Biomechanical Evaluation and Comparison of Microprocessor and Mechanical Prosthetic Knee Mechanisms

By

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Signed:

Date:

I would like to dedicate this work to my mum (Allison Crimin)

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I could not have completed this work without the help and support of the following people.

I would like to thank Stephan Solomonidis, I was very fortunate and privileged to work with him, without his care, dedication and patience I would never have flourished. I hope that we will be friends for many years to come.

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ABSTRACT

For the lower limb amputee, one of the principal aims of rehabilitation is to allow them to maximise their functional ability with the prosthesis, the first step of which is the selection of an appropriate foot, knee and socket. As the histories of all individuals who have suffered a lower limb amputation differ, knee and foot components are now designed and manufactured by a number of leading manufacturers, such as Otto-Bock, Össur and Blatchfords. Of all the lower limb prosthetic components now produced by such leading manufacturers, it is claimed that those that incorporate an embedded system will help facilitate a more natural gait.

It was Blatchfords who first revolutionised lower limb technology with the commercial release, in 1991, of the intelligent prostheses (IP), which incorporated a microprocessor that controlled the swing phase of gait. There has since been further development of microprocessor controlled prosthetic knees (MCPKs), and they now assist the user during swing and stance as well. Considering the high relative cost, there has been debate about the efficacy of MCPKs compared to non-microprocessor controlled knees (non-MCPKs). Despite the well-documented, positive feedback from MCPK user trials, there is little scientific evidence quantifying why the prosthetic user generally prefers the MCPK compared to the non-MCPK.

Therefore, the objective of this investigation was to quantify the benefits of MCPKs and, in doing so, to establish the user group that may benefit most from this class of knee.

In pursuance of this aim, six trans-femoral prosthetic users were recruited, all of whom were capable of outdoor community ambulation, though their abilities did vary; they could be described as either K2 (restricted outdoor) or K3 (unrestricted outdoor) ambulators according to Medicare Functional Classification Level (MFCL). The participants were asked to ambulate in two crossover groups in an indoor laboratory environment while wearing, an MCPK (Blatchfords Orion) and a non-MCPK (Otto Bock 3R80), which were incorporated into their prosthesis during level, ramp, and stair ambulation activities. The kinetics of motion were captured using force plates, and kinematics using infrared cameras.

The results of this investigation suggest that for ambulation beyond level walking, the restricted, rather than the unrestricted, outdoor community ambulator would benefit most from the MCPK. The outcomes indicated an improved involuntary response by the MCPK, and that the MCPK offered improved voluntary control. Despite the improved involuntary response and voluntary control during the level and ramp activities, the stair activities did not highlight that the MCPK offered such advantages. Furthermore, the outcomes of this study have shown that it is possible to use simple tests in the clinical environment to determine whether the voluntary or involuntary control can be considered as having improved through the use of the MCPK, and these include indoor ramp ascent and descent activities, and recording the ground reaction force during level walking.

CONTENTS

CHAPTER 1 INTRODUCTION

Before the Second World War trans-femoral (TF) lower limb prostheses were rudimentary, they were made of wood, and incorporated simple hinge mechanisms to emulate biological knee function. The two world wars catalysed the development of mechanically-complex knee mechanisms due to the number of veterans returning home having lost limbs (Tang et al. 2008).One such example was the '*Mauch Swing-N-Stance* (S-N-S)' mechanism, which used a hydraulic cylinder to provide knee resistance. The hydraulic resistance facilitated stability and voluntary control during stance, and allowed some involuntary knee response during swing as the user was able to adjust their self-selected walking speed (SSWS). A further benefit of this design was that it provided the TF prosthetic user with a commercially available knee joint that could be fine-tuned according to their requirements (Mauch 1968).

A variety of mechanical or non-microprocessor controlled prosthetic knee designs (non-MCPKs) remained the norm until the early 1990s, at which point the first microprocessor controlled prosthetic knee (MCPK), the *Blatchford Intelligent Prosthesis IP*, became commercially available. This knee used a microprocessor to control the rate of fluid flow inside a pneumatic cylinder, which controlled the resistance to swing-phase flexion and extension during swing. This design facilitated a change of knee resistance in response to the user's slow, average or fast walking pace. The nature of pneumatic cylinders is such that resistance to stance phase flexion was not feasible, and traditional non-MCPK stabilising mechanisms had to be used during stance.

Towards the end of the same decade, further research suggested that the microprocessor control of swing phase reduced the metabolic cost of ambulation, whilst allowing the user to walk with an increased range of cadences (Buckley et al. 1997). Subsequent microprocessor designs, such as *the Otto Bock C-Leg*, controlled stance as well as swing phase (Hafner et al. 2007). Evidence suggested that the primary advantage of these mechanisms over non-MCPKs was superior stance phase stability (Bellmann et al. 2010, Burnfield et al. 2012).

After the development of the C-Leg, many more MCPKs became commercially available, and increasingly prescribed. Documented feedback from MCPK users reported that they expressed reduced cognitive effort during gait (Gerzeli et al. 2009). These perceived advantages have not been substantiated or quantified by objective scientific evidence. However, a particular make and model of knee may not provide a solution for all users as the requirements and capabilities of individuals depend on a variety of factors – such as socket comfort, residual limb proprioception, the time since amputation, and personal aspirations and lifestyle. Moreover, there is still considerable debate with respect to whether the more active than less active outdoor user groups will benefit most from microprocessor designs (Hafner et al. 2009).

The primary objectives of this investigation are to establish whether the MCPK offers improved voluntary control during stance and involuntary response during swing when compared to the non-MCPK. Additionally, the study also aims to provide simple clinical tests to assist the prescription of the MCPK.

However, given that every prosthetic user has a unique [style of] gait, evaluating the 'quality' of participants' ambulation technique presented a considerable challenge. There is an on-going debate about the most suitable means of analysing and evaluating individual gait pathology whilst also giving due consideration to the complex interaction of the prostheses and the user during ambulation.

Prior to the study's commencement, a two-part/two-phase literature review was conducted. The aim of the first review was to summarise and critically appraise the current understanding of methods used to examine bipedal ambulation. The review also aimed to ascertain the measured outcomes employed in previous studies into the gait of trans-femoral prosthetic users.

The second part of the literature review on prosthetic knees sought to gain an understanding of MCPK and non-MCPK design. The literature review revealed that the sensory inputs of the MCPK embedded system are used determine the direction of loading around the knee during ambulation in order to allow the user additional voluntary control and improved involuntary response. This review facilitated the identification of appropriate outcome measures and clinical tests for the assessment of the activity of the user in the gait laboratory. To date, the MCPK mechanism has not been evaluated to understand how the prosthesis measures and adapts to the ambulation pattern of the user. Therefore, it was considered that using measured outcomes to determine voluntary and involuntary user control over both the MCPK and the non-MCPK would reveal how the prosthetic leg system integrated itself with the residual limb.

The intention was to gain a better understanding of how the limbs should integrate themselves with the user by better understanding the design of the two types of knee. Essentially, the primary research question is whether the MCPK will provide additional benefits to the prosthetic ambulator, and what these benefit are. It hypothesised that the MCPK embedded system would allow such lower limb systems to become integrated with the user through improving the voluntary control during stance, and the involuntary control during swing.

To evaluate this hypothesis, biomechanical outcomes were objectively compared using an MCPK *(Blatchford's Orion)* and a non-MCPK (*Otto Bock 3R80)* in a crossover study with six participants in a gait laboratory. The participants were outdoor community ambulators, four of whom could be considered restricted, and two unrestricted, according to the Medicare Functional Classification Level (MFCL). It is considered that restricted ambulators walk when necessary, whereas, unrestricted ambulators also walk for recreational purposes. The participants were asked to perform level walking, ramp, and stair activities, allowing capture and analysis of the kinematics and kinetics of motion. The participants' ambulation technique when using both prosthetic knee designs was then compared using established outcome measurements to evaluate the effects of both non-MCPK and MCPK.

The low participant recruitment number of six, as well as individual ambulation styles, resulted in outcomes that did not lend themselves to general inter-subject statistical explanations.

Therefore, participant intra-subject statistical outcomes of lower limb moments, angles and powers were evaluated qualitatively so that it was possible to draw general conclusions about wearing the two evaluation prostheses. After evaluating the objective outcomes in a qualitative manner, evidence will be presented to indicate whether the restricted or the unrestricted outdoor ambulator benefits most from the MCPK.

Subsequent chapters present the project procedure and computational methods, along with a chapter validating the methods used in this study by providing the results of the primary investigator who acted as the study normal control. The final chapters then present the experimental results by describing the participants in individual cases studies, and by using intra-subject statistics, before going on to discuss the primary conclusions.

CHAPTER 2 LITERATURE REVIEW OF GAIT AND ITS ANALYSIS

2.1 INTRODUCTION

As detailed in appendix 1, there are multiple studies that use novel outcomes to describe the effects that the non-MCPK and the MCPK have on patterns of ambulation. These novel techniques will be critically investigated over the course of the first literature review chapter in order to determine whether they could have been used to answer the primary research question of whether or not the MCPK will provide additional benefits of voluntary control and involuntary response to the prosthetic ambulator.

Many of the novel outcomes use mechanical energy transfers and define the mechanical energetic efficiency of ambulation accordingly, in order to consider whether a particular lower-limb prosthesis is beneficial compared to another. For example, Radcliffe (1955) first proposed that the action of reducing knee flexion during stance minimises the oscillation of the trajectory body COM, which minimises the energetic cost of ambulation. However, this is a controversial topic and it is reviewed for the purpose of determining whether the sinusoidal body COM trajectory during ambulation could be used to describe ambulatory efficiency using lower limb trans-femoral knee prostheses. It is pertinent to progress the review by introducing the reader to the novel techniques – such as step-to-step transitions during double support – that, at the time of writing, are commonly used to evaluate the mechanical efficiency of ambulation. The reason for this is that these techniques are often considered appropriate to describe the general benefit of lower limb trans-femoral prostheses. They are also reviewed and criticised in the first part literature review.

The first part literature review then concludes the review by considering the techniques first introduced by Prince et al. (1994) to evaluate energy transfers in the lower limb. This paper proposed that the prosthetic joint reaction force could be used to estimate the energy returned to the body, and hence would be a worthwhile tool if appropriate. After this final discussion, the literature review provides a summary of this chapter before embarking on a review of the knee prostheses considered for this evaluation.

The second part literature review specifically investigated the mechanisms of the non-MCPK and the MCPK to understand how the embedded system of the MCPK allows the knee to integrate itself with the user. The design review provided an insight into how standard outcomes such as moments and angles could be used to determine the different ambulation patterns from wearing two prostheses that would be evaluated.

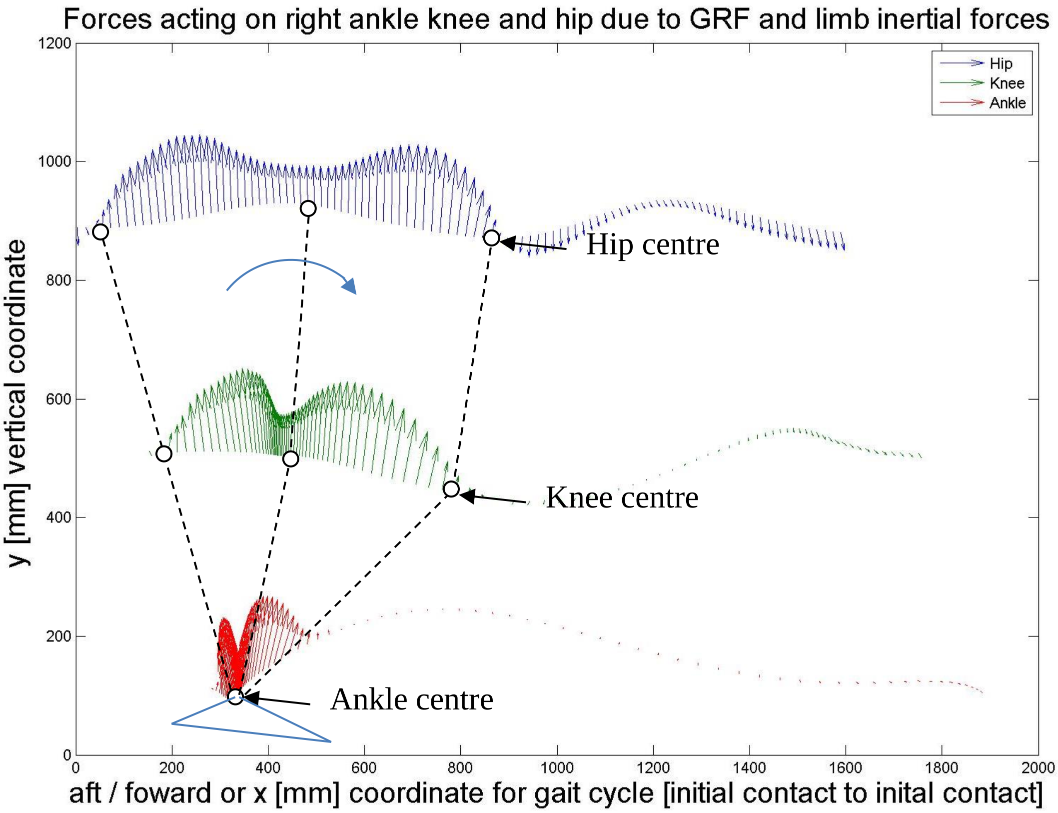

Figure 2.1 Reaction forces acting on the ankle, knee and hip (distal to proximal) in global coordinates for an able body control

2.2 BODY SUPPORT, PROPULSION, WORK AND KNEE FLEXION

When considering how the lower limbs support and propel the body, Figure 2.1 illustrates that force on the hip mainly acts in the vertical direction, providing evidence that the hip mainly supports the trunk. It is also shown that the direction of ankle reaction force has a greater horizontal component than the force acting on the hip joint, illustrating the propulsive role of the ankle. Hence, this simple illustration demonstrates how the proximal aspect of the lower limb provides support, and the distal lower limb assists with propulsion.

Therefore, if the limited proprioception of the residual limb positioned in the socket is considered, it is possible to visualise the difficulties that the prosthetic user will face when supporting and transferring their body mass. They cannot manipulate the force transmitted up the lower prosthetic limb in the same manner as can be achieved with biological limb musculature. Consequently, during stance the option of least instability is to maintain an extended knee were possible and perform gait deviations, such as trunk flexion and extension to manipulate the direction of the ground reaction force (GRF). Additionally, as the trans-femoral prosthetic ambulator does not have their biological knee and ankle, they have to use their hip musculature alone to provide propulsion and support. The forces that act on the lower limb body segments, and body COM can be used to determine this mechanical work done during ambulation. Hence, the following literature review will demonstrate how mechanical work has been used to quantify the ambulatory efficiency of the lower limb prosthetic user.

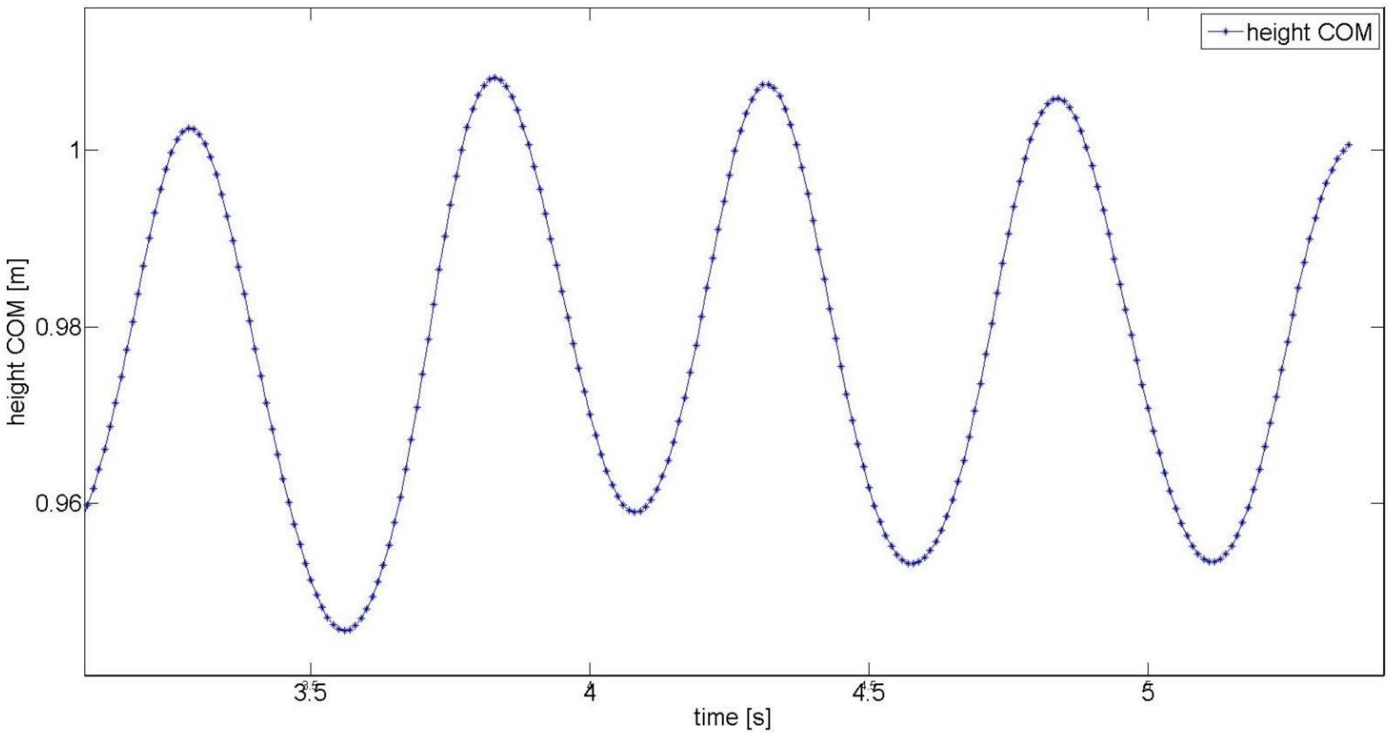

Figure 2.2 Trajectory of the body COM in the sagittal plane

Analysis of human ambulation has shown that the most efficient walking speed is approximately 1.3m/s ± 15% (Figure 2.3). It is well documented that, if the walking speed deviates above or below the optimal, there is a significant increase in energy expenditure (Novacheck 1997).

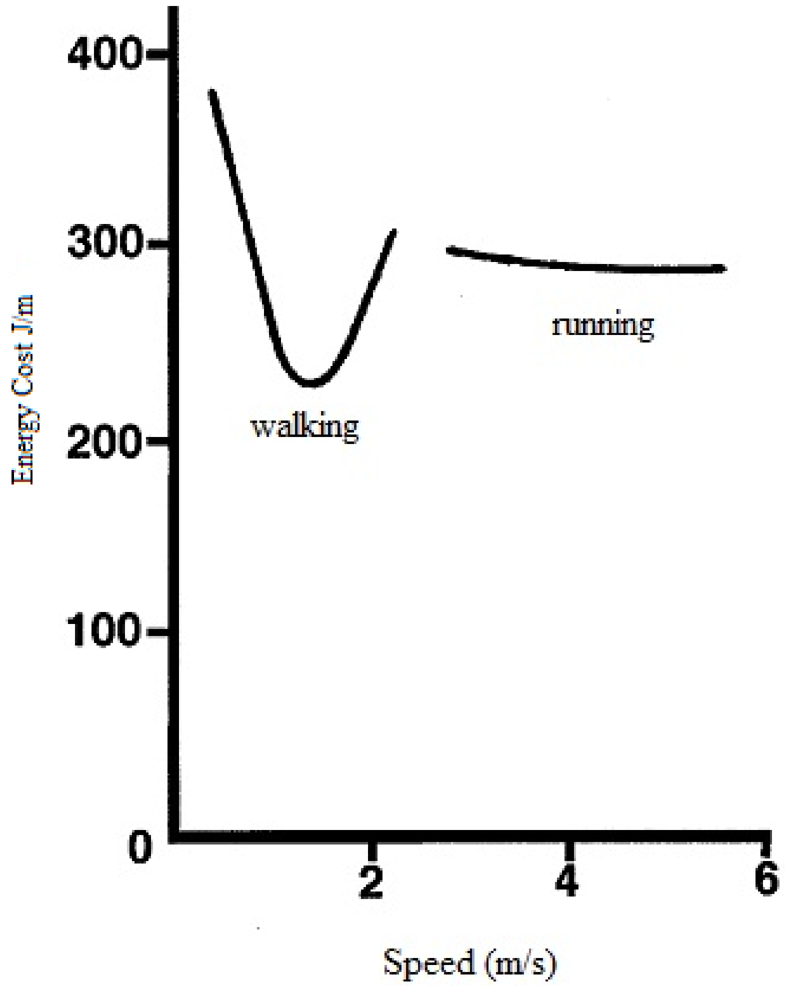

Figure 2.3 Oxygen consumption trend during walking and running (Novacheck 1997)

When considering the body COM trajectory of the study normal control, Figure 2.2 illustrates that, in the sagittal plane, it is sinusoidal in nature, and this accords with what is often found in the literature, such as Perry (1992) .

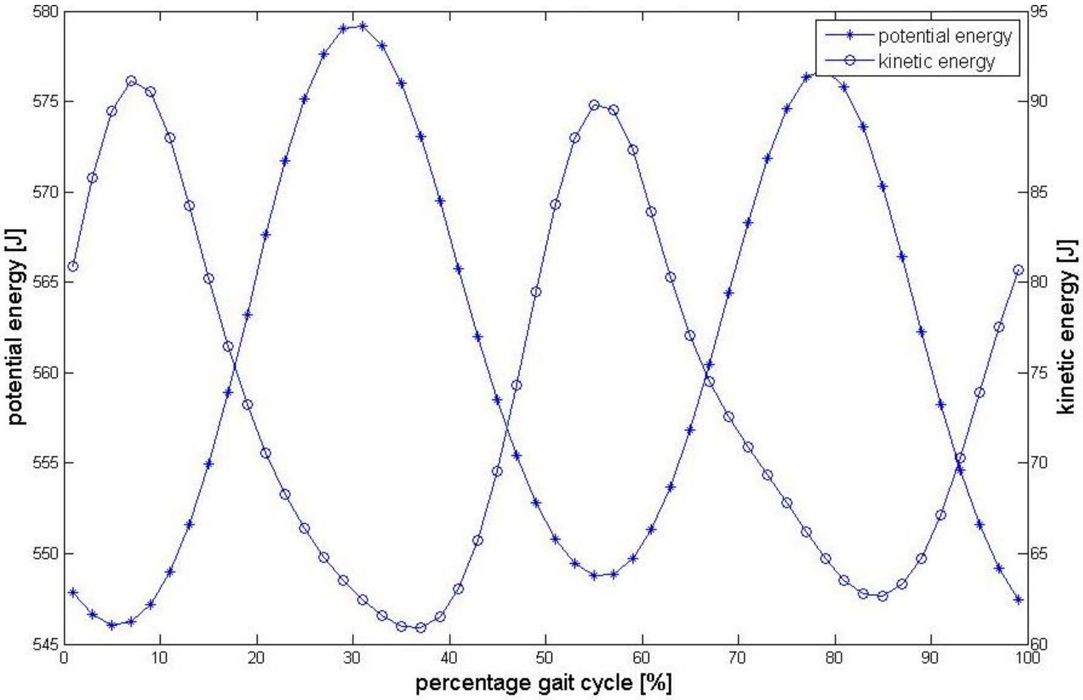

Figure 2.4 The conservative energy exchange of an able body control, averaged from ten trials at a self-selected walking speed

Therefore, the height (h) of the body COM as illustrated in Figure 2.2 can be approximately represented by a sine wave as shown in Equation 2.1, with the offset (b), the mean height of the body COM, and a wave with an amplitude (a), and frequency ω.

$$h(t) = asin\omega t + b \tag{2.1}$$

By integrating the instantaneous trajectory height to determine the total displacement over one step-cycle, it is possible to determine that the sum of the total height gained and lost walking on the level is equal to the mean body COM height (Equation 2.2).

$$h = \left[-\frac{a}{\omega}cos\omega t + bt\right]_0^{2\pi} \tag{2.2}$$

As the $cos\omega t$ term over the step cycle 2π reduces to zero, the height of the body COM at the end of the gait cycle is equal to the mean body COM height (b). Therefore, no mechanical work is done when walking on the level in the vertical direction.

$$h = -\frac{a}{\omega} + \frac{a}{\omega} + bt = bt \tag{2.3}$$

Therefore, even though Saunders et al. (1953) and Perry (1992) suggested that reduced knee flexion during stance reduced the mechanical energy requirement of ambulation, this theory is not proven when considering conservative energies. Equation 2.3 reveals that, over the course of the step cycle and when walking on the level, knee flexion during stance does not result in work done in the vertical direction over the step cycle.

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Indeed, it has been shown that, as knee flexion increases or decreases, the amplitude (a) of the sine wave as shown in Equation 2.1 would respectively increase or decrease, and as a result there would be a respective change in the mean height of the body COM (Gard et al. 1999). Therefore, even though additional knee flexion causes greater vertical displacement of the body COM in the sagittal plane, the scientific evidence at the time of writing does not show that there is an analytical relationship between the vertical displacement of body COM trajectory and metabolic energy expenditure due to knee flexion and extension. Even though there is a logical argument, and investigators such Winter (1976) documented that the modulus of work done should be considered, such methods are erroneous as the work done on the body COM, by the musculature against gravity should not be considered positive. As documented by Kuo 2007 muscles work with approved metabolic efficacy when they work with an external force rather than against. Therefore, such mechanical methodologies, and simplifications using mechanical work cannot provide a clear understanding of the metabolic cost of gait due to knee flexion. Because, the body COM is being lifted and is allowed to fall in a controlled manner using muscles, thus simply taking the mechanical work modulus when the energetic efficiency of muscles changes and when gravity assists illustrates such methods are mechanically meaningless. Clearly, a relationship does exist between metabolic efficiency, knee flexion and body COM trajectory, and knee flexion during stance is beneficial for many activities – it may reduce the metabolic energy cost, though this is a research area in itself. Hence, this study will not evaluate prosthetic knee flexion during stance and correlate this with the mechanical work done on the body COM in the vertical direction to comment on the energetic efficiency of ambulation.

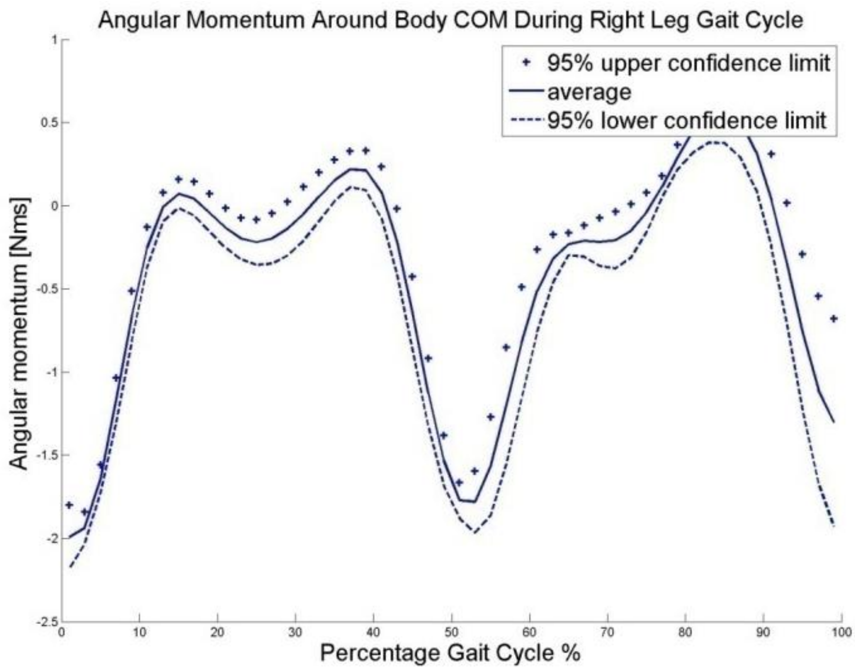


Figure 2.5 Angular momentum around the body COM during level ambulation

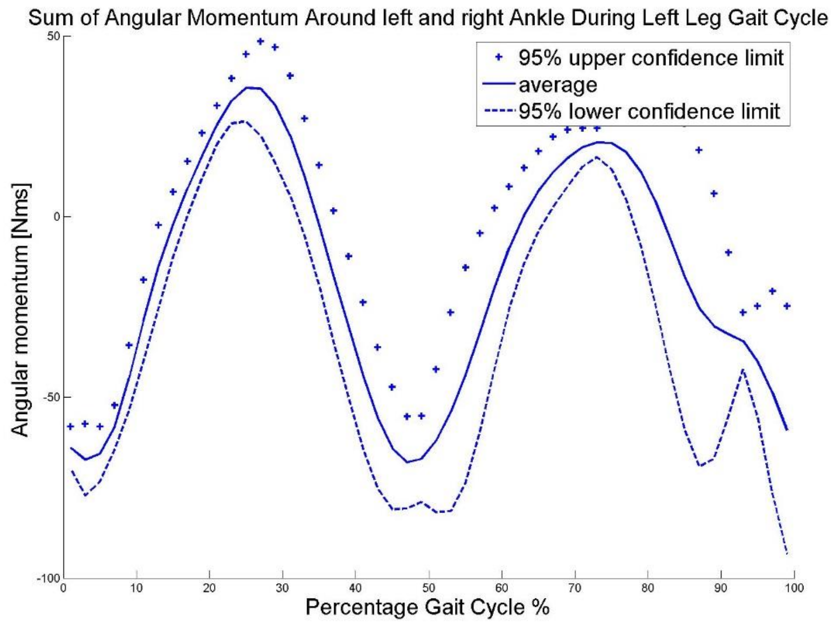


Figure 2.6 Angular momentum around the body COM during stair descent

2.3 BODY MOMENTUM

Robotics has shown that body momentum can be used to indicate stability during ambulation (Bennett et al. 2011). Consequently, the total support moment as proposed by Winter (1980) does not have a physical meaning, as the sum of the moments that act around the lower limb (ankle, knee and hip) is not equivalent to the momentum time rate of change (the moment) acting around the body COM.

The angular momentum of an able bodied control COM, Figure 2.5, is of a similar pattern as that shown by Bennett et al. (2010). However, it is also interesting to note that the angular momentum difference of the body COM is subject to greater variation during stair ascent and descent when compared to level walking (Figure 2.6). The confidence intervals of these plots clearly demonstrate that, as expected, the angular momentum and stability of the body is highly controlled. Descending stairs does not appear to be a safe activity, and as a consequence is unlikely to be repeatable as level walking (Rogers 2011).

However, how can the momentum of the body be used in a consideration of/while considering the ambulatory patterns of either a normal walker or prosthetic user? It has been proposed that the momentum of the body can be used as a metabolic cost indicator during the step-to-step transition (Houdijk et al. 2009), especially when comparing the efficiency of knee prostheses. As a result, this technique is explored and discussed in further detail below.

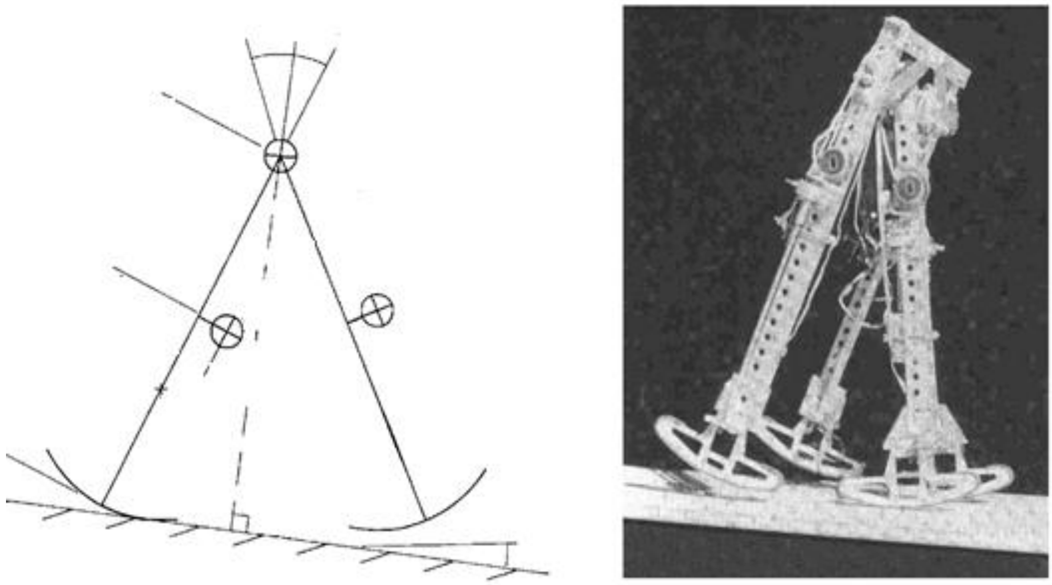


Figure 2.7 Passive dynamic walker adapted from MMcGeer 1990)

2.4 STEP TO STEP TRANSITIONS / DOUBLE SUPPORT

A number of engineering texts describe that, in the absence of external forces, body momentum (in the general sense) will be conserved (Meriam et al. 2008). During ambulation, because the GRF acts on our feet, the momentum of the ambulator cannot be conserved.

On initial contact, body kinetic energy is lost as it is converted to either or both sound and heat, or is absorbed by the musculature as it dampens the impact. During steady state walking, the angular momentum around the body COM is highly regulated (Figure 2.5). A relationship exists between the GRF, the COM and the Centre of Pressure (COP), and in fact this relationship is used in designs for the control algorithms needed to generate bipedal kinematics in both mechanical walkers and simulations (Popovic et al. 2004, Poskriakov 2006, Bennett et al. 2011).

Passive dynamic walkers, Figure 2.7, give a fascinating insight into the mechanics of gait without muscle control. Even though a contradiction in terms, passive dynamic walkers are so called because they are powered by the exchange of conservative energies, as they have no actuator mechanisms or muscles. The loss of system energy – mainly kinetic energy (KE) on initial contact – is compensated by setting the walker on a slope (McGeer 1990). These models give a simple but useful insight into the interaction of the bipedal walker with the environment during double support. Nevertheless, the limiting assumptions used to hypothesise that the major energetic cost of human gait is during double support are questionable.

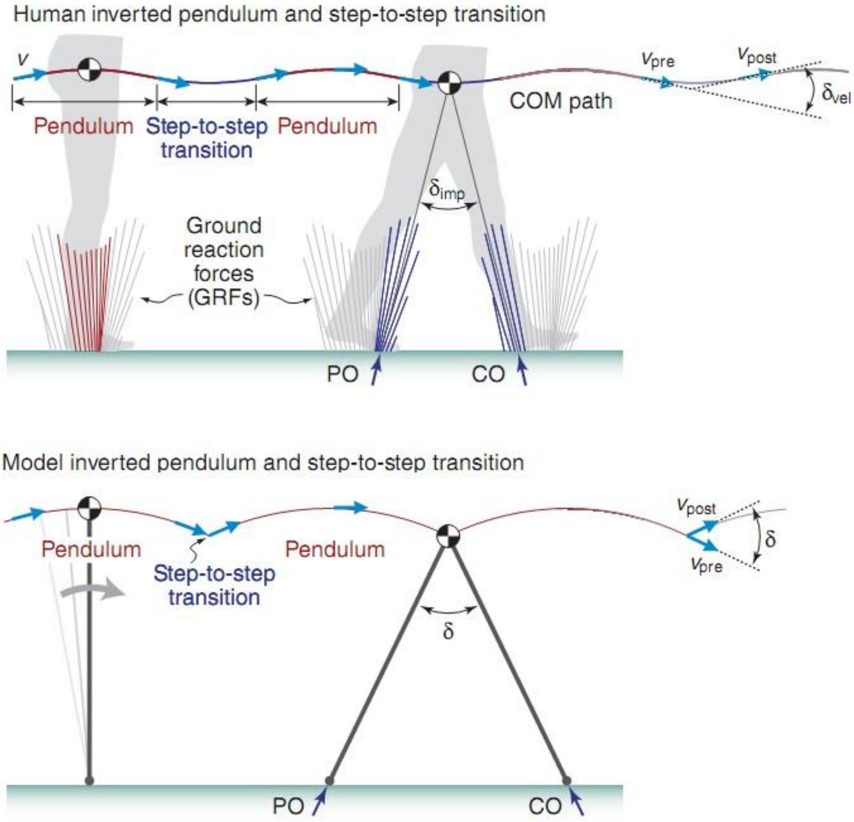


Figure 2.8 Step to step transitions (Adamczyk et al. 2009)

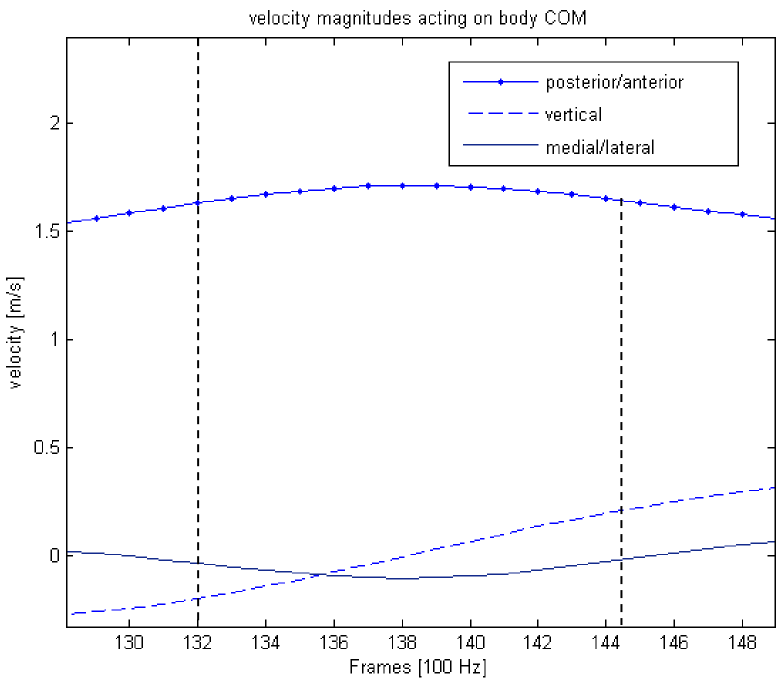


Figure 2.9 Change in body velocity components during double support

During double support, rather than potential energy it is the body COM velocity, and therefore, the kinetic energy that primarily change because the body COM is at its lowest point during the gait cycle. Using Figure 2.8 it is then possible to describe that, during the double support period, the GRF, acting on the trailing leg, performs positive work, while the GRF performs negative work on the leading leg. Moreover, if the prosthetic limb did not provide a push-off force or impulse to reduce the vertical body COM velocity to zero, the leading contralateral leg would have to perform all the work to redirect the body COM velocity (Adamczyk et al. 2009, Donelan et al. 2002a, Donelan et al. 2002b, Kuo 2007, Kuo 2001, Houdijk et al. 2009, Kuo et al. 2005, Kuo 2002). For the able-bodied control, Figure 2.9, it is evident that the vertical component of body COM velocity does approach zero before initial contact. However, it will now be shown that the analytical solution derived to show that the work done during double support is proportional to the product of the average walking velocity and step length squared is limited to mechanical walkers with hypothetical linear step lengths. As detailed in Figure 2.8, the average body COM walking velocity is ($\bar{v}$), the velocity before initial contact is (v_{pre}), and the velocity after initial contact is (v_{post}). Equation 2.4 describes how the average walking velocity is proportional to the walking velocity before initial contact.

$$v_{pre} \propto \bar{v} \qquad 2.4$$

Accepting that the velocity redirection angle delta (δ) is directly related to step length (S) Figure 2.8, even though the correlation between COM redirection angle and step length was not shown to be truly linear (R=0.68).

Equation 2.5 can be used to describe the proportionality between velocity redirection and step length (Adamczyk et al. 2009).

$$\delta \propto s \tag{2.5}$$

It can therefore be accepted that Equation 2.6 describes the relationship between the body COM velocity magnitude before and after initial contact:

$$v_{post} = v_{pre} \tan \delta \tag{2.6}$$

During double support it is reasonable to assume that the change of potential energy is negligible, and the work done (W) mainly relates to the change of kinetic energy.

$$W = \frac{1}{2} m\left(v_{mid}^2 - v_{post}^2\right) \tag{2.7}$$

Therefore, substituting Equation 2.6 into 2.7 it can be shown that the instantaneous work rate or power developed during double support is equal to:

$$W = \frac{1}{2} m v_{pre}^2 \tan^2 \delta \tag{2.8}$$

However, determining the angle of redirection over several runs for an able-bodied control, it was calculated that the angle of velocity redirection was greater than that which could be assumed using small angle asumption. As a 15 degrees redirection angle was approximately caculated taking the dot product of the velocity vector of the body COM just before initial contact with the velocity of the body COM after toe-off. Therefore, the small angle assumption of of δ=tanδ, means that it is unreasonable to assume Equation 2.9 is relevent for a human walker with non-linear step lengths.

$$W = \frac{1}{2} m v_{pre}^2 \delta^2 \tag{2.9}$$

Consequently, it is also not reasonable to assume the work done (W) is proportional to the product of the average walking velocity and redirection angle squared.

$$W \propto \left(v_{pre}.\delta\right)^2 \tag{2.10}$$

Thus, the work done during double support is not proportional to the product of the average walking velocity and step length squared as shown in Equation 2.11.

$$W \propto (\bar{v}.s)^2 \tag{2.11}$$

When Houdijk et al. (2009) compared prosthetic ambulators with normal controls, the negative work by the leading contralateral leg increased, and the positive work by the prosthetic push-off leg decreased. However, even though the prosthetic users displayed a 12% metabolic work increase when compared to the control able-bodied ambulators there was no difference when comparing the able-bodied ambulators and prosthetic users. Although, it was concluded that "the increased mechanical work for the step-to-step transition from prosthetic to intact limb contributes to the increased metabolic energy cost of amputee walking". Furthermore, Donelan et al. (2002a) claimed that the correlation fit between the values (R^2=0.79-0.89) suggests that "the mechanical work of step to step transitions does indeed determine the observed increases in metabolic cost". Even though this evidence suggested a linear correlation, the significance was not reported, and the mechanical work rate or power of ambulation was correlated with total metabolic expenditure, not the work relating to the double support period alone. Thus, summarising the evidence provided, it is not possible to suggest that velocity redirection (and thus linear momentum of the body) during double support is a predictive measure of metabolic cost.

Hence, the step-to-step efficiency method will not be used to evaluate the ambulation efficiency of the participants recruited for this study. The difficulty describing the push-off instance using mechanical reduction is that there are a number of mechanisms, such as propulsion for swing, or the body, and controlled roll off during double support (Neptune et al. 2001). The push-off instance therefore presents a considerable challenge when trying to understand its mechanism, even though many publications describe the main propulsion period of gait cycle being the push-off instance provided by the musculature during double support (Murdoch 1970, Rodgers 1988, Gordon et al. 1980, Sadeghi et al. 2001). It is not appropriate to assign this singular role to the plantarflexor muscle group, as this description may not necessarily assist the understanding of the mechanism driving forward progression, and therefore the mechanical cost of ambulation.

When Sutherland et al. (1980) used a tibial nerve block to temporarily paralyse the plantarflexor muscle group, there was corresponding increase in magnitude of velocity COM. The velocity increase was mainly attributed to the fact that there was no longer controlled roll off. The controlled roll off is often described as the mechanism of using the heel, ankle and metatarsal rocker as discussed by Perry (1992) to assist the body by rolling like a wheel. Therefore, to gain further insight into the body COM velocity and acceleration, and therefore the propulsion of the body, as the latter represents the direction of the resultant force acting on the body the sagittal plane velocity and acceleration components were plotted of an able control when they walked in parallel with the global coordinate system (Figure 2.10). The body COM trajectory determined from a seven-segment model was differentiated to determine the body COM velocity and acceleration respectively.

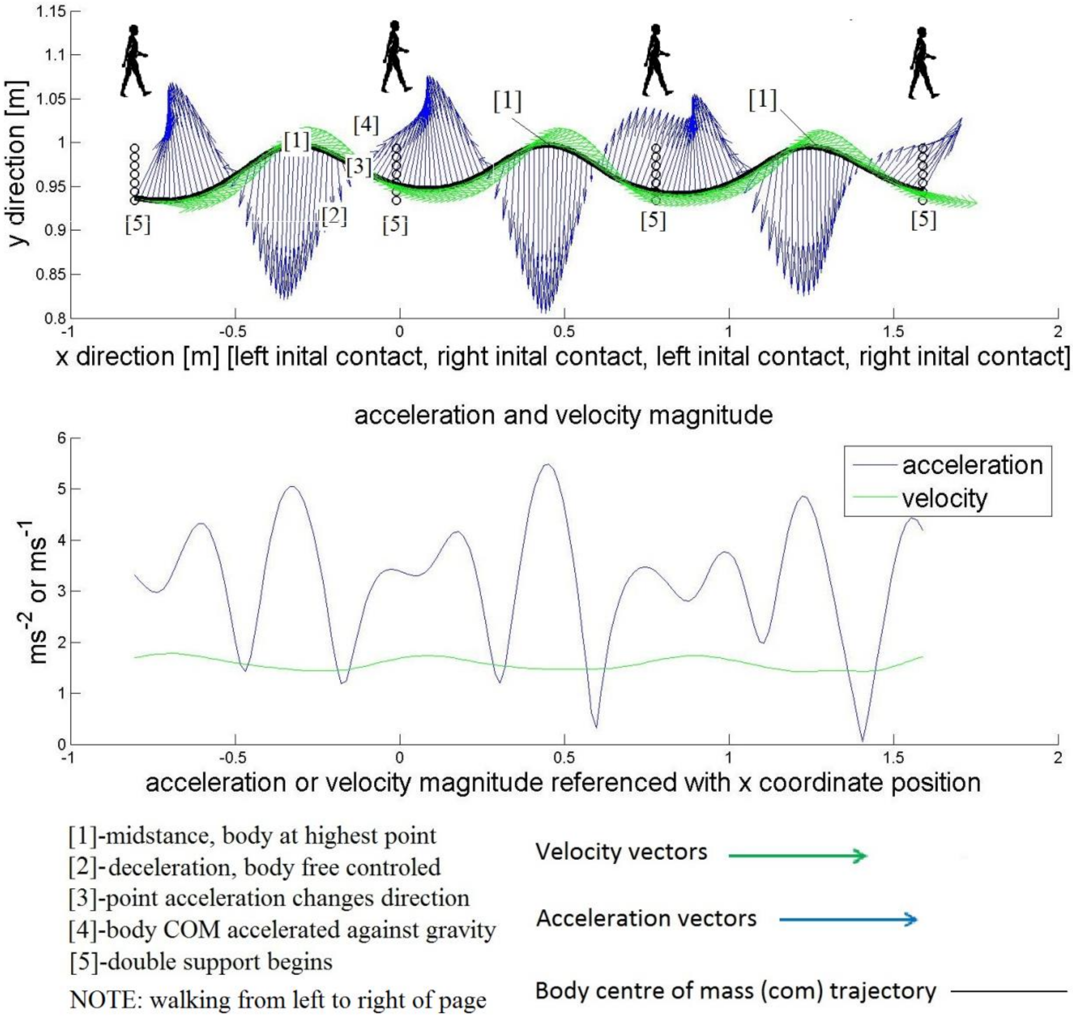
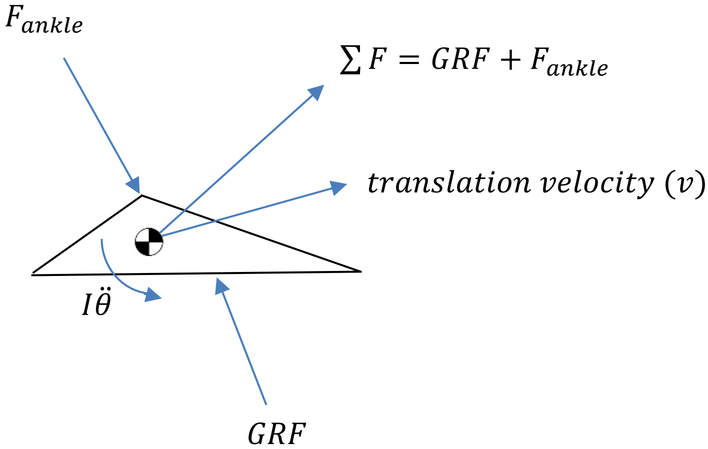


Figure 2.10 Vector plot of able-bodied COM velocity and acceleration Crimin et al (2014)

Note: the vertical dashed lines indicate double support. It should be noted that, to redirect the body COM velocity before initial contact, the body COM is accelerated vertically against gravity before double support.

Figure 2.10 illustrates that the body COM for a normal individual is not gaining acceleration after mid-stance under the influence of gravity. Instead, after mid-stance the free fall of the body COM is controlled by reducing the acceleration magnitude in the direction of gravity. Neptune et al. (2001) also agrees with these experimentally-obtained observations. When the three functional roles of the GAS and soleus (SOL) were investigated, the Electromyography (EMG) muscle activities read from able-bodied controls revealed that the SOL does indeed influence the body acceleration during late stance before double support. From this propulsion pattern, it is evident that, before initial contact and not just during the push-off instance of double support, the plantarflexors play a significant propulsive role. Scientific evidence presented by Crimin et al (2014) illustrated that, when a group of trans-tibial unilateral prosthetic users were assessed during ramp ascent, the propulsion of their trailing prosthetic limb was lacking before initial contact of their contralateral leading limb rather than during double support. However, even though the acceleration vectors provide a visual description of how the propulsion of the body is affected, this method of data reduction does not lend itself to objectionable analysis. Therefore, it is not an appropriate method to use in this study. Furthermore, the propulsion that our body experiences as we move in a horizontal plane highlights the fact that one instance of the gait cycle, such as double support, cannot be used to predict the metabolic cost of ambulation. Consequently, step-to-step efficiency was not used to determine the participants' ambulatory efficiency when evaluating the prostheses under consideration. The final popular energy technique presented in biomechanics literature, and commonly used to assess lower limb prosthetics, is the energy transfer across joints. Consequently, this technique will now be reviewed.



$$\sum F = GRF + F_{ankle} \qquad 2.12$$

The power (P) developed by the applied (sum of the forces) and inertial moment acting on the foot is given by $P = F.v + I\ddot{\theta}$ 2.13

Figure 2.11 The Work rate (power) developed by applied force (GRF) acting on foot

2.5 JOINT POWER AND ENERGY TRANSFER

Biomechanics appears to have adopted certain untested “truths” that relate to the determination of energy flow around and storage in the human body. Essentially, the dot product of the reaction force at a joint is taken with the translational joint velocity and used to describe the flow around and storage of energy in the segment in question. For example, the dot product of the ankle reaction force taken with its velocity, if positive, is used to described energy flowing into the foot; if negative, it is used to describe energy flowing out of the foot (Prince et al. 1994, Gordon et al. 1980, Winter 1976).

Using the foot during stance as an example, when drawing the free body diagram (FBD), Figure 2.11, the GRF, the ankle centre reaction force, and the inertial moment acting on the foot COM should all be considered. Using dynamic equilibrium, the applied force (F) acting on the foot COM can be determined. Taking the dot product of this applied force (F) with the foot COM velocity (v), the mechanical power or mechanical work rate of the applied force acting on the foot COM can be evaluated. It should also be noted that the velocity of the body segment COM should be considered, not the velocity of the ankle centre.

The mechanical work rate of the moment (M) acting around the joint can also be evaluated. Therefore, the total instantaneous power developed by the external forces acting around the ankle is the product of moment acting around the ankle and the joint angular velocity. Therefore, the power developed by the external forces acting around the ankle and the power developed by the applied force acting on the foot COM cannot be used simultaneously to consider the work done by the foot.

If this method is used as described in investigations such as Morgenroth et al. (2011), the power developed by the applied force acting on the foot will effectively be doubled. When the ankle moment, or foot COM reaction force, is in the same sense/direction as the angular or translational velocity, it can be said that work is done on the body (in the general sense). By the same account, work is done against the body when the sense of the force or moment is in opposition to the direction of travel (Meriam et al. 2008). However, these equations define the mechanical (energy) state of the body (in the general sense) in motion (Spiegel 1967, Meriam et al. 2008). They do not describe the intrinsic energy flow and storage in the musculature, or the structure of a prosthetic device. Therefore, as described by Prince et al. (1994), it cannot be implied that the differences in the kinetic and potential energy, calculated using inverse dynamics compared to the work done by the resultant force, will highlight the energy stored or lost in the foot.

Estimating the effects of the energy differences using discrete body mechanics will result in gross errors. This is because the estimation of inertial properties, damping of the foot structure, and the non-linear viscoelastic response of the foot structure encased in a foot shell and shoe will result in considerable inaccuracies. The work rate of the ankle reaction force is ultimately the mechanical work rate of the GRF being transmitted up the leg to propel the body COM, not the intrinsic "recovered" strain energy being released in the foot. To consider the energy storage and return within a structure such as the prosthetic foot, the effect that the dynamics of motion has on the structure of the prosthetic foot should be considered using the methods of solid body continuum mechanics.

Consider the simple example of a vertically suspended spring on which a bob is attached; the spring will displace and find a new position of equilibrium. If the bob is now forced to oscillate like a pendulum, the radius of rotation will not remain constant, because the dynamic forces of motion cause the spring to shorten, or lengthen. From the spring length and property of stiffness (an outcome of material and geometry), the stored energy of the spring can be evaluated. This simple illustration demonstrates that, while the applied forces of motion need to be known, the inherent geometric properties of the pendulum system also need to be understood.

At a point of rotation such as the ankle, knee or hip centre, when the muscles pull, the forces at this contact point of the joint are equal and opposite so cancel each other out. Hence, only the applied moment and relative angular velocity between the two segments need to be considered when evaluating the mechanical power developed. Cleary, work can be done on or against the segment, and this work changes the conservative energy state (kinetic and potential energy) of the body segment.

One method to consider internal energy flow within a structure as complicated as the human body would be to use a dynamic finite element technique that considers geometric, material and boundary nonlinearities. Even for the prosthetic foot this will be considerable, although it is likely to show the transfer of strain energy along the foot to be minimal (Postema et al. 1997, Bonnet et al. 2012). For the biological limb, the development of an accurate model that considers ligaments, tendons, bone and musculature would reveal the true internal energy transfers within the lower limb. However, internal energy transfers are different from the work rates of the applied external forces acting on the body segment considered.

Therefore, the work rate of the force alone cannot be used to take "into account the energy storage or dissipation and recovery within the compliant structure of the foot prosthesis" or the biological limb, as described by Prince et al. (1994).

In summary, mechanical work cannot be used to describe the energy transfer in the lower limb prosthesis or natural limb. When positive mechanical work is done by the musculature around the knee, for example, metabolic energy is clearly expended (Robertson et al. 1980). When negative mechanical work is done by the musculature around the knee, metabolic work is still expended. The difference is the improved efficiency with which muscles contract when performing positive or negative mechanical work (Kuo 2007). Hence, negative mechanical work may only indicate that the muscles are working at an optimal state of efficiency. Inverse dynamics alone cannot be used to determine whether the mechanical work strains the musculature complex or components of a prosthetic device, when considering how strain energy is transferred across the lower limb. Therefore, such techniques will not be used in this study to consider whether the non-MCPK or the MCPK allows improved transfer of energy across the knee joint.

2.6 SUMMARY

When using measured outcomes to assess the quality of ambulation, assumptions should be made to allow conclusions to be drawn. However, as highlighted by this biomechanics literature review, well-worn methods used to predict energy transfers, or measures used to evaluate the metabolic cost of ambulation, use assumptions that do not allow them to be used for this study. The literature review revealed that mechanical step-to-step efficiency during double support with a prostheses cannot be used to determine the ambulatory efficiency of the prosthetic user. It was shown that these models are appropriate for mechanical bipedal machines where step literality can be considered, but that they have limitations when considering the prosthetic ambulator. Therefore, the use of mechanical power to predict metabolic efficiency of using the non-MCPK and the MCPK devices will likely lead to inaccurate results. Rigid body mechanics cannot be used to estimate internal energy transfers that result from either the strain of a tendon, or the deformation of a prosthetic device using the techniques developed by Prince et al. (1994). The power developed around the joint of a prosthetic device such as the knee can only be used to determine whether the device or joint absorbs or generates power.

In summary, biomechanics appears to have adopted methods that should be further questioned and developed. This questioning approach will allow an integrated representation of structure, musculature and mechanics to be visualised. Hence, the second part literature review is used to determine what differences should be considered when evaluating the ambulation technique adopted when using the MCPK and non-MCPK device.

CHAPTER 3 LITERATURE REVIEW OF TRANS-FEMORAL LOWER LIMB PROSTHESES

3.1 INTRODUCTION

Studies such as Hafner et al. (2007) and Gerzeli et al. (2009) used qualitative scorings to show that, compared to the non-MCPK, the MCPK reduced the cognitive effort of ambulation. Moreover, they also showed that, compared to the non-MCPK, the MCPK provided both social and economic benefits despite the additional MCPK product and fitting cost (by the order of four times the magnitude before fitting). However, there is limited independent non-manufacturer evidence to substantiate the user-reported benefits of improved stability and reduced cognitive effort. Furthermore, it has also been considered that, compared to the restricted outdoor ambulator, the unrestricted outdoor walker will get the greatest benefit from the MCPK, due to their additional physical ability (NHS 2012).

Considering the limited biomechanical evidence highlighting why the prosthetic user benefits from the MCPK the purpose of this study is to investigate the biomechanical benefits of ambulating with the MCPK compared to the non-MCPK. Therefore, the objectives of this study are threefold. First, it aims to determine how the non-MCPK mechanical mechanism, and in the case of the MCPK the additional embedded system, allows the prostheses to function in harmony with the user, which will be determined by considering in-voluntary and voluntary control. The second objective is to use the biomechanical outcomes to determine whether or not each of the two knee types suit a particular user group – either the un-restricted or restricted outdoor ambulator.

Finally, these outcomes will in turn be used to make suggestions for clinical practice that could assist the prescription of the MCPK and non-MCPK devices.

In the case of the prosthetic user, the prosthesis represents an additional microsystem that is intimately associated with, but is not part of, the human system. The prostheses function is not similar to the real limb; there is no rigid attachment, proprioception or energy storage. Ultimately, the mechanical system of the non-MCPK, when interacting with the residual limb and the ground, will behave as it has been designed. In contrast, the MCPK incorporates appropriate sensory inputs that allow the embedded system to read the user's pattern of ambulation, and to assist in the control of the mechanical system. Therefore, in order to properly consider the benefit of different types of prosthesis by evaluating the kinematics and kinetics of motion, the mechanism by which the prosthesis functions should first be understood. The term 'function' in this thesis is used to describe the knee system, which can be thought of as the mechanical mechanism, and in the case of the MCPK, as the additional sensory inputs of the embedded system. Hence, the review of the non-MCPK and MCPK advanced in this second part literature review will also assist in the selection of appropriate measured outcomes that may be used to investigate the interaction of the prostheses with users. The interaction of the user with their knee prosthesis can be thought of as the voluntary control over the knee during stance and the involuntary response of the knee during swing as the user's self-selected walking speed (SSWS) changes.

In summary, the research questions posed are: does the difference of ambulation technique using the two prostheses demonstrates that the two knee mechanisms function as they were designed to?; if the biomechanical outcomes can be used to evaluate the prosthetic design, can biomechanical outcomes be used to suggest which knee type would suit a particular user group?; and, can the biomechanical outcomes be used to suggest simple measures that can be used in clinical practice to assist prosthetic prescription?

3.2 GENERAL TRANS-FEMORAL PROSTHESES OVERVIEW

Lower limb prostheses prior to the two world wars were rudimentary (Figure 3.1). The knee joints relied on simple, uniaxial hinge mechanisms, and lacked braking or resistive control.

Figure 3.1 Trans-femoral prosthetic design during first world war (BBC 2012)

Consequently, the stability of the knee was primarily under the voluntary control of the residual limb musculature. Additional stability could be achieved through the geometric alignment of the knee centre; it would be located posteriorly with respect to the hip centre when the knee was in an extended position, as shown in Figure 3.2.

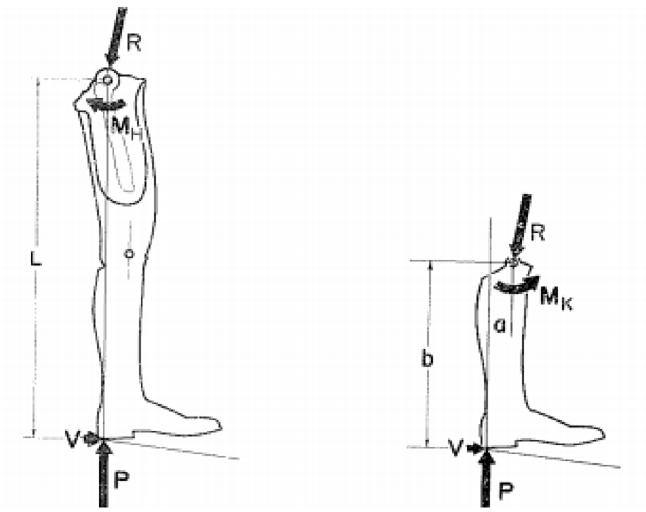


Figure 3.2 Geometric alignment of the knee (Murdoch 1970)

P is the vertical component of the GRF, V is the shear component of the GRF, R is the reaction force, M refers to the respective moments, and L, b and a, are the indicated lengths. Therefore, the sum of the moments around the hip centre is:

$$M_H - VL = 0 \tag{3.1}$$

The sums of the moments around the knee centre are:

$$-M_k - Vb + Pa = 0 \tag{3.2}$$

Substitution of equation 3.1 into 3.2 gives:

$$M_H = \frac{L}{b} M_k + \frac{L}{b} Pa \tag{3.3}$$

If the thigh is not extended, there is no knee stabilization moment (M_k=0Nm), and if the knee centre is aligned by adjusting variable “a”. The anterior alignment of the knee centre with respect to the hip centre will cause the GRF to flex the knee, and posterior alignment of the knee centre with respect to the hip centre will cause the GRF to extend the knee.

As the world wars catalysed trans-femoral prosthetic development, subsequent designs included weight-activated brakes, such as the Bock knee that locked during stance and reduced the possibility of the knee buckling (Zahedi et al. 2005). However, due to the constant resistance of spring extension assist these knee mechanisms only allowed the user to walk at their SSWS. When ambulating at speeds outwith their SSWS, notable gait deviations were seen, such as vaulting to allow foot ground clearance during swing.

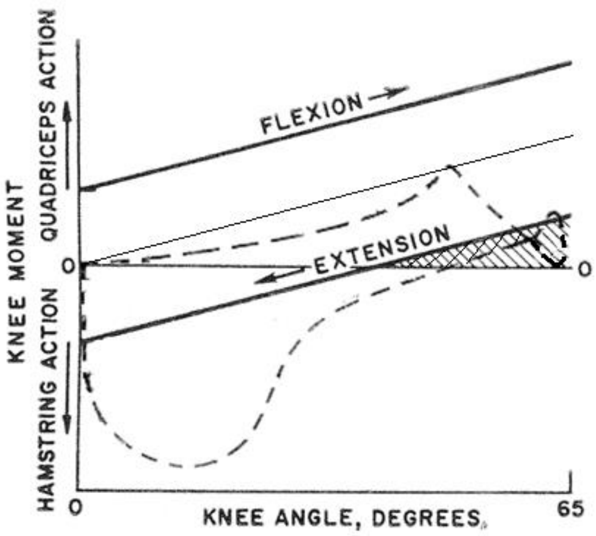


Figure 3.3 Phasic work pattern of constant friction knee device and biological knee adapted from Murdoch (1970)

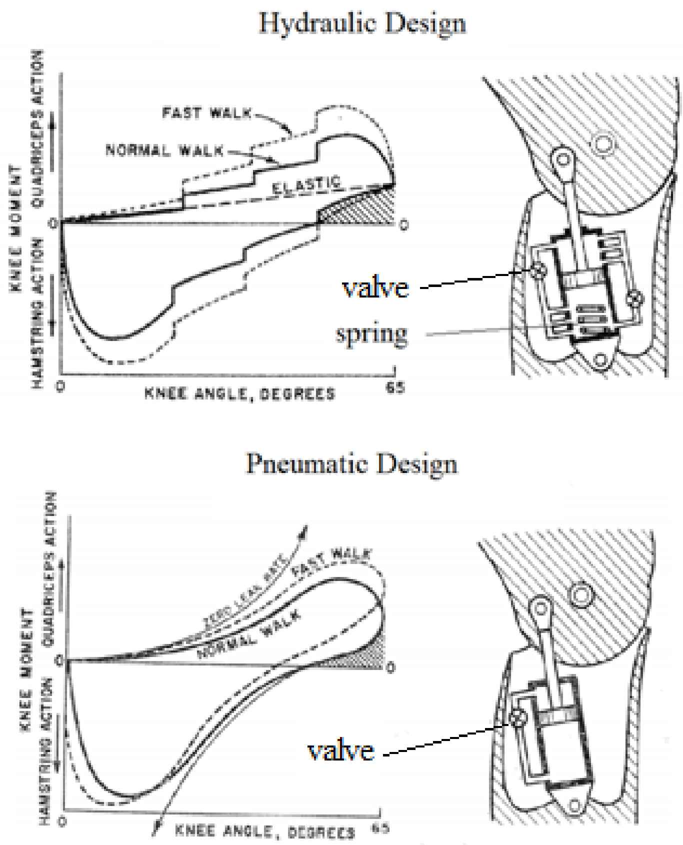


Figure 3.4 Phasic work pattern of hydraulic and pneumatic knee device adapted from Murdoch (1970)

Furthermore, knee flexion during pre-swing was compromised when the user required substantial knee resistance to stabilise the knee during stance. This was because, at terminal stance, an over-stabilised knee joint results in the ambulator using considerable effort to bring their knee to flexion (Radcliffe 1955). Consequently, noticeable gait deviations were seen when the prosthetic user required excessive knee alignment either or both resistance to ensure a stable knee throughout stance. The solid lines in Figure 3.3 illustrate that the characteristics of using a linear elastic element to provide swing extension basis are equal flexion and extension moments. The area under the curve represents the work done on the shank during swing. When the shank was extended during swing, the compressed spring released elastic energy, and positive work is done which assisted knee extension. The energy provided by the spring to extend the shank is given by the hatched area under the extension line. The phasic work pattern of elastic element on the prosthetic leg under spring extension bias is also greater than the mechanical work performed by the quadriceps, as highlighted by the dashed curve. This additional work causes the prosthetic knee to swing into extension rapidly, resulting in a noisy knee impact. This outcome necessitated the solution for designs that controlled the swing phase more effectively and allowed the user to walk with a greater range of walking speeds (Murdoch 1970). This led to the evolution of mechanical knees that incorporated hydraulic and pneumatic cylinders whose fluid flow to either side of the piston was regulated by adjusting an orifice aperture (Figure 3.4). The orifice aperture on modern mechanical knees, such as the Otto Bock 3R80 knee, is still indirectly adjusted by the prosthetist selecting valve settings by directly manipulating external thumb dials to control the flexion and extension resistance.

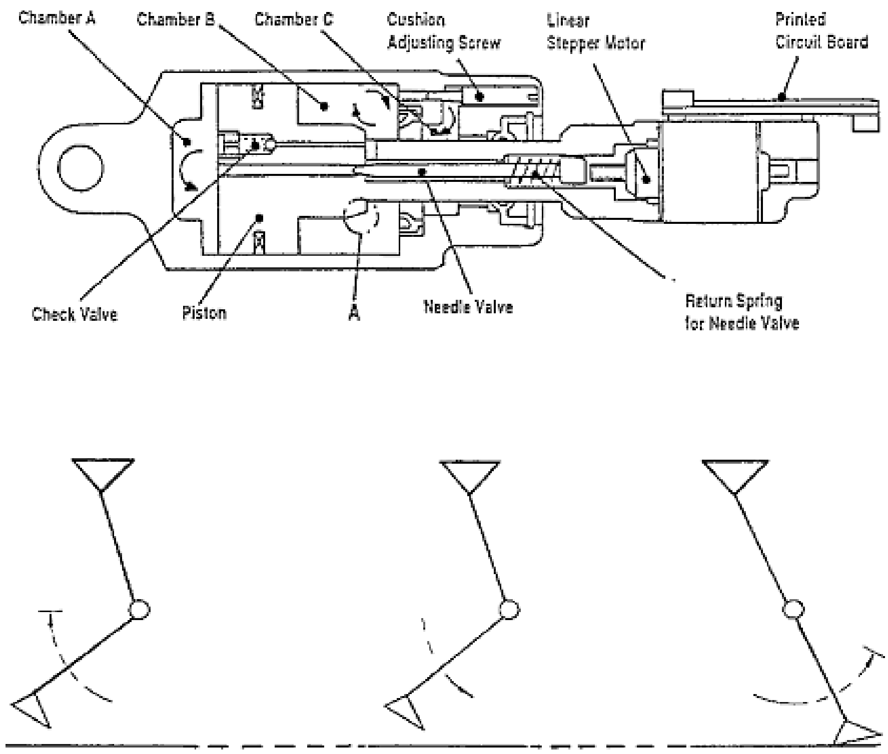
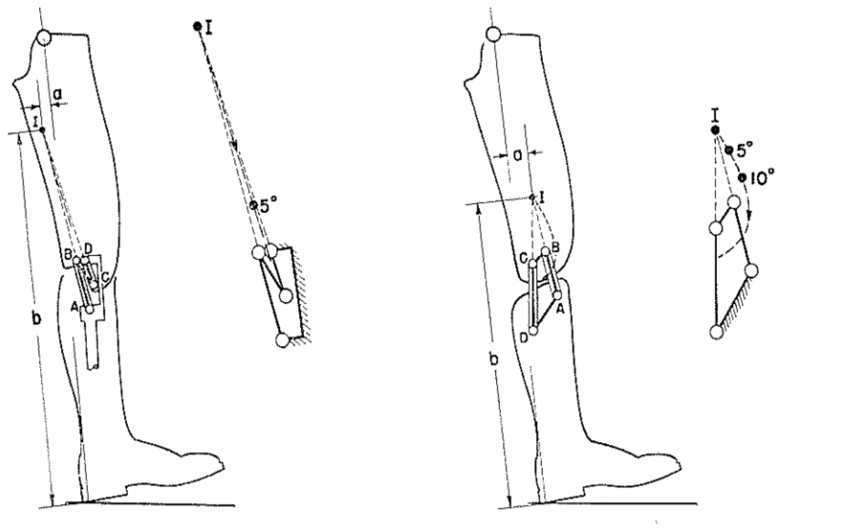


Figure 3.5 Schematic of the intellegent prostheses pnematic cylinder (Buckley et al. 1997)



The positve stability four bar linkage with the instantaneous knee centre behind the hip centre

The negative stability four bar linkage with the instantantaneous knee centre infront of the hip centre

Figure 3.6 Polycentic knee joints (Murdoch 1970)

These optimal resistive settings are usually selected based on the prosthetist observing the most natural leg extension during ambulation, as well as user feedback while walking in the clinic on a level surface at their SSWS. The non-linear compression rate of hydraulic and, more notably, of pneumatic designs allows the leg swing rate to adjust to the users' walking speeds as it naturally deviates from the SSWS (Figure 3.4). Polycentric knee mechanisms tackled stance stability and swing initiation by manipulating the instantaneous geometric alignment using four-bar linkages (Figure 3.6). These knee designs provided the user with "positive" or "negative" stability, and the preferential choice depended on whether the user required greater or less stability during stance. The polycentric design with negative stability primarily placed the knee centre in an anterior position with respect to hip centre and, therefore, this design required the greatest voluntary control. Conversely, the designs that placed the knee centre in a posterior position with respect to hip centre reduced the voluntary control required by the user. However, users of both designs of knee became increasingly unstable during late stance knee flexion, and again required significant musculature control to prevent the knee from buckling. Therefore, these devices are usually only appropriate for the most active community ambulators (Tang et al. 2008).

However, the involuntary response of both the hydraulic and the pneumatic knee designs to the change of user walking speed was limited, and eventually led to the release of the Blatchfords intelligent prosthesis (IP). The IP was the first commercially-available prosthesis that incorporated an embedded system to control the swing phase. The IP microprocessor achieved this function by automatically adjusting the valve settings during ambulation as the walking speed varied.

This was possible because the IP used the ratio of the stance and swing phase timings for average, as well as for walking speeds outwith this range during the knee calibration routine (Zahedi et al. 2005). The identified stance/swing ratios stored by the microprocessor during user calibration were then used to adjust the needle valve accordingly, as well as the knee resistance during ambulation. The needle valve position was adjusted by a stepper motor controlled by the microprocessor output and this ultimately influenced the orifice effect (resistance to fluid flow) and, therefore, knee resistance (Buckley et al. 1997). The knee extension rate of the IP notably changed with walking speed, and allowed the leg to swing with the frequency of step time leading to the ambulator performing fewer gait deviations. Evidence provided by Buckley et al. (1997) and Chin et al. (2007) presented a trend of reduced metabolic energy expenditure, while Datta et al. (2005) reported findings of even greater significance.

However, the stance control of the prosthetic knee provides a greater challenge, as the selection of a resistance that is suitable for both stance and swing is a compromise between the voluntary control during stance and the involuntary swing response. The hydraulic device also requires an elastic element incorporated into the design, to provide knee extension assistance during swing, because hydraulic designs provide substantial knee extension resistance during swing (Figure 3.4). The IP separated the swing and stance mechanism, essentially by incorporating a weight-activated drum brake that would engage and release during stance, and by using the pneumatic cylinder for swing phase control, as described. However, subjective evaluation of the IP revealed that it lacked the “yielding” braking effect during stance, when compared to the hydraulic knee designs.

Model	Year	Advantages	Disadvantages	Indications
Single axis with friction control	Pre-war	Inexpensive and reliable	Suitable for one cadence and difficult to use on uneven terrain	Restricted access to regular health care
Pneumatic & Hydraulic controlled knee mechanism	1950s	Allowed a greater range of walking speeds	Increased weight and cost relative to simpler designs	Restored some physiological function in patients with good physical condition
Four-bar linkage polycentric knee joint	1950s	Good stance stability and flexion control	Higher cost relative to single axis knee	Good for patients with knee disarticulation
Microprocessor controlled prostheses	1990s	Adjusted to the cadence and style of the user with less cognitive control compared to mechanical design	Expensive and needs charged	Restores more physiological function in patients with good physical condition compared to using pneumatic or hydraulic designs

Table 3.1 Overview of trans-femoral prostheses (Tang et al. 2008)

In retrospect, a knee that could respond to an appropriate input and electronically switch between stance and swing was clearly the next evolutionary step. During the late 90s, Otto Bock released the C-leg a knee that incorporated an embedded system, which controlled the switching of knee resistance during stance and swing phase. This breed of knee is generally known as the microprocessor controlled prosthetic knee (MCPK). Since the C-Leg's release, there have been many new designs of MCPK, such as the Otto Bock Genium, the Össur Rheo knee and the Blatchfords Orion knee, to name the mainstream commercially-available MCPK products at the time of writing. However, the Orion MCPK will be discussed in detail, as it is the specific MCPK design that was evaluated in this study.

Even though microprocessor controlled prosthetic knees, (MCPKs) include stance phase control, mechanical prostheses are now lighter and also have improved stance and swing phase capability, such as the hydraulic 3R80 Otto Bock device. Though such mechanical knee designs would only be generally prescribed for the high activity user (NHS 2012). Current opinion is that only the user capable of utilising the 3R80 or similar can be considered as being able to benefit from the design functionality of the MCPK (Tang et al. 2008). Furthermore, the stance philosophy of the mechanical prosthesis or non-microprocessor controlled prosthetic knees (non-MCPKs) is similar to that of MCPKs. The users of both prostheses still require the average mechanical yield settings with which they feel most comfortable during stance when ambulating in the clinic environment to be selected for them during setup. However, the MCPK selects additional resistances for the knee during swing so that the user can walk with a greater range of walking speeds.

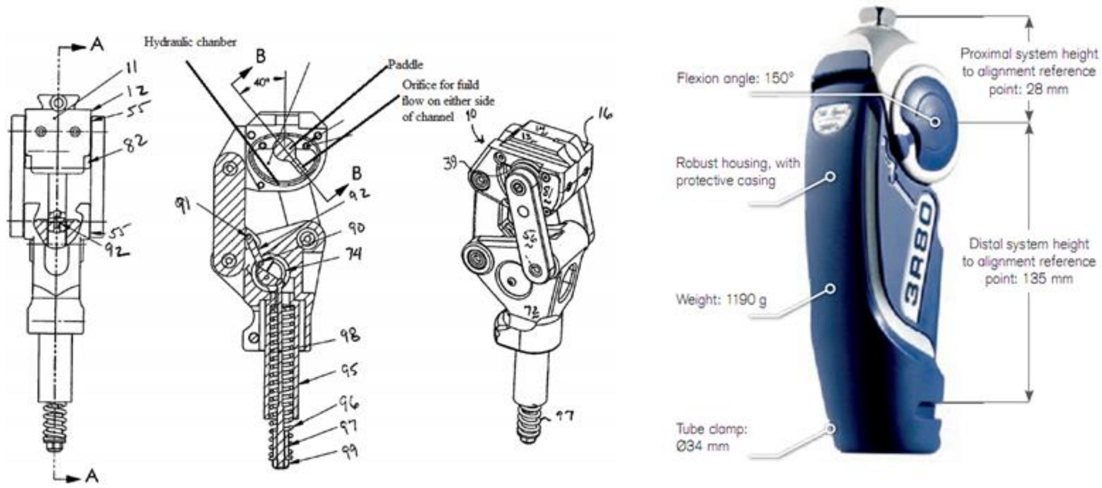


Figure 3.7 Image of the 3R80 knee from OttoBock website at the time of wrting, and assembly drawing from (Wild 2006)

Technical features	3R80 Knee
mass (g)	1190
approved for body mass (kg)	3R80-1 ≤ 75kg 75kg > 3R80 ≤ 100kg
maximum knee flexion angle °C	150
measurement frequency (Hz)	Not applicable
static alignment	0-5 mm posterior placement of knee axes
mechanical function	Rotary hydraulic
Activity level	K3 and K4 according to Medicare Functional Classification level (MFCL)
functions	Swing and stance control

Table 3.2 3R80 knee technical features summary

3.3 3R80 PROSTHETIC OVERVIEW

The 3R80 prosthetic knee target market, as detailed on the Otto Bock website at the time of writing, is for the “unrestricted outdoor walker” or the “unrestricted outdoor walker with especially high demands” (Bock 2013). Essentially, the 3R80 knee target is the active outdoor ambulator, and it is marketed as being capable of responding to low, medium and brisk walking speeds, with some flexion action during stance phase, and extension assist during swing. Therefore, this knee should be capable of operating within the laboratory environment, and should provide an unbiased competitor benchmark against which to compare the Orion MCPK functionality.

In brief, the mechanism of the 3R80 knee relies on the rotary motion of a paddle, as identified on Figure 3.7, with two separate valves used to control the flexion and extension resistance (Wild 2006). The adjustment of the valves is altered using screw controls to set the orifice effect, and therefore the knee flexion and extension resistance. The valve settings are fine-tuned during dynamic alignment, and the threshold settings finally selected by the user are achieved with prosthetist assistance. This technique generally allows the best compromise between perceived security and the ease with which the user is able to flex their knee.

The spring that provides extension assist during swing fits into the cups as shown on Figure 3.7. When the knee flexes during late stance, the ferule rotates and pulls a cable assisting spring compression. During swing, the spring provides energy return by recoiling, which assists with the extension of the knee. Due to the non-linear resistance of the hydraulic fluid, this allows the knee to respond to varying user walking speeds.

Figure 3.8 Image of the Orion knee from the website at the time of wrting

Technical features	Orion Knee
mass (g)	1350g
approved for body mass (kg)	125Kg
maximum knee flexion angle °C	130
static alignment	0-10 mm anterior
mechanical function	hydraulic & pneumatic
main structural materials	Stainless steel, carbon fibre composite, aluminium alloy and polyurethane
Activity level	K3 according to Medicare Functional Classification level (MFCL)
Functions	Swing and stance control

Table 3.3 Orion knee technical features summary (Blatchfords 2013)

3.4 ORION PROSTHETIC OVERVIEW

As described on the Blatchfords website at the time of writing, the Orion knee is designed to "regulate the knee speed" and provide "security" when "walking on stairs, slopes and over flat terrains" (Blatchfords 2013). This should result in "fewer falls for the person wearing the prostheses, and a very natural and relaxed gait". The stance phase security is provided by the hydraulic resistance and the swing phase by the pneumatic resistance.

However, as with the 3R80 knee during calibration, user feedback, and prosthetist judgment and experience ensure the best compromise between knee security and flexion ability. On fitting the Orion prostheses the full reset option should be selected, which includes the calibration and self-teaching routine. However, a "soft" reset does exist, and this allows the self-teaching mode to be entered alone.

The two main advantages of the Orion knee from a commercial viewpoint are that the calibration procedure allows it to be setup according to the defined and regulated protocol with greater ease, and in a reduced amount of time. Furthermore, the embedded system also allows the knee extension resistance to respond more appropriately to a greater range of user walking speeds. This is because the range of walking speeds that the user feels are most appropriate for themselves are stored by the microprocessor during setup/calibration. The prosthesis control system taken from Sykes et al. (2009) details the basic layout of the embedded Orion knee control system (Figure 3.9).

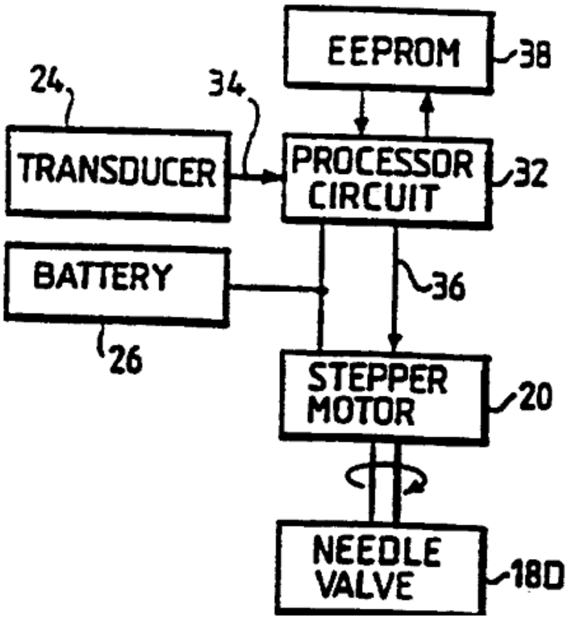


Figure 3.9 Prosthesis control system (Sykes et al. 2009)

The microcontroller at the heart of the embedded system will have a number of dedicated transducer input pins. The transducer includes both strain gauge inputs, likely used to determine stance duration, and a magnetic sensor to determine knee flexion magnitude and piston stroke length. These inputs are amplified, converted from analogue to digital signal by the microprocessor control unit (MCU), and then processed to provide the appropriate output to the stepper motor. The stepper motor is used to adjust the valve aperture, which alters the resistive moment required to flex or extend the knee (Figure 3.9).

The rational basis of the Orion knee's algorithm appears to be repeatability. As described in Zahedi et al. (1999) the gait of an individual becomes less repeatable as lower limb loss becomes more proximal. In turn, the aim of the controlling algorithm is to reduce the variability or deviation of kinematic and kinetic outcomes. To do so, the transducer of the embedded system provides instantaneous inputs to the MCU that are also associated with repeatable kinematic and kinetic quantities.

During the calibration routine, the Orion microprocessor stores the stance duration period and the user-selected threshold limits, both of which switch the knee from stance to swing mode. These inputs are further processed and stored as Electronically Erasable Programmable Read-Only Memory (EEPROM), allowing individual user preferences to be set accordingly.

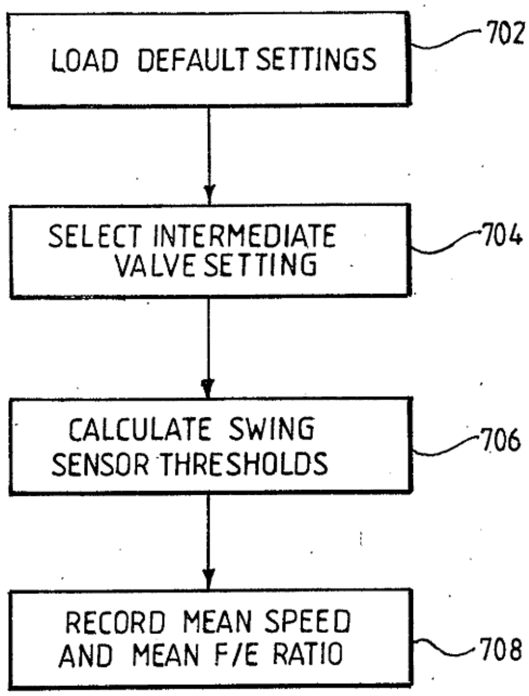
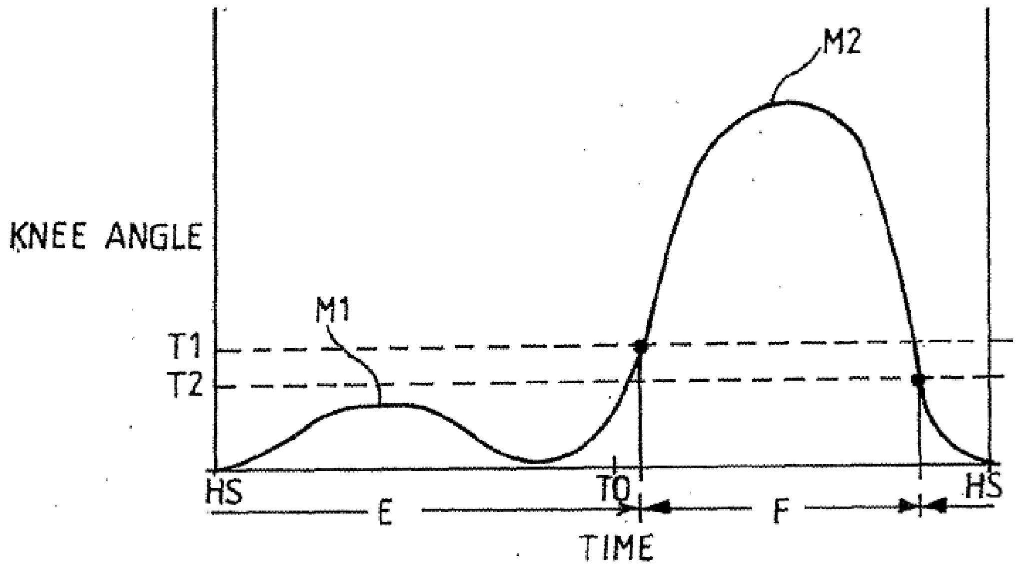


Figure 3.10 Calibration routine (Sykes et al. 2009)

The calibration routine should only be entered once the prosthesis is fitted to the user; the initial boxed settings are representative of those used by a typical prosthetic user, and are usually later fine-tuned on an individual basis. To enter the calibration routine the prosthesis programme full reset mode is first selected, and in turn this allows new hydraulic stance and swing yield resistances to be set. The toe load stance release, and target stance and swing phase ratios for a given walking pace at the users' normal, slow and fast walking speed are then subsequently set. However, over the long term a subsequent self-teaching mode iteratively derives the appropriate resistive settings and boundary conditions for walking speed deviations from those initially stored during user calibration.

As the timing and duration of stance phase is dependent on the user walking speed, and as the rate of the knee extension during swing is dependent on the stance period, the MCU, with the assistance of the prosthetist during calibration, uses the stance phase period to control knee resistance in order that premature or late knee extension does not occur. Essentially, the statistical relationship between stance and swing duration decreases or increases the swing phase period, while the walking speed increases or decreases relative to the SSWS. For a given walking speed, the threshold values T1 and T2 are used to determine the cut-off points, or tolerance values, for the flexion/extension ratio (F/E) (Figure 3.11). The plotted F/E ratio provides a means of determining the resistive knee values during swing phase for a given walking pace. Walking speeds above an SSWS result in a higher F/E ratio, and walking speeds below the SSWS result in a lower F/E ratio.



Graph 3.1 F/E ratio and threshold values (Sykes et al. 2009)

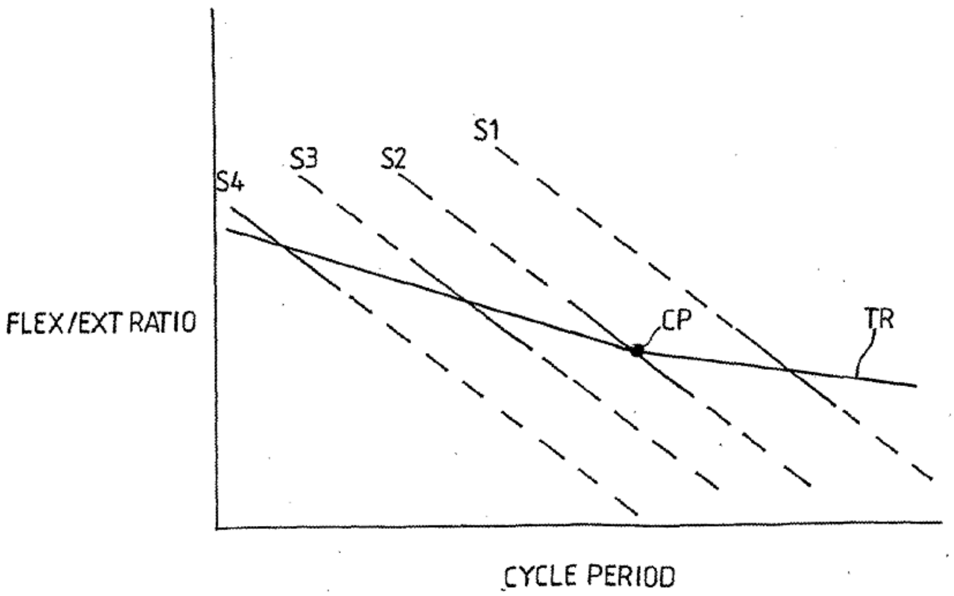


Figure 3.11 Target relationship from calibration (Sykes et al. 2009)

It is documented that, when the F/E ratio is plotted against the gait cycle period, it changes in an optimal linear fashion, it should be noted that when the graph is plotted against cycle period, which decreases with increasing walking speed. The greater walking speed originates at the origin. As the swing ratio increases the linear relationship moves from the right to the left of the x-axis. The trend line TR results from the knowledge that, as walking speed increases, the F/E ratio will also increase, allowing a trend line to be extrapolated from the calibration point (CP). During the calibration walk, the CP point is selected from several steps (Figure 3.11).

The CP is determined when walking at a slow, medium and fast pace. However, for swing phase, a finer resolution is needed, and positions AB1 and AB2 are determined using linear interpolation (Figure 3.12). Once the calibration point is reached, the algorithm automatically enters into a self-teaching mode and the user’s walking speeds are tailored with respect to the predicted F/E ratio. The self-teaching mode also modifies the calibration ratios determined during user setup, and allows the stored knee resistances to be refined. The relationship between the FE ratio and cycle period is given by two straight-line relationships that intercept at the point CP.

When the prosthesis is used in the self-teaching mode, the algorithm has a positive and negative voting system to adjust the piston valve, and therefore knee resistance as well. Essentially, when periodic impulses from the transducers deviate from those stored, the MCU recognises that the walking pace no longer matches the stored values. The voting system result, likely to be the sum of the microprocessor working register output, is used to determine whether the valve setting should be adjusted.

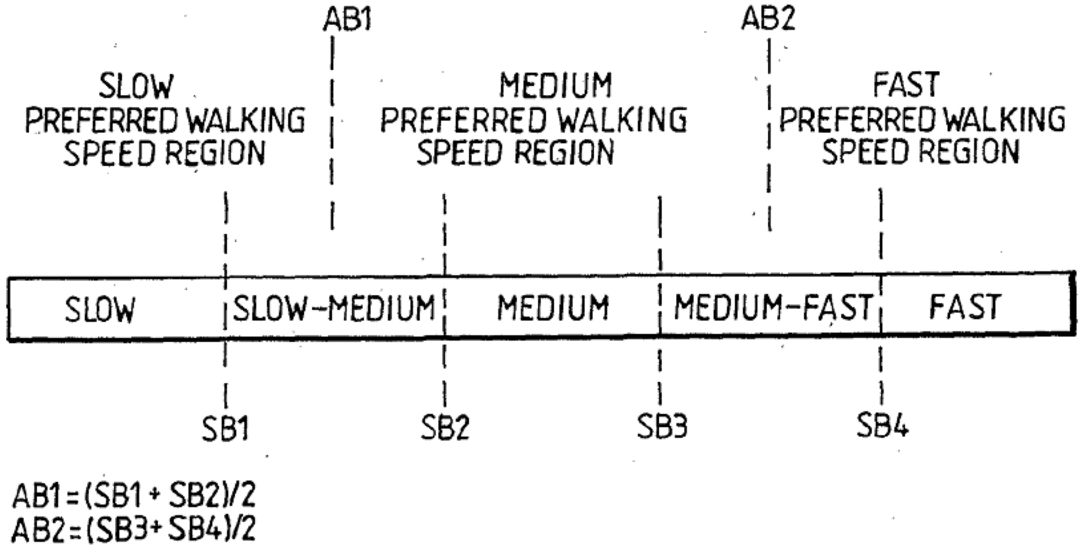


Figure 3.12 Speed boundaries for knee swing resistance (Sykes et al. 2009)

During stance, the strain gauge circuit provides a signal to indicate the direction of the external moment about the knee during stance. Furthermore, during stance release, the toe load identified during calibration uses the strain gauge circuit signal to define the stance release threshold. Hence, when the toe load exceeds this threshold, the yield resistance is reduced from the supporting stance resistance to a lower hydraulic resistance, which allows the knee to transition from stance to swing more easily.

From the above description, it is clear that the testing procedure is unable to consider all Orion benefits, such as the ability of the knee to recognise the users' change in walking pattern over the long term. However, the ability of the Orion knee to electronically switch between stance and swing mode will be considered, as will the adjustment of swing phase damping as the SSWS changes with the plane of ambulation when transitioning from the level to slope and vice versa will be considered.

Figure 3.13 Echelon foot from maufacturer’s website

Max. Amputee weight:	100kg / sizes 22-24
	125kg / sizes 25-30
Activity level:	3
Size range:	22cm-30cm
Component weight:	900g
Build height:	115mm sizes 22-24
	120mm sizes 25-26
	125mm sizes 27-30
Heel height:	10mm

Table 3.4 Blatchford specification guidelines

3.5 ECHELON FOOT

The articulated Echelon foot was chosen for this study because of its ability to plantarflex or dorsiflex directly under the influence of the GRF, and find a position of total surface ground contact. During normal ambulation, after initial contact the position of maximum foot stability or total surface ground contact is achieved by the coordinated effort of the knee and ankle. Consequently, instability is created around the prosthetic knee of the trans-femoral prosthetic user when they cannot move their foot to a stable flat position. However, it is also imperative that the foot choice will not cause foot slap, but will instead allow the foot to make a controlled ground contact while maintaining knee stability. Therefore, the concept of the "self-aligning" "biomimetic" Echelon ankle was a further development of the uniaxial foot, as described in Radcliffe (1955), enhanced by modern technology. However, when compared to the more conventional articulated ankle with plantarflexion and dorsiflexion bumpers, the Echelon ankle allows the plantar and dorsiflexion resistance to be more precisely fine-tuned to the individual's requirements. This mechanism reportedly allows the body to find a more natural position during stance which in turn alleviates instability around the knee and hip when ambulating on a variety of terrains (Moser et al. 2008).

Thus, the knee equivalent of this ankle could be compared to the non-MCPK, whereby the best average resistance for all terrains and walking speeds relies on the selection of an optimal resistance. However, since the time of writing a new Élan foot, with microprocessor control that can temper its resistive values according to the incline of the terrain, has been introduced.

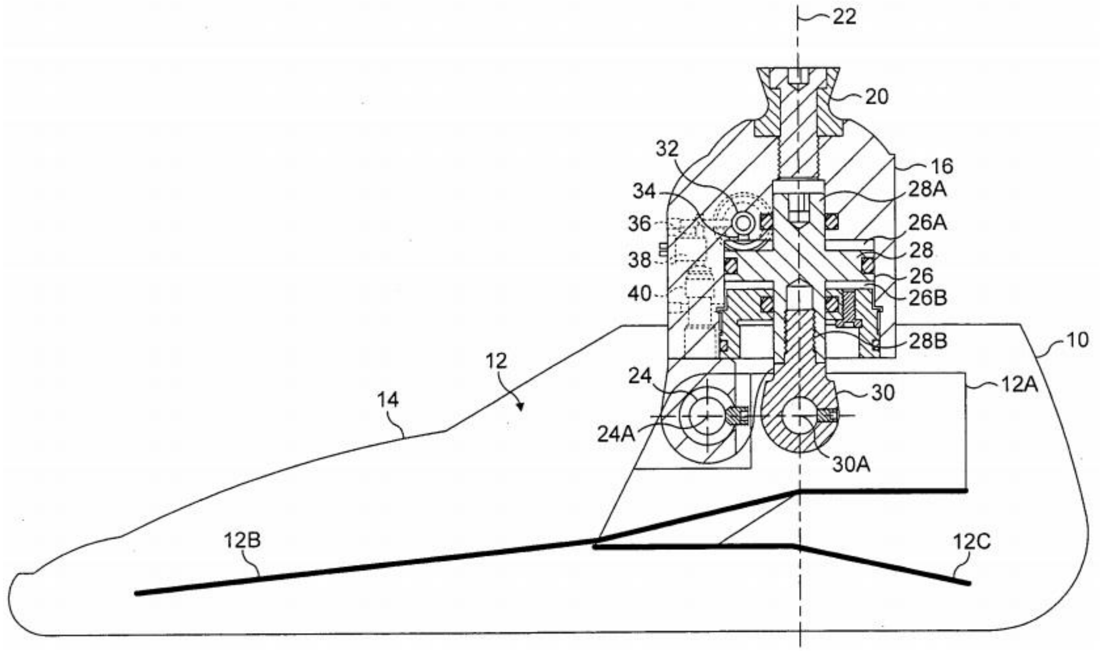


Figure 3.14 Side elevation of Echelon foot with foot shell (Moser et al. 2008)

The basic function of the Echelon ankle allows for a maximum of 3^{o} dorsiflexion and 6^{o} plantarflexion, and the resistances for both plantar- and dorsiflexion can be individually set. The foot is able to plantar- and dorsiflex around the fixed rotation point 24A, shown in Figure 3.14, and on doing so will result in the actuation of piston 28 in cylinder 26. In essence, when the foot dorsiflexes the hydraulic fluid in the lower chamber 26B will be compressed and forced though the one way valve 40 to the upper chamber 26A. Foot plantarflexion causes the hydraulic fluid in the upper chamber 26A to be compressed and forced through a parallel one-way valve to the lower chamber 26B. These individual valves for both plantar and dorsiflexion allow the orifice resistance to be fine-tuned on an individual plantar and dorsiflexion basis.

3.6 DETERMINATION OF MEASURED OUTCOMES TO EVALUATE THE NON-MCPK AND MCPK

As it is the primary objective of this study to determine the biomechanical benefits of the MCPK relative to the non-MCPK, the purpose of this second part literature review was to highlight functional differences between the two prostheses in order to determine appropriate ambulatory characteristics to measure. The review of the two prostheses revealed that, relative to the 3R80 non-MCPK, the Orion MCPK might have given additional voluntary control during stance because, as described in section 3.4, the toe load identified during calibration uses the strain gauge circuit signal to set the stance release threshold. Therefore, when the toe load reaches the threshold value, the identified strain gauge circuit output magnitude during late stance is used to reduce knee resistance. This reduction of knee resistance allows the knee to transition from stance to swing with greater ease. Hence, this indicates that reviewing the timing with which the knee and ankle moment change direction during late stance would reveal whether the recruits experienced additional voluntary control.

To assess the additional involuntary control, the review revealed the stance period, and thus the walking speed that is used to set the appropriate knee damping for swing. As the knee also has the ability to determine set points between the slow and average, and fast and average walking pace this indicates that it was not necessary to determine the knee involuntary response at the extreme walking speeds. Instead, it was appropriate to measure the change of walking speed with respect to the activity, such as level or ramp ambulation.

The statistical power of the study was insufficient to expect that the instances of the gait cycle that were identified in this chapter would reveal that the voluntary control and involuntary response would differ. Therefore, with the limited participant numbers, and with the understanding of how the two knees that were to be evaluated should integrate themselves with the user, as it was expected that it would be possible to use the moment graphical outcomes qualitatively on an individual basis to explore the differences between the two knees. The additional expected benefits of the Orion knee included using the toe load to assist when the knee resistance remained high during stance; it was considered that this mechanism would increase the user voluntary control. Furthermore, the additional involuntary response is usually thought to be the ability of the user to walk with a significantly greater or reduced respective SSWS. However, this chapter again revealed that the Orion MCPK has the ability to adjust its swing rate as the user walking speed naturally varies depending on the plane of ambulation. Hence, this required analysis beyond the realms of level walking to ascertain the involuntary response. It was expected that a ramp and stair activity might be more likely to show that the Orion MCPK provides additional voluntary control. As a result, it was realised that a study of A/B crossover design was required to evaluate these instances using individual case studies. Moreover, as both unrestricted and restricted outdoor ambulators were recruited for this study, evaluating every participant qualitatively would reveal if the Orion MCPK influenced the voluntary and involuntary control equally for outdoor walkers with varying abilities.

3.7 SUMMARY

In summary, the greatest step forward in lower limb prosthetic technology after the development of hydraulic units was arguably the development of the IP, as the user was able to walk with a greater range of speeds. However, the advantage that hydraulic units have over the IP during stance is that, on reaching the user- and prosthetist-defined knee brake or release limit, the fluid response allows the hydraulic knee to respond more gradually, whereas the mechanical drum brake of the IP will brake and release with less yielding feedback. Therefore, when Otto Bock developed the C-leg with hydraulic resistance and sensory feedback control for both stance and swing phase, the user could still walk with a greater range of walking speeds as offered by the IP but with greater security during stance. This brake and release mechanism was controlled by the microprocessor using the strain gauge circuit signal to indicate the direction of the external moment about the knee during stance. Hence, during stance release, the toe load identified during calibration uses the strain gauge circuit signal to define the stance release threshold, a mechanism that allows the knee to more easily transition from stance to swing.

Understanding the mechanism of the two prostheses evaluated made it possible to identify the instances of gait cycle that would highlight in-voluntarily and voluntary control differences and, therefore, the ambulatory characteristics to measure. It was also determined that the involuntary response could be evaluated considering the stance period, and that correlating this with an outcome that reflected the knee resistance would assist the understanding of involuntary response. This philosophy was adopted, as it investigated how the limb worked with the user rather than simply presenting the magnitude of kinematic and kinetic differences.

Number of lower limb amputations in UK by cause and year April 1997 to March 2007										
Year	97/98	98/99	99/00	00/01	01/02	02/03	0304	04/05	05/06	06/07
Trauma	323	400	443	448	432	443	390	441	391	337
Dysvascularity	2231	2865	3051	3464	3506	3724	3354	3572	3045	3300
Others	2005	1895	1478	1386	1329	1097	1026	781	1140	937
Total	4559	5160	4972	5298	5267	5264	4770	4794	4576	4574

Table 3.1 Cause of lower limb amputation in the UK (NHS 2010)

CHAPTER 4 METHODOLOGY

4.1 TESTING OBJECTIVES

The review of the 3R80 non-MCPK and the Orion MCPK revealed that, when compared with that of the former, the functionality offered by the Orion MCPK would not significantly affect the biomechanical outcomes when walking in an indoor level environment. Moreover, in each case the evaluated prostheses had to be fitted and adjusted for ambulation in the indoor level environment. Consequently, activities were required within this environment that would challenge the participants wearing the evaluation prostheses beyond the realms of level indoor walking. Hence, both ramp and stair ambulation activities were incorporated into the gait laboratory sessions.

Particular attention was given to the knee resistance break and release control moment when transitioning from stance to swing because the user should have additional control of their MCPK at late stance to allow for easier swing initiation. As revealed by the review of the Orion MCPK in the preceding chapter, the additional voluntary control is enhanced by the nature of the Orion's mechanism inasmuch as the embedded system can read the calibrated toe load and reduce the knee resistance. Furthermore, due to the volume of testing it was not possible to evaluate the involuntary response of the non-MCPK and the MCPK at the participants' slow, average and fast indoor walking pace. However, it was expected that the Orion MCPK would allow for a more natural adjustment of SSWS as the plane of ambulation changes, due to the microprocessor-controlled damping response.

The voluntary control during stance and the involuntary response during swing was investigated by analysing the ambulatory kinetics and kinematics during exercises that included level indoor walking, ramp, and stair activities. The voluntary control was investigated primarily by considering the prosthetic and anatomical joint moments to reveal if there were patterns. The involuntary response was considered by investigating the knee damping response as the participants' SSWS naturally altered when they transitioned from level walking to ramp ascent and vice versa. The knee damping was not measured directly; instead, it was considered indirectly by determining the mechanical energy absorbed around the knee.

The purpose of this chapter, in brief, is twofold: to elaborate on the number of participants recruited; and to detail how the study was designed to maximise the investigation of the two knees investigated, as this would affect the manner in which the outcomes from the laboratory study were evaluated, and the strength of the conclusions. The chapter will begin by providing a general description of the prosthetic user population in the United Kingdom, and the user group that is most likely to be prescribed the MCPK. It will then go on to discuss the limitations of the participant pool that is finally recruited, as well as how recruitment affected the study design and analysis of the data.

Year	97/98	98/99	99/00	00/01	01-Feb	02-Mar	03-Apr	04-May	05-Jun	06-Jul
Trauma	323	400	443	448	432	443	390	441	391	337
Dysvascularity	2231	2865	3051	3464	3506	3724	3354	3572	3045	3300
Others	2005	1895	1478	1386	1329	1097	1026	781	1140	937
Total	4559	5160	4972	5298	5267	5264	4770	4794	4576	4574

Table 4.1 Cause of lower limb amputation in the UK from April 1997 to March 2007 (NHS 2010)

rating	Description
K0	MFLC-0—Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility.
K1	MFLC-1—Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
K2	MFLC-2—Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
K3	MFLC-3—Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
K4	MFLC-4—Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete.

Table 4.2 Medicare Functional Classification level (MFCL)

4.2 GENERAL PARTICIPANT CONSIDERATIONS BEFORE RECRUITMENT

Despite the most-significant reason for a trans-femoral amputation in the United Kingdom being the outcome of peripheral vascular disease (PVD) (Table 4.1), only 10% of amputees in this group become ambulators, and even then they often have only limited walking ability. As a consequence they use a prosthesis with a locked knee, or else use a wheelchair (Datta et al. 2005, Tang et al. 2008). Therefore, it is probable that this group would be rated with a K0 ambulation ability (Table 4.2). Prosthetic users rated with K0 ambulation ability are therefore unlikely to benefit from prosthetic use, let alone MCPK use, and as a consequence were excluded from this study.

However, it can be reasoned that the K1 user group would benefit from the MCPK, although Kaufman et al. (2007) suggested that further investigation is required. Hence, with the short familiarisation period that was available for this study, it was unlikely that a K1 group would have utilised the Orion MCPK limb advantageously. It was determined through the evaluation of the study normal control, as discussed fully in section 4.9, that, on average, ten ambulatory periods were required to ensure good data repeatability using the test protocol. Therefore, recruiting participants to complete laboratory sessions over a 2-3 day period would not have given the K1 participant group the opportunity to complete the necessary number of repetitions, due to the difficulty of asking indoor walkers to complete up to 200-250 tests runs over level, ramp and stair ambulation activities.

As the majority of active walkers rated with a K2 or K3 community ambulation ability as discussed in Datta et al. (2005) and Mâaref et al. 2010 are more likely to have lost their limb as the result of an accident than medical condition, it was decided that our group should be composed of such walkers. It was decided that this group of outdoor ambulators had the ability to take part in the rigorous testing protocol. Moreover, these group of K2 “limited” and K3 “unlimited” community ambulators are still “restricted” by their ambulation skills and, compared to a K4 user group, have a greater opportunity to improve their ambulatory technique. If a K4 user group had been selected such obvious advantages may not have been highlighted, as differences in their ambulatory style may have been subtle and hard to quantify, as they could have utilised a 3R80 non-MCPK with the similar outcome as an Orion MCPK.

However, the limitation of having just one 3R80 non-MCPK, one Orion MCPK, and one state-registered prosthetist imposed considerable time constraints on the project. This, combined with the inability to allow the recruits to undertake community ambulation acclimatisation over an extended period due to a lack of insurance, led to the realisation that focusing on a group of prosthetic users with specific ambulation skills would be more appropriate. However, it was realised that focusing on a group of prosthetic users with specific ambulation skills compared to users with a wide range of abilities would also assist statistical analysis, as results would not become as diluted (Bland 1987).

Moreover, when considering the previous experience of potential volunteers it was realised that analysing a population of community ambulators who already had experience with high-end prosthetic components would help minimise the effects of the short acclimatization period. However, users who were already accustomed to their MCPK may have displayed accentuated gait deviations without sufficient time to become acclimatised to the non-MCPK control. Consequently, these considerations, along with the final number of participants recruited, shaped the final study design and method of analysis.

Prosthetic user selection criteria	Additional Notes
They are unilateral trans-femoral prosthetic users	The study was concentrated on the unilateral prosthetic user.
They have used a prosthetic limb for more than two years	This was to ensure that the participants had suitable experience using lower limb prosthetic components and would be able to adapt to the two evaluation prostheses.
Subject mass less than 100kg	The maximum user weight limit.
The residual limb has a full range of motion and muscle control	Evaluated using the Thomas test to ensure that residual limb had a good range of motion and strength.
They are community ambulators	This was to ensure that the participants were capable of taking part in the test activities of level, ramp and stair ambulation.
They do not have any language or cognitive problems	to minimise the chance that participants did not respond to instructions, and to ensure that they had the ability to adapt to the test prostheses with minimal acclimatisation.
They do not have any co-morbid or health concerns	To reduce the opportunity of secondary conditions proceeding limb loss minimising the prospect of the participants displaying improvements over the short study duration.

Table 4.3 Participant selection criteria

participant	sex / age / body mass without prosthetic limb	everyday prosthesis	reason for amputation/ date of amputation / side	Medicare Functional Classification level
A	male / 53 years / 81 kg	IP/3R80	trauma / 1991 / left	K3
B	male / 51 years / 84 kg	3R80	tumour / 1980 / right	K2
C	female / 37 years / 61 kg	C-Leg	tumour / 1993 / right	K3
D	male / 52 years / 95 kg	3R80	trauma / 1979 / right	K2
E	male / 56 years / 84 kg	C-Leg	trauma / 1995 /right	K2
F	male / 53 years / 84 kg	C-Leg	trauma / 1996 / right	K2

Table 4.4 Participant summary

4.3 PARTICIPANT RECRUITMENT AND ACCLIMATISATION

Once ethical NHS approval (Ref: GN11OR435) was granted, invitations titled "Evaluation of microprocessor knee mechanisms" were left at the WESTMARC limb-fitting centre at the Southern General Hospital, and the Biomedical Engineering department at the University of Strathclyde. The approved application forms are saved in the appropriate folder on the compact disk appendix of this thesis. The original pool of ten identified participants, were sent a participation information sheet and a letter inviting them in for an initial consultation at the University of Strathclyde. The initial consultation also gave the potential volunteers the opportunity to ask questions with respect to the time commitment required for this study, while also giving clinician the opportunity to assess whether the potential recruits had sufficient time and health to participate in the study.

At the initial consultation at the Biomedical Engineering department at the University of Strathclyde, the potential recruits' residual limb musculature strength and range of extension were evaluated using the Thomas test. Moreover, as detailed in Table 4.3, a variety of parameters were considered to ensure that the recruits were appropriate for the study. From the initial group of ten candidates who applied, six participants were chosen. The inclusion criteria were decided upon to ensure that the recruits selected had the ability to participate in a number of laboratory exercises in a repeatable manner. The gait laboratory activities involved level walking, ramp and stair ambulation. The participants were required to repeat each activity a sufficient number of times so an average of ten gait periods for both the prosthetic and contralateral limb were captured.

Consequently, the recruits were required to participate in the gait laboratory sessions over a 2-3 day period to allow an adequate data set to be collected. It was for this reason that, the four additional candidates were rejected, as they did not have the residual limb strength to ambulate in a repeatable manner using both the 3R80 and the Orion knee. From the six candidates who were selected, both the restricted and unrestricted outdoor ambulators were recruited. This outcome also shaped the investigation, as did the inability to allow the participants to ambulate outside due to the lack of insurance, and the inability to service the prostheses. As the aim of the investigation was to determine both the voluntary control and involuntary response of the two knee prostheses, and the fact that both the K2 and K3 users were capable of using both knee types. Evaluating K2 and K3 user groups led to the opportunity to investigate whether the Orion MCPK would benefit the outdoor recreational walker (K3), or the outdoor walker who is able to ambulate when required (K2).

The exclusion of indoor walkers, and individuals who suffered lower limb loss as a result of peripheral vascular disease (PVD), prevented this study from considering limited and unlimited household ambulators who may have also benefited from the Orion MCPK. However, it was accepted that these were study limitations, and that while the population pool was not representative of the United Kingdom lower limb prosthetic user population, the population recruited would allow the primary research questions to be asked – questions such as, what are the benefits of the Orion MCPK compared to the 3R80 non-MCPK? and is it possible to identify outcomes that could be used to assist prescription of the MCPK in the clinical environment? Furthermore, as described on page 137, recruiting a slightly larger population pool would not have increased the study power.

During the initial clinical consultation, visual assessment of the participants' walking ability was performed with the assistance of a state-registered prosthetist, to ensure that the residual limb was free from pathologies and the general health of the would-be volunteer was sufficient to allow them to be able to ambulate in the gait laboratory during a morning and afternoon session. The clinical assessment was required, as the protocol required each prosthetic user to participate in a level walking, stair and ramp ambulation procedure, with both evaluation prostheses, this protocol required outdoor community ambulators. However, this proved a considerable challenge due to the limited number of trans-femoral prosthetic users available within commuting distance who were also able ambulate without locking their knee.

On successful socket fabrication, both evaluation prostheses were fitted to the socket – which will be discussed shortly – and this gave the participants the opportunity to familiarise themselves with the prostheses during clinical sessions. Three provisional testing dates were then set for each participant to visit the gait laboratory in the Wolfson Building at the University of Strathclyde. However, the minimum participant acclimatisation time of three, as recommended by English et al. (1995) was not possible. However, as it was important for the individuals concerned to familiarise themselves with their prostheses before the commencement of the laboratory sessions, the participants were given the time they required to do so before the data acquisition process began. This in turn highlighted the requirement to recruit participants who could adapt to a new prosthesis with a short familiarisation period.

4.4 PROSTHESES SELECTION

The Blatchfords Orion MCPK was initially selected, as it was the premium MCPK available when the gait laboratory sessions were scheduled to take place. Therefore, an appropriate non-MCPK was also required. It was considered that selecting a non-MCPK, which originated from a competitor would minimise the selection bias because the non-MCPK was similar in design to the C-Leg, another high end MCPK with a microprocessor. This decision ensured that a premium non-MCPK product, rather than an entry-level non-MCPK, was the mechanical benchmark. Moreover, it was also considered that selecting a mechanical benchmark from the same manufacturer as the MCPK may automatically result in the non-MCPK benchmark underperforming with respect to the MCPK, because it was expected that internal company procedure would have already benchmarked the MCPK with respect to the non-MCPK. Hence, selecting a competitor non-MCPK would evaluate the MCPK against a competitor's device, and minimise the risk of the knee component choice biasing outcomes.

The same foot was used to eliminate/reduce variables in the testing procedure so that we knew that the differences were caused only by the difference in knee joint selection, the Blatchfords Echelon foot with both hydraulic planter and dorsi-flexion resistance was fitted to the evaluation prostheses. The Echelon foot design allowed it to be easily fitted to both prostheses with the same alignment, and at the time of testing it was a premium foot that was a likely to be fitted to such prosthetic knee types. Moreover, the same foot was selected for both prostheses to minimise component and alignment variability between the two knees.

As the socket is an integral component in the lower limb prosthetic, a new ischial containment socket was fabricated for each of the six participants, as this was also their everyday socket. Furthermore, to reduce the variability of socket design, all the sockets were fabricated by the same prosthetist utilising the same production technique. This procedure required at least three visits to the National Centre, University of Strathclyde, by each participant to allow the new socket to be cast and modified. After bench alignment, the knee prosthesis to be evaluated was fitted to the participant and final dynamic adjustments were made. Every participant had at least 2-3 hours to familiarise themselves with their prosthesis during the initial clinical sessions.

4.5 STUDY DESIGN

To compare the Orion and 3R80 knees, a crossover study design was utilised. This involved capturing the kinematics and kinetics of six participants walking with the Blatchfords Orion MCPK and the Otto Bock 3R80 non-MCPK in random order. A number of mechanical and human factors influenced the selection of the 3R80 control prosthesis, while the Orion knee prosthesis was the MCPK benchmark that was available at the University of Strathclyde in the Biomedical Engineering department. The parameters considered included the selection bias, mechanical variability between prosthetic components, alignment, the acclimatisation period available, and the walking ability of the recruited participants.

The advantage of the crossover study design was that the participants were able to act as their own control. As will be discussed in section 4.8, due to the low recruitment number of six participants, the power of the study was too low to enable the statistical analysis of inter-subject results. The crossover study design allowed the results to be statistically analysed on an intra-subject basis, and therefore allowed individual patterns to be discussed on a qualitative basis. To ensure that results were repeatable and accurate, normal data was captured using a normal control prior to participant evaluation as discussed in section 4.9.

To enable the analysis of the effects of voluntary and involuntary control on the ambulation technique adopted by the participants wearing the two prostheses, the involuntary response and involuntary control was examined. The recruits participated in the activities of level, ramp and stair ambulation to allow the effects of voluntary and involuntary control of the evaluation prostheses to be investigated.

4.6 TEST ACTIVITIES

Assessing the requirements of the prosthetic user in the laboratory environment will always be approximate, as the indoor laboratory environment will not challenge them to the same extent as the outdoor environment. However, because the gait laboratory offers an environment where variables are easier to control, and where participant safety can be prioritised, the choice of this environment over an outdoor environment does have its advantages when evaluating prosthetic performance.

Even though there is no definitive set of activities used to quantify the gait of an individual, there are certain activities such as, stairs, ramps, stumbles, change of pace and distraction that are used to evaluate the gait of an individual. These test types suggest that analysis of prosthetic gait beyond the realms of level indoor laboratory walking is perceived as being necessary. The “Amputee mobility predictor with prosthesis” (AMPPro) uses categories such as: sitting balance, transfers, standing balance, gait and stairs to quantify amputee mobility. These subjective tests appear to have good reliability, and are recommended as a clinical and a research tool (Condie et al. 2006). Multiple studies have also determined their own measured outcomes as being the important measures for quantifying the prosthetic user's ability with a particular prostheses (Condie et al. 2006, Franchignoni et al. 2004, Gailey et al. 2002, Hafner et al. 2007). This implies that the choice of measured outcomes is also influenced by the subjective opinion of the investigator.

Observational studies such as, Hafner et al. (2007), Franchignoni et al. (2004) and Datta et al. (2005), used qualitative scoring to assess the attributes of gait through the observation of patterns of locomotion, but they do not quantify why there is a change. Such studies are useful when identifying the activities of daily living (ADL) that prove the greatest challenge to the prosthetic user. Activities that may help the participant to recover from a stumble or a push, as detailed in the nudge test, as described in Bellmann et al. (2010) were not used, as performing the test in a safe manner would have involved the use of a harness, which could potentially have increased participant anxiety levels and thereby influenced the outcome. Furthermore, initiating a trip with repeatability and accuracy, and with the participant prepared, is not a clinically relevant test.

It was expected that there would be little difference when comparing the measured outcomes of the user wearing each evaluation prosthesis while walking in an indoor environment. However, level walking is the standard gait laboratory procedure, and is generally used in most studies as a gold standard comparator test (Condie et al. 2006).

As the MFCL, Table 4.2, outlines that environmental barriers such as curb negotiation are the greatest challenge to the prosthetic user when walking outside, activities beyond level walking were included in the testing protocol. Further, as stair and slope ambulation were also documented as the top three list of activities that the lower limb prosthetic user finds most difficult, they were included in this evaluation as well (Datta et al. 2005, Franchignoni et al. 2004).

Moreover, it was expected that, due to the challenge faced by prosthetic users on negotiating terrains outwith level walking, the kinematics and kinetics would reveal the greatest functional differences between the two evaluation prostheses. When the user changes their ambulation speed, the involuntary response and, therefore, the swing phase damping response of the MCPK compared to the non-MCPK, should be notable. Hence, rather than forcing the participants to walk at a range of speeds on the level, the responses of the swing phase damping as the SSWS altered during level, ramp and stair ambulation activities were investigated. Conversely, through considering the knee moment and period of stance, the voluntary control the participants exerted over both knee prostheses was also evaluated. It was expected that, during ramp and stair ambulation activities, the Orion MCPK brake and release mechanism would also enhance the user's voluntary control.

To investigate the functional design aspects of voluntary control and involuntary response, the initial contact instance, late stance and swing period were evaluated by capturing the kinematics and kinetics of ambulation during the test activities. The ethos of the analysis was to use the difference in ambulation patterns to understand whether the different knee designs fulfilled their purpose, and whether the differences could be described as improved when using either the non-MCPK or MCPK. This was achieved mainly by investigating the functional involuntary response of the knee as the SSWS varied during the ambulation activities, and by examining the brake and release mechanism during initial contact and late stance to determine the voluntary control the user had over their knee.

<table>
<tr><th colspan="2">Test Protocol</th><th>Test Repetitions</th><th>Estimated test time to run test (minutes)</th><th>Number of subjects per test day</th><th>Total Time (minutes)</th><th>Total Test Time (hours)</th></tr>
<tr><td colspan="2">1-Level walking</td><td>10</td><td>5</td><td>1</td><td>100</td><td>2</td></tr>
<tr><td rowspan="2">2-Ascent and Descent</td><td>Slope (7 degrees)</td><td>10</td><td>5</td><td>1</td><td>100</td><td>2</td></tr>
<tr><td>Stair (33 degree angle with four steps)</td><td>10</td><td>5</td><td>1</td><td>100</td><td>2</td></tr>
<tr><td colspan="5">Total</td><td>300</td><td>6</td></tr>
</table>

Table 4.5 Summarised test structure

4.7 TEST PROCEDURE

Prior to testing, each subject was given the time they required to acclimatise them self to their prosthesis socket and foot, and they provided verbal conformation when they were ready to partake in the test activities. After acclimatisation, anatomical prominences and equivalent malleoli positions on the prosthetic foot and knee were identified and consistently located for marker placement. Once the static capture was completed, the participants were positioned in order that they could take at least three steps before striking the force plate, to ensure that they had a steady ambulatory rhythm (Miller et al. 1996).

