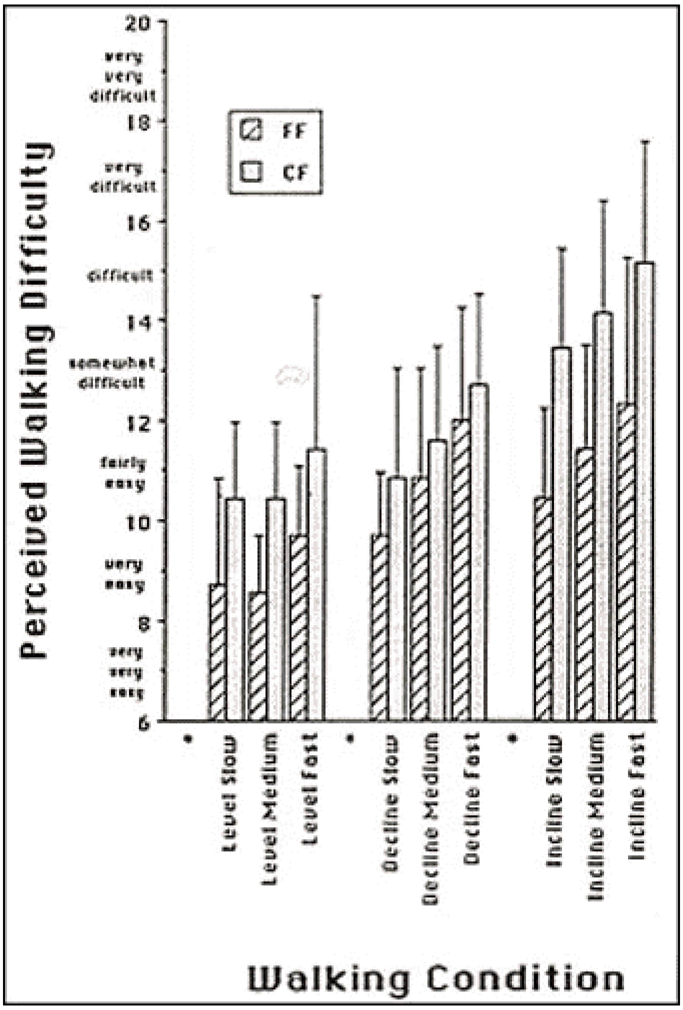


Figure 2.17 McFarlane et al (1991) Borg RPE scale responses, on level, decline and incline ground (group means and standard deviations)

The results showed that flex foot walking was less difficult than SACH foot walking across all grades and speed conditions. The greatest difference was on level and incline walking. In general, the subjects found it easier to walk on the level surface than the incline and found walking at faster speeds more difficult than slow or medium speeds. MacFarlane et al (1991) summarised that the ability of the flex foot's carbon shaft to reform in late stance releasing stored energy could explain the comparative ease with which the subjects felt when walking on inclines and at faster speeds.

These examples of subjective analysis of the feet consistently favours the ESAR foot. Active patients commonly comment on the improved power absorption and generation capabilities of the foot and also its adaption to uneven terrain and reduced stump discomfort (MacFarlane et al 1991; Menard M.R, Murray 1989; Murray et al 1988; Postema et al 1997; Thomas et al 2000). The objective analysis also shows results that agree with these findings but due to previously discussed limitations with prosthetic research including number of subjects, types of study used and environment, they are not often considered statistically significant. The nature of subjective analysis leaves it open to interpretation, less so in numerical rating scales and thus lacks some statistical significance. However, the consistent agreement in the results regarding ESAR feet significant or not, cannot be ignored and must hold some merit. The problems with Prosthetic research cannot be easily overcome but combining objective and subjective results would strengthen the research. Indeed, the argument could be made that subjective analysis carries more importance, as the patient's opinion is more relevant than the data produced by testing equipment.

2.4 EVIDENCE BASED PRACTICE- ARGUMENTS FOR AND AGAINST

Evidence based practice (EBP) in its simplest form, is clinicians finding the best available evidence and referring to it when making every day clinical decisions. Sackett et al (2000) summed it up as integrating individual clinical expertise with the best available external evidence from formal research studies.

Within medicine, evidence based practice has developed a firm foothold. The usage of EBP can date back to the 1970's, when physicians such as Archie Cochrane (2003) noted there was a vast lack of knowledge regarding the effects of alternative treatments given to patients. He also noted that many medical practices were based upon non-randomised data. Since then the medical field has led the way regarding EBP, which has in turn been adopted by many of the allied health professions.

However, reviewing the literature on evidence based practice it was found very few included prosthetics and that there is more than one school of thought with regards to the effectiveness of evidence-based practice. This may give one potential reason why there is the lack of prosthetic inclusion.

The argument of the effectiveness of EBP appears to be very much polarised. Some feel it is necessary and cannot be ignored while others feel it only hinders good practice.

Advocates of evidence-based practice generally feel this is the best way forward. They feel in various forms it provides justification and guidelines for prescription in today's culture of increasing choice and rising technology. Uellendahl (2006) states: '…patients, clinicians, and payers require quality outcome measures to determine which prosthetic systems and methods provide optimal outcomes'. Those who are pro EBP feel one benefit would be the growth of Prosthetic research done by prosthetists themselves. Alarmingly, Ramstrand et al (2008) found the majority of prosthetic research was performed by representatives from other professional groups. Only 12% of primary authors who published in Prosthetics and Orthotics International Journal and 34% of primary authors who published in the Journal of Prosthetics and Orthotics, actually held qualifications in Prosthetics and Orthotics. An increase in prosthetic research would be valuable in reducing the use of products that bear no significant improvement on their predecessors and could also help to reduce the cost of the prosthetic service in Britain.

The research methods used within medicine such as randomised controlled trials (RCT) are considered 'gold standard'. However, they cannot always be used in prosthetics and therefore prosthetists would need to adapt. Nick Midgley (2009) argues that EBP practice does not translate well into clinical practice and that the research design itself is given priority over the external validity of the findings. He states that smaller-scale; qualitative research needs to be given greater prominence within EBP. Midgley was referring to child psychology, however this could also apply to Prosthetics, as quantative and qualitative data can be much more insightful within its research than purely qualitative. Smaller cause and effect studies could also prove useful (Neuman 2006; Ramstrand , Brodtkorb 2008; Woods et al 2000).

At present the common reason for this lack of EBP in Prosthetics is that clinicians do not have the time or training for validated research. However for prosthetists, to maintain the respect of their peers, this will have to be overcome with the help of employers and undergraduate education (Ramstrand , Brodtkorb 2008). Those in favour of EBP feel it is simply becoming outdated not to perform any type of evidence based practice and that in not doing so prosthetist are leaving themselves open to criticism and litigation.

There are also those who oppose EBP and do so because they feel it is not practical; there is little use to it and the reasons for it are not in the patient's best interests.

A practical criticism of EBP is that busy clinicians simply do not have the time to search and appraise clinical research (Ramstrand, Brodtkorb 2008) and that many of them will need to develop new skills to enable them to do so Docherty (2005). There is also the concern that many clinicians do not have easy access to literature. It has been argued that validated research such as randomised blinded control trials (RBCT) do not lend themselves well to Prosthetics, as it is virtually impossible to blind all those concerned to a product and even if this was achieved, RBCT's are not flawless. Kirk-Smith et al (2000) examined randomised double blind clinical trials and found the existence of anomalous and unexplainable results from RBCT's that have prompted suggestions that unknown and unidentifiable biases may exist. It is also thought that it is '…difficult to quantify an outcome within Prosthetic tests, as the outcomes are contingent upon variables that are unique to each patient' Neuman (2006).

Opponents of evidence based practice also feel it has no benefits, as the studies often find no significant differences with respect to gait outcomes and even if a significant outcome is found, it may not have clinical importance Neuman (2006).

One claim against evidenced based practice, which is agreed by many, is that it does not allow for critical thinking that it supposedly encourages. Instead it can promote '…dependency on pre-interpreted, pre-packaged sources of evidence' Upshur (2006) or as some would describe it ' cookbook practice' (Docherty 2005; Ramstrand , Brodtkorb 2008; Sackett et al 1996). Evidence based practice is thought to suppress clinical freedom and this 'cookbook' approach results in the categorisation and pigeon holing of patients rather than treating them as individuals.

The most scathing attack on evidence-based practice is that, it was initiated due to the increasing cost of health care and that it is not aimed at helping users but rather to serve cost-cutters and administrators (Brenner, Carl 2008; Docherty 2005; Sackett et al 1996).

Evidence based practice is a concept that compared to medicine is new for Prosthetics. The papers that raise the issue for and against are predominantly discussing medicine but the general principles are valid in the small profession of Prosthetics. It could be said that now more than ever, the profession needs to be proving the benefits of their clinical decisions to their peers. Products cannot be continually used without showing their worth. The rapid growth in technology and reduction of trusts budget simply will not allow for this apparent mindless behaviour. Furthermore, the litigation culture that is creeping into Britain is also making it necessary.

The rise in Prosthetic evidence based practice will require a large shift in culture for practitioners. They will need further education and time from employers to allow them to achieve this goal. The evidence based approach will also need to be further developed to be compatible with Prosthetics, as research methods described earlier such as RBCT's are not easily achieved in a day to day clinic.

2.5 WALKING ON INCLINES- DETAILED LITERATURE REVIEW

Biomechanics of gait, as it has already been shown, has focused largely on walking on a horizontal surface. However, this is not a true reflection of everyday life which also includes ambulating on slopes. Walking on inclines is important to understand as it can be the cause of slips, falls and general lack of confidence in walking for amputees. (McIntosh et al 2006).

A review of the literature revealed that the data available on amputee incline walking is very limited with the majority focusing on energy storing and conventional feet on level surfaces and many using treadmills for testing.

Four papers relevant to the current incline study; examining unilateral transtibial amputees walking on slopes were reviewed. Three that have been evaluated show objective results and one gives subjective results. Subjective studies tend to be shorter with a smaller amount of detail compared to objective studies but, their results are just as relevant to clinicians as they reflect the amputee's opinions.

2.5.1 Uphill and Downhill Walking in Unilateral Lower Limb Amputees (Vrieling et al 2008)

Vrieling et al's (2008) paper aimed to examine the adjustment strategies to the gait in unilateral trans femoral and trans tibial amputees in uphill and downhill walking. For the purposes of relating the findings to the current study, the focus of this review will only take into account the testing of the trans tibial subjects on downhill walking and the comparison with able bodied subjects.

Twelve unilateral trans tibial amputees and ten able bodied subjects walked down a 5-degree slope at self - selected walking velocity (SSWV) within a gait lab. As with the aim of this study hip, knee and ankle angles were recorded in the sagittal plane. Vrieling et al (2008) hypothesised that during downhill walking prosthetic ankle dorsiflexion would not increase from late stance to mid swing. It was also hypothesised that to compensate for higher impact forces there would be an increase in contralateral knee flexion in early stance compared too able bodied (AB) subjects. The former hypothesis is acceptable, as the amputee could not influence the movement of the prosthetic ankle through swing and is more of a fact than a hypothesis. The more interesting information would be how the hip and knee angle would be affected during stance phase of gait. The second hypothesis could be questioned as it is possible for the sound limb to have reduced knee flexion compared to able bodied subjects rather than increased. Vrieling et al (2008) noted in their study on the slope that the prosthetic limb has increased hip and knee flexion throughout gait descending an incline. This could be to compensate for the lack of movement at the prosthetic ankle joint. If the subject also increased the flexion in the remaining sound limb, they would have an unstable crouched gait which would put a lot of strain on the quadriceps. The expected results of this study was that the sound limb would have similar flexion in late stance as able bodied subjects but this may vary with the foot the subject is wearing. The variation in prosthetic feet used in their study is a factor that has not been considered in Vrieling et al's (2008) hypothesis. It would also help this thesis if a hypothesis had been included relating to early stance, as this is likely to be the point when subjects feel the most unstable when walking down on slopes.

Vrieling et al's (2008) subject information was clear yet data on how the sample size was decided upon has not been included. Time varied greatly from when the amputees had their amputation, which considering the subjective data recorded in this thesis appears to be an important factor in how well a subject can walk. The longer they have been an amputee the better they walk. The difference in types of prosthetic feet being used in this study also has to be considered as they vary greatly; for example, the Otto Bock C walk foot is a much more dynamic foot than the Griessinger. These differences in the feet will influence the subjects gait at all lower limb joints thus significantly influencing the results.

During testing Vrieling et al's (2008) subjects performed four walks on the slope and due to the previous discussion regarding number of walks; for accurate results this would seem too few. To allow for some poor data capture, it would have been better to have additional walks, this research performed ten walks for this reason.

The results of Vrieling et al's (2008) work were displayed clearly in graph form for example figure 2.18. However, there were no units and disappointingly did not include an in depth discussion relating to the resulting angles at the ankle and how they were measured which would have been relevant to this thesis.

It was surprising to see the results of the hip angle in early stance figure 2.18, as the amount of flexion in the residual side was very close to the able bodied subjects. The hip could have been expected to have larger compensatory angles due to the lack of movement at the prosthetic ankle.

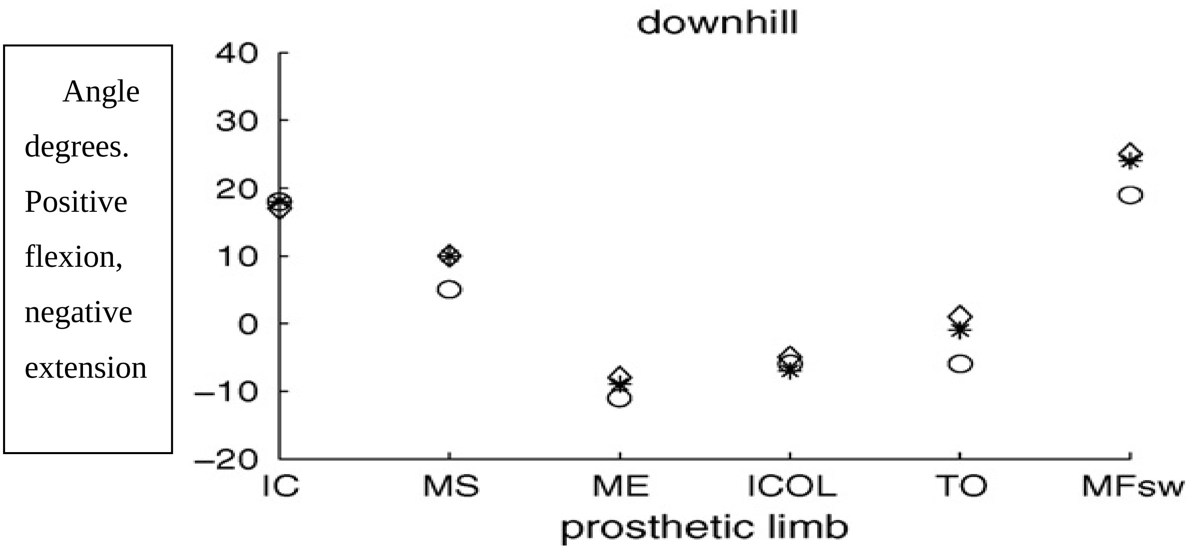
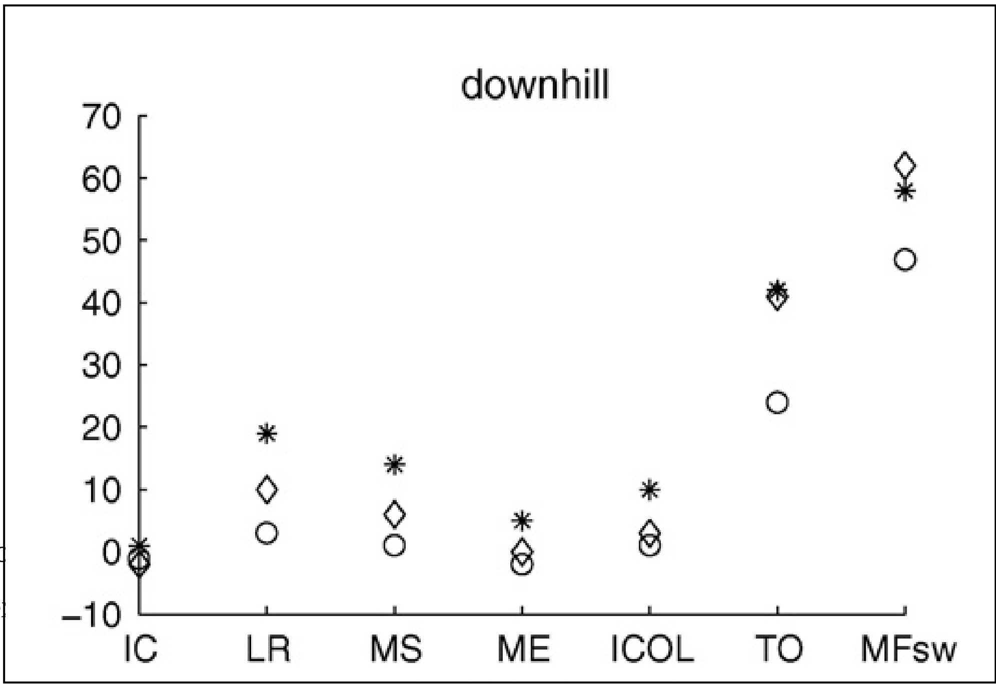


Figure 2.18 Vrieling et al (2008) mean hip angles relative to the pelvis of the prosthetic limb and non-affected limb in TF (○), TT (◊) and able bodied (*)**.** Positive flexion, negative extension



The main goal of Vrieling et al’s (2008) work was to establish how amputees adjust their gait pattern to downhill walking and the discussion focused on particular findings at the knee, hip and ankle angles. Results of the residual knee showed the flexion angle increased in late stance through to swing figure 2.19. This finding was correct; however, the size of the flexion angle was approximately. 10-15 degrees less than would be assumed compared to able bodied subjects.

The results at the hip joint figure 2.18 showed reduced extension angle on the affected side at initial contact of the sound limb due to a shorter step length. The step length should be commented upon and is an explanation for this change in angle but more importantly the lack of plantar flexors on the effected side giving no active push off in late stance should be noted. This causes a shorter step because the patient has no power in the prosthetic limb to push forward, which would result in a longer step and larger flexion angle at the sound hip joint.

Vrieling et al (2008) hypothesized that an increase in sound limb knee flexion would compensate for a higher impact force, as shortening of the sound limb would lower the body centre of gravity and reduce the height to the ground of the affected limb thus reducing the impact force figure 2.19. Vrieling et al (2008) thought the residual knee would also flex as the sound knee had thus reducing the impact force on the sound limb. However, they feel this hypothesis was not proven because the shorter prosthetic length already ensured lowering of the body. This finding could be questioned as it is often routine practice to shorten a trans femoral limb to allow for improved ground clearance. However, it is unclear what benefit could be gained from purposely shortening a trans tibial limb.

Vrieling et al’s (2008) work has contributed to the much needed research into amputee gait on inclines and will be useful for comparing the results with the current research. However, as stated in Vrieling et al’s (2008) conclusion, the results are limited by the variation in prosthetic feet used, the sample size and in addition the data capture technique.

2.5.2 Elderly Unilateral Transtibial Amputee Gait on an Inclined Walkway: A Biomechanical Analysis. Vickers et al (2008)

Vickers et al (2008) paper was included in the review as this was very similar to the current investigation. The aim of Vickers et al’s (2008) research was to analyse gait characteristics of five male and three female elderly amputees walking on an incline and comparing results to age matched controls; identifying differences in elderly gait. The paper examined various biomechanical aspects of gait in the sagittal plane. This review will focus on downhill tempro-spatial characteristics, ground reaction forces (GRF), kinematics and kinetics. This topic is being investigated due to the lack of evidence available regarding elderly amputees walking on slopes especially since descending slopes is considered more demanding than ascending.

The subjects in this study are all using SACH or single axis feet. Vickers et al (2008) correctly stated that the majority of elderly amputees are given conventional feet and most specifically the SACH foot. However, they also state that in the past the single axis foot was also given. The single axis foot may have been routinely prescribed in the past due to lack of options. It is the author’s opinion that, as a result of its quick movement into foot flat in early stance, it would now be more likely used for hip disarticulation and trans femoral amputees rather than a trans tibial especially elderly amputees as they may struggle to overcome the plantar flexion angle in MS.

Within their introduction Vickers at al (2008) suggest some recommendations for further research, one of which is quantification of gait characteristics which inhibit proficient walking. As a practicing prosthetist the author feels this would indeed be a beneficial area of research as it could be formed into a useful outcome measure tool for physiotherapists to use within amputee rehabilitation. Another recommendation was further kinematic and kinetic analysis of gait at different walking speeds. Walking speed can be a very individual preference. Therefore, how is it decided what speed a subject should walk at during testing? It is hoped that as with so many studies previously done it is not performed on a treadmill as this is a very unrealistic walking terrain for a subject.

Later within their introduction, Vickers et al (2008) state a further aim of the study is to quantify the effects of a conventional prosthetic foot on gait walking on an incline, which they feel identifies a source of limitations. The foot is likely to be a dominant factor in any gait limitations. However, the findings will be of interest as the question remains to how much the amputee’s own abilities with regards fitness, gait habits and socket comfort influence the results as well. It should also be noted that the SACH foot is one of many conventional feet which can all perform differently from one another. Caution should be taken with the results of this as other conventional feet could have given different information. No hypothesis was included in this paper.

The majority of the subjects within the study appear to have been well chosen. However, two of the subjects are using the single axis foot rather than the SACH. This variation may cause differences in the results due to the previously stated faster foot flat. One subject has only been an amputee for six months. This is very soon to start analysing their gait, as they are very early in their rehabilitation. One subject’s amputation is a result of trauma so they may be more able than the other subjects who have vascular disease or cancer. No description of how the sample size was decided upon has been included.

Within their methodology the walkway has been described and illustrated showing it is almost identical to the slope used within this thesis making the results valuable as a comparison.

For data capture and analysis Vickers et al (2008) used a Vicon system and an analysis system called Clinical Manager to process the data captured. From the experience of this research Vicon analysis software (plug in gait) was a very unpredictable system to use; giving data that was unreliable resulting in a bespoke program in Mat Lab being developed. It is not noted if Vickers et al (2008) had such problems or how they were overcome. It is also not noted how the markers were attached to help reduce noise in the data from skin movement or how their positions were accurately located and what actions they took if any markers came off. While testing with the moderate activity feet for the current thesis it was found capturing the data was highly dependent on finding the joint location and being able to attach a marker to it that would not be affected by the movement of skin. Data captured using markers stuck directly to the skin was too noisy due to skin movement. Therefore, a cluster design was developed that attached with straps. This greatly reduced the distortion in the data. A qualified prosthetist located the joints required for testing. These issues have not been addressed in Vickers et al's (2008) work and they may have caused inaccuracies in their results.

The amputees within Vickers et al's (2008) study walked at a self-selected pace which is reasonable, as mentioned earlier. It is not noted however what socket the subjects were wearing. Was it a brand new socket or was it their own? At any level of amputation, the comfort of the socket is arguably the most influencing factor in how well and comfortably an amputee will walk.

The results of Vickers et al (2008) study were well presented in graph and table format and gave large amounts of information.

The temporal spatial data all appears agreeable. The study found the important findings were the reduced stride length; cadence and walking speed of the amputee's compared to normal subjects which is to be expected no matter the age of the amputee.

Vickers et al (2008) found the ankle joint remained dorsiflexed throughout stance. Figure 2.20

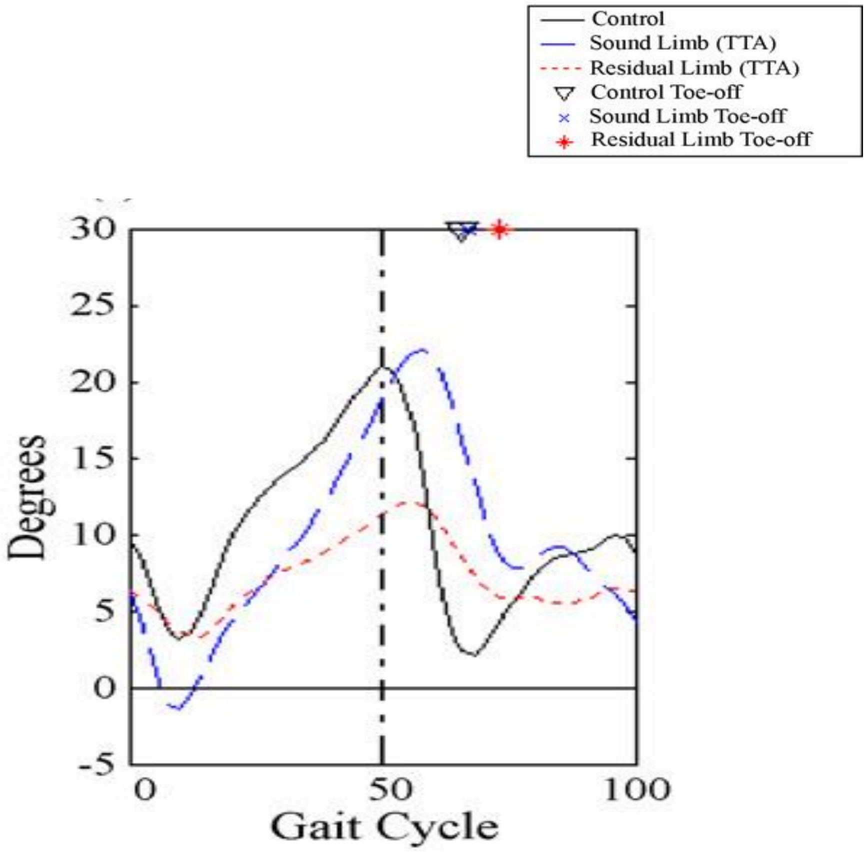


Figure 2.20 Vickers et al (2008) Ankle Angles. Positive dorsiflexion, negative plantar flexion.

It is unclear if the dorsiflexion angle seen in Vickers et al (2008) paper would be a welcome result for an amputee or not. It does allow the ankle to behave more like a normal subject however, due to age and general fitness, it could also be a result of the amputees being unable to overcome the dorsiflexion moment in order to stabilise themselves descending the slope. This would result in more work being done by the remaining muscles of the amputated limb, thus showing a disadvantage of an ankle joint that has the same ROM as a natural ankle.

Vickers et al (2008) found the hip remained in flexion throughout stance which is likely compensating for the increased knee flexion.

The vertical ground reaction force (GRF) of Vickers et al's (2008) subjects showed a much more flattened graph than the controls Figure 2.21

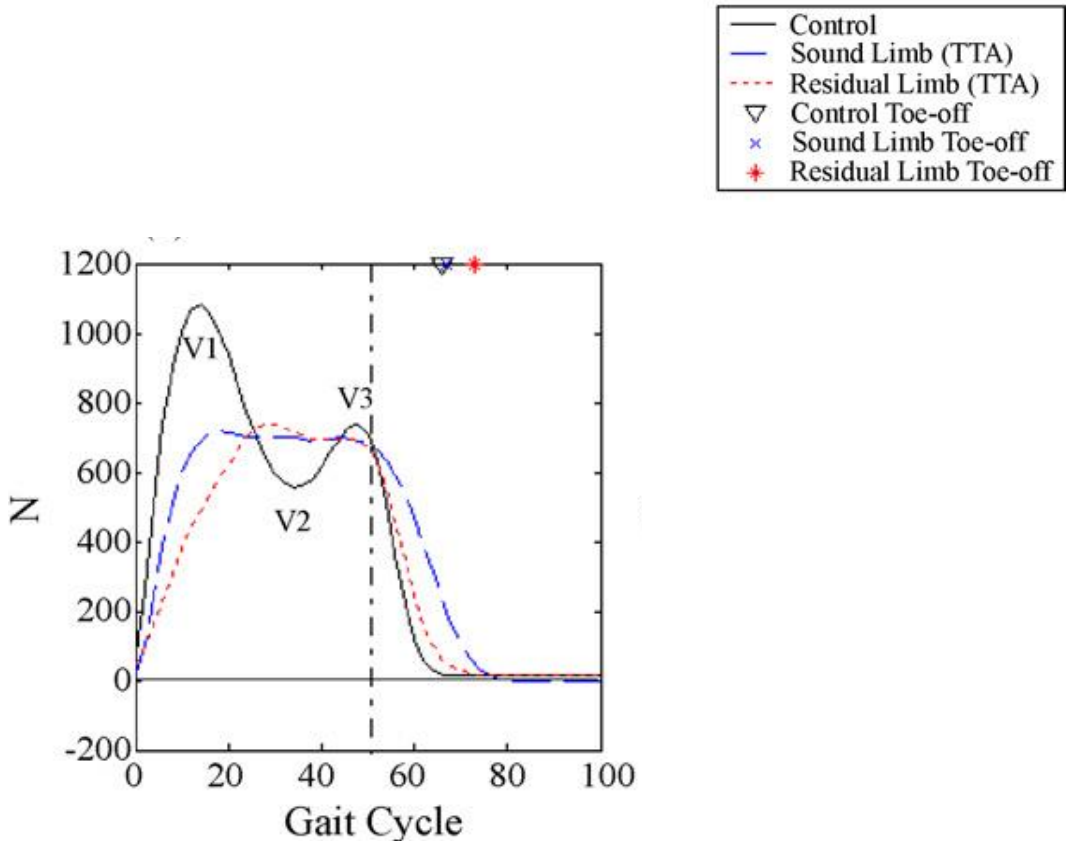


Figure 2.21 Vickers et al (2008) GRF Vertical Descending slope. Time normalised and averaged for all participants.

The controls had definite peaks at 10%, 30% and 50% of gait. However, the amputees had one peak at MS and lower GRF than the first and last peak of normal subject.

Vickers et al (2008) found the moments of the subjects had a similar shape as the normal subjects however they were reduced in magnitude which is likely due to the slower walking speed which is a reasonable assumption. As with the above papers it was not clear what sign convention had been used. However, as a result of interpreting the graphs it was seen external moments were being shown.

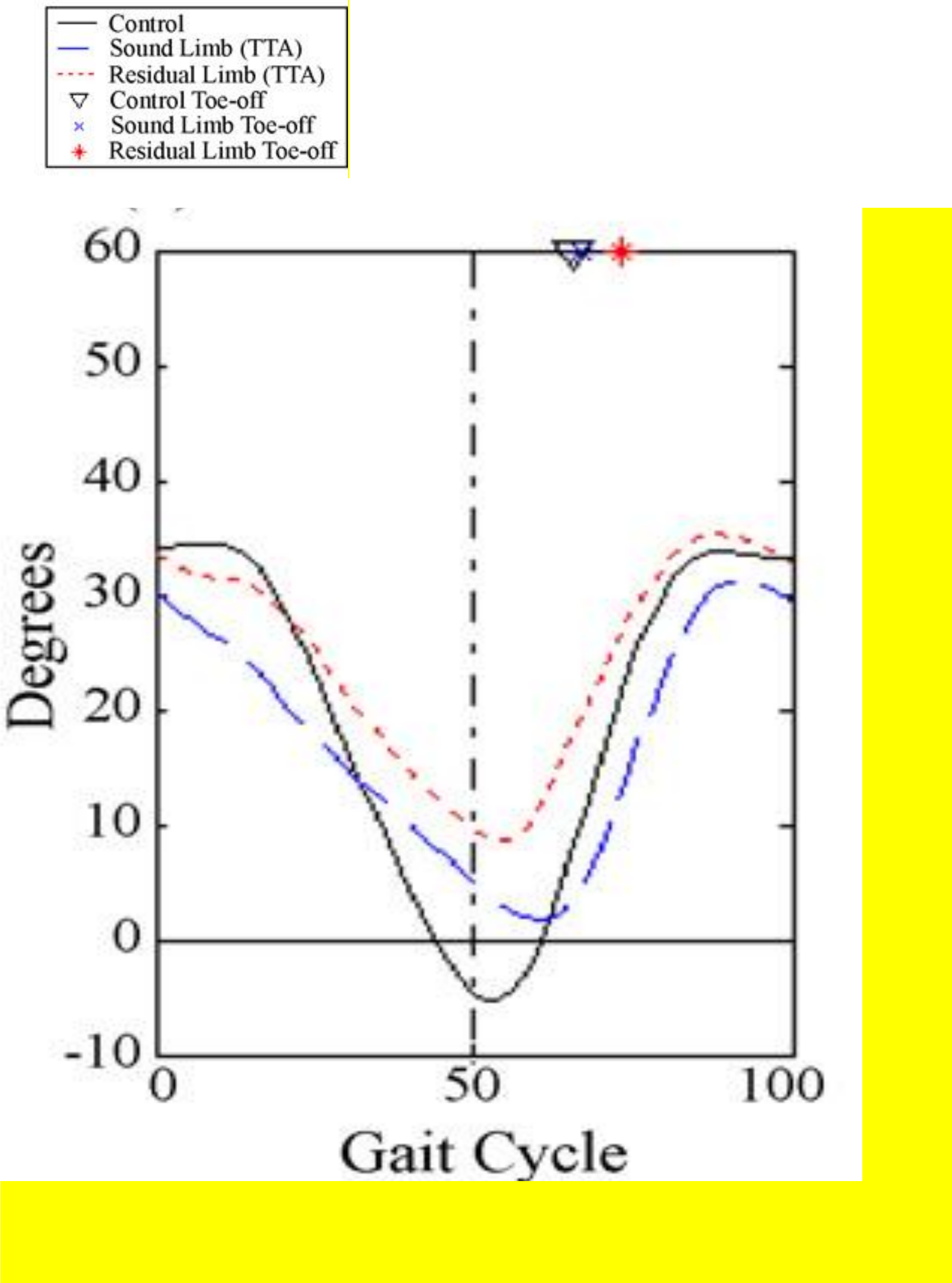


Figure 2.22 Vickers et al (2008) Hip angles and hip moments positive flexion, negative extension.

In the discussion Vickers's et al (2008) state the main difference between amputees and normal subjects walking on an incline is instability in stance caused by the reduced ROM at the ankle joint. The evidence from all the studies mentioned in this review supports this statement. It is claimed that one source of the instability is the stiffer heel in the SACH foot; prolonging the time between HS and foot flat. This could be true but it could also be said that on softer more uneven terrain this lengthened time could give the amputee a chance to adapt to the ground better. The single axis foot was used in Vickers et al (2008) study. Its characteristics have not been discussed, which is disappointing as its differing motion at IC would give an interesting insight into how stability is effected when the foot plantar flexes. The feet in Vickers et al (2008) study have also been discussed with regard to their slight power return at toe off, which is very unlikely to be a result of the foots actions, as these feet are not designed to provide energy return Figures 2.23 and 2.24.

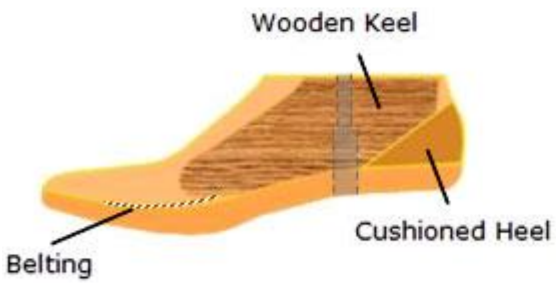


Figure 2.23 Cross section of a SACH foot (Ottobock plc)

Figure 2.24 Cross section of a single axis foot (Ottobock plc)

The amputees reduced time on the residual limb is also discussed. Vickers et al (2008) summarise that the amputees feeling of instability and lack of active push off causes them to spend less time through stance on the effected side which is agreeable. However, the effect of socket comfort has not been considered in this context. The force distribution over the stump is altered while walking down a slope and may be a cause of some discomfort for the amputee. Therefore, they will remove their weight from the limb as fast as possible.

Vickers et al (2008) note that at the end of stance phase the sound ankle does not plantar flex and it is surmise that this is due to the subject not being able to balance their entire weight through the toes of the sound limb. This could be an inaccurate assumption as there is no reason the subject could not push off from this side using the forefoot. The lack of plantar flexion may simply be a result of the subject not needing to do this as the downward angle of the slope will carry the body forward allowing the subject to prepare for the next heel strike.

Vickers et al (2008) concluded that amputees would walk better down slopes if they had an increased ROM at the ankle, yet it is not clear how much of an increase would be needed. As they compared their results to a normal subject it can be assumed that a normal ROM is what Vickers et al (2008) think would be most effective. This assumption does have some sound reasoning. However, amputees have lost a significant portion of a limb leaving them with muscles imbalance, lack of proprioception and requiring the use of an unnatural devise to take all of their weight. Therefore, should they ever really walk exactly the same as a normal subject or should we simply be aiming for a gait that is optimal to their particular situation?

Vickers et al (2008) have contributed a significant amount of information regarding amputees walking on slopes. Their findings using conventional feet have proved an interesting comparison to the results using moderate activity feet. However, the comparison may be limited by the differences in the subjects and use of data capture and analysis tools.

2.5.3 Perception of Walking Difficulty by Below-Knee Amputees Using a Conventional Foot versus the Flex Foot. Macfarlane et al (1991)

Macfarlane et al (1991) took part in a purely subjective investigation comparing the ESAR flex foot with the conventional SACH foot walking on a treadmill set at different gradients and walking speeds. Their aim was to subjectively compare the amputee's perception of walking difficulty while wearing each foot.

This research was included because it is an example of a subjective study involving amputees walking on a slope answering a short questionnaire much like the questionnaire included in this study. The comparison is limited because the incline was set at various gradients and the walking speed was set at different speeds which was not the case in the current research.

MacFarlane et al (1991) took part in this study as the body of research comparing below knee (BK) gait using different prosthetic components is limited. Support was provided by Flex Foot which raises the question of bias, however it has been used in this thesis as it is a good example of a simple direct subjective study rather than for its results. It was hypothesized that the subjects will find walking with the flex foot easier than the conventional foot. It is commented upon by MacFarlane et al (1991), that how easy or difficult subjects find using a prosthesis is important and could be a factor to consider when prescribing a prosthetic foot. It is felt this is an understatement and is not something that could be considered in a prescription but should be and can make the overall difference between one component and another.

Seven male uni lateral traumatic BK amputees were tested in the study. All subjects had used both foot types previously which is an advantage as it ensures the subjects are walking at their most natural gait and not trying to adapt to a new foot. Each subject was given an activity score rating using the Day's activity classification criteria (appendix 6). This score is a valuable outcome measure for rehabilitation however, when deciding on which foot a subject should be given, the manufacturers activity scores may be more appropriate, as this will ensure a subject is given the correct category of foot for their weight and activity level (appendix1,2,3).

Each of the tests were completed on a treadmill. The use of the treadmill is understandable as it allows convenient testing on various gradients and at different speeds. However, the treadmill is a very unrealistic terrain to walk on and often contains shock absorbers which would likely alter a subject's perception of the prosthetic foot. The subjects chose their own walking speed. Allowing them to do this was a worthwhile choice as it is often chosen for them when walking on a treadmill which can lead to an unnatural gait for the subject. However, the subjects walking speed was determined by them walking on level ground, which was then translated to the treadmill. Walking speed on a slope is likely to differ from that on level ground and as a result it may have been advisable to set the speed on the slope first. Testing on a purpose built slope allows for a more natural speed as the subjects can alter it as needed.

Each subject wore each foot over three different gradients on the treadmill- level, -8.5 degrees decline and +8.5 degrees' incline. Each gradient test consisted of a differing speed of slow (2.0mph), medium (2.5mph) and fast (3.0mph). After each stage the subject was asked to evaluate the relative ease or difficulty he was experiencing walking under that condition. This was done by asking the subject to select a number which best represented his ease or difficulty of walking as described on a scale Figure 2.16.

The scale chosen was a modified Borg rating of perceived exertion (RPE) scale, figure 2.16, which is a validated tool. MacFarlane et al (1991) validated their adapted version by comparing the subjects test responses to the interview data collected at the end of the test. It is unknown if this test of validity is acceptable. It could be asked if it was needed at all as surely a test of exertion would have been just as appropriate in this study. If the subject felt, they had to exert themselves more with one foot over another is that not also telling the researcher that it is more difficult to walk with one foot rather than another?

In addition to the questionnaire the subjects were asked to answer which foot they preferred in their own words. The answer to this question is difficult to quantify but still provides a valuable insight into the study, as the subject may report something about the foot the researcher had not considered.

The results of the walking difficulty scale found that walking with the conventional foot was more difficult than walking with the ESAR flex foot.

Walking difficulty was significantly affected by grades, speeds and type of foot worn. Across all speeds and inclines walking with the flex foot was easier; subjects found level walking easier than incline and walking fast more difficult than walking slow or medium figure 2.17.

The results were verified by strong statistical significance, which can be lacking in small subjective studies. The description of the statistics was difficult to follow.

The response from the questionnaire also overwhelmingly favoured the flex foot . Comments were noted for all feet at all levels and speeds. During level walking and incline walking reasons given for subjects preferring the ESAR flex foot (FF) included "helps recover itself" whereas "you have to pull up the conventional foot (CF)". It is assumed the user is referring to the energy return characteristic of the carbon toe spring in the FF during late stance when they make the former comment and the lack of energy return in CF in the latter comment. However, this is an example of how questionnaires need to be used with caution. The reasoning for each comment needs to be assumed and could be interpreted differently by someone else. Studies with only questionnaires included could be less significant than those including both objective and subjective data. Further comments about decline walking were the "FF controls speed better" and the "normal leg prefers the FF". MacFarlane et al (1991) feel this indicates that the CF had a tendency to make subjects fall forward and downhill. This is a fairly reasonable assumption but at the same time if the subjects did feel they were falling, it is surprising they did not mention this in a comment.

One subject favoured the CF foot over the FF but only for the fast decline walking speed, as the subject felt the CF cushioned the heel strike more than the FF. However, the subject gave the CF an 11 (very easy) and the FF a 9 (very very easy) for the same test condition. During this test condition the subject chose not to wear a shoe with the FF and wore a trainer with the CF. MacFarlane et al (1991) stated that the difference in shoes may have assisted this subject while wearing the CF; contributing to his response. It is felt the difference between wearing a shoe and not would have indeed made this difference. During testing a subject not wearing a shoe should not have been allowed, as the shoe will most certainly alter the subject's perception of the limb; especially if the limb had been aligned while wearing shoes which has not been stated in this case.

The findings of this study proved the hypothesis that subjects would find walking with the flex foot easier than walking with the conventional foot over different grades and speeds. MacFarlane et al (1991) reasoned that the dynamic design of the FF provided cushioning at heel strike and push off in late stance making it more comfortable to walk with than the CF. This reasoning does seem sound and subjects preferring the FF over the CF over various conditions is in agreement with the findings of Alaranta et al (1994).

MacFarlane et al (1991) have shown that even a short subjective study can provide vital information about prosthetic components. The walking scale has given numerical evidence about how the FF and CF perform in various conditions and the questionnaire has given an amputee’s perspective on how each foot performs. As there is some ambiguity in the questionnaire results it can be said that including objective information would boost the significance of the research. As this is not always practical in working prosthetic clinics subjective research should still be encouraged to improved evidence based practice.

2.5.4 Biomechanical Analysis of Ramp Ambulation of Trans tibial Amputees with an Adaptive Ankle Foot System. Fradet et al (2010)

Fradet et al (2010) took part in a project to test the benefits of quasi-passive prosthetic ankles namely the Ossur Proprio foot, on the gait of trans tibial amputees walking on a ramp. This paper was included in the literature review because it is often concluded that amputees gait on inclines would improve if they had an increased ROM at the ankle. It was hoped this paper will help prove or disprove this theory.

The Proprio foot adjusts the ankle angle by means of a microprocessor-controlled motor that uses accelerometer signals as input. The foot has the ability to automatically adjust its ankle angle depending on the terrain it is on. This is called adapt mode. The foot enables ankle dorsiflexion during ramp ascent and ankle plantar flexion during ramp descent figure 2.25

The Proprio foot can also be fixed at a specific angle, which was the case for this study, when it was set in neutral mode i.e. ankle angle of 90 degrees for part of the study for comparison purposes.

Figure 2.25 Ossur Proprio Foot

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Fradet et al (2010) aimed to verify effects of adaption of the ankle angle as proposed by the Proprio foot designers. Kinematics and kinetics in trans tibial amputees during walking on ramps were compared with the adjusted prosthetic ankle i.e. in adapt mode and with the prosthetic ankle set to a fixed neutral angle to simulate conventional prosthetic ankle joint behaviour. These results were then compared to control subjects whose data were spread over a wide range and should therefore be considered with regards to patterns of angles and moments rather than magnitude. It should be noted, that fixing the ankle at neutral was not entirely accurate because some conventional feet may not be specifically designed to achieve a large range of ankle flexion/extension however, it does still achieve some from deflection of the cosmesis.

The results were to be compared to matched normal subjects and the subject's sound limb. Although the test included ramp ascent and descent, for the purposes of this literature review ramp descent will only be focused on.

Fradet et al (2010) hypothesis was that the ankle adaption will not lead to a more physiological gait during ramp descent.

	Trans Tibial amputees	**Controls**
Number	16	16
Gender	16 males	6 females,10 males
Age (years)	50.3 ±11.8	31.1±10.3
Mass (kg)	83.7±15.0	71.7±10.0
Height (cm)	178±6	173±8
Time since amputation (years)	25.3±20.9	
Cause of amputation	3 tumours, 13 trauma	

Table 2.10 Fradet et al (2010) Subjects' characteristics

Sixteen uni-lateral trans tibial amputees and sixteen control subjects were included in the research but, it is not noted how the sample size was chosen (table 2.10) The patients were given K-level scores of K3 and K4, which correspond too active and very active to note their activity. As with the previous study by MacFarlane et al (1991) it is felt that it would have been more appropriate to include Ossur's activity score, in order to match the subjects correctly for the correct category of foot. It should also be noted, that subjects of this activity level would be unlikely to be fitted with a conventional prosthetic foot as simulated by the neutral position of the Proprio, which is a problem of many studies, noted previously. When describing the inclusion criteria Fradet et al (2010) also stated that subjects should have "the will to handle the new prosthetic ankle". It is unclear what this statement actually means.

Sixteen is a significant number of subjects to be included in a prosthetic study and the spread of the subjects appears very good, especially the cause of amputations as there are no indications that underlying health conditions could affect the results.

They have all also been amputees for at least five years indicating they are established walkers.

Each amputee was fitted with the Proprio and aligned using LASAR posture (Ottobock plc) giving as accurate an alignment as possible. The subjects were then allowed to use the foot indoors and outside for fourteen days to familiarise themselves with its actions. This feature in the study is welcome, as it allowed the subjects to get used to the foot, especially as they are very unlikely to have used anything of its kind before, thus improving the results further. Subjects then walked in a gait lab on a custom made ramp set at 7.5 degrees, which is similar to the 7-degree slope used in this study, which makes the results interesting as a comparison. It is noted that the data was captured using a VICON system but what markers were used have not been included, how they were positioned or how they were attached; again information that would have been useful for this study.

For ramp descent the recognition of terrain mode was switched off in the Proprio foot due to the limited length of the slope not allowing the foot to adjust in time. The ankle was then set to adapt mode with a maximum plantar flexion angle of 2.1 degrees. The foot was also tested at a neutral 90-degree angle to simulate a conventional foot. Each subject walked down the ramp 8 times with the two different ankle settings at a SSWV.

The subject joint angles, internal moments and powers were calculated in the sagittal plane. They were time normalised to the gait cycle and averaged across both legs for the controls and amputees.

Patients walked slower compared to controls during ramp decent. Changing to adapt mode did not alter this fact. Between adapt mode and neutral mode there were significant differences between angle measures and maximum plantar flexion moment was significantly increased.

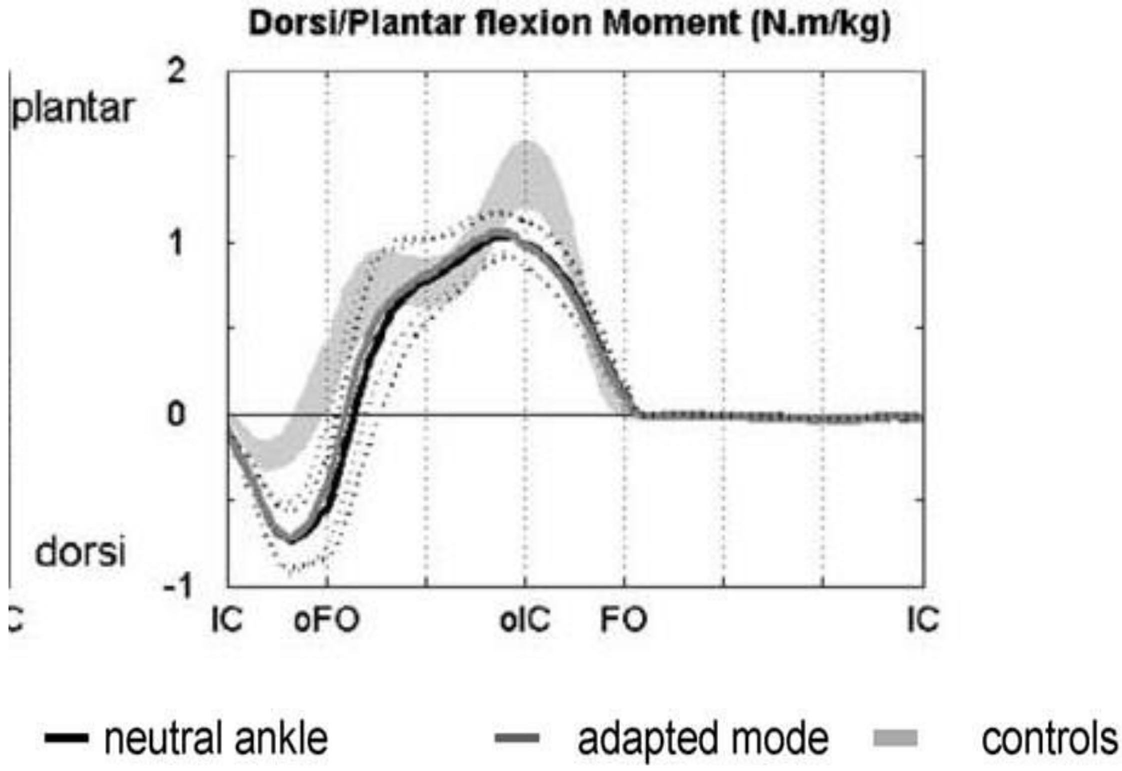


Figure 2.26 Fradet et al (2010) ankle moment descending slopes

At the hip in adapt mode, the difference between amputees and controls decreased for the hip moment. Figures 2.27

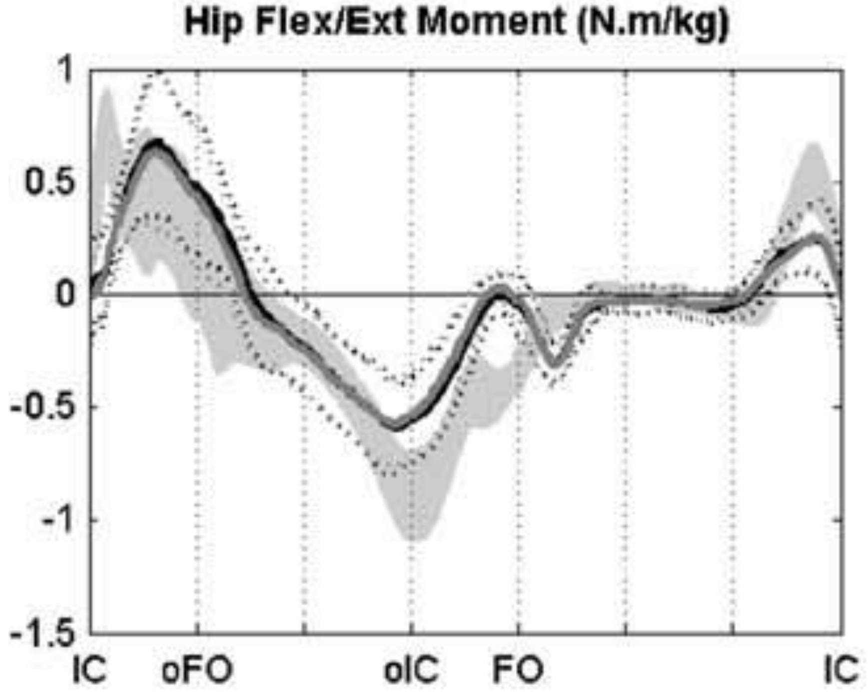


Figure 2.27 Adapted from Fradet et al (2010) Hip moment, positive extending, negative flexing.

When walking in adapt mode, the differences between subject's sound side and control subjects, increased for ankle angles and for knee angles as the knee flexion was reduced during MS Figure 2.28 and 2.29

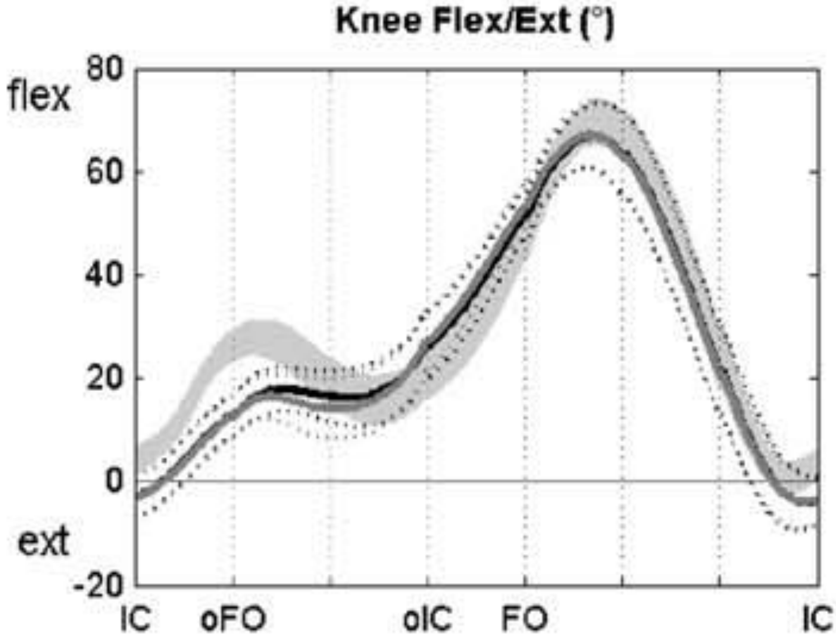


Figure 2.28 Fradet et al Knee angle, positive flexion, negative extension

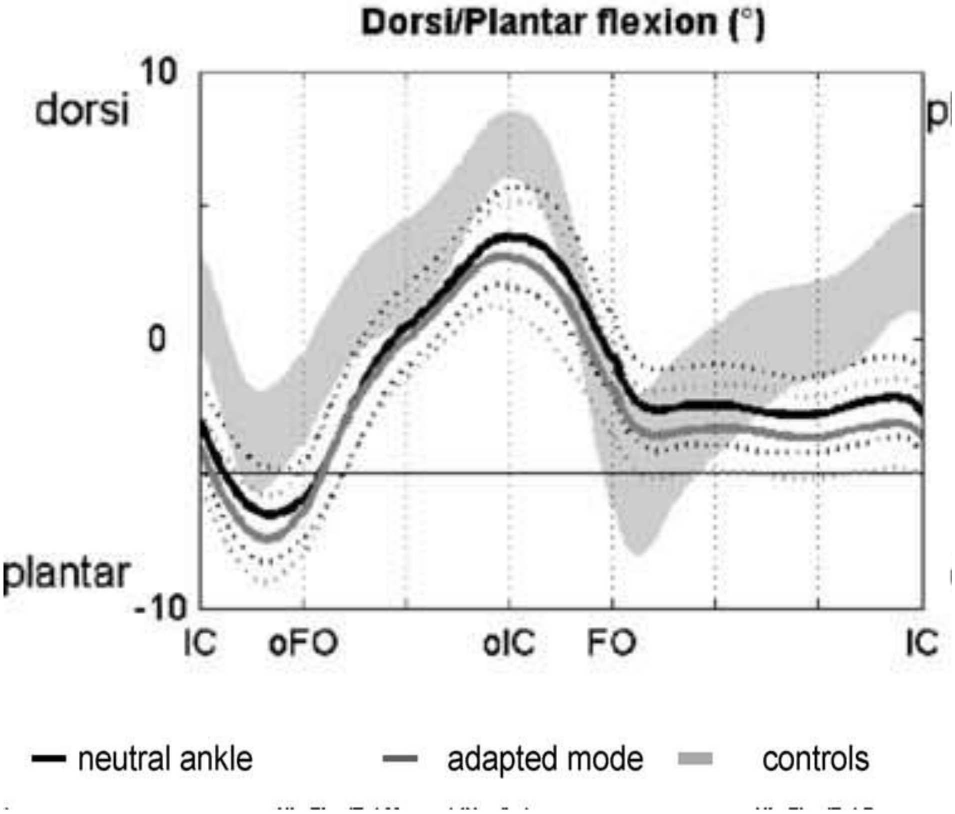


Figure 2.29 Fradet et al Ankle angle positive dorsiflexion, negative plantar flexion

Fradet et al (2010) also chose to use a further outcome measure called the normal distance (ND). The normal distance represents the difference between individual gait data and the average value of the reference data. A value of 0 would indicate a perfect similarity between the individual gait data and the average value of the reference data. The ND gave a quick reference when examining the results, for example in adapt mode on the sound side the hip moment acted slightly closer to the controls compared to neutral mode figures 2.27. The ND at the hip moment was 0.90±0.23. As a comparison the ND for the same limb for the knee moment was 1.14±0.41.

In the discussion Fradet et al (2010) compare walking on slopes to walking down stairs which became confusing. It is felt that this can also be misleading because amputees will walk differently in each of these environments. During rehabilitation, amputees are taught a very specific technique when walking down stairs which involves precise positioning of the foot on each step, which does not take place when walking down slopes. This results in a poor comparison.

Fradet et al (2010) found that due to lack of movement in the foot at terminal stance the amputees compensated by flexing the knee.

None of the changes in kinematics or kinetics in adaptive mode in the involved side was clinically relevant. However, Fradet et al (2010) felt this may not be expected since the change in plantar flexion was only 2.1 degrees. The choice of limiting the angle of the ankle may have been required but it did hinder the study significantly, as this then became very like all other tests on feet walking on slopes, rather than providing that sought after information of how a foot with a greater ROM would perform on a slope.

Fradet et al (2010) note the hip and knee flexion on the sound side is much reduced and is caused by the stiffer prosthetics foot burdening the body being lowered and causes the sound limb to be stretched further. When these results are compared to the control subjects there is very little difference. It is likely this would not be the case if the subjects were above knee amputee, which shows the importance of retaining the knee joint.