The ambulatory activities required the participants to ambulate in an indoor laboratory environment on the level, on a 5-meter long ramp inclined at 7 degrees, and on a set of four stairs with 33 degrees of inclination (Table 4.5). This method was repeated until ten successful force plate strikes for the two prosthetic limbs and the biological limb had been captured at the participants' self-selected walking speeds.

Even though the activities shown in Table 4.5 are listed in a particular order, the test order of activities for each participant was assigned randomly. This was to ensure that the test order did not influence the outcome of the results when ambulating with the two prostheses. To ascertain the integration of the evaluation prostheses with the users, three critical periods of the gait cycle were evaluated – initial contact, late stance and swing phase. Statistical analysis was used to evaluate the measured outcomes that were in turn used to quantify the involuntary response and voluntary control of the knee prostheses.

4.8 STATISTICAL POWER

The interpretation of kinematic and kinetic measured outcomes is crucially linked with the main project objective, to understand the functional benefit of the prosthetic knee damping response, and to understand the voluntary control the user can exhibit over the brake and release mechanism of their knee. The greatest limitation of the study methodology is that posed by the low number of recruited participants in combination with the limited familiarisation time available for each participant.

The limited accuracy and precision of data recorded during ambulation is commonly thought to be a result of the variability of gait itself, marker placement and skin marker movement (McGinley et al. 2009, Zahedi et al. 1987). However, marker placement on equivalent sites according to the anatomical landmarks of the prosthesis at least has the advantage of being repeatable (van der Linden et al. 1999). A source of further inaccuracy is accumulated from deriving body segment parameters using regression formula (Hinrichs 1985). However, the inaccuracies in the determination of the local segment COM seen in cadaver studies can be minimised by matching variables such as age and ethnic origin to the individual being studied (Dumas et al. 2007). Therefore, certain inaccuracies can be quantified with statistical explanation, while others such as anatomic marker placement can be kept to a minimum with a clear and robust testing protocol (Bland 1987, McGinley et al. 2009). The difficulty of comparing results from previous studies relates to the lack of a standard protocol when testing and reporting outcomes of gait analysis, which means that, despite there being many studies to draw upon, it is only possible to draw inferences (McGinley et al. 2009, Condie et al. 2006).

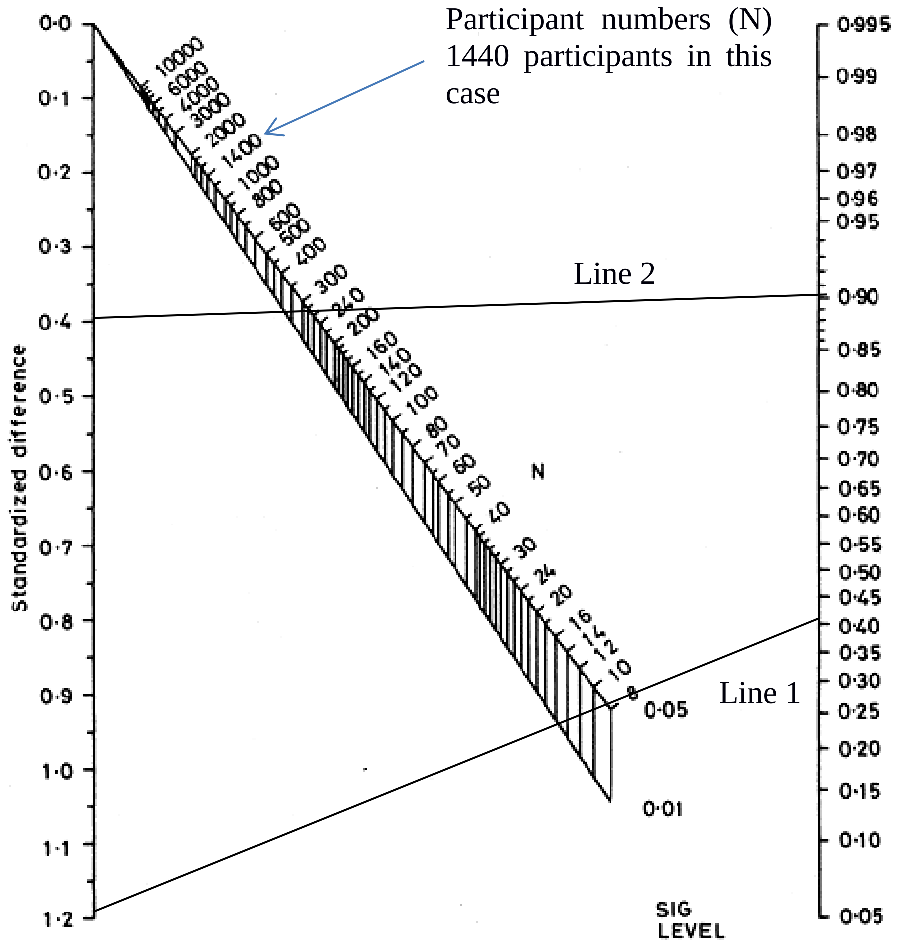


Figure 4.1 Nomogram for a two-sample comparison of a continuous variable (Altman 1980)

Using the methods described by Whitley et al. (2002), the inter-subject statistical power of this study can only be, at best, 40%, as shown by line 1 on Figure 4.1. That is, there is only a 40% chance of observing the specified difference when comparing inter-subject differences, and comparing these to the wider prosthetic user population. The magnitude of the specified difference is the standard difference of the outcome being considered, and in real terms, it is what the investigator can consider appropriate. Even if the study had recruited twelve participants instead of six, its power would not have drastically improved. As shown by line 2 on Figure 4.1, to achieve statistically significant results that could be extrapolated to the wider prosthetic community, two hundred participants would have had to have been recruited. Because the power of this study is low, the methodologies developed and detailed within should be considered for use with a greater population size in order to further evaluate the differences of the MCPK and non-MCPK. As the power of the study is low, the results were never likely to have provided robust inter-subject statistical evidence. Consequently, the results were also evaluated qualitatively on an individual basis by considering the graphical outcomes.

To assist the exploration and discussion of the results on an individual basis, and to help minimise test order effects, the study was of A/B, B/A crossover design. As described in section 4.5, page 64, the stance stability of the MCPK was designed to be controlled by the user through the adjustment of their toe load. Hence, the moment and angle graphical outcomes were also used, along with the intra-subject statistical analysis, to consider whether the difference of outcome using the two prostheses can be considered beneficial.

Furthermore, to consider the swing phase involuntary response, the mechanical energy absorption during swing was also considered on an individual and group basis while the user walking speed changed when transitioning from level walking to ramp ascent and vice versa. This will not only allow the results to be used to investigate whether the Orion MCPK allows the user to walk at their natural pace for a given terrain, but it will also help to determine whether or not the MCPK minimises energy expenditure.

Therefore, in summary the qualitative and statistical analysis of individual results will be used to consider whether individual patterns of using the two prostheses are beneficial. Further quantitative assessment of inter-subject patterns will be used to determine whether these patterns are seen across the participant pool, and whether these results can be used to suggest that the MCPK will provide greater benefit to the un-restricted or restricted outdoor ambulator. This evidence in turn will be used to provide clinical indications for prosthetic prescription when considering the fitting of either the non-MCPK or MCPK.

4.9 ANALYSIS, DATA CONFIDENCE AND MEASURED OUTCOMES

To ensure sufficient data repeatability, the objective of participant laboratory sessions was to capture at least ten gait cycles. Figure 4.2 displays the data repeatability using 95% confidence intervals evaluated using the t-test.

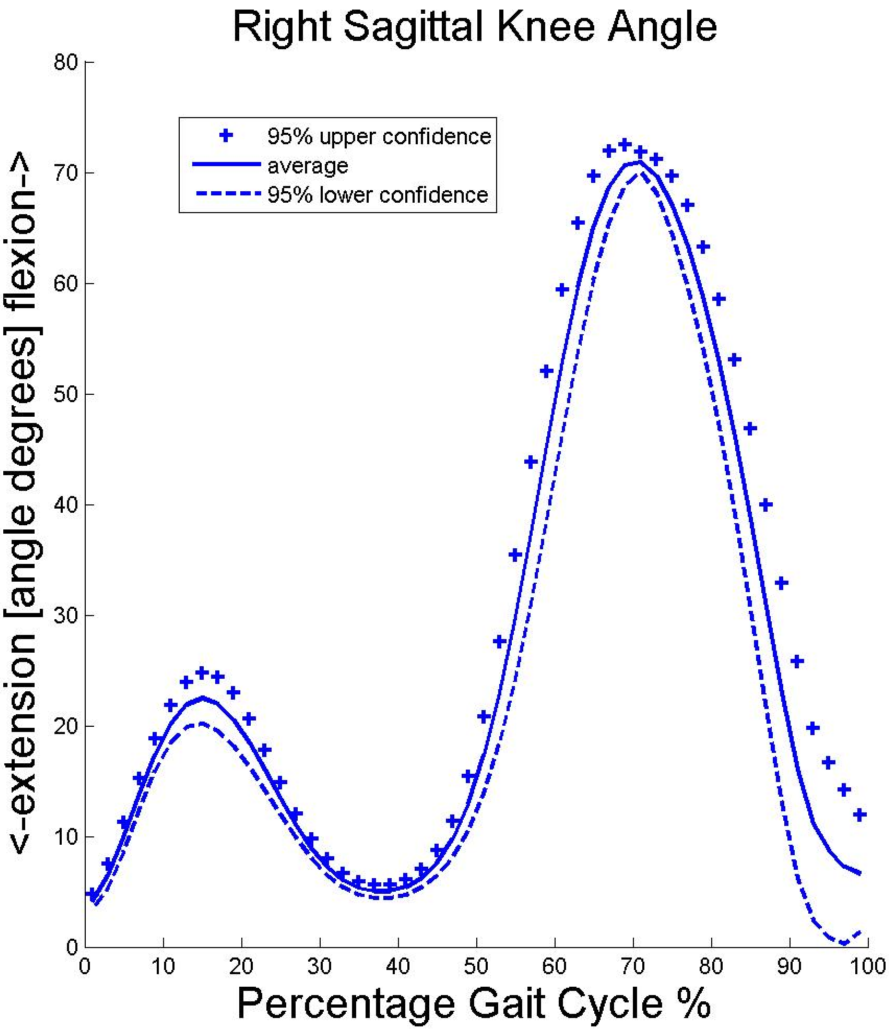


Figure 4.2 Knee flexion and extension angle of the study normal control plotted with 95% confidence intervals from ten successive trials that involved removing and replacing the static calibration markers after the third and sixth trail.

To evaluate the intra-subject data normality, the z-test was used to test the null hypothesis at a significance of 5% that the data are a random sample with a normal distribution. The z-test indeed revealed that ten repeated measured outcomes such as a knee angle calculated from the kinematics were normally distributed. Therefore, to guarantee intra-subject comparisons with a minimum of two groups of ten data points, every participant was required to pace the gait laboratory over 250-300 repetitions when they partook in the three test activities of level, ramp and stair ambulation. The intra-subject results from this crossover study on wearing the test prostheses were statistically compared on an individual basis using the one way Analysis of Variance ANOVA (Brook 2009). However, the ANOVA could not be used to evaluate inter-subject comparisons, as they varied drastically due, for example, to the handrail being used for support by certain individuals when wearing either of the test prostheses. Consequently, inter-subject measured outcomes from the two cross-over groups were compared using the non-parametric Kruskal-Wallis medians test as described in MathWorks 2013. Unless otherwise stated, the null hypothesis was evaluated at a significance of 5% that, in the outcome considered, there was no difference between wearing either the Orion or the 3R80 knee.

In summary, the null hypothesis, when using the ANOVA or the Kruskal-Wallis medians test, evaluates the significance of there being no difference between the compared means or medians of the measured outcome considered.

Therefore, if the difference between the means or medians being compared reaches a significance of 5% (p=0.05) the ANOVA or Kruskal-Wallis test indicates that there is likely to be no difference in the outcome being evaluated for 1 in every 20 steps. Consequently, there is a 95% chance (19 in 20 steps) of the user experiencing, for example, a knee extension moment, the magnitude of which is significantly different while wearing either test prosthesis. Hence, if the significance of the difference between an evaluated knee moment reaches 1% (p=0.01), the knee moment on initial contact using the test prostheses will likely be different for every 99 steps in 100.

Due to the crossover nature of this study, the inter-subject significance between the two crossover groups of six participants wearing the test prostheses was compared without "data normalisation". Additionally, when the ambulation patterns between individuals significantly vary, as seen in this investigation, data normalisation can cause further ambiguity.

To explore the relationships between two quantitative variables – the walking velocity and mechanical energy absorbed around the knee, for example – the linear correlation value of the scatterplot was used to evaluate the strength of this relationship. The correlation coefficient (R) plus the significance value (p) of the correlation is the likelihood of obtaining a correlation as great as that observed.

Figure 4.3 3R80 in PROS.A. bench alignment jig

4.10 SOCKET FABRICATION

Following a complete lower limb and functional assessment conducted by a State Registered Prosthetist, a new check socket Ischial containment socket with silicon ‘seal in liner’ was fabricated for each of the six participants by a state-registered prosthetist. The lower limb range of motion (ROM) and residual limb muscle power was assessed prior to casting, and any limitation in ROM was accommodated by the alignment of the socket.

From the residual limb cast, a plaster mould was poured and modified according to the Össur’s liner manufacturer’s instructions. A colourless thermosetting polymeric material was then draped, and vacuum formed over the plaster mould of the residual limb to produce the participant's socket profile. The socket was then fitted to the participant using the setup and alignment protocol that will now be described.

The 3R80 knee was first bench aligned according to Otto Bock’s guidelines using the PROSA bench alignment jig, because the tool is designed for ease of use with Otto Bock components. The PROS.A. bench alignment tool was used to initially align the 3R80 prosthetic knee with the Echelon foot according to the Otto Bock protocol. After bench alignment, the prosthesis was fitted to the user before static alignment was assessed using the laser posture device, as the 3R80 knee already has an inbuilt pylon tube, and the Orion knee does not. The pylon tube was attached to the Orion knee in a neutral position. This allowed the Echelon foot to be attached to the Orion knee with the same pyramid alignment as the 3R80 knee.

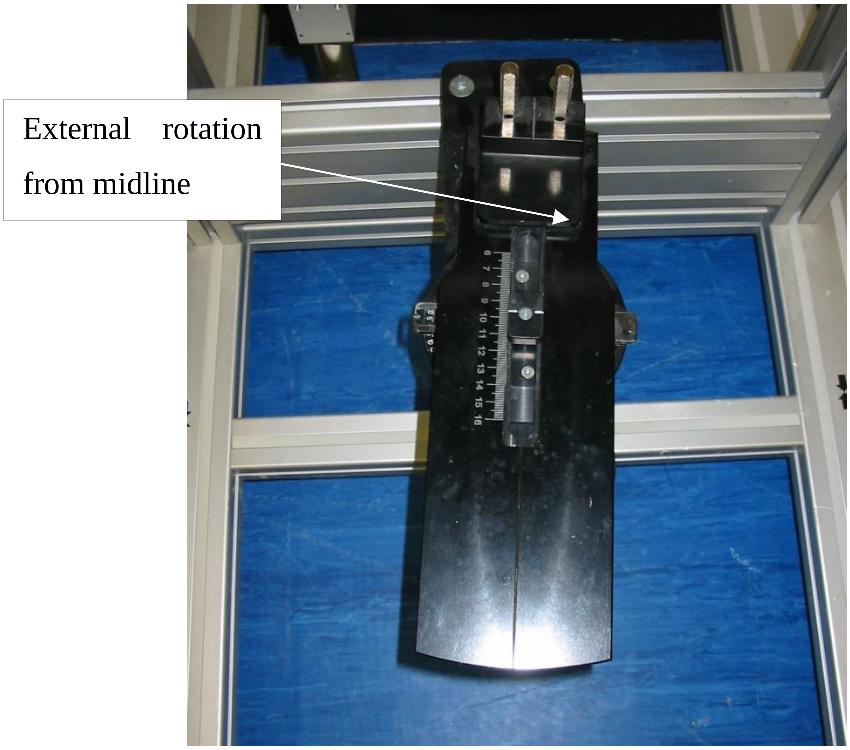


Figure 4.4 External rotation of the foot

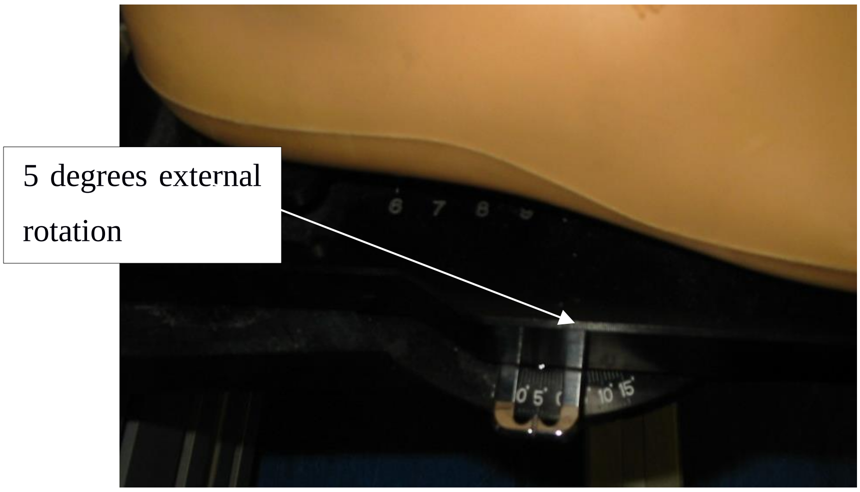


Figure 4.5 Setting of heel height

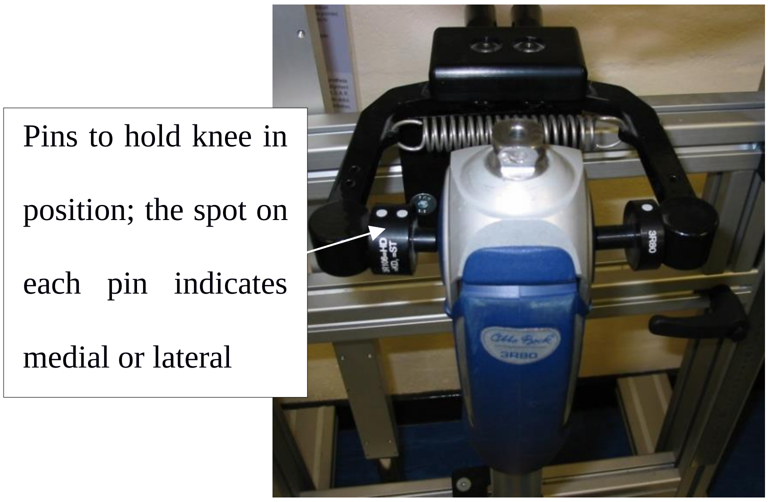


Figure 4.6 Zero offset pins holding the knee centre in position

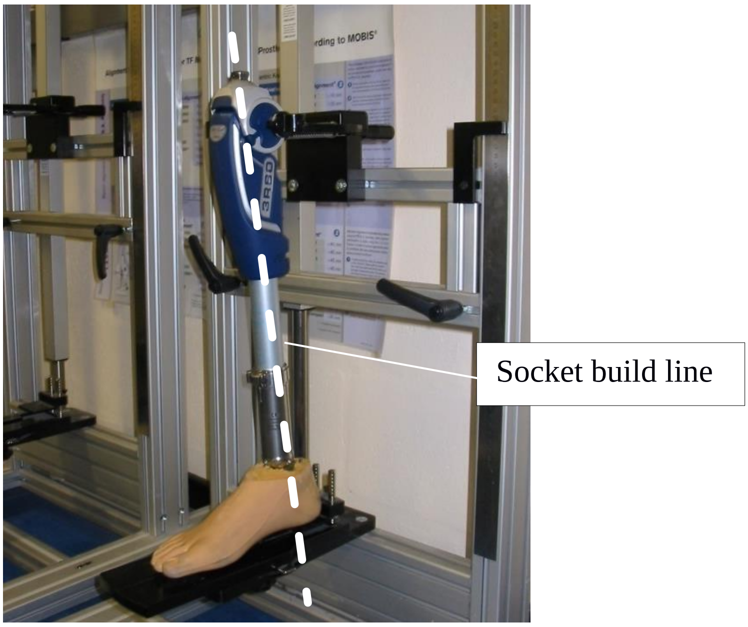


Figure 4.7 Build line of the 3R80 prosthesis

On placing the Echelon foot on the jig footplate, the foot was externally rotated by five degrees from a sagittal midline, with an appropriate heel height to account for the shoe heel height + 5mm (Figure 4.4). Guidelines for the Blatchford Echelon foot include keeping the build line of the length equal to 1/3 of the foot length from the heel, or 0 to 10 mm behind the anterior pivot point. To complete the leg assembly, the knee was positioned on the male pyramid adapter of the foot, and was held in position using the zero offset pins (Figure 4.6). This allowed the build line to pass through the knee centre once the aligned foot was attached to the pylon tube (Figure 4.7)

An inflatable bladder was then used to fix the socket, and lower the check socket onto the knee. An appropriate double pyramid adaptor and connection cap were then positioned on the male knee pyramid adaptor (Figure 4.8). Using the midline of the socket as a reference, the socket was then lowered onto the connection cap. The connection points were then marked, allowing the socket to be removed, drilled and then attached using bolts and a bonding agent.

During bench alignment of the 3R80 knee, the build line should pass through the knee centre and, for the Orion knee, it is recommended that the build line passes through or is anterior to the knee centre by up to 10mm. Because the 3R80 knee lay in a posterior position with respect to the identified Orion knee centre, the same pyramid alignment resulted in the two evaluation prostheses being aligned according to their manufacturers' guidelines.

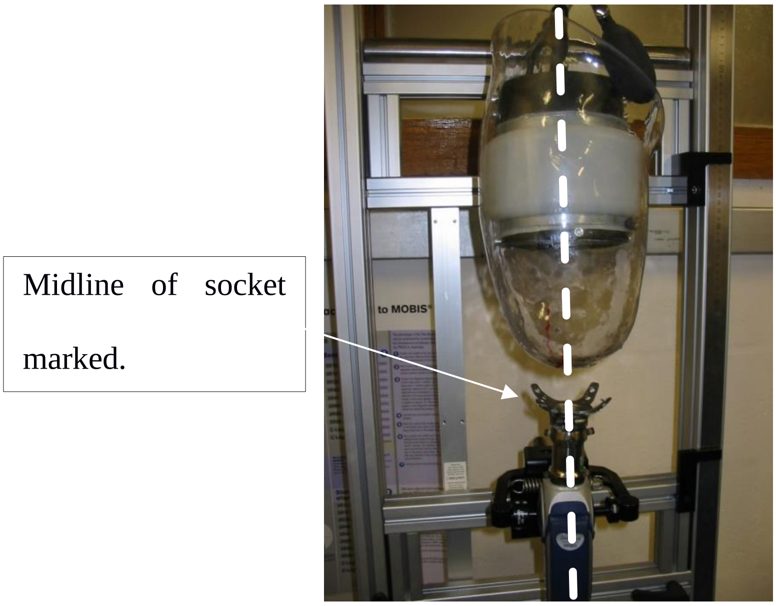


Figure 4.8 Positioning of socket

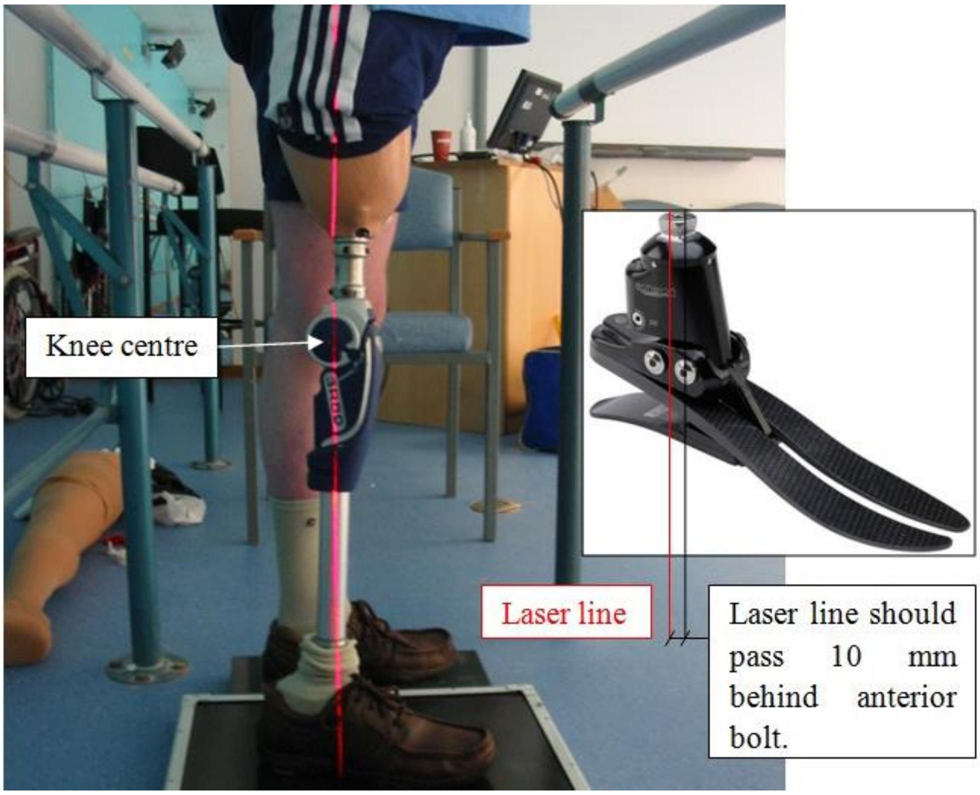


Figure 4.9 Static alignment, with laser project of load line

4.11 STATIC ALIGNMENT

The Otto Bock laser posture device enabled the static alignment procedure, with the projection of a clear laser load line onto the sagittal plane of the body. Adjustments were made to ensure the load line passed through the knee centre of the 3R80 prosthesis. Because none of the participants had yet experienced a foot with damped dorsi or plantar flexion capabilities, the foot was locked in a neutral position after the initial static alignment.

The participants then had the opportunity to walk and acclimatize themselves to the knee and the weight of the foot. The yield settings of the Echelon foot were then changed to allow 3 degrees dorsi- and then 6 degrees plantarflexion, after which the static alignment was checked to ensure the prosthesis was setup within required manufacturer tolerance. The alignment of the prosthesis was adjusted to allow the participant to assume a quite natural standing position, without compensatory trunk flexion or extension being used to maintain balance. This clinical session also gave the participants the opportunity to provide feedback with respect to their socket comfort. If necessary, this allowed socket modifications to be made, following which an additional clinical session was organised to ensure that the participants would be comfortable and confident during the laboratory sessions.

4.12 DYNAMIC ALIGNMENT

Dynamic alignment involved observation of the prosthetic user while walking, to ascertain whether final prosthetic adjustments could improve the individual's gait. Final adjustments ensured the gait was as symmetrical as possible, and were achieved by changing the knee or foot alignment in both the sagittal and transverse planes. The Orion knee was fitted to the socket with the same pyramid alignment after the static and dynamic alignment of the 3R80 knee, and minimal changes were made to the alignment after fitting.

After the final dynamic adjustments, the laser posture device was used to check that the load line was in a posterior position with respect to the anterior Echelon ankle pivot point, and anterior to either knee centre. This was done to ensure that both limbs were indeed set up according to the manufacturer's guidelines. This stance was chosen to ensure that the effects that the two prostheses had on the kinematics and kinetics of ambulation were an outcome of user control over the evaluation prostheses, and not prosthetic alignment. However, in retrospect it would have been advantageous had the two alignments been quantified, as this would have assisted in the evaluation of the singular effect that alignment has on user kinematics and kinetics. However, it is questionable whether a single alignment can be considered "optimal" (Zahedi et al. 1986). Even though the prosthetist endeavours to align the prosthesis optimally on an individual basis, it has indeed been shown that "optimally" aligning the prosthesis on an individual basis does not always result in the same alignment.

Because, there were a range of alignments that resulted from the disassembling and realigning same prosthesis, suggesting the user can suitability control their prosthesis with a range of alignments (Zahedi et al. 1986). However, all the participants in this study were comfortable using the described alignment procedure adopted for this study based on participant response during the clinical sessions. This suggests that the alignment procedure adopted for this study was sufficient.

Finally, during the dynamic calibration of the Orion knee, the clinician manually adjusted threshold settings based on clinical observations and user feedback. The Orion knee was programmed by first adjusting the yield settings while the participant sat from a standing position, and secondly by setting the knee to respond to a slow, medium and fast walking pace. However, the algorithm of the embedded system also assists final dynamic adjustments when the knee is being calibrated to assist the user walking at speeds outwith their SSWS. After an initial acclimatisation period with both prostheses, three dates for the gait laboratory sessions of this evaluation study were then provisionally booked.

On the first test day, either the 3R80 or the Orion knee was assigned to the participant randomly. On fitting the prosthesis, data capture began after the participant felt comfortable, confident, and ready to ambulate.

4.13 SUMMARY

This chapter has reasoned that the criteria for choosing the three main activities of level, ramp and stair ambulation for the testing protocol. The activities of ramp and stair ambulation provided the greatest challenge to the outdoor ambulator and allowed for the assessment of the two knee designs under consideration. The test activities identified were used to quantify the functional aspects of the 3R80 non-MCPK and Orion MCPK – those being the user's voluntary control over the knee brake and release mechanism, on initial contact and late stance respectively, and the involuntary response of the swing phase mechanism as the user walking speed varies. This study is of crossover design, and the prosthetic knee that the user first ambulated with was chosen at random. To minimise test variables, the Echelon foot was fitted to the Orion knee after alignment with the 3R80 knee; minimal dynamic alignments were made when fitted to the Orion knee. This approach was adopted to help minimise differences such as components, as well as various alignments affecting the results significantly. However, both prosthetic knees were set up according to their manufacturers' guidelines, and all participants were comfortable while ambulating in the laboratory.

During the recruitment process both K2 and K3 outdoor community ambulators were enrolled. The recruitment of participants with slight differences in ambulation ability assisted the evaluation of the prosthetic response during swing, and of the voluntary control the user can exhibit over their knee during stance. This enabled the analysis of whether or not a particular user group would benefit from the MCPK, and assisted in the recommendation of suitable tests in the clinical environment that would enable the prescription of such knees.

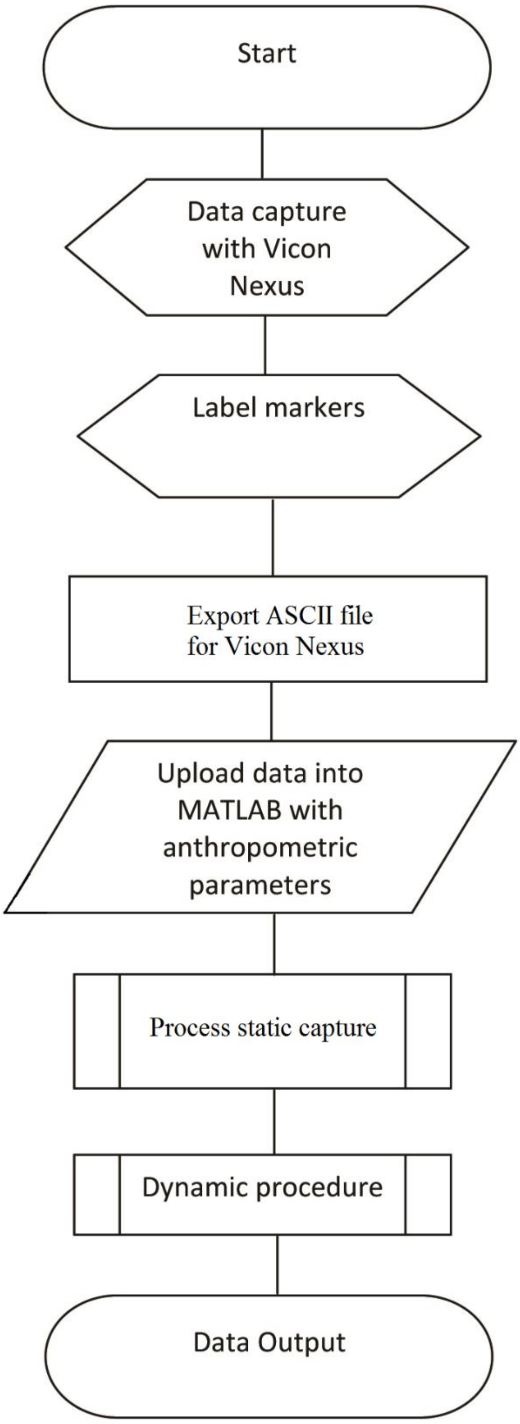


Figure 5.1 Flow process of procedure used to evaluate recruited participants

CHAPTER 5 BIOMECHANICAL ANALYSIS

5.1 ALGORITHM & DATA PROCESSING

Even though the main activity of human gait is in the sagittal plane, every body segment has its own local sagittal plane. Therefore, projecting the local joint moments and limb angles onto the global reference frame, will give approximated solutions when walking parallel with the sagittal plane of the global coordinate system. Especially when analysing pathological gait, as the local sagittal plane of all the body segments will grossly deviate from the global sagittal plane, due to transverse and coronal actions. Hence, even if the sagittal plane motion, as in this study is only considered, three-dimensional analyses should be used to determine sagittal outcomes. From a practical point of view, three-dimensional analysis is easier to programme, while vector mechanics also naturally considers the orientation of the ambulator with respect to the global system. This is advantageous, because results will always be presented in an expected pattern, and is not dependent on orientation of the individual with respect to the global coordinate system. The sequence of data capture, and main processing events are summarised in the flow diagram, as shown in Figure 5.1. The Vicon MX system (*Vicon Oxford, UK*) was used to capture and reconstruct the kinematic and kinetic data, and deliver discrete numerical values. The kinematic data was captured using six T40 and six T60 integrated system cameras. While the kinetics were measured with four external force plates at 1000Hz, and were added as peripheral Vicon devices. The captured kinematic and kinetic data was the exported from Vicon NEXUS in ASCII file format, and MATLAB version R2011a was used to process the data and calculate the required measured outcomes.

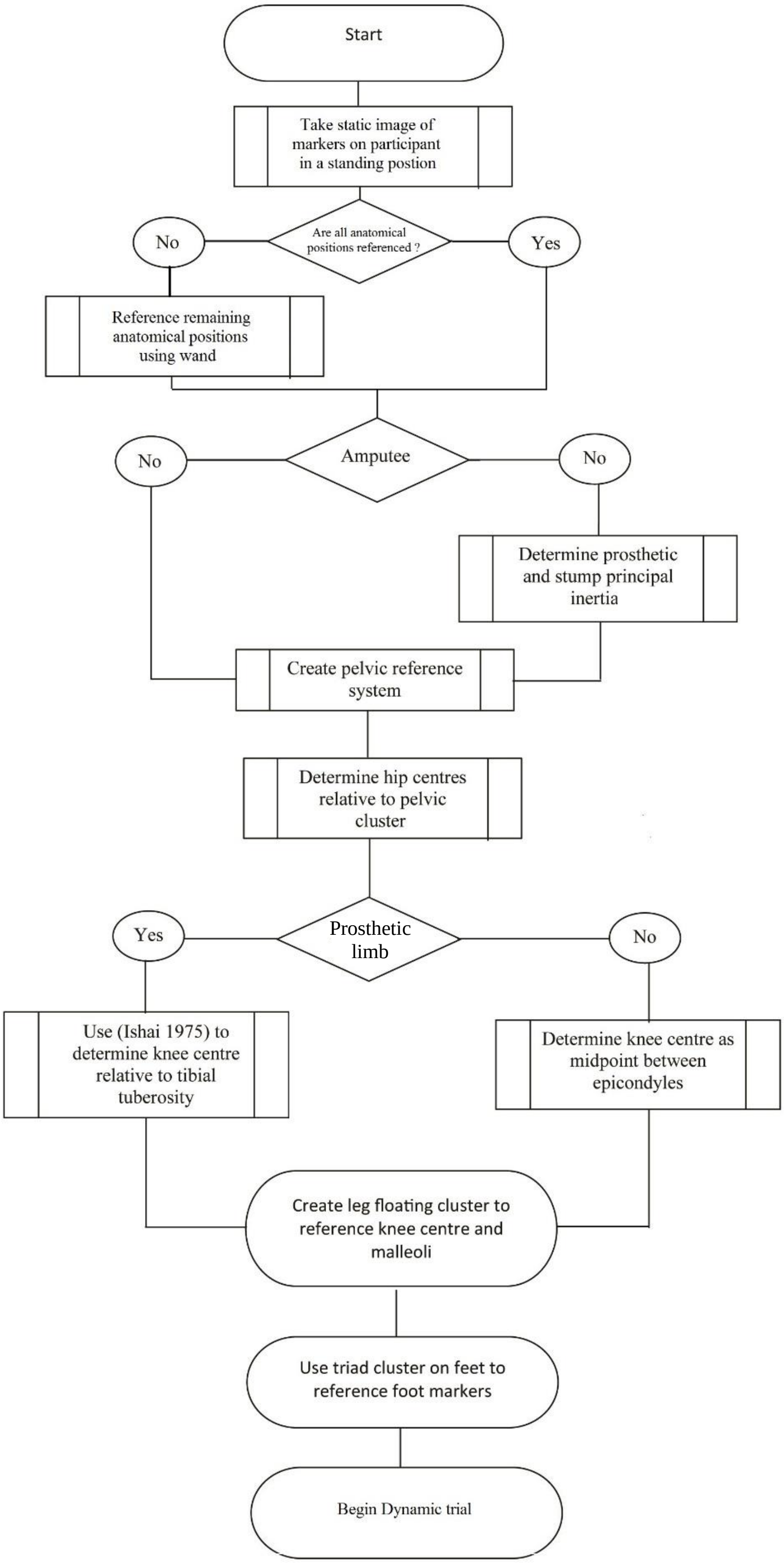


Figure 5.2 Static capture procedure

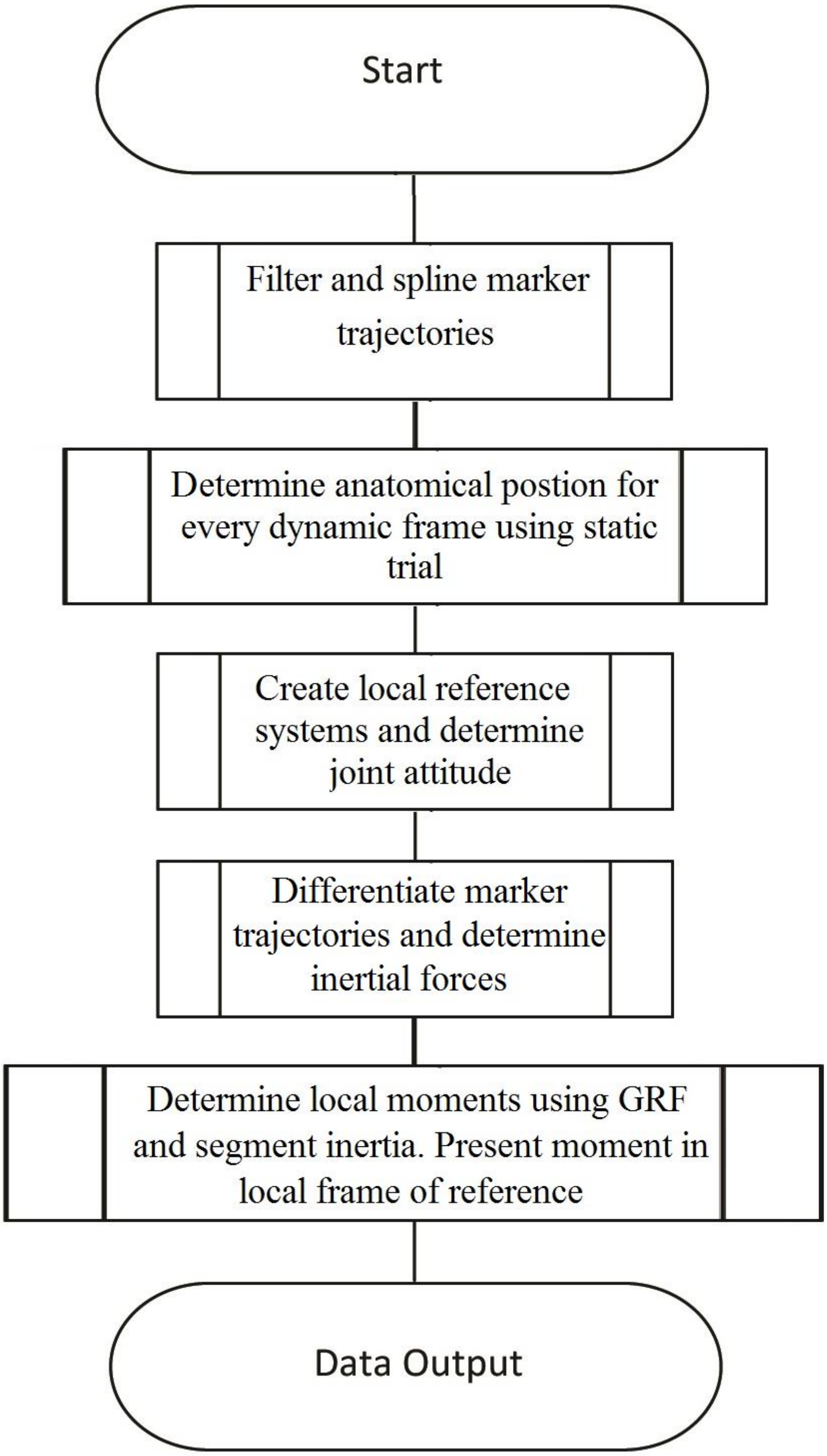


Figure 5.3 Dynamic processing procedure

To run the programme, the required anthropometric parameters, as detailed in the MATLAB file, and given in page 234 were populated. They were then used in the custom "static_upload1", "dynamic_upload1" and "gait_analysis" functions, utilising a series of internal MATLAB, and other custom functions. However, rather than describing every written function in detail, the template function files are provided with additional notes in the appropriate folder of the compact disk appendix attached to this thesis. Instead, this chapter will highlight the main and most significant processing techniques, including, the filtering of kinematics, and methods used to determine the inertial properties. Both Figure 5.2 and Figure 5.3 respectively give an overview of the static capture and dynamic flow process. The purpose of the static capture process as shown on Figure 5.2 is to reference the anatomical markers, positioned on the pelvis and lower limbs from cluster reference systems. Additionally, as highlighted on Figure 5.2, the procedure to determine the biological knee and ankle centre also differs from that of the prosthetic limb.

The purpose of the dynamic processing methods was to use the static capture to determine the trajectories of anatomical prominences in the global reference frame. Hence, from known anatomical prominences in global coordinates the structural framework of the lower limbs was built, allowing the translational, angular velocities and accelerations of the lower limb segments COM to be determined. This in turn, allowed the local segment attitudes, and joints moments to be determined. To check that the algorithm provided correct results, a two-dimensional "hand calculation" for an instance during stance was compared to the computed result for the same frame instance.

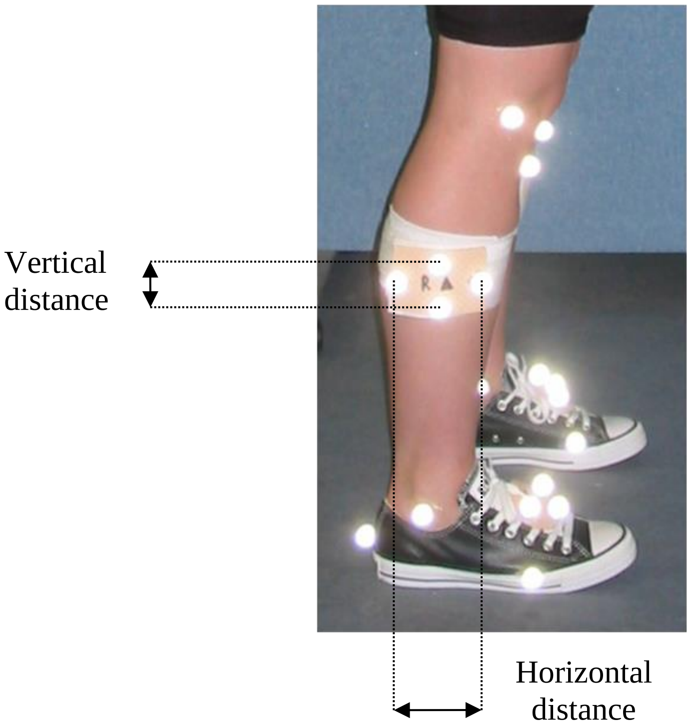


Figure 5.4 Right leg cluster

	true distance (mm)	mean calculated distance (mm)	standard deviation (mm)	difference (mm)
vertical vector	42.7	42.77	± 0.35	0.07
horizontal vector	79.8	80.08	± 0.35	0.28

Table 5.1 Measured and determined distances between cluster markers

5.2 MARKERS AND KINEMATIC DATA COLLECTION

To track and reference the kinematics of motion, the trajectory of 14 millimetre diameter retro-reflective spheres were captured using Vicon MX infrared cameras. As the markers generally weigh less than 2 grams, the inertial affects can be considered minimal, and can be attached to the skin using hypoallergenic double-sided tape. To ensure that marker coordinates were collected within an acceptable tolerance. The actual measured centre-to-centre distance of separated cluster markers on a cluster base, as shown in Figure 5.4 for the right leg cluster during a walking trial were compared to the calculated distances using vector algebra. It is shown in Table 5.1, that the measured and calculated distances were known within an acceptable tolerance.

Furthermore, to quantify whether collected trajectory components can be captured with an acceptable accuracy. A marker was placed in a known measured position, $\begin{bmatrix} 595 \\ 395 \\ 53 \end{bmatrix} mm$ with respect to the Vicon frame of reference in the main capture volume. The coordinates given by the Vicon system for this marker position were $\begin{bmatrix} 593 \\ 395 \\ 53 \end{bmatrix} mm$, hence, it was accepted the kinematic data was returned with sufficient accuracy.

As the regression equations used to predict the location hip centre, using anthropometric measures such as inter-ASIS distances, may determine the location of the hip centre with less than 10% accuracy. Because, skin motion may cause the marker to move up to twenty millimetres from its respective anatomical position, the regression formulas and skin marker motion artefacts are greater sources of inaccuracy compared to inaccuracies of tracking markers (Fuller et al. 1997, Bell et al. 1990).

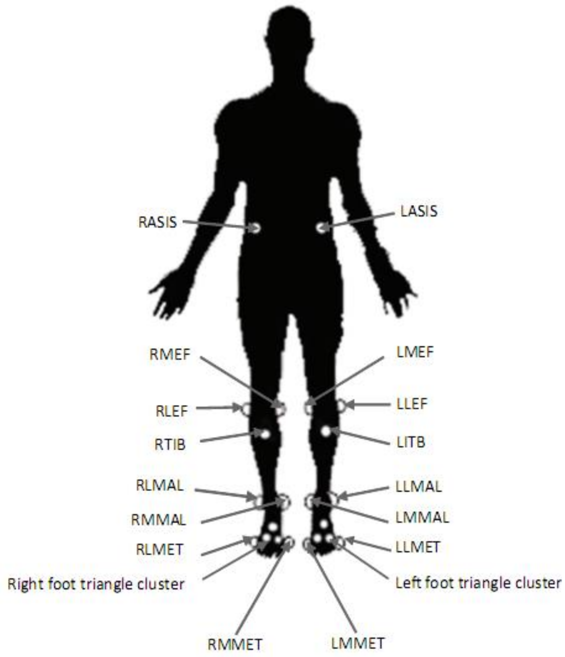


Figure 5.5 Anterior view of anatomical positions that were identified in the Coronal plane during static capture

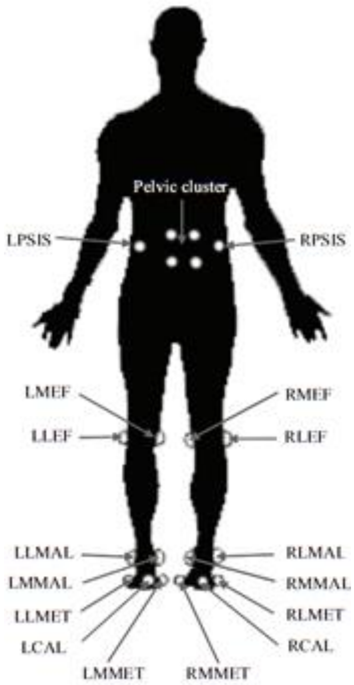


Figure 5.6 Posterior view of anatomical positions that were identified in the Coronal plane during static capture

Hence, considerable effort was taken to find and develop a maker set that would reduce the inaccuracies caused by skin maker motion. The lower limb marker set that was eventually adopted was an evolution of that developed and designed by Ishai. (1975) as shown on Figure 5.5 - Figure 5.8, whose maker names are given in Table 5.2. This marker set determines the knee centre from the tibial frame of reference, and is therefore advantageous when capturing kinematic data of trans-femoral amputee. As described by Fuller et al. (1997), the thigh rigid mounted cluster can lead to erroneous errors due to soft tissue artefact, and that is without considering socket motion relative to the residual limb. Hence, the methods used to build the structure of the lower limb framework are discussed.

Marker	Placement description
LASIS or RASIS	Left or right anterior ASIS maker placed directly over the left anterior superior iliac spines
LPSIS or RPSIS	Left or right posterior ASIS maker placed directly over the left posterior superior iliac spines
LLEF or RLEF	Left or right lateral epicondyle marker placed directly over epicondyle
LMEF or RMEF	Left or right medial epicondyle marker placed directly over epicondyle
LTIB or RTIB	Left or right tibial tuberosity marker placed directly over the tuberosity
LLMAL or RLMAL	Left or right lateral malleolus marker placed directly over malleolus
LMMAL or RMMAL	Left or right medial malleolus marker placed directly over malleolus
LCAL or RCAL	Left or right hindfoot marker placed directly over left calcaneus
LLMEL or LMMET	Left or right lateral metatarsal marker placed at head of the fifth metatarsal
RLMET or RMMET	Left or right lateral metatarsal marker placed at head of the fifth metatarsal

Table 5.2 Marker placement description

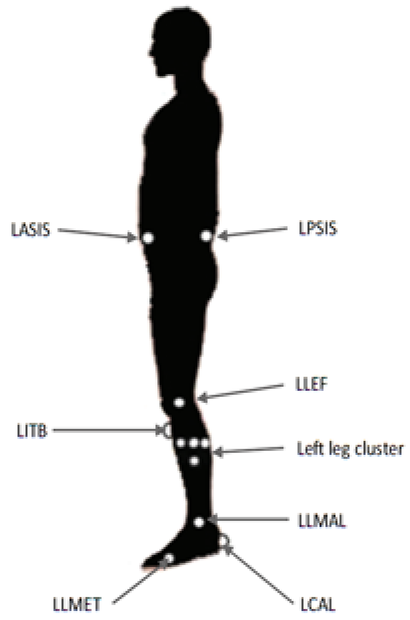


Figure 5.7 Left sagittal view of anatomical positions that were identified during static capture

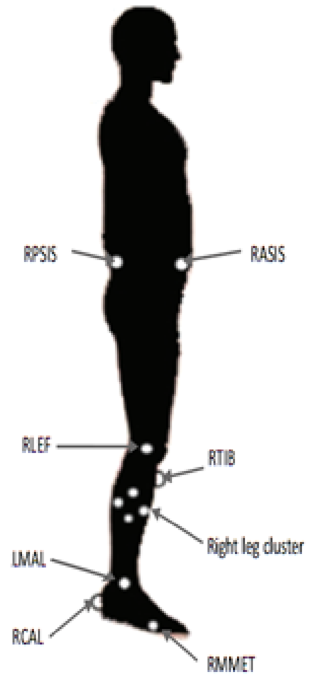


Figure 5.8 Right sagittal view of anatomical positions that were identified during static capture

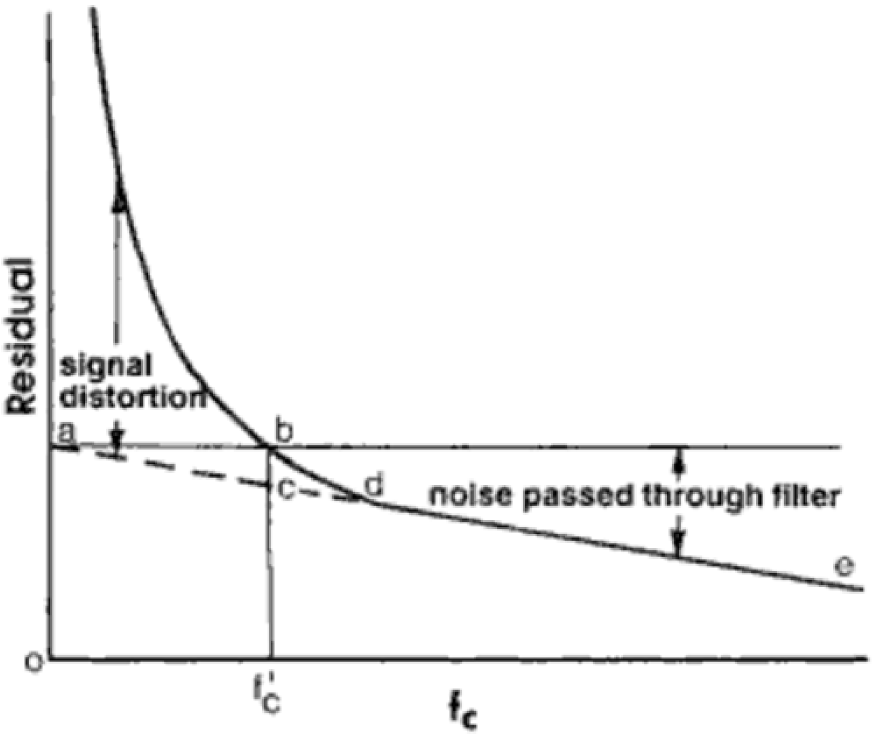


Figure 5.9 Schematic plot of residuals (differece in signal magnitude between filtered and unfiltered signial) against filter frequency (Winter 1979)

5.3 CLUSTER DESIGN AND FILTERING

Angeloni et al. (1993) has shown that the use of clusters can significantly reduce kinematic noise compared to the reliance on skin mounted makers. As a result, clusters were attached using Velcro straps to the legs and feet. Moreover, Manal et al. (2000) also demonstrated that mounting four rather than three markers on a cluster is superior, although it was not possible to use this three marker arrangement on the feet due to the limited separation of the makers on the foot cluster base. Moreover, even though single makers attached to the feet do not suffer from skin marker movement, foot clusters allow the participants to descend the steps during the stair activities without the calcaneus marker located on the heel catching the back of the step during stair descent. The T-shaped design of the left leg cluster, and cross-shaped design of the right leg cluster, was to highlight the left and right leg when looking at the reconstructed markers on screen.

Historically, the low pass Butterworth filter has been used in biomechanics, as the required amplitudes and frequencies remain relatively unaffected (Robertson et al. 1980). Therefore, a function was created that incorporated both the MATLAB splining function to fill trajectory gaps of less than six data points, and Butterworth filter to remove noise. All trajectory data was reversed filtered using a sharp tenth order roll off filter with a 20Hz cut-off frequency to correct data phase shifting, as described by Pezzack et al. (1977). The residual plotting technique described by Winter (1979), and shown graphically in Figure 5.9, was used to determine the cut-off frequencies and will now be discussed. The optimal cut-off frequency as shown in Figure 5.9 is a compromise between signal and noise attenuation. The residual signal amplitude is the difference in amplitude of the filtered and unfiltered data.

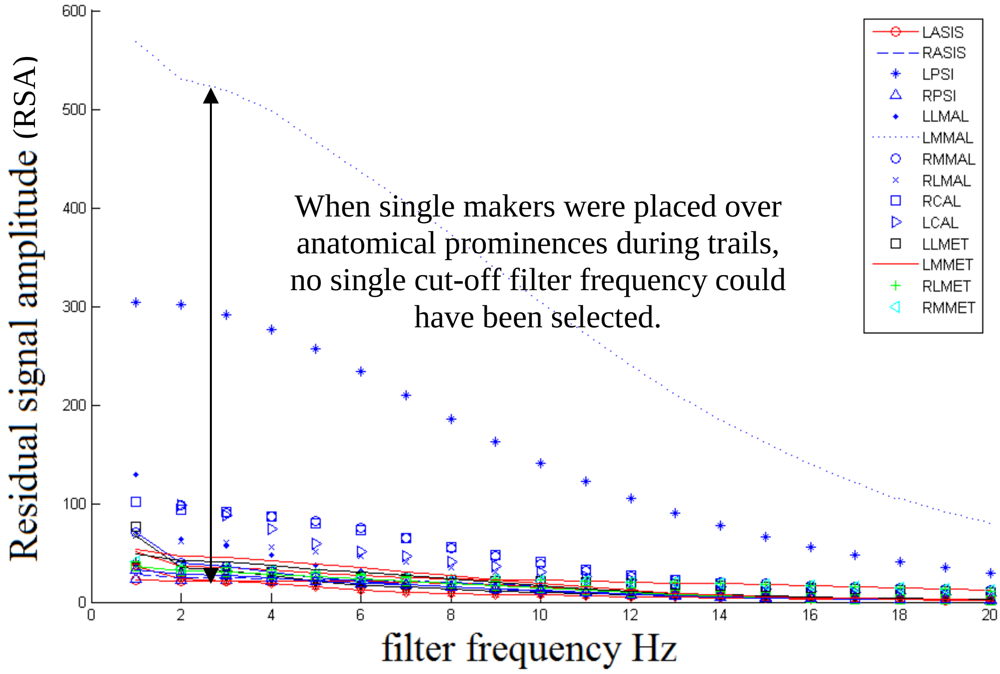


Figure 5.10 Marker trajectory resdiuals plotted aginst filter frequency, using single anatomical markers

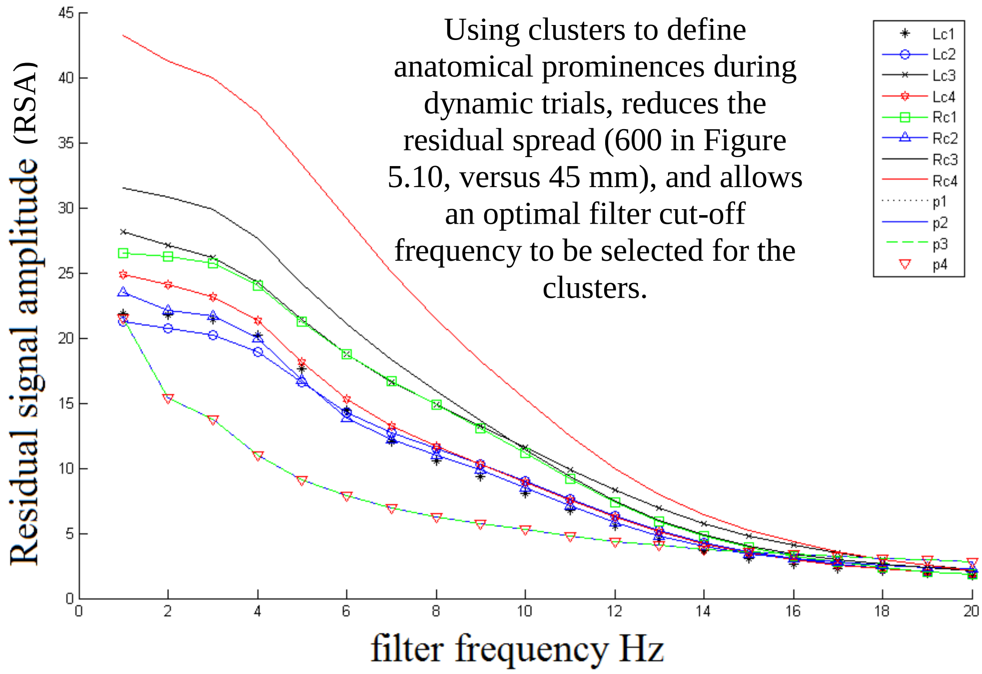


Figure 5.11 Marker trajectory resdiuals plotted aginst filter frequency, using single culsters alone

When using single markers to reference anatomical prominences during dynamic trails instead of using cluster systems it was not possible to select one cut-off frequency that was suitable for all the marker trajectories (Figure 5.10). However, when using clusters to reference anatomical prominences during the static capture from the local floating systems, it is possible as illustrated Figure 5.11, to select a suitable cut-off frequency for all trajectory components. Furthermore, when comparing the residual signal amplitude (RSA) using anatomical markers, and anatomical markers with cluster referencing, the RSA spread as illustrated by Figure 5.10 and Figure 5.11 is 10 times greater using anatomical markers without cluster referencing.

Moreover, when plotting the power spectrum of cluster trajectories captured during a dynamic trial before filtering using the MATLAB fast Fourier transform (FFT) function. The single sided power spectrum illustrated that the trajectories of the markers were made up of periodic sinusoidal components that ranged from 0Hz to 15Hz. Moreover, when iteratively plotting the unfiltered cluster trajectories as illustrated in Figure 5.13, it is shown the main signal remains relatively unaffected by the filtering process at 20Hz compared to 10Hz. Consequently, it was decided that a 20Hz cut-off frequency was acceptable, because filtering the trajectories at lower frequencies (10Hz), resulted considerable trajectory distortion.

Morover, when also considering the precision and accuracy that the position of a anatomical marker can be referenced using a cluster Table 5.1, without high frequency skin harmonics directly oscillating as skin maker, the recorded and actual position of the marker should be known with acceptable precision.

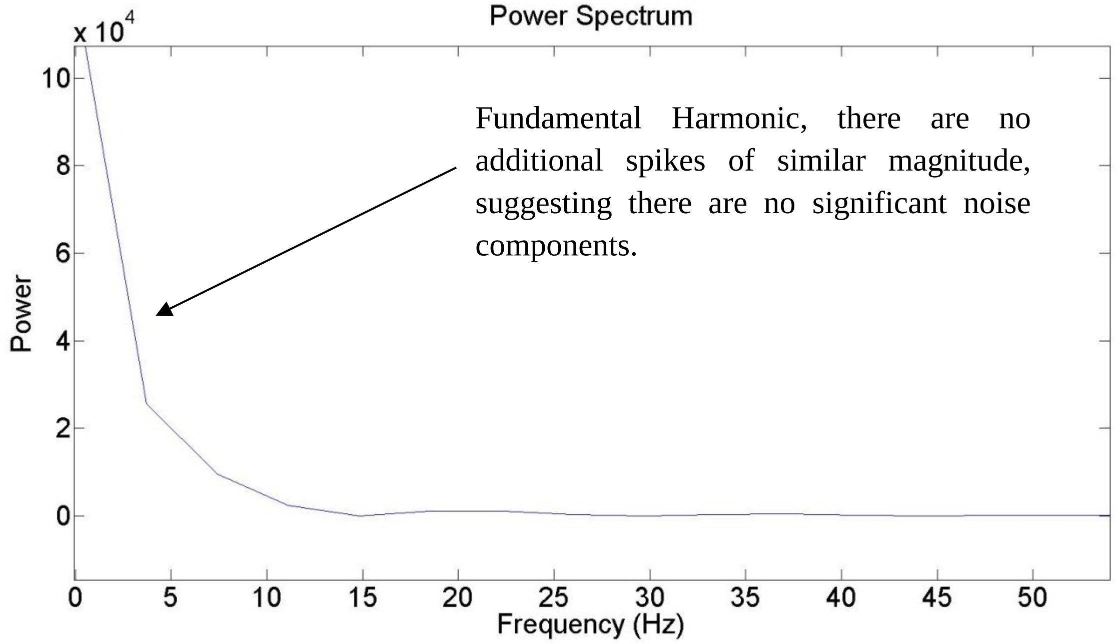


Figure 5.12 Single sided amplitude spectrum plot of a foot marker

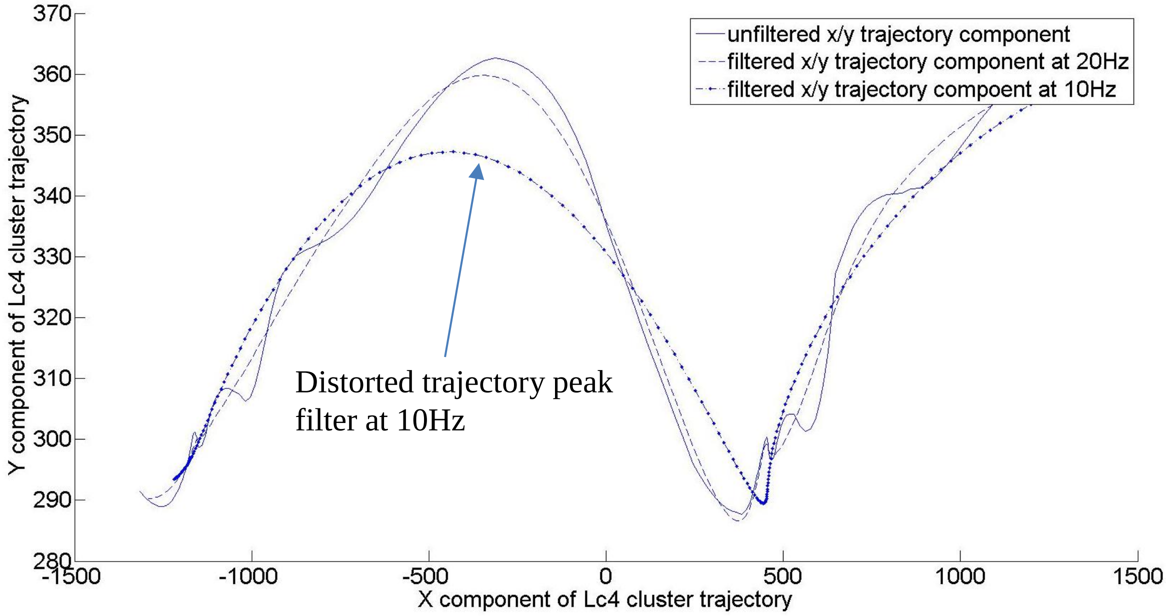


Figure 5.13 Filtered / unfiltered X/Y trajectory component of a limb cluster captured during a dynamic trial. The 10 Hz low pass filtered trajectory was significantly distorted when compared the 20Hz low pass filtered trajectory.

5.4 DATA NORMALISATION

Dimensional analysis is used in fluid mechanics to describe the relationship/s between physical quantities using non-dimensionless groups. This approach is often used due to a large number of problems that rely on experimental data rather than analytical solutions (Munson et al. 1999).

Based on primary quantitative properties such a mass, length, time and temperature qualitative descriptions of secondary properties can be written, such as Nm to describe the magnitude of a moment around a point. However, many biomechanical studies often “normalise” units using body weight as shown on Winter 1979) page 200, and this gives a non-meaningful unit of length.

This can be overcome when normalising by both height and weight, which may result in over “overcorrection”. Normalisation by body height and weight accounts for a range of 7 to 82% of data variance at all anatomical points. The exception is the ankle and hip adduction moment, as it was shown that 22% of ankle angle flexion/extension variance can be accounted for by normalising by body height, while 6% of hip adduction variance when normalising by body weight and height (Moisio et al. 2003). Consequently, this suggests there are no appropriate general methods allowing biomechanical outcomes to be normalised. Moreover, primarily due to the reasoning that each prosthetic user has a unique gait, introducing patterns that cannot be accounted for when normalising using body anthropometrics, the data in this study will not be body mass or limb length “normalised”.

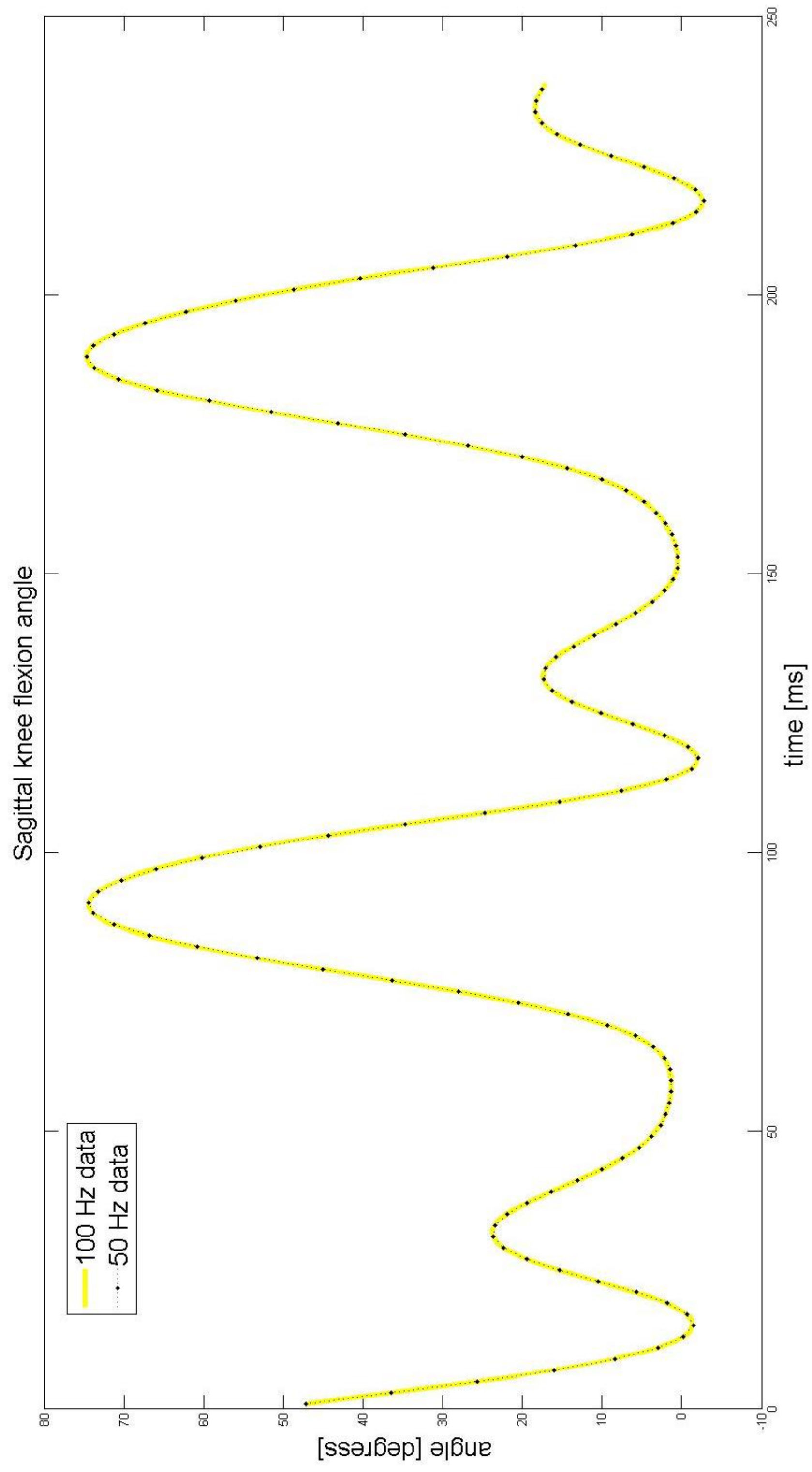


Figure 5.14 Data that was reconstructed at a lower sampling rate, and compared to the original capture signal.

However, the gait period was time normalised to a relative percentage (0-100%) time base, and was the identified period from initial contact to initial contact of the ipsilateral limb. As discussed by Zahedi et al. (1987) simply scaling the data to a relative base distorts the data amplitude. Therefore, the gait period was identified using the first initial contact instance from the force plate signal, and the next initial contact from the velocity of the calcaneus maker that was recorded by the kinematics on the first initial contact using the force plate signal. Fast Fourier analysis was then used to bring the identified gait period into the frequency domain before reconstructing the data in a new percentage time domain. This was achieved using the inbuilt MATLAB functions to reconstruct the data so that it comprised of a percentage number of discrete data points. The data was interpolated so that it consisted of fifty discrete points rather the 100, as 90 discrete kinematic data points were approximately collected per gait cycle, with the frame rate capture of 100Hz. This was to avoid interpolating more points from fewer points, as this can lead to data aliasing. The knee flexion and extension plot Figure 5.14, was created by plotting the angle orientation with respect to time, then plotting the normalised data points at the appropriate time instances, it can be seen that no visible signal distortion is evident.

5.5 REFERENCE SYSTEMS AND DATA PRESENTATION

From the externally placed markers, a framework representing the skeletal structure and positions of joints can be defined. To create local body reference systems that are comparable between subjects and studies, the repeated identification of palpable anatomical landmarks is required. For this study, from the identified anatomical landmarks, a local right hand coordinate system for the thigh and leg segments were defined (Wu et al. 2002, Wu et al. 2005). The x direction is perpendicular to the coronal plane of the segment, the y direction is perpendicular to the transverse segment plane, and the z direction is perpendicular to the sagittal plane. Therefore, the z direction of each lower limb points from left to right. The anatomical landmarks were not used to define the x, y and z principal directions in sequential order. For the reason that, marker placement on a particular segment, due to segment symmetry favoured defining the long segment axis first, rather than a transverse axis. Therefore, the direction of the transverse axis was defined after the long axis of the segment was first defined; the third transverse axis was floating, and completely defined by the plane of the long and transverse axes.

Grood et al. (1983) is often credited in biomechanics for introducing the idea of the “floating axes”, however, this definition is commonly used in mechanics. For example, the orthogonal reference system of a cube is defined by the geometry of its three faces. However, when defining an orthogonal reference system for a cylinder, the symmetry is not exclusively defined. A principal direction can be set up along the centre of the cylinder, a second at ninety degrees to this axis in any direction, and a third at ninety degrees to the plane defined by the two initial axes.

This third axis is dependent on the initial two axes, and is known as the floating axes. One of the advantages of arranging the axes symmetrically with respect to a body, is that the products of inertia vanish, and simplifying the problem at hand considerably (Meriam et al. 2008).

Furthermore, the use of an orthogonal system ensures liner independence of reference system bases. In brief, if a skew angular system is used as suggested by Grood et al. (1983), any one of the base vectors may be made up by the linear superposition of the other two bases, and linear independence will therefore not exist. This can be easily recognised if you were to draw the three axis x, y and z in the same plane, there is redundancy, and the bases are no longer uniquely defined. The z base axis could be made up by the linear superposition of the x and y base axis. When the bases are skew angular, adjoint covariant vectors should be defined, though they do not lend themselves to matrix algebra (Lanczos 1964).

Therefore, all local reference systems will be orthonormal, while all moments will be given in the proximal frame of reference. Furthermore, the moment acting around the anatomical point of rotation will be given in the proximal frame of reference. That is for example, the hip moment given, is the applied hip moment in the pelvic frame of reference. It should also be considered that while the applied moment is of similar magnitude to the internal muscle moment, they are not the same, though for the purpose of this study they can be considered equal. To evaluate the internal muscle moment, dynamic equilibrium can be used to evaluate an unknown internal moment around a point of rotation, once the boundary conditions of moments acting on the segment have been evaluated.

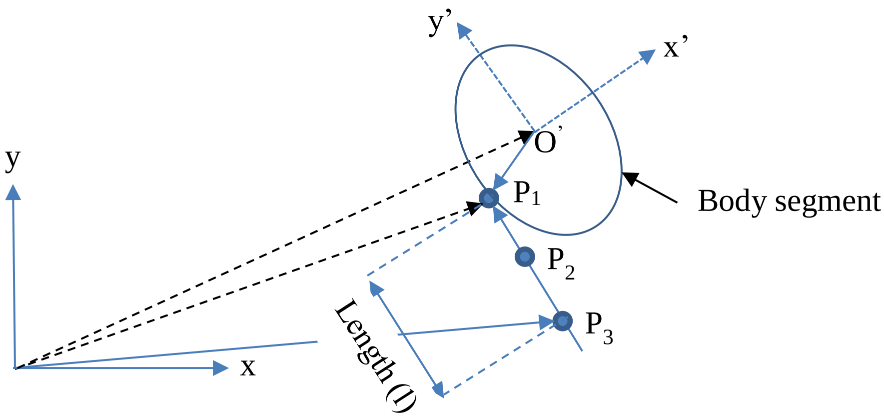


Figure 5.15 Identification of anatomical prominences with respect to a local floating reference frame origin (O') using a single marker (P_1) or wand (P_2 & P_3)

5.6 STATIC CAPTURE

As already discussed, the general purpose of the static capture is to allow anatomical prominences that have been identified by maker placement, to be referenced from some convenient point. This is generally thought to reduce noise caused by skin motion around the anatomical prominence during ambulation. As Shown on Figure 5.5 - Figure 5.8, clusters were attached to the feet, shanks and thighs because, they provided a convenient floating system with no physical relevance to the segment in question, and were only used to reference the anatomical markers attached to the segment.

When referencing a single marker (P_1) from a local reference system with origin O, as shown in Figure 5.15, the following transformation is made.

$$P_1' = [R]^{-1}[P_1 - O'] \qquad 5.1$$

R is the second order tensor describing the reference bases x' and y', though the process is as equally applicable in 3-dimesional space. Furthermore, the inverse of local system (R) is identical to its transformation, as the base system is orthonormal.

The following transformation is made to locate the anatomical position (P_1) with respect to the local cluster system using the two collinear markers whose positions are identified using global coordinates, as indicated on Figure 5.15 (Hood 2011).

$$P_1 = [R]^{-1}\left(P_3 + \left[\frac{P_2 - P_3}{|P_2 - P_3|}\right] l - O'\right) \qquad 5.2$$

This method was used to identify the pelvic ASIS during the static capture, as the additional adipose tissue, and garments worn by the participants made it impractical to locate these prominences using single anatomical makers. The other lower limb anatomical prominences were only referenced using the wand when the main static capture failed to reference all anatomical prominences. The other positions were the medial prominences, as the individual markers were commonly knocked off, or blinded from the view of the cameras.

To ensure that there was one main static capture referencing all the anatomical prominences in the global coordinate system. The anatomical prominences, referenced using the wand static capture, were reconstructed in the main static capture. As the main static capture also positioned the local cluster coordinates with respect to the global reference frame, it was possible to identify where the hip, knee and ankle centres lay with respect to the floating clusters that were attached to the limbs and waist. Hence, the cluster marker trajectories can be identified in global coordinates during the dynamic trail when the participant was ambulating. Consequently, the following discussion will now describe how the external markers were used to determine the underlying lower limb joint centres.

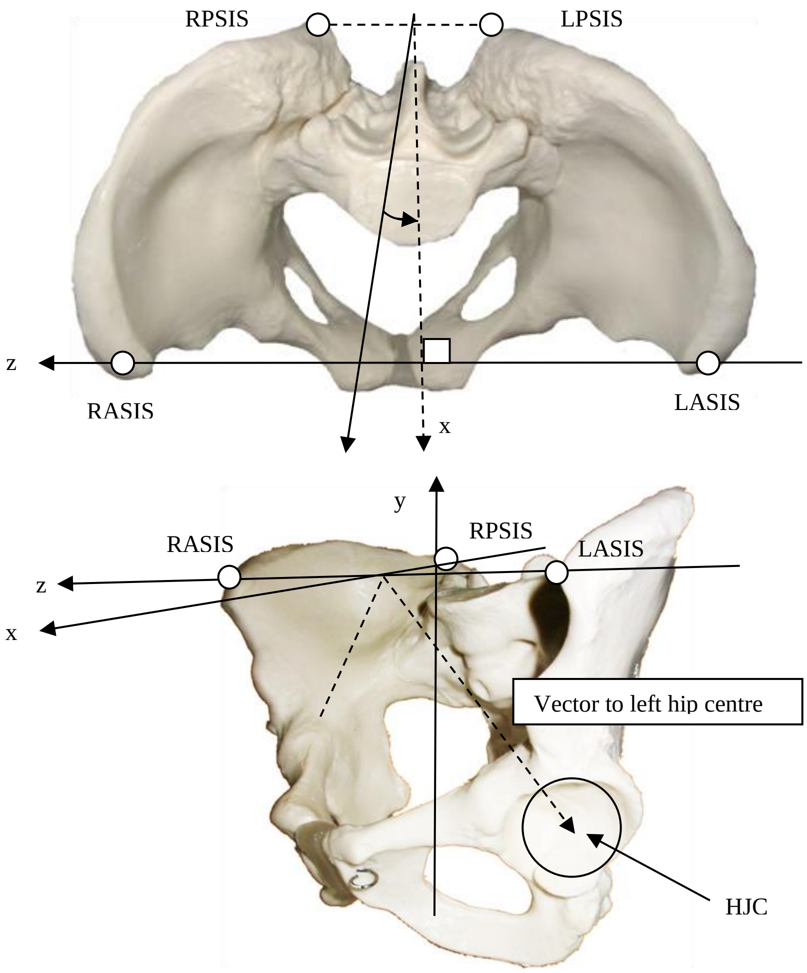
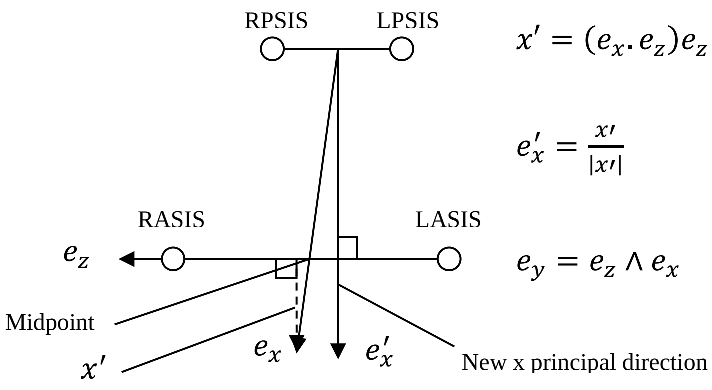


Figure 5.16 Pelvic frame of reference



$$x' = (e_x . e_z)e_z - e_x \tag{5.3}$$

$$e'_x = \frac{x'}{|x'|} \tag{5.4}$$

$$e_y = e_z \wedge e_x \tag{5.5}$$

Figure 5.17 Defining reference system of pelvis uing Gram Schmidt

5.7 PELVIC FRAME OF REFERENCE

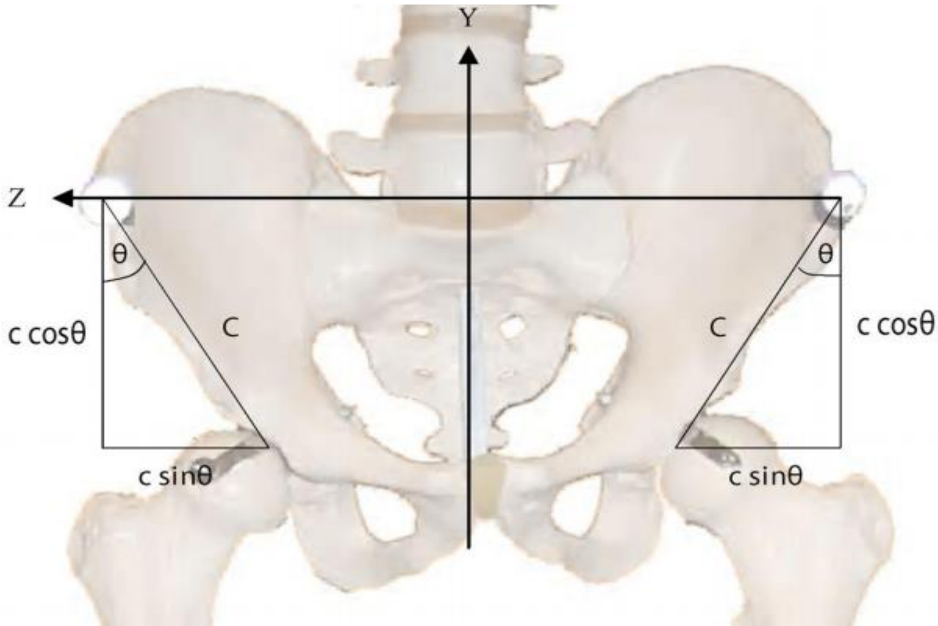
The hip joint centre (HJC) centre is located at the centre of the acetabular rim perimeter, and is usually referenced from some convenient point in the pelvic reference system (Seidel et al. 1995). There are both invasive and non-invasive procedures that are available to determine the location of the hip joint centres (HJCs) relative to anatomical prominences.

However, methods that are considered invasive, such as radiographic techniques are still not without error, as they use two-dimensional (2D) projections to reconstruct a three-dimensional (3D) position. Furthermore, even though computer tomography methods do not lead to unnecessary radiation exposure. The expense of obtaining these 3D images, do not allow such techniques to be routinely used (Kirkwood et al. 1999, Camomilla et al. 2006, Seidel et al. 1995).

All methods though, will need to locate the HJC relative to a pelvic reference system. Of the locations used to create a pelvic reference system, the four most commonly identifiable prominences are the anterior and superior iliac spine positions, as shown on Figure 5.16. For this study, the principal z direction of the pelvic system lies on the two collinear points as shown on Figure 5.16. The x principal direction of the pelvic reference system lays in the plane of the fours ASIS markers, and originates at the midpoint of the two posterior markers. To ensure the x and z principal directions are orthogonal the Gram Schmidt orthogonalisation procedure is used as shown in Figure 5.17 (Davis et al. 1991). Finally, the y eigenvector of the pelvic reference system is defined as being orthogonal to the z, x plane.

However, many techniques are used to locate the HJCs from this conveniently placed pelvic reface system, such as anthropometric methods. These geometric methods rely on regression equations that are highly error prone, and as shown by Bell et al. (1990) the HJC is likely to only be located within a ±2cm accuracy. Furthermore, when comparing the accuracy of both functional and anthropometric measures, both are sensitive to fleshy movements and palpating. Conversely, anthropometric methods that use the pubic centre as a reference point combined with other measures such as pelvic width and depth, have been shown to provide the greatest accuracy (Seidel et al. 1995, Kirkwood et al. 1999, Bell et al. 1989). However, it was felt that locating the pubic bone of recruited volunteers is likely to cause unnecessary embarrassment due to the location; therefore, these predictive measures were excluded from this study.

Of the other non-invasive methods that could be potentially used to determine the HJCs, functional methods potentially can provide the greatest accuracy compared to geometric/anthropometric methods. This is achieved by capturing residual limb trajectories during a reference capture, which are then used to determine the HJC with respect to the individuals' pelvic frame. However, there are still inherent inaccuracies associated with functional methods, due either to computation, kinematic noise or the subjects having a poor range of hip motion (Bell et al. 1990, Kirkwood et al. 1999, Camomilla et al. 2006). Hence, it was decided that additional errors that would have be introduced by carrying out this functional routine when the participants were in a seated position when their prosthesis was removed.



Newington cage statistical formula:

$$c = 0.115L_{leg} - 0.0153 \tag{5.6}$$

$$\theta = 0.5\,rads \tag{5.7}$$

$$\beta = 0.314\,rads \tag{5.8}$$

The z-projection length identified in the local coordinate system lies along the Z eigenvector positioned in global space. The length $c\,\sin(\theta)$ is also used in the sagittal plane as shown in Figure 5.19.

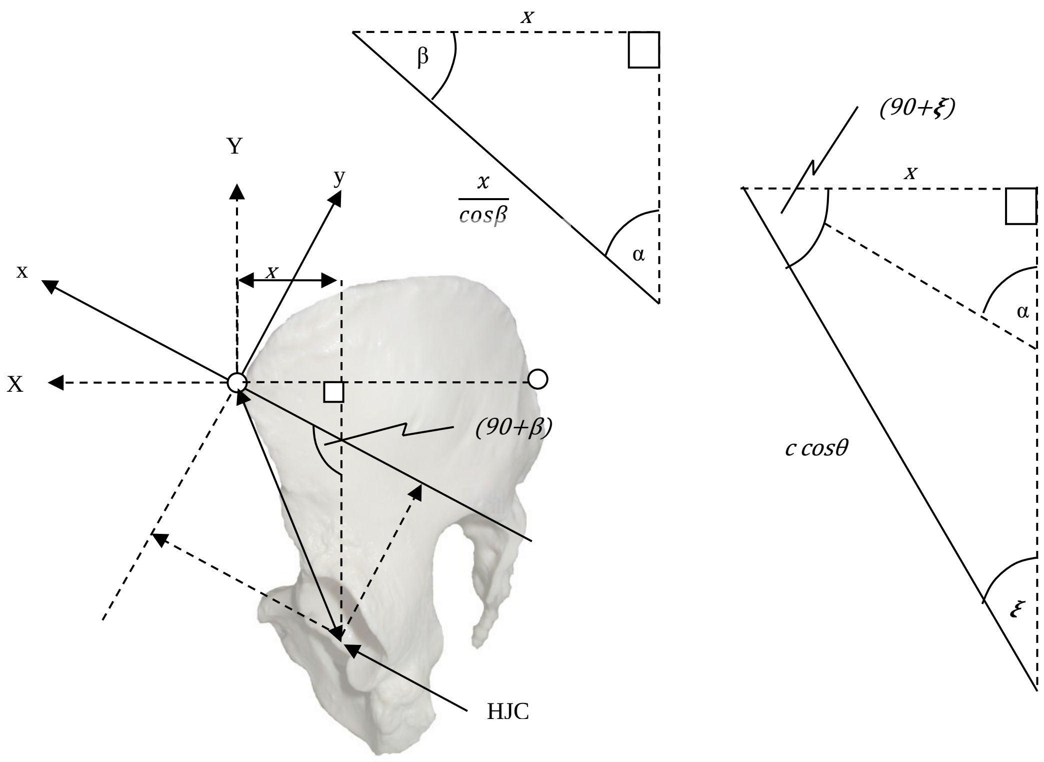
$$z_{right\ leg} = \frac{ASIS\ distance}{2} - c\,\sin(\theta) \tag{5.9}$$

$$z_{left\ \ leg} = c\,\sin(\theta) - \frac{ASIS\ distance}{2} \tag{5.10}$$

Figure 5.18 Prediction of the Z projection lengths in the coronal plane of the pelvic reference system

The method that was finally decided upon was the Newington model, detailed in Davis et al. (1991), as it involved taking more than one statistical measure into consideration which included, pelvic depth, pelvic width and the predicted pelvic height. The regression formulas that were used to predict HJC, use the set of angle coefficients θ (28.4±6.6°) and β (18±4°), and the modulus vector c in the coronal plane as shown on Figure 5.18. The measures (θ, β and c) are then used to predict the three projection lengths of the vector locating the HJC from the convenient location of the mid-point of the anterior ASIS, in a rotated pelvic reference system with respect to the plane of the anterior and posterior ASIS (lower case z, y & z), detailed in Figure 5.19. The global pelvic system eigenvectors (upper case Z, Y & Z) of the pelvic system, defined by the anterior and posterior ASIS, are used to locate the HJCs from this physically convenient pelvic reference system during the static trial. Therefore, during the dynamic trail it is possible to identify the position of the HJCs in global coordinate system Equation 5.11, for every frame captured, allowing the anatomical moment directions and magnitudes to be known in the global frame before being transformed.

$$\left[R_{global}\right] = [e_{X_{global}} \quad e_{Y_{global}} \quad e_{Z_{global}}] = \begin{bmatrix} 1 & 0 & 0 \\ 0 & 1 & 0 \\ 0 & 0 & 1 \end{bmatrix} \qquad 5.11$$



The analytical solution of sin and cosine zeta is required for substitution later, and includes the quantity X, that can be measured with respect to the X and Y pelvic system shown.

$$sin(\xi) = \frac{X}{c\ cos(\theta)} \qquad 5.12$$

$$\cos(\xi) = \left[1 - \frac{X^2}{c^2\ cos^2(\theta)}\right]^{1/2} \qquad 5.13$$

Figure 5.19 prediction of the X & Y projection lengths in the (sagittal plane)

The equations given in Davis et al. (1991), will now be derived to further highlight assumptions made. It should be noted that the local coronal pelvic plane orientation (y and z direction) has the same orientation as the Y and Z frame referenced in global coordinates (Figure 5.18). Hence, the projection length, ccosθ is first determined in the coronal plane as shown on Figure 5.18. However, the transverse plane of the Davis et al. (1991) pelvic system is orientated by the angle β (18±4°) with respect to the transverse plane of the pelvic system defined by the orientation of the ASIS. In the sagittal plane, the upper right angle triangle Figure 5.19, can be removed from the lower larger right angle triangle, and allows the X-projection length using similar triangles as shown in Figure 5.20, to be identified in the pelvic frame of reference detailed below.

$$sin(\beta + \xi) = \frac{X}{c\cos(\theta)} \qquad 5.14$$

$$x = c\,cos(\theta)[sin(\beta)cos(\xi) + cos(\beta)sin(\xi)] \qquad 5.15$$

Equation 5.11 and 5.12 as shown on Figure 5.19 are substituted into equation 5.14 to eliminate the unknown ξ.

$$x = c\,cos(\theta)sin(\beta)\left[1 - \frac{X^2}{c^2cos^2(\theta)}\right]^{1/2} + c\,cos(\theta)cos(\beta)\frac{X}{c\,cos(\theta)} \qquad 5.16$$

$$x = c\,cos(\theta)sin(\beta)\left[1 - \frac{X^2}{c^2cos^2(\theta)}\right]^{1/2} + xcos(\beta) \qquad 5.17$$

The Y-projection length is also determined using similar triangles above:

$$cos(\beta + \xi) = \frac{Y}{c\cos(\theta)} \qquad 5.18$$

$$y = c\,cos(\theta)\,cos(\beta + \xi) \qquad 5.19$$

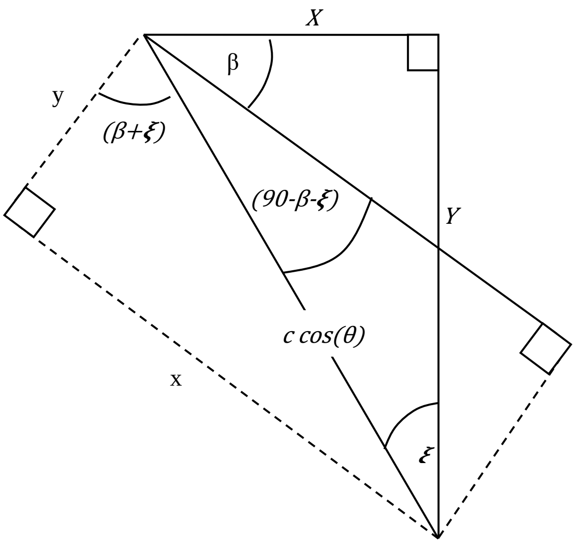


Figure 5.20 The use of simlar triangles from Figure 5.19

$$y = c\ cos(\theta)\ [cos(\beta)cos(\xi) - sin(\beta)sin(\xi)] \qquad 5.20$$

Equation 5.12 and 5.13 can now be substituted into equation 5.20 to eliminate ξ.

$$y = c\ cos(\theta)cos(\beta)\left[1 - \frac{X^2}{c^2cos^2(\theta)}\right]^{1/2} - c\ cos(\theta)sin(\beta)\frac{X}{c\ cos(\theta)} \qquad 5.21$$

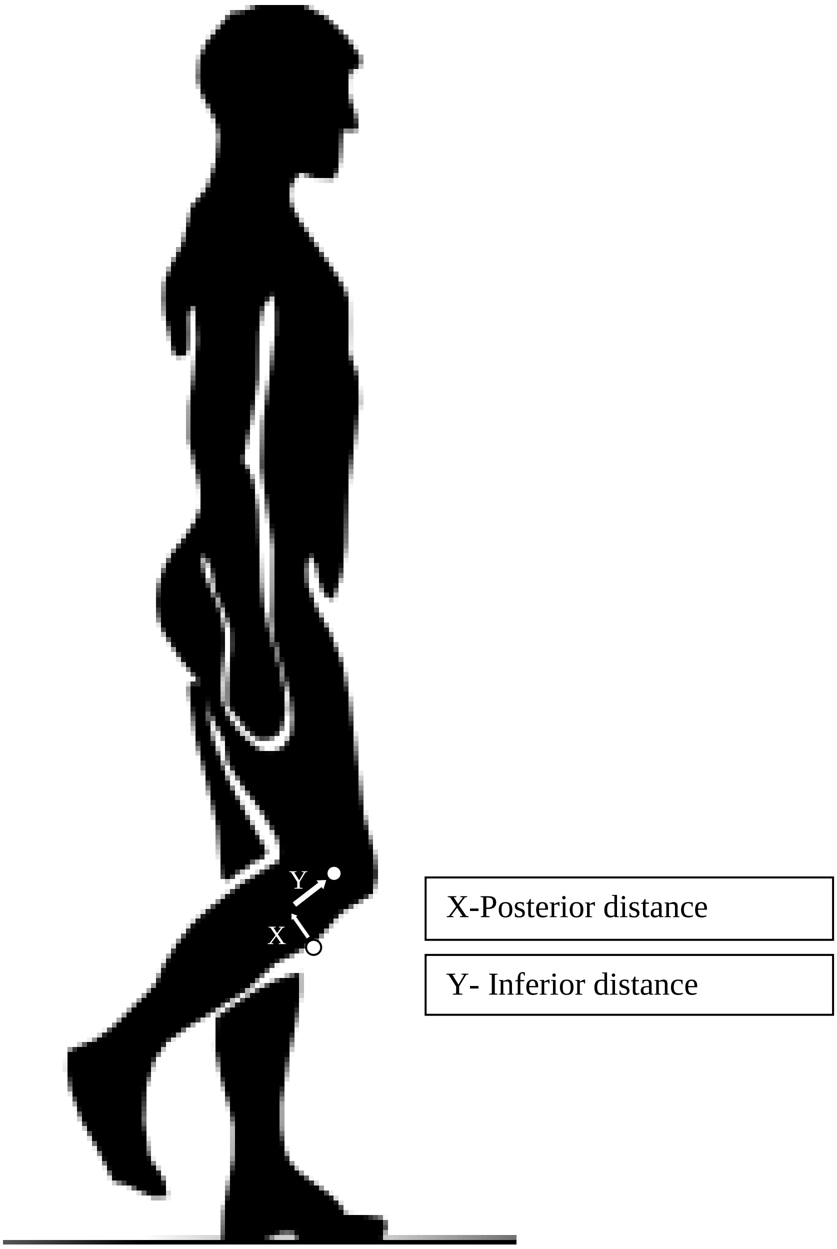
$$y = xsin(\beta) - c\ cos(\theta)cos(\beta)\left[1 - \frac{X^2}{c^2cos^2(\theta)}\right]^{1/2} \qquad 5.22$$

On comparison of Equation 5.17 and 5.22 with the presented solution described in Davis et al. (1991), it is obvious that the square root term in the analytical solution determining the x & y projected lengths has be ignored, as it clearly has a magnitude of less than 1. Finally, the derived projected vector lengths (lower case) x, x and z in equation 5.9, 5.10, 5.17 & 5.22 are the components of the vector locating the HJCs from the collinear midpoint of the two anterior ASIS in the orientated Davis et al. (1991) system. Therefore, the components in the pelvic reference system defined by the plane of the ASIS are found by transforming the coordinates in the x, y and z reference frame by the angle β.

$$\begin{bmatrix} X \\ Y \\ Z \end{bmatrix} = \begin{bmatrix} cos\beta & -sin\beta & 0 \\ sin\beta & cos\beta & 0 \\ 0 & 0 & 1 \end{bmatrix} \begin{bmatrix} x \\ y \\ z \end{bmatrix} \qquad 5.23$$

However, to obtain the position of the HJCs in global coordinates they need to be post multiplied by the eigenvectors s of the XYZ pelvic system.

$$\begin{bmatrix} X_{global} \\ Y_{global} \\ Z_{global} \end{bmatrix} = \begin{bmatrix} X_{ASIS} \\ Y_{ASIS} \\ Z_{ASIS} \end{bmatrix} + \begin{bmatrix} e_{X_{pelvis}} & e_{Y_{pelvis}} & e_{Z_{pelvis}} \end{bmatrix} \begin{bmatrix} X \\ Y \\ Z \end{bmatrix} \qquad 5.24$$



Inferior distance = height from TT to condoyle Plateau +24.3 5.25

Posterior distance = half the maker diameter + (0.75 x knee width-21.6) 5.26

Figure 5.21 location of the knee centre in the sagittal plane

5.8 THIGH, LEG AND FOOT REFERENCE SYSTEM

Once the HJCs locations are known with respect to the origin positioned in the pelvic reference system during the static capture, the knee centre (KC) is located with respect to the tibia frame of reference. When Ishai (1975) initially developed the marker system used in this study to locate the KC from the tibia, the global coordinates of marker positions were not instantaneously given during the static capture. As a result, the measured distances between markers allowed the KC position to be determined global coordinates; essentially the measurements/distances between markers in the tibia reference frame were part of the static trail. However, Due to the spatial ability of cameras now used for gait analysis, this process is far simpler and more accurate, and reduces the number of limb measurements that need to be taken. Because, medial and lateral markers can now be placed on limbs during a static capture, this negates the requirement to use eight regression equations to predict the KC location from external makers. Of these original equations, only two are required, along with the measured distance from the tibia tuberosity to condyle plateau. The assumption that the tibia tuberosity (TT) lies in the same plane as the KC still holds. The predictive regression equations were determined from the analysis of eight tibias obtained from the Department of Anatomy, University of Glasgow. They predict the posterior and inferior distance of the KC from the TT based on knee width, in the tibia frame of reference as shown in Figure 5.21. Once the x and y components are known, the 3D vector locating the KC from the TT can be created by linear superposition in the local tibia reference frame. As it is assumed the TT and KC lie in the same plane, the z component (medial/lateral) of this local vector has no magnitude.

Step 1: z-direction

$$z = \frac{LMEF - LLEF}{|LMEF - LLEF|} \qquad 5.27$$

Step 2: y-direction

$$y = \frac{LMEF + LLEF}{2} - \frac{LMMAL + LLMAL}{2} \qquad 5.28$$

$$y = \frac{y}{|y|} \qquad 5.29$$

Step 3: x-direction

$$x = y \wedge z \qquad 5.30$$

Step 4: y-direction is adjusted to ensure an orthogonal system

$$y = z \wedge x \qquad 5.31$$

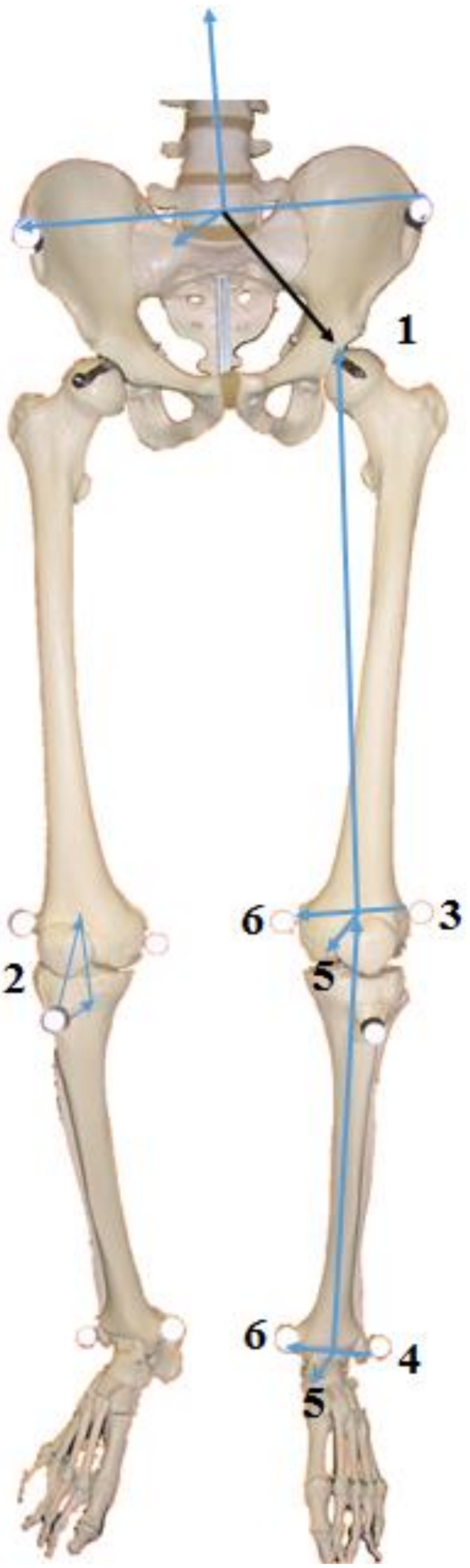
$$KC_{global} = LTIB + [R_{knee\ reference\ sytem}][local\ vector\ from\ LTIB\ to\ KC] \qquad 5.32$$

$$KC_{cluster} = \left[R_{cluster\ reference\ system}\right]^{-1}\left[KC_{global} - \frac{LMMAL + LLMAL}{2}\right] \qquad 5.33$$

Figure 5.22 Determintaion of knee reference systems principal directions

The knee width, and orientation of the knee axis, was determined using the two epicondyles markers. The long y-axis was determined using the midpoint of the malleoli markers and epicondyle markers. While, the right hand cross product was used to determine the x direction of the reference system (Figure 5.22). Once the x, y and z vectors are known, they were normalised, and then became the eigenvectors of the local knee reference system during the static calibration. Hence, the regression formulas as shown in equation 5.25 and 5.26, predict the projected length of the vector from the TT to KC along the axes of local knee coordinate system during the static trial when the knee was extended. Consequently, the position of the knee centre is known with respect to the TT in the shank reference system during the static trial. Therefore, the knee centre is known in global coordinates, and can be referenced from a convenient position on the shank using the local floating cluster system. However, the ankle centre (AC) was simply taken as the midpoint of the malleoli markers, and were referenced from the floating shank cluster system during the static capture process.

On the participant's prosthetic side during the static trail, the KC as well as the AC was simply determined as the midpoint between the two makers placed on the medial and lateral positions of the joint. These points were also referenced from the local floating shank system on the prosthetic side. Once, the position of the AC, KC and HC was known with respect to the floating systems attached to the body segments, the long axial direction of the thigh and shank can be easy ascertained during the dynamic trail. The coronal orientation of the knee was determine during the dynamic trail by referencing its orientation during the static trial with respect to the shank floating system, in a standing position.



1. The Hip centre is first located in global space using the pelvic reference frame.

2. The relative position of the knee centre was determined with respect to the tibial tuberosity.

3. The orientation of the knee axis is determined using the epicondyle markers

4. The ankle centre is determined as the mid-point of the malleolus markers, and axis by the orientation of the malleoli markers.

5. The plane that is normal to the long and transverse axis of the thigh and shank segment defines the direction that is normal to the coronal plane.

Figure 5.23 Mechanical axes of lower limbs

As a number of relative motions occur within the foot, as it consists of twenty-five joints, many foot reference systems can therefore be defined. It was finally decided that the hind-foot model, defined predominately by placing markers on the calcaneus and metatarsals would be appropriate. Because, the prosthetic foot can be modelled as one segment, as shown by previous University of Strathclyde studies such as those by Goh (1982) and MacLellan (2006).

The landmarks commonly used to create a single foot system are the upper ankle or talocrural joint, which can be identified from the external bony malleoli landmark around the talus (Harris et al. 2008). This model was copied with the one exception that the positions of these markers were referenced with respect to cluster triad attached to the shoe. As shown on Figure 5.24, the calcaneus and metatarsals markers were used to define the plane of the foot, and the direction normal to this plane. The long axis of the foot was determined from the calcaneus maker, and the midpoint of the metatarsal markers. Finally, the direction normal to the sagittal plane was defined as the medial lateral direction to ensure base system orthogonality.

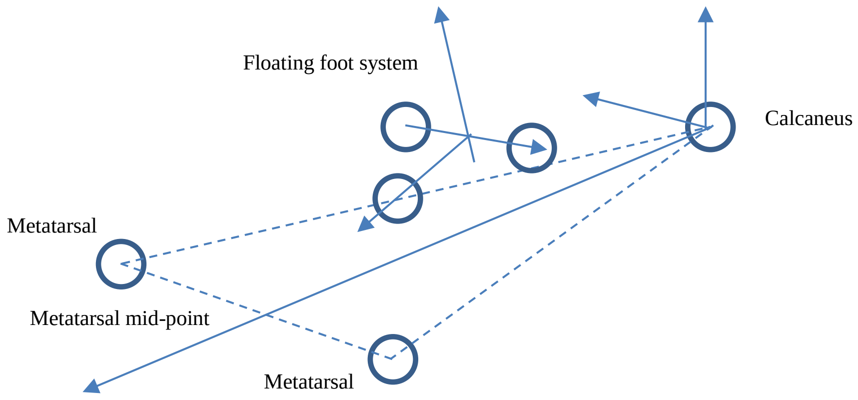
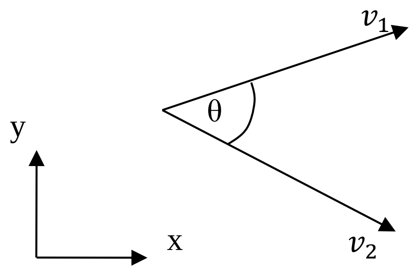


Figure 5.24 Markers on the foot used to define foot reference system

5.9 ANGLES

Orientation is not absolute, and joint attitude by convention is given as the relative orientation of reference systems To allow the results from different gait laboratories to be compared, standard methods of defining segment reference systems exist (Woltring 1991).

For the purpose, of calculating the flexion and extension angles, three non-collinear positions on the segment are commonly used define a plane from which the reference system directions are created. Therefore, markers placed on epicondyles and malleoli allow a tibial frame of reference to be set up in a repeatable manner across individuals (Grood et al. 1983, Cole et al. 1993). Therefore, the angles do not describe what is happening at the joint in detail, they simply describe that the orientation, for example, of the shank with respect to the thigh. However, the methods described by Grood et al. (1983), used to define the thigh and shank reference systems do not appear reliable, as the angle between the bases change with every frame. Because, the reference system are skew angular, as the orientations of the markers placed on anatomical prominences define the principle detections of the segment in question without manipulation. This ultimately means the relative segment orientation will be affected by the orientation of base eigenvectors with respect to each other, as the angles between the bases of the skew angular system is changing as a direct result of skin marker motion. Moreover, as will be discussed, linear independence will therefore not exist (Lanczos 1964). Thus, using a systematic method to describe an orthonormal system ensures the same reference systems are comparable on every frame, while also reducing mathematical uncertainty.



$$\theta = \cos^{-1}\left[\frac{v_1.v_2}{|v_1.v_2|}\right] \qquad 5.34$$

Figure 5.25 Dot product to calculate angle between vectors

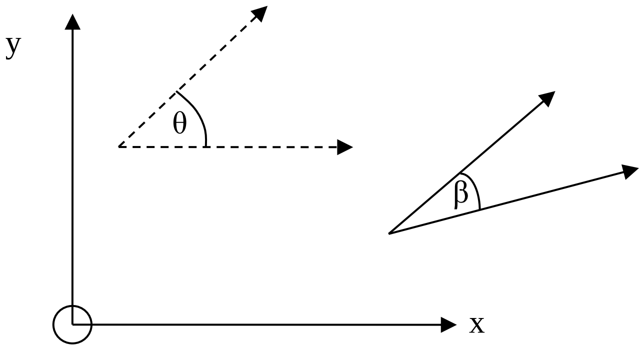


Figure 5.26 projection of angles

In a plane, the absolute angle between two vectors can be calculated as shown in Figure 5.25. The magnitude of the angle between the two vectors is the angle measured on the plane of the two vectors. However, when the angle between the two vectors is measured from a different plane/orientation, this measured angle is the projected view (Figure 5.26). The true angle theta, measured on the plane of two vectors is different from the angle β observed by the observer. As the plane created by the two vectors does not lie on the x, y plane of the global coordinate system (GCS) as seen by the observer.

In pioneering gait analysis, it was assumed that the absolute flexion/extension angles were equal in magnitude to the projected angles. As the subjects' sagittal plane was assumed to be parallel with the sagittal plane of the global axes, though these angles have been shown to be "kinematically unreliable" (Woltring 1991). Indeed, as it will be shown in the results section when comparing the results of this study to that of other researches. It appears many researches still present moments that act around joints in the global reference frame, determining the absolute or true angle between eigenvectors of the reference systems is not a valid method to interpret joint attitude.

Therefore, to ensure the flexion/extension angle is defined consistently, the relative orientation of the distal segment is given with respect to the proximal segment. Once segment reference systems are created, the dot product between the two bases is achieved by multiplying the transpose of the respective reference systems in question as shown in Equation 5.35 (Lanczos 1964).

$$[R] = [R_{Distal}]^T[R_{Proximal}] \tag{5.35}$$

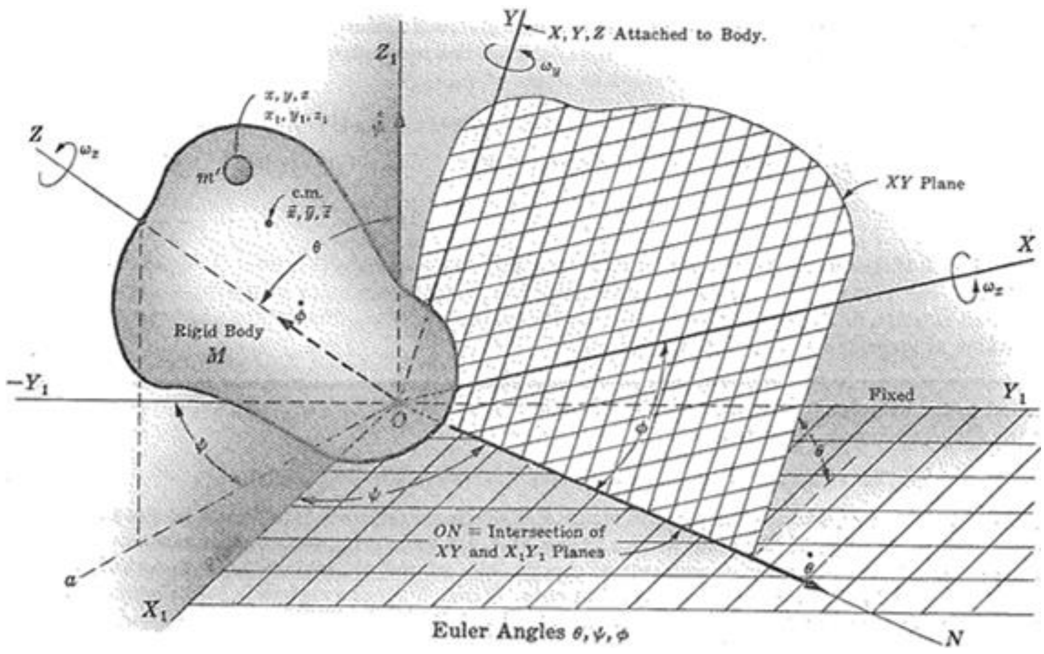


Figure 5.27 the three independent Euler angles (Wells 1967)

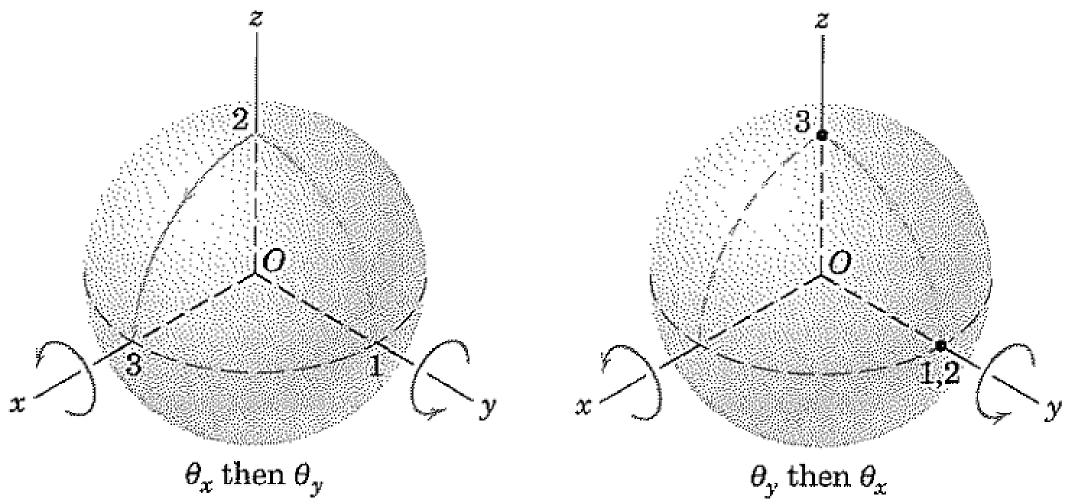


Figure 5.28 finite rotations (Meriam et al. 2008)

The attitude matrix [R] as shown in equation 5.33 can be used to determine the unique independent angles of a finite rotation. Moreover, as shown in Figure 5.28, a finite rotation is not commutative, and cannot be solved for using proper vectors. A proper vector on the other hand can only be used for infinitesimal rotations, and therefore obeys the parallelogram law of addition, as shown in Figure 5.28 (Meriam et al. 2008). Form the image on the left, a rotation around the x then y-axis will result in the position starting at point one, and ending at point three. Conversely, a rotation around the y then x-axis will result in the same point moving to a different position. Therefore, the attitude matrix [R] is parameterised by the three independent angles, whose order of rotation is uniquely defined.

If X_1, Y_1, and Z_1 are the base vectors of the proximal reference segment, and X, Y, and Z are the base vectors of the distal segment reference system. The line of node (ON) is determined by the intersection of the X Y plane with the X_1 Y_1 plane, or equivalent. The line of node can then be used to determine the projected independent angles: Ψ, θ and Ø as illustrated in Figure 5.27. If the XYZ system was rotated so X Y plane is parallel with the X_1 Y_1 plane, the angle Ø will be zero. Consequently there would only be two independent angles, and the matrix [R] would be singular, as described by Wells (1967), and gimbal lock will result.

The derivation of three independent three angles α, β and γ will now be investigated to demonstrate why and how errors are caused of gimbal lock. First, consider three sequential rotations $\alpha, \beta\ and\ \gamma$ around the x, y and z-axis, as shown by equation 5.36 over the page.

$$[R_{kji}] = R_k(\gamma)R_j(\beta)R_i(\alpha) \quad 5.36$$

The right hand rotation around the x, y and z-axes are given as follows:

$$R_i(\alpha) = \begin{bmatrix} 1 & 0 & 0 \\ 0 & \cos(\alpha) & \sin(\alpha) \\ 0 & -\sin(\alpha) & \cos(\alpha) \end{bmatrix} \quad 5.37$$

$$R_j(\beta) = \begin{bmatrix} \cos(\beta) & 0 & \sin(\beta) \\ 0 & 1 & 0 \\ -\sin(\beta) & 0 & \cos(\beta) \end{bmatrix} \quad 5.38$$

$$R_k(\gamma) = \begin{bmatrix} \cos(\gamma) & -\sin(\gamma) & 0 \\ \sin(\gamma) & \cos(\gamma) & 0 \\ 0 & 0 & 1 \end{bmatrix} \quad 5.39$$

Giving Equation 5.40 as shown below:

$$[R_{kji}] = \begin{bmatrix} \cos(\beta)\cos(\gamma) & -\cos(\alpha)\sin(\gamma) - \cos(\gamma)\sin(\beta)\sin(\alpha) & \cos(\gamma)\cos(\alpha)\sin(\beta) - \sin(\gamma)\sin(\alpha) \\ \cos(\beta)\sin(\gamma) & \cos(\gamma)\cos(\alpha) - \sin(\beta)\sin(\gamma)\sin(\alpha) & \cos(\gamma)\sin(\alpha) + \cos(\alpha)\sin(\beta)\sin(\gamma) \\ -\sin(\beta) & -\cos(\beta)\sin(\alpha) & \cos(\beta)\cos(\alpha) \end{bmatrix}$$

The angles α, β and γ can be solved for, by setting up the three suggested independent equations as shown below, however, other equations may also be considered.

$$R_{31} = -\sin(\beta) \quad 5.41$$

$$R_{32} = -\cos(\beta)\sin(\alpha) \quad 5.42$$

$$R_{11} = \cos(\beta)\cos(\gamma) \quad 5.43$$

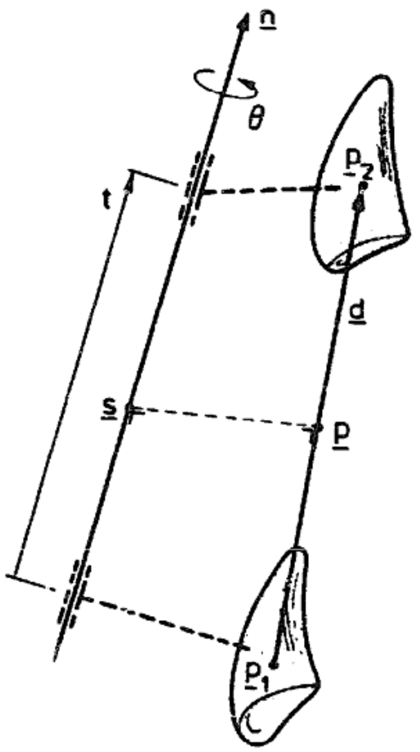


Figure 5.29 Finite Helical Axis for joint motion description (Woltring 1991)

If the angle γ does not really exist as demonstrated by Figure 5.30 during stance, when the transverse plane of the proximal and distal reference system is parallel, approximately sixty-three degrees of eversion and inversion was observed using Equations 5.41-5.43. This clearly is incorrect, and is a result of gimbal lock; hence, other reliable parameterisations are required to solve joint angles.