In adapt mode none of the compensation mechanisms improved. Compared to controls the differences in ankle kinematics and hip flexion at IC were increased making the benefits of the Proprio foot questionable. Fradet et al (2010) found research that stated that on slopes of less than 15 degrees the ankle remains predominantly dorsiflexed, so they concluded that maybe they should have set the ankle in dorsi flexion rather than plantar flexion. Setting a prosthetic ankle in dorsiflexion for slope decent would likely cause massive instability for an amputee and even more dramatic compensation techniques. This would be ill advised.

In contrast to the objective data, that does not show any obvious benefits of the Proprio foot, the subjects commented that they liked the foot and felt safe and had good support during roll over. With an obvious discrepancy between the objective and subjective data, it can be seen a more in depth questionnaire on the foot would have further enhanced the research.

As commented upon previously the reason this study was of interest to this thesis was the hope that it would further investigate the effects of walking with a foot with an increased ROM on a slope that previous studies have commented would benefit the amputee. Thus it was disappointing to see that this ROM was actually restricted and resulted in findings that were not vastly different from other prosthetic foot research. There was also no discussion on the neutral alignment of the Proprio foot.

Feet with greater ROM at the ankle are now entering the market so Fradet et al (2010) have provided a starting point for the much needed studies into the effects of this ROM. It is hoped that in the future the foot will be able to function to its full potential and the opinion of the users will also be taken into account.

2.6 CONCLUSION OF LITERATURE REVIEW

Research regarding Prosthetic feet is greatly lacking in content and significance, despite the many studies carried out. There is a dominance of ESAR feet and conventional feet being tested on horizontal surfaces or treadmills and more recently, we are seeing an increase in testing involving feet with mobile ankles. The majority of this work has been carried out by the manufacturing companies. Therefore, further independent studies are needed to rule out bias. A gap appears to have been created in research regarding the increasingly prescribed moderate activity feet and very little on incline walking. McIntosh et al (2006) reported that normal subjects found walking down inclines precarious and required greater ROM and exertion of forces across the hip, knee and ankle McIntosh et al (2006). With amputees being limited in the former areas the risk of slipping and falling is increased and therefore a need for investigation into the problem is necessary. It is hoped this MPhil thesis will help fill the void in the current literature by examining the Kinematic and Kinetic effect on the lower limb joints, when using multi axis feet while walking down a slope. Which could also encourage more evidence-based prescription within prosthetics.

The human foot is designed to bear weight and allow locomotion. These functions are achieved through the combination of 26 bones, 33 joints and over one hundred muscles, tendons and ligaments figure 3.0. The foot comprises of a forefoot, midfoot and hind foot with a longitudinal and transverse arch. These structures produce a complex mechanical device that can move on different axes; adapt to many different terrains; provide propulsion; shock absorption and is energy efficient Whittle, MW (2001).

The primary task of the Prosthetic foot is to mimic these efficient features yet in the past technology has limited how much can be achieved. However, with the introduction of stronger, lighter more flexible materials we are getting closer to this goal with the Assure, Epirus and Tribute feet all being examples of this progress.

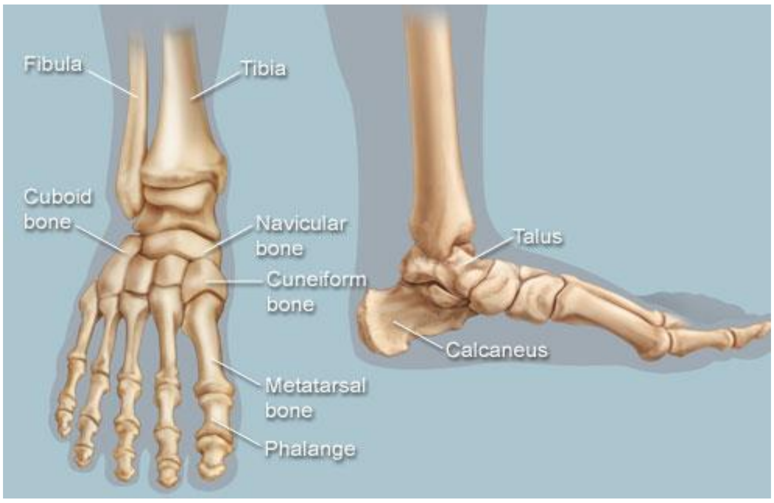


Figure 3.0 Bones of the foot.

3.1 BLATCHFORDS EPIRUS FOOT

Company Design Aim: To produce a Prosthetic foot that will allow natural ground compliance to make walking feel comfortable and harmonious with body posture figure 3.1.

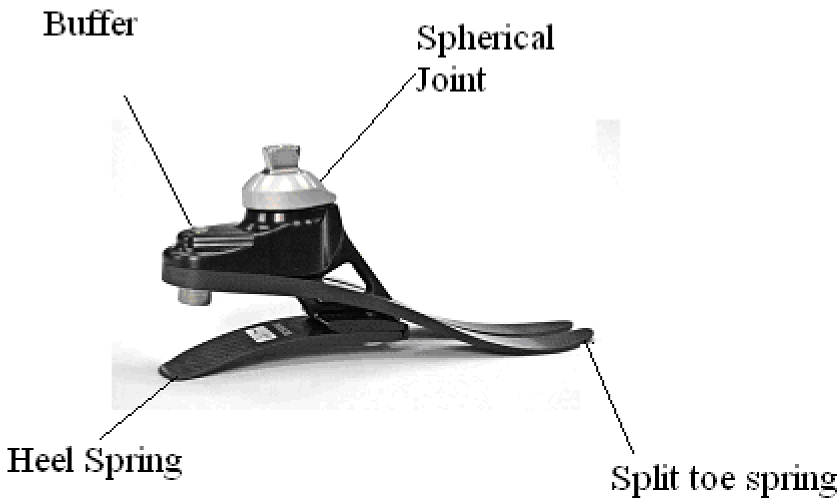


Figure 3.1 Blatchfords Epirus Foot

3.1.1 Design Philosophy

Double spring toe lever simulates the action of the medial and lateral arches of the foot allowing a degree of pronation and supination on uneven terrain. The heel and toe springs combine with the multi-axis joint to provide a dynamic balance replicating the longitudinal arch of the foot during weight bearing.

3.1.2 Key Features

- The integral buffer allows adjustment of the plantar flexion characteristics for each individual.
- Movement at heel strike is an optimized combination of ankle plantar flexion from the spherical joint and heel spring deflection.
- The Epirus spherical joint provides anatomically positioned ankle motion, plantar flexion, dorsiflexion, medial and lateral and torsional movement.
- Ground compliance through mid-stance is achieved through inversion / eversion of the ankle plus the tripod action of the independent heel and

split toe springs, with an additional benefit of some resilient torsional movement due to the ankle.

- Dorsiflexion movement and energy return is provided primarily by the efficient toe spring.
- Foot shell with cosmetic attachment plate.

3.2 OSSUR ASSURE FLEX FOOT

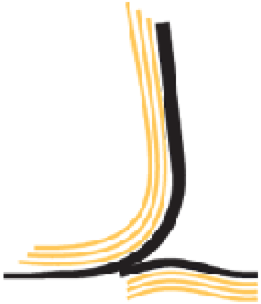
Company Design Aim: To produce a foot that will allow diabetic and vascular amputees a soft, smooth rollover whilst providing stability and dynamic response figure 3.2.

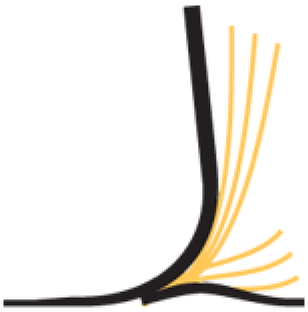
Figure 3.2 Ossur Assure Foot

3.2.1 Design Philosophy

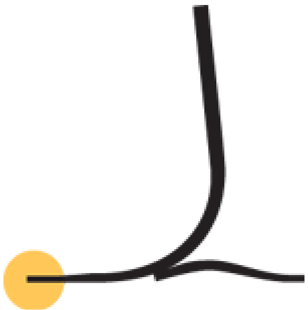
Designed for limited ambulators. Flex-Foot Assure incorporates an active heel and full length toe lever. These work together to provide a proportional response throughout early and late stance which aids in protecting the vulnerable sound limb.

3.2.2 Key Features

 The layering of the carbon fibre ensures that the deflection of the forefoot from midstance to toe off is proportional to the user's weight and impact level. Ossurs definitions of activity and impact levels are seen in (appendix 1).

 The carbon fibre heel absorbs the energy created during initial contact through loading in early stance.

Vertical forces generated at initial contact are stored and translated as Active Tibial Progression. This motion reduces the need to actively push the body forward using the sound foot.

The full length toe lever matches the length of the sound foot giving a smoother gait. It also ensures maximum time is spent on the Prosthetic foot to prevent drop off at the end of stance.

3.3 COLLEGE PARK TRIBUTE FOOT

3.3.1 Design Philosophy

Company Design Aim: To produce a multi axis Prosthetic foot that is simple and cost effective aimed at the moderate activity individual figure 3.3.

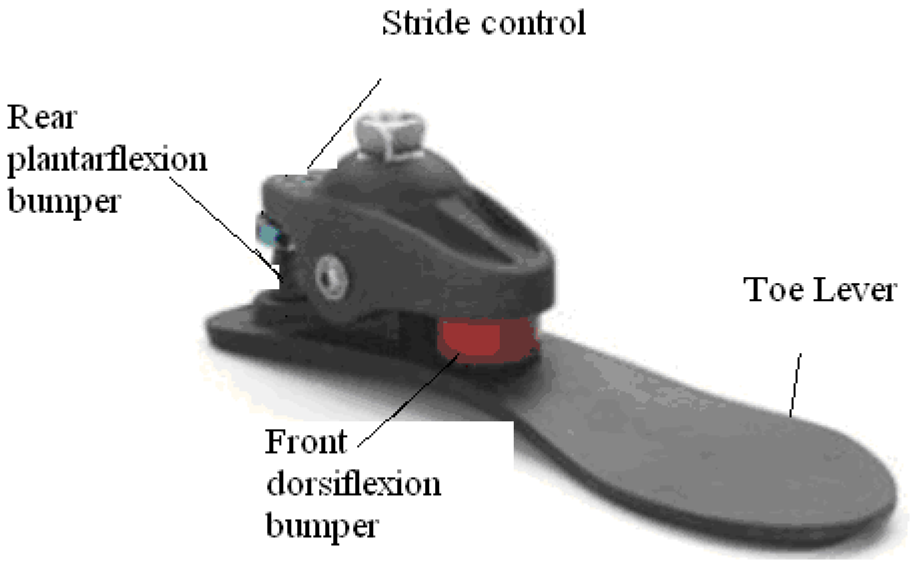
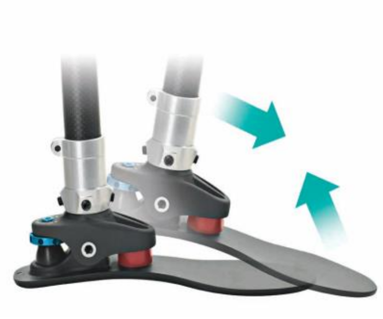


Figure 3.3 College Park Tribute Foot

3.3.2 Key Features

- Multi axial for stability on uneven terrain including transverse rotation.

- Controlled dynamic response with the use of the full length toe lever.



- Adjustable stride control to customize gait. The stride control can be adjusted with the foot shell attached; adjustments affect plantar flexion and dorsiflexion resistance.

3.4 AUTHORS SUBJECTIVE EXPERIENCE OF FEET CHOSEN

Much like many practicing clinicians the author's choice to prescribe the Assure, Epirus and Tribute feet was driven by the information provided by the manufacturers rather than any substantial clinical evidence.

All of the feet were given to patients who were considered moderately active i.e. people who lead active daily lives but do not take part in any high impact sports or running. The positive and negative aspects of the feet, in the author's opinion, that have been found to date are listed below:

3.4.1 Epirus

Approximately 10 used to date.

<u>Positives</u>

- Cosmetic
- Little maintenance needed.
- Amputee users report a comfortable gait with one reporting excellent ground compliance when walking across fields of grass.
- Users weight and activity level are taken into account when prescribing.
- None rejected

<u>Negatives</u>

- Expensive

3.4.2 Assure

Approximately 20 used to date.

<u>Positives</u>

- Reasonable Price
- Cosmetic
- Little maintenance required.
- Users report an easy gait on smooth and rough ground.
- Users weight and activity level are taken into account when prescribing.
- None rejected.

<u>Negatives</u>

- The higher build height can be difficult to accommodate when users have a long trans tibial stump.

3.4.2 Tribute

Approximately 20 used to date.

Positives

- Reasonable price
- Users weight and activity level are taken into account when prescribing.
- Can further adjust the stiffness of heel bumper to optimise gait.
- Users report a comfortable gait.
- Cosmetic and easy to remove foot shell for maintenance.

Negatives

- Must be careful that users do not come close to the 100kg weight limit as feet have been known to split across the carbon fibre toe lever.

4.1 DESCRIPTION OF THE INCLINABLE WALKWAY

This study was undertaken at the Biomedical Engineering Department gait laboratory at the University of Strathclyde Glasgow on an instrumented walkway. The walkway was inclined and measured 1.2m wide and 4.5m long with a horizontal platform at the top with an area of 0.97m. The angle of inclination was 7 degrees see figure 4.0. The steel framed walkway had a rubber sheeting surface. A Kistler force plate (Kistler Instrumented AG, Eulachstrasse 22, Postfach, CH-8408 Winterthur, Switzerland) containing force transducers was located under the walkway on the ground. The force plate was secured to the frame in the middle of the walkway 2.27m from the bottom via an extended frame and set at the same incline. The force plate was balanced and set to capture data at a 100Hz sampling frequency. It was ensured there was clearance around the force plate to make sure true force readings were measured and not shear forces. Handrails were positioned right around the slope for the subject's safety.

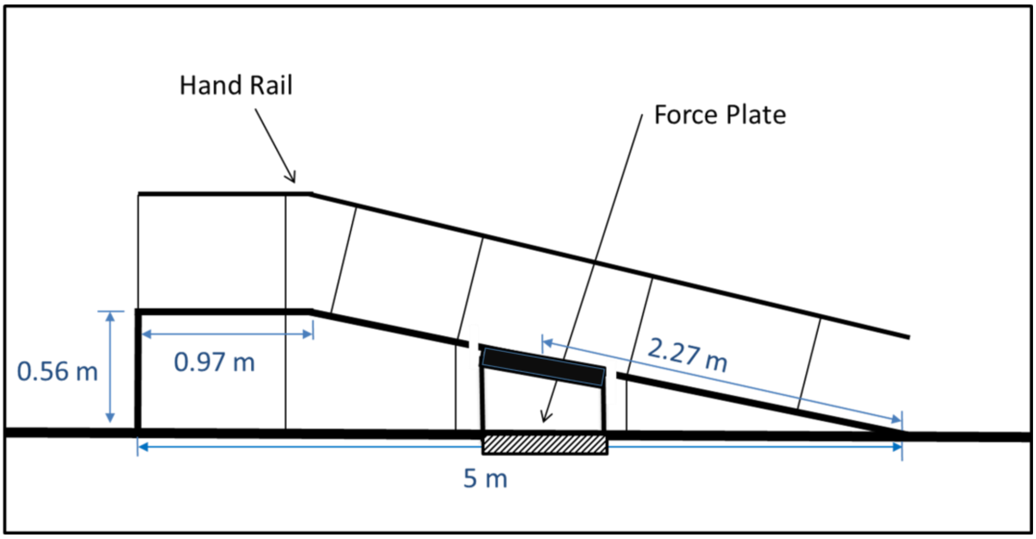


Figure 4.0 Diagram of inclined walk way

4.2 MEASUREMENT OF GAIT DYNAMICS

The Vicon Nexus MX Motion Analysis system (Vicon – UK, 14 Minns Business Park, West Way, Oxford OX2 0JB, UK) was used to collect Kinetic and Kinematic data. Twelve infrared cameras recording at 100Hz captured the location and trajectory of 33 retro reflective spherical markers positioned bilaterally in specific locations see Table 4.0, by a qualified prosthetist. Equivalent land marks on the prosthetic shank and foot were estimated using the intact limb. The sound ankle joint position was assumed to be between the markers placed on the medial and lateral malleoli, and this was imitated as close as possible on the prosthetic foot by positioning the markers in a repeatable position for each foot type. For static capture of the data, a combination of single and cluster markers was used. However, where there was excessive tissue coverage for example the anterior superior Iliac spines a wand was used for static image capture see Figures 4.1- 4.4. For dynamic capture of data only cluster markers were used as they were not attached directly to the skin thus reducing the noise in the data due to skin movement when walking. The clusters were arranged in specific configurations to allow them to be easily identified, labelled and positioned. They would act as reference points for anatomical structures including the hip, knee and ankle joints Crimin et al (2014).

MATLAB (version 7.12.0.635 R2011a) was used to analyse the static and dynamic data, Crimin et al (2014). The static and dynamic CSV files were uploaded and all gaps in the dynamic kinematic data were splined using MATLAB and low pass filtered using a 10^{th} order Butterworth filter with a 20Hz cut off frequency. The cut off frequency was determined using techniques described by Winter 1979 where residuals are plotted against filter frequencies.

A modified marker set designed by Ishai 1975 was used to determine the knee centre from the tibial tuberosity, in a knee frame of reference. The approximate knee joint frame of reference was determined using the long axes of the leg defined as the vector connecting the midpoints of the malleoli and epicondyles. A second vector connecting the epicondyle markers was used to create a plane from which the normal to the x direction could be defined. The z direction is then normal to the x y plane.

Due to difficulties in locating the tibial tuberosity on the residual limb, the knee centre was determined as the midpoint between the two epicondyles, but still referenced from the midpoint of the malleoli. Finally, the ankle centres were described as the midpoint between the malleoli on the contralateral leg and the midpoint of two equivalent markers which were consistently placed on the prosthetic leg. Segment angles are described as distal limb motion relative to proximal limb, for example the hip angle is the relative orientation between the thigh and pelvis.

To calculate moments around defined virtual points such as the ankle, knee and hip centres both the external contact force and inertial properties were considered with the distal acting on proximal segment. The positive moment at each joint occurred when the ankle dorsiflexed, the knee extended and the hip flexed. Leva (1996) was used to estimate the contralateral limb inertial properties. The residual limb properties were estimated using a truncated cone considering an inner bone diameter of 30mm with a bone density of 2000kg/m^3 and muscle density of 1000kg/m^3. The prosthetic foot moment of inertia as well as the socket was determined using simple harmonic motion by setting the components to oscillate with a small angle (generally less than 5 degrees) and timing the period of oscillation. To calculate the ankle moment, the boundary conditions of the foot segment can be considered at the centre of pressure(COP). The computational method adopted considered the force plate moment and force at the local force plate reference system, this method of calculation eradicates the noise of estimating the position of the foot COP. However, for the remaining segments the reaction moment and force of the distal segment, for example, the reaction moment and force of the ankle and acting on the foot was considered equal and opposite to the moment and force acting on the shank segment.

The kinematic and kinetic results will be influenced by the accuracy of marker positioning. The markers were placed on anatomical landmarks using judgement by eye with the prosthetic ankle joint centre proving to be the most challenging to locate. Locating the ankle joint centre for different prosthetic feet is a difficult task as it varies throughout the full ROM in a gait cycle. For this investigation the markers were placed in the same position, depending on the foot, in order to achieve repeatable results. The markers were placed as close as possible to the sound ankles position where they could be secured and would still be seen by the cameras.

Another consideration when interpreting the kinematic and kinetic results would be the static alignment of the limb. The static alignment caused the absolute angle between the leg and foot mechanical axes (appendix 5) to differ with each subject wearing each foot. This difference should be taken into account when analysing the data produced. This cannot be avoided. A foot that has not be aligned to the manufacturers specification will not function to its maximum potential and the wearer will have difficulty achieving as natural a gait as possible.

Marker	Placement description
LASIS	Left anterior ASIS marker placed directly over the left anterior superior iliac spine
RASIS	Right anterior ASIS marker placed directly over the right anterior superior iliac spine
LPSIS	Left posterior PSIS marker placed directly over the left posterior superior iliac spine
RPSIS	Right posterior PSIS marker placed directly over the right posterior superior iliac spine
LLEF	Left lateral epicondyle marker placed directly over epicondyle
LMEF	Left medial epicondyle marker placed directly over epicondyle
LTIB	Left tibial tuberosity marker placed directly over the tuberosity
RLEF	Right lateral epicondyle marker placed directly over epicondyle
RMEF	Right medial epicondyle marker placed directly over epicondyle
RTIB	Right tibial tuberosity marker placed directly over the tuberosity
LLMAL	Left lateral malleolus marker placed directly over malleolus
LMMAL	Left medial malleolus marker placed directly over malleolus
RLMAL	Right lateral malleolus marker placed directly over malleolus
RMMAL	Right medial malleolus marker placed directly over malleolus
LCAL	Left hind foot marker placed directly over left calcaneus

Marker	Placement description
LLMEL	Left lateral metatarsal marker placed at head of the fifth metatarsal
LMMET	Left medial metatarsal marker placed at head of the first metatarsal
RCAL	Right hind foot marker placed directly over left calcaneus
RLMET	Right lateral metatarsal marker placed at head of the fifth metatarsal
RMMET	Right medial metatarsal marker placed at head of the first metatarsal

Table 4.0 Marker Placment Description (see Figures 4.1-4.4 for illustration)

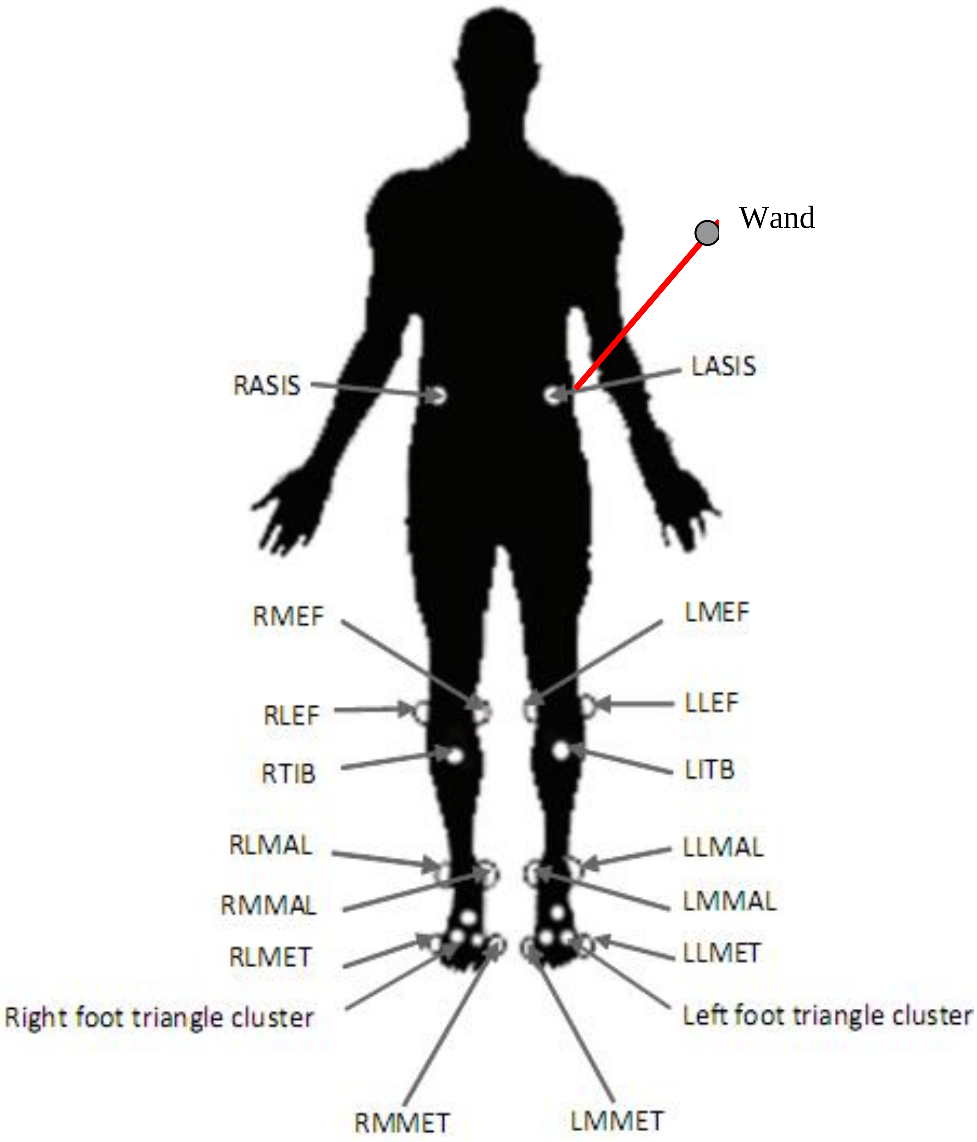


Figure 4.1 Anterior View of marker placement

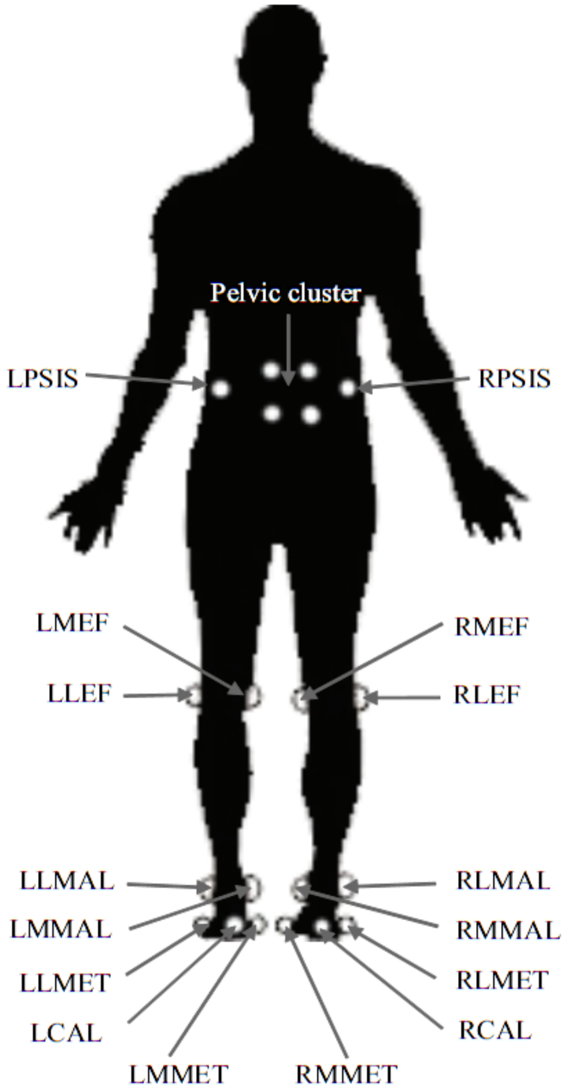


Figure 4.2 Posterior View of Marker Positions

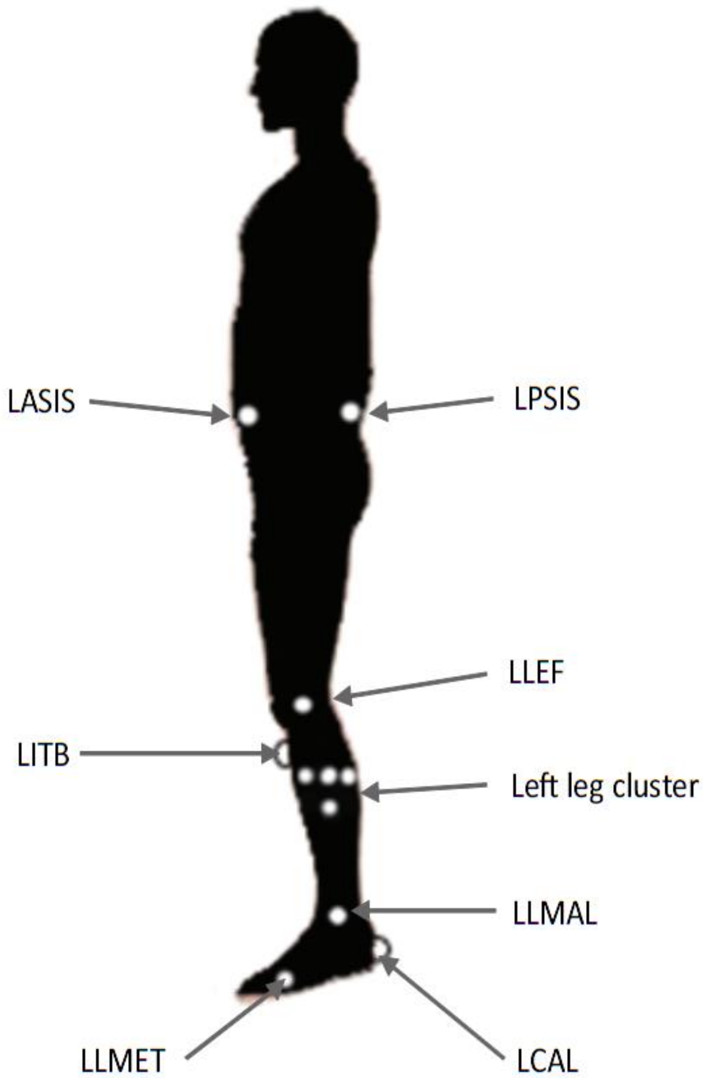


Figure 4.3 Left Leg view of marker positions

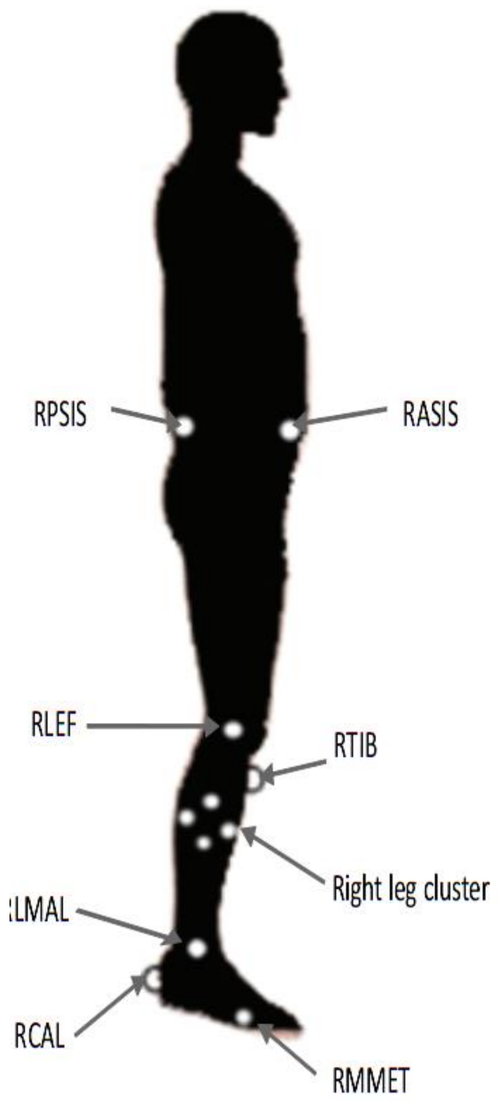


Figure 4.4 Right leg view of marker placement

4.3 PROTOCOL

Each amputee subject was tested on each Prosthetic foot. Each foot was aligned on a flat surface according to the manufacturer's recommendations.

All subjects first had a practice walk up and down the slope with each prosthetic foot to identify a comfortable walking speed. All subjects wore their own trainers. The subjects ascended and descended the incline until ten clean force plate strikes were captured with each limb and each prosthetic foot coming down the slope. Subjects were allowed as many breaks as required throughout testing.

The control subject also used the same marker set and walked down the slope until ten clean force plate strikes were captured.

4.4 QUESTIONNAIRE

Six unilateral trans tibial amputees walked down a 7-degree slope 10 times at a SSWV wearing the 3 different prosthetic feet. Descriptive data of the subjects are presented in table 5.0. After testing each of the three feet the subjects were asked to answer one question taken from an adapted validated Activities-specific Balance Confidence (ABC) scale Powell, Myers (1995) questionnaire Figure 4.5 (appendix 4). The question they were asked to answer was; "For the activity of walking down the ramp, can you indicate your level of self-confidence by choosing a corresponding number from the rating scale 0% to 100%, with 0% meaning you have no confidence and 100% meaning you feel completely confident?"

Activity: Walking down a ramp? ___________ % Epirus Foot ___________ % Assure Foot ___________ % Tribute Foot

Figure 4.5 ABC Scale questionnaire

CHAPTER 5. RESULTS

5.1 SUBJECT SAMPLE

A sample size of 9 was determined using the statistics program Minitab Version 15. This program required estimates for calculations and these were taken from Vickers et al's (2008) study of Elderly Unilateral Trans tibial Amputee Gait on an inclined walkway: A biomechanical analysis. This study is similar and of interest to the intended research and in particular the results of the dorsiflexion angle for the controls and amputees when descending the slope.

Using Vickers et al (2008) study a standard deviation of 3 degrees was chosen. It was estimated that the difference between normal and amputee's dorsiflexion angle at heel strike is approximately 5 degrees, which will represent our difference. A p-value of 0.05 and power of 78% were used resulting in a sample of 9. A sample size of 9 allowed for an expected drop out of subjects of which there were 3 resulting in 6 subjects taking part in the study.

5.2 SUBJECTS

Of the remaining subjects out of nine, five male and one female unilateral trans tibial amputees were recruited from the Prosthetics department of the Southern General Hospital Glasgow. The selection criteria stated that all subjects needing to be uni lateral trans tibial amputees with a stump length no less than 13cm. The subject must have used a prosthetic limb for at least 2 years and their stump needed to have a full range of motion and muscle control. The participant’s mass needed to be no more than 100kg and considered to be within the individual foot manufacturer’s activity scales for moderate activity (Appendix 1,2,3). Each subject wore their own or a copy of their own socket, their own trainers and walked at a self-selected pace. All amputee subjects walked with all 3 prosthetic feet. One control subject was also asked to walk down the slope and their data was used for comparison.

Prior to commencement of the study the subjects were informed of the research aims and written consent was provided. Ethics approval was granted by the West of Scotland Research Ethics Committee ID number 50106.

In order to statistically analyse the data produced an average of each joint angle, moment and GRF was noted for each prosthetic foot table (5.1-5.4). Friedman's two-way analysis of variance was performed at each joint to identify any significant differences in prosthetic feet as shown by Field A (2009). Each foot was compared and contrasted between the other and the joint means were compared to the control subjects means.

Amputee Participant	**Age (years)**	**Gender**	**Cause of amputation**	**Side**	**Years since amputation**	**Height (cm)**	**Mass (kg)**
A	60	M	Trauma	L	22	169	70
B	66	M	Trauma	L	17	169	75
C	70	M	Vascular	L	5	178	69
D	54	F	Congenital	R	24	165	65
E	37	M	Trauma	R	9	175	92
F	40	M	Trauma	L	5	177	98

Table 5.0 Amputee participant details

5.3 STATISTICAL ANALYSIS

The characteristics of the subjects are presented in table 5.0. The descriptive statistics for the parameters tested are shown in table 5.1-5.3. All subjects excluding one were male. It can also be seen that trauma was the main cause of amputation which is not representative of the population to date reported by Scott et al (2010). There is a wide spread in years since amputations but none below 5 years. Therefore, all subjects will have a well-established gait pattern. The age of subjects is spread between 37-70 years with the majority of the amputees being close to the mean age of 68.5 years reported by Scott et al (2010)

5.3.1 Hypothesis 1: Within Subject Comparison

It was hypothesised that all prosthetic feet would perform in a similar way with no significant differences. Friedman's two-way analysis of variance was used to test this theory. This test was chosen because the data did not meet the assumptions for parametric tests due to the small sample size. Friedman's analysis allowed within subject differences to be discovered in each of the following areas: joint angles, joint moments and GRF. The results in tables (5.1-5.10) represent an average of all subject's prosthetic side with each prosthetic foot in early stance.

Joint (Angle)	Foot	N	Max	Min	Mean	SD
Hip (°)	Assure	6	54.09	22.16	34.5	11.5
	Epirus	6	45.97	19.69	31.6	9.3
	Tribute	6	69.37	22.50	43.4	15.5
Knee (°)	Assure	6	31.11	-1.02	0.9	14.5
	Epirus	6	28.07	-3.64	3.8	15.7
	Tribute	6	38.05	-3.79	4.3	14.2
Ankle (°)	Assure	6	-17.75	-4.22	-12.7	5.9
	Epirus	6	-14.48	-0.58	-9.3	6.5
	Tribute	6	-13.27	-3.39	-9.1	4.9

Table 5.1 Average joint angle maximum, minimum, mean and SD in early stance (0%) for prosthesis

Friedman's analysis of variance was performed at each joint in order to identify any differences in the prosthetic feet with significance set at p<.05. The joint angles showed no significant differences at the hip p=0.22, knee p=0.61 and ankle p=0.85. However, there were noticeable differences of greater than 10° between the max angle of the Tribute and Epirus feet at the hip and knee joints.

Joint Moment	Foot	N	Max	Min	Mean	SD
Hip (Nm)	Assure	6	36.40	-0.30	8.9	7.2
	Epirus	6	52.72	-0.51	12.4	12.2
	Tribute	6	63.20	0.66	16.5	15.6
Knee (Nm)	Assure	6	27.32	0.40	7.5	7.9
	Epirus	6	35.87	0.22	9.1	11.1
	Tribute	6	38.38	0.55	10.8	11.6
Ankle (Nm)	Assure	6	6.07	-0.51	-2.8	3.6
	Epirus	6	-6.95	-2.01	-5.2	4.3
	Tribute	6	-9.89	-3.17	-3.7	5.0

Table 5.2 Average Joint Moment, maximum, minimum, mean and SD in early stance (0%) for prosthesis

Friedman's test revealed no significant differences between prosthetic feet when examining the knee and ankle moments p=0.31 and p=0.12. However, there was a significant difference found at the hip moment p=0.009.

X^2 (2, n = 6) = 9.33, p <.05). Inspection of the Median values for hip moment show an increase from 6.65 and 6.6 respectively for the Assure and Epirus with an increase to 9.78 for the Tribute foot.

Joint	Foot	N	Max	Min	Mean	SD
GRF (N)	Assure	4	217.46	8.85	65.0	13.9
	Epirus	5	156.55	20.18	64.9	22.2
	Tribute	5	147.99	13.07	81.5	26.3

Table 5.3 Average joint vertical GRF (in relation to the force plate) maximum, minimum, mean and SD in early stance (0%) for prosthesis

No significant differences were seen in the GRF for all prosthetic feet p=0.78. However, the Assure foot had a much larger max GRF overall and smaller min compared to the other feet.

Friedman's test revealed only one significant finding which was for the moment at the hip p=0.009. It could be seen the Tribute foot performed differently when compared to the Assure and Epirus. All other joint kinetics showed no significant results. Therefore, for the majority of the tests the hypothesis 1 was proved correct as none of the feet performed significantly differently from another except for one measurement.

5.3.2 Hypothesis 2: Between Subjects Comparison

It was also hypothesised the control subject would walk very differently compared to the amputee subjects. The control subject's anatomical foot was compared at each measured point to each prosthetic foot. In order to achieve suggestive data, it was necessary to do a comparison of means, as the number of subjects taking part determined it would be a mixed design of within subject and between subjects analysis, which would have been ill advised. Thus comparison of means only allows for exploratory analysis of this data. In future for statistical testing it would be advisable to match the number of amputees and control subjects evenly.

5.3.3 Comparison of Means

The tables (5.4-5.10) below show the mean of the angle, moment and GRF at the hip, knee and ankle joint for all amputee subjects using each prosthetic foot. They also show the mean of the control subject after walking down the slope 10 times. The difference between amputee and control subject means have been displayed and compared.

Angle Hip		**Mean (Degrees)**	**Difference (Degrees)**
	Control	**37.3**	-
	Assure	34.5	2.8
	Epirus	31.6	5.5
	Tribute	43.4	6.1

Table 5.4 Mean hip Angle for control subject and amputees with each prosthetic foot and difference between foot and control.

Angle Knee		**Mean (Degrees)**	**Difference (Degrees)**
	Control	**5.8**	-
	Assure	0.9	4.8
	Epirus	3.8	1.9
	Tribute	4.3	1.5

Table 5.5 Mean knee angle for control subject and amputees with each prosthetic foot and difference between foot and control.

Angle Ankle		**Mean (Degrees)**	**Difference (Degrees)**
	Control	**0.3**	-
	Assure	-12.7	12.4
	Epirus	-9.3	9
	Tribute	-9.1	8.8

Table 5.6 Mean ankle angle for control subject and amputees with each prosthetic foot and difference between foot and control.

The comparison of joint angles showed the Tribute foot performed closer to normal in two of the three joints with the knee joint showing the smallest difference of 1.5 degrees. When compared to the other feet the Assure foot consistently demonstrated a noticeable difference.

Moment Hip		Mean (Nm)	Difference (Nm)
	Control	**25.3**	-
	Assure	8.8	16.4
	Epirus	12.4	12.9
	Tribute	16.5	8.8

Table 5.7 Mean Hip moment for control subject and amputees with each prosthetic foot and difference between foot and control.

Moment Knee		Mean (Nm)	Difference (Nm)
	Control	**16.8**	-
	Assure	7.5	9.3
	Epirus	9.1	7.6
	Tribute	10.8	6

Table 5.8 Mean Knee moment for control subject and amputees with each prosthetic foot and difference between foot and control.

Moment Ankle		Mean (Nm)	Difference (Nm)
	Control	**-1.4**	-
	Assure	-2.8	-1.4
	Epirus	-5.2	-3.8
	Tribute	-3.8	-2.4

Table 5.9 Mean Ankle moment for control subject and amputees with each prosthetic foot and difference between foot and control.

The moments again showed the Tribute foot to act closest to the control in two of the three joints. However, the Assure foot had the smallest difference at the ankle joint of 1.4Nm but at the hip and knee it had the largest difference overall.

Ground Reaction Force		Mean (N)	Difference (N)
	Control	**41.8**	-
	Assure	65.0	23.2
	Epirus	64.9	23.2
	Tribute	81.5	39.7

Table 5.10 Mean Vertical GRF (relative to the force plate) for control subject and amputees with each prosthetic foot and difference between foot and control.

The GRF (ground reaction force) showed Assure and Epirus to differ equally when compared to the control with a variance of 23.2N.

5.3.4 Summary of Hypotheses

It was hypothesised that there would be no kinematic/kinetic difference at the joints amongst prosthetic feet but there would be a difference between amputee gait and control subjects gait. Friedman's test proved the former hypotheses was incorrect as there was a significant difference between the Assure, Epirus and Tribute foot when testing the moment at the hip p=0.009. The second hypothesis was proved correct when comparing the mean between amputees and control subject. Most markedly the ground reaction force differed by an average of 28.7N. The smallest difference was seen for the moment at the ankle using the Assure foot of 1.4Nm.

5.4 OBJECTIVE RESULTS KINEMATICS

Subjects gait was analysed at four points in the gait cycle, initial contact (IC), mid stance (MS), 50% and swing. The effect each foot has on the hip, knee and ankle at these points was measured and compared to a control subject. Positive angles were ankle dorsiflexion, knee flexion and hip flexion relative to the pelvis (Appendix 11).

Joint angles between each subject were very similar in pattern with the size of the angles varying which may relate to the subject but could also be influenced by the static alignment and marker positioning. Compared to the control subject the closest matching joint movement was the knee joint, which in the normal subject remained flexed throughout the gait cycle but in some amputee subjects is extended at IC. The ankle joint for the control subject and amputees remained in plantar flexion throughout gait except for a brief spell in dorsiflexion at 50%. The hip joint on the prosthetic side followed the pattern of flexion extension and flexion again at 50% of gait, which closely matched the control subject. However, at 50% the control subject reached a neutral to slight extension angle whereas the amputees predominantly remained flexed.

5.4.1 Control Subject Joint Angles

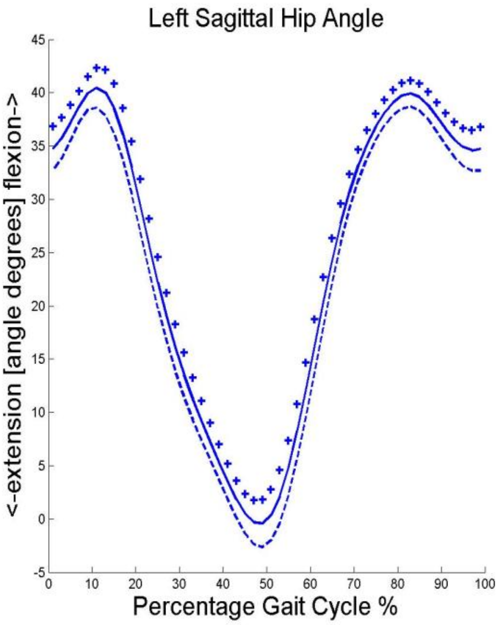


Figure 5.0 Control Left Hip angle

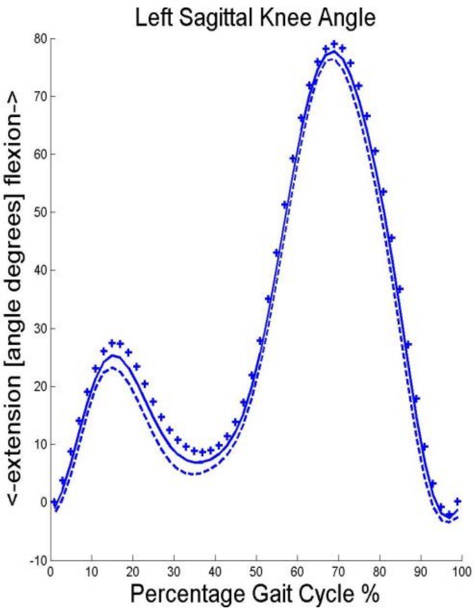


Figure 5.1 Control Left Knee angle

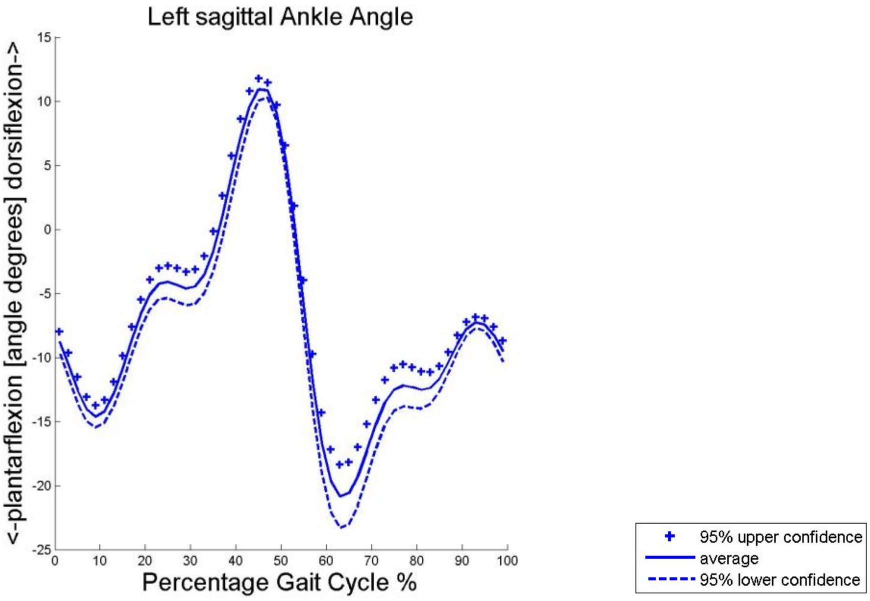
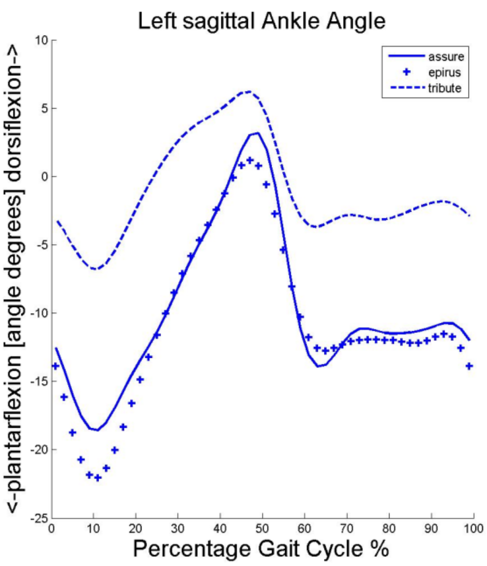


Figure 5.2 Control Left ankle angle



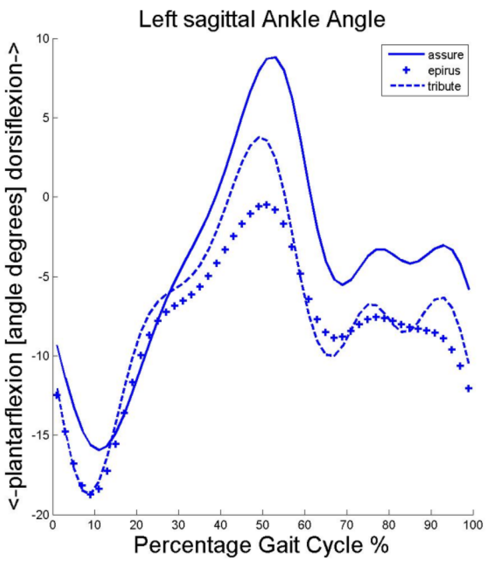
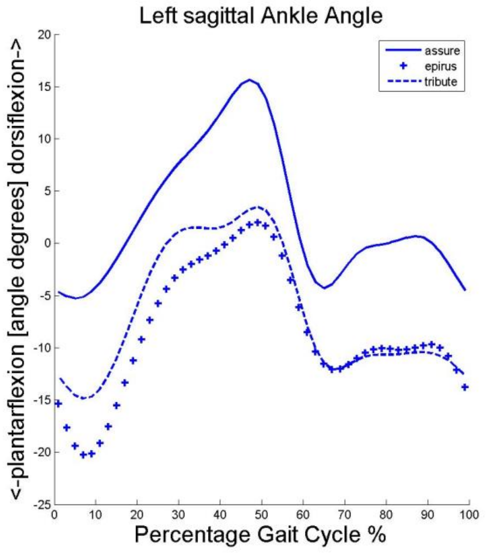


Figure 5.3 Pt A Pros ankle angle

Figure 5.4 Pt B Pros ankle angle



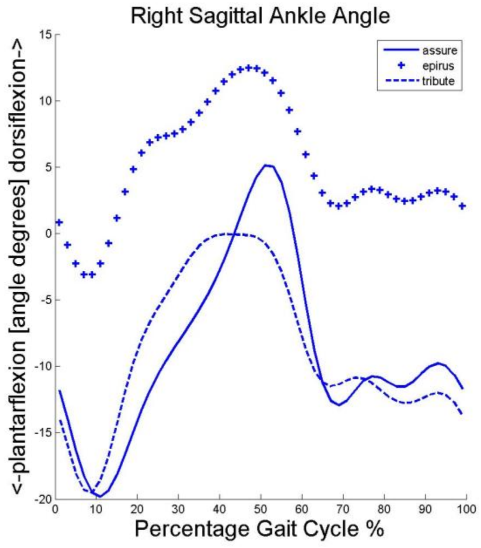
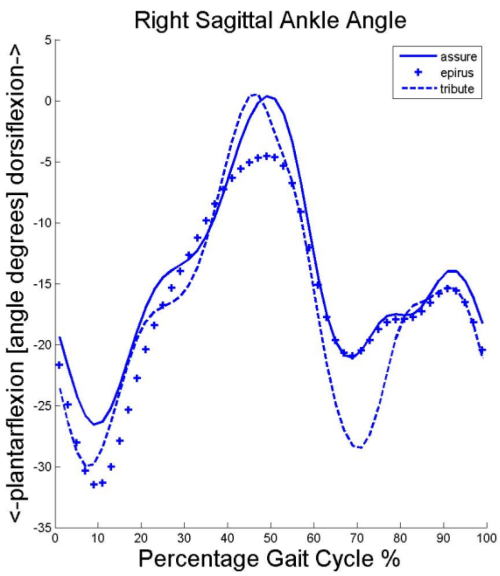


Figure 5.5 Pt C Pros ankle angle

Figure 5.6 Pt D Pros ankle angle



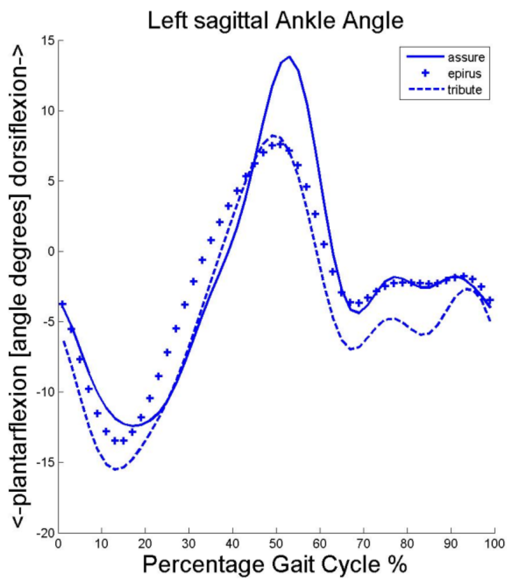


Figure 5.7 Pt E Pros ankle angle

Figure 5.8 Pt F Pros ankle angle

5.4.2 Prosthetic Ankle Joint Angles

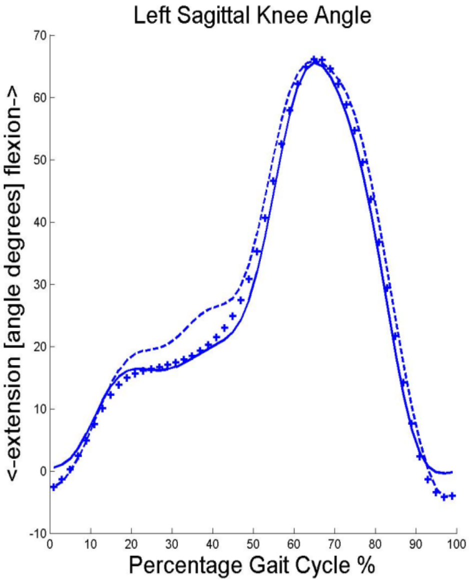
The ankle joints of all three prosthetic feet showed a very similar pattern of movement compared to the normal subject figures 5.0-5.8. The prosthetic feet remained largely in plantar flexion throughout gait. However, the control subject reached a point of 5 degrees plantar flexed at MS then moved sharply into dorsiflexion which peaked at 50%. The maximum dorsiflexion angle of the control subject was in general significantly higher than the amputees.

The sound ankle showed no obvious pattern of movement when the subject was wearing any of the feet but this varied in magnitude and direction of angles compared to the amputated side and control subject (appendix 8).

The Tribute foot showed varying degrees of plantar flexion with a range of 14-3 degrees and at 50% of gait five subjects had small amounts of dorsiflexion.

The Assure foot also showed a pattern of varying plantar flexion angles that were higher than Tribute ranging from 19 to 3 degrees. At MS Pt C dorsiflexed 4 degrees and at 50% dorsi flexed a further 15 degrees. At 50% all subjects dorsiflexed and during TO Pt C showed a dorsiflexion angle of 3 degrees and Pt B reached plantigrade.

The Epirus foot also had a majority of subjects in plantar flexion ranging from 22 to 1 degree throughout gait. However, Pt D remained in dorsiflexion but to a lesser degree than the normal subject. At 50% half the subject’s planter flexed and half dorsiflexed.



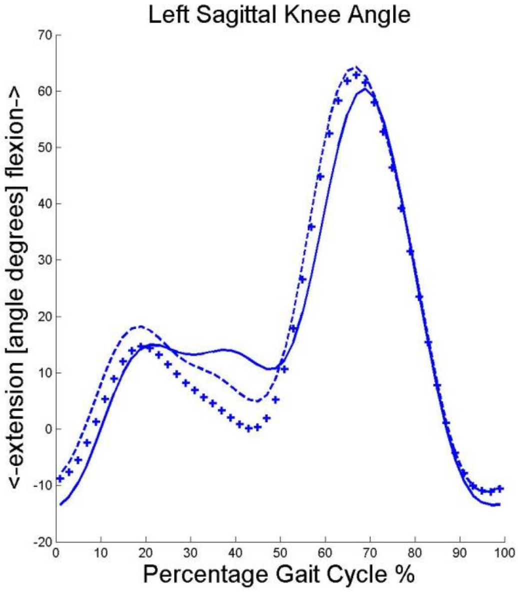
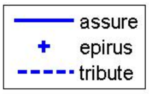
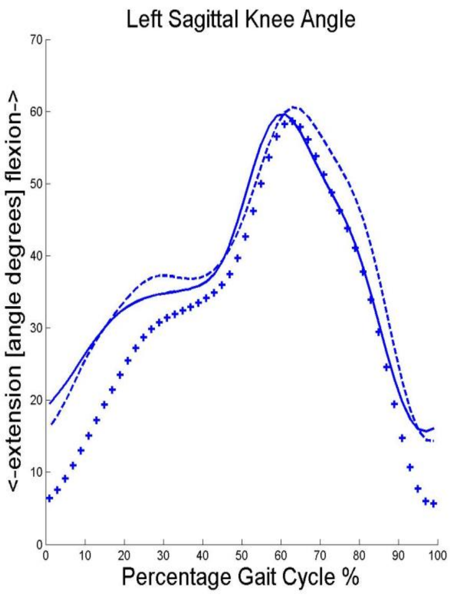


Figure 5.9 Pt A Pros Knee angle

Figure 5.10 Pt B Pros Knee angle





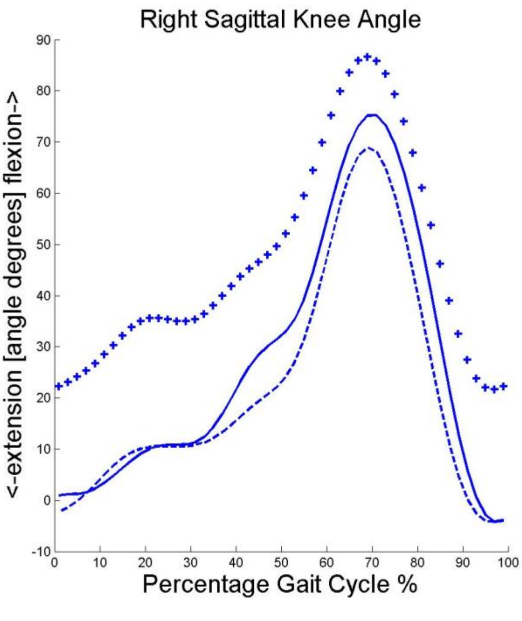
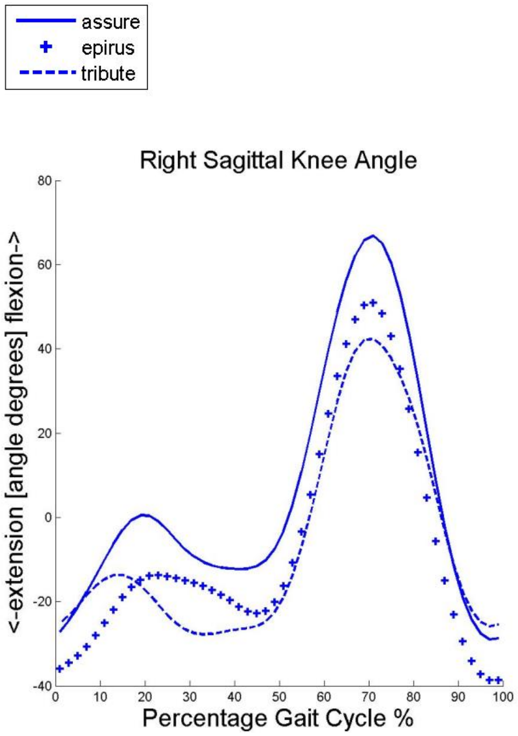


Figure 5.11 Pt C pros Knee angle

Figure 5.12 Pt D pros Knee angle



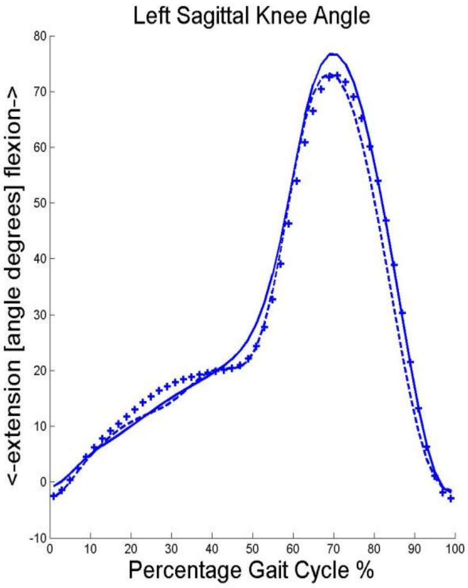


Figure 5.13 Pt E pros Knee angle

Figure 5.14 Pt F pros knee angle

5.4.3 Prosthetic Knee Joint Angle

As with the normal subject the amputees knee joint flexed throughout descending the slope except during IC where the majority of amputees where in extension. Figures 5.9-5.14.

The sound knee also showed a flexion pattern throughout stance on the slope (appendix 7).

The Tribute foot had only Pt C in flexion at IC and all the other subjects were extended. Compared to the normal subject there were some increased angles of flexion at 50% (Pt’s A and C) but similar angles at TO and swing.

The Assure foot showed a variation in angles at IC with three subjects making contact with the slope in neutral, two subjects in extension and one in flexion. The angle of flexion at TO and swing were close too normal however all other phases of gait were dissimilar.

The Epirus foot allowed two subjects to achieve flexion at IC with all other subjects extending. Angles of flexion at MS and 50% were unlike the normal subject but again during TO and swing gait was closely reflected.

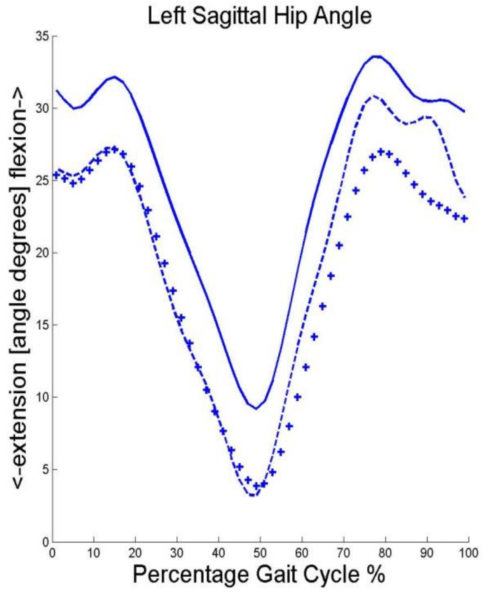


Figure 5.15 Pt A pros Hip angle

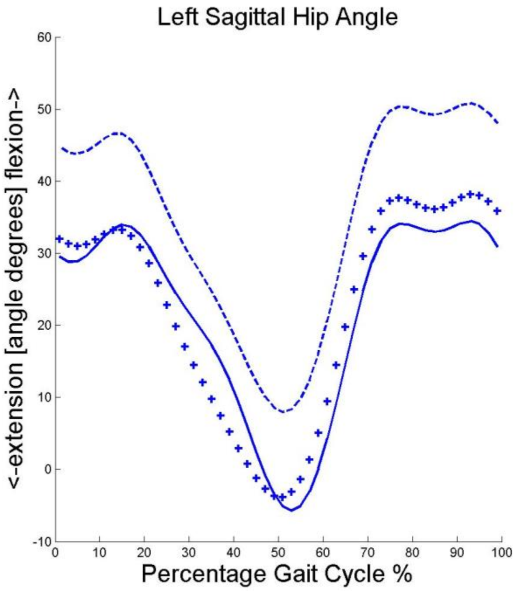
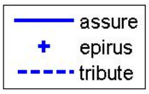


Figure 5.16 Pt B pros Hip angle



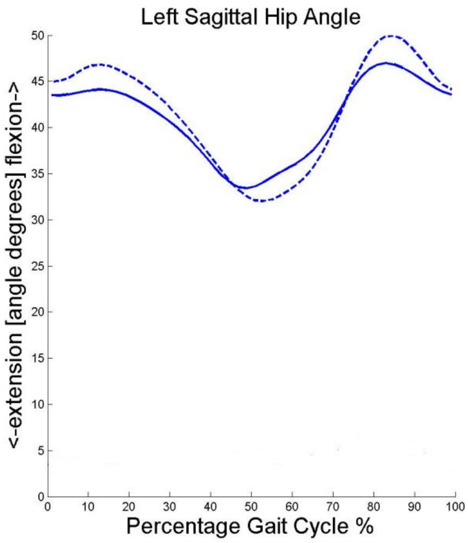


Figure 5.17 Pt C pros Hip angle

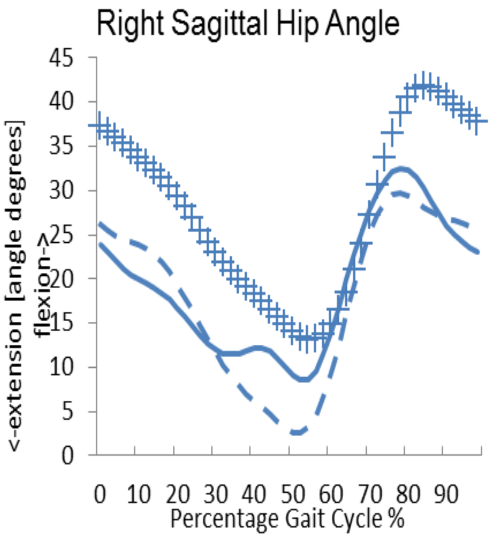
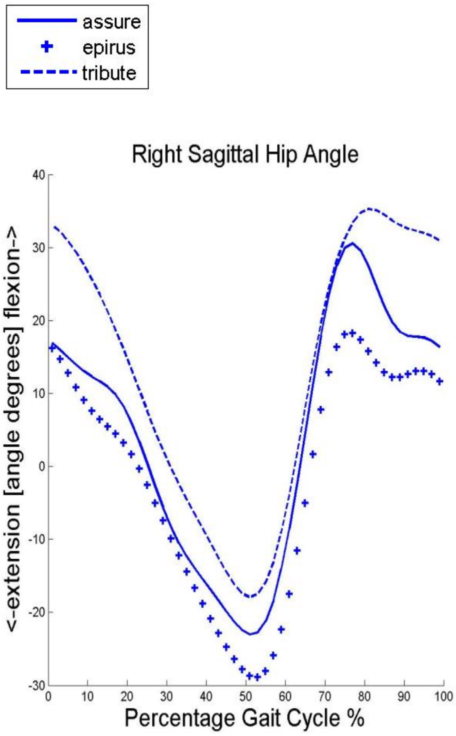


Figure 5.18 Pt D pros Hip



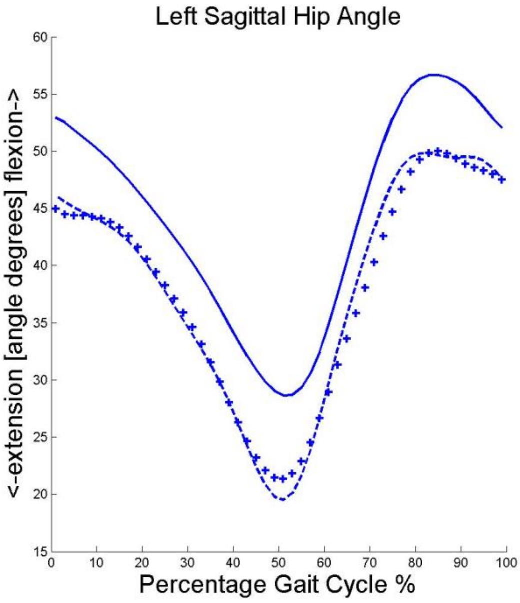


Figure 5.19 Pt E pros Hip angle

Figure 5.20 Pt F pros Hip angle

5.4.4 Prosthetic Hip Joint Angle

When descending a slope, the normal subject flexed throughout IC and MS then moved into extension briefly at 50%-TO then back into flexion for swing phase. While coming down the slope it was seen the majority of amputee subjects remained flexed throughout gait Figures 5.15-5.20.

For the sound limb Pt's A, B and E all showed a brief hip extension angle at 50% of stance and pt's E and F remained in flexion throughout. (Appendix 7).

The Tribute foot demonstrated flexion pattern at the hip for all subjects except Pt E who moved into extension from MS to TO. In some cases, (Pt's B, D and F) the angles of flexion were largely higher in amputees than in the normal subject.

The Assure foot also has a flexion pattern with the exception of Pt E who extended from 50% to TO.

The Epirus foot influenced the hip angle by keeping it largely in flexion for all subjects throughout gait. However, Pt E extended from MS to TO.

5.5 KINETICS

Joint moments were examined in reference to the external moment created by the ground reaction force (GRF). If the GRF was ahead of the ankle joint this was a positive dorsiflexion moment. If the GRF was anterior to the knee joint this was a positive extension moment and if it was anterior to the hip joint it was a positive flexion moment (Appendix 10). The joint moments for all amputees followed a similar pattern at each joint no matter which foot they were wearing. For all phases of gait and for all feet the moments at the hip matched the control subject pattern. The moments at the knee and ankle for all feet followed a similar pattern to the control subject with varying values.

5.5.1 Control Subject Joint Moments

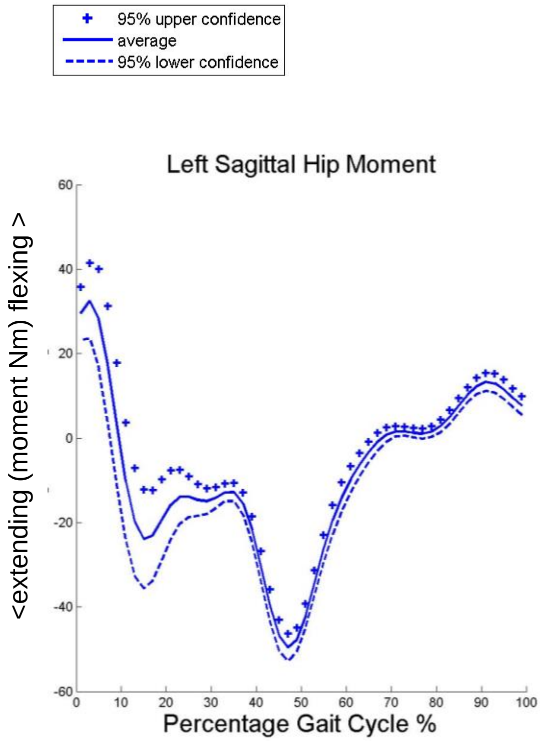


Figure 5.21 Control Hip Moment

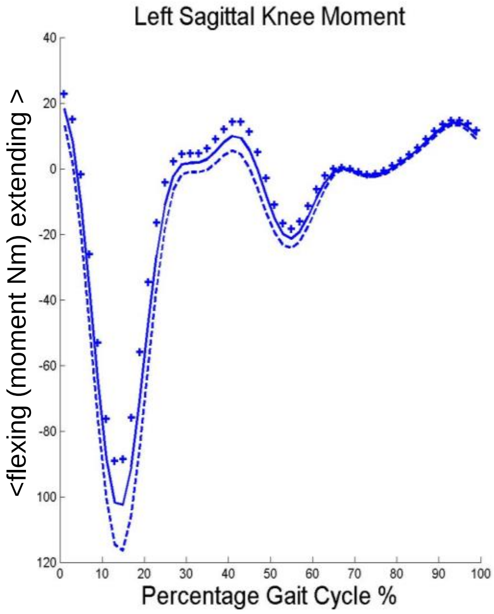


Figure 5.22 Control Knee moment

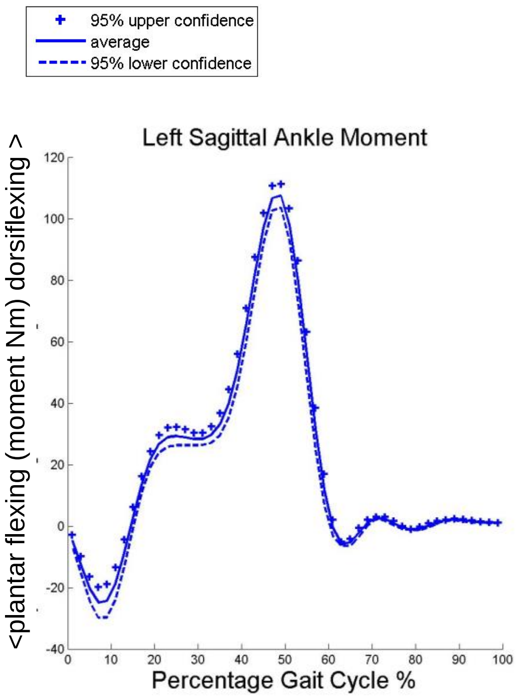


Figure 5.23 Control Ankle Moment

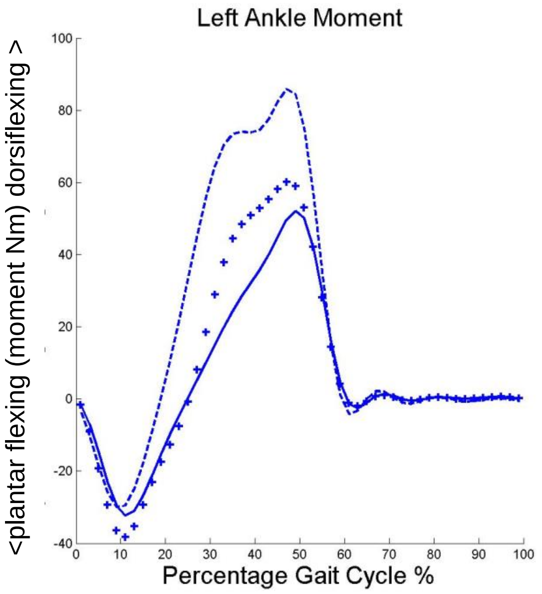


Figure 5.24 Pt A pros Ankle moment

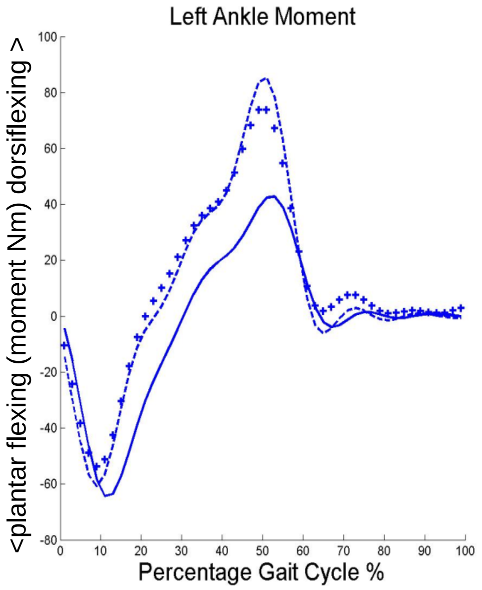
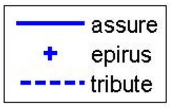


Figure 5.25 Pt B pros Ankle moment



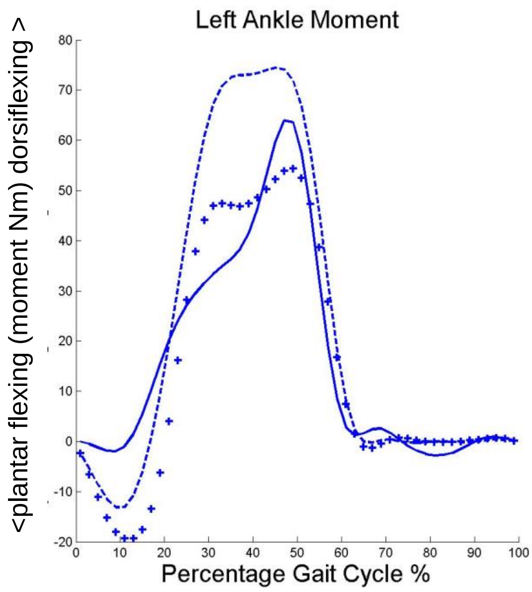


Figure 5.26 Pt C pros ankle moment

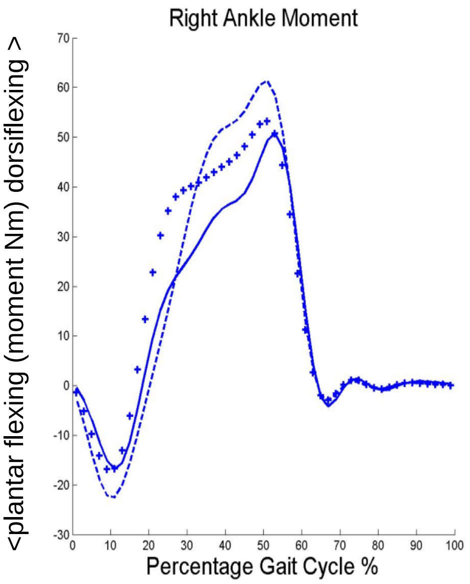


Figure 5.27 Pt D pros ankle moment

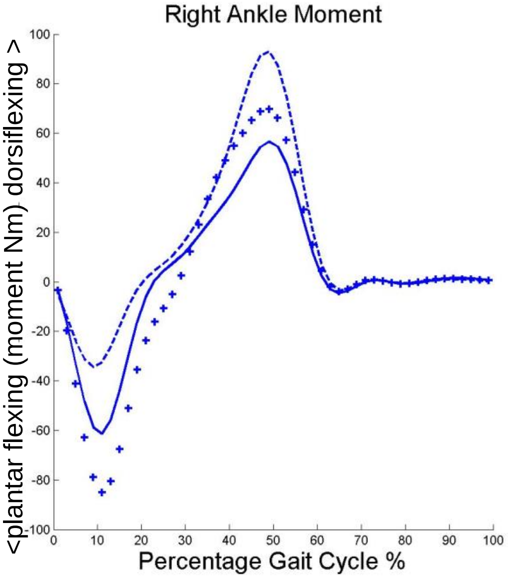


Figure 5.28 Pt E pros ankle moment

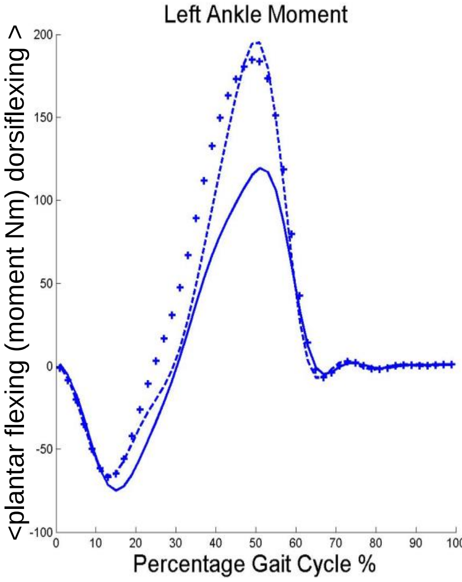


Figure 5.29 Pt F pros ankle moment

5.5.2 Prosthetic Ankle Joint Moment

The ankle moment for all six amputee subjects followed the same pattern with the exception of MS with varying sizes of moment. This may be due to differing walking speeds Figures 5.24-5.29. During IC and TO the amputee subjects matched the controls neutral moment. During MS the control subject dorsiflexed however only patient's C and D matched this moment with all the others showing a plantar flexion moment. At 50% of gait all subjects with all feet dorsiflexed matching the control subject. During TO the amputees continued to show a neutral to dorsiflexion moment and the control subject changed to a plantar flexion moment.

As with the ankle joint angles the moments of the sound limb were varied compared to the control subject and amputated limb (Appendix 7).

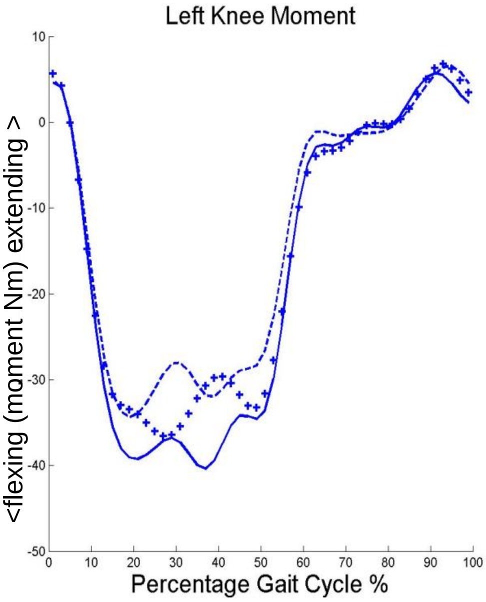


Figure 5.30 Pt A pros knee moment

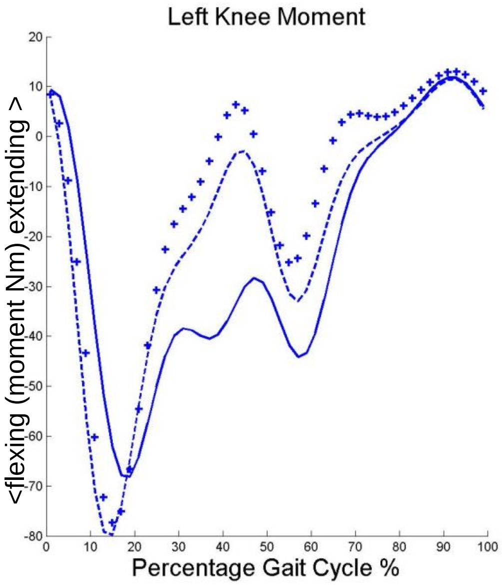
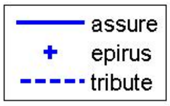


Figure 5.31 Pt B pros knee moment



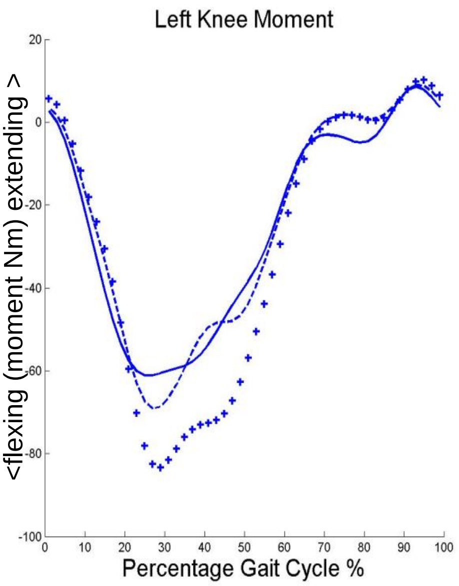


Figure 5.32 Pt C pros knee moment

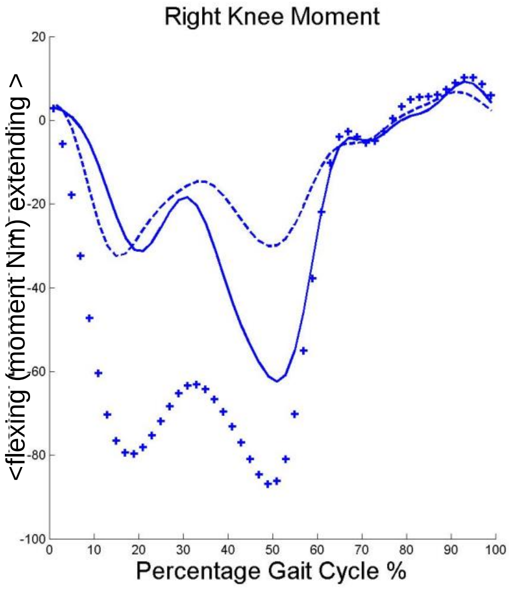


Figure 5.33 Pt D pros knee moment

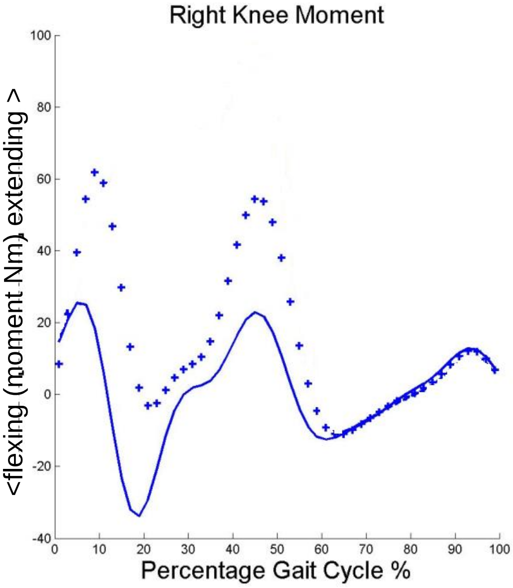


Figure 5.34 Pt E pros knee moment

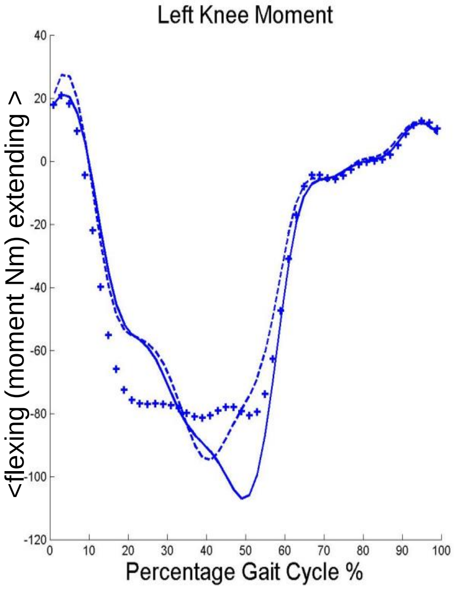


Figure 5.35 Pt F pros knee moment

5.5.3 Prosthetic Knee Joint Moment

The moment around the knee joint of the amputees except Pt E were the opposite of the control subject from IC to 50%. During TO the control subject knee showed a neutral moment as did patients A, C, and D. However, patient's E and F showed a flexion moment and patient B an extension moment figures 5.30-5.35. Patients E's data showed many more variations compared to the others; using the Tribute Foot Pt E showed an extension moment throughout stance. However, there were no other significant differences with the other two feet.

The Epirus foot showed a much larger flexion moment than the other two feet for patient C and D at MS and 50% of gait. The sound knee showed a predominently flexion moment throughout stance with all feet (appendix 7).

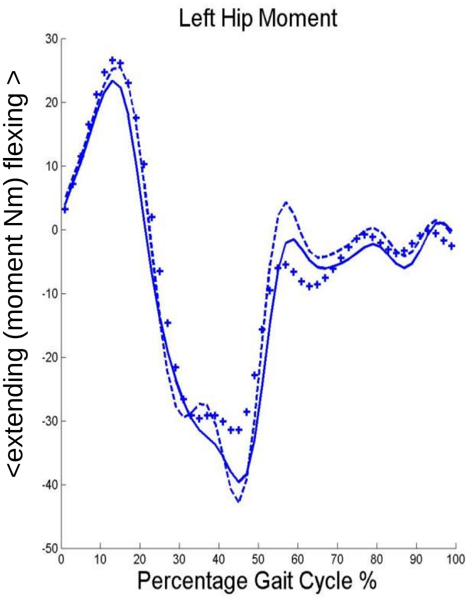


Figure 5.36 Pt A pros hip moment

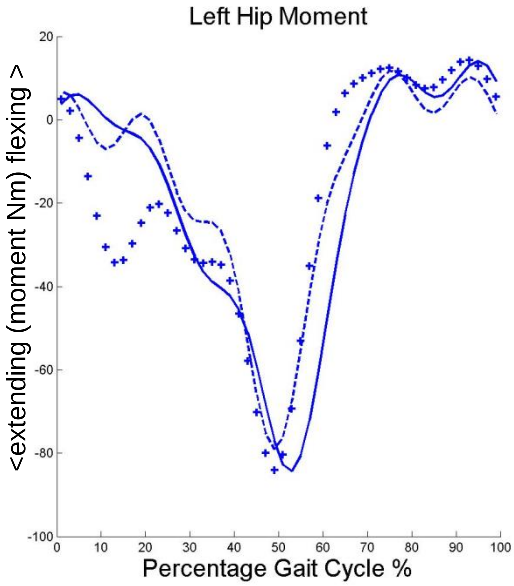
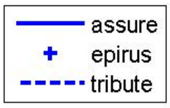


Figure 5.37 Pt B pros hip moment



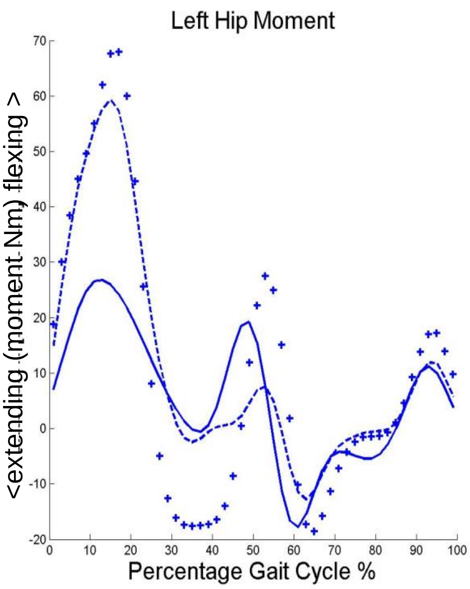


Figure 5.38 Pt C pros hip moment

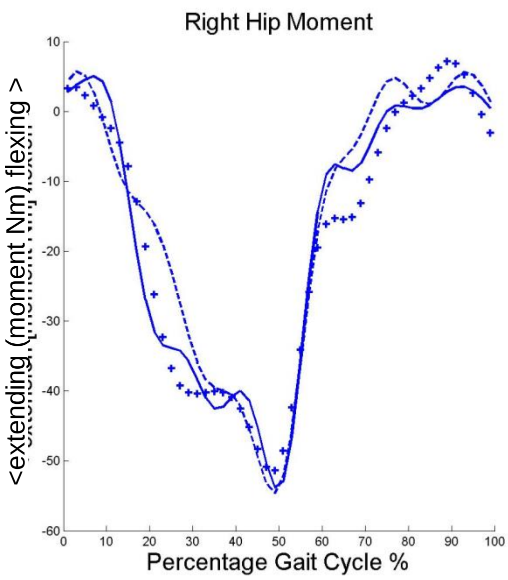


Figure 5.39 Pt D pros hip moment

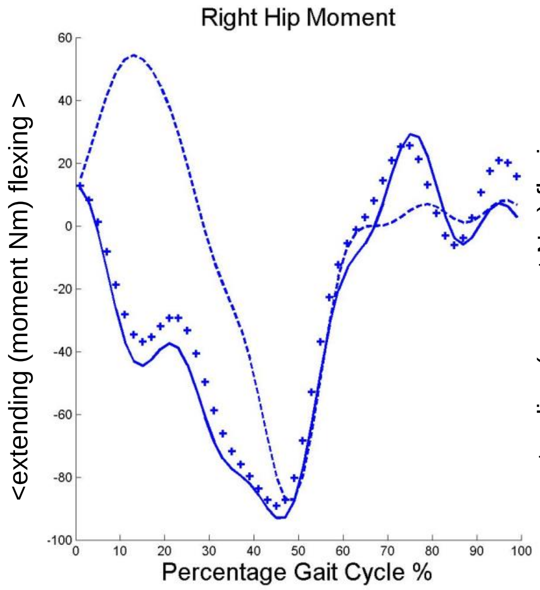


Figure 5.40 Pt E pros hip moment

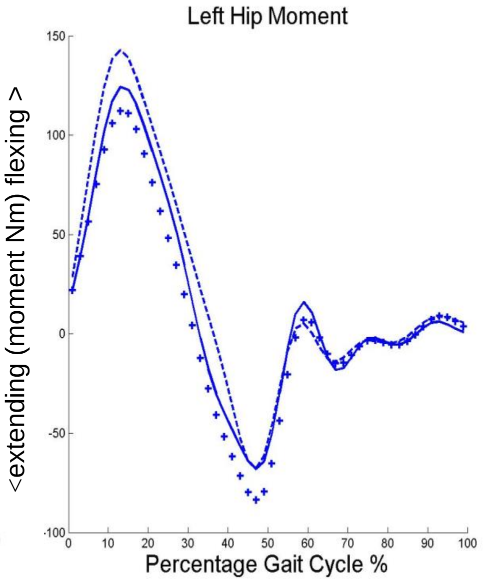


Figure 5.41 Pt F pros hip moment

5.5.4 Prosthetic Hip Joint Moment

The moment around the hip joint for all amputee subjects with all feet had the same pattern as the control subject Figures 5.36-5.41.

The moment at the sound hip also showed the same pattern as the control subject except for a brief moment in extension for pt A at IC (appendix 7).

5.5.5 Ground Reaction Force (GRF)

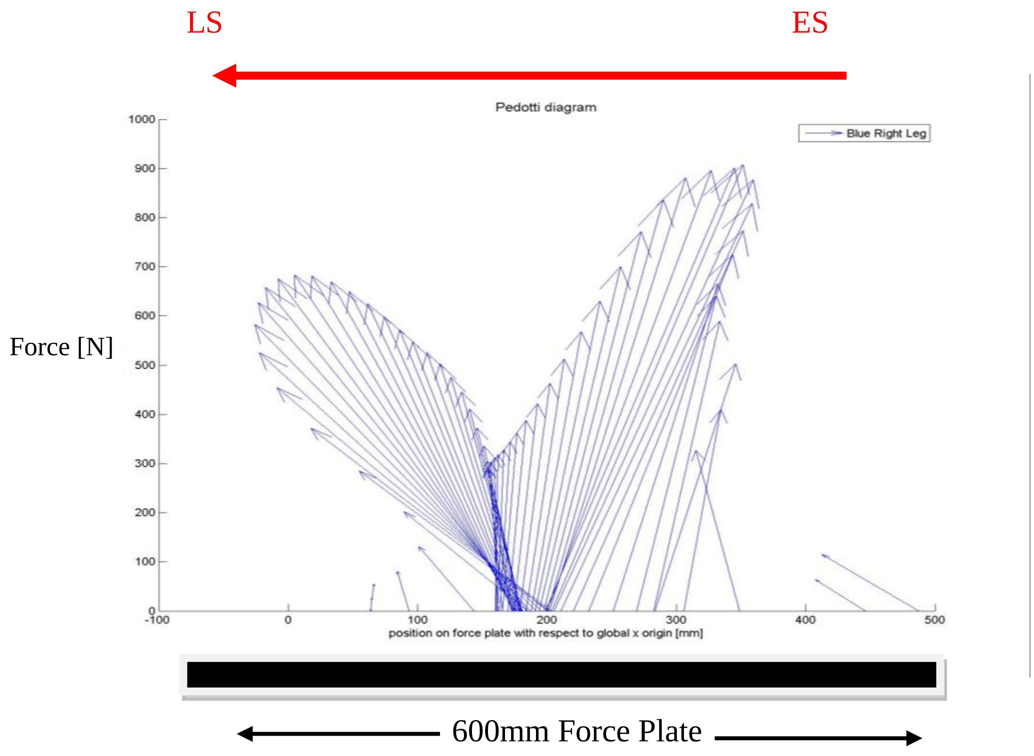


Figure 5.42 Control subject GRF Pedotti down slope

Control Subject

The control subject GRF shows a butterfly shaped pedotti with peaks in ES and LS and a trough in MS figure 5.42. The vectors in ES are widely spaced reaching a peak of 900N, which reduces to a trough of 300N through mid-stance, finishing with a LS peak of 700N. Late stance shows a small area of backward displacement and some outliers can be seen due to force plate error.

Patient A

Assure

Patient A was most confident with the Assure foot. Figure 5.43 shows the GRF for the amputated side has vectors that are evenly spaced. Early stance (ES) shows a maximum of 700N, which reduces to a trough of 600N through mid-stance, finishing with a late stance (LS) force of 400N. On the sound side the subject lingers a little in

ES reaching a maximum force of 900N. At MS the sound side vectors are evenly spaced. However, it shows a sharp increase in force to 750N to provide push off. In LS there is also a small area where the GRF folds back and some outliers can be seen.

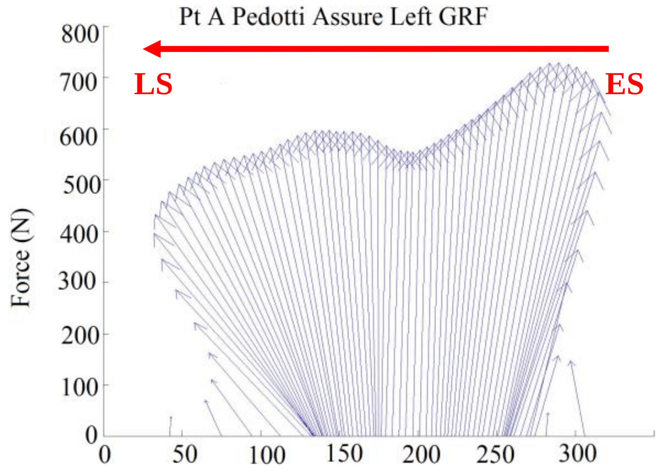
<u>Epirus</u>

The GRF in ES build in magnitude slowly to a maximum of 700N. This drops to 550N throughout MS and stays constant, dropping off to zero in LS to a very small area of GRF backward displacement figure 5.45.

The sound side had a much larger magnitude of peaks and troughs. ES was brief showing a sharp peak at 900N, which reduced to 700N throughout MS and dropped further toward LS to 500N. The GRF in LS reached a maximum of 750N but had a widespread area of GRF backward displacement figure 5.46.

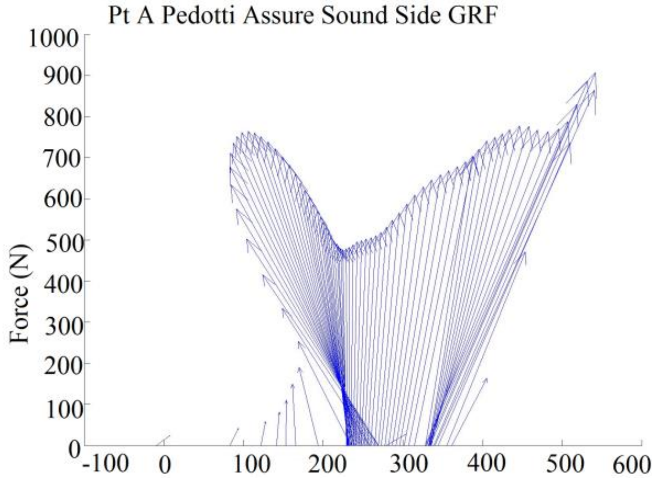
<u>Tribute</u>

The residuum vector showed a reduced force in ES which remained fairly constant until LS. The maximum ES vector reached 650N however this did not lower a great deal throughout MS until LS where the force reduced to 550N. LS had a wider spread GRF backward displacement than any of the other feet figure 5.47. Pt A's sound foot is in contact with the ground over a very short distance and barely achieved a MS when using the Tribute foot. ES is very quick with a peak of 750N, which then shows evenly spaced descending vectors through a very brief MS that rise sharply in LS giving a wide spread fold in the GRF figure 5.48.



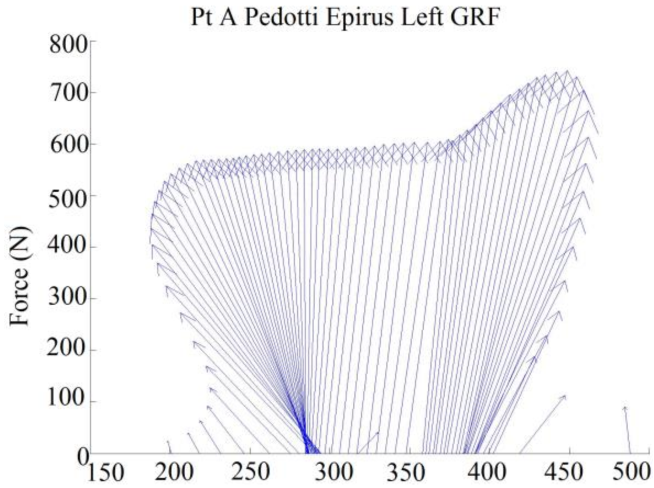
Position on force plate with respect to local x origin (mm)

Figure 5.43



Positon on force plate with respect to local x origin (mm

Figure 5.44



Position on force plate with respect to local x origin (mm)

Figure 5.45

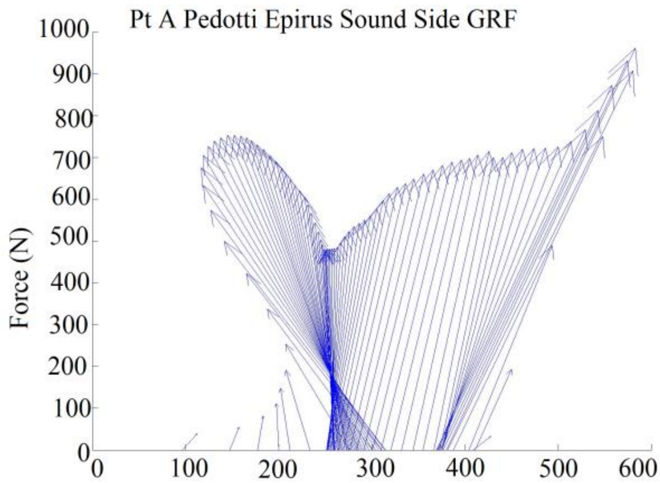


Figure 5.46

Position on force plate with respect to local x-origin (mm)

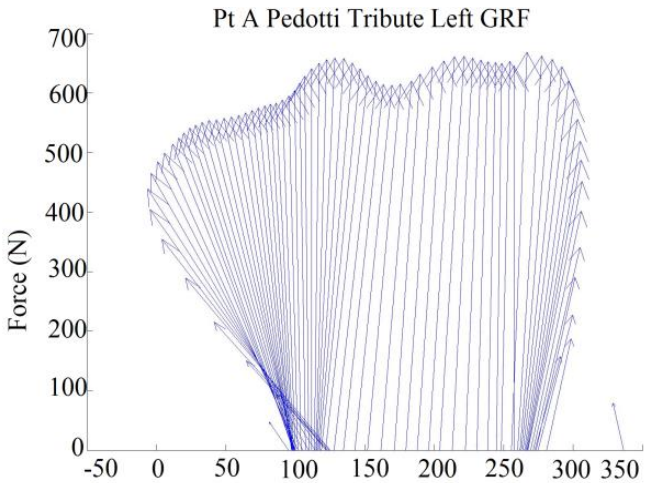


Figure 5.47

Position on force plate with respect to local x origin (mm)

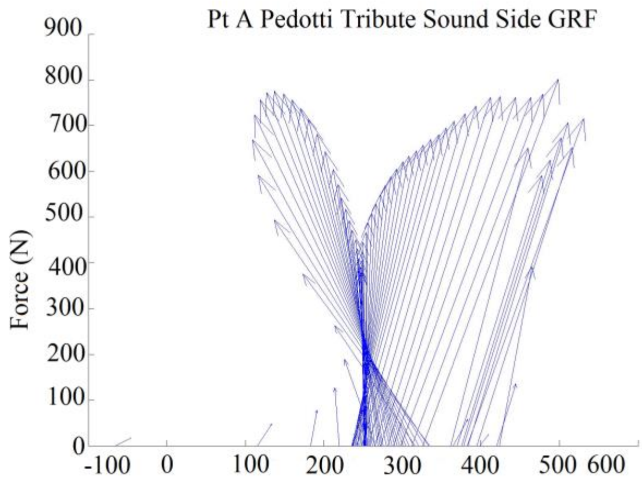


Figure 5.48

Position on force plate with respect to local x origin (mm)

Patient B

Patient B was most confident walking with the Tribute foot. All feet sound and prosthetic displayed similar shape except the Assure prosthetic side. The feet showed a high peak of between 1000-1500N in ES which reduced to 300-500N in MS climbing in LS to approx. 600N. The backward displacement effect was seen in LS stance for all sound feet but not the prosthetic and all except the Assure showed outliers in ES. The Assure prosthetic foot made contact with the ground for a shorter period of time and showed a smaller difference between MS and LS GRF figure 5.49.

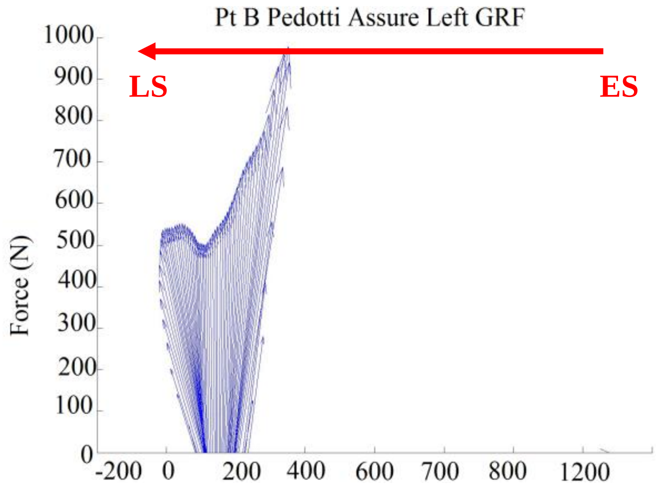


Figure 5.49

Position on force plate with respect to local x origin (mm)

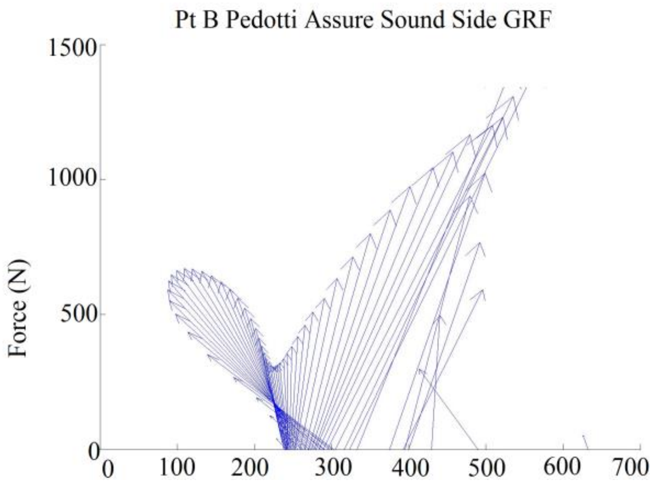


Figure 5.50

Position on force plate with respect to local x origin (mm)

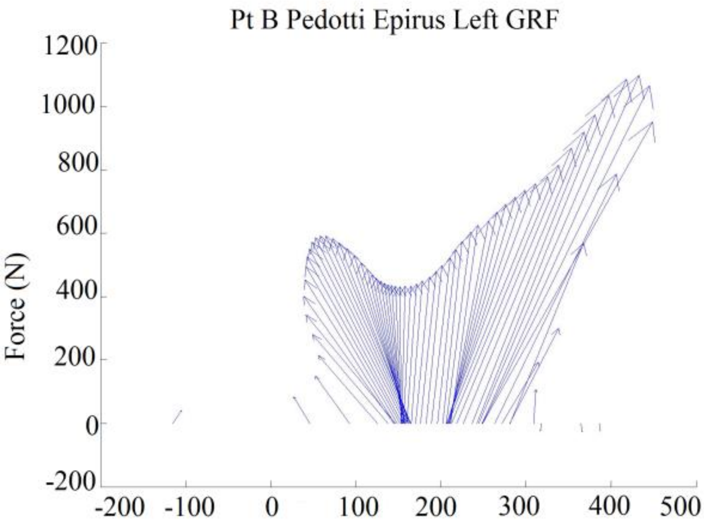


Figure 5.51

Position on force plate with respect to local x origin (mm)

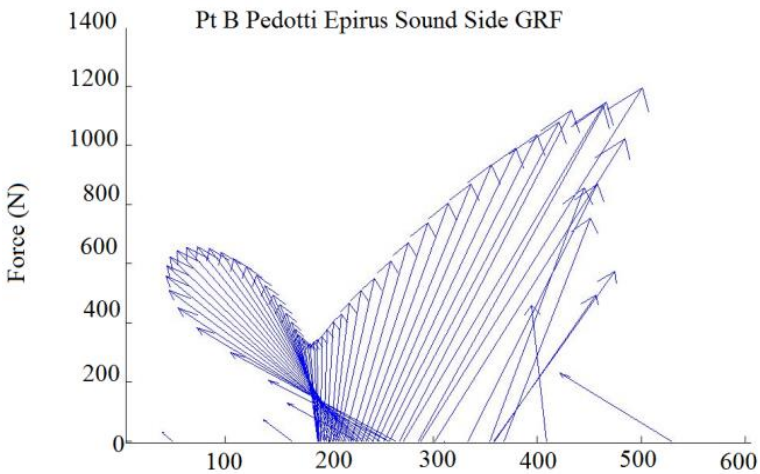


Figure 5.52

Position on force plate with respect to local x origin (mm)

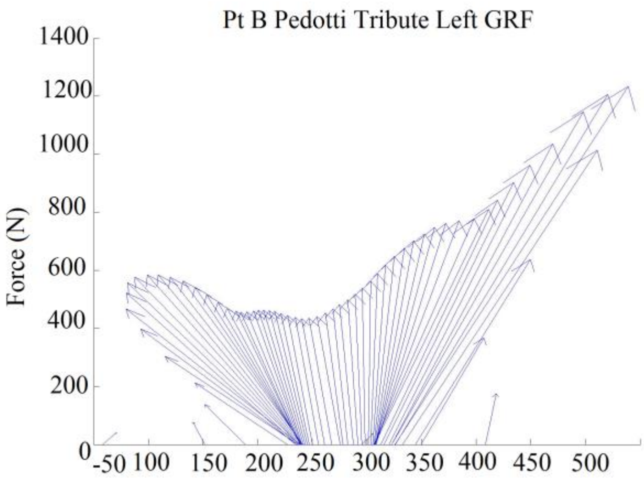


Figure 5.53

Position on force plate with respect to local x origin (mm)

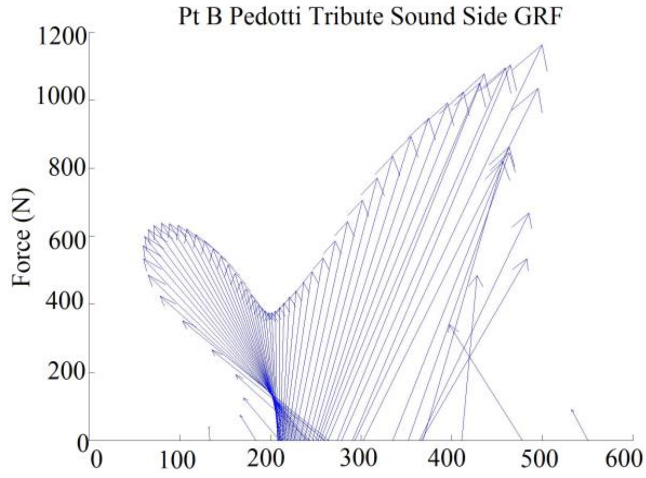


Figure 5.54

Position on force plate with respect to local x origin (mm)

Patient C

Epirus

Patient C was most confident walking with the Epirus foot. ES showed a low GRF. The subject's vectors on the amputated side climb evenly to a peak at MS of 650N which drop to 550N in LS figure 5.57. The sound side does show a higher force in ES peaking at 900N but the vectors throughout the rest of stance remained close to 600N with no GRF backward displacement in LS figure 5.58.

Assure

The residuum spends a very short amount of time in contact with the slope. There did not appear to be a significant ES or LS. The first contact with the slope resulted in wide spread backward displacement of the GRF and the peak force occurred at 600N figure 5.55. The sound side also had little contact with the slope but there was evenly spread vectors in ES reaching a maximum force of 800N. There was a short MS which dropped to 550N and climbed in LS to 700N. LS was very concentrated and had a small distance of GRF displacement figure 5.56.

Tribute

The time spent by the residuum loading the Tribute foot was much longer and gave more evenly distributed vectors than the Assure foot. The subject still did not achieve a significant force in ES and reached a maximum peak force of 700N during MS. In LS there was a small distance of GRF backward displacement and a peak force of 600N figure 5.59. The sound side did not show an evenly distributed pedotti as in the amputated side. There is a GRF fold in ES and a peak force of 900N. Throughout MS the vectors were very tightly bunched together with no obvious LS high force to be seen figure 5.60

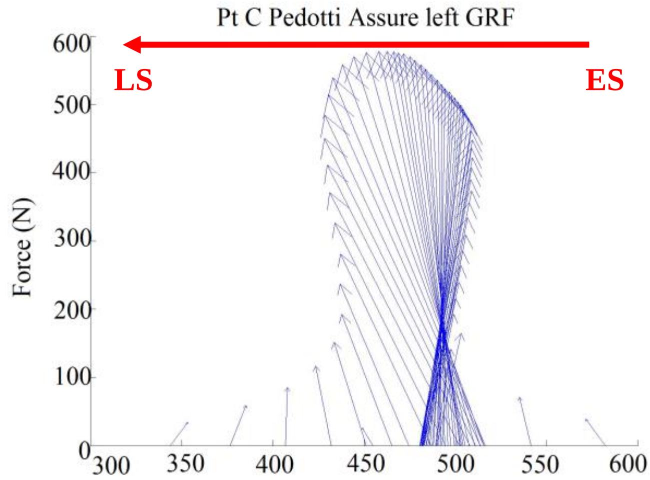


Figure 5.55

Position on force plate with respect to local x origin (mm)

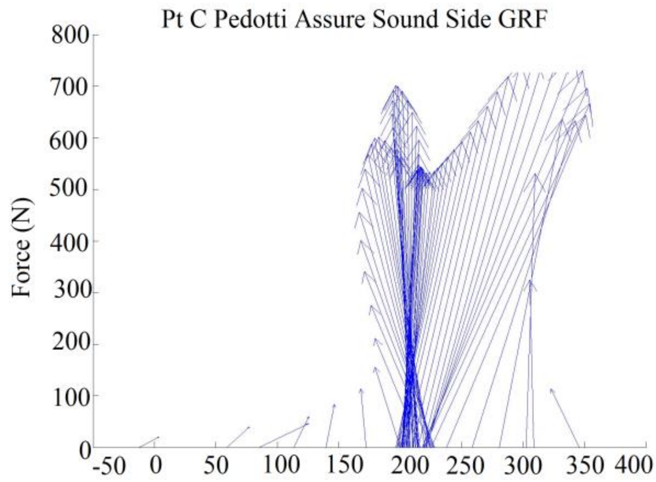


Figure 5.56

Position on force plate with respect to local x origin (mm)

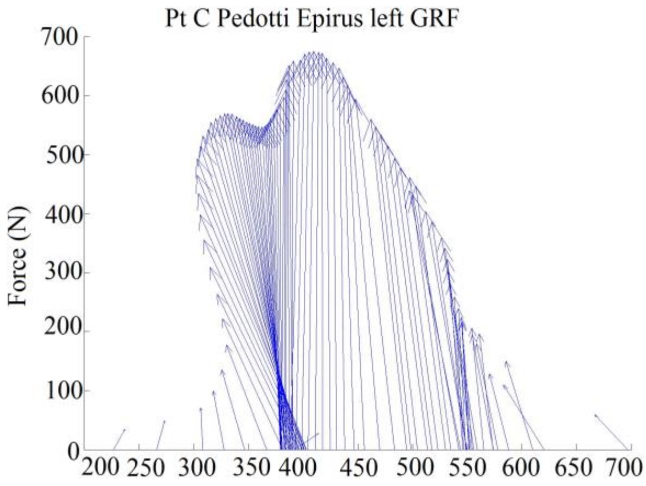


Figure 5.57

Position on force plate with respect to local x origin (mm)

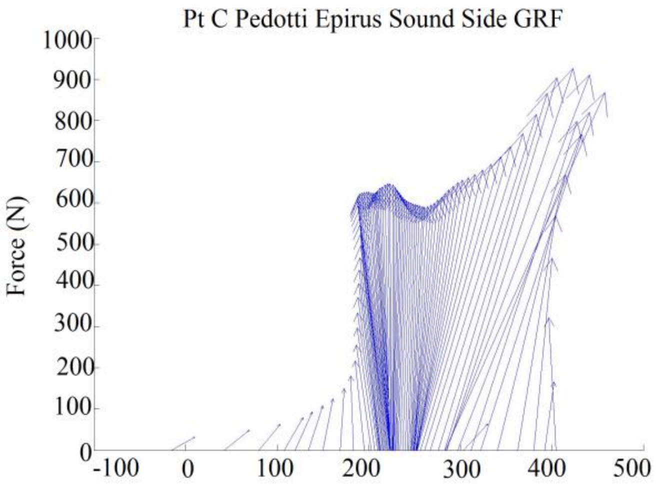


Figure 5.58

Position on force plate with respect to local x origin (mm)

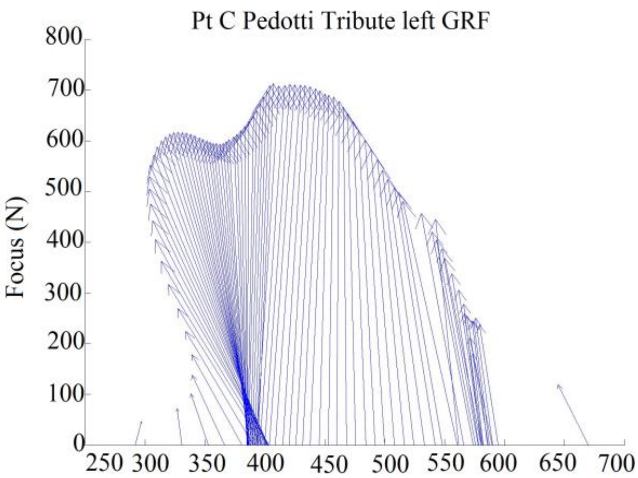


Figure 5.59

Position on force plate with respect to local x origin (mm)

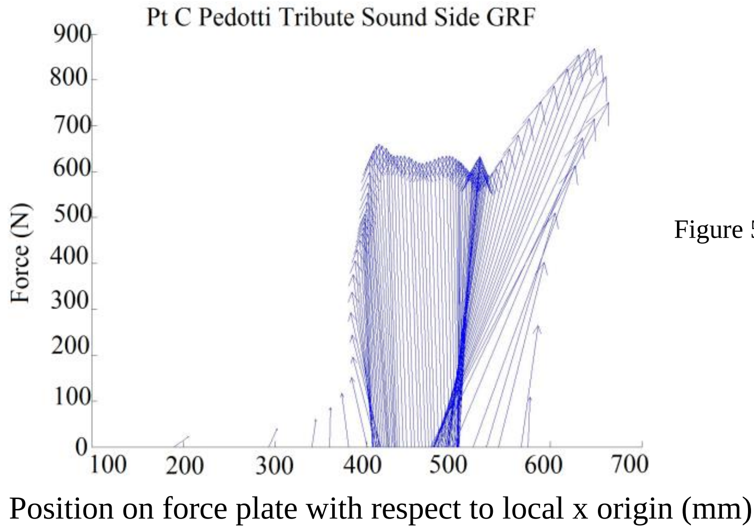


Figure 5.60

Patient D

Patinet D was most confident walking with the Tribute foot. With all the feet the sound limb showed an almost normal butterfly shape. The prosthetic limb showed a pedotti that was spread over a wider distance than the sound limb. The prosthetic limbs displayed a similar shape that peaked in ES to approximately 700N then showed another rise in MS and dropped in LS to approximately 500-550N. All graphs showed a GRF fold in LS and all had outliers in ES and LS. The tribute sound foot shape stood out as its ES and LS peaks were almost the same giving a perfect butterfly and it was spread over the shortest distance figure 5.67.