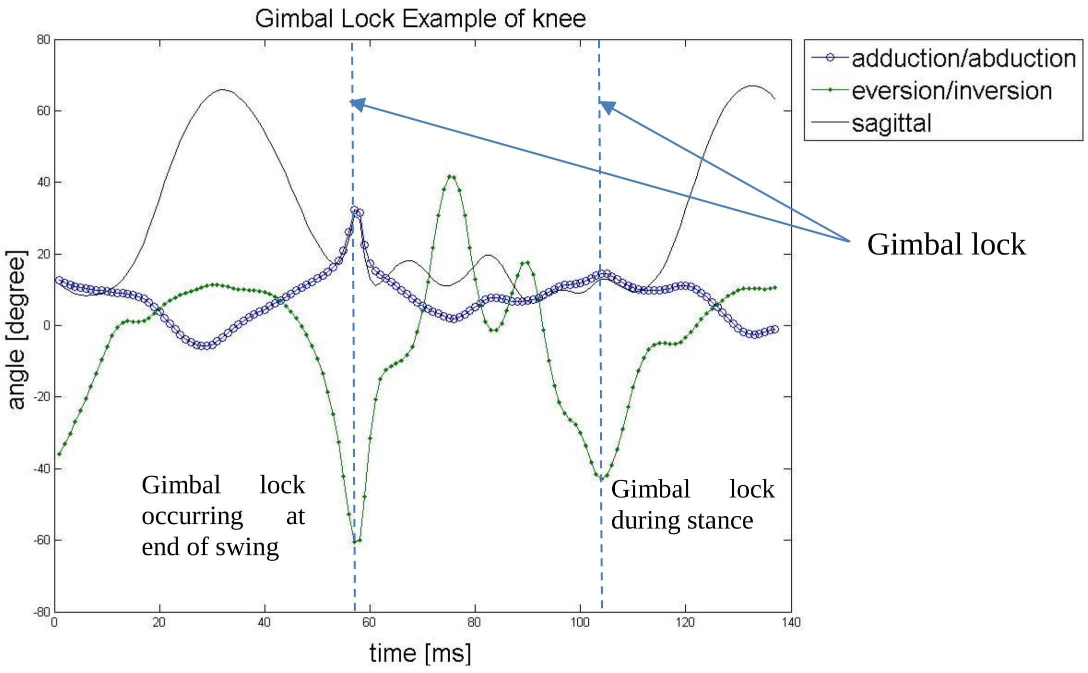
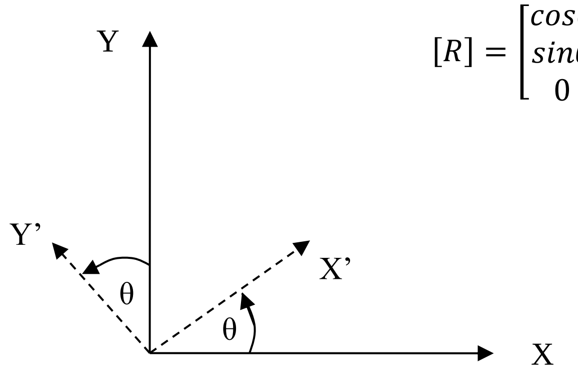


Figure 5.30 Example of Gimbal lock during stance and end of swing when the knee is extended (shown by the two dashed vertical lines)

Helical angles provide a robust solution, as any finite movement can be considered as a displacement from a point p1 to p2, and a absolute rotation (Figure 5.29). The absolute rotation can then reduced to three independent angles along the axis of the desired reference sytem (Woltring 1991).

A detailed proof of helical rotations is provided by Spoor et al. (1980), however, a physical interpretation of the analytical solution will now be given instead. It is known that a plane rotation around a third orthogonal axis n is given by the matrix [R], as shown in Figure 5.31 below. The trace of the matrix [R], is the first invariant (I_1) of the second order tensor, and describes the orientation of the eigenvectors, X' and Y' with respect to the base X and Y vectors (Equation 5.44). This equation can then be solved to give the angle theta (Equation 5.47).



$$[R] = \begin{bmatrix} cos\theta & -sin\theta & 0 \\ sin\theta & cos\theta & 0 \\ 0 & 0 & 1 \end{bmatrix} \qquad 5.44$$

$$trace(R) = 2cos\theta + 1 \qquad 5.45$$

Therefore the angle of rotation around the n axes is:

$$R_{11} + R_{22} + R_{33} = 2cos\theta + 1 \qquad 5.46$$

$$\theta = \cos^{-1}\left(\frac{R_{11}+R_{22}+R_{22}-1}{2}\right) \qquad 5.47$$

The analytical solution for the axis of rotation whose derivation is described in Spoor et al. (1980).

$$\mathrm{n} = \frac{1}{2\sin\theta}[R - R^T] \qquad 5.48$$

Figure 5.31 Plane rotation in three dimensional space

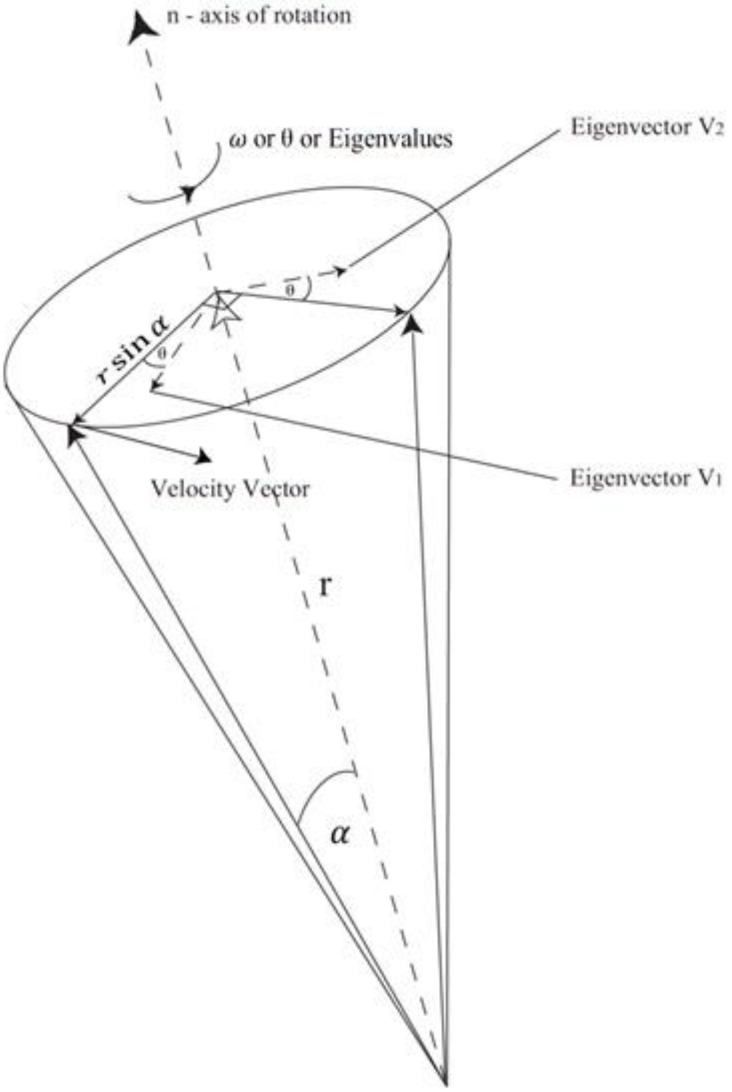


Figure 5.32 Axes of roataion around a cone adapted from Meriam (2008)

The axis n, about which the distal reference system rotates with respect to the proximal reference system shown on Figure 5.32. The base vectors X' and Y' Figure 5.32, are related to the eigenvectors V_1 and V_2, and the angle of rotation is given by the angle theta. Hence, it can be seen that reducing the rotation matrix to canonical Equation 5.49, that the matrix of eigenvectors (M), and the spectral matrix of eigenvalues (Λ) is easily obtained. As shown in Equation 5.50-5.52, reducing to canonical form, gives a pair of complex conjugate eigenvalues, whose phase relates to the magnitude of the rotation around the axis of rotation n. The final third eigenvalue, has a magnitude of one, and is associated with the eigenvector about which the rotation has taken place.

$$[R][M] = [M][\Lambda] \qquad 5.49$$

This gives:

$$[R][M] = [v_1 \quad v_2 \quad n]\begin{bmatrix} a+bj & 0 & 0 \\ 0 & a-bj & 0 \\ 0 & 0 & 1 \end{bmatrix} \qquad 5.50$$

Or

$$[R][M] = [v_1 \quad n \quad v_2]\begin{bmatrix} a+bj & 0 & 0 \\ 0 & 1 & 0 \\ 0 & 0 & a-bj \end{bmatrix} \qquad 5.51$$

Or

$$[R][M] = [n \quad v_1 \quad v_2]\begin{bmatrix} 1 & 0 & 0 \\ 0 & a+bj & 0 \\ 0 & 0 & a-bj \end{bmatrix} \qquad 5.52$$

To ensure decomposition of the rotation along the desired right had system, as a relative rotation can be to the right or left. The right had cross product of the eigenvectors V_1 and V_2 is taken. Equation 5.53 can then be used to decompose the absolute rotation into three independent Euler angles of rotation.

$$\begin{bmatrix}\theta_1\\ \theta_2\\ \theta_3\end{bmatrix} = |a \pm bj| \begin{bmatrix}e_1\\ e_2\\ e_3\end{bmatrix} \text{(Equation 5.53)}$$

This numerical method provides a robust solution, as it does not depend on the correct interpretation of the analytical solution by the computing algorithm. Finally, these numerical results are comparable to the "Euler" method of setting up three independent equations as shown in Figure 5.33 below.

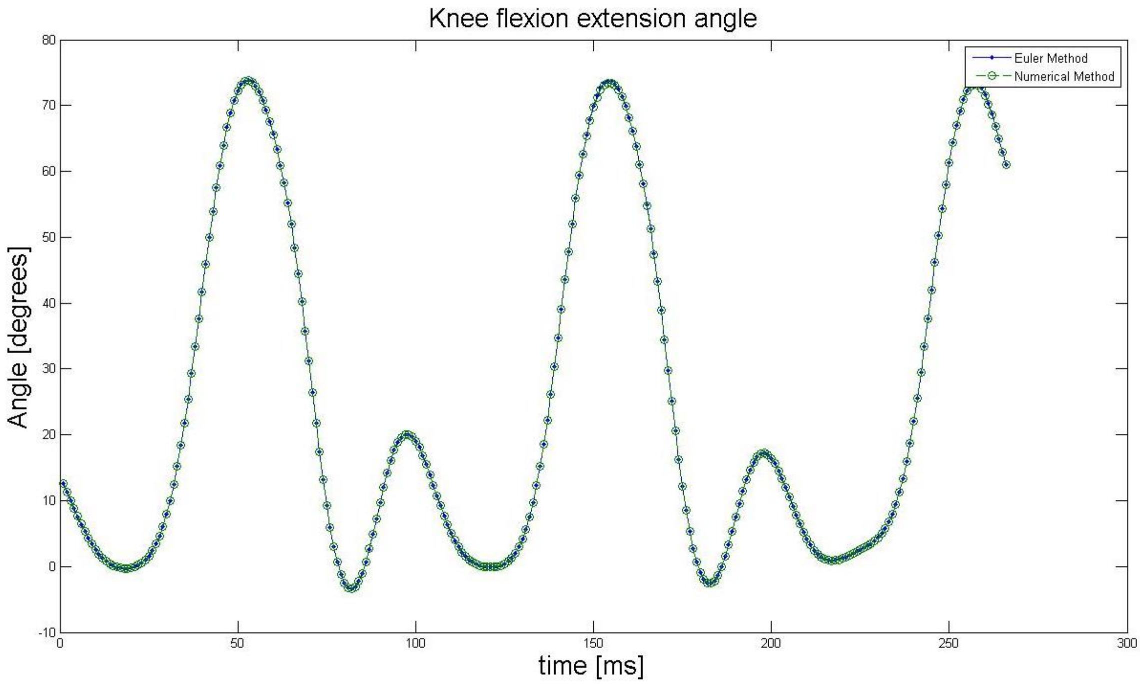


Figure 5.33 The "Euler method" and "helical angles" method compared by evaluating the knee flexion and extension angle in the sagittal plane.

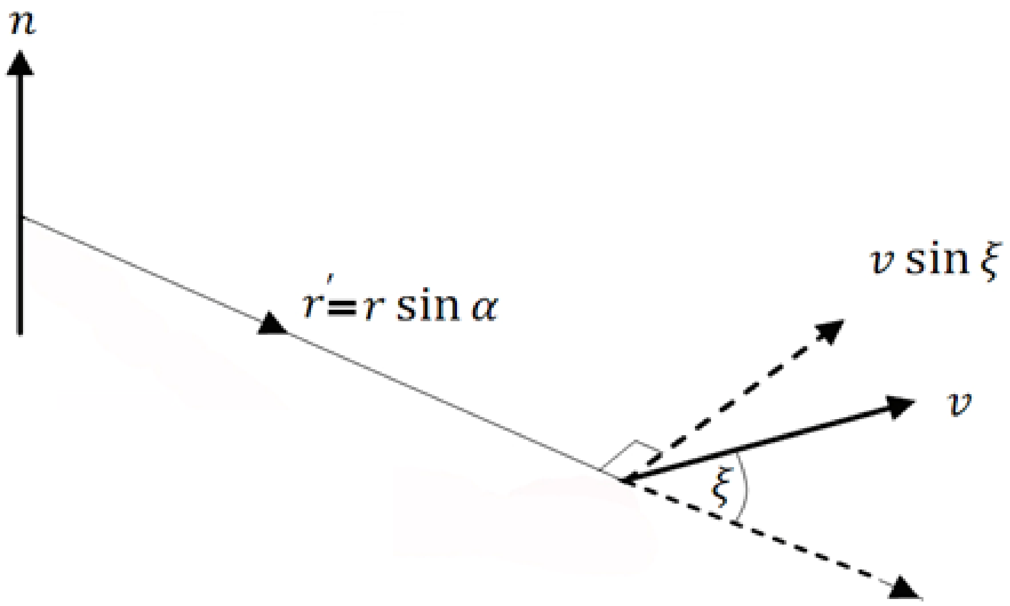


Figure 5.34 Angular velocity around a poitn of rotation

5.10 ANGULAR VELOCITY AND ACCELERATION

From inspection of Figure 5.34 the rate of rotation or angular velocity around the helical axes n is given by the angular velocity (ω), and its magnitude is the absolute value. In two-dimensional space only the absolute value or pseudo scalar is determined, as the helical axes is the normal to the plane of rotation. However, in three dimensions, the rotation of a body still occurs about a plane, and the velocity of the body still lies in this plane, as discussed in James et al. (2000) page 227.

$$|\omega| = \frac{|v|}{|r'|} \qquad 5.54$$

Now consider the angular velocity of the body shown in Figure 5.32, at the time instant now highlighted Figure 5.34, it is shown that the body has both normal and radial velocity components and that the angular velocity around the axis of rotation is equal to the cross product of the translation velocity with radius of curvature. This is equivalent to determining the magnitude of angular velocity around an axis n.

Therefore:

$$r' \wedge v = |r'||v| \sin \xi \, n \qquad 5.55$$

Inspection of Figure 5.34 reveals that the tangential velocity is equal to:

$$|v \sin \theta| = |\omega||r'| \qquad 5.56$$

Rearranging the above equation 5.56, and considering that the body is rotating around an axis n gives:

$$\omega = \frac{|v| \sin \xi}{|r'|} n \qquad 5.57$$

Substitution Equation 5.56 into Equation 5.57 gives a practical compact analytical expression.

$$\omega = \frac{r' \wedge v}{|r'|^2} \qquad 5.58$$

Clearly, the angular acceleration can also be determined using a similar expression to give:

$$\dot{\omega} = \frac{r' \wedge a}{|r'|^2} \qquad 5.59$$

It should be noted that the translational velocity or acceleration, substituted into the above formula are the relative components with respect to the point of rotation, as displayed by Figure 5.34.

Kistler plate	model	Dimensions, Kistler frame of reference: x , y and z	Sensitivity coefficients (pC/N)		
			Fx	Fy	Fz
Plate 1	9261A	400 x 600 x 60	-3.7	-3.7	-3.8
Plate 2	9281C	400 x 600 x 100	-8	-8	-3.8
Plate 3	9281C	400 x 600 x 100			
Plate 4	9281C	400 x 600 x 100			

Table 5.3 The force plate specifications used in this evaulation

5.11 KINETICS

The GRF during the ambulation activities was measured using four Kistler force plates (*Kistler, Winterthur, Switzerland*), as detailed below in Table 5.3. From the measured GRF acting on the body during ambulation it is possible to evaluate the internal load that acts on the lower limb structure of the body at considered joints such as the ankle, knee and hip. However, accuracy is improved if both segment static weight and inertia response of the segment in question, and that of distal segment is taken into account. Essentially the contact load of the adjacent distal segment should be considered. Failure to consider the adjacent segment loading, especially when determining lower limb joint kinetics that are increasing proximal to the torso, will lead to significant error (Krabbe et al. 1997). For example, when considering the ankle reaction force during stance, the static load and inertial response of distal foot segment is minimal and does not significantly contribute to the overall result, and consequently was not ignored in this evaluation.

To consider the forces that act on the body during ambulation the free body diagram (FBD) on Figure 5.35 illustrates that for the stance foot, equilibrium is initially considered between the origin of the force plate and the ankle, rather the centre of pressure (COP) and the ankle. As determining the COP first, will clearly lead to additional computational noise. A full 2D solution using a Lagrangian approach Appendix 4, page 235, was used as a check to validate the numerical programme.

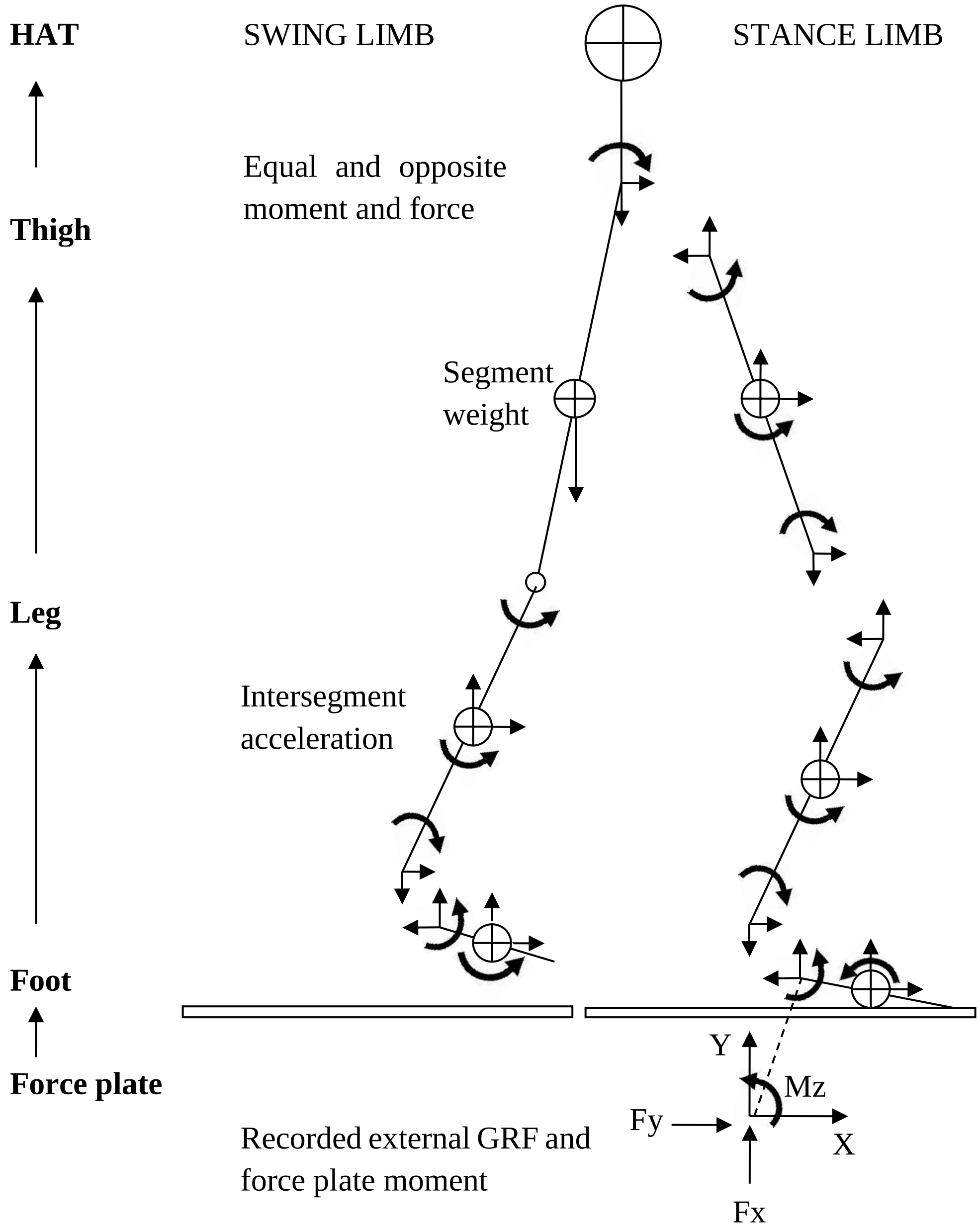


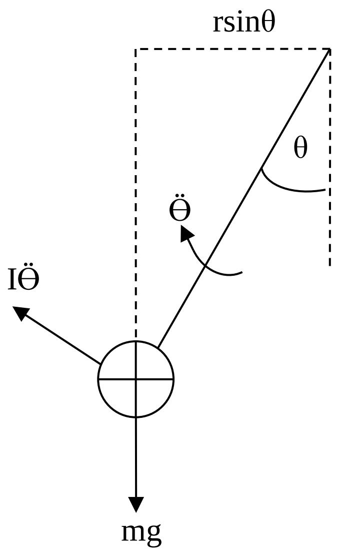
Figure 5.35 The free body diagram of the lower limb body segments during ambultion

5.12 INERTIA

Once local reference systems are defined, the kinematics can then be obtained with relative ease. However, the inertial properties of segments such as the segment mass, COM position or moment of inertia have to be estimated. A number of methods are available to help predict or estimate the COM position, mass and moment of inertia. As with many studies the decision was made to assume that, the mass of the segment is arranged symmetrically with respect the mechanical reference system. Because, this assumption allows the elimination of the products of inertia, allowing Euler's principal equations of motion to be applied directly.

The three main methods used to obtain the inertial properties of the lower limbs, include cadavers, living subjects and mathematical models. The advantage of using cadavers, is that segment inertia and mass centre positions can be obtained directly; by assuming simple harmonic motion as shown by Figure 4.36, and balancing the segment on a knife edge. However, the data accuracy is questionable, not because of the investigators efforts, but the difficulty in obtaining this data (Dumas et al. 2007).

Living tissues will clearly be more representative of limb inertial properties, compared to that of cadaver properties. As there is no loss of and settling of body fluids, along with inaccuracies of determining anatomical centres. However, the assessment of live subjects also presents challenges from the point of view of trying to perform simple pendulum tests, or the cost of scanning the individual.



M is the unknown applied moment, r is the radius of curvature and m is the mass

$$M = I\ddot{\theta} + mgrsin\theta \qquad 5.60$$

For unforced small angle oscillations less than 5 degrees

$$0 = \frac{r}{g}\ddot{\theta} + \theta \qquad 5.61$$

$$r = g\omega_n^2 = \frac{4g\pi^2}{T^2} \qquad 5.62$$

$$I = mr^2 \qquad 5.63$$

The radius of gyration is detonated by r, the period of oscillation by T, and circular natural frequency by ω.

Figure 5.36 Simple harmonic motion was used to estimate the prosthetic limb moment of inertia

Moreover, the properties from both cadavers and living subject studies are often used to provide a set of statistical formula to help predict the limb attributes outwith the genealogy of the studied population (Hinrichs 1985, Hall 1999). These linear regression equations are usually correlated with body mass or limb length, and are considered to have limited accuracy. There are equations that have multiple correlation factors, and usual require additional limb properties such as the proximal or distal limb circumference, and are considered to have greater accuracy (LVaughan et al. 1999).

Determining the inertial properties using geometric shapes as shown in Figure 5.37 enables individual characteristics of the body to estimated using an analytical solution. The main advantage is that outcomes are not influenced by the genealogy of the considered population. However, the density of the segment in question is considered to be homogenous and arranged symmetrically with respect to the principal axes of the reference system (Hall 1999). At the time of writing, it is surprising that different density layers of bone and muscle are not considered. Hence, this method was used to determine residual limb properties, and will shortly be described.

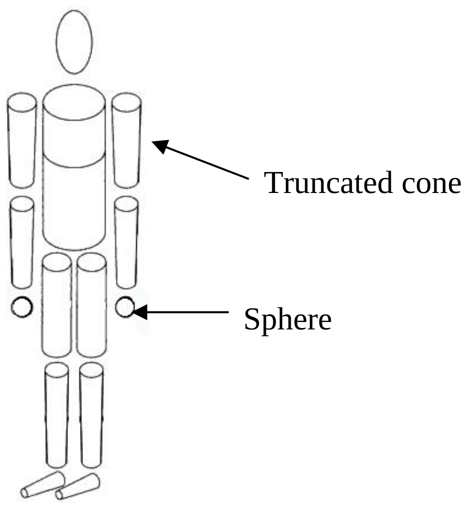


Figure 5.37 the Hanavan model of geometric shapes

Investigator	numbers used in study	type
Harless (1860)	3	cadaver
Braune & Fischer (1892)	6	cadaver
Fischer (1906)	2	cadaver
Dempster (1955)	16	cadaver
Clauser et al (1975)	26	cadaver
Chandler et al (1975)	12	cadaver
Bernstein (1931)	100	live
Drillis & Contini (1966)	24	live
Contini (1972)	18	live
Zatsiorsky & Seluyanov (1983)	100	live

Table 5.4 Summary of sudies examining the weight, volume and COM of the human body (Hall 1999)

However, on examining the origin of segment parameters available from various studies as shown in Table 5.4, the decision was made to use parameters derived from Zatsiorsky and Seluyanov and modified by Leva (1996). As the original Zatsiorsky and Seluyanov study considered a far larger population than the more popular studies of Dempster or Clauser, and was modified by Leva (1996) who adjusted the inertial properties so that the moment of inertial properties were appropriate for the mechanical axis used in this study, these inertial properties appeared to be the most appropriate to use at the time of writing. Furthermore, a report by Rao et al. (2006), who compared the inertial results of seven subject using the methods of Havavan (1964), Dempster (1955), Chandler (1975), Zatsiorsky and Seluyanov as modified by Leva (1996). Recommended using regression formula derived from Zatsiorsky and Seluyanov after statistical comparison.

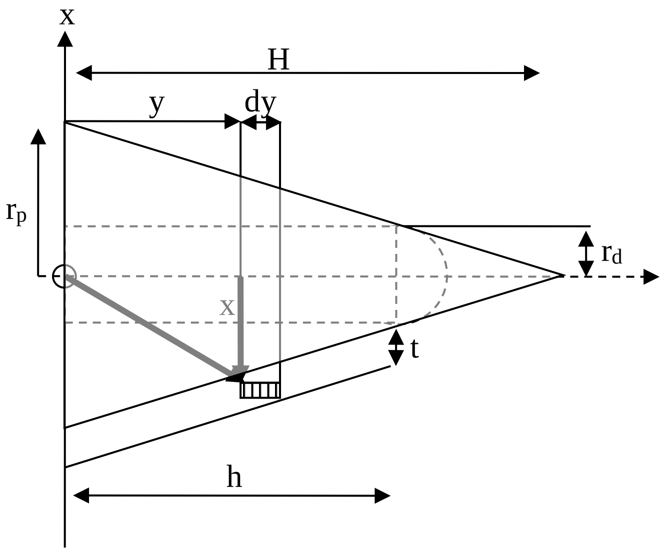
However, the Zatsiorsky and Seluyanov regression equations predict contralateral limb properties based on the body mass of an individual without lower limb loss. Hence, a method was required to predict the body mass of the recruited participants using anthropometric measures without lower limb loss. The prediction methods developed by Lorenz et al. (2007) were considered robust for estimating body mass, as they were developed to estimate the body mass of bedbound patients before the administration of drugs. The equations predicting body mass were developed considering the three anthropometric parameters of height, waist circumference and hip circumference from a population of 3000 participants, and gave a mean absolute difference of 2.7kg.

	analytical solution estimation	jelly filled socket estimation
proximal circumference (mm)	500	500
distal circumference (mm)	450	450
residual limb length (mm)	160	160
socket mass (kg)	3.65	4.13
radius of gyration (mm)	0.12	0.15

Figure 5.38 Jelly filled ischial containment socket with cow femur used to verify moment of inertia determined analytically

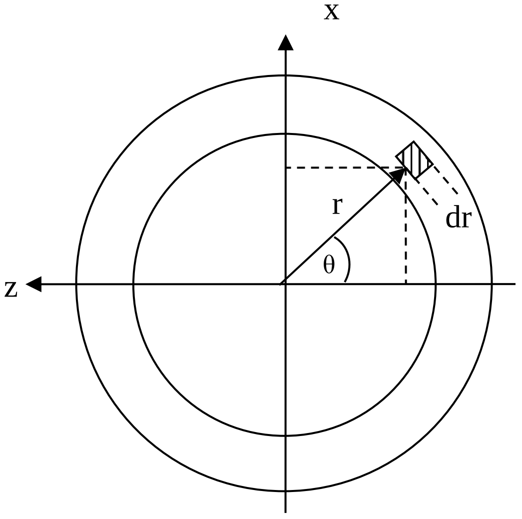
The given coefficients in the Lorenz et al. (2007), were then used to create a function that determined the mass of the participants as if they still possessed both their biological limbs. To determine the moment of inertia around prosthetic ankle and knee, simple harmonic motion was assumed, the components were set to perform a unforced oscillation around the ankle and knee with an angle of less than 5 degrees (Spiegel 1967).

An analytical solution was used to estimate the thigh inertial properties resulting from the residual limb and socket. However, rather than approximating the residual limb and socket as a homogeneous rod as shown in LVaughan et al. (1999). A truncated cone, with a cylinder shaped hollow was used to consider a femur bone with a 30mm diameter, and density of $2032kgm^3$. A hollow truncated cone of $1032kgm^3$ was used to estimate the muscle and flesh moment of inertia. The bone and muscle density data was respectively taken from Krzywick et al. (1967) & Park et al. (2007). Finally, a hollow truncated cone ending with a hemisphere was used to determine the socket moment of inertia. However, the solution was verified by estimating the residual limb properties physically using a jelly filled ischial containment socket with an implanted cow femur (Figure 5.38). The analytical solutions were solved for using an algebraic programme, although the equations and boundary conditions used to set up such a model are now described.



Where the gradient of the cone surface is

$$n = \frac{\delta y}{\delta x} = \frac{r_d - r_p}{h} \qquad 5.69$$



$$r^2 = x^2 + z^2 \qquad 5.65$$

$$z = rcos\theta \qquad 5.66$$

$$x = rsin\theta \qquad 5.67$$

The elemental volume

$$dv = dAdy \qquad 5.68$$

$$dv = drrd\theta dy \qquad 5.69$$

$$I = \sum m_i r_i^2 \qquad 5.70$$

$$I = \int r^2 dm \qquad 5.71$$

$$I = \rho \int r^2 dv \qquad 5.72$$

Figure 5.39 The cone model used to determine the moment of inertia around the residual limb

Equations 5.70-5.72 describe the derivation of the mass moment of inertia in general terms; to determine the mass moment of inertia around the transverse axis the following substitutions were made.

$$I_{zz} = I_{xx} = \rho \int_0^h \int_0^{2\pi} \int_{r_i}^{r_o} (y^2 + x^2)\, r dr d\theta dy \text{ (Equation 5.73}$$

However, the variable x should be substituted with Equation 5.67, as it is a variable, and will not be integrated.

$$I_{zz} = I_{xx} = \rho \int_0^h \int_0^{2\pi} \int_{r_i}^{r_o} (y^2 + r^2 \sin^2 \theta)\, r dr d\theta dy \qquad 5.74$$

For the polar moment of inertia:

$$I_{yy} = \rho \int_0^h \int_0^{2\pi} \int_{r_i}^{r_o} r^2\, r dr d\theta dy \qquad 5.75$$

$$I_{yy} = \rho \int_0^h \int_0^{2\pi} \int_{r_i}^{r_o} r^3\, dr d\theta dy \qquad 5.76$$

The limit for the inner cone surface for both equations 5.74 and 5.76:

$$\mathrm{r_i} = ny + r_p \qquad 5.77$$

The limit for the outer cone surface for both equations 5.74 and 5.76:

$$\mathrm{r_0} = ny + (r_p + t) \qquad 5.78$$

The determined analytical solutions were then used to write a function that estimated the inertial properties on the prosthetic side. The COM position of the residual limb and socket was estimated with respect to the origin as shown in Figure 5.39, using a first moment area summation, from the known position of the individual point masses that were representative bone, muscle and socket.

5.13 SUMMARY

The described rigid body analysis was provided, because these considerations appeared to exert the greatest influence over data repeatability. Despite this, improvements can still be made, such as decreasing error due to skin movement, or using functional methods to locate anatomical centres, such as the hip joint with greater accuracy.

The difficulties of capturing ambulation data only became evident with routine data capture throughout the development process on the study normal control. However, further practical aspects of the data capture process had to be envisaged, to ensure repeatable data capture of the prosthetic ambulators during the laboratory sessions. Hence, thigh markers were removed to avoid relative socket motion with respect to the residual limb. Further considerations included the use of the wand to help minimise the error effects of additional adipose tissue covering their pelvic ASIS, the participants sitting down to rest and knocking their anatomical markers off, or catching their calcaneus marker on the stair, or covering anatomical markers with their clothing. To overcome the challenges clusters were attached to limb segments to allow anatomical positions to be referenced, using a wand or signal anatomical markers during the static capture process.

Finally, as described, the use of local segment reference frames improves the data precision and repeatability, which will now be discussed in the proceeding chapter of “Validation of biomechanical outcomes”. This validation was achieved by evaluating and comparing the data of the normal control used in this study with that of literature.

CHAPTER 6 VALIDATION OF THE BIOMECHANICAL OUTCOMES

6.1 INTRODUCTION

The purpose of describing and comparing the ambulation outcomes of a normal individual (male 1.67m, 70kg) with those presented in the literature is to highlight the difficulties of comparing the results from other studies, and to provide a background as to how the graphical outcomes should be read. Before embarking on the description of pathological gait, the events and lower limb musculature function, as well as the kinematic and kinetic outcomes of the non-pathological gait cycle, will now be described. The gait cycle is most frequently broken into a period, which begins and ends with initial contact of the same limb while walking on a level surface (Figure 6.1). The gait period can be further split into the stance and swing phase; stance and swing account for approximately 60% and 40% of the gait cycle period, respectively. The stance phase period is characterised by five key events and includes initial contact, foot flat, mid-stance, heel-off and toe-off. The swing phase, on the other hand, is characterised by three events, – lower limb acceleration, mid-swing and lower limb deceleration, as detailed on Figure 6.1 (Novacheck 1997).

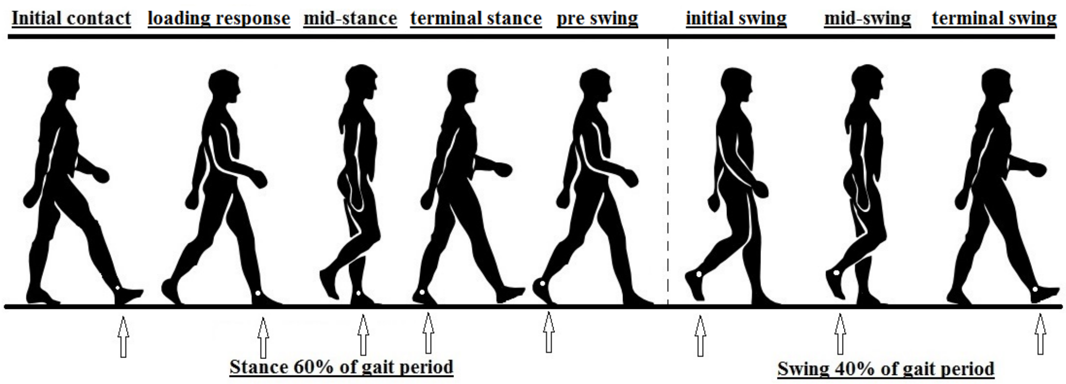
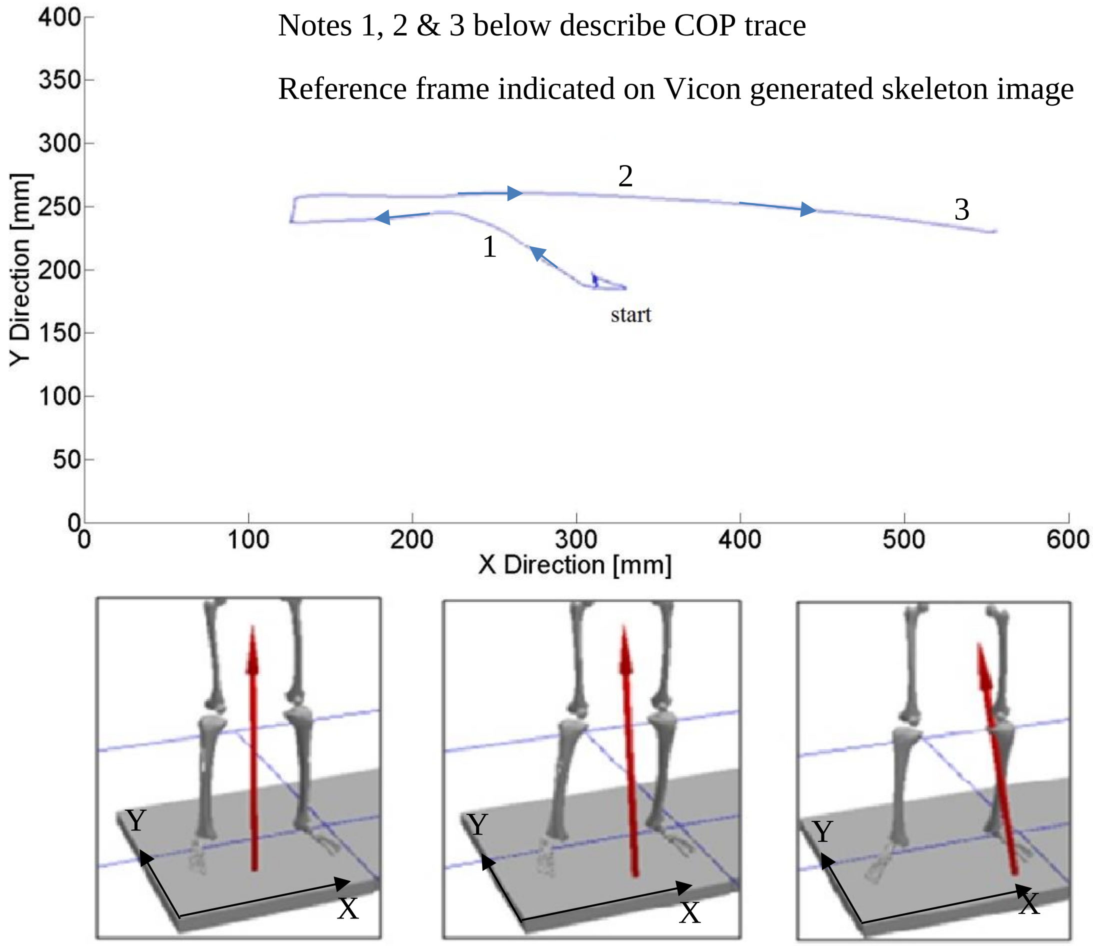


Figure 6.1 Gait cycle period during level ambulation, adapted from Novacheck (1997)



1-Initially, the body weight is shifted to what will be the swing leg.

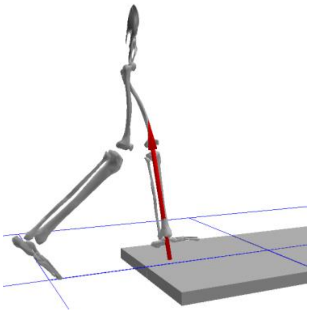
2-The body weight if shifted to the stance leg.

3-Single stance is achieved when the contralateral leg is lifted. The total body weight then acts on the stance leg.

Figure 6.2 Coronal view of the body COP trace on force plate during gait initiation, by normal control with Vicon generated skeleton

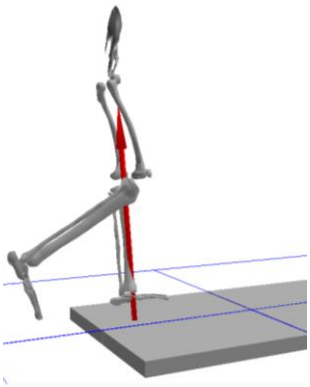
A brief synopsises of the musculature activity during gait initiation and ambulation will now be described to assist the interpretation of kinematic and kinetic outcomes.

To initiate ambulation from a standing position, a greater proportion of body weight is shifted laterally to what will become the swinging limb, before the entire body weight is transferred to what will become the stance limb. On doing so, the position of the tibia on the stance limb will either be adjusted from an ankle plantarflexed to a dorsiflexed position, or from a dorsiflexed position to a position of greater plantarflexion, depending on the original tibia orientation with respect to the foot. Once the tibia is favourably orientated, the body weight is dropped forward under eccentric Soleus muscle control as the hip is flexed and the swinging limb is lifted (Figure 6.2). Active control of the Iliopsoas hip flexor muscle (which is attached to the anterior brim of the pelvis, ahead of the hip joint) helps active initiation of swing (Lovejoy 1988, Perry 1992). The rate at which the contralateral leg is brought to swing directly influences the body momentum and the anteriorly-directed component of the GRF (Perry 1992). However, a minimum of two, but usually three, steps are required before a steady oscillatory state of conservative energies and walking velocity is reached (Miller et al. 1996). To reduce the loss of body momentum upon initial contact, the foot acts like the rim on a wheel using a series of three rocker motions around the heel, ankle and forefoot respectively (McGeer 1990, Perry 1992). After initial contact, the heel rocker, with the assistance of the pretibial muscle group, controls the rate of foot plantarflexion or foot flat. The dorsiflexor muscle group also directly assists the forward pull of the tibia and the progression of the leading limb during mid-stance, with the quadricep muscles, which are tied to the tibia, pelvis and femur, extending the knee and the hip pulling the HAT COM forward.



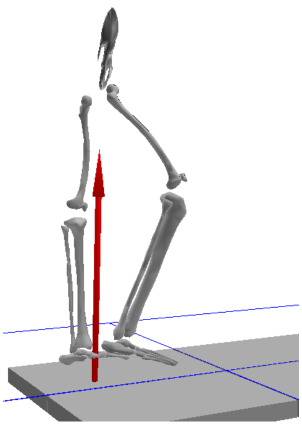
Upon foot flat, the body starts to pivot around the ankle joint, creating the ankle rocker. Consequently, the foot begins to dorsiflex under the controlled action of the plantarflexors.

Figure 6.3 Initial contact - ankle rocker motion of normal control with Vicon generated skeleton



The swinging limb helps to maintain body angular momentum.

Figure 6.4 Midstance - ankle rocker motion of normal control with Vicon generated skeleton



During late stance, the hamstring muscle group decelerate the swinging leg.

Figure 6.5 Late stance - ankle rocker motion of normal control with Vicon generated skeleton

Before initial contact, the COM is ahead of the stance foot, creating a moment around the ankle, Figure 6.5. When this is combined with the simultaneous concentric assistance of the plantarflexor muscles, the heel begins to rise, the thigh and leg are decelerated, and the trunk is accelerated (Zajac 2002). This action creates a moment primarily around the metatarsals, creating the forefoot rocker. Upon initial contact of the leading leg, the trailing limb is rapidly unloaded, and the GRF acts to flex the knee joint. The reduced load and instability, along with the release of musculotendon elastic energy in the plantarflexors, is a passive unstable mechanism that leads to toe-off, and helps propel the leg into swing (Zajac et al. 2003). During swing, the thigh biarticular muscles, combined with the inertial effects of the shank, help extend the knee before initial contact. The result is that the quadricep muscles initially accelerate the thigh during early swing phase, and the antagonistic hamstring muscle group decelerates the thigh during late swing (Lovejoy 1988).

However, other studies such as Piazza et al. (1996) and Arnold et al. (2007) have used muscle simulations to investigate knee flexion and extension during swing, and have shown the dynamic response of the leg to be minimal. Piazza et al. (1996) were surprised to find that the gastrocnemius (GAS) played a role extending the knee during swing. However, if the inertial force is acting to extend the knee, this force will act to cause an eccentric plantarflexor contraction, and it is therefore probable that the GAS is active during this period. Moreover, Arnold et al. (2007) also considered the role of pelvic rotation under the control of stance leg musculature. It was shown that the angular knee acceleration towards extension in early stance is achieved when the pelvis is also rotated posteriorly.

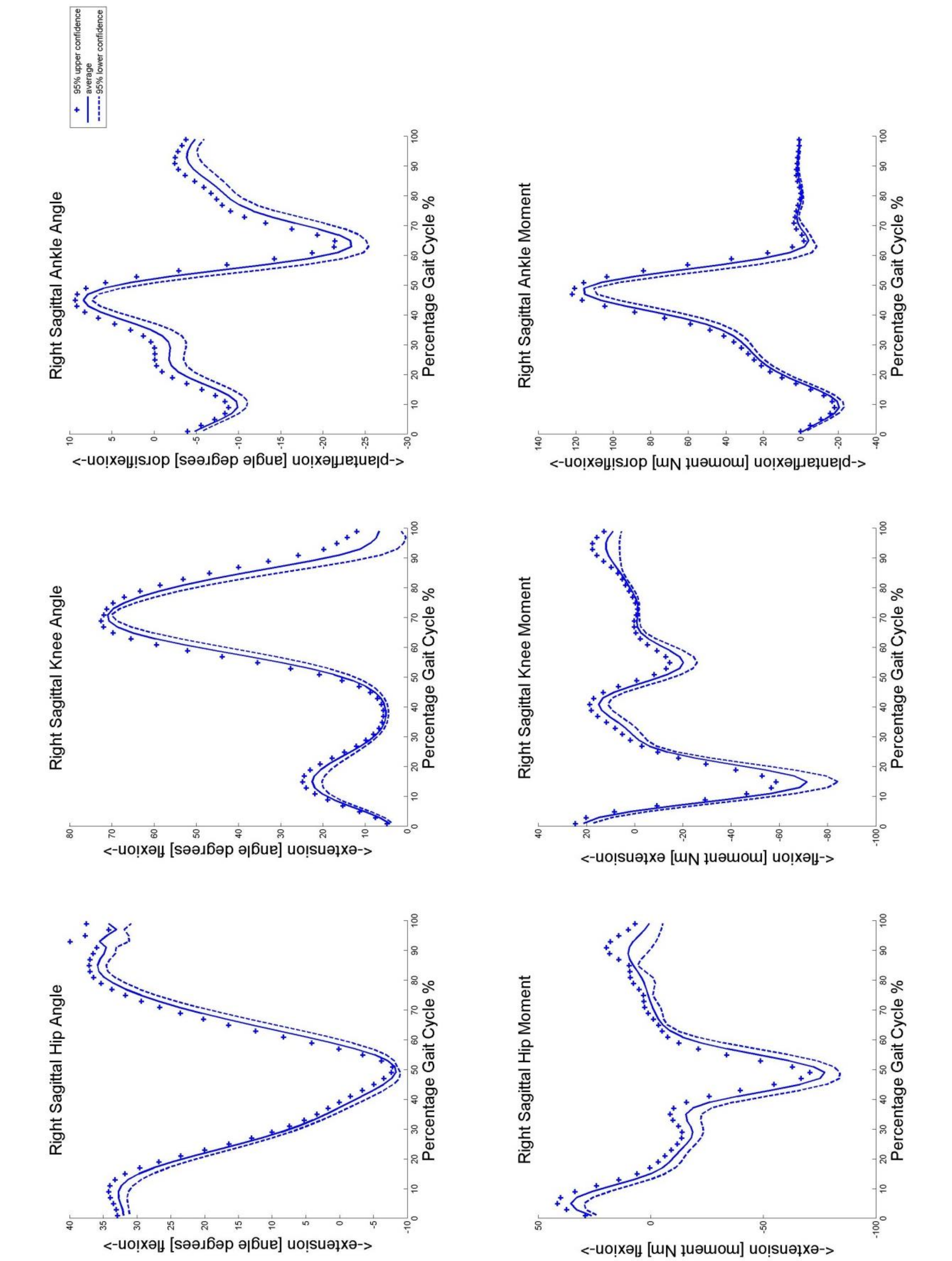
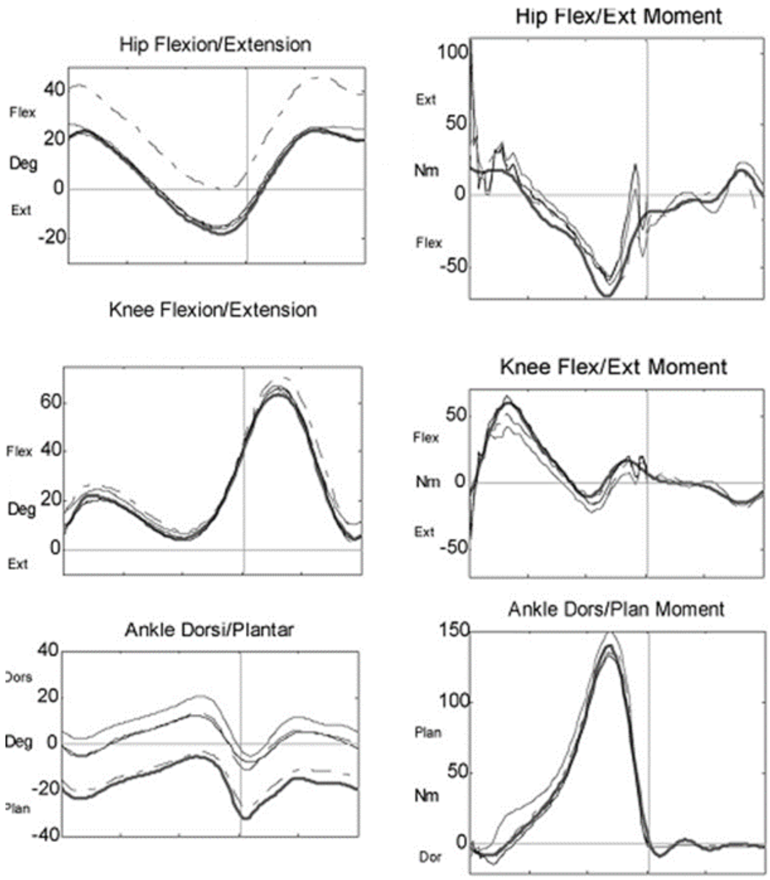


Figure 6.6 Kinematics and kinetics of able-bodied control during level walking

Furthermore, towards the end of swing, the posterior rotation of the pelvis and swing leg musculature both help accelerate the knee towards flexion. Ultimately, this combined body action illustrates that the abled-bodied ambulator will use their whole body to manage the control of their gait. The motion of the knee during swing, for example, is not only affected by direct muscle control, and highlights why the lower limb prosthetic user exaggerates their body control, to maintain knee stability.

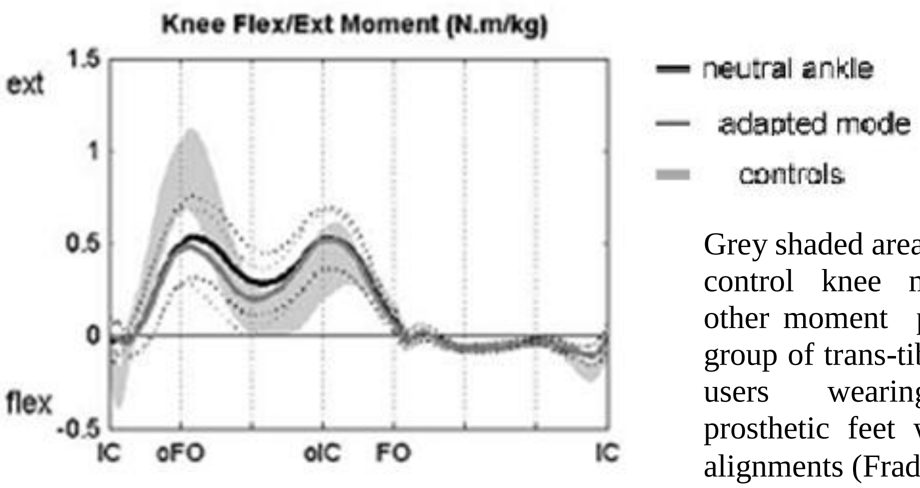
The relative standard, most commonly used to illustrate the musculature control of the above-described motions, is the sagittal plane kinematics and kinetics during stance and swing (Figure 6.6). The sagittal outcomes provided in Figure 6.6 are that of the evaluated normal, able-bodied participant used in this study during level ambulation, and a representative of published literature results. The “joint angle” is the distal segment orientation with respect to the proximal segment, and the given moment is the applied external moment acting on the proximal segment in the proximal frame of reference. Moreover, the results presented give the mean ambulation pattern of ten gait periods with 95% confidence intervals. The ten trials were the amalgamation of three gait trials for the same normal control, and therefore included three separate static capture processes, thus providing evidence that the test protocol and repeatability of results can be relied upon. Furthermore, these results are comparable to the results described in Ferrari et al. (2007), as shown on Figure 6.7 (over page).



Mean kinematic and kinetic outcomes during level ambulation using five gait protocols using same normal control as indicated.

Line style indicates data collection protocol: T3Dg (dash), PiG (dot lines), SAFLo (dash-dot), CAST (black solid), and LAMB (grey thick solid) for all four-trial repetitions.

Figure 6.7 Results of abled-bodied controls adapted from Ferrari et al. (2007), likely (not stated) presented in global coordinates acting on the proximal segment



Grey shaded area is the normal control knee moment. The other moment patterns are a group of trans-tibial prosthetic users wearing different prosthetic feet with different alignments (Fradet et al. 2010)

Figure 6.8 Knee moment pattern during ramp ascent adapted from Fradet et al. (2010), likely (not stated) presented in global coordinates acting on the proximal segment

6.2 PRESENTATION OF MOMENTS

Even though the moments in Ferrari et al. (2007) Figure 6.7, are defined, they are not consistently presented. The given ankle and hip moment given appear to be acting on the proximal segment, while the knee moment pattern appears to be the one acting on the distal segment when the direction of the external moment acting on the ankle, knee and hip is considered – that is, from distal to proximal for the ankle and hip, and vice versa for the knee.

However, the lack of consistency in displaying results is a common problem, while other publications, such as Robertson (2004) Gordon et al. (2004: 157) and Fradet et al. (2010) are incorrect. Consider the knee moment result presented on Figure 6.8 by Fradet et al. (2010): the presented ankle and hip moment is one that acts on the distal segment, while the direction of the knee moment is unclear. If the knee moment pattern is taken as internal muscle moment, then at initial contact the internal hamstring musculature will apply a flexion moment against the GRF extending the knee. Then, after initial contact during early stance, the internal thigh musculature applies an internal extension moment around the knee. However, during late stance, the moment direction suggests that the knee has become locked, and does not flex. During swing the internal flexion musculature is acting when the knee is extending, this is to be expected during swing. Therefore, the outcomes during stance and swing appear to contradict themselves. Even though the knee moment pattern is for ramp ascent, the results for the normal control during level walking and ramp ascent must follow a similar pattern but with different amplitudes. Furthermore, it is surprising that the same investigator can accept these knee moment differences during ramp ascent, when compared to level.

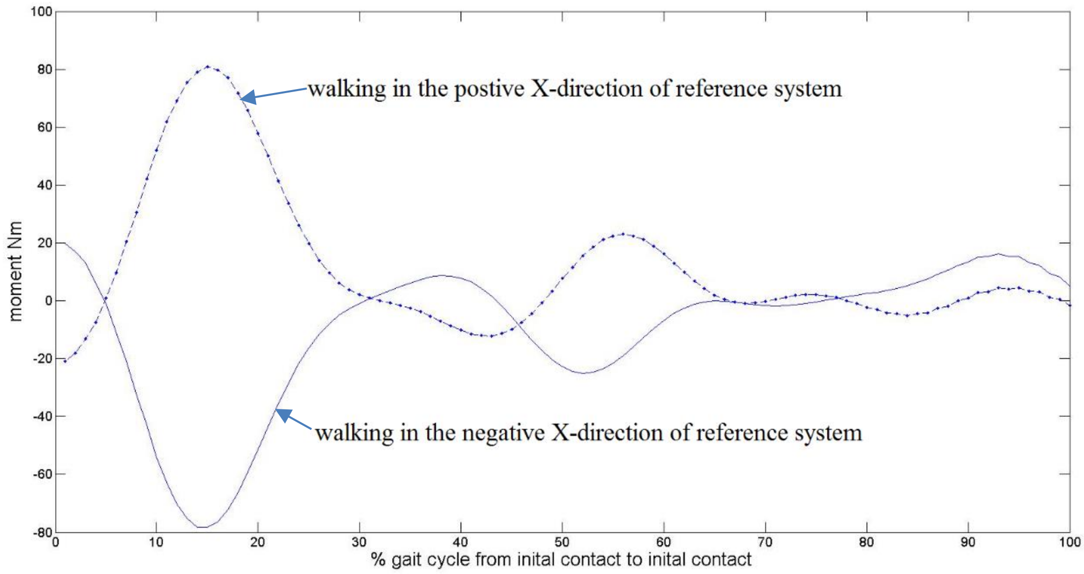


Figure 6.9 knee moment in global coordinates from initial contact to initial contact for normal control walking in positive and negative x-direction of reference system

However, the results shown by Ferrari et al. (2007) appear to be the outcome of the knee moments being plotted in the global frame of reference rather than the local frame, as the participant walks in the negative direction with respect to reference axes (Figure 6.9). The global knee moment is of a similar pattern to that given on Figure 6.8, this is obviously not convenient, and is difficult to understand, because the anatomical moments are not in the appropriate frame of reference – especially important when considering the prosthetic user. Representing moments in a global rather than local reference frame will distort compensatory actions when the lower limb segment planes moving away from the global sagittal planes, distorting the moment magnitudes and directions that are physically meaningful. Even though Ferrari et al. (2007) details the moments as the "resultant moment of the external force", the direction of the moments should be detailed for the reader. Furthermore, consider the results presented in Robertson (2004: 157), reproduced from Meglan and Todd (1994) (Figure 6.10): the knee moment follows the same pattern as that shown by Fradet et al. (2010), and is also likely to be in global coordinates.

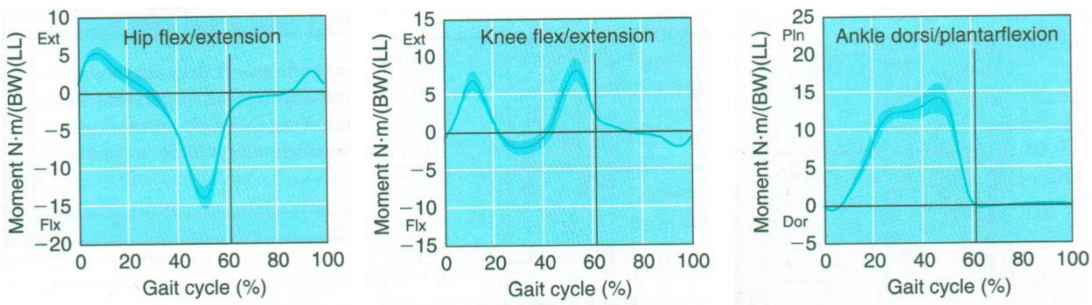


Figure 6.10 Mean anatomical moments from Meglan and Todd (1994), and given in Roberston et al. (2004) page 157. Moments are presented in the distal coordinate system for a normal population during level ambulation

Moreover, the results are normalised using body mass and leg length, and it is therefore possible that the patterns of motion, and thus the amplitude of the peaks, have been distorted. As described in section 5.4, page 90 the results of this study will not be normalised in such a manner. Even though the body mass and limb lengths affect the moment magnitudes that act around the joints of the lower limbs, simply quotienting the moment values by these scalar quantities on an individual basis does not equate to a normalisation of outcomes to allow inter-subject comparisons to be made with ease. If it were that simple, the effects of walking velocity and muscle strength could be considered using this same philosophy. Given that this is clearly not the case, it seems fair to say that the literature has become riddled with outcomes that need to be interpreted with care.

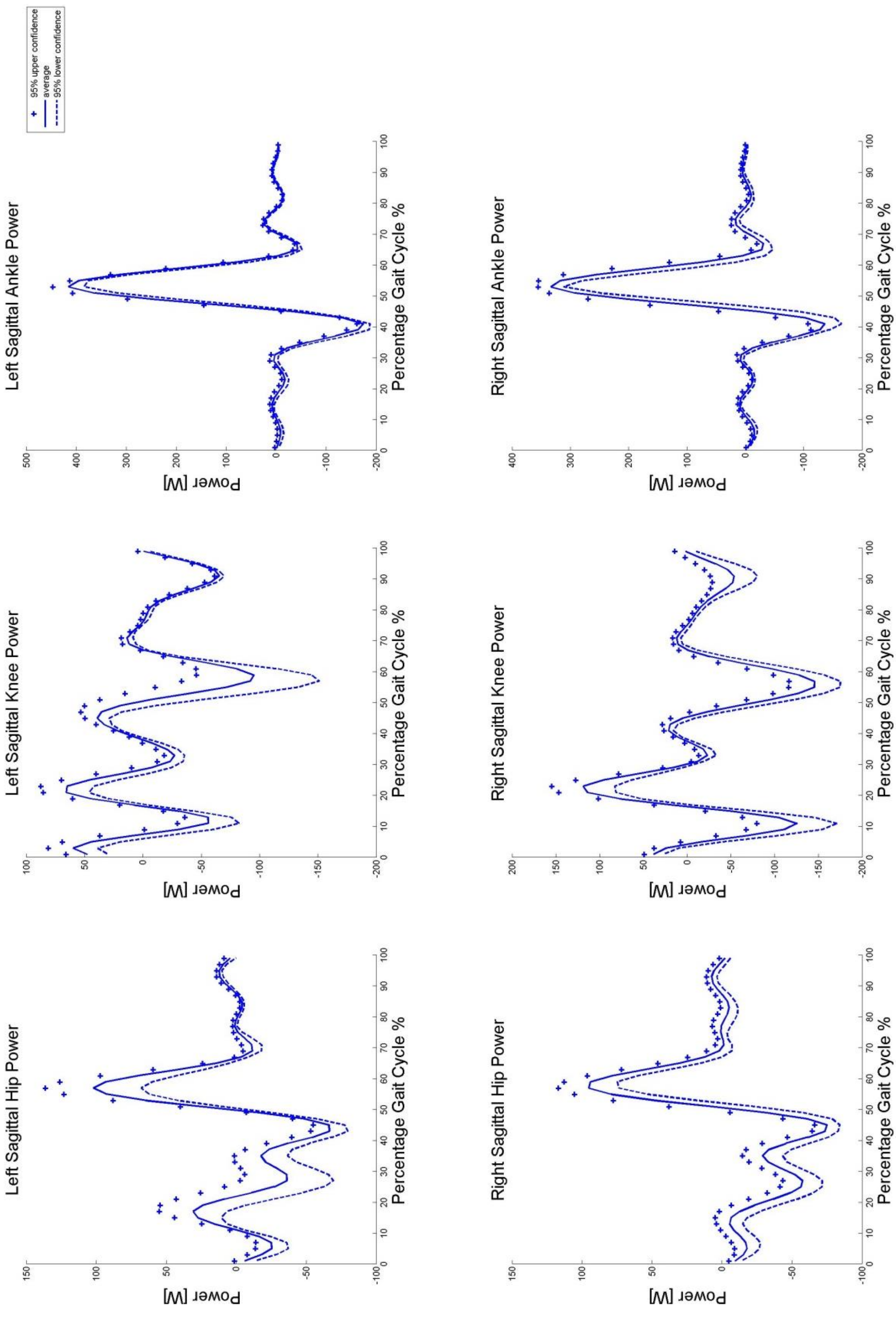


Figure 6.11 Powers of able-bodied control during level ambulation

6.3 ANATOMICAL POWER DURING LEVEL AMBULATION

The instantaneous trace of the mechanical power developed by the musculature around the hip, knee and ankle joint are illustrated in Figure 6.11. These power traces can be integrated, and they allow the mechanical work done around the respective joints to be evaluated. The integration of these power traces during a complete cycle of stance and swing reveals, for this normal control subject, that 21J, -13J and 6J of mechanical work is done around ankle, knee & hip respectively. These results appear comparable with the magnitudes and patterns of Seroussi et al. (1996), as given in Figure 6.12. This highlights the fact that during level ambulation the positive power developed around the ankle joint is responsible for the larger part of body propulsion, when considering the timing of the peak ankle power during the “push-off” instance of the gait cycle. However, as shown in Figure 6.11 , the power developed around the hip joint appears to peak, as it did with the ankle, during the push-off instance of the gait cycle (Seroussi et al. 1996). This indicates that push–off power (and energy) comes from both the ankle and the hip.

The negative work developed by the musculature around the knee during level indoor ambulation indicates that the muscles around the knee work agnostically with the GRF, resulting in mechanical work absorption. It is not fully understood whether this work is transferred by the musculature to other joints, or if it is used to strain the surrounding musculature complex, thereby allowing the energy to be released around that joint at a later point (Zajac et al. 2003). However, it is clear that the role of the knee, and the work required of it, do change when ambulating outwith the level walking environment and this will be discussed shortly.

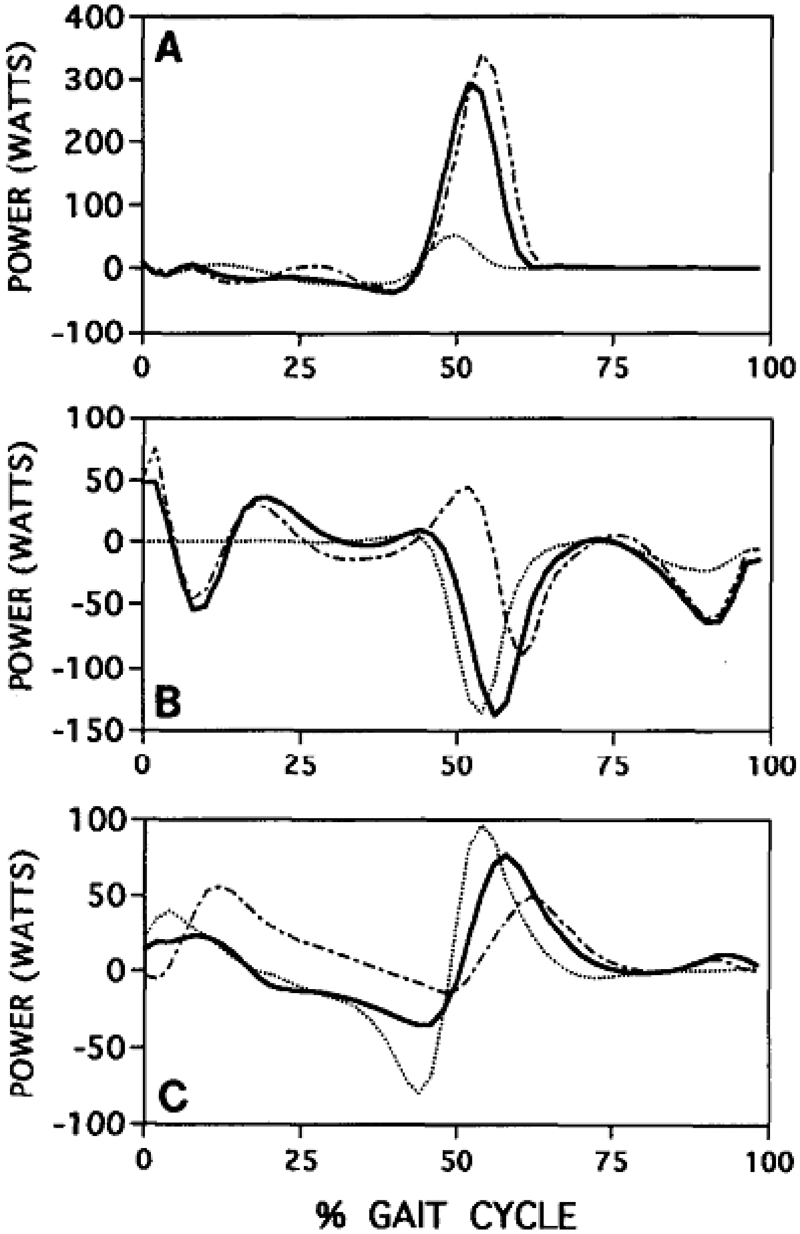


Fig 4. Comparison of joint power between normal ambulation (——) versus amputee subjects' ambulation for the intact (-·-·-) and prosthetic (·····) limb, shown separately: (A) ankle, (B) knee, and (C) hip.

Figure 6.12 Results of eight able-bodied normal controls, and eight "nondysvascular" trans-femoral prosthetic users (Seroussi et al. 1996).

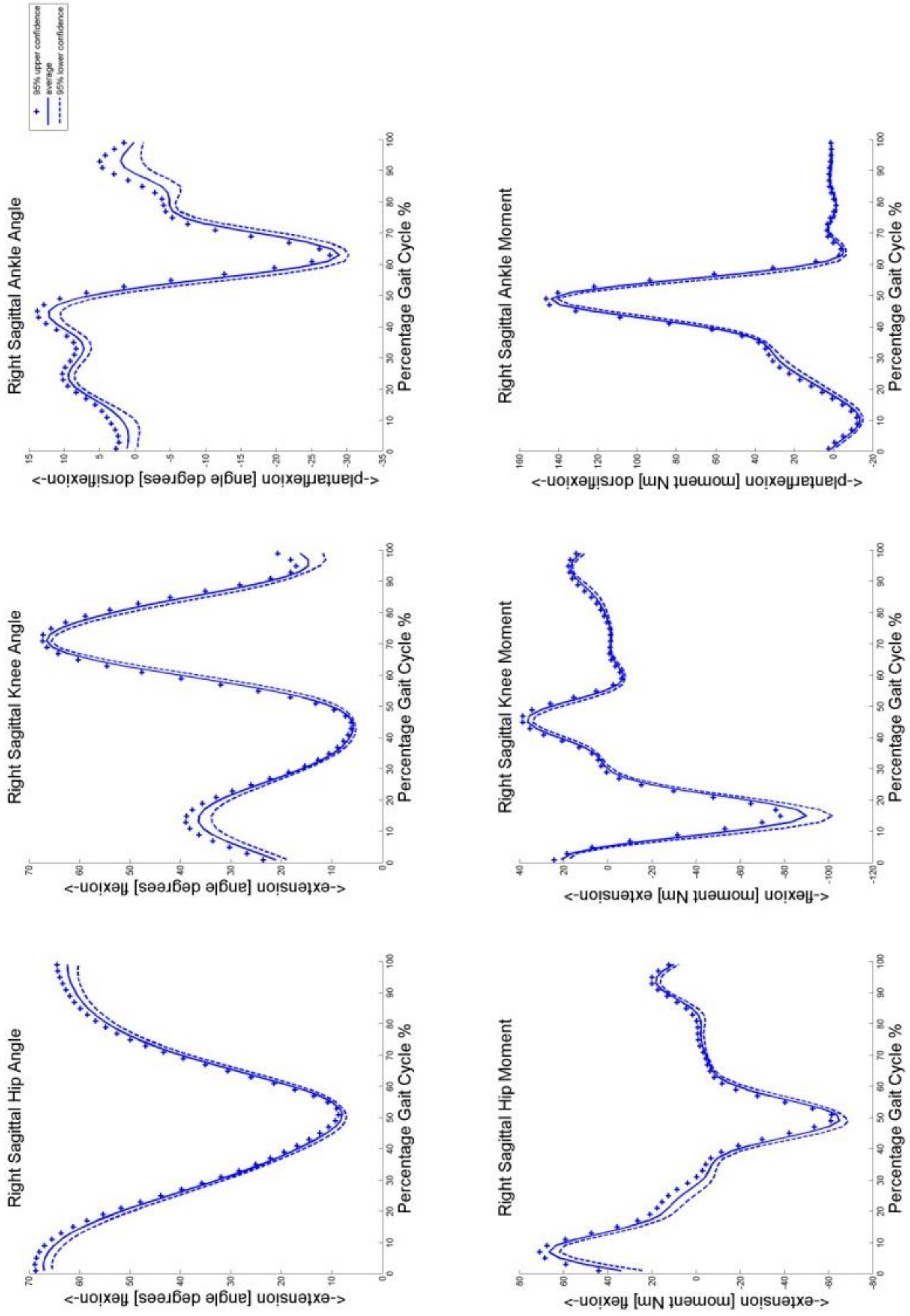


Figure 6.13 Kinematics and kinetics of able-bodied control during ramp ascent

6.4 GAIT BEYOND LEVEL AMBULATION (RAMP ASCENT)

The measured kinematic and kinetic outcomes during a 7 degrees ramp ascent illustrate substantially altered kinematics compared to level ambulation (Figure 6.13). During stance, an additional 10 degrees of knee flexion were maintained, when compared to indoor level ambulation as shown on Figure 6.6. The hip angle was also flexed by an additional 15 degrees throughout the gait cycle when compared to level ambulation. In fact, the thigh does not go into extension with respect to the pelvis during late stance, as would be the case during level walking. During late stance, a maximum thigh extension of ten degrees flexion is obtained comparted to 5 degrees of extension during the same phase of level ambulation. Moreover, the early to mid-stance foot dorsiflexion angle has increased by 5 degrees, with a corresponding 5-degree decrease in the maximum plantarflexion angle during toe-off. These kinematic differences during ramp ascent when compared to level ambulation are also shown by McIntosh et al. (2006), as shown on Figure 6.15. However, McIntosh et al. (2006) does not show the same magnitude of late stance flexion as shown in Figure 6.13. This is for the reason that the pelvic angles in McIntosh et al. (2006) were derived using the same methods as Davis et al. (1991), and were referred relative to the fixed laboratory global coordinate system, rather than the pelvis as shown section 5.7. Furthermore, as described in page 100, the Davis et al. (1991) formula predicting the projection lengths of the hip centre with respect to the mid-ASIS reference systems are approximated.

Unlike the kinematics, the external moment patterns are of a similar shape to the level ambulation patterns, and the push-off ankle moment has increased approximately by 20Nm, from 120Nm to 140Nm during ramp ascent.

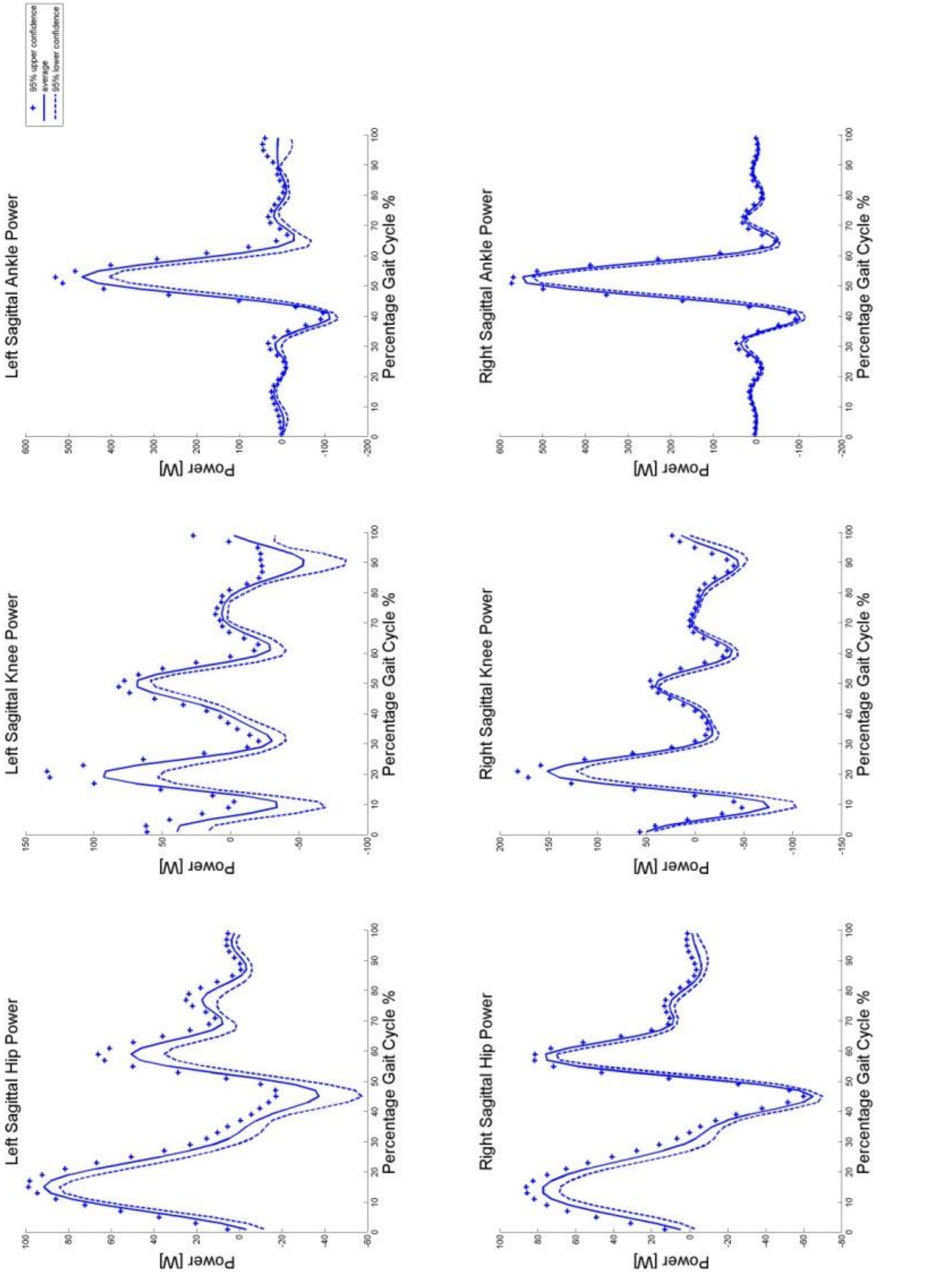
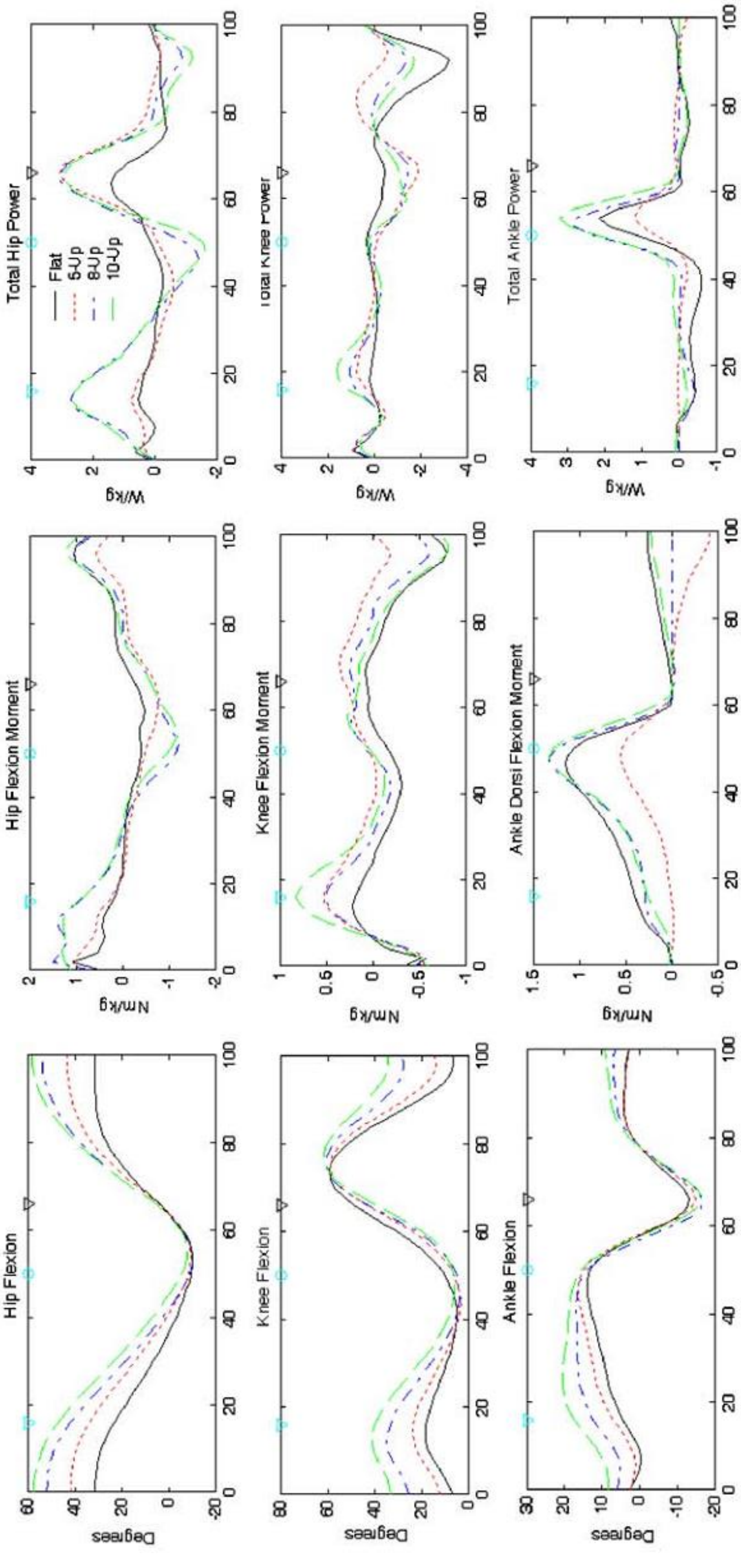


Figure 6.14 Anatomical powers of able-bodied control during ramp ascent

The peak flexion moment around the knee during early stance has also increased in magnitude by approximately 20Nm during mid-stance, from -80Nm to -100Nm. However, the peak external hip flexion and extension moment is arranged with greater symmetry around the 0Nm horizontal, with respective peaks and troughs of 70Nm. When compared to level ambulation, the external extension moment troughs by an additional 25Nm. The increased moment and trough peaks are also illustrated by McIntosh et al. (2006), also shown on Figure 6.15. However, the knee moments appear to be acting on the distal segment, and appear "upside down" when compared to the knee moment in Figure 6.13.

For an able-bodied control, another notable feature of ramp ascent compared to level ambulation is the additional work requirement. The integral of the power curves in Figure 6.14, show the work requirements of the ankle, knee and hip during ramp ascent to be 53J, 4J, and 19J, respectively - and this is also comparable to the results in McIntosh et al. (2006). As expected, compared to the work requirement of the ankle (21J), knee (-13J) & hip (6J) during level walking for the same able bodied control, ramp ascent requires more mechanical work. The hip musculature during level walking Figure 6.11, provides the greatest mechanical effort during late stance. However, during ramp ascent, the effort provided by the hip musculature on initial contact is also considerable, followed by negative power absorption and then positive work during late stance. As with level walking, the power developed around the knee during ramp ascent fluctuates, and the muscles around the knee mainly develop positive mechanical work during ramp ascent, compared to absorption during level walking.



The mean angles moments and powers (left to right) during ramp ascent at 6, 8 and 10 degrees as indicated. The thigh flexion and extension angle is with respect to the global coordinate system, while the moments are likely to be in global coordinates acting on the proximal segment. As described "hip flexion moment, positive is extension; knee flexion moment, positive is extension, ankle dorsiflexion moment, positive is plantar flexion"

Figure 6.15 Angles, moments and powers for the ankle knee and hip adapted from McIntosh et al. (2006) for eleven normal controls during ramp ascent

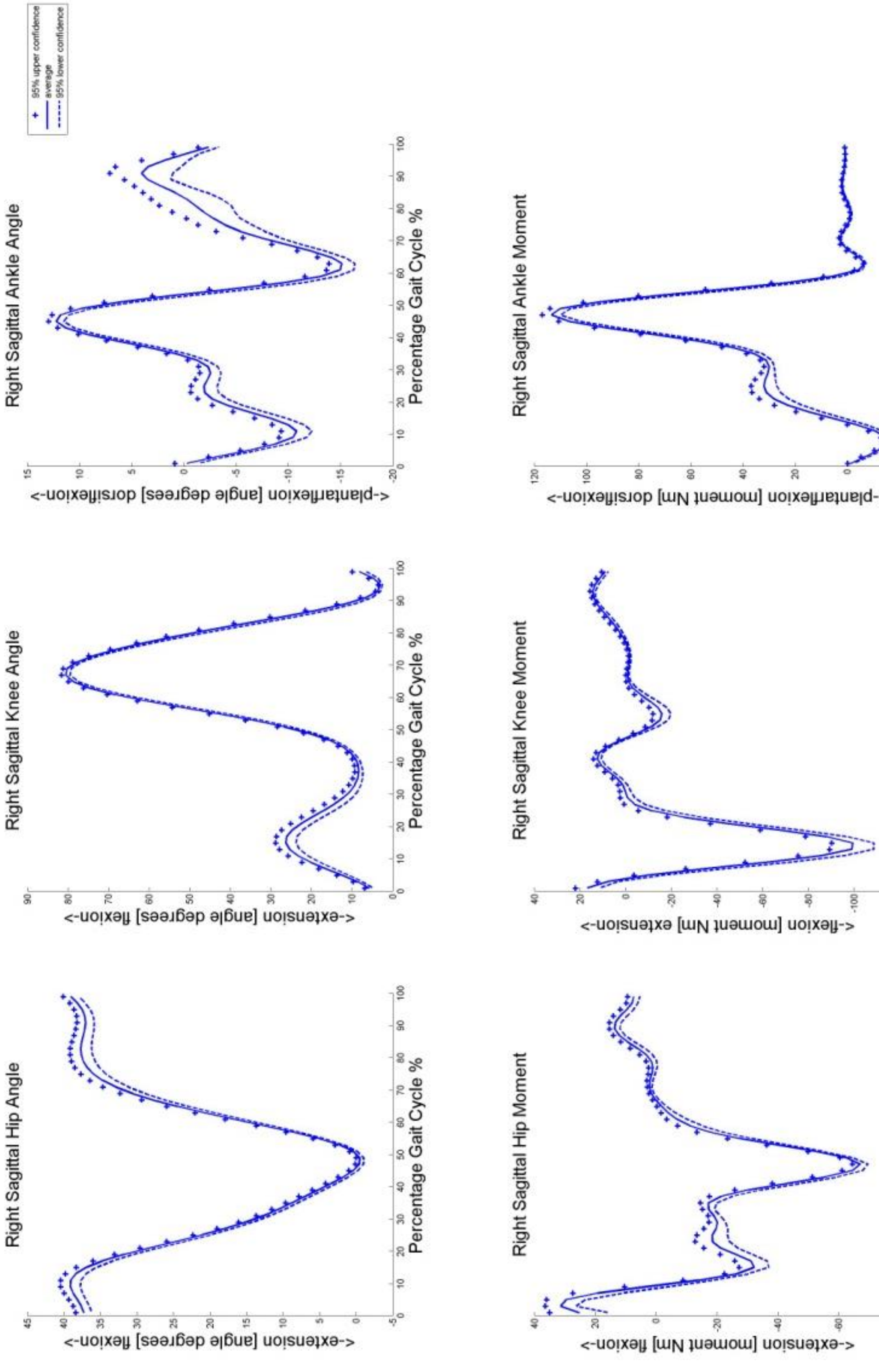


Figure 6.16 Kinematics and kinetics of able bodied control during ramp descent

6.5 GAIT BEYOND LEVEL AMBULATION (RAMP DESCENT)

Unlike ramp ascent, while descending the knee was not flexed during the stance period by the same magnitude; the maximum knee flexion peaks above 20 degrees, Figure 6.16, and has more similarity to that of level ambulation, Figure 6.6. The thigh flexion angle during ramp descent also shares more with level ambulation than it does with [ramp] ascent, as the thigh goes into 1-2 degrees extension during late stance rather than remaining extended. Moreover, during ramp descent the foot plantar and dorsi-flexion angle is closer to that in level walking than that in ramp ascent. It is during the push-off instance of the gait cycle period, when the foot is plantar-flexing, that the most notable difference may be observed: the foot for the same control displays 10 degrees less plantarflexion during ramp descent, than with level ambulation. In retrospect, this outcome is to be expected, as initial contact is below the height of the trailing foot, and consequently the relative orientation of the tibia with respect to the foot will result in reduced plantarflexion. McIntosh et al. (2006) also displayed these results (Figure 6.19), and illustrates that the plantar-flexion angle at toe-off reduces with increasing gradient of ramp descent.

However, it is kinetic outcomes which illustrate greater differences when comparing the hip and ankle moment during ramp descent when comparing the outcomes of ramp ascent and level walking. On ramp descent, during mid-stance (Figure 6.16) the hip moment plateaus – a slight plateau can also be observed during level walking, though it is not as obvious. This may indicate that the hip provides vital stabilisation during mid-stance, especially when the body is falling with a greater loss of height during ramp descent, as the leading foot makes initial contact below the height of the trailing foot.

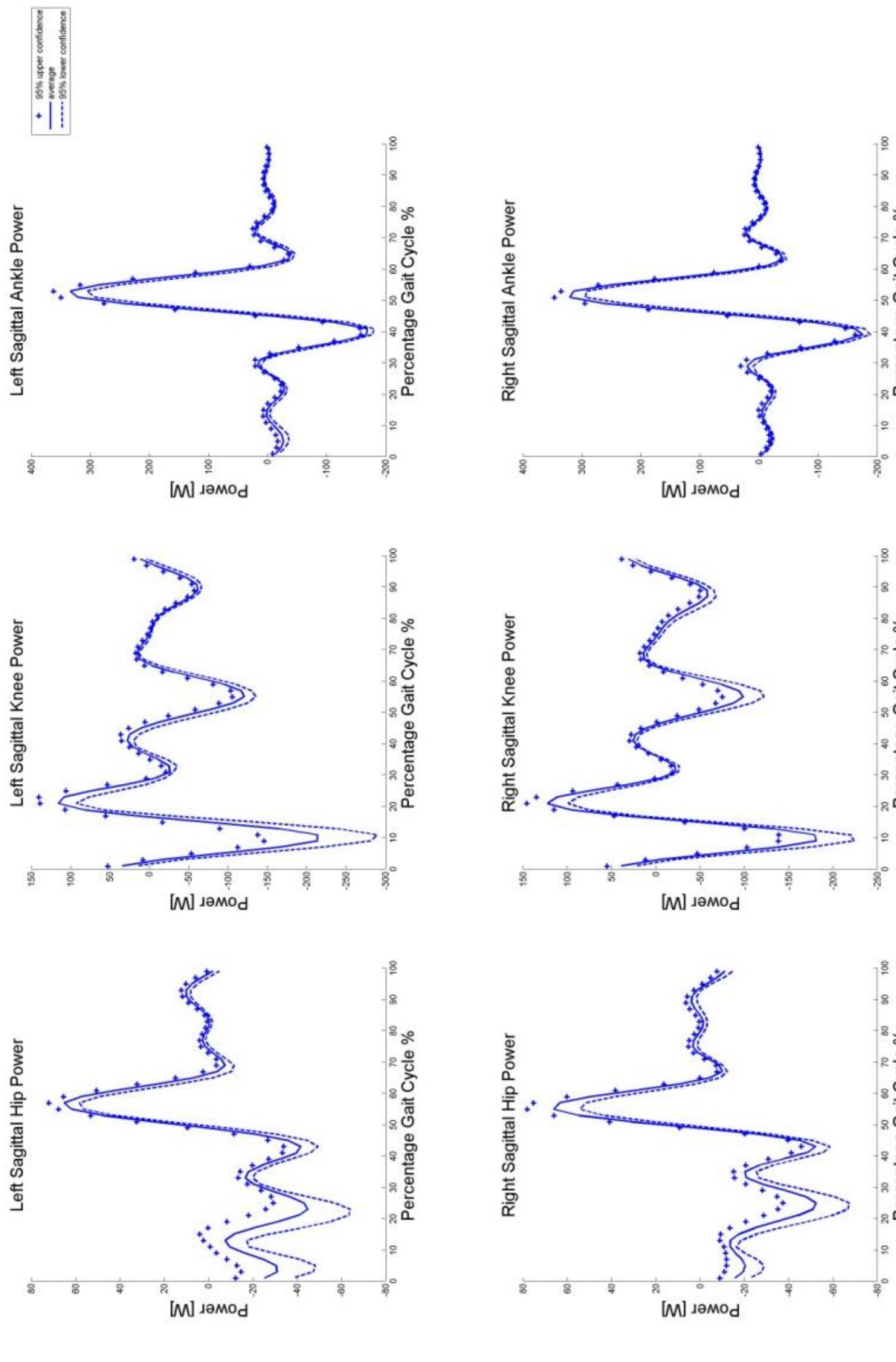


Figure 6.17 Anatomical powers of able bodied control during ramp descent

However, there is a minimal difference when comparing the external knee moment pattern during ramp ascent with that of level ambulation. During ramp descent, the peak external flexion moment acting around the knee in the early stance phase increased by approximately 20Nm (-100Nm versus -80Nm) when compared to level ambulation. However, when comparing these results to McIntosh et al. (2006), as shown on Figure 6.19, the “normalisation” procedure appears, as it does with other investigators, to have “flattened” the moment graphs, making meaningful comparison difficult. However, it is the ankle moment on McIntosh et al. (2006), as shown on Figure 6.19, that deviated most from the results of this study, because McIntosh et al. (2006) presents a pattern of a double peaked dorsiflexion moment throughout the whole stance period. However, the ankle moments provided by Redfern et al. (1997), given on Figure 6.18, are similar to the ankle moments presented in this thesis for a normal control during descent.

The power traces that are integrated for the ankle, knee and hip, Figure 6.17, show that 16, -29 and -8J of work are done respectively. These results mainly indicate mechanical energy absorption during descent compared to the positive work associated with level walking (21J, -13J and 6J) and ramp ascent (53J, 4J & 19J). Even though integration of the power curve around the knee shows mechanical power absorption, it does not mean that the muscles are not expending metabolic work. However, this will be at a lower rate than it would be if positive mechanical work was being done (Kuo 2007). Hence, the negative powers during descent show that the muscles contracting around the knee are still expending metabolic work. However, the muscles are working at a reduced metabolic rate when compared with level ambulation.

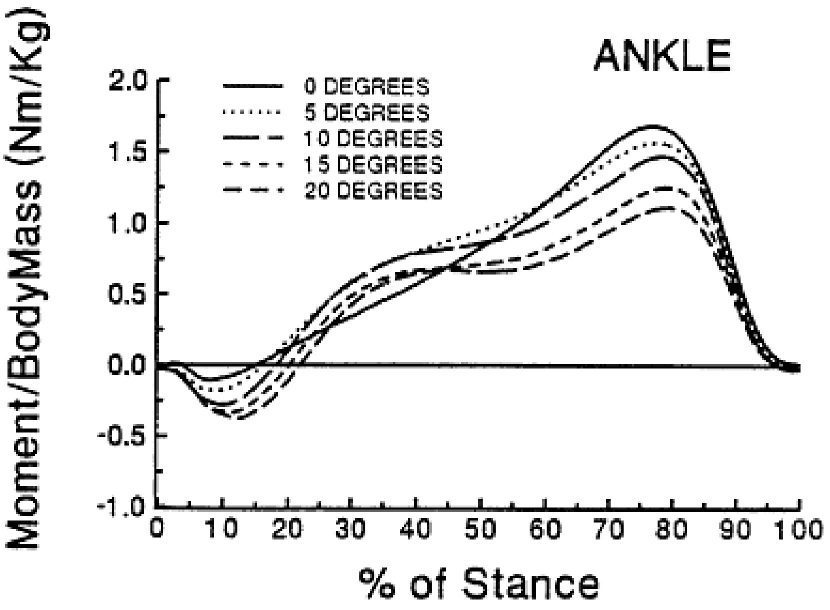
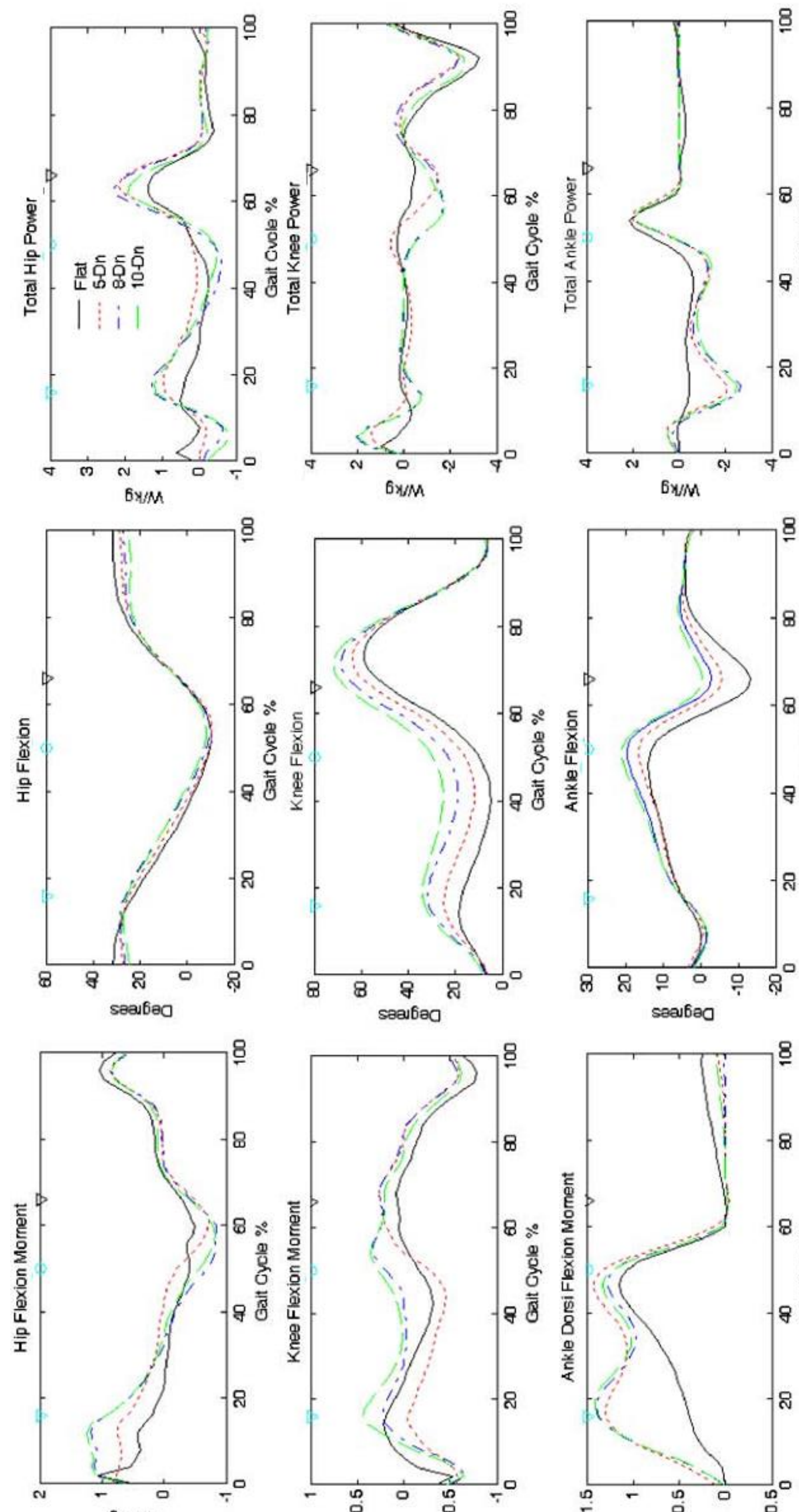


Fig. 4. Ensemble joint moments for stance phase as ramp angle is varied. Moments are normalized by body mass. (Positive moment, extension for hip and knee; plantar flexion for ankle).

Figure 6.18 Mean ankle moment adapted from Redfern et al. (1997), for fifteen normals during ramp descent



The mean angles moments and powers (left to right) during ramp descent at 6, 8 and 10 degrees as indicated. The thigh flexion and extension angle is with respect to the global coordinate system, while the moments are likely to be in global coordinates acting on the proximal segment. As described "hip flexion moment, positive is extension; knee flexion moment, positive is extension, ankle dorsiflexion moment, positive is plantar flexion"

Figure 6.19 The angles, moments and powers for the ankle knee and hip adapted from McIntosh et al. (2006) for eleven normal controls during ramp descent.

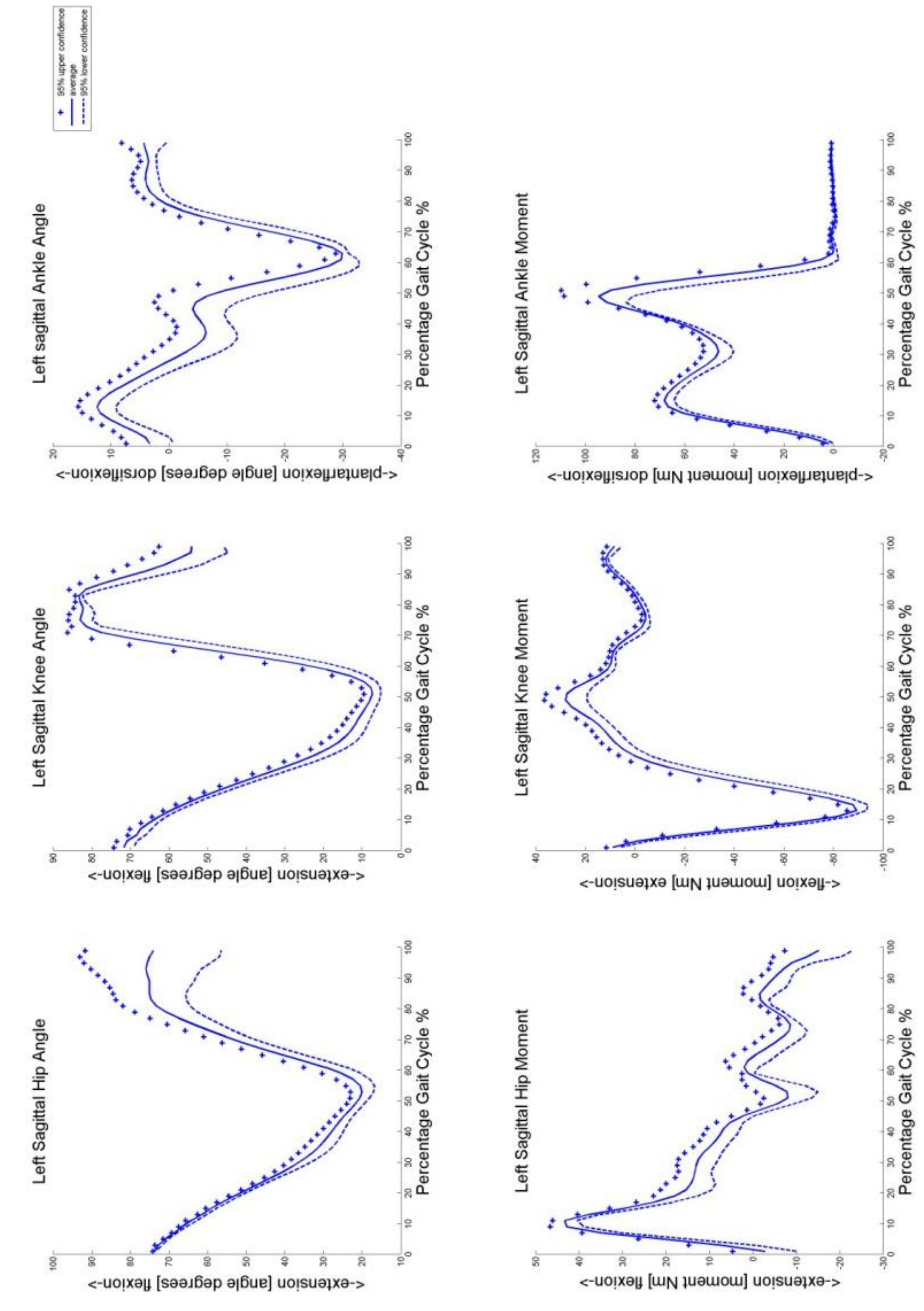


Figure 6.20 Kinematics and kinetics of able-bodied control during stair ascent

6.6 GAIT BEYOND LEVEL AMBULATION (STAIR ASCENT)

When negotiating stairs, the patterns of ambulation differ considerable when compared level walking and even ramp ambulation. It is illustrated by Figure 6.20 that the thigh mainly remains flexed with respect to the pelvis throughout the whole gait cycle. The thigh during ramp ascent remained flexed with a minimum flexion angle of 10 degrees; however, during stair ascent this minimum flexion angle increased to 20 degrees. This is not surprising, as the leading limb is placed on the leading step and the body is lifted above the height of the trailing foot, giving no opportunity for thigh extension (Broer 1966). Other similarities with ramp ascent include the knee flexion on initial contact rather than extension. During stance, the knee continues to extend rather than flex, as seen during ramp ascent, as the body is lifted to the next step, before flexing again during the late stance period (Figure 6.20). When compared to level walking, rather than plantar-flexing after initial contact the foot dorsi-flexes, but still plantar-flexes during late stance. This again has similarities with ramp ascent, because the pendular motion of the tibia around the ankle after initial contact reduces the angle between the foot and shank. This is because, on initial contact, the foot does not make "heel strike" but predominantly lands on the toe, so there is no foot plantarflexion after initial contact as is seen with level ambulation. Therefore, as discussed by Perry (1992), it is better to refer to the contact of the foot on the ground as initial contact, rather than heel strike.

The lower limb moments are also substantially altered during stair ascent compared to level walking or ramp ascent, and they provide a vivid illustration of the observed kinematic outcomes.

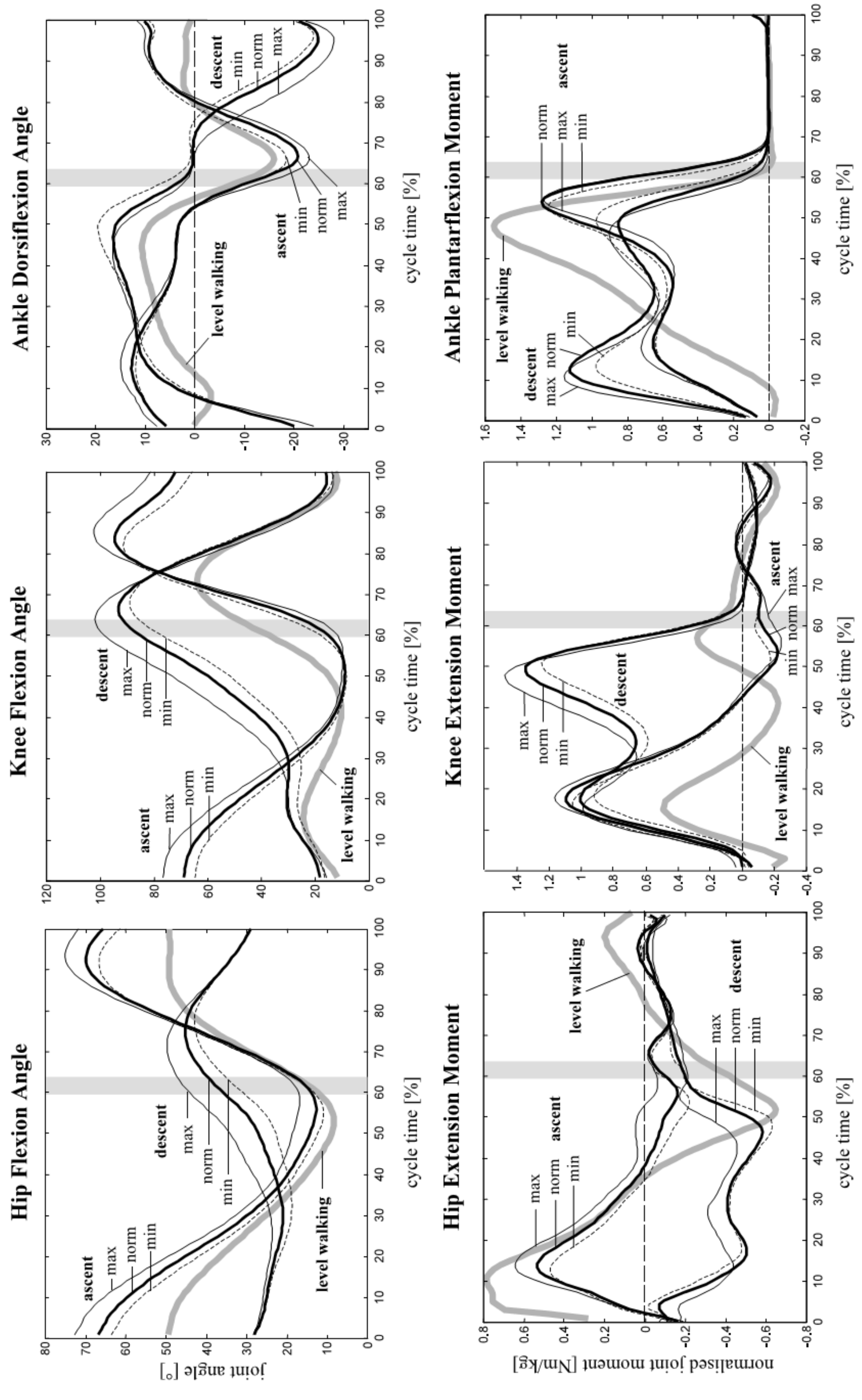


Figure 6.21 The mean lower limb kinematics and kinetics during stair ascent and descent at 24°(min), 30° (norm) and 42° (max) from Riener et al. (2002)

The external flexion moment that acted around the hip during stance, Figure 6.20, demonstrated that the thigh extension musculature resisted the pull of gravity during stance because the GRF is mainly flexing the thigh during stance. Additionally, as seen with level ambulation and ramp ascent and descent, an external knee flexion moment acted after initial contact and during stance, providing evidence that the internal extensor muscles extended the knee and lifted the body. However, the ankle kinetics, Figure 6.23, demonstrated interesting deviations from level or ramp ambulation. The reason for this is that an external dorsiflexion moment acted throughout the majority stance, showing that the plantarflexor muscles work hard for more than the labelled push-off instance of the gait cycle. These moment patterns can be seen on Riener et al. (2002), and are provided in Figure 6.21 for reference.

For stair ascent, and as shown by Riener et al. (2002), comparing the results of the normal control in this study with those of the ankle kinematics (Figure 6.22) demonstrates that, after initial contact, the foot appeared to dorsiflex rather than plantarflex. However, in Protopapadaki et al. (2007), the moment plots illustrates that the foot dorsiflexed rather than plantarflexed. This outcome is intriguing, and may be down to the fact that the inclination of the stairs was 32°, with four steps, compared to the 33° inclination used in this study with the same number of steps. In contrast, Riener et al. (2002) varied the stair inclination (24°, 30°, 42°), and used a stair test rig with five steps. However, both investigators evaluated the participants' bare-foot, and the normal control evaluated on Figure 6.22 wore their "everyday" shoes.

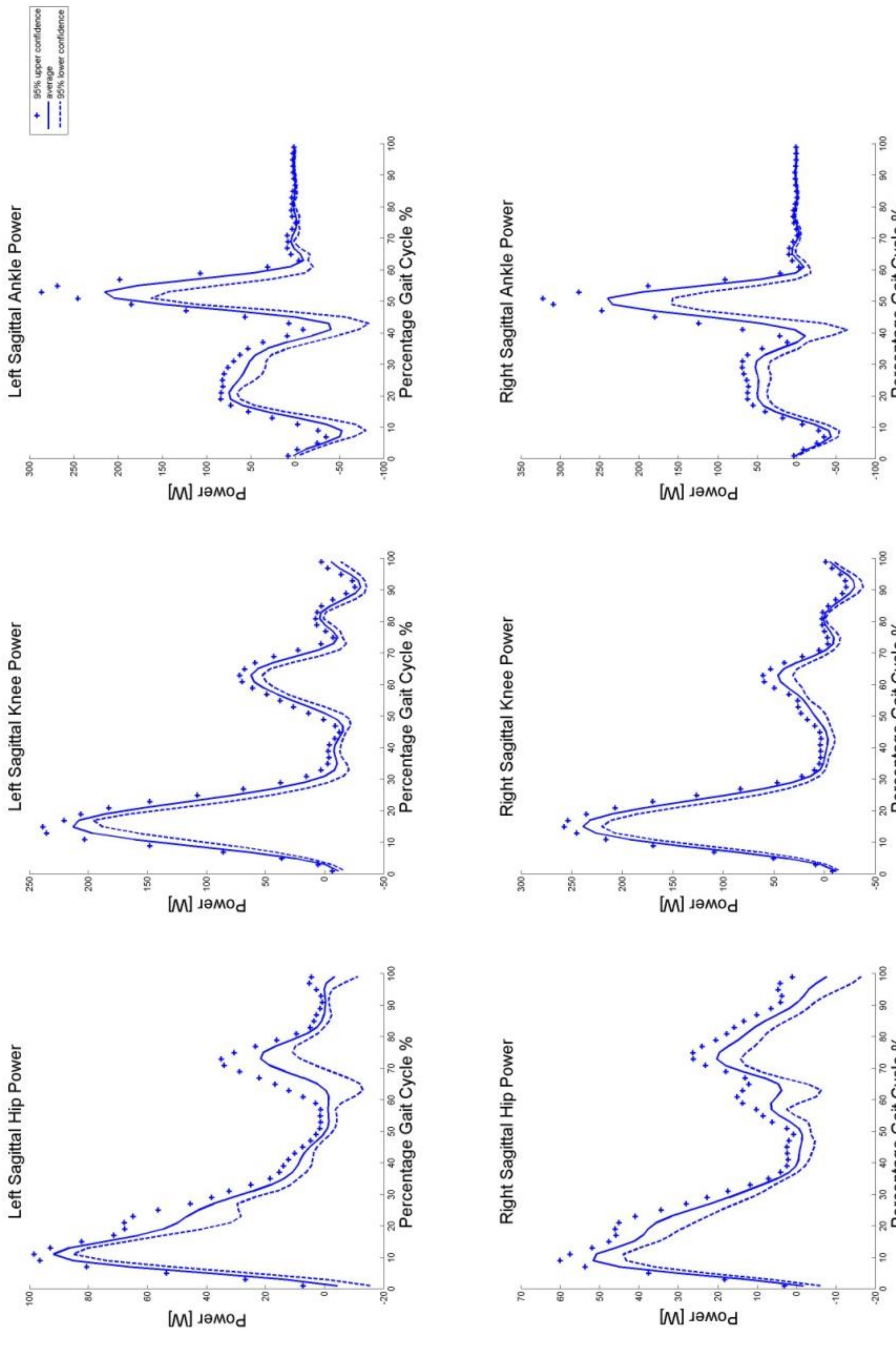


Figure 6.23 Anatomical powers of able-bodied control during stair ascent

As discussed by Broer (1966) the action of stair climbing is not smooth; it interrupts the flow or progression of the body, and even step width can alter the technique adopted. The step width in this study was 24cm, whereas in Riener et al. (2002) it varied between 25 and 31cm, due to the inclination change, and in Protopapadaki et al. (2007) it was 28cm. This evidence does not conclusively explain the slight difference of foot plantarflexion in Riener et al. (2002), but it does illustrate the difficulty of comparing the results of studies that use similar setups in varying laboratories.

Furthermore, an inspection of anatomical powers reveals that positive work (39, 52 & 23 J) is mainly performed around the ankle, knee and hip respectively, when compared to level walking (21, -13 and -6 J) for the same subject. The result of having to raise the body, as also noted by Riener et al. (2002), Figure 6.15, illustrates that the musculature around the knee and hip worked harder during early stance than late stance, when compared to level ambulation.

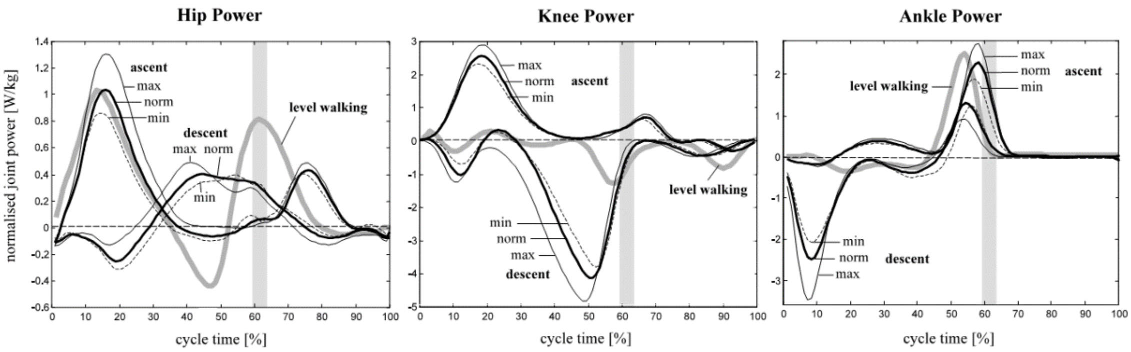


Figure 6.24 The mean powers developed around the hip, knee and ankle and normalised by body weight during stair ascent and descent at 24° (min), 30° (norm) and 42° (max) from Riener et al. (2002). The grey shaded vertical bar indicate toe-off.

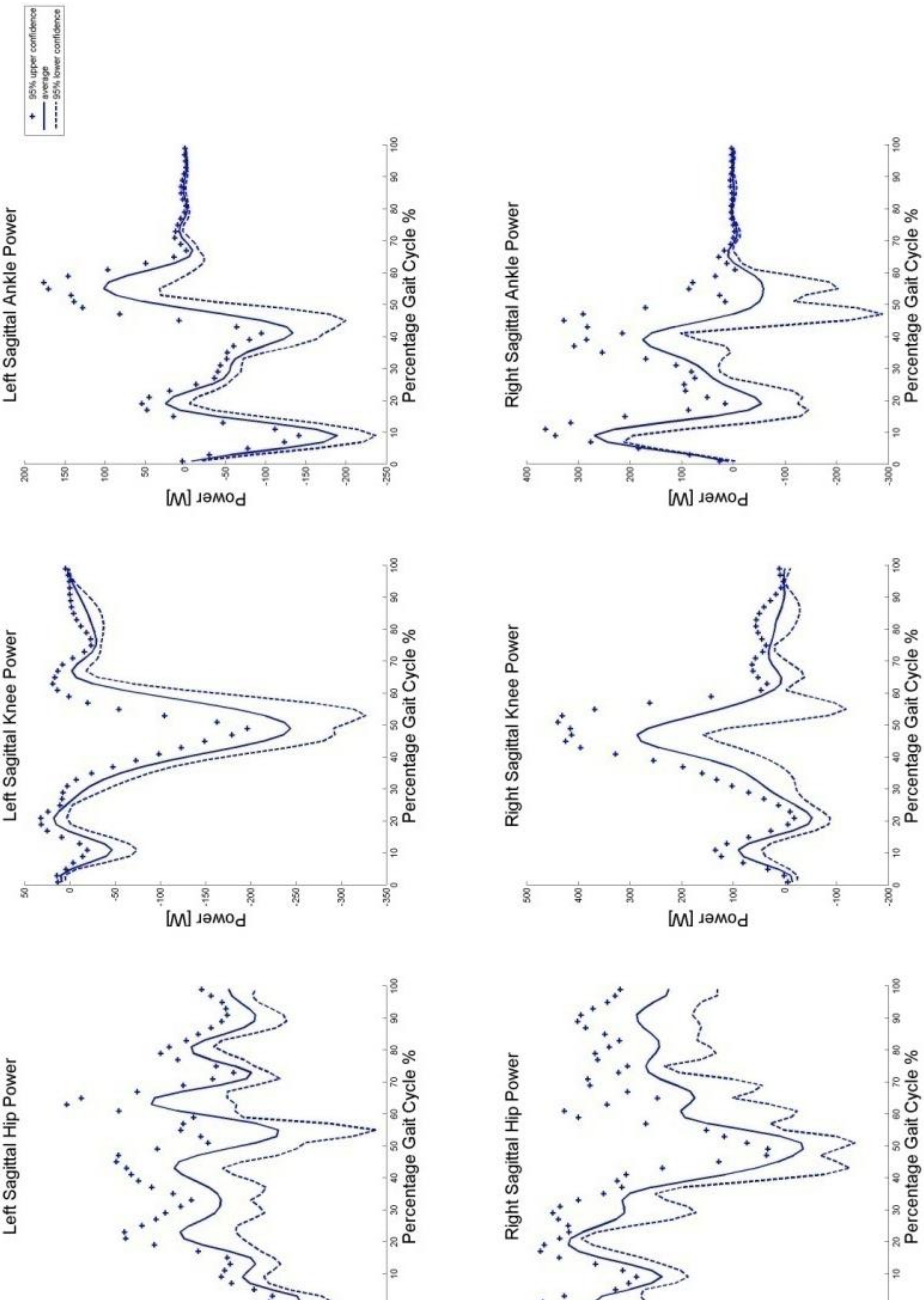


Figure 6.25 Anatomical powers of able bodied control during stair descent

6.7 GAIT BEYOND LEVEL AMBULATION (STAIR DESCENT)

When inspecting the lower limb kinematics and kinetics of stair descent, compared to the other ambulation activities – even stair ascent – the increased standard deviation of the measured outcomes (as shown in Figure 6.25) suggests that the greatest challenge for the ambulator, in terms of stability, is negotiating walking surfaces that do not have constant a gradient. Indeed, as discussed by Broer (1966), in comparison with the energy expenditure of stair ascent, the difficulty of stair descent is one of safety.

The total mechanical work done by the musculature around the ankle, knee and hip (-42, -71 and 3 J) reveals that the lower limbs mainly absorbed energy during descent in comparison with level walking (21, -13 and -6 J), as the muscles work against gravity. The power patterns for both the right and left limb vary, and were not as consistent between the left and right side as with the other test activities, because of the presented greater standard deviation. It is the power trace of the left, rather than the right, limb that follows the Redfern et al. (1997) pattern of results more closely (Figure 6.24). However, as shown by the wide spread of confidence intervals, stair descent is actually quite strenuous, even for a competent ambulator, as muscle effort is not as repeatable on the right as on left side. The kinematics illustrate that, with respect to the pelvis, the thigh adopts an unusual pattern of motion compared to the other activities. It can be observed on Figure 6.26, that the thigh flexion angle appears "upside down" with respect to the other test activities. However, an external extension moment acts around the hip during early stance, as the leading limb is rapidly extended, when the body is lowered to the next step.