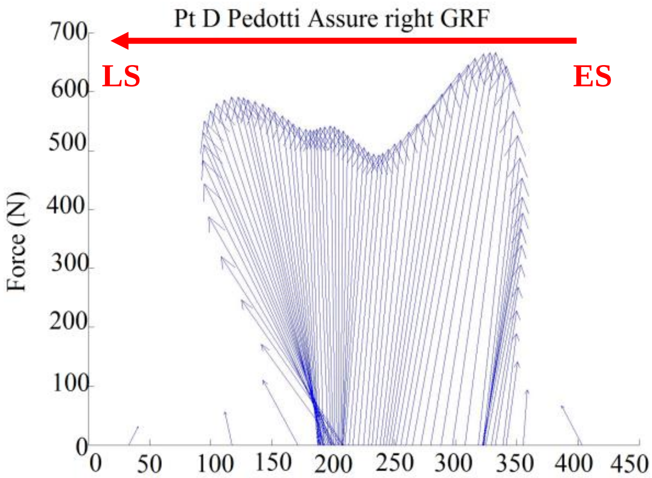


Figure 5.61

Position on force plate with respect to local X origin (mm)

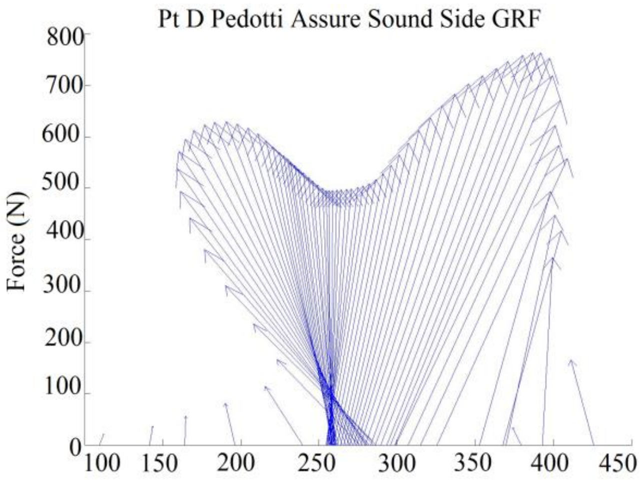


Figure 5.62

Position on force plate with respect to local X origin (mm)

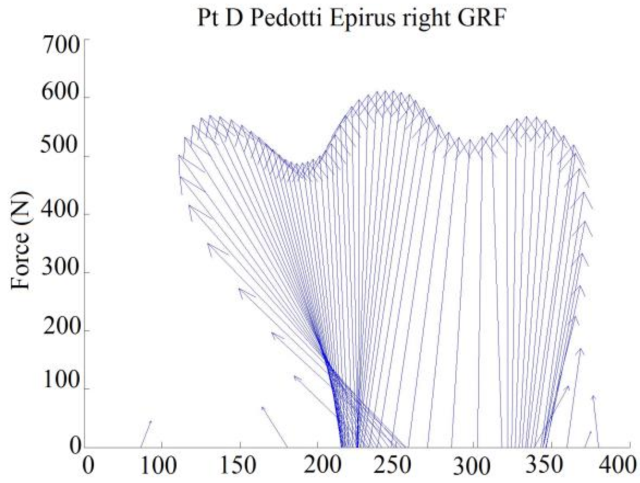


Figure 5.63

Position on force plate with respect to local x origin (mm)

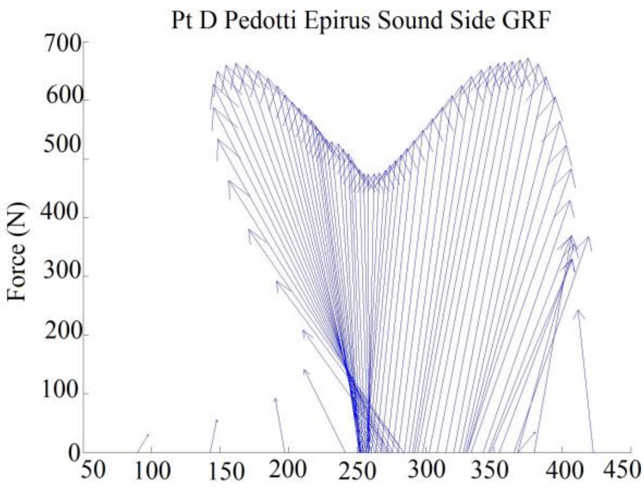


Figure 5.64

Position on force plate with respect to local X origin (mm)

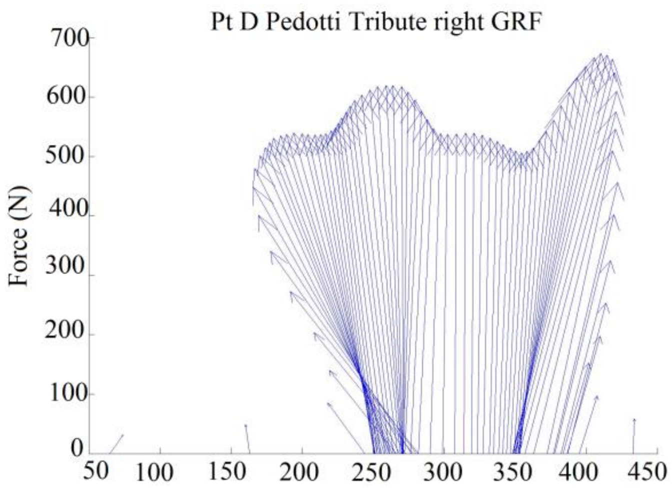


Figure 5.65

Position on force plate with respect to local X origin (mm)

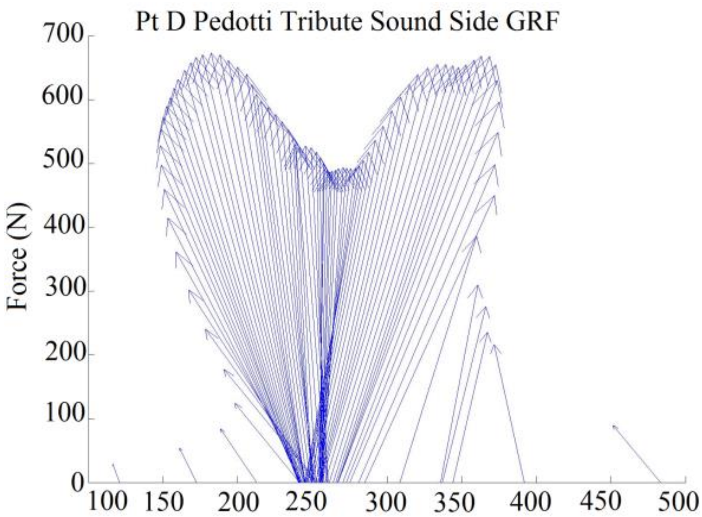


Figure 5.66

Position on force plate with respect to local X origin (mm)

<u>Patient E</u>

Patient E gave a high ABC score to all the prosthetic feet. However, they were most confident walking with the Assure foot. A high GRF of 1400-1600N was seen in ES for all feet on the sound and prosthetic side. This GRF force dropped sharply in MS to 500-600N and climbed again in LS to 600-800N. All pedotti graphs showed the patient walked a short distance but only the sound feet displayed GRF backward displacement in LS. The vectors were all relatively evenly spread but showed some outliers in ES.

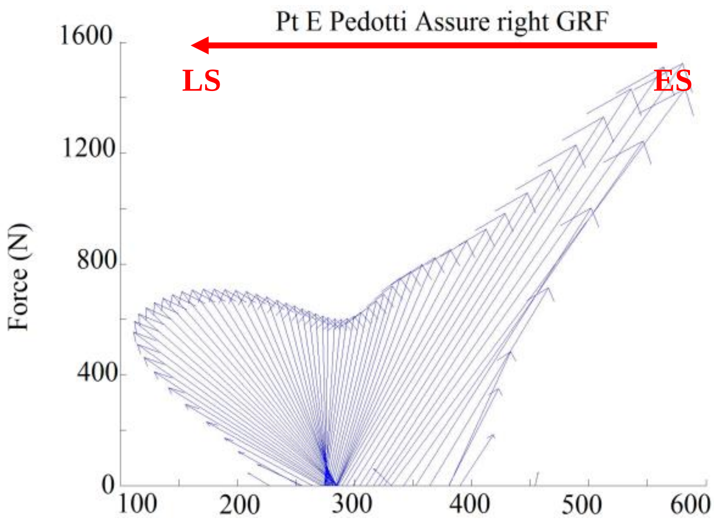


Figure 5.67

Position on force plate with respect to local x origin (mm)

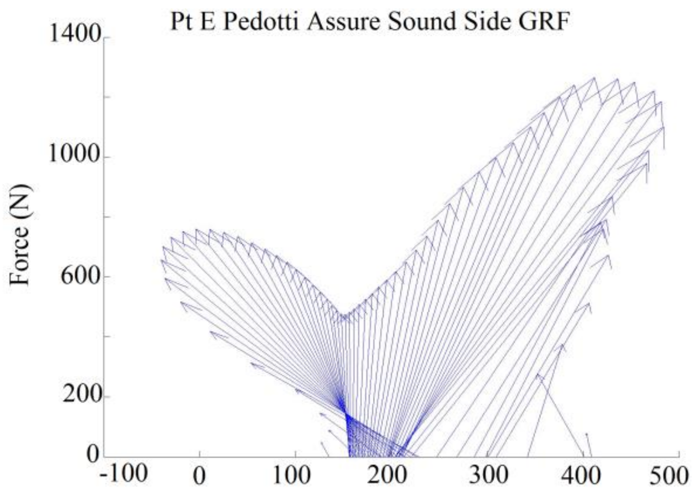


Figure 5.68

Position on force plate with respect to local x origin (mm)

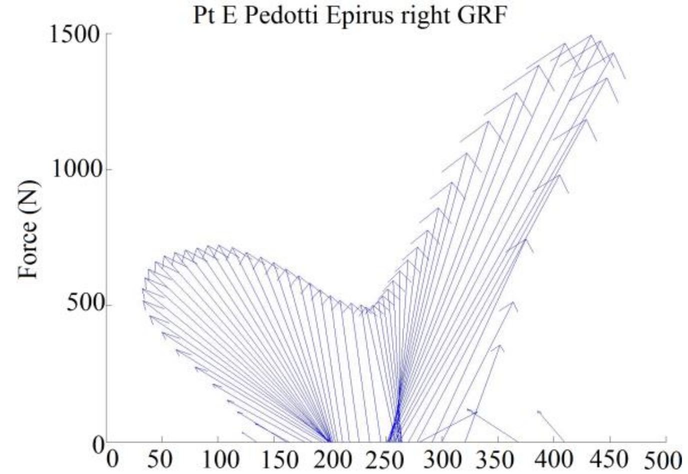


Figure 5.69

Position on force plate with respect to local x origin (mm)

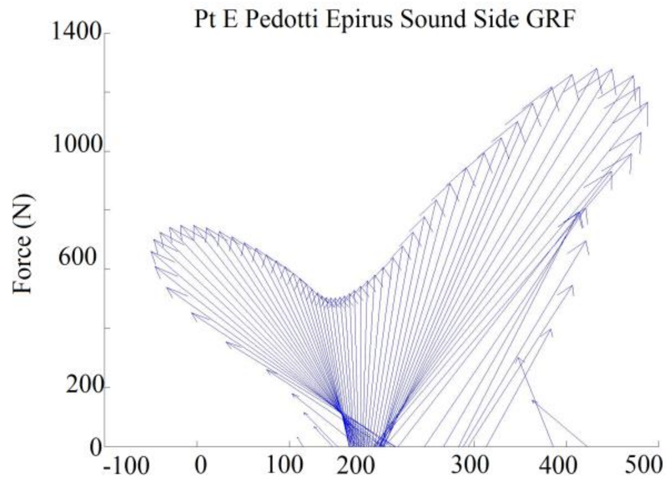


Figure 5.70

Position on force plate with respect to local x origin (mm)

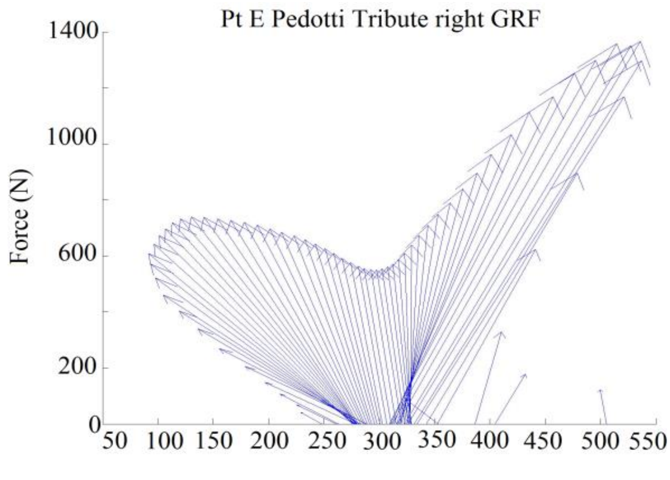


Figure 5.71

Position on force plate with respect to local x origin (mm)

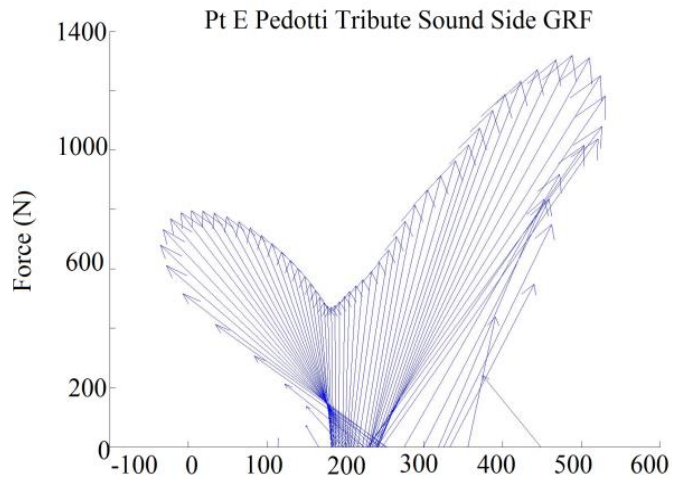


Figure 5.72

Position on force plate with respect to local x origin (mm)

Patient F

Tribute

Patient F was most confident using the Tribute foot. However, the peak GRF was high for all feet Figure 5.77 The residuum's GRF shows the butterfly shape of a normal subject with the first peak in ES reaching 1800N then dropping gradually to 1600N at MS but climbing back up to 1900N in LS. The sound limb vectors were butterfly in shape but had a steeper drop for the second peak. In ES there was some ant/post shifting over a small distance but had a large peak of 2000N. The GRF at MS reduced to 1400N which finished with the third peak for LS reaching 2000N figure 5.78.

Assure

The amputated limb gave smooth even vectors through stance producing a graph close to a normal subject in shape. During ES the vectors show the body mass accelerating up to 1800N which then decelerates down to 1600N during MS and back up again to 2000N for LS figure 5.73. The sound limb moves rapidly through stance. During ES contact there is some ant/post shift with vectors moving posterior to the limb with a peak GRF of 2000N. The GRF drops quickly during MS stopping at 1400N and sharply rising again for a large GRF of 2500N during LS figure 5.74.

Epirus

The Epirus GRF followed the same shape as a normal subject on the prosthetic side. In ES the GRF force passed behind the limb for a longer period reaching a peak of 1800N. This reduced to 1500N at MS and climbed back up to 1900N during LS figure 5.75. The sound limb GRF was much less constant with ant/post shift in ES and a peak of 1900N falling sharply at MS to 1200N then rising quickly again to 2000N figure 5.76.

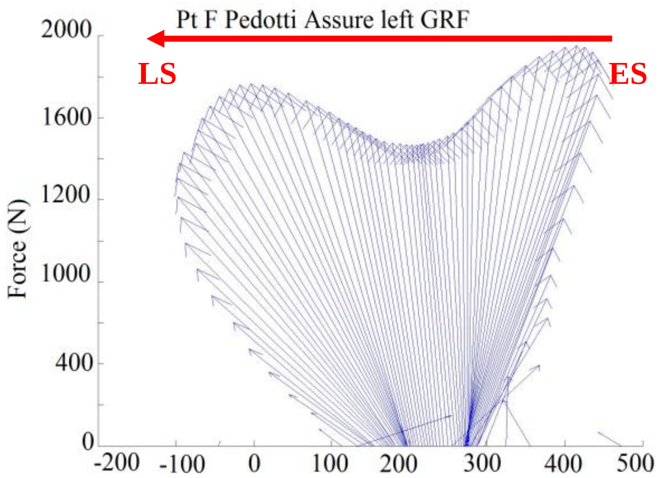


Figure 5.73

Position on force plate with respect to local x origin (mm)

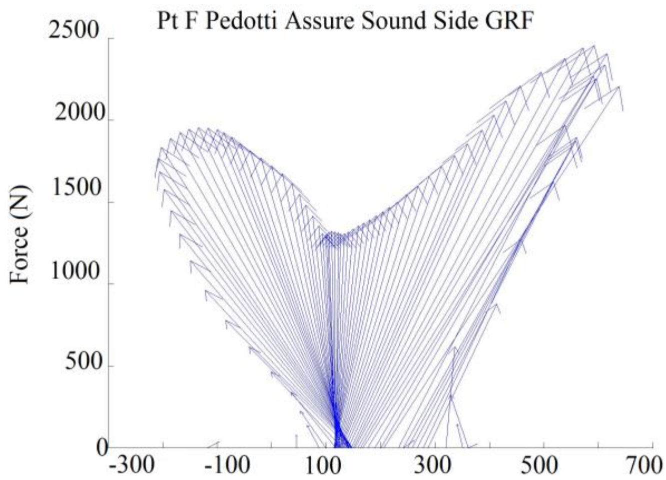


Figure 5.74

Position on force plate with respect to local x origin (mm)

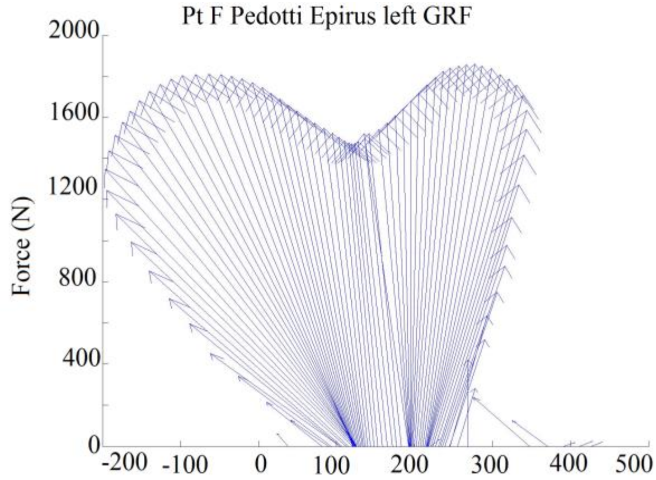


Figure 5.75

Position on force plate with respect to local x origin (mm)

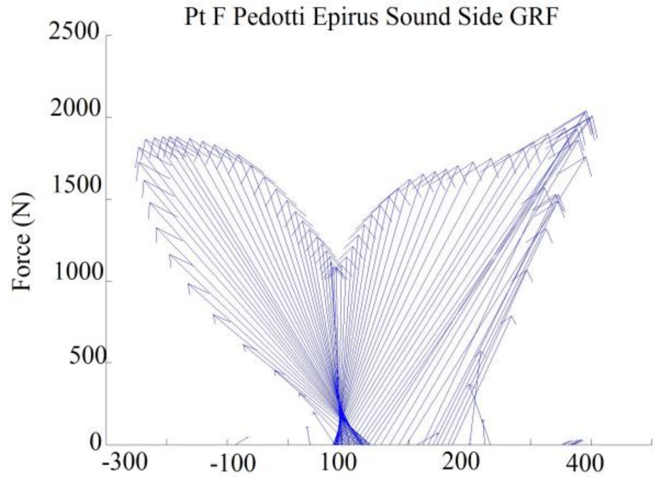


Figure 5.76

Position on force plate with respect to local x origin (mm)

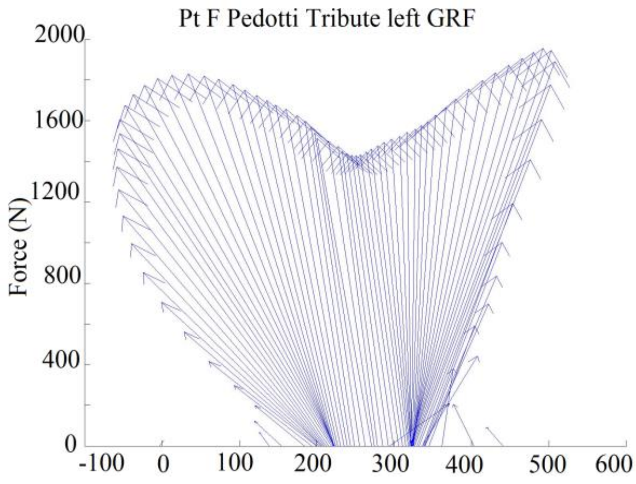


Figure 5.77

Position on force plate with respect to local x origin (mm)

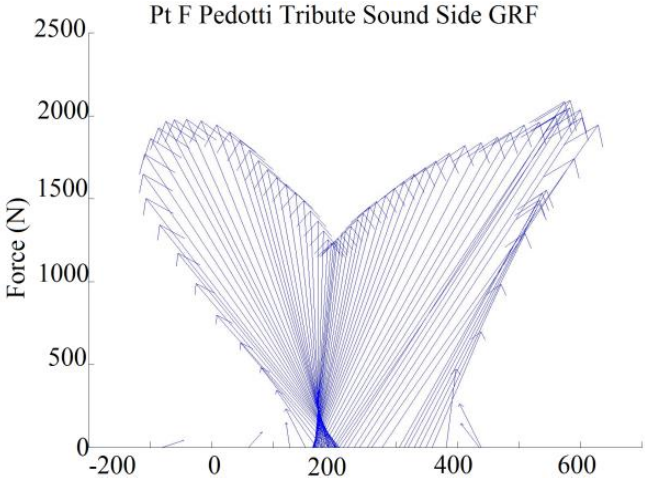


Figure 5.78

Position on force plate with respect to local x origin (mm)

5.6 QUESTIONNAIRE RESULTS

Subjects	Epirus Foot % confidence	Assure Foot % confidence	Tribute foot % confidence
A	85	95	90
B	60	50	70
C	65	45	55
D	50	75	100
E	87	100	80
F	98	90	100
Mean	**74.2**	**75.8**	**82.5**

Table 5.16 Results of ABC questionnaire

Table 5.16 represents the results of the ABC confidence walking down a slope questionnaire. As illustrated three subjects felt extremely confident walking down the incline with the Assure and Tribute foot and one with the Epirus. Their confidence level was 90% and above with three subjects actually feeling completely confident. Three subjects were fairly confident showing scores 80% and above; one with Tribute and two with Epirus. All of the feet had a subject feel 50-55% confident with only Assure having a score lower at 45%. However, subject C's scores were all relatively low which could relate to the amount of time the subject has been an amputee compared to the others or their general health.

When deciding which foot, the subjects felt most secure walking with, Tribute was chosen first three times, the Assure foot was chosen first twice and the Epirus foot once. When choosing which foot, they felt least confident with the Assure was chosen three times, the Epirus twice and the Tribute once. The Tribute had the highest mean confidence figure 5.80.

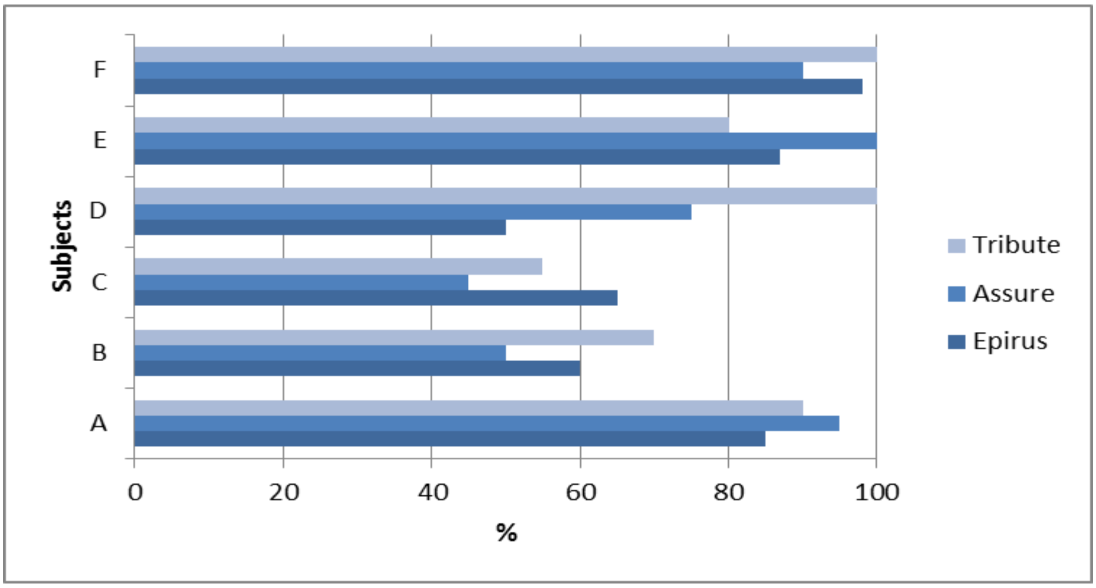
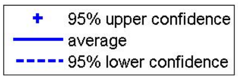


Figure 5.79 Graphed results of ABC questionnaire

Graphs of control subject and patient F have been included to use as a reference when reading the discussion.

Control key 

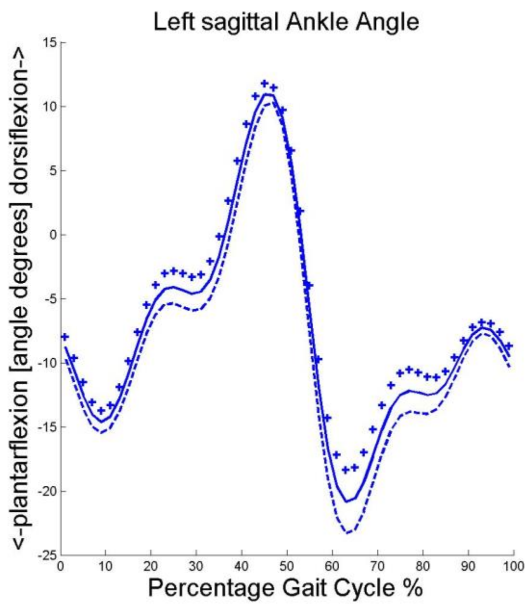


Figure 6.0 Control subject ankle angle

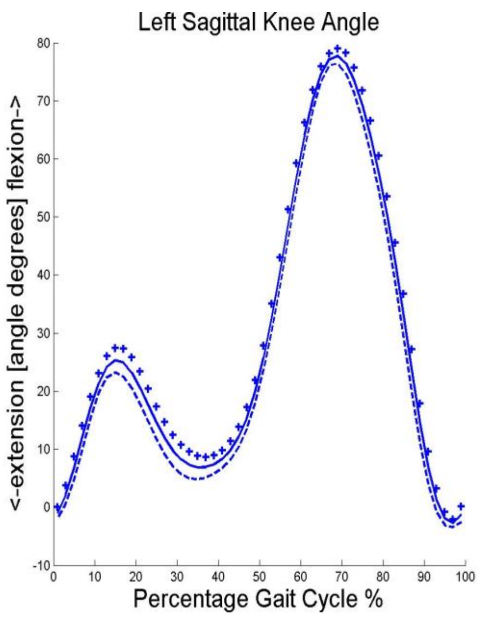
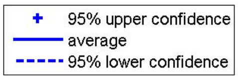
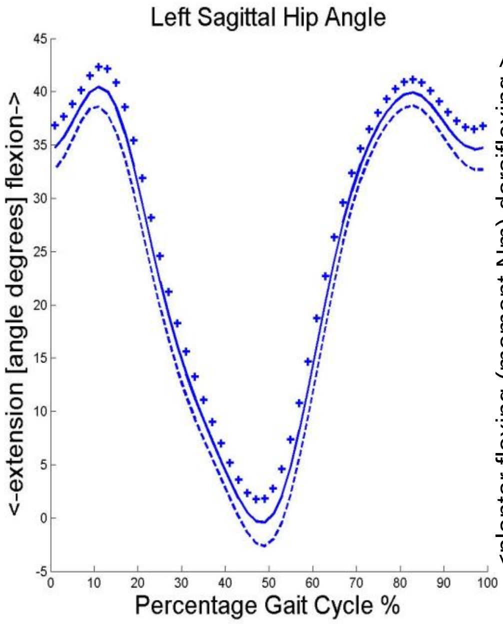


Figure 6.1 Control Subject Knee angle





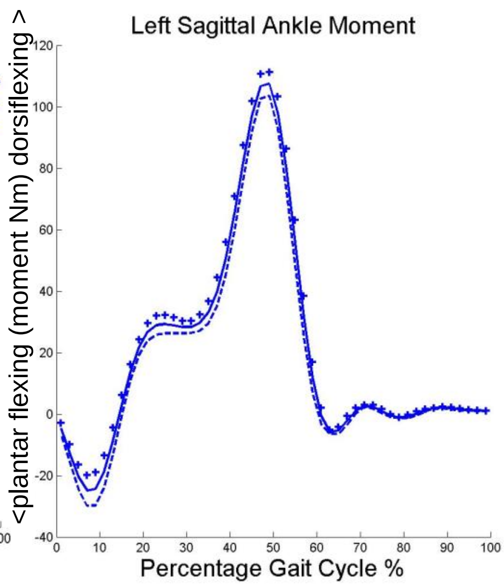
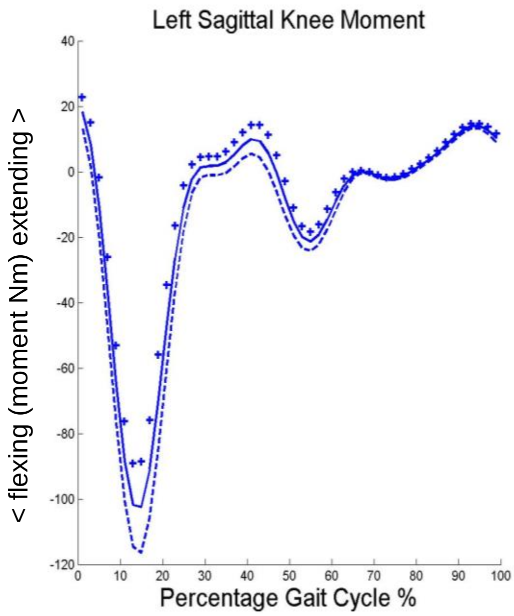


Figure 6.2 Control subject Hip Angle Figure 6.3 Control Subject ankle moment



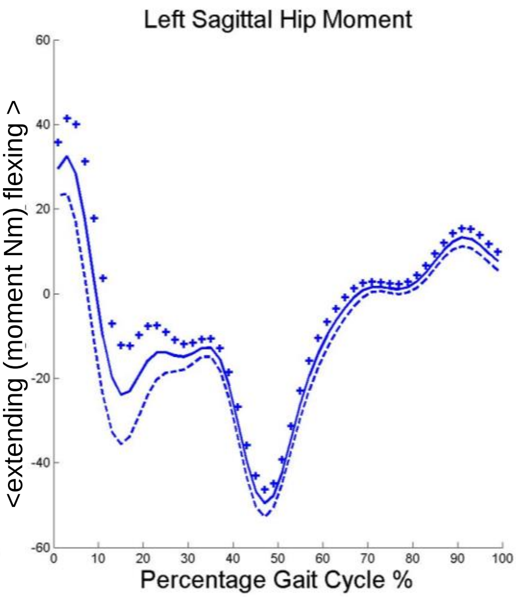


Figure 6.4 Control subject Knee moment Figure 6.5 Control Subject Hip Moment

The goal of this study was to biomechanically examine three prosthetic feet in the sagittal plane (Ossur Assure, Blatchford Epirus and College Park Tribute) walking down an incline. The prosthetic feet were compared and contrasted with each other and a control subject. Sound limb angle and moment data was however noted (appendix 8) to be inconclusive but was out with the scope of this study, as the focus was on the prosthetic limb. For ease of reference, an example of the kinematic and kinetic data for Pt F and control subject have been included again at the beginning of this chapter.

In addition to the objective data a short questionnaire was completed by the amputee subjects asking how confident they felt walking with each prosthetic foot.

There were differences between the prosthetic feet and the control subject in relation to ankle, hip and knee angles and moments however, the differences were not found to be statistically significant (appendix 11). The hip and knee on the prosthetic side remained mostly flexed throughout stance apart from a brief angle of extension for the knee at IC for some subjects. This was unlike the control subject who flexed at the knee at IC, and like two participants extended at the hip by a small amount at 50% of the gait cycle. The ankle angles were similar to the control subject. However, the able bodied subject had a larger angle of dorsiflexion at 50% of the gait cycle than most of the prosthetic feet.

The moment at the knee on the prosthetic side began extending at IC but was flexing throughout the rest of stance. The moment at the hip was the opposite of the knee by flexing at IC and extending throughout the remainder of stance. At IC the ankle recorded a zero moment which changed to a plantar flexing moment then quickly reverted to a dorsiflexing moment throughout stance with some variations at 50%; this coincided with the control subject. All subjects gait slowed down while walking down the incline relative to their normal walking speed.

It was hypothesised that there would be very little difference between prosthetic feet and a large difference between amputees and normal subject, which was proved correct.

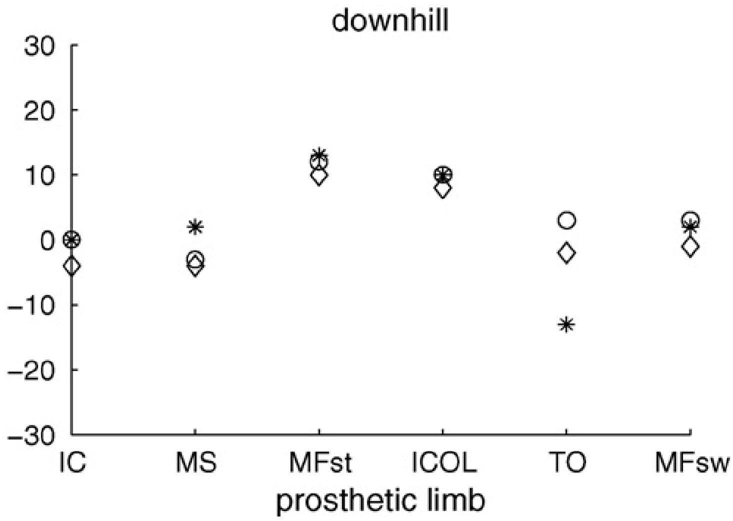


Figure 6.6 Vrieling et al (2008) mean ankle angles relative to the vertical of the prosthetic limb and non-affected limb in TF (○), TT (◊) and able bodied (*) Positive dorsiflexion, negative plantar flexion.

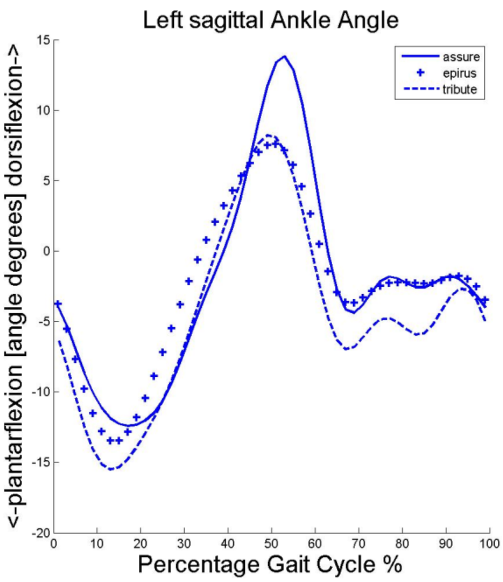


Figure 6.7 Pt F ankle angle

6.1 JOINT KINEMATICS

The ankle joint angle followed a mainly plantar flexed pattern. From IC to 15% the amputee's ankle joint was plantar flexed, which agrees with the findings of Vrieling et al (2008) figure 6.6. This also agreed with Fradet et al (2010) findings when the ankle was in neutral and adapt mode, but differed from their control who dorsi flexed at this phase of gait figure 2.29. It is likely that at IC the amputees may feel at their most vulnerable so forced a plantar flexed position using their body weight to provide stability. However, it could also be due to the foot not having sufficient range of dorsiflexion and simply conforming to the sloped surface. Subject D was able to achieve dorsiflexion throughout stance however; this subject only gave the Epirus foot a confidence of 50% choosing it last out of all the feet.

At 50% of the gait cycle the majority of all subjects were able to match the dorsiflexion pattern of the normal subject. However, on subject's C and F a dorsiflexion angle of 15 degrees was seen which was more than the controls 12 degrees. All subjects wearing the Assure foot reached dorsiflexion at 50% and the results were divided when wearing the Epirus and Tribute. The Assure's longer carbon spring may provide the stability needed for subjects to allow further anterior tilt of the shin, or they may simply not be able to overcome the angle of the slope at this point in gait due to the stiffness of the foot and have to dorsiflex. At TO all amputees moved back into plantar flexion which agrees with the control subject in Vrieling et al's (2008) work (figure 6.6) but disagrees with Vickers et al (2008) figure 2.20. Normal subject's plantar flexion in late stance accounts for the gastrocnemius and tibialis posterior muscles pushing off to prepare for swing phase. As the amputee cannot achieve active push off this may again be a result of a sense of instability or conforming to the slope angle.

Vickers et al (2008) ankle joint kinematics (figure 2.20) differed from this study and Vrieling et al's (2007) research figure 6.6. Vickers et al (2008) found the ankle joint remained dorsiflexed throughout stance. This study disagreed with Vickers et al (2008). A majority plantar flexion angle was found in this study all through stance except at 50 % of gait which was also the case for Vrieling et al (2008) but them

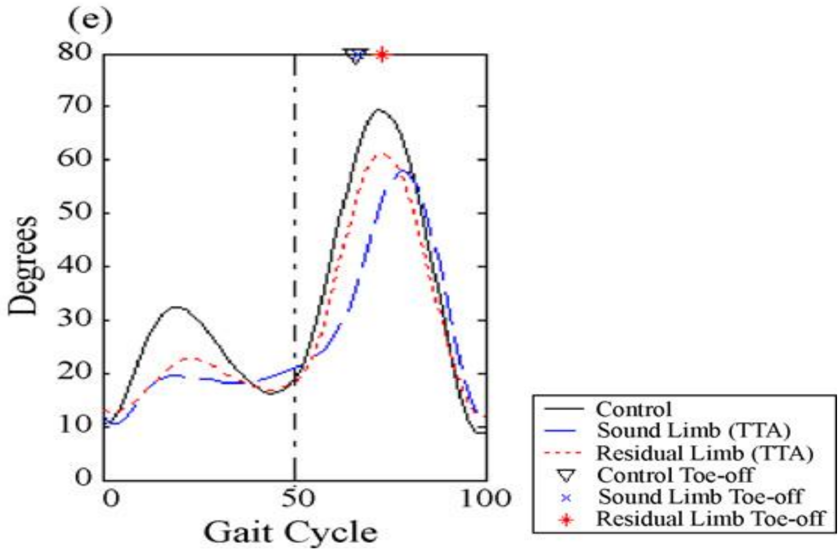
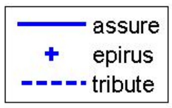
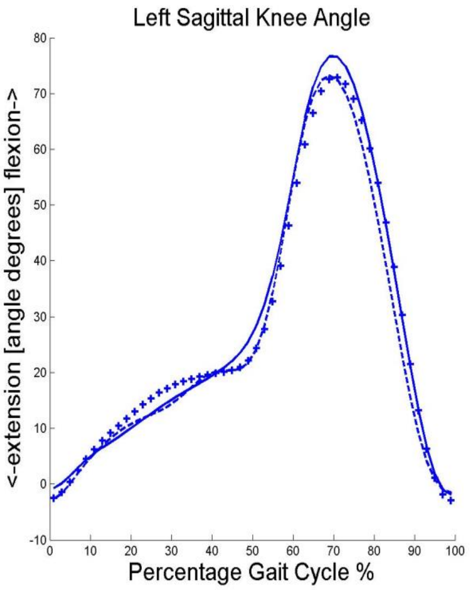


Figure 6.8 Vickers et al (2008) Knee Angle. Positive flexion, negative extension





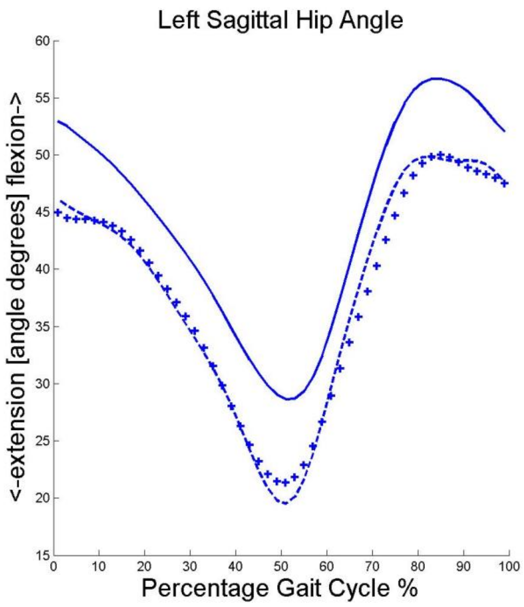


Figure 6.9 Pt F Knee Angle

Figure 6.10 Pt F Hip Angle

angle of plantar flexion was lower than this research. These differences in ankle angle could be due to the differing prosthetic feet.

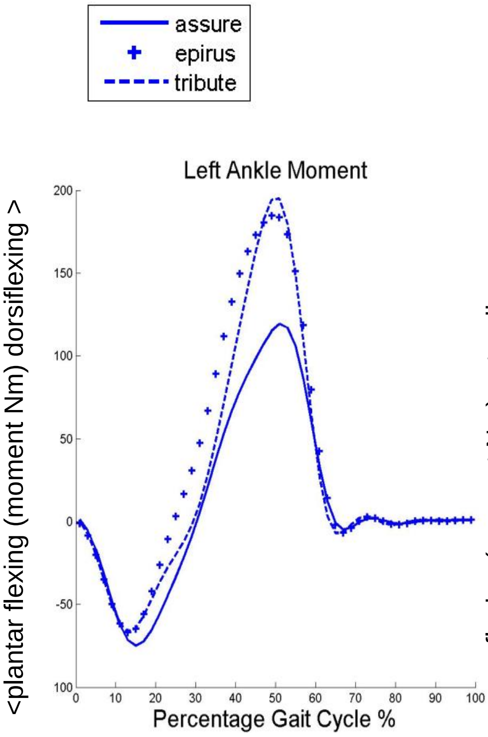
The hip and knee joint angle on the prosthetic side followed a mainly flexed pattern. At IC the knee joint was extended for many subjects as with Vrieling at al (2008) subjects and is likely a reaction to the plantar flexion at the ankle and work of the quadriceps controlling the rate of flexion figure 2.19. The knee then remains flexed throughout stance phase which may be because the subjects need to compensate for the lack of dorsiflexion of the foot which in turn then allows them to progress through stance. The angles of knee flexion for each foot are varied but are generally lower than the normal subject. This is in agreement with Vickers et al (2008) and Vrieling et al (2008) figure 6.8 and 2.19.

The hip joint remained flexed throughout stance, which was in agreement with the findings of Vickers et al (2008) but was unlike the control subject who extended from 50% to TO to facilitate the heel strike of the contralateral limb figure 2.22. The flexion at the hip further compensated for the plantar flexed angle of the foot and flexion at the knee. Therefore, the amputee’s sound limb heel strike may be a result of a shorter step length and slower walking speed. Pt E was able to extend his hip through late stance with every foot figure 5.19. However, this is likely due to walking technique rather than the prosthetic foot’s influence.

6.2 JOINT KINETICS

The pattern of the moments of this study agree with the joint kinetic results of Vickers et al (2008) but the magnitudes are difficult to compare due to the differing feet.

The GRF on the prosthetic limb remained ahead of the ankle throughout stance creating a dorsiflexing moment quickly after 10% of the gait cycle following a brief period plantar flexing figure 6.11. Unlike the amputees the control subject moves into a plantar flexing moment at TO to aid in push off prior to swing phase figure 6.3. However, as the amputees have no active plantar flexors the dorsiflexing moment dominates. Due to a lack of proprioception the dorsiflexing moment experienced by the amputees may make them feel unstable which could explain the plantar flexed



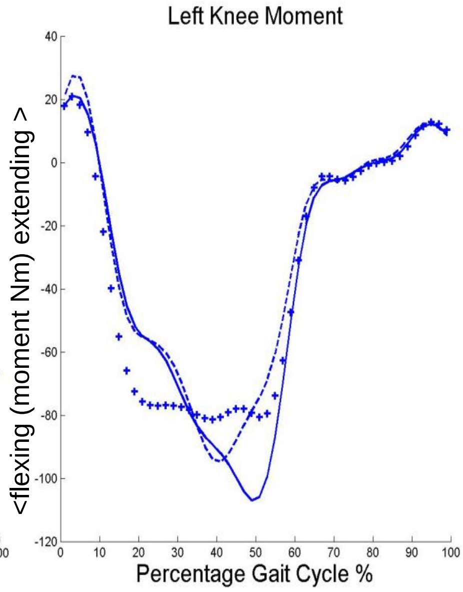


Figure 6.11 Pt F Ankle Moment   Figure 6.12 Pt F Knee Moment

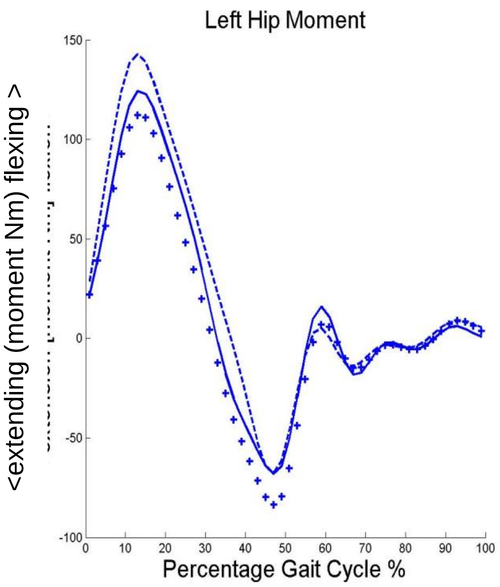


Figure 6.13 Pt F Hip moment

angle seen in MS. At 50% of gait the subjects allow the ankle to dorsiflex with the moment as they need the anterior tilt of the shin to allow them to progress over the foot or this would result in difficulty balancing and increased effort Figures 5.24-5.29.

The GRF at IC of the prosthetic limb passes ahead of the knee and hip creating an extension moment at the knee and flexion moment at the hip much like the control subject whose knee flexes at IC figures 5.30-5.41. The work of the quadriceps controls the rate of flexion at heel strike which is encouraged by the plantar flexion angle and moment at the ankle. It is theorized that this extension moment at IC provides the amputee with a brief spell of stability in order to steady them on the slope before the flexion moment dominates. The hip joint allows itself to flex which helps lower the body centre of gravity making the subject feel safer. From MS to TO the GRF passes behind the knee and hip producing a flexion moment at the knee and extension moment at the hip. The knee still needs to compensate for the lack of dorsiflexion at the foot by flexing however, the hip flexors are required to overcome the extension moment created in order to also compensate for the limited ROM at the ankle.

None of the feet outperformed the others in kinetics or kinematics. There were some differences but this could be attributed to individual’s own abilities and gait habits.

As well as the subject’s gait influencing the results there is also the question of accuracy in marker positioning. Exact positioning of joint centres is very difficult and is a common problem within research. Locating the joint centre through palpation is often the preferred method yet it can be subjective resulting in misleading data. Stagni et al (2000) found that incorrect location of the hip joint centre propagated error into the angles and moments at both hip and knee joints. The hip and knee joint centre on the prosthetic side can be fairly accurately located as they are still present however the prosthetic ankle joint is more difficult. Many studies involving the prosthetic ankle joint do not include a description of how the joint centre was located because like this study a best estimate from the intact side must have been used. Rusaw and Ramstrand (2010) investigated this method and found that the motion of the prosthetic foot does not reflect the motion of the sound foot leading to systematic errors in the results. In reality the ankle joint of the Assure foot, for example, sits in the space between the toe spring and shank which could not be marked through gait. Therefore, the closest solid position was chosen. As with the tribute foot, the ankle joint centre will sit below the foot shell where the camera would not be able to see a marker. Again the closest position was chosen. When interpreting the results this limitation should be taken into consideration.

It is also theorised that the marker positioning and subsequent results are heavily dependent on the calibration and alignment of the limb. Data capture for each subject required a static calibration and each subject's limb was aligned to their own posture and manufacturer's guidelines. It can be seen from the kinematic results in this study that the subjects do not stand in any standard neutral position appendix 5. However, this result is subjective to the prosthetist aligning the limb and could vary if aligned by another prosthetist. Indeed, Zahedi et al (1982) found that an amputee can tolerate several alignments ranging in some parameters by as much as 148mm in shifts and 17 degrees in tilts. This point has not been noted in other studies reviewed which is surprising as limb alignment is fundamental to prosthetic use and will have a significant effect on any objective or subjective findings.

6.3 SUBJECTIVE

The Assure and Epirus feet Figure's 3.1-3.3 have similar key features including a carbon fibre heel and full length toe spring. The Epirus also includes a split toe. The heel spring works alongside other aspects of the foot in providing ankle plantar flexion by heel spring deflection. The full length toe lever is designed to aid push off in late stance. The split toe acts to provide ground compliance at mid stance.

The Tribute foot differs from the former feet as it contains polyurethane rear foot and forefoot bumpers that allow adjustable plantar flexion control at heel strike and varied mid/late stance control. It also includes a full length carbon fibre toe lever.

It was hypothesized that due to these differences between the Epirus/Assure and Tribute feet the subjects would feel equally confident walking with the former feet and show differing results with the latter foot. The findings of the study showed this was not the case, as there was a varied spread of confidence levels between the Epirus and Assure; the lowest difference being 8% and the highest being 25%. The feet that actually showed the closest confidence ratings were the Epirus and Tribute with the range difference only being between 2% and 10% however, one subject reported a 50% difference table 5.16.

These results demonstrate that there must be other factors additional to foot design that contribute to how confident an amputee will be when walking down an incline. These factors may include, how long they have been an amputee, what the cause of the amputation was, for example does it influence their general fitness such as vascular disease, age, and are the foot category recommendations suitable to allow the foot to perform optimally? This study has too few subjects to produce a definitive answer to these questions. Yet it can be seen Subject C reported the lowest confidence ratings and he is the oldest with a cause of amputation being vascular disease whereas, subject's E and F were the youngest with trauma as their cause of amputation and they both produced the highest confidence results.

The ABC Scale questionnaire (appendix 4) showed there was no one foot that all subjects felt particularly confident with walking down an incline.

The subjective and objective results together show that between all three moderate activity feet there was no clear winner in performance biomechanically or perceived safety and confidence. The subjects' angles and moments results did not indicate which foot a subject may have preferred. However, the GRF and power results showed some correlation which will be discussed further on. The fact remains no matter how many objective tests are done within the gait lab the most valuable results to a clinician are the opinion of the patient as they will not wear a prosthetic device they feel uncomfortable using.

6.4 GROUND REACTION FORCE

The joint angle and moment data did not conclusively show one foot performing better than the others and the ABC questionnaire also did not significantly discover one foot that subjects felt better using than the others. However, the questionnaire did determine which foot each individual patient felt most confident using which it was discovered could be deduced from the GRF results.

The Pedotti graphs drawn for the GRF have a limitation as the data shown only considers a single walk over the force plate and the data can be difficult to interpret. Therefore, these preliminary results must be considered with caution. It should be noted that a correlation between objective and subjective data is present making the findings interesting. A comparison between the sound limb and prosthetic limb helped show differences in the feet and indicate which the patient may prefer.

Indications from the GRF graphs that a foot may be performing well for a subject were:

- Area of GRF backward displacement, as if this is brief this could show the subjects felt stable at this point in gait and did not dwell in order to compensate.
- Shape of the graph i.e. if the graphs followed the same shape as a normal GRF, a butterfly shape with peaks in ES and LS, being similar in size but both larger than the trough during MS.
- Amount of force required by the sound limb in LS. If it was large this may indicate the subject needed to work harder to compensate for the lack of push off of the prosthetic foot. Or it could also show the subject is happy to land on the prosthetic side with a greater impact; indicating confidence in its stability.
- Time the subjects moved into LS. If the LS force climbed very sharply this could indicate lack of control in late stance for the amputee as they may have fallen forwards quickly onto the toe.
- The distribution of the vectors: a graph with evenly spaced vectors and peaks at the correct point in gait would indicate a steady smooth gait. Tightly packed vectors could also show the patient dwelled on the foot for longer. If

a subject dwelled for a long period it could indicate a reluctance to load the opposite foot or difficult moving through stance.

This study's subjects displayed a lower GRF and flattened graphs for some subjects much like Vickers et al (2008) figure 2.21. However, none of the subjects had the same butterfly shape as the control (figure 5.42) and Vicker et al (2008), yet subject's E and F were close figures 5.67-5.78. These differences in results between the studies could be attributed to differing feet, age and fitness of subjects.

The feet the subjects preferred all showed the above characteristics in their GRF, patients A (figure 5.43-5.48), C (figure 5.55-5.60) and F's (figure 5.73-5.78) results will be further discussed as examples in detail as was they are examples of average, poor and good walkers.

6.4.1 Subject A

Patient A gave the Assure foot their highest confidence score of 95% table 5.16. Subject A had a very fast stable gait and showed no hesitation while walking down the slope figures 5.43-5.44. The Assure foot pedotti for this patient was very smooth with even distribution between vectors and no points of dwelling throughout the gait cycle. There was one high point in ES but none in LS that would have almost produced a non-amputee's gait pattern. Indeed, the longer carbon fibre spring contained within the Assure foot, may have been expected to produce a higher push off force in LS compared to the other two feet but this was not the case. The subject remained on the foot for a relatively long period of time showing they were confident enough to bear weight and not keen to transfer load to the sound side. Conversely, less time was spent on the sound foot compared to the prosthetic side while using the Assure foot. This indicated subject A had a relatively fast gait and that they were happy to load the prosthetic side with no delay. There were sharp peaks in ES and LS again suggesting a fast pace. The GRF displacement on the sound side using the Assure foot was spread over the smallest area compared to the other prosthetic feet. This suggested the subject did not dwell on the foot for long.

Subject A gave the Tribute foot their second highest confidence rating of 90%. When compared to the Assure graph the Tribute foot gave almost the same peak GRF in ES of 690N figures 5.47-5.48. However, unlike the Assure the Tribute foot

GRF remained high throughout stance. This indicated there may not have been a definitive ES contact and the subject may have made initial contact with foot flat which remained throughout the rest of stance. Again there is no obvious LS toe off which may be expected when walking down a slope. At the end of stance, the tribute foot did show a small area of GRF displacement which the Assure foot did not. This displacement may show the subject's reluctance to load the toe for a very short period of time, but could also be attributed to a more plantar flexed alignment.

While wearing the Tribute foot subject A spent less time on the sound foot compared to using the Assure foot. The pedotti shows a definite ES and LS but very little MS and a wider area of GRF displacement. The subject's fast pace is likely the cause of the short time spent on the foot. However, it is felt the wider area of GRF displacement may be due to the subject's reluctance to load the prosthetic foot making them less confident than when they use the Assure foot.

Finally, subject A gave the Epirus foot their lowest confidence rating of 85%. The pedotti was similar to the Assure foot however it showed no further peaks after ES and included a very brief period of GRF displacement which is likely due to the alignment figures 5.45-5.46. With such close likeness in prosthetic side graphs it may have been expected that the Epirus foot would have been given the second highest confidence rating rather than the Tribute. However, the sound foot GRF provided some indications that the subject may have been unsure of this foot. The vectors had a wider spread in ES than the Assure suggesting the subject was not as keen to load the prosthetic foot, taking their time. The GRF displacement was larger, showing some hesitation before ES contact of the contralateral foot.