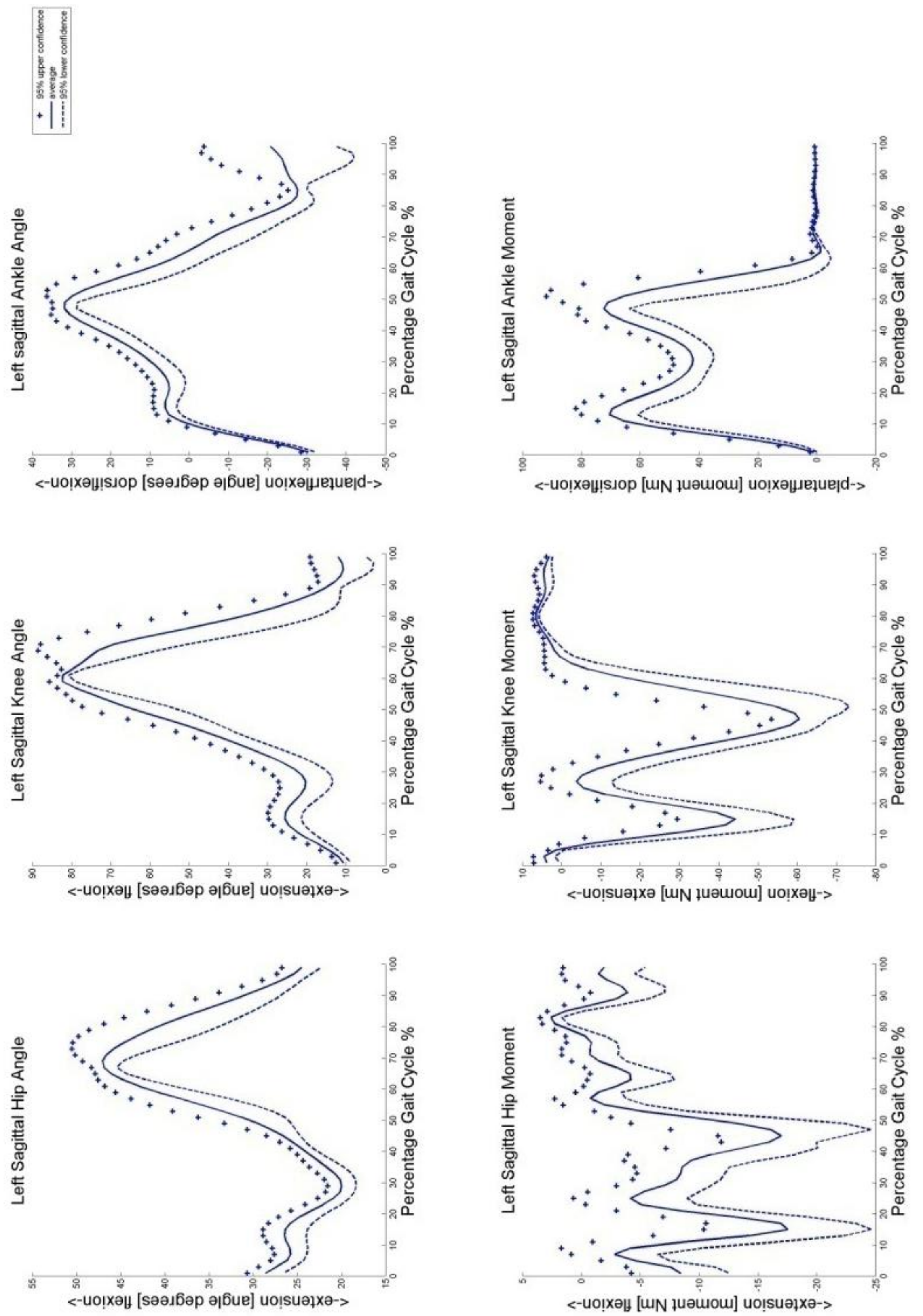


Figure 6.26 Kinematics and kinetics of able-bodied control during stair descent

One possible explanation as to why the kinematics and kinetics are not as controlled relative to ramp descent could come from consideration of the fact that repetition allows an individual to perform a process with greater skill, and that this hip pattern is unlikely to be performed unless negotiating a terrain similar to stairs. The knee and ankle kinematics reveal that the stance limb is lowering the body during stair descent with almost uninterrupted progression. Indeed, the results of Riener et al. (2002), Figure 6.21, also illustrate this point. The knee gains increasing flexion as the body is lowered, and the foot assumes a position of greater dorsiflexion as the body COM moves ahead of the ankle centre. On initial contact, because the body weight is primarily focused on the forefoot, the GRF will tend to cause an external dorsiflexion moment. As stance progresses, the COP moves posteriorly to the direction of travel, Figure 6.27, reducing the external dorsiflexion moment, before moving towards the metatarsals and increasing the dorsiflexion moment at toe-off.

In terms of muscle control, after the forefoot makes initial contact, as shown by the plantarflexion angle, the external GRF acts to flex knee while dorsiflexing the foot. After the foot makes total surface contact, the knee flexion and dorsiflexion moment peak and trough respectively before gaining magnitude again as the body is lowered. These trough patterns illustrate that the ankle, knee and hip are being used in a similar manner to lower the body (Figure 6.26). However, both stair ascent and descent, as shown by the kinetic and kinematic outcomes, are likely to cause the greatest difficulty for the prosthetic ambulator, due to the difficulty they presented for the normal control.

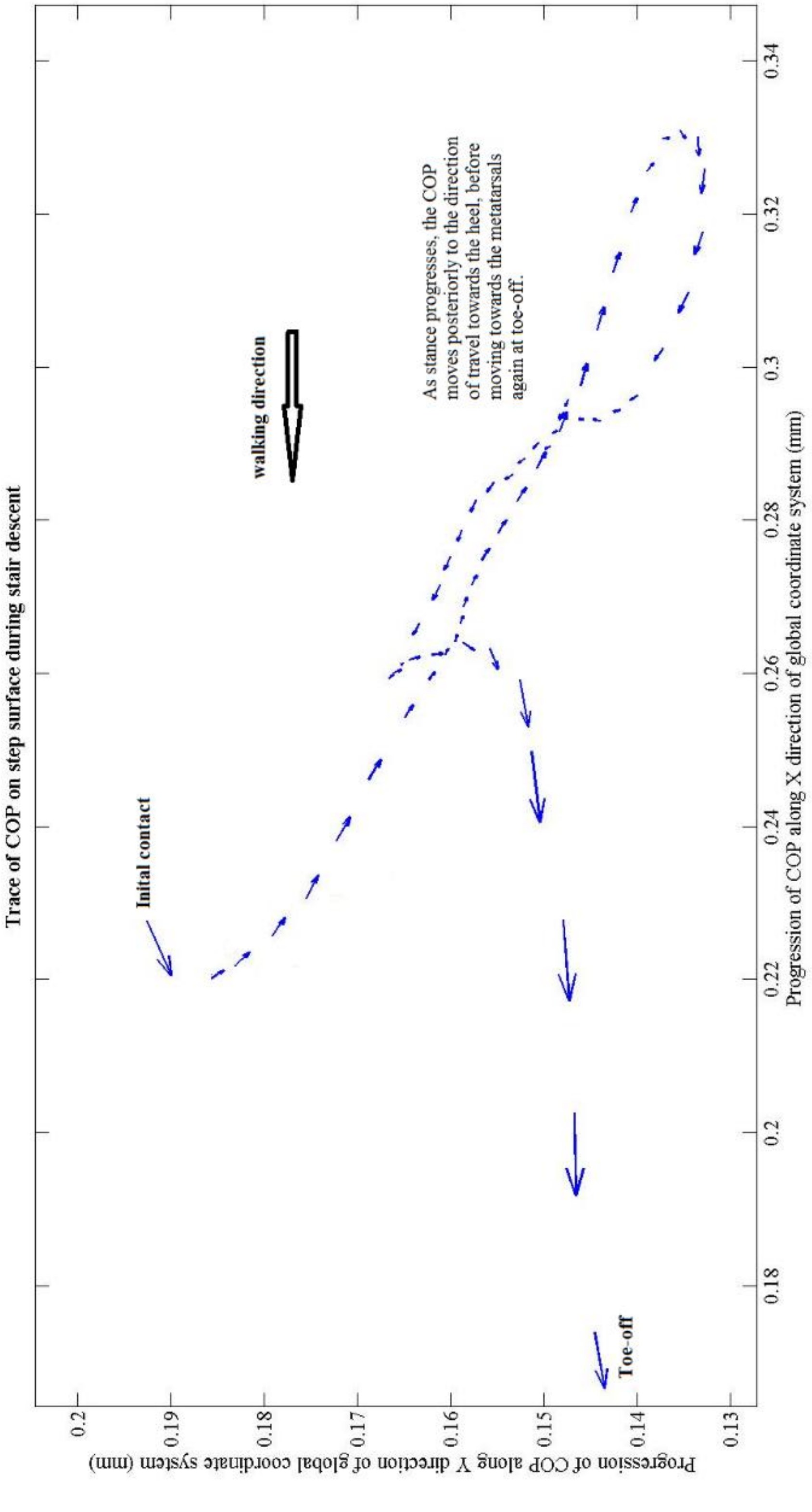


Figure 6.27 Trace of COP of normal control during stair descent

6.8 SUMMARY

Through comparison of the outcomes of the normal control used in this study with that of literature, the similarities and differences, highlighted the difficulties of presenting data in a consistent and known manner. All moments and angles presented in this study are in a proximal local frame of reference, and all moments are acting from the distal to proximal segment. The importance of presenting outcomes in a defined and known manner cannot be underestimated. As illustrated, during the discussion of data presentation it was not known whether moments were given in local or global frame, and if it is the latter as highlighted by Figure 6.9, the moment direction changes depending on whether the individual walks in a positive or negative reference direction. Therefore, when moments are presented in studies of individuals ascending and then descending a ramp it is not whether the direction of ambulation with respect to the global reference frame should be considered. Thus, stating that the moment is external or internal does not provided the reader with sufficient information to have confidence that moments are presented consistently and in a known direction.

Finally, this chapter has also been used to show how the kinetics and kinematics of motion can be used to interpret musculature function when an individual is ambulating. However, as illustrated by the results in this chapter, and discussed in section 4.9, considerable effort was made to maximise data precision and accuracy to allow the comparison of intra and inter subject outcomes. Although, further difficulties are presented as described in the proceeding results chapter when these outcomes are used to describe the interaction of the prostheses with that of the user.

CHAPTER 7 RESULTS

7.1 INTRODUCTION

The participant results are presented over two chapters. This first chapter provides an individual case study for all participants and the second provides a statistical summary of the intra- and inter-subject outcomes. The individual case studies include a full description of results pertaining to participant A, and a highlighted summary for participants B-F. Table 7.1 gives the order of participant graphs presented in this section, and for Participants B-F in the respective appendices. Graphical outcomes are also saved in the digital appendix attached to this thesis.

The purpose of this results chapter is illustrate how the angle, moment and power plots were qualitatively interpreted to investigate the user voluntary control and involuntary response. As identified in the Orion MCPK overview page 44, it is in mid to late stance period that the Orion knee should be able to provide additional voluntary control. Moreover, the involuntary response of the Orion MCPK should be improved compared to the 3R80 non-MCPK. Throughout the description of the graphical outcomes, therefore, notable intersubject features that repeatability occurred are highlighted. These outcomes were used to determine the measured outcomes that were most appropriate to evaluate the instances of gait that were identified as being important in the assessment of in-/voluntary response and control. Finally, the discussion chapter provides an amalgamated synthesis of the two results chapters to determine whether there are additional benefits associated with the MCPK. These differences and outcomes are also used to address whether it is possible to assist the prescription of the MCPK in the clinical environment.

Figure (X.NO)	layout of figures in participant sections
Figure X.1	prosthetic limb kinematics and kinetics – level walking
Figure X.2	contralateral limb kinematics and kinetics – level walking
Figure X.3	prosthetic (side) and anatomical (side) powers – level walking (Orion)
Figure X.4	prosthetic (side) and anatomical (side) powers – level walking (3R80)
Figure X.5	prosthetic limb kinematics and kinetics – Ramp ascent
Figure X.6	contralateral limb kinematics and kinetics – Ramp ascent
Figure X.7	prosthetic (side) and anatomical (side) powers – Ramp ascent (Orion)
Figure X.8	prosthetic (side) and anatomical (side) powers – Ramp ascent (3R80)
Figure X.9	prosthetic limb kinematics and kinetics – Ramp descent
Figure X.10	contralateral limb kinematics and kinetics – Ramp descent
Figure X.11	prosthetic (side) and anatomical (side) powers – Ramp descent (Orion)
Figure X.12	prosthetic (side) and anatomical (side) powers – Ramp descent (3R80)
Figure X.13	prosthetic limb kinematics and kinetics – Stair ascent
Figure X.14	contralateral limb kinematics and kinetics – Stair ascent
Figure X.15	prosthetic (side) and anatomical (side) powers – Stair ascent (Orion)
Figure X.16	prosthetic (side) and anatomical (side) powers – Stair ascent (3R80)
Figure X.17	prosthetic limb kinematics and kinetics – Stair descent
Figure X.18	contralateral limb kinematics and kinetics – Stair descent
Figure X.19	prosthetic (side) and anatomical (side) powers – Stair descent (Orion)
Figure X.20	prosthetic (side) and anatomical (side) powers – Stair descent (3R80)

Table 7.1 Presentation order of participant graphical results in their appropriate appendices

7.2 PARTICPANT OVERVIEW

Before commencing with the description of participant results, a summary of subjective observations and participant feedback will be presented. The six participants recruited were all considered to be outdoor community ambulators. Participants A and C were the most active ambulators and were able to ambulate recreationally without walking aids (Table 7.2**)**. They were therefore classed as unrestricted or K3 ambulators according to the Medicare Functional Classification level (MFCL). Participants B, D, E and F were classed as restricted outdoor K2 ambulators because they tended to walk outside when required, rather than recreationally. Moreover, as detailed in Table 7.2, these participants also used walking aids, and tended to demonstrate more apparent gait deviations during ambulation.

The subjective feedback from the participants suggested that they preferred the Orion prosthesis (Table 7.2). The kruskal-wallis test was used to evaluate the mean percentage score when using the 3R80 (77%) and Orion (88%) knees; the significance of the difference was less than 1% ($P<0.01$). Because of the calibration procedure, it was not possible to blind the participants from the fact that they were using the Orion knee, and it was therefore expected that having the opportunity to use "state of the art" technology could bias the participants' preference towards the Orion prosthesis.

Participant C, E & F, as detailed by were C-leg users, and preferred the C-Leg MCPK when compared to the Orion MCPK. However, this is hardly surprising, considering that they used the C-leg as their everyday prosthesis. All of the participants commented that they would have liked to have taken the leg home and use it for a week to be able to properly compare the Orion with the C-leg MCPK.

Participant	Sex / Age / Body mass without prosthetic limb	Everyday prosthesis	Reason for amputation/ date of amputation / side	Medicare Functional Classification level	Participant Subjective Scoring NMCPK / MCPK (%)	Additional notes
A	**male / 53 years / 81 kg**	IP/3R80	trauma / 1991 / left	K3	80/90	Confident ambulator requires no additional aids, mainly uses the 3R80 but also has an IP. He did not use handrail support during the ramp activities.
B	**male / 51 years / 84 kg**	3R80	tumour / 1980 / right	K2	70/90	Suffers from a hip flexion contracture, their ambulation technique displays compensatory actions such as lateral trunk bending combined with a long prosthetic step, they also used the handrail for support during ramp activities when using the Orion, and 3R80.
C	**female / 37 years / 61 kg**	C-Leg	tumour / 1993 / right	K3	85/95	Professional swimmer before amputation and leads active lifestyle still, although they did demonstrate some lateral trunk sway and vaulting. She did not use the handrail for support during the ramp activities.
D	**male / 52 years / 95 kg**	3R80	trauma / 1979 / right	K2	75/80	Not active, and uses a walking stick outside, also suffers from lower back pain, as a result this individual is cautious when ambulating. They also showed signs of an abducted gait, and used the handrail for support during ramp activities.
E	**male / 56 years / 84 kg**	C-Leg	trauma / 1995 /right	K2	80/85	Uses walking stick outside, although does not suffer from any secondary complaints. Did show some vaulting and used handrail during ramp ascent and descent.
F	**male / 53 years / 84 kg**	C-Leg	trauma / 1996 / right	K2	70/90	Suffers from diabetes and is not very active, will mainly use their prosthesis indoors, and demonstrated some circumduction, still likes to be able to walk outside when required. He only used the handrail for support during the ramp activities when using the 3R80.

Table 7.2 Subjective participant scoring, parameters and subjective notes.

In summary, Participant C was a competent ambulator but demonstrated lateral trunk bending, though this gait deviation did not skew the results considerably. However, the benefit of assessing the ambulatory ability of a competent user of the C-Leg was that it indicated whether the perceived benefit of the MCPK is the result of the user's familiarity with their everyday MCPK, or of how the MCPK generally integrates itself with the user. As Participant C would ambulate recreationally with their dogs and was a professional swimmer, their outcomes demonstrated a competent ambulator. Consequently, they were rated as an unrestricted outdoor K3 ambulator.

Participant E (the other C-Leg user) also displayed gait deviations, which included vaulting, and would normally use a walking stick outside. Consequently, this participant was rated as a K2 restricted outdoor ambulator and, they also preferred their C-leg, which in retrospect is to be expected considering that they use a walking stick outside, as well as the short evaluation period using the Orion MCPK. However, this outcome was also beneficial when trying to assess whether it was the Orion MCPK functionality that actually affected the ambulation technique adopted by the participant, or whether it was familiarity with their C-leg.

Participant F, the final C-leg user, was interested purchasing the Orion MCPK, as he felt it offered a considerable cost saving in comparison with having to purchase a new C-leg, and that the Orion was not "far behind the C-leg". These subjective comments appear to support the objective evidence gathered during the ambulation study because Participant F did not use the handrail for support when using the Orion, and did when using the 3R80 knee.

During the gait laboratory sessions, Participant F did display circumduction, which was highlighted by the reduced knee flexion (maximum 30 degrees) during swing of their prosthetic side compared to their contralateral side (maximum knee flexion angle of 55 degrees). Moreover, as participant F would only ambulate outdoors when required, and used an additional walking aid when doing so, they were rated as a restricted outdoor K2 ambulator.

When considering Participant D, they were also rated as a restricted K2 outdoor ambulator because they were generally inactive and used a walking stick outside. They also suffered from lower back pain, walked with an abducted gait, and were consequently cautious when ambulating. In retrospect, it was unsurprising that they used the handrail for support during ramp activities.

However, it was Participant B, an everyday 3R80 user, who demonstrated the most exaggerated compensations – including lateral trunk bending towards the prosthetic side during stance, combined with a long prosthetic step, likely caused by their hip flexion contracture. Therefore, this Participant B was rated as a K2 ambulator. As a consequence, the participant was unable to ambulate outside without additional aids. Hence, the kinematic and kinetic outcomes using both prosthesis types were significantly different, and as a result this participant may not have been the ideal candidate, as they were unlikely to have used either knee prosthesis effectively. However, when using their 3R80 prosthesis, which was the same as their everyday prosthesis, their gait aesthetics were not considerably improved.

The first participant recruited, A, was a competent ambulator who had considerable experience with the Blatchfords intelligent prosthesis (IP).

However, he was using the 3R80 prosthesis on a daily basis at the time of the evaluation, as he felt it gave improved security during stance. The main compensatory technique adopted by this participant, and all the participants in general, is that they would only raise the heel of their trailing contralateral limb after “foot flat” of the leading prosthetic foot. Undoubtedly, this was the result of not feeling secure until their leading prosthetic foot made total surface contact. Participant A was rated as an unrestricted K3 outdoor ambulator as they did not use additional walking aids and liked to ambulate outside recreationally.

The results of this study will now be described to suggest the most relevant outcomes in the assessment of user in-voluntary response and voluntary control. The voluntary control is the control the user has over their knee resistance during stance, and the involuntary response is the knee automatic adjusting its resistance during swing. The three main stages of the gait cycle objectively quantified and discussed in chronological order are initial contact, toe-off and swing. These were the critical instances of the gait cycle, identified in Chapter 3, for which the Orion and 3R80 knee devices were generally designed to provide support and control. The differences in involuntary response and voluntary control between the two test prostheses were evaluated primarily by considering the measured outcomes, such as the external moment acting around the joint in question, and mechanical work developed by the muscles. In turn, the prosthetic function will be used to ascertain whether the restricted (K2) or unrestricted (K3) outdoor ambulator will benefit most from microprocessor controlled prosthetic knee mechanisms.

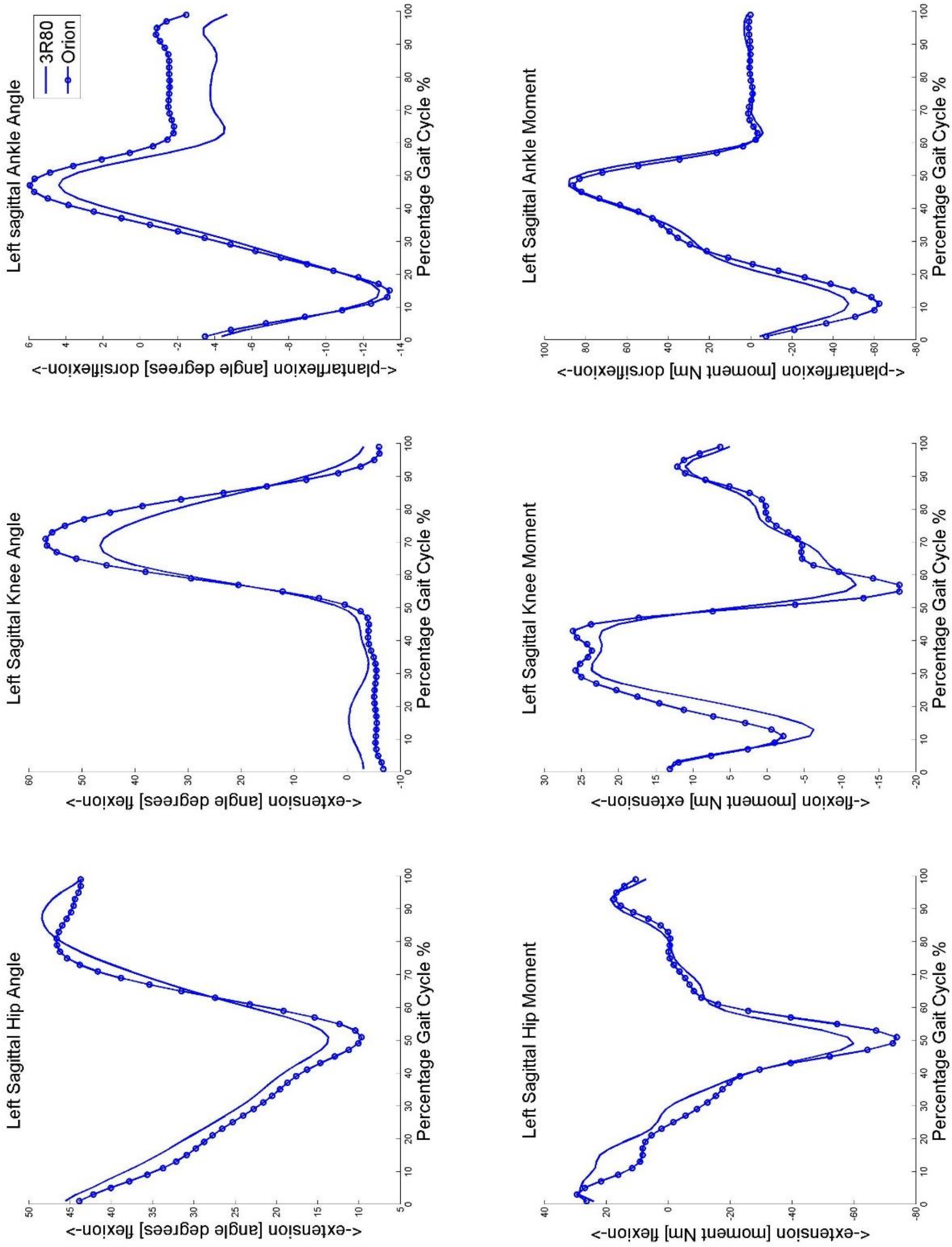


Figure 7.1 Participant (A) prosthetic limb kinematics and kinetics – level walking

7.3 LEVEL AMBULATION (PARTICIPANT A)

All of the participants recruited for this study can be considered outdoor community ambulators and, as described, Participant A was an unrestricted K2 ambulator. The kinematic outcomes of participant A are the typical known ambulation patterns of the trans-femoral prosthetic user. As also shown in Jaegers et al. (1993), on their prosthetic side when using both knee types, the participant does not flex their knee during stance (Figure 7.1). Furthermore, it should be noted that both prosthetic knees are hyper-flexing by a few degrees. Even though the pylon tube is not extending beyond the thigh, the anterior positon of the mechanical ankle joint on the prosthetic Echelon foot with respect to the pylon tube results in the origin of the mechanical axis lying ahead of the thigh mechanical axis when the knee is fully extended, as illustrated in Figure 7.2.

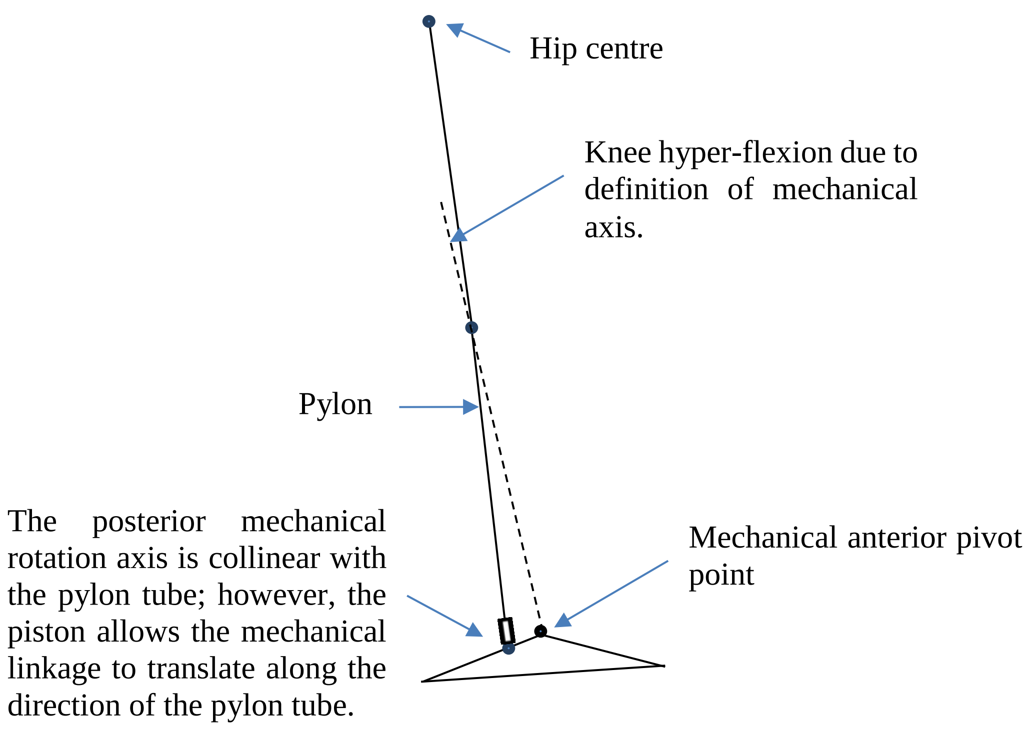


Figure 7.2 Anterior placement of mechanical ankle joint

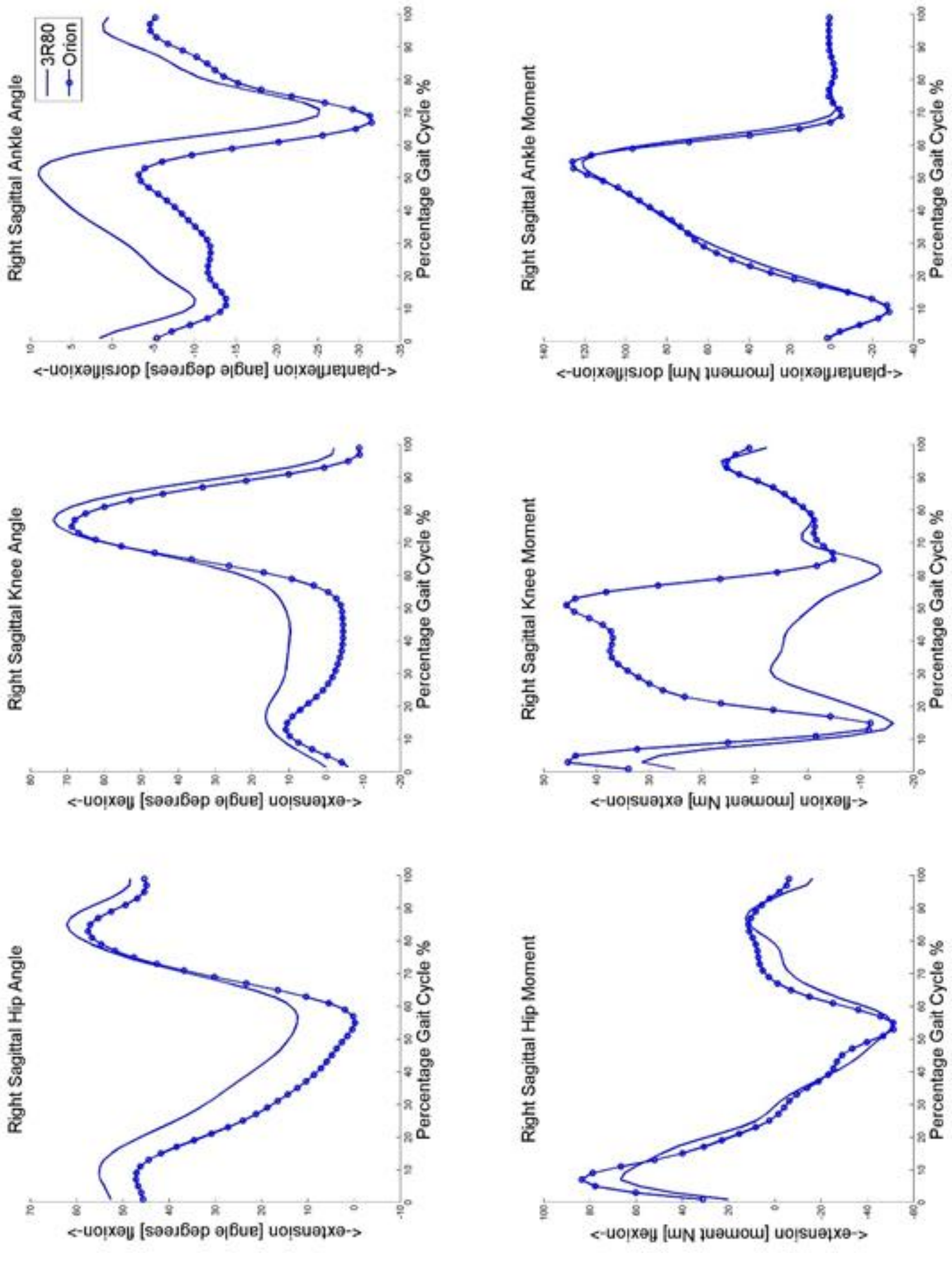


Figure 7.3 Participant (A) contralateral limb kinematics and kinetics – level walking

As illustrated by Figure 7.1, after initial contact the Echelon foot plantarflexes and the findings reveal that it is in a position of greater plantarflexion throughout swing when attached to the 3R80 knee. The ankle kinematic outcomes coincide with increased walking speed wearing the Orion knee, which also results in an increased step length (Table 7.3). Hence, the shank on the trailing prosthetic limb will become more dorsiflexed at late stance with respect to the trailing prosthetic foot when attached to the Orion knee (Figure 7.4). Other kinematic differences, such as the magnitude of knee flexion during the swing as illustrated by Figure 7.1, were also likely to have been effected by walking speed differences.

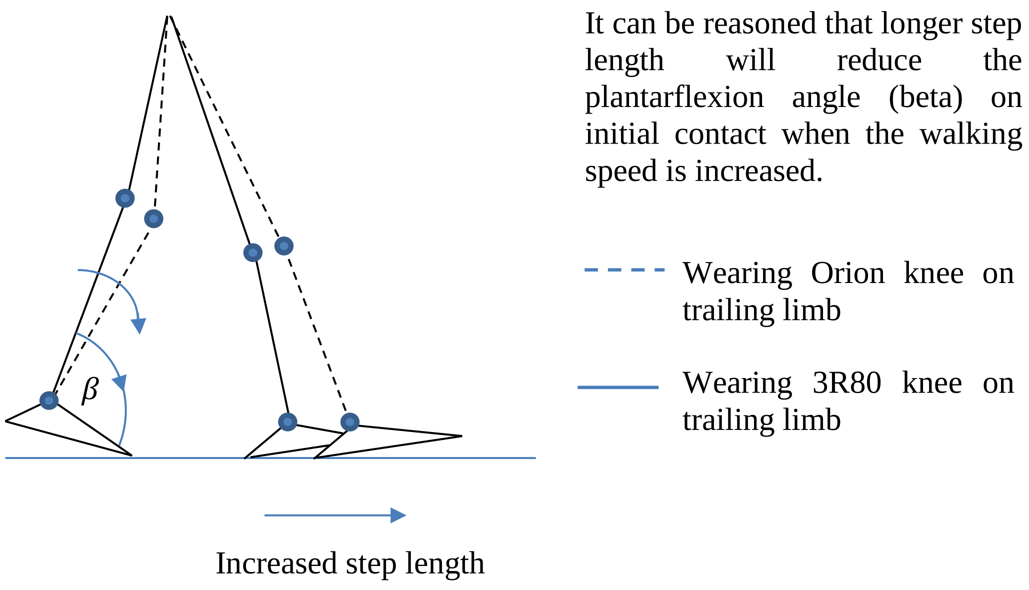
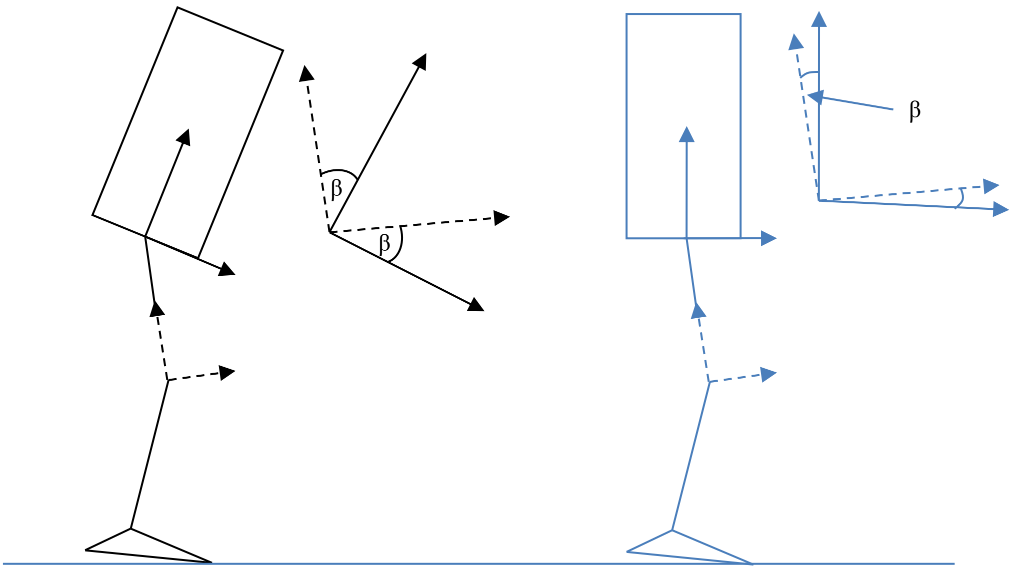


Figure 7.4 Plantarflexion angle of the prosthetic trailing foot during initial contact with a short and long step length respectively wearing the 3R80 and Orion knee

Participant	Level (m/s)		Ramp ascent (m/s)		Ramp descent (m/s)	
	3R80	Orion	3R80	Orion	3R80	Orion
A	1.03	1.35	1.00	1.08	0.85	1.02
B	1.17	0.98	1.05	1.03	0.89	0.73
C	1.38	1.40	1.18	1.13	1.38	1.38
D	1.27	1.21	1.17	1.06	1.15	0.88
E	0.97	1.62	0.85	0.89	0.65	0.68
F	0.98	0.98	0.91	0.96	0.82	0.82

Table 7.3 Walking speed of particpants during ambulation activities



Thigh flexion increased wearing 3R80 knee due to increased trunk flexion.

Thigh extension increased wearing Orion knee due to decreased trunk flexion.

Figure 7.5 The influence of trunk flexion and extension on the thigh flexion and extension angles

Again, on wearing the 3R80 and then the Orion knee, and as the walking speed of participant A increased from 1.03 m/s to 1.35 m/s while ambulating on the level, as detailed in Table 7.3, on wearing the 3R80 then Orion knee, when ambulating on the level. The magnitude of knee flexion during swing also increase, as expected, because the kinetic energy of the swinging limb would have increased.

Surprisingly, despite participant A being a competent walker, during level ambulation the contralateral limb kinematics and kinetics were less repeatable than was the prosthetic side wearing both knee types (Figure 7.3). On wearing the Orion, the thigh during stance on the contralateral side, as indicated by Figure 7.3, was in a position of greater extension during stance. The reduced thigh flexion on initial contact appears to indicate that the trunk was also likely to have been in an orientation of greater extension, as detailed on Figure 7.5. This body posture would have affected the distal limb kinematics. However, when wearing the Orion the contralateral external knee moment, and the hip flexion and extension angles, displayed more similarity to the able-bodied patterns of motion, as seen in Figure 6.6, page 124A . The increased contralateral knee extension moment did increase the knee hyperextension.

Figure 7.6 shows the mechanical power developed by the musculature on the contralateral side, and the power developed around the prosthetic knee and ankle joint during level ambulation when wearing the Orion knee. As expected, because the prosthetic ankle and knee joint were not powered, the magnitude of the power curve peaks are less than the magnitude of the negative troughs, demonstrating that the prosthetic joints mainly absorb power.

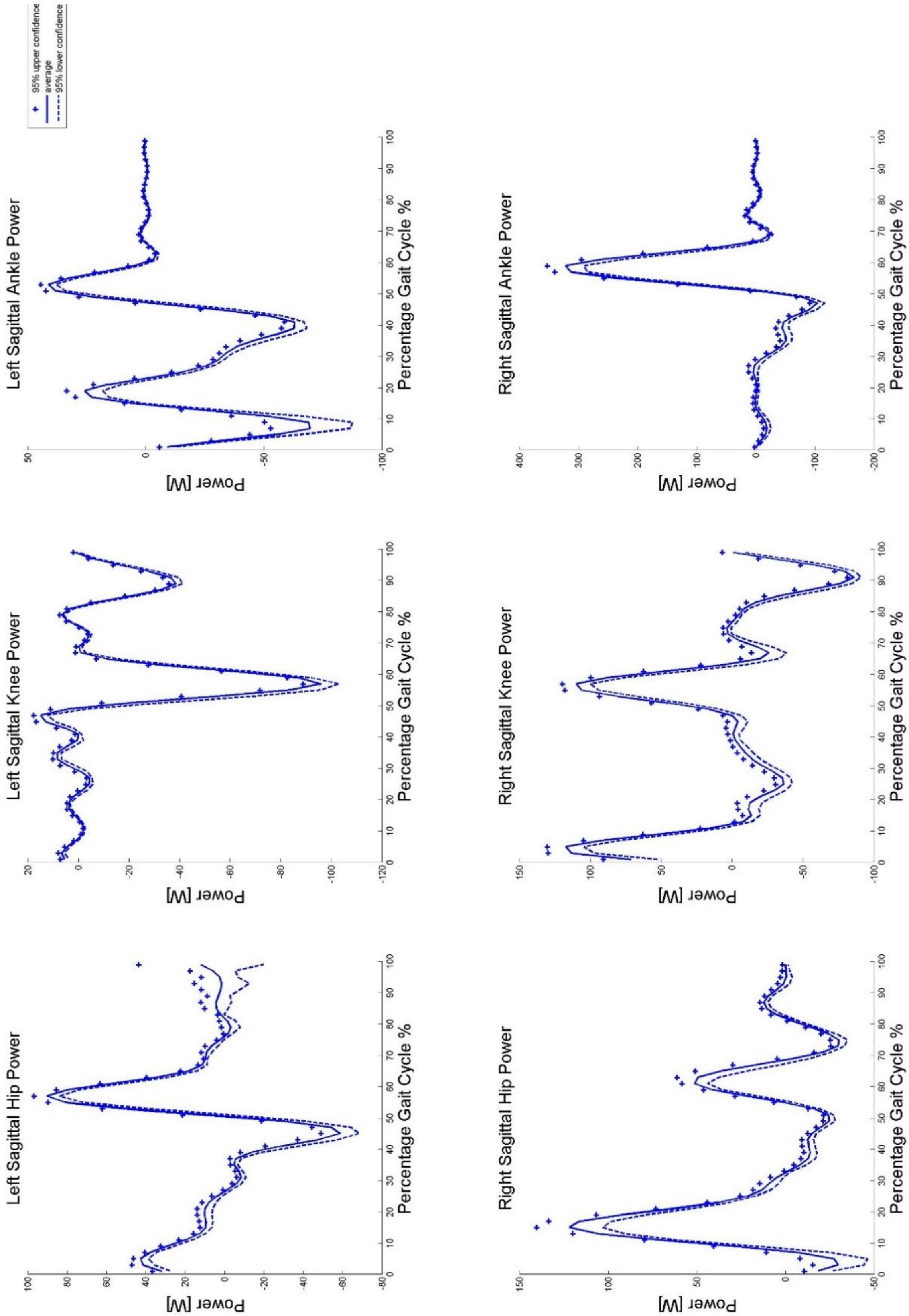


Figure 7.6 Participant (A) prosthetic (Left) and anatomical (right) powers – level walking (Orion)

It is unlikely this energy is stored or transferred, as discussed on page 29. Instead, the energy is likely to be converted to heat as the hydraulic fluid is compressed though one-way valves, and then expands on exiting the valves. The prosthetic knee joint does not provide net energy generation over the course of the gait cycle, and energy absorption mainly occurs during swing. This is to be expected, as the purpose of the swing phase hydraulics is to appropriately damp the knee to allow it to either extend in time, or to prevent sudden leg extension. This pattern is also emulated for the 3R80 knee, as shown over the page (Figure 7.7). Consequently, in the succeeding results chapter the energy absorbed by the knee during the swing phase is correlated with walking velocity (determined from stance using the force plate signal). This was achieved by evaluating the power absorbed by the prosthetic knee types, integrating the power curve during swing, and then correlating the absorbed energy with the walking speed. This analysis was used to provide an understanding of whether the knee function/mechanism allowed the 3R80 and Orion knees to respond to the change in users' walking speed. This was determined through analysing the users' walking speed when transitioning from the level to ramp ascent and vice versa.

Another comparable result between the two prostheses is the ankle power trace of the Echelon foot. It can be observed that there is a small peak prior to mid-stance, and another during the push-off instance when the Echelon foot is fitted to the Orion (Figure 7.6) and 3R80 knees (Figure 7.7). This suggests that the carbon fibre keel of the foot may be rebounding after earlier deformation on initial contact, or after mid-stance as the user pushes back on their foot to provide some push-off during heel rise and the toe-off instance.

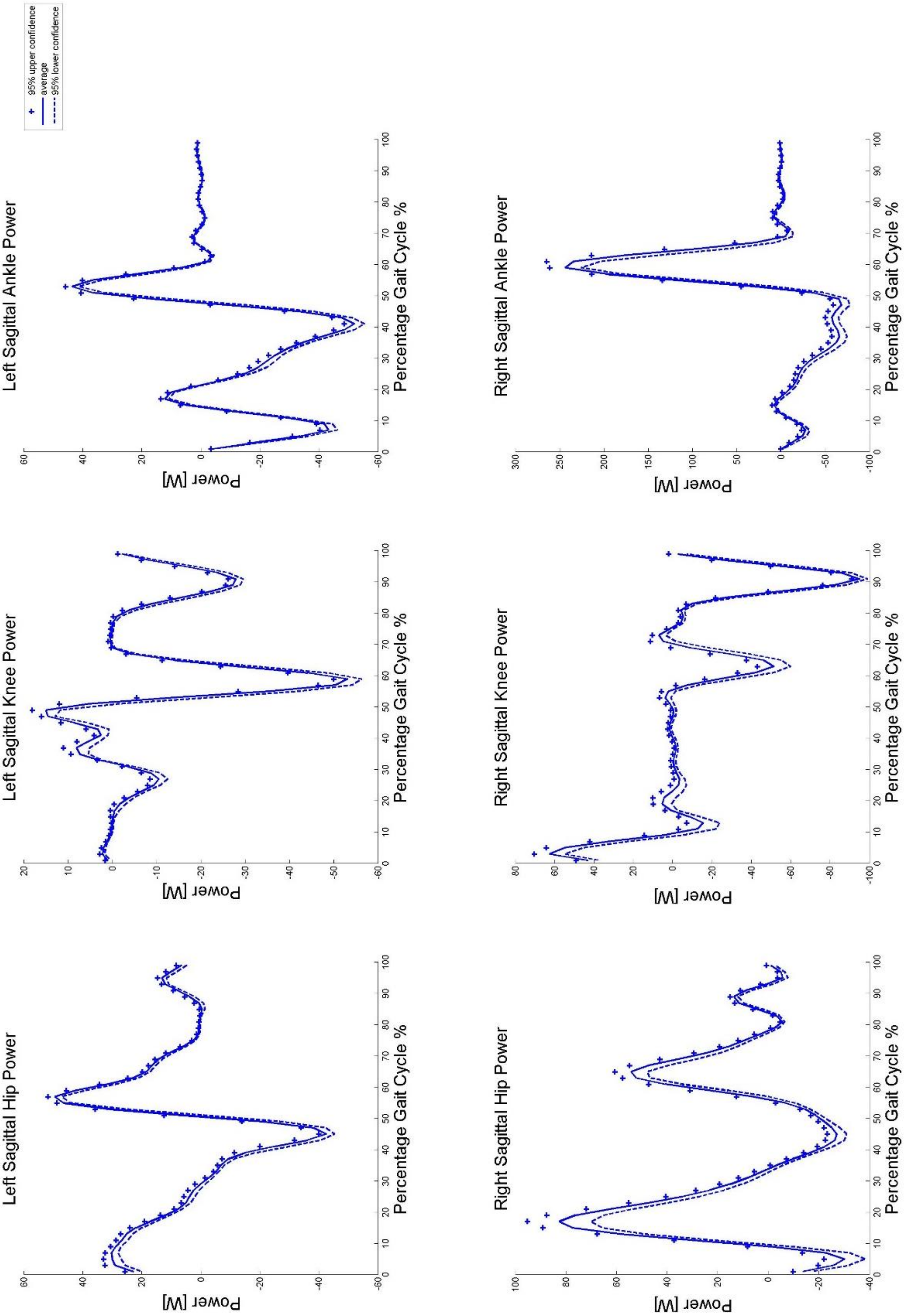


Figure 7.7 Participant (A) prosthetic (Left) and anatomical (right) powers – level walking (3R80)

However, this study will not concentrate on the energy return of the Echelon foot when attached to the 3R80 and the Orion; it is highlighted here merely to provide the reader with some guidance as to how to read the results. The mechanical power generation by the contralateral hip musculature while wearing the 3R80 knee, as demonstrated by Figure 7.7, reveals a small peak of positive work on initial contact, which presumably is the work of the thigh extensors extending the knee. Throughout the majority of stance, there is then power absorption. However, the main peak of contralateral hip musculature exertion was during early swing, and was the likely result of the musculature accelerating the lower limb to extend the knee before initial contact.

Consequently, the mechanical work developed by the hip musculature on the contralateral side was used to evaluate musculature compensations as detailed in Highsmith (2011), and summarised in appendix 11.1, page 229. The statistical summary of the mechanical work done by the contralateral musculature is provided in the following statistical results summary (page). The purpose of this analysis was to evaluate whether the mechanical power developed by the contralateral thigh musculature is reduced using either the 3R80 or the Orion knee. By focusing on possible reduced muscle effort, this analysis was used to determine whether or not contralateral compensations are reduced while wearing the Orion knee.

However, compared to the indoor level walking environment the outdoors will provide a greater challenge to the prosthetic ambulator. Therefore, this study also evaluated the involuntary response and voluntary control, by challenging the participants' skills with ramp and stair activities. As expected, the participants adopted various techniques to control their prostheses.

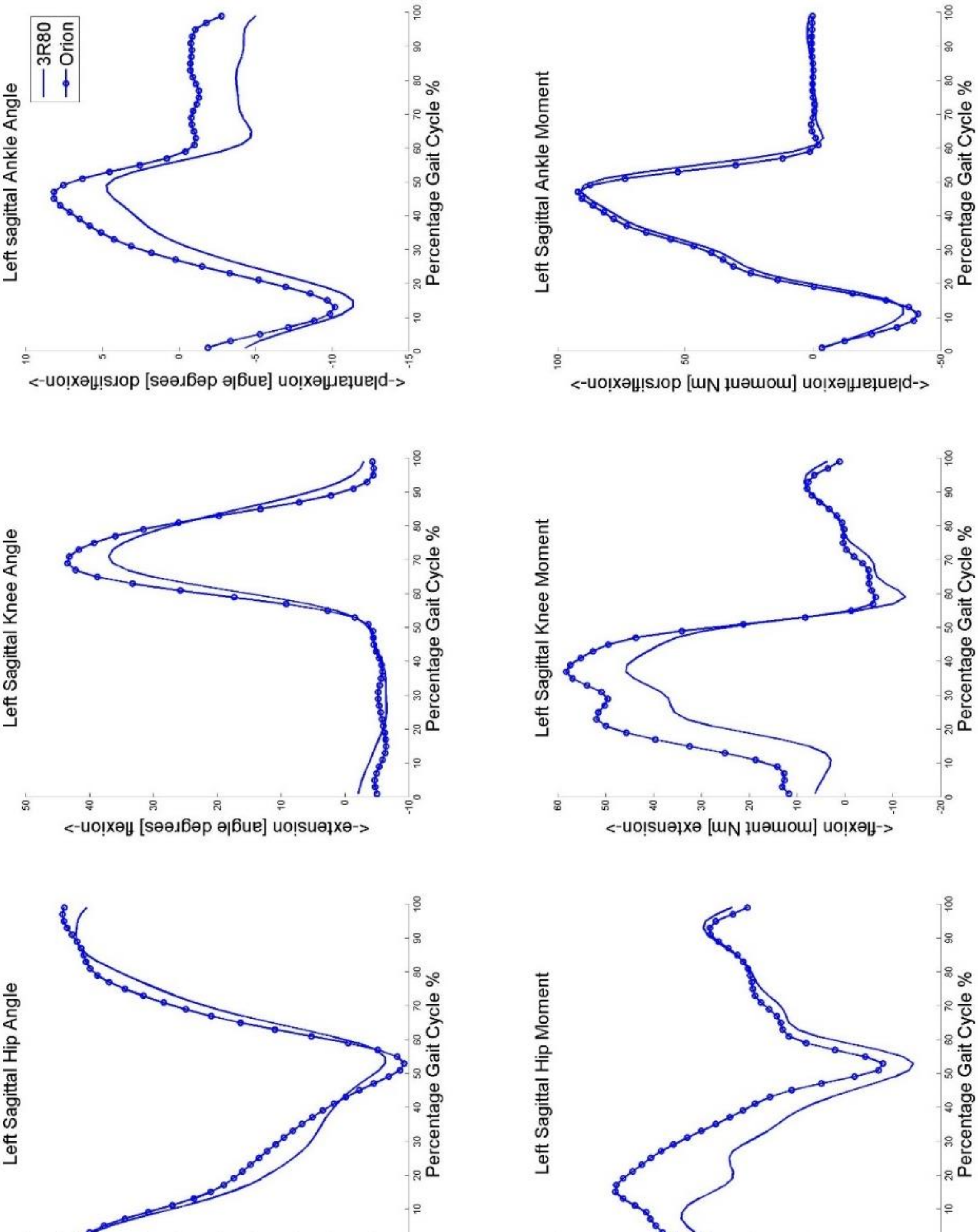


Figure 7.8 Participant (A) prosthetic limb kinematics and kinetics – Ramp ascent

7.4 RAMP ASCENT (PARTICIPANT A)

The kinematic similarities between level ambulation, Figure 7.1, and ramp ascent, Figure 7.8, included the lack of knee flexion during stance on the prosthetic side. This is hardly surprising, as illustrated by the external prosthetic knee moment on Figure 7.8. During ramp ascent the GRF extends the knee because the knee centre is ahead of the body COM. Hence, during ramp ascent the knee was stable, and the participants, as demonstrated by Participant A, only used GRF to flex their knee prior to heel rise and swing. When comparing the knee moment to that of the normal control during ramp ascent, as illustrated on page 130A, the normal control can flex their knee using their musculature. However, the prosthetic user, as demonstrated by Participant A, can only manipulate their trunk to control the magnitude and direction of the GRF to assist knee flexion when their devices are not powered. Another interesting aspect indicated by the results during ramp ascent, was the reduced external flexion moment acting around the hip during early stance when using the 3R80 knee. Hence, it can be reasoned that the increased internal musculature extension moment around the hip on the prosthetic side, when the wearing the Orion, is indicative of the greater effort required from Participant A to pull him-self up the ramp. These hypotheses will be further evaluated by considering the intersubject hip and knee moments during ramp ascent in the following statistical results and discussion chapter. The inter- and intra-subject statistical summary of the knee moments on initial contact are provided on page 170-174 of the statistical treatment of results chapter.

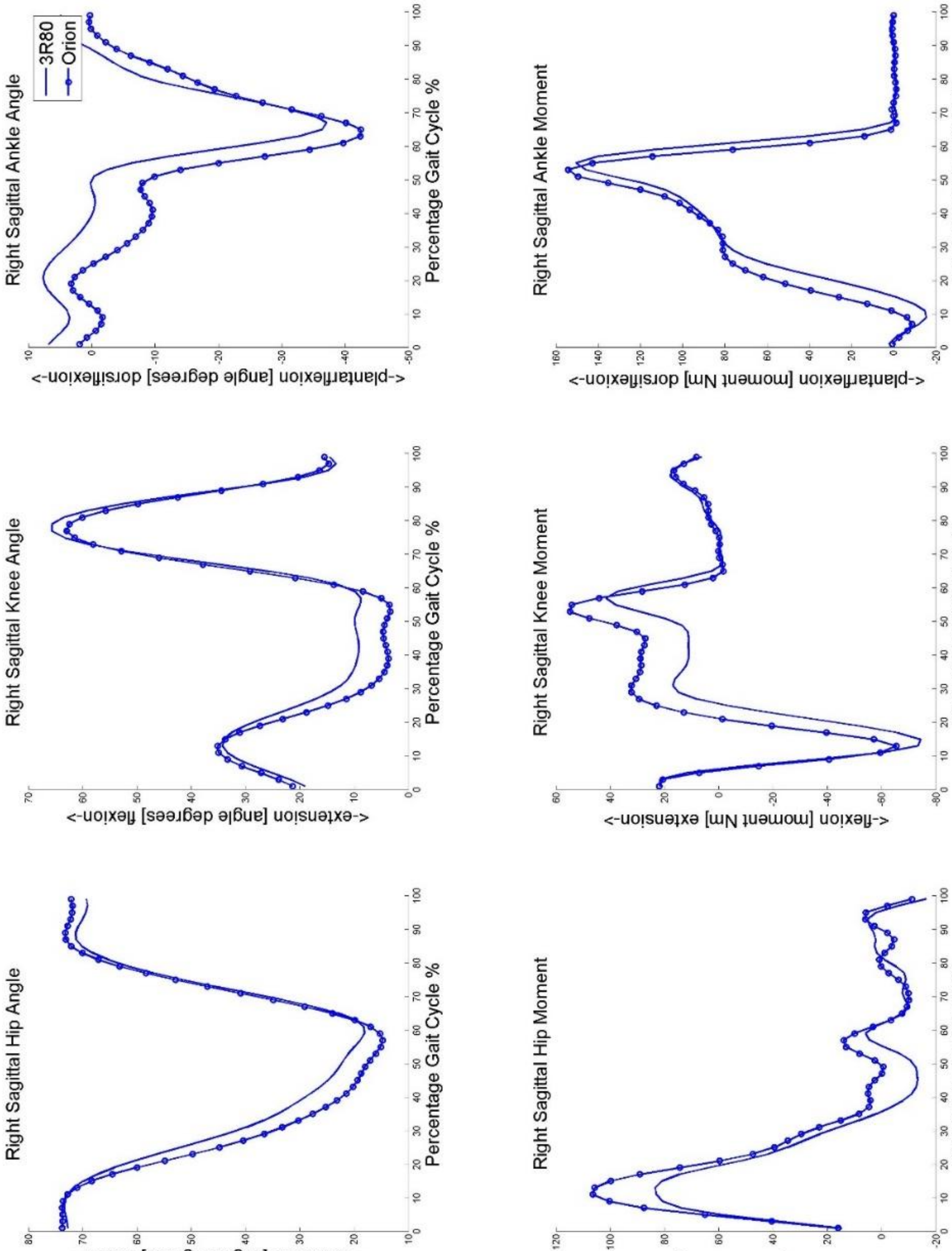


Figure 7.9 Participant (A) contralateral limb kinematics and kinetics – Ramp ascent

During ramp ascent, the kinematics and kinetics of the contralateral limb, Figure 7.9, are similar to the outcomes of the normal control used in this study. On initial contact, their contralateral knee was already flexed. The moment control around the knee then highlights the fact that they were using their musculature to maintain further controlled knee flexion and then extension.

An observable difference with respect to the contralateral hip moment after mid-stance is the maintained thigh flexion with respect to the pelvis (Figure 7.9). This indicates that the participant was compensating for their prosthetic limb by using their trunk, and leaning forward to move their thigh into a position of greater flexion with respect to the pelvis. This moment control suggests that the thigh musculature is holding the thigh in position by means of an isometric contraction, which is maintained by active muscle effort.

Additionally, the action of flexing the trunk during contralateral limb stance, when the prosthetic side is in swing, will reduce the flexion moment that acts around the prosthetic knee on initial contact. However, as highlighted by Participant A, the minimal internal thigh flexion moment also suggests that the fall of the body was being controlled in order to minimise the expected prosthetic load on initial contact. Hence, the GRF magnitudes and knee moment patterns will be used to assess the initial contact confidence, as statistically summarised on page 173A. The power developed by the residual musculature and contralateral limb, during ramp ascent and while using the Orion knee, are given on Figure 7.10. The results are as expected, and were very similar to the outcomes when wearing the 3R80 knee.

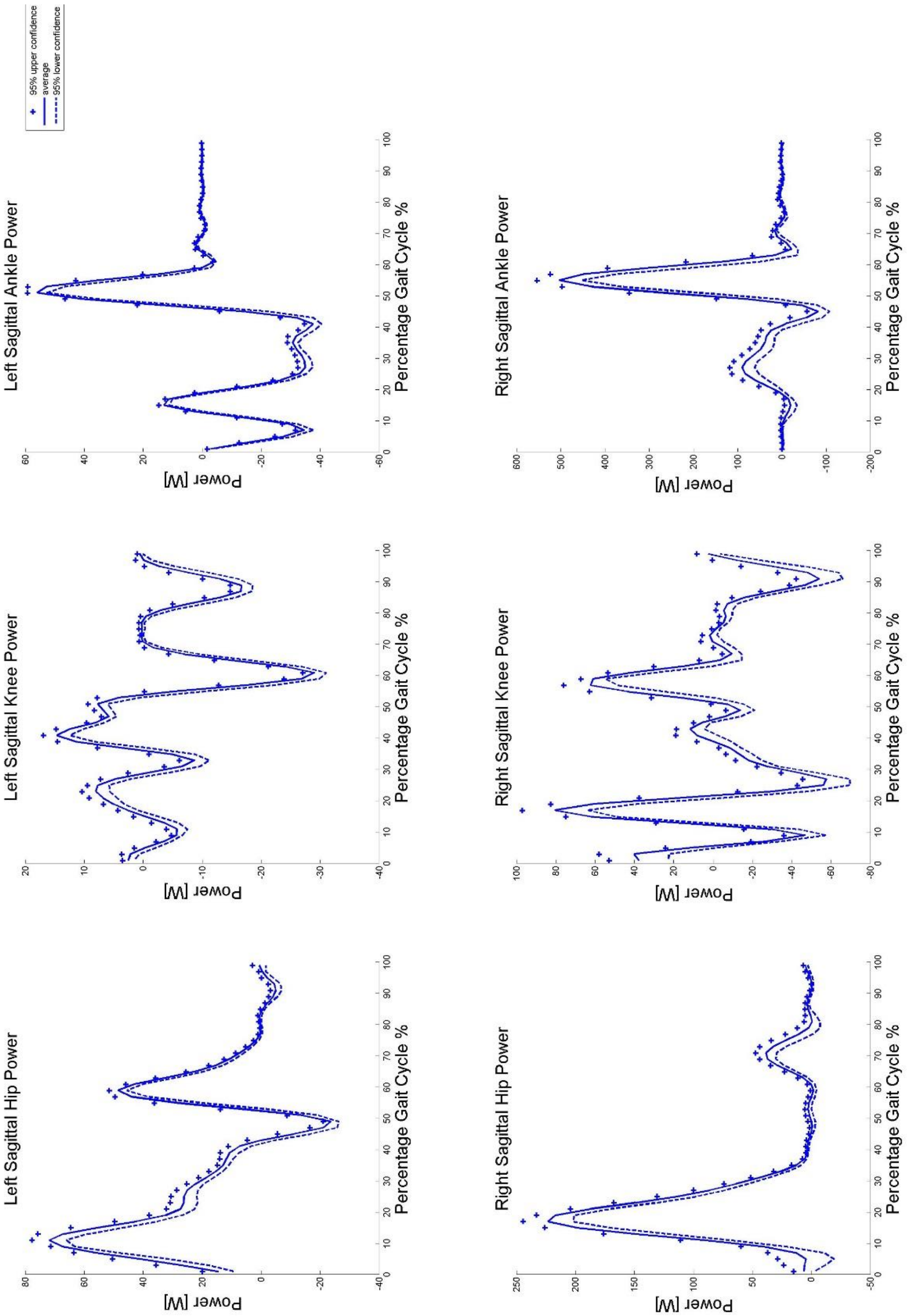


Figure 7.10 Participant (A) prosthetic (Left) and anatomical (right) powers – Ramp ascent (Orion)

Consequently, only the Orion results are presented here; however, a full set of participant result are given in appendices.

As might be expected, the mechanical power developed by a biological ankle is greater than the power developed around the prosthetic ankle joint – indeed, it is approximately ten times greater. However, as described for level ambulation, there was an instance of positive work done around the prosthetic ankle during the toe-off period. However, while participant A ascended the seven degree ramp, neither the prosthetic nor the contralateral knee provided the same magnitude of output (approximately ¼ of) relative to the ankle or thigh. The peaks of the power trace representing the biological knee were as expected, though – of greater magnitude than the peaks of the prosthetic knee (50 versus 10 W).

Another noteworthy feature seen during the swing period of level walking was the two double troughs of power absorption around the knee, which are presented on Figure 7.10. This outcome highlights that the damping response used by the prosthetic knee prevents excessive knee flexion at toe-off, as well as preventing the knee extending too rapidly towards the end of swing. This indicates that the energy analysis described on page 174A of the statistical treatment of results summary is the most appropriate method to analyse the involuntary response.

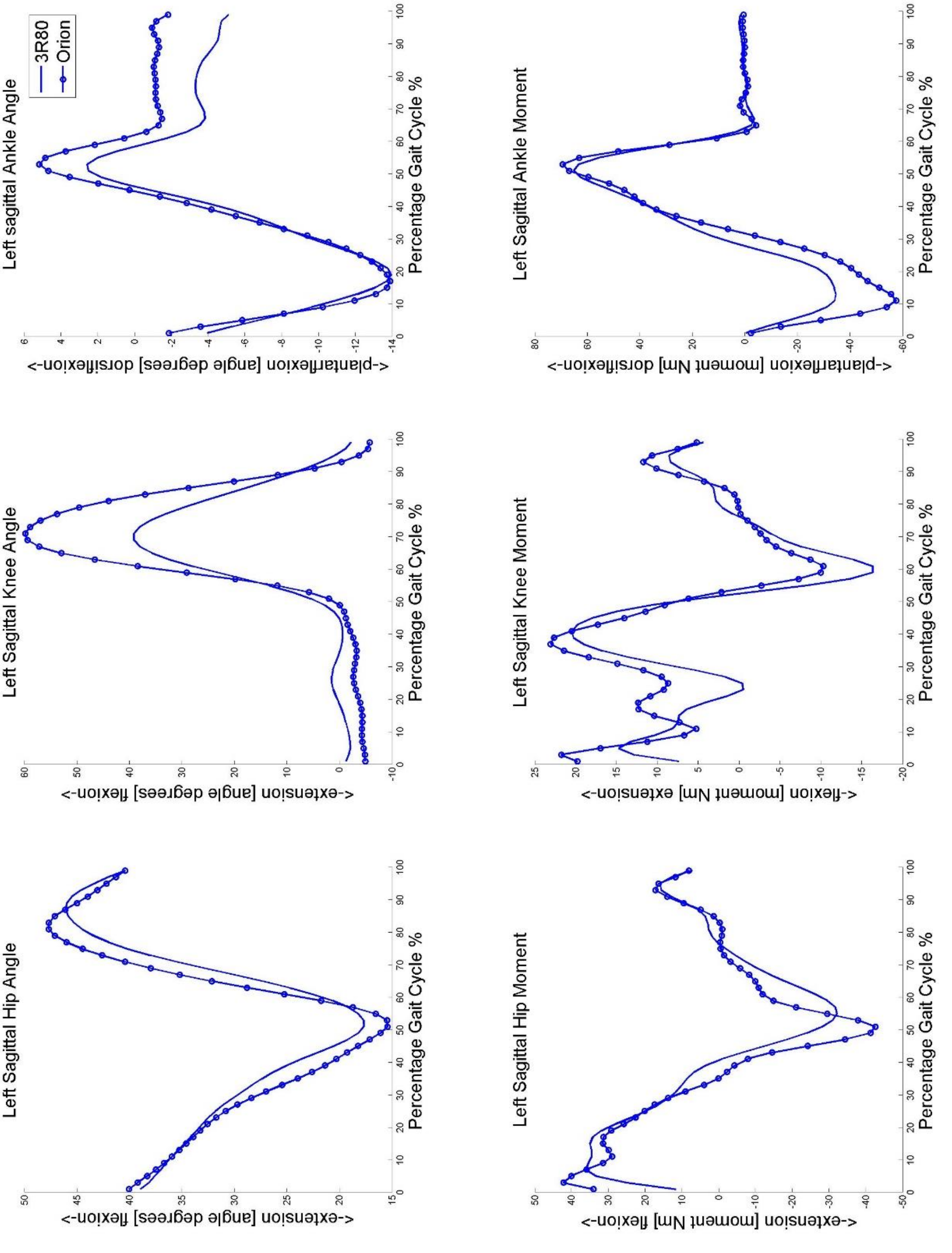


Figure 7.11 Participant (A) prosthetic limb kinematics and kinetics – Ramp descent

7.5 RAMP DESCENT (PARTICIPANT A)

As has already been described, during level ambulation and ramp ascent participant A was unable to flex their knee during stance, and again a similar pattern was observed during descent. Because, the prosthetic knee was not inherently stable; therefore compensations are expected by the residual limb thigh musculature. Figure 7.11 illustrates the participant maintained a slight extension moment around the knee during stance by maintaining thigh musculature extension for early and mid-stance stance. Indeed in general, it was observed, and as represented by the kinetics and kinematics, that the participants would only allow their prosthetic knee to flex once their leading contralateral limb made initial contact. As illustrated by Figure 7.11, the external moment acting around the prosthetic knee was generally pulled into rapid flexion during the late stance period. Moreover, as demonstrated by the other participant results, which will be discussed later, the moment control around the knee and ankle at this instance generally varied depending on whether the participant was a restricted or an unrestricted outdoor ambulator. These differences will be highlighted for the other participants, and will be used to determine whether or not the Orion knee offers inherent beneficial voluntary control for the prosthetic user with poorer ambulatory skills.

When using the evaluation prostheses, though there are limited kinematic and kinetic differences on the prosthetic side, there is a notable difference on the contralateral side, as described above for level ambulation. Again, this implies that compensations are made to control body posture, in order to maintain optimal control of the prosthesis.

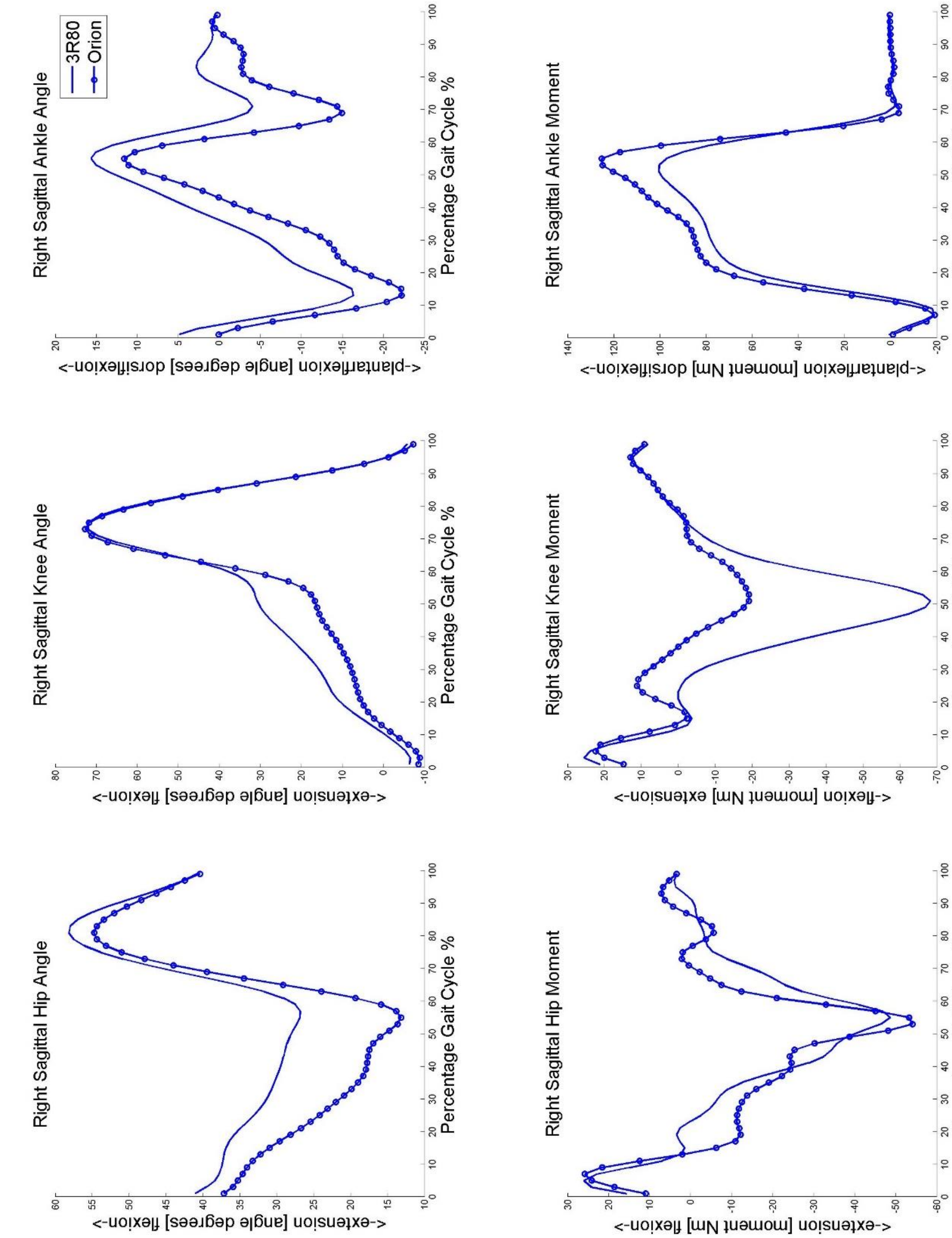


Figure 7.12 Participant (A) contralateral limb kinematics and kinetics – Ramp descent

During descent, the biological knee gradually gains flexion magnitude, which implies that the body is lowered with caution, to prevent the leading prosthetic foot experiencing a sudden impact on initial contact. Hence, there is no flexion and extension pattern as seen with the normal control. However, another noteworthy outcome of this motion was demonstrated when the 3R80 knee was fitted to the prosthesis, as the participant experienced a contralateral knee flexion moment of greater magnitude (Figure 7.3). This appears to indicate that, despite having similar hip moment patterns, the inherent functional differences of the knee types had a considerable effect on the gait patterns. Again, as already suggested by the results of this participant, the knee moment when the prosthetic side makes initial contact will be used to infer whether the 3R80 or the Orion knee improves the stability of the prosthetic side. These results will also be compared with the mechanical power developed by the contralateral hip musculature to determine whether the knee stability results and the contralateral musculature effort patterns are intertwined.

It is also illustrated by Figure 7.12 that, with respect to the pelvis, the thigh was in a greater state of flexion during the early part of the gait cycle when the 3R80 was fitted to the prosthetic side. Comparing the contralateral and prosthetic side hip flexion and extension angles highlights the fact that the participant also walked with improved symmetry while wearing the 3R80.

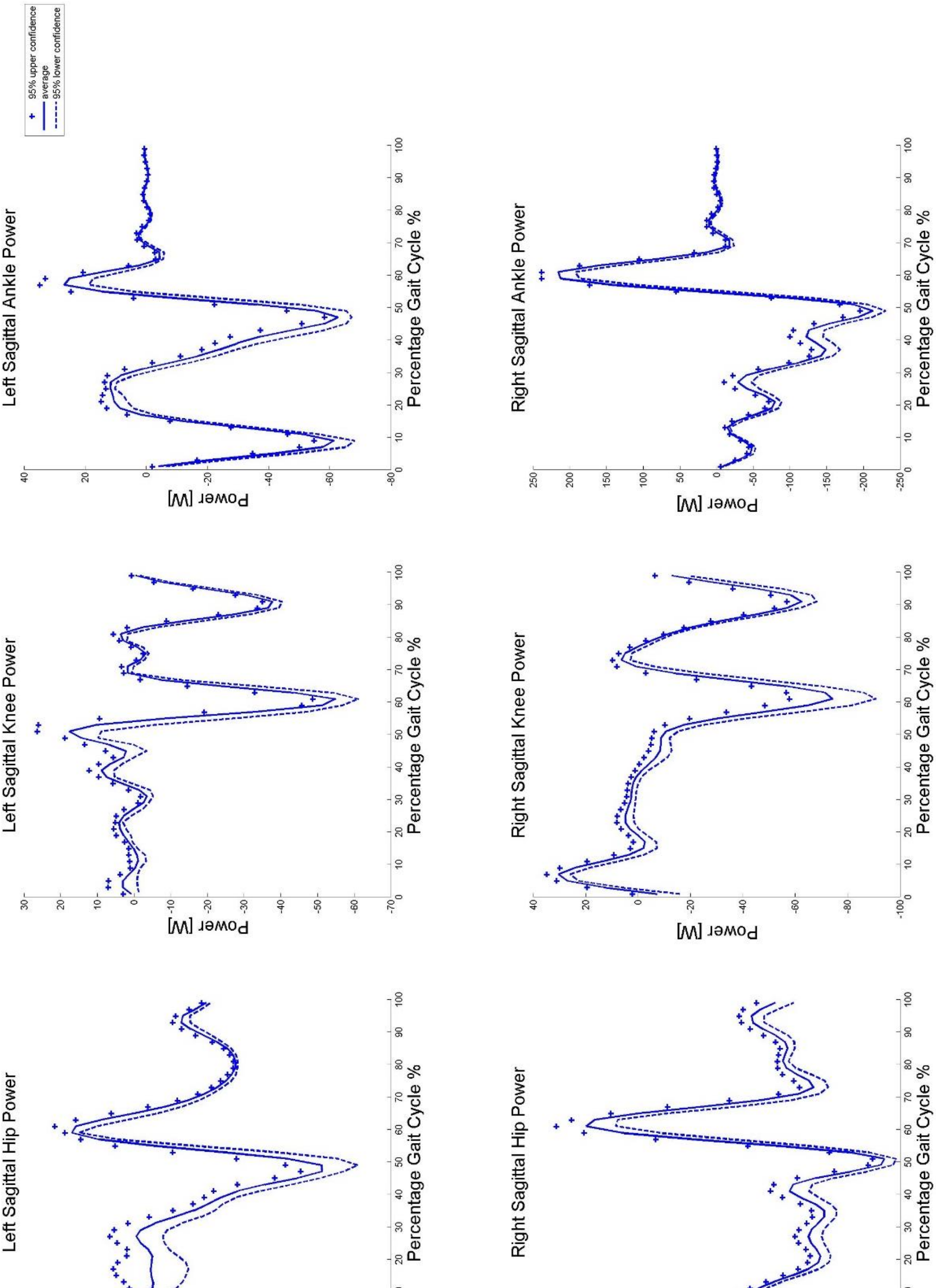


Figure 7.13 Participant (A) prosthetic (Left) and anatomical (right) powers – Ramp descent (Orion)

As with ramp ascent, the power traces of the 3R80 and Orion were of a similar pattern during ramp descent, and consequently only the Orion results are presented (Figure 7.13). Again, as seen during level ambulation and ramp ascent, substantial mechanical power was only developed by the biological ankle of the contralateral limb relative to the prosthetic side during the push-off instance. However, the peak push-of power is less during ramp descent (200W) than it is during ramp ascent (500W), and is actually more comparable with level ambulation.

However, unlike level ambulation, Figure 7.6, and ramp ascent, Figure 7.10, there are two troughs of power absorption around the biological knee during swing. During level ambulation and ramp ascent, this pattern was only observable around the prosthetic knee. Hence, this outcome appears to illustrate that the biological knee extension, as well as the prosthetic knee extension, moment was controlled against the pull of gravity during descent.

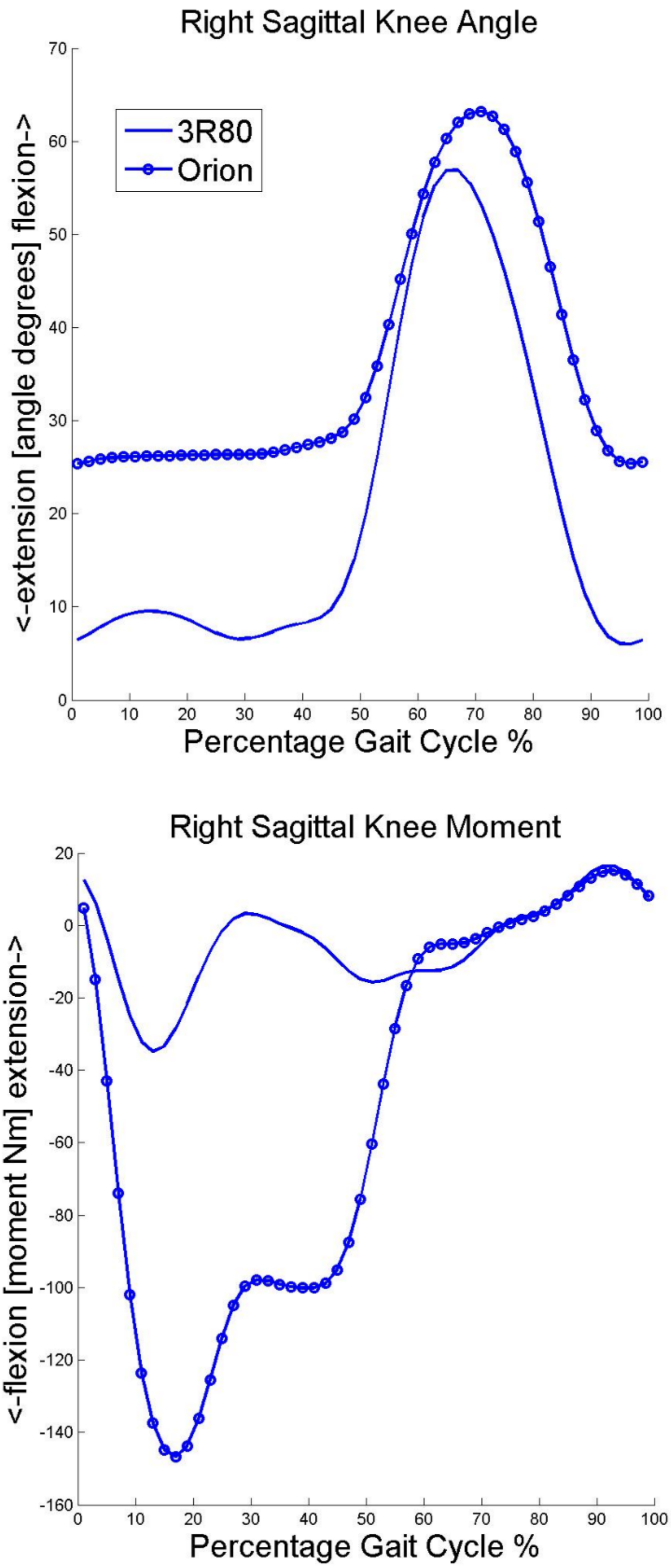
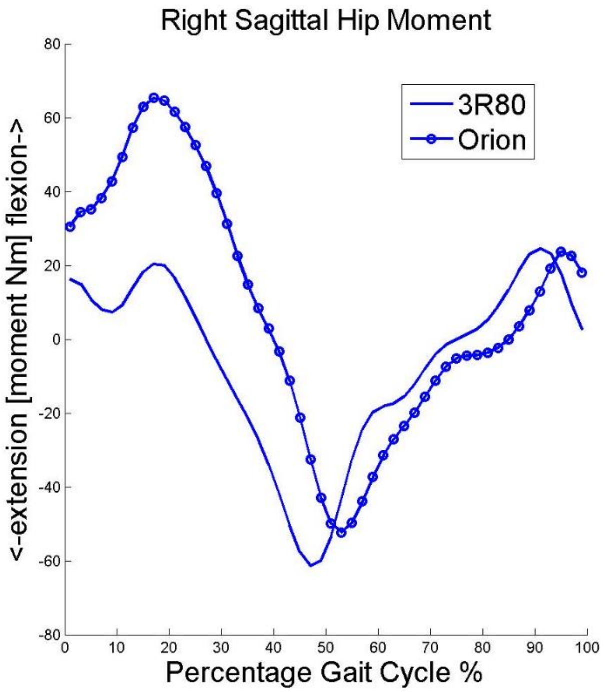


Figure 7.14 Participant B – Prosthetic side knee flexion and extension angle (top) and moment during level ambulation (bottom)

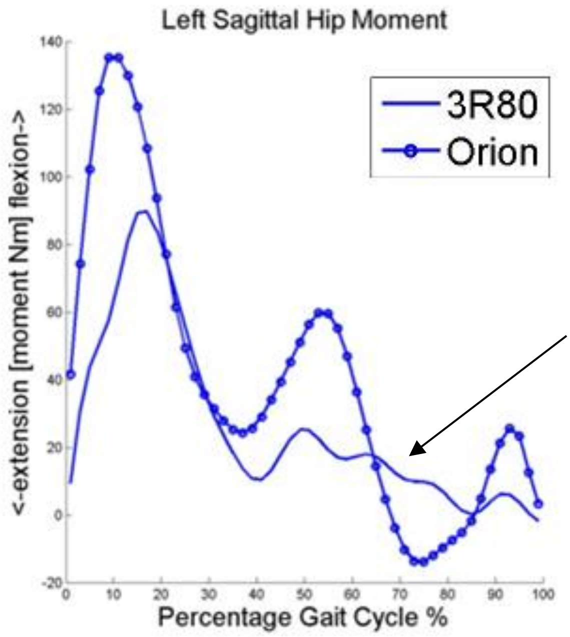
7.6 PARTICIPANT (B) RESULTS

Participant B was considered to be one of the restricted K2 outdoor ambulators, and suffered from a hip flexure contracture, lateral trunk bending and a long prosthetic step, which clearly influenced the kinematic and kinetic patterns during ambulation. When walking on the level, the maximum external stance flexion moment while wearing the Orion was greater (-140Nm) than it was while wearing the 3R80 (-40 Nm), as illustrated by Figure 7.14. Clearly, this was influenced by the fact that, during ambulation, the Orion knee was approximately 15 degrees more flexed when compared to the 3R80, something which would have stemmed from the yield value settings selected by the participant during knee calibration. However, this pattern was also observed during ramp ascent and descent, suggesting that the inherent function of the knee, and the manner in which it is controlled by the user, should both be investigated. When compared to participant A, Participant B was not a competent ambulator, especially, when considering that they could not ascend and descend the ramp without using the handrail when wearing the Orion knee. Participant B relied on the knee resistance to provide security during stance, and allowed a flexion moment to act around the knee instead of an extension moment. At the late stance instance, during heel rise, the flexion moment around the knee was actually reduced on swing initiation. This outcome will therefore be discussed and developed further to ascertain whether this result is indicative of the having greater voluntary control over the Orion knee. It should also be noted that this outcome was not evident from the results of participant A, the unrestricted ambulator.



The external hip flexion moment using the 3R80 knee relative to the Orion knee on the prosthetic side was reduced.

Figure 7.15 Participant B external hip flexion and extension moment during ramp ascent on the prosthetic side



The internal hip flexion moment towards the end of stance suggests that the hip extensors are being used to minimise the impact of the leading prosthetic limb (Figure 7.17).

Figure 7.16 Participant B external contralateral hip flexion and extesion moment during ramp ascent

During ramp ascent, and from observation of the graphical results as shown for participant B on Figure 7.15, the early stance sagittal hip moment on the prosthetic is reduced when using the 3R80 knee compared to the Orion knee. As the knee should be inherently stable during ramp ascent, the improved hip moment shape using the Orion knee suggests that the musculature is being used to better effect. Therefore, the statistical analysis page , and discussion page 203, will be used to ascertain whether this effect was seen by other participants, and what the outcome suggests.

When comparing the contralateral hip moment during ramp ascent with level ambulation and ramp descent (Figure 7.16), it appears that the contralateral hip musculature was being used to control the fall of the body COM, and therefore reducing the impact experienced by the leading prosthetic limb on initial contact (Figure 7.17). Hence, the contralateral musculature effort will be analysed statistically to determine how confident the participants were when ambulating with either test prosthesis. Of further interest is the fact that this trunk control was noted during stair descent for the normal control, therefore suggesting that, in situations where safety may be compromised, able-bodied individuals control the fall of their trunk in a similar manner to maintain and/or maximise their stability.

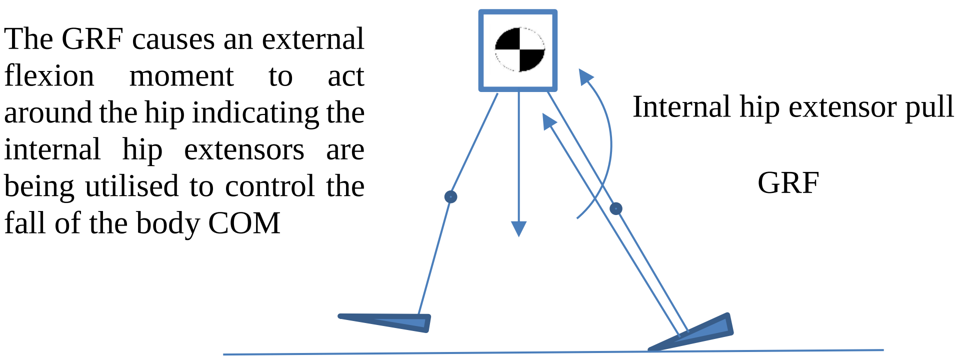


Figure 7.17 Hip flexor musculature before initial contact of prosthetic leading limb.

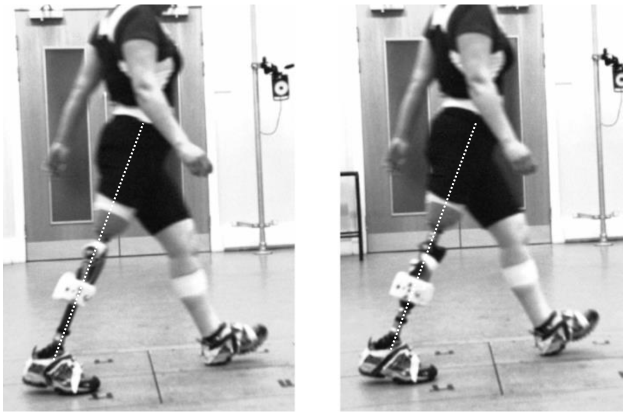


Figure 7.18 Level ambulation 3R80 (left) & Orion (Right)

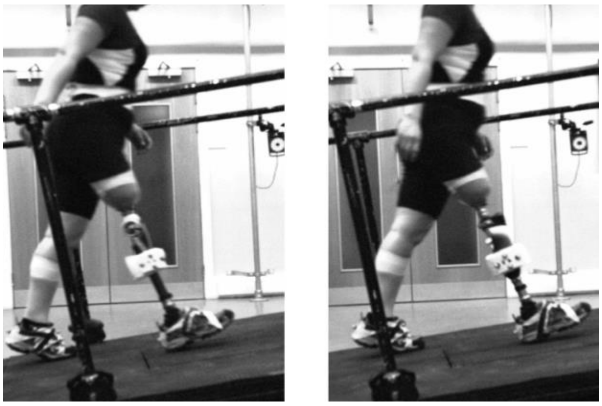


Figure 7.19 Ramp ascent 3R80 (left) & Orion (Right)

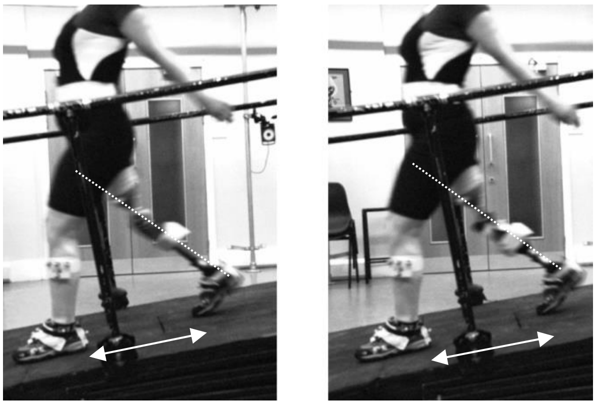


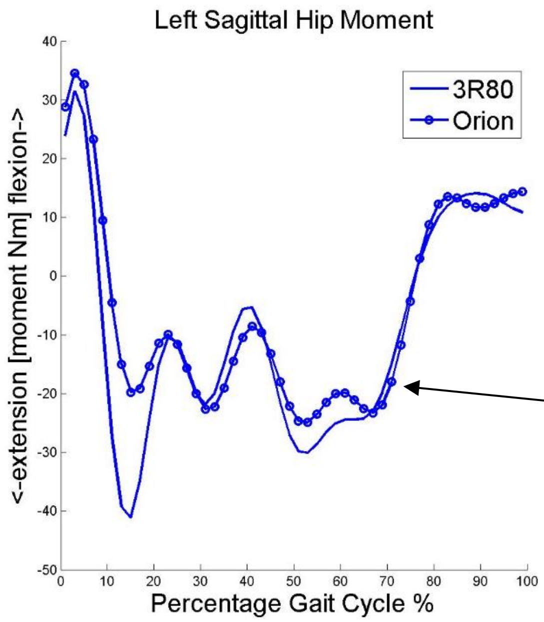
Figure 7.20 Ramp descent 3R80 (left) & Orion (Right)

7.7 PARTICIPANT (C) RESULTS

Participant C was considered a K3 unrestricted outdoor ambulator, other than the compensatory motions that included lateral sway towards their prosthetic side and vaulting during swing on their prosthetic side. The only striking and immediate difference between the kinematics on both the prosthetic and contralateral side is the increased flexion angle of the thigh relative to the pelvis during all activities using the Orion. Therefore, the moment control of the thigh musculature will be used to investigate whether the evaluation knees offered any differences in voluntary control.

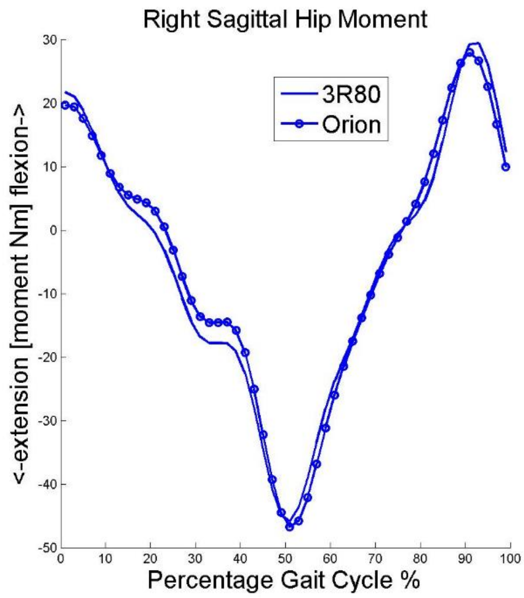
Inspection of Figure 7.19 reveals that, during ramp ascent and at the same point in the gait cycle, the participant throws their arm back with increased magnitude when using the 3R80 in order to stabilise their knee. Hence, this arm motion will effect trunk posture, and this subjective pictorial evidence appears to show that the increased thigh flexion using the Orion knee is “improved”, when compared to the 3R80 knee. However, during level ambulation and ramp descent, as shown in Figure 7.18 and Figure 7.20 respectively, there appears to be no obvious difference of motion the while participant wore both evaluation prostheses. Therefore, the kinematic outcomes have to be relied on to quantify these differences.

The external moment patterns around the hip joint on the prosthetic side, during level walking and ramp ascent, are similar to the patterns of the able-bodied control. However, the hip moment patterns around the contralateral side during ramp descent indicate that, as was seen with participants A and B, participant C is also making body compensations to prepare their leading prosthetic limb for initial contact (Figure 7.21).



No internal hip flexion towards the end of stance. Suggesting that compensation are being made during ramp descent before initial contact of the prosthetic side.

Figure 7.21 Particiapnt C External hip moment contol around contralateral side during ramp descent with Orion and 3R80



The external flexion moment acting around the hip during both stance and swing were similar using the two prostheses types on the prosthetic side for participant C.

Figure 7.22 The external sagittal hip moment for participant C during ramp ascent on the prosthetic side

As with participants A and B the contralateral hip musculature was evaluated statistically to assess these hypotheses (page). However, the hip kinetics did not imply that there is a particular improvement in additional felt security or confidence using the evaluation prostheses (Figure 7.22).

Finally, on comparing the knee moments when wearing both the 3R80 and the Orion knees, the patterns are very similar in magnitude and direction. During ramp descent, the participant allowed a flexion moment to act around both knees during stance (page 256). This therefore suggests that they would have the confidence to utilise any prosthesis that was given to them. Hence, this appears to show that the functional differences offered by the two knee types did not have a profound effect on the voluntary control exerted by the participant over the prosthetic knee. This outcome is similar to the results of participant A, and therefore implies that the respective functionalities of the 3R80 and the Orion may offer distinct advantages to particular user groups.

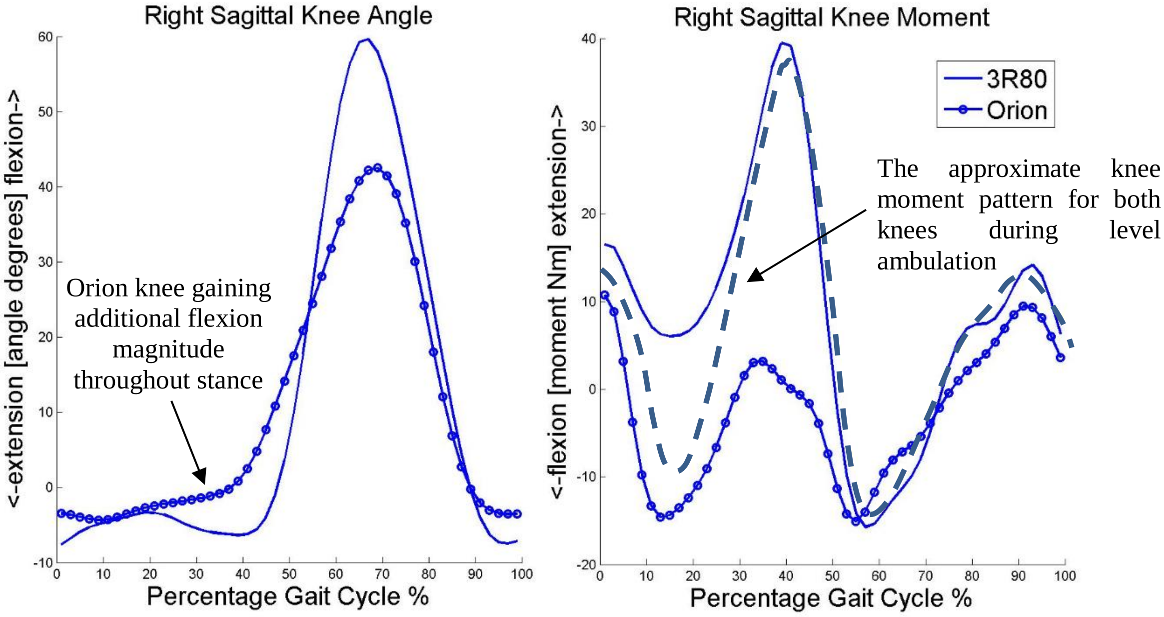


Figure 7.23 Participant D's prosthetic knee moments and angles during ramp descent

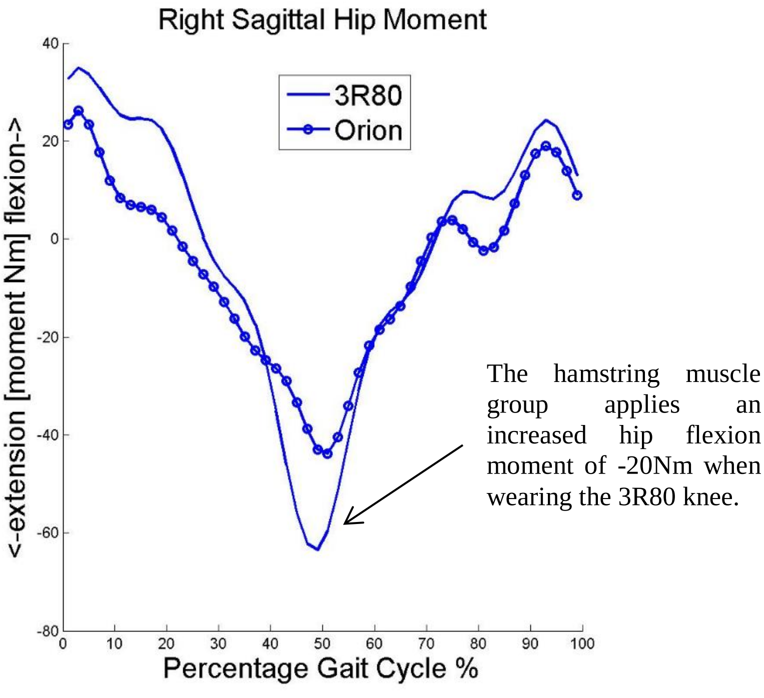


Figure 7.24 Participant D hip moment around the hip on the prosthetic side during ramp descent

7.8 PARTICIPANT (D) RESULTS

Participant D was considered one of the restricted K2 outdoor ambulators, and when ambulating outside he used a walking stick. Therefore, it was expected that if the Orion knee could offer additional benefits during the ramp activities, they would be evident during ramp descent. At the end of stance, and when using the Orion knee, the participant did not initiate swing with a flexion moment as one was already acting around the knee, and had been since an earlier part of the stance phase (Figure 7.23). Instead, the Orion knee becomes increasingly flexed, and appears to show that the participant experienced improved felt security during ambulation. Conversely, when wearing the 3R80 prosthesis, the knee angle and moment illustrate that the participant forces the knee to maintain maximum extension before initiating flexion for swing during the final instance of stance. The additional thigh extension moment during late stance, as the 3R80 knee extension moment peaks, essentially illustrates that the residual limb musculature is being used to maintain the extension of the knee.

This result was also displayed by the kinematic and kinetic outcomes when Participant B descended the ramp, and was not evident when the two unrestricted ambulators, Participants A and C, descended the ramp. Consequently, these graphical outcomes will be further discussed and compared in order to comment on the difference of voluntary control between the 3R80 and the Orion knee when the knee stability is compromised.

As seen with the previous participants (A, B & C), the contralateral limb demonstrated that, during both level ambulation and ramp descent, compensatory actions are made to prepare the prosthetic limb for initial contact.

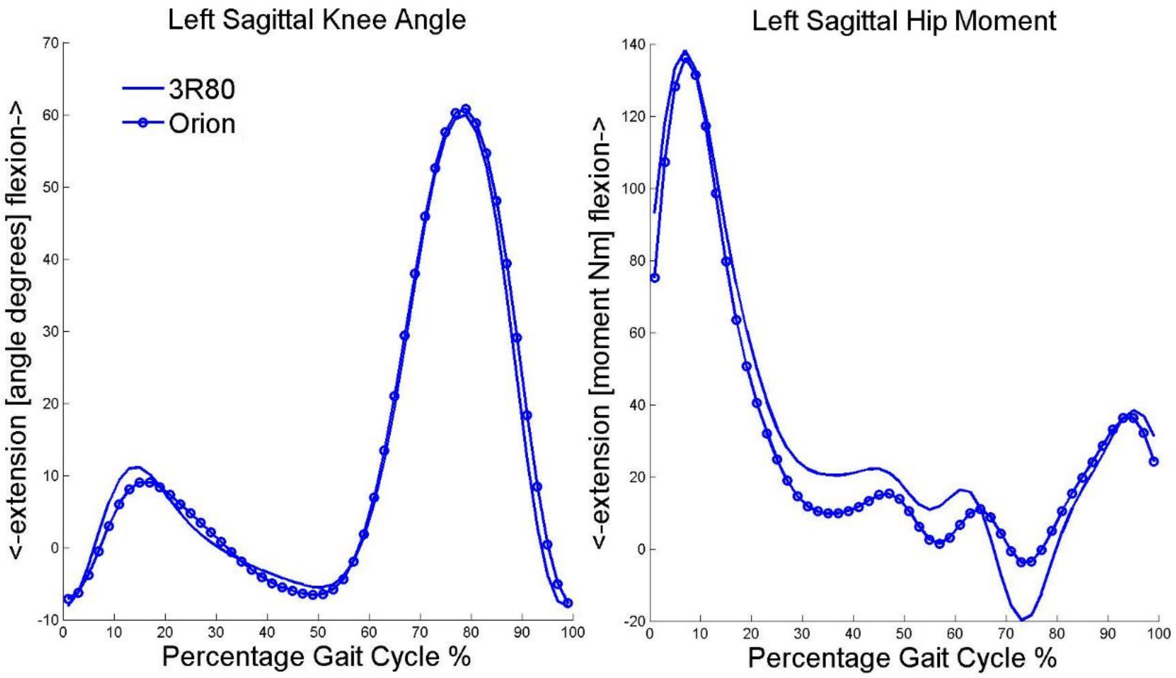


Figure 7.25 Participant D contralateral knee flexion/extension angle and moment during level ambulation

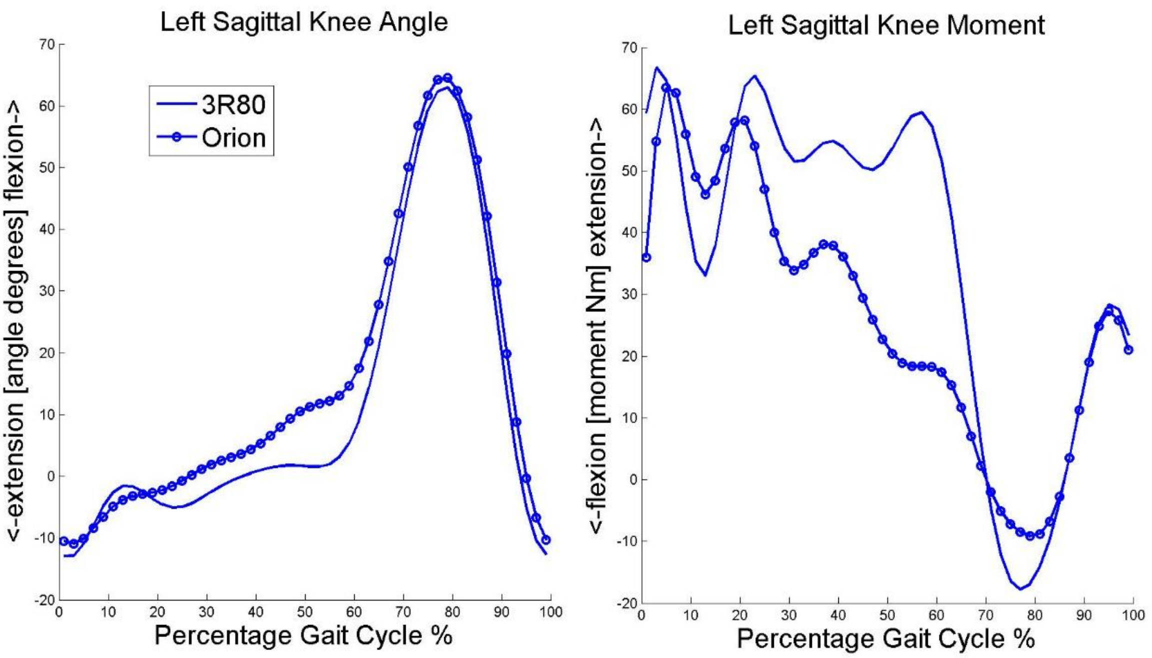


Figure 7.26 Participant D contralateral knee flexion/extension angle and moment during ramp descent

Participant D appears to use their thigh flexion musculature to use their thigh flexion musculature in such a way as to lower their body with caution during both level ambulation (Figure 7.25) and ramp descent (Figure 7.26). However, it is during ramp descent that differences in the compensatory actions become more pronounced. When walking on the level the contralateral limb has sufficient musculature strength to control the fall of the body and maintain normal knee flexion and extension throughout stance. However, the knee moment during descent illustrates that it is only while using the 3R80 knee that the participant allows the extension moment around the contralateral knee to reduce before initial contact with the leading prosthetic side. Throughout stance, it appears that, to prepare the leading prosthetic limb for initial contact, the knee becomes increasingly flexed as the body is lowered. This may reveal that the participant feels a greater level of security when they are ambulating with the Orion knee. Furthermore, as this moment pattern control has been seen in relation to the other restricted outdoor ambulator participants (A, B and C), the contralateral hip compensations will be compared qualitatively to determine whether there are any general differences between using the 3R80 and the Orion knee. These qualitative outcomes will also be compared with the statistical summary of initial contact knee moment results on page 170-174, to determine whether it is possible to state that the knee stability results are directly related to contralateral outcomes.

As Participant D was also able to descend the ramp with a flexion moment acting around the Orion knee, without holding the handrail, this outcome will also be qualitatively compared to a similar outcome that was demonstrated by Participant B's results. The reason for this is that it appears to suggest that these restricted ambulators are able to exert additional voluntary control over their knees.

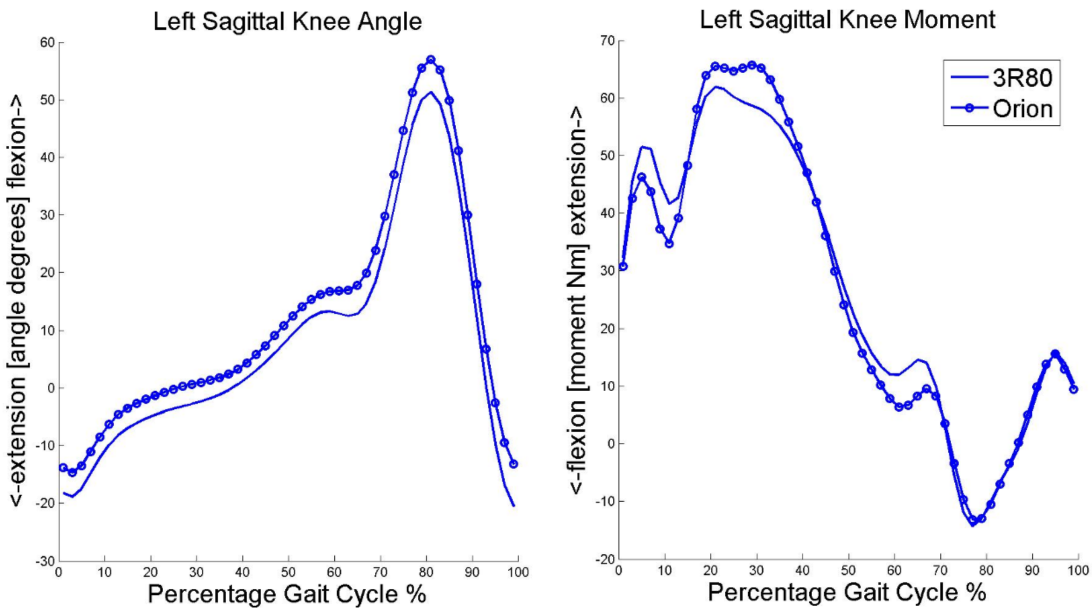


Figure 7.27 Particpant E contralateral knee angle and moment descending a 7 degrees ramp descent

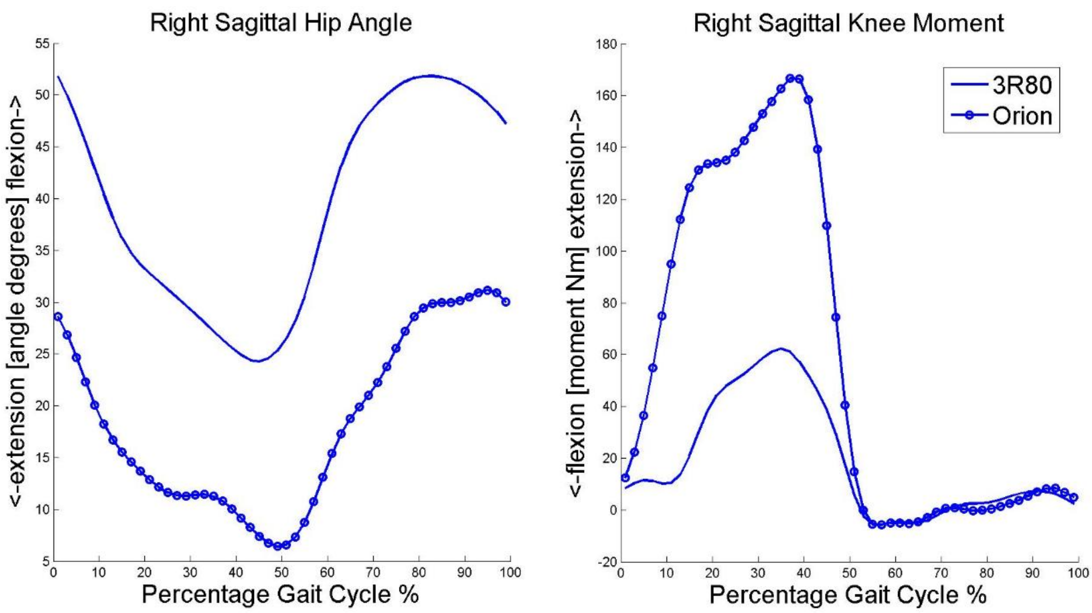


Figure 7.28 Participant E hip kinematics on the prosthetic side and prosthetic knee kinetics during ramp ascent

7.9 PARTICIPANT (E) RESULTS

Participant E was considered one of the restricted K2 outdoor ambulators, and during level ambulation both the kinematics and kinetics illustrate that the participant has a similar level of voluntary control over both prosthesis types. There is no prosthetic knee flexion during stance, and the kinematics and kinetics on the contralateral side indicated that both knee types were used in a similar manner. For example, during ramp descent, and as was demonstrated by the other participants, the internal thigh extension musculature was utilised during late stance to stabilise the contralateral knee before initial contact of the leading prosthetic side (Figure 7.27). This provides further evidence that contralateral compensations and knee stability on initial contact while using the 3R80 and Orion knees should be compared and discussed. However, it was the prosthetic side during the ramp activities that appeared to show that different compensations were adopted when wearing the 3R80 and Orion knees.

During ramp ascent, the thigh kinematics and knee kinetics demonstrated that when wearing the 3R80 knee the participant's body truck COM was flexed (Figure 7.28). Conversely, when wearing the Orion knee their thigh was extended by an additional 20 degrees with respect to the trunk when compared to wearing the 3R80 knee, even though this may be used to suggest that the Orion knee provided inferior stability, as the extension moment around the knee during stance is considerable. The participant used the handrail during stance wearing both knees, and as a result, the kinematic and kinetic outcomes are skewed. Consequently, it is difficult to extract meaningful outcomes from this activity for this participant.

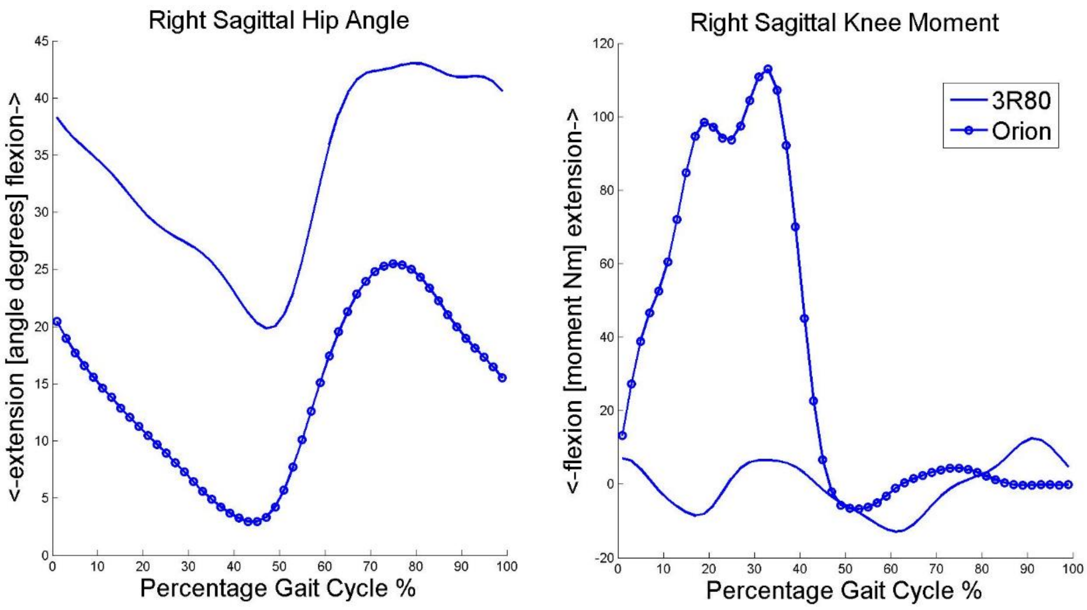


Figure 7.29 Participant E hip kinematics on the prosthetic side and prosthetic knee kinetics during ramp descent

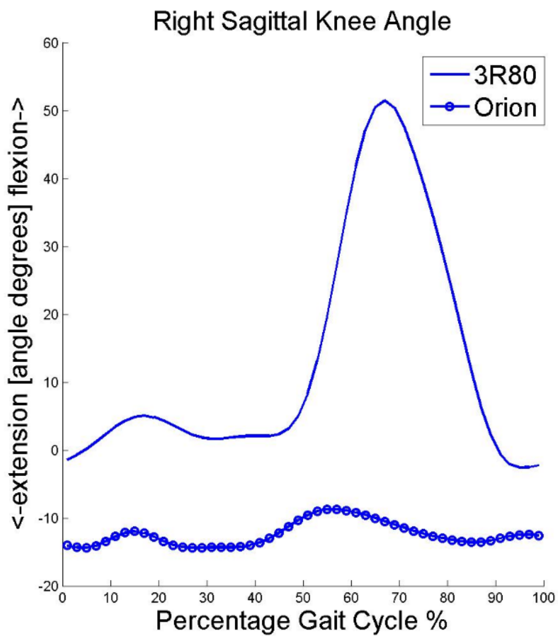


Figure 7.30 Participant E prosthetic knee kinematics and kinetics during ramp descent.

During ramp descent, the kinematics and kinetics displayed similar outcomes: wearing the 3R80 knee, the trunk assumed a position of greater flexion with respect to the thigh. The 3R80 knee moment during stance acted to extend the knee, while no moment acted around the Orion knee (Figure 7.29). Furthermore, as displayed by the knee kinematics, it appears that the knee was simply used as a static body support (Figure 7.30). Again, as with ramp ascent the handrail was used, which prevents effective use of the outcomes in the evaluation of the voluntary control and involuntary response of the 3R80 and Orion knees.

These idiosyncrasies may be the result of participant E being a C-leg user, and therefore the participant may have required a longer acclimatisation period. However, as described, the participant used the handrail during the ramp ambulation activities, and consequently the results during this activity were skewed significantly. This outcome was surprising considering the similarity of results on the contralateral and prosthetic side during level ambulation. However, these outcomes may suggest that the participant was not confident during the ramp activities and therefore may not be confident in an outdoor environment. Consequently, the effect this set of results has on the statistical analysis, considering the small sample size of six, should be borne in mind.

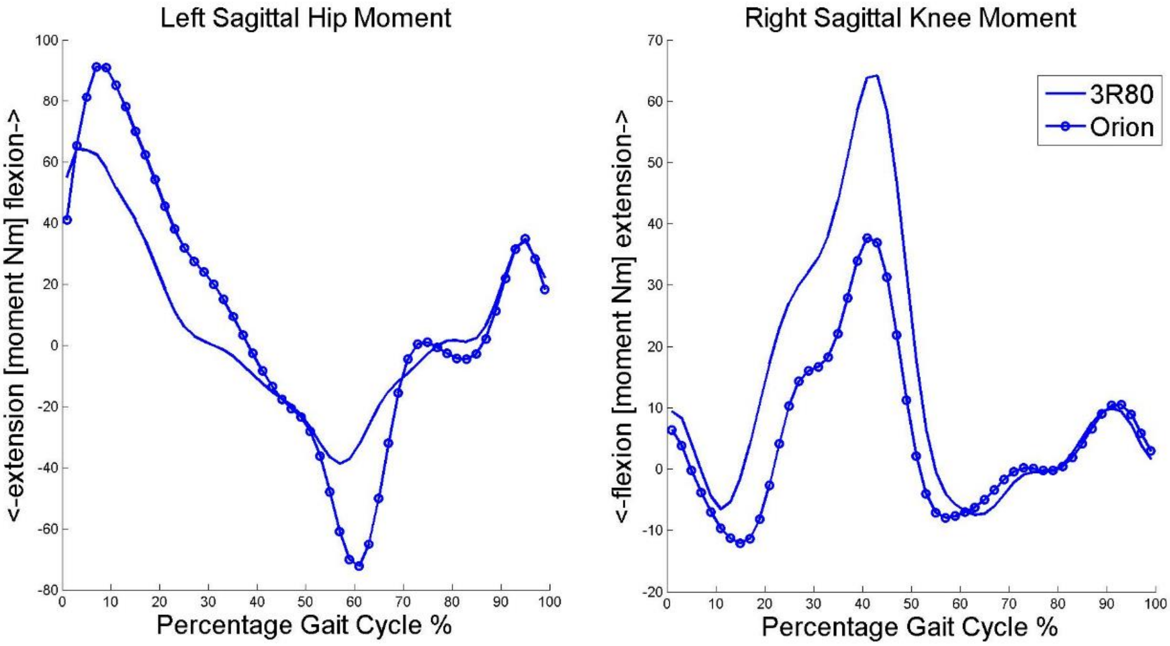


Figure 7.31 Participant F the moment around the hip on the contralateral side and moment around the knee on the prosthetic side

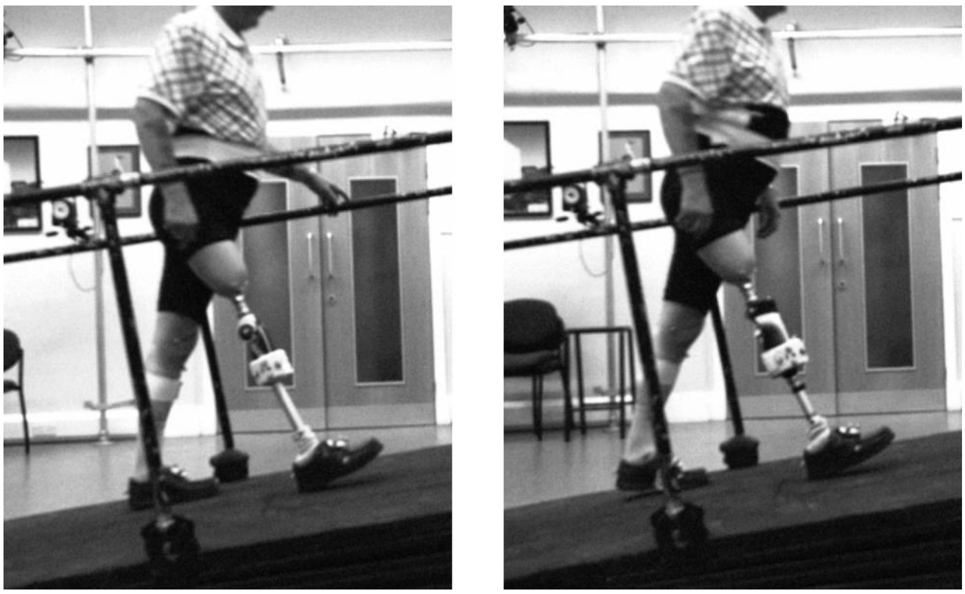


Figure 7.32 participant F ascending the ramp with the 3R80 (left) and Orion knee (right)

7.10 PARTICIPANT (F) RESULTS

During level ambulation, the hip moment on the contralateral side, and the knee moment on the prosthetic side, illustrate differences that may suggest improved control using the Orion knee. The late stance knee 60 Nm moment peak using the 3R80 knee, compared to the lower 40 Nm peak using the Orion (Figure 7.31), appears to indicate that the participant feels an increased level of stability using the Orion knee. Furthermore, the external hip moment on the contralateral side displays symmetrical peaks of flexion and extension, in comparison to the “flatter” moment peaks using the 3R80. However, as with the other participants, the ambulation strategy adopted outwith level walking highlighted greater differences when wearing the evaluation prostheses.

During ramp ascent, Figure 7.32, the camera evidence displays that Participant F felt more confident and stable with the Orion than with the 3R80 knee as they only used the handrail when ambulating with the latter. The thigh kinematics on the prosthetic side show that the residual limb assumes a position of greater thigh flexion with respect to the trunk while wearing the Orion knee (Figure 7.33). This outcome is also reflected by the thigh kinetics, where the peak residual limb flexion moment, when wearing the Orion knee during early stance, demonstrates more similarity with normal ambulation kinetics. This outcome appears to demonstrate that the residual limb musculature is being used with greater effect. Hence the statistical results of the hip musculature moment outcomes on initial contact page are used along with the qualitative discussion page 203, to determine whether it can be inferred that, even though the hip moment during ramp ascent is increased, the residual limb musculature is used more effectively using the Orion knee.