Subject A's GRF pedotti on the amputated side was unlike the control subject. Due to the slower walking speed and lack of push off force the only similarity seen was the peak in ES for all prosthetic feet. The sound limb GRF followed a similar pattern to the control subject; more so when using the Assure foot. The time spent in ES was brief and due to the slower walking speed the force at MS did not reduce as sharply. However, a significant LS force was present, along with a wider spread of posterior displacement.

In conclusion, the features of the Assure pedotti graphs that indicated the subject felt most confident with the Assure foot compared to the others were: the increased time spent on the prosthetic foot and the wide even spread of the vectors; the short time spent on the sound side with the area of GRF displacement in LS and the similarities between the control subject and the sound limb. As subject A was a relatively light fit person with a fast pace gait, they may have benefitted from the longer carbon spring keel in the Assure foot; giving more energy return and stability in stance compared to the shorter keels of the other prosthetic feet.

6.4.2 Subject C

Subject C's gait was not as assertive as subject A's which could be seen from the lower confidence scores that they gave to each foot table 5.16. Subject C was much slower and more cautious on level ground and coming down the slope. Subject C felt most confident walking with the Epirus foot giving it a confidence score of 65%. As with all the pedotti graphs on the amputated side for this subject there was no definitive high GRF in ES, which indicates the subject did not achieve any definite heel strike. As the subject was a cautions ambulator they are likely to put the foot flat on the ground to make them feel more secure. The Epirus graph showed these characteristics with a peak at MS as the subject felt most confident to fully load the foot at this point figures 5.57-5.58. Throughout stance phase the ankle joint was plantar flexed which provided added stability to the subject's knee; reducing the feeling of falling forward and allowing them to fully load the foot at MS. During LS there was a short section of GRF displacement as the subject dwells on the prosthetic toe possibly to slow down forward progression but again no significant push off. The time spent on the Epirus foot for subject C was longer than subject A, which could be linked to the slower walking speed.

The sound side graphs all showed an increased force in ES. However, while walking using the Epirus foot the GRF was the highest at this point with wide spread vectors. This indicated that the subject committed their weight to the limb but did not progress quickly. The vectors in LS were very tightly packed showing the subject was dwelling but continuing forward and produced very little push off. The above factors may allude to evidence that the subject was unsure of the foot and lacked confidence. However, subject C's hesitant gait must be considered as these features are likely to be habitual.

Subject C gave the second highest confidence rating to the Tribute foot of 55%. The GRF pedotti for the Tribute foot was very similar to the Epirus foot figure 5.59-5.60. Both showed no ES contact. A peak in MS due to the plantar flexed ankle, GRF displacement in LS and the vectors widely spread. Therefore, it would be difficult to conclude which foot the subject may prefer. However, the sound foot presentation when using the Tribute foot gives some idea that the Epirus may be better. Compared to the former foot the GRF for the Tribute's contralateral foot can be seen to dwell earlier in stance showing hesitation in progressing. This is not seen with the Epirus foot. The remainder of stance then goes onto to display further tightly packed vectors which indicates a short time loading the foot.

The lowest confidence rating given by subject C was 45% for the Assure foot. The GRF pedottis while using this foot were very different when compared to the previous feet figures 5.55-5.56. The graph for the amputated side showed very few normal characteristics with no obvious phases of gait. The subject appears to make initial contact with his foot flat but feels unstable as there is a wide area of GRF displacement in early stance which shows the amputee is trying to counteract the force that is moving them down the slope. This then leads to a short period in late stance with no push off as the weight is quickly moved to the sound limb.

The sound limb displays a high force in ES with widely spaced vectors where the subject has landed heavily but in a controlled manner due to the instability of the prosthetic limb. This is followed by dwelling in late stance with very little push off force and a short area of GRF displacement as the subject prepares to load the prosthetic limb that they clearly lack confidence using.

Subject C produced no GRF pedotti's that resembled the control subject's gait. None of the prosthetic feet produced a peak in ES and unsurprisingly none showed a definitive push off force. The sound limb did show a high peak in ES but due to the subject's instability it can be assumed this was not a controlled action and they may have simply fallen onto the heel.

As previously stated subject C was a very cautions ambulator compared to subject A, which could not only be seen in the results of the ABC questionnaire but also in the results of the GRF. Subject C preferred the Epirus foot but showed very similar results with the Tribute foot. Both of these feet relied on snubbers and bumpers and have a shorter keel than the Assure foot which may suit a subject with a less forceful gait. It has been noted that feet with more energy storing capabilities such as the Assure require energy to be put into them to allow the user to get any feedback from them; otherwise they can feel stiff which may have been the case for subject C.

6.4.3 Subject F

Subject F was a young fit person whose amputation was due to trauma that left no other injuries and has an excellent gait and this could be seen by the extremely high scores this subject gave every foot table 5.16. Their confidence in walking probably has little to do with the parts that make up their prosthetic limb. Subject F felt most confident using the Tribute foot with a score of 100%. However, as there was very little difference in the ABC scores for each foot (Epirus 98% and Assure 90%) the graphs will be discussed together figures 5.73-5.78.

The pedotti graphs for the last subject were very close in shape to a non-amputee, showing two peaks; one in ES and one in LS and a trough in MS. The vectors are spread over a wider area and are evenly spaced indicating a smooth roll over. Unlike the previous subjects discussed, there appears to be a definite push off force which is slightly lower than the ES force. This may be due to the subject actually achieving some energy return from all the feet or may be due to the force in ES being comparatively lower, thus making the force in LS appear high. The GRF at MS does not fall as quickly and as low as the control subject but remains relatively high compared to the other subjects. This variation can be attributed to subject F walking slower than the control and the subject pushing into the slope by contracting their quadriceps in order to control the rate of knee flexion. The magnitude of the GRF in early and late stance for the amputated and sound side appears very high. Indeed, it is significantly more than the subject’s body weight and could be attributed to the subject’s muscle strength.

The sound side again demonstrated almost normal graphs with the subject spending very little time in MS caused by the fast pace of walking, which is then seen again by the relatively short distance of GRF displacement in LS for all feet. The subject appears to have no hesitation walking with any of the feet.

It could be seen from subject F's gait that it would be very difficult to come to the conclusion they were an amputee. Indeed, their gait was so good it was very difficult to deduce from the GRF results which foot they may have preferred. Interestingly the subject chose the Tribute foot as their preferred option. It may have been assumed, that due to the Assure foot's greater energy storing and release capabilities as a result of its design, they would have chosen it as the favourite. This conclusion helps reinforce the argument that objective results can be misleading and require subjective data to provide a more comprehensive picture.

In conclusion, the results of the GRF when walking down a slope have been shown to have potential when trying to decide which foot a subject may feel most confident using. The posterior displacement of the GRF was an interesting feature. It occurred most often in LS on the sound side and was common to almost all of the feet and the control subject. As it occurred with the control subject it is reasonable to assume it could be a natural stabilising mechanism when walking downhill. When the width, distribution of vectors and position in gait were assessed it proved insightful.

This exploratory data needs to be carefully examined and must include the sound foot and be used in conjunction with subjective results. Simple observations about a subject's gait are also an important factor, such as, speed and overall ability to walk naturally, as this will influence how difficult it is to interpret the data.

When walking down the slope each subject adopted their own strategies to enable them to complete the task safely. It was seen that the knee and hip joints compensated for the lack of motion at the ankle foot complex and surprisingly similarities in foot design did not lead to similar outcomes. As the results showed no outstanding performing prosthetic foot compared to another, it can only be concluded that the outcome was dependant on the subject's natural ability to walk which, was demonstrated by how close they were to matching the control subject's gait. It can be seen in appendix 9 that the individuals result showed better more consistent data than the subjects compared, again highlighting natural ability. The GRF provided an interesting insight into being able to marry up the objective and subjective results, which is vital within the clinical environment and would warrant further study.

While performing this research, the question of evidence based practice being helpful and/or achievable within a prosthetic clinical setting has been ever present. The research can be said to be helpful as it provided evidence that would make it ethical for a prosthetist to decide on a foot prescription based on price. Therefore, the prosthetist would be justified in choosing the cheapest foot which would in turn save the NHS approximately £300 per foot. Factors which limited the scope of this study included, dedicating time to a project, participant numbers, the environment and cost of components. These factors were much more evident while performing the objective research and it is thought that a full time researcher would be required. However, the subjective research did not pose as many problems yet, its results were just as important. If objective research cannot be routinely done then more subjective studies should be investigated, as some evidence based practice is better than none at all.

The primary limitations of this study were considered to be; the small number of participants, the positioning of the anatomical markers, the examination of the GRF and the question of it being appropriate to compare amputee gait with able bodied gait.

The original sample size for this study was nine which reduced to six by its conclusion. A small sample number was used for this work because we had limited access to the number of feet that could be donated from the companies and it was important we used new products to rule out any problem due to wear and tear. The lead researcher was a full time practicing prosthetist. Therefore, time to dedicate to the experimentation was limited and it has to be noted that there is only a small window of opportunity to test prosthetic products because they become outdated so quickly.

The difficulty of positioning of the anatomical markers appears to be a subject that is not mentioned often in research but must be an issue. The testing for this study had to be repeated more than anticipated to ensure satisfactory results and this it is suspected stems from the positioning of the anatomical markers; specifically, the ankle foot markers. Accurately locating and marking the ankle joint centre of a prosthetic foot posed a serious challenge as the joint centre was not obvious and would often sit in open space. As with many studies the centre point of the lateral malleoli of the sound limb was considered the ankle joint centre and then replicated on the amputated side but it is likely this is not the case.

The link between GRF and subjective results was an unexpected finding that came late in the research but proved very interesting. The GRF pedotti graphs were taken from a single walk down the slope thus limiting the data and influencing the significance of the results.

As the study progressed it became clear that it may not be useful to try and make an amputee walk exactly like an able bodied subject. There are large fundamental differences between these two groups that become increasingly marked with more proximal amputations. The variations also increase when you consider the cause of limb loss such as a congenital subject who will have significant developmental changes in muscles and bone. Or alternatively a subject who has lost a limb due to trauma that could have been left with other, not as obvious changes, to their muscle balance and skeletal structure. It is understood there needs to be a bench mark in order to have outcome measures to work toward when rehabilitating amputees but a more individual approach may be better.

For further study it would be more efficient to have a dedicated researcher who only compared and contrasted prosthetic products. This person would be able to test various products in a shorter space of time making the data very relevant to what is being used to date. As well as this, being able to use more of each component and a much larger sample size would greatly improve the significance of the findings. Subjects could be used from all over Scotland rather than from one prosthetic centre.

Developing a system that could locate and accurately mark the ankle joint centre of various prosthetic feet could also greatly improve the findings of many prosthetic research projects.

Further study into the link between GRF and subjective opinion could also benefit from a dedicated researcher as increased sample size, walk tests and improved marker positioning would provide much enhanced data.

The final recommendation for future work would be investigating the optimal amputee gait. If outcome measures could be developed, that are tailored to each individual amputee when performing research then the results may provide some interesting insights.

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10.1 APPENDIX 1 OSSUR IMPACT LEVELS

The prosthetics manufacture Ossur has developed a system of catergorising products relative to a persons weight and activity level. This catergory is required when ordering a product to enable it to work most efficiently for the user. Each impact level describes the tasks the person is able to complete before they can be placed within this catergory. Eg a highly active person would be considered a 4 and a very low activity person would be a 1.

1. Low Impact level:

Designed to enable single or slightly varied cadence walking.

Daily activities involving limited and steady walking with minimal loading force on the foot.

Example: shopping, gardening, household tasks.

2. Moderate Impact level:

Designed to enable varied cadence walking.

Daily activities involving typically normal and repetitive actions with moderate amount of loading forces on the foot.

Example: longer walks, golfing and other moderate impact activities.

3. High Impact level:

Designed to enable high cadence walking.

Daily activities involving rigorous and repetitive actions with high level of impact on the foot.

Example: Construction work, jogging, jumping, excessive lifting and other higher impact activities.

4. Extreme level:

Designed to enable high impact sports.

Activities with repeated extreme level of impact on the foot.

Example: track and field, sprinting and long-distance running

.

10.2 APPENDIX 2 BLATCHFORDS PRESCRIPTION GUIDE

The prosthetics manufacture Blatchfords require a person to be put into a catergory before a part can be ordered. Blatchfords catergorys are divided into activity level and impact level. The activity level is spread between K0 and K4 with 0 being the least active person and 4 being the most active person. The impact level is described as low if the person doesn't take part in any high impact activities such as walking and golf. The impact is described as exstreme if a person is taking part in exstremely high impact events such as jumping or competing in professional level sports.

Activity Level	Description
K0	The amputee does not have the ability to move independently and uses a prosthesis for cosmetic purposes only.
K1	Indoor Walker-limited to indoor walking the amputee is able to walk on level surfaces at slow cadence.
K2	Limited Walker- Within a limited outdoor range, the amputee has the ability to walk at low or medium speed and can manage small obstacles such as curbs, steps and uneven surfaces.
K3	Active Walker- Daily activities include walking with rapid and variable cadence over uneven terrain and negotiating most environmental obstacles encountered.

K4	Very active, sports participant- Daly activities that exceed basic walking including rigorous, high-impact, high-energy activities like athletics, children's games and rugged work.

Table 10.1 Blatchfords Prescription guide

Prescription Impact Guide

The impact levels shown define appropriate selection of K3 and K4 foot springs

Impact Level	Description
Low	Daily walking and occasional sports such as golf and hiking
Moderate	Aggressive walking, frequent or daily sports such as jogging.
High	Daily activities such as distance running, climbing, lifting and carrying heavy objects for vocational purposes.
Extreme	Rigorous daily walking at high cadence, competitive athlete in track and field type events, has vocation that requires jumping or loading of the prosthesis beyond normal levels.

Table 10.2 Blatchfords Impact level description

10.3 APPENDIX 3 COLLEGE PARK IMPACT LEVEL DESCRIPTIONS

The prosthetic company College Park require each person to be divided into a category depending on their weight and activity level when ordering a prosthetic foot. They have three levels of activity low, moderate and high. A description for each is given to help guide the prescriber.

Level	**Description**
Low	Daily activities include mostly level ground walking, moving around in the home and community
Moderate	Daily activities include up to unlimited walking, climbing stairs and occasional moderate lifting (This does not include running)
High	Daily activities include fast walking, jogging, running, lifting heavy objects and/or recreational sports.

Table 10.3 College Park Prescription guide

10.4 APPENDIX 4 THE ACTIVITIES-SPECIFIC BALANCE CONFIDENCE (ABC) SCALE*

The ABC is a self administered or administered via personal or telephone interview questionnaire that measures how confident a subject feels while taking part in one or all of 16 tasks. The subject needs to rate thier confidence in the tasks from 0-100% with 100% being the most confident. The subjects percentage answers are totalled and divided by 16 to give their ABC score.

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following

rating scale:

0% 10 20 30 40 50 60 70 80 90 100%

no confidence completely confident

"How confident are you that you will not lose your balance or become

unsteady when you…

1. …walk around the house? ____%
2. …walk up or down stairs? ____%
3. …bend over and pick up a slipper from the front of a closet floor ____%
4. …reach for a small can off a shelf at eye level? ____%
5. …stand on your tiptoes and reach for something above your head? ____%
6. …stand on a chair and reach for something? ____%
7. …sweep the floor? ____%
8. …walk outside the house to a car parked in the driveway? ____%
9. …get into or out of a car? ____%
10. …walk across a parking lot to the mall? ____%
11. …walk up or down a ramp? ____%

12. …walk in a crowded mall where people rapidly walk past you? ____%

13. …are bumped into by people as you walk through the mall?____%

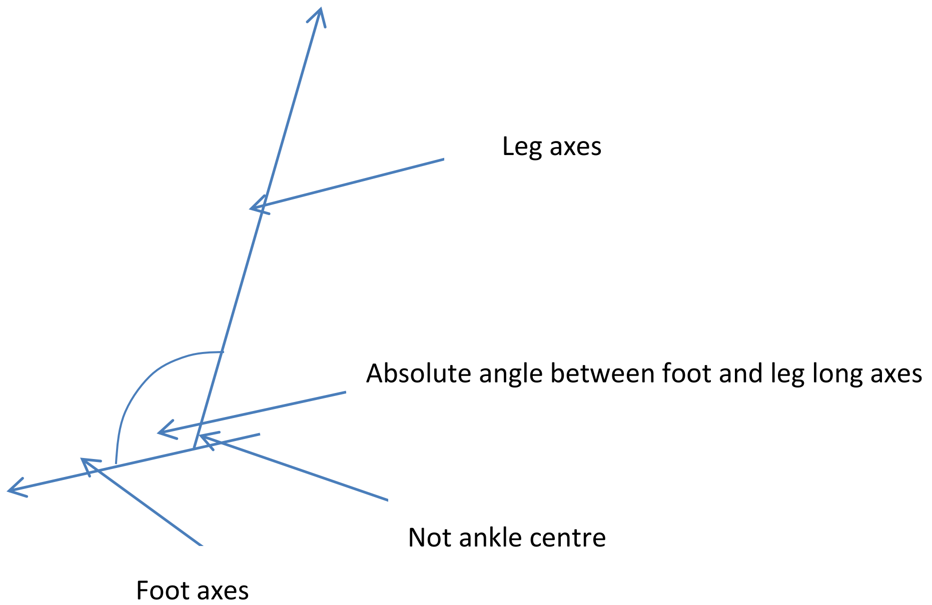
14. … step onto or off an escalator while you are holding onto a railing? ____%

15. … step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing? ____%

16. …walk outside on icy sidewalks? ____

10.5 APPENDIX 5 ABSOLUTE ANGLE

The absolute angle is the static angle measure between the leg long axis and foot long axis. The absolute angle became important when considering the moment and angle results as they are likley to be influenced by the static alignment of the limb. Table 10.4 shows the absolute angle for each subject using each prosthetic foot.



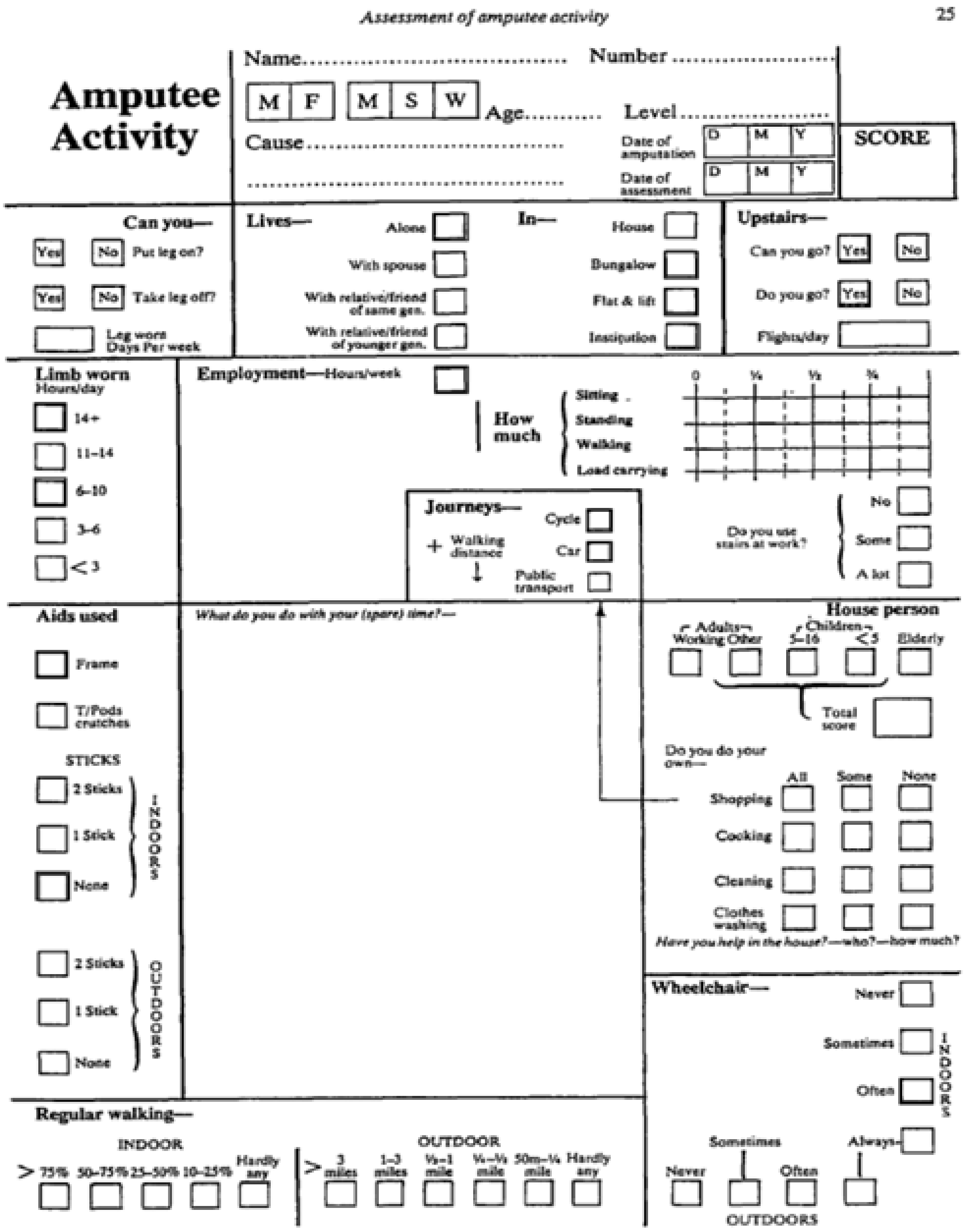
Notes: I or pointing from the midpoint of malleoli to midpoint of epicondyles foot long axes vector pointing from calcaneus to midpoint of metatarsals.

Figure 10.1 Absolute angle

absolute angle between leg and foot mechanical axes during static calibration						
	assure		Epirus		tribute	
subject	left	right	left	right	left	right
A	104	102	118	105	101	109
B	92	88	95	98	95	94
C	96	105	92	96	91	96
D	93	101	95	97	92	95
E	108	98	108	91	112	91
F	93	94	93	88	92	90

Table 10.4 Absolute angle between leg and foot during static calibration

10.6 APPENDIX 6 DAY ACTIVITY SCORE



Assessment of amputee activity 25

Amputee Activity

Name........ Number........

M F | M S W | Age........ Level........

Cause........

Date of amputation D M Y

Date of assessment D M Y

SCORE

Can you—
Yes No Put leg on?
Yes No Take leg off?
Leg worn Days Per week

Lives—
Alone
With spouse
With relative/friend of same gen.
With relative/friend of younger gen.

In—
House
Bungalow
Flat & lift
Institution

Upstairs—
Can you go? Yes No
Do you go? Yes No
Flights/day

Limb worn Hours/day
14+
11–14
6–10
3–6
< 3

Employment—Hours/week

How much: Sitting, Standing, Walking, Load carrying — 0, ¼, ½, ¾, 1

Journeys—
Walking distance
Cycle
Car
Public transport

Do you use stairs at work? No / Some / A lot

Aids used
Frame
T/Pods crutches

STICKS
INDOORS: 2 Sticks, 1 Stick, None
OUTDOORS: 2 Sticks, 1 Stick, None

What do you do with your (spare) time?—

House person
Adults: Working, Other; Children: 5–16, < 5; Elderly
Total score

Do you do your own— (All / Some / None)
Shopping
Cooking
Cleaning
Clothes washing

Have you help in the house?—who?—how much?

Wheelchair—
INDOORS: Never, Sometimes, Often
OUTDOORS: Never, Sometimes, Often, Always

Regular walking—
INDOOR: > 75%, 50–75%, 25–50%, 10–25%, Hardly any
OUTDOOR: > 3 miles, 1–3 miles, ½–1 mile, ¼–½ mile, 50m–¼ mile, Hardly any

10.7 APPENDIX 7 CONFIDENCE GRAPHS

Each subjects moment and angle at the hip, knee and ankle were added to the appendix to show the spread of the data with upper and lower confidence intervals of 95%. Each subject with each prosthetic foot has been included.

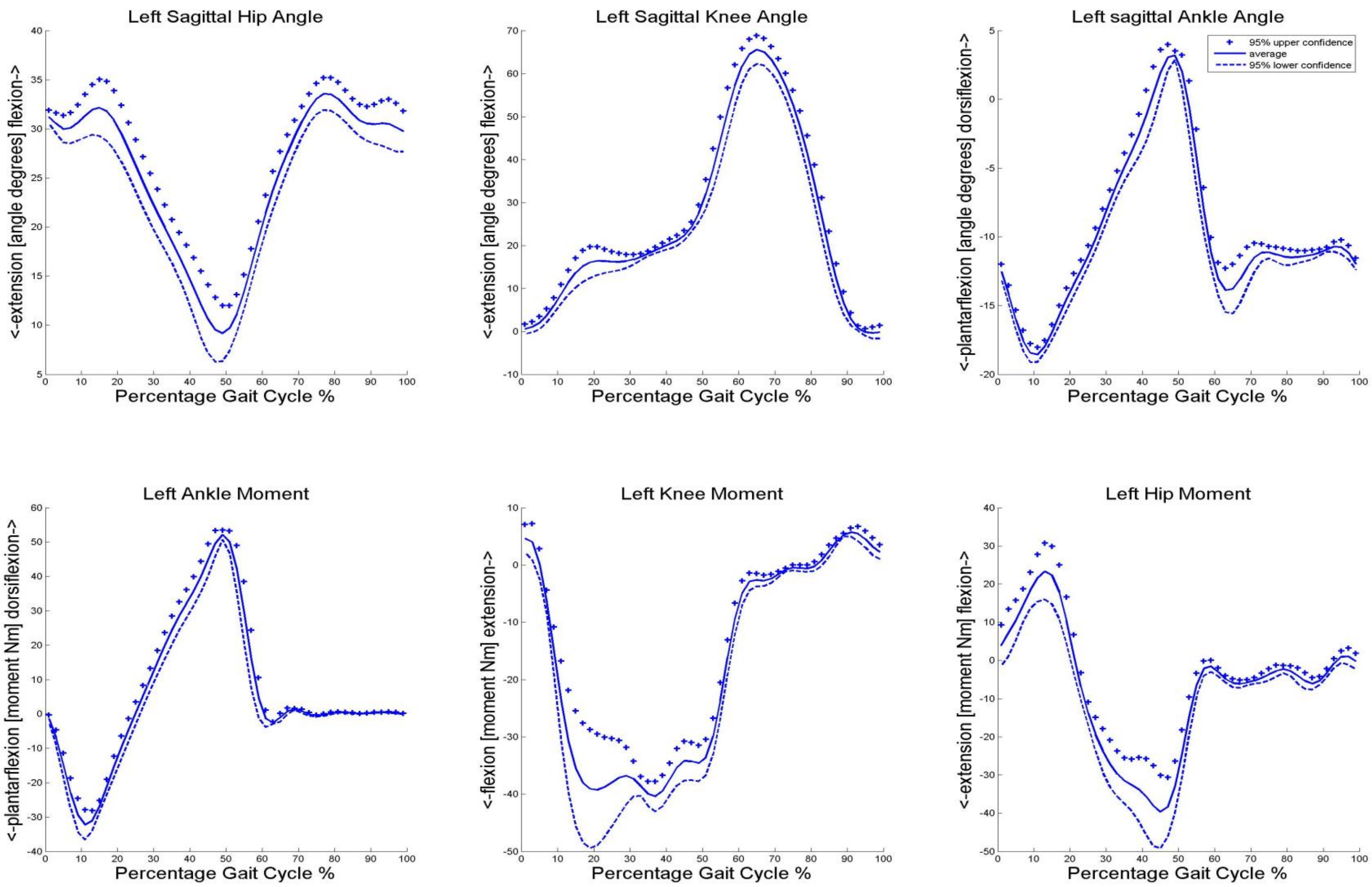


Figure 10.2 Patient A Prosthetic side Assure foot with confidence limits included

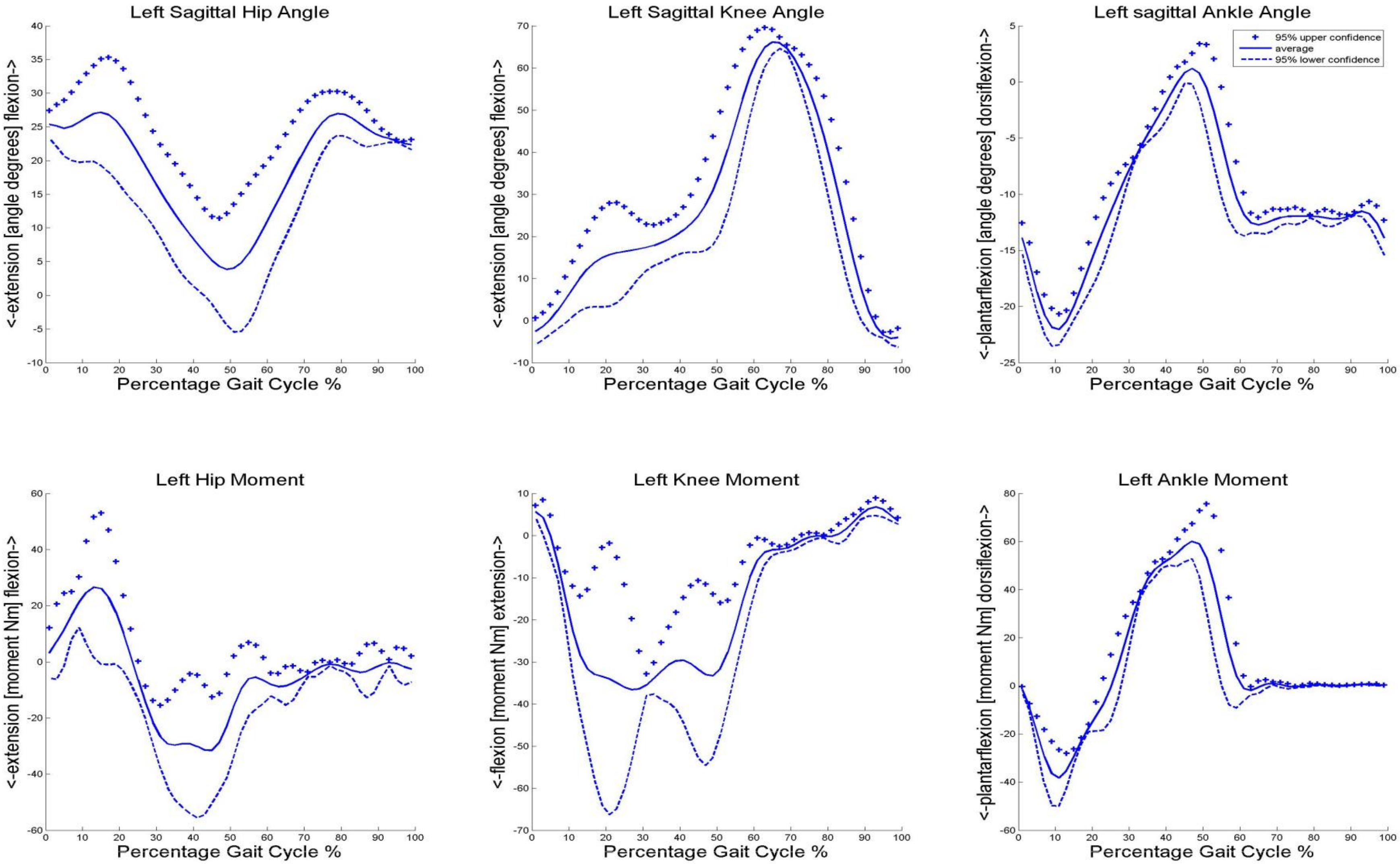


Figure 10.3 Patient A Prosthetic side Epirus foot with confidence limits included

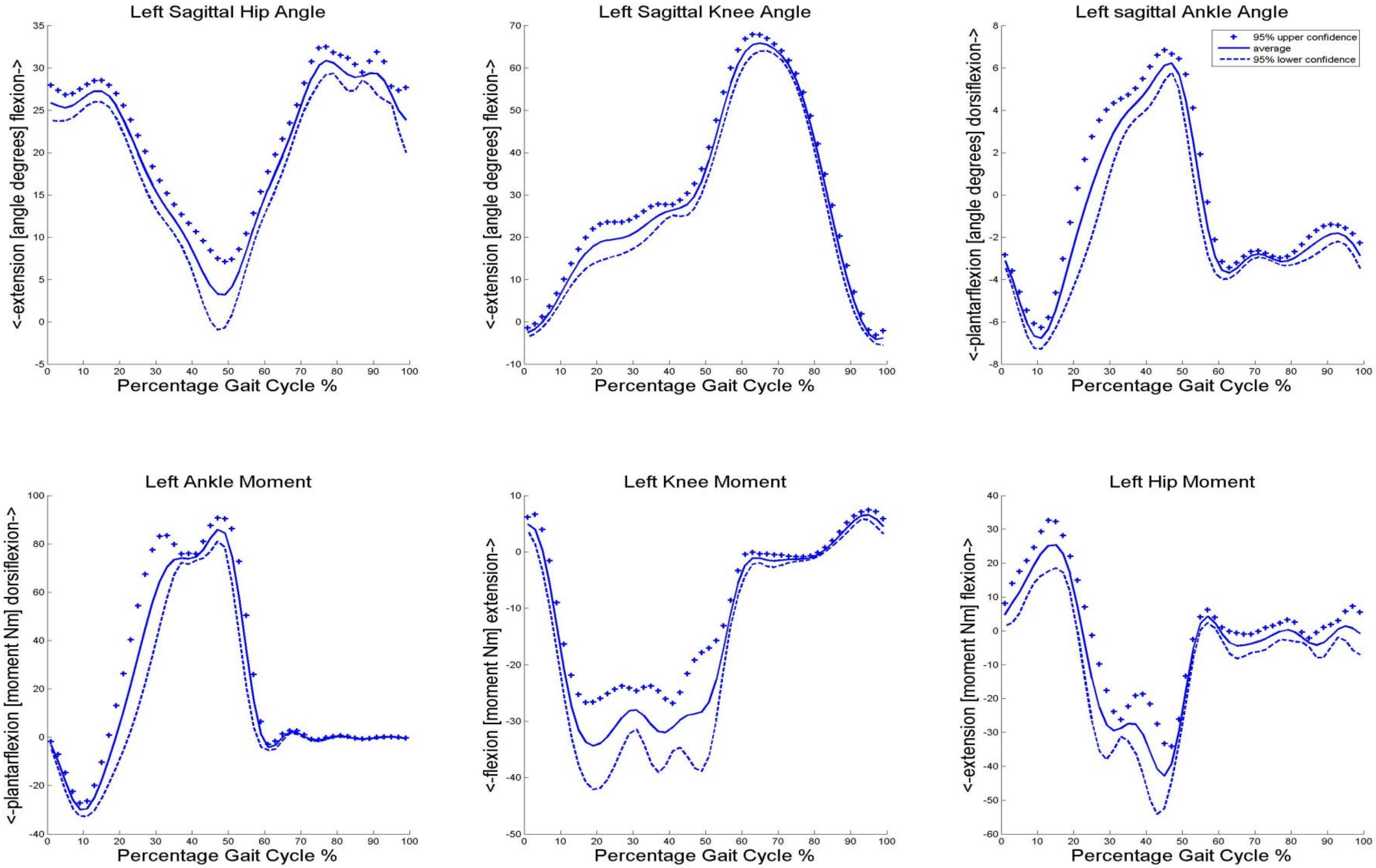


Figure 10.4 Patient A Prosthetic side Tribute foot with confidence limits included

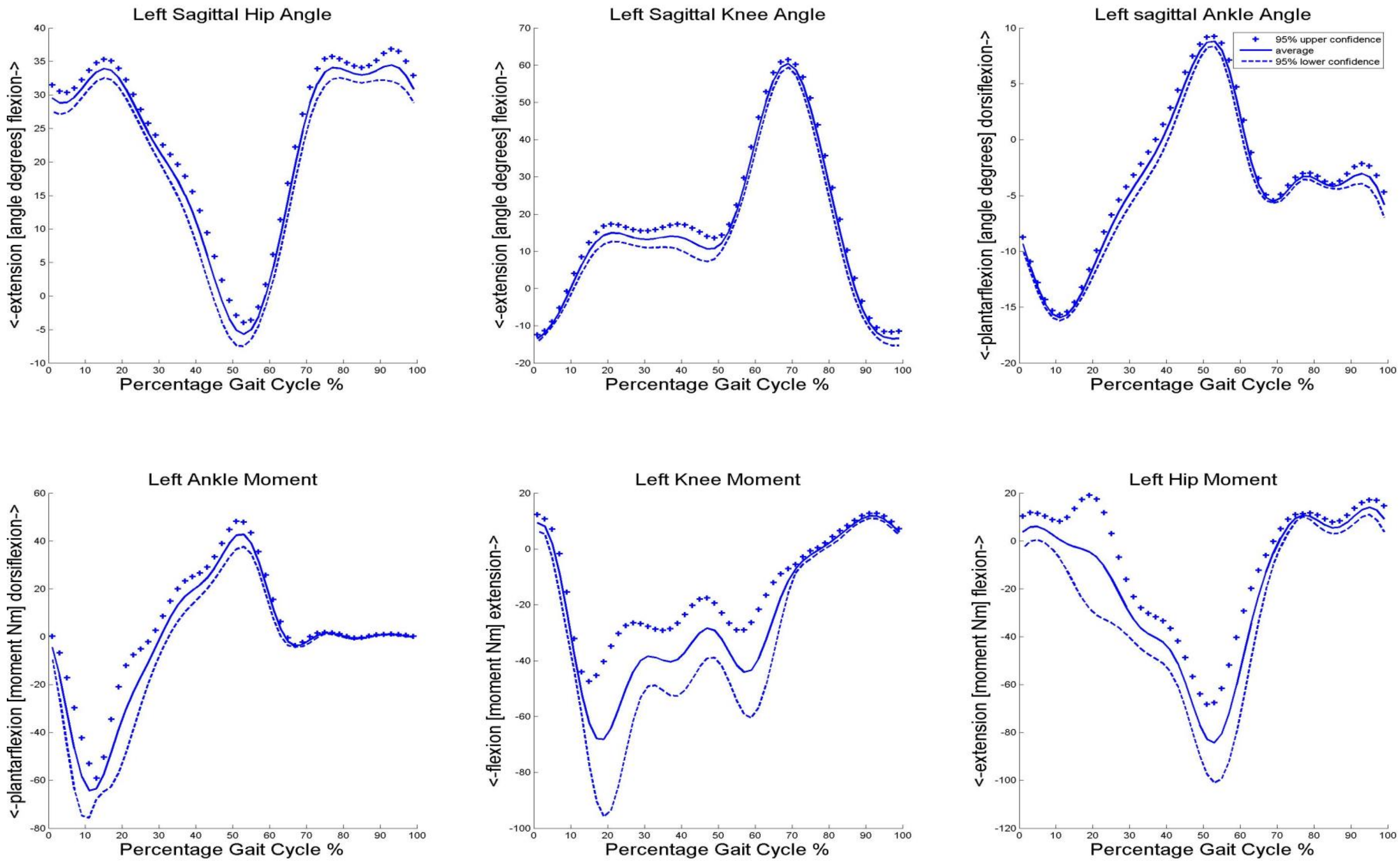


Figure 10.5 Patient B Prosthetic side Assure Foot with confidence limits included

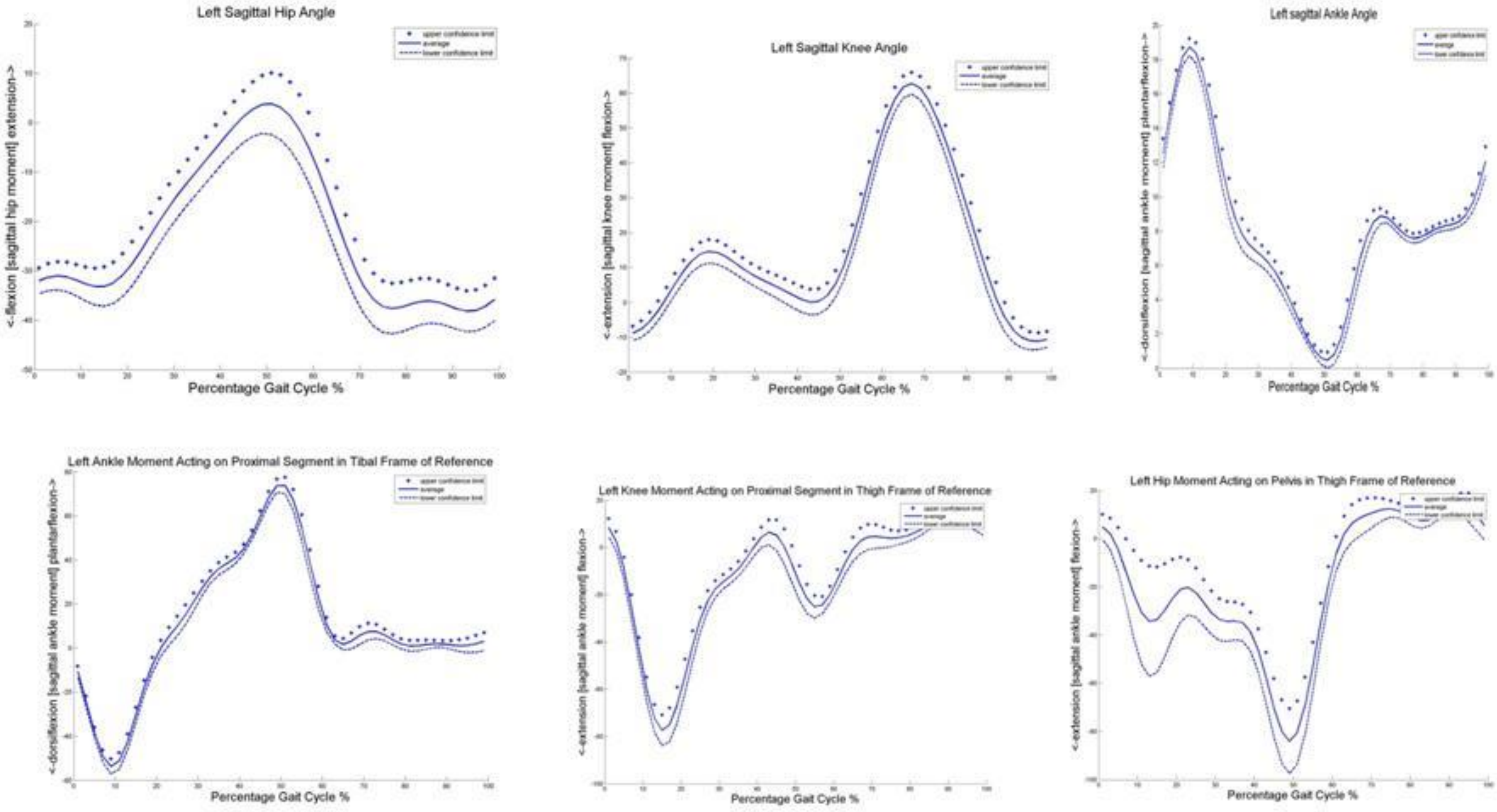


Figure 10.6 Patient B Prosthetic side Epirus Foot with confidence limits included

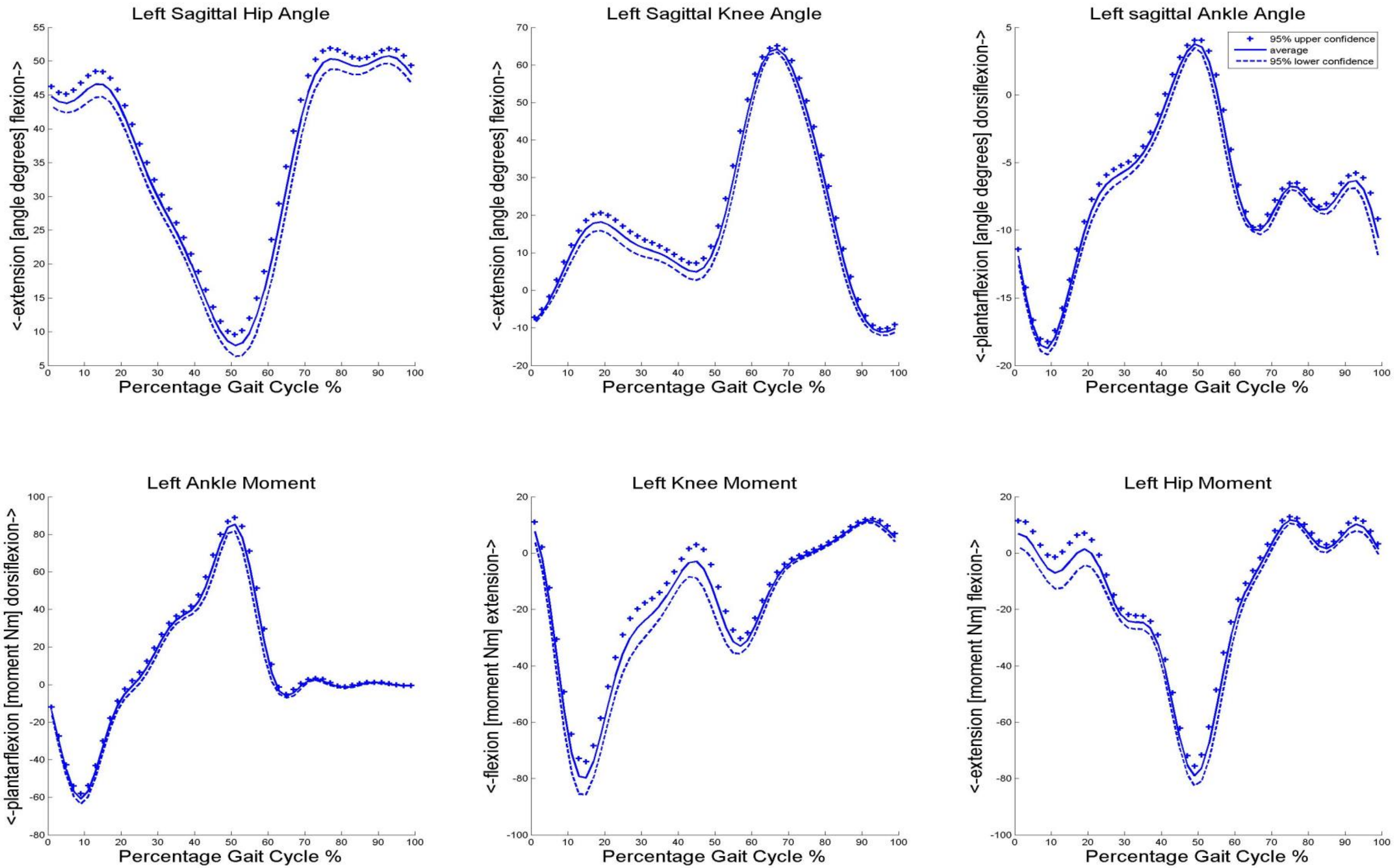


Figure 10.7 Patient B Prosthetic side Tribute foot with confidence limits included

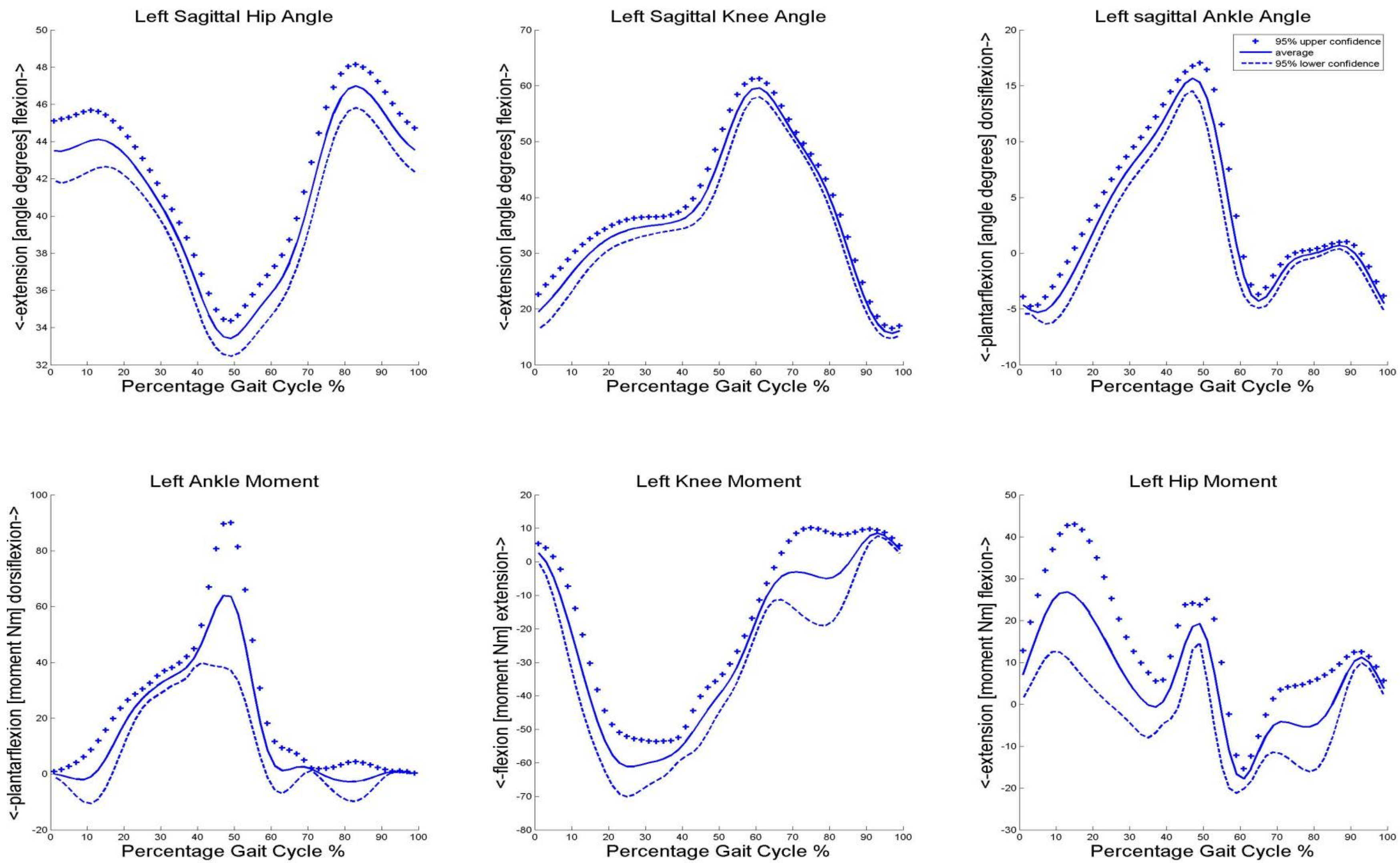


Figure 10.8 Patient C Prosthetic side Assure foot with confidence limits included

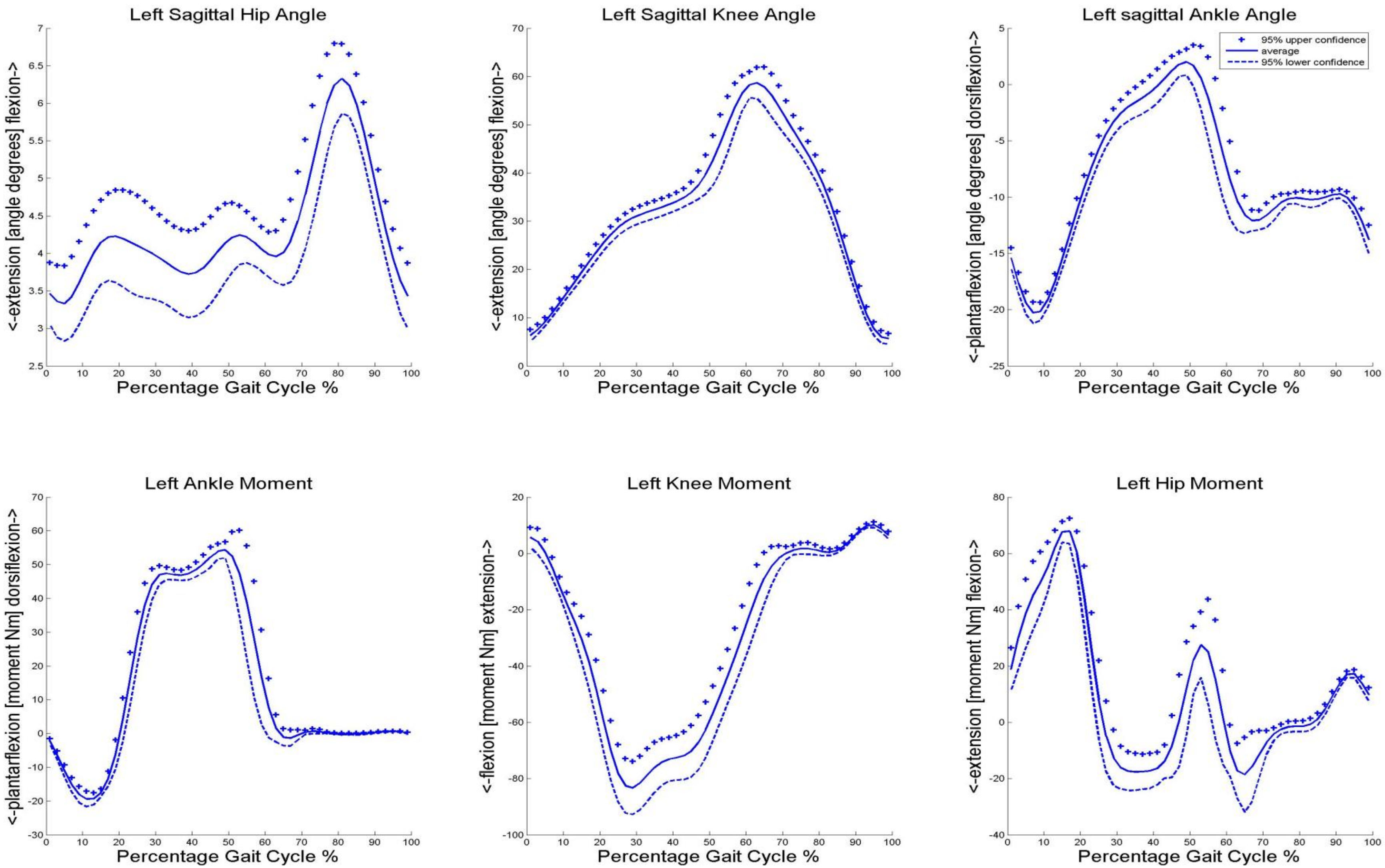


Figure 10.9 Patient C Prosthetic side Epirus foot with confidence limits included