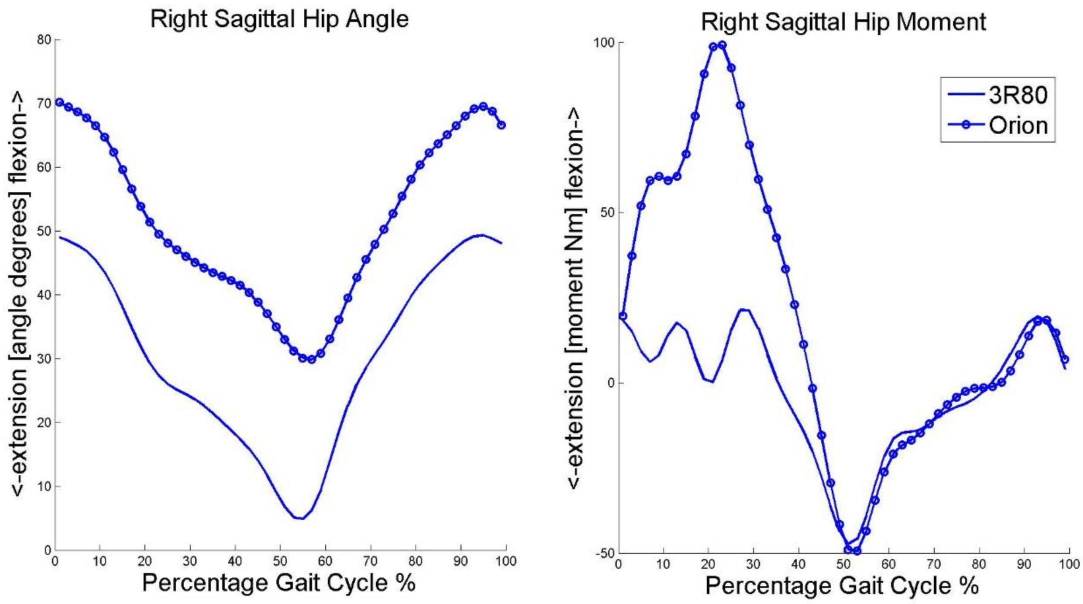


Figure 7.33 Participant F prosthetic side hip kinematics and knee kinetics during ramp ascent

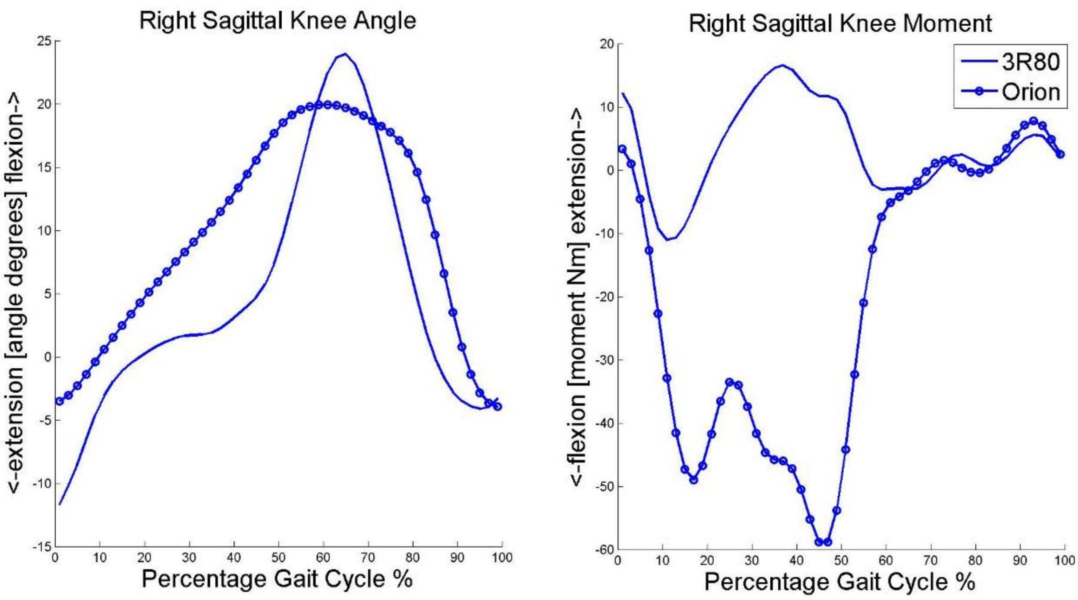


Figure 7.34 Participant F prosthetic side knee kinematics and knee kinetics during ramp descent

During ramp descent, Participant F also used the handrail for support when using the 3R80 knee but did not when using the Orion. These outcomes are also similar to those of participants B & D during ramp descent using the Orion knee, and appear to illustrate functional differences between the control of the Orion and the 3R80 knee. As the Orion knee gradually gains flexion magnitude during ramp descent while a flexion moment is acting around the knee, as illustrated Figure 7.34, this outcome highlights that the Orion user is able to control their knee resistance, allowing the Orion to support their body weight during descent. The kinematics and kinetics, when compared to the outcomes of the normal control, are not aesthetically similar, although they did allow this participant to descend the ramp with confidence.

7.11 SUMMARY

Individual case studies were presented for the participants to highlight both similarities and differences between the restricted (participants B, D, E & F) and unrestricted (participants A & C) outdoor ambulators. From this small sample size, the results suggest that the Orion functionality gave a certain group of participants (the restricted ambulators) additional knee stability when walking in situations that are more likely to cause knee instability. This pattern of results is intriguing as the outcomes are not from a large population. Hence, these results will be further analysed and discussed in chapter 9, after the results are presented statistically, in order to investigate these patterns of motion more thoroughly.

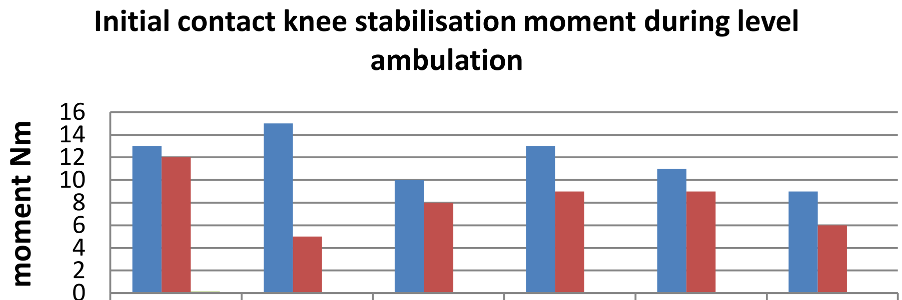
Another aspect of prosthetic knee control that is intertwined with the contralateral outcomes is prosthetic knee initial contact stability and contralateral compensation. Again, as with the voluntary control aspects of the Orion knee, it was during descent that the participants appeared to use their contralateral musculature to reduce the impact experienced by their leading prosthetic limb. Therefore, the statistical summary of initial contact knee moments will be compared qualitatively to determine whether it is possible to state that the observed difference using the 3R80 or Orion knee can be considered and improved.

When considering the involuntary response of the knee, it was both the knee flexion peaks and the power absorbed during swing that indicated that there is a difference in voluntary control between the 3R80 and the Orion. Therefore, in the following statistical summary chapter, the walking speed and the energy absorbed around the knee during swing are compared for all activities.

CHAPTER 8 SATISTICAL TREATMENT OF RESULTS

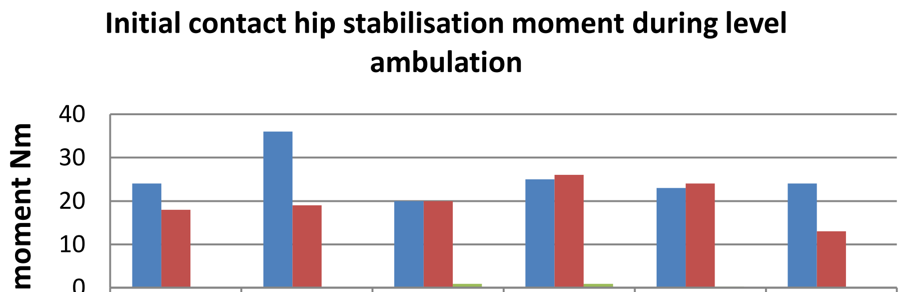
8.1 INTRODUCTION

In the previous chapter, individual case studies were presented for each participant in order to provide an insight into repeated inter-subject ambulation patterns. This approach was taken because the low statistical power of the study prevented the statistical analysis from revealing significant inter-subject patterns, as discussed on page 137-143. Essentially, it was expected that the group results would not show inter-subject statistical significance. Therefore, this chapter also presents intra-subject crossover results. This approach allowed the ambulation patterns to be assessed on an individual qualitative basis throughout the discussion of results in the preceding chapter. The inter-subject results chapter is arranged chronologically, and presents a statistical summary of the gait at initial contact and swing. These were identified as the critical periods of the gait cycle (as discussed in chapters 3 and 4), and will be used in the following discussion to highlight the voluntary control and involuntary response aspects of the 3R80 and Orion knees. Instances such as late stance/toe-off were discussed qualitatively, using graphical outcomes, in chapter 7. The statistical description begins with the intra- and inter-subject summaries of hip, knee and ankle moments, which were used to in the discussion of voluntary control. The involuntary knee response for level walking and ramp ascent and descent was investigated using both temporal parameters and the correlation between walking speed and mechanical energy absorbed around the knee. Measured outcomes are also provided for stair ambulation in a separate section at the end of the chapter, as these general results did not illustrate patterns that allowed comparison with level or ramp ambulation.



	A	B	C	D	E	F
3R80	13	15	10	13	11	9
Orion	12	5	8	9	9	6
p	0.15	0.00	0.02	0.00	0.01	0.00

Figure 8.1 Individual significances are shown for the statistical comparsion of knee moments (extension is positive) on the prothetic side during initial contact for paticipants A-F. On a group basis the knee moment was reduced with a significance of 2% (p=0.02) using the Orion knee.



	A	B	C	D	E	F
3R80	24	36	20	25	23	24
Orion	18	19	20	26	24	13
p	0.10	0.00	0.92	0.89	0.27	0.00

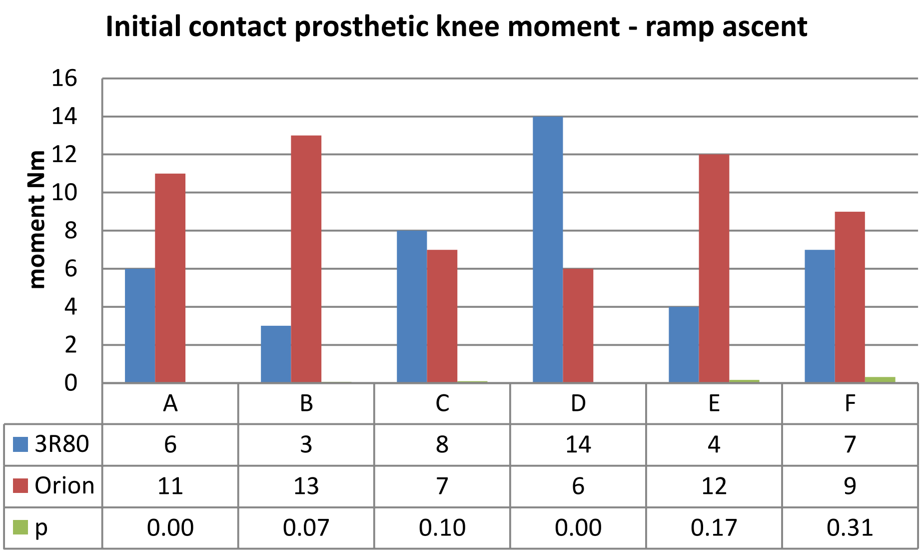
Figure 8.2 Individual significances are shown for the statistical comparsion of hip moment (flexion is positive) on the prothetic side during initial contact for paticipants A-F. On a group basis the hip moment was reduced with a significance of 10% (p=0.1) using the Orion knee.

8.2 STATISTICAL SUMMARY OF INITIAL CONTACT DURING LEVEL WALKING, RAMP ASCENT AND RAMP DESCENT

To determine the initial contact stability, the hip and knee extension moment on initial contact was statistically evaluated. As discussed on section 3.2 in the literature review, the knee extension moment is thought to represent the voluntary control the ambulator has over their knee. Moreover, to maintain a stable knee on initial contact the hip musculature is used to extend the residual limb to provide knee extension. Therefore, if the knee provides improved stability through increased knee resistance, the hip musculature extension effort can be reduced on initial contact. If the knee were to be considered on its own, it could be assumed that a reduced knee extension moment on initial contact would imply that the knee was less stable. Therefore, initial contact stability should be evaluated using both the hip moment and the knee moment on the prosthetic side.

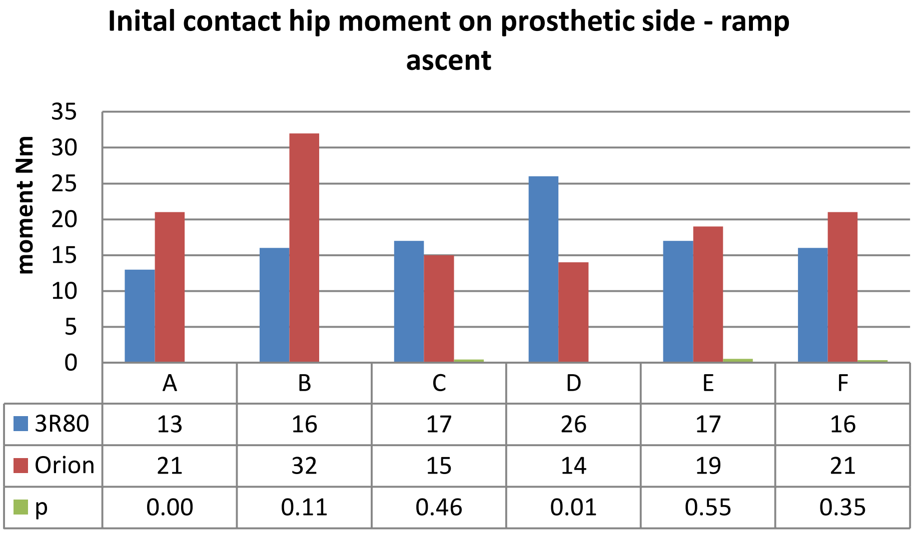
For this evaluation, and for all instances of level walking (participants A-F), the extension moment around the Orion knee was significantly reduced ($P<0.05$) on initial contact (Figure 8.1), and this is despite the low power of the study. However, according to the inter-subject hip results, this was not the case, for the hip musculature extension moment (Figure 8.2). On an individual basis, however, the hip moment was significantly reduced ($P<0.05$) for participants B & F, the two restricted K2 ambulators.

During ramp ascent, as shown in Figure 8.3, the inter-subject results did not demonstrate a significant difference ($P>0.05$) in the knee moment magnitude on the prosthetic side.



	A	B	C	D	E	F
3R80	6	3	8	14	4	7
Orion	11	13	7	6	12	9
p	0.00	0.07	0.10	0.00	0.17	0.31

Figure 8.3 The initial contact prosthetic knee moment during ramp ascent using the Orion knee was increased with a significance of 20% (p=0.20) by an average magnitude of 3Nm

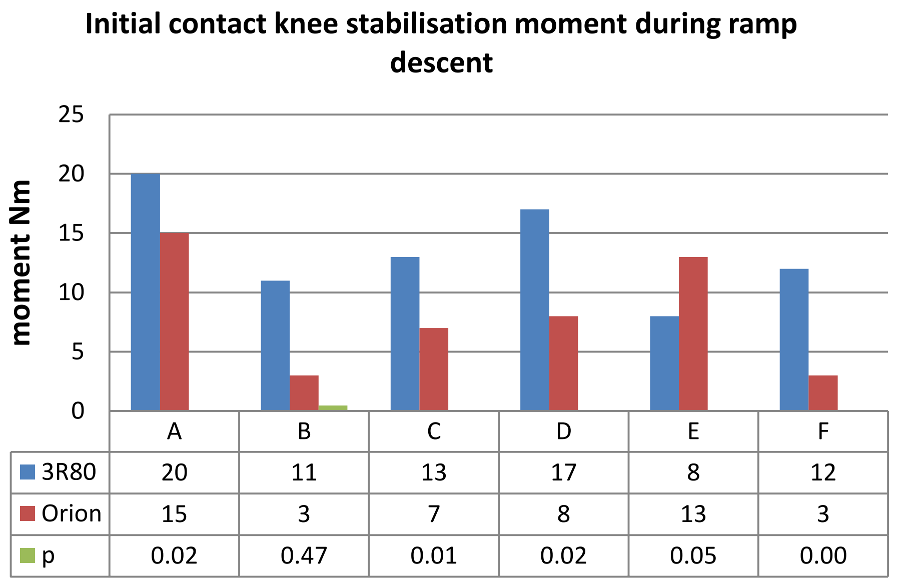


	A	B	C	D	E	F
3R80	13	16	17	26	17	16
Orion	21	32	15	14	19	21
p	0.00	0.11	0.46	0.01	0.55	0.35

Figure 8.4 The initial contact hip moment on the prosthetic side during ramp ascent using the Orion knee was increased with a significance of 42% (p=0.42) by an average magnitude of 2Nm

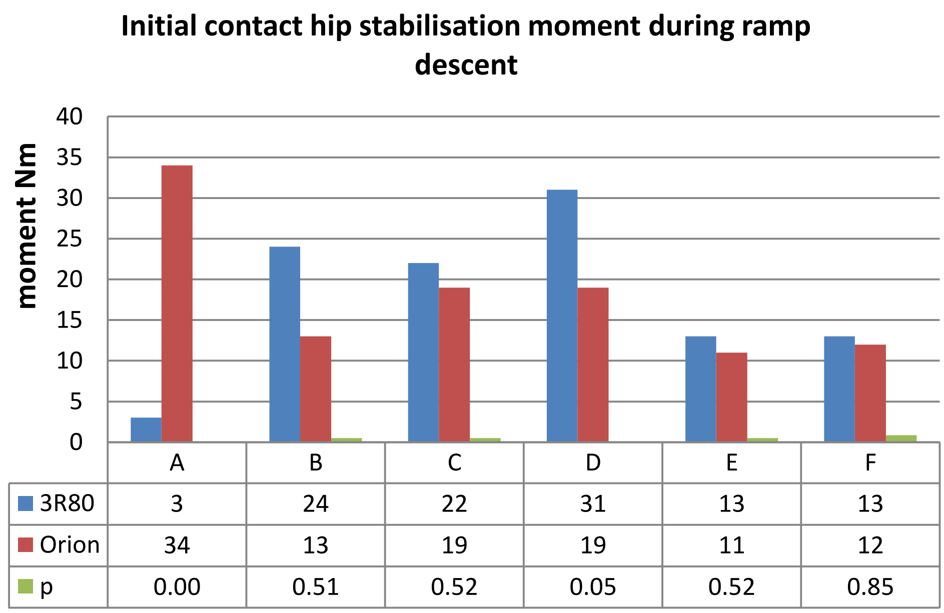
These results were also mirrored by the hip extension moment (Figure 8.4), and did not vary with significance (P>0.05) on initial contact. However, as detailed on the bar charts, the unrestricted ambulator (Participant A) and the restricted ambulator (participant D) experienced a knee and hip moment that was significantly different wearing the 3R80 and Orion knee. The difficulty in interpreting the ramp ascent results is that the handrail introduced variability during the activities. Participant B used the handrail for support while using the 3R80, but not while using the Orion knee. Furthermore, participant F also used the handrail for support while wearing the 3R80 knee, but not while wearing the Orion. Participant E used the handrail for support using both knees, and Participant D used the handrail for support during ascent with both knees, but only used it during descent with the 3R80. Therefore, even though the intra-subject results revealed that the two K2 participants (B & F) did not experience improved voluntary control during ramp ascent, they did not use the handrail when wearing the Orion, and did with the 3R80. As described for level ambulation, these two K2 ambulators were the only two participants who demonstrated a reduced hip extension moment. Consequently, these results will be discussed qualitatively on an individual basis to extract meaningful general outcomes.

For ramp descent, the inter-subject outcomes did not reveal a significant difference (P>0.05). However, the intra-subject results for participants A, C, D and F revealed that the knee moment was significantly reduced (P<0.05) wearing the Orion. However, it was only the intra-subject outcomes of the unrestricted ambulator participant A that revealed that their hip musculature extension moment on initial contact was significantly reduced (P<0.05).



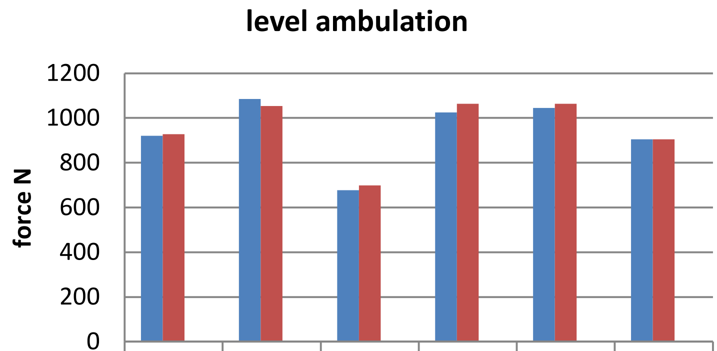
	A	B	C	D	E	F
3R80	20	11	13	17	8	12
Orion	15	3	7	8	13	3
p	0.02	0.47	0.01	0.02	0.05	0.00

Figure 8.5 The knee extension moment during ramp descent, for five of the participants (A, C, D & F), was significantly reduced using the Orion on an indivduail basis, and on a group basis the significance was 10% (p=0.1)



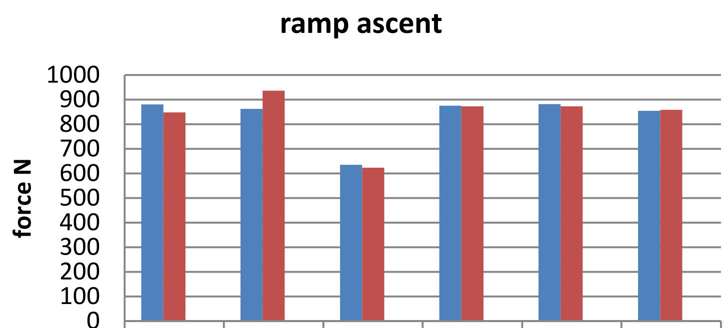
	A	B	C	D	E	F
3R80	3	24	22	31	13	13
Orion	34	13	19	19	11	12
p	0.00	0.51	0.52	0.05	0.52	0.85

Figure 8.6 The mean initial contact hip moment during ramp descent using the Orion and 3R80 knee differed with a significance of 75% (p=0.75)



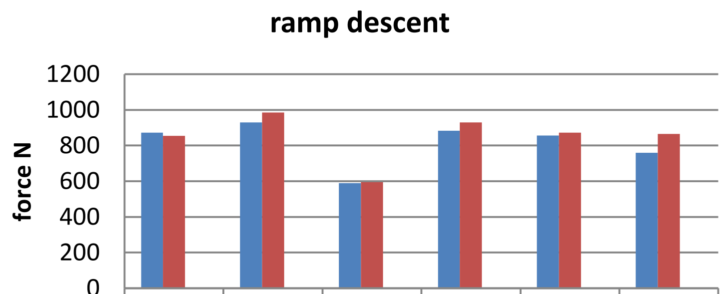
	A	B	C	D	E	F
3R80	921	1085	677	1025	1045	905
Orion	927	1053	698	1064	1063	905
p	0.60	0.19	0.04	0.05	0.23	0.98

On a group basis, the GRF magnitude on initial contact increased with a significance of 69%, and by a mean magnitude of 9N using the Orion knee.



	A	B	C	D	E	F
3R80	880	862	635	875	881	854
Orion	848	936	623	872	872	858
p	0.03	0.05	0.10	0.93	0.70	0.70

On a group basis, the GRF magnitude on initial contact increased with a significance of 63%, and by a mean magnitude of 4N using the Orion knee.



	A	B	C	D	E	F
3R80	873	929	589	883	856	760
Orion	855	986	595	929	873	865
p	0.45	0.10	0.82	0.01	0.16	0.00

On a group basis, the GRF magnitude on initial contact increased with a significance of 62%, and by a mean magnitude of 36N using the Orion knee.

Figure 8.7 Prosthetic knee initial contact GRF magnitude during level ambulation (top), ramp ascent (middle) and ramp descent (bottom).

However, as with ramp ascent and in addition to the restricted K2 ambulators B and F, Participant D also used the handrail for support wearing the 3R80 but not while wearing the Orion. As ramp descent represents a terrain that compromises knee stability, the voluntary control differences will be discussed in the following chapter, and will be compared with the level walking and ramp ascent results. This is will be achieved through a consideration of the intra subject graphical outcomes presented in the preceding case study.

To ensure that individual hip and knee extension results were not the outcome of discomfort or anxiety, the magnitude of the GRF on initial contact was compared statistically, and this revealed that there was no statistical difference ($P>0.05$) when wearing the two knee types (Figure 8.7). Therefore, it can be concluded that the significant differences represented by the hip musculature moment and knee control were not the outcome of a participant walking tentatively with one prosthesis but not with the other.

The mid to late stance period is not analysed statistically, as the graphical differences of moment control around the hip, knee and ankle presented in chapter 7 do not represent a signal instance that could be statistically investigated. However, the graphical differences were such that they could be used as a basis for a qualitative discussion about the differences of voluntary control during the mid to late stance period using the Orion and 3R80 knees.

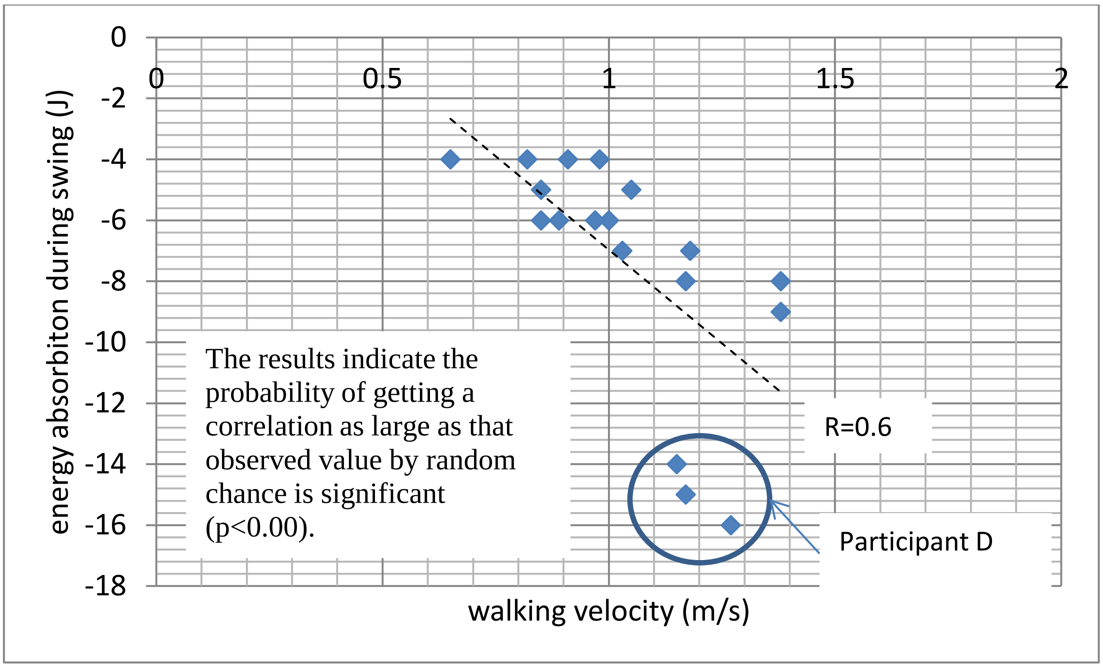


Figure 8.8 Correlation relationship between walking velocity and mechanical energy absorption around the 3R80 knee during level and ramp ambulation.

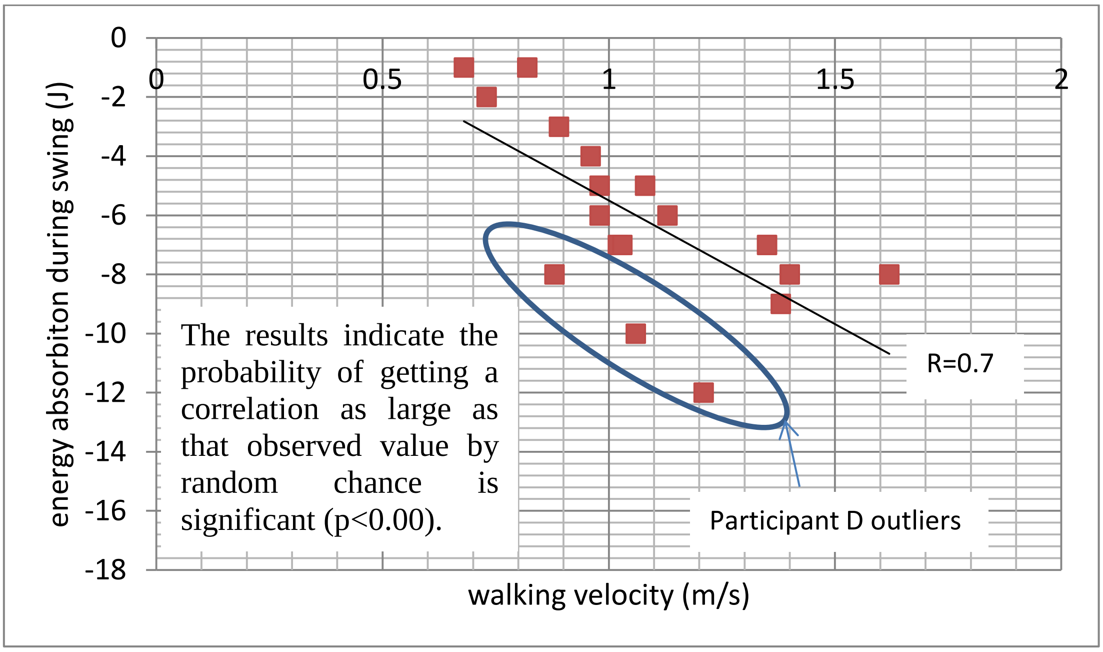


Figure 8.9 Correlation relationship between walking velocity and mechanical energy absorption around the Orion knee during level and ramp ambulation.

8.3 STATISTICAL SUMMARY OF KNEE INVOLUNTARY RESPONSE

The involuntary swing response of the prosthetic knee is designed to allow the lower limb to swing with step time, and to enable the ambulator to adjust their walking cadence as required. As the Orion MCPK has additional sensory inputs to adjust the knee resistance according to the ambulator's walking speed, measured outcomes were required that allow this difference to be determined. Because the knee extension rate during swing is dependent on walking speed, the participant walking speed was correlated with the mechanical energy absorbed during swing around the knee, as shown on Figure 8.8 & Figure 8.9. The reason for this was the assumption that the mechanical energy absorption would reveal whether the knee damping was high or low; it was expected that greater energy absorption would indicate that the knee damping was high and vice versa, and that this could be used to evaluate the knee involuntary response.

The correlation plots reveal that there is a correlation between the mechanical energy absorbed and walking velocity. If the outliers on the correlation plots are considered using individual and group activity plots, as illustrated on Figure 8.10 & Figure 8.11, it can be determined that, on Figure 8.8 and Figure 8.9, participant D's results are also outliers. Removing these outliers increases the strength of the correlation to R^2=0.8 and R^2=0.9 using, respectively, the non-MCPK and the MCPK. Therefore, these results indicate there is a linear relationship between the mechanical energy absorbed by the knee during swing with walking velocity. These correlations are further discussed in the following chapter in order to evaluate the functional design of the 3R80 and the Orion. Hence, the ability of the 3R80 and Orion resistance to respond to a change of user walking speed is assessed.

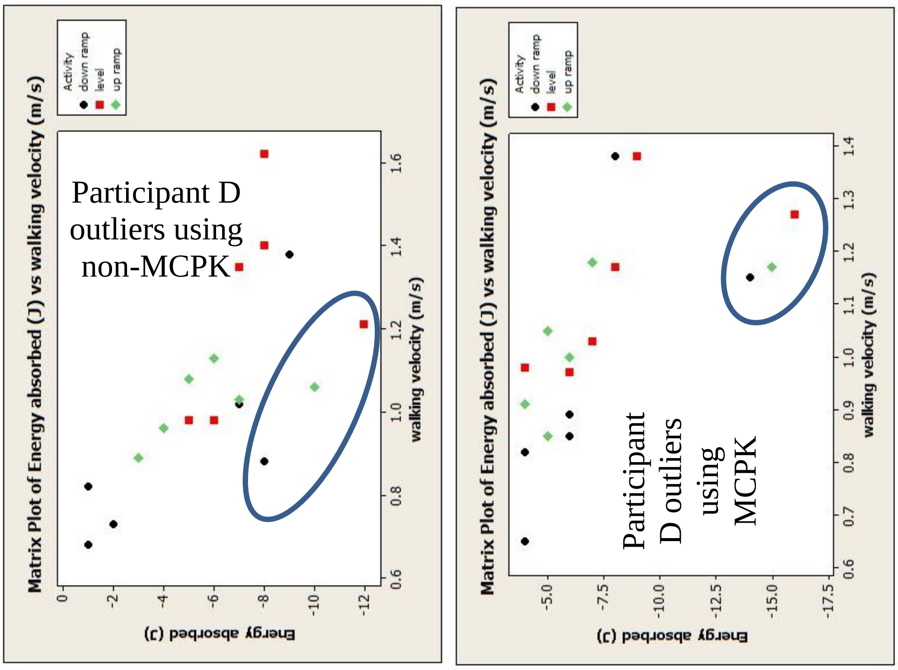


Figure 8.10 Activity plot of walking velocity and mechcanical energy absorbed around the 3R80 (left) and Orion knee (right) during level and ramp ambulation.

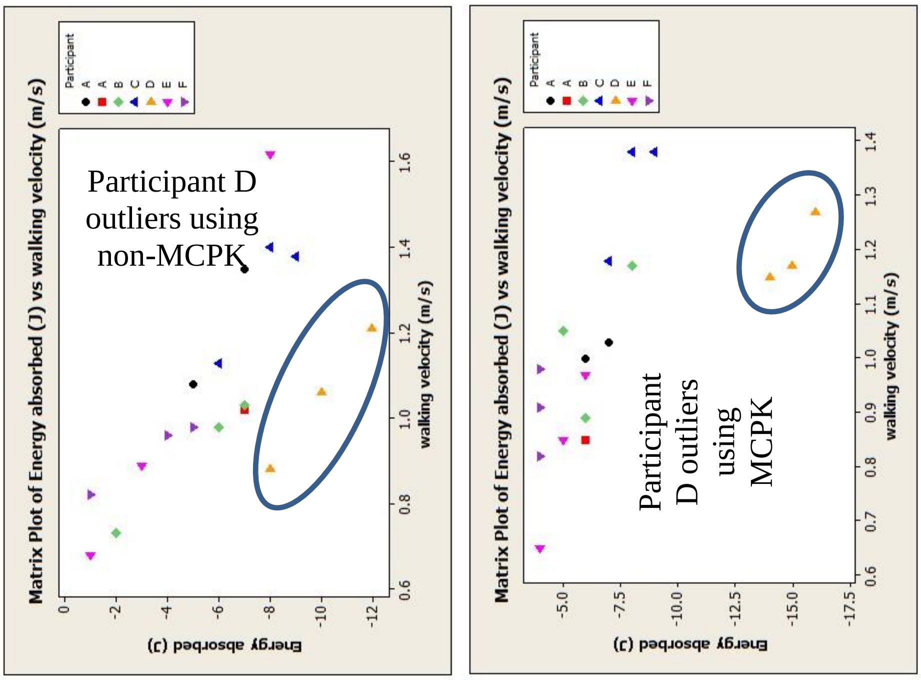


Figure 8.11 Individual group plots of walking velocity and energy absorbed around the 3R80 (left) and Orion knee (right) during level and ramp ambulation.

However, to in order to evaluate whether or not the ability of either knee to adapt to user walking speed provides any benefit (with benefit being considered as the knee's ability to adjust to the user's walking speed as the terrain varied), the stance period was measured during level ambulation, ramp ascent and ramp descent (Table 8.1).

The table of results statistically compares the difference in walking speed on the level, and during ramp ascent and descent. This was considered a more relevant evaluation than forcing the participants to walk at their slow, medium and fast speeds, as detailed in studies such as Kirker (1996). These parameters have been evaluated previously and have often been considered to offer certain benefits, which are elaborated on in the discussion (page 192). Therefore, if it were shown that, as the terrain varied, the Orion knee could adjust to variations in walking speed with greater significance than the 3R80, this would mean that the knee design improves the involuntary response for the restricted user ambulating outside. Table 8.1 illustrates that, when comparing the median ambulatory results during level walking and ramp ascent and descent, participants C, E and F (respectively the K2 unrestricted, and two K3 restricted ambulators) did not show a significantly different walking speed using either prosthesis ($P>0.05$). However, closer inspection of the results reveals that participant E was the only one not to demonstrate a greater change of walking speed (i.e. the difference between maximum and minimum walking speeds) while wearing the Orion, as compared to the 3R80. This result suggests that there is a difference of voluntary response between the 3R80 and the Orion, which will consequently be deliberated in further detail in the following discussion chapter.

stance period prosthetic side												
	participant A		participant B		participant C		participant D		participant E		participant F	
	3R80	Orion	3R80	Orion	3R80	Orion	3R80	Orion	3R80	Orion	3R80	Orion
stance period level (s)	0.94	0.83	0.68	0.77	0.61	0.60	0.60	0.62	0.74	0.72	0.77	0.76
stance period ramp ascent (s)	0.99	0.91	0.73	0.82	0.69	0.73	0.70	0.78	0.86	0.76	0.88	0.89
stance period ramp descent (s)	0.93	0.87	0.73	0.84	0.58	0.60	0.64	0.74	0.80	0.71	0.84	0.78
average stance period (s)	0.95	0.87	0.71	0.81	0.63	0.64	0.65	0.71	0.80	0.73	0.83	0.81
1/(average stance period (s))	1.05	1.15	1.40	1.23	1.59	1.55	1.55	1.40	1.25	1.38	1.21	1.23
significance (p) between 3R80 and Orion stance period	**0.05**		**0.02**		**0.77**		**0.30**		**0.14**		**0.72**	
maximum difference % period change	**6%**	**10%**	**7%**	**8%**	**19%**	**23%**	**18%**	**25%**	**17%**	**7%**	**13%**	**17%**
significance (p) of period change	0.00	0.00	0.14	0.00	0.00	0.00	0.00	0.00	0.00	0.05	0.00	0.00
F - statistic	7.58	39.57	2.11	9.37	114.68	126.25	131.35	165.75	11.93	3.44	44.39	0.00
notes	USD	ASD	NSD	LSD	ASD	USD	ASD	ASD	LSD	NSD	LSD	USD

The rows in **bold** font suggest participants A, B, C, D & F experienced a greater change in stance phase period during level walking, ramp ascent and ramp descent when using the Orion compared to the 3R80 knee. This in turn suggests that the swing phase resistance of the Orion knee adjusts with greater efficacy, allowing the user to reduce or increase their SSWS to a comfortable walking speed for the terrain gradient. This result on an individual basis was significant at 5% ($P<0.05$) for participant A, B & D.

Table 8.1 Stance phase timings on the prosthetic side using the Orion and 3R80 Knee (ASD – all significantly different) (NSD – none significantly different) (USD – up significantly different from level and down) (LSD – level significantly different form up and down ramp.)

	peak GRF as percentage of body weight during ascent			peak GRF as percentage of body weight during descent		
participant	**3R80**	**Orion**	**P**	**3R80**	**Orion**	**P**
A	105%	111%	0.59	37%	68%	0.55
B	136%	142%	0.43	74%	99%	0.55
C	74%	86%	0.29	28%	49%	0.69
D	136%	123%	0.73	136%	86%	0.23
E	123%	99%	0.89	86%	99%	0.86
F	123%	117%	0.06	99%	99%	0.93
Mean	116%	113%		77%	83%	

Table 8.2 Stair ascent and descent peak GRF during stance as a percentage of body weight on the prosthetic side

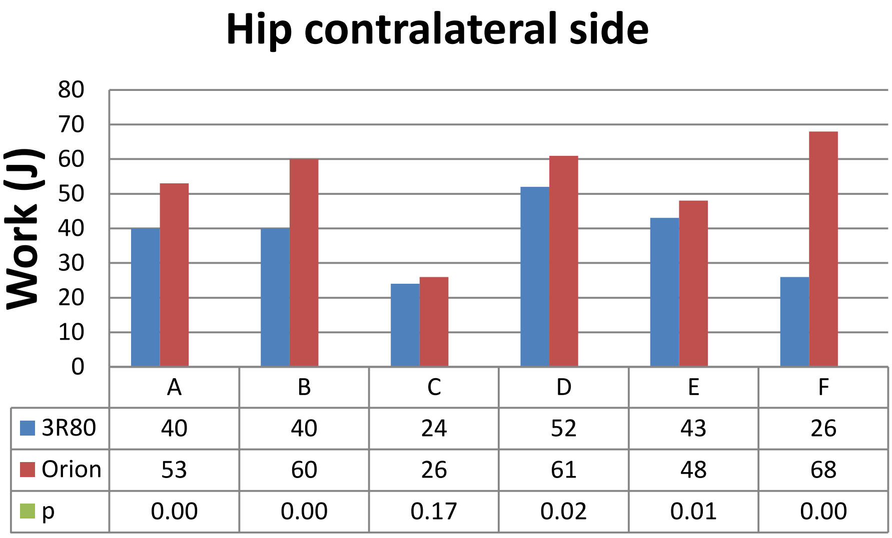
	stair ascent			stair descent		
subject	**3R80**	**Orion**	**P**	**3R80**	**Orion**	**p**
A	NA	NA	0.59	NA	NA	0.55
B	0%	50%	0.43	0%	350%	0.55
C	18%	17%	0.29	50%	100%	0.69
D	0%	25%	0.73	40%	25%	0.23
E	25%	13%	0.89	57%	43%	0.86
F	80%	0%	0.06	83%	0%	0.93
mean	**25%**	**21%**		**46%**	**104%**	

Table 8.3 The magnitude of the Stair ascent and descent moments around the knee and hip on the prosthetic side, as a percentage magnitude of the contralateral side during stair ascent

8.4 STAIR AMBULATION

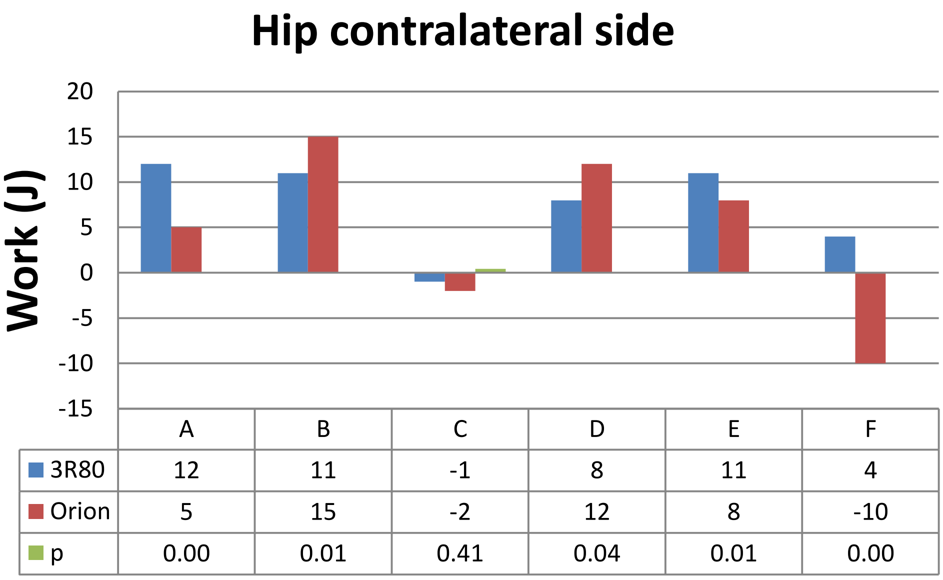
All of the participants were challenged considerably during the stair ambulation exercises, as was demonstrated by the fact that they all used the handrail for support. However, out of the six participants, during stair descent the two unrestricted ambulators A & C adopted a step over step technique, as did the restricted ambulator, participant D. However, they adopted this technique using both knee prostheses, and no additional voluntary control differences were evident. Inspection of the intra-subject moment graphical outcomes revealed that there were no repeated ambulation patterns that could be compared. Therefore, the GRF magnitude was evaluated to consider the support, and the propulsion, using either prosthesis. The maximum GRF magnitude during stance on the prosthetic side was expressed as a percentage of the body weight using the two evaluation prostheses, as shown on Table 8.2. The results show that there were no intra-subject statistical differences comparing the GRF during stair ascent descent.

To ascertain if there were any differences in voluntary control, the prosthetic side moment magnitude was expressed as a percentage of the contralateral side to allow the assessment of contralateral limb compensation (Table 8.3). The results revealed that there were no statistical differences using either knee prosthesis. However, the poor repeatability of the results during the stair activities, as highlighted by the graphical outcomes, did not allow statistical analysis to be used with confidence. Therefore, these outcomes will also be qualitatively assessed using graphical outcomes in the discussion.



	A	B	C	D	E	F
3R80	40	40	24	52	43	26
Orion	53	60	26	61	48	68
p	0.00	0.00	0.17	0.02	0.01	0.00

Figure 8.12 The work developed by the contralateral hip musculature during ramp ascent using the 3R80 and Orion knees, with a respective mean group average of 38J & 53J that varied with an intersubject significance of 1% (p=0.01).



	A	B	C	D	E	F
3R80	12	11	-1	8	11	4
Orion	5	15	-2	12	8	-10
p	0.00	0.01	0.41	0.04	0.01	0.00

Figure 8.13 The work developed by the contralateral hip musculature during ramp descent using the Orion and 3R80 knees with a respective group average 5J & 8J with an intersubject significance of 75% (p=0.75).

8.5 CONTRALATERAL LIMB COMPENSATIONS

It was expected that, when ambulating with the 3R80 and the Orion knee on the prosthetic side, the contralateral side would also be affected. Therefore, in order to determine whether the measured differences on the prosthetic side resulted in differences that could be considered improved on the contralateral side, the mechanical work developed by the contralateral hip musculature during ramp ascent (Figure 8.12) and during ramp descent (Figure 8.13) was used to evaluate compensatory muscle effort. The ramp ambulation exercises were evaluated, as they were more likely to highlight differences in the ambulation patterns than level walking because these activities compromise propulsion and stability to a greater extent than is the case with level walking. Moreover, compared to the stair ambulation these results were repeatable, and therefore allowed the intra-subject outcomes to be assed statistically.

During ramp ascent, it would be expected that differences in contralateral limb work would indicate the magnitude of the compensatory action adopted to assist body propulsion. However, during ramp descent it can be reasoned that the prosthetic knee security on initial contact is the primary concern. The mechanical work developed by the contralateral thigh musculature was therefore evaluated in order to determine whether increased or reduced prosthetic knee security on initial contact resulted in improved musculature control on the contralateral side.

An outcome that was readily used in the literature, as will be presented in the discussion, was the stance period of the contralateral side. Hence, the contralateral spatial temporal parameters, Table 8.4, were used to assess whether ambulatory symmetry could be considered improved using either prosthesis.

stance period contralateral side												
	participant A		participant B		participant C		participant D		participant E		participant F	
	3R80	Orion	3R80	Orion	3R80	Orion	3R80	Orion	3R80	Orion	3R80	Orion
gait period level (s)	0.78	0.72	0.79	0.92	0.68	0.68	0.74	0.76	0.94	0.86	0.92	0.94
gait period ramp ascent (s)	0.88	0.83	0.94	0.95	0.75	0.76	0.80	0.83	1.12	1.02	1.05	1.09
gait period ramp descent (s)	0.85	0.81	0.88	1.02	0.67	0.67	0.78	0.86	1.09	1.08	1.03	0.97
average gait period (s)	0.84	0.78	0.87	0.96	0.70	0.70	0.78	0.82	1.05	0.99	1.00	1.00
1/(average gait period (s))	1.20	1.27	1.15	1.04	1.43	1.42	1.29	1.23	0.95	1.01	1.00	1.00
significance (p) between 3R80 and Orion gait period	**0.33**		**0.15**		**0.93**		**0.28**		**0.50**		**1.00**	
maximum difference % period change	**13%**	**16%**	**19%**	**10%**	**12%**	**15%**	**9%**	**13%**	**19%**	**25%**	**14%**	**15%**
significance (p) of period change	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
F - statistic	23.93	50.75	14.67	13.82	57.63	135.14	17.81	28.76	36.75	50.65	74.39	38.24
notes	LSD	LSD	LSD	DSD	USD	ASD	LSD	LSD	LSD	LSD	LSD	USD

The rows in **bold** font suggest that there was no difference in the stance phase period on the contralateral side using either the 3R80 or Orion knee. Furthermore, during the level and ramp ambulation activities the stance phase period also changed significantly with both evaluation prostheses. However, as summarised in Table 8.3, the average stance period increased marginally on the contralateral side using the Orion knee.

Table 8.4 Stance phase timings on the contralateral side using the Orion and 3R80 Knee (ASD – all significantly different) (NSD – none significantly different) (USD – up significantly different from level and down) (LSD – level significantly different form up and down ramp.)

The analysis revealed that all participants experienced a statistically different ($P<0.05$) stance period on contralateral side using both test prostheses. To further evaluate the symmetry of ambulation using the two evaluation prostheses, Table 8.5 presents the period of stance during level walking and ramp ambulation activities for both the 3R80 and Orion knees. The outcomes reveal that the stance period on the contralateral side differed significantly when wearing the two evaluation prostheses. Outcomes such as stance period were also readily used by other studies to evaluate the effect of MCPKs relative to non-MCPKs, and will be compared in the following discussion to draw conclusions.

	3R80 stance		**Orion stance**	
	contralateral side	**prosthetic side**	**contralateral side**	**prosthetic side**
Time (s)	1.21	0.87	1.28	0.88
Mean difference (s)	0.34		0.40	

Table 8.5 Average stance period using the 3R80 and Orion knee during level and ramp ambulation

8.6 SUMMARY

The statistical summary presented in this chapter provides both the intra-subject and inter-subject statistical outcomes. The critical periods of the gait cycle on the prosthetic side that were statistically presented in this chapter included the initial contact instance and the swing period. The initial contact period was considered by evaluating the hip and knee moments to provide an insight into the stability provided by both knees. The swing period was evaluated by considering mechanical energy absorption around the knee and the spatial temporal parameters. These parameters were used to consider the respective damping responses of the knees as well as their ability to adjust to the user's walking speed. However, the stance/toe-off period is discussed qualitatively using the hip moment musculature outcomes presented in chapter 7. In contrast to level walking and ramp ambulation, a stand-alone statistical summary was provided for the stair ambulation activities. The reason for this was that the outcomes were not repeatable, and could not be integrated with the results of level walking and ramp ambulation. These outcomes were used to assist in the discussion of whether or not the Orion knee provided additional voluntary control during stance, as well as the level of support/stability that was provided by the two prostheses.

The work developed by the hip musculature on the prosthetic side was also considered in order to evaluate the compensatory hip musculature effort during level walking and ramp ascent. Contralateral hip moment graphical outcomes, presented in Chapter 7, are also used to discuss compensatory actions that prevent the prosthetic knee buckling on initial contact. The contralateral limb spatial temporal parameters are also provided to assist the evaluation of whether or not the Orion knee improved ambulatory symmetry relative to the 3R80 knee.

CHAPTER 9 DISCUSSION

9.1 INTRODUCTION

In the results chapter it was observed that the prosthetic and contralateral limb dynamics are affected differently according to which prosthesis the user is wearing. However, how can differences in postural compensations be used to determine whether an ambulation style is better or worse? Normally, similarities to the biological limb is investigated by measuring the step symmetries, energy transferred, or the magnitude of the moments acting around joints. However, the user's experience of their prosthesis relates, in short, to how it "feels", so if their gait pattern is not normal but their experience is improved, gait outcomes cannot necessarily be used to demonstrate their experience in the outdoor environment. Hence, even though gait outcomes are used to give an insight into whether the postural compensations are better or worse, they may offer limited explanation; it is still the responsibility of the investigator to amalgamate a picture of gait through experience and interpretation. As discussed on page 70, the power of this study is unsuitable for substantiating group differences statistically, and consequently intra-subject significances are used qualitatively to assess differences using the two knee prostheses. Consequently, this discussion will use the measured outcomes to evaluate the efficacy to which the mechanisms of the two prostheses allowed their systems to integrate themselves with the user, providing user voluntary control during stance, and allowing for the possibility of involuntary response during swing.

The review of the Orion MCPK functionality in Chapter 3 ultimately revealed that the voluntary control function is based on the ambulator using the toe load, to control the knee resistance. This mechanism should in theory allow the user to maintain high knee resistance at critical instances such as initial contact and toe off. The results revealed that, during ramp descent, three of the restricted K2 outdoor ambulators were able to wear the MCPK without using the handrail. Therefore, the hip, knee and ankle outcomes are evaluated to assist in determining whether the MCPK allows for additional voluntary control. Additionally, the contralateral musculature outcomes will be used to evaluate whether contralateral limb compensations were reduced using the Orion MCPK.

The discussion of the knee's involuntary response during swing phase, as the user's cadence changes, will be advanced by considering walking speed and the power absorbed by the knee during swing. The evidence from the statistical analysis of results highlighted that the power absorbed around the knee does vary with walking velocity. This evidence will be used to address whether it is the 3R80 or Orion knee mechanism that allows the user greater control over their walking speed as the terrain changes.

However, as described during the account of the stair activities, the outcomes cannot be investigated statistically due to the large inter-subject variations. They will, though, be subjectively discussed to provide more insight into the difficulties faced during stair ambulation.

The discussion will finalise the study by suggesting future work, possible design considerations and providing indictors to assist with the prescription of MCPK devices, if it can be shown that there are distinct biomechanical advantages.

9.2 THE INITIAL CONTACT RESPONSE

The role of the prosthetic knee on initial contact is primarily to provide stability, while also hopefully reducing the residual hamstring musculature exertion. Kaufman et al. (2007) page 231 and Bellmann et al. (2010) page 227, evaluated the stability of the trans-femoral prosthetic user, and both suggested that the MCPK improved stability. Kaufman et al. (2007) evaluated postural stability using an equilibrium score, which was determined using novel measures such as “sway” to evaluate participants standing on a force plate whose inclination was changed. However, it can be reasoned that there is a difference between postural stability and walking ability. Bellmann et al. (2010) evaluated stability by tripping the participants during a “tug test”, an evaluation whereby the harnessed participant was purposely tripped using a length of string tied to their lower limb prosthesis. However, the trip test is not clinically relevant, as tripping participants at selected instances depends on the subjective impression of the investigator. Moreover, the participants were harnessed and likely prepared, aware that they were going to be tripped. Consequently, by considering the knee moment on initial contact, this study evaluated the stability of the knee when ambulating on the level and during ramp activities. The hip moment on the prosthetic side was also used to evaluate whether the change in knee stability resulted in a change in residual limb musculature exertion.

As shown in the results, page 170A, the Orion knee extension moment was significantly reduced ($P<0.05$) on an individual basis for participants B-F during level walking. Moreover, participants B and F experienced a significantly reduced hip musculature extension moment on initial contact wearing the Orion knee.

The difference was insignificant ($P>0.05$) for the other participants, even though the knee moment on initial contact was reduced using the Orion knee. This suggests that the Orion knee does reduce the level of musculature effort on initial contact for these two restricted outdoor ambulators, and this indicates that stability is improved using the Orion knee, as less musculature effort was used for knee stabilisation.

When considering the initial contact knee moment during ramp ascent page 171A, the Orion knee moment, for participant A, was significantly increased ($P<0.05$) along with the hip moment, while participants B, E and F experienced a statistical trend ($P>0.05$) of an increased knee and hip moment. Conversely, the hip and knee moment was significantly reduced ($P<0.05$) on initial contact for participants C and D. However, during ramp ascent, the restricted ambulators, participants B and F, used the handrail for support while using the 3R80, but not while using the Orion. This outcome explains why the individual results did not illustrate a significant difference: the use of the handrail skewed the results, and for this small population this outcome suggests that the Orion knee offers the unrestricted ambulator additional stability during ramp ascent. Moreover, when considering the initial contact response for the participants (A & C) who did not use the handrail during ramp ascent whose statistical results did not inherently demonstrate that the Orion or the 3R80 provided greater stability by evaluating the hip and knee moment. This outcome highlights that other factors, such as activity (level walking, ramp or stair ambulation), influence participants' knee requirements and therefore the statistical results on initial contact. The knee moment results during level walking revealed that all the participants experienced a significantly reduced knee moment on initial contact, so why is this result not repeated by all the participants during ramp ascent?

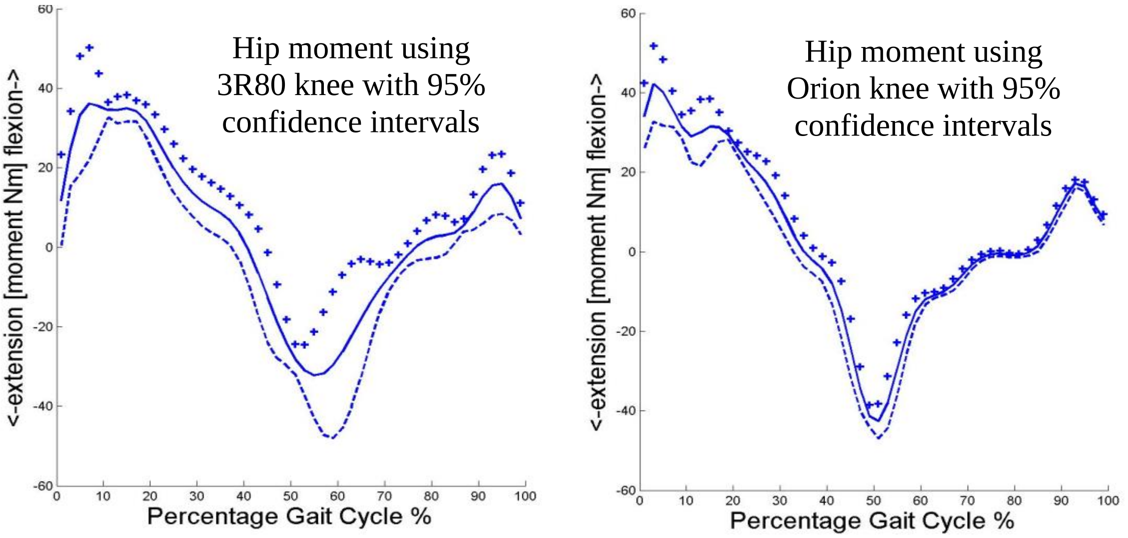


Figure 9.1 Participant A, external hip moment on prosthetic side 3R80 (left) and Orion knee (right) during ramp descent

The musculature control around the hip at the instance of initial contact during ramp ascent may be used, as discuss to stabilise the knee, although the participant is not only concerned with the stability of their knee at this instance. During ramp ascent, it can be proposed that considerable musculature effort made is in lifting the body COM. Therefore, it appears that the initial contact response is a reflection of other factors during ambulation, and may indicate why compared to level walking the knee moment is not reduced, as stability and propulsion is a compromise.

During ramp descent, it would be expected that knee stability would be of primary concern, as illustrated by Figure 7.14, page 158A, participant B experienced a reduced knee moment using the 3R80 knee, though the reduction was the result of handrail support. Conversely, participants A, C, D and F (page 172), experienced a significantly reduced ($P<0.05$) knee moment on initial contact using the Orion knee. Inspection of the hip moments revealed that it was significantly increased for participant A, while the other participants experienced a statistical trend ($P>0.05$) of a reduced hip moment on initial contact. However, Figure 9.1 highlights that the standard deviation using 95% confidence intervals reveals that Participant A did experience improved confidence using the Orion knee, as demonstrated by the reduced standard deviation. Additionally, as with ramp ascent, participant F also did not use the handrail ambulating with the Orion during descent. Therefore, these results imply that their stability was improved throughout stance using the Orion knee despite the use of the handrail wearing the 3R80 knee.

The Orion knee resistance during stance does not change depending on whether the user changes walking speed, or whether they are descending a ramp.

Indeed, if the user feels confident selecting a particular knee resistance using the 3R80 knee, they would likely select a similar knee resistance using another knee. If this were not the case, it would have been possible for all participants to reduce their residual hip extension on initial contact simply by increasing the knee resistance. In retrospect, it would have been beneficial to measure the knee joint resistance at the end of the participant evaluation. However, the GRF magnitude on initial contact, as provided by Figure 8.7 page 173A, does not differ when using either the 3R80 or the Orion knee. This indicates that it was not reduced confidence in either knee that, during ramp ascent (participants B and F) and ramp descent (participants B, D and F), which caused the restricted outdoor ambulators to show a reduced knee moment while using the Orion knee.

Hence, these outcomes reveal a need to understand how the fundamental design differences between the MCPK and the non-MCPK influence the voluntary control and involuntary response of the two knee mechanisms. Interestingly, it may not be the knee mechanism on initial contact that results in improved confidence. Instead, if the prosthetic user has more voluntary control during stance they may have greater confidence at critical instances such as initial contact. To investigate these fundamental differences the moments around the ankle and knee during stance will now be discussed.

9.3 VOLUNTARY CONTROL DURING STANCE PHASE

For the indoor walker stability is paramount, and they therefore often prefer to walk with a locked knee. However, the function required by the community ambulator is the ability to flex the knee under the voluntary control of the residual musculature (Burnfield et al. 2012).

The literature review of the 3R80 and Orion knees in Chapter 3, section 3.4, revealed that the knee damping was unable to adjust adaptively during stance. However, the resistance offered by the hydraulic knee damping allows the knee to be aligned in a geometrically unstable position during ambulation when the GRF acts to flex the knee. In addition to the 3R80 knee, the Orion knee during setup has the ability, while the heel and toe of the foot are loaded, to store threshold yield settings such as the direction and magnitude of the moment acting around the knee during stance. These threshold yield settings are determined from the voltage differential between strain gauges during knee calibration. In theory, this allows the knee resistance to be programmed to respond, and to make a stepped change of knee resistance, at these instances during the gait cycle – that is, to respectively increase or reduce the knee resistance at certain instances during the gait cycle, such as initial contact or toe-off. Even though the Orion knee has additional triggers to assist the knee flexion resistance, these design considerations demonstrate why the Orion user does not flex and extend their knee during stance; it is not simply because of the lack of power, but is instead because of its digital on and off manner that the knee provides voluntary control.

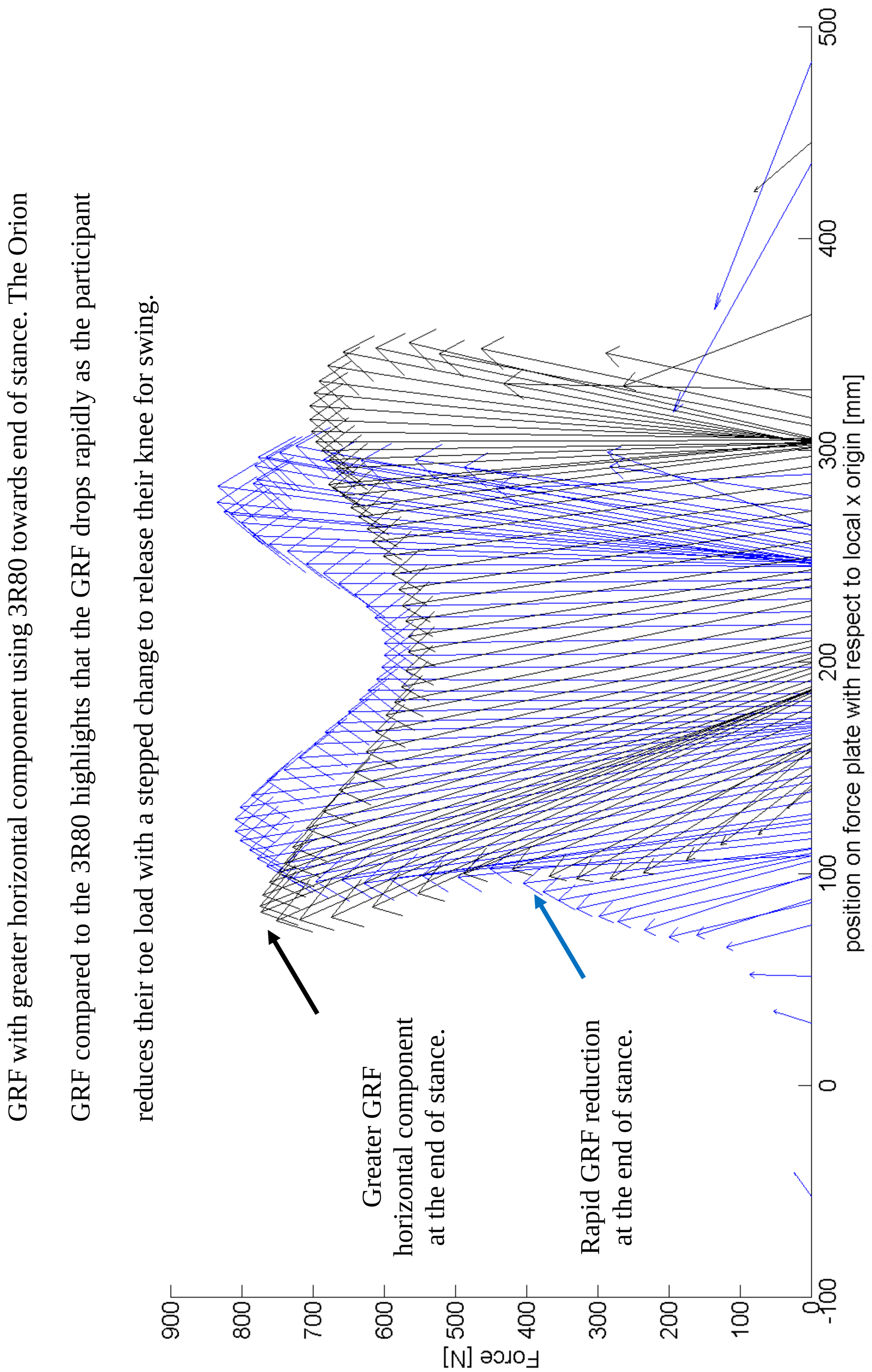


Figure 9.2 Participant D Pedotti during ramp descent Orion (blue) 3R80 (black) direction of ambulation from right to left

As discussed in the previous section 9.2, the initial contact response of the restricted outdoor ambulators appeared to illustrate that their initial contact stability was improved. This may be the result of the user having additional voluntary control with the Orion MCPK, which led to improved initial contact confidence. To support this reasoning, evidence from the results will now be evaluated, and will show that the additional stability and voluntary control seen with the Orion MCPK is a result of the user's ability to manipulate the voltage output from the strain gauge circuit positioned around the knee.

The observable difference highlighted while exploring the graphical results was the exerted voluntary control over the knee moment during the stance phase when participants B, D, and F descended the ramp. It was these restricted outdoor ambulators, and not participants A and C (the unrestricted outdoor ambulators), who appeared to benefit most. Participant E, as described, he was not confident, and his ambulation patterns, as described in the results page 164, highlight that the participant was unstable using both knee prostheses during the ramp and stair activities.

The Pedotti diagram shown on Figure 9.2 illustrates the different voluntary control methods used by participant D descending the ramp. During ramp descent when using the 3R80 knee, when comparing the magnitude and direction of the GRF using the Orion knee, the GRF components have greater horizontal orientation. This highlights that when using the Orion knee Participant D used their toe load in a different manner to control the direction of GRF acting on the foot, and thus moment around the knee.

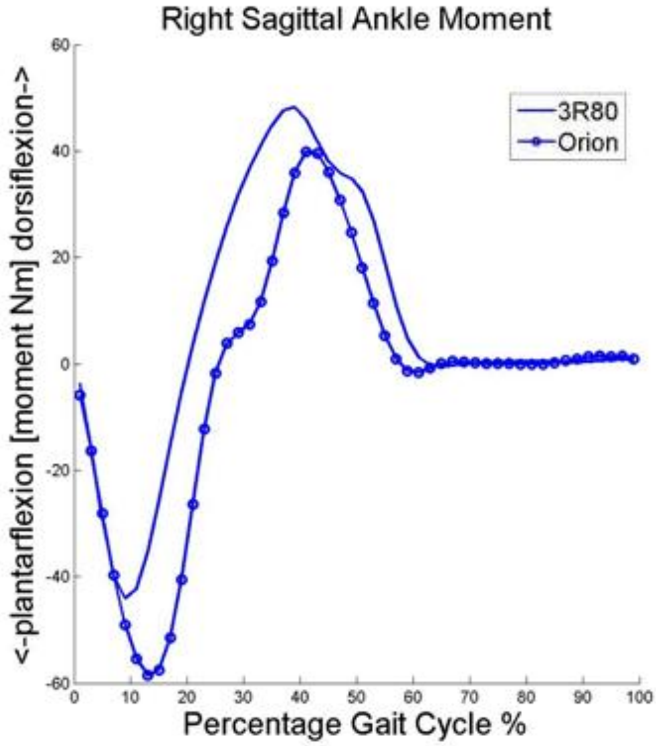


Figure 9.3 Participant F prosthetic ankle moment plot during ramp descent

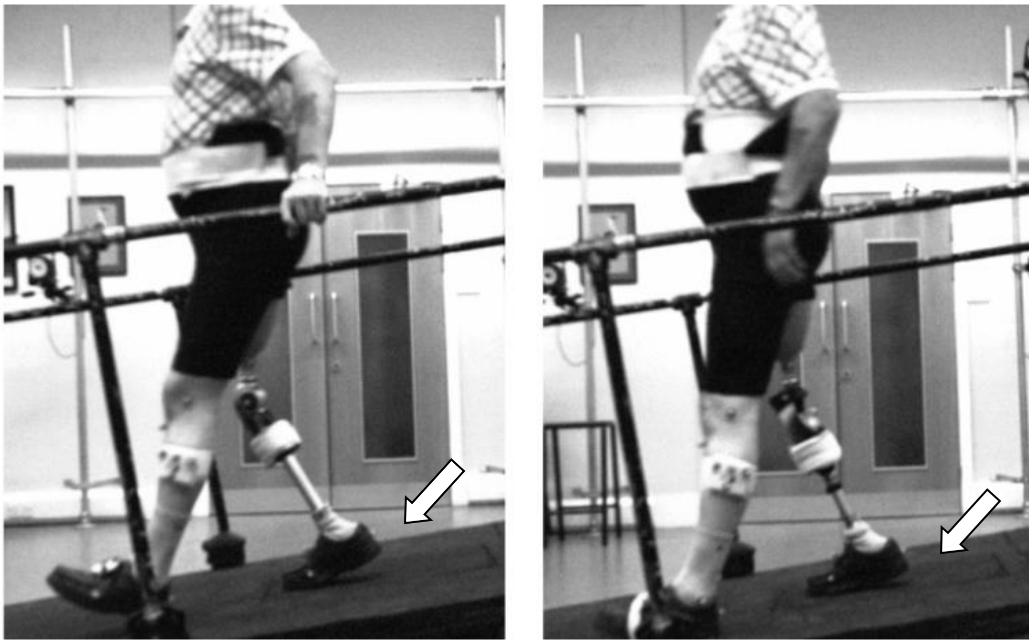


Figure 9.4 An image of participant F during ramp descent during heel rise with their prosthetic trailing foot

Therefore, the result indicates that participant D has different voluntary control strategies over the knees during stance phase. Essentially, the calibrated knee load that is defined during user setup has to be reached (achieved by reducing the toe load) before the high stance resistance of the knee will reduce, thereby allowing the knee to transition into swing (Figure 9.2, 188A). Therefore, if a participant reduces their toe load slowly with minimal heel rise, the strain gauge circuit of the Orion knee will maintain the high stance knee resistance, and support an additional knee flexion moment throughout stance. This method of control allows the user to flex the knee during activities such as ramp descent in a safe manner while still maintaining a high stance resistance.

When considering the prosthetic knee moment during ramp descent for participant F, Page 167A, Figure 7.34, it is possible to discern a considerable extreme. Observation of the external knee moment and flexion angle highlights that the Orion knee resistance must have been maintained until toe-off. This is because, during stance, the knee was continuously flexing under the action of the external flexion moment and did not buckle while supporting the participant's body weight (Figure 9.4). Furthermore, even though participant F supported their body weight using the handrail while wearing the 3R80 knee the dorsiflexion moment around the ankle is reduced wearing the Orion during late stance (Figure 9.3). This outcome demonstrates that participant F gained additional voluntary control by minimising their toe load, as indicated by the reduced plantarflexion moment, and thus delayed their Orion knee reducing resistance until they were confident to do so.

Additionally, during ramp descent participant B could descend the ramp using the Orion knee without handrail support, and could allow a flexion moment to act around their knee throughout the whole of stance page 158A, Figure 7.14. Observation of the knee flexion moment using both knees is considerable, and was a result of their hip flexion contracture. However, the Orion knee was additionally flexed by 15 degrees throughout stance, and illustrates that the participant must have felt confident to let such a high flexion moment act. The high flexion moment compared to the 3R80 highlights that they must have used their toe load to gain additional voluntary control over the Orion knee to prevent it from buckling during the ramp activity to allow them to descend with confidence.

It was hypothesised in chapter 3 page 44, that the Orion user may have additional voluntary control over the MCPK. Indeed, the results show that participants B, D and F did exhibit this additional control and, though from only a small group using the Orion knee during slope descent, these results appear to highlight some fundamental advantages to using the MCPK. The outcomes show that it is possible for the Orion user to maintain high knee resistance by managing their prosthetic toe load based on these results, the Orion user can maintain high knee resistance during ramp descent by minimizing heel rise towards toe-off with reduced plantarflexion.

The 3R80 knee requires cyclic motion, whereby the leg flexion towards the end of stance enables spring compression, and thus the storage of elastic strain energy (Figure 9.5).

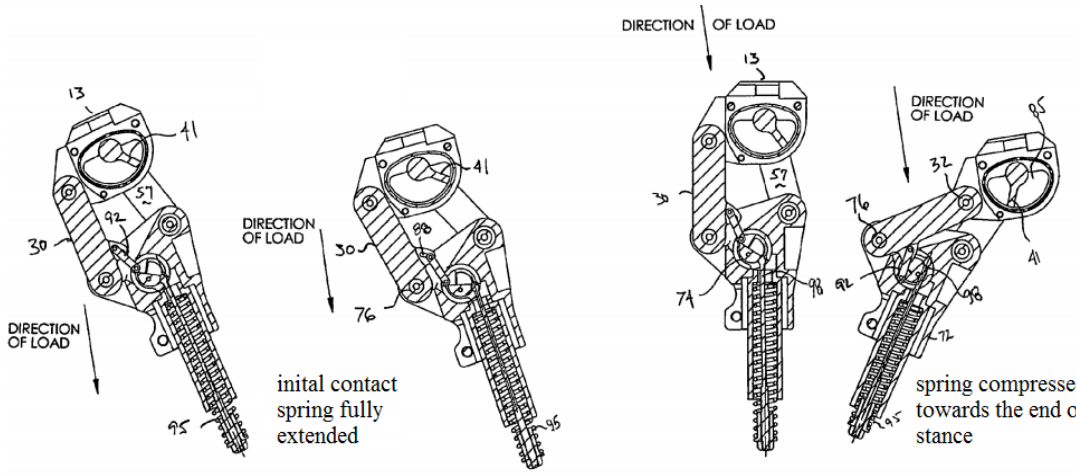


Figure 9.5 Direction of loading and spring compression when the non-MCPK is fitted to a user (Wild 2006), direction of walking from left to right.

This stored elastic energy is required to provide leg extension during swing, as the hydraulic resistance is likely to be too great for the user to extend their knee against the fluid resistance using dynamic effects alone. This mechanism indicates that, outwith level walking on an ideal terrain, the 3R80 knee forces the user to make postural compensations to assist their knee extension during swing, which affects stability. Furthermore, as the three participants (B, D and F) were the least capable of the community ambulators the results also show that the Orion knee may best serve the user who requires additional support outside the laboratory environment, where the terrain may compromise knee stability. Hence, this section provides strong evidence, based on the moment control around the knee, that the restricted outdoor ambulator is able to exert additional voluntary control during late stance. This mechanism also appears to improve the confidence of these ambulators on initial contact, as discussed in section 9.2. There is no evidence to support the claim that the knee resistance selected for each knee was fundamentally different. This outcome implies that it is the voluntary control during stance that gives the user greater confidence using the Orion knee, which it turn leads to a reduced hip musculature extension on initial contact.

9.4 INVOLUNTARY RESPONSE

The involuntary swing phase response of the Orion knee is an example of a feed-forward system, as the knee damping response is determined during stance and cannot be changed once the knee enters swing. To assist the understanding as to why certain measured outcomes were used to measure the involuntary response of the knee, a brief synopsis of the mechanisms used by the 3R80 and the Orion knees to determine the swing phase damping will now be given in the context of the discussion.

During setup of both knees, clinical observation and patient input is required to select the appropriate knee resistance for controlling the knee extension rate during swing. The clinician will determine whether or not the knee accelerates too rapidly into flexion or extension at both toe off and initial contact, and will then adjust the resistance accordingly. The user will also provide feedback with respect to how the knee flexion and extension feels, which provides the clinician with input to further alter the knee resistance if required.

With the Orion and 3R80 knees, the extension rate is controlled using a mechanical mechanism that adjusts the resistance to fluid flow. However, the Orion knee mechanical mechanism is under the control of the embedded system and is able to respond to the users' slow, average and fast walking paces. During the calibration procedure, an average resistance is manually selected along with an upper and lower value, all based on the user walking with their corresponding slow, average and fast walking paces. From these set points, two further knee resistance values are determined using interpolation – the medium slow, and medium fast walking paces.

The 3R80 knee can only rely on the compressibility of the fluid through a fix orifice, which allows the marginal adjustment of the extension rate as the walking deviates from the SSWS. Therefore, there is potential for the 3R80 knee to also be able to adjust to small changes in walking speed forced on the user by the changing terrain.

Therefore, in the laboratory environment the force plate signal was used to measure the stance period of the participants (as detailed in the results section 8.3 page 174A), in order to ascertain indirectly what effect the prostheses have on their SSWS. This outcome was used to determine the potential ability of the Orion knee to adapt to the natural variation in the participants' SSWS, evidenced by an involuntary knee response as the terrain changes. This was achieved by comparing the change of walking speed when walking on the level, and during ramp ambulation activities. Inspection of Table 8.1 page 176, reveals that participants A, B, C, D & F experienced a greater change in stance phase period in all activities when using the Orion, rather than the 3R80, knee. This is not surprising; as the 3R80 knee undergoes dynamic adjustment during level indoor walking at a SSWS as does the Orion, although it is also calibrated to respond to walking speeds outwith the SSWS.

To compare, for example, participant A's prosthetic side stance period for both knees: using the Orion knee, it was 0.83, 0.91 & 0.87 seconds ($P<0.05$) for level walking, ramp ascent and ramp descent, respectively; while for the 3R80 it was 0.94, 0.99 & 0.93 seconds ($P<0.05$). This represents a maximum 10% change in stance phase period using the Orion, compared to a 6% change using the 3R80 knee.

It is therefore suggested that the Orion knee allowed a more natural change of walking pace by adjusting the swing phase rate as the user's SSWS changed, and that this illustrates improved involuntary control. This result was also replicated by participants B, C, D and F, as all these participants experienced a significantly greater change ($P<0.05$) in walking pace using the Orion Knee; only Participant E experienced a greater change in walking pace using the 3R80 knee. This outcome appears to suggest that neither the unrestricted nor the restricted walker seems to have benefitted from greater efficacy using the Orion knee.

Furthermore, when comparing the average walking speeds during the level and ramp activities, only participants A and B experienced a significantly increased ($P<0.05$) walking speed while using the Orion knee, while the other users experienced no change at all. This outcome suggests that the benefit offered by the Orion is not to be found in an increased average walking pace during normal ambulatory activities, but resides instead in the ability to change the walking pace more naturally with respect to the terrain, whether it is level walking or ramp ascent. This outcome also suggests that the involuntary swing phase response may not only be beneficial for a certain user group of outdoor walkers.

To further understand the involuntary response of both knee mechanisms, the mechanical energy absorbed during level ambulation and ramp ascent/descent was correlated with walking velocity and plotted (as shown in the results on page 174A). The mechanical energy absorbed around the knee was used as an indication of knee resistance as it was reasoned that, for example, increased knee resistance for a given walking speed would result in increased energy absorbed around the knee.

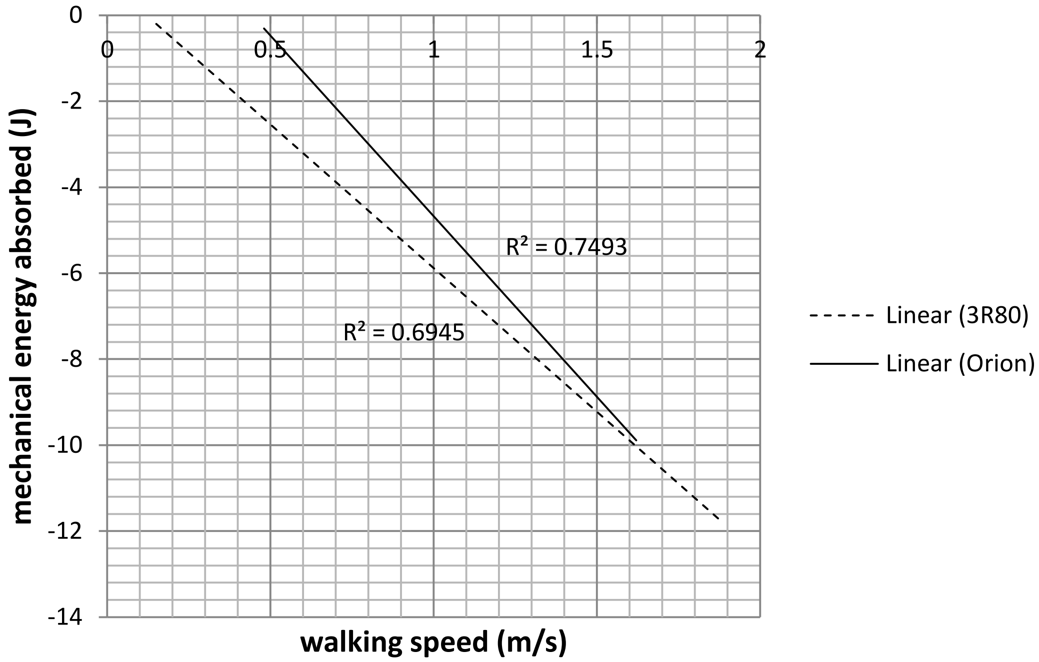


Figure 9.6 Linear correlation relationship between walking velocity and mechanical energy absorption around the 3R80 and Orion knees during level and ramp ambulation, removing particpant D outliers.

At the beginning of swing the prosthetic knee damps both the rearward (flexion) swing of the leg, preventing excessive heel rise, and the forward swing of the leg, preventing sudden extension (Mauch 1968, Herr et al. 2003).

Hence, during swing, the Orion knee should not experience over damping, especially at slow walking speeds because the resistance can reduce, thereby preventing the user having to compensate for too slow an extension by using their musculature. Conversely, the Orion knee can increase its damping in accordance with the user's walking speed and, as a result, the mechanical energy absorption using this knee type was expected to be greater. Additionally, the level of overshoot damping reflects user confidence, because musculature is likely to be more aggressively used to extend the knee in a timely fashion during swing when the user feels less confident (Bellmann et al. 2010). As the energy for swing is provided by the musculature, the mechanical energy wastage is likely to be reflected by increased metabolic cost. However, the metabolic cost of ambulation was not considered in this study. The trend of mechanical energy absorption was used to investigate the involuntary response of the two knee mechanisms through the correlation of walking speed with mechanical energy absorption (page 174A). However, as the investigation was carried out at the users' average walking speeds for level walking, ramp ascent, and ramp descent it was expected that the walking speed energy correlation would allow the two knees to be fairly compared.

The graphical results demonstrated that there is a stronger relationship between walking velocity and prosthetic knee energy absorption when using the Orion than there is when using the 3R80 knee (Figure 9.6, page 196A).

Therefore, the correlation shows that, during swing, there is a trend of reduced mechanical energy absorption using the Orion knee relative to the 3R80. The reason for this is that, for the MCPK, the knee damping adjusts automatically when walking speed varies as, for example, when transgressing from level to ramp ambulation.

The outliers on the correlation plots can be identified as participant D's using individual group and activity plots, page 175A, if they are neglected, the strength of the correlation would increase to R^2=0.8 and R^2=0.9. Therefore, it appears valid to suggest that there is indeed a linear relationship between knee damping with walking velocity, and because the damping was not directly measured, the mechanical energy absorbed can be used to indicate the resistance of knee motion during swing. Indeed, the results illustrate the fact that there is a trend of reduced mechanical energy absorption around the Orion knee during swing at walking speeds lower than 1.5m/s. This highlights that the involuntary response of the knee, may reduce residual limb musculature expenditure. Moreover, these group results show that both the outdoor restricted and unrestricted ambulators benefited from this improved voluntary response. Therefore, combined with the evidence that the user appears to be able to alter their walking pace with respect to the terrain they are traversing, and that the knee's involuntary response is improved on a group basis, these results show that the Orion knee's involuntary response is beneficial for all lower limb prosthetic users.

Buckley et al. (1997) reported reduced metabolic energy expenditure using the intelligent prostheses , at lower rather than faster walking speeds. Evidently, at walking speeds lower than the average SSWS, knee pneumatics minimised the damping response, thereby negating the requirement to extend the knee with haste.

The results of this study appear to conform this trend because, for both knees, the mechanical energy absorption converged at faster walking speeds, while it diverged at slower walking speeds, as summarised on Figure 9.6. This indicates that the metabolic energy saving is made at slower walking speeds, as described in Buckley et al. (1997). However, the experimentation of Buckley et al. (1997) was carried out on a treadmill, and this study evaluated the SSWS of the participants during level ambulation, ramp ascent and ramp descent. The two procedures indicated that a microprocessor controlled swing response does reduce the energy required to ambulate. However, this study cannot describe the relationship between metabolic and mechanical energy expenditure.

In comparison with other studies which forced the participants to walk at their extreme speeds, such as Kirker et al. (1996), the participants in this study were asked to ambulate at their SSWS for the given terrain. The present study found similar outcomes, suggesting that the procedure and methodology were correct. However, this study used measures that could also be used to suggest that the improved involuntary response benefit would translate to the outdoor environment. The walking speed and mechanical energy absorption correlation was used to determine differences in knee response as the users' walking speed naturally varied as the plane of ambulation changed. This analysis illustrated that both un-restricted and restricted ambulators will benefit from MCPK involuntary response because the results revealed that both user groups benefited from a greater range of walking speed using the Orion MCPK.

9.5 STAIR AMBULATION

The difficulty of analysing and discussing the ambulation techniques adopted by the participants during the stair ambulation exercise is that the kinematic and kinetic outcomes highlighted that both prostheses were used as a static body support. The results generally did not show that the participants experienced improved voluntary control, or involuntary response. Therefore, to explore the support provided by the two prostheses, a comparison was made between the magnitude of the moments acting around the lower limbs and GRF Peaks, given on page , were compared.

During stair ascent, the peak GRF magnitude, expressed as percentage of body weight, indicated that the peak stance GRF of 116% and 113% ($P<0.05$) of body weight using the 3R80 and Orion knee was minimal. Because, the normal control's push-off force was, on average, 40% greater than body weight.

Conversely, during descent, the peak GRF magnitude difference during stance on the prosthetic side was 77 % and 83% ($P>0.05$) using the 3R80 and Orion knee, and indicated the extent of handrail support. Moreover, as further demonstrated by the tabular results page , the intrasubject subject results highlighted that there were no differences using either the 3R80 or Orion knee, which were obscured by the mean intersubject statistical outcomes.

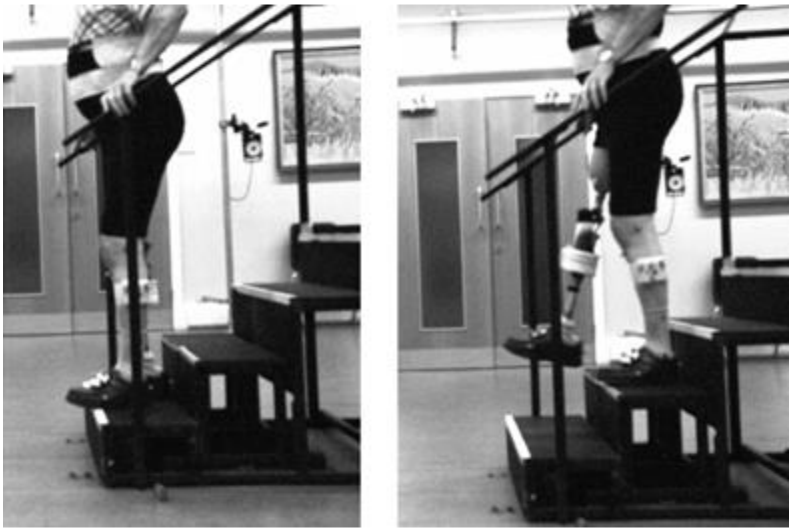
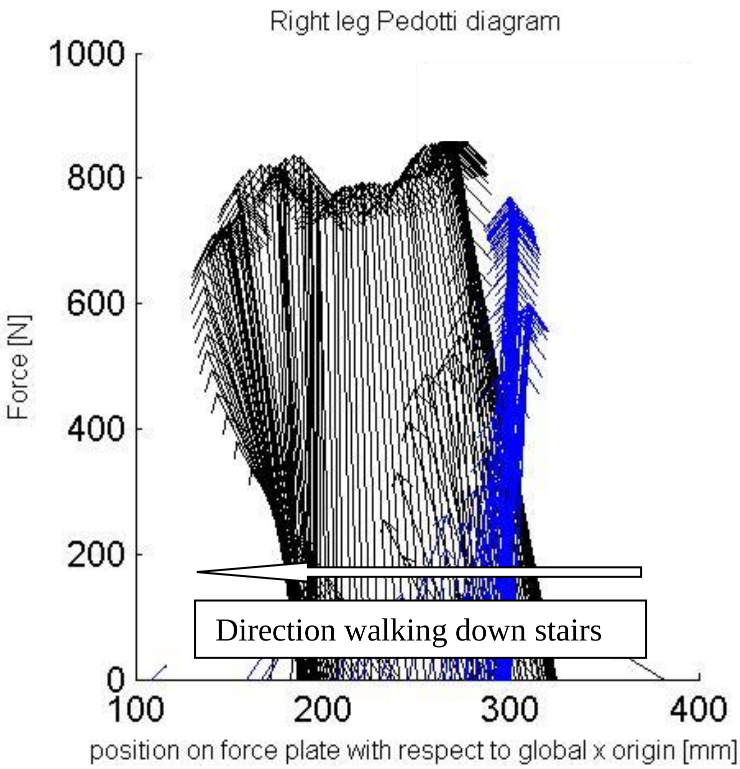


Figure 9.7 Participant F – The prosthetic side during descent is simply lifted and placed on the step below



As shown by the Pedotti diagram, during descent the GRF does not travel along the prosthetic foot (blue) in the same manner as the contralateral foot (black), and dwells at a point on the foot.

This is the result of the forefoot being used to manipulate the direction of the GRF to flex their knee.

Figure 9.8 Participant E Pedotti diagram during stair descent using 3R80, contralateral side (black) and prosthetic side (blue), body weight 1000N

Further pictorial evidence from stair descent suggests that, on the prosthetic side, these participants cannot/are unable to lower their bodies with any additional control (Figure 9.7).

As the peak GRF magnitude does not illustrate how the GRF progresses along the foot, the Pedotti diagram for participant F during stair descent is given on Figure 9.8, for both the prosthetic and the contralateral legs. The outcomes show that, during initial contact on the prosthetic side, the entire prosthetic foot is placed on the step, and the external force dwells at a point on the forefoot. However, during stance on the contralateral side, the external GRF progresses along the foot and does not dwell at a single point. Furthermore, as shown on Figure 9.9 by participant F, due to the lack of proprioception, the participants in this study required visual feedback with respect to their foot placement. Conversely, during ramp descent, the lower limb prosthetic user does not appear to require the same level of visual feedback as they seem to do during stair negotiation.

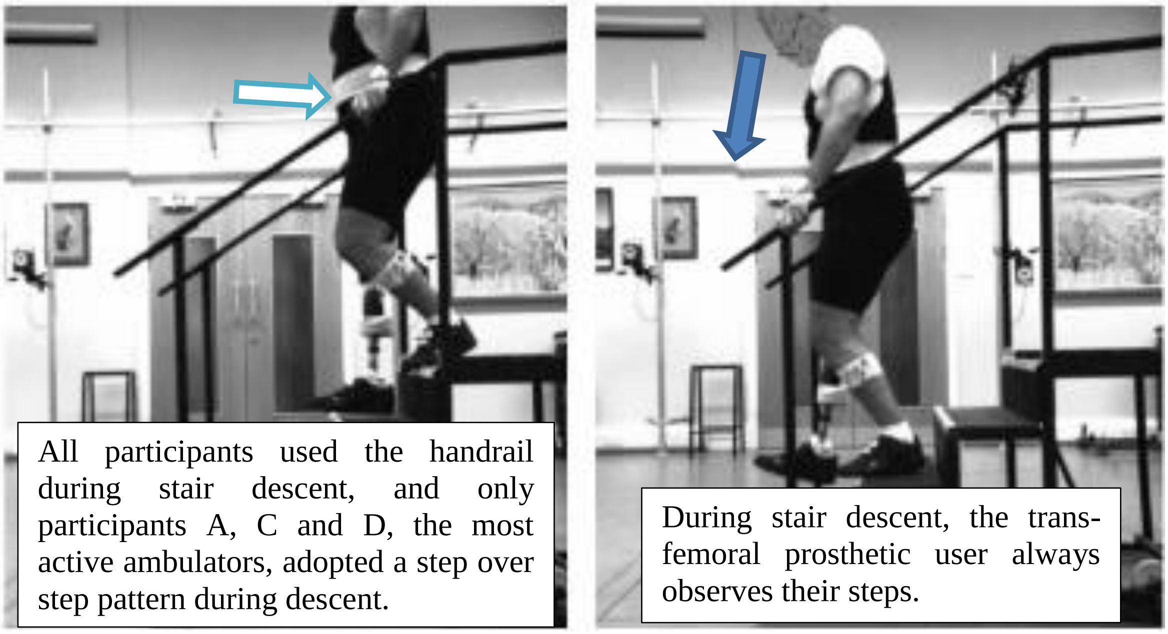


Figure 9.9 Participant E during stair descent using the Orion knee

Figure 9.10 Participant C – When comparing Figure 9.9 with this figure, it can be seen that participant C places their prosthetic toe further over the edge of the step

It is suggested that when descending a ramp, the prosthetic user can place their foot ahead of their trunk with a greater spatial range than they are able to do during stair descent. This is predominantly the result of the above knee prosthetic user either avoiding the step edge, or using it to create a reaction force to flex their knee, and of course not wanting to stumble (Figure 9.9).

During stair descent on the contralateral side, the direction of the moment acting around the knee and hip is one of flexion– because the musculature will be used to lower the body. However, only participant A experienced an external flexion moment around their residual hip during descent (page 243). This suggests that only participant A used their musculature on the prosthetic side to assist knee flexion, and therefore had confidence to “ride” their knee down the steps. Even though participants B-D did experience a flexion moment around their Orion knee, they did not exert an external hip flexion moment that was comparable with the contralateral side. Again, this illustrates that they mainly lowered their body using their arm musculature through handrail support, rather than using the railing for additional support as seen during ramp descent, as the moment magnitudes were comparable with the prosthetic side when not using the handrail. During stair ascent all the participants used their contralateral limb to raise the prosthetic side to the same step; essentially, the prosthesis was used as a static support for the residual limb. This outcome is illustrated by page , where it can be observed that the peak moments around both knees were not substantial.

This shows that the residual limb musculature was not used to flex or extend the knee. These findings are in contradiction with other investigations, which found improved results when comparing the C-leg MCPK with a non-MCPK. Hafner et al. (2007) concluded that the subjective results of their evaluation represented a significant improvement when negotiating slopes and stairs, even though the subjective scorings did not agree with the participants' reported subjective feedback.

Kahle et al. (2008) also compared, and subjectively evaluated, twenty-one participants using the Mauch SNS non-MCPK with the C-Leg. The subjective analysis was used to present a picture of greater benefit using the MCPK. For example, many of the participants were K2 ambulators and could not descend step over step using the non-MCPK, but could using the MCPK. In contrast, the present study revealed that participant D, who could be considered a restricted outdoor ambulator, was able to descend step over step using both the evaluation prostheses. In contrast to Hafner et al. (2007) and Kahle et al. (2008), Bellmann et al. 2010 used biomechanical analysis to compare the contralateral differences using the C-Leg, Hybrid Knee, Rheo Knee and Adaptive 2 on the prosthetic side. The evaluation revealed that the use of the C-leg resulted in the reduction of the peak stance contralateral limb loading at 5% significance, when comparing the Rheo knee and Adaptive 2 knee. As all these knees are MCPKs, it is not possible to tell if they would reduce the contralateral limb loading when compared to the non-MCPK. However, considering that, when using at least one of the four knee types, most of the nine participants used the handrail during stair ambulation, it is not surprising that the statistical evaluation presented a significant difference.

In summary, the magnitude of the GRF loading outcomes clearly highlighted that, during stair ascent, the trailing prosthetic side is not used to assist body propulsion. Moreover, during stair descent the initial contact loading indicated that the body was gingerly lowered using the upper body. Furthermore, throughout stance the peak moments around the hip and knee show that there was no coordinated effort to flex or extend their knee. This outcome demonstrates that resistive technology that uses a socket residual limb interface does not appear to give the lower limb prosthetic user voluntary control over their knee. Additionally, as the knee remained extended during stance, there was no swing involuntary response. Therefore, neither does it appear that resistive MCPK technology improves the ambulation technique during stair ascent or descent. However, the population evaluated is not representative of all lower limb prosthetic users, and the further study of athletic ambulators with very good muscle control may reveal that they have the ability to use these types of prostheses with improved voluntary control.

9.6 CONTRALATERAL LIMB COMPENSATIONS

When considering the transfemoral prosthetic user's contralateral side, investigators such as Mâaref et al. (2010) page 231, and Barr et al. (2002) page 227, examined the spatio-temporal parameters. Therefore, when considering the effect that the two evaluation prostheses had on the contralateral side in this study, the temporal spatial parameters were initially considered as well. The temporal spatial parameters of the contralateral limb, revealed that the stance period on the contralateral side was not significantly affected (P>0.05) when using either of the test prostheses on an individual basis.

Moreover, when using the stance period measure to compare the gait symmetry for both the 3R80 and Orion knees during level and ramp ambulation, the results demonstrated that the difference was significant 5% (P<0.05), for all participants on an individual basis. The group results also revealed that the stance period asymmetry actually increased from 0.34 to 0.40s when using, respectively, the 3R80 and the Orion knee; and they further revealed that the difference between the asymmetries were significant at 1% (P<0.01). However, it could be argued that the magnitude of the difference wearing either knee is negligible when considered practically.

Investigation of the literature revealed that, when Barr et al. (2002) examined one K3 prosthetic user over a seven-year period using the Four Bar Endolite knee/Endolite Dynamic Response foot, Össur Total Knee 2000/Pathfinder I foot, and C-Leg knee/IC40 C-walk foot, the period of stance on the contralateral side also increased using the MCPK.

Furthermore, the work of Mâaref et al. (2010) examined the temporal parameters of participants, and considered the latency period (a term used to describe the time between full knee extension and initial contact of the ipsilateral foot) for two user groups. One group wore the C-leg, and another a pneumatic swing phase controlled unit. The outcomes illustrated that the latency period was reduced using the C-leg, although the latency period of the contralateral side also increased.

Therefore, combining the evidence from this study and that from Mâaref et al. (2010) and Barr et al. (2002), it appears that the Orion knee does not necessarily reduce the stance period of the contralateral side, which is also true for other MCPKs. It could be assumed that improved knee resistance will automatically increase user confidence, and therefore gait synergy. However, ambulation is made up of multiple proprioceptive inputs that are processed by the neural network, and are used to drive muscle motion. Therefore, trying to quantify whether contralateral limb motion is "better" or "worse" is somewhat trivial. However, there is insufficient general evidence to consider the increased stance period as having improved, and this certainly appears to be an outcome of using the MCPK.

However, when Highsmith et al. (2010) compared the contralateral limb symmetries of three cross over groups wearing the power knee, the Mauch SNS and the C-leg during sit to stand tests, it was reported that the moments developed by the thigh musculature showed improved symmetry. Even though the sit to stand tests did not involve ambulation, this appears to suggest that powered devices are needed to improve asymmetries between the contralateral and prosthetic sides.

Hence, the hip moment control on the contralateral side will be further discussed in order to better understand the relationship between the prosthetic and contralateral sides.

The hip and knee compensations of the contralateral limb appear to have been used by the participants in this study to minimise the impact of the leading prosthetic limb, in order to make the body as stable as possible before initial contact on the prosthetic side. This outcome was evident when inspecting the hip moment during for participant B shown on page 159A, Figure 7.16, participant C during ramp descent on page 161A, Figure 7.21. Essentially, the moment outcomes during late stance show that the contralateral hip musculature was used to maintain an external flexion moment (or reduced extension) around the hip, and highlights the fact that the contralateral thigh is not being fully extended during late stance, allowing the body COM to move ahead of the trailing contralateral limb with confidence. It is suggested that this is to help minimise the loading response experienced by the leading prosthetic limb. These contralateral limb outcomes are also comparable to those of an abled-bodied control during ambulation activities that require greater muscle exertion when compared level walking. It is shown that, during an ambulation activity such as stair descent, the ankle, knee and hip external moment and angle plateau. These patterns of motion for able-bodied control can be seen in full for ramp ascent, ramp descent, stair ascent and stair descent, and are given on page 130A, 133A, 136A and 140A respectively. The combined knee moments and angle plateaus suggest that the muscles crossing the knee are contracting isometrically.

Thus, even for an able-bodied walker the late stance musculature control highlights the fact that the contralateral limb makes compensations to help minimise the impact on initial contact, which presumably is to help minimise instability. Therefore, it is not entirely surprising that this moment pattern was seen for the contralateral limb, as highlighted for participants B and F.

To further explore whether the contralateral limb compensations could be considered better or worse, the mechanical work done by the musculature during stance was therefore considered for both knee prostheses (page). However, it was expected that, when considering contralateral limb compensations, the results for the ramp descent activities would present the most obvious differences because the body would be falling from a greater height and, in order to minimise the load experienced by the leading prosthetic limb, would therefore require greater contralateral musculature control than in the other activities.

As demonstrated by participants B, D & F, the restricted outdoor ambulators exhibited improved voluntary control primarily during ramp descent using the Orion knee. The work outcomes of these users on the contralateral side are significantly different ($P<0.05$), and appear to show that more work was required by the contralateral side during descent using the Orion knee. However, these participants used the handrail during ramp descent wearing the 3R80, but not while wearing the Orion. The difference between participant F and participants B & D is that participant F performed negative work around the contralateral limb using the Orion knee, and positive work using the 3R80 knee. This outcome indicates that the musculature was working with greater efficiency on the prosthetic side while wearing the Orion knee.

As discussed on page 21 in the literature review, negative work indicates that the muscles are contracting against an external force whose action is lengthening the muscles. This action results in negative work by definition, and is more metabolically efficient than performing positive mechanical work. Indeed, this outcome highlights that when using the Orion knee this user has the confidence to allow the hip musculature to be used against the force of gravity to lower their body. This reasoning is supported by the results of participant C, the most active outdoor ambulator recruited. This pattern of negative work was not seen, during descent, with participants A and E, although the positive work was significantly reduced ($P<0.05$) using the Orion knee on the prosthetic side. However, participant E used the handrail wearing both the 3R80 and Orion knees, therefore this result cannot be as straightforwardly interpreted.

When considering the contralateral limb musculature during ascent, it can be suggested that, when compared to descent, compensation technique is not used to minimise the impact of initial contact on the prosthetic side (page). This is because the fall of the body is minimal, as the walking surface is rising ahead of the ambulator. Instead, it can be suggested that increased contralateral limb work ($P>0.05$) during ramp ascent, as seen in participants A, B, D, E and F, highlights that the contralateral limb's musculature is used with improved efficacy. Participant C did not show any difference in positive work during ascent. It is argued that increased work by the contralateral side during ascent illustrates that the musculature is being used to greater effect.

This is because this outcome also reflected the residual limb outcomes during ramp ascent, demonstrating that when using the Orion knee the musculature could be used with improved efficacy to assist with the lifting of the body. Hence, the work output of both the contralateral and prosthetic sides increased using the Orion knee during ramp ascent. Moreover, considering that the work output was reduced during ramp descent wearing the Orion knee, these patterns of results –increased work output during ascent, and reduced output during descent – indicate that the Orion knee is not simply increasing the effort required by the user, as a work increase would also be required during ramp descent.

Johansson et al. (2005) measured, via oxygen uptake, the metabolic rate of eight unilateral trans-femoral (K3) prosthetic users walking on a treadmill while wearing the variable damping knee (Mauch SNS), and compared this with the metabolic rate measured while wearing the C-leg and the Rheo Knee. It was shown that there was a trend of reduced metabolic consumption using the C-Leg, and they therefore illustrated that the mechanical or metabolic work of the contralateral hip musculature was reduced during ambulation with the MCPK. Indeed, these results from the present study suggest a similar outcome, where the mechanical work expenditure around the contralateral side during ramp descent indicates that both un-restricted and restricted outdoor ambulators benefited from the MCPK. However, as discussed on page 69, the limited participant numbers prevented, as was the case with the Johansson et al. (2005) study, the intersubject outcomes being used to suggest that these improvements would be experienced by the wider prosthetic user community.

In summary, while the evaluation of the spatial temporal parameters did not tend to reveal that there were particular advantages for any of the unrestricted outdoor ambulators who displayed beneficial outcomes on the prosthetic side, the moment outcomes around the hip did reveal that, during the level walking and ramp activities, the hip moment control was similar to the moment control of an able bodied ambulator during stair descent. It was suggested that these hip moment musculature control outcomes had the effect of minimising the impact of the leading limb, and therefore to ensure maximal stability on initial contact. This is not altogether unexpected here as initial contact for the prosthetic user is an instance in the gait cycle, which could potentially cause the knee to buckle. Using the mechanical work to evaluate contralateral limb musculature effort during the stance period of ramp descent, as this activity would result in greater musculature effort developed to provide stability compared to ramp ascent or level walking, this outcome revealed that the contralateral hip musculature of both the restricted and unrestricted MCPK user did less work to prepare the prosthetic side for initial contact. Therefore, this appears to show that the involuntary response of the MCPK also assists both the restricted and unrestricted ambulator, as the hip musculature effort on the contralateral side was reduced.

9.7 CLINICAL MEASURES TO ASSIT MCPK PERSCRIPTION

The purpose of this section is to amalgamate various clinical indicators that can be used to prescribe the MCPK. Since clinics are not generally able to offer biomechanical investigations to patients, due both to the cost of equipment and the need for skilled operators providing simple clinical outcomes to assist the practitioner in ascertaining whether the patient will gain additional voluntary control or involuntary response wearing the MCPK.

As a consequence of the low study power (see page 69), the qualitative discussion of intrasubject results was required, and revealed that the Orion MCPK provided additional voluntary control and involuntary response benefits relative to the 3R80 non-MCPK. However, while the Blatchfords Orion and Ottobock 3R80 knees represent, respectively, the MCPK and non-MCPK, the outcomes cannot represent all non-MCPKs and MCPKs. Since the time of the evaluation, Össur, Ottobock and Blatchfords have developed further iterations of their designs, and released products that contain additional sensors such as gyroscopes. It can be assumed that these iterations will further improve the voluntary control and the involuntary response. These changes may affect the guidelines suggested in this section to help prescribe MCPKs in general.

As with this study, the most formidable difficulty is the acclimatisation period. While this study did not offer community ambulation acclimatisation, the participants had 2-3 clinical sessions before the laboratory sessions to become familiar with their knee. Therefore, it cannot necessarily be expected that the patient will display improved benefits using the MCPK over a single clinical session.

Moreover, as products advance and the embedded system of the MCPK gains complexity with additional sensory inputs and outputs, the level of training required will also increase. Hence, this learning period may also increase the longevity of the assessment period, and this may not be practical or easy in the clinical environment. The initial learning period may depend of a variety of factors, such as age, lifestyle, personal goals, residual limb health, secondary medical conditions, and time since amputation.

The individual subjective evaluation of the moment graphical outcomes indicated that the MCPK provided the most benefit for the restricted outdoor (K2) ambulator, rather than to the unrestricted outdoor (K3) ambulator. This greater benefit was to be found primarily in the K2 user's ability to control the toe load during late stance in order to release the prosthetic knee for swing, and it visibly increased the stability of participants B, D and F during ramp descent. That is, they used the handrail for support during ramp descent wearing the 3R80 knee, but did not while wearing the Orion.

This suggests that, in the clinical environment, a ramp structure could be used to investigate whether the MCPK would be able to provide the restricted outdoor ambulator with improved stability. However, as previously discussed, due to the hip moment data repeatability, it could be surmised that participant A's initial contact response and stance stability were improved (page 185A). Unless a gait analysis was carried out, this outcome could not be investigated for participant A, implying that, for the unrestricted ambulator in the clinical environment, it may not be easy to investigate whether the MCPK is providing a significant benefit.

Moreover, the magnitude of the GRF during initial contact cannot be used to investigate such improvements page 173A, since there were no significant differences wearing either the Orion MCPK or the 3R80 non-MCPK. However, as described on (page 188), if evaluated subjectively the Pedotti diagram appears to illustrate that, during late stance – as indicated by the direction and spread of the GRF – the user is able to manipulate their toe load to assist the instance at which the knee resistance will reduce, when they require the knee to transition to swing. Even though Pedotti diagrams can be used to interpret the difference seen during ramp descent, this highlights that clinics would require a ramp with an inbuilt forceplate. Furthermore, as discussed, this outcome may not be evident during a signal clinical session, meaning that several clinical sessions may be required. This may cause difficulty if the patient cannot take the limb home, or if they have to return it after a month of community use.

The parameter that highlighted that the participants experienced an improved involuntary response was the walking speed, determined using the force plate signal to measure the stance period (page 192). It was shown that both the unrestricted and restricted ambulators recruited for this study were able to alter walking speed with greater magnitude when using the Orion MCPK and transitioning from level ambulation to ramp ascent and vice versa, even though there was no difference in average walking speed. Hence, in the clinical environment it may be possible to determine whether the individual's involuntary response is improved using the duration of the force plate signal during level and ramp ambulation. This does not necessarily have to be ascertained by forcing the patient to walk at their fast and slow walking speed.

Instead, as described in this study, understanding whether the knee can naturally adjust its involuntary response as the walking surface rises and falls will allow the clinician to ascertain whether the patient can realise involuntary control benefits walking on the level outside. Therefore, there are clinical indictors that can be gleaned from observing ambulation on a ramp, and using a force plate to ascertain whether the patient will benefit from the MCPK. These include not using the handrail during ramp ascent and descent while wearing the MCPK; subjectively investigating the toe load, as described in this study, to determine whether the direction and magnitude of the GRF is being manipulated and suggestive of improved voluntary control. This study revealed that the MCPK user manipulates the progression of the GRF to control the timing of the reduction in knee resistance, thereby allowing the knee to move to swing. However, these factors may only be beneficial after clinical training.

These conditions are only general, and it is suggested that pilot trials should be carried out in the clinical environment. This will assist in the development of a protocol to put in place a robust set of criteria to investigate whether the patient would find greater benefit from the MCPK. Such criteria might include, for example, determining a general number of sessions over which the patient should demonstrate improvements. Essentially, these clinical sessions could also be used to determine the feasibility of the suggested clinical outcomes on the general population. However, the evidence from this study indicates that these clinical outcomes will provide an appropriate starting point to evaluate the efficacy of prescribing the MCPK in the clinical environment.

9.8 STUDY LIMITATIONS AND STRENGTHS

Ideally, the evaluation would have had a larger sample size (page 69). However, the other pros and cons of the study, and how the limitations were minimised, will now be highlighted below.

9.9 STUDY LIMITATIONS

Short acclimatisation period: The total acclimatisation period was spread over 2-3 morning clinical sessions, and a 2-3 hour period prior to the gait laboratory assessment. Therefore, the initial effect that the prosthesis has on user biomechanics can be evaluated effectively. However, as all the participants were experienced ambulators, and had experience with the Ottobock 3R80 non-MCPK and the C-leg Ottobock MCPK, it was expected that the outdoor ambulators would familiarise themselves with the evaluation prostheses with a minimal acclimatisation period.

Participant Feedback: When asked to provide feedback during discussion, and to score the respective knee out of 100, the everyday C-Leg users reported that they would have preferred to have taken the Orion knee home before they could be confident with their scoring.

Environmental barriers: Due to the restriction of ethics, insurance, an inability to service the prostheses, and only having one Orion and one 3R80 knee unit, this study was limited to the gait laboratory. However, this does allow one test variable such as ramp ambulation to be evaluated without instantaneous camber variations.

Selection of components: Although not recommended by manufacture guidelines, the Blatchfords Echelon foot was fitted to a 3R80 Otto Bock knee. However, all participants were confident and comfortable ambulating with the 3R80 knee and the Echelon foot.

Sample population: Participant selection was not made at random from a large population, as they were all community ambulators. By chance, however, both K2 and K3 community ambulators were recruited and their differing abilities, assisted in the interpretation of results.

9.10 STUDY STRENGTHS

The strengths of this study are the outcomes of the robust test protocol, and the manner in which the numerical processing allowed repeatable results to be obtained and evaluated.

Study design: The clinical study was of crossover design to minimise test order effects. Moreover, as all participants acted as their own control, it was possible to evaluate the outcomes objectively, using both statistics and the qualitative assessment of graphical outcomes.

Component selection: To limit mechanical variability, and allow a true crossover study to be performed, only the knee components were substituted. This minimised alignment differences being experienced when using the two knee types, and ensured that only the knee component substitution affected the outcomes.

Data Accuracy: Sufficient data was collected to allow normally distributed data pools to be compared when intra-subject evaluations were made. Hence, the protocol and evaluation tools can be relied upon.

Sample population: All the participants were outdoor community ambulators and were able to complete the research protocol.

9.11 POSSIBLE MCPK DEVELOPMENTS AND FUTURE RESEARCH AREAS

The greatest, most obvious limitation of resistive lower limb technology is its inability to generate work. The challenge of generating work does not lie so much in the ability of the battery or motor technology, but in the ability of the user to control the work output. Resistive knee technology, as discussed, reads its position and external force environment to work synchronously with the user. The program/algorithm of the embedded system has to envisage all the possible situations that the user can encounter using its artificial sensors. This will obviously be influenced by the experience of the engineers designing the prostheses, and the life cycle of the product; from a prosthetic development point of view, the outcomes of this study suggest that further enhancement of the voluntary control element of the MCPK would be beneficial. This may allow the user to initiate knee flexion through instantaneous adjustments of knee resistance.

Whether this control could be achieved independently through knee function, or by combining peripheral socket signals with the knee embedded system, would require further investigation. One method that could be used to allow MCPKs to better adjust knee resistance and deliver power would be to have the ability to think ahead. Currently, the MCPK user primarily utilises the prosthetic response through reliance on the adjustment of the swing phase as the walking speed varies, and the voluntary control through manipulating the timing of the stance phase release.

However, microprocessor control gives the knee an ability to "think ahead", by reading the direction in which the user wants to move their knee. The instantaneous moment, angular orientation and angular rate of change can be used to predict the future trajectory of the knee. The compromise would be that there would be decreasing accuracy with the prediction over larger time increments, although the high processing speed of the microprocessor may allow the knee to think a half or a quarter of a second ahead, allowing for the timely delivery of power, or for the adjustment of knee damping to be more forgiving. This feature could be adjustable, allowing the "thinking" feature to be balanced on an individual user basis. This class of predictive controllers is a research area itself, and will likely become commonplace in prosthetics as the 21st century unfolds.

Hence, possible areas of further research could involve using the collected kinematics and kinetics to determine the predictive methods that could be used by the microprocessor of the MCPK, to predict the ambulators' trajectories. This in turn would show how in theory the predictive controller could be used to develop the MCPK. From a practical point of view, the heel, toe and pylon of the prosthesis could be strain gauged so that it would be possible to measure the prosthetic loading directly, in order to evaluate the correlation between toe loading and knee security on initial contact and toe-off. This study would highlight plausible improvements that could be made to the microprocessor algorithm, and may show that a foot providing sensory feedback would improve user control over the knee.

However, when considering clinical outcomes such as those alluded to in the previous section (9.7), a study that involved the collaboration between a university gait laboratory and a clinical practice would ensure that a wide range of lower limb transfemoral users could be assessed using the MCPK and non-MCPK. Consequently, this would provide a large database of how the experience of previously used knee, and even foot, components may affect the non-MCPK user being fitted with the MCPK.

However, this study would also be beneficial for patients who recently suffered lower limb loss, as the social, financial and biomechanical effects could be documented and understood. Institutions such as universities cannot determine the clinical hours, nor meet the cost of running such facilities, without collaboration with clinical practices. This study would be able to define extensive parameters with which to evaluate the lower limb prosthetic user, as there would be a better understanding of how long a particular user might expect to take before showing improvements using MCPK. Moreover, it would also highlight whether a particular MCPK may offer a more cost effective solution for a particular type of lower limb prosthetic user. The simple measures that were suggested in this study could be improved upon and adapted so as to make it possible to assess indoor ambulators, and to develop a scoring sheet that considers biomechanical effects as well as the social and the economic impact of the MCPK.

<table>
<tr><th colspan="2">Outcomes / Activity</th><th>Initial contact stability</th><th>Voluntary control during stance</th><th>Involuntary (swing) response</th><th>Contralateral outcomes</th></tr>
<tr><td colspan="2">level walking</td><td colspan="2">Participants: B & F
The significantly reduced (P<0.05) hip and knee extension moment using MCPK (page 170A), compared to non-MCPK indicates improved stability, as discussed on page 183-184, this improved initial contact stability is also suggestive of improved voluntary control during stance by these two restricted walkers.
Participants: A, C, D & E
The hip and knee moments did not demonstrate that either the MCPK or non-MCPK provided these participants with improved stability (P>0.05), it should be noted that participants A & C were classified as the un-restricted outdoor ambulators.</td><td rowspan="3">Participants: A, B, C, D & F
The stance period results, beacuse, they are directly related to walking speed (page 176, Table 8.1) indicate that both the K2 and K3 ambulators wearing the MCPK were able to alter their walking speed with a greater range during the activities of level walking, ramp ascent and ramp descent, and provide evidence that the involuntary swing response was improved. The evidence indicated that only user A & B experienced and increased walking speed with the MCPK (P<0.05) while the other participants experienced no change as discussed page 192-194.
Participants: A - F
The correlation of walking speed with mechanical energy absorbed around the non-MCPK & MCPK demonstrates that all users reduced their residual limb musculature exertion with the MCPK when the terrain, such as ramp ascent causes the ambulator to reduce their walking speed (page 195A).</td><td rowspan="3">Participants: A - F
The stance period indicated that the gait asymmetry wearing the MCPK was greater when compared to wearing the non-MCPK during level and ramp ambulation (page 179) and, the difference was significant 5% (P<0.05), for all participants on an individual basis (page 203).
Participants A, B, D, E & F
The trend of increased contralateral limb work (P>0.05) during ramp ascent (page 178A), highlights that the contralateral limb's musculature is used with improved efficacy when the participants wore the MCPK (page 207).
Participants: B, D & F
The contralateral work results (page 178A) during stance indicated that there was greater musculature exertion (P>0.05) wearing the MCPK when descending the ramp (page 207), however, see qualitative outcomes,Table 9.2, as these participants did not use handrail wearing MCPK and did while wearing the non-MCPK.
Participants: A, C & E
Despite participant E using the handrail, from these identified participants there was significantly reduced musculature effort during stance (page 178A) on the contralateral side during ramp descent (page 207).</td></tr>
<tr><td rowspan="2">ramp</td><td>ascent</td><td colspan="2">Participants: A
The significantly increased (P>0.05) hip and knee extension moment using MCPK throughout stance (page 171A) demonstrates improved musculature usage with MCPK compared to non-MCPK, due to the nature of the ramp ascent activity the knee should be inherently more stable therefore, the increased moments indicate improved propulsion (page 184-185).
Participants: B, C, D, E & F
The hip and knee moments did not demonstrate improved musculature usage (P>0.05), see qualitative outcomes (Table 9.2).</td></tr>
<tr><td>descent</td><td>Participants: A
Hip moment graph confidence limits show that residual hip musculature was used with improved repeatability suggesting improved user confidence wearing MCPK (page 185A).
Participants: B, C, D, E & F
The hip and knee moments did not demonstrate (P>0.05) improved stability comparing outcomes wearing MCPK compared to non-MCPK (page 185-186). However, the qualitative outcomes Table 9.2, illustrated that the MCPK offered improved stability.</td><td>Participants: B
The MCPK external knee flexion moment compared to the non-MCPK result (page 158A, Figure 7.14) demonstrates that the user was able to support their body weight using additional voluntary control as discussed page 190.
Participants: D
Pedotti diagram (page 188A, Figure 9.2) illustrates that towards end of stance that the MCPK toe load was used maintain additional voluntary control over knee at late stance.
Participants: F
Prosthetic MCPK moment graph (page 167A, Figure 7.34) illustrates that the knee resistance was maintained throughout stance, and was reduced prior to swing using additional voluntary control, as discussed page 189.</td></tr>
<tr><td rowspan="2">stair</td><td>ascent</td><td colspan="2">Participants: A, B, C, D, E & F
The average peak GRF for all participants on the prosthetic side did not vary with significance (P>0.05, page 177A) wearing the non-MCPK (116% of body weight) and MCPK (113% of body weight). The results show that the participants used the handrail to propel themselves up the steps, and therefore used the prosthesis as a static support, as discussed on page 198.</td><td rowspan="2">Participants: A-F
During the stair activities the participants did not flex their knee, and lifted their limb, i.e their prosthetic knee did not enter into swing phase.</td><td rowspan="2">Participants: A-F
Due to the nature of this activity when using both evaluation prostheses the participants relied heavily on both the handrail and the contralateral limb musculature, and as a result the quantitative outcomes did not lend themselves to analysis for this activity.</td></tr>
<tr><td>descent</td><td colspan="2">Participants: A, B, C, D, E & F
The average peak GRF for all participants on the prosthetic side did not vary with significance (P>0.05, page 177A) wearing the non-MCPK (83% of body weight) and MCPK (77% of body weight). The results show that the participants used the handrail to support their body weight during stair descent, discussed page 198.</td></tr>
</table>

Table 9.1 Quantitative outcomes, participants A & C are the un-restricted ambulators, and Participants B, D, E & F are restricted ambulators

9.12 SUMMARY

Table 9.1 and Table 9.2, respectively provide a tabular summary of the quantitative and qualitative outcomes, and where appropriate the reader is asked to refer to qualitative outcomes when reading quantitative outcomes, and vice versa. The tables list the activity (level walking, ramp ascent etc.) in the far left hand column, and the variable measured outcomes (initial contact, voluntary control, etc.) in the top row. Results are also grouped across the activities and, or the measured outcomes, for example, the involuntary response results are amalgamated in single column across the level walking and ramp activities rows, because they were considered together. Additionally, the initial contact and voluntary control measured outcomes were grouped together over a single row for the given activity (such as level walking, ramp ascent etc.), as these results were not considered in isolation.