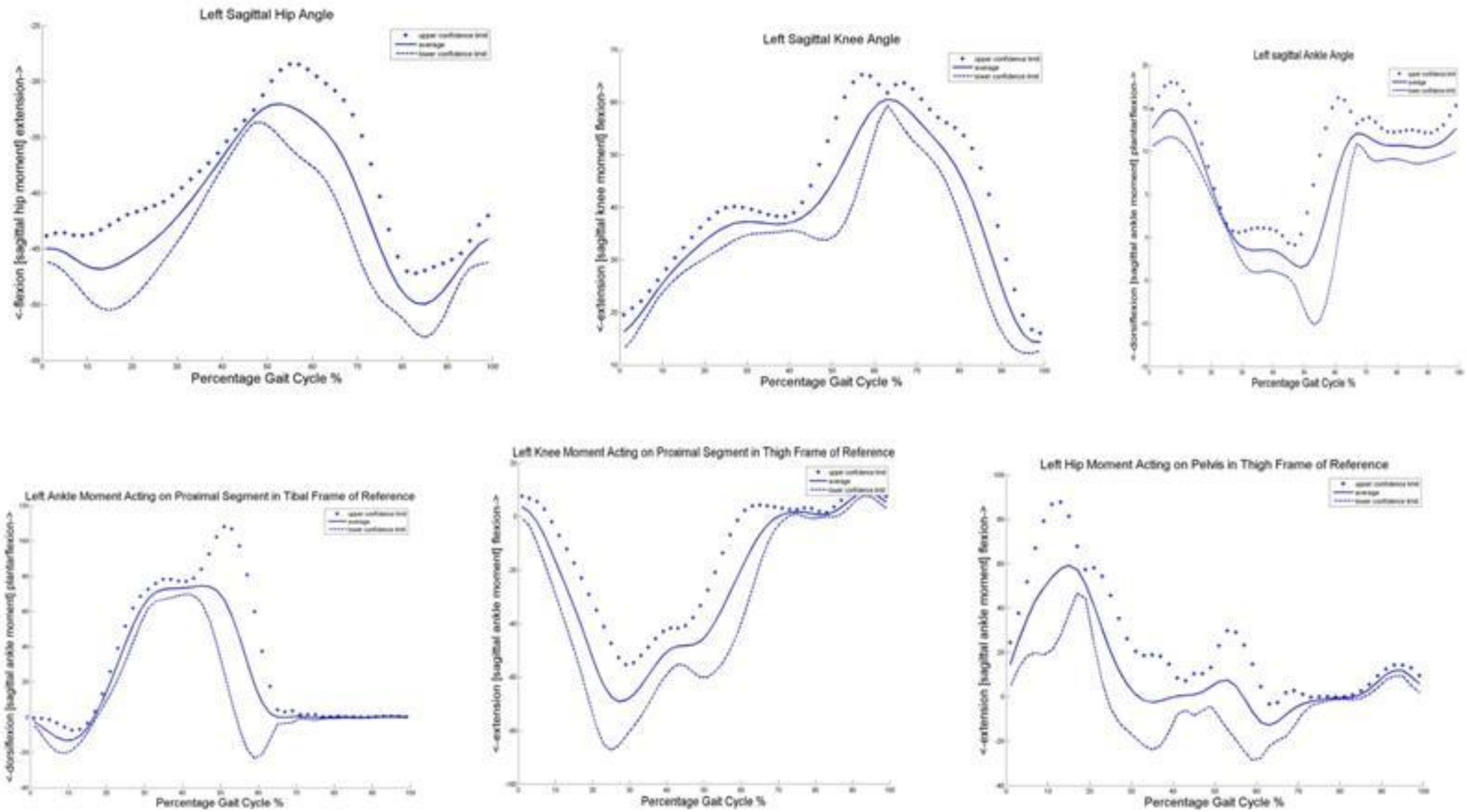


Figure 10.10 Patient C Tribute foot with confidence limits included

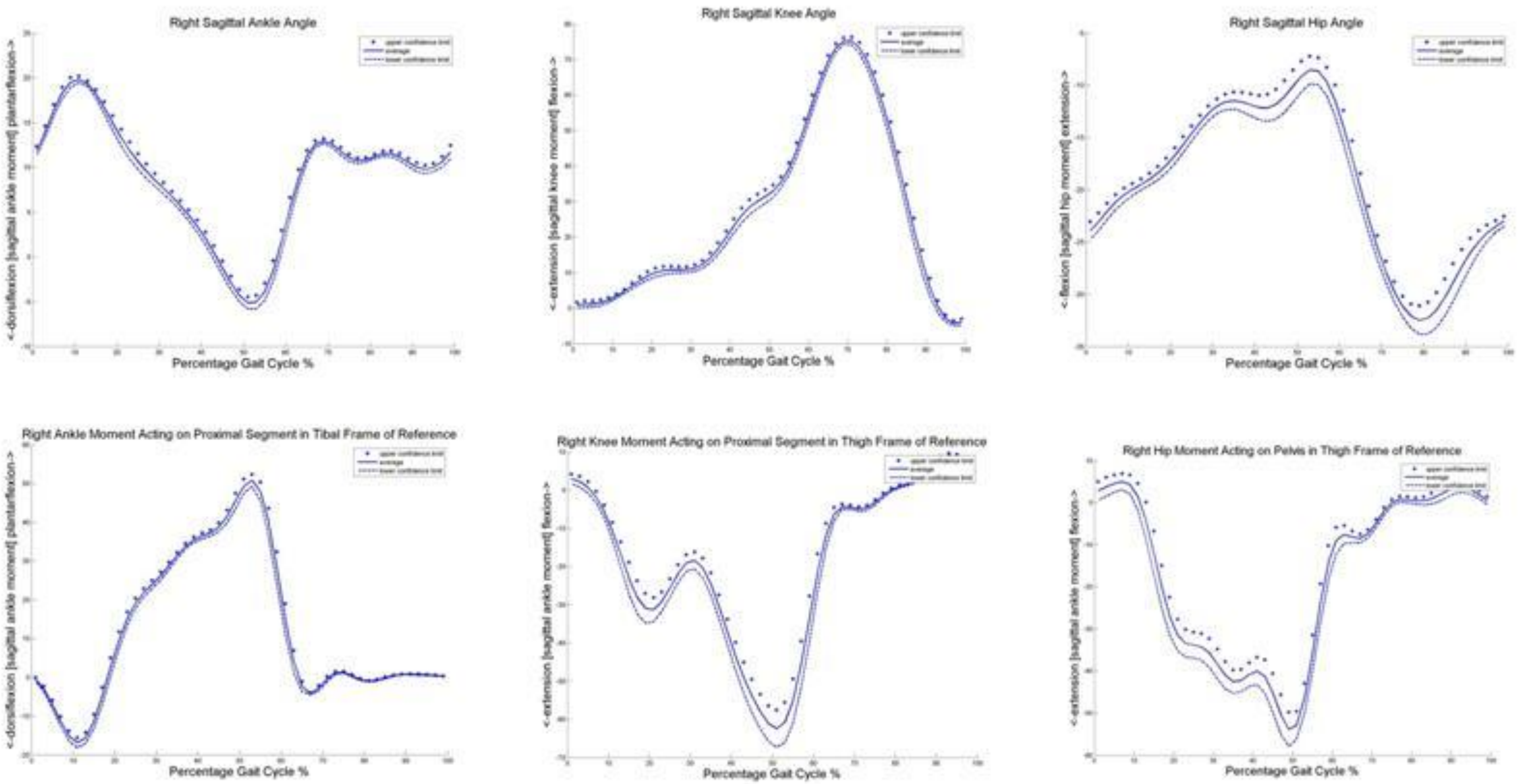


Figure 10.11 Patient D Assure foot with confidence limits included

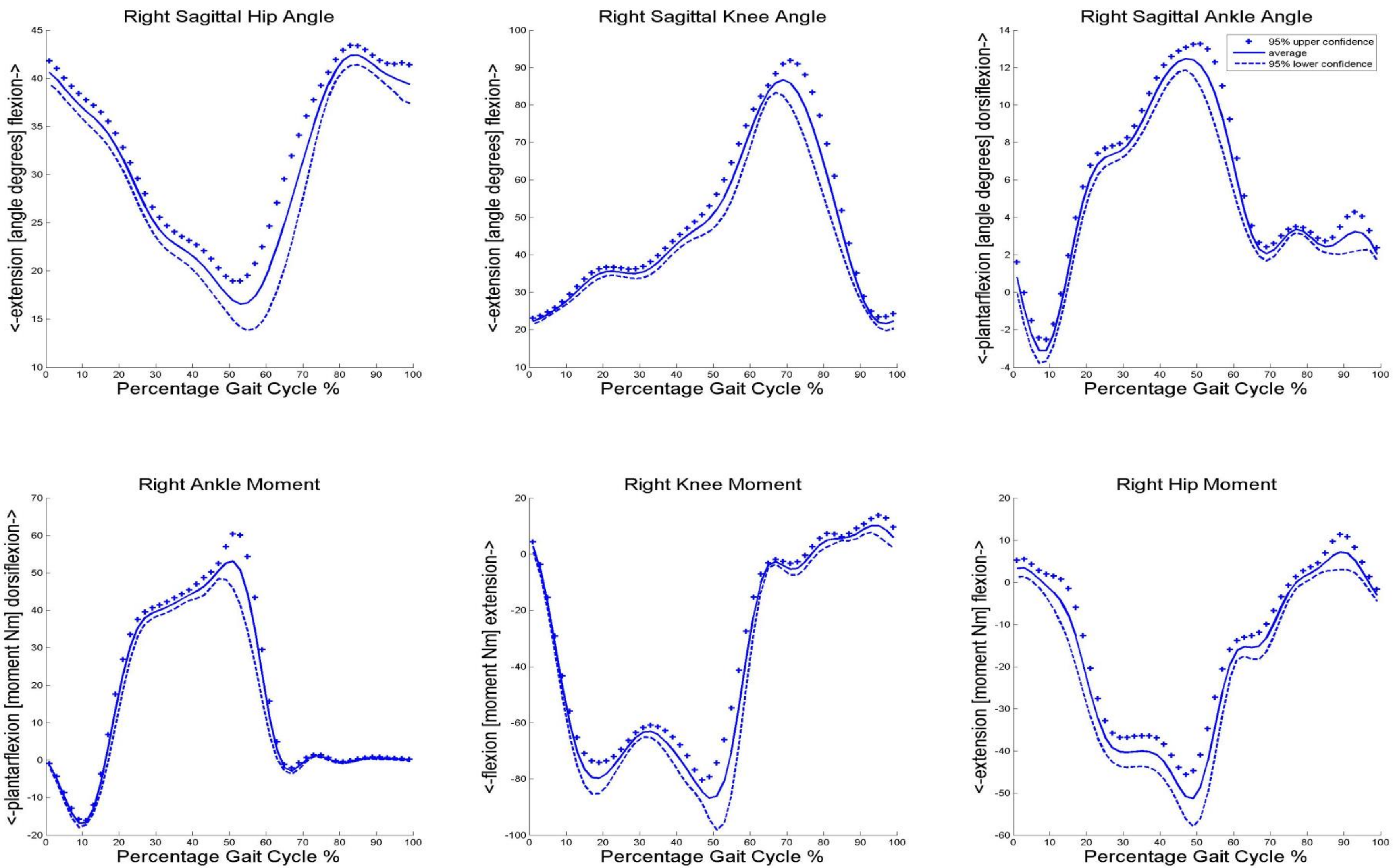


Figure 10.12 Patient D Epirus foot with confidence limits included

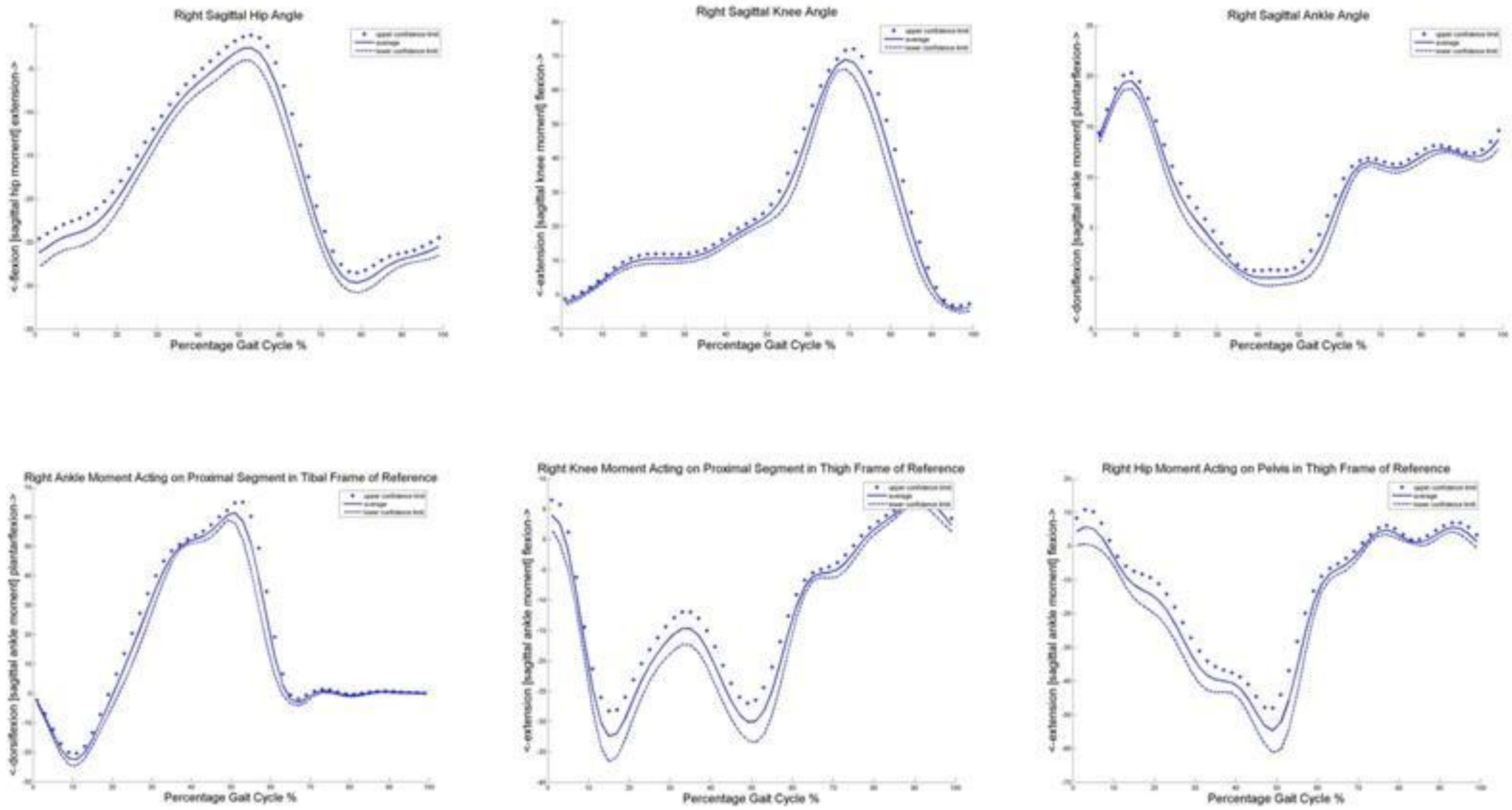


Figure 10.13 Patient D Tribute foot with confidence limits included

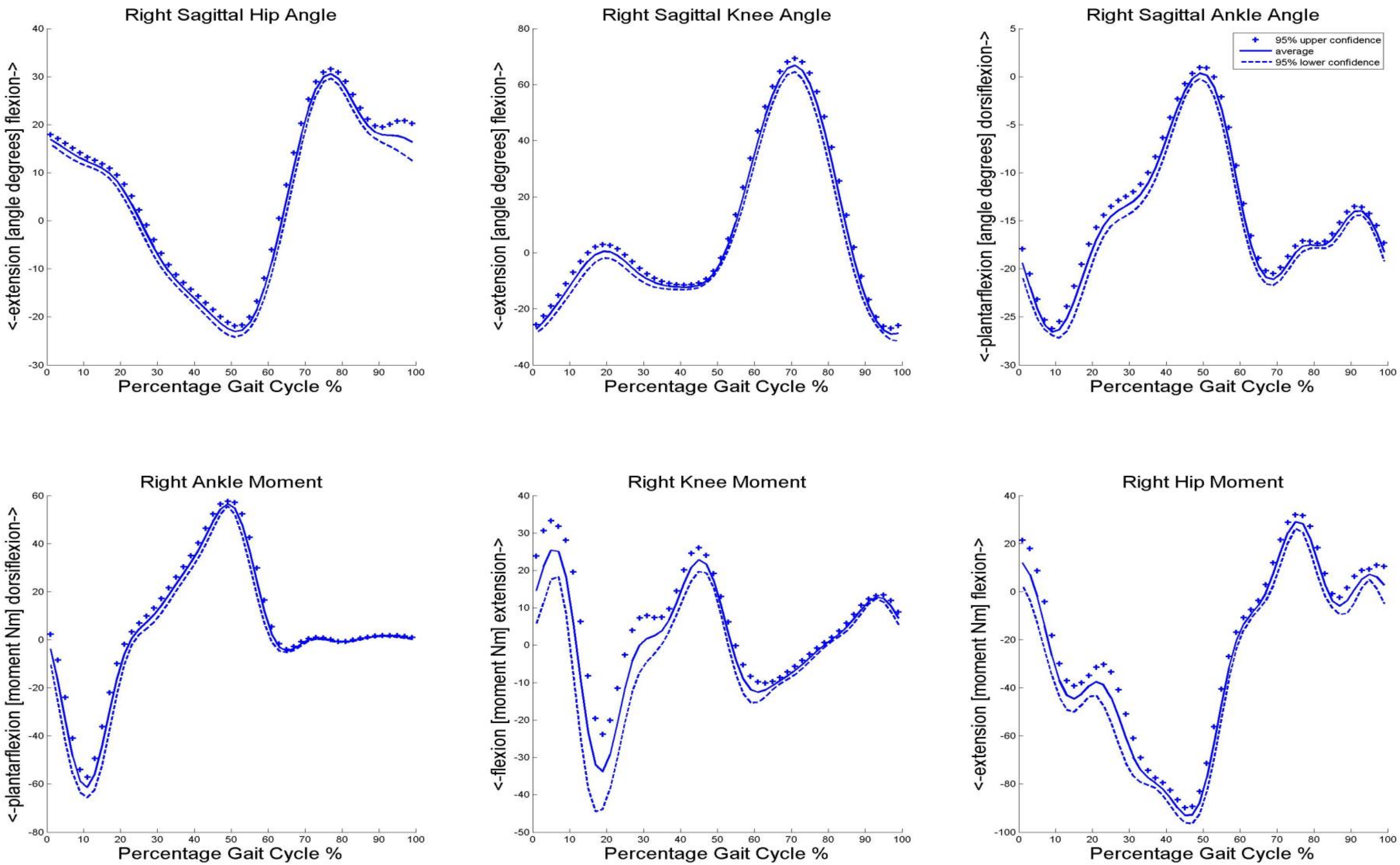


Figure 10.14 Patient E Prosthetic side Assure foot with confidence limits included

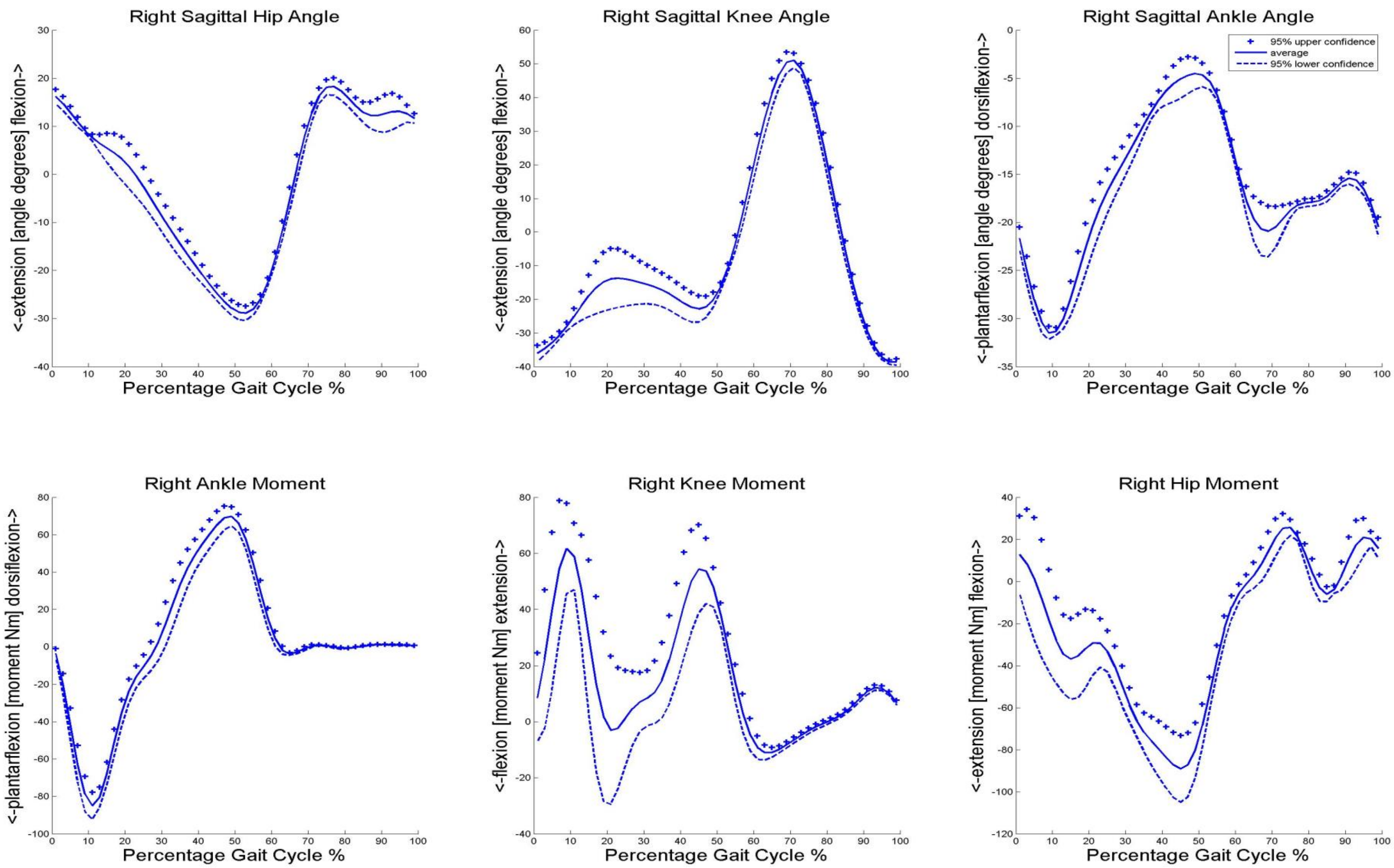


Figure 10.15 Patient E Prosthetic side Epirus foot with confidence limits included

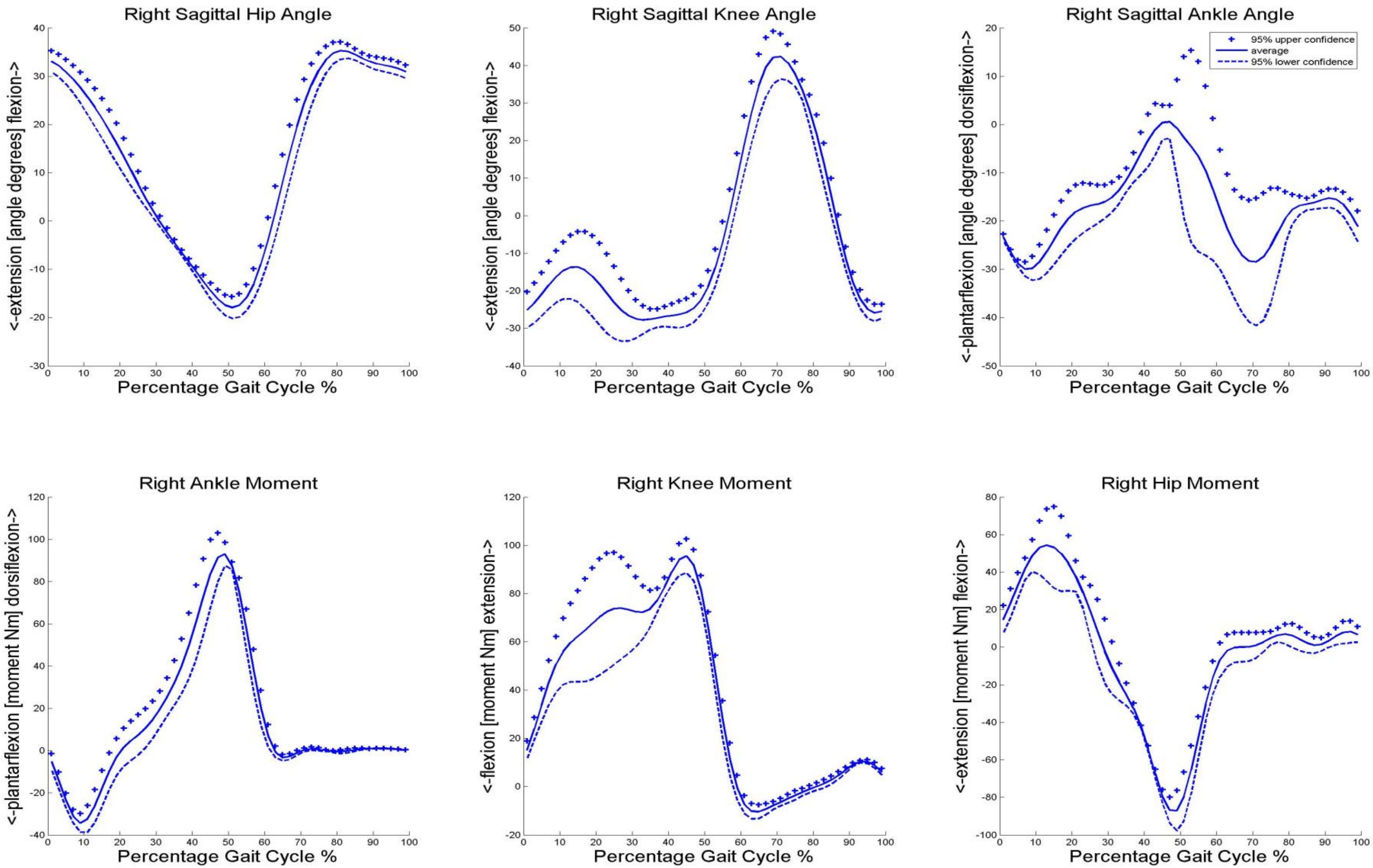


Figure 10.16 Patient E Prosthetic side Tribute foot with confidence limits included

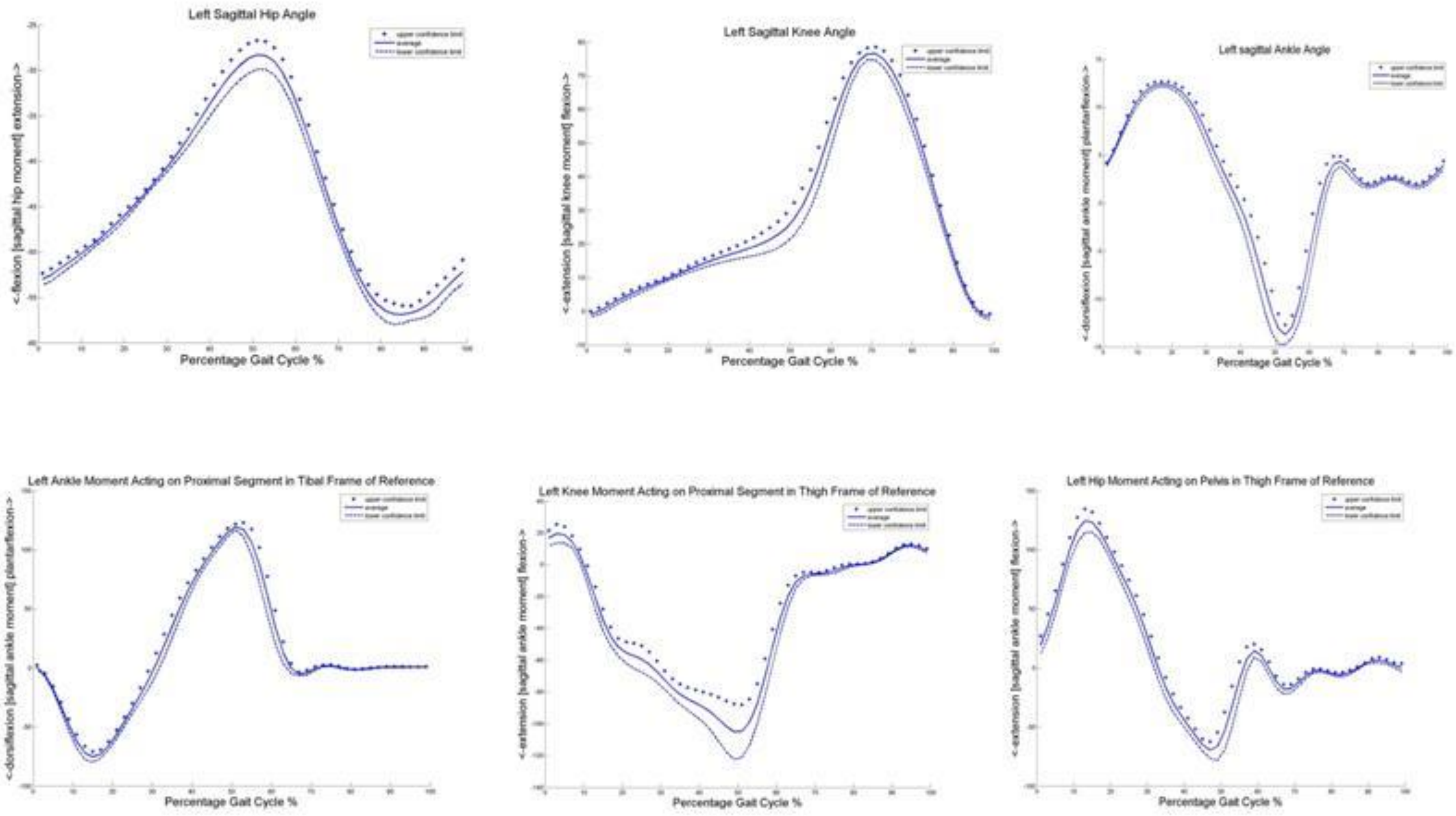


Figure 10.17 Patient F Assure foot with confidence limits included

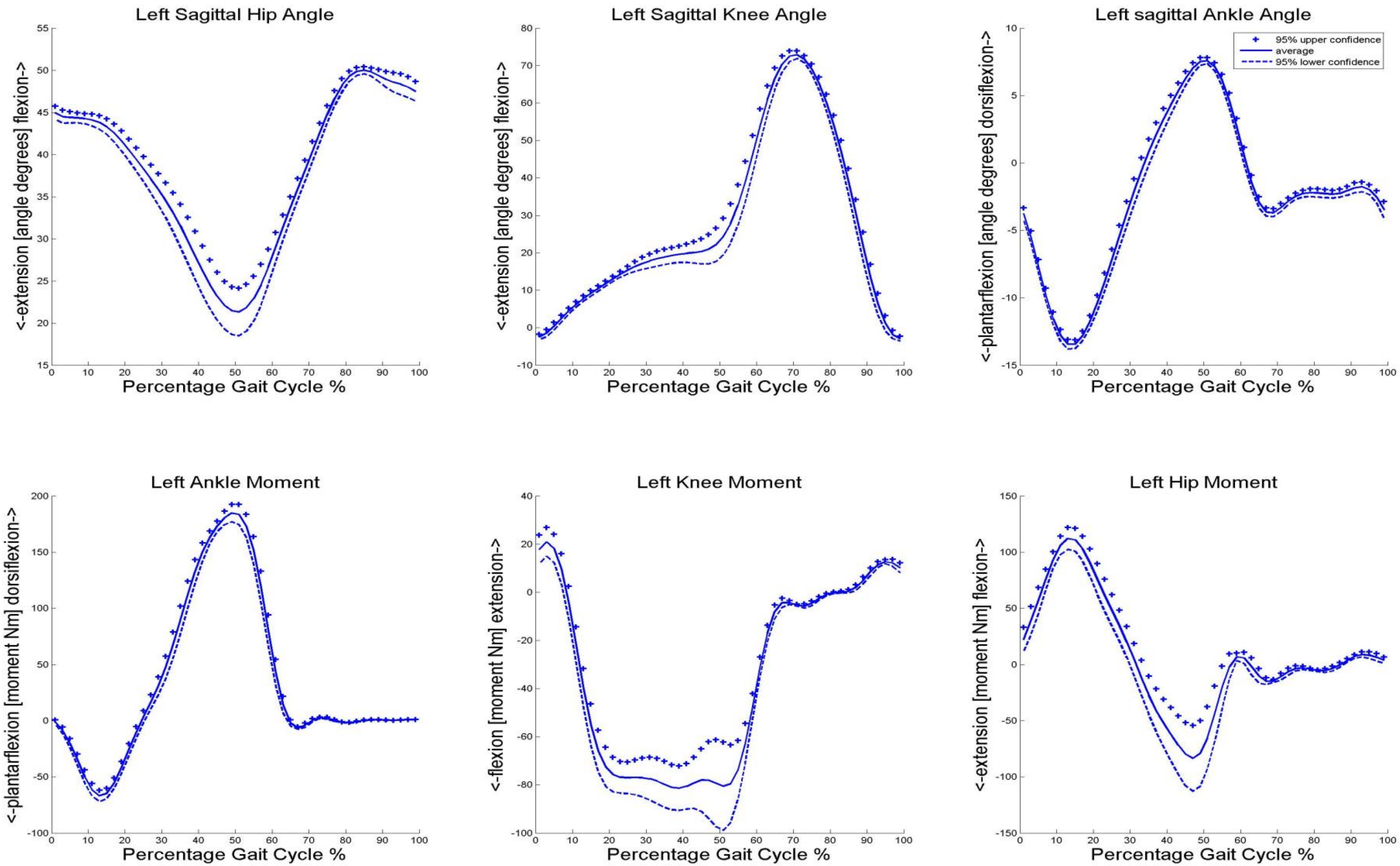


Figure 10.18 Patient F Prosthetic side Epirus foot with confidence limits included

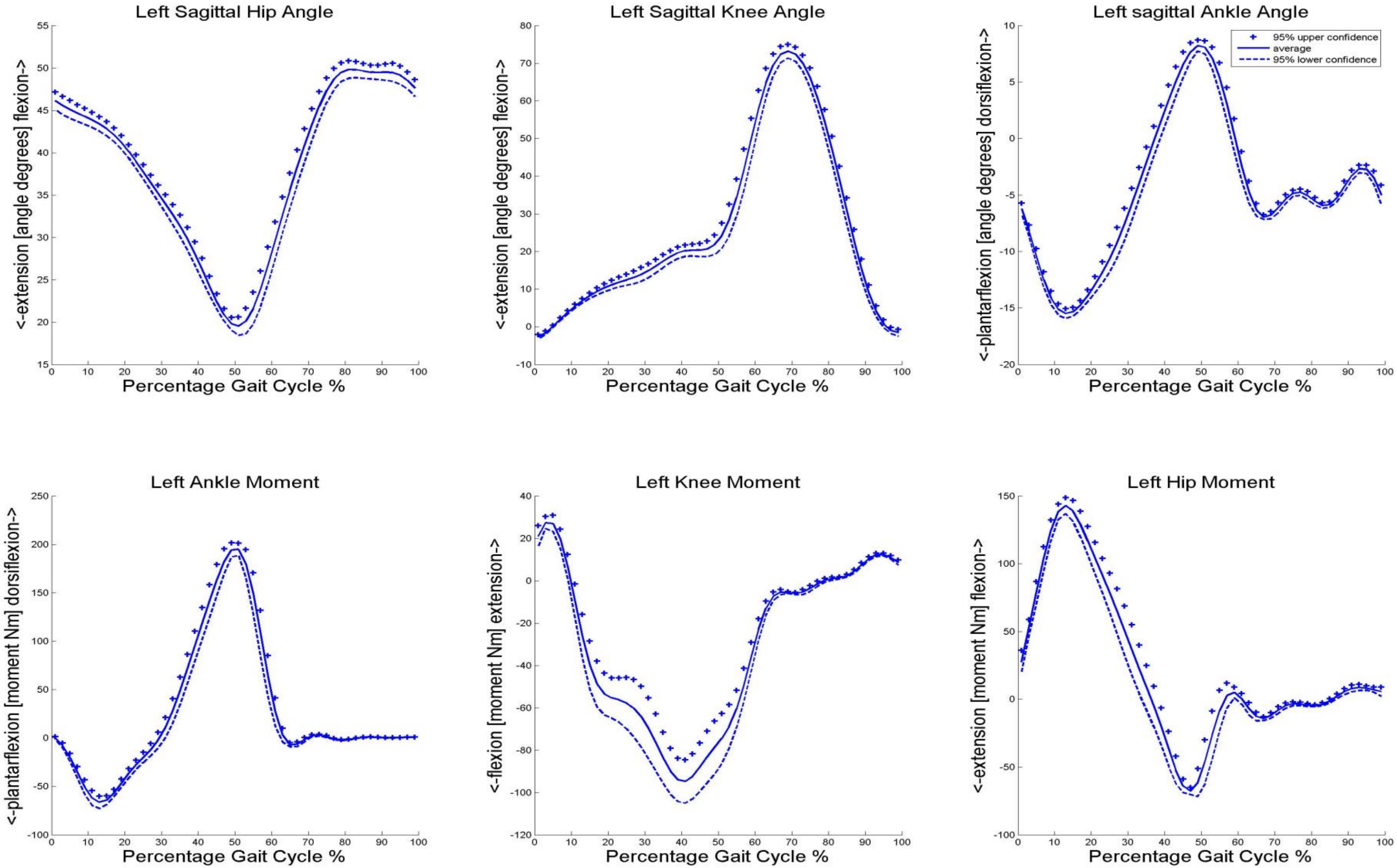


Figure 10.19 Patient F Prosthetic side Tribute foot with confidence limits included

10.8 APPENDIX 8 SOUND LIMB RESULTS WITH EACH PROSTHETIC FOOT

The moment and angle data for the hip, knee and ankle on the sound side for each subject with each foot was included for reference. The kinetic and kinematic for the sound foot data was beyond the scope of this study.

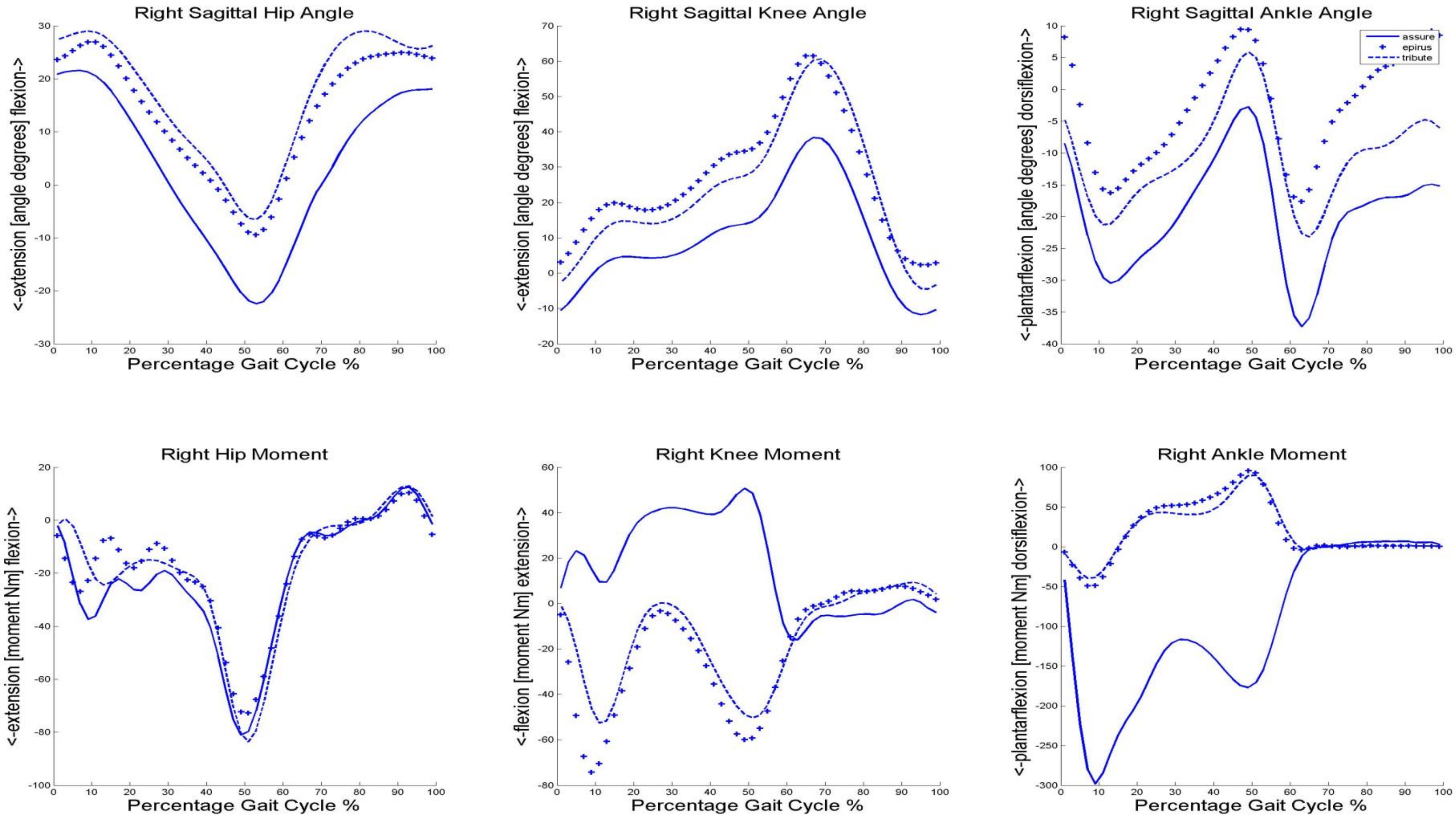


Figure 10.20 Patient A Sound limb angles and moment results

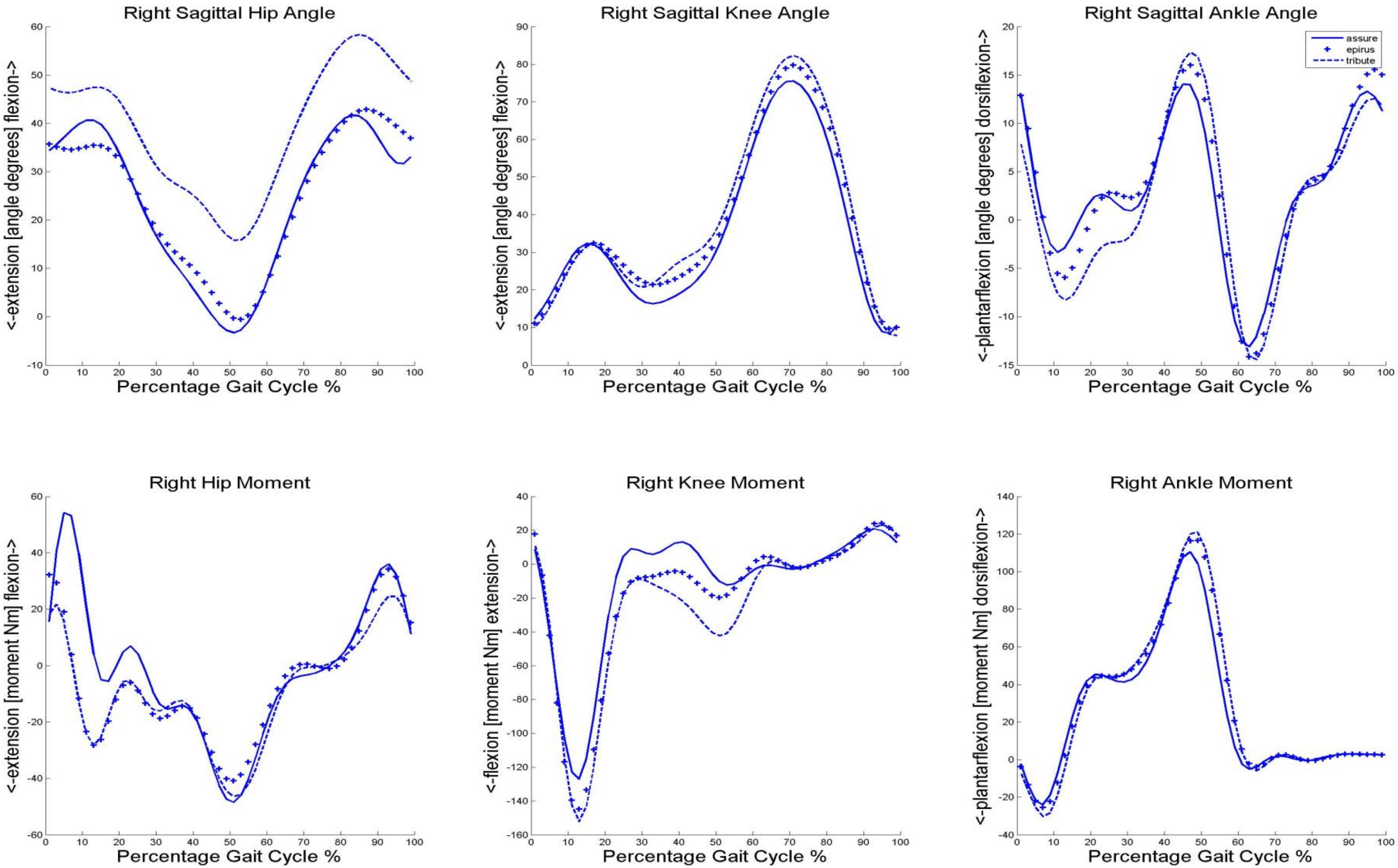


Figure 10.21 Patient B Sound limb angles and moment results

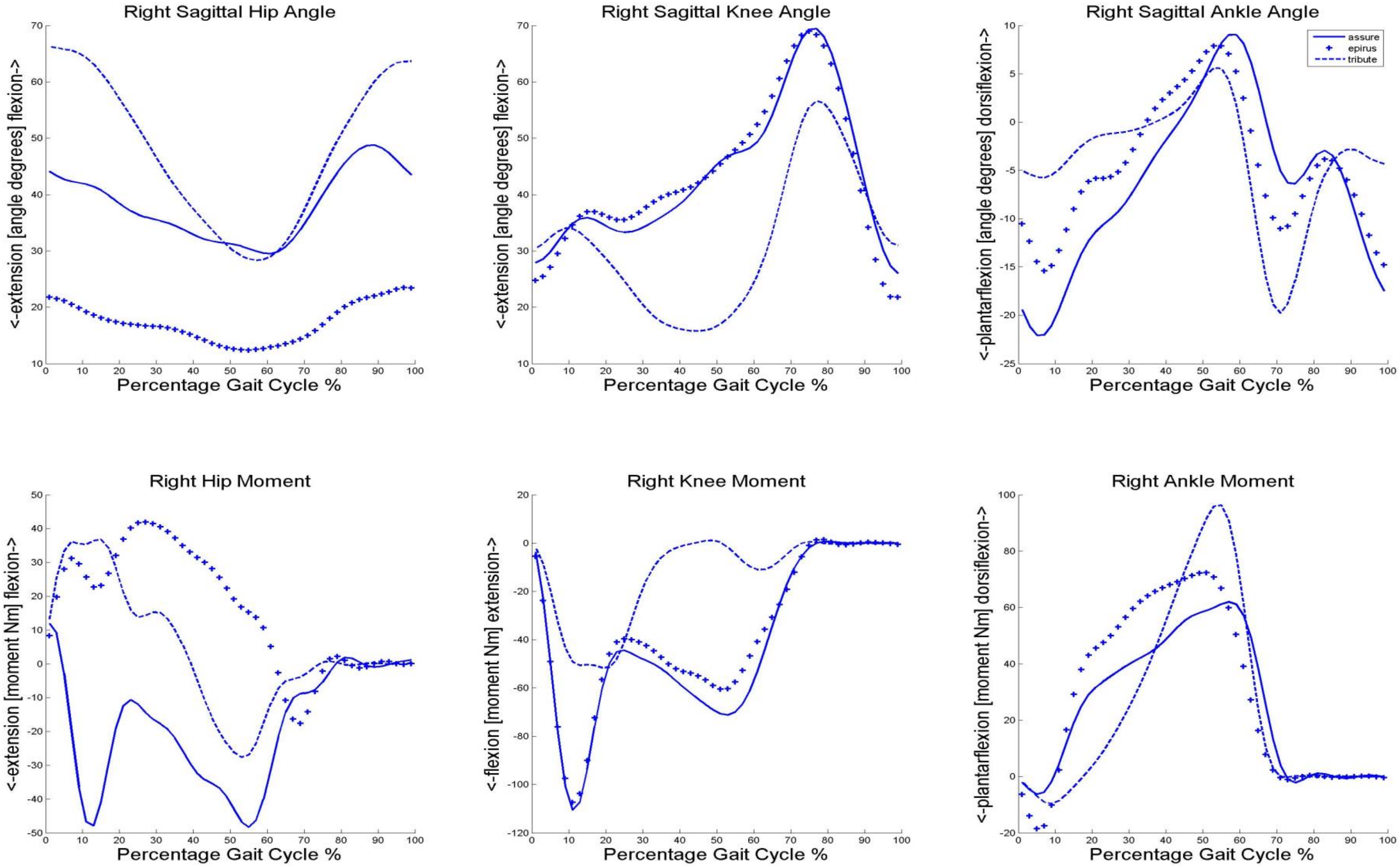


Figure 10.22 Patient C Sound limb angles and moment results.

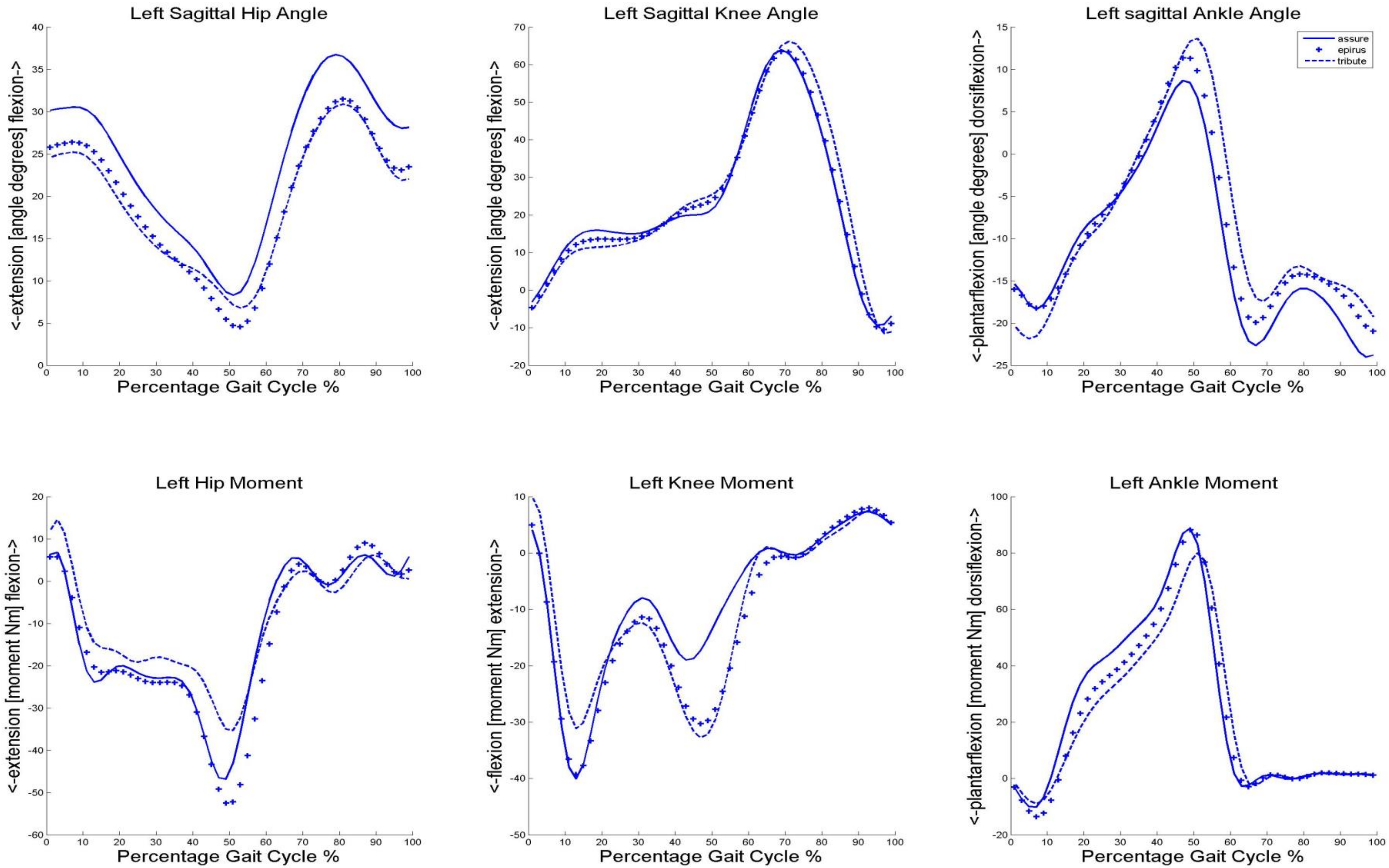


Figure 10.23 Patient D Sound limb angles and moment results

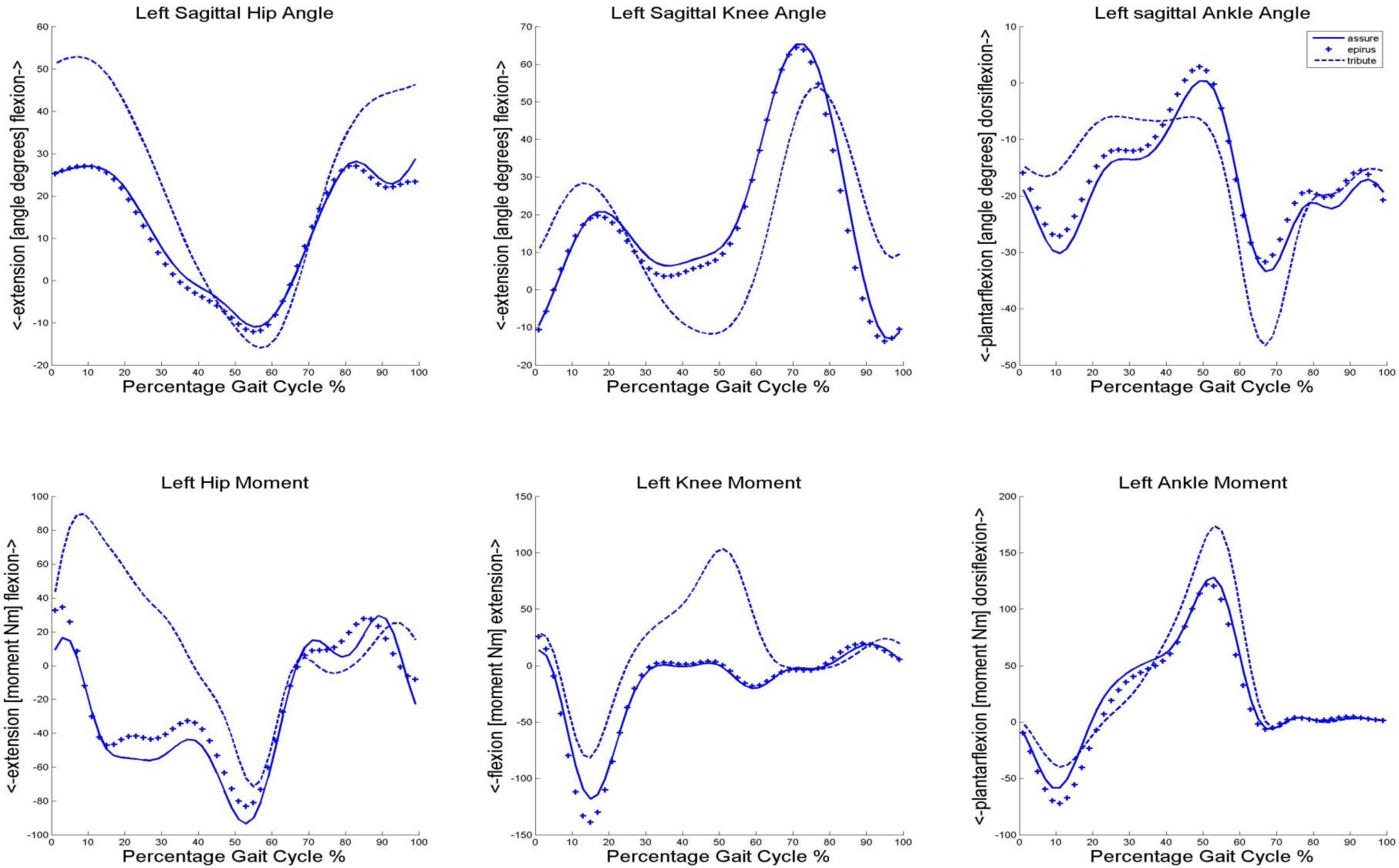


Figure 10.24 Patient E Sound limb angles and moment results

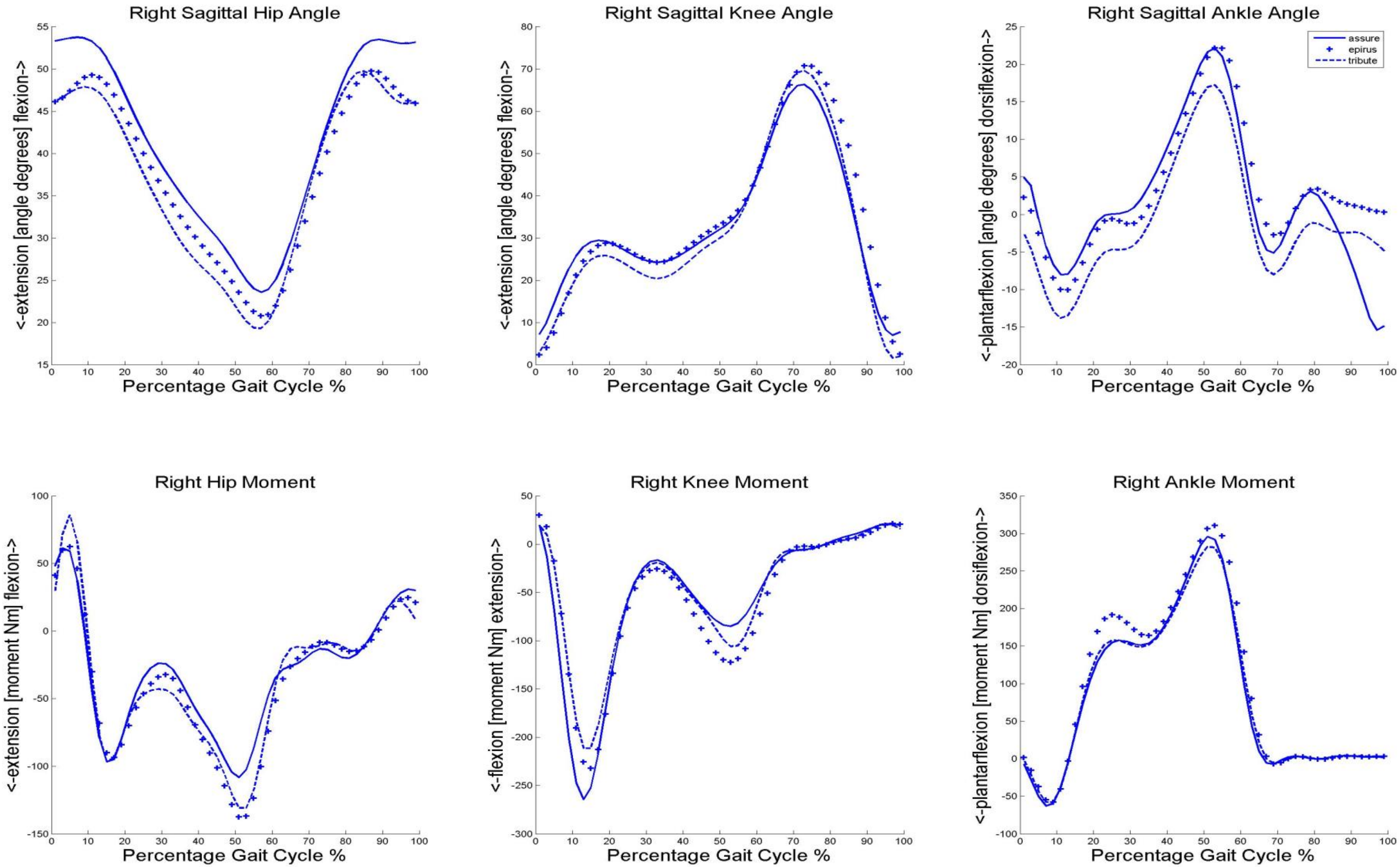


Figure 10.25 Patient F Sound limb angles and moment results

10.9 APPENDIX 9 MAT LAB RAW ANGLE AND MOMENT DATA OF EACH PATIENT USING EACH FOOT

The kinematic and kinetic results for every walk down the slope each subject did using each foot has been included to show the spread and repeatability of the results.