In summary, during level walking the hip and knee moments demonstrated that both the restricted outdoor ambulators' participant B and F experienced improved stability on initial contact using the MCPK, and is suggestive of improved stability during stance. However, there were no qualitative outcomes, which allowed differences to be drawn upon when observing the participants during level walking. In contrast to the level walking, during the ramp activity the quantitative outcomes did not reveal that there was a significant difference ($P<0.05$) when considering the two evaluation prostheses. Instead, the qualitative outcome of not using the handrail when wearing the MCPK, and doing so when wearing the non-MCPK when the restricted ambulators (participant B & F) during ramp ascent, and the restricted ambulators (participant B, D & F) during ramp descent, highlighted this difference using the two prostheses.

<table>
<tr><th colspan="2">Outcomes / Activity</th><th>Initial contact stability</th><th>Voluntary control during stance</th><th>Contralateral outcomes</th><th>Participant feedback</th></tr>
<tr><td colspan="2">level walking</td><td colspan="3">Participants: A-F
Qualitative results did not suggest differences.</td><td rowspan="5">Participants: A - F
The participants respectively scored the MCPK (88%) and non-MCPK (77%) out of 100%, the score differed with a significance of 1% (P<0.01), indicating that they preferred the MCPK (page 143). However, it should be restated that the number of participants was low.
Participant C:
Participant C indicated that while she preferred the MCPK (Orion) to the non-MCPK (3R80) they preferred their own everyday MCPK (C-leg) model, and would not change even if it would be financially beneficial.
Participant F:
This participant said that while their MCPK (C-leg), which they owned, was a "little better" than the MCPK (Orion) used in the evaluation they felt that the cost difference warranted investigating the option of buying the MCPK (Orion) used in the investigation (page 144).</td></tr>
<tr><td rowspan="2">ramp</td><td>ascent</td><td colspan="3">Participants: B & F
The handrail was not used for additional support by these two restricted walkers wearing the MCPK compared to non-MCPK, and therefore indicated improved stability. Additionally, despite the use of the handrail wearing the non-MCPK compared to MCPK the quantitative outcomes,Table 9.1, highlighted that the residual limb musculature was used with improved efficacy as demonstrated by the trend (P>0.05) of and increased thigh exertion (by increased mechanical work) during ascent (see quantitative outcomes).
Participants: D & E
The use of the handrail for support by these two restricted outdoor walkers wearing both evaluation prostheses indicated that neither participant experienced improved stability or propulsion during ramp ascent.
Participants: A & C
These participants did not use the handrail wearing either evaluation prostheses, illustrating, that these un-restricted walkers did not experience improved stability wearing the MCPK (page 184).</td></tr>
<tr><td>descent</td><td colspan="3">Participants: B, D & F
The handrail was not used for additional support when wearing MCPK compared to non-MCPK by these restricted outdoor walkers, and indicates improved stability (page 206). This is in contrast to the quantitative outcomes, which did not demonstrate significant difference (P>0.05) wearing either prostheses, and indicated a trend of increased residual limb work (see quantitative outcomes).
Participants: E
This restricted walker used handrail for support wearing both evaluation prostheses (page 188).
Participants: A & C
These un-restricted outdoor walkers did not use handrail wearing either evaluation prostheses indicating that the users did not experience a difference, this observation was confirmed by the quantitative results (page 185).</td></tr>
<tr><td rowspan="2">stair</td><td>ascent</td><td colspan="3">Participants: A - F
During the stair ascent activity all the participants using either evaluation prostheses lifted their prosthetic side to the same step as the contralateral side, and did not adopt a step-over-step technique, they all the banaster during ascent (page 198).</td></tr>
<tr><td>descent</td><td colspan="3">Participants: A - F
When wearing both the non-MCPK and MCPK all participants observed their foot placement to ensure that they could maintain knee stability, only participants A, C and D adopted a step over step technique and could do so wearing both prostheses, they all held the banister during descent (page 200).</td></tr>
</table>

Table 9.2 Qualitative outcomes, participants A & C are the un-restricted ambulators, and Participants B, D, E & F are restricted ambulators

In turn, the qualitative outcomes assisted evaluating the quantitative outcomes that were skewed by the participants using the handrail because, the lower limb moments could not be straight-forwardly interpreted. For the stair activities, both quantitative and qualitative outcomes did not show that the participants in this study experienced benefits of stability and, or propulsion using either prostheses.

The contralateral outcomes of this study were analysed quantitatively by investigating the mechanical power developed by the hip musculature during stance, when ascending and descending a ramp. The quantitative (mechanical work of residual limb during stance) and qualitative outcomes (certain restricted walkers not using the handrail), made it was possible to conclude that during ascent the musculature was used with improved efficacy, and assisted propulsion as demonstrated by the increased mechanical work. Conversely, during descent it was reasoned that the stability was improved as less mechanical work was expended by the musculature. However, the stance period, measured using the forceplate, highlighted that there was greater asymmetry when using the MCPK compared to use of the non-MCPK.

The involuntary response outcomes that were evaluated statistically using the measure of stance period demonstrated that the MCPK offered improved involuntary response to all users by allowing the knee to adjust to the ambulators' natural waking speed on a given terrain with improved efficacy. This primary outcome indicated that the MCPK would be beneficial for all users, while the other stance phase outcomes indicated that the restricted walker rather than the un-restricted walker would benefit most from improved stability and control.

Finally, the outcomes that would be appropriate to use in the clinical environment, and would show whether the patient will find additional benefit of using the MCPK, are using qualitative outcomes (handrail use) during ramp activities to consider propulsion and stability during ascent, and stability during descent. Additionally, by measuring the stance period during level walking and a ramp activity (by the use of a pressure sensor mat rather than an expensive force plate) the involuntary response can be considered. Biomechanical assessment may help to identify differences, though these measures need to be used in conjunction with qualitative outcomes, as they do not provide a vivid picture of ambulatory outcomes when considered in isolation. Additionally, biomechanical measures are expensive due to technology required, and are difficult to obtain, as considerable work is required to capture, validate and process the data. However, simple biomechanical analysis such as using the Pedotti diagram may provide an illustrative difference, though is subject to the investigators' interpretation, and guidelines may be required to assist the interpretation of such analysis.

CHAPTER 10 CONCLUSION

The primary objective of this study was to evaluate the benefits of the MCPK with respect to the non-MCPK. At the time of writing, there were many non-independent studies supported by manufacturers, which claimed that the MCPK gave additional stability during stance by allowing for improved stumble recovery, or by allowing the user to walk with an increased range of walking speeds. Conversely, by focusing on qualitative scoring and the economic and social benefits, independent studies mainly concentrated on the subjective evidence. The present study realised the benefits of the MCPK by recognising how the design of the knee allowed the prosthesis to interact with the user. The biomechanical outcomes were then used to fulfil the secondary objective of this study, which was to suggest simple measures that could be used in the clinical environment to assist prescription of MCPK devices.

When evaluating a product that interacts with a user, such as a prosthetic knee, the product will respond in a predetermined manner for a given set of inputs. In the case of the microprocessor-controlled prosthetic knee, the literature review revealed that this predetermined response is achieved through the knee being able to sense the direction of the loading during stance, and the orientation of the knee during swing. However, it should be considered that, even though there are design similarities between the Orion MCPK evaluated in this study and other passive resistive MCPK products, there will also be differences that cannot be quantified by this study. In many respects the design philosophy of the 3R80 and Orion knees are similar. During stance, both knees provide sufficient resistance to flexion, which in turn provides stability and prevents the knee from buckling.

Furthermore, the interaction of the prosthetist and the user during setup allows for the selection of an appropriate average knee resistance for all ambulatory activities. However, the outcomes presented in this study provide general evidence to show that, when compared to the non-MCPK, the MCPK is able to improve the voluntary control and involuntary response.

During ambulation with the Orion MCPK and 3R80 non-MCPK, the user can directly influence, with residual limb control, the flexion and extension moment experienced around the knee. However, the evidence presented in this evaluation illustrated that the user of the Orion MCPK was able to manipulate the toe load to exert additional voluntary control over their knee. This was made evident by the restricted outdoor users (B, D & F) who, during ramp descent, minimised their toe load in mid to late stance so that their knee resistance did not reduce until they were confident to allow their knee to enter swing. The ability to use the toe load in such a manner was reflected by the measured outcomes, such as the Pedotti diagram, and the ankle and knee moment outcomes on the prosthetic side, and was made evident by the fact they did not use the handrail during descent wearing the MCPK, but did when wearing the non-MCPK. There was no evidence to suggest that this outcome of improved voluntary control was the result of a difference in the knees mechanical design. Instead, because both knees had similar alignments, and as stance resistance was provided using hydraulic pressure it can be reasoned that the participants would have selected a similar knee resistance using both knees in this study. In retrospect, it would have been beneficial to measure the knee resistance using a bench test after each participant evaluation. However, it was only evident upon review of the results that the knee resistance during stance does not significantly vary during ambulation.

Instead, it was the control system of the MCPK under the voluntary control of the toe load, which allowed the user to switch the knee resistance from a high stance resistance, to a low swing resistance.

A functional requirement of the prosthetic knee during swing is to damp both the rearward swing of the knee, preventing excessive heel rise, and the forward swing of the knee, preventing sudden extension. The remaining thigh musculature is still used to extend the knee and, as a result, metabolic energy is still expended by the user. The inter-statistical evidence suggested that, during level walking and both ramp ascent and ramp descent, MCPK users would experience a reduction in prosthetic knee mechanical energy absorption. Therefore, it can be inferred that this would also result in reduced metabolic energy expenditure at slower walking speeds. The spatial temporal parameters also reveal that the damping response of the MCPK allowed the user a more natural change of walking pace with respect to the ambulation terrain. Hence, this evidence suggests that the outdoor ambulator would experience an improved involuntary response in the outdoor environment when the terrain forces them to make adjustments to their walking speed.

When considering the contralateral side, the differences when ambulating with the two evaluation knee prostheses, the results indicated that both the un-restricted and restricted outdoor walker would experience improved mechanical work output on their contralateral side. The outcomes during ramp descent primarily highlighted that there were reduced contralateral limb compensations, as demonstrated by the reduced residual limb work output.

It was argued this was the outcome of the participants expending less effort to reduce the impact of their prosthetic side on initial contact, as seen with the MCPK.

Overall, the results generally illustrate that MCPK prescription is not just for the very active individual, but also for the less able community ambulator who requires improved stability and knee control. However, all the participants in this study benefited from the MCPK involuntary knee response. These outcomes show that in the clinical environment, if the patient demonstrates improved stability and control without handrail use during ramp activities, they will benefit from the MCPK. A force plate could also be used to trace the foot centre of pressure during level walking and ramp activities to evaluate voluntary control by considering toe load – though this sort of outcome does rely on the subjective interpretation of the examiner. However, the acclimatisation period of this study was spread over three clinical sessions before the commencement of the laboratory investigation. Hence, the patient would require acclimatisation, something which, if it is to be achieved in the clinical environment, would require consideration. Therefore, if a definite set of measures are to be compressed into a set of check box outcomes, a clinical study is required to investigate the influence of other factors, such as age, time since amputation and training. However, without further investigation this study would recommend that the restricted outdoor ambulator, rather than the unrestricted ambulator, would get the greatest benefit from using the MCPK.

CHAPTER 11 APPENDICES

11.1 SUMMARY OF MICROPROCESSOR CONTROLLED PROSTHESIS (APPENDIX 1)

paper	Study Type	Study Objective	Patient Characteristics	Method	Outcomes	Conclusion	limitations
Barr et al. 2012	experimental controlled clinical trial	To assess the functional outcomes of the following three prostheses: the Four Bar Endolite knee/Endolite Dynamic Response foot, Össur Total Knee 2000/Pathfinder I foot and C-Leg knee/IC40 C-walk foot.	active K3 amputee who had a traumatic amputation with a short stump (10.2cm)	The kinematics, kinetics and temporal parameters of one subject over a seven-year period were measured. The subject was given a four-month acclimatisation period before data capture.	The shear breaking forces were found to increase using the c-leg. Furthermore, the double support period decreased using the c-leg but the stance time of the contralateral leg increased. The kinematic data was not evaluated because repeatability was poor.	Suggested that along with user outcomes the c-leg improved stability and confidence. However also suggested further studies are needed	It was not reported if the results were significant. Furthermore, the period between prosthetic evaluations (time since amputation etc.) will have effected results.
Bellmann et al. 2010	experimental and observational controlled clinical trial	To investigate and identify functional differences of 4 microprocessor-controlled prosthetic knee joints (C-Leg, Hybrid Knee, Rheo Knee and Adaptive 2).	All nine subject were active walkers (k3-K4) who lost their limb traumatically or a result of tumour.	Energy composition was determined during level walking at a slow, self-selected and fast walking speed, using a treadmill with oxygen analysis; the rest metabolic rate was not ascertained. The functionality of the prosthesis was also assessed during stair ascent/descent and slope assent/descent (10 degrees). Finally, a trip test was used to evaluate prostheses stability.	The rate of swing was more controlled, as it was concluded the knee extended with less interruption. In addition, it was described that the knee was locked and ready before initial contact compared to other models, which only resisted the external moment on initial contact. Trip performance was also evaluated where the swing leg was manually prevented from extending .It was concluded the C-leg prostheses provided the greatest stability. Finally, it was also shown there was no difference of energy expenditure during level walking.	The C-leg was shown to be the preferential prosthesis	All subjects used the C-Leg as their day-to-day prosthesis, while the study is Otto bock biased. Furthermore, the trip test not clinically relevant, as preventing the leg from extending at selected points is very subjective while the environment of the tug test is also not fully explained. Finally, kinetic outcomes such as hip moments on the prosthetic side do not seem realistic.

paper	Study Type	Study Objective	Patient Characteristics	Method	Outcomes	Conclusion	limitations
Chin et al. 2007	experimental controlled clinical trial	to determine whether there was reduced metabolic consumption, when walking with the intelligent prostheses (IP) compared to walking with their everyday stance phase controlled mechanical Otto Bock prosthesis	Two elderly subjects (age 75 & 81) who both suffered a traumatic amputation, the second subject suffered from "slight morbidity concerns".	The subjects underwent a twelve-week training programme of which the second subject did not complete. However, both subjects were able to complete their five-minute walking test at their SSWS.	The physiological cost index (PCI = (pulse rate at end of walk – pulse rate at rest) (bpm)/walking speed (m/min)) revealed the both subjects had a reduced energy expenditure with improved cadence and step length.	It was concluded that the elderly could benefit from swing phase controlled prostheses.	Only two subjects were evaluated, furthermore, the improvement could have been a result of intensive training
Datta et al. 2005	experimentally controlled clinical trial	To determine whether there was a reduced energy cost when walking with the IP compared to a mechanically controlled pneumatic design.	Ten active walkers with a mean age of 38 years	The energy consumption was determined at rest and at five different walking speeds, during which time oxygen consumption was measured. Gait kinematics were also captured using a four-camera system.	The results showed no difference in kinematics, however, at the slower walking speeds the IP was shown to cause a significant reduction in metabolic energy expenditure.	There were no kinematic differences, and only significantly reduced energy expenditure at lower speeds	There was no significant reduction in energy expenditure at higher walking speeds, however not all subjects could ambulate at the higher walking speeds which would have affected the significance of results. Additionally, the training to use the IP will have influenced the results.
Hafner et al. 2007	Controlled clinical trial with both experimental and observational research, of crossover design, assessing the mechanical prosthesis (MP) first, MCPK, MP and finally the MCPK.	To determine whether there was improved functionality during level ambulation stair and ramp ascend/descent when wearing the C-leg compared to wearing an MP.	Twenty-one subject initially recruited due to a variety of reasons only 17 subjects left. They experienced no comorbidity factors and were younger the average amputee population	The analysis primarily included subjective scoring techniques, as the users rated themselves, and were scored by investigators. Objectionable evaluation included measurement of the step frequency and step length. Cognitive scoring was also used to assess whether the MCPK took the thinking out of walking.	It was shown overall that there was a significant improvement in the step length when ambulating on the level with the C-leg. The subjective results show there was significant improvement when negotiating slopes and stairs. Even though the amputees reported improved cognitive performance, a similar pattern was not noted by the examiner. However, the recall time for a series of numbers was reduced while walking and talking on the mobile phone when ambulating on the street	Overall there was improved performance when using the C-leg	The subjects own prosthesis acted as the subjects control prosthesis, which may influence the scale of improvement when transgressing to the MCPK

paper	Study Type	Study Objective	Patient Characteristics	Method	Outcomes	Conclusion	limitations
Herr et al. 2003	experimental controlled clinical trial	To determine whether a MCPK using the magnetorheological principal enabled more biologically realistic kinematics such as knee flexion in early stance and swing	Twelve normal subjects age, weight and height matched to an amputee population of four	Kinematic data collection was achieved on ten walking trails at seventeen different walking speeds.	The swing phase flexion angles, and stance phase flexion angles were compared	It was shown the amputees using the MCPK had early stance knee flexion and more biologically realistic swing phase flexion angles	Little information was provided about subject training and statistical analysis was not given.
Highsmith et al. 2011	experimental clinical cross-over sectional study with three groups	To determine the loading symmetry/asymmetry when standing from a seated position and sitting from a standing position, using normal subjects, power knee, C-leg and Mauch SNS user groups	Four groups of seven (normal, power knee, C-leg and Mauch SNS group), the C-leg and Mauch group contained more subjects with comorbidities.	The sit to stand and stand to sit times were evaluated while GRF, knee, and hip moments were used to comment upon asymmetries.	The sit to stand, and stand to sit times for all prosthetic users groups, and normal controls were comparable. However, in general the GRF and knee moments for the prosthetic user groups were asymmetric compared to able-bodied control. Only the hip moments were more symmetric when using the power knee.	There were positive differences that may be clinically meaningful even though not statistically significant	The C-leg and Mauch group contained more subjects with comorbidities. Furthermore, only three repetitions of each activity were carried out.
Highsmith et al. 2010	single subject case study	To determine whether the Össur power knee could enable sitting and standing when compared to C-leg users.	Single subject who suffered a limb loss due to diabetes.	The sit to stand and stand to sit times were evaluated while GRF, knee, and hip moments were used to comment upon asymmetries.	The Power knee improved hip moment symmetry while sitting and knee moment when moving from a seated position to a standing pose compared to the C-leg.	The power knee resolved gross asymmetries in prosthetic/contralateral limb loading compared to using a resistive C-Leg device.	Only one subject evaluated with no statistical explanation.
Jepson et al. 2008	experimental controlled clinical trial	To determine the benefit of ambulation with a swing and stance phase controlled adaptive prosthesis compared to the mechanically regulated Catech knee prosthesis.	Five subjects with a mean age of 41 years.	Subjects had to ambulate in a figure of 8 over a twenty-five meter course while wearing a heart rate monitor. Kinematic and kinetic data collection was also achieved using the Vicon system and Kistler force plate. Subjective results were also obtained with questioners.	Spatial temporal parameters were analysed along with the physiological cost index. There was no obvious difference in kinetic parameters, and consequently they were not reported.	The Outcomes suggest there is no significant difference in spatial temporal parameters and physiological cost index, therefore the MCPK offered little advantage	The paper despite the plethora of data collection did not report upon kinetic outcomes to evaluate stability objectively. Furthermore, the physiological cost index is unlikely to be accurate enough to report upon significant findings.

paper	Study Type	Study Objective	Patient Characteristics	Method	Outcomes	Conclusion	limitations
Johansson et al. 2005	experimental controlled clinical trial	Determine the self-selected walking speed (SSWS), change of kinematics and kinetics and energy consumption using the Mauch SNS, C-leg and Rheo Knee.	Eight subjects of K3 walking ability were recruited for this study.	Prosthesis was first assigned in random order. First, the metabolic rate using oxygen uptake was determined followed by kinematic analysis. This was used to comment upon mechanical work. Finally, EMG readings of the gluteus maximums and Gluteus Medius muscles were also obtained.	The outcomes present evidence showing the MCPK technology does enable reduced energy expenditure. However, the Rheo knee did result in a reduced energy expenditure compared to the C-leg; however, it was not significant at 5%. Furthermore, EMG reading suggested the Rheo enabled the greatest reduction in muscular activity.	variable damping knees (MCPK) are more effective than mechanical knees, however the Rheo offers advantages over the C-leg	Not an independent study, although appears to be carried out fairly. Overall, mechanical and metabolic outcomes are well presented.
Kahle et al. 2008	experimental controlled clinical trial	To evaluate the waking speed and ability of subjects to descend stairs using the mechanical knee prosthesis (Mauch SNS) and then C-Leg.	Twenty-one subjects recruited of which nineteen manged to complete. Out of the nineteen subject nine were rated as K2 ambulators	The walking speed over a 75m course at a self-selected waking speed (SSWS) and free walking speed (FPWS) over even terrain, and FPWS over uneven terrain was used to evaluate walking speed. Questioners were used to evaluate participant feedback and subjective evaluation was used to evaluate stair descent.	A 75m SSWS and FPWS over even terrain, and FPWS on uneven terrain revealed that the C-leg enabled a significant increase in walking speed. The subject feedback did show a preference towards the C-leg. However, other factors other the biomechanics influenced this opinion such as finance and cosmetics. Finally, stair ambulation was also considered to have improved.	The C-leg was shown to be the preferential prostheses, because of increased walking speed ability.	In reality step over step stair descent will not occur. While there was limited, kinetic outcomes to assess biomechanics.
Kaufman et al. 2011	experimental controlled clinical trial	To propose a new method to compare gait symmetry of prosthetic users ambulating with the Mauch SNS and C-leg prosthesis	Fifteen amputee and twenty able bodied subjects recruited. All amputee subjects were healthy, walking ability not stated.	Subjects were ask to walk on level, and kinematic and kinetic data was captured.	A statistical method known as Singular Value De-composition was used to comment in the symmetry of stance, swing phase angles and moments.	it was shown overall there was a significant improvement in gait symmetry using the C-leg	Heavily relied on statically significance, however improved flexion noted during stance may have come from prosthetic alignment.

paper	Study Type	Study Objective	Patient Characteristics	Method	Outcomes	Conclusion	limitations
Kaufman et al. 2007	experimental controlled clinical trial	To determine the postural stability when unilateral trans-femoral amputees changed from wearing The Mauch SNS unit to C-leg	15 subjects of K3 and K4 Medicare Functional Classification Level	The subjects were asked to stand in a platform whose orientation could be manipulated along with visual inputs to test postural stability. Kinematic and kinetics were also collected	Postural stability was quantified using an equilibrium score, determined form sway. Kinematic and kinetics were also collected to report in knee angle and moment.	The C-leg allows for improved postural stability, thus walking ability. In addition, the knee angle was shown to be one of flexion rather than extension using the C-Leg.	There is a big jump between postural stability and walking ability. Even though they are linked, the prosthetic alignment likely to also effect results. Also study funded by Otto Bock
Kirker et al. 1996	experimental controlled clinical trial	Primarily to determine whether there was reduced metabolic energy expenditure when ambulating with the intelligent prosthesis (IP) compared to ambulating with a pneumatic swing phase controlled prosthesis.	6 unilateral active walkers	Subject's walking speeds were first determined when ambulating in corridor, after which they were asked to walk on treadmill with their two different prosthesis at the predetermined slow, normal and fast walking speed.	The subjects were to walk on a treadmill until their slow target, normal and fast walking speed was reached. Their oxygen consumption was measured along with their walking velocity and step symmetry, while wearing a pneumatic swing phase control and IP prosthesis	the symmetry of gait was improved when walking with the IP	The oxygen consumption method was unlikely to have be accurate enough to determine a difference of energy expenditure.
Mâaref et al. 2010	Case controlled clinical trial	Primarily to identify the latency period, the time between knee extension during swing and initial contact for two groups of amputees wearing a swing phase controlled leg and C-leg with able-bodied subjects acting as the control group.	29 amputee subjects with a main exclusion criterion of vascular disease and 15 able-bodied control subjects.	The amputee subjects were split into two groups (11 and 14) and were asked to walk in the gait lab along with the normal subjects, and kinematic and kinetic data was collected	The outcomes show that the latency period of the prosthetic leg was significantly shorter when subjects wore the C-leg. However, the latency period of the contralateral leg was also greater. Furthermore, it was shown the latency period was significantly shorter for amputees with the shortest residual limb length and below the age of 45.	The C-leg was determined to improve the latency period at the end of swing showing amputees were more confident ambulating with the C-leg	The study failed discuss the increased latency period of the contralateral leg when using the C-leg.

paper	Study Type	Study Objective	Patient Characteristics	Method	Outcomes	Conclusion	limitations
Orendurff et al. 2006	experimental controlled cross-over clinical trial	determine the oxygen cost during ambulation with the Mauch SNS and C-leg prostheses	8 subjects able to ambulate until 2 minutes of steady state oxygen consumption was reached	Amputee subjects were asked to ambulate around a rectangular corridor at four speeds in random order at 0.8 m/s, 1.0 m/s, 1.3 m/s, and a previously chosen speed. They were followed by a cart with equipment measuring their oxygen consumption.	The outcomes show there was no statistical difference in the metabolic cost when ambulating with the C-leg compared to ambulating with the Mauch SNS prostheses	Ambulation with the C-leg resulted in reduced energy expenditure.	Following the subject with a cart will have likely effected the results, while accuracy is not reported.
Perry et al. 2004	single experimental subject case study	To primarily determine the metabolic cost of a bilateral amputee ambulating with stubbies, the Mauch SNS and C-leg.	One subject study who was bilateral amputee	The metabolic cost measured while walking outside on a 60m track, achieved by monitoring inhaled/exhaled air. Kinematics and kinetics were also determined on walking with the C-Leg in the gait lab.	The metabolic cost of ambulation was determined November 1997 when walking with "stubbies" and Mauch SNS prosthesis. The Metabolic cost, was also determined in March 2003 on walking with the C-Leg.	The results showed ambulation with the C-leg prosthesis significantly reduced metabolic expenditure.	The oxygen consumption test when wearing the C-leg was carried out 6 years after the initial test. Consequently, both fitness and familiarity will significantly affect differences found.
Petersen et al. 2010	experimentally controlled clinical trial	To determine the symmetry of gait using spatial temporal parameters on habitual C-leg users being fitted with the 3R60 prosthetic knee	Five K3-4 lower limb users who had an amputation due to trauma or cancer.	Kinematic and kinetic data collection at a walking speed of 1.1 m/s on wearing their own C-leg and 3R60 knee after a week acclimatisation.	Temporal parameters revealed the stance duration was not significantly increased on the prosthetic side when using the C-leg. While spatial parameters revealed there was no significant difference in the step length	The results show there was no significant improvement in symmetry when walking with the C-leg	The participants were forced to walk at a reported average speed of 1.1ms, which would likely have had a significant effect on results. Integrating the Pedotti diagram in not physically meaningful
Schaarschmidt et al. 2012	experimentally controlled clinical trial	To understand why there is gait asymmetry, and investigate if the C-leg compared to the 3R80 improves asymmetry.	Five unilateral C-leg users without comorbidities.	Subjects were asked to walk at four different speeds (0.5, 0.8, 1.1 and 1.4 m/s) on the treadmill for 60 second periods, while the GRF was recorded first with the C-leg Then 3R80.	The GRF and temporal spatial parameters were used to report on the symmetry of gait.	the GRF was observed to have improved symmetry, however the temporal spatial parameters were not subject to improved symmetry	There was a least a 10% error in GRF calculations.

paper	Study Type	Study Objective	Patient Characteristics	Method	Outcomes	Conclusion	limitations
Segal et al. 2006	experimental case controlled study	To study symmetry, limb loading, kinematic, and kinetic response of the Mauch SNS and C-leg prosthetic limbs.	Eight subjects who used a Mauch SNS unit, and they did not suffer from comorbidities.	The subjects were asked to walk on the level at their self-selected walking speed (SSWS) and a controlled walking speed (CWS), while both kinetic and kinematic data was obtained.	The outcomes show that prosthetic knee response does not allow the stance knee to flex. The walking speed and step length of the prosthetic side increased using the C-leg the prosthetic limb loading wearing the C-leg decreased.	There was improved spatial temporal parameters.	Different feet fitted to the prostheses.
Buckley et al. 1997	Experimental controlled clinical trial	Determine whether there is reduced energy expenditure when ambulating with the IP compare to a pneumatic swing phase controlled prostheses (PSPC).	Three subjects who suffered a traumatic lower limb loss.	The subjects were first asked to ambulate on a treadmill with the IP prosthesis at the slow, normal, and fast walking pace for an eight-minute period, their walking pace was forced to change every minute. This was then repeated for the pneumatic swing phase controlled device using the same walking speeds.	The results indicate a trend of reduce energy expenditure at a walking pace other than the self-selected walking speed (SSWS).	The results of reduced energy expenditure at the SSWS are expected, as the PSPC is optimally set for a SSWS.	Small population size.

11.2 TEMPLATE "M" FILE USED TO RUN GAIT ANALYSIS (APPENDIX 2)

```
clearvars -except static normalised_data
%============================anthropomrtrics==========================
gender='male';
data_sheet.trunk_length=0;%mm
data_sheet.marker_diameter=14;%mm
data_sheet.height=0;%mm
%for amputee only
data_sheet.waist=0;%mm
data_sheet.hip=0;%mm
data_sheet.body_mass=0;%kg
data_sheet.foot_length=0;%mm
%mm from tibial tuberosity marker to condyle plateau
data_sheet.condyle_plateu_L=0;
data_sheet.condyle_plateu_R=0;
%STUMP and PROSTHETIC PARAMTERS
data_sheet.level='N/A'; %(AK) or below (BK) knee amputation
%dimensions in mm or kg
data_sheet.proximal_end_circumference=0;
data_sheet.distal_end_circumference=0;
data_sheet.stump_length=0;
%leg mass for AK
data_sheet.socket_wall_thickness=0;
data_sheet.socket_mass=0;
%leg mass for BK
data_sheet.leg_mass=0;
%number of leg ossolations in ten seconds
data_sheet.time_leg_coronal=0;
data_sheet.time_leg_transverse=0;
data_sheet.time_leg_sagittal=0;
%foot mass
data_sheet.foot_mass=0;
%number of foot ossolations in ten seconds
data_sheet.time_foot_coronal=0;
data_sheet.time_foot_transverse=0;
data_sheet.time_foot_sagittal=0;
%centre of mass in mm measured from proximal end
data_sheet.leg_centre_of_mass=0;
data_sheet.foot_centre_of_mass=0;
```

11.3 LAGRANGIAN ANALYTICAL SOLUTION (APPENDIX 3)

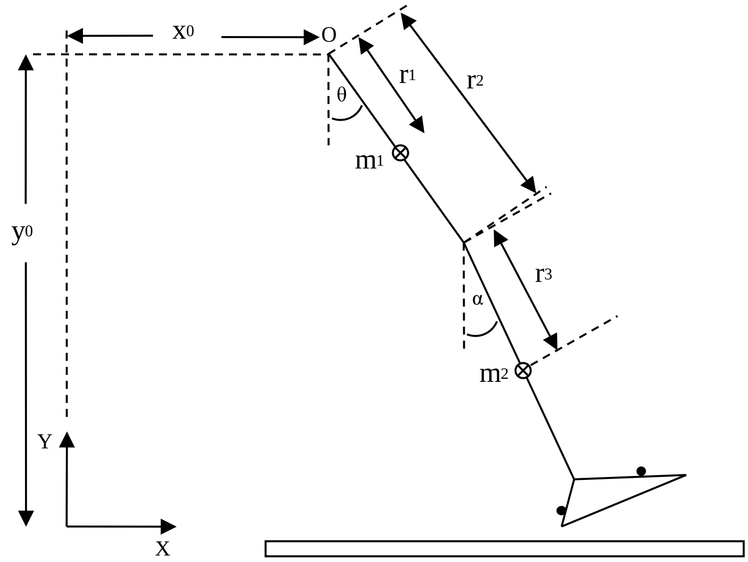


Figure 11.1 Free body diagram of lower limb in swing

The Lagrange's equation of motion for known non-conservative forces, Fq_r, and unknown forces Fq_r' acting on a conservative system is given by:

$$\frac{d}{dt}\left(\frac{\partial L}{\partial \dot{q}_r}\right) - \frac{\partial L}{\partial q_r} = Fq_r + Fq_r'$$

Where the Lagrangian function is defined:

$$L = T - V$$

Total potential energy of the lower limb system

$V = v_1 + v_2$

$V = m_1 g h_1 + m_2 g h_2$

Where h_1 from the origin or hip centre

$$h_1 = y_0 - r_1 \cos(\theta)$$

Therefore

$$v_1 = m_1 g[y_0 - r_1 \cos(\theta)]$$

Where h_2 from the origin or hip centre

$$h_2 = y_0 - r_2 \cos(\theta) - r_3 \cos(\alpha)$$

Therefore

$$v_2 = m_2 g[y_0 - r_2 \cos(\theta) - r_3 \cos(\alpha)]$$

Therefore

$$V = m_1 g[y_0 - r_1 \cos(\theta)] + m_2 g[y_0 - r_2 \cos(\theta) - r_3 \cos(\alpha)]$$

Kinetic energy for m_1

Liner velocity of point O $\dot{x}$ *and* $\dot{y}$

Total kinetic energy of the lower limb leg system

$$T = \frac{1}{2} m_1 (\dot{x}_1^2 + \dot{y}_1^2) + \frac{1}{2} m_2 (\dot{x}_2^2 + \dot{y}_2^2)$$

The coordinates of the thigh COM with respect to the origin or hip centre

$$x_1 = x_0 + r_1 \sin(\theta)$$

$$y_1 = y_0 - r_1 \cos(\theta)$$

The relative velocity of the thigh COM with respect to the hip centre

$$\dot{x}_1 = \dot{x}_0 + r_1\dot{\theta} \cos(\theta)$$

$$\dot{y}_1 = \dot{y}_0 + r_1\dot{\theta} \sin(\theta)$$

The square of the x_1 and y_1 velocity terms

$$\dot{x}_1^2 = \dot{x}_0^2 + 2\dot{x}_0 r_1\dot{\theta} \cos(\theta) + r_1^2\dot{\theta}^2 cos^2(\theta)$$

$$\dot{y}_1^2 = \dot{y}_0^2 + 2\dot{y}_0 r_1\dot{\theta} \sin(\theta) + r_1^2\dot{\theta}^2 sin^2(\theta)$$

The total velocity of thigh COM v_1 relative to hip centre

$$v_1^2 = \dot{x}_1^2 + \dot{y}_1^2$$

$$v_1^2 = \dot{x}_0^2 + 2\dot{x}_0 r_1\dot{\theta} \cos(\theta) + r_1^2\dot{\theta}^2 cos^2(\theta) + \dot{y}_0^2 + 2\dot{y}_0 r_1\dot{\theta} \sin(\theta) + r_1^2\dot{\theta}^2 sin^2(\theta)$$

$$v_1^2 = \dot{x}_0^2 + \dot{y}_0^2 + r_1^2\dot{\theta}^2[sin^2(\theta) + cos^2(\theta)] + 2\dot{x}_0 r_1\dot{\theta} \cos(\theta) + 2\dot{y}_0 r_1\dot{\theta} \sin(\theta)$$

$$v_1^2 = \dot{x}_0^2 + \dot{y}_0^2 + r_1\dot{\theta}^2 + 2r_1\dot{\theta}[\dot{x}_0 \cos(\theta) + \dot{y}_0 \sin(\theta)]$$

The coordinates of the knee centre with respect to the origin or hip centre

$$x_2 = x_0 + r_2 \sin(\theta)$$

$$y_2 = y_0 - r_2 \cos(\theta)$$

The coordinates of the leg COM with respect to the knee centre

$$x_3 = x_2 + r_3 \sin(\alpha)$$

$$y_3 = y_2 - r_3 \cos(\alpha)$$

The coordinates of the leg COM with respect to the hip centre

$$x_3 = x_0 + r_2 \sin(\theta) + r_3 \sin(\alpha)$$

$$y_3 = y_0 - r_2 \cos(\theta) - r_3 \cos(\alpha)$$

The velocity of the leg COM relative to the hip centre

$$\dot{x}_3 = \dot{x}_0 + r_2\dot{\theta} \cos(\theta) + r_3\dot{\alpha} \cos(\alpha)$$

$$\dot{y}_3 = \dot{y}_0 + r_2\dot{\theta} \sin(\theta) + r_3\dot{\alpha} \sin(\alpha)$$

The square of the x_3 and y_3 velocity terms

$$\dot{x}_3^2 = \dot{x}_0^2 + 2\dot{x}_0 r_2\dot{\theta} \cos(\theta) + 2\dot{x}_0 r_3\dot{\alpha} \cos(\alpha) + r_2^2\dot{\theta}^2 cos^2(\theta) + r_3^2\dot{\alpha}^2 cos^2(\alpha) + 2r_2 r_3\dot{\theta}\dot{\alpha} \cos(\theta) \cos(\alpha)$$

$$\dot{y}_3^2 = \dot{y}_0^2 + 2\dot{y}_0 r_2\dot{\theta} \sin(\theta) + 2\dot{y}_0 r_3\dot{\alpha} \sin(\alpha) + r_2^2\dot{\theta}^2 sin^2(\theta) + r_3^2\dot{\alpha}^2 sin^2(\alpha) + 2r_2 r_3\dot{\theta}\dot{\alpha} \sin(\alpha) \sin(\theta)$$

The total velocity of leg COM v_3 relative to hip centre

$$v_3^2 = \dot{x}_3^2 + \dot{y}_3^2$$

$$v_3^2 = \dot{x}_0^2 + 2\dot{x}_0 r_2\dot{\theta}\cos(\theta) + 2\dot{x}_0 r_3\dot{\alpha}\cos(\alpha) + r_2^2\dot{\theta}^2 cos^2(\theta) + r_3^2\dot{\alpha}^2 cos^2(\alpha)$$
$$+ 2r_2r_3\dot{\theta}\dot{\alpha}\cos(\theta)\cos(\alpha) + \dot{y}_0^2 + 2\dot{y}_0 r_2\dot{\theta}\sin(\theta) + 2\dot{y}_0 r_3\dot{\alpha}\sin(\alpha)$$
$$+ r_2^2\dot{\theta}^2 sin^2(\theta) + r_3^2\dot{\alpha}^2 sin^2(\alpha) + 2r_2r_3\dot{\theta}\dot{\alpha}\sin(\alpha)\sin(\theta)$$

$$v_3^2 = \dot{x}_0^2 + \dot{y}_0^2 + r_2^2\dot{\theta}^2 + 2r_2r_3\dot{\theta}\dot{\alpha}\cos(\theta-\alpha) + r_3^2\dot{\alpha}^2$$
$$+ 2r_2\dot{\theta}[\dot{y}_0\sin(\theta) + \dot{x}_0\cos(\theta)] + 2r_3\dot{\alpha}[\dot{y}_0\sin(\alpha) + \dot{x}_0\cos(\alpha)]$$

$$L = T - V$$

$$L = \frac{1}{2}m_1\left[\dot{x}_0^2 + \dot{y}_0^2 + r_1\dot{\theta}^2 + 2r_1\dot{\theta}[\dot{x}_0\cos(\theta) + \dot{y}_0\sin(\theta)]\right]$$
$$+ \frac{1}{2}m_2\left[\dot{x}_0^2 + \dot{y}_0^2 + r_2^2\dot{\theta}^2 + 2r_2r_3\dot{\theta}\dot{\alpha}\cos(\theta-\alpha) + r_3^2\dot{\alpha}^2\right.$$
$$\left.+ 2r_2\dot{\theta}[\dot{x}_0\cos(\theta) + \dot{y}_0\sin(\theta)] - 2r_3\dot{\alpha}[\dot{x}_0\cos(\alpha) + \dot{y}_0\sin(\alpha)]\right]$$
$$- \left[m_1 g[y_0 - r_1\cos(\theta)] + m_2 g[y_0 - r_2\cos(\theta) - r_3\cos(\alpha)]\right]$$

$$\frac{\partial L}{\partial \theta} = \frac{1}{2}m_1\left[2r_1\dot{\theta}[\dot{y}_0\cos(\theta) - \dot{x}_0\sin(\theta)]\right]$$
$$+ \frac{1}{2}m_2\left[2r_2\dot{\theta}[\dot{y}_0\cos(\theta) - \dot{x}_0\sin(\theta)] - 2r_2r_3\dot{\theta}\dot{\alpha}\sin(\theta-\alpha)\right]$$
$$- [m_2 g r_2\sin(\theta) + m_1 g r_1\sin(\theta)]$$

$$\frac{\partial L}{\partial \dot{\theta}} = \frac{1}{2}m_1\left[2r_1\dot{\theta} + 2r_1[\dot{x}_0\cos(\theta) + \dot{y}_0\sin(\theta)]\right]$$
$$+ \frac{1}{2}m_2\left[2r_2^2\dot{\theta} + 2r_2r_3\dot{\alpha}\cos(\theta-\alpha) + 2r_2[\dot{x}_0\cos(\theta) + \dot{y}_0\sin(\theta)]\right]$$

$$\frac{\partial L}{\partial \dot{\theta}} = \frac{1}{2} m_1 \big[2r_1 \dot{\theta} + 2r_1 [\dot{x}_0 \cos(\theta) + \dot{y}_0 \sin(\theta)] \big]$$

$$+ \frac{1}{2} m_2 \left[2r_2^2 \dot{\theta} + 2r_2 r_3 \dot{\alpha} \cos(\theta - \alpha) + 2r_2 [\dot{x}_0 \cos(\theta) + \dot{y}_0 \sin(\theta)] \right]$$

$$\frac{d}{dt}\left(\frac{\partial L}{\partial \dot{\theta}}\right) = \frac{1}{2} m_1 \big[2r_1 \ddot{\theta} + 2r_1 [\ddot{x}_0 \cos(\theta) - \dot{x}_0\, \dot{\theta} \sin(\theta) + \ddot{y}_0 \sin(\theta) + \dot{y}_0\, \dot{\theta} \cos(\theta)] \big]$$

$$+ \frac{1}{2} m_2 \Big[2r_2^2 \ddot{\theta} + 2r_2 r_3 \ddot{\alpha} \cos(\theta - \alpha) - 2r_2 r_3 \dot{\alpha} \sin(\theta - \alpha)(\dot{\theta} - \dot{\alpha})$$

$$+ 2r_2 \big[\ddot{x}_0 \cos(\theta) - \dot{x}_0\, \dot{\theta} \sin(\theta) + \ddot{y}_0 \sin(\theta) + \dot{y}_0\, \dot{\theta} \cos(\theta) \big] \Big]$$

$$\frac{d}{dt}\left(\frac{\partial L}{\partial \dot{\theta}}\right) - \frac{\partial L}{\partial \dot{\theta}} = \Bigg[\frac{1}{2} m_1 \big[2r_1 \ddot{\theta} + 2r_1 [\ddot{x}_0 \cos(\theta) - \dot{x}_0\, \dot{\theta} \sin(\theta) + \ddot{y}_0 \sin(\theta)$$

$$+ \dot{y}_0\, \dot{\theta} \cos(\theta)] \big]$$

$$+ \frac{1}{2} m_2 \Big[2r_2^2 \ddot{\theta} + 2r_2 r_3 \ddot{\alpha} \cos(\theta - \alpha) - 2r_2 r_3 \dot{\alpha} \sin(\theta - \alpha)(\dot{\theta} - \dot{\alpha})$$

$$+ 2r_2 \big[\ddot{x}_0 \cos(\theta) - \dot{x}_0\, \dot{\theta} \sin(\theta) + \ddot{y}_0 \sin(\theta) + \dot{y}_0\, \dot{\theta} \cos(\theta) \big] \Big] \Bigg]$$

$$- \Bigg[\frac{1}{2} m_1 \big[2r_1 \dot{\theta} + 2r_1 [\dot{x}_0 \cos(\theta) + \dot{y}_0 \sin(\theta)] \big]$$

$$+ \frac{1}{2} m_2 \left[2r_2^2 \dot{\theta} + 2r_2 r_3 \dot{\alpha} \cos(\theta - \alpha) + 2r_2 [\dot{x}_0 \cos(\theta) + \dot{y}_0 \sin(\theta)] \right] \Bigg]$$

$$\frac{\partial L}{\partial \alpha} = \frac{1}{2} m_2 \left[-2r_2 r_3 \dot{\theta} \dot{\alpha} \sin(\theta - \alpha) - 2r_3 \dot{\alpha}^2 [\dot{y}_0 \sin(\alpha) - \dot{x}_0 \sin(\alpha)] \right]$$

$$- [m_2 g r_3 \dot{\alpha} \sin(\alpha)]$$

$$\frac{\partial L}{\partial \dot{\alpha}} = \frac{1}{2} m_2 \left[2r_2 r_3 \dot{\theta} \cos(\theta - \alpha) + 2r_3^2 \dot{\alpha} - 2r_3 [\dot{x}_0 \cos(\alpha) + \dot{y}_0 \sin(\alpha)] \right]$$

$$\frac{d}{dt}\left(\frac{\partial L}{\partial \dot{\alpha}}\right) = \frac{1}{2} m_2 \Big[2r_2 r_3 \ddot{\theta} \cos(\theta - \alpha) - 2r_2 r_3 \dot{\theta} \sin(\theta - \alpha) \left(\dot{\theta} - \dot{\alpha}\right) + 2r_3^2 \ddot{\alpha}$$

$$- 2r_3 [\ddot{x}_0 \cos(\alpha) - \dot{x}_0 \sin(\alpha) + \ddot{y}_0 \sin(\alpha) + \dot{y}_0 \cos(\alpha)] \Big]$$

$$\frac{d}{dt}\left(\frac{\partial L}{\partial \dot{\alpha}}\right) - \frac{\partial L}{\partial \dot{\alpha}} = \frac{1}{2} m_2 \Big[\Big[2r_2 r_3 \ddot{\theta} \cos(\theta - \alpha) - 2r_2 r_3 \dot{\theta} \sin(\theta - \alpha) \left(\dot{\theta} - \dot{\alpha}\right) + 2r_3^2 \ddot{\alpha}$$

$$- 2r_3 [\ddot{x}_0 \cos(\alpha) - \dot{x}_0 \sin(\alpha) + \ddot{y}_0 \sin(\alpha) + \dot{y}_0 \cos(\alpha)] \Big]$$

$$- \left[2r_2 r_3 \dot{\theta} \cos(\theta - \alpha) + 2r_3^2 \dot{\alpha} - 2r_3 [\dot{x}_0 \cos(\alpha) + \dot{y}_0 \sin(\alpha)] \right] \Big]$$

The inertial moment acting around the hip centre described algebraically:

$$\frac{d}{dt}\left(\frac{\partial L}{\partial \dot{\alpha}}\right) - \frac{\partial L}{\partial \dot{\alpha}} = \frac{1}{2} m_2 \Big[2r_2 r_3 \ddot{\theta} \cos(\theta - \alpha) - 2r_2 r_3 \dot{\theta} \sin(\theta - \alpha) \left(\dot{\theta} - \dot{\alpha}\right) + 2r_3^2 \ddot{\alpha}$$

$$- 2r_3 [\ddot{x}_0 \cos(\alpha) - \dot{x}_0 \sin(\alpha) + \ddot{y}_0 \sin(\alpha) + \dot{y}_0 \cos(\alpha)]$$

$$- 2r_2 r_3 \dot{\theta} \cos(\theta - \alpha) - 2r_3^2 \dot{\alpha} + 2r_3 [\dot{x}_0 \cos(\alpha) + \dot{y}_0 \sin(\alpha)] \Big]$$

11.4 PARTICIPANT (A) RESULTS (APPENDIX 4)

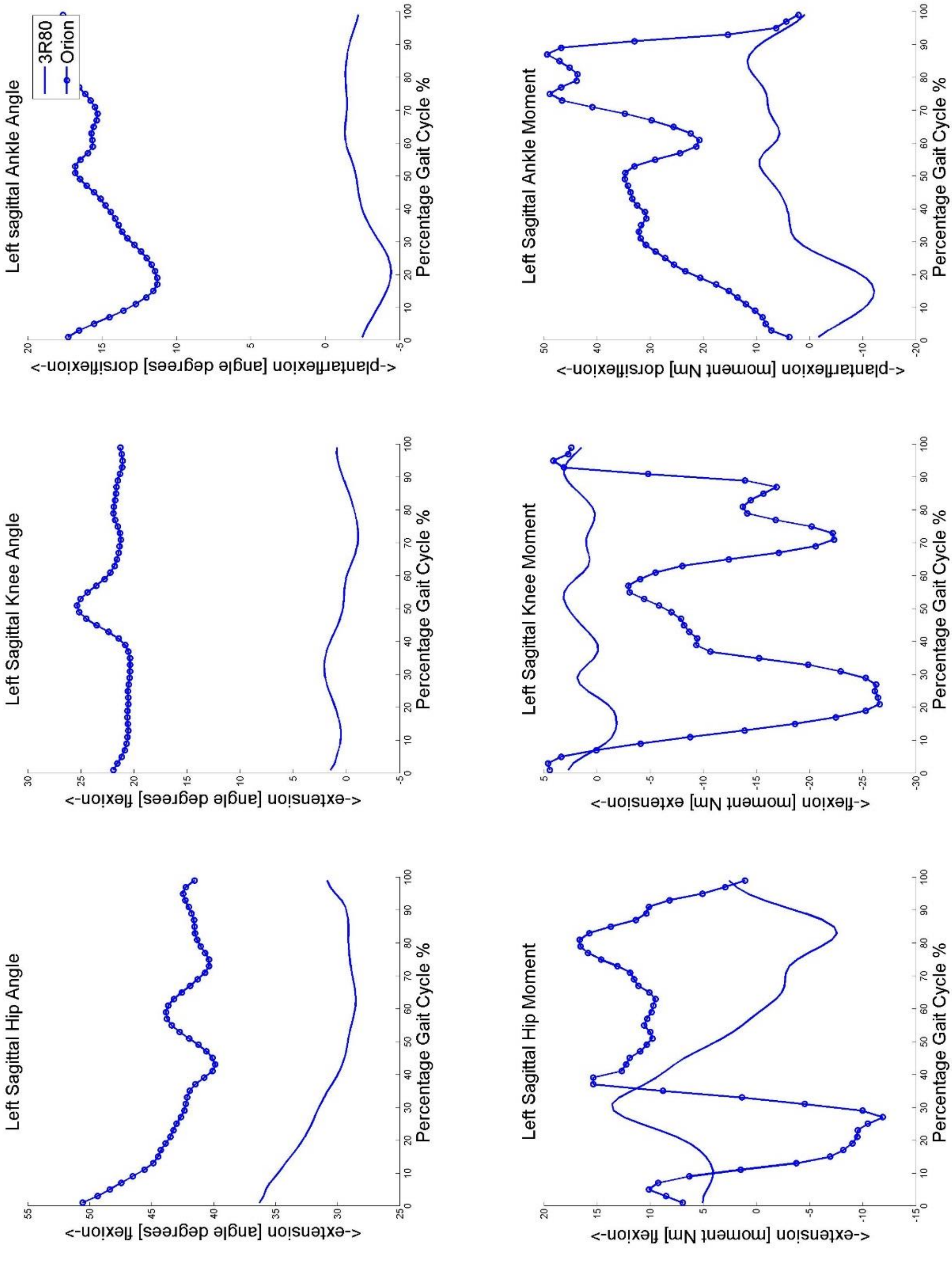


Figure 11.2 Participant (A) prosthetic limb kinematics and kinetics – stair ascent

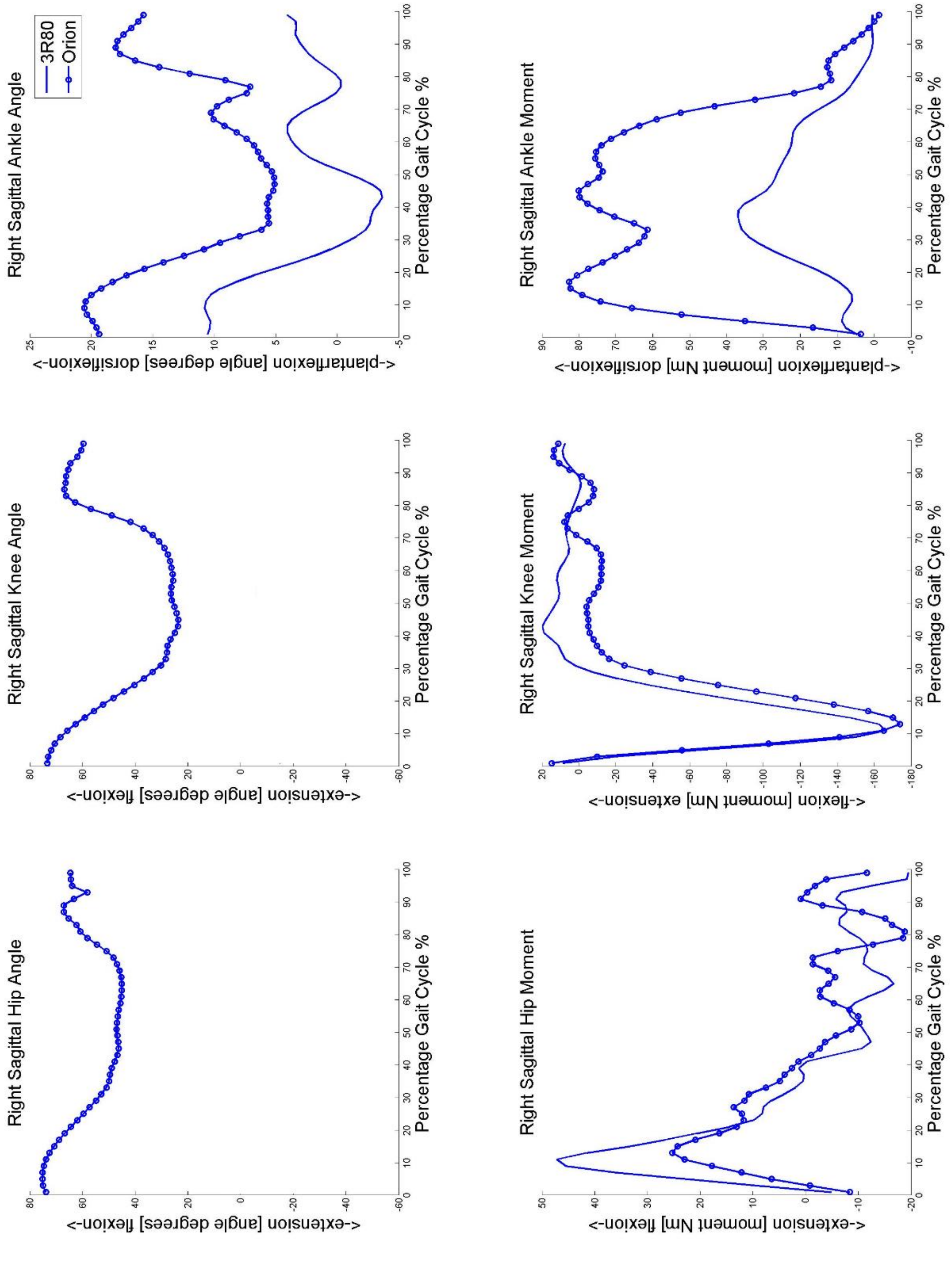


Figure 11.3 Participant (A) contralateral limb kinematics and kinetics – stair ascent

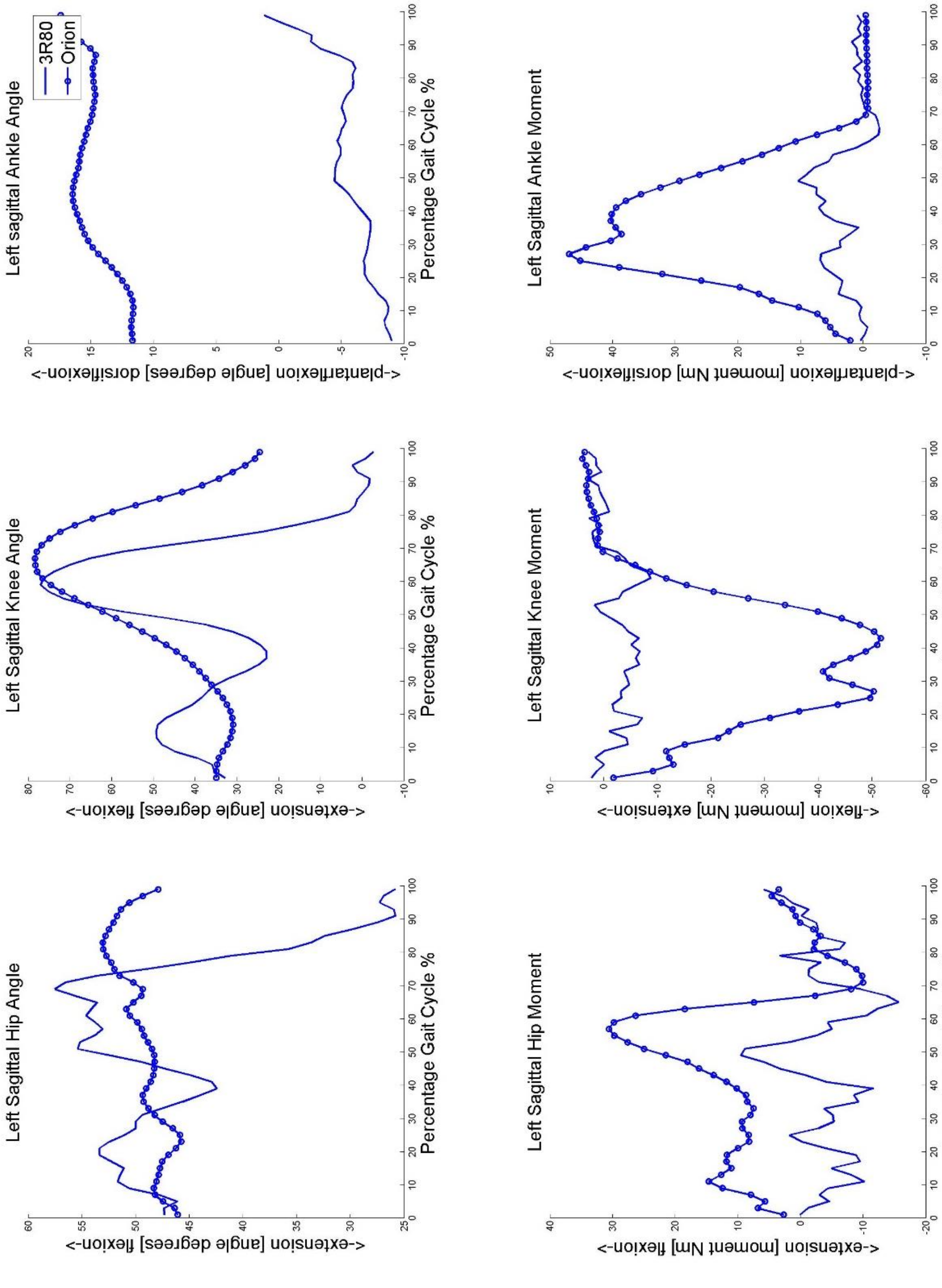


Figure 11.4 Participant (A) prosthetic limb kinematics and kinetics – stair descent

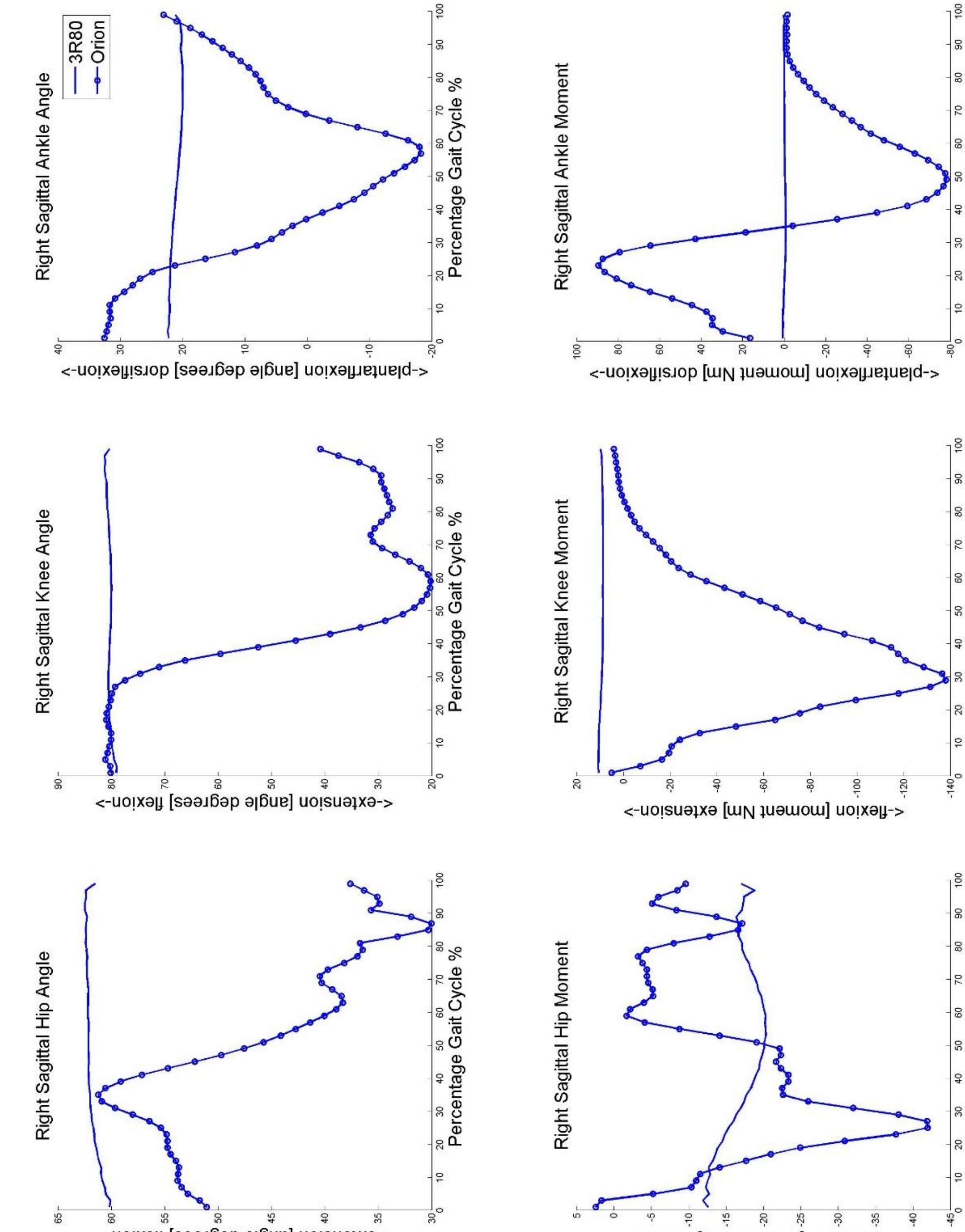


Figure 11.5 Participant (A) contralateral limb kinematics and kinetics – stair descent

11.5 PARTICIPANT (B) RESULTS (APPENDIX 5)

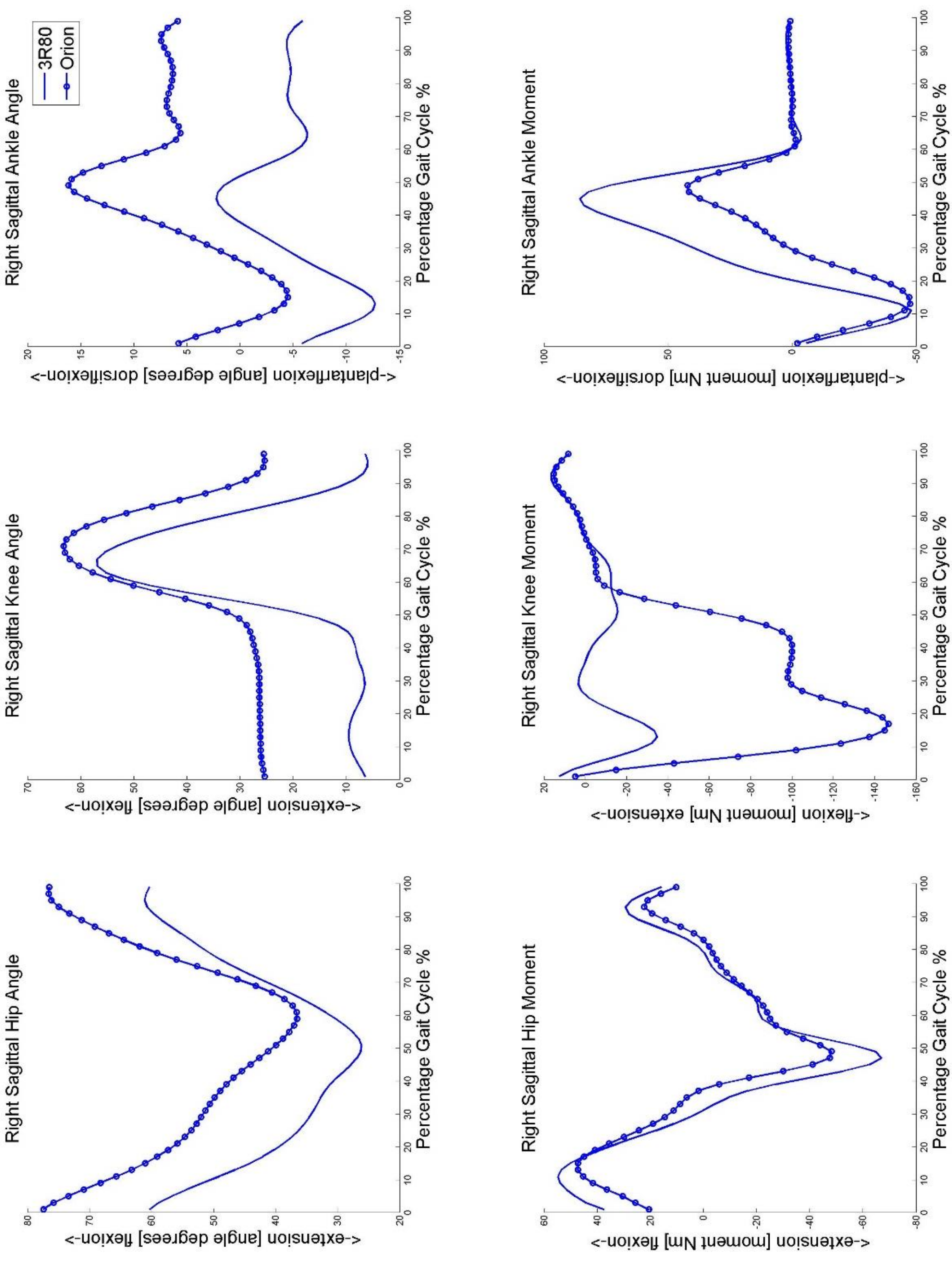


Figure 11.6 Participant (B) prosthetic limb kinematics and kinetics – level walking

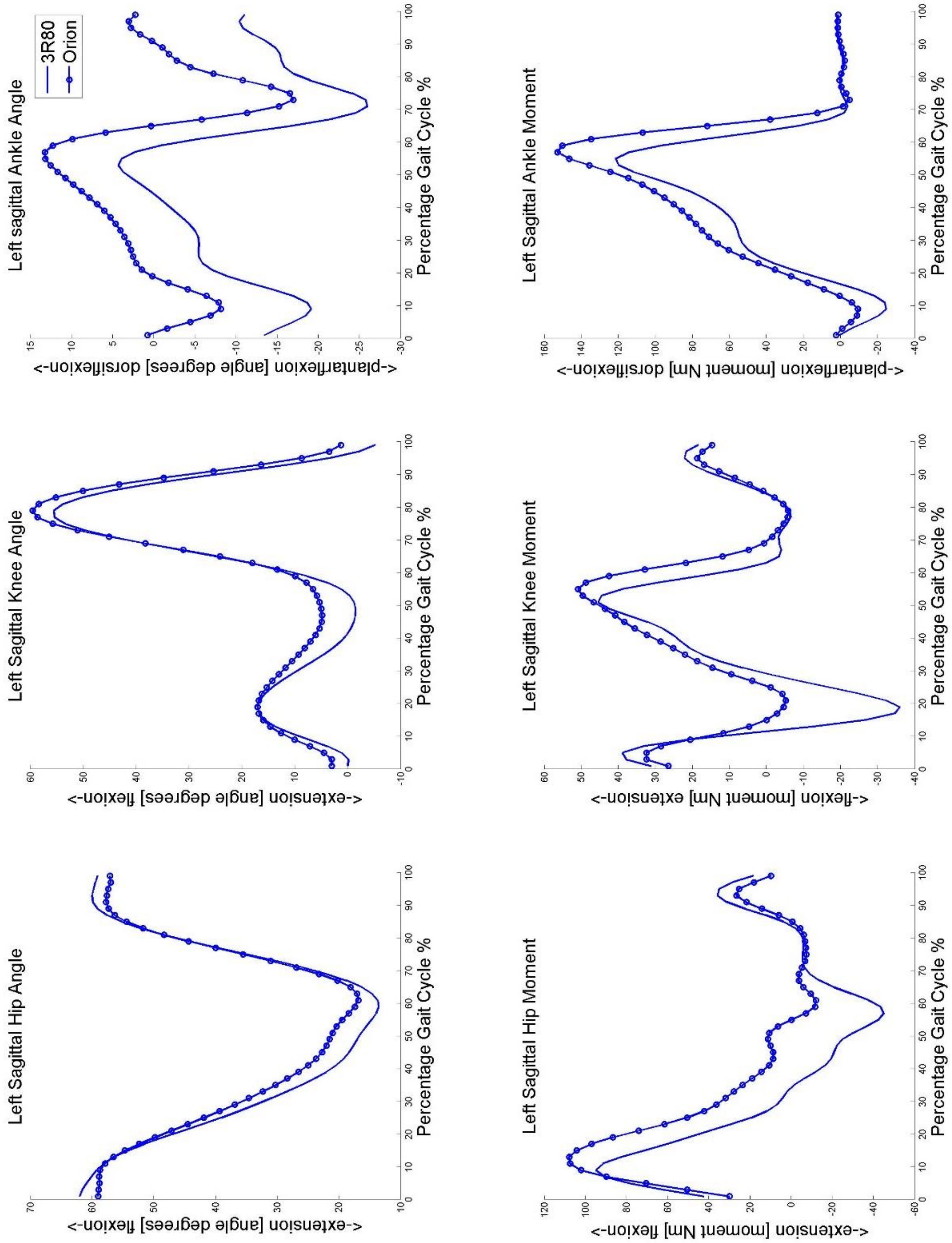


Figure 11.7 Participant (B) contralateral limb kinematics and kinetics – level walking

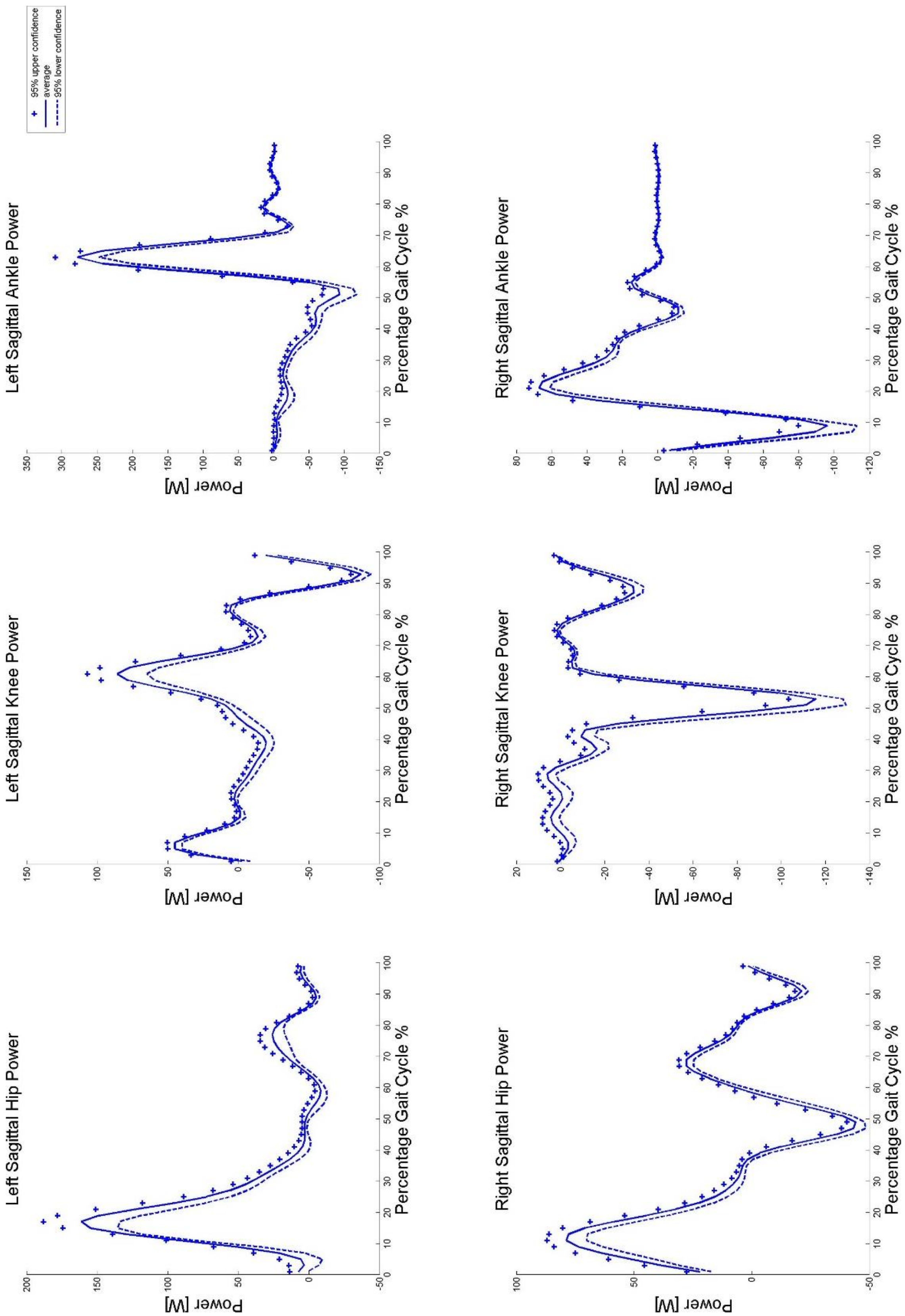


Figure 11.8 Participant (B) prosthetic (right) and anatomical (Left) powers – level walking (Orion)

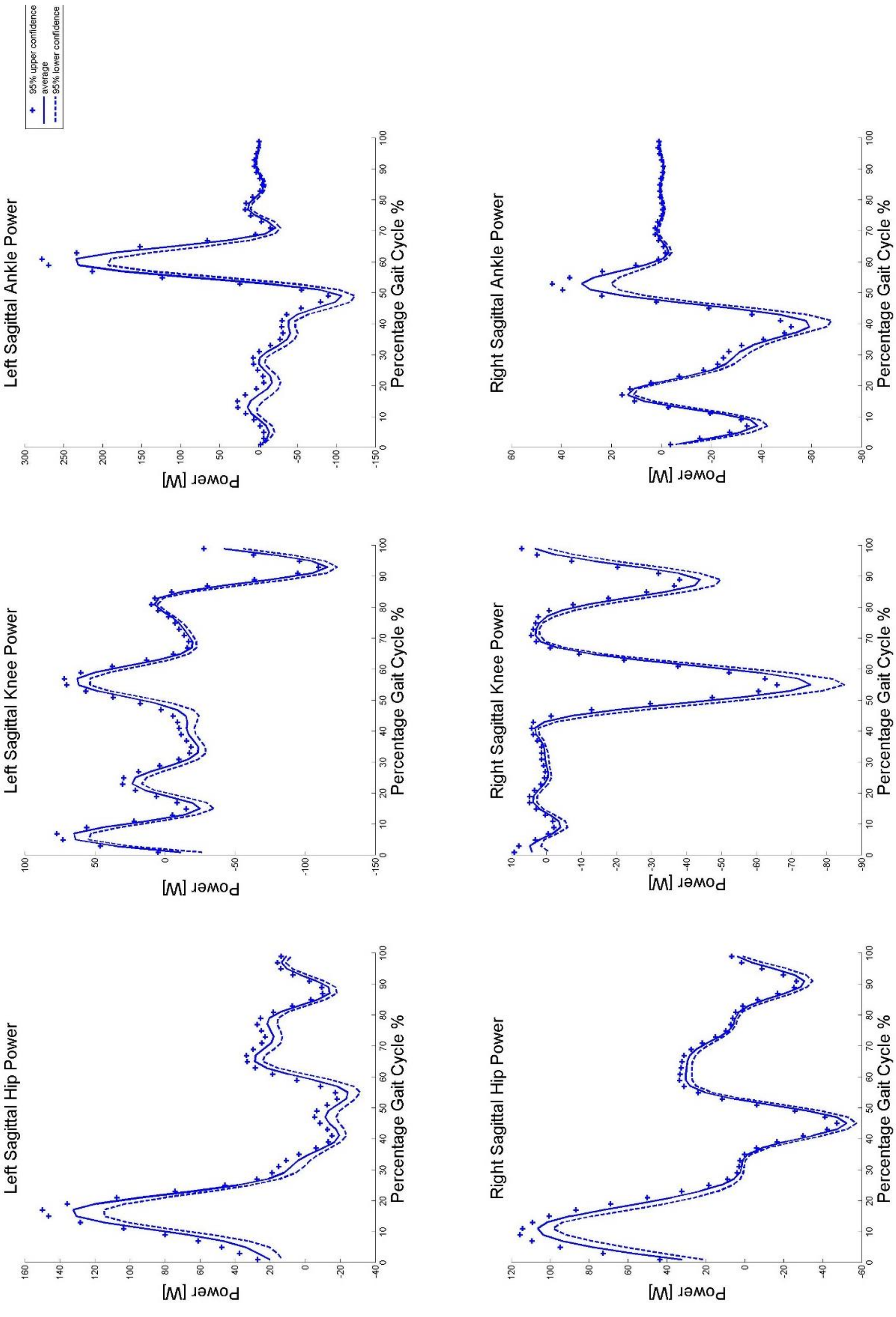


Figure 11.9 Participant (B) prosthetic (right) and anatomical (Left) powers – level walking (3R80)

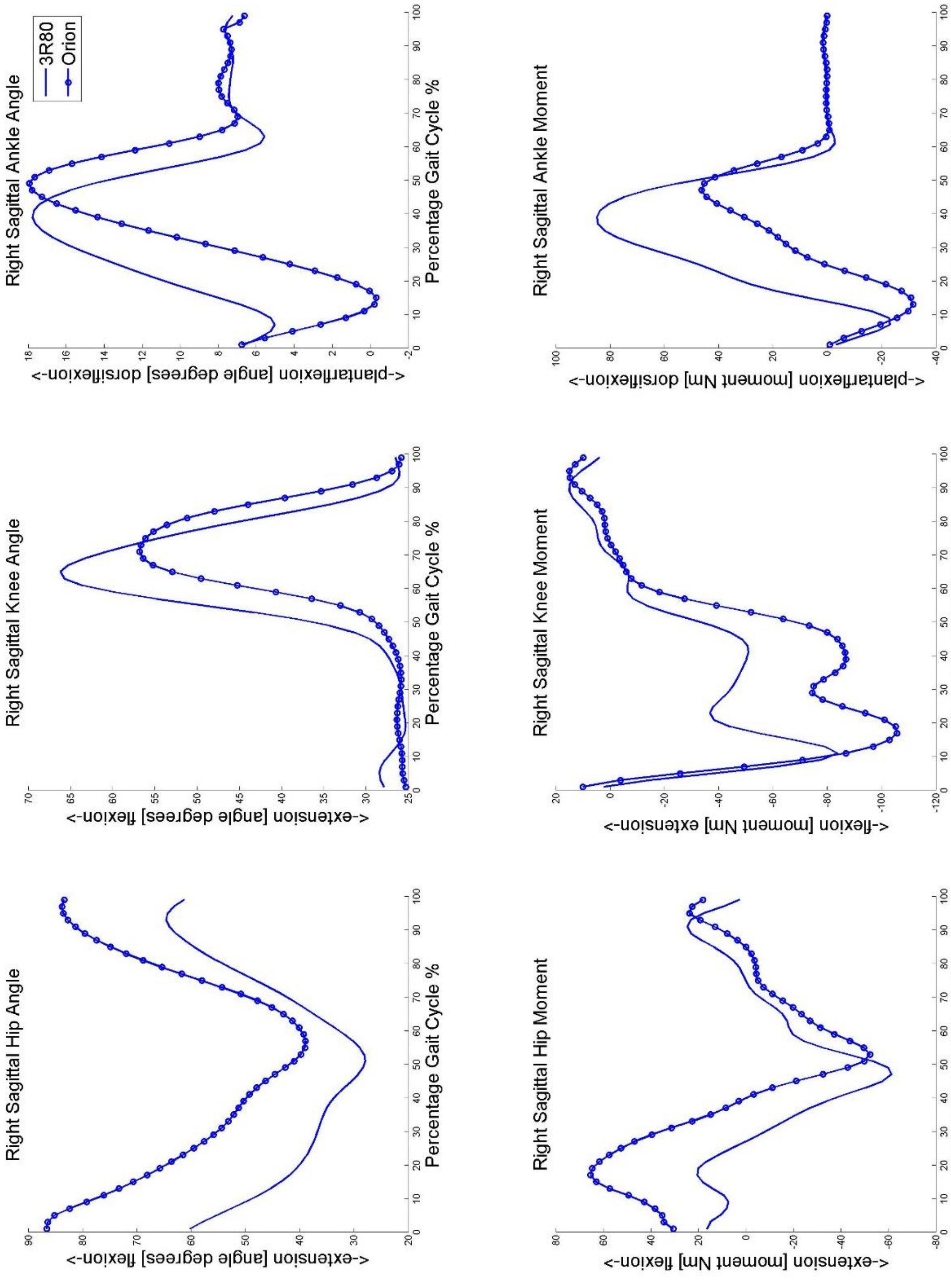


Figure 11.10 Participant (B) prosthetic limb kinematics and kinetics – Ramp ascent

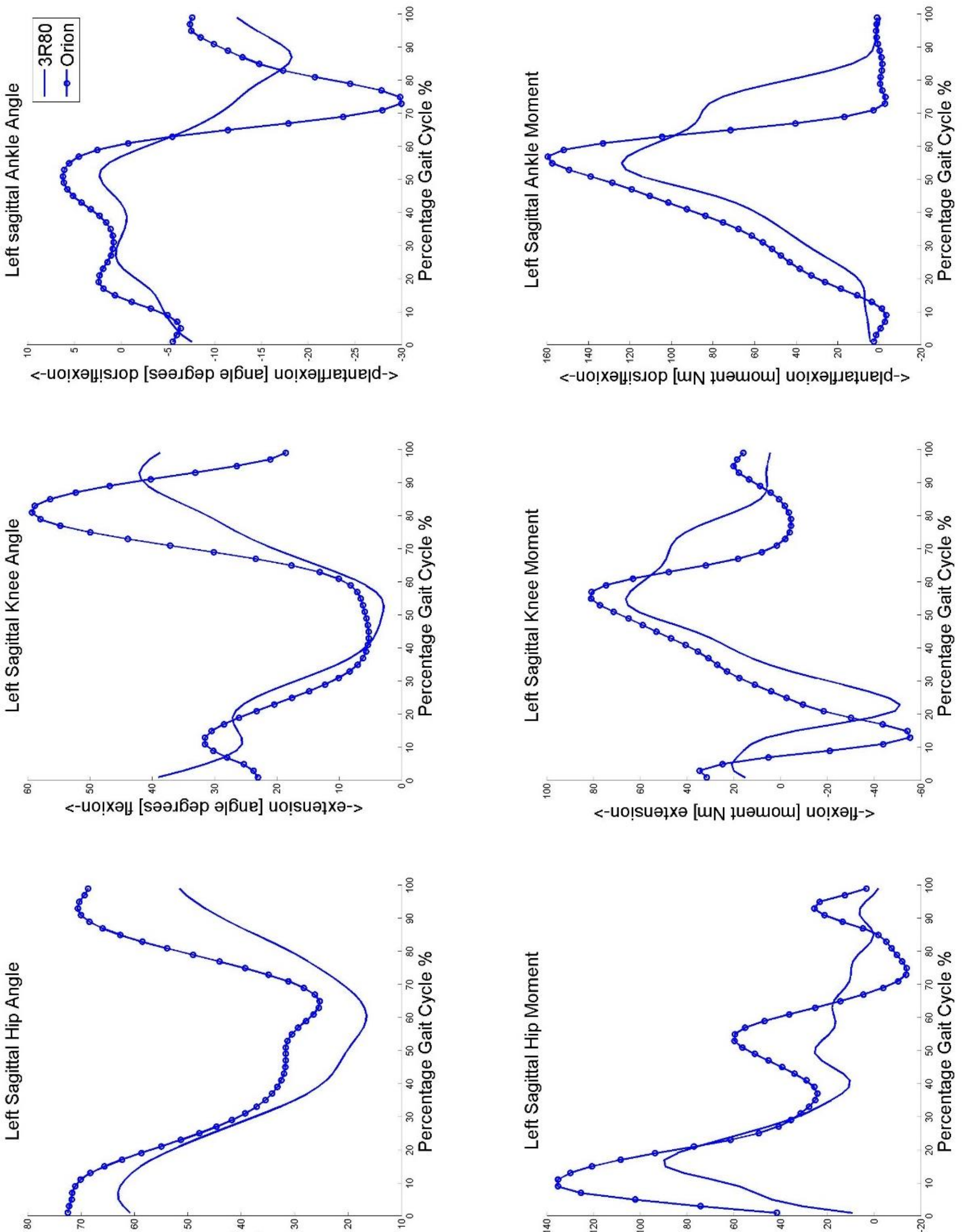


Figure 11.11 Participant (B) contralateral limb kinematics and kinetics – Ramp ascent

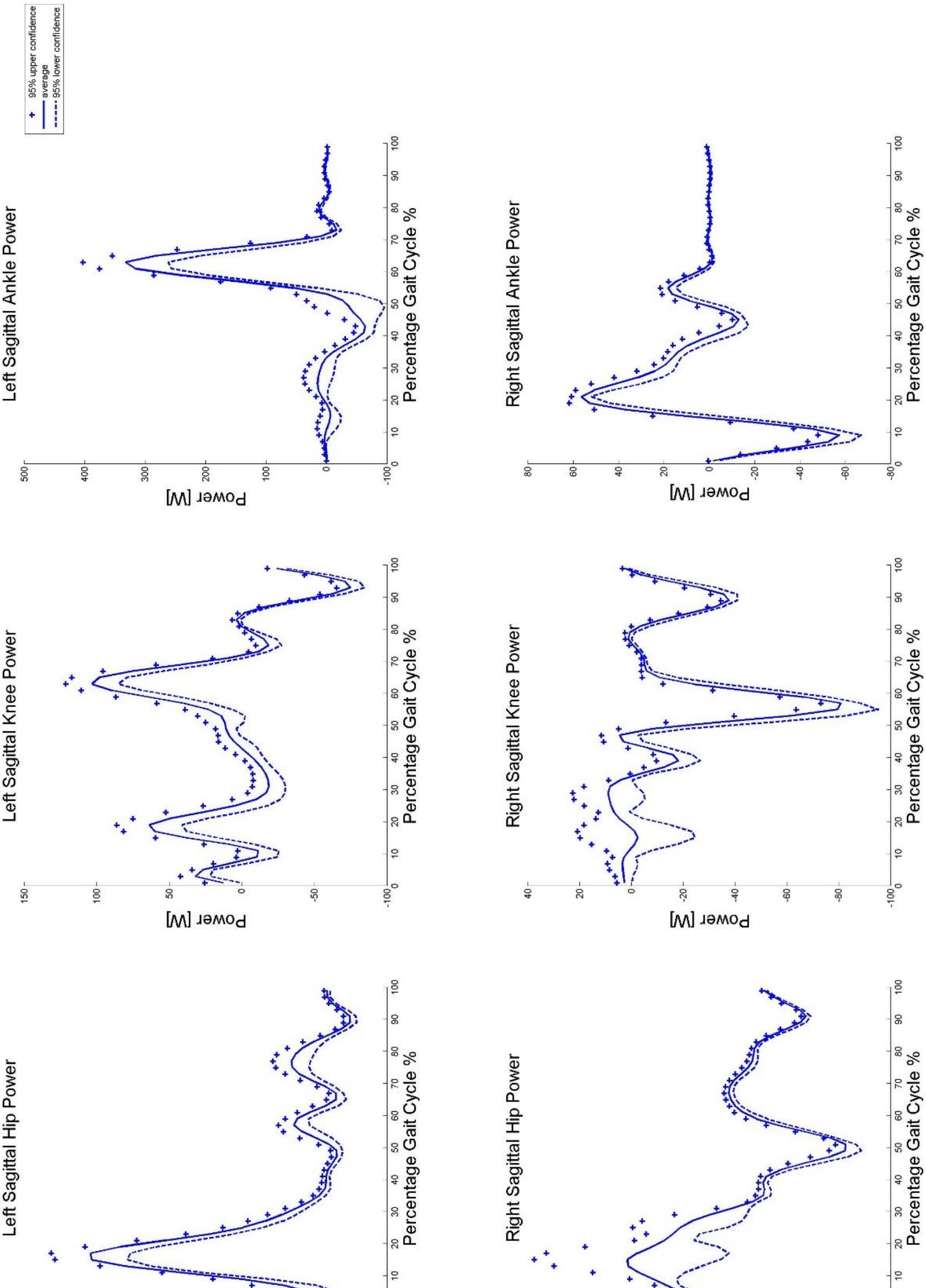


Figure 11.12 Participant (B) prosthetic (right) and anatomical (Left) powers – Ramp ascent (Orion)

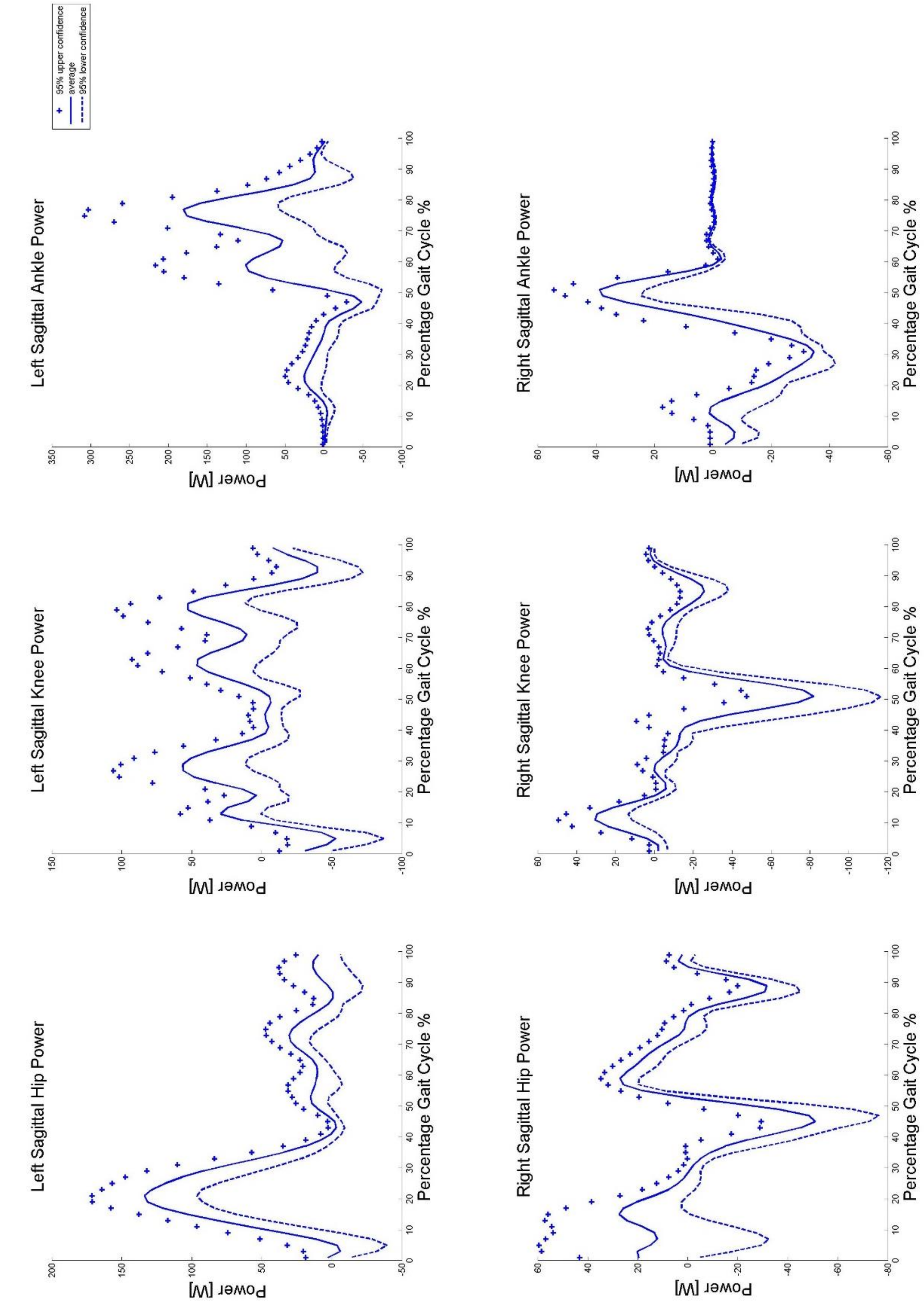


Figure 11.13 Participant (B) prosthetic (right) and anatomical (Left) powers – Ramp ascent (3R80)

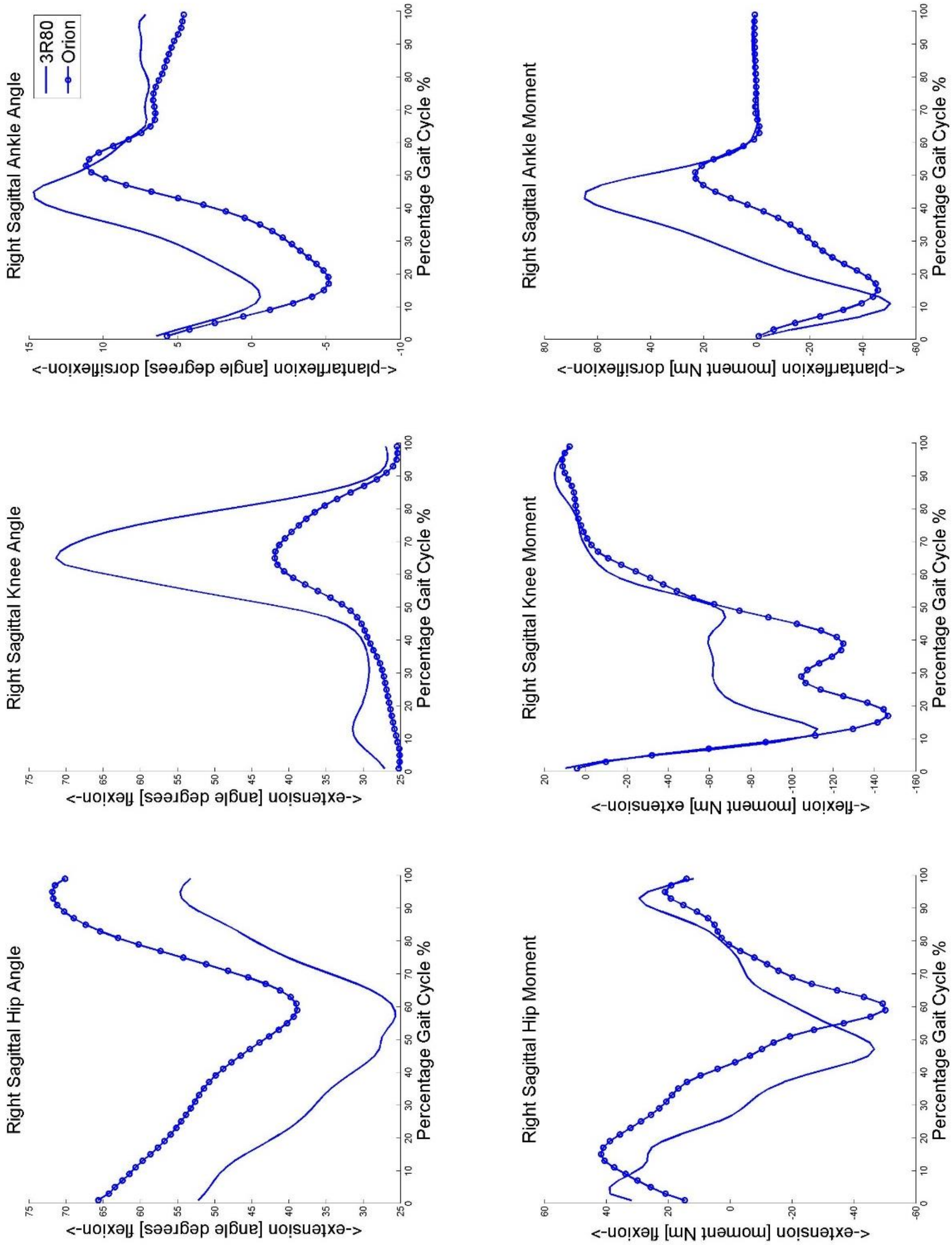


Figure 11.14 Participant (B) prosthetic limb kinematics and kinetics – Ramp descent

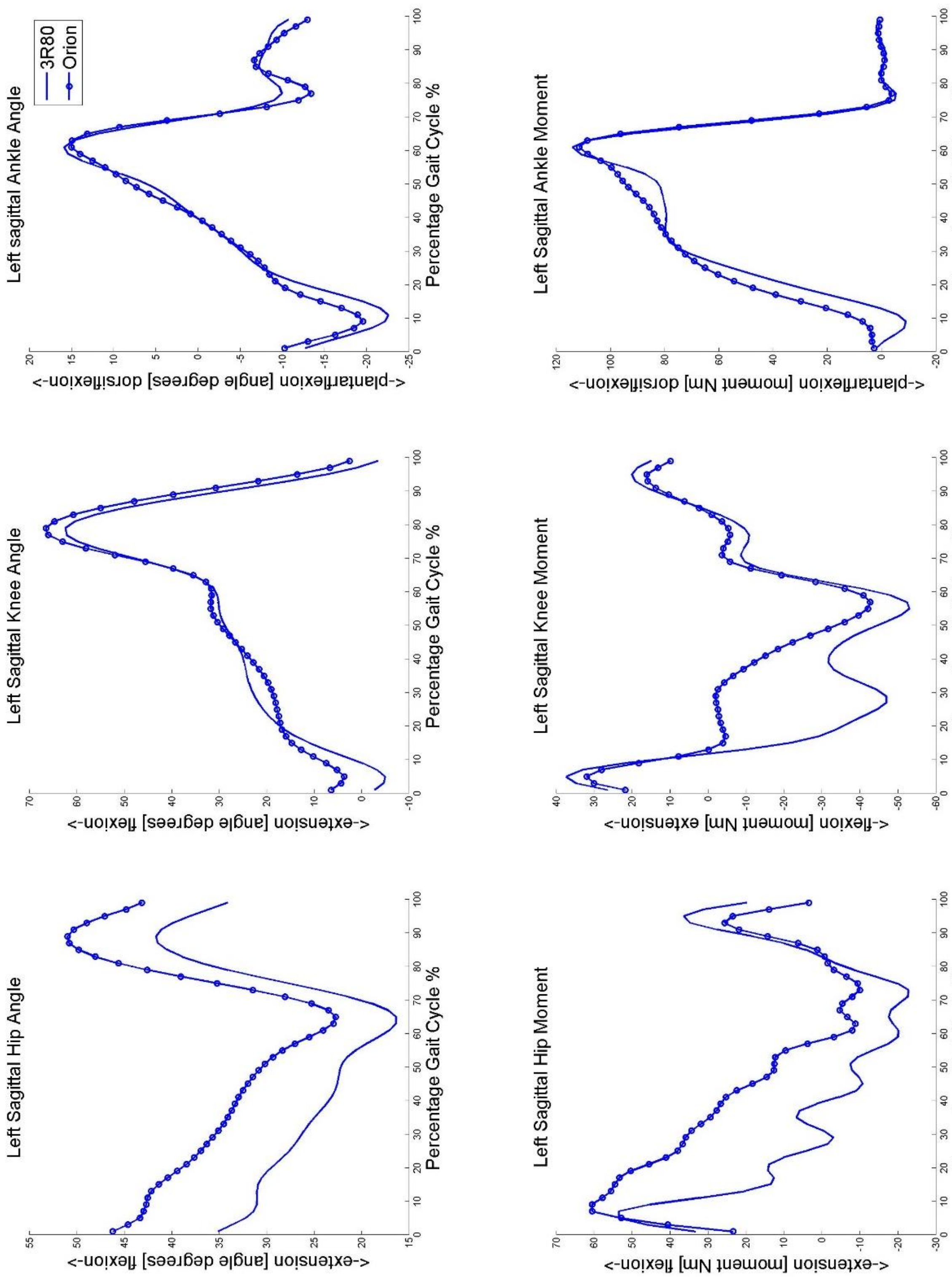


Figure 11.15 Participant (B) contralateral limb kinematics and kinetics – Ramp descent

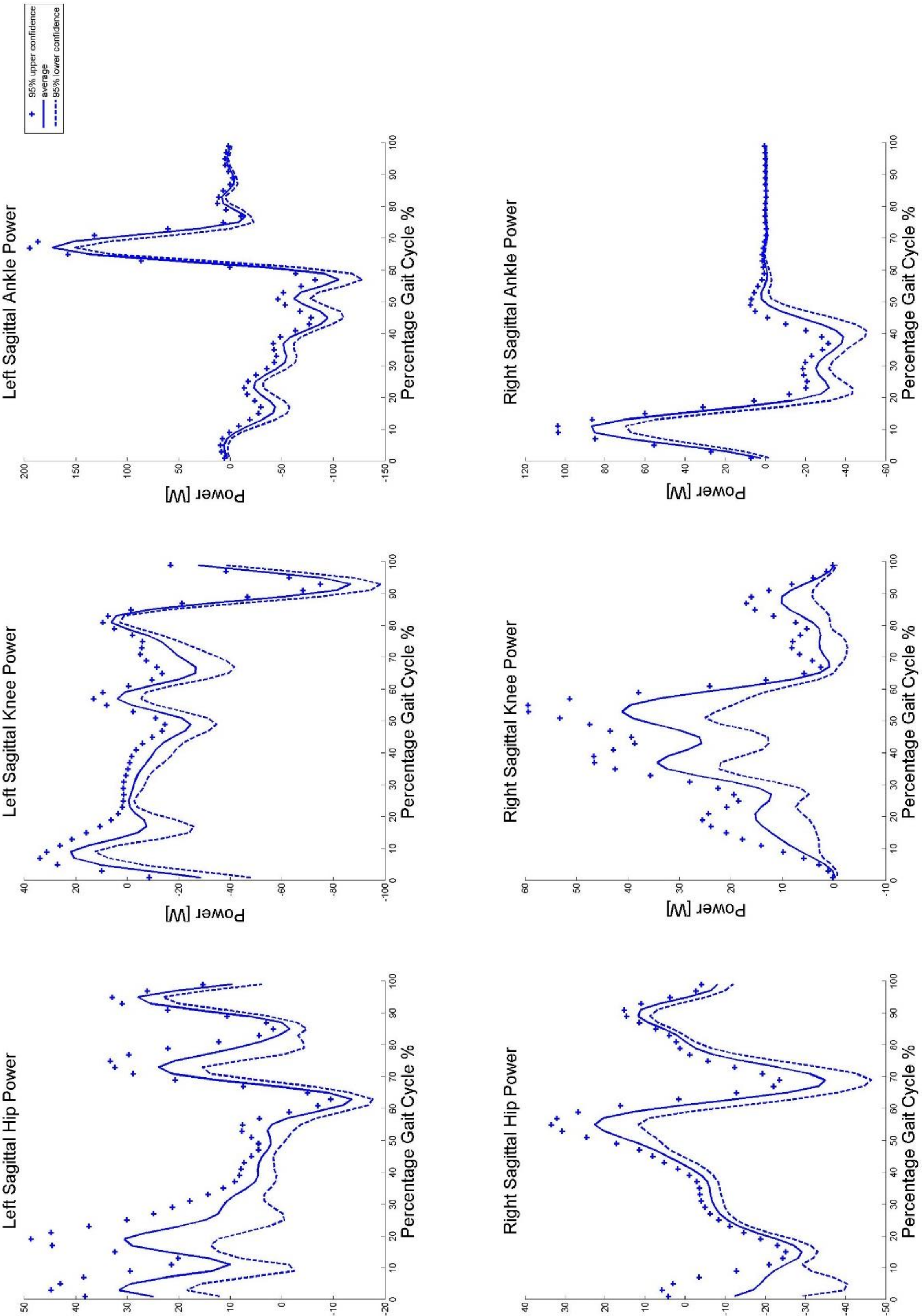


Figure 11.16 Participant (B) prosthetic (right) and anatomical (Left) powers – Ramp descent (Orion)

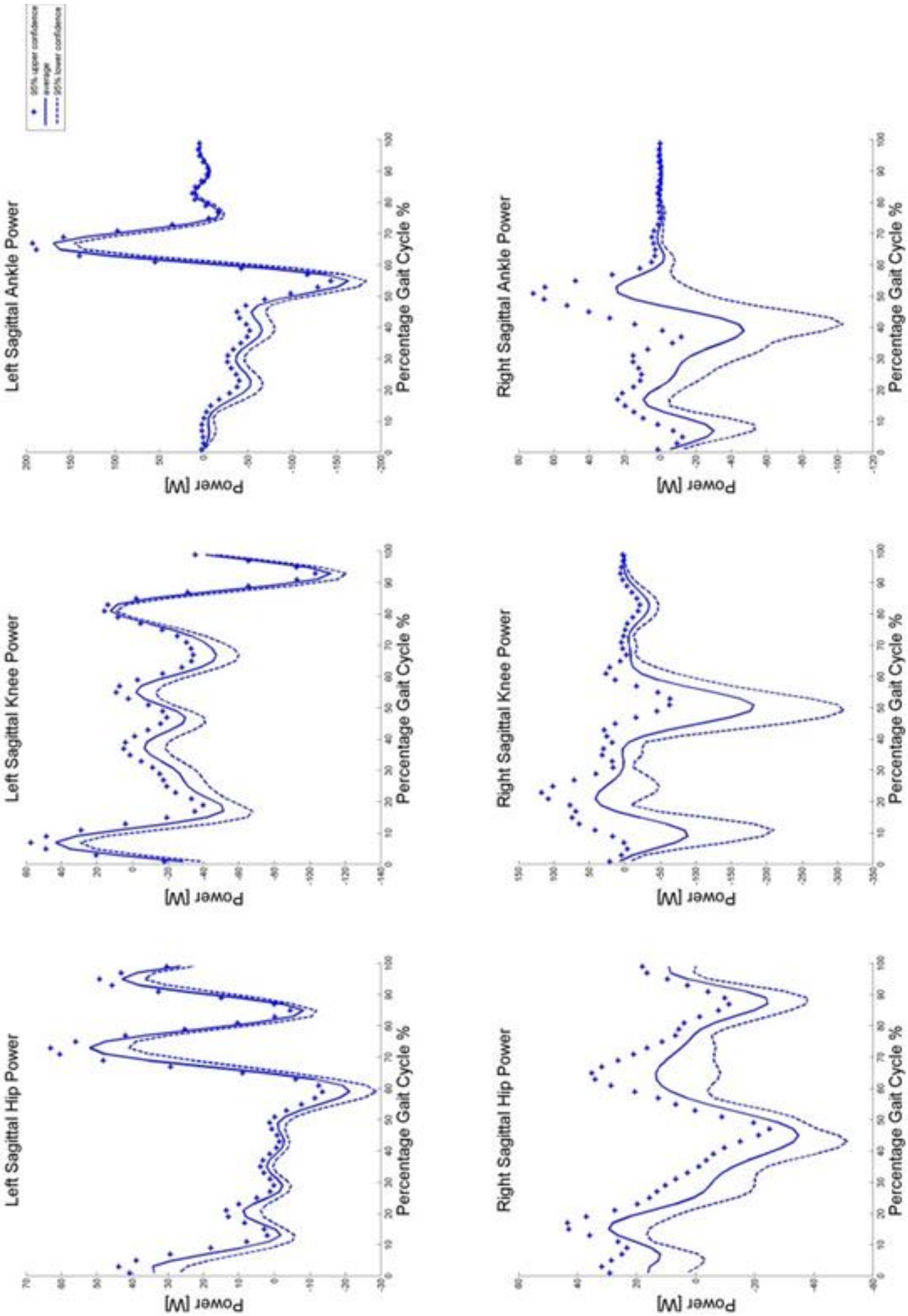


Figure 11.17 Participant (B) prosthetic (right) and anatomical (Left) powers – Ramp descent (3R80)

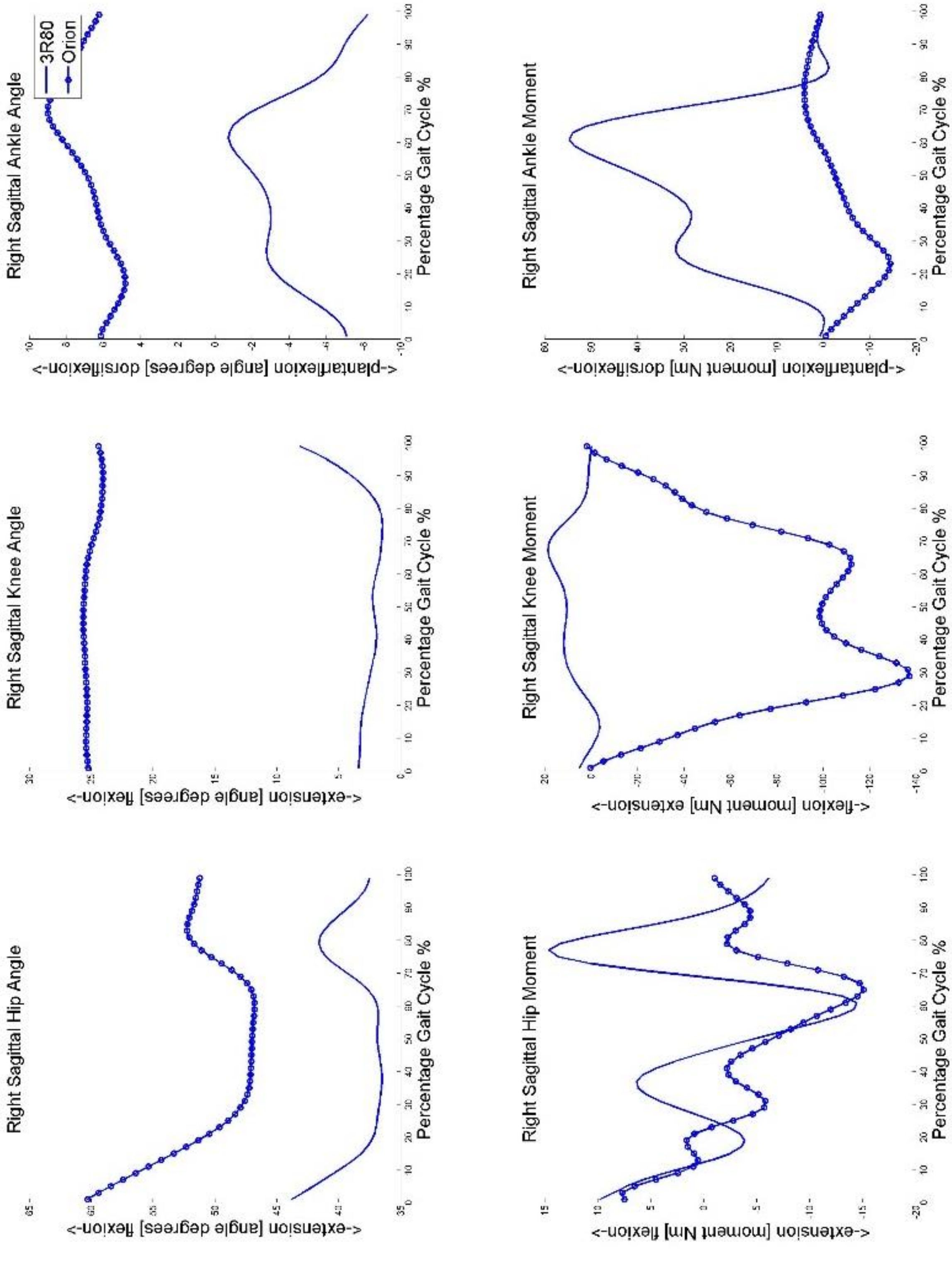


Figure 11.18 Participant (B) prosthetic limb kinematics and kinetics – stair ascent

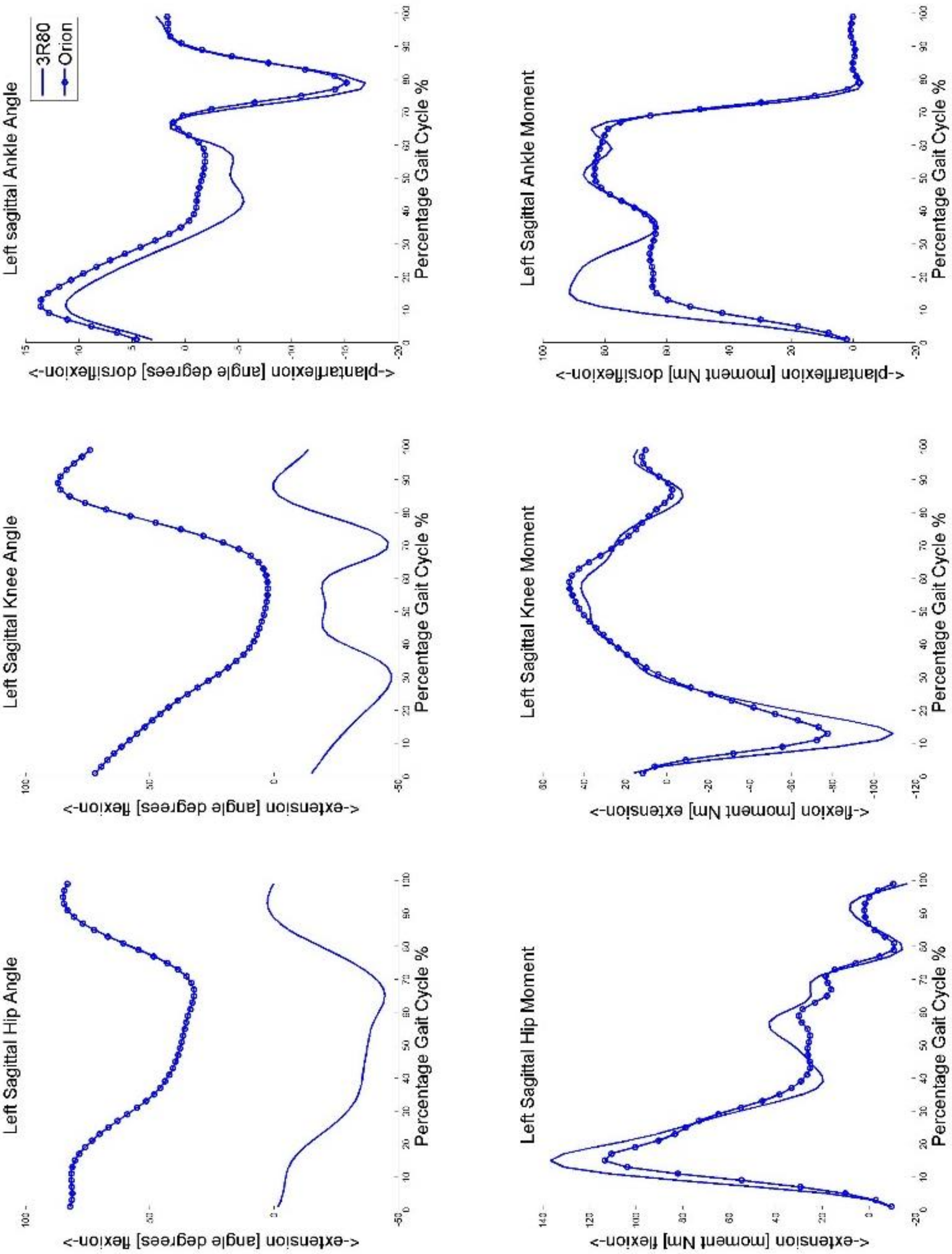


Figure 11.19 Participant (B) contralateral limb kinematics and kinetics – stair ascent

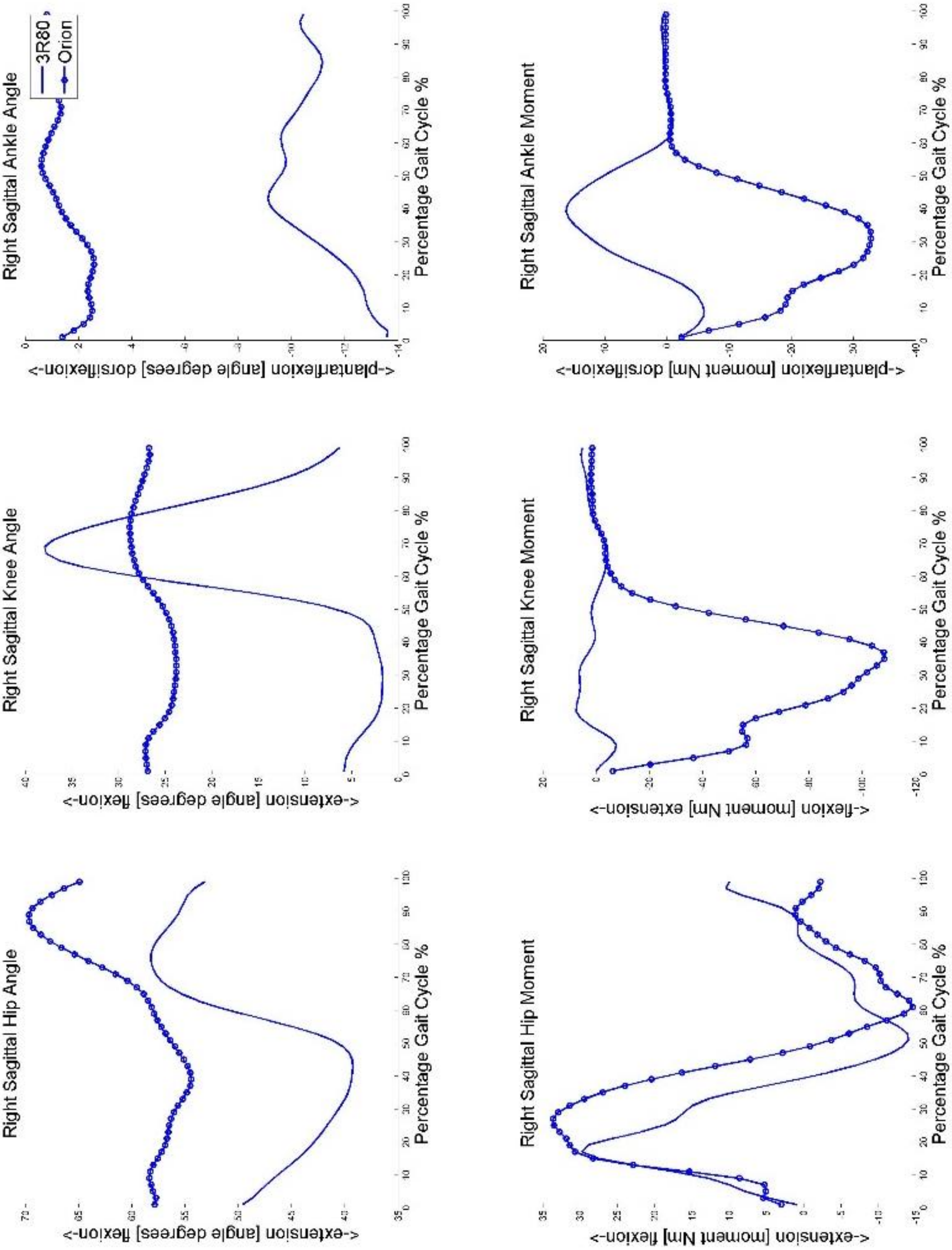


Figure 11.20 Participant (B) prosthetic limb kinematics and kinetics – stair descent

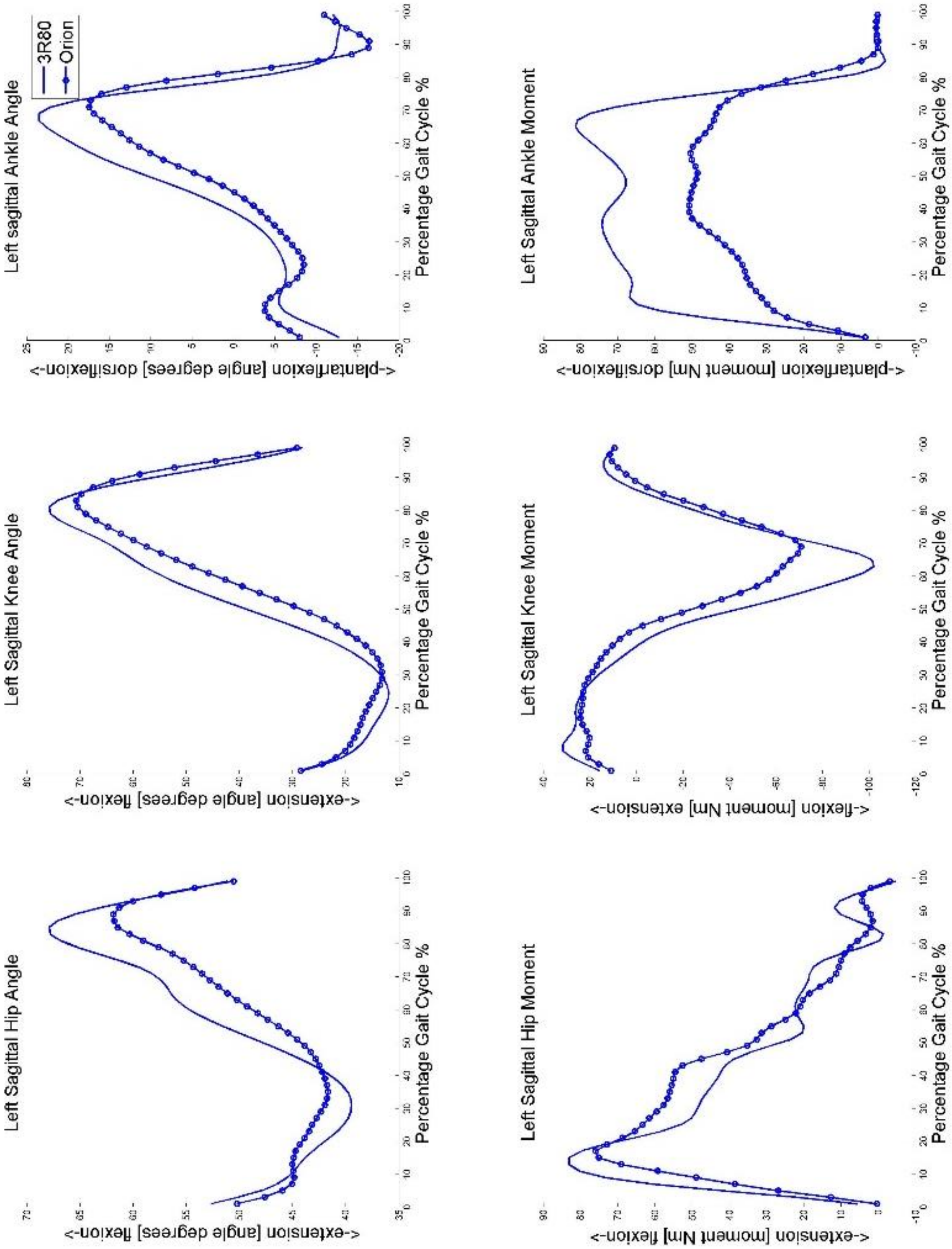


Figure 11.21 Participant (B) contralateral limb kinematics and kinetics – stair descent

11.6 PARTICIPANT (C) RESULTS (APPENDIX 6)

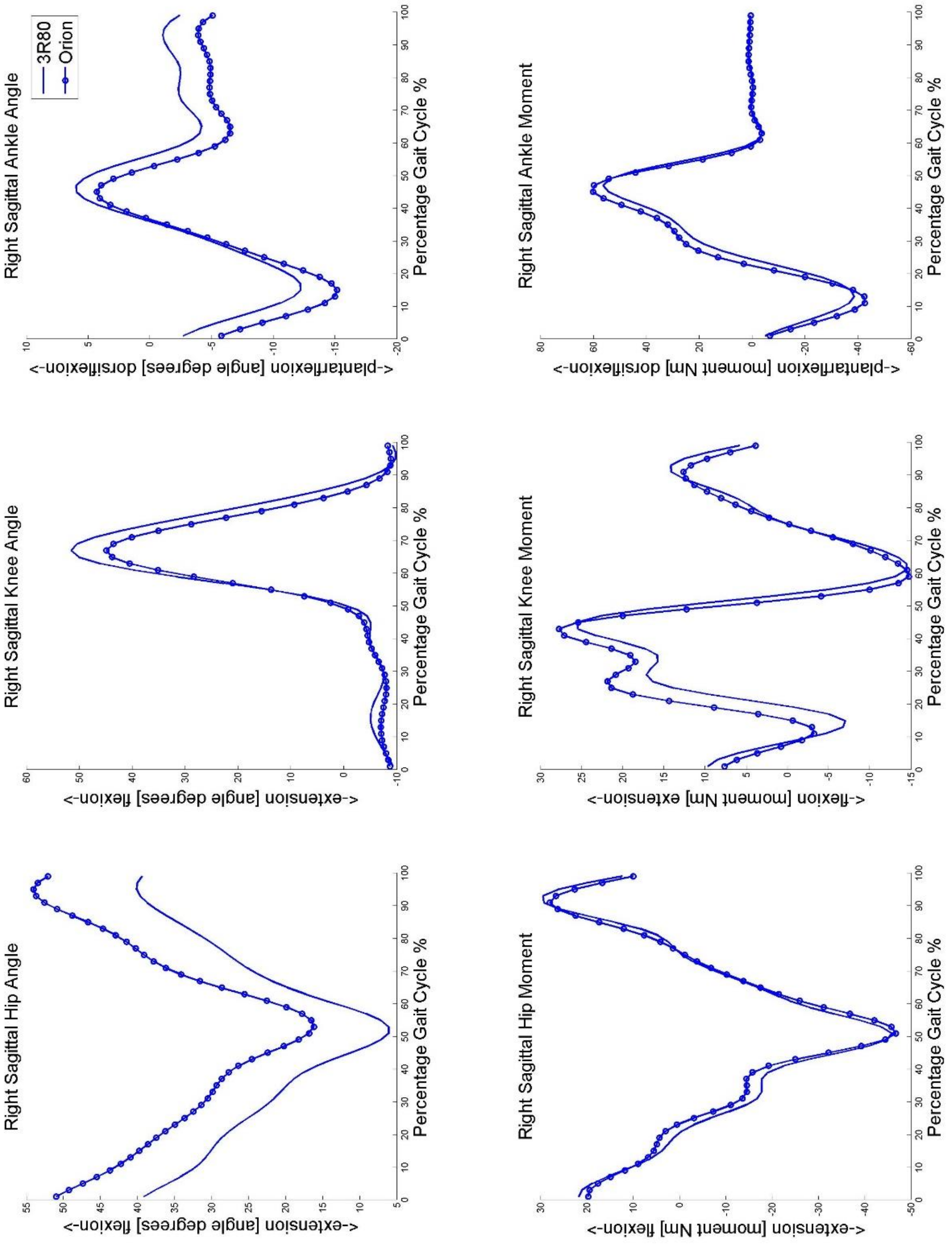


Figure 11.22 Participant (C) prosthetic limb kinematics and kinetics – level walking

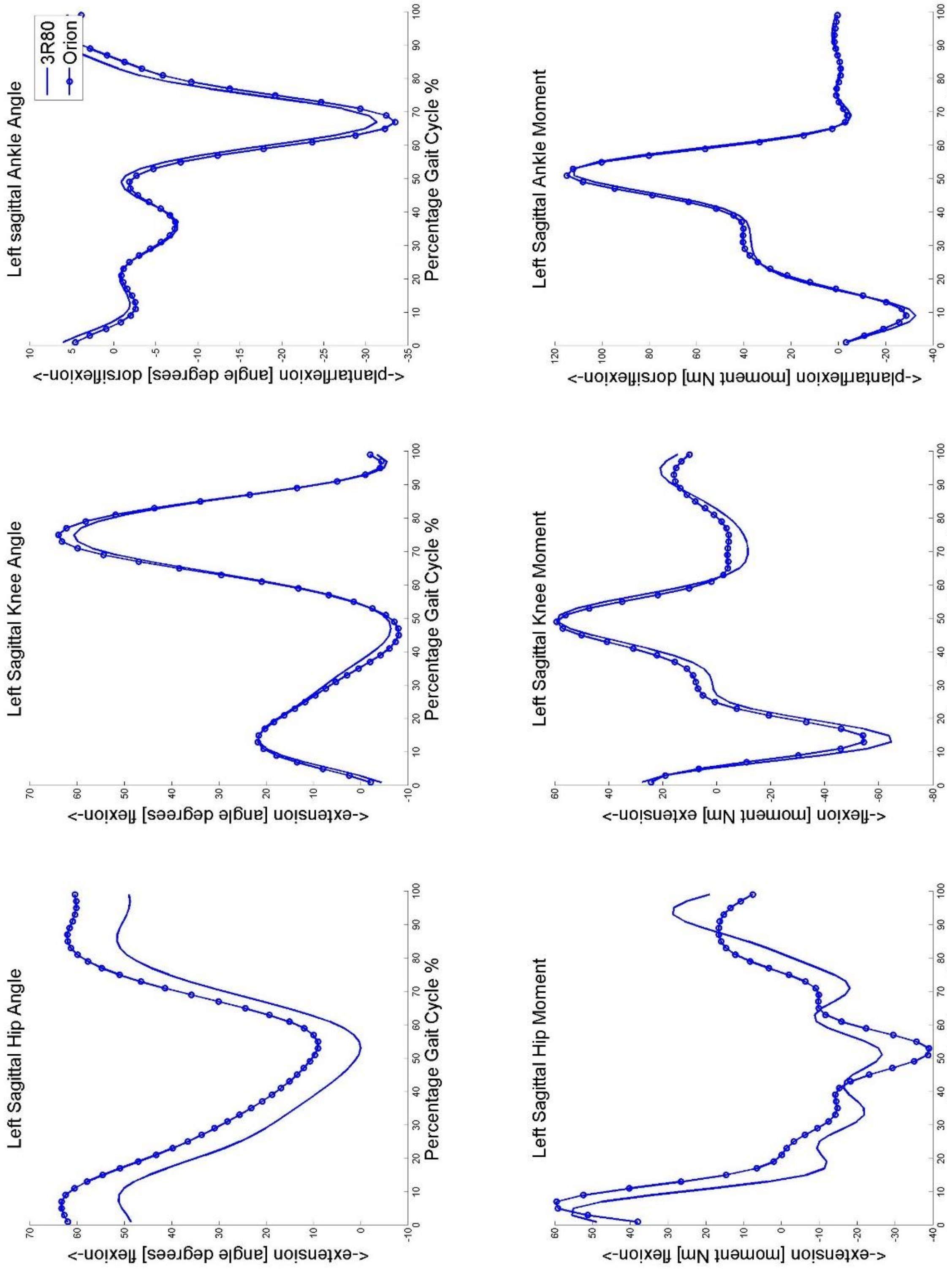


Figure 11.23 Participant (C) contralateral limb kinematics and kinetics – level walking

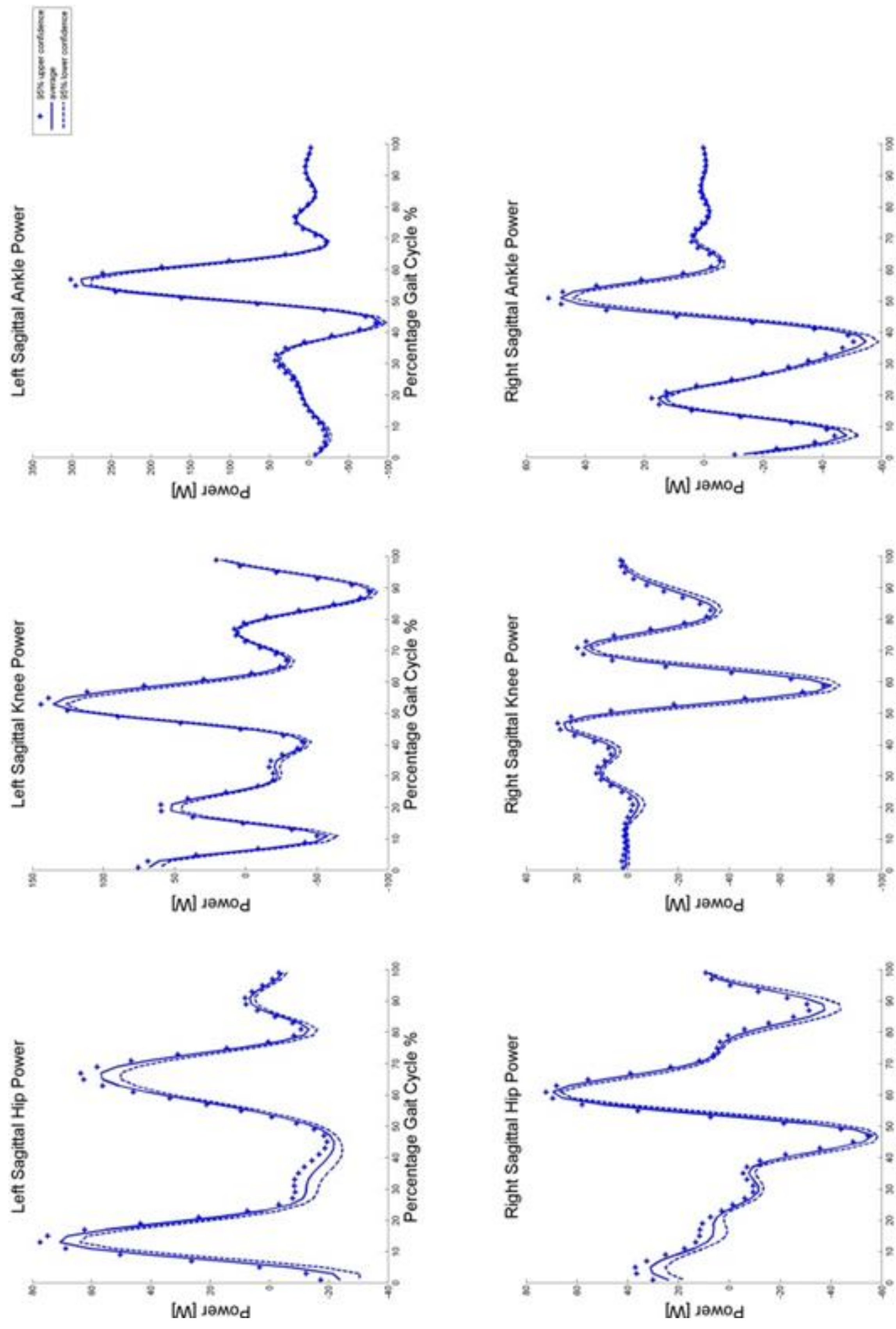


Figure 11.24 Participant (C) prosthetic (right) and anatomical (Left) powers – level walking (Orion)

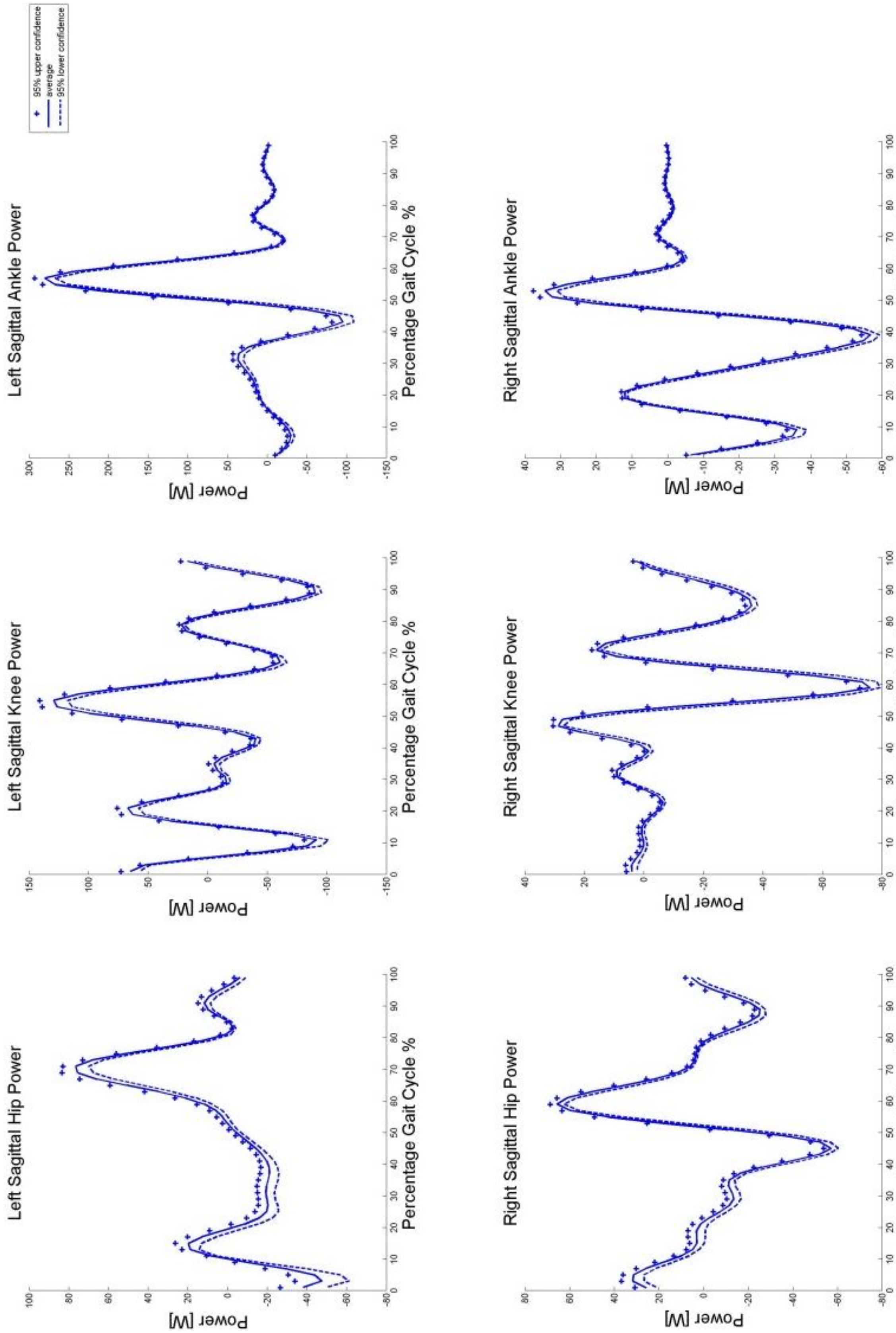


Figure 11.25 Participant (C) prosthetic (right) and anatomical (Left) powers – level walking (3R80)

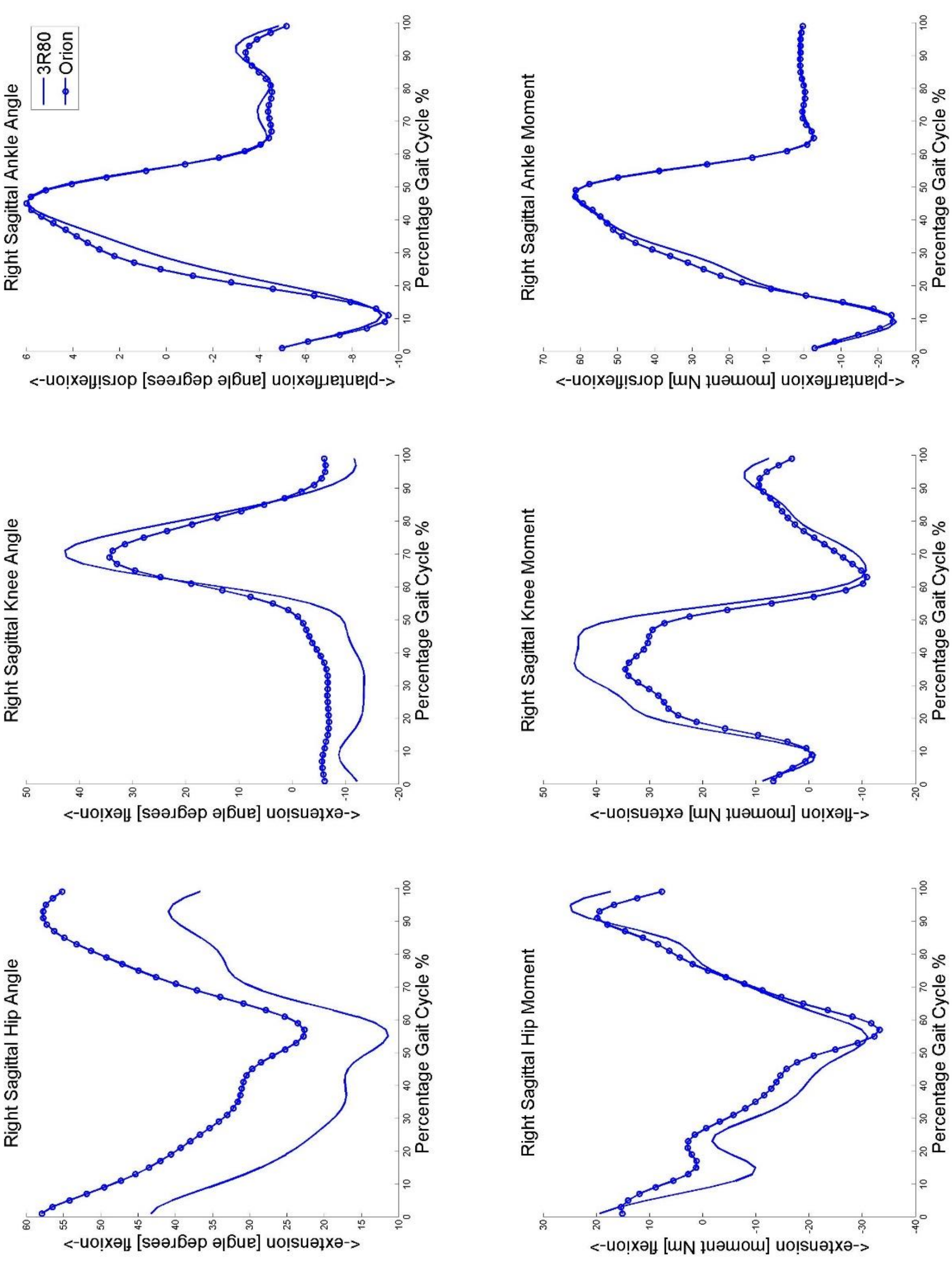


Figure 11.26 Participant (C) prosthetic limb kinematics and kinetics – Ramp ascent

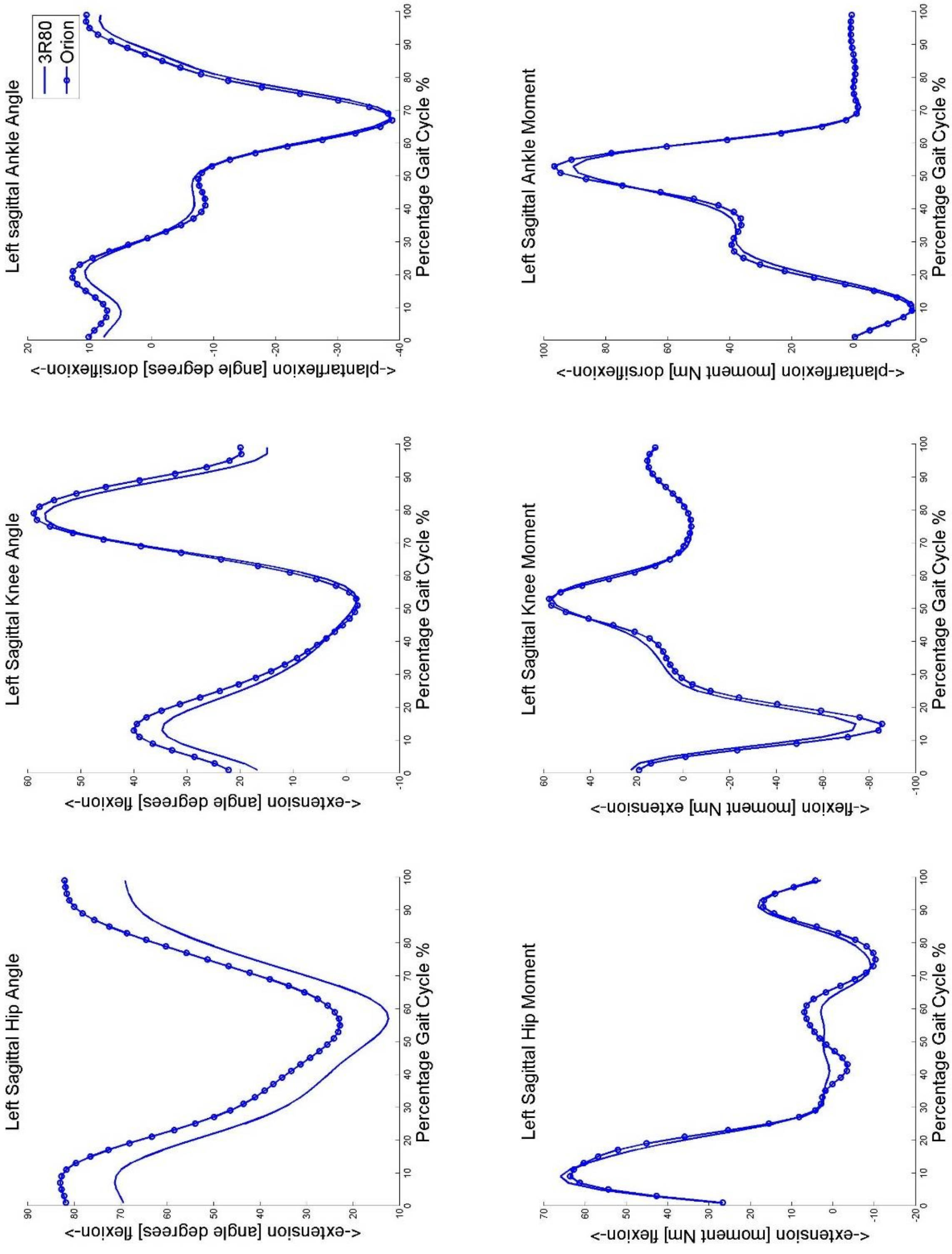


Figure 11.27 Participant (C) contralateral limb kinematics and kinetics – Ramp ascent

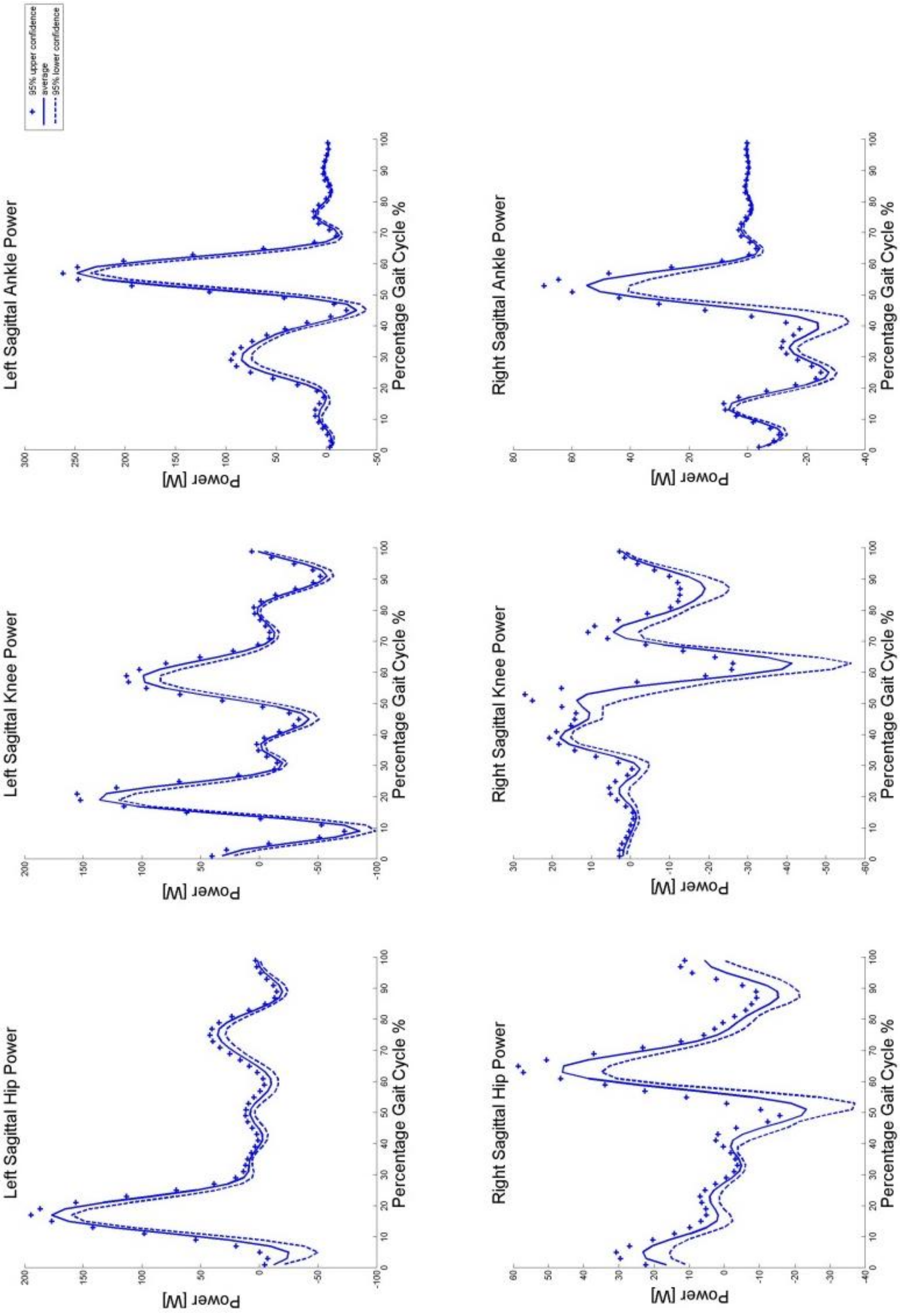


Figure 11.28 Participant (C) prosthetic (right) and anatomical (Left) powers – Ramp ascent (Orion)

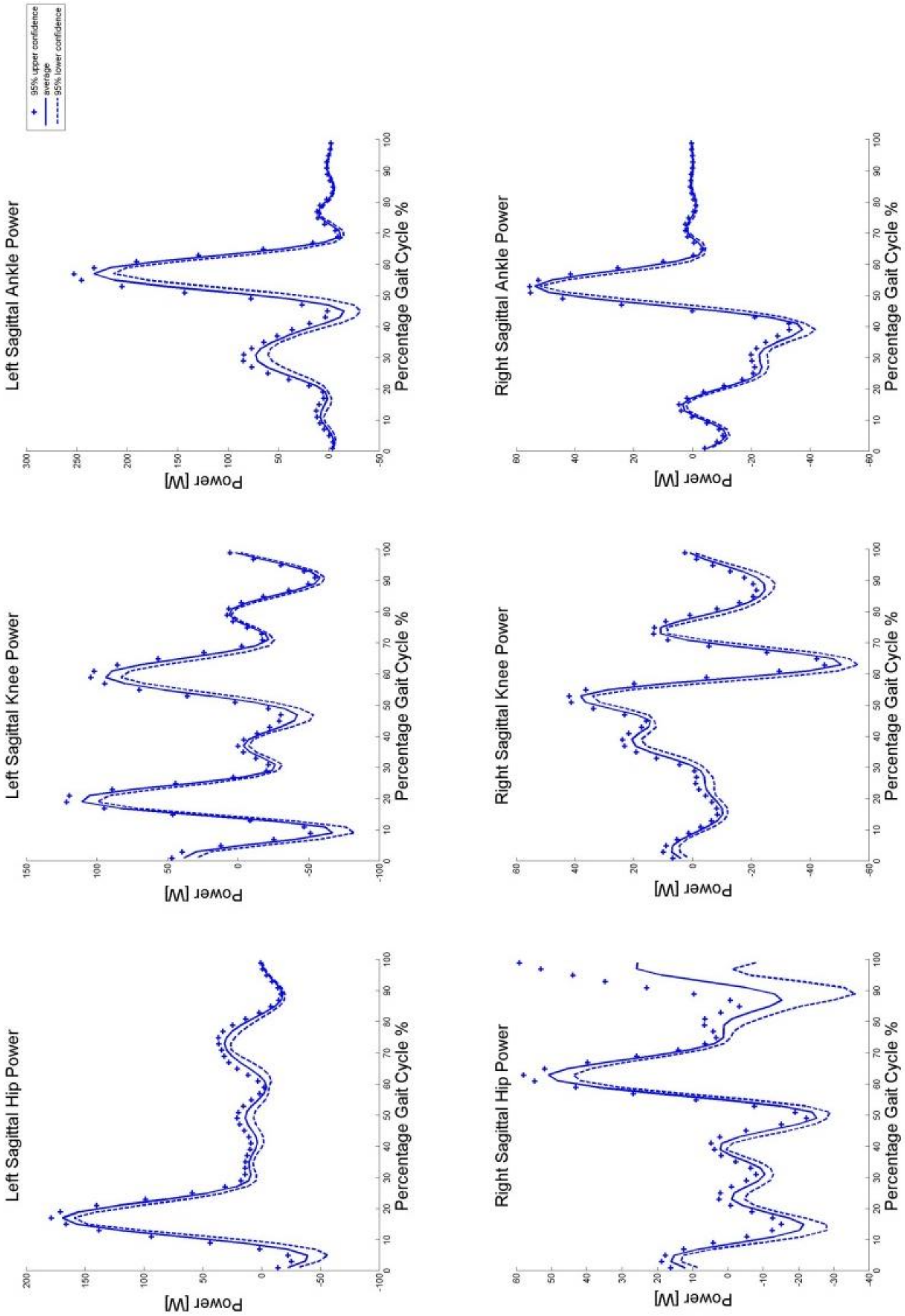


Figure 11.29 Participant (C) prosthetic (right) and anatomical (Left) powers – Ramp ascent (3R80)

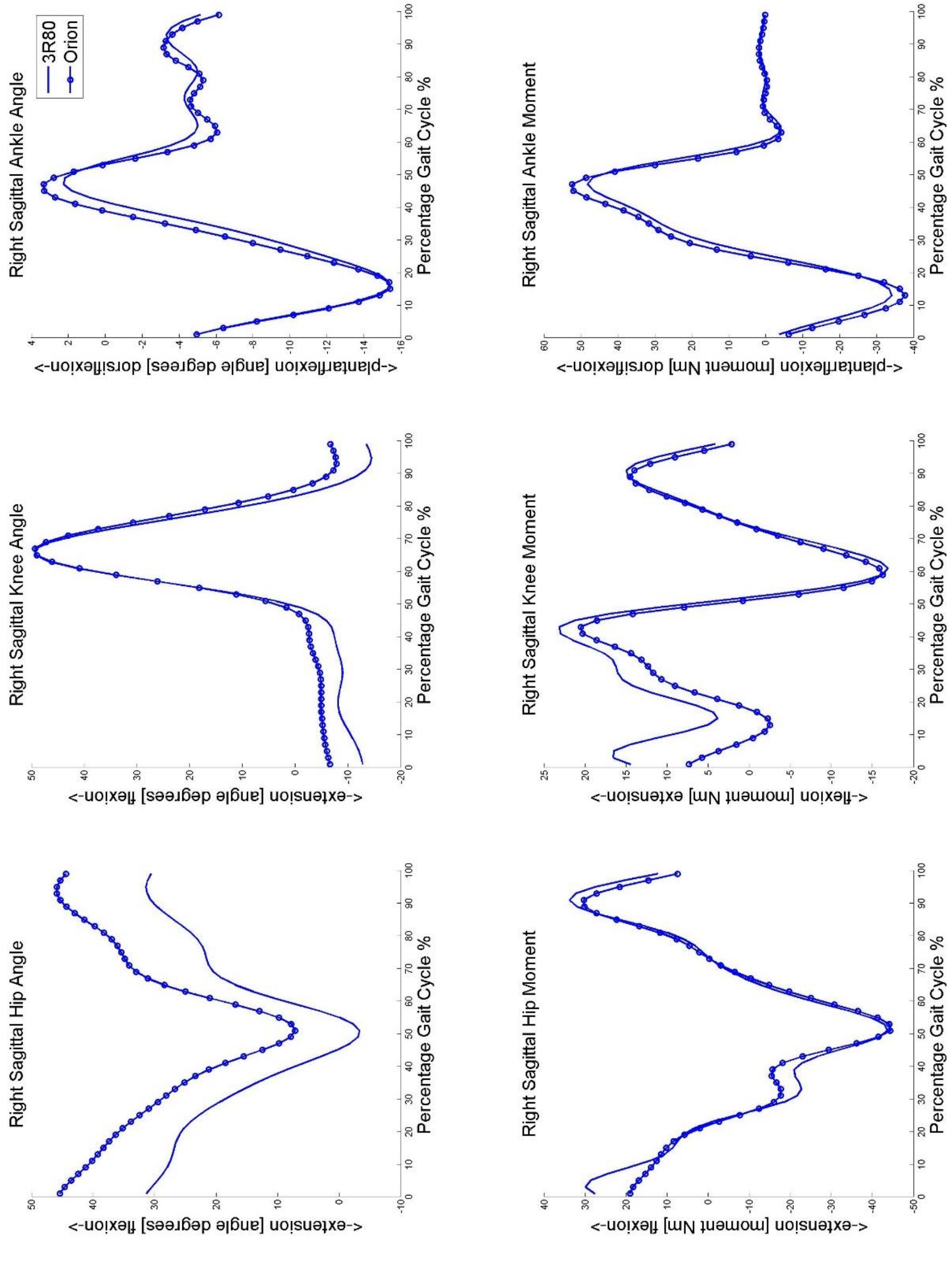


Figure 11.30 Participant (C) prosthetic limb kinematics and kinetics – Ramp descent

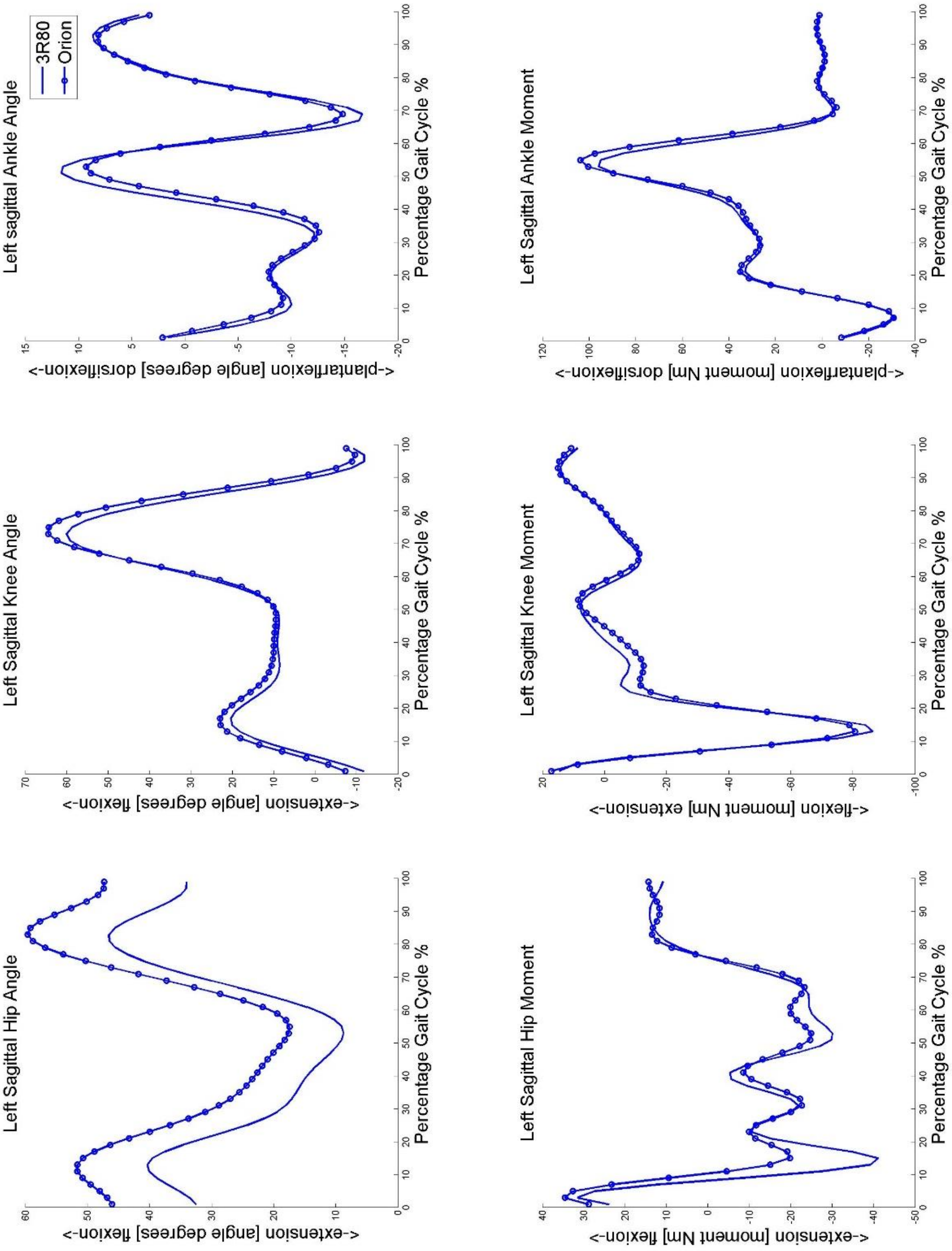


Figure 11.31 Participant (C) contralateral limb kinematics and kinetics – Ramp descent

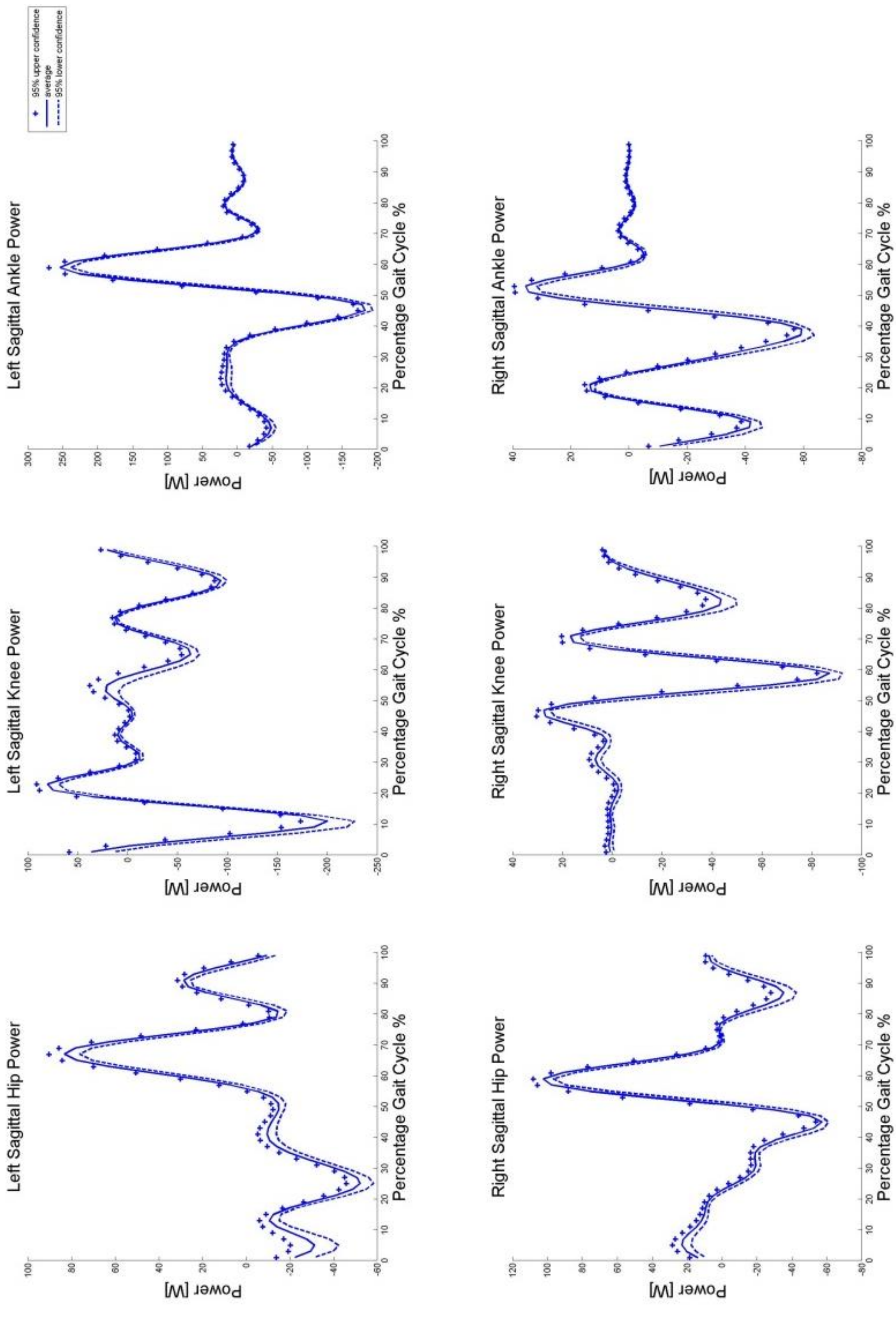


Figure 11.32 Participant (C) prosthetic (right) and anatomical (Left) powers – Ramp descent (Orion)

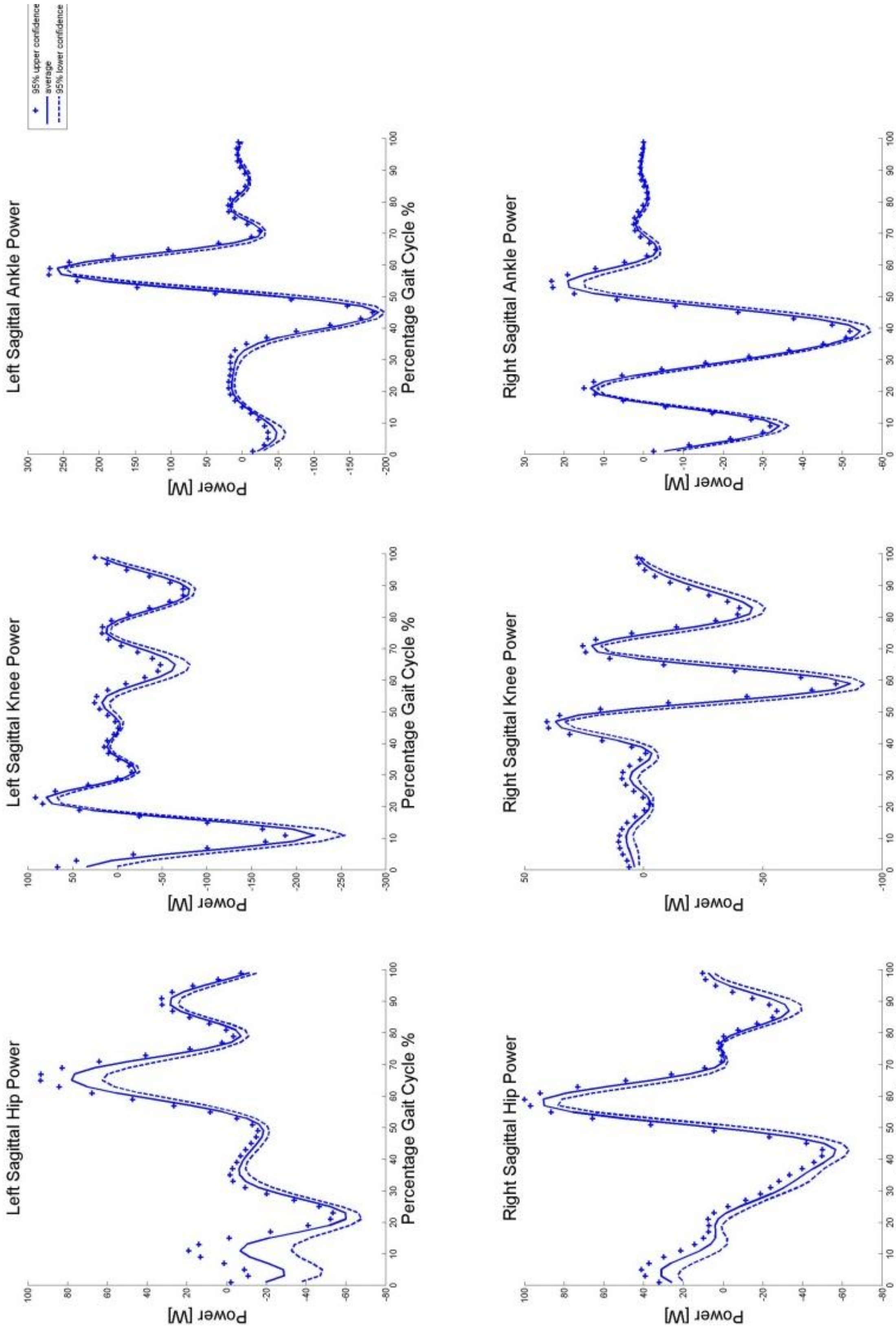


Figure 11.33 Participant (C) prosthetic (right) and anatomical (Left) powers – Ramp descent (3R80)

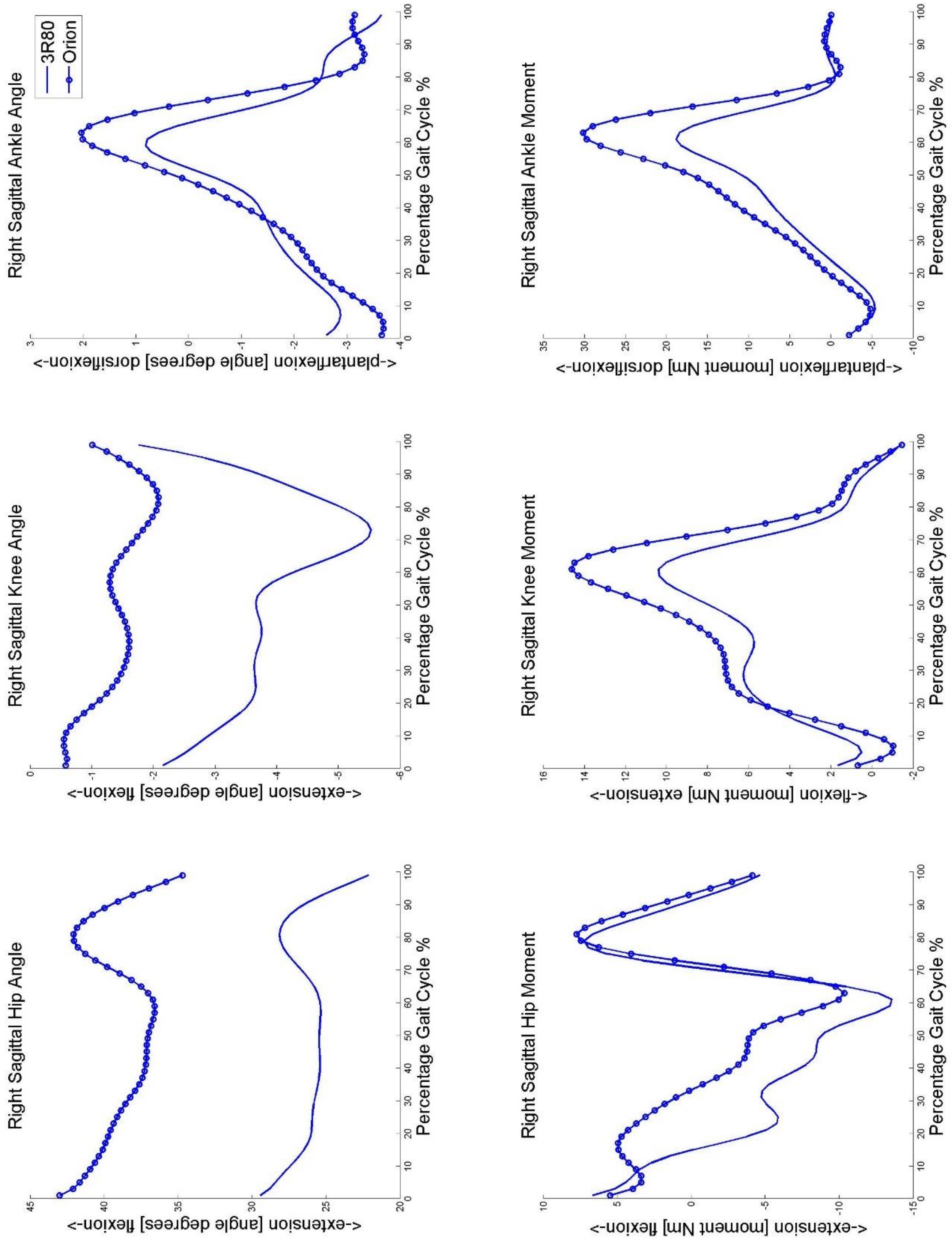


Figure 11.34 Participant (C) prosthetic limb kinematics and kinetics – stair ascent

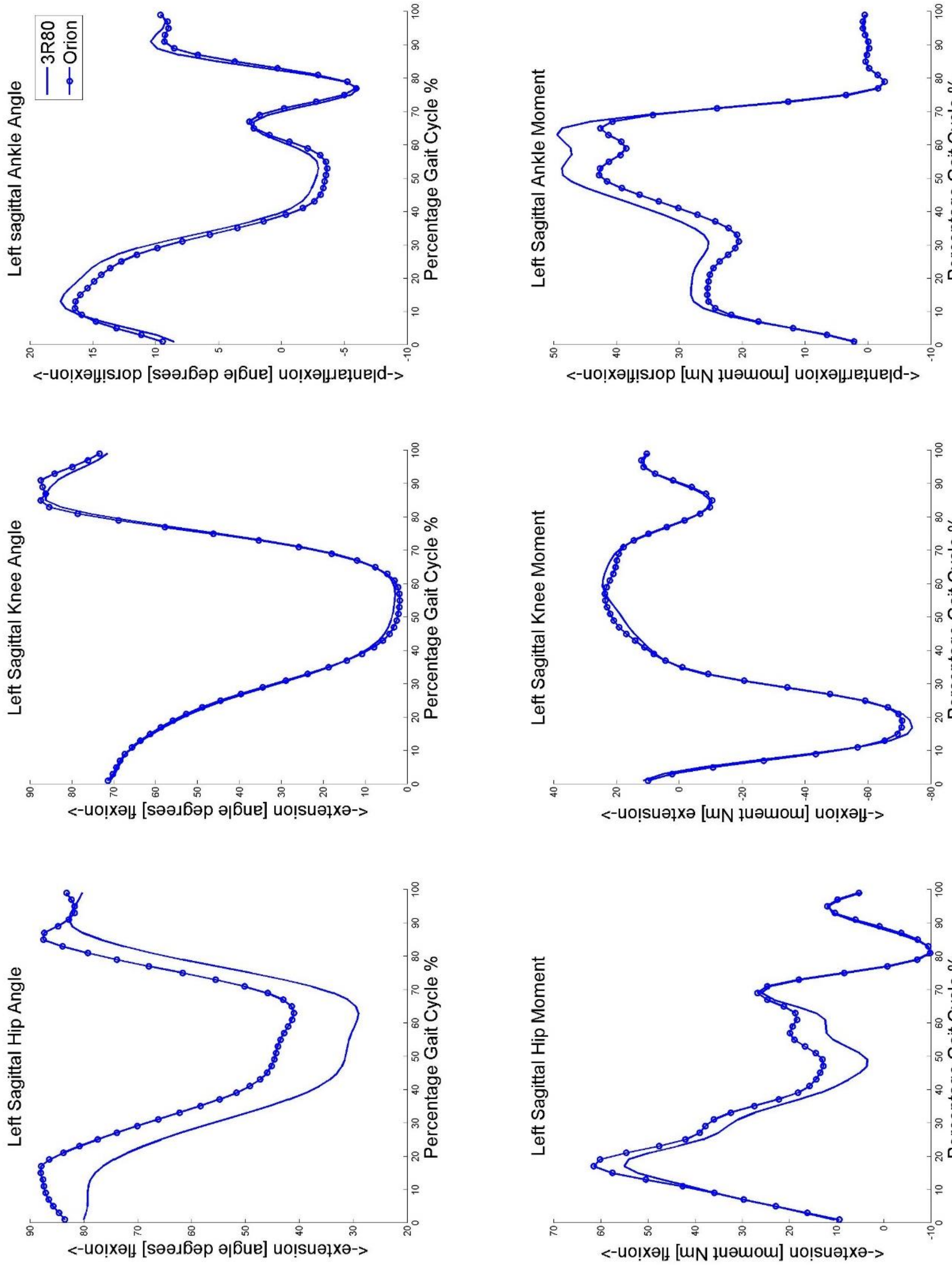


Figure 11.35 Participant (C) contralateral limb kinematics and kinetics – stair ascent

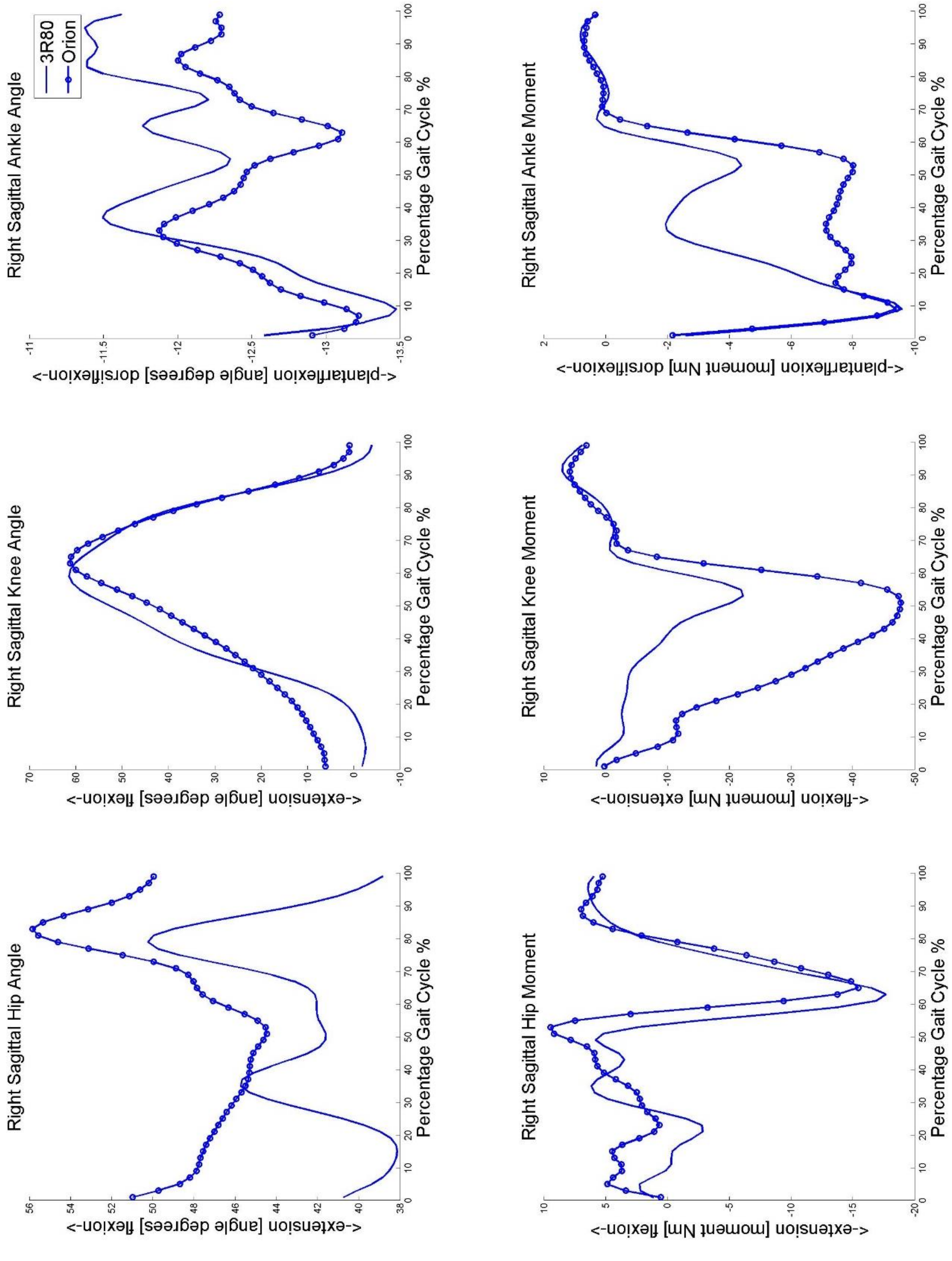


Figure 11.36 Participant (C) prosthetic limb kinematics and kinetics – stair descent

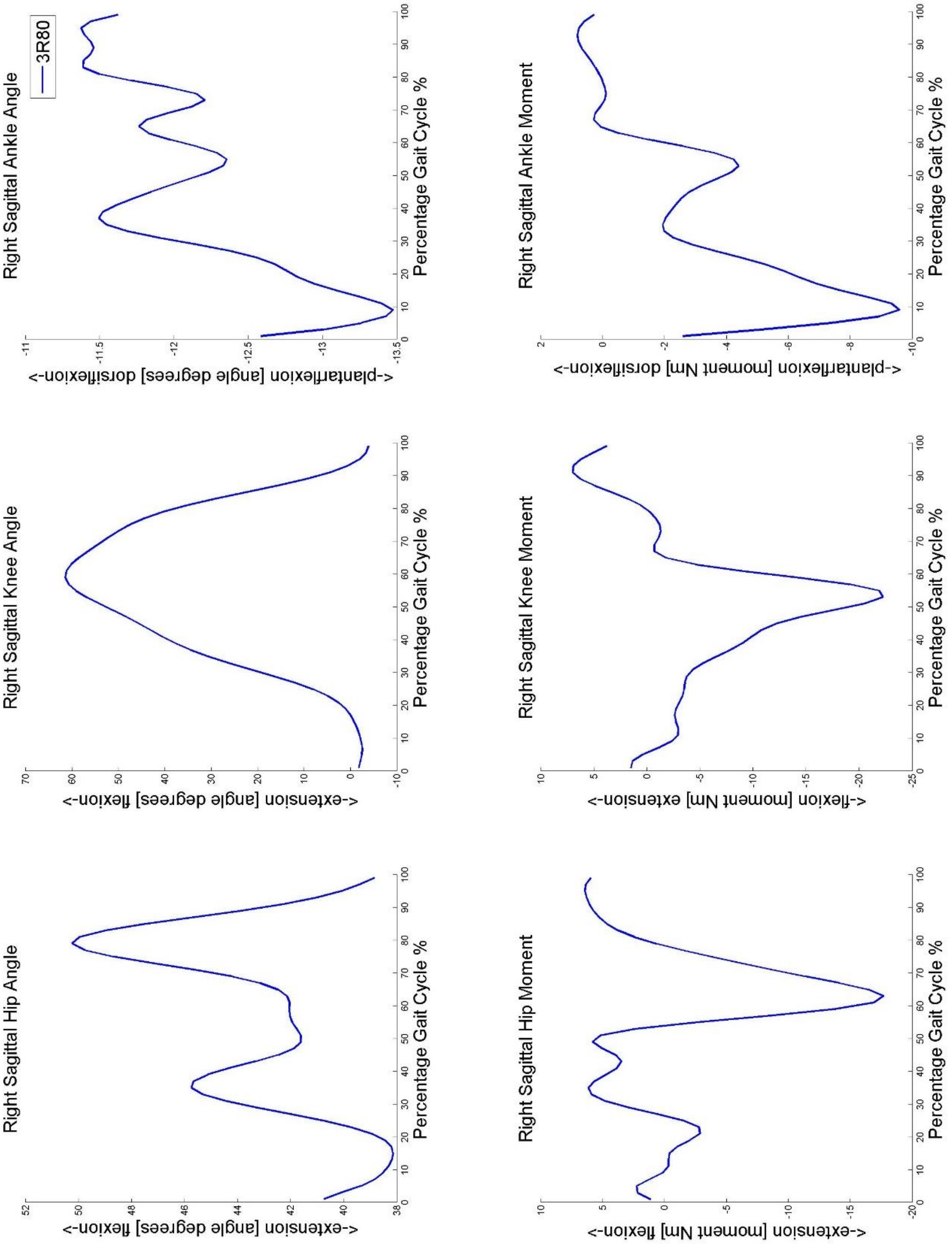


Figure 11.37 Participant (C) contralateral limb kinematics and kinetics – stair descent

11.7 PARTICIPANT (D) RESULTS (APPENDIX 7)

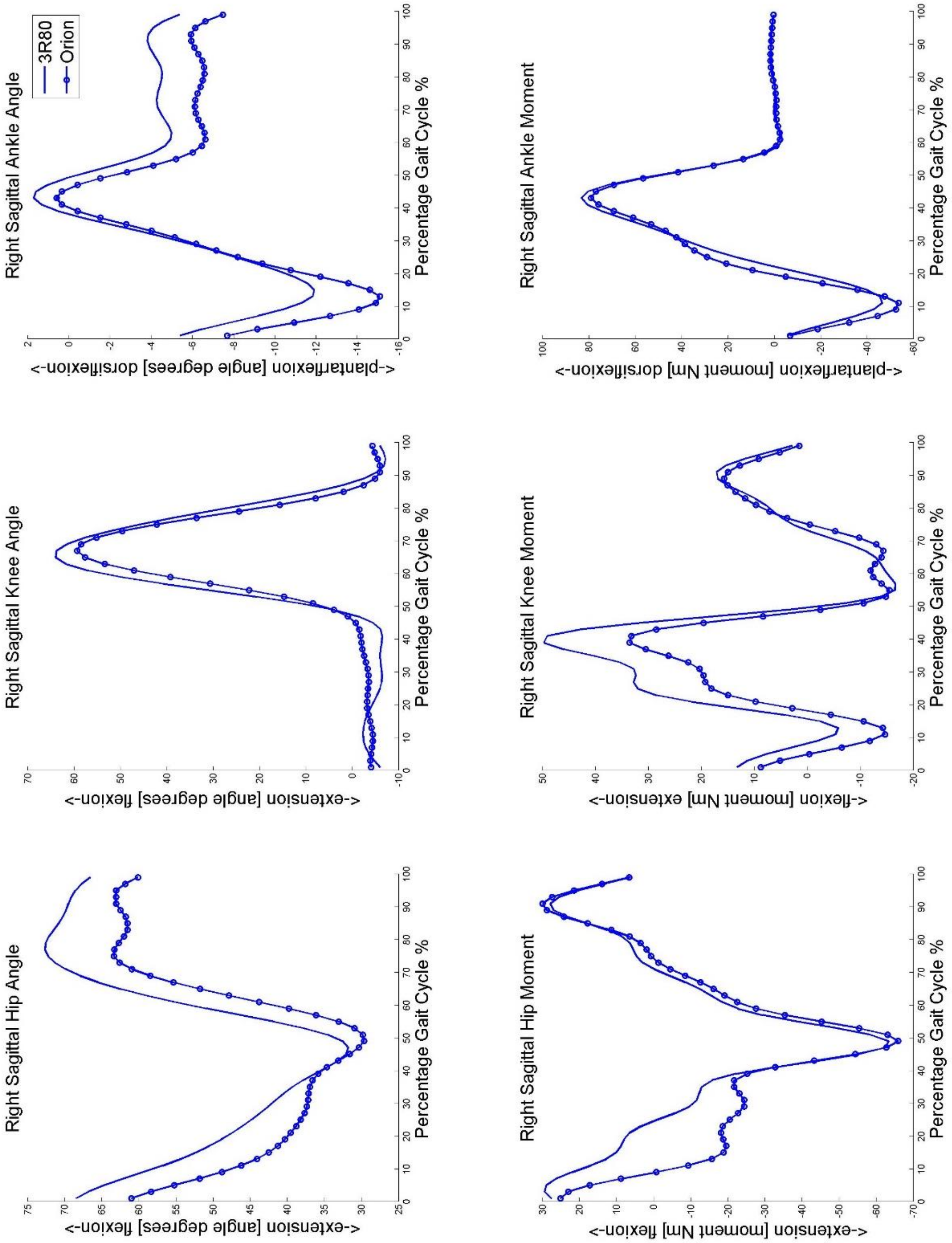


Figure 11.38 Participant (D) prosthetic limb kinematics and kinetics – level walking

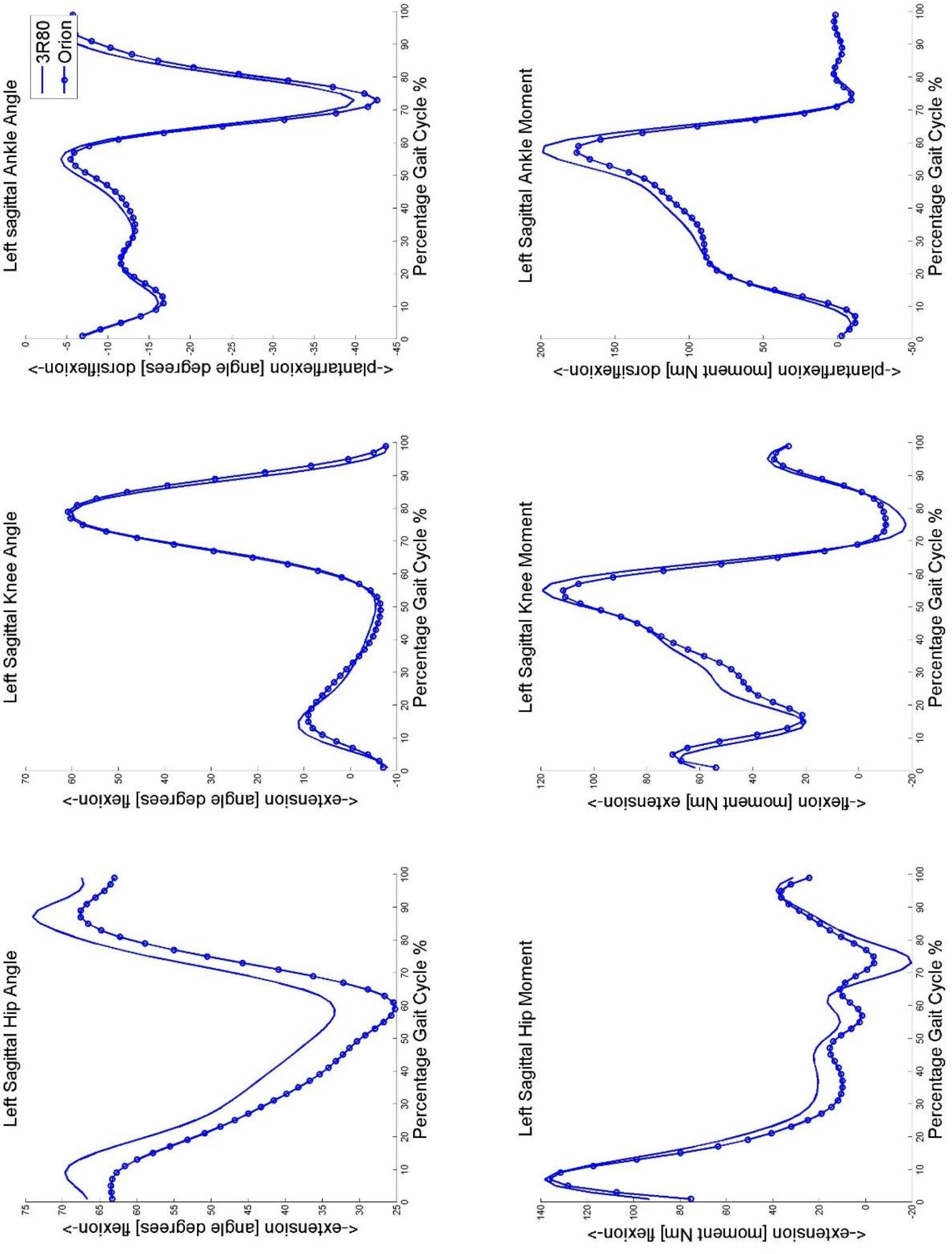


Figure 11.39 Participant (D) contralateral limb kinematics and kinetics – level walking

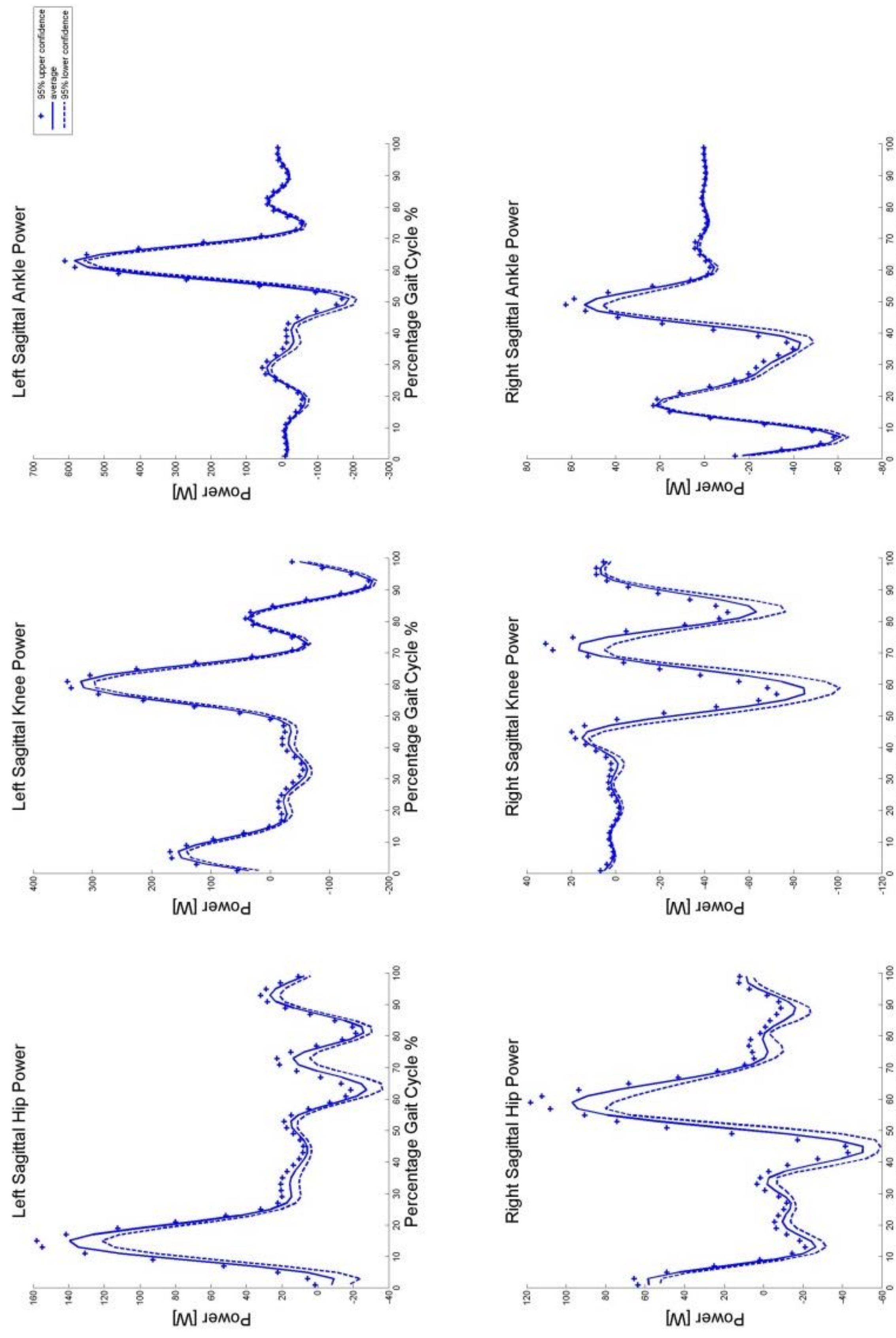


Figure 11.40 Participant (D) prosthetic (right) and anatomical (Left) powers – level walking (Orion)

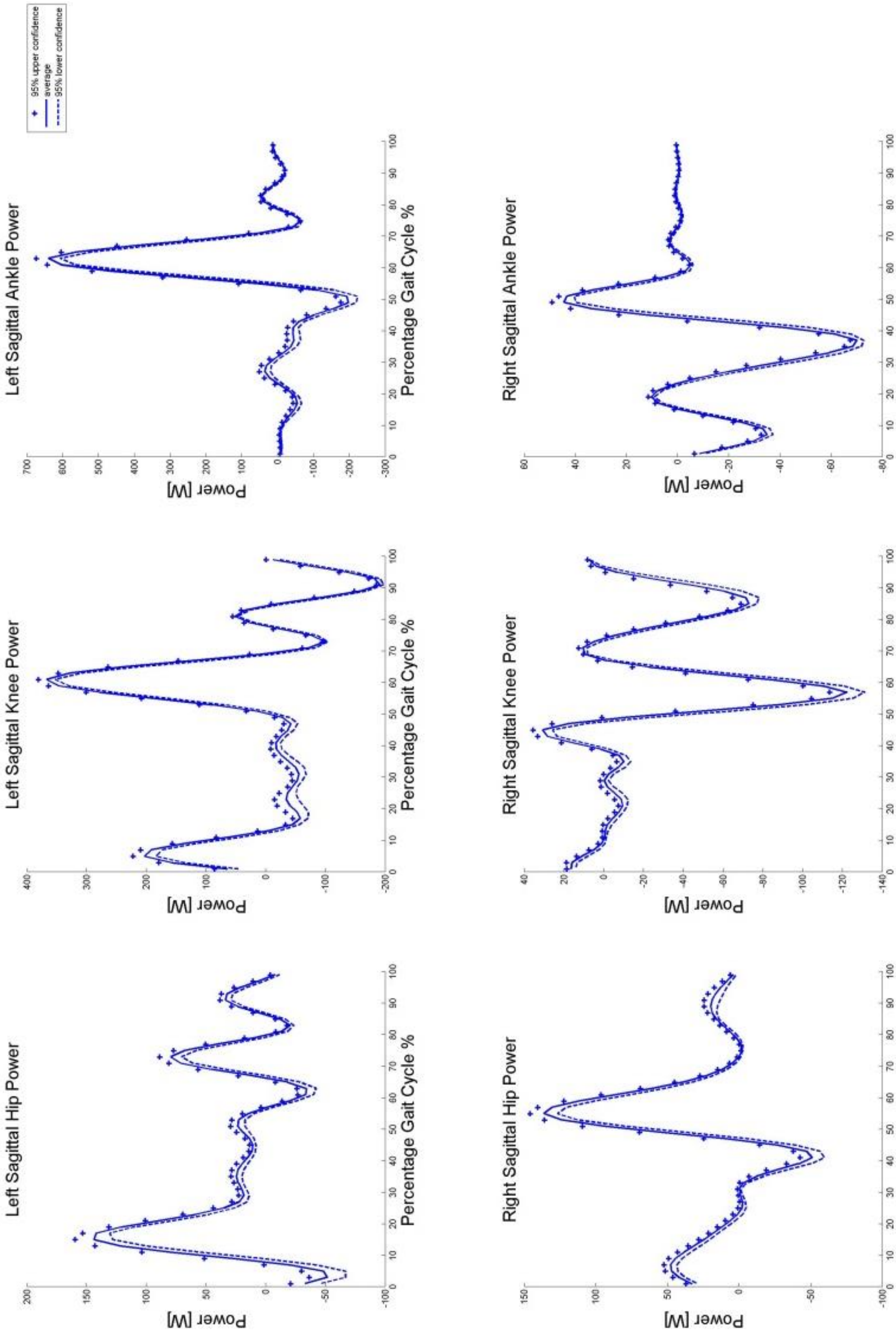


Figure 11.41 Participant (D) prosthetic (right) and anatomical (Left) powers – level walking (3R80)

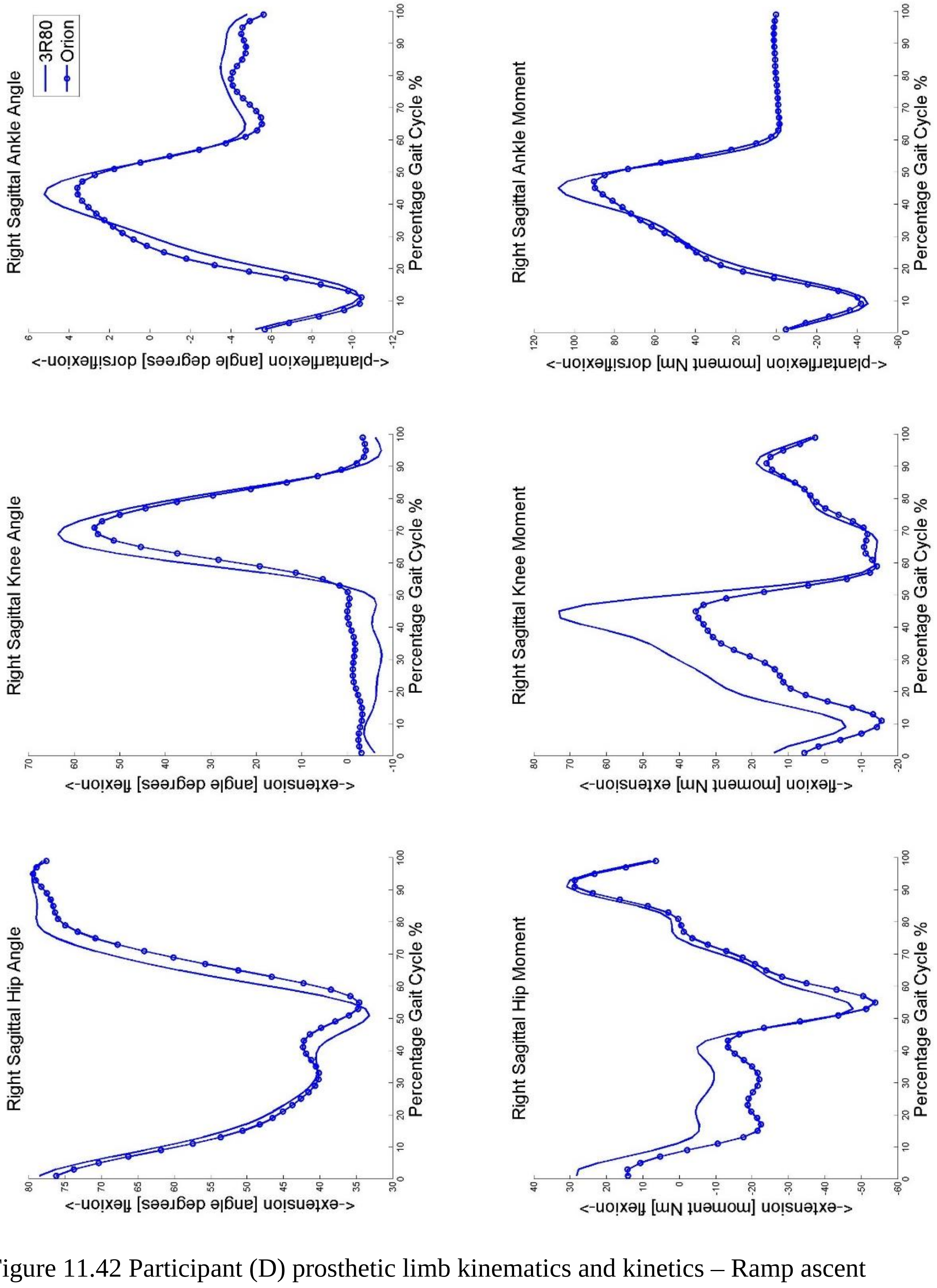


Figure 11.42 Participant (D) prosthetic limb kinematics and kinetics – Ramp ascent

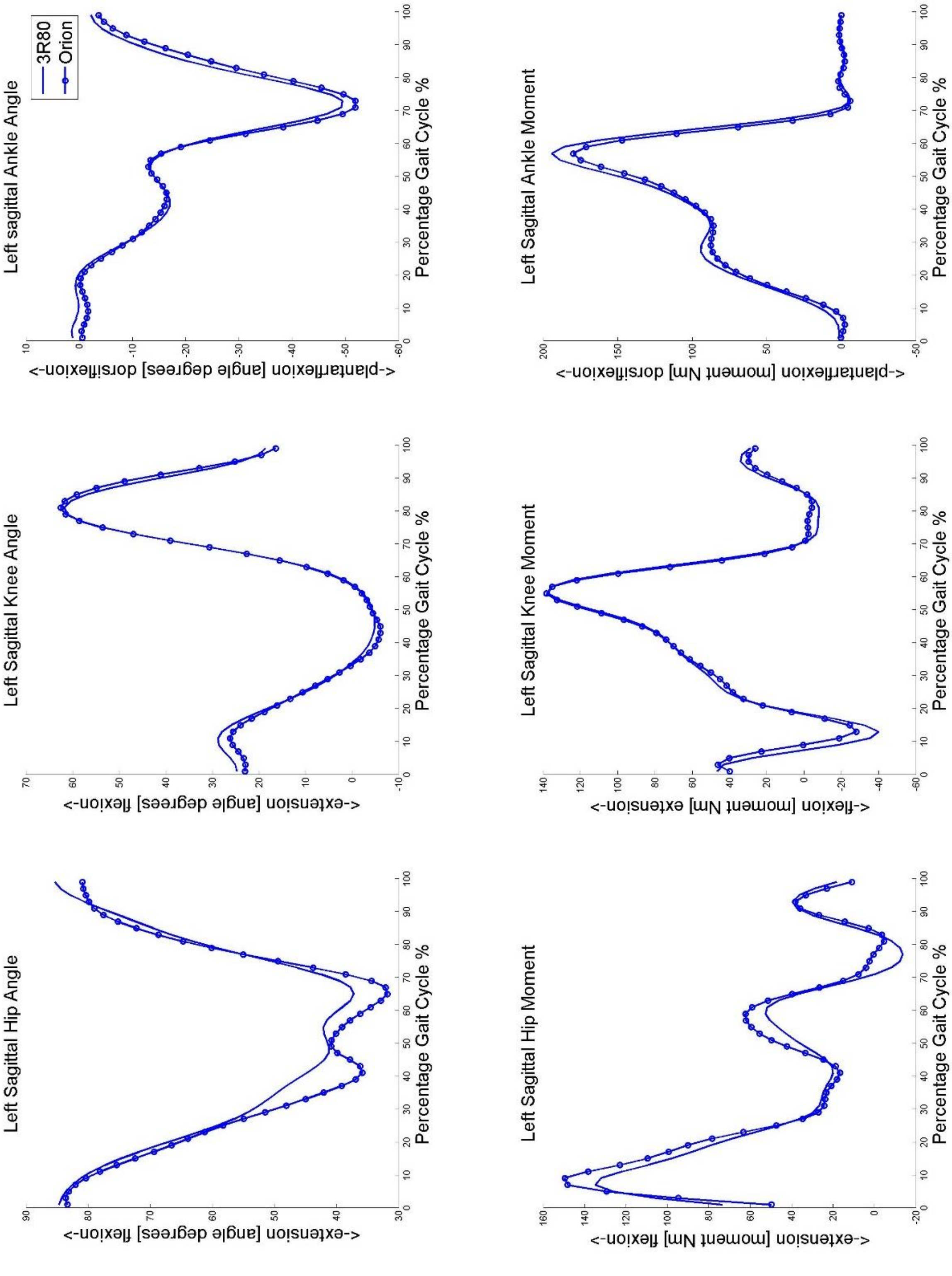


Figure 11.43 Participant (D) contralateral limb kinematics and kinetics – Ramp ascent

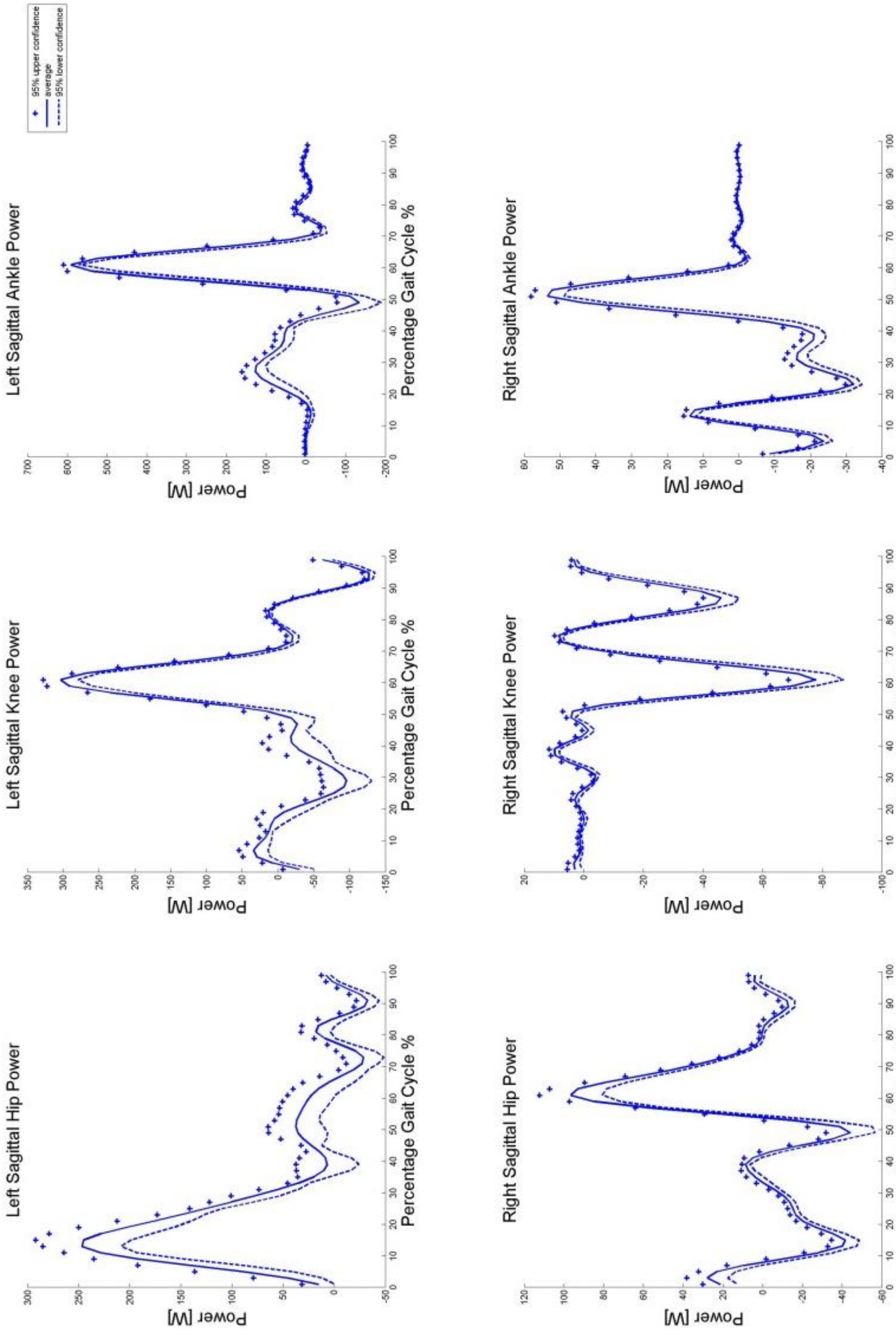


Figure 11.44 Participant (D) prosthetic (right) and anatomical (Left) powers – Ramp ascent (Orion)

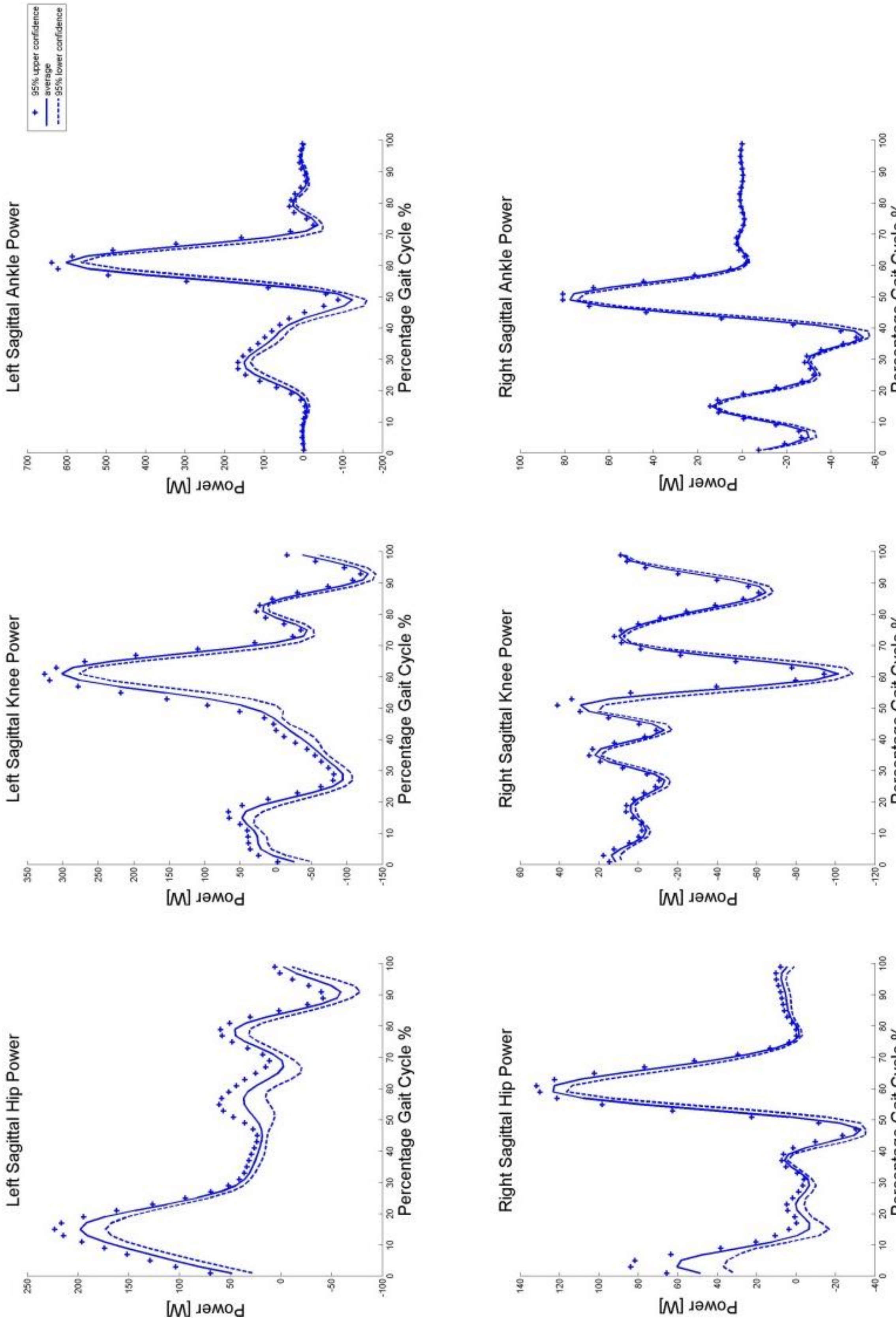


Figure 11.45 Participant (D) prosthetic (right) and anatomical (Left) powers – Ramp ascent (3R80)

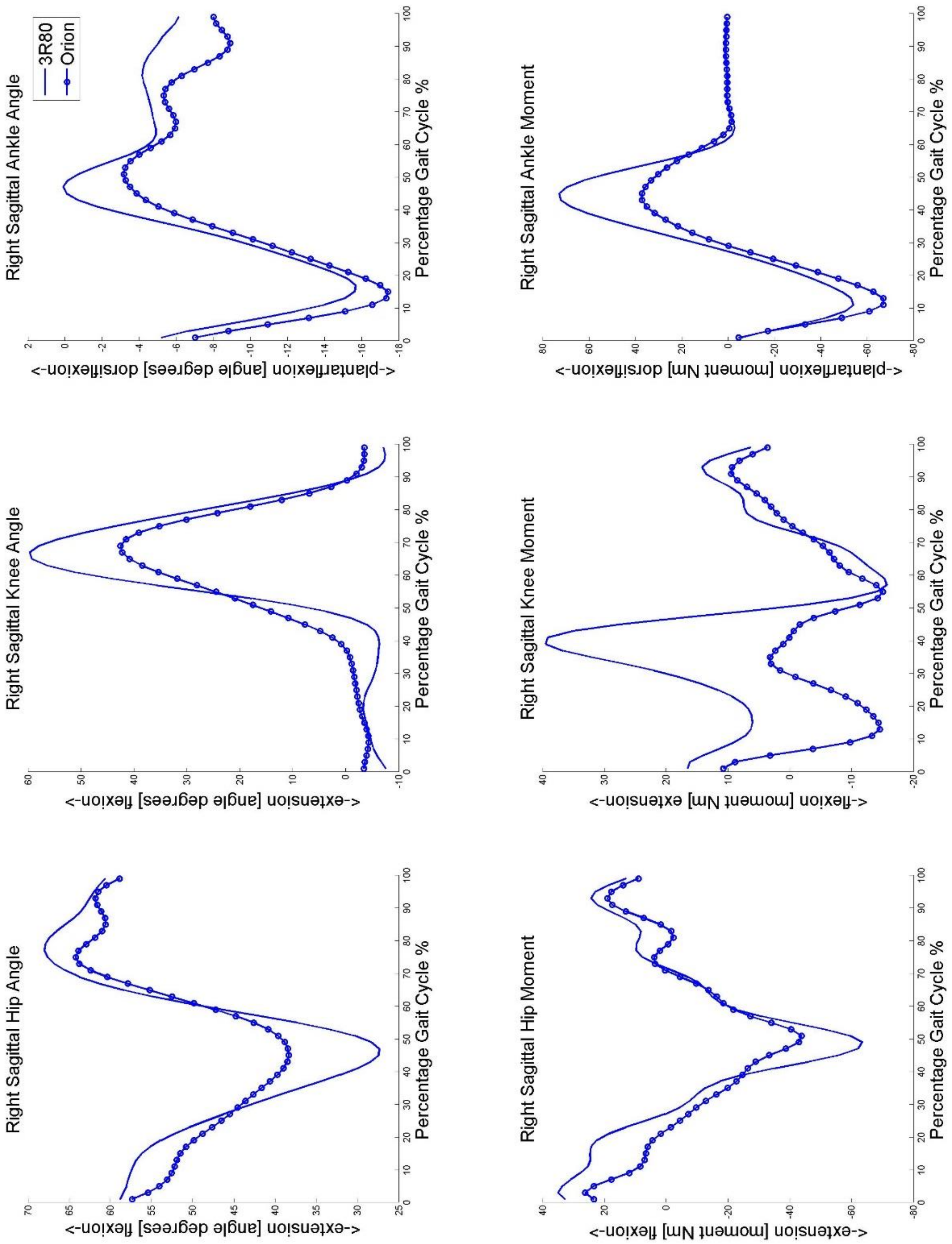


Figure 11.46 Participant (D) prosthetic limb kinematics and kinetics – Ramp descent

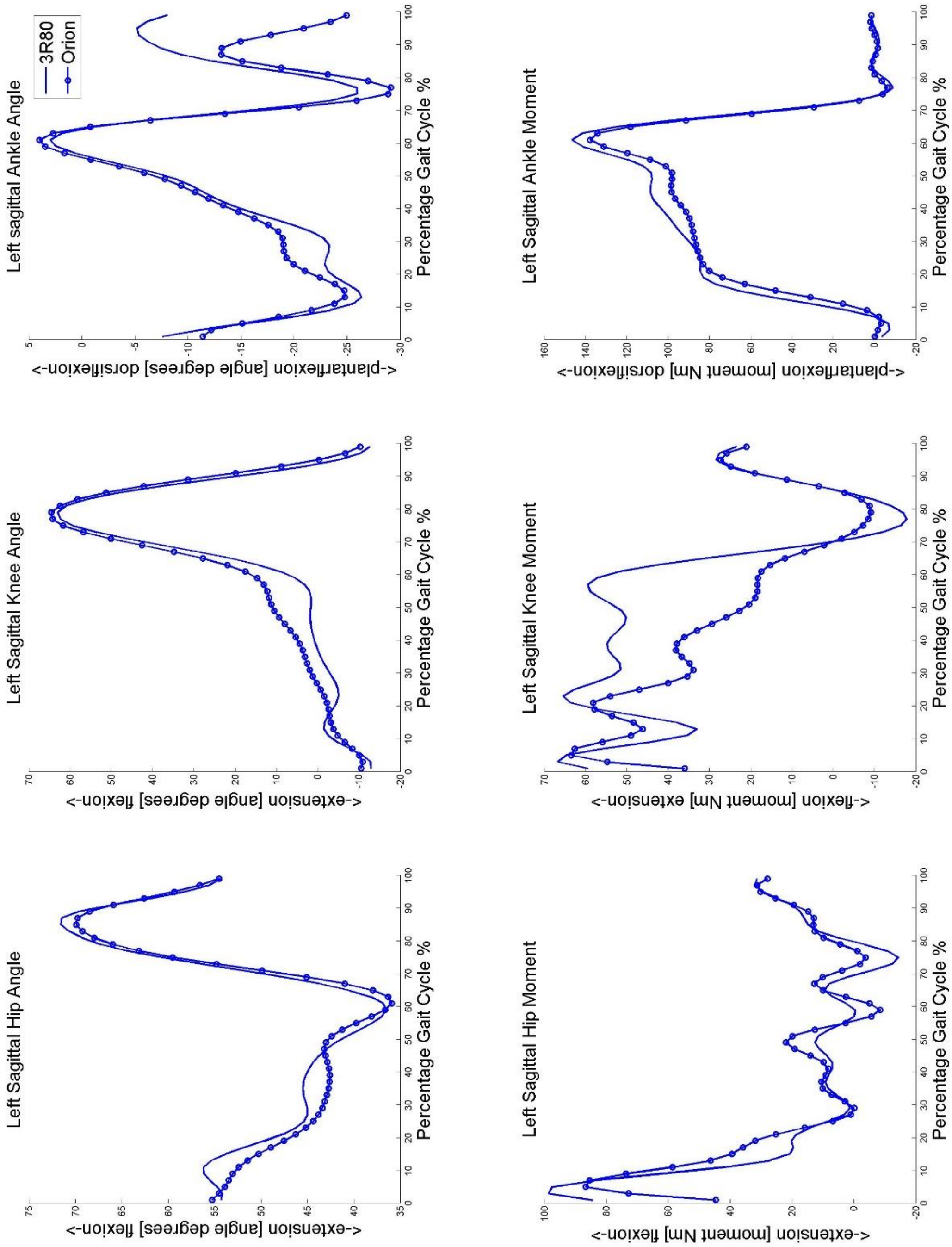


Figure 11.47 Participant (D) contralateral limb kinematics and kinetics – Ramp descent

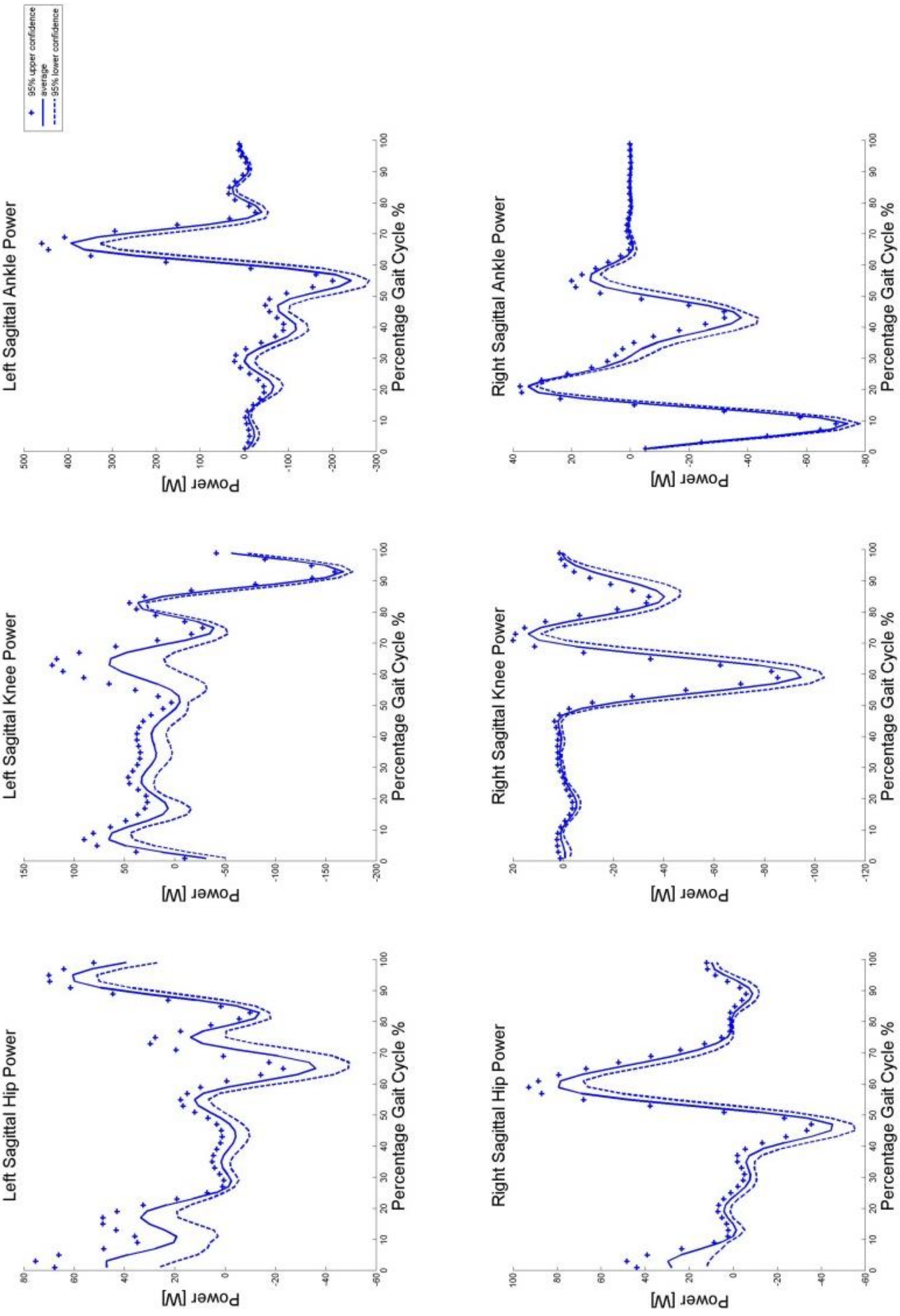


Figure 11.48 Participant (D) prosthetic (right) and anatomical (Left) powers – Ramp descent (Orion)

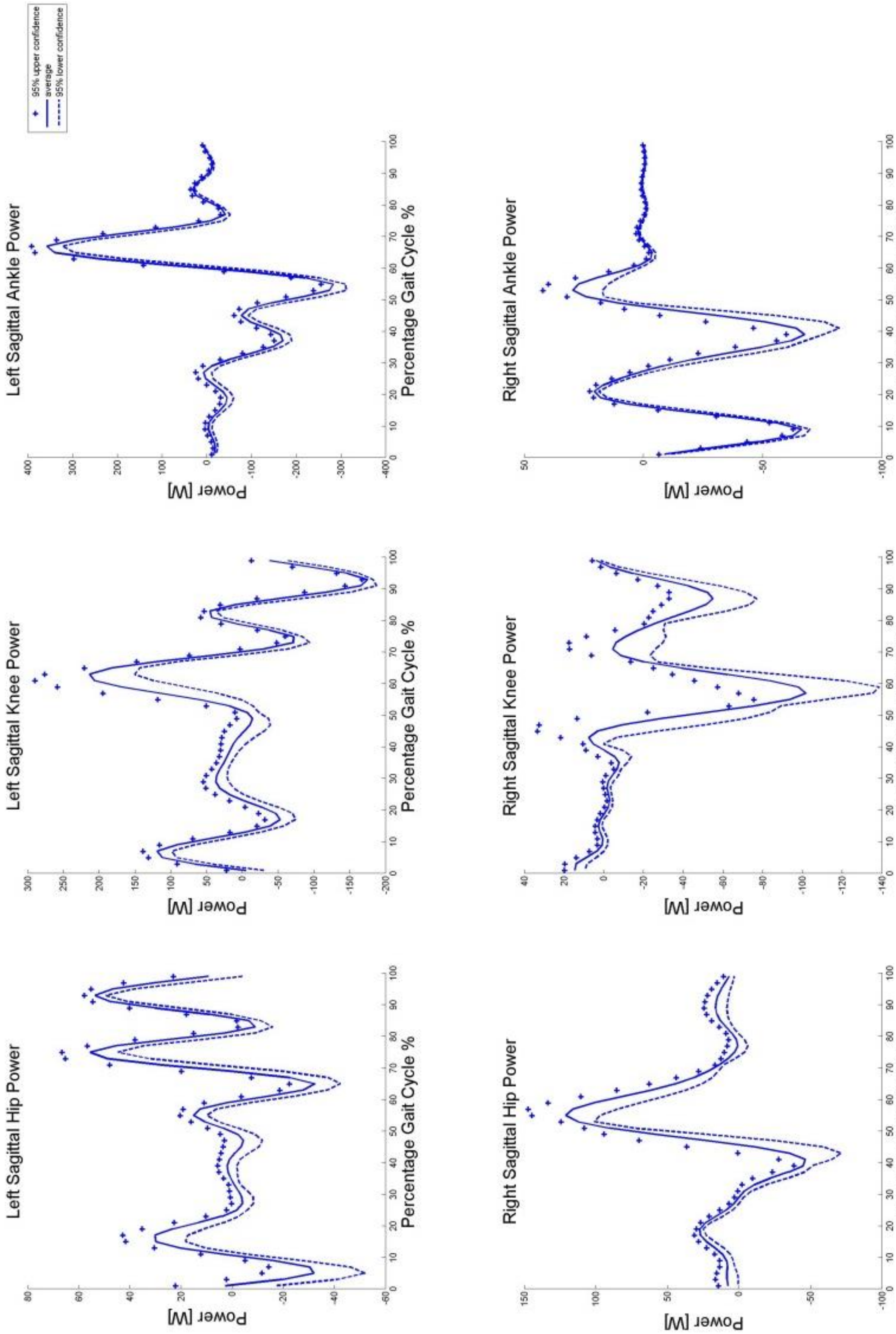


Figure 11.49 Participant (D) prosthetic (right) and anatomical (Left) powers – Ramp descent (3R80)

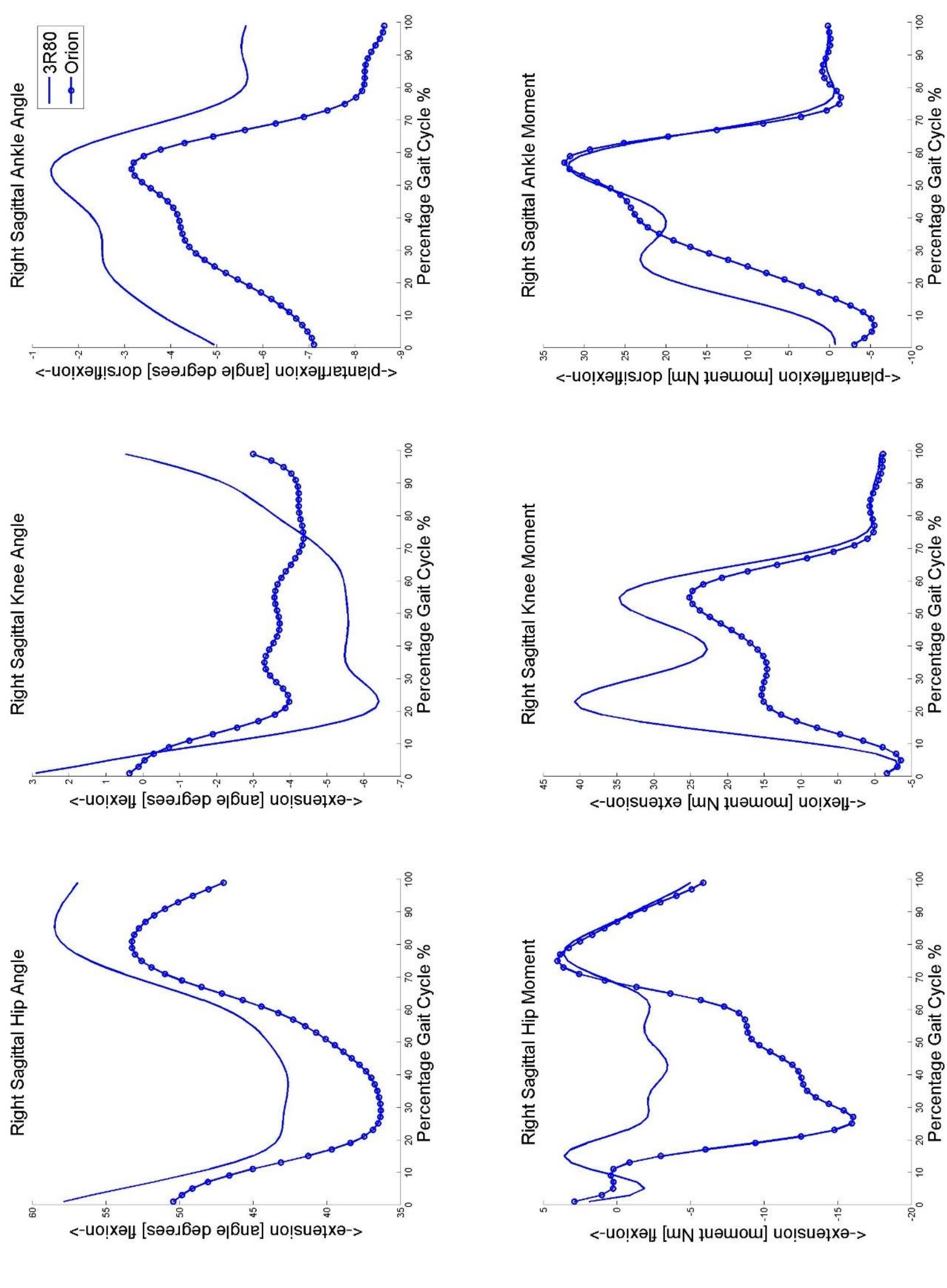


Figure 11.50 Participant (D) prosthetic limb kinematics and kinetics – stair ascent

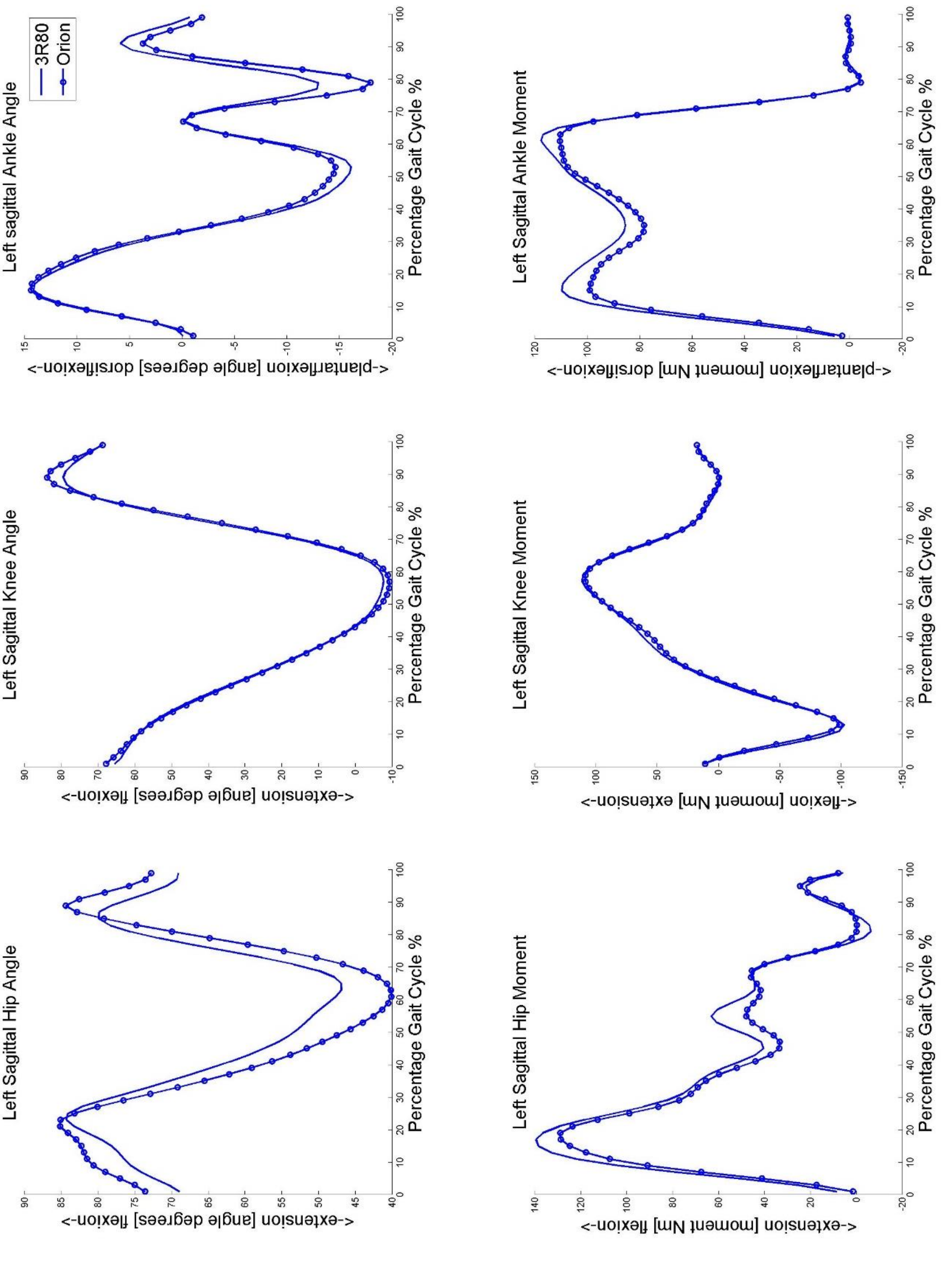


Figure 11.51 Participant (D) contralateral limb kinematics and kinetics – stair ascent

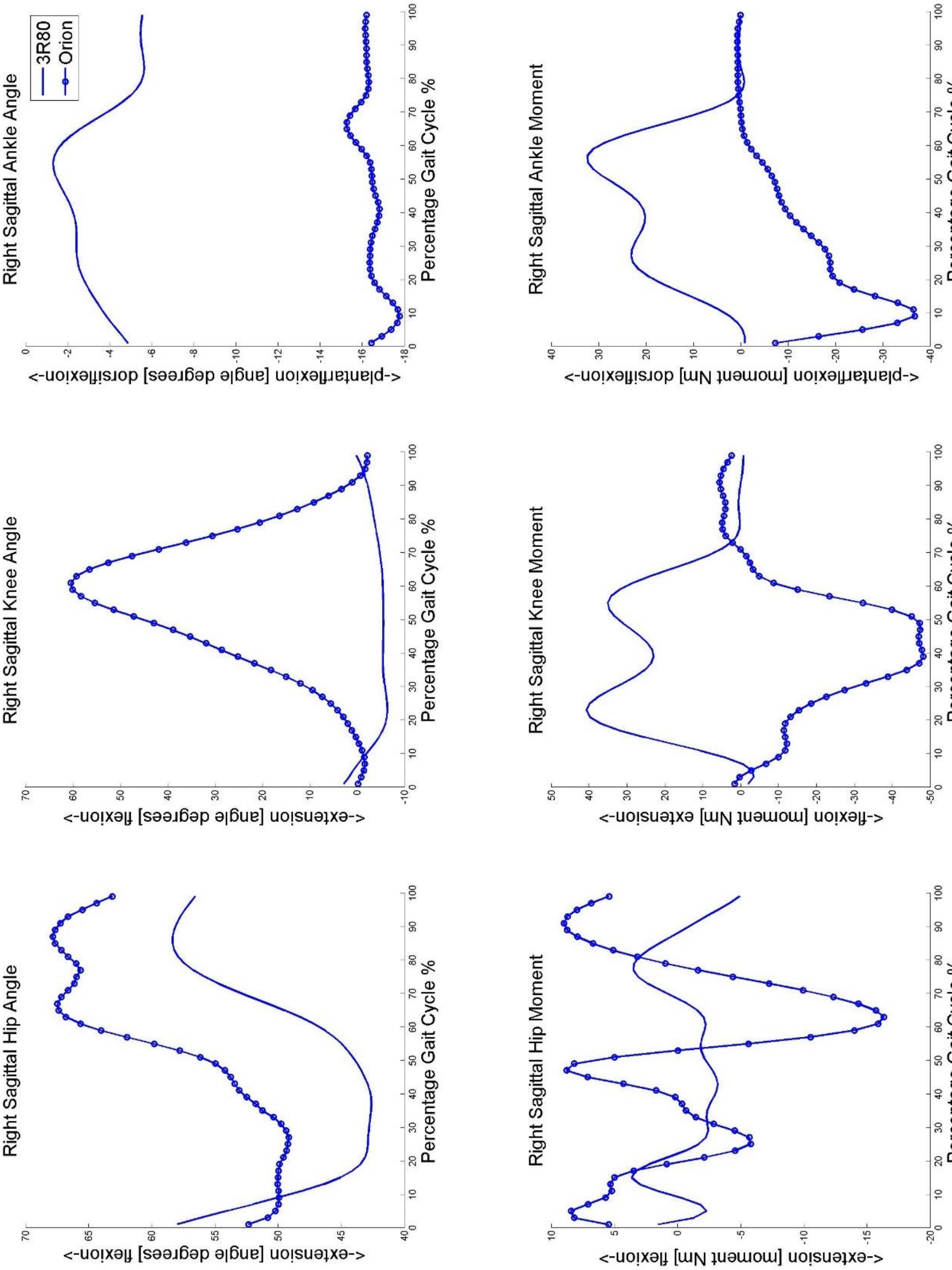


Figure 11.52 Participant (D) prosthetic limb kinematics and kinetics – stair descent

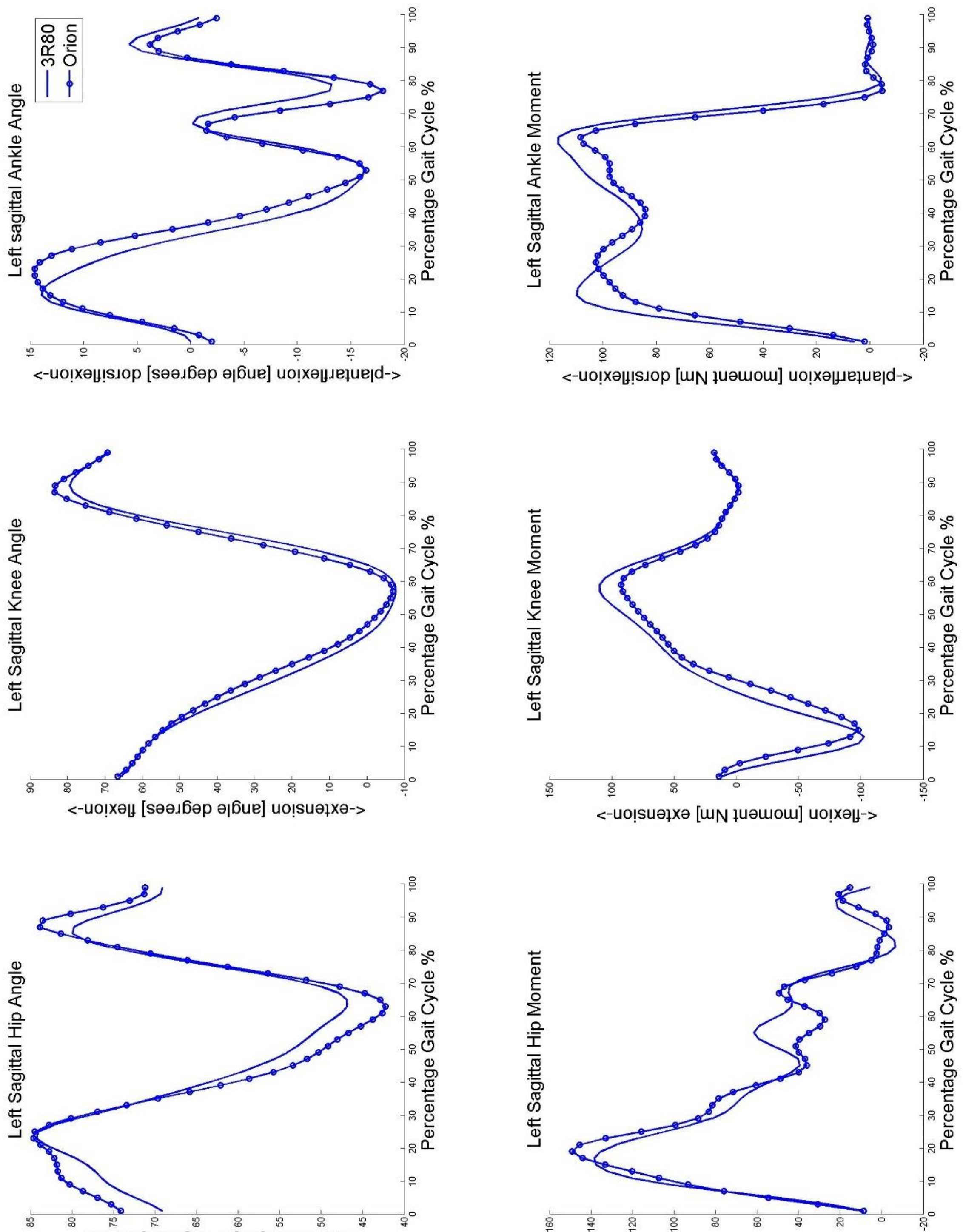


Figure 11.53 Participant (D) contralateral limb kinematics and kinetics – stair descent