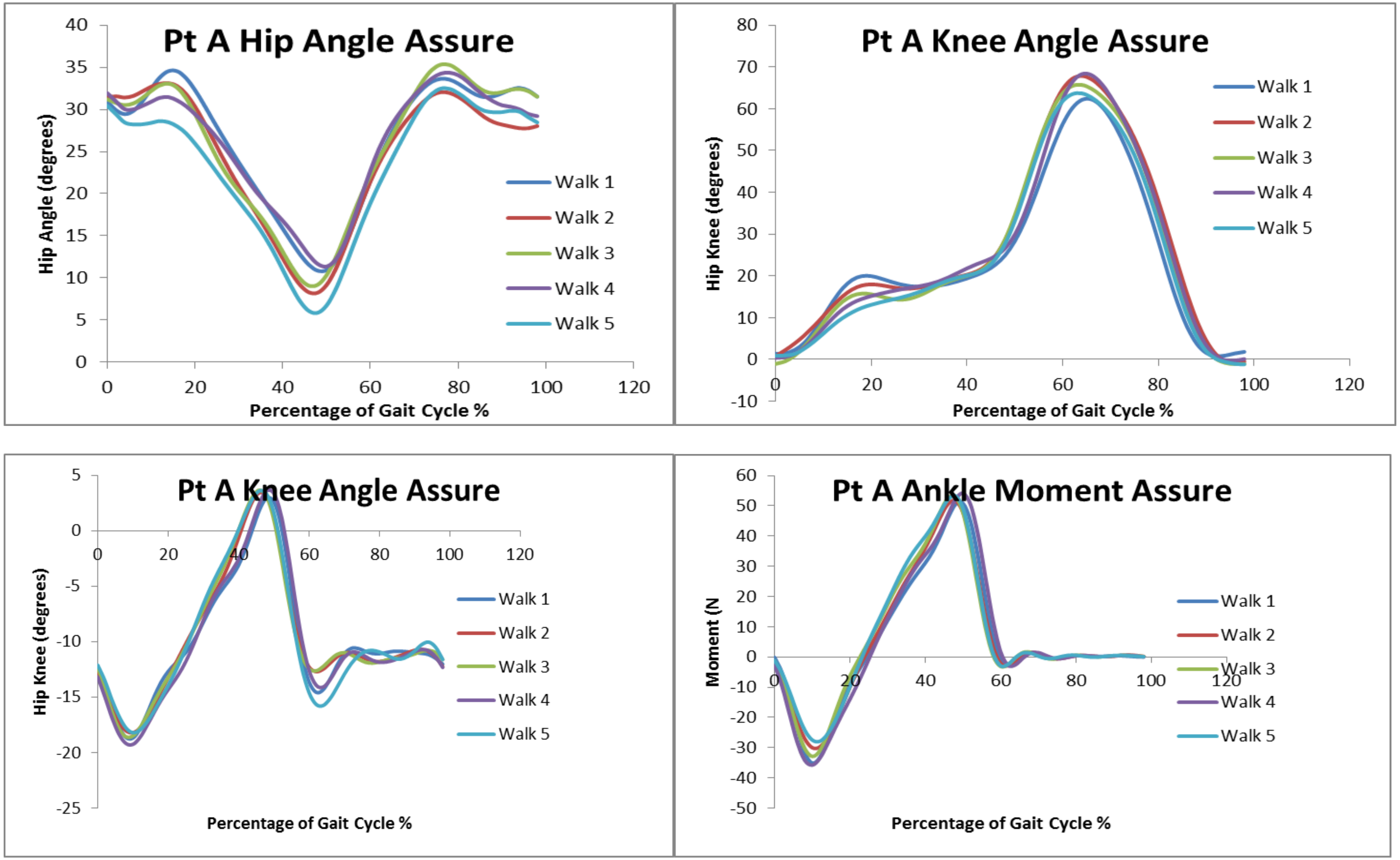


Figure 10.26 Pt A Angle and moment data for all walks with Assure foot (prosthetic side) all walks on slope

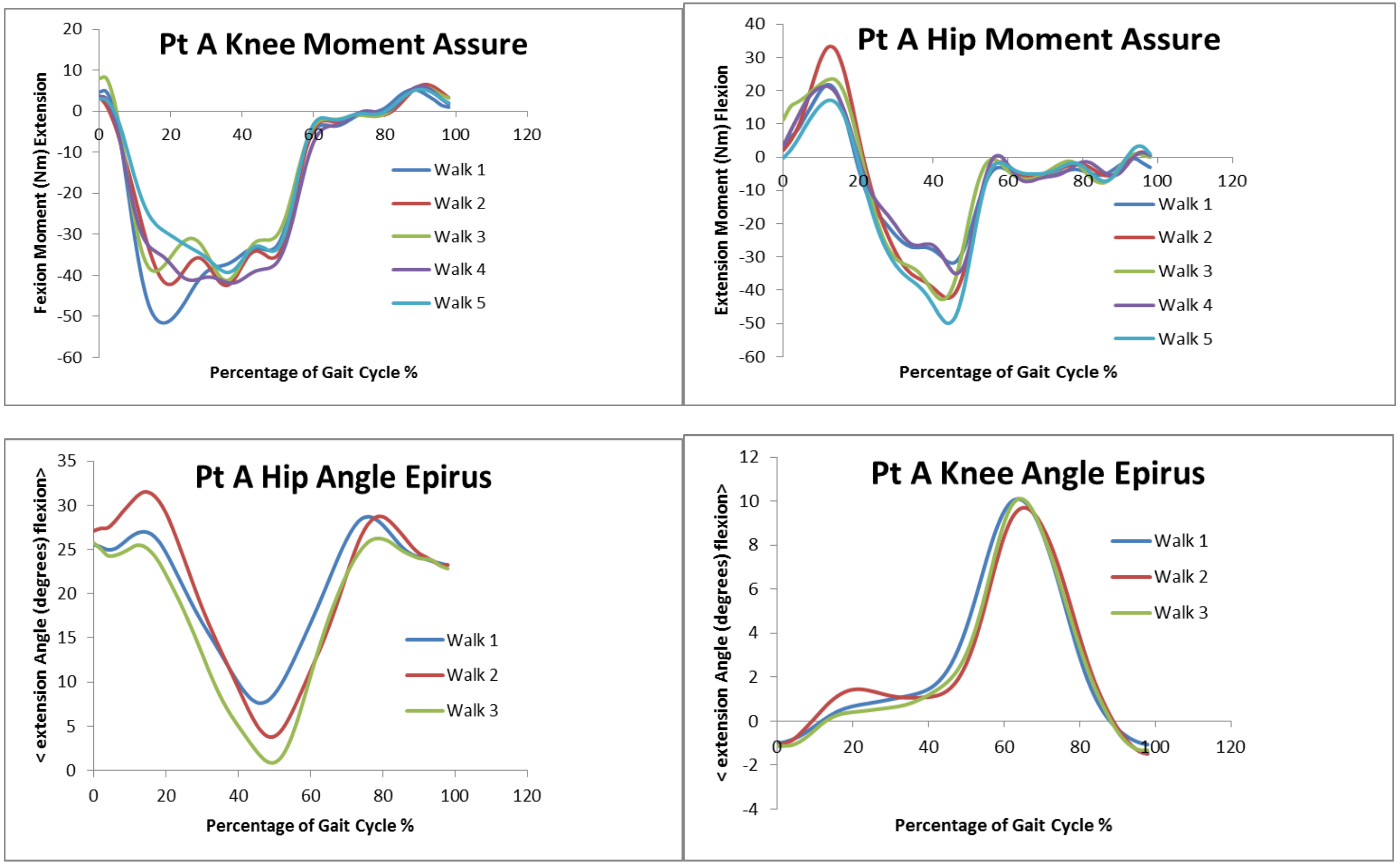


Figure 10.27 Pt A angle and moment data for assure and epirus feet (prosthetic side) all walks on slope

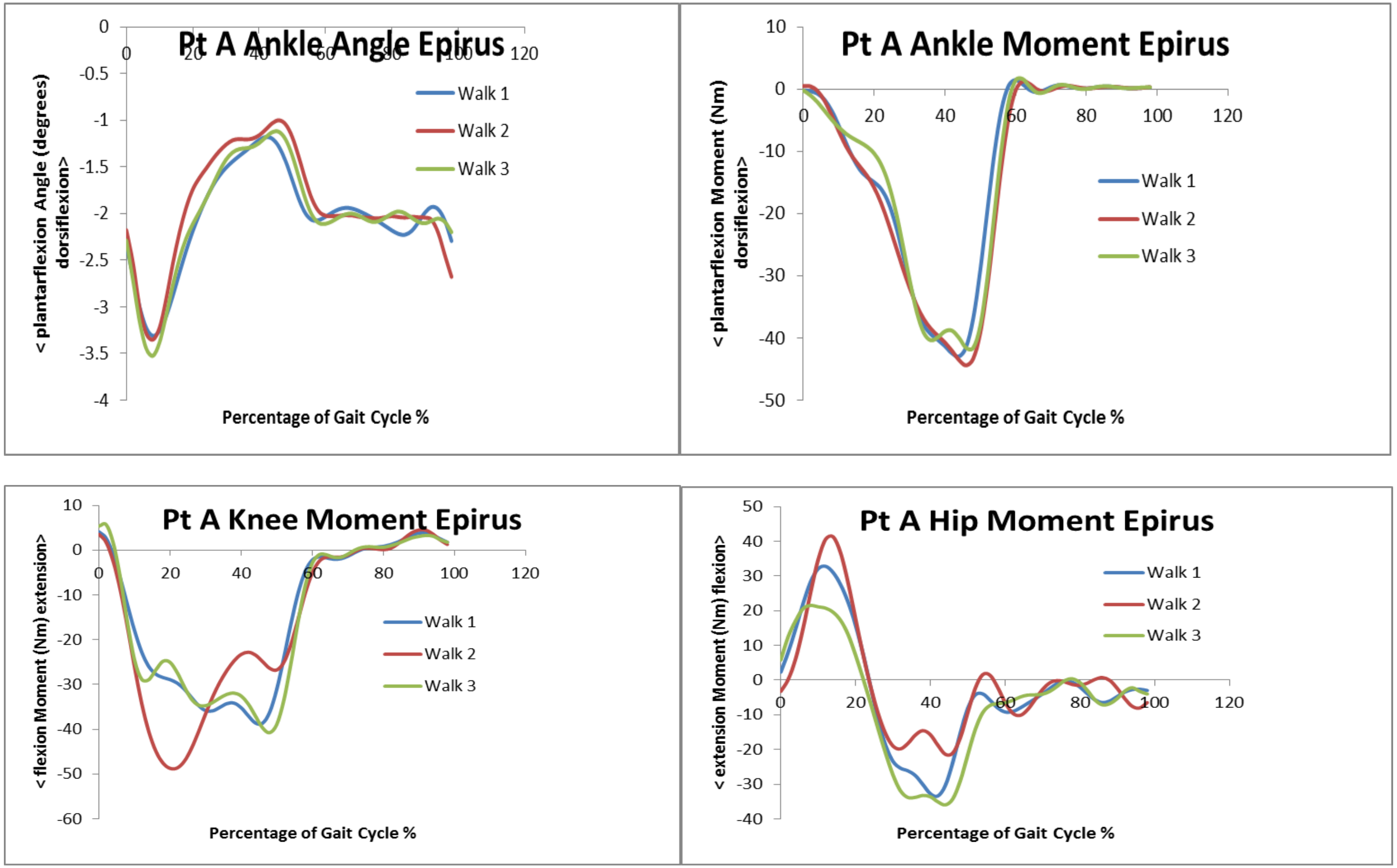


Figure 10.28 Pt A angle and moment data with epirus foot (prosthetic side) all walks on slope

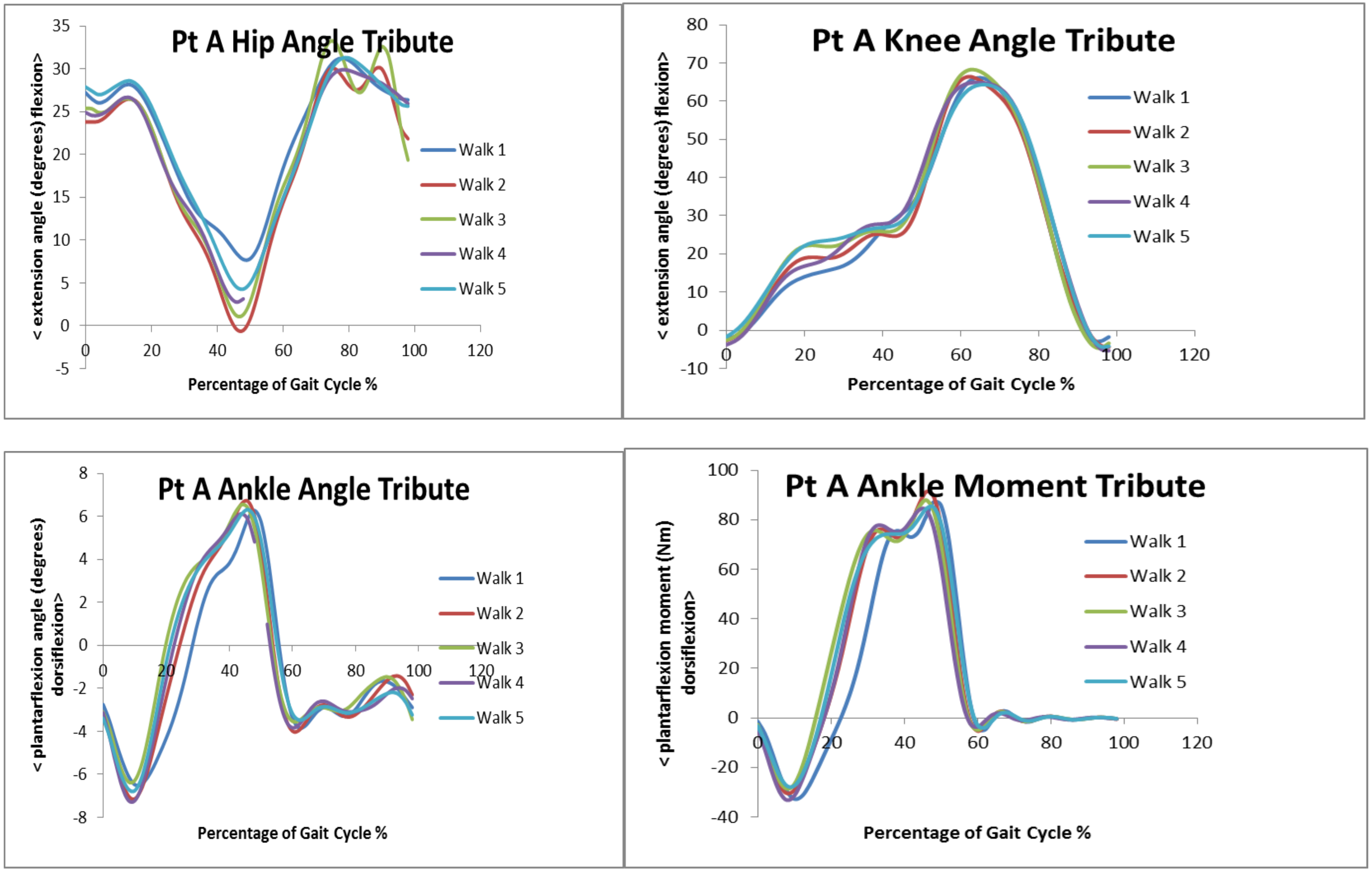


Figure 10.29 Pt Angle and moment data tribute foot (prosthetic side) all walks on slope

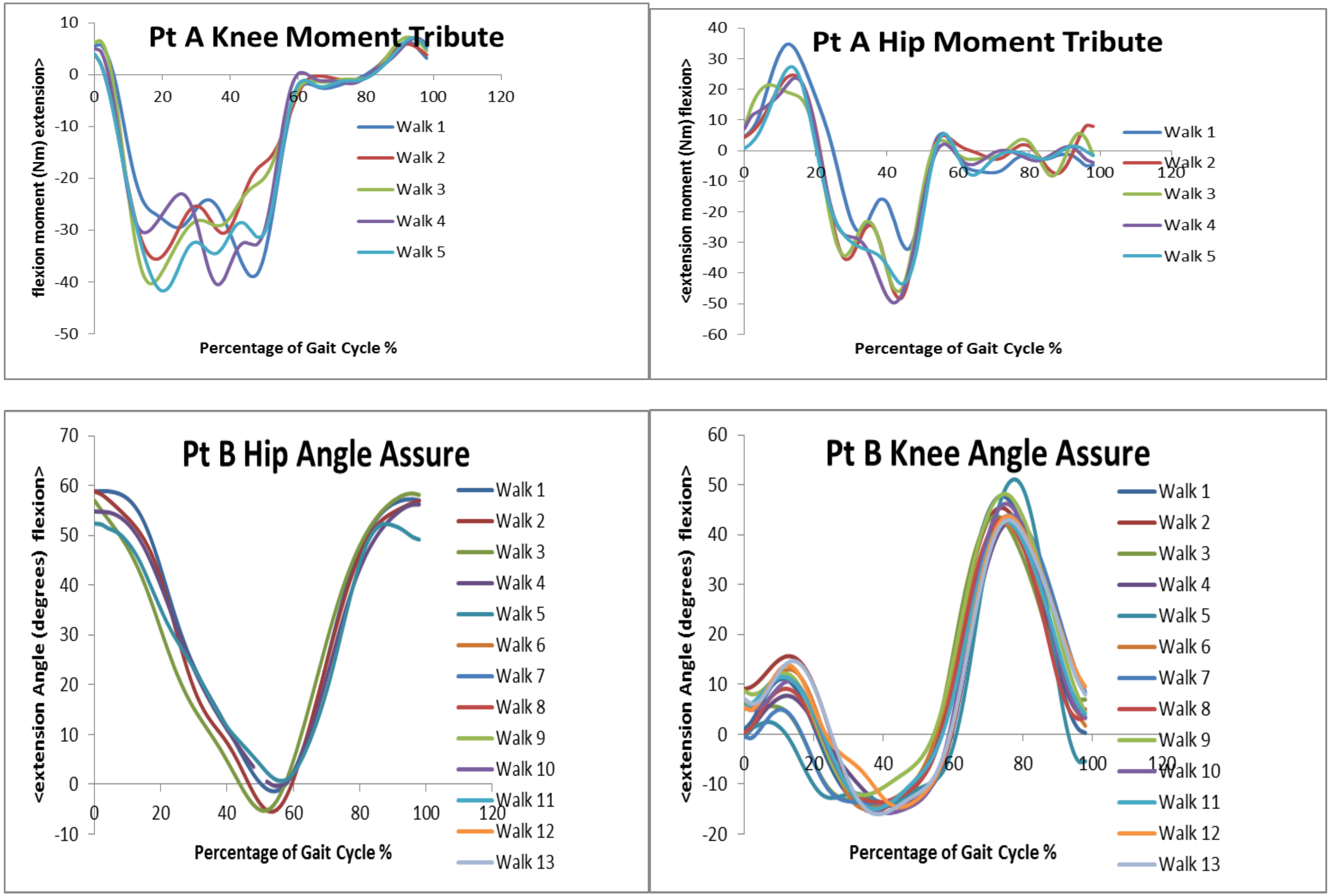


Figure 10.30 Pt A Angles and moments Tribute foot and Pt B angles and moments Assure foot (prosthetic side).

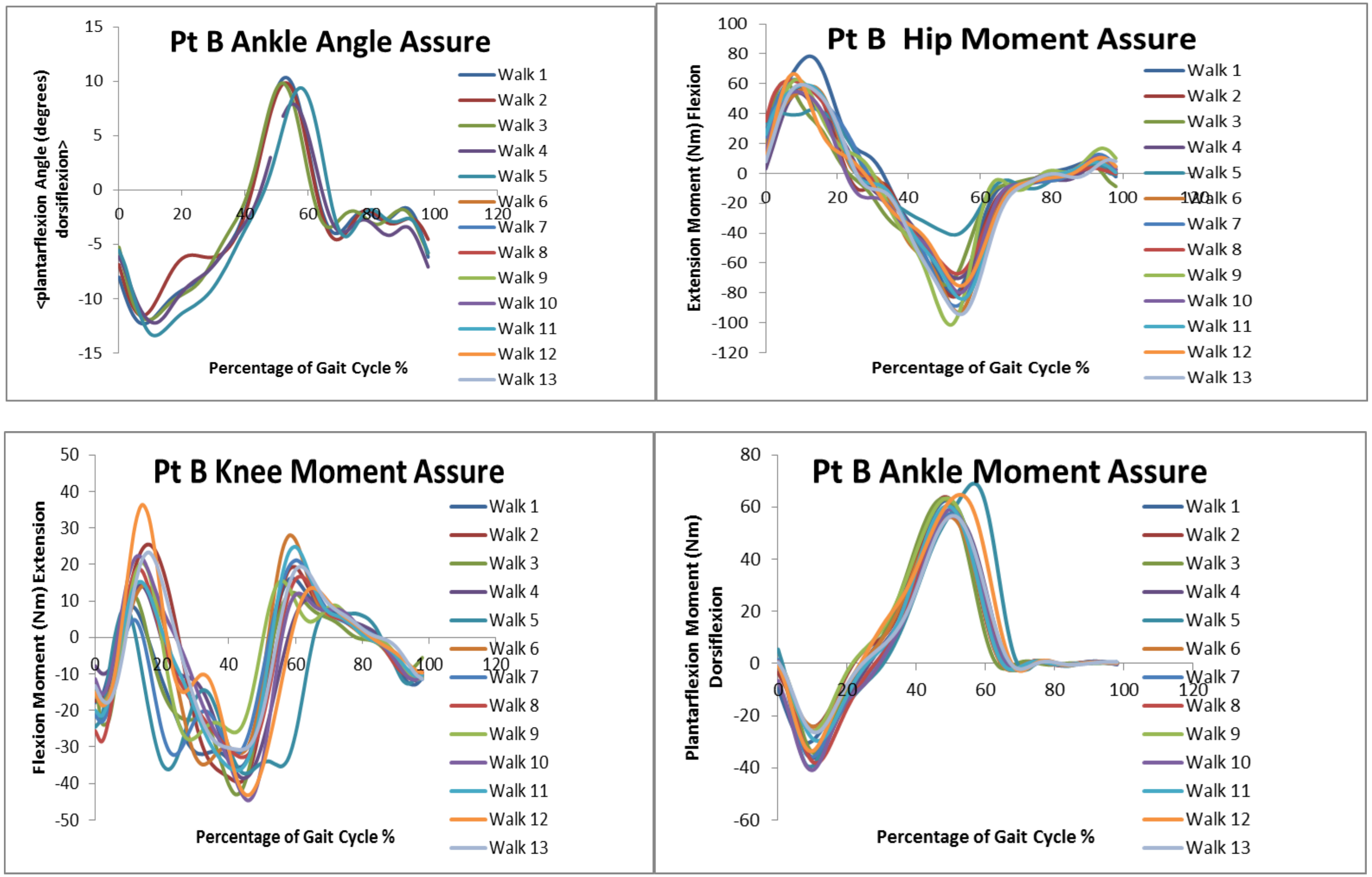


Figure 10.31 Pt B angles and moments Assure foot (prosthetic side) all walks on slope

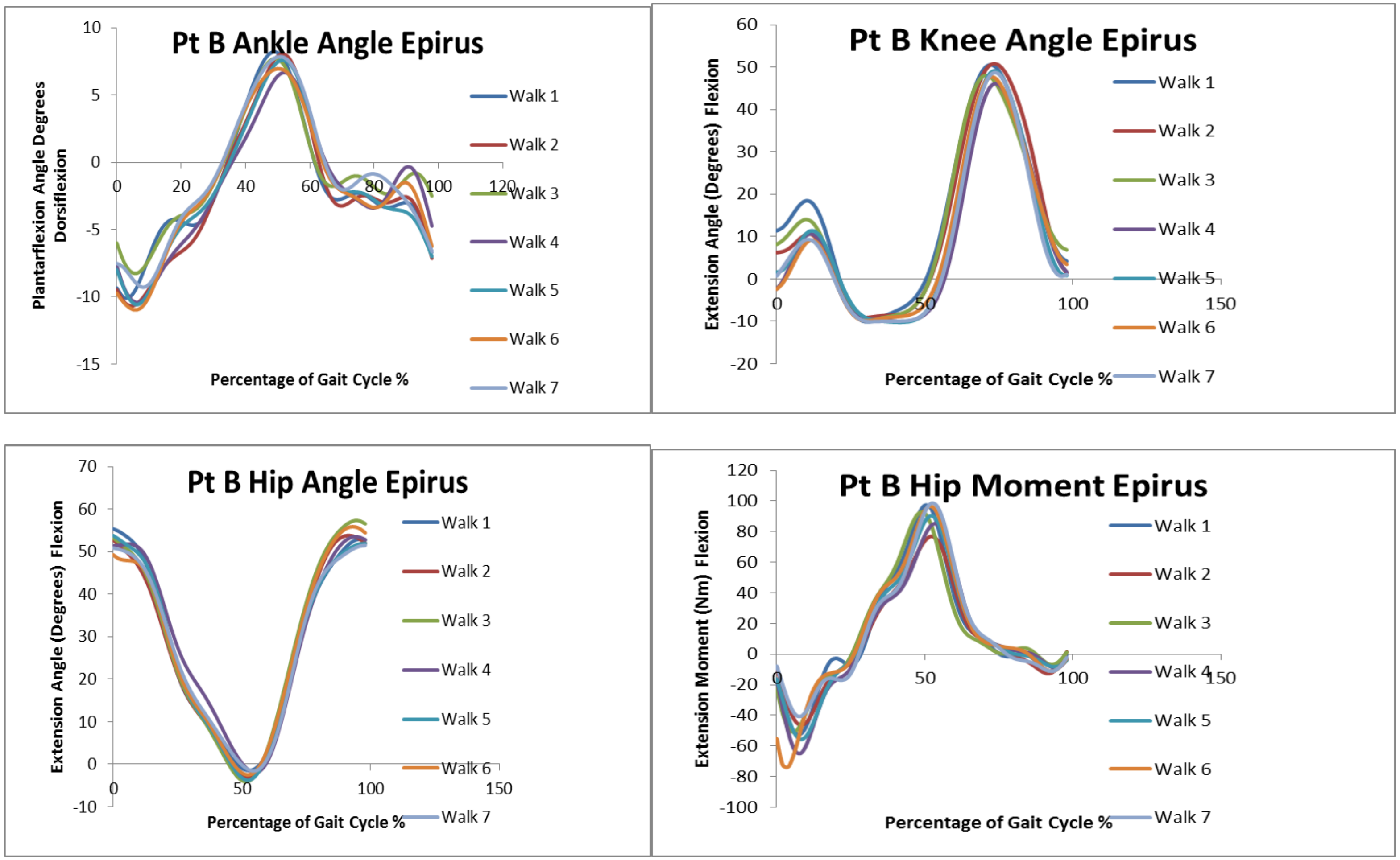


Figure 10.32 Pt B angles and moments epirus foot (prosthetic side) all walks on slope

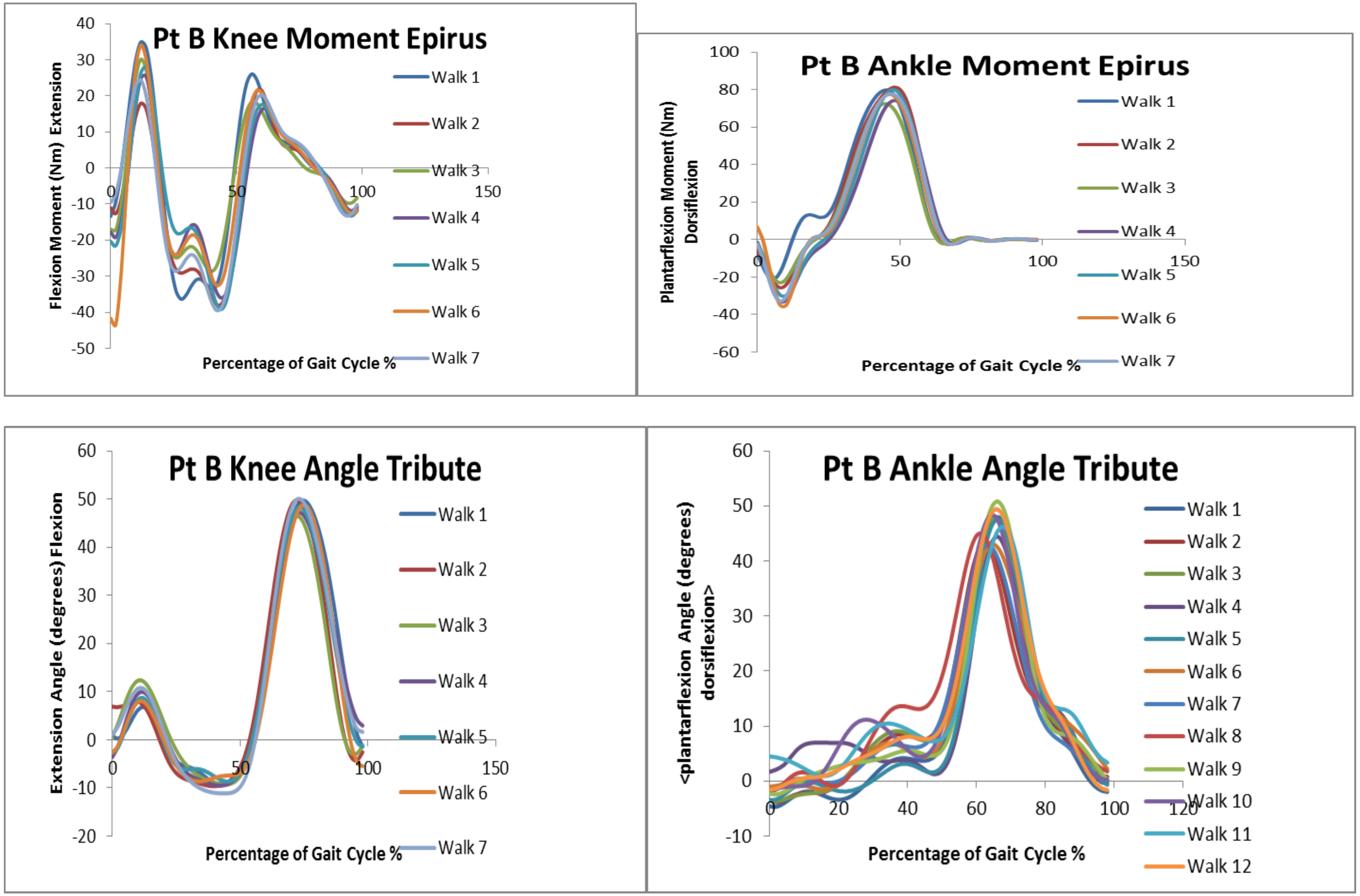


Figure 10.33 Pt B angles and moments epirus and tribute foot (prosthetic side) all walks on slope

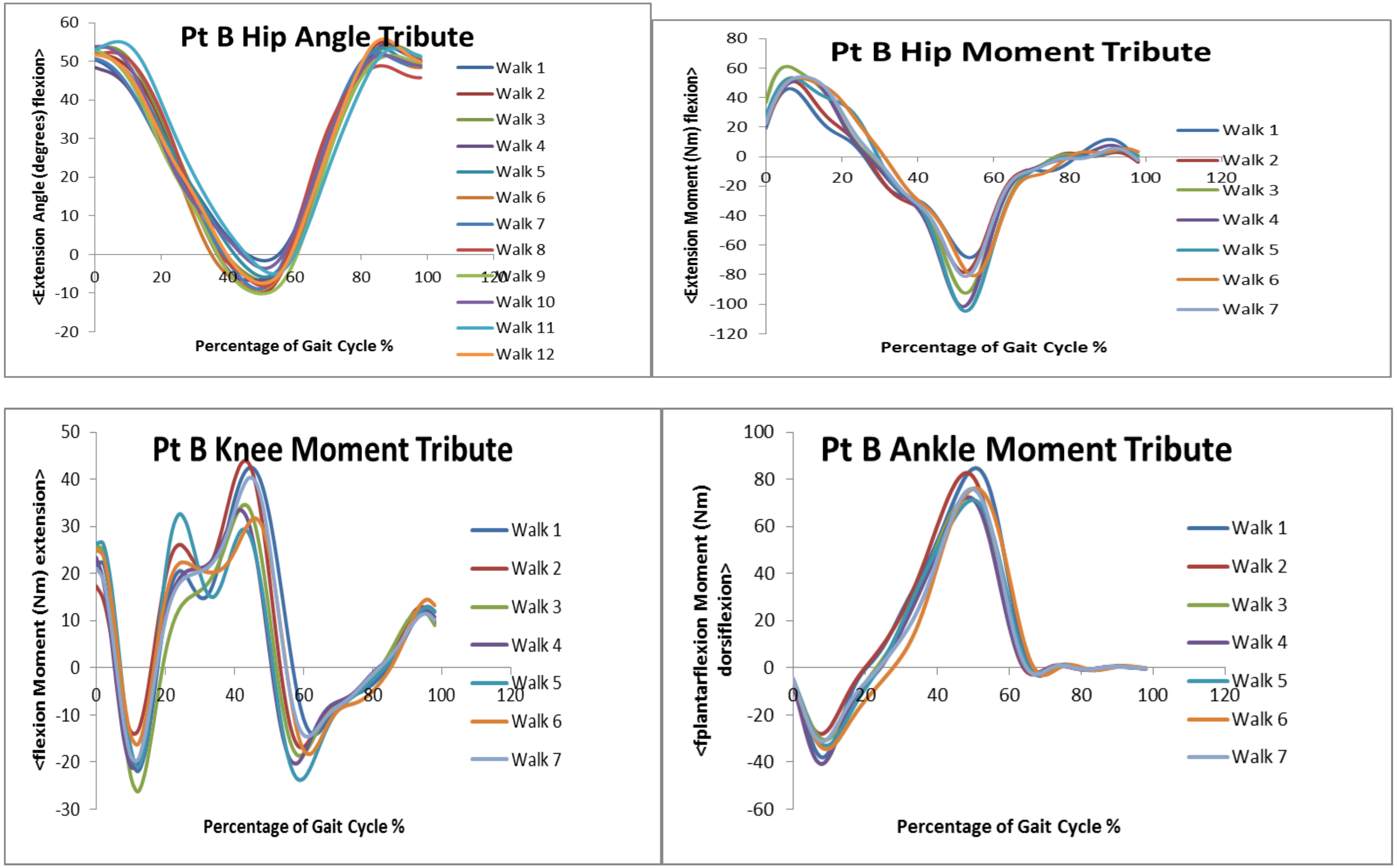


Figure 10.34 Pt B angles and moments tribute foot (prosthetic side) all walks on slope

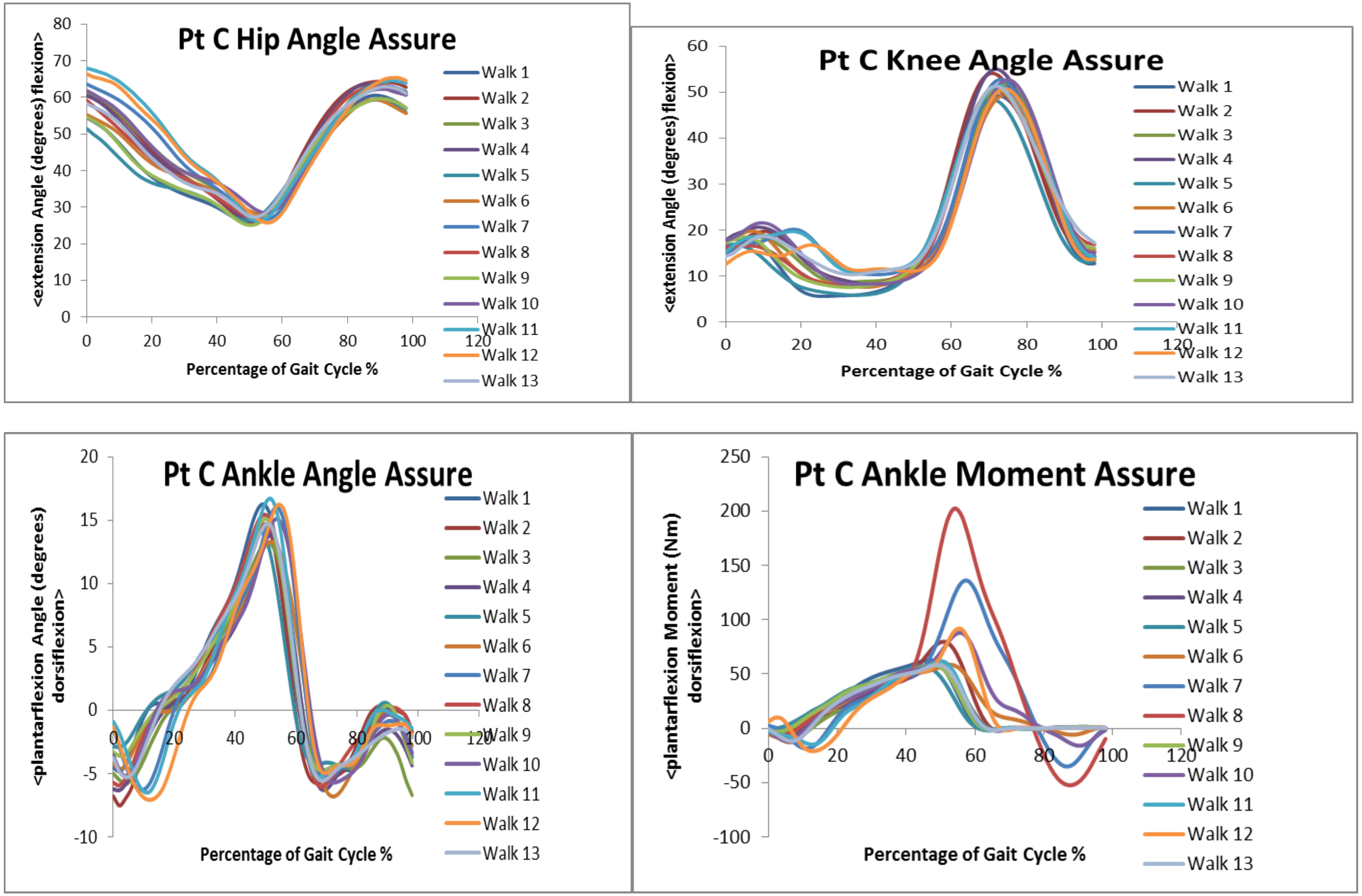


Figure 10.35 Pt C angles and moments assure foot (prosthetic side) all walks on slope

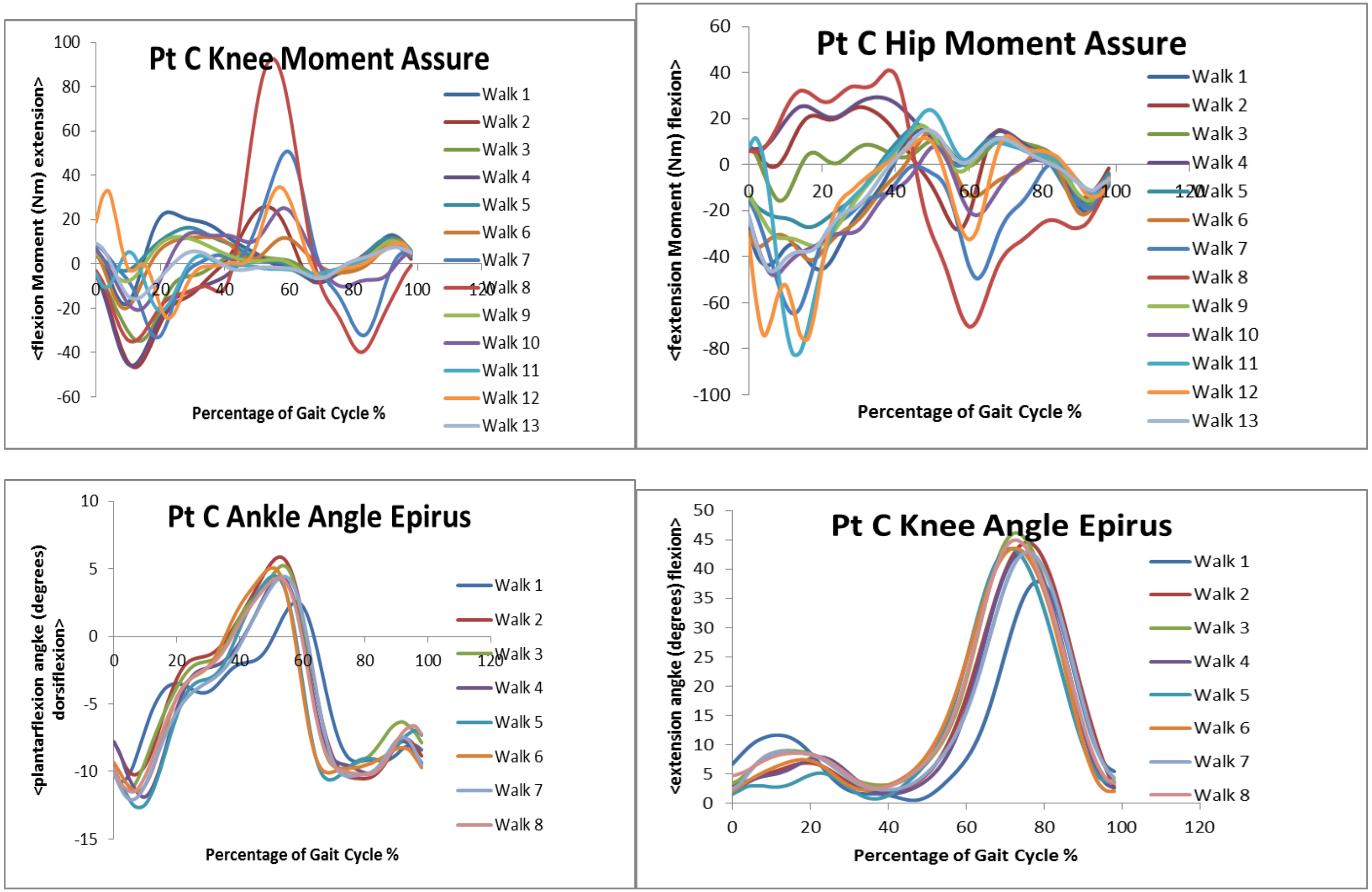


Figure 10.36 Pt C angles and moments assure and epirus foot (prosthetic side) all walks on slope

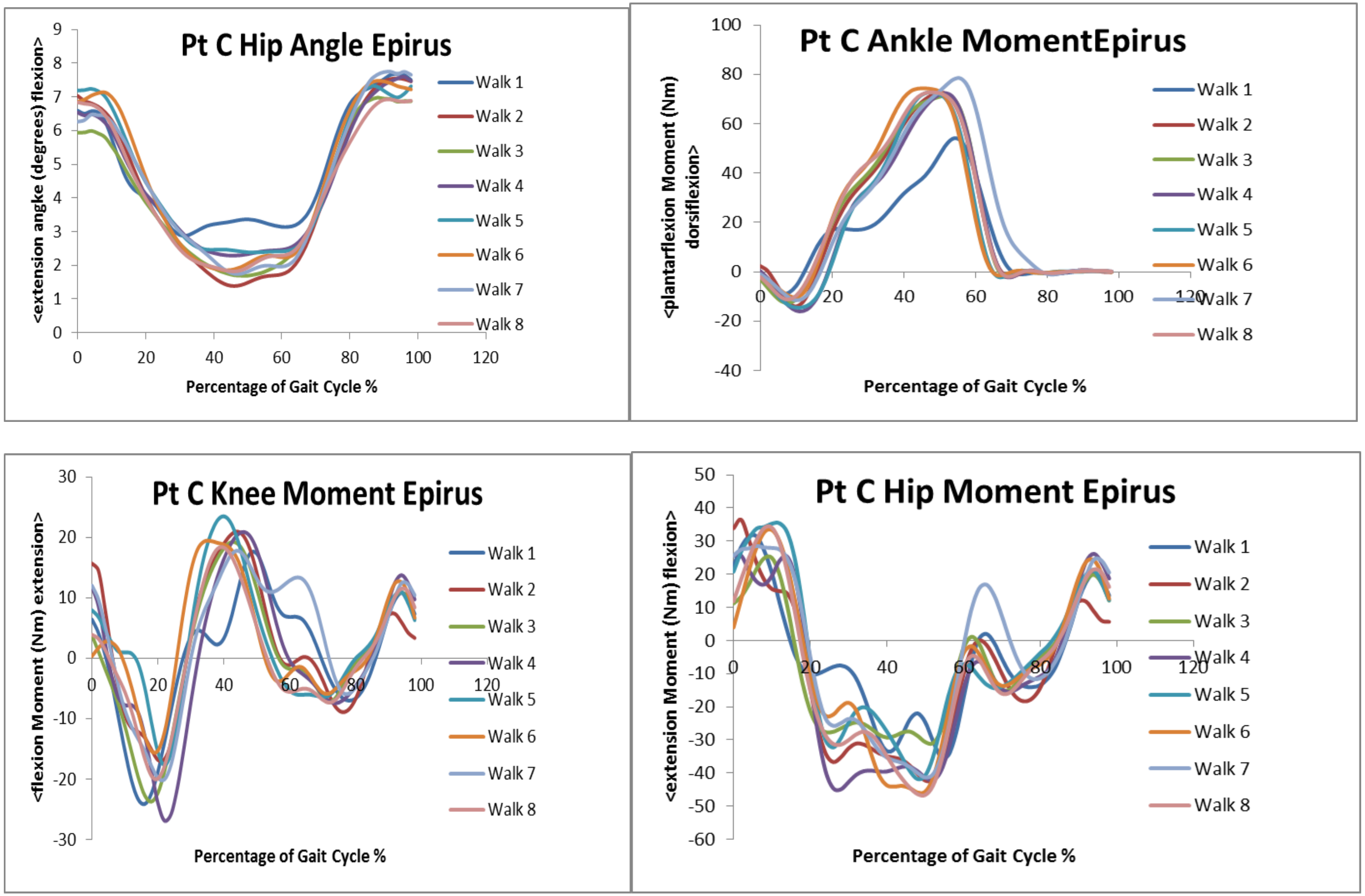


Figure 10.37 Pt C angles and moments epirus foot (prosthetic side) all walks on slope

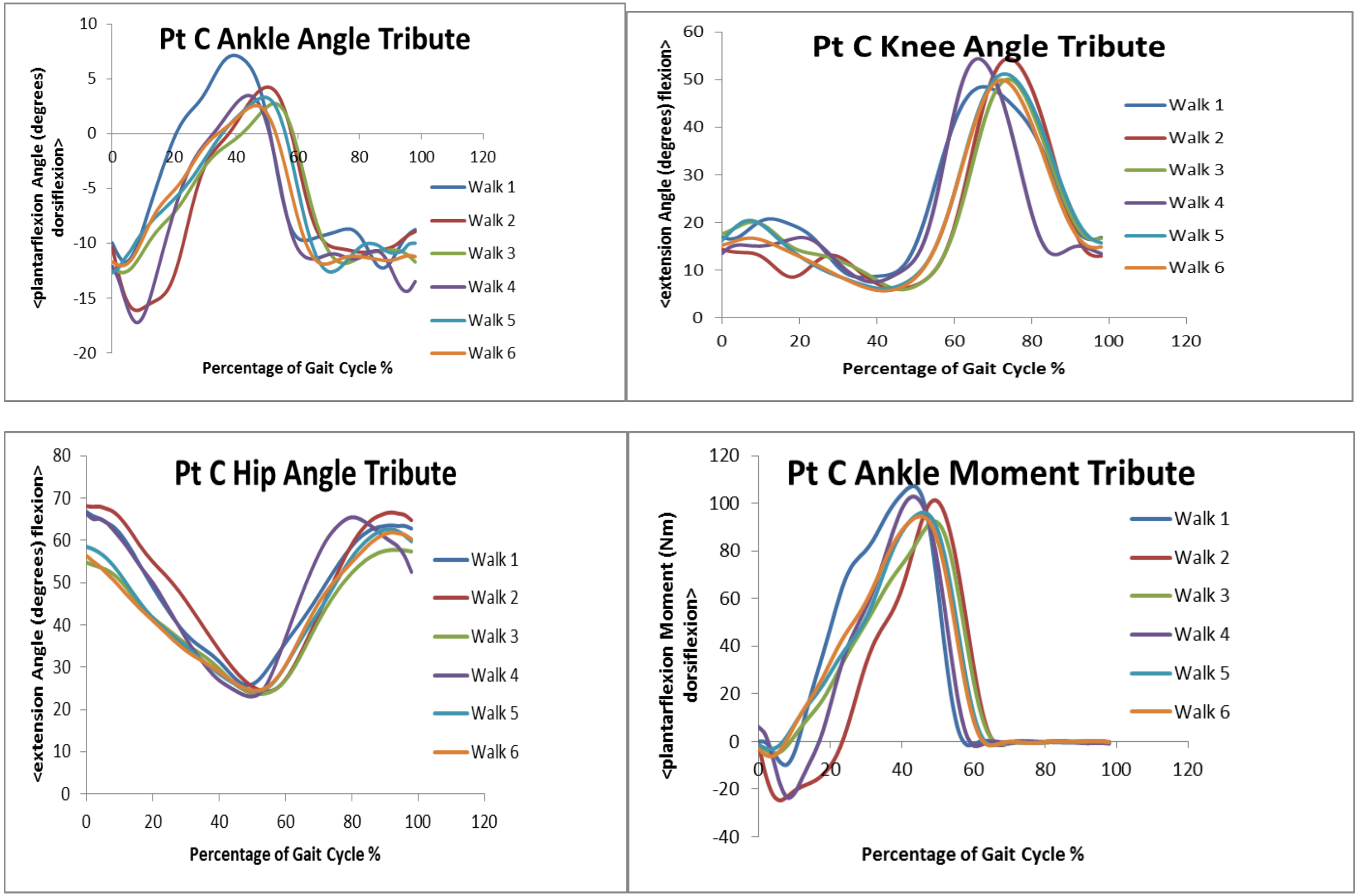


Figure 10.38 Pt C angles and moements tribute foot (prosthetic side) all walks on slope

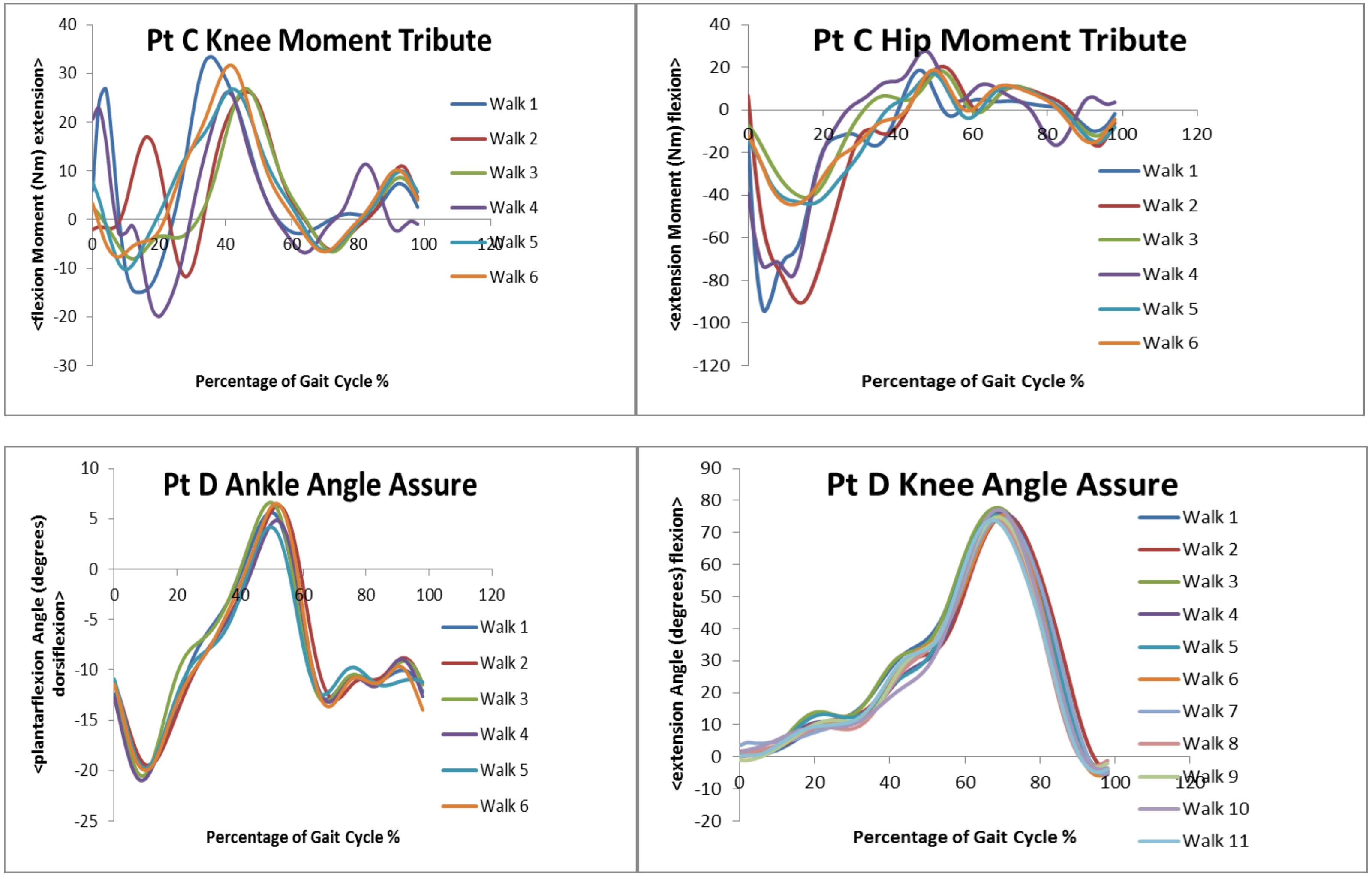


Figure 10.39 Pt C tribute foot and Pt D assure foot angles and moments (prosthetic side) all walks on slope

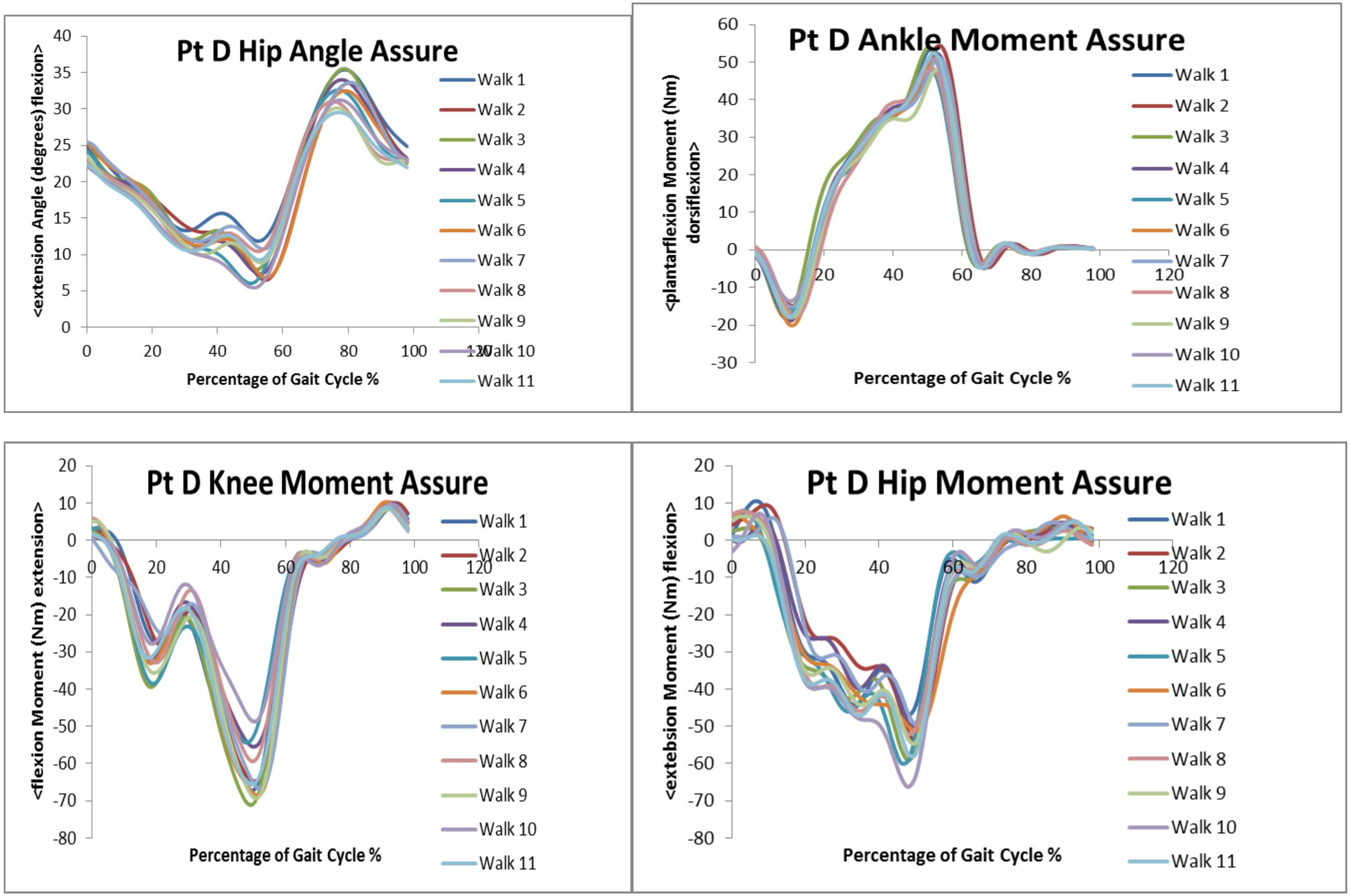


Figure 10.40 Pt D assure foot angles and moments (prosthetic foot) all walks on slope

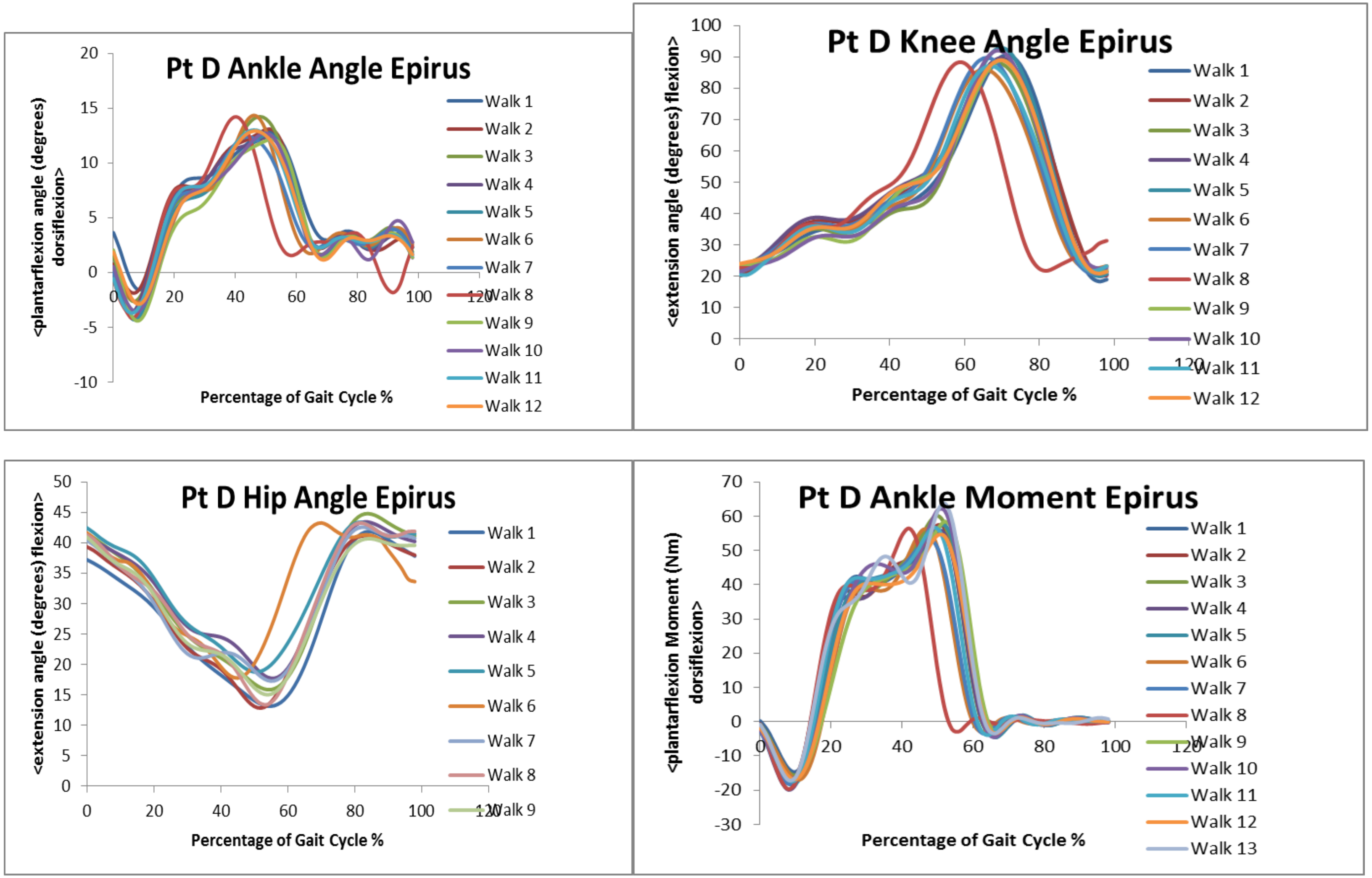


Figure 10.41 Pt D epirus foot angles and moments (prosthetic side) all walks on slope

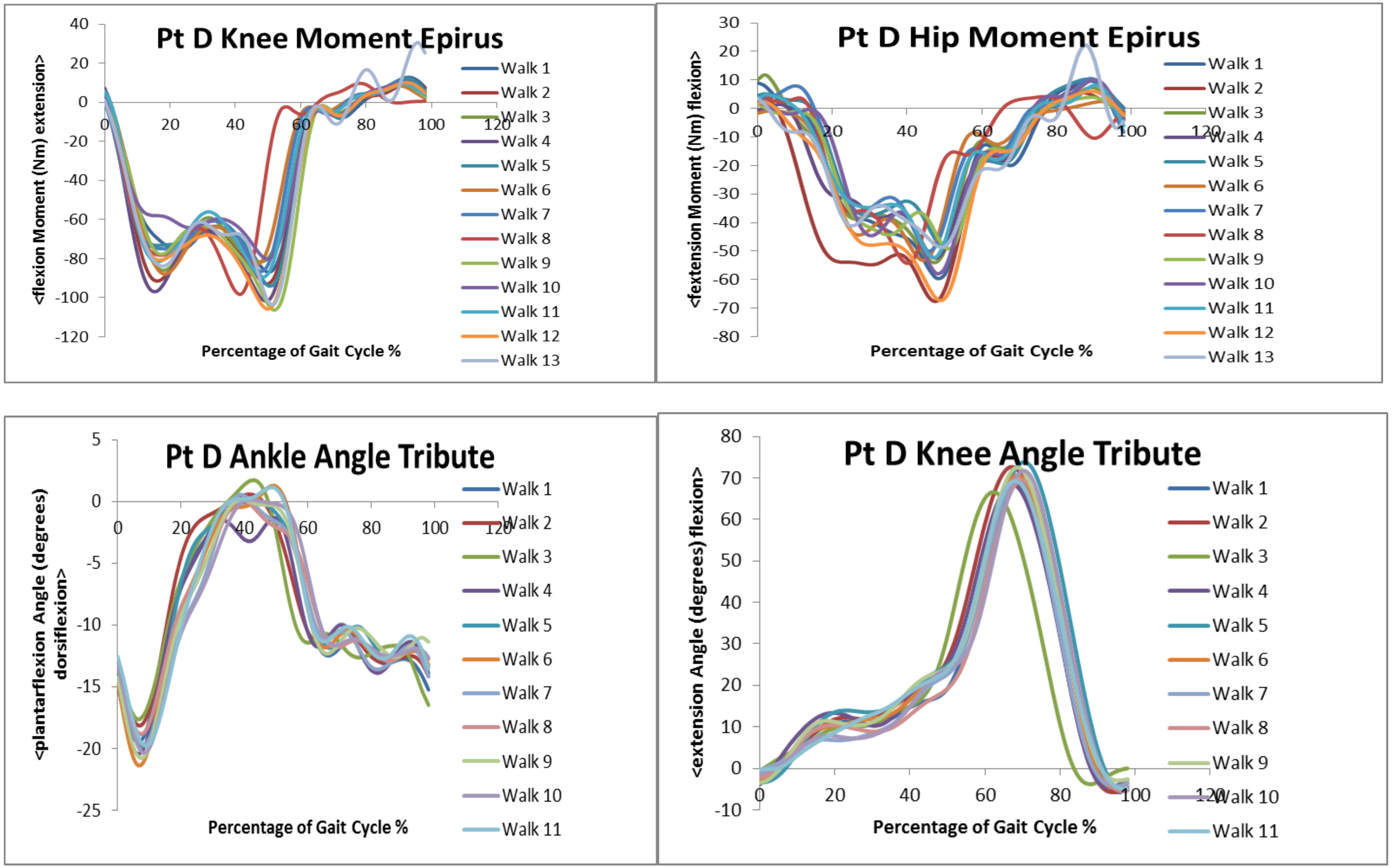


Figure 10.42 Pt D epirus and tribute foot angles and moments (prosthetic side) all walks on slope

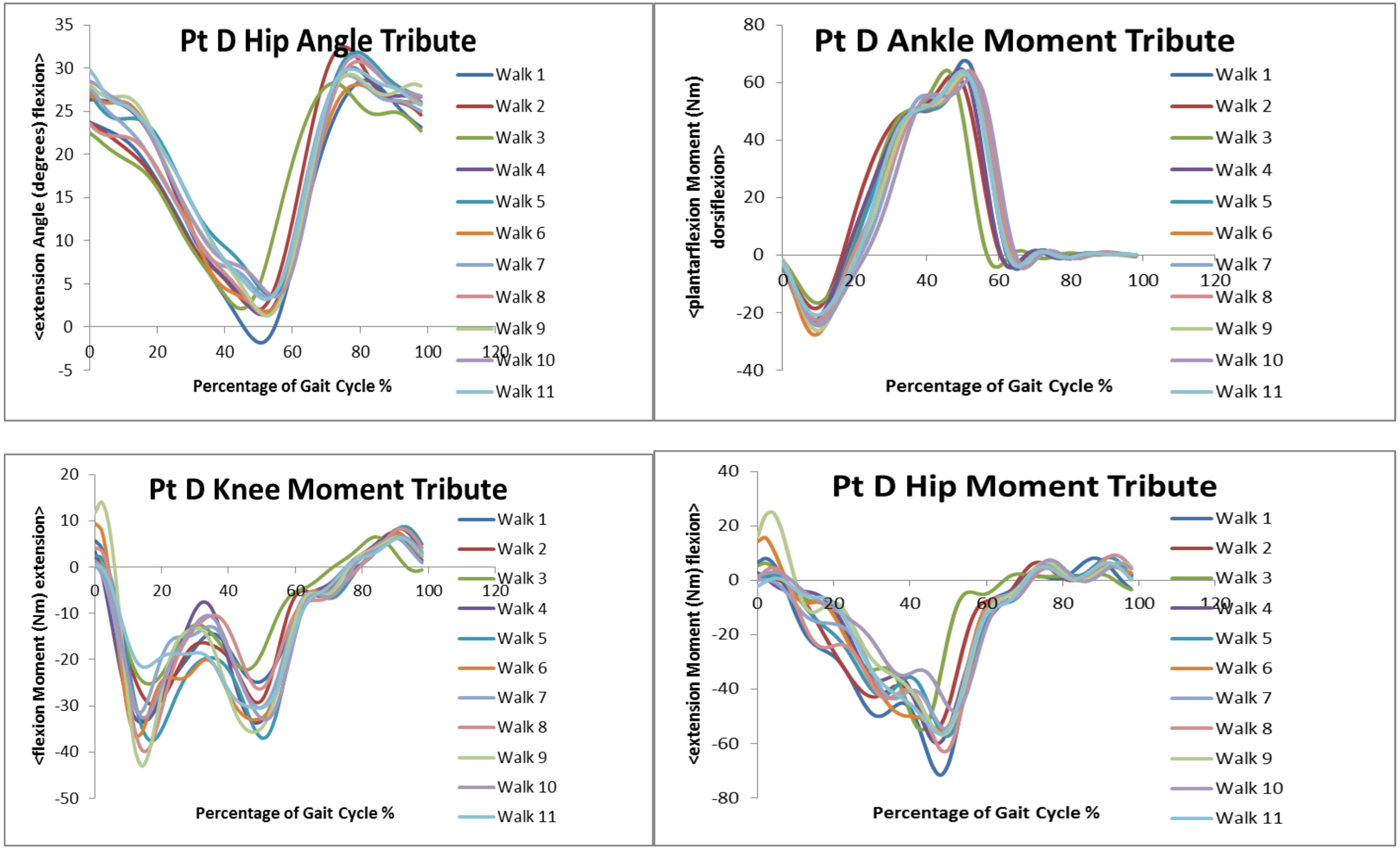


Figure 10.43 Pt D angles and moment tribute foot (posthetic side) all walks on slope

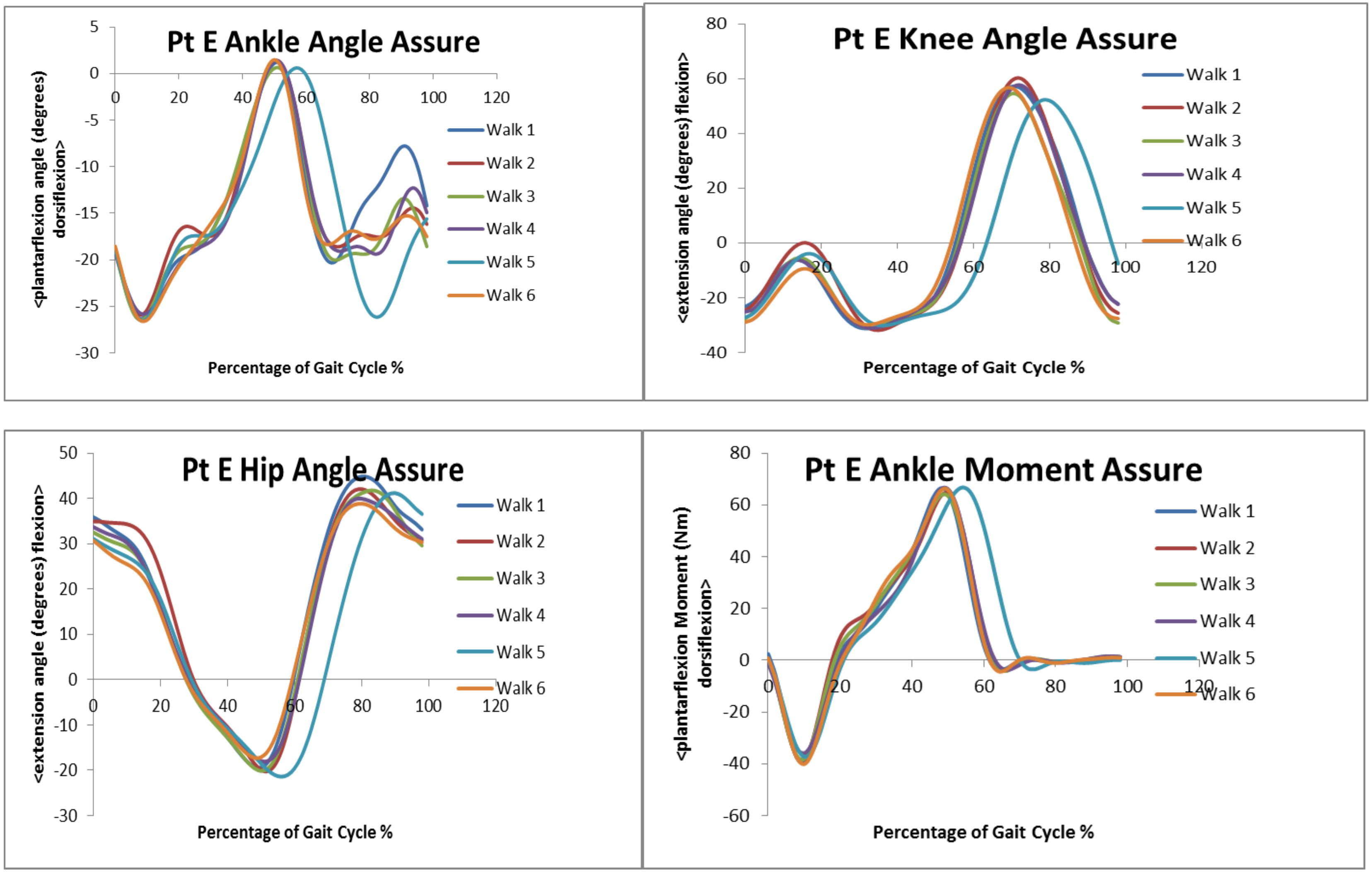


Figure 10.44 Pt E assure foot angles and moments (prosthetic side) all walks on slope

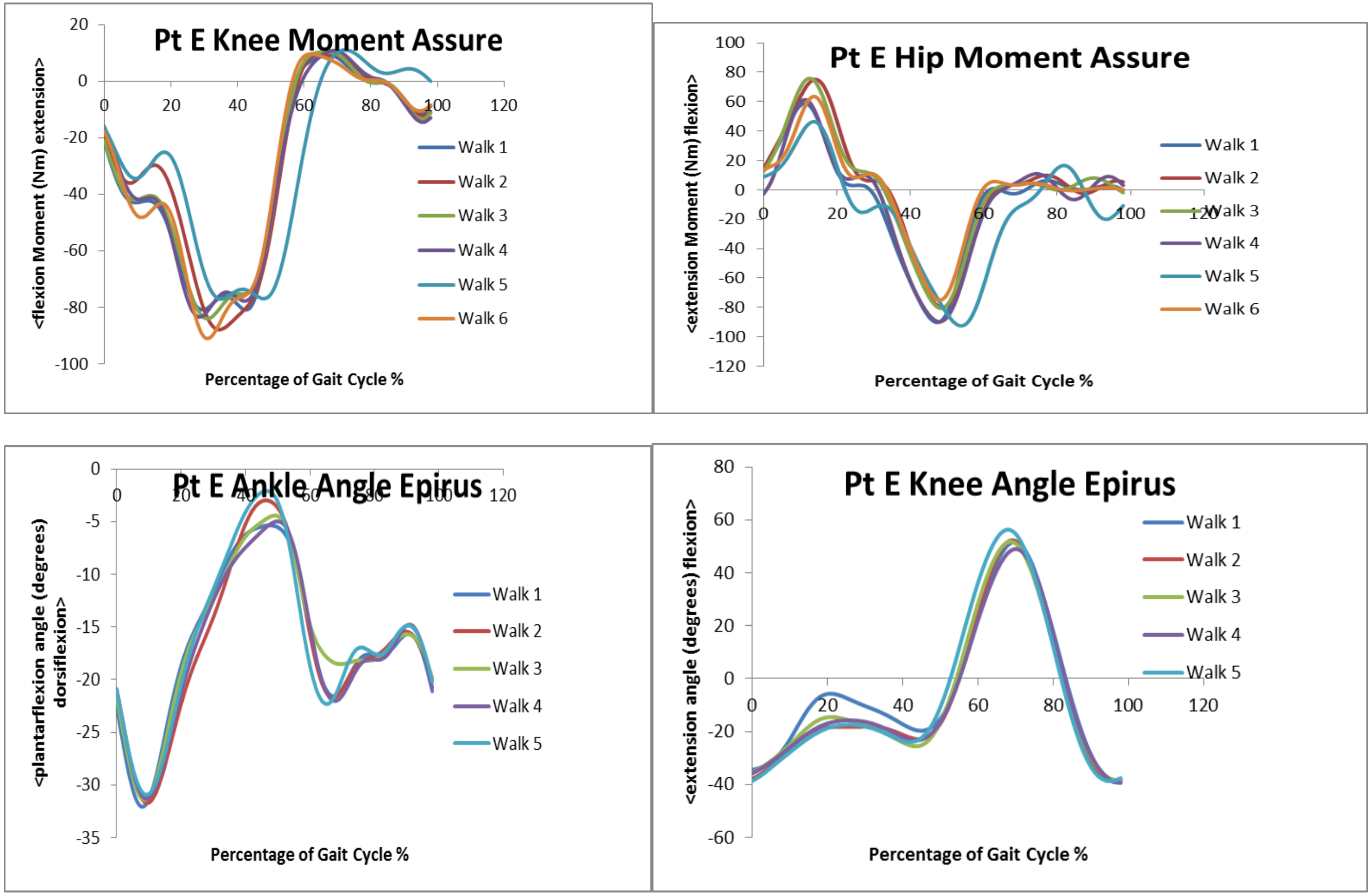


Figure 10.45 Pt E assure and epirus foot angles and moments (prosthetic side) all walks on slope

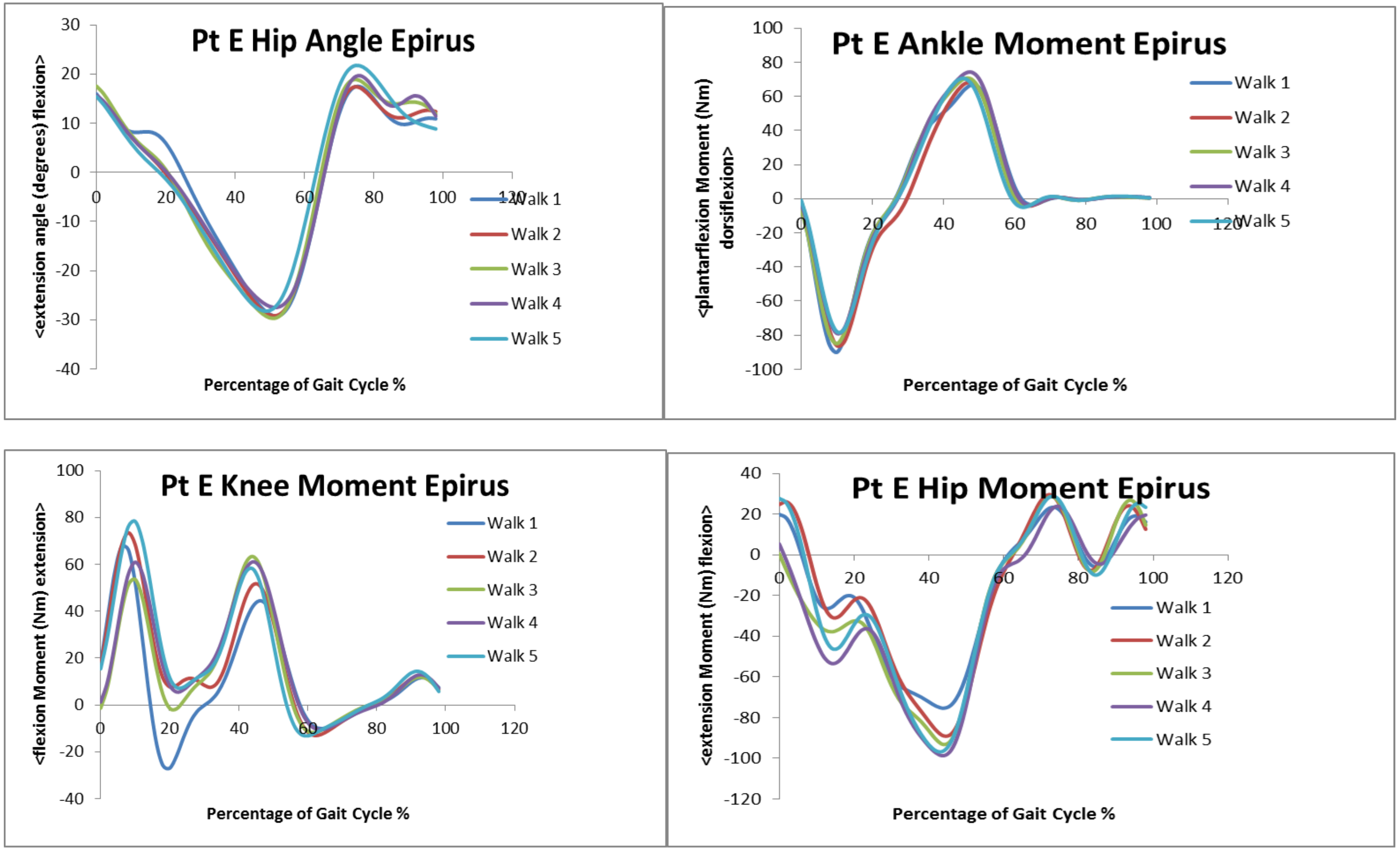


Figure 10.46 Pt E epirus foot angles and moments (prosthetic side) all walks on slope

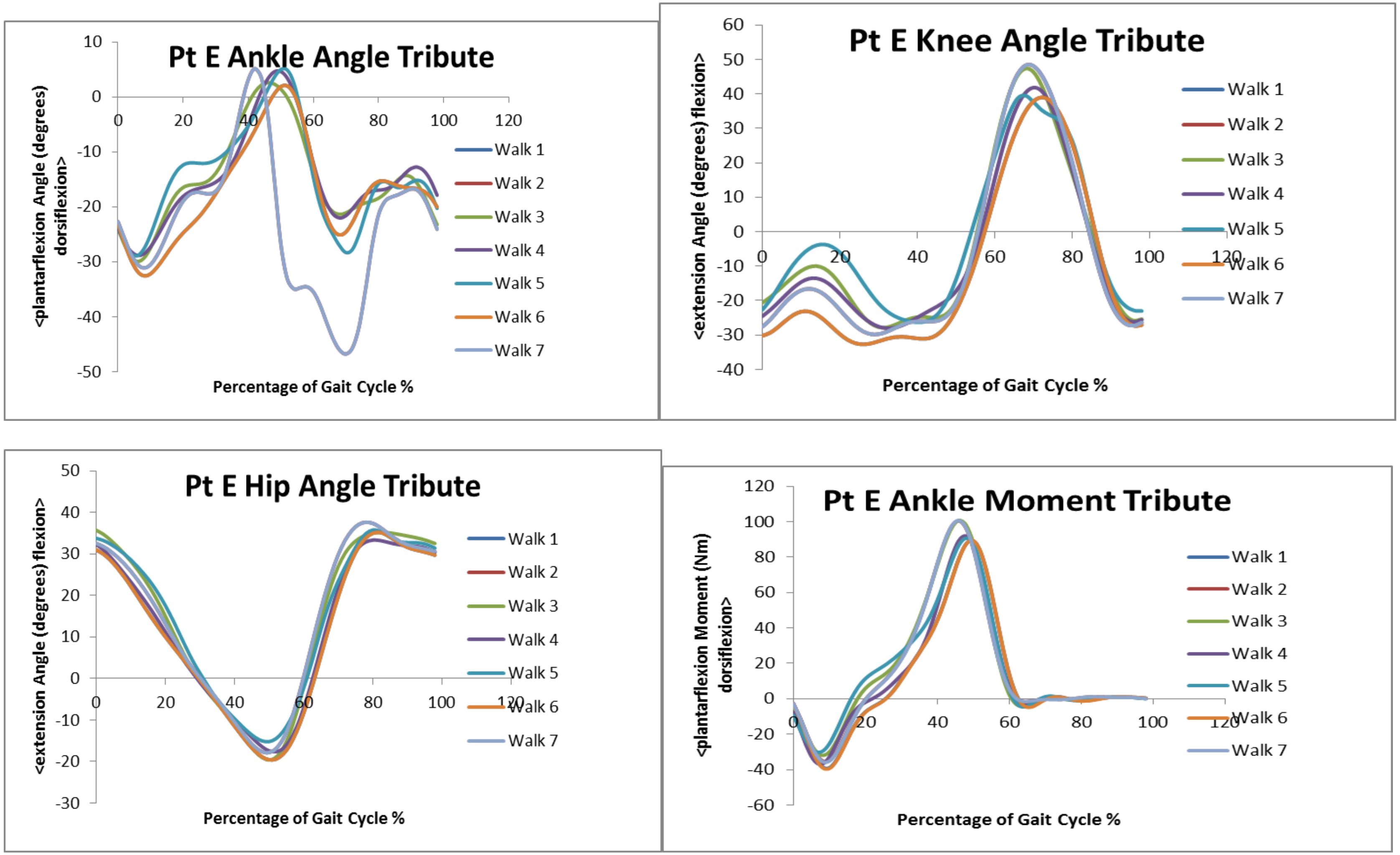


Figure 10.47 Pt E tribute foot angles and moments (prosthetic side) all walks on slope

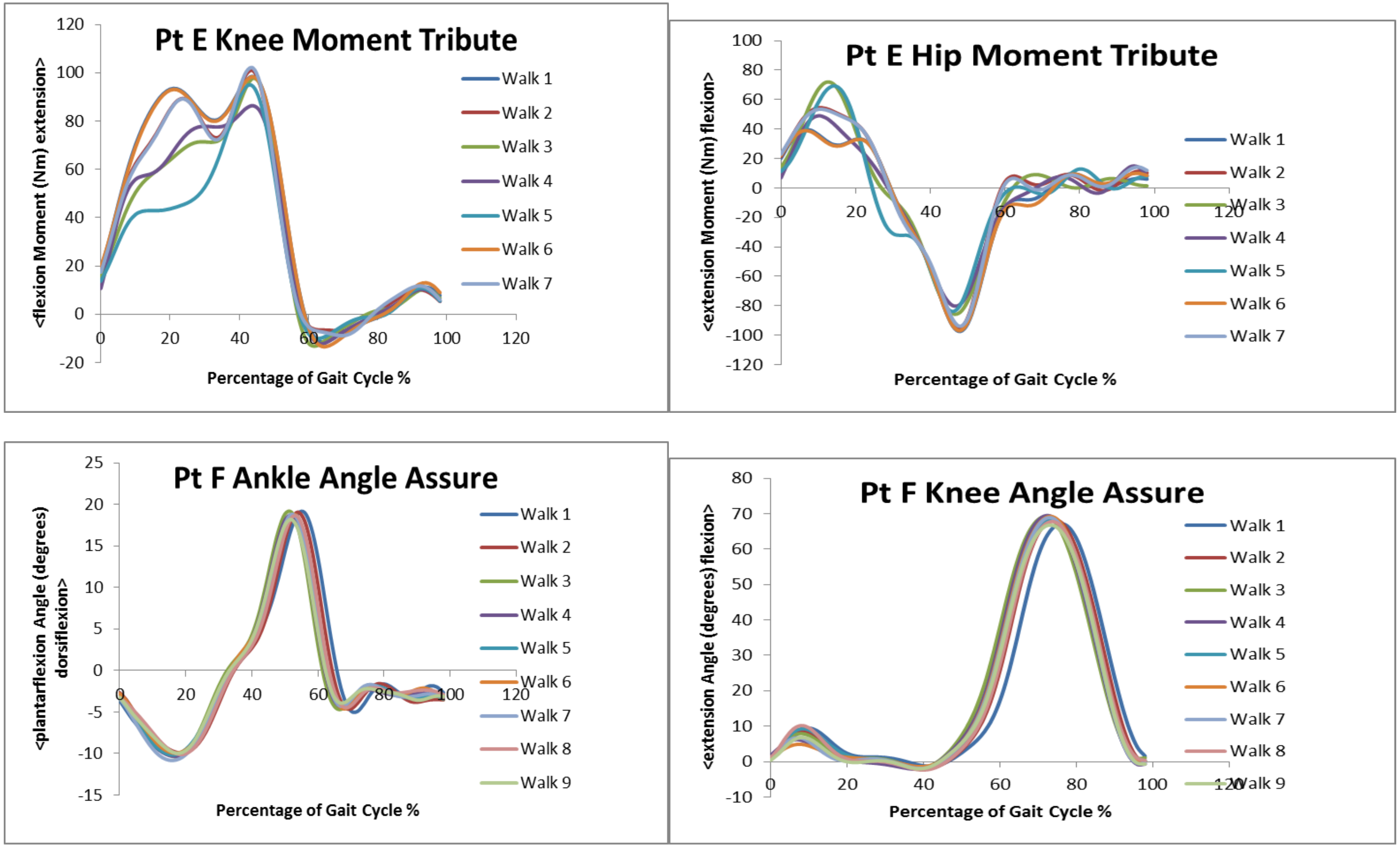


Figure 10.48 Pt E tribute and assure foot angles and moments (prosthetic side) all walks on slope

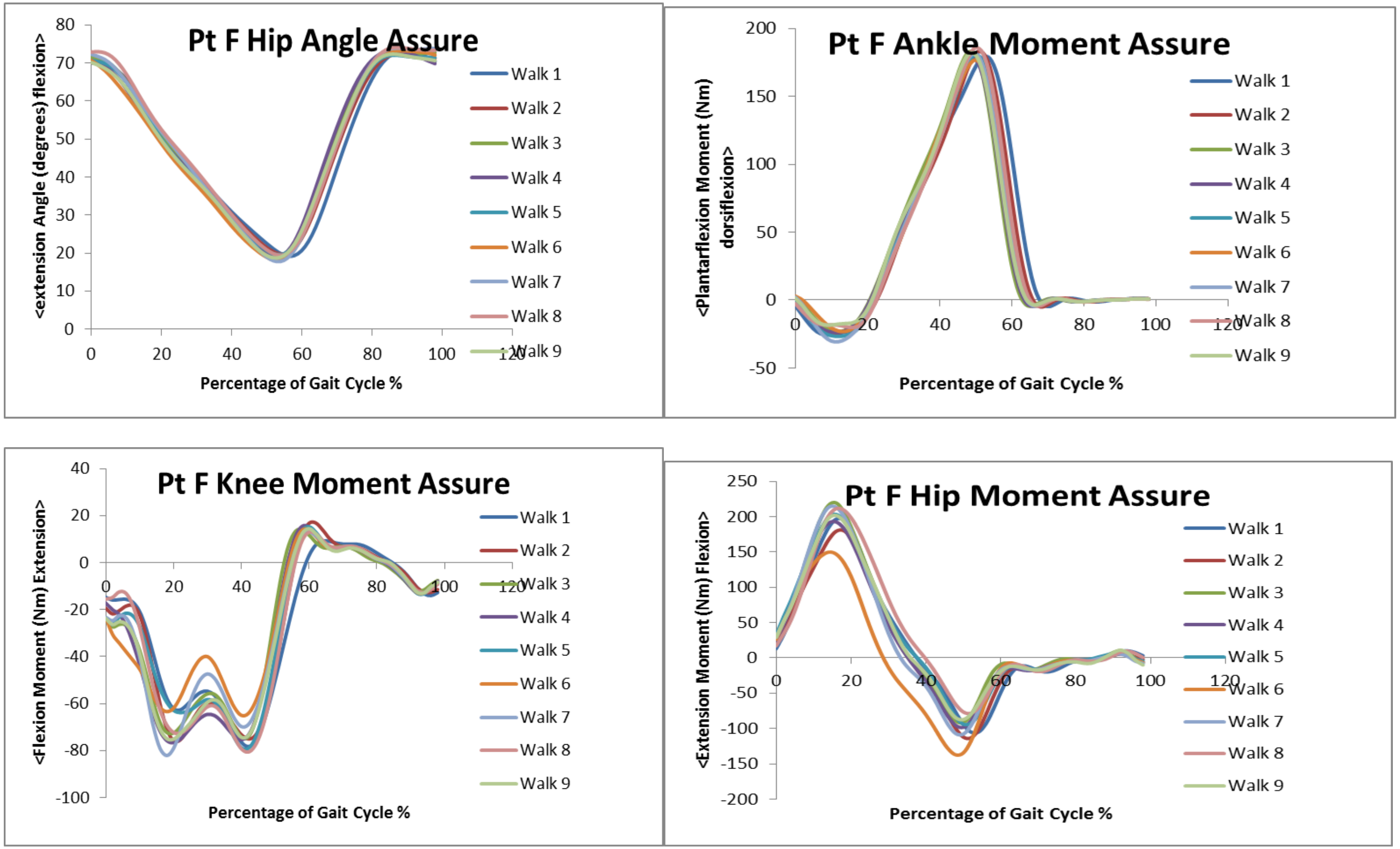


Figure 10.49 Pt F assure foot angles and moments (prosthetic side) all walks on slope

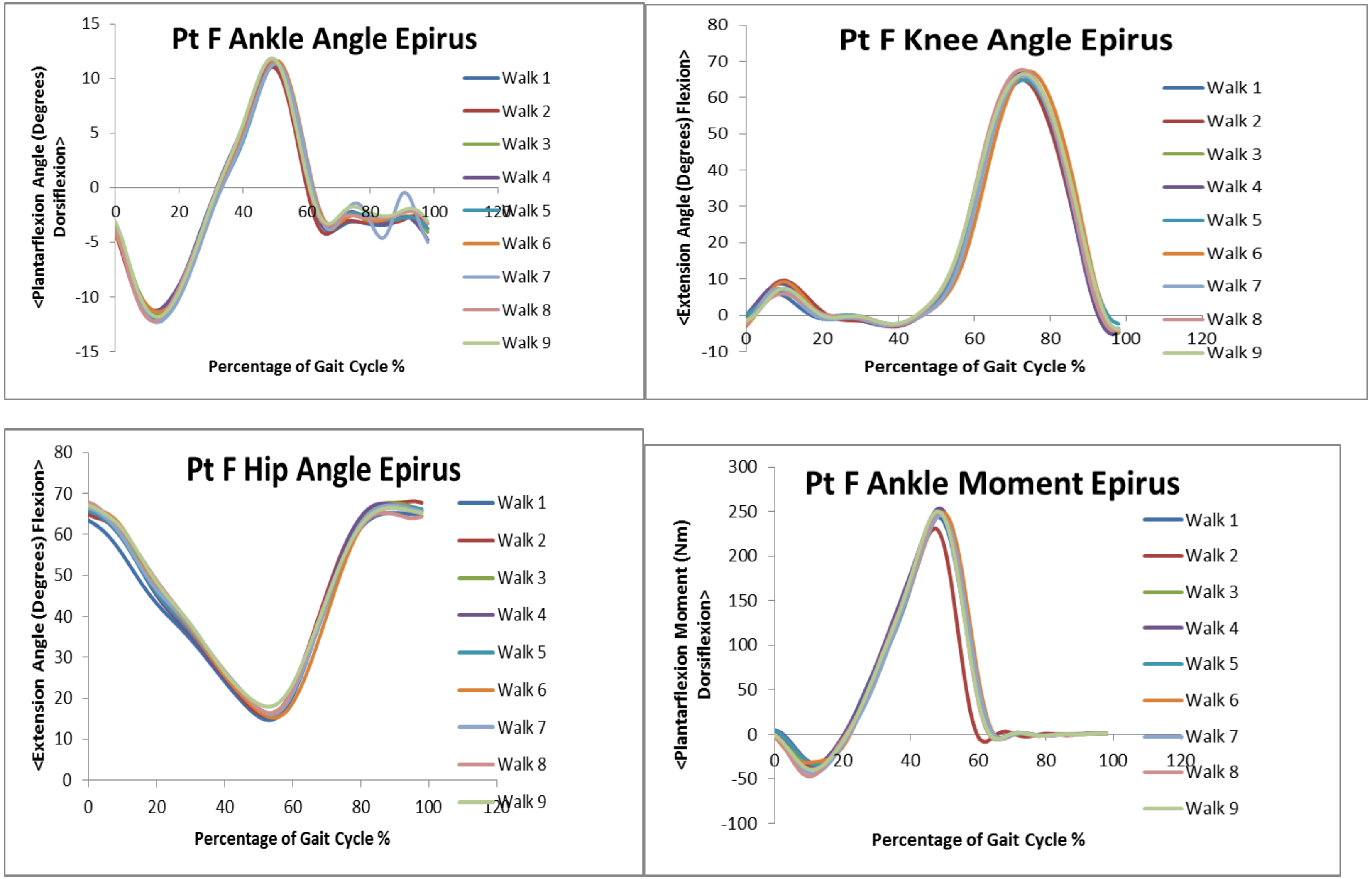


Figure 10.50 Pt F epirus foot angles and moments (prosthetic side) all walks on slope

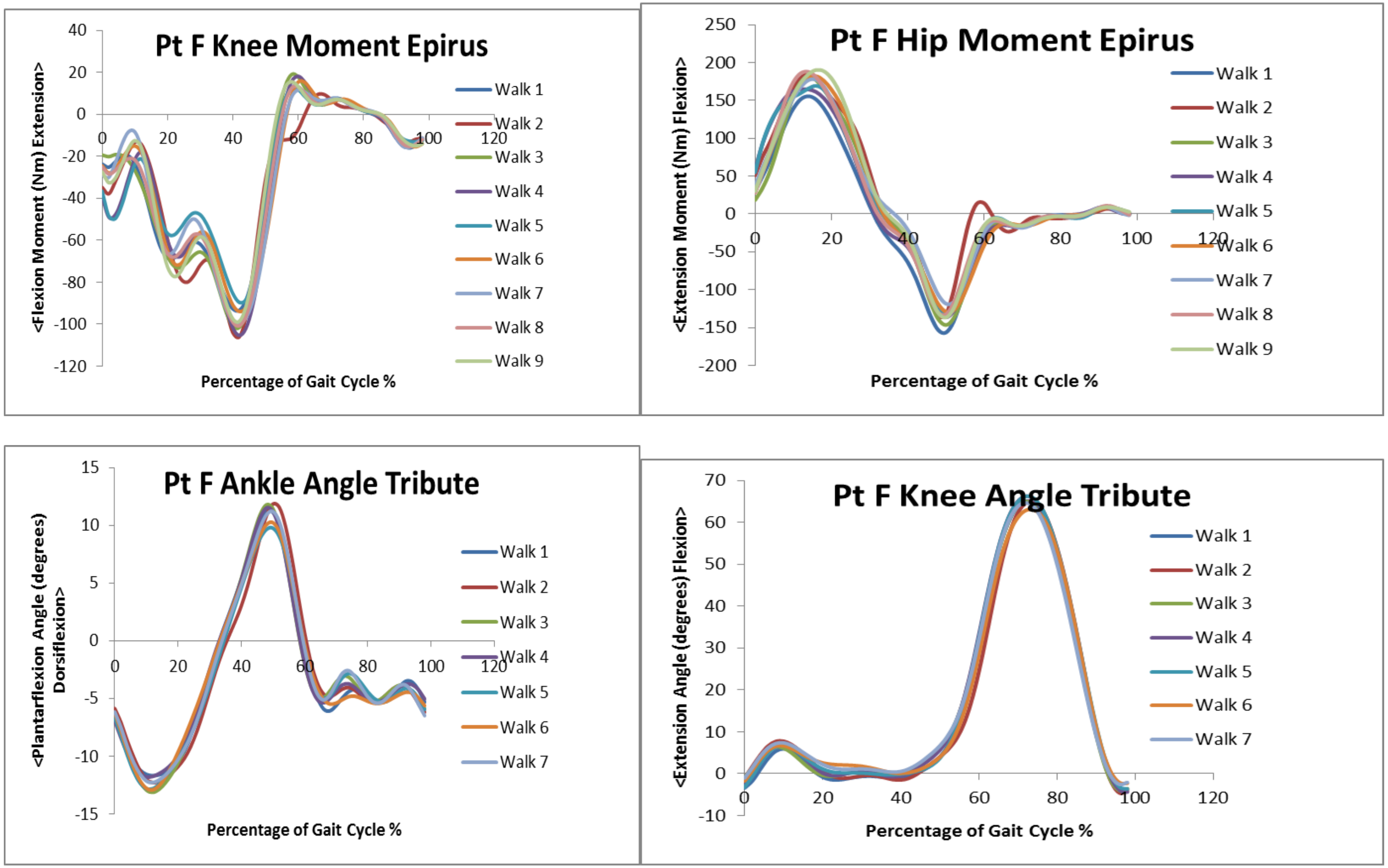


Figure 10.51 Pt F epirus and tribute foot angles and moments (prosthetic side) all walks on slope

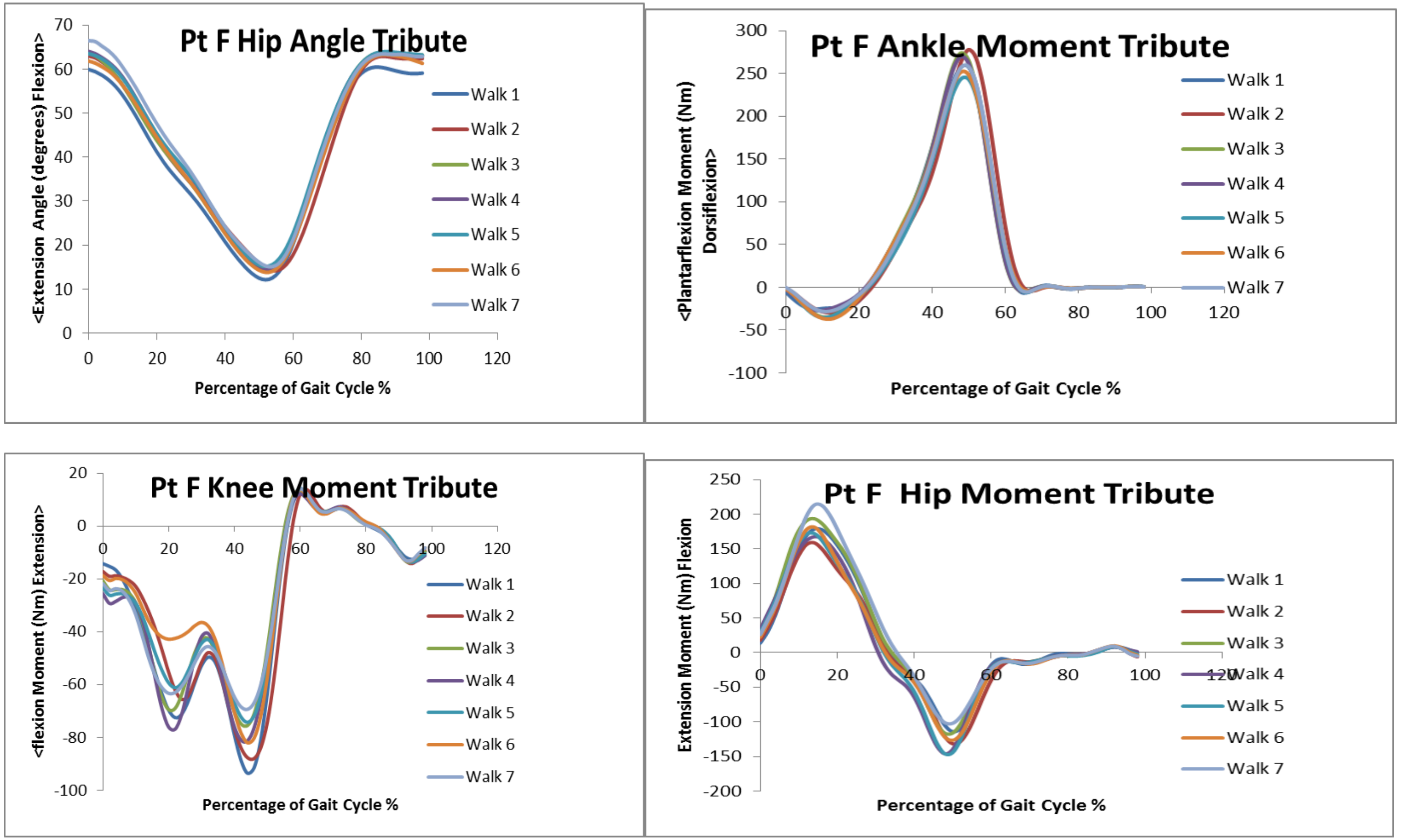


Figure 10.52 Pt F tribute foot angles and moments (prostheic side) all walks on slope

10.10 APPENDIX 10 DIRECTION OF MOMENTS AT DISTAL JOINTS

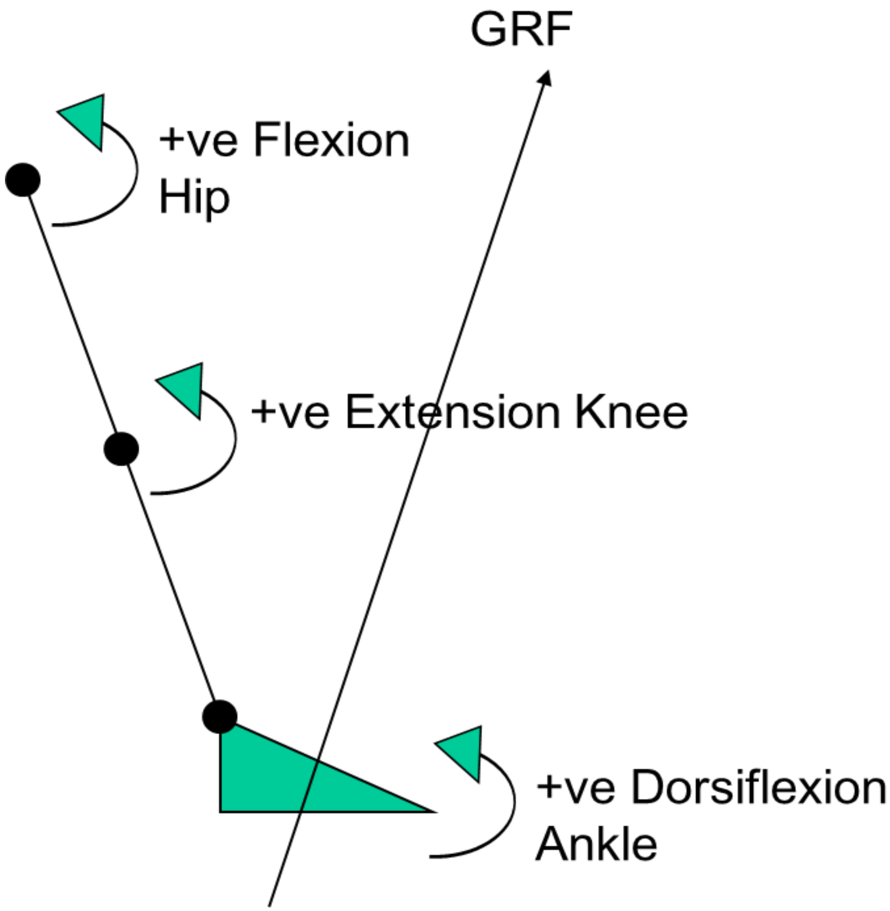
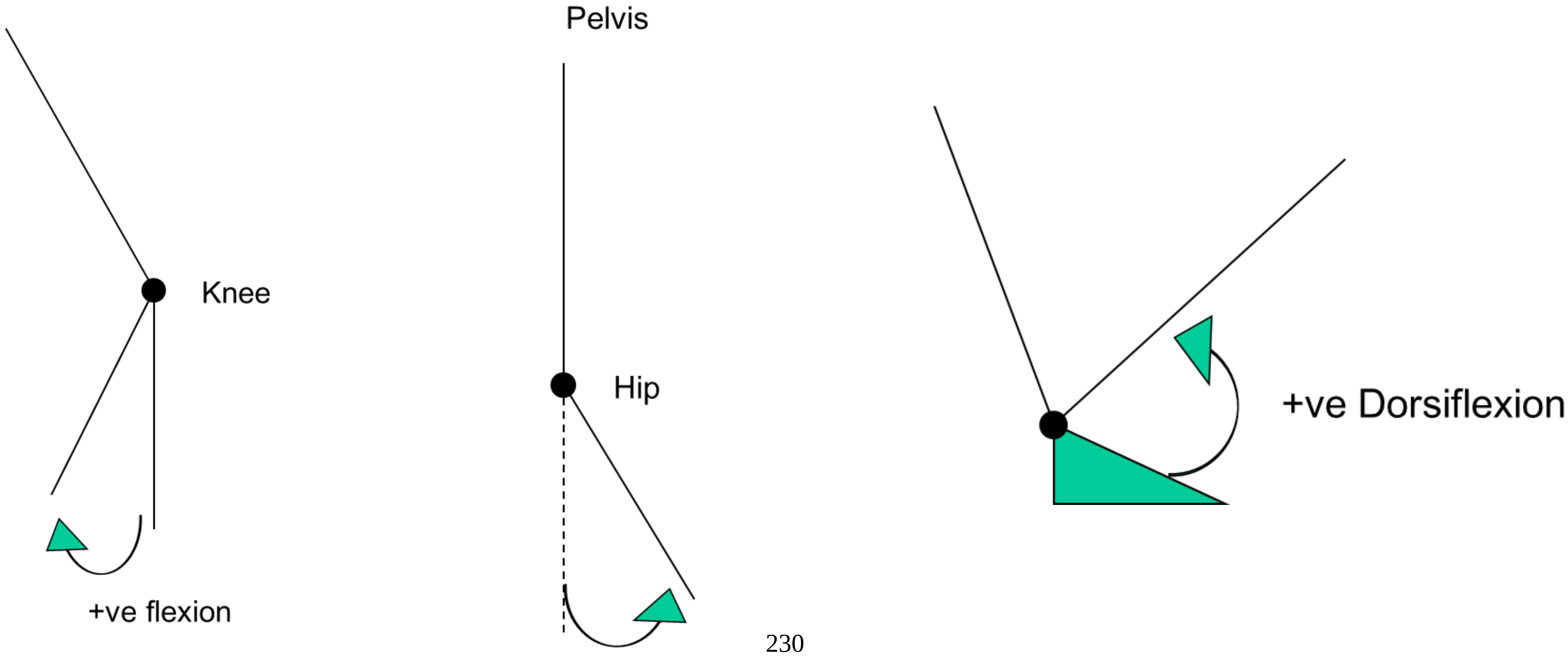


Figure 10.53 Direction of positive moments ankle, knee and hip.

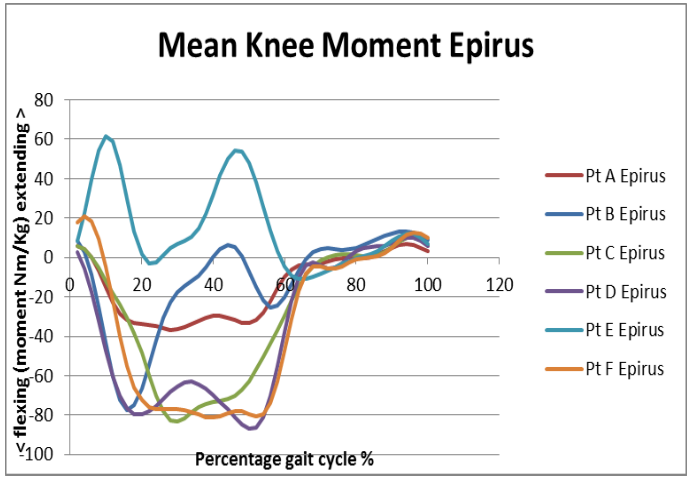
10.11 APPENDIX 11 DIRECTION OF ANGLES AT DISTAL JOINTS

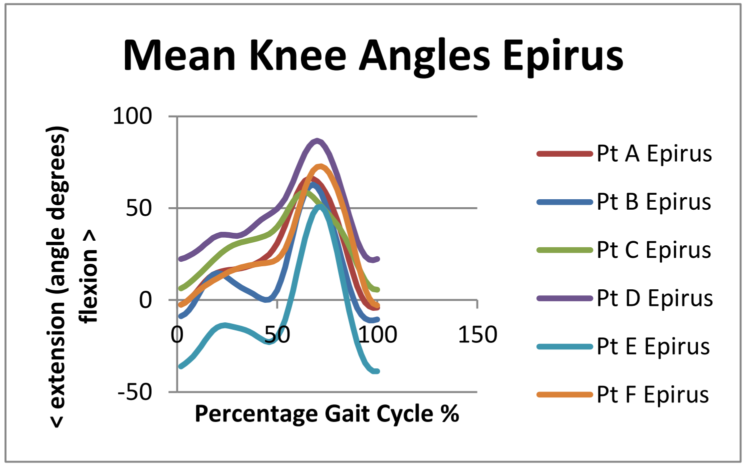
Figure 10.54 Positive direction of angles for the knee, hip (relative to pelvis) and ankle.

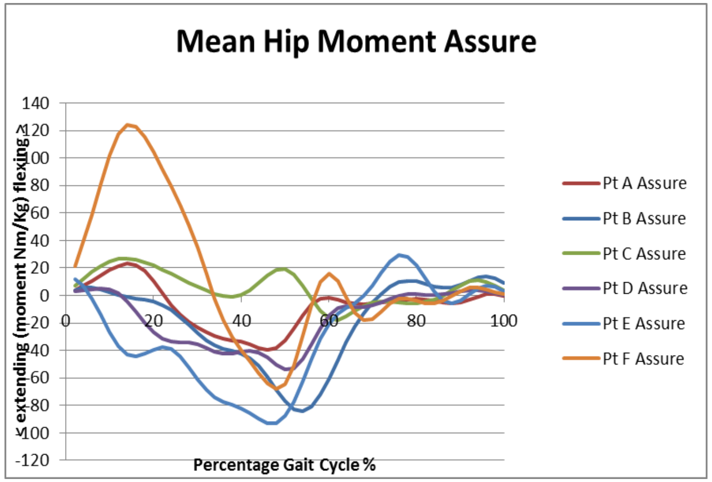


10.12 APPENDIX 12 SAMPLE OF MEANS FOR ANKLE MOMENT AND ANGLE. ALL WALKS USNG TRIBUTE FOOT

The mean moment and angle at each joint for each prosthetic foot for each subject were drawn together in an attempt to find a trend with a subject or a prosthetic foot. None were found however, a sample was included to illustrate this finding.







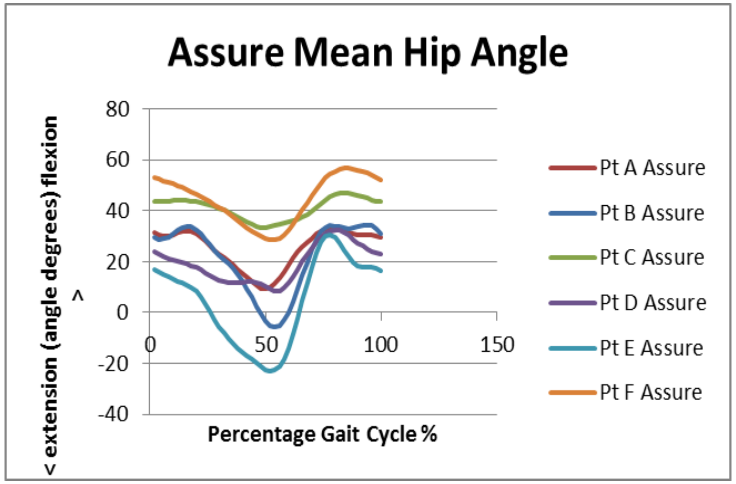


Figure 10.55 Sample of Means for all walks for hip angle and moment and knee angle and moment using the Epirus and Assure

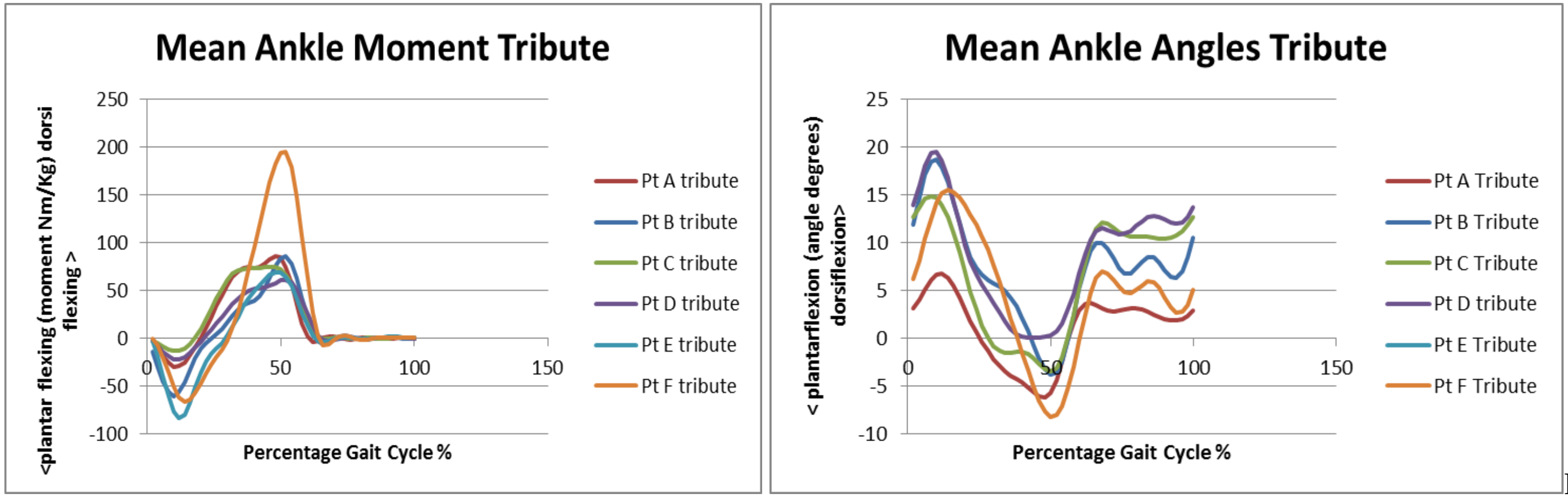


Figure 10.56 Sample of Means for all walk for ankle moment and angle using tribute foot.

10.13 APPENDIX 13 LITERATURE REVIEW FLOW DIAGRAM

Schematic diagram of literature search when inclusion and exclusion criteria applied