11.8 PARTICIPANT (E) RESULTS (APPENDIX 8)

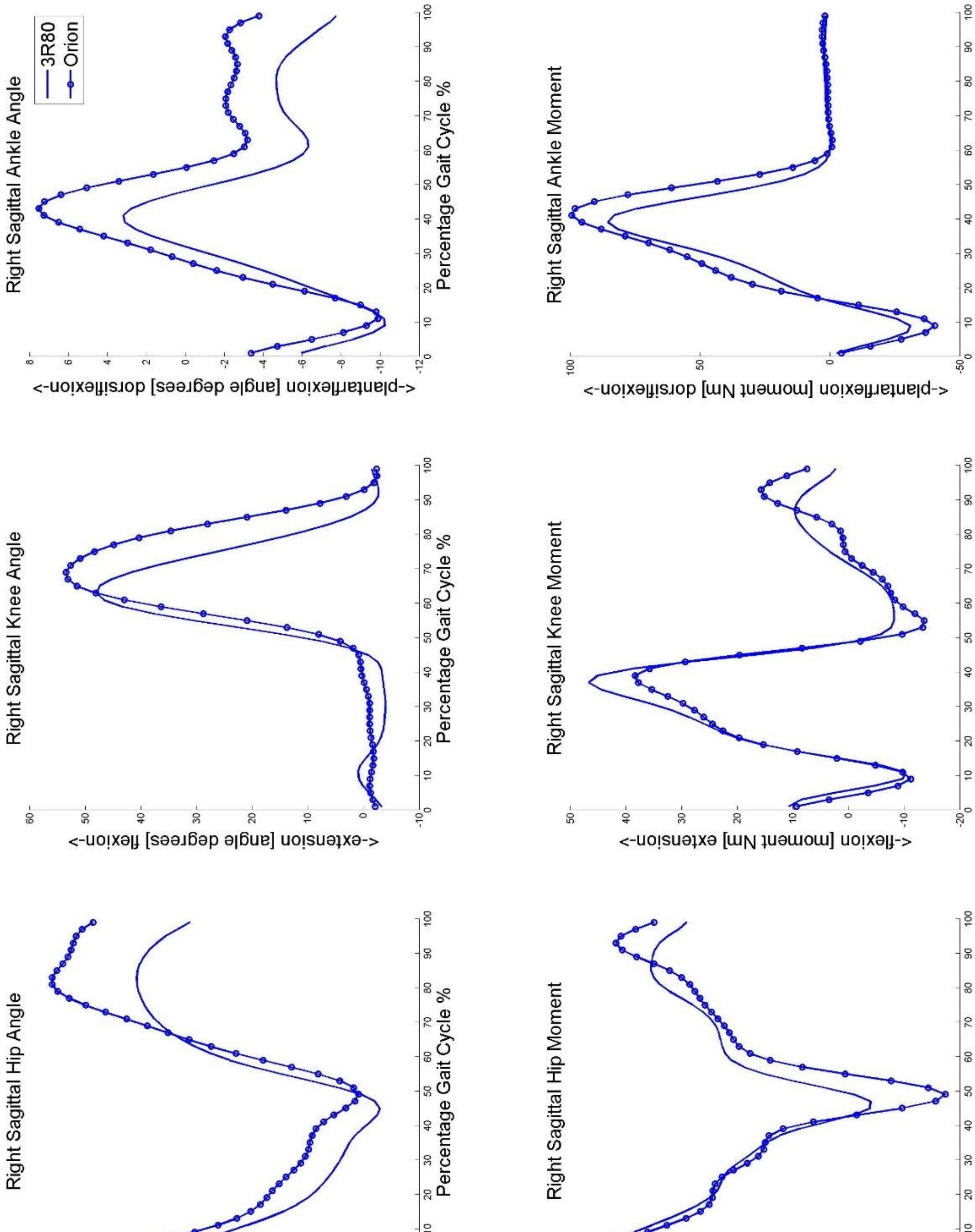


Figure 11.54 Participant (E) prosthetic limb kinematics and kinetics – level walking

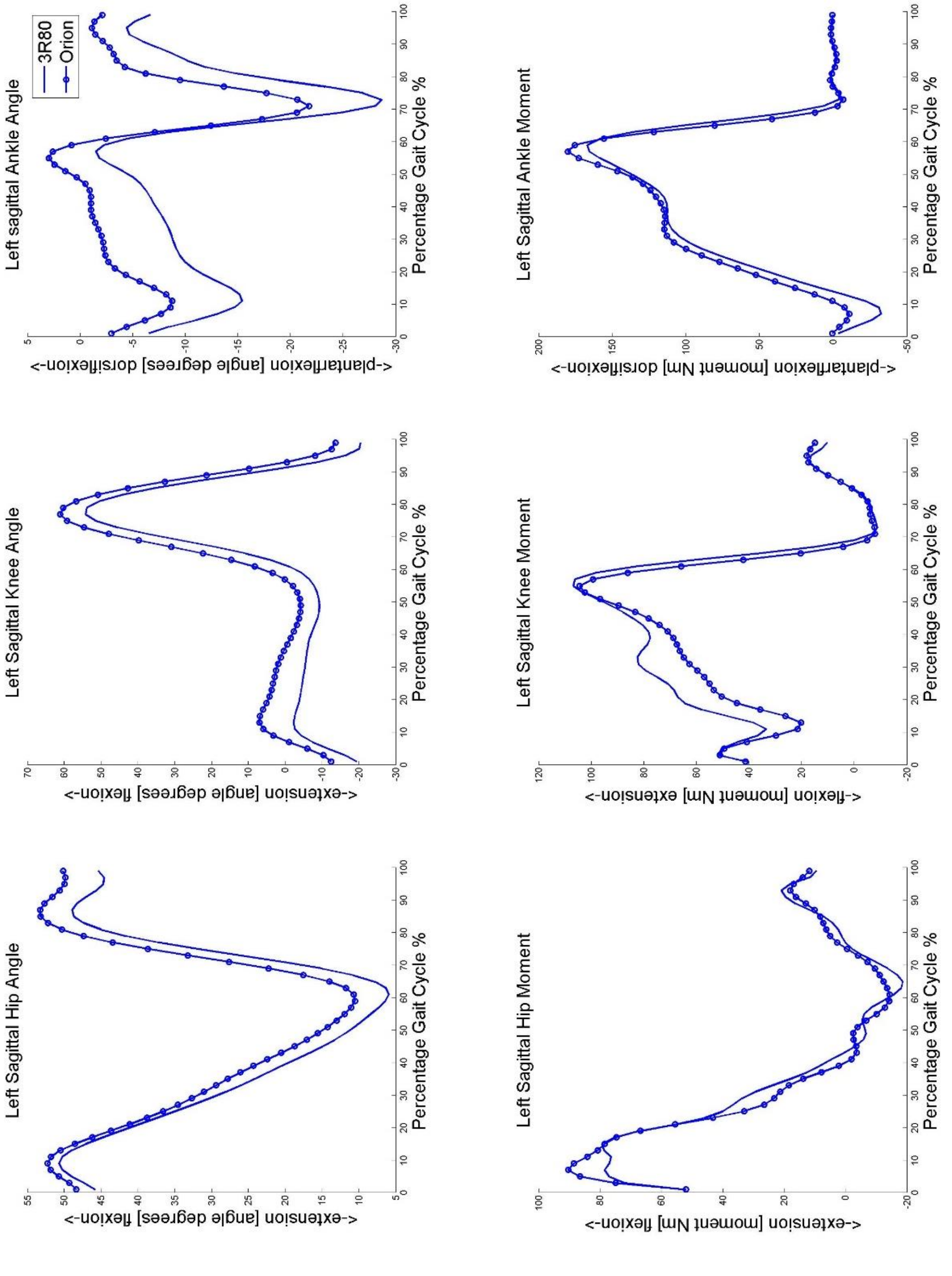


Figure 11.55 Participant (E) contralateral limb kinematics and kinetics – level walking

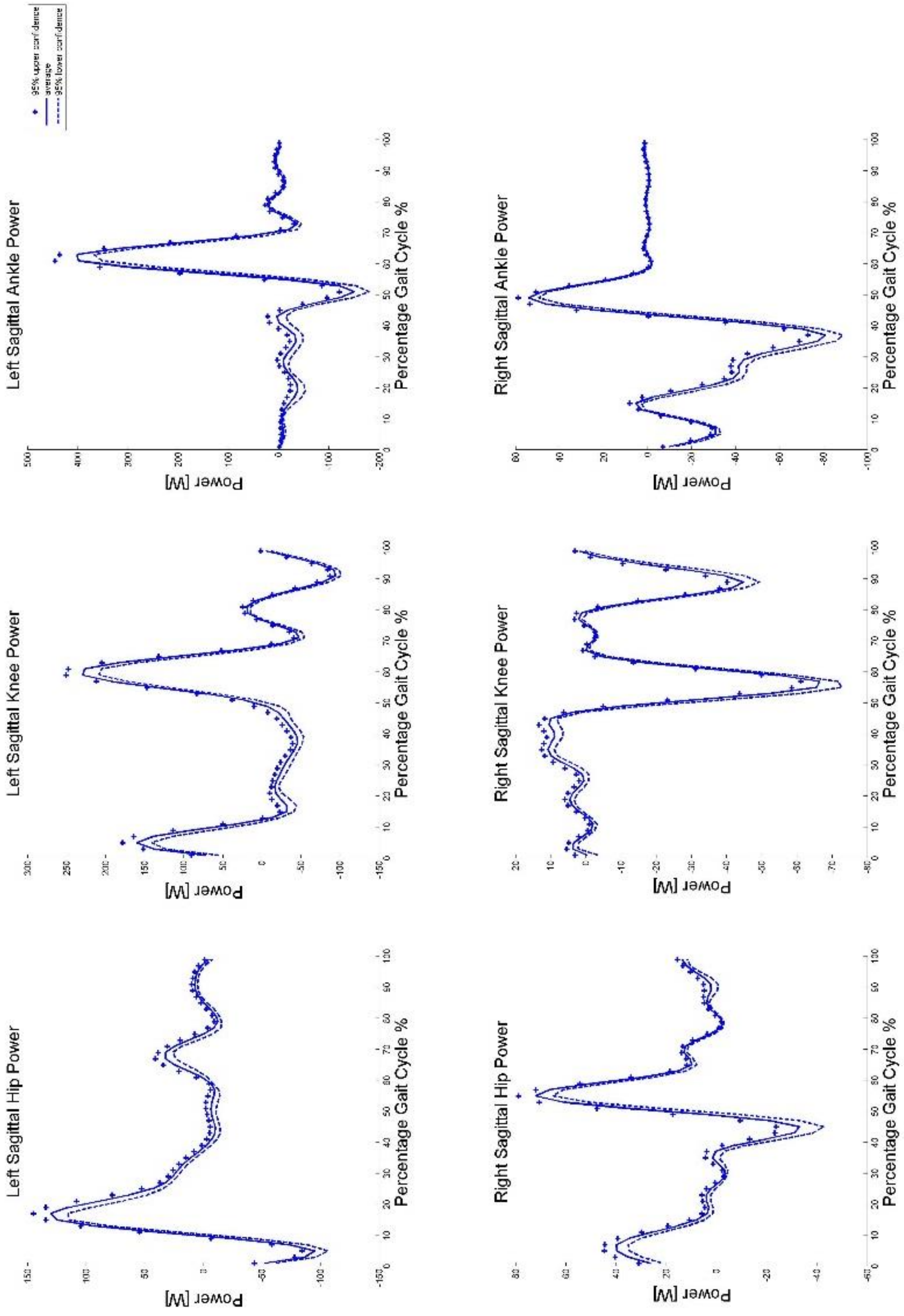


Figure 11.56 Participant (E) prosthetic (right) and anatomical (Left) powers – level walking (3R80)

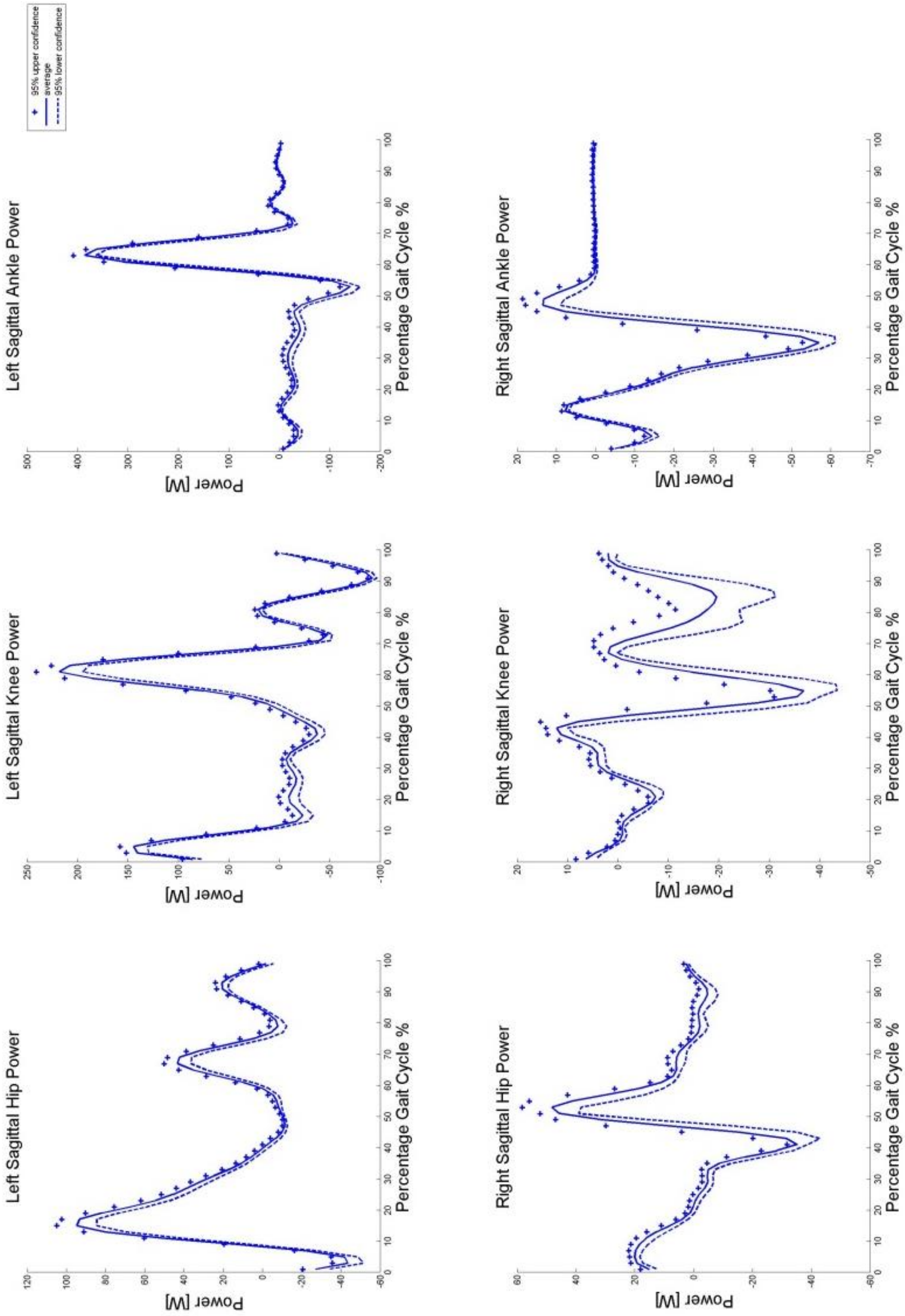


Figure 11.57 Participant (E) prosthetic (right) and anatomical (Left) powers – level walking (Orion)

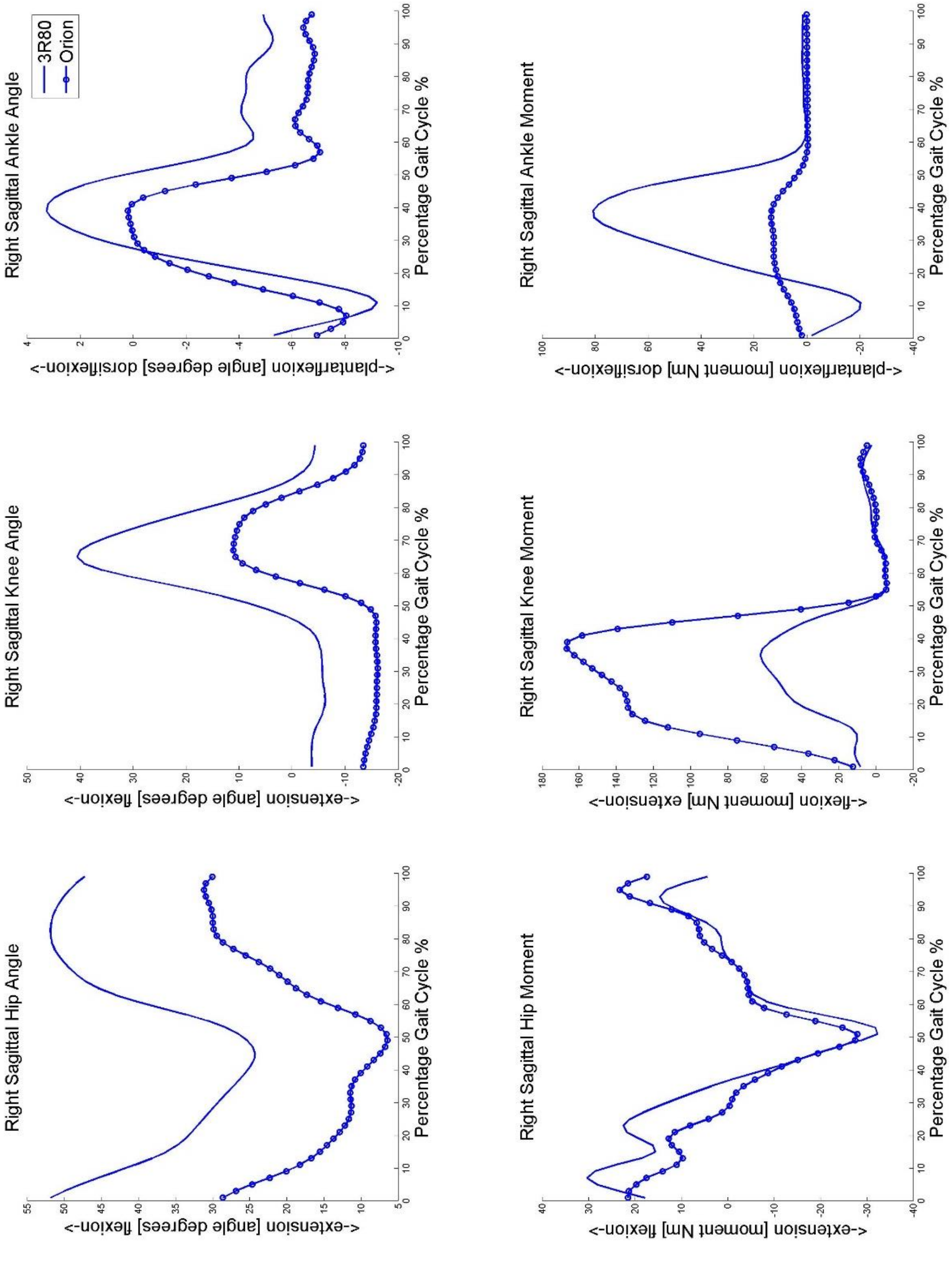


Figure 11.58 Participant (E) prosthetic limb kinematics and kinetics – Ramp ascent

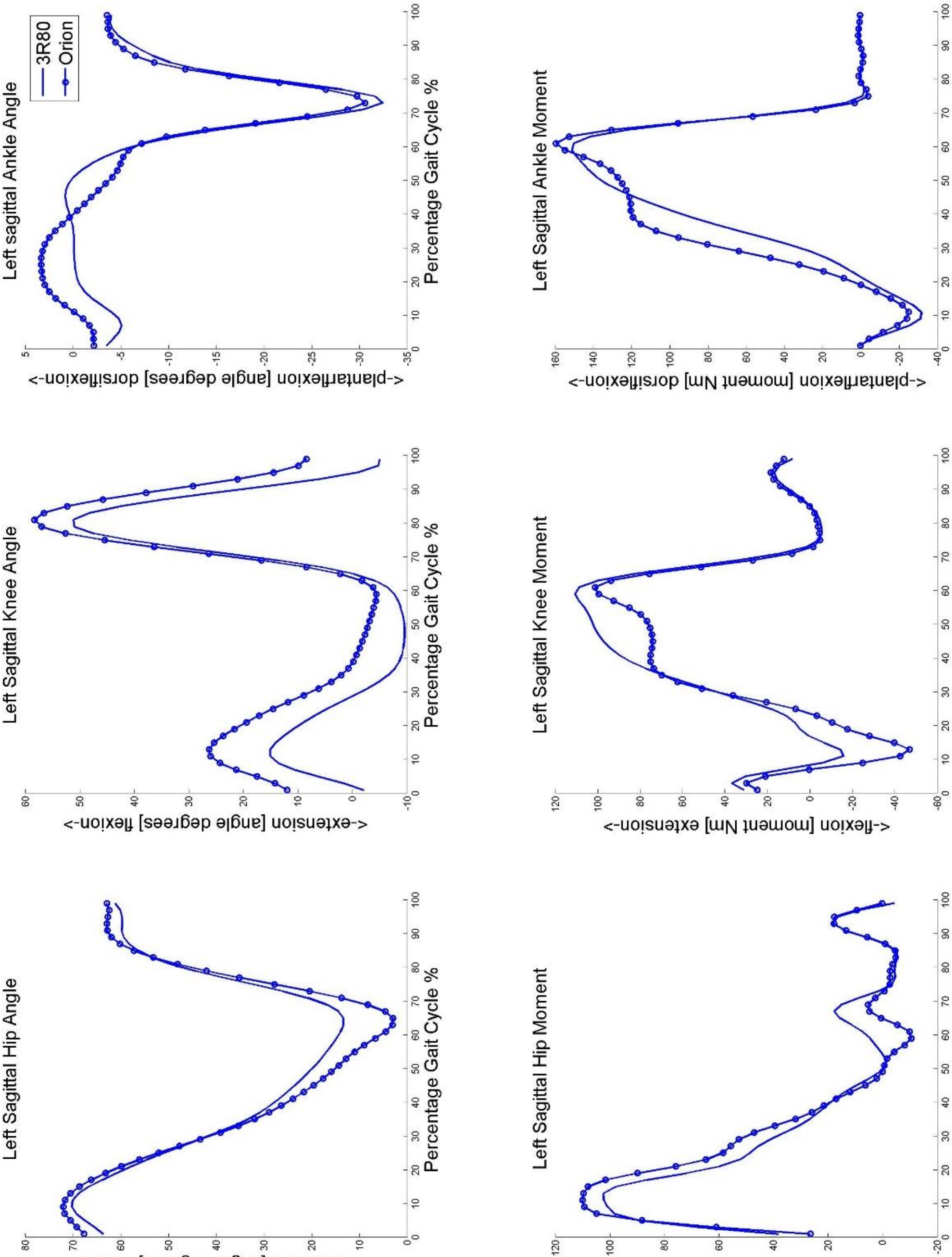


Figure 11.59 Participant (E) contralateral limb kinematics and kinetics – Ramp ascent

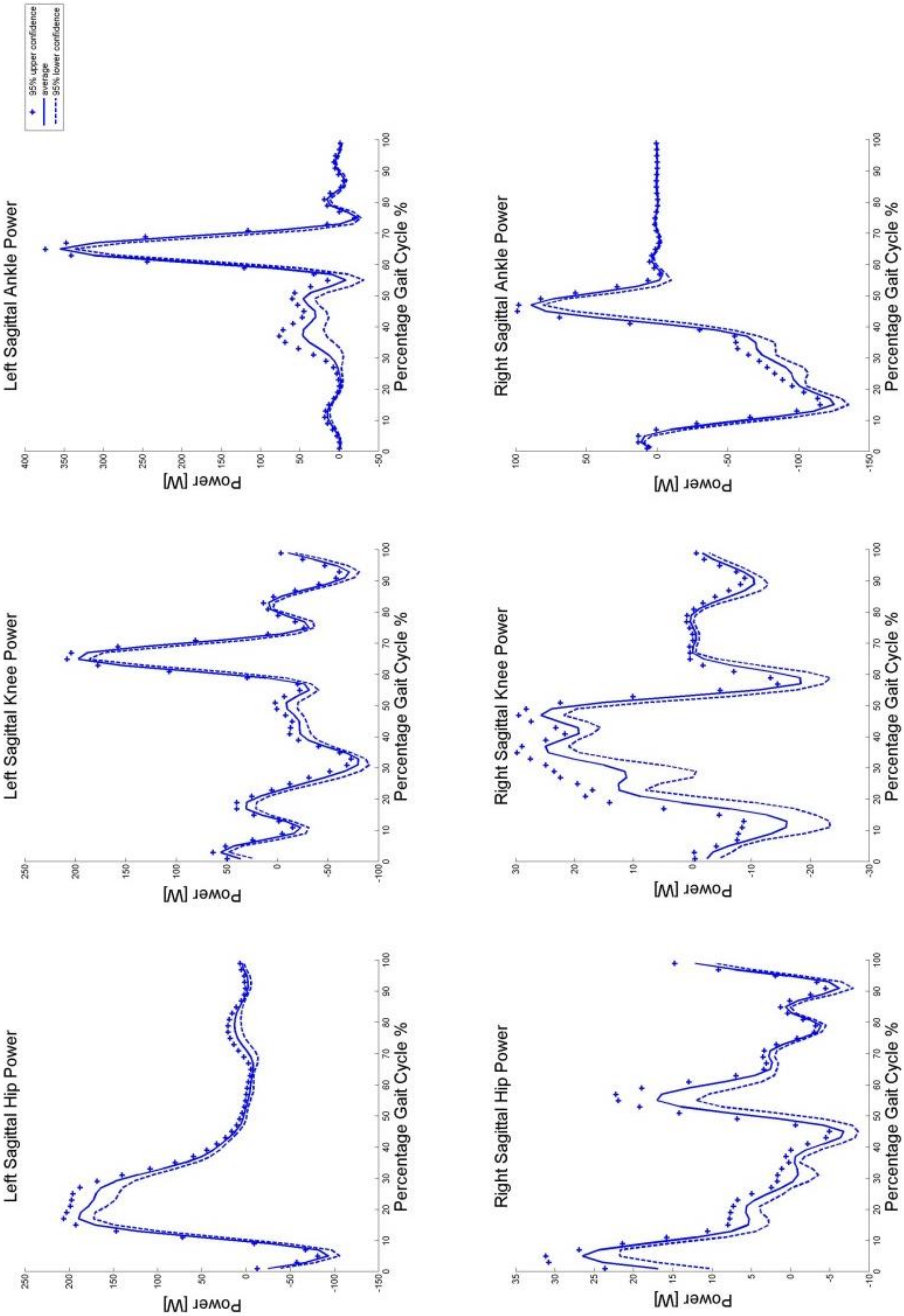


Figure 11.60 Participant (E) prosthetic (right) and anatomical (Left) powers – Ramp ascent (3R80)

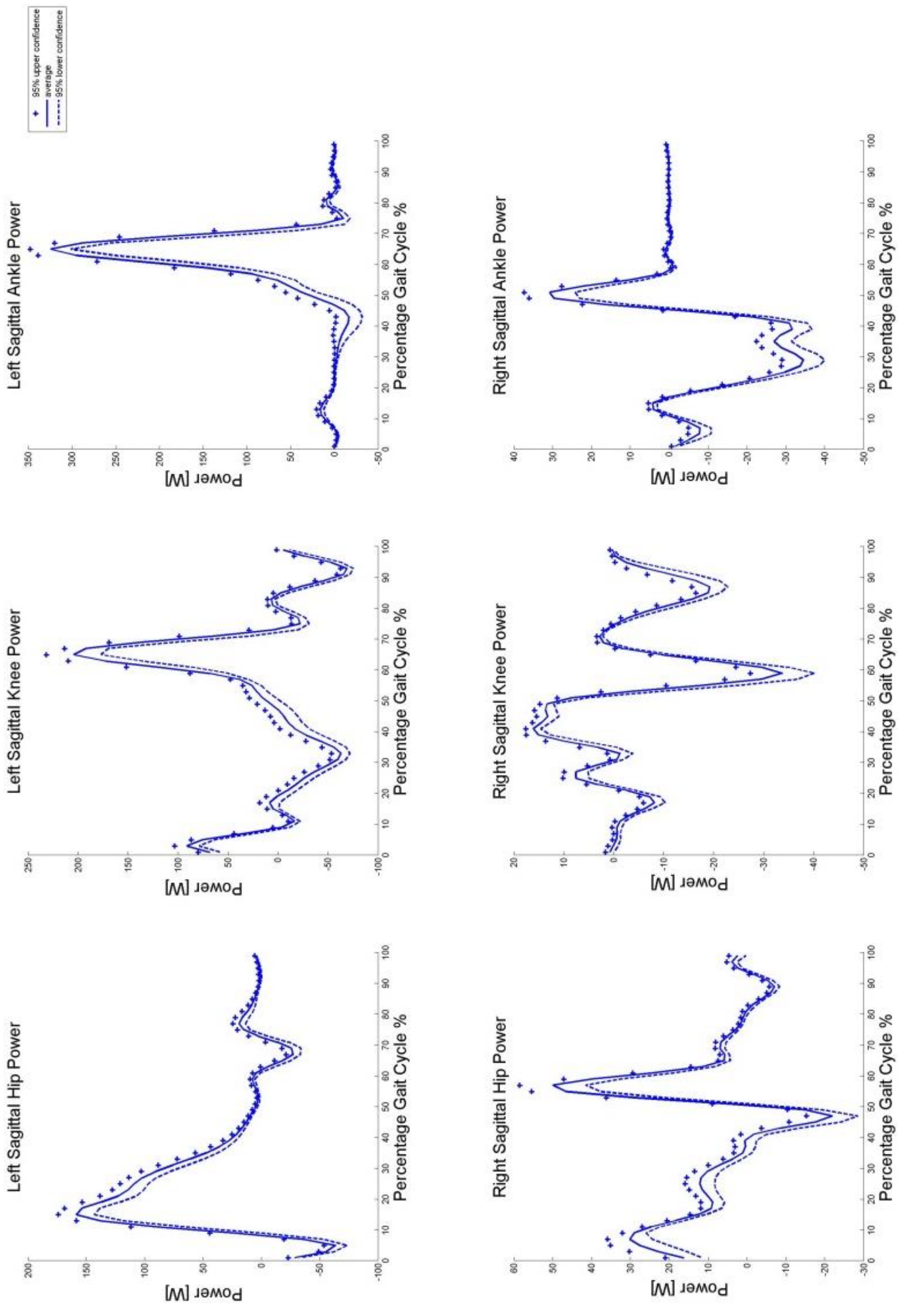


Figure 11.61 Participant (E) prosthetic (right) and anatomical (Left) powers – Ramp ascent (Orion)

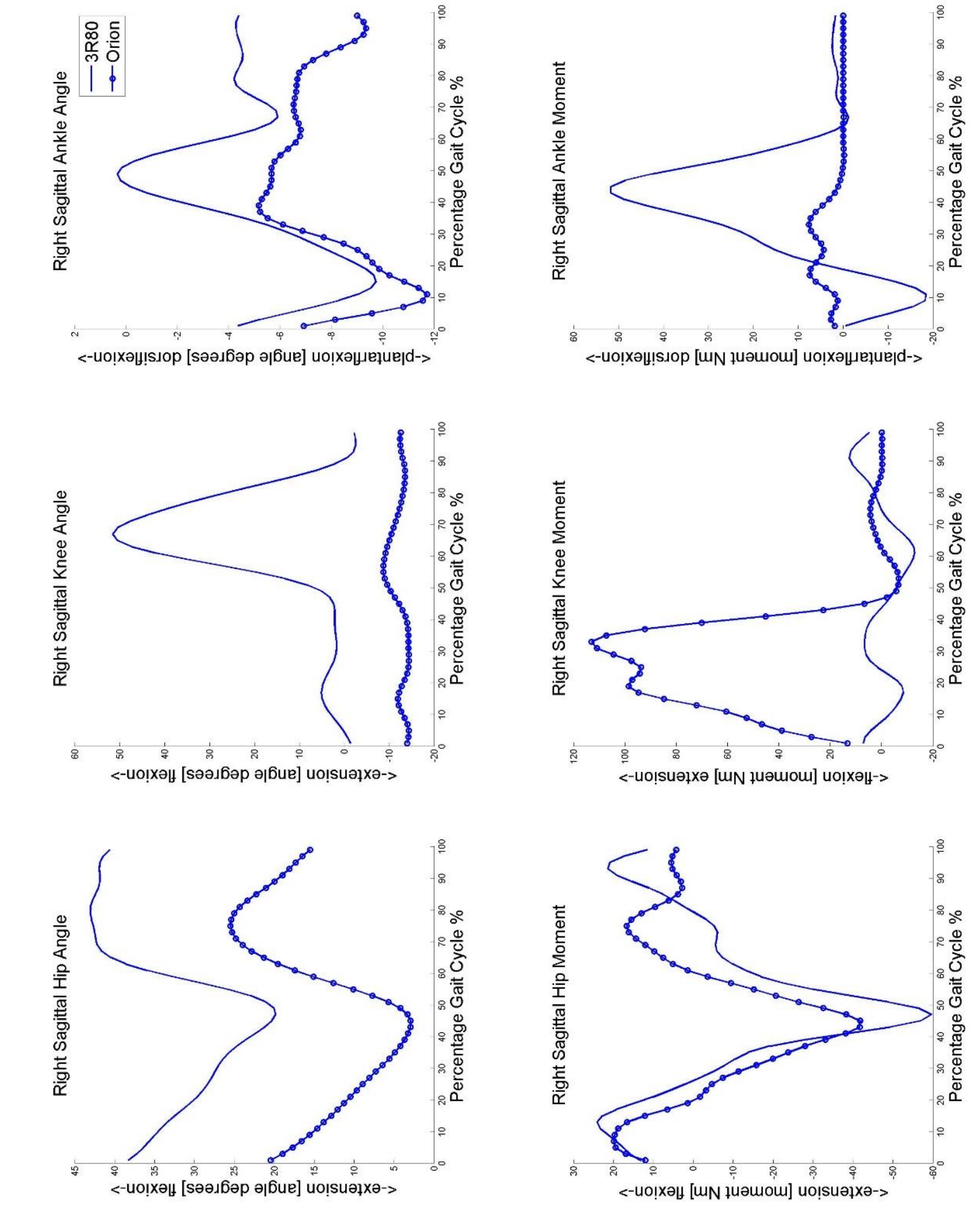


Figure 11.62 Participant (E) prosthetic limb kinematics and kinetics – Ramp descent

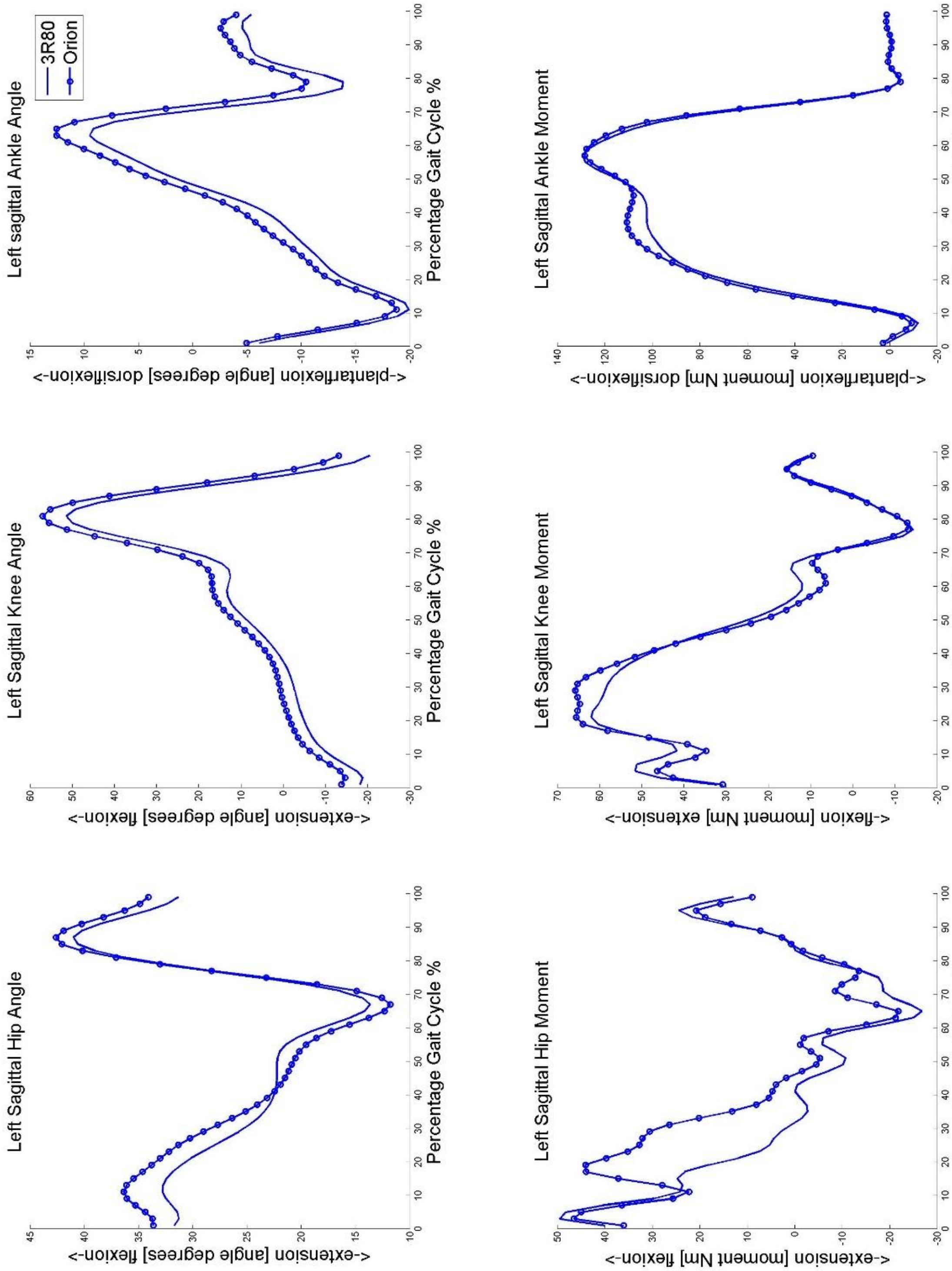


Figure 11.63 Participant (E) contralateral limb kinematics and kinetics – Ramp descent

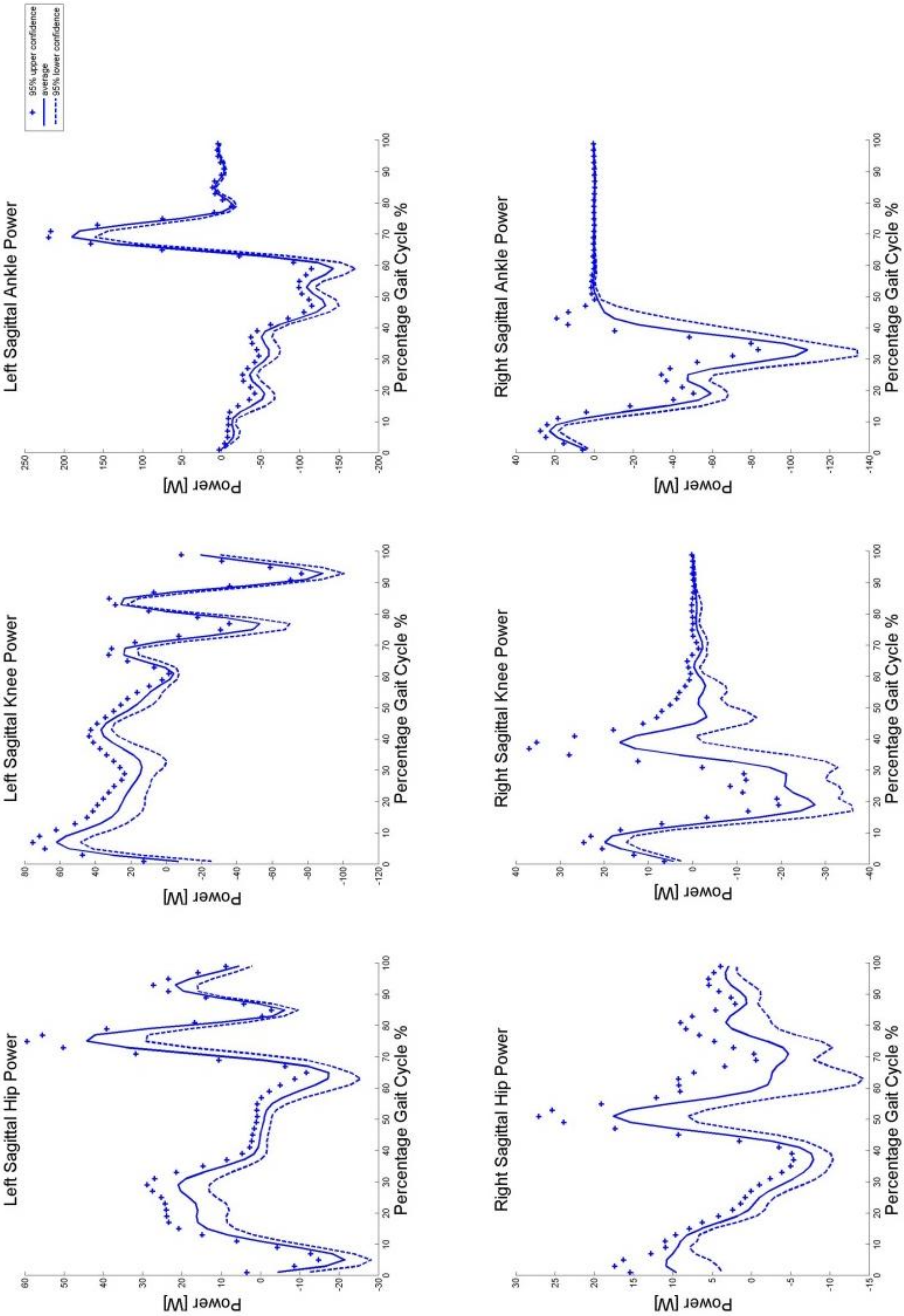


Figure 11.64 Participant (E) prosthetic (right) and anatomical (Left) powers – Ramp descent (Orion)

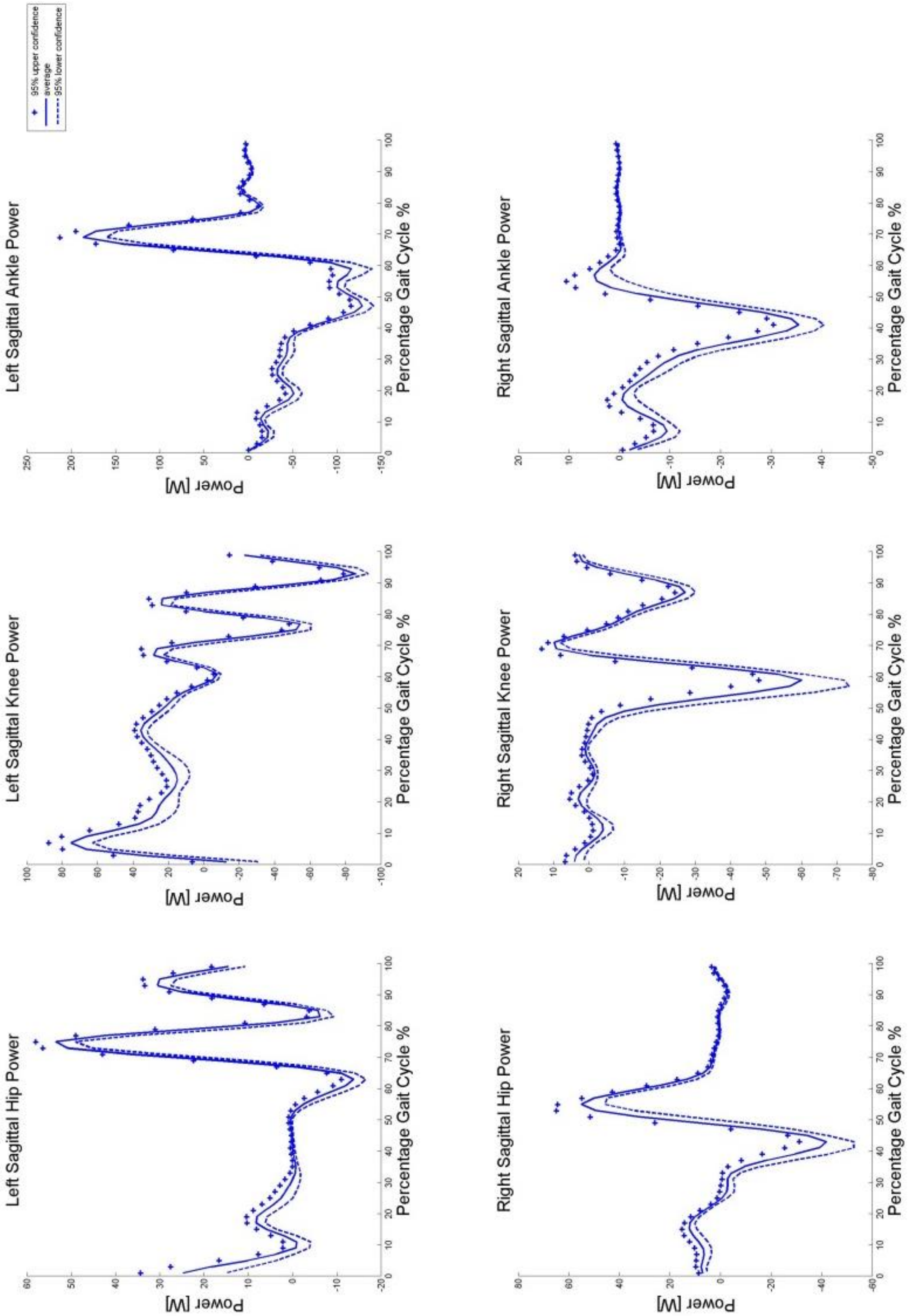


Figure 11.65 Participant (E) prosthetic (right) and anatomical (Left) powers – Ramp descent (3R80)

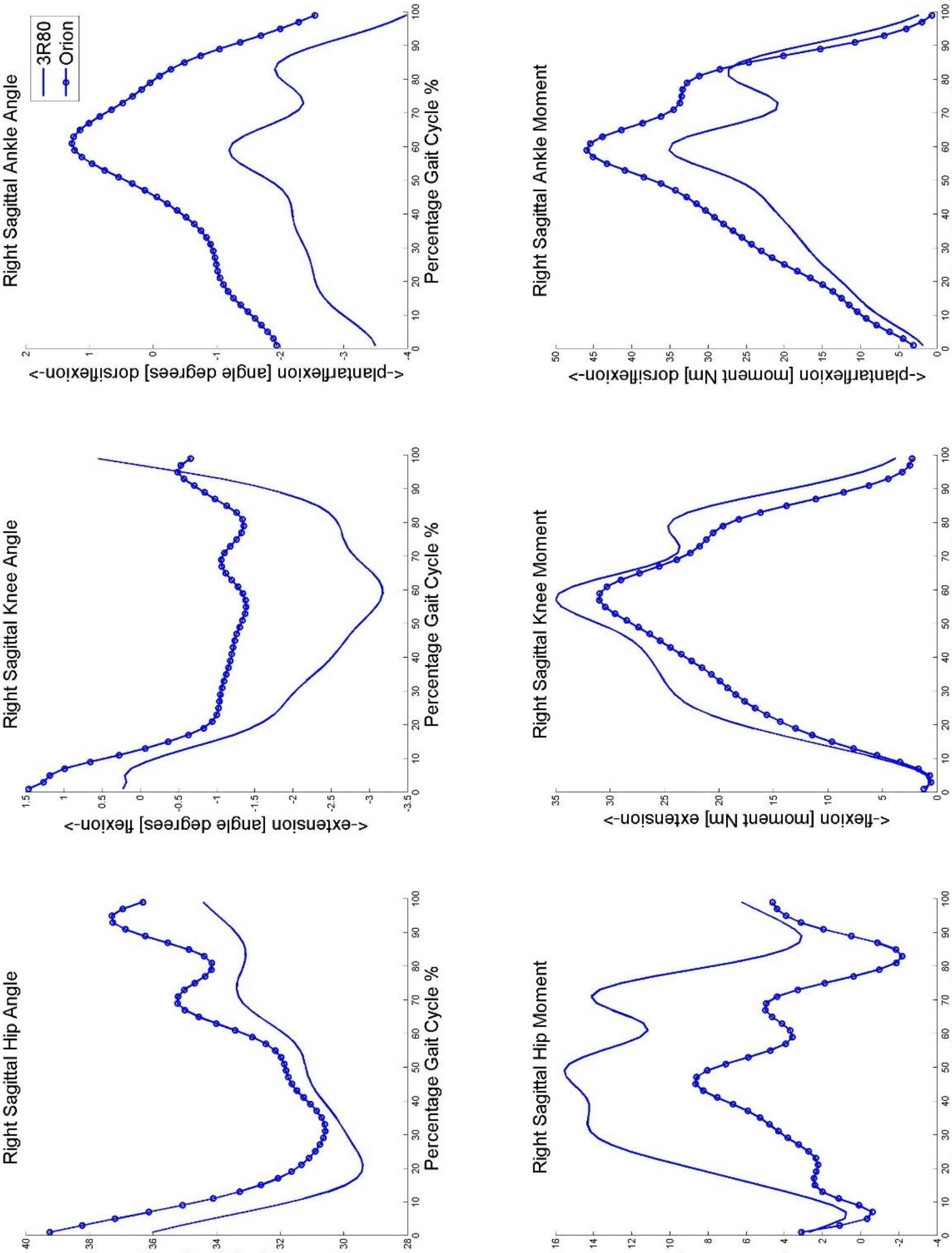


Figure 11.66 Participant (E) prosthetic limb kinematics and kinetics – stair ascent

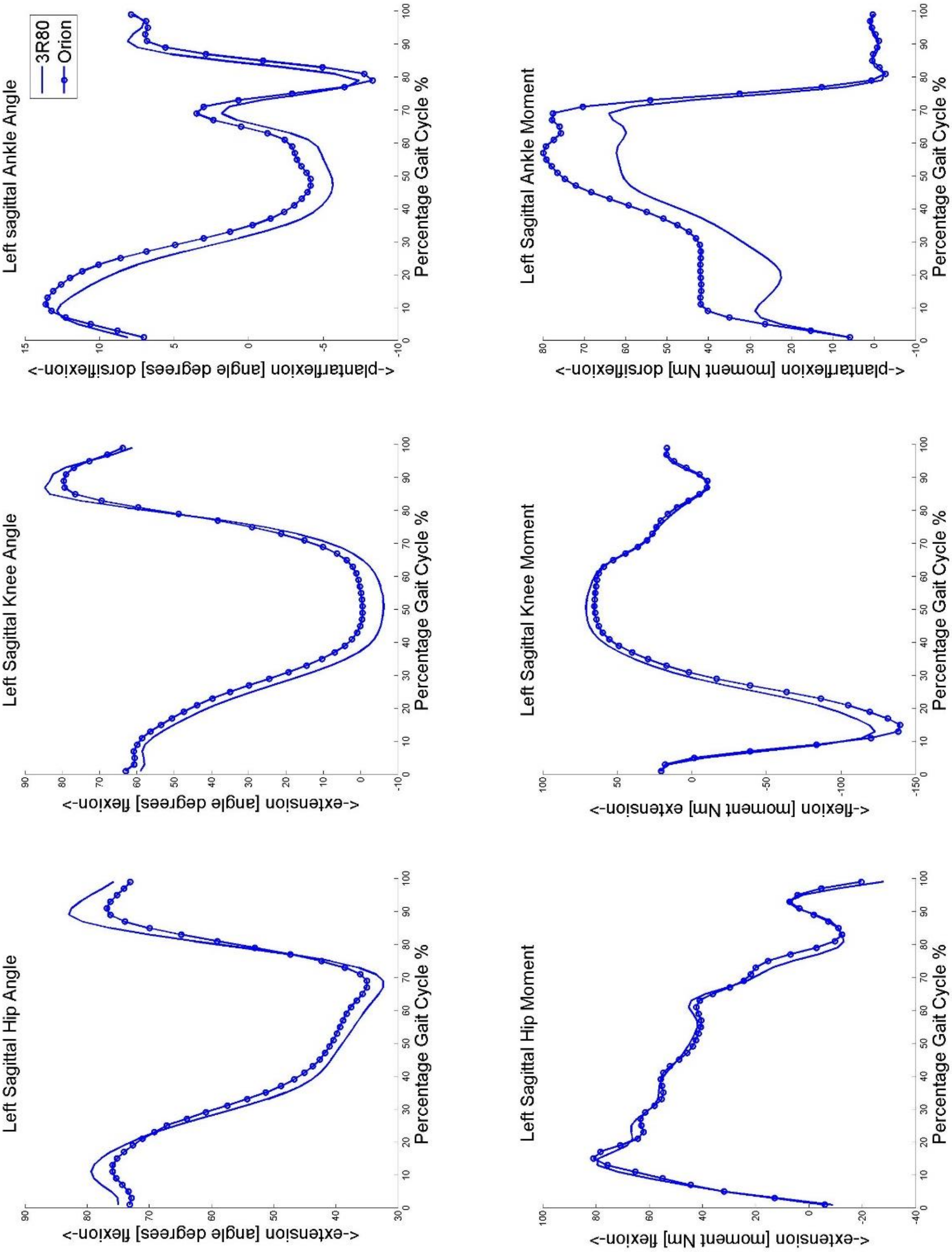


Figure 11.67 Participant (E) contralateral limb kinematics and kinetics – stair ascent

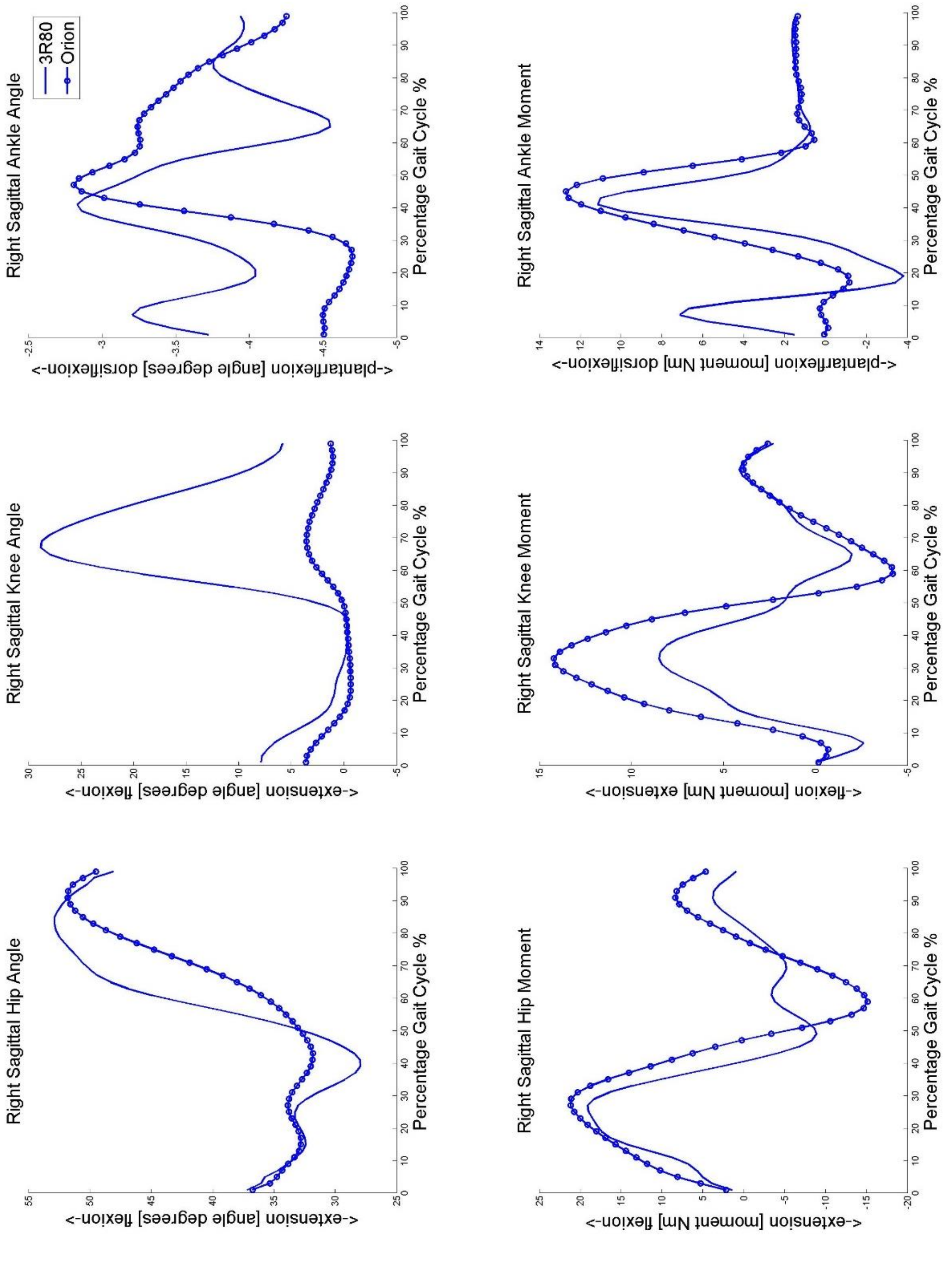


Figure 11.68 Participant (E) prosthetic limb kinematics and kinetics – stair descent

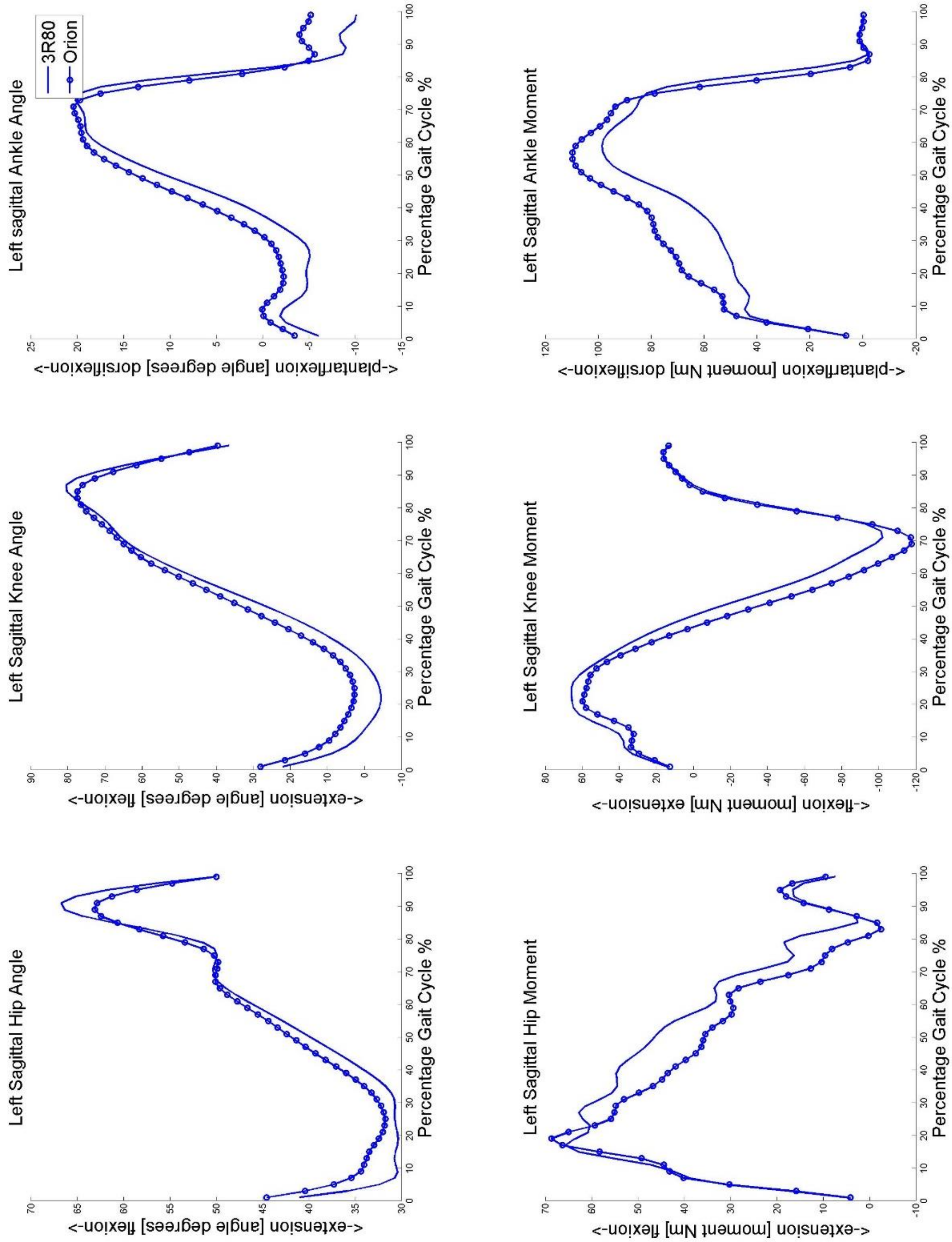


Figure 11.69 Participant (E) contralateral limb kinematics and kinetics – stair descent

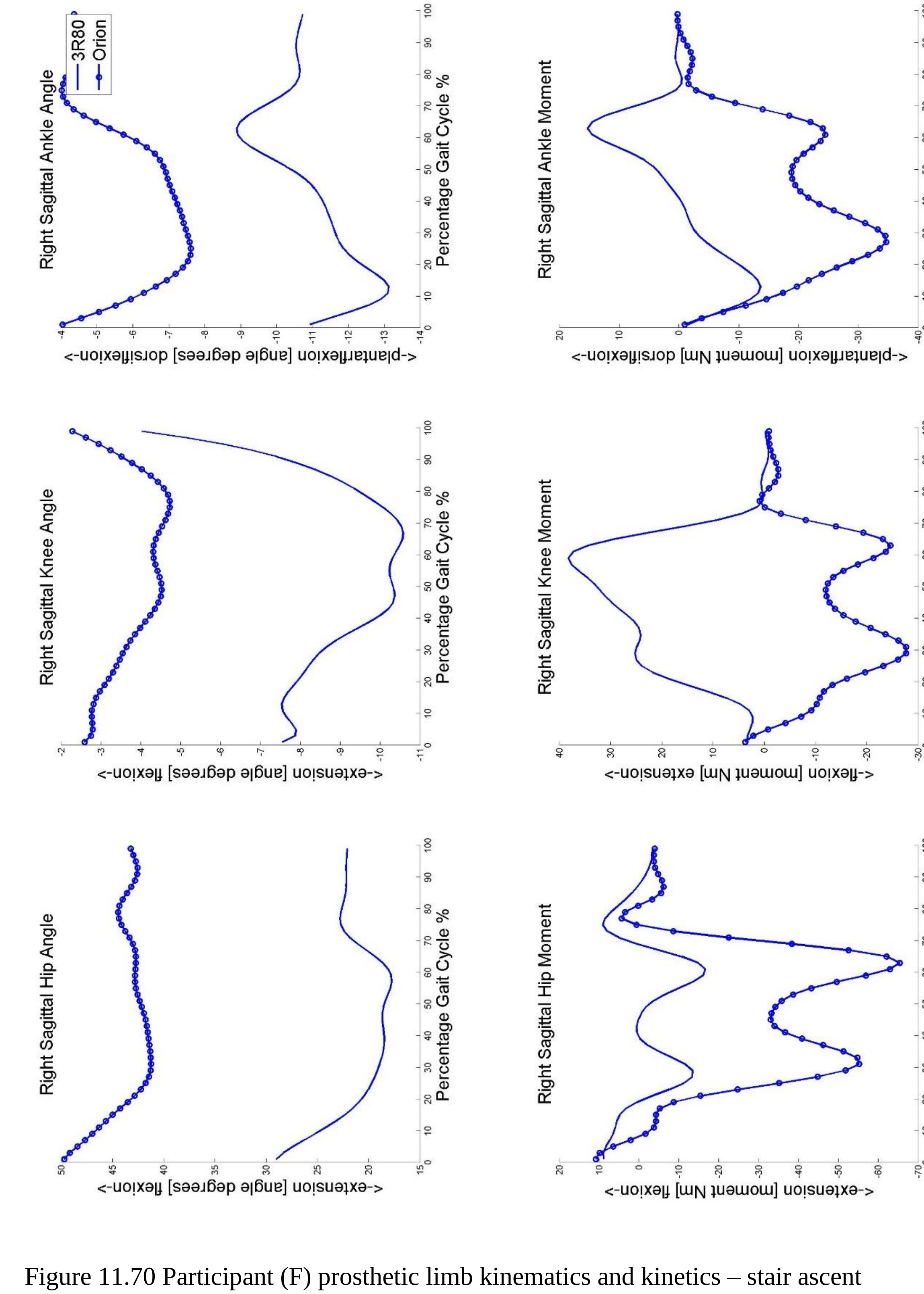


Figure 11.70 Participant (F) prosthetic limb kinematics and kinetics – stair ascent

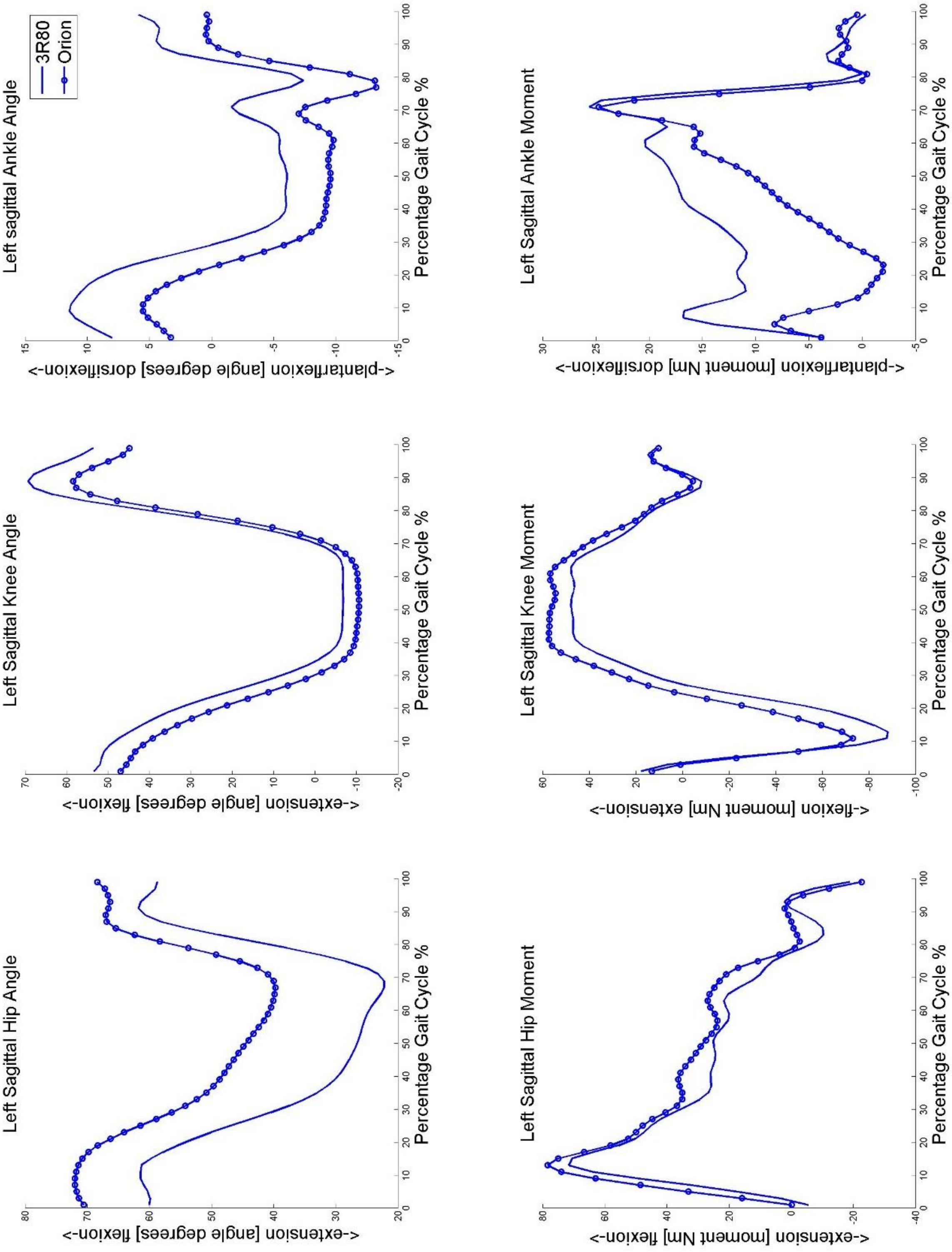


Figure 11.71 Participant (F) contralateral limb kinematics and kinetics – stair ascent

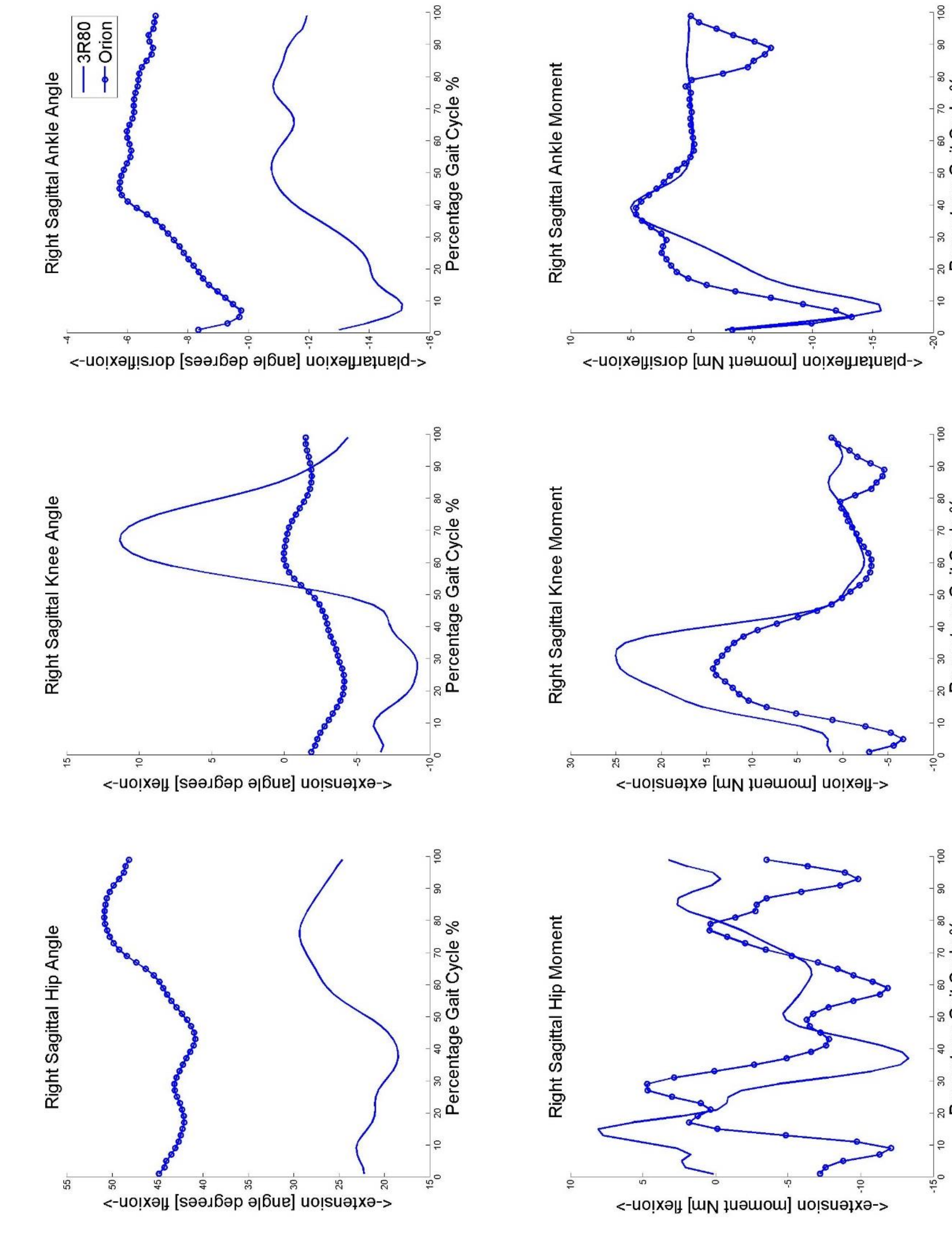


Figure 11.72 Participant (F) prosthetic limb kinematics and kinetics – stair descent

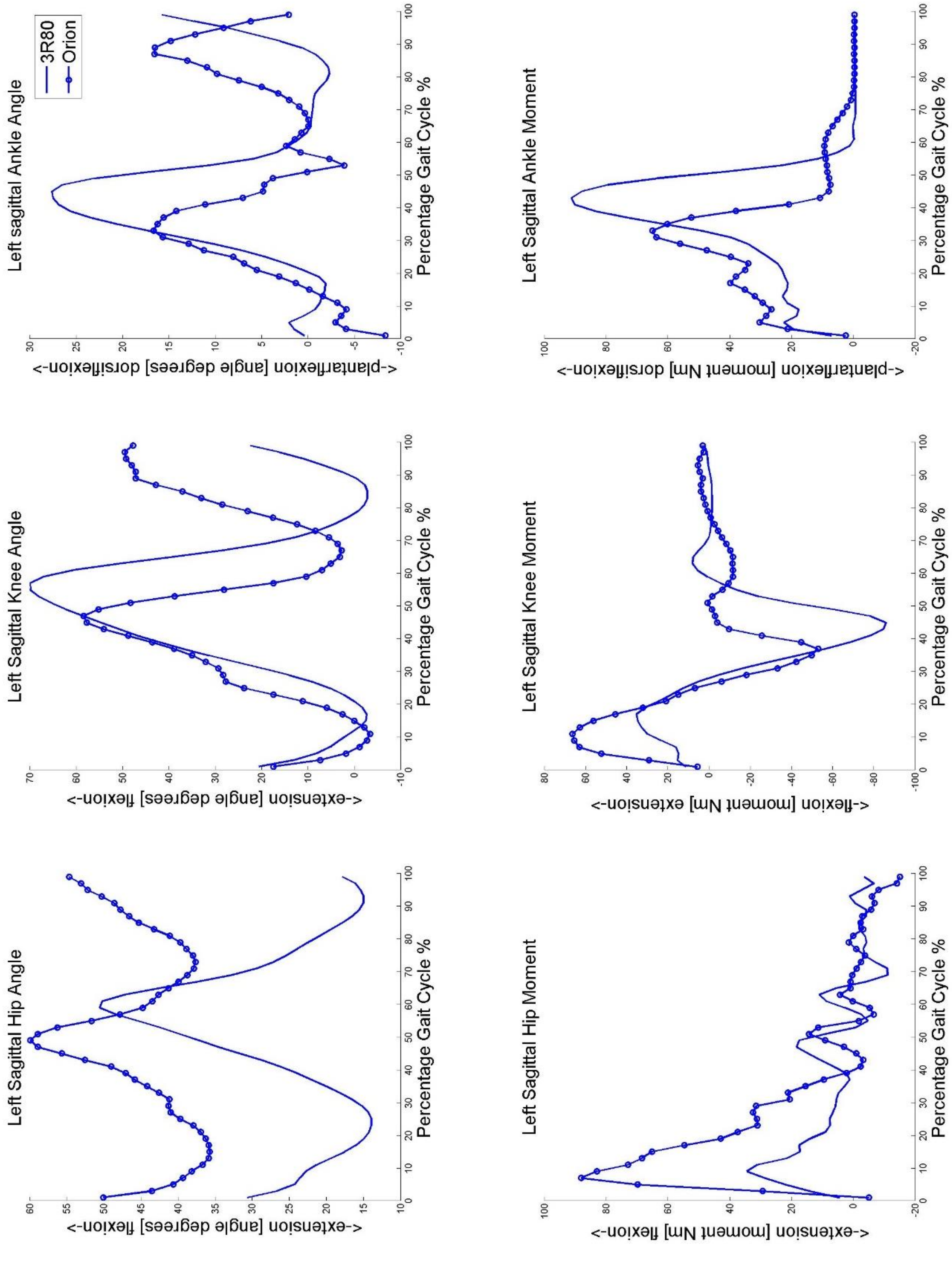


Figure 11.73 Participant (F) contralateral limb kinematics and kinetics – stair descent

11.9 PARTICIPANT (F) RESULTS (APPENDIX 9)

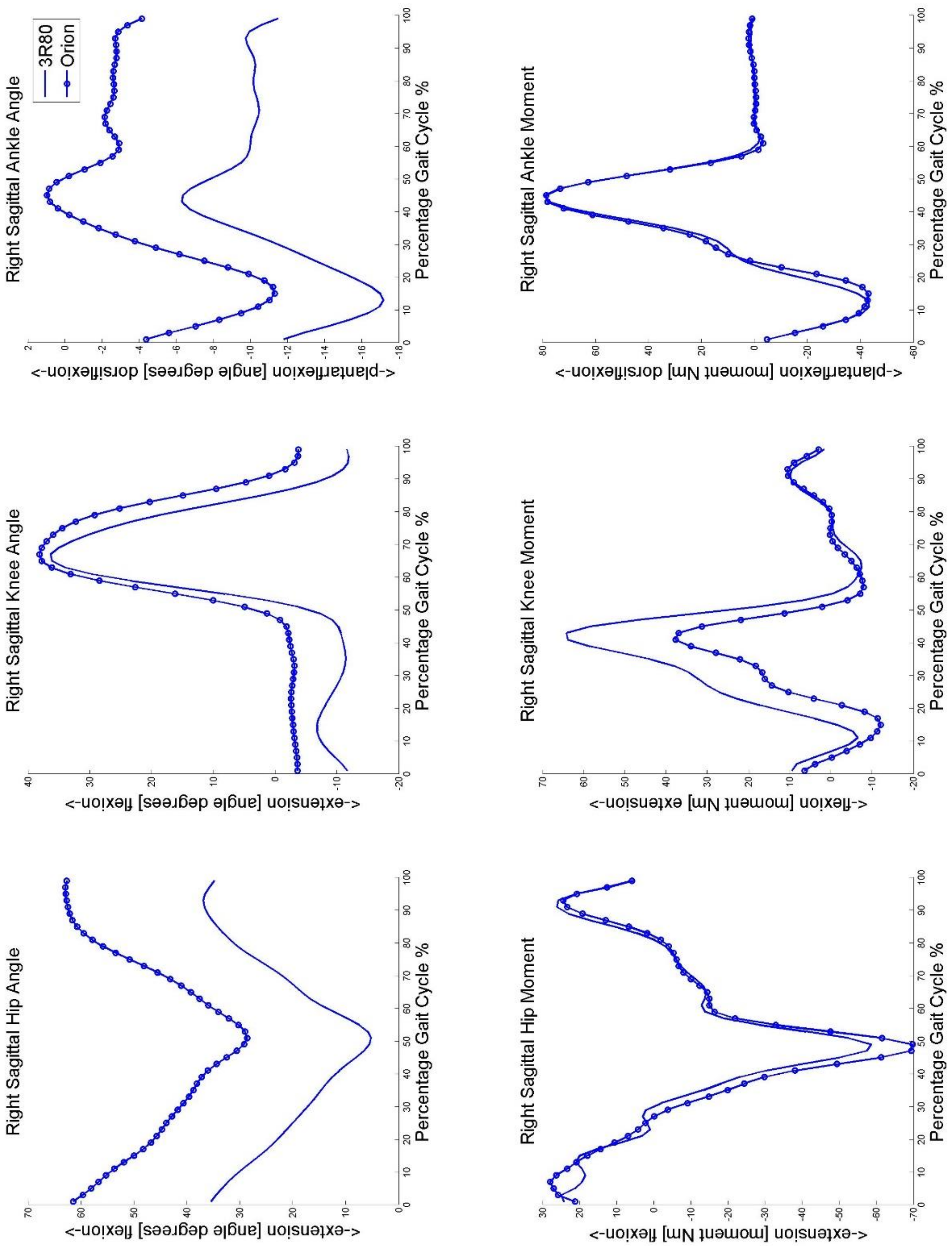


Figure 11.74 Participant (F) prosthetic limb kinematics and kinetics – level walking

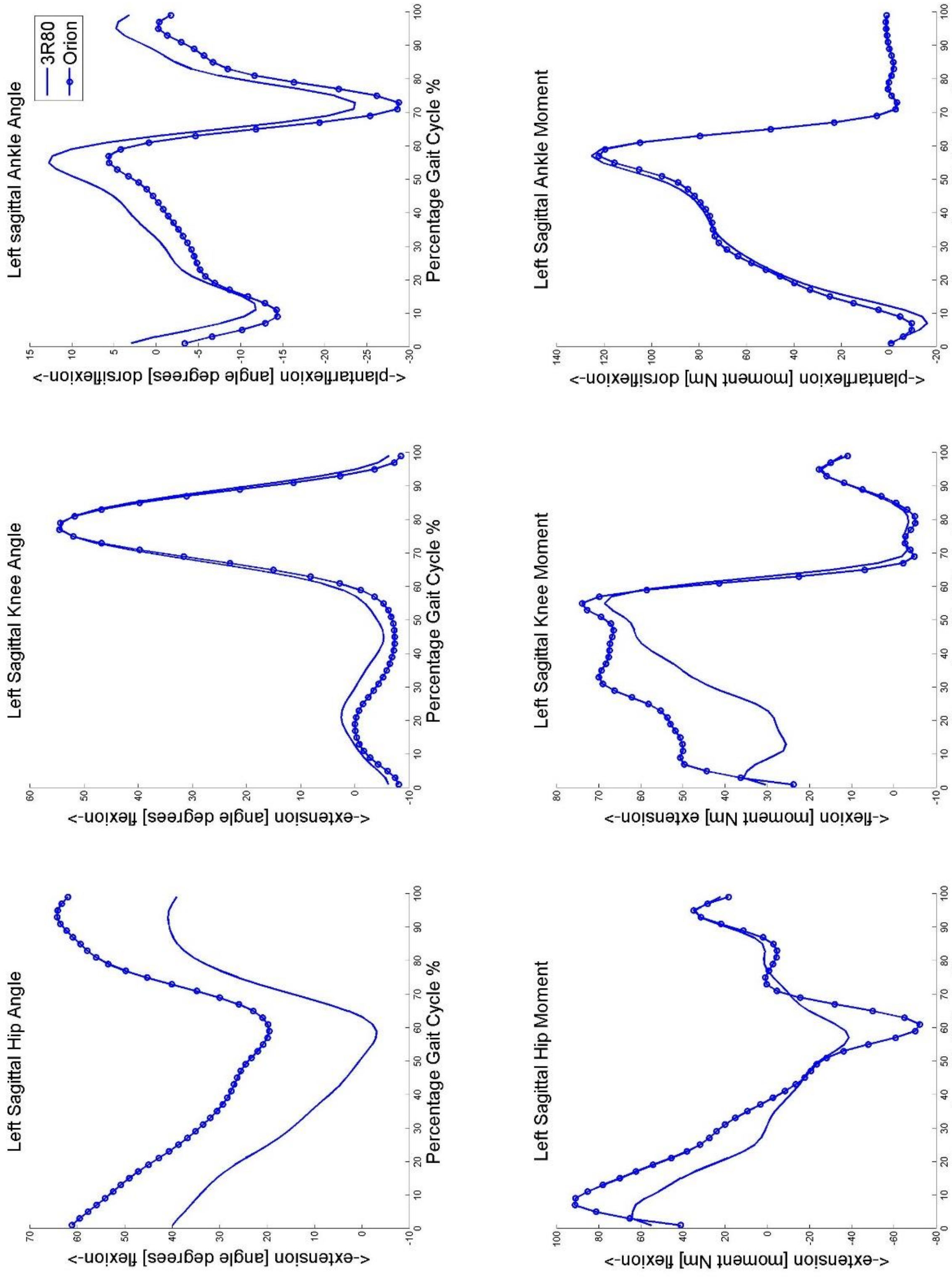


Figure 11.75 Participant (F) contralateral limb kinematics and kinetics – level walking

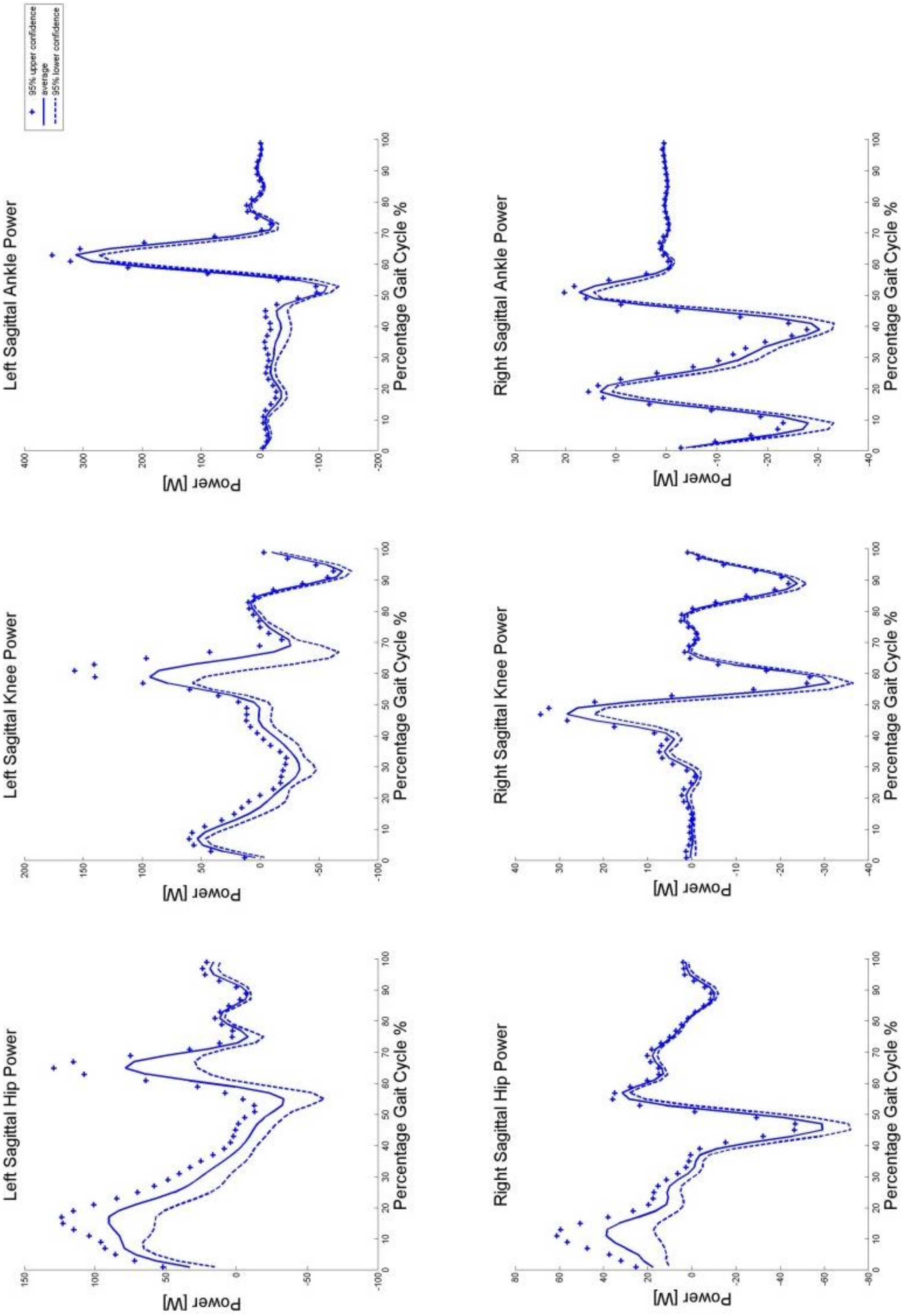


Figure 11.76 Participant (F) prosthetic (right) and anatomical (Left) powers – level walking (Orion)

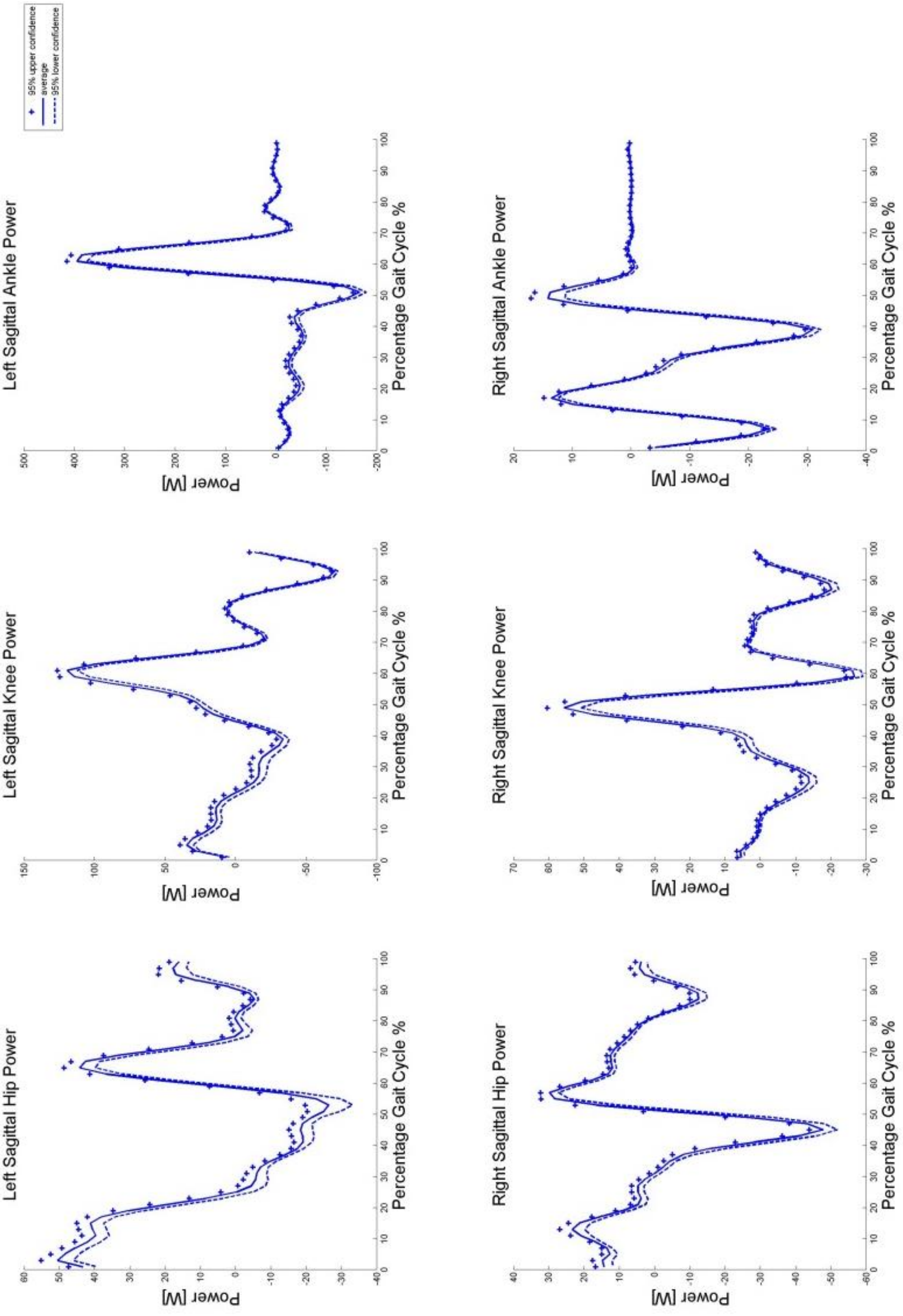


Figure 11.77 Participant (F) prosthetic (right) and anatomical (Left) powers – level walking (3R80)

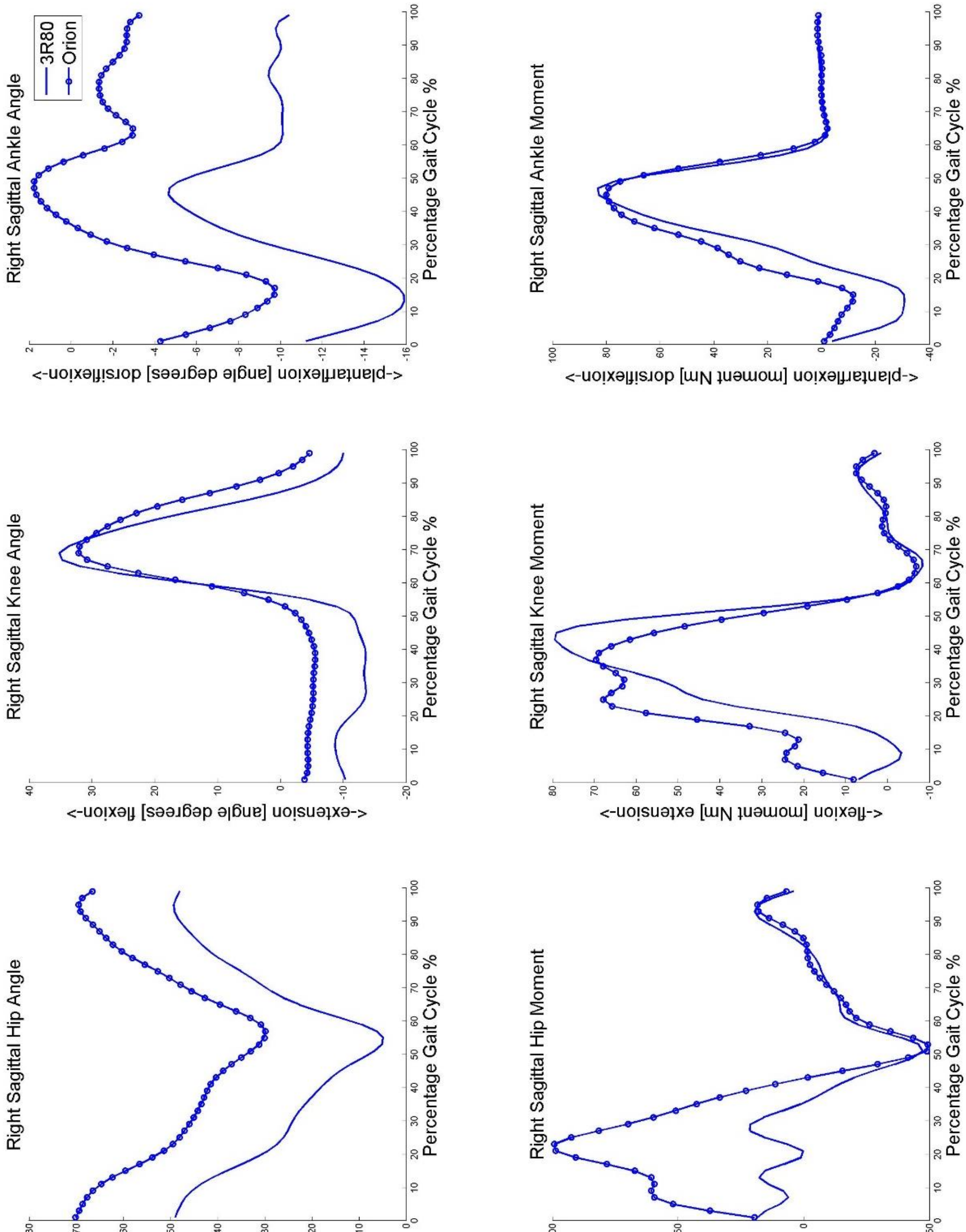


Figure 11.78 Participant (F) prosthetic limb kinematics and kinetics – Ramp ascent

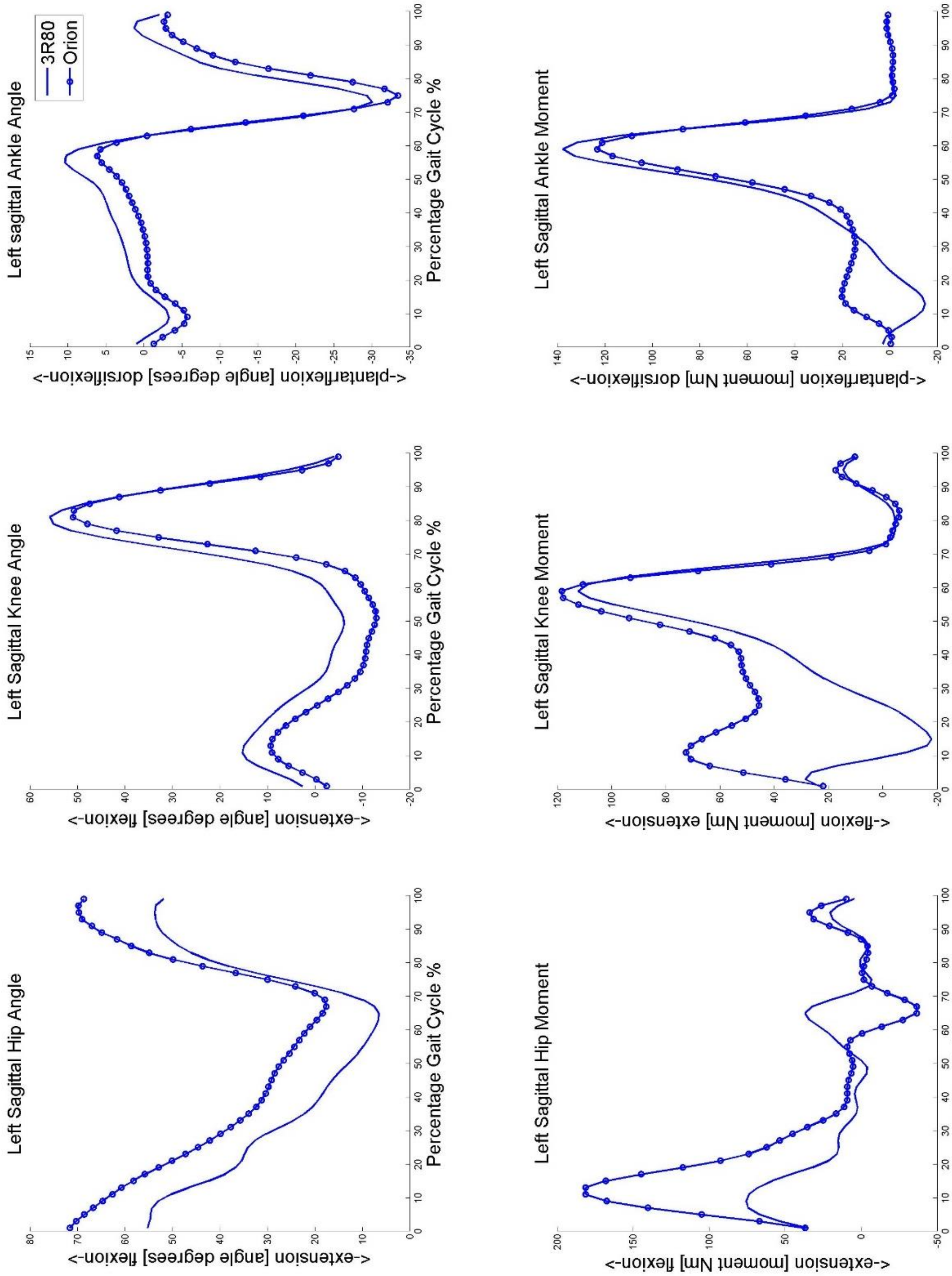


Figure 11.79 Participant (F) contralateral limb kinematics and kinetics – Ramp ascent

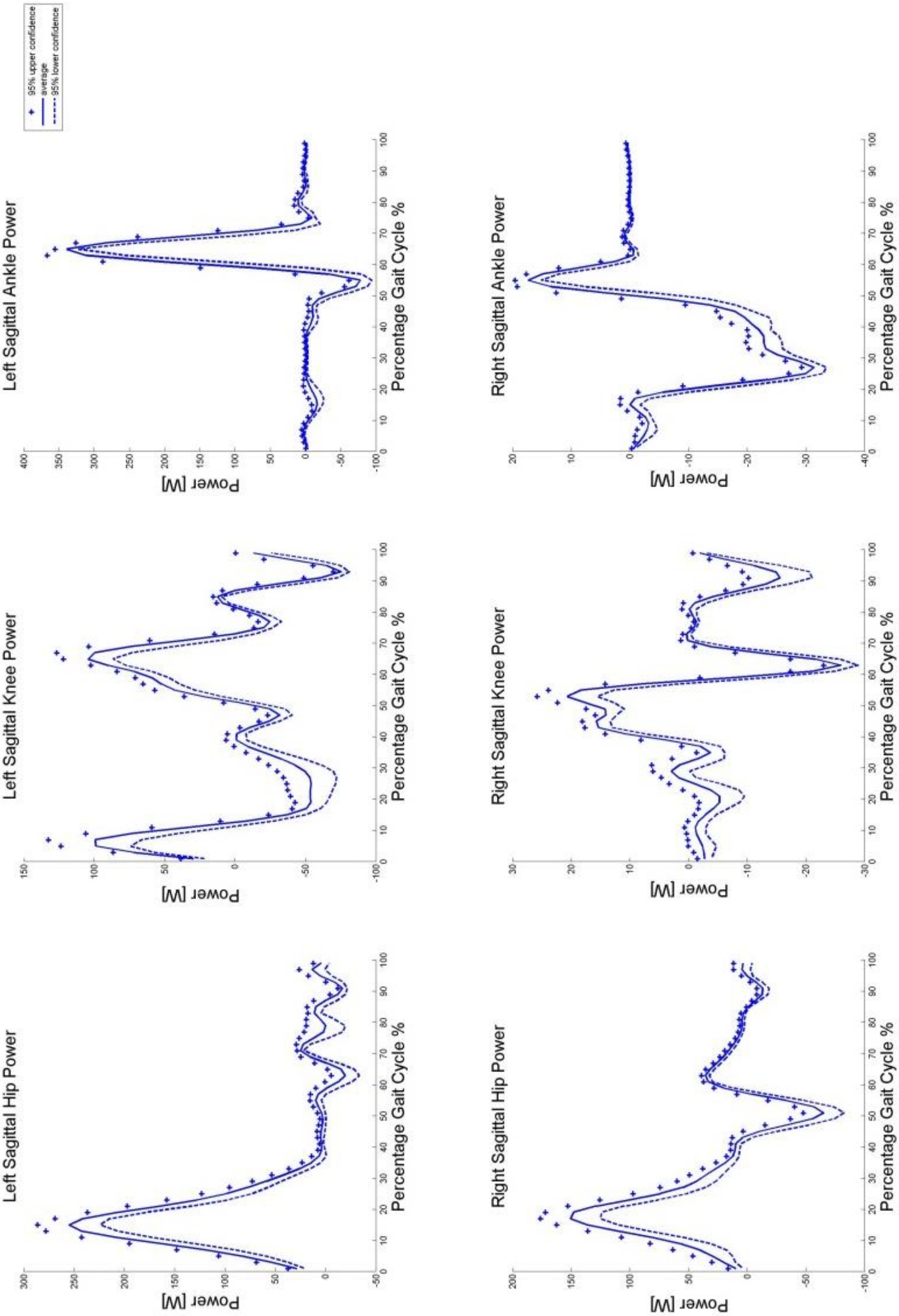


Figure 11.80 Participant (F) prosthetic (right) and anatomical (Left) powers – Ramp ascent (Orion)

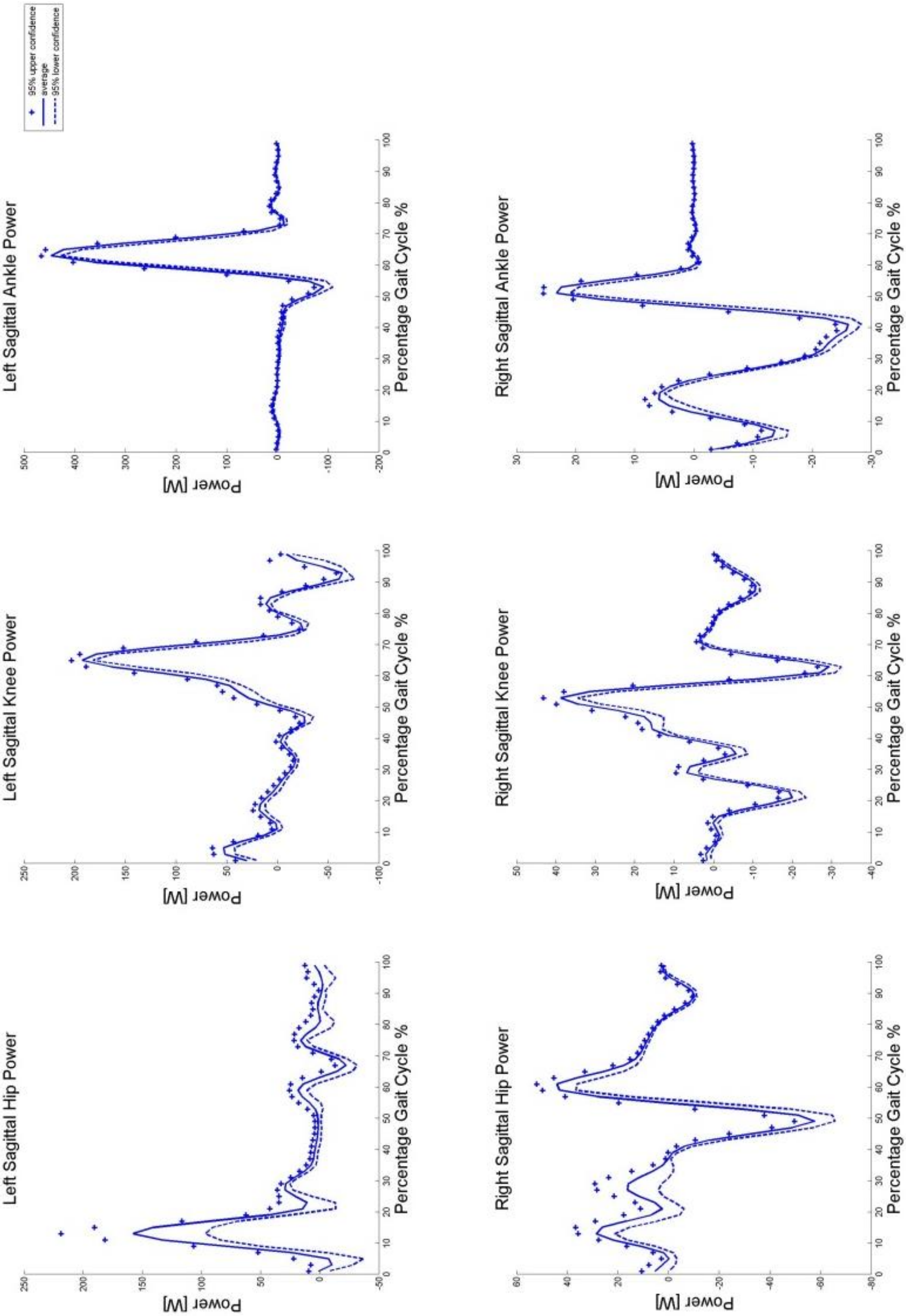


Figure 11.81 Participant (F) prosthetic (right) and anatomical (Left) powers – Ramp ascent (3R80)

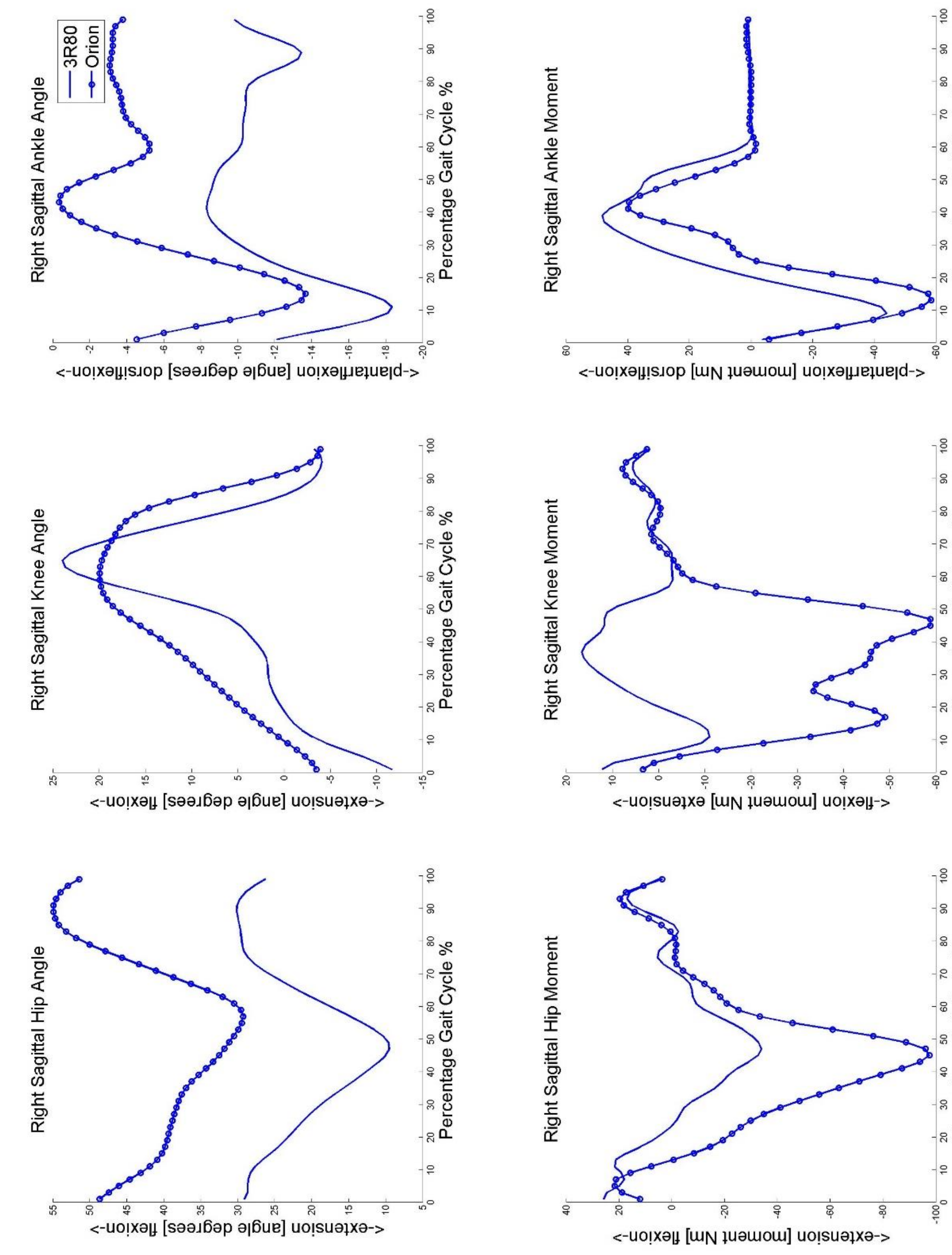


Figure 11.82 Participant (F) prosthetic limb kinematics and kinetics – Ramp descent

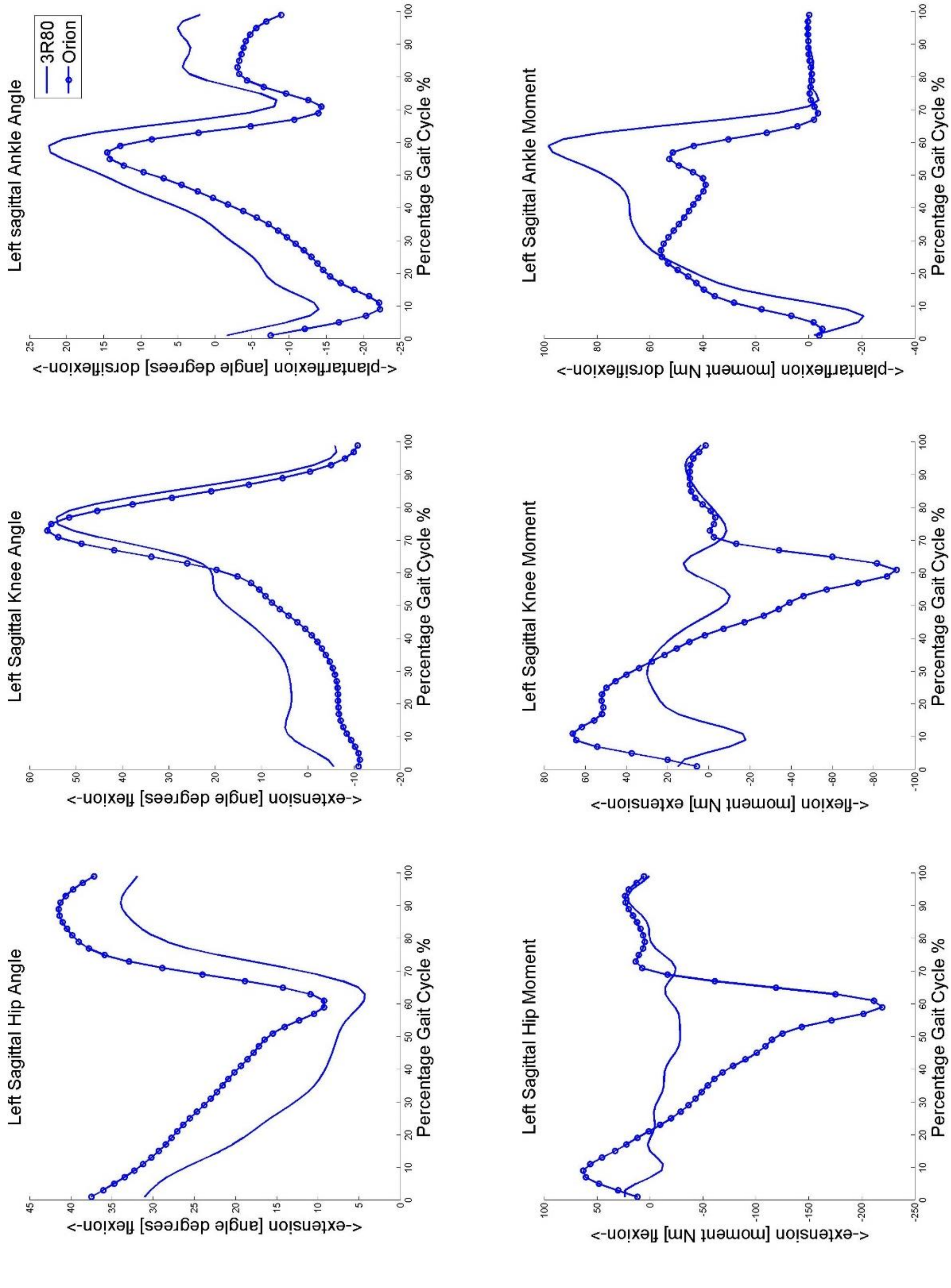


Figure 11.83 Participant (F) contralateral limb kinematics and kinetics – Ramp descent

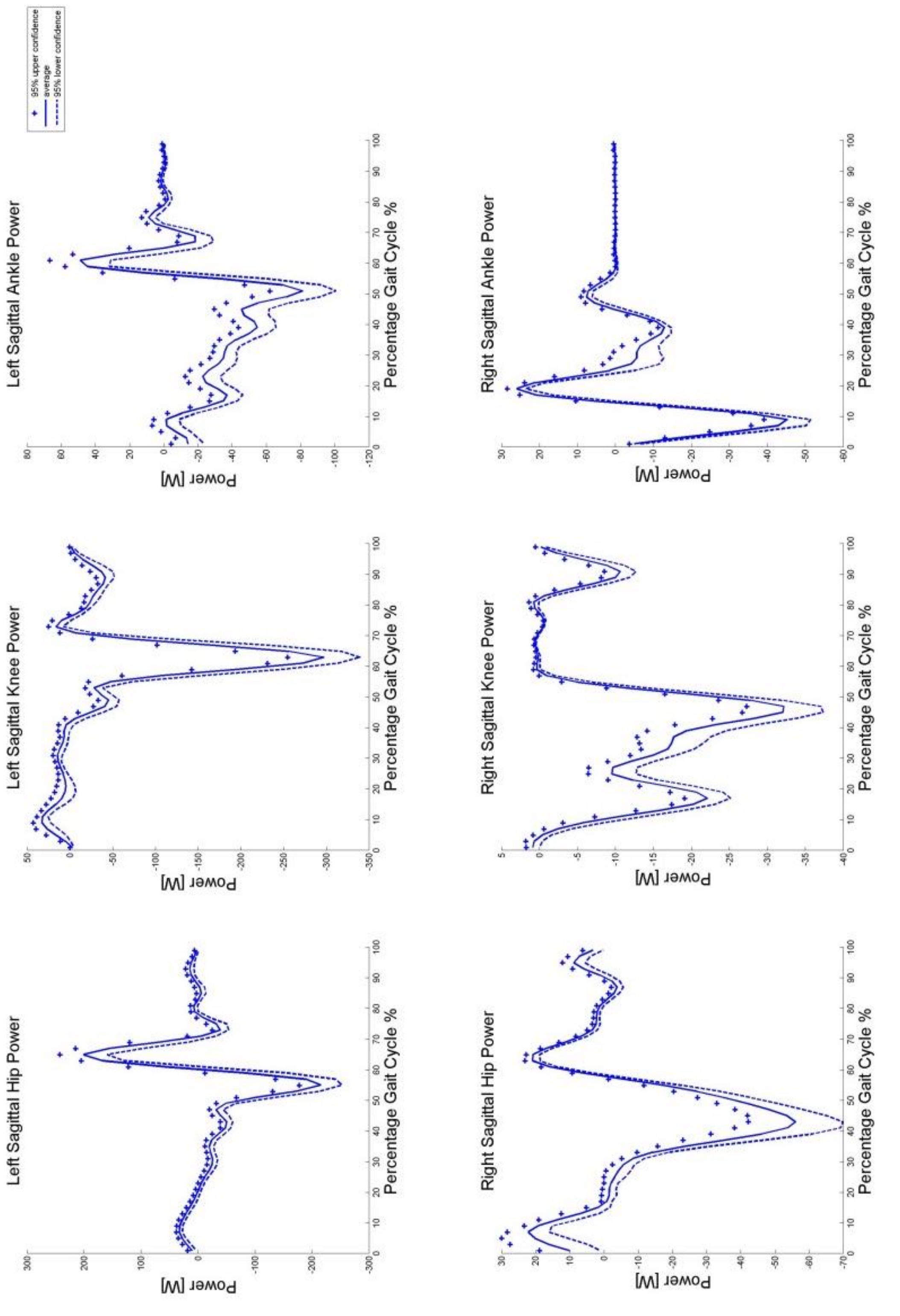


Figure 11.84 Participant (F) prosthetic (right) and anatomical (Left) powers – Ramp descent (Orion)

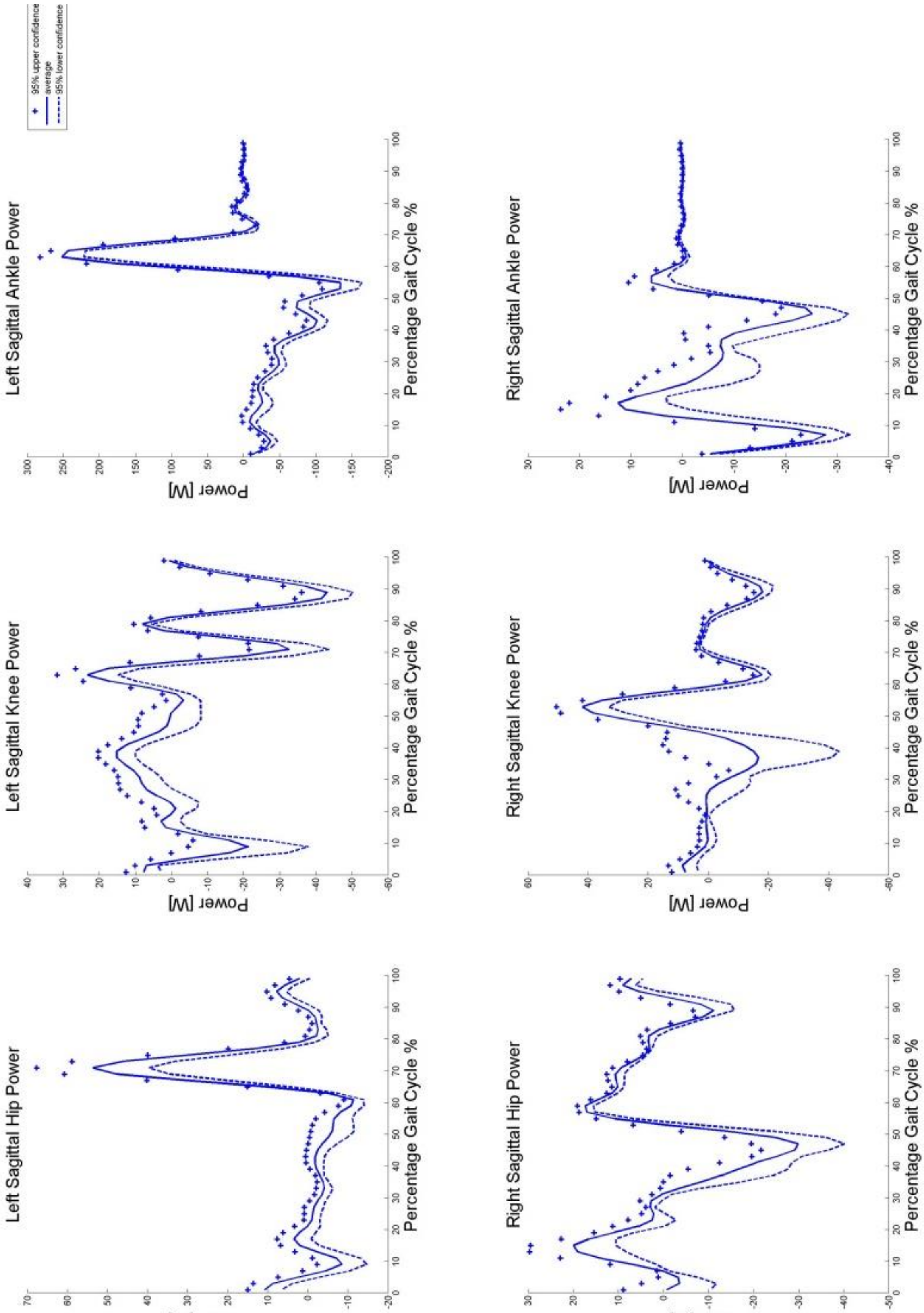


Figure 11.85 Participant (F) prosthetic (right) and anatomical (Left) powers – Ramp descent (3R80)

